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Insomnia and Risk of Stroke

People who find it difficult to fall asleep or stay asleep may be at higher risk of having a stroke, according to a study of over 31,000 people published in the journal *Neurology*.¹

Researchers from the Virginia Commonwealth University, School of Medicine, Richmond in Virginia set out to examine the association between insomnia and incident stroke. For this, they sourced data of 31,126 individuals with an average age of 61 years from the Health and Retirement Study between 2002 and 2020. Fifty-seven percent were female. None of the selected participants had ever suffered a stroke. Symptoms of insomnia like difficulty falling asleep, waking up often during the night, waking up too early and nonrestorative sleep (i.e., not feeling rested in the morning) were self-reported through a questionnaire. The scores ranged from 0 to 8; higher scores indicated more severe insomnia.

Over a follow-up period of 9 years, 2,101 cases of stroke occurred. After adjusting for other risk factors for stroke such as smoking, alcohol and sedentary life, the risk of stroke was increased 16% in people with 1 to 4 symptoms of insomnia compared to those who did not have insomnia with hazard ratio (HR) of 1.16.

A total of 19,149 participants reported 1 to 4 symptoms; of these, 1,300 had a stroke. There were 6,282 people without any symptoms of insomnia; among these, 365 had a stroke. Those who had 5 to 8 symptoms of

insomnia were at a 51% increased risk of stroke with a HR of 1.51. Out of the 5,695 subjects with 5 to 8 symptoms, 436 developed a stroke.

Subjects younger than 50 years were nearly 4 times more likely to experience a stroke (HR 3.84) compared to those older than 50 years (HR 1.38) when participants with 5 to 8 symptoms were compared with those without any symptoms of insomnia. Of the 458 subjects younger than 50 years having 5 to 8 symptoms, 27 had a stroke. And, out of the 654 people aged ≥50 years with the same number of symptoms, 33 had a stroke.

This study demonstrates the link between insomnia and risk of stroke; however, it does not establish causality. Greater the number of insomnia symptoms, higher was the risk indicating a dose-response relationship. Individuals younger than 50 years were particularly at risk. This risk was mediated by comorbid diseases such as hypertension, heart disease, diabetes and depression. Physicians should be aware of this association and assess their patients for insomnia. Management of insomnia with medications or psychotherapy may help prevent stroke.

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Ayurveda and Endocrinology: Common Ground, Common Goals

ABSTRACT

In this editorial, we explore Ayurvedic concepts of health, and analyze how they relate to modern endocrinology. We expand our discussions to inclusion of other South Asian schools of medicine, as well as philosophical and metaphysical models of South Asian thought. A detailed assessment suggests that Ayurveda is based upon sound endocrine and metabolic foundation, which can serve as a framework for person-centered, integrative management of modern pandemics such as diabetes, obesity and other endocrine disorders. We call for awareness and understanding of the common ground, as well as common goals of Ayurveda and modern endocrinology.

Keywords: Holistic health, integrated health, integrative health, mind-body medicine, one health, person-centered medicine

Ayurveda is an ancient discipline, with a well-structured framework that allows for scientific classification and scientific study of disease and disorders. It is a tribute to their clinical acumen and insightful genius that in spite of nonavailability of modern investigative and diagnostic tools, Ayurvedic physicians of the past were able to craft a rational rubric for medical management.¹

Endocrinology is a young branch of science with a 'modern' history that goes back to just a century. The discovery of hormones, and the methods of measuring them, are relatively recent developments in the evolution of medicine. In this opinion piece, we explore similarities and contrasts between the description of endocrine glands, hormones and their disorders in Ayurveda and modern medicine.

OF CHAKRAS AND GLANDS

Traditional Indian philosophy describes a series of 'chakras' (or wheels), located at specific levels of the body's meridian. These chakras have been equated to the main glands of the body. It must be noted, however,

that the chakra system has not been mentioned in classic Ayurvedic texts. But they have rather been a part of religious and quasi-religious texts, related to various Oriental religions, including Buddhism and Hinduism.

Chakras were correlated with the endocrine system for the first time by Cajzoran Ali, an American yoga therapist, in 1928. Further discussion and dialogue took place in the mid-20th century. The book "Bodymind: A Synthesis of Eastern and Western approaches to Self-awareness, Health and Growth", and a journal article, "Bodymind and the Evolution to Cosmic Consciousness" were published in 1977.²

The chakras do bear uncanny similarity with the endocrine glands, as described in modern biology. Multiple books and treatises have been written on these connections, without any authentic Ayurvedic basis.^{3,4} It is pertinent to note that most of the modern equivalents of the 'chakras', and their functions, have been discovered after the first correlation by Cajzoran Ali. Ongoing advance means that we still continue to find newer hormones, and decipher more functions of existing ones.

Table 1 lists the major chakras and their glandular equivalents. This list is representative, and lay literature throws up differing versions of the same. Some lists include the pineal gland, which has been clearly identified in Indian texts as the 'third eye' (teesri aankh). The pineal gland secretes the hormone melatonin.⁵ Though considered vestigial by earlier endocrinologists, researchers are now unraveling various functions of this organ.

OF OJAS, TEJAS, PRANA AND HORMONES

Ayurveda does not use the word 'hormone', but then, neither did modern medicine till about a century ago.⁶ However, it lists three forms of subtle energy: *prana*, *tejas* and *ojas*. *Ojas*, loosely translated as radiance, vigor or essence, is what influences the physical, psychosocial and spiritual health of an individual. Ayurveda views *ojas* as a quantifiable liquid, which cannot be seen with the naked eye, and which cannot be compared to any other body tissue. *Charaka* states that *ojas* dwells in the heart, and is predominantly white, yellowish and red. Earlier commentators have thought of *ojas* as white blood cells or immune factors.⁷ Apart from *ojas*, two other subtle forms of energy have been described in Ayurveda. These are *prana* and *tejas*. *Tejas* is defined as 'inner radiance' or 'fire of the mind', while *prana* means breath or essence of life.⁸

Ojas, *tejas* and *prana*, we feel, can be likened to hormones of the human body. Present in minute quantities, hormones circulate in the vascular system. *Ojas* is thought to reside in the heart, and we now know that the heart is both a source of as well as a target of hormones. Loss of *ojas* has been described in Ayurveda.⁷ The description of *ojo visramsya*, *oja vyapth* and *ojokshaya* is similar to that of progressively worsening Addisonian crisis, myxedema coma or hyponatremia.

The concept of *ojas* includes mind-body medicine, and this is true for hormones as well: the mind (hypothalamus) secretes endocrine molecules and responds to changes in their concentration as well.

Table 1. Endocrine Glands and Chakras

Sahasra	Thousand petalled	Hypothalamus
Ajna/Agnya	Command	Pituitary
Vishuddha	Purest	Thyroid
Anahita	Unstruck	Heart
Manipura	Jewel city	Navel/Adrenals
Svadhishthana	Self-established	Gonads
Muladhara	Root of spine	? Autonomic system

OF TEJAS AND PHEROMONES

Tejas, i.e., 'inner radiance' or 'fire of the mind' may be likened to pheromones, as well as to the adrenergic system. *Tejas* not only imparts glow, luster, courage and fearlessness, but also creates an aura which attracts (or repels) other persons.

Pheromones are chemicals which can act like hormones outside the person's body. While Ayurveda speaks of a subtle body or astral body (*sukshma sharira*), apart from the physical body (*sthula sharira*).⁹ Tibetan and Bhutanese traditional medicine clearly mention six types of body, including astral, cosmic and bliss bodies. It is possible that the functionality of pheromones, which has not been elucidated completely by modern science till date, contributes to these states, as well as the rainbow body described in Tibetan philosophy. These schools of health also speak of the human as a microcosm, existing in an environmental macrocosm. The modern concept of 'one health', which integrates human, animal and environmental health is similar to the microcosm-macrocosm analogy.¹⁰ We take this opportunity to add a third aspect, the mesocosm, to this analogy. We define the mesocosm as that part of the immediate environment, which can be modulated directly by an individual being. Pheromones may be the connection between the microcosmic and mesocosmic spheres of existence.

OF DOSHAS AND METABOLISM

Ayurvedic physiology is based upon the equilibrium of three doshas, *vata*, *pitta* and *kapha*.¹¹ Disequilibrium or imbalance leads to disease. An exactly similar concept exists in modern medicine. Unregulated *vata* is a state of catabolism; excess *kapha* means maladaptive anabolism, and *pitta* represents balanced 'eubolism'. This framework can be used as an approach to various endocrine disorders, including hypo- and hyperthyroid, adrenal and gonadal diseases. Insulinopenia (type 1 diabetes) and insulin resistance (obese type 2 diabetes) correspond to *vata* and *kapha* as well.

Ayurvedic physicians use the tridoshic analogy to classify not only physical phenotype, but emotional behavior and body secretions as well. The appraisal of body secretions as being *vata*, *pitta* or *kapha* may be taken as a surrogate marker for modern-day biochemical and hormonal assays. Each dosha has specific physiologic functions, which may be extrapolated to endocrine balance. *Vata*, thought to reside in the infraumbilical region of the abdomen, oversees the autonomic regulation of urination, excretion and blood pressure. Excessive *vata* suggests a hyperadrenergic state, while

deficiency implies inadequate sympathetic activity. *Pitta*, located in the supraumbilical area of the abdomen, maintains digestion, body temperature and bodily health. Perhaps *pitta* can be considered the equivalent of the incretin system or the gut microbiome, and the intestine can be considered the seat of *pitta*, as its actions may be mimicked by a healthy gastrointestinal endocrine system. *Kapha* is present in the chest region; it keeps the body stable and strong, through hydration and lubrication. In moderation, *kapha* represents a state of anabolism. If unregulated, however, it may lead to “maladaptive anabolism”, as in acromegaly, Cushing’s syndrome, obesity, type 2 diabetes or polycystic ovary syndrome. It would be difficult to ascribe a single glandular equivalent to *kapha*, however.

OF SPECIFIC DISORDERS

Apart from these overarching concepts, classic Ayurvedic texts refer to specific endocrine disorder such as goiter, diabetes (*prameha*) (both type 1 and type 2) and hypogonadism. In fact, the list of “eight despicables” reads like an endocrine checklist: over-tall, over-short, over-hairy, hairless, over-black, over-fare, over-obese, over-lean (persons).¹²

OF PERSON-CENTERED CARE

Ayurvedic interventions are person-centered in their approach. Specific therapies are decided, based upon the phenotype as well as emotional status of the person. In this manner, the subject is similar to modern endocrinology, which also speaks of person-centered care. The Quadruple of Atreya highlights the need for team work between patient, physician, “attendant” or caregiver and drug therapy.¹³ The same style of working is seen in endocrinology, where the health care team works along with the person being treated, and his or her family, to achieve optimal outcomes.

OF PRAGMATISM AND PRACTICE

We have access today to modern means of identifying and measuring hormones, assessing their function and categorizing their diseases. This allows us to correct various dysfunctions, and achieve better health. As women and men of healing, we must be passionate about our work. At the same time, we must be dispassionate while assessing information, and evaluating insight. We should also be mindful that no science is static, and no discipline exists in isolation.

Endocrinology is a young offshoot of modern medicine, which continues to uncover and discover newer aspects of its own existence. Increasingly, we appreciate the

multiple links and connections of our subject with other fields of medicine and surgery as well as non-medical sciences.

Realization of this reality makes us humble, not humiliated, and allows us to continue learning, while claiming leadership in our chosen field of work. It is with this attitude and approach that we should view any and every other science, including Ayurveda. Reading and analyzing the subject, finding comparisons and contrasts, and utilizing beneficial aspects for the well-being of our patients, is the way forward. This is what we hope to achieve through this opinion piece.

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Invasive Monitoring in the Intensive Care Unit

LP SAIKUMAR DORADLA*, M VADIVELAN*

ABSTRACT

The purpose of monitoring of the patient in an intensive care unit (ICU) is to improve patient care, like bringing about a change in the treatment or transfer of the patient to a step-down unit. Monitoring also shows the extent of compliance with a formulated standard of care or the degree of deviation from the expected standard of care. The monitoring used for a patient admitted to an ICU can be invasive or noninvasive. Invasive monitoring in an ICU includes arterial blood pressure, transesophageal Doppler, central venous pressure (CVP) measurement, pulmonary artery catheterization, arterial blood gas (ABG) analysis and measurement of intracranial pressure (ICP) and intra-abdominal pressure (IAP). Monitoring of the physiologic parameters depends on the underlying illness of the patient and the availability of equipment in the ICU.

Keywords: Invasive monitoring, intensive care unit

Patients admitted to an intensive care unit (ICU) require constant and intensive monitoring of their vital parameters. This helps in deciding about the future management of patients who have been stabilized and in modification of treatment in the acutely ill, unstable patient.

The components of invasive monitoring in the ICU are as follows:

- Invasive blood pressure (BP) monitoring
- Transesophageal Doppler (TED)
- Measurement of central venous pressure (CVP)
- Pulmonary artery catheterization
- Arterial blood gas (ABG) analysis
- Intracranial pressure (ICP) measurement
- Intra-abdominal pressure (IAP) measurement.

INVASIVE BP MONITORING¹

Indications

Continuous 'beat-to-beat' BP monitoring is useful in patients receiving inotropic drugs and head injury patients. Both groups of patients require close control of BP, which can be achieved by this technique.

Advantages

This method can be used in patients with gross peripheral edema, morbidly obese patients, patients in shock and patients who require repeated ABG analysis. It also allows measurement of cardiac output by pulse contour analysis of arterial pressure waveform.

The origin of pulse contour method of measuring cardiac output is derived from variations in the pulse pressure waveform. Pulse pressure is directly proportional to stroke volume and inversely related to vascular compliance. Pulse contour analysis is calibrated to injection dilution method. Stroke volume is calculated and compared with stroke volume as determined by the dilution technique; and the cardiac output is then calculated. With beat-to-beat waveform analysis, cardiac output can be determined continuously. Lithium is the contrast agent most commonly used with the injection dilution method for external calibration of pulse contour analysis devices (lithium indicator cardiac output [LiDCO], pulsed-induced contour cardiac output [PiCCO]).

Lithium indicator dilution cardiac output²

It is a minimally invasive technique of arterial pulse analysis that allows continuous, real-time cardiovascular monitoring. It is safe, accurate and simple to use. It is contraindicated in patients with intracardiac shunts, patients with atrial fibrillation and those on lithium therapy or patients receiving muscle relaxants.

Pulse-induced contour cardiac output

It is a pulse contour analysis with intermittent thermodilution measurement that enables continuous hemodynamic monitoring using femoral or axillary artery catheter.

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Complications

- Infection (But less frequent than venous lines)
- Local thrombosis
- Damage to local nerves
- Bleeding/hematoma formation
- Pseudoaneurysm formation

TRANSESOPHAGEAL DOPPLER²

TED measures blood flow velocity in the descending aorta by a Doppler transducer (4 MHz continuous wave or 5 MHz pulsed wave) placed at the tip of a flexible probe. It estimates preload, myocardial contractility and vascular tone. A study has found 86% correlation between cardiac outputs as determined by esophageal Doppler and pulmonary artery catheterization.

Advantages

- Minimally invasive
- Can be inserted rapidly
- Allows real-time measurement

Limitations

Interference occurs by nasogastric tube.

- Can get dislodged by movement which may result in loss of signal.
- Inability to obtain continuous reliable measurements of hemodynamic parameters.

CENTRAL VENOUS CANNULATION

Indications

- Patients requiring rapid resuscitation by infusion of fluids or blood.
- Patients requiring measurement of CVP.
- Patients requiring long-term drug administration.
- Patients undergoing hemodialysis.
- Patients undergoing plasmapheresis.
- Patients requiring placement of pacemaker.

Complications

- **Immediate:** Bleeding, arrhythmia, air embolism and pneumothorax.
- **Delayed:** Infection and venous thromboembolism.

PULMONARY ARTERY CATHETERIZATION³

Flow-directed pulmonary artery catheters, also called Swan-Ganz catheters are used in the diagnosis and

management of a range of conditions in critically ill patients. Pulmonary artery catheterization can yield direct measurements of central venous, right-sided intracardiac, pulmonary arterial and pulmonary capillary wedge pressures.

Automated thermodilution techniques can be used to estimate cardiac output. Systemic and pulmonary vascular resistance can be calculated on the basis of vascular pressures and cardiac output.

Indications

Despite the widespread use of pulmonary artery catheters in hemodynamically unstable patients, no study has definitively demonstrated improved outcome in critically ill patients managed using pulmonary artery catheterization. Role of invasive hemodynamic monitoring in critically ill patients is controversial as the pulmonary artery catheter is yet to be proven to improve patient outcome.

Accepted indications for pulmonary artery catheterization have been generated largely on the basis of clinical experience. The decision to place a pulmonary artery catheter should be based upon a specific question regarding a patient's hemodynamic status that cannot be answered satisfactorily by clinical or noninvasive assessment.

If the answer could change management, then placement of the catheter is indicated.

Diagnostic Uses

- To differentiate between mechanisms of pulmonary edema (cardiogenic and noncardiogenic).
- To diagnose left-to-right intracardiac shunt.
- To measure intracardiac pressures.

Therapeutic Uses

- Management of perioperative patient with unstable cardiac status.
- Management of patients following cardiac surgery.

Complications

There are three categories of complications related to the use of pulmonary artery catheters:

- Complications related to insertion of the pulmonary artery catheter.
- Sustained ventricular arrhythmias occur in up to 3% of patients.
- Right bundle branch block (RBBB) develops during approximately 5% of catheter insertions.

Complications related to maintenance and use of catheter

- pulmonary artery perforation is the most feared complication. It has a mortality of more than 30% and usually requires emergent thoracotomy for management. Self-limited pulmonary hemorrhage following perforation can result in the formation of a pulmonary artery pseudoaneurysm. Risk factors for pulmonary artery rupture are pulmonary hypertension, advanced age, mitral valve disease, hypothermia and anticoagulant therapy.
- Migration of the catheter may result in pulmonary infarction.
- Thromboembolic events may occur with catheters acting as a nidus for thrombus formation.
- Catheter-related infections with possible bloodstream infection.

Complications related to data interpretation

under ideal conditions, the tip of the catheter sits in zone 3 of the lung, where the arterial pressure exceeds the venous pressure and the venous pressure exceeds the alveolar pressure, thereby creating a continuous column of blood from the catheter tip to the left atrium (LA) when the balloon is inflated. Also, the LA pressure is similar to left ventricular end-diastolic pressure (LVEDP).

These conditions may not necessarily apply in many settings, and can result in hemodynamic data, which can be inaccurate. Sources of error are improperly calibrated pressure monitors, transduction of airway pressures under non-zone 3 conditions and over estimation of pulmonary capillary wedge pressure (PCWP) due to incomplete pulmonary artery branch occlusion. Also, interobserver variability in the interpretation of hemodynamic data among ICU physicians and anesthesiologists can lead to misinterpretation of accurately measured data.

ABG ANALYSIS

Analysis of ABG gives an idea about the oxygenation status and allows the clinician to assess the elimination of carbon dioxide and metabolic parameters of the critically ill patient. The information obtained from ABG analysis allows better goal directed management of the ICU patient.

Parameters reflected in the ABG report are pH, PO₂, PCO₂, SaO₂, bicarbonate (HCO₃⁻) and base excess.⁴

- **pH:** Normal arterial blood pH is 7.35-7.45. pH <7.35 indicates acidosis and pH >7.45 indicates alkalosis.

- **PO₂:** Normal range is 75-100 mmHg. Values of PO₂ <60 indicate the need for mechanical ventilation in the patient.

Conditions with low PO₂ in ICU are:⁴ Hypoventilation, impaired diffusion, ventilation/perfusion mismatch and shunting.

PaO₂/FiO₂ ratio (P/F):⁴ Normal ratio >500

Ratio between 300-500 – Mild hypoxemia

Ratio between 200-300 – Acute lung injury (ALI)

Ratio <200 – Acute respiratory distress syndrome (ARDS).

PaO₂/FiO₂ ratio (P/F) is used for evaluating the severity of lung involvement in ALI/ARDS.⁴

Oxygen index (OI) accounts better for the influence of ventilator pressures on oxygenation value. In patients with ARDS, OI >8.1 is usually in agreement with P/F <200. However, patients with ALI having an OI of 5.3-8.1 frequently had P/F <200.⁵

- **PCO₂:** Normal range is 35-45 mmHg. A high value is indicative of respiratory acidosis and suggests hypoventilation, while a low value indicates respiratory alkalosis due to hyperventilation.
- **SaO₂:** Normal range is 95-100.
- **HCO₃⁻:** Normal range is 22-30 mEq/L. Low HCO₃⁻ value indicates metabolic acidosis whereas a high HCO₃ value is suggestive of metabolic alkalosis.

$$\text{Oxygen index (OI)}^6 = \frac{\text{Mean airway pressure} \times \text{FiO}_2 \times 100}{\text{PaO}_2}$$

- **Base excess (BE):** Normal range is -2 to +2 mEq/L. BE may indicate tissue acidosis. But, it is a crude indicator of tissue dysoxia. Tissue hypoperfusion may occur in the absence of a significant change in the BE.⁷

ICP MONITORING

Normal ICP is in the range of 10-15 mmHg.

Indications for ICP Monitoring

- Head injury
- Intracerebral hemorrhage
- Subarachnoid hemorrhage
- Hydrocephalus
- Cerebrovascular stroke
- Cerebral edema
- Brain tumors

Devices for ICP Monitoring

- Intraventricular catheter (Gold Standard)
- Epidural catheter
- Subdural catheter

Measurement of ICP is useful in the calculation of cerebral perfusion pressure (CPP).

$$\text{CPP} = \text{Mean arterial BP} - \text{ICP}.$$

Normally, CPP is more than 60 mmHg.

Newer Fiberoptic ICP Monitors⁸

Advantages

- They have a smaller diameter, so they cause less damage to brain tissue.
- Allow simultaneous measurement of ICP and local cerebral blood flow by using Doppler flowmetry.
- Also measure brain tissue oxygen pressure, CO₂ pressure, pH and other metabolic parameters.

Disadvantages

- Cannot be used for cerebrospinal fluid (CSF) drainage.
- Cannot be recalibrated *in situ*.

IAP MONITORING

Studies have shown that there is no correlation between abdominal girth and IAP measurements. Sensitivity of physical examination for intra-abdominal hypertension has been estimated to be 40% to 60% approximately. Normal IAP value ranges between 0 and 5 mmHg. Direct measurements of IAP with an intraperitoneal catheter are precise. However, the less invasive and inexpensive technique of intravesical manometry is the recommended standard.

There are 4 grades of intra-abdominal hypertension:

- Grade I: IAP is between 12-15 mmHg
- Grade II: IAP is between 16-20 mmHg
- Grade III: IAP is between 21-25 mmHg
- Grade IV: IAP is >25 mmHg.

Indications

- Severe acute pancreatitis.
- Intra-abdominal bleeding (rupture of abdominal aortic aneurysm).

The risk of developing intra-abdominal hypertension is minimal in:⁹

Mechanically ventilated patients with positive end-expiratory pressure (PEEP) <10 cm H₂O and PaO₂/FiO₂ ratio >300.

- Patients with body mass index (BMI) <30 kg/m².
- Patients without pancreatitis, hepatic failure, cirrhosis of liver with ascites, gastrointestinal bleeding or in patients undergoing laparotomy and the use of vasopressors/inotropes on admission.

Presently, there are no clear guidelines to select the patients in whom IAP measurements should be performed.⁹

CONCLUSION

In critical care, monitoring is essential in the daily care of ICU patients as the optimization of the patient's hemodynamic parameters, ventilation, temperature and metabolism is the key to improving patients' survival.

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In constipation associated with piles,
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Effective bowel regulator

DS Tablets / Churna / Tablets

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Dosage:

Tablets: 1 to 2 tablets at bedtime with
warm water based on severity

Churna: ½ to 1 teaspoonful at bedtime
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Since 1950

An Open-labeled Clinical Study to Evaluate the Safety and Efficacy of "Anuloma DS" in Improving Constipation

VARUNI BG

ABSTRACT

Background: Constipation is a common gastrointestinal problem in the general population. Despite a plethora of well-established and safe treatment options, the improvement is not satisfactory for many patients. This has prompted interest in alternative therapeutic strategies for constipation. **Methods:** This open-label, non-comparative single-arm clinical study evaluated the efficacy and safety of the polyherbal formulation "Anuloma DS", 1 tablet daily at bedtime, in improving bowel movements in 30 adult patients with functional constipation. Patients were evaluated at baseline (Visit 1, Day 0) and follow-ups during Visit 2 (Day 7 $\pm$ 2), Visit 3 (Day 14 $\pm$ 2) and Visit 4 (End of the Study) at Day 30 $\pm$ 2. **Results:** There was a significant increase in the mean of spontaneous bowel movement every week from day 7 to days 14 and 30. All constipation symptoms such as abdominal bloating (aadmana), abdominal pain/discomfort (aanaha), feeling of incomplete evacuation and straining during passing stool improved significantly as did the SGA and the PGA scores. **Conclusion:** Anuloma DS is highly effective for the treatment of chronic functional constipation. No treatment-related side effects were reported by the study participants.

Keywords: Chronic functional constipation, polyherbal, spontaneous bowel movement, SGA score, PGA score

Constipation is a common gastrointestinal problem in the general population, as well as in patients with various disorders, with an overall global prevalence of 12% to 19%.¹ Various drugs such as bulking agents, stimulants, stool softeners and osmotic agents are used in clinical practice.^{2,3} Conventional treatment of constipation is well-established and safe, but it does not provide satisfactory improvement for many patients, prompting interest in alternative therapeutic strategies⁴ as possible solutions to the problem of constipation. The formulation used in this study, i.e., "Anuloma DS", is an Ayurvedic proprietary medicine that contains different medicinal plants such as *Cassia lanceolata* (Senna), *Apium leptophyllum* (Ajmoda), *Cuminum cyminum* (Cumin), *Terminalia chebula* (Haritaki), *Glycyrrhiza glabra* (Liquorice), *Zingiber officinale* (Ginger) and Halite (Rock salt). A study was conducted with the aim to evaluate the efficacy and safety of "Anuloma DS" tablets in persons suffering from functional constipation.

METHODS

The primary objective of the study was to evaluate the efficacy of "Anuloma DS" tablet in improving bowel movements in adult patients with constipation. Evaluation of the safety and tolerability of "Anuloma DS" tablet was the secondary objective of the study.

The study designed as an open-label, non-comparative single-arm clinical study enrolled subjects visiting OPDs for the treatment of improper bowel movements. After baseline assessment at visit 1, eligible subjects were instructed to take Anuloma DS 1 tablet per day at bedtime for a period of 30 days. Written informed consent was obtained from all participants on day 0.

The study was carried out according to the Declaration of Helsinki, Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research and International Conference on Harmonization (ICH) guidelines for Good Clinical Practice (GCP).

The inclusion criteria were male and female adults, aged 18 to 65 years, suffering from chronic constipation and subjects who were willing to sign consent forms and were able to present for follow-ups. Chronic functional constipation was diagnosed based on the

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presence of 2 or more of the following symptoms, for at least 12 weeks in the preceding year.

- Straining with >25% of bowel movements.
- Sense of incomplete evacuation with >25% of bowel movements.
- Hard or pellet-like stools with >25% of bowel movements.
- Manual evaluation maneuvers with >25% of bowel movements.
- Feeling of anorectal blockage with >25% of bowel movements.
- Number of bowel movements 2 or less per week.

The exclusion criteria were pregnant women or women child-bearing potential who were likely to become pregnant, patients with history of mechanical obstruction, mega colon/mega rectum or a diagnosis of pseudo-obstruction or hospitalization for any gastrointestinal or abdominal surgical procedure during the 3 months before the start of the study. Participants with clinically significant cardiovascular, liver, lung or other systemic disease; neurologic or psychiatric disorders or those who had participated in another clinical trial with an active intervention or drug or device with the last dose taken within 60 days were also excluded from the trial. No concomitant medication was allowed during the study. However, if participants reported any clinical symptoms during the study, the study physician prescribed the appropriate medication, which was documented.

The primary endpoint of the study was the change in the number of weekly spontaneous bowel movements (SBM) from baseline to the end of the study. This was evaluated by the participants' self-reported number of spontaneous defecations per week.

The secondary endpoints were:

- Change in the subjective symptom scores (e.g., abdominal bloating, abdominal pain/discomfort, straining during passing of stool and feeling of incomplete evacuation) from baseline to end of the treatment using a predefined 4-point scale.
- Change in Subjective Global Assessment (SGA) scores from the day 7 to end of treatment to end of treatment using a predefined 5-point scale.
- Change in Physician Global Assessment (PGA) scores from the day 7 to end of treatment to end of treatment using a predefined 5-point scale.
- Change in general health symptoms, vital signs, hematology, renal function, liver function, serum

lipids and urinalysis parameters from baseline to end of treatment.

The 30-day study duration consisted of 4 assessment points, including baseline (Visit 1, Day 0) and follow-ups during Visit 2 (Day 7 $\pm$ 2), Visit 3 (Day 14 $\pm$ 2) and Visit 4 (End of the Study) at Day 30 $\pm$ 2. Patients underwent history and physical examination at all assessment points. They were also examined for SBM score and subjective symptom scores on 4-point scale. Laboratory investigations including liver function test, kidney function test, complete blood profile, serum lipids and urine analysis were performed at Visit 1 and Visit 4. SGA and PGA scores on 5-point scale were evaluated during follow-up visits. Concomitant medications and adverse events were also assessed.

Data were abstracted and presented as a number, percentage, mean and standard deviation (SD). All efficacy and safety variables were summarized using descriptive statistics. Data comparison between baseline and follow-up visits was performed using a paired *t*-test or one-way analysis of variance (ANOVA), as appropriate, and data were expressed as mean, SD, 95% confidence interval (CI) and *p*-value. A *p* value of 0.05 was considered statistically significant. Statistical analysis was done using statistical software SPSS 10.0.

RESULTS

A total of 30 subjects with a mean age of 45.63 $\pm$ 14.34 years (range 19-64 years) including 12 (40%) females and 18 (60.0%) males were recruited for the study. The demographic information of the participants is summarized in Table 1.

Assessment of Spontaneous Bowel Movements

SBM were assessed at days 7 (V2), 14 (V3) and 30 (V4) on the basis of the participants' self-reported number of spontaneous defecations per week using one-way ANOVA test. Results showed a significant increase

Table 1. Summary of Demographic Data of the Subjects (n = 30)

Parameters	Range	Number (%)	Mean	SD
Age (year)	1-64	-	45.63	14.34
Male	-	18 (60)	-	-
Female	-	12 (40)	-	-
Height (cm)	152-181	-	167.63	8.50
Weight (kg)	54.40-76.30	-	64.56	6.87

in the mean of SBM per week from day 7 to days 14 and 30. Change in SBM score at day 30 was found to be statistically significant ($p < 0.0001$) compared to the day 7 (Table 2 and Fig. 1).

Assessment of Constipation Symptoms

Constipation symptoms such as abdominal bloating (aadmana), abdominal pain/discomfort (aanaha), feeling of incomplete evacuation, and straining during passing stool were assessed on a 4-point scale at all assessment points. All constipation-related symptom scores were significantly ($p < 0.0001$) reduced at days 7, 14 and 30 compared to baseline (Table 3 and Fig. 2).

The total constipation symptom score was also significantly reduced from 8.87 ± 1.41 (baseline) to 5.60 ± 1.40 at day 7, 3.30 ± 1.54 at day 14 and 1.47 ± 1.14 at day 30.

Table 2. Comparison of SBM Score at Visit 2 with Follow-up Visits 3 and 4 (n = 30)

Parameters	Visits (V)	Mean score (mean $\pm$ SD)	Change from V1 (mean $\pm$ SD)	95% CI of Diff.	P value
SBM	V2	1.20 ± 0.41	-	-	<0.0001***
	V3	1.47 ± 0.51	-0.27 ± 0.52	-0.631 to 0.098	
	V4	2.20 ± 0.76	-1.0 ± 0.74	-1.364 to -0.636	

Level of significance ***P < 0.001.

*P < 0.05, **P < 0.01, ***P < 0.001.

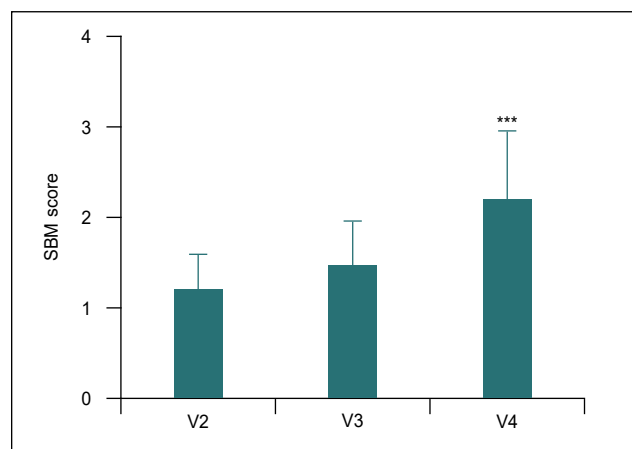


Figure 1. Comparison of SBM score at V2 with V3 and V4 using the one-way ANOVA test.

Level of significance ***P < 0.001.

*P < 0.05, **P < 0.01, ***P < 0.001.

Table 3. Comparison of Mean Change in Symptom Scores from V1 to Different Follow-up Visits (n = 30)

Parameters	Visits (V)	Mean score (mean $\pm$ SD)	Change from V1 (mean $\pm$ SD)	95% CI of Diff.	P value
Abdominal bloating	V1	2.03 ± 0.85	-	-	<0.0001***
	V2	1.40 ± 0.77	0.63 ± 0.61	0.102-1.158	
	V3	0.93 ± 0.78	1.10 ± 0.84	0.572-1.628	
	V4	0.50 ± 0.63	1.53 ± 0.94	1.002-2.058	
Abdominal pain/discomfort	V1	2.0 ± 0.95	-	-	<0.0001***
	V2	1.27 ± 0.69	0.73 ± 0.91	0.243-1.217	
	V3	0.70 ± 0.60	1.30 ± 1.06	0.813-1.787	
	V4	0.37 ± 0.49	1.63 ± 1.07	1.143-2.117	
Feeling of incomplete evacuation	V1	2.43 ± 0.50	-	-	<0.0001***
	V2	1.50 ± 0.51	0.93 ± 0.69	0.576-1.284	
	V3	0.83 ± 0.59	1.60 ± 0.72	1.246-1.954	
	V4	0.23 ± 0.43	2.20 ± 0.66	1.846-2.554	
Straining during passing stool	V1	2.40 ± 0.50	-	-	<0.0001***
	V2	1.43 ± 0.63	0.97 ± 0.67	0.546-1.394	
	V3	0.87 ± 0.78	1.57 ± 0.82	1.106-1.954	
	V4	0.37 ± 0.49	2.03 ± 0.72	1.606-2.454	
Total score	V1	8.87 ± 1.41	-	-	<0.0001***
	V2	5.60 ± 1.40	3.27 ± 1.17	2.313-4.227	
	V3	3.30 ± 1.54	5.57 ± 1.68	4.613-6.527	
	V4	1.47 ± 1.14	7.40 ± 1.59	6.443-8.357	

Comparison of V1 score versus different follow-up visits (V2, V3 and V4) was performed by one-way ANOVA test. Level of significance ***P < 0.001.

*P < 0.05, **P < 0.01, ***P < 0.001.

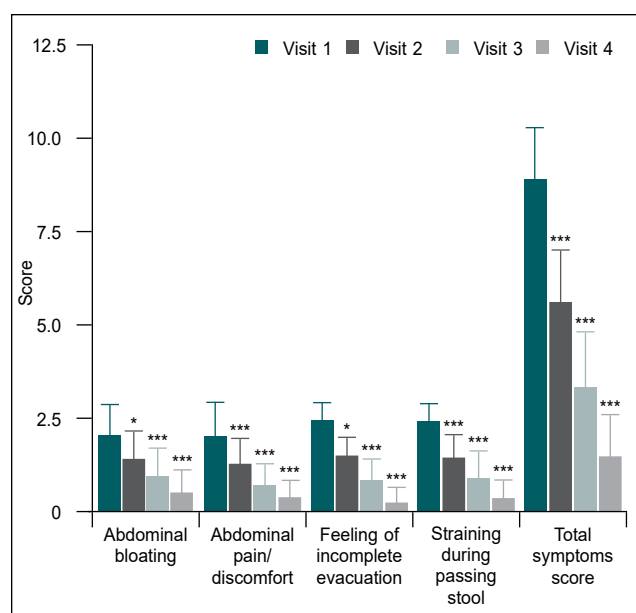


Figure 2. Comparison of mean change in symptom scores from V1 to different follow-up visits (n = 30).

Comparison of V1 score versus different follow-up visits (V2, V3 and V4) was performed by one-way ANOVA test. Level of significance ***P < 0.001.

*P < 0.05, **P < 0.01, ***P < 0.001.

Assessment of SGA and PGA Scores

The SGA and PGA scores were evaluated on a 5-point scale on days 7, 14 and 30. When compared to day 7, both scores were significantly ($p < 0.0001$) lower on days 14 and 30 (Table 4 and Fig. 3). The SGA score decreased significantly from 2.30 ± 0.79 (day 7) to 1.30 ± 0.70 and 0.67 ± 0.66 at days 14 and 30, respectively. The PGA score was also significantly reduced from 1.80 ± 0.76 (day 7) to 1.0 ± 0.64 and 0.60 ± 0.50 at days 14 and 30, respectively.

Safety Assessment

No treatment-related abnormalities were observed in the general appearance, eyes, ear, nose, throat, abdomen, heart and chest during all study visits. The baseline vital signs were also compared on days 7, 14 and 30. Changes in heart rate at days 14 and 30, systolic blood pressure (SBP) at day 30 and diastolic blood pressure (DBP) at days 7, 14 and 30 were found to be statistically significant; however, all the vital sign parameters were within normal range (Table 5 and Fig. 4).

No significant differences in complete blood count (CBC) parameters were noted between baseline and day 30, and all values were within the normal range (Table 6 and Fig. 5).

The serum levels of blood urea nitrogen (BUN) and creatinine were in the normal range at both assessment points, but the reduction in serum creatinine level at

Table 4. Comparison of Baseline SGA and PGA Scores with Different Follow-up Visits (n = 30)

Parameters	Visits (V)	Mean score (mean $\pm$ SD)	Change from V1 (mean $\pm$ SD)	95% CI of Diff.	P value
SGA	V2	2.30 ± 0.79	-	-	<0.0001***
	V3	1.3 ± 0.70	1.0 ± 0.69	0.5454-1.455	
	V4	0.67 ± 0.66	1.63 ± 0.89	1.179-2.088	
PGA	V2	1.80 ± 0.76	-	-	<0.0001***
	V3	1.0 ± 0.64	0.80 ± 0.66	1.989-3.077	
	V4	0.60 ± 0.50	1.20 ± 0.81	2.389-3.477	

Comparison of V2 versus V3 and V4 scores was performed by one-way ANOVA test. Level of significance ***p < 0.001.

*P < 0.05, **P < 0.01, ***P < 0.001.

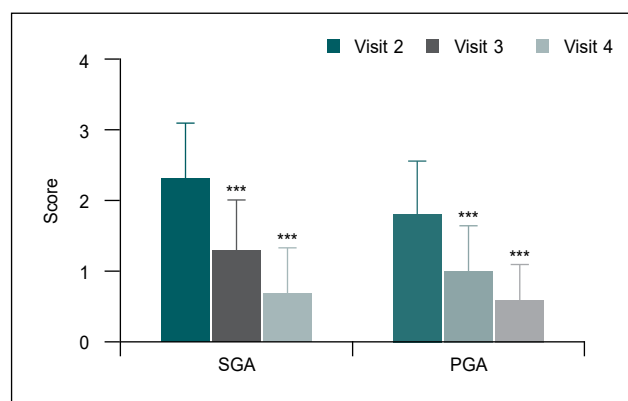


Figure 3. Comparison of V2 SGA and PGA scores with different follow-up visits (n = 30).

Comparison of V2 versus V3 and V4 scores was performed by one-way ANOVA test. Level of significance ***P < 0.001.

*P < 0.05, **P < 0.01, ***P < 0.001.

day 30 was statistically significant ($p < 0.05$) (Table 7 and Fig. 6).

The serum lipids parameters were not remarkably changed at day 30 when compared to baseline and all serum lipid parameters were within the normal range (Table 8 and Fig. 7).

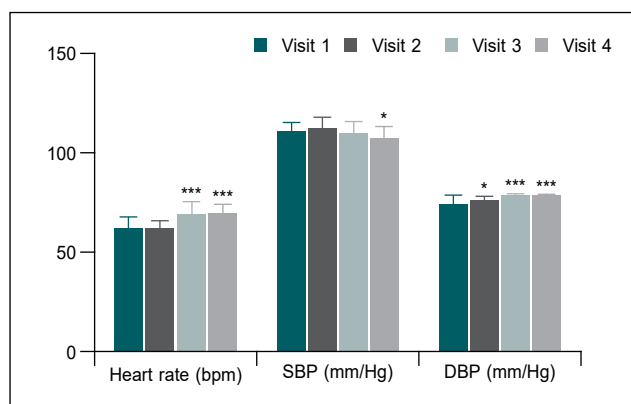
The liver function parameters including serum levels of serum glutamic-oxaloacetic transaminase (SGOT) and serum glutamic-pyruvic transaminase (SGPT) as well as total bilirubin were not remarkably changed at day 30 when compared to baseline and all liver

Table 5. Comparison of Mean Change in Vital Signs from Baseline to Different Follow-up Visits (n = 30)

Parameters	Visits (V)	Mean score (mean $\pm$ SD)	Change from V1 (mean $\pm$ SD)	95% CI of Diff.	P value
Heart rate (bpm)	V1	62.0 $\pm$ 5.89	-	-	-
	V2	61.53 $\pm$ 4.31	0.47 $\pm$ 3.92	-0.9967 to 1.930	0.519
	V3	68.70 $\pm$ 6.46	-6.70 $\pm$ 7.41	-9.468 to -3.932	<0.0001***
	V4	69.0 $\pm$ 5.34	-7.0 $\pm$ 7.91	-9.955 to -4.045	<0.0001***
SBP (mm/Hg)	V1	109.90 $\pm$ 5.42	-	-	-
	V2	111.50 $\pm$ 6.36	-1.53 $\pm$ 6.11	-3.815 to 0.749	0.18
	V3	109.30 $\pm$ 6.49	0.67 $\pm$ 5.52	-1.395 to 2.729	0.514
	V4	106.5 $\pm$ 6.68	3.40 $\pm$ 8.42	0.2569 to 6.543	0.035*
DBP (mm/Hg)	V1	74.13 $\pm$ 2.69	-	-	-
	V2	75.87 $\pm$ 2.61	-1.73 $\pm$ 3.79	-3.147 to -0.320	0.018*
	V3	77.93 $\pm$ 1.39	-3.80 $\pm$ 4.14	-4.974 to -2.626	<0.0001***
	V4	77.90 $\pm$ 1.30	-3.77 $\pm$ 2.85	-4.830 to -2.703	<0.0001***

Statistical analyses were performed using paired *t*-test. Comparison: V1 versus V2, V3 and V4, where level of significance **P* < 0.05 and ****P* < 0.001.

P* < 0.05, *P* < 0.01, ****P* < 0.001.

**Figure 4.** Comparison of mean change in vital sign parameters at different visits.

Statistical analysis was performed using paired *t*-test. Comparisons: V1 versus V2, V3 and V4, where level of significance **P* < 0.05 and ****P* < 0.001.

P* < 0.05, *P* < 0.01, ****P* < 0.001.

Table 6. Comparison of Mean Change in Blood Parameters from V1 to V4 (n = 30)

Parameters	Visits (V)	Mean score (mean $\pm$ SD)	Change from V1 (mean $\pm$ SD)	95% CI of Diff.	P value
RBC (million/cu mm)	V1	5.15 $\pm$ 0.08	-	-	-
	V4	5.25 $\pm$ 0.08	-0.1 $\pm$ 0.20	-0.171 to -0.021	0.014*
Hb (g/dL)	V1	14.60 $\pm$ 1.04	-	-	-
	V4	14.67 $\pm$ 0.98	-0.07 $\pm$ 0.31	-0.180 to 0.049	0.249
WBC (10 ⁹ /L)	V1	8.53 $\pm$ 1.31	-	-	-
	V4	8.70 $\pm$ 1.22	-0.17 $\pm$ 0.59	-0.391 to 0.047	0.120
Neutrophils (%)	V1	53.13 $\pm$ 2.58	-	-	-
	V4	54.61 $\pm$ 2.81	-1.48 $\pm$ 4.15	-3.027 to 0.069	0.060
Lymphocytes (%)	V1	37.08 $\pm$ 1.94	-	-	-
	V4	35.92 $\pm$ 2.42	1.16 $\pm$ 3.44	-0.125 to 2.443	0.075
Monocytes (%)	V1	5.58 $\pm$ 1.79	-	-	-
	V4	5.54 $\pm$ 1.46	0.040 $\pm$ 1.62	-0.565 to 0.645	0.893
Eosinophils (%)	V1	3.45 $\pm$ 1.44	-	-	-
	V4	3.23 $\pm$ 1.61	0.22 $\pm$ 1.98	-0.516 to 0.963	0.542
Basophils (%)	V1	0.76 $\pm$ 0.19	-	-	-
	V4	0.71 $\pm$ 0.17	0.06 $\pm$ 0.29	-0.053 to 0.166	0.299
Platelet count (x1000/cu mm)	V1	344.0 $\pm$ 30.63	-	-	-
	V4	340.5 $\pm$ 23.58	4.367 $\pm$ 4.37	-4.201 to 12.93	0.306
ESR (mm 1st hour)	V1	10.77 $\pm$ 3.66	-	-	-
	V4	10.53 $\pm$ 2.95	0.23 $\pm$ 4.22	-1.341 to 1.807	0.764

Statistical analysis was performed using paired *t*-test. Comparisons: V1 versus V4, where level of significance **P* < 0.05.

P* < 0.05, *P* < 0.01, ****P* < 0.001.

function parameters were within the normal range (Table 9 and Fig. 8).

Urinalysis parameters showed no significant difference between two evaluation points: baseline and day 30.

No adverse effects or serious adverse effects were observed during the study period. However, one participant at visit 3 and one participant at visit 4 had diarrhea; however, this effect was found to be unrelated to "Anuloma DS" treatment.

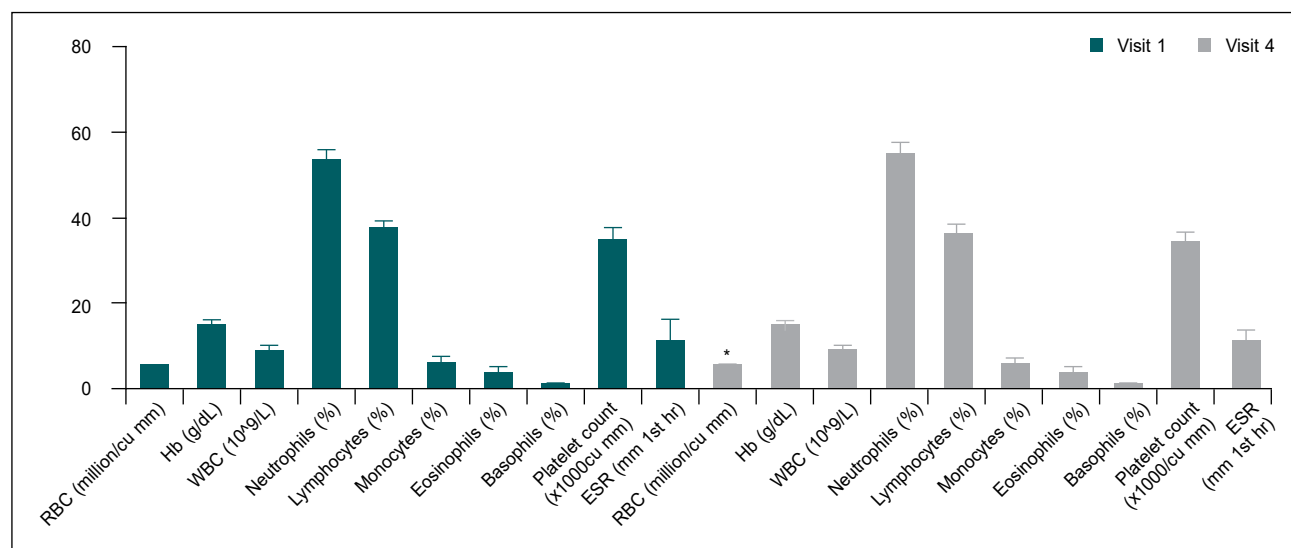


Figure 5. Comparison of mean change in blood parameters at different visits.

Statistical analysis was performed using paired *t*-test. Comparisons: V1 versus V4, where level of significance **P* < 0.05.

P* < 0.05, *P* < 0.01, ****P* < 0.001.

Table 7. Comparison of Mean Change in BUN and Serum Creatinine from V1 to V4 (n = 30)

Parameters	Visits (V)	Mean score (mean ± SD)	Change from V1 (mean ± SD)	95% CI of Diff.	P value
BUN (mg/dL)	V1	15.05±4.37	-	-	-
	V4	14.51±4.25	0.54 ± 6.65	-1.945 to 3.023	0.661
Serum creatinine (mg/dL)	V1	0.94±0.157	-	-	-
	V4	0.93±0.925	0.01 ± 0.28	-0.095 to 0.117	0.829

Statistical analysis was performed using paired *t*-test. Comparisons: V1 versus V4.

REVIEW OF LITERATURE

C. lanceolata or Senna has been used as a laxative and purgative. The laxative property of Senna is attributed to anthraquinone glycosides called sennosides - Sennoside A and sennoside B.⁵ By stimulating intestinal peristalsis, it causes rapid expulsion of feces. Senna also increases secretion of fluids by the colon causing softening of stool so that it can easily pass through the intestine.⁶

T. chebula or Haritaki, has traditionally been prescribed to improve gastrointestinal motility and it has relieved constipation.⁷ The aqueous extract of *T. chebula* seeds caused a dose-dependent increase in the frequency of rat ileum motility and tension of contraction. The fecal number and fecal water content also increased dose-dependently. These results support the use of

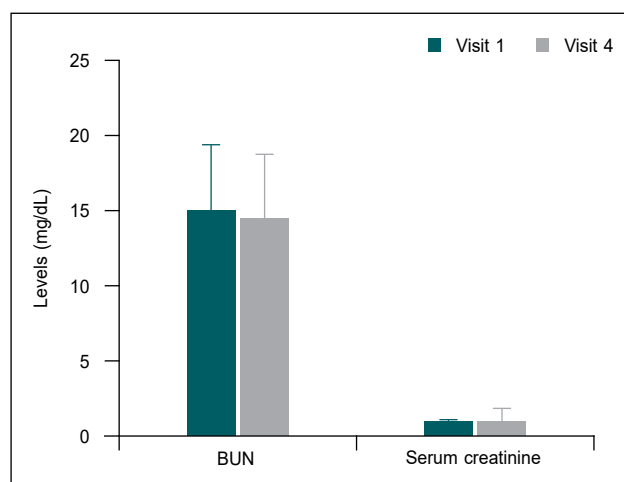


Figure 6. Comparison of mean change in kidney function test parameters at different visits.

Compared V1 kidney function parameters with V4 using paired *t*-test.

T. chebula for the treatment of constipation.⁸ Its prokinetic activity has been demonstrated in an experimental study where it significantly increased gastric emptying.⁹ Due to its prokinetic activity, it increases intestinal peristalsis. *T. chebula* enhances the process of digestion, regulates colon function and stimulates absorption of nutrients.¹⁰ The purgative action of an oil obtained from *T. chebula* has been demonstrated in a study.^{11,12} In a short-term clinical trial, *T. chebula* helped in complete evacuation of the bowel in patients suffering from constipation.^{12,13}

Also known as Liquorice, *G. glabra* has mild laxative activity and through its demulcent action, it can protect the intestinal lining by increasing mucus production.¹⁴

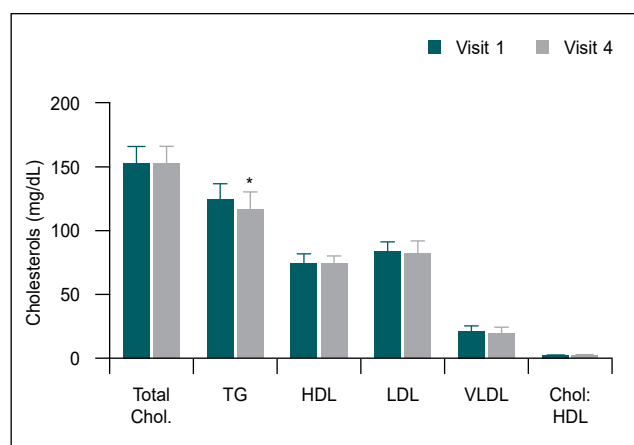
Table 8. Comparison of Mean Change in Lipid Parameters from V1 to V4 (n = 30)

Parameters	Visits (V)	Mean score (mean $\pm$ SD)	Change from V1 (mean $\pm$ SD)	95% CI of Diff.	P value
Total cholesterol (mg/dL)	V1	151.7 $\pm$ 13.98	-	-	-
	V4	156.1 $\pm$ 13.27	-4.47 $\pm$ 18.46	-11.36 to 2.425	0.195
TG (mg/dL)	V1	123.9 $\pm$ 12.73	-	-	-
	V4	116.1 $\pm$ 14.17	7.80 $\pm$ 17.72	1.184 to 14.42	0.023*
HDL cholesterol (mg/dL)	V1	73.77 $\pm$ 7.94	-	-	-
	V4	73.97 $\pm$ 6.09	-0.20 $\pm$ 10.98	-4.301 to 3.901	0.921
LDL cholesterol (mg/dL)	V1	83.33 $\pm$ 7.64	-	-	-
	V4	81.83 $\pm$ 9.83	1.50 $\pm$ 11.88	-2.937 to 5.937	0.495
VLDL cholesterol (mg/dL)	V1	20.83 $\pm$ 4.25	-	-	-
	V4	18.93 $\pm$ 5.09	1.90 $\pm$ 7.02	-0.721 to 4.521	0.149
Chol:HDL ratio (mg/dL)	V1	2.07 $\pm$ 0.25	-	-	-
	V4	2.13 $\pm$ 0.29	-0.06 $\pm$ 0.42	-0.213 to 0.103	0.482

Statistical analysis was performed using paired *t*-test. Comparisons: V1 versus V4, where level of significance *P < 0.05.

*P < 0.05, **P < 0.01, ***P < 0.001.

TG = Triglyceride; HDL = High-density lipoprotein; LDL = Low-density lipoprotein; VLDL = Very-low-density lipoprotein.

**Figure 7.** Comparison of mean change in serum cholesterol levels from V1 to V4.

Statistical analysis was performed using paired *t*-test. Comparisons: V1 versus V4, where level of significance *P < 0.05.

*P < 0.05, **P < 0.01, ***P < 0.001.

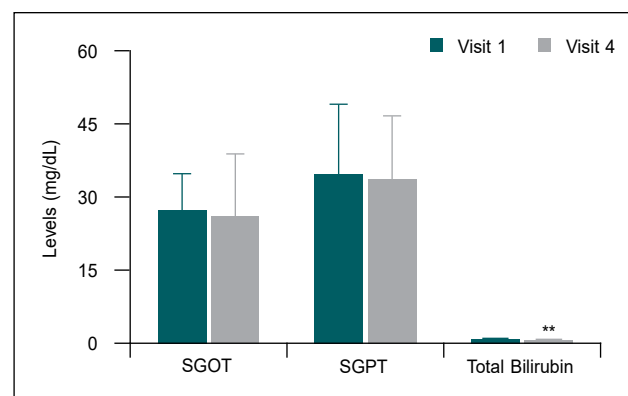
Glycyrrhizin, a phytoactive constituent of *G. glabra*, has anti-inflammatory activity.¹⁵ An essential oil

Table 9. Comparison of Mean Change in Liver Function Parameters from V1 to V4 (n = 30)

Parameters	Visits (V)	Mean score (mean $\pm$ SD)	Change from V1 (mean $\pm$ SD)	95% CI of Diff.	P value (V1 vs. V4)
SGOT (IU/L)	V1	27.20 $\pm$ 7.54	-	-	-
	V4	26.02 $\pm$ 12.82	1.18 $\pm$ 13.76	-3.960 to 6.316	0.643
SGPT (IU/L)	V1	34.60 $\pm$ 14.45	-	-	-
	V4	31.96 $\pm$ 14.60	2.64 $\pm$ 19.02	-4.463 to 9.737	0.454
Total bilirubin (mg/dL)	V1	0.81 $\pm$ 0.22	-	-	-
	V4	0.56 $\pm$ 0.28	0.23 $\pm$ 0.35	0.114 to 0.392	0.0013**

Statistical analysis was performed using paired *t*-test. Comparisons: V1 versus V4, where level of significance **P < 0.01.

*P < 0.05, **P < 0.01, ***P < 0.001.

**Figure 8.** Comparison of mean change in liver function parameters from V1 to V4.

Statistical analysis was performed using paired *t*-test. Comparisons: V1 versus V4, where level of significance **p < 0.01.

*P < 0.05, **P < 0.01, ***P < 0.001.

obtained from the fruit of *C. cyminum* has antiparasitic, appetizing, digestive and carminative properties.¹⁶ By enhancing intestinal peristalsis, cumin can relieve bloating and dyspepsia and thus facilitate excretion of waste material from the stomach and intestines.¹⁷ In a pilot study of patients with irritable bowel syndrome (IBS), a significant reduction in abdominal pain, bloating, incomplete defecation, fecal urgency was noted following the use of cumin extract. Stool consistency improved as did the frequency of bowel movement in patients with constipation-predominant IBS.¹⁶

Z. officinale or Ginger has several bioactive compounds mainly gingerols, zingerone, gingerenone-A and 6-dehydrogingerdione, zingiberene and β -sesquiph-

llandrene among others. By increasing the muscular activity in the gastrointestinal tract, these active constituents increase stimulate digestion, absorption, relieve constipation and flatulence.^{18,19} Dry ginger powder is oily. It lubricates the inner wall of the intestine, especially the large intestine and facilitates elimination of feces. It also breaks down the hard feces in the colon so that the stool becomes soft and can be easily excreted.²⁰ *A. leptophyllum* is called “Ajmoda” in Hindi. It is antispasmodic in nature and has been used to cure stomach aches and diarrhea because of its powerful antibacterial, antifungal and anti-inflammatory properties.²¹ All types of salts have been described as having appetizing, digestive stimulant and laxative activities.²² Halite, commonly known as Rock salt or Saindhava lavana is considered best among all salts and according to Ayurveda should be used daily. It enhances healthy metabolism and helps in the process of digestion. Salt is carminative, improves appetite and alleviates heartburn. Hence, it is prescribed for digestive disorders and as a laxative.²³

CONCLUSION

The results of the present clinical study demonstrated that Anuloma DS is highly effective for the treatment of chronic functional constipation, as evidenced by the increased in SBM score, and decrease constipation symptoms as well as SGA and PGA scores through the synergistic therapeutic actions of its constituent herbs. Furthermore, during the 30-day treatment period, no significant changes in vital signs, hematological profile, lipid profile, renal and liver functions, or urinalysis parameters were observed. There were no treatment-related side effects reported by any of the study participants.

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Minimal Intubating Dose of Succinylcholine: A Comparative Study of 0.4, 0.5 and 0.6 mg/kg Dose

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ABSTRACT

Muscle relaxants are integral part of modern balanced anesthesia and succinylcholine, a depolarizing drug, is in use despite its adverse effects. The excellent intubating condition, fastest onset and shortest duration of action make it an excellent choice for anesthesiologists. The conventional dose of 1.5-2 mg/kg is commonly used for obtaining relaxation for intubation. This study was conducted with much smaller dose of succinylcholine as 0.4, 0.5 and 0.6 mg/kg to evaluate the acceptable intubating dose at 60 seconds, which was unlikely to have any untoward/side effects.

Keywords: Succinylcholine, low dose, intubation

Muscle relaxants are integral part of balanced anesthesia since first dose of curare in 1942. For last-half century, succinylcholine continues to be used as relaxant for rapid intubation due to its unparalleled efficacy, rapid onset with short duration of action thus providing excellent intubating conditions. Succinylcholine is considered the best drug in the hands of anesthesiologists in emergency condition for rapid sequence intubation due to its rapid onset.

In conventional dose of 1.5-2 mg/kg, various side effects of succinylcholine can become evident. Various adverse events such as cardiac arrhythmias, exaggerated potassium reflux, increased intraocular and intracranial pressure, masseter spasm, myalgia due to muscle fasciculations can occur susceptible population at usual conventional doses.

Rocuronium has recently gained popularity as relaxant for fast intubating conditions but has longer duration of action, which is undesirable in various situations. In spite of all claims by newer muscle relaxants, benefits of succinylcholine cannot be overlooked. Knowing the

potential side effects of succinylcholine at conventional doses, minimal dose should be used to avoid possible complications.

AIMS OF STUDY

This study was aimed to assess three minimal doses of succinylcholine for muscle relaxation for intubation. In present study, we compared succinylcholine in three minimal doses of 0.4, 0.5 and 0.6 mg/kg for its efficacy in providing satisfactory intubating condition.

Inclusion Criteria

- Age 15 to 65 years of either sex posted for elective surgery.
- American Society of Anesthesiologist (ASA) Grade I and II.

Exclusion Criteria

- Patient refusal.
- Posted for any emergency surgery.
- Patients with coexisting diseases such as any cardiac, renal, diabetes, hypertension, electrolyte imbalance, etc.
- Any history of allergic reaction to any drugs involved.
- Anticipated difficult airway.

MATERIAL AND METHODS

After institutional ethical clearance, total of 120 patients (40 in each group) were included in this prospective,

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CLINICAL STUDY

randomized double-blind study after applying inclusion and exclusion criteria.

- Group A: 0.4 mg/kg diluted into total of 2 mL volume with normal saline.
- Group B: 0.5 mg/kg diluted into total of 2 mL volume with normal saline.
- Group C: 0.6 mg/kg diluted into total of 2 mL volume with normal saline.

Methodology

After obtaining prior written informed consent, detailed pre-anesthetic check-up were done for all patients included in the study. Patients were shifted to operation theater after overnight fasting of 6 hours and standard monitors (NIBP, SpO₂, ECG, capnography) were attached.

All patients were pre-medicated with injection glycopyrrolate 0.2 mg and injection fentanyl 2 mg/kg intravenously (IV) and pre-oxygenated with 100% oxygen for 3 minutes. Patients were induced with injection propofol 2 mg/kg IV. After loss of eyelash reflex, set dose of succinylcholine was administered to the patient by a helping colleague not involved in the study. After 1 minute (60 seconds), laryngoscopy to assess intubating condition was done by the investigator and patient was intubated.

Maintenance of anesthesia was done with oxygen, nitrous oxide (50:50), isoflurane, vecuronium and intermittent positive pressure ventilation (IPPV). Patients were reversed with injection neostigmine 0.05 mg/kg and injection glycopyrrolate 0.01 mg/kg at the end of surgery and extubated after thorough oral suctioning.

Clinically, intubating conditions were observed as described by Cooper et al as in the following:

Score	Jaw relaxation	Vocal cord	Response to intubation
0	Poor (impossible)	Closed	Severe coughing/bucking
1	Minimal	Closing	Mild cough
2	Good (easy)	Minimal movement	Mild diaphragmatic movement
3	Excellent	Open	None
Total score: 8-9: Excellent; 6-7: Good; 3-5: Fair; 0-3: Poor.			

If difficult/poor intubating conditions were encountered, then additional dose of injection propofol 0.5 mg/kg

was given and return of spontaneous ventilation was awaited. Injection vecuron 0.1 mg/kg was then given and patient was then intubated after 3 minutes. Such patients automatically had score of 0 or poor intubating condition. In no circumstances, second dose of succinylcholine was given.

Vitals Monitoring and Statistical Analysis

Vitals (heart rate, systolic blood pressure, diastolic blood pressure) were noted at pre-induction state and then at 0, 1, 2, 3, 5 and 10 minutes post-intubation. All data were compared statistically using Epi Info 3.3.2 database and analysis of variance (ANOVA) analysis was used for inter-group comparison. P value <0.05 was considered significant and p value <0.001 was highly significant.

RESULTS

We were able to intubate all patients with different observations. On analysis of demographic profile, maximum proportion (46.6%) was from age group 15 to 25 and 35 to 45 years. All the three study groups were comparable with demographic profile and were found to be statistically insignificant (Tables 1-3). In our study, we found that intubating condition was dosedependent at fixed time interval of 60 seconds. Eighty percent of patients with 0.4 mg/kg, 95% with 0.5 mg/kg and 100% patients with 0.6 mg/kg had excellent to fair intubating condition (Table 4).

Our study revealed that all patients with 0.6 mg/kg succinylcholine, had excellent intubating condition

Table 1. Group-wise Age Distribution

Age (years)	Group A	Group B	Group C	Total
15-25	8 (20%)	9 (22.5%)	11 (27.5%)	28 (23.3%)
25-35	7 (17.5%)	8 (20%)	6 (15%)	21 (17.5%)
35-45	10 (25%)	8 (20%)	10 (25%)	28 (23.3%)
45-55	3 (7.5%)	8 (20%)	9 (22.5%)	20 (16.7%)
55-65	12 (30%)	7 (17.5%)	4 (10%)	23 (19.2%)
Total	40 (100%)	40 (100%)	40 (100%)	120 (100%)

Table 2. Group-wise Sex Distribution

Sex	Group A	Group B	Group C	Total
Male	22 (55%)	24 (60%)	23 (57.5%)	69 (57.5%)
Female	18 (45%)	16 (40%)	17 (42.5%)	51 (42.5%)
Total	40 (100%)	40 (100%)	40 (100%)	40 (100%)

Table 3. Group-wise Weight Distribution

Weight (kg)	Group A	Group B	Group C	Total
30-40	3 (7.5%)	4 (10%)	4 (10%)	11 (9.2%)
40-50	8 (20%)	11 (27.5%)	10 (25%)	29 (24.2%)
50-60	8 (20%)	11 (27.5%)	10 (25%)	29 (24.2%)
60-70	15 (20%)	14 (35%)	16 (40%)	45 (37.5%)
70-80	6 (15%)	3 (7.5%)	1 (2.5%)	10 (8.3%)
Total	40 (100%)	40 (100%)	40 (100%)	120 (100%)

Table 4. Clinical Intubating Condition in Different Groups

	Group A	Group B	Group C
Jaw relaxation			
Poor	1 (2.5%)	Nil	Nil
Minimal	7 (17.5%)	2 (5%)	Nil
Good	11 (27.5%)	12 (30%)	8 (20%)
Excellent	21 (52.5%)	26 (65%)	32 (80%)
Vocal cord movement			
Closed	Nil	Nil	Nil
Closing	6 (15%)	1 (2.5%)	Nil
Minimal movement	12 (30%)	14 (35%)	6 (15%)
Open	22 (55%)	25 (62.5%)	34 (85%)
Response to intubation			
Severe coughing/bucking	2 (5%)	1 (2.5%)	Nil
Mild cough	6 (15%)	1 (2.5%)	Nil
Mild diaphragmatic movement	13 (32.5%)	12 (30%)	2 (5%)
None	19 (47.5%)	26 (65%)	38 (95%)

with onset of action as fast as 1.0 mg/kg dose. Thus in our view, dose higher than 0.6 mg/kg has no added advantage and unnecessarily produces side effects. There was maximum proportion (90%) showing excellent intubating condition in Group C as compared to Groups A and B. On the other side, good condition was found maximum (55%) in Group B compared to Group A and C. Fair and poor condition was found maximum in Group A (55% and 20%, respectively) (Table 5).

It was observed that 20% patients in 0.4 mg/kg group and 5% patients in 0.5 mg/kg group had poor intubating condition with some movement of vocal cords. However, post-extubation none of the endotracheal (ED) tube showed any blood on its tip. In our study, we did not use neuromuscular monitoring and solely depended on clinical judgment, hence exact onset and recovery

Table 5. Distribution of Intubating Condition among Study Groups

Condition	Group A	Group B	Group C	Total
Excellent	0 (0)	12 (30%)	36 (90%)	48 (40%)
Good	10 (25%)	22 (55%)	2 (5%)	34 (28.4%)
Fair	22 (55%)	4 (10%)	2 (5%)	28 (23.3%)
Poor	8 (20%)	2 (5%)	0 (0%)	10 (8.3%)
Total	40 (100%)	40 (100%)	40 (100%)	120 (100%)

time could not be assessed. We solely concentrated on minimal intubating dose and associated intubating condition.

DISCUSSION

The usual intubating dose for succinylcholine is 1.0-1.5 mg/kg IV to achieve satisfactory intubating condition at 1 minute. This dose is associated with various adverse effects¹ and has drawbacks, which attracted too many adverse comments. Succinylcholine still enjoys patronage of many anesthesiologists because it provides excellent intubating conditions and has shorter onset of action. The efficacy of small dose of succinylcholine for providing acceptable intubating conditions at 60 seconds was reported by Stewart et al² in their study titled "Comparison of high and low doses of succinylcholine". Later Nimmo et al³ reported "Effectiveness and sequelae of very low-dose of succinylcholine". These studies did not get attention because of fear that respiration will return faster and intubation will be difficult.

Stewart et al² reported that 26 (96%) of 27 patients receiving 1.5 mg/kg succinylcholine and 30 (94%) of 32 patients receiving 0.5 mg/kg had acceptable intubating conditions. However, in patients with a full stomach or in those with raised intracranial pressure, excellent intubating conditions are warranted.

ED 95 of succinylcholine is 0.3 mg/kg and traditional dose of 1.0-1.5 mg/kg is too high ($3 \times$ ED) and produces side effects, which has been well proven in study conducted by Smith et al.⁴ Same has been proposed by Kopman⁵ study. Naguib et al⁶ compared 0.3, 0.4, 0.5, 1.0 and 2.0 mg/kg dose of succinylcholine and found no difference of intubating condition at 60 seconds with doses of 1.0 and 2.0 mg/kg. Naguib et al^{7,8} also found the incidence of excellent intubating conditions following induction with 2 µg/kg fentanyl and 2 mg/kg propofol to be 43.3%, 60.0%, 63.3%, 80.0% and 86.7% of patients after 0.3, 0.5, 1.0, 1.5 and 2.0 mg/kg

succinylcholine, respectively. El-Orbany et al⁹ in their study found that small doses of succinylcholine like 0.5, 0.6 and 0.8 mg/kg are sufficient for good intubating conditions at 60 seconds.

Benumof et al¹⁰ observed that recovery occurred much earlier with 0.5 mg/kg than with 1.0 mg/kg dose of succinylcholine and this created additional benefits. Another study by Ellango et al¹¹ opined that intubating condition was much better with 1.0 mg/kg compared to 0.5 mg/kg but desaturation was more with 1.0 mg/kg dose. Ezzat and colleagues¹² studied the optimal succinylcholine dose for intubating emergency patients in a retrospective comparative study. They studied succinylcholine as a muscle relaxant agent in doses of 0.45 mg/kg, 0.6 mg/kg or 1 mg/kg and found that increasing the succinylcholine dosage shortened the onset time, prolonged the duration of action and the duration of abdominal fasciculation significantly. Tracheal intubation was 100% successful in the three groups of patients.

Sorensen et al¹³ studied rapid sequence induction and intubation with rocuronium-sugammadex compared with succinylcholine in a randomized trial. They used either succinylcholine (1 mg/kg⁻¹) or rocuronium (1 mg/kg⁻¹) and found that median time from tracheal intubation to spontaneous ventilation was 406 seconds with succinylcholine and 216 seconds with rocuronium-sugammadex. The median time from tracheal intubation to 90% recovery of the first twitch in train-of-four (T_1 90%) was 518 seconds with succinylcholine and 168 seconds with rocuronium-sugammadex and intubating conditions and time to tracheal intubation were not significantly different.

Few studies have shown desaturation of oxyhemoglobin during apneic period. Though we did not include it in our protocol, none of the patients enrolled in our study showed any sign of desaturation as all were preoxygenated for 3 minutes and intubated at 60 seconds.

CONCLUSION

Succinylcholine due to its rapidity of onset and offset with excellent effect still enjoys patronage of many anesthesiologists. By using low dose of succinylcholine many side effects can be avoided and can be safely used in patients.

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CASE REPORT

Pleomorphic Adenoma of the Hard Palate: A Multidisciplinary Approach

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ABSTRACT

Pleomorphic adenoma is the most common salivary gland tumor accounting for 80% of all major salivary gland tumors. It is a benign salivary gland neoplasm that constitutes 3% to 10% of the neoplasms in the head and neck region.¹ Salivary gland neoplasms represents less than 1% of all tumors. This article is being showcased as a special case due to the fact it was done at a Taluk Hospital and also because ENT and oromaxillofacial surgeons were involved during the surgery.

Keywords: Pleomorphic adenoma, palate, minor salivary gland

Pleomorphic adenoma is a benign mixed tumor composed of epithelial and myoepithelial cells arranged with various morphological patterns; it is demarcated from the surrounding tissues by a fibrous capsule. Pleomorphic adenoma commonly affects the parotid gland and palate is the most common site wherein minor salivary glands are affected.

Other intraoral sites that could be involved are lip, buccal mucosa, floor of the mouth, tongue, tonsil, pharynx and retromolar area. In the palate region, it commonly affects the posterolateral surface of the hard palate.²

Surgical excision of the tumor is the only modality of treatment.

CASE REPORT

A 50-year-old lady presented to the ENT OPD with a mass in the oral cavity, which she had noticed since 6 months. The mass slowly grew to the present size and was painless. There was no history of stridor, dysphagia or chewing difficulties due to the swelling.

On examination, the growth measured 2.5 × 2.5 cm in size. It appeared smooth with no ulcerations or bleeding points, etc. thus ruling out a malignant growth (Fig. 1).

On palpation, the swelling was unilocular, nontender, firm, immobile with a well-defined margin. The mucosa over the growth was stretched and lymph nodes of the neck appeared normal.



Figure 1. Hard palate growth.

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CASE REPORT

The patient was then counseled for surgery after getting a plain computed tomography (CT) scan (Fig. 2) to rule out any erosion of the palate. The scan also revealed a soft tissue mass in the hard palate region.

Prior to the surgery, as an OPD procedure, alginate impression was taken by the oromaxillofacial surgeon and a 3D cast was made using type 2 dental stone to fabricate an obturator post surgery.

This obturator was used to protecting the surgical wound from infection in the postoperative period and prevent dehiscence as the surgical site was devoid of any soft tissue graft.

Routine blood investigations were also done and after obtaining physician's fitness the patient underwent surgical excision of the growth under general anesthesia.

The growth was excised in total after ensuring that there were no residual extracapsular projections, which could lead to a further recurrence. The defect was sutured and the prefabricated obturator with an antiseptic dressing comprising of a povidone-iodine gauze was kept *in situ*, with a nasogastric tube inserted in order to ensure no

contamination of the wound occurred once feeding was started (Fig. 3).

The excised mass was sent for histopathological examination (Figs. 4-6).

The microscopic picture showed epithelial and stromal components (Fig. 7). The epithelial component had epithelial cells arranged in tubules, acini, chords; cystic spaces were also seen. The stromal component had myxoid and hyalinized areas with spindle cells which goes in favor of pleomorphic adenoma.

On the 5th postoperative day, the patient was discharged with oral antibiotics and instructions regarding oral hygiene and advised to follow-up after a week to the ENT OPD (Fig. 8).

The patient has been followed up for 3 months, has excellent healing with no complaints and no signs of recurrence.



Figure 2. CT scan film of the patient showing the hard palate region.



Figure 3. Intraoperative photo of the growth excised with bite block *in situ*.



Figure 4. The palatal mass excised in total.

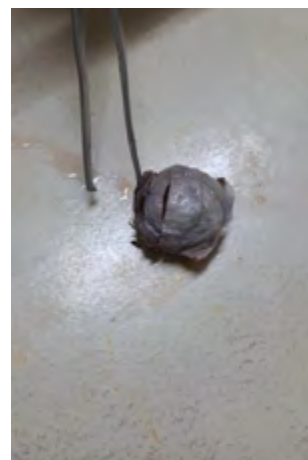


Figure 5. Pathological specimen of the growth.



Figure 6. Cut section of the specimen.

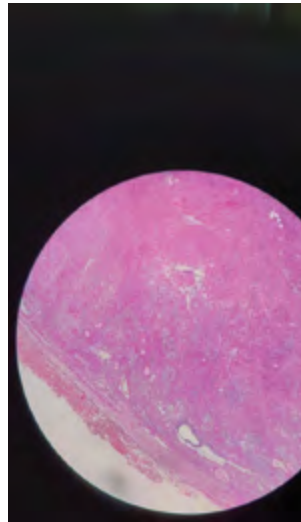


Figure 7. Microscopic picture of the specimen.



Figure 8. One week post-op picture with healthy granulation tissue.

DISCUSSION

Pleomorphic adenomas are derived from a mixture of ductal and myoepithelial elements.³ They are the commonest benign salivary gland tumors (80%) as well as the commonest benign tumor of the minor salivary gland. It occurs most frequently on the palatal area (73%),⁴ commonly seen on the posterolateral aspect of the palate. Females are more affected than males with a ratio of 2:1; commonly seen in the 40 to 50 years age group.

It is detected and treated earlier than tumors of the major salivary gland.⁵ If the overlying mucosa is ulcerated, then malignancy should be suspected.

CT scan is an important diagnostic tool in such tumors as it helps to determine the extent of the lesion. Since it

is a benign tumor, it is less likely to cause invasion of the bone; however, it may cause bone resorption due to pressure effect.⁶

Tumors of the hard palate are usually excised down to the periosteum including the overlying mucosa with 1 cm margin at the periphery. Pleomorphic adenoma does not recur after adequate surgical excision. Reasons for recurrence include incomplete excision of the tumor in total, seeding or cutting through the microscopic extracapsular projection.⁶

CONCLUSION

The patient recovered well after the surgery, and on the 5th postoperative day, she was discharged with oral antibiotics and instructions for oral hygiene. Follow-up examinations showed excellent healing with no signs of recurrence.

Pleomorphic adenomas are derived from a mixture of ductal and myoepithelial elements and are the most common benign salivary gland tumors. They frequently occur in the palatal area, with females being more affected than males. Complete surgical excision is the treatment of choice, and recurrence is rare if the tumor is adequately removed.

This case highlights the successful management of a pleomorphic adenoma in the hard palate, emphasizing the importance of multidisciplinary involvement and thorough surgical excision for optimal patient outcomes.

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The Pyramid of Transgender Health Therapeutics

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ABSTRACT

Transgender care needs a multidisciplinary team approach. The awareness about transgender health has increased over the past few years in India. The pyramid of transgender health helps to demystify the care of transgender individuals. The 7 S's of lifestyle modification need to be followed in the routine clinical care of transgender individuals. The individuals also need psychological care and support, metabolic and medical care, endocrine management, and later surgery in some cases. The policy makers can use the pyramid to decide about financial help to the community for their holistic care. The physicians involved in the care of transgender individuals can also take guidance about comprehensive care and management of transgender and gender diverse individuals.

Keywords: Transgender health, gender diversity, gender affirmation, hormone therapy

Transgender health is a complex multidimensional topic, which requires inputs from various clinical, as well as non-clinical disciplines. In recent years, transgender health has become more visible in India. Though the number is still inadequate, many health care systems now offer comprehensive health services to the transgender community. It does become daunting, however, to start a green-field transgender health service, or to begin integrating transgender health into pre-existing health care systems. We propose a pyramid of transgender health therapeutics, which can be used as a template by health care professionals, planners, policymakers and payers, to address this challenge. This model helps 'demystify' transgender health, and

allows addressal of various health needs in a step-wise manner. It will also assist planners and policymakers in ensuring efficient coverage of the marginalized transgender persons and gender diverse community. Payers, such as insurance companies and government-funded schemes, can use this pyramid to streamline transgender health care delivery (Fig. 1). The base of the pyramid, for transgender health and for all chronic health care, is lifestyle modification. This includes the 7 S's, as elucidated in Table 1. These should be integrated and offered at all levels of health care, from primary upwards.

In transgender and gender diverse individuals, this advice should be linked with pragmatic psychological

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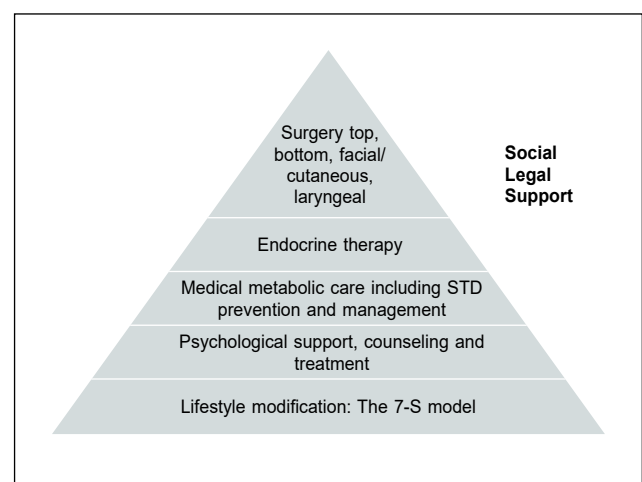


Figure 1. The Pyramid of transgender therapeutics.

Table 1. The 7 S's of Lifestyle Modification: Primary Care for Transgender Persons

Sensible sustenance (diet)
Structured physical activity (exercise)
Stress management (psychological first aid)
Sleep hygiene
Substance abuse avoidance
Safe and sage sex practices
Social support

support, counseling and treatment. Psychological first aid is a useful concept which finds traction in emergency situations. However, similar aid is needed by many transgender persons seeking health care. All health care providers should be skilled at offering such support. Persons who require more in-depth psychological care may be referred to a mental health professional. Infection (sexually transmitted disease or STD) prevention and treatment, as well as metabolic care, is an important part of transgender medicine. Such interventions should be offered at the secondary health care level, and also at the primary care level, if possible.

Endocrine interventions, including gender affirmative hormonal therapy (GAHT) should be available at all endocrine tertiary care institutions. However, services may not exist in all centers, or may be over worked because of the heavy burden of endocrine and metabolic illness. Therefore, it makes sense to create centers of excellence across the country, which can provide not only endocrine, but surgical support as well. Primary and secondary care physicians need to be aware of side effects of GAHT and monitor general and cardiometabolic health and seek timely referral.

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Regular oncology monitoring as per guidelines, at secondary and tertiary care level should not be overlooked. Transgender surgery is a complex field, which includes top surgery, bottom surgery/Laser and laryngeal modification. This forms the apex of the pyramid of transgender therapeutics.

SUMMARY

The model that we propose offers a simple, yet robust method of integrating health care provision. A family-centric and family-strengthening systemic approach, which seeks to normalize/depathologise diversity and nonconformity by listening to and learning from the lived experience of the individual, provides care tailored to the needs of the individual.

The care providers need to be taught, trained and certified, ensuring that they are proficient enough to look two decades ahead and possess the capability of providing lifelong holistic care with compassion. We reiterate as well as sensitization of health care providers of all cadres is essential if effective, person-friendly care is to be provided to the community. Social, legal and financial support will be needed at all stages. We hope this opinion piece will stimulate reflection, and spearhead action, towards achieving optimal care for all transgender and gender diverse individuals.

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Role of Nutrition in Heart Disease

BS BAL

CONCERNS

- Unhealthy dietary patterns (i.e., excessive intake of sodium and processed foods; added sugars; unhealthy fats; low intake of fruit and vegetables, whole grains, fiber, legumes, fish and nuts) increases the probability of developing cardiovascular disease (CVD).¹
- CVD often presents with multiple comorbidities, such as obesity, diabetes, hypertension or dyslipidemia.¹
- CVD includes a spectrum of disorders affecting the heart and blood vessels, like hypertension, stroke, atherosclerosis, peripheral artery disease and vein diseases.¹
- Other factors like lack of exercise, overweight and obesity, stress, alcohol consumption or a smoking habit also contributes.¹

SOLUTION

- The surge in the incidence of CVD has made it a public health priority, particularly the prevention of CVD (or cardiovascular [CV] events) through lifestyle interventions.¹
- Scientific evidence proves nutrition might be the most preventive factor of CVD death, and may even have the potential to reverse heart disease.¹
- Additionally, diet also helps to manage other risk factors like excess weight, hypertension, diabetes or dyslipidemia.¹

DIETARY PATTERNS

- Healthy dietary patterns are associated with lower plasmatic concentrations of pro-inflammatory markers.¹
- A Western-type diet (meat-based dietary pattern) is associated with higher levels of low-grade inflammation.¹
- Thus, CVD guidelines recommend a healthy diet.¹

- Dietary intervention renders a preferable combination of multiple foods and nutrients.¹
- Thus, healthy dietary patterns have a greater spectrum of benefits than the potential effects of a single nutrient supplementation.¹
- All healthy dietary patterns encourage a high intake of fiber, antioxidants, vitamins, minerals, polyphenols, monounsaturated and polyunsaturated fatty acids (MUFA and PUFA, respectively); low intake of salt, refined sugar, saturated and trans fats and carbohydrates of low glycemic load.¹
- This can be simplified as high intake of fruits, vegetables, legumes, fish and seafood, nuts, seeds, whole grains, vegetable oils (mainly, extra-virgin olive oil [EVOO]), and dairy foods together with a low intake of pastries, soft drinks and red and processed meat.¹
- Mediterranean and Dietary Approaches to Stop Hypertension (DASH) interventions reduces the incidence CVD by down-regulating low-grade inflammation and better control of body weight, which also helps to improve other risk factors.¹

Mediterranean Diet

- Mediterranean diet (MedDiet) benefits CVD by controlling the risk factors to improve blood pressure (BP), lipid profile, glucose metabolism, arrhythmic risk or gut microbiome.¹
- MedDiet also has an anti-inflammatory effect on the vascular wall.¹
- MedDiet also modulates the expression of pro-atherogenic genes as cyclooxygenase-2 (COX-2), monocyte chemoattractant protein (MCP)-1 and low-density lipoprotein receptor-related protein (LRP1), reducing plasmatic levels of plaque stability and rupture-related molecules as matrix metalloproteinase (MMP)-9, interleukin (IL)-10, IL-13 or IL-18.¹

DASH Diet

- DASH dietary pattern is associated with improvements in BP, body weight, glucose-insulin homeostasis, blood lipids and lipoproteins, inflammation

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grade, endothelial function, the gut microbiome, CVD risk and total mortality.¹

- The DASH diet recommends a high intake of fruits and vegetables, legumes, low-fat dairy, whole grain products, nuts, fish and poultry; a reduced intake of saturated fat, red meat and processed meats, and sweet beverages; and a low intake of sodium and refined grains.¹
- DASH diet protects from CVD by reducing the inflammatory markers and oxidative stress.¹

FOODS

Fruits and Vegetables

- The European Society of Cardiology (ESC) and American Heart Association Nutrition Committee firmly support the daily consumption of multiple servings of both fruits and vegetables to reduce the risk of CVD.¹

Olive Oil

- Olive oil rich diets have anti-inflammatory effects.¹
- Bioactive components of EVOO cause improvements in inflammatory status, oxidative stress and endothelial dysfunction.¹

Nuts

- Nuts, particularly peanuts and walnuts have the potential to reduce the CVD morbidity and mortality.¹
- Consuming 20-30 g/day of unsalted nuts and almonds, or 150 g/week is recommended to improve blood lipids and reduce CVD risk.²

Wine and Other Fermented Alcoholic Beverages

- Some epidemiologic studies and randomized controlled trials (RCTs) have shown that regular moderate consumption of fermented alcoholic beverages, mainly red wine and beer, has cardio-protective effects.¹ They can also exert a positive effect on CV risk factors.¹
- There exists no recommendation to start drinking alcohol for health benefits.²

NUTRIENTS

Fiber

- Dietary fiber intake decreases cholesterol concentrations and BP, while deficiency of fiber intake is associated with CVD development.¹

- Higher dietary fiber intake lowers the relative risk of total all-cause mortality.¹

- Dietary fiber decreases glucose absorption, down-regulates the expression of oxidative stress-related cytokines or the inflammatory response mediated by gut microbiota exposed to fiber.¹ It is recommended to consume 14 g/1000 kcal, or 25 g dietary fiber for adult women and 38 g for adult men.²

Micronutrients

- Micronutrients have protective effects in CVD by reducing endothelial cells damage, improving the production of nitric oxide (NO) and inhibiting the oxidation of low-density lipoprotein cholesterol (LDL-C).¹
- Deficiency of dietary antioxidants (Zn, Se and vitamin C & E) leads to a higher CVD risk.¹

BIOACTIVE COMPOUNDS

Bioactive compounds have a beneficial effect on atherosclerosis development by reducing levels of LDL-C, improving inflammatory and oxidative stress biomarkers.¹

Omega-3 Fatty Acids

- PUFAs, like omega-3 fatty acid (Ω -3 PUFA), α -linolenic acid (ALA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are known to be the potential antiatherogenic agents.¹
- They reduce CV risk by improving the lipid and lipoprotein profile, oxidation, thrombosis, endothelial function, BP, plaque stability, CV mortality, platelet aggregation, modulating concentration or expression of pro-inflammatory markers (adhesion molecules, cytokines, etc.) and immune cells.¹

Lycopene

- Lycopene reduces atherosclerotic risk, particularly in early stages of atherosclerosis, by preventing endothelial dysfunction (NO bioavailability and blood flow) and LDL oxidation.¹
- Lycopene also improves the metabolic profile (by impairing cholesterol synthesis) and BP, through reductions in arterial stiffness, and modulation of the expression of pro-inflammatory markers and platelet aggregation.¹

Phytosterols

- A daily dose of 2-3 g of plant sterols or phytosterols causes LDL-C reduction of early 6% to 15% of the total concentration.¹

POLYPHENOLS

- Polyphenols are obtained from food sources like fruit and vegetables, red wine, black and green tea, coffee, EVOO, chocolate, nuts, seeds, herbs and spices.¹
- Polyphenols delay the progression of atherosclerosis by regulating signaling and transcription pathways, like nuclear factor kappa B (NF- κ B); antioxidant systems; preventing leukocyte migration and later infiltration inside plaque; reducing adhesion molecules levels; inhibiting encoding of pro-inflammatory cytokines; reducing BP because of the enhanced NO production; and improving lipid metabolism, coagulation activity and endothelial function.¹
- There exists a negative association between the consumption of polyphenols or polyphenols-rich foods and CVD.¹
- Polyphenols cause significant reductions of LDL-C, systolic BP, fasting glucose, body mass index (BMI), hemoglobin A1c or tumor necrosis factor (TNF)- α

levels and significant increments of high-density lipoprotein cholesterol (HDL-C).¹

- They also have anti-inflammatory and immune-modulating effects.¹

CONCLUSION

- There exists an intimate relationship between nutrition and CVD.
- Thus, healthy dietary habits along with an active lifestyle should be promoted as early as possible in children and young adults.
- The evidence supports consumption of healthy dietary patterns, like the MedDiet or DASH diet, against other unhealthy dietary patterns, like the Western diet.

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Frailty: A Predictor of Hospitalization in COPD Patients

Frail patients with chronic obstructive pulmonary disease (COPD) are more likely to be hospitalized for acute disease exacerbations, suggests a recent study presented at ATS 2023, held last month in Washington, DC. The study findings were also published in the *American Journal of Respiratory and Critical Care Medicine*.¹ In this prospective study, 172 patients with COPD were enrolled from May 2018 to January 2019 to determine the factors that were predictive of hospitalization. The median age of the selected patients was 68 years and they were followed up for 12 to 15 months. Symptoms were evaluated with the COPD assessment test (CAT) score and modified Medical Research Council (mMRC) dyspnea scale; the FRAIL scale was used to measure frailty, while comorbidities were examined with the Charlson Comorbidities Index.

Twelve percent of the patients were smokers, 22% had asthma-COPD overlap syndrome. Almost half (48.3%) of the patients were found to be frail. The median CAT score was 15, the median MRC score was 3, while the median score on the FRAIL scale was 2. The median FEV1% post-bronchodilator was 51.3%. Majority (86.6%) were taking the prescribed treatment; of these, 75% were also using inhaled steroids along with long-acting bronchodilators. Nearly 20% of the participants gave a history of being hospitalized for exacerbation of COPD at the time of their recruitment. The hospitalization rate was found to be 0.33 per patient during the follow-up. At the time of the first assessment, the hospitalization rate was 9.4% and at the last evaluation, this had reduced to 3.8%. "Only frailty and "time in follow-up" were statistically and clinically relevant".

For every 1 unit increase in frailty on the FRAIL scale, the likelihood of COPD hospitalization increased 41% with aOR of 1.41. This study therefore demonstrated that frail COPD patients are at greater risk of related hospitalization. Identification of frail patients may allow targeted interventions to reduce the risk of exacerbations and subsequent hospitalization.

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Insight into Medicolegal Issues

ARE ADVANCE MEDICAL DIRECTIVES LEGAL IN INDIA?

Yes, in the landmark judgment titled as “**Common Cause versus Union of India, 2018 (5) SCC 1** passed by the Hon’ble Constitution Bench of 4 Judges of the Supreme Court of India, it has duly held that the advance medical directives are legal in India.

Further in the said judgment, the Hon’ble Apex Court has laid down certain guidelines and directions w.r.t. advance medical directives which shall remain in force till the Parliament makes legislation on this subject.

The Hon’ble Supreme Court has held that:

In our considered opinion, Advance Medical Directive would serve as a fruitful means to facilitate the fructification of the sacrosanct right to life with dignity. The said directive, we think, will dispel many a doubt at the relevant time of need during the course of treatment of the patient.

That apart, it will strengthen the mind of the treating doctors as they will be in a position to ensure, after being satisfied, that they are acting in a lawful manner. We may hasten to add that Advance Medical Directive cannot operate in abstraction. There has to be safeguards. They need to be spelt out. We enumerate them as follows:

(a) Who can execute the Advance Directive and how?

- i. The Advance Directive can be executed only by an adult who is of a sound and healthy state of mind and in a position to communicate, relate and comprehend the purpose and consequences of executing the document.
- ii. It must be voluntarily executed and without any coercion or inducement or compulsion and after having full knowledge or information.
- iii. It should have characteristics of an informed consent given without any undue influence or constraint.
- iv. It shall be in writing clearly stating as to when medical treatment may be withdrawn or no specific medical treatment shall be given which will only have the effect of delaying the process of death that may otherwise cause him/her pain, anguish and suffering and further put him/her in a state of indignity.

(b) What should it contain?

- i. It should clearly indicate the decision relating to the circumstances in which withholding or withdrawal of medical treatment can be resorted to.
- ii. It should be in specific terms and the instructions must be absolutely clear and unambiguous.
- iii. It should mention that the executor may revoke the instructions/authority at any time.
- iv. It should disclose that the executor has understood the consequences of executing such a document.
- v. It should specify the name of a guardian or close relative who, in the event of the executor becoming incapable of taking decision at the relevant time, will be authorized to give consent to refuse or withdraw medical treatment in a manner consistent with the Advance Directive.
- vi. In the event that there is more than one valid Advance Directive, none of which have been revoked, the most recently signed Advance Directive will be considered as the last expression of the patient’s wishes and will be given effect to.

(c) How should it be recorded and preserved?

- i. The document should be signed by the executor in the presence of two attesting witnesses, preferably independent, and countersigned by the jurisdictional Judicial Magistrate of First Class (JMFC) so designated by the concerned District Judge.
- ii. The witnesses and the jurisdictional JMFC shall record their satisfaction that the document has been executed voluntarily and without any coercion or inducement or compulsion and with full understanding of all the relevant information and consequences.
- iii. The JMFC shall preserve one copy of the document in his office, in addition to keeping it in digital format.
- iv. The JMFC shall forward one copy of the document to the Registry of the jurisdictional District Court for being preserved. Additionally, the Registry of the District Judge shall retain the document in digital format.
- v. The JMFC shall cause to inform the immediate family members of the executor, if not present at the time of execution, and make them aware about the execution of the document.

- vi. A copy shall be handed over to the competent officer of the local Government or the Municipal Corporation or Municipality or Panchayat, as the case may be. The aforesaid authorities shall nominate a competent official in that regard who shall be the custodian of the said document.
 - vii. The JMFC shall cause to handover copy of the Advance Directive to the family physician, if any.
- (d) When and by whom can it be given effect to?**
- i. In the event the executor becomes terminally ill and is undergoing prolonged medical treatment with no hope of recovery and cure of the ailment, the treating physician, when made aware about the Advance Directive, shall ascertain the genuineness and authenticity thereof from the jurisdictional JMFC before acting upon the same.
 - ii. The instructions in the document must be given due weight by the doctors. However, it should be given effect to only after being fully satisfied that the executor is terminally ill and is undergoing prolonged treatment or is surviving on life support and that the illness of the executor is incurable or there is no hope of him/her being cured.
 - iii. If the physician treating the patient (executor of the document) is satisfied that the instructions given in the document need to be acted upon, he shall inform the executor or his guardian/close relative, as the case may be, about the nature of illness, the availability of medical care and consequences of alternative forms of treatment and the consequences of remaining untreated. He must also ensure that he believes on reasonable grounds that the person in question understands the information provided, has cogitated over the options and has come to a firm view that the option of withdrawal or refusal of medical treatment is the best choice.
 - iv. The physician/hospital where the executor has been admitted for medical treatment shall then constitute a Medical Board consisting of the Head of the treating Department and at least three experts from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least 20 years who, in turn, shall visit the patient in the presence of his guardian/close relative and form an opinion whether to certify or not to certify carrying out the instructions of withdrawal or refusal of further medical treatment. This decision shall be regarded as a preliminary opinion.
 - v. In the event the Hospital Medical Board certifies that the instructions contained in the Advance Directive ought to be carried out, the physician/hospital shall forthwith inform the jurisdictional Collector about the proposal. The jurisdictional Collector shall then immediately constitute a Medical Board comprising the Chief District Medical Officer of the concerned district as the Chairman and three expert doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least 20 years (who were not members of the previous Medical Board of the hospital). They shall jointly visit the hospital where the patient is admitted and if they concur with the initial decision of the Medical Board of the hospital, they may endorse the certificate to carry out the instructions given in the Advance Directive.
 - vi. The Board constituted by the Collector must beforehand ascertain the wishes of the executor if he is in a position to communicate and is capable of understanding the consequences of withdrawal of medical treatment. In the event, the executor is incapable of taking decision or develops impaired decision-making capacity, then the consent of the guardian nominated by the executor in the Advance Directive should be obtained regarding refusal or withdrawal of medical treatment to the executor to the extent of and consistent with the clear instructions given in the Advance Directive.
 - vii. The Chairman of the Medical Board nominated by the Collector, that is, the Chief District Medical Officer, shall convey the decision of the Board to the jurisdictional JMFC before giving effect to the decision to withdraw the medical treatment administered to the executor. The JMFC shall visit the patient at the earliest and, after examining all aspects, authorise the implementation of the decision of the Board.
 - viii. It will be open to the executor to revoke the document at any stage before it is acted upon and implemented.
- (e) What if permission is refused by the Medical Board?**
- i. If permission to withdraw medical treatment is refused by the Medical Board, it would be open to the executor of the Advance Directive or his family members or even the treating doctor or the hospital staff to approach the High Court by way of writ petition under Article 226 of the Constitution. If such application is filed before the High Court, the

Chief Justice of the said High Court shall constitute a Division Bench to decide upon grant of approval or to refuse the same. The High Court will be free to constitute an independent Committee consisting of three doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least 20 years.

- ii. The High Court shall hear the application expeditiously after affording opportunity to the State counsel. It would be open to the High Court to constitute Medical Board in terms of its order to examine the patient and submit report about the feasibility of acting upon the instructions contained in the Advance Directive.
- iii. Needless to say that the High Court shall render its decision at the earliest as such matters cannot brook any delay and it shall ascribe reasons specifically keeping in mind the principles of "best interests of the patient".

(f) Revocation or inapplicability of Advance Directive

- i. An individual may withdraw or alter the Advance Directive at any time when he/she has the capacity to do so and by following the same procedure as provided for recording of Advance Directive. Withdrawal or revocation of an Advance Directive must be in writing.
- ii. An Advance Directive shall not be applicable to the treatment in question if there are reasonable grounds for believing that circumstances exist which the person making the directive did not anticipate at the time of the Advance Directive and which would have affected his decision had he anticipated them.
- iii. If the Advance Directive is not clear and ambiguous, the concerned Medical Boards shall not give effect to the same and, in that event, the guidelines meant for patients without Advance Directive shall be made applicable.
- iv. Where the Hospital Medical Board takes a decision not to follow an Advance Directive while treating a person, then it shall make an application to the Medical Board constituted by the Collector for consideration and appropriate direction on the Advance Directive.

DOES A DECISION TAKEN IN GOOD FAITH AMOUNT TO NEGLIGENCE?

A decision taken in good faith is not a crime. Defenses are available to the doctors under Indian Penal Code (IPC) sections 88, 92 and 93.

⇒ **Section 88.** Act not intended to cause death, done by consent in good faith for person's benefit: Nothing, which is not intended to cause death, is an offence by reason of any harm which it may cause, or be intended by the doer to cause, or be known by the doer to be likely to cause, to any person for whose benefit it is done in good faith, and who has given a consent, whether express or implied, to suffer that harm, or to take the risk of that harm.

The illustration along with this section is: "A, a surgeon, knowing that a particular operation is likely to cause the death of Z, who suffers under a painful complaint, but not intending to cause Z's death and intending in good faith, Z's benefit, performs that operation on Z, with Z's consent. A has committed no offence".

⇒ **Section 92.** Act done in good faith for benefit of a person without consent: Nothing is an offence by reason of any harm which it may cause to a person for whose benefit it is done in good faith, even without that person's consent, if the circumstances are such that it is impossible for that person to signify consent, or if that person is incapable of giving consent, and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done with benefit.

The illustration along with this section is: Z is thrown from his horse, and is insensible. A, a surgeon, finds that Z requires to be trepanned. A, not intending Z's death, but in good faith, for Z's benefit, performs the trepan before Z recovers his power of judging for himself. A has committed no offence. A, a surgeon, sees a child suffer an accident which is likely to prove fatal unless an operation be immediately performed. There is no time to apply to the child's guardian. A, performs the operation in spite of the entreaties of the child, intending, in good faith, the child's benefit. A committed no offence.

⇒ **Section 93.** Communication made in good faith. No communication made in good faith is an offence by reason of any harm to the person to whom it is made, if it is made for the benefit of that person. Illustration A, a surgeon, in good faith, communicates to a patient his opinion that he cannot live. The patient dies in consequence of the shock. A has committed no offence, though he knew it to be likely that the communication might cause the patient's death.

HCFI Dr KK Aggarwal Research Fund

Round Table Environment Expert Zoom Meeting on “Importance of Circular Economy in Addressing Waste Management Issues”

June 18, 2023 (Sunday, 12 noon - 1 pm)

- Circular economy is an economic system of closed loop which keeps the product, material and services in circulation for as long as possible.
- Earlier the material is used to make product which when they reached end-of-life became waste and were dumped in landfills and were not re-used.
- In circular economy, resources are mined in such a way that they are made into products and reused for as long as possible and then they become waste. This reduces material use, redesigns material, products and services are less resource-intensive and recaptures waste as a resource to manufacture new material.
- Circular economy is based on 7 R's: Rethink, Reduce, Reuse, Repair, Refurbish, Recover and Recycle. These form the basis to minimize waste and to gain wealth from waste.
- Circular economy is embraced within the sustainable materials approach.
- Benefits include improving security of raw material, boosting economic growth, job creation.
- Circular economy has the potential to address waste management issues, protect environment, reduce impact of climate change, improve economics and elevate social justice.
- The Government of India has brought in the concept of extended producer responsibility (EPR) in waste management. This reduces material consumption, use more of secondary material as much as possible and promotes ecodesign of products.
- Mission LiFE (Lifestyle for Environment) is a mass movement for “mindful and deliberate” use of resources instead of mindless and destructive consumption of resources. There are 75 action points in different sectors.
- Mission LiFE also gels with the circular economy; transition from throwaway culture to circular economy.
- The ultimate aim of circular economy is no waste. Maximum use of this concept will increase quantity of resources and reduce quantity of waste.
- Earlier waste was discarded, then came the term “waste is wealth” and now it is known as “displaced resource”. It is no more considered as waste.
- Bringing the waste into mainstream is circular economy.
- Niti Aayog has focused on 11 end-of-life products/ recyclable materials or waste: Municipal Solid Waste and Liquid Waste, Scrap Metal (Ferrous and Non-Ferrous), Lithium Ion (Li-ion) Batteries, solar panels, gypsum, Toxic and Hazardous Industrial Waste, Used Oil Waste, Agriculture Waste, Tyre and Rubber Recycling and End-of-life Vehicles (ELVs).
- Waste generated in the domestic sector needs to be quantified.
- Landfill site should be the last option. Minimum waste should go to landfill site.
- Incineration of waste at high temperature converts waste to air pollution and if dioxides and furans are not checked, they are released in the environment.
- Nature-based solutions should be adopted. Attitude needs to be changed.
- We still do not have adequate infrastructure. Waste has to be connected with infrastructure.
- Until the cycles and systems are established, success will not be easy.
- Municipalities need to be strengthened.
- Circular economy has always been ingrained in our Indian culture. We are a conservation-based society and not consumption-based society.
- Revival of this idea is good and that it is pushed by the government is also a very welcome step.
- More important than recycle is to reduce.
- Recycling of industrial waste cannot be handled by the common man. This should be done by producers to their ultimate destruction without damaging the environment.

- Consumers should reduce their consumption based on their needs.
- Today, we don't know how to reuse products. This may be due to lack of vocational training, which used to be imparted earlier.
- All our developmental indexes are consumption-based.
- Recovery of precious materials from e-waste is not as much as is being done in many European countries.
- Waste should be handed over only to authorized waste collector for scientific recycling of waste.
- PET plastic industry in India is estimated to be around 400 million US dollars, according to the National Chemical Laboratory.
- Municipal solid waste is the most serious issue mainly because of lack of segregation.
- All metro cities should have recycling plants. Delhi has no recycling plant for plastic.
- Lack of adequate infrastructure or funding or lack of will/intention could be the reasons for the slow progress.
- The Central Pollution Control Board (CPCB) portal is tracking the complete process of EPR in plastic waste management, which has become mandatory now.
- E-waste and battery waste rules also have provisions for EPR.
- The producers should draw up a complete process of recycling of product after end of life and educate the public about it. This should be mandatorily written on the package.

Participants: Dr Anil Kumar, Mr Paritosh Tyagi, Dr Dipankar Saha, Dr SK Gupta, Dr Sanjeev Agrawal, Mr Neeraj Tyagi, Mr Rajeev Sharma

Coronavirus Updates

Covid cases in India continue to decline

With 169 new COVID cases recorded 8th June, the total number of active cases in the country has declined to 2555, as per latest data from the Health Ministry. The active cases now constitute 0.01% of the total infections. The national recovery rate currently stands at 98.81%. With two deaths occurring in the last 24 hours, the total death toll is 5,31,888. The case fatality rate is 1.18%. The total number of vaccine doses administered till date is over 220.66 crores... (Source: *Economic Times*, June 9, 2023).

EMA supports WHO call to update COVID vaccines

The European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) have upheld the WHO's call to update the COVID-19 vaccine to target the currently circulating strains of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) namely the XBB variants. According to these organizations, the monovalent XBB-containing vaccines could be considered a reasonable choice till further data is available... (Source: *Reuters*, June 6, 2023).

Health-related quality of life in long COVID worse than in advanced cancers

A study from the UK suggests that the health-related quality of life in patients with long COVID experience is worse than those with advanced cancers such as stage 4 lung cancer. They experience fatigue that is comparable to or worse than that seen in patients with cancer-related anemia or severe kidney disease ... (Source: *PTI*, June 8, 2023).

Rheumatic disease patients not at higher risk of long COVID

Patients with inflammatory rheumatic diseases are not at a significantly higher risk of long COVID, suggests a study presented at the 2023 annual meeting of the European Alliance of Associations for Rheumatology (EULAR).

The symptoms such as fatigue and poor fitness in these patients that resemble that of long COVID could be due to the underlying disease ... (Source: *Medscape*, June 7, 2023).

Safety of COVID vaccines in children younger than 5 years

Analysis of data of more than 2,47,000 COVID mRNA vaccine doses, Pfizer-BioNTech or Moderna, administered to children aged ≤5 years did not show any major side effects of the vaccine. No cases of myocarditis or pericarditis were reported within 21 days of taking the vaccine. One case each of pulmonary embolism and hemorrhagic stroke were found, but they were correlated to pre-existing congenital abnormalities... (Source: *Pediatrics*, June 6, 2023).

Less than 100 new cases recorded in India

A total of 96 new cases of COVID-19 were reported (15th June) in the country, according to latest data from the Union Health Ministry. While the total tally of COVID cases rose to 4,49,93,282, the number of active cases

declined to 2017 from 2,555 last week. Total deaths so far are 5,31,893... (Source: PTI, June 16, 2023).

FDA recommends monovalent XBB COVID vaccine

An FDA (Food and Drug Administration) advisory committee has recommended removing the wild strains of SARS-CoV-2 and formulating a monovalent COVID-19 vaccine, targeting only the XBB-sublineages, which now account for more than 95% of the circulating variants in the United States. The sublineages currently under consideration include XBB.1.5, XBB.1.16 or XBB.2.3... (Source: FDA, June 15, 2023).

Recovery of loss of smell or taste in COVID-19

Around 75% of patients who lost their sense of taste and smell recovered completely and nearly 21% had partial recovery. Less than 3% reported no recovery of taste and smell. Nearly 60% of the 36 million people who developed COVID-19 in 2021 reported loss of smell or taste. Recovery was less likely among those who had severe infection ... (Source: Laryngoscope, June 2, 2023).

Incident GI complications in long COVID

Patients with COVID-19 are at 36% greater risk of developing new-onset gastrointestinal (GI) complications within 30 days after recovery from the acute phase of the infection and experience disorders like functional dyspepsia, gastroesophageal reflux disease, peptic ulcer disease, acute gastritis, cholangitis, peptic ulcer disease, irritable bowel syndrome, acute pancreatitis. Constipation and diarrhea were also common among these patients... (Source: Nature Communications, March 2023).

Postural orthostatic tachycardia syndrome in COVID-19

Patients who recover from COVID-19 may develop postural orthostatic tachycardia syndrome (POTS) within 6 to 8 months of the infection. Fatigue, tachycardia (≥ 30 from the normal resting heart rate), orthostatic intolerance and cognitive impairment are major symptoms. Its early identification and management is crucial. A high index of suspicion is required for diagnosis... (Source: Cureus. March 31, 2023).

COVID-19 cases in India

With 40 new COVID infections recorded in 30th June, the total number of active cases has now declined further to 1,513 from 1,533 a day before, according to updated data from the Union Health Ministry. The

total numbers of COVID cases are nearly 4.5 crores. The recovery rate is 98.8%. Total COVID-related deaths are 5,31,906 with case fatality rate of 1.18%. Over 220.66 crore doses of COVID vaccine have been administered till date... (Source: The Hindu, July 1, 2023).

Moderna seeks FDA approval for its updated COVID vaccine

Moderna has developed a new COVID-19 vaccine targeting the XBB 1.5 strain, which is currently the dominant circulating strain. The company has applied to the FDA seeking approval of its new vaccine. According to Moderna, the common side effects of the new updated vaccine include headache, fatigue, chills, injection site pain... (Source: Medscape, June 26, 2023).

EU.1.1: A new variant of COVID virus

A new SARS-CoV-2 variant named "EU.1.1" has been detected in the United States. It is an XBB sublineage related to the XBB.1.5 variant and emerged in early June. The EU.1.1 currently accounts for ~2% of COVID cases in the United States. So far, detection of the new variant has not led to increase in hospital admissions. Although it is more transmissible than XBB.1.5, its parent lineage, there are no red flags so far... (Source: Medpage Today, June 27, 2023).

Prolonged prone ventilation associated with reduced mortality in intubated COVID patients

A study published in the journal *Chest* has found that 30-day and 90-day mortality was less when intubated COVID patients received prone position ventilation for prolonged duration amounting to 24 hours or more compared to those who received intermittent prone position ventilation. There was a small increase in facial edema in these patients, but the overall related complications remained the same... (Source: Chest, March 2023).

Persons with blood group A are at high risk of COVID-19

A new study has shown that the SARS-CoV-2 preferentially infects the blood group A cells suggesting that blood group may be a predictor of COVID-19 infection. In this study, the receptor binding domains of SARS-CoV-2, including Delta and Omicron variants, exhibited specificity for blood group A and displayed a preferential ability to infect blood group A expressing cells... (Source: Blood, June 27, 2023).

With inputs from Dr Monica Vasudev

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India Live 2023

HOW EFFECTIVE IS FRACTIONAL FLOW RESERVE AT GUIDING THE TREATMENT OF CORONARY ARTERY DISEASE?

Dr Kirti Punamiya, Mumbai

Unlike coronary angiography alone, fractional flow reserve (FFR) assists interventional cardiologists in accurately determining whether coronary atherosclerotic plaques are responsible for myocardial ischemia and needs to be revascularized. FFR is unparalleled in diagnostic performance compared to nonhyperemic indices and noninvasive techniques. It continues to be the gold standard for the detection of ischemia-inducing coronary stenoses. FFR-guided percutaneous coronary intervention (PCI) is reported to be superior to angiography-guided PCI and over medical therapy alone.

FAME 2 trial investigators demonstrated that in patients with stable coronary artery disease (CAD), FFR-guided PCI, compared with medical therapy alone, improved the outcome. A meta-analysis supported current guidelines advising FFR-guided PCI strategy for CAD. FFR-guided PCI was associated with lower major adverse cardiac events/major adverse cardiac and cerebrovascular events (MACE/MACCE), death myocardial infarction (MI), repeat revascularization, and death or MI than angiography-guided PCI strategy. Revascularization guided by FFR in patients with CAD and stenoses >50% yields better outcomes than revascularization based on a visual analysis of angiographic stenosis severity alone. DEFER and FAME trials have shown that in patients with stable CAD, conservative management of stenoses that could be angiographically severe but are not hemodynamically relevant is safe.

FFR is, therefore, an important tool to guide treatment in CAD.

DECIPHERING THE ROLE OF STENT DESIGN AND POLYMER – FROM ACUTE TO LONG-TERM RESULTS

Dr Alope Finn, USA

Drug-eluting stents (DES) differs in thromboresistance, which is an important requirement for short-term dual antiplatelet therapy (DAPT). Under aspirin and clopidogrel monotherapy in the porcine arteriovenous (AV) shunt model, XIENCE™ stent showed the lowest

amount of platelet aggregation and inflammation in shunt models compared to leading biodegradable polymer stents as well as permanent polymer DES. When considering short-term DAPT, the capability of thromboresistance in individual stents is important. Those differences of thromboresistance in stents may require a different duration of DAPT for each type of stent. The results of XIENCE 28 and 90 lend further support that short-term DAPT with the XIENCE™ stent is feasible and safe. The results of STOPDAPT-2 ACS suggest ACS patients per se should continue on DAPT for at least 6 to 12 months if feasible. Long-term outcomes with XIENCE™ remain good in part because of the stability of the PVDF-HFP polymer and its effects on coronary inflammation.

ARE YOU APPROACHING THE GRAY ZONE?

Dr TS Kler, New Delhi

Fractional flow reserve is considered the gold standard in invasive hemodynamic assessment of epicardial coronary artery stenoses. FFR informs the clinician about how much the blood flow is reduced and can be improved after revascularization. For instance, an FFR of 0.60 means that coronary blood flow is 60% of what should be in the absence of epicardial stenosis, and it could improve by 40% after PCI. FFR is highly reproducible, has an unsurpassed spatial resolution, and is easy to measure during diagnostic coronary angiography. FFR ≤ 0.75 has a 100% positive predictive value, while FFR > 0.80 has more than 95% negative predictive value for reversible myocardial ischemia at noninvasive functional testing. In the era of DES, the threshold of 0.80 was adopted in the FAME 1 and 2 trials to guide clinical decision-making since, in a minority of patients, an FFR value between 0.75 and 0.80 has been found to be associated with typical exercise-induced-angina and reversible flow maldistributions. Revascularization of coronary stenosis with FFR ≤ 0.80 has been associated with improved clinical outcomes in randomized trials and routine clinical practice. For patients in the 'gray zone', i.e., FFR values of 0.75-0.80, physician decision-making informed by all clinical information (e.g., anginal symptoms and noninvasive evidence of ischemia) is especially important.

A recent study revealed that in comparison with low-FFR lesions (< 0.75), those in the gray-zone FFR (0.75-0.80)

are less likely to have improvement or more likely to have impairment in flow after PCI. The findings suggested that the index of microcirculatory resistance measurement may help identify lesions in the FFR gray zone that are most likely to improve. FFR measurements represent a continuum of ischemic values, and a single dichotomous threshold oversimplifies the answer to whether a lesion should be revascularized.

OLD FRIEND DES, NEW BUDDY BRS AND CAMERAMAN OCT

Dr Girish B Navasundi, Bengaluru

Metallic DES remain in arteries permanently. They not only increase the likelihood of adverse outcomes but also increase the risk of comorbidities if additional procedures need to be done in the same artery. However, a more recent kind of stent known as a bioresorbable scaffold (BRS) offers a transient scaffold to the lesion to re-establish blood flow; however, after the vessel blockage is treated and healing is complete, the BRS completely dissolves, leaving the artery in its natural state with no foreign residue. Earlier, there were multiple limitations associated with the first-generation BRS, such as:

- Increased strut thickness
- Lack of radiopacity
- Need for special storage requirements
- Increased risk of late ST
- Limitation of size matrix.

However, the new generation BRS is more advanced than the first-generation BRS and offers special features, such as:

- Hybrid cell design
- 100 µm strut thickness
- High vessel conformability
- Optimal side branch access
- Estimated degradation in 2 to 3 years
- 1.2 mm low-profile delivery system
- Low balloon overhang
- Short, abrupt balloon overhangs.

“Stents are used in the procedure to provide a scaffold for the lesion, not to provide lumen gain”.

IVUS – IMAGE ARTEFACTS

Dr Arun Mohanty, New Delhi

Artefacts in intravascular ultrasound (IVUS) imaging are an infrequently inevitable phenomenon due to the

inherent limitations of the ultrasound modality itself. In most cases, it is brought on by external electrical interference, which can be caused by the number of equipment placed in the lab.

On the other hand, near-field artefacts can be classified into:

- Air bubble artefacts
 - Air trapping in the sheath of the IVUS catheter
 - Primarily responsible for poor imaging quality.
- Ring down artefacts
 - Bright halo of variable thickness caused by the interference of rotating piezoelectric crystals in the catheter
 - Produced by acoustic oscillations in transducers
 - Creates a zone of uncertainty adjacent to the transducer surface
 - Common in the solid-state system.
- Blood speckle artefacts/stagnant flow
 - Intensity of blood speckle artefacts increases with the frequency of the catheter
 - Stasis produced by the interference is most visible when a catheter is across a tight stenosis.

But it has to be pointed out that reverberations caused by air bubbles are easily avoidable by saline flushing the IVUS catheter before use, whereas contrast flush can help in dealing with the stagnant flow.

There are several other types of artefacts, such as:

- Shadowing artefacts can be caused by calcium, stent or guidewire. As a result of the shadow effect, analysis of the vessel behind the artefact becomes difficult.
- Guide catheter artefact.
- Catheter motion artefact can be divided into the catheter to-and-fro motion artefact and nonuniform rotational distortion (NURD).
- Side lobe artefact
 - Intense reflections of the side beam from the edge of strong reflectors, such as calcium and stent, which forms the image along with the original image
 - Follow the circumferential sweep
 - Mistaken for malapposition or dissection.
- Transducer position artefact
 - Mostly seen in large and tortuous vessels
 - Can cause vessel folding and catheter eccentricity.

Hence, it is essential to recognize the artefact to get a true image of the situation and proceed with the correct treatment. Other key points to remember are:

- Air in the catheter is one of the most common avoidable artefacts.
- NURD can be avoided by a larger size guide, proper care of the hemostatic valve and catheter alignment.
- Measurement error due to the catheter to-and-fro motion or angulation must be considered for device sizing.

LEFT MAIN INTERVENTIONS – PCI OR CABG?

Dr Samin Sharma, USA

Patients with obstructive left main coronary artery (LMCA) disease have often been treated with coronary artery bypass grafting (CABG). The EXCEL trial has, however, shown that PCI with an everolimus-eluting stent is a suitable and less invasive option in patients with a SYNTAX score <32. There was a significant difference between PCI and CABG in terms of the 30-day incidence of procedural MI. Large MIs, including ST-segment elevation MIs, were more common with bypass surgery than with PCI.

A systematic review and meta-analysis suggested that PCI and CABG may be reasonable approaches to revascularization in patients with significant LMCA stenosis and predominantly low to intermediate CAD complexity. Patient preference should be considered regarding the risks of periprocedural complications of surgery and long-term repeat revascularization after PCI. Patients with low surgical risk may benefit from CABG; however, if a patient is not a good candidate for surgery or wishes to avoid the morbidity associated with CABG, PCI is a reasonable option.

RENAL ARTERY STENOSIS

Dr Atul Mathur, New Delhi

Renal artery stenosis (RAS) is a frequently encountered problem in clinical practice. A wide range of diagnostic modalities and treatment approaches for RAS is available to clinicians. With the advent of endovascular interventions, selecting the best course for a given patient has only become more challenging.

This disease encompasses a broad range of pathophysiology, the most common being fibromuscular dysplasia and atherosclerotic renal artery disease. Depending on the degree of narrowing, patients can develop renal vascular hypertension. The results of several trials,

including ASTRAL, EMMA, SNRASCG and DRASTIC, are debatable. Renal angioplasty can reduce systolic and diastolic pressure.

If the patient has indications for renal angiography, it must be done. The ongoing CORAL trial gives hope and shows a positive expectation for renal stenting. Available evidence has supported stenting in RAS in reducing blood pressure, improving the management of refractory hypertension, and preserving or improving renal function.

OPTIMIZING THE FUTURE OF YOUR ACS PATIENTS: MORE STENTS OR MORE PILLS?

Dr Robert Jan Van Geuns, Rotterdam, Netherlands

It is challenging to select between stents or a pill. But regarding the MACE rate after ACS, a study published in 2015 showed that the risk of a recurrent event after 3 years was around 20%. However, another study titled RENOVATE-COMPLEX-PCI showed that intravascular imaging-guided PCI would reduce target vessel failure compared to angiography-guided PCI in treating patients with complex coronary artery lesions.

Meanwhile, another study published in the *New England Journal of Medicine* showed that increased pills improved the MACE rate after ACS. According to the study, 1 mmol/L reduction in low-density lipoprotein (LDL) reduced the event by more than 20%. But the researchers of the study observed a very low adherence rate to statins. They found that over 50% of people do not stick to or use statins.

Hence, based on the inferences taken from the following studies, it was concluded that:

- Optimize your PCI results with selected imaging (IVUS/optical coherence tomography [OCT])
- Selective stenting of bystander lesions (FFR)
- Optimize your secondary preventions with intensive medications.

ANGIOGRAPHY VS. OCT TO GUIDE PCI

Dr Sarita Rao, Indore

Angiography-guided PCI has considerable limitations. On the other hand, the superior spatial resolution of OCT can provide meaningful clinical benefits.

A recent study determined the effect on long-term survival of using OCT during PCI. The cohort study was based on the Pan-London (United Kingdom) PCI registry. OCT was used in 1.3% of patients, IVUS was used in 12.6% of patients, and angiography alone in

the remaining patients. OCT-guided procedures were associated with greater procedural success rates and reduced in-hospital MACE rates.

A significant difference in mortality was observed between patients undergoing OCT-guided PCI (7.7%) compared to patients who underwent either IVUS-guided (12.2%) or angiography-guided (15.7%) PCI, with differences noted for both elective and ACS subgroups.

This large observational study suggested that OCT-guided PCI was associated with improved procedural outcomes, in-hospital events and long-term survival in comparison with standard angiography-guided PCI.

OCT-BASED CALCIUM SCORING ALGORITHM

Dr Takashi Akasaka, Japan

Coronary artery calcification is becoming more prevalent and severe with up to 25% of individuals, or 1 in 4, having moderate to severe calcium. Coronary artery calcifications severely affect PCI outcomes if identified and mistreated. Several studies have shown that calcified lesions limit stent expansion, which is a major predictor of stent failure, such as stent thrombosis and restenosis.

Hence, OCT imaging makes it possible to visualize and quantify the characteristics of coronary calcification, which helps determine the best method for lesion preparation. In addition, OCT enables assessment and optimization of stent deployment including treatment of underexpansion and edge dissections. The advantage of OCT in coronary calcification quantification has led to a scoring system to predict stent under expansion and consequently stent failure.

OCT calcium score: An OCT-based calcium scoring algorithm that measures calcium depth can be used to find calcific lesions that would benefit from plaque reduction prior to stent insertion. This method examines the calcium length, calcium angle and thickness, which are some of the most crucial metrics used to forecast the success and necessity of calcium modification devices.

- Thickness >0.5 mm
- Angle >50% vessel arc
- Length >5 mm.

Evaluation of calcium thickness is key in predicting stent expansion. In OCT, the light can penetrate calcium

thus evaluate its thickness. In cases with heavily calcified lesion:

- OCT allows to demonstrate the position, distribution and thickness of the calcium.
- OCT-based calcium scoring system from 0 to 4 maximum calcium angle, maximum calcium thickness and calcium length should be useful to decide the procedure for getting enough stent expansion by making calcium plate fracture.
- Calcium plate fracture can be made by high pressure ballooning with noncompatible scoring or cutting balloon if the thickness of the layer is <500 µm.

RENOVATE TRIAL

Dr Rony Mathew, Ernakulam

Imaging-guided PCI is the future of interventional cardiology. Newer data related to clinical outcomes after intravascular imaging-guided PCI for complex coronary artery lesions, compared with outcomes after angiography-guided PCI, is needed to establish the integration of imaging in PCIs.

“RENOVATE-COMPLEX-PCI” is a new study recently presented in ACC 2023 that investigated whether **Imaging-guided PCI** using IVUS or OCT would improve clinical outcomes compared with **Angiographic-guided PCI** alone in patients with complex coronary artery lesions. One thousand six hundred thirty-nine patients were randomized in a 2:1 ratio of imaging and angiography-only PCI guidance and were followed to a median of 2.1 years.

Highlights of the clinical study results

- Across the study, the primary endpoint of target vessel failure was met (OCT/IVUS 7.7% vs. Angio alone 12.3%, $p = 0.008$ at 3 years).
- Intravascular imaging-guided PCI was linked to a 37% lower incidence of target-vessel-related MI or death from cardiac causes than angiography-guided PCI.
- In a non-randomized comparison between the two imaging types, OCT showed a numerically lower rate of events (5.8% vs. 8.0%) than IVUS.
- An exploratory sub-analysis of the study, reported in the *NEJM* supplement, showed that stent optimization led to better results, and OCT had a numerically better stent optimization rate.

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News and Views

Muscle Fat: A Novel Risk Factor for Cognitive Impairment

Older adults with high amounts of fat in the skeletal muscles are at risk of greater and faster cognitive decline, according to a new study published June 7, 2023 in the *Journal of the American Geriatrics Society*.¹

Rosano et al measured the intermuscular adipose tissue of the thigh muscle using CT scans in 1,634 adults, aged 69 to 79 years at year 1 and year 6. They also evaluated the participants for cognitive function using the mini-mental state exam (3MS) at years 1, 3, 5, 8 and 10. Almost half (48%) of the selected study subjects were female and 35% were Black.

The researchers found that the intermuscular adipose tissue of the thigh muscle increased by 4.85 cm² (Year 1-6) and the cognitive function declined by 3.20 points (Year 6-10) on the 3MS test. Increase in thigh fat content of 4.85 cm² was associated with decrease of an additional 3.60 points on 3MS.

In this study, a 5-year increase in the fat content of thigh muscle was significantly associated with cognitive impairment suggesting skeletal muscle adiposity as a novel risk factor for cognitive decline. This association between muscle fat and cognitive decline was independent of muscle strength, body composition including the traditional risk factors for dementia. Hence, older adults must be advised to lead a healthy lifestyle with a healthy and well-balanced diet and daily exercise.

Reference

1. Rosano C, et al. Increase in skeletal muscular adiposity and cognitive decline in a biracial cohort of older men and women. *J Am Geriatr Soc*. 2023 Jun 7.

Upper-Extremity Impairments in Type 1 Diabetes

Patients with type 1 diabetes have a high prevalence of upper-extremity impairments such as frozen shoulder, carpal tunnel syndrome, trigger finger and Dupuytren contracture, according to a recent study published in the June 2023 issue of the journal *Diabetes Care*.¹

This cross-sectional study aimed to determine the prevalence of four upper-extremity impairments namely frozen shoulder, carpal tunnel syndrome, trigger finger and Dupuytren contracture among 2,245 Danish patients with type 1 diabetes. The matched

control group included 841 individuals from the general population. Socioeconomic and clinical data was sourced from national registers. The symptoms and diagnosis of upper-extremity impairments were self-reported via questionnaires.

Results showed that patients with type 1 diabetes were 3 times more likely to have frozen shoulder and carpal tunnel syndrome with odds ratio (OR) of 3.5. The prevalence of Dupuytren contracture was 4 times higher with OR of 4.3, while the prevalence of trigger finger was 5 times higher with OR of 5.0. Type 1 diabetes patients had a higher probability of coexisting impairments compared to the control group. The study also explored various factors associated with upper-extremity impairments. The association was greater among those with long-standing diabetes. A correlation between older age, higher body mass index (BMI), female sex, higher glycated hemoglobin (HbA1c), macro- and microvascular complications and higher risk of occurrence of upper-extremity impairments was also observed.

Although the study only demonstrates an association, nevertheless these findings do show a high prevalence of upper-extremity impairments among patients with type 1 diabetes. Hence, they should be regularly screened for upper-extremity impairments for timely interventions since they have significant adverse effects on working ability and consequently work performance and productivity. Additionally, it may contribute to low health-related quality of life.

Reference

1. Wagner S, et al. Upper-extremity impairments in type 1 diabetes: results from a controlled nationwide study. *Diabetes Care*. 2023;46(6):1204-8.

“Arexvy” the First RSV Vaccine Approved by EU Against Common Respiratory Virus

The European Commission has approved the first RSV (Respiratory Syncytial Virus) vaccine “Arexvy” for persons aged 60 and older manufactured by GlaxoSmithKline. The approval comes shortly after the United States approved the medicine, last month.

The vaccine results from decades of research into how to protect susceptible people from the prevalent sickness.

RSV often causes mild, cold-like symptoms, but it can be dangerous for young children, the elderly, those with weakened immune systems and people with underlying medical issues. In extreme situations, it can result in pneumonia and bronchiolitis, an inflammation of the tiny airways deep inside the lungs. Analysts have predicted that the market for this newly launched vaccine might be worth more than \$10 billion in the following 10 years. Pfizer and Moderna are two more manufacturers expected to release similar products shortly.

Arexvy's clearance was recommended by the drug watchdog for the European Union in April, following a trial with 25,000 participants across 17 nations. The European Medicines Agency reported that the vaccination provided 83% protection against RSV-related illnesses in persons 60 or older, with typically few adverse effects. The vaccine uses a synthetic protein and an adjuvant material to encourage antibodies and T cells that aid in warding off RSV infection.

By the end of the year, Moderna hopes to have received approval for and access to their RSV vaccine. Previously, the European Union approved an RSV preventative medicine in 2022 developed by the French pharmaceutical company Sanofi and the British pharmaceutical company AstraZeneca.

(Source: <https://medicalxpress.com/news/2023-06-eu-vaccine-common-respiratory-virus.html>)

Rise Against Liver Diseases: A Step Forward in NASH Awareness

Indians are mostly affected by many lifestyle-related diseases, such as nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH).

NAFLD affects people who drink little to no alcohol due to the buildup of extra fat in the liver cells. A person has a simple fat buildup called nonalcoholic fatty liver (NAFL) when there is no inflammation or cell damage present, while a person has NASH when there is inflammation or cell damage in addition to the simple fat buildup, which may lead to difficulties in the future. Even while NASH can have major health consequences, those who have it frequently experience few or no symptoms, leading to progressive inflammation and swelling and the production of scar tissue over time.

The National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases, and Stroke (NPCDCS) was established by the Global Liver Institute to stop liver fibrosis (NAFLD) and to take proactive preventative actions against this threat.

A National Level Centre of Excellence has been established to create standards for diagnosis, raise public awareness, educate health care workers, and create a framework for monitoring and assessment. A liver biopsy is necessary in severe instances, but basic blood tests and radiologic examinations can screen for NAFLD.

The NPCDCS has started a media campaign to raise awareness of noncommunicable diseases (NCDs) across the country using a variety of offline and online media platforms. Recently, patient monitoring and adherence to preventive and treatment measures have been made easier for patients by introducing patient support groups and patient awareness initiatives like LivAlert.

(Source: <https://health.economictimes.indiatimes.com/news/industry/step-up-for-nash-livalert-to-confront-the-silent-threat-of-liver-diseases/100830633>)

"Kangaroo Mother Care" Increase the Child's Chances of Survival: Study

The findings of a review of research conducted in India and published in the *BMJ Global Health Journal* reported that a form of care involving skin-to-skin contact between a mother and her prematurely delivered infant might dramatically increase the child's chances of survival.

The study discovered that the intervention appeared to be much more beneficial in lowering mortality and infection when it started within 24 hours of delivery and continued for at least 8 hours daily.

The World Health Organization (WHO) advises "kangaroo mother care" (KMC) as the recommended level of care after a low birth weight infant's condition has stabilized clinically. However, still, it needs to be clarified what the best strategy is.

The study evaluated 31 trials, including 15,559 newborns. It revealed that KMC appears to lower mortality risk by 32% either during labor and delivery in a hospital or by 28 days following delivery while also lowering the risk of severe infection by 15%. The mortality benefits were larger when the daily KMC length was at least 8 hours, as opposed to KMC of a lower duration.

The review's authors stated that there was generally little to no risk of bias in the included studies and that there was moderate to strong confidence in the strength of the evidence supporting the primary outcomes.

(Source: <https://www.tribuneindia.com/news/health/close-contact-between-mother-and-premature-baby-may-boost-infants-survival-study-514705>)

Residual Dyspnea Predictive of Poor Response to Single-inhaler Triple Therapy in Asthma

Asthma patients, who remain symptomatic despite treatment with inhaled corticosteroids/long-acting β_2 agonists may be prescribed single-inhaler triple therapy (SITT) as short-term treatment. To investigate factors that would predict a beneficial response with SITT in patients with asthma, researchers from Japan enrolled 45 patients in a retrospective study.¹ These patients had been prescribed the SITT from March 2019 to March 2021. Predictors of responsiveness to 4 weeks of therapy were assessed. The demographic information along with data about residual respiratory symptoms, type 2 biomarkers and pulmonary function prior to the use of SITT was obtained from the medical records of the patients.

Three-fourth (75%) of the enrolled patients were found to respond to the short-term treatment with SITT. Patients who did not respond to the inhaler therapy had significantly lower forced vital capacity (FVC) (%predicted) values and experienced dyspnea more often than responders. The type 2 biomarkers (sputum and blood eosinophils, exhaled nitric oxide levels and serum periostin) were comparable between the two groups.

Factors found to be predictors of poor or no response to SITT were residual dyspnea, low FVC (%predicted) and FVC (%predicted) <80% with OR of 0.14, 1.05 and 0.11, respectively. On multivariate analysis, residual dyspnea prior to being prescribed the inhaler therapy was associated with poor response to SITT (OR 0.14). Patients with residual dyspnea also had significantly lower forced expiratory flow 25-75 (FEF₂₅₋₇₅) (%predicted) values compared to patients who did not have residual dyspnea before the use of SITT.

At least 75% of the patients responded to short-term treatment with the SITT in this study; this effect was independent of the demographics or type 2 phenotype. Residual dyspnea, indicative of small airways dysfunction, therefore may be predictive of poor response to inhaler therapy in these patients, as shown in this study.

Reference

1. Ito K, et al. Residual dyspnea may predict small airways dysfunction and poor responsiveness to single-inhaler triple therapy in asthmatic patients. *Am J Respir Crit Care Med*. 2023;207:A1299.

Early versus Interval Postpartum IUD Placement

Early placement of intrauterine device (IUD) at 2 to 4 weeks after childbirth was not inferior to later placement

at 6 to 8 weeks postpartum with comparable complete expulsion rates between the two groups, according to a study published in *JAMA*.¹

The randomized noninferiority trial was conducted with the objective to determine IUD expulsion rates inserted in the early postpartum versus IUDs placed at the standard interval after childbirth. For this, 404 women, with mean age of 29.9 years, who had delivered between March 2018 to July 2021 were selected for the study. IUD was inserted 2 to 4 weeks after delivery in 203 women, while 210 received it after 6 to 8 weeks of childbirth. A total of 294 women who underwent IUD placement were available for follow-up at 6 months.

Complete expulsion, which was the primary study outcome, occurred in 2% (3/149) in the early placement group compared to none (0/145) in the interval placement group with between-group difference of 2.0. The partial expulsion rate, a secondary outcome, was 9.4% in the early placement group versus 7.6% in the interval placement group with a between-group difference of 1.8. At 6 months, the use of IUDs, which was also a secondary outcome of the study, was comparable between the two groups; 69.5% (early group) versus 67.2% (interval group).

Based on these findings, the study concluded that early IUD placement was noninferior to later postpartum IUD placement for complete expulsion, but not for partial expulsion. "Understanding the risk of expulsion at these time points may help patients and clinicians make informed choices about the timing of IUD placement", conclude the authors.

Reference

1. Averbach S, et al. Early vs interval postpartum intrauterine device placement: a randomized clinical trial. *JAMA*. 2023;329(11):910-7.

Stem Cell-based Therapy can Repair Damage to the Heart and Enhance Function

According to a study published in the *Nature Partner Journal, Regenerative Medicine*, stem cells transplanted into an injured heart have the ability to repair damaged tissue and improve heart function. Ischemic heart disease, caused by diminished blood flow to the heart, is the most common cause of death worldwide.

The study developed a new protocol for producing heart muscle precursor cells using pluripotent or immature stem cells. They injected these precursor cells into the area of the heart damaged by myocardial infarction and found that they could grow into new heart muscle cells.

Previous studies have shown that transplanting beating heart cells into the damaged area of the heart leads to ventricular arrhythmia. Hence, the researchers transplanted nonbeating heart cells into the damaged heart in the study. After the transplantation, the cells expanded and acquired a rhythm similar to the rest of the heart.

They also observed that after transplanting nonbeating heart cells, the incidence of arrhythmias was cut by half.

(Source: <https://www.daijiworld.com/news/newsDisplay?newsID=1088393>)

Sixty Percent of Diabetes Cases Found in India are Reversible: ICMR Chief

According to recent data from a 12-year study investigating the incidence of metabolic NCDs, including diabetes, India has nearly doubled the number of people with diabetes than previously expected.

The Indian Council of Medical Research-India Diabetes (ICMR-INDIAB) study, a cross-sectional population-based survey of individuals aged 20 and older drawn from urban and rural areas of 31 states and union territories, discovered a diabetes prevalence in the population of 11.4% or 101 million people. This is 1.68 times higher than the previously estimated 60 million diabetes cases in India.

The new study published in *The Lancet* showed that the prevalence of prediabetes, hypertension, general obesity and dyslipidemia in India is around 15.3%, 35.5%, 39.5% and 81.2%, respectively.

Dr Rajiv Bahl, Chief of the ICMR, stated that prediabetes is entirely reversible and that 60% of diabetes cases can be reversed by following a healthy diet and regular exercise regimen.

A total of 1,13,043 individuals were included in the study, of which 79,506 were from rural areas, and 33,537 were from urban areas. The study also showed that Punjab was the leader in obesity, hypertension and dyslipidemia, all risk factors for major NCDs.

(Source: <https://www.tribuneindia.com/news/health/60-pc-diabetes-reversible-icmr-chief-on-finding-101-mn-diabetics-in-india-515676>)

NPPA Fixed the Retail Prices of 23 Drugs, Including Diabetes and Blood Pressure Drugs

Recently, the National Pharmaceutical Pricing Authority (NPPA) fixed the retail prices of 23 formulations, including the medications used to treat diabetes and high blood pressure. The national drug pricing

regulator has set the prices of the drugs based on the decision made during the 113th Authority meeting held on May 26, 2023. The prices of these drugs were fixed as per the Drugs (Price Control) Order, 2013.

The NPPA has fixed the price of 1 tablet of diabetes drugs, namely gliclazide ER and metformin hydrochloride tablets, at Rs. 10.03. Similarly, the retail price of 1 tablet of antihypertensive medications such as telmisartan, chlorthalidone and cilnidipine tablets has been fixed at Rs. 13.17.

The retail price of 1 tablet of the pain reliever medications trypsin, bromelain, rutoside trihydrate and diclofenac sodium has been fixed at Rs. 20.51. The NPPA has also revised the ceiling price of 15 scheduled formulations under the Drugs (Prices Control) Order 2013 (NLEM 2022).

They have also fixed the ceiling price for two scheduled formulations.

(Source: https://www.business-standard.com/industry/news/nppa-fixes-retail-prices-of-23-drug-including-diabetes-blood-pressure-123060900710_1.html)

Incidence of New-onset Type 2 Diabetes in Lean NAFLD

NAFLD typically occurs in persons with obesity. But now NAFLD is increasingly being observed in those with normal BMI and has been termed “lean NAFLD”. Although the disease is less severe in the lean, it progresses through a similar spectrum of diseases and shares similar comorbid metabolic disorders like type 2 diabetes, dyslipidemia and metabolic syndrome as in NAFLD in persons with obesity.¹

To determine the incidence of new-onset type 2 diabetes among people with lean NAFLD, a meta-analysis of studies was carried out.² Published studies on lean NAFLD up to December 2022 were screened after a thorough search of PubMed, Scopus, Cochrane and Web of Science databases and 16 observational studies were selected for the final meta-analysis.

Out of the 3,04,975 adult patients included, 7.7% had lean NAFLD. Over a follow-up period of 5.05 years, there were nearly 1,300 cases of incident diabetes.

Analysis of data published in the journal *Diabetes Research and Clinical Practice* showed that participants with lean NAFLD were twice more likely to develop incident diabetes compared to those who did not have NAFLD with a hazard ratio (HR) of 2.72. The adjusted HR (aHR) of incident diabetes in subjects with overweight/obesity but without NAFLD was 1.32. While among the participants with overweight/obesity and

NAFLD, the aHR was 2.98. Patients with NAFLD were nearly 3.5 times more likely to develop type 2 diabetes, if they had advanced high NAFLD fibrosis scores with HR of 3.48.

This study shows that the risk of type 2 diabetes was higher in people with lean NAFLD compared to the lean without NAFLD. The risk of developing diabetes was equivalent between the lean and overweight/obese individuals with NAFLD suggesting that NAFLD, more than overweight/obesity, was a risk factor for type 2 diabetes in this patient group. Patients with increasing NAFLD fibrosis score were at greater risk.

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1. Ahadi M, et al. A review of non-alcoholic fatty liver disease in non-obese and lean individuals. *J Gastroenterol Hepatol*. 2021;36(6):1497-507.
2. Gao Y, et al. Lean nonalcoholic fatty liver disease and risk of incident type 2 diabetes mellitus: a literature review and meta-analysis. *Diabetes Res Clin Pract*. 2023;200:110699.

Diabetes, Weight Loss Drug can Reduce Alcohol Dependence by Half

According to a study published in *eBioMedicine*, semaglutide can help reduce alcohol dependence by half. Semaglutide is the first medication to act on the glucagon-like peptide 1 (GLP-1) receptor that is available in tablet form. The findings of the study showed that the drug significantly reduced alcohol consumption and alcohol consumption in conjunction with relapses in the test subjects. Interestingly, semaglutide reduced alcohol intake equally in male and female test subjects. Relapses in alcohol consumption is a significant problem for the individual with alcohol dependence, as they tend to drink more than before the withdrawal after relapse.

In the study, the researchers examined the mechanism by which the medication reduced alcohol consumption. They found that the drug reduced alcohol-induced reward in the brain, which reduced alcohol consumption. They explained that semaglutide affected the brain's reward system in test subjects, especially the nucleus accumbens area of the brain, which is part of the limbic system.

(Source: <https://www.daijiworld.com/news/newsDisplay?newsID=1088981>)

Even Moderate Alcohol Consumption can Increase the Risk of Over 60 Diseases

In a study published in *Nature Medicine*, moderate consumption of alcohol was associated with an increased risk of 60 diseases, including cataracts and

gastric ulcers. Each year more than 3 million deaths are reported due to the consumption of alcohol, with an increasing prevalence in many low and middle-income countries.

In the study, researchers from the University of Oxford, UK and Peking University, China, enrolled 5,12,000 adults from urban and rural areas in China and assessed the effect of alcohol consumption on 200 different diseases.

The study's findings showed that alcohol consumption increased the risk for 61 diseases among men. WHO has established 28 conditions out of these 61 diseases as alcohol-related disorders. These 28 diseases included stroke, gastrointestinal cancers, etc.

Further, genetic analysis to probe the link of alcohol consumption with various diseases showed that every 4 drinks per day were associated with a 14% increased risk of established alcohol-related disease, a 6% higher risk of conditions not previously known to be alcohol-related, and twofold increased risk of liver cirrhosis and gout. A higher intake of alcohol was also associated with an increased risk of stroke in a dose-response manner. However, no such association was observed between alcohol consumption and increased risk for ischemic heart disease.

(Source: <https://www.timesnownews.com/health/even-moderate-alcohol-intake-can-raise-risk-for-over-60-diseases-study-article-100913796#:~:text=Even%20if%20you%20consume%20alcohol,ulcers%2C%20warned%20a%20new%20study>)

Impact of Hair Cortisol Levels in Newborns on Sleep

Neonates born with higher levels of cortisol in their hair take longer time to sleep at 7 months of age, suggests a study presented at the recently concluded annual meeting of the Associated Professional Sleep Societies, SLEEP 2023 and also published in the journal *Sleep*.^{1,2}

Researchers from University of Colorado, University of Denver and University of Illinois obtained hair cortisol from 70 infants within 2 days of birth, more than half of whom were female (57.1%). The average gestational age at birth was 39.4 weeks. These infants were a part of the Care Project, a longitudinal study in Denver, Colorado. None of them had received exogenous glucocorticoids prenatally. Sleep was evaluated with the aid of the Brief Infant Sleep Questionnaire (BISQ), filled by the parents, when the infants were 7 months old. The aim of the study was to investigate if neonatal hair cortisol was associated with sleep health in infancy. Neonatal hair cortisol is an index of cortisol production by the fetus.

After adjusting for gestational age at birth and family income-to-needs ratio, the researchers found that higher neonatal hair cortisol levels were indicative of poor sleep at 7 months in the form of longer sleep onset latency as assessed by the BISQ. However, no association was noted between neonatal hair cortisol levels and nighttime sleep duration, number of night awakenings and nighttime wake duration.

This study demonstrates that higher fetal cortisol levels during late pregnancy may adversely affect sleep in infants suggesting a prenatal influence on sleep during infancy. Cortisol is the stress hormone. It is produced by the activity of the hypothalamic-pituitary-adrenal (HPA) axis. The sleep cycle may be disrupted if the HPA axis is active resulting in high levels of cortisol. This manifests as fragmented sleep, insomnia and overall shorter sleep time. The authors write that “specifically, cortisol may inform the shift from multiphasic to monophasic sleep as well as the accumulation of sleep pressure throughout the day, impacting sleep onset latency.”

However, only sleep onset latency was affected and not overall sleep. Nevertheless, these findings merit further studies to investigate the impact of high neonatal cortisol on sleep during childhood.

References

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2. Newborns with higher hair cortisol levels take longer to fall asleep. May 30, 2023. <https://www.sleepmeeting.org/newborns-higher-hair-cortisol-levels-take-longer-fall-asleep/>. Accessed June 12, 2023.

Early Hysterectomy and Risk of Heart Disease

The risk of heart disease is known to be higher among postmenopausal women. A new study from South Korea has shown that women who had a hysterectomy done before 50 years of age were at a higher risk for heart disease, stroke in particular. The study findings are published in *JAMA Network Open*.¹

Jin-Sung Yuk from the Dept. of Obstetrics and Gynecology, Sanggye Paik Hospital, Inje University College of Medicine, Seoul, Republic of Korea and co-researchers conducted this retrospective study to examine if hysterectomy before age 50 years increased the risk of new onset cardiovascular disease (CVD). For this, they sourced data of 55,539 women who underwent a hysterectomy, with a median age of 45 years, from the National Health Insurance database from January 2011 to December 2014 and matched them with 55,539 women, who did not undergo a hysterectomy.

Over nearly 8 years (median) of follow-up, the hysterectomy group had a greater risk of CVD with the incidence of heart disease being 115 per 1,00,000 person-years compared with 96 per 1,00,000 person-years in the nonhysterectomy group. After adjustment for multiple variables, women who underwent hysterectomy were at a higher risk of developing heart disease compared to those who did not have the surgery with HR of 1.25. The risk of stroke was found to be significantly increased among women in the hysterectomy group with HR of 1.31. But the occurrence of myocardial infarction (HR 1.06) and coronary artery revascularization (HR 1.03) were similar between both groups. When women who also had an oophorectomy were excluded from the analysis, the risk of heart disease was still higher in women with hysterectomy (HR 1.24).

These findings suggest that hysterectomy in women younger than 50 years resulting in early menopause is associated with increased risk of heart disease, especially stroke. The authors write that “because the incidence of CVD was not high, a change in clinical practice may not be needed”. Nevertheless, women undergoing early hysterectomy should be educated about the risk of heart disease and recommended a healthy lifestyle to prevent a cardiovascular event.

Reference

1. Yuk JS, et al. Association of early hysterectomy with risk of cardiovascular disease in Korean women. *JAMA Netw Open*. 2023;6(6):e2317145.



What is the Importance of Life Force?

A physical body becomes useless once the life force is gone. The same body, which was lovable to everyone, becomes a liability after death. Everyone wants to dispose it as early as possible as keeping a dead body at home is considered a bad omen.

During the transfer of dead body from one place to another, nobody wants to keep the body in a vehicle other than a hearse van, whose job is only to transport dead bodies. No family will be willing to carry the dead body of a person in a car in which the deceased person has been traveling or driving for years.

May be for any reason, health or rituals, once you touch a dead body you are required to take a bath before you commence your daily routine.

Within a matter of hours, in absence of life force, the physical body starts disintegrating and in a matter of days, it shows signs of self-destruction and putrefaction.

This vital force is nothing but the soul, aatma, brahma, spirit or consciousness, described in different Vedic texts.

Adi Shankaracharya in his book Bhaja Govindam Shloka 6 says:

*yávat-pavano nivasati dehe
távat-pocchati kuśalam gehe,
gatahati váyau dehápáye
bháryá bibhyati tasmin káye.(6)*

“Till the life force remains in the body, people come and enquire about your welfare. But, the moment the life force goes out, even your wife is afraid of coming anywhere near your body”.

Life force can be equated to the network of information in computer, radio, television or mobile phone. All these gadgets, without data, are useless and are thrown away. This silent data, which can be retrieved by operational and application software, represent the life force or soul of these electronic gadgets.

Just as one does not give importance to a computer without data, one should not give importance to the physical body. It is the life force within the body which is respected and cared for and that is what real “I” or “We” is. All glories of the body are only until the life force remains in it.

In Bhagavad Gita, Lord Krishna in Chapter 2 (2.23) says about this life force or atman: “Fire cannot burn it, weapon cannot cut it, water cannot wet it, air cannot dry it; it is immortal”.

Life force has no dimensions: height, weight, color or image. It is immortal, omnipotent, omniscient and omnipresent. The weight of a live and a dead body immediately after the death is the same.

It is the same life force, which dwells in everybody and during life is modified by actions, memory and desire cycles. If one gets attached to any of the three, one starts getting detached from the soul or the life force. People who are in touch with their life force all the time attain peace and happiness and die young in old age.

Most Vedic mahavakyas say that it is the same spirit, which dwells in everybody and hence every person in the society should be welcomed and treated with equal importance. Aham Brahmasmi, Tat Tvam Asi, Vasudhaiva Kutumbakam, etc. are few such examples.

According to Adi Shankaracharya, one can achieve non-duality only by seeing God in everyone. ‘Athithi devo bhava’ is also based on the same principle.



Two Monks and a Pretty Lady

Once upon a time a big monk and a little monk were traveling together. They came to the bank of a river and found the bridge was damaged. They had to wade across the river.

There was a pretty lady who was stuck at the damaged bridge and couldn't cross the river.

The big monk offered to carry her across the river on his back to which the lady accepted.

The little monk was shocked by the move of the big monk and was thinking "How can big brother carry a lady when we are supposed to avoid all intimacy with females?" But he kept quiet.

The big monk carried the lady across the river and the small monk followed unhappily. When they crossed the river, the big monk let the lady down and they parted ways with her.

All along the way for several miles, the little monk was very unhappy with the act of the big monk. He was making up all kinds of accusations about big monk in

his head. This got him madder and madder. But he still kept quiet. And the big monk had no inclination to explain his situation.

Finally, at a rest point many hours later, the little monk could not stand it any further; he burst out angrily at the big monk. "How can you claim yourself a devout monk, when you seize the first opportunity to touch a female, especially when she is very pretty?"

All your teachings to me make you a big hypocrite.

The big monk looked surprised and said, "I had put down the pretty lady at the river bank many hours ago, how come you are still carrying her along?"

Moral: This very old Chinese Zen story reflects the thinking of many people today. We encounter many unpleasant things in our life, they irritate us and they make us angry. But like the little monk, we are not willing to let them go away. There is no point in remaining hurt by the unpleasant event after it is over. Learn to move on in life!

■ ■ ■ ■

Use of Wearable Activity Trackers During Hospital Stay to Hasten Patient Recovery

Wearable activity trackers may be a useful and cost-effective intervention to enhance patient recovery during hospital stay, according to a new study reported in *JAMA Network Open*.¹

Researchers from University of South Australia in Adelaide conducted a systematic review and meta-analysis of 15 studies involving 1,911 patients undergoing rehabilitation for stroke or orthopedic-related problems, mixed rehabilitation and various surgical and medical patients. The objective was to find out if interventions using wearable activity tracking devices could increase physical activity or reduce sedentary behavior and thereby improve clinical outcomes in hospitalized adults.

Compared to standard care, the use of wearable activity trackers increased overall physical activity with higher daily step counts (826 steps more) and reduced sedentary behavior (-35.46 min daily) among inpatients, which were also the primary study outcomes. They also achieved 10 minutes more of active time daily versus usual care. A significant improvement in physical function was also noted. But no improvement in pain or mental health, the secondary outcomes, was found. Likewise, no significant association was noted for duration of hospitalization or odds of re-hospitalization, which were examined as hospital efficiency outcomes.

Immobility during hospitalization is associated with several complications, which may prolong length of hospital stay and sometimes may be potentially fatal. This study shows that wearing activity trackers helped hospitalized patients to become more active and reduced sedentary behavior thereby hastening patient recovery.

Reference

1. Szeto K, et al. Interventions using wearable activity trackers to improve patient physical activity and other outcomes in adults who are hospitalized: a systematic review and meta-analysis. *JAMA Netw Open*. 2023;6(6):e2318478.



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Lighter Side of Medicine

HUMOR UPSET IS UNHEALTHY

The mother of a problem child was advised by a psychiatrist, "You are far too upset and worried about your son. I suggest you take tranquilizers regularly."

On her next visit the psychiatrist asked, "Have the tranquilizers calmed you down?"

"Yes," the boy's mother answered.

"And how is your son now?" the psychiatrist asked.

"Who cares?" the mother replied.

WHAT IT MEANS?

Five years old Becky answered the door when the Census taker came by.

She told the Census taker that her daddy was a doctor and wasn't home, because he was performing an appendectomy.

"My," said the census taker, "that sure is a big word for such a little girl. Do you know what it means?"

"Sure! Fifteen hundred bucks and that doesn't even include the anesthesiologist!"

KNOWLEDGE IS WORTH AS MUCH AS GOLD

The next day, TV news reported that 100 million was taken from the bank. The robbers counted and counted and counted, but they could only count 20 million. The robbers were very angry and complained "We risked our lives and only took 20 million; the bank manager took 80 million with a snap of his fingers. It looks like it is better to be educated to be a thief!"

This is called "Knowledge is worth as much as gold!"

STANDING THERE ALL BY YOURSELF

One day, there were a couple of kids in a psychology class. The teacher stands up and says to the class "stand up if you think you're stupid!" After about 5 minutes, Little Johnny stood up and the teacher says "do you think you're stupid Johnny?"

To which Little Johnny replies "No miss I just hate to see you standing there all by yourself!!!"

BUT IT CERTAINLY CURED

A guy is walking up to a doctor's office when a nun comes running out screaming and crying.

The guy walks in and says, "Doc, what's with the nun?"

The doctor says, "Oh, I just told her she's pregnant."

The guy says, "The nun's pregnant?"

The doctor says, "No. But it certainly cured her hiccups!"

SALES PRACTICE

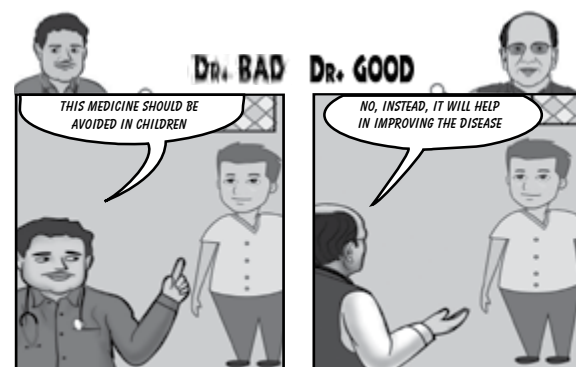
The out-of-work newlywed took a temporary job as a vacuum cleaner salesman to make ends meet. After 3 days of intensive training, the sales manager told him to go home and practice his pitch on his wife.

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

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

Dr. Good and Dr. Bad

SITUATION: A child in whom prediabetes was identified was prescribed GLP-1 analog.



LESSON: It has been reported that GLP-1 analogs aid in obtaining favorable outcomes, especially in terms of blood sugar levels, lipid profile, body mass, insulin resistance and islet β -cell function. These drugs have emerged as an effective option for treating prediabetes in children.

Exp Ther Med. 2017;13(4):1426-30.

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

Books

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

Articles in Books

Strong MS. Recurrent respiratory papillomatosis. In: Scott Brown's Otolaryngology. Paediatric Otolaryngology Evans JNG (Ed.), Butterworths, London 1987;6:466-470.

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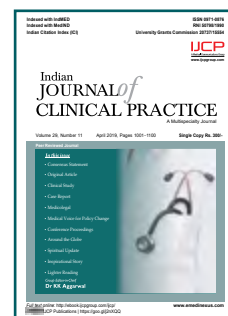
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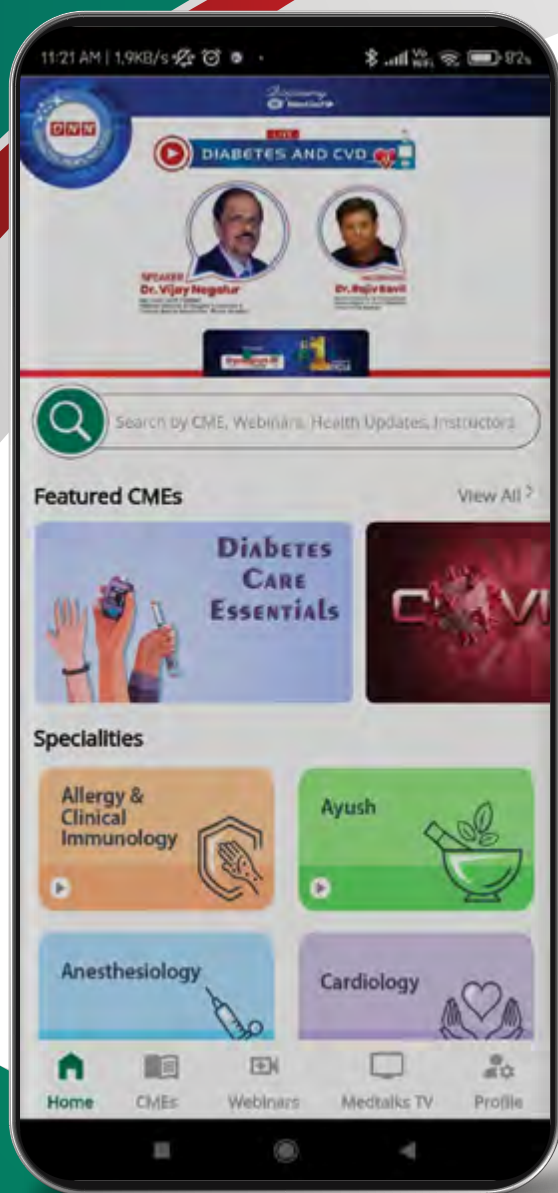
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