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RSSDI Indian Diabetes

EDUCATOR JOURNAL

Theme of the Month

Diabetes and Mental Health

To keep Members of Diabetes Care team abreast about
DSME/DSMS - (Diabetes Self management Education/Support) Concepts

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*DSME: Diabetes Self-Management Education, DSMS: Diabetes Self-Management Support

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FOREWORD

Research Society for the Study of Diabetes in India (RSSDI) founded by Prof MMS Ahuja in the year 1972 is the biggest scientific association of healthcare professionals involved in promoting diabetes education and research in India. RSSDI is happy to collaborate with USV to support their endeavour to make India the 'Diabetes care capital of the world'. Through this collaboration, RSSDI would like to strengthen the cadre of diabetes educators by empowering them with recent updates in diabetes management helping bridge the gap between the physician and the patient. Today, the rule of 50% is prevailing in terms of awareness, detection, treatment and control in T2DM. Our aspiration is to achieve 90-90-90-90 i.e.90% of people with diabetes should be made aware, 90% should be detected, 90% of those detected should be treated, and 90% of those treated should reach their goals.

Indian Diabetes Educator Journal (IDEJ) is the first of its kind in India, and the longest running monthly diabetes educator journal since April 2015 & continues its endeavour to spread awareness, knowledge and enable healthcare teams to manage individuals with diabetes and empower them for self-care. RSSDI IDEJ will continue to keep the members of diabetes care team abreast with concepts of Diabetes Self-Management Education/Support (DSME/S) with a reach of 44000 doctors and diabetes educators digitally.

World Mental Health Day is celebrated every year on 10th October. People with diabetes are 2 to 3 times more likely to have mental health issues than people without diabetes. This month's IDEJ issue is a platform to spread information about the ways in which diabetes impacts psychological health and various aspects of prevention and management of mental health issues associated with diabetes.

We sincerely thank our contributors for making this issue delightful reading for our readers. We dedicate this journal to all the healthcare professionals who are working relentlessly towards making "India–The Diabetes Care Capital of the World."

Sincere Regards,

Dr. Sanjay Agarwal
RSSDI Secretary

Disclaimer: This Journal provides news, opinions, information and tips for effective counselling of people with diabetes. This Journal intends to empower your clinic support staffs for basic counselling of people with diabetes. This journal has been made in good faith with the literature available on this subject. The views and opinions expressed in this journal of selected sections are solely those of the original contributors. Every effort is made to ensure the accuracy of information but Hansa Medcell or USV Private Limited will not be held responsible for any inadvertent error(s). Professional are requested to use and apply their own professional judgement, experience and training and should not rely solely on the information contained in this publication before prescribing any diet, exercise and medication. Hansa Medcell or USV Private Limited assumes no responsibility or liability for personal or the injury, loss or damage that may result from suggestions or information in this book.

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The diagnosis of diabetes can be a life-altering event. Diabetes is fundamentally a chronic metabolic disorder with well-recognized psychological links and consequences. Whether it be type 1 diabetes (T1D), where the body does not make any insulin at all, or type 2 diabetes (T2D), when the pancreas produces some insulin but not enough, it can mean changes to one's lifestyle that a person with diabetes (PwD) may not be ready for and can also mar the relationships with friends or family. Depression is 2 to 3 times more common among people with diabetes than in those without diabetes; in fact, three out of five PwD experience emotional or mental health problems due to their condition.

Diabetes can lead to a great deal of distress, common mental health problems such as anxiety, depression, sleep disorders, and even the risk of suicide. It adversely affects multiple domains of cognitive function, such as attention, concentration, memory, executive function, and information processing speed, and can significantly reduce the quality of life. Pediatric diabetes especially presents unique psychosocial challenges to patient management, and these may affect the academic performance of children and the career choices of affected individuals.

Common psychiatric disorders (CPDs) are associated with the development of overweight and obesity, the most substantial risk factors for developing and maintaining T2D. Depression may hinder treatment adherence and blood glucose control. Likewise, existing diabetes can make mental health conditions worse. Diabetes distress is distinct from depression, resulting from the emotional burden (e.g., worry, frustration, anger, burnout) of managing T2D. A patient's level of diabetes distress, independent risk factors for depression, and glycemic control are all intimately connected. Poor psychological well-being remains directly proportional to poor glycemic control.

What are the differences between diabetes distress and depression?

Diabetes distress	Depression
Mainly an affective response to diabetes morbidity and burden of the disease	A complex response and involves a range of other reactions dissimilar from the affective response
Specific affective reactions may include worry, fear, guilt, sadness, anger, frustration, and burnout	Response usually includes cognitive, affective, social, motivational, vegetative, and interpersonal disturbances
Prevalence is greater	Prevalence is relatively lesser
Diabetes and diabetic distress seem to be linearly related	Diabetes and depression seem to have reciprocal connections in many cases
Not a significant risk factor for developing medical complications	Is a significant risk factor for developing medical complications
Has been a relatively consistently associated with HbA1c levels	Has not been shown to have consistent associations with HbA1c levels
Interventions may involve psychoeducation, supportive therapy, counseling, and other simple behavior management methods	Interventions may involve use of complex psychological interventions such as CBT and ACT

Abbreviations: HbA1c: Glycated hemoglobin, CBT: Cognitive behavioural therapy, ACT: Acceptance and commitment therapy

Some risk factors for depression in PwD

- Young age at diabetes diagnosis
- Overweight or obesity [high body mass index (BMI)]
- Suboptimal blood glucose control
- Diabetes-related complications/comorbidities
- Lower education level

Antidepressant drugs and diabetes

Antidepressants have been shown to help improve diabetes in some cases (fluoxetine, escitalopram), but in other instances, they can worsen existing diabetes. They can lead to new-onset diabetes in individuals with no symptoms (mianserin, mirtazapine). Antidepressants that raise blood sugar include duloxetine, sertraline, fluvoxamine, and paroxetine. Some antidepressants can lead to weight gain, and significant weight gain can lead to insulin resistance and higher diabetes risk. However, the association between new diabetes and antidepressant use cannot always be explained only by weight gain.

Antihyperglycemic agents and depression

The investigators of diabetes, antidiabetic medications and risk of depression – a population-based cohort and nested case-control study (2022) reported that their Danish patients with T2D had a 14% higher risk of later depression. They further pointed out that higher insulin doses and sulfonylurea were associated with a higher risk of depression, whereas using metformin, DPP4 inhibitors, GLP1 RAs, and SGLT2 inhibitors was associated with lower depression risk.

The prevalence of CPDs in T2D patients is higher than in the general population. Since CPDs favor the onset and persistence of T2D, integrated diabetic-psychiatric therapy is required to improve or remission T2D in patients with comorbid CPDs.

Management

Mental health must be high on our list of priorities for managing diabetes. It is a fact that having a mental health problem can make it harder to stick to the diabetes care plan in an individual PwD.

Psychological interventions such as cognitive behavior therapy, acceptance and commitment therapy, behavioral activation, and counseling strategies such as educational programs, problem-solving training, and motivational interviews all have proven very effective in coping with diabetes distress, managing comorbid mental health problems, and increasing adherence to self-care and behaviors that would ensure healthy metabolic milieu.

Prevention and screening

Screening for depression in diabetes, clinics should be routine [using the patient health questionnaire (PHQ-9)]. Treatment of depression should be integrated with diabetes care to make the therapy more holistic.

While variables are always out of our control (family history, genetics, etc.), steps can be taken to mitigate the risk of experiencing diabetes distress and depression. Below are some steps that may help to reduce risk.

Keep blood glucose at optimal levels	Apply mindfulness and meditation techniques
Eat a nutrient-dense diet	Spend time in nature
Exercise regularly	Take time for relaxation and self-care
Maintain optimal weight	Get enough sleep
Minimize alcohol use	Seek emotional support from friends, family, and the community

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Association between Gestational Diabetes Mellitus and Postpartum Depression

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Gestational diabetes mellitus (GDM) and postpartum depression (PPD) are prevalent conditions during the perinatal period. GDM is a medical disorder that affects around 14% of pregnant women and typically emerges before the third trimester. It is characterized by a transient form of glucose intolerance caused by insulin resistance and dysfunction of pancreatic beta cells during pregnancy.

On the other hand, PPD is a common type of mental disorder that occurs after childbirth. It is marked by persistent and severe depression along with various symptoms that can manifest within two weeks post-delivery. Approximately, 10-15% of mothers are impacted by PPD. This condition poses a potential risk to the well-being of the mother-baby relationship, potentially negatively influencing infant development.

The likelihood of developing depression during the antenatal or postnatal periods is 2 to 4 times higher in women with GDM compared to those without GDM. This connection between GDM and PPD can be partly attributed to psychological factors. The diagnosis of GDM itself can be perceived as a stressful life event, a known contributor to PPD risk. Physiologically, abnormal glucose metabolism in GDM might disrupt the hypothalamic-pituitary-adrenal axis and trigger cytokine-related inflammatory responses, both associated with depression. These changes could potentially lead to reduced serotonin production in the central nervous system. PPD has a profound effect on the mother's mental health and social adjustment, leading to disruptions in breastfeeding and caregiving abilities for her child.

Interrelationship between GDM and PPD

Recognizing these interrelationships between GDM and PPD is critical for offering comprehensive care to pregnant and postpartum women. A holistic approach that addresses both physical and emotional well-being is vital for ensuring positive outcomes for both mothers and infants. This approach includes early identification, effective management, and support for GDM and PPD, as well as acknowledging and managing potential mental health implications arising from gestational diabetes.

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Coping with Diabetes Distress

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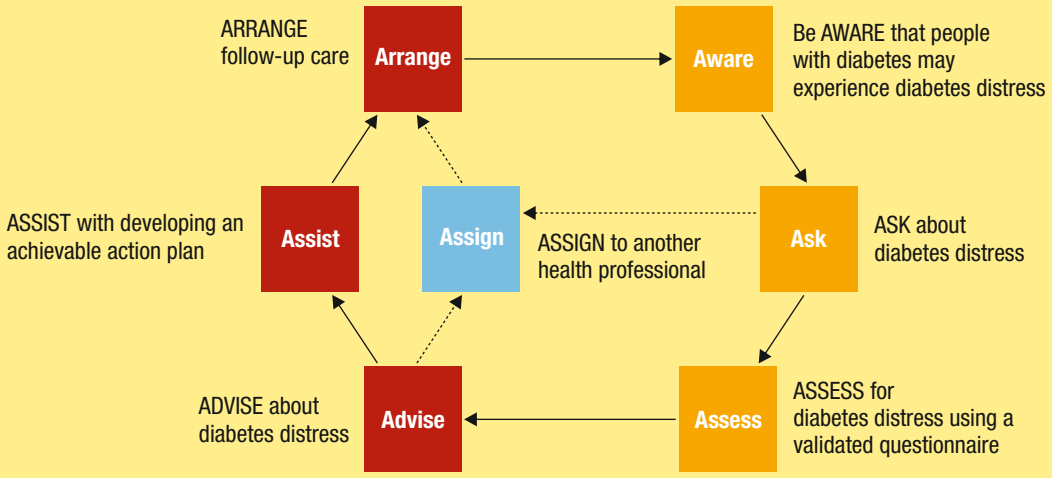
Lately, mental disorders are considered major health concerns and common causes of disability as they lead to a major loss of productive years. Management of diabetes poses a lot of challenges. Diabetes distress is one of the mental health disorders commonly found in people with diabetes.

It is a state of mind when people feel stressed, guilty, or depressed due to having diabetes and trying to manage it themselves. Despite having similarities, depression and diabetes distress are distinct categories that need various assessment and management techniques. Diabetes distress, in contrast to serious depression, does not suggest psychopathology because it's a normal response to diabetes, whereas depression describes how people feel about their lives in general. One in five people with type 2 diabetes and one in four people with type 1 diabetes have high levels of diabetes distress which have negative effects on their diabetes management. Severe and prolonged diabetes distress, if left unresolved may lead to negative medical and mental health effects such as decreased physical activity, fewer healthy food choices, failure to take medications as directed, less frequent self-monitoring of blood glucose, increased HbA1c levels, more frequent or severe hypoglycemia, and a reduced standard of life. Therefore, it's important to recognize the significance of these diabetes-related emotions.



This dynamic model illustrates a seven-step procedure that can be used in medical practice to identify and support a person with diabetes distress

Tips that individuals with diabetes can use to cope with diabetes distress

- **Be mindful about emotions:** If frustration or stress lasts more than 1-2 weeks, it may be an indication that the person needs support in managing their diabetes so they can feel better.
- **Discuss feelings and negative reactions of other people with medical professionals:** Inform the doctor, nurse, diabetes educator, social worker, or psychologist about the feelings or negative comments from other people. As they may help to cope with these feelings of being judged by others due to diabetes. They might also advise speaking with other mental health professionals.
- **Find out if financing is available to cover the cost of diabetes supplies and medications:** Talk to the pharmacist and medical professionals and check with community health centers about the government or other programs which can assist people with cost and provide insulin, diabetes medicines, and supplies (test strips, syringes, etc.).
- **Talk with family and friends and let them assist in diabetes management:** Inform your family and friends about your diagnosis, as they can then help you better with the management of medications, monitoring your blood glucose levels, preparing healthy meals, accompanying you in physical activity and doctor's visits.

- **Speak with other people having diabetes:** They can lessen the feelings of loneliness and overwhelm. Find out about online or community diabetes support groups.
- **Take one task at a time:** Considering all the things to do to keep diabetes under control can be stressful. Make a list of everything that needs to be done every day in order to manage diabetes distress. Aim to complete every task independently, one at a time.
- **Take it slow:** Step up physical activities gradually, goals don't have to be accomplished right away. Start by walking twice a day or every other day, but the ultimate aim must be to walk for 150 minutes in the week at least.
- **Make time for enjoyable activities:** Make time to schedule and engage in activities that can be truly enjoyed; they could be making a phone call to a friend, having a game with kids or grandkids, or working on a creative project. Find out and participate in local events with a friend or family.

Due to the prevalence of diabetes distress and its effects on self-care, it is important that each meeting with the health care professional gives the person with diabetes a chance to communicate how they are feeling about living with diabetes.

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Challenges in the Management of Diabetes in Psychiatry Inpatient Settings

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Diabetes Mellitus (DM) has a complex and reciprocal relationship with mental illnesses. DM shares metabolic features such as insulin resistance and impaired glucose regulation with certain mental disorders like schizophrenia and depression. Various environmental (epigenetic) factors like unhealthy diet, lack of physical exercise, inadequate sleep, and chronic stress affecting the hypothalamus-pituitary-adrenal axis and sympathetic nervous system may be the causes of metabolic dysregulation and associated psychiatric illnesses. Mental illness reduces the likelihood that a person with diabetes will be properly treated. Rates of severe psychological distress are twice as high in people with diabetes compared with the rates among those without the disease. In addition, severe psychological distress is negatively associated with processes of diabetes care (e.g., access to prevention services) and outcomes. For young people with type 1 diabetes, previous psychiatric referral is a significant risk factor for death from acute diabetes-related events such as hypoglycemia or coma.

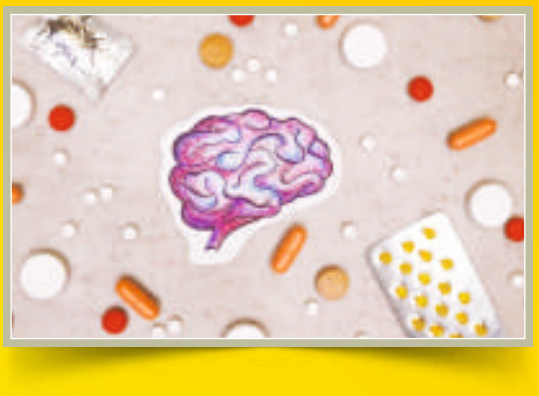
Managing diabetes in psychiatric inpatients, especially in persons with severe mental illness (SMI) presents several unique challenges that require careful consideration and management. Coordination between medical and psychiatry teams is crucial for improved outcomes in these patients. There is currently a lack of monitoring and standardization of diabetes care in psychiatric inpatients. Here are some of the key challenges.

Use of psychotropics causing sedation

Psychotropics used for reducing aggression very commonly cause sedation. Regular monitoring of blood glucose, especially to detect hypoglycemia, is vital in these patients. If not treated with any antihyperglycemic agents, frequently it results in hyperglycemia. We use antidiabetic agents with the least hypoglycemic potential. DPP 4 inhibitors and/or metformin are given immediately after meals (after ensuring adequate oral intake).

Complex medication regimens

Psychiatric inpatients often have multiple medications prescribed to manage their mental health condition. Adding antidiabetic medications to this often complicates medication regimens. It increases the risk of non-adherence. Patients with schizophrenia and bipolar mood disorder are prescribed atypical antipsychotics like clozapine and olanzapine. These drugs often cause an increase in blood glucose levels. Stopping them to revert to normoglycemia, especially in mentally stabilized patients, continues to be a challenge for us.



Mental health impact

The stress associated with hospitalization can worsen mental health symptoms, potentially affecting blood glucose levels due to hormonal changes.

Scheduling for electroconvulsive therapy (ECT)

Routine preprocedure evaluation and care should be exerted prior to scheduled ECT sessions. We need to relax the blood glucose level criteria occasionally in patients with severe suicidal ideation/attempt and in very aggressive patients who can harm others.

Challenges in patients admitted for alcohol deaddiction

Patients admitted for alcohol deaddiction are likely to go into alcohol withdrawal syndrome. During withdrawal, we frequently encounter fluctuations in blood glucose levels due to erratic oral intake. DPP 4 inhibitors and metformin are not advisable in them; hence ultra-short-acting insulin analogues in small doses are used for blood glucose control. Many times due to chronic alcoholic pancreatitis, they develop secondary diabetes. Patients with secondary diabetes admitted for deaddiction require careful titration of insulin doses.

Self-care and adherence

Patients with SMI usually struggle with self-care tasks, including monitoring blood glucose levels, taking medicines as prescribed, administering insulin, or adhering to dietary advice. Cognitive impairments or lack of motivation further limit their ability to manage diabetes independently.

Eating disorders

Eating disorders can be prevalent, especially among persons with type 1 DM. These disorders can impact diabetes management, as patients may restrict food intake or engage in binge eating, leading to unpredictable blood glucose levels.

Safety, supervision, and decision-making capacity

In an inpatient psychiatric setting, patients do not have access to their medications or diabetes supplies without supervision due to safety concerns. This can disrupt their usual diabetes management routine. Patients with SMI usually have compromised decision-making capacity, making it difficult to involve them in treatment decisions for their diabetes management.

Limited physical activity

Psychiatric inpatients have restricted physical activity due to the nature of the setting. Lack of exercise can worsen glycemic control in these patients.

Stigma and motivation

The stigma associated with both mental illness and diabetes can affect patients' motivation to manage their conditions. They may be less inclined to engage in diabetes self-care.

Communication between teams

Effective communication between the diabetes management team and the inpatient staff is essential. Patients with cognitive impairments or communication difficulties may find it challenging to accurately convey their diabetes management needs.

Discharge planning

A patient's transition from the inpatient psychiatric setting back to the community requires close coordination between psychiatrists, diabetologists, nurses, dietitians, and social workers. Ensuring access to necessary medications, diabetes supplies, and follow-up appointments is crucial.

Addressing these challenges requires a multidisciplinary approach that involves collaboration between the teams involved in the care of psychiatry inpatients. Diabetes management plans should be tailored to the individual needs and capabilities of each patient. Additionally, providing education and support to both patients and their families can improve long-term outcomes by promoting understanding and self-care skills.

Acknowledgement:

Dr. Amol Pathrikar, Dr. Vikrant Patankar, Dr. Amol Deshmukh
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Resources:

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Interview with Dr. Sanjay Kalra and Dr. Hitesh Punyani

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Dr. Hitesh Punyani is a well-known Diabetologist and General Physician currently associated with Chaitanya Cardio-Diabetes Centre, Delhi. He has 26 years of experience in internal medicine and has worked in many reputed hospitals. He is known for his attention to accurate diagnosis and for treating patients empathetically. He has also participated in research work and various workshops and published many papers. He is also an active member of the Research Society for the Study of Diabetes in India (RSSDI).

Diabetes and Mental Health

1. How does diabetes impact a person's mental health, and what are some common psychological challenges that individuals with diabetes might face?

Ans. Diabetes has a bidirectional relationship with mental health. The diagnosis of diabetes, and its complications or change of therapy, leads to stress. Individuals with diabetes may face 'diabetes distress', i.e., feelings of apprehension, dejection or fear, due to a perceived inability to cope with the challenges and demands of living with diabetes. This, in turn, impacts

acceptance and adherence to prescribed therapy, worsens outcomes, and reduces quality of life. Additionally, people with diabetes have a greater risk of developing mental health conditions such as anxiety, depression psychosis, substance abuse, and eating disorders.

2. Are there specific types of diabetes (type 1, type 2, gestational) that are more closely linked with mental health issues, and if so, why is this the case?

Ans. While all types of diabetes are linked with mental health issues, they seem to be more common in people with type 1 diabetes. This is because type 1 diabetes self-care is more complex, and therefore, more challenging. The need to master multiple skills, virtually overnight, leads to psychological impairment in a great proportion of people living with type 1 diabetes. People with diabetes who develop complications that need intensive or intrusive therapy, or those with significantly decreased quality of life, are also prone to mental ill-health. Examples include people with acute myocardial infarction or stroke, those who need repeated hospitalization for heart failure, and those who require renal replacement therapy.


TYPE 1 DIABETES

3. How do you differentiate between common emotional reactions to people living with diabetes and more serious mental health issues that may require professional intervention?

Ans. There are clear-cut diagnostic criteria that must be met, to label a person as having a mental illness. These criteria should be followed before labeling anyone as having a mental disorder. Many people living with diabetes experience emotional reactions. These are normal. Professional intervention should be sought if feelings of fear, apprehension, self-guilt or worthlessness, or lack of happiness are extreme, pervasive, recurrent, or present for a long period of time. Help should also be taken if these symptoms are contributing to inadequate self-care, suboptimal acceptance of therapy, and poor outcomes. Immediate mental professional help must be sought if a person exhibits suicidal thoughts or behavior.

4. What role does a diabetes educator have to play in preventing or managing mental health issues in people living with diabetes?

Ans. A diabetes educator has an important role to play in preventing and managing mental health issues and promoting mental health in people living with diabetes. Psychological first aid should be offered by the diabetes educator to all people who need it. 'Therapy by the ear', i.e., patient listening, followed by appropriate therapeutic patient education (TPE), is the ideal way to share diabetes education. Most emotional challenges can be handled by empathic support and counseling from the diabetes educator. Some people may require a referral to a qualified mental health professional. The educator can facilitate this by taking cognizance of 'red flag' signs and making the caregivers aware of the need for mental health management.


DIABETES EDUCATOR

5. Are there any lifestyle changes or habits that you recommend to your patients with diabetes to promote better mental well-being and emotional resilience?

Ans. Mental well-being and emotional resilience are associated with a healthy lifestyle. Regular meals, physical activity and exercise, participation in games and in social activities, all contribute to mental well-being. We encourage our patients to strengthen their social connections, start new hobbies, and seek spiritual solace. This helps maintain a balanced mind and contributes to good glucose control as well.

Diet in the Treatment of Mood Disorders

Dr. Kunal Jhaveri

MD (Medicine)

Consultant Physician, Vishesh Clinic of Internal Medicine, Ahmedabad

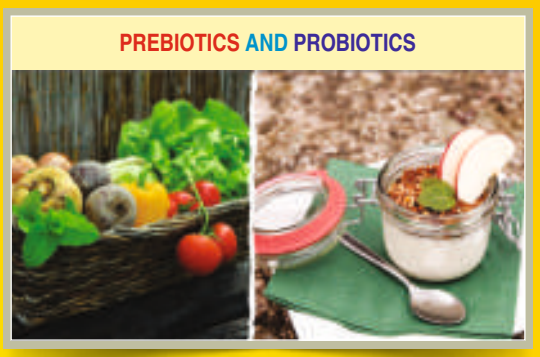
Individuals with diabetes are more likely to experience depressive symptoms than those without diabetes. Diabetes and depression are said to have a bidirectional adverse association. Individuals with diabetes mellitus have clinical and subclinical symptoms of anxiety more frequently than people without diabetes. Insomnia, anxiety, panic disorders, or post-traumatic stress syndrome are some of the major culprits for uncontrolled diabetes.

Obstructive sleep apnea common in individuals with diabetes affects sleep quality, causes excessive daytime sleepiness and lethargy, weight gain, and cognitive deficits that affect glucose control. Psychological issues affect the well-being of a significant proportion of the people living with diabetes, and hence, new approaches to management are needed. In addition to counseling and pharmacological therapy, studies suggest dietary aspects may be beneficial and contribute to overall wellness.

Mental health illnesses such as mood disorders have been found to be linked to heightened inflammation. Intake of trans fats and refined carbohydrates [refined flour (maida) based foods like bread, pav, biscuits, rusk, toast, fast foods, processed foods, etc.] are associated with increased inflammation and may increase the risk of mental health illnesses.

Studies are inconclusive on the role of different macronutrient combinations – carbohydrate, protein, and fat, in relation to depression and mood disorders. Studies have shown that unhealthy dietary patterns with high saturated fat and trans fat are associated with more depressive symptoms while intake of healthy fats such as omega 3 fatty acids, Mediterranean dietary patterns and other healthy patterns characterized by fish, fruit, and vegetable intake are inversely associated with depressive symptoms. A higher intake of nuts, whole grains, and legumes is also found to be associated with a reduced risk of psychiatric disorders.

In addition to antibiotic exposure and genetic factors, diet is a potentially modifiable determinant of the diversity, relative abundance, and functionality of the gut microbiome. The brain and gut have bidirectional interactions called as 'brain-gut-microbiome axis' or 'gut-brain axis'. Thus, there is a significant association between food intake, gut health, and psychological health. The use of prebiotics and probiotics as a part of a nutrition-based strategy for gut microbiota modulation may be beneficial in improving psychological health. A study found that probiotic intake by healthy individuals can alter the brain's response to a task that requires emotional attention and may even reduce symptoms of mental illness.



All the discussed dietary modifications have always been a part of healthy dietary regimens for individuals with diabetes. We must create environments and develop measures that promote healthy, nutritious diets while reducing the consumption of highly processed, high-fat, and refined carbohydrate foods. This will provide benefits even beyond the well-known effects on physical health and blood glucose control, including improved psychological well-being.

Resources:

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Eating Disorder and Diabetes

Dr. Hemant Kumar Jain

MBBS, MD (Medicine)

Assistant Professor of Medicine, Govt. Medical College, Datia, Madhya Pradesh

The prevalence of diabetes mellitus (DM) has increased globally. People with type 2 diabetes mellitus (PWD) are prone to psychiatric conditions such as eating disorders and depression. Weight gain, body dissatisfaction, a history of dieting, and depression have all been demonstrated to contribute to the emergence of eating disorders in PWD. The most prevalent eating disorder in PWD is binge eating disorder (BED), yet it is still underdiagnosed and undertreated. In the general population, BED affects 3.5% of females and 2% of males, while studies in PWD have shown that the prevalence ranges from 2.5 to 25.6%.

BED and bulimia nervosa share the traits of frequent episodes of binge eating and losing control of one's eating habits. BED involves eating more quickly than usual, eating despite a lack of physical hunger, and eating until feeling uncomfortably full. It does not involve the inappropriate compensatory behaviors that occur in bulimia nervosa with the goal of avoiding weight gain, such as the use of laxatives, excessive exercise, and vomiting. For a minimum of six months, these eating episodes must occur at least twice each week. PWD are more likely to develop eating disorders if they are:

- Dissatisfied with their appearance
- Life is out of control
- Diabetes is taking up too much of their lives
- Anxious or depressed
- Pressured or controlled by others
- Fixated on having perfect blood glucose levels

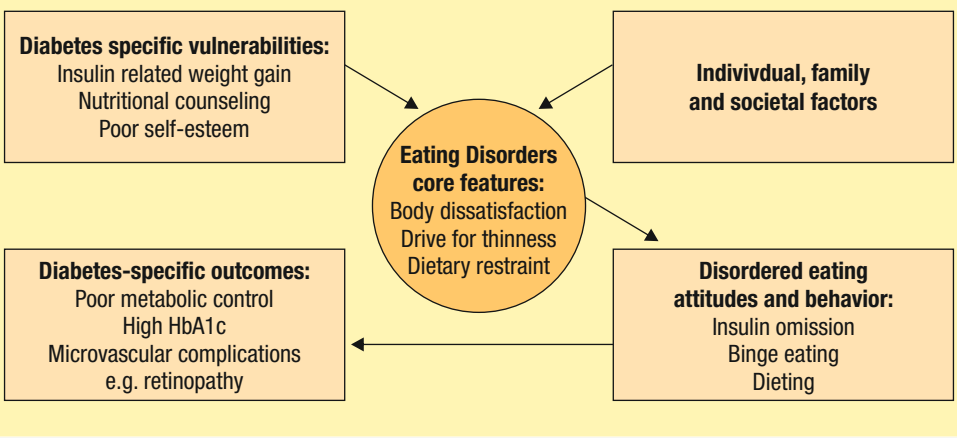


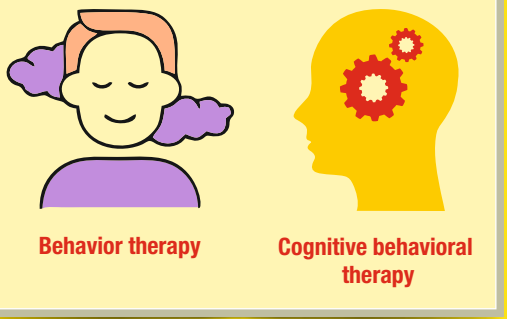
Figure 1: Model of the interaction between type 1 diabetes and eating disordersb (Daneman *et al.*, 2002)

Abbreviations: HbA1c: Glycated hemoglobin

Following are a few indicators of disordered eating

- Increase in HbA1c or blood glucose fluctuations
- Experiencing diabetic ketoacidosis (DKA)
- Eating a lot of food frequently while feeling out of control
- Secrecy about diabetes management
- Attempting to reduce weight via becoming ill or limiting insulin
- Concerns about body image and fear of gaining weight
- Depression and anxiety
- Fear of hypos
- Diabetes distress
- Remorse, shame, and judgment over one's eating habits, glucose levels, weight, or physical appearance
- Failure to acknowledge the gravity of symptoms and problems
- Exercising excessively without eating enough

Treatment



The effects of eating disorders can be severe and in some cases, even life-threatening. Psychotherapies are frequently used in the most successful treatments. Individual therapy, group therapy, or a combination of the two are all possible forms of treatment. Medical and dietary requirements require special consideration. In addition to cognitive behavioral treatment, the PWD may be given antidepressant medication. A multidisciplinary approach is essential. A psychiatrist, dietician, psychotherapist, and primary care physician should be involved in treatment.

Better outcomes are linked to early intervention. Due to embarrassment, remorse, or feelings of unworthiness, patients may not reveal such food-related difficulties. It is advised that healthcare practitioners take a proactive approach. In order to effectively treat each individual, a comprehensive and customized intervention is needed. In these situations, the interdisciplinary team's advice is crucial.

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Personalized Counseling for Individuals with Diabetes Distress: A Doctor's Experience on the MyCare Patient Support Program

Dr. Avik Basu

MBBS, MD, MRCP-1(UK), CCEBDM (PHFI)

General Physician and Diabetology Practitioner, Kolkata

A 78-year-old lady with long-standing type-2 diabetes mellitus is being managed by Dr. Avik Basu

Here's what Dr. Avik Basu has to say:

This elderly lady has been living with diabetes for 20 years, and had uncontrolled glucose readings. Her fasting blood glucose was 202 mg/dL, postprandial was 390 mg/dL, and HbA1c was 12.5%. She was very upset and disturbed about her health and uncontrolled glucose levels.

Since the COVID outbreak, she had confined herself indoors without much activity. Her diabetes regimen included four oral medications, including a sulfonylurea, and basal insulin. I understood that she lived alone and finds it difficult to cook/clean, and sometimes skipped her meals.

She was in need of constant support and motivation so I made necessary modifications in her medication and referred her to MyCare Diabetes Educator (MDE) Ms. Russa Banerjee. Russa was very empathetic in her approach and planned a customized diet and also corrected her meal timings and planned an exercise regimen for her. Russa, also did regular telephonic follow-ups and home visits where she examined her insulin administration technique.

After four months, she entered my clinic with a smile, her HbA1c had dropped by 5% and she had also gained 1.5 kg of weight. Russa's compassionate and assertive guidance helped her to correct her injection technique and bring down basal insulin by 6 units. She now felt more energized and motivated to do household chores and cook. She was also thankful for Russa's regular phone calls to check on any hypoglycemic episodes and to teach her how to monitor regularly with help of a glucose monitoring device.

Ms. Russa Banerjee

NDEP and T1DE Certified Diabetes Educator

Here's what the MDE Russa had to say:

The patient was initially very overwhelmed with all aspects of diabetes management as she was all alone, but gradual step-by-step empathetic approach helped her to make small changes and as she saw the results, she became much more positive and was motivated towards getting her glucose levels under control.

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*PWD: People with Diabetes

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A — A1C REDUCTION
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R — RENAL BENEFITS

E — ENSURES ADHERENCE

Abridged Prescribing Information

Indication: It is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.
Dosage and Administration: The recommended dose is one tablet daily. Each tablet contains a fixed dose of dapagliflozin, Sitagliptin and Metformin Hydrochloride.
Adverse Reactions: Most common adverse reactions reported are: Dapagliflozin- Female genital mycotic infections, nasopharyngitis, and urinary tract infections. Sitagliptin- Upper respiratory tract infection, nasopharyngitis and headache. Metformin- Diarrhea, nausea/vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache.
Warnings and Precautions: Dapagliflozin: Volume depletion; Ketoacidosis in Patients with Diabetes Mellitus; Urosepsis and Pyelonephritis; Hypoglycaemia; Genital Mycotic infections
Sitagliptin: General- Sitagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Acute pancreatitis: Hypoglycaemia when used in combination with other anti-hyperglycaemic medicinal product; Renal impairment; Hypersensitivity reactions including anaphylaxis, angioedema, and exfoliative skin conditions- Stevens-Johnson syndrome; Bullous pemphigoid. Metformin Hydrochloride: Lactic acidosis; In case of dehydration (severe diarrhoea or vomiting, fever or reduced fluid intake), metformin should be temporarily discontinued and contact with a healthcare professional is recommended.
Contraindications: Hypersensitivity to the active substance of Dapagliflozin, Sitagliptin & Metformin or to any of the excipients listed. Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis). Diabetic pre-coma; Severe renal failure (eGFR<30mL/min); Acute conditions with the potential to alter renal function such as: Dehydration, Severe infection, Shock; Acute or chronic disease which may cause tissue hypoxia such as: Cardiac or respiratory failure, Recent myocardial infarction, Shock, Hepatic Impairment, Acute Alcohol intoxication, alcoholism
Use in a special population: Pregnant Women: Due to lack of human data, drug should not be used during pregnancy. Lactating Women: It should not be used during breastfeeding. Paediatric Patients: The safety and efficacy of drug has not yet been established. No data are available. Geriatric Patients: In Patients > 65 years, it should be used with caution as age increases.

Additional information is available on request.
Last updated: January 01, 2023

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January 2023[1]

ESC*
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Long term continuous usage of High Dose Glimepiride:

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Meta analysis of 21 well established trials[2]

5% Reduction of Weight Vs Baseline Weight[2]

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1. Glimepiride use is associated with reduced cardiovascular mortality in patients with type 2 diabetes and chronic heart failure, a prospective cohort study | European Journal of Preventive Cardiology | Oxford Academic (oup.com) 2. Ther Adv Endocrinol Metab 2020. Vol 11:1-12 DOI: 10. 1177/2042018820926000. # Data on file * As compared to non-glimepiride group
EET: Epoxyeicosatrienoic acid; sEH: soluble Epoxide Hydrolase; AHAs: antihyperglycemic agents; T2DM: Type 2 Diabetes Mellitus

Prescribing Information

Information: Metformin hydrochloride (as prolonged release) and glimepiride tablets. Glycomet-GP 0.5/Glycomet-GP 0.5 Forte/ Glycomet-GP 1/ Glycomet-GP 1/850/ Glycomet-GP 2/ Glycomet-GP 2/850/ Glycomet-GP 3/ Glycomet-GP 3/850/ Glycomet-GP 4/ Glycomet-GP 4/850/ Glycomet-GP 1 Forte/ Glycomet-GP 2 Forte/ Glycomet-GP 3 Forte/ Glycomet-GP 4 Forte Abridged Prescribing Information **Composition:** Glycomet GP 0.5mg: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500mg and glimepiride IP 0.5mg • Glycomet GP 0.5 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP 0.5mg • Glycomet GP 1: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 1 mg. • Glycomet GP 1/850: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 1 mg. • Glycomet GP 2: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 2 mg. • Glycomet GP 2/850: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 2 mg • Glycomet GP 3: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 3 mg. • Glycomet GP 3/850: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 3 mg. • Glycomet GP 4: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 4 mg. • Glycomet GP 4/850: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 4 mg. • Glycomet GP 1 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP 1mg. • Glycomet GP 2 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP 2mg. • Glycomet GP 3 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP 3mg. • Glycomet GP 4 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP mg. **Indication:** For the management of patients with type 2 diabetes mellitus when diet, exercise and single agent (glimepiride or metformin alone) do not result in adequate glycaemic control. **Dosage and Administration:** The recommended dose is one tablet daily during breakfast or the first main meal. Each tablet contains a fixed dose of glimepiride and Metformin Hydrochloride. The highest recommended dose per day should be 8 mg of glimepiride and 2000mg of metformin. Due to prolonged release formulation, the tablet must be swallowed whole and not crushed or chewed. **Adverse Reactions:** For Glimepiride: hypoglycaemia may occur, which may sometimes be prolonged. Occasionally, gastrointestinal (GI) symptoms such as nausea, vomiting, sensations of pressure or fullness in the epigastrium, abdominal pain and diarrhea may occur. Hepatitis, elevation of liver enzymes, cholestasis and jaundice may occur; allergic reactions or pseudo allergic reactions may occur occasionally. For Metformin: GI symptoms such as nausea, vomiting, diarrhea, abdominal pain, and loss of appetite are common during initiation of therapy and may resolve spontaneously in most cases. Metallic taste, mild erythema, decrease in Vit B12 absorption, very rarely lactic acidosis, Hemolytic anemia, Reduction of thyrotropin level in patients with hypothyroidism, Hypomagnesemia in the context of diarrhea. Encephalopathy, Photosensitivity, hepatobiliary disorders. **Warnings and Precautions:** For Glimepiride: Patient should be advised to report promptly exceptional stress situations (e.g., trauma, surgery, febrile infections), blood glucose regulation may deteriorate, and a temporary change to insulin may be necessary to maintain good metabolic control. Metformin Hydrochloride may lead to Lactic acidosis; in such cases metformin should be temporarily discontinued and contact with a healthcare professional is recommended. Sulfonylureas have an increased risk of hypoglycaemia. Long-term treatment with metformin may lead to peripheral neuropathy because of decrease in vitamin B12 serum levels. Monitoring of the vitamin B12 level is recommended. Overweight patients should continue their energy-restricted diet, usual laboratory tests for diabetes monitoring should be performed regularly. **Contraindications:** Hypersensitivity to the active substance of glimepiride & Metformin or to any of the excipients listed. Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis, diabetic pre-coma). Severe renal failure (GFR≤30ml/min). In pregnant women. In lactating women Acute conditions with the potential to alter renal function (dehydration, severe infection, shock, intravascular administration of iodinated contrast agents); acute or chronic disease which may cause tissue hypoxia (cardiac or respiratory failure, recent myocardial infarction, shock); hepatic insufficiency; acute alcohol intoxication, alcoholism. **Use in a special population:** Pregnant Women: Due to a lack of human data, drugs should not be used during pregnancy. Lactating Women: It should not be used during breastfeeding. Pediatric Patients: The safety and efficacy of drugs has not yet been established. Renal impairment: A GFR should be assessed before initiation of treatment with metformin containing products and at least annually thereafter. In patients at increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6 months.

Additional information is available on request.

Last updated: March 13, 2023

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Effect of Exercise on Mental Health

Dr. Riyas C.

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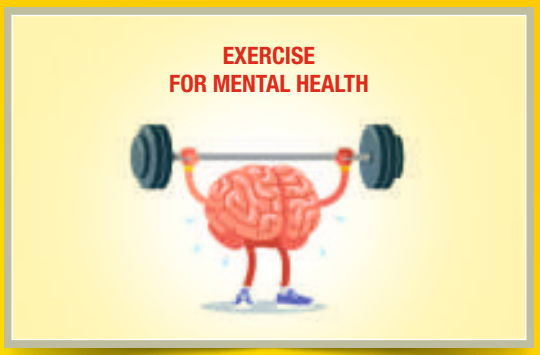
Physical and mental health are very closely linked and each can have a profound impact on the other. Individuals with type 2 diabetes mellitus (T2DM) are more likely to experience depression because of the numerous challenges that come along with managing the condition.

Diabetes distress and depression impair glycemic control in people with T2DM and thus increase the possibility of subsequent complications. Both in the general population and in individuals with comorbid conditions including cardiovascular disease and diabetes, physical activity has been shown to have antidepressant benefits. Research shows that poor glycemic control can add to the development of depression while several lines of evidence suggest that physical activity can not only help in improving glycemic control but also improve the quality of life in people with T2DM.

Researchers have studied three main types of physical activity – aerobic, muscle strengthening, and bone strengthening. Of which, the majority of the health benefits of physical activity have been studied with moderate- or vigorous-intensity aerobic activity. Aerobic activity also called endurance or cardio activity includes brisk walking, running, bicycling, jumping rope, and swimming. Whereas, muscle and bone strengthening consists of resistance training, weight lifting and weight-bearing activity respectively. A twelve-week study conducted to investigate the effects of longer aerobic exercise training on mental health and self-esteem of men with type 2 diabetes concluded regular aerobic exercise training is an effective strategy in improving self-esteem and mental health and also promoting life quality among these individuals.

Exercise boosts mental health by reducing anxiety, negative mood, and depression and by improving self-esteem and cognitive function. With regular exercise (habitual effect), improvements occur in trait anxiety (long-term anxiety), deep sleep, and components of executive function (such as the ability to plan and organize; monitor, inhibit, or facilitate behaviors; initiate tasks; and control emotions). For health benefits, a minimum of 150 minutes (2 hours and 30 minutes) to 300 minutes (5 hours) a week of moderate-intensity, or 75 minutes (1 hour and 15 minutes) to 150 minutes (2 hours and 30 minutes) a week of vigorous-intensity aerobic physical activity, or a similar mix of aerobic activity at both a moderate and intense level is advisable. It is suggested to spread out aerobic exercise throughout the course of the week. Thus, physical activity may have two-way benefits for populations with comorbid mental and physical health problems: (i) it may reduce depressive symptoms via biological and psychosocial mechanisms and (ii) enhance physical health either by treating the comorbid condition itself or by preventing secondary complications linked with the comorbid condition. Cross-sectional studies reveal an association between regular physical exercise and improved mental health and emotional well-being. Studies also indicate a link between physical exercise and reduced risk of developing a mental disorder.

Despite its various health benefits, physical activity continues to be overlooked. Unlike antidepressants, which are widely prescribed, physicians do not frequently evaluate or recommend physical exercise in routine treatment. Thus, the challenge remains to translate evidence on the health benefits of exercise to real-world situations in the healthcare system. Policies and guidelines are urgently needed to support the recommendation of physical activity for the management of depression in therapeutic settings.



Resources:

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Link between Diabetes and Dementia

Dr. Vivek Kumar Verma

MBBS, MD (Medicine)

Assistant Professor and Head, Dept. of General Medicine, Autonomous State Medical College, Hardoi

Individuals with diabetes are at two times higher risk of developing dementia, which may cause it to develop a few years earlier. Type 2 diabetes mellitus (T2DM) affects various organs of the body, including the brain. The association between cognitive impairment and T2DM is not well understood, and the underlying mechanism is complex. Yet, abnormal insulin function and impaired glucose metabolism are often associated with cognitive impairment. Figure 1 describes the pathway through which hyperglycemia results in cognitive impairment. Hyperglycemia leads to vascular damage, blood-brain barrier impairment, mitochondrial dysfunction, increased oxidative stress, insulin resistance, neuroinflammation, and synaptic failure resulting in oxidative damage and neuronal injury. Chronic hyperglycemia is toxic to neurons and leads to the formation of advanced glycated end products, leading to neuronal injury.

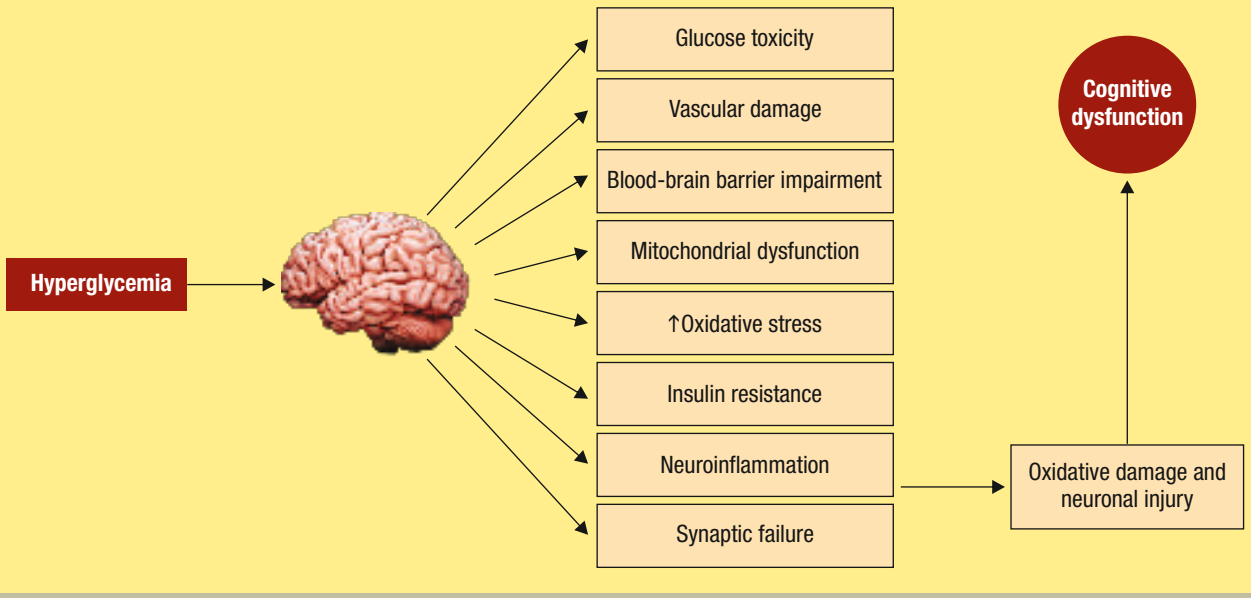

Figure 1: Pathway through which hyperglycemia results in cognitive impairment

Nerve cells are susceptible to hyperglycemia because neuronal glucose uptake is highly dependent on external glucose concentration, which is four to five times greater in individuals with diabetes. Levels of neurotrophic support factors, such as nerve growth factor and insulin-like growth factor, are found to be decreased in individuals with diabetes. This also leads to nerve malnourishment. Dyslipidemia and inflammation are the other important factors causing neuronal damage, leading to cognitive impairment.

In the brain, insulin and related proteins are essential for cell survival. Many brain processes, such as learning and memory, appear to be dominated by glucose and insulin. Chronically high or low blood glucose levels may cause brain damage and cognitive impairment by disrupting insulin activity. Insulin insensitivity in liver, fat, and muscle cells/tissues may also correspond to insulin resistance at the level of the brain. The regions of the brain affected are cognition, memory, and learning. Insulin plays a role in the cell-level memory formation process called long-term potentiation. Insulin also regulates a chemical messenger called acetylcholine, which plays a role in memory. Thus, the link between diabetes and dementia is multifactorial. The risk of Alzheimer's disease, which is a type of dementia, is also high in people with diabetes, which significantly affects the quality of life. It increases the burden on individual's families, the health and social care system, and society in general.

In the light of accelerating rates of both diabetes and dementia worldwide, understanding their correlation and developing new strategies to manage both conjointly is important.

Resources:

1. Diabetes and dementia risk: Another good reason to keep blood sugar in check. *American Heart Association*. Available at: https://www.heart.org/en/news/2021/07/21/diabetes-and-dementia-risk-another-good-reason-to-keep-blood-sugar-in-check
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Frequently Asked Questions on Diabetes and Mental Health

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1. I am a 34-year-old male, during my annual health check-up, I was diagnosed with type 2 diabetes and advised to start with insulin to control the severely elevated blood glucose levels. I do not understand 'Why Me?'. No one in my family except for my grandmother has diabetes which was also diagnosed later in her life, but was controlled with medication. Out of all my siblings, I have the most hectic schedule and very rarely do I get the time to go out with friends too. Why am I the only one to develop diabetes and that too so severe that I need insulin?

Ans. Type 2 diabetes is closely associated with family history, ethnicity, and genetics. Nevertheless, environmental factors also play a role. Your grandmother has diabetes, which means you may have a genetic predisposition to it and along with environmental factors like poor dietary choices, hectic schedules, and sedentary lifestyle, it presents itself sooner than it used to in past generations. However, if managed well, one can lead a normal good quality life with diabetes. Firstly, understand that you are not put on insulin as the diabetes is out of control. Studies have shown that early initiation with insulin helps to preserve the beta cells of the body, so they can rest and eventually work better. Timely initiation of insulin helps in preventing diabetes progression and reduces risk of diabetes-related complications and has less serious adverse effects. So, trust the doctor and follow a healthy lifestyle to keep the blood sugar in control to enjoy a normal life.

2. My father is 72 years old, with type 2 diabetes, since 15 years. He was managing his blood glucose levels very well at the start. For the past few years, he has been neglecting his condition and isn't regular with his medication and diet. He was also shifted to insulin as his blood glucose levels were very high. We are very confused with this sudden shift in his behavior. Kindly advise what should be done?

Ans. What your father is going through is called a "Diabetes Burnout". This is commonly seen in individuals with long-standing diabetes mellitus. Diabetes burnout is the phrase used to describe a feeling of frustration and resentment toward the condition. It is frequently a state of mind that is attained after years of coping with the ailment. Have a discussion with him as to what part of the management is stressing him out. It is important that there is family support when it comes to making changes in diet and following a healthy lifestyle. Everyone in the family should follow a healthy routine and diet as there is no specific diabetic diet. You can also be an exercise partner to your father so that he enjoys his exercise and is regular in it. Get him to socialize with his family or friends. You can get him to meet a diabetes educator and share his challenges. If you still feel he is feeling very low, you must seek help from a mental health professional as emotional disturbance can cause his blood glucose levels to go high.

3. I am a 16-year-old female, diagnosed with type 1 diabetes (T1D) 3 years ago. I've recently started going to college. Due to my hectic college hours and long travel, I am finding it difficult to manage my glucose levels. Sometimes, I also end up skipping my lunch as I am busy with my coursework. My classmates aren't aware of my health condition and I am not comfortable injecting insulin in front of them, which leads to severe spikes in my blood glucose levels. I'm very confused and stressed right now. Please advise, how do I manage everything?

Ans. Stress brought on by diabetes is common, even years post-diagnosis. It's challenging and taxing to have a lot of new things to learn and remember while also having to pay close attention to what you eat, as well as inject insulin daily and perform frequent blood glucose checks. While all this is true, remember "Patience is the name of the game". Focus on one aspect at a time. Get in touch with a qualified nutritionist and plan diabetes-friendly convenient meal options. You must understand that diabetes is a very manageable condition and not a disease that you should be ashamed of, instead talk about it with your peers. Once you have educated them on your condition, you will have their support too in reminding you of self-care and things will get easier. Try to be a part of T1D support groups. There you will get to interact with other individuals with T1D having similar challenges as yours and you can get ideas on how to manage them.

Did You Know?

Walnuts are beneficial for mental health.

Walnuts, 'the brain shaped nuts', are receiving much attention due to the link between their consumption and improved health status, especially brain health. Walnuts have an excellent bioactive nutrient composition, they are known to improve blood glucose levels, lower blood pressure and cholesterol levels, improve brain health and sleep quality as well as have a profound effect on gut microbiota.

Walnuts are super nuts for brain health. Polyunsaturated fatty acids (PUFAs) like α-linolenic acid (ALA) and linolenic acid (LA) present in walnuts are known to improve brain health and function as well as prevent cognitive decline associated with Alzheimer's disease.

ALAs from walnuts are transformed into eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in the body. EPA and DHA are crucial for sustaining synaptic plasticity, neuronal membrane stability, gene expression, and neurogenesis, as well as lowering oxidative stress and modulating immune function and thus is essential for brain function.

Polyphenols present in walnuts stimulate neuronal calcium homeostasis in the striatum and hippocampus areas of the brain, necessary for both primary and secondary memory functions. The polyphenol content of walnuts is different when compared to other tree nuts as might impact the gut-brain axis in relation to serotonin production. Walnuts also play a role in preventing depressive symptoms and elevating mood.

Additional bioactive substances found in walnuts, including arginine, tocopherols, folate and melatonin, support neurological health and cognitive wellness by regulating blood pressure, high-density lipoprotein (HDL) function, glucoregulation, endothelial vasodilator function, oxidative status, and vascular inflammation.

Taking into account, numerous health benefits, walnuts can be considered as an excellent snack option by people with diabetes, can curb mid-meal hunger pangs and elevate mood.

Resources:

1. Poulose SM, Miller MG, Shukitt-Hale B. Role of walnuts in maintaining brain health with age. *J Nutr*. 2014;144(4 Suppl):561S-566S. doi:10.3945/jn.113.184838
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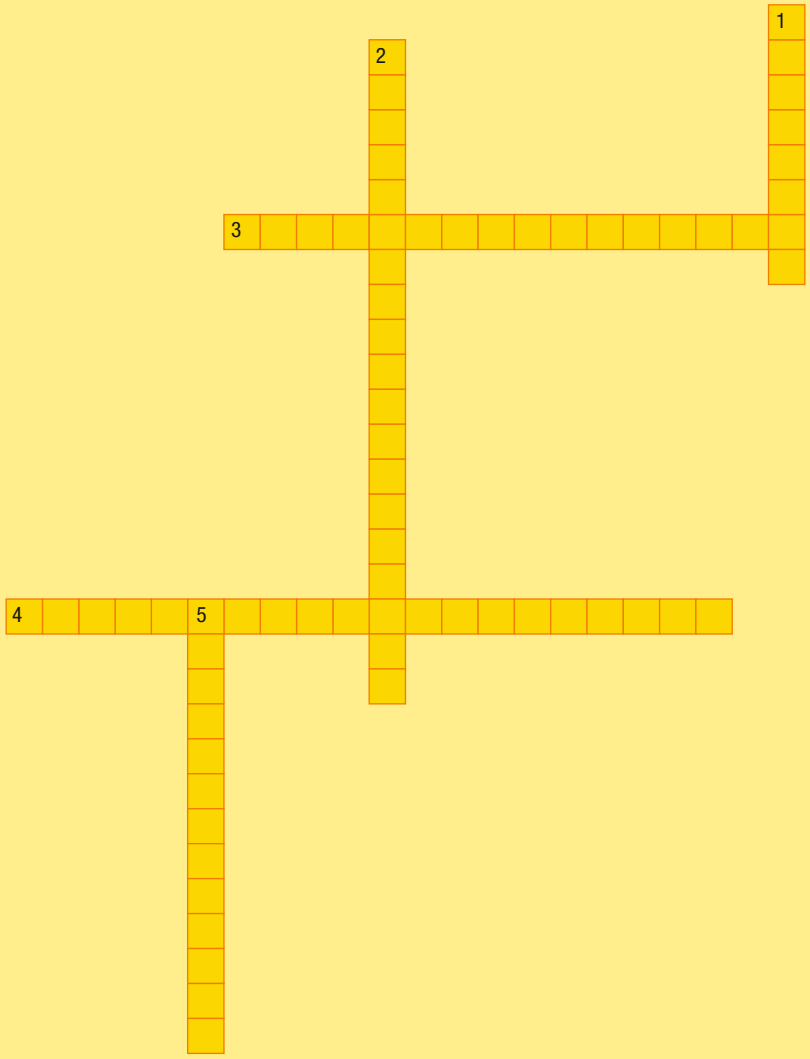
Dia-Games

Crossword



ACROSS

3. A state of mind when people feel stressed, guilty, or depressed due to having diabetes.
4. A common type of mental disorder that occurs after childbirth.

DOWN

1. This helps in improving mood and blood glucose levels.
2. A condition that involves eating more quickly than usual, without feeling hungry.
5. A chemical messenger which plays a role in memory.

Answers

Across: 3. Diabetes distress, 4. Postpartum depression

Down: 1. Exercise, 2. Binge eating disorder, 5. Acetylcholine

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- **Global Innovator with 100% Accessibility**
- **Lesser Risk of Hypoglycemia**
- **Lower Risk of Weight Gain[2]**

T2DM: Type 2 Diabetes Mellitus; **HbA1c**: Hemoglobin A1c

1. SWITCH STUDY (Data on file) 2. Diabetes Obes Metab 2017; 19(1):65-72. doi: 10.1111/dom.12790. Epub 2016 Oct 17. PMID: 27753202

Information

Metformin hydrochloride (as prolonged release) and glimepiride tablets

Glycomet-GP 0.5/Glycomet-GP 0.5 Forte/ Glycomet GP 1/ Glycomet GP 1 HS/ Glycomet GP 2/ Glycomet-GP 2 HS/ Glycomet GP 3/ Glycomet-GP 3 HS/ Glycomet-GP 4/ Glycomet-GP 4 HS/ Glycomet-GP 1 Forte/ Glycomet-GP 2 Forte/ Glycomet GP 3 Forte/ Glycomet GP 4 Forte.

Abridged Prescribing Information:

Compositions: • Glycomet GP 0.5 mg: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 0.5 mg. • Glycomet GP 0.5 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000 mg and glimepiride IP 0.5 mg. • Glycomet GP 1 (1st)-uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 1 mg. • Glycomet GP 1 HS: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 1 mg. • Glycomet GP 2: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 2 mg. • Glycomet GP 2HS0: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 2 mg. • Glycomet GP 3: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 3 mg. • Glycomet GP 3HS0: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 3 mg. • Glycomet GP 4: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 4 mg. • Glycomet GP 4HS0: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000 mg and glimepiride IP 4 mg. • Glycomet GP 1 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000 mg and glimepiride IP 1 mg. • Glycomet GP 2 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000 mg and glimepiride IP 2 mg. • Glycomet GP 3 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000 mg and glimepiride IP 3 mg. **Indications:** Glycomet GP is indicated for the management of patients with type 2 diabetes mellitus (T2DM) when diet, exercise and single agent metformin hydrochloride or glimepiride alone do not result in adequate glycemic control. **Dosage and Administration:** Dosage of Glycomet GP should be individualized on the basis of effectiveness and tolerability while not exceeding the maximum recommended daily dose of glimepiride 8mg and metformin 2000 mg. Initial dose: 1 tablet of Glycomet GP should be administered once daily during breakfast or with the first main meal. Do not crush or chew the tablet. In several cases the tablet may remain intact during transit through the gastrointestinal (GI) tract and will be eliminated in feces as hydration mass (ghost matrix). Patients should be advised that this is normal as all drug components have already been released during GI transit. **Contraindications:** In patients hypersensitive to glimepiride, other sulfonylureas, other sulfonamides, metformin or any of the excipients of Glycomet GP, pregnancy and lactation, diabetic ketoacidosis, diabetic pre-coma, in patients with eGFR<30 ml/min/ 1.73 m², acute conditions with the potential to alter renal function (dehydration, severe infection, shock, intravascular administration of iodinated contrast agents), acute or chronic disease which may cause tissue hypoxia (myocardial infarction, shock, cardiac/respiratory failure), hepatic insufficiency, acute alcohol intoxication, alcoholism. **Warnings:** Keep out of reach of children. Patient should be advised to report promptly exceptional stress situations (e.g. trauma, surgery, febrile infections). Blood glucose regulation may deteriorate and a temporary change to insulin may be necessary to maintain good metabolic control. In case of lactic acidosis, patient should be hospitalized immediately. **Precautions:** In the initial weeks of treatment, the risk of hypoglycemia may be increased and necessitates especially careful monitoring. Glycemic (metformin) levels should be determined before initiating treatment and regularly thereafter, at least annually in patients with normal renal function. Intravascular contrast studies with iodinated materials can lead to acute alteration of renal function, in patients in whom such study is planned, Glycomet GP should be temporarily discontinued at the time of or prior to the procedure, and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been re-evaluated and found to be normal. Use of Glycomet GP should be discontinued 48 hours before any surgical procedure. **Adverse reactions:** For glimepiride – hypoglycaemia, temporary visual impairment, GI symptoms like nausea, vomiting, abdominal pain, diarrhoea may occur, increases liver enzymes, cholestasis and jaundice may occur; allergic reactions may occur occasionally. For metformin – GI symptoms like nausea, vomiting, abdominal pain or discomfort may occur.

In case of any adverse events, kindly contact: pv@usv.in

For the use of registered medical practitioner / hospital or laboratory

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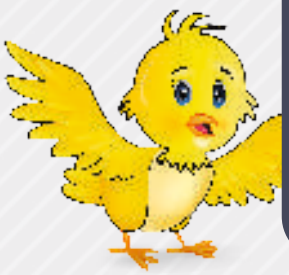

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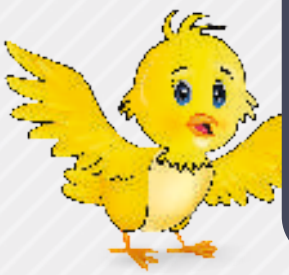

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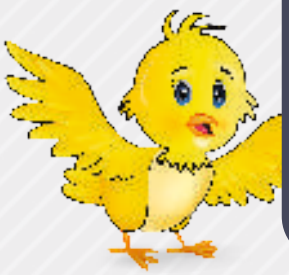

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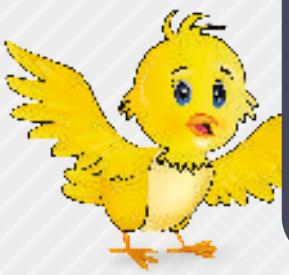

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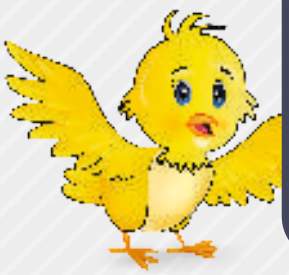

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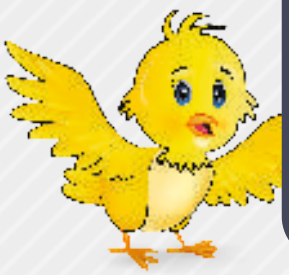

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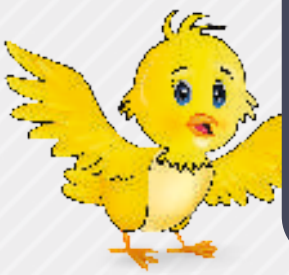

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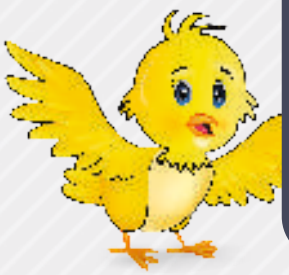

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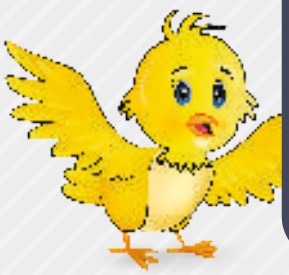

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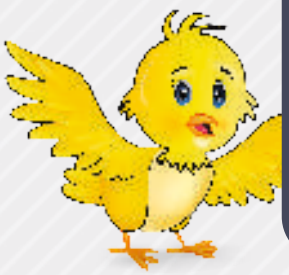

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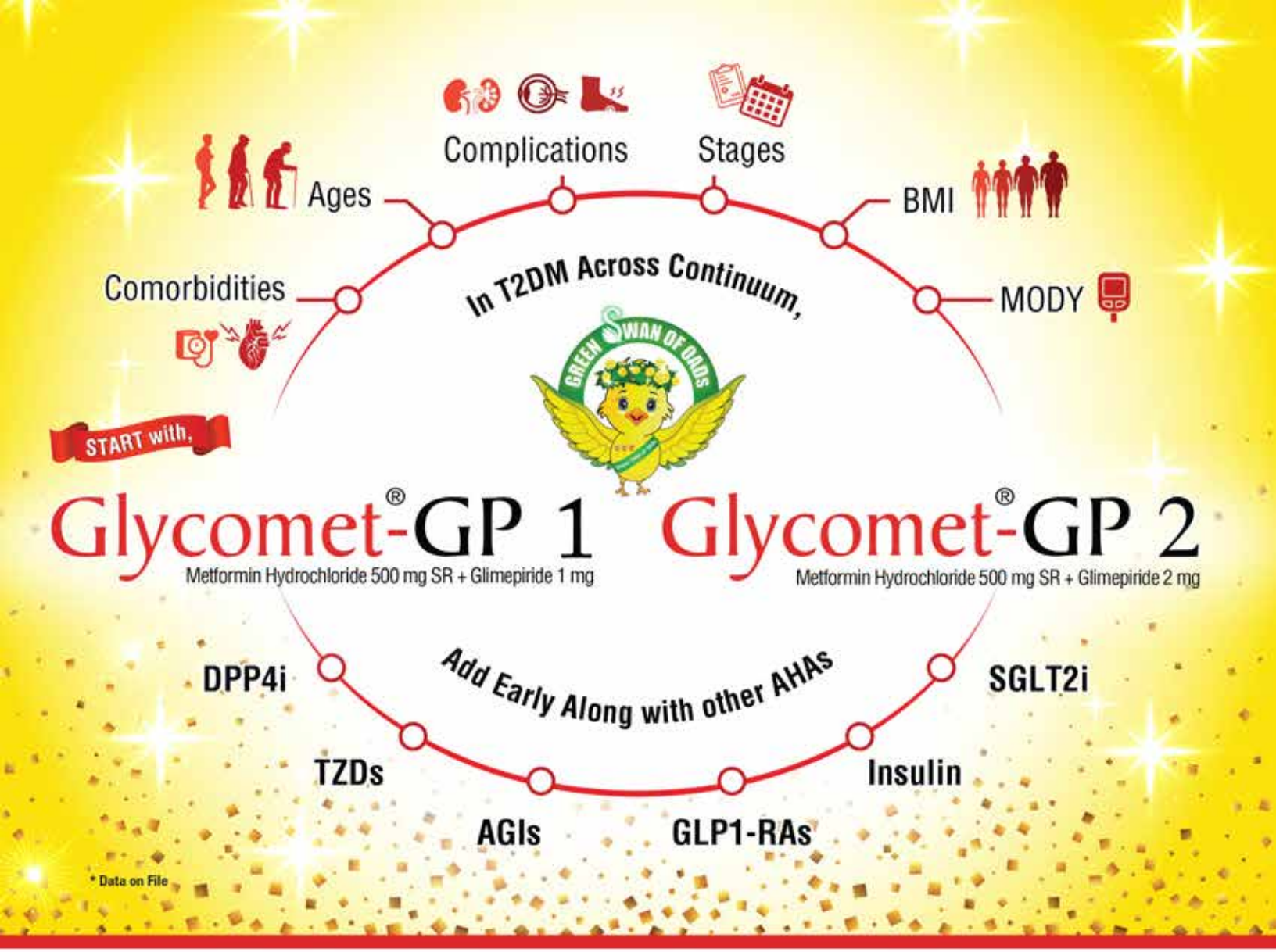

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Prescribing Information

Information: Metformin hydrochloride (as prolonged release) and glimepiride tablets. Glycomet-GP 0.5/Glycomet-GP 0.5 Forte/ Glycomet-GP 1/ Glycomet-GP 1/850/ Glycomet-GP 2/ Glycomet-GP 2/850/ Glycomet-GP 3/ Glycomet-GP 3/850/ Glycomet-GP 4/ Glycomet-GP 4/850/ Glycomet-GP 1 Forte/ Glycomet-GP 2 Forte/ Glycomet-GP 3 Forte/ Glycomet-GP 4 Forte Abridged Prescribing Information **Composition:** Glycomet GP 0.5mg: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500mg and glimepiride IP 0.5mg.• Glycomet GP 0.5 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP 0.5mg.• Glycomet GP 1: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 1 mg. • Glycomet GP 1/850: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 1 mg. • Glycomet GP 2: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 2 mg. • Glycomet GP 2/850: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 2 mg.• Glycomet GP 3: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 3 mg. • Glycomet GP 3/850: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 3 mg. • Glycomet GP 4: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 500 mg and glimepiride IP 4 mg. • Glycomet GP 4/850: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 850 mg and glimepiride IP 4 mg. • Glycomet GP 1 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP 1mg. • Glycomet GP 2 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP 2mg. • Glycomet GP 3 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP 3mg. • Glycomet GP 4 Forte: Each uncoated tablet contains metformin hydrochloride IP (as prolonged release form) 1000mg and glimepiride IP mg. **Indication:** For the management of patients with type 2 diabetes mellitus when diet, exercise and single agent (glimepiride or metformin alone) do not result in adequate glycaemic control. **Dosage and Administration:** The recommended dose is one tablet daily during breakfast or the first main meal. Each tablet contains a fixed dose of glimepiride and Metformin Hydrochloride. The highest recommended dose per day should be 8 mg of glimepiride and 2000mg of metformin. Due to prolonged release formulation, the tablet must be swallowed whole and not crushed or chewed. **Adverse Reactions:** For Glimepiride: hypoglycaemia may occur, which may sometimes be prolonged. Occasionally, gastrointestinal (GI) symptoms such as nausea, vomiting, sensations of pressure or fullness in the epigastrium, abdominal pain and diarrhea may occur. Hepatitis, elevation of liver enzymes, cholestasis and jaundice may occur; allergic reactions or pseudo allergic reactions may occur occasionally. For Metformin: GI symptoms such as nausea, vomiting, diarrhea, abdominal pain, and loss of appetite are common during initiation of therapy and may resolve spontaneously in most cases. Metallic taste, mild erythema, decrease in Vit B12 absorption, very rarely lactic acidosis, Hemolytic anemia, Reduction of thyrotropin level in patients with hypothyroidism, Hypomagnesemia in the context of diarrhea, Encephalopathy, Photosensitivity, hepatobiliary disorders. **Warnings and Precautions:**: For Glimepiride: Patient should be advised to report promptly exceptional stress situations (e.g., trauma, surgery, febrile infections), blood glucose regulation may deteriorate, and a temporary change to insulin may be necessary to maintain good metabolic control. Metformin Hydrochloride may lead to Lactic acidosis; in such cases metformin should be temporarily discontinued and contact with a healthcare professional is recommended. Sulfonylureas have an increased risk of hypoglycaemia. Long-term treatment with metformin may lead to peripheral neuropathy because of decrease in vitamin B12 serum levels. Monitoring of the vitamin B12 level is recommended. Overweight patients should continue their energy-restricted diet, usual laboratory tests for diabetes monitoring should be performed regularly. **Contraindications:** Hypersensitivity to the active substance of glimepiride & Metformin or to any of the excipients listed. Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis, diabetic pre-coma). Severe renal failure (GFR≤30ml/min). In pregnant women. In lactating women.Acute conditions with the potential to alter renal function (dehydration, severe infection, shock, intravascular administration of iodinated contrast agents); acute or chronic disease which may cause tissue hypoxia (cardiac or respiratory failure, recent myocardial infarction, shock); hepatic insufficiency; acute alcohol intoxication; alcoholism. **Use in a special population:** Pregnant Women: Due to a lack of human data, drugs should not be used during pregnancy. Lactating Women: It should not be used during breastfeeding. Pediatric Patients: The safety and efficacy of drugs has not yet been established. Renal impairment: A GFR should be assessed before initiation of treatment with metformin containing products and at least annually thereafter. In patients at increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6 months.

Additional information is available on request.

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In case of any adverse events, kindly contact: pv@usv.in For the use of registered medical practitioner, hospital or laboratory.

USV Private Limited Corvette Team

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