5

Summary and Conclusion

GDM referred to as glucose intolerance with first onset during pregnancy is emerging as a major public health problem in women with its increasing prevalence globally. Many studies have demonstrated the impact of GDM on maternal and foetal outcomes highlighting the need for comprehensive management of pregnant women targeted towards prevention of GDM. Although guidelines and recommendations from both national and international health organizations exist for GDM, their actual implementation in clinical practice is still questionable. Hence the present study was undertaken with the objective to study the existing practices/protocols in the management of GDM, identify the lacunae in the current practices, develop and implement a sustainable standard operating protocol for improved MNT practices.

The methodology of the study was carried out in four phases.

Phase I of the study included a baseline survey which was carried out in four multispeciality hospitals and three maternity hospitals in Kochi, Kerala to understand the current practices and protocols followed in the management of GDM through purposive sampling criterion. Details regarding demographic profile, current practices and protocols were collected from 200 HCPs comprising 35 obstetricians, 14 diabetologists, 21 neonatologists, 55 dietitians, 35 nurses, 7 diabetes educators, 14 physiotherapists, 5 psychologists, 7 biochemists and 7 quality control managers of the respective hospitals involved in GDM management using a validated questionnaire. Details regarding treatment received with respect to the current practices and protocols followed in the selected hospitals, demographic profile, anthropometric measurements, diet and lifestyle patterns, biochemical investigations, previous medical and obstetric history, delivery details, maternal and foetal outcomes were obtained from 160 pregnant women comprising 106 GDM and 54 Non-GDM women using a validated interview schedule according to an inclusion and exclusion criteria after obtaining informed consent. Both GDM and Non-GDM women were recruited in the study to identify and compare the similarities and/or differences in the management practices followed among GDM and Non-GDM women. A

gap analysis was done between the current practices or protocols followed in and the national guidelines to identify the differences or lacunae in the existing GDM practices.

In Phase II, after identification of lacunae in the existing GDM practices in the hospitals, development, validation and optimisation of a sustainable standard operating protocol (SSOP) for medical nutrition therapy of GDM was done based on the GDM guidelines given by various organizations such as AND, Institute of Medicine and the National Guidelines, Government of India. The SSOP based MNT comprised guidelines for "GDM risk screening, nutrition assessment, nutrition intervention, nutrition monitoring and evaluation". The validation of the developed SSOP was done among ten healthcare professionals comprising five doctors and five dietitians using content validity index. Optimisation of the SSOP was done by implementing the SSOP among ten pregnant women who were subdivided into experimental (N=5) and control group (N=5) based on their willingness to be allotted to the respective group. The SSOP was then implemented from the first trimester till delivery spanning a period of nine to ten months and assess the glycaemic control and also the maternal and foetal outcomes.

In Phase III a Mobile App was developed based on the SSOP for MNT of GDM. Use of mobile applications in healthcare sectors have become common now aiding in patient care and management, monitoring, maintenance of health record and time management. Use of mobile for computing purposes especially while planning the patient care plan is very helpful as it is faster and provides more accurate access. Hence, the need for a Mobile App for the SSOP based MNT was greatly felt so as to easily conduct all the processes in the SSOP such as "GDM risk screening, nutrition assessment, nutrition diagnosis, nutrition intervention, nutrition monitoring and nutrition evaluation." The App was intended to aid healthcare professionals in GDM risk screening as well as planning of the subsequent steps in SSOP for MNT. The validation of the App was done by the same healthcare professionals who did the validation of the SSOP in Phase II. The optimisation of the App was conducted by sharing the App among 25 doctors and 25 dietitians in order to analyse the usability of the App. The App was used by the investigator in the implementation phase of the SSOP.

Phase IV of the study was conducted in one multispeciality hospital where permission was given to conduct the study. Pregnant women who came for antenatal

checkups at the outpatient unit of the department of obstetrics and gynaecology of selected hospital were recruited through purposive sampling criterion based on the inclusion and exclusion criteria. Face to face discussions and Power point presentations were conducted among the medical, paramedical and administrative team of the selected hospital before implementation of the SSOP. The SSOP based MNT implementation began with the GDM risk screening of all pregnant women visiting the hospital in their first trimester and recruitment into the study. A sample of 372 pregnant women were screened as GDM high risk, average risk and low risk and categorized into two groups, namely experimental group and control group each comprising of 186 participants. Pregnant women who agreed to follow the protocol based MNT throughout the gestation period formed the experimental group while the others formed the control group. The experimental group followed the SSOP based MNT while the control group followed the existing MNT practices in the selected hospital. All the pregnant women were followed from first trimester till delivery spanning a period of nine months to one year as delivery dates differed among the pregnant women. During the first trimester, eight pregnant women were withdrawn from the experimental group as there were two miscarriages, three abortions and three drop outs in the study. Hence the total sample size reduced to 364 pregnant women comprising 178 participants in experiment group and 186 participants in control group. The experimental groups were provided the SSOP based MNT as follows.

GDM high risk women were given a customised diet plan with diet counselling of 20 minutes duration and monthly nutrition reviews until delivery. Additionally, a group contact was created among the high risk group and sharing of three healthy recipe videos, real-time plate checks, clearing of diet-related queries and reminders for MNT guidelines and gestational weight gain was done.The GDM average risk women were give diet counselling of 20 minutes duration without a customised diet plan and three MNT reviews (one MNT review for each trimester) until delivery. A group contact was also created for this group with the purpose to send only MNT reviews. The GDM low risk women were not given any customised diet plan or nutrition reviews, but were provided diet counselling of 20 minutes at the first visit when they were recruited into the study. Furthermore, the high risk and average risk women in the experimental group were also advised to do 30 minutes of walking 3-5 times per week as part of the intervention however the results were not analysed as consistency could not be achieved due to doctor’s recommendation for rest

among participants. As part of nutrition education, two webinars of one hour duration was conducted on topics such as nutrition in pregnancy, importance of understanding gestational weight gain, gestational diabetes mellitus and its prevention among experimental group at every trimester with the help of educational tools such as Power point presentation. Checking the process flow and rectification of problems encountered from time to time and monitoring of all pregnant women was done by the investigator until all women delivered.

A knowledge attitude practice survey was conducted among a subset of 45 pregnant women in the experimental group before and after the nutrition education to analyse the effectiveness of the nutrition education provided to them. A detailed e-booklet on lactation and complementary feeding was developed and given to all participants after delivery irrespective of the groups that they belonged to.

Demographic details, anthropometric measurements, biochemical investigations, clinical data and diet patterns, gestational weight gain, delivery details, maternal and foetal outcomes of all participants were taken using the same interview schedule used in Phase I. All the study participants were followed until their delivery and all patient details noted from the Electronic Medical Record (EMR) of the selected hospital except for diet patterns which was directly taken through a 24-hour dietary recall. The findings of the study are described as follows.

Phase I: Baseline Survey on Current Practices and Protocols in the Management of GDM among HCPs

Demographic Profile of HCPs

- Based on gender, females outnumbered males in all the three categories namely doctors, dietitians and AHP and it was interesting to note that all 55 dietitians, as a category were all female.
- ANOVA done among the mean ages of HCPs showed significant difference between groups ($F=29.465$, $p<.001$). The mean age of doctors (43.73 ± 8.56, $p<.001$) was significantly greater compared to dietitians (33.87 ± 7.63, $p<.001$) and allied health personnel (34.92 ± 8.17, $p<.001$) indicating that compared to dietitians and allied health personnel, doctors had seniority with respect to age.
- The educational qualification among the HCPs significantly differed with all diabetologists and neonatologists having specialization in their field with MD or

DNB compared to 22 obstetricians with MD or DNB. Forty seven dietitians were post graduates and among allied health personnel, all diabetes educators, psychologists, biochemists and quality control managers were post graduates compared to 29 nurses and 7 physiotherapists who were graduates.

- ANOVA done among mean years of clinical experience among HCPs showed significant difference ($F=15.628, p<.001$). The mean years of clinical experience of doctors (13.91 ± 8.38, $p<.001$) was significantly greater compared to dietitians (8.58 ± 6.85, $p<.001$) and AHP (7.80 ± 5.62, $p<.001$). However, there was no significant difference seen in the years of clinical experience between dietitians and AHP ($p=0.805$) demonstrating that doctors had greater clinical experience compared to dietitians and allied health personnel equipping them with more knowledge on the strategies for GDM management.

Concepts and Perceptions of HCPs about GDM and Practices and Protocols for GDM Management

Responses of HCPs on GDM

- The views of HCPs on the prevalence of GDM and other factors were significantly different at five percent level with 89.1 percent responses from dietitians compared to 81.4 percent among doctors and 70.7 percent from allied health personnel.
- The perception of HCPs regarding risk factors for GDM also notably differed with 84.3 percent doctors, 69.1 percent dietitians and 64 percent AHP, showing distinct views. Similarly, regarding offspring complications, 61.4 percent doctors, 43.6 percent dietitians and 38.6 percent AHP showed varied perceptions.
- These differences in the concepts of GDM among HCPs can create barriers in adherence of guidelines or protocols existing in the selected hospitals towards proper GDM management practices.
- The responses of doctors, dietitians and AHP did not show significant difference on their perceptive about preventive measures for GDM indicating that all HCPs had a positive outlook towards implementation of preventive measures for GDM.

Delivery Outcomes commonly seen by HCPs among GDM women

- Ninety percent of doctors and 67.9 percent AHP stated polyhdramnios/oligohydramnios as the frequently seen delivery outcome, which significantly differed compared to 49.1 percent dietitians.

- The perception of HCPs on other delivery outcomes such as assisted showed significant difference with 81.4 percent doctors and 70.9 percent dietitians having distinct views compared to 50 percent AHP. Similarly the responses of HCPs significantly differed for post partum haemorrhage with 64.3 percent from doctors and 33.93 percent from AHP compared to only 18.2 percent from dietitians.
- It is recommended to do early screening and interventions for GDM preferably at first trimester to prevent the occurrence of such maternal complications.

Foetal complications commonly seen by HCPs among infants of GDM women

- Macrosomia was the frequently seen foetal complication among infants of GDM women by 95.7 percent doctors, 87.3 percent dietitians and 87.5 percent AHP.
- The responses of HCPs namely doctors, dietitians and AHP significantly differed for all other foetal complications such as spontaneous abortion, birth injuries, congenital malformations and neonatal hypoglycemia with 68.6 percent, 74.3 percent and 62.9 percent for spontaneous abortion; 92.9 percent, 50 percent and 20 percent for birth injuries; 36.4 percent, 63.6 percent and 53.6 percent for congenital malformations and 28.6 percent, 32.1 percent and 75 percent for neonatal hypoglycaemia respectively.
- Early interventions for GDM should be aimed towards prevention of such foetal complications.

Responses of HCPs on Protocols in GDM Management

- The responses of HCPs significantly differed with respect to integrated approach, as stated by 67.1 percent doctors, 72.7 percent dietitians and 44 percent AHP respectively. Their perception on the use of evidence-based national guidelines also was significantly differed at one percent level with all doctors showing a positive response compare to 94.5 percent responses from dietitians and 81.3 percent responses from AHP.
- There are deficiencies in the management strategies for GDM existing in the selected hospitals, highlighting the need for developing a multidisciplinary team approach and adopting evidence-based guidelines for provision of optimum care and treatment for such populations.

- All other management strategies such as use of standard operating protocols, documenting effectively, training of HCPs and conducting Multidisciplinary Rounds (MDR) did not show any significant difference among the groups suggesting that all HCPs considered these strategies as important in the management of GDM.

Gap Analysis of Current Practices and Protocols with National Guidelines regarding Medical Management of GDM

- The gaps identified in screening, assessment and diagnostic procedures for GDM namely early screening and use of operating guidelines for GDM, assessment of BMI based on pre-pregnancy weight and gestational weight gain and timing and criteria used for diagnostic procedures of GDM emphasise the need for a protocol based GDM management strategy to necessitate a systematic process flow for screening, assessment and diagnosis of GDM.
- The gaps identified in intervention, monitoring and evaluation for GDM such as MNT and exercise as the first line of intervention for GDM, choice of medicines, interdepartmental referrals, hyperglycaemia management of GDM women, hypoglycaemia management of offsprings, preliminary procedures for labour or delivery and routine time of delivery recommends the need for a standard operating procedures so that uniformity in intervention procedures can be maintained by HCPs involved in GDM management.
- The gaps identified in monitoring and evaluation procedures showed that postnatal reviews, pre-conception counselling and OGTT monitoring after delivery, post partum FBS and PPBS checks, follow up and evaluation procedures every year were not carried out effectively in the selected hospitals. It is thus essential to set up standard operating protocols in hospitals for regular monitoring and evaluation procedures for GDM management.

Concepts and Perceptions of Dietitians about MNT Practices and Protocols for GDM Management

Role and Importance of MNT

- Forty three (78.2%) dietitians reported glycaemic control as the prominent factor that influenced the need for MNT followed by 39 (70.9%) dietitians stating patient's doubts as the factor influencing the need for MNT.

- The departmental or institutional protocol with responses only from 8 (14.5%) dietitians was found to be the least influencing factor for the need of MNT, indicating that patient referrals to dietitians for MNT planning of GDM were not part of a standard operating protocol of the respective multispeciality hospital or maternity hospitals.

Confidence Level of Dietitians to follow SSOP for MNT and their Understanding of Evidence-based MNT guidelines for GDM

- Confidence level of dietitians showed that 29 dietitians (52.7%) were in the 'very confident' category indicating their confidence level in MNT planning for GDM. Twenty eight dietitians (50.5%) were in the 'confident' category suggesting their understanding of evidence-based MNT guidelines. There is still scope for improvement in MNT planning and increasing awareness among dietitians on the use of evidence-based MNT guidelines for GDM management.

MNT Components discussed for Diet Counselling of GDM

- Responses of dietitians on the mostly discussed and least discussed topics while providing diet consultation to GDM women revealed carbohydrate quantity and distribution as the mostly discussed topic and use of artificial sweeteners as the least discussed topic while providing diet consultation for GDM women.
- Postprandial blood glucose target levels was found to be the second least discussed topic indicating that the need for achievement of postprandial blood glucose target levels, as described in national guidelines were not part of diet consultation given by majority of the dietitians. These findings recommend training of dietitians to improve the diet consultation provided to GDM women.

Type, Duration and Frequency of Diet Counselling for GDM

- Forty eight dietitians stated providing individualised diet consultations to GDM women than group consultation and forty three dietitians reported the duration of diet consultation to be 30 to 60 minutes per GDM women and the frequency of diet consultations to be two per GDM women. The results showed inadequacies in the diet consultation provided to GDM women underlining systematic MNT referrals to dietitians for effective management of GDM.

Gap Analysis of Current MNT Practices and Protocols with National Guidelines for GDM Management

- The gaps identified on MNT practices were in pre-pregnancy BMI and gestational weight gain assessment based nutrient calculations and inconsistencies in the use of operating guidelines for MNT planning. These gaps emphasize the need for improving the awareness of dietitians towards the use of protocol-based MNT practices for GDM management.

Current Practices and Management of GDM as per Responses of Pregnant Women

Demographic profile of Pregnant Women

- There was homogeneity in the age of the pregnant women who participated in the study with a mean age of GDM women being 30.59±4.57 years, and Non-GDM women being 29.56±4.13 years respectively.
- The educational qualification of both groups was comparable with 56.6 percent graduates in GDM group compared to 46.3 percent in Non-GDM group and 40.7 percent post graduates in Non-GDM women compared to 29.2 percent in GDM women respectively. These findings showed both GDM and Non-GDM women to be well-educated. However, 64.2 percent women GDM group and 59.3 percent Non-GDM women were not working or had quit their job after becoming pregnant.
- Gravidity of the participants showed 56.6 percent GDM women to be multigravida and 57.4 per cent in Non-GDM women.
- The period of gestation significantly differed between groups with 62.3 percent GDM women in second trimester and 85.2 per cent Non-GDM women in third trimester respectively. The status of delivery at the end of the study period was also found to significantly differ with 94.4 percent delivered Non-GDM women compared to 34 percent delivered GDM women.

Anthropometric Measurements and BMI categorisation of Pregnant Women

- The mean height and mean weight were only comparable and did not vary among both groups. The mean BMI of 25.16±4.47kg/m^2 in GDM women and 23.97±4.27 kg/m^2 assessed were not statistically significant among groups and were within the overweight category as per WHO Asian Classification for BMI.

Biochemical tests and OGTT among Pregnant Women

- The RBS and HbA1c were statistically significant between both groups. GDM women had a greater mean RBS of 105.25±22.34g/dl compared to 88.93±9.94mg/dl in Non-GDM women although it is within normal limits for both groups.
- The mean HbA1c value of 5.79% among GDM women clearly indicates the impaired glucose tolerance within this group compared to HbA1c level of 5.25% among Non-GDM women.
- The mean haemoglobin levels were comparable among groups and were above the cut-off value of 11g/dl and the mean TSH levels of both groups were also found to be within the normal range for pregnancy.
- All of the mean OGTT values including fasting, after 1 hour value and after 2 hour values were found to be highly significant at one percent level in GDM women compared to Non-GDM women.
- The evident difference in the mean blood glucose levels between groups underlines diagnostic screening using OGTT to be done for GDM detection.

Clinical details of Pregnant Women

- The antenatal complications observed among the GDM and Non-GDM women was not significant indicating that occurrence of antenatal problems among both groups did not vary.

Dietary Assessment of Pregnant Women

- The energy and fat intake was slightly lower RDA among GDM women with 0.6 percent deficit in energy and .01 percent in fat, whereas among Non-GDM women both energy and fat intake were exceeding RDA with 12 percent excess in energy and eight percent in fat intake respectively.
- Carbohydrate intake was found to be in excess in both groups ranging from 46 to 72 per cent than RDA. Proteins which are one of the important macronutrients required in additional amounts during pregnancy, was deficient in both groups ranging from 2 to 11 percent than RDA for proteins.
- Calcium, iron and fibre were deficient among both the groups with the iron intake found to be shockingly deficient by a percent ranging from 72 to 75 percent than RDA.

- The findings of the present study indicate the need for educating both GDM and Non-GDM women on making the right choices of food, adequate in quantity and quality so as to meet the nutritional requirements for the mother as well as the growing foetus.

Concepts, Perceptions about GDM among Pregnant Women

Risk factors of GDM

- The presence of family history of Type 2 DM showed significant difference with 64.2 percent in GDM women compared to 33.3 percent in Non-GDM women. All other risk factors such as PCOS, hypothyroidism and GDM in previous pregnancy did not show any significant difference although the presence of these factors was greater in GDM women than Non-GDM women.

Understanding the Consequences of GDM among Pregnant Women

- The awareness of GDM and non-GDM women on the consequences of GDM on pregnancy significantly differed with 55.7 per cent GDM women having an understanding the impact of GDM on pregnancy compared to 35.2 per cent in non-GDM women.
- The readiness of GDM and Non-GDM women towards their current pregnancy as planned or unplanned did not show any significant difference ($p=0.542$) between groups. Fifty (92.6%) Non-GDM women and 95 (89.6%) GDM women positively stated that their current pregnancy was planned, suggesting their readiness for motherhood.

Perception towards Managing Pregnancy among Pregnant Women

- The mean scores for the importance of making changes in lifestyle to manage pregnancy (9.08±.68 in GDM and 8.72±.81 in Non-GDM women) and confidence level for adopting these lifestyle changes (8.40±.90 in GDM and 7.76±.99 in Non-GDM women) were statistically significantly for GDM women compared to Non-GDM women.
- GDM women were seen to have a better understanding of the impact of GDM and also greater readiness to make changes in lifestyle to manage pregnancy compared to Non-GDM women.

Details of MNT practices and Physical Activity among Pregnant Women

MNT Practices received among Pregnant Women

- The MNT practices received by GDM and Non-GDM showed significant difference at 1 percent level for MNT received, time of receiving MNT and the HCP who provided the MNT.
- It was noted tha 77.4 percent GDM women received MNT compared to 48.1 percent Non-GDM women. The time of receiving MNT also significantly differed among both groups with 64.2 percent GDM women receiving MNT at the time of detection of GDM and 13.2 percent receiving MNT after delivery. Whereas, 11.1 percent Non-GDM received MNT upon IP admission and 37 percent Non-GDM women receiving it after delivery.
- The duration of MNT of less than two weeks or initiation of MNT along with medicines was found in 48.1 percent GDM women suggesting that the MNT duration as per national guidelines were not followed in the selected hospitals. All these deficiencies in the MNT practices followed in the surveyed hospitals recommend the need for protocol based MNT practices.

Physical Activity Patterns among Pregnant Women

- The physical activity patterns in GDM and Non-GDM women did not show any significant difference for type, duration and frequency of exercise as evidenced by walking being done by 56.6 percent GDM women compared to 33.6 percent Non-GDM women.
- The duration of walking of 15-30 minutes was stated by 56.7 percent Non-GDM compared to 51.7 percent GDM women and a frequency of greater than five times per week was reported by 83.9 percent Non-GDM women compared to 72.1 percent GDM women.
- The rest recommendation advised by doctor and the hours of inactivity also did not show any marked difference indicated by 5-6 hours of inactivity during the day among 42.5 percent GDM women and 40.7 percent Non-GDM women respectively.
- The need to raise awareness on the importance of being physically active during pregnancy unless contradicted was noted and should be part of GDM management.

Details of Delivery Outcomes among Pregnant Women

- The mode of labour, birth outcome and adverse foetal outcomes were the parameters found to show significant difference among GDM and Non-GDM women.
- The mode for labour between groups was statistically significant with spontaneous labour possible only for 13.9 percent GDM women compared to 35.3 percent in Non-GDM women and emergency or induced labour was needed in 86.1 percent GDM women compared to 64.7 percent in Non-GDM women respectively.
- Birth outcomes namely preterm birth significantly differed among groups with 27.8 percent in GDM women compared to 5.9 per cent in Non-GDM women and term births of 94.1 percent in Non-GDM women compared to 72.2 percent in GDM women respectively. The birth weight of newborns of 84.3 percent Non-GDM women were within the normal range of 2.5 to 4kg compared to the newborns of 77.8 per cent GDM women.
- The mode of delivery was comparable among groups with 41.2 percent vaginal deliveries in Non-GDM women compared to 33.3 percent in GDM women. Whereas, 61.1 percent caesarean deliveries were noted in GDM women compared to 52.9 percent in Non-GDM women. Other modes of delivery namely vacuum and forcep assisted deliveries were negligible with 5.6 percent in GDM and 5.9 percent in Non-GDM women respectively.
- There was no significant difference in the adverse maternal outcomes observed among both the groups. However, the presence of adverse foetal outcomes was statistically significantly with 61.1 percent in GDM women compared to 30.2 percent in Non-GDM women.
- GDM women were found to be more susceptible for induced labour, preterm delivery and adverse foetal outcomes compared to Non-GDM women emphasising the need for early interventions towards prevention of GDM for safe maternal and foetal outcomes.

Patient Education Activities for GDM Management

- The investigator observed that four out of seven hospitals conducted patient education activities such as out-patient group sessions on topics such as what to expect during pregnancy, need for proper diet and antenatal yoga led by the

respective HCPs namely a obstetrician, a dietitian and a yoga instructor once a month

Phase II : Development, Validation and Optimisation of a SSOP for MNT of GDM women

Development of SSOP

- Based on the limitations observed in Phase I of the study, a SSOP was developed based on the nutrition care process (nutrition assessment, diagnosis, intervention, monitoring and evaluation) for GDM as follows.
- **Segment I - GDM Risk Screening** was taken up as the initial step in the development of SSOP to identify pregnant women at risk of developing GDM. It involved using GDM risk screening form and classifying pregnant women as high risk, average risk and low risk
- **Segment II – Nutrition Assessment** was the next segment in the SSOP which involves collecting and assessing anthropometric details , biochemical investigations, clinical data and dietary patterns to evaluate the pre-pregnancy BMI, expected gestational weight gain and nutrient intake.
- **Segment III** – Nutrition diagnosis is derived after the completion of nutrition assessment which "is written as a statement called Problem-Etiology-Signs and Symptoms (PESS) statement, which describes the individual's specific problem".
- **Segment IV** – Nutrition Intervention forms the fourth segment in the SSOP, which involves three unique nutrition interventions based on the severity of the GDM risk assessed The three nutrition interventions based on GDM risk are
    - Nutrition Intervention 1 for GDM High Risk Women comprised of prescribing a customised diet plan and diet counselling for 20 minutes with walking for 30 minutes and MNT review visit every month. Additionally, revision of customised diet plans every trimester, nutrition education sessions in the form of two webinars of one hour duration, sharing of healthy recipe videos and reminders through group contact and provision of an e-booklet on lactation and complementary feeding practices (after delivery) were also included in the intervention.

- Nutrition Intervention 2 for GDM Average Risk Women consisted of providing diet counselling of 20 minutes with walking for 30 minutes without a customised diet plan and MNT review visit every trimester. Additionally, nutrition education sessions in the form of two webinars of one hour duration and provision of an e-booklet on lactation and complementary feeding practices (after delivery) were also included in the intervention. All GDM average risk women were send reminders through group contact for MNT reviews only.
- Nutrition Intervention 3 for GDM Low Risk Women comprised of providing only one session of diet counselling for 20 minutes. No customised diet plan or MNT review visit were provided to this group. However, nutrition education sessions in the form of two webinars of one hour duration and provision of an e-booklet on lactation and complementary feeding practices (after delivery) were included in the intervention.

- **Segment V** – Nutrition Monitoring and Evaluation Nutrition forms the last segment in the SSOP which involves monitoring of anthropometric details, biochemical investigations, clinical data, and MNT reviews.
  - Nutrition monitoring for GDM high risk women was conducted every month for all the described parameters as well as for clarifying diet-related queries. Dissemination of dietary guidelines and monitoring of gestational weight gain was done by sending reminders through group contacts using social media.
  - Nutrition monitoring for GDM average risk women was done once every trimester for clarifying diet-related queries during their scheduled antenatal reviews with the obstetrician. No reminders were sent through group contacts for dissemination of dietary guidelines and monitoring of gestational weight gain.
  - No face to face interview or use of social media for nutrition monitoring was done for GDM low risk women. However, these women were monitored through the EMR of the selected hospital.

- Nutrition evaluation comprising maternal and foetal outcomes among pregnant women, impact of nutrition education, adequacy of total gestational weight gain at delivery, detection of GDM among participants and effect of SSOP on maternal and foetal outcomes was done for all GDM risk groups.

Validation of SSOP

- The validation of SSOP based MNT by the target group of 10 HCPs namely obstetricians, diabetologists and dietitians using content validity index showed a scale-level content validity index/average (S-CVI/Ave) value of 0.99 which was greater than the accepted CVI value of 0.78 and confirmed the SSOP to achieve satisfactory level of content validity.

Optimisation of SSOP

- Optimisation of the SSOP done by implementation of SSOP on ten pregnant women equally grouped into experimental (N=5) and control group (N=5).
- GDM risk screening resulted in two pregnant women from control group and three pregnant women from experimental group being in GDM high risk category.
- The nutrition assessment conducted revealed that there were three pregnant women with greater BMI (BMI>25kg/m^2) in experimental group compared to one in control group.
- Dietary assessment showed the mean energy intake to be significantly exceeding than RDA in control group whereas it met RDA requirements in the experimental group.
- The mean nutrient intakes of proteins, calcium and iron were significantly lower than RDA for both groups.
- Nutrition diagnosis related to knowledge deficit in following healthy diet during pregnancy was found among three pregnant women in control group compared to two in experimental group. Inadequate oral intake related nutrition diagnosis was found in two pregnant women in experimental group compared to none in the control group.

- Nutrition intervention as per SSOP was given to the experimental group, while the control group received nutrition intervention as per the existing MNT practices of the selected hospital.
- The nutrition monitoring and evaluation indicated equal number of pregnant women in both groups getting diagnosed with GDM. The mean postprandial blood sugar (PPBS) was significantly different with 115.25mg/dl in control group compared to 100.75mg/dl in the experimental group. No adverse maternal outcome was observed in the experimental group compared to one adverse maternal outcome in control group. Similarly three women had adverse foetal outcomes in the control group compared to one adverse foetal outcome in the experimental group.

Phase III: Development, Validation and Optimisation of a Mobile App for SSOP of MNT for HCPs

Development of Mobile App

- The developed Mobile App for SSOP consisted of a total of 8 screens comprising of Welcome screen, Login screen, Add/Update/Delete patient screen, Patient's personal details screen, Medical details screen, Laboratory details screen, Medicine details screen and the Result details screen.
- The Welcome screen was designed with a unique background image of a pregnant woman and depiction of the logo in the centre of the screen. A short text was also added to the welcome screen so that user's get an idea of the main functionality of the App.
- Login Screen was the second screen of the App where the user was prompted to create an acccount or sign in based on the accoount's status (already created or new account).
- The Add/Update/Delete Patient screen aids the user for multiple functions like adding a patient, deleting a patient and updating the details already entered of a patient. The user log in and log out feature was also included in this screen.
- The Personal details screen was designed to collect the all individual details of patient including employment, activity level and hospital registration number of the patients.

- Medical details screen captured anthropometric details such as height, pre-pregnancy weight, and current weight for calculating pre-pregnancy BMI and ideal body weight.
- The laboratory details screen functions to capture all the relevant biochemical parameters of the patient such as haemoglobin, fasting blood glucose, post prandial blood glucose, random blood glucose, glycosylated haemoglobin, thyroid stimulating hormone, oral glucose tolerance test values, self monitoring of blood glucose values and blood pressure.
- The Medicine details screen helps in entering all the medications that have been prescribed to the patient along with the dosage and time for taking those medications. Separate fields are provided to type the name, dosage and description of medications.
- The Result screen or MNT Planning Screen is the most important screen of the App which displays the results of GDM risk assessment, BMI, expected gestation weight, total weight gain needed for the entire period of pregnancy, excess or deficit in gestational weight gain for the current period of gestation, energy and protein requirement and the percentage distribution of nutrients namely carbohydrates, proteins and fat.

Validation of Mobile App

- The validation of the Android App done by the target group of 10 HCPs namely obstetricians, diabetologists and dietitians using content validity index showed a scale-level content validity index/average (S-CVI/Ave) value of 0.88 which was greater than the accepted CVI value of 0.78 and confirmed that the Android App developed achieved satisfactory level of content validity.

Optimisation of Mobile App

Assessment of Usability of Mobile App among Selected HCPs

- Optimisation of the Mobile App among 50 HCPs comprising 25 doctors and 25 dietitians using the SUS Grade showed that the mean SUS score was not found to be significantly different ($p=0.128$) with 78.90 ± 7.18 among doctors and 82.20 ± 7.85 among dietitians. The mean scores calculated from both groups corresponded to an

overall grade of A- and A respectively indicating that the Mobile App was highly acceptable in terms of its usability.

- It was observed that SUS scores based adjective rating scale produced scores ranging from 73 to 85 from 12 doctors and 13 dietitians which came into the "excellent" category. Additionally, SUS scores ranging from 85 to 100 were given by 10 dietitians and five doctors which came under the "best imaginable" category confirming that the Mobile App was highly rated as suitable as per the adjective rating scale.

Phase IV: Implementation and Evaluation of SSOP for MNT among Pregnant Women

Demographic Profile of Pregnant Women

- Mean age of 27.42±3.80yrs in experimental group and 29.01±3.37yrs in control group was found to be significantly different at 1 percent level and the pregnant women in both groups largely belonged to the age group of 27-35 years.
- Ninety two out of 178 (51.7%) pregnant women in experimental group were primigravida whereas 109 (58.6%) pregnant women in the control group were multigravida.
- Although 65.2 percent graduates and 31.5 percent post graduates comprised in experimental group and 62.9 percent graduates and 32.6 percent post graduates in control group respectively, only 47.8 percent in control group and 42.1 percent in experimental group were working.

SSOP based GDM Risk Screening of Pregnant Women

GDM Risk Screening

- Age was the only GDM risk factor which showed significant difference among experimental and control group with 83.3 per cent pregnant women in the control group having age greater than 25 years compared to 69.1 per cent in the experimental group.
- Other GDM risk factors such as BMI greater than 25 kg/m^2, family history of Type 2 DM and previous history of GDM, previous history of PCOS or hypothyroidism, previous history of still birth or macrosomia were only comparable and did not show any significant difference among groups.

Categorisation of GDM risk

- The GDM risk categorisation estimated among both groups did not show significant difference suggesting the homogeneity in the distribution of GDM high risk, average risk and low risk pregnant women within the study groups.

GDM Risk Screening and Diagnosis of GDM

- GDM risk screening and GDM diagnosis assessed resulted in 58.3 percent GDM high risk women of control group being detected with GDM which was statistically significant compared to 38.5 percent in experimental group. Similarly, compared to 36.7 percent of GDM average risk women becoming detected with GDM in the control group, only 30.6 percent GDM average risk women of experimental group got detected with GDM. Even in the GDM low risk category, significant difference was seen with only 10 percent GDM low risk women of experimental group getting detected with GDM compared to 20 percent in the control group.
- These findings suggest that GDM risk screening can be a useful tool in identifying pregnant women at risk of developing GDM as GDM diagnosis was largely seen in the high risk category followed by average risk category and least in the low risk category in both groups..

Detection of GDM in Pregnant Women

- The OGTT results reveal that 94 of 186 (50.5%) pregnant women were detected with GDM in the control group compared to 60 of 178 (33.7%) in experimental group which was highly significant at 1 percent level.
- The SSOP based MNT initiated from the first trimester was effective in reducing the number of pregnant women becoming diagnosed with GDM.

SSOP based Assessment of Pregnant Women

Anthropometric measurements and Body Mass Index (BMI)

- Mean height was the only variable showing significant difference between the groups. The mean BMI estimated using height and pre-pregnancy weight was 24.68±3.74kg/m^2 in experimental group and 24.84±3.75kg/m^2 in control group indicating that their mean BMIs were not significantly different and were under the overweight category as per the WHO Asian Classification for BMI.

Biochemical investigations (First trimester)

- The biochemical investigations compared between groups at first trimester showed significant difference only in glycosylated haemoglobin (HbA1c). However, these values were within normal limits indicating that both groups maintained euglycaemia during the first trimester. The mean value of all other biochemical markers namely RBS, FBS, Hb and TSH levels did not show any marked difference among groups and were also found to be within the normal limits. These results indicate maintenance of homeostasis in both groups.

Oral Glucose Tolerance Test (OGTT)

- The blood glucose values of the OGTT revealed no significant difference among the experimental and control groups with respect to fasting, after one hour and after two hours blood glucose values.
- The OGTT criteria used between groups also did not show any notable difference with 92.1 percent in experimental group and 86 percent in control group stating IADPSG as the commonly used diagnostic criteria for GDM detection.

Clinical assessment (Antenatal period)

- Antenatal complications were not seen in 77.5 per cent experimental group compared to 53.8 percent in control group which was found to be highly significant at 1 per cent level.
- The Chi square analysis of antenatal complications among groups were statistically significant with the control group having 13.4 percent foetal defects, 17.7 percent foeto-placental anomalies and 15.1 per cent maternal complications compared to 1.1 percent foetal defects, 15.2 percent foeto-placental anomalies and 6.2 percent maternal complications in the experimental group respectively.
- SSOP which was implemented from the first trimester was helpful in reducing antenatal complications in experimental group.

Dietary assessment

- Energy, fat and carbohydrate intake was found to be in excess for both the groups ranging from 11 to 24 percent than the RDA for energy, 38 to 43 percent for

carbohydrates and 15 to 23 percent for fat; but discouragingly protein intake was less than the RDA among both the groups (0.08 to 25 % deficit).

- Calcium, iron and fibre intake were deficient among both the groups. Among all the nutrients, iron which is the most important mineral to prevent anaemia was shockingly deficient by a percent ranging from 76 to 79 percent when compared with the RDA.
- The nutrient intake of experimental group exceeded RDA for energy, carbohydrate and fat and was deficient in proteins and micronutrients namely iron, calcium and fibre whereas the nutrient intake of control group exceeded RDA for energy, carbohydrate, proteins and fat and was deficient only in micronutrients such as iron, calcium and fibre.

SSOP based Diagnosis of Pregnant Women

Derivation of Nutrition Diagnosis

- The nutrition diagnosis derived as a PES statement was not statistically significant indicating knowledge deficit related to poor awareness on healthy diet and proper food choices both in quantity and quality existing among both groups.
- The other nutrition diagnoses derived namely excess energy intake related to excess consumption of calorie dense and high carbohydrate foods and inadequate oral intake related to nausea and vomiting was did not vary among groups suggesting the presence of these nutrition problems in both groups.
- Imparting proper nutrition education to pregnant women on the need for meeting the nutrition requirements and making proper food choices both in quantity and quality during pregnancy is thus an essential element of nutrition intervention.

SSOP based Intervention of Pregnant Women

Assessment of Nutrition Education Sessions using Knowledge, Attitude and Practice (KAP) study in a Selected Sample of Pregnant Women

- The KAP pre and post test scores of participants for knowledge, attitude and practice showed significant difference indicating that the nutrition educations sessions were effective in improving their knowledge on topics such as nutrition during pregnancy, gestational weight gain, gestational diabetes mellitus and its prevention.

- It is thus suggested to provide nutrition education sessions every trimester of pregnancy for improving the awareness of pregnant women about proper nutrition during pregnancy.

Requirement of Medical and Nutritional Interventions among Pregnant Women

- There was no significant difference in the MNT along with exercise, OHA and insulin-related interventions received by pregnant women who were detected with GDM in both groups for effective blood glucose control.
- Thus SSOP based MNT along with exercise alone was not found to be sufficient in glycaemic control among GDM women and wherever MNT fails, OHA or insulin should be initiated for treatment.

SSOP based Monitoring of Pregnant Women

Blood Glucose Monitoring among Pregnant Women

- The mean FBS values among both groups were not found to significantly differ however, the mean PPBS of 107.56 mg/dl in the experimental group receiving SSOP based MNT and 114.96mg/dl in the control group following existing MNT showed significant difference indicating that the SSOP based MNT facilitated in the control of postpradial blood sugar levels in experimental group compared to control group

Gestational age at Delivery and Total Weight Gained among Pregnant Women

- The mean gestational age at delivery and the total weight gain after delivery did not show any significant difference between the target groups.
- The gestational age at delivery for both groups did not extend according to the time of delivery (≥39 weeks) as per national guidelines. The average total weight gain was found to be within the normal range of pregnancy for both groups.

Adequacy of Gestational Weight Gain (GWG) among Pregnant Women

- Low gestational weight gain of 42 cases in experimental group and 42 cases in control group indicated that the number of pregnant women with low GWG did not vary among groups.
- Significant difference was seen between groups with 78 (43.8%) pregnant women in experimental group achieving adequate GWG compared to 60 (32.2%) pregnant

women in the control group. A higher GWG was found in 84 (45.2%) pregnant women belonging to the control group compared to 58 (32.6%) pregnant women in the experimental group.

- The results revealed that the SSOP based MNT was effective in achieving adequate GWG and reducing high GWG among the pregnant women in the experimental group compared to those pregnant women who received the existing MNT in the control group

SSOP based Evaluation of Pregnant Women

Delivery Details among Pregnant Women

- There was significant difference in the mode of delivery with 69.9 percent vaginal deliveries, 29.6 caesarean deliveries in control group compared to 61.2 percent vaginal deliveries and 33.7 percent caesarean deliveries in experimental group. However, there was no difference in induction of labour among the pregnant women in both groups.
- The results of birth outcome, presence of low birth weight (<2.5kg) and higher birth weight (>4kg), mean birth weight, apgar scores of babies born to experimental group and control group were also comparable only with no significant difference between groups.

Maternal Outcomes among Pregnant Women

- Among the various maternal outcomes perineal tear was found in the control group with 28 cases compared to 15 cases in experimental group which was just significant at 5 percent.
- The presence of adverse maternal outcomes among control group was significantly higher at 18.9 percent compared to 10.2 percent in the experimental group (p=.019) indicating that the SSOP based MNT was beneficial in preventing the occurrence of adverse maternal outcomes in experimental group compared to control group.

Multiple Logistic Regression for Identifying Factors Affecting Adverse Maternal Outcomes

- Logistic regression done for identifying the risk factors for the occurrence of adverse maternal outcomes showed that the model was statistically significant at the χ^2 value = 27.305 and P-value less than 0.001.

- The model explained only 12.8 per cent of the variation in the occurrence of adverse maternal outcome and correctly classified 86.3 per cent of the cases.
- P-value showed that intervention (SSOP based MNT), previous history of PCOS and history of Type 2 DM significantly affecting the outcome of having GDM.
- Adjusted odds ratio indicated that experimental group has less chance of having adverse maternal outcome compared to control groups.
- Experimental group exhibits adverse maternal outcome, 0.505 times lower than that of control group. Pregnant women having history of PCOS were 1.944 times more likely to have adverse maternal outcome compared to those not having history of PCOS.
- Also, those having history of GDM were 3.897 times more likely to have adverse maternal outcome compared to those not having the history of GDM.

Foetal Outcomes among Newborns of Pregnant Women

- Hypernatraemia was the adverse foetal outcome showing statistical significance among the both categories of pregnant women. The presence of hyperbilirubinemia was just significant at 5 percent level with an occurrence of 17.2 percent in control group compared to 10.1 percent in the experimental group. All other foetal outcomes namely respiratory distress syndrome, sepsis, low birth weight, macrosomia, birth injury, congenital malformation and hypoglycaemia were not significantly different in the both categories.
- Among both groups, the presence of adverse foetal outcomes assessed was 50 percent in control group which was significantly higher compared to 30.3 percent in experimental group projecting the desirable effect of SSOP based MNT on the prevention of adverse foetal outcomes.

Multiple logistic regression for identifying risk factors affecting adverse foetal outcomes

- Logistic regression for identifying the risk of having adverse foetal outcomes revealed that the model was statistically significant at the χ^2 value = 17.09 and P-value less than 0.01. The model explained only 6.28 percent of the variation in the occurrence of adverse foetal outcome and correctly classified 62.1 per cent of the cases.

- P-value showed that only SSOP based MNT has significance in the model. P-value for all other independent variables was greater than 0.05 indicating that these variables were not influencing the occurrence of adverse foetal outcome.
- Adjusted odds ratio indicated that experimental group had lesser chance of having adverse foetal outcome compared to control group. Experimental group exhibited adverse foetal outcome; 0.428 times lower than that of control group.
- The SSOP based MNT implemented in the study from the first antenatal visit till delivery, has the potential to lower the occurrence of adverse foetal outcomes.

Multiple Logistic Regression for Identifying the Risk Factors of GDM

- Logistic regression for identifying the risk factors of presence of GDM revealed that the regression model was statistically significant at the χ^2 value = 49.04 and P-value less than 0.001.
- The model explained only 16.9 per cent of the variation in GDM and correctly classified 65.7 per cent of the cases. Wald test was used to test the significance of each independent variable.
- P-value showed that SSOP based MNT, BMI status, family history of Type 2 DM, and history of GDM significantly affecting the outcome of having GDM.
- Adjusted odds ratio indicates that experimental group has less chance of having GDM compared to control groups.
- Experimental group exhibits GDM 0.519 times lower than that of control groups. Pregnant women having BMI greater than or equal to 25 were 2.223 times more likely to have GDM compared to those with BMI less than 25.
- Also pregnant women having a family history of Type 2 DM were 1.865 times more likely to have GDM compared to those not having the family history of Type 2 DM. Pregnant women having previous history of GDM were 6.368 times more likely to have GDM compared to those not having previous history of DM.

Comparison of Mode of delivery, Birth weight of Newborns and Presence of Adverse Maternal and Foetal Outcomes among Pregnant Women (Phase I) and Pregnant women (Phase IV)

- The mode of delivery compared among pregnant women of Phase I and pregnant women of experimental group in Phase IV showed notable difference at one percent

level of significance with 109 vaginal deliveries (61.2%) among the experimental group of Phase IV compared to 32 vaginal deliveries (36.8%) in the pregnant women belonging to Phase I.

- The birth weight of babies evaluated for underweight (birth weight < 2.5kg) among both groups showed 16 underweight newborns among pregnant women of Phase I compared to 12 underweight newborns in the experimental group of Phase IV which was significant at one percent level.
- The differences in mode of delivery and presence of underweight among the newborns among both groups indicate that the SSOP based MNT intervention provided to the experimental group of Phase IV has been beneficial in resulting in vaginal deliveries and reduction of low birth weight infants.
- The presence of adverse maternal compared among the pregnant women in Phase I and the experimental group in Phase IV also showed significant difference with 18.4 percent adverse maternal outcomes in Phase I compared to 9.6 percent in Phase IV.
- Additionally, the presence of adverse foetal outcomes compared among the pregnant women in Phase I and the experimental group in Phase IV also showed significant difference with 47.1 percent adverse foetal outcomes in Phase I compared to 30.3 percent in Phase IV respectively.
- These results further ascertain the positive effect of the SSOP based MNT intervention towards reducing the occurrence of adverse maternal and foetal outcomes.

Hypothesis

The results of Phase IV of the study showed statistically significant difference in the presence of adverse maternal and foetal outcomes among pregnant women who received the protocol based MNT compared to those who received the existing MNT practices at the selected hospital at one percent level of significance. Hence, hypothesis (H0) was rejected and alternate hypothesis (H1) was accepted.

Conclusion

The evolving change in lifestyle patterns of the modern era has significantly contributed to the global increase in the prevalence of diabetes mellitus affecting people irrespective of gender or age. The lifestyle changes among women in particular have

adversely affected their reproductive health. Pregnancy complications such as GDM have transgenerational impacts and ensuring a healthy and complication-free gestation assures safe motherhood. There are national and international health organisations constantly working towards improvement in treatment strategies by providing evidence based guidelines for GDM management to improve maternal health. Although there are existing procedures and protocols for GDM management in hospitals, there is still scope for improvement in these management strategies as was evidenced in this study. The systematic practices of a protocol for GDM management are not only sustainable but ensure positive maternal and foetal outcomes and better postpartum maternal and neonatal health.

Limitations

- Blood investigations for glucose monitoring could not be carried out as required.
- Recording of gestational weight gain was possible only based on review visits scheduled instead of regular monthly visits.
- The follow up of study participants for post natal care was not possible as most delivered women did not come for further monitoring after 6 weeks.

Recommendations

- GDM risk screening at first antenatal visit to be made mandatory as part of initial screening.
- Women at risk for GDM should be provided MNT as the first intervention and further followed up as per evidence-based MNT protocol.
- A multidisciplinary team approach is crucial and should be included for effective implementation of protocol-based GDM management strategies.
- Sensitising the stakeholders such as HCPs, allied health personnel, quality control team and administrators of hospitals needs to be done to ensure smooth flow of processes and procedures enlisted in protocols.