1 Introduction

Maternal nutrition significantly impacts the health of the mother and the development of the fetus. Optimum nutrition status minimises maternal complications such as anaemia, gestational diabetes mellitus, pre-eclampsia, and foetal problems such as preterm birth, low birth weight and birth defects. The period leading to conception is also critical as it lays the foundation of a healthy pregnancy and the future development of the baby. Maternal health during gestation and its association with gestational diabetes mellitus (GDM) is currently attracting attention due to the implications of GDM on the mother and the baby. Although there is some understanding of proper nutrition during pregnancy, the misconception of "eating for two" still exists in many families. Maintenance of ideal body weight, following a nutritious and balanced diet, involving in adequate physical activity, entering pregnancy at a younger age, correcting or controlling any metabolic imbalances or health conditions before conception, educating oneself of the signs and symptoms of pregnancy-related problems and complications, following the antenatal regimen adviced by the doctor and readiness to pregnancy are all factors that influence a safe and healthy pregnancy journey. Rapid urbanisation, which is associated with increasing prevalence of non-communicable diseases, has also impacted GDM not only in urban areas but also in rural areas. Public health strategies thus need to focus on bringing about improvements in health care and efforts must be taken for increasing the awareness on GDM, its risk factors and complications in both urban and rural sectors.

The available data on GDM points towards its increasing incidence in women of all ethnicities and social strata. The International Diabetes Federation (IDF) Atlas 2021 revealed the Southeast Asian region had the highest prevalence of GDM at 28 percent compared to 8.6 percent in the Middle East and North American regions and an estimated 87.5 percent affected with hyperglycaemia in pregnancy was found among low and middle income countries. Savitha and Mageshwari (2013) reported an exponential increase in the incidence of gestational diabetes mellitus from four to six percent in the early 90s to 16 to 20 percent of all pregnancies in India. The trend of its increase is similar

to Type 2 DM posing a greater risk for maternal and foetal complications (Bhavadharini et al., 2016). In a recent meta-analysis and systematic review conducted on the national and region wise prevalence of GDM in India, an overall prevalence rate of 13 percent was reported and the highest GDM prevalence rate was found in Northern regions with 16.1 percent followed by 12.6 percent in Southern regions (Mantri et al. 2024).

GDM defined as " any degree of glucose or carbohydrate intolerance with onset or first recognition during pregnancy" (Metzger et al., 2007; Seshiah et al., 2006) is not a newly identified metabolic problem occurring in pregnancy, but dates back to the early 1800s were it was first described by Heinrich Bennewitz, who reported symptoms of excessive thirst and increased urination in one of his patient who delivered a macrosomic baby and ending up with stillbirth. This further led researchers in the late 1800s and early 1900s to conduct further studies on GDM and also develop a classification system for prediction of pregnancy complications of GDM and establish robust treatment plans for positive maternal and foetal outcomes.

During pregnancy, there are a series of physiological and metabolic changes occurring in the woman's body supporting the growth and development of the foetus. In the first trimester, the insulin sensitivity increases to enhance the uptake of glucose to build up reserves for the additional energy needs that occur during the later part of pregnancy. But as pregnancy proceeds, the elevated levels of hormones namely estrogen, progesterone and other placental hormones diminish the insulin sensitivity leading to insulin resistance thereby causing a slight elevation in blood glucose. This is a normal phenomenon that is necessary to transport glucose across the placenta to nourish the growing foetus. The pregnant woman's body adjusts to these changes by secreting more insulin for maintenance of glucose homeostasis and when this fails it leads to GDM.

There are several risk factors for GDM such as advanced maternal age, higher pre-pregnancy body mass index, obesity, family history of Type 2 DM, hypothyroidism and polycystic ovarian syndrome which needs to be closely monitored for early detection and management of GDM. Previous history of stillbirth, macrosomia, premature delivery, pregestational smoking and being a primigravida also were reported as risk factors influencing GDM (Zhang et al., 2021).

Globally, lifestyle changes have caused a marked increase in the incidence of obesity, leading to the rise in GDM thereby paving the way for a wide spectrum of complications in pregnancy (Ye et al., 2022). These potential changes such as obesity, overweight, etc have in one way contributed to the dip in pregnancy rates from 7.9% (NFHS 2015-16) to 6.8% (NFHS 2019-21) and fertility rates from 2.2% (NFHS 2015-16) to 2.0% (NFHS 2019-21). GDM has been reported to influence the frequency of stillbirth and miscarriage among other factors (Kuppusamy et. al, 2023).

GDM thus is a precursor to future type 2 DM, necessitating preventive measures (Kalra et al., 2011) as its immediate and long lasting complications affect not only the woman but also her offspring. Herath et al. (2017) in a decade long follow-up study found that the risk for diabetes mellitus is ten times higher in women with GDM compared to Non-GDM women. Additionally, the risk of Type 2 DM extends beyond the GDM women to her offspring. A multiethnic long-term investigation conducted by Holder et al. (2014) revealed a five-fold increase in the likelihood of impaired glucose tolerance among children born to women with GDM than those without it. Extensive research on GDM and its consequences has provided evidence that intrauterine exposure of foetus to maternal hyperglycaemia can lead to adverse outcomes such as childhood obesity and glucose intolerance in the future.

The "foetal origin of adult disease" - Barker hypothesis stated that “gestational programming may critically influence adult health and disease” (Barker, 1995). As there is a possibility of GDM to recur in the female offspring of a GDM woman and the susceptibility of GDM occurrence to continue from one generation to the next generation, it is crucial to take measures towards prevention of GDM. Preventive measures must encompass proper lifestyle, adequate nutrition and physical activity along with the initiation of early screening and identification of women at risk of GDM at the first antenatal period itself and continued till delivery and regular annual follow-up of those detected with GDM. Preventive measures for not developing Type 2 DM in children need to be begin from the time they are in the mother’s womb and continued from early childhood throughout life (Tuomilehto, 2005).

In 1964, O'Sullivan and Mahan introduced the initial diagnostic screening exam for gestational diabetes mellitus (GDM). They defined GDM as “occurring when a pregnant

woman, during a three-hour 100-gram oral glucose tolerance test, displayed glucose levels surpassing 2 standard deviations above the average on at least two out of the four readings".

After the diagnostic test for GDM by O'Sullivan and Mahan, many other diagnostic screening methods came up in the medical fraternity however no universal consensus was achieved. The WHO Expert Committee on Diabetes Mellitus released the first guideline on diabetes mellitus in 1965 and continued to publish newer guidelines in 1980, 1985, 1999 and 2013. In India the treatment for GDM began in the late 1990s but there were wide variations in the approach of the treatment provided for GDM women in government and private-run healthcare facilities. India also did not have a standardised screening method and diagnostic process for GDM management (Thanawala et al., 2021).

Later, various national and international health organisations proposed several criteria for diagnosing GDM. These criteria however differed in their specifications, such as the requirement for fasting or non-fasting status, the quantity of glucose administered, the count of blood samples and the total threshold values evaluated for detecting GDM (Linnenkamp, 2014). Currently, WHO (1999), DIPSI, ADA and IADPSG recommendations are the commonly used methods for screening and diagnosis of GDM. The results from the Hyperglycemia Adverse Pregnancy Outcome (HAPO) study, involving 23,316 women, clearly established the correlation between hyperglycemia and maternal and neonatal complications, strongly advocating for the development of preventive strategies for GDM.

The Government of India issued the guidelines for GDM management in 2014. It underwent revision in 2018, and still continues to be the existing operating guidelines for GDM in India. These guidelines address screening techniques, diagnosis criteria, and management of GDM, as well as the training of healthcare workers at various levels. However, the uniform and consistent implementation of these guidelines across all regions of the country remains a challenge. GDM risk screening is another essential component to be considered as part of initial screening process to identify those at risk of developing GDM. When GDM is identified early, implementing evidence-based lifestyle intervention can lower the chances of the mother and her baby developing adverse outcomes. A study by Ryan et al. (2018) on early screening techniques and subsequent management strategies of GDM resulted in improved maternal and foetal outcomes especially emergency caesarean surgery, neonatal hypoglycaemia and macrosomia.

The management and treatment of women diagnosed with gestational diabetes mellitus is an emerging challenge for the healthcare system. Thus the current management strategies for GDM require the integration of a multidisciplinary team comprising physicians, specialists, nurses and pharmacists to achieve optimal patient results and prevent further complications. The development of prevention strategies for GDM would facilitate proper treatment of gestational diabetes mellitus and help improve maternal and foetal outcomes (Quintanilla et. al, 2024).

However, there are barriers that cause hindrances in proper management of GDM. From the viewpoint of healthcare professionals, the obstacles for effective GDM management are categorised at two levels namely the individual level and the health system level. At the individual level, it is doubtful that women diagnosed with GDM can manage GDM because of missing out on follow-up visits scheduled at the healthcare facility. At the health system level, the lack of adequate personnel hinders the effective dissemination of treatment practices regarding the management of GDM. The shortage of resources such as lack of IEC material, glucometers, the strips used for it, etc. makes it difficult to assist those with GDM to manage their condition effectively. Finally, there is a lack of standard protocols for managing GDM, which creates confusion at all levels of the healthcare system causing inefficient management of GDM (Sahu et al., 2021).

A multidisciplinary approach is essential in GDM as GDM management involves extensive medical, nutritional, behavioural and lifestyle considerations that move beyond simple glucose management. Bagias et al. (2021) explains the necessity of multidisciplinary approach for GDM management in each antenatal visit to ensure both maternal and foetal well-being. They emphasize that each visit should encompass lifestyle interventions, glycaemic control, maternal blood pressure, proteinuria and other obstetric complications. A multidisciplinary team comprising obstetricians, endocrinologists, nutritionists, nurses and diabetes educators can collectively address these multifaceted aspects of care. Furthermore, a study by Harthi et al. (2022) underscores the significance of multidisciplinary approach in GDM management. They found that the implementation of a structured comprehensive multidisciplinary programme for GDM management resulted in a positive impact on enhancing maternal and foetal outcomes.

In India, the Women in India with Gestational Diabetes Strategy (WINGS-10) study is one of the extensive studies which has given conclusive evidence that a structured model

of care for GDM women has resulted in the achievement of pregnancy outcomes similar to those without GDM (Uma et.al, 2017). The lack of such comprehensive protocols is evident in most healthcare setups in India. As a consequence, there is a rise in the number of GDM patients each year even though steps are being taken towards screening and treatment. According to Kintiraki and Goulis (2018), a multidisciplinary treatment approach that includes lifestyle modifications, medical nutrition therapy, adequate physical activity and pharmacological intervention is the best approach to GDM management.

Although MNT has been described as the first line of treatment in all the different guidelines, medication has been adopted at diagnosis itself in many instances. Screening for GDM is also done at different points during pregnancy thus failing to detect and treat the condition early. Evidence indicates that MNT should be the first management approach for GDM women and can aid in the reduction of pregnancy complications and also effectively manage glycaemic control (Thomas de et al., 2013). Studies have demonstrated that 70 to 85 percent of GDM women were able to maintain glycaemic targets with MNT alone (Mayo et al., 2015).

The main objectives of MNT should be (i) to ensure adequacy of nutrients for both the mother and the growing foetus (ii) to avoid ketosis in the mother (iii) to promote optimal growth of the foetus and (iv) to avoid excessive gestational weight gain in the mother. It is also important to ensure that nutrition plans are individualised based on the mother's weight, cultural and ethnic preferences so that compliance with the MNT can be achieved (Vasile et al., 2021). There is evidence that modified dietary interventions lower FBS and PPBS values thereby decreasing the need for medication in GDM women as well as reducing macrosomia in their offsprings (Yamamoto et al., 2018)

Studies on calorie restriction, low glycaemic index (GI) diets, and dietary approaches to stop hypertension (DASH) diets have reported effective glycaemic control and positive maternal and fetal outcomes however heterogeneity in the duration and type of medical nutrition therapy interventions, baseline characteristics of the population and small sample size of studies limits arriving at a consensus on the best MNT approach for GDM management (Yamamoto et al, 2018). Another study suggested that there is room for enhancing conventional nutritional guidance for women diagnosed with GDM. However, the optimal dietary regimen for managing GDM remains uncertain. (Hernandes et al., 2018).

A systematic review and critical appraisal of guidelines for MNT for GDM reported shortcomings in the clinical practice guidelines established by large organisations and advisory bodies. These were primarily deficient in identifying MNT as a holistic GDM care model with the exception of guidelines from the Academy of Nutrition and Dietetics (The Academy, USA). Furthermore, only the clinical practice guidelines developed by The Academy incorporated a standardised approach for providing MNT for GDM, utilising the Nutrition Care Process (NCP) which involves four distinct phases: nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation (Tsirou et al., 2019). The clinical practice guidelines of The Academy recommend that GDM women should be referred to a registered dietitian for providing individualised MNT that includes an initial nutrition education (60–90 min) followed by at least two individual review visits (30–45 min duration). It is also important to make sure that diet advice and nutrition counselling provided by the dietician are easy to comprehend and practical guidance on using and including healthy food options and cooking methods are done to motivate women to eat healthy (Kapur et al., 2020).

Medical Nutrition Therapy is the cornerstone of GDM management (Tsirou et al., 2019) and following the NCP is crucial for effective nutritional management of GDM. A study done by registered dietitians on the impact of GDM nutrition practice guidelines (NPG) on pregnancy outcomes showed that the implementation of NPG reduced insulin usage and significantly lowered glycosylated haemoglobin in the NPG group compared to those following the usual MNT group (Reader et al., 2006).

According to Duarte-Gardea et al. (2018), the recent guidelines for GDM by the Academy of Nutrition and Dietetics, focusing on individualised MNT based on NCP is helpful for GDM women for effective blood glucose control as well as attain proper weight gain while providing essential macro and micronutrients. A recent study focusing on individualised nutrition intervention showed better control of gestational weight gain, improved glucose tolerance and lipid metabolism and early onset of lactation. There was also a marked reduction in the occurrence of adverse maternal and foetal outcomes (Lou et al., 2023).

The development of such a comprehensive MNT protocol involving all the facets of NCP became imperative to ensure early GDM risk screening and early nutritional

intervention, aimed at mitigating the incidence of GDM and minimising adverse outcomes on the mother and her child.

Research Gap

While national guidelines for managing GDM exist, their effective implementation remains uncertain, particularly as the prevalence of GDM continues to rise in India. Implementing a protocol-driven, personalised medical nutrition therapy based on the nutrition care process becomes imperative in this scenario as MNT is the first step in the management of GDM. The need for GDM risk screening to identify those at risk for GDM and planning of an early nutrition intervention based on NCP seemed to be the best preventive approach for GDM. Bridging this research gap highlights the necessity to investigate current practices and establish a sustainable standard operating protocol for MNT for GDM. Validating and implementing this protocol is crucial for reducing adverse maternal and fetal outcomes, thereby preventing diabetes mellitus among women and future generations. By promoting good nutritional practices among women to ensure optimum health of mothers, attain the best possible start for our future generations and thus align with "Sustainable Development Goal 3 (SDG3), which aims to ensure healthy lives and promote well-being for all at every stage of life".

The objectives of the study were framed as follows.

Primary Objective

To

- Develop and optimise a Sustainable Standard Operating Protocol (SSOP) for Medical Nutrition Therapy (MNT) for GDM management
- Evaluate the maternal and foetal outcomes on implementation of the SSOP among selected pregnant women

Secondary Objectives

To

- Assess the current practices and protocols followed for GDM management and identify the lacunae in MNT for GDM in selected hospitals
- Develop a mobile application for the SSOP of GDM management
- Implement the SSOP among selected pregnant women and assess the maternal and foetal outcomes

Hypothesis (H0)

- There is no significant difference in the maternal and foetal outcomes with a protocol-based MNT compared to the existing MNT practices for GDM in the selected hospital.

Alternate Hypothesis (H1)

- There is a significant difference in the maternal and foetal outcomes with a protocol-based MNT compared to the existing MNT practices for GDM in the selected hospital.