

## CLINICAL PHARMACY NEWSLETTER

## A Newsletter of Drug and Prescribing Information

Published by

Clinical Pharmacy Services Department, Govt. Medical College & Hospital, Ooty (A Unit of Department of Pharmacy Practice, JSS College of Pharmacy, Ooty)

### Volume XXVII Issue 04

#### **OCTOBER - DECEMBER 2022**

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## Will my eating habits put me at risk for diabetes?

Diabetes is a rapidly growing health challenge and potential epidemic across the low-and-middle-income countries. It is projected that by 2025 the number of cases with diabetes in India would be 69.9 million with a vast majority still undiagnosed. This is primarily driven by dietary transitions and insufficient or lack of physical activity altering the physiological milieu, leading to overweight or obesity and diabetes.

Diabetes mellitus is defined as "a metabolic disorder characterized by hyperglycemia resulting from either the deficiency in insulin secretion or the action of insulin." Poorly controlled type 2 diabetes is associated with an array of microvascular, macrovascular complications.

Microvascular complications of diabetes include retinal, renal, and possibly neuropathic disease. Macrovascular complications include coronary artery and peripheral vascular disease.

DM can be of three major types, based on etiology and clinical features. These are DM type 1 (T1DM), DM type 2 (T2DM), and gestational DM (GDM).

#### **Physical Activity and Lifestyle**

Numerous studies have found significant association between physical inactivity and T2DM. A prospective study was carried out among more than a thousand nondiabetic individuals from the high-risk population of Indians. During an average follow-up period of 6-year, it was found that the diabetes incidence rate remained higher in less active men and women from all BMI groups. The existing evidence suggests a number of possible biological pathways for the protective effect of physical activity on the development of T2DM. First, it has been proposed that physical activity increases sensitivity to insulin.

Obesity and diabetes are linked to those who sit for hours watching TV, using the computer, cellphones, or playing video games while consuming unhealthy meals, as per research. According to another study, slow eaters are less likely to develop diabetes than quick eaters.

The parasympathetic nervous system triggers salivation and increases insulin production in

reaction to the expectation that glucose will enter the bloodstream when we anticipate or smell a meal. However, when we eat while preoccupied, such as while working on laptops, watching TV, or talking on the phone, the parasympathetic nervous system shuts down, which prevents salivary secretion, reduces insulin production, and so the glucose level in the blood rises above the normal level. When this practice is repeated over time, the body develops a habit of producing less insulin, which may lead to diabetes in the future.

#### Relation between Diet and Type 2 DM

Recently, evidence suggested a link between the intake of soft drinks with obesity and diabetes, resulting from large amounts of high fructose corn syrup used in the manufacturing of soft drinks, which raises blood glucose levels and BMI to dangerous levels. It was also found that diet soft drinks contain glycated chemicals that markedly augment insulin resistance. Food intake has been strongly linked with obesity, not only related to the volume of food, but also in terms of the composition and quality of diet. High intake of red meat, sweets and fried foods, contribute to the increased risk of insulin resistance and T2DM.

#### Junk foods and diabetes

Junk foods are unhealthful foods. They are usually high in calories in fat, sugar, salt, and processed carbohydrates, and low in useful nutrients, such as fibre, vitamins, and minerals.

Junk food includes many types of fast food, processed foods, and premade snack foods.

Junk foods may contribute to diabetes in the following ways:

Rapid effect on blood sugar levels: Highly processed foods that are high in calories and low in vitamins, minerals, and fibre break down quickly in the body and can cause a rapid rise in blood sugar levels.

Weight gain: Due to its poor nutritional qualities and ability to encourage overeating, people who eat junk food may gain weight. Excess weight and body fat are major risk factors for developing type 2 diabetes, which accounts for 90–95%.

High blood pressure: Junk food is typically very

very high in sodium (salt), which contributes to high blood pressure. High blood pressure is linked to an increased risk of type 2 diabetes.

**Triglyceride levels:** Junk foods are high in trans and saturated fats, which can raise levels of triglycerides, a type of fat that is present in the blood. High levels of triglycerides increase the risk of developing type 2 diabetes.

According to 2016 study published in Experimental Physiology, regularly eating junk foods can cause as much damage to the kidneys of people without diabetes as it does to those with the disease itself. Junk food also causes high blood sugar levels similar to those experienced by people with type 2 diabetes.

#### Mindful eating

**Observe:** Listening to your body and stopping when you're satisfied. Eating when our body tells us to eat (i.e., stomach growling, energy low). Respect your body and health

Aware: Tasting vs. mindless munching. Chew properly, eat slowly

At the moment: When eating, just eating. Be fully present. Turn off the TV. No multitasking. Don't hurry

Savour: Notice the texture, aroma, and flavour

Parenting has never been easy. But the widespread adoption of smartphones and the rise of social media has introduced a new wrinkle to the challenges of parenthood. It is the parents' obligation to instil a healthy lifestyle in their children because small misdemeanour in the childhood can lead to major issues later in life.

Future generation can be like:

"Waiter, I'd have chicken sausage pizza, pesto spaghetti, Chocolate

waffles, and a double shot of insulin" So it is better to control diabetes before it controls you.

#### References:

- 1. Centers for Disease Control and Prevention. National Diabetes Statistics Report. CDC. Available at https://www.cdc.gov/diabetes/data/statistics-report/index.html. Reviewed January 18, 2022; Accessed: January 28, 2022.
- 2. Ludwig J, Sanbonmatsu L, Gennetian L, Adam E, Duncan GJ, Katz LF, et al. Neighborhoods, obesity, and diabetes--a randomized social experiment. N Engl J Med. 2011 Oct 20. 365(16):1509-19. [QxMD MEDLINE Link].
- 3. U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Physical Activity Guidelines for Americans, 2nd edition. Washington, DC: U.S. Department of Health and Human Services; 2018. https://health.gov/paguidelines/second-edition/ External link. Updated January 14, 2019. Accessed January 14, 2019.
- 4. Assy N, Nasser G, Kamayse I, Nseir W, Beniashvili Z, Djibre A, et al. Soft drink consumption linked with fatty liver in the absence of traditional risk factors. Can J Gastroenterol. 2008;22:811–6. [PMC free article] [PubMed] [Google Scholar]
- 5. Kahan S, Manson JE. Nutrition counseling in clinical practice: how clinicians can do better. JAMA2017;318:1101-2. doi:10.1001/jama.2017.10434 pmid:28880975CrossRefPubMedGoogle Scholar

#### Narcolepsy in Pediatric Patients

Narcolepsy is a sleep disorder characterized by excessive sleepiness, sleep paralysis, hallucinations, and in some cases episodes of cataplexy (partial or total loss of muscle control, often triggered by a strong emotion such as laughter)

Narcolepsy is a chronic neurodegenerative disease caused by autoimmune destruction of hypocretin producing neurons.

TYPES: Basically, it is classified into two major types:

Narcolepsy Type 1(NT1): This type of narcolepsy involves a combination of excessive daytime sleepiness and one or both of the following:

- a. Cataplexy (Sudden muscle weakness that occurs while a person is awake)
- b. Low CSF hypocretin-1 levels

Narcolepsy Type 2 (NT2): This type of narcolepsy is characterized by continuous excessive sleepiness, but no cataplexy or hypocretin deficiency.

Pediatric narcolepsy usually begins between the age of 12-17 years.

The prevalence rate of narcolepsy is around 10.0/100,000.

In US pediatric population, the estimated prevalence of diagnosed narcolepsy increased from 6780 in 2013 to 7,606 in 2016

Estimated age-based prevalence was 0.7/100,000 for 0-6 years, 6.9/100,000 for 7-12 years and 24.0 for 12-17 years

NT2 seems to be less frequent compared to NT1 also in the pediatric population.

#### Etiology

The exact etiology of narcolepsy is unknown, but it could occur due to Hypocretin deficiency.

It could be triggered by:

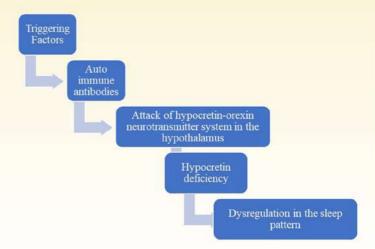
Autoimmune attack

Inherited genetic abnormality

Major psychological stress

Infections (streptococcal infections)

#### Pathophysiology



Clinical Presentation: The most common signs and symptoms includes Sleep attacks, Cataplexy, Hypnagogic hallucinations, and Sleep paralysis.

Complications: The complications include Obesity, Physical harm, Attention deficit/hyperactivity disorders, Anxiety disorders, Cognitive dysfunction

#### Diagnosis:

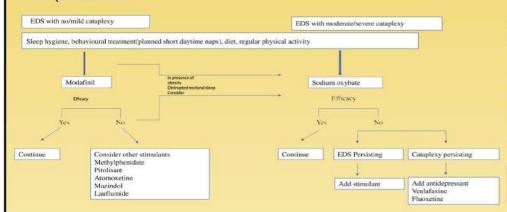
Polysomnography

Multiple sleep latency test

CSF hypocretin levels

Epworth Sleepiness Scale for Children and Adolescents (ESS-CHAD)

#### HLA DQB1\*602 allele



#### Treatment:

Behavioral Treatment: It can be started by implementing any of the following measures:

Sleep hygiene

Small day time naps

Physical activity

#### Pharmacological Treatment:

No pharmacological therapy is approved by Food and Drug Administration/European Medicines Agency (FDA/EMA) for narcoleptic patients under the age of 16 years. Adult medications were used off-label in the paediatric population based on empirical data in adult narcoleptics and shared among expert sleep disorders clinicians for children. The following treatment algorithm is suggested.



#### References

- 1. Narcolepsy Symptoms, Treatment & Remedies—Sleep Foundation [Internet]. Sleep Foundation. [cited 3 September 2020]. Available from: https://www.sleepfoundation.org/articles/narcolepsy#:~:text=Narcolepsy
- 2. Narcolepsy Overview and Facts—Sleep Education [Internet]. Sleepeducation.org. 2020 [cited 3 September 2020]. Available from: http://sleepeducation.org/essentials-in-sleep/narcolepsy/overview-facts
- 3. A. Morse, G. Lecholai, M. Yang, et al. Prevalence of Diagnosed Pediatric Narcolepsy in the US population. Sleep. 2019; 42(1).
- 4. A. Gupta, G. Shukla, V. Goyal. Clinical and polysomnographic characteristics in 20 North Indian patients with narcolepsy: A seven-year experience from a neurology service sleep clinic. 2012; 60(1): 75-78
- 5. Narcolepsy Causes [Internet]. nhs.uk. 2020 [cited 3 September 2020]. Available from: https://www.nhs.uk/conditions/narcolepsy/causes/#:~:text=Many%20cases%20of%20narcolepsy%20are,the%20brain%20that%20produce %20hypocretin.
- 6. T. Morgenthaler, V. Kapur, T. Brown, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. American Academy of Sleep Medicine Report. SLEEP. 2007;30(12)

## Drug Profile - Teplizumab

#### **BRAND NAME:** Tzield

CLASS: Humanized IgG1 kappa CD3- directed monoclonal antibody

**INDICATION:** Indicated to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients 8 years of age and older with Stage 2 type 1 diabetes

MECHANISM OF ACTION: Anti-CD3 therapy has traditionally been used to prevent graft-versus-host-disease in organ transplantation, but more recently has been explored to prolong the onset of (T1D) in high-risk patients. Targeting T cells can be achieved through antibodies against the T cell receptor (TCR) component CD3. Although the mechanism of action of Teplizumab has not been fully elucidated, it may involve partial agonistic signalling and deactivation of pancreatic beta cell autoreactive T lymphocytes. Fc-receptors can bind to the "tail-end" anti-CD3 antibodies in an antigen-non-specific manner and lead to severe adverse effects related to cytokine

release syndrome (CRS). Teplizumab was designed as a Fc-non-binding antibody in order to reduce the incidence of CRS. On November 17, 2022, Teplizumab was approved by the FDA.

One hypothesis is that Teplizumab acts as a partial agonist at the TCR, increasing the number of exhausted T cells positive for KLRG1(Killer cell lectin-like receptor subfamily G member 1), TIGIT(T-cell immunoreceptor with Ig) , and CD8(cluster of differentiation 8). These exhausted T cells persist but cannot perform effector functions and, therefore, would be unlikely to contribute to further  $\beta$  cell destruction. Other studies have noted changes in the T cell populations of clinical responders, including an increase in circulating CD8+ central memory (CD8CM) T cells. It is clear, that treatment is most effective in patients who have not yet progressed to Stage 3 and who have an active immune response

**DOSE:** Premedication (first 5 days of dosing): NSAID or acetaminophen, an antihistamine, and/or an antiemetic; may

administer additional doses of premedication if needed. 65 mcg/m(2) IV on day 1, 125 mcg/m(2) IV on day 2, 250 mcg/m(2) IV on day 3, 500 mcg/m(2) IV on day 4, and 1030 mcg/m(2) on days 5 through 14; infuse each dose over at least 30 minutes and do not administer 2 doses on the same day.

**DOSAGE REGIMEN:** Administer by IV infusion over 30 min qDay x 14 consecutive days

Day 1: 65 mcg/m2

Day 2: 125 mcg/m2

Day 3: 250 mcg/m2

Day 4: 500 mcg/m2

Days 5-14: 1,030 mcg/m2

AVAILABILITY: Teplizumab injection is available as a

preservative-free, sterile, clear, and colorless solution in a 1 mg/mL single-dose vial. Teplizumab has been launched in the USA by the biopharmaceutical company Provention Bio, Inc. There is no information regarding its availability in India yet.

COST: Provention Bio Inc has priced its diabetes drug Teplizumab at \$13,850 a vial.

**COMMON SIDE EFFECTS:** Decreased levels of certain white blood cells, rash, and headache.

VOLUME OF DISTRIBUTION: In a 60 kg subject, Teplizumab has a central volume of distribution (Vd) of 2.27L.

METABOLISM: As a monoclonal antibody, Teplizumab is expected to be metabolized into small peptides by proteases throughout the body.

HALF LIFE: In a 60 kg subject, Teplizumab has a mean terminal elimination half-life of 4.5 days.

CLEARANCE: In a 60 kg subject, Teplizumab has a clearance of 2.7 L/day.

WARNING & PRECAUTIONS: Premedicating and monitoring for symptoms of Cytokine Release Syndrome, risk of serious infections, risk of hypersensitivity reactions, the need to administer all age-appropriate vaccinations prior to starting Teplizumab as well as avoiding concurrent use of live, inactivated and mRNA vaccines.

#### USE IN SPECIFIC POPULATION:

Pregnancy: May cause fetal harm

Lactation: A lactating woman may consider pumping and discarding breast milk during and for 20 days after Teplizumab administration.

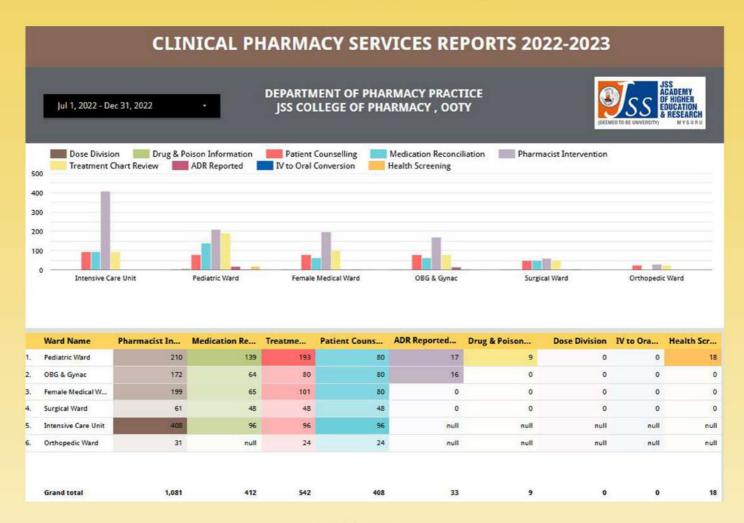
The availability of a disease-modifying agent could lead to a major shift in the approach to T1DM management. If it receives FDA approval, Teplizumab has the potential to positively impact the health outcomes and quality of life of many patients with T1DM. Early identification of those patients who could most benefit from the use of Teplizumab would be critically important.

#### References

- 1. FDA approves first drug that can delay onset of type 1 diabetes. (n.d.). U.S. Food and Drug Administration; FDA. Retrieved December 2, 2022, from https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-can-delay-onset-type-1-diabetes
- 2. Clinical Case. (2022, November 18). Tzield (teplizumab) dosing, indications, interactions, adverse effects, and more. http://reference.medscape.com/drug/tzield-teplizumab-4000164
- 3. Evans, E. I., PharmD Clinical Assistant Professor Department of Clinical, PharmD Candidate 2023 Howard University College of Pharmacy Oluwaranti Akiyode, Phar, BCPS, Dean, C. I., Howard University College of Pharmacy Washington, & Samp; DC. (2022, November 18). Potential agent for delaying type 1 diabetes mellitus.
- 4. Herold KC, Bundy BN, Long SA, Bluestone JA, DiMeglio LA, Dufort MJ, Gitelman SE, Gottlieb PA, Krischer JP, Linsley PS, Marks JB, Moore W, Moran A, Rodriguez H, Russell WE, Schatz D, Skyler JS, Tsalikian E, Wherrett DK, Ziegler AG, Greenbaum CJ; Type 1 Diabetes TrialNet Study Group. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. N Engl J Med. 2019 Aug 15;381(7):603-613. doi: 10.1056/NEJMoa1902226. Epub 2019 Jun 9. Erratum in: N Engl J Med. 2020 Feb 6;382(6):586. PMID: 31180194; PMCID: PMC6776880.
- 5. Warshauer JT, Bluestone JA, Anderson MS. New Frontiers in the Treatment of Type 1 Diabetes. Cell Metab. 2020 Jan 7;31(1):46-61. doi: 10.1016/j.cmet.2019.11.017. Epub 2019 Dec 12. PMID: 31839487; PMCID: PMC6986815.
- 6. Sherry N, Hagopian W, Ludvigsson J, Jain SM, Wahlen J, Ferry RJ Jr, Bode B, Aronoff S, Holland C, Carlin D, King KL, Wilder RL, Pillemer S, Bonvini E, Johnson S, Stein KE, Koenig S, Herold KC, Daifotis AG; Protégé Trial Investigators. Teplizumab for treatment of type 1 diabetes (Protégé study): 1-year results from a randomised, placebo-controlled trial. Lancet. 2011 Aug 6;378(9790):487-97. doi: 10.1016/S0140-6736(11)60931-8. Epub 2011 Jun 28. PMID: 21719095; PMCID: PMC3191495.



#### CP SERVICES REPORT:



#### **Publications**

- 1. Patnool Rihana B, Vithya T, Wadhwani Ashish, Balasubramaniam V, **Ponnusankar S**. Streptococcal infections: Race to multidrug resistance-A review. Journal of Applied Pharmaceutical Science. 2022; 12(9):001-10.
- 2. Sadagoban GK, Thomas Grace, Baiju Aiswarya, Philip Shwetha Mariam, Borra Swathi Swaroopa. ICT-enabled teaching and learning modalities followed in pharmacy education during COVID-19 in India. Journal of Applied Pharmaceutical Science. 2022;12(11):001-9.
- 3. Chandrasekar Keerthana, Navaswetha T, Vasudevan H, Kumar S Naveen, Arun KP. Review on Population Pharmacokinetics of Amikacin in Paediatrics. Journal of Pure Applied Microbiology. 2022;16(4):2303-2309.







#### **Invited Pharmacy Lecture Series 2022**

Report on Invited Pharmacy Lecture(IPL) series 2022

Lecture: 1

Date of Presentation: 19.12.2022

Speaker:

Dr Vijay Suppiah Senior Lecturer in Pharmacy UniSA Clinical and Health Sciences University of South Australia

#### Title of the presentation:

Risks associated with psychotropic polypharmacy in a hospitalized patient cohort



New Connections and new learning: Pharmacy Practice-"Learning in the flow of work"

Making learning is a part of everyday work – and everyone's experience at work differs of course, and it multiplies at different places. Internship training for Pharm D students is an opportunity to learn new and provide service to the needy patient population. To enhance their learning experience, the institute has created new connections and new learning opportunity from various practice settings.

Dr Vijay Suppiah is a pharmacy academic with research interests in pharmacogenomics in multimorbidity, especially in mental disorders. His research projects are based on patients' genetic make-up in informing medication choices, mainly in cancer and mental health. Additionally, he is also interested in the use of and long-term effects of psychotropic educations across the lifespan.

Dr Vijay ardently started his presentation on Risks associated with psychotropic polypharmacy in hospitalized patients and mentioned the common side effect associated with typical and traditional use of anti-psychotic drugs; sedation. Dr Vijay then emphasized the fact of increasing prevalence of psychiatric disorders like depression and anxiety among the Australians and the common drugs used to treat the same. Even though the common side effects are effectively managed either by the patients themselves or by the health care providers, Dr Vijay mentioned that QT prolongation in ECG of patients taking such drugs was generally overlooked, and it was the need of the hour to diagnose such patients in the early stages. QT prolongation is a heart rhythm disorder that can potentially cause fast, chaotic heartbeats. Long QT syndrome can be inherited or caused by a medication or condition. It often goes undiagnosed or is misdiagnosed. People with this condition may not develop symptoms for a long time. When symptoms do occur, they can be severe and may include sudden fainting, seizures or even sudden death.

Dr Vijay eventually summarized the studies done by his team to identify the patients on anti-psychotics who may be at higher risk for developing QT Prolongation. He also emphasized about various enzymatic predisposing factors that may either way affect the QT prolongation induced by such drugs. The study summaries were really additional information to the student participants of this webinar and the session was concluded by Dr S Ponnusankar after an interesting Q/A session.

There were nearly 60 above participants who were fruitfully benefited with this lecture.

Lecture: 2

Date of Presentation: 20.12.2022

Speaker:

Dr Suphat Subongkot Associate Professor Faculty of Pharmaceutical Sciences Khon Kaen University, Thailand

## **Title of the presentation:** Practical Review on Cancer

Management



Dr. Subongkot, Associate Professor at Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand. His responsibilities include didactic teaching in Advanced Pharmacotherapy course for Undergraduate, Master, and Doctorate of Clinical Pharmacy and also of Clinical Pharmacy and Clinical Pharmacotherapy Training Training

Program, and he serves as a Residency/Fellowship Coordinator under the College of Pharmacotherapy (Thailand). His past experiences involved clinical coordination with the medical team and oncology services at rush university medical center, Chicago; teaching responsibility in the experiential and did acticportion of the Chicago College of Pharmacy; preceptorship for pharmacy students and residents; conducting Clinical Researches at Rush University Medical Center, Chicago, IL.

Dr Subongkot started his online lecture from the basics of cancer and also mentioned the world-wide epidemiological datasets of cancer and also talked about the WHO cancer facts. Eventually, Dr Subongkot inculpated his talk towards the risk factors of developing cancer and its pathogenesis. He also underlined different genetic factors that put a person at high risk of developing cancer. Dr Subongkot then explained in detail about the physiological changes in the cell cycle and explained its mechanisms at molecular level. Dr Subongkot reiterated about the chemotherapeutic agents and also about the common side effects associated with their proper management. The session was then concluded by Dr S Ponnusankar, Professor and Head, Department of Pharmacy Practice. There were nearly 50 and above participants who were fruitfully benefited with this lecture.



# World Antimicrobial Awareness Week

18-24 November



SPREAD AWARENESS STOP RESISTANCE





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