Indexed with IndMED
Indexed with MedIND
Indian Citation Index (ICI)

ISSN 0971-0876
RNI 50798/1990
University Grants Commission 20737/15554

IJCP
A Medical Communications Group
www.ijcpgroup.com

Indian JOURNAL of CLINICAL PRACTICE

A Multispecialty Journal

Volume 33, Number 7 December 2022, Pages 1–60 **Single Copy Rs. 300/-**

Peer Reviewed Journal

In this issue

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Indian JOURNAL of CLINICAL PRACTICE
A Multispecialty Journal
Volume 33, Number 7, December 2022

EDITORIAL

GUEST EDITORIAL

ORIGINAL ARTICLE

REVIEW ARTICLE

CASE REPORT

BRIEF COMMUNICATION

Published, Printed and Edited by
Dr Veena Aggarwal, on behalf of
IJCP Publications Ltd. and
Published at
3rd Floor, 39 Daryacha, Hauz Khas Village,
New Delhi - 110 016
E-mail: editorial@ijcp.com

Printed at
New Edge Communications Pvt. Ltd., New Delhi
E-mail: edgecommunication@gmail.com

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EDITORIAL

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HCFI Round Table Environment Expert Zoom Meeting on "India's Low-carbon Strategy and Outcome of COP27"

NOVEMBER 20, 2022 (SUNDAY, 12 NOON – 1 PM)

- The 27th Conference of Parties (COP27), the UN Climate Change Conference, took place between 6th and 18th November in Sharm El-Sheikh, Egypt. One of the decisions taken there was to establish a loss and damage fund. This is a very important decision for the developing countries. Another was regarding making good on the long promised 100 billion dollars per year for climate finance for developing countries.
- The UN Secretary General called for a giant leap on climate ambition and also stressed the need to drastically reduce emissions. He said that we must not cross the red line that takes our planet over the 1.5° temperature limit. He asked not to relent in the fight for climate justice and climate ambition and said that we can and must win the battle for our lives together.
- On November 14, India released its long-term climate action strategy, the long-term low-carbon strategy called the "long-term low greenhouse gas emission development strategies" (LT-LEDS). This deals with how it will take steps such as rapidly expanding renewable energy sources and exploring greater role for nuclear energy to reach the target of zero net emissions by 2070. India is in a good position in greenhouse emissions.
- A progress on loss and damage fund is heartening to note. The issue is the conflict of interest and some things have been politicized because of which there is lack of convergence of thinking and action taken.
- Four major pillars of discussions in COP27, which have been deliberated in detail at the conference, are ending deforestation, clarity on article 6, climate adaptation that is fit for the purpose and loss and damage funding.
- Loss and damage refers to the irreparable destruction caused by disasters due to climate change.
- However, more clarity is required as to mechanisms as to how these projects or credits of carbon reduction will be traded and climate partners will implement them.
- Deforestation was also the main agenda in COP26, which as recorded by satellite is at a very high pace. Around 3.75 million hectares or 10 football pitches per minute is the disappearing rate for the forest. We have to arrest this fast pace.
- The rift between developing nations and developed nations was clearly visible at COP27 be it for finance, emissions or even fossil fuels.
- India has opposed draft text on agriculture in COP27 stating that the developed countries are blocking a

pro-poor and pro-farmer decision by insisting on expanding the scope for mitigation to agriculture, thereby compromising the very foundation of food security in the world. In most developing countries across the world, agriculture is practiced by small and marginal farmers who till hard, toil hard and brave the vagaries of extreme weather and climate variability as well as the additional stress of climate change.

- India also said that the world is facing climate crisis today because of historic excessive cumulative emissions by the developed world.
- India had proposed to phase out fossil fuel. All European countries supported it but it was omitted in the draft proposal. Use of coal will further make it difficult to achieve the targets.
- Cooperation of all stakeholders is very important for successful implementation of India's long-term low-carbon development strategy. There is a need for awareness programs.
- The cover text also does not mention when a loss and damage finance facility will be launched and what its contours will be.
- The 20-page document, described as a 'non-paper' by the UN Framework Convention on Climate Change, is 8,400 words long as compared to the Glasgow Pact, which was around 4,600 words and was in itself one of the longest cover texts in the history of UN climate summits.
- Citing the 6th Assessment Report of the Intergovernmental Panel on Climate Change, Indian negotiators had told the Egyptian COP27 presidency that meeting the long-term goal of the Paris Agreement "requires phase down of all fossil fuels".
- A national greenhouse emission inventory is required to formulate a good action plan to reduce those greenhouse gases, which are responsible for the climate change.
- The major contributor to the greenhouse gas emissions particularly the oil industries, power plant and Oil and Natural Gas Commission (ONGC) are doing pioneering strategies in this regard.
- In the transport sector many activities are going on parallelly, starting from fuel changes, electric vehicles, ethanol blended fuel, hydrogen fuel. Additionally, we have to also focus on the old traditions of bicycles and pedestrians. But in urban areas, we do not have pedestrian friendly or cycle-friendly tracks.
- If we look at the transport or trip length, normally more than 50% to 60% trip length is below 6 km. This is possible by cycle. If it is made cycle-friendly, probably 50% of the trip can be catered through cycling. Trip length impacts energy, fuel and carbon and we can go to zero emissions. This is one of the requirements not only from government but also the stakeholders. A change in mindset and behavior is the need of the hour. If public transport system like metros, buses can be further improved then probably this will sort out another 20% of the problem to an eco-friendlier one.
- With regard to private vehicles, there have been rapid changes in fuel, electric vehicle (EV) policy has been announced with the target that by 2025, 30% of vehicles must be EV. This is a very difficult target as there are existing vehicles, for which there has to be a scrapping policy as well as enforcing policy of the government. Many vehicles are not being checked for pollution under control (PUC) or are not insured. There should be a separate ministry for this so that scrapped vehicles can be managed in a proper manner.
- On carbon removal, the focus will be on economic, technical and political feasibility of carbon capture, utilization and storage (CCUS), which is highly uncertain.
- A transition to a low-carbon pathway will involve cost pertaining to the development of new technologies, new infrastructure and other transition costs. This transition will have lot of economic impact.
- Overall if we look into decarbonization of transport in urban area almost every household has one cycle even in urban and rural areas. For longer trips, a better public transport system is required. There is the metro. In many cities like Ahmedabad, there are dedicated bus corridors called Bus Rapid Transit system, which is quite equivalent to metro corridors. They have hi-tech information system, hi-tech speed and have maintained quality. If this is there in other cities also, hopefully we may be able to achieve decarbonization of transport.
- The impact of airplane transport on the environment so far has not been taken into account till date. Airplanes also generate pollution.
- Other policies like work from home can also reduce the trip length. E-commerce is another

way to reduce our trip length. Our existing low-cost living style can help. Countries like Japan consider quality of life as the most important parameter rather than the human development index. Recycling is already in our culture. It is time to bring back our old culture and traditions into our day-to-day lifestyle.

- The COVID-19 pandemic has taught us how to increase immunity with the help of diet, lifestyle and exercise. During any adversity, a vulnerable person gets infected easily and falls sick. The weaker sections suffer more. We need to follow-up on tried things used to improve immunity and vitality.
- Crop cycle should be changed depending on the availability of water as well as the climate. We need to be alert and know which grain has to be sown. The millet program by the Government of India is a very timely and good initiative. There can be other programs so that we are prepared for the variations in climate, which may be well-anticipated or even unanticipated. So in both situations, preparation will serve both the purposes to face the likely adversities that we may encounter.
- All six colors and seven tastes must be included in diet. Locally grown food must be consumed. This will reduce the carbon footprint.
- All the countries worldwide are putting their efforts in finding ways to minimize the effects of climate change and greenhouse gas emissions for a better environment and living conditions on this planet.

Participants: Mr Paritosh Tyagi, Dr SK Tyagi, Dr Ravindra Kumar, Dr Sanjeev Agrawal, Dr Anil Kumar, Mr PK Jain, Mr Neeraj Tyagi, Mr Pradeep Khandelwal, Mr Rajeev Sharma, Dr S Sharma

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Exercise Regimen is an Important Critical Factor in Diabetes Care

Several studies have indicated that taking part in a regular workout regime can improve blood glucose control, prevent or delay the onset of type 2 diabetes and counter insulin resistance by boosting the body's sensitivity to insulin. Additionally, regular physical activity positively affects blood pressure and cardiovascular health by lowering harmful low-density lipoprotein (LDL) cholesterol and triglycerides, raising healthy high-density lipoprotein (HDL) cholesterol, strengthening muscles and bones, reducing anxiety and improving your general well-being. All forms of exercise, such as aerobic, resistance or doing both in a structured workout regime, have been shown to lower glycated hemoglobin (HbA1c) values in people with diabetes. Resistance training and aerobic exercise both help to lower insulin resistance; however, combining the two types of exercise proved more beneficial than doing either one alone. In a recent meta-analysis, aerobic, resistance and combined exercise training were found to be associated with HbA1c reductions of 0.67% after 12 or more weeks of training. Similarly, another meta-analysis involving 10 studies revealed that resistance training reduced HbA1c by 0.48% and effectively improved the lower metabolic risk factors in diabetes individuals and improve overall metabolic health. On the other hand, several studies have shown that moderate to high levels of aerobic activity are significantly linked to decreased cardiovascular and total mortality risks. According to the most recent American Diabetes Association (ADA) recommendations, individual aerobic activity sessions should preferably last at least 30 minutes each day and be carried out 3 to 7 days a week. In individuals with type 2 diabetes, aerobic exercise boosts the number of mitochondria, insulin sensitivity, oxidative enzymes, blood vessel compliance and responsiveness, immune system activity, lung function and cardiac output. (*Source: https://health.economictimes.indiatimes.com/news/industry/the-importance-of-a-workout-regime-to-check-diabetes/95337629*)

New Genus of Fungus Discovered by BHU Botanists to Treat Cancer

According to a report published in the journal *Phytotaxa*, a new genus of fungus has been discovered from the samples collected in Uttarakhand. The discovery is considered important because new antibiotics and other important mixtures (metabolites) derived or developed using the new fungi can be used to treat different types of cancer. The new genus of fungus, called "*Neokamalomyces Indicus*", was discovered by botanists from the Banaras Hindu University (BHU) and researchers from the Agharkar Research Institute (ARI), Pune, and the Kerala Forest Research Institute (KFRI), Kerala. Dr Raghvendra Singh, Senior Assistant Professor at BHU, stated that the samples of leaves of the banyan tree (with yellow and brown spots) diseased by the fungus were collected from Uttarakhand during a survey in July 2019. (*Source: https://daijiworld.com/news/newsDisplay?newsID=1017119*)

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Endocrine Fluidity

ABSTRACT

This communication describes the concept of endocrine fluidity, defining it as the phenomenon of changing endocrine and metabolic function, in health and/or in disease, over time. Awareness of physiological endocrine fluidity helps avoid overdiagnosis and unnecessary investigations. Knowledge of endocrine fluidity in pathological conditions allows the astute physician to keep a high index of clinical suspicion for relevant diseases. The concept of endocrine fluidity can be used to anticipate, and address changes in the clinical course of a disease, and to allow for possible deviations from the expected natural trajectory.

Keywords: Circadian rhythm, cyclicity, endocrinology, hormones, physiology

The word fluidity is a noun, which describes the physical property of a substance that enables it to flow. Fluidity has been used to describe not only physical substances like liquids, but also intelligence, cognition, movements and business transactions.[1] In medicine, fluidity is used in the context of anatomy (membrane fluidity) as well as physiology (gender fluidity). We use this word to create a construct, endocrine fluidity, which encompasses both physiological and pathological aspects of hormonal action.

PHYSIOLOGICAL FLUIDITY

Circadian rhythms, or physical, mental, behavioral and hormonal changes that follow a 24-hour cycle, are well known to science. Most circadian rhythms are controlled from the suprachiasmatic nucleus of the hypothalamus, which operates various feedback mechanisms. The Nobel Prize 2017 was awarded to Hall, Rosbash and Young for isolating the gene which controls the biological clock.[2]

Other rhythms have also been described, including ultradian (less than 24-hour cycle), circasemidian (12-hour cycle) and infradian (longer than 24-hour cycle).[3] These can be considered a form of endocrine fluidity. Table 1 lists some physiological examples of endocrine fluidity. The changes in the hypothalamic-pituitary-gonadal axis that govern the monthly rhythm of ovarian physiology in menstruating women may also be viewed as a form of endocrine fluidity.

Another example of fluidity is gender fluidity.[4] Though not related directly to hormonal levels, gender fluidity or change in perceived gender, can be considered a physiological form of life.

PATHOLOGICAL FLUIDITY

Endocrine fluidity can be noticed in endocrine pathology as well. Cyclic Cushing's syndrome, pulsatile prolactin secretion from pituitary adenomas and cyclic pheochromocytoma are examples of this. Hashitoxicosis represents another form of endocrine fluidity, albeit over a longer time frame.

Type 1.5 diabetes, both LADA (late-onset autoimmune diabetes of adult) and Flatbush diabetes (ketosis prone type 2 diabetes) represent forms of metabolic fluidity. Changes in insulin requirement in persons with diabetes, which are so familiar to endocrinologists are the clinical presentations of this fluidity. Another manifestation is the change in diagnostic label that is not so uncommon

Table 1. Endocrine Fluidity

Physiological
• Circadian, ultradian, infradian rhythms
• Changes in pituitary, thyroid, breast size during puberty, pregnancy, lactation
• Gender fluidity
Pathological
• Cyclic Cushing's
• Pheochromocytoma crisis
• Adrenal crisis
• Hashitoxicosis
• Functional testosterone deficiency
• Weight cycling
• Triphasic response after pituitary surgery
• Type 1.5 diabetes
▪ Flatbush
▪ LADA
Physician-centered
• Changes in guidelines based on current evidence
• Changes in therapeutic targets/strategies/tools based upon change of
▪ Age
▪ Natal status
▪ Comorbid status

in endocrine clinics. Diabetes, metabolic bone disease and gonadal disease often change their presentation, and this fluidity reflects as a change in diagnosis.

PHYSICIAN-CENTERED FLUIDITY

Yet another form of endocrine fluidity is created by endocrinologists themselves. Therapeutic targets, therapeutic strategies and pharmacological tools change with advances in research.[5] This leads to frequent changes in the information and advice that physicians share with their patients. From a patient perspective, this can be construed as a form of medical fluidity, and specifically as endocrine fluidity. While part of this fluidity can be explained by advances in science, some are due to changes phases of life. The targets for glucose, blood pressure, lipid and thyroid health, for example, vary according to age group, natal status and comorbidities.

SUMMARY

Endocrine fluidity is an easily observed phenomenon, both in physiology and disease. Awareness about the condition will help physicians offer counseling and reassurance to those with physiological variants of fluidity, and prescribe appropriate diagnostic and therapeutic interventions for those who need them.

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Surgical Masks are Equally Effective in Providing Protection against COVID as N95

According to a study published in the journal *Annals of Internal Medicine*, surgical masks were found to be as effective as N95 masks in preventing the spread of COVID-19 among health care providers at hospitals. In the study, researchers at McMaster University in Canada tracked 1,009 health care workers at 29 sites in Canada, Egypt, Israel and Pakistan. The author of the study noted that there were conflicting recommendations on the use of N95 masks during the pandemic. The US CDC recommended N95s for routine care of patients with COVID-19, while the WHO and CPHA recommended either surgical masks or N95 respirators. However, several low- and middle-income countries are still struggling to procure N95 masks due to their high cost. Hence, they designed this study to compare the effectiveness of both masks against viral respiratory infection or clinical respiratory illness. The study is a systematic review of 4 RCTs on masks conducted between 1990 and March 2020. The findings of the study showed that the use of surgical masks did not increase viral respiratory infections or clinical respiratory illness. (*Source: https://www.daijiworld.com/news/newsDisplay?newsID=1024802*)

ORIGINAL ARTICLE

Diabetes Risk Score in Indian Population: Experience from Central India

JAIDEEP KHARE*, HARSHA PAMNANI†, ANUVRAT BHATNAGAR‡, SHAIFALI BANSAL#, SUSHIL JINDAL¥

ABSTRACT

Introduction: Diabetes is a major health problem in the world causing significant morbidity and mortality. Currently, 77 million people in India and 463 million people are living with diabetes across the world, and this number is expected to rise to 101 million in India and 578 million globally by 2030. The key to reduce the morbidity and mortality is early diagnosis and management. The Madras Diabetes Research Foundation (MDRF) has developed an Indian Diabetes Risk Score (IDRS) to identify people who are at risk of developing diabetes or are undiagnosed. Thus, we conducted a study to calculate the IDRS of people from Central India and identify those who are at risk of getting diabetes. **Methods:** A total of 1,500 patients or attendants, aged 18 to 60 years (mean age 41.2 years), visiting the Endocrinology clinic, and not diagnosed with diabetes earlier were included in the study after taking proper consent and IDRS was calculated. **Results:** The male-to-female ratio was 914:586. The mean IDRS was 51.29 in our population with 35.93%, 18.2% and 45.87% of screened subjects having a score of <30, 30-60 and ≥60, respectively. **Conclusion:** Forty-five percent people of the population was at high risk of diabetes as estimated by IDRS, which proved to be an effective and economical tool to identify persons at increased risk of diabetes and diagnose the undiagnosed cases and start early management to reduce the morbidity and mortality.

Keywords: Diabetes, Indian Diabetes Risk Score, Madras Diabetes Research Foundation

Diabetes is a major health problem in the world leading to considerable morbidity and mortality. Prevalence of diabetes is expected to rise exponentially, currently 77 million people in India and 463 million people are living with diabetes across the world, and this number is expected to rise to 101 million in India and 578 million globally by 2030 which could mostly be attributed to unhealthy lifestyle, increasing life expectancy, illiteracy, lack of awareness and low socioeconomic status.[1] The key to reducing the morbidity and mortality is early diagnosis and management. The Madras Diabetes Research Foundation (MDRF) has developed an Indian Diabetes Risk Score (IDRS) to identify people who are at risk of developing type 2 diabetes or are yet undiagnosed.[2]

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Thus, we conducted a study to calculate the IDRS of people from Central India and identify those who are at risk of getting diabetes or those who are not diagnosed with diabetes using IDRS.

MATERIAL AND METHODS

This was an observational cross-sectional study conducted at our Endocrine Outpatient Department (OPD).

All patients or attendants visiting the Endocrinology OPD, willing and not diagnosed with diabetes earlier were included in the study after taking proper informed consent. Patients who were critically ill, pregnant, had history of diabetes or not willing to participate in the study were excluded.

A total of 1,500 volunteers were enrolled who met the inclusion criteria and IDRS was calculated as described in Table 1. We also recorded the random capillary glucose levels with glucometer and correlated it with IDRS. Glucometer reading of more than 140 mg/dL was considered deranged.

RESULTS

One thousand five hundred volunteers, aged between 18 and 60 years (mean age 41.2 years) were included in the study. The male-to-female ratio was 914:586.

Table 1. Prevalence of Various Risk Factors in Our Study Population

	Score	Male (n = 914)	Female (n = 586)	Total (n = 1,500)
Age (years)				
<35	0	281	207	488
35-49	20	343	224	567
≥50	30	290	155	445
Abdominal obesity				
Waist circumference (cm)				
<80 Female, <90 Male	0	401	145	546
80-89 Female, 90-99 Male	10	348	237	585
>90 Female, >100 Male	20	165	204	369
Physical activity				
Exercise (Regular) + Strenuous exercise	0	121	86	207
Exercise (Moderate)	10	387	149	536
Exercise (Mild)	20	147	291	438
No	30	259	60	319
Family history of diabetes				
No	0	134	175	309
1 Parent	10	568	281	849
Both parent	20	212	130	342
Maximum score	**100**	**51.25**	**51.37**	**51.29**

Table 2. Distribution of the Study Population According to the Risk Score

Score	Male (%)	Female (%)	Total (%)
<30	326 (35.76)	213 (36.34)	539 (35.93)
30-60	161 (17.62)	112 (19.11)	273 (18.20)
≥60	427 (46.72)	261 (44.45)	688 (45.87)
Total	**914**	**586**	**1,500 (100)**

Table 3. Correlation Between IDRS and Deranged Blood Glucose Profile

Score	N (%)	Deranged blood glucose (RBS >140 mg/dL or FBS >100 mg/dL with glucometer [% of cases])
<30 (Low)	539 (35.93)	7 (1.29)
30-60 (Moderate)	273 (18.20)	23 (8.42)
≥60 (High)	688 (45.87)	268 (38.95)

The mean IDRS in our study population was 51.29. Details of various risk factors are described in Table 1. And, 35.93%, 18.2% and 45.87% of the screened volunteers had a score of <30, 30-60 and ≥60, respectively (Table 2).

Seven (1.29%), 23 (8.42%), 268 (38.95%) volunteers were identified with deranged blood glucose levels with IDRS of <30, 30-60 and ≥60, respectively (Table 3).

DISCUSSION

Diabetes is a major health problem in the world. Early diagnosis and management can reduce the associated morbidity and mortality by preventing complications related to diabetes. There is a perceived need for a tool, which is not only economical but also socially acceptable and reliable to identify persons at risk of diabetes. MDRF has developed the IDRS, which has all the above-mentioned qualities to identify people who are at risk of developing diabetes or are undiagnosed type 2 diabetes. IDRS identified people as low-risk, moderate-risk or high-risk if score was <30, 30-60 or ≥60, respectively.

Hence, we calculated the IDRS in our population and identified the prevalence of various components of

IDRS and correlated it with glucometer readings for capillary glucose levels.

In our study, the mean IDRS was 51.29 suggesting that our population is at moderate-risk for diabetes; 35.93%, 18.2% and 45.87% of screened volunteers had a score of <30, 30-60 and ≥60, respectively.

Nandeshwar et al in their study in 2010 identified 2.80% subjects as low-risk, 28.40% as moderate-risk and 68.80% as high-risk as per the IDRS.[3] This increase in low- to moderate-risk group and decrease in high-risk group population may be because of increasing awareness among people regarding diabetes and its complications due to several awareness programs and activities conducted by medical fraternity.

Seven (1.29%), 23 (8.42%), 268 (38.95%) volunteers were identified with deranged blood glucose levels with IDRS of <30, 30-60 and ≥60, respectively. Our findings were also in concordance with those of Mohan et al, which suggested that only 43% population with IDRS ≥60 need to be screened for diabetes, which will help in significant reduction in financial burden.[2]

CONCLUSION

Forty-five percent people of our population is at high risk of diabetes as estimated by IDRS, which is an effective and economical tool to identify the people who are at increased risk of diabetes and diagnose undiagnosed people with diabetes.

Thus, we recommend regular use of IDRS to identify people at increased risk of diabetes and screen them for diabetes and its complications to start early management and reducethe diabetes-related morbidity and mortality.

LIMITATION OF STUDY

Possibility of sample bias cannot be ruled out as volunteers were from single tertiary care center.

Conflict of Interest

Declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

Funding

This research did not receive any specific grant from any funding agency in the public, commercial or not-for-profit sector.

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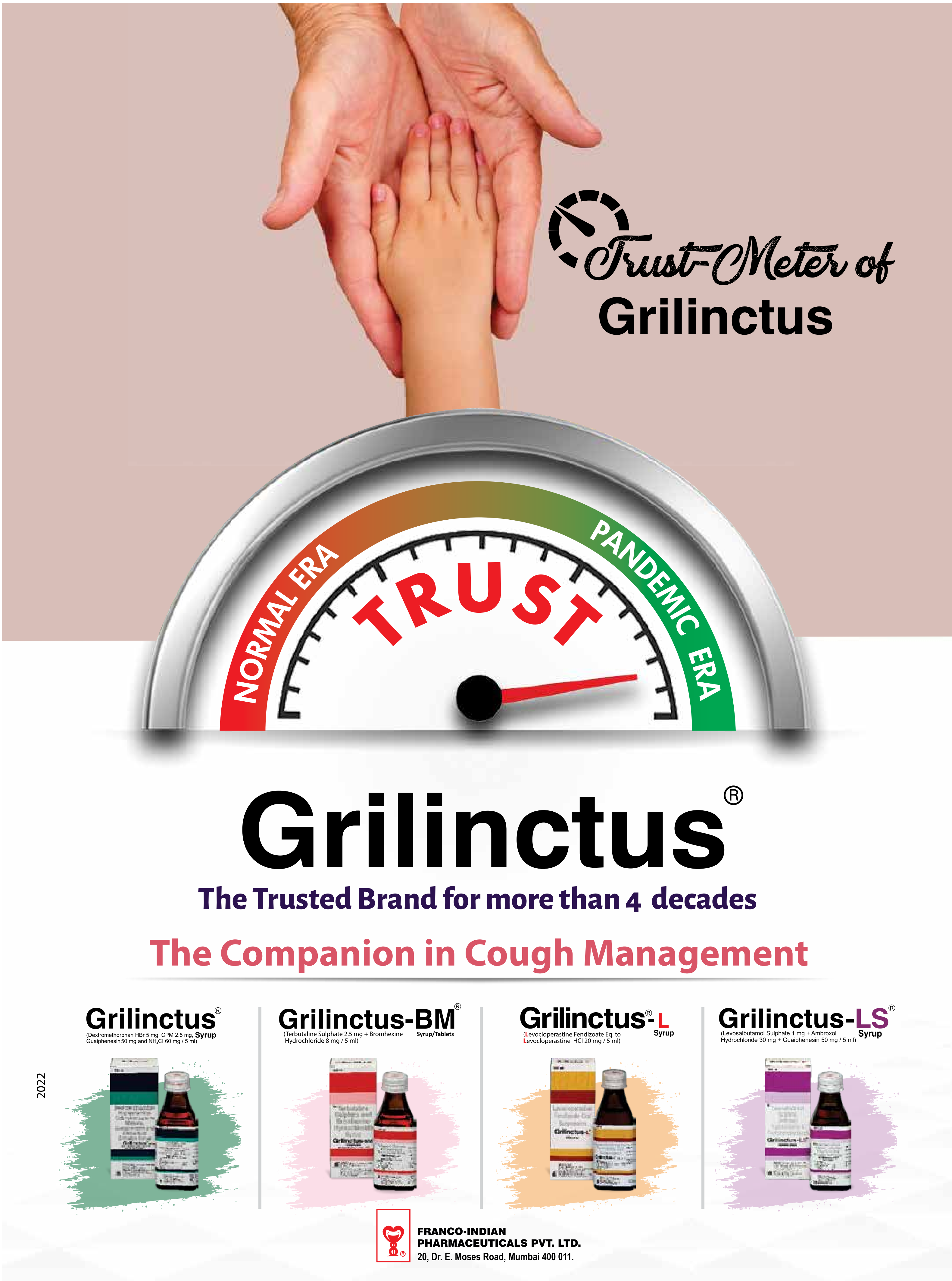
Aspirin are Preventive Drug in People with a High Risk of Strokes and Heart Attack

According to a study published in the journal *The Lancet*, the risk of stomach bleeding caused by long-term aspirin use can be decreased with a brief course of antibiotics. Aspirin is known as a useful preventative drug in low doses for people at high risk of strokes or heart attacks; however, on rare occasions, it can provoke internal ulcer bleeding.

Earlier, the findings of the HEAT (*Helicobacter pylori* Eradication Aspirin) trial led by Dr (Prof) Chris Hawkey from the University of Nottingham revealed that aspirin can cause ulcers in the stomach caused by a particular type of bacteria, *H. pylori*, to bleed by thinning the blood.

On the other hand, the findings of the recent "STAR" (Simple Trials for Academic Research) trial showed that ulcer bleeding can be significantly reduced following a 1-week course of antibiotics. In the study, more than 30,000 patients were enrolled and randomly assigned to receive antibiotics or placebos. These participants were followed for up to 7 years.

The study results showed that over the first 2½ years, only 6% of the participants who received antibiotic treatment were admitted to the hospital because of ulcer bleeding, in comparison to 17% of the patients who received dummy tablets. Similarly, in the group that received the dummy drug, the first hospitalization for ulcer bleeding occurred after 6 days in comparison to 525 days following antibiotic treatment. (*Source: https://www.tribuneindia.com/news/health/study-finds-how-regular-aspirin-use-can-cause-stomach-bleeding-448021*)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REVIEW ARTICLE

Alcohol Use Disorders and Diabetes Mellitus

PRIYANKA SAHA*, YATAN PAL SINGH BALHARA†

ABSTRACT

Alcohol use disorder is a chronic relapsing brain disorder and is associated with high mortality and morbidity. Chronic alcohol use worsens diabetes and associated diabetes-related complication. Alcohol use, especially over the long-term, can impact the glycemic control in persons with diabetes mellitus. Heavy consumption of alcohol in people with diabetes can lead to worsening of diabetes-related complications like diabetic ketoacidosis, altered lipid metabolism, peripheral neuropathy, sexual dysfunction and cardiovascular disease. This review aims to describe the association between alcohol use and glucose tolerance, effects of alcohol on the pre-existing diabetes; association between alcohol use, diabetes mellitus and diabetes-related complications and interaction of medicines used to treat diabetes with alcohol.

Keywords: Alcohol, alcohol use disorders, diabetes mellitus, insulin, glycemic control

Diabetes mellitus affects 537 million adults globally and a substantial proportion of them are from low- and middle-income countries. In 2021, diabetes accounted for 6.7 million deaths worldwide.[1] Alcohol is responsible for around 5% of the global burden of disease. Alcohol contributes a substantial burden socio-economically as well as for the alcohol-attributable diseases. When it comes to middle- and lower-income countries, the mortality and morbidity risks due to alcohol are more in comparison to high-income countries.

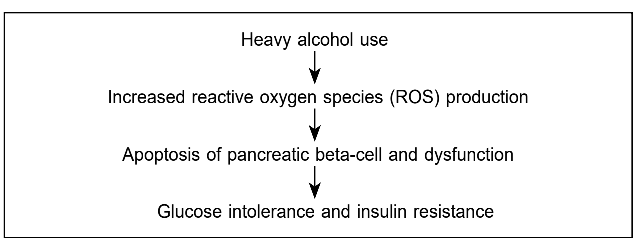
Alcohol consumption has been implicated as an independent and modifiable risk factor for the development of diabetes mellitus.[2] Several cohort studies have examined the association between alcohol and risk of developing type 2 diabetes mellitus (T2DM). It has been proposed that there is a U-shaped relationship between alcohol consumption and risk of developing diabetes. While moderate alcohol use may reduce the risk of T2DM,[3] heavy alcohol use increases the risk.[4] In addition, alcohol can have an immediate deleterious effect on diabetes control by worsening hypoglycemia, particularly in individuals using insulin or insulin secretagogues and can also contribute to weight gain.

The current article discusses the association of alcohol intake and glucose tolerance, and the effect of alcohol on blood glucose levels. Furthermore, this article also explores the existing literature on association between alcohol and diabetes mellitus and the pharmacological interventions for alcohol use disorder.

ASSOCIATION BETWEEN ALCOHOL INTAKE AND GLUCOSE TOLERANCE

Following alcohol consumption in individuals with or without diabetes, the glucose disposal rate as well as insulin secretion are increased. Heavy alcohol use leads to beta-cell dysfunction, which predisposes an individual to diabetes mellitus. In individuals with alcohol dependence, appetite regulating peptides like ghrelin and leptin are altered leading to insulin resistance further contributing to the development of diabetes mellitus.[5] Common genetic variants have been shown to interact with diabetes and heavy alcohol use.[6]

There are also conflicting results, where some studies state reduced risk of diabetes with moderate alcohol use, some reported nil and some showed positive association.



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One of the earliest occurrences in glucose intolerance is the production of ROS.[5] Animal models have also shown a reduction in glutathione following alcohol administration. Glutathione is an antioxidant and helps in fighting free radical production.[7]

In a well-fed state, there is a surge in blood glucose level after food intake. In normal individuals, in the absence of diabetes, there is uptake of glucose in the muscle and fat tissues. The existing glucose is converted into glycogen, which acts as a reserve when there is fall in blood glucose level. In type 1 diabetes mellitus (T1DM), since there is no insulin or minimal insulin production, blood glucose level tends to remain high with gradual impairment in both protein and fat metabolism giving rise to serious complications. In T2DM, on the other hand, there is normal to high insulin production and the body initially tries to resist the effect of insulin. In due course, the body cannot produce enough insulin further giving rise to complications.[8]

Chronic heavy alcohol use leads to decreased insulin secretion and sensitivity. In an individual with pre-existing diabetes, alcohol can worsen fasting as well as postprandial glucose level. Several randomized control trials have looked into the short-term and medium-terms effects of alcohol on blood glucose level in individuals with diabetes.

In the studies (Table 1), which have examined the effect of alcohol use on blood glucose levels, the dose of alcohol has ranged from 12 to 80 g. Majority of the studies had nonsignificant change in the blood glucose level after alcohol consumption. No adverse events of hypoglycemia and withdrawal were reported in any of the studies. Light-to-moderate alcohol consumption has no effect on blood glucose level. Another important factor to note is that the average alcohol intake over a short period of time might not capture the changes in blood glucose level. The pattern of alcohol consumption varies and measurement at a single time frame can give confounding results. Also the effect of heavy alcohol use

Table 1. Effects of Alcohol on Blood Glucose Level in Pre-existing Diabetes

Author (Year)	Type of study	Sample size	Mean alcohol use	Times of glucose measurement	Insulin use	Result
Gepner et al (2015)[9]	RCT	68	16 g of white wine	104 weeks	11%	White wine decreased fasting glucose by 1 mmol/L. Improvement in glycemic control was observed.
Gepner et al (2015)[9]	RCT	73	17 g of red wine	104 weeks	13%	No significant decrease in blood glucose level.
Nakamura et al (2009)[10]	RCT	12	12 g of white wine	26 weeks	36%	No significant change in blood glucose level.
Nakamura et al (2009)[10]	RCT	12	12 g of red wine	26 weeks	36%	No significant change in blood glucose level.
Kerr et al (2009)[11]	RCT	10	48-80 g of white wine	2 and 4 hours	Yes	Significant change in blood glucose level after 4 hours.
Bantle et al (2008)[12]	RCT	18	24 g of wine	2, 4 and 24 hours	No	No effect on plasma glucose or insulin level.
Bantle et al (2008)[12]	RCT	17	18 g of wine	4 weeks	No	No effect on plasma glucose or insulin level.
Dalgaard et al (2004)[13]	RCT	11	40 g of ethanol with food	0.5, 2, 4 and 24 hours	No	Alcohol subdues incretin responses in postprandial phase. No significant difference in blood glucose level.
Koivisto et al (1993)[14]	RCT	10	61 g (vodka, red wine and cognac)	0.5 hours	Yes	No significant increase in blood glucose level.
Koivisto et al (1993)[14]	RCT	16	61 g (vodka, red wine and cognac)	0.5, 2, 4 and 24 hours	No	No effect on postprandial blood glucose level. Serum insulin was higher after 3 hours of food and alcohol intake.

in glucose level in patients with pre-existing diabetes requires research.

Future prospective studies are required to look into the long-term changes associated with alcohol use in pre-existing diabetes.

ASSOCIATION BETWEEN ALCOHOL AND DIABETES MELLITUS

Many studies have explored the role of alcohol as an independent risk factor for diabetes mellitus. As early as 1971, Phillips et al[15] stated that a mean alcohol dose of 233-516 mg/dL causes insulin resistance and glucose tolerance. Taking this into account further cross-sectional studies also had similar findings. A meta-analysis by Baliunas et al in 2009[16] explored the association of alcohol use and diabetes mellitus, where findings of heavy drinkers (>50 g of alcohol/day in women and >60 g of alcohol/day in men) and nondrinkers were similar. No clear conclusion could be figured from the study.

Leggio et al in 2009 looked into the results from the multisite COMBINE study and evaluated the association between blood glucose level, heavy alcohol consumption and craving for alcohol during the treatment process in a sample of 1,324 patients. Baseline blood glucose level was found to have a positive association with percentage of heavy drinking days during treatment suggesting a role of blood glucose in heavy alcohol use.[17]

A 12-year follow-up study conducted by Lee et al in 2017, which investigated the association of pattern of alcohol consumption and risk of T2DM reported that heavy drinking pattern (>30 g/day) increased the risk of incident diabetes, whereas with light or moderate drinking, the risk was reduced.[18]

A 12-year follow-up study by Jang et al in 2019, which aimed to determine whether longitudinal association between genetic variants of *GCK* (glucokinase) or *INSR* (insulin receptor) in heavy alcohol users was associated with the risk of developing diabetes concluded that the risk of diabetes was increased in chronic heavy alcohol users who had the C allele of *GCK.* Chronic heavy alcohol consumers who had *INSR* haplotype negative also were at a higher risk of developing diabetes mellitus.[6]

ROLE OF ALCOHOL IN DIABETES-RELATED COMPLICATIONS

A systematic review was conducted in 2004 which aimed to look into the effect of alcohol use in incidence, management and complications of diabetes mellitus. Thirty-two studies met the inclusion criteria and affirmed that compared to moderate alcohol use, heavy alcohol consumption was associated with 43% increased risk of developing diabetes mellitus. Two experimental studies looked into the effect of alcohol into diabetic medication-related compilations and found that chlorpropamide (sulfonylurea) was associated with reduced ethanol elimination.[19]

Alcohol can worsen the complications associated with diabetes mellitus and the mechanisms by which it does so areas described below:

- **Diabetic ketoacidosis:** Although ketoacidosis is more common in people with T1DM as they completely lack insulin, nevertheless heavy alcohol use can cause ketoacidosis in a person who is not a known diabetic as well. On prolonged heavy alcohol consumption, an individual usually does not consume food and develops low blood glucose levels and can also reduce gluconeogenesis. However, some may have increased levels as in absence of insulin there is less glucose uptake in the tissues. Two important factors resulting in ketoacidosis are lack of insulin and increased glucagon levels.[8]
- **Altered lipid metabolism:** Individuals with diabetes are prone to develop dyslipidemia. Initial change in liver pathology following daily alcohol use is fatty liver and heavy alcohol use further leads to steatosis, which sensitizes the liver for further injury.[20] Some of the alterations in lipid metabolism seen with alcohol use are increased triglyceride (TG) level, decreased low-density lipoprotein (LDL) and elevated high-density lipoprotein (HDL). A study by Shimomura et al in 2013 investigated the role of alcohol and lipid parameters in 1,477 diabetic individuals and classified their alcohol use into light, moderate and heavy drinkers. Results showed alcohol intake had an inverse relation with high TG/HDL cholesterol ratio in individuals with light and moderate alcohol use, whereas in heavy drinkers the ratio was higher.[21] Polymorphism of alcohol dehydrogenase, aldehyde dehydrogenase, genes related to lipid metabolism and apolipoprotein E can lead to altered lipid metabolism in individual with diabetes mellitus and alcohol use.[22,23]
- **Peripheral neuropathy:** Clinical presentation of peripheral neuropathy can range from asymptomatic to symptoms such as tingling and numbness, burning sensation and pain, which can be debilitating and is common amongst individuals

with diabetes and alcohol use. Diabetic peripheral neuropathy affects small C fibers and to some extent A_{delta} fibers, whereas in alcoholic neuropathy large fibers are involved, which result from thiamine deficiency.[24] Alcohol and diabetes can amplify each other's effect in causing peripheral neuropathy. A study conducted in 1980 looked into the effect of alcohol intake in 541 individuals with diabetes experiencing symptomatic peripheral neuropathy. In this sample, 15% were heavy drinkers and 7% had frank alcohol use disorder and it was found that symptomatic peripheral neuropathy was much higher among the heavy drinkers.[25]

- **Cardiovascular disease:** Chronic heavy alcohol use is associated with hypertension, increased risk of hemorrhagic strokes, cardiomyopathy, heart failure and arrhythmia.[26] The relationship between alcohol in individuals with diabetes and acute coronary syndrome has been described as a J-shaped curve where the risk is lowest among light drinkers (<12 g/day) and highest amongst moderate to heavy drinkers (12-24 g and >24 g/day).[27] The probable mechanisms proposed were increased TG level and decrease in HDL leading to cardiovascular problems.
- **Sexual dysfunction:** Mechanisms underlying erectile dysfunction in diabetes mellitus and alcohol are multifactorial and can be vascular, neurogenic and hormonal. Diabetic neuropathy *per se* worsens the autonomic and somatic nerve processes, which play a role in erection. Low testosterone level has been associated with diabetes mellitus and chronic alcohol use. A study in Japan investigating the pattern of alcohol use causing erectile dysfunction in individuals with T2DM reported a 43% prevalence of erectile dysfunction. Weekly consumption of alcohol <60 g in patients with T2DM was associated with lower erectile dysfunction suggesting an inverse relationship with frequency of alcohol consumption and erectile dysfunction.[28]

DRUG INTERACTIONS – ALCOHOL USE DISORDER AND DIABETES MELLITUS

The US Food and Drug Administration (FDA) has approved naltrexone, acamprosate and disulfiram for the treatment of alcohol use disorder.[29] Other non-FDA approved medications like baclofen, topiramate, gabapentin and nalmefene have also been used to treat alcohol use disorder (Table 2).

There can be both pharmacodynamic as well as pharmacokinetic drug interactions of antidiabetic medications with alcohol. Where kinetic interactions occur at the level of metabolism or absorption of the drug, pharmacodynamic interactions primarily occur at the receptor or tissue level. Table 3 describes the interactions of medications used for treatment of diabetes with alcohol.

Table 2. Medications for Alcohol Use Disorder

Medicines	Dosage	Adverse effects
Naltrexone	50 mg/day	Nausea, vomiting, decreased appetite, abdominal pain (unsafe in patients with liver disease)
Injectable naltrexone	FDA approved injectable naltrexone 380 mg/month intramuscularly	
Acamprosate	1998 mg/day orally in 3 divided doses	GI upset, diarrhea (safe in patients with liver disease)
Disulfiram	250-500 mg/day	Drowsiness, metallic taste, peripheral neuropathy, hepatitis, psychosis, optic neuritis, confusional state
Baclofen	30-80 mg in 3 divided doses Starting from 5 mg 3 times a day and then 10 mg 3 times a day followed by 20 mg 3 to 4 times a day. Titration of dose to be done in 3 to 7 days till treatment goal is achieved. Can be increased up to 180 mg.	Drowsiness, headache, confusion
Topiramate	75-300 mg/day in 2 divided doses	Paresthesia, difficulty in attention and concentration, pruritus, anorexia
Gabapentin	600-1800 mg/day in 3 divided doses	Dizziness, peripheral edema, gait disorder
Nalmefene	5-80 mg/day in once daily or twice daily dosing	Nausea, vomiting, headache

Table 3. Interaction of Medicines Used to Treat Diabetes with Alcohol

Medicine	Mechanism	Studies
Chlorpropamide (sulfonylurea)	Inhibits aldehyde dehydrogenase in the brain and liver. Can cause disulfiram-like reaction (flushing, nausea, vomiting, sweating) if taken along with alcohol.	Ohlin et al (1982)[30]
Glyburide	Can cause disulfiram-like reaction if taken along with alcohol.	Johnson & Seneviratne (2014)[31]
Tolbutamide	Increased metabolism of tolbutamide. Can cause disulfiram-like reaction if taken along with alcohol.	Carulli et al (1971)[32]; Kater et al (1969)[33]
Tolazamide	Can cause disulfiram-like reaction if taken along with alcohol.	Jones (2004)[34]
Glipizide	Alcohol delays the absorption and elimination of gliclazide.	Johnson & Seneviratne (2014)[31]
Metformin	Alcohol increases effect of metformin on lactate metabolism.	Schaffalitzky de Muckadell et al (1979)[35]; Dubas & Johnson (1981)[36]
Troglitazone	Worsening of liver function when simultaneously taken.	Johnson & Seneviratne (2014)[31]
Insulin	Alcohol potentiates the action of insulin by lowering the glucose level.	Johnson & Seneviratne (2014)[31]

FUTURE CONSIDERATIONS

Co-occurrence of alcohol use (including alcohol use disorders) and diabetes is a significant clinical and public health issue. The effect of heavy alcohol use in glucose level in patients with pre-existing diabetes needs more research. There are gaps in literature about anticraving agents for alcohol use disorder and medications used for diabetes mellitus. More studies are required to know about the course and outcome, profile of patients and quality of life in patients with diabetes and alcohol use disorder to have a better understanding. Indian studies about this are minimal and need further attention.

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REVIEW ARTICLE

Effectiveness of Teaching Standardized Protocol on Safe Medication Administration Process Upon the Level of Knowledge among Nurses at a Tertiary Care Hospital, Chennai

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ABSTRACT

Strategies to improve medication safety focused on acute care settings. Twenty-six studies and descriptions of quality improvement projects were identified. Strategies used to focus on recommendations to prevent medication errors at various stages, from a nationwide voluntary organization to improve safety of patients and empower education system of nurses and other health care providers in safe practices in health care system and vast growing technology.

Keywords: Medication errors, health care delivery, lack of communication, monitoring side effects of drugs, adverse drug reactions, sentinel events, high-risk and alert medications, strategies to reduce medication errors and legal implications

"Success is not final, failure is not fatal: it is the courage to continue that counts." —*Winston Churchill*

Medication errors produce a variety of problems for patients, ranging from minor discomfort to substantial morbidity that may prolong hospitalization or lead to death. The 1999 IOM (Institute of Medicine) report implicates medication errors, at least in part, as a direct cause of up to 98,000 patients death annually. Drug errors associated with morbidity and mortality increase inpatient health care costs by an estimated $4700 per hospital admission, or approximately $2.8 million annually for a 700-bed teaching hospital. In addition, time spent by the health care team tracking errors, such as missed doses, can have an effect on time available for direct patient care.

Medication safety is a significant issue in hospitals and throughout health care. Great improvements are needed, and hospitals are making great efforts to reduce errors and increase this aspect of patient safety. Effective leadership and appropriateness of intervention are associated with successful change implementation. Health care professionals play a vital role in improving the quality of care and also in monitoring the quality assurance of patients in health-care settings. Examining the root cause analysis of events, to promote personnel training and communication barriers for corrective action of health care professionals to deliver quality of care to clients. Therefore adding new technology, revising policies and procedures, and providing more education have often been the approaches taken to reduce medication errors.

NEED AND RELEVANCE OF STUDY

In the Harvard Medical Practice Study, Leape and colleagues examined more than 30,000 hospital discharges selected at random from 51 hospitals in the State of New York in 1984. The researchers found that 3.7% of hospitalizations involved adverse events that prolonged hospital stay or were manifested as a new disability at the time of discharge. About one in four

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of these adverse events were judged to be attributable to negligence, and 58% were judged to be preventable.

James Reason (1995), a leading author in error management believed people generally do not act in isolation, but that their behavior is influenced by circumstances. He maintained that the likelihood of an unsafe act being committed is heavily influenced by the nature of the task and by the local workplace conditions. Examples include, increasing staffing and decreasing workload, software enhancement or modification, eliminating or reducing distractions, checklists and clinical or critical pathways, eliminate look-alike and sound-alike's, read back and enhanced documentation and communication. Moreover, there are medication errors that require necessary interventions to sustain life.

Optimization of the medication process can be obtained by adopting various strategies such as medication standardization, clinical pathway/critical pathway, electronic physician order entry system or computerized physician order entry (CPOE) system, barcode technology, electronic medication administration record (EMAR), medication reconciliation (updating current medications prescribed for the patients from admission till discharge).

OBJECTIVES

- To assess the pre- and post-test level of knowledge regarding safe medication administration process in experimental and control group of nurses to enhance quality monitor to improve patient care among nurses.
- To evaluate the effectiveness of teaching standardized protocol by comparing the pre- and post-test level of knowledge regarding safe medication process in experimental and control group of nurses to enhance quality monitor to improve patient care among nurses.
- To find out the difference between pre- and post-test level of knowledge regarding safe medication process in experimental and control group of nurses to enhance quality monitor to improve patient care among nurses.

REVIEW OF LITERATURE

A literature review is an organized written presentation of what has been published on a topic by scholars. Burns and Groove (2004). The review of literature for this study is presented under the following headings:

- Literature related to medication administration errors among nurses
- Literature related to rates and types of medication administration errors
- Literature related to knowledge on medication administration process among nurses
- Literature related to technology and medication errors among nurses
- Literature related to medication errors and prevention strategies for nurses.

Literature Related to Medication Administration Errors among Nurses

Oliveira et al (2016) systematically conducted a literature review by utilizing the databases: MEDLINE, CINAHL, LILACS, SciELO, BDENF and Cochrane from studies in English, Portuguese or Spanish, published by 2015. Of 594 potential studies, 8 comprised the final sample of the review. The Nursing Activities Score (NAS; 37.5%) and the Therapeutic Intervention Scoring System (TISS; 37.5%) were the instruments most frequently used for assessing nursing workload. Six studies (75.0%) identified the influence of work overload in events of infection, PU (pressure ulcer) and medication errors. This study identifies evidences of the influence of nursing workload on the occurrence of adverse events (AE) in adult patients admitted to the intensive care unit (ICU). Thus, it concludes that the nursing workload of patients in the ICU influenced the occurrence of AE, and nurses must monitor this variable daily to ensure proper sizing of staff and safety of care by prevention of medication errors.

Literature Related to Rates and Types of Medication Administration Errors

A randomized controlled trials (RCTs) and controlled trials (CTs) reporting rates of medication administration errors (MAEs) or related adverse drug events between an intervention group and a comparator group was conducted by Keers et al (2014). Risk ratios (RRs, with 95% confidence intervals [CIs]) were used to examine the effect of an intervention. Ten electronic databases were searched between 1985 and November 2013. Six RCTs and 7 CTs were included. Types of interventions clustered around four main themes: medication use technology (n = 4); nurse education and training (n = 3); changing practice in anesthesia (n = 2) and ward system changes (n = 4). Reductions in MAE rates were reported by 5 studies; these included automated drug dispensing (RR 0.72, 95% CI 0.53-1.00), CPOE (RR 0.51, 95% 0.40-0.66), barcode-assisted medication administration with electronic administration records (RR 0.71, 95% CI 0.53-0.95), nursing education/training using simulation (RR 0.17, 95% CI 0.08-0.38) and clinical pharmacist-led training (RR 0.76, 95% CI 0.67-0.87). Increased or equivocal outcome rates were found for the remaining studies. Weaknesses in the internal or external validity were apparent for most included studies. There is a need to identify effective interventions to minimize the threat posed by MAEs. The study concludes with review and critically appraise interventions designed to reduce MAEs in the hospital setting. There is emerging evidence of the impact of specific interventions to reduce MAEs in hospitals, which warrant further investigation using rigorous and standardized study designs. Theory-driven efforts to understand the underlying causes of MAEs may lead to more effective interventions in the future.

Literature Related to Knowledge on Medication Administration Process among Nurses

Pirinen et al (2015), conducted a study to describe the different stages of Medication Administration Process (MAP) from the registered nurses (RNs') perspective. A qualitative descriptive research design, with a purposive sample involving thematic interviews of 20 RNs and questions to them in a paper form, was conducted in two medical units. Data were analyzed by using deductive content analysis. The results revealed that RNs confront numerous problems such as equivocal prescriptions, problems with information technology (IT), unavailability or incompatibility of the medicines, a substantial amount of generic substitutions and changing medicine brands. Disruptions and distraction run through each stage of the MAP, excluding prescribing. The RNs desire support in all stages of the MAP. There are areas to improve in each stage of the MAP from the RNs perspective. Real-time and ubiquitous documentation, along with software including the data and knowledge required in medication management, is needed.

Literature Related to Technology and Medication Errors among Nurses

A total of 2,603 articles were initially identified by Hutton et al (2017) and 10 studies, which used prospective before-and-after study design, were fully reviewed in this article. A systematic search of databases was performed from 1998 to December 2016. Studies measuring the effect of bar-coding technology on medication errors were included in a full-text review. Studies with the outcomes other than medication errors such as efficiency or workarounds were excluded. The results of this review show that bar-coding technology may reduce medication errors in hospital settings, particularly on preventing targeted wrong dose, wrong drug, wrong patient, unauthorized drug and wrong route errors. However, few studies have addressed the impact of bar-coding technology with strong prospective methodologies and the research, which has been conducted from both in-pharmacy and bedside implementations.

Literature Related to Medication Errors and Prevention Strategies for Nurses

An cross-sectional descriptive study was conducted by Gorgich et al (2016), to investigate the causes of medication errors and strategies to prevention of them from nurses and nursing student viewpoint. This cross-sectional descriptive study was conducted on 327 nursing staff of Khatam-al-Anbia Hospital and 62 intern nursing students in nursing and midwifery school of Zahedan, Iran, enrolled through the availability sampling in 2015. The data were collected by the valid and reliable questionnaire. To analyze the data, descriptive statistics, *t*-test and analysis of variance (ANOVA) were applied by use of SPSS software version 16. The results showed that the most common causes of medication errors in nursing were tiredness due to increased workload (97.8%), and in nursing students it was drug calculation (77.4%).

The most important way for prevention in nurses and nursing student's opinion, was reducing the work pressure by increasing the personnel, proportional to the number and condition of patients and also creating a unit for medication calculation. Also, there was a significant relationship between the type of ward and the mean of medication errors in two groups. Based on the results, it was recommended that nurse-managers resolve the human resources problem, provide workshops and in-service education about preparing medications, side effects of drugs and pharmacological knowledge. Using electronic medications cards is a measure, which would reduce medications errors.

METHODOLOGY AND PROCEDURES

Research Design

- Research design: Experimental research design-Quasi (pre- and post-test design).
- Research setting: Tertiary care hospital, Chennai.
- Sampling technique: Probability systematic random sampling technique.

- Target population: The target population comprised of all nurses who satisfied the inclusion criteria.
- Accessible population: Comprised of nurses who satisfied the inclusion criteria at a tertiary care hospital, Chennai.
- Sample size: Fifty (25 in experimental and 25 in control) registered nurses/midwives at tertiary care hospital, Chennai.

Description of the research tool

Tool consisted of 3 sections

- **Section I** – Demographic data: It included the baseline information about the nurses.
- **Section II** – Structured questionnaire to assess the level of knowledge regarding safe medication administration process (SMAP)*. The score was interpreted as follows:

  Scoring key

  - Adequate – ≥75%
  - Moderately adequate – 50-75%
  - Inadequate – <50%

  The scoring key was graded into adequate knowledge, moderately adequate knowledge and inadequate knowledge on percentage basis.
- **Section III** – Practice observation checklist to assess the enteral route on SMAP*, by using standardized protocol.

ETHICAL CONSIDERATIONS

Prior permission was obtained from concerned management of hospital. Confidentiality of the information was maintained.

Method of data collection: Observation method.

Plan for data analysis: Descriptive and inferential statistics method.

Analysis and Findings

As per the data most of the nurses were aged between 20 to 29 years (84%, 100%) group, has female (84%, 100%), graduate nurses (64%, 60%) working in general wards (32%, 36%), with years of experience (56%, 36%), employed permanently (56%, 44%) belongs to nuclear family (76%, 72%) in experimental and control group, respectively.

Major Findings

- With regard to knowledge, a significant percentage of nurses had inadequate knowledge (60%, 80%), moderately adequate (40%, 20%) in pre-test (Fig. 1), whereas after teaching standardized protocol on SMAP 100% in experimental and 96% in control group had adequate knowledge; 4% in moderately adequate in post-test and none of them had inadequate knowledge (Fig. 2).
- With regard to the mean (M) and standard deviation (SD) for the pre-test scores of level knowledge on teaching standardized protocol on SMAP (M = 11.16, SD = 2.528), (M = 10.48, SD = 2.023) showed no significant difference at $p > 0.05$. On the other hand, after receiving knowledge the mean and SD (M = 23.60, SD = 0.866), (M = 22.84, SD = 1.028) of post-test scores were adequate knowledge when compared with pre-test scores (Fig. 3). The difference was found to be statistically significant at $p < 0.01$ in experimental and control group of nurses, respectively.

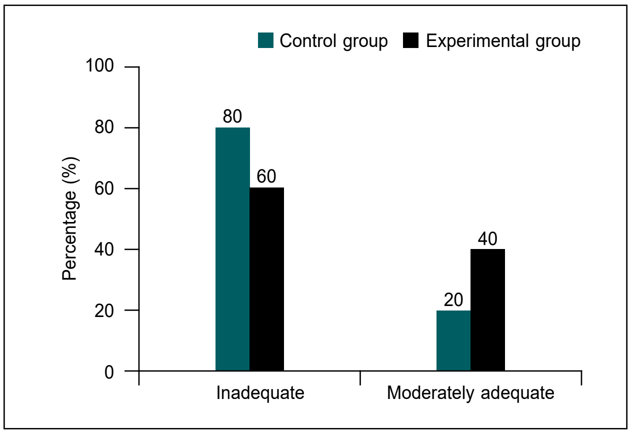

Figure 1. Percentage distribution of level of knowledge pre-test scores on SMAP in experimental and control group during medication process.

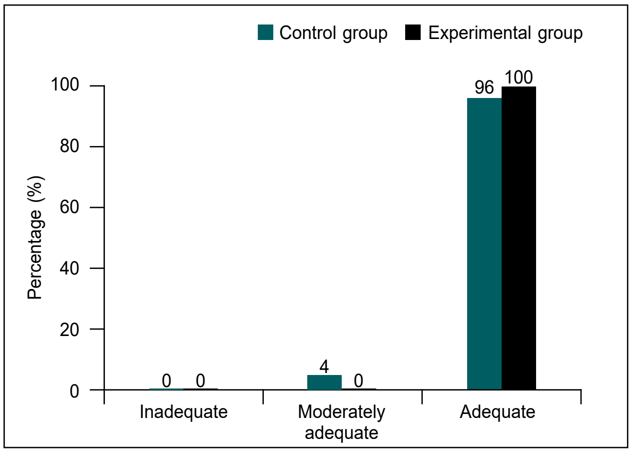

Figure 2. Percentage distribution of level of knowledge post-test scores on SMAP in experimental and control group during medication process.

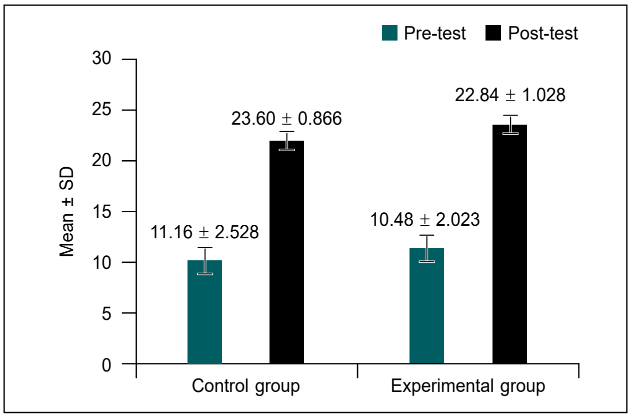

Figure 3. Comparison of mean and SD on pre- and post-test level of knowledge scores on SMAP in experimental and control group of nurses during medication process.

With regard to the mean and SD for the enteral route of medication administration in first post-test observation scores on SMAP (M = 33.7, SD = 0.723), (M = 18.84, SD = 0.374) among nurses was significant at $p < 0.01$. On the other hand, the enteral route of medication administration in second post-test observation scores (M = 35.56, SD = 0.712), (M = 18.84, SD = 0.374) was statistically significant at $p < 0.001$ in experimental and control group of nurses; the difference was found statistically significant at $p < 0.001$, respectively.

Association Findings

These findings reveal that age, gender, educational qualification, area of clinical experience, occupation and type of family were influencing the level of knowledge on SMAP among nurses, which led them to face challenges in health care delivery system (HCDS). Many researchers have recommended by increasing pharmacological knowledge of nurses as a strategy to reduce serious of medication compliance and adverse reaction of drugs. Therefore, nurses are required to update their knowledge about medicines, especially newer drugs. Obviously, it is absolutely impossible to eliminate all medication compliance. However, the role of nursing administrators in reducing and preventing these errors is vital. Reporting medication errors is an ethical duty to maximize the benefits of patient care. It can thus improve patient safety and health. Therefore, managers should have a positive attitude toward the reporting of medication compliance by nurses. Intervention and prevention programs should primarily focus on this type of medication error. More than 75% of nurses strongly agree that continuous education and up-to-date information of pharmacology are necessary to avoid medication errors.

Enhanced communication skills and better interactions among members of the health care team and the patients' are essential. Reducing medication compliance is an ongoing process of quality improvement. Thus, faculty systems must be redesigned and seamless, computerized integrated medication delivery must be inculcated by health care professionals for adequate training to use such technological advances.

IMPLICATIONS

Nursing Practice

Therefore, it is suggested to train nurses and hospital administrators on facilitators and barriers of error reporting in order to enhance patient safety. Effective prevention of these type of errors depends on the presence of a well-organized reporting system which is able to set targets for costs, quality of information, responsiveness, employee satisfaction and degree of innovation to establish drug distribution system, in respect of quality and cost-effectiveness and represents the best and most cost-effective way of preventing medication errors. Thus, the researchers intend to develop a protocol as prevention strategy for reduction of medication compliance in order to define the differences in quality and cost-effectiveness to enhance the quality improvement among nurses.

Nursing Education

Nursing students can be altruistic and optimistic if they are molded from the beginning. Almost all the nurses follow written guidelines for administering medication. Potential problems were identified in documenting side effects/adverse reactions of medications, storage of medications, student self-administration practices and appropriate authorization of nonprescription drug use. Faculty might consider curriculum revisions that incorporate safety medication use throughout nursing courses. Educational programs to raise awareness and reduce hospital MAEs in children have been delivered to doctors, nurses and graduating students.

Nursing Administration

The role of nursing administrators in reducing and preventing these errors is vital. Although most medication compliance issues can be minor and may not harm the patients, they need more supervision and planning. Nurses involved in a hospital administration should conduct regular skill training programs to empower the novice nurses with three domains (cognitive, conative and affect).

Nursing Research

Many researchers have recommended increasing pharmacological knowledge of nurses as a strategy to reduce serious medication errors. Preparing future generations of nursing professionals with a positive career will be a unique challenge. The Joint Commission International (JCI) advocates the pursuit of continuous improvement in decreasing medication errors so as to enhance patient safety.

RECOMMENDATIONS

- A similar study can be conducted on a large sample to generalize the findings.
- The study can be replicated in different settings.
- A different (exploratory/prospective) study design can be conducted to evaluate awareness about medication errors amongst health care personnel in various hospital settings.

CONCLUSION

Nurses are most involved in safe medication administration process, although they provide a vital function in detecting and preventing errors that occurred in the prescribing, transcribing, dispensing and administration stages. Research addressing the complex process of medication use in hospitals is urgently needed and requires a new approach to produce valid knowledge from studies done in this field to equip nurses with updated knowledge and skills so as enhance continuous quality improvement to deliver optimum standardized health care services to patients.

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CASE REPORT

Repeatedly Recurrent Supernumerary Bilateral Fibroadenoma Breast with Family History of Breast Cancer in a Young Girl: A Surgeon's Dilemma

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ABSTRACT

More than 4 fibroadenomas in a single breast are uncommon. Repeated recurrences of supernumerary fibroadenomas, in multiple numbers, after excision, are extremely rare. The malignant potential of breast fibroadenoma increases significantly in women with complex fibroadenomas, proliferative disease or a family history of breast cancer. Such a condition poses a management dilemma to the surgeon. Prophylactic bilateral mastectomy is controversial, and requires a rigorous assessment of risk benefit ratio and a better assessment of psychosocial impact and ethical issues. More often than not, the patient prefers repeat excision and close surveillance as the most agreeable course of action; the relatively higher risk of malignancy notwithstanding. Repeated excision as new fibroadenomas appear seems to be a feasible option.

Keywords: Fibroadenoma breast, multiple fibroadenoma, recurrent fibroadenoma, supernumerary fibroadenoma

Breast fibroadenoma is a fairly common condition, accounting for nearly 50% of all breast biopsies, and about 75% biopsies in women under 20 years of age.[1,2] The malignant potential of breast fibroadenoma is low at 0.125% to 0.02%.[3] But, the same risk increases significantly in women with complex fibroadenomas, proliferative disease or a family history of breast cancer.[4]

Although up to four fibroadenoma in a single breast are not very uncommon,[5,6] Haagensen (1986) and Foster et al (1988) in their two different studies found the incidence to be nearly 16% of all fibroadenomas. But, more than that in a single breast is rare.[7] It is possible that many such cases remain unreported. Nevertheless, recurrence of supernumerary fibroadenoma seems to be extremely rare.

Both conservative and surgical management of isolated fibroadenoma have their advocates, generally allowing expectant treatment in younger females up to 30 years of age, and more aggressive surgical treatment for patients who are more than 30 years of age.[8,9] The question becomes tricky when there are recurrences, or when there is a family history of breast cancer.

We present such a case. The uniqueness of this case lies in the fact that, besides being young and having supernumerary fibroadenomas (6 in 1 breast and 3 in the other), she had repeated recurrences, in multiple numbers after excision, and had a family history of breast cancer.

CASE REPORT

A 21-year-old young girl presented to our surgical clinic with history of multiple lumps in both breasts for the past 3 years. She had similar lumps about 5 years ago, which were removed from her left breast and were reported to be benign. She noticed that the lumps reappeared within 2 years after surgery, but she postponed consulting a doctor presuming them to be benign as earlier. When some of the lumps attained large size, she came in for treatment.

On clinical examination, 6 lumps in the left breast and 3 in the right breast were palpable. Ultrasound and radio mammograms, and fine needle aspiration cytology confirmed the benign nature of these lesions.

The patient's mother had died of breast cancer at less than 50 years of age, and her maternal grandfather

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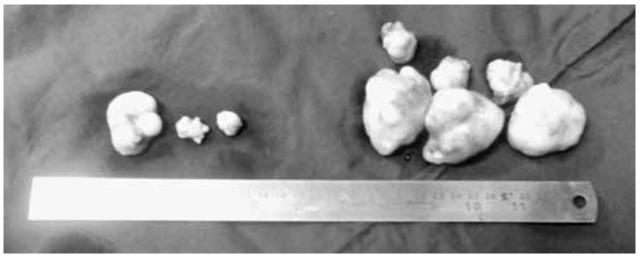

Figure 1. Surgically removed fibroadenomas, 3 from the right breast and 6 from the left breast.

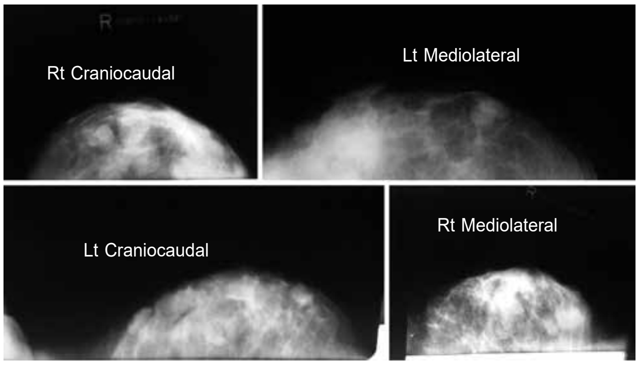

Figure 2. Radio mammography report, at the time of the second recurrence, showing multiple fibroadenomas, 10 in the right breast and 5 in the left breast.

had carcinoma cheek, although he had died of some other cause. Six lumps from the left breast and 3 from the right breast were removed (Fig. 1) and sent for histopathological examination. All were reported to be benign fibroadenomas. The girl refused for *BRCA* gene mutation assessment, but agreed for a follow-up in case of recurrence.

On her last clinical visit on 7th September, 2016, the radio mammography and sonography reports revealed 10 fibroadenomas in the right breast and 5 in the left breast (Fig. 2).

DISCUSSION AND REVIEW OF LITERATURE

Although breast fibroadenoma is a fairly common disease with a number of 2 to 4 being seen in nearly 16% of all fibroadenomas; finding more than 6 fibroadenomas in a single breast is rare. In 1993, Williamson et al mentioned that they could find only 6 such cases in the literature.[7]

Fibroadenomas are formed as a result of minor aberrations in the normal process of development and maturation of the breast tissue, and are identical to hyperplastic lobules as shown by various histological studies.[10-12] In our case, it was perhaps an ongoing process as evident by such a rapid recurrence in such large numbers. We presume that there were budding fibroadenomas of undetectable size present in both breasts at the time of first and second surgeries, and, may be there would be some present during the subsequent surgeries till this growth period stops at a certain age.

A Mayo Clinic Study (2015) concluded that, although complex, fibroadenomas were more likely to have concomitant high-risk histological features like incomplete involution and proliferative disease without atypia, they alone were not high-risk markers for breast cancer.[13]

As such, the malignant potential of fibroadenoma breast is extremely low. Zheng et al (2015) could find less than 130 such cases in literature.[14] Wu et al (2014) in a detailed analysis of literature mentioned the incidence as 0.125% to 0.02%.[3] Pick et al (1984),[15] went on to assert that the only importance of fibroadenoma, as far as breast malignancy is concerned, is to contribute to its early detection; and as such they are the parameter independent of the development of cancer in either ipsilateral or contralateral breast.

But, the scenario changes when there is a family history of breast cancer. Dupont et al (1994) in a very well-structured study found that patients having complex fibroadenoma breast and a family history of breast cancer had a relative risk of 3.72 as compared to controls without a family history, of developing cancer.[4]

Based on the rich data on the natural history of fibroadenoma, (be it single or multiple) and also based on their own experience, Greenberg et al (1998)[8] recommended that expectant management for single as well as multiple fibroadenomas is preferable if they are diagnosed before the age of 35 years, and are not increasing in size on a 6-monthly follow-up. In case no regression occurs after the age of 35 years, or if they are increasing in size, they must be excised. Fibroadenoma(s) detected after the age of 35 years can still be observed for 6 to 12 months, but must be excised if they persist beyond that or are increasing in size. In patients with family history of breast cancer, or known changes of complex fibroadenoma, excision biopsy is recommended without delay.

Although the role of *BRCA 1/2* gene mutation assessment as a cancer risk predictor is well-established, role of prophylactic mastectomy in high-risk women is still seen with scepticism. Lostumbo et al (2004) in their Cochrane review article, and Rhiem and Schmutzler (2014) in their well-researched article have stressed that a more rigorous assessment of risk benefit ratio and a better assessment of psychosocial impact and ethical issues is required before issuing an undisputable verdict.[16,17]

Our patient was counseled at length about her increased chances of contracting a malignancy in her breast because her mother had died of breast cancer at an early age of below 50. The girl understood her risk, but absolutely refused to consider a radical surgery like bilateral mastectomy, and, for that matter, even to check her *BRCA* gene status. We agreed upon a close follow-up and removal of lumps as they appear.

Post the second excision, and on her last clinical visit on 7 September, 2016, she had 10 fibroadenomas in the right breast and 5 in the left breast. She was advised excision of the recurrent fibroadenomas once again.

CONCLUSION

More than 4 fibroadenomas in a single breast is an extremely rare condition, and repeated recurrence in multiple numbers in such a case is extremely rare.

Early excision irrespective of age must be done, where there is a family history of breast cancer. Prophylactic bilateral mastectomy is a difficult and controversial decision even when there are repeated recurrences in large numbers. It requires a more rigorous assessment of risk benefit ratio and a better assessment of psychosocial impact and ethical issues. More often than not, the patient prefers repeat excision and close surveillance as the most agreeable course of action, the relatively higher risk of malignancy notwithstanding.

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■■■■

BRIEF COMMUNICATION

Therapeutic Patient Education in Transgender Care

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ABSTRACT

This communication visits the concept of therapeutic patient education (TPE), and explores its relevance to transgender health care. It suggests a novel term, therapeutic education (TE), and defines it as "educational activities essential to the optimization of health, offered by health care providers duly trained in the field of education, designed to help a transgender individual (or a group of individuals and their families) to manage their treatment and prevent avoidable complications, while maintaining or improving their quality of life. It describes the soft and hard skills required for TE, and suggests a classification that can help in structuring TE programs.

Keywords: Gender affirmation, person-centered care, quality of life, transgender care, transgender health, therapeutic education

Therapeutic patient education (TPE) is a well-accepted concept that has found utility in the management of various chronic diseases. The World Health Organization (WHO) has highlighted the need to help health care providers acquire the competencies that are necessary to help patients self manage their chronic disease. TPE is defined as "education activities essential to the management of pathological conditions, managed by health care provides duly trained in the field of education, designed to help a patient (or a group of patients and their families) to manage their treatment and prevent avoidable complications, while keeping or improving their quality to life."[1] TPE provides a therapeutic effect additional to that produced by the other interventions, including pharmacological and nonpharmacological therapies.

REWORDING THE DEFINITION

While the definition of TPE in its present form serves the cause of chronic disease, such as diabetes mellitus, it is unsuited to transgender health. The words "pathological" and "patient" are not only inappropriate, but inaccurate as well, while describing the life of transgender persons.[2] Negating the relevance of TPE to transgender health, just because of these two words, however, is akin to throwing the baby out with the bath water. A more apt nomenclature may be therapeutic transgender person education, or simply, therapeutic education (TE).

From a transgender health perspective, TE is best defined as "educational activities essential to the optimization of health, offered by health care providers duly trained in the field of education, designed to help *a transgender individual (or group of individuals and their families)* to manage their treatment and prevent avoidable complications, while maintaining or improving their quality of life."

RELEVANCE

Transgender health is a complex science, which needs active participation from the transgender individual.[3] Learning about one's gender identify, navigating the health care ecosystem and society at large, as well as practicing necessary self-care activities, requires significant education.[4] This information and knowledge is best shared through TE.

COMPETENCIES

The competencies required for TE providers and diabetes patients have been described in detail.[1] Reference training programs must be crafted for health care providers, based upon robust educational principles and

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evidence-based medicine. These programs must sensitize them to the need for trans-friendly communication, and equip them with tools for effective teaching. Apart from these soft skills, hard skills such as psychological, social and legal support, as well as endocrine, psychiatric and surgical aspects of transgender care should be covered.

It may be apt to create a hierarchy of competencies required for transgender TE. Primary skills include those required for all transgender persons, such as how to navigate social, legal and health care knowledge related to gender affirmative interventions, while tertiary competencies are a label for information that may be needed for specific issues that impact a few people in an individualized manner

THE WAY FORWARD

The way forward is to integrate transgender health in medical, nursing and paramedical curricula and practice, as well as integrate TE in transgender health. Just as TPE has changed our approach to chronic disease management; a focus on TE will revolutionize our attitude to transgender health and transgender care.

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Multidisciplinary Experts Reach a Consensus on Ending COVID as Public Health Threat

According to a new article published by the *Press Trust of India*, specific efforts and resources will be required to save lives as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continues to circulate among the Indian population. Other than saving lives through continued efforts and resources, a large panel of multidisciplinary experts from over 100 countries recommended five other actions to end coronavirus disease 2019 (COVID-19) as a public health threat.

To develop a global consensus, a Delphi study was used, which included a panel of 386 academic, health, NGO, government and other experts from 112 countries and territories who took part in three rounds of structured consultation. The results of the study included a set of 41 statements and 57 recommendations across six major areas, namely communication, health systems, vaccination, prevention, treatment and care and inequities.

The top three consensus recommendations are a whole-of-society strategy that involves multiple disciplines, sectors and actors to avoid fragmented efforts; a whole-of-government approach to identify, review and address resilience in health systems to make them more responsive to people's needs; and a vaccines-plus approach that includes a combination of COVID-19 vaccination, other structural and behavioral prevention measures, treatment and financial support measures. Other recommendations published in the journal *Nature*, with at least 99% agreement, include communicating effectively with the public, rebuilding public trust and engaging communities in managing the pandemic response.

The study added that over 180 organizations from 72 countries have already endorsed the findings of the consensus study, which was led by the Barcelona Institute for Global Health (ISGlobal). (*Source: https://health.economictimes.indiatimes.com/news/industry/multidisciplinary-experts-across-countries-reach-consensus-on-ending-covid-as-public-health-threat/95301057*)

Do No Harm or Harm Reduction: The Ethical Dilemma

Medical profession is a noble profession, which comes with lot of responsibilities. The relationship between the doctor and patient is a fiduciary relationship and doctors must adhere to the principles of medical ethics (autonomy, non-maleficence, beneficence and justice), rules (fidelity, confidentiality, privacy and veracity) and virtues (compassion, kindness, respect, etc.) in their interactions with the patients, which have been laid down by various professional bodies and associations as professional codes of conduct and standards for doctors. The Hippocratic Oath, the oldest of these codes of ethics, still holds true today.

Let's take a look at different codes of ethics and the principles therein.

In the **Hippocratic Oath,** the aspect that is instructive and serves as guide to physicians in respect of non-maleficence states that: "*I will follow that system of regimen, which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to anyone if asked, nor suggest any such counsel.*"

In the **Declaration of Geneva**, and as amended in Sydney 1968, physicians were expected and indeed mandated to: "*…maintain the utmost respect for human life from the time of conception; even under threat, ... not [to] use medical knowledge contrary to the laws of humanity.*"

The International Code of Medical Ethics states that: "*A doctor must always bear in mind the obligation of preserving life.*"

In India, at the time of registration with the Medical Council, the doctors are given a declaration as per the Appendix 1 of **Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002** which is reproduced hereunder:

> ***"A. DECLARATION***
>
> *At the time of registration, each applicant shall be given a copy of the following declaration by the Registrar concerned and the applicant shall read and agree to abide by the same:*
>
> 1) *I solemnly pledge myself to consecrate my life to service of humanity.*
> 2) *Even under threat, I will not use my medical knowledge contrary to the laws of Humanity.*
> 3) *I will maintain the utmost respect for human life from the time of conception.*
> 4) *I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient.*
> 5) *I will practice my profession with conscience and dignity.*
> 6) *The health of my patient will be my first consideration.*
> 7) *I will respect the secrets which are confined in me.*
> 8) *I will give to my teachers the respect and gratitude which is their due.*
> 9) *I will maintain by all means in my power, the honor and noble traditions of medical profession.*
> 10) *I will treat my colleagues with all respect and dignity.*
> 11) *I shall abide by the code of medical ethics as enunciated in the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002."*

The **World Medical Association in its Medical Ethics Manual** has stated that:

> *"Beneficence - literally, 'doing good'. Physicians are expected to act in the best interests of their patients.*
>
> *Non-maleficence - literally, not doing wrong. Physicians and medical researchers are to avoid inflicting harm on patients and research subjects."*

United Nations Educational, Scientific and Cultural Organization in Universal Declaration on Bioethics and Human Rights which addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions. The relevant articles of the said Declaration are reproduced hereunder:

> ***"Article 4 - Benefit and harm:***
>
> *In applying and advancing scientific knowledge, medical practice and associated technologies, direct and*

indirect benefits to patients, research participants and other affected individuals should be maximized ***and any possible harm to such individuals should be minimized.***

Article 5 - Autonomy and individual responsibility:

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 8 - Respect for human vulnerability and personal integrity:

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 10 - Equality, justice and equity:

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 - Non-discrimination and non-stigmatization:

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms."

Indian Council of Medical Research in 2000 in its book titled as **"Ethical Guidelines for Biomedical Research on Human Participants"** has stated that:

"All the research involving human participants should be conducted in accordance with the ***four basic ethical principles, namely autonomy (respect for person/participant) beneficence, non-maleficence (do no harm) and justice****. The guidelines laid down are directed at application of these basic principles to research involving human participants."*

International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by the **Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)** provides the general ethical principles as:

"GENERAL ETHICAL PRINCIPLES

All research involving human subjects should be conducted in accordance with three basic ethical principles, namely respect for persons, beneficence and justice. It is generally agreed that these principles, which in the abstract have equal moral force, guide the conscientious preparation of proposals for scientific studies. In varying circumstances they may be expressed differently and given different moral weight, and their application may lead to different decisions or courses of action. The present guidelines are directed at the application of these principles to research involving human subjects.

Respect for persons incorporates at least two fundamental ethical considerations, namely:

a) respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and

b) protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Beneficence refers to the ethical obligation to maximize benefits and to minimize harms. *This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, non-maleficence (do no harm).*

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research. Differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons; one such distinction is vulnerability.

"Vulnerability" refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons."

Obligation of non-maleficence: moral dilemma in physician-patient relationship by Peter F Omonzejele in his book - A Peer-review Journal of Biomedical Sciences, June 2005 Vol. 4 No. 1 pp. 22-30:

"The principles and rules of medical ethics are derived from the Hippocratic oath and various declarations

(Declaration of Geneva as amended in Sydney 1968, Declaration of Tokyo 1975, Declaration of Oslo 1970, Declaration of Helsinki 1975, etc.) regulating medical practice. Despite the Hippocratic oath and various declarations, a certain aspect (non-maleficence) of the oath and declaration is sometimes breached in what seems to be in the "interest" of patients in circumstances that constitute moral dilemmas.

The physician-patient relationship is fiduciary. The patient believes and trusts that the physician would apply his professional expertise in his/her (the patient's) interest and benefit. Even more importantly, the patient believes that his/her physicians (based on the principle of non-maleficence) would do nothing to harm him/her. The principle of non-maleficence runs through from the Hippocratic oath to current versions and amendments of medical ethics.

Non-maleficence in general and medical non-maleficence in particular, recommends that one ought not to inflict evil or harm."

Not only has medicine undergone tremendous advancements over the years, the social milieu has changed and the patients have changed as well, which is reflected in the doctor-patient relationship; from "*paternalism*", where doctors were "*parent figures*" taking medical decisions on behalf of their patients to the current "*patient-centric*" where the patient is an "*equal partner*".

Regardless, the core values of the practice of medicine are still based on the principles of non-maleficence, derived from the doctrine of "*primum non-cere*", which means "first do no harm" and its natural corollary, beneficence or "do good", which means doing the right thing for the patient.

Harm reduction is now a new term in non-maleficence. The basic ethical duty of the doctor is to treat on the principle "first do no harm". But doctors will often end up with social determinants of health where they will have to choose between the two devils and in that situation the answer is to choose the lesser devil and this is what is called a harm reduction strategy.

It has been recognized as a public health strategy since the 1980s, when it was first used as an alternative to abstinence-only interventions for adults with substance abuse disorders who were unwilling to quit.

Harm reduction is an umbrella term for interventions aiming to reduce the problematic effects of behavior. Harm reduction has a human rights agenda in that it is committed to bringing effective treatment to groups that have traditionally been denied quality care. It is scientific in that it is committed to the discovery and implementation of evidence-based interventions.

Doctors practice harm reduction every day. To list a few:

- Rational use of drugs and investigations is a harm reduction approach. It requires that "*patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community*" (WHO 1985).
- The 'Five Rights' of safe medication administration by the Institute of Healthcare Improvement also promote rational use of drugs: Right patient, Right drug, Right time, Right dose and Right route. Four more 'Rights' have been added to this: Right documentation, Right action (reason for prescribing the medication), Right form and the Right response.
- Antimicrobial stewardship programs, which are being advocated to curb the rising prevalence of antimicrobial resistance.
- The "Choosing Wisely" campaign, an initiative of ABIM (American Board of Internal Medicine Foundation) launched in 2012 encourages a dialogue between the doctor and the patient about "*what is appropriate and necessary treatment*" and helps patients to choose care that is: "*Supported by evidence, not duplicative of other tests or procedures already received, free from harm and truly necessary.*"
- To reduce prescription errors, the Medical Council of India (MCI) has issued guidelines that require a doctor to write in capital letters.
- Vaccination is an established harm reduction strategy.
- Maintaining basic hygiene and hand washing are also ways of harm reduction.

No doctor practices medicine to harm the patient. Yet, patients are exposed to some potential harm.

There are risks of side effects with the prescribed medications; there are implied risks in every intervention or procedure. While a major surgery may be uneventful, sometimes unanticipated accidents can occur even in a minor surgery, despite all care. This makes medicine "a double-edged sword".

Would this be a violation of the principle of non-maleficence?

The **"principle of double effect"** differentiates intended and non-intended effects of an action. The intended effect is good and primary; however, associated with the intended effect is the necessary but bad and unintended (secondary) effect. To be morally justifiable, it must satisfy certain conditions: (*JMBR*. 2005;4(1):22-30).

- "*The action itself (independent of its consequences) must not be intrinsically wrong (it must be morally good or at least morally neutral).*
- *The agent must intend only the good effect and not the bad effect. The bad effect can be foreseen, tolerated and permitted but must not be intended; it is therefore allowed but not sought.*
- *The bad effect must not be a means to the end of bringing about good effect, that is, the good effect must be achieved directly by the action and not by the way of the bad effect.*
- *The good result must outweigh the evil permitted, that is, there must be proportionality or favorable balance between the good and bad effects of the action.*"

Harm is inflicted when the doctor has a duty of care towards the patient, there is a breach of the said duty and the patient has suffered harm as a consequence of a breach of that duty. This is liable for medical negligence or malpractice claim.

Difference of opinion, error of judgment, medical errors and medical accidents are not medical negligence. Experiencing a bad outcome does not always mean medical negligence. This has also been the position of the Supreme Court of India in its various judgments.

Harm reduction has often invited criticism as seemingly; it is seen to allow subjects to continue with the harmful behavior.

But, harm reduction accepts, without being judgmental, that some individuals are unwilling or averse to the idea of quitting risky health behaviors such as smoking or use of drugs and so takes the view that it is better to reduce the associated harm by some means, rather than pressurizing them to abide by total abstinence.

According to the National Health Care for the Homeless Council (2010), "*harm reduction is not at odds with abstinence; instead it includes it as one possible goal across a continuum of possibilities… Harm reduction neither condones nor condemns any behavior. Instead, it evaluates the consequences of behaviors and tries to reduce the harms that those behaviors pose for individuals, families and communities.*"

Harm reduction currently accommodates a vast array of interventions. It is best exemplified by needle exchange programs for the injection drug users, which aim to prevent HIV transmission and other blood-borne infectious diseases, as well as prevent overdose, including naloxone distribution and opiate substitution treatment (methadone, buprenorphine).

Other examples are prioritizing less risky drinking habits for underage drinkers to reduce the risk of alcohol poisoning, encouraging safe sex and replacing binge eating with healthier alternatives. More extreme interventions would be, for example, providing clean razors for those engaged in self-injurious behavior, or educating intravenous femoral vein injectors how to inject drugs to safer sites.

Some harm reduction techniques have already become a norm (e.g., opiate substitution treatment), while others remain highly controversial (e.g., educating injecting users on how to properly inject drugs in order to minimize health consequences).

India is the world's second largest consumer and third largest producer of tobacco. According to WHO, India is home to 12% of the world's smokers. Tobacco is an important "modifiable" risk factor for non-communicable diseases. India also has the highest oral cancer rates globally. Tobacco therefore is a major preventable cause of premature morbidity and mortality. Around 9 lakh people die every year due to diseases attributable to tobacco use (*Press Information Bureau,* March 1, 2016). This makes tobacco a major public health issue and tobacco control of great importance. Hence, harm reduction strategy should also be applied to tobacco.

While the duty and obligations of physicians to their patients remain unequivocally that of beneficence and non-maleficence, patient autonomy has now come to the forefront. The patients' choices about their treatment should be respected as should be their right to make decisions about their health. This also forms the basis of "informed consent", which is not only an ethical, but also a legal requirement today.

The Revised Declaration of Geneva adopted on October 17, 2017, now called the "Physician's Pledge" also puts the patients' interests and well-being foremost and in keeping with the changing times, has emphasized on patient autonomy.

- "*THE HEALTH AND WELL-BEING OF MY PATIENT will be my first consideration;*
- *I WILL RESPECT the autonomy and dignity of my patient;*
- *I WILL SHARE my medical knowledge for the benefit of the patient and the advancement of health care.*"

Doctors should also respect the principle of justice in health care, where justice means fairness of access to treatment.

"Do no harm" is a utopian concept as medicine is not an exact science; it is an art based on science. No two patients are alike and clinical decisions are tailored to individual patients. Probability and uncertainty are part of the practice of medicine where complications are bound to occur and accidents are inevitable.

In a Guest Editorial published in the journal *Advances in Chronic Kidney Disease*, Kellerman PS writes, "*On a daily basis, we physicians weigh the benefits against the risks in almost everything we do, both diagnostically and therapeutically*" (*Adv Chronic Kidney Dis*. 2012; 19(3):127-8).

As Harvard Health Publishing also writes in its Blog "*The fact is that when difficult, real-time decisions must be made, it's hard to apply the "first, do no harm" dictum because estimates of risk and benefit are so uncertain and prone to error.*"

While quitting the harmful behavior is the optimal goal, the patient ought to be given the option of harm reduction.

But, despite the apparent conflict between "Do no harm" and "harm reduction" and the ethical dilemma it poses, it is important to remember that doctors should act in the best interest of the patient, i.e., "*Salus aegroti suprema lex*".

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Effect of Nasal and Plasma SARS-CoV-2 RNA Levels on Symptom Duration

Levels of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA in the plasma and respiratory tract may explain why some patients with acute coronavirus disease 2019 (COVD-19) quickly recover, while others take longer, suggests a recent study published in *Clinical Infectious Diseases*.[1]

Researchers from the United States set out to examine the correlation between the plasma and nasal SARS-CoV-2 RNA concentrations and symptom duration in 559 untreated, non-hospitalized adult patients with confirmed COVID-19 with onset of symptoms since ≤10 days and ongoing symptoms 48 hours before enrollment. The symptom score (median) at baseline was 10. They included the placebo recipients in the phase II/III multicenter Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)-2/A5401 platform trial between August 2020 and July 2021 when the ancestral strain, Alpha and Delta variants were the predominant circulating strains. The trial was conducted in the outpatient setting. Majority of the study subjects were unvaccinated and just 7% of them had taken the vaccine; 86% patients aged ≥55 years and those with comorbid conditions such as chronic lung disease, moderate to severe asthma, body mass index (BMI) >35 kg/m^2, diabetes, hypertension, heart disease or chronic kidney/liver disease were at higher risk of progressing to severe infection.

SARS-CoV-2 was detected in plasma in 467 subjects at baseline, while 523 had anterior nasal SARS-CoV-2 RNA. Eighty-nine of the 467 patients in whom plasma RNA was detected presented with more severe symptoms when the study began. Participants with baseline anterior nasal RNA of ≥6 $\log_{10}$ copies/mL took 16 days for symptom improvement versus patients with ≤2 $\log_{10}$ copies/mL, whose symptoms improved in 9 days. Their symptoms also took longer time to resolve (25 vs. 15 days). When the association of anterior nasal RNA and symptoms of acute COVID-19 was examined, resolution of cough and shortness of breath were delayed in patients with anterior nasal RNA of ≥6 $\log_{10}$ copies/mL with adjusted hazard ratio (aHR) of 0.63. However, fatigue or body ache resolved without delay. Among patients with detectable plasma SARS-CoV-2 RNA, resolution of cough (aHR 0.67), shortness of breath (aHR 0.67) and body pain (aHR 0.74) was delayed. No such association was observed for fatigue.

This analysis shows that resolution of acute COVID-19 symptoms is delayed in patients with SARS-CoV-2 viremia and high anterior nasal RNA levels. According to the authors, these findings suggest the potential use of nasal and plasma SARS-CoV-2 RNA levels as prognostic markers to assess duration of symptoms and predict recovery in acute COVID-19 patients being managed as outpatients.

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HCFI Dr KK Aggarwal Research Fund

HCFI Round Table Environment Expert Zoom Meeting on "UN Climate Change Conference 2022 (UNFCCC - COP27)" – Part 1

October 30, 2022 (Sunday, 12 noon - 1 pm)

- Environment has become an issue across the world and everybody living on the earth today is suffering. For e.g., Europe has had a drought because of war, some parts of India are getting excess rains, while some parts are facing a drought. The air quality index (AQI) level in Delhi is around 450 today. Because of the Russia Ukraine war, gas is not available. Now they will go back to coal again because of which there will be more of sulfur, more AQI level of pollution in the air.
- The top 10 most polluted cities in India are not Delhi or any other metropolitan city but they are some of the very smaller towns where air pollution is much high. Water and sound pollution has also to be considered alongside.
- The UN climate change Conference of the Parties of the UNFCCC (COP27) is being held in Egypt from the 6th to 18th November.
- The UNFCCC came into existence subsequent to the Rio Summit in 1992. UNFCCC came into force in 1994. Since then, these meetings are held annually towards the end of the year except for 2020, when it could not happen because of pandemic.
- The last summit (COP26) was in Glasgow under the presidency of the UK. This year, the presidency will now be held by Egypt. Presidency does have a role because they set up agenda and assign priority to the subjects to be discussed.
- COP27 will help build on the outcomes of COP26 to deliver action on issues critical to tackling climate emergency like urgently reducing greenhouse emissions, building resilience, delivering on commitment to financing climate actions in developing countries to face the growing energy crisis, record greenhouse emissions and increasing extreme weather conditions like heat wave, floods, forest fires, etc.
- The COP27 seeks renewed solidarity between countries to deliver on the landmark Paris agreement for people and the planet.
- We must unite to limit the greenhouse warming below 2° and work hard to meet the 1.5° target. This requires bold and immediate actions from all parties particularly those who are in a position to do so and those who can make efforts. Unless developing countries are supported, we cannot achieve the target of 2° or 1.5° because survival is of priority for these countries.
- Such ambitious transformative actions provide a paradigm shift for more sustainable climate resilient, low emission and carbon neutral future based on the science.
- Implementation requires serious input and contribution from all stakeholders, government and non-governmental.
- There will be different thematic days in the conference including Finance Day, Science Day, Youth and Future Generation Day, Decarbonization Day, Adaptation and Agriculture Day, Gender Day, Water Day, Africa Day, Energy Day, Biodiversity Day.
- We need to focus on sustainable features and principles that use of renewable energy particular focus on solar power, energy efficiency issues, e-mobility, sustainable and smart transport system, water use and conservation, adopting proper waste management process like including recyclable and environment-friendly alternatives.
- The environmental conditions today are not as much the question of performance as of attitude. Stubble burning (parali) is an example of attitude. Clouded minds, vested interests and failure to commit are the problems that COP faces. The Glasgow Pact is very often quite vague and also often not translated into actionable details.
- Monitoring is another area, which is very difficult to manage. Unless monitoring is done of some scale with comparable instruments, monitoring data may be of no or little value. All countries are not well-equipped equally. Moreover, there are interest which require the data to be either suppressed or even manipulated. Very often suppression of data is not so much of dishonesty, but conclusions drawn from the remaining data are different from facts. However, a change of heart is difficult to take place.

- The UNFCCC process has been quite disappointing. Lot of action has to happen outside of the UNFCCC forum.
- The sentiment is that the developed countries, who are mainly responsible for climate change, have not come up with their commitments. Neither commitments in reducing their own emissions nor giving technology and finance to developing countries.
- We had commitments under the Kyoto Protocol but they were not met in the 1st commitment period in 2012 and also in the 2nd commitment period ending in 2020. We had a pre-2020 commitment. 2020 has gone without any commitments being met by the developed countries. Now, we have a new agenda that is pre-2030 commitment.
- The main agenda is that the developing countries have a lot of development deficit. We have 1 billion people who are below poverty line in the world. A quarter of them may be in India. The hunger problem is huge. These vulnerable populations are also vulnerable to climate change.
- Development is the best defense to adaptation. Developing countries cannot be denied their rights to develop. India is home to 17% global population but our historical Greenhouse Gas (GHG) emissions have been only 4% (Intergovernmental Panel on Climate Change [IPCC]).
- It has been recognized for the first time that the whole problem is because of global carbon budget.
- The extreme events which we are witnessing now are a result of 1.1°, which we have reached right now. 1.1 is because of concentration of ≥415 ppm of carbon dioxide in the global atmosphere. This is a global problem.
- India has done a lot in climate action. We are amongst the fastest growing renewable energy sectors in the world. There is a lot of investment coming in other sectors as well like green hydrogen emission. We are also doing a lot of research in carbon capture utilization storage. A lot of transition is happening in the transport sector whether in terms of freight corridors or public transportation and e-vehicles. In developed countries, almost 33% emissions come from transport sector whereas in India, it is 9.7% right now.
- The climate change problem is a problem of consumption. Unless people can be convinced to reduce consumption, this problem is not going to be solved.
- There are many conventional sources of energy, which have long drawn investments. They have to be phased out in a timely manner.
- The main agenda for COP27 will be loss and damage finance facility. There have been losses because of extreme weather events and there are damages, which are permanent. Loss and damage was also identified in the Paris agreement in paragraph 52 of 1/CP2, according to which there will not be any financial liability or compensation due to loss and damage arising out of climate change. In the last 5 to 6 years, there is a lot of momentum in creating a loss and damage finance facility.
- Other agenda include Global Stocktake every 5 years, which was agreed upon in the Paris Agreement. The next Global Stocktake is coming up in 2023. This is important in examining the commitments of the developed countries in terms of how much they have reduced their own emissions and given their funds. In 2009, 100 billion dollars would move from developed to developing countries. But this commitment is far from being fulfilled.
- There is lot of ongoing discussion on the definition of climate finance. Many times funds given for road development, hydroelectric power plants, etc. have been dubbed as climate finance. This is a contentious issue.
- The special circumstances of Africa are also going to be on the Agenda. Many African countries want special status given to Africa as this is the most vulnerable and poor part of the world.
- The way forward and the only solution is that India has to invest in research and innovation, develop its own technologies and rapidly invest in frontier technologies which will help in future. The technology developed for climate change has to be freely available or not much of profit.
- We have to change our lifestyle and see that we don't profiteer from this disaster, otherwise we will continue to have rising emissions. Right now it stands at 52 billion tons every year. We need to reduce it to 25 to 30 billion tons by 2030 to have any chance of achieving the target of 1.5° or 2°.
- COP27 will be an agenda for a thorough review of whatever commitments have already been made and implementing whatever had been committed to. Not much headway is expected to be achieved in this also. Earlier, we had BRIC (Brazil, Russia, India and China) countries asking for their share now of African countries and Latin American countries are also asking for their share.

- Lifestyle changes have to be emphasized upon. Last one decade in every COP, Indian Govt. has been advocating for lifestyle changes. If the west adopts our lifestyle changes, the emission will automatically come down by 40% or so.
- India had said in COP that luxury emissions cannot be and shall not be equated to survival emissions. We have survival emissions, while developed countries are emitting luxury emissions.
- Any change in temperature will affect the livelihood of the human population dependent on the coast especially fishermen. It will also result in salt water intrusion and alteration in major rainfall pattern, which will affect the yield of crops including fisheries.
- We need to identify corporates and ask them to adopt all coastal villages. This can be a simple and workable solution in India because external finances are not going to come because of the pandemic and the war.
- Using cycles for transport will reduce the carbon footprint. The Ministry of Environment, Forest and Climate Change (MoEFCC) and the United Nations Environment Programme (UNEP) had published a book on low-carbon lifestyles in 2016, which describes various activities and calculates how much GHG is reduced with each activity. In 2015, the Prime Minister had released a book 'Parampara' at COP21 in Paris. The ministry has published a brochure, which describes activities in terms of per capita emissions – such as meat consumption, food wastage. Samanvay, which is a combination of traditional and modern approach to low-carbon pathway was also published by the Ministry.

Participants: Dr Anil Kumar, Mr Vivek Kumar, Mr Paritosh Tyagi, Mr Ajay Raghav, Mr Pradeep Khandelwal, Mr Ankit Sethi, Dr Ravindar Kumar, Mr PK Jain, Mr Neeraj Tyagi, Mr Rajeev Sharma, Dr M Dwarakanath

HCFI Round Table Environment Expert Zoom Meeting on "UN Climate Change Conference 2022 (UNFCCC - COP27)" – Part 2

November 6, 2022 (Sunday, 12 noon - 1 pm)

- COP27, beginning today will continue till 18th November under the Presidency of Egypt. Many commitments have been made in earlier summits, but their implementation is in question.
- Important issues in COP27 are climate finance, extreme weather-related events like floods, heat waves, forest fires, which incur huge damage. This is an important issue from the Indian point of view. Another important issue where India will focus is lifestyle for environment.
- Many developing countries including India have adopted the industrialization model to increase the economic growth. Industrialization has changed our whole lifestyle. It has led migrations and nuclear families. Increase in economic activity is leading to increase in emissions. Pre-industrialization, our economic activity was dependent on agriculture or non-industrialized activities. Instead of asking developed countries for financial help to reduce industrial emissions, all countries should have an alternate development model.
- India is an agricultural country, so if we need to make lives of our people better we need to revert back to agriculture society, then we will be able to achieve lifestyle for environment.
- The solution to the problem is to go to the root of the problem. We have to start working on alternative models of development to successfully achieve the targets.
- Climate change is a global problem. All countries should rethink on the model that is appropriate for their country for the betterment of their citizens. At this date, our top most priority must be to change our lifestyle. It has to become a citizen's movement.
- But on the flip side, if industrialization is stopped, this will lead to unemployment.
- Water and sanitation problem, air pollution and water pollution still persist in our country. We should see holistically if we are willing to stop air pollution caused by any industry. Every industry should give an undertaking how much pollution it is causing. Until we reuse water the problem will remain the same. Along with conservation of water we should be able to reuse the wastewater. The depleting groundwater levels may lead to water wars in the future.
- We have to look for a sustainable development approach keeping industrialization and agriculture parallel to each other.
- GHG emissions must be reduced. Small scale industries where alternative energy can be used so that pollution is reduced can be adopted.
- Innovative researches can be done in environment. Industrialization should be environment-friendly. Consent to operate should be made stricter to control air pollution.

- The key aim of COP27 is to increase GHG reduction efforts to keep the temperature limit agreed in Paris Agreement. Others include increased global efforts on adaptation and climate financing and making progress on supporting developing countries in loss and damage.
- The Paris Agreement adopted in December 2015 aims to avoid dangerous climate change by limiting global warming to below 2° above preindustrial levels and pursuing efforts to limit the temperature rise to 1.5° and to make financial clause consistent with climate objectives. It entered into force on 4th November 2016 and 198 UNFCC chief parties adopted the agreement & 193 states & EU have now ratified it.
- In COP15 held in Copenhagen in 2009, the developed countries had committed that 100 billion USD per year would be given to developing countries by 2020 and every year thereafter through 2025 to help developing countries tackle the effects of climate change. But they have failed in doing so.
- The Indian delegation will be led by Union Environment Minister Bhupender Yadav. India has a pavilion with the theme of *LiFE - Lifestyle for Environment* at COP27.
- At COP27, India would seek clarity on the definition of "climate finance" to be able to accurately assess the extent of finance flows for climate action and nudging developed countries to enhance supply of technology and finance needed to address climate change and resulting disasters.
- If the burden on poor countries is very high, they will keep environment secondary and focus on industrialization.
- The absence of a definition allows developed countries to greenwash their finances and passes off loans as climate-related aid. India will seek clarity as to what constitutes climate finance, whether it is loans, grants or subsidies. It should be in the form of a grant and not loan and should be clearly defined.
- Developing countries, including India, will also push rich countries to agree to a new global climate finance target, also known as the new collective quantified goal on climate finance (NCQG). This help should be in trillions and not in billions as the costs of addressing and adapting to climate change have grown. The discussion on NCQG in the ad-hoc working group must focus on the quantity of the resource flow and its quality and scope.
- Any consensus on an enhanced scale of financial mobilization could be a welcome takeaway from COP27.
- Poor and developing countries also want to see a new finance facility to fund the "loss and damage" resulting from climate change – for example money needed for relocating people displaced by floods. Developed nations have opposed this new fund which will hold them legally liable for massive damages caused by climate change.
- The existing financial mechanisms, like Global Environment Facility, Green Climate Fund and Adaptation Fund, under the UNFCCC have not been able to mobilize or deliver funds for loss and damage due to climate change, as these are under-funded, most of the money is for mitigation (preventing and reducing emissions) and accessing it is cumbersome and time-consuming.
- At COP26 in Glasgow, parties agreed to develop a Mitigation Work Program (MWP) to urgently scale up mitigation ambition and implementation. Mitigation means avoiding and reducing emissions, ambition means setting stronger targets and implementation means meeting new and existing goals.
- Proper waste management is needed to reduce greenhouse emissions, particularly for developing countries. Methane is 25 times more potent than carbon dioxide emission.
- Lack of proper disposal of waste leads to several problems which we are facing now. Today the landfill sites, which were once outside city are now in the cities and are now affecting people living around them.
- Decentralization solutions should be encouraged in waste management. Composting is an environment-friendly solution. Earlier every household has garbage and it was made into compost at that level itself. Plastic was not popular then. Nonrecyclable things like plastics, etc. should be burned and waste to energy should be produced from the waste keeping in mind the waste emission control norms. These have to be monitored regularly. Till we control emissions from transport sector, industry sector and waste sector, we cannot achieve the GHG reduction targets. It is now time to focus on the level of source.
- Lifestyle in India is still environmental-friendly as we still rely a lot on nonmechanical vehicles like cycles.

- If we make a 7-point program and concentrate on 7 critical goals, we can achieve the Sustainable Development Goals (SDGs 3, 5, 11, 12 and 13).
- Protect communities and natural ecosystems from damage caused by GHG emissions and generate opportunities for people by catalyzing global transition to a low-carbon economy.
- Drive up scale of clean, affordable power for systems throughout the world to deliver sustainable socioeconomic development.
- Ensure world's food ecosystem their impact on the environment, ensure opportunity and sustainability, feed 9.6 billion people by 2030. Alleviate poverty, enhance food security.
- Conserve biodiversity, and mitigate climate change by reducing forest loss and restoring productivity through graded deforested lands.
- Achieve a water-secure future by mapping, measuring and mitigating global water waste.
- Improve quality of life in cities by developing and scaling environmentally, socially and economically sustainable urban and transport solutions.
- Ensure implementation of Kigali Amendment of the UN and the Montreal Protocol for ozone and full compliance and recovery of petroleum gases.

Participants: Dr Anil Kumar, Dr SK Gupta, Dr Sanjeev Agrawal, Dr Ravindra Kumar, Mr Neeraj Tyagi, Mr Pradeep Khandelwal, Mr Arun Kumar, Dr S Sharma

Coronavirus Updates

Masks now "optional" but "preferable", says India's Aviation Ministry

The Union Civil Aviation Ministry has relaxed the mandatory requirement of in-flight masks during domestic and international flights considering the decreasing coronavirus disease 2019 (COVID-19) cases. Not wearing face masks during the flight will not incur any penalty. However, the government recommends that masking is preferable, i.e., travelers should use them. The requirement of filling the Air Suvidha for inbound travelers is still applicable… (*Source: PTI, Nov. 16, 2022*)

Slight uptick in new weekly COVID-19 cases, says WHO

Last week saw a rise of 2% in the number of new weekly cases worldwide. The number of weekly deaths on the other hand saw a decline of 30%. More than 2.3 million new cases were reported, as per the latest 118th Edition of WHO's Weekly Epidemiological Update on COVID-19. The Western Pacific Region recorded an increase of 18%; cases increased by 15% in the South-East Asia Region and 12% in the Region of the Americas. However, cases declined in the European Region (-21%), Eastern Mediterranean Region (-12%) and the African Region (-8%)… (*Source: WHO, Nov. 16, 2022*)

BN.1: The new Omicron subvariant in the US

The BN.1 Omicron subvariant is gradually gaining foothold in the United States and accounts for around 4.3% of new COVID-19 cases, as per the Centers for Disease Control and Prevention (CDC). The prevalence is higher (6.2%) in the western parts of the country. The numbers of hospitalizations are also slowly rising… (*Source: CBS News, Nov. 14, 2022*)

Australia recommends against a third booster dose

In view of the rising cases in the country, health authorities in Australia have advised all eligible citizens to be updated on their booster doses. However, they have recommended against taking the third booster shot of the COVID-19 vaccine in the new vaccination recommendations. The average daily cases have increased by 47% in the last week compared to the preceding week… (*Source: Medscape, Nov. 16, 2022*)

Impact of indoor relative humidity on COVID-19 outcomes

A study from MIT has found that indoor relative humidity between 40% and 60% is associated with fewer COVID-19 cases as well as mortality. Relative humidity less than 40% or more than 60% are associated with adverse outcomes. This analysis of COVID-19 data along with meteorological measurements from 121 countries is published in the November 2022 issue of the *Journal of the Royal Society Interface*… (*Source: J R Soc Interface, Nov. 16, 2022*)

With inputs from Dr Monica Vasudev

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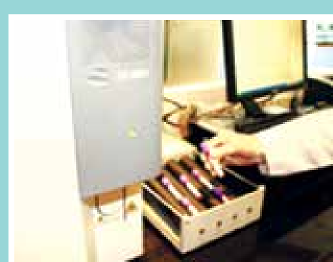

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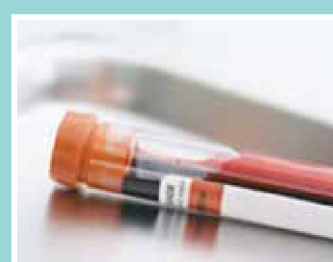

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Diabetes India 2022: 12th World Congress of DiabetesIndia

HFPEF: ROLE OF THE DIABETOLOGIST IN TACKLING A MULTIDISCIPLINARY PROBLEM

Dr Eberhard Standl, Germany

- The pathophysiology of type 2 diabetes and cardiorenal-metabolic syndrome have the same cluster complications such as insulin resistance, dysmetabolism, low-grade inflammation, oxidative stress, etc. these factors are driving the progression of type 2 diabetes and in turn affect the kidney and heart.
- Hence, the role of a diabetologist in this multidisciplinary paradigm starts with an assuring diagnosis of heart failure.
- Assuring that the patient complies with the recommended cardiologic therapy (β-blockers, diuretics, statins and antithrombotics).
- Based on the patient history, diabetologists should address an appropriate cardio-metabolic approach including appropriate glucose-lowering therapy, a suitable exercise regimen, etc.
- Lastly, he/she should co-operate with cardiologists/nephrologists to reduce the risk of cardiovascular (CV) and renal outcomes.

GLUCOSE VARIABILITY AND ITS IMPLICATIONS

Dr Tsvetalina Tankova, Bulgaria

- Unpredictable fluctuations in blood glucose levels make it difficult to optimize insulin doses and reach desired glycemic targets.
- Glucose variability is a strong predictor of hypoglycemia leading to poor glucose control; increased risk of diabetes burden and poor compliance.
- Glycemic variability seems to have more deleterious effects than sustained hyperglycemia on endothelial function and oxidative stress and thus in the development of diabetic complications.
- Glycated hemoglobin (HbA1c) is the gold standard for the assessment of glycemic control, yet it has a lot of limitations.
- Glucose variability evaluated from continuous glucose monitoring (CGM) data should be considered in the overall clinical representation of glycemic control. Time in range has been shown to be associated with complications in both type 1 and type 2 diabetes.

CARDIOVASCULAR RISK FACTOR MANAGEMENT AND PROGNOSIS IN PATIENTS WITH DYSGLYCEMIA

Dr Jaakko Toumilehto, Finland

The 2019 ESC Guidelines on diabetes, prediabetes and cardiovascular diseases (CVDs) has given specific recommendations on CV risk categories in patients with diabetes mellitus (DM), for the use of laboratory, ECG and imaging testing for CV risk assessment in asymptomatic patients with DM, for lifestyle modifications in DM and pre-DM, for glycemic control in an individual with DM, for the management of blood pressure (BP) in patients with DM and pre-DM, for the management of dyslipidemia with lipid-lowering drugs, antiplatelet therapy in primary prevention in DM.

A few important recommendations are:

- Moderate to vigorous physical activity, notably a combination of aerobic and resistance exercise, for ≥150 min/week is recommended for the prevention and control of DM unless contraindicated, such as when there are severe comorbidities or a limited life expectancy.
- A Mediterranean diet, rich in polyunsaturated and monounsaturated fats, should be considered to reduce CV events. Vitamin or micronutrient supplementation to reduce the risk of DM or CVD in DM is not recommended.
- Tight glycemic control is recommended targeting near-normal HbA1c (<7.0% or <53 mmol/mol) to decrease microvascular complications.
- Antihypertensive drug treatment is recommended for people with DM when office BP is >140/90 mmHg.
- Lifestyle changes including weight loss if overweight, physical activity, alcohol restriction, sodium restriction and increased consumption of fruits, vegetables and low-fat dairy are recommended in patients with DM and pre-DM.
- To manage BP in patients with DM and pre-DM, it is recommended that treatment is initiated with

a combination of a renin-angiotensin-aldosterone system (RAAS) blocker with a calcium channel blocker or thiazide/thiazide-like diuretics.

- Statins are recommended as the first-choice lipid-lowering treatment in patients with DM and high low-density lipoprotein cholesterol (LDL-C) levels: administration of statins is defined based on the CV risk profile of the patient and the recommended LDL-C or non-HDL-C (high-density lipoprotein cholesterol) target levels.
- Lifestyle interventions (with a focus on weight reduction and decreased consumption of fast absorbed carbohydrates and alcohol) and fibrates should be considered in patients with low HDL-C and high triglyceride levels.
- In patients with DM at high/very high-risk, aspirin (75-100 mg/day) may be considered for primary prevention in the absence of clear contraindications.

POSITION OF AN SGLT2 INHIBITORS + DPP-4 INHIBITORS COMBINATION PILL IN THE MANAGEMENT OF A PERSON WITH T2DM

Dr JJ Mukherjee, Kolkata, West Bengal

- Sulfonylureas (SUs), metformin is often the last choice in T2DM treatment due to the declining trend of glycemic control time with monotherapy. Hence, a need to shift toward combination therapy, a step also supported by 2019 ADA-EASD (American Diabetes Association-European Association for the Study of Diabetes) updated guidelines.
- Diabetes should be treated based on the pathophysiological functions, such as neurotransmitter dysfunction, increased glucagon secretion and increased lipolysis.
- If Hb1Ac is more than 17 mmol/mol above the individualized Hb1Ac, considering early combination therapy is viable.
- Metformin + Dipeptidyl peptidase-4 (DPP-4) inhibitors combination produces early efficacy and reduces the risk of hypoglycemia. However, metformin + sodium-glucose co-transporter-2 (SGLT2) inhibitors + DPP-4 inhibitors + glucagon-like peptide-1 receptor agonist (GLP-1RA) provides a combination of early efficacy, and reduced risk of hypoglycemia, weight gain BP, CV events and renal failure.
- SGLT2 inhibitors and DPP-4 inhibitors have a complimentary efficacy and can reduce Hb1Ac levels to <7% in 24 weeks by regulating the pathophysiology of the disease progression.

HALTING THE PROGRESSION OF PREDIABETES TO DIABETES: MYTH OR REALITY?

Dr Adrian Vella, Rochester, MN

- Islet cell function and insulin signaling are the primary regulators of glucose metabolism in humans.
- Abnormal glucagon suppression is an early change in the pathogenesis of type 2 diabetes.
- To date, no therapy clearly changes the natural history of prediabetes progression.
- As such if treatment is to be undertaken there needs to be a careful appraisal of the risk vs. benefits.

EARLY COMBINATION THERAPY FOR THE TREATMENT OF T2DM

Dr Ralph A DeFronzo, San Antonio, TX

The ominous octet of hyperglycemia: decreased insulin secretion, decreased incretin effect, increased lipolysis, increased glucose reabsorption, decreased glucose uptake, neurotransmitter dysfunction, increased hepatic glucose production and increased glucagon secretion.

The treatment of T2DM

- Will require multiple drugs in combination to correct multiple pathophysiologic defects.
- Should be based upon known pathogenic abnormalities, and NOT simply on the reduction in HbA1c.
- Must be started early in the natural history of T2DM, if progressive β-cell failure is to be provided.

When effect of SU and metformin therapy when compared with conventional therapy led to a 37% reduction in microvascular complications. Pathophysiology based (DEFRONZO) algorithm is lifestyle + triple combination: pioglitazone + metformin/SGLT2 inhibitors + GLP-1RA to result in HbA1c <6.5%.

GLYCEMIC MANAGEMENT IN PATIENTS WITH CKD

Dr Guillermo Umpierrez, USA

- Overall, 80% of chronic kidney disease (CKD) cases are undiagnosed in diabetes patients with 6-time more probability of death by CVD than advance to end-stage renal disease (ESRD) and dialysis.
- The clinical diagnosis of diabetic kidney disease in a patient with diabetes is based on the reduced kidney function or presence of albuminuria with diabetic retinopathy and/or type 1 diabetes for more than 10 years.

- However, in the absence of any sign or symptom of the primary cause of kidney damage, most patients usually progress to ESRD.
- Management approaches to diabetes and reducing the progression of CKD is multifactorial such as BP-lowering, treatment of dyslipidemia, RAAS and sympathetic nervous system blockade, glycemic control, SGLT2 inhibitors and other medications.

The EMPA-Reg, CANVAS and DECLARE trials showed that empagliflozin, canagliflozin and dapagliflozin were associated with slower progression of kidney disease and clinically proven fewer renal events in comparison to placebo in standard care.

DIABETES TREATMENT IN AN ELDERLY PATIENT

Dr Florian Toti, Albania

- Patients have different requirements depending on their diabetes status.
- Many choices exist to individualize treatment.
- Reinforce healthy lifestyle, treat blood sugar, lipids and BP.
- Avoid using medications to achieve HbA1c <7.5% in most adults ≥65 years old; moderate control is generally better.
- There is no evidence that using medications to achieve tight glycemic control in most older adults with type 2 diabetes is beneficial.
- Tight control has been consistently shown to produce higher rates of hyperglycemia in older adults.

IS THERE A CURRENT PLACE FOR SULFONYLUREAS IN DIABETES MANAGEMENT?

Dr Anuj Maheshwari, Lucknow, Uttar Pradesh

The availability of new drug classes has sparked a debate regarding the utility and viability of SUs as a therapeutic option with views on CV risks and hypoglycemia. However, this may hold true for older SUs due to their non-selective mechanisms of action.

Sulfonylurea has reigned over the other antidiabetic agents in diabetes management for over 40 years. The development of modern SUs that do not block ischemic preconditioning has rendered the University Group Diabetes Program (UGDP) controversy moot and preserved a place for SUs in the treatment of type 2 diabetes. Modern SUs are proven to be effective, safe and well-tolerated in various clinical situations.

Sulfonylurea, when compared to the other oral antidiabetic agents (OADs) has the highest efficacy in reducing HbA1c levels by up to 2%, moderate risk of hypoglycemia, neutral CV event and a cost-effect therapy. Sulfonylureas are also reported as the most cost-effective therapy compared to other OADs.

There have been several key studies advocating the superiority of SU, namely, the UKPDS trial which reported that intensive glucose therapy with the SU has reduced the risk of microvascular complications. In a 10-year follow-up study of the trial, it was determined that SU maintained a risk reduction in microvascular, macrovascular and myocardial infarctions up to 9%.

Similarly, the ADVANCE trial and ADVANCE-ON echoed the same results with the added benefit of renal outcomes. The trial showed that intensive glucose control strategically reduced HbA1c by 6.5% thereby reducing the risk of renal failure and nephropathy by 11% and 21%, respectively.

TOSCA.IT and CAROLINA trial established the status of SU as an OAD with a safe CV profile with similar risk reduction in 3P-Mace and 3P-Mace with hospitalization. Meanwhile, CAROLINA study reassured that the use of SU leads to weight gain in the initial therapy, yet it is stabilized over the long-term, especially with glimepiride.

Also, the use of SU with metformin was reported to have negated the weight gain and hypoglycemia. In cases of elderly patients, people in Ramadan or patients diagnosed with CKD, gliclazide was a choice for reducing the risk of secondary failure and Hb1Ac. Hence, it can be confirmed that SU is an effective second-line agent for glycemic control for type 2 diabetes.

The renaissance of SUs therapy might ensure that it remains the drug of choice for uncontrolled diabetes in the future with enough room for flexibility.

GETTING BASICS RIGHT IN IMPROVING OUTCOMES FOR PEOPLE WITH DIABETES

Dr Sunil Kota, Berhampur, Odisha

Vascular complications are common in patients with type 1 and 2 diabetes. Annual screening for retinopathy with retinal eye exams, for nephropathy with urine albumin-to-creatinine ratio and neuropathy with physical examination allows early identification and appropriate interventions; these may delay progression or intensity. Metabolic control of glucose levels. Blood pressure with a combination of lifestyle interventions and pharmacological therapy (including insulin) can prevent the onset or delay the progression of each of these diabetes-related microvascular and neuropathic complications. We need to be alert for emerging risk factors.

BETA-CELL PRESERVATION: MYTH OR FACT?

Dr Vijay Negalur, Thane, Maharashtra

Prolonged hyperglycemia leads to oxidative stress, endoplasmic reticulum (ER) stress, hypoxic stress and cytokine induction leading to β-cell compensation, stress and later failure and de-differentiation.

Beta-cell identity is fragile, but islet identity is stable: islet cells share chromatin structure and methylome. Other than hormone genes, they represent flexibility and plasticity states rather than stable subtypes.

FoxO1 plays an important role in the de-differentiation and re-differentiation of β cells. Reprogramming of other cell types to β cells is a possibility and can be a potential treatment option for diabetes in the future.

GLP-1, SGLT2 inhibitors, thiazolidinediones, metformin and intensive insulin therapy offer β-cell protection and preservation.

DIABETES PREVENTION: PRIMARY CARE. WISH OR REALITY?

Dr Francesc Xaviers Cos, Spain

- The FINDRISC questionnaire is a practical screening tool applicable to the European population, particularly in primary health care.
- Men and women with a FINDRISC score above 20 points had a prevalence of glucose alterations of approximately 80%. Fifty percent of men and women had type 2 diabetes that had not been diagnosed before.
- A structured diabetes prevention program based on an intensive intervention in the lifestyle of high-risk people is feasible, effective and cost-effective in primary care.
- Implementation and long-term lifestyle program benefits require further research and commitment from the public health department and primary care community.

OVERCOMING BARRIERS TO IMPROVE OUTCOMES IN UNINSURED PATIENTS WITH DIABETES

Dr Otis W Kirksey, USA

"People don't care about how much you know until they know how much you care." –Theodore Roosevelt

- Neighbourhood Medical Centre (NMC) is a federally qualified Health Centre that provides services including primary care, chronic disease management, mental health, dental care, specialty care, case management, etc.
- About 18% of the NMC patients have been diagnosed with diabetes with 22% of the hypertension patient population; however, after diabetic education, most of the patients have switched to SGLT2 inhibitor docks.
- Social Determinants of Health (SDOH) has identified economic stability, education, social and community context, health and health care, neighborhood, and built environment as the barriers to healthy outcomes.
- NMC Diabetes Education and Management Service (DEMS) is a pharmacist-led multidisciplinary composed of certified diabetes and education specialist, medical assistants, nurses, physician, practitioners, mental health counselors and case management counselors. The overall goal of the DEMS management plan is to decrease the progression of and improve the quality of life and include patients with HbA1c levels of more than 9%, patients with a history of noncompliance and patients with multiple comorbidities.

SGLT2 INHIBITORS – ORGAN BENEFITS, WITH EMPHASIS ON CKD AND HEART FAILURE

Dr Jiten Vora, UK

- SGLT2 inhibitor therapy is recommended for all diabetes patients, irrespective of the subtypes and sometimes for patients without a diabetes diagnosis for organ protection.
- CKD progression is a major risk among diabetes patients, with more than 50% having lost kidney functions to an extent.
- SGLT2 inhibitors produces a protective effect at all stages of renal disease, from prevention of development and progression to nephropathy and ESRD, as well as renal death. From the perspective of CV failure, it improves CV outcomes (composite primary endpoint of CV death or HHF) in patients with or without pre-existing HFrEF, diabetes, CKD and different types of background HFrEF medical therapy.
- Several studies have also proven the positive effect of SGLT2 inhibitors in HFrEF, predominantly in cases of HHF such as CANVAS program, VERTIS program, DECLARE-TIMI 58, etc.

News and Views

Risk Factors for New-onset Postpartum Hypertension

Almost one-quarter of women in a retrospective study developed *de novo* postpartum hypertension after 6 weeks and within a year of childbirth in a new research published in the journal *Hypertension*.[1]

In this single-center study, researchers analyzed medical records of 2,465 women with a pregnancy length of at least 20 weeks who had delivered at the Boston Medical Center from 2016 to 2018. These women were not hypertensive and also did not have gestational hypertension. Fifty-four percent were non-Hispanic Black, while 18% were Hispanic or Latino. They aimed to determine the risk of new-onset postpartum hypertension in this study group defined as blood pressure (BP) ≥140/90 mmHg on two separate readings. A BP reading of ≥160/110 mmHg was considered as severe high BP. BP readings in the first year after delivery were noted from the medical records.

Twelve percent of women (n = 298) without hypertension were found to have developed *de novo* postpartum hypertension within 1 year of childbirth; of these, 17% (n = 51) had severe hypertension. Although the majority could be diagnosed soon after childbirth, 22% women were diagnosed as hypertensive ≥6 weeks after delivery. Age ≥35 years, cesarean births or cigarette smoking (current or former) were identified as the risk factors for hypertension. The risk of new-onset postpartum high BP was 29% higher among women who had all these three risk factors. The risk increased to 36% if the women were also non-Hispanic Black.

Since 22% cases were diagnosed after 6 weeks of delivery, this study draws attention to the need to monitor women even beyond the required routine postpartum follow-up. Not doing so could miss many cases of new-onset hypertension, which may remain undiagnosed and cause significant maternal morbidity and mortality.

Reference

1. Parker SE, et al. De novo postpartum hypertension: incidence and risk factors at a safety-net hospital. Hypertension. 2022 Nov 15;101161HYPERTENSIONAHA12219275.

COVID-19 and Risk of Epilepsy

Coronavirus disease 2019 (COVID-19) patients are at greater risk of developing seizures or epilepsy within 6 months of the infection compared to those who had influenza, suggests a new study published online November 16 in the journal *Neurology*.[1]

In this study, researchers from the UK and the US examined electronic health records of 81 million people with COVID-19 to explore the association between COVID-19 and epilepsy in the 6 months post-infection. A total of 1,52,754 COVID-19 patients were matched as per age, sex and medical conditions with 1,52,754 patients with influenza within the same time frame.

Results showed that risk of developing epilepsy or seizures was increased by 55% within the 6 months after the infection compared to influenza patients with hazard ratio of 1.55. The incidence rate of new-onset epilepsy or seizures was 0.94% in those who had COVID-19 versus 0.60% in those who had influenza. COVID-19 patients younger than 16 years of age and who were managed as outpatients were at greater risk.

The overall risk of developing seizures or epilepsy was <1% in this study. However, this could translate into much bigger numbers given the huge number of COVID infections. It further highlights the risk even in patients with mild infections. And the fact that the risk was increased in younger patients, as shown in this study, underscores the need to prevent COVID-19 in this age group. The authors caution the need to especially monitor cases of mild infections “who may have more subtle features of seizures, such as focal aware seizure” in the post-infection period.

Reference

1. Taquet M, et al. Incidence of epilepsy and seizures over the first 6 months after a COVID-19 diagnosis: a retrospective cohort study. Neurology. 2022 Nov 16:10.1212/WNL.000 0000000201595.

Outdoor Artificial Light at Night: A Potential Risk Factor for Diabetes?

Does long-term exposure to outdoor artificial light at night (LAN) have an impact on glucose homeostasis and the prevalence of diabetes? To decode this question, researchers from China enrolled 98,658 participants from the China Noncommunicable Disease Surveillance Study from 162 sites across mainland China in 2010. Their mean age was 42.7 years. Women comprised almost half (49.2%) of the study population.

Exposure to outdoor LAN for a minimum duration of 6 months was determined with the help of satellite data. Exposure levels were categorized into five quintiles. People residing in areas of higher quintiles of outdoor light were older, had higher body mass index (BMI) and household income and lived in an urban area.

Analysis of data revealed a positive association between chronic exposure to outdoor LAN and glucose levels both fasting and postprandial, glycosylated hemoglobin (HbA1c) and insulin resistance measured via HOMA-IR (homeostatic model assessment for insulin resistance) even after adjusting for many important diabetes risk factors. However, artificial light had a negative correlation with beta-cell function as quantified by HOMA-B. Diabetes prevalence was significantly associated with per-quintile LAN exposure (PR 1.07). With every quintile exposure to artificial LAN, the risk in prevalence of diabetes increased by 7% with a prevalence ratio of 1.07. Diabetes prevalence was increased by 28% among participants exposed to the highest level of exposure to nighttime light (median 69.1 nW cm^{-2} sr^{-1}) compared to those exposed the least (median 1.0 nW cm^{-2} sr^{-1}) with an adjusted prevalence ratio of 1.28.

Rapid urbanization and industrialization has increased artificial LAN. Excessive use of night outdoor artificial light causes what has been called light pollution. While the glittering lights are mesmerizing, they negatively affect health as demonstrated in this study. It shows that frequent exposure to the bright outdoor lights at night is associated with greater risk of hyperglycemia, insulin resistance and diabetes and suggests artificial LAN as a potential novel risk factor for diabetes. Disruption in the circadian rhythm has been hypothesized as the underlying mechanism. However, the study has shown only an association between the two and does not prove a causal relationship.

Reference

1. Zheng R, et al. Outdoor light at night in relation to glucose homoeostasis and diabetes in Chinese adults: a national and cross-sectional study of 98,658 participants from 162 study sites. Diabetologia. 2022 Nov 14.

More Than 1 Billion Young People at Risk of Hearing Loss from Unsafe Listening

More than 1 billion young people are at risk of hearing impairment or hearing loss because of exposure to loud noise from personal listening devices and at loud music venues, according to a recent study published in the *BMJ Global Health*.[1]

In this systematic review and meta-analysis, researchers aimed to find out the prevalence of unsafe listening practices from exposure to personal listening devices (PLDs) such as ear buds, headphones and loud entertainment venues in the age group ranging between 12 and 34 years. They also sought to determine the number of people at risk of hearing loss consequent to this practice. Thirty-three studies (corresponding to data from 35 records) conducted between 2000 and 2021 involving 19,046 participants were selected; 17 studies related to use of PLDs, while the remaining 18 focused on loud entertainment venues.

Upon unsafe exposure to PLDs, the pooled prevalence was estimated to be 23.81%. For loud entertainment venues, the prevalence was estimated to be 48.20%. The meta-analysis further estimated that up to 1.35 billion (range 0.67-1.35 billion) young persons could be at risk of loss of hearing from exposure to unsafe listening practices. Unsafe listening is quite prevalent in society, as also indicated in this study. It is recognized as a modifiable risk factor for hearing loss in teenagers and young adults. The findings of this study urge policymakers to formulate and implement policies regarding unsafe exposure to sound for safe listening to prevent hearing loss.

Reference

1. Dillard LK, et al. Prevalence and global estimates of unsafe listening practices in adolescents and young adults: a systematic review and meta-analysis. BMJ Glob Health. 2022;7(11):e010501.

First FDA Approved Treatment to Delay-onset of Symptomatic Type 1 Diabetes: Will it be a Game Changer?

Teplizumab-mzwv, an injectable monoclonal antibody has been FDA approved as a treatment to delay the onset of stage 3 type 1 diabetes in adults and children (aged ≥8 years) with stage 2 type 1 diabetes. Teplizumab-mzwv is an anti-CD3-directed antibody.[1,2]

In stage 1 type 1 diabetes, two or more type 1 diabetes-associated islet autoantibodies are positive; however, the patient is asymptomatic and normoglycemic. In stage 2, dysglycemia develops and patients are mostly asymptomatic. Stages 1 and 2 are presymptomatic type 1 diabetes. Stage 3 is when type 1 diabetes can be clinically diagnosed. It is symptomatic type 1 diabetes and manifests with the classical symptoms of diabetes (polyuria, polydipsia, fatigue, unexplained weight loss, blurred vision) or may present with diabetic ketoacidosis.[3]

Dosage form: 2 mg per 2 mL (1 mg/mL) single-dose vial.

Dose and administration: Teplizumab-mzwv is administered as IV infusion once daily × 14 days over a minimum duration of 30 minutes. Use a nonsteroidal anti-inflammatory drug (NSAID)/paracetamol, antihistamine and/or antiemetic as premedication for the first 5 days (minimum) of administration. Dose is calculated based on the body surface area.

- Day 1: 65 μg/m^2
- Day 2: 125 μg/m^2
- Day 3: 250 μg/m^2
- Day 4: 500 μg/m^2
- Days 5 through 14: 1,030 μg/m^2

Side effects: Skin rash, headache, lymphopenia.

Warning and precautions

- Two doses should not be given on the same day. Obtain baseline complete blood count (CBC) and liver enzymes before starting treatment.
- A minimum of two positive pancreatic islet autoantibodies must be obtained to confirm stage 2 type 1 diabetes prior to starting treatment. Type 2 diabetes must be excluded.
- Monitor the patient for cytokine release syndrome: check liver enzymes; discontinue treatment if ALT or AST are increased more than 5 times the upper limit of normal.
- Assess for serious infections during and after treatment. Stop treatment if a serious infection develops. Avoid in patients with active serious infection or chronic active infection except for localized skin infections.
- Monitor white blood cell count during treatment; discontinue the drug in case of lymphopenia (<500 cells/μL) lasting 1 week or longer. Hypersensitivity reactions may occur.
- Administer all age-appropriate vaccinations before starting treatment; avoid simultaneous administration of live, inactivated and mRNA vaccines. Live vaccines should be administered ≥8 weeks before treatment and inactivated/mRNA vaccines ≥2 weeks prior to treatment.

References

1. US FDA news release. FDA approves first drug that can delay onset of type 1 diabetes. Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-can-delay-onset-type-1-diabetes
2. Tzield prescribing information. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761183s000lbl.pdf
3. Insel RA, et al. Staging presymptomatic type 1 diabetes: a scientific statement of JDRF, the Endocrine Society, and the American Diabetes Association. Diabetes Care. 2015;38(10):1964-74.

Stressful Life Events and Long COVID

More than half of COVID-19 patients report major stressful events in the post-COVID period. Those who suffer such events within 1 year of surviving COVID-19 are more likely to develop long COVID symptoms, suggests a new research published in the *Journal of the Neurological Sciences*.[1]

In this prospective study of hospitalized COVID-19 patients, Frontera et al evaluated long-term outcomes and other post-acute COVID symptoms at 6 and 12 months after COVID. A total of 451 COVID survivors were evaluated; 383 finished a 6-month follow-up, while 242 completed a 12-month follow-up.

Within a year after hospital discharge, 77 (17%) of the patients examined died and 51% reported major life stressor events such as financial insecurity, food insecurity, death of a close contact and new disability. On multivariate analysis, the presence of these life stressors was strongly predictive of adverse outcomes 1 year after post-COVID hospitalization in terms of disability, difficulty in activities of daily living (ADL), depression, fatigue, sleep problems and post-acute symptoms of COVID-19. The adjusted odds ratios for these associations ranged between 2.5 and 20.8.

Older patients, female patients and those who had disability at the starting point of the study were more likely to have poor outcomes post-hospitalization. Greater severity of the COVID-19 infection was associated with prolonged post-acute symptoms and difficulties in ADL. Older patients were more likely to experience disability, problems with ADL and cognition and depression. Women patients reported more anxiety along with difficulties in ADL.

This study spotlights the contribution of stressful life events on the outcomes after hospitalization for COVID-19 while reiterating the role of established risk factors such as advanced age, severity of infection in post-COVID acute symptoms and long COVID symptoms. A holistic approach is required when managing such patients and the psychosocial factors also need to be addressed for optimum patient recovery.

Reference

1. Frontera JA, et al. Life stressors significantly impact long-term outcomes and post-acute symptoms 12-months after COVID-19 hospitalization. J Neurol Sci. 2022;443:120487.

The First Fungal Priority Pathogens List

The World Health Organization (WHO) has published the first list of fungal priority pathogens, which pose a danger to public health. The list includes 19 fungi that cause invasive systemic fungal infections, both acute and subacute. These have been categorized into three based on their public health impact and/or emerging antifungal resistance risk into critical, high and medium priority.

- The *critical priority* fungi are *Candida auris, Candida albicans, Cryptococcus neoformans* and *Aspergillus fumigatus*.
- The *high priority* group includes *Histoplasma* spp., *Fusarium* spp., *Nakaseomyces glabrata* (*Candida glabrata*), Mucorales, *Candida tropicalis, Candida parapsilosis* and Eumycetoma causative agents.
- The fungi in the *medium priority* list are *Lomentospora prolificans, Scedosporium* spp., *Pichia kudriavzeveii (Candida krusei), Cryptococcus gattii, Coccidioides* spp., *Talaromyces marneffei* and *Paracoccidioides* spp. and *Pneumocystis jirovecii*.

The report highlights the need for improving surveillance, support for R&D and public health interventions to prevent or reduce antifungal drug resistance.

Earlier in 2017, the WHO had released the first bacterial priority pathogens list keeping in view the rising antibiotic resistance. (*Source: WHO fungal priority pathogens list to guide research, development and public health action. Geneva: World Health Organization; 2022. Available at: https://www.who.int/publications/i/item/9789240060241*)

Poorer Outcomes in Children with Bronchopulmonary Dysplasia Attending Daycare

Preterm children with chronic respiratory disease such as bronchopulmonary dysplasia (BPD) are likely to experience greater respiratory morbidity if they attended daycare when compared with children not in daycare, according to findings of a multicenter study recently published in *Journal of Pediatrics*.[1]

This multicenter study from the United States enrolled 341 children from 9 specialty clinics across the country to examine if daycare visits had any impact on disease severity with greater utilization of health care services for respiratory illnesses in children aged ≤3 years. These patients had been preterm infants born before 34 weeks of gestation with BPD (71% severe) for which they needed follow-up as outpatients between 0 and 3 years of age. Data on daycare attendance, clinical features, emergency room (ER) visits and chronic respiratory symptoms was collected.

The researchers found that children with BPD who attended daycare were nearly 3 times more likely to visit the ED for acute care with an adjusted odds ratio (aOR) of 2.81. They were also four times more likely to use systemic steroids with aOR of 4.23. Compared to children aged ≤3 years not in daycare, those attending daycare had higher probability of experiencing breathing problems (aOR 4.03) and activity limitations (aOR 2.66). They also needed rescue medications (aOR 7.38).

When the study subjects were analyzed according to age, children aged 6 to 12 months (vs. 12 months, 12-24 months) attending daycare were found to have the most severe presentation of the disease with greater chances of hospital admissions.

This study demonstrates that preterm children diagnosed with BPD had greater likelihood of using systemic steroids, ER visits and having long-term respiratory symptoms if they attended daycare. Based on these findings, the researchers suggest daycare as a potentially modifiable risk factor to reduce the adverse outcomes in children with BPD up to 3 years of age. Hence, parents seeking daycare for their children, particularly the preschoolers, should be advised of the risks likely to be associated with daycare attendance.

Reference

1. McGrath-Morrow SA, et al. Daycare attendance is linked to increased risk of respiratory morbidities in children born preterm with bronchopulmonary dysplasia. J Pediatr. 2022;249:22-28.e1.

Study Finds Aerosol Pollution may Rise by 5% Causing Serious Health Issues

A study from Bose Institute, Kolkata, revealed that aerosol pollution is predicted to increase by 5% in Jharkhand, which is classified as a "very sensitive" (red zone), region. To cut emissions, the experts recommended increasing the reliance on thermal power facilities. Particulate matter (PM2.5 and PM10), sea salt, dust, black and organic carbon are among the substances that are found in high concentrations in aerosols and cause severe health hazards if inhaled. The study stated that PM2.5 can be indirectly measured by using aerosol optical depth (AOD), which is a quantitative indication of the amount of aerosol present in the atmosphere.

The study mentioned that if AOD has a value between 0 and 1. 0, then it denotes the clearest sky with the maximum visibility. The value 1 indicates extremely hazy conditions. AOD values between 0.3 and 0.4 are considered to be in the blue zone (less vulnerable), 0.4 and 0.5 are considered to be in the orange zone (vulnerable), and over 0.5 is considered to be in the red zone (highly vulnerable). With more than 0.5 AOD, Jharkhand is considered a red zone and if the level increases by 5%, the AOD may surpass 0.6 the next year.

The increase in AOD level may seem slight, but Jharkhand is already in high danger, making the state much more vulnerable in the future. The primary sources of aerosol pollution were thermal power plants (TPP), followed by solid fuel combustion and vehicle emissions. To reach the 0.4 level, Jharkhand must reduce TPP emissions by 70% to 80%.

The Jharkhand State Pollution Control Board's chairman, Sashikar Samantha, stated that they were striving towards zero emissions. (*Source: https://timesofindia.indiatimes.com/city/ranchi/aerosol-pollution-may-rise-by-5-likely-to-impact-health-finds-study/articleshowprint/95368290.cms?val=3728*)

Pause in Immunization During the Pandemic has Resulted in New Polio Cases in Several Countries

According to an expert associated with the Bill & Melinda Gates Foundation, a pause in immunization due to the COVID-19 pandemic has led to the finding of fresh polio cases in countries like the US, the UK and Mozambique. Dr Ananda Sankar Bandyopadhyay, Deputy Director of Technology, Research and Analytics at the Foundation's Polio Team, stated that these findings on the poliovirus are a reminder that the virus will remain a threat if it exists anywhere in the world.

Dr Bandyopadhyay noted that any case of polio can be attributed to low immunization rates. He added that when the COVID-19 pandemic first hit in 2020, polio campaigns were briefly paused for 4 months to protect communities and health workers from the coronavirus. However, this move has led to an increased spread of the poliovirus in several countries.

In July 2022, poliovirus was found in an unvaccinated adult man in Rockland County, New York, as well as in several wastewater samples near his residence there. Further, poliovirus was also detected in sewage in North and East London between February and May 2022.

In May, the virus was found in Mozambique when a child contracted the disease. It was the second imported case of wild poliovirus in southern Africa after one in Malawi was detected in mid-February this year. (*Source: https://www.newindianexpress.com/world/2022/oct/27/new-polio-cases-found-in-nations-due-to-pause-in-immunisation-during-covid-time-expert-2512205.html*)

Micronutrients Manage Mental Health Better

According to the WHO's World Mental Health Report, released in June 2022, among the 1 billion people who suffered from some mental disorder, 15% were working-age individuals. The prevalence of anxiety and depression soared by a startling 25% worldwide in the first year of the pandemic.

Recent research suggests that nutrient-based medications could help in the treatment of mental illnesses in both individuals and populations. Numerous nutrients have been linked in studies to improved brain function. Five micronutrients—Vitamin B12, C, D, Zn and omega-3 fatty acids—were recommended by experts as aiding in better mental health management.

B vitamins are well known for their ability to affect mood. Depression may be associated with low levels of vitamin B12 and other B vitamins including folate and vitamin B6. A B12 shortage can result in fatigue and memory loss. B vitamin supplementation may enhance mental health and positively impact cognitive performance.

Lack of vitamin C can cause dopamine and serotonin levels in the brain to drop, which can alleviate or even cure the symptoms of anxiety, depression and bipolar disorder.

Vitamin D is found to regulate the functions of the central nervous system. Hence, a deficiency in vitamin D has been linked with depression. It has been observed that vitamin D supplements lessen depressive symptoms in those who are depressed. In addition to improving immune function, zinc affects the brain and emotions. Numerous mental and emotional disorders have been linked to it. A lack of zinc can lead to emotional instability and difficulty handling stress.

Omega-3 is essential to prevent brain aging and preserve cognitive function and also the development of children's brains. Studies show that omega-3 fatty acids can manage several mood disorders including bipolar disorder, severe depression and postpartum depression and also help aid in controlling major depression and schizophrenia. (*Source: https://www.hindustantimes.com/lifestyle/health/role-of-micronutrients-in-boosting-mental-health-101667815533452.html*)

■■■■

Managing Grief by Free Expressive Writing

The loss of a loved one is often painful. The resultant grief makes it hard to eat, sleep and leads to loss of interest in routine life, affecting behavior and judgment.

Some can feel agitated, some may feel like crying, some may want to withdraw from the world and others may struggle with feelings of sorrow, anger, guilt, despair, irritability or anxiety.

It is well known that disclosing your emotions by way of writing can boost your immune function and your mood and well-being. On the contrary, holding in strong feelings can increase blood pressure and heart rate.

One can write on a piece of paper, in his personal book, on the open website or keep it in the mind. One doesn't have to preserve the emotions and can throw away the writings.

In absence of deeply troubling situations, such as suicide or a violent death, which are best explored with the help of an experienced therapist, one can choose writing as a way to express the grief.

- Start writing for 15 to 30 minutes a day for 3 to 4 days.
- Continue up to a week if it is helping.
- Continue writing for 15 to 30 minutes once a week for a month.
- Writing has stronger effects when it extends for more number of days.
- Remember, writing about grief and loss can trigger strong emotions (one may cry or feel deeply upset).
- Several people find journal writing valuable and report feeling better afterward.
- Don't worry about grammar or sentence structure.
- Truly let go. Write down how you feel and why you feel that way.

(*Source: Harvard News Letter*)

■■■■

Autism Spectrum Disorder Makes Eye Contact Difficult with Others

People with autism spectrum disorder (ASD) find making eye contact with others in everyday situations challenging. Even though eye contact is an essential part of everyday interactions, scientists have been unable to examine the neurological bases of live social interaction involving eye contact in ASD due to the challenge of simultaneously scanning two people's brains.

A published study in the journal *PLOS ONE* stated that researchers used functional near-infrared spectroscopy, a noninvasive optical neuroimaging technique, to examine brain activity during brief social interactions between pairs of individuals, each consisting of a typical participant and one with ASD. They found that the dorsal parietal region of the brain contains specific brain regions linked to the social symptomatology of autism. The study revealed that these brain reactions to live face and eye contact might serve as a biomarker for the diagnosis of ASD and a test of the effectiveness of treatments for autism. The researchers further noticed that persons with ASD displayed considerably less dorsal parietal cortex activity during eye contact than participants without ASD. Additionally, the less activity in this area of the brain was seen, the more severe the overall social symptoms of ASD as determined by ADOS (Autism Diagnostic Observation Schedule, 2nd Edition) scores.

Real eye-to-eye contact caused synchronized neural activity in these regions between normal people, while looking at a video face did not. The absence of this expected increase in neural connectivity in ASD is consistent with the challenges faced in social interactions. (*Source: https://theprint.in/health/study-reveals-why-those-with-autism-avoid-eye-contact/1208276/*)

Addiction to Worry

Carole started counseling with me because she was depressed. She had been ill with chronic fatigue syndrome for a long time and believed her depression was due to this. In the course of our work together, she became aware that her depression was actually coming from her negative thinking – Carole was a constant worrier. Many words out of her mouth centered on her concerns that something bad might happen. “What if I never get well?” “What if my husband gets sick?” “What if I run out of money?” (Carole and her husband ran a very successful business and there was no indication that it would not go on being successful). “What if my son gets into drugs?” “What if my kids don’t get into good colleges?” “What if someone breaks into the house?”

Her worry was not only causing her depression, but was also contributing to her illness, if not actually causing it. Her worry caused so much stress in her body that her immune system could not do its job of keeping her well. Yet even the awareness that her worry was causing her depression and possibly even her illness did not stop Carole from worrying. She was addicted to it. She was unconsciously addicted to the sense of control that worry gave her.

I understood this well because I come from a long line of worriers. My grandmother’s whole life was about worrying. She lived with us as I was growing up and I don’t remember ever seeing her without a look of worry on her face. Same is with my mother – constant worry. Of course, I picked up on it and also became a worrier. However, unlike my mother and grandmother, who worried daily until the day they died, I decided I didn’t want to live that way. The turning point came for me the day my husband and I were going to the beach and I started to worry that the house would burn down and my children would die. I became so upset from the worry that we had to turn around and come home. I knew then that I had to do something about it.

As I started to examine the cause of worry, I realized that worriers believe that worry will stop bad things from happening. My mother worried her whole life and none of the bad things she worried about ever happened. She concluded that nothing bad happened because she worried! She really believed that she could control things with her worry. My father, however, never worried about anything, and nothing bad ever happened to him either. My mother believed that nothing bad happened to my father because of her worry! She really believed until the day she died (from heart problems that may have been due to her constant worry) that if she stopped worrying, everything would fall apart. My father is still alive at 92, even without her worrying about him!

It is not easy to stop worrying when you have been practicing worrying for most of your life. In order for me to stop worrying, I needed to recognize that the belief that worry has control over outcomes is a complete illusion. I needed to see that, not only is worry a waste of time, but that it can have grave negative consequences on health and well-being. Once I understood this, I was able to notice the stomach clenching that occurred whenever I worried and stop the thought that was causing the stress.

Carole is in the process of learning this. She sees that her worry makes her feel very anxious and depressed. She sees that when she doesn’t worry, she is not nearly as fatigued as when she allows her addiction to worry to take over. She sees that when she stays in the moment rather than projecting into the future, she feels much better. The key for Carole in stopping worrying is in accepting that worry does not give her control.

Giving up the illusion of control that worry gives us is not easy for anyone who worries. Yet there is an interesting paradox regarding worry. I have found that when I am in the present moment, I have a much better chance of making choices that support my highest good than when I’m stuck thinking about the future. Rather than giving us control, worry prevents us from being present enough to make loving choices for ourselves and others. Worrying actually ends up giving us less control rather than more!

(*Source: https://www.streetdirectory.com/travel_guide/print_article.php?articleId=7990*)

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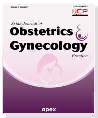
Asian Journal of Obs & Gynae Practice 	4	1,500/- ☐	NA
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Lighter Side of Medicine

HUMOR

I AM DRIVING

A wife was making breakfast of fried eggs for her husband.

Suddenly, her husband burst into the kitchen.

'Careful,' he said, 'CAREFUL! Put in some more butter! Oh my Gosh! You're cooking too many at once. TOO MANY! Turn them! TURN THEM NOW! We need more butter. Oh my Gosh! WHERE are we going to get MORE BUTTER? They're going to STICK! Careful. CAREFUL! I said be CAREFUL!

You NEVER listen to me when you're cooking! Never! Turn them! Hurry up! Are you CRAZY? Have you LOST your mind? Don't forget to salt them. You know you always forget to salt them. Use the salt! USE THE SALT! THE SALT!'

The wife stared at him. 'What in the world is wrong with you? You think I don't know how to fry a couple of eggs?'

The husband calmly replied, 'I just wanted to show you what it feels like when I'm driving.'

FOR CRYING OUT LOUD

With all the new technology regarding fertility, an 88-year-old woman was able to give birth to a baby recently. When she was discharged from the hospital and went home, various relatives came to visit. "May we see the new baby?" one of them asked. "Not yet," said the mother. "I'll make coffee and we can visit for a while first."

Another half hour passed before another relative asked, "May we see the new baby now?"

"No, not yet," said the mother. A while later and again the guests asked, "May we see the baby now?"

"No, not yet," replied the mother.

Growing impatient, they asked, "Well, when can we see the baby?"

"When it cries!" she told them.

"When it cries?" they gasped. "Why do we have to wait until it cries?"

"Because, I forgot where I put it."

COMPUTER GENDER

Why computers should be considered masculine?

- In order to get their attention, you have to turn them on.
- They have a lot of data but are still clueless.
- They are supposed to help you solve your problems, but half the time they ARE the problem.
- As soon as you commit to one, you realize that, if you had waited a little longer, you could have had a better model.

Why computers should be considered feminine?

- No one but their creator understands their internal logic.
- The native language they use to communicate with other computers is incomprehensible to everyone else.
- Even your smallest mistakes are stored in long-term memory for later retrieval.
- As soon as you make a commitment to one, you find yourself spending half your paycheck on accessories for it.

Dr. Good and Dr. Bad

SITUATION: A patient with T2DM was advised endoscopic sinus surgery for nasal polyposis.

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LESSON: Patients with diabetes mellitus who have to undergo endoscopic sinus surgery are at increased risk for postoperative medical complications; however, diabetes mellitus does not seem to influence the risk in this set of patients. In addition, it may not have an impact on endoscopic sinus surgery-related mortality, readmission or reoperation rates.

Int Forum Allergy Rhinol. 2017;7(6):584-90.

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Methods

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– Method of allocating the subjects into different groups.
– Statistical methods used for presentation and analysis of data i.e., in terms of mean and standard deviation values or percentages and statistical tests such as Student's 't' test, Chi-square test and analysis of variance or non-parametric tests and multivariate techniques.
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References

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Examples of common forms of references are:

Articles

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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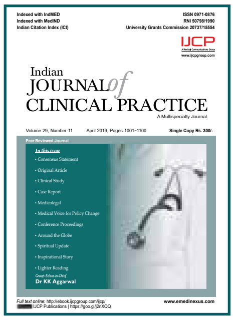

Indian Citation Index (ICI),
MedIND (http://medind.nic.in/)
ISSN number 0971-0876
The Medical Council of India (UGC, ICI)
IndMed (http://indmed.nic.in/)
University Grants Commission (20737/15554).
RNI number 50798/1990.

Indian Journal of Clinical Practice is published by the IJCP Group. A multispecialty journal, it provides clinicians with evidence-based updated information about a diverse range of common medical topics, including those frequently encountered by the Indian physician to make informed clinical decisions. The journal has been published regularly every month since it was first launched in June 1990 as a monthly medical journal. It now has a circulation of more than 3 lakh doctors.

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R.N.I. No. 50798/1990
Date of Publication 13th of Same Month
Date of Posting 13-14 Same Month

POSTAL REGISTRATION NO. DL(S)-01/3200/2021-2023
POSTED AT LPC DELHI RMS DELHI-110006