

## Medtalk with Dr KK Aggarwal

**Switching to oral antibiotics once an endocarditis patient is stable is safe** and noninferior to continued intravenous (IV) antibiotic treatment as shown in the randomized Partial Oral Treatment of Endocarditis (POET) trial.

The group getting oral tablets after at least 10 days of IV antibiotics had a 9.0% rate of all-cause mortality, unplanned cardiac surgery, embolic events or relapse of bacteremia with the primary pathogen by 6 months after completion of treatment. That rate was noninferior to the 12.1% in the IV-only antibiotic group (hazard ratio [HR] 0.72,  $p = 0.40$ ), Henning Bundgaard, MD, of Rigshospitalet in Copenhagen, reported at the European Society of Cardiology (ESC) meeting in Munich, Germany and simultaneously online in the *New England Journal of Medicine*.

**FREED trial shows no cardioprotection with febuxostat:** Febuxostat lowered high uric acid levels and reduced kidney injury in at-risk elderly patients compared with other management, but this effect did not translate to cardioprotection. The primary endpoint of the trial included death due to any cause; cerebrovascular disease; nonfatal coronary artery disease; heart failure requiring hospitalization; arteriosclerotic disease requiring treatment; renal impairment and atrial fibrillation. Febuxostat has greater renoprotective effect; however, cardiovascular protection may not be expected compared with renal protection.

**Early percutaneous coronary intervention (PCI) in non-ST-segment myocardial infarction (NSTEMI) offers no extra benefit:** A strategy of sending patients with suspected NSTEMI for invasive investigation within 12 hours of symptoms did no better than delaying their trip to the cath lab until 24 hours after event onset. During a median follow-up of 4.3 years, a composite endpoint (death from any cause, nonfatal myocardial infarction [MI], hospital admission for refractory ischemia or hospital admission for heart failure) occurred in 27.5% of the very early group versus 29.5% of the deferred group ( $p = 0.29$ ), reported Thomas Engstrom, DMSci, PhD, of the University of Copenhagen.

**Thinning of retina may be an early sign of Parkinson's disease** and thinner the retina, the greater the severity of disease. Retinal thinning was most

notable in the two inner layers of the five layers of the retina, in those with Parkinson's disease. For example, for those with Parkinson's disease, the inner most layer of the retina in one section of the eye had an average thickness of 35  $\mu\text{m}$  compared to an average thickness of 37  $\mu\text{m}$  for those who did not have the disease. In addition, the thinning of the retina corresponded with the loss of brain cells that produce dopamine (*Neurology*, August 15, 2018).

**Irbesartan may reduce rate of aortic dilation in Marfan's:** Treatment with the antihypertensive drug irbesartan is well-tolerated and slowed enlargement of the aorta in patients with Marfan syndrome as per the randomized AIMS study. At 5 years, the rate of aorta dilation among irbesartan-treated patients was 0.53 mm per year compared with 0.74 mm in those on placebo, for a 0.22 mm per-year difference (95% confidence interval [CI] 0.02-0.41,  $p = 0.03$ ) (Michael Mullen, MD, of St. Bartholomew's Hospital in London at a late-breaking trials briefing at the ESC meeting). This study supports the use of irbesartan to reduce the rate of aortic dilation in patients with Marfan syndrome.

**A drug-coated balloon (DCB) is on par with second-generation stents** for use in native vessels measuring 2-3 mm in diameter. In a 758-person, all-comers population with an indication for PCI, the paclitaxel-eluting DCB was associated with as many major adverse cardiac events at 12 months as drug-eluting stents. The endpoint of cardiac death, nonfatal MI and target vessel revascularization occurred in 7.5% of patients who received DCB compared with 7.3% of patients who received DES (BASKET-SMALL 2 study, *The Lancet*).

**US Food and Drug Administration (FDA) takes action against 21 websites illegally marketing** potentially dangerous, unapproved and misbranded versions of opioid medications, including tramadol as part of agency's effort to target illegal online sales. The warning letters issued by the FDA to each of the networks state that they must immediately stop illegally selling these products to American consumers.

In an advisory on **Electronic Nicotine Delivery Systems (ENDS)** issued on recently, the Union Health Ministry has advised States/Union Territories, to

ensure that any ENDS are not sold (including online sale), manufactured, distributed, traded, imported and advertised in their jurisdictions, in larger public health interest and in order to prevent the initiation of ENDS by nonsmokers and youth with special attention to vulnerable groups. ENDS include e-Cigarettes, Heat-Not-Burn devices, Vape, e-Sheesha, e-Nicotine Flavored Hookah and the like devices that enable nicotine delivery (*MOHFW, August 28, 2018*)

**Sexually transmitted diseases (STDs) are increasing in the US:** Researchers from the Centers for Disease Control and Prevention (CDC) have shown that STDs rates have been increasing every year since 2013 with the number of new STD diagnoses the highest ever in 2017. There were 2.3 million cases of chlamydia, gonorrhea and syphilis diagnosed in 2017, with syphilis diagnoses up by 76% and gonorrhea diagnoses up by 67% since 2013. Chlamydia was the most commonly reported condition (*National STD Prevention Conference in Washington*).

**Think before you prescribe. Consider a more convenient option when prescribing antiviral drug for herpes zoster:** Herpes zoster or shingles is a viral infection characterized by pain followed by a vesicular rash. It is caused by reactivation of the varicella zoster virus (VZV). The aim of treatment is to hasten healing, reduce the severity and duration of pain and also to reduce the chances of complications such as post-herpetic neuralgia. Timely administration of antiviral drugs - acyclovir, valacyclovir and famciclovir - decreases viral shedding and reduces the acute pain in patients with uncomplicated infection. These clinical benefits have been demonstrated in various clinical trials.

Acyclovir has to be administered five times daily, which may hinder patient compliance to prescribed treatment. This is especially of concern in the elderly, in whom herpes zoster is most prevalent.

Valacyclovir, the prodrug of acyclovir is administered thrice-daily as treatment for herpes zoster and the serum levels achieved are 3 to 5 times higher than those obtained with oral acyclovir. Famciclovir is a prodrug of penciclovir and is also administered thrice-daily as treatment for herpes zoster.

Therefore, when compliance is a concern or convenience of dosing is required, valacyclovir and famciclovir are useful and convenient alternatives to acyclovir as treatment for herpes zoster.

**No aspirin in diabetes:** In the ASCEND trial, aspirin significantly reduced the risk for serious vascular

events by 12% but also significantly increased the risk for major bleeding by 29%. No effect on gastrointestinal or any other cancer was seen. Aspirin is not needed in patients with good control of blood sugar, blood pressure and cholesterol and in nonsmokers (ESC 2018 Congress; also published simultaneously in the *New England Journal of Medicine*).

**Compounded drugs:** The US FDA has proposed excluding three substances from a list of ingredients that could be used to manufacture compounded medications in bulk for use by hospitals and doctors' offices. Compounded medications are custom-made medications that traditionally were formulated by pharmacies for specific patients. Those substances included vasopressin, bumetanide and nicardipine hydrochloride.

**Preauthorization for health insurance claims under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PMJAY)** will be completed and communicated to the hospital within 30 minutes. The preauthorization stage is a provisional sanction that would keep a check on any false claims where people avail health insurance despite them not being essential because the money will be reimbursed. The PMJAY scheme will have set guidelines for preauthorization and the process will be mandatory for 636 of the 1,350 packages offered.

**Medical apathy:** A ward boy at a government hospital in Kanpur, Uttar Pradesh was seen treating a woman with head-injury on the floor outside the emergency ward. The doctor in-charge allegedly said that he was tending to other patients at the hospital when the ward boy started to treat to the injured woman. He added that strict action will be taken against the ward boy for starting the treatment in such unhygienic condition as the floor outside the hospital. Anything more than first aid cannot be provided by unqualified persons (*TOI*).

**India's first biojet fuel flight:** SpiceJet operated India's first test flight powered by biojet fuel, according to the airline. A Bombardier Q400 aircraft, partially using biojet fuel, took off from Dehradun and landed at the airport in the national capital. The airline said it successfully operated "India's first ever biojet fuel flight". The flight was powered with a blend of 75% air turbine fuel (ATF) and 25% biojet fuel, it said. Made from *Jatropha* crop, the fuel has been developed by the CSIR-Indian Institute of Petroleum (IIP), Dehradun, SpiceJet said. Around 20 people, including officials from aviation regulator DGCA and SpiceJet, were in the test flight. The duration of the flight was around 25 minutes, according to an airline executive (*PTI, August 27, 2018*).

**FDA update:** The FDA is warning consumers not to purchase a sexual enhancement product promoted as FDA-approved and sold on social media. Deputy Secretary-general Surachoke Tangwiwat said the product labeled as "Girly Sex" had never been examined or approved for use, and customers are strongly advised not to use it.

**Is your gut inflamed?** The following may be the symptoms.

- *Food sensitivities:* If you feel bloated, gassy and just downright blah after you eat certain foods, it might be a sign that you have gut inflammation, also known as leaky gut syndrome. The most common food sensitivities are to gluten and dairy, but you can develop sensitivities to other foods as well.
- *Migraines:* There is a link between gut and brain health. Inability to concentrate, attention deficit disorder (ADD), migraine and attention deficit hyperactivity disorder (ADHD) might actually be linked to what's going on in your gut.
- *Chronic fatigue syndrome or fibromyalgia:* Gluten intolerance is a contributing factor.
- *Autoimmune diseases*
- *Persistent skin problems:* Acne, rosacea or eczema. A disruption in your gut bacteria can also allow yeast, commonly called Candida, to thrive. Candida colonizes the gut, causing it to become leaky, which in turn allows the yeast to escape via the bloodstream. Once escaped, this yeast can affect your mood, hair, nails and skin.
- *Anxiety and depression:* Inflammation in your gut can negatively affect your mood. Markers of inflammation are elevated in depressed patients.
- *Gastrointestinal issues:* Gas, bloating, diarrhea or irritable bowel syndrome it's likely that your gut is inflamed due to stress, food intolerances, infection or environmental toxins.

Remove all inflammatory foods that can damage the gut such as gluten, dairy, corn, soy and eggs, as well as toxic foods, including sugar, caffeine and alcohol. Restore the beneficial bacteria in the gut with high-quality, high-potency probiotics.

**Are pacemakers and defibrillators affected by electric cars?** Electromagnetic interference from increasingly popular electric cars presents no risk to people with cardiac implantable electronic devices (CIEDs), including pacemakers and implantable cardioverter defibrillators, new research suggests. The cross-sectional study evaluating electric cars and

electromagnetic interference with cardiac implantable electronic devices was published online April 24 in the *Annals of Internal Medicine*.

**Labeling for fluoroquinolones to include more side effects:** In a written reply to Lok Sabha, Anupriya Patel, Minister of State for Health and Family Welfare, stated that "in view of the action of US FDA on labeling changes of fluoroquinolones, the Drug Controller General of India is examining the issue in consultation with subject expert committee of CDSCO".

A recent FDA review found instances of hypoglycemic coma where users of fluoroquinolones experienced hypoglycemia. In the US, the Blood Glucose Disturbances subsection of the labeling for all systemic fluoroquinolones will be required to explicitly reflect the potential risk of coma with hypoglycemia. The FDA first added a Boxed Warning to fluoroquinolones in July 2008 for the increased risk of tendinitis and tendon rupture.

**Indoor pollution and ventilation (Dr KK Aggarwal and Mr JK Jain):** Ventilation is the process of exchanging indoor air with outdoor air to create a comfortable indoor environment for humans. Ventilation-related problems account for as much as 60% of indoor air quality problems.

Complaints related to poor ventilation may be due to high concentrations of indoor pollutants with inadequate air exchange, inadequate distribution of ventilated air and ventilation of polluted outdoor air as primary issues. Improper maintenance of heating, ventilation and air-conditioning can cause lung symptoms and Legionellosis.

In a meta-analysis of six studies comparing symptoms in workers in mechanically ventilated air-conditioned buildings with workers in naturally ventilated buildings, there was a 2- to 3-fold increase in the prevalence of work-related headaches, lethargy and upper respiratory/mucous membrane symptoms in those working in mechanically ventilated buildings. These symptoms include lethargy and headache in >50% of workers and breathlessness and chest tightness in about 20%. Other common symptoms included dry or itchy eyes and stuffy or runny nose. There is an association between empirically increased ventilation rates and decreased symptoms, including headaches, respiratory symptoms, nose and throat symptoms and skin complaints

**Four doctors booked under the Indian Penal Code (IPC) 337 and 338 but where is the grievous hurt? Missing a diagnosis is not grievous hurt:** In Pune, a baby born with deformity, missed on ultrasound.

Patient's prenatal check-ups were done at Ashwamegh Nursing Home. None of the doctors notified that the baby had a deformity. They instead said that the baby was fine and their reports, too, claimed that the child was fit. When the baby was born on November 4, 2016, the baby was born with deformities in his right leg, left hand and had no passage for urine. The father went to the then Commissioner of police Rashmi Shukla.

*Section 337 in the IPC:* Causing hurt by act endangering life or personal safety of others.—Whoever causes hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both.

*Section 338 in the IPC:* Causing grievous hurt by act endangering life or personal safety of others.—Whoever causes grievous hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine which may extend to one thousand rupees, or with both.

**Stent only in culprit vessel:** The early benefit of treating the culprit lesion only in patients with acute MI complicated by cardiogenic shock was maintained at 1 year in the CULPRIT-SHOCK trial, although with a surprising uptick in rehospitalizations for congestive heart failure. Compared with immediate multivessel PCI, culprit-lesion-only PCI with the possibility for staged revascularization of nonculprit lesions lowered the risk for the primary composite endpoint of death from any cause or renal replacement therapy by 13% at 1 year ( $p = 0.048$ ).

**Go for CT angio in cases of stable angina:** Adding CT coronary angiography (CTCA) to standard care in patients with stable chest pain significantly reduces mortality rates from coronary heart disease (CHD) or nonfatal MI after 5 years, without increasing coronary intervention rates as per Scottish Computed Tomography of the HEART Trial (SCOT-HEART) presented at the ESC Congress 2018 in Munich, Germany and published simultaneously August 25 in the *New England Journal of Medicine*. Performing CTCA during diagnostic testing was associated with a 41% reduction in the combined primary endpoint: rates of death from CHD and nonfatal MI.

**Study raises question on the role of aspirin in primary prevention:** In the Aspirin to Reduce Risk

of Initial Vascular Events (ARRIVE) trial, aspirin at a daily dose of 100 mg was not seen to reduce the long-term risk for cardiovascular or cerebrovascular events in a trial that randomly assigned more than 12,000 nondiabetic adults with multiple cardiovascular (CV) risk factors but no history of CV events. Nor was the risk for stroke reduced. But daily aspirin was associated with more gastrointestinal bleeding. The ARRIVE trial was initiated a decade ago to find out answers to long-standing questions about whether aspirin is cardioprotective in a primary prevention setting, in this case in patients thought to be at moderate CV risk.

**How should doctors discuss treatment options with older kidney failure patients?** A study appearing in published online July 26, 2018 in the *Clinical Journal of the American Society of Nephrology* identified 4 different approaches to discussing the option of dialysis versus conservative management for older patients with kidney failure for decision-making: Paternalist, informative (patient-led), interpretive (with doctors as guides steering patients towards an optional treatment) and institutionalist (guided by institutional culture and incentives).

Five themes characterized differences between these approaches regarding how nephrologists prioritized the following:

- Patient autonomy
- Patient engagement and deliberation (disclosing all options, presenting options neutrally, eliciting patient values, explicit treatment recommendation)
- The influence of institutional norm
- The importance of clinical outcomes (such as survival, dialysis initiation)
- Role of the physician (educating patients, making decisions, pursuing active therapies, managing symptoms).

**Two arteries graft better than one artery and one vein, says ART study:** After 10 years of follow-up, outcomes were better in patients receiving two arterial grafts in performing coronary artery bypass graft (CABG) surgery than in those receiving a combination of artery and veins as per Arterial Revascularization Trial (ART) study. In the primary endpoint of the study (10-year mortality), 329 CABG patients who were treated randomized to the single arterial graft died during the study period compared with 315 patients who died who were originally assigned to receive two arterial grafts (HR 0.96, 95% CI 0.82-1.12), reported David Taggart, MD, PhD, of the University of Oxford in the United Kingdom.

**Intra-arterial phenargan is a known complication in 2 in 57,575 cases:** In a 2001 case, Delhi's VIMHANS Hospital and a doctor have been asked to pay Rs. 20 lakh as compensation on grounds of treatment offered to a 12-year-old boy, which led to the amputation of four fingers of his right hand on grounds of giving an intra-arterial injection of phenargan instead of an IV route.

**What should have been the argument?** According to the package insert, aspiration of dark blood does not preclude intra-arterial placement of the needle because blood can become discolored upon contact with promethazine.

**Review of literature:** Promethazine (phenargan) injection is a commonly used product that possesses antihistamine, sedative, antimotion sickness and antiemetic effects. The drug is also a known vesicant which is highly caustic to the intima of blood vessels and surrounding tissue.

Formulated with phenol, promethazine has a pH between 4 and 5.5. Although deep intramuscular injection into a large muscle is the preferred parenteral route of administration, product labeling states that the drug may be given by slow IV push, which is how it is typically given in most hospitals.

However, due to the frequency of severe, tragic, local injuries after infiltration or inadvertent intra-arterial injection, Institute of Safe Medical Practices recommends that the FDA re-examine the product labeling and consider eliminating the IV route of administration.

Severe tissue damage can occur regardless of the route of parenteral administration, although IV and inadvertent intra-arterial or subcutaneous administration results in more significant complications, including: burning, erythema, pain, swelling, severe spasm of vessels, thrombophlebitis, venous thrombosis, phlebitis, nerve damage, paralysis, abscess, tissue necrosis and gangrene. Sometimes surgical intervention has been required, including fasciotomy, skin graft and even amputation.

The true extent of this problem may be unknown. However, scores of reports suggest that patient harm may be occurring more frequently than recognized.

According to the package insert, "Proper IV administration of this product is well-tolerated, but use of this route is not without some hazards." To reduce the risk of these hazards, manufacturer labeling recommends to: give the drug in concentrations no >25 mg/mL; administer the drug at a rate no

>25 mg/min; inject the drug through the tubing of an infusion set that is running and known to be functioning satisfactorily and to stop the injection immediately if the patient reports burning to evaluate possible arterial placement or perivascular extravasation.

#### How to use

- ⦿ Since 25 mg/mL is the highest concentration of promethazine that can be given IV, stock only this concentration (not the 50 mg/mL concentration).
- ⦿ Consider 6.25-12.5 mg of promethazine as the starting IV dose, especially for elderly patients.
- ⦿ Dilute the drug in 10-20 mL of normal saline if it will be administered via a running IV, or prepare the medication in minibags containing normal saline. Extravasation can also be recognized more quickly when promethazine is diluted than if the drug is given in a smaller volume.
- ⦿ Give the medication only through a large-bore vein (preferably via a central venous access site, but absolutely no hand or wrist veins). Check patency of the access site before administration. *Note: according to the package insert, aspiration of dark blood does not preclude intra-arterial placement of the needle because blood can become discolored upon contact with promethazine. Use of syringes with rigid plungers or small bore needles might obscure typical arterial backflow if this is relied upon alone.*
- ⦿ Administer IV promethazine through a running IV line at the port furthest from the patient's vein.
- ⦿ Administer IV promethazine over 10-15 minutes.
- ⦿ Before administration of the drug, tell patients to let you know immediately if burning or pain occurs during or after the injection.
- ⦿ Take consent.
- ⦿ Build an alert that the drug is a vesicant and should be diluted and administered slowly through a running IV.
- ⦿ Consider safer alternatives like ondansetron.

#### Some cases

- ⦿ Necrosis caused by intra-arterial injection of promethazine: *case report:* Promethazine injections have led to necrosis and gangrene of the distal upper extremity when inadvertently injected into an artery. There have been few case reports of this alarming complication in the literature. We report on 2 cases of intra-arterial promethazine injection that led to amputation (Foret AL, et al. *J Hand Surg Am.* 2009;34(5):919-23).

- Accidental intra-arterial injection of promethazine HCI during general anesthesia: Report of a case (Mostafavi H. *Anesthesiology*. 1971;35:645).
- Accidental intra-arterial injection: A case report, new treatment modalities, and a review of the literature (Keene JR, et al. *J Oral Maxillofac Surg*. 2006;64(6):965-8).
- An unusual adverse event with the use of IV bolus of promethazine (phenergan): The earlier used sedatives like promethazine, pethidine and pentazocine (fortwin) are not commonly used these days but at times they are used especially in periphery for postoperative sedation and in gynecological surgeries and wards. We hereby report an unusual adverse event associated with the use of IV bolus of promethazine. With this case report we want to highlight that if promethazine is to be used for any purpose it should be given preferably intramuscular and if given IV, should be diluted and given slowly in a good running cannula. (However, patient in spite of receiving 20 mg pethidine was anxious. For that 12.5 mg of promethazine was given as slow IV push. Same dose of promethazine is repeated after 1 hour intraoperatively. Rest of the intraoperative period was uneventful. No other drug was injected after promethazine. In the postoperative period, a bluish discoloration was noted on the dorsum of the hand in which the cannula was secured. And on touch the dorsum of the hand was cold) (Singh A, et al. *Int J Res Med Sci*. 2018;6(1):347-8).

**The Delhi High Court has ruled that unsuccessful sterilization operation does not mean medical negligence, if the patient and her relatives were informed about chances of its failure:** In the matter titled as “**Lok Nayak Hospital versus Prema, RFA No. 56/2006**” the Hon’ble High Court of Delhi vide judgment dated 06.08.2018 has held that medical negligence is not proved in case of unsuccessful sterilization operation, if the doctor/hospital has duly got the consent form and other forms signed by the patient and counter signed by her relatives in which it was specifically mentioned by the doctor/hospital that the operation need not be always successful and there are always some chances of failure, and if the operation is not successful the hospital or the concerned Doctor will not be held responsible.

#### **Facts of the Case**

The respondent/plaintiff filed the subject suit by pleading that she was operated upon on 15.5.2001 in

the appellant’s/defendant’s hospital by the concerned doctor namely Dr Deepa. Respondent/plaintiff pleaded that she took all postoperative care including taking all prescribed medicines as also precaution but after a few months of the operation, she suspected that she had conceived and therefore when she went to the Physical Health Centre at Dayalpur, Delhi, on 21.10.2002 and has got herself examined on 23.10.2002, it was discovered that respondent/plaintiff was pregnant as the tubectomy operation performed on her had failed. Respondent/plaintiff pleaded that Dr. Deepa (Defendant No. 1 in the suit) fell short in taking reasonable and due care while performing the sterilization operation, resulting in defect and deficiency in the operation, therefore respondent/plaintiff became pregnant again to have her 7th child. After serving a legal notice/Ex. P-3 and which was replied to by the appellant/defendant no. 2 vide reply dated 24.1.2003, Ex. P-2, the subject suit was filed.

The suit was contested by the appellant/defendant and it was denied that there was any negligence while performing the sterilization operation. The appellant/defendant pleaded that the respondent/plaintiff before performing her operation had signed two forms on 14.5.2001, and which forms were also counter-signed by the sister-in-law/Bhabhi of the respondent/plaintiff namely Ms. Suman, and that in these forms Ex. PW-1/D-1 and Ex. PW-1/D-2, it was specifically mentioned by the appellant/defendant that the operation need not be always successful and there are always some chances of failure, and if the operation is not successful the appellant/defendant or the concerned Doctor will not be held responsible. The contents of these documents were explained to the respondent/plaintiff in Hindi in the presence of her sister-in-law/Bhabhi, namely Ms. Suman. It was denied that the appellant’s/defendant’s doctors had given an assurance that the operation would be 100% successful. Appellant/defendant contended that the respondent/plaintiff was herself responsible because she could have got done the abortion in time, but she did not get such abortion done. The suit was therefore prayed to be dismissed.

The only relevant issue was issue no. 1 and the trial court has decided this issue in favor the respondent/plaintiff. Trial court has held that the respondent/plaintiff had not signed the forms Ex. PW1/D-1 and Ex. PW-1/D-2 inasmuch as she has specifically denied the signing of these forms by her and her sister-in-law/Bhabhi/Ms. Suman, and consequently, the trial court believed such stand of the respondent/plaintiff. Trial court has also held that since the concerned doctor namely Dr Deepa, defendant no. 1 in the suit, did not depose and

adverse inference has to be drawn against the appellant/defendant. Trial court has also observed that the signing of the forms Ex. PW1/D-1 and Ex. PW-1/D-2 by the respondent/plaintiff were not believable because the forms are dated 14.5.2001 and the operation was conducted on 15.5.2001. Trial court therefore held that the appellant/defendant was guilty of negligence in performing tubectomy operation which resulted in the birth of the respondent's/plaintiff's 7th child, and therefore the suit was decreed for the sum of Rs. 2,20,000/-

#### *Issue before the Hon'ble High Court*

The only issue to be decided by the Hon'ble High Court was whether the trial court has rightly held that the appellant/defendant was guilty of negligence on account of the sterilization operation conducted on the respondent/plaintiff being unsuccessful.

#### *Judgment of the Hon'ble High Court*

8. Firstly, it is to be noted that the only allegation of negligence alleged by the respondent/plaintiff against the appellant/defendant is that the tubectomy/sterilization operation failed. Since medically there is never a 100% chance of success in sterilization operations, the mere fact that the operation was not successful, that by itself cannot be a reason to hold the appellant/defendant and its doctors guilty of negligence. This aspect is no longer *res integra* and is so held by a Division Bench of this Court in the case of *Smt. Madhubala Vs. Govt. of NCT of Delhi*, 118 (2005) DLT 515 (DB).

13. At this stage, I may note that the trial court has arrived at a completely perverse and illegal finding that the forms Ex. PW-1/D-1 and Ex. PW-1/D-2 do not bear the signatures of the respondent/plaintiff and her sister-in-law/Bhabhi/Ms. Suman and inasmuch simple denial by the respondent/plaintiff of her thumb impression on forms Ex. PW-1/D-1 and Ex. PW-1/D-2 and the signatures of her sister-in-law/Bhabhi/Ms. Suman is not enough because of various reasons. Firstly, signing of such forms is always and invariably got done by any private or public hospital before a tubectomy/sterilization operation. Secondly, the documents Ex. PW1/D-1 and Ex. PW-1/D-2 contain the thumb impressions of the respondent/plaintiff and whereas a signature can be forged but thumb impressions can never be forged. Thirdly, admittedly, the name of the sister-in-law/Bhabhi of the respondent/plaintiff is Ms. Suman and how would the appellant/defendant have known the name of the sister-in-law/Bhabhi of the respondent/plaintiff

as Ms. Suman and who has signed as her full name Suman on the two forms. Trial court therefore ought not to have believed the self-serving denial of the respondent/plaintiff of her thumb impression and signatures of her sister-in-law/Bhabhi/Ms. Suman on the forms Ex. PW-1/D-1 and Ex. PW-1/D-2.

14. In my opinion, the trial court has also unnecessarily laid emphasis on the defendant no. 1/Dr Deepa in the suit for not appearing and deposing and therefore adverse inference has been drawn against the appellant/defendant, inasmuch as in my opinion there was no need of the defendant no. 1/Dr Deepa to appear and depose inasmuch there was no specific case of negligence against the defendant no. 1/Dr Deepa except that the operation was unsuccessful. Once the forms Ex. PW-1/D-1 and Ex. PW-1/D-2 are proved it cannot be argued by the respondent/plaintiff that there was 100% assurance given of the operation of being successful and which medically also is never 100% success.

#### *Advisory*

*Dr KK Aggarwal and Ira Gupta*

Before performing tubectomy/sterilization operation, every doctor and hospital should specifically inform the patient and her relatives that medically the said operation is not 100% successful. There should be an informed consent form, which specifically mentions that sterilization operations are not 100% successful and the same should be signed by the patient and her relatives (with their name). The thumb impressions of the patient and her relatives should also be taken as the same cannot be forged along with their signatures.

**Alcohol consumption is responsible for 2.8 million deaths per year across the globe**, with cancer the leading cause of alcohol-related death among people aged 50 years and older. There is no safe level of alcohol consumption. The findings come from the latest version of the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD), which analyzed data on 28 million people from 195 countries to estimate the prevalence of alcohol consumption, the amounts consumed, and the associated harms and published in the *Lancet* on August 23.

**Rivaroxaban dosages for primary venous thromboembolism (VTE) prevention are lower (7.5 mg)** than the currently recommended levels for reducing the post-discharge risk for recurrent VTE based on the EINSTEIN CHOICE trial.

A monoclonal antibody, previously known by its chemical name lanadelumab, has been FDA

approved to treat patients with types I and II hereditary angioedema, a disease that affects about 1 in 50,000.

**Faulty J&J hip implant, patients to get compensation:**

The Union health ministry will establish committees at the Central and State levels to track and compensate patients who received a faulty artificial hip implant that was recalled worldwide by the manufacturer Johnson & Johnson (J&J), in 2010. Close to 4,700 people with damaged hip joints in India received the implant before 2010, when it was recalled, of which only 1,080 were tracked and compensated. Of them, 275 underwent revision surgeries and the remaining are being closely monitored by their surgeons for side effects.

Following complaints from patients, the Health Ministry set up an 11-member committee on February 7, 2017, to investigate patient complaints of adverse events against J&J's metal-on-metal Articular Surface Replacement (ASR) hip implant devices - XL Acetabular Hip System and Hip Resurfacing System. The committee was chaired by Dr Arun K Agarwal, former Dean of Maulana Azad Medical College, and submitted its report on February 19, 2018. It said specialists must assess cases individually for treatment and compensation of at least Rs. 20 lakh. Metal-on-metal hip implants have been largely discontinued because of the associated complications. With other implants, the revision surgery rate would be around 3-5%, but with this particular brand, it was a higher 10-12% (HT).

*In view of extraordinary rise in prices of raw materials pushing up formulation prices significantly, pharmaceutical industry associations have urged the Central government to increase ceiling prices of drugs under National List of Essential Medicines (NLEM).*

**Medical device margins set to be capped at 65% in India:**

Prime Minister Narendra Modi is likely to accept government think tank NITI Aayog's recommendation to cap trade margin at 65% for medical devices. According to NITI Aayog's formula, the MRP of a device will be decided by adding the trade margin to the price at the first point of sale (stockist). The trade margin is the difference between the price at which the manufacturers/importers sell to stockists and the price charged to consumers.

This will give flexibility to the company to make any amount of margin before they bill it to the stockist. As per the companies many expenditures are incurred by the importing companies, including clinical education on deployment, and therefore trade margins should start from the first point of sale that is the stockist. High

margins with the company will not be able to correct the so-called companies' distribution of money to the end users and the hospitals.

**The National Diabetes Education Program (NDEP) has revised its "Guiding Principles" for management of diabetes and prediabetes:**

Supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and CDC, though not official guidelines, it emphasizes the importance of diabetes self-management education and support, and of providing patient-centered care using shared decision-making and individualized care and include 10 guiding principles. A new guiding principle 6 "Address Overweight and Obesity in the Management of Diabetes" has been also added to the existing guiding principles.

**Always wear your seat belt when you drive, the prime minister does:**

Press Information Bureau has shared an inspiring video on Twitter to promote road safety awareness, which shows Prime Minister Narendra Modi putting on his seat belt as soon as he enters his car.

**A1c measurement during the first trimester of pregnancy**

may aid in early detection of women at risk for gestational diabetes as per a study in August 16 in *Scientific Reports*. Among participants, the risk for gestational diabetes increased linearly with first-trimester A1c. Also, the addition of first-trimester A1c to conventional risk factors enhanced gestational diabetes predictive capability.

**Noninvasive brain stimulation technology delivered during sleep may improve memory:**

Investigators found closed-loop transcranial alternating-current stimulation delivered overnight to augment endogenous slow-wave oscillations in humans improves generalized memory. The study was published online July 23, 2018 in the *Journal of Neuroscience*.

**Prehabilitation prior to cardiac surgery**

can improve postoperative outcomes for frail older adults. A three-pronged approach called NEW, a component of the enhanced recovery protocols targets nutritional status (N), exercise capacity (E) and worry reduction (W) to support the growing number of older patients undergoing complex cardiac procedures. The article was published in the July 2018 issue of the *Canadian Journal of Cardiology*.

A new study at the McMaster University, Ontario, Canada has shown that **an average salt consumption, between one and half teaspoons daily, will not constitute a health risk**. But it adds that a quantity that exceeds 5 g, or 2½, of salt may be quite dangerous



for the heart. It also showed that even for those who consumed too much salt, the health risk would be eliminated if people improved the quality of their diets by eating fruits, vegetables, dairy foods, potatoes and other potassium-rich foods.

**Congress MP Shashi Tharoor has suggested** that the Kerala government request the World Health Organization (WHO) to supply 2 million anti-cholera vaccines to minimize the risk of water-borne diseases in the flood-ravaged state.

**Two new user friendly initiatives launched by the ESIC** (Employees' State Insurance Corporation) "IVR (Interactive Voice Response)/Help Desk" for ESIC Toll Free No. - 1XXX-XX-2526 and production of "seven Audio-Visual clips on ESI Benefits" aim to empower insured persons and their beneficiaries and create awareness among other stakeholder, as per a press release from Ministry of Labour & Employment. The audiovisuals are available on You Tube (ESIC HQ You Tube Channel).

**Breath tests to detect cancer have a relatively high level of sensitivity and specificity** as per a new meta-analysis of early trials of the concept published online August 16 in *JAMA Oncology*. A breath test detects and quantifies preidentified, named volatile organic compounds (VOCs) within exhaled breath in order to diagnose cancer, explain the study authors, led by George Hanna, MD, PhD, a surgeon at the Imperial College London in the United Kingdom. The concept is already in use in other areas of clinical practice, including breathalyser devices for ethanol detection, carbon 13 urea breath testing for *Helicobacter pylori* and exhaled nitric oxide testing in asthma.

**Adding blood sugar and estimated glomerular filtration rate (eGFR) to high-sensitivity cardiac troponin** level testing in the emergency department is more sensitive and specific for determining risk for MI and death in patients with MI symptoms than hs-cTn testing alone as per Peter A. Kavsak, PhD, an associate professor from the Department of Pathology and Molecular Medicine at McMaster University in Hamilton, Ontario, Canada in August 20 issue of *Canadian Medical Association Journal*. Elevated blood sugar in patients with ST-segment elevation MI can indicate the patient is hemodynamically unstable, has a larger infarct size, and has increased risk for death within 30 days. Also, eGFR independently predicts major adverse cardiac outcomes in those with acute coronary syndrome.

The Supreme Court of India has said that the **right to healthcare prevails over right to voluntary**

**retirement by doctors** in the larger public interest as medical services are part and parcel of right to life itself. Right to retire as a fundamental right can't be supreme then the right to life, said the bench of Justice Arun Mishra and Justice S. Abdul Nazeer in their judgment pronounced recently. "When services are required, denial of voluntary retirement is permissible under the rules applicable in the State of Uttar Pradesh", the court said.

**Moderation and variety are the answer when it comes to the use of edible oils:** But when it comes to coconut oil it has been called as a "pure poison". Last year, the American Heart Association (AHA) released a report advising against using coconut oil. Existing data showed the fat increased bad cholesterol in seven out of seven trials, just as butter, beef fat and palm oil. The fat in coconut oil is far more saturated (82%) than butter (63%) and beef fat (50%). Coconut oil is almost all saturated fat and if consumed alongside a diet high in saturated fats, you may be consuming well over the government recommended 20 g/day for women and 30 g/day for men. People are turning to coconuts as a guilt-free fat amongst a trend of low carb/high fat diets.

United we stand, divided we fall is a phrase well-known to us all. The power of unity is tremendous. Emphasizing this, Dr. Vera Luiza da Costa e Silva, the Head of the WHO Framework Convention on Tobacco Control Secretariat has said, "**Combat against devastating effects of tobacco can only be won 'if the UN stands united'**". United Nations agencies must join forces at the policy level and refuse interference from tobacco companies in their programs, so the destructive impact of tobacco can be effectively addressed and lives can be saved. According to a report by WHO and the UN Development Programme (UNDP) "The Who Framework Convention on Tobacco Control An Accelerator for Sustainable Development", it is estimated that up to 1 billion people could die from tobacco-related diseases this century. Currently, over 7 million people die every year due to tobacco use. Tobacco costs, the global economy over a trillion dollars annually in medical expenses and lost productivity. It also has environmental impacts- deforestation and soil degradation for tobacco cultures, as well as water and soil pollution from cigarette littering.

**Back to the basics: Hand wash is the best:** *Clostridium difficile* is a rising problem and is most often found in hospitals. It is responsible for 20% of antibiotic-associated diarrhea and causes 29,000 annual deaths in

the US alone. *C. difficile* survives alcohol-based sanitizers because of its hard shell. The only way to get rid of it is vigorous hand washing using soap, which flushes the bacteria down the drain.

**“United to end tuberculosis: an urgent global response to a global epidemic”** The first high-level UN meeting on TB seeks to accelerate the end of the disease. Heads of State will gather in New York on 26 September this year at the United Nations General Assembly first-ever high-level meeting on TB to accelerate efforts in ending TB and reach all affected people with prevention and care. The theme of the meeting is “United to end tuberculosis: an urgent global response to a global epidemic”.

It follows on from a very successful Ministerial Conference on Ending TB in Moscow on 16-17 November, 2017 which resulted in high-level commitments from Ministers and other leaders from 120 countries to accelerate progress to end TB.

**National Vector Borne Disease Control Programme (NVBDCP): Observe one dry day in a week:** NVBDCP has appealed to the public to observe “one dry day in a week where water in all the containers around the house like flower pot bases, empty vessels, coolers, tyres, buckets, etc. are emptied out into a dry area because dengue mosquitoes breed in stagnant clean water and the eggs hatch in a week. All water filled vessels and tanks should be kept tightly covered and any rubbish lying around like plastic cups, old containers, tyres, coconut shells, etc. should be thrown out and check around the compound every week.

NVBDCP asked the people to ensure that that everybody sleeps under mosquito nets, especially pregnant women and children, both during the day and night.

**Tobacco Quit-line on packs from 1st September:** The Union Health and Family Welfare Ministry has issued a notification to print ‘Quit-line’ number on tobacco packets. The notification has been issued on April 03. Along with the Quit-line – a helpline number to quit smoking, the government has asked the tobacco manufacturers to put two set of pictorial warnings on the tobacco products as well.

- ⦿ The Health Ministry has amended the “Cigarettes and other Tobacco Products (Packaging and Labelling) Rules, 2008”
- ⦿ During the rotation period, there shall be two images of specified health warning which shall appear consecutively on the package with an interregnum period of 12 months.

- ⦿ ‘Tobacco causes cancer’ and the word ‘Tobacco causes painful death’ shall appear in white font color on a red background.
- ⦿ The helpline number reading – ‘Quit today call 1800-11-2356’ shall appear in white font colour on a black background.

**Global Adult Tobacco Survey (GATS 2) Findings**

- ⦿ Prevalence of tobacco use has reduced by 6% points.
- ⦿ The number of tobacco users has reduced by about 81 lakhs.
- ⦿ 28.6% of adults aged between 15 and above (26.7 crore) use tobacco in any form.
- ⦿ 19.9 crore adults in rural areas and 6.8 crore adults in urban areas use tobacco.
- ⦿ Every fifth adult (19.9 crore) uses smokeless tobacco and every tenth adult (10.0 crore) uses smokeless tobacco.
- ⦿ 3.2 crore adults resort to dual use of tobacco.
- ⦿ 19.0% of men, 2.0% of women and 10.7% (99.5 million) of all adults currently smoke tobacco.
- ⦿ 29.6% of men, 12.8% of women and 21.4% (199.4 million) of all adults currently use smokeless tobacco.
- ⦿ 42.4% of men, 14.2% of women and 28.6% (266.8 million) of all adults currently use tobacco (smoked and/or smokeless tobacco).
- ⦿ 55.4% of current smokers are planning or thinking of quitting smoking and 49.6% of current smokeless tobacco users are planning or thinking of quitting smokeless tobacco use.
- ⦿ 48.8% of current smokers were advised by healthcare provider to quit smoking and 31.7% of current smokeless tobacco users were advised by healthcare provider to quit use of smokeless tobacco.

**Prince Aly Khan Hospital's Health Service Aga Khan survey of schoolgoing children on cigarette smoking**

- ⦿ 27% children are addicted to cigarette smoking.
- ⦿ 6.3% children consume hookah.
- ⦿ 24% children are addicted to tobacco products.
- ⦿ 9% children smoke cigarette currently.
- ⦿ 16% children mix tobacco in supari and consume it.
- ⦿ 71% boys and 20% of girls are addicted to smoking.
- ⦿ 54% children of class 10 smoke.
- ⦿ 94% were aware of the consequences. Yet still, continue to smoke.

(Source: *mymedicalmantra.com*, December 2017)