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Mens Rea and Undisclosed Knowledge are Essential to Establish Criminal Negligence

A WhatsApp message has been circulating that Supreme Court has said that criminal charges are not applicable to doctors. The judgment is of 2012 and not new.

It is a settled law that unless a criminal intent is proved (*mens rea*) or there is an element of undisclosed knowledge, criminal sections are not applicable to doctors.

Here are some salient excerpts from the said judgment.

In the matter titled as **"CBI, Hyderabad versus K. Narayana Rao, Criminal Appeal No. 1460 of 2012, the Hon'ble Supreme Court of India** vide judgment dated 21.09.2012 has dealt with the main question whether the panel lawyer of the bank has committed any offence by giving false legal opinion on the basis of the documents provided to him by the bank. After hearing the case and after analyzing all materials and documents on record, the Hon'ble Supreme Court held that the panel lawyer of the Bank has not committed any fraud as he has given his legal opinion on the basis of the documents provided to him by the bank.

Nowhere in the judgment, it has been held that criminal charges are not applicable to doctors. The judgment only takes reference of the law laid down by the Hon'ble Supreme Court in the matter titled as "Jacob Mathew versus State of Punjab, (2005) 6 SCC 1 wherein it has been held that:

> *"To determine whether the person charged has been negligent or not, he has to be judged like an ordinary competent person exercising ordinary skill in that profession. It is not necessary for every professional to possess the highest level of expertise in that branch which he practices."*

In the judgment, the Hon'ble Supreme Court has only held that **no professional can given guarantee to his/her client and a professional may be held liable for negligence on one of the two findings**, viz., either he was not possessed of the requisite skill which he professed to have possessed, or, he did not exercise, with reasonable competence in the given case, the skill which he did possess. The relevant paragraph of the judgment is reproduced hereunder:

> *"23) A lawyer does not tell his client that he shall win the case in all circumstances. Likewise a physician would not assure the patient of full recovery in every case. A surgeon cannot and does not guarantee that the result of surgery would invariably be beneficial, much less to the extent of 100% for the person operated on. The only assurance which such a professional can give or can be given by implication is that he is possessed of the requisite skill in that branch of profession which he is practicing and while undertaking the performance of the task entrusted to him, he would be exercising his skill with reasonable competence. This is what the person approaching the professional can expect. Judged by this standard, a professional may be held liable for negligence on one of the two findings, viz., either he was not possessed of the requisite skill which he professed to have possessed, or, he did not*

exercise, with reasonable competence in the given case, the skill which he did possess."

FACTS OF THE CASE

(a) According to the prosecution, basing on an information, on 30.11.2005, the CBI, Hyderabad registered an FIR being RC 32(A)/2005 against Shri P. Radha Gopal Reddy (A-1) and Shri Udaya Sankar (A-2), the then Branch Manager and the Assistant Manager, respectively of the Vijaya Bank, Narayanaguda Branch, Hyderabad, for the commission of offence punishable under Sections 120-B, 419, 420, 467, 468, 471 read with Section 109 of the Indian Penal Code, 1860 (in short 'the IPC') and Section 13(2) read with Section 13(1)(d) of the Prevention of Corruption Act, 1988 for abusing their official position as public servants and for having conspired with private individuals, viz., Shri P.Y. Kondala Rao – the builder (A-3) and Shri N.S. Sanjeeva Rao (A-4) and other unknown persons for defrauding the bank by sanctioning and disbursement of housing loans to 22 borrowers in violation of the Bank's rules and guidelines and thereby caused wrongful loss of Rs. 1.27 crores to the Bank and corresponding gain for themselves. In furtherance of the said conspiracy, A-2 conducted the pre-sanction inspection in respect of 22 housing loans and A-1 sanctioned the same.

(b) After completion of the investigation, the CBI filed charge sheet along with the list of witnesses and the list of documents against all the accused persons. **In the said charge sheet, Shri K. Narayana Rao, the respondent herein, who is a legal practitioner and a panel advocate for the Vijaya Bank, was also arrayed as A-6. The duty of the respondent herein as a panel advocate was to verify the documents and to give legal opinion. The allegation against him is that he gave false legal opinion in respect of 10 housing loans.** It has been specifically alleged in the charge sheet that the respondent herein (A-6) and Mr. K.C. Ramdas (A-7)-the valuer have failed to point out the actual ownership of the properties and to bring out the ownership details and name of the apartments in their reports and also the falsity in the permissions for construction issued by the Municipal Authorities.

(c) Being aggrieved, the respondent herein (A-6) filed a petition being Criminal Petition No. 2347 of 2008 under Section 482 of the Code before the High Court of Andhra Pradesh at Hyderabad for quashing of the criminal proceedings in CC No. 44 of 2007 on the file of the Special Judge for CBI Cases, Hyderabad. By impugned judgment and order dated 09.07.2010, the High Court quashed the proceedings insofar as the respondent herein (A-6) is concerned.

(d) Being aggrieved, the CBI, Hyderabad filed this appeal by way of special leave.

JUDGMENT OF THE HON'BLE SUPREME COURT

"16) We have already extracted the relevant allegations and the role of the respondent herein (A-6). The only allegation against the respondent is that he submitted false legal opinion to the Bank in respect of the housing loans in the capacity of a panel advocate and did not point out actual ownership of the properties. As rightly pointed out by Mr. Venkataramani, learned senior counsel for the respondent, the respondent was not named in the FIR. The allegations in the FIR are that A-1 to A-4 conspired together and cheated Vijaya Bank, Narayanaguda, Hyderabad to the tune of Rs. 1.27 crores. It is further seen that the offences alleged against A-1 to A-4 are the offences punishable under Sections 120B, 419, 420, 467, 468 and 471 of IPC and Section 13(2) read with Section 13 (1)(d) of the Prevention of Corruption Act, 1988. It is not in dispute that the respondent is a practicing advocate and according to Mr. Venkataramani, he has experience in giving legal opinion and has conducted several cases for the banks including Vijaya Bank. As stated earlier, the only allegation against him is that he submitted false legal opinion about the genuineness of the properties in question. It is the definite stand of the respondent herein that he has rendered Legal Scrutiny Reports in all the cases after perusing the documents submitted by the Bank. It is also his claim that rendition of legal opinion cannot be construed as an offence. He further pointed out that it is not possible for the panel advocate to investigate the genuineness of the documents and in the present case, he only perused the contents and concluded whether the title was conveyed through a document or not. It is also brought to our notice that LW-5 (Listed Witness), who is the Law Officer of Vijaya Bank, has given a statement regarding flaw in respect of title of several properties. It is the claim of the respondent that in his statement, LW-5 has not even made a single comment as to the veracity of the legal opinion rendered by the respondent herein. In other words, it is the claim of the respondent that none of the witnesses have spoken to any overt act on his part or his involvement in the alleged conspiracy. Learned senior counsel for the respondent has also pointed out that out of 78 witnesses no one has made any relevant

comment or statement about the alleged involvement of the respondent herein in the matter in question.

17)…The above particulars show that the respondent herein, as a panel advocate, verified the documents supplied by the Bank and rendered his opinion. It also shows that he was furnished with Xerox copies of the documents and very few original documents as well as Xerox copies of Death Certificate, Legal heirship Certificate, Encumbrance Certificate for his perusal and opinion. It is his definite claim that he perused those documents and only after that he rendered his opinion. He also advised the bank to obtain Encumbrance Certificate for the period from 21.04.2003 till date. It is pointed out that in the same way, he furnished Legal Scrutiny Reports in respect of other cases also.

22) The High Court while quashing the criminal proceedings in respect of the respondent herein has gone into the allegations in the charge sheet and the materials placed for his scrutiny and arrived at a conclusion that the same does not disclose any criminal offence committed by him. It also concluded that there is no material to show that the respondent herein joined hands with A-1 to A-3 for giving false opinion. In the absence of direct material, he cannot be implicated as one of the conspirators of the offence punishable under Section 420 read with Section 109 of IPC. The High Court has also opined that even after critically examining the entire material, it does not disclose any criminal offence committed by him. Though as pointed out earlier, a roving enquiry is not needed, however, it is the duty of the Court to find out whether any prima facie material available against the person who has charged with an offence under Section 420 read with Section 109 of IPC. In the banking sector in particular, rendering of legal opinion for granting of loans has become an important component of an advocate's work. In the law of negligence, professionals such as lawyers, doctors, architects and others are included in the category of persons professing some special skills.

23) A lawyer does not tell his client that he shall win the case in all circumstances. Likewise a physician would not assure the patient of full recovery in every case. A surgeon cannot and does not guarantee that the result of surgery would invariably be beneficial, much less to the extent of 100% for the person operated on. The only assurance which such a professional can give or can be given by implication is that he is possessed of the requisite skill in that branch of profession which he is practicing and while undertaking the performance of the task entrusted to him, he would be exercising his skill with reasonable competence. This is what the person approaching the professional can expect. Judged by this standard, a professional may be held liable for negligence on one of the two findings, viz., either he was not possessed of the requisite skill which he professed to have possessed, or, he did not exercise, with reasonable competence in the given case, the skill which he did possess.

24) In Jacob Mathew vs. State of Punjab & Anr. (2005) 6 SCC 1 this court laid down the standard to be applied for judging. To determine whether the person charged has been negligent or not, he has to be judged like an ordinary competent person exercising ordinary skill in that profession. It is not necessary for every professional to possess the highest level of expertise in that branch which he practices.

25) In Pandurang Dattatraya Khandekar vs. Bar Council of Maharashtra & Ors. (1984) 2 SCC556, this Court held that "…there is a world of difference between the giving of improper legal advice and the giving of wrong legal advice. Mere negligence unaccompanied by any moral delinquency on the part of a legal practitioner in the exercise of his profession does not amount to professional misconduct.

26) Therefore, the liability against an opining advocate arises only when the lawyer was an active participant in a plan to defraud the Bank. In the given case, there is no evidence to prove that A-6 was abetting or aiding the original conspirators.

27) However, it is beyond doubt that a lawyer owes an "unremitting loyalty" to the interests of the client and it is the lawyer's responsibility to act in a manner that would best advance the interest of the client. Merely because his opinion may not be acceptable, he cannot be mulcted with the criminal prosecution, particularly, in the absence of tangible evidence that he associated with other conspirators. At the most, he may be liable for gross negligence or professional misconduct if it is established by acceptable evidence and cannot be charged for the offence under Sections 420 and 109 of IPC along with other conspirators without proper and acceptable link between them. It is further made clear that if there is a link or evidence to connect him with the other conspirators for causing loss to the institution, undoubtedly, the prosecuting authorities are entitled to proceed under criminal prosecution. Such tangible materials are lacking in the case of the respondent herein.

28) In the light of the above discussion and after analyzing all the materials, we are satisfied that there is no prima facie case for proceeding in respect of the charges alleged insofar as respondent herein is concerned. We agree with the conclusion of the High Court in quashing the criminal proceedings and reject the stand taken by the CBI.

29) In the light of what is stated above, the appeal fails and the same is dismissed."

AMERICAN FAMILY PHYSICIAN

Nonoperative Management of Cervical Radiculopathy

MARC A. CHILDRESS, BLAIR A. BECKER

ABSTRACT

Cervical radiculopathy describes pain in one or both of the upper extremities, often in the setting of neck pain, secondary to compression or irritation of nerve roots in the cervical spine. It can be accompanied by motor, sensory, or reflex deficits and is most prevalent in persons 50 to 54 years of age. Cervical radiculopathy most often stems from degenerative disease in the cervical spine. The most common examination findings are painful neck movements and muscle spasm. Diminished deep tendon reflexes, particularly of the triceps, are the most common neurologic finding. The Spurling test, shoulder abduction test, and upper limb tension test can be used to confirm the diagnosis. Imaging is not required unless there is a history of trauma, persistent symptoms, or red flags for malignancy, myelopathy, or abscess. Electrodiagnostic testing is not needed if the diagnosis is clear, but has clinical utility when peripheral neuropathy of the upper extremity is a likely alternate diagnosis. Patients should be reassured that most cases will resolve regardless of the type of treatment. Nonoperative treatment includes physical therapy involving strengthening, stretching, and potentially traction, as well as nonsteroidal anti-inflammatory drugs, muscle relaxants, and massage. Epidural steroid injections may be helpful but have higher risks of serious complications. In patients with red flag symptoms or persistent symptoms after four to six weeks of treatment, magnetic resonance imaging can identify pathology amenable to epidural steroid injections or surgery.

Keywords: Cervical radiculopathy, spondylosis, disk herniation, degenerative arthritis, radicular pain

Cervical radiculopathy describes pain in one or both of the upper extremities, often in the setting of neck pain, secondary to compression or irritation of nerve roots in the cervical spine. It can be accompanied by motor, sensory, or reflex deficits.[1] The annual incidence is 107 per 100,000 men, and 64 per 100,000 women. It is most prevalent in persons 50 to 54 years of age.[2]

The underlying pathology is typically degenerative, including spondylosis and disk herniation.[2] Osteoarthritis in these conditions causes bony hypertrophy, most commonly at the facet joints or uncovertebral joints.[3] In 22% of cases, nerve compression occurs as a result of disk herniation.[2] Nerve impingement occurs more rarely with trauma.

ANATOMY

The cervical nerve roots exit the spine laterally through neural foramina. Each foramen is bordered by joints that are prone to degenerative arthritis, or spondylosis (Figure 1). Anterior to the foramen is the uncovertebral joint, and posterior to the foramen is the facet joint.

The intervertebral disk lies anterior and medial to the neural foramen, and in the setting of herniation, can protrude onto the exiting nerve root. Trauma can lead to instability that injures the nerve root proximally as well.[3]

In a feature unique to the cervical spine, each nerve root from C1 to C7 exits above its corresponding vertebral

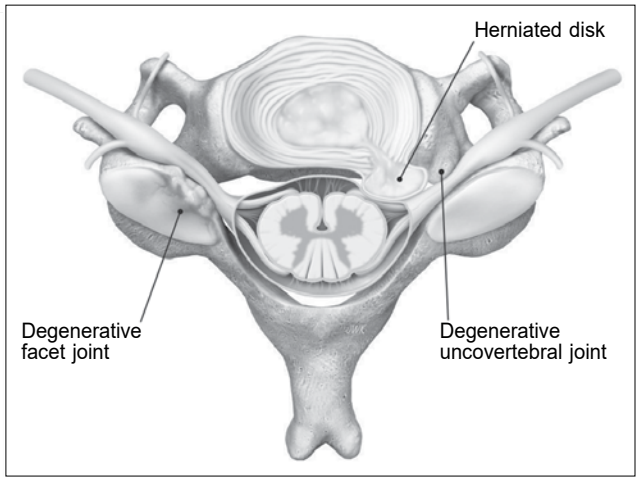

ILLUSTRATION BY JOHN KARAPELOU

Figure 1. Cervical spine anatomy. Cervical nerve root impingement commonly results from bony hypertrophy at the uncovertebral joint or the facet joint, or from disk herniation.

MARC A. CHILDRESS, MD, is the associate director of the Primary Care Sports Medicine Fellowship at Virginia Commonwealth University Fairfax Family Practice.

BLAIR A. BECKER, MD, is a faculty physician at the Group Health Family Medicine Residency, Seattle, Wash.

Source: Adapted from Am Fam Physician. 2016;93(9):746-754.

level. The exception is the C8 nerve root, which exits below the seventh vertebra. The motor portion of the cervical nerves (ventral nerve root) exits the spinal cord anteriorly, whereas the sensory portion (dorsal nerve root) exits posteriorly before forming the dorsal root ganglion and joining the ventral nerve root to form a mixed spinal nerve.

Spondylosis Types

Spondylosis leading to radiculopathy can occur at the uncovertebral and facet joints. The uncovertebral joint's location anterior to the nerve root means that bony hypertrophy here tends to affect the anterior aspect of the nerve root. Conversely, facet joint arthritis affects the posterior aspect of the nerve root. Degenerative loss of disk height and resulting arthritic hypertrophy can also decrease the diameter of the neural foramen and can contribute to nerve root impingement.[3]

Disk Herniation Types

There are three main types of disk herniation that lead to nerve root impingement (Figure 2). The most common is intraforaminal, which results in predominantly sensory radicular symptoms. The next most common is posterolateral, which results in weakness and potentially muscle atrophy. Rarer midline herniations directly compress the spinal cord and result in symptoms of myelopathy, such as upper extremity numbness, weakness, gait disturbance, ataxia, and urinary incontinence.[4]

HISTORY

Radicular pain is the most common symptom in cervical radiculopathy, followed by paresthesia. Weakness is reported by about 15% of patients.[2] The distribution of numbness should be noted. In most cases, the affected nerve root can be identified by the history and physical examination alone[5] (Figure 3). Some patients also report pain that radiates to the posterior shoulder and periscapular region, which is relatively nonspecific.[3] Patients may report worsening of symptoms with neck extension or lateral flexion to the affected side.

The patient should be asked about red flag signs and symptoms of myelopathy, malignancy, and spinal abscess that require immediate workup (Table 1).

PHYSICAL EXAMINATION

The most common physical examination findings in persons with cervical radiculopathy are painful neck movements and muscle spasm. Diminished deep tendon reflex is the most common objective neurologic finding, with triceps involvement being the most prevalent. Weakness is the next most common finding.[2] The most common nerve root affected is C7, followed by C6.[2,6,7]

Knowledge of cervical myotomes and dermatomes is helpful (Table 2[8]), but radicular pain may manifest outside classic dermatomal borders.[4]

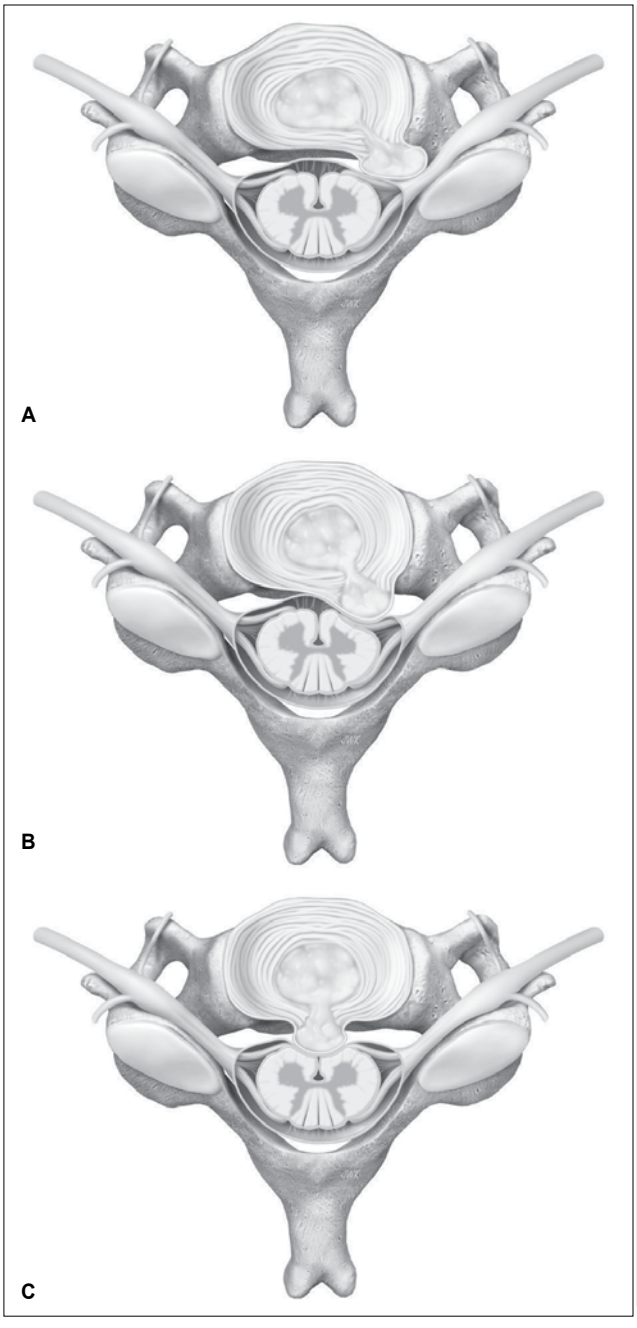

Figure 2. Disk herniation types. (**A**) Intraforaminal. (**B**) Posterolateral. (**C**) Midline.

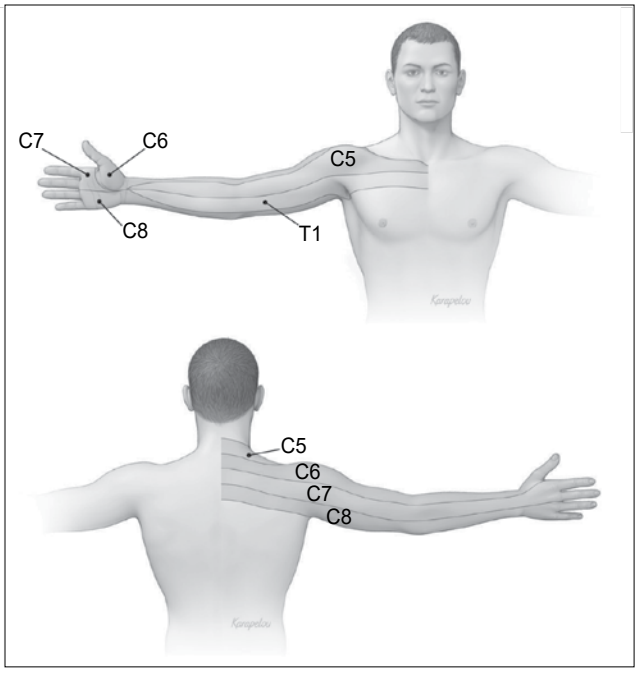

Figure 3. Relevant cervical dermatomes. Sensory symptoms often correlate with specific dermatomes.

Figure 4. Spurling maneuver. Lateral flexion and extension of the neck with axial compression.

Table 1. Red Flags in the Evaluation of Radicular Neck Pain

Condition	Historic findings	Examination findings
Malignancy	Fever, history of cancer, night pain, weight loss	Variable, gait abnormality; unilateral neurologic findings more common than bilateral
Myelopathy	Decreased dexterity, urinary urgency	Ataxia, clonus, hyperreflexia
Spinal abscess	Fever, history of intravenous drug use, immunocompromise	Neurologic deficit

Provocative Maneuvers

The Spurling test is a highly specific[7,9-11] and sensitive[11,12] manoeuvre validated by operative, magnetic resonance imaging (MRI), and electrodiagnostic findings. It involves passively moving the patient's neck into lateral flexion and extension, then applying gentle downward axial compression (Figure 4). The purpose of this maneuver is to constrict the neural foramen; a positive result is the reproduction of radicular symptoms.

The shoulder abduction test is similar in specificity to the Spurling test, based on electrodiagnostic correlation.[7] The test involves placing the palm of the affected limb on top of the patient's head. A positive result is the relief of radicular symptoms.

The more complicated upper limb tension test is less commonly used, but is the most sensitive test for ruling out cervical radiculopathy[7,10,12] (Figure 5). The maneuver can be thought of as a cervical nerve tension analog to the straight leg raise test for the lumbar spine. It consists of initially placing the patient in a supine position with the shoulder in a neutral position and the elbow and wrist flexed. The examiner then abducts the shoulder to 90 degrees, extends the elbow and fingers, and extends and supinates the wrist while the patient deviates the neck to the contralateral and then ipsilateral sides. A positive result is reproduction of pain at any step of the maneuver.

There have been reports that the Valsalva maneuver may provoke radicular symptoms, but the sensitivity and specificity of this test are not known.[3]

OTHER CAUSES OF CERVICAL NERVE ROOT IMPINGEMENT

Other causes of nerve root impingement often present with a unique constellation of symptoms (Table 3). Spinal tumors most often cause myelopathy, although osteochondromas and schwannomas can cause radiculopathy. Because these lesions tend to occur within the dura mater, the Valsalva maneuver can exacerbate symptoms. Tumors stemming from thyroid, esophageal, pharyngeal, and lung tissue have been reported to compress individual cervical nerves distal to the neural foramen, as have sarcoidosis and arteriovenous malformations.[3]

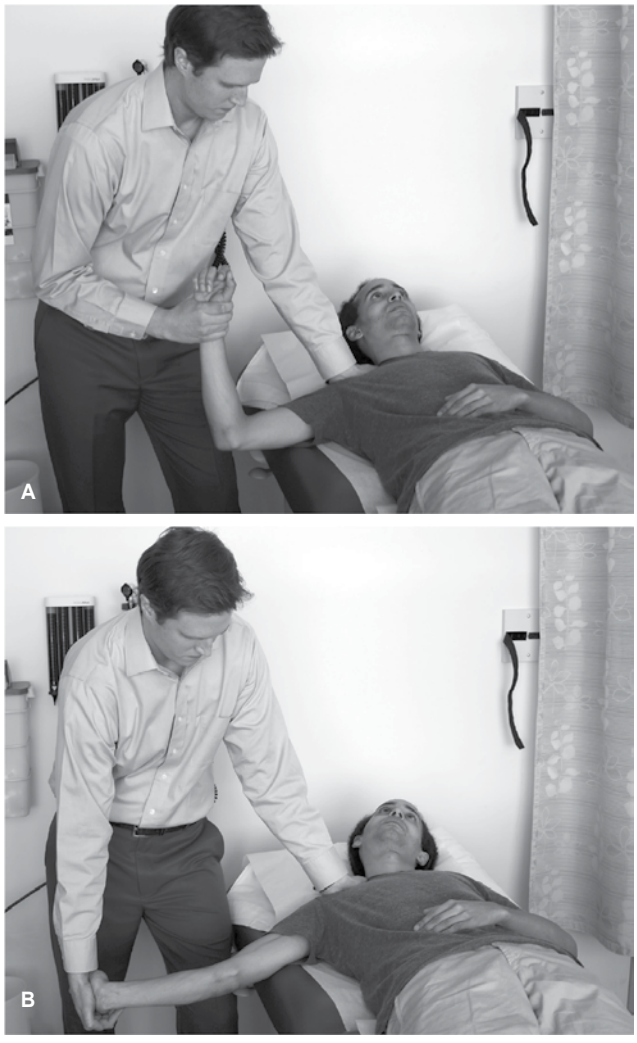

Figure 5. Upper limb tension test. (**A**) Scapular depression with shoulder abduction. (**B**) Contralateral flexion of the neck with extension of the elbow, wrist, and fingers, and supination of the wrist.

IMAGING

Radiography

Although plain radiographs of the cervical spine are useful for ruling out instability (Figure 6), they are relatively nonspecific for diagnosing cervical radiculopathy. About 65% of asymptomatic patients 50 to 59 years of age will have radiographic evidence of significant cervical spine degeneration, regardless of radiculopathy symptoms.[13] C5 to C6 is the most common level affected, followed closely by C6 to C7. Plain radiography should be ordered if there is a history of trauma, red flags for malignancy, or failure to improve at four to six weeks. The series should include an oblique view, which can sometimes reveal bony hypertrophy at the neural foramina.

MRI

MRI is indicated in patients with complex cervical radiculopathy (Figure 7), which is defined by a high suspicion for myelopathy or abscess, persistent or progressive objective neurologic findings, or failure to improve after four to six weeks of conservative treatment.[1,14-18] MRI is not helpful in most cases of cervical radiculopathy because of its significant rates of false-negative and false-positive findings. About 57% of patients older than 64 years who do not have symptoms of cervical radiculopathy have evidence of disk herniation, and 26% have spinal cord impingement.[19]

Computed Tomographic Myelography

MRI has mostly supplanted computed tomographic myelography as the first-line imaging modality for complex cervical radiculopathy.[14] However, computed tomographic myelography remains the test of choice to clarify clinically apparent nerve root impingement in patients with equivocal MRI findings.[14,20]

ELECTRODIAGNOSTIC TESTING

There is insufficient evidence to support the routine use of electrodiagnostic testing in the workup of cervical radiculopathy.[1] Electromyelography does, however, have clinical utility when peripheral neuropathy of the upper extremity is a likely alternate diagnosis. It can be challenging to differentiate proximal from distal nerve root impingement, but a working knowledge of common peripheral neuropathies is useful (Table 4).

NONOPERATIVE TREATMENT

Most patients with cervical radiculopathy will improve with nonoperative care[2,15] (Figure 8). However, no treatment modalities are supported by evidence from high-quality studies.

Physical Therapy

A Cochrane review found low-quality evidence to support cervical, shoulder, scapulothoracic, and upper arm strengthening and stretching in the acute phase for treatment of radicular pain.[16,17] A randomized controlled trial (RCT) showed significant improvement in patients receiving twice-weekly supervised physical therapy and home physical therapy compared with control patients in the first six weeks of cervical radiculopathy.[18] Several cohort studies and randomized trials drew similar conclusions.[21,22]

Table 3. Differential Diagnosis for Cervical Radiculopathy

Condition	Key clinical feature	Diagnostic evaluation
Abscess	Fever, neurologic deficit, pain	Blood cultures, complete blood count, erythrocyte sedimentation rate, MRI
Anterior interosseus nerve entrapment	Grip and pinch weakness, no pain	EMG
Arteriovenous malformation	Numbness, paresthesias, variable pain, weakness	MRI, ultrasonography
Carpal tunnel syndrome	Numbness in radial 3½ fingers, paresthesias, thenar weakness	Hand symptom diagram, Tinel and Phalen tests with or without EMG
Cervical myelopathy	Ataxia, decreased dexterity, urinary urgency	MRI, tests for clonus and hyperreflexia
Cubital tunnel syndrome	Flexor digitorum profundus weakness, numbness in ulnar half of ring and little fingers, paresthesias	Tinel test with or without EMG
Extraspinal malignancy (e.g., thyroid, esophageal, pharyngeal, or Pancoast tumor)	Variable	Variable
Herpes zoster	Vesicular rash	Viral culture
Parsonage-Turner syndrome (brachial plexopathy)	Acute onset of pain, then numbness and weakness	EMG with or without MRI
Posterior interosseus nerve entrapment	Finger and wrist weakness, pain	EMG with or without MRI
Radial tunnel syndrome	Pain only at the radial forearm	Diagnostic injection
Reflex sympathetic dystrophy	Edema, pain, skin discoloration	Bone scintigraphy
Rotator cuff tendinosis	Shoulder pain with potential radiation to arm	Ultrasonography
Thoracic outlet syndrome	Pain, swelling, vascular insufficiency	Adson, Roos, and Wright tests with or without angiography
Tumor	Fever, gait abnormality, pain, paresthesias, weakness, weight loss	MRI

EMG = Electromyography; MRI = Magnetic resonance imaging.

Traction

Many physical therapy regimens for cervical radiculopathy include mechanical traction. Based on low-quality evidence, several systematic reviews and RCTs have concluded that traction is no better than placebo.[23-28] A more recent RCT found that 10 sessions of supervised mechanical traction over four weeks, in addition to physical therapy, were superior to physical therapy alone at six and 12 months.[29] There was also significant improvement at 12 months in a group treated with four weeks of physical therapy and home over-the-door traction. Two other studies reached similar conclusions.[30,31]

Soft Collar

Although one study found superior gains in function with a semi-hard collar compared with physical therapy and placebo, a systematic review and several RCTs found little improvement in pain with the use of soft and semi-hard collars for cervical radiculopathy.[24,27,31]

Figure 6. Cervical radiography, oblique view. Bony intervertebral foraminal stenosis at the left C3-C4 level caused by uncovertebral osteophyte and facet joint hypertrophy.

IJCP SUTRA 86: *Avoid radiation.* It is better to avoid frequent or long-term exposure to prevent any form of cancer. See if another imaging method, like MRI, can be used for evaluation instead, because CT scans pack about 500 times the radiation of X-rays.

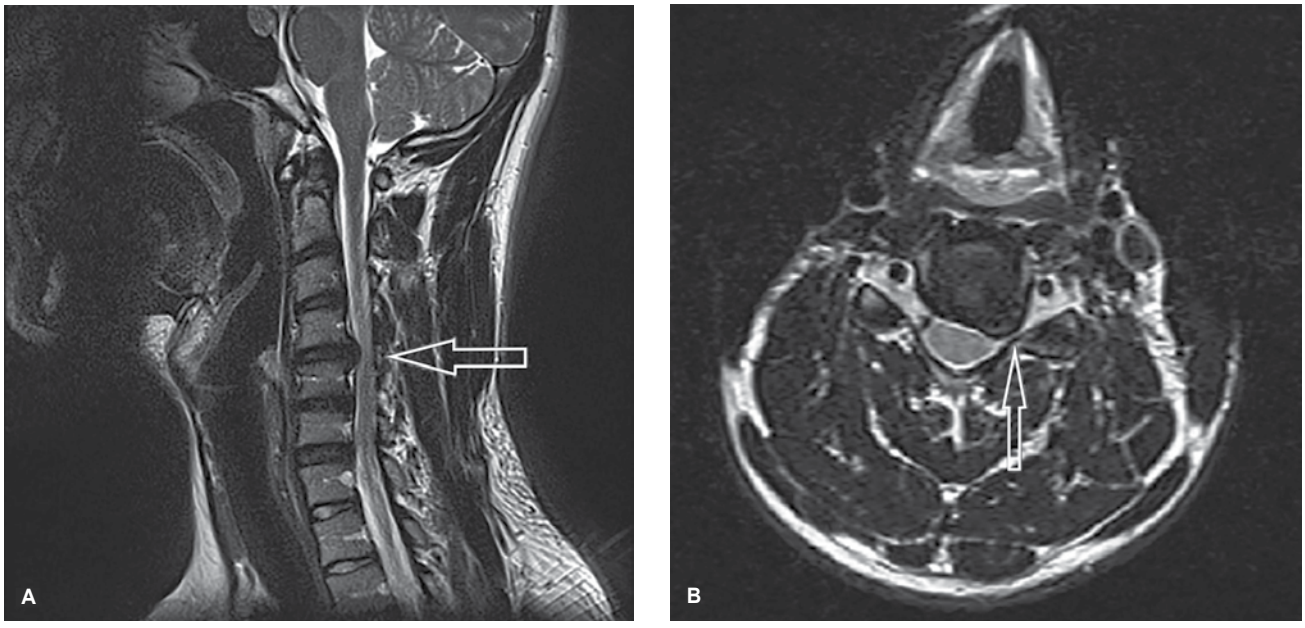

Figure 7. T2-weighted cervical magnetic resonance imaging. (**A**) Sagittal view of a large paracentral/foraminal disk protrusion at the C4-C5 level indenting the anterior the cal sac and flattening the anterior surface of the cord. (**B**) Axial view of the same lesion. The disk protrusion caused severe left intervertebral foraminal stenosis and compressed the left C5 nerve within the foramen.

Table 4. Differentiating Common Peripheral and Cervical Nerve Root Compressions

Condition	Affected nerve	Signs and symptoms	Cervical nerve root mimicker	Distinguishing feature
Carpal tunnel syndrome	Median	Paresthesias, thenar weakness, numbness in radial 3½ fingers	C6, C7	No triceps or wrist extensor weakness in carpal tunnel syndrome
Cubital tunnel syndrome	Ulnar	Paresthesias, grasp weakness, numbness in ulnar half of ring and little fingers	C8, T1	No thumb interphalangeal flexion weakness in cubital tunnel syndrome
Posterior interosseus nerve entrapment	Peripheral interosseus nerve branch of the radial nerve	Pain, wrist and finger extensor weakness	C7	No triceps or wrist flexor weakness in posterior interosseus nerve entrapment

Massage

A Cochrane review of 15 trials that included studies on neck pain with and without radiculopathy found low-quality evidence to support the use of classical, modified strain/counterstrain, and traditional Chinese massages for the improvement of pain and function compared with placebo or education alone.[32] Further studies are needed to establish the benefit of these treatments.

Oral Medications

Nonsteroidal anti-inflammatory drugs and muscle relaxants are often prescribed for treatment of acute cervical radiculopathy. A Cochrane review concluded that there is limited evidence to support the use of these agents in the setting of acute neck pain, but did not specifically address radiculopathy.[33] A small RCT found that a short course of oral corticosteroids reduced radiculopathy-related pain in the short term.[34]

Steroid Injection

Steroid injection can be considered for patients whose symptoms persist after four to six weeks of conservative management. A 2007 Cochrane review found low-quality evidence to support the use of epidural steroid injections in patients with chronic cervical radiculopathy.[35] A more recent systematic review found good-quality evidence to support steroid injections for cervical radiculopathy caused by disk herniation, but only fair evidence for radiculopathy caused by spondylosis.[36] An RCT showed significant benefit in

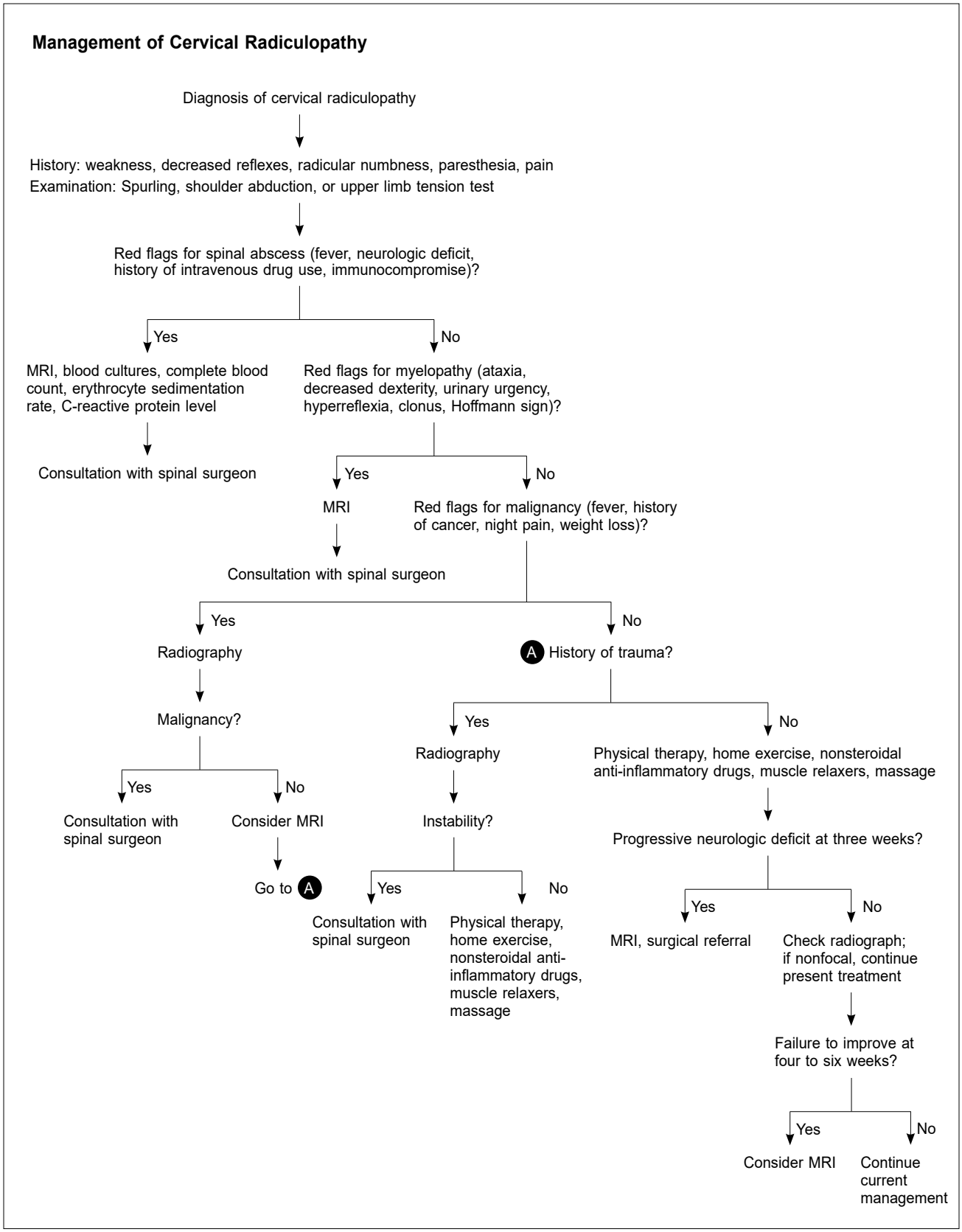

Figure 8. Algorithm for the management of cervical radiculopathy.

MRI = Magnetic resonance imaging.

pain and function with epidural steroid injections for at least one year in patients who had not improved with physical therapy and nonsteroidal anti-inflammatory drugs.[37] Several cohort studies showed significant improvements in recalcitrant radicular pain with epidural steroid injections, in most cases for at least one year.[9,35,38-40] Patients should be counseled about the risk of potential complications, including dural puncture, meningitis, epidural abscess, and nerve root injury.

PROGNOSIS

Most patients with cervical radiculopathy will improve regardless of treatment modality.[2] In fact, roughly 88% will improve within four weeks of nonoperative management.[15] In a retrospective case series, 80% of those with objective weakness or reflex deficit improved within three weeks of conservative management.[41] Repeat examination at follow-up is crucial. Progression of an objective neurologic finding at any point may signify advancing nerve root compression and should trigger an MRI and referral to a spinal surgeon.

The optimal timing for referral in cases of recalcitrant but nonprogressive radiculopathy is not clear. There is evidence to support referral within four to eight weeks.[15,42] Radiography and MRI can be considered if there is no improvement at four to six weeks. If imaging reveals evidence of nerve root impingement that correlates with physical examination findings, referral to a spinal surgeon is recommended.

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

REFERENCES

1. Bono CM, Ghiselli G, Gilbert TJ, et al.; North American Spine Society. An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders. Spine J. 2011;11(1):64-72.
2. Radhakrishnan K, Litchy WJ, O'Fallon WM, Kurland LT. Epidemiology of cervical radiculopathy. A population-based study from Rochester, Minnesota, 1976 through 1990. Brain. 1994;117(pt 2):325-335.
3. Levine MJ, Albert TJ, Smith MD. Cervical radiculopathy: diagnosis and nonoperative management. J Am Acad Orthop Surg. 1996;4(6):305-316.
4. Rothman RH, Marvel JP Jr. The acute cervical disk. Clin Orthop Relat Res. 1975;(109):59-68.
5. Kuijper B, Tans JT, van der Kallen BF, Nollet F, Lycklama A Nijeholt GJ, de Visser M. Root compression on MRI compared with clinical findings in patients with recent onset cervical radiculopathy. J Neurol Neurosurg Psychiatry. 2011;82(5):561-563.
6. Ghasemi M, Golabchi K, Mousavi SA, et al. The value of provocative tests in diagnosis of cervical radiculopathy. J Res Med Sci. 2013;18(suppl 1): S35-S38.
7. Vallée JN, Feydy A, Carlier RY, Mutschler C, Mompoint D, Vallée CA. Chronic cervical radiculopathy: lateral-approach periradicular corticosteroid injection. Radiology. 2001;218(3):886-892.
8. Eubanks JD. Cervical radiculopathy: nonoperative management of neck pain and radicular symptoms. Am Fam Physician. 2010;81(1):33-40.
9. Rubinstein SM, Pool JJ, van Tulder MW, Riphagen II, de Vet HC. A systematic review of the diagnostic accuracy of provocative tests of the neck for diagnosing cervical radiculopathy. Eur Spine J. 2007;16(3):307-319.
10. Shah KC, Rajshekhar V. Reliability of diagnosis of soft cervical disc prolapse using Spurling's test. Br J Neurosurg. 2004;18(5):480-483.
11. Wainner RS, Fritz JM, Irrgang JJ, Boninger ML, Delitto A, Allison S. Reliability and diagnostic accuracy of the clinical examination and patient self-report measures for cervical radiculopathy. Spine (Phila Pa 1976). 2003;28(1):52-62.
12. Shabat S, Leitner Y, David R, Folman Y. The correlation between Spurling test and imaging studies in detecting cervical radiculopathy. J Neuroimaging. 2012;22(4): 375-378.
13. Friedenberg ZB, Miller WT. Degenerative disk disease of the cervical spine. J Bone Joint Surg Am. 1963;45:1171-1178.
14. Modic MT, Masaryk TJ, Ross JS, Mulopulos GP, Bundschuh CV, Bohlman H. Cervical radiculopathy: value of oblique MR imaging. Radiology. 1987;163(1):227-231.
15. Spurling RG, Segerberg LH. Lateral intervertebral disk lesions in the lower cervical region. J Am Med Assoc. 1953;151(5):354-359.
16. Gross A, Kay TM, Paquin JP, et al.; Cervical Overview Group. Exercises for mechanical neck disorders. Cochrane Database Syst Rev. 2015;(1):CD004250.
17. Boyles R, Toy P, Mellon J Jr, Hayes M, Hammer B. Effectiveness of manual physical therapy in the treatment of cervical radiculopathy: a systematic review. J Man Manip Ther. 2011;19(3):135-142.
18. Kuijper B, Tans JT, Beelen A, Nollet F, de Visser M. Cervical collar or physiotherapy versus wait and see policy for recent onset cervical radiculopathy: randomised trial. BMJ. 2009;339:b3883.
19. Teresi LM, Lufkin RB, Reicher MA, et al. Asymptomatic degenerative disk disease and spondylosis of the cervical spine: MR imaging. Radiology. 1987;164(1):83-88.
20. Bartlett RJ, Hill CR, Gardiner E. A comparison of T2 and gadolinium enhanced MRI with CT myelography in cervical radiculopathy. Br J Radiol. 1998;71(841):11-19.
21. Cleland JA, Fritz JM, Whitman JM, Heath R. Predictors of short-term outcome in people with a clinical diagnosis of cervical radiculopathy. Phys Ther. 2007;87(12): 1619-1632.

22. Persson LC, Carlsson CA, Carlsson JY. Long-lasting cervical radicular pain managed with surgery, physiotherapy, or a cervical collar. A prospective, randomized study. Spine (Phila Pa 1976). 1997;22(7):751-758.
23. Thoomes EJ, Scholten-Peeters W, Koes B, Falla D, Verhagen AP. The effectiveness of conservative treatment for patients with cervical radiculopathy: a systematic review. Clin J Pain. 2013;29(12):1073-1086.
24. Graham N, Gross A, Goldsmith CH, et al. Mechanical traction for neck pain with or without radiculopathy. Cochrane Database Syst Rev. 2008;(3):CD006408.
25. van der Heijden GJ, Beurskens AJ, Koes BW, Assendelft WJ, de Vet HC, Bouter LM. The efficacy of traction for back and neck pain: a systematic, blinded review of randomized clinical trial methods. Phys Ther. 1995;75(2):93-104.
26. Young IA, Michener LA, Cleland JA, Aguilera AJ, Snyder AR. Manual therapy, exercise, and traction for patients with cervical radiculopathy: a randomized clinical trial [published corrections appear in Phys Ther. 2009;89(11):1254-1255, and Phys Ther. 2010;90(5):825]. Phys Ther. 2009; 89(7):632-642.
27. Pain in the neck and arm: a multicenter trial of the effects of physiotherapy, arranged by the British Association of Physical Medicine. Br Med J. 1966;1(5482):253-258.
28. Klaber Moffett JA, Hughes GI, Griffiths P. An investigation into the effects of cervical traction. Part 1: clinical effectiveness. Clin Rehabil. 1990;4:205-211.
29. Fritz JM, Thackeray A, Brennan GP, Childs JD. Exercise only, exercise with mechanical traction, or exercise with over-door traction for patients with cervical radiculopathy, with or without consideration of status on a previously described subgrouping rule: a randomized clinical trial. J Orthop Sports Phys Ther. 2014;44(2):45-57.
30. Jellad A, Ben Salah Z, Boudokhane S, Migaou H, Bahri I, Rejeb N. The value of intermittent cervical traction in recent cervical radiculopathy. Ann Phys Rehabil Med. 2009;52(9):638-652.
31. Swezey RL, Swezey AM, Warner K. Efficacy of home cervical traction therapy. Am J Phys Med Rehabil. 1999;78(1):30-32.
32. Patel KC, Gross A, Graham N, et al. Massage for mechanical neck disorders. Cochrane Database Syst Rev. 2012;(9):CD004871.
33. Peloso P, Gross A, Haines T, et al.; Cervical Overview Group. Medicinal and injection therapies for mechanical neck disorders. Cochrane Database Syst Rev. 2007;(3):CD0000319.
34. Ghasemi M, Masaeli A, Rezvani M, Shaygannejad V, Golabchi K, Norouzi R. Oral prednisolone in the treatment of cervical radiculopathy: a randomized placebo controlled trial. J Res Med Sci. 2013;18(suppl 1):S43-S46.
35. Kwon JW, Lee JW, Kim SH, et al. Cervical interlaminar epidural steroid injection for neck pain and cervical radiculopathy: effect and prognostic factors. Skeletal Radiol. 2007;36(5):431-436.
36. Diwan S, Manchikanti L, Benyamin RM, et al. Effectiveness of cervical epidural injections in the management of chronic neck and upper extremity pain. Pain Physician. 2012;15(4):E405-E434.
37. Stav A, Ovadia L, Sternberg A, Kaadan M, Weksler N. Cervical epidural steroid injection for cervicobrachialgia. Acta Anaesthesiol Scand. 1993;37(6):562-566.
38. Bush K, Hillier S. Outcome of cervical radiculopathy treated with periradicular/epidural corticosteroid injections: a prospective study with independent clinical review. Eur Spine J. 1996;5(5):319-325.
39. Castagnera L, Maurette P, Pointillart V, Vital JM, Erny P, Sénégas J. Long-term results of cervical epidural steroid injection with and without morphine in chronic cervical radicular pain. Pain. 1994;58(2):239-243.
40. Cicala RS, Thoni K, Angel JJ. Long-term results of cervical epidural steroid injections. Clin J Pain. 1989; 5(2):143-145.
41. Honet JC, Puri K. Cervical radiculitis: treatment and results in 82 patients. Arch Phys Med Rehabil. 1976;57(1):12-16.
42. Räsänen P, Ohman J, Sintonen H, et al. Cost-utility analysis of routine neurosurgical spinal surgery. J Neurosurg Spine. 2006;5(3):204-209.

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Trans Fats

Formula of 2

- For each increase of 2% of energy from trans fats, the relative risk for incident coronary heart disease was 2 (Nurses' Health Study).
- Limit consumption of trans fats to less than 1% of daily calories (American Heart Association). This means that if you consume 2,000 calories daily, then you should not take more than 2 g trans fats.
- FDA permits writing "0 Trans-Fats" on the food label on foods that contain less than 0.5 g of trans fats per serving.

Trans Fats in Indian Food (100 g)

- 7%: Bhatura, Paratha, Poori, Tikkis
- 5%: French fries

Practice Guidelines

EARLY PEANUT INTRODUCTION AND PREVENTION OF PEANUT ALLERGY IN HIGH-RISK INFANTS: CONSENSUS COMMUNICATION

In westernized countries, 1% to 3% of children have a peanut allergy, with almost 100,000 new cases each year in the United States and United Kingdom. This consensus communication focuses on new data that support introducing peanuts early in infants, and it aims to assist with decisions about introduction; it can be used for guidance while formal guidelines are being developed. The consensus communication is from a variety of organizations, including the American Academy of Allergy, Asthma & Immunology; American Academy of Pediatrics; American College of Allergy, Asthma & Immunology; Australasian Society of Clinical Immunology and Allergy; Canadian Society of Allergy and Clinical Immunology; European Academy of Allergy and Clinical Immunology; Israel Association of Allergy and Clinical Immunology; Japanese Society for Allergology; Society for Pediatric Dermatology; and World Allergy Organization.

Although previous guidelines suggest that there is no need to wait to introduce peanuts until after four to six months of age, they also did not specifically recommend introducing peanuts in high-risk infants between four and six months of age, and certain guidelines state that some high-risk infants should have consultation with an expert before introduction. Recent data suggest that early introduction is safe and effective in selected patients.

LEAP Trial

The LEAP (learning early about peanut allergy) trial, which is the first prospective randomized study regarding early peanut introduction, evaluated 640 infants at high risk living in the United Kingdom. Infants were considered high risk if they did not have a history of egg tolerance, but did have a wheal diameter of at least 6 mm on a skin prick test when exposed to raw hen's egg white; had a wheal diameter of at least 3 mm when exposed to pasteurized hen's egg white, as well as associated allergy symptoms; had severe eczema requiring topical corticosteroids or calcineurin inhibitors that lasted at least 12 of 30 days twice in infants younger than six months or 12 of 30 days twice in the past six months in children older than six months; or scored at least a 40 on the modified SCORAD (scoring atopic dermatitis) evaluation.

The study included infants four to 11 months of age who were randomized to avoid products containing peanuts until five years of age or to eat products containing peanuts at least three times per week. Approximately 17% of infants not consuming peanuts had a peanut allergy by five years of age compared with about 3% of infants consuming peanuts (absolute risk reduction = 14%; number needed to treat = 7.1; relative risk reduction = 80%). The risks associated with introducing peanuts early in life was low, with only seven children in the group that consumed peanuts having reactions during the baseline food challenge, indicating that introducing peanuts early is a safe and reasonable approach. It should be noted that infants with a lower risk were not evaluated in the LEAP trial; therefore, data on early peanut introduction in general or low-risk populations are lacking.

Interim Guidance

In infants at high risk who live in countries with a prevalence of peanut allergies, products containing peanuts should be introduced at four to 11 months of age; waiting any longer can result in an increased risk of allergy. Infants in the LEAP trial who were in the peanut consumption group ate a median of 7.7 g of peanut protein each week in first two years; examples of foods consumed include smooth peanut butter mixed with milk or fruit, Bamba snacks, peanut soup, and ground peanuts mixed with other foods. The LEAP trial did not assess consumption of a different amount of peanut protein, length of treatment needed, or possible risks of discontinuing or intermittently eating peanut products.

Consultation with an allergist or expert in managing allergies may be beneficial in infants who have an atopic disease early in life or egg allergies in the first four to six months; these specialists can assist with diagnosis and determine how appropriate early peanut introduction would be. Skin prick testing, an observed peanut challenge, or both may be evaluation options in this population.

Source: Adapted from Am Fam Physician. 2016;93(1):61-62.

Photo Quiz

SKIN ULCERS OF UNKNOWN ETIOLOGY

A 41-year-old woman presented to the emergency department with leg ulcers and ecchymoses on her ears that began to develop one month prior. The leg ulcers began as painful, fluid-filled blisters and evolved into ulcers with a black crust. The lesions had appeared and resolved several times over the previous three years, but she did not seek medical attention. She took prednisone intermittently for psoriasis and had a long history of cocaine abuse.

Physical examination showed multiple ulcerated lesions on the anterior aspect of both lower extremities (Figure 1) and multiple tender purpuric lesions on both ears (Figure 2). The examination showed psoriatic plaques on her legs, elbows, and fingers. Her vital signs were normal. A complete blood count, comprehensive metabolic panel, and coagulation laboratory test results were normal. Urine toxicology testing was positive for cocaine. She had an elevated C-reactive protein level (96.3 mg per L [917.16 nmol per L]) and erythrocyte sedimentation rate (48 mm per hour).

Question

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

A. Levamisole-induced vasculitis.

B. Necrobiosis lipoidica diabeticorum.

C. Pyoderma gangrenosum.

D. Septic emboli.

E. Wegener granulomatosis.

Discussion

The answer is A: levamisole-induced vasculitis. A skin biopsy showed a leukocytoclastic vasculitis consistent with levamisole-induced vasculitis. Levamisole is an antihelminth drug that was used as an antineoplastic agent, but adverse effects such as agranulocytosis and an ulcer-causing vasculopathy have now limited its use to veterinary medicine. It is commonly used to lace cocaine because of its psychoactive effects. It is estimated that 70% of cocaine in the United States contains levamisole.[1,2]

Figure 1.

Figure 2.

The lesions associated with levamisole exposure are most commonly purpura on the ears, nose, and cheeks. Skin ulcers with a hemorrhagic base may also occur. These lesions usually resolve spontaneously within a few weeks of discontinuing the drug, but can recur with subsequent exposure.[2-4]

Necrobiosis lipoidica diabeticorum occurs in patients with diabetes mellitus or a strong family history of the disease. It is characterized by single or multiple asymptomatic red to yellow, shiny plaques that gradually enlarge and contain dermal blood vessels. Ulceration of the plaques is common and can occur with or without trauma. The pathogenesis is unknown, but biopsy can confirm the diagnosis.[5]

Source: Adapted from Am Fam Physician. 2016;93(1):57-58.

Summary Table

Condition	Cause	Characteristics
Levamisole-induced vasculitis	Levamisole exposure	Purpura on the ears, nose, cheeks; skin ulcers with a hemorrhagic base
Necrobiosis lipoidica diabeticorum	Unknown but associated with diabetes mellitus	Single or multiple asymptomatic red to yellow, shiny plaques; gradual enlargement and possible ulceration
Pyoderma gangrenosum	Neutrophil dysfunction	Painful pustules and rapidly progressive ulcers with violaceous undermined borders, surrounding erythema, and a purulent base
Septic emboli	Heart valve infection	Sudden development of painful, purpuric skin ulcers; other systemic signs of bacteremia
Wegener granulomatosis	Autoimmune vasculitis	Necrotic ulcers, palpable purpura, digital infarcts; skin, lung, and kidney involvement

Pyoderma gangrenosum is an idiopathic condition associated with inflammatory bowel disease, arthritis, joint inflammation, and malignancy. It is characterized by painful pustules and rapidly progressive ulcers with violaceous undermined borders, surrounding erythema, and a purulent base. The pathogenesis is believed to be related to neutrophil dysfunction. It is a diagnosis of exclusion.[5]

Bacteria and pus from vegetations on an infected heart valve may cause septic emboli. They travel via the bloodstream and can cause the sudden development of painful, purpuric skin ulcers. They are associated with other systemic signs of bacteremia, including fever, malaise, myalgias, arthralgia, and elevated white blood cell count.[6,7]

Wegener granulomatosis is a small to medium vessel autoimmune vasculitis that is characterized by skin, lung, and kidney involvement. Skin findings include necrotic ulcers, palpable purpura, and digital infarcts. Patients with this condition have lung nodules, upper respiratory tract disease, and segmental necrotizing glomerulonephritis.[5,7]

REFERENCES

1. Metwally O, Hamidi M, Townsend L, Abualula H, Zaitoun A, Lall T. The cocaine trail: levamisole-induced leukocytoclastic vasculitis in a cocaine user. Subst Abus. 2013;34(1):75-77.
2. Pillow MT, Hughes A. Levamisole-adulturated cocaine induced vasculitis with skin ulcerations. West J Emerg Med. 2013;14(2):149-150.
3. Abdul-Karmin R, Ryan C, Rangel C, Emmett M. Levamisole-induced vasculitis. Proc (Bayl Univ Med Cent). 2013;26(2):163-165.
4. Lee G, Negash D, Arseneau R. Chronic levamisole-induced vasculitis: a case report. BCMJ. 2012;54(6):302-304.
5. Panuncialman J, Falanga V. Unusual causes of cutaneous ulceration. Surg Clin North Am. 2010;90(6):1161-1180.
6. Zembowicz A, Navarro P, Walters S, Lyle SR, Moschella SL, Miller D. Subcutaneous thrombotic vasculopathy syndrome: an ominous condition reminiscent of calciphylaxis: calciphylaxis sine calcifications? Am J Dermatopathol. 2011;33(8):796-802.
7. Suresh E. Diagnostic approach to patients with suspected vasculitis. Postgrad Med J. 2006;82(970):483-488.

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Sugar

- Soft drinks contain >10% sugar.
- Indian sweets with chashni (sugary syrup) contain more than 50% sugar.
- Indian sweets contain more than 30% sugar (non-chashni).
- ORS contains 2% sugar.
- Keep Lp(a) - <30 mg/dL

Abbott

START with STEMETIL
DIZZINESS CONTROL

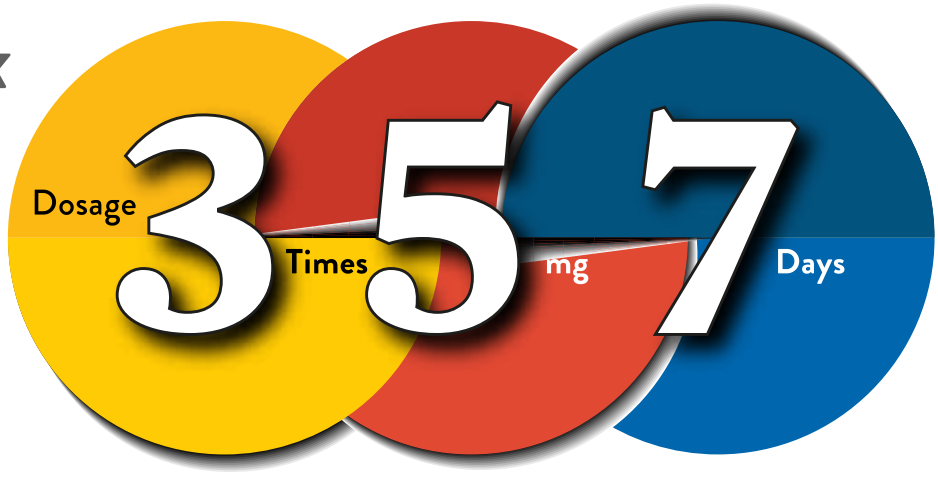
IN DIZZINESS# WITH NAUSEA-VOMITING, ANXIETY

Stemetil MD

Prochlorperazine maleate 5mg Mouth Dissolving tablets

Faster Relief, Better Control

℞



Vestibular compensation takes up to 7 days for completion[1]

AVAILABLE AS

Mouth dissolving tablet[2]

Inj 12.5 mg (for acute cases)[2]

Abridged Prescribing Information
Stemetil MD (Prochlorperazine mouth dissolving tablets)
Composition: Each tablet contains: Prochlorperazine maleate 5mg I.P.
Indications: Symptomatic treatment of vertigo due to Meniere's syndrome, labyrinthitis and other causes; nausea and vomiting of any aetiology, including that associated with migraine; in the treatment of schizophrenia, acute mania and as an adjunct in short term management of anxiety. **Dosage and Administration:** *Prevention of nausea and vomiting:* 5-10 mg twice or thrice daily. *Treatment of nausea and vomiting:* 20 mg stat followed, if necessary, by 10 mg two hours later. *Vertigo and Meniere's syndrome:* 5 mg thrice daily increasing, if necessary, to a total of 30 mg daily. After several weeks dosage may be reduced gradually to 5-10 mg daily. *Prevention of migraine:* 5 mg three or four times daily. *Treatment of migraine:* 20 mg stat, followed by 10 mg two hours later, if required. *Schizophrenia and other psychotic disorders:* Treatment varies depending on the condition. *Adjunct in the short term management of anxiety:* 15-20 mg daily in divided doses initially, but this may be increased, if necessary, to a maximum of 40 mg daily in divided doses. **Contraindications:** Hypersensitivity to phenothiazines or history of narrow angle glaucoma. **Precautions and Warnings:** Keep out of reach of children. Should be used with caution in elderly patients. To avoid in patients with renal and hepatic dysfunction, epilepsy, Parkinson's disease. To be avoided in pregnancy unless the treating Physician considers it essential. Nursing mothers: Breast-feeding should be suspended. **Adverse effects:** Generally well tolerated. Transient drowsiness, mild skin reactions, liver dysfunction, postural hypotension, extrapyramidal symptoms and rarely cardiovascular disorders have been reported. **Presentation:** 5 mg of Mouth Dissolving tablets: Strip of 10 tablets.

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

Please read the full prescribing information before usage.
Additional Information available on request with the Medical Services Division, Abbott Healthcare Pvt. Ltd., Floor 18, Godrej BKC, Plot No. C – 68, BKC, Near MCA Club, Bandra (E) Mumbai – 400 051

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

INDSTE181205 27 FEB 2018

An Update on the Treatment of Vertigo and Dizziness

ASHOK K GUPTA

ABSTRACT

Balance disorders are manifested typically with symptoms of dizziness and vertigo. Accurate diagnosis still poses a major challenge in the management of the disease. The various treatment options available for the management of vertigo and dizziness include the treatment of underlying vestibular disease, treatment of the symptoms and aim to promote recovery of the patient. The present article reviews original research articles, systematic reviews and meta-analyses to present a detailed update on the current and new treatment strategies and modalities.

Keywords: Vertigo, dizziness, balance disorder, disease-specific treatment, vestibular therapy, symptomatic treatment, prochlorperazine, cinnarizine, betahistine.

Balance disorders occur due to various diseases and are typically presented with symptoms of dizziness and vertigo.[1] They also form one of the most common reasons for seeking medical help. Acute dizziness and vertigo also require interdisciplinary cooperation.[2]

Vertigo is not a well-defined disease; however, symptoms can occur in heterogeneous entities diagnosed and treated primarily by the involvement of otolaryngologists, neurologists, internal medicine and primary care physicians.[3] Dizziness is a common symptom frequently with benign causes; however, some causes may be potentially life-threatening. One of the major challenges in the management of dizziness is accurate diagnosis due to lack of dedicated vestibular labs and injudicious use of vestibular suppressant medications.[4]

METHODOLOGY

PubMed, Cochrane database and Google Scholar were the databases used for the literature search. The search strategy included a combination of 'key word search' and 'backward chronological search'. The search terms included dizziness, vertigo, epidemiology, prevalence, incidence, treatment, management, diagnosis, guidelines. Boolean operators were used for the search. Twenty-three original research articles, systematic reviews and meta-analyses were included for the development of this review (Table 1).

MANAGEMENT OF VERTIGO AND DIZZINESS

Appropriate management of vertigo requires correct diagnosis which includes identifying the origin of dizziness as a problem with the vestibular system and then determining the site and origin of that problem. The treatment of vertigo is classified into three categories:[3]

- Specific to the underlying vestibular disease
- Aimed at alleviating the symptoms of vertigo
- Aimed at promoting recovery.

Disease-specific Treatments

There are various conditions which lead to vertigo affecting either the peripheral vestibular apparatus in the inner ear or the central nervous system. In many conditions, the treatment of the underlying condition successfully improves the symptoms while in some cases the symptoms are not improved but the treatment is important for overall prognosis of the patient.[3]

The different conditions in which the disease-specific treatment is helpful in diminishing the symptoms or in altering the disease course are:[3]

- Vestibular neuritis
- Vestibular migraine
- Benign paroxysmal positional vertigo
- Meniere's disease
- Multiple sclerosis
- Vertebrobasilar ischemia

Professor and Head (Unit II)
Dept. of Otolaryngology, Head and Neck Surgery, PGIMER, Chandigarh
Editor-in-Chief
Clinical Rhinology - An International Journal
E-mail: drashokpgi@hotmail.com

Table 1. Literature Search Strategy

Databases	Search terms	Result	Comments
PubMed, Cochrane, Google Scholar	Treatment of vertigo, management of vertigo, treatment of dizziness, management of dizziness, pharmacotherapy of vertigo and dizziness	23 Original research articles + systematic reviews + meta-analyses	Published literature corresponding only to human subjects and in English language were selected

- Herpes zoster
- Perilymphatic fistula
- Vestibular schwannoma
- Superior canal dehiscence
- Episodic ataxia type 2
- Cogan's syndrome.

Symptomatic Treatment

Medications are used to suppress vestibular symptoms and are effective in alleviating acute episodes of vertigo lasting at least a few hours or days. However, these drugs are not beneficial in the treatment of very brief episodes of vertigo except in those cases where the frequency of symptoms is very high. There are three general classes of drugs used to suppress the vestibular system:[5]

- Antihistamines such as meclizine, dimenhydrinate, diphenhydramine
- Benzodiazepines such as diazepam, lorazepam, clonazepam, alprazolam
- Antiemetics such as prochlorperazine, promethazine, domperidone, ondansetron.

These medications are effective in ameliorating vertigo, particularly in the acute setting.

Antihistamines are considered to be the drug of choice in most patients, with meclizine being the drug of choice in pregnant women.[6]

Benzodiazepines are sedating in nature and are generally used when antihistamines do not produce the desired results.[3]

The phenothiazine antiemetics (especially prochlorperazine and promethazine) are also sedating and are specifically reserved for patients with severe vomiting. In a study conducted to compare the efficacy of cinnarizine ± head exercises with prochlorperazine ± head exercises, it was seen that prochlorperazine resulted in subjective improvement in more patients, it had fewer side effects and response to the treatment was also reported to be more in cases with vertigo of peripheral origin.[7]

In another double-blind crossover trial, comparing therapeutic effects of prochlorperazine and betahistine on patients with confirmed Meniere's disease, the two were found to be of equal efficacy based on the reduction in the number of vertigo attacks.[8]

Symptomatic treatments are only given till the cessation of severe symptoms and vomiting (usually within 1-2 days). This is significant to prevent compromising long-term adaptation to vestibular loss by the brain.[9] Certain animal studies have also shown benzodiazepines and antiemetics to be associated with impaired central vestibular compensation.[5]

Drugs such as cinnarizine and flunarizine have been used as antivertigo drugs and prevent motion sickness and are used as vestibular depressants. These drugs also possess anticholinergic, antihistaminergic and antidopaminergic action.[10]

A list of commonly used therapeutic drugs used for vertigo is given in Table 2.[7,11]

Vestibular Rehabilitation

Central nervous system compensation has been shown to guide clinical recovery following peripheral vestibular injury occurring in advance of improved peripheral vestibular function in human and animal models.[5,12-14] The primary target of vestibular rehabilitation is central compensation and an early rehabilitation is found to be more effective than late intervention.[15-17]

Physical Therapy

Physical therapy has been cited to play a pivotal role in the contemporary management of vertigo and imbalance. Physical therapy has been found to be one of the most efficacious modalities in the management of balance disorders, based on the advancements in the understanding of vestibular physiology and how it changes in different diseases. Organ-targeted physiotherapy has shown remarkable improvement in different measures, particularly in cases where defective sense organs were specifically stimulated. Virtual reality exercises have also shown promising results in patients of psychogenic vertigo.[18]

Table 2. Commonly Used Drugs for Vertigo

Drugs	Dose and duration	Mechanism of action	Side effects	Effects on vestibular compensation
Cinnarizine	75 mg/day for 3 days	Selective calcium channel blocker, acts largely on the peripheral vestibular labyrinth by affecting local calcium ion flux. Lowers whole blood viscosity Is effective for vertiginous syndrome caused by over-reactivity or unbalanced activity of labyrinthine apparatus in the inner ear. Suppresses the eye movement response or nystagmus	Sedation Pedal edema Extrapyramidal disorders	Delays vestibular compression
Betahistine	48 mg/day, 3-6 months	Increases cochlear and vestibular blood flow Increases histamine turnover in the central nervous and vestibular system Increase in the level of histamine in damaged vestibular nuclei reduces inhibition by intact vestibular nuclei by H3 hetero-antagonistic action	Mild side effects including gastrointestinal complaints, fatigue and altered taste	Facilitates vestibular compensation
Prochlorperazine	10-15 mg/day	Decreases abnormal excitement in the brain No effect upon any measure of nystagmic or perceptual vestibular function	Mild sedation Dry mouth	Delays vestibular compensation
Diazepam	5 mg/ 6-8 hours	Causes inhibition throughout the central nervous system, including activity in the vestibular nerve and vestibular nuclei	Drowsiness Dizziness Respiratory depression	Delays vestibular compensation

Source: Kameswaran M, Sarda K. Therapeutic interventions in vertigo management. *Int J Otorhinolaryngol Head Neck Surg.* 2017;3(4):777-85.

There are several potential benefits of vestibular rehabilitation exercises:[19,20]

- Activity promotes adaptation
- Activity facilitates strategic substitution
- Inactivity has secondary negative effects.

Osteopathic Manipulative Treatment

In 2013, it was reported by Fraix et al[21] that osteopathic manipulative treatment (OMT) can improve balance in patients with chronic dizziness. It has also been reported that OMT is typically successful in managing benign paroxysmal positional vertigo (BPPV) by repositioning maneuvers such as Epley maneuvers, Semont maneuvers, home exercises, etc. and sometimes with medication. OMT could also be helpful in the treatment of refractory BPPV.[22]

SURGERY

As per the current literature, surgical intervention is indicated in slightly more than 1% of the patients at specialist hospitals.[23] Surgical procedures are recommended as an only remaining alternative in patients who suffer from defined vertigo symptoms after exhaustion of pharmaceuticals as well as other conservative treatments and who are facing severely impaired quality-of-life. Before attempting surgical therapy, the diagnosis has to be accurate and a sufficiently long conservative treatment should be given to the patient.[24]

Generally, function preserving procedures are preferred, if possible. For patients with Meniere's disease, saccus surgery is an effective method with minimal side effects and can also be repeated if required. The occlusion of the respective semi-circular canal is reported to be beneficial in cases of BPPV. In case of a suspected erosion of a semi-circular canal due to cholesteatoma or acute inflammatory disease of the mastoid, surgery is immediately needed.[24]

AN INDIAN PERSPECTIVE

A multicenter, prospective, registry was conducted in adult patients across 37 centers in India to evaluate the clinicoetiological pattern and pharmacotherapy practices of new onset vertigo. The study results revealed that vestibular vertigo, BPPV are the dominant type in Indian patients with new onset vertigo. Betahistine and prochlorperazine were found to top the physician's preference list with equal benefits and safety profile in preventing recurrence. With an additional antinausea and antiemetic

property, prochlorperazine was stated to have an added advantage in vertigo management and also in improving the patient satisfaction.[25]

CONCLUSION

It is important to note here that in acute vertigo syndromes, the ear, nose and throat (ENT) physician plays a special role and responsibility in the interdisciplinary work-up, since ontological disorders are the most common causes of vertigo and dizziness. In any case, an ENT consultation is warranted. Appropriate management of vertigo requires the correct diagnosis. The treatment of vertigo is classified into 3 categories - specific to the underlying vestibular diseases, aimed at alleviating the symptoms of vertigo and aimed at promoting recovery. In nonpharmacological therapy, physical therapy has been cited to be one of the most efficacious modalities in the management of balance disorders. A multicenter prospective registry reported that in India, prochlorperazine and betahistine are the two most preferred drugs in the management and prevention of recurrence of vertigo and episodes of dizziness.

REFERENCES

1. Bouccara D, Rubin F, Bonfils P, Lisan Q. Management of vertigo and dizziness. Rev Med Interne. 2018 Feb 26. pii: S0248-8663(18)30040-7. [Epub ahead of print]
2. Löhler J, Eßer D, Wollenberg B, Walther LE. Management of acute vertigo and dizziness: Patients in emergency departments in Germany. HNO. 2018;66(6):472-479.
3. Furman JM, Barton JJS. Treatment of vertigo. 2015. Available at: https://www.uptodate.com/contents/treatment-of-vertigo?search=treatment%20of%20vertigo&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed on June 6, 2018.
4. Das S, Chakraborty S, Shekar S. Dizziness in a tertiary care centre in Sikkim: our experience and limitations. Indian J Otolaryngol Head Neck Surg. 2017;69(4):443-8.
5. Strupp M, Arbusow V, Brandt T. Exercise and drug therapy alter recovery from labyrinth lesion in humans. Ann N Y Acad Sci. 2001;942:79-94.
6. Leathem AM. Safety and efficacy of antiemetics used to treat nausea and vomiting in pregnancy. Clin Pharm. 1986;5(8):660-8.
7. Singh AK, Chaturvedi VN. Prochlorperazine versus cinnarizine in cases of vertigo. Indian J Otolaryngol Head Neck Surg. 1998;50(4):392-7.
8. Aantaa E, Skinhoj A. Controlled clinical trial comparing the effect of betahistine hydrochloride and prochlorperazine maleate on patients with Meniére's disease. Ann Clin Res. 1976;8(4):284-7.
9. Baloh RW. Clinical practice. Vestibular neuritis. N Engl J Med. 2003;348(11):1027-32.
10. Singh KR, Singh M. Current perspectives in the pharmacotherapy of vertigo. Otorhinolaryngol Clin Int J. 2012;4(2):81-5.
11. Kameswaran M, Sarda K. Therapeutic interventions in vertigo management. Int J Otorhinolaryngol Head Neck Surg. 2017;3(4):777-85.
12. Dieterich M, Brandt T. Functional brain imaging of peripheral and central vestibular disorders. Brain. 2008;131(Pt 10):2538-52.
13. zu Eulenburg P, Stoeter P, Dieterich M. Voxel-based morphometry depicts central compensation after vestibular neuritis. Ann Neurol. 2010;68(2):241-9.
14. Parietti-Winkler C, Gauchard GC, Simon C, Perrin PP. Long-term effects of vestibular compensation on balance control and sensory organisation after unilateral deafferentation due to vestibular schwannoma surgery. J Neurol Neurosurg Psychiatry. 2010;81(8):934-6.
15. Helmchen C, Klinkenstein JC, Krüger A, Gliemroth J, Mohr C, Sander T. Structural brain changes following peripheral vestibulo-cochlear lesion may indicate multisensory compensation. J Neurol Neurosurg Psychiatry. 2011;82(3):309-16.
16. Hillier SL, Hollohan V. Vestibular rehabilitation for unilateral peripheral vestibular dysfunction. Cochrane Database Syst Rev. 2007;(4):CD005397.
17. Bamiou DE, Davies RA, McKee M, Luxon LM. Symptoms, disability and handicap in unilateral peripheral vestibular disorders. Effects of early presentation and initiation of balance exercises. Scand Audiol. 2000;29(4):238-44.
18. Biswas A, Barui B. Specific organ targeted vestibular physiotherapy: The pivot in the contemporary management of vertigo and imbalance. Indian J Otolaryngol Head Neck Surg. 2017;69(4):431-42.
19. Mathog RH, Peppard SB. Exercise and recovery from vestibular injury. Am J Otolaryngol. 1982;3(6):397-407.
20. Schubert MC, Minor LB. Vestibulo-ocular physiology underlying vestibular hypofunction. Phys Ther. 2004;84(4):373-85.
21. Fraix M, Gordon A, Graham V, Hurwitz E, Seffinger MA. Use of the SMART Balance Master to quantify the effects of osteopathic manipulative treatment in patients with dizziness. J Am Osteopath Assoc. 2013;113(5):394-403.
22. Tegeler L, Blumer J. OMT may be helpful in the management of benign paroxysmal positional vertigo. J Am Osteopath Assoc. 2018;118(1):51-2.
23. Patnaik U, Srivastava A, Sikka K, Thakar A. Surgery for vertigo: 10-year audit from a contemporary vertigo clinic. J Laryngol Otol. 2015;129(12):1182-7.
24. Volkenstein S, Dazert S. Recent surgical options for vestibular vertigo. GS Curr Top Otorhinolaryngol Head Neck Surg.2017;16:Doc01.
25. Kameswaram 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 multicentre registry in India. Int J Otorhinolaryngol Head Neck Surg. 2017;3(2):404-13.

Schwannoma in the Neck Region: A Rare Entity

SUBRAMANIAM VINAYAK EASWERAN*, RAGHVENDRA UDUPA†, MAMATA HEGDE‡

ABSTRACT

Schwannoma is a benign nerve sheath tumor composed of Schwann cells. Schwannoma, which originates from the cervical vagus nerve, is an extremely rare neoplasm. It mostly presents as a painless, slow growing lateral mass. Complete surgical resection is the recommended treatment of choice. Male-to-female ratio is 1:1. Fine needle aspiration cytology and imaging modalities have decreased the problem of misdiagnosis.

Keywords: Schwannoma, cervical vagus nerve, complete surgical resection

Schwannoma is a benign nerve sheath tumor composed of Schwann cells. Schwannomas are also known as neurilemmomas, neuromas or paragangliomas. Schwannoma was first established as a pathological entity by Verocay in 1908 who later called it 'neurinoma' in 1910. Stout, in 1935, termed it as 'neurilemmoma'. Most cases of schwannoma are asymptomatic and present as a neck mass. Male-to-female ratio is 1:1. Age of predilection is 30-60 years. Here, we present a case of a 60-year-old woman who presented with a swelling in the right side of the neck.

CASE REPORT

A 60-year-old woman presented to the OPD with a swelling in the right side of the neck on 4/1/17. On advising her an excision of the growth, she was lost to follow-up. Again, on 25/1/18, she presented to the OPD, ready for surgery. Figure 1 shows the swelling on the right side of the neck. On getting her investigated and working her up for surgery, the investigation results were as follows: Hemoglobin (Hb) - 11.2 g/dL, total leukocyte count (TC) - 5,300 cells/mm^3, differential count (DC) - $N_{64}L_{27}E_5B_4$, urea - 28.4 mg/dL, creatinine - 1.05 mg/dL, RBS - 101.7, Integrated Counselling and Testing Centre (ICTC) - negative, electrocardiography (ECG) - normal, fine needle aspiration cytology (FNAC) - scanty hemorrhagic material present with significant cells.

Excision biopsy was advised. Surgical excision of the growth was planned (Fig. 2); surgery was done under sedation on 29/1/18 (Figs. 3 and 4). Parts were

Figure 1. Swelling on right side of the neck (pre-op).

Figure 2. Swelling being palpated on table.

*ENT Specialist
Dept. of ENT
†Anesthesiologist
Dept. of Anesthesia
Pandit General Hospital, Sirsi, Uttar Kannada, Karnataka
‡Pathologist
Dept. of Pathology
Marikamba Hospital, Sirsi, Karnataka
Address for correspondence
Dr Subramaniam Vinayak Easweran
Dept. of ENT
Pandit General Hospital, Sirsi, Uttar Kannada - 581 401, Karnataka
E-mail: vinoo121071@gmail.com

Figure 3. Incision made on the swelling.

Figure 4. Incision deepened till the growth.

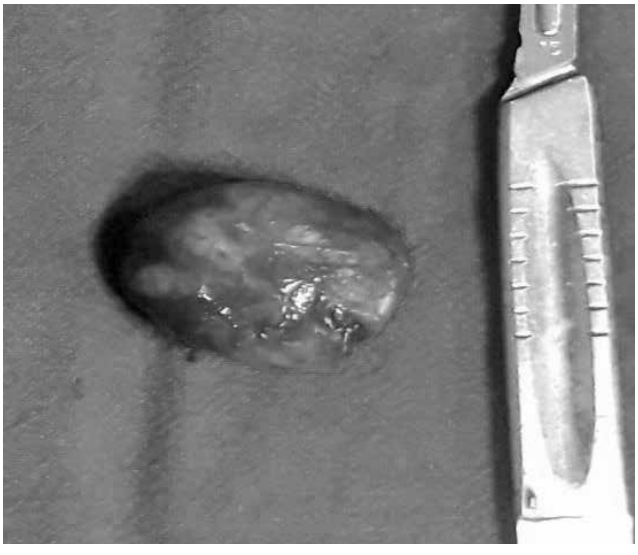


Figure 5. Growth excised *in toto*.

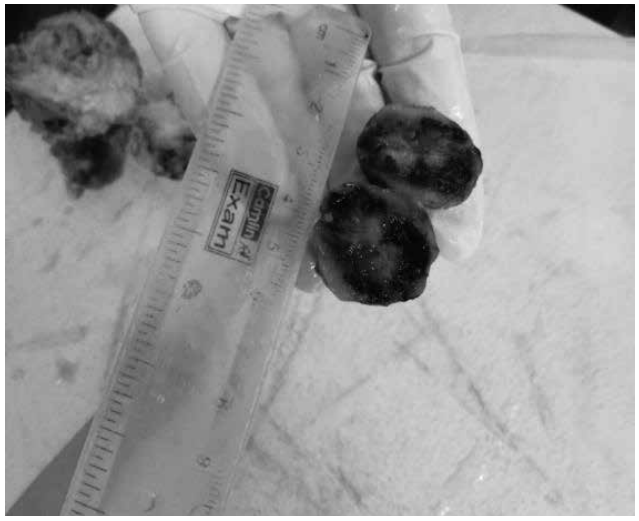


Figure 6. Growth sent for histopathological examination.

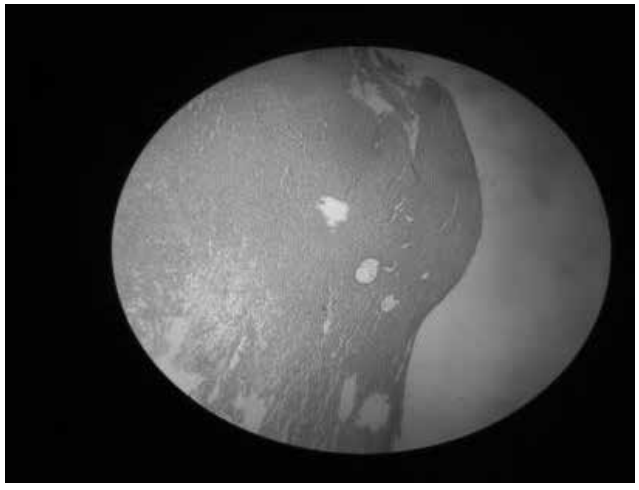


Figure 7. Microscopic picture of the growth.

Figure 8. Follow-up after suture removal.

cleaned and draped, local infiltration given. Growth was excised and sent for histopathological examination (HPE) (Figs. 5 and 6). Patient was discharged on 31/1/18.

HPE report revealed a nodular mass of 2 × 1 and 5 × 1 cm; cut section grey white, grey brown areas. Microscopic findings revealed capsulated spindle cell with myxoid areas with collagen and few lymphocytes, congested blood vessels with prevascular hyalinization (Fig. 7). Histological diagnosis was spindle cell neoplasm - schwannoma.

Follow-up

Patient was told to follow-up after 10 days for suture removal (Fig. 8).

DISCUSSION

A schwannoma may arise from any peripheral, cranial or autonomic nerve except olfactory and optic nerves. Among cranial nerves, they arise from glossopharyngeal, accessory, hypoglossal and vestibulocochlear nerves. Paragangliomas, branchial cyst, malignant neck tumors and cervical lymphadenopathies could be the differential diagnosis. Surgical resection of the tumor is the treatment of choice.

Approximately 25-45% of extracranial schwannomas are present in the head and neck area. Involvement of the vagus nerve is reported in 10%. Diagnostic techniques in the form of FNAC and imaging modalities have reduced the problem of misdiagnosis.

On microscopic examination, the tumor exhibits two main type of cells, namely Antoni A and B. Antoni A are composed of compact spindle cells and B are composed of region of loose Schwann cells. There is no clear evidence of malignant potential and risk of recurrence after removal.

SUGGESTED READING

1. Simsek G, Sahan M, Gunsoy B, Arikok A, Akin I. Schwannoma of cervical vagus nerve: a rare benign neurogenic tumor. Otolaryngol Online J. 2013;3(3).
2. Colreavy MP, Lacy PD, Hughes J, Bouchier-Hayes D, Brennan P, O'Dwyer AJ, et al. Head and neck schwannomas - a 10 year review. J Laryngol Otol. 2000;114(2):119-24.
3. Langner E, Del Negro A, Akashi HK, Araújo PP, Tincani AJ, Martins AS. Schwannomas in the head and neck: retrospective analysis of 21 patients and review of the literature. Sao Paulo Med J. 2007;125(4):220-2.
4. Leu YS, Chang KC. Extracranial head and neck schwannomas: a review of 8 years experience. Acta Otolaryngol. 2002;122(4):435-7.
5. Torossian JM, Beziat JL, Abou Chebel N, Devouassoux-Shisheboran M, Fischer G. Extracranial cephalic schwannomas: a series of 15 patients. J Craniofac Surg. 1999;10(5):389-94.
6. Beaman FD, Kransdorf MJ, Menke DM. Schwannoma: radiologic-pathologic correlation. Radiographics. 2004; 24(5):1477-81.
7. Biswas D, Marnane CN, Mal R, Baldwin D. Extracranial head and neck schwannomas - a 10-year review. Auris Nasus Larynx. 2007;34(3):353-9.
8. Batsakis JG, Sneige N. Parapharyngeal and retropharyngeal space diseases. Ann Otol Rhinol Laryngol. 1989;98 (4 Pt 1):320-1.

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Vitamin D Deficiency - A Reversible Cause of Proximal Myopathy: A Case Report

SUBHASH MEEL*, SAMEER AGGARWAL†, DEEPAK JAIN‡, HK AGGARWAL#, RAHUL CHAUDA*, PROMIL JAIN¥

ABSTRACT

A 22-year-old married Hindu female, vegetarian, with lower socioeconomic status, presented with an insidious onset progressive bilateral lower limb symmetrical proximal muscle weakness without sensory and bladder and bowel involvement, from last 2 years. Bone scan reports were suggestive of mineral and bone disease. Vitamin D deficient osteomalacia was diagnosed based on elevated serum alkaline phosphatase levels, raised intact parathyroid hormone levels, decreased 25-hydroxyvitamin [25(OH)D] levels. Patient's symptoms improved after oral active vitamin D and calcium administration. The present case highlights the importance of considering vitamin D deficiency in patients presenting with musculoskeletal symptoms and a routine evaluation for vitamin D deficiency should be considered in all patients.

Keywords: Vitamin D deficiency, proximal myopathy, hypocalcemia, osteomalacia

Although the prevalence of vitamin D deficiency is common worldwide, it is often under-estimated. It is estimated that vitamin D deficiency or insufficiency affects around 1 billion population worldwide.[1] According to the previously published study reports, the prevalence of varying degrees of vitamin D deficiency with low dietary calcium intake in Indian population is extensive (50-90%).[2] However, the exact incidence of myopathy in individuals with hypovitaminosis D is unknown. Proximal myopathy has been reported to be present in 60-75% of patients with vitamin D deficiency.[1]

The weakness usually occurs in proximal muscles and it is often minimal and subclinical. Osteomalacia, by definition, means that osteoblasts have laid down a collagen matrix, but there is a defect in its ability to be mineralized. In children, a defect in the mineralization of the osteoid in the long bones and the failure or delay in the mineralization of endochondral new bone formation at the growth plate leads to the classic skeletal deformities of rickets. However, in adults, the mineralization defect takes on a different character due to the failure of mineralization of newly formed osteoid at sites of bone turnover of periosteal or endosteal apposition. Here, we present a case of severe muscle weakness with osteomalacia due to vitamin D deficiency, which rendered the patient wheel chair bound.

CASE REPORT

A 22-year-old female visited our outpatient clinic with weakness of bilateral lower limbs, which was gradually progressive from last 2 years. The patient, who was wheel chair bound from past 3 months, complained of bilateral lower limb pain, backache, severe fatigue and inability to walk without support and to get up from squatting position and slight difficulty in combing of hair and lifting of weight from last 3 months. There was no history of any trauma/steroid intake/periodic paralysis/chronic diarrhea/carpopedal spasm/hematuria/neck swelling/palpitations/tremors/jaundice/height loss/fragility fracture/antiepileptic intake/antitubercular intake. Patient had history of recent blood transfusions and was currently on oral iron and multivitamins supplements.

On examination, patient was conscious, well-oriented, had pallor with slight dark complexion. Her vitals were

*Resident
†Professor
‡Associate Professor
#Senior Professor and Head
Dept. of Medicine
¥Associate Professor
Dept. of Pathology
Pt. BD Sharma University of Health Sciences, Rohtak, Haryana
Address for correspondence
Dr Deepak Jain
Associate Professor
Dept. of Medicine
Pt. BD Sharma University of Health Sciences, Rohtak - 124 001, Haryana
E-mail: jaindeepakdr@gmail.com

blood pressure (BP) - 120/80 mmHg, pulse - 84 bpm, respiratory rate (RR) - 16/min, body mass index (BMI) - 19.4 kg/m^2. She had regular bowels, bladder habits and sleep cycle. Her cardiovascular, respiratory and abdominal examinations were normal.

On central nervous system (CNS) examination revealed symmetrical proximal muscle weakness in bilateral lower limb with power of 3/5 at hip joint and in upper limb with power of 4/5 at shoulder joint and brisk deep tendon reflexes (DTR), and there was no sensory involvement. Skeletal examination revealed tenderness over lower back, hip and shin. Rest of the examination was normal.

Lab investigations revealed hemoglobin (Hb) - 10.4 g/dL, total leukocyte count (TLC) - 4,500, differential leukocyte count (DLC) - $P_{68}L_{28}M_2E_2$, platelet count - 4.2 lac. Kidney and liver function tests were normal. Patient had low serum calcium - 8.0 mg/dL, low serum phosphate - 1.8 mg/dL), raised serum alkaline phosphatase (ALP) - 874 IU/dL and serum albumin - 3.8 g/dL. Serum intact parathyroid hormone (PTH) level was 93.06 pg/mL (normal: 10-65 pg/mL) and serum 25-hydroxyvitamin D [25(OH)D] level was 18.68 nmol/L (normal: 75-100); immunoglobulin A anti-tissue transglutaminase antibodies (IgA-tTG) level was normal. The urine was negative for urinary albumin and glucose and pH was 6.0; 24-hour urinary calcium was 49.3 mg/day (100-300 mg/day). Antinuclear antibodies (ANA), thyroid function test and total creatine phosphokinase (CPK) level were normal. The bone mineral density (BMD) T-score and Z-score, as measured by dual-energy X-ray absorptiometry, was -2.7 and -2.5 at the lumbar spine and -2.8 and -2.0 at the femoral neck, respectively, indicating a low BMD for her chronological age.

Radiographic images revealed a pseudo-fracture in the right radial shaft and lower end of left femur (Fig. 1), bilateral superior pubic rami (Fig. 2), and first, second and fifth metatarsal bones along with diffuse osteopenia in B/L tarsals, metatarsals and phalanges (Fig. 3). Bone scan (technetium 99m-methyl diphosphonate [^{99m}Tc-MDP]) showed abnormal increased uptake by skull bone, scapula and upper limb bones, multiple ribs and vertebrae, pelvic bone, lower end of left femur and multiple metatarsal bones (Fig. 4). Electrophysiological study was suggestive of myopathy.

On the basis of examination and investigation, patient was diagnosed as a case of vitamin D deficiency with secondary hyperparathyroidism. The patient was treated with once weekly doses of cholecalciferol 60,000 IU along with calcium carbonate 500 mg twice-daily.

Figure 1. X-ray right forearm and lower end of left femur shows looser zone.

Figure 2. X-ray pelvis shows pseudo-fracture.

Figure 3. X-ray shows looser zone (*thick arrows*) and diffuse bone resorption (*thin arrows*).

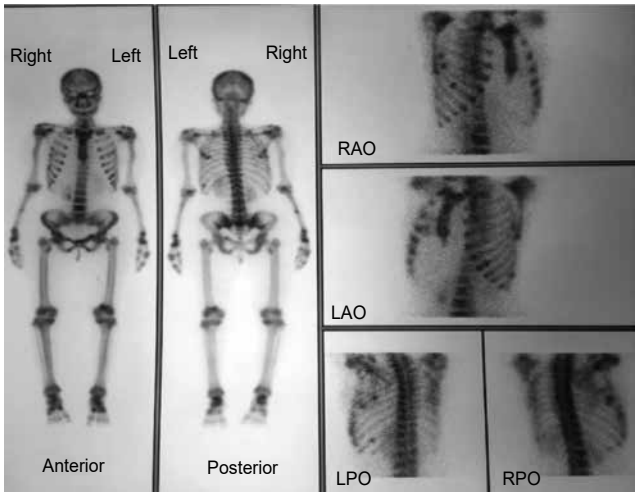

Figure 4. Bone scan.

Follow-up conducted at 4 weeks showed a gradual improvement in her symptoms. She was able to get up from chair and move without support and got significant relief in pain and fatigue. Levels of serum calcium and phosphorus were normalized but serum alkaline phosphatase (ALP) levels were still high (814 IU/L). At 3-month follow-up, pain, muscle weakness and gait disturbance had been completely alleviated and she resumed her routine daily activities. Biochemical parameters showed normal serum calcium, phosphorus as well as serum PTH and ALP. Patient is now on regular follow-up.

DISCUSSION

It has been estimated that over 1 billion people worldwide have vitamin D deficiency.[3] Vitamin D deficiency leads to decreased intestinal absorption of calcium and phosphorus, causing hypocalcemia and hypophosphatemia. Consequently, PTH secretion increases to overcome hypocalcemia which ultimately causes bone demineralization and osteomalacia in adults. In adults, osteomalacia usually does not present with any overt skeletal signs. However, patients with osteomalacia complain of throbbing, aching bone discomfort. Bone discomfort is worse when sitting or lying in bed. This is usually associated with proximal muscle weakness and aching in muscles.[4-6] Pressing on the skeleton resulting in discomfort is consistent with a trigger point that can lead to the misdiagnosis of fibromyalgia. In many cases, these patients are suffering from periosteal bone discomfort consistent with osteomalacia.

Several studies have shown an association between vitamin D deficiency and proximal myopathy. In most of the patients, muscle weakness, which is usually minimal, is revealed mostly on detailed history and physical examination. In infants, myopathy is evident from muscle weakness and hypotonia.[7] Adults may present with predominant proximal muscle weakness with difficulty in getting up from squatting position or climbing stairs. Other clinical characteristics of the disease include uniform generalized muscle wasting with preservation of sensation and DTR, and waddling gait.[8] Bone pain may also be present.

The case presented here had disabling muscle weakness and was not able to walk independently. Her serum calcium level was low-normal with low serum phosphorus with secondary hyperparathyroidism and elevated serum ALP. Normal serum levels of calcium and phosphorus in healthy individuals are achieved predominantly through interaction between the two hormones: PTH and calcitriol. In patients with vitamin D deficiency, secondary hyperparathyroidism causes release of calcium stored in bone and reabsorption of calcium by kidneys to maintain normal serum calcium till bony calcium is available. Hence, mild-to-moderate vitamin D deficiency is usually accompanied by normal blood levels of calcium, high-normal or elevated levels of PTH, elevated levels of ALP, a low 24-hour urine calcium excretion rate. Overt hypocalcemia and/or hypophosphatemia may appear only in patients with severe and long-standing vitamin D deficiency.[9]

However, the exact cause of the muscle weakness and bone discomfort is not fully understood, it is believed that because the major cause of osteomalacia is vitamin D deficiency and because skeletal muscle has a vitamin D receptor (VDR), the lack of 1,25-dihydroxyvitamin D [1,25(OH)2D] interacting with the skeletal muscle VDR increases muscle weakness.[10]

Metabolic myopathies may be often accompanied by secondary hypovitaminosis D. Biopsies can help in differentiating hypovitaminosis D myopathy (HDM) from other myopathies, but this is rarely performed in current clinical practice due to its invasiveness and better availability of noninvasive biochemical and radiological markers.

The mechanism of HDM remains controversial, and it is still not clear whether vitamin D deficiency itself or in association with secondary hyperparathyroidism is the primary cause of muscle tissue and functional abnormalities. PTH production, induced by low vitamin D levels, may confer direct effects on skeletal muscles.

It is important to evaluate vitamin D deficiency as a cause of myopathy in suspected cases. Severe vitamin D

deficiency is easily treatable. Generally, advocated strategy is to prescribe a loading dose (50,000 IU of oral vitamin D once a week for 2-3 months or three times weekly for 1 month). A previous analysis of multiple loading algorithms indicated that a minimum total dose of 6,00,000 IU best predicted an end-of-treatment 25(OH)D concentration >30 ng/mL. For mild-to-moderate deficiency (11-25 ng/mL), a shorter term treatment or lower dose may be effective. In cases with recurrent deficiency, maintenance daily dose of 800-2,000 IU or more will be required. Treatment using high-dose vitamin D for 6 months or more may be essential for full normalization of HDM.

The present case highlights the significance of considering treatable causes first in patients presenting with musculoskeletal symptoms. A routine test for hypovitaminosis D should be considered in patients with musculoskeletal symptoms such as bone pain, myalgia and generalized weakness; as there is an increased chance for misdiagnosing hypovitaminosis D-associated symptoms as fibromyalgia, chronic fatigue, age-related weakness or depression.

CONCLUSION

It is always worthwhile to look for common and treatable factors causing metabolic bone disease. HDM is a common cause for proximal muscle weakness and osteomalacia. Raised ALP and PTH levels should always be worked up to diagnose vitamin D deficiency, which is easily treatable. Myopathy linked to vitamin D deficiency is completely reversible.

REFERENCES

1. Plotnikoff GA, Quigley JM. Prevalence of severe hypovitaminosis D in patients with persistent, nonspecific musculoskeletal pain. Mayo Clin Proc. 2003;78(12):1463-70.
2. Harinarayan CV, Joshi SR. Vitamin D status in India - its implications and remedial measures. J Assoc Physicians India. 2009;57:40-8.
3. Holick MF. Vitamin D deficiency. N Engl J Med. 2007;357(3):266-81.
4. Kennel KA, Drake MT, Hurley DL. Vitamin D deficiency in adults: when to test and how to treat. Mayo Clin Proc. 2010;85(8):752-7; quiz 757-8.
5. DeLuca HF. Overview of general physiologic features and functions of vitamin D. Am J Clin Nutr. 2004;80 (6 Suppl):1689S-96S.
6. Boland R. Role of vitamin D in skeletal muscle function. Endocr Rev. 1986;7(4):434-48.
7. Ziambaras K, Dagogo-Jack S. Reversible muscle weakness in patients with vitamin D deficiency. West J Med. 1997;167(6):435-9.
8. Prineas JW, Mason AS, Henson RA. Myopathy in metabolic bone disease. Br Med J. 1965;1(5441):1034-6.
9. Schott GD, Wills MR. Muscle weakness in osteomalacia. Lancet. 1976;1(7960):626-9.
10. Yoshikawa S, Nakamura T, Tanabe H, Imamura T. Osteomalacic myopathy. Endocrinol Jpn. 1979;26 (Suppl):65-72.

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J How a different perception of nature can be perceived.

Role of Doxycycline in the Management of Dengue Fever

PRACHI GARG

ABSTRACT

Dengue is the fastest growing mosquito-borne viral infection whose global incidence has drastically risen in the last few years. Currently, there is no direct antiviral therapy available against the dengue viruses; most of the management is aimed at maintaining adequate intravascular volume. Doxycycline, an antibiotic derived from tetracycline with broad antimicrobial and anti-inflammatory activities has been shown to possess antiviral properties. The current article reviews the role of doxycycline in the inhibition of dengue virus and the effect of doxycycline on clinical outcome in the treatment of dengue fever. The anti-dengue activity and anti-inflammatory activity of doxycycline may prove to be helpful in reducing the severity of clinical symptoms such as dengue fever, severe dengue hemorrhagic fever and dengue shock syndrome.

Keywords: Doxycycline, dengue fever, antiviral, anti-inflammatory, cytokines, receptor antagonists

Dengue fever is a rising endemic in many parts of the world. As per World Health Organization (WHO) estimates, there are about 390 million cases of dengue fever worldwide, out of which almost 96 million cases are in need of medical treatment.[1] In spite of several preventive measures taken by the WHO to control the spread of dengue virus (DENV) infection, new outbreaks have been reported in several parts of the world during post monsoon season. A recent map-based study by the University of Oxford estimated that India has the largest number of dengue cases, with about 33 million symptomatic and another 100 million asymptomatic infections occurring every year.[2] In view of this, the DENVs are considered to be important arthropod-borne viruses from a medical and public health perspective.

DENGUE FEVER AND ASSOCIATED COMPLICATIONS

Dengue virus is a member of the family *Flaviviridae*, genus *Flavivirus*. It is an acute infectious disease characterized by biphasic fever, headache, pain in various parts of the body, prostration, rash, lymphadenopathy and leukopenia. Severe or more complicated forms of dengue are associated with a severe febrile illness characterized by abnormalities of hemostasis and increased vascular permeability, which in some instances leads to a hypovolemic shock. Four distinct serotypes of dengue virus including DENV-1, DENV-2, DENV-3 and DENV-4 exist with numerous virus strains found across the world.[3,4]

CURRENT MANAGEMENT OF SEVERE DENGUE INFECTION

The optimal approach towards dengue control and management is prevention of the viral infection. Approach for the prevention of DENV infection and disease in endemic areas includes mosquito control, personal protective measures and vaccination.[5] Since infection with one DENV type provides long-term protection against reinfection with that same type, dengue vaccine is a feasible option. Following infection with one type, there is short lived immunity and cross protection against disease caused but the other three DENV types as well.[6] A number of dengue vaccine candidates are currently under development while one vaccine,[7,8] CYD-TDV (Dengvaxia) has been licensed for use in a few endemic countries in Latin America and Southeast Asia.[9]

There is no direct antiviral therapy available against the DENVs. Management is supportive primarily consisting of maintaining adequate intravascular volume.[5]

Most of the current strategies for anti-dengue drug discovery are targeted towards finding potent inhibitors against virus entry and its serine protease activity, which is crucial for viral replication.

DOXYCYCLINE AND ITS CURRENT CLINICAL USE

Doxycycline is a tetracycline derivative that has broad antimicrobial and anti-inflammatory activity.

Director, Heart Care Foundation of India

Doxycycline has been shown to possess antiviral activities and is used efficiently to treat tick-borne infections that transmit bacterial, protozoal and viral infections to humans.[10] Its antiviral activity has been reported against herpes simplex virus,[11] retrovirus[12] and DENV.[13] It inhibits DENV replication with effective concentrations (EC_{50}) value estimated to be 55.6 μM.[14]

ROLE OF DOXYCYCLINE IN INHIBITION OF REPLICATION OF DENGUE VIRUS

Inhibitory Effect Against Dengue Virus

Computational docking studies have shown that doxycycline inhibits DENV plaque formation by disrupting the conformational changes in the viral envelope that are necessary for virus entry.[14]

In a study, it has shown that doxycycline exhibits the highest inhibitory effect against dengue NS2B-NS3pro as compared to other tetracycline derivatives and mefenamic acid. Virus replication was observed to be significantly reduced in DENV-infected cells after applying doxycycline at 50% EC_{50}, which were considerably less than 50% cytotoxic concentrations (CC_{50}) values.[15]

DENV possesses positive single-stranded RNA that is translated to polyprotein by the host cells' ribosome. Virus polyprotein is cleaved by viral NS2B-NS3 serine protease and cellular protease to 10 structural and nonstructural proteins.[16] Disruption of viral NS2B-NS3pro would lead to inhibition of viral replication in host cells.[17] Doxycycline has negatively charged moieties and hydrophobic groups and was found to noncompetitively inhibit dengue NS2B-NS3pro with K_i values of 55.6 μM. It is also known that the binding between the dengue protease subunits depends on the interaction between negatively charged amino acids in NS2B and positively charged amino acids in NS3.[18] Hence, doxycycline may inhibit the activity of dengue protease by disturbing the binding between enzyme subunits that lead to significant reduction in its activity.[15]

The value of selectivity index of doxycycline has been shown to be lower than the selectivity index of ribavirin, a nucleoside analog that has shown the inhibition of the DENV methyltransferase.[19] The low side effects associated with doxycycline along with its positive effect on the cytokine levels in patients with dengue infection[20] make it a potential candidate for the treatment of dengue fever.

In an another study where anti-dengue properties of doxycycline were determined against four DENV serotypes *in vitro*, it was demonstrated that doxycycline interfered with DENV protease and impaired virus binding to the host cells, leading to reduced viral replication in infected cells.[21]

Modulation of Cytokine and Cytokine Receptor/Antagonist

Elevated levels of cytokines are considered to be a hallmark of various bacterial and viral infections including dengue.[22-24] Pro-inflammatory cytokines such as interleukin (IL)-6, IL1-β and tumor necrosis factor (TNF) are thought to be the primary factors leading to the majority of symptoms such as fever, malaise and coagulopathies associated with infections. The imbalance between cytokines and their anti-inflammatory counterparts serve as the primary prognostic indicator of disease outcome.[25-27] Agents that can downregulate the levels of cytokines have come up as potential therapeutic agents.[28] Tetracycline administration in patients with tick-borne encephalitis has shown a marked positive shift in the ratio of cytokines to their respective soluble receptors.[29]

A study conducted to investigate the effectiveness of tetracycline and doxycycline to modulate the levels of cytokines and soluble receptor/receptor antagonists in patients with dengue fever or dengue hemorrhagic fever showed that both tetracycline and doxycycline can modulate pro-inflammatory cytokine levels. Similar effect was observed for IL-1RA but not for TNF-R1. The compounds showed rapid downregulation within 3 days of treatment and continuing through Day 7.[20]

In the case of dengue hemorrhagic fever, doxycycline was found to be superior over tetracycline in modulating TNF-R1 concentration. A direct comparison between the two also showed that doxycycline was a much better immunomodulator as compared to tetracycline.[20]

EFFECT OF DOXYCYCLINE ON CLINICAL OUTCOME TREATMENT OF DENGUE FEVER

The anti-dengue activity of doxycycline combined with its anti-inflammatory effects may assist in attenuating dengue clinical symptoms like dengue fever, severe dengue hemorrhagic fever and dengue shock syndrome.[15]

A study was conducted to determine the effect of doxycycline treatment on cytokine levels, including TNF and IL-6, and mortality in dengue patients at high risk of complications. The study results showed that doxycycline can provide a clinical benefit to dengue patients at high

risk of complications. It was suggested that this effect could be mediated by decreasing pro-inflammatory cytokine levels.[30]

CONCLUSION

The results from these studies indicate that doxycycline may prove helpful in providing clinical benefits in the treatment of DENV infection by modulating the cytokine cascade as well as by its ability to interact with the DENV E protein to inhibit a conformational change which is an essential step in the process by which the virus enters the susceptible cells.

The anti-dengue activity and anti-inflammatory activity of doxycycline may prove to be helpful in reducing the severity of clinical symptoms such as dengue fever, severe dengue hemorrhagic fever and dengue shock syndrome. Since, there are no animal models available for dengue infection, clinical studies are required to obtain conclusive evidence of anti-dengue properties of doxycycline.

REFERENCES

1. Singh M, Chakraborty A, Kumar S, Kumar A. The epidemiology of dengue viral infection in developing countries: A systematic review. J Health Res Rev. 2017;4(3):104-7.
2. Bhatt S, Gething PW, Brady OJ, Messina JP, Farlow AW, Moyes CL, et al. The global distribution and burden of dengue. Nature. 2013;496(7446):504-7.
3. Henchal EA, Putnak JR. The dengue viruses. Clin Microbiol Rev. 1990;3(4):376-96.
4. Wilder-Smith A, Schwartz E. Dengue in travelers. N Engl J Med. 2005;353(9):924-32.
5. Thomas SJ, Rothman AL, Srikiatkhachom A, Kalayanarooj S. Dengue virus infection: prevention and treatment. March 2017. [Online]. Available at: https://www.uptodate.com/contents/dengue-virus-infection-prevention-and-treatment?source=search_result& search=Doxycycline+in+dengue&selectedTitle=20~150. Accessed 11th December, 2017.
6. Endy TP, Nisalak A, Chunsuttitwat S, Vaughn DW, Green S, Ennis FA, et al. Relationship of pre-existing dengue virus (DV) neutralizing antibody levels to viremia and severity of disease in a prospective cohort study of DV infection in Thailand. J Infect Dis. 2004;189(6):990-1000.
7. Durbin AP, Whitehead SS. Dengue vaccine candidates in development. Curr Top Microbiol Immunol. 2010;338:129-43.
8. Guirakhoo F, Pugachev K, Zhang Z, Myers G, Levenbook I, Draper K, et al. Safety and efficacy of chimeric yellow Fever-dengue virus tetravalent vaccine formulations in nonhuman primates. J Virol. 2004;78(9):4761-75.
9. World Health Organization. Questions and Answers on DEngue Vaccines. [Online]. Available at: http://www.who.int/immunization/research/development/dengue_q_and_a/en/.
10. Buckingham SC. Tick-borne infections in children: epidemiology, clinical manifestations, and optimal management strategies. Paediatr Drugs. 2005;7(3):163-76.
11. Kirchner JT, Emmert DH. Sexually transmitted diseases in women. *Chlamydia trachomatis* and herpes simplex infections. Postgrad Med. 2000;107(1):55-8, 61-5.
12. Sturtz FG. Antimurine retroviral effect of doxycycline. Methods Find Exp Clin Pharmacol. 1998;20(8):643-7.
13. Inglot AD. Comparison of the antiviral activity in vitro of some non-steroidal anti-inflammatory drugs. J Gen Virol. 1969;4(2):203-14.
14. Yang JM, Chen YF, Tu YY, Yen KR, Yang YL. Combinatorial computational approaches to identify tetracycline derivatives as flavivirus inhibitors. PLoS One. 2007;2(5):e428.
15. Rothan HA, Buckle MJ, Ammar YA, Mohammadjavad P, Shatrah O, Noorsaadah AR, et al. Study the antiviral activity of some derivatives of tetracycline and non-steroid anti-inflammatory drugs towards dengue virus. Trop Biomed. 2013;30(4):681-90.
16. Clum S, Ebner KE, Padmanabhan R. Cotranslational membrane insertion of the serine proteinase precursor NS2B-NS3(Pro) of dengue virus type 2 is required for efficient in vitro processing and is mediated through the hydrophobic regions of NS2B. J Biol Chem. 1997;272(49):30715-23.
17. Geiss BJ, Stahla H, Hannah AM, Gari AM, Keenan SM. Focus on flaviviruses: current and future drug targets. Future Med Chem. 2009;1(2):327-44.
18. Erbel P, Schiering N, D'Arcy A, Renatus M, Kroemer M, Lim SP, et al. Structural basis for the activation of flaviviral NS3 proteases from dengue and West Nile virus. Nat Struct Mol Biol. 2006;13(4):372-3.
19. Benarroch D, Egloff MP, Mulard L, Guerreiro C, Romette JL, Canard B. A structural basis for the inhibition of the NS5 dengue virus mRNA 2'-O-methyltransferase domain by ribavirin 5'-triphosphate. J Biol Chem. 2004;279(34):35638-43.
20. Castro JE, Vado-Solis I, Perez-Osorio C, Fredeking TM. Modulation of cytokine and cytokine receptor/antagonist by treatment with doxycycline and tetracycline in patients with dengue fever. Clin Dev Immunol. 2011;2011:370872.
21. Rothan HA, Mohamed Z, Paydar M, Rahman NA, Yusof R. Inhibitory effect of doxycycline against dengue virus replication in vitro. Arch Virol. 2014;159(4):711-8.
22. Bethell DB, Flobbe K, Cao XT, Day NP, Pham TP, Buurman WA, et al. Pathophysiologic and prognostic role of cytokines in dengue hemorrhagic fever. J Infect Dis. 1998;177(3):778-82.

23. Hober D, Poli L, Roblin B, Gestas P, Chungue E, Granic G, et al. Serum levels of tumor necrosis factor-alpha (TNF-alpha), interleukin-6 (IL-6), and interleukin-1 beta (IL-1 beta) in dengue-infected patients. Am J Trop Med Hyg. 1993;48(3):324-31.

24. Green S, Vaughn DW, Kalayanarooj S, Nimmannitya S, Suntayakorn S, Nisalak A, et al. Early immune activation in acute dengue illness is related to development of plasma leakage and disease severity. J Infect Dis. 1999; 179(4):755-62.

25. Girardin E, Roux-Lombard P, Grau GE, Suter P, Gallati H, Dayer JM. Imbalance between tumour necrosis factor-alpha and soluble TNF receptor concentrations in severe meningococcaemia. The J5 Study Group. Immunology. 1992;76(1):20-3.

26. Lehmann AK, Halstensen A, Sørnes S, Røkke O, Waage A. High levels of interleukin 10 in serum are associated with fatality in meningococcal disease. Infect Immun. 1995;63(6):2109-12.

27. van Dissel JT, van Langevelde P, Westendorp RG, Kwappenberg K, Frölich M. Anti-inflammatory cytokine profile and mortality in febrile patients. Lancet. 1998;351(9107):950-3.

28. Dinarello CA. Anti-cytokine therapeutics and infections. Vaccine. 2003;21 Suppl 2:S24-34.

29. Atrasheuskaya AV, Fredeking TM, Ignatyev GM. Changes in immune parameters and their correction in human cases of tick-borne encephalitis. Clin Exp Immunol. 2003;131(1):148-54.

30. Fredeking TM, Zavala-Castro JE, González-Martínez P, Moguel-Rodríguez W, Sanchez EC, Foster MJ, et al. Dengue patients treated with doxycycline showed lower mortality associated to a reduction in IL-6 and TNF levels. Recent Pat Anti-infect Drug Discov. 2015;10(1):51-8.

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1. Del Rosso JQ. Oral doxycycline in the management of acne vulgaris: current perspectives on clinical use and recent findings with a new double-scored small tablet formulation. The Journal of clinical and aesthetic dermatology. 2015 May;8(5):19-26.
2. Del Rosso JQ. Clinically Important Considerations with the Use of Oral Doxycycline. The National Society for Cutaneous Medicine. 2017 Nov; 1(3):143-7.
3. Sykes JE, Papich MG. Chapter 8 - Antibacterial Drugs. Canine and Feline Infectious Diseases. [ebook]. 2014. [cited 2018 Mar 12]. Available from: https://www.sciencedirect.com/topics/agricultural-and - biological-sciences/tetracycline-antibiotics
4. Data on file.
5. CDC. Pelvic Inflammatory Disease (PID). [internet]. [cited 2018 Mar 13]. Available from: https://www.cdc.gov/std/tg2015/ pid.htm.
6. WHO. Annex 1 19th WHO Model List of Essential Medicines (April 2015). [internet]. 2015. [cited 2018 Mar 12]. Available from: http://www.who.int/medicines/publications/essentialmedicines/ EML2015_8-May-15.pdf

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Rapidly Progressive Cerebellar Ataxia in a Case of Unsuspected Celiac Disease: Early Diagnosis Leads to Reversibility

ARVIND VYAS*, DIVYA GOEL†

ABSTRACT

Subacute late-onset cerebellar ataxia in a patient can be due to varied causes. The common ones are infectious, drug-related, autoimmune and paraneoplastic pathologies. As majority of these causes are deemed treatable, they should be investigated in a sporadic case of ataxia. Celiac disease can have neurological complications in about 10% of cases but those are usually a secondary feature of this disease. This case report features a case of rapidly progressive cerebellar ataxia as the sole presentation of unsuspected celiac disease.

Keywords: Cerebellar ataxia, rapidly progressive, celiac disease

Cerebellar ataxia can be classified according to the age of onset. Its occurrence below 40 years of age is considered early-onset and above this is labeled late-onset ataxia. Another type of classification is done by the type of symptom onset- sudden, acute, subacute or chronic. Where sudden cerebellar ataxias of late-onset are usually due to stroke and chronic ones are mostly due to degenerative causes, the acute and subacute ones are those, which may have a treatable etiology.

The commonly postulated causes of late-onset cerebellar ataxias are infectious (e.g., prion disease), drug-related (e.g., phenytoin), autoimmune (e.g., anti-glutamic acid decarboxylase [GAD], steroid responsive encephalopathy with autoimmune thyroiditis, gluten sensitive ataxia) and paraneoplastic. A battery of tests is needed to arrive at the correct diagnosis. Celiac disease is one such cause and is rendered treatable if neurological symptoms have not advanced much. It presents with cerebellar ataxia in about 10% of patients. The ataxia is usually insidious in onset and follows abdominal symptoms. But rare presentations, like rapidly progressive cerebellar ataxia with lack of abdominal symptoms, need to be screened for autoimmune and paraneoplastic causes.

CASE REPORT

A 58-year-old male presented with 20 days history of vomiting, headache, vertigo and subacute onset ataxia, which progressed rapidly over next 5 days. A week later, he noticed some slurring of speech but his ataxia remained static after initial progression. He had no accompanying history of any drug intake, fever, weight loss or headache. He cleared his bowel twice everyday with no change in frequency or consistency of his stools. He did not have any significant past or family history.

His general examination was unremarkable. Positive findings in his neurological examination were those of asymmetrical cerebellar signs in the form of intention tremors, dysdiadokokinesia and mild dysmetria more prominent on right. His speech was cerebellar and gait ataxic. Ocular examination did not reveal any nystagmus. His higher mental functions, motor and sensory examination were unremarkable. Initially on the basis of his rapidly progressive symptoms and subsequent achievement of a static course, we thought it of as cerebellitis.

His routine laboratory investigations were normal. Thus, we conducted magnetic resonance imaging (MRI) brain and cerebrospinal fluid (CSF) examination, both of

*Senior Professor
†Senior Resident
Dept. of Neurology
SMS Medical College, Jaipur, Rajasthan
Address for correspondence
4-Ba-19, Jawahar Nagar, Jaipur, Rajasthan - 302 005
E-mail: drdivyagoel@hotmail.com

which proved out to be normal. Thus, we thought of ruling out autoimmune and paraneoplastic causes. He was started on injectable methylprednisolone in the meantime but without any improvement in his symptoms, leading us to stop it after 3 days. His antinuclear antibody and tumor markers were negative, thyroid profile including antithyroid peroxidase antibodies were normal. Anti-tissue transglutaminase (anti-tTG) titer came out to be positive, thus we subjected the patient to intestinal biopsy for confirmation. He was commenced on a gluten-free diet and was discharged in a stable condition with his biopsy report awaited. He came for follow-up after 10 days with improvement in ataxia and his histopathology report showed changes in favor of celiac disease type 3a, according to the modified Marsh classification.

DISCUSSION

Celiac disease is an autoimmune enteropathy due to gluten sensitivity manifesting as diarrhea, steatorrhea, weight loss,[1] and occasionally neurological symptoms such as cerebellar ataxia, peripheral neuropathy, myoclonus, chorea, palatal tremor and opsoclonus-myoclonus.[2] Cerebellar ataxia is one of the most common presentations of celiac disease as is shown in previous studies, but majority of patients have a long-standing celiac disease before the onset of neurological symptoms. This case has been reported owing to the subacute onset and rapid progression of ataxia in a patient of unsuspected celiac disease, though similar cases have been reported in literature.

A case presented with rapidly progressive ataxia, dysarthria and bilateral lateral rectus palsy in the presence of minimal abdominal symptoms. He was worked up for celiac disease and was found to be positive but had a fulminant course of his symptoms, not responding to gluten restriction, steroids or other immunosuppressants, culminating into death due to myocardial infarction.[1] The mean age of gluten ataxia is 53 years and has no gender predominance. There are many mimickers of gluten ataxia in this age group, including paraneoplastic cerebellar degeneration, anti-GAD ataxia and cerebellar variant of multiple system atrophy (MSA-C). The rare presentation of rapidly progressive ataxia, as is seen in the reported case, mimics paraneoplastic cerebellar degeneration and anti-GAD ataxia. The search for primary and tumor markers needs to be conducted. Lack of autonomic dysfunction differentiates it from MSA-C.[2]

The mechanism of neurological complications in celiac disease is yet uncertain. The proposed mechanisms are: (1) Malabsorption of various neuroprotective nutrients and (2) antigliadin antibody neurotoxicity.[3] There are experiments proposing that Purkinje cells in cerebellum share the same antigen epitope as the gluten peptides resulting in cerebellar involvement.[2] Thus, a gluten-free diet can actually benefit the patients of gluten ataxia.

This case study highlights the importance of rare and atypical presentation of celiac disease and early screening for antibodies followed by biopsy confirmation, which can lead to reversibility of the neurological symptoms of this disease.

REFERENCES

1. Hermaszewski RA, Rigby S, Dalgleish AG. Coeliac disease presenting with cerebellar degeneration. Postgrad Med J. 1991;67(793):1023-4.
2. Hadjivassiliou M, Sanders DS, Woodroofe N, Williamson C, Grünewald RA. Gluten ataxia. Cerebellum. 2008;7(3):494-8.
3. Pellecchia MT, Scala R, Filla A, De Michele G, Ciacci C, Barone P. Idiopathic cerebellar ataxia associated with celiac disease: lack of distinctive neurological features. J Neurol Neurosurg Psychiatry. 1999;66:32-5.

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Complications of Intrauterine Insemination

MANISHA T KUNDNANI*, RUTVIJ DALAL†, NANDITA P PALSHETKAR‡, HRISHIKESH D PAI‡

ABSTRACT

Intrauterine insemination (IUI), a commonly performed procedure in the treatment of infertility, is one of the easiest and safe procedures as it is the least invasive method for assisted reproduction. In most women, complications of IUI are rare; however, they can sometimes occur, which may be directly or indirectly related to the procedure. These could be due to ovarian stimulation like ovarian hyperstimulation syndrome (OHSS), multiple pregnancies or due to the insemination procedure like pain, infections, trauma and bleeding, etc. Other complications that may rarely occur include abortion, ectopic pregnancy and accidental insemination with the wrong sample. Of these, OHSS is an iatrogenic and one of the most dreaded complications associated with ovarian stimulation. It is associated with a wide-spectrum of clinical signs and symptoms, ovarian enlargement, fluid shift from intravascular to extravascular compartment and changes in biochemical parameters.

Keywords: Intrauterine insemination, infertility, complications, OHSS

Intrauterine insemination (IUI) is one of the easiest and safe procedures as it is the least invasive method for assisted reproduction. Still, complications can sometimes occur, which may be directly or indirectly related to the procedure. The treating physician should have a complete knowledge and understanding of these complications to minimize their incidence and also should be capable of treating them in case they occur. The complications can be divided as:

- Due to ovarian stimulation
- Due to insemination procedure
- Other complications.

COMPLICATIONS DUE TO OVARIAN STIMULATION

IUI is usually combined with controlled ovarian stimulation and natural cycle IUI is rare. Controlled ovarian stimulation (COS) can be associated with certain complications, which can be divided into immediate and delayed: *Immediate*: Ovarian hyperstimulation syndrome (OHSS) and multiple pregnancies; *Delayed*: Risk of ovarian cancer.

* Past Fellow of National Board Reproductive Medicine
†Fellow in Reproductive Medicine
‡Senior Consultant
Lilavati Hospital and Research Centre, Mumbai, Maharashtra
Address for correspondence
Dr Rutvij Dalal
Fellow in Reproductive Medicine
Lilavati Hospital and Research Centre, Mumbai, Maharashtra
E-mail: rutvij.dalal@gmail.com

Ovarian Hyperstimulation Syndrome

OHSS is an iatrogenic and one of the most dreaded complications associated with ovarian stimulation. It is associated with a wide-spectrum of clinical signs and symptoms, ovarian enlargement, fluid shift from intravascular to extravascular compartment and changes in biochemical parameters. It is usually seen after stimulation with gonadotropins; however, can rarely occur after clomiphene citrate use.

Incidence

The incidence of OHSS ranges from 3% to 23% and varies according to the ovulation induction protocols and the risk profile of population being studied.[1] The incidence of mild, moderate and severe of OHSS is 8-23%, 0.005-7% and 0.008-2%, respectively.

Pathophysiology

The exact pathophysiology is still not elucidated. The major events are neovascularization and increased vascular permeability that lead to acute fluid shift from the intravascular to extravascular compartment. This shift occurs due to release of vasoactive substances from the ovary under the influence of human chorionic gonadotropin (hCG). These are renin-angiotensin, interleukins, nitric oxide and vascular endothelial growth factor (VEGF).[2] It has recently been identified that increased sensitivity of the follicle-stimulating hormone (FSH) receptor to hCG is responsible for spontaneous OHSS occurring during pregnancy.[3]

Classification of OHSS

OHSS has been classified into various stages and grades according to the clinical symptoms, signs, ultrasonographic findings and laboratory parameters. The most commonly used is the Golan's classification which has divided it in 3 stages: mild, moderate and severe and 5 grades (Table 1).[4] The severest grade of OHSS is further classified by Navot as severe and critical life-threatening depending on clinical and biochemical findings to indicate when management in an intensive care setting should be considered (Table 2).[5]

The purpose of clinical staging is to guide patient management. In general, mild and moderate forms of OHSS can be treated expectantly in the outpatient department (OPD). Those with severe form should be admitted and those with critical OHSS are best managed in consultation with other specialists in intensive care setting.

Complications of OHSS

- Vascular complications: Venous compression, immobility and state of hypercoagulability can cause deep vein thrombosis. Cerebrovascular complications can occur secondary to these thromboembolic events.
- Liver dysfunction
- Renal dysfunction
- Respiratory compromise
- Adnexal torsion, rupture or hemorrhage.

Table 1. Golan's Classification of OHSS[4]

Grade I: *Mild* - Abdominal discomfort/distension

Grade II: *Mild* - Features of Grade I along with nausea, vomiting and/or diarrhea, ovaries enlarged 5-12 cm

Grade III: *Moderate* - Features of mild OHSS and USG e/o ascites

Grade IV: *Severe* - Features of moderate OHSS *plus* clinical e/o ascites and/or hydrothorax with/or difficulty in breathing

Grade V: *Severe* - All of the above *plus* changes in blood volume, increased blood viscosity due to hemoconcentration, coagulation disturbances and diminished renal perfusion and function

Table 2. Clinical Signs and Laboratory Criteria of OHSS[5]

	Mild-to-moderate	Severe	Critical
Ovarian enlargement	5-12 cm	>12 cm	Variable
Abdominal distension	Moderate	Severe	Tense
Clinical ascites	None	Yes	Tense
Hydrothorax	None	Possible	Yes
Pericardial effusion	None	Infrequent	Infrequent
Decreased renal function	None	Infrequent	Frequent
Renal failure	None	None	Possible
Thromboembolism	None	None	Possible
ARDS	None	None	Possible
Hemoconcentration	<45%	45-55%	>55%
WBC count	<15,000	15-25,000	>25,000
Liver enzymes	Normal	Elevated	Elevated
Creatinine (ng/mL)	<1.0	1-1.5	>1.6
Creatinine clearance (mL/min)	>100	50-100	<50

ARDS = Acute respiratory distress syndrome; WBC = White blood cell.

Prediction

Various factors have been identified to help define patients at high risk for OHSS (Table 3). All patients undergoing ovulation induction should be closely monitored with:

- **Ultrasound follicular monitoring:** All follicles including the smaller ones should be measured. The small (<9 mm) and intermediate follicles are more dangerous as these continue to grow and produce estradiol following hCG administration.[6]

  Patients with polycystic ovary syndrome (PCOS) are more likely to develop OHSS than those without polycystic ovaries as these have high sensitivity to gonadotropin stimulation due to large cohort of FSH sensitive small antral follicles.[7]
- **Serum estradiol levels:** A high level and a steep rise can predict likelihood of developing OHSS.

Prevention

- **Withholding hCG:** hCG trigger is usually given when the follicles reach 16-25 mm in size and estradiol level reaches 200-400 pg/mL per leading follicle. hCG is withheld in an IUI stimulated cycle if serum estradiol levels are more than 1,500 pg/mL. USG findings of more than 6 leading follicles can also be used as a criterion to withhold hCG.

  Also, if estradiol levels are more than doubling during 2-3 days (steep slope) then it should be regarded as a serious warning sign and hCG should be withheld in that cycle. When hCG is withheld:
  - Follicles can be aspirated and embryos cryopreserved
  - Continue GnRH agonists after stopping gonadotropins. Once down regulation occurs, cycle can be restarted at a lower dosage.
- **Delaying hCG (coasting):** When estradiol levels are high, hCG is withheld, gonadotropin-releasing hormone (GnRH) agonist is continued and gonadotropins are stopped till estradiol (E2) falls, following which hCG is given.[8] Withholding hCG causes apoptosis of granulosa cells and atresia of large number of follicles. Long coasting periods; however, have a negative impact on number of oocytes, implantation and pregnancy rates.[9,10]
- **Decreasing dose of hCG:** Lower dose of hCG (5,000 units instead of 10,000) may avoid hyperstimulation by exerting shorter periods of stimulation.
- **Use of GnRH agonist instead of hCG for luteinizing hormone (LH) surge:** As period of stimulation is lesser with GnRH agonist surge, there is no hyperstimulation. The rates of fertilization, implantation, clinical pregnancy, ongoing pregnancy and abortion rates observed are similar to hCG.[11]
- **Follicle aspiration:** Follicle aspiration can decrease the chance of OHSS.[12] However, some studies contradict this.
- **Albumin/hydroxyethyl starch:** This increases the serum oncotic pressure and prevents leakage of fluid in the third space. This is used as a prophylactic measure. The disadvantage is that its oncotic action lasts only for 36 hours.
- **Conversion to an *in vitro* fertilization (IVF) cycle, cryopreservation of embryos** and subsequent transfer in a later cycle. This helps decrease the chances of OHSS with the advantage of not losing the cycle and replacing the frozen thawed embryos in a later cycle.
- **Steroids:** Methyl prednisolone has been tried in cases of OHSS.[13]
- **Cabergoline:** This dopamine receptor agonist inactivates VEGF receptor and prevents increased vascular permeability. It is administered in a dose of 0.5 mg/day, starting from the day of hCG, for 8 days. The incidence of OHSS is significantly reduced.[14]

Table 3. Risk Factors for OHSS

Predicting factors	High risk	Low risk
Age	<35	>36
PCOS	Present	Absent
Build	Lean, thin	Heavy
No. of follicles	Multiple	Few
History of OHSS	Present	Absent
Induction protocol	GnRH agonist	CC or hMG
Luteal supplementation	Yes	No
Outcome	Pregnant	Not pregnant

OHSS = Ovarian hyperstimulation syndrome; PCOS = Polycystic ovary syndrome; GnRH = Gonadotropin-releasing hormone; CC = Clomiphene citrate; hMG = Human menopausal gonadotropin.

Treatment

The condition is self-limiting and usually resolves in 10-14 days. The treatment depends on the severity of the disease. The investigations and monitoring of OHSS patients is summarized in Table 4.

Table 4. Investigations and Monitoring of OHSS Patients

General condition: Regular charting of
- Vital signs: Pulse rate, respiratory rate, temperature
- Weight chart
- Abdominal girth
- Input-output record

Biochemical tests:
- Hematocrit
- Serum electrolytes
- Liver function tests
- Renal function tests
- Coagulation profile
- Blood gases and acid base balance
- Serum β-hCG

Ultrasonographic examination
- Ovarian size
- Amount of ascites
- Presence of hydrothorax
- Pregnancy: Single/multiple

Mild OHSS/Grade I

The treatment is usually conservative and is done on an outpatient basis with a close follow-up. One should reassure the patient. She should be advised to have plenty of fluids and to avoid exertion.

Grade II

Minimize physical activity and take plenty of fluids. Analgesics and antiemetics may be used as required. Serum hematocrit and electrolytes should be monitored. Input-output record should be maintained. Reassessment is required if there is increase in weight of more than 2 kg or if there is worsening of symptoms.

Indication of hospitalization

- Grade II or III OHSS if:
  - Intolerable nausea or vomiting
  - Hypotension
  - Pleural effusion
  - Ascites
  - Hematocrit >48%
  - Sodium <135 mg/L
  - Potassium level >5.0 mg/L
  - Serum creatinine >1.2 mg.
- All cases of Grade IV or V.

Aim

- Correction of circulatory volume
- Correction of electrolyte imbalance
- Maintaining renal function
- Prevention of thrombosis.

Maintaining intravascular volume: As there is hyponatremia, normal saline with or without glucose is the main crystalloid used. Plasma expanders like albumin are also used as there is protein loss in the third space. Other fluids like mannitol, dextran and fresh frozen plasmas can also be used.

Prevention of thrombosis: Low dose heparin can be used in cases where there is altered coagulation profile. Thromboembolic events require therapeutic anticoagulation with heparin.

Diuretics: These are used if oliguria persists in spite of restoring intravascular volume or in case of pulmonary edema. If renal failure still does not resolve with these measures, dopamine is added to dilate the renal vasculature.

Ascites: Paracentesis is done if there is severe discomfort, venous return is compromised, respiratory distress, renal compromise or hemoconcentration unresponsive to medical therapy. It should only be done if patient is hemodynamically stable.

Paracentesis of hydrothorax: This is done in cases of pleural effusion leading to dyspnea. Severe respiratory compromise may require ventilatory support.

Termination of pregnancy: If critical condition still doesn't improve, one may consider termination of pregnancy.

Laparotomy is required in cases of ovarian torsion, hemorrhage and rupture.

Multiple Pregnancies

This is an inevitable complication associated with ovarian stimulation. This is increased more when gonadotropins are used for ovarian stimulation compared to clomiphene citrate. It is very important to carefully monitor the patients undergoing COS *plus* IUI to minimize the incidence of multiple pregnancies. These births are associated with significant maternal morbidity and also preterm birth with its sequel of neonatal mortality and morbidity.

Women at high risk of multiple pregnancies are usually less than 30 years of age; with 6 or more than 6 pre-ovulatory follicles and with peak serum estradiol more

than 1,000 pg/mL. The following options are available to such women:

- Cancel the cycle and reinitiate with a lower gonadotropin dose in the next cycle
- Limited oocyte aspiration
- Conversion to IVF
- Proceed with the cycle and multifetal pregnancy reduction.

Risk of Ovarian Cancer

Earlier studies have suggested a threefold increase in incidence of ovarian cancer in women who undergo ovulation induction.[15] However, the recent reports have not replicated these findings.[16,17] Some reports; however, suggest an increased incidence of borderline tumors.[18] It should be kept in mind, the cancers are over diagnosed in infertile women because of close medical surveillance.

It has; however, been recommended that these drugs should not be used consecutively for more than 6 cycles and not more than a total of 12 cycles. Smallest dose for shortest possible duration should be used.

COMPLICATIONS DUE TO INSEMINATION PROCEDURE

These are rare and not life-threatening. These are:

- Infection
- Trauma and bleeding
- Pain
- Noninfective salpingitis
- Allergic reaction
- Antisperm antibody
- Vasomotor symptoms.

Infection

The risk of infection with IUI is rare and is estimated to be 1.8 per 1,000 women.[19] The reasons for such low risk are:

- The population has already been screened for infection
- The risk of acquiring sexually transmitted disease (STD) during treatment is rare
- Sperm preparation techniques are thought to remove microbes.[20]

Infection can; however, occur sometimes. The sources of infections are:

- Local source: Resident urethral flora, hands, glans penis
- Airborne bacteria in the semen collection room
- Contamination due to faulty technique:
  - Collection in unsterile container
  - Nonsterile preparation techniques
  - Cannula tip touching the vagina
  - Contamination with cervical flora.

The organisms commonly isolated are *Escherichia coli, Neisseria gonorrhoeae, Trichomonas vaginalis*, Streptococcus, Ureaplasma, etc.

Prevention

- Aseptic techniques and quality control should be maintained.
- Sperm wash media can be supplemented with antibiotics.
- Educate patient on proper semen collection techniques.

Administration of prophylactic antibiotics does not alter the infection rates. The role of prophylactic antibiotics is still a matter of debate.

Trauma and Bleeding

IUI is a relatively simple and easy procedure and proper technique can avoid trauma. Trauma and bleeding; however, can sometimes occur due to injury to the internal os or the endometrium by the insemination cannula or by injury to the cervical lip by Allis/Vulsellum.

Bleeding after IUI is associated with low pregnancy rates.[21]

Pain

Pain can occur because of uterine cramps. Severe cramps have been reported in 6-17% of cases.[22] Pain can be due to instrumentation. Also in cases of difficult IUI, trauma to the endometrium can cause release of prostaglandins, which can cause cramping pain. Prostaglandins can also be introduced with seminal plasma. Good semen washing techniques and reducing the volume of inseminate can minimize this problem.

Noninfective Salpingitis

Any foreign substance like sperm preparation ingredients like percoll can irritate the endometrium and can cause noninfective salpingitis. Proper washing of sperms with density gradients can prevent these.

Allergic Reaction

These are rare. Mild reactions may not be seen immediately but can occur later. Severe anaphylaxis can

rarely occur. It can be due to semen itself, ingredients of sperm wash media or due to allergy to penicillin or bovine albumin.

Vasomotor Symptoms

Vasomotor symptoms such as nausea, bradycardia and diaphoresis can occur rarely.

Antisperm Antibody

During IUI, a large dose of antigenic sperms is deposited into the uterine cavity directly, bypassing the cervix, which otherwise acts as a barrier and modifies the antigenic load. The sperms are then cleared by the macrophages into the peritoneal cavity. A high immunogenic load may increase the production of antibodies. Different women; however, have different immune response and most reports do not support the hypothesis of formation of antibodies with IUI.

OTHER COMPLICATIONS

- Abortion
- Ectopic pregnancy
- Accidental insemination with wrong sample.

Abortion

Abortion rate with IUI is estimated to be 20-30%.[23,24] This could be attributed to higher age of these women and increased incidence of multiple pregnancy. Early diagnosis and close monitoring of these patients compared to general population also results in higher reported abortion rates.

Ectopic Pregnancy

The incidence of ectopic pregnancy is higher in women undergoing IUI and other assisted reproductive technology (ART) procedures. The incidence is higher in women with history of tubal disease. Even in those without such history, the incidence is about 5 times higher than in general population.

Accidental Wrong Samples

When more than one sample is processed at one time, there is a possibility of mixing of samples. To avoid such a situation:

- Label all samples
- Use separate syringes and pipettes for separate samples
- Properly identify the sample before loading the cannula
- More than one person should check the sample
- Gynecologist should recheck the identity before inseminating.

REFERENCES

1. Schenker JG, Weinstein D. Ovarian hyperstimulation syndrome: a current survey. Fertil Steril. 1978;30(3):255-68.
2. Kosaka K, Fujiwara H, Yoshioka S, Fujii S. Vascular endothelial growth factor production by circulating immune cells is elevated in ovarian hyperstimulation syndrome. Hum Reprod. 2007;22(6):1647-51.
3. De Leener A, Caltabiano G, Erkan S, Idil M, Vassart G, Pardo L, et al. Identification of the first germline mutation in the extracellular domain of the follitropin receptor responsible for spontaneous ovarian hyperstimulation syndrome. Hum Mutat. 2008;29(1):91-8.
4. Golan A, Ron-el R, Herman A, Soffer Y, Weinraub Z, Caspi E. Ovarian hyperstimulation syndrome: an update review. Obstet Gynecol Surv. 1989;44(6):430-40.
5. Navot D, Bergh PA, Laufer N. Ovarian hyperstimulation syndrome in novel reproductive technologies: prevention and treatment. Fertil Steril. 1992;58(2):249-61.
6. Blankstein J, Shalev J, Saadon T, Kukia EE, Rabinovici J, Pariente C, et al. Ovarian hyperstimulation syndrome: prediction by number and size of preovulatory ovarian follicles. Fertil Steril. 1987;47(4):597-602.
7. Van Der Meer M, Hompes PG, De Boer JA, Schats R, Schoemaker J. Cohort size rather than follicle-stimulating hormone threshold level determines ovarian sensitivity in polycystic ovary syndrome. J Clin Endocrinol Metab. 1998;83(2):423-6.
8. Merviel P, Claeys C, Héraud MH, Lourdel E, Lanta S, Barbier F, et al. Coasting and ovarian stimulation protocols in high-responder patients undergoing assisted conception. Gynecol Obstet Fertil. 2005;33(9):703-12.
9. Owj M, Tehrani Nejad ESh, Amirchaghmaghi E, Ezabadi Z, Baghestani AR. The effect of withholding gonadotropin (a coasting period) on the outcome of in vitro fertilization cycles. Eur J Obstet Gynecol Reprod Biol. 2007;133(1):81-5.
10. Nardo LG, Cheema P, Gelbaya TA, Horne G, Fitzgerald CT, Pease EH, et al. The optimal length of 'coasting protocol' in women at risk of ovarian hyperstimulation syndrome undergoing in vitro fertilization. Hum Fertil (Camb). 2006;9(3):175-80.
11. Shapiro BS, Daneshmand ST, Garner FC, Aguirre M, Ross R. Comparison of human chorionic gonadotropin and gonadotropin-releasing hormone agonist for final oocyte maturation in oocyte donor cycles. Fertil Steril. 2007;88(1):237-9.
12. Zhu WJ, Li XM, Chen XM, Zhang L. Follicular aspiration during the selection phase prevents severe ovarian hyperstimulation in patients with polycystic ovary syndrome who are undergoing in vitro fertilization. Eur J Obstet Gynecol Reprod Biol. 2005;122(1):79-84.

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Hydatid Cyst Mimicking as Ovarian Tumor

SUMITRA YADAV*, HK KANSAL†, ANITA SINGH‡, SANJAY PATIDAR‡

ABSTRACT

Hydatid disease remains endemic in various parts of the world due to the close association that exists between sheep, dogs and humans. Humans are the accidental intermediary hosts in the biologic cycle of the *Echinococcus granulosus*, which is the most frequent hydatidosis in the environment. USG and CT are both excellent imaging modalities for the detection of hydatid cysts. CT provides 3-D view and delineates the cyst, which is useful when diagnosis is uncertain, or when rupture or infection has occurred.

Keywords: Hydatid disease, abdominal lump, adnexal mass

Hydatid disease is a cyclozoonosis in which humans are accidental intermediary hosts in the biologic cycle of *Echinococcus granulosus*, the most frequent etiologic agent for hydatidosis. It usually involves the liver (75%), lungs (5-15%) and other organs in the body such as the spleen, brain, heart, kidneys and ovary (10-20%). Hydatid disease evokes much interest not only for the diversity of the anatomical and clinical forms it produces but also for the problems of diagnosis and therapy it creates, particularly when located at unusual sites.

CASE REPORT

A 70-year-old lady presented with a history of abdominal lump since 1-2 years, which was gradually increasing in size. Patient had persistent dull-aching pain abdomen. Initially the size of the lump was 3-4 × 4 cm in right iliac fossa; now it was 10 × 8 cm. It was associated with history of loss of appetite and weight loss. Patient also had history of constipation on and off for which she used to take medication (i.e. laxative) sometimes. There was no history of cough, vomiting, jaundice, malena, hemoptysis and hematemesis. She was P_2L_2; married for 50 years and menopausal since 20 years. Physical examination revealed severe general cachexia (weight 30 kg) and a large mass (10 × 8 × 6 cm size) arising from pelvis on right side of abdomen. The mass was dull on percussion without any fluid thrill or shifting dullness, it appeared solid to cystic in consistency with ill-defined margins. There was no hepatosplenomegaly and lymphadenopathy. Further investigations were done to find out the exact extent and nature of disease.

Laboratory investigations: Hemoglobin (Hb) 7 g/dL; total and differential leukocyte counts were normal; renal and liver function tests were also normal; sputum for acid-fast bacilli (AFB) was negative; CA-125 - 50 IU/mL.

USG of abdomen and pelvis: Normal liver, echogenic mass in the spleen of size 2.5 cm. An adnexal mass was seen on the right side, which was cystic in consistency, size 12.3 × 10.3 cm with septations, solid component seen posterior to urinary bladder in pelvis; uterus/ovary not visualized.

Magnetic resonance imaging (MRI) of whole abdomen and pelvis showed an 8.4 × 5 cm sized right adnexal mass, which appeared heterogeneously hyperintense on T_2 and hypo on T_1 images. It appeared well-marginated and revealed dense calcification. A predominantly cystic lesion in the left adnexae measuring 9 × 9 cm displacing the uterus to the right was also seen. It revealed multiple nodular mural components as well as multiple septae and locules within. No evidence of T_1 hyperintensity was seen to suggest fat/hemorrhagic products. Rim calcification was seen. The fat planes appeared well-preserved and

*Associate Professor and Unit Head
†Senior Resident
‡Residents
Dept. of Obstetrics and Gynecology
MGM Medical College and MYH Hospital, Indore (MP)
Address for correspondence
Dr Sumitra Yadav
30, Nayapura, Aerodrome Road
Indore - 452 005, MP
E-mail:drsumitrayadav@yahoo.co.in, asas20asas@gmail.com

the bowel loops were displaced; the urinary bladder appeared displaced anteriorly and Foley's catheter was seen *in situ*. Intervening fat planes were preserved. No significant pelvic lymphadenopathy or free fluid was seen. Ureters were not dilated. The liver was normal in size and density - no focal lesion was seen. The gallbladder, biliary tree and pancreas were normal. The portal vein, splenic vein and spleen were normal. There was focal hyperintense lesion with hypointense smooth uniform rim seen in the splenic parenchyma measuring approximately 4.4 × 3.2 cm. Calcifications were seen in the both adrenals; kidneys were normal except for a simple cyst in upper pole of left kidney. No retroperitoneal lymphadenopathy was seen. The bowel loops were normal.

Outcome

The patient was taken for exploratory laparotomy after transfusing 2 units of blood, with 1 unit blood in hand. Intraoperatively, the bowel loops were found to be adherent to the underlying mass. Blunt dissection done and uterus could not be easily identifiable. That mass appeared as caseous material. Dissection was completed taking due precautions. There were dense adhesions and on left side of ovary there were daughter hydatid cysts, 6-7 in number and sized 4-5 cm size. Pericyst and daughter cysts (Figs. 1 and 2) were removed with some difficulty. Betadine washing was done. Samples were collected from both sides for histopathology. A drain was kept in the pelvic area.

Histopathology Report

Material for examination: Left ovarian cyst, right ovarian caseous material (Fig. 3).

Microscopic: Hematoxylin and eosin (H&E) stained sections studied from ovarian tissue show cyst wall comprising of acellular eosinophilic laminated material. Brood capsule and scolices were also appreciated. Features were suggestive of hydatid cyst ovary.

DISCUSSION

Hydatid disease remains endemic in various parts of the world due to the close association that exists between sheep, dogs and humans. Humans become infected by accidental ingestion of food or water contaminated by tapeworm eggs. Humans are the accidental intermediary hosts in the biologic cycle of the *E. granulosus*, which is the most frequent hydatidosis in the environment. After ingestion, the eggs pass into the small bowel, where they hatch and are absorbed. The parasites then travel through the bloodstream and eventually establish cystic lesions in various organs. The liver is the most likely organ to be involved through portal drainage, but any organ may be infected. Each cystic lesion contains fluid and multiple secondary daughter cysts. The development of the parasitic larval stage in the organs of the host manifests in the form of cysts (hydatids). A typical hydatid cyst consists of three

Figure 1. Pericyst (Hydatid cyst material) in right-sided ovary.

Figure 2. Left ovarian cysts.

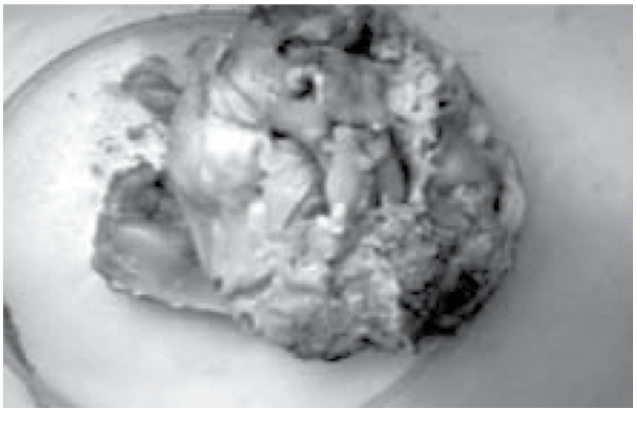

Figure 3. Caseous material in right-sided ovarian tissue.

layers:[1] Pericyst, ectocyst and endocyst. Complications are seen in one-third of cases.

The most common complication is rupture of cyst, which may result in anaphylactic shock and formation of localized or generalized secondary-echinococcosis.[2] Fever with chills and rigors can occur if the cyst is secondarily infected. Jaundice, biliary colic and urticaria will develop if there is an intrabiliary rupture of the cyst.[3] Intrathoracic rupture may lead to shoulder pain and phlegmatic cough containing blood and bile.[4] Ultrasonography (USG) and computed tomography (CT) are both excellent imaging modalities for the detection of hydatid cysts. However, USG is less accurate in localizing and delineating the extent of the cyst though it's cost-effective. The sensitivity of CT scan is 90-100%.[5] It provides 3-D view and delineates the cyst, which is useful when diagnosis is uncertain or when rupture or infection has occurred.[6]

The World Health Organization (WHO) has outlined the treatment guidelines for hydatid cysts. Surgery is the treatment of choice for all patients with symptomatic disease and who are fit for surgery.[7]

REFERENCES

1. Milicevic M. Hydatid disease. In: Blumgart LH (Ed.). Surgery of the Liver and Biliary Tract. 2nd Edition, New York: Churchill Livingstone; 1994. pp. 1121-50.
2. Dew H. Some complications of hydatid disease. Br J Surg. 1930;18(70):275-93.
3. Humayun MS, Rady AM, Soliman GM. Obstructive jaundice secondary to intrabiliary rupture of hepatic hydatid cyst. Int Surg. 1989;74(1):4-6.
4. Saidl F. Surgery of Hydatid Disease. 1st Edition, Philadelphia: WB Saunders; 1976:112-21.
5. Safioleas M, Misiakos E, Manti C, Katsikas D, Skalkeas G. Diagnostic evaluation and surgical management of hydatid disease of liver. World J Surg. 1994;18(6):859-65.
6. El-Tahir MI, Omojola MF, Malatani T, al-Saigh AH, Ogunbiyi OA. Hydatid disease of liver: evaluation of ultrasound and computed tomography. Br J Radiol. 1992;65:390-2.
7. WHO Informal Working Group on Echinococcosis. Guidelines for treatment of cystic and alveolar echinococcosis in humans. Bull World Health Organ. 1996;74(3):231-42.

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13. Lainas T, Petsas G, Stavropoulou G, Alexopoulou E, Iliadis G, Minaretzis D. Administration of methylprednisolone to prevent severe ovarian hyperstimulation syndrome in patients undergoing in vitro fertilization. Fertil Steril. 2002;78(3):529-33.
14. Alvarez C, Martí-Bonmatí L, Novella-Maestre E, Sanz R, Gómez R, Fernández-Sánchez M, et al. Dopamine agonist cabergoline reduces hemoconcentration and ascites in hyperstimulated women undergoing assisted reproduction. J Clin Endocrinol Metab. 2007;92(8):2931-7.
15. Whittemore AS, Harris R, Itnyre J, Halpern J. Characteristics relating to ovarian cancer risk: collaborative analysis of 12 US case-control studies. I. Methods. Collaborative Ovarian Cancer Group. Am J Epidemiol. 1992;136(10):1175-83.
16. Cusidó M, Fábregas R, Pere BS, Escayola C, Barri PN. Ovulation induction treatment and risk of borderline ovarian tumors. Gynecol Endocrinol. 2007; 23(7):373-6.
17. Brinton LA, Moghissi KS, Scoccia B, Westhoff CL, Lamb EJ. Ovulation induction and cancer risk. Fertil Steril. 2005;83(2):261-74; quiz 525-6.
18. Ayhan A, Salman MC, Celik H, Dursun P, Ozyuncu O, Gultekin M. Association between fertility drugs and gynecologic cancers, breast cancer, and childhood cancers. Acta Obstet Gynecol Scand. 2004;83(12):1104-11.
19. Sacks PC, Simon JA. Infectious complications of intrauterine insemination: a case report and literature review. Int J Fertil. 1991;36(6):331-9.
20. Wong PC, Balmaceda JP, Blanco JD, Gibbs RS, Asch RH. Sperm washing and swim-up technique using antibiotics removes microbes from human semen. Fertil Steril. 1986;45(1):97-100.
21. Kerin JF, Quinin P. Supercervical placement of spermatozoa: utility of intrauterine and tubal insemination. In: Soules MR (Eds.). Controversies in Reproductive Endocrinology and Infertility. New York: Elsevier; 1989.
22. Allen NC, Herbert CM 3rd, Maxson WS, Rogers BJ, Diamond MP, Wentz AC. Intrauterine insemination: a critical review. Fertil Steril. 1985;44(5):569-80.
23. Lalich RA, Marut EL, Prins GS, Scommegna A. Life table analysis of intrauterine insemination pregnancy rates. Am J Obstet Gynecol. 1988;158(4):980-4.
24. Dodson WC, Haney AF. Controlled ovarian hyperstimulation and intrauterine insemination for treatment of infertility. Fertil Steril. 1991;55(3):457-67.

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"No one should die of heart disease just because he/she cannot afford it"

About Sameer Malik Heart Care Foundation Fund

"Sameer Malik Heart Care Foundation Fund" it is an initiative of the Heart Care Foundation of India created with an objective to cater to the heart care needs of people.

Objectives

- Assist heart patients belonging to economically weaker sections of the society in getting affordable and quality treatment.
- 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.

Activities of the Fund

Financial Assistance

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.

Drug Subsidy

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.

The HCFI Fund has also tied up for providing up to 50% discount on imaging (CT, MR, CT angiography, etc.)

Who is Eligible?

All heart patients who need pacemakers, valve replacement, bypass surgery, surgery for congenital heart diseases, etc. are eligible to apply for assistance from the Fund. The Application form can be downloaded from the website of the Fund. http://heartcarefoundationfund.heartcarefoundation.org and submitted in the HCFI Fund office.

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.
- The HCFI Fund has the right to print/publish/webcast/web post details of the patient including photos, and other details. (Under taking needs to be given to the HCFI Fund to publish the medical details so that more people can be benefitted).
- 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.

Free Diagnostic Facility

The Fund has installed the latest State-of-the-Art 3 D Color Doppler EPIQ 7C Philips at E – 219, Greater Kailash, Part 1, New Delhi.
This machine is used to screen children and adult patients for any heart disease.

Free Education and Employment Facility

HCFI has tied up with a leading educational institution and an export house in Delhi NCR to adopt and to provide free education and employment opportunities to needy heart patients post surgery. Girls and women will be preferred.

Laboratory Subsidy

HCFI has also tied up with leading laboratories in Delhi to give up to 50% discounts on all pathological lab tests.

Help Us to Save Lives

The Foundation seeks support, donations and contributions from individuals, organizations and establishments both private and governmental in its endeavor to reduce the number of deaths due to heart disease in the country. All donations made towards the Heart Care Foundation Fund are exempted from tax under Section 80 G of the IT Act (1961) within India. The Fund is also eligible for overseas donations under FCRA Registration (Reg. No 231650979). The objectives and activities of the trust are charitable within the meaning of 2 (15) of the IT Act 1961.

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About Heart Care Foundation of India

Heart Care Foundation of India was founded in 1986 as a National Charitable Trust with the basic objective of creating awareness about all aspects of health for people from all walks of life incorporating all pathies using low-cost infotainment modules under one roof.

HCFI is the only NGO in the country on whose community-based health awareness events, the Government of India has released two commemorative national stamps (Rs 1 in 1991 on Run For The Heart and Rs 6.50 in 1993 on Heart Care Festival- First Perfect Health Mela). In February 2012, Government of Rajasthan also released one Cancellation stamp for organizing the first mega health camp at Ajmer.

Objectives

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

Heart Care Foundation Blood Donation Camps

The Heart Care Foundation organizes regular blood donation camps. The blood collected is used for patients undergoing heart surgeries in various institutions across Delhi.

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This Fund is dedicated to the memory of **Sameer Malik** who was an unfortunate victim of sudden cardiac death at a young age.

- HCFI has associated with Shree Cement Ltd. for newspaper and outdoor publicity campaign
- HCFI also provides Free ambulance services for adopted heart patients
- HCFI has also tied up with Manav Ashray to provide free/highly subsidized accommodation to heart patients & their families visiting Delhi for treatment.

http://heartcarefoundationfund.heartcarefoundation.org

RTI Applications and their Replies

Supreme Court of India

RTI Application dated 03.09.2016 and its reply dated 03.10.2016

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	Yes, a dispensary is available/functioning in the court premises. Timing of the dispensary are 10 AM to 5 PM.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	Yes, staff/employees of court have been imparted training in Cardiac First Aid including CPR.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	No.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Yes.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	Yes, one CATS (Centralized Accident and Trauma Services) Ambulance is stationed at the Supreme Court premises.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Yes.
7.	How many people have died in the last 5 years in the court premises?	None.

RTI Application dated 05.02.2018 and its reply dated 23.02.2018

Sr. No.	Questions	Answer
1.	Has any "Automated external defibrillator" (AED) been installed in the court premises after the reply dated 03.10.2016? If yes, how many?	No.
2.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	As per record, the information is nil.

High Court of Delhi

RTI Application dated 03.09.2016 and its reply dated 24.09.2016

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	Yes, there is a dispensary functioning in the court premises. The Dispensary runs in two shifts: Morning shift: 9 AM to 3 PM Evening shift: 2 PM to 8 PM.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	No.

3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	The information sought relates to the Directorate of Health, Government of NCT of Delhi, Karkardooma, Delhi. Hence, a copy of your application is being transferred to the PIO, O/o. Directorate of Health, Government of NCT of Delhi, Karkardooma, Delhi
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Yes. First Aid medicines for sudden cardiac arrest (SCA) are available in Delhi High Court Medical and Health Centre.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	One CATS Ambulance remains available at Medical Unit during the working hours i.e., 8 AM to 8 PM.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Doctors are available in the dispensary within the High Court premises.
7.	How many people have died in the last 5 years in the court premises?	The information sought relates to the Directorate of Health, Government of NCT of Delhi, Karkardooma, Delhi. Hence, a copy of your application is being transferred to the PIO, O/o. Directorate of Health, Government of NCT of Delhi, Karkardooma, Delhi

RTI Application dated 05.02.2018 and its reply dated 20.02.2018

Sr. No.	Questions	Answer
1.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	No.
2.	Has any "Automated external defibrillator" (AED) been installed in the court premises after the reply dated 24.09.2016? If yes, how many?	The information sought relates to the Directorate of Health, Government of NCT of Delhi, Karkardooma, Delhi. A copy of your application has already been transferred vide this Court's Letter No. 2612-13/RTI/DHC/139/2018 dt. 08.02.2018 to the PIO, O/o. Directorate of Health, Government of NCT of Delhi, Karkardooma, Delhi with a request to provide the information sought for by you directly to you.
3.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	The information sought relates to the Directorate of Health, Government of NCT of Delhi, Karkardooma, Delhi. A copy of your application has already been transferred vide this Court's Letter No. 2612-13/RTI/DHC/139/2018 dt. 08.02.2018 to the PIO, O/o. Directorate of Health, Government of NCT of Delhi, Karkardooma, Delhi with a request to provide the information sought for by you directly to you.

Tis Hazari Court

RTI Application dated 05.02.2018 and its reply dated 28.02.2018

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	There are two dispensaries in Tis Hazari Court Complex one is in Tis Hazari Court building and other in Lawyers Chamber Area, Civil Wing, Tis Hazari Court Complex, Delhi. The timings of the dispensary in Tis Hazari Court building are 9:30 AM to 3:30 PM

2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	Information sought does not pertain to General Branch (Central), Tis Hazari Courts, Delhi.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	Information sought does not pertain to General Branch (Central), Tis Hazari Courts, Delhi.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Information sought does not pertain to General Branch (Central), Tis Hazari Courts, Delhi.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	One ambulance stations in Tis Hazari Court Complex during court working hours.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Doctors are available as per the timing of the dispensaries.
7.	How many people have died in the last 5 years in the court premises?	Information sought does not pertain to General Branch (Central), Tis Hazari Courts, Delhi.

Further, the Office of CDMO, Central District, the Directorate of Health Services, Govt. of NCT of Delhi has given its reply dated 19.04.2018

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	Yes, there are two functional Delhi Govt. Dispensaries in court premises and timings being 9:30 AM to 3:30 PM.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	Staff of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR).
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	No.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	No.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	One full time CATS ambulance stationed in court premises. If needed more ambulances, response time is 8 to 10 minutes.
6.	Whether there is a doctor available in the working hours of court in the court premises?	The timings of the dispensary being 9:30 AM to 3:30 PM
7.	How many people have died in the last 5 years in the court premises?	No such data is available.

Patiala House Court

RTI Application dated 03.09.2016 and its reply dated 07.09.2016

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the Court premises? If so, what are the timings of such dispensary?	Yes, there is a dispensary available/functioning in the Patiala House Court premises, New Delhi.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	

3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?
6.	Whether there is a doctor available in the working hours of court in the court premises?
7.	How many people have died in the last 5 years in the court premises?

RTI Application dated 05.02.2018 and its reply dated 05.03.2018

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	Yes, there is a dispensary available/functioning in the Patiala House Court premises, New Delhi and the timings of dispensary are 9:30 AM to 3:30 PM.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	The information sought relates to the IO, CDMO Incharge, New Delhi District, Directorate of Health Services, Government of NCT of Delhi, Nangal Raya, New Delhi. Hence, the application is being transferred to them u/s 6(3) of the RTI Act for taking necessary action under the provisions of RTI Act, 2005.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	The information sought relates to the IO, CDMO Incharge, New Delhi District, Directorate of Health Services, Government of NCT of Delhi, Nangal Raya, New Delhi. Hence, the application is being transferred to them u/s 6(3) of the RTI Act for taking necessary action under the provisions of RTI Act, 2005.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	The information sought relates to the IO, CDMO Incharge, New Delhi District, Directorate of Health Services, Government of NCT of Delhi, Nangal Raya, New Delhi. Hence, the application is being transferred to them u/s 6(3) of the RTI Act for taking necessary action under the provisions of RTI Act, 2005.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	CATS ambulance is there for Delhi Govt. sanctioned at Patiala House Courts for dealing with Emergent conditions.
6.	Whether there is a doctor available in the working hours of court in the court premises?	The information sought relates to the IO, CDMO Incharge, New Delhi District, Directorate of Health Services, Government of NCT of Delhi, Nangal Raya, New Delhi. Hence, the application is being transferred to them u/s 6(3) of the RTI Act for taking necessary action under the provisions of RTI Act, 2005.
7.	How many people have died in the last 5 years in the court premises?	The information sought relates to the IO, CDMO Incharge, New Delhi District, Directorate of Health Services, Government of NCT of Delhi, Nangal Raya, New Delhi. Hence, the application is being transferred to them u/s 6(3) of the RTI Act for taking necessary action under the provisions of RTI Act, 2005.

Further, the Office of CDMO, New Delhi District, the Directorate of Health Services, Govt. of NCT of Delhi has given its reply dated 03.04.2018

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	Dispensary is available in court premises and timings are 9:30 AM to 3:30 PM. CATS ambulance is stationed with in Court premises.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	Court staff/employees as per verbal enquiry from Court administration by Medical Officer Incharge, are not trained in Cardiac First Aid including CPR.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	AED is available in CATS ambulance stationed in court premises.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	All emergent conditions are dealt by CATS ambulance and medicines are available accordingly including First Aid medicines for SCA.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	CATS ambulance is stationed with in court premises.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Yes.
7.	How many people have died in the last 5 years in the court premises?	As per verbal enquiry from Court administration by Medical Officer Incharge, data as such is not maintained and death has not occurred since 2016 in court premises.

Saket Court Complex

RTI Application dated 05.02.2018 and its Reply dated 27.03.2018 by CDMO, South District, Directorate of Health Services, Govt. of NCT of Delhi

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the Court premises? If so, what are the timings of such dispensary?	Delhi Government Dispensary in Saket Court Complex. Timing 9 AM to 3 PM and from 3 PM to 5 PM, emergency only.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	Yes, all staff is trained in CPR.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	One AED available in dispensary.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	First Aid medicine available in dispensary.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	There is no tie-up of DGD Court Complex, Saket with any Ambulance Service. However, a CATS Ambulance is stationed within the premises of the court for the required needs.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Yes, one doctor available in court dispensary/emergency unit 9 AM to 5 PM.
7.	How many people have died in the last 5 years in the court premises?	One patient died in court complex, who was brought dead in emergency unit during 5 years.

Karkardooma Court

RTI Application dated 03.09.2016 and its reply dated 08.09.2016

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	There is dispensary functioning in the court premises.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	No record is available regarding the training of staff/ employees in Cardiac First Aid including CPR.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	
6.	Whether there is a doctor available in the working hours of court in the court premises?	
7.	How many people have died in the last 5 years in the court premises?	

Thereafter, 3 different RTI Applications dated 01.03.2018 were sent to three different districts of Karkardooma Court, Reply dated 23.03.2018 by CDMO, Shahdara District, Directorate of Health Services, Govt. of NCT of Delhi

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	Yes, there is one dispensary running in Karkardooma Court premises under District Shahdara and its timings are 10 AM to 4 PM.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	No, all staff/employees of court are not trained in CPR.
3.	Has any "Automated external defibrillator" (AED) been installed in the court premises after reply dated 08.09.2016? If yes, how many?	No, automated external defibrillator (AED) is being installed in the dispensary.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Yes, First Aid medicines of cardiac arrest are available in DGD Karkardooma Court.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	A CATS ambulance base station is situated in Karkardooma Court premises.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Yes, two doctors are available in Karkardooma Court premises (DGD Karkardooma Court).
7.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	The information asked is not available in this office records.

East District, Karkardooma Court

Reply dated 22.03.2018 by CDMO, East District, Directorate of Health Services, Govt. of NCT of Delhi

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	Under the jurisdiction of CDMO (East District) there is no dispensary functioning in the court premises.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	In the light of above this query does not pertain to this office.
3.	Has any "Automated external defibrillator" (AED) been installed in the court premises after reply dated 08.09.2016? If yes, how many?	Does not pertain to this office.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	In the light of above this query does not pertain to this office.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	Does not pertain to this office.
6.	Whether there is a doctor available in the working hours of court in the court premises?	In the light of above this query does not pertain to this office.
7.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	In the light of above this query does not pertain to this office.

Reply dated 23.03.2018 by Public Information Officer, East District, Karkardooma Court, Delhi

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	There is a govt. dispensary functioning in the court premises and doctors are available in the working hours.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	No such record is available regarding the training of staff/employee in cardiac, automated external defibrillator (AED) and First Aid medicines for sudden cardiac arrest (SCA).
3.	Has any "Automated external defibrillator" (AED) been installed in the court premises after reply dated 08.09.2016? If yes, how many?	No such record is available regarding the training of staff/ employee in cardiac, automated external defibrillator (AED) and First Aid medicines for sudden cardiac arrest (SCA).
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	No such record is available regarding the training of staff/ employee in cardiac, automated external defibrillator (AED) and First Aid medicines for sudden cardiac arrest (SCA).
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	CATS ambulance service is available in Karkardooma Court Complex for 24 hours.
6.	Whether there is a doctor available in the working hours of court in the court premises?	
7.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	

North East District, Karkardooma Court

Reply dated 27.03.2018 by CDMO, North East District, Directorate of Health Services, Govt. of NCT of Delhi

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	There is no dispensary functioning in the court premises under district North East.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	Not applicable.
3.	Has any "Automated external defibrillator" (AED) been installed in the court premises after reply dated 08.09.2016? If yes, how many?	Not applicable.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Not applicable.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	The information does not pertain to this office.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Not applicable.
7.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	No such information is available in this office.

Dwarka Court

RTI Application dated 03.09.2016 and its reply dated 17.09.2016

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	There is one dispensary under Delhi Government Health Schemes available/functioning in the court premises with its working timing from 10 AM to 4 PM on all working days.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	This is hard to find out whether any court staff/employee trained/capable of conducting Cardiac First Aid including cardiopulmonary resuscitation (CPR) in case of any such emergency condition but court staff have been imparted awareness program by National Disaster Response Force and District Disaster Management group recently in this regard.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	As per information available from the dispensary functioning in the court premises, no such device (Automated external defibrillator) is installed in the court premises.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Yes, First Aid medicines for sudden cardiac arrest (SCA) available in the court dispensary.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	As per information availed from the dispensary there is tie-up of ambulance services i.e., CATS, Delhi with the dispensary functioning in the court premises for the purpose of such emergencies.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Yes the doctor is available during the working hours of the court.
7.	How many people have died in the last 5 years in the court premises?	No such case of death came in existence/reported to be occurred during the time period.

RTI Application dated 05.02.2018 and its reply dated 17.03.2018

Sr. No.	Questions	Answer
1.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	It is difficult to find out whether court staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR). However, there is one dispensary under Delhi Government Health Scheme available/ functioning in the court premises with its working timing from 10 AM to 04.00 P.M. on all working days and two CATS ambulances have been stationed in this court complex to meet out urgent medical emergency. One ambulance i.e., Advance Life Supporting System is stationed near the Administrative Block and second Ambulance i.e., Basic Life Supporting System is stationed near Gate No. 02 inside the court complex.
2.	Has any "Automated external defibrillator" (AED) been installed in the court premises after reply dated 17.09.2016? If yes, how many?	As per the information availed from the dispensary functioning in the court premises, no such device (Automated external defibrillator) is installed in the court premises and no such case of death came in existence/ reported to be occurred i.e., from 2016 till date in the court premises.
3.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	As per the information availed from the dispensary functioning in the court premises, no such device (Automated external defibrillator) is installed in the court premises and no such case of death came in existence/ reported to be occurred i.e., from 2016 till date in the court premises.

Reply dated 02.04.2018 by CDMO, Dwarka, Directorate of Health Services, Govt. of NCT of Delhi

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	Yes, there is one dispensary under Delhi Government Health Schemes available/functioning in the premise of Dwarka Courts, South West District, Delhi functioning properly with its timing from 10 AM to 04 PM on all working days.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	It is to inform in this regard that two dispensary staff (Paramedical Staff) are trained in conducting the aforesaid function in respect of Cardiac First Aid including cardiopulmonary resuscitation (CPR) in case of an emergency.
3.	Has any "Automated external defibrillator" (AED) been installed in the court premises after reply dated 08.09.2016? If yes, how many?	No, there is no such device (Automated external defibrillator) functioning/installed as on date in this dispensary situated in South West District Court premise.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Yes, there is availability of First Aid medicines for sudden cardiac arrest (SCA). It is further to inform that there are 2 CATS ambulances stationed in this court complex to meet out urgent medical emergency. One ambulance i.e., Advance Life Supporting System is stationed near the Administrative Block and Second Ambulance i.e., Basic Life Supporting System is stationed near Gate No. 02 inside the court complex and staff deputed in the same will occupy in Room No. 105A, Pool Car Section, Administrative Block, Dwarka Court Complex during 9 AM to 6 PM and after 6 PM to 9 AM. The staff deputed will remain in Porta Cabin near Gate No. 3.

5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	Yes, there is availability of First Aid medicines for sudden cardiac arrest (SCA). It is further to inform that there are 2 CATS ambulances stationed in this court complex to meet out urgent medical emergency. One Ambulance i.e., Advance Life Supporting System is stationed near the Administrative Block and Second Ambulance i.e., Basic Life Supporting System is stationed near Gate No. 02 inside the court complex and staff deputed in the same will occupy in Room No. 105A, Pool Car Section, Administrative Block, Dwarka Court Complex during 9 AM to 6 PM and after 6 PM to 9 AM. The staff deputed will remain in Porta Cabin near Gate No. 3.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Yes, the doctor is available during the working hours of the court on all working days.
7.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	

Reply dated 21.03.2018 by CDMO, North District, Directorate of Health Services, Govt. of NCT of Delhi

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	No dispensary under the jurisdiction of CDMO, North District is functioning in the court premises.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	Does not pertain to CDMO, North District.
3.	Has any "Automated external defibrillator" (AED) been installed in the court premises after reply dated 08.09.2016? If yes, how many?	Does not pertain to CDMO, North District.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Does not pertain to CDMO, North District.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	Does not pertain to CDMO, North District.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Does not pertain to CDMO, North District.
7.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	Does not pertain to CDMO, North District.

Reply dated 15.03.2018 by CDMO, West District, Directorate of Health Services, Govt. of NCT of Delhi

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	Not pertain to this office.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	Not pertain to this office.
3.	Has any "Automated external defibrillator" (AED) been installed in the court premises after reply dated 08.09.2016? If yes, how many?	Not pertain to this office.
4.	Are First Aid medicines for Sudden Cardiac Arrest (SCA) available in the court premises?	Not pertain to this office.

5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	Not pertain to this office.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Not pertain to this office.
7.	How many people have died in the last 2 years i.e., from 2016 till date in the court premises?	Not pertain to this office.

National Consumer Disputes Redressal Commission

RTI Application dated 03.09.2016 and its reply dated 28.09.2016

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	No.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	No.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	No.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	No.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	No.
6.	Whether there is a doctor available in the working hours of court in the court premises?	No.
7.	How many people have died in the last 5 years in the court premises?	Nil.

RTI Application dated 05.02.2018 and its reply dated 26.02.2018

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	No.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	No.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	No.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	No.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	No.
6.	Whether there is a doctor available in the working hours of court in the court premises?	No.
7.	How many people have died in the last 5 years in the court premises?	Nil.

Delhi State Consumer Disputes Redressal Commission

RTI Application dated 03.09.2016 and its reply dated 26.09.2016

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	As far as this Commission is concerned, the information is nil.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	No.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	As far as this Commission is concerned, the information is nil.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Not available in this Commission premises.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	As far as this Commission is concerned, no such tie-up with the ambulance services.
6.	Whether there is a doctor available in the working hours of court in the court premises?	No such facility is available in this Commission.
7.	How many people have died in the last 5 years in the court premises?	As per the available record of this Commission, the report is nil.

RTI Application dated 05.02.2018 and its reply dated 01.03.2018

Sr. No.	Questions	Answer
1.	Whether there is a dispensary available/functioning in the court premises? If so, what are the timings of such dispensary?	This facility is not available in this Commission.
2.	Are all the staff/employees of court trained in Cardiac First Aid including cardiopulmonary resuscitation (CPR)? (CPR: If a person stops breathing effectively, CPR is a life-saving technique used to restore oxygenated blood flow to the vital organs?	As regard to this para information is Nil.
3.	Is there any "Automated external defibrillator" (AED) installed in the court premises? If yes, how many?	Nil.
4.	Are First Aid medicines for sudden cardiac arrest (SCA) available in the court premises?	Nil.
5.	Is there any tie-up of court with ambulance services for the purposes of emergencies and if so, in how many minutes such ambulance can reach the court premises?	Not available.
6.	Whether there is a doctor available in the working hours of court in the court premises?	Not available.
7.	How many people have died in the last 5 years in the court premises?	As per record information is nil.

■ ■ ■ ■

Summary of the Replies Received by HCFI in Case of Separate CSR/Charitable Entity/Account in Government Hospitals

KK AGGARWAL*, IRA GUPTA

The Hon'ble High Court of Delhi vide judgment dated 17.04.2014 in the matter titled as "**Mohd. Ahmed (minor) versus Union of India & Others, Writ petition (Civil) No. 7279/2013** had held that:

"SUGGESTIONS BY THE COURT

81. This Court suggests that both the Central and State Governments should consider the following suggestions:

i. All government hospitals could have a separate CSR/Charitable entity/account wherein donations can be received. The donations could be subject to an audit.

ii. Each hospital could have a designated officer, to whom applications for assistance can be made by patients in need. The decision to whom financial assistance could be provided, be left to the Medical Superintendent/CEO of the Hospital along with Head of the Departments. Delhi could be adopted as the first model state.

iii. The Ministries of Corporate Affairs and Finance could consider providing extra credit (for instance increased credit) for donations in certain sectors, such as health.

iv. The Government could adopt a holistic approach to facilitate donations, so that the tax regime supports the said efforts.

v. All donations in cash and kind must be accounted for, with complete transparency to ensure no misuse or misappropriation of donations.

vi. Government hospitals could put up list on the State Department of Health website of the drugs, implants and devices they require for EWS/BPL patients. This way people would donate as per the need of each hospital. This could be revised on a monthly basis.

vii. The State Government may put up a list of drugs, implants and devices which are excluded from its budget for which donations would be welcome.

viii. Both the Central and State Governments could create a revolving fund to take care of recurring expenditure of patients suffering from chronic and rare diseases.

ix. The Government could constitute a High Powered Interdisciplinary Committee to:

- *Develop and update a list of guiding principles/best practices in the area of donations in healthcare.*
- *Develop a policy for tackling rare diseases and promoting the development of orphan drugs.*
- *Evolve new and innovative methods for attracting spending in the area of healthcare.*
- *This Committee could have representatives from various State and Central Government departments, private and government hospitals, non-governmental organizations working in the area of healthcare, representatives of patients rights groups, representatives of pharmaceutical and other companies in the healthcare sector."*

In view of the above suggestions as given by the Hon'ble High Court of Delhi in the matter titled as **Mohd. Ahmed (minor) versus Union of India & Others, Writ petition (Civil) No. 7279/2013,** the Heart Care Foundation of India (HCFI) had sent one RTI application dated 02.04.2018 to Ministry of Health and Family Welfare, Central Government of India and one RTI application dated 02.04.2018 to Ministry of Health and Family Welfare, Delhi Government thereby seeking following information:

1. Whether all government hospitals have a separate CSR/Charitable entity/account wherein donations

*Group Editor-in-Chief, IJCP Group

can be received? If yes, please provide the list of the hospitals having separate CSR/Charitable entity/account.

2. Who is the designated officer in each hospital to whom applications for assistance can be made by patients in need?
3. What steps/measures the Government has adopted to facilitate donations, so that the tax regime supports the said efforts?
4. Do Government hospitals put up list on the State Department of Health website of the drugs, implants and devices they require for EWS/BPL patients? If yes, please provide the list of all such hospitals.
5. Does the State Government put up a list of drugs, implants and devices which are excluded from its budget for which donations would be welcome? If yes, please provide the list of drugs, implants and devices which are excluded from the budget for which donations are welcome
6. Have the Central and State Governments created a revolving fund to take care of recurring expenditure of patients suffering from chronic and rare diseases? If yes, please provide the details of such revolving fund.
7. Has the Government constituted a High Powered Interdisciplinary Committee to:
    a. Develop and update a list of guiding principles/best practices in the area of donations in healthcare.
    b. Develop a policy for tackling rare diseases and promoting the development of orphan drugs.
    c. Evolve new and innovative methods for attracting spending in the area of healthcare.
    d. This Committee could have representatives from various State and Central Government departments, private and government hospitals, non-governmental organizations working in the area of healthcare, representatives of patients rights groups, representatives of pharmaceutical and other companies in the healthcare sector.

After sending the said RTI applications, the Heart Care Foundation of India had received numerous replies from the Delhi Government and also from various Government Hospitals of Delhi. The details of the hospitals from where replies have been received are as follows:

Sr. No.	Hospital Name	Date of Reply
1.	Aruna Asaf Ali Government Hospital	10.04.2018
2.	Deep Chand Bandhu Hospital	16.04.2018
3.	Sardar Vallabh Bhai Patel Hospital	16.04.2018
4	Guru Nanak Eye Centre, Maharaja Ranjit Singh Marg	18.04.2018
5.	Maharishi Valmiki Hospital	24.04.2018
6.	Babu Jagjivan Ram Memorial Hospital	25.04.2018
7.	Maulana Azad Institute of Dental Sciences	26.04.2018
8.	Ch. Brahm Prakash Ayurved Charak Sansthan (under Government of NCT Delhi)	28.04.2018
9.	Dr. Hedgewar Arogya Sansthan	01.05.2018
10.	Janakpuri Super Speciality Hospital Society	01.05.2018
11.	Lal Bahadur Shastri Hospital	02.05.2018
12.	Institute of Liver and Biliary Sciences	04.05.2018
13.	Nehru Homeopathic Medical College & Hospital	04.05.2018
14.	Guru Gobind Singh Government Hospital	04.05.2018
15.	Acharya Shree Bhikshu Government Hospital	05.05.2018
16.	Jag Pravesh Chandra Hospital	07.05.2018
17	Rao Tula Ram Memorial Hospital	08.05.2018
18.	Satyawadi Raja Harish Chandra Hospital	08.05.2018
19.	Sanjay Gandhi Memorial Hospital	08.05.2018
20.	Chacha Nehru Bal Chikitsalaya	09.05.2018
21.	A & U Tibbia College and Hospital	09.05.2018
22.	Institute of Human Behaviour and Allied Sciences	10.05.2018
23.	Dr. Baba Saheb Ambedkar Hospital	10.05.2018
24.	Govind Ballabh Pant Institute of Postgraduate Medical Education & Research	11.05.2018
25.	Attar Sain Jain Eye & General Hospital	11.05.2018
26.	Deen Dayal Upadhyay Hospital	14.05.2018
27.	Shri Dada Dev Matri Avum Shishu Chikitsalaya	15.05.2018
28.	Lok Nayak Hospital	16.05.2018
29.	Safdarjung Hospital & VMMC	25.05.2018

QUERYWISE REPLY

Query No. 1

Whether all government hospitals have a separate CSR/ Charitable entity/account wherein donations can be received? If yes, please provide the list of the hospitals having separate CSR/Charitable entity/account.

Reply

It is very shocking that in none of the Government hospitals in the capital State of the country, Delhi, there is separate CSR/Charitable entity/Account wherein donations can be received by the government hospitals.

However, following hospitals have replied that they have other provisions for obtaining donations:

Sr. No.	Name of the Hospital	Reply
1.	Deep Chand Bandhu Hospital	Any such requirement for the proper patient care is dealt through the hospital budget.
2.	Lal Bahadur Shastri Hospital	Fully funded by Government of NCT of Delhi and they do not have any provision to accept the donations.
3.	Institute of Liver and Biliary Sciences	Registered under Section 80G of the Income Tax Act for getting charitable donations.
4.	Guru Gobind Singh Government Hospital	As per Article 5.5.2(c) of Article of Association of Rogi Kalyan Samiti of Guru Gobind Singh Government Hospital the Rule and Bye Laws, donations/gifts as money/kind/land worth up to Rs. 25,000/- may be accepted on behalf of hospital RKS by the Member Secretary, and up to Rs. 50,000/- by the executive Committee on behalf of the hospital RKS. Donations/ gifts as money/kind/land worth more than Rs. 50,000/- shall be accepted only after approval of the Governing Body of the Hospital RKS.
5.	Institute of Human Behaviour and Allied Sciences (IHBAS)	IHBAS does not have a separate bank account for receiving donations from domestic donors. It receives donations from domestic donors by way of cheque or draft. However, IHBAS has an FCRA account for receiving donations from foreign donors. The donors are invited to transfer the donations through electronic mode to the above account. Also, this institute has created "Poor Patient Fund" with an initial amount of Rs. 10.00 Lakh from its own resources to meet the urgent medical expenses of poor patients being treated in this hospital/institute.

Query No. 2

Who is the designated officer in each hospital to whom applications for assistance can be made by patients in need?

Reply

Out of 29 hospitals, only in 10 hospitals a designated officer has been appointed to whom applications for assistance can be made by patients. The list of 10 hospitals in which designated officer has been appointed along with the name of the designated officer is as follows:

Sr. No.	Name of the Hospital	Designated Officer
1.	Aruna Asaf Ali Government Hospital	Medical Superintendent
2.	Ch. Brahm Prakash Ayurved Charak Sansthan	Nursing Superintendent, Deputy Medical Superintendent
3.	Dr. Hedgewar Arogya Sansthan	Dr. Reetesh Ranjan, Sr. Medical Officer/Nodal Officer (EWS/DAK) Dr. Hedgewar Arogya Sansthan, Karkardooma, Delhi – 110032
4.	Guru Gobind Singh Government Hospital, Raghubir Nagar	Nodal Officer DAK/EWS
5.	Acharya Shree Bhikshu Government Hospital	All the services in this hospital are free. Different Nodal Officers are there for different causes. For any grievances, Dr. Rashmi Gandhi (Room No. 111) can be contacted.
6.	Rao Tula Ram Memorial Hospital	Medical Superintendent, RTRMH
7.	A & U Tibbia College and Hospital	PMS/HOD
8.	Institute of Human Behaviour and Allied Sciences	Director and MS/DMS
9.	Lok Nayak Hospital	Social Worker
10.	Safdarjung Hospital & VMMC	There are doctors and specialists who can be approached for immediate medical help. If any other allied help relating to healthcare/patient care is required, Medical Superintendent/Additional Medical Superintendent can be approached.

Query No. 3

What steps/measures the Government has adopted to facilitate donations, so that the tax regime supports the said efforts?

Reply

No reply has been received by Heart Care Foundation of India, neither from the Central Government nor from the State Government, on this query till date 16.06.2018.

Only 2 hospitals out of 29 hospitals have given reply to this query. The rest of the hospitals have simply stated that the said information does not pertain to them or information not available. The 2 hospitals which have given information are:

Sr. No.	Name of the Hospital	Reply
1.	Ch Brahm Prakash Ayurved Charak Sansthan	Extension under Section 12A & 80G is available for donations.
2.	Institute of Human Behaviour and Allied Sciences	Donations to IHBAS are exempted from income tax under Section 80G of Income Tax Act.

Query No. 4

Do Government hospitals put up list on the State Department of Health website of the drugs, implants and devices they require for EWS/BPL patients? If yes, please provide the list of all such hospitals.

Reply

No reply has been received by Heart Care Foundation of India, neither from the Central Government nor from the State Government, on this query till date 16.06.2018.

Only 9 hospitals out of 29 hospitals have given reply to this query. The rest of the hospitals have simply stated that the said information does not pertain to them or information not available. The 9 hospitals which have given information are:

Sr. No.	Name of the Hospital	Reply
1.	Institute of Liver and Biliary Sciences	No such list is put on website of ILBS for the drugs, implants and devices. However, facility for free treatment to poor patients is there who are identified on the basis of income certificate issued by Revenue Department GNCTD or National Food Security Card and Resident criteria i.e., bonafide resident of Delhi for more than 3 years, identified on the basis of Ration Card, Driving License, Aadhar Card, Voter ID, Domicile certificate issued from the area SDM, Passport and Extract from the Electoral Roll. All such patients are provided completely free treatment at ILBS based on above criteria.
2.	Guru Gobind Singh Government Hospital, Raghubir Nagar	It does not display any list on website
3.	Acharya Shree Bhikshu Government Hospital	All the patients are provided free medicines and basic implants.
4.	Rao Tula Ram Memorial Hospital (RTRM)	RTRM Hospital put up on its website a list of all drugs and surgical consumables available in the hospital. These drugs and surgical consumables are provided free of cost to all patients, including EWS and BPL patients.
5.	Satyawadi Raja Harish Chandra Hospital	As per government policy free consultation, investigation and treatment is provided to all patients. This includes supply of essential drug provided by the government. In emergency cases, investigations and treatment including operating procedures are done free of cost. The facility of free treatment to the poor patients is also available at 37 private hospitals where the patients can go directly or through the referral from the Government hospital. The list of private hospitals is also available at the website of the health department.
6.	Sanjay Gandhi Memorial Hospital	There is no separate list for EWS/BPL patients in this hospital.
7.	Institute of Human Behaviour and Allied Sciences	It has not uploaded any such information in the website.
8.	Lok Nayak Hospital	No list of drugs, implant and device required for EWS/BPL patients are available.
9.	Safdarjung Hospital & VMMC	No

Query No. 5

Does the State Government put up a list of drugs, implants and devices which are excluded from its budget for which donations would be welcome? If yes, please provide the list of drugs, implants and devices which are excluded from the budget for which donations are welcome.

Reply

No reply has been received by Heart Care Foundation of India, neither from the Central Government nor from the State Government, on this query till date 16.06.2018.

Only 1 hospital out of 29 hospitals have given reply to this query. The rest of the hospitals have simply stated that the said information does not pertain to them or information not available. The 1 hospital which has given information is:

Sr. No.	Name of the Hospital	Reply
1.	Acharya Shree Bhikshu Government Hospital	There is no such provision in this hospital.

Query No. 6

Have the Central and State Governments created a revolving fund to take care of recurring expenditure of patients suffering from chronic and rare diseases? If yes, please provide the details of such revolving fund.'

Reply

Vide reply dated 02.05.2018, the Ministry of Health & Family Welfare, Government of India (PH Division) has stated that as per the National Policy for Treatment of Rare Diseases, a corpus has to be created under National Health Mission as Central assistance to the States with an initial amount of Rs. 100 crore for funding treatment of rare and genetic diseases. The States also have to create a similar corpus at State level for part funding for treatment of rare diseases.

Vide reply dated 18.05.2018 the Directorate General of Health Services, Government of NCT of Delhi has stated that a cabinet note is being prepared with respect to the creation of revolving fund to take care of recurring expenditure of patients suffering from chronic and rare diseases.

Only 6 hospitals out of 29 hospitals have given reply to this query. The rest of the hospitals have simply stated that the said information does not pertain to them or information not available. The 6 hospitals which has given information are:

Sr. No.	Name of the Hospital	Reply
1.	Deep Chand Bandhu Hospital	Any such requirement for the proper patient care is dealt through the hospital budget.
2.	Ch. Brahm Prakash Ayurved Charak Sansthan	No such fund created by State/Central Government in our institution.
3.	Satyawadi Raja Harish Chandra Hospital	No.
4.	A & U Tibbia College and Hospital	There is no specific head of A/C.
5.	Dr. Baba Saheb Ambedkar Hospital	There is no such type of fund till date 08.05.2018.
6.	Safdarjung Hospital & VMMC	Has provided the list of patients suffering from chronic and rare diseases.

Query No. 7

Has the Government constituted a High Powered Inter-disciplinary Committee to:

a. Develop and update a list of guiding principles/ best practices in the area of donations in healthcare.

b. Develop a policy for tackling rare diseases and promoting the development of orphan drugs.

c. Evolve new and innovative methods for attracting spending in the area of healthcare.

d. This Committee could have representatives from various State and Central Government departments, private and Government hospitals, non-Governmental organizations working in the area of healthcare, representatives of patients rights groups, representatives of pharmaceutical and other companies in the healthcare sector.

Reply

Vide reply dated 02.05.2018 the Ministry of Health and Family Welfare, Government of India (PH Division) has stated that Government of India has formulated a National Policy for treatment of rare diseases in 2017. The Department of Industrial Policy and Promotion and the Department of Pharmaceuticals have been requested to take up with the manufactures of orphan drugs to explore possibilities for manufacturing these drugs domestically.

Vide reply dated 18.05.2018 the Directorate General of Health Services, Government of NCT of Delhi has stated 'yes' - that means the Government has constituted a High Powered Interdisciplinary Committee.

■■■■

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Note on Agreement, Contract, Consent

KK AGGARWAL*, IRA GUPTA

Question: What is an agreement?

Answer: The term "agreement" has been defined in Section 2(e) of the Indian Contract Act, 1872 as *"every promise and every set of promises forming the consideration for each other."*

The term "promise" has been defined in Section 2(b) of the Indian Contract Act, 1872 as *"when the person to whom the proposal is made signifies his assent thereto, the proposal is said to be accepted. A proposal, when accepted, becomes a promise."*

Black's Law Dictionary defines the term "agreement" as:

> *"A mutual understanding between two or more persons about their relative rights and duties regarding past or future performances; a manifestation of mutual assent by two or more persons."*

Thus, from the above it is opined that an agreement is an accepted proposal. Every agreement is the result of a proposal from one side and its acceptance by the other.

Question: What is contract?

Answer: An agreement is regarded as contract when it is enforceable by law. According to Section 2(h) of the Indian Contract Act, 1872 *"an agreement enforceable by law is a contract"*. Thus, an agreement which the law will enforce is a contract.

The conditions of enforceability of an agreement is defined in Section 10 of the Indian Contract Act, 1872. According to Section 10 of the Indian Contract Act, 1872, an agreement is a contract when it is made for some consideration, between parties who are competent, with their free consent and for a lawful object. The provisions of Section 10 of the Indian Contract Act, 1872 is reproduced hereunder:

> *"Section 10 of Indian Contract Act, 1872: What agreements are contracts—*
>
> *All agreements are contracts if they are made by the free consent of parties competent to contract, for a lawful consideration and with a lawful object, and are not hereby expressly declared to be void.*
>
> *Nothing herein contained shall affect any law in force in India and not hereby expressly repealed, by which any contract is required to be made in writing or in the presence of witnesses, or any law relating to the registration of documents."*

Black's Law Dictionary defines the term "contract" as:

> *"An agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law."*

Thus, every contract is an agreement but every agreement is not a contract. An agreement becomes a contract when the following conditions are satisfied:

1. There is some consideration for it.
2. The parties are competent to contract.
3. Their consent is free.
4. Their object is lawful.

Question: What are the types of contract?

Answer: The contracts are of two types - express contract and implied contract. As per the provisions of Section 9 of the Indian Contract Act, 1872, if the proposal or its acceptance is made in words, then the promise is express and if the proposal or its acceptance is made otherwise than in words, then the promise is implied. The provision of Section 9 of the Indian Contract Act, 1872 is reproduced hereunder:

> *"Section 9: Promises, express and implied–*
>
> *In so far as the proposal or acceptance of any promise is made in words, the promise is said to be express. In so far as such proposal or acceptance is made otherwise than in words, the promise is said to be implied."*

The Hon'ble High Court of Madras in the matter titled as "Maharashtra Rajya Sahakari Kappos Utpadak Panan Mahasangha Ltd. Versus Manga Bhaga Choudhary, (2009) 3 MadLJ 721, has held that a contract implied in fact requires meeting of minds. The courts have to refuse to read an implied term into a contract which is silent on the point or did not clearly indicate the nature of terms.

*Group Editor-in-Chief, IJCP Group

Examples of implied contract: a bid at an auction is an implied offer to buy.

Stepping into omnibus and consuming eatables at a self service restaurant both create implied promises to pay for the benefits enjoyed.

Thus, an implied contract is one inferred from conduct of parties and arises where one person renders services under circumstances indicating that he expects to be paid therefore, and the other person knowing such circumstances, avails himself of benefit of those services. An express contract is an actual agreement of the parties, the terms of which are openly uttered or declared at the time of making it, being stated in distinct and explicit language, either orally (oral agreement) or in writing (written agreement).

Question: Who can enter into a contract?

Answer: As per the provisions of Section 10 of the Indian Contract Act, 1872 the parties must be competent to contract. The competence to contract is defined in Section 11 of the Indian Contract Act, 1872 which is reproduced hereunder:

> *"Section 11 of Indian Contract Act, 1872: Who are competent to contract—Every person is competent to contract who is of the age of majority according to the law to which he is subject, and who is of sound mind, and is not disqualified from contracting by any law to which he is subject."*

Thus, as per the provisions of Section 11 of the Indian Contract Act, 1872, the following persons are incompetent to enter into a contract:

1. Minors
2. Persons of unsound mind
3. Persons disqualified by law to which they are subject.

Question: What is the age of majority?

Answer: According to the provisions of Section 3 of the Indian Majority Act, 1875, the age of majority is generally eighteen (18), except when a guardian of a minor's person or property has been appointed by the Court, in which case it is twenty-one (21). The provisions of the Section 3 of the Indian Majority Act, 1875 is reproduced hereunder:

> *"Section 3 of Indian Majority Act, 1875: Age of majority of persons domiciled in India. -*
>
> *(1) Every person domiciled in India shall attain the age of majority on his completing the age of eighteen years and not before.*
>
> *(2) In computing the age of any person, the day on which he was born is to be included as a whole day and he shall be deemed to have attained majority at the beginning of the eighteenth anniversary of that day."*

Illustrations:

(a) *Z is born in India on the first day of January 1850, and has an Indian domicile. A guardian of his person is appointed by a Court of Justice. Z attains majority at the first moment of the first day of January 1871.*

(b) *Z is born in India on the twenty-ninth day of February 1852, and as an Indian domicile. A guardian of his property is appointed by a Court of Justice. Z attains majority at the first moment of the twenty-eight day of February 1873.*

(c) *Z is born on the first day of January 1850. He acquires a domicile in India. No guardian is appointed of his person or property of any Court of Justice, nor is he under the jurisdiction of any Court of Wards. Z attains majority at the first moment of the first day of January 1868.*

Question: What is the effect of the minor's agreement?

Answer: Section 10 of the Indian Contract Act, 1872 requires that the parties to a contract must be competent and Section 11 of the Indian Contract Act, 1872 declares that the minor is not competent to contract. However, it is not clear from the provisions of aforesaid sections that if the minor enters into an agreement, then whether such agreement is voidable at the option of the minor or whether such agreement is void altogether.

The said controversy whether such minor's agreement is voidable or void has been resolved in 1903 by the Judicial Committee of the Privy Council in their well-known pronouncement in "Mohori Bibee versus Dhurniodas Ghose, ILR (1903) 30 Cal 539 (PC) wherein it has been observed by Lord North that:

> *"Looking at these sections, their Lordships are satisfied that the Act makes it essential that all contracting parties should be "competent to contract," and expressly provides that a person who by reason of infancy is incompetent to contract cannot make a contract within the meaning of the Act. This is clearly borne out by later sections in the Act. Sect. 68 provides that, "If a person incapable of entering into a contract, or any one whom he is legally bound to support, is supplied by another person with necessaries suited to his condition in life, the person who has furnished such supplies is entitled to be reimbursed from the property of such incapable person." It is beyond question that an infant falls within the class of persons here referred*

to as incapable of entering into a contract; and it is clear from the Act that he is not to be liable even for necessaries, and that no demand in respect thereof is enforceable against him by law, though a statutory claim is created against his property. Under ss. 183 and 184 no person under the age of majority can employ or be an agent. Again, under ss. 247 and 248, although a person under majority may be admitted to the benefits of a partnership, he cannot be made personally liable for any of its obligations; although he may on attaining majority accept those obligations if he thinks fit to do so. The question whether a contract is void or voidable presupposes the existence of a contract within the meaning of the Act, and cannot arise in the case of an infant. Their Lordships are, therefore, of opinion that in the present case there is not any such voidable contract as is dealt with in s. 64.

A new point was raised here by the appellants' counsel, founded on s. 65 of the Contract Act, a section not referred to in the Courts below, or in the cases of the appellants or respondent. It is sufficient to say that this section, like s. 64. starts from the basis of there being an agreement or contract between competent parties, and has no application to a case in which there never was, and never could have been, any contract. It was further argued that the preamble of the Act showed that the Act was only intended to define and amend certain parts of the law relating to contracts, and that contracts by infants were left outside the Act. If this were so, it does not appear how it would help the appellants. But in their Lordships' opinion the Act, so far as it goes, is exhaustive and imperative, and does provide in clear language that an infant is not a person competent to bind himself by a contract of this description."

Thus, the minor's agreement being void, ordinarily it should be wholly devoid of all effects. If there is no contract, there should be no contractual obligation on either side.

Further, the law declared by the Privy Council in the matter titled as Mohori Bibee versus Dhurniodas Ghose, ILR (1903) 30 Cal 539 (PC) is that a minor's agreement is absolutely void but it is confined to cases where the minor is charged with obligations and the other contracting party seeks to enforce those obligations against the minor.

In the matter titled as "A.T. Raghava Chariar versus O. M. Srinivasa Raghava Chariar, ILR (1916) 40 Madras 308", the Hon'ble Madras High Court has held that:

"What is meant by the proposition that an infant is incompetent to contract or that his contract is void is that the law will not enforce any contractual obligation of an infant.

Nothing in the Contract Act prevents an infant from being promisee, where consideration passes from minor, he can enforce the promise of the adult promisor; if the consideration for the promise is transfer of property by minor, promise would be unenforceable. Minor is wholly incompetent to transfer property. Minor can seek cancellation of the transfer of property to him by returning the consideration to the other party."

Accordingly, a minor is allowed to enforce a contract which is of some benefit to him and under which he is required to bear no obligation.

Question: If minor enters into an agreement by misrepresenting his age, then will there be any estoppel against him?

Answer: The minor is not estopped from setting up the defense of infancy. There can be no estoppel against a statute. The policy of law of contract is to protect persons below age from contractual liability and naturally the doctrine of estoppel cannot be used to defeat that policy.

The Hon'ble High Court of Bombay in the matter titled as "Gadigeppa Bhimappa Meti versus Balangowda Bhimangowda, AIR 1931 Bombay 561", has held that:

"The court is of opinion that where an infant represents fraudulently or otherwise that he is of age and thereby induces another to enter into a contract with him then in an action founded on the contract the infant is not estopped from setting up infancy."

Question: Can minor's agreement be ratified after the minor attains the age of majority?

Answer: The person cannot on attaining majority ratify an agreement made by him during his minority. Ratification relates back to the date of the making off the contract and therefore, a contract which was then void cannot be made valid by subsequent ratification.

In the matter titled as "Bhola Ram Harbans Lal versus Bhagat Ram, AIR 1927 Lahore 24" it was held that it would be a contradiction in terms to say that a void contract can be ratified.

If it is necessary to ratify the contract made by the minor, then a fresh contract should be made on attaining majority.

Question: Is a person of unsound mind or an insane person competent to contract?

Answer: In English Law, a person of unsound mind is competent to contract, although he may avoid his

contract if he satisfies the court that he was incapable of understanding the contract and the other party knew it. The contract is voidable at his option. It becomes binding on him only if he affirms it.

However, in India, the agreement of a person of unsound mind is absolutely void. According to Section 11 of the Indian Contract Act, 1872, a person of unsound mind is not competent to contract. The provision of Section 11 of the Indian Contract Act, 1872 is reproduced hereunder:

> *"Section 11 of Indian Contract Act, 1872: Who are competent to contract—Every person is competent to contract who is of the age of majority according to the law to which he is subject, and who is of sound mind, and is not disqualified from contracting by any law to which he is subject."*

Question: What is a sound mind for the purposes of contracting?

Answer: According to Section 12 of the Indian Contract Act, 1872, a person is said to be of sound mind for the purpose of making a contract if, at the time when he makes it, he is capable of understanding it and of forming a rational judgment as to its effect upon his interests. However, a person who is usually of unsound mind may make a contract when he is of sound mind. But a person who is usually of sound mind may not make a contract when he is of unsound mind. The provisions of Section 12 of the Indian Contract Act, 1872 is reproduced hereunder:

> *"Section 12 of the Indian Contract Act, 1872: What is a sound mind for the purpose of contracting:*
>
> *A person is said to be of sound mind for the purpose of making a contract, if, at the time when he makes it, he is capable of understanding it and of forming a rational judgment as to its effect upon his interests.*
>
> *A person who is usually of unsound mind, but occasionally of sound mind, may make a contract when he is of sound mind.*
>
> *A person who is usually of sound mind, but occasionally of unsound mind, may not make a contract when he is of unsound mind."*

Illustrations:

(a) A patient in a lunatic asylum, who is at intervals of sound mind, may contract during those intervals.

(b) A sane man, who is delirious from fever, or who is so drunk that he cannot understand the terms of contract, or form a rational judgment as to its effect on his interests, cannot contract whilst such delirium or drunkenness lasts.

Question: Is consent of parties essential while executing agreement?

Answer: According to Section 10 of the Indian Contract Act, 1872, an agreement is a contract when it is made for some consideration, between parties who are competent, with their free consent and for a lawful object. The provisions of Section 10 of the Indian Contract Act, 1872 is reproduced hereunder:

> **"Section 10 of Indian Contract Act, 1872: What agreements are contracts—**
>
> *All agreements are contracts if they are made by the free consent of parties competent to contract, for a lawful consideration and with a lawful object, and are not hereby expressly declared to be void.*
>
> *Nothing herein contained shall affect any law in force in India and not hereby expressly repealed, by which any contract is required to be made in writing or in the presence of witnesses, or any law relating to the registration of documents."*

Thus, one of the essential requirement of a contract is free consent of the parties.

Question: What is the meaning of the term "consent"?

Answer: The Oxford Law Dictionary defines the term consent as:

> *"Deliberate or implied affirmation; compliance with a course of proposed action. Consent is essential in a number of circumstances. For example, contracts and marriages are invalid unless both parties give their consent. Consent must be given freely, without duress or deception, and with sufficient legal competence to give it."*

The Black's Law Dictionary defines the term consent as:

> *"Agreement, approval, or permission as to some act or purpose, esp. given voluntarily by a competent person; legally effective assent."*

Section 13 of the Indian Contract Act, 1872 defines the term consent as:

> *"Two or more persons are said to consent when they agree upon the same thing in the same sense."*

Thus, an agreement upon the same thing in the same sense is known as true consent or *consensus ad idem* and is at the root of every contract.

Question: What is the meaning of the term "free consent"?

Answer: According to Section 14 of the Indian Contract Act, 1872, consent is said to be free when it is not caused

by coercion, undue influence, fraud, misrepresentation and mistake. The provisions of Section 14 of the Indian Contract Act, 1872 is reproduced hereunder:

> *"Section 14 of the Indian Contract Act, 1872: Free consent defined:*
>
> *Consent is said to be free when it is not caused by:*
>
> *(1) Coercion, as defined in Section 15, or*
>
> *(2) Undue influence, as defined in Section 16, or*
>
> *(3) Fraud, as defined in Section 17, or*
>
> *(4) Misrepresentation, as defined in Section 18, or*
>
> *(5) Mistake, subject to the provisions of Sections 20, 21 and 22."*

Consent is said to be so caused when it would not have been given but for the existence of such coercion, undue influence, fraud, misrepresentation or mistake.

When consent to an agreement is caused by coercion, undue influence, fraud or misrepresentation, the agreement is a contract voidable at the option of the party whose consent was so caused. For example, if the person is induced to sign an agreement by misrepresentation, then such person may either uphold the agreement or reject it, when he comes to know about the truth. If such person confirms the agreement, such agreement becomes binding on both the parties including that person whose consent was obtained by misrepresentation.

On the other hand, when the consent is caused by mistake, the agreement is void and is not enforceable at the option of either party.

Question: What is void agreement?

Answer: Section 2(g) of the Indian Contract Act, 1872 defines void agreement as:

> *"an agreement not enforceable by law is said to be void".*

Thus, according to Section 2(g) of the Indian Contract Act, 1872, an agreement not enforceable by law is void.

According to Black's Law dictionary, the term void means of no legal effect. The term void contract is by Black's Law Dictionary a contract that is of no legal effect, so that there is really no contract in existence at all. A contract may be void because it is technically defective, contrary to public policy, or illegal.

As per Oxford Dictionary of Law, a void contract is:

> *"A contract that has no legal force from the moment of its making. Void contracts occur when there is lack of capacity to contract and by the operation in some instances of the doctrine of mistake."*

Question: What is voidable contract?

Answer: Section 2(i) of the Indian Contract Act, 1872 defines voidable contract as:

> *"an agreement which is enforceable by law at the option of one or more of the parties thereto, but not at the option of the other or others, is a voidable contract."*

Question: Are contracts valid if the consent is caused by coercion, undue influence, fraud and misrepresentation?

Answer: According to Section 14 of the Indian Contract Act, 1872, consent is said to be free when it is not caused by coercion, undue influence, fraud, misrepresentation and mistake. However, when consent to an agreement is caused by coercion, undue influence, fraud or misrepresentation, the agreement is a contract voidable at the option of the party whose consent was so caused.

Section 19 of the Indian Contract Act, 1872 deals with voidability of agreements without free consent which is reproduced hereunder:

> *"When consent to an agreement is caused by coercion, fraud or misrepresentation, the agreement is a contract voidable at the option of the party whose consent was so caused.*
>
> *A party to a contract whose consent was caused by fraud or misrepresentation, may, if he thinks fit, insist that the contract shall be performed, and that he shall be put in the position in which he would have been if the representations made had been true.*
>
> *Exception—If such consent was caused by misrepresentation or by silence, fraudulent within the meaning of Section 17, the contract, nevertheless, is not voidable, if the party whose consent was so caused had the means of discovering the truth with ordinary diligence.*
>
> *Explanation—A fraud or misrepresentation which did not cause the consent to a contract of the party on whom such fraud was practised, or to whom such misrepresentation was made, does not render a contract voidable."*

Further as per the provisions of Section 19A of the Indian Contract Act, 1872, if the consent is caused by undue influence, then such agreement is voidable at the option of the party whose consent was caused by undue influence. The relevant provision of the

Section 19A of the Indian Contract Act, 1872 is reproduced hereunder:

> *"Section 19A of the Indian Contract Act, 1872, Power to set aside contract induced by undue influence–*
>
> *When consent to an agreement is caused by undue influence, the agreement is a contract voidable at the option of the party whose consent was so caused.*
>
> *Any such contract may be set aside either absolutely or if the party who was entitled to avoid it has received any benefit thereunder, upon such terms and conditions as to the Court may seem just."*

Thus, in case the consent is caused by coercion, undue influence, fraud or misrepresentation, then the agreement is voidable. The party affected by the factors that make the contract voidable, has to avoid it because otherwise it remains valid. Thus, he has the option either to avoid the contract or in alternatively to affirm it. If the contract is affirmed, it becomes enforceable by both the parties and if it is avoided, it becomes void against both. When the party affected by such facts, avoids the contract, then the effect of rescission is that the contract is set aside and the parties are restored to their original position.

Question: Are contracts valid if the consent is caused by mistake?

Answer: According to Section 14 of the Indian Contract Act, 1872 when the consent is caused by mistake, the agreement is void. Instances of consent caused by mistake are:

1. Mistake of fact by both the parties: According to Section 20 of the Indian Contract Act, 1872, when both the parties to the agreement are mistaken relating to the fact which is essential for the agreement, then such agreement is void. The provision of Section 20 of the Indian Contract Act, 1872 is reproduced hereunder:

   > *"Section 20: Agreement void where both parties are under mistake as to matter of fact:*
   >
   > *Where both the parties to an agreement are under a mistake as to a matter of fact essential to the agreement the agreement is void.*
   >
   > *Explanation–An erroneous opinion as to the value of the thing which forms the subject – matter of the agreement, is not to be deemed a mistake as to a matter of fact."*

2. Mistake as to law–According to Section 21 of the Indian Contract Act, 1872 a contract is void if the same is caused by mistake as to any law not in force in India. The provision of Section 21 of the Indian Contract Act, 1872 is reproduced hereunder:

   > *"Section 21 of the Indian Contract Act, 1872 – Effect of mistakes as to law-*
   >
   > *A contract is not voidable because it was caused by a mistake as to any law in force in India; but a mistake as to a law not in force in India has the same effect as a mistake of fact."*

3. Mistake as to fact by one of the party - According to Section 22 of the Indian Contract Act, 1872, when one of the party to the agreement is mistaken relating to the fact which is essential for the agreement, then such agreement is void. The provision of Section 22 of the Indian Contract Act, 1872 is reproduced hereunder:

   > *"Section 22 of the Indian Contract Act, 1872 – Contract caused by mistake of one party as to matter of fact –*
   >
   > *A contract is not voidable merely because it was caused by one of the parties to it being under a mistake as to a matter of fact."*

Question: What is the meaning of consent for medical treatment?

Answer: Consent for the purpose of medical treatment means grant of permission by the patient for an act to be carried out by the doctor, such as a diagnostic, surgical or therapeutic procedure.

The doctor-patient contract is almost always of the implied type, except where a written informed consent is obtained because no formal contract is usually written when a patient visits a doctor.

The Black's Law Dictionary defines the terms express consent and implied consent as:

> *"Express consent - Consent that is clearly and unmistakably stated.*
>
> *Implied consent - 1. Consent inferred from one's conduct rather than from one's direct expression. — Also termed implied permission. 2. Consent imputed as a result of circumstances that arise, as when a surgeon removing a gallbladder discovers and removes colon cancer."*

Thus, it can be said that the relationship between a doctor and his patient is of an implied contract. Although there is no written or oral explicit contract between them, it is implied that the doctor is expected to cure the patient and the patient pays fees in consideration.

Illustrations:

i. A patient enters a doctor's clinic and sits in the examination chair, his consent is implied for examination, diagnosis and consultation.

ii. Persons who offer medical advice and treatment implicitly state that they have the skill and knowledge to do so, that they have the skill to decide whether to take a case, to decide the treatment, and to administer that treatment.

Question: What is the importance of consent in medical treatment?

Answer: In medical field, the consent plays a remarkable legitimate role, specially in the field of medical negligence. The consent should be free consent as envisaged in Section 10 of the Indian Contract Act, 1872. Consent must be voluntary, competent and informed. Voluntary means that when the patient gives consent, he or she is free from extreme duress and is not intoxicated or under the influence of medication and the doctor has not coerced the patient into giving consent.

The earliest expression of this fundamental principle, based on autonomy, is found in the Nuremberg Code of 1947. The Nuremberg Code was adopted immediately after World War II in response to medical and experimental atrocities committed by the German Nazi regime. The code makes it mandatory to obtain voluntary and informed consent of human subjects. Similarly, the Declaration of Helsinki adopted by the World Medical Association in 1964 emphasizes the importance of obtaining freely given informed consent for medical research by adequately informing the subjects of the aims, methods, anticipated benefits, potential hazards, and discomforts that the study may entail. Several international conventions and declarations have similarly ratified the importance of obtaining consent from patients before testing and treatment.

The 3 Judges Constitution Bench of Hon'ble Supreme Court of India in the landmark judgment titled as "Samira Kohli versus Prabha Manchanda, AIR 2008 SC 1385" has held that:

> *"….Except where consent can be clearly and obviously implied, there should be express consent. There is, however, a significant difference in the nature of express consent of the patient, known as 'real consent' in UK and as 'informed consent' in America. In UK, the elements of consent are defined with reference to the patient and a consent is considered to be valid and 'real' when (i) the patient gives it voluntarily without any coercion; (ii) the patient has the capacity and competence to give consent; and (iii) the patient has the minimum of adequate level of information about the nature of the procedure to which he is consenting to. On the other hand, the concept of 'informed consent' developed by American courts, while retaining the basic requirements consent, shifts the emphasis to the doctor's duty to disclose the necessary information to the patient to secure his consent. 'Informed consent' is defined in Taber's Cyclopedic Medical Dictionary thus:*
>
> > *"Consent that is given by a person after receipt of the following information: the nature and purpose of the proposed procedure or treatment; the expected outcome and the likelihood of success; the risks; the alternatives to the procedure and supporting information regarding those alternatives; and the effect of no treatment or procedure, including the effect on the prognosis and the material risks associated with no treatment. Also included are instructions concerning what should be done if the procedure turns out to be harmful or unsuccessful."*
>
> *In Canterbury v. Spence - 1972 [464] Federal Reporter 2d. 772, the United States Courts of appeals, District of Columbia Circuit, emphasized the element of Doctor's duty in 'informed consent' thus: "It is well established that the physician must seek and secure his patient's consent before commencing an operation or other course of treatment. It is also clear that the consent, to be efficacious, must be free from imposition upon the patient. It is the settled rule that therapy not authorized by the patient may amount to a tort - a common law battery - by the physician. And it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification. Thus the physician has long borne a duty, on pain of liability for unauthorized treatment, to make adequate disclosure to the patient."*
>
> *[Emphasis supplied]*

The basic principle in regard to patient's consent may be traced to the following classic statement by Justice Cardozo in Schoendorff vs. Society of New York Hospital - (1914) 211 NY 125:

> *"Every human being of adult years and sound mind has a right to determine what should be done with his body; and a surgeon who performs the operation without his patient's consent, commits an assault for which he is liable in damages."*
>
> *This principle has been accepted by English court also. In Re: F. 1989(2) All ER 545, the House of Lords while dealing with a case of sterilization of a mental patient*

reiterated the fundamental principle that every person's body is inviolate and performance of a medical operation on a person without his or her consent is unlawful. The English law on this aspect is summarized thus in Principles of Medical Law (published by Oxford University Press -- Second Edition, edited by Andrew Grubb, Para 3.04, Page 133):

> *"Any intentional touching of a person is unlawful and amounts to the tort of battery unless it is justified by consent or other lawful authority. In medical law, this means that a doctor may only carry out a medical treatment or procedure which involves contact with a patient if there exists a valid consent by the patient (or another person authorized by law to consent on his behalf) or if the touching is permitted notwithstanding the absence of consent."*

The Hon'ble National Consumer Disputes Redressal Commission in the matter titled as C. Jayapal Reddy versus G. S. Rao, Managing Director, Yashoda Group of Hospitals, 2014 (1) CPJ 271 (NCDRC) has held that:

> *"6. We feel necessary to discuss about What is the valid consent?*
>
> *Consent is not a one-off event of signatures on paper and not a submission of the patient to a particular treatment but rather a process of communication. It is then perceived as a proactive process empowering the patient to consciously decide on what s/he considers best. Thus, consent is a process of communication requiring the fulfilment of certain established elements, like competence, sufficient disclosure, understanding and volunteering.*
>
> *The ICMR guidelines acknowledge the patients consent as a necessary prerequisite to the medical process. However, consent is not systematically required as it is formulated in the case of redesign of treatment, though, with the existing formulation, the achievement of the written consent is misguiding and may ultimately allow the practitioner to override the patients opinion.*
>
> *The doctrine of informed consent finds its common law roots in the landmark decision of Justice Cardozo in Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914), in which he wrote:*
>
> > *Every human being of adult years and sound mind has a right to determine what shall be done with his own body and a surgeon who performs an operation without his patients consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained."*

Question: Is it necessary to obtain consent of the patient in India?

Answer: In India, the patient has a legal right to autonomy and self-determination enshrined within Article 21 of the Constitution of India, 1950. The patient can refuse treatment except in an emergency situation where the doctor need not get consent for treatment. The provision of Article 21 of the Constitution of India, 1950 is reproduced hereunder:

> *"Article 21. Protection of life and personal liberty—No person shall be deprived of his life or personal liberty except according to procedure established by law."*

Apart from the requirement of consent being there under law of torts and various laws of the country, there is now specific provision i.e., the Clause 7.16 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 which places the responsibility on the doctor to obtain consent from the patient, or his guardian in case of minor, before performing operation and if the doctor fails to obtain consent, then the same amounts to professional misconduct rendering the doctor for disciplinary action. The relevant provision of Clause 7.16 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 is reproduced hereunder:

> *"Before performing an operation the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of minor, or the patient himself as the case may be. In an operation which may result in sterility the consent of both husband and wife is needed."*

The 3 Judges Constitution Bench of Hon'ble Supreme Court of India in the landmark judgment titled as "Samira Kohli versus Prabha Manchanda, AIR 2008 SC 1385" has held that:

> *"18. We may also refer to the code of medical ethics laid down by the Medical Council of India (approved by the Central Government under Section 33 of Indian Medical Council Act, 1956). It contains a chapter relating to disciplinary action which enumerates a list of responsibilities, violation of which will be professional misconduct. Clause 13 of the said chapter places the following responsibility on a doctor:*
>
> > *"13. Before performing an operation the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of a minor, or the patient himself as the case may be. In an operation which may result in sterility the consent of both husband and wife is needed."*

We may also refer to the following guidelines to doctors, issued by the General Medical Council of U.K. in seeking consent of the patient for investigation and treatment:

> *"Patients have a right to information about their condition and the treatment options available to them. The amount of information you give each patient will vary, according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes. For example, patients may need more information to make an informed decision about the procedure which carries a high risk of failure or adverse side effects; or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life.*
>
> *x x x x x You should raise with patients the possibility of additional problems coming to light during a procedure when the patient is unconscious or otherwise unable to make a decision. You should seek consent to treat any problems which you think may arise and ascertain whether there are any procedures to which the patient would object, or prefer to give further thought before you proceed."*

The Hon'ble National Consumer Disputes Redressal Commission in the matter titled as "Saroj Chandhoke versus Ganga Ram Hospital, 2007 (3) CPJ 189 (NCDRC) has held that:

"(ii). Consent:

> *These days, complete information with regard to surgery is required to be given to the patient so that the patient becomes aware of the procedure which is sought to be followed by the Surgeon. It should not be presumed that a patient may not/need not know the procedure or is incapable of understanding the medical terms and, therefore, there is no use in explaining them. There cannot be a presumption that all patients are ignorant about their anatomy or the adverse effects or benefits of surgery, and, in any case, those days are over. Hence, properly informed written consent before operation is the necessity."*

The Hon'ble National Consumer Disputes Redressal Commission in the matter titled as "H. S. Tuli versus Post Graduate Institute of Medical Education & Research, 2008 (1) CPJ 392 (NCDRC)" has held that:

> *"Express Written Consent:*
>
> *Express written consent is to be obtained for: (i) all major diagnostic procedures; (ii) general anesthesia; (iii) surgical operations: (iv) intimate examinations; (v) examination for determining age, potency and virginity; and (vi) in medicolegal cases.*
>
> *32. Brain surgery is a major surgery requiring several hours and use of general anesthesia. Informed consent for high risk in writing has to be obtained either from the patient or from her close relatives and if that is not taken and if the patient becomes paralyzed or dies then certainly there are chances that the patient's relatives would allege negligence on the part of the treating surgeons and the hospital. Hence, informed consent is very essential."*

Thus, a medical practitioner cannot examine, treat or operate upon the patient without the patient's consent, except by committing a trespass or assault. This consent, which may be implied, amounts to an agreement on the part of the patient to permit the treatment in question and is sufficient for an implied promise to exercise proper care and skill. Further the consent obtained should be legally valid.

Question: What is the meaning of informed consent?

Answer: Informed consent means voluntary agreement made by a well advised and mentally competent patient to be treated or randomized into a research study.

The Black's Law Dictionary defines informed consent as:

> *"informed consent. 1. A person's agreement to allow something to happen, made with full knowledge of the risks involved and the alternatives. • For the legal profession, informed consent is defined in Model Rule of Professional Conduct 1.0(e). 2. A patient's knowing choice about a medical treatment or procedure, made after a physician or other healthcare provider discloses whatever information a reasonably prudent provider in the medical community would give to a patient regarding the risks involved in the proposed treatment or procedure. — Also termed knowing consent. [Cases: Health 906.]".*

Question: In which situations consent is not necessary to be obtained by the doctor or hospital?

Answer: In case of medical emergency, the doctor can operate on the patient without his or her consent and the doctor is protected by the defense of medical necessity of obtaining consent from the patient.

The 3 Judges Constitution Bench of Hon'ble Supreme Court of India in the landmark judgment titled as "Samira Kohli versus Prabha Manchanda, AIR 2008 SC 1385" has held that:

> *"…The doctor, therefore, is required to communicate all inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and*

the likely effect if the patient remained untreated. This stringent standard of disclosure was subjected to only two exceptions: (i) where there was a genuine emergency, e.g. the patient was unconscious; and (ii) where the information would be harmful to the patient, e.g., where it might cause psychological damage, or where the patient would become so emotionally distraught as to prevent a rational decision."

The Hon'ble Madras High Court in the matter titled as "Arun Balakrishnan Iyer versus Soni Hospital, AIR 2003 Madras 389" has held that:

"22. When the doctor opines, in good faith, that emergency steps need to be taken in the interest of the patient, but fails to take such steps, he would be failing in his duty; and such failure would be a wrongful omission. Therefore, unless the patient proves that there was no such emergency or that those acts were not done bonafide, the doctor or surgeon cannot be found fault with."

Question: Whether consent given for diagnostic surgery, can be construed as consent for performing additional or further surgical procedure?

Answer: If in the course of one operation, there is a medical emergency requiring a medical procedure, the doctor can operate on the patient without his or her consent and is protected by the defense of medical necessity.

The 3 Judges Constitution Bench of Hon'ble Supreme Court of India in the landmark judgment titled as "Samira Kohli versus Prabha Manchanda, AIR 2008 SC 1385 has held that the doctor can act without the consent of the patient where it is necessary to save the life or preserve the health of the patient. However, the principle of necessity by which the doctor is permitted to perform further or additional procedure (unauthorized) is restricted to cases where the patient is temporarily incompetent (being unconscious), to permit the procedure delaying of which would be unreasonable because of the imminent danger to the life or health of the patient. Thus, unless the unauthorized additional or further procedure is necessary in order to save the life or preserve the health of the patient and it would be unreasonable (as contrasted from being merely inconvenient) to delay the further procedure until the patient regains consciousness and takes a decision, a doctor cannot perform such procedure without the consent of the patient. The relevant paragraphs of the judgment are reproduced hereunder:

"16. The next question is whether in an action for negligence/battery for performance of an unauthorized surgical procedure, the Doctor can put forth as defense the consent given for a particular operative procedure, as consent for any additional or further operative procedures performed in the interests of the patient. In Murray vs. McMurchy - 1949 (2) DLR 442, the Supreme Court of BC, Canada, was considering a claim for battery by a patient who underwent a cesarian section. During the course of cesarian section, the doctor found fibroid tumors in the patient's uterus. Being of the view that such tumors would be a danger in case of future pregnancy, he performed a sterilization operation. The court upheld the claim for damages for battery. It held that sterilization could not be justified under the principle of necessity, as there was no immediate threat or danger to the patient's health or life and it would not have been unreasonable to postpone the operation to secure the patient's consent. The fact that the doctor found it convenient to perform the sterilization operation without consent as the patient was already under general anesthetic, was held to be not a valid defense. A somewhat similar view was expressed by Courts of Appeal in England in Re: F. (supra). It was held that the additional or further treatment which can be given (outside the consented procedure) should be confined to only such treatment as is necessary to meet the emergency, and as such needs to be carried out at once and before the patient is likely to be in a position to make a decision for himself. Lord Goff observed:

"Where, for example, a surgeon performs an operation without his consent on a patient temporarily rendered unconscious in an accident, he should do no more than is reasonably required, in the best interests of the patient, before he recovers consciousness. I can see no practical difficulty arising from this requirement, which derives from the fact that the patient is expected before long to regain consciousness and can then be consulted about longer term measures."

The decision in Marshell vs. Curry - 1933 (3) DLR 260 decided by the Supreme Court of NS, Canada, illustrates the exception to the rule, that an unauthorized procedure may be justified if the patient's medical condition brooks no delay and warrants immediate action without waiting for the patient to regain consciousness and take a decision for himself. In that case the doctor discovered a grossly diseased testicle while performing a hernia operation. As the doctor considered it to be gangrenous, posing a threat to patient's life and health, the doctor removed it without consent, as a part of the hernia operation. An action for battery was brought on the ground that the consent was for a hernia operation and removal of testicle was not

consent. The claim was dismissed. The court was of the view that the doctor can act without the consent of the patient where it is necessary to save the life or preserve the health of the patient. Thus, the principle of necessity by which the doctor is permitted to perform further or additional procedure (unauthorized) is restricted to cases where the patient is temporarily incompetent (being unconscious), to permit the procedure delaying of which would be unreasonable because of the imminent danger to the life or health of the patient.

17. It is quite possible that if the patient been conscious, and informed about the need for the additional procedure, the patient might have agreed to it. It may be that the additional procedure is beneficial and in the interests of the patient. It may be that postponement of the additional procedure (say removal of an organ) may require another surgery, whereas removal of the affected organ during the initial diagnostic or exploratory surgery, would save the patient from the pain and cost of a second operation. Howsoever, practical or convenient the reasons may be, they are not relevant. What is relevant and of importance is the inviolable nature of the patient's right in regard to his body and his right to decide whether he should undergo the particular treatment or surgery or not. Therefore at the risk of repetition, we may add that unless the unauthorized additional or further procedure is necessary in order to save the life or preserve the health of the patient and it would be unreasonable (as contrasted from being merely inconvenient) to delay the further procedure until the patient regains consciousness and takes a decision, a doctor cannot perform such procedure without the consent of the patient."

The Hon'ble National Consumer Disputes Redressal Commission in the matter titled as "Saroj Chandhoke versus Ganag Ram Hospital, 2007 (3) CPJ 189 (NCDRC)" has held that:

"VI. Conclusion:

In conclusion it is held that:

(i) In a simple Hysterectomy operation, the Complainant lost her ovaries and left kidney. She was required to undergo other operations for control of fecal discharge from vagina. She was required to stay in the hospital for complete cure for months.

(ii) Informed consent was obtained only for TAH. There was no necessity of trying to operate via vaginal route.

(iii) No consent was obtained for removal of ovaries in advance planned surgery.

(iv) In the present case, the question is not whether TAH is preferable to VH. The patient was prepared for TAH and had given written consent for TAH and no consent was obtained or no information was given to the patient that her ovaries would be removed. In such set of circumstances, it cannot be said that because a surgeon is expert in the field he/she can carry out the surgery of his choice. If he/she does so, he/she does it at his/her risk in case of mishap.

No doubt, in case of emergency there can be deviation in mode of surgery, but not in a planned surgery where express consent for a particular mode is taken from the patient, particularly, when there is no emergency.

(v) Before performing surgery, properly informed written consent is must. No doubt, while operating, to control adverse situation or to save the life of the patient or for benefit of the patient, other procedure could be followed or other part of the body could be operated.

(vi) As held in Spring Meadows Hospital (supra) it is to be seen that superiority of the Doctor is not abused in any manner. Further, if during the operation any mishap occurs because of error of judgment, it would be deficiency in service or negligence, if that would not have been committed by a reasonably competent professional man professing the standard and type of skill that a surgeon held out as having. The Opposite Party No. 2 is an expert Gynecologist who has performed many such operations as contended by her and Opposite Party No. 1 is a known big Hospital. In such a case, it is difficult to accept that for no fault there was avulsion of vein to such an extent that left kidney was required to be removed. Inference could be that there was some error which resulted in cut of a vein."

Question: Whether the doctor is required to obtain consent of the patient in case of accident?

Answer: In Re F (Mental Patient: Sterilization), 1990 (2) AC 1, Lord Bridge has observed that doctors and other healthcare professionals would otherwise face on intolerable dilemma, if they administer the treatment which they believe to be in the interest of the patient, they might face an action for trespass to the person, but if they withhold that treatment they could be in breach of duty of care in negligence.

The Indian Medical Council (Professional Conduct, Etiquette & Ethics) Regulation, 2002 casts a duty on

all medical practitioners i.e. all medical practitioners must attend to sick and injured immediately and it is the duty of the medical practitioners to make immediate and timely medical care available to every injured person whether he is injured in accident or otherwise. The relevant provisions of Indian Medical Council (Professional Conduct, Etiquette & Ethics) Regulation, 2002 is reproduced hereunder:

> ***"2. Duties of physicians to their patients***
>
> *2.1 Obligations to the sick*
>
> *2.1.1 Though a physician is not bound to treat each and every person asking his services, he should not only be ever ready to respond to the calls of the sick and the injured, but should be mindful of the high character of his mission and the responsibility he discharges in the course of his professional duties. In his treatment, he should never forget that the health and the lives of those entrusted to his care depend on his skill and attention. A physician should endeavor to add to the comfort of the sick by making his visits at the hour indicated to the patients. A physician advising a patient to seek service of another physician is acceptable, however, in case of emergency a physician must treat the patient. No physician shall arbitrarily refuse treatment to a patient. However for good reason, when a patient is suffering from an ailment which is not within the range of experience of the treating physician, the physician may refuse treatment and refer the patient to another physician.*
>
> *2.1.2 Medical practitioner having any incapacity detrimental to the patient or which can affect his performance vis-à-vis the patient is not permitted to practice his profession.*
>
> *2.4 The Patient must not be neglected:*
>
> *A physician is free to choose whom he will serve. He should, however, respond to any request for his assistance in an emergency. Once having undertaken a case, the physician should not neglect the patient, nor should he withdraw from the case without giving adequate notice to the patient and his family. Provisionally or fully registered medical practitioner shall not willfully commit an act of negligence that may deprive his patient or patients from necessary medical care.*
>
> *3.5 Treatment after Consultation*
>
> *No decision should restrain the attending physician from making such subsequent variations in the treatment if any unexpected change occurs, but at the next consultation, reasons for the variations should be discussed/explained. The same privilege, with its obligations, belongs to the consultant when sent for in an emergency during the absence of attending physician. The attending physician may prescribe medicine at any time for the patient, whereas the consultant may prescribe only in case of emergency or as an expert when called for."*

The Hon'ble Supreme Court of India in the matter titled as "Parmanand Katara versus Union of India, AIR 1989 SC 2039" has held that:

> *"There can be no second opinion that preservation of human life is of paramount importance. That is so on account of the fact that once life is lost, the status quo ante cannot be restored as resurrection is beyond the capacity of man. The patient whether he be an innocent person or be a criminal liable to punishment under the laws of the society, it is the obligation of those who are in-charge of the health of the community to preserve life so that the innocent may be protected and the guilty may be punished. Social laws do not contemplate death by negligence to tantamount to legal punishment.*
>
> *Article 21 of the Constitution casts the obligation on the State to preserve life. The provision as explained by this Court in scores of decisions has emphasized and reiterated with gradually increasing emphasis that position. A doctor at the Government hospital positioned to meet this State obligation is, therefore, duty-bound to extend medical assistance for preserving life. Every doctor whether at a Government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life. No law or State action can intervene to avoid/delay the discharge of the paramount obligation cast upon members of the medical profession. The obligation being total, absolute and paramount, laws of procedure whether in statutes or otherwise which would interfere with the discharge of this obligation cannot be sustained and must, therefore, give way. On this basis, we have not issued notices to the States and Union Territories for affording them an opportunity of being heard before we accepted the statement made in the affidavit of the Union of India that there is no impediment in the law. The matter is extremely urgent and in our view, brooks no delay to remind every doctor of his total obligation and assure him of the position that he does not contravene the law of the land by proceeding to treat the injured victim on his appearance before him either by himself or being carried by others. We must make it clear that zonal regulations and classifications cannot also operate as fetters in the process of discharge of the obligation and irrespective of the fact whether under instructions or rules, the victim has to be sent elsewhere or how the police shall be contacted, the guideline indicated in the*

1985 decision of the Committee, as extracted above, is to become operative. We order accordingly.

The Hon'ble National Consumer Dispute Redressal Commission in the matter titled as "Pravat Kumar Mukherjee versus Ruby General Hospital & Ors., 2005 (2) CPJ 35" has held that:

"Considering the aforesaid law, it is apparent that: emergency treatment was required to be given to the deceased who was brought in a seriously injured condition; there was no question of waiting for the consent of the patient or a passer by who brought the patient to the hospital, and was not necessary to wait for consent to be given for treatment;

There is nothing on record to suggest that the Doctor has informed the patient or the relatives or the person who has brought him to the hospital with regard to dangers ahead or the risk involved by going without the operation/treatment at the earliest.

Consent is implicit in such cases when patient is brought to the hospital for treatment, and a surgeon who fails to perform an emergency operation must prove that the patient refused to undergo the operation not only at the initial stage but even after the patient was informed about the dangerous consequences of not undergoing the operation."

Thus, the patient's consent is not necessary in case of accident/emergency as in such cases, the consent is implied when the patient is brought to the hospital. Further, it is an obligation on the doctor to treat his patient without any delay.

Question: If minor is in emergency, then whose consent is valid?

Answer: According to the Clause 7.16 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002, the doctor has to obtain consent from the patient or his guardian in case of minor before performing operation and if the doctor fails to obtain consent, then the same amounts to professional misconduct rendering the doctor for disciplinary action. The relevant provision of Clause 7.16 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 is reproduced hereunder:

"Before performing an operation the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of minor, or the patient himself as the case may be. In an operation which may result in sterility the consent of both husband and wife is needed."

However, in case of emergency involving children when their parents or guardian are not available, then the consent is taken from the person-in-charge of the child e.g., a school teacher can give consent for treating a child who becomes sick during a picnic away from home town or the consent of the headmaster of a residential school. Such person-in-charge of the child are known as in loco parentis i.e., acting as temporary guardian of a child.

Question: Are all consent given for medical treatment valid?

Answer: According to Section 10 of the Indian Contract Act, 1872, an agreement is a contract when it is made for some consideration, between parties who are competent, with their free consent and for a lawful object. Thus, for the purpose of entering into a contract, free consent is one of the essential.

According to Section 14 of the Indian Contract Act, 1872, consent is said to be free when it is not caused by coercion, undue influence, fraud, misrepresentation and mistake.

Thus, if the patient or his guardian gives consent under coercion, undue influence, fraud, misrepresentation or mistake or by a person who is minor, or is mentally unsound, not fully conscious, intoxicated or who is ignorant of the implications of such consent, then such consent is not valid.

Blanket consent given at the time of admission may be invalid.

Separate consent for specific procedure and for anesthesia before conducting the procedure may be taken.

A signed written consent form by itself does not constitute valid consent, though it is an evidence of consent given by the patient or his guardian. The following components are essential for a valid consent form:

1. The patient gives it voluntarily without any coercion
2. The patient has the capacity and competence to give consent.
3. The patient has an adequate level of information about the nature of the procedure to which he is consenting.

■■■■

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PCI IN SVG: HOW I DO IT?

Dr Ashok Seth, New Delhi

The commandments of SVG PCI - How I do it? Use guides with good support/backup - Multipurpose, amplatz, grafts guides (avoid Judkins right guide). Use 'stealth bomber approach" - Wire gently with soft tip wires and find path, use moderate support wires - Do not move extra support wires backwards and forwards too much. Pre-treat - Prevent slow flow. For large bulky thrombus - IC Reopro; thrombectomy devices. Predilate - Small balloon, feel the lesion compliance and pressure; in case of fuzzy, shaggy, ulcerated, thrombotic lesion, there is no need to predilate. Use protection devices liberally - Become expert with filter device, distal balloon occlusion device, proximal protection device. Immediate accessibility to - PA pressure monitoring, IABP, multipurpose probing catheters, adenosine → Nitroprusside.

MULTIVESSEL STENTING IN STEMI

Dr Praveen Chandra, Gurugram

In STEMI, primary PCI of culprit lesion is the treatment of choice. Approximately 50% of patients with STEMI have multivessel disease (MVD). Possible approaches for treatment of MVD in AMI: Total revascularization of critical lesions in cardiogenic shock; PCI of infarct related artery (IRA)/non-IRA in same sitting; perform PCI at the time of treating the culprit lesion based on FFR measurements; noninvasive (imaging) ischemia/viability testing and revascularize lesions perfusing ischemic/viable territories (staged procedure); leave the remaining lesions alone and act only if additional events occur (conservative approach). According to the CULPRIT-SHOCK trial, culprit lesion only PCI is superior to multivessel PCI. Deferring treatment of angiographically significant coronary lesions in noninfarct related arteries with an FFR >0.8 is safe and efficient.

HOW DOES OCT GUIDANCE HELP IN CALCIFIED LESIONS?

Dr Ajit Menon, Mumbai

Calcification correlates with advanced atherosclerosis, increased age and comorbidities. The presence of calcified and rigid lesions makes PCI challenging. Adjuvant techniques are often required to achieve satisfactory stent results. Angiography has been shown to have low sensitivity (48%) for calcium detection, except for severe calcification. Optical coherence tomography (OCT) precisely detects calcium as a signal poor or heterogeneous region with sharply delineated leading, and/or lateral borders. Based on pathology, OCT estimates the area of calcification more accurately than intravascular ultrasound (IVUS) since the light penetrates calcium without shadowing. OCT also enables the operator to distinguish between superficial and deep calcium with accurate measurement of the minimum distance from the lumen, the thickness of the calcified plate, and circumferential arc distribution. OCT could thus be a more useful clinical tool for quantifying calcified plaques.

ROTATIONAL ATHERECTOMY AND ELCA BASICS

Dr Samuel Mathew, Chennai

The presence of CAC may lead to: unsuccessful PCI owing to undilatable lesions; balloon ruptures; coronary dissection, perforation or rupture; asymmetric, malapposed and underexpanded stent; higher incidence of major adverse cardiac events; higher incidence of restenosis and target lesion revascularization; higher incidence of periprocedural MI; higher incidence of stent thrombosis.

Indications for use of ELCA: total occlusions - traversable by guidewire; underexpanded stents due to calcific and nonyielding vessel; in-stent restenosis; saphenous vein grafts; moderately calcified; failed balloon; ostial lesions; long lesions.

Lessons in heavily calcified lesions - Rota significantly reduces complications; not using Rota often leads to longer and much more difficult procedures, and the cost balances out because of the balloons you are using up; be quick to adapt - sometimes when balloon fails to dilate, you can switch to Rotablator with caution; slow flow and no reflow can be minimized; major complications can be reduced with good technique and experience.

WHAT IS THE SIGNIFICANCE OF OCT IN LEFT MAIN DISEASE?

Dr Ashwin B Mehta, Mumbai

OCT is a light-based imaging modality that yields high resolution *in vivo* images of the coronary artery (axial

resolution 10-20 μm). OCT has a resolution 10x greater than that of IVUS with 20x faster image capture. It thus provides precision information very quickly and assists the physicians in the treatment of cardiovascular disease, including left main coronary artery (LMCA) disease. OCT can be employed to assess atherosclerotic plaque and visualize thrombus, and to evaluate the lumen area with accurate automated measurements. During PCI, it can be of help in stent placement and may be used to assess stent apposition and tissue coverage and assist in the identification and quantification of stent coverage. OCT is indicated for the assessment of lesions and for guidance of stent sizing and implantation. Intracoronary imaging enables evaluation of the distribution of plaque including the extent of calcified plaque. OCT can even help assess the thickness of calcium plaques, which may affect the lesion preparation strategy. Dissections resulting from predilatation are also detected by OCT that can be taken into account when assessing the required stent length.

HOW DOES FFR ASSESSMENT HELP IN ACS?

Dr Florim Cuculi, Switzerland

Fractional flow reserve (FFR) assessment provides anatomical and physiological information that can help tailor treatment strategies in CAD. FFR is an evidence-based diagnostic tool of physiological significance of coronary artery stenosis in patients with stable CAD. Some randomized clinical trials have shown the efficacy of FFR-guided PCI in ACS. FFR values in the culprit vessel are higher during acute episodes when compared to measurements taken after the microcirculation has had some time to recover. These states are perhaps most marked in acute STEMI. Some studies support the use of FFR in evaluating the severity of non-culprit lesions during ACS following revascularization of the culprit vessel. The COMPARE-ACUTE trial compared FFR-guided complete revascularization (n = 295) with culprit artery only revascularization (IRA, n = 590) among patients with primary PCI presenting with STEMI. In STEMI patients, FFR-guided compete revascularization was superior to the IRA group in MACE points at 12 months. There were no differences in MI and mortality. FFR demonstrates diagnostic accuracy and reproducibility in AMI, especially in intermediate lesions. The measurement of FFR in non-culprit stenoses of patients with MI, can be reliably performed during the acute phase of the disease and allows for planning a more appropriate strategy of individualized treatment. FFR could become an essential tool for physicians not only in stable CAD, but also during PCI of patients with ACS.

HAS THE SCENARIO CHANGED WHEN IT COMES TO CHOOSING BETWEEN PCI AND CABG FOR MULTI-VESSEL DISEASE?

Dr MS Hiremath, Pune

For multivessel CAD, CABG generally has lower rates of MI and repeat revascularization than PCI, and shows a trend toward better survival as CAD complexity increases, but a higher rate of stroke. In the BEST trial among 880 Asian patients with multivessel CAD, complete revascularization was achieved more often with CABG than PCI. At 2 years, the primary endpoint (death, MI or target-vessel revascularization) was similar between groups (PCI, 11%; CABG, 8%), although the difference became statistically significant by 5 years (15% vs. 11%). On the primary endpoint, treatments did not differ in nondiabetic patients (hazard ratio, 1.07). PCI may offer early safety benefits for stroke, bleeding and potentially, mortality but poses a greater need for repeat revascularization. Later mortality is similar with the two procedures, but MI rates may be higher after PCI. Overall, the data suggests few differences, except for patients with diabetes and for those in whom complete revascularization cannot be attained. Technological and pharmacological advances have changed the practice of PCI, including the introduction of safer and more effective DES; more judicious use of PCI, based on FFR measurements; PCI optimization with IVUS and OCT; and improved antithrombotic and antiplatelet agents. The less invasive approach thus has an edge which most patients tend to prefer. Recommendations of either PCI or CABG for a coronary intervention should be individualized and evidence-based. The overall clinical scenario should take into account the clinical presentation, anatomic SYNTAX score, patient's age, comorbidities, renal function, mental and neurologic status, and the tolerance for long-term treatment with dual antiplatelet medications, as well as patient expectations and preferences.

WHAT IS THE ROLE OF FFR IN MULTIVESSEL DISEASE?

Dr G Sengottuvelu, Chennai

The use of an FFR-guided strategy for complete revascularization can considerably decrease the number of unnecessary interventions during multivessel PCI and the number of subsequent revascularizations. The significance of FFR in patients with multivessel coronary disease undergoing revascularization was shown in the FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) study. FFR-guided PCI was associated with lower 1-year adverse events and

reduced costs. In the FAME 2 study, FFR-guided PCI, compared with medical therapy alone, improved the outcome. Patients without evidence of ischemia had favorable outcomes without PCI. The FIND study done in India revealed that FFR reduced CABG and number of stents.

Dr Sengottuvelu highlighted the fact that FFR is load dependent i.e., FFR value depends on the area of myocardium supplied by that vessel. In a nice case demonstration he showed in multivessel disease how the CTO of RCA with collaterals from LAD can falsely cause significant FFR of a borderline LAD lesion. FFR to LAD after treating the RCA CTO gave the true value of FFR. He also highlighted that FFR is the gold standard in left main and its importance when patient has other vessel disease. In these situations, other tests like nuclear perfusion imaging become less reliable. Finally, he emphasized the critical role of FFR in multiple serial lesions to identify the culprit lesion.

BIFURCATION PCI OPTIMIZATION WITH OCT

Dr Prabhu C Halkati, Belgaum

Routine stenting of both branches offers no benefit over stenting of the main branch (MB) only, with provisional stenting of the side branch (SB), making the provisional strategy the preferred approach. OCT is a high resolution intravascular (IV) imaging tool used to assess coronary lesions and evaluate the results of stenting. In bifurcation lesions, it is particularly helpful in guiding several steps, such as immediate automated online detection of the lumen area after pullback will assist in the rapid assessment of the vessel morphology and minimum lumen area; it is particularly useful for guidance of interventions in bifurcations, where knowing the reference diameter of the vessel distal and proximal to the SB is critical in correctly sizing the diameter and length, both of the stent and post-dilatation balloon. OCT visualization of the distal and proximal edges of the stent will rule out the presence of dissections, undetectable by angiography alone. OCT is thus a useful tool which helps in optimization of bifurcation stenting in the following conditions: assessment of size and length of the lesion of SB; severity of SB disease; stent strategy plan - provisional stenting vs. two stents; post-stent - plaque shift to SB (snow-plow).

DIAGNOSIS AND TREATMENT OF VULNERABLE PLAQUE

Dr CG Bahuleyan, Kerala

Vulnerable plaques are the lesions which destabilize and rupture, causing acute thrombosis of the coronary arteries. Vulnerable plaques exist in different proportion in patients with stable as well as unstable ischemic heart disease. These plaques are characterized by features like thin cap fibroatheroma (TCFA), large lipid core, spotty calcification, neovascularization, cholesterol crystals and accumulation of inflammatory cells like macrophages. Non-invasive methods like CT-coronary angiography and MRI help detect plaque characteristics. Although IV imaging, like IVUS, virtual histology IVUS, near-infrared spectroscopy (NIRS) and OCT, have been found to be more promising in the delineation of coronary plaques. By virtue of high resolution potential (10-20 times axial resolution), OCT provides better visualization of blood vessel wall details and lesion characteristics. Features like TCFA, lipid rich core and calcific nodule and deposits of macrophages can be identified. Further characterization of deeper aspects of plaques cannot be detected with OCT. Novel OCT based 3-D quantification of the fibrous cap and other advances in coronary imaging may help in predicting the relationship of vulnerable plaques and future clinical events more accurately. Clinical trials using statins have been shown to stabilize plaques by increasing the thickness of fibrous cap in patients with unstable angina. Patients with vulnerable plaques with no limitation of coronary flow can possibly be managed by aggressive medical treatment at present. Clinical case - 65-year-old male patient with MV disease and stable angina. The borderline mid LAD lesion showed characteristic features of vulnerable plaque on OCT analysis with reduction of minimal lumen area (MLA). Performing angioplasty and stenting similar lesion merely on the basis of vulnerable plaque characteristics is currently not evidence-based. However in this case, FFR indicated ischemia and therefore, stenting was done.

DEFERRED STENTING

Dr Anand Rao, Mumbai

Primary PCI with stenting is the current standard treatment for patients with STEMI. To date, attempts to avoid embolization by using thrombectomy or distal protection devices have not been efficacious. In patients undergoing primary PCI, deferred stent implantation is associated with improvement in surrogate outcomes, but does not appear to improve clinical outcome. In some trials, it has shown improvement in the microvascular blush grades and LVEF. Individualization is required in patients with large thrombus burden, especially when thrombectomy devices are in big question. Large scale

RCTs with long-term follow-up might shed further light on clinical endpoints such as death, heart failure and reinfarction.

ROLE OF IVUS IN CTO

Dr Ajith Pillai, Puducherry

In addition to optimizing stent expansions, routine use of IVUS significantly brings down the contrast usage and fluoroscopy time. Clinical utility of IVUS: wire penetration of proximal cap; re-entry in cases of subintimal GW passage; reverse-CART; when r-CART fails, IVUS helps in seeing/preventing complications: Identifies large subintimal plane; presence of intramural and extramural hematoma; prediction of no-reflow.

STENT THROMBOSIS: ROLE OF OCT

Dr G Sengottuvelu, Chennai

OCT, with its unique features of high resolution, plays a vital role in diagnosis and management of stent thrombosis. Not all stent thrombosis are equal. One needs to identify the specific cause of stent thrombosis, the etiology of which varies depending on the time course - subacute, late and very late. Identification of specific causes of stent thrombosis can help make the strategy specific to the cause and can prevent recurrent stent thrombosis.

MANAGEMENT OF INTRACORONARY THROMBUS

Dr Arun Srinivas, Mysore

Intracoronary thrombus subsequent to plaque rupture and causing partial or complete occlusion of a coronary artery is the basic pathophysiologic event in acute STEMI. The mainstay pharmacological treatments for thrombus-containing lesions include aspirin, heparin, GPIIb/IIIa platelet receptor antagonists, thienopyridines, direct thrombin inhibitors and thrombolytic agents. The 4 main contemporary technologies for mechanical thrombus extraction are manual aspiration catheters, power-sourced thrombectomy devices, ultrasound sonication and embolic protection systems. Thrombus aspiration should not be used as a routine strategy in patients with STEMI. Use of filter-based distal protection devices does not affect the incidences of complete ST resolution and peak creatine kinase. Routine thrombectomy does not enhance outcomes and should be reserved for large thrombus before or after stent implantation. It seems reasonable to perform adjunctive thrombectomy in patients with angiographically large thrombus burden before primary PCI.

LEFT MAIN BIFURCATION STENTING AND LESSONS FROM DKCRUSH 5

Dr Viveka Kumar, New Delhi

LMCA supplies 75% of the left ventricular myocardium (100% in a left dominant circulation), thus making its disease ominous. SYNTAX and EXCEL trials show the equivalence of PCI to CABG in patients with SYNTAX score of <32. However, major challenge persists in the form of involvement of left main bifurcation in 80% of the cases associated with a high restenosis and thrombosis rate. Main branch stenting (1 stent approach), provisional stenting and dedicated bifurcation stenting are the options available for tackling left main bifurcation. However, the best method has remained controversial. The initial experience from the Nordic bifurcation study, BBC ONE trial and CACTUS trial has shown no advantage of dedicated 2-stent strategy over a provisional one. But the applicability of this data to left main bifurcation remains flawed due to paucity of left main bifurcation cases in these studies. Provisional stenting is limited by the fact that crossover to a 2-stent strategy is required in more than one-third of the cases. Rescue or bailout stenting in these cases may be associated with imprecise stent placement, incomplete stent expansion or failure to deliver a stent leading to poorer outcome as compared to a dedicated 2-stent approach. Of the dedicated 2-stent strategies available (T stenting and protrusion, V stenting, Culotte technique and double kissing (DK) crush technique), DK crush technique has shown the best results. DKCRUSH-III trial compared DK crush technique with culotte technique and showed better 12-month MACE free survival with DK crush (93.8% vs. 83.7%). DKCRUSH-V trial compared DK crush with provisional stenting. At 12 months, primary endpoint (target lesion failure) was noted in 10.7% patients in the provisional stenting group and 5.0% in the DK crush group. DK crush also resulted in lower rates of target vessel MI (2.9% vs. 0.4%) and definite or probable stent thrombosis (3.3% vs. 0.4%). On subgroup analysis, DK crush performed better in both simple and complex bifurcation lesions. It remains important to note that DK crush is a challenging technique and the primary operators in the trial were required to perform at least 300 PCI/year and 20 left main PCI/year for 5 years to be a part of the trial.

Left main PCI should be attempted by experienced operators at high volume centers. While DK crush is the preferred dedicated 2-stent strategy for true bifurcation lesions, single-stent strategy may be used in cases with insignificant left circumflex ostial disease.

News and Views

Fathers are One of the Best, Yet Most Underutilized Child Development Resources, Says UNICEF

To mark Father's Day this month, UNICEF has launched a new parenting site as part of its 'Super Dads' campaign recognizing father's role in their children's early development. UNICEF is calling for more support for fathers globally, including for policies that give parents the time and resources they need to spend quality time with their children. The online site will bring together fathers from across the world to share their parenting tips, their struggles, their needs and their successes. It will also feature 'mini parenting master classes', the first of which features UNICEF Global Chief of Early Childhood Development Dr Pia Britto explaining to Sesame Street's Grover the importance of protection, stimulation and good nutrition for healthy brain development.

The 'Super Dads' campaign is intended to remind parents everywhere that when fathers nurture their young ones in their earliest years of life - by providing love and protection, playing with them and supporting their nutrition - their children will learn better, have less behavioral issues and become healthier, happier human beings.

"More than just a second parent or an extra set of hands, fathers are one of the best child development resources we have, and if we are going to give children the best start in life, we all need to fully recognize and utilize this role," said UNICEF Chief of Early Childhood Development Dr Pia Britto… (*UNICEF, June 7, 2018*)

Tonsillectomy During Childhood Increases Long-term Risk of Respiratory Diseases

Removal of adenoids and tonsils in childhood is associated with increased long-term risk of respiratory, allergic and infectious diseases, according to a study of almost 1.2 million children published online June 7, 2018 in *JAMA Otolaryngology–Head & Neck Surgery*.

US FDA Approves Venetoclax for CLL/SLL Patients with/without 17p Deletion

The US Food and Drug Administration (FDA) has approved venetoclax for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy.

Antiplatelet Therapy can be Restarted After Spontaneous ICH

A retrospective analysis first published May 30, 2018, in the journal *Neurology* concluded that restarting antiplatelet therapy in patients with spontaneous mild-to-moderate intracerebral hemorrhage is not associated with worse functional outcomes or health-related quality-of-life at 90 days.

Elobixibat Safe and Effective for Treatment of Chronic Constipation

Results of a phase III trial reported online May 24, 2018 in *The Lancet Gastroenterology & Hepatology* demonstrate the safety and effectiveness of elobixibat in chronic constipation. Elobixibat is a minimally absorbed inhibitor of ileal bile acid transporter.

Insomnia Increases Risk of Heart Disease

Insomnia or poor sleep with polysomnography-short sleep was associated with a 29% higher risk of incident cardiovascular disease, says a study published in the June 2018 issue of the journal *Sleep*.

At One-month Mark in Ebola Outbreak, the Focus Shifts to Remote Areas

One month into the response to an Ebola outbreak in the Democratic Republic of the Congo, the focus has moved from urban areas to some of the most remote places on earth. The shift comes after a series of unprecedented actions that have led to cautious optimism about the effectiveness of the response.

The first phase of the response focused on protecting the town of Bikoro and the city of Mbandaka from a potentially exponential increase in cases, which could have threatened major cities in the country as well as its neighbours along the river.

"The next phase is all about expeditionary surveillance: teams of epidemiologists fanning out over hundreds of kilometers by motorcycles through the remote rainforests," said Dr Peter Salama, Deputy Director-General of Emergency Preparedness and Response at WHO, who returned from his second mission to the country on 8 June. "They are working to find each case quickly, tracking the contacts and engaging the communities, including the indigenous population

in and around the villages of Itipo and Iboko. We need to pursue the virus wherever it heads and remain agile, responsive and super focused."

As the response in-country continues, the World Health Organization (WHO) is supporting 9 countries bordering the Democratic Republic of the Congo to scale up their national emergency preparedness and response capacities. A plan finalized on 7 June outlines how these countries can review their readiness to respond, while identifying any gaps in their capabilities. WHO is working closely with the Ministries of Health and wider government stakeholders, and partners in these countries to put these measures in place.

- On 9 May, the day after country declared an outbreak of Ebola virus disease in Bikoro, the first WHO and Ministry of Health Response Team arrived in the provincial capital Mbandaka to begin setting up the specialized cold chain needed to store a vaccine.
- By 11 May, teams had started to trace contacts of all active cases and WHO partners were setting up treatment centers in Bikoro. The next day, an air bridge was established to Bikoro and a mobile lab deployed to speed up testing for infection.
- And then, just 6 days after the alert, the first batch of more than 4,000 doses of vaccine was on its way from Geneva to Kinshasa. This marked the first time vaccines were available so early in a response.
- Ring vaccination of contacts began on 21 May.
- On 4 June, an Ethics Committee in the country approved the use of 5 investigational therapeutics under the framework of compassionate use, following recommendations from a group of experts convened by WHO. This is the first time such treatments were available in the midst of a response.

(*WHO, June 10, 2018*)

Feeling of Loneliness, and not Living Alone, is Bad for the Heart

Feeling lonely rather than living alone is bad for the heart and a strong predictor of premature death, according to a study presented June 9, 2018 at EuroHeartCare 2018, the European Society of Cardiology's annual nursing congress. Feeling lonely was associated with poor outcomes in all patients regardless of their type of heart disease, and even after adjusting for age, level of education, other diseases, body mass index, smoking, and alcohol intake.

US FDA Approves Pegfilgrastim Biosimilar for Cancer Infection Risk

The US FDA has approved the first biosimilar to pegfilgrastim (Neulasta, Amgen) - pegfilgrastim-jmdb - a granulocyte colony-stimulating factor used to reduce infection risk in patients with nonmyeloid cancer who are receiving myelosuppressive chemotherapy that has a clinically significant incidence of febrile neutropenia.

Breastfeeding Modifies Gut Microbiome to Prevent Overweight

New data from the Canadian Healthy Infant Longitudinal Development (CHILD) study published online June 4 in *JAMA Pediatrics* show that breastfeeding may protect infants from becoming overweight in the first year of life by altering the gut microbiome, while formula feeding may stimulate changes in gut microbiota that are associated with overweight.

Progressive Loss of Visual Field Impairs Driving Skills in Glaucoma Patients

With progressive loss of visual field, patients with glaucoma lose the ability to negotiate curves and show greater mean reaction time on the divided-attention task, suggests a study presented May 2, 2018 at ARVO 2018, the annual meeting of The Association for research in Vision and Ophthalmology, in Honolulu, Hawaii.

Kitchen Towels are a Source of Bacteria that may Cause Food Poisoning

A study from Mauritius presented June 9, 2018 at the ASM Microbe meeting in Atlanta has suggested kitchen towels as an important source of bacteria that may cause food poisoning. Bacterial growth was found in 49% of the kitchen towels and the chances of bacterial growth increased in proportion to a large family size, more children in the study and extended family. Multipurpose towels had higher colony forming unit (CFU) than single use towels and humid towels had higher CFU than dry ones.

Paraguay is Malaria-free, Says WHO

The WHO has certified Paraguay as having eliminated malaria, the first country in the Americas to be granted this status since Cuba in 1973. "It gives me great pleasure today to certify that Paraguay is officially free of malaria. Success stories like Paraguay's show what is possible. If malaria can be eliminated in one country, it can be eliminated in all countries," said Dr Tedros

Adhanom Ghebreyesus, WHO Director General, in a recorded statement.

Paraguay was identified as one of 21 countries with the potential to eliminate malaria by 2020 in 2016. Through the "E-2020 initiative," WHO is supporting these countries as they scale up activities to become malaria-free… (*WHO, June 11, 2018*).

In utero Exposure to Diabetes Increases Risk of Future Type 2 Diabetes in Offspring

According to a study published online June 11, 2018 in *JAMA Pediatrics*, *in utero* exposure to type 2 diabetes and gestational diabetes increased the risk for developing type 2 diabetes before the age of 30 compared with those who had no exposure to diabetes (3.19 vs. 0.80 vs. 0.26 cases per 1,000 person-years, respectively, $p < 0.001$).

Erectile Dysfunction Increases Risk for Heart Disease

Men with erectile dysfunction were twice as likely to experience heart attacks, cardiac arrests, sudden cardiac death and fatal or nonfatal strokes regardless of other risk factors, such as cholesterol, smoking and high blood pressure, according new research published June 11, 2018 in the journal *Circulation*.

Preconception Vitamin D Levels Influence Chances of Conception and Successful Pregnancy

Women who are not infertile but have a history of pregnancy loss are more likely to conceive and deliver a live infant if their preconception levels of vitamin D are sufficient, suggests a new study published online May 30, 2018 in the *Lancet Diabetes & Endocrinology*.

EMA Grants Marketing Authorization to Myalepta for Leptin Deficiency

The European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) has recommended granting of marketing authorization for Myalepta indicated for the treatment of complications of leptin deficiency in patients with generalized or partial lipodystrophy which is often associated with severe metabolic abnormalities, including hypertriglyceridemia, insulin resistance and/or diabetes. Myalepta, which is a recombinant human leptin analog, will be available as an 11.3 mg powder for solution for injection.

ESC/ESH 2018 Guidelines for Management of Hypertension

The new 2018 European Society of Cardiology (ESC) and European Society of Hypertension (ESH) guidelines recommend treating to a systolic BP target targeting systolic blood pressure to 130 mmHg, and lower if possible, but not lower than 120 mmHg. The recommended target is less than 140 mmHg for patients aged 65 and older, as tolerated, but not less than 130 mmHg.

Mediterranean Diet Reduces Risk of Progression to Advanced ARMD

New data presented May 1 at ARVO 2018, the annual meeting of the Association for Research in Vision and Ophthalmology, in Honolulu, Hawaii show that eating a Mediterranean diet may reduce the risk of progression to advanced age-related macular degeneration by around 40%.

Ten New Swachh Iconic Places Launched Under Swachh Bharat Mission

Ten new iconic sites, namely, Raghavendra Swamy Temple (Kurnool, Andhra Pradesh); Hazardwari Palace (Murshidabad, West Bengal); Brahma Sarovar Temple (Kurukshetra, Haryana); VidurKuti (Bijnor, Uttar Pradesh); Mana village (Chamoli, Uttarakhand); Pangong Lake (Leh-Ladakh, J&K); Nagvasuki Temple (Allahabad, Uttar Pradesh); ImaKeithal/market (Imphal, Manipur); Sabarimala Temple (Kerala) and Kanvashram (Uttarakhand) have been taken up under Phase III of the flagship project Swachh Iconic Places (SIP) of the Swachh Bharat Mission.

Launched in 2016, the Phase I iconic places are: Ajmer Sharif Dargah, CST Mumbai, Golden Temple, Kamakhya Temple, Maik arnika Ghat, Meenakshi Temple, Shri Mata Vaishno Devi, Shree Jagannath Temple, The Taj Mahal and Tirupati Temple.

Phase II of Swachh Iconic Places was launched in Nov 2017, and included Gangotri, Yamunotri, Mahakaleshwar Temple, Charminar, Convent and Church of St. Francis of Assissi, Kalady, Gomateswara, Baidyanath Dham, Gaya Tirth and Somnath Temple… (*Press Information Bureau, Ministry of Drinking Water & Sanitation, June 12, 2018*).

USPSTF Recommends Against ECG Screen in Low Risk Asymptomatic Adults

In a statement published June 12, 2018 in *JAMA*, the USPSTF has recommended against screening with resting or exercise ECG to prevent cardiovascular events in asymptomatic adults at low risk of cardiovascular events. (*D recommendation*).

US FDA Approves Gamified Neurorehabilitation System

The US FDA has approved a mobile neurorehabilitation therapy system 'MindMotion GO (MindMaze)' for use in patients with light- and medium-severity neurologic impairments to motivate and engage them in daily rehabilitation.

Depression Common in Patients not Able to Return to Work Following a Heart Attack

New research published in the journal *Circulation: Cardiovascular Quality and Outcomes* has shown that 90% of people who suffer a major heart attack return to work. But, those who cannot return to work or work less report poor quality-of-life, depression and moderate to extreme financial hardship, including difficulty affording medications.

Individuals with High BP Below the Threshold for Treatment Initiation also at Risk of Dementia

New findings from the long-running Whitehall II study of over 10,000 civil servants has found 50 years old who had blood pressure that was higher than normal but still below the threshold commonly used when deciding to treat the condition, were at increased risk of developing dementia in later life. The study is published June 13, 2018 in the *European Heart Journal*.

HerbList, a NIH Mobile App on Herbal Products

The National Institutes of Health's National Center for Complementary and Integrative Health has launched HerbList™, an app for research-based information about the safety and effectiveness of herbal products. It is available on the Apple App Store and Google Play Store. The app is designed to help consumers, patients, healthcare providers, and other users to quickly access information about the science of popular herbs and herbal supplements including kava, acai, ginkgo, turmeric and more than 50 others marketed for health purposes.

Avoid Aerobic Fitness Training in Early Subacute Stroke

According to results of the PHYS-STROKE study presented May 18, 2018 at the 4th European Stroke Organisation Conference (ESOC) 2018 in Gothenburg, Sweden, aerobic fitness training in the early subacute phase of stroke should be avoided. Subacute stroke was defined in the study as days 5-45 after stroke, and a Barthel index less than 65 who were unable to sit unsupported for 30 seconds.

Health Minister Launches Accelerated Plan for Elimination of Lymphatic Filariasis

The Union Health Minister Shri JP Nadda released the accelerated plan for elimination of lymphatic filariasis 2018 at the 10th meeting of Global Alliance to Eliminate Lymphatic Filariasis (GAELF).

During his inaugural address, Shri Nadda said that India as a Global leader is committed to eliminating lymphatic filariasis transmission and disease burden so that our future generations are free from lymphatic filariasis. With the concerted efforts of Government, state governments and development partners, 100 districts out of total 256 endemic districts have achieved elimination target and stopped Mass Drug Administration after successful validation by Transmission Assessment Survey (TAS) and are under post-MDA surveillance.

The Union Health Minister further said that the strategy to eliminate lymphatic filariasis in India is based on twin pillars of Mass Drug Administration once in a year to interrupt transmission i.e., no new case and to cater to the patients already afflicted with the disease with morbidity management. There is also an urgent need for total integration of different departments for mobilizing the community and to enhance awareness among the affected communities about the disease and its treatment … (*PIB, Ministry of Health and Family Welfare, June 13, 2018*)

Personalized Goals and Financial Incentives Motivate Heart Patients to Increase their Physical Activity

A new trial published June 13, 2018 in the *Journal of the American Heart Association* has observed that wearable devices combined with financial incentives and personalized goal-setting significantly increased physical activity among ischemic heart patients. Patients in the incentive group significantly increased their physical activity levels, 1,368 more steps per day and after the financial incentives were stopped in the follow up period, the incentive group still increased their physical activity by 1,154 steps per day compared to the control group.

Patients with Type 2 Diabetes at Risk of Parkinson's Disease Later in Life

People with type 2 diabetes had a 31% increased risk of developing Parkinson's disease later in life, according to a large study published in the June 13, 2018, online issue of *Neurology*. Younger patients aged 25-44 years were at greater risk. The risk was 49% higher in patients who had complications of diabetes.

Spiritual Prescriptions – Controlling the Inner Noise

KK AGGARWAL

Yoga Sutras of Patanjali define yoga as restraint of the mental states (Chapter 1.2). In the state of total restraint, the mind is devoid of any external object and is in its true self or the consciousness. To control the mind many Vedic scholars have given their own formulas.

Being in touch with one's own consciousness requires restraining of the mind, intellect and ego on one hand and the triad of rajas, tamas and satwa on the other hand. Every action leads to a memory, which in turn leads to a desire and with this a vicious cycle starts.

The mental turmoil of thoughts can be equated to the internal noise and the external desires and objects to an external noise.

The process of withdrawing from the external noise with an aim to start a journey inwards the silent field of awareness bypassing the internal noise is called pratihara by Yoga Sutras of Patanjali. It involves living in a satwik atmosphere based on the dos and don'ts learnt over a period of time or as told by the scriptures.

To control inner noise based thoughts we either need to neutralize negative thoughts by cultivating opposite thoughts or kill the origin of negative thoughts.

Not allowing thoughts to occur has been one of the strategies mentioned by the scholars. One of them has been neti–neti by Yagnayakya.

The other method is to pass through these inner thoughts and not get disturbed by it and that is what the process of meditation is. This can be equated to a situation where two people are talking in an atmosphere of loud external noise. For proper communication one will have to concentrate on each other's voice for long till the external noise ceases to disturb. In meditation, one concentrates on the object of concentration to such an extent that the noisy thoughts cease to bother or exist.

One of the ways mentioned by Adi Shankaracharya in Bhaja Govindam and by Yoga Sutras of Patanjali (Chapter 2.35) is that whenever one is surrounded by evil or negative thoughts one should meditate open the contrary thoughts. For example, if one is feeling greedy, one can think of donating something to somebody. Deepak Chopra in his book Seven Laws of Spiritual Success talks in detail about the importance of giving and sharing. He says you should never visit friends or relations empty handed. You should always carry some gift of nature, which if nothing is available can be a simple smile, compliment or a flower. By repeatedly indulging into positive behavior and thoughts, you can reduce the internal noise, which helps in making the process of meditation or conscious living a simpler one.

Washing out negative thoughts is another way mentioned by many Vedic scholars. Three minutes writing is one such exercise which anybody can do. Just before sleep anybody can do 3 minutes writing where you can write down all your emotions and then discard the paper. Another exercise is to reward or punish oneself at bed time for the activities done during the day by either patting or slapping yourself.

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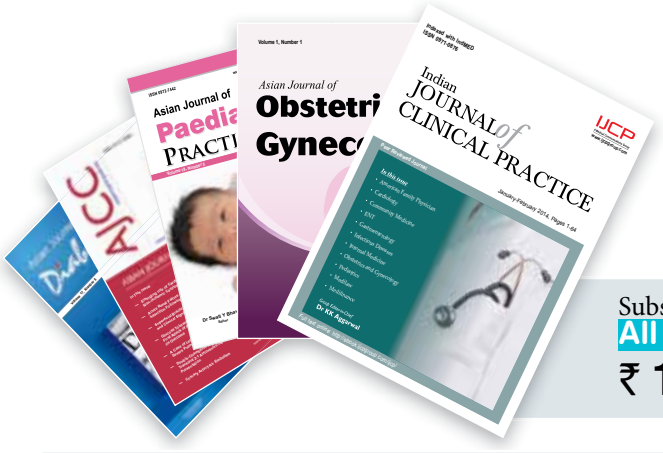

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Lighter Side of Medicine

HUMOR

JEALOUSY

The guy approached a beautiful looking woman in a mall and asked, "You know, I've lost my wife here in the mall. Can you talk to me for a couple of minutes?"

"Why?" she asks.

"Because every time I talk to a beautiful woman, my wife appears out of nowhere."

NOBEL PRIZE

A man is driving down a country road, when he spots a farmer standing in the middle of a huge field of grass. He pulls the car over to the side of the road and notices that the farmer is just standing there, doing nothing, looking at nothing.

The man gets out of the car, walks all the way out to the farmer and asks him, "Ah excuse me mister, but what are you doing?"

The farmer replies, "I'm trying to win a Nobel Prize."

"How?" asks the man, puzzled.

"Well I heard they give the Nobel Prize to people who are outstanding in their field."

A FOLLOWING PERSON

A teacher was sitting at her desk grading papers when her first-grade class came back from lunch. Alice informed the teacher, "Paul has to go to the principal's office."

"I wonder why," the teacher mused.

"Because he's a following person," Alice replied.

"A what?" the teacher asked.

"It came over the loudspeaker: 'The following persons are to go to the office.'"

STOP FOLLOWING ME!

A man was walking home alone one night when he heard a "BUMP....BUMP....BUMP..." behind him. Walking faster, he looked back, making out an image of an upright coffin banging its way down the middle of the street towards him...."BUMP...BUMP... BUMP..."

The man began to run toward his home, and the coffin bounced after him faster....faster...BUMP BUMP BUMP!

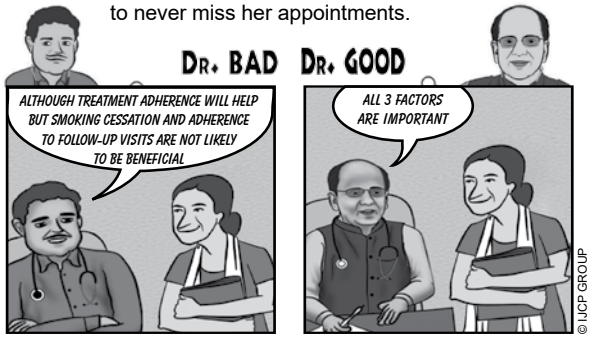
He ran up to his door, fumbled with his keys, opened the door, rushed in, and locked it behind him. The coffin crashed through his door, with the lid of the coffin clapping BUMP...BUMP...BUMP... on the heels of the terrified man. The man rushed upstairs to the bathroom and locked himself in, heart pounding.

With a CRASH, the coffin broke down the door, coming slowly toward him. The man while screaming, reached for something, anything....all he can find was a box of cough drops which he hurled at the coffin.

... and suddenly "the coffin stops!"

Dr. Good and Dr. Bad

SITUATION: A 43-year-old woman diagnosed with type 2 diabetes (high HbA1c level) on hypoglycemic drugs was a chronic smoker and was advised to quit smoking. Moreover, she was informed about the importance of treatment adherence and was asked to never miss her appointments.



LESSON: A study has identified various factors that help in determining improvement in HbA1c levels. These include baseline HbA1c, treatment adherence and attendance to visits. In addition, it showed that patients who stop smoking have greater adherence to hypoglycemic agents and those who receive therapeutic education are more likely to maintain the appointments. However, those on insulin have poorer adherence and are more likely to miss the appointments.

Endocrinol Diabetes Nutr. 2017;64(10):531-8.

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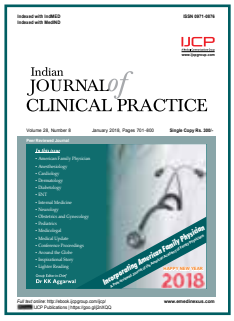

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Books

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

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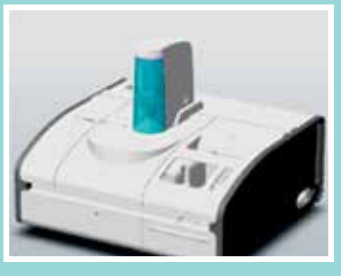

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For More Information call: 9582363695, E-mail naina.a@talkingpointcommunications.com
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