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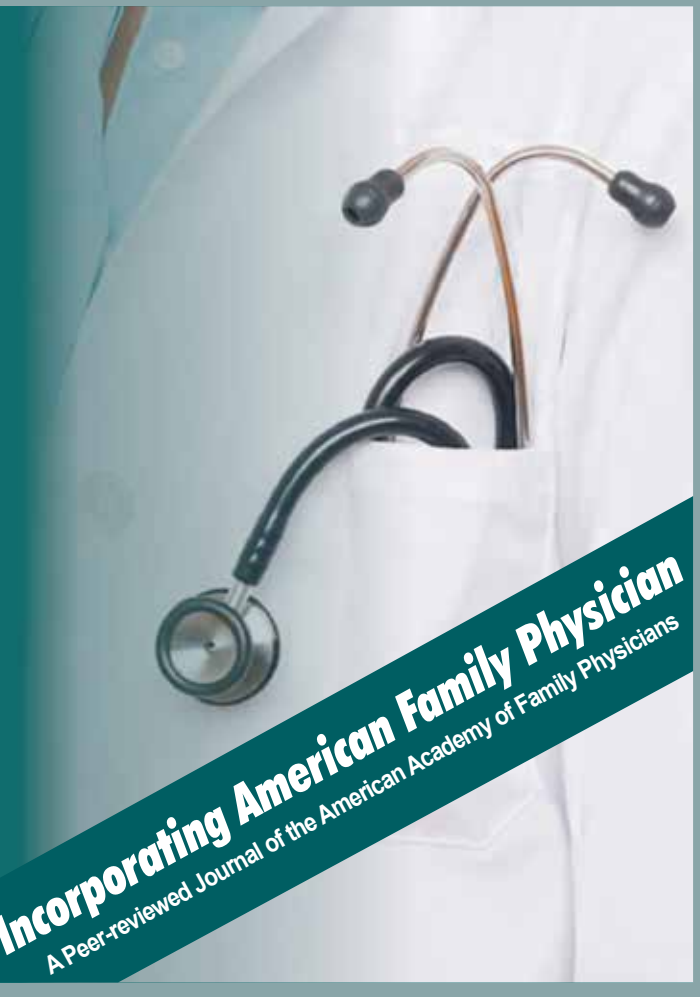

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Urine Examination is Like Liquid Kidney Biopsy

- Urinalysis consists of three components: Gross evaluation, dipstick analysis and microscopic examination of the urine sediment.
- Indications.
- In a patient with evidence of kidney disease.
- Someone with albuminuria.
- Acute or chronic reduction in the glomerular filtration rate (GFR).
- In a patient with suspected kidney disease (edema, systemic lupus erythematosus, small-vessel vasculitis, newly identified hypertension).
- Known or suspected kidney stones.
- Urine dipstick showing microscopic hematuria.

SAMPLE COLLECTION

- The urine specimen must be properly collected.
- The specimen should be collected into a clean dry container.
- Patients should be asked to clean the external genitalia and provide a midstream specimen for analysis.
- The specimen should be examined at room temperature within 2 hours of retrieval. If this is not feasible, the sample should be refrigerated at 2-8°C and then re-warmed to room temperature prior to assessment.

Gross Assessment	
Turbid	Infection, precipitated crystals or chyluria
Yellow	Lighter when urine is dilute and darker when concentrated.
Red to brown	**Post centrifuged** red color is in the urine sediment (hematuria) or the supernatant (heme).
White	Pyuria, phosphate crystals, chyluria
Pink	Uric acid crystals, due to propofol
Green	Administration of methylene blue, propofol or amitriptyline
Black	Hemoglobinuria, myoglobulinuria or ochronosis (alkaptonuria)
Purple	Bacteriuria in patients with urinary catheters

Urine Sediment	
10 mL centrifuged at 3000 rpm for 5 minutes	Evaluates epithelial cells, casts, crystals
Uric acid or amorphous crystals	In acid urine. Acute kidney injury (AKI) with uric acid crystals suggest tumor lysis syndrome
Cystine	Cystinuria
Calcium oxalate	Any pH. AKI & calcium oxalate crystals: Ethylene glycol ingestion
Calcium phosphate	Alkaline pH
Magnesium ammonium phosphate crystals (struvite) and calcium carbonate-apatite	Constituents of struvite stones which occurs only when ammonia production is increased and the urine pH is elevated in the setting of a urinary tract infection with a urease-producing organism, such as Proteus or Klebsiella
Bacteria or fungi	Infection
Red blood cells (RBCs) Transient: Young, following exercise or sexual intercourse, menstruation, underlying malignancy in 50+, cystitis or prostatitis Persistent: Kidney stones, malignancy, and glomerular disease.	Hematuria may be gross or microscopic (two or more RBCs per high-powered field in a spun urine sediment). mL of blood per liter of urine can induce a visible color change.
White blood cells (WBCs)	Commonly associated with bacteriuria or sterile pyuria in interstitial nephritis, renal tuberculosis and nephrolithiasis. Urine eosinophils seen in acute interstitial nephritis.
Renal tubular epithelial cells	Renal tubular cells are 1.5-3 times larger than white cells and are further distinguished by a round, large, centrally-located nucleus
Transitional epithelial cells	Originate anywhere from the renal pelvis to the proximal urethra and are slightly larger than renal tubular epithelial cells. They may have a pear-like or oval appearance
Squamous epithelial cells	Are derived from the distal urethra or external genitalia. They are large and irregular in shape with a small central nucleus, and their presence represents contamination by genital secretions
Casts	Cylindrical structures formed in the tubular lumen and assume the shape and size of the renal tubule in which they are formed.
RBC casts	Glomerular hematuria, proliferative glomerulonephritis
WBC casts	Pyelonephritis or noninfectious (interstitial nephritis, proliferative glomerulonephritis)
Renal tubular epithelial cell casts	Desquamation of the tubular epithelium, including acute tubular necrosis (ATN), acute interstitial nephritis and proliferative glomerulonephritis
Granular casts	ATN
Hyaline casts	Small volumes of concentrated urine or with diuretic therapy and are generally nonspecific
Lipid droplets	Nephrotic syndrome. Because of the apparent requirement for increased glomerular permeability, lipiduria is almost always diagnostic of some form of glomerular disease
Waxy casts	Are nonspecific and may be observed in a variety of acute and chronic kidney diseases.
Broad casts	Associated with advanced chronic kidney disease.

 IJCP SUTRA 87: Multiple blood cultures, each containing large volumes of blood, are required to detect bacteremia. *Clin Infect Dis.* 1996;23:40.

Urine Dipstick	
Heme	If a urine dipstick of the red supernatant is positive for heme, the patient has either hemoglobinuria or myoglobinuria. Negative heme test can be seen with ingestion of rifampin or phenytoin, food dyes, beets (beeturia), rhubarb or senna and acute intermittent porphyria.
Leukocyte esterase	Is a marker for the presence of WBCs? Excessively dilute urine may favor cell lysis and lower the threshold for test positivity. By contrast, a concentrated urine may impede cell lysis and therefore produce a false-negative result.
Nitrite	**Infection.** Bacteriuria or frank infection may still be present in the absence of nitrite positivity. This would occur with organisms expressing low levels of nitrate reductase (Enterococcus), or when urine dwell time in the bladder is short.
Albumin	A screen for the presence of such proteins may be performed with the sulfosalicylic acid test. Moderately increased albuminuria in the range of 30-300 mg/day (formerly called "microalbuminuria") cannot be detected with dipstick testing. A patient with severely increased albuminuria that is normally detectable by the dipstick (more than 300 mg/day, formerly called "macro albuminuria") may still have a negative dipstick if the urine is very dilute.
Hydrogen ions	pH ranges from 4.5 to 8. The appropriate renal response to acidemia is to increase urinary acid excretion, with the urine pH falling below 5.3 and usually below 5. A higher value may indicate the presence of renal tubular acidosis
Specific gravity (SG)	**SG** varies with the osmolality, rising by app 0.001 for every 35-40 mosmol/kg increase in urine osmolality. Osmolality of 280 mosmol/kg (which is isosmotic to normal plasma) = SG 1.008 or 1.009.
Glucose	With normal eGFR glycosuria = plasma glucose >180 mg/dL Urine sugar with normal blood sugar: defect of proximal tubule reabsorption in Fanconi syndrome, multiple myeloma, heavy metal exposure and drugs tenofovir, lamivudine, cisplatin, valproic acid and aminoglycosides, sodium-glucose cotransporter 2 inhibitors, etc.

- **Hematuria with dysmorphic RBCs, RBC casts and proteinuria:** Proliferative glomerular disease, which, in the setting of rapidly declining kidney function, constitutes a nephrologic emergency.
- **Heavy proteinuria with absent or minimal hematuria:** Nonproliferative glomerular diseases including severe diabetic nephropathy or membranous nephropathy, focal segmental glomerulosclerosis, minimal change disease and amyloidosis.
- **Granular or epithelial cell casts and renal tubular epithelial cells:** ATN.
- **Isolated pyuria:** Urinary tract infection (UTI).
- **Normal or near-normal urinalysis:** AKI, ATN, prerenal AKI, urinary tract obstruction, hypercalcemia, cast nephropathy in multiple myeloma, hypertensive emergency, scleroderma, thrombotic microangiopathies, polyarteritis nodosa, tumor lysis syndrome, acute phosphate nephropathy.

In CKD, a normal urinalysis most commonly indicates: persistent states of decreased effective circulating volume, such as in patients with heart failure; urinary tract obstruction; chronic tubulointerstitial diseases; myeloma cast nephropathy and ischemic or hypertensive nephrosclerosis.

■■■■

Formula of 10

Aspirin should be given to all apparently healthy men and women whose 10 years risk of CHD event is 10% or greater.

Metabolic Syndrome

Formula of 40: 40% of adults over age 40 have metabolic syndrome.

AMERICAN FAMILY PHYSICIAN

Diagnosis of Acute Stroke

KENNETH S. YEW, ERIC M. CHENG

ABSTRACT

Stroke can be categorized as ischemic stroke, intracerebral hemorrhage, or subarachnoid hemorrhage. Awakening with or experiencing the abrupt onset of focal neurologic deficits is the hallmark of the diagnosis of ischemic stroke. The most common presenting symptoms of ischemic stroke are speech disturbance and weakness on one-half of the body. The most common conditions that can mimic a stroke are seizure, conversion disorder, migraine headache, and hypoglycemia. Taking a patient history and performing diagnostic studies will usually exclude stroke mimics. Neuroimaging is required to differentiate ischemic stroke from intracerebral hemorrhage, as well as to diagnose entities other than stroke. The choice of neuroimaging depends on availability of the method, the patient's eligibility for thrombolysis, and presence of contraindications. Subarachnoid hemorrhage presents most commonly with sudden onset of a severe headache, and noncontrast head computed tomography is the imaging test of choice. Cerebrospinal fluid inspection for bilirubin is recommended if subarachnoid hemorrhage is suspected in a patient with a normal computed tomography result. Public education about common presenting stroke symptoms may improve patient knowledge and clinical outcomes.

Keywords: Acute stroke, ischemic stroke, intracerebral hemorrhage, subarachnoid hemorrhage, focal neurologic deficits, neuroimaging, noncontrast head computed tomography

The symptoms of acute stroke can be misleading and misinterpreted by clinicians and patients. Family physicians are on the front line to recognize and manage acute cerebrovascular diseases. Rapid, accurate examination of persons with stroke symptoms can reduce disability and help prevent recurrences.

CLASSIFYING STROKE

Stroke can be classified by pathologic process and vascular distribution affected. Defining the overall pathologic process is critical for decisions on thrombolysis, antithrombotic therapy, and prognosis. Hemorrhagic stroke has a higher mortality rate than ischemic stroke.[1] In the United States, 87% of all strokes are ischemic, secondary to large-artery atherosclerosis, cardioembolism, small-vessel occlusion, or other and undetermined causes.[1,2] The remaining 13% of strokes are hemorrhagic in intracerebral or subarachnoid locations.[1]

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Source: Adapted from Am Fam Physician. 2015;91(8):528-536.

RISK FACTORS

Although there are many risk factors for stroke, such as age, family history, diabetes mellitus, chronic kidney disease, and sleep apnea, the major modifiable risk factors include hypertension, atrial fibrillation, smoking, symptomatic carotid artery disease, and sickle cell disease.[1] Physical inactivity; regular consumption of sweetened beverages; and low daily consumption of fish, fruits, or vegetables are also associated with an increased risk of stroke.[1] In women, current use of oral contraceptives, migraine with aura, the immediate postpartum period, and preeclampsia confer small absolute increases in risk of stroke.[1]

CLINICAL DIAGNOSIS

History and Physical Examination

In a community-based study, primary care physicians practicing in an emergency setting had a 92% sensitivity for diagnosing stroke and transient ischemic attack based on history and examination.[3] The overall reliability of a clinician's diagnosis of stroke is moderate to good, with lower reliability in less experienced or less confident examiners.[4] The most common historical feature of an ischemic stroke is awakening with or acute onset of symptoms, whereas the most common physical findings are unilateral weakness and speech disturbance.[5] The most common and reliable symptoms and signs of

ischemic stroke are listed in Table 1.[4-7] The most common symptoms and signs of posterior circulation stroke are listed in Table 2.[8] Figure 1 provides an algorithm for stroke diagnosis. A critical piece of information is the time of onset. This value does not assist in diagnosing stroke, but it determines whether a patient meets the 3- or 4.5-hour eligibility windows for thrombolysis among persons with a diagnosis of ischemic stroke.[9]

Physicians managing acute stroke should become familiar with the National Institutes of Health Stroke Scale (NIHSS). The NIHSS is a 15-item scale that can be performed in about five minutes. Although it can help distinguish stroke from stroke mimics,[10] its chief use is to reliably evaluate stroke severity to determine whether tissue plasminogen activator administration is appropriate. It is also used to predict prognosis. Reliable use of the NIHSS requires training,[11] which can produce excellent inter-rater reliability of scoring across physicians and nurses.[12] Free online training is available from the National Stroke Association at http://www.stroke.org/site/PageServer?pagename=nihss.[13]

Studies of missed stroke diagnosis have found weakness and fatigue, altered mental status, syncope, altered gait and dizziness, and hypertensive urgency to be the most common presenting symptoms in patients admitted for a diagnosis other than stroke who were later confirmed to have had a stroke.[14,15] However, such nonspecific symptoms are not usual presentations of stroke.

Table 2. Most Common Symptoms and Signs of Posterior Circulation Stroke

Symptom or sign	Prevalence (%)[8]
Symptoms	
Dizziness	47
Unilateral limb weakness	41
Dysarthria	31
Headache	28
Nausea or vomiting	27
Signs	
Unilateral limb weakness	38
Gait ataxia	31
Unilateral limb ataxia	30
Dysarthria	28
Nystagmus	24

Information from references 8.

The history and physical examination for common stroke symptoms should uncover the diagnosis of stroke even in uncommon presentations.

Posterior circulation strokes may be challenging to diagnose. One potential area of confusion is when patients present with dizziness, which is a common concern in general but an uncommon presentation for stroke. In a population-based study of adults older than 44 years presenting to the emergency department or directly admitted to the hospital with a principal concern of dizziness, only 0.7% of patients with isolated dizziness symptoms had an ultimate diagnosis of stroke or transient ischemic attack, although their stroke was missed by the initial examiner 44% of the time.[16]

However, in patients presenting with acute vestibular syndrome[17] defined by one hour or more of acute, persistent, continuous vertigo or dizziness with spontaneous or gaze-evoked nystagmus, plus nausea or vomiting, head motion intolerance, and new gait unsteadiness, one-fourth or more have a posterior circulation stroke.[18,19] As many as two-thirds of patients with acute vestibular syndrome caused by stroke have no obvious neurologic findings.[19] A battery of three bedside tests of eye movement is more sensitive than early magnetic resonance imaging (MRI) for diagnosing posterior stroke in this setting and is highly specific.[18,20] Table 3 describes the conduct and operating characteristics of each test and the battery.[18-20] A video demonstrating these tests is available at http://content.lib.utah.edu/cdm/single item/collection/ehsl-dent/id/6/rec/5.

Reliably distinguishing between hemorrhagic and ischemic stroke can be done only through neuroimaging. Patients with hemorrhagic stroke are more likely to have headache, vomiting, diastolic blood pressure greater than 110 mm Hg, meningismus, or coma, but none of these findings alone or in combination is reliable enough to ascertain a diagnosis.[21]

Subarachnoid hemorrhage (SAH) presents differently from intracerebral hemorrhage or ischemic stroke. About 80% of patients with aneurysmal SAH report a sudden onset of what they describe as the worst headache of their life.[22] A previous sentinel headache two to eight weeks before aneurysmal rupture is a critical historical finding present in up to 40% of patients with SAH.[22] Findings accompanying the headache can include vomiting, photophobia, seizures, meningismus, focal neurologic signs, and decreased level of consciousness.[22,23] Funduscopy should be performed because intraocular hemorrhages are present in one in seven patients with aneurysmal SAH.[24] Because the

bleeding occurs outside the brain, persons with SAH may not have focal neurologic signs.

Stroke Mimics and Differential Diagnosis

Clinicians should consider a broad differential diagnosis when evaluating suspected stroke (Table 4[7,9,10,16,19,25-34]). Seizure, conversion or somatoform disorder, migraine headache, and hypoglycemia are the most common stroke mimics.[10,25-30] Checklists to ascertain eligibility for intravenous thrombolysis explicitly include detection of hypoglycemia, hyperglycemia, and recent seizures.

The rates of misdiagnosis of stroke in studies of consecutive patients not treated with thrombolysis vary from 25% to 31%.[10,25,35] Of patients receiving thrombolysis, 1.4% to 16.7% are found to have a stroke mimic.[26-31] Factors associated with greater risk of a stroke mimic are younger age, lower baseline NIHSS scores, history of cognitive impairment, and nonneurologic abnormal physical findings.[10,26-31] Patients with a stroke mimic are more likely to present with global aphasia without hemiparesis than patients demonstrated to have a stroke.[26,31]

DIAGNOSTIC TESTS AND IMAGING

Table 5 lists initial diagnostic studies recommended by current guidelines for patients with suspected stroke.[9]

The purpose of these studies is to uncover stroke mimics, diagnose critical comorbidities such as myocardial ischemia, and detect contraindications to thrombolytic therapy. No combination of stroke biomarkers has been shown to give additional diagnostic certainty over that of clinical history and examination alone.[36]

All patients with stroke symptoms should undergo urgent neuroimaging with noncontrast computed tomography (CT) or MRI.[9,37] The primary purpose of neuroimaging in a patient with suspected ischemic stroke is to rule out the presence of nonischemic central nervous system lesions and to distinguish between ischemic and hemorrhagic stroke. Figures 2 and 3 show examples of intracerebral and subarachnoid hemorrhages on noncontrast CT.[7] Noncontrast CT is considered sufficiently sensitive for detecting mass lesions, such as a brain mass or abscess, as well as for detecting acute hemorrhage. However, less than

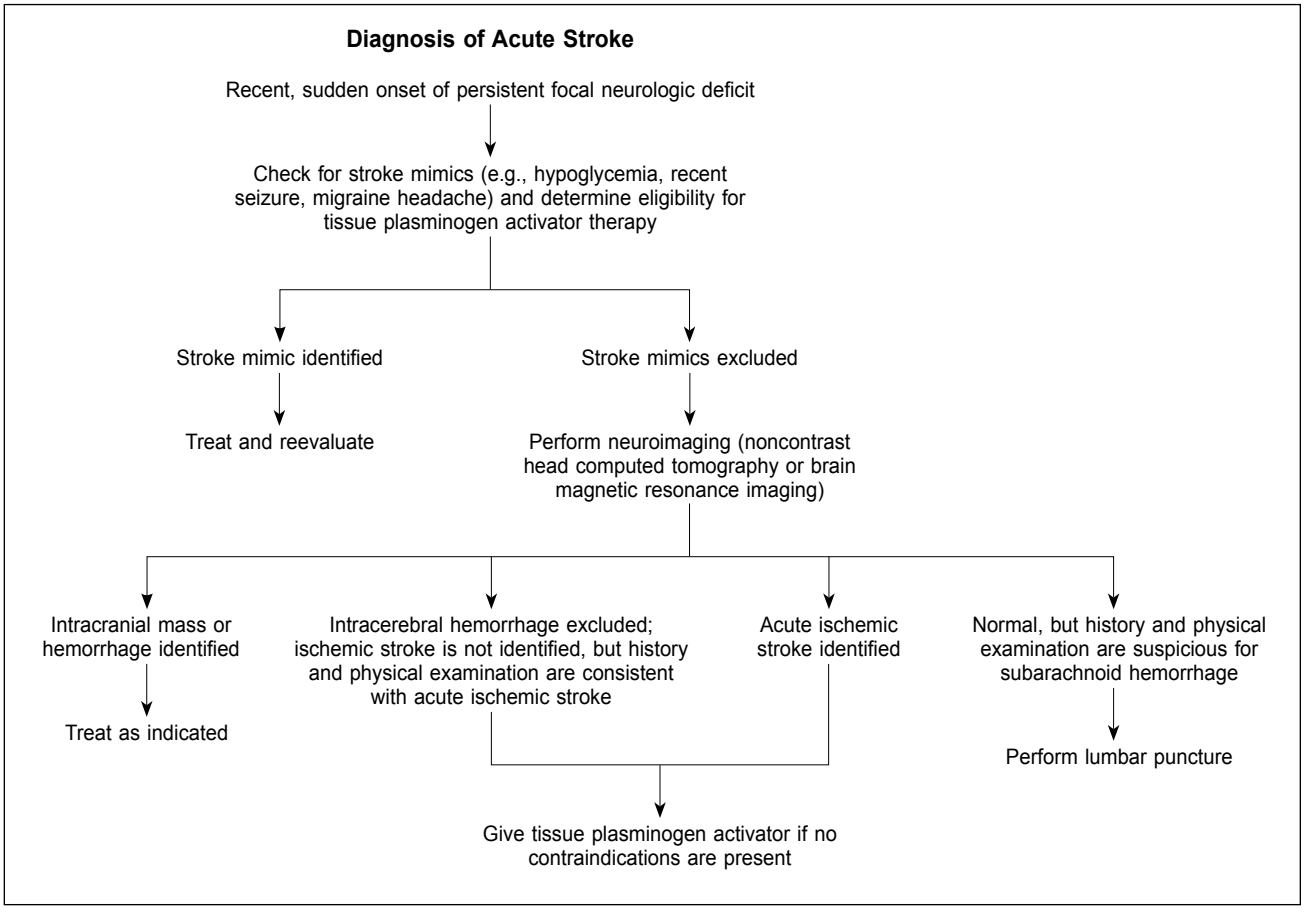

Figure 1. Algorithm for the diagnosis of acute stroke.

IJCP SUTRA 91: The optimal volume for each blood culture in adults is 20 mL (10 mL introduced into an aerobic bottle and 10 mL introduced into an anaerobic bottle). *Pediatrics.* 2007;119:891.

Table 3. Bedside Predictors of Stroke and Other Central Etiologies in Patients with Acute Vestibular Syndrome

Bedside diagnostic predictor	Test description	Sensitivity (95% CI)	Specificity (95% CI)	LR+ (95% CI)	LR– (95% CI)
Normal result on horizontal head impulse test	Turn the patient's head laterally 10 to 20 degrees while observing his or her eyes. A normal result is for the eyes to stay fixed on a target. An abnormal result is for the eyes to rapidly move back to the target once head movement stops. The test also may be performed by turning the patient's head back to center from 10 to 20 degrees off-center.[20]	0.85 (0.79 to 0.91)	0.95 (0.90 to 1.00)	18.39 (6.08 to 55.64)	0.16 (0.11 to 0.23)
Direction-changing nystagmus	Nystagmus in the setting of acute vertiginous syndrome is normally unidirectional, with the fast beat of nystagmus away from the affected side and a slow return toward the affected side. Nystagmus is enhanced when the eye moves toward the side of the fast beat and decreases or disappears when the eye moves toward the side of slow beat. With central lesions, the fast beat of nystagmus may change directions toward the direction the eyes are moving, hence the term "direction-changing nystagmus."[20]	0.38 (0.32 to 0.44)	0.92 (0.86 to 0.98)	4.51 (2.18 to 9.34)	0.68 (0.60 to 0.76)
Skew deviation	Normally during the cover-uncover test there is no eye movement. Upward or downward movement on the cover-uncover test (refixation) indicates skew deviation and is associated with a central lesion.[20]	0.30 (0.22 to 0.39)	0.98 (0.95 to 1.00)	19.66 (2.76 to 140.15)	0.71 (0.63 to 0.80)
HINTS positive	HINTS positive is a normal head impulse test result, direction-changing nystagmus, refixation on cover test (skew deviation), or any combination of these findings.[18]	96.8 (92.4 to 99.0)	98.5 (92.8 to 99.9)	63.9 (9.13 to 446.85)	0.03 (0.01 to 0.09)

Note: The analysis included patients with diagnoses other than stroke, including demyelination, brainstem hemorrhage, and other causes comprising a minority of the diagnoses.[18,19]

CI = Confidence interval; HINTS = Head impulse, nystagmus, test of skew; LR+ = Positive likelihood ratio; LR– = Negative likelihood ratio.

Information from references 18 through 20.

two-thirds of strokes are detected by noncontrast CT at three hours postinfarction.[38] Noncontrast CT has even lower sensitivity for small or posterior fossa strokes.[9]

Multimodal MRI sequences, particularly diffusion-weighted images, have better resolution than noncontrast CT, and therefore have a greater sensitivity for detecting acute ischemic stroke.[37,38] MRI sequences (particularly gradient recalled echo and diffusion-weighted sequences) are as sensitive as noncontrast CT for detecting intracerebral hemorrhagic stroke.[9,37,38] Figure 4 shows the head noncontrast CT and diffusion-weighted MRI of a patient with a previous stroke and a new acute stroke.

MRI has better resolution than noncontrast CT, but noncontrast CT is faster, more available, less expensive, and can be performed in persons with implanted devices (e.g., pacemakers) and in persons with claustrophobia. If a patient is within the time window of intravenous thrombolytic therapy, guidelines recommend that noncontrast CT or MRI be performed to exclude intracerebral hemorrhage and evaluate for ischemic changes.[9] In patients younger than 55 years presenting with stroke-like symptoms, MRI yields a lower rate of misdiagnosis than noncontrast CT because of a lower prevalence of vascular risk factors and a higher prevalence of central nervous system stroke mimics in this age group.[39,40] Patients presenting with acute vestibular syndrome or suspected posterior infarction should undergo acute diffusion-weighted MRI.[37] Because MRI may miss up to 15% of posterior strokes in the first 48 hours,[18] a negative MRI result

Table 5. Immediate Diagnostic Studies: Evaluation of a Patient with Suspected Acute Ischemic Stroke

All patients
Noncontrast brain CT or brain MRI
Blood glucose
Oxygen saturation
Serum electrolytes/renal function tests*
Complete blood count, including platelet count*
Markers of cardiac ischemia*
Prothrombin time/INR*
Activated partial thromboplastin time*
ECG*
Selected patients
TT and/or ECT if it is suspected the patient is taking direct thrombin inhibitors or direct factor Xa inhibitors
Hepatic function tests
Toxicology screen
Blood alcohol level
Pregnancy test
Arterial blood gas tests (if hypoxemia suspected)
Chest radiography (if lung disease suspected)
Lumbar puncture (if subarachnoid hemorrhage is suspected and CT scan is negative for blood)
Electroencephalogram (if seizures are suspected)

CT = Computed tomography; ECG = Electrocardiography; ECT = Ecarin clotting time; INR = International normalized ratio; MRI = Magnetic resonance imaging; TT = Thrombin time.

*Although it is desirable to know the results of these tests before giving intravenous recombinant tissue-type plasminogen activator, fibrinolytic therapy should not be delayed while awaiting the results unless (1) there is clinical suspicion of a bleeding abnormality or thrombocytopenia, (2) the patient has received heparin or warfarin, or (3) the patient has received other anticoagulants (direct thrombin inhibitors or direct factor Xa inhibitors).

Reprinted with permission from Jauch EC, Saver JL, Adams HP Jr, et al.; American Heart Association Stroke Council; Council on Cardiovascular Nursing; Council on Peripheral Vascular Disease; Council on Clinical Cardiology. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44(3):881. http://stroke.ahajournals.org/content/44/3/870.full.

should be followed by a repeat MRI in three to seven days or bedside oculomotor testing to exclude a false-negative result.

Although acute neuroimaging is essential, it may be possible to efficiently obtain imaging of the carotid arteries to detect carotid stenosis, such as when MRI of the brain is combined with magnetic resonance angiography of the neck. Current guidelines do not address acute imaging of cervical vessels, but it is recommended as part of the subsequent evaluation of

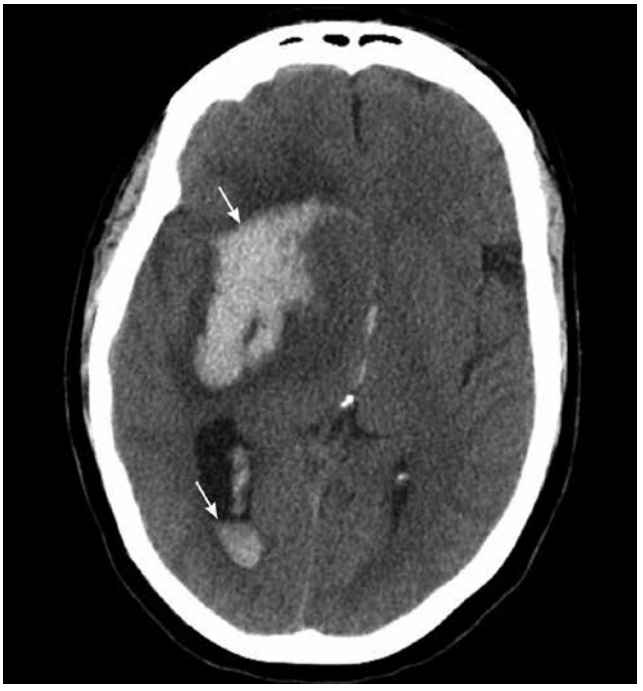

Figure 2. Head computed tomography showing intracerebral hemorrhages (*arrows*).

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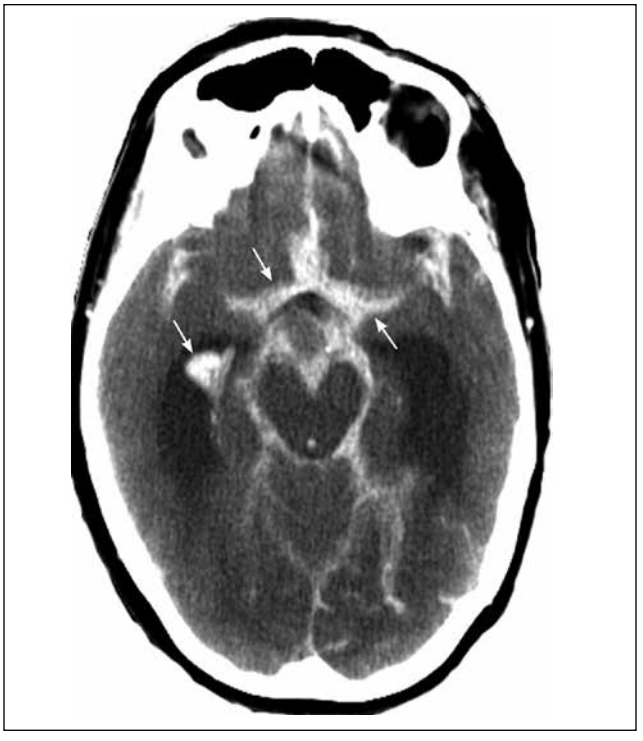

Figure 3. Head computed tomography showing subarachnoid hemorrhages (*arrows*). Note that acute hemorrhage appears hyperdense (*white*) on computed tomography.

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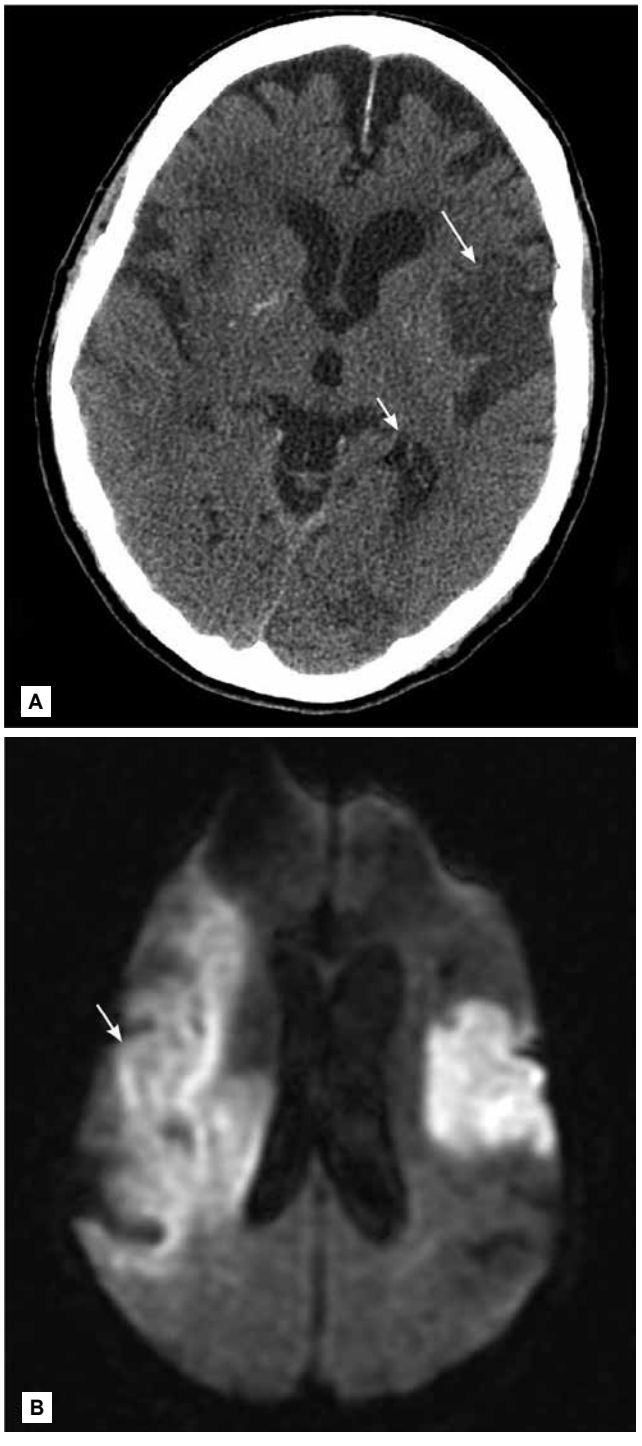

Figure 4. (A) Noncontrast computed tomography showing two hypodense regions indicating old infarctions in the distribution of the left-middle cerebral (*long arrow*) and posterior cerebral arteries (*short arrow*). **(B)** Diffusion-weighted magnetic resonance imaging obtained shortly after the computed tomography reveals a new extensive infarction (*arrow*) in the right-middle cerebral artery distribution not evident on the computed tomography.

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patients with confirmed stroke or transient ischemic attack,[9] which is beyond the scope of this article. Acute intracranial vascular imaging is recommended if intravascular therapy is being considered, as long as it does not delay intravenous thrombolysis.[9]

Unlike ischemic stroke and intracerebral hemorrhage, diagnosing SAH requires a different diagnostic approach. The frequency of misdiagnosis of SAH is about 12%.[22] Noncontrast CT is the imaging test of choice for persons with suspected SAH.[22] Noncontrast CT has a sensitivity of nearly 100% for detecting subarachnoid blood in the first 72 hours.[22] The sensitivity of noncontrast CT to detect subarachnoid blood declines over time, whereas MRI remains highly sensitive to intracranial blood for up to 30 days, making it the preferred test for delayed presentations.[22,23]

Persons with suspected SAH and a normal noncontrast CT result should undergo a lumbar puncture to detect bilirubin, a breakdown product of red blood cells in the cerebrospinal fluid.[23] Because red blood cell breakdown can take up to 12 hours, the lumbar puncture should be delayed until 12 hours after the initial onset of symptoms to accurately distinguish SAH from a traumatic tap.[23,41] The yellow color caused by bilirubin, which is called xanthochromia, can be detected by visual inspection or spectrophotometry.[23,41] Spectrophotometry is more sensitive than visual inspection, but is not widely available.[23,41] Bilirubin can be detected up to two weeks after the initial onset of symptoms. If SAH is detected, persons should immediately undergo CT, MRI, or catheter angiography to look for an aneurysm.

TRAINING PATIENTS TO RECOGNIZE STROKE SYMPTOMS

Patients and family members should be educated about stroke symptoms and the need for urgent evaluation.[9] Consistent data show considerable room for improvement in stroke knowledge in the general population.[42] However, there are limited data to support the effectiveness of public media campaigns to improve stroke knowledge and to link improved knowledge of stroke symptoms to behavior or clinical outcomes.[43,44] A recent study showed that knowledge of two warning signs of stroke was associated with activation of emergency medical services, which suggests a goal for public education campaigns.[45] The American Stroke Association is promoting the F.A.S.T. (face drooping, arm weakness, speech difficulty, time to call 9-1-1) campaign to improve patient knowledge about stroke and to expedite activation of 9-1-1 services.[46]

Note: For complete article visit: www.aafp.org/afp.

REFERENCES

1. Go AS, Mozaffarian D, Roger VL, et al.; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2014 update: a report from the American Heart Association. Circulation. 2014;129(3):e28-e292.
2. Adams HP Jr, Bendixen BH, Kappelle LJ, et al. Classification of subtype of acute ischemic stroke. Definitions for use in a multicenter clinical trial. TOAST. Trial of Org 10172 in Acute Stroke Treatment. Stroke. 1993; 24(1):35-41.
3. Morgenstern LB, Lisabeth LD, Mecozzi AC, et al. A population-based study of acute stroke and TIA diagnosis. Neurology. 2004;62(6):895-900.
4. Hand PJ, Haisma JA, Kwan J, et al. Interobserver agreement for the bedside clinical assessment of suspected stroke. Stroke. 2006;37(3):776-780.
5. Nor AM, Davis J, Sen B, et al. The Recognition of Stroke in the Emergency Room (ROSIER) scale: development and validation of a stroke recognition instrument. Lancet Neurol. 2005;4(11):727-734.
6. Goldstein LB, Simel DL. Is this patient having a stroke? JAMA. 2005;293(19):2391-2402.
7. Yew KS, Cheng E. Acute stroke diagnosis. Am Fam Physician. 2009;80(1):33-40.
8. Searls DE, Pazdera L, Korbel E, Vysata O, Caplan LR. Symptoms and signs of posterior circulation ischemia in the New England Medical Center Posterior Circulation Registry. Arch Neurol. 2012;69(3):346-351.
9. Jauch EC, Saver JL, Adams HP Jr, et al.; American Heart Association Stroke Council; Council on Cardiovascular Nursing; Council on Peripheral Vascular Disease; Council on Clinical Cardiology. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44(3):870-947.
10. Hand PJ, Kwan J, Lindley RI, Dennis MS, Wardlaw JM. Distinguishing between stroke and mimic at the bedside: the brain attack study. Stroke. 2006;37(3):769-775.
11. Schmülling S, Grond M, Rudolf J, Kiencke P. Training as a prerequisite for reliable use of NIH Stroke Scale. Stroke. 1998;29(6):1258-1259.
12. Josephson SA, Hills NK, Johnston SC. NIH Stroke Scale reliability in ratings from a large sample of clinicians. Cerebrovasc Dis. 2006;22(5-6):389-395.
13. National Stroke Association. NIH Stroke Scale. 2014; NIHSS online education. http://www.stroke.org/site/PageServer?pagename=nihss. Accessed October 21, 2014.
14. Lever NM, Nyström KV, Schindler JL, Halliday J, Wira C III, Funk M. Missed opportunities for recognition of ischemic stroke in the emergency department. J Emerg Nurs. 2013;39(5):434-439.
15. Dupre CM, Libman R, Dupre SI, Katz JM, Rybinnik I, Kwiatkowski T. Stroke chameleons. J Stroke Cerebrovasc Dis. 2014;23(2):374-378.
16. Kerber KA, Brown DL, Lisabeth LD, Smith MA, Morgenstern LB. Stroke among patients with dizziness, vertigo, and imbalance in the emergency department: a population-based study. Stroke. 2006;37(10):2484-2487.
17. Hotson JR, Baloh RW. Acute vestibular syndrome. N Engl J Med. 1998;339(10):680-685.
18. Newman-Toker DE, Kerber KA, Hsieh YH, et al. HINTS outperforms ABCD2 to screen for stroke in acute continuous vertigo and dizziness. Acad Emerg Med. 2013;20(10):986-996.
19. Tarnutzer AA, Berkowitz AL, Robinson KA, Hsieh YH, Newman-Toker DE. Does my dizzy patient have a stroke? A systematic review of bedside diagnosis in acute vestibular syndrome. CMAJ. 2011;183(9):E571-E592.
20. Newman-Toker DE. 3-Component H.I.N.T.S. battery. http://content. lib.utah.edu/cdm/singleitem/collection/ehsl-dent/id/6/rec/5. Accessed July 20, 2014.
21. Runchey S, McGee S. Does this patient have a hemorrhagic stroke?: clinical findings distinguishing hemorrhagic stroke from ischemic stroke. JAMA. 2010;303(22): 2280-2286.
22. Connolly ES Jr. Rabinstein AA, Carhuapoma JR, et al.; American Heart Assoication Stroke Council; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular Nursing; Council on Cardiovascular Surgery and Anesthesia; Council on Clinical Cardiology. Guidelines for the management of aneurysmal subarachnoid hemorrhage: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2012;43(6):1711-1737.
23. Moore SA, Rabinstein AA, Stewart MW, Freeman WD. Recognizing the signs and symptoms of aneurysmal subarachnoid hemorrhage. Expert Rev Neurother. 2014;14(7):757-768.
24. van Gijn J, Kerr RS, Rinkel GJ. Subarachnoid haemorrhage. Lancet. 2007;369(9558):306-318.
25. Hemmen TM, Meyer BC, McClean TL, Lyden PD. Identification of nonischemic stroke mimics among 411 code strokes at the University of California, San Diego, Stroke Center. J Stroke Cerebrovasc Dis. 2008;17(1):23-25.
26. Förster A, Griebe M, Wolf ME, Szabo K, Hennerici MG, Kern R. How to identify stroke mimics in patients eligible for intravenous thrombolysis? J Neurol. 2012;259(7): 1347-1353.
27. Artto V, Putaala J, Strbian D, et al.; Helsinki Stroke Thrombolysis Registry Group. Stroke mimics and intravenous thrombolysis. Ann Emerg Med. 2012; 59(1):27-32.
28. Tsivgoulis G, Alexandrov AV, Chang J, et al. Safety and outcomes of intravenous thrombolysis in stroke mimics: a 6-year, single-care center study and a pooled analysis of reported series. Stroke. 2011;42(6):1771-1774.

IJCP SUTRA 95: Single liver abscesses with diameter > 5 cm - For percutaneous management, catheter drainage is preferred over needle aspiration. *AJR Am J Roentgenol.* 2007;189:W138.

29. Vroomen PC, Buddingh MK, Luijckx GJ, De Keyser J. The incidence of stroke mimics among stroke department admissions in relation to age group. J Stroke Cerebrovasc Dis. 2008;17(6):418-422.
30. Mehta S, Vora N, Edgell RC, et al. Stroke mimics under the drip-and-ship paradigm. J Stroke Cerebrovasc Dis. 2014;23(5):844-849.
31. Guillan M, Alonso-Canovas A, Gonzalez-Valcarcel J, et al. Stroke mimics treated with thrombolysis: further evidence on safety and distinctive clinical features. Cerebrovasc Dis. 2012;34(2):115-120.
32. Qureshi AI, Ezzeddine MA, Nasar A, et al. Prevalence of elevated blood pressure in 563,704 adult patients with stroke presenting to the ED in the United States. Am J Emerg Med. 2007;25(1):32-38.
33. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders. 2nd edition. Cephalalgia. 2004; 24(suppl 1): 9-160.
34. Liou KC, Chen LA, Lin YJ. Cervical spinal epidural hematoma mimics acute ischemic stroke. Am J Emerg Med. 2012;30(7):1322.e1-e3.
35. Merino JG, Luby M, Benson RT, et al. Predictors of acute stroke mimics in 8187 patients referred to a stroke service. J Stroke Cerebrovasc Dis. 2013;22(8):e397-e403.
36. An SA, Kim J, Kim OJ, et al. Limited clinical value of multiple blood markers in the diagnosis of ischemic stroke. Clin Biochem. 2013;46(9):710-715.
37. Wintermark M, Sanelli PC, Albers GW, et al. Imaging recommendations for acute stroke and transient ischemic attack patients: A joint statement by the American Society of Neuroradiology, the American College of Radiology, and the Society of NeuroInterventional Surgery. AJNR Am J Neuroradiol. 2013;34(11):E117-E127.
38. Latchaw RE, Alberts MJ, Lev MH, et al.; American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, and the Interdisciplinary Council on Peripheral Vascular Disease. Recommendations for imaging of acute ischemic stroke: a scientific statement from the American Heart Association. Stroke. 2009;40(11):3646-3678.
39. Ferro JM, Massaro AR, Mas JL. Aetiological diagnosis of ischaemic stroke in young adults. Lancet Neurol. 2010;9(11):1085-1096.
40. Bhattacharya P, Nagaraja N, Rajamani K, Madhavan R, Santhakumar S, Chaturvedi S. Early use of MRI improves diagnostic accuracy in young adults with stroke. J Neurol Sci. 2013;324(1-2):62-64.
41. Cruickshank A, Auld P, Beetham R, et al.; UK NEQAS Specialist Advisory Group for External Quality Assurance of CSF Proteins and Biochemistry. Revised national guidelines for analysis of cerebrospinal fluid for bilirubin in suspected subarachnoid haemorrhage. Ann Clin Biochem. 2008;45(pt 3):238-244.
42. Kleindorfer D, Khoury J, Broderick JP, et al. Temporal trends in public awareness of stroke: warning signs, risk factors, and treatment. Stroke. 2009;40(7):2502-2506.
43. Lecouturier J, Rodgers H, Murtagh MJ, White M, Ford GA, Thomson RG. Systematic review of mass media interventions designed to improve public recognition of stroke symptoms, emergency response and early treatment. BMC Public Health. 2010;10:784.
44. Reeves MJ. Reducing the delay between stroke onset and hospital arrival: is it an achievable goal? J Am Heart Assoc. 2012;1(3):e002477.
45. Mosley I, Nicol M, Donnan G, Thrift AG, Dewey HM. What is stroke symptom knowledge? Int J Stroke. 2014;9(1):48-52.
46. American Heart Association; American Stroke Association. Stroke warning signs and symptoms. http://strokeassociation.org/STROKEORG/WarningSigns/Stroke-Warning-Signs-and-Symptoms_UCM_308528_SubHomePage.jsp. Accessed July 24, 2014.

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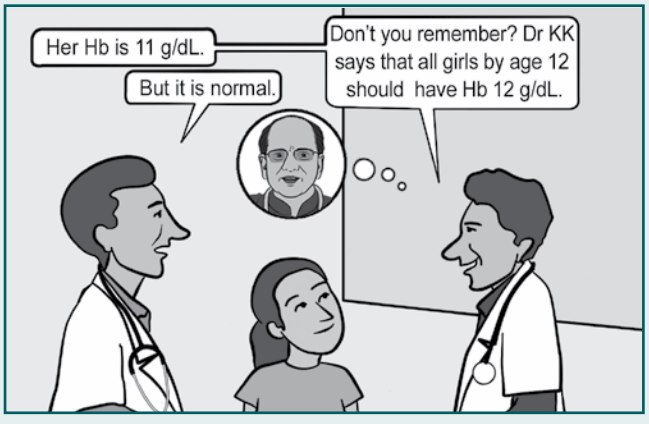
CHAT WITH DR KK

Hb 12 by Age 12



Practice Guidelines

AAP RELEASES PRACTICE GUIDELINE ON DIAGNOSIS, MANAGEMENT, AND PREVENTION OF BRONCHIOLITIS

Bronchiolitis, which is the most common reason infants are hospitalized in the first year of life, is typically caused by viral lower respiratory tract infection (e.g., respiratory syncytial virus [RSV]) and often causes acute swelling, edema, epithelial cell necrosis in small airways, and increased production of mucus. Typically, symptoms start as rhinitis and cough; these can evolve into tachypnea, wheezing, rales, accessory muscle use, or flaring of the nostrils. This guideline on the diagnosis, management, and prevention of bronchiolitis in children one to 23 months of age from the American Academy of Pediatrics (AAP) updates a previous guideline published in 2006.

Recommendations

Diagnosis

Strong Recommendations. Based on studies with minor limitations or consistent findings in multiple observational studies, the diagnosis for bronchiolitis should be established using a history and physical examination; severity of the condition should be established in the same manner. The goal of the history and physical examination is to distinguish between suspected bronchiolitis and other illnesses or conditions. Important aspects of the history include the patient's underlying conditions; how respiratory problems are affecting his or her mental status, feeding, and hydration; and the caregiver's ability to provide care and bring the child back to the office, if needed. When performing a physical examination, it may be necessary to observe the patient over time to fully determine status.

Moderate Recommendations. The following recommendations are based on studies with minor limitations or consistent findings in multiple observational studies:

- Risk factors for severe disease (e.g., age younger than 12 weeks, history of prematurity, cardiopulmonary disease, immunodeficiency) should be evaluated when choosing how to assess for and manage bronchiolitis.
- When establishing a diagnosis using the history and physical examination, radiography and laboratory tests do not need to be routinely performed. Radiography should be performed initially only in patients with airway complications or in whom respiratory effort necessitates admission to the intensive care unit.

Treatment

Strong Recommendations. Based on well-designed trials and meta-analyses on applicable populations, systemic corticosteroids should not be given to children with bronchiolitis. Although good evidence indicates that corticosteroids are beneficial in other respiratory disease, data regarding their use for bronchiolitis are negative, with the most recent Cochrane review and a large multicenter randomized trial demonstrating that their use as monotherapy is not significantly beneficial. Additionally, aside from prolonged viral shedding, no evidence exists of the adverse effects of corticosteroids when used for bronchiolitis; therefore, their safety profile is uncertain.

The following strong recommendations are based on studies with minor limitations or consistent findings in multiple observational studies:

- Albuterol, salbutamol, and epinephrine should not be given to infants with bronchiolitis. Alpha- and beta-adrenergics have not been shown to be consistently beneficial in patients with bronchiolitis in a majority of randomized controlled trials. Additionally, a few systematic reviews and meta-analyses have indicated that, although bronchodilators possibly help with symptom scores, they do not help in resolving the illness, lessen the need to be hospitalized, or, if hospitalized, shorten the stay. With regard to epinephrine, a Cochrane review determined there was a lack of evidence to support its use in the inpatient setting; two randomized trials determined that its use vs. placebo or albuterol did not shorten the length of stay in the hospital or other outcomes in the inpatient setting; and a large multicenter trial determined that it lacked effectiveness vs. placebo, and caused a longer stay in the hospital when used on a fixed schedule vs. being used only as needed. The use of epinephrine in outpatients remains controversial.
- Antibacterial drugs should not be given, unless the patient has or is suspected to have a bacterial

Source: Adapted from Am Fam Physician. 2015;91(8):578-580.

infection. Randomized controlled trials have demonstrated no benefit from the routine use of antibacterial drugs in children with bronchiolitis.

Although validating studies cannot be performed, in situations where the benefits outweigh the harms, nasogastric or intravenous fluids should be given to patients unable to maintain hydration via the oral route. The indications should be based on the level of respiratory distress in the patient.

Moderate Recommendations. The following recommendations are based on studies with minor limitations or consistent findings in multiple observational studies:

- Nebulized hypertonic saline should not be given to children with bronchiolitis who present to the emergency department. Evidence has shown that saline does not reduce hospitalizations in emergency settings.
- Chest physiotherapy should not be used in children with bronchiolitis.

Weak Recommendations. Based on studies with minor limitations or consistent findings in multiple observational studies, nebulized hypertonic saline can be given to children with bronchiolitis who are in the hospital. Most evidence supports the safety and effectiveness of 3% saline for helping improve symptoms, after one day's use, in patients with mild to moderate disease. Additionally, data support use of 3% saline for shortening hospital stays of greater than three days.

Based on single or few observational studies or multiple studies with inconsistent findings or major limitations, physicians can opt not to use continuous pulse oximetry. Additionally, based on expert opinion, case reports, or reasoning from first principles, if a patient's oxyhemoglobin saturation is greater than 90%, supplemental oxygen does not have to be given, and physicians can opt to not provide it.

Prevention

Strong Recommendations. The following recommendations are based on studies with minor limitations or consistent findings in multiple observational studies:

- Palivizumab should not be given to otherwise healthy infants with a gestational age of at least 29 weeks; however, it can be given as outlined below in the moderate recommendations section.
- When caring for children with bronchiolitis, alcohol-based rubs should be used for hand cleaning; however, if unavailable, soap and water can be used. RSV can be carried on hands of caregivers and then spread to others. Hands should be cleaned before and after having direct contact with the patient, after contact with items around the patient, and before putting on and after removing gloves. When the patient is in the hospital, adhering to procedures for hand cleaning and using protective items like gloves can help lower the chance of cross infection.
- When evaluating a child for bronchiolitis, counseling about exposing the child to tobacco smoke, as well as smoking cessation (if needed), should be provided to the parents. When a child is exposed to tobacco smoke, he or she has a higher risk of bronchiolitis. Additionally, if the child has bronchiolitis, the disease can worsen when exposed to smoke.

Moderate Recommendations. The following recommendations are based on studies with minor limitations or consistent findings in multiple observational studies:

- During the first 12 months of life, palivizumab should be given during the RSV season to children with hemodynamically significant heart disease or chronic lung disease of prematurity (less than 32 weeks' gestation and requiring more than 21% oxygen in the first 28 days of life). It should be given as a maximum of five monthly doses (15 mg per kg per dose).
- Women should be encouraged to breastfeed their child for six months or longer to reduce morbidity from respiratory infections. One meta-analysis found a 72% decrease in the risk of hospitalization from respiratory illness in children exclusively breastfed for at least four months vs. children given formula. Additionally, it has been demonstrated that respiratory infections are less common in children who have been breastfed.

The following recommendations are based on single or few observational studies or multiple studies with inconsistent findings or major limitations:

- During evaluation for bronchiolitis, caregivers should be asked whether the child is exposed to tobacco smoke.
- Health care personnel and patients' families should be taught about bronchiolitis diagnosis, treatment, and prevention options that are based on evidence. Allowing families of patients to share in the decision-making process is essential when providing patient-centered care, and despite the lack of effective treatments for bronchiolitis, providing families key information still has the possibility to significantly affect patterns of care.

Photo Quiz

A GEOMETRIC SUMMERTIME RASH

A 17-year-old girl presented with a bruise-like rash on her legs. The rash had appeared three days prior, after she had eaten limes and rolled down a grassy hill with friends. The rash was initially brightly erythematous, and it was associated with a burning sensation. She had a history of asthma and eczema.

The physical examination revealed multiple linear and geometric hyperpigmented patches on her medial thighs bilaterally (Figures 1 and 2). The rash was in a "kissing" pattern in the flexural aspect of her knee.

Question

Based on the patient's history and physical examination findings, which one of the following is the most likely diagnosis?

A. Allergic contact dermatitis.

B. Chemical burn.

C. Child abuse.

D. Phytophotodermatitis.

Discussion

The correct answer is D: phytophotodermatitis. Phytophotodermatitis is a phototoxic eruption (i.e., an enhanced sunburn) that occurs when the skin is exposed to a photosensitizing compound called a psoralen, then exposed to sunlight. The most common source of psoralen is citrus fruits such as lemons, limes, and bergamot oranges. Other sources include figs, parsnips, celery, carrots, dill, and mustard. Heat, sweating, and wet skin intensify the process. Phototoxic reactions differ from photoallergic reactions in that they can happen at any time, without prior sensitization.[1-3] Phytophotodermatitis is more common in the summer. It may occur as an occupational hazard of bartenders, agricultural workers, florists, gardeners, and grocers.[4]

Phytophotodermatitis typically presents 24 hours after exposure with an erythematous rash that is accompanied by vesicles and a burning sensation. Symptom severity peaks within 48 to 72 hours, then

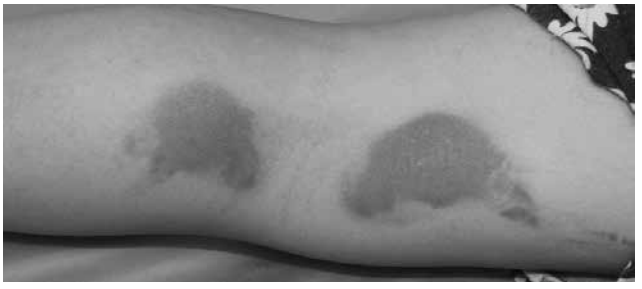


Figure 1.

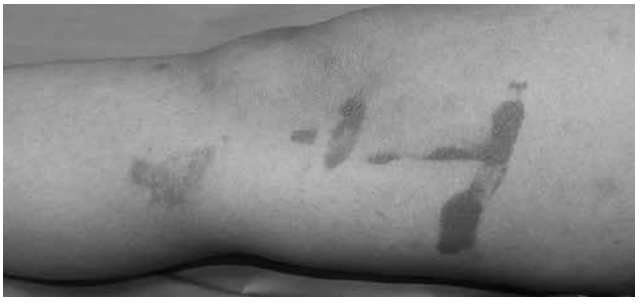


Figure 2.

characteristic hyperpigmentation gradually develops. The hyperpigmentation lasts weeks to months, but may occasionally last years in individuals with darker skin. The distribution offers diagnostic clues. Irregular or bizarre sunburns, preferential involvement of the dorsal hands and fingers, drip marks, hyperpigmented handprints, or kissing lesions on flexural surfaces suggest phytophotodermatitis.[1-3]

The treatment of choice is cool compresses, with topical corticosteroids if the reaction is severe and edematous. To prevent recurrence, sun protection and hand washing after exposure to foods known to contain psoralen should be emphasized.[1-3]

Allergic contact dermatitis manifests as an acute eczematous dermatitis after prior sensitization. The rash is characterized by pruritic papules and vesicles on an erythematous base. Causes include exposure to plants such as poison ivy and oak, topical medications such as bacitracin, metals such as nickel, and personal care products such as cosmetics, perfumes, lotions, and soaps. Allergen exposure, pruritus, and expansion of the rash slightly beyond the site of exposure differentiate allergic contact dermatitis from phytophotodermatitis.

Chemical burns may be difficult to distinguish from phytophotodermatitis because both present with

Source: Adapted from Am Fam Physician. 2015;91(9):649-650.

Summary Table

Condition	Rash characteristics	Exposures
Allergic contact dermatitis	Pruritic papules and vesicles on an erythematous base, at the site of exposure or diffusely across the body	Plants (e.g., poison ivy and oak), topical medications (e.g., bacitracin), metals (e.g., nickel), personal care products (e.g., cosmetics, perfumes, lotions, soaps); prior sensitization is required
Chemical burns	Erythematous plaques and vesicles that resolve with hyperpigmentation	Cleaning agents, car battery acid, bleach, ammonia, denture cleaners, teeth whitening products, swimming pool chlorinating products
Child abuse	Geometric lesions resembling hands or fingers in various stages of healing; bruising in atypical locations (e.g., ear, soft tissue, cheek)	Injury secondary to foreign objects; patterns that are incongruous with history
Phytophotodermatitis	Brightly erythematous geometric patches associated with burning; resolves with hyperpigmentation, which may last for months	Psoralen; common sources include citrus fruits (e.g., lemons, limes, bergamot oranges), figs, parsnips, celery, carrots, dill, and mustard

erythema, vesicles, and eventual hyperpigmentation in odd, geometric shapes. Clinical history of exposure can differentiate between these two diagnoses.

Child abuse should be considered in the differential diagnosis of any injured child. Clues to abuse include an unusual distribution or location of lesions, a handprint bruise that is adult-sized, or a pattern of bruises or marks in various stages of healing and incongruous with the patient's history.[5,6]

REFERENCES

1. Goskowicz MO, Friedlander SF, Eichenfield LF. Endemic "lime" disease: phytophotodermatitis in San Diego County. Pediatrics. 1994;93(5):828-830.
2. Egan CL, Sterling G. Phytophotodermatitis: a visit to Margaritaville. Cutis. 1993;51(1):41-42.
3. Hankinson A, Lloyd B, Alweis R. Lime-induced phytophotodermatitis. J Community Hosp Intern Med Perspect. 2014;4(4):25090.
4. Seligman PJ, Mathias CG, O'Malley MA, et al. Phytophotodermatitis from celery among grocery store workers. Arch Dermatol. 1987;123(11):1478-1482.
5. Committee on Child Abuse and Neglect, American Academy of Pediatrics. When inflicted skin injuries constitute child abuse. Pediatrics. 2002;110(3):644-645.
6. McDonald KC. Child abuse: approach and management. Am Fam Physician. 2007;75(2):221-228.

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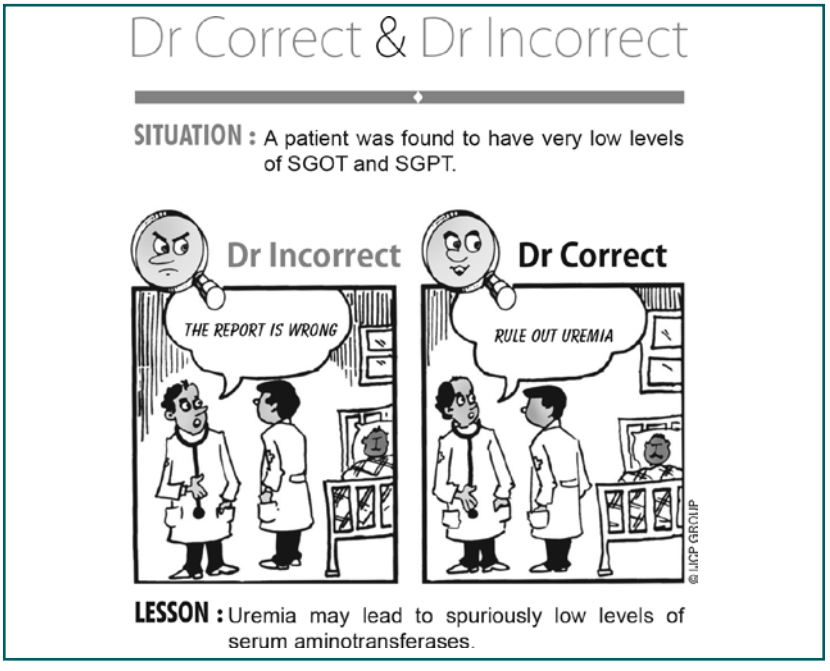

XY Female with Complete Androgen Insensitivity Syndrome with Bilateral Inguinal Hernia

BHAVANA S

ABSTRACT

Complete androgen insensitivity syndrome (CAIS) is an X-linked recessive rare disorder in which the individual is phenotypically female and genotypically male; a male pseudohermaphrodite. CAIS is suspected when the individual is evaluated for primary amenorrhea, infertility or when unilateral/bilateral inguinal hernia is diagnosed in girls. We report the case of a 30-year-old, married lady presented to Gynecology OPD with complaints of swelling in the groin, on both the sides since 4 months. She was investigated and all her blood tests were of male range and in accordance with CAIS. Bilateral gonadectomy with herniorraphy was done and the patient was discharged on estrogen replacement therapy.

Keywords: Complete androgen insensitivity syndrome, inguinal hernia, bilateral gonadectomy, herniorraphy, estrogen replacement therapy

The complete androgen insensitivity syndrome (CAIS), previously called testicular feminization syndrome is an X-linked recessive rare disorder. The individual is phenotypically female and genotypically male; a male pseudohermaphrodite. The individuals are reared as girls and the condition is suspected when the individual is evaluated for primary amenorrhea, infertility or when unilateral/bilateral inguinal hernia is diagnosed in girls.

CASE REPORT

A 30-year-old, married lady presented to Gynecology OPD with complaints of swelling in the groin, on both the sides since 4 months. The swelling increased on coughing, straining; reduced on lying down. There was no history suggestive of obstruction/irreducibility. She had not attained menarche. She is married to a widower since 8 years. The husband has 2 children from first wife. They have no problems during sexual intercourse. She has 3 siblings; all are married and have children.

On examination, she was a tall, well-built and well-nourished female. Height - 167 cm, weight - 74 kg, arm span - 165 cm, thyroid - normal, secondary sexual characters-axillary hair and pubic hair absent, breasts-Tanner 3 (well-developed with pale areolae, immature nipple (Fig. 1). The abdomen was soft. The external genitalia was female. On per speculum examination, 4 cm

Figure 1. External appearance: Female, absent axillary and pubic hair, well developed breasts present.

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Figure 2. Intraoperative appearance of the contents of the herniating sac on the left side: Gonad, tubular structure, fibromuscular band.

long blind vaginal pouch was seen. The inguinal region on the right and left side showed, a pyriform nontender swelling of 2.5 × 2.5 cm^2 and 2 × 2 cm^2, respectively, descending till upper part of labia majora. The swellings were felt above and medial to pubic tubercle and cough impulse was present. Thus clinically bilateral inguinal hernia was diagnosed.

Sonography showed absent uterus and ovaries, oval hypoechoic structures on both sides of inguinal region suggestive of bilateral inguinal hernia. The abdominal organs were normal. Laparoscopy confirmed absence of uterus and ovaries. The chromosomal analysis, Trypsin and Giemsa produce G-banded chromosomes (GTG) banded karyotyping showed 46 XY pattern. The blood investigations: Serum testosterone - 3.04 ng/mL (male range 1.8-9.0 ng/mL, female 0.2-1.2 ng/mL); luteinizing hormone or LH - 21.04 mIU/mL (male age 20-70 years: 1.5-9.3 mIU/mL, >70 years 1.3-34.6 mIU/mL); follicle-stimulating hormone (FSH) - 2.53 mIU/mL (male 1.4-18.1 mIU/mL); serum estradiol 55.17 - pg/mL (male 11.6-42.0 pg/mL). All the blood tests were of male range and in accordance with CAIS.

After counseling, the patient was posted for surgery: Bilateral gonadectomy with herniorrhaphy. Intraoperatively the contents of the sac were gonads, tubular remnant and fibromuscular band on both sides (Fig. 2). The histopathology report confirmed testicular tissue with smooth muscle fragments, on both the sides. The postoperative period was uneventful. The patient was discharged on the 10th day. Estrogen replacement therapy with tablet premarin 0.625 mg daily was advised.

DISCUSSION

Androgen insensitivity syndrome is a rare disorder with incidence of 1 in 20,000-99,000 genetic males and the prevalence is 0.8-2.4% in phenotypic females with inguinal hernia.[1] The basic etiology is the loss of function- mutation in the androgen receptor gene. The affected individuals have 46 XY karyotype, normal testes, normal production of testosterone, normal conversion to dihydrotestosterone, normal amount of antimullerian hormone. Thus the uterus, cervix, fallopian tubes and proximal vagina do not develop. In the fetal period, insensitivity to testosterone prevents masculinization of external genitalia. The lower one-third of vagina develops, as it originates from urogenital sinus and presents as a blind vaginal pouch. There is absence of axillary and pubic hair, lack of acne, absence of voice changes at puberty. The breasts are well-developed due to conversion of testosterone to estradiol. The testes may be located anywhere along the path of embryonic testicular descent in the abdomen, inguinal canal or labia. About 80-90% of individuals with CAIS develop inguinal hernia.[1]

The testes in CAIS individuals cause pubertal feminization. Some studies have shown carcinomatous changes in the testes of the children of CAIS in the age group of 13-14 years and believe that testicular biopsy is warranted as soon as the syndrome is diagnosed. The recent studies reveal tumor incidence (dysgerminoma, gonadoblastoma) of 0.8% in CAIS and 5.5% in AIS overall, and the risk increases markedly after puberty and reaches 33% at the age of 50 years.[1,2] Thus, gonadectomy is advised after puberty. Once the testes have been removed, estrogen needs to be supplemented to maintain external female form, to prevent osteoporosis and cardiovascular changes due to the deprivement of estrogen.[1]

The studies have shown that individuals reported psychological trauma at diagnosis, which was compounded by interaction with the medical care system.[1] During counseling it was found that, the patient was reared as a female and leading a happy married life. Thus informing the patient about the karyotype would be inadvisable and would have devastating psychological problems to the patient and family. Thus, they were informed that mullerian aplasia occurred and gonads were abnormally located, with chances of malignancy and should be removed. The interaction and counseling of the affected individual and family needs sensitivity and care.

REFERENCES

1. Oakes MB, Eyvazzadeh AD, Quint E, Smith YR. Complete androgen insensitivity syndrome - a review. J Pediatr Adolesc Gynecol. 2008;21(6):305-10.
2. Cools M, Drop SL, Wolffenbuttel KP, Oosterhuis JW, Looijenga LH. Germ cell tumors in the intersex gonad: old paths, new directions, moving frontiers. Endocr Rev. 2006;27(5):468-84.

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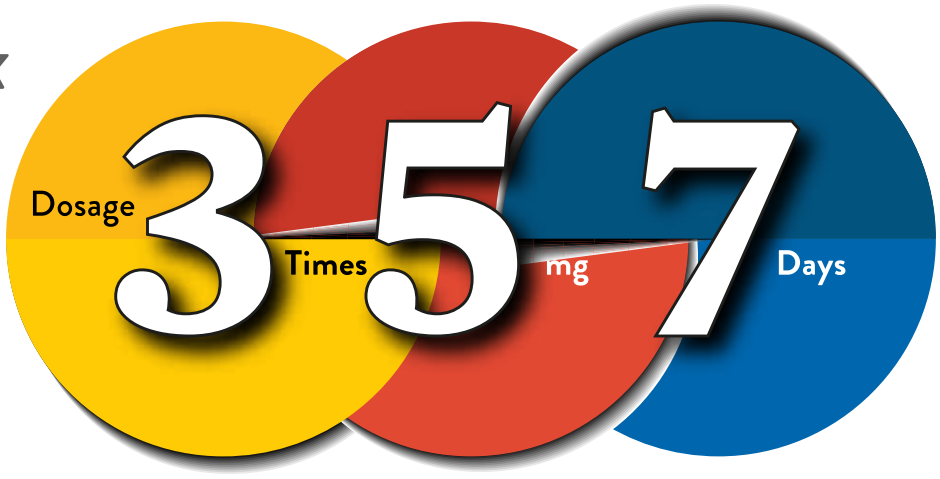

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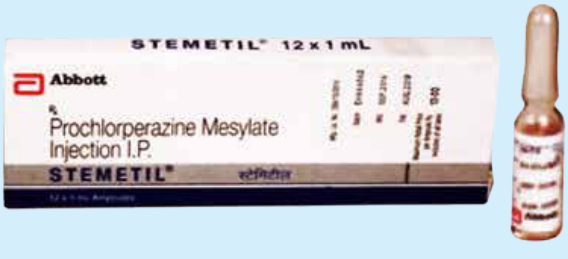

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1. Curthoys et al.1998. Vestibular Compensation. Therapy.Adv.Otorhinolaryngol. Basel, Karger, 55-82-110 2. Prochlorperazine. Prescribing Information. 2015 # Of Vertiginous Origin

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Management Approach to Vertigo at Primary Care Level in India: An Expert Opinion

DIVYA PRABHAT*, GB KULKARNI†, PRANAV KELKAR‡

ABSTRACT

Vertigo is the most common presentation of dizziness encountered by a general physician. However, there is an ongoing debate regarding the diagnosis and management of vertigo, worldwide. Even though vertigo is common in India, there is still a paucity of data from Indian milieu regarding patient- and physicians' approach towards the management of vertigo. Concerns pertaining to lack of awareness amongst patients, imprecision in patients' reporting of vertigo symptom quality, risk of misdiagnosis and the management approach in Indian setting are still unanswered. Therefore, an expert panel was formed to discuss the clinical gaps in the field of dizziness and vertigo therapy, from an Indian perspective, so as to drive the accurate diagnosis and disease management. The present work presents the expert opinion with respect to the prevailing clinical practice in an Indian setting.

Keywords: Dizziness, management, primary care, vertigo

Dizziness is a complex symptom that reflects a disturbance in balance perception. According to the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology and Head and Neck, dizziness can be defined as a hallucination of motion without any real movement in relation to gravity.[1] Dizziness was traditionally classified into four categories based on the patient's description, viz.: (1) vertigo, (2) presyncope, (3) disequilibrium and (4) light-headedness.[2,3]

Vertigo is the most common presentation of dizziness encountered by a general physician.[3] Almost every individual experiences vertigo as a transient spinning dizziness at least once during their lifetime. As per the statistics, dizziness, including vertigo, affects about 15% to over 20% of adults yearly, as reported in large population-based studies.[4] Its prevalence rises with age and is about 2-3 times higher in women than in men.[4]

Vertigo is a symptom, not a diagnosis. Vertigo is commonly caused due to a pathology in the peripheral or central vestibular apparatus and can be of benign or serious nature. Differentiating between simple and serious causes of vertigo is a challenging process of elimination, based on patient's description of their symptoms and the interpretation of signs found on examination, especially at the primary care level. The patient often complains, "I feel as if I am rocking, or moving in some other way" or "I feel as if the room is spinning".

The family physician (general practitioner [GP]) has a very important role to play in the management of vertigo. Nonetheless, even though GPs are the first to treat vertigo patients, there is still paucity of published evidence on the specific management strategies in general practice setting. This gives a skewed view of the prevalence of causes of such symptoms.[5]

IMPACT ON THE QUALITY-OF-LIFE

As the global population continues to age, vertigo is becoming a growing public health problem. Patients with vertigo, irrespective of the age, often experience intense emotional distress, with symptoms of anxiety, fear and depression. Moreover, in patients who present with new onset of vertigo, imbalance, nausea and vomiting are often challenging. These physical, emotional and functional disturbances associated with vertigo may impact the professional, social and overall day-to-day activities of these patients. These impairments may be substantial, however, data suggest that the impact of vertigo on the health-related quality-of-life (QoL) may be significantly underestimated.[6-8]

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Further, as vertigo can significantly impair the daily life, even during asymptomatic periods, simple symptom assessment may not be adequate; the patient may be more apprehensive about the subsequent unpredictable episode of vertigo than by the symptom itself.

Multiple studies have demonstrated the impact of vertigo on overall QoL.[9-12] Different authors have emphasized on the fear of new vertigo attacks, increase in distress and phobias as a result of the labyrinthopathies.[12-14] Unlike global data, studies assessing the QoL of Indian patients with vertigo is scarce. A recent concluded registry by Kameswaran et al indicated that 50% of patients with vertigo present with associated symptoms such as nausea and vomiting, which can have a negative impact on the overall QoL.[15] However, it should be noted that definition of age and the instrument used to assess the QoL differed in all the studies, bringing about a difference in the estimates of the impact on QoL. Further, while some studies included patients with acute objective measurable medical problems, others included etiologically heterogeneous patient population.

Falls are common in patients presenting with vertigo. Many of these patients with vertigo suffer from postural instability, disturbances and risk of falling. Those with central syndromes are at risk of recurrent and injurious falling. Hence, owing to the multifaceted nature of the symptom, associated risk of falls and fractures, and impact on QoL, there is a need for an individualized approach for the management of vertigo. The fall rates and fear of falling should be assessed and used to guide the regimen of rehabilitation therapy.

IDENTIFY THE NEED GAPS

Given the complexities and the seriousness of symptom, the American Academy of Family Physicians (AAFP) devised a treatment algorithm in 2010, aiding GPs to diagnose and treat patients with dizziness. However, in the light of new evidence and owing to the significant advancement in this field, the guideline was recently revised in 2017. In this revised approach, the type or quality of dizziness symptoms was given little or no diagnostic weight. Instead, timing and triggers were given significance to categorize patients for diagnosis.[3] However, there are concerns regarding the implementation of this algorithm in an Indian setting. This is primarily due to the following need gaps prevalent in India:

- Lack of awareness amongst patients
- Imprecision in patients' reporting of vertigo symptom quality
- Increasing risk of misdiagnosis in patients with vertigo
- Lacunae in the management approach by the primary care physicians
- Lack of physician-patient interaction
- Lack of treatment algorithm
- Misuse of timing and triggers to categorize patients for diagnosis
- Pharmacological interventions used in the management of vertigo.

METHODOLOGY

To discuss the knowledge-practice gaps in the field of vertigo and to understand the prevailing clinical practice pattern in an Indian setting, an expert meeting was held in September 2017. The panel comprised of experts in the vestibular vertigo therapy area, which led to the conception of the present manuscript. This article was developed based on:

- Discussion by experts who were convened to review the epidemiological data on the prevalence of vertigo in an Indian context, level of patient awareness, extent of misdiagnosis at the primary care setting, diagnostic approach generally adapted and the commonly used anti-vertigo agents at the primary care level.
- A thorough review of literature from both national and global sources covering various aspects of vertigo like incidence (global and India data), impact on QoL of the patients, patient awareness, extent and reasons of misdiagnosis, guidelines followed and the commonly used investigational techniques.

The literature search strategy used for developing the present report is mentioned in Table 1.

Based on the experts' discussion and literature review, the article was formulated. Experts reviewed the content and shared their comments/suggestions with the writing group who revised the draft accordingly.

LITERATURE REVIEW AND EXPERT OPINION

Epidemiological Data on Dizziness and Vertigo

Literature Evidence

Global data has shown that about one out of three elderly people suffer from dizziness.[4] The 1-year prevalence of dizziness was reported to be 18.2% in a community of elderly population.[16] Santana et al

Table 1. Literature Search Strategy

Databases searched	Search terms	Result	Comments
PubMed and Google Scholar	Dizziness, Vertigo, epidemiology, incidence, prevalence, treatment, diagnosis, outcome, guidelines, screening and management were combined using Boolean operators AND/OR	38 research articles, systematic reviews or meta-analyses were used for the preparation of this expert opinion	Published literature corresponding only to human subjects and in English language were considered for this report

reports that dizziness is present in 5-10% of the world population and the prevalence rate is 65% in individuals older than 65 years.[17] Another study reports that amongst patients within the age of 65 years, dizziness is the second most prevalent symptom in the world, and above this age, it is the most prevalent.[18] Studies have further documented a high prevalence of benign paroxysmal positional vertigo (BPPV) and vestibular migraine (VM), as well as of comorbid anxiety at the population level. These incidences may vary depending on the setting, patient age and biases (e.g.; investigator, study design).

The statistics of prevalence of dizziness in India is not available. A study conducted in a rural population in India reported an overall prevalence of 0.71%.[19] The psychogenic vertigo (0.03%) was most common form of vertigo reported in this population. However, a recently concluded registry conducted across many centers in India reported that BPPV accounted for a considerable percentage of the overall burden of vertigo. It was reported in this study that peripheral causes were predominant in majority (74%) with BPPV being the most frequent (68%). This was followed by other causes like migraine (central cause, 68.9%), which is mainly associated with lifestyle issues.[15] Another study conducted in a teaching tertiary care hospital in Central India reported the magnitude of vertigo in geriatric patients attending outpatient clinic to be 3%, inflicting a considerable healthcare burden. In this study, BPPV constituted 22% versus 78% of non-BPPV group.[20]

Expert Opinion

There are only few studies evaluating the prevalence of dizziness and vertigo in Indian population. However, an important limitation of these studies is that they were conducted in a specific subgroups of population. Therefore, obtaining the burden of disease in general population is an unmet need. The experts opined that the epidemiologic data from primary care settings, such as on the number and type of dizziness problems seen, prognoses, sensitivity and specificity, diagnostic approaches and the risk-benefit ratio on the management strategies is crucial for improving clinician awareness of these disorders and may aid in improvement in identification, differential diagnostic work-up and effective treatment in the large group of patients with dizziness and vertigo.

Further, the experts propounded that the prevalence assessed in the published literature were either through questionnaire based surveys, or from the statistics retrieved from National Health Insurance claims database. The experts unanimously agreed that the wide variation in prevalence between these studies could be attributed to differences in ethnicity, subgroup selected and study design. Nonetheless, the nation-wide statistics unfolding prevalence of dizziness and vertigo needs to be ascertained in Indian-milieu. Moreover, the experts recommended that the clinical value of most of the epidemiologic findings may not be established by statistical significance, but by minimizing the relevant bias, which could have had an impact on the validity, reliability and reproducibility of the data, along with its generalizability.

Lack of Awareness amongst Patients

Literature Evidence

The underestimation of dizziness and vertigo symptoms with regard to their impact on individual and healthcare is due to the fact that large percentages of the cases remain underdiagnosed. Neuhauser et al in 2008 reported that 42% of the patients with vertigo never consulted a physician despite reporting symptoms of at least moderate severity.[21] Yardley et al and Hannaford et al in their study noted a much higher percentage of participants with dizziness who did not consult a GP (60% and 77%, respectively).[22,23] In another study by Bittar et al, though 67% of symptomatic respondents claimed that dizziness or vertigo does interfere with their daily activities, only 46% of respondents sought medical help, and this frequency of medical consultation is higher among women and the elderly.[24] These data sheds light on the lack of seriousness and awareness amongst patients towards the condition.

In consistence with the global data, Kameshwaran et al[25] in a recent study reported that knowledge, attitude and practice patterns amongst Indian vertigo patients are inadequate, highlighting the need for awareness and scientific education amongst these patients. According to this report, a significant proportion of patients had misconception that vertigo is the feeling of fainting due to height (76.2%); feeling of nausea and vomiting while in motion (75.7%) or the feeling of drifting to one side while walking (76.3%). Even though majority of the patients were aware that vertigo is a feeling of moving or spinning when not in motion, about three-fourth of the population had misapprehensions about the associated signs and symptoms related to the disease (~76%). Furthermore, more than half of the patients (60.2%) even believed that vertigo is transmitted from parents to children and is often associated with mood swings. According to this study, only 58.3% believed that medication for the treatment of vertigo should be taken in consultation with the physicians. More importantly, out of 1167 patients who participated in this study, none (0%) practiced high level of precaution towards vertigo. This first-of its kind study highlighted that knowledge, attitude and practice patterns amongst Indian vertigo patients are inadequate and healthcare providers should be trained to provide effective counseling to these patients.

Expert Opinion

There is an unmet need to enhance awareness about vertigo and the significance of having oneself assessed after the first episode. This is keeping in mind, the evidence that an early assessment can facilitate early intervention particularly in central causes of vertigo. Usually, patients do not perceive the need for seeking prompt advice of a GP after the first episode of dizziness/vertigo. Further, many a times, the patient does not follow the GP's advice about taking a full course of medications prescribed to him/her and is irregular in follow-up visits. The GP is consulted only when the episode of vertigo recurs and is accompanied by nausea and vomiting.

The GPs should be trained to provide counseling to the patients for effective disease management and the need for treatment compliance/follow-up visits. The experts were of the opinion that new ways of reaching out to the patients should be envisioned. This may include increasing community awareness events such as marathons, increasing media outreach through social communities, blogs, creating social media presence through health awareness campaigns consisting of role plays, interactive sessions, hand-outs and medical camps. The posters and pictures depicting the symptoms of vertigo, elucidating the impact and the need for effective disease management, at the primary health centers, can improve patient awareness.

Increasing Risk of Misdiagnosis in Patients with Dizziness/Vertigo

Literature Evidence

Diagnostic approach

Vertigo is a diagnostic challenge because of a broad differential diagnosis (Table 2). A robust systematic approach can aid in preventing misdiagnosis. Qian et al[26] reported a high misdiagnosis rate of BPPV (60.0%) in a study in 80 patients conducted in an outpatient dizziness clinic. BPPV and VM are largely underdiagnosed, while Meniere's disease, which is about 10 times less frequent than BPPV, appears to be overdiagnosed.[26] Misdiagnosis has a significant financial impact on the patients, owing to the increased cost due to inappropriate treatment and investigations. The conventional approach to the evaluation of patients who present with dizziness or vertigo has been based on defining the type of symptom when assessing the most likely cause.[2,27] The problem with the type being used as the principal factor in the diagnostic process was that it is neither a reliable symptom attribute reported by patients nor a valid discriminator among different causes of dizziness or vertigo.[28,29] Furthermore, research that queried patients

Table 2. Differential Diagnosis of Vertigo: Common Causes

Peripheral causes
Benign paroxysmal positional vertigo
Meniere's disease
Vestibular neuritis
Labyrinthitis
Central causes
Vestibular migraine
Vascular
Multiple sclerosis
Vestibular epilepsy
Other causes
Psychiatric
Medication induced
Cardiovascular/metabolic
Orthostatic

presenting to the emergency department with vertigo symptoms that included a test-retest paradigm reported low reliability of patient reports on the type of the disease.[28] This led to a high magnitude of misdiagnosis, with rates estimated in the range of 74-81%.[30,31] Physicians often use a generalized approach to a patient with vertigo, relying on the word used by the patient. The other likely reasons for frequent misdiagnosis were misuse of timing and triggers to categorize patients for diagnosis, and misconceptions linked to hallmark eye examination findings, overweighting age, vascular risk factors, neuro-examination to screen for stroke and overuse and over reliance on head CT to rule out neurologic causes. To overcome this concern of misdiagnosis, the AAFP in 2017 proposed the revised guidelines on the approach for the evaluation and management of dizziness. In this revised approach, the type or quality of symptoms was given little or no diagnostic weight. Instead, timing and triggers were given significance to categorize patients for diagnosis.[3]

Management approach by the primary care physicians

Although vertigo may be caused by a variety of conditions, often requiring a multidisciplinary approach, they rarely prompt referral to a specialist or a hospital admission for specific investigation. Only about 9-13% of these patients are referred to the specialists such as neurologists, cardiologists and otolaryngologists.[32] Further, reports indicate that though primary care physicians or GPs exhibit a concerned attitude towards potentially life-threatening problems, these clinicians tend to rely on observation and medication prescription as primary management strategies for vertigo. Both advanced tests and referrals to specialists were suggested for only about 10% of patients. The clinicians reported more concern about serious underlying causes of vertigo when their diagnostic certainty was lower. Physicians tended to treat conservatively the more classic symptoms of vertigo, which often have self-limited causes and to conduct more investigations when a neurologic or cardiologic diagnosis was suspected.[33]

Physician-patient interaction

Another concern in the management of dizziness is the downfall of doctor-patient communication, and bedside examination. With the advancement of technology, physicians are now becoming more reliant on technology for obtaining patient information, making diagnosis and in carrying out treatments. Experts feel that physicians are doing fewer physical examinations due to the prevalence of advanced medical technology examination.[34] Moreover, with the advancement of medical technology, the use of Electronic Health Record (EHR) could decrease the narrative notes taking skills and clinical knowledge. In a study of 78 primary care physicians in New York, Hoff indicated that physicians tended to cut-and-paste boilerplate text into their reports of patient visits. Hoff also reported that physicians increasingly lost their ability to understand and abstract the richness and uniqueness of patients' information given in the standardized EHR format, consequently undercutting their ability to make informed decisions around diagnosis and treatment.[35]

Imprecision in patients' reporting of vertigo symptom quality

Another challenge in the diagnosis and management of vertigo is the imprecision in patients' reporting of symptom quality.[28] Usually, the descriptions of the quality of the disease provided by the patients are unclear, inconsistent and unreliable, casting doubt on the validity of the traditional approach to the patient with dizziness. Further, dizziness or vertigo is often presented as a secondary complaint, while narrating patient history. Moreover, sensory symptoms are difficult for many patients to describe.

Expert Opinion

The experts reiterated the importance of consultation after an episode of dizziness or vertigo. This will help in ruling out serious causes such as cerebrovascular events. Further, they emphasized on the need for alternative approaches for the management of vertigo, emphasizing timing and triggers over type, as the investigating factor. The experts unanimously stressed on the need for empowering GPs with tools for accurate diagnosis. The GPs should be trained to provide counseling to the patients for effective disease management and the need for treatment compliance/ follow-up visits. The GPs should be reminded about the importance of history taking as most cases of vertigo can be diagnosed by history alone. Further, there is an unmet need to increase awareness amongst GPs to recognize the importance of precise assessment of vertigo and prompt referral of cases, if required. The experts recommended multiple initiatives to achieve this goal. One of them is implementing training by involving government and non-governmental organizations. Experienced Ear-Nose-Throat (ENT) specialists and/or neurologists should be a part of this training curriculum. Further, the experts discoursed the content of the training modules to educate the primary care physicians in dizziness therapy area. The training content should provide an 'easy to use' and a simplified

algorithm for history taking and in addition should include practical modules on how to conduct bedside examination of a dizzy patient. The algorithm should be in line with the revised AAFP guidelines. The training module should also include hands-on demonstration of the HINTS (Head-Impulse—Nystagmus—Test-of-Skew) examination, Doll's eye test, head rotation test and Huntenberg test. The experts further agreed that evaluation of nystagmus is an area of improvement in general practice. This can be addressed by an expert demonstration on how to evaluate nystagmus in a dizzy patient in a general practice setting.

The experts opined that owing to the multifaceted nature, the only way to address dizziness or vertigo is by adapting a multipronged method. This includes, reassurance, pharmacotherapy and patient education on vestibular rehabilitation exercise. There is evidence to support the efficacy of vestibular rehabilitation programs for unilateral peripheral vestibular disorder and these programs should be considered. The GPs should describe the different mechanisms for recovery with vestibular rehabilitation, the exercises commonly used, and which are most suitable. The panel expressed concern on decreased physician-patient consultation time. Effective doctor-patient communication is essential for a shared perception on nature of the problem, goals of treatment and psychosocial support.

Role of Pharmacotherapy in the Management of Vertigo

Literature Evidence

The treatment of patients with vertigo of unknown cause is empirical. An organized and methodical approach to management of these patients is essential to maximize patient satisfaction. Clinically, treatment options for patients with vertigo include symptomatic, specific and prophylactic approaches. The treatments aim at the elimination of vertigo, thereby improving the QoL and reducing the risk of falls and fractures; enhancement or at least noncompromising of the processes of 'vestibular compensation' to allow the brain to find a new sensory equilibrium in spite of the vestibular lesion; and the reduction of neuro-vegetative and psycho-affective signs (nausea, vomiting, anxiety) that often accompany vertigo. Vestibular suppressants and antiemetic drugs are the mainstay of treatment of vertigo.

Vestibular suppressants are drugs that reduce the intensity of vertigo and nystagmus evoked by a vestibular imbalance. These also reduce the associated motion sensitivity and motion sickness. Conventional vestibular suppressants consist of three major drug groups: anticholinergics, antihistamines and benzodiazepines (Table 3).

Table 3. Vestibular Suppressant Medications

Medication	Dosage
Antiemetics	
Metoclopramide	5-10 mg orally every 6 hours, or 5-10 mg slowly IV every 6 hours
Prochlorperazine	5-10 mg orally or IM every 6-8 hours
Antihistamines	
Promethazine	25 mg every 6 hours orally, IM or rectally every 4-12 hours
Dimenhydrinate	50 mg orally every 6 hours
Meclizine	12.5-50 mg orally every 4-8 hours
Benzodiazepines	
Diazepam	2-10 mg orally or IV every 4-8 hours
Lorazepam	1-2 mg orally every 4 hours

Expert Opinion

The experts are of the opinion that knowledge, attitude and practices of GPs are not adequate with regard to pharmacotherapy. They asserted the importance of vestibular suppressants in symptomatic management of vertigo in the acute phase. Each of the vestibular suppressants has a unique pharmacological profile and hence this demands careful selection of the patient for a particular vestibular suppressant. Of the available vestibular suppressants, cinnarizine and prochlorperazine are the commonly prescribed molecules by the GP.

The experts opined that prochlorperazine improves vestibular as well as associated vegetative symptoms of vertigo. In addition to its anticholinergic and antidopaminergic activity, prochlorperazine acts on serotonergic neurotransmitter system and hence could be the reason for being the drug of choice for short-term symptomatic management of vertigo associated with anxiety as a psychiatric comorbidity. Further, prochlorperazine is less sedative than cinnarizine and cinnarizine combinations and other fixed-dose combination of vestibular suppressants. The experts unanimously agreed that EPS (extrapyramidal symptoms) is not a concern if prochlorperazine is prescribed for short-term (up to 7 days) symptomatic management of vertigo, as 5 mg TDS (oral). Also, the experts suggested that precaution should be exercised while prescribing prochlorperazine in patients at

extremes of age. Moreover, they opined that cinnarizine is more efficacious in peripheral vertigo (without nausea and vomiting) than prochlorperazine.

The experts unanimously agreed that the GP should be discouraged to adopt a SOS approach (to be taken as and when needed) to treat mild-to-moderate dizziness in an OPD setting. A complete course of the vestibular suppressant for 3-7 days is recommended. However, in some cases such as an established Meniere's or VM, SOS prochlorperazine can be used to abort an acute episode of vertigo. Furthermore, the experts believed that GPs should be trained to provide counseling and reassurance to the patients for effective disease management.

CONCLUSION

In conclusion, the experts identified lack of patient awareness, misdiagnosis by GP and inappropriate use of pharmacotherapy to be the key unmet needs in Indian scenario. There is a wide variation in the prevalence of vertigo due to differences in ethnicity, subgroup selected and study design. The epidemiologic data from primary care settings may help enhance the awareness of these disorders at the physician level and aid in appropriate management of vertigo. Further, there is an increasing need for patient awareness about vertigo, which can be attained by community awareness events. The GPs should be empowered with tools for accurate diagnosis and should be trained to provide counseling to the patients. Further, it is important to ensure that the GPs are trained for appropriate referral of cases. This can be attained by implementing physician education programs for GPs. The training content should provide an 'easy to use' and a simplified algorithm for history taking and in addition should include practical modules on how to conduct bedside examination of a dizzy patients. The relevance of patient-doctor interaction and reassurance should be emphasized in these programs. Furthermore, there is a need for alternative approaches for the management of vertigo, emphasizing timing and triggers over type, as the investigating factor. Vestibular suppressants are crucial in the management of acute phase vertigo. Given the heterogeneity of treatment effect, a link between patient presentation and the type of molecule is quintessential. Prochlorperazine acts on serotonergic neurotransmitter system and hence could be the reason for being the drug of choice for short-term symptomatic management of dizziness or vertigo associated with anxiety and vomiting. Cinnarizine is more efficacious in peripheral vertigo, without nausea and vomiting. Another area of intervention at the physician and patient level is the vestibular rehabilitation in vertigo management. Vestibular rehabilitation therapy is a highly effective modality for most with disorders of the vestibular or central balance system. There is a need for customized vestibular rehabilitation therapy programs at GP clinics, than the generic exercises in resolving symptoms of vertigo.

Conflict of Interest

An expert group discussion was organized in association with Abbott Healthcare Pvt. Ltd. This article is based on the views expressed during the afore-said expert group discussion. The views expressed in the said discussion are solely of the panel members.

REFERENCES

1. Committee on Hearing and Equilibrium guidelines for the diagnosis and evaluation of therapy in Menière's disease. American Academy of Otolaryngology-Head and Neck Foundation, Inc. Otolaryngol Head Neck Surg. 1995;113(3):181-5.
2. Drachman DA, Hart CW. An approach to the dizzy patient. Neurology. 1972;22(4):323-34.
3. Muncie HL, Sirmans SM, James E. Dizziness: Approach to evaluation and management. Am Fam Physician. 2017;95(3):154-62.
4. Neuhauser HK. The epidemiology of dizziness and vertigo. Handb Clin Neurol. 2016;137:67-82.
5. Hanley K, O' Dowd T. Symptoms of vertigo in general practice: a prospective study of diagnosis. Br J Gen Pract. 2002;52(483):809-12.
6. Ten Voorde M, van der Zaag-Loonen HJ, van Leeuwen RB. Dizziness impairs health-related quality of life. Qual Life Res. 2012;21(6):961-6.
7. Grauvogel J, Kaminsky J, Rosahl SK. The impact of tinnitus and vertigo on patient-perceived quality of life after cerebellopontine angle surgery. Neurosurgery. 2010;67(3): 601-9; discussion 609-10.
8. Weidt S, Bruehl AB, Straumann D, Hegemann SC, Krautstrunk G, Rufer M. Health-related quality of life and emotional distress in patients with dizziness: a cross-sectional approach to disentangle their relationship. BMC Health Serv Res. 2014;14:317.
9. Handa PR, Kuhn AM, Cunha F, Schaffleln R, Ganança FF. Quality of life in patients with benign paroxysmal positional vertigo and/or Ménière's disease. Rev Bras Otorhinolaringol. 2005;71(6):776-83.
10. Grimby A, Rosenhall U. Health-related quality of life and dizziness in old age. Gerontology. 1995;41(5):286-98.
11. Hsu LC, Hu HH, Wong WJ, Wang SJ, Luk YO, Chern CM. Quality of life in elderly patients with dizziness: analysis of the Short-Form Health Survey in 197 patients. Acta Otolaryngol. 2005;125(1):55-9.

12. Santos EM, Gazzola JM, Ganança CF, Caovilla HH, Ganança FF. Impact of dizziness on the life quality of elderly with chronic vestibulopathy. Pro Fono. 2010;22(4):427-32.
13. Savastano M, Maron MB, Mangialaio M, Longhi P, Rizzardo R. Illness behaviour, personality traits, anxiety, and depression in patients with Menière's disease. J Otolaryngol. 1996;25(5):329-33.
14. Kuhn AMB, Bocchi EA, Bulbarelli K, Casagrande MC. Vertigo and its psychological implications. In: Ganança MM, Vieira RM, Caovilla HH. Principles of Otoneurology. São Paulo: Atheneu; 1998. pp. 101-5.
15. Kameswaran M, Pujari S, Singh J, Basumatary LJ, Sarda K, Pore R. Clinicoetiological pattern and pharmacotherapy practices in patients with new onset Vertigo: findings from a prospective multicenter registry in India. Int J Otorhinolaryngol Head Neck Surg. 2017; 3(2):404-13.
16. Sloane P, Blazer D, George LK. Dizziness in a community elderly population. J Am Geriatr Soc. 1989;37(2):101-8.
17. Santana GG, Doná F, Ganança MM, Kasse CA. Vestibulopathy in the elderly. Collective Health. 2011;48:52-6.
18. Scherer S, Lisboa HRK, Pasqualotti A. Dizziness in elderly individuals: otoneurological diagnosis and interference on the quality of life. Rev Soc Bras Fonoaudiol. 2012; 17(2):142-50.
19. Abrol R, Nehru VI, Venkatramana Y. Prevalence and etiology of vertigo in adult rural population. Indian J Otolaryngol Head Neck Surg. 2001;53(1):32-6.
20. Saxena A, Prabhakar MC. Performance of DHI score as a predictor of benign paroxysmal positional vertigo in geriatric patients with dizziness/vertigo: a cross-sectional study. PLoS One. 2013;8(3):e58106.
21. Neuhauser HK, Radtke A, von Brevern M, Lezius F, Feldmann M, Lempert T. Burden of dizziness and vertigo in the community. Arch Intern Med. 2008;168(19):2118-24.
22. Yardley L, Owen N, Nazareth I, Luxon L. Prevalence and presentation of dizziness in a general practice community sample of working age people. Br J Gen Pract. 1998;48(429):1131-5.
23. Hannaford PC, Simpson JA, Bisset AF, Davis A, McKerrow W, Mills R. The prevalence of ear, nose and throat problems in the community: results from a national cross-sectional postal survey in Scotland. Fam Pract. 2005; 22(3):227-33.
24. Bittar RS, Lins EM. Clinical characteristics of patients with persistent postural-perceptual dizziness. Braz J Otorhinolaryngol. 2015;81(3):276-82.
25. Kameswaran M, Pujari S, Basumatary L, Singh J, Sarda K. Knowledge, attitudes and practices relating to vertigo among newly diagnosed patients: Findings of a prospective, observational registry in India. J Assoc Physicians India. 2017;65(3):26-33.
26. Qian SX, Li F, Zhuang JH, Chen Y, Yang HL, Zhou XW, et al. Misdiagnosis and associated costs of benign paroxysmal positional vertigo. Natl Med J China. 2017;97(14):1057-60.
27. Drachman DA. A 69-year-old man with chronic dizziness. JAMA. 1998;280(24):2111-8.
28. Newman-Toker DE, Cannon LM, Stofferahn ME, Rothman RE, Hsieh YH, Zee DS. Imprecision in patient reports of dizziness symptom quality: a cross-sectional study conducted in an acute care setting. Mayo Clin Proc. 2007;82(11):1329-40.
29. Tarnutzer AA, Berkowitz AL, Robinson KA, Hsieh YH, Newman-Toker DE. Does my dizzy patient have a stroke? A systematic review of bedside diagnosis in acute vestibular syndrome. CMAJ. 2011;183(9):E571-92.
30. Kerber KA, Morgenstern LB, Meurer WJ, McLaughlin T, Hall PA, Forman J, et al. Nystagmus assessments documented by emergency physicians in acute dizziness presentations: a target for decision support? Acad Emerg Med. 2011;18(6):619-26.
31. Royl G, Ploner CJ, Leithner C. Dizziness in the emergency room: diagnoses and misdiagnoses. Eur Neurol. 2011;66(5):256-63.
32. Jayarajan V, Rajenderkumar D. A survey of dizziness management in General Practice. J Laryngol Otol. 2003;117(8):599-604.
33. Sloane PD, Dallara J, Roach C, Bailey KE, Mitchell M, McNutt R. Management of dizziness in primary care. J Am Board Fam Pract. 1994;7(1):1-8.
34. Verghese A, Horwitz RI. In praise of the physical examination. BMJ. 2009;339:b5448.
35. Hoff T. Deskilling and adaptation among primary care physicians using two work innovations. Health Care Manage Rev. 2011;36(4):338-48.

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Comparison of Two Sample Collection Techniques for Adequacy and Accuracy in Cases of Genital Tuberculosis

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ABSTRACT

Tuberculosis (TB), caused by bacteria of the *Mycobacterium tuberculosis* complex, is one of the oldest diseases known to affect humans and is a major cause of death worldwide. The diagnosis of genital TB is difficult due to lack of reliable confirmatory investigation. Here, we have compared two techniques of sample collection for detection by polymerase chain reaction (PCR). **Material and methods:** We studied 60 cases attending the Gynecology OPD for symptoms suggestive of genital TB. Both endometrial aspirate and biopsy were taken in all cases. The samples were analyzed by PCR and the results were compared. **Results:** Endometrial aspirate had a detection rate of 41% as compared to endometrial biopsy, which had a detection rate of 36.7%. The difference was statistically significant. **Conclusion:** Endometrial aspirate had a better detection rate than endometrial biopsy.

Keywords: Genital tuberculosis, endometrial aspirate, endometrial biopsy, PCR

Tuberculosis (TB), caused by bacteria of the *Mycobacterium tuberculosis* complex, is one of the oldest diseases known to affect humans and is a major cause of death worldwide. The disease most often affects the lungs, although other organs are involved in up to one-third of cases. The morbidity associated with this condition has major health implications. The disease has a worldwide distribution and the incidence is high in developing countries.

Female genital TB is an important cause of significant morbidity with short- and long-term sequelae especially infertility in affected women. The precise incidence of genital TB is difficult to ascertain as it is underreported due to asymptomatic cases and lack of reliable confirmatory investigation. Genital TB is responsible for 1% of all gynecological admissions in India. The frequency of occurrence of genital TB is fallopian tubes (90-100%), endometrium (50-60%), ovaries (20-30%), cervix & vulva and vagina (1%).[1]

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In recent years, polymerase chain reaction (PCR) technique has evolved as a useful and rapid, sensitive and specific molecular biological technique for the diagnosis of pulmonary and extrapulmonary TB. PCR assay target various gene segments including a 65 kD protein encoding gene. TB is diagnosed within 1-2 days with sensitivity and specificity reaching up to 100%.[2]

There are many methods of sample collection out of which endometrial aspirate and endometrial biopsy are mostly used for detection of genital TB. We have carried out this study with an aim to identify the better way of sample collection.

MATERIAL AND METHODS

A total of 60 cases were selected from OPD of Obstetrics and Gynecology, SN Medical College, Agra, Uttar Pradesh. Before conducting the study, the consent of Institutional Ethical Committee was taken. It was a prospective comparative study. Sixty female cases of 20-50 years of age were selected from the OPD in whom genital TB was suspected.

Inclusion criteria were unexplained infertility, infertility cases with tubal pathology, pelvic inflammatory disease (PID) not responding to routine antibiotic treatment, unexplained menorrhagia, unexplained secondary amenorrhea, chronic pelvic pain and oligomenorrhea. Exclusion criteria were pregnant females, suspicion of malignancy and unmarried females. All the 60 cases

enrolled in the study were subjected to a thorough history taking, general, systemic and pelvic examination. The study was evaluated by PCR where samples were taken by endometrial aspiration and endometrial biopsy in all 60 cases. All the women with clinically suspected genital TB were called preferably premenstrual for endometrial biopsy and endometrial aspiration. Endometrial biopsy and endometrial aspiration were done in the same sitting in the OPD. In case woman was amenorrheic or irregular bleeding was present then the procedure was done at the time of presentation. In case of cervical stenosis, where procedure was not possible in OPD then it was undertaken under short general anesthesia. The specimens, extracted by biopsy and aspiration were sent for PCR.

RESULTS

Genital TB is more common in the reproductive age group. Table 1 shows the distribution of cases according to age, residence, parity and socioeconomic status of the cases. The mean age in this study was 28 ± 6.3 years. Most of the cases, 65% in the study came from rural areas and only 35% belonged to an urban area. Clinical features suggestive of genital TB were more common in nulliparous and primiparous cases, which constituted 38.3% (23/60) and 30% (18/60) of the cases. Distribution of cases according to socioeconomic status in the table well-illustrated genital TB to be the disease of the poor with Class III, IV and V forming 31.7%, 30% and 28.3% cases, respectively.

Table 2 shows that infertility was the most common gynecological symptom in genital TB, out of which primary infertility was 33.3% and secondary infertility was 26.7%. Other complaints were menorrhagia (13.3%), oligomenorrhea (10%), secondary amenorrhea (3.3%), postmenopausal bleeding (3.3%), pelvic pain (33.3%) and vaginal discharge (26.7%). Some women presented with two or more complaints simultaneously.

Table 3 shows the difficulties encountered in sample collection in the two techniques. Endometrial aspiration and biopsy are routine outdoor procedures; 50% of the aspirations and 35% of biopsies were relatively easy. Difficulties were encountered in some cases during sample collection, which were more during biopsy than aspiration. As mentioned in the Table 3, 24 cases had pain during biopsy while only 20 cases complained of pain during aspiration. Rest 5 and 8 cases had bleeding during aspiration and biopsy, respectively. The differences were statistically significant. Procedure was abandoned in favor of general anesthesia in cervical stenosis (2 and 3 in aspiration and biopsy, respectively) and uncooperative cases (3 and 4 in aspiration and biopsy, respectively).

Table 1. Patient Profile

Age		
20-29	36	60
30-39	21	35
40-49	03	05
Locality		
Rural	39	65
Urban	21	35
Parity		
P0	23	38.3
P1	18	30
P2	10	16.7
P3	06	10
>P3	03	5
Socioeconomic status		
I	00	00
II	06	10
III	19	31.7
IV	18	30
V	17	28.3

Table 2. Distribution of Cases According to Presenting Complaints

Chief complaints	No. of patients	Percentage (%)
Primary infertility	20	33.3
Secondary infertility	16	26.7
Menorrhagia	8	13.3
Oligomenorrhea	6	10
Secondary amenorrhea	2	3.3
Postmenopausal bleeding	2	3.3
Pelvic pain	20	33.3
Vaginal discharge	16	26.7
Weight loss	18	30
Low-grade fever	8	13.3
Malaise	12	20
Night sweat	11	18.3

 Echocardiography every three to five years if the mitral valve area (MVA) is > 1.5 cm^2. 2014 American Heart Association/American College of Cardiology (AHA/ACC) Valve Guideline.

Table 3. Distribution of Cases According to Difficulties Encountered During Sample Collection

Difficulties during sample collection	Endometrial aspiration		Endometrial biopsy	
	No.	%	No.	%
Pain	20	33.3	24	40
Bleeding	5	8.3	8	13.3
Uncooperative cases	3	5	4	6.7
Cervical stenosis	2	3.3	3	5
Failure of procedure	4	6.7	10	16.7
No difficulties	30	50	21	35

Table 4. Detection Rate of the Two Techniques

	PCR positive cases	Detection rate
Endometrial aspirate	25/60	41.7%
Endometrial biopsy	22/60	36.7%
Endometrial aspirate and biopsy	18/60	30%

Table 4 shows that out of 60 samples of aspiration, 41.7% were positive and 58.3% were negative by PCR for TB. Similarly out of 60 samples of endometrial biopsy, 36.7% were positive and 63.3% were negative by PCR.

DISCUSSION

The study was undertaken to compare the two techniques of sample collection, endometrial biopsy and endometrial aspirate in detection of *M. tuberculosis* by PCR in suspected cases of genital TB.

In the present study of 60 cases, it was found that majority of the cases were in the age group of 20-29 years (60%). Mean age was 28.6 years. Similar results were reported by Abdul Hakim et al, where the mean age was 29.4 years. Majority of the cases, 65% resided in the rural area. These findings were similar to those by Nezar et al (2009) and Abdul Hakim Ali Aleryani et al (2014).[3] Our study shows that 31.3%, 30% and 28.3% cases were of low socioeconomic status i.e., Class III, IV and V, respectively, according to Modified BG Prasad Classification. Other studies done by Shaheen et al (2006) and Shahzad et al (2012)[4] also reported majority of cases belonging to low socioeconomic status. Genital TB usually presents with infertility among women of reproductive age group. Our study also found that most common presenting complaint was infertility. Those cases where other factors including male infertility were excluded, genital TB was implicated as a causative factor in majority of cases. Whether primary or secondary, infertility followed by pelvic pain, vaginal discharge, menorrhagia, oligomenorrhea, secondary amenorrhea and postmenopausal bleeding were other complaints. Other constitutional symptoms like weight loss, low-grade fever, night sweat and malaise were also present.

In our study, endometrial aspiration and biopsy were taken in all 60 cases and send for PCR. It was seen that 41.7% cases were positive by PCR in endometrial aspirate. Other authors reported similar results. Sharma et al in a study of 28 cases of endometrial aspirate reported a PCR positivity rate of 46.4%. Jindal et al[5] studied 443 cases of endometrial aspirate reported a PCR positivity rate of 38.15%. Endometrial biopsy was positive by PCR in 36.7%. Kumar et al[6] reported a positivity result on endometrial biopsy in 31.3% cases. Thangappah et al also reported 36.7% PCR positive cases (Table 5).[7,8]

Comparative studies however have reported conflicting results (Table 6).[9,10]

It could be explained by the fact that endometrial aspirate involves instillation of normal saline into the endometrial cavity followed by its aspiration. This implies washing off entire endometrium of its surface cells while in endometrial biopsy we take out tissue only from the cornual site. Tubercular pathology at other sites in the endometrium can be missed out resulting in false negative findings.

Table 5. Comparative Results of Other Studies

Authors	Year	No. of cases (endometrial aspirate and biopsy)	Results of endometrial aspirate	Result of endometrial biopsy
Bhanu et al[8]	2005	21 endometrial aspiration and 15 biopsy	47% positive by PCR	53.3% positive by PCR
Thangappah et al[7]	2011	49 endometrial aspirate and biopsy	44% positive by PCR	36.7% positive by PCR
Our study	2015	60 endometrial aspiration and biopsy	41.7% positive by PCR	36.7% positive by PCR

Table 6. Comparative Results Reported Conflicting Results

Authors	Year	Results						
		Infertility	Pelvic pain	Menorrhagia	Oligomenorrhea	Amenorrhea	Dysmenorrhea	Vaginal discharge
Gatongi et al[9]	2005	43-74%,	42.5%	19%	54%	14%	12-30%	
Bhanothu et al[10]	2014	100%	15.34%	4.45%	12.87%	8.91%	46.53	
Our study	2015	60%	33.3%	13.3%	10%	3.3%		26.7%

Also, in most of the studies, sample collection was hysteroscopic-guided, whereas in our study this was a blind procedure carried out in the OPD. This could explain the low detection rate of endometrial biopsy in our study.

Several studies have taken separate groups for aspiration and biopsy, whereas we carried out both the procedures in the same case. This could be a reason for the discrepancy in the results.

CONCLUSION

Based on this study, we can thus say that genital TB, in present scenario is one of the common causes of infertility, so genital TB should always be considered as a probable cause in the diagnostic work-up of an infertile couple, especially in a population with high prevalence. The key to optimal outcome lies in early diagnosis and treatment of TB.

There are a lot of investigations for TB but they take more time with low sensitivity and accuracy. PCR is the most sensitive test to diagnose TB in a short period of time.

We found that endometrial aspiration has a better detection rate of genital TB in clinically suspected cases than endometrial biopsy. Aspiration is also technically easier as it is performed on an outpatient basis and is a more effective procedure as it involves the surface of the entire endometrial cavity. Biopsy if carried out under hysteroscopic guidance can result in improved detection rate but this requires admission and administration of anesthesia.

REFERENCES

1. Kumar S. Female genital tuberculosis. In: Sharma SK, Mohan A (Eds.). Tuberculosis. 2nd Edition, Delhi: Jaypee; 2009. pp. 441-8.
2. Murray P, Baron E, Pfaller M. Manual of Clinical Microbiology. 1999;410.
3. Nezar M, Goda H, El-Negery M, El-Saied M, Wahab AA, Badawy AM. Genital tract tuberculosis among infertile women: an old problem revisited. Arch Gynecol Obstet. 2009;280(5):787-91.
4. Shahzad S. Investigation of the prevalence of female genital tract tuberculosis and its relation to female infertility: An observational analytical study. Iran J Reprod Med. 2012;10(6):581-8.
5. Jindal UN, Verma S, Bala Y. Favorable infertility outcomes following anti-tubercular treatment prescribed on the sole basis of a positive polymerase chain reaction test for endometrial tuberculosis. Hum Reprod. 2012;27(5):1368-74.
6. Kumar P, Shah NP, Singhal A, Chauhan DS, Katoch VM, Mittal S, et al. Association of tuberculous endometritis with infertility and other gynecological complaints of women in India. J Clin Microbiol. 2008;46(12):4068-70.
7. Thangappah RB, Paramasivan CN, Narayanan S. Evaluating PCR, culture & histopathology in the diagnosis of female genital tuberculosis. Indian J Med Res. 2011;134:40-6.
8. Bhanu NV, Singh UB, Chakraborty M, Suresh N, Arora J, Rana T, et al. Improved diagnostic value of PCR in the diagnosis of female genital tuberculosis leading to infertility. J Med Microbiol. 2005;54(Pt 10):927-31.
9. Gatongi DK, Gitau G, Kay V, Ngwenya S, Lafong C, Hasan A. *Female genital tract tuberculosis*. Obstet Gynaecol. 2005;7:75-9.
10. Bhanothu V, Theophilus J, Rozati R. Detection of Mycobacterium tuberculosis among infertile patients suspected with female genital tuberculosis. Am J Infect Dis Microbiol. 2014;2(2):22-33.

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A Hole in Fundus of Primigravid Uterus: An Unusual Finding at Cesarean Section

REKHA RANI*, SHIKHA SINGH†, URVASHI VERMA‡, RUCHIKA GARG*, DIVYA YADAV#, SAROJ SINGH$, SURENDRA KUMAR¥, SHWETA CHAUHAN¶, RAGINI¶

ABSTRACT

The spontaneous rupture of the primigravid uterus before the onset of labor is an obstetric rarity. Invariably, there is a history of antecedent scarring. A case of uterine rupture or defect in uterine musculature, an unusual finding at cesarean section, is reported. The probable mechanism of rupture/defect in fundus is discussed. Admission at 32 weeks and cesarean section at 36 weeks is recommended in the next pregnancy.

Keywords: Fundal defect, rupture uterus, primigravid uterus, pregnancy, cesarean section

Uncomplicated uterine perforation has been considered a benign event. Since the advent of operative hysteroscopy, there have been several reports of uterine rupture during pregnancy in patients who have undergone that procedure when complicated by known or unsuspected uterine perforation. Large fundal defects without rupture have also been reported. In general, a small midline or fundal injury with a blunt instrument does not have clinically significant sequelae if bleeding is minimal, but large rents or those caused by sharp or electrosurgical instruments may result in a need for diagnostic laparoscopy to completely evaluate the patient for bleeding or visceral injury. Lateral perforations involve risk of injury to vessels and should be further inspected with diagnostic laparoscopy or interventional radiology, angiography.

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Whenever electrical or laser injury to the bowel or bladder is suspected, laparoscopy or laparotomy is required for complete evaluation. The risk of peritonitis, sepsis and death are most often associated with unrecognized and untreated thermal injuries to the viscera.

CASE REPORT

A 24-year-old primigravida, married for 4 years, was admitted as a referred patient at term. She had a history of 4 years of infertility, having conceived following infertility treatment. She had a prior diagnostic laparoscopy for infertility 2 years back. The patient had no complaints. There was no abdominal pain, nor any bleeding/leaking per vaginum. The patient's gestational age at admission was 41 weeks.

On examination at admission, her vitals were stable. The uterus was at term, relaxed, with the fetus in breech presentation and with absent liquor. The fetal heart beat was regular. Per vaginum examination showed that the cervix was long and os closed. Her pelvis was borderline. All antenatal investigations were within normal limits. Her ultrasonography (USG) showed single live intrauterine pregnancy of 41 weeks 3 days with frank breech with absent liquor. The patient was admitted and in view of her precious post-dated pregnancy with frank breech and absent liquor and previous infertility treatment. The decision was taken for an emergency cesarean section. Her cesarean section was done and after delivery of the baby which was a healthy male child, weighing 3.44 kg, the uterus was exteriorized for examination. A 3 × 2.5 cm defect (Fig. 1) was found on the fundus

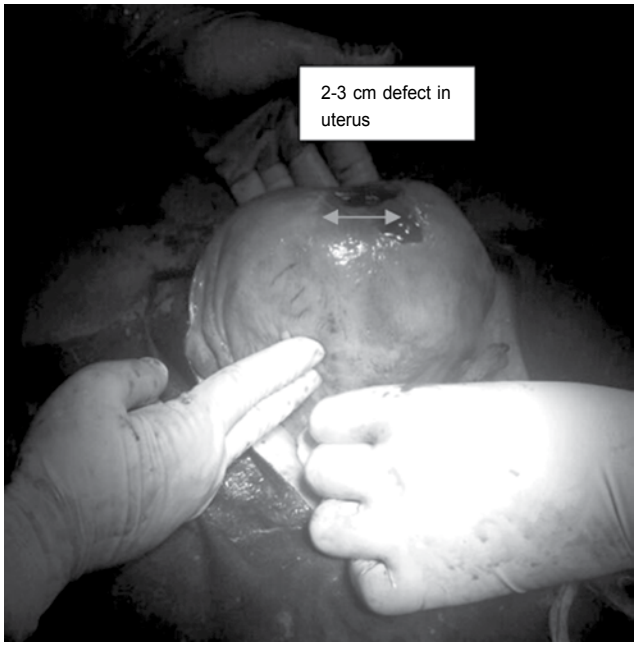

Figure 1. A 2.5 × 3 cm defect seen in the fundal part of the uterus.

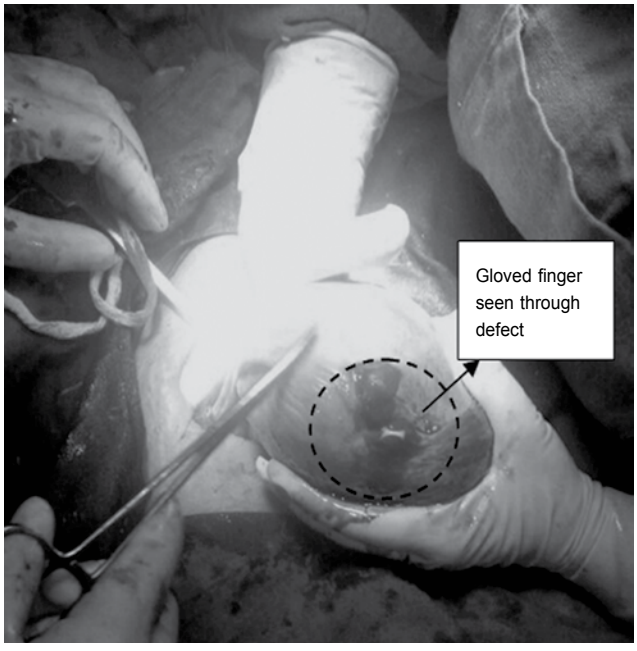

Figure 2. Defect on the fundus communicating with the uterine cavity.

anteriorly and communicating with the uterine cavity (Fig. 2). The defect was covered with fimbrial part of right fallopian tube (Fig. 3). However, in spite of the rent, there was no active bleeding from its edges. There was no tear into fresh uterine tissue. The scar tissue surrounding the hole in the uterus was excised and a two-layer closure was achieved. The lower segment of uterus and the abdomen were closed in the routine

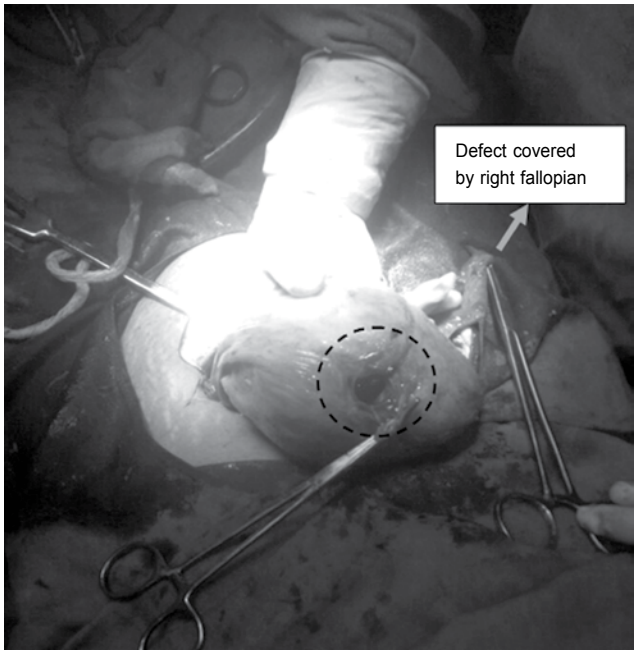

Figure 3. The defect covered by fimbrial part of right fallopian tube.

fashion. The patient made an uneventful recovery and was discharged on the 10th postoperative day.

DISCUSSION

The term 'rupture uterus' is used to denote a breach in the substance of the gravid uterus musculature from any cause after fetal viability.[1] It constitutes a life-threatening obstetric emergency with significant effects on the reproductive function of women. Uterine rupture typically is classified as either complete when all layers of the uterine wall are separated, or incomplete when the uterine muscle is separated but visceral peritoneum is intact.[2]

The majority of cases of uterine rupture occur in a patient where pregnancy follows a previous cesarean section. Direct trauma to the uterus is another rare cause of uterine rupture. The signs and symptoms of rupture of the uterus would manifest when the scar ruptures or the window extends in early labor. Silent rupture, dehiscence or windows should not be considered in the same category as true uterine ruptures. They represent no extension into fresh uterine tissue, lack symptoms, cannot be diagnosed, involve no blood loss or shock. The hazard to the mother or baby is minimal, as in this case.

The uterine wall may be weakened by previous procedures like manual removal of the placenta or curettage with or without perforation for retained

products of conception following abortion. At present maternal death as a consequence of uterine rupture occurs at a rate of 0-1% in developed nations and 5-10% in developing countries.[3,4]

In our case, the previous diagnostic laparoscopy may have caused trochar injury on the fundus.[5] Rupture uterus is one of the worst obstetric emergencies in which the life of both mother and child are in danger, the incidence ranges from 0.2% to 0.6%. Factors that can predispose to uterine rupture are multiparity, advanced maternal age, a scarred uterus, malpresentations, contracted pelvis, misuse of oxytocic drugs and rarely obstetric maneuvers like external cephalic or internal podalic version, and following instrumental deliveries.[6] Fetal morbidity invariably occurs because of catastrophic hemorrhage leading to fetal anoxia, with uterine rupture and expulsion of the fetus into the peritoneal cavity. The chance of fetal survival is minimal. Immediate diagnosis and delivery by laparotomy can save the baby.[7]

CONCLUSION

We report this case to highlight the fact that although spontaneous rupture of the gravid uterus is a very rare complication in primigravid women. It can still occur and it should be diagnosed and treated promptly. Patients with a prior dilatation and curettage, diagnostic laparoscopy and other uterine interventions should be monitored and screened for myometrial thickness prior to conception and antenatally by ultrasound and magnetic resonance imaging.

REFERENCES

1. Ian Donald's Practical Obstetric Problems. New Delhi: BI Publication Private Limited. 5th Edition; 1996. pp. 795-804.
2. Padhye SM. Rupture of the pregnant uterus - a 20 year review. Kathmandu Univ Med J (KUMJ). 2005;3(3):234-8.
3. Mokgokong ET, Marivate M. Treatment of the ruptured uterus. S Afr Med J. 1976;50(41):1621-4.
4. Rahman J, Al-Sibai MH, Rahman MS. Rupture of the uterus in labor. A review of 96 cases. Acta Obstet Gynecol Scand. 1985;64(4):311-5.
5. Nkwabong E, Kouam L, Takang W. Spontaneous uterine rupture during pregnancy: case report and review of literature. Afr J Reprod Health. 2007;11(2):107-12.
6. Ahmadi S, Nouira M, Bibi M, Boughuizane S, Saidi H, Chaib A, et al. Uterine rupture of the unscarred uterus. About 28 cases. Gynecol Obstet Fertil. 2003;31(9):713-7.
7. Mahbuba, Alam IP. Uterine rupture - experience of 30 cases at Faridpur Medical College Hospital. Faridpur Med Coll J. 2012;7(2):79-81.

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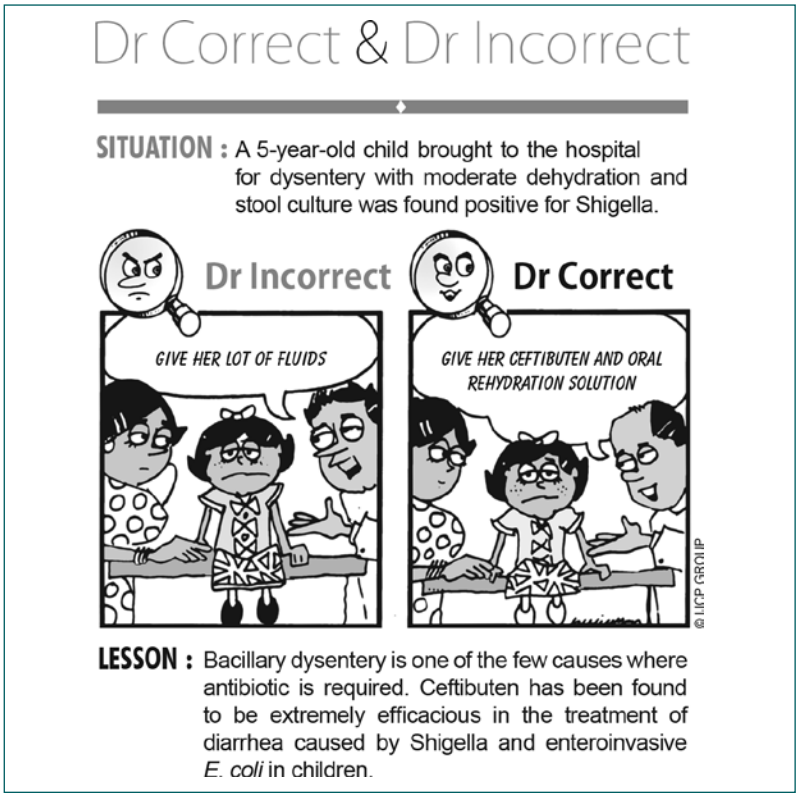

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Unexpected Intruder: An Interesting Case of Placenta Increta

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ABSTRACT

Placenta accreta, a condition with high morbidity, is anticipated in women with risk factors for the same. Danger when anticipated is easier handled than when taken by surprise. Here we report a case of placenta increta with an unusual presentation.

Keywords: Placenta accreta, placenta increta, adherent placenta, severe morbidity, increasing cesarean section rates

Adherent placenta is an abnormal attachment of the placental villi to the decidua and can present with varying degrees of invasion into the myometrium.[1] Placenta increta is one of the rarer forms of adherent placenta. It is a serious condition associated with severe morbidity and even mortality. The risk factors include prior cesarean and uterine curettage.[2]

This condition affects 1 in 2,500 pregnancies.[1] The increasing cesarean section rates has contributed to the alarming increase in adherent placenta but the risk remains low in an unscarred uterus. Here we discuss a case of placenta increta in a patient with no known risks for adherent placenta, who was successfully managed conservatively.

CASE REPORT

Mrs SA, a 24-year-old primiparous lady was referred to our center with failed attempt at manual removal of placenta, after an uncomplicated vaginal delivery at term in a nursing home.

On reviewing her history, she had been a second gravid with one previous spontaneous abortion at 2 months. She had no history of uterine curettage. The index pregnancy had been uneventful. She had spontaneous onset of labor at 39 weeks and delivered vaginally - a healthy 2.7 kg boy baby. However, placenta failed to separate even 2 hours after the delivery. Manual removal was tried in that nursing home, which was unsuccessful. Hence, patient was referred for tertiary care to Sri Ramachandra Medical College, Chennai.

On examination in the casualty, her general condition was satisfactory with a blood pressure (BP) of 110/70 mmHg. She had tachycardia with heart rate ~110-130 bpm. On abdominal examination, uterus was 28 weeks in size and firm in consistency. On vaginal examination, os was closed with ~100 g of clots in the vagina.

Ultrasound (Fig. 1) showed placenta at the fundus and post wall invading into the myometrium, with thinning of myometrium at the fundus. USG was followed by magnetic resonance imaging (MRI) (Figs. 2 and 3), which confirmed the earlier diagnosis of placenta increta with more than 60-70% of myometrial invasion; maximum thickness of the myometrium was 5 mm at the fundus.

In view of placenta increta, we decided on uterine artery embolization (UAE) after counseling the patient and her family.

The procedure was done under LA. Selective catheterization of both uterine arteries was done followed by embolization using graded polyvinyl alcohol (PVA) particles.

Completion angiograms confirmed complete absence of abnormal blush and vascularity on either side. After the embolization, patient was given one dose of intramuscular methotrexate 50 mg.

Two days after the embolization, patient developed spikes of fever hemoglobin level progressively dropped from 8.4 mg/dL on D1 to 5.4 on D3 along with drop

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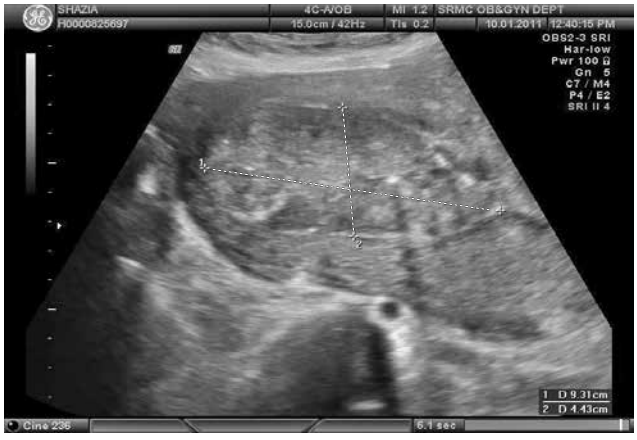

Figure 1. Ultrasound showing adherent placenta.

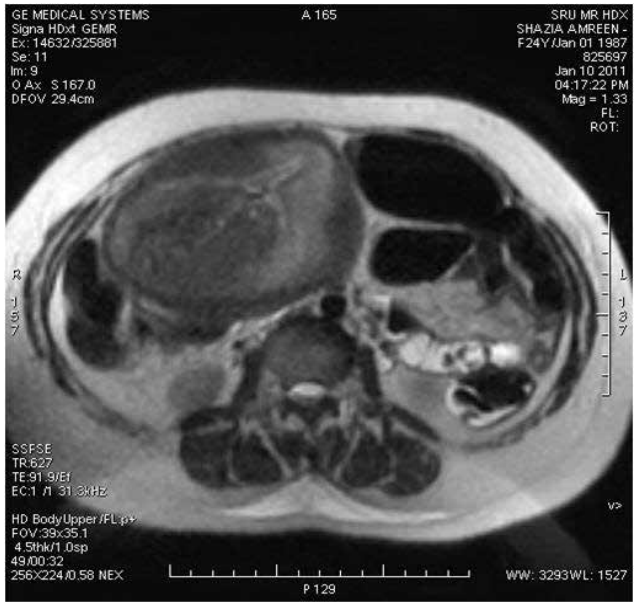

Figure 2. MRI showing placenta increta.

in total count from 17,000 to 4,500. Further doses of methotrexate was withheld because of pancytopenia. Three units of packed cell was transfused. Patient recovered well and was discharged on Day 7.

Patient has been following up on OP basis for the last 3 months. Clinical examination showed progressive involution of the uterus. Fundal height decreased from 28 weeks prior to the embolization to 14 weeks after 6 weeks and serial ultrasound has shown consistent decrease in the size of placenta from 8.6 × 6.0 to 8.0 × 5.8 at 3 weeks and 6.7 × 5.4 cm at 6 weeks with no flow on Doppler. Beta-hCG (human chorionic gonadotropin) returned to normal after 3 weeks. Eighty-two days after the procedure, patient expelled the placenta (Fig. 4) following 6 days of pain abdomen and moderate amount of bleeding per vaginum.

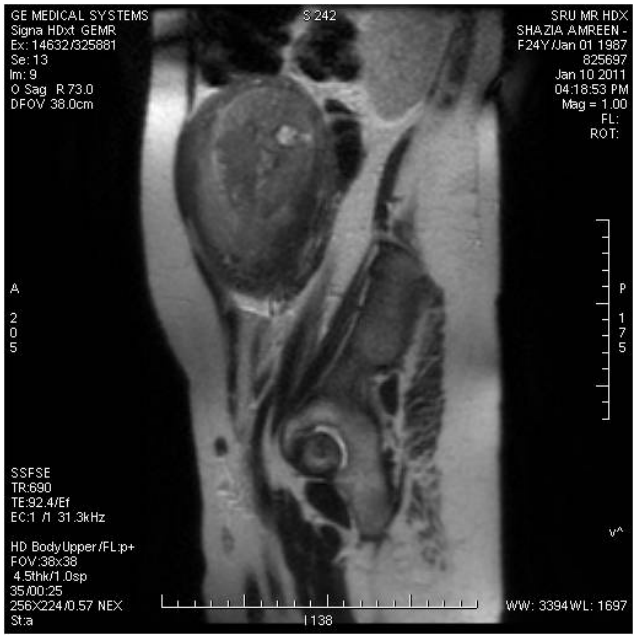

Figure 3. MRI showing thinning of myometrium at the fundus.

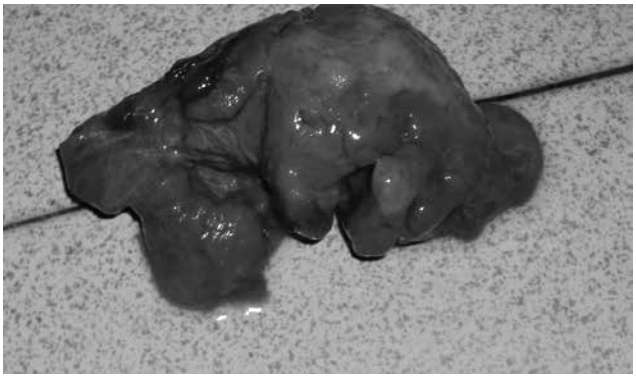

Figure 4. The expelled placenta on Day 82.

DISCUSSION

A placenta accreta occurs when there is abnormally firm attachment of placental villi to the uterine wall with the absence of the normal intervening decidua basalis and Nitabuch's layer. There are 3 variants of this condition: 1) *Accrete*: The placenta is attached to the myometrium - incidence reported is 75%; 2) *Increta*: The placenta extends into the myometrium and is seen in 17% of patients with adherent placenta and 3) *Percreta* reported in 5-7% - the placenta extends through the entire myometrial layer and uterine serosa.

About 88% of placenta accreta cases are associated with placenta previa and 78% have a history of previous cesarean birth.[3] The risk of placenta accreta is 0.03% for primi, without placenta previa.[4]

Placenta accreta can be diagnosed using ultrasound or MRI. When one imaging modality is inconclusive, the other modality may be useful for clarifying the diagnosis.[5] Sonographic features that have been associated with placenta accreta include:[6]

- Loss of normal hypoechoic retroplacental zone.
- Multiple vascular lacunae within placenta, giving "Swiss cheese" appearance.
- Blood vessels or placental tissue bridging uterine-placental margin, myometrial-bladder interface or crossing uterine serosa.
- Retroplacental myometrial thickness of <1 mm.
- Numerous coherent vessels visualized with 3-dimensional power Doppler in basal view.

Serial MRI, in conjunction with β-hCG assays, has been shown to provide an accurate and noninvasive imaging modality to confirm ablation of residual trophoblastic tissue.[7] When analyzing the role of conservative management of placenta accreta - it has been found to have a good success rate along with a reduction in the hysterectomy rate from 84% to 15%, proving that leaving the placenta *in situ* is a safe alternative to removing the placenta.[8,9]

Conservative management of placenta accreta with methotrexate although successful in uterine preservation, has not been found to be effective in prevention of significant delayed hemorrhage.[10]

UAE for placenta accreta has been found to be a safe and effective method for persistent but noncatastrophic obstetric bleeding[11] and this modality has been well-established as an adjunctive treatment in cases, where the placenta is left *in situ*. Prophylactic UAE with PVA particles, to reduce uterine and placental blood flow, postoperatively has been found to be effective[12] and subsequent fertility is not impaired by the procedure.[13]

Methotrexate has been used to accelerate reduction in placental mass and combination of methotrexate with UAE has also been reported.[14] Expulsion of the retained placenta has been reported to occur as long as 7-8 weeks later.[15]

CONCLUSION

Placenta increta occurs rarely in patients without risk factors nevertheless this condition must always be considered in women with retained placenta. UAE is a safe and effective nonsurgical method in the management of adherent placenta in a hemodynamically stable patient.

REFERENCES

1. ACOG Committee on Obstetric Practice. ACOG Committee opinion. Number 266, January 2002: placenta accreta. Obstet Gynecol. 2002;99(1):169-70.
2. De Lange M, Rouse GA. Ob/Gyn Sonography: An Illustrated Review. Pasadena, Calif: Davies Publishing Inc; 2004.
3. Armstrong CA, Harding S, Matthews T, Dickinson JE. Is placenta accreta catching up with us? Aust N Z J Obstet Gynaecol. 2004;44(3):210-3.
4. Silver RM, Landon MB, Rouse DJ, Leveno KJ Spong CY, Thom EA, et al; National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. Maternal morbidity associated with multiple repeat cesarean deliveries. Obstet Gynecol. 2006;107(6):1226-32.
5. Dwyer BK, Belogolovkin V, Tran L, Rao A, Carroll I, Barth R, et al. Prenatal diagnosis of placenta accreta: sonography or magnetic resonance imaging? J Ultrasound Med. 2008;27(9):1275-81.
6. Publications Committee, Society for Maternal-Fetal Medicine, Belfort MA. Placenta accreta. Am J Obstet Gynecol. 2010;203(5):430-9.
7. Sonin A. Nonoperative treatment of placenta percreta: value of MR imaging. AJR Am J Roentgenol. 2001;177(6):1301-3.
8. Kayem G, Davy C, Goffinet F, Thomas C, Clément D, Cabrol D. Conservative versus extirpative management in cases of placenta accreta. Obstet Gynecol. 2004;104(3):531-6.
9. Sentilhes L, Ambroselli C, Kayem G, Provansal M, Fernandez H, Perrotin F, et al. Maternal outcome after conservative treatment of placenta accreta. Obstet Gynecol. 2010;115(3):526-34.
10. Mussalli GM, Shah J, Berck DJ, Elimian A, Tejani N, Manning FA. Placenta accreta and methotrexate therapy: three case reports. J Perinatol. 2000;20(5):331-4.
11. Uchiyama D, Koganemaru M, Abe T, Hori D, Hayabuchi N. Arterial catheterization and embolization for management of emergent or anticipated massive obstetrical hemorrhage. Radiat Med. 2008;26(4):188-97.
12. El-Messidi A, Morissette C, Faught W, Oppenheimer L. Application of 3-D angiography in the management of placenta percreta treated with repeat uterine artery embolization. J Obstet Gynaecol Can. 2010;32(8):775-9.
13. Chauleur C, Fanget C, Tourne G, Levy R, Larchez C, Seffert P. Serious primary post-partum hemorrhage, arterial embolization and future fertility: a retrospective study of 46 cases. Hum Reprod. 2008;23(7):1553-9.
14. Sherer DM, Gorelick C, Zigalo A, Sclafani S, Zinn HL, Abulafia O. Placenta previa percreta managed conservatively with methotrexate and multiple bilateral uterine artery embolizations. Ultrasound Obstet Gynecol. 2007;30(2):227-8.
15. Chan BC, Lam HS, Yuen JH, Lam TP, Tso WK, Pun TC, et al. Conservative management of placenta praevia with accreta. Hong Kong Med J. 2008;14(6):479-84.

Extensive Dorso-lumbar En-plaque Meningioma Mimicking Ligamentum Flavum Hypertrophy

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ABSTRACT

We report a case of extensive dorso-lumbar en-plaque meningioma that was mimicking ligamentum flavum hypertrophy and review the literature. A 65-year-old male presented with history of low back pain of 2-year duration with worsening of the pain since past 2 months. On examination, he had flaccid paraplegia with bowel and bladder involvement. Magnetic resonance imaging findings were suggestive of extensive ligamentum flavum hypertrophy. The patient underwent D9-L2 laminectomy. The dura was thickened and extensively vascular and the lesion could be partially excised. Histopathology was suggestive of meningioma. Spinal en-plaque meningiomas are rare and challenging lesions associated with poorer outcome.

Keywords: En-plaque, meningioma, spinal tumor

Spinal en-plaque meningiomas are rare and challenging lesions and[1-4] rarely en-plaque spinal meningioma can mimic ossification of the ligamentum flavum, and only reported once in the literature.[4] We report a case of extensive dorso-lumbar en-plaque meningioma that was the mimicking ligamentum flavum and review the literature.

CASE REPORT

A 65-year-old male presented with history of low back pain of 2-year duration and worsening of the pain since past 2 months. He also developed progressive weakness of both the lower limbs with complete loss of movements since past 15 days. He had urinary retention 1 week back for which he was catheterized. He also complained of constipation since last 15 days. There was no history of trauma or fever. His general and systemic examination was normal. Higher mental functions and cranial nerves were normal. Neurological functions in upper limbs were normal. There was flaccid paralysis in both lower limbs with grade 0/5 power. There was complete loss of sensation below D-10 level to all modalities. Anal sphincter tone was lax. All deep tendon reflexes in lower limbs were absent. Abdominal reflexes were absent and plantars were not elicitable.

Magnetic resonance imaging (MRI) of dorso-lumbar spine showed dorsally placed mildly hyperintense lesion on T1 images becoming hypointense on T2 images extending from D9-L2 level (Fig. 1). A diagnosis

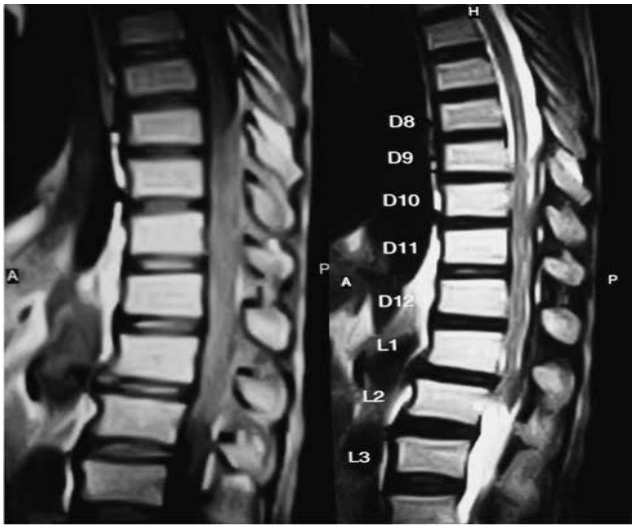

Figure 1. Dorsally placed extensive lesion from D9-L2 level.

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Figure 2. Extensively vascular and thickened dura.

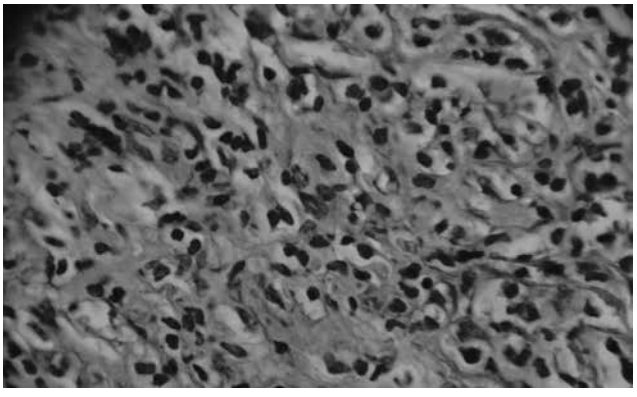

Figure 3. Histopathology showed that the tumor was a meningioma (H&E, 40x).

of ligamentum flavum hypertrophy was suspected. The patient underwent D9-L2 laminectomy. There was extensively vascular and thickened dura (Fig. 2). Because of an ill-defined plain of cleavage between the dura and the cord, the tumor could be excised partially. Histopathology was suggestive of meningioma (Fig. 3). There was no improvement in his neurological deficits.

DISCUSSION

En-plaque spinal meningioma though rare, but can involve dura extensively with significant neurological deficits.[4-7] These lesions can be suspected on computerized tomography (CT) and MRI and present as an unusual stratified architecture, with a conspicuous highly calcified component attached to the dura that may surround it posteriorly and laterally.[5] In our case, the imaging features were similar but we did not suspect this diagnosis. The surgical treatment of en-plaque meningioma is more complex than that of classic meningioma.[1,2,5] However, in patients with good plane of cleavage complete tumor removal is possible[1,2,5] and the wide dural defect can be closed with autologous fascia lata graft.[5] The difficulty may be due to the infiltration of surrounding structures and associated arachnoid scarring that may render complete resection difficult to achieve.[7-9] Spinal en-plaque meningiomas have a poorer prognosis than that of classic meningiomas with regard to the possibility of a definitive surgical cure.[1,4,5]

REFERENCES

1. Caroli E, Acqui M, Roperto R, Ferrante L, D'Andrea G. Spinal en plaque meningiomas: a contemporary experience. Neurosurgery. 2004;55(6):1275-9; discussion 1279.
2. Niijima K, Huang YP, Malis LI, Sachdev VP. Ossified spinal meningioma en plaque. Spine (Phila Pa 1976). 1993;18(15):2340-3.
3. Stechison MT, Tasker RR, Wortzman G. Spinal meningioma en plaque. Report of two cases. J Neurosurg. 1987;67(3):452-5.
4. Gamache FW Jr, Wang JC, Deck M, Heise C. Unusual appearance of an en plaque meningioma of the cervical spinal canal. A case report and literature review. Spine (Phila Pa 1976). 2001;26(5):E87-9.
5. Messori A, Rychlicki F, Salvolini U. Spinal epidural en-plaque meningioma with an unusual pattern of calcification in a 14-year-old girl: case report and review of the literature. Neuroradiology. 2002;44(3):256-60.
6. Pittella JE, da Costa CC, Giannetti AV, Perpétuo FO. October 2000: a 47 year old man with long-standing progressive tetraparesis. Brain Pathol. 2001;11(2):261-2.
7. Yamaki T, Ikeda T, Sakamoto Y, Ohtaki M, Hashi K. Lymphoplasmacyte-rich meningioma with clinical resemblance to inflammatory pseudotumor. Report of two cases. J Neurosurg. 1997;86(5):898-904.
8. Klekamp J, Samii M. Surgical results for spinal meningiomas. Surg Neurol. 1999;52(6):552-62.
9. Samii M, Klekamp J, Carvalho G. Surgical results for meningiomas of the craniocervical junction. Neurosurgery. 1996;39(6):1086-94; discussion 1094-5.

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Rule of 2 for Hypertension

- Patients with prehypertension are at 2 times the risk of developing hypertension.
- Limiting alcoholic consumption to no more than 2 drinks (1 oz or 30 mL ethanol; e.g., 24 oz beer, 10 oz wine, or 3 oz 80-proof whiskey) per day in most men alone can reduce blood pressure by 2 mmHg.

IJCP SUTRA 114: Patients with moderate MS who are in sinus rhythm or atrial fibrillation (AF) and have peak pulmonary artery systolic pressures less than 50 mmHg can participate in low and moderate static and low and moderate dynamic competitive sports (class IA, IB, IIA, and IIB) *J Am Coll Cardiol.* 2005;45:1334.

Assessment of Parents' and Child's Attitude as Barrier to Dietary Compliance in Celiac Disease

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ABSTRACT

Celiac disease is an immune-mediated systemic disorder in genetically susceptible individuals triggered by consuming a protein called gluten, which is found in wheat, barley and rye in genetically susceptible individuals. Classic symptoms include gastrointestinal problems such as chronic diarrhea, abdominal distension, malabsorption, loss of appetite and failure of children to grow normally. The general treatment for celiac disease is a gluten-free diet which entails strict avoidance of all products containing the proteins from wheat, barley and rye. Noncompliance is a major problem and the greatest challenge which the physicians face is in predicting the compliance to the gluten-free diet in children. This study was undertaken to evaluate the impact of celiac disease and the gluten-free diet on the lifestyle and well-being of children with celiac disease and their families, with the aim to identify factors affecting compliance to gluten-free diet and to assess parents' and child's attitude as barrier to dietary compliance in children with celiac disease.

Keywords: Celiac disease, autoimmune disorder, genetic, gluten, compliance to the gluten-free diet

Celiac disease is an immune-mediated systemic disorder elicited by gluten and related prolamins in genetically susceptible individuals and characterized by the presence of a variable combination of gluten-dependent clinical manifestations, celiac disease-specific antibodies, HLA-DQ2 or HLA-DQ8 haplotypes and enteropathy.[1] Recently, the prevalence of celiac disease across the European countries was shown to be 1.5% based on people who had positive biopsy and tissue transglutaminase (tTG) results.[2] In the United States, the overall prevalence of celiac disease in children up to 5 years of age is 1 in 104.[3] This disease is quite prevalent in India also with rates of 1 in 96 in North India.[4] Lifelong adherence to a gluten-free diet is the cornerstone treatment of celiac disease.[5] A gluten-free diet entails strict avoidance of all products containing the proteins from wheat, barley and rye.[6] It is strongly recommended that gluten elimination from diet must be strict and lifelong not only to control symptoms but also to improve quality-of-life and decrease the risk of complications.[7] Although a well-planned gluten-free diet may provide adequate nutrition, it may be restrictive. Strict adherence to gluten-free diet may be more challenging in children and adolescents than in adults. Compliance to gluten-free diet varies from 45% to 81% in children as reported by the North American Society of Pediatric Gastroenterology, Hepatology and Nutrition.[8]

Noncompliance is a major problem and the greatest challenge, which the physicians face is in predicting the compliance to the gluten-free diet in children. Noncompliance may occur due to factors like temptation and not liking the taste of gluten-free diet and alternative food grains.[9] In adolescents, peer pressure, unclear labeling on ready-to-eat food and nonavailability of gluten-free diet at party, marriages, and so forth have contributed to noncompliance.[10] An increasingly hectic lifestyle of teenagers has contributed to a greater reliance on packaged foods which often contain gluten, thus making it inconvenient for them to adhere to restrictive diet.[10] Since parents are usually responsible for food preparation for children, low level of knowledge about the diet in the parents, nonavailability of gluten-free foods and unclear labeling lead to noncompliance in

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children.[11] Many children experience psychological reactions to being placed on a restrictive diet (e.g., feeling deprived, depressed, angry and anxious), which have been found to further decrease compliance.[12] This study evaluates the impact of celiac disease and the gluten-free diet on the lifestyle and well-being of children with celiac disease and their families, with the aim to identify factors affecting compliance to gluten-free diet and to assess parents' and child's attitude as barrier to dietary compliance in children with celiac disease. This study is significant and will contribute to the current body of research by providing healthcare practitioners with information as to what predicts the compliance to gluten-free diet, which may be used to better understand education techniques for dietary instruction so that the children living with celiac disease have less of morbidity and achieve their normal growth potential. Participants will contribute to the understanding of celiac disease and the challenges individuals face with the gluten-free diet.

MATERIAL AND METHODS

The present study was conducted by Dept. of Pediatrics, SMS Medical College and Attached Hospitals, Jaipur, Rajasthan, India. A total number 134 celiac disease children with and parents visiting the gastroenterology super specialty clinic were studied. These children visited the clinic for growth monitoring and compliance assessment. Hundred consecutive children aged between 2 years and 15 years, diagnosed with celiac disease as per revised the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) criteria for diagnosis of celiac disease 1990,[13] on gluten-free diet for more than 6 months were enrolled in the study after getting the requisite clearance from the Institute Research Review Board. Children less than 2 years and more than 15 years of age, those who did not have a documented positive serology and/or biopsy suggestive of celiac disease as per revised ESPGHAN criteria 1990, those on gluten-free diet for less than 6 months and those children whose parents did not consent to be included in the study were excluded.

All children enrolled in the study, after signing of the written informed consent form, were evaluated for dietary compliance based on a 5-day dietary recall form. A child who had taken even one food article containing gluten in last 5 days was considered noncompliant and those who had strictly taken no gluten in their diet in that period were considered compliant. Diet recall was done by parents for children in preschool age up to 5 years since parents were the only one giving the eatables to these children. Children, above 5 years of age, going to school and interacting with peers, were actively involved in the dietary recall along with the parents. Parents and children in the study group were assessed for dietary compliance followed by a questionnaire based interview. Psychosocial parameters were assessed by standard Pediatric Symptom Checklist (PSC). Dietary compliant and noncompliant groups were compared and assessed for factors affecting the dietary compliance. Predictability of all of these factors was assessed using binary logistic regression analysis with backward elimination to find out the best predictors of compliance.

RESULTS AND DISCUSSIONS

Three types of barriers to compliance were noted. Barriers derived from parent's attitude, those derived from child's attitude and those caused by effect of celiac disease on feelings of children suffering from celiac disease.

Barriers Related to Child's Attitude

Table 1 shows results of assessment of child's attitude as a barrier to compliance to gluten-free diet, 63.08% of children in compliant group found it easy to keep compliance to gluten-free diet 57.14% of children in noncompliant group found it fairly difficult to maintain gluten-free diet. In noncompliant group, 74.29% children found it difficult to maintain gluten-free diet at school; 80% found it difficult to maintain gluten-free diet at family parties and marriages; 62.86% found difficult to comply to diet when with friends. 69.23% in compliant group and 85.79% in noncompliant group found difficulty in complying to diet while traveling.

When they were assessed regarding sharing of responsibility in maintaining gluten-free diet, 66.15% of compliant children were found to be sharing responsibility of keeping the diet, as compared to 28.57% of noncompliant children who shared responsibility of keeping the diet. It was noted that 42.86% of noncompliant children reported the taste of gluten-free diet as bad, while 66.15% of children in compliant group found it very good or good and only 3.08% of compliant children reported food as bad. A statistically significant difference was observed when most of these results were compared.

In the present study, the questionnaire included questions related to child's attitude in response to the disease and gluten-free diet. While 63.08% of children in compliant group found keeping gluten-free diet easy; only 20% of noncompliant children found it easy to maintain a

Table 1. Barriers Related to Child's Attitude

Question	Response	Compliant No. (%)	Noncompliant No. (%)	P value
Finds keeping diet difficult	Difficult	4 (6.15)	8 (22.86)	<0.001
	Fairly difficult	20 (30.77)	20 (57.14)	
	Easy	41 (63.08)	7 (20.00)	
Child shares responsibility	Y	43 (66.15)	10 (28.57)	<0.001
	N	22 (33.85)	25 (71.43)	
Finds taste of gluten-free diet	Bad	2 (3.08)	15 (42.86)	<0.001
	Satisfactory	20 (30.77)	16 (45.71)	
	Good	39 (60.00)	3 (8.57)	
	Very good	4 (6.15)	1 (2.86)	
Finds difficult to maintain diet at school	Y	27 (41.54)	26 (74.29)	<0.001
	N	38 (58.46)	9 (25.71)	
Finds difficult to maintain diet at party/marriage	Y	24 (36.92)	28 (80.00)	<0.001
	N	41 (63.08)	7 (20.00)	
Finds difficult to maintain diet while traveling	Y	45 (69.23)	30 (85.71)	0.814
	N	20 (30.77)	5 (14.29)	
Finds difficult to maintain diet with friends	Y	24 (36.92)	22 (62.86)	<0.001
	N	41 (63.08)	13 (37.14)	

gluten-free diet, while 57.14% of noncompliant children found it fairly difficult and 22.86% children found it difficult to maintain the diet. Our study also found that 66.15% of compliant patients were fairly responsible in maintenance of gluten-free diet as compared to 28.57% in noncompliant group. These results show that compliant patients are more involved in maintenance of their diet. Active involvement of child is significantly related ($p \leq 0.001$) in our study to compliance as in study by Chauhan et al in 2010.[9] In a study by Anson et al (1990), 71% of compliant children's mothers and 44% of noncompliant children's mothers thought that the children shared responsibility in keeping diet.[11]

Barriers Related to Parental Attitude

Table 2 shows 24.62% of parents of children in compliant group hardly felt a burden on their budget, while 94.28% of parents with children in noncompliant group felt a fairly heavy or heavy burden on their budget as compared to 75.38% of parents with children in compliant group who felt a fairly heavy or heavy burden on their budget. It was seen that 87.69% of parents of children in compliant group cooked more than once for their children as compared to 71.43% of parents of children in noncompliant group. In compliant group, 72.31% of parents believed that special diet was hardly a burden to the family, whereas in noncompliant group 57.14% parents felt it as a burden. Also, 36.92% of parents of children in compliant group were not hesitant to discuss the child's condition and were interacting with other parents of celiac disease in gastrology clinics; these parameters were significantly lower in noncompliant group i.e., 14.29%. In compliant group, 64.62% of parents and in noncompliant group, 71.73% of parents believed that the disease will interfere with their child's marriage; 93.28% of parents of children in noncompliant group and 75.38% of parents of children in compliant group also felt a financial burden by gluten-free diet. In noncompliant group, 71.43% of parents cooked more than once for their children as compared to 87.69% of parents with children in compliant group. All these parameters had a significant correlation ($p \leq 0.001$) with compliance and show that noncompliance was most common in parents who consider special diet a burden to budget and family and hence they avoided cooking fresh meals for the children. Hence, cheap and easy to cook food will help this disease bearing families.

Table 2. Barriers Related to Parents' Attitude

Question	Response	Compliant No. (%)	Noncompliant No. (%)	P value
Finds burden on budget	Heavily	12 (18.46)	16 (45.71)	<0.001
	Fairly	37 (56.92)	17 (48.57)	
	Hardly	16 (24.62)	2 (5.71)	
Feels burden on self	Y	18 (27.69)	20 (57.14)	<0.001
	N	47 (72.31)	15 (42.86)	
Cooks food once or more than once	>Once	57 (87.69)	25 (71.43)	<0.001
	Once	8 (12.31)	10 (28.57)	
In contact with other parents of children with celiac disease	Y	24 (36.92)	5 (14.29)	0.012
	N	41 (63.08)	30 (85.71)	
Believe that disease will interfere with child's marriage	Y	42 (64.62)	25 (71.43)	0.225
	N	23 (35.38)	10 (28.57)	

Study by Lee et al in 2003[14] also shows that financial burden of gluten-free food may affect compliance. Anson et al in 1990[11] also showed that 50% of noncompliant group parents considered diet a burden on family's budget. However, this did not significantly affected compliance in their study. In his study, 56% of compliant parents considered special diet a burden; however, compliant and noncompliant parents did not differ significantly with regard to this parameter. In the study by Chauhan et al in 2010,[9] 60.7% of compliant parents believed that special diet was hardly a burden, while 84.6% in noncompliant felt it as a burden. Olsson et al in 2008[15] and Lee et al in 2003,[14] both have shown that availability of cheap gluten-free food was a significant factor affecting compliance. Increase availability of cheap food items is needed for celiac patients.

It was observed that 36.92% of parents of children in compliant group were not hesitant to discuss the condition with others and were able to interact with other parents in the clinic. These rates were 14.29% in noncompliant group, which were significantly lower. This shows that efforts are required on part of healthcare providers to break the stigma among the parents and increase their interaction mutually and with medical faculty to ensure compliance. Rashid et al (2005) reported compliance rates of 95% in those children whose families were a part of celiac support group, Canadian Celiac Association (CCA).[16] These families regarded CCA as the best source for the information provided to them about their child's disease. Hence, this significant association of compliance with the knowledge imparted about celiac disease with the help of celiac support groups and involvement of dieticians and regular follow-up will definitely improve compliance to the gluten-free diet.

Barriers Related to Child's Feelings

In the present study, 47.69% of the compliant children never felt left out of the activities at school, while only 22.86% of noncompliant children never felt left out of the activities at school. Also, 14.28% of noncompliant children and 7.69% of compliant children believed that their teacher and friends didn't understand the disease all or most of the time; 45.72% of noncompliant children and 3.08% of complaint children felt different from other kids because of disease. It was seen that 72.31% of compliant children were not having any problem in bringing gluten-free diet to school, parties while in noncompliant group this was true for 28.57% only, 62.86% felt embarrassed to bring gluten-free diet at parties. When they were inquired about their social life and asked to grade it, 9.23% children in compliant group believed that they were left out of activities at school or friends' home due to their disease all or most of the time while 48.57% children in noncompliant group believed that they were left out of activities at school or at friends' home all or most of the time. In noncompliant group, 2.86% felt different from others all the time while 42.86% felt different most of the times as compared to 0% and 3.08%, respectively in the compliant group. Due to their disease; feeling of embarrassment of bringing gluten-free diet to parties was higher in noncompliant group as compared to compliant group i.e., 80% and 27.69%, respectively Table 3.

Table 3. Barriers Related to Child's Feelings

	Compliant group No. (%)					Noncompliant group No. (%)					P value
	A	B	C	D	E	A	B	C	D	E	
Feel left out of activities at school or friends home	0 (0.00)	6 (9.23)	27 (41.54)	31 (47.69)	1 (1.54)	1 (2.86)	16 (45.71)	10 (28.57)	8 (22.86)	0 (0.00)	<0.001
Felt different from other kids	0 (0.00)	2 (3.08)	24 (36.92)	39 (60.00)	0 (0.00)	1 (2.86)	15 (42.86)	10 (28.57)	9 (25.71)	0 (0.00)	<0.001
Felt embarrassed to bring gluten-free foods to parties	1 (1.54)	6 (9.23)	11 (16.92)	47 (72.31)	0 (0.00)	3 (8.57)	15 (42.86)	4 (11.43)	10 (28.57)	3 (8.57)	<0.001
Felt angry about following a special diet	0 (0.00)	12 (18.46)	39 (60.00)	14 (21.54)	0 (0.00)	14 (40.00)	8 (22.86)	10 (28.57)	3 (8.57)	0 (0.00)	<0.001
Felt their teacher and friends didn't understand the disease	0 (0.00)	5 (7.69)	13 (20.00)	42 (64.62)	5 (7.69)	2 (5.71)	3 (8.57)	12 (34.29)	15 (42.86)	3 (8.57)	<0.001
Felt that they can be healthy without following a special diet	1 (1.54)	1 (1.54)	20 (30.77)	43 (66.15)	0 (0.00)	6 (17.14)	8 (22.86)	14 (40.00)	7 (20.00)	0 (0.00)	<0.001
Avoid restaurants	33 (50.77)	17 (26.15)	6 (9.23)	6 (9.23)	3 (4.62)	18 (51.43)	8 (22.86)	2 (5.71)	2 (5.71)	5 (14.29)	0.171
Avoid traveling	23 (35.38)	33 (50.77)	8 (12.31)	1 (1.54)	0 (0.00)	20 (57.14)	5 (14.29)	3 (8.57)	7 (20.00)	0 (0.00)	<0.001
Found difficult to determine which food is gluten-free	8 (12.31)	17 (26.15)	32 (49.23)	8 (12.31)	0 (0.00)	16 (45.71)	10 (28.57)	6 (17.14)	2 (5.71)	1 (2.86)	<0.001
Felt they were no invited out	1 (1.54)	6 (9.23)	9 (13.85)	40 (61.54)	9 (13.85)	4 (11.43)	1 (2.86)	3 (8.57)	18 (51.43)	9 (25.71)	0.002

A = All the time; B = Most of the time; C = Some of the time; D = Never; E = Not answered.

Feeling of anger for following special diet was also higher in noncompliant group as compared to compliant group i.e., 91.43% and 78.46%, respectively, 21.54% never felt angry to follow gluten-free diet in compliant group, while this count is 8.57% in noncompliant group who never felt angry to follow gluten-free diet. In compliant group, 66.15% of children understood the importance of following a gluten-free diet and never felt that they can be healthy without following a special diet while in noncompliant group only 20% understood this. Also, 74.28% children in noncompliant group had problems all or most of the times in identifying the gluten-free food stuff as compared to 38.46% in compliant group who had this problem all or most of the time; 72.31% in compliant group believed that their teachers and friends understood the nature of their disease compared to 51.43% in noncompliant group; 10.77% in compliant group always or most of the time felt that they were not invited for meals outside because of the disease, while 14.29% in noncompliant group believed so all or most of the time. Most of all, these questions showing the perception of the child about the disease and gluten-free diet significantly affected compliance ($p \leq 0.001$).

School Environment

While only 41.54% of compliant patients mentioned that it was difficult for them to maintain compliance at school, 74.29% of noncompliant patients found it difficult to maintain diet at school. Rashid et al (2005) also reported >50% of children felt left out of activities at school and had problems related to compliance.[16] Olsson et al in 2008 showed that for adolescents, school was the most difficult place to comply with gluten-free diet.[15] Other children bringing mainly gluten containing

foods and peer pressure about taking packed food items containing gluten were responsible for difficulty in maintaining compliance at school.

Family Party and Marriages

Noncompliant children also found it difficult to maintain gluten-free diet at family party/marriages (80%), compared to 36.92% in the compliant group. Gluten containing food as the main dietary item served at above places was a problem for both compliant and noncompliant groups who had problems in maintaining diet at such places. Anson et al (1990) have also reported nonavailability of food at party/marriages as barriers to compliance to gluten-free diet.[11]

Traveling

While traveling, majority number of children in both compliant group (69.23%) and noncompliant group (85.71%) face problems with maintaining special diet. This shows the need of easily available packed gluten-free diet and properly labeled as being gluten-free for on-the-go consumption.

Taste of Gluten-free Diet

In response to question related taste of gluten-free food, 66.15% of compliant patients graded taste of gluten-free diet to be very good or good, while only 11.43% in noncompliant group graded it to be good or very good. Child's liking taste of gluten-free diet is significantly associated with compliance ($p \leq 0.001$). Butterworth et al (2004) have also reported better compliance in patients who were frequently explained and educated by dieticians regarding selection and preparation of gluten-free meals to improve the taste of the meals.[17] These results highlight importance of counseling and education of parents and children in selecting and preparing gluten-free foods. Parents should be taught about preparing palatable, easily available gluten-free foods for their children.

In our study, 18.46% of complaint and 62.86% of noncompliant children felt angry about having to follow a special diet all or most of the time, while 66.15% of compliant and only 20% of noncompliant children never believed that they can be healthy without following a special diet. We also found that majority of both compliant children (86.15%) and noncompliant children (71.43%) avoided traveling because of the fact that gluten-free diet is not easily available. Rashid et al (2005) also studied the effect of child's feeling on compliance to gluten-free diet. In their study, 13% of compliant children felt left out of school activities due to their disease and 11% of compliant children felt that their teacher did not understand their disease. While 18% children felt themselves different from other kids, 23% were embarrassed to bring gluten-free food to parties. In his study, 23% children felt angry about having to follow a special diet.[16] These results indicate that these dietary restrictions have significant impact on child's social activities including school and extracurricular events. It affects their participation in school, parties and enjoyable social activities such as birthday parties. Non- availability of gluten-free items in restaurants and during travel made them to avoid it. The acceptance of diet was better in children in the study by Rashid et al as compared to those in our study which may be because of support provided by the CCA, the celiac support group which makes the children more comfortable with their condition and made them accept the diet better and hence the role of support groups re-emphasized.[16]

Psychosocial Problem Related to Noncompliance

In our study, the mean score is increasing as the age increases in the children suffering from celiac disease in both compliant and noncompliant patients. Hence, an older child is at more risk of noncompliance.

CONCLUSIONS

These results will contribute to the current body of research by providing healthcare practitioners with a framework for better dietary instructions to ensure maximum adherence to gluten-free diet.

REFERENCES

1. Husby S, Koletzko S, Korponay-Szabó IR, Mearin ML, Phillips A, Shamir R, et al; ESPGHAN Working Group on Coeliac Disease Diagnosis; ESPGHAN Gastroenterology Committee; European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. European Society for Pediatric Gastroenterology, Hepatology, and Nutrition guidelines for the diagnosis of coeliac disease. J Pediatr Gastroenterol Nutr. 2012; 54(1):136-60.
2. Celiac UK. Professional eXG, newsletters/january-2011-professional-exg, January 2011.
3. Hoffenberg EJ, MacKenzie T, Barriga KJ, Eisenbarth GS, Bao F, Haas JE, et al. A prospective study of the incidence of childhood celiac disease. J Pediatr. 2003;143(3):308-14.
4. Makharia GK, Verma AK, Amarchand R, Bhatnagar S, Das P, Goswami A, et al. Prevalence of celiac disease in the northern part of India: a community based study. J Gastroenterol Hepatol. 2011;26(5):894-900.
5. Bhatnagar S, Gupta SD, Mathur M, Phillips AD, Kumar R, Knutton S, et al. Celiac disease with mild to moderate histologic changes is a common cause of chronic

diarrhea in Indian children. J Pediatr Gastroenterol Nutr. 2005;41(2):204-9.

6. Rubio-Tapia A, Hill ID, Kelly CP, Calderwood AH, Murray JA; American College of Gastroenterology. ACG clinical guidelines: diagnosis and management of celiac disease. Am J Gastroenterol. 2013;108(5):656-76; quiz 677.
7. Haines ML, Anderson RP, Gibson PR. Systematic review: The evidence base for long-term management of coeliac disease. Aliment Pharmacol Ther. 2008;28(9):1042-66.
8. Hill ID, Dirks MH, Liptak GS, Colletti RB, Fasano A, Guandalini S, et al; North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. Guideline for the diagnosis and treatment of celiac disease in children: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. J Pediatr Gastroenterol Nutr. 2005;40(1):1-19.
9. Chauhan JC, Kumar P, Dutta AK, Basu S, Kumar A. Assessment of dietary compliance to gluten free diet and psychosocial problems in Indian children with celiac disease. Indian J Pediatr. 2010;77(6):649-54.
10. Errichiello S, Esposito O, Di Mase R, Camarca ME, Natale C, Limongelli MG, et al. Celiac disease: predictors of compliance with a gluten-free diet in adolescents and young adults. J Pediatr Gastroenterol Nutr. 2010; 50(1):54-60.
11. Anson O, Weizman Z, Zeevi N. Celiac disease: parental knowledge and attitudes of dietary compliance. Pediatrics. 1990;85(1):98-103.
12. Mazzone L, Reale L, Spina M, Guarnera M, Lionetti E, Martorana S, et al. Compliant gluten-free children with celiac disease: an evaluation of psychological distress. BMC Pediatr. 2011;11:46.
13. Revised criteria for diagnosis of coeliac disease. Report of Working Group of European Society of Paediatric Gastroenterology and Nutrition. Arch Dis Child. 1990;65(8):909-11.
14. Lee A, Newman JM. Celiac diet: its impact on quality of life. J Am Diet Assoc. 2003;103(11):1533-5.
15. Olsson C, Hörnell A, Ivarsson A, Sydner YM. The everyday life of adolescent coeliacs: issues of importance for compliance with the gluten-free diet. J Hum Nutr Diet. 2008;21(4):359-67.
16. Rashid M Cranney A, Zarkadas M, Graham ID, Switzer C, Case S, et al. Celiac disease: evaluation of the diagnosis and dietary compliance in Canadian children. Pediatrics. 2005;116(6):e754-9.
17. Butterworth JR, Banfield LM, Iqbal TH, Cooper BT. Factors relating to compliance with a gluten-free diet in patients with coeliac disease: comparison of white Caucasian and South Asian patients. Clin Nutr. 2004;23(5):1127-34.

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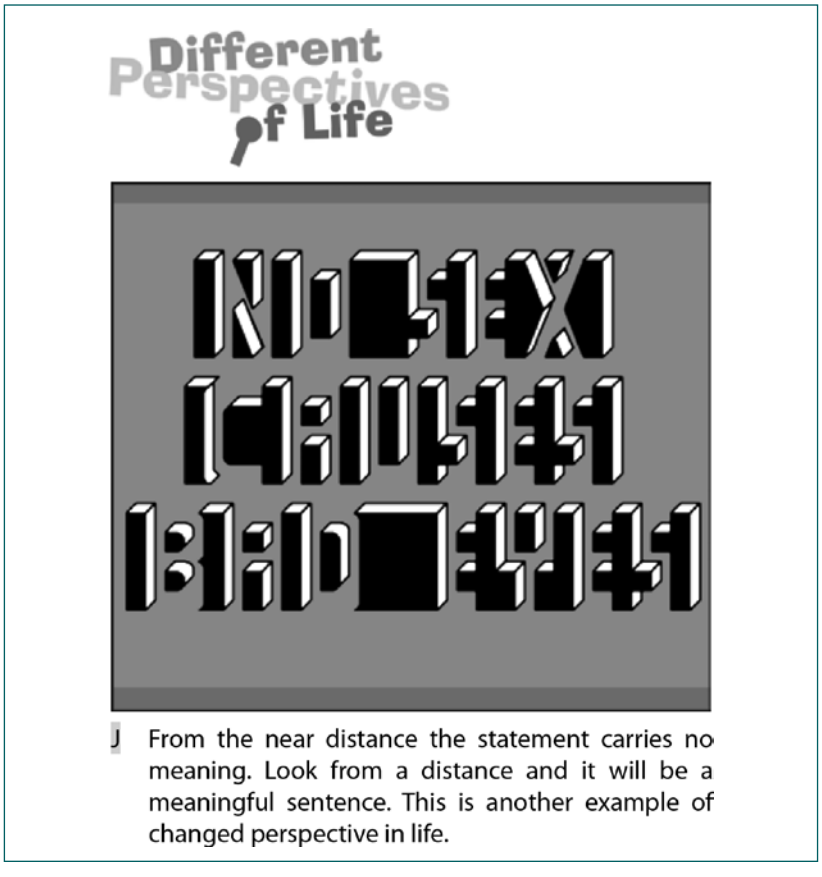

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- Raise awareness about the fundamental right of individuals to medical treatment irrespective of their religion or economical background.
- Sensitize the central and state government about the need for a National Cardiovascular Disease Control Program.
- Encourage and involve key stakeholders such as other NGOs, private institutions and individual to help reduce the number of deaths due to heart disease in the country.
- To promote heart care research in India.
- To promote and train hands-only CPR.

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Financial assistance is given to eligible non emergent heart patients. Apart from its own resources, the fund raises money through donations, aid from individuals, organizations, professional bodies, associations and other philanthropic organizations, etc.

After the sanction of grant, the fund members facilitate the patient in getting his/her heart intervention done at state of art heart hospitals in Delhi NCR like Medanta – The Medicity, National Heart Institute, All India Institute of Medical Sciences (AIIMS), RML Hospital, GB Pant Hospital, Jaipur Golden Hospital, etc. The money is transferred directly to the concerned hospital where surgery is to be done.

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The HCFI Fund has tied up with Helpline Pharmacy in Delhi to facilitate patients with medicines at highly discounted rates (up to 50%) post surgery.

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Important Notes

- The patient must be a citizen of India with valid Voter ID Card/ Aadhaar Card/Driving License.
- The patient must be needy and underprivileged, to be assessed by Fund Committee.
- The HCFI Fund reserves the right to accept/reject any application for financial assistance without assigning any reasons thereof.
- The review of applications may take 4-6 weeks.
- All applications are judged on merit by a Medical Advisory Board who meet every Tuesday and decide on the acceptance/rejection of applications.
- The HCFI Fund is not responsible for failure of treatment/death of patient during or after the treatment has been rendered to the patient at designated hospitals.
- The HCFI Fund reserves the right to advise/direct the beneficiary to the designated hospital for the treatment.
- The financial assistance granted will be given directly to the treating hospital/medical center.
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- The HCFI Fund does not provide assistance for any emergent heart interventions.

Check List of Documents to be Submitted with Application Form

- Passport size photo of the patient and the family
- A copy of medical records
- Identity proof with proof of residence
- Income proof (preferably given by SDM)
- BPL Card (If Card holder)
- Details of financial assistance taken/applied from other sources (Prime Minister's Relief Fund, National Illness Assistance Fund Ministry of Health Govt of India, Rotary Relief Fund, Delhi Arogya Kosh, Delhi Arogya Nidhi), etc., if anyone.

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- Providing Financial Support for Heart Care Interventions
- Reversal of Sudden Cardiac Death Through CPR-10 Training Workshops
- Research in Heart Care

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- HCFI also provides Free ambulance services for adopted heart patients
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Dosulepin: Role in the Management of Depression, Anxiety and Chronic Pain

SAJJAN SINGH

ABSTRACT

Depression has high global prevalence and is associated with anxiety and chronic pain. Impairment of neurotransmitters such as serotonin and noradrenaline may lead to the triad (depression, anxiety and pain). Tricyclic antidepressants (TCAs) inhibit the reuptake of these neurotransmitters and are ideal for the treatment of the triad on account of high efficacy and low cost. Dosulepin or dothiepin hydrochloride, a TCA, is structurally a thio-analogue of amitriptyline and is considered better than other TCAs. Many clinical studies have reported dosulepin as an antidepressant, anxiolytic and analgesic. However, limited data are available to support the clinical use of dosulepin for the treatment of the triad. Even the available guidelines present debatable recommendations on the clinical use of dosulepin. Thus, the present review emphasizes on the role of dosulepin in the management of the triad along with description of guideline recommendations about dosulepin.

Keywords: Analgesic, antidepressant, chronic pain, dosulepin

Depression has a high prevalence worldwide with considerably increased rates of morbidity and mortality. About 340 million people suffer from depression at any given time at a global level.[1] In India, the prevalence of depression is 9%, whereas the prevalence of major depressive episode is 36%.[2] Depression is observed more frequently in urban females between 40 and 49 years of age, as compared to males. However, elevated rates (3.5%) of depression are also reported among the elderly.[3] Approximately 85% of patients with depression also experience symptoms of anxiety, whereas 70% of patients with depression and anxiety also experience the ill effects of chronic pain, as depression is an indicator of persevering pain. Disabled functioning, brought about by pain, may prompt social seclusion, which may ultimately lead to a negative impact on depression. The psychological and physical distress of persistent pain may also cause an episode of major depression.[4-6] Tricyclic antidepressants (TCAs), on account of their high efficacy and low cost, are preferred for the treatment of pain and depression. The American Pain Society and American College of Physicians guidelines also support the use of TCAs in relieving low back pain.[7] TCAs have demonstrated good clinical response in neuropathic pain, headaches, low back pain, fibromyalgia and irritable bowel syndrome (IBS).[8] A systematic review by Mikocka-Walus et al also concluded that TCAs decreased pain, gut irritability and urgency of defecation successfully.[9]

Dosulepin (International Nonproprietary Name; INN and British Approved Name; BAN) also known as dothiepin hydrochloride (United States Adopted Names; USAN), is one of the first-generation TCAs which exhibits antidepressant and anxiolytic action. It is one of the most commonly used drugs for chronic pain too.[10-13] The present review article emphasizes on the role of dosulepin in the triad of depression, anxiety and chronic pain along with description of the guideline recommendations about dosulepin.

INTERRELATIONSHIP BETWEEN DEPRESSION, ANXIETY AND CHRONIC PAIN

The pathophysiological pathways for depression and anxiety disorders are similar to those causing pain. Various brain areas such as periaqueductal gray, amygdala and hypothalamus play a major role in depression, anxiety and pain. Stress increases the release of corticotropin-releasing hormone (CRH) which prompts overproduction of adrenocorticotropic hormone (ACTH) and glucocorticoids (GC). Prolonged

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release of GC brings about more considerable hippocampal harm by causing neuron death, gliosis and atrophied perikaryal and decreases the release of neurotransmitters.[14] Moreover, increase in the level of stress may also lead to the production of pro-inflammatory cytokines. Stimulation of the hypothalamic-pituitary-adrenocortical axis and activation of monoamine reuptakes also take place by pro-inflammatory cytokines, which may ultimately impair the central monoaminergic neurotransmitters such as serotonin and norepinephrine. This further plays a key role in disturbing pain modulation systems as well as promote depression and anxiety.[15,16]

Many studies have also supported the co-occurrence of this triad (depression, anxiety and pain) as pain is notified by many patients who are suffering from depression and/or anxiety. A retrospective study evaluating the prevalence of depression, anxiety disorders and pain among 7,83,829 newly admitted nursing home residents (65 years of age or older) reported that 36% of residents had depression and/or, anxiety disorder, whereas, 53% of residents were reported having pain in last 5 days.[17] Similarly, a longitudinal cohort study conducted on 614 participants to examine the impact of pain symptomatology on depression and anxiety onset and to determine the associations between subthreshold depressive and anxiety symptoms reported an association of depression and anxiety with six pain locations (neck, back, head, orofacial area, abdomen and joints; hazard ratio [HR] = 1.96-4.02; $p < 0.05$), increasing number of pain locations (HR = 1.29; $p < 0.001$) and higher severity of pain (HR = 1.57; $p < 0.001$).[18] These studies indicate that chronic pain and depression may have contrary effect on treatment response, which may increase the probability of suicidal behavior.[19,20]

DOSULEPIN: HISTORY

Dosulepin, a thio-analogue of amitriptyline, was synthesized by Rajsner and Provita in 1962 in the Research Institute for Pharmacy and Biochemistry, Prague. It was first used as an antidepressant in Czechoslovakia in 1964.[21] Dosulepin was compared with amitriptyline for efficacy and safety in 1974 and was found to have lesser side effects as compared to amitriptyline.[22] It was introduced in India in 1987.[23] Early clinical work on dosulepin suggested that the drug has antidepressant, anxiolytic and analgesic properties.[16,24] Pharmacokinetic properties of dosulepin are presented in Table 1.

Table 1. Pharmacokinetic Properties of Dosulepin

Molecular formula	$C_{19}H_{21}NS$
IUPAC* name	(3Z)-3-(6H-benzo[c][1]benzothiepin-11-ylidene)-N,N-dimethylpropan-1-amine
Molecular weight	295.45 g/mol
Bioavailability	30%
Volume of distribution	45
Plasma protein binding	85%
Plasma half-life	22 hours
Clearance	1.4/kg/hour
Route of elimination	Dosulepin and its metabolites are excreted mainly in the urine (56%) and feces (15%)

*IUPAC = International Union of Pure and Applied Chemistry.

DOSULEPIN: MECHANISM OF ACTION, PHARMACOKINETICS AND SAFETY

Mechanism of Action

The mechanism of action followed by dosulepin for the management of the triad of pain, depression and anxiety is presented in Figure 1. Dosulepin treats depression and anxiety by increasing transmitter levels at central synapses as it inhibits the reuptake of noradrenaline and serotonin in addition to other transmitters. It also inhibits α-adrenergic, H_1-histaminergic and *N*-methyl-D-aspartate (NMDA) receptors which are involved in pain. It also inhibits calcium and sodium channels and has weak stimulatory effect on μ-opioid receptors.[7] It also affects monoamine levels and produces adaptive changes in the brain by balancing both, noradrenaline receptor numbers and noradrenaline-induced cyclic-AMP formation.[25]

Pharmacokinetics

It is absorbed from the gastrointestinal tract (GIT) within 2-4 hours and is extensively metabolized in the liver. Its metabolites are northiaden, dosulepin-S-oxide and northiaden-S-oxide which are excreted in the urine as well as in the feces. A half-life of about 14-24 hours (dosulepin) and 23-46 hours (metabolites) has been reported.[26] Other pharmacokinetic properties of dosulepin are presented in Table 1.

Safety

Dosulepin has a very less margin of safety between the maximum therapeutic dose and toxic dose.[27] The onset of action is similar as other TCAs, while it may have less intolerable side effects as compared to amitriptyline and

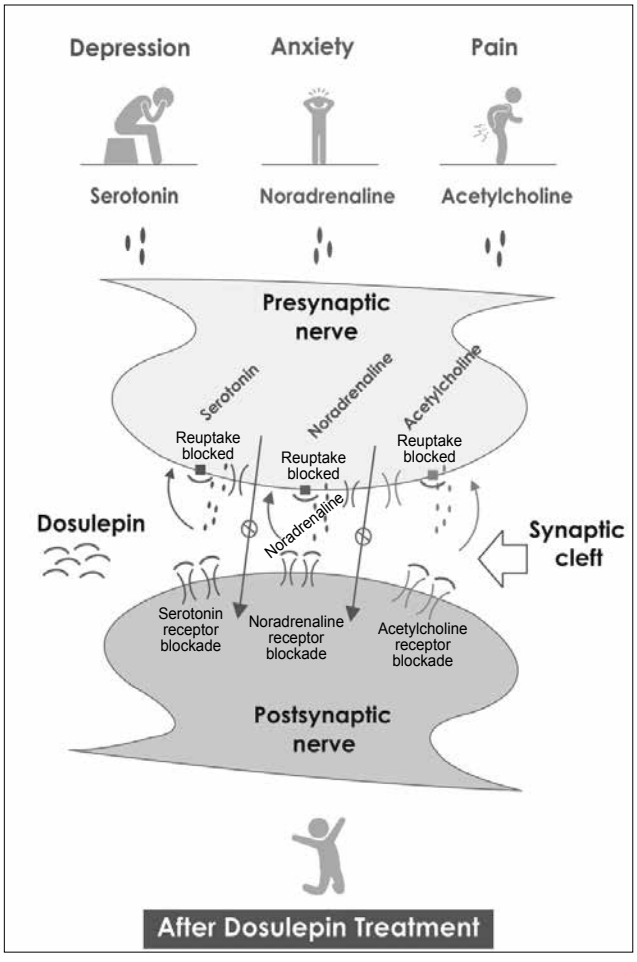

Figure 1. Mechanism of action of dosulepin.

imipramine.[28] In a 6-week double-blind parallel treatment study of 33 depressed outpatients, dosulepin had lesser anticholinergic, central nervous system and cardiovascular adverse effects as compared to amitriptyline.[29] It also produces less cardiotoxicity than other TCAs.[27] It is very well-tolerated in the geriatric population also.[28]

DOSULEPIN: ROLE IN DEPRESSION

Dosulepin is widely used in the treatment of major depressive illness.[17] In a double-blind study, 30 depressed patients were given once-a-day dosage of dosulepin against a thrice-daily dosage regimen randomly. Both treatments were equally effective in relieving the symptoms of depression.[30] In another single-blind, randomized, parallel-group 6-week study which included 60 adult patients, dosulepin (50-150 mg) was comparable to imipramine (50-150 mg) in terms of efficacy as assessed by Hamilton Rating Scale for depression (HAM-D), global scale for severity of illness and clinician's overall assessment of efficacy.[31] Rubino et al also conducted a retrospective study to compare the suicidal tendency of patients taking venlafaxine with dosulepin and other antidepressant drugs. Dosulepin was associated with lower risk of suicide as compared to venlafaxine. The unadjusted and adjusted hazard ratios for venlafaxine compared with dosulepin were 2.54 (1.07-6.02) and 1.31 (0.53-3.25).[32] Similarly, Mahapatra and Hackett compared the safety and antidepressant efficacy of venlafaxine and dosulepin (150 mg/day) in 92 geriatric patients (aged 64-87 years). Adjusted mean scores on the Montgomery-Asberg Depression Scale (MADRS) and HAM-D decreased significantly ($p = 0.05$) from baseline to the end of the study in both groups.[33] Moreover, in a randomized, double-blind, parallel-group study, 101 patients suffering from major depressive disorder (MDD) had received either clomipramine (25-150 mg daily) or dosulepin (75-150 mg daily) for up to 6 weeks. The findings revealed similar mean scores on the HAM-D scale (23.5 for clomipramine, 23.6 for dosulepin). Withdrawal from treatment (20 patients for clomipramine, 9 for dosulepin) was significantly different ($p = 0.0105$) and there were fewer adverse events with dosulepin treatment.[7] In a single-blind randomized, parallel group study on 5 patients, both dosulepin and amitriptyline had shown a significant decrease in the mean aggregate Hamilton score ($p < 0.01$).[34] Overall, clinical studies conducted on dosulepin affirmed its use as an efficient, safe as well as well-tolerated medication for the treatment of depression. Moreover, low incidence of side effects has been observed with the use of dosulepin.[30]

DOSULEPIN: ROLE IN ANXIETY

In an open, single-arm, prospective study, 25 rheumatoid arthritis patients with comorbid MDD were given 75 mg/day dosulepin for 6 weeks. A significant reduction ($p < 0.05$) in mean Hamilton Anxiety Rating Scale (HAM-A) scores was observed at 2 weeks (6.52 ± 3.34), 4 weeks (4.0 ± 2.25) and at 6 weeks (5.72 ± 3.26) as compared to baseline (21.64 ± 5.93).[35] In a prospective, multicenter, randomized, double-blind study, 100 patients with mixed symptoms of anxiety and depression were given alprazolam (2.33 mg) and dosulepin (115 mg) for over 4 weeks. Patients demonstrated significant ($p < 0.001$) improvement with the given therapy.[36] Similarly, in a double-blind 3-week trial of chlordiazepoxide and dosulepin on 88 patients with anxiety, tension and emotional disturbance, there was significant improvement with dosulepin as compared to chlordiazepoxide based on difference between final and initial scores ($p < 0.05$,

Mann-Whitney *U*-test).[37] Two double-blind studies conducted on 23 and 55 patients with depression and anxiety, respectively, compared dosulepin with amitriptyline and reported dosulepin to be more effective and tolerable as compared to amitriptyline.[38,39] According to the clinical studies conducted on dosulepin for its anti-anxiety property, dosulepin was observed to be an effective and well-tolerated medication for treatment of the patients experiencing anxiety.

DOSULEPIN: ROLE IN PAIN

The efficacy of dosulepin for pain was assessed in a 9-week randomized placebo-controlled double-blind study conducted on 93 patients for the treatment of psychogenic facial pain. About 71% of patients were pain free in the dosulepin group at 9 weeks as compared with 47% in the placebo group.[40] Similarly, significant reduction in the tender points index ($p < 0.01$) and subjective pain severity scores ($p < 0.01$) was observed with dosulepin (75 mg/day single dose) compared with placebo in the treatment of primary fibromyalgia syndrome.[41] In another 4-year review of a double-blind trial of dosulepin on 71 patients with idiopathic facial pain, 43% of them were shown to be pain free.[42] Arnold et al had included 9 randomized controlled trials with TCAs including amitriptyline and dosulepin in a meta-analysis and review, which had shown a good clinical response in approximately 30% of patients with fibromyalgia demonstrating improvement in all outcomes viz. fatigue, sleep, pain, stiffness and tenderness.[43] Similarly, in a 6-week randomized double-blind study, 60 clinically depressed patients with chronic back pain were given TCAs at an initial dose of 50 mg and final dose of 300 mg. Significant decline in frequency of pain ($p = 0.05$), impact of pain on activity ($p = 0.04$) and impact of pain on sleep ($p = 0.02$) were observed after 4 weeks.[44] Studies therefore, indicate the therapeutic efficacy of dosulepin as a treatment option for chronic pain, independent of its action in depression and anxiety.

DOSULEPIN: ROLE IN TRIAD OF DEPRESSION, ANXIETY AND CHRONIC PAIN

TCAs work as double duty medications due to their analgesic as well as antidepressant properties.[45] Dosulepin 150 mg daily was given to 48 female outpatients with rheumatoid arthritis, depression and/or anxiety in a double-blind, placebo-controlled study. Results showed a reduction in pain level (F [d.f. 1,39] = 5.7, $p = 0.02$), hospital anxiety and depression (HAD) depression ($r = 0.63$, $p < 0.0005$), HAD anxiety ($r = 0.46$, $p = 0.001$) and HAM-D ($r = 0.37$, $p = 0.01$).[46] In another similar study, dosulepin (75 mg) was given for 4 weeks to alleviate pain in 60 either 'depressed' or 'not depressed' patients with classical or definite active rheumatoid arthritis. It was found that dosulepin produced a significant reduction in pain ($p < 0.01$ at Week 5) with improved Hamilton Rating Scale for Depression (HRSD) and the Cassano-Castrogiovanni self-evaluation rating scale.[47] Further studies need to be conducted on dosulepin so as to determine its efficacy in treatment of the triad of depression, anxiety and chronic pain.

GUIDELINE RECOMMENDATIONS

According to guidelines for the management of common mental disorders, Ministry of Health and Family Welfare, Government of India, the diagnostic criteria for depressive episode are:

- Person having depressed mood for almost the whole day for at least 2 weeks
- Children (>12 years) and adolescents having irritating behavior or depression
- Loss of interest or pleasure in activities that are normally pleasurable
- Decreased energy or easily fatigued.[48]

The American Psychiatric Association (APA) released guidelines on treatment of patients with depressive disorder and recommended 25-50 mg/day starting dose and 100-300 mg/day usual dose of dosulepin.[49] According to the Indian Psychiatric Society Clinical Practice Guidelines, 75-225 mg/day dose of dosulepin is recommended for the management of depression.[50] The European Federation of Neurological Societies (EFNS), Canadian Pain Society (CPS) and Neuropathic Pain Special Interest Group of IASP (NeuPSIG) have recommended TCAs as the first-line therapy for the management of chronic neuropathic pain.[51-53] As per the recent clinical guidelines by the National Institute for Health and Clinical Excellence in conjunction with the National Collaborating Centre for Mental Health, only specialists or general physicians with a special interest in psychiatry should prescribe dosulepin.[54]

CONCLUSION

Impairment of neurotransmitters, such as serotonin and noradrenaline, may cause depression, anxiety and pain. TCAs inhibit the reuptake of these neurotransmitters and play a vital role in the management of pain, depression and anxiety. Dosulepin, a TCA, modulates the release of neurotransmitters with lesser adverse

effects and higher efficacy, as compared to other TCAs. However, the data available in support of the clinical use of dosulepin for the treatment of the triad of chronic pain, anxiety and depression are limited. Furthermore, the available guidelines present disparate recommendations on the use of dosulepin. More clinical studies and clear guideline recommendations are warranted in future to demonstrate the efficacy of dosulepin in the clinical management of the triad.

KEY MESSAGES

Tricyclic antidepressant such as dosulepin or dothiepin hydrochloride is preferred for the treatment of pain, anxiety and depression owing to its high efficacy, safety, low cost and lower incidence of sedative, cardiac and anticholinergic adverse effects.

Acknowledgments

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REFERENCES

1. Chiriţă AL, Gheorman V, Bondari D, Rogoveanu I. Current understanding of the neurobiology of major depressive disorder. Rom J Morphol Embryol. 2015;56 (2 Suppl):651-8.
2. Bohra N, Srivastava S, Bhatia MS. Depression in women in Indian context. Indian J Psychiatry. 2015;57(Suppl 2): S239-45.
3. National Mental Health Survey of India, 2015-16 supported by Ministry of Health and Family Welfare Government of India Implemented by National Institute of Mental Health and Neuro Sciences Bengaluru in collaboration with partner institutions. Available at: http://indianmhs.nimhans.ac.in/Documents/reports/Summary.pdf. Accessed on 03/05/2017.
4. Möller HJ, Bandelow B, Volz HP, Barnikol UB, Seifritz E, Kasper S. The relevance of 'mixed anxiety and depression' as a diagnostic category in clinical practice. Eur Arch Psychiatry Clin Neurosci. 2016;266(8):725-36.
5. de Heer EW, Gerrits MM, Beekman AT, Dekker J, van Marwijk HW, de Waal MW, et al. The association of depression and anxiety with pain: a study from NESDA. PLoS One. 2014;9(10):e106907.
6. Welch CP, Tweed JA, Smithers A, Gostick NK, Raniwalla J. A double-blind, comparative study of dothiepin and clomipramine in the treatment of major depressive illness. Int J Clin Pract. 1997;51(6):360-3.
7. Sindrup SH, Otto M, Finnerup NB, Jensen TS. Antidepressants in the treatment of neuropathic pain. Basic Clin Pharmacol Toxicol. 2005;96(6):399-409.
8. Chou R, Huffman LH; American Pain Society; American College of Physicians. Medications for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. Ann Intern Med. 2007; 147(7):505-14.
9. Mikocka-Walus AA, Clarke D, Gibson P. Can antidepressants influence the course of inflammatory bowel disease? The current state of research. Eur Gastroenterol Hepatol Rev. 2009;5:48-53.
10. Dosulepin Hydrochloride. Martindale: The Complete Drug Reference. London, UK: Pharmaceutical Press. 5 December 2011.
11. Verdu B, Decosterd I, Buclin T, Stiefel F, Berney A. Antidepressants for the treatment of chronic pain. Drugs. 2008;68(18):2611-32.
12. Ryder SA, Stannard CF. Treatment of chronic pain: antidepressant, antiepileptic and antiarrhythmic drugs. Cont Educ Anesth Crit Care Pain. 2005;5(1):18-21.
13. Wing YK. Recent advances in the management of depression and psychopharmacology. Hong Kong Med J. 2000;6(1):85-92.
14. Gerrits MM, van Marwijk HW, van Oppen P, van der Horst H, Penninx BW. Longitudinal association between pain, and depression and anxiety over four years. J Psychosom Res. 2015;78(1):64-70.
15. Bair MJ, Robinson RL, Katon W, Kroenke K. Depression and pain comorbidity: a literature review. Arch Intern Med. 2003;163(20):2433-45.
16. Nekovarova T, Yamamotova A, Vales K, Stuchlik A, Fricova J, Rokyta R. Common mechanisms of pain and depression: are antidepressants also analgesics? Front Behav Neurosci. 2014;8:99.
17. Ulbricht CM, Hunnicutt JN, Lapane KL. Triad of suffering: pain, depression, and anxiety among newly admitted nursing homes residents. Am J Geriatr Psychiatry. 2016;24(3):S124.
18. Gerrits MM, van Oppen P, van Marwijk HW, Penninx BW, van der Horst HE. Pain and the onset of depressive and anxiety disorders. Pain. 2014;155(1):53-9.
19. Cocksedge K, Shankar R, Simon C. Depression and pain: the need for a new screening tool. Prog Neurol Psychiatry. 2016;20:26-32.
20. Verrocchio MC, Carrozzino D, Marchetti D, Andreasson K, Fulcheri M, Bech P. Mental pain and suicide: a systematic review of the literature. Front Psychiatry. 2016;7:108.
21. Rajsner M, Protiva M. Synthetic ataractics. VII. 11-(3-Dimethylaminopropylidene)-6, 11-dihydrodibenzo (b,e) thiepin. Cesk Farm. 1962;11:404-9.
22. Lambourn J, Rees JA. A general practitioner study of dothiepin and amitriptyline. J Int Med Res. 1974;2:210.
23. Ramakrishnan K, Kulkarni VN, Paul AD, Bakshi JS. Clinical experience with dothiepin in an Indian population. J Drug Dev. 1991;4(3):151-9.
24. Rydzynski, Z. Investigation of antidepressant activity of prothiaden. Neurologia Neurochirurgia i Psychiatiia Polska. 1966;16:1159-62.

25. Lancaster SG, Gonzalez JP. Dothiepin. A review of its pharmacodynamic and pharmacokinetic properties, and therapeutic efficacy in depressive illness. Drugs. 1989;38(1):123-47.
26. Wilson SE, Chen M, Darji H. Rapid-acting antidepressants and underlying mechanisms. Int J Public Health Science (IJPHS). 2016;5:347-53.
27. Zusky P, Manschreck TC, Blanchard C, Rosenbaum J, Elliot C, Lou P. Dothiepin hydrochloride: treatment efficacy and safety. J Clin Psychiatry. 1986;47(10):504-7.
28. Khan AU. A comparison of the therapeutic and cardiovascular effects of a single nightly dose of Prothiaden (dothiepin, dosulepin) and Lentizol (sustained-release amitriptyline) in depressed elderly patients. J Int Med Res. 1981;9(2):108-12.
29. Feinmann C, Harris M, Cawley R. Psychogenic facial pain: presentation and treatment. Br Med J (Clin Res Ed). 1984;288(6415):436-8.
30. Sharma SD. A comparison of a divided and a single dose regime of dothiepin and its therapeutic efficacy. Indian J Psychiatry. 1981;23(4):355-9.
31. Vyas JN, Sharma P, Singhal AK, Agarwal S. A comparative study of dothiepin (prothiaden) and imipramine in depression. Indian J Psychiatry. 1989;31(2):151-6.
32. Rubino A, Roskell N, Tennis P, Mines D, Weich S, Andrews E. Risk of suicide during treatment with venlafaxine, citalopram, fluoxetine, and dothiepin: retrospective cohort study. BMJ. 2007;334(7587):242.
33. Mahapatra SN, Hackett D. A randomised, double-blind, parallel-group comparison of venlafaxine and dothiepin in geriatric patients with major depression. Int J Clin Pract. 1997;51(4):209-13.
34. Joshi VS, Gangdev P, Sousa De Alan. A comparative study of dothiepin and amitriptyline in major depression. J Comm Psychiatry. 1988;11:27-32.
35. Dhavale HS, Gawande S, Bhagat V, Durge V, Londhe V, Kini S, et al. Evaluation of efficacy and tolerability of dothiepin hydrochloride in the management of major depression in patients suffering from rheumatoid arthritis. J Indian Med Assoc. 2005;103(5):291-4.
36. Cropper M, Garner A, McEwan GD, Munt DF, Rushbrook LA, Stevens V, et al. A double-blind comparative study of alprazolam and dothiepin hydrochloride in the treatment of anxiety associated with depression. Pharmatherapeutica. 1987;5(2):76-82.
37. Johnson F, Sacco FA, Yellowley TW. Chlordiazepoxide and dothiepin compared in anxiety-depression in general practice. Practitioner. 1973;211(263):362-4.
38. Sharma SD. A double-blind comparison of dothiepin and amitriptyline in the treatment of depression with anxiety. J Assoc Physicians India. 1981;29(9):725-9.
39. Lipsedge MS, Rees WL. A double-blind comparison of dothiepin and amitriptyline for the treatment of depression with anxiety. Psychopharmacologia. 1971;19(2):153-62.
40. Stratas NE. A double-blind study of the efficacy and safety of dothiepin hydrochloride in the treatment of major depressive disorder. J Clin Psychiatry. 1984;45(11):466-9.
41. Caruso I, Sarzi Puttini PC, Boccassini L, Santandrea S, Locati M, Volpato R, et al. Double-blind study of dothiepin versus placebo in the treatment of primary fibromyalgia syndrome. J Int Med Res. 1987;15(3):154-9.
42. Feinmann C. The long-term outcome of facial pain treatment. J Psychosom Res. 1993;37(4):381-7.
43. Arnold LM, Keck PE Jr, Welge JA. Antidepressant treatment of fibromyalgia. A meta-analysis and review. Psychosomatics. 2000;41(2):104-13.
44. Hameroff SR, Weiss JL, Lerman JC, Cork RC, Watts KS, Crago BR, et al. Doxepin's effects on chronic pain and depression: a controlled study. J Clin Psychiatry. 1984;45(3 Pt 2):47-53.
45. The pain anxiety connection depression. Available at: http://www.health.harvard.edu/healthbeat/the-pain-anxiety-depression-connection. Accessed on 28/4/2017.
46. Ash G, Dickens CM, Creed FH, Jayson MI, Tomenson B. The effects of dothiepin on subjects with rheumatoid arthritis and depression. Rheumatology (Oxford). 1999;38(10):959-67.
47. Sarzi Puttini P, Cazzola M, Boccassini L, Ciniselli G, Santandrea S, Caruso I, et al. A comparison of dothiepin versus placebo in the treatment of pain in rheumatoid arthritis and the association of pain with depression. J Int Med Res. 1988;16(5):331-7.
48. Guidelines for the management of common mental disorders, Ministry of Health & Family Welfare Government of India. Available at: http://clinicalestablishments.nic.in/WriteReadData/606.pdf. Accessed on 28/4/2017.
49. Armstrong C. APA releases guidelines on treatment of patients with major depressive disorder. Am Fam Physician. 2011;83(10):1219-27.
50. Gautam S, Jain A, Gautam M, Vahia VN, Grover S. Clinical practice guidelines for the management of depression. Indian J Psychiatry. 2017;59(Suppl 1):S34-S50.
51. Attal N, Cruccu G, Baron R, Haanpää M, Hansson P, Jensen TS, et al; European Federation of Neurological Societies. EFNS guidelines on the pharmacological treatment of neuropathic pain: 2010 revision. Eur J Neurol. 2010;17(9):1113-e88.
52. Moulin DE, Clark AJ, Gilron I, Ware MA, Watson CP, Sessle BJ, et al; Canadian Pain Society. Pharmacological management of chronic neuropathic pain - consensus statement and guidelines from the Canadian Pain Society. Pain Res Manag. 2007;12(1):13-21.
53. Dworkin RH, O'Connor AB, Audette J, Baron R, Gourlay GK, Haanpää ML, et al. Recommendations for the pharmacological management of neuropathic pain: an overview and literature update. Mayo Clin Proc. 2010;85(3 Suppl):S3-14.
54. Dosulepin: measures to reduce risk of fatal overdose. Drug Safety Update. 2007;1(5):7.

Commissioning Mother Entitled for Maternity Leave in Case of Surrogacy

KK AGGARWAL*, IRA GUPTA

The Department of Personnel and Training of Ministry of Personnel, Public Grievances and Pensions, Government of India has vide office memorandum bearing No. 13018/6/2013 - Estt.(L) vide dated 29 January, 2018 has instructed all Ministries/ Departments to give wide publicity and to implement the directions given by the Hon'ble High Court of Delhi in the order dated 17th July, 2015 in the Writ Petition No.844/2014 titled as Ms. Rama Pandey, Teacher, Kendriya Vidyalaya V/s UoI & Others.

In the year 2015, one women namely Mrs. Rama Pandey, one Kendriya Vidyalaya teacher had approached the Hon'ble High Court of Delhi as her application dated 06.06.2013 for grant of maternity and Child Care Leave (CCL) was rejected. By this application, the petitioner sought 180 days maternity leave and 3 months CCL. Along with the said application the petitioner had deposited the requisite documents like surrogacy agreement and birth certificate of the child.

However, vide communication dated 10.10.2013, petitioner's request was rejected by Respondent No. 3, based on, inputs received from Respondent No. 2 vide two communications dated 04.09.2013 and 19.09.2013. It was conveyed to the petitioner that there was no provision for grant of maternity leave in cases where the surrogacy route is adopted.

The petitioner was, however, informed that the CCL could be sanctioned, in her favour, under Rule 43-A, which was applicable to "female government servants". In the background of the aforesaid stand, the petitioner was requested to submit an application for CCL, in case she was desirous of availing leave on that account.

The petitioner being aggrieved, approached this court by way of the instant petition, filed, under Article 226 of the Constitution. After hearing the submissions of all the parties, the Hon'ble High Court of Delhi held that:

"24. In view of the discussion above, the conclusion that I have reached is as follows:-

(i). A female employee, who is the commissioning mother, would be entitled to apply for maternity leave under Sub-rule (1) of Rule 43.

(ii). The competent authority based on material placed before it would decide on the timing and the period for which maternity leave ought to be granted to a commissioning mother who adopts the surrogacy route.

(iii). The scrutiny would be keener and detailed, when leave is sought by a female employee, who is the commissioning mother, at the pre-natal stage. In case maternity leave is declined at the pre-natal stage, the competent authority would pass a reasoned order having regard to the material, if any, placed before it, by the female employee, who seeks to avail maternity leave. In a situation where both the commissioning mother and the surrogate mother are employees, who are otherwise eligible for leave (one on the ground that she is a commissioning mother and the other on the ground that she is the pregnant women), a suitable adjustment would be made by the competent authority.

(iv). In so far as grant of leave qua post-natal period is concerned, the competent authority would ordinarily grant such leave except where there are substantial reasons for declining a request made in that behalf. In this case as well, the competent authority will pass a reasoned order."

Source: (i) Department of Personnel & Training order dated 29.01.2018 for maternity leave of commissioning mother in case of surrogacy. (ii) Judgment dated 17th July, 2015 passed by the Hon'ble High Court of Delhi in the Writ Petition No. 844/2014 titled as Ms. Rama Pandey, Teacher, Kendriya Vidyalaya V/s UoI & Others.

*Group Editor-in-Chief, IJCP Group

No.13018/6/2013 -Estt.(L)
Government of India
Ministry of Personnel, Public Grievances and Pensions
Department of Personnel & Training
***

JNU Old Campus, New Delhi
Dated 29 January, 2018

OFFICE MEMORANDUM

Subject: Writ Petition No.844/2014 in the High Court of Delhi filed by Ms. Rama Pandey, Teacher, Kendriya Vidyalaya V/s UoI & Others – reg.

The undersigned is directed to enclose herewith Hon'ble High Court of Delhi's Order dated 17th July, 2015 in the Writ Petition No.844/2014 in the High Court of Delhi filed by Ms. Rama Pandey, Teacher, Kendriya Vidyalaya V/s UoI & Others.

2. All Ministries/Departments are advised to give wide publicity of its contents to the concerned officers.

3. This issues with the approval of Secretary (P).

(Sandeep Saxena)
Under Secretary to the Govt. of India
011-26164316

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IJCP SUTRA 123: In patients with T2DM and CAD glycemic variability is not associated with coronary collateral artery formation. *Coron Artery Dis.* 2017 Jun 21.

IN THE HIGH COURT OF DELHI AT NEW DELHI

Judgement reserved on: 12.12.2014

Judgement delivered on: 17.07.2015

WP(C) No. 844/2014

Rama Pandey ..... **Petitioner**

Versus

Union of India & Ors. ..... **Respondents**

Advocates who appeared in this case:

For the Petitioner: Mr Sunil Kumar and Mr Rahul Sharma, Advocates

For the Respondents: Mr Jasmeet Singh, CGSC with Ms Kritika Mehra, Adv. for R-1.
Mr S. Rajappa & Dr. Puran Chand, Advs. for R- 2 & 3.

CORAM

Hon'ble Mr. Justice Rajiv Shakdher

Rajiv Shakdher, J

FACTS

1. A synthesis of science and divinity (at least for those who believe in it), led to the culmination of the petitioner's desire for a child. Married, on 18.01.1998, to one Sh. Atul Pandey, the petitioner's, wish to have a child was fulfilled on 09.02.2013, albeit via the surrogacy route. Her bundle of joy comprised of twins, who were born on the aforementioned date, at a city hospital.

1.1 To effectuate the aforesaid purpose, the petitioner had entered into an arrangement with, one, Ms Aarti, wife of Mr Surya Narayan (hereafter referred to as the surrogate mother). The arrangement required the surrogate mother to bear a child by employing the *in-vitro* fertilization (IVF) methodology. The methodology used and agreed upon required the genetic father to fertilize, *in-vitro*, the ovum supplied by a designated donor. The resultant embryo was then required to be transferred and implanted in the surrogate mother. This arrangement, along with other terms and conditions, which included rights and obligations of the commissioning parents, as also those of the surrogate mother, were reduced to a written agreement dated 08.08.2012 (in short the surrogacy agreement).

2. The fact that the surrogacy agreement reached fruition, is exemplified by the birth of twins, as indicated above, on 09.02.2013. This far, the petitioner was happy; her unhappiness, however, commenced with rejection of her application dated 06.06.2013, for grant of maternity and Child Care Leave (CCL). By this application, the petitioner sought 180 days maternity leave and 3 months CCL. This application was addressed to Respondent No. 3, with a copy to Respondent No. 2.

2.1 Respondent No. 3 vide a covering letter of even date, i.e., 06.06.2013, forwarded the petitioner's application to Respondent No. 2, along with the requisite documents i.e., the surrogacy agreement and the birth certificate of the children. Respondent No. 3, sought clarification with regard to the request made by the petitioner for sanctioning the maternity leave. A perusal of the covering letter would show that the leave sought for the purposes of child care was not being objected to. A doubt, was raised only qua maternity leave.

2.2 Evidently, vide communication dated 10.10.2013, petitioner's request was rejected by Respondent No. 3, based on, inputs received from Respondent No. 2 vide two communications dated 04.09.2013 and 19.09.2013. The first communication appears to have been sent by Kendriya Vidyalaya Sangathan (KVS), [Headquarters], while the second was, evidently, sent by KVS (D.R.). These communications, though, are not on record.

2.3 In sum, it was conveyed to the petitioner that there was no provision for grant of maternity leave in cases where the surrogacy route is adopted. The petitioner was, however, informed that the CCL could be sanctioned, in her favour, under Rule 43-A, which was

applicable to "female government servants". It now transpires that reference ought to have been made to Rule 43 and not Rule 43-A; a fact which was confirmed by the counsel for Respondent No. 2 and 3.

2.4 In the background of the aforesaid stand, the petitioner was requested to submit an application for CCL, in case she was desirous of availing leave on that account.

3. The petitioner being aggrieved, approached this court by way of the instant petition, filed, under Article 226 of the Constitution. Notice on this limited aspect was issued in the writ petition on 05.02.2014. Though counsels for parties were asked to file written submissions; except for Respondent No. 2 none of the other parties filed written submissions in the matter. Counsels for respondents have not filed any counter affidavit in the matter. The reason for that, perhaps would be, that the facts in the matter are not in dispute. The issue raised in the writ petition is, a pure question of law.

4. I may only note that on 10.02.2015, respondents placed before this court an office memorandum dated 09.02.2015, issued by the Ministry of Personnel, Public Grievances, Pensions, Department of Personnel and Training (DoPT), Govt. of India which, in turn, relied upon the office memorandum dated 09.01.2015, issued by the Ministry of Human Resources and Development.

4.1 The stand taken, based on the said office memorandums, was that, there was no provision for grant of maternity leave to female employees, who took recourse to the surrogacy route for procreating a child. Furthermore, it was indicated that for grant of "adoption leave", a valid adoption had to be in place.

4.2 Having said so, the DoPT recommended grant of maternity/adoption leave to the petitioner keeping in mind the welfare of the child and, on consideration of the fact that the child was in her custody. The recommendation made was, that, not only should the petitioner be allowed 180 days of leave as was permissible in situations dealing with maternity leave/adoption leave but that she, should also be allowed, CCL, in case, an application was made for the said purpose. It was further indicated that the said two sets of leave would not be adjusted from the petitioner's leave account. The said recommendation was, however, made without prejudice to the policy, rules and/or instructions that the government may frame in that behalf in due course.

4.3 In the light of the aforesaid development, the counsel for both parties indicated that since the answer to the issue of law remains unarticulated (though the grievance of the petitioner may have been redressed), this court ought to deliberate upon the same and pronounce its judgement in the matter.

4.4 It is based on the stand taken by the counsels for the parties, I proceed to decide the issues raised, in the matter.

SUBMISSIONS OF COUNSELS

5. The counsel for the petitioner has equated the position of a commissioning mother to that of a biological mother who bears and carries the child till delivery. It is the submission of the learned counsel for the petitioner, that more often than not, as in this case, the commissioning parents have a huge emotional interest in the well-being of both the surrogate mother and the child, which the surrogate mother carries, albeit under a contractual arrangement. The well-being of the child and the surrogate mother can best be addressed by the commissioning parents, in particular, the commissioning mother. This object, according to the learned counsel, can only be effectuated, if maternity leave is granted to the commissioning mother.

5.1 The fact that a commissioning mother has been judicially recognised as one who is similarly circumstanced, as an adoptive mother, was sought to be established by placing reliance on the judgement of the Madras High Court in the case of: ***K. Kalaiselvi vs. Chennai Port Trust***, dated 04.03.2013, passed in WP(C) No. 8188/2012.

6. Counsels for the respondents, on the other hand, while being sympathetic to the cause of the petitioner, expressed their disagreement with the submission that maternity leave could be extended to the petitioner or female employees who are similarly circumstanced.

6.1 Mr Rajappa, who appeared for Respondent No. 2 and 3, in particular, made submissions, which can be, broadly, paraphrased as follows:

(i) There is no provision under the extant rules for granting maternity leave to women who become mothers via the surrogacy route. Therefore, in law, no entitlement to maternity leave, in these circumstances, inhered in the petitioner.

(ii) The prime objective for grant of maternity leave is to protect the health and to provide safety to pregnant women in workplace, both during pregnancy and after delivery. Lactating mothers, who need to breast-feed their children, fall within a "specific risk group", and hence, are given maternity leave, based on factors which are relatable to safety and health parameters.

(iii) A woman, who gives birth to a child, undergoes mental and physical fatigue and stress and, is often, subjected to confinement both during and after pregnancy. These circumstances do not impact the commissioning mother, who takes recourse to the surrogacy route. Therefore, there is no justification for according maternity leave in such like cases.

(iv) If leave is granted to the commissioning mother, it could set a precedent for grant of leave in future to a single male or female parent or to same sex parents as well, who may take recourse to the surrogacy route.

(iv)(a). Therefore, the legislature would be the best forum for the enactment of necessary rules/ regulations to deal with such like situations, including the situation which arose in the present case.

(v) In the K. Kalaiselvi's case, the Madras High Court was interpreting Rule 3-A of the Madras Port Trust (Leave) Regulations, 1987, pertaining to leave, made available, to female employees on adoption of a child. The court, in that case, equated the circumstances which arise in the case of the adoptive mother with those which emerge in the case of a female employee, who takes recourse to a surrogacy route. Accordingly, Rule 3-A of the aforementioned regulations was interpreted to include a female employee who ventured to have a child via a surrogate arrangement. Such parity, in principle, was erroneous for the following reasons: Firstly, in the absence of a valid adoption, the relevant Rule, in the instant case, does not get triggered. Secondly, such an interpretation would involve re-writing of the Rules by reading adoptive parent as the Commissioning Parent.

REASONS

7. I have heard the learned counsels for the parties. According to me, what needs to be borne in mind, is this : there are two stages to pregnancy, the pre-natal and post-natal stage. Biologically pregnancy takes place upon union of an ovum with spermatozoon. This union results in development of an embryo or a foetus in the body of the female. A typical pregnancy has a duration of 266 days from conception to delivery. The pregnancy brings about physiological changes in the female body which, inter alia, includes, nausea (morning sickness), enlargement of the abdomen, etc.[1]

7.1 Pregnancy brings about restriction in the movement of the female carrying the child as it progresses through the term. In case complications arise, during the term, movement of the pregnant female may get restricted even prior to the pregnancy reaching full-term. It is for these reasons, that maternity leave of 180 days is accorded to pregnant female employees.

7.2 Those amongst pregnant female employees, who are constitutionally strong and do not face medical complications, more often than not, avail of a substantial part of their maternity leave in the period commencing after delivery. Rules and regulations framed in this regard by most organizations, including those applicable to Respondent No. 3, do not provide for bifurcation of maternity leave, that is, division of leave between pre-natal and post-natal stages.

7.3 The reason, perhaps, why substantial part of the leave is availed of by the female employees (depending on their well-being), post delivery, is that, the challenging part, of bringing a new life into the world, begins thereafter, that is, in the post-natal period. There are other factors as well, which play a part in a pregnant women postponing a substantial part of her maternity leave till after delivery, such as, family circumstances (including the fact she is part of a nuclear family) or, the health of the child or, even the fact that she already has had successful deliveries; albeit without sufficient time lag between them.

8. Thus, it is evident that except for the physiological changes and difficulties, all other challenges of child rearing are common to all female employees, irrespective of the manner, she chooses, to bring a child into this world.

9. But the law, as it stands today, and therefore, the rules and regulations as framed by most organisations do not envisage attainment of parenthood via the surrogacy route.

9.1 It is not unknown, and there are several such examples that legislatures, usually, in most situations, act ex-post facto. Advancement in science and change in societal attitudes, often raise issues, which require courts to infuse fresh insight into existing law. This legal technique, if you like, is often alluded to as the "updating principle". Simply put, the court by using this principle, updates the construction of a statute bearing in mind, inter alia, the current norms, changes in social attitudes or, even advancement in science and technology. The principle of updating resembles another principle which the courts have referred to as the "dynamic processing of an enactment". The former is described in Bennion on Statutory Interpretation at page 890 in the following manner:-

> *"..An updating construction of an enactment may be defined as a construction which takes account of relevant*

changes which have occurred since the enactment was originally framed but does not alter the meaning of its wording in ways which do not fall within the principles originally envisaged by that wording.

Updating construction resembles so-called dynamic interpretation, but insists that the updating is structured rather than at large. This structuring is directed to ascertaining the legal meaning of the enactment at the time with respect to which it falls to be applied. The structuring is framed by reference to specific factors developed by the courts which are related to changes which have occurred (1) in the mischief to which the enactment is directed, (2) in the surrounding law, (3) in social conditions, (4) in technology and medical science, or (5) in the meaning of words..."

9.2 The updating principle on account of development of medical science and technique was applied in the following case: ***R vs. Ireland, [1998] AC 147.***

9.3 Similarly, change in social conditions have persuaded courts to apply the updating construction principle to inject contemporary meaning to the words and expressions used in the existing statute. See: ***Williams and Glyn's Bank Vs. Boland, [1981] AC 487 at page 511 placetum 'D' and R Vs. D, [1984] AC 778.***

9.4 In respect of dynamic processing, the following observations in Bennnion on Statutory Interpretation, 5th Edition, at page 502, being apposite, are extracted hereinafter:-

"..Few Acts remain for very long in pristine condition. They are quickly subjected to a host of processes. Learned commentators dissect them. Officials in administering them develop their meaning in practical terms. Courts pronounce on them. Donaldson J described the role of the courts thus:

'The duty of the Courts is to ascertain and give effect to the will of Parliament as expressed in its enactments. In the performance of this duty the Judges do not act as computers into which are fed the statutes and the rules for the construction of statutes and from whom issue forth the mathematically correct answer. The interpretation of statutes is a craft as much as a science and the judges as craftsmen, select and apply the appropriate rules as the tools of their trade. They are not legislators, but finishers, refiners and polishers of legislation which comes to them in a state requiring varying degrees of further processing.

When practitioners come to advise upon the legal meaning, they need to take account of all this. The Act is no longer as Parliament enacted it; it has been processed.."

(Emphasis is mine)

9.5 The fact that this is a legitimate interpretative tool, available to courts, is quite evident upon perusal of the ratio of the following judgements.

9.6 A classic example of application of the updating of construction principle, is the judgement, in the case of ***Fitzpatrick vs. Sterling Housing Association Ltd, 1999 (4) All E.R. 705,*** where the word 'family' was read to include two persons of same sex who were cohabitating and living together for a long period of time with a mutual degree of inter-dependence.

9.7 This is an interesting case where the court while applying the afore-stated principle interpreted the meaning of the word, 'family', by having regard to the prevalent social habits and attitudes. In this case, the plaintiff, who was the appellant before the House of Lords, had approached the court for protection from eviction on the ground that he had lived in a stable relationship with the original tenant of the same sex, who had since then died. The defendant/respondent (i.e. landlord) declined to recognise him as a tenant as he was neither the wife nor the husband of the original tenant. The courts below had accepted the plea of the respondent/defendant (i.e. the landlord). The House of Lords while allowing the appeal by a majority of 3:2 made the following apposite observations. The discussion thus veered around whether the appellant/ plaintiff was the spouse of the original tenant.

"...It is not an answer to the problem to assume (as I accept may be correct) that if in 1920 people had been asked whether one person was a member of another same-sex person's family the answer would have been "No". That is not the right question. The first question is what were the characteristics of a family in the 1920 Act and the second whether two same-sex partners can satisfy those characteristics so as today to fall within the period "family". An alternative question is whether the word "family" in the 1920 Act has to be updated so as to be capable of including persons who today would be regarded as being of each other's family, whatever might have been said in 1920. See: R v Ireland [1998] AC 147, 158, per Lord Steyn; Bennion, Statutory Interpretation, 3rd ed (1997), p 686 and Halsbury's Laws of England, 4th ed reissue, vol 44 (1) 1995), p 904, para 1473...

..It seems to be suggested that the result which I have so far indicated would be cataclysmic. In relation to this Act it is plainly not so. The onus on one person claiming that he or she was a member of the same-sex original tenant's family will involve that person establishing rather than merely asserting the necessary indicia of the relationship. A transient superficial relationship will not do even if

it is intimate. Mere cohabitation by friends as a matter of convenience will not do. There is, in any event, a minimum residence qualification; the succession is limited to that of the original tenant. Far from being cataclysmic it is, as both the judge in the country court and the Court of Appeal appear to recognise, and as I consider, in accordance with contemporary notions of social justice. In other statutes, in other contexts, the same meaning may or not be the right one. If a narrower meaning is required, so be it. It seems also to be suggested that such a result in this statute undermines the traditional (whether religious or social) concepts of marriage and the family. It does nothing of the sort. It merely recognises that, for the purposes of this Act, two people of the same sex can be regarded as having established membership of a family, one of the most significant of human relationships which both gives benefits and imposes obligations..."

[Also see: ***Ghaidan v. Mendoza, 2002 (4) All E.R. 1162; Goodwin vs U.K., (2002) 2 FCR 577; Bellinger vs. Bellinger, (2002) 1 All E.R. 311 (dissenting judgement of Thorpe LJ at page 335)*** and ***A. vs West Yorkshire Police, 2004 (3) All E.R. 145].***

9.8 A constitution bench of our Supreme Court in the case of ***State (through CBI) Vs. S.J. Choudhary, (1996) 2 SCC 428*** applied the updating construction principle when it was faced with an issue whether the opinion of a typewriter expert would be admissible in evidence in view of the language employed in Section 45 of the Indian Evidence Act, 1872 (in short the Indian Evidence Act). The objection taken by the accused in a criminal proceeding, which was sustained right up to the High Court was based upon observations in an earlier judgement of the Supreme Court in ***Hanumant Vs. State of Madhya Pradesh, 1952 SCR 1091*** that the opinion of a typewriting expert was not admissible. The Constitution Bench of the Supreme Court ruled otherwise and while doing so, adverted to the updating construction principle by reading into the word, 'science' which appeared alongside the expression, 'handwriting' to include a person who was an expert in typewriters. The following observations of the Supreme Court being apposite are extracted hereinafter:-

"..10. Statutory Interpretation by Francis Bennion, Second edition, Section 288 with the heading "Presumption that updating construction to be given" states one of the rules thus:

It is presumed that Parliament intends the court to apply to an ongoing Act a construction that continuously updates its wording to allow for changes since the Act was initially framed (an updating construction). While it remains law, it is to be treated as always speaking. This means that in its application on any date, the language of the Act, though necessarily embedded in its own time, is nevertheless to be construed in accordance with the need to treat it as current law."

In the comments that follow it is pointed out that an ongoing Act is taken to be always speaking. It is also, further, stated thus:

"In construing an ongoing Act, the interpreter is to presume that Parliament intended the Act to be applied at any future time in such a way as to give effect to the true original intention. Accordingly the interpreter is to make allowances for any relevant changes that have occurred, since the Act's passing, in law, social conditions, technology, the meaning of words, and other matters. Just as the US Constitution is regarded as 'a living Constitution', so an ongoing British Act is regarded as 'a living Act'. That today's construction involves the supposition that Parliament was catering long ago for a state of affairs that did not then exist is no argument against that construction. Parliament, in the wording of an enactment, is expected to anticipate temporal developments. The drafter will try to foresee the future, and allow for it in the wording.

An enactment of former days is thus to be read today, in the light of dynamic processing received over the years, with such modification of the current meaning of its language as will now give effect to the original legislative intention. The reality and effect of dynamic processing provides the gradual adjustment. It is constituted by judicial interpretation, year in and year out. It also comprises processing by executive officials."

11. *There cannot be any doubt that the Indian Evidence Act, 1872 is, by its very nature, an 'ongoing Act.'*

12. *It appears that it was only in 1874 that the first practical typewriter made its appearance and was marketed in that year by the E. Remington and Sons Company which later became the Remington typewriter - Obviously, in the Indian Evidence Act enacted in 1872 typewriting could not be specifically mentioned as a means of writing in Section 45 of the Evidence Act. Ever since then, technology has made great strides and so also the technology of manufacture of typewriters resulting in common use of typewriters as a prevalent mode of writing. This has given rise to development of the branch of science relating to examination of questioned typewriting...."*

(Emphasis is mine)

9.9 Similarly, the Supreme Court in two other cases recognised the progress of science and technology by

bringing in line, the scope and meaning of the words and expressions used in existing statutes, with current norms and usage. The first case is the judgement delivered in ***Senior Electric Inspector vs. Laxminarayan Chopra, (1962) 3 SCR 146,*** where it held, that the expression 'telegraph line' in the Indian Telegraph Act, 1885 would include a wireless telegraph having regard to the change in technology.

10. The second case is the judgement in ***M/s. Laxmi Video Theatres and Ors. Vs. State of Haryana and Ors., (1993) 3 SCC 715.*** In this case, the definition of the word 'cinematograph' as contained in Section 2(c) of the Cinematograph Act, 1952 was held to cover video cassette recorders and players for representation of motion pictures on television screen.

10.1 Also See ***State of Maharashtra Vs. Dr. Praful B. Desai, (2003) 4 SCC 601.***

11. With the advent of New Reproductive Technologies (NRT) or what are also known as Assisted Reproductive Technologies (ART), (after the birth of the first test-tube baby Louise Joy Brown, in 1978), there has been a veritable explosion of possibilities for achieving and bringing to term a pregnancy. It appears that in future one would have three kinds of mothers:

(i) a genetic mother, who donates or sells her eggs;

(ii) a surrogate or natal mother, who carries the baby; and

(iii) a social mother, who raises the child.[2]

11.1 India's first test-tube baby Kanupriya alias Durga, brought to fore the use of similar technology in India. The reproduction of children by NRTs or ARTs, raises several moral, legal and ethical issues. One such legal issue arises in the instant case.

11.2 Though the science proceeded in this direction in the late 1970, the practice of having children via surrogacy is, a more recent phenomena. The relevant leave rules were first framed in 1972; to which amendments have been made from time to time. While notions have changed vis-a-vis parenthood (which is why provisions have been incorporated for paternity leave; an aspect which I will shortly advert to), there appears to be an inertia in recognising that motherhood can be attained even via surrogacy.

11.3 Rule 43 implicitly recognises that there are two principal reasons why maternity leave is accorded. First, that with pregnancy, biological changes occur. Second, post childbirth "multiple burdens" follow. (See: ***C-366/99 Griesmar, [2001] ECR 1-9383***)

11.4 Therefore, if one were to recognise even the latter reason the commissioning mother, to my mind, ought to be entitled to maternity leave.

11.5 It is clearly foreseeable that a commissioning mother needs to bond with the child and at times take over the role of a breast-feeding mother, immediately after the delivery of the child.

11.6 In sum, the commissioning mother would become the principal caregiver upon the birth of child; notwithstanding the fact that child in a given situation is bottle-fed.

11.7 It follows thus, to my mind, that the commissioning mother's entitlement to maternity leave cannot be denied only on the ground that she did not bear the child. This is dehors the fact that a commissioning mother may require to be at the bed side of the surrogate mother, in a given situation, even at the pre-natal stage; an aspect I have elaborated upon in the latter part of my judgement.

11.8 The circumstances obtaining in the present case, however, indicate that the genetic father made use of a donor egg, which then, was implanted in the surrogate mother.

11.9 The surrogate mother in this case had no genetic connection with the children she gave birth to. The surrogate mother however, carried the pregnancy to term.

12. Undoubtedly, the fact that the surrogate mother carried the pregnancy to full-term, involved physiological changes to her body, which were not experienced by the commissioning mother but, from this, could one possibly conclude that her emotional involvement was any less if, not more, than the surrogate mother?

12.1 Therefore, while the submission advanced by Mr Rajappa that maternity leave is given to a female employee who is pregnant, to deal with biological changes, which come about with pregnancy, and to ensure the health and safety, both of the mother and the child, while it is in her womb, is correct; it is, I am afraid, an uni-dimensional argument, offered to explain the meaning of the term "maternity", as found incorporated in the extant rules.

12.2 The rules as framed do not restrict the grant of leave to only those female employees, who are themselves pregnant as would be evident from the discussion and reasons set forth hereafter. For this purpose, in the first instance, I intend to examine the scope and effect of the Rules to the extent relevant for the purposes of issues raised in the writ petition.

12.3 The word 'maternity' has not been defined in the Central Civil Services (Leave) Rules, 1972 (in short the Leave Rules), which respondents say are applicable to the petitioner.

12.4 Rule 43, which makes provision for maternity, for the sake of convenience, is extracted hereinbelow:

> *"...43. Maternity Leave:*
>
> *(1) A female Government servant (including an apprentice) with less than two surviving children may be granted maternity leave by an authority competent to grant leave for a period of (180 days) from the date of its commencement.*
>
> *(2) During such period, she shall be paid leave salary equal to the pay drawn immediately before proceeding on leave.*
>
> ***Note:-** In the case of a person to whom Employees' State Insurance Act, 1948 (34 of 1948), applies, the amount of leave salary payable under this rule shall be reduced by the amount of benefit payable under the said Act for the corresponding period.*
>
> *(3) Maternity leave not exceeding 45 days may also be granted to a female Government servant (irrespective of the number of surviving children) during the entire service of that female Government in case of miscarriage including abortion on production of medical certificate as laid down in Rule 19: `Provided that the maternity leave granted and availed of before the commencement of the CCS (Leave) Amendment Rules, 1995, shall not be taken into account for the purpose of this sub-rule'.*
>
> *(4) (a) Maternity leave may be combined with leave of any other kind. (b) Notwithstanding the requirement of production of medical certificate contained in sub-rule (1) of Rule 30 or sub-rule (1) of Rule 31, leave of the kind due and admissible (including commuted leave for a period not exceeding 60 days and leave not due) up to a maximum of one year may, if applied for, be granted in continuation of maternity leave granted under sub-rule (1).*
>
> *(5) Maternity leave shall not be debited against the leave account..."*

12.5 A perusal of Rule 43 would show that a female employee including an apprentice with less than two surviving children, can avail of maternity leave for 180 days from the date of its commencement. Sub-rule (3) of Rule 43 is indicative of the fact that where the female employee has suffered a miscarriage, including abortion, she can avail of maternity leave not exceeding 45 days. Importantly, clause (a) of sub-rule (4) of Rule 43, states that maternity leave can be combined with leave of any other kind. Furthermore, under clause (b) of sub-rule (4) such a female employee is entitled to leave of the kind referred to in Rule 31(1) notwithstanding the requirement to produce a medical certificate, subject to a maximum of two years, if applied for, in continuation of maternity leave granted to her. Sub-rule (5) of Rule 43 states that, maternity leave shall not be debited against leave account.

13. There are three other Rules to which I would like to refer to. These are Rules 43-A, 43-AA and 43-B.

13.1 Rule 43-A[3] deals with paternity leave available to a male employee for the defined period, where "***his wife***" is confined on account of child birth. The said Rule allows a male employee, including an apprentice, with less than two surviving children, to avail of 15 days leave during the confinement of his wife for child birth, that is, up to 15 days "***before***" or "***up to 6 months***" from the date of delivery of the child.

13.2 Sub-rule (4) of Rule 43-A makes it clear that if paternity leave is not availed of within the period specified above, such leave shall be treated as lapsed.

13.3 Like in the case of a female employee, paternity leave can be combined with leave of any other kind, and the said leave is not debited against the male employee's leave account. This position emanates upon reading of sub-rule (3) and sub-rule (4) of Rule 43-A above.

13.4 Rule 43-AA[4] deals with paternity leave made available, to a male employee, for the defined period, albeit from the date of "***valid adoption***".

13.5 The aforementioned rule is pari materia with Rule 43-A, in all other aspects; the only difference being that the paternity leave of 15 days available to the male employee should be availed of within 6 months from the date of a valid adoption.

13.6 Under the Leave Rules, a female employee is also entitled to leave if she were to adopt a child as against taking recourse to the surrogacy route. In other words, there is a provision in the Leave Rules for **Child Adoption Leave.** The relevant provision in this behalf is made in Rule 43-B[5].

13.7 Rule 43-B, which enables the female employee with fewer than two surviving children, to avail of child adoption leave for a period of 180 days affixes, inter alia, a condition that there should be in place a "***valid adoption***" of a child below the age of one year. The period of 180 days commences immediately after the date of valid adoption. [See sub-rule (1) of Rule 43-B]

13.8 Clause (a) of sub-rule (3) of Rule 43-B enables a female employee to combine child adoption leave with leave of any other kind. Clause (b) of sub-rule (3) of Rule 43-B, entitles a female employee in continuation of child adoption leave granted under sub-rule (1), on valid adoption of a child to apply for leave of the kind due and admissible (including leave not due and commuted leave not exceeding 60 days without production of medical certificates) for a period up to one year, albeit reduced by the age of adopted child on the date of "valid adoption". In other words, this sub-rule allows a female employee to apply for any other leave which is due and admissible in addition to child adoption leave. There is, however, a proviso added to the said sub-rule which prevents a female employee to avail of such leave if she already has two surviving children at the time of adoption.

13.9 As in the other rules, child adoption leave is not to be debited against the leave account.

14. Thus, a reading of Rule 43 would show that while it is indicated in sub-rule (1) as to when the period of leave is to commence, that is, from the date of maternity; the expression 'maternity' by itself has not been defined. As a matter of fact, sub-rule (3) of Rule 43 shows that if the pregnancy is not carried to full term on account of miscarriage, which may include abortion, a female employee is entitled to leave not exceeding 45 days.

15. There are two ways of looking at Rule 43. One, that the word, 'maternity' should be given the same meaning, which one may argue inheres in it, on a reading of sub-rule (3) of Rule 43; which is the notion of child bearing. The other, that the word "***maternity***", as appearing in sub-rule (1) of Rule 43, with advancement of science and technology, should be given a meaning, which includes within it, the concept of motherhood attained via the surrogacy route. The latter appears to be more logical if, the language of Rule 43-A, which deals with paternity leave, is contrasted with sub-rule (1) of Rule 43. Rule 43-A makes it clear that a male employee would get 15 days of leave "***during the confinement of his wife for child birth***", either 15 days prior to the event, or thereafter, i.e. after child birth, subject to the said leave being availed of within 6 months of the delivery of the child.

15.1 There is no express stipulation in sub-rule (1) of Rule 43 to the effect that the female employee (applying for leave) should also be one who is carrying the child. The said aspect while being implicit in sub-rule (1) of Rule 43, does not exclude attainment of motherhood via surrogacy. The attributes such as "***confinement***" of the female employee during child birth or the conditionality of division of leave into periods before and after child birth do not find mention in Rule 43(1).

15.2 Having regard to the aforesaid position emanating upon reading of the Rules, one is required to examine the tenability of the objections raised by the respondents.

16. The argument of the respondents, in sum, boils down to this: that the word 'maternity' can be attributed to only those female employees, who conceive and carry the child during pregnancy. In my view, the argument is partially correct, for the reason that the word 'maternity' pertains to the 'character, condition, relation or state of a mother'.[6] In my opinion, where a surrogacy arrangement is in place, the commissioning mother continues to remain the legal mother of the child, both during and after the pregnancy. To cite an example: suppose on account of a disagreement between the surrogate mother and the commissioning parents, the surrogate mother takes a unilateral decision to terminate the pregnancy, albeit within the period permissible in law for termination of pregnancy – quite clearly, to my mind, the commissioning parents would have a legal right to restrain the surrogate mother from taking any such action which may be detrimental to the interest of the child. The legal basis for the court to entertain such a plea would, in my view, be, amongst others, the fact that the commissioning mother is the legal mother of the child. The basis for reaching such a conclusion is that, surrogacy, is recognized as a lawful agreement in the eyes of law in this country. [See Baby ***Manji Yamada v. Union of India, (2008) 13 SCC 518***]. In some jurisdictions though, a formal parental order is required after child birth.

16.1 Therefore, according to me, maternity is established vis-a-vis the commissioning mother, once the child is conceived, albeit in a womb, other than that of the commissioning mother.

16.2 It is to be appreciated that Maternity, in law and/or on facts can be established in any one of the three situations: First, where a female employee herself conceives and carries the child. Second, where a female employee engages the services of another female to conceive a child with or without the genetic material being supplied by her and/or her male partner. Third, where female employee adopts a child.

16.3 In so far as the third circumstance is concerned, a specific rule is available for availing leave, which as indicated above, is provided for in Rule 43-B. In so far as the first situation is concerned, it is covered under

sub-rule (1) of Rule 43. However, as regards the second situation, it would necessarily have to be read into sub-rule (1) of Rule 43.

16.4 To confine sub-rule (1) of Rule 43 to only to that situation, where the female employee herself carries a child, would be turning a blind eye to the advancement that science has made in the meanwhile. On the other hand, if a truncated meaning is given to the word 'maternity', it would result in depriving a large number of women of their right to avail of a vital service benefit, only on account of the choice that they would have exercised in respect of child birth.

17. The argument of the respondents that the underlying rationale, for according maternity leave (which is to secure the health and safety of pregnant female employee), would be rendered nugatory—to my mind, loses sight of the following:

(i) First, that entitlement to leave is an aspect different from the right to avail leave.

(ii) Second, the argument centres, substantially, around, the interest of the carrier, and in a sense, gives, in relative terms, lesser weight to the best interest of the child.

17.1 In a surrogacy arrangement, the concern of the commissioning parents, in particular, the commissioning mother is to a large extent, focused on the child carried by the gestational mother. There may be myriad situations in which the interest of the child, while still in the womb of the gestational mother, may require to be safeguarded by the commissioning mother. To cite an example, a situation may arise where a commissioning mother may need to attend to the surrogate/gestational mother during the term of pregnancy; because the latter may be bereft of the necessary wherewithal. The lack of wherewithal could be of : financial nature (the arrangement in place may not suffice for whatever reasons), physical condition or emotional support or even a combination of one or more factors stated above. In such like circumstances, the commissioning mother can function effectively, as a caregiver, only if, she is in a position to exercise the right to take maternity leave. To my mind, to curtail the commissioning mother's entitlement to leave, on the ground that she has not conceived the child, would work, both to her detriment, as well as, that of the child.

18. The likelihood of such right, if accorded to the commissioning mother, being misused can always be curtailed by the competent leave sanctioning authority.

18.1 At the time of sanctioning leave the competent authority can always seek information with regard to circumstances which obtain in a given case, where application for grant of maternity leave is made. The competent authority's scrutiny, to my mind, would be keener and perhaps more detailed, where leave is sought by the commissioning mother at the pre-natal stage, as against post-natal stage. If conditions do not commend that leave be given at the pre-natal stage, then the same can be declined.

18.2 In so far as post-natal stage is concerned, ordinarily, leave cannot be declined as, under most surrogacy arrangements, once the child is born, its custody is immediately handed over to the commissioning parents. The commissioning mother, post the birth of the child, would, in all probability, have to play a very crucial role in rearing the child.

18.3 However, these are aspects which are relatable to the time and the period for which maternity leave ought to be granted. The entitlement to leave cannot be denied, to my mind, on this ground.

19. In this context, I may only refer to a judgement of the Labour Court of South Africa, in Durban in ***MIA v. State Information Technology Agency (Pty) Ltd., (D312/2012) [2015] ZALCD20*** (dated: 26 March 2015). The applicant before the court, who was a male employee, challenged the refusal by his employer to grant him maternity leave on the ground that he was not the biological mother of the child under the surrogacy agreement.

19.1 The principal ground of challenge was that such refusal constituted unfair discrimination on the grounds of gender, sex, family responsibility and sexual orientation, as provided in Section 61 of the Employment Equity Act (Act 55 of 1998).

19.2 The provision pertaining to maternity leave, as adverted to in the judgement, was contained in Section 25 of the Basic Conditions of Employment Act (Act 75 of 1997). The relevant part, as extracted in the judgement, is set out hereineblow:

> *"..(1). An employee is entitled to at least four consecutive months maternity leave.*
>
> *(2). An employee may commence maternity leave –*
>
> *a. at any time from four weeks before the expected date of birth, unless otherwise agreed; or b. x x x x"*

19.3 The common case between the parties was that the respondent-employer's policy was similar to the provisions of the Basic Conditions of the Employment Act. The respondent-employer policy provided "paid maternity leave of a maximum of four months", and

that, the said leave was to be taken "***four weeks prior to the expected date of birth or at an earlier date***".

19.4 In defence, the argument of the respondent-employer was that, its policy was not discriminatory, and therefore, it was argued that the word 'maternity' defined the character of the leave viz. that it was a right which was to be enjoyed only by female employees. In the pleadings, the respondent-employer averred that its maternity leave policy was specifically designed to cater to the following:

> *"...to cater for employees who give birth .... based on an understanding that pregnancy and childbirth create an undeniable physiological effect that prevents biological mothers from working during portions of the pregnancy and during the post-partum period.*
>
> *Thus at least 10 weeks of maternity leave benefits have been introduced to protect birth mothers from an earning interaction due to the physical incapacity to work immediately before and after childbirth.."*

19.5 The ruling of the Court sheds some light, in my view, on the issue at hand. The observations made in the judgement being relevant, are extracted hereinbelow.

> *"...[13] This approach ignores the fact that the right to maternity leave as created in the Basic Conditions of Employment Act in the current circumstances is an entitlement not linked solely to the welfare and health of the child's mother but must of necessity be interpreted to and take into account the best interests of the child. Not to do so would be to ignore the Bill of Rights in the Constitution of the Republic of South Africa and the Children's Act. Section 28 of the Constitution provides:*
>
> *28 Children:*
>
> *(1) every child has a right-*
>
> *a.…*
>
> *b. To family care or parental care …*
>
> *[14] The Children's Act specifically records not only that the act is an extension of the rights contained in Section 28 but specifically provides:*
>
> ***Best interests of child [is] paramount***
>
> *In all matters concerning the care, protection and well-being of a child the standard that the child's best interest is of paramount importance must be applied.*
>
> *[15] Surrogacy agreements are regulated by the Children's Act.*
>
> *[16] The surrogacy agreement specifically provides that the newly born child is immediately handed to the commissioning parents. During his evidence the applicant explained that for various reasons that he and his spouse had decided that he, the applicant, would perform the role usually performed by the birth mother by taking immediate responsibility for the child and accordingly he would apply for maternity leave. The applicant explained that the child was taken straight from the surrogate and given to him and that the surrogate did not even have sight of the child. Only one commissioning parent was permitted to be present at the birth and he had accepted this role.*
>
> *[17] Given these circumstances there is no reason why an employee in the position of the applicant should not be entitled to "maternity leave" and equally no reason why such maternity leave should not be for the same duration as the maternity leave to which a natural mother is entitled…"*

(Emphasis is mine)

20. In our Constitution, under Article 39(f), which falls in part IV, under the heading Directive Principles of the States policy, the state is obliged to, inter alia, ensure that the children are given opportunities and facilities to develop in a healthy manner. Similarly, under Article 45, State has an obligation to provide early childhood care.

20.1 Non-provision of leave to a commissioning mother, who is a employee, would, to my mind, be in derogation of the stated Directive Principles of State Policy as contained in the Constitution.

21. In this context, regard may also be had to Article 6 of the United Nations Convention on Rights of Child (UNCRC).

21.1 Article 6 of the UNCRC provides that the States, which are party to the Convention, shall recognise that every child has the inherent right to life. A State-party is thus obliged to ensure, to the maximum extent possible, the survival and development of the child. Undoubtedly, India is a signatory to the UNCRC.

21.2 There is no municipal law, which is in conflict with the provisions of Article 6 of the UNCRC. The State, therefore, is obliged to act in a manner which ensures that it discharges its obligations under the said Article of the UNCRC. [See ***Jolly George Varghese v. Bank of Cochin, (1980) 2 SCC 360; Vishaka v. State of Rajasthan, (1997) 6 SCC 241 and National Legal Services Authority Vs. Union of India, (2014) 5 SCC 438 at para 484 to 487 / para 51 to 60***].

22. The Madras High Court in ***K. Kalaiselvi's*** case equated the position of an adoptive parent to that of a

parent who obtains a child via a surrogacy arrangement. The observations of the court, to that effect, are found in the following paragraphs of the judgement.

> *"..13. Alternatively, he contended that if law can provide child care leave in case of adoptive parents as in the case of Rule 3-A[7] of the Madras Port Trust (Leave) Regulations, 1987, then they should also apply to parents like the petitioner who obtained child through surrogate agreement since the object of such leave is to take care of the child and developing good bond between the child and the parents.*
>
> *14. However, the learned counsel for the Port Trust contended that in the absence of any specific legal provision, the question of this court granting leave will not arise.*
>
> *15. In the light of these rival contentions, it has to be seen whether the petitioner is entitled for a leave similar to that of the leave provided under Rule 3-A and whether her child's name is to be included in the FMI Card for availing future benefits?*
>
> *16. This court do not find anything immoral and unethical about the petitioner having obtained a child through surrogate arrangement. For all practical purpose, the petitioner is the mother of the girl child G.K.Sharanya and her husband is the father of the said child. When once it is admitted that the said minor child is the daughter of the petitioner and at the time of the application, she was only one day old, she is entitled for leave akin to persons who are granted leave in terms of Rule 3-A of the Leave Regulations. The purpose of the said rule is for proper bonding between the child and parents. Even in the case of adoption, the adoptive mother does not give birth to the child, but yet the necessity of bonding of the mother with the adoptive child has been recognised by the Central Government. Therefore, the petitioner is entitled for leave in terms of Rule 3-A. Any other interpretation will do violence to various international obligations referred to by the learned counsel for the petitioner. Further, it is unnecessary to rely upon the provisions of the Maternity Benefit Act for the purpose of grant of leave, since that act deals with actual child birth and it is mother centric. The Act do not deal with leave for taking care of the child beyond 6 weeks, i.e., the post-natal period. The right for child care leave has to be found elsewhere. However, this court is inclined to interpret Rule 3-A of the Madras Port Trust (Leave) Regulations, 1987 also to include a person who obtain child through surrogate arrangement..."*

22.1 The ratio of the judgement, to my mind, is that, an adoptive parent is no different from a commissioning parent, which seeks to obtain a child via a surrogacy arrangement. The Madras High Court thus interpreted Rule 3-A of the Madras Port Trust Regulation to include a female employee who seeks to obtain a child via a surrogacy arrangement.

23. In the instant case, in so far as Rule 43-B obtains, the situation is somewhat similar to that which prevailed in ***K. Kalaiselvi's*** case.

23.1 Having said so, in my opinion, the impediment perhaps in applying the ratio set forth in ***K. Kalaiselvi's*** case would be, if at all, on account of the presence of the expression, 'valid adoption', in Rule 43-B; which is also one of the objections taken by the respondents to the entitlement to leave by a commissioning mother under the said Rule.

23.2 For the sake of completeness I must refer to the judgement of the Kerala High Court on somewhat similar issue in the matter of ***P. Geetha vs. The Kerela Livestock Development Board Ltd. 2015 (1) KLJ 494.*** However, the gamut of rules that this court is called upon to examine are not, in their entirety, similar to the ones that were before the Kerala High Court. To cite an example in ***P. Geetha's*** case the rules framed by the Kerala Livestock Development Board did not provide for paternity leave.

23.3 Therefore, in my view, in such like situations, the appropriate course would be to allow commissioning mothers to apply for leave under Rule 43(1).

24. In view of the discussion above, the conclusion that I have reached is as follows:-

(i). A female employee, who is the commissioning mother, would be entitled to apply for maternity leave under sub-rule (1) of Rule 43.

(ii). The competent authority based on material placed before it would decide on the timing and the period for which maternity leave ought to be granted to a commissioning mother who adopts the surrogacy route.

(iii). The scrutiny would be keener and detailed, when leave is sought by a female employee, who is the commissioning mother, at the pre-natal stage. In case maternity leave is declined at the pre-natal stage, the competent authority would pass a reasoned order having regard to the material, if any, placed before it, by the female employee, who seeks to avail maternity leave. In a situation where both the commissioning mother and the surrogate mother are employees, who are otherwise eligible for leave (one on the ground that she is a commissioning mother and the other on the ground that she is the

pregnant women), a suitable adjustment would be made by the competent authority.

(iv). In so far as grant of leave qua post-natal period is concerned, the competent authority would ordinarily grant such leave except where there are substantial reasons for declining a request made in that behalf. In this case as well, the competent authority will pass a reasoned order.

25. The writ petition is disposed of, in the aforementioned terms.

26. Parties shall, however, bear their own costs.

July 17, 2015 **Rajiv Shakdher, J.**

kk/yg

REFERENCES

1. Dorland's Illustrated Medical Dictionary, 30th Edition, Saunders Publication.
2. See: Feminist Perspectives on Law, Chapter 4: Facilitating Motherhood, pages 121-123.
3. **43-A. Paternity leave:**

   (1) A male Government servant (including an apprentice) with less than two surviving children, may be granted Paternity Leave by an authority competent to grant leave for a period of 15 days, during the confinement of his wife for childbirth, i.e., up to 15 days before, or up to six months from the date of delivery of the child.

   (2) During such period of 15 days, he shall be paid leave salary equal to the pay drawn immediately before proceeding on leave.

   (3) The paternity leave may be combined with leave of any other kind.

   (4) The paternity leave shall not be debited against the leave account.

   (5) If Paternity Leave is not availed of within the period specified in sub-rule (1), such leave shall be treated as lapsed.

   Note:- The Paternity Leave shall not normally be refused under any circumstances.]
4. **43-AA. Paternity Leave for Child Adoption.-**

   (1) A male Government servant (including an apprentice) with less than two surviving children, on valid adoption of a child below the age of one year, may be granted Paternity Leave for a period of 15 days within a period of six months from the date of valid adoption.

   (2) During such period of 15 days, he shall be paid leave salary equal to the pay drawn immediately before proceeding on leave.

   (3) The paternity leave may be combined with leave of any other kind.

   (4) The Paternity Leave shall not be debited against the leave account.

   (5) If Paternity leave is not availed of within the period specified in sub-rule (1) such leave shall be treated as lapsed.

   [Note 1]: - The Paternity Leave shall not normally be refused under any circumstances.]

   [Note 2]: - "Child" for the purpose of this rule will include a child taken as ward by the Government servant, under the Guardians and Wards Act, 1890 or the personal law applicable to that Government servant, provided such a ward lives with the Government servant and is treated as a member of the family and provided such Government servant has, through a special will, conferred upon that ward the same status as that of a natural born child.]
5. **43-B. Leave to a female Government servant on adoption of a child:**

   (1) A female Government servant, with fewer than two surviving children, on valid adoption of a child below the age of one year may be granted child adoption leave, by an authority competent to grant leave, for a period of [180 days] immediately after the date of valid adoption.

   (2) During the period of child adoption leave, she shall be paid leave salary equal to the pay drawn immediately before proceeding on leave.

   (3) (a) Child adoption leave may be combined with leave of any other kind.

   (b) In continuation of the child adoption leave granted under sub-rule (1), a female Government servant on valid adoption of a child may also be granted, if applied for, leave of the kind due and admissible (including leave not due and commuted leave not exceeding 60 days without production of medical certificate) for a period upto one year reduced by the age of the adopted child on the date of valid adoption, without taking into account child adoption leave. Provided that this facility shall not be admissible in case she is already having two surviving children at the time of adoption.

   (4) Child adoption leave shall not be debited against the leave account.]

   [Note: - "Child" for the purpose of this rule will include a child taken as ward by the Government servant, under the Guardians and Wards Act, 1890 or the personal Law applicable to that Government servant, provided such a ward lives with the Government servant and is treated as a member of the family and provided such Government servant has, through a special will, conferred upon that ward the same status as that of a natural born child.]

   The said Rule was substituted by notification dated 31.03.2006 and was published in the gazette of India on 27.04.2006; to take effect from 31.03.2006.

   It appears that prior to the insertion of Rule 43-B, the said rule was numbered as 43-A and was inserted vide notification dated 22.10.1990, which was published in the gazette of India, on 26.01.1991. The said notification was, however, substituted by another notification dated 04.03.1992, which in turn was published in the gazette of India on 14.03.1992.
6. Black's Law Dictionary, 6th Edition at page 977.
7. Rule 3-A - Leave to female employees on adoption of a child :

   A female employee on her adoption a child may be granted leave of the kind and admissible (including commuted leave without production of medical certificate for a period not exceeding 60 days and leave not due) upto one year subject to the following conditions :

   (i) the facility will not be available to an adoptive mother already having two living children at the time of adoption;

   (ii) the maximum admissible period of leave of the kind due and admissible will be regulated as under :

   (a) If the age of the adopted child is less than one month, leave upto one year may be allowed.

   (b) If the age of the child is six months or more, leave upto six months may be allowed.

   (c) If the age of the child is nine months or more leave upto three months may be allowed.

Life-saving Machines, Devices and Equipments Like CPAP Machine are Covered Under Insurance Policy

KK AGGARWAL*, IRA GUPTA

The life-saving machines and devices such as pacemaker, continuous positive airway pressure (CPAP), biphasic positive airway pressure (BiPAP), orthopaedic implants, intracardiac valve replacements, vascular stents, relevant laboratory diagnostic tests, X-ray and such similar implants and machines are often prescribed by registered medical practitioners to their patients.

Such machines are duly covered under the insurance policy/mediclaim policy.

If any patient is advised to use CPAP machine for his/her treatment and such patient has an insurance policy/ mediclaim policy in his/her name, then the insurance company has to make the payment of the cost of CPAP machine to such patient as the same is covered by the insurance policy. Even if there is no specific clause in insurance policy/mediclaim policy stating that the CPAP machine is covered under the insurance policy, then also the insurance company has to pay the patient for the cost of CPAP machine as the same is life-saving machine and without it the treatment of the patient is not complete.

In the matter titled as "**New India Assurance Co. Ltd. versus Ganashyamadas A. Thakur,**" vide order and judgement dated 07.02.2014, **Hon'ble National Consumer Disputes Redressal Commission** had held that:

> *"The fact that Respondent/Complainant wife had taken treatment as an in-patient at M/s Bhagwan Mahaveer Jain Hospital for Severe Obstructive Sleep Apnea is not in dispute. It is further an admitted fact that on discharge she was advised CPAP usage at night as a continuing part of the treatment to regulate her breathing and ensure that there was adequate inflow of oxygen since the CPAP had to be used alongwith 1-2 litre oxygen/minute. Keeping in view this important fact, we find force in the conclusion reached by the Fora below that like the pacemaker, which is used to control abnormal heart rhythms, the CPAP device though not an implant is a CPAP to keep the airways open and thus like the pacemaker is not only an integral part of treatment but necessary for patient survival. No doubt Clause 2.4 of the policy does not mention CPAP but it is obviously not a comprehensive list because it talks of various devices like pacemaker. As stated above, since the CPAP device like the pacemaker is important for the patient treatment and survival, it may not be reasonable to exclude it. Apart from this, in the exclusion clause, on which the Petitioner/OP had relied before the Fora below, it is stated that the Insurance Company will not be liable to make any payment in respect of the equipments, such as braces, non-durable implants, eyeglasses, contact lenses, etc. These may be important but are not life-saving equipments unlike the CPAP. So far as the hospitalization of Respondent/Complainant daughter is concerned, we also agree with the conclusion reached by the Fora below and directing the Petitioner/ OP for reimbursement of the same."*

In the matter titled as **Narender Kumar Jain versus United India Insurance Company Limited, the Hon'ble State Consumer Dispute Redressal Commission of Delhi** has held that:

> *"(10) The policy documents generally cover diseases and treatments that are more common and the rest is covered by general terms like similar expenses. The question to be examined is whether case of CPAP machine should be considered under the category of similar expenses. The mere fact that clause 1(d) of the terms and conditions of the policy does not specifically mentioned CPAP machine cannot be the sole ground for rejection of the claim of the appellant. It has to be examined the view of the other items mentioned in clause 1(d), the relevant part of the clause is reproduced below:*
>
> > *1.0 in the event of any claim/s becoming admissible under this scheme, the company will pay to the insured person the amount of such expenses as would fall under different heads mentioned below, and as are reasonably and necessarily incurred*

*Group Editor-in-Chief, IJCP Group

thereof by or on behalf of such insured person, but not exceeding the sum insured in aggregate mentioned in the schedule hereto A) Room, B) Nursing Expenses. C) Surgeon,. D) Anaesthesia, Blood, Oxygen, Operation Theatre Charges, Surgical Appliances, Medicines and Drugs, Diagnostic Materials and X-ray, Dialysis, Chemotherapy, Radiotherapy, Cost of pacemaker, artificial limbs and cost of organs and similar expenses.

It is evident from the Clause 1(d) that it mentions a number of heads that are life-threatening and are essential part of treatment. It also mentions equipments like pacemakers which helps the heart function properly. It also mentions artificial limbs and organs. There is no justification to deny why purchase of pacemakers which helps in functioning of heart is accepted and that of CPAP machine which helps in breathing is denied claims. Absence of both is life-threatening though there may be difference of degree.

11) On the ground mentioned above, we are of the considered view that CPAP machine is covered in Clause 1(d) of the Policy under the expression other expenses and allow the claim of the appellant."

In a similar case titled as **"The New India Assurance Co. Ltd. & Anr. Versus Mrs. Sonali Sareen & Anr."** during the course of treatment in Sir Ganga Ram Hospital, the patient was recommended to purchase the CPAP/BiPAP machine. Since the purchase of the machine was recommended by the treating doctor complainant purchased the same for a sum of Rs. 70,000/- and thereafter lodged the claim under the cashless insurance policy. The Ld. District Forum had held that purchase of machine was the part of the treatment and without this machine the patient could not have been treated. Thus, the denial of the payment of this price of the machine tentamounts to deficiency of service on the part of the insurance company. The said order and judgement passed by Ld. District Forum had been duly accepted by the Hon'ble State Consumer Disputes Redressal Commission vide order dated 09.12.2014.

Thus, in view of the above, in numerous cases, the National Consumer Dispute Redressal Commission and State Consumer Dispute Redressal Commission of Delhi have rightly held that the CPAP machine being the life-saving machine are completely covered by the insurance policy and the claim of the patient for the same has to be paid by the insurance company.

All the doctors, registered medical practitioners, hospitals, nursing homes, etc. are advised to educate their patient that the CPAP machine being a life-saving machine is duly covered by the insurance policy/mediclaim policy obtained by them and they should immediately contact their insurance company for claiming the reimbursement of the cost of the said machine.

■■■■

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CDSCO Issues Draft Clinical Trials Rules, 2018

KK AGGARWAL

SEVENTH SCHEDULE

Formulae to Determine the Quantum of Compensation in the Cases of Clinical Trial Related Injury or Death

1. Formula in case of clinical trial related death:

Compensation = (B × F × R)/99.37

Where,

B = Base amount (i.e. 8 lacs)

F = Factor depending on the age of the trial subject as per Annexure 1 (based on Workmen Compensation Act)

R = Risk Factor depending on the seriousness and severity of the disease, presence of comorbidity and duration of disease of the trial subject at the time of enrollment in the clinical trial between a scale of 0.5 to 4 as under:

(1) 0.5: Terminally ill patient (expected survival not more than (NMT) 6 months)

(2) 1.0: Patient with high risk (expected survival between 6 to 24 months)

(3) 2.0: Patient with moderate risk

(4) 3.0: Patient with mild risk

(5) 4.0: Healthy Volunteers or trial subject of no risk.

However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lacs should be given.

2. Formula in case of clinical trial related injury (other than death):

For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the trial subject as referred to in section of this Schedule.

The quantum of compensation in case of Clinical Trial related SAE (serious adverse event) should not exceed the quantum of compensation which would have been due for payment in case of death of the trial subject since the loss of life is the maximum injury possible. As per the definition of SAE, the following sequelae other than death are possible in a clinical trial subject, in which the trial subject shall be entitled for compensation in case the SAE is related to clinical trial.

(i) A permanent disability

In case of SAE causing permanent disability to the trial subject, the quantum of compensation in case of 100% disability shall be 90% of the compensation which would have been due for payment to the nominee (s) in case of death of the trial subject.

The quantum for less than 100% disability will be proportional to the actual percentage disability the trial subject has suffered.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = (C × D × 90)/(100 × 100)

Where,

D = Percentage disability the trial subject has suffered.

C = Quantum of Compensation which would have been due for payment to the trial subject's nominees) in case of death of the trial subject.

(ii) Congenital anomaly or birth defect

The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect.

(a) Still birth;

(b) Early death due to anomaly;

(c) No death but deformity which can be fully corrected through appropriate intervention;

(d) Permanent disability (mental or physical).

The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi).

Group Editor-in-Chief, IJCP Group

The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death.

In case of birth defect leading to sub-clause (c) & (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

(iii) Chronic life-threatening disease

(iv) Reversible SAE in case it is resolved

In case of clinical trial related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalization of the trial subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day shall be calculated based upon the minimum wage of the unskilled worker (in Delhi).

Since, in case of hospitalization of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalization in such case shall be double the minimum wage.

Accordingly, following formula shall be applicable for determination of compensation:

$$\textbf{Compensation} = 2 \times W \times N$$

Where,

W = Minimum wage per day of the unskilled worker (in Delhi)

N = Number of days of hospitalization.

ANNEXURE-1

Factor (F) for Calculating the Amount of Compensation

Age	Factor (F)	Age	Factor (F)	Age	Factor (F)
1	2	1	2	1	2
Not more than…		32	203.85	49	156.47
16	228.54	33	201.66	50	153.09
17	227.49	34	199.40	51	149.67
18	226.38	35	197.06	52	146.20
19	225.22	36	194.64	53	142.68
20	224.00	37	192.14	54	139.13
21	222.71	38	189.56	55	135.56
22	221.37	39	186.90	56	131.95
23	219.95	40	184.17	57	128.33
24	218.47	41	181.37	58	124.70
25	216.91	42	178.49	59	121.05
26	215.28	43	175.54	60	117.41
27	213.57	44	172.52	61	113.77
28	211.79	45	169.44	62	110.14
29	209.92	46	166.29	63	106.52
30	207.98	47	163.07	64	102.93
31	205.95	48	159.80	65 or more	99.37

■■■■

69th Annual Conference of Cardiological Society of India (CSI 2017)

CAD - DIFFERENT STROKES

Prof Naveen Garg, Lucknow

A 52-year-old diabetic presents with chest pain with transient ST elevation on ECG; coronary angiography shows minor plaques

- About 5% patients can have acute myocardial infarction (AMI) with normal coronaries (or mild plaquing). Atherosclerotic CAD is still the commonest cause.
- Clinical setting and awareness of the conditions that mimic infarction can help differentiate the conditions.
- The shape of the ST-segment elevation, the leads involved, other features of the ECG are very helpful. In cases with slightest of doubt, coronary angiography should be done in early presenters.
- Once cardiac etiology is ruled out, other diagnosis should be sought.
- **Clinical possibilities in a patient presenting with chest pain with transient ST elevation with normal coronaries or minor plaquing:** Myocardial infarction with recanalyzed vessel; nonatherosclerotic CAD (hypercoagulable states, coronary embolism, arteritis, coronary artery anomalies, myocardial bridge, substance abuse); coronary vasospasm (Prinzmetal's angina); Takotsubo cardiomyopathy; noncardiac chest pain with transient ST elevation due to some other cause than AMI.
- **Causes of ST elevation other than AMI:** Normal variants; early repolarization; LBBB; LVH; WPW syndrome; hyperkalemia; pulmonary embolism; acute pericarditis; acute myocarditis; Brugada syndrome; abdominal causes; neurogenic: SAH and head injury.

TACKLING AF IN PATIENTS UNDERGOING SURGERY FOR VALVULAR HEART DISEASE

Dr Anil Patwardhan, Mumbai

"Ablate we must, tools may vary"

- STS 2017 Clinical Practice Guidelines: Surgical ablation for AF can be performed without additional risk of operative mortality or major morbidity, and is recommended at the time of concomitant mitral operations to restore sinus rhythm (*Class I, Level A*) (*Ann Thorac Surg*. 2017;103(1):329-41).
- STS 2017 Clinical Practice Guidelines: Surgical ablation for AF can be performed without additional risk of operative mortality or major morbidity, and is recommended at the time of concomitant isolated AVR, isolated CABG and AVR *plus* CABG operations to restore sinus rhythm (*Class I, Level B nonrandomized*) (*Ann Thorac Surg*. 2017;103(1):329-41).
- 2017 HRS/EHRA/ECAS Expert Consensus Statement: All patients with symptomatic AF (all types) undergoing other cardiac surgery. Class I indication for mitral valve Sx, Class IIa for AVR/CABG.

MAJOR TRIALS WITH MAJOR IMPACT: COMPASS TRIAL

Dr Pankaj Jariwala, Hyderabad

- Rivaroxaban 2.5 mg b.i.d. + aspirin 100 mg o.d.: Reduces CV death, stroke, MI; increases major bleeding without a significant increase in fatal, intracranial or critical organ bleeding and provides a net clinical benefit.
- No significant benefit of rivaroxaban alone.
- In patients with established stable atherosclerotic disease, rivaroxaban + aspirin resulted in a modest 1.3% absolute risk reduction in CV death, stroke or nonfatal MI, with a trend toward improved mortality. This benefit was offset by a 1.2% increased absolute risk in major bleeding.

Criticism

- Exclusion of 2,320 participants after run-in period (due to failure to adhere/tolerate) raises possibility of selection bias and decreased generalizability.
- Study terminated early due to efficacy of rivaroxaban + aspirin vs. aspirin alone. Thus, the study may overestimate the degree of benefit of rivaroxaban + aspirin and potentially

underestimate the degree of increased bleeding with this therapy.

- The lack of statistical significance of the observed trend towards improved mortality with combination rivaroxaban + aspirin may be due to underpowering for this outcome.

CURRENT CONCEPTS IN RIGHT HEART FAILURE

Dr Mandeep Mehra, USA

- Right heart failure is defined as a clinical syndrome due to an alteration of structure and/or function of the right heart system that leads to suboptimal delivery of blood flow to the pulmonary circulation and/or elevated venous pressures-at rest or with exercise.
- Differences between the RV and LV structure, inform management. The RV is unique in cellular physiology and in therapeutic response from the LV.
- Alterations in metabolism in RV include increased oxygen requirement, lower oxygen extraction reserve and higher dependence on coronary flow and lower glucose-based oxygen consumption/gm of myocardium.
- Key principles: *Considerations and goals:* Increased preload, in and of itself, rarely causes RHF; LV function determines RV function; RV coronary perfusion is dependent on aortic perfusion pressure; AV synchrony and tachycardia control; abnormal RV adaptation (chronic).
- The unique procedures for RV rescue are atrial septostomy, aorto-pulmonary windows and mechanical support-ECMO, Tandem, RV impella.

SEVERE TRIPLE VESSEL DISEASE IN A PATIENT WITH LVEF 20%

Dr Y Vijayachandra Reddy, Chennai

- This is a very high-risk group of CAD but should not be dubbed as "No-Option group" without proper workup.
- Myocardial viability assessment is important as options of management, CABG or PCI, depend on LAD territory viability.
- Nonviable LAD territory, poor target vessels for CABG, severe comorbidities with high surgical score, shift management to CHIP PCI (complex high-risk indicated patient PCI).
- CHIP-PCI demands hemodynamic support at times (IABP, Impella, short-term mechanical circulatory support). The benefits of revascularization are maximum in this group.

BARIATRIC SURGERY FOR PREVENTION OF CVD AND DIABETES

Dr Surendra Ugale, Hyderabad

- Obesity is associated with increased total and CV mortality due to accelerated atherosclerosis.
- Structural changes in the heart including concentric LV hypertrophy and left atrial enlargement may predispose to the development of heart failure and atrial fibrillation.
- Bariatric surgery produces marked weight loss, with reversal/resolution of coronary risk factors including hypertension, diabetes, dyslipidemia and inflammation; also significant reduction in LV mass and prevention of LA enlargement.
- Surgically-induced weight loss is associated with ~50% reduction in the risk of CV events and 10-year CV mortality.

PH-DIRECTED THERAPY IN COPD

Prof MN Krishnan, Calicut

Routing treatment of COPD with pulmonary hypertension (PH) reducing drugs is controversial. Treatment of COPD with mild/moderate PH with ET1/PDE5 inhibitors is not beneficial and may be harmful. There is evidence that sildenafil in patients with COPD and severe PH with/without right heart failure is beneficial to improve hemodynamics, exercise tolerance and QoL. Further large randomized studies are required to conclusively establish the role of PH-directed therapy in COPD.

UPDATED ASSESSMENT AND TREATMENT OF DIABETES WITH HYPERTENSION

Dr Rajiv Agarwal, New Delhi

Hypertension is common among patients with diabetes. More than 60% of T2DM have hypertension. There is evidence that ASCVD morbidity and mortality have decreased for people with diabetes since 1990 likely due in large part to improvements in BP control.

It is imperative that doctors and patients stay abreast of the most current care recommendations that can lead to improved cardiovascular health for people with diabetes and will ultimately result in better overall health.

Latest updated assessment and treatment of hypertension among people with diabetes, including advances in care, a position statement by the ADA

recommend a lower BP target of <130/80 mmHg in patients with a high risk of cardiovascular disease. The updated recommendations are based on review of 137 clinical trials and meta-analyses including ACCORD BP, ADVANCE BP, HOT and SPRINT trials.

The report "strongly recommends" that home BP monitoring be carried out by all hypertensive patients with diabetes with periodic reporting. New recommendations provide lifestyle management plans for lowering BP that include suggestions for weight loss, a Dietary Approaches to Stop Hypertension (DASH)-style food plan and increased physical activity.

The new ADA 2017 treatment of hypertension in patients with diabetes guideline recommends <130/80 mmHg BP goal for patients with diabetes at high risk of cardiovascular disease. This recommendation further strengthens the use of azilsartan in T2DM with high risk of cardiovascular disease.

Azilsartan is the latest approved ARB, and it has shown its superiority in terms of efficacy, safety and metabolic effects compared to other ARBs in patients with prediabetes and T2DM in a pooled analysis of over 3,800 patients in randomized controlled trials. Evidence suggests that azilsartan exhibits greater BP-lowering effect than valsartan and olmesartan. Data also suggest its beneficial antidiabetic and cardioprotective properties. It is more potent than most other ARBs for inhibiting binding of angiotensin II to human AT1 receptor membrane preparations, and reduces 24-hour BP in hypertensive patients without serious comorbidities more effectively than maximum approved doses of the well-known ARBs olmesartan, valsartan and candesartan.

Azilsartan, thus represents the future of hypertension management in patients with diabetes.

DIAGNOSING HFpEF: CAN WE SIMPLIFY IT?

Dr Partho P Sengupta, USA

- HFpEF is a complex heterogeneous disorder.
- Current schemes for assessing DD and filling pressures have limitations.
- Contemporary HFpEF diagnosis should rely on clinical findings + echo, when in doubt use exercise echo, cardiac cath.
- AI techniques may help automate and improve precision in noninvasive assessment of LV filling pressures.
- Novel screening tools are needed; wavelet transform EKG may be an attractive solution.

HFpEF: Treatment Pearls

- Garden-variety HFpEF: Treat BP, DM, obesity, refer for clinical trial if AF, trial of cardioversion.
- CAD-HFpEF: Treat like HFrEF (BB, ACEI/ARB, revascularization).
- Right heart failure - HFpEF: Diuresis/ultrafiltration, digoxin.
- HCM-HFpEF: Verapamil, diltiazem, long-acting metoprolol.
- Valvular HFpEF: Treat valvular disease if possible.
- High output HFpEF: Treat underlying cause, diuretics/UF.

EXPLAINING CVD EPIDEMIC IN URBANIZED SOUTH ASIANS WORLDWIDE: A NEW CAUSAL SYNTHESIS

Prof Raj Bhopal, Scotland

- Indians in urbanized environments, in common with other South Asians, are at unusually high risk of coronary heart disease (and type 2 diabetes).
- The evidence in support of the main explanations for this observation e.g., insulin resistance or fetal nutritional insufficiency is unconvincing.
- Public health and clinical medicine currently need to focus on the established causes e.g., hypertension and tobacco use.
- Some promising, relatively new explanatory ideas for future research include stiffening of collagen in the vasculature, possibly promoted by dietary components.

IV IRON THERAPY IN HF: IS IT READY FOR IMPLEMENTATION?

Dr Dharmendra Jain, Varanasi

Iron deficiency is a prevalent and clinically relevant comorbidity in up to 50% of patients with chronic heart failure (CHF). Iron deficiency in CHF patients is associated with impaired quality-of-life (QoL), reduced exercise capacity and increased mortality, irrespective of the presence of anemia.

Three randomized trials (CONFIRM-HF, FAIR-HF and EFFECT-HF), of intravenous (IV) ferric carboxymaltose, in the treatment of iron deficiency in CHF patients with reduced left ventricular ejection fraction (LVEF) demonstrated improvement of symptoms, functional capacity and QoL. These beneficial effects were

independent of the presence of anemia. CONFIRM-HF and subsequent meta-analyses indicated that treatment of iron deficiency may reduce the rate of hospitalizations for worsening CHF.

Although, oral iron is available at lower cost than IV iron, its use does not translate into beneficial effects in CHF patients with iron deficiency. Therefore, current guidelines advise establishing evidence-based pharmacological and device therapy to improve symptoms and prognosis in patients with CHF. In addition, screening for iron deficiency is recommended.

According to the ESC guidelines for acute HF and CHF, IV ferric carboxymaltose should be considered for treating iron deficiency in ambulatory symptomatic patients with reduced LVEF in order to alleviate HF symptoms, and to improve exercise capacity and QoL and should be considered as a routine part of HF care.

PHYSICAL ACTIVITY FOR CVD PREVENTION: EVIDENCE-BASED RECOMMENDATIONS

Dr Charan P Lanjewar, Mumbai

- CVD is preventable.
- Consider physical activity for CVD prevention as well as treatment.
- Regular physical activity decreases all-cause mortality and CVD mortality.
- Physical activity is beneficial to all irrespective of age, sex, race, etc.
- Regular physical activity can produce long-term health benefits.
- Health benefits of physical activity outweigh risks of adverse events for all.
- At least 150 minutes a week of moderate aerobic physical activity (30 min for 5 days/week) or 75 minutes a week of vigorous aerobic physical activity (15 min for 5 days/week) is recommended.

RHEUMATIC MITRAL REPAIR: REPLACEMENT IS NOT THE ONLY OPTION

Dr Amit Chandra, Gurugram

- Majority of rheumatic mitral valves in our country are replaced because the durability of rheumatic mitral repair (in terms of freedom from re-operation) is inferior to mechanical valves (82% vs. 95% at 10 years), even though there is considerable survival advantage with repair over replacement (90% vs. 70% survival at 10 years). Thus, it makes sense to develop a strategy/technique, whereby the durability of rheumatic mitral repair is improved to achieve >90% freedom from re-op to be able to compete with mechanical valves.
- Two newer studies have found that just by selecting patients older than 40 years of age (when the rheumatic process has died down) and an aggressive resection, the investigators were able to achieve a freedom from re-op of 94% and 98% at 10 years, respectively.
- We have developed a comprehensive strategy at Medanta that includes the above mentioned strategy (patient selection and radical resection with reconstruction) in addition to a new technique to obtain large valve opening in stenotic valves called "Medanta correction". This has given us excellent results in 97 patients that we have operated over 5 years with no re-operation.
- Thus, it is possible to have a rheumatic mitral repair with durability equivalent to mechanical valves, and, with the advantages that repair provides to the patient, it is the best that a patient can have.

WHEN AND HOW TO LOOK FOR CVD IN ASYMPTOMATIC DIABETIC PATIENTS?

Dr Dayasagar Rao V, Hyderabad

- Nearly 65% deaths in patients with diabetics are due to CVD (CAD/CVA/HF).
- Degree of atherosclerosis in diabetic patients is more extensive with accelerated progression in poorly-controlled diabetes.
- Do all asymptomatic patients with DM need CV investigations? No. Only patients with following characteristics should be investigated further: Age >40 years; DM >10 years; more number of associated CV risk factors, in addition to DM (HT, hyperlipidemia, strong f/h/o premature CAD, smoker); DM with co-existent vascular disease in other territories (PAD, H/o stroke/carotid bruit, microalbuminuria).
- Should all patients suspected of CAD undergo coronary angiogram? No. Stepwise approach is desirable starting with; resting EKG (pathological Q waves), TMT - positive at low workload <5 METS, CAC score >400 AU, if high probability of CAD is present, stress MPI should be done. In those with high risk perfusion defect, area of perfusion defect >10% of LV, perfusion defects in

multiple vascular territories, E/O stress-induced LV dysfunction.

- Those with high risk perfusion defects should be subjected to invasive coronary angiogram in asymptomatic patients with diabetes.

PULMONARY HT: CASE-BASED MANAGEMENT OPTIONS

Dr Suvro Banerjee, Kolkata

A 66-year-old gentleman with severe COPD with PASP 66 mmHg and right HF

- Severe pulmonary hypertension is uncommon in COPD. If severe pulmonary hypertension is present in a patient with COPD, other associated causes such as left heart disease, CTEPH or pulmonary arterial hypertension (PAH) need to be excluded.
- In patients with COPD and pulmonary hypertension, treatment of COPD remains the cornerstone of management. There is paucity of proven therapies for pulmonary hypertension and right ventricular failure secondary to COPD.
- Drugs used in treatment of left heart failure have not been shown to be effective in right heart failure. Diuretics are used to reduce fluid congestion.
- Long-term oxygen therapy has been shown to improve survival.
- PAH-specific therapies are not recommended currently for pulmonary hypertension associated with chronic lung disease. Lung transplantation or heart lung transplantation remains the last resort.

PULMONARY HYPERTENSION

Dr Rahul Mehrotra, New Delhi

- Systematic evaluation of a patient of dyspnea is paramount for early diagnosis of pulmonary hypertension.
- Echocardiography is the key investigation for screening of patients suspected of having pulmonary hypertension.
- Upfront combination therapy with ambrisentan and tadalafil is the current best approach based on available evidence. Other supportive therapies should be given as per recommendations.
- Patients should be systematically followed up with clinical examination, exercise capacity, echocardiography, biomarker (BNP/NT-ProBNP) and right heart catheterization, whenever required.

ADVANCES IN HF MANAGEMENT: FROM DIAGNOSTICS TO THERAPEUTICS - ECHO FOR PROGNOSIS IN HF

Dr John Gorcsan, USA

- A comprehensive echo Doppler examination adds prognostic information.
- Advances in strain imaging have added to EF in prognosis.
- Global longitudinal strain is an important new method to assess cardiac function.

HEMODYNAMIC SUPPORT IN LM INTERVENTION

Dr Seung-Woon Rha, Korea

- How to prepare and prevent hemodynamic instability during complex LM intervention? Inotropes and prophylactic IABP.
- How to overcome the disastrous complication of hemodynamic compromise developed during the LM intervention? Inotropes, IABP, ECMO, experienced PCI skills or surgical back-up.

PREVENTION OF CVD BEYOND LIPID-LOWERING THERAPY: KEY MESSAGES FROM 2016 ESC GUIDELINES ON CVD PREVENTION

Dr Massimo F Piepoli, Italy

- In 2015, the total healthcare expenditure in Europe for CVD was € 210 billion a year.
- The emphasis in the 2016 European Guidelines on cardiovascular prevention in clinical practice is on: Prevention of CVD at the population level: smoking cessation, healthy diet, physical activity, alcohol abuse, healthy environment; disease specific prevention: atrial fibrillation, CAD, CHF, cerebrovascular disease, peripheral artery disease.
- The risk estimation charts classify persons based on the level of risk; low to moderate risk (score <5%): should be offered lifestyle advice to maintain their status; high risk (score ≥5% <10%): should be given intensive lifestyle advice, and may be given drug treatment; very high risk (score ≥10%): drug treatment more frequently required.

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IJCP SUTRA 144: To minimize or eliminate heat cramps, grasp the upper thigh between the thumb and index finger and squeeze hard until the cramp goes away.

News and Views

Note on Action Against False Assumptions of Medical Practitioners

The Delhi Medical Council Act, 1997 has been enacted to provide for the Constitution of the Delhi Medical Council, and the maintenance of a register of medical practitioners who are engaged in the practice of modern scientific system of medicine and all its branches in the National Capital Territory of India and for matters connected therewith.

According to Section 27 of the Delhi Medical Council Act, any person who falsely assumes that he is a medical practitioner as defined in Clause (7) of Section 2 and practises the modern scientific system of medicine, shall be punishable with rigorous imprisonment which may extend up to 3 years or with fine which may extend up to Rs. 20,000/- or with both.

The above mentioned offence of false assumption of any person as a medical practitioner practising modern system of medicine is a punishable offence which is a cognizable and non bailable offence as per Schedule II of CrPC.

When the Delhi Medical Council comes to know about any person who is falsely assuming himself/herself as a medical practitioner practising modern system of medicine, then Delhi Medical Council files a police complaint against the said person. On receiving the complaint from Delhi Medical Council, the Police officials promptly register FIR against the said person.

The SHO shall adequately brief Division/Beat staff to gather information about the quacks proactively. Credentials of such persons violating provisions of Section 27 of Delhi Medical Council Act, 1997 shall be verified by the police from Delhi Medical Council. If the report of the Delhi Medical Council discloses that the said person is a quack, then SHO shall promptly register a case under appropriate sections of law.

The cognizance of theses offences can be taken by the Court only on the complaint of the competent authority under Section 28(2) of the Delhi Medical Council Act, 1997. After completion of investigation, the SHO shall forward the outcome of investigation to the Delhi Medical Council. Thereafter, the Delhi Medical Council would file a complaint in the Court in accordance with law. After the filing of the complaint by Delhi Medical Council in the Court, the SHO will file chargesheet (final report of police investigation) in the Court.

The Deputy Commissioner of Police, Delhi Police has vide circular dated 22.05.2014 clarified to all police officers about the cognizance of the offence under Section 27 of the Delhi Medical Council Act, 1997.

Source: *(i) Delhi Medical Council Act, 1997. (ii) Circular dated 22.05.2014 of Deputy Commissioner of Police*

CIRCULAR

No. 15/2014

Subject- Action~ against false assumption of medical practitioners (Quacks).

False assumption of medical practitioner in terms of the Delhi Medical Council (DMC) Act, 1997 and the Delhi Bhartiya Chikitsa Parishad (DBCP) Act, 1998 is a cognizable and non-bailable offence under the respective Act as per schedule II of CrPC.

2. Section 27 of the DMC Act, 1997 reads as under:

   "*Any person who falsely assumes that he is a medical practitioner or practitioners as defined in Clause (7) of Section 2 and practices the modern scientific system of medicine, shall be punishable with rigorous, imprisonment which may extend up to 3 years or with fine which may extend up to Rs. 20,000- or with both*".

3. Section 30 of the DBCP Act, 1998 reads as under:

   "Any person who falsely assumes that he is a practitioner as defined in Clause (K) of Section 2 and practices the Bhartiya Chikitsa (Indian System of Medicine) shall be punishable with rigorous imprisonment which may extend up to three years and with fine which may extend upto fifty thousand rupees".

4. In case a complaint is received from the DMC and the DBCP warranting action u/s 27 of the DMC Act, 1997 or u/s 30 of the DBCP Act, 1998 respectively, FIR should be registered promptly.

5. SHOs adequately brief Division/Beat' staff to gather information about quacks proactively. Credentials of such persons violating provision of Section 27 of the

DMC Act, 1997 and Section 30 of the DBCP Act, 1998 shall be got verified from the concerned Council.

If the report of the concerned Council discloses that the suspect is a quack, the SHO shall promptly register a case under appropriate sections of law.

Cognizance of these offences can be taken by the Court only on the complaint of the competent authority empowered u/s 28(2) of the DMC Act, 1997 and u/s 31(2) the DBCP Act, 1998 respectively. After completion of investigation, the SHO shall forward the outcome of investigation to the concerned Council. The concerned Council would then file a complaint in Court in accordance with law. After Filing of such complaint, SHO will file chargesheet in the Court.

Contact details of the Councils:

a. Delhi Medical Council
Room No. 308A, 3rd Floor, Administrative Block
Maulana Azad Medical College Campus,
New Delhi - 110002
Phone: 011-23237962, Fax: 011-23234416
E-mail: delhimedicalcouncil@gmail.com
Website.: delhimedicalcouncil.org

b. Delhi Bhartiya Chikitsa Parishad
Csc-III, First Floor, Preet Vihar, Delhi - 110092,
B Block, Preet Vihar - 92
Phone: 011-22059046, Telefax: 011-22059032
E-mail: dbcp111@gmail.com
Website: www.dpcp.co.in

This supersedes the earlier Circular No. 2/2014 dated 8.01.14 issued on this subject.

(Harendra K. Singh)
Dy. Commissioner of Police:
Head Quarters, Delhi

No. 2829-2925/Record Branch/PHQ dated, Delhi, the 22.05.2014. Copy forwarded for information & necessary action to:

All Spl.CsP/Joint CsP/Addl. CsP, Delhi.

All Districts/Units Addl.CsP/DCsP including P/PTC, Crime, Railways, IGI Airport, Sp1. Cell, SPUWAC and FRRO, Delhi. SO to CP/Delhi.

LA to CP, FA to CP, Delhi & DCP/PRO.

All ACsP/PHQ.

All Inspectors, PHQ.

SO to DCP/HQ, Delhi

All ACsP/C&T Branch/PHQ
HAR/PHQ with 5 spare copies

New York Surgeon Gets 13 Years in Prison for Medicare Fraud

Medscape Excerpts: New York surgeon Syed Imran Ahmed, MD, was sentenced in federal court in Brooklyn to 13 years in prison for multimillion-dollar Medicare fraud, according to a statement released by the US Department of Justice (DOJ).

He was also asked to pay $7.3 million in restitution, forfeit $7.3 million, and pay a $20,000 fine.

Ahmed, of Glen Head, New York, who specialised in wound care and weight loss, was convicted in July 2016 on one count of healthcare fraud, three counts of making false statements related to healthcare matters, and two counts of money laundering.

"*Dr Syed Ahmed treated Medicare like a personal piggy bank, stealing over $7.2 million by making fraudulent claims for medical procedures he never performed.*"

"*Dr Ahmed will now pay the price for violating the trust that Medicare places in doctors. His 13-year prison sentence and the heavy payments imposed should send a powerful message of deterrence to other medical professionals.*"

Evidence presented at the 11-day trial by the government showed that from January 2011 through December 2013, Ahmed billed Medicare approximately $85 million for wound debridement procedures and incision-and-drainage procedures that he didn't perform.

"*Ahmed wrote out lists of phony surgeries and sent the lists to his billing company in Michigan with instructions that they be billed to Medicare. Ahmed also directed that the surgeries be billed as though they had taken place in an operating room so as to increase the payout for the fraudulent scheme.*"

In some of the claims, Ahmed billed for multiple procedures on the same patient on the same day for several days in a row.

Comment: Criminalisation of medical practise is now a routine all over the world.

Medical Board of California Accuses Gastroenterologist of Gross Negligence

- Dr Dhaliwal is a gastroenterologist at Newport Beach, Calif-based Hoag Hospital.
- As per the Board Dr Dhaliwal repeatedly performed negligent acts, failed to maintain accurate records and violated the medical practice act when treating a 73-year-old, now deceased, man.
- Dr Dhaliwal first saw the patient in April 2011. The man was taking three separate drugs to treat diabetes and coronary artery disease.

- Dr Dhaliwal had the man undergo laboratory studies, an upper endoscopy, a colonoscopy and an abdomen scan.
- A lesion was apparent in the upper part of the man's liver.
- Additional testing was recommended. The lesion wasn't found in a follow-up ultrasound, so an MRI was recommended to get a closer look. Dr Dhaliwal allegedly did not order any additional imaging, nor did he follow-up on the lesion or any abnormal liver radiographic findings.
- Dr Dhaliwal did conduct an upper endoscopy a few days later, but allegedly misidentified the patient as a 73-year-old female in his notes.
- A pathology report noted the patient had either an infection or stomach ulcers. The pathology report asked Dr Dhaliwal to advise the patient to schedule a follow-up. Allegedly, Dr Dhaliwal did not schedule a follow-up, nor did he adjust any of the man's medications, despite a risk of peptic ulcer disease-related bleeding or other complications.
- The man was admitted to the hospital by another physician in October 2011. The lesion on his liver was allegedly "significantly larger." The new physician scheduled imaging treatment, unaware that imaging had recently been done.
- The patient returned to Dr Dhaliwal in late October 2011. Dr Dhaliwal allegedly noted the liver lesion, but neither evaluated it nor attempted to treat it. Between October 2011 and August 2012, Dr Dhaliwal allegedly made no mention of the liver lesion in any of his notes.
- The patient was hospitalised due to liver pain in August 2012. Dr Dhaliwal consulted on the case. He attributed the pain to bloating, while noting an imaging scan found a mass on the patient's liver. Allegedly, his physician's note ended with, "Overall the patient has a poor prognosis."
- The patient died October 2012 of liver cancer. Physicians said the mass was too large to properly remove.
- The Board submitted the allegations and is considering future disciplinary action against Dr Dhaliwal, including revoking his medical license. [*Beckers GI & Endoscopy*]

Lessons and Comments: Dr KK Aggarwal

- Even clerical errors can be put against you (mistakenly writing F and not M).
- Always respond to comments written by Radiologist or Pathologist. If you do not follow their advise reason it out in your file.
- Always explain every finding to the patient even if you want to ignore it?
- Always ask the patient about previous investigations.
- You are often prosecuted for not investigating a case.

FDA Warns Against Women Using Domperidone, to Increase Milk Production

Women may be using an unapproved drug, domperidone, to increase milk production the US Food and Drug Administration (FDA) is warning breastfeeding women not to use this product because of safety concerns.

Domperidone increases the secretion of prolactin, a hormone that is needed for lactation, 30-40 mg dose the effects can be seen.

Domperidone is approved in India to treat certain gastric disorders, it is not approved in any country for enhancing breast milk production in lactating women and is also not approved in the US for any indication.

There have been several published reports of cardiac arrhythmias, cardiac arrest and sudden death in patients receiving an intravenous form of domperidone.

Domperidone may increase the risk of cardiac arrhythmias therefore, an electrocardiogram should be performed at baseline and while on treatment. Domperidone should be withheld if the corrected QT is >450 ms in men and >470 ms in women.

The chance of abnormal heartbeats or sudden death are higher when used at doses more than 30 mg/day or in patients older than 60 years.

All 'D' preparations contains domperidone 10 mg and 'D-SR' preparations contains domperidone 30 mg.

Transgender, Biological Male Breastfeeds

A transgender woman became the first to be able to breastfeed his baby. The journal *Transgender Health* published a case study last month highlighting a 30-year-old unnamed biologically male transgender woman who is believed to be first case of "induced lactation in a transgender woman". The transgender woman's partner was pregnant and not interested in

breastfeeding, the transgender woman was more than willing to take on the role of providing the baby's primary food source. Transgender woman has not received any kind of "gender-affirming" surgery. But with the help of extensive hormone therapy, the study states that the transgender woman was able to breastfeed their child naturally for at least 6 months.

Doctors used protocols for "non-puerperal induced lactation," a process used to help women lactate. Spironolactone was used to suppress testosterone, while estradiol and progesterone were used to mimic the high levels of the hormones produced during pregnancy. Domperidone, to increase milk production and banned by US FDA was also used, along with a breast pump. [*Samuel Smith. The Christian Post*]

Insurance Company: Will not Pass Claim if Lab Report not Signed by Qualified Doctor

New India Assurance Company has now issued a circular to all the regional offices across the country instructing them not to approve medical claims if the reports are signed by unqualified staff.

The insurance company circular states that the reports attached for approval of insurance claims will have to be signed by a registered medical practitioner, registered with the Medical Council of India (MCI) and having a post-graduate certification in pathology. The circular states that the instructions of the Supreme Court of India and the MCI have to be strictly adhered to by all offices without any exception.

Illegal laboratories and unqualified staff pose major risks to the health of innocent patients and are making a killing despite the central government and various courts issuing directives prohibiting such activities [*Pune Mirror*]

Father Charged for Medical Negligence

A father's alleged mismanagement of his teenage son's diabetes led to charges. Robert Glazner, 49, was charged recently with second-degree reckless homicide. He faces up to 25 years in prison if found guilty. Glazner's son, 15-year-old Bryden, died in August 2017 from complications related to diabetes. The father did not ensure Bryden was taking his insulin properly. The teen was diagnosed with type 1 diabetes in 2014 and authorities say Glazner was resistant to being educated on how to treat the disease. A judge ordered Glazner jailed under a $100,000 cash bond.

WHO: Stop Rushing Women in Labour

Doctors should not intervene to speed up a woman's labour unless there are real risks of complications, says the WHO. Overturns decades of previous advice, which said that labour which progressed at a slower rate than 1 cm of cervical dilation per hour in the first stage was risky. Women are often given the drug oxytocin to speed up labour and end up with epidurals because of the pain, followed by forceps or vacuum deliveries and in some cases a cesarean section. Many women want a natural birth and prefer to rely on their bodies to give birth to their baby without the aid of medical intervention.

If labour is progressing normally, and the woman and her baby are in good condition, they do not need to receive additional interventions to accelerate labour.

48% Dip in Indian Doctors Who Went Overseas in 2017

In what must come as good news to a stretched healthcare system, the number of doctors going abroad dipped by 48% in 2017 compared to the previous year and 51% over 2015. Doctors say policy changes in western countries such as US and UK have made it tougher for Indians there while the improving infrastructure and salary back home are proving to be a draw.

Medical experts say the country needs far more doctors than the 10.4 lakh practising as of 2017 - the ratio is one doctor to 1,596 patients, the government admitted last year. There is a heavy geographical skew in the current distribution as well, with just five states accounting for 52% of the force. According to the MCI, the number of doctors seeking the Good Standing Certificate (GSC), issued to Indian doctors who wish to serve abroad, stood at 1,469 at the end of 2017, compared to 2,985 in 2015 and 2,802 in 2016. Dr Niranjan Reddy, who has just returned from the United States, says, "My wife's still working there, but the situation is not the same as last year. The politics has changed policies and the locals are also protesting the selection of too many Indians into residencies." Fall in salaries in US forcing docs to return. There are multiple factors that we must consider. Earning good money is no longer difficult in India, there are also social pressures that come into play, which is why several of them are seen returning to India," says Dr A Jagadeesh of Abhaya Hospital. "But yes, changes in policies abroad have had a huge impact."Reddy says that apart from policy changes, diminishing salaries in the US have tipped the balance and would continue to do so. "In the last 4-5 years, the

salaries of doctors in the US - barring cardiologists - has reduced by 30-40%. Contrary to this, in India, the salaries are going up. Also, the way private clinics work here is very encouraging for many doctors."

Another doctor who worked in the UK until recently says access to insurance in India has proved a game-changer. More people are able to afford expensive procedures, thereby allowing the healthcare industry to pay doctors better.

Shortfall Concerns: The fall in migration, however, is not enough to impact the ground situation in India significantly, say medical experts.

As of September 2017 - the latest data available - there are 10.4 lakh doctors registered and practising in India. Just five states - Maharashtra, Tamil Nadu, Karnataka, Andhra Pradesh (includes Telangana) and Uttar Pradesh - account for 5.4 lakh doctors or 52% of the pool. Also, according to MCI, at any point in time, only 80% of them - 8.3 lakh - are available for service, which means that India has one doctor for 1,596 people. This is a slight improvement from 10.1 lakh doctors in April 2017, and 9.5 lakh doctors in 2015. "We need to have tens of more colleges coming up in rural areas if we want to see more doctors registering and practising in India," says Dr Ajit Benedict Ryan of Hosmat Hospital. "Even among the doctors we have, a majority are in urban areas, and mostly in big cities."

Hyderabad: No Doctors Sign on Bill, No Insurance

Public sector insurance companies have stated that they will only reimburse bills if the laboratory reports are countersigned by a registered medical practitioner.

These instructions have been issued based on the orders of the MCI and the Supreme Court. Regional branches and third-party administrators have been asked to check medical reports and not grant reimbursements unless they are signed by a registered practitioner.

The MCI in its order dated June 14, 2017, has said that only persons qualified with an MBBS or an MD in pathology, biochemistry, or microbiology are eligible to sign laboratory reports.

Eighty percent of laboratory reports are signed by persons with MSc or PhD degrees in applied sciences, life sciences, medical microbiology, medical biochemistry or biotechnology. This practice is not followed in accredited hospitals and diagnostic centres as the rules do not permit it.

The issue was stirred up when the National Accreditation Board for Testing and Calibration Laboratories sought clarification on who was eligible to sign medical reports. Insurance companies have taken a cue from this and amended their reimbursement policy.

Beware: Lassa Fever in Nigeria

- Do not ignore any fever with deafness in Nigerians.
- Why talk in India: Large number of patients from Nigeria come for treatment in India.
- Lassa fever is a viral hemorrhagic fever caused by Lassa virus.
- In West Africa; each year, there are approximately 3,00,000 cases and 5,000 deaths.
- The primary mode of transmission to humans is via exposure to infected Mastomys rodents (direct contact with urine or faeces, inhalation of aerosolised rodent excretions).
- Person-to-person transmission may occur after exposure to Lassa virus in the blood, urine, faeces, or other bodily secretions of an infected individual.
- Lassa fever infection is not spread through casual contact.
- Individuals with Lassa fever infection are not believed to be contagious prior to onset of symptoms.
- The incubation period is 1-3 weeks.
- Most (80%) have mild symptoms (low-grade fever, malaise, and headache).
- The most common complication of Lassa fever is deafness, which occurs in up to one-third of patients and may develop in the setting of mild or severe illness.
- Disease progresses in 20% cases with pharyngitis, cough, nausea, vomiting, diarrhoea, myalgias, retrosternal chest pain, back pain, and abdominal pain.
- Most recover after 8-10 days of symptoms.
- Death usually occurs within 2 weeks.
- One percent of Lassa virus infections result in death.
- The diagnosis is suspected in individuals with fever, malaise, headache, pharyngitis, cough, nausea, vomiting, diarrhoea, myalgia, chest pain or hearing loss in the setting of relevant epidemiologic exposure.
- The diagnosis of Lassa fever is usually established via serum enzyme-linked immunosorbent serologic assay, which can detect immunoglobulin (Ig)M and IgG antibodies and Lassa antigen.

- Serum IgM is detectable 10-21 days after symptom onset; serum IgG is detectable approximately 21 days after symptom onset.
- Treatment of Lassa fever involves intravenous ribavirin or oral ribavirin.
- Clue: Platelet count low but always >1 lakh; low TLC, fever with deafness, SGOT > SGPT >10:1, high amylase (dengue like illness with negative serology.

Fake News

Dr Naresh Trehan denies any disinvestment or sale of Medanta Group. In a personal conversation with me he said it was a fake news.

It is also false that he has any personal health issues.

To Err is Human Now No More True in Medical Practice: The Famous Dr Bawa-Garba Case

Dr KK Aggarwal
Recipient of Padma Shri

A single clinical error can do away with all the good that we do as doctors.

The case of Dr Hadiza Bawa-Garba, a trainee paediatrician in the NHS-UK, convicted for homicide for the death of a child from sepsis, and hounded by the General Medical Council (GMC), is every junior doctor's fear today.

Case synopsis

Jack, a 6-year-old boy with Down syndrome was referred by a GP for nausea, vomiting and diarrhoea on February 18, 2011. At 10:30 am Jack was assessed by Dr Bawa-Garba, a trainee paediatrician in the NHS-UK, who made a presumptive diagnosis of fluid depletion from gastroenteritis and gave IV fluid bolus and started maintenance fluids. The patient had a past history of repaired atrioventricular canal defect and was on enalapril.

The doctors ordered a chest X-ray, which was done at 12.30 pm. Blood count, renal function and inflammatory markers were also done. Blood gases showed that Jack was acidotic with a pH of 7 and a lactate of 11. The metabolic profile confirmed her working diagnosis of shock from gastroenteritis; but, judging from the tests she ordered, pneumonia was in her differential. Repeat blood gas showed pH of 7.24, heading towards a normal pH of 7.4.

Dr Bawa-Garba looked at the chest X-ray only at 3 pm, which showed pneumonia. She prescribed antibiotics, which were given at 4 pm. At 4:30 pm, she met Dr O'Riordan, her boss, in the hospital corridor. She showed him Jack's blood gas results and explained her plan of action. Her boss did not see Jack.

In the ward, Jack received enalapril. Dr Bawa-Garba had not prescribed enalapril, and she clearly stated in her treatment plan that enalapril must be stopped. Nor was enalapril given by the nursing staff. But, she did not make it clear to the mother not to give it, who subsequently gave it to the child that day at 7 pm (*Wikipedia*). He suffered a cardiac arrest 1 hour after receiving enalapril. CPR was interrupted because Dr Bawa-Garba mistakenly believed that there was a DNR order for Jack, but was then continued with. Jack died from streptococcal sepsis at 9.20 pm.

The verdict

Dr Bawa-Garba, and the two nurses who were caring for Jack, were charged with manslaughter. The doctor was not only clueless, but also grossly negligent.

Clinical errors or mistakes by the doctor cited were delay in getting chest X-ray, delay in reading the X-ray, which would have helped reaching a diagnosis of sepsis much earlier and delay in prescribing the antibiotics for the same.

Unwittingly, the court was exposing system failures, but Dr Bawa-Garba was being held responsible for each failed component. Expert doctors opined that had Jack received antibiotics within 30 minutes, rather than 6 hours, his chances of survival would have increased dramatically.

Dr Bawa-Garba was found guilty of manslaughter by gross negligence for the preventable death from sepsis; the jury returned the verdict 10:2 and was sentenced to 2 years in prison, suspended for 2 years. GMC appealed against that decision and called for Bawa-Garba's "erasure from the medical register".

The case made by the GMC was allowed in the High Court of Justice and on the 28th January 2018, the Court ruled that the doctor's name be erased from the Medical Register, ostensibly to protect public confidence in the profession.

Final comments

The case of Dr Hadiza Bawa-Garba and the Court action taken by the GMC against Dr Bawa-Garba and the subsequent erasure of her name from the Medical Register has created controversy, and has raised several areas of concern for doctors working not only in UK, but all over the world. One being that Dr Bawa-Garba has been unduly punished for system failings, especially the understaffing. It has also generated fear among junior doctors. A reflective note written by Dr Bawa-Garba on e-portfolio was allegedly used in evidence against her.

More than 8,000 doctors have signed a petition in her support, a crowd funding campaign has raised over £260,000 for an appeal against the decision.

Dr Bawa-Garba was held responsible for a sequence of failings.

- She did not recognise the early features of sepsis in the child and as such appropriate antibiotic treatment was delayed.
- She appeared not to recognise the implications of seriously deranged blood gas results and failed to fully communicate the implications to her consultant.
- When the child suffered a cardiac arrest, there was a further problem as the patient was wrongly identified as another child for whom a DNACPR order applied.

Inquiry revealed that multiple errors and failings contributed to the mishap. No one cause could be found that led to the death of the patient.

- Dr Bawa-Garba had only recently returned to work following maternity leave.
- She was covering the work of another registrar, with her supervising consultant teaching on a different site, and the two junior colleagues, for whom she had supervisory responsibility, had no pediatric experience.
- She was expected to review unwell patients and perform procedures on six wards over four floors, field the GP calls and struggle without a functioning IT system.
- The patient was shifted to a bed previously occupied by a patient with a DNR order; that change had been made without her knowledge. She was blamed for failing to recognise this.

Implications of this Judgement for us

Such a case has now happened in the UK. We face this situation every day in India. And an event such as this is waiting to happen in our country.

Resident doctors can be called the backbone of the hospital. They work long shifts. At times, they may have to continue shift, which may extend to as long as 36 hours, to cover for their colleague without break, putting the needs of the patients first rather than their own. Such an overworked and exhausted doctor is liable to make mistakes.

In Martin F. D'Souza vs. Mohd. Ishfaq SCI: 3541 of 2002, dated 17.02.2009, the Supreme Court of India had observed that: "The higher the acuteness in an emergency and the higher the complication, the more are the chances of error of judgement..." Errors can be made in an emergency even by experts and may not amount to negligence.

The judgement in the case of Dr Bawa-Garba may impact decisions in cases of medical negligence in India too and error of judgement may no longer be a defence.

We have been fighting against criminal prosecution of doctors, but such judgements may weaken our stand on this issue.

What this judgement also implies that if you are overworked, ask for help. And, if there is staff shortage or you do not have adequate staff to share the volume of work, report it to your superior.

But even with the prevalent staff shortages, inadequate or poor infrastructure, can residents/doctors really refuse to work to save themselves from such a possible criminal conviction? And also from possible employer retribution?

Like a batsman in cricket, a single error can ruin your career.

With the rising trend of litigation and violence against the medical profession, clinical medicine may well become defensive medicine.

What can be done?

For Residents

- Let your senior know about lack of adequate staffing, availability of support, IT functionality or other system issues.
- If you write your experience in e-Portfolio, do not put the name of the patient or other such details.
- Do not make any judgemental statement about any patient or staff involved in patient care. Avoid emotive language.
- Consult with your seniors for such potentially serious cases.

For Consultants

- Be proactive in ensuring a safe and supportive environment for your staff so that they can report incidents and clinical concerns. Encourage reflective practice for your residents without fear of legal action.
- Discuss such issues with residents as their Educational Supervisor or Clinical Supervisor.

Who am I? Know Your Soul Profile

KK AGGARWAL

"I am not my physical body, as I know, once my body dies, nobody wants to touch it." (Adi Shankaracharya in the *Bhaja Govindam*)

"I am not my mind as I know whenever I am in trouble; the mind asks the heart for help." (Deepak Chopra in the *Seven Spiritual Laws of Success*)

"I am my consciousness which is residing in the core of my heart." (*Svetasvatara Upanishad 5.8*)

"This consciousness is nothing but a web of energized information situated in the void." (*Chandogya Upanishad* Chapter XII - the Birth of the Gross from the Subtle)

"The consciousness is timeless, has no beginning, no end, weapons cannot cut it, air cannot dry it, water cannot wet it and fire cannot burn it." (*Bhagavad Gita 2.23, 24*).

Each one of us has a physical profile (as defined by our height, complexion, collar number, waist size, etc.) as well as a mental or ego profile. A few examples of ego profile are my bank balance, car, job designation, locality of residence, size of house, contacts, power, clothes', etc.

Similarly, each one of us also has a soul profile. We should give sometime to ourselves for knowing our soul profile and revisit it at least once in a week.

According to Deepak Chopra, to know the soul profile one should ask seven questions to his or her consciousness while sitting in a meditating pose or in state of relaxation. The answer to each question should be either in three words or three phrases.

- What is my purpose of life?
- What is my contribution going to be for my friends and family?
- Three instances in my life when I had my peak experiences.
- Names of three people who inspire me the most.
- Three qualities which I admire in others the most.
- Three of my unique talents.
- Three qualities I best express in my relationship.

These 21 answers will characterize your soul profile or will be your passport for every action you perform in your life.

In day-to-day's life, one should act from the soul profile and not from the ego profile. Soul profile cannot be manipulated while the ego profile can be.

There are only three ways of improving one's soul profile and these are:

- The choices one makes should be soul-profile oriented and not ego-profile oriented. Whenever there is an opportunity for an action, ask the head for choices, then ask the heart to choose one, and finally order the hand to take action. A soul-based action is the one which is based on the truth, is necessary, and which makes the person and the people around him or her, both happy.
- Total clarity of vision of "What do I want" and also "What I don't want".
- Learn to enter into discontinuity of thought processes using "beej mantra" or doing primordial sound meditation 20 minutes in the morning and 20 minutes in the evening.

These can also be equated to the eight limbs of Yoga Sutras of Patanjali, where the "choices I make" represents Yama and Niyama, "what do I want" represents Dharma and the "entering into discontinuity" represents Dhyana and Samadhi.

Group Editor-in-Chief, IJCP Group

■■■■

Rule of 4

- At 4 years, 40% of patients with untreated prehypertension develop hypertension. Treating prehypertension reduces the chances of developing hypertension by 16% (4×4).
- Patients with diabetes and pre hypertension are at 4 times risk of developing heart disease.
- First BP should be checked at the age of 4.

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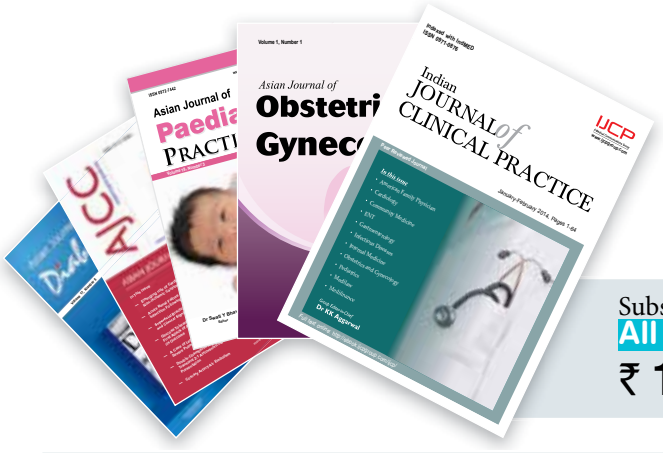

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Lighter Side of Medicine

HUMOR

A NICE BOY?

One night a teenage girl brought her new boyfriend home to meet her parents, and they were appalled by his appearance: leather jacket, motorcycle boots, tattoos and pierced nose.

Later, the parents pulled their daughter aside and confessed their concern. "Dear," said the mother diplomatically, "he doesn't seem very nice."

"Oh please, Mom," replied the daughter, "if he wasn't nice, why would he be doing 500 hours of community service?"

VIRUSES

Coming to a hard drive near you, the worst computer viruses yet:

- AT&T Virus: Every 3 minutes it tells you what great service you're getting.
- Government Economist Virus: Nothing works, but all your diagnostic software says everything is fine.
- Politically Correct Virus: Never calls itself a "virus." Instead, it's an "electronic microorganism."
- Government Spokesman Virus: Nothing works but all your diagnostic software says everything is fine.
- Right to Life Virus: Won't allow you to delete a file, regardless of how old it is. If you attempt to erase a file, it requires you to first see a counselor about possible alternatives.

COMPUTER POWER

The businessman dragged himself home and barely made it to his chair before he dropped, exhausted.

His sympathetic wife was right there with a tall cool drink and a comforting word.

"My, you look tired," she said. "You must have had a hard day today. What happened to make you so exhausted?"

"It was terrible," her husband said, "The computer broke down and all of us had to do our own thinking."

SALES PRACTICE

The out-of-work newlywed took a temporary job as a vacuum cleaner salesman to make ends meet. After 3 days of intensive training, the sales manager told him to go home and practice his pitch on his wife.

The next morning, the manager asked the novice how he made out.

"Well," the man began, "I did what you said, and after I finished, I asked her if she would buy the vacuum cleaner from me. She said 'Yes.' Then I asked her 'Why?' She replied, 'Because I love you.'"

TELL HIM I CAN'T SEE HIM

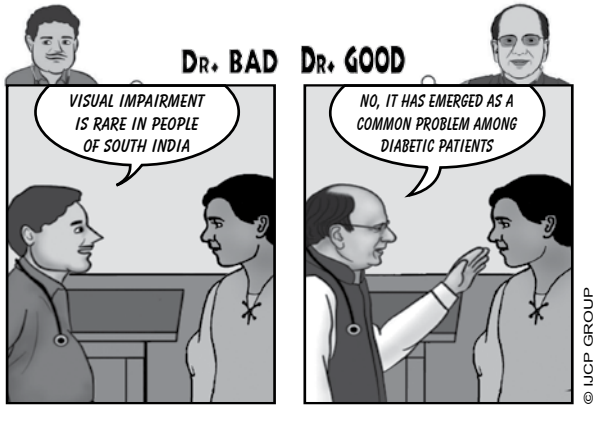
While he was talking to me, his nurse came in and said,

"Doctor, there is a man here who thinks he's invisible."

The doctor said, "Tell him I can't see him."

Dr. Good and Dr. Bad

SITUATION: A type 2 diabetic male from South India complained of visual impairment.



LESSON: According to a recent study conducted on the South Indian population, visual impairment appears to be a major problem among diabetic individuals. Refractive error and cataract are the leading but treatable causes of incident visual impairment in this population.

Indian J Ophthalmol. 2017;65(7):589-95.

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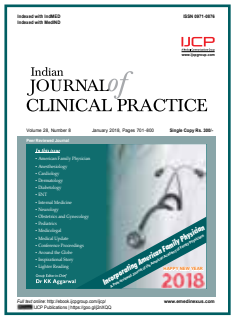
CLINICAL PRACTICE



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The Medical Council of India (UGC, ICI)

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If you have any Views, Breaking news/article/research or a rare and interesting case report that you would like to share with more than 3 lakh doctors send us your article for publication in IJCP at editorial@ijcp.com.

Dr KK Aggarwal
Padma Shri Awardee
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Manuscripts should be prepared in accordance with the 'Uniform requirements for manuscripts submitted to biomedical journals' compiled by the International Committee of Medical Journal Editors (Ann. Intern. Med. 1992;96: 766-767).

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The boxed checklist will help authors in preparing their manuscript according to our requirements. Improperly prepared manuscripts may be returned to the author without review. The checklist should accompany each manuscript.

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- The covering letter should explain if there is any deviation from the standard IMRAD format (Introduction, Methods, Results and Discussion) and should outline the importance of the paper.
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Summary

- The summary of not more than 200 words. It must convey the essential features of the paper.
- It should not contain abbreviations, footnotes or references.

Introduction

- The introduction should state why the study was carried out and what were its specific aims/objectives.

Methods

- These should be described in sufficient detail to permit evaluation and duplication of the work by others.
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The following information should be given:

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Results

- These should be concise and include only the tables and figures necessary to enhance the understanding of the text.

Discussion

– This should consist of a review of the literature and relate the major findings of the article to other publications on the subject. The particular relevance of the results to healthcare in India should be stressed, e.g., practicality and cost.

References

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Examples of common forms of references are:

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Paintal AS. Impulses in vagal afferent fibres from specific pulmonary deflation receptors. The response of those receptors to phenylguanide, potato S-hydroxytryptamine and their role in respiratory and cardiovascular reflexes. Q. J. Expt. Physiol. 1955;40:89-111.

Books

Stansfield AG. Lymph Node Biopsy Interpretation Churchill Livingstone, New York 1985.

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