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GENITAL HYGIENE IN DIABETES

*Shambhavi Kamat

Patients of Type 1 and Type 2 Diabetes are at a higher risk of developing infections. Some infections are exclusively found in diabetics while some others may be found to be recurrent or of elevated severity in diabetics. Many a times, it is found that '*pruritus vulvae*' or '*pruritus scroti*' i.e. itching of the vulva (external part of the female genitals) or scrotum is one of the presenting symptoms of diabetes.

Urinary tract infections are common in patients with uncontrolled diabetes, autonomic neuropathy (damage of nerves that control everyday functions like blood pressure, bladder voiding, etc) and bladder obstruction. Many infections are asymptomatic and confined only to the bladder. These infections have a high recurrence rate in a diabetic due to the impaired immune response to bacteria.

Infections, if ignored and left untreated may cause serious complications. Invasion by vaginal warts, herpes simplex virus 2 (HSV-2) and pelvic inflammatory disease may culminate in development of diabetic ketoacidosis in Type 1 diabetic. A complication of bacterial infection, known as '*emphysematous cystitis*', although rare, is life-threatening. It is characterised by air bubbles in and around the bladder wall along with formation of cysts, confirmed by imaging and radiology. It is caused by invasion of the bladder wall by gas-forming bacteria like E. Coli, Klebsiella, Candida and other species. Cystitis must be treated immediately and on priority even if the patient is asymptomatic. If left untreated, the infection spreads to other organs in the pelvis including the uterus, kidneys and adrenal glands. Antibiotic treatment is usually continued for a longer time than usual and urine culture is repeated to make sure the infection is completely eradicated.

A routine infection is generally treatable with conventional anti-fungal creams and broad-

spectrum antibiotics like Fluconazole while some resistant strains may require specific antibiotic medications. Passing RBCs and WBCs in the urine along with the presence of fever is usually indicative of tissue invasion. In such cases, strong antibiotics like amphotericin and flucytosine are usually given via an IV (intravenous) drip.

Candidiasis is a common fungal infection of the vulva and perineum (area between the anus and genitals), especially in diabetics. It is usually caused due to improper cleaning practices and inadequate hygiene. It can be treated with oral (tablets) or topical (locally applied) antifungal medications. In fact, many gynaecologists prescribe these anti-fungal medications as a prophylaxis without waiting for the culture reports. This may cause resistance in the bacterial strains and may ultimately result in a more extensive antibiotic schedule, most likely for a longer duration.

Some symptoms of a genito-urinary infection are:

- Polyuria (frequent urination)
- Dysuria (painful urination)
- Decreased urinary continence
- Malodour
- Pruritus
- Vulvovaginitis (vaginal discharge and intense itching)
- Rashes
- Inflammation or red patches on skin
- Thrush.

Under normal circumstance, the urino-genital tract has a healthy microflora and yeast that keeps our body safe from pathogenic micro-organisms by fighting them. In addition to this, the leucocytes (WBCs) provide an excellent defence system and work to eliminate pathogens by digesting them, or engulfing them and then

* Dietitian at Dr. Chandalia's Diabetes Endocrine Nutrition Management & Research Centre

destroying them. Under presence of a normal genital microflora, it is almost impossible for a pathogen to latch on and cause imbalance. However, when the microflora is altered, it may cause an increase in the pH, thereby decreasing the acidic environment. As the acidic environment is a means of natural defence, the altered pH provides a suitable ground for pathogenic growth and results in bacterial infections.

Bacteria and yeast are able to thrive when provided with sugars. In the process of making bread, sugar is added to the mixture of dry yeast and lukewarm water, likewise, it is only natural that yeast would have the same reaction to the glucose provided to the tissues via blood. Thus, even in presence of a normal microflora, elevated blood glucose levels provide substrate for growth of yeast and leads to infection. Chronic hyperglycemia i.e. blood glucose levels above 200 mg/dL may cause impaired response to bacteria, further encouraging pathogenic growth.

A bacterial infection may also be due to the use of certain anti-diabetic medications, eg: *SGLT-2 Inhibitors*. SGLT-2 Inhibitors or Sodium Glucose Co-transporter-2 Inhibitors are a class of oral anti-diabetic medications that work on the kidney. These drugs increase excretion of glucose in the urine, thereby decreasing the level of glucose in the blood. However, if the patient is not adequately hydrated, it poses a significant risk of developing yeast infections as the bacteria are not flushed out of the system well enough. Thus, medical practitioners usually advise patients to take these medications with 1 glass of water and follow it up with another glass. Commonly used drugs in the SGLT-2 Inhibitors class include empagliflozin, canagliflozin and dapagliflozin. Ertugliflozin and ipragliflozin are currently undergoing phase III trials where their long-term efficacy and safety is being evaluated. Yeast infections are commonly seen in females and uncircumcised male diabetics who are taking SGLT-2 Inhibitors.

Vaginal douching, if practiced, must be strictly discouraged by the medical practitioner. Douching is a practice that is, surprisingly, very

common in females. Under this practice, certain substances are sprayed on or into the vagina to “flush”, “soak” or “clean” it. The mixtures available in the market contain antiseptics and fragrant compounds. Some women even use vinegar as a home remedy! The use of these products throws the vaginal pH and healthy microflora off balance and encourages bacterial infection. In fact, women who practice douching have been shown to suffer from bacterial vaginosis more frequently than ones who do not practice it. Instead, it is advisable to wash your genitals with water and a mild unscented soap.

A few precautions that can be taken in order to prevent any bacterial infections are as follows:

- Appropriate blood glucose control
- Consumption of probiotics (either as yoghurt, probiotic drinks or pharmaceutical supplements)
- Adequate hydration (2.5-3 litres per day for an adult, while patients taking SGLT-2 Inhibitors must make sure to have at least 4 litres a day)
- Keeping genitals clean and dry. Bacteria and fungi love moisture! Males must clean the area under the foreskin regularly as this can be a breeding ground for a varied species of bacteria.
- Wear clean, cotton underwear that allows air to pass through the cloth. Avoid wearing the same underwear for more than 16 hours. You may change it before going to bed.
- Avoid tight-fitting garments, especially bottoms that sticks to the skin and causes irritation.
- Don't wear sweat-laden clothes. Bacteria revel in environments that provide them warmth and moisture!
- Avoid using talcum powders that are heavily scented. While they do make you feel fresh and dry, it increases risk to developing ovarian cancer in women and may cause irritation and itching.
- After using the restroom, wipe the perineum from front to back, instead of the other

way around. This decreases the risk of transmission of fecal bacteria to the genital area.

- Washing hands after using the restroom is a must.
- Females must avoid using scented tampons or feminine sprays. These products destroy the pH balance of the vagina and kill all the good bacteria while allowing bad bacteria to grow.

We all accept that *prevention is better than cure*. It is important to understand that the first and foremost preventive measure against genitor-urinary infections is management of persistent hyperglycemia. Managing hyperglycemia considerably reduces the risk of developing such complications. This should be done by taking the prescribed medications, exercising regularly and developing healthy eating habits. These 3 components play an indispensable role in preventing these infections by ensuring management of blood sugars.

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THE TRUTH ABOUT WHITE BREAD: A DANGER TO YOUR HEALTH

***Darius Umrigar**

We know that there are many people round the world who enjoy eating white bread. But today, we would like to give you some facts that may shock and surprise you. It's not only that white bread isn't good for your health; it can actually be a real danger to your health!

The Swiss government has been aware of the dangers of eating white bread for decades and in order to get its populace to stop eating it; Switzerland has placed a tax on the purchase of white bread. The tax money is given to bakers to reduce the price of whole wheat bread to encourage people to switch.

The Canadian government passed a law prohibiting the "enrichment" of white bread with synthetic vitamins. Bread must contain the original vitamins found in the grain, not imitations. Essentially, white bread is *dead* bread. Frequently, consumers are not told the truth about this and so called "enriched" flour.

Why is the color of white bread so white when the flour taken from wheat is not?

It is because the flour used to make white bread is chemically bleached, just like you bleach your clothes. When you are eating white bread, you are also eating residual chemical bleach. Flour mills use different chemical bleaches, all of which are pretty bad.

Here are a few of them:

- Oxide of nitrogen,
- Chlorine,

- Chloride,
- Nitrosyl
- Benzoyl peroxide

Further they are mixed with various chemical salts. One bleaching agent, chloride oxide, combined with whatever proteins are still left in the flour, produces alloxan.

Alloxan is a poison and has been used to produce diabetes in laboratory animals. Chlorine oxide destroys the vital wheat germ oil. It will also shorten the flour's shelf life.

Good Nutrition: You won't find it In white bread In the process of making flour white, half of the good unsaturated fatty acids, that are high in food value, are lost in the milling process alone, and virtually all the vitamin E is lost with the removal of wheat germ and bran. As a result, the remaining flour in the white bread you buy contains only poor quality proteins and fattening starch. But that is not the whole story as to the loss of nutrients.

Here are some other statistics about the huge loss of nutrients when white bread is made: •

- About 50% of all calcium is lost
- 70% of phosphorus
- 80% of iron
- 98% of magnesium
- 75% of manganese
- 50% of potassium
- 65% of copper is destroyed when white

* D.Sc (Honoris Causa); MD (Alternative Medicine); DNYS (Delhi), ND (Mumbai)

bread is made.

- 80% of thiamin,
- 60% of riboflavin,
- 75% of niacin,
- 50% of pantothenic acid.
- About 50% of Pyridoxine is also lost.

Scientific study has confirmed what the Swiss have known for years these horrific numbers are the results of a study run by the University of

California, college of agriculture. It is obvious, from what we have learned, that white bread should be avoided.

Whole wheat, rye and grain breads made with whole wheat flour are healthy.

It is a good idea to always read the labels and minimize consumption of foods that contain artificial flavors, colors, bleached flour, preservatives, hydrogenated or partially hydrogenated oils.

POSTPARTUM WEIGHT RETENTION

*Samina Burhanpurwala

Obesity in young adult women negatively impacts in many ways:

- Increases risk of diabetes and heart disease.
- Negatively affects conception and fertility.

Postpartum weight is basically a woman's weight immediately after delivery of fetus, amniotic fluid and placenta. Therefore, Postpartum Weight Retention (PPWR) is the amount of weight that remains at this time minus the pre-pregnancy weight. There are several important factors that determine PPWR, which includes:

- 1) Pre-pregnancy weight
- 2) Gestational Weight Gain
- 3) Breastfeeding
- 4) Occupation
- 5) Physical activity
- 6) Dietary habits
- 7) Smoking & alcohol
- 8) Parity

PRE-PREGNANCY BMI CLASSIFICATION:

Being overweight or obese before conception is associated with complications during antenatal and perinatal periods such as:

- 1.) High Gestational Weight gain
- 2.) Retaining more weight postpartum
- 3.) Hypertension
- 4.) Giving birth to heavier infants
- 5.) Gestational Diabetes Mellitus
- 6.) Emergency C-section

These factors also increase the risk of stillbirth, and fetal malformations.

Table 1: Pre-pregnancy BMI classification:

Nutritional status based on the WHO and Asian criteria values		
Nutritional status	WHO criteria BMI cut-off	Asian criteria BMI cut-off
Underweight	< 18.5	< 18.5
Normal	18.5- 24.9	18.5- 22.9
Overweight	25- 29.9	23-24.9
Pre-Obese	-	25-29.9
Obese	≥ 30	≥ 30
Obese Type I	30- 40	30- 40
Obese Type II	40.1- 50	40.1- 50
Obese Type III	> 50	> 50

Taking into account the variations in energy requirement among pregnant women, the United States Institute of Medicine (IOM 2009), have come up with new recommendations for weight gain during pregnancy and have suggested that pre-pregnancy BMI should be taken into consideration when assessing weight gain during pregnancy.

Table 2: IOM Gestational weight gain recommendations:

Weight Category	WHO Asia Pacific Criteria-BMI (kg/m ²)	IOM recommended weight gain (Kg)
Underweight	< 18.5	12-18
Normal weight	18.5-22.9	11.5-16
Overweight	23-24.9	7-11.5
Obese	≥ 25	5-9

BMI: Body Mass Index, IOM: Institute of Medicine, WHO: World Health Organization

* Dietitian at Dr. Chandalia's Diabetes Endocrine Nutrition Management & Research Centre

WHAT MAKES UP THE BABY WEIGHT???

Although a weight gain of 12-18 Kg for women with a normal pre-pregnancy BMI may feel like too much — BUT, a newborn baby doesn't actually weigh that much — those extra Kg do serve a purpose. As mentioned earlier and illustrated in the figure below, pregnancy weight also come from the placenta, fat stores, amniotic fluid, growing uterus, breasts tissue and increased blood volume in the woman's body.

Table 3: Normal distribution of weight during pregnancy

WEIGHT DISTRIBUTION	WEIGHT (Kg)
Baby	3.6 kg
Fat stores	2.3-4 kg
Uterus growth	0.9- 2.3 kg
Blood volume	1.8 kg
Breast tissue	0.9- 1.4 kg
Placenta	0.9- 1.4 kg
Amniotic Fluid	0.9- 1.4 kg

The weight from fat stores, blood supply and breast tissue is not just localized to abdomen.

DIET, BREASTFEEDING & EXERCISE:

- An additional intake of 600 Kcal/day (0-6 months) and 350 Kcal/day (7-12 months) is recommended to satisfy nutritional demands during lactation period. Reduced caloric intake will cause fatigue and negative impact on mood especially in women who breastfeed.
- Do not overeat or go on a calorie restricted diet. Since returning to pre-pregnancy weight is a common goal among postpartum women, focus should be on healthy diet. Therefore one should have good nutrition and exercise which will eventually result in positive weight loss.
- Include protein rich foods such as cereals, pulses, low fat dairy products, lean meat, fish and eggs.
- **Increase intake of calcium rich foods.** The recommended daily allowance of calcium

during gestation and lactation period is 1,200 mg/day. Since vitamin D enhances calcium absorption, calcium rich foods can be combined with vitamin D rich foods.

Sources: Ragi, lentils, Amaranth (rajgeera), turnip greens, kale, methi leaves, low fat milk and milk products, soybeans, tofu, soy milk, tempeh, dried figs, sesame seeds (til), lean meat, eggs, oysters, sardine, canned salmon, tuna, mackerel, egg yolks.

- Considering the Indian scenario, most women do not obtain enough calcium from dietary sources and hence can benefit from calcium supplementation.
- Requirement for iron return to pre-pregnancy levels (25 mg/day) in postpartum period. Iron supplementation is recommended when blood loss is higher than usual i.e. during vaginal delivery. Iron rich foods can be combined with vitamin C rich foods to improve iron absorption.

Sources: Oysters, beef liver, organ meat, poultry, egg yolk, whole grains, ragi, tofu, spinach, figs, and dried fruits such as apricots, raisins, and prunes. Vitamin C rich foods such as citrus fruits, papaya, sprouted pulses & legumes, green bell peppers, broccoli and green leafy vegetables can be consumed along with iron rich foods to enhance iron absorption.

- Adequate intake of fluid (3-3.5 Litres/ day) and fiber rich foods is required to have regular bowel movements.
- Reduce the intake of starchy, high fat and deep fried foods since it will provide not much nutrients and in a way make the person less active.
- According to IOM (Institute of Medicine) guidelines, moderate consumption of alcohol and caffeine-containing products are not contraindicated during lactation period.
- Alcohol should be avoided as much as possible. But if required, can be consumed after breastfeeding and not before because it may affect the infant who is breastfed.

BREASTFEEDING:

- WHO recommends breastfeeding up to 6 months of age. Breast milk is the best nutrition mothers can offer to their newborn. Breastfeeding offers tremendous health benefits to both mother and child.
- Breastfeeding is also good for women with Diabetes. But to prevent low blood sugar levels due to breastfeeding, such women should plan to have a snack or sip adequate fluids before or during nursing.
- Moderate consumption of caffeine is acceptable during breastfeeding.
- Breastfeeding before exercise may reduce the discomfort of engorged breasts.

PHYSICAL ACTIVITY:

Regular physical activity is important in facilitating a faster return to pre-pregnancy weight.

- Any aerobic exercise that gives a feeling of relaxation, restore muscle strength, healing, support emotional well-being, and not adversely affect their ability to breastfeed is permitted.
- Also in women with history of GDM, 100 minutes per week of moderate intensity exercise has been shown to reduce the risk of developing Type 2 Diabetes ahead.
- Brisk walking, Yoga (Eg: Suryanamaskar), spot jogging, squats also can be recommended. The type and level of exercise will depend on each woman's medical history, mode of delivery (vaginal or caesarean), level of fitness, and post delivery recovery.

“EATING FOR THE TWO” MISCONCEPT

During gestation and lactation period, women are often advised to ‘*eat for two*’. While it is true that a pregnant woman needs nutrition for two – herself and her child, this does not mean to actually eat twice as much as you normally do which results in excessive weight gain during pregnancy.

Healthy growth of the fetus depends on the nutrition mothers provide to the fetus. Balanced nutrition and right exercise can help the baby develop a healthy weight with less risk of disease.

Many studies have found that an overfed fetus may end up as an overweight adolescent too. Few studies have also suggested that higher levels of blood markers in the umbilical cord indicate that the baby has more fat and may continue having more fat into late childhood and adolescence. The cord blood markers leptin and adiponectin indicate the degree of fat in the child at birth, but the relationships between these markers and the child's risk of obesity in later life is not clear.

CONSEQUENCES OF INCREASED GESTATIONAL WEIGHT GAIN**A] Maternal Outcomes:**

Impaired Glucose Tolerance and Gestational Diabetes: Increased insulin resistance and β -cell dysfunction can lead to impaired glucose tolerance and therefore GDM.

Hypertensive Disorders: Women, who are overweight /obese in their pre-gravid period, have a high risk of developing pregnancy-induced hypertensive disorders such as hypertension, pre-eclampsia, eclampsia.

C-section: Women with weight gain above recommended range have an increased risk of cesarean section, which affects their recovery period following birth.

Increased Postpartum weight Retention: Studies reported that women with gestational weight gain above recommended IOM guidelines have been shown to have increased postpartum weight retention

B] Fetal Outcomes:

Birth Defects: GWG above recommended IOM range, increases the risk of fetal birth defects such Neural Tube Defects (NTDs) and Heart defects.

Macrosomia: Women with increased weight gain during pregnancy will give birth to a larger than average baby (Macrosomia or Large for Gestational Age) with a birth weight of more than 4000 grams Adverse outcomes of macrosomia includes neonates having shoulder dystocia (if the baby is too big to fit through the birth canal) or injuries

to the brachial plexus (if the shoulders are pressed firmly, during birth process, brachial nerves then stretch or teardown) during labor.

Childhood Obesity: Many studies have shown to have a strong link between maternal obesity and macrosomia to childhood obesity. One of the suggested mechanisms revolves around the concept of over-nutrition. Maternal over-nutrition may result in fetal over-nutrition, which will affect fetal adipose tissue deposition. Since adipose cell number appears to remain fixed in 1st 2 years of life, excess no. of fat cells formed in this early years may result long-running excess adiposity.

In conclusion, it seems important to focus on gestational weight gain of all BMI groups regardless of the women's pre-pregnancy BMI, as gestational weight gain above IOM recommendations increases women's risk of postpartum weight retention in underweight, normal, overweight and obese women. Decreased fat intake and increased physical activity in postnatal period and complete breastfeeding contribute to lower postpartum weight retention. Understanding the changes in dietary quality after gestation, with methods that analyze the diet, may contribute to the formulation of efficient interventions program with focus on both nutrition and exercise during pregnancy and this may help limit their gestational weight gain and thus reduce postpartum weight retention.

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DIABETIC PERIPHERAL NEUROPATHY AND MANAGEMENT

*Rajiv Kovil

Diabetic Peripheral Neuropathy (DPN) is the most common complication of diabetes and has been reported to affect 50% of patients with the metabolic disorder-Diabetes Mellitus. DPN is a major cause of morbidity and increased mortality. It is defined as nerve damage due to constant high blood sugar levels resulting in painful neuropathic symptoms and insensitivity such as numbness, loss of sensation and sometimes pain in feet, legs or hands, which may increase the risk of burns, injuries and foot ulceration. DPN projects a major healthcare challenge for medical professionals and patients as well.

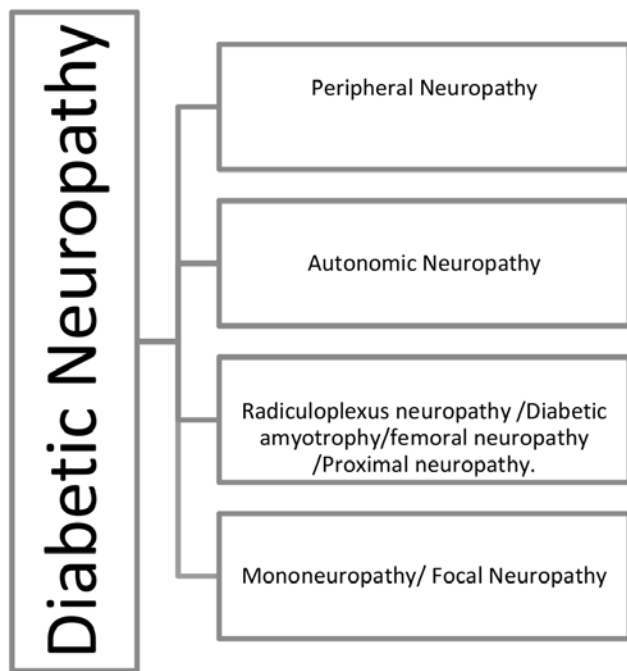


Figure 1: Classification

Classification of Diabetic Neuropathy:

- 1) **Peripheral neuropathy:** most common type of neuropathy affecting the feet and legs followed by hands and arms. Symptoms experienced by patient may include- numbness, temperature changes, tingling or burning sensation, sharp pains or cramps,

increased sensitivity to touch, weakened muscles, reflex, balance and coordination loss, foot problems like ulcers, infections, along with bone and joint pain.

- 2) **Autonomic neuropathy:** Here the nerves of autonomic nervous system are affected. This causes-Hypoglycemia unawareness-patient remains unaware of his/her blood sugars being low, bladder problems such as urinary tract infections/ urinary retention, constipation, uncontrolled diarrhea or both, slow emptying of stomach causing nausea, vomiting, bloating and loss of appetite, difficulty faced while swallowing, problems in controlling body temperature causing increased or decreased sweating, changes in visual activity, increased heart rate at rest, extreme blood pressure changes while standing or sitting leading to giddiness and sexual problems like-erectile dysfunction, vaginal dryness and decreased sexual response.
- 3) **Radiculoplexus neuropathy (diabetic amyotrophy):** This neuropathy affects the nerves of lower extremities - the thighs, hips, buttocks or legs. Prevalence is more in people with type 2 diabetes and older adults. It is also called as diabetic amyotrophy, femoral neuropathy or proximal neuropathy. Symptoms are more dominant on one side of the body and may spread to the other side. Patient experiences- severe pain in hip and thigh, muscles of the thigh weak and shrink, difficulty faced by patients while rising from a sitting position, also there is abdominal swelling.
- 4) **Mononeuropathy or Focal Neuropathy:** Here a specific nerve in the face or torso or leg is damaged. Most common in older adult however, doesn't cause any long-term

* Diabetologist at Dr. Kovil's Diabetes Care Centres

problems. The symptoms seen here are pain in foot or shin, lower back or pelvis, front of thigh, chest or abdomen, double vision, aching behind one eye, paralysis on one side of your face (Bell's palsy) Carpal tunnel syndrome is a common type of compression

neuropathy in people with diabetes. It causes numbness or tingling sensation in patient's hand or fingers.

Having Classified Diabetic Neuropathy, we will be focusing on Diabetic Peripheral Neuropathy (DPN) further in the article.

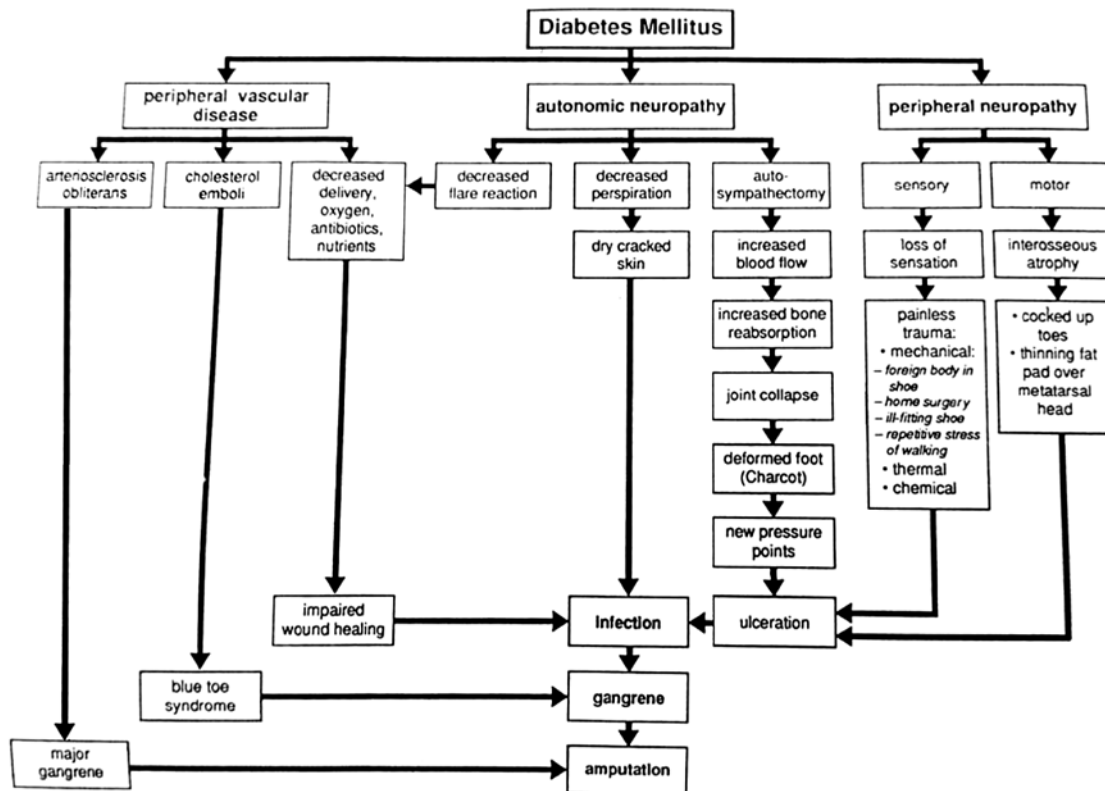


Figure 2: Pathogenesis. (From Levin ME: Diabetic foot lesions: Pathogenesis and management.)

Risk factors for Diabetic Peripheral Neuropathy:

Poor glycemic control, duration of diabetes, hyperlipidemia (particularly hypertriglyceridemia), elevated albumin excretion rates and obesity have been reported by several researches as risk factors for developing diabetic neuropathy.

Cause of Diabetic Peripheral Neuropathy:

Both vascular factors and metabolic interactions are involved at all stages of diabetic peripheral neuropathy.

- Damage to nerves and blood vessels- Uncontrolled high blood sugar damages nerves it weakens the walls of capillaries which supply nerves with oxygen and

nutrients thus interfering with their ability of sending signals, leading to diabetic neuropathy. However nerve damage is due to multiple factors like:

- Inflammation in the nerves caused by an autoimmune response
- Genetic factors
- Smoking and alcohol abuse- they damage both nerves and blood vessels and increase the risk of infection.

Clinical manifestations of Diabetic Peripheral Neuropathy:

- Loss of sensation as nerves affected
- Increased chances of foot ulceration

- Pain, burning, or tingling sensation in the nerves affected
- The pain and discomfort are described as pins and needles/prickling/burning/cold/pinching/buzzing/sharp/deep stabs
- Majorly affects hands and feet.
- Muscle weakness for instance difficulty in walking or getting up from a chair. Difficulty grabbing things or carrying things with your hands.
- Problem with balancing- unsteadiness and loss of co-ordination

Diagnosis of Diabetic Peripheral Neuropathy:

Physical examination and reviewing patient's symptoms with medical history should be done to diagnose DPN. Check for-overall muscle strength and tone, tendon reflexes and sensitivity to touch and vibration. At every visit, doctor/Diabetologist should check patient's feet for sores, cracked skin, blisters, bone and joint problems. The American Diabetes Association recommends that all people with diabetes should have comprehensive foot examination annually.

Specific tests to help diagnose diabetic neuropathy:

- Monofilament testing- The Semmes – Weinstein 5.07 monofilament is calibrated to take 10 grams of force to bend it when touched on the skin of the foot. If this degree of force goes undetected by patient it is termed as loss of protective sensation (LOPS) in the foot. Should be done annually as a part of foot assessment.
- The 128 Hz tuning fork is another regularly used testing method to test vibratory sensation. It is bilaterally tested over the tip of the great toe.
- Quantitative sensory testing-This noninvasive test is used for small fiber neuropathy testing
- Quantitative Sudomotor Axon Reflex Testing- this test is used to measure postganglionic sympathetic cholinergic function. Here local sweating is produced through iontophoresis of acetylcholine;

a mild electrical current is used to draw acetylcholine into the skin, which activates local sweat glands. The axon reflex-mediated sweat output is detected by passing dry gas over the no stimulated region and quantifying the change in humidity of the gas.

- Skin Biopsy- used to investigate the structural integrity of small nerve fibers. A standard 3-mm dermatologic punch biopsy is taken from any part on the body, the lateral distal leg, the lateral distal thigh, and the lateral proximal thigh to look for a length-dependent pattern).
- Nerve conduction studies- used to diagnose carpal tunnel syndrome it measures how quickly the nerves in arms and legs conduct electrical signals.
- Electromyography (EMG) -Performed along with nerve conduction studies, measures electrical discharges produced in muscles.

The quality and severity of neuropathic pain is assessed using a suitable scale. The diabetic neuropathy symptom score (DNS) is a scoring system used to assess pain, numbness, tingling and ataxia

Table 1: Diabetic neuropathy symptom score (DNS)

DNS items	Rate
Unsteadiness in walking	0 = absent, 1 = present
Numbness	0 = absent, 1 = present
Burning, aching pain or tenderness in legs or feet	0 = absent, 1 = present
Prickling sensations	0 = absent, 1 = present

Management of Diabetic Peripheral Neuropathy:

The most important factors for overall management of neuropathic patients involve good glycemic control and cardiovascular health. The goals of treatment are to slow progression, manage complication and relieve pain. Individual requirements, presence of other co-morbidities should be considered, and management of

painful neuropathy must be tailored made to help patients relieve from symptoms.

How to slow progression: Keep blood sugars within target range. Target range for patients is based on several factors which include- patient's age, how long has he/she have had diabetes and overall health.

The American Diabetes Association generally recommends the following target blood sugar levels:

- Between 80 and 130 mg/dL (4.4 and 7.2 mmol/L) before meals
- Less than 180 mg/dL (10.0 mmol/L) two hours after meals

Keeping blood pressure under control and maintaining a healthy weight and lifestyle will also help slow or prevent DPN progression

Pain-relieving prescription treatments may include:

- **Anti-seizure drugs- Recommendation by ADA is the use of pregabalin (Lyrica).** Other drugs used to treat neuropathy are gabapentin (Gralise, Neurontin) and carbamazepine (Carbatrol, Tegretol). Side effects may include drowsiness, dizziness and swelling.
- **Antidepressants-there are 2 classes of antidepressants used for treating DPN**
 - 1) Tricyclics: including amitriptyline, desipramine (Norpramin) and imipramine (Tofranil) helps provide relief for mild to moderate symptoms. Side effects include dry mouth, sweating, weight gain, constipation and dizziness.
 - 2) Serotonin and norepinephrine: ease pain with fewer side effects. ADA recommends duloxetine (Cymbalta) as a first treatment. Side effects such as nausea, sleepiness, dizziness, decreased appetite and constipation can be noted

An antidepressant may be combined with an anti-seizure drug or pain-relieving medication.

Foot Problems: Foot problems such as sores

which don't heal, ulcers and even amputation, are a common complication in diabetic neuropathy. A comprehensive foot examination annually or examining patient's feet at each visit can help prevent many of the complication listed above.

For healthy feet:

- Check feet daily using a mirror or ask help from a friend or family member to examine the feet for blisters, cuts, bruises, cracked and peeling skin, redness, and swelling.
- Keep feet clean and dry. Wash them every day using lukewarm water and mild soap. Avoid soaking feet. Dry feet and areas between your toes by either blotting or patting using a soft towel.
- Moisturize feet it will prevent cracking. Avoid getting lotion in areas between your toes, as this will cause fungal growth.
- Cut toenails straight across and file the edges carefully so there are no sharp edges.
- Wear clean, dry socks. Look for socks made of cotton or moisture-wicking fibers without tight bands or thick seams.
- Wear cushioned right fitting shoes to prevent problems such as corns and calluses.

To conclude, diabetic peripheral neuropathy reduces quality of life and accounts for considerable morbidity and mortality. Glycemic control is the prime focus of treatment and management Painful DPN is difficult to treat. Based on trial evidence, first line therapies include a TCA, the SNRI duloxetine and the anticonvulsant pregabalin. Combination therapy will help patients with more severe pain. Annual foot evaluation or examining lower extremities at follow up visits helps in the long run for early detection and for delaying progression.

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QUESTION AND ANSWERS

Q) What is the role of fibre in controlling blood glucose and lipid levels?

Dietary fibre is a type of carbohydrate found in plant-based foods. It's not absorbed or digested by the body, but plays an important role in maintaining good health. There are two types of dietary fibre – soluble and insoluble. Most foods contain both types, but are usually richer in one type than the other.

Sources of fibre:

Soluble fibre: Found in oat, oat bran, linseeds, barley, fruit and vegetable, nuts, beans, pulses, soya and lentils.

Insoluble fibre: Good sources include: whole-wheat bread, bran, wholegrain cereals, nuts, seeds and the skin of some fruit and vegetables.

Physiological and Metabolic Effects of Fibre

Delayed gastric emptying: Fibres form viscous gel within the stomach, so that the release of the chyme from the stomach into duodenum is delayed.. Thus nutrient remains in stomach for longer time and slows down the digestion process. Carbohydrates and lipids that remain in stomach undergo a slow digestion thus creating a feeling of post prandial satiety.

Binding capacity: Mucilaginous fibres such as guar gum, pectin and psyllium delay glucose absorption, lower blood glucose concentration and affect hormonal response to their absorbed nutrient. Such effects reduce post prandial blood glucose concentration and insulin needs and beneficial for diabetic patients.

Lowering of serum cholesterol concentration: With the excretion of bile acids in feces, less amount of bile undergoes for recirculation. Cholesterol is used for synthesis of new bile acids. The net effect is lower serum cholesterol. Fibre present in psyllium, guar gum, oat and pectin lowers serum cholesterol.

Role of Fibre in lowering blood glucose levels

Diet rich in fibre benefits both Type 1 and Type 2 diabetics. Diet rich in fibre lowers insulin requirements, increases peripheral tissue sensitivity to insulin, aids in weight control and lowers blood pressure. Soluble fibre such as pectin, gums in fruits and beta glucan in oats increase intestinal transit time, delays gastric emptying and also slows down glucose absorption leading to slow rise in blood glucose levels over a period of time. Insoluble fibres such as cellulose and lignins from grains and vegetables decrease intestinal transit time, increase fecal bulk, delay glucose absorption and slow starch hydrolysis. Diets high in fibre improve glucose metabolism without increasing insulin secretion. They lower fasting serum and peripheral insulin concentration in response to oral glucose administration in diabetic person.

Role of Fibre in lowering cholesterol levels

Soluble fibre present in form of beta glucan content of oats, pectin in fruits, guar gum from beans, psyllium husk, fibre present in beans and fibre from fruits and vegetables have following effects :

- Cholesterol synthesis is inhibited by acetic, propionic and butyric acids produced by bacterial fermentation.
- Clearance of LDL cholesterol.
- Slows gastric emptying and binds bile acids.
- Reduces serum fibrinogen and therefore reduces blood clot formation.
- Reduces fatty acid absorption.
- Lowers blood pressure by increasing absorption of calcium and magnesium.

TWINKLE JAIN

Q) Which classes of oral hypoglycemic agents are suitable for GDM?

The use of oral hypoglycemic agents (OHAs) is a matter of debate. Currently, the United States Food and Drug Administration (FDA) does not approve the use of any OHA during pregnancy. The American Diabetes Association also does not consider OHAs safe during pregnancy. However, the UK National Institute of Health and Care Excellence (NICE) has concluded that 2 drugs- Metformin and Glyburide are safe during pregnancy. As of now, Insulin remains the drug of choice of GDM due to its safety and efficacy.

Three drugs have a promising future in terms of management of GDM, i.e. Glyburide (Second generation sulphonylureas), Metformin (Biguanide) and Acarbose (α -glucosidase inhibitor). The primary mechanism by which each drug works to reduce blood glucose levels is different. Glyburide increases Insulin secretion, Metformin decreases endogenous production of glucose in the liver while Acarbose reduces absorption of carbohydrates from the small intestine. While the first two have considerable amount of research backing their use in GDM, Acarbose is not widely researched yet. Well-controlled clinical trials have been difficult to perform as it is difficult to distinguish teratogenicity due to increased blood glucose levels or due to OHA exposure. However, one of the criteria of safety of a drug is whether or not it crosses the placenta.

Glyburide (*Glibenclamide*) is the most widely researched OHA when it comes to management of GDM. The placental transfer is minimal and it has a favourable effect on the blood sugar levels. However, its safety during the first trimester is questionable and may lead to increased neonatal morbidity. It has also shown to cause neonatal hypoglycemia in some cases which may be harmful to the fetus. However, research has shown that there is no significant difference in the mother's blood glucose levels and pregnancy outcomes when glyburide is

compared with insulin. The safety of other sulphonylureas has not been evaluated yet.

Metformin is a biguanide that is widely used in treating diabetes and PCOS. Clinical trials donot show any difference in pregnancy outcomes when compared with insulin. Metformin crosses the placenta in large amounts but has not shown to cause any fetal malformation or teratogenicity. Metformin has also shown to reduce early pregnancy loss in pregnant women with PCOS. Use of metformin is considered safe in pregnancy, especially with pregnant women with PCOS. Another benefit of using metformin is that it does not cause fetal hypoglycemia as does glyburide. However, these trials have had a small sample size and thus, results from a well-controlled, randomized clinical trial is still awaited. The efficacy of metformin as a monotherapy is still debatable and is best used as an adjunct to insulin therapy.

Acarbose as a nutrient blocker has had very few but promising results in management of GDM. Since only 2% gets absorbed into the body, the chances of it getting transmitted through the placenta are very low. It is especially helpful in controlling post-prandial hyperglycemia. When the effect of acarbose, glyburide and insulin was measured in terms of blood glucose levels, there was no significant difference in the effect of these three. However, there is a lack of observational data and no randomized, controlled trial to showcase the safety and efficacy of this drug in terms of maternal and neonatal outcomes is available.

The use of OHAs, especially glyburide, has brought about a change in the approach to management of GDM but more high-quality research and randomized clinical trials are required to confirm their safety. The convenience that comes with taking pills at meal times when compared to the struggle of multiple daily injections of insulin is surely a reason enough to delve into. The major obstacle to the creation of evidence-based criteria is the fear of the potential adverse drug effects on the fetus.

SHAMBHAVI KAMAT

WHAT'S COOKING?

SPROUTS CHAAT



Ingredients:

- Boiled sprouts 15gm
- Chickpea 15gm
- Onion , chopped 20 g
- Cucumber , chopped 1 medium
- Chaat masala ½ tsp
- Cumin seed powder ½ tsp
- Coriander leaves 1 tsp
- Mint leaves(chopped) 1 tsp
- Lemon juice ½ tsp
- Salt, red chili powder & pepper to taste

Method:

1. Steam the sprouts
2. Soak Chickpeas overnight. Drain out the water and boil with 3 cups of water and a pinch of salt till it tenders
3. Mix sprouts, chick peas, onion, cucumber, green coriander leaves, chaat masala red chili powder, cumin seed powder, mint leaves, lemon juice, salt and pepper. Serve hot

Energy (Kcals)	Protein (gms)	Carbohydrates (gms)	Fats (gms)	GI
110	7.4	25	1.5	Low

BUCKWHEAT DHOKLA



Ingredients

- Buckwheat flour 20g
- Low fat curds 1 tbsp.
- Ginger-chilli paste 1 tsp
- Oil ¼ tsp
- Chopped coriander 1 tbsp
- Salt to taste

Method

1. Mix buckwheat flour, curd and ginger chilli paste well to make the dhokla batter

2. Keep aside to ferment for 2 to 3 hours
3. Add salt to the batter and mix well
4. Mix gently and pour the batter into a greased thali
5. Steam for 10 minutes till the dhoklas are firm
6. Serve hot garnished with coriander

Energy (Kcals)	Protein (gms)	Carbo-hydrates (gms)	Fats (gms)	GI
109	3.9	16	2.1	Low

HOW KNOWLEDGEABLE ARE YOU?

- 1) Diabetes caused by a clearly recognizable cause is known as –
 - a. Primary diabetes
 - b. Type 2 diabetes
 - c. Secondary diabetes
 - d. Maturity Onset Diabetes of the Young
- 2) Which ethnic groups are more likely to develop type 2 diabetes?
 - a. Latinos
 - b. African – Americans
 - c. Caucasians
 - d. Pima Indians
- 3) Risk factors for type 2 diabetes include all of the following except –
 - a. Sedentary lifestyle
 - b. Advanced age
 - c. Smoking
 - d. Obesity
- 4) Which of the following is not essential to assess the risk of an overweight/obese subject for developing type 2 diabetes?
 - a. Body mass index
 - b. Waist circumference
 - c. Family history of diabetes
 - d. Birth weight
- 5) Which of the following statement is true about metabolic syndrome?
 - a. Associated with lower body obesity
 - b. Associated with increased risk for diabetes mellitus and cardiovascular disease
 - c. Associated with type 1 Diabetes mellitus
 - d. Associated with Alzheimer's disease
- 6) Among female children and adolescents, the first sign of type 1 diabetes may be:
 - a. Rapid weight gain
 - b. Constipation
 - c. Genital candidiasis
 - d. Insomnia
- 7) Which region of the world has the highest incidence rates of childhood-onset type 1 diabetes?
 - a. Africa
 - b. Asia
 - c. Eastern Europe
 - d. Northern Europe
- 8) Which of the following drugs is associated with clinical weight gain?
 - a. Sibutramine
 - b. Pioglitazone
 - c. Pramlintide
 - d. Metformin
- 9) Fruits, vegetables and cereals are potent sources of except
 - a. Antioxidants
 - b. Carbohydrate
 - c. Saturated fat
 - d. Dietary Fibre
- 10) The essential fatty acids that must be derived from the diet are:
 - a. Stearidonic acid and eicosatetraenoic acid
 - b. Eicosapentaenoic acid and docosapentaenoic acid
 - c. Linoleic and alpha-linolenic acid
 - d. Gamma-linoleic acid and arachidonic acid

ANSWERS:

1) d
2) a
3) c
4) d
5) b
6) a
7) d
8) a
9) c
10) c

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BOOK REVIEW

RSSDI text book of Diabetes Mellitus; Editor-in-Chief: H B Chandalia, Executive Editor: G R Sridhar, Editors: A K Das, S V Madhu, V Mohan, P V Rao

Jaypee Brothers Medical Publishers; New Delhi; 2014; pages 1457; Price Rs 2995

The third edition of RSSDI Text Book of Diabetes Mellitus (D M) has been published six years after the second edition. It is authored and edited by those clinicians and professors who have been teaching and practising diabetes over many years within the country. A few chapters are contributed by Non-resident Indians. As pointed out by the editor-in-chief, this edition has undergone considerable revision. The material published both within the country and outside till the end of 2013 has been critically analysed and included. A few topics which are paid scant attention in other books, like-the complexity of insulin resistance, the criteria applicable to metabolic syndrome in Asians, challenges in the management of children and elderly with diabetes, musculoskeletal manifestation of diabetes, malnutrition modulated diabetes, Latent Autoimmune Diabetes in Adults (LADA), neonatal diabetes and the role of Yoga and relaxation techniques are unique to this book.

The flow chart on the management of diabetic ketoacidosis available in this book should be in possession of all ICUs. The colour pictures of retinopathy, foot lesions, skin diseases and musculoskeletal manifestation are well presented. The role of alternate therapy is extensively

discussed. The guidelines for the beginner to organise a diabetic clinic and optimal health care for diabetes amidst diversity of social, economic and regional food habits is noteworthy. The limitation of stem cell therapy as of now is a good reminder. Some controversial issues are discussed in individual chapters. Much alike the chapter on A Glimpse in the Future, I wish a full chapter was devoted to controversies in diabetes. New chapters added in this edition are valuable and discuss important current issues. These include Sleep and Type 2 diabetes-mellitus, Early-onset Type 2 DM, Nutrient blockers and Bromocriptine, Insulin Pump Therapy, Glycemic Management in Hospitalized Patients, Continuous Glucose Monitoring System, Vitamin D and DM, HIV in Diabetes, Diabetes and Cancer.

The appendix is retained from the previous edition and gives a wealth of information applicable to Indian subjects like BMI and waist circumference and laboratory values in S I and conventional units. The index has attained perfection. The novel feature of this edition is mentioning the chapter number on the right edge of each page.

The book will prove to be valuable to students, physicians, diabetologists, endocrinologists and providers of diabetes care. It should be on the shelf of every medical library. The availability of this book has made the Western text books redundant. The single volume covering so many topics is bulky and heavy. I wish it was brought out in two volumes.

**C. Munichoodappa. F.R.C.P.C.
Diplomate, American Board in Internal Medicine
Bangalore
Email id: dr.munichoodappa@gmail.com**

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DIABETES TODAY

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INSULIN GLARGINE INJECTION

TOUJEOTM SoloStar[®] Abridged Prescribing Information

COMPOSITION: Insulin glargine 300 U/mL. 1 mL contains 10.91 mg insulin glargine LP, corresponding to 300 U of insulin glargine. **INDICATION:** For the treatment of diabetes mellitus in adults. **DOSAGE AND ADMINISTRATION:** ToujeoTM is given subcutaneously. ToujeoTM is administered once daily, at any time during the day, preferably at the same time every day. The recommended daily starting dose is 0.2 U/kg once daily followed by individual dosage adjustments. When needed, patients can administer their injections up to 3 hours before or after their usual time of administration. The desired blood glucose levels as well as the doses and timing of anti-hyperglycaemic medications must be determined and adjusted individually. ToujeoTM is not the insulin of choice for the treatment of diabetic ketoacidosis. Changing from once-daily basal insulin products to once-daily ToujeoTM can be done unit-to-unit based on the previous basal insulin dose. Changing from twice-daily basal insulin products to once-daily ToujeoTM, the recommended initial ToujeoTM dose is 80% of the total daily dose of the basal insulin that is being discontinued. ToujeoTM must not be mixed with any other insulin products, ToujeoTM must not be diluted. The safety and effectiveness of ToujeoTM has not been established in paediatric patients (under 18 years of age). ToujeoTM can be used in elderly patients, in patients with renal impairment and in patients with hepatic impairment. Close glucose monitoring is recommended. **SAFETY-RELATED INFORMATION Contraindications:** ToujeoTM must not be used in patients hypersensitive to insulin glargine or any of the excipients. **Warnings:** No Core Safety Information **Precautions: General:** Insulin treatment generally requires appropriate diabetes self-management skills including glucose monitoring, proper injection technique and hypo and hyperglycaemia management. Patients and their relatives must know what steps to take if hyperglycaemia or hypoglycaemia occurs or is suspected, and they must know when to inform a physician. Hypoglycaemia: The time of occurrence of hypoglycaemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen is changed. As with all insulins, particular caution should be exercised, and intensified blood glucose monitoring is advisable, in patients in whom sequelae of hypoglycaemic episodes might be of particular clinical relevance. The prolonged effect of subcutaneous ToujeoTM may delay recovery from hypoglycaemia. In patients with renal impairment or severe hepatic impairment, insulin requirements may be diminished. In the elderly, progressive deterioration of renal function may lead to a steady decrease in insulin requirements. Hypoglycaemia can generally be corrected by immediate carbohydrate intake. So that initial corrective action can be taken immediately, patients must carry a minimum of 20 grams of carbohydrates with them at all times. Intercurrent illness: Requires intensified metabolic monitoring. In many cases urine tests for ketones are indicated, and often it is necessary to adjust the insulin dose. **Medication errors prevention:** Insulin label must always be checked before each injection to avoid medication errors between ToujeoTM and other insulins. The patients must also be instructed to never use a syringe to remove ToujeoTM from the SoloStar pre-filled pen into a syringe and not to re-use the needles. **Pregnancy & Lactation:** It is essential for patients with pre-existing or gestational diabetes to maintain good metabolic control throughout pregnancy to prevent adverse outcomes associated with hyperglycaemia. Toujeo can be used during pregnancy, if clinically needed. Insulin requirements may decrease during the first trimester and generally increase during the second and third trimesters. Immediately after delivery, insulin requirements decline rapidly. Careful monitoring of glucose control, is essential in such patients. Patients with diabetes must inform their doctor if they are pregnant or are contemplating pregnancy. **Adverse Reactions:** Hypoglycaemia is most frequent and may occur if the insulin dose is too high in relation to the insulin requirement. A marked change in glycaemic control may cause temporary visual impairment. Lipodystrophy may occur at the injection site. Allergic reactions at the injection site includes redness, pain, itching, hives, swelling or inflammation. Immediate type allergic reactions are rare

For full prescribing information please write to Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

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For the use of a registered medical practitioner or a hospital or a laboratory only. SAN GLA17121565 04/18



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Compared to Glimepiride and Sitagliptin,
INVOKANA[®] 100mg is non-inferior^{1,3}
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Invokana[®]
canagliflozin tablets

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References:

1. INVOKANA[®] India Prescribing Information (January 2014) 2. Lavallo-González FJ et al. Diabetologia. 2013;56(12):2582-92 3. Cefalu WT et al. Lancet 2013;382(9896):941-50 4. Leiter LA et al. Diabetes Care. 2014. 5. Stenlöf K et al. Diabetes Obes Metab. 2013;15(4):372-82.

For the use of a Registered Medical Practitioner or a Hospital or Laboratory Canagliflozin tablets 100mg / 300mg

INVOKANA[®]

Composition and Strength: Canagliflozin 100 mg / 300mg. Each 100 mg tablet contains 102 mg Canagliflozin hemihydrate, equivalent to 100 mg Canagliflozin. Each 300 mg tablet contains 306 mg Canagliflozin hemihydrate, equivalent to 300 mg of Canagliflozin.
Pharmaceutical form: 100 mg - The tablet is yellow, capsule-shaped, immediate-release and film-coated, with "CFZ" on one side and "100" on the other side. 300 mg - The tablet is white, capsule-shaped, immediate-release and film-coated, with "CFZ" on one side and "300" on the other side. **Therapeutic Indications:** INVOKANA[®] is indicated as an adjunct to diet and exercises to improve glycemic control in adults with type 2 diabetes mellitus as monotherapy and combination therapy. **Dosage and Administration:** The recommended starting dose for adult > 18 years is 100 mg or 300 mg once daily orally preferably before the first meal of the day. A starting dose of 100 mg once daily should be used in patients on loop diuretics and patients > 75 years of age. In patients with an eGFR 45 mL/min/1.73 m² to < 60 mL/min/1.73 m², the dose of INVOKANA[®] is limited to 100 mg once daily. The 300 mg dose may be considered for patients with an eGFR < 45 mL/min/1.73 m² [CrCl < 45 mL/min], as it would not be effective in these settings. In patients with evidence of reduced intravascular volume with INVOKANA[®] treatment. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Precautions:** INVOKANA[®] has not been studied in pediatric patients (< 18 years), patients with type 1 diabetes and is therefore not recommended for use. INVOKANA[®] should not be used for the treatment of diabetic ketoacidosis or in patients with an eGFR < 45 mL/min/1.73 m² [CrCl < 45 mL/min], as it would not be effective in these settings. In patients with evidence of reduced intravascular volume, correcting this condition prior to initiation of INVOKANA[®] is recommended. **Drug Interactions:** The metabolism of INVOKANA[®] is primarily via glucuronide conjugation mediated by UDP glucuronosyl transferase 1A9 (UGT1A9) and 2B4. If a combined inducer of these UGTs and drug transport systems (e.g., rifampicin, phenytoin, barbiturates, phenobarbital, ritonavir, carbamazepine, efavirenz) must be co-administered with INVOKANA[®], monitor HbA1c in patients receiving INVOKANA[®] 100 mg once daily with consideration to increasing the dose to 300 mg once daily if additional glycemic control is needed. INVOKANA[®] neither inhibits cytochrome P450 CYP1A2, CYP2A6, CYP2C9, CYP2D6, or CYP2E1, CYP2B6, CYP2C8, CYP2C9, nor induces CYP1A2, CYP2C9, CYP2B6, CYP3A4 at higher than therapeutic concentrations. INVOKANA[®] is a P-glycoprotein (P-gp) substrate, and inhibits P-glycoprotein mediated transport of digoxin with low potency. Patients taking digoxin or other cardiac glycosides (e.g., digitoxin) should be monitored appropriately. **Pregnancy, Breast-feeding and Fertility:** There are no adequate and well-controlled studies in pregnant women. INVOKANA[®] should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known if INVOKANA[®] is excreted in human milk. A risk to the breast-fed child cannot be excluded. The effect of INVOKANA[®] on fertility in humans has not been studied. **Adverse reactions:** In clinical studies of INVOKANA[®] the most commonly reported adverse reactions during treatment (> 5%) were vulvovaginal candidiasis, urinary tract infection, and polyuria or pollakiuria. Other adverse reactions in clinical studies of INVOKANA[®] that occurred at a rate < 2% in placebo-controlled studies were adverse reactions related to reduced intravascular volume (postural dizziness, orthostatic hypotension, hypotension, dehydration, and syncope), skin rash, and urticaria. In the event of an overdose, it is reasonable to employ the usual supportive measures, including monitoring of vital signs and observation of clinical conditions. **Overdose:** Single doses up to 1600 mg of INVOKANA[®] in healthy subjects and INVOKANA[®] 300 mg twice daily for 12 weeks in patients with type 2 diabetes were generally well-tolerated. In the event of an overdose, it is reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. INVOKANA[®] is not expected to be dialyzable by peritoneal dialysis.

Storage: Store below 30°C and in dry place. Protect from light. Keep out of reach of children.

Warning: To be sold by retail on the prescription of Registered Medical Practitioner only. Version: CCDS 09 Jan 2014

For complete prescribing information, please contact: Johnson & Johnson Private Limited, Arena Space, Behind Majas Depot, Off J.V. Link Road, Jogeshwari (E), Mumbai 400060



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