"Pharmacist as Educators in Optimizing Identification and Management of Gestational Diabetes Mellitus and Its Outcomes in Newborns-An Interventional Study"

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For the award of the degree of

Doctor of Philosophy

In the Faculty of Pharmacy Practice

By

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(Registration No: KLEU/Ph.D.14-15/DO12140021)

Under the Guidance of

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2021

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Thankful I ever remain…

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LIST OF ABBREVIATIONS USED

1. ADA : AMERICAN DIABETIC ASSOCIATION
2. ACOG : AMERICAN COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS
3. AGRP : AGOUTI-RELATED PEPTIDE
4. AMPK :AMP-ACTIVATED PROTEIN KINASE
5. ADRS : ADVERSE DRUG REACTIONS
6. BMI : BODY MASS INDEX
7. CI :CONFIDENCE INTERVAL
8. CPAP :CLINICAL PHARMACIST-ASSISTED PROGRAM
9. DIPSI : PREGNANCY STUDY GROUP INDIA
10. DM : DIABETES MELLITUS
11. EDCS : ENDOCRINE DISRUPTING CHEMICALS
12. FBG : FASTING BLOOD GLUCOSE
13. GCT : GLUCOSE CHALLENGE TEST
14. GDM : GESTATIONAL DIABETES MELLITUS
15. GDP : GROSS DOMESTIC PRODUCT
16. GA : GESTATIONAL AGE
17. GAD : GLUTAMIC ACID DECARBOXYLASE
18. GCK : GLUCOKINASE
19. GI : GLYCEMIC INDEX
20. GLUT4: GLUCOSE TRANSPORTER 4
21. HBA1C: GLYCOSYLATED HEMOGLOBIN
22. HAPO : HYPERGLYCEMIA AND ADVERSE PREGNANCY OUTCOME
23. HI : HUMAN INSULIN
24. IGF : 1 INSULIN-LIKE GROWTH FACTOR 1
25. IADPSG: INTERNATIONAL ASSOCIATION OF PREGNANCY STUDY GROUP
26. IDDM : INSULIN DEPENDENT DIABETES MELLITUS
27. IDF : INTERNATIONAL DIABETES FEDERATION
28. IMR : INFANT MORTALITY RATE
29. IRS-I : INSULIN RECEPTOR SUBSTRATE
30. MDG : MILLENNIUM DEVELOPMENT GOAL

31. MMR : MATERNAL MORTALITY RATE
32. NIDDM:NON- INSULIN DEPENDENT DIABETES MELLITUS
33. MDI : MULTIPLE DAILY INJECTIONS
34. NDDG: NATIONAL DIABETES DATA GROUP
35. NPY : NEUROPEPTIDE Y
36. OGTT : ORAL GLUCOSE TOLERANCE TEST
37. PPP : PURCHASING POWER PARITY
38. PPBS : POST PRANDIAL BLOOD SUGAR
39. PCOS : POLYCYSTIC OVARIAN SYNDROME
40. P13K : PHOSPHATIDYLINOSITOL 3-KINASE
41. RPG : RANDOM PLASMA GLUCOSE
42. RBS : RANDOM BLOOD SUGAR
43. RBC : RED BLOOD CELLS
44. RCT : RANDOMISED CONTROLLED TRIAL
45. SD : STANDARD DEVIATION
46. SMBG : SELF-MONITORING OF BLOOD GLUCOSE
47. T1DM : TYPE 1 DIABETES MELLITUS
48. T2DM :TYPE 2 DIABETES MELLITUS
49. WHO : WORLD HEALTH ORGANIZATION

ABSTRACT

Background

Gestational diabetes mellitus (GDM) is allied with high levels of morbidity, not only globally but also amongst Asians and Indians. GDM is known for deleterious effects on both the mother and child. Compliance to treatment is poor and underscores the need for regular monitoring, counselling and reinforcement. Apart from compliance to treatment, patients fail to adhere to diet plans and permissible exercise regimens, which lead for deleterious maternal and neonatal outcomes. Clinical pharmacists contribute towards achieving adherence through counselling (audio-visual aids), pharmaceutical care, monitoring, facilitating diet and exercise.

Objective

To assess the outcome of clinical pharmacist counselling on GDM patients for better self-care and healthy outcomes.

Materials and Methods

Single centric, randomized, interventional study was carried out at KLE's hospital Belagavi, Karnataka, India. GDM diagnosed subjects were recruited with written informed consent. Structured counselling was imparted to the intervention group and followed-up were done. Blood glucose, glycosylated haemoglobin, assessment of knowledge, maternal and neonatal outcome were recorded to evaluate the effect of intervention. Percentage, mean, standard deviation, Chi-squared test, t-test, correlation, etc. were calculated with SPSS, $P \leq 0.05$ was consider significant.

Results

The age, education, religion, occupation, socio-economic strata, distribution pattern were similar in both the intervention and control groups (P>0.05). Prior to the intervention, participants demonstrated average knowledge of GDM. Subject 3.54% of control group had excellent knowledge about GDM compared to 7.6% subjects of intervention group and difference between the group was statistically significant (P=0.015). The decrease in fasting blood glucose, post-prandial glucose and glycosylated haemoglobin were observed in both the groups, difference was not significant. Appropriate gestation age was (79.13%) in intervention group compared to (73.4%) control group. The average APGAR score of neonates in intervention group was 9 and in control group was 8. Maximum healthy neonates were found 56.51% in intervention group compare to 22.57% of control group, maximum NICU admissions were observed 77.43% in control group in comparison 43.49% of intervention group, the difference between the group was found statistically significant (P<0.05).

Conclusions

Present study concluded that the intervention, especially involving patient education with counselling and demonstration of physical exercises permissible, structured meal plans helped restore glycaemic levels in GDM patients, showed the better maternal and neonatal outcome. This study strongly advocates for the presence of a clinical pharmacist in clinic protocols for the management of GDM.

Keywords: Gestational diabetes mellitus, Blood glucose, Glycosylated haemoglobin, Gestation age, Macrosomia

TABLE OF CONTENTS

LIST OF TABLES

List of figures (Sl .No figures pages)

1.1 Background

Diabetes is characterized by inadequacies in secretion of insulin, action of insulin, or together and causes lasting dysfunction, damage, and failure of different organs.[1] Defect in feedback loops of insulin secretion by pancreatic islet β-cells (β-cell dysfunction) and action in insulin-sensitive tissues (insulin resistance) causes abnormal blood glucose levels.[2] Insulin resistance causes increased glucose creation by liver and decreased glucose uptake by adipose tissues and muscles. However, β-cell dysfunction causes insufficient insulin release, to maintain normal glucose in the blood.[3] Determinants of this metabolic disorder may be genetic, epigenetic and improper lifestyle or their combinations. By the year 2045, India is expected to exceed China as the country with the largest diabetic population of the world with the probable projection of 134 million people with diabetes.[1] The American Diabetes Association (ADA) recognizes more than 50 specific types of diabetes.[4] Gestational Diabetes Mellitus (GDM) is ace subtype of the diabetes threat plaguing the world today.

The World Health Organization (WHO) defines GDM as "Hyperglycaemia primarily detected during gravidity that does not meet diagnostic criteria for diabetes mellitus".[5] Untreated, GDM may result in a sequence of adverse events likewise, foetal macrosomia hyperinsulinemia and hypoglycaemia, preeclampsia, as well as premature delivery may be needed C-section.[6] Although, most of GDM cases are asymptomatic at an early stage.

The GDM prevalence is directly dependent on population being studied, strategies for screening and used criteria for diagnostic. Prevalence reported from United Kingdom was 5.3 to 7.0 %, United States of America 2.0 to 6.0 %. Report

from various countries indicate that African, Asian, Indian and Hispanic women showed high prevalence.[7,8]

As of 2015 the International Diabetes Federation reported 16.2% live birth from women who had hyperglycaemia in gestation, among that 85% were gestational diabetes mellitus.[9] Asiatic females are more disposed to develop GDM in comparison of European, literature indicate that female from India have 11-fold higher jeopardy of evolving glucose intolerance in gestation then the Caucasian women.[10]

GDM occurrence in Indian population is gradually snowballing from 2% of 1982 to 7.2% of 1991 and almost folded to 16.55% in 2002. However, a total of ~6 million women reported having hyperglycaemia in pregnancy, of which, 90% women had GDM in 2013.[11, 12] Routine screening during gestation help to identify and diagnosed the GDM as it is asymptomatic majority of times. At any given point in time, 4 million subjects are estimated to be affected. The GDM prevalence reported from India were 3.8% from Kashmir, 6.9% reported from Mysore, 9.5% reported from western India and 17.9% reported from Tamil Nadu.[13-17] Recent studies which used different criteria reported high prevalence 35% from Punjab and 41% from Lucknow (Fig. 1).[18-19]

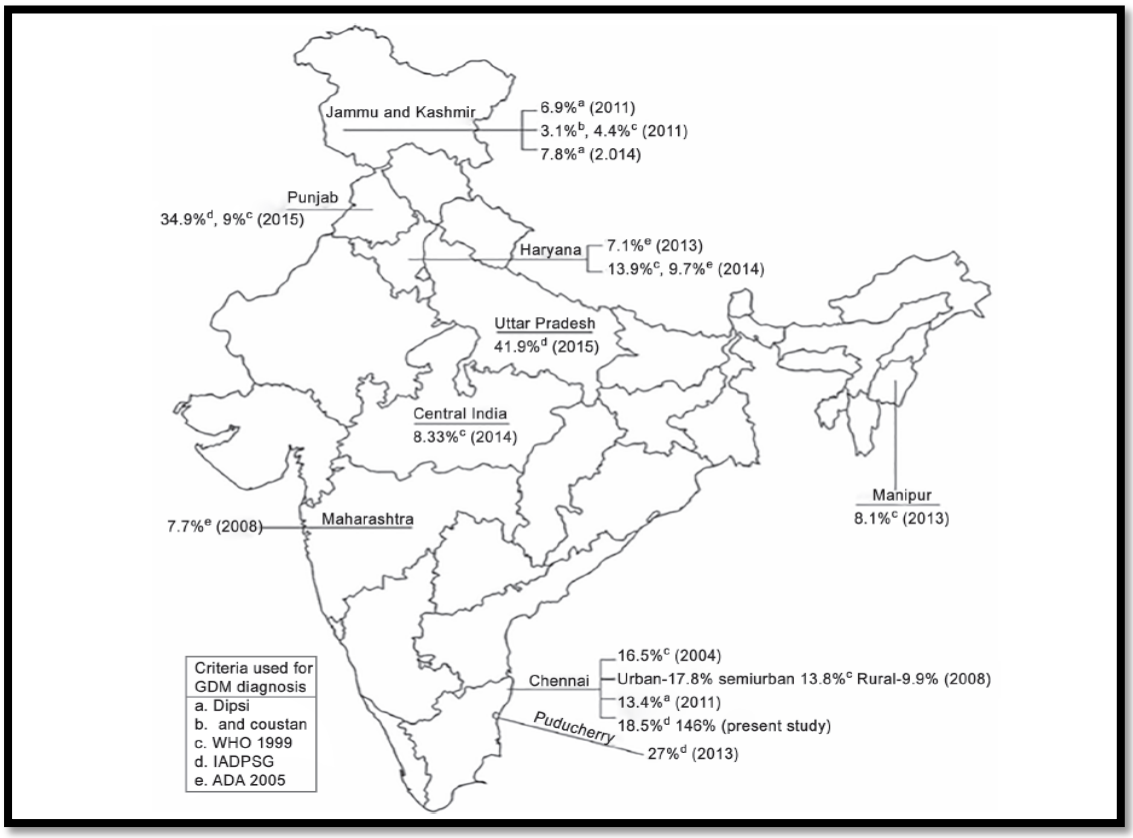


Figure 1: Geographical representation of Prevalence of GDM across India

During the first trimester, adiposities bind insulin more effectively to fulfil increased glucose demand by the fates.[20] With the advancement of the gestation period, the concentration of placental hormones like oestrogen, lactogen and cortisol increases and contribute enhanced insulin resistance Thus, reduced insulin sensitivity helps to increase glucose supply to foetus to meet the nutrient requirement for foetal growth.[21, 22] Another chronic form of insulin resistance during the gestation period antedates pregnancy and aggravates physiological changes. Most GDM cases show both kinds of resistance and contribute to the evolution of the disease. GDM originates because of insufficient insulin secretion in retort to demands and thus causes elevated blood glucose levels. Insulin secretion deficiency may be due to defective beta cells or insufficient insulin release. Autoimmune disease or genetic

abnormality may affect the function of beta cells and result in chronic insulin resistance.[23]

The risk factors associated with GDM form an intricate pattern consisting of genetic, physiological, geographical, ethnic and environmental attributes. A ancestral antiquity of diabetes mellitus in first degree relations, caesarean, of a previous child born with macrosomia, history of miscarriages and preeclampsia, polyhydramnios, excessive foetal growth, foetal malformations or death, maternal age more than 35 years, polycystic ovarian syndrome, ethnicity, especially South Asian and South East Asians and obesity and sedentary lifestyle predisposes the pregnancy towards GDM.[24-29]

GDM has multiple ramifications as it affects maternal, neonate health and may complicate further pregnancies as well. Pregnant subjects with GDM had jeopardy of pre-eclampsia in the antepartum period as well caesarean and operative births.[29] There is a resemblance to pattern of children of women with extreme obesity and GDM during pregnancy. The children born to mothers of both conditions suffer from macrosomia, neonatal hypoglycaemia, hyperbilirubinemia and respiratory distress syndrome. Other symptoms include hypoglycaemia, polycythaemia and hypocalcaemia.[30] The unfortunate effects of GDM include cardiovascular disorders, obesity traced to early childhood days or worse, still birth. [Mithal A etal., 2015] Shoulder dystocia may also be caused by foetal macrosomia, or by GDM, independent of the former disorder.[31]

There are different diagnostic criteria to estimate degrees of hyperglycaemia together with the risk associated with mother and foetus life. WHO 1999 criterion involves oral intake of 75 mg glucose on a fasting stomach and a two hourly test which should give the blood glucose level below or equal to 140 mg/dL to test

negative.[32] The more globally accepted criterion is the IADPSG (International association of diabetes and pregnancy study groups). It should yield result of fasting glucose level to be >92mg/dl; on the administration of similar dosage the one hourly after result to be ≥180mg/dl and the two hourly value to be ≥153mg/dL to test negative.[32] This one-step strategy of IADPSG may be assumed to significantly raise GDM prevalence 5-20 % as only single value is enough for the diagnosis.[33] Although this criterion may directly affect the costs and need of medical infrastructure, the American diabetes association (ADA) recommends this criterion as it is based on effects on the outcome of these deliveries rather than end points, for example, prediction of future diabetes of mother.[34] A Two-Step Strategy developed by National Institutes of Health (NIH) in 2013 that used a 1 hour 50-g glucose load test (GLT) and for those who are screened positive will be shadowed by a three hour 100 g OGTT test.[35] The American College of Obstetricians and Gynaecologists (ACOG) recommends two-steps strategy.[36] The HBA1c test at 24 to 28th week for the screening of GDM does not function well.[37]

Another criterion followed in India is the DIPSI (Diabetes in Pregnancy Study group in India) which requires the non-fasting two hourly value to be below or equal to 140 mg/dL. This is especially suitable in the Indian setting where it is unlikely that a pregnant woman may report to the dispensary on a fasting stomach and there is uncertainty regarding the compliance of a second visit.[38]

The American Association of Diabetes Educators listed seven essential factors for improved outcomes in Diabetes: the psychological aspects of living with diabetes are one significant factor, along with solving problems associated with self-care. A clinical pharmacist is thus expected to conduct a personalized plan for each individual with a holistic approach comprising of insulin administration, dietary support and

physical exercise regime.[39] A pharmacist associated with the diabetes clinics must play an important role in management of GDM as well as associated complications. There are very few studies from India; hence, present study was planned to assess the role of clinical pharmacists and their efficacy in management of GDM and the consequent effects on the new-born. Awareness generation forms are an important constituent of the management procedure. Early diagnosis by regular glucose monitoring and control by nutritional therapy and customized dietary modifications combined with intensified metabolic management of the pregnant women may help to reduce the burden of GDM.[38] It may help to optimize the women's health as well as healthy neonates. A clinical pharmacist may help to achieve adherence to therapy in GDM and it would be an optimal intervention to reduce morbidity and mortality in GDM mothers and neonates.

Pharmaceutical care has been demarcated as "the responsible provision of drug to achieve definite outcomes that improve a patient's quality of life.".[40] A Pharmacist, being the part of the healthcare unit, should be patient care centred. They may provide evidence-based therapies together with associating patients with these pharmacotherapies and educate the patients about the purpose and scope of therapies. In case of diabetes, studies have shown pharmacist based medical therapy programs helped in the management of diabetes and reduced HbA1c levels.[41] Patient education about the adverse effects of any therapy for example insulin uptake may help to better management of the disease.[42] Drugs of diabetes at a time may cause severe hypoglycaemia in case of restricted caloric intake or long hour exercises. At that time, the patient should be aware of the signs of hypoglycaemia and how they can manage it. Clinical pharmacist advise to the patients would help to regular monitoring of their blood glucose levels to keep it in a safe range. Patients on metformin need to be

counselled about the adverse effect likely nausea, vomiting, diarrhoea etc. and how to manage it. Additionally, vitamin B12 may also be checked routinely in anaemic cases as the deficiency may cause megaloblastic anaemia in diabetic cases. Besides educating about therapeutic aspects, a pharmacist may also help in the diet and weight management of the patients. Variety of strategies like audio-video recordings may be help to convey the message more effectively.[43] In the case of GDM patients, exercise, diet control and weight management are–very important to avoid complications. Clinical pharmacist may help to edify about ailment, its management and risk of macrosomic babies. The patient must be aware of controlling glucose levels during labour and early feeding and early feeding and may reduce the risk of neonatal hypoglycaemia.[44] A clinical pharmacist is expected to aid the patient in the management of diabetes through insulin dosage, different types of insulin, management of missed dosage, medications contraindicated with insulin and the need to strategize the intake of meals to maintain a uniform glucose level, along with stimulating a lifestyle change and physical activity regime.

1.2 Justification

As per the American National Diabetes Prevention Program, education inputs may help to prevent the progression of GDM to diabetes (T2DM).[45] Although all the guidelines of GDM are well-defined in terms of exercise, diet and insulin therapy, compliance to the principles of management is difficult by patients. Optimal therapy requires regular monitoring, counselling and reinforcement. Common observations reveal that compliance to therapy, diet plans and permissible exercise patterns is lacking, as a consequence of which, there are issues pertaining to adherence to therapy as well as those associated with adverse outcomes such as pre-term births, stillbirths and other adverse neonatal issues, eventually resulting in greater neonatal

morbidity and mortality together with the added burden of possible maternal morbidity and mortality and herein lies the crux of the problem. Thus, this study arose from the need for standardizing and optimizing patient educational techniques to enhance compliance and thereby, contribute towards better maternal and neonatal outcomes. The current study has been planned to assess the effect of counselling on GDM patients by a clinical pharmacist to enhance the knowledge in these pregnant women for better self-care and healthy outcomes. We hypothesized that a clinical pharmacist may help in complete adherence to medical nutrition therapy coupled with regular glucose monitoring to result the better maternal and neonatal outcome.

1.3 HYPOTHESIS OF THE STUDY

Gestational diabetes mellitus commonly treated by doctors and nurses by using the hypoglycemic agents and dietary modifications. If GDM left untreated, it may result in sequence of adverse events (foetal macrosomia hyperinsulinemia and hypoglycaemia, preeclampsia, as well as premature delivery). The addition of clinical pharmacist counselling (for education of GDM, diet, monitoring glycemic level, and possible effect on neonates) in this study may increase the maternal and neonatal outcome. The present study, therefore aims to explore the following assumption.

Addition of clinical pharmacist counseling will be equally effective in the management of GDM outcome as routine counselling given by doctors and nurses. The null hypothesis of the study is clinical pharmacist counseling does not enhance GDM management prevention of complications and outcome of newborns.

1.4 OBJECTIVES

Primary objectives:

1. Role of clinical pharmacist on impact of health education in management of gestational diabetes mellitus
2. Role of socio-economic factors in management of gestational diabetes mellitus

Secondary objectives

1. Effect of gestational diabetes mellitus on newborn outcome
2. Guidelines and recommendation of health education in management of gestational diabetes mellitus

Gestational diabetes is ace of the types of diabetes mellitus which is documented solitary during gestation. Gestational diabetes mellitus affects the body as similar in other form of diabetes mellitus, give rise to blood glucose level and deprived neonatal outcome. It was well recognized during the last century that women with diabetes mellitus (DM) had poor outcomes for newborn. During, 1940s women with DM showed abnormally high incidence of neonatal mortality and adverse foetal outcome. First definition of GDM was given in 1950s the condition as a transient maternal condition which distress the foetal outcomes negatively and subsided after delivery. Progressive development in the knowledge of GDM was observed consecutively in 1960s for interpretation of the oral glucose tolerance test (OGTT) and in 1980s cutoff values of OGTT for blood glucose was adapted.

2.1 Fundamentals of Gestational Diabetes Mellitus

Earlier, GDM was demarcated as *"any degree of glucose intolerance that was first recognized during pregnancy, regardless of whether the condition may have predated the pregnancy or persisted after the pregnancy."* Although this description of GDM permitted uniform detection and classification of the condition, it suffered from the inherent shortcoming of temporal imprecision. Gestational diabetes mellitus (GDM), reported to be most common pregnancy complications, allied with a moderately rise upthe jeopardy of maternal and perinatal outcomes.[46, 47]Lifestyle changes reported to offer benefits to GDM women health and their neonates.[46]It was hypothesized that some of these helpful effects might be due to the inflection of the mother microbiota during pregnancy.[47, 48]Moreover, specific bacterial abundance allied with variant nutrient and energy intake.[49-51]During the progression of normal pregnancy, it is reported that gut microbiota gut microbiota remain stable or change dramatically, rise up of proteobacteria and actinobacteria.[48, 52] The prevalence of women of childbearing

age for type 2 diabetes has increased and noticeable rise in undiagnosed pregnant women with type 2 diabetes.[48]

As a consequence, prenatal visit is appropriate to assess women having jeopardy of type 2 diabetes as per standard criteria discussed in detail subsequently.

Subjects identified with diabetes in the first trimester need to be categorized based on existing pre-gestational diabetes (type-I or type 2 or monogenic), accordingly lifestyle alteration for risk diminution as they have a greater propensity to develop type 2 diabetes and GDM, although this needs further validation by studies.[53, 54] Basically, GDM is a type of diabetes which diagnosed first time in second or third trimester of pregnancy which was not there (Type 1 or type 2 diabetes) previously and is "hyperglycemic below diagnostic threshold for diabetes in pregnancy" basis the WHO 2013 definition.[47, 55]

It is imperative to note that diagnosis of GDM in early pregnancy are on the basis of either fasting plasma glucose (FPG) or oral glucose tolerance test (OGTT) results, it is backed by evidence because the diagnostic criteria for GDM according to International Association of Diabetes and Pregnancy Study Groups (IADPSG) for 75g OGTT and screening criteria implemented were not arrived from first trimester of pregnancy.[47, 56] It is also pertinent to note that GDM women need to be necessarily screened for pre-diabetes and subsequently for type 2 diabetes on a life-long basis because of two principal reasons – firstly, GDM predisposes women to a greater risk of developing type 2 diabetes post-deliveryand, secondly, effective preventative measures are available.[49-52] The existence of several modalities employed in the screening a diagnosis of GDM globally as a consequence of which, accurate epidemiological estimation is difficult.[57]

2.1.1 Epidemiology of GDM

2.1.1.1 Prevalence of GDM

Estimates of the International Diabetes Federation (IDF) demonstrated that almost 14% of gestations, translating into live births globally about 18 million/year, pretentious in gestational diabetes data of 2017.[58] The highest prevalence of GDM was observed in South-East Asia (24.2%) and the lowermost was observed in Africa (10.5%). Nearly 90% subjects of hyperglycemia in gestation reported from countries of low- and middle-income, which are having limited healthcare access to mothers.[59] Also, most of the prevalence data in low- and middle-income nations is restricted to the urban areas and there exists paucity of data from the rural settings.[60] GDM is, indeed, an emerging problem of public health importance in India as well. The reported prevalence of GDM among the urban Indian population ranges between 16% and 17.8%.[61] However, another published report places the rate of GDM prevalence between 3.8% and 21%, depending on the criteria and methodology employed.[60]Siddiqui S, et al., in a recently-published, multi-centric North Indian study demonstrated prevalence rates of GDM across various cities of North India, as shown in Table 1.[61]

No.	Cities	GDM Prevalence
1.	Bhilai	10.77%
2.	Muzaffarpur	3.07%
3.	Delhi	14%
4.	Overall prevalence	10%

Table 1. Prevalence rates of GDM across North Indian cities

In an earlier study carried out by Reddy KM, et al., in Telangana, India, demonstrated that prevalence of GDM was 1.83%.[60] Prior studies have shown the GDM prevalence rates of several cities in South India, as mentioned in Table 2.[62]

No.	Cities	GDM Prevalence
1.	Chennai	16.2%
2.	Thiruvananthapuram	15%
3.	Aluva	21%
4.	Erode	18.8%
5.	Bangalore	12%

Table 2. Prevalence rates of GDM across south Indian Cities

A recently-published meta-analysis by Behboudi-Gandevani S, et al. proved that the diagnostic criteria employed has a direct impact on the prevalence rates of GDM, and that the absence of evidence-based gold standards for accurate diagnosis could hinder the correct identification of pregnant women with GDM. Studies using the IADPSG criteria had a 6-11 folds higher prevalence compared to other subgroups. GDM, with high prevalence rates as described above, is allied with a high degree of maternal morbidity as well as mortality.[63]

2.1.1.2 Morbidity associated with GDM

The adverse connotation amid maternal glucose levels and maternal and fetal consequences is demonstrably clear and is also applicable to insignificant glucose levels. However, hyperglycemia and Adverse Pregnancy Outcome (HAPO) study testified and proven that these contrary consequences are sovereign of additional issues which include BMI and weight gain in gestation.[64, 65] These include hypertensive disorder, pre-term birth, proneness to unwanted surgical procedures, enduring metabolic comorbidities.

2.1.1.2 (A) Hypertensive disorders: During gestation hypertensive disorders can be categorized into three classes - namely, chronic hypertension, pre-eclampsia and gestational hypertension.[66] According to the HAPO study, highest BMI GDM subjects had eight times more propensity towards development of pre-eclampsia compared to women with the lowest BMI.[64] Barden A, et al. demonstrated that GDM subjects were found at a greater jeopardy of preeclampsia in comparison of controls.[67]However, another retrospective study by Esakoff TF, et al. demonstrated that chronic hypertensive GDM subjects had a shielding impact against the development of pre-eclampsia and pregnancy induced hypertension.[68] Nevertheless, hypertensive disorders, in the long run, augment the jeopardy of type 2 diabetes mellitus, metabolic disorder and cardiovascular diseases (CVDs) development.[69]

2.1.1.2 (B) Pre-term birth: The HAPO study reported that 6.9% of the total study participants were born pre-term, which was significantly allied with an upsurge in glucose levels of mother post-OGTT,which was not allied with fasting blood glucose levels.[64]

2.1.1.2 (C) Proneness to unwanted surgical procedures: GDM generally leads to the development of large babies within the maternal uterus and several such babies suffer from shoulder dystocia, as seen from subsequent sections. The vaginal delivery of large babies is, oftentimes, traumatic and compels the GDM women to undergo surgical procedures and perineotomy that would otherwise be deemed unnecessary.[70,71] Oftentimes, adverse complication, such as shoulder dystocia, associated with GDM, can be resolved only by performing a Cesarean section. By virtue of itself being a major surgical procedure, there exists an associated risk of problems for example infections, thrombosis, wound dehiscence and bleeding.[71]

The HAPO study demonstrated that 16.0% and 7.7%, respectively, of the total study population, had to undergo a primary Cesarean delivery and a repeated Cesarean delivery. These were found to be allied with amplified mother glucose post OGTT and fasting glucose levels.[64] Also, the Toronto Trihospital study demonstrated that despite abridged infant's birth weights, Cesarean sections were still performed on women with GDM, leading to the suggestive inference that GDM, might be a possible indicator for Cesarean mode of delivery.[72] In a study of 392 patients with gestational diabetes mellitus, it was found that 57.4% subjects underwent elective cesarean deliveries. Amongst the maternal characteristics, it was determined that mean age and pre-gestational BMI (p<0.01) were reported greater in cesarean delivery.[73] Luck ML, et al. demonstrated the GDM was allied with an amplified jeopardy of delivery by Cesarean section in women with and without health insurance coverage (Medicaid). According to this study, amongst the women covered by Medicaid, GDM women significantly more prone for Cesarean sections in comparison of without GDM (39.5% *vs.* 27.5%, p<0.001). At the same time, GDM women lacking for Medicaid were significantly more prone for Cesarean section than women without GDM and without Medicaid (38.7% *vs.* 27.7%, p<0.001).[74]Another study involving 237 term, pregnant women with GDM demonstrated that, GDM significantly rise up the jeopardy of emergency C-section delivery (adjusted OR=1:9; p=0.039) for nulliparous women when adjusted for age, BMI and gestational weight gain compared to normal pregnant women.[75]

2.1.1.2 (D) Enduring metabolic comorbidities in women: Abandoned hyperglycemia in GDM subjects increases their propensity of emerging T2DM in future. Bellamy L, et al. confirmed that GDM women stood at 7.43 times greater prone for developing T2DM compared to without GDM women.[76] Song C, et al., in a

meta-analysis of 30 cohort studies comprising over 2 million pregnant women, established that women with prior GDM had a 7.76-fold unadjusted and 17.92-fold adjusted shared jeopardy of diabetes in comparison of women without GDM. Observed jeopardy to be highest during the initial 3-6 years after GDM.[77] Kramer CK, et al., in a recent pooled meta-analysis of 9 studies reported data from 5,390,591 subjects (101,424 cardiovascular issues), demonstrated that subjects with GDM had 2-fold higher jeopardy of future cardiovascular events (RR=1.98) in comparison of women without GDM. Moreover, this risk was unaffected by incident T2DM. However, it is reported that jeopardy of cardiovascular events is 2.3 folds in the first 10 years post pregnancy (RR=2.31).[78]Hopmans TE, et al., in a methodical assessment of 8 studies comprising data from 276,829 patients, revealed that women with gestational diabetes had a 9.5%-37.0% risk of developing T2D and a 0.28%-15.5% risk of developing CVD compared to women without gestational diabetes.[79]

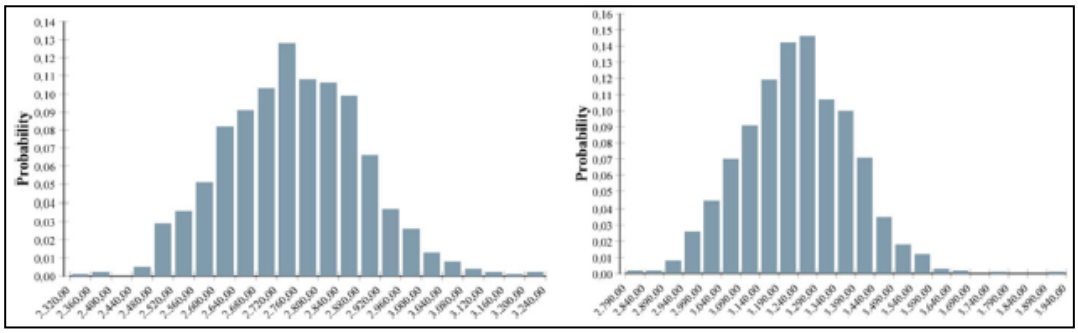
2.1.1.3 Mortality associated with GDM

There exists a strong association between GDM and the risk factors contributing towards maternal mortality, including postpartum hemorrhage, obstructed labor and pre-eclampsia.[80]Usage of continual glucose monitoring in pregnancy with type 1 diabetes is allied with better neonatal outcomes, plausible to compact exposure to maternal hyperglycaemia. Eig DS etal., 2017 reported that CGM designated potential to benefit in non-glycaemic health outcomes.[81]

2.1.2 Financial Burden of GDM

The economic and financial implications of gestational diabetes to individuals as well as nations is enormous, as described hereunder. A recently-published Mexican modeling study led by Sosa Rubi SG, et al. demonstrated that a GDM pregnancy

resulted in a total additional cost of $1576.2 per case, and that, considering the variability in incidence rates of GDM across Mexico, there could be an additional annual burden of $86.8-$827.4 million.[82] Dall TM, et al., in a recently-published study, demonstrated that the economic burden associated with gestational diabetes was almost $1.6 billion and that the annual burden per case averaged $5,800.[83]Meregaglia M, et al., in an Italian study, concluded that there was an overall cost per case difference of €817.8 (+ 29.2%) between GDM and normal pregnancies resultant in excessive financial burden€44.8 million to the national exchequer. Monte Carlo simulations revealed that probabilistic sensitivity analysis generated a cost per case variance of €464.9-€1164.8 in 80% of the simulations.The Monte Carlo probability distributions depicted in figure-2 for inpatient cost per case in euglycemic and GDM subjects.[84]



(A) **(B)**

Figure2: Monte Carlo probability distributions in (A) euglycemia (B) GDM

Another Italian study by Danielli L, et al. demonstrated that every single GDM pregnancy resulted in 22.4% additional costs compared to a normal one, corresponding to a €636.5 per case difference and totaladditionaldrain of approximately €34.9 million for healthcare system of nation.[85]A Chinese study led by Xu T, et al.2017revealed that the cost of a GDM pregnancy was ¥6677.37

(approximately $1929.87), on an average, amounting to 95% more than a pregnancy without GDM, eventually, resulting in an annual societal economic burden of ¥19.36 billion (approximately $5.59 billion) and 2,60,000 quality-adjusted life years lost.[86] Indian studies on GDM and on diabetes, in general, have laid emphasis on the costs borne by individual patients and have not focused on costs incurred by the national exchequer and have been discussed in subsequent sections below.[87, 88]

2.1.3 Risk Factors for GDM

There are numerou sjeopardyissuesallied with GDM, it include overweight/obesity, [Okosun IS 2004] excessive gestational weight gain,[89]adoption of western dietary habits,[90]ethnicity,[91] genetic polymorphisms,[92] advanced maternal age,[93] intrauterine situation (low or high birth weight),[94] having a personal or family history of GDM,[95] and other insulin resistance disease, for example polycystic ovarian syndrome (PCOS),[96]each of them have direct bearing on impaired β-cell function and insulin sensitivity.[57]

2.1.4 Clinical Presentation of GDM

The clinical presentation of diabetes mellitus in pregnancy might appear varied. Most pregnant patients may not present with the classical triad of symptoms including polydypsia, polyphagia and polyuria. Nevertheless, they mightextant with prior history of medical complications of diabetes mellitus (includes lingering hypertension/ kidney issues) and obesity. Pregnancy outcomes are directly influenced by the gestational age at presentation.[97] Moreover, in settings such as India, GDM can become enormously psychologically stressful for both pregnant women and their families.[98,99]

2.1.5 Pathophysiology of GDM

There exists interplay between β-cell impairment and chronic insulin resistance together with a plethora of other factors, which together precipitate GDM. Other organ-system that serve to precipitate GDM comprise the brain, adipose tissue, liver, muscle and placenta. The contributing factors to the underlying pathophysiology of GDM have been explained as follows:

2.1.5.1 β-Cell Dysfunction

β-cell dysfunction arises when β-cells mislay the capability to effectively detect blood glucose levels and secrete adequate insulin in retort resulting in extended, extreme insulin secretion in retort to chronic fuel excess, although the precise mechanisms could vary.[100-102]Dysfunction of β-cell is aggravated by numerous factors including insulin resistance, reduction in insulin-stimulated glucose uptake and results in blood glucose level increase. All this together compelled the β-cells to increase the secretion of more insulin. This process also known as glucotoxicity and plausibly results over the time in β-cell apoptosis.[103] This results in a hyperglycemia, insulin resistance and further deterioration in β-cell function. Many animal studies quoted that the number of β-cell number is a vital factor of glucose homeostasis. Drastic, short-term decreases in β-cell mass burdens the residual β-cells, leading to sternlyabridgedinsulin secretion stimulated by glucose and internal insulin stores reduction.[104]Rosik J etal. 2020 reported epigenetic down regulation of transcription factor (which is necessary for normal β-cell differentiation in the embryo) is related with the loss of β-cell.[105]Thus, it is the triumvirate of all 3 factors – namely, reduced β-cell mass, number and dysfunction – that eventually precipitate GDM.

2.1.5.2 Insulin Resistance

Insulin resistance occurs when cells do not exhibit adequate response to insulin. Glucose transporter 4 (GLUT4) which is responsible for transporting the glucose for cells, its insufficiently plasma membrane translocation is a result of letdown the insulin signaling.

In GDM, insulin-stimulated glucose uptake rate is abridged by 54% in comparison of normal pregnancies.Along with altered expression of Insulin Receptor Substrate (IRS-I), Phosphatidylinositol 3-kinase (P13K) and GLUT4 (Figure-3).[106]

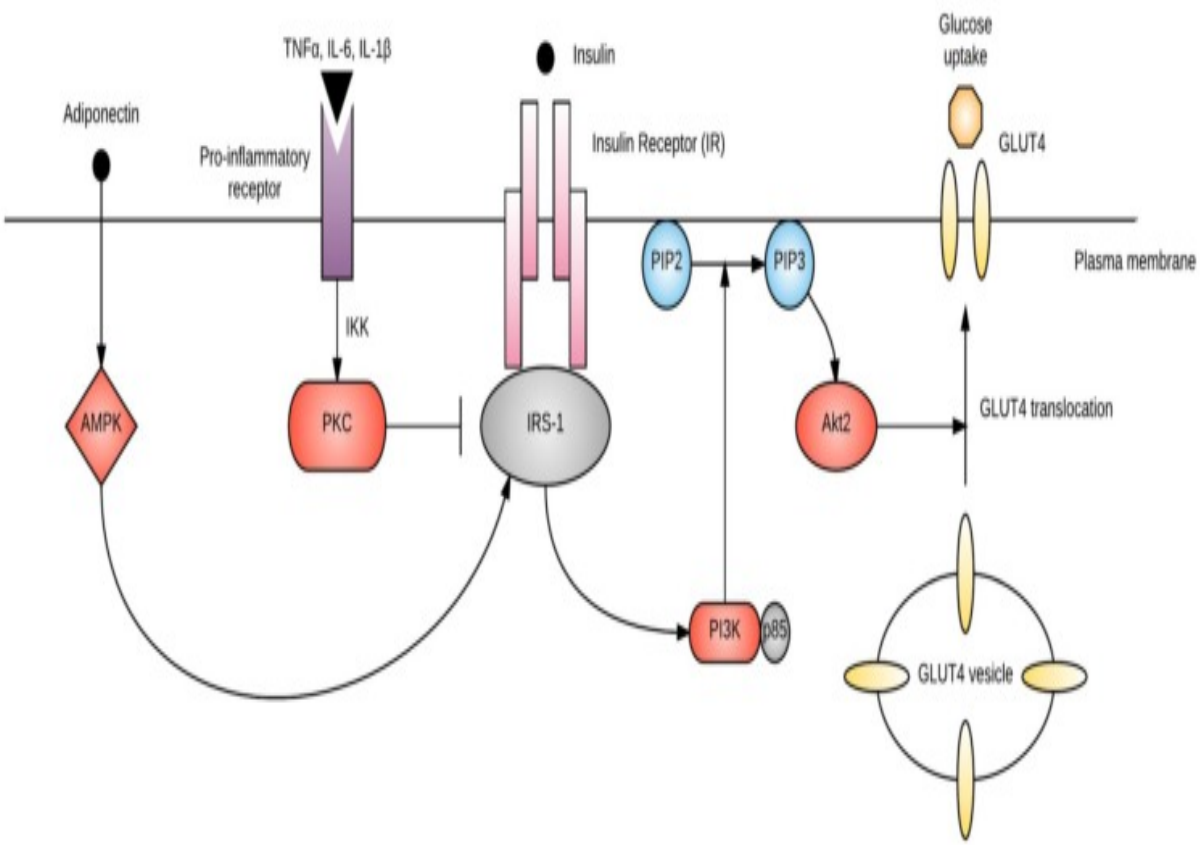


Figure 3: Schematic of insulin signaling (adapted from Plows JF, *et al.* 2018)

Most of molecular fluctuations persist beyond pregnancy. Numerous aforementioned jeopardyissues for GDM gave the impact through intrusion of

insulin signaling. The β-cell dysfunction, insulin resistance and GDMrelationship has been illustrated in Figure 4.[107]

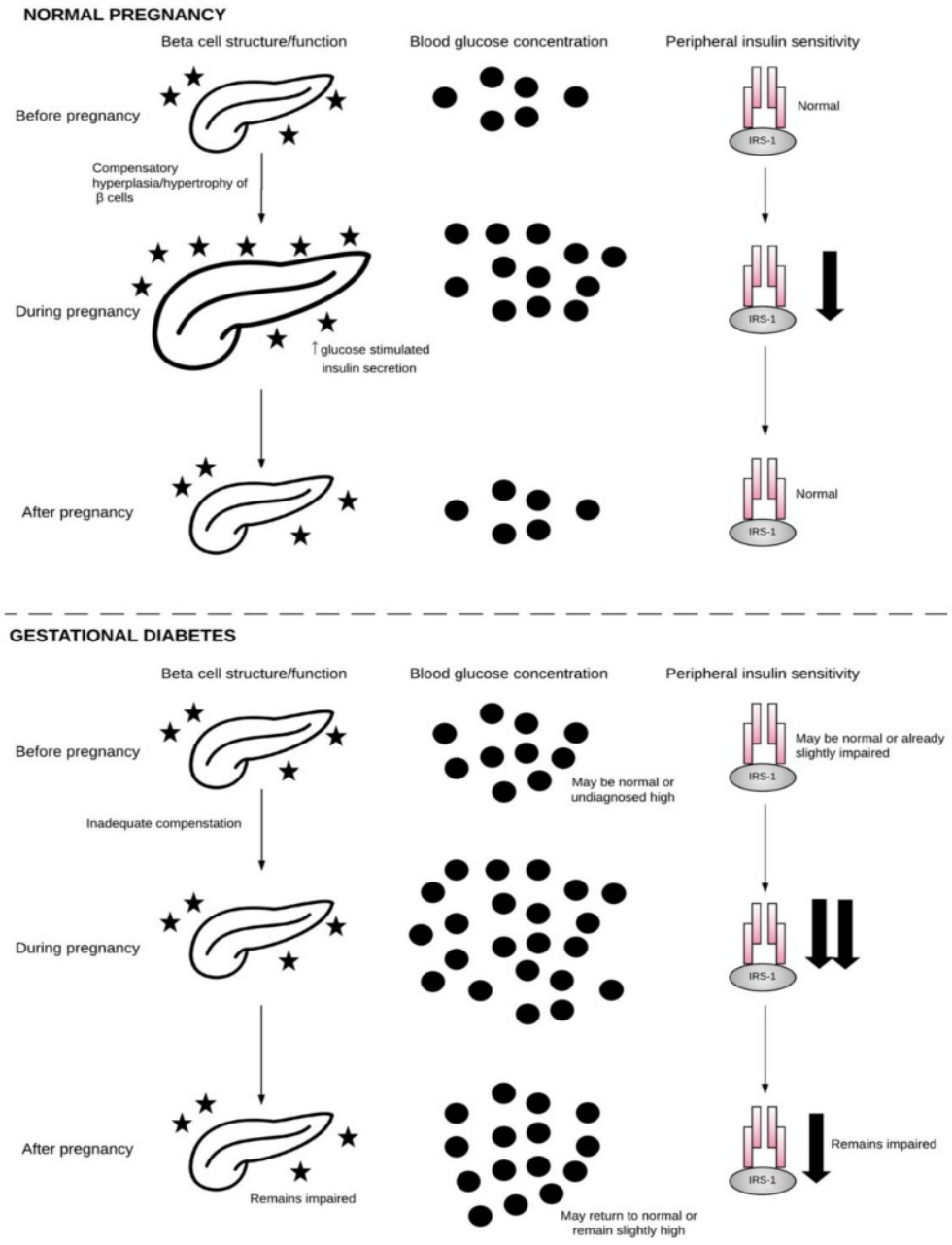


Figure 4: Schematics of the inter-relationship betweenβ-cell dysfunction, insulin resistance and GDM (Adapted from: Plows JF, *et al.* 2018)

2.1.5.3 Neurohormonal Networks

Neurohormonal networks contribute to the pathogenesis of disorders of insulin resistance, including GDM, by regulating hunger, active energy spending and metabolic rate. A complexnetwork between central as well as peripheral signals.[108, 109]These networks influence glucose utilization, adiposity which is controlled by circadian clock.[110, 111]Adipokines include leptin and adiponectin are amongst the important regulators of neurohormonal metabolic control.

2.1.5.3(A) Leptin

Leptin is known as satiation hormone, it is secreted majorly by adipocytes in retort to sufficient energystores. It mainly acts on arcuate nucleus of hypothalamus neurons which decreases hunger and upsurge energy disbursement by the appetite stimulator inhibition, namelyneuropeptide Y (NPY) and agouti-related peptide (AgRP), activation of pro-opiomelanocortin (POMC).[112] Leptin resistance arises in normal gravidity to a certain extent, which boost storage of fat more than the body requirement.

There is greater leptin resistance in GDM, leading to hyperleptinemia.[113]The placenta is accountable for the mainstream of plasma leptin during pregnancy.[114]Placental leptin secretionaugmented in GDM due to placental insulin resistance and it results in hyperleptinemia. It facilitates amino acid transportation across the placenta, contributory to macrosomia in fetal.[115]

2.1.5.3(B) Adiponectin

Adiponectin, like leptin, is a hormone primarily release by adipocytes.[116] However, unlike leptin, it has a stronger association with insulin resistance compare to adiposity.[117]Adiponectin augments insulin signaling through numerous factors in liver viz; fatty acid oxidation, inhibits gluconeogenesis by actuating insulin sensitive cells

for AMP-activated protein kinase (AMPK), enables the deed of IRS-1 (as in Figure 2) and peroxisome proliferator-activated receptor alpha (PPARα).[118]Besides of that, up-regulation of insulin gene and insulin granules exocytosis from β-cells stimulates by adiponectin.[119]Furthermore, numerous cytokines such as tumor necrosis factor-alpha (TNF-α), interleukin-6 (IL-6), interferon-gamma (IFN-γ), and leptin controlled the placenta expression of low concentration of adiponectin. Restrictive fetal development results from adiponectin induced impair of insulin and amino acid transportation across the placenta. Hence, maternal glucose intolerance and fetal macrosomia is associated with placenta adiponectin gene methylation.[120]

2.1.5.4 Adipose Tissue

Adipose tissue ensures the safe partitioning of energy as well as active secretion of circulatory factors, including adipokines having widespread metabolic effects.

2.1.5.4(A) Energy Storage

Early gestation is characterized as increase in adipose tissue mass and whereas pregnancy in late stages mobilizes fats from adipose tissues for fetus growth, boththe process gets affected in GDM.[121]In GDM, there is abridged adipocyte diversity and augmentedsize of adipocyte (hypertrophy), along with insulin signaling regulators, adipogenic factors, fatty acid transporters downregulation.[122]Safely dispose of excess energy, lipo-toxicity and other peripheral organs majorly hinder by insulin resistance and decreased adipocytes. GDM is allied with deposition of lipid in muscle and liver.[123, 124]

2.1.5.4(B) Adipose Tissue Inflammation

In GDM, the mingling concentrations of pro-inflammatory cytokines are reported to be increasedby Fasshauer M et al 2014 and Ategbo JM et al 2006.[125, 126]Kirwan JP etal., 2002 reported a strong association among plasma TNF- α and insulin resistance.[127] Augmentation of TNF-α, IL-1β and respective receptors are reported in placenta of GDM subjects.[127,128]Lappas M etal., 2010 reported that the placenta of GDM subjects secrete fewer pro-inflammatory cytokines (IL-1β, TNF-α and M1P1B) compared to healthy subject placenta, suggesting a complex relationship between pro-inflammatory cytokines and GDM.[129]

2.1.5.4(C) Visfatins

Adipokine named as Visfatin issecret by the adipose tissue in human body. It binds to receptor and elicit hypoglycemia which is almost similar to insulin binding to the insulin receptor-1. Membranes of fetal, myometrium, bonemarrow, liver muscle, heart, lung, kidney, macrophage and neutrophils all expressed visfatins, moreover visfatins secreted in breast milk as well. There are ambiguities concerning the role of visfatin in human beings, visfatinalso reported to regulate energy homeostasis, thereby known factor in the pathogenesis of GDM. Visfatin affects many functions which includes gene regulation for oxidative stress and inflammatory response, circadian rhythm and β-cell function also gets affected.[130]

2.1.5.5 Liver

GDM is associated with gluconeogenesis, which amplified in the fasting condition and not sufficientlydecline the glucose availability.[106]Other factors, viz. augmented protein intake and breakdown of musclesand serve as substrate for

gluconeogenesis.[131]Yet, the liver is not primarily intricate in the pathophysiology of GDM.[132]

2.1.5.6 Skeletal and Cardiac Muscle

During the GDM, it is found that function and number of mitochondria of skeletal muscle cell decreased.[133]It results fromearly life programming, genetic back ground, sedentary life or chronic inactivity. In such GDM cases, decline in number and function of mitochondria adds less glucose utilization and worsen the diabetic status.

2.1.5.7 The Gut Microbiota

Gut microbiota plays a major role in the development of GDM. Fugmann M et al., 2015 conducted a study on GDM subjects stool bacteria and reported that in comparison of normal pregnancy GDM subjects had lesserFirmicutes phylum bacteria and high yield of Prevotellaceaefamily bacteria.[134]Basically Firmicutes are known for metabolism of polysaccharides derived from dietary plant, thereby justifying thediet relatedjeopardy factors for GDM.[135]Thus, Firmicutes plays a keyprotagonistfor GDM pathogenesis independent of diet, precise mechanism for thatis unclear. Prevotellaceae possibly upsurge the gut permeability and they are known for mucin-metabolism. Usually control of gut penetrability is depends onclose junction of proteins, like zonulin (ZO-1). Heightened “free” ZO-1 of plasma and serum is reported to allied to GDM. Increased gut permeability facilitates the inflamogen movement from gut to systemic circulation, promoting systemic insulin resistance.[136-138]

2.1.5.8 Oxidative Stress

Increased blood glucose is indirectly linked with oxidative stress and GDM women overproduce the free radicals and partake free-radical scavenging mechanisms are also impaired.[139]Pesseler D et al., reported that the reactive oxygen species (ROS) interfere with both IRS-1 and GLUT4 which result in insulin inhibition and stimulate glucose uptake.[140]Glycogen synthesis in the liver and muscle also get slowdown and affected. Pro-inflammatory cytokines, for example TNF-α, aggravate oxidative strain by upregulate the activation and expression of ROS precursors, namely NADPH oxidase 4 (NOX4).[141]Studies conducted byJayadian P et al 2014 demonstrated that replete of iron supplementation in women is allied with GDM.[142]On the other hand, selenium and zinc have an inverse association with GDM.[143]Homocysteine is another contributor towards GDM through oxidative stress. Even small amount of homocysteine exposure of β-cells results in dysfunction and impaired insulin secretion.[144]A meta-analysis by Gong T, et al. reported high and significant homocysteine levels in GDM subjects in comparison of without GDM.[145]Studies indicate vitamins B-complex group (folic acid, B12, B6, and B2)isvital for homeostasis of homocysteine. This is one of the plausible explanations for deficits and inequities of these micronutrients being relatedto GDM.[146]

2.1.5.9 Placental Transport

The placenta is one of the contributors for insulin resistance development in pregnancy due to its hormones and cytokines secretion. During GDM, placenta getsaffected by hyperglycemia and results ininadequate carriage of essential nutrients lipids, glucose, amino acids:

2.1.5.9 (A) Glucose: Glucose is the chief source of energy which need to be available all the time for the fetus and the placenta. Therefore, placental transport of glucose not require the insulin. Transport of glucose in placenta occurs via GLUT1 and sodium-independent diffusion.[147]However, expression of insulin from placenta still occurand results in influence placental metabolism of glucose.[148] This indicates that placenta is delicate to hyperglycemia and this results in increased fetal growth and macrosomia.

2.1.5.9 (B) Amino Acids/ Proteins: Transportation of amino acids across the placenta is a key factor of the growth of fetal. Increased System A and L activity reported to be associated with GDM, which is surplus by inflamogen, such as IL-6, and TNF-α.[149,150]Altered amino acid transport is one possible mechanism explaining the contribution of excess protein intake to GDM.

2.1.5.9 (C) Lipids: Although GDM has been knownfor hyperglycemia, the rising incidence of GDM allied obesity has drawn focus on hyperlipidemia role in GDM. Placental gene expression pathway of lipids is reported to get affected majorly by 67% whereas, glucose pathway gets affected only 9% in GDM. Placental lipid genes activation allied with the GDM compared to T1DM.[151]GDM influence the transport of key nutrient such as glucose, amino acids and fatty acids in placenta and all theseare responsible for placental function and fetal growth.

In addition, GDM has also been observed to be associated with other changes in the placenta, including global DNA hypermethylation,[152]expression of proteins and their epigenetic and proteomic modifications,[153, 154]expression of microRNAs (miRNAs) intricates in various cellular developments – counting proliferation, differentiation and apoptosis – which, in turn, precipitate the pathogenesis of GDM.[155, 156]Endocrine disrupting chemicals (EDCs) specifically bisphenol A (BPA) is reported to be allied

with GDM, and it could be results of EDCs induce exosome signaling from the placenta.[157] Report confirms that EDCs are associate and plays a role in methylation alteration.[158]A summary of the pathophysiology of hyperglycemia in GDM[159]has been illustrated in Figure 5.

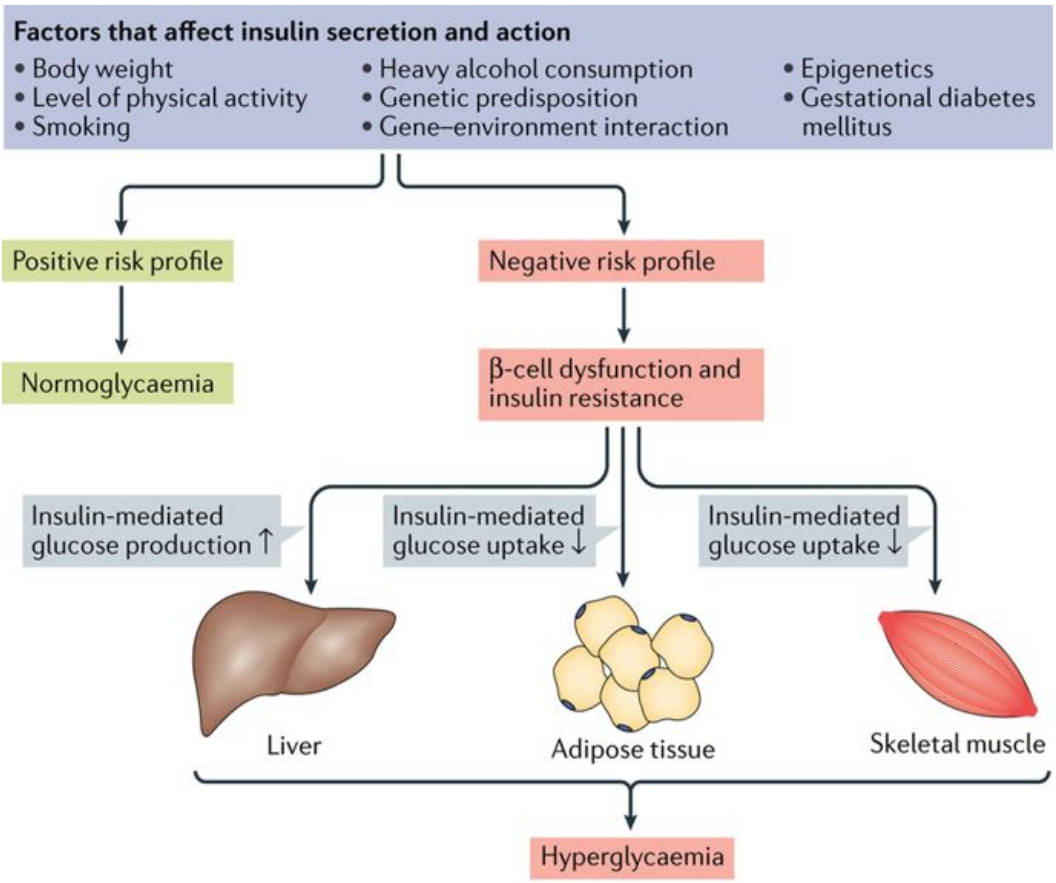


Figure 5: Pathophysiology of hyperglycemia in GDM

2.1.6 Diagnostic criteria of GDM

Renderingof American Diabetes Association, diagnosis of gestational diabetes is based on standard diagnostic criteria for diabetes. This criterion involves the monitoring of plasma glucose level for fasting plasma glucose (FPG) or plasma glucose value after 2 hours of 75-g oral glucose tolerance test (OGTT) orglycosylated hemoglobin value, the same has been elucidated in Table 3.[47]

FPG ≥126 mg/dL (7.0 mmol/L)[#]
OR
2-h PG ≥200 mg/dL (11.1 mmol/L) during OGTT[##]
OR
A1c ≥6.5% (48 mmol/mol).[^]
OR
Classic symptoms subject of hyperglycemia,random plasma glucose ≥200 mg/dL (11.1 mmol/L).
[#]No caloric intake for continuous 8 hours define as fasting.* [##]Test as described by WHO, using 75-g anhydrous glucose dissolved in water.* [^]Test Should performed in laboratory using NGSP certified and standardized to DCCT assay.* * In the presence of unequal hyperglycemia, two abnormal test results from the same sample or in two separate test samples required to make diagnosis.

Table 3. ADA Diagnostic Criteria for Gestational Diabetes Mellitus

The WHO recommends the following criteria for the diagnosis of GDM[161]:

- Fasting plasma glucose: 5.1–6.9 mmol/L
- 1-hour post-load plasma glucose: ≥10.0 mmol/L
- 2-hour post-load plasma glucose: 8.5–11.0 mmol/L

The Diabetes in Pregnancy Study Group India (DIPSI) has developed a one-step diagnostic procedure to overcome the practical issues in performing glucose tolerance test in the fasting state. The test has been customized to Indian settings and encompasses the administration of a 75-g oral glucose and drawing ablood sample at

2 hrs for the estimation of plasma glucose. Following a 75-g oral glucose load, the diagnosis can be made on the basis of the criteria outlined in Table 4.[160]

2-h plasma glucose levels	Diagnostic Criteria
≥200 mg/dL	Diabetes
≥140 mg/dL	GDM
≥120 mg/dL	DGGT
DIPSI: Diabetes in Pregnancy Study Group India; **DGGT:** decreased gestational glucose tolerance; **GDM:** gestational diabetes mellitus	

Table 4: Diagnostic Criteria for DIPSI

The test need to conduct between 24 weeks and 28 weeks of pregnancy. The advantages of this test are that it is simple, economical and feasible.[160]

2.2 Management of Gestational Diabetes Mellitus

2.2.1 Overarching Principles in the Management of GDM

The following recommendations of the ADA govern the overall management of GDM[161]:

1. Lifestyle changesplays a key role in management of gestational diabetes mellitus and could be sufficient for the treatment of women, medications need to be added if require to attain glycemic targets. (Level of Evidence: A)

2. The preferred medication for hyperglycemia treatment in GDM is Insulin as it do not crosses the placenta up tosome extent. Metformin and glyburide should not be used as first-line agents, as both cross the placenta to the fetus. All oral agents lack long-term safety data. (Level of Evidence: A)

3. Metforminneed to discontinue once pregnancy confirmed in the case of polycystic ovary syndrome and ovulation treatment. (Level of Evidence: A)

2.2.1.1 Lifestyle Changes:

Lifestyle modifications, including physical activity and weight management depending on pre-gestational weight form essential prerequisites of GDM management. The recommendationfor glycemic targets from Fifth International Workshop-Conference on Gestational Diabetes Mellitus include[161]:

- Fasting <95 mg/dL (5.3 mmol/L)
- One-hour postprandial <140 mg/dL (7.8 mmol/L)
- Two-hour postprandial <120 mg/dL (6.7 mmol/L)

Studies have demonstrated that 70–85% of women diagnosed with GDM are capable of controlling GDM with lifestyle modification alone.[162]

2.2.1.2 Medical Nutrition Therapy

Individually structured nutrition design known as medical nutrition therapy for a pregnant woman with GDM.[163,164]An ideal nutrition plan should be such that it provides for appropriate calorific intake towards promoting the health of neonate and mother, attainment of glycemic targets and apt gestationalweight gain. While specific, definitive and optimized calorific intake patterns for pregnant women with GM do not exist, the nutrition plan should be prepared on the basis of a nutrition assessment guided by the Dietary Reference Intakes (DRI). DRI recommends following minimum requirement for all pregnant women[165]:

- 175 g of carbohydrates
- 71 g of protein
- 28 g of fiber

The type of carbohydrate and amount will have a direct bearing on glucose levels, especially post-meal excursions.

2.2.1.3 Pharmacologic Therapy

It has been proven in large-scale randomized trials that treatment of GDM with lifestyle modifications and insulin results in improved perinatal outcomes.[166]Insulin gets the priority and recommendation for the treatment in the management of GDM.[165]Metformin and glyburide have demonstrated limited efficacy in reducing glucose levels in GDM; however, these medicines are not suggested as first-line treatment for GDM as it is capable of crossing the placental barrier and there exists no data on the safety of the offspring.[167-170]

2.2.1.3 (A) Sulfonylureas

Sulfonylureas are capable of crossing the placenta and proved to be associated for neonatal hypoglycemia. Some of the potential drawbacks of glyburide have been outlined below:

- It is reported for a higher susceptibility of macrosomia and neonatal hypoglycemia in comparison of insulin or metformin[171]
- Non-inferior to insulin for neonatal hypoglycemia, macrosomia and hyperbilirubinemia (composite outcome)[172,173]
- Non-availability of long-term safety data for offsprings[172, 173]

2.2.1.3 (B) Metformin

In comparison of insulin, metformin possesses the less weight gain of mother and lower risk of neonatal hypoglycemia.[171]However, it carries the risk of prematurity. Metformin crosses the placentaand umbilical cord, which results in higher blood concentration of metformin in comparison of corresponding mother blood

concentration of metformin.[174]Four-years follow-up study of metformin in polycystic ovary syndrome, reported to increase BMI and obesity in offspring's.[176, 177]

On the basis of several randomized, double-blind controlled trials, a comparison of metformin with other remedies for ovulation initiation in women with polycystic ovary syndrome have not been proven beneficial in avoiding spontaneous miscarriagein GDM subjects, and there is no evidence-based study which support the use of metformin in such patients after confirmation of pregnancy.[178, 181]

2.2.1.3(C) Insulin

According to the ADA, subjects need to follow the prescribed guidelines for insulin usage. Manifold daily insulin injections and incessant subcutaneous insulin infusion have proved beneficial effect and delivery strategies, none of them found to be superior then other during the pregnancy.[182]Howsoever precise, the management of GDM poses inherent challenges for both the patient and the growing fetus.

2.2.2 Challenges in the Management of GDM and their combative measures

The challenges associated with the management of GDM are as listed below:

2.2.2.1 Lack of patient awareness: Oftentimes, patients are not aware of the importance regular glucose monitoring, dietary management and treatment adherence. As a result, they tend to skip medications and not maintain glycemic targets. Patients inadequate knowledge pertain to diet related issues and disease management results in impaired glycemic control and malnutrition of both mother and the fetus.

The inadequate knowledge of patients on dietary issues and disease management results in malnutrition for mother and fetus along with impaired glycemic control.

Patients need to be educated on these aspects at every stage. It is important that patients rely on credible and authentic sources of information that are valid, reliable and comprehensive.[183]

2.2.2.2 Glucose Monitoring: There are no specific clinical guidelines and clinical trials reports to specify the frequency of glucose monitoring for the GDM women who are on lifestyle and diet management.

In routine practice monitoring of blood glucose usually done for 3-4 times in a day at least on 2 days of the week,pharmacotherapy gets initiated on surpass the blood glucose limits twice in a week. Urine glucose monitoring does not serve to be a useful strategy in GDM patients. However, to notice inadequate caloric intake, monitoring of urine ketone is useful for the patient who are on diet management.[184]

2.2.2.3 Delivery associated Challenges: There is dearth of concrete and definitive data pertain to delivery mode and time of GDM women. Generally, when blood glucose of women is normal or near normal, delivery should be at term. Usually, GDM gravidities are not recommended to wait beyond the term. While cesarean sectionnot reported toassociate forsubstantialdecreasein birth trauma or lower costs, early delivery was allied with decrease of macrosomia but other neonatal complications continued to exist.[184]

2.2.2.4 Postpartum management: Data indicate that 40-60% of GDM women tends to evolve type 2 DM in future and similarly predisposed to a jeopardy of recurrent GDM in imminent pregnancies. They should be regularly screened for type 2 DM

startfrompost-delivery six weeks and yearlyafterwards. In addition of that, an OGTT must be performed postpartum, 1 year post-delivery, and every 3 years afterwards.[184]

2.2.2.5 Costs of Treatment: The GDM women, who do not have health insurance and incur the expenses out of pocket for the GDM management, cost of GDM management become the snag for them. The purchase of equipment's such as glucometers and their accessories, medicines and diet alterations lead them to incur enormous monetaryloads. Specially in rural areas, limited income, limited availability and distance of public health centers, intermittent travel cost for follow-ups results in accruing financial burdens. All together this indicate that, to achieve the decrease in GDM burden of India accessible health care service and increase in public health care centers need to be developed.[183]

2.2.2.6 Behavioral Factors: Oftentimes, the inability of patients to adapt themselves to lifestyle modifications coupled with inherent personal and familial beliefs and practices could lead to a conflict between personal choices and preferential habits and trying to meet glycemic targets.[185]Gestational Diabetes can result in serious deleterious effects in the newborn.

2.2.3 Expected outcomes in newborns and their Mechanisms

The expected outcomes in newborns of GDM mothers can be as described in macrosomia, β-cell dysfunction, dystocia and brain injury, stillbirth, long-term non-communicable diseases, inter-generational GDM.

2.2.3.1 Macrosomia: In GDM, placental transportation of glucose, amino acids and fatty acids reported to increase, which kindle the endogenicrelease of insulin and insulin-like growth factor 1 (IGF-1) in the fetus. These all together could result in

fetal overgrowth, leading to macrosomia at birth.[186]Fetal macrosomia could affect about 15-45% newborns of GDM women and mentioned ≥4.0 Kg birth weight.[187]

2.2.3.2 β-cell dysfunction: The excess production of insulin in the fetus can strain the evolving pancreatic β-cells, causative to β-cell disfunction and insulin resistance, even prenatally.[188]

2.2.3.3 Dystocia and Brain Injury: Macrosomia is a jeopardy factor for shoulder dystocia.Therefore, GDM pregnancies are majority of time delivered by caesarean section.[189]GDM women babies firmly depends on maternal hyperglycemia, it leads the babies to the risk of hypoglycemia (hyper-insulinemia) and if not managed properly, it can result in brain injury.[191]The prevalence of shoulder dystocia among offsprings of GDM mothers is about 3%.[192]Maternal diabetes and obesity are associated with a 2-to-4-fold higher risk of shoulder dystocia.[193]The prevalence rates of shoulder dystocia, on the basis of birth weights,[192]have been mentioned in Table 5.

Birth weights	**4000 to 4250 g**	**4250 to 4500 g**	**4500 to 4750 g**	**≥4750 g**
Unassisted births to diabetic mothers	8.4%	12.3%	19.9%	23.5%
Delivery by vacuum extraction or forceps	12.2%	16.7%	27.3%	34.8%

Table 5: Prevalence of shoulder dystocia by birth weight and nature of delivery

2.2.3.4 Stillbirth: GDM has confirmed to upsurge the peril of stillbirth.[194]Stacey T, et al., in a recently-published UK-based case-control study, demonstrated the risk of GDM subjects, reported 44% high risk of late stillbirth than those women not on

jeopardy (aOR=1.44). At the same time, women with elevated fasting plasma glucose levels but not identified as GDM,reported a 4-fold greater risk of late stillbirth in comparison of women with normal fasting plasma glucose levels (aOR=4.22).[195]A retrospective review of the Texas vital health records database demonstrated that there was a rise in the overall rate of stillbirth to 26.7/10,000 pregnancies in the morbidly obese group. The coexistence of pregestational diabetes mellitus further increased it to 209.8/10,000 gestations in the morbidly obese group.[196]An Asian meta-analysis demonstrated that the history of stillbirths in mothers could be a more likelyjeopardyissue for evolving GDM in further pregnancies (OR=2.39).[197]

2.2.3.5 Long-term Non-communicable diseases: Literature indicate that the GDM gravidities women have more jeopardy of there is an upsurge in the certain metabolic disorder, obesity, T2DM and CVD.Babies of GDM women have nearlyduple the jeopardy of emerging childhood obesity in comparison of non-diabetic mothers, even after regulatingthe cofounders namely maternal basal metabolic index, glucose tolerance impairment can be noticedat young age of 5 years.[198-200]A reevaluation of the HAPO study demonstrated that the babies of GDM women exhibited higher rates of abnormal glucose tolerance (4.7% *vs.* 1.7%, p=0.04), overweight or obesity, BMI and BP together and a trend towards abridged β-cell function in comparison of babies of non GDM women.[201]

2.2.3.6 Inter-generational GDM: Women more likely to experience GDM in their own pregnancies, causal to a malicious intergenerational cycle of GDM.[202] Primarily, it is necessary to educate mothers on the risk factors, presentation and changes during GDM and equip them with measures to combat the same.

2.2.4 Educating Patients about GDM

Some of the strategies employed to educate patients on GDM, based on studies carried out in the past, are as follows: An Iranian study, published in 2018, brought out a health education strategy for GDM patients covering the following strategic pointsawareness and aptitude, Knowledge about diabetes, empowerment and training of Mothers, quality, continuity, resources of information, Lifestyle, Mental health, family role for support.[203]

2.2.4.1. Awareness and ability: Provision of awareness of diabetes and its self-care during pregnancy and helping them gain knowledge and skills in four thematic areas – necessityto know diabetes, empowerment and training for mothers, quality, continuous effort, and appropriate information source.

2.2.4.2. Knowing diabetes: Augmenting and improving mothers' understanding of diabetes, treatment compliance and making dietary recommendations.

2.2.4.3. Mothers' training and empowerment: Skill acquisition and training for blood glucose monitoring, appropriate mode of administration and dose adjustment for insulin along with nutritional and diet planning and overall disease management.

2.2.4.4. Continuity and quality: Addressing the mothers' need for quality and continuous counseling and education so as to cope with the disease in reality.

2.2.4.5. Information resources: Authentic and credible information given to mothers regarding correct feeding, indications and procedure to handle blood sugar changes together with provision of information brochures, books, leaflets, packages to educates about the management of diabetes in pregnancy.

2.2.4.6. Lifestyle: Provision of accurate and definitive information on feeding and necessity of physical activity during gestation, including demonstration of suitable exercises during pregnancy and the provision of nutrition knowledge and management. Exercise training was modified to meet the needs of individual mothers. Nutritional counseling and knowledge transfer were also customized to individual requirements and detailed with proper meal plans.

2.2.4.7. Mental health: Mental health imparted across all three categories: counseling, interaction, and spirituality and religion.

2.2.4.7. (a) Counseling – Psychological support imparted to GDM mothers included training in stress reduction techniques together with psychological counseling and services for diabetic pregnant mothers.

2.2.4.7. (b) Interaction: Apprising healthcare providers of the mush-needed positive interaction from their side, enabling doctors de-stress their patients and relieve their anxiety and focusing on quality interactions between healthcare providers and GDM mothers rather than laying much emphasis on numerical values of various parameters.

2.2.4.7. (c) Spirituality and religion: Provision of adequate focus on the religious beliefs, practices and traditions of GDM pregnant women so as to enable them relax, unwind and de-stress.

2.2.4.8. Role of a Supportive family: Enhancing measures to improve family support for better and quality maternal and fetal outcomes, including the life partner support and psychological atmosphere at residence.

2.2.4.8 (a) The unique role of the Husband: Educating patients' husbands about the requirement of their emotional attention and presence, thereby, enabling behavioral change in many cases.

2.2.4.8 (b) The psychological atmosphere at home: Emphasising the need for peace and bringing about a change in the attitudes and behaviors of family members, especially during pregnancy.

Oftentimes, women have limited or incomplete understanding of the requirements for self-care and self-management while suffering from GDM. This is especially true about women coming from the lower socioeconomic strata of society and is common among migrant populations as well. Such women require educational and supportive services that are culturally acclimatized and understandable even at low levels of literacy. This helps them set goals, manage diabetes better and eventually, adhere to their self-management plans, thereby successfully combating GDM.[204]

The Women in India with GDM Strategy (WINGS) model of care (MOC) encompassed an educational framework so as to include multiple levels of educational strategies,[198]as shown below in Figure 6.

Figure 6: Framework for development of WINGS GDM model of care (Adapted from Kayal A. etal. Indian J endocrMetab 2016)

This study had proper tools, protocols, information booklets and implementation strategies in place. The activity aimed to respond to as well as address some perilous gaps in GDM care predominant in low-resource settings. The GDM MOC was established using best practices and developed clinical guidelines and was implemented in Chennai on small group of subjects to confirm the methodsuitability and viability. The studyengrossed on importance of close follow-ups and interactions of study subjects and health care worker. The output from MOC could have long term implications, if it succeeds then mayofferenhanced quality of care to GDM subjects in low-resource setup.[205]

2.3 Role of the clinical pharmacist in the management of GDM

Clinical pharmacists play a pivotal as well as collaborative role in GDM patients management. Comprehensive coordinated care with easy access for patient and target for high standard with quality and safety primarily aimed by patient centered medical model care.[206-208]Clinical pharmacists form an integral part of the entire process of patient education. After diagnosis confirm the GDM, the subject might favorablyselect to refer the subject to clinical pharmacist. Here, clinical pharmacists double up as certified diabetes educators. The clinical pharmacist educates the patient on self-monitoring of blood glucose (SMBG) and regarding the significance of accurately recording and tracking the values. The clinical pharmacist may also equip the patient with tasterdiet plans and commendations for workout. Preferably, the subject should follow-up every week, with SMBG and foodrecords. Clinical pharmacist consults the healthcare provider for pharmacotherapy initiation if glycemic targets not achieved within 2 weeks. The clinical pharmacist and clinician could collaboratively identify the best course of action suited for the patient and this

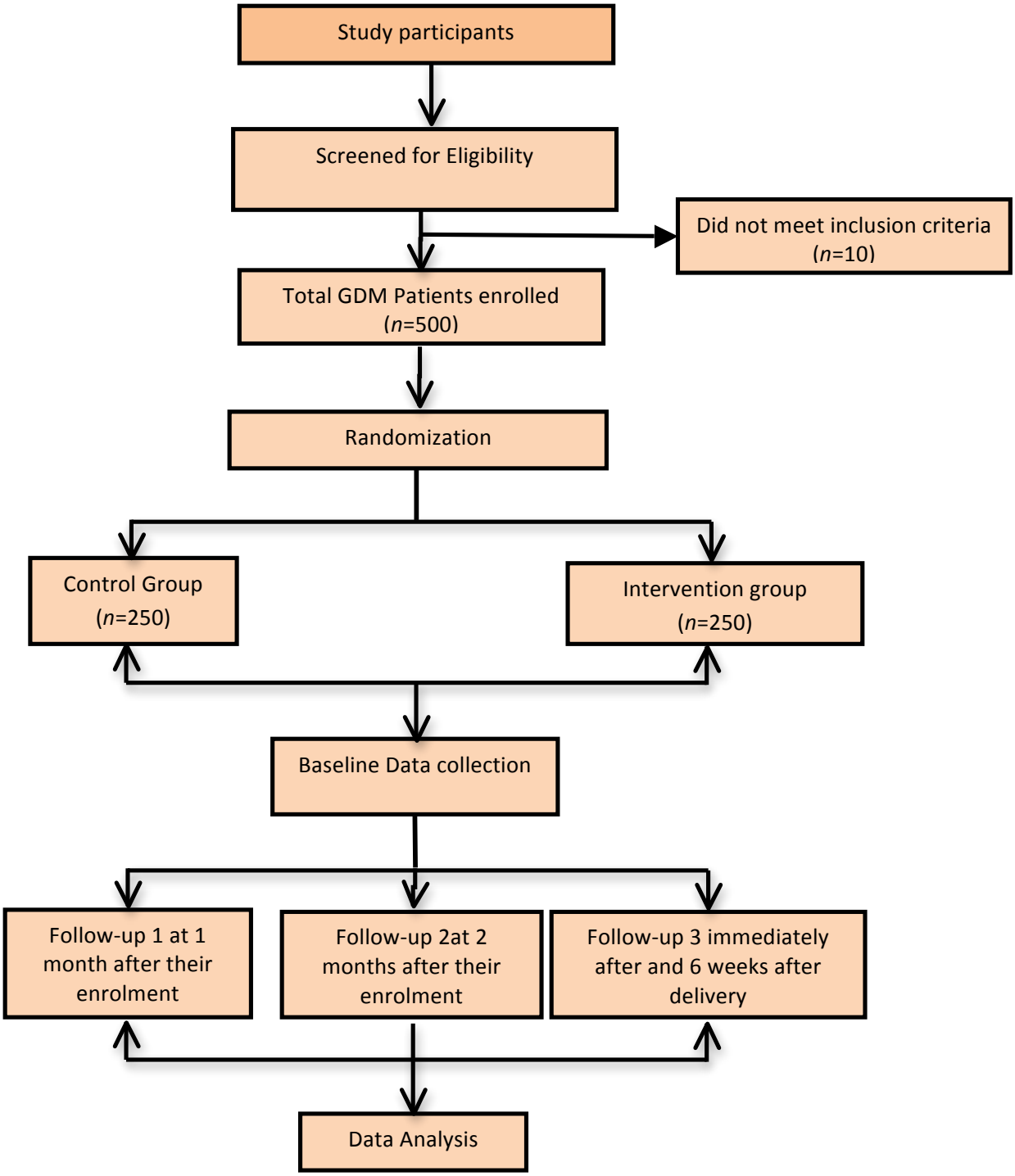
could be customized in accordance with the varying needs of each patient. The HCP brings in his/her vast experience and knowledge of the management of GDM while the clinical pharmacist provides his/her expertise in selecting the appropriate medications.[206-208]

Clinical pharmacists, by virtue of their training and skill-set, not only help track and monitor patient care provision, but also help provide appropriate referral services as and when necessary, thereby, reducing disparities in care and improving maternal as well as fetal outcomes.[206-208]Pharmacists, by expanding the scope of their services, could assist GDM patients with choosing the right kind of glucometers for SMBG and train patients to use them correctly. Moreover, they are capable of setting individualized reminders for GDM patients and at the same time, strengthening and reinforcing the training already imparted to the patients.[209]Apart from all these functions, they could also play a major role in training patients in the self-administration of insulin in case the need arises.[210]A recent Jordanian study also demonstrated that clinical pharmacists assisted services in the management of pregnancy and hyperglycemia, which elicited significant improvement in patients' knowledge levels and enhanced better disease control and management.[210]This randomized controlled study had two study arms, including an intervention group receiving a clinical pharmacist-assisted program (CPAP) and a control group that did not receive the intervention. The intervention, in the form of the CPAP, comprised provision of optimized drug therapy and intensive education as well as subject's knowledge-enhancement about diabetes, Quality of life (QoL) on the measurement of SF-36 including complications of mother, achievement of therapeutic outcomes in terms of fasting plasma glucose (FPG) control, and HbA1c. The results favored the

intervention group, as illustrated in Figure 6, thereby, vouching for the role of clinical pharmacists in the management of GDM.[211]

3.1 Study Protocol

The study protocol is presented in CONSORT flow diagram, which was followed to complete the research study.



3.2 Ethical Clearance and CTRI registry

This study was approved by institutional Ethics committee, vide letter no KLEU/Ethic/2015-16/D-72 dated 23-March-2015 (Annexure-I) and permitted by the Medical director & CEO, KLE's Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi, Karnataka. The study was registered with the Clinical Trial Registry – India (CTRI) *vide* Ref. No: CTRI/2017/01/007622 (Annexure-II).

3.3. Subjects recruitment

Study participants were enrolled in their second and third trimester of pregnancy as per inclusion and exclusion criteria and were followed up after 6 weeks post-delivery to study the effects of GDM in neonates.

3.3.1. Inclusion criteria:

1. Subjects aged from 18 to 45 years
2. Resident within a radius of 5 km from Belgaum
3. Willing to participate in the study

3.2.2. Exclusion criteria:

1. Endocrine and renal complications
2. Complications associated with pregnancy, such as polyhydraminous, etc.
3. Multiple gestations
4. Prior Type 2 DM

3.4 Study duration

The present study was carried out for a period of three years between March 2015 to Feb 2018. Patients were enrolled into the study from March 2015 to July 2017. The study period was extended further for 6 months to complete the follow-up of last recruited subjects.

3.5 Study site

Subjects were screened from the out- patient department of Obstetrics & Gynaecology, Diabetes, Endocrinology and Medicine of KLE's Dr. Prabhakar Kore Charitable Hospital & Medical Research Centre, Belagavi, Karnataka, India. This is a tertiary care hospital with 2200 bed capacity providing medical care to patients approaching from northern part of Karnataka and neighboring states.

3.6 Study Design and informed consent

The present study was an interventional, randomized controlled trial. The informed consent (Annexure-III and IV) and patient information sheet (Annexure-V and VI) were provided in the vernacular languages based on the comprehensibility and convenience of understanding of the study participants. Patients given written informed consent were only enrolled in the study.

3.7 Questioner and data collection tools

The project related information of study participants was recorded by filling the questioner forms. Questionnaires given to subject to fill were translated into the local languages (Kannada and Marathi). The questioner prepared for socio-demographic parameters, including age in years, sex and socio-economic status were based on the modified B. G. Prasad's Classification**.** The counselling materials, including the flipchart and pamphlets were also translated into the vernacular languages.

3.8 Sample Size:

The sample size was calculated using the following formula:

$$n = \frac{2(Z_\alpha+Z_\beta)^2\, pq}{(P_0-P_1)^2}$$

Where:

Z_α is the standard normal variate = 1.96 at 95% CI, Z_β = 0.84, p = the population using complete ANC services, q = the population not using the complete ANC services and is calculated as 1-p, P_0& P_1= the estimated outcomes in each group (which implies the clinically important target difference between the intervention groups)

Thus, the calculated minimum sample size of the study was:

$$N = \frac{2\,(1.96+0.84)^2 \times 20 \times 80}{(10)^2}$$

Calculated sample size = 250.88

Where:P_0=20%, P_1=10%, p=20%, q=80%, Z_α=1.96, Z_β= 0.84. for 95% CI.

The sample size has been increased by 10% owing to attrition

3.9 Randomization

The Subjects were divided into two groups i.e. Control Group (women with GDM + doctor & nurse counselling) and Intervention Group (women with GDM + doctor& nurse counselling + clinical pharmacist counselling). Randomization was done by using snooze method, in this method a computer-generated randomized number sequence was made and these were placed in opaque sealed envelopes, asshown in figure-7 Enrolled patients were requested to select the sealed envelope and accordingly they were placed in control and intervention group.

Figure 7: Sealed opaque envelopes used for randomization

3.9.1. Control group: Study participants having GDM at the time of recruitment were counselled by the physician (treating doctor) or nurse in regards to the medications and dietary modifications.

3.9.2. Intervention Group: Study participants having GDM at the time of recruitment were counselled from the physician ornurse in regards to the medications and dietary modifications along with clinical pharmacist counselling was imparted.

3.9.2.1. Counselling of enrolled subjects

Participants of intervention group received counseling, which includes insulin therapy, monitoring and management of GDM, regular follow-up.

(a) Insulin Therapy Counselling: The study participants were counselled about the importance of taking insulin injections regularly at the right dose and at the right time. Self-administration of insulin injections was also demonstrated to them to ensure that they have grasped the technique accurately. They were advised to watch out for the signs of reactions that could occur whilst administering insulin and were instructed to report the same to the treating physician. Queries elicited by the study participants were also addressed during the counselling session.

(b) Diet Counselling: Importance of Healthy dietary habits and management were counselled during the course of their pregnancy. Adequate information in regardto the various nutrients of dietary intake, importance of diet and weight gain during their pregnancy for themselves and for the developing baby were also recommended. The importance of adequate intake of water and fluids was also emphasized. Subjects were also asked to maintain the records of glycaemic levels.

(c) Monitoring of GDM: specific emphasis was laid on the importance of maintaining normal glycaemic levels and their impact on themselves and to the developing baby. Subjects were given glucometer and were advised on the methods

for regular glucose self-monitoring. Demonstration sessions were given on the same. Subjects were counselled regarding the frequency of glucose self-monitoring, normal range of values for fasting and post-prandial glucose levels and the deleterious consequences of hypoglycemic and hyperglycemic states on themselves and on the developing baby. The study participants were advised to watch out for fluctuations in their blood glucose levels and were instructed to report the same to the treating physician.

(d) Regular follow-up: Strict regular follow up at each visit was done to monitor the glucose levels and their impact on the developing baby. Regular counselling sessions were done for the same. Queries elicited by the study participants were also addressed during the counselling session.Regular calls were made either to their residence or on their registered mobile number informing about their subsequent follow-up visits; briefing them on all the points covered in the previous counselling sessions. SMS were sent out to the study participants notifying them about the date and time of their subsequent follow-up visits. In case of a missed follow-up visit or failure to turn up, a call was made to their residence or their registered mobile number so as to enquire about the reasons for missed follow-up and assistance was provided to schedule another appointment at the earliest mutual convenience.

3.9.2.2. Tools used for counselling

Counselling was carried out using various tools. Structured counselling was carried out using pamphlets and flipcharts, pertaining to GDM with specific emphasis on adherence to treatment, dietary modifications, appropriate exercise regimens and the importance of regular follow-ups with the treating physician.

3.10 Assessment of enrolled subjects

The assessment of study participants was carried out at baseline, after delivery and 6 weeks of post-delivery. The following assessments were carried out.

3.10.1. Blood glucose measurement

Fasting blood glucose, post-prandial glucose and glycosylated hemoglobin was measured as per the methods mentioned below.

3.10.1.1. Fasting glucose measurement

Subjects of the study were asked to not eat anything in morning before measuring the blood glucose. The finger of subjects was cleaned and then pricked with lancet to get a drop of blood, the blood drop was applied on a pre-chemical treated disposable 'test-strip', and strip was inserted inglucometer. The reaction between the test strip and the blood took some time and final reading after reaction was detected by glucometer and expressed in mg/dL.

3.10.1.2. Post-prandial glucose measurement

For postprandial glucose testing, the blood sample was collected after a regular meal, finger was cleaned and then pricked with lancet to get a drop of blood, the blood drop was applied on a chemically treated, disposable 'test-strip', which was inserted into aglucometer.The reaction between the test strip and the blood took some time and final reading after reaction was detected by glucometer and expressed in mg/dL.

3.10.1.3. Glycosylated haemoglobin measurement

Blood sample 3 ml was collected with the help of sterile single use syringe in anti-coagulant vials containing di-potassium ethylenediaminetetraacetic acid (K2 EDTA). The collected sample was submitted in pathology laboratory for measuring the glycosylated haemoglobin with the help of D-10 (Bio-Rad, USA). The method used for measuring the glycosylated haemoglobin was based on ion-exchange high

performance liquid chromatography (HPLC). Diluted samples injected into the analytical flow path, and applied to the analytical cartridge. Instrument deliver the gradient of buffer to increase ionic strength to the cartridge. Hemoglobin get separated due to gradient of buffer based on ionic interactions with cartridge material. Separated hemoglobin passedto filter photometer for the measurement of absorbance. Absorbance was further use to calculate the quantitative value of glycosylated hemoglobin and expressed in percentage.[212]

3.11 Blood pressure measurement

The calibrated BP apparatus (Deluxe-65076) and stethoscope (Deluxe-ST002) made by Diamond, Pune, India was used to measure blood pressure. Subjects were allowed to sit and settle down forapprox 10 minutes before measuring blood pressure. Blood pressure was measured by enfolding cuff around the unadorned and stretched out arm, the cuff was inflated to restrict the blood flow at brachial artery. The inflated air of cuff was slowly let out of the cuff, it results in decrease of air pressure in cuff. The first pounding sound observed with the help of stethoscope placed near elbow indicate the starts of blood flow in brachial artery, this was considered as systolic blood pressure. The observed pounding sound stops when blood pressure fall compare to cuff air pressure and was considered as diastolic blood pressure.[213]

3.11.1 Hemoglobin measurement

Blood sample 3 ml was collected with the help of sterile single use syringe in anti-coagulant vials containing di-potassium ethylene diamine tetra acetic acid (K2 EDTA). The collected sample was submitted in pathology laboratory for measuring the haemoglobin with the help of automated hematology analyser Mindray

BC-6800 (Mindray, China). The results of each samples were recorded in g/dL and interpreted.[214]

3.11.2 Body weight and height measurement

Digital human weighing scale (DS-215 Essae Teraoka, Bangalore, Karnataka, India was used to measure the body of study participants. Subjects of the study were requested to stand silent and not move for one minute. The weight showed on weighing balance was recorded in kilogram. Manual counted wall mounted bench ruler was used to measure the height of study participants. Study participants were requested to stand bare-foot on floor and stand straight without tilting the body to either side. The wooden slice measuring 50 x 30 cm was placed over the head to record the corresponding height on wall mounted bench ruler, height was recorded in centimeters (cm).

3.11.3 Adverse drug reaction monitoring

The study participants were followed-up every day to collect the information of adverse drug reaction. The observed adverse drug reactions were redness, rashes, hypoglycemia, headache, dizziness. The observed adverse drug reactions were counted and expressed in percentage.

3.12 Questioners used for the study participants

Socio-demographic details such as age, education, religion, place of residence, occupation, socio-economic status, physical activity, body mass index and history of diabetes and tobacco consumption of the study participants were collected as per the questioners (Annexure I). To record the changes in knowledge regarding GDM, its controlling factor and consequences, study participants were asked to fill questioner as per their comfort in vernacular language (Annexure-II (Marathi language), Annexure-III (Kannada language)). The responses for GDM knowledge question were

scored in the following manner. Those who answered correctly were interpreted as having adequate knowledge and were graded with a score of 1 for each correctly-answered question while a score of 0 was assigned to every incorrect answer. Finally, the sum of total points was calculated and these total scores were converted into percentage of correct and incorrect responses. The outcome of study participants and neonates for gestation age, term, birth weight, and observed complications were recorded as per the questioner (Annexure-IV). The frequency of responses record to the individual questions were recorded according to the procedure as described in 3.11. Methodology.

3.13 Observation time points

3.13.1 Baseline observation

Details, particulars and history of study participants were recorded, such as age, education, religion, place of residence, occupation, socio-economic status, family history of diabetes, body mass index, history of tobacco consumption, physical activity, hemoglobin, weight and diet were recorded at baseline after enrolling subjects in the study. To assess the knowledge changes in study participants, subjects were asked to respond the questions to fill questioner, knowledge assessment was carried out after enrolling patients in study and before delivery. To assess the maternal outcome, term of delivery, parity, risk factors for mothers, risk factors for neonates were recorded at delivery by filling the questioners. Neonates outcome were assessed based on baseline data of neonates such as gestational age, APGAR score, blood glucose level after 1 hour and 3 hours of birth, observed complications, NICU admissions, medical support required by neonates and hospital stay duration were recorded in neonates after delivery.

3.14.2. Observation with specific intervals

Parameters such as fasting blood sugar, post-prandial sugar, glycosylated hemoglobin, blood pressure was recorded (3.9. Methodology) in study participants at baseline, 1 month after enrollment, before delivery and post 6 weeks of delivery.

3.14.3. Assessment carried out after completion of intervention

Compliance to the doctor's advice, reason for non-compliance, choice in obtaining advice, preference of choice to the component of counseling tools, ease of understanding the leaflet were recorded after completion of intervention duration.

3.14.4. Effect assessment observation

Effect on treatment modality uses (Medical nutrition therapy, Oral hypoglycemic agent, insulin uses) and diet followed were recorded at baseline, 1-month post baseline and 6 weeks post-delivery. However, the insulin uses were categorized in intermittent and chronic uses, insulin uses were recorded at baseline, before delivery and after six weeks of delivery by filling the questioner.

3.14 Follow up of the study population

All study participants were followed-up beyond delivery up to the post- partum period and monitored for GDM and pregnancy outcomes (both maternal and neonatal). During the follow-up for antenatal care, an evaluation of the study participants was carried out for dietary habits, exercise patterns, RBS monitoring, insulin intake and adherence to their prescribed medications. The study participants and their families were informed about the completion of the study one month prior to the termination of the study. For ethical considerations, all participants were followed by routine appointment with the treating physicians.

3. 13 Statistical Analysis

The collected data were organized carefully taking into consideration the issues of data safety, completeness of information and missing items. Checking and re-checking of the data were carried out by the double entry process and all unmatched records were re-entered to ensure completeness of the data. Data was tabulated in Microsoft excel and analyses by using SPSS Version 20 (Armonk, NY: IBM Corp.). WHO Anthrop (Version 3.2.2, January 2011) was also used for the entry and analysis of study data. Descriptive analysis for frequency, percentage, means, medians, range and standard deviations were carried out. Hypothesis testing tools (Chi-square test, Z-test, correlation and binary logistic regression model) were used as inferential statistics. Logistic regression models were run to establish the relationship of covariates, wherever applicable. Test values, degrees of freedom, Odds Ratios (OR, adjusted and/or unadjusted) and the *p*-values of the respective tests were specified, $P<0.05$ was considered significant. The results of study were disseminated with the help of appropriate charts, graphs, tables and narratives.

Results of the study are divided in three major portions, first is baseline data of women, second portion is management of GDM and third portion is outcome of mother and neonates after intervention.

4.1. Baseline data of the study participants

Baseline data of study participants includes the number of women enrolled in study, follow-up status of study participants, age, education status, religion, place of residence, occupation, socio-economic status, family history of diabetes, body mass index, history of tobacco consumption, physical activity involvement and type of diet plan followed by the study participants.

4.1.1. Enrollment of subjects

A total of 456 patients who consented for the study were enrolled in the present study. Out of them 226 women were enrolled in control group and 230 women were enrolled on intervention group.

4.1.2. Follow-up status

Among the 226 women of control group 90.4 % women completed the follow-up and remaining 9.6 % lost to follow-up. However, in intervention group 92 % women were completed follow-up and remaining 8 % lost to follow-up (Figure-8).

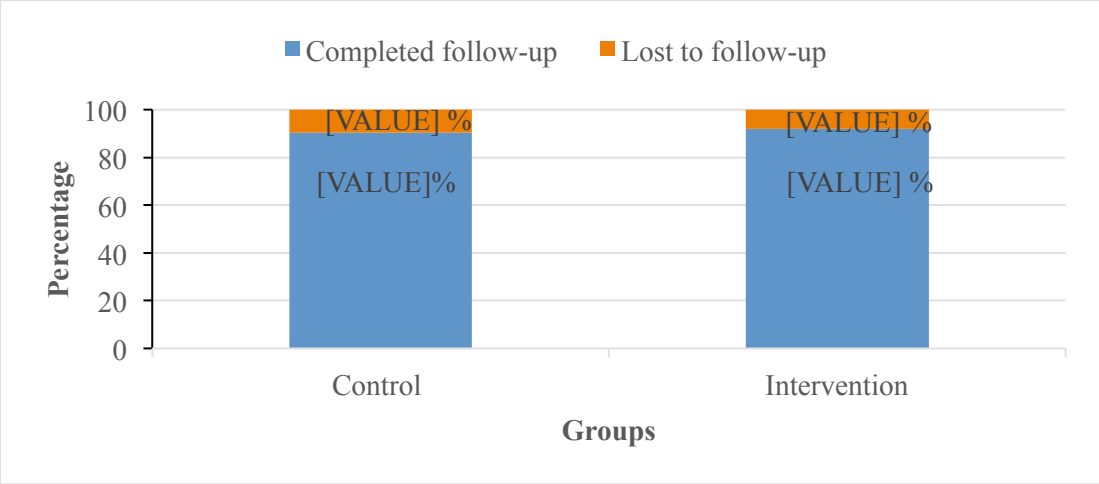


Figure 8: Distribution of GDM mothers completing the study and being lost to follow-up

4.1.3 Age distribution of GDM mothers in study groups

The age-wise distributions of diabetes of the GDM women enrolled into this study have been portrayed in Figure-9. Results indicate that majority of women in both the groups belongs to the 20-30 years age group, 218 (87.2 %) women of control and 225 (90 %) women of intervention group belongs to 20-30 years age group. However, 31 (12.4 %) and 25 (10 %) women were belonging to 31-40 years age group in control and intervention groups respectively. Only 1 (0.4 %) women was found to belong to >40 year age category. The comparison was made between the group and found that the difference in both control and intervention groups was not significant (P>0.05).

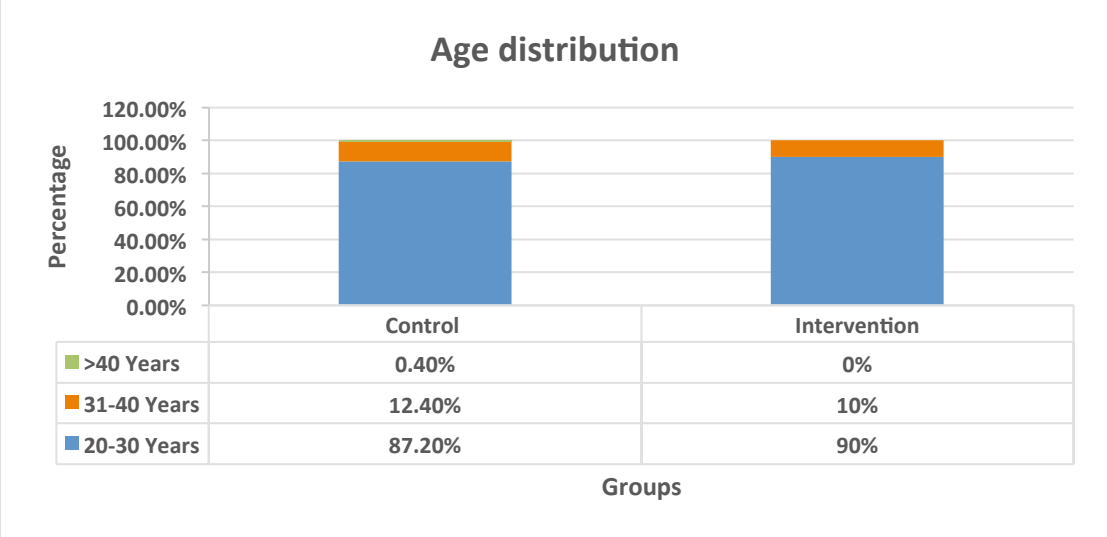


Figure 9:Age distribution of GDM women's in study groups

4.1.4. Educational Status of the study population

The educational status of pregnant women with GDM is presented in Figure 10. Majority of study participants were found to be educated up to primary school level, 52.4% and 62% of the GDM mothers of control and intervention groups were educated up to the primary school level respectively. This was followed by illiterate GDM mothers being 18% and 16.4% in the control and intervention groups

respectively. However, GDM mothers educated up to the SSLC level was found 16.4% and 8.4% in the control and intervention groups respectively, followed by educated up to the collegiate level 6.8% and 7.2% in the control and intervention groups respectively. GDM mothers educated upto the post-graduate level was found 6.4% and 6% respectively in control and intervention groups. The diiference between the group was found to be not significant (P>0.069).

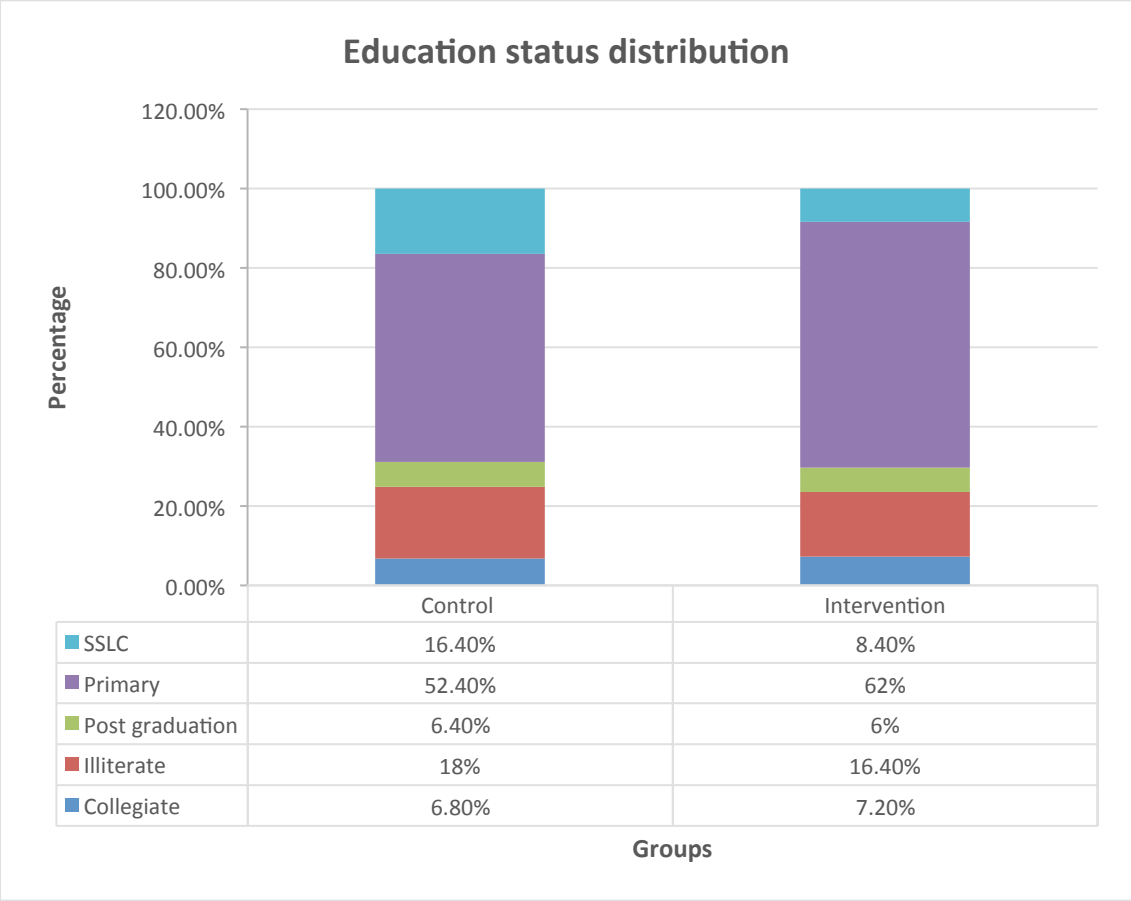


Figure 10: Distribution of the study population by their educational status

4.1.5 Religion based distribution of the study population

Figure 11represents the distribution of GDM mothers in the study population by religions (Hindu, Muslim, Christian).In the present study, majority of the women participants belonged to Hindu community in control (50.80%) and intervention (58.8%), women belonging to the Muslim community were found to be 43% and 40%

respectively in control and intervention groups. This was followed by women from the Christian community were less in groups, 2% in control and 1.2% in intervention groups. The comparison was made between the group and found not significant (P>0.180).

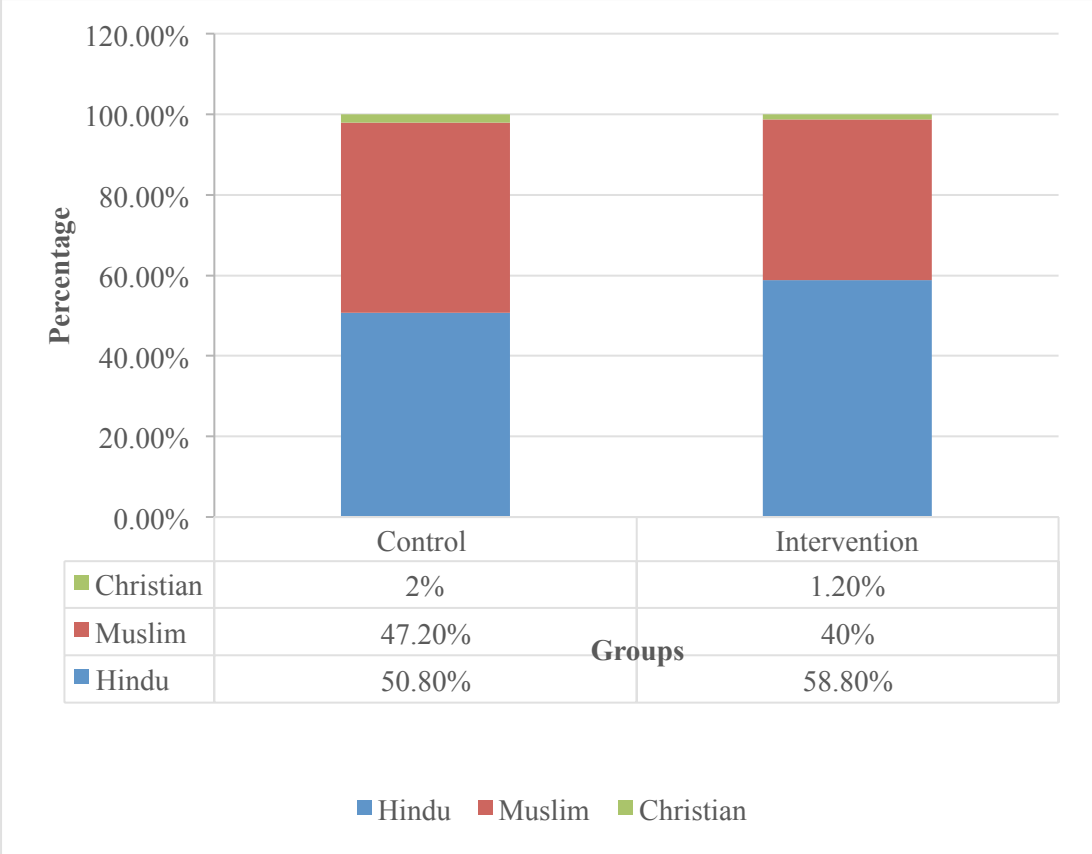


Figure 11: Distribution of the study participants based on religions among the groups

4.1.6 Place of residence

The place of residence of the GDM women in both the groups were comparable, with majority of the mothers, viz. 38.8% in control group and 47.6% in intervention group coming from the slum areas. However, 38%women of control group and 34% women of intervention Group belong to the urban areas. Whereas, remaining 23.2% and 18.4% participants of control and intervention group were residing in rural areas.

Comparison were made between the group and found not statistically significant (P>0.05) (Figure -12).

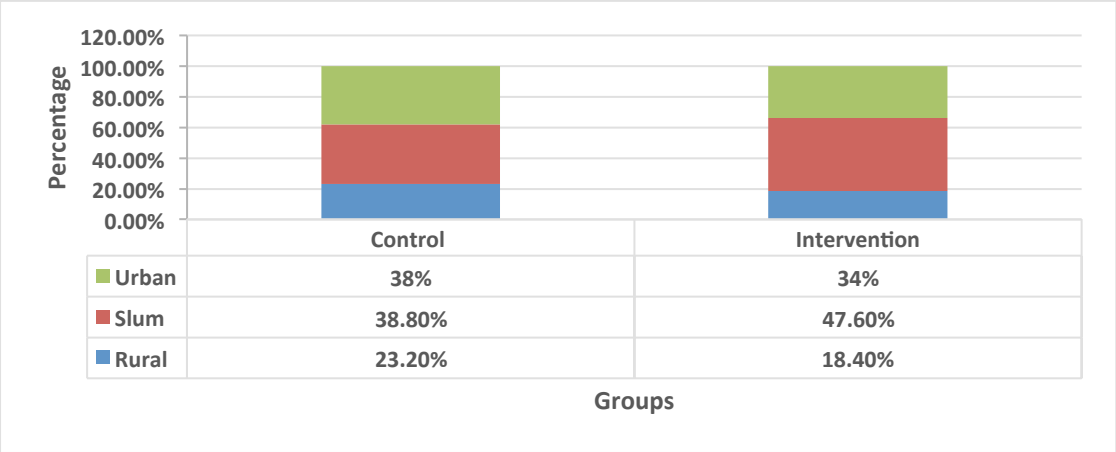


Figure 12: Distribution of the study population by place of residence

4.1.7. Distribution of study participants based on occupation

Figure 13 represents the distribution of GDM mothers of study population by occupation (working, house wife, others). In the present study, majority of the women participants belonged to working group, in control 122 (48.80%) and intervention 115 (46%). Women belonging to the house wife were found to be 120 (48.00%) and 125 (50.00%) in control and intervention groups respectively. This was followed by women from the others category which was found less in both groups, 8 (3.20%) in control and 10(4.00%) in intervention groups. The comparison was made between the group and found not significant (P>0.50).

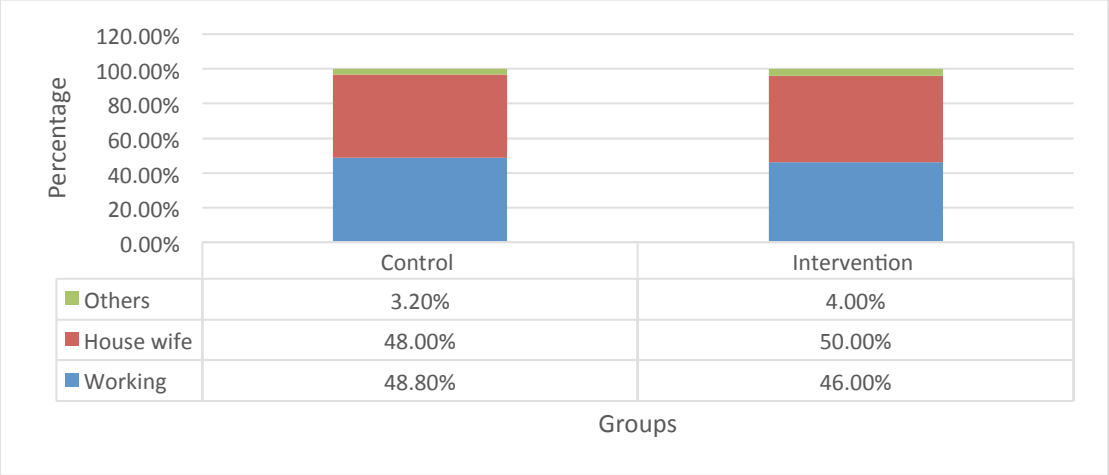


Figure 13: Distribution of the study population by occupation

4.1.8. Distribution of study participants based on socio-economic status

Figure 14 represents the distribution of study population by socio-economic status (upper middle. upper lower, lower). In the present study, women participants belong to upper lower strata in control 123 (49.20%) and intervention 124 (49.60%) group. Women belonging to the upper middle strata were found to be 100 (40.00%) in control and 92 (36.80%) in intervention groups respectively. Women belong to lower socio-economic status was 27 (10.80%) from control group and 34 (13.60%) from intervention group. The comparison was made between the groups and found not significant (P>0.50).

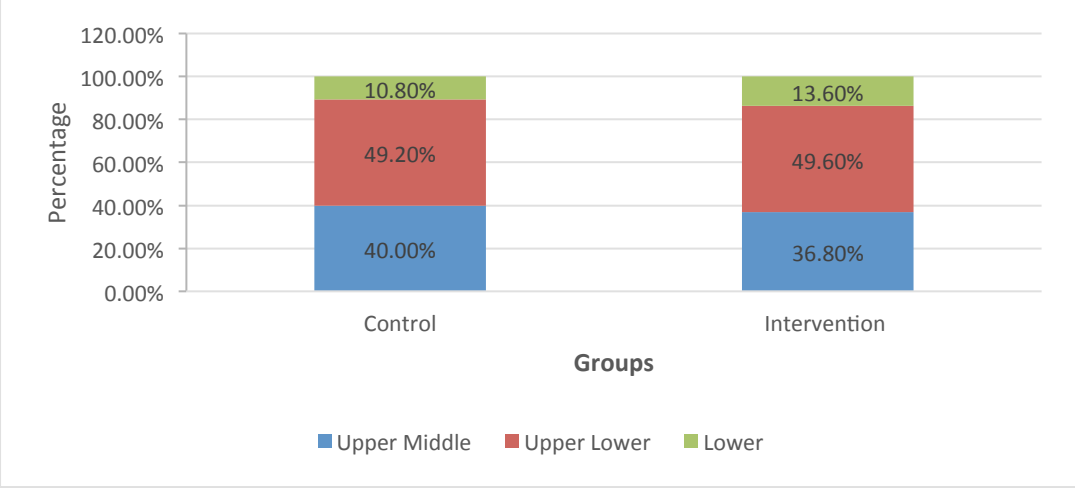


Figure 14: Distribution of the study population by socio-economic status

4.1.9 Family history of diabetes

Family history of diabetes among the pregnant women is depicted in figure 15. Among the study participants, majority of the women reported family history of diabetes mellitus. About 65.2% Women of control group and 67.20% of intervention group reported positive family history of diabetes mellitus. The comparison between the group was made and the difference was not significant with P value (P=0.705).

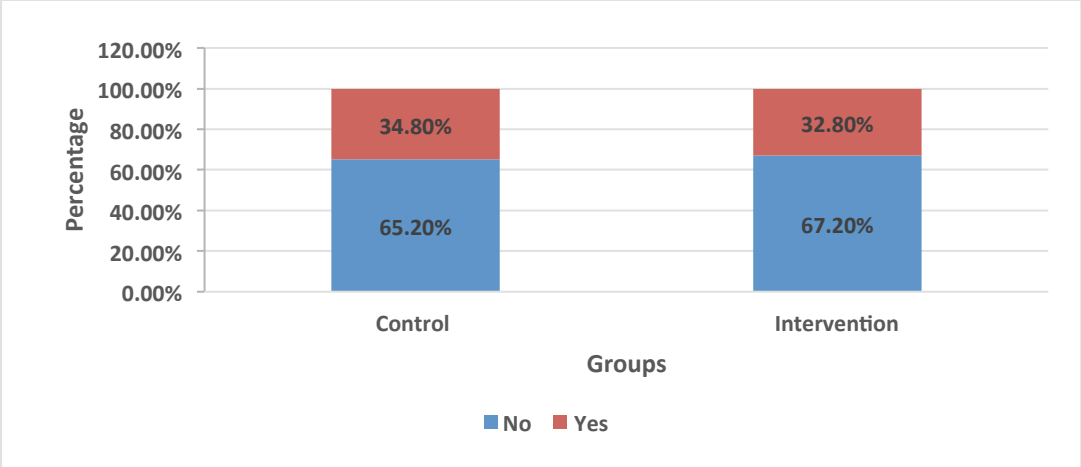


Figure15. Family history of diabetes mellitusamong the study participants

4.1.10 Distribution of study participants based on body mass index

In this study majority of GDM subjects 169 (67.6%) of control group and 166 (66.4%) of intervention group had body mass index between 19.8 to 26.0 Kg/m^2. Women found to have BMI of >26 Kg/m^2 were 77 (30.8%) in control and 83 (33.2%) in intervention group, eventually, women having BMI <19.8 Kg/m^2 were 4 (1.6%) in control group and 1 (0.4%) in intervention group as presented in figure-16. The mean difference of BMI between the control and intervention group was not statistically significant(P>0.05).

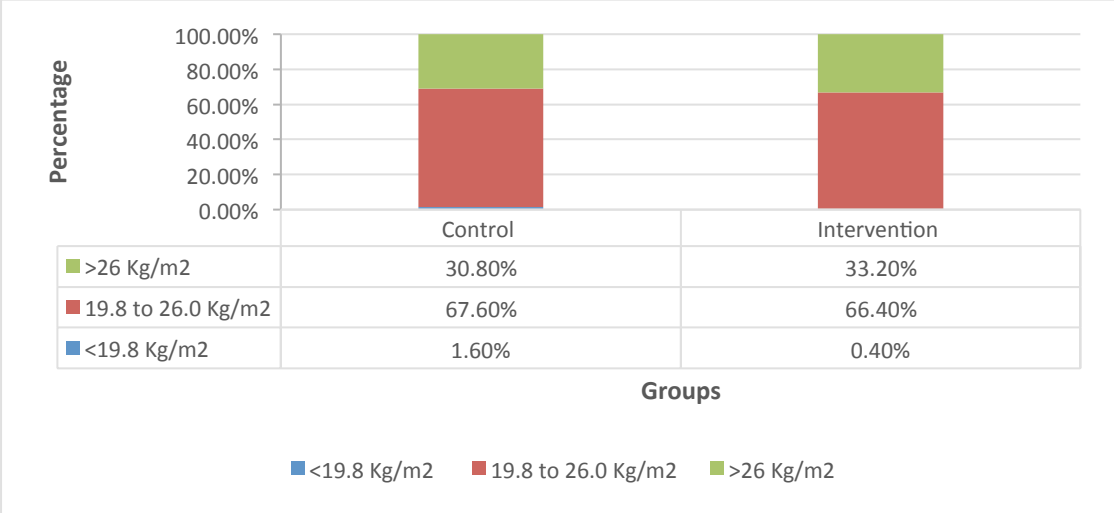


Figure 16: Distribution of study participants based on BMI

4.1.11. Distribution of study participants based on history of tobacco consumption

It was observed that 14 (5.60%) women of control group and 11 (4.40%) women of intervention group reported history of tobacco consumption. Remaining 236 (94.40%) women of control group and 239 (95.60%) women of intervention group do not have tobacco consumption history as provided in figure-17. The difference between the group was not found statistically significant (P>0.05).

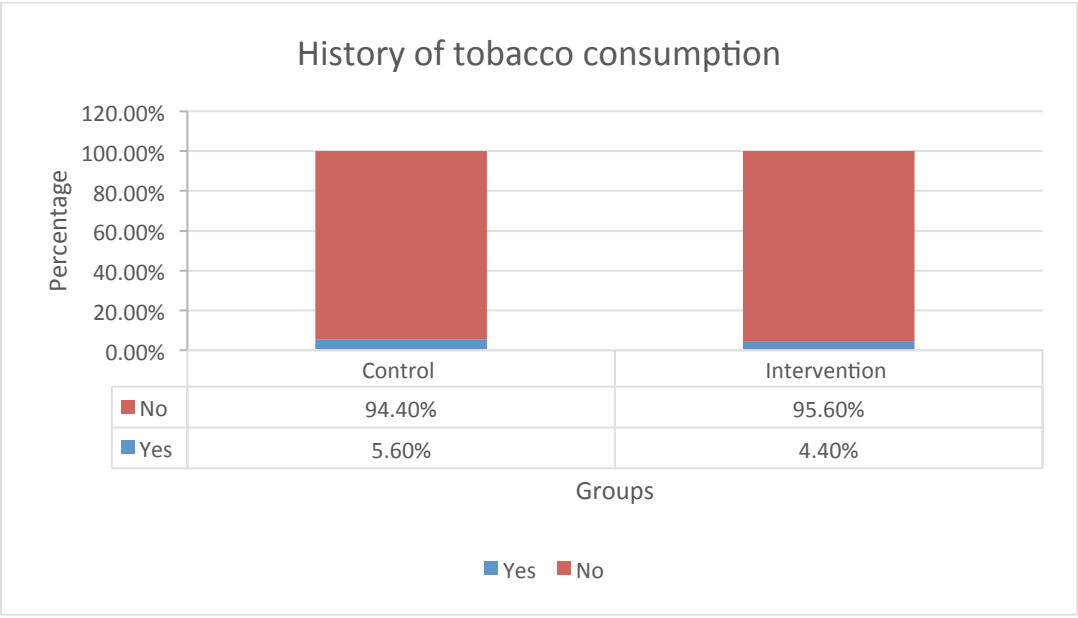


Figure 17: Distribution of participants based on history of tobacco consumption

4.1.12 Proportion of GDM mothers performing physical activity before GDM Diagnosis

In this study, it was found that the proportion of study participants engaging themselves in physical activity was comparatively less compared to those who did not. Only 37.6% and 38.4% of the study participants of control and intervention groups respectively reported that they perform physical activity. Graph of physical activity performing participants portrayed in figure-18.

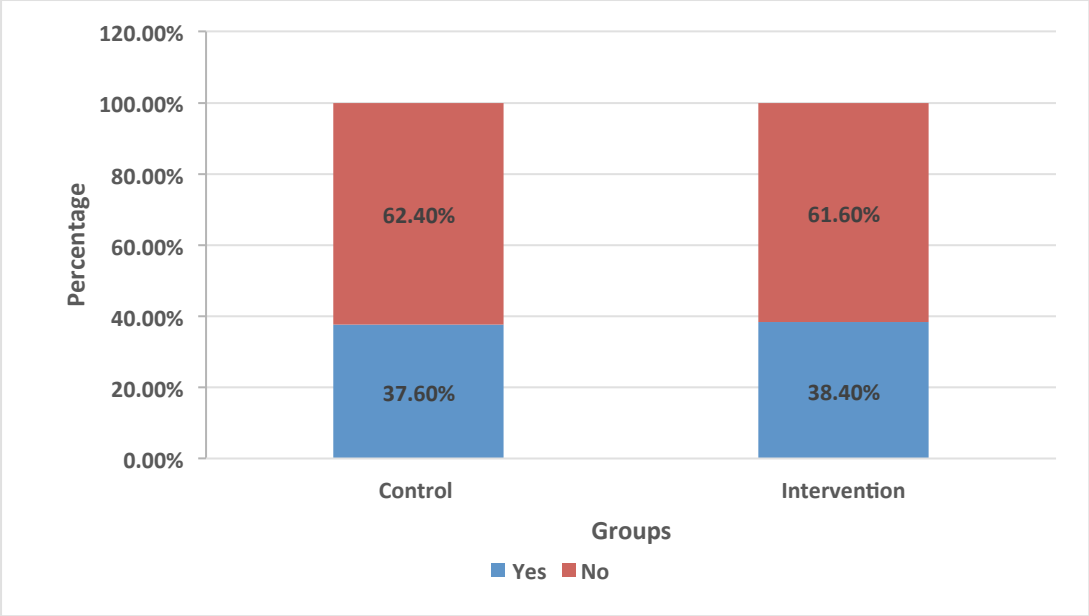


Figure 18: Proportion of participants indulging in physical activity

4.1.12.1 Nature of physical activity

In the present study, 62.40% of GDM women of control group and 61.60 % of GDM women of intervention were not found to indulge in any physical activity. However, 34% and 30% of GDM women of control and intervention group respectively had practiced walking while 3.2% and 7.2% had practiced Yoga. Graph of physical activity performing participants is depicted in figure 19.

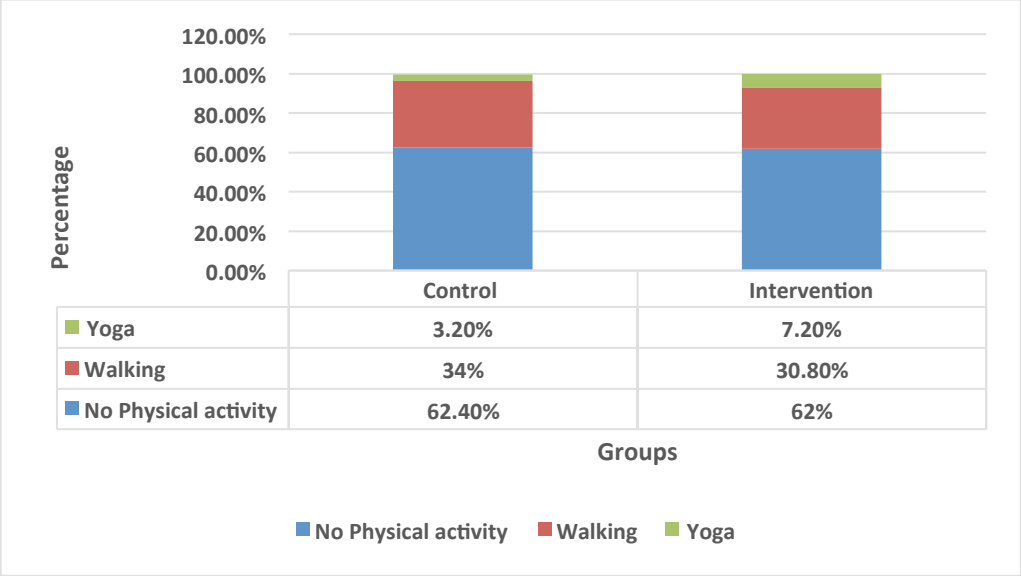


Figure 19: Distribution of participants indulging in various physical activity

4.1.12.2. Duration of physical activity

The duration of physical activity practiced by GDM women in both the groups was very less as 77.9% of GDM women in control and 83.16% of GDM women in intervention group practiced physical activity for less than 15 minutes. There were very few women practicing physical activity for 15-30 minutes, 30-45 minutes and 46-60 minutes as shown in Figure 20.

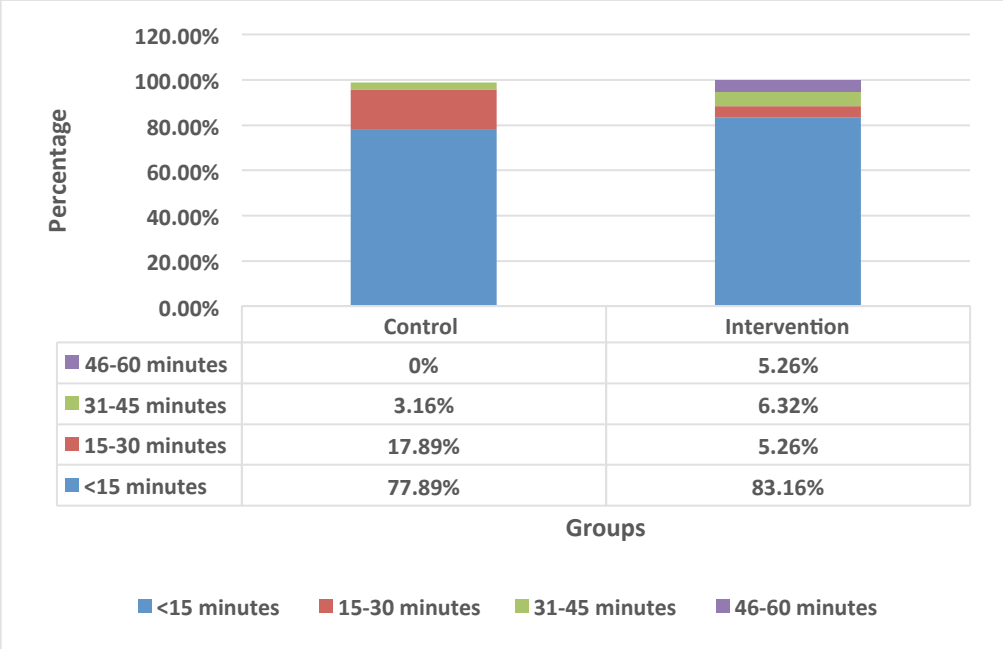


Figure20: Distribution of study participants based on duration of physical activity

4.1.13 Type of diet in GDM Women in control and intervention group

Figure 14 show the baseline comparison of diet among the study groups. In the present study, 46.6% women of control and 48.4% women of intervention group followed ovo-vegetarian diet (P=0.903).This was followed by vegetarian diet by 27.60% women of control group and 26.40% women of intervention group. There were women who followed mixed diet, 26% women of control group and 25.2% of intervention group were found to followed mixed diet. The graph (Figure 21) shows that the pattern of diet in both groups was comparable.

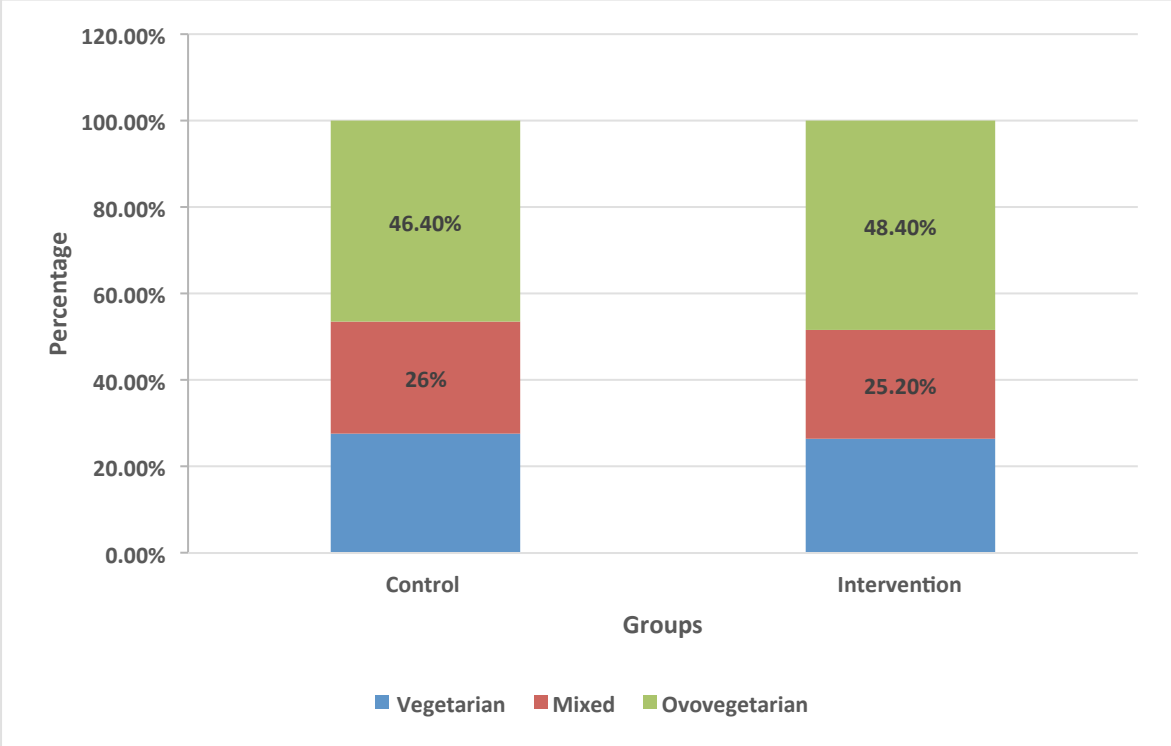


Figure 21.Distribution of study women based on diet

4.1.13.1. Following any diet plan at baseline

In this study, the rate of compliance to the diet plan was comparable in both the groups 45.60% and 44.80%, in control and intervention groups respectively. Remaining women 54.40% and 55.20% of control and intervention group respectively were not following any diet plan as shown in figure-22. Mean of both the groups were compared, difference between the control and intervention group was not statistically significant (P=0.928).

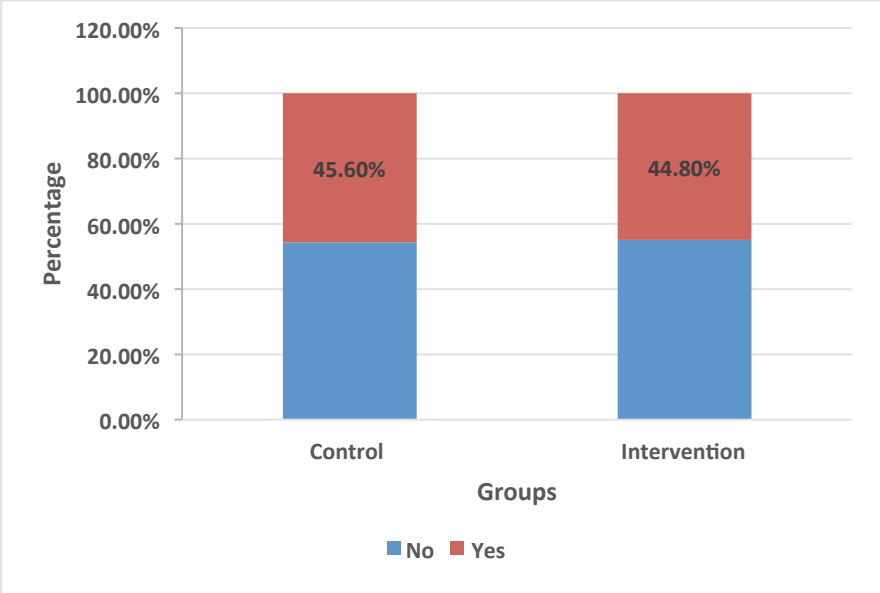


Figure 22. Distribution of study population following any diet plan at baseline

4.2 Baseline data of gestational diabetes mothers of study groups

Baseline gestational diabetes pattern of control and intervention group includes blood glucose level at fasting and post-prandial, glycosylated haemoglobin and systolic, diastolic blood pressure

42.1 Blood glucose and glycosylated haemoglobin baseline data of study participants

The mean fasting blood glucose levels at baseline were 110.36 ± 2.64 mg/dL and 108.5 ± 1.22 mg/dL for control and intervention groups respectively. However, the mean postprandial blood glucose levels at baseline were 154.15 ±4.5 mg/dL and

153.89 ± 5.6 mg/dL for control and intervention groups respectively as provided in figure-23. The HbA1c levels at baseline were 6.06 ± 0.18 % and 6.13 ± 0.38 % for control and intervention groups respectively. When comparison was made between the groups, the difference between the control and intervention groups was not significant (P>0.05). The graphical representation of blood glucose and HbA1c are provided in figure-24.

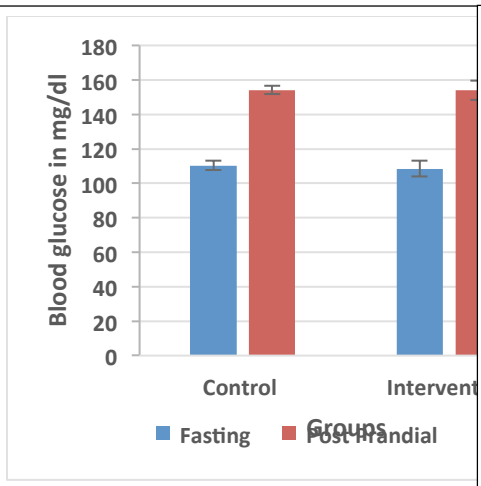


Figure 23: Blood glucose of study participants

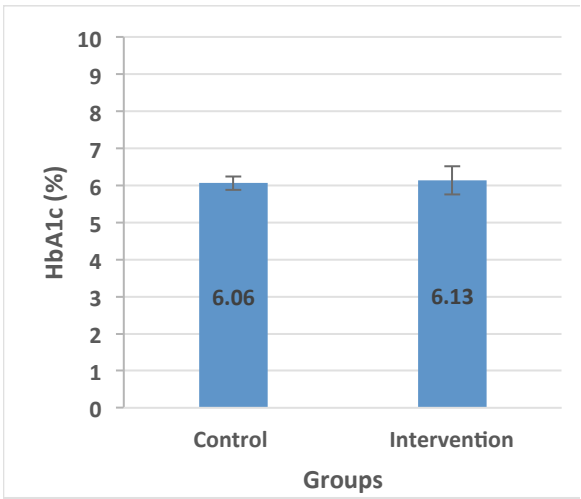


Figure 24: HbA1c of study participants

4.2.2 Blood pressure data of study participants

Blood pressure of control and intervention group is provided in figure-25. The mean systolic blood pressure (SBP) at baseline were 123.58 ± 9.37 mmHg and 122.76 ± 9.11mmHg for control and intervention group respectively (P>0.319). On the other hand, the mean diastolic blood pressure (DBP) at baseline were 76.93 mmHg and 75.88 mmHg for control and intervention group respectively (P>0.089). When comparison of mean were done between the groups, the differences in mean was not found to be significant (P>0.05).

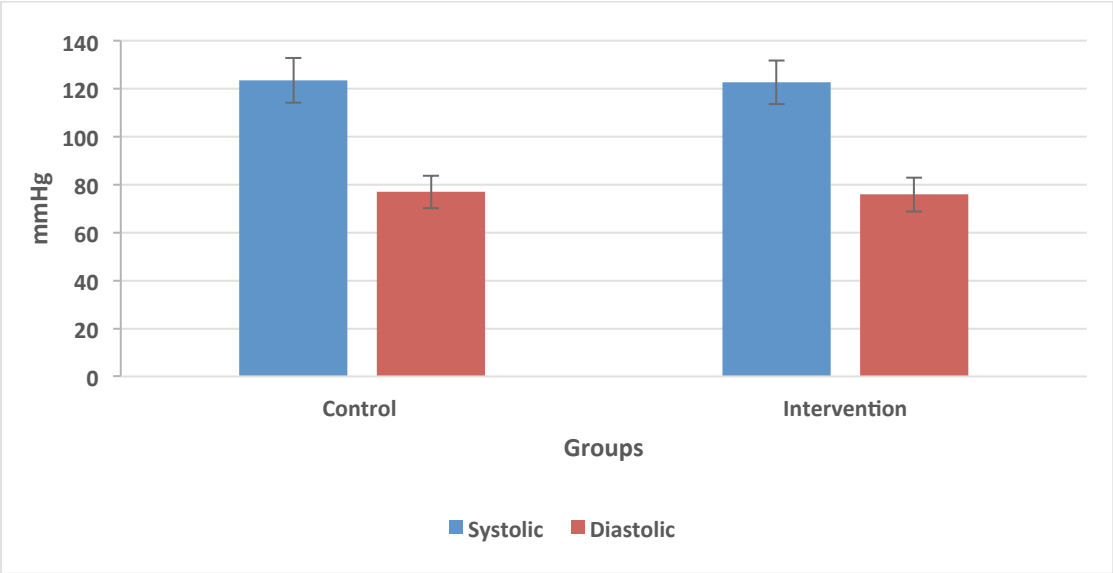


Figure 25: Blood pressure among the study participants at baseline

4.2.3 Mean hemoglobin levels of study population

The mean hemoglobin levels of the pregnant women are presented in figure-26. The mean hemoglobin levels were classified according to the WHO Classification of haemoglobin levels. Among the study participants, 56 (25%)women ofcontrol and 65 (28.3%)women of intervention were found to belong to the category of haemoglobin levels less than 10 mg/dL. However, 150 (66%)women of control group and146 (63.40%)women of intervention group were found to belong to the category of haemoglobin levels between 10-12 mg/dL. Whereas, 20 (9%)women of control group and 19 (8.3%) women of intervention group were found to be having hemoglobin levels 12 mg/dL. Mean of the groups were compared, the difference between the control and intervention groups were not found to be statistically significant (P>0.70).

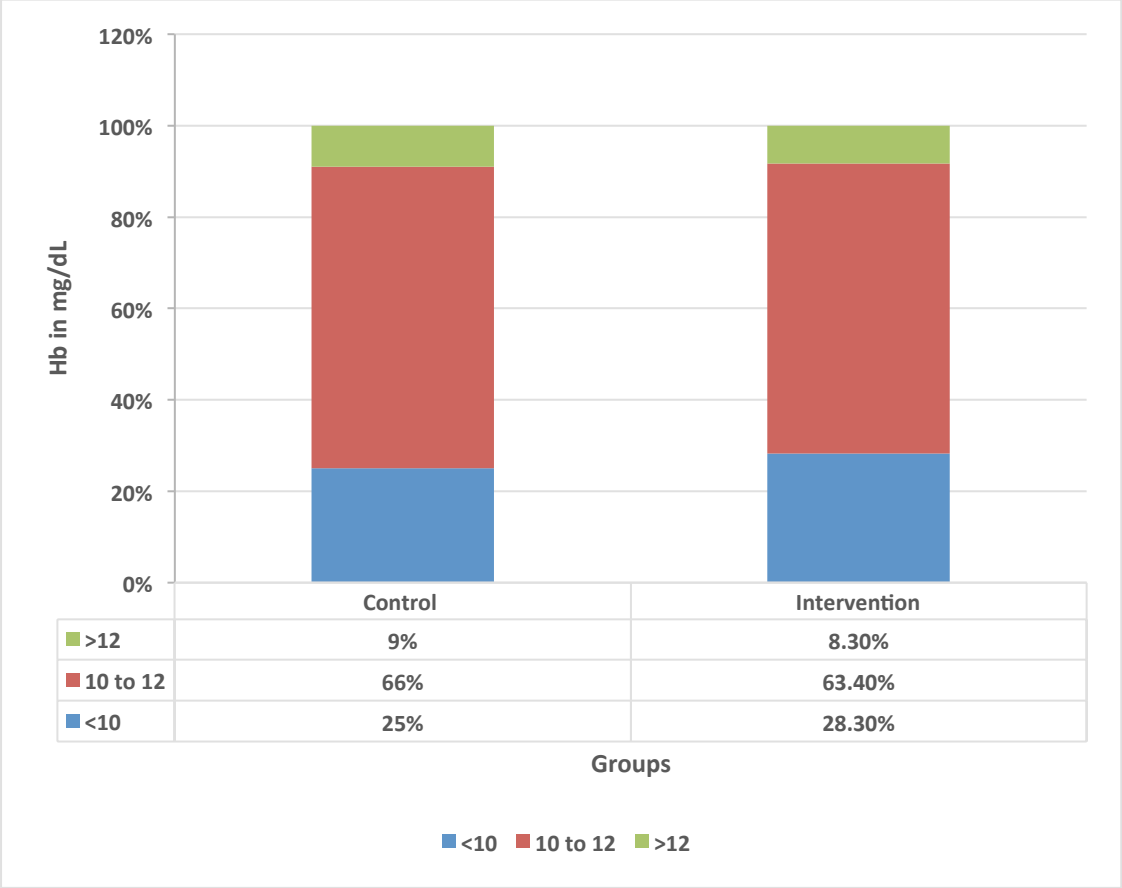


Figure 26. Distribution of study participants based on hemoglobin as per WHO classification

4.3 Observation carried out during the study duration

Findings observed during the study duration includes changes in body weight during pregnancy, glycemic levels, blood pressure, self-care practices, compliance to doctor's advice, reasons for non-compliance to doctor's advice, patient preference in obtaining advice, preference to the component of advice, observed adverse drug reactions, changes in treatment modalities and followed diet over the period of study.

4.3.1. Changes in body weight during pregnancy

The mean weight gain during pregnancy is presented in figure-27. About 138 (61%) and 140 (61%)women of control and intervention group showed a mean weight gain

of >10 Kg respectively. About 78 (34.5%) women of control group and 80 (35%) women of interventiongroup showed the increase of 10-12 kg gain during pregnancy,whereas, 12-14 kg body weight gain was observed in 10 (4.4%) women of control group and 10 (4%) women of intervention group. The mean difference of body weight gain between the control and intervention groups was not significant (P=0.998).

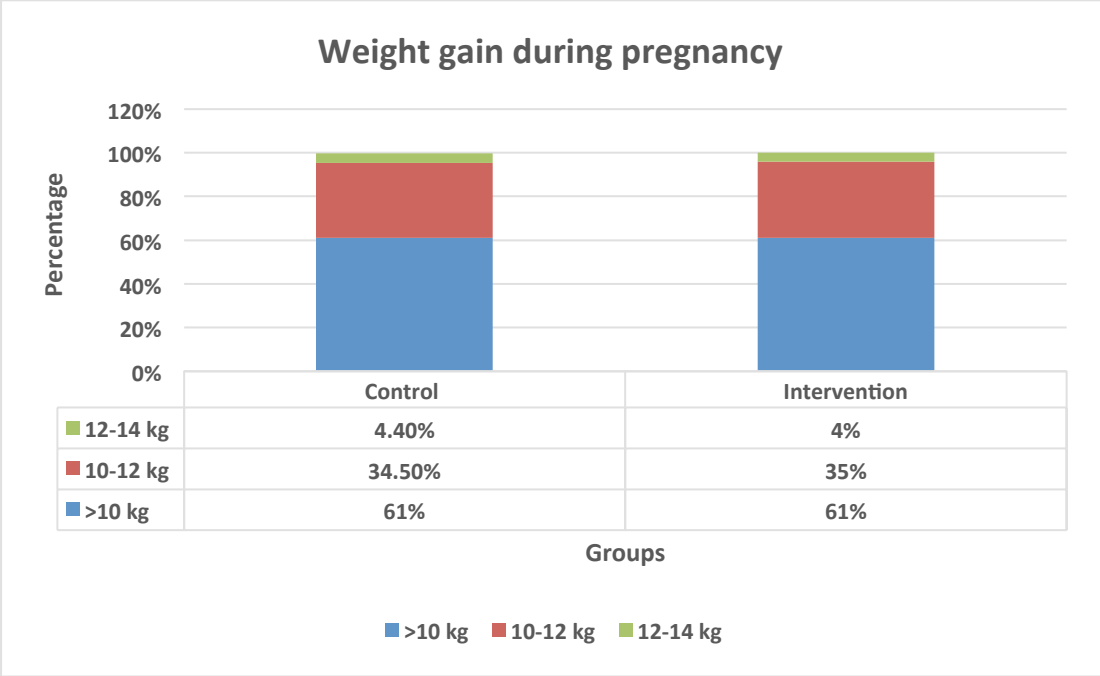


Figure 27: Changes in body weight gain during pregnancy

4.3.2 Gestational glycaemic levels ofstudy groups

There was a substantial decrease observed in the fasting plasma glucose (FPG) levels in control as well as intervention group from baseline through to post-delivery period (110.36±2.64 mg/dL to 88.8±2.99 mg/dL in control group and 108.5±2.13 mg/dL to 88.02±3.41 mg/dL in intervention group (Figure-28). A similar decrease was seen in post-prandial glucose levels (PPPG) from 154.15±4.5mg/dL baseline to 137.52±14.6 mg/dL after six weeks of delivery in control and 153.89±5.6 mg/dL baseline to 122.52±5.8 mg/dL after six weeks of delivery in intervention group (Figure-29) as

well as for HbA1c levels 6.06±0.18 baseline to 5.64±3.3 mg/dL after six weeks of delivery in control group and 6.13±0.381 baseline to 5.12±5.1 mg/dL after six weeks of delivery in intervention group (Figure-30).The percentage HbA1C mean difference between the control and intervention groups was found to be significant (P<0.005).

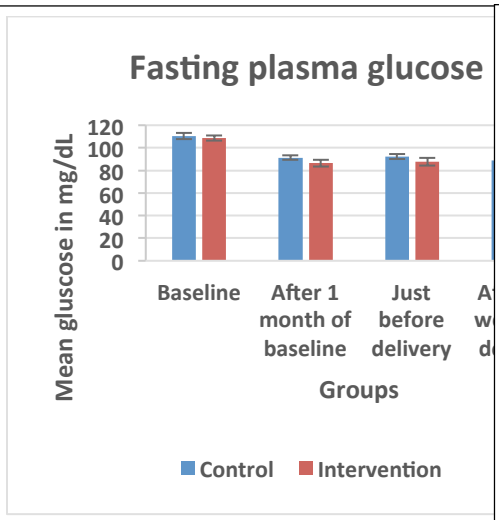


Figure 28: Fasting plasma glucose o groups at various interval

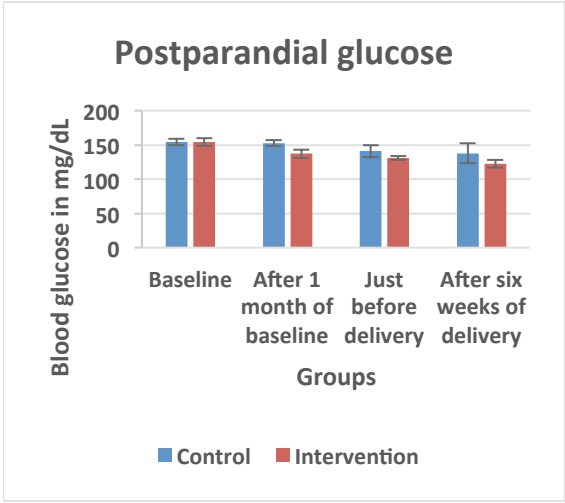


Figure 29: Postprandial plasma glucose of study groups at various interval

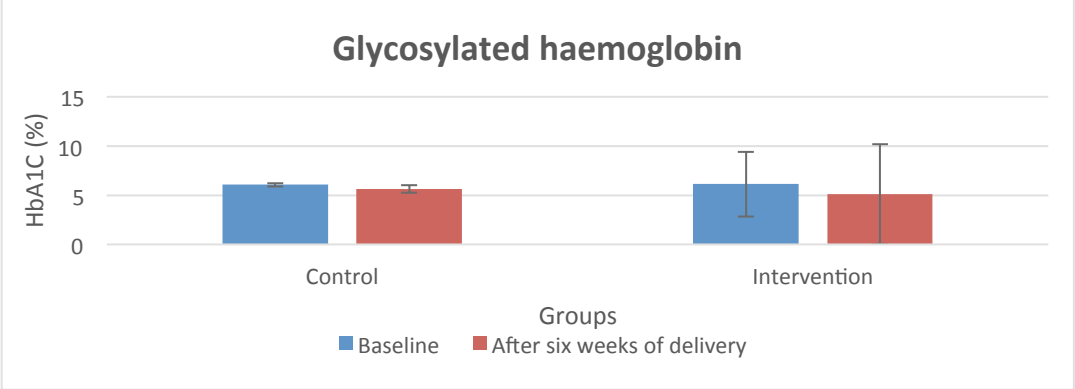


Figure 30: Glycosylated haemoglobin of study groups at various interval

4.3.3. Mean blood pressure of study participants

Figure-31 depicts systolic and Figure-32 shows the diastolic mean blood pressure of both control and intervention groups. In control group increase was observed in blood

pressure from 120/80 mmHg at baseline to 130/70 mmHg at 1 month after baseline and decreased to 110/70 mmHg just before delivery and stabilized at 120/80 mmHg at 6 weeks post-delivery. In intervention group there was a slight increase in BP from 120/80 mmHg at baseline to 130/80 mmHg to 1 month after baseline and decreased to 110/80 mmHg just before delivery and stabilized at 120/80

mmHg at 6 weeks post-delivery. The mean difference between the groups was not found to be statistically significant(P>0.05)

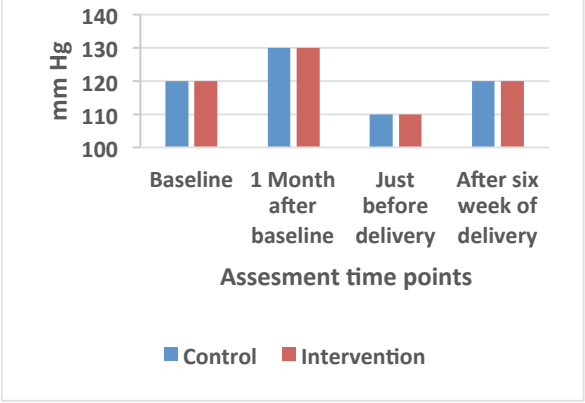


Figure 31: Systolic blood pressure of study participant at various intervals

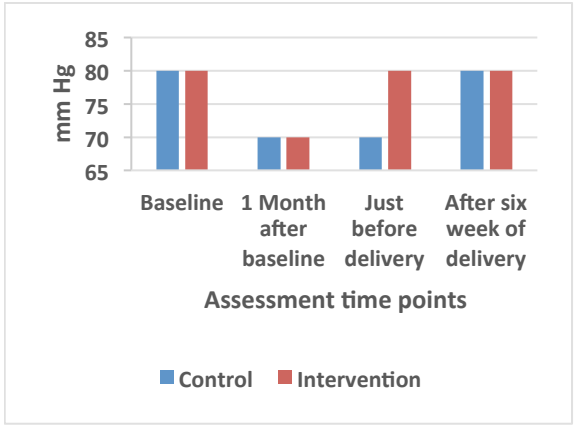


Figure 32: Diastolic blood pressure of study participant at various intervals

4.3.4. Patient self-care practices among the study groups

In present study, the proportion of study participants adhering to self-care practices was comparable in both the groups, 40.71% of control group and 45.22% in intervention group.The mean difference between the control and intervention group was not found to be statistically significant (P=0.345). Graphical representation of self-care practice is provided in figure-33.

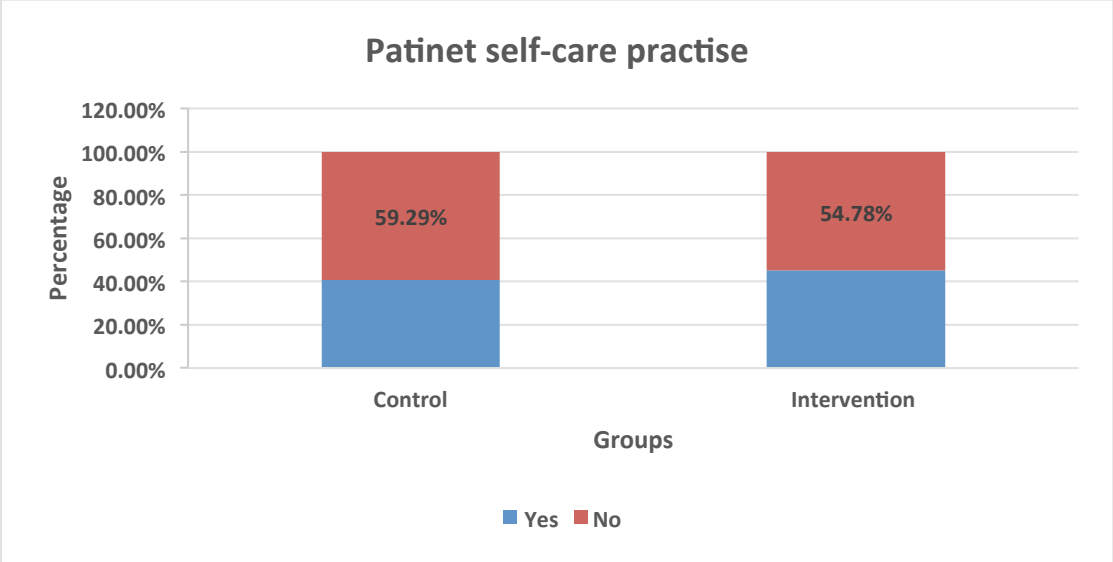


Figure 33: Proportion of patients indulging in self-care practices

4.3.5. Findings of compliance to doctor's advice in study groups

Proportion of study participant's complying with the doctor's advice was significantly higher in GDM mothers 79.13% in intervention group compared to 57.52% of control group. Proportion of GDM mother who did not comply with doctor's advice was significantly lower in intervention group, 42.48% in control group and 20.87% in intervention group. The difference between the control and intervention groups was found to be statistically significant (P<0.001). Compliance of graph for doctor's advice to management is provided in figure-34.

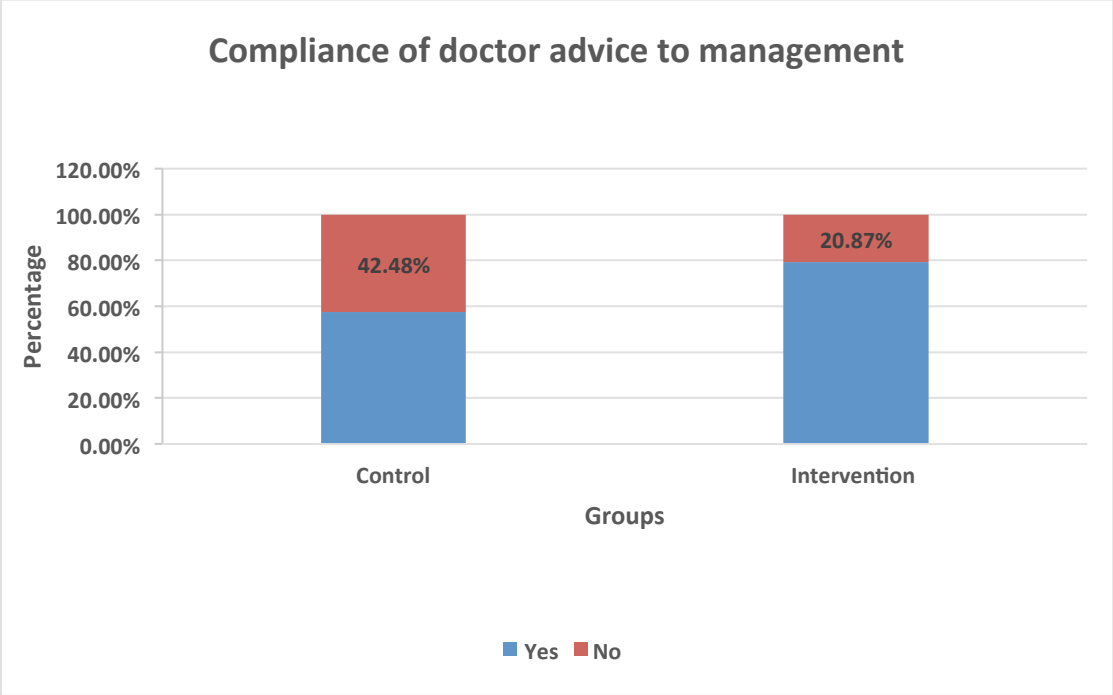


Figure 34: Proportion of study participants complying with doctor's advice

4.3.6. Reasons for non-compliance to doctor's advice by study participants

The reasons for non-compliance to doctor's advice amongst study participants is provided in figure 35. In this study, lack of knowledge was the principal reason for non-compliance to doctor advice, being 31.86% women of control group compared to 1.74% of intervention group. The reason-No resource was 4.42% women in control group and 6.96% women in intervention group. Women who reported no time was 6.19% in control group and 12.17% in intervention group. The difference observed between the control and intervention group was statistically significant (P<0.001).

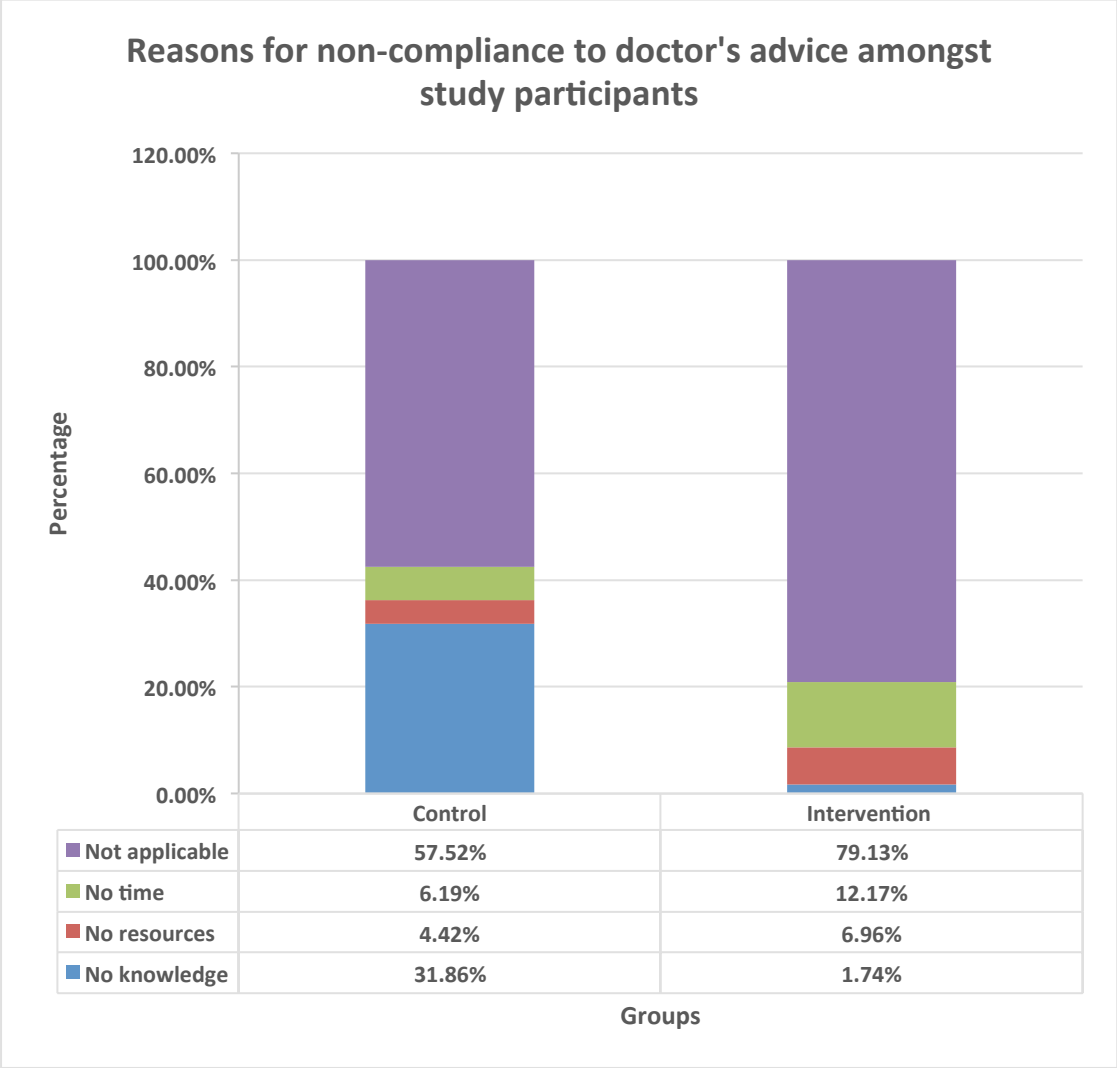


Figure 35: Reasons for not following advice for management of GDM

4.3.7. Patients preference of choice in obtaining advice in intervention group

In the present study, majority of the study participants of intervention group preferred seeking and obtaining advice from all the three i.e. doctor, pharmacist and nurse together (96.96%), followed by those seeking advice from the pharmacist alone (2.17%) and those seeking advice from the doctor alone (0.87%). However, none of the patients preferred obtaining advice only from the nurse as depicted in Figure-36.

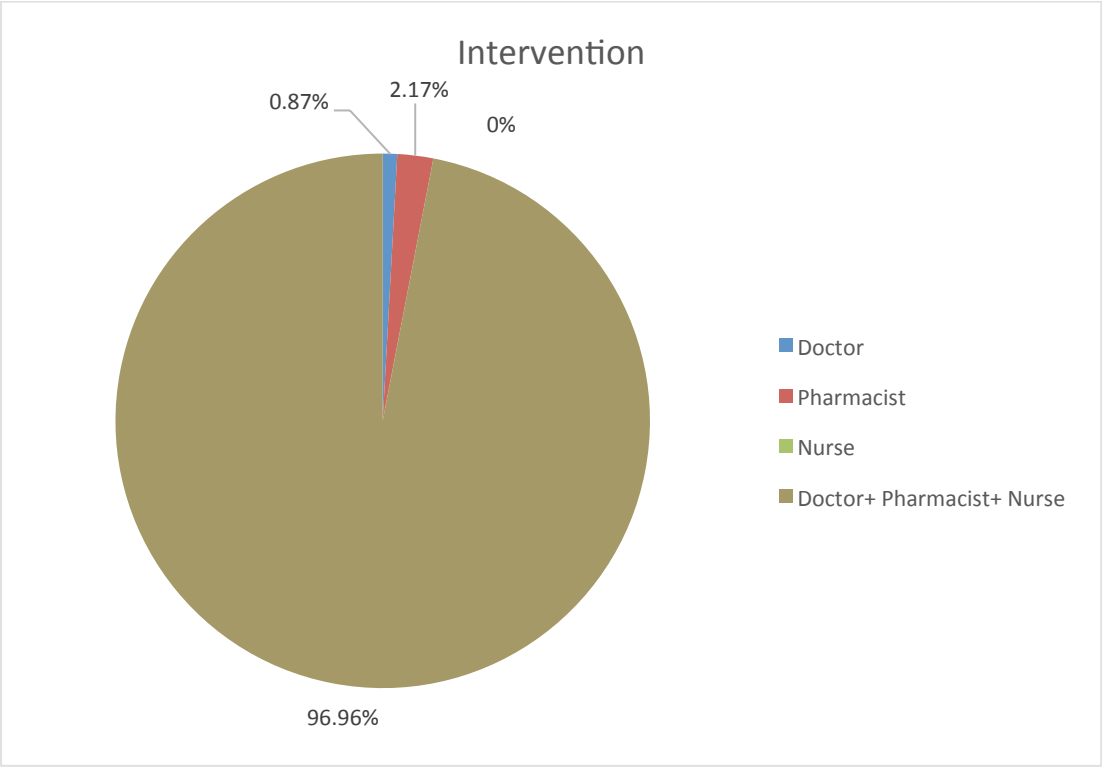


Figure 36: Patients preference of choice in obtaining advice among the intervention group

4.3.8. Components of interventional advice deemed effective by the patients

In this study, majority of the study participants (83.48%) of intervention group opined that all the components of advice including oral discussions, demonstrations, flipcharts, pamphlets, video clippings and phone calls and messages were effective. Whereas, only phone calls and messages were effective was reported by 7.83% and only the video clipping was effective was reported by 6.09% and graphical representation is depicted in Figure 37.

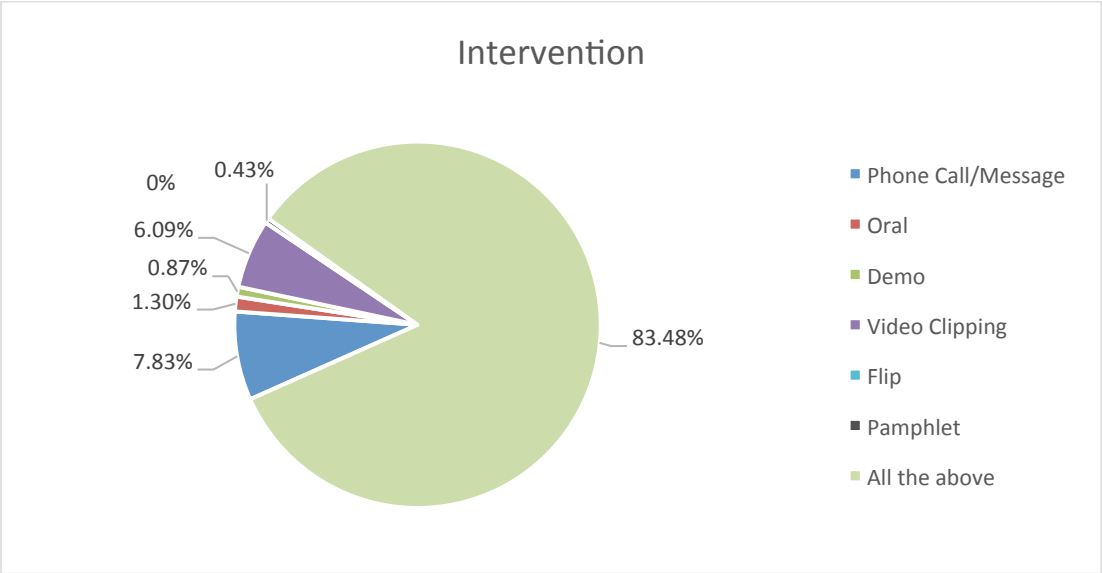


Figure 37: Components of interventional advice deemed effective by the study subjects

4.3.9. Ease of understanding of the study leaflet in the Intervention Group

In the present study, majority of the women 79.6% of intervention group found easy to read and 78.4% understood the information in the leaflet. They also reported ease of understanding in terms of the design of the materials as 85.6%, layout as 85.6%, printing as 67.2% and content as 86.4%, as indicated in Figure 38.

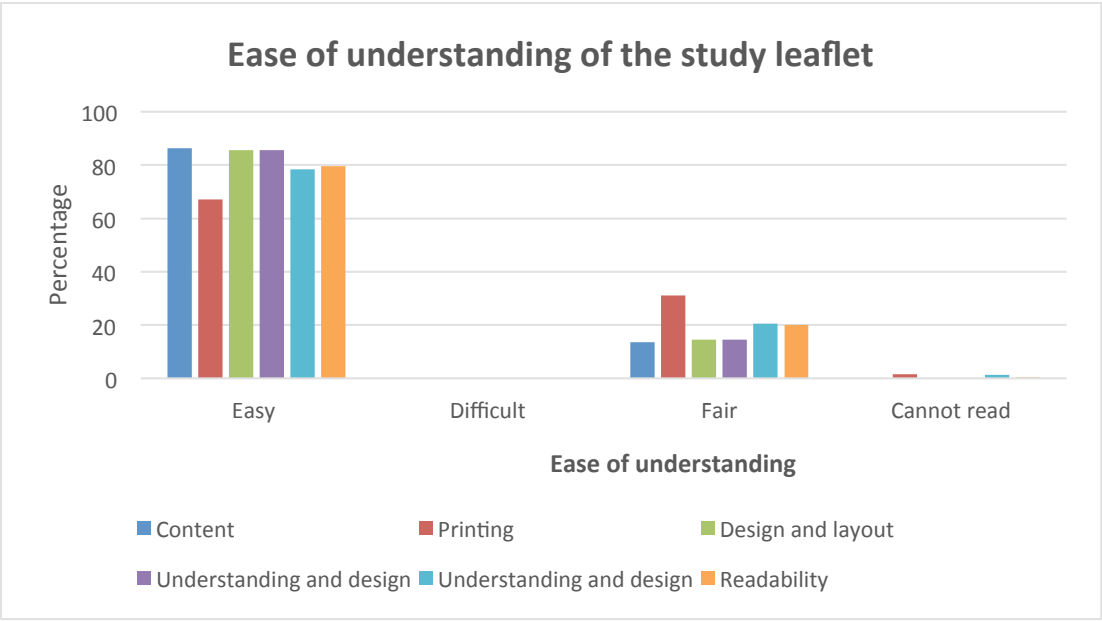


Fig. 38: Ease of understanding of the study leaflet in the intervention group

4.3.10. Adverse drug reactions recorded during the study among the study groups

The common ADRs encountered in the study have been graphically presented in figure 39. In the present study, 195 (86.28%) women of control group and 226 (98.26%) women of intervention group did not report any adverse drug reactions (ADRs). Among those who reported ADRs, hypoglycemia was the most common ADR in both control 10 (4.42%) and intervention 3 (1.3%) group. Dizziness was reported by 7 (3.10%) women, headache by 5 (2.21%), redness by 3 (1.33%)of control group. When ADRs were compared statistically among the groups, it was found to be statistically significant P<0.05. The photograph of observed adverse drug reaction are provided in figure 40.

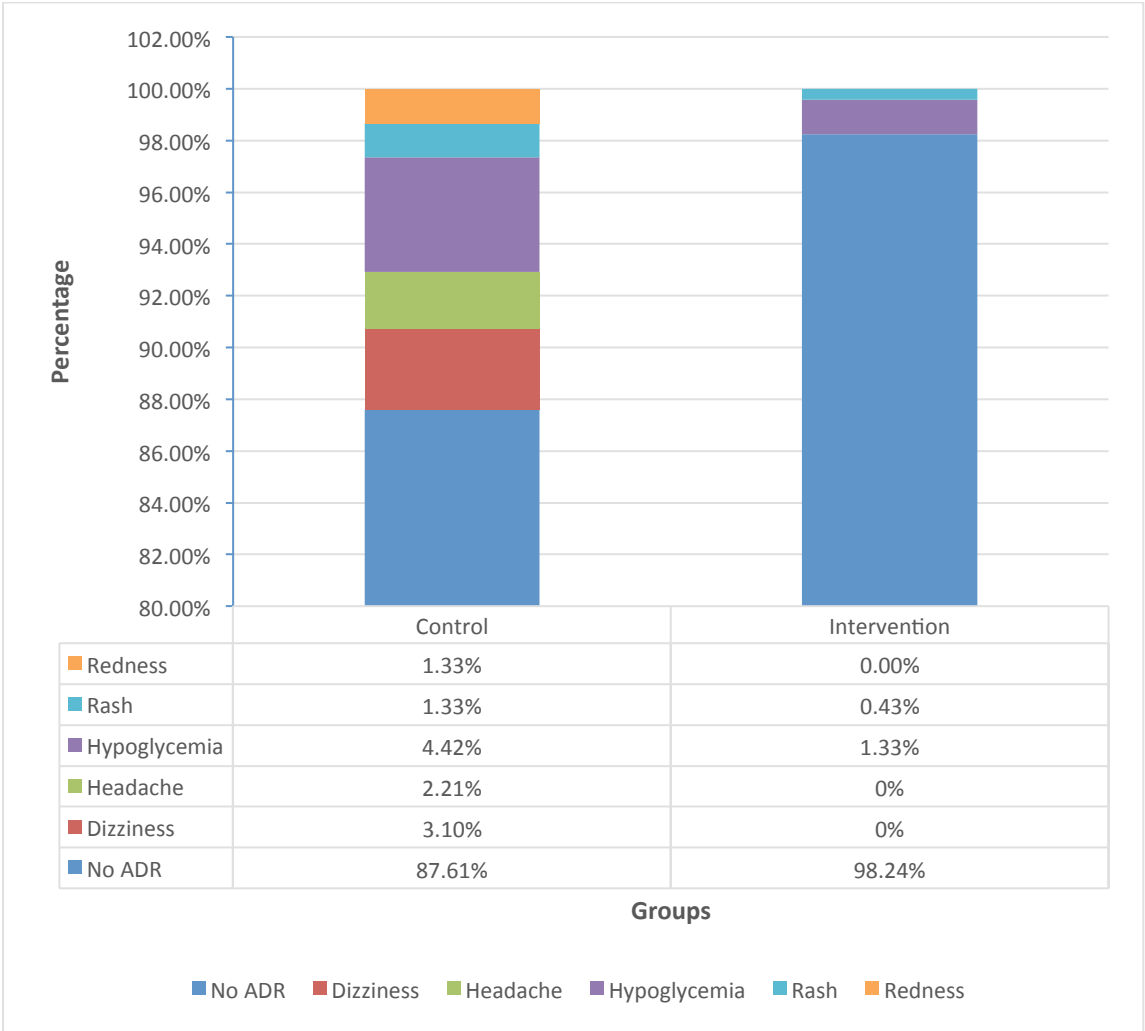
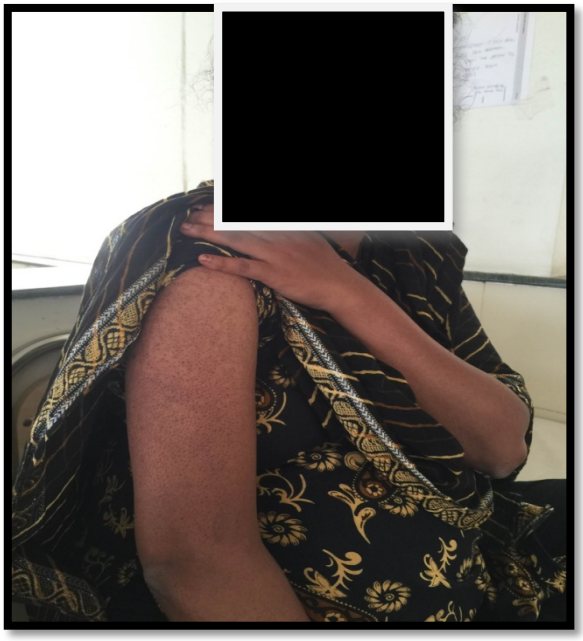


Figure 39: Adverse drug reaction reported by study participants of study groups'



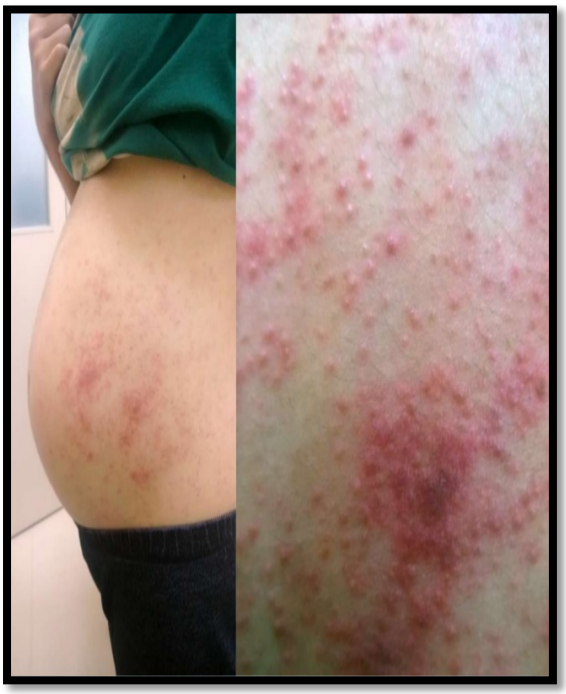


Figure 40: Observed adverse drug reaction redness and rashes on the skin

4.3.11. Treatment modalities in the management of GDM

The success of the treatment relies on glycemic control with dietary modification and pharmacological intervention. Medical nutrition therapy was observed to increase progressively in both the groups, control group showed the increase 182(80.5%), 188 (83%) and 215 (95%) at baseline, 1 month after baseline and after six weeks of delivery respectively. Whereas, medical nutrition therapy in intervention group increased to 195 (84.5%), 215 (93%) and 226 (98%) at baseline, 1 month after baseline and after six weeks of delivery respectively. Oral hypoglycemic agent used by women in both the control and intervention groups were, 2 (1%), 3 (1%) and 11 (5%) women at baseline, 1 month after baseline and six weeks of delivery respectively in control group, whereas, 3 (1.3%), 3 (1%) and 4 (2%)women at baseline, 1 month after baseline and six weeks of delivery respectively in intervention group. It was found that the insulin use comparatively decreased in intervention group. Insulin use as observed in 42 (18.5%), 35 (15%) and 0 (0%) women at baseline, 1 month after baseline and after six weeks of delivery respectively in control group, in comparison to 32 (14%), 12 (5%), and 0 (0%)women at baseline, 1 month after baseline and after six weeks of delivery respectively in intervention group. The treatment modalities uses results for GDM management are provided in figure-41 for medical nutrition therapy, figure-42for oral hypoglycemic agents and figure-43 for insulin usage.

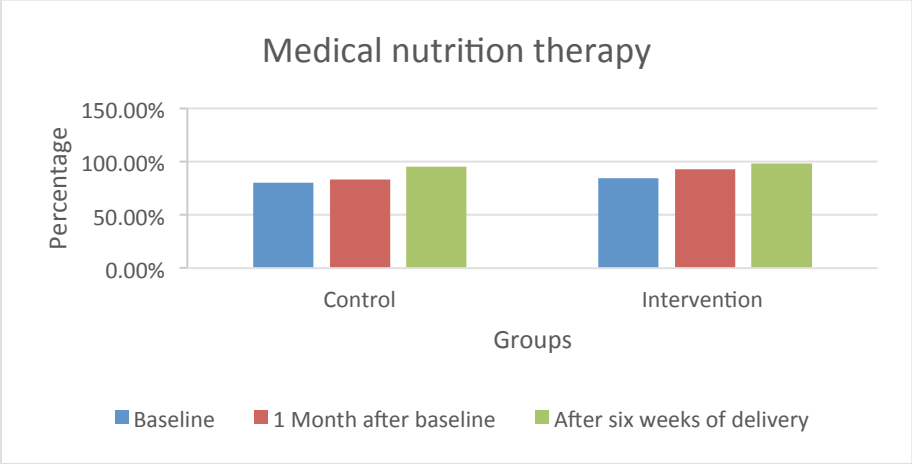


Figure 41: Medical nutrition therapy used for GDM management in study groups

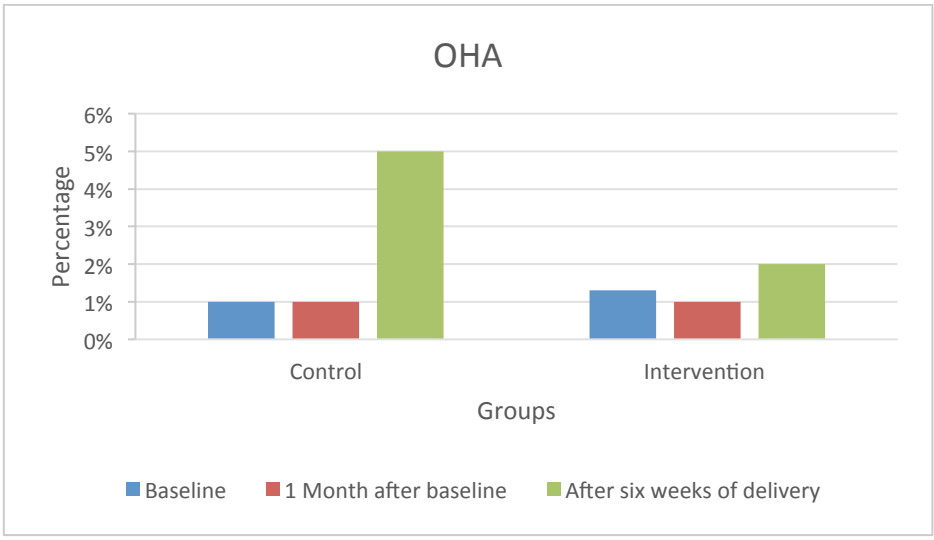


Figure 42: Oral hypoglycemic agent used for GDM management in study groups

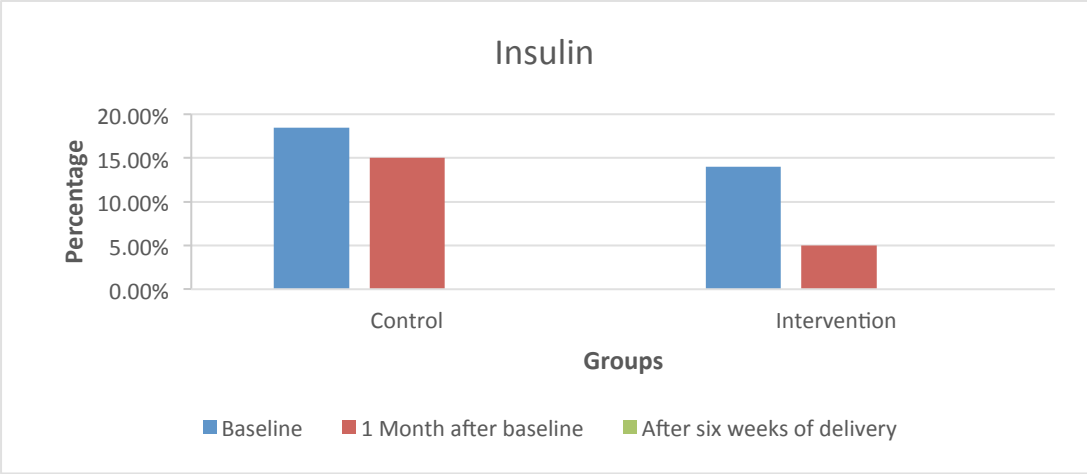


Figure 43: Insulin uses for GDM management in study groups

4.3.12. Diet followed at different intervals

Figure 44shows one month post baseline and figure 45 represent before delivery percentage of GDM women who followed the diet and not followed the diet. In control group, 137 (60.62%) GDM women were found who adhered to the diet plan at 1 month after baseline, which increased to 202 (89.38%) women at the time of before delivery. Whereas, 89 (39.38%) women did not follow diet plan at 1 month after baseline which decreased up to 24 (10.62%) women at the time of before delivery. In intervention group, 225 (97.82%) GDM women followed the diet plan at 1 month after baseline, which was further increased to 229 (99.57%) women at the time of before delivery. However, at 1 month before baseline 5 (2.17%) women did not follow diet plan which further decreased to 1 (0.43%) woman at before delivery. The mean difference between the group was statistically significant (P<0.01).

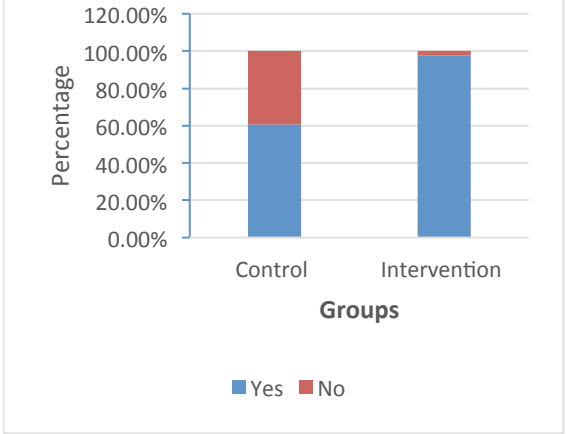


Figure 44: Graph of diet followed at 1 month after baseline

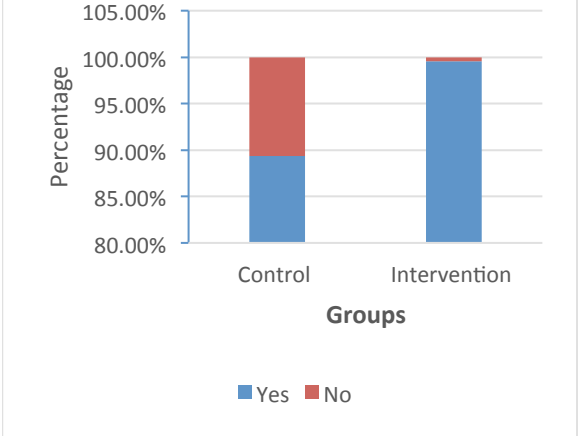


Figure 45: Graph of diet followed before delivery

4.3.13. Insulin use at each of assessment periods in study groups

Figure 46 and 47 depicts insulin use at each of the assessment periods. In the present study, there was a decrease in intermittent insulin use from baseline to before delivery

in both control group 32 (14.1%) women at baseline to 20 (8.8%) women at before delivery and in intervention group (26 (11.3%) women at baseline to 7 (3%) women at before delivery. The difference in intermittent insulin use between the control and intervention group was statistically significant (P<0.001). Chronic insulin use was found to be increase in control group and decrease in intervention group between baseline to before delivery. Control group showed 10 (4.4%) women at baseline which increased to 15 (7%) in women who used chronic insulin at delivery, whereas intervention group showed 6 (3%) women at baseline and 4 (2%) women who used chronic insulin at delivery. The difference in chronic insulin uses between the groups was statistically significant (P<0.001) at before delivery.

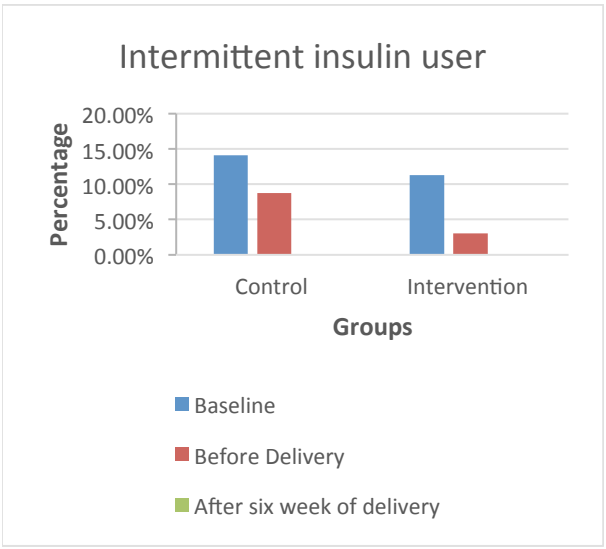


Figure 46: Graph of intermitter insulin user in study groups

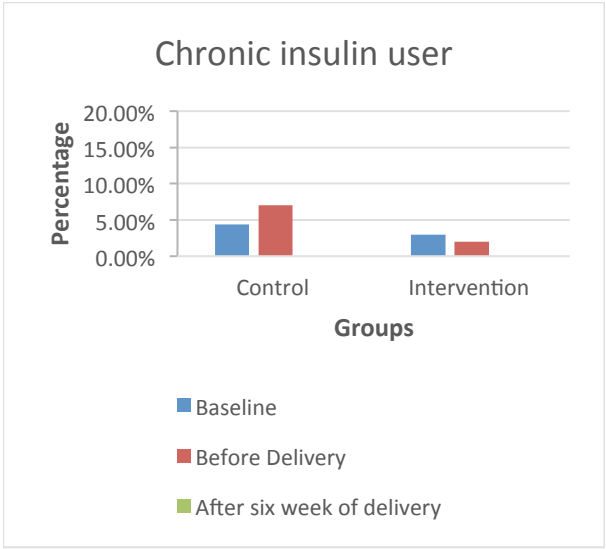


Figure 47: Graph of intermitter insulin user in study groups

4.4 Outcome of GDM mother's delivery in study groups

Outcome of GDM mother's delivery includes the term of delivery, parity, risk factors for mother, risk factors for neonates, knowledge for GDM and score.

4.4.1. Maternal delivery outcomes

Maternal delivery outcomes of GDM mothers enrolled in the study have been enumerated in Figure-48. Majority of the deliveries in both the control group(66.3%) and intervention group(83%) were term deliveries. This was followed by pre-term deliveries in control(22.12%) and intervention groups(9.5%) respectively, post-term deliveries were11.5%in control and 9%in intervention group. The mean difference between the groups were compared and found that the difference in the mean was significant (P<0.005).

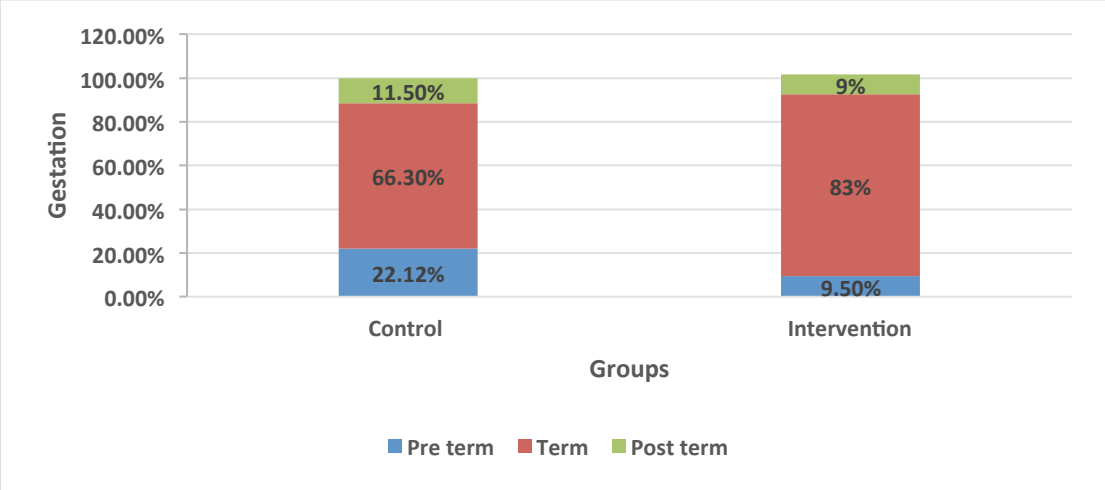


Figure48: Distribution of delivery outcome in study groups

4.4.2 Parity among the study participants

Majority of the GDM mothers in both control and intervention group were prim parous, 173 (78%) in control and 176 (76.5%) in intervention group. This was followed by those with nulliparous mothers, 38 (15.2%) women in control and 38 (16.5%) women in intervention group. Study women with <2 children were found in both the groups, 15 (6%) in control group and 16 (6.4%) in intervention group. The comparison of parity outcome between the group were made and found that the difference was not significant (P value 0.989). Graphical representation of parity among the study participants are provided in figure-49.

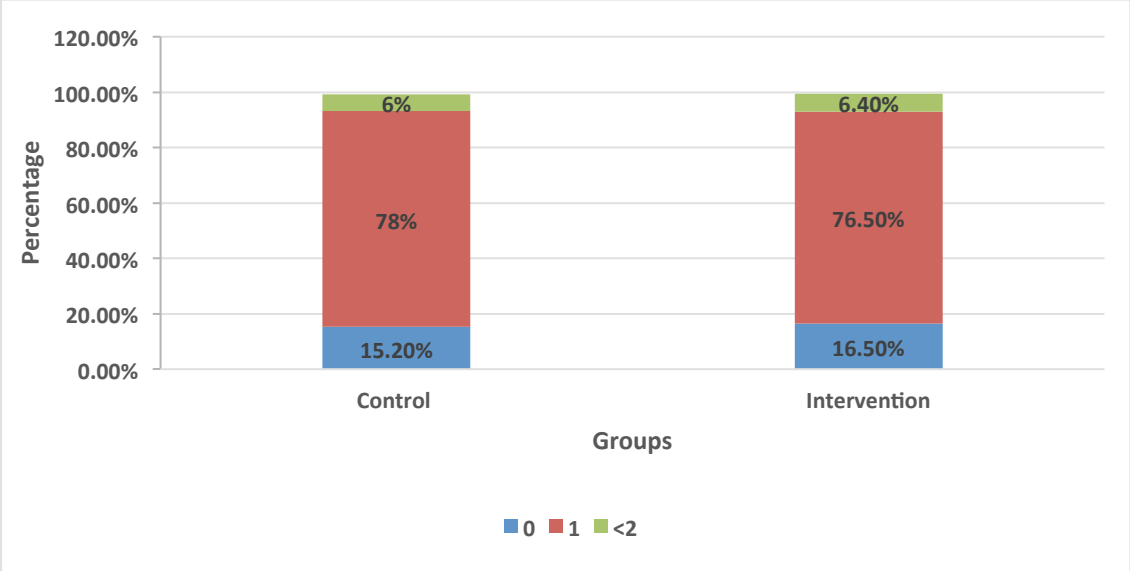


Figure49: Segregation of the study population by parity

4.4.3 Risk factors for study participants

The distribution of study population by the risk factors for gestational diabetes has been portrayed in figure-50. Amongst the study participants 10 (4%) of control group and 16 (7%) of intervention group reported to have history of abortion. History of gestational diabetes mellitus was12 (5%) in subjects of control group and 10 (4%) in subjects of intervention group participants. Women 68 (30%) in control group and 67 (29.1%) in intervention group had a family history of diabetes mellitus. Family history of hypertension was present in43 (17.2%) and 48 (19.2%) women in the control and intervention groups respectively. History of preeclampsia was present in 10 (4%) of control group and 7 (3%) in intervention group women respectively, whereas anemia was found in 22 (9%) women of control group and 17 (7%) women of intervention group. Hypothyroidism was present in 21 (8.4 %) and20 (8 %) women in control and intervention group respectively. The differences in all the risk factors were not statistically significant (P>0.05).

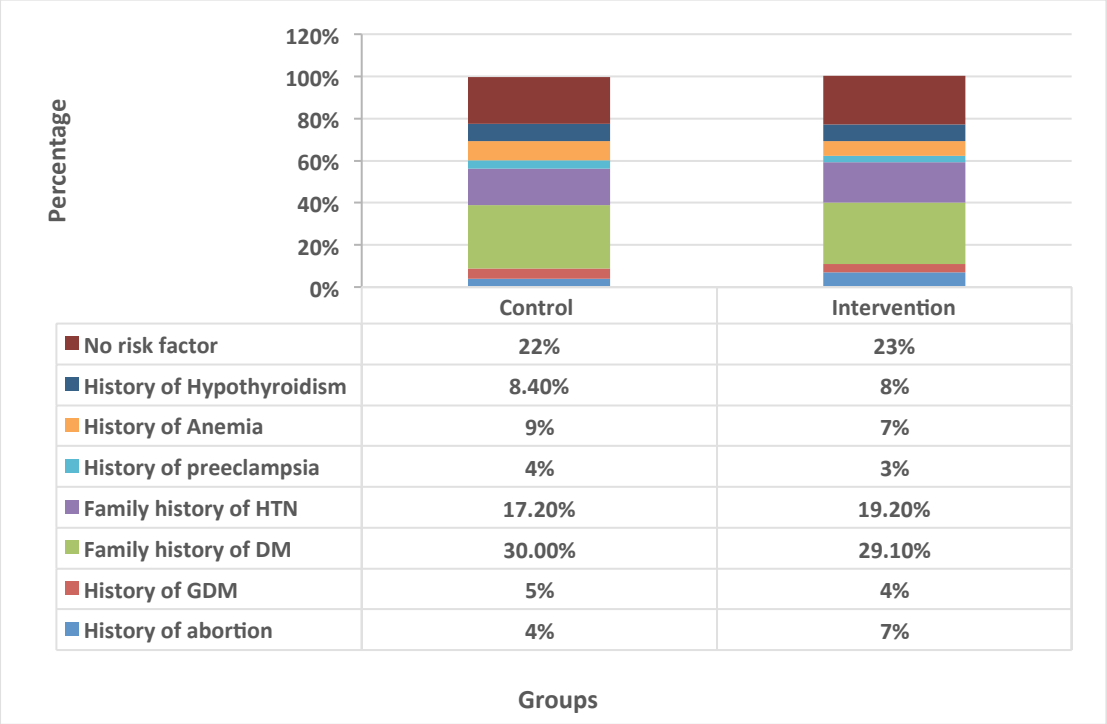


Figure 50: Distribution of Study Population by Risk Factors for GDM

4.4.4. Risk factors for neonates of study participants

The distribution of study population by the risk factors for GDM babies born to GDM mothers enrolled in the study has been depicted in figure51.Among the neonates, 8 (3.2%)neonates of control group and 9 (4%)neonates of intervention group were found to have history of jaundice,and 8 (3.2%)neonates of control group and 6(2.4%)neonates of intervention group were found to havehistory of hypoglycaemia.History of still birth was in 4 (2%) neonates of control group and 2 (0.8%) neonates of intervention group(P>0.05). History of macrosomia in babies was found in4 (2 %)neonatesin control group and 3 (1.2 %) neonates in intervention group(P>0.05). History of NICU admission was found in 10 (4 %)neonates of control group and 8 (3.2 %)neonates of intervention group of women(P>0.05).

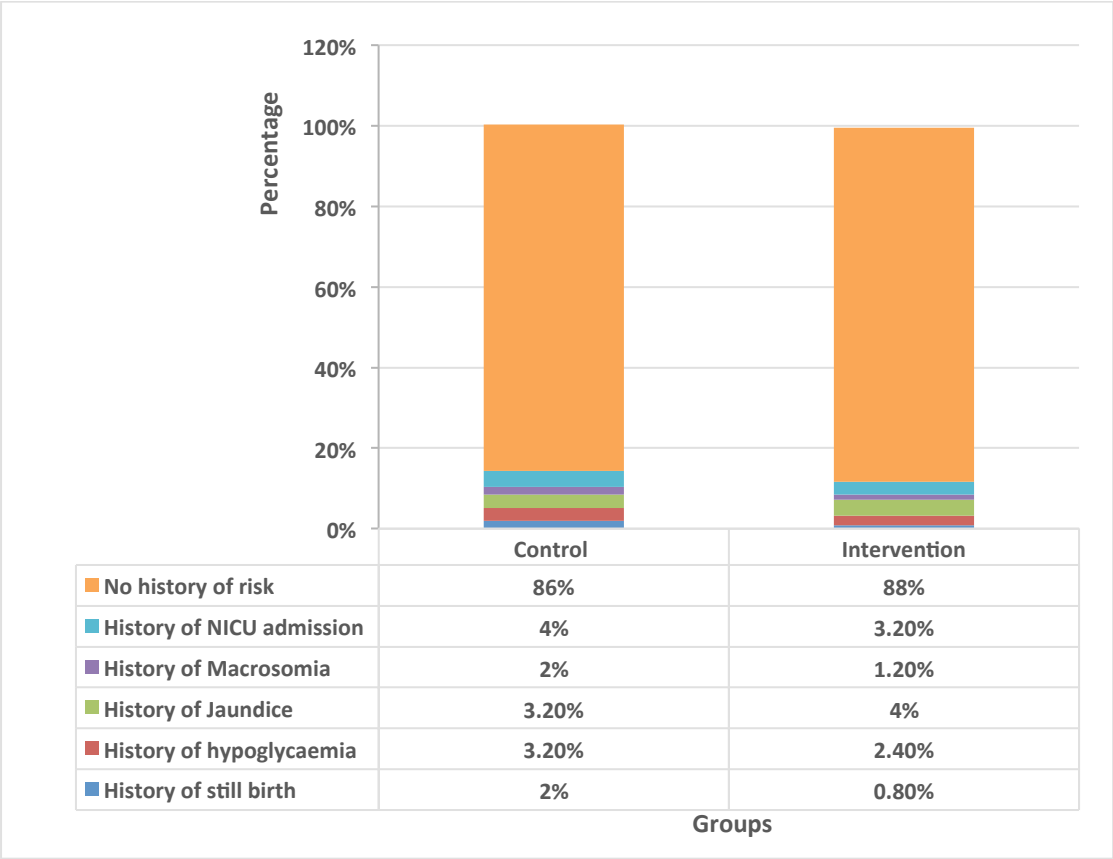


Figure 51: Distribution of risk factors for babies born to GDM mothers ofstudy groups

4.4.5 Changes in the knowledge of study participants

It was observed that the knowledge about GDM, diet, risk factor, treatment/management, complications and consequences to the baby at base line was found almost similar in both the control and intervention group. However, knowledge and answers to questions related to GDM and its management showed significant ($P<0.05$) improvement in intervention group. The knowledge and answer of questions about treatment of GDM was significantly ($P<0.01$) increased. Knowledge about diet was found to be statistically significantly increased ($P<0.01$) regarding risk factors ($P<0.01$), treatment/management ($P<0.01$), complications ($P<0.05$) and baby consequences ($P<0.001$). Post intervention, results of majority of the questions asked showed mean difference of pre-intervention and post-intervention found to be statistically significant differences ($P<0.05$). It can be observed from the results that

post intervention there was an improvement in providing correct answers as compared to control group, thereby demonstrating the success of intervention group (Figure-52).

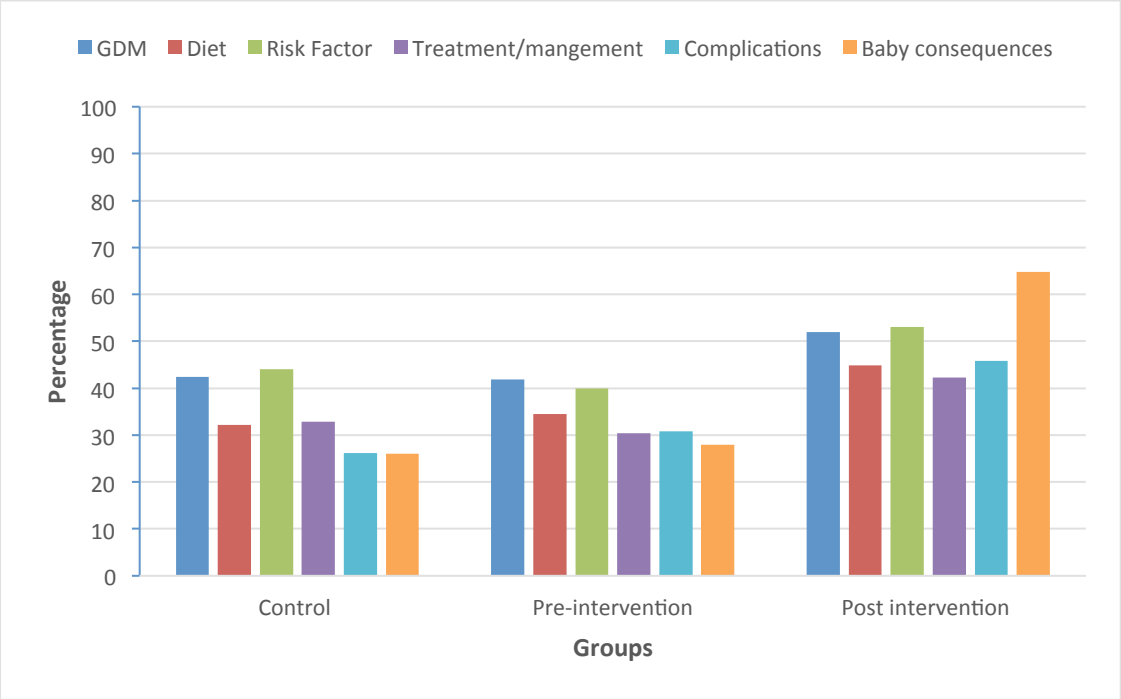


Figure 52: Baseline and post intervention knowledge regarding GDM

4.4.6 Knowledge Scores in pre and post intervention

Knowledge score was categorized as excellent, good, average and poor category (Table-1). Intervention group showed participants increase in excellent category from 3 (1.3%) baseline to 19 (7.6%) post-intervention and in Good category 38 (16.5%) women at baseline to 57 (25%) post-intervention. Decrease in women of Average category was observed from 145 (63.04%) at baseline to 124 (53.9%) after post-intervention, whereas decrease in Poor category women was from 44 (19.13%) as baseline to 30 (13%) at post-intervention. The difference in knowledge scores within the group, between the pre-intervention and post-intervention duration was statistically significant ($P<0.01$). Results showed that at baseline there was no significant difference between the mean knowledge in both the groups (Figure-53).

The difference in mean of baseline and post intervention was found to be significant (P<0.001).

Knowledge	Pre-Intervention (Control group)	Pre-Intervention (Intervention group)	Post Intervention (Intervention group)
	No. (%)	No. (%)	No.(%)
Excellent	6(2.65%)	3(1.30%)	19(7.60%)
Good	54(23.89%)	38(16.5%)	57(25%)
Average	115(50.88%)	145(63.04%)	124(53.9%)
Poor	51(22.57%)	44(19.132%)	30(13%)
Total	**226**	**230**	**230**

Table 6:Demonstrates the baseline and post-intervention knowledge regarding GDM

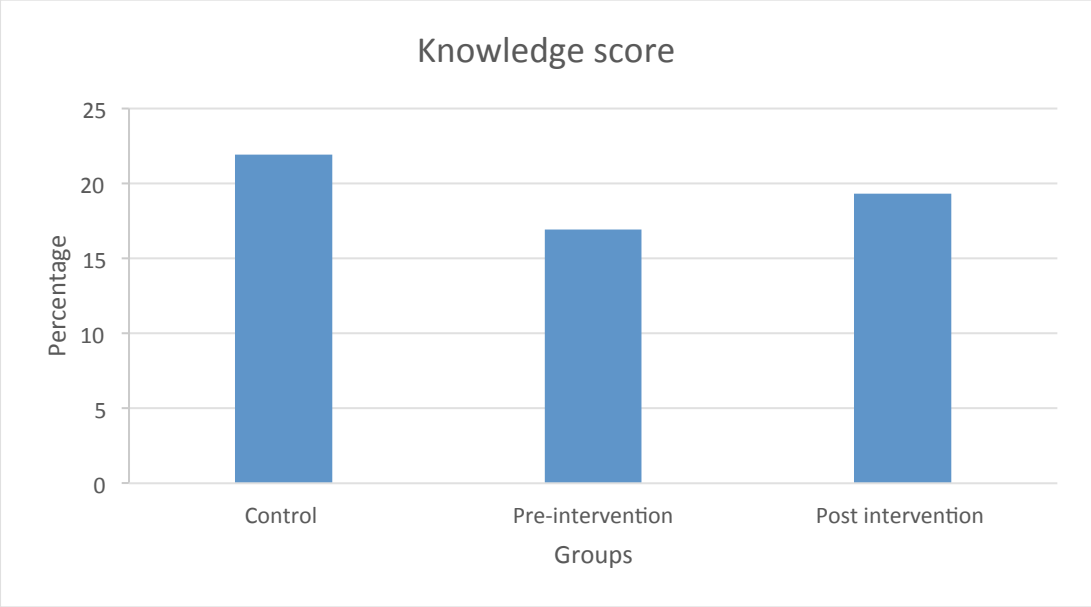


Figure 53: Changes in mean knowledge score of study participants

4.5 Neonates outcome from study participants

Neonates outcome was assessed on the basis of gender of neonates, gestational age, APGAR score, blood glucose levels of neonates, NICU admission, neonatal complications and duration of hospital stay of neonates.

4.5.1 Baseline data of neonates

The Baseline results of neonates have been illustrated in figure 54-56. In this study, majority of the babies born from enrolled GDM mothers were male in both control 131 (58%) and intervention 144 (63%) groups. Majority of the babies born to the GDM mothers enrolled in this study were appropriate for gestational age (AGA) in both control group 166 (73.4%) and intervention group 182 (79.13%) women. About 36 (16%) women from control group and 27(12%) women from intervention group had babies who were small for gestational age (SGA), whereas 21 (9.2%) women of control group and 18 (8%) women of intervention group have babies who were large for gestational age (LGA). The average APGAR scores of the children born to GDM mothers in control group was 8 and for intervention group was 9. The result, indicate that intervention group has shown better outcome in comparison to control group as number of women who had appropriate gestational age babies and high average APGAR score reported.

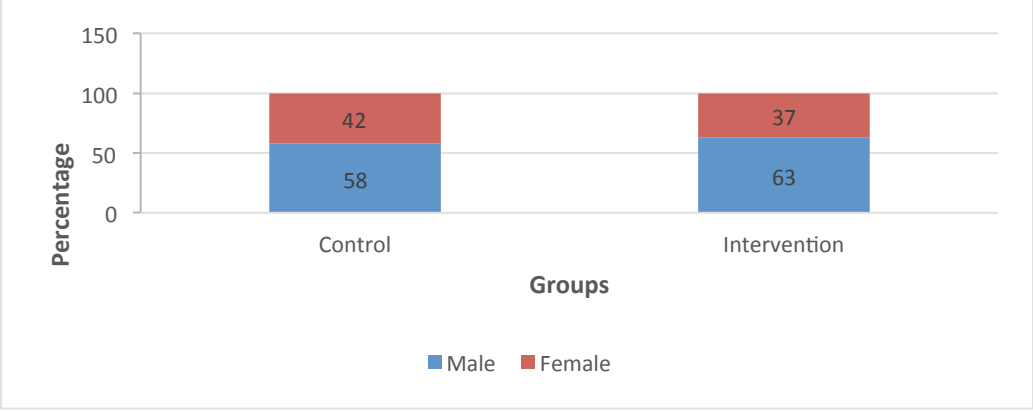
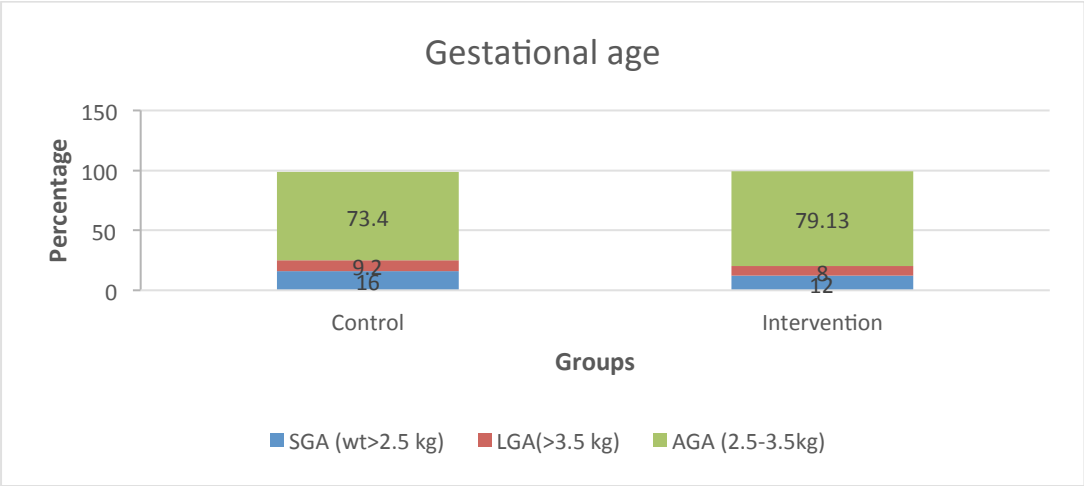


Figure 54: Distribution of child gender among the study groups



SGA-Small for gestational age, LGA-Large for gestational age, AGA-Appropriate for gestational age

Figure 55: Distribution of child based on gestational age among the study groups

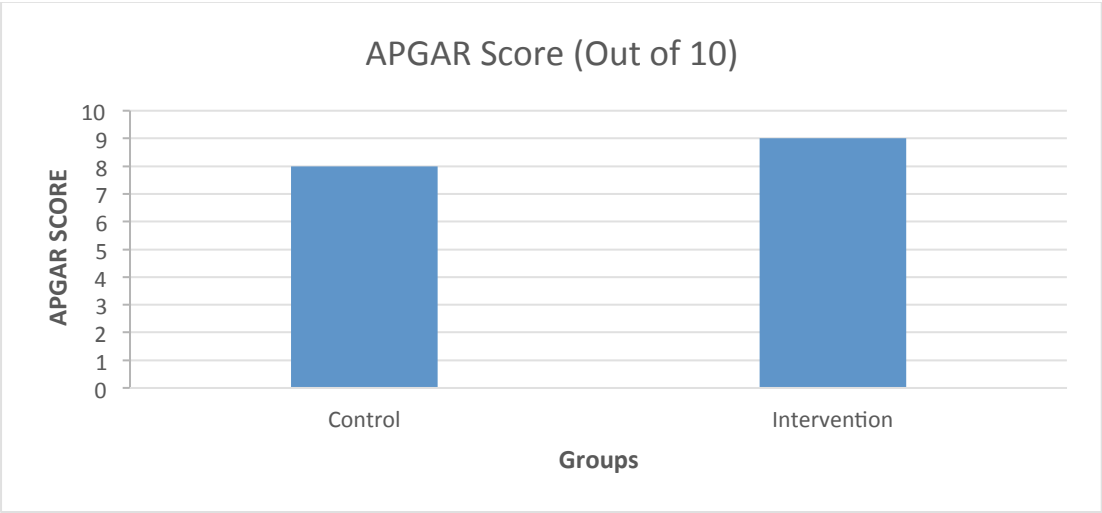


Figure 56: Result of average APGAR scores among the study groups

4.5.2. Blood glucose levels of neonates

The neonatal blood glucose levels are depicted in figure-57. In the present study, there was a decrease in neonatal blood glucose levels immediately after birth and 24 hours after birth in both control and intervention groups. The mean blood glucose of control group was 86 mg/dL immediate after delivery and 77 mg/dL after 24 hours of delivery, whereas in intervention group blood glucose was 76 mg/dL immediately

after birth and 59 after 24 hours of delivery. The Graph portraying the blood glucose level of neonates are provided in figure-57.

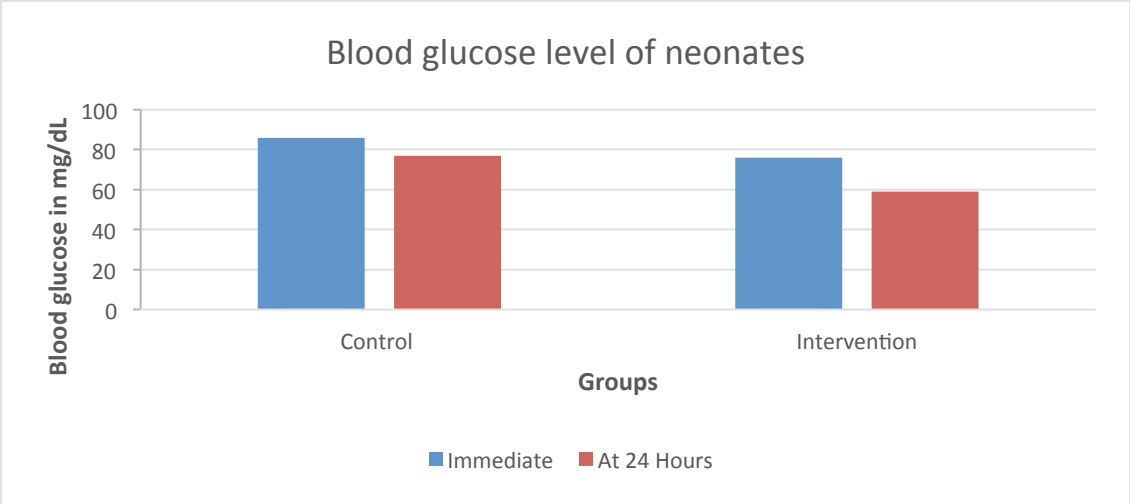
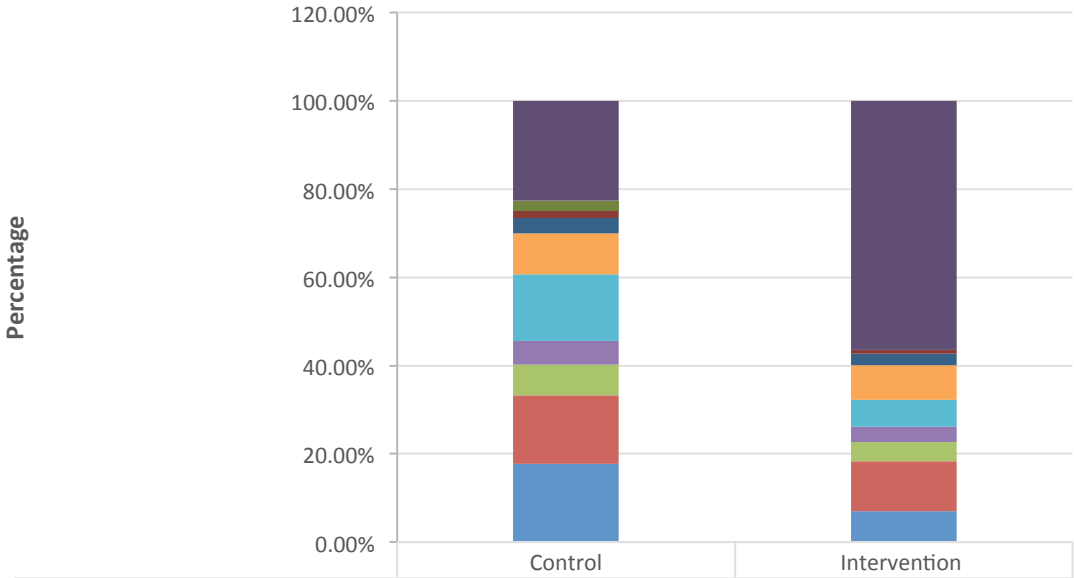


Figure 57: Blood glucose level of neonates amongst the study groups

4.5.3. Neonatal outcomes in GDM participants of study groups

In this study, neonatal outcome is presented in figure 58. It was found that the 22.57% women of control group and 56.51% women of intervention group were healthy, which do not require any medical assistance, whereas NICU admission was seek from 40 (17.7%) women of control group and 16 (6.96%)women of intervention group, the mean difference between the control and intervention group was found to be statistically significant (P<0.01). Neonatal mortality was observed in 5 (2.21%) neonates of control group and nil (0%) neonate of intervention group, the mean difference between the control and intervention group was found to be statistically significant (P<0.05). Hyperbilirubinemia was observed in 35 (15.49%) neonates of control group and 26 (11.30%) neonates of intervention group. Respiratory distress syndrome was also found in the study groups, 16 (7.08%)neonates from control group and 10 (4.35%) neonates from intervention group reported. Hypocalcemia was observed in 12(5.31%) neonates of control group and 8 (3.48%) neonates of intervention group, whereas hypoglycemia was observed in 34 (15.04%) neonates of

control group and 14 (6.09%) neonates of intervention group. Macrosomia was reported by 21 (9.29%) neonates of control group and 18 (7.83%) neonates of intervention group, however congenital abnormalities was observed in 8 (3.54%) neonates of control and 6 (2.61%) neonates of intervention group. The difference between the group was compared and it found that hyperbilirubinemia, respiratory distress syndrome, hypocalcaemia, hypoglycemia, macrosomia and congenital abnormalities were not significant.



	Control	Intervention
Healthy	22.57%	56.51%
Neonatal mortality	2.21%	0.00%
Surgical	1.77%	0.87%
Congenital abnormalities	3.54%	2.61%
Macrosomia	9.29%	7.83%
Hypoglycemia	15.04%	6.09%
Hypocalcaemia	5.31%	3.48%
Respiratory distress syndrome(RDS)	7.08%	4.35%
Hyperbilirubinemia	15.49%	11.30%
Neonatal Intensive Care Unit admission	17.70%	6.96%

Figure 58: Distribution of neonatal outcomes of study participants

4.5.4.NICU admission of neonates

The details of neonates born to GDM mothers enrolled in the present study admitted to the NICU are mentioned in figure 59. It was found that the 77.43% neonates of control group and 43.49% neonates of intervention group were admitted in Neonatal Intensive Care Unit (NICU), remaining neonates 22.57% neonates of control group and 56.51% neonates of intervention group were healthy (Figure-59). Among the NICU admitted babies, 32 (14.15%) neonates of control group and 16 (7%) neonates of intervention group were found to belong to appropriate gestational age, 6 (3%) neonates of control group and 3 (1.3%) neonates of intervention group were having small gestational age, remaining 2 (1%) neonates of control group and 1 (0.4%) neonate of intervention group were large to gestational age. The graphical presentation of gestational age of neonatal admitted in NICU are provided in figure 60. Total 13 (6%) neonates of control group and 6 (3%) neonates of intervention group were delivered by caesarean section (Figure 61), macrosomia was observed in 3 (1.3%) neonates of control group and 2 (1%) neonates of intervention group (Figure 62) respectively.

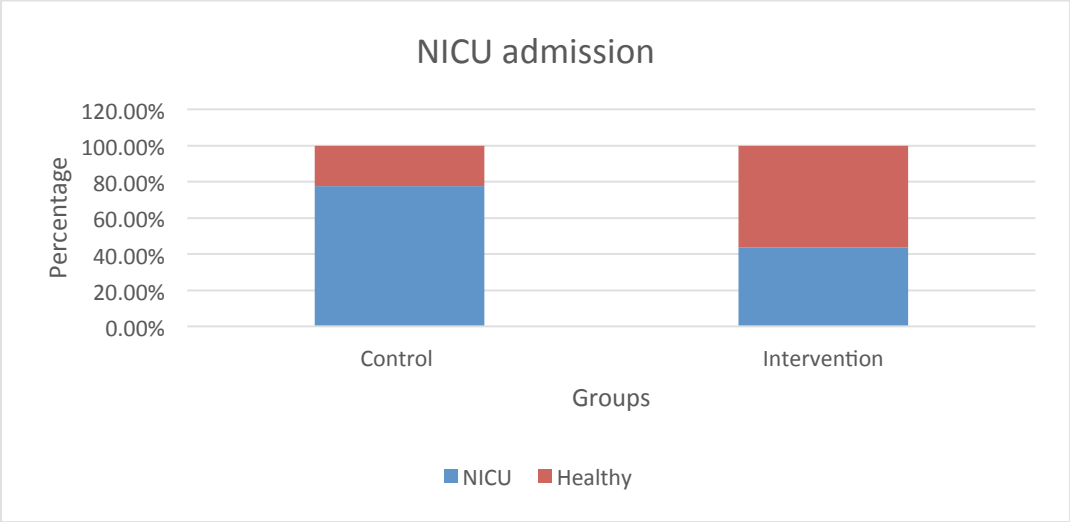


Figure 59: Distribution of NICU admission amongst the study groups

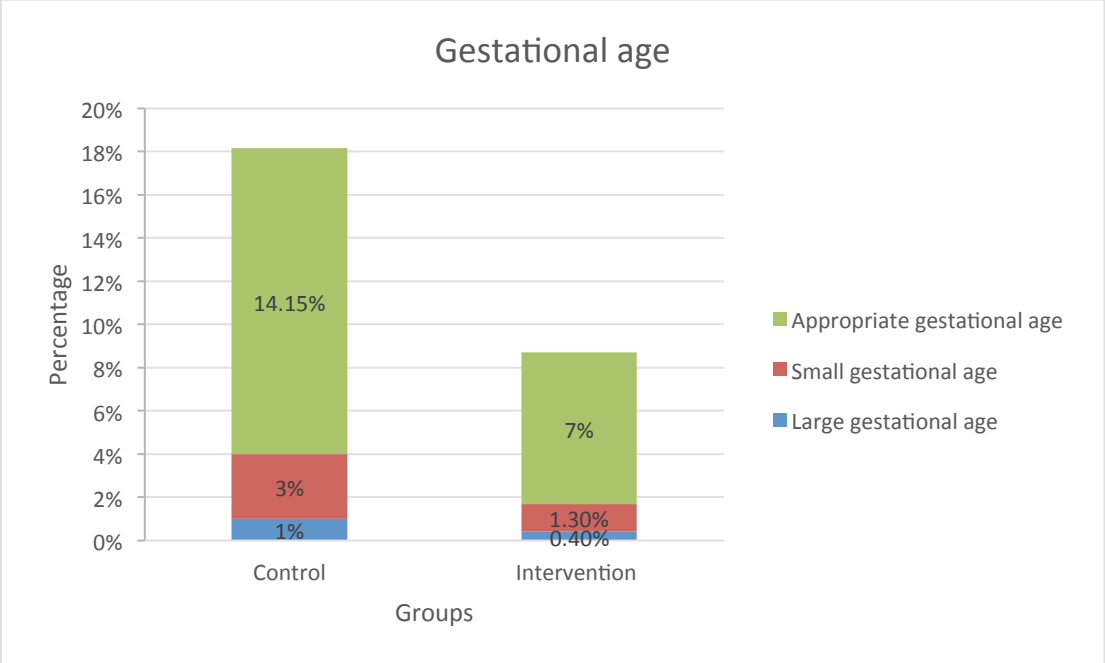


Figure 60: Distribution of gestational age among the NICU admitted neonates of study

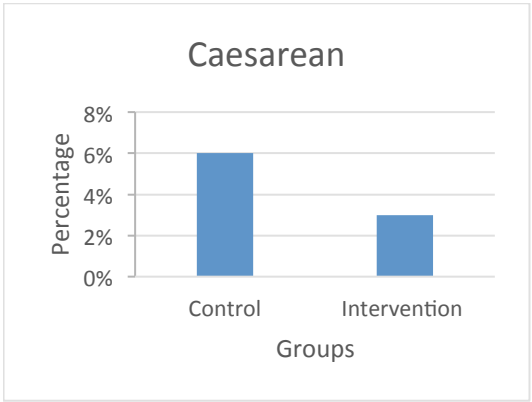


Figure 61: Mode of delivery in NICU admitted neonates

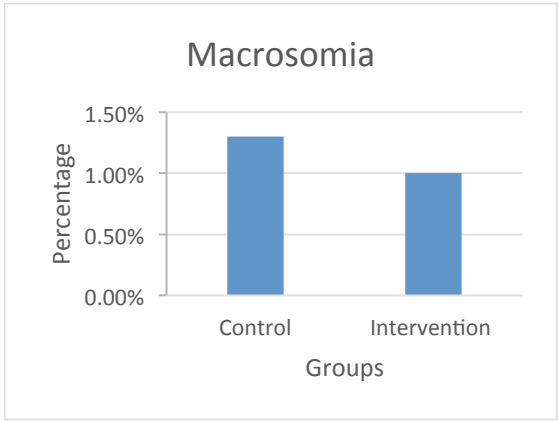


Figure 62: Macrosomia in NICU admitted neonates

4.5.5. Neonates hypoglycaemia

Neonatal hypoglycaemia was observed in 11 (5%) neonates of control group and 6 (3%) neonates of intervention group after 1 hour of delivery, whereas 5 (2.2%) neonates of control group and 3 (1.3%) neonates of intervention group had hypoglycaemia after 3 hours of delivery (Figure 63).

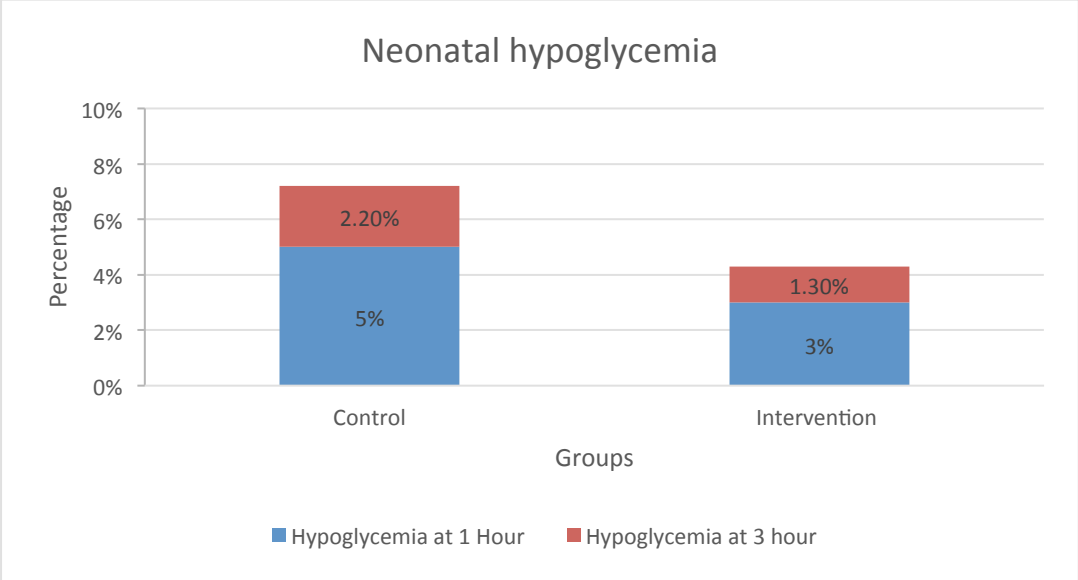


Figure 63: Blood glucose level of NICU admitted neonates at various intervals

4.5.6. Hospital stay duration of neonates

Duration of hospital stay was observed among the NICU admitted neonates and observed that the mean duration of hospital stay was 4 days in control group and 3 days in intervention group of NICU admitted neonates (Figure 64). During the NICU admission, neonates were given phototherapy in neonatal jaundice representative photograph of which is provided in figure 65. Figure 66 demonstrates the breastfeeding and spoon-feeding session given by mothers.

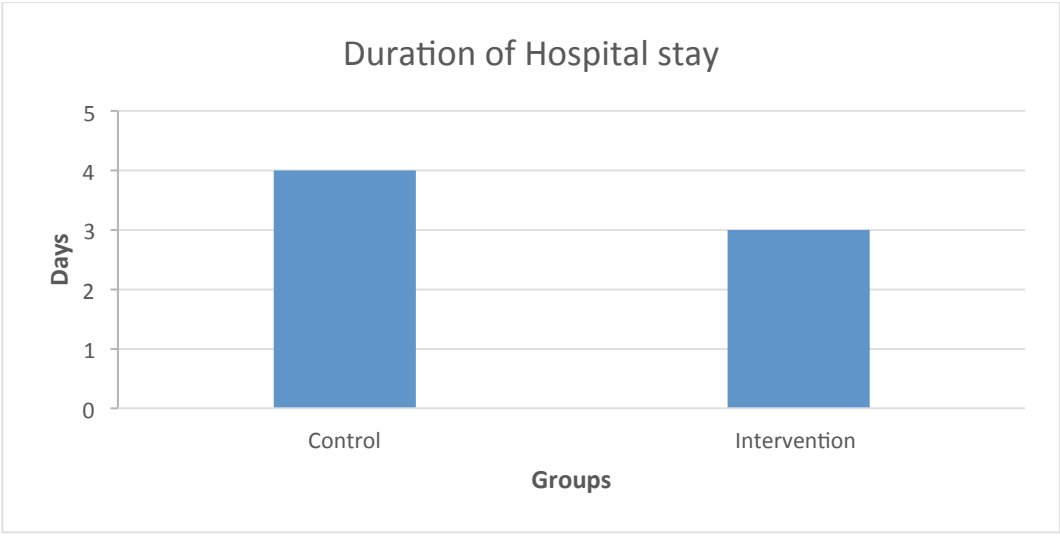


Figure 64: Duration of hospital stay in NICU admitted neonates

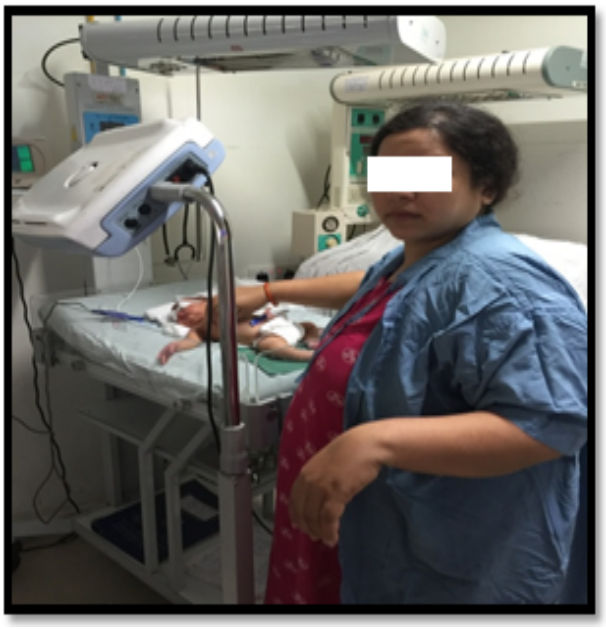


Figure 65: Phototherapy of neonates with neonatal jaundice

Figure 66: Breastfeeding and spoon-feeding session by mothers

Observed neonatal complication in NICU admitted neonates were hyperbilirubinemia, Low APGAR score, Respiratory Distress Syndrome. It was found that 6 (3%) neonates of control group and 4 (2%) neonates of intervention group had hyperbilirubinemia, Low APGAR score was observed in 6 (3%) neonates of control group and 3 (1.3%) neonates of intervention group. Respiratory distress syndrome was observed in 5 (2.2%) neonates of control group and 3 (1.3%) neonates of intervention group (Figure 67).

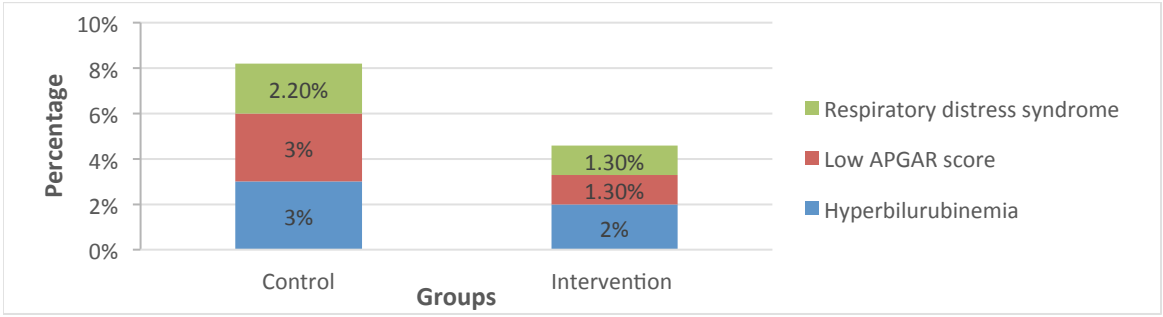


Figure 67: Distribution of neonatal complication in NICU admitted neonates of study

4.5.7. Medical support received by neonates

NICU admitted neonates were distributed based on support received, which are provided in figure 68. Phototherapy was required in 6 (3%) neonates of control group and 4 (2%) neonates of intervention group, ventilator support was required by 8 (3.5%) neonates of control group and 4 (2%) neonates of intervention group. Breast feeding wastaken by 28 (12.3%) neonates of control group and 11 (5%) neonatesof intervention group as presented in figure 68.

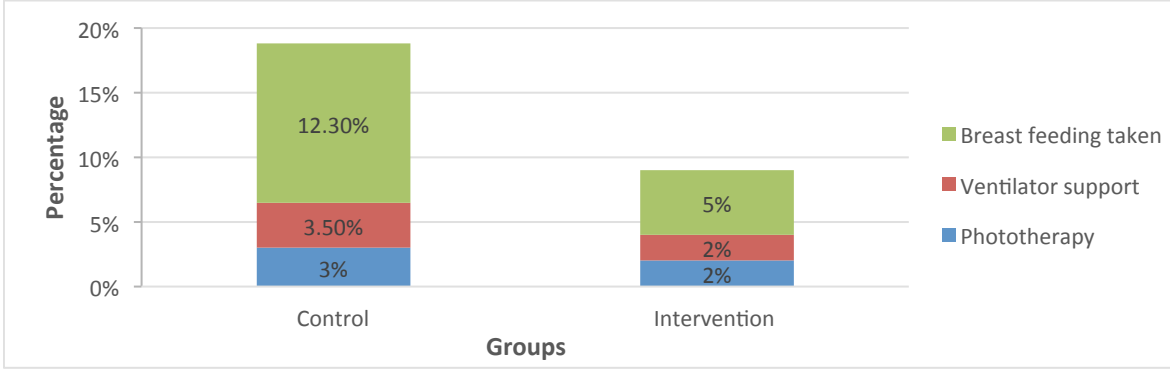


Figure 68: Distribution of support received in NICU admitted neonates of study

4.5.8. Hospital stay duration of neonates

Duration of hospital stay was observed among the NICU admitted neonates and observed that the mean duration of hospital stay was 4 days in control group and 3 days in intervention group of NICU admitted neonates (Figure 66).During the NICU admission, neonates were given phototherapy in neonatal jaundice representative photograph provided in figure 65 and figure 66demonstrate the breastfeeding and spoon-feeding session given by mothers.

4.6 Multivariate analysis in relation to various parameters among the study groups

Table-7 depicts the cumulative multivariate analysis for control as well as intervention group. In the present study, Neonatal Intensive Care Unit admissions,

hypoglycemia and neonatal mortality were significantly less in intervention group compared to control group. Difference between the groups for hyperbilirubinemia, respiratory distress syndrome, hypocalcaemia, macrosomia, congenital abnormalities were not statistically significant.(Table 7).

Parameters	**Group C (n=226)**	**Group I (n=230)**	**P value**
Neonatal Intensive Care Unit admission	1	0.08	<0.01*
Hyperbilirubinemia	1	0.84	0.64
Respiratory Distress Syndrome	1	0.67	0.40
Hypocalcemia	1	0.74	0.48
Hypoglycemia	1	0.27	0.02*
Macrosomia	1	0.79	0.51
Congenital abnormalities	1	0.87	0.72
Surgical	1	0.91	0.77
Neonatal mortality	1	0.17	<0.01*
ADRs	1	0.55	0.04*

Table 7: Multivariate analysis of neonatal complication between the groups

Gestational diabetes mellitus (GDM) described as any glucose intolerance at onset or during the pregnancy.[215,216] The prevalence of gestation diabetes has been reported from various states, 3.8% in urban block of Kashmir,[217] 9.5% in Western India,[218] 35% in Punjab.[219] The difference in prevalence could be ascribed to socioeconomic status and age of pregnant women in respective region. Pregnancy induces metabolic process change as it progresses, placental hormones (antagonist to insulin) force body to increase insulin secretion as compensatory mechanism. Progressively pancreatic β cells fail to compensate which results in scantiness of insulin and lead to GDM. Risk factors such as family history of diabetes, history of stillbirth, Polycystic ovary syndrome, history of abortion, age ≥ 25, multiparity ≥ 2, and a history of preterm delivery in relation to GDM.[220] GDM consequences for maternal are preeclampsia, polyhydramnios, delayed wound healing, long term effect is type 2 diabetus mellitus. Fetal get much affected, reported consequences are congenital anomaly, macrosomia, hypoglycaemia, hypocalcaemia, apnea, stillbirth etc.[221] Early detection and treatment of GDM patient can prevent the complication and provides good fetal outcome. GDM patients belong to mild category are can be controlled by diet and exercise (aerobic and resistance), whereas sever category GDM patient require antidiabetogenic medications (metformin and insulin). Counselling of the patient plays an important role in its management. This help patient to understand the importance of exercise, diet control, blood glucose control. During pregnancy, body requirement for calories increases which require for growth and development of fetal. Therefore, GDM patient's need to sustain tolerable calories without distressing blood glucose level to have a healthy baby. Education is an important factor in this disease, if patients are educated about the disease, disease progression and options to control the harmful effect, it could help in maintaining blood sugar and increasing the positive outcome.

The present study was planned with the specific objectives to understand the role of clinical pharmacist on impact of health education in management of GDM. This study will help to understand the effect of GDM on new-born outcome and role of socio-economic factors in management of GDM.

Based on inclusion and exclusion criteria, females diagnosed with GDM between March 2015 – July 2017 were enrolled in the study from KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi, Karnataka, India. Subjects were randomly divided into two groups ie. Control Group (Routine treatment from doctor) and Intervention Group (Routine treatment from doctor and in addition clinical pharmacist counselling (counselling for insulin therapy and technique, healthy dietary habits to maintain glycaemic level, monitoring of GDM, importance of regular follow-up and the impact of GDM on themselves and fetal). The study groups subjects were evaluated pre intervention (baseline) and post intervention with questioner in regards their knowledge about GDM, the socio-demographic parameters, including age, sex and socioeconomic status were based on the modified B. G. Prasad's classification were also recorded. The records were maintained for primary outcomes during the study period for exercise program, dietary habits, random blood sugar, insulin intake, adverse drug reaction, birth outcomes, neonatal outcomes (NICU admission, metabolic complication, hypoglycaemia, gestational age, birth weight, macrosomia, congenital abnormalities, birth trauma, convulsion, birth asphyxia, prematurity and neonatal mortality). The secondary outcomes included the impact of socio-economic parameters on maternal and neonatal outcomes. All the subjects of the study were followed-up beyond delivery up-to the post-partum period and monitored for GDM and pregnancy outcomes (Both maternal and neonatal). Computer-based data management software's, SPSS Version 20 (Armonk, NY: IBM

Corp.) and WHO Anthrop (Version 3.2.2, January 2011) were used for the entry and analysis of the data.

A multicentric study done by Siddiqui S et al., 2019 in north India, reported mean age of GDM women at baseline in all three centres of study was 26 -30 years.[222] Sreekanthan K et al., 2014 completed a study on GDM subject in south India and reported 25-32 years age.[223] Study conducted in Delhi by Kumari R, et al., 2018 at tertiary care centre reported mean age 28.87± 4.33 of women with GDM.[224] Lao TT, et al., 2001 conducted a study and suggested the jeopardy of GDM significantly and temporally increased after the age of 25 years.[225] Abu-Heija AT, et al., 2017 reported that maternal age had a profound effect on maternal GDM amongst Omani women.[226] In this study. most of the GDM women were aged between 21 to 30 years (87.2% in group A and 90% group B). The age distribution pattern among the recruited subjects was similar in both the groups as the mean difference was not statistically significant (P=0.83).

Education status plays a key role in every aspect of life and so is the case in GDM. Siddiqui S, et al., 2019 reported increase in prevalence rates with increasing educational qualification of GDM women. Subject post-graduates or above (17.14%), undergraduates (10.67%), secondary (2.13%), primary education (3.57%).[222] Study carried out by Rajput R, et al., 2013 reported that majority of the GDM women were those who completed intermediate/middle/ high school (61.3%) followed by post-graduate professionals (21.9%) followed by women with just primary schooling (11.9%) and Illiterate (4.9%).[227] Bo S, et al., 2003 reported higher levels of GDM in lower educational levels and lower levels of GDM as educational levels of the pregnant women increased.[228] Innes KE, et al. 2002 reported an inverse association

among the educational level of the pregnant woman and GDM.[229] In the present study, maximum observed subjects were from Primary 52.40 % (control group) and 62 % (intervention group), followed by illiterate 18 % (control group) and 16.40 % (intervention group), SSLC 16.40 % (control group) and 8.4 % (intervention group), post-graduation 6.40 % (control group) and 6.00 % (intervention group). Comparison was made between the group and found that the mean difference was not statistically significant (P=0.069). Study findings indicate that education has negative association with GDM and therefore number of subjects decreases as education status increases. The disparity of present findings was observed with the report published by Siddiqui S, et al., 2019. Our findings were found to be almost similar with Rajput R. et al., 2013, Bo S, et al., 2003 and Innes KE et al. 2002.[227-229]

Study published by Kumari R, et al., 2018 conducted research in Delhi and found that the majority of GDM subject were from Hindu religion (91.8%), followed by Muslim (7.6%), Christian (0.6%) and Budhist (0%).[228] Ennazhiyil SV, et al., 2019 conducted a study on GDM subject in Kerala and reported Hindu (57.66 %) followed by Muslim (38.74) and Christian (3.60 %) among the study subjects.[230] Arora GP et al., 2015 reported study from the Punjab region, demonstrated that women from the Hindu religion (54.67 %), Sikh (43.33%) and other religion (2.00 %).[219] In the present study, most of the subjects belonged to the Hindu community 50.80% in control group and 58.8% in intervention group. Whereas Muslim were 47.20 % in control group and 40.00 % intervention group, Christian in control group were 2.00 % and in intervention group were 1.20 %. The comparison of difference in mean were carried out and found that the mean difference was not statistically significant (P=0.18). The reported result was found to be in conformity with other Indian studies. Majority of

subjects of both the group belongs to Hindu, this could be attributed to the fact that Hindu comprise the largest religious community in India.

Arora GP, et al., 2015 reported that among the study subject 38.8 % belonged to urban habitation and 31.9 % belongs to rural habitation.[219] Ennazhiyil SV, et al., 2019 study carried out at Kerala reported that among the recruited subject 39.6% were belongs to rural population and 23.4 % from urban population.[230] In the present study, as area of residence 38.8 % subjects of control group and 47.6% subject of intervention group belongs to slum. Whereas, 38 % subjects of control group and 34 % subject of intervention group belongs to urban, rural population were 23.30 % subjects of control group and 18.40% subject of intervention group. The comparison of mean was done between the group and found not to be significant (P=0.12). The present study indicates that majority of GDM subjects belongs to urban and slum area and correlate with the findings of Indian studies.

Study published by Rajput R, et al., 2013 had majority of subject presenting with GDM from the upper lower (39.2%), lower middle (37.7 %), upper lower (39.2%), upper middle (19.6%) and upper class (3.30%).[227] Report published by Kumari R, et al., 2018 showed majority of subject belongs to middle class (63.50 %) followed by lower (19.4%) and upper class 17.1%).[224] In the present study, majority of subjects belongs to upper lower from control group was 49.20 % and from intervention group 49.60 %. Whereas, upper middle-class subjects in control group was 40.00 % and in intervention group was 36.80 % subjects. Majority of subject were found to belongs to upper strata (upper middle and upper lower strata). This conforms to Indian studies on women presenting with GDM published by Rajput R et al., 2013 and Kumari R. et al., 2018.[224, 227]

Kumari R, et al. 2018 reported that only 22.4% women presenting with GDM had a family history of diabetes mellitus.[224] However, Ennazhiyil SV, et al., 2019 reported 57.65 % of subjects with GDM had a family history of diabetes mellitus. Among 57.65 % subjects of family history of diabetes, 19.8% women with GDM had a positive family history from their maternal side, 11.71% on their paternal side and 10.81% women had a family history of diabetes on the part of both parents.[230] According to Siddiqui S, et al., 2018 reported 52.17% subjects had family history of diabetes and it was a strong predictor of GDM.[222] Family history has been proven to be an independent predictor of GDM, as elucidated by Muche AA, et al., 2019.[231] In the present study, 34.80 % from control group and 32.80 % from intervention group reported a positive family history of diabetes mellitus. The result of current study was found to be in line with the reports published by Kumari R, et al., 2018 and Muche AA, et al., 2019.[224, 231]

Singh H, et al., 2019 reported psychoeducational intervention for GDM using a video telehealth platform and demonstrated significant improvement of GDM knowledge levels post-assessment significantly (P=0.009).[232] Sargees B, et al., 2019 reported 55.7% subjects of control group and 51.4% subjects of intervention groups demonstrated fair levels of knowledge prior to intervention and increase to 61.4% and 70%, respectively after intervention.[233] Elnour AA, et al., 2008 conducted a randomized controlled clinical trial of 165 GDM patients in the United Arab Emirates (UAE), reported significant (P<0.05) improvements in the intervention group knowledge of diabetes.[234] In the current study, prior to the intervention by the clinical pharmacist, majority of the study participants (control group and intervention group) pre-intervention demonstrated only an average (50.88% control and 63.04 % intervention groups) knowledge of GDM, followed by those demonstrating good

(23.89 % control and 16.5 % intervention groups) and poor (22.57 % control and 19.13% in intervention group) knowledge levels of GDM, few subjects (2.65 % control and 1.30 % in intervention groups) demonstrated excellent levels of knowledge of GDM. Post intervention subjects increase was observed in good (from 16.5 % to 25 %) and excellent knowledge (1.30 % to 7.60 %) and decline in subject number was observed in poor (19.13% to 13%) and average knowledge (63.04 % to 53.9 %) subjects. These findings are in consonance with the findings of similar studies carried out by Singh H et al., 2019, and Elnour AA, et al., 2008.[232, 234]

Toony LF, et al., 2018 reported that majority of the questions correctly answered in the post-intervention by more than 50% of the subjects pertained to the GDM definition (100%), allied risk factors (75%), management (71.7%), ways of diagnosis (83.3%) and consequences to the baby (78.3%). In the present study, improvement was observed in correct answer pertaining to knowledge about GDM (41.8% baseline to 51.95 % at post intervention), associated risk factor (40% baseline to 53.04% post intervention), knowledge about diet (34.53 % baseline to 44.92 % post intervention), knowledge about treatment and management (30.45 % baseline to 42.28 % post intervention), knowledge about complications (34.4 % baseline to 43.91 % post intervention), knowledge about consequences to baby (28 % baseline to 64.78 % post intervention). Study findings shows the improvement in knowledge which indirectly help for better outcome for maternal and fetal. The finding of the study correlate with the findings reported by Toony LF et al., 2018. [235]

The present study findings show that consistent decline in fasting blood sugar was observed in both the groups. Intervention group showed 108.5 ± 2.64 at base line, 86.3 ± 2.87after a month to baseline, 87.7 ± 3.6 just before delivery and 88.02 ± 3.41 after six weeks of delivery. Fasting blood glucose level was found to be significant

decrease after one month of base line (P≤0.000) and just before delivery (P≤0.001). The findings of this study indicate that intervention group showed the maximum decline in blood glucose level over the period of study in comparison of control group. Hussain Z, et. al., 2015 conducted a research at antenatal clinic of Hospital Pulau Pinang, Malaysia and reported that patient who have adequate knowledge of GDM have shown lowest blood glucose (5.17 ± 0.82 mmol/l) in comparison of inadequate knowledge of GDM (5.91±1.19 mmol/l), the observed difference was reported to be significant (P<0.01).[236] Mirfeizi M, et. Al., 2017 conducted a study on 149 subjects and reported significant (P<0.001) decrease in intervention groups (nutrition therapy with education and insulin therapy with education) at 1-hour (post-intervention) blood glucose in comparison of control groups (nutrition therapy without education and insulin therapy without education).[237] The result of present study correlates with the studies published on education intervention effect in GDM subjects.[236, 237] The results of the study show consistent decline in post prandial blood sugar in both the control and intervention groups. Intervention group showed 153.89 $\pm$ 5.6 at base line, 137 $\pm$ 6.1 after a month to baseline, 130.9 $\pm$ 2.8 just before delivery and 122.52 $\pm$ 5.8after six weeks of delivery. Post prandial blood glucose level was found to be significant decrease after one month of base line (P≤0.000), just before delivery (P≤0.000). The result of this study showed that maximum decline was observed in intervention group in comparison of control group. It proves that the intervention was found to be effective in control of blood glucose level among the subjects of intervention group. The decline in post HbA1c was observed in both the groups. Intervention group showed 6.13 $\pm$ 0.38 at base line and 5.12 $\pm$ 5.1 after six weeks of delivery. HbA1c was found to be significant decrease at just before delivery (P≤0.008). HbA1c result indicate that the intervention was found to be effective

among the study subjects. Mirfeizi M, et. Al., 2017 conducted a study on 149 subjects and compared the HbA1C results of intervention groups (nutrition therapy with education and insulin therapy with education) and control groups (nutrition therapy without education and insulin therapy without education), reported non-significant (P>0.376) changes in HbA1C between the control and intervention groups.[237] The reason of discrepancy in HbA1C post intervention with the studies published Mirfeizi M, et. Al., 2017 could be the duration of intervention and frequency of test done. In the present study HbA1C was done at base line and after six weeks of delivery, whereas Mirfeizi M, et al., 2017 done at base line and after two months of intervention. The findings of consistent decline in fasting, post prandial and HbA1c correlate with each other and confirm that the intervention was effective to maintain the blood glucose level.

The result of present study showed that the compliance with doctor's advice was 57.52 % subjects from control group and 79.13 % subjects from intervention group. Remaining subjects of both the group showed non-compliance of doctor's advice. Compliance to advice plays an important role in better outcome, this could be understood from the findings that the intervention group subject showed the more compliance to doctor advice as they were additionally educated by clinical pharmacist about the importance of maintaining blood glucose level, diet, and GDM consequences to mother and baby. The subjects of intervention group were in better situation to understand of the disease and its progress which resulted in maximum compliance to doctor's advice. The finding of this study is in consonance with several published studies in the field. Butt M, et al., 2017 in a clinical pharmacist-led intervention study amongst GDM patients, demonstrated significantly improved medication adherence in the intervention group (P=0.03) as against the corresponding

non-significant improvement in the control group (P>0.05). The study also revealed that there was a significant decline in the proportion of patients with poor treatment adherence levels from the baseline to the end of the study in the intervention group (P=0.02).[238] Gillani SW, et al., 2017 demonstrated a significant mean increase in medication adherence rates from baseline (83.21% to 89.50%) while the control group did not show any significant difference in medication adherence practices.[239] Moreover, according to this study, medication adherence rates were higher (83%) amongst patients <40 years of age. In the present study, non-compliance with the doctor's advice was attributed to several factors such as lack of knowledge, lack of time and lack of resources, in that decreasing order of succession. Some of the barriers to medication adherence include anxiety of the diagnosis of GDM, subjects dearth of knowledge for diabetes and its enduring effects on the mother and neonates, difficulty in self-monitoring of blood glucose levels because of the need for manifold blood samples, complexities associated with therapy and insulin administration, lack of financial resources and overall poor socio-economic status inadequate access to health care, for uninsured and low-income patients, poor quality of services at healthcare facilities, inadequacy of family, community and peers support, inability to understand patient education and communication materials in their native language coupled with the existence of several socio-cultural and religious beliefs and practices. On the contrary, factors such as psychosocial support from peers, community and family and adequate services at healthcare facilities were seen to be enablers, paving the way for better management of GDM. Moreover, join group sessions with family and perceive from GDM women; easy availability and access of diabetes dietician with personalized diet recommendation including traditional food items and minimum possible monetary burden; free distribution of blood glucose

monitoring apparatus, transport of women for follow-up; children care during clinic visit; and training for self-glucose monitoring by a clinical pharmacist furthered the path for greater compliance with medical advice, thereby, becoming enablers in achieving optimal glycaemic levels.

A randomised controlled trial by Kolu P, et al., 2012 reported that a established GDM diagnosis was linked with substantial total health care costs upsurge and that active lifestyle counselling by primary health care workers may offer to reduce high costs of secondary care.[240] Xu T, et al., 2017 demonstrated that while there was a pressing need for bringing down expenses pertaining to investigations and medications during GDM, there also exists a simultaneous need for economic GDM prevention treatments to diminish GDM morbidities, complications from GDM and the consequent economic burden that distresses society, families and persons.[241] Lenoir-Wijnkoop I, et al., 2015 reiterated the necessity for effective precautionary management tactics and public health interventions on life style, food habit and physical activity that could be customised to country-specific needs.[242] The present study result showed that intervention was found to be effective, it does not require much cost to implement.

It is important to understand the patient mind set, with whom they are more comfortable, feels easy to ask their doubt and accept the advices. In the present study majority of intervention group subjects (96.96% subjects) preference was to obtain advice from all three medical care person (Doctor, Pharmacist, Nurse). However, 0.87 % to only doctor's, 2.17 % to only pharmacist and 0% patient showed the preference to obtain advice only from nurse. A smaller number of subjects prefer to get advice from single source, majority subject showed for all three medical care persons. This

could be understood from the results that taking advice from all three medical care persons helps them to understood the disease, control of disease and its progression.

The selection of right and suitable tool to solve the problem is like solving the half of the problem before starting it actually. To understand the right tool for education, subject's opinion regarding thought to be effective were also assessed in this study and found that maximum (83.48% subjects) preference were given to all the available options (oral advice, Demo, Pamphlet, Video clipping, phone call, message) and a small number of subjects opt for single option i.e. oral advice 1.30%, Demo 0.87%, Pamphlet 0.43%, video clipping 6.09% and Phone call or message 7.83%. The finding of the study indicate that the information disseminated by multiple tools were more preferred instead single tool, this could be due to getting same information from multiple sources clarify the doubt without asking and even without thinking about it as this would be new to subjects.

In the present study, the rate of hospitalization was comparable in both control group and intervention group (97.35% vs 95.22%; P=0.323). Significantly higher number of women (79.13%) in intervention group with a single event of hospitalization compared to 44.25% in control group (P<0.001). The episodes of hospitalizations for glycaemic control was significantly high in control group (62.39%) compared to intervention group (20.87%) (P<0.001). Elimination the barriers to optimal glycaemic control, as suggested by Martis R, et al., 2016 enables GDM women achieve glycaemic levels, thereby, obviating the need for hospitalisation to manage glycaemic levels.[243] The finding of present study correlate with the report published by Martis R et al., 2016 and showed the minimization of hospital admission for glycaemic control.

New born outcome can be the effective measure tool for the assessment of effect of intervention. The result of the study indicates a small number of subjects (12%) of small gestational age were observed of intervention group, large gestational age (8%) subjects, majority of appropriate gestation age subjects (79.13%) of intervention group. Maximum positive outcome was observed in intervention group, which correlate with the APGAR score. Neonate outcome of study indicate that blood glucose of both the group was found to be with in the normal range at birth and after 24 hours. However, the maximum decrease in blood glucose was observed in the intervention group in comparison of control group. Result showed that the minimum NICU (Neonatal Intensive Care Unit) admission (6.96%), hyperbilirubinemia (11.30 %), respiratory distress syndrome (4.35 %), hypocalcaemia (3.48 %), hypoglycaemia (6.09 %), microsomia (7.83%) and 0% mortality was observed in intervention group in comparison of control group. The maximum increase in positive outcome and maximum decrease in neonatal health issue observed in intervention group, which indicate the positive effect of intervention. These results concur with several studies in the field, Al-Hashimi I, et al., 2007 in a literature review, reported that an educational intervention encompassing diet, modest exercise, self-monitoring of blood glucose and individual health edification resulted in healthier neonatal outcomes.[244] Toony EL, et al. 2018 also concluded that health edification plays an imperative role in increasing patients' awareness regarding the GDM risk and its appropriate management in order to reduce its hitches both for the mother and the neonates.[235] Crolan-Olah MA et. Al., 2019 and Sayakhot P in 2016 concluded that educational interventions that eventually lead to implementing a low glycemic index diet and increasing levels of activity succeed in tumbling maternal blood glucose levels and dipping insulin necessities in pregnancy. [245, 246 Crolan-Olah MA et. Al., 2019 and

Sayakhot P in 2016] Reducing maternal blood glucose levels is linked with a decrease of macrosomia and maternal weight improvement. Hieronymus L, et al., 2016 in the EMPOWR study, demonstrated the implementation of a culturally sensitive diabetes self-management education module as part of the pregnancy-centred experience resulted in greater patient satisfaction levels and acceptability.[247] Carter EB, et. Al., 2016 demonstrated that GDM subjects with high pre-natal visits have better glycaemic control in the 3 months prior to delivery and less prone to deliver preterm babies or babies requiring NICU admission.[248] The finding of present study correlate with the other studies published in the field and indicate that the educating patient help for better outcome of mother and neonatal.

During the study, several challenges were faced, especially in terms of lack of awareness of GDM, its etiopathophysiology, precautions and management paradigms. Oftentimes, patients exhibited their lack of awareness as regards the correct method for monitoring of blood glucose levels, administration of insulin, monitoring of weight, dietary and exercise recommendations, follow-ups with their healthcare providers and so on. Oftentimes, patients are not aware of the importance regular glucose monitoring, dietary management and treatment adherence. As a result, they tend to skip medications and not maintain glycaemic targets. The limited knowledge of patients on diet and disease management can lead to malnutrition for both the mother and the fetus together with impaired glycaemic control. Patients need to be educated on these aspects at every stage. It is important that patients rely on credible and authentic sources of information that are valid, reliable and comprehensive. To the GDM subjects with lifestyle and diet-managed, specific clinical guidelines or controlled trials for frequency of glucose monitoring not available. In routine practice monitoring of blood glucose usually done for 3-4 times in a day at least on 2 days of

the week, pharmacotherapy gets initiated on surpass the blood glucose limits twice in a week. Urine glucose monitoring does not serve to be a useful strategy in GDM patients. However, to notice inadequate caloric intake, monitoring of urine ketone is useful for the patient who are on diet management.

There is dearth of concrete and definitive data pertain to delivery mode and time of GDM women. Generally, when blood glucose of women is normal or near normal, delivery should be at term. Usually, GDM gravidities are not recommended to wait beyond the term. While cesarean section not reported to associate for substantial decrease in birth trauma or lower costs, early delivery was allied with decrease of macrosomia but other neonatal complications continued to exist.

Data indicate that 40-60% of GDM women tends to evolve type 2 DM in future and similarly predisposed to a jeopardy of recurrent GDM in imminent pregnancies. They should be regularly screened for type 2 DM start from post-delivery six weeks and yearly afterwards. In addition of that, an OGTT must be performed postpartum, 1 year post-delivery, and every 3 years afterwards. A review of the various interventions employed for the deterrence and control of GDM in China revealed that the constituent components of maximum interventions included all aspects of GDM management, such as dietary, exercise, medication, health education, psychological (abbreviated as DEMHP).[86]

Clinical pharmacists, as discussed earlier, could contribute effectively in the betterment of GDM women outcome, as elucidated by several studies. The American Association of Diabetes Educators (AADE) provides appropriate training to specialised Diabetes Educators who could carry out the role of diabetes education. Moreover, the AADE Gestational Diabetes Management (GDM) Practice Paper covers all aspects of the module, such as diagnoses, treatment and prevention of

GDM. In the Indian context, Mishra S, et al. 2018 mentioned that health education measures would help in achieving optimal health outcomes and also suggested and recommended the integration of guidelines and health education measures with the general public health/ primary healthcare services.[249]

Based on the findings of this study, it was understood that educating patients contribute directly in the betterment of patient regrading maintaining blood sugar, GDM consequences to maternal and fetus. The recommendation can be made from the present study findings includes the counselling for insulin therapy, physical exercise, healthy diet, monitoring of GDM, importance of follow-up. Patient need to understand the importance of constant, periodical monitoring of glucose level and taking insulin as prescribed by physician, in right dose, at right time, correct method of administration with hands on training. Counselling to make patient understand the role of regular exercise, time duration and frequency of exercise, precise nature of exercise according to the trimester of pregnancy. Practical demonstration of exercise with detailed information about precautions to be taken whilst performing exercise. Counselling for healthy diet and adequate intake of fluids with detailed information about right kind of food as per trimester, recommended dietary intake of various nutrients and importance of triumvirate of diet. Information should be given about poor dietary habits and its impact on subject and on the developing baby. The counselling sessions shed light on the parameters that would be monitored at each follow-up visit, the reasons for monitoring and the impact of the same on themselves and the developing baby. They were also given adequate information as regards the consequences of missing out on follow-up the consequences of the same. The study participants were need to advised to watch out for signs signaling issues related to mother or developing baby and report the same to treating physician.

Clinical pharmacists associated with diabetes clinics contribute as vital part in the management of GDM. Studies across the world have demonstrated that clinical pharmacists could help ameliorate the severity of GDM by advising the patients on the dietary, exercise and physical activity patterns to be followed during the course of GDM, the importance of regular monitoring of their blood glucose levels, the importance of adherence to prescribed medications as well as the pivotal role played by regular follow-ups with their treating physicians. There is dearth of studies from India on the role of clinical pharmacists in the management of GDM and its associated complications. It was hypothesized that counselling of women with GDM by a clinical pharmacist serves to enhance the management of GDM in such patients, prevents complications and eventually results in favourable outcomes in newborns. This study not only evaluates the role of clinical pharmacists and their efficacy in management of GDM but also undertakes an objective assessment of the impact of such intervention on neonatal outcomes in GDM women. The present study explores the role of pharmacists in optimizing adherence to therapy in GDM mothers, which, helps to reduce morbidity and mortality in neonates born to these mothers.

A total of 500 subjects who consented for the study were enrolled. Among the enrolled subject 91.2% participants completed the study while 8.8% participants were lost to follow-up. Out of 456 subjects, 226 subjects were in control group and 230 subjects were in intervention group. Control group received the routine medication and counseling by doctors and nurses, where as in intervention group additionally clinical pharmacist counseling was given. After collecting the demographic and socio-economic details of subjects, baseline parameters (blood glucose, glycosylated hemoglobin, blood pressure, BMI, knowledge assessment questioner) were recorded and counseling were started in both the groups. Blood glucose, glycosylated

hemoglobin was recorded with specific interval at 1 month after enrollment, before delivery and post 6 weeks of delivery. After completion of intervention, compliance to doctor's advice, reason for non-compliances, uses of treatment modality (medical nutrition therapy, oral hypoglycemic agents and insulin uses), maternal and neonatal outcome were recorded.

The subject distribution pattern of age, education, religion, place of residence and occupation was found similar in both the groups. Socio-economic status was assessed in accordance with the Modified B. G. Prasad's Classification. Majority of the study participants (49.40%) belonged to class III socio-economic strata, followed by Class II (38.4%) and eventually followed eventually by Class IV (12.2%).

At the first visit majority of the patients were on medical nutrition therapy followed by insulin and then oral anti-hyperglycaemic agents. On second visit majority of the patients were on medical nutrition therapy, followed by insulin and then oral anti-hyperglycaemic, a greater proportion of study participants were switched over from insulin to medical nutrition therapy between the first and second consultative visits. However, on delivery, majority of the patients were on medical nutrition therapy followed by oral anti-hyperglycaemic agents, insulin therapy was totally obliterated at delivery from the treatment regimen of study participants.

Prior to the intervention, majority of the study participants demonstrated average knowledge of GDM. Post-intervention, 3.54% women of control group had excellent knowledge about GDM compared to 7.6% women of intervention group and this mean difference was found significant (P=0.015). Substantial increase in excellent levels of knowledge (7.6%) about GDM accompanied by a substantial decrease in participants showing poor levels of knowledge (12%) for GDM.

Majority of the study participants in intervention group preferred seeking and obtaining advice from all three doctor, pharmacist and nurse (96.96%), followed by those seeking and obtaining advice only from the pharmacist (2.17%) and obtaining advice only from the doctor (0.87%). None of the patients preferred obtaining advice only from the nurse. Participants adhering to the prescribed meal plan, the rate of compliance was comparable in both the groups. Study subjects indulged in physical activity, majority of them preferred walking followed by yoga. The duration of physical activity in maximum study subjects was less than 15 minutes. This was followed by those engaged in physical activity of 15 to 30 minutes followed by those indulging in 30 to 45 minutes and 45 to 60 minutes of physical activity.

The decrease in fasting blood glucose and post-prandial glucose was observed in both the groups. Results shows that the maximum decrease was observed in intervention group. However, the observed decrease between baseline data and post intervention data was not found statistically significant between the groups. The decrease in HbA1c was also observed in both the groups, however the difference between the group was not significant. Control group 86.28% subjects and 98.26% participants of intervention group did not report any adverse drug reactions (ADRs). Among those who reported ADRs, hypoglycaemia was the most common ADR in both control group (4.42%) and intervention group (1.3%).

Number of subjects who had normal term delivery was more in both the groups, however the intervention group showed significantly more subjects with normal term delivery. Majority of neonates who had appropriate gestation age was found to be more (79.13%) in intervention group compared to (73.4%) control group. The average APGAR score of children's born to GDM mothers in intervention group was 9 and in control group was 8, which was less compare to intervention group.

Neonatal outcome indicates that the maximum number of healthy neonates were found 56.51% in intervention group compare to 22.57% in control group, the difference was found statistically significant. The maximum number of NICU admission was observed 77.43% in control group in comparison 43.49% of intervention group. The minimum number of caesarean and macrosomia, neonatal hypoglycaemia was observed in intervention group compare to control group. Base on the findings of the study it can be concluded that the given intervention was found to be effective as evidenced by maternal and neonatal outcome.

The present study was planned to evaluate the effect of clinical pharmacist education to GDM women as intervention in addition to routine medication and advices of doctors and nurses. The intervention (patient education with counselling and demonstration of physical exercises permissible as well as support with well-structured meal plans) was given by clinical pharmacist and patients were monitored with specific interval for blood parameters, compliance to medication, and their adherence to their prescribed meal plans and exercise regimens. Based on the findings of the study it can be conclude that the intervention paved the way for greater restoration of glycaemic levels in women with GDM.

Based on the findings of compliance to doctors and nurse's advice, it can be concluded that the intervention played a significant role in increasing the knowledge pertain to GDM and its consequences, which resulted in better outcome (decline in uses of oral hypoglycaemic agents and insulin by GDM subjects, increase in healthy neonate outcome). The study also revealed that the levels of patient's satisfaction were higher, with a large number of patients seeking advice from all three (doctor, nurse and clinical pharmacist) rather than from either of them alone.

Medical nutrition therapy results indicate the consistently increase in number of subjects from baseline to 1 month after baseline and six weeks of delivery. The significant decline observed in intermittent and chronic insulin user of intervention group, based on that it can be conclude that the addition of pharmacist for counselling and education of subjects was effective and found improving maternal outcome.

Based on the findings of delivery outcome, it can be concluded that the intervention improved the delivery outcome as term delivery and appropriate gestational age, maximum APGAR. The maximum healthy neonates were from intervention group in comparison of control group, based on the findings it can be

conclude that given intervention was effective to improve the maternal and neonate's outcome. Based on the findings of this study, it can be concluded that the intervention was more effective in comparison of control group, therefore we can reject the null hypothesis.

The role of the clinical pharmacist should essentially involve for patient counselling, health education (both, in general and GDM specific), sensitisation regarding timely and methodical monitoring of glycaemic levels, medication adherence, prompt follow-ups, permissible and acceptable dietary and physical activity patterns, adherence and sensitisation regarding the benefits of following a structured plan until delivery. The educational intervention should also include the ill-effects of not following structured plan, including the propensity of development of adverse maternal and perinatal outcomes.

This study strongly recommends mandating the involvement of a clinical pharmacist in the regular counselling process as part of the management of patients with GDM. This strong advocacy for the presence of a clinical pharmacist is aimed at better outcomes for GDM women- both maternal and neonatal. The role of the clinical pharmacist would be that of supplementing the treating physician in the provision of optimal care to the patient in order to elicit better outcomes. Moreover, present study findings strongly advocate replication of the study as part of a multi-centric randomized controlled trial in order to test the validity of the study findings.

8.1 FUTURE SCOPE OF THE STUDY

1. The similar kind of studies need to be carried in future with a large sample size
2. Multicentre study needs to be carried out to confirm the outcome
3. In future studies addition of some more parameters (ECG, Liver function test, Kidney function test, lipid profile, TSH) would give in-site of the response.
4. In future studies home-visit by clinical pharmacist can be planned to reduce the drop-outs

8.2 LIMITATIONS OF THE STUDY

The study was conducted in a tertiary care hospital .GDM being prevalent in all socio economic strata, control and prenatal outcome could be variable in different health care settings such as primary health care center, Hence the results of the study cannot be generalised for GDM mothers seeking care in different health settings. We recommend a multicentre center involving different health care settings with large numbers to study the outcome of GDM mothers.

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Annexure – I

ETHICAL CLEARANCE LETTER

KLE UNIVERSITY
(Formerly known as KLE Academy of Higher Education & Research, Belagavi)
[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No F.9-19/2000-U.3(A)]
'Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (GoI)
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To,
Ms. Vineeta Dhyani
College of Pharmacy, Belagavi
Ph.D.Scholar 2014-15

Dear Research Scholar,

Sub:- Regarding Ethical Clearance.

The KLE University **Ethics Committee on Human Subjects** for Ph. D Research Project met on **23rd March 2015** to consider your application for approval of the research project **"Pharmacists as Educators in optimizing identification and management of gestational diabetes mellitus and its outcomes in newborns – An interventional study".**

As there are no ethical issues involved in your proposed research project, the committee has provided approval for this research project.

You are requested to report to Ethical Committee in case of the following:

1. Any deviation from or change of the protocol.
2. All serious adverse events.
3. Any changes in study documents.

(Dr. Anita Dalal)
Member Secretary,
Ph.D. Ethical Committee(Human),
K.L.E. University,
Belagavi.

DIRECTOR ACADEMIC AFFAIRS KLE UNIVERSITY

(Dr. Anil Hogade)
Chairman
Ph.D. Ethical Committee(Human),
K.L.E. University,
Belagavi.

CC to: - The Director Academic Affairs, KLE University, Belagavi.
- The Director Research Foundation, KLE University, Belagavi.
- The Registrar, KLE University, Belagavi

Annexure – II

APPROVAL OF GUIDESHIP

KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research, Belagavi)
[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9-19/2000-U.3(A)]
'Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (GoI)
Office of the Director of Academic Affairs,
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444/2493779 FAX: 0831-2493777 Web: http://www.kleuniversity.edu.in E-mail: diracademic@kleuniversity.edu.in

Ref. No. KLEU/AA/14-15/D- 485

6th January 2015

ORDER

Sub: Approval of change in guideship

With reference to the above, I wish to inform that your request for change in guideship is accepted by the competent authority of the KLE University. Your guide will be Dr. (Mrs) N. S. Mahantshetti, Principal, J N Medical College, Belgavi and Co-Guide will be Dr. A. D. Taranalli, Dean, Faculty of pharmacy.

The other terms and conditions including research topic, submission of thesis / dissertation, etc. approved by the KLE University for the Ph.D. Program shall remain unaltered.

(Dr. S. G. Karadesai)
Director, Academic Affairs

To,
Ms Vineeta Dhyani
Ph. D Scholar - Batch 2014-15,
KLE University, Belagavi.

CC to:

1) Dr. (Mrs) N. S. Mahantshetti, Principal, J N Medical College, Belgavi.
2) Dr. A. D. Taranalli, Dean, Faculty of pharmacy, College of Pharmacy, Belgavi.
3) Special Officer to Hon. Vice-Chancellor, KLE University, Belgavi
4) The Controller of Examination, KLE University, Belgavi.

Annexure – III

CO-GUIDE ALLOTMENT LETTER

KLE UNIVERSITY

KLE UNIVERSITY EMPOWERING PROFESSIONALS

(Formerly known as KLE Academy of Higher Education & Research, Belgaum)
[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9-19/2000-U.3(A)]
'Accredited **'A' Grade** by NAAC Placed in Category 'A' by MHRD(GoI)

Office of the Director of Academic Affairs.
JNMC Campus, Nehru Nagar, Belgaum-590 010, Karnataka State, India
☎: 0831-2444444/2493779 **FAX:** 0831-2493777 **Web:** http://www.kleuniversity.edu.in **E-mail:** diracademic@kleuniversity.edu.in

Ref. No. KLEU/AA/15-16/D- 181 14th August 2015

To,

Dr. M.S. Ganachari,
Prof. & Head
Dept. of Pharmacy Practice,
College of Pharmacy,
Belagavi.

Sub: Co-guide allotment for the Ph.D. Research Scholars.
Ref.: UGC Letter No. D.O.No.. F. 10-6/2011(PS) Misc. dated 6th July 2015.

Sir,

With reference to the subject, you have been nominated as co-guide for the following student mentioned below.

Sl. No.	Name of the candidate	FT/PT	Name of the Institution
1	Miss Veenita Dhyani 2014-15 batch	FT	College of Pharmacy, Belagavi

The candidate has to follow all the terms and conditions mentioned in the Rules and Regulations for the degree of Doctor of Philosophy (Ph.D.) in health Sciences & Interdisciplinary area of the University.

Thanking you,

Yours faithfully,

Dr. S. G. Karadesai
Director, Academic Affairs

DIRECTOR ACADEMIC AFFAIRS

CC to:
1) The Registrar, KLE University, Belagavi
2) Dr. N.S. Mahantshetti , Professor of Paediatrics, JNMC, Belagavi– Guide
3) The Principal, College of Pharmacy, Belagavi
4) The Controller of Examinations, KLE University, Belgaum
5) Dr. A. D. Taranalli- Former Co-Guide
6) Above Research Scholar

Annexure – IV

PERMISSION LETTER

KLE UNIVERSITY'S

COLLEGE OF PHARMACY,

JNMC CAMPUS, NEHRU NAGAR, BELGAUM-590 010. KARNATAKA, INDIA.
(Recognised by PCI, AICTE & Accredited by NBA & 'A' Grade by NAAC)
A Constituent Unit of KLE Academy of Higher Education and Research
[Under section 3 UGC Act, 1956 vide Govt. of India Notification No. F.9-19/2000-U.3 (A)]
ಕೆಎಲ್ಇ ವಿಶ್ವವಿದ್ಯಾಲಯದ ಔಷಧೀಯ ಮಹಾವಿದ್ಯಾಲಯ, ಬೆಳಗಾವಿ-೫೯೦ ೦೧೦.

Ref. No. KLEUCOP : 223/2015-16 *Date :* 20/06/2015

To,
The principal
KLE's Dr Prabhakar Kore Hospital and MRC,
Belagavi -590010

Sub- Permission conduct Ph.D Research work in clinical department

Respected sir,

With reference to above mentioned study, I would like to take your permission for conduct of Ph.D Research work. I have already taken ethics committee approval.

S. No	Name	Title of the project:	Registration no-
01.	Vineeta Dhyani	"Pharmacists as Educators in optimizing Identification and Management of Gestational Diabetes Mellitus and its outcomes in newborns –An interventional study"	DO1214021

Kindly consider the same

Thanking you

KLE University College of Pharmacy Belagavi 590010

Enclosure –
Ethics Committee Approval

Prof. (DR.) V.P RASAL
(Principal)

PRINCIPAL
J. N. Medical College
K.L.E. Dr. P. K. C. Hospital, Belgaum
20/06/15

Page 1 of 1

PHONE : 0831-2471399 Fax No: 2472387 Web:http://www.klepharm.edu E-mail : principal@klepharm.edu

Annexure – V

PERMISSION LETTER

KLES
DR. PRABHAKAR KORE HOSPITAL
&
MEDICAL RESEARCH CENTRE
NEHRUNAGAR, BELAGAVI-590010.
KARNATAKA - INDIA

ಕೆ.ಎಲ್.ಇ. ಸಂಸ್ಥೆಯ
ಡಾ. ಪ್ರಭಾಕರ ಕೋರೆ ಆಸ್ಪತ್ರೆ ಮತ್ತು
ವೈದ್ಯಕೀಯ ಸಂಶೋಧನಾ ಕೇಂದ್ರ
ನೆಹರು ನಗರ, ಬೆಳಗಾವಿ - 590 010, ಕರ್ನಾಟಕ

Phone : 0831 - 2473777 (16 Lines)
Fax : 0831 - 2470732
E-mail : medicaldirector@klehospital.org
Website : http://www.klehospital.org

Through
Prof (Dr) N.S Mahantashetti,
Professor
Department of Pediatrics
KLE`s Dr Prabhakar Kore Hospital and MRC,
Belagavi -590010

Date-19-jun-2015

To,
Prof (Dr) M.K.Swamy
Professor Head,
Department of Gynecology,
KLE's Dr Prabhakar Kore Hospital and MRC,
Belgaum.

Sub: Permission to conduct dissertation work in Department of Gynecology

Sir,

I VINEETA DHYANI, Student of PhD have planned my dissertation work in Department of Gynecology. With respect to the above mentioned subject.I would like to take your permission for conducting dissertation work from June2015 to Nov 2016 in Department of Gynecology. Ethical approval has already been obtained from ethical committee. A detail of the project is provided below.

Title of the project: "Pharmacists as Educators in optimizing Identification and Management of Gestational Diabetes Mellitus and its outcomes in newborns –An interventional study"

Duration of the study: June2015 to Nov 2016

Kindly permit for the same and do the needful.
Thanking you.

Yours sincerely,

Dr. M K SWAMY
Prof & Head OBG
KMC Reg No. 13453

Prof (Dr) N.S Mahantashetti
Department of Pediatrics
Professor
KLE's Dr Prabhakar Kore Hospital and MRC,

Vineeta Dhyani
PhD Research scholar
(Pharmacy Practice)

Annexure-VI

PLAGIARISM REPORT

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 FAX: 0831-2493777 Web: http://www.kledeemeduniversity.edu.in E-mail: info@kledeemeduniversity.edu.in

Ref. No. KAHER/AA/20-21/D- 030221001

2nd February 2021

Madam,

The soft copy of Ph.D. research thesis of **Ms. Vineeta Dhyani, Faculty of Pharmacy** of KAHER, Belagavi has been submitted for anti-plagiarism check at the office of the undersigned through "Turn-it-in" package. The scan has been carried out and the scanned output reveals a match percentage of **8%** which is within the acceptable limit of 10%.

To obtain the comprehensive report of the plagiarism test, research scholar can send a mail to **diracademic@kledeemeduniversity.edu.in** along with the Registration Number, Name of the Scholar, Name of Guide/Co-guide and title of the thesis.

Dr.(Mrs.) Roopa M. Bellad
Director, Academic Affairs

To,

Ms. Vineeta Dhyani
Full-Time Ph.D. Scholar, 2015-16 Batch
Faculty of Pharmacy,
College of Pharmacy, KAHER
Belagavi.

DIRECTOR * Deemed-to-be University * ACADEMIC AFFAIRS

Cc to :

1. The Principal, College of Pharmacy, Belagavi.
2. Dr. N. S. Mahantshetti, Principal & Prof. of Pediatrics, JNMC, Belagavi – **Guide**
3. Dr. M.S. Ganachari, Dean, Faculty of Pharmacy & Prof. College of Pharmacy, Belagavi-**Co-guide**

Annexure VII

PUBLICATIONS

Dhyani et al., IJPSR, 2018; Vol. 9(11): 4968-4973. E-ISSN: 0975-8232; P-ISSN: 2320-5148

IJPSR (2018), Volume 9, Issue 11 (Research Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

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PERFORMANCE IMPLICATIONS OF CLINICAL PHARMACIST INFORMATION ON GESTATIONAL DIABETES MELLITUS AT A TEACHING HOSPITAL IN SOUTHERN INDIA

Vineeta Dhyani [1], N. S. Mahantashetti [2], M. S. Ganachari [1] and Sanjay Kumbar [3]

Department of Pharmacy Practice [1], KLE Academy of Higher Education & Research, Belagavi - 590010, Karnataka, India.
Department of Paediatrics [2], Department of Community Medicine [3], Jawaharlal Nehru Medical College, KLE Academy of Higher Education & Research, Belagavi - 590010, Karnataka, India.

Keywords:

Gestational diabetes mellitus, Body mass index, Glycemic control, Pharmaceutical care, Self-monitoring, Patient counselling

Correspondence to Author:
Vineeta Dhyani

Research Scholar,
Department of Pharmacy Practice,
KLE University College of Pharmacy,
Nehru Nagar, Belagavi - 590010,
Karnataka, India.

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ABSTRACT: Context: Gestational diabetes mellitus (GDM) early diagnosis of disease can reduce the morbidity and mortality by prevention of maternal and fetal complications. **Aims:** To assess the impact of clinical pharmacist knowledge on GDM mothers. Setting Tertiary care teaching hospital of North Karnataka, India. **Methods and Materials:** A randomized controlled cross-sectional study was carried out for a period of 4 years. Pregnant women with GDM were divided into control (C) and interventional (I) groups. Group C patients received only physicians' counselling whereas, group I patients received both clinical pharmacist counselling and physicians' counselling. Both the groups were screened for blood glucose levels at baseline and follow-up. **Results:** A total of 500 (group C, n=250 and group I, n=250) mothers diagnosed to have GDM participated in the study and randomized into two groups. Initially the knowledge of GDM among pregnant women was poor. After the clinical pharmacist counselling, knowledge was enhanced, which prompts better education and use of new methods such as phemplets, audio visual methods and flipcharts. **Conclusions:** The results of this study showed noteworthy changes in knowledge after clinical pharmacist structured counselling.

INTRODUCTION: Gestational diabetes mellitus (GDM) is one of the major health issues and the most common metabolic disorders in pregnant women characterized by glucose intolerance of varying degree with onset or first recognition during pregnancy [1, 2]. In India, the prevalence of GDM varies widely, depending on the population studied and the diagnostic test employed, may range from approximately 4% to 40% of all pregnancies [3]. Moreover, Indian women are 11 times more vulnerable to GDM, compared to Caucasians [4].

QUICK RESPONSE CODE

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DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.9(11).4968-73

GDM is a serious heal issue which need to be addressed urgently, it is estimated that about 4 million women are affected by GDM in India [3].

Based on the recent reports from South India, GDM complicates 17.8% of the pregnancies in urban areas, 13.8% in semi-urban areas, and 9.9% in rural areas based on 2 h 75 g post glucose value ≥ 140 mg/dL [5, 6]. Modern lifestyle which include increasing urbanization, decreasing levels of physical activity, changes in dietary patterns, advanced maternal age and obesity are some of the factors which influence the risk of GDM in Indian women [5, 7]. Moreover, ancestral disparities and a family history of diabetes also intensify the GDM risk which attribute to adverse perinatal outcomes, including increased risk of cardiovascular diseases, early childhood obesity, increased rates of pre-eclampsia, caesarean and even stillbirths [5, 8].

Dhyani et al., IJPSR, 2018; Vol. 9(11): 4968-4973. E-ISSN: 0975-8232; P-ISSN: 2320-5148

Infants born to mothers with GDM are at an increased risk of macrosomia, hypoglycemia, jaundice, respiratory distress syndrome, polycythemia, and hypocalcemia [7, 9].

Data suggests that medications alone are not enough to manage GDM, educational strategies need to be implemented. In the United States, the national Diabetes Prevention Program has shown the positive impact of educational interventions to prevent progression of GDM to type 2 diabetes [10]. Early counselling of families has been recommended by the Fifth International Workshop Conference on GDM [11] to avoid excessive maternal and fetal weight gain. Educational programs have been recommended that emphasize reduced fat and energy intake, regular physical activity and regular clinic visits. However, in India, despite higher frequency of GDM, studies regarding patients' awareness are seldom investigated.

We hypothesized that, counselling of the pregnant women by the clinical pharmacist along with a physician, may enhance the knowledge in pregnant women which may result in adoption of a healthy lifestyle, better healthcare-seeking pattern, better self-care. Thus, prevention and early diagnosis of the disease may help to reduce the morbidity and mortality by prevention of complications among the mothers and new-born.

SUBJECTS AND METHODS:

Study Design: This cross-sectional study was conducted for a period of 4 years (October 2014 to March 2017) at a tertiary care teaching hospital of north Karnataka, India **Fig. 1**. Pregnant women were divided into group C (control group, patients received counselling by physicians only) and group I (interventional group, patients received counselling by clinical pharmacists along with physicians).

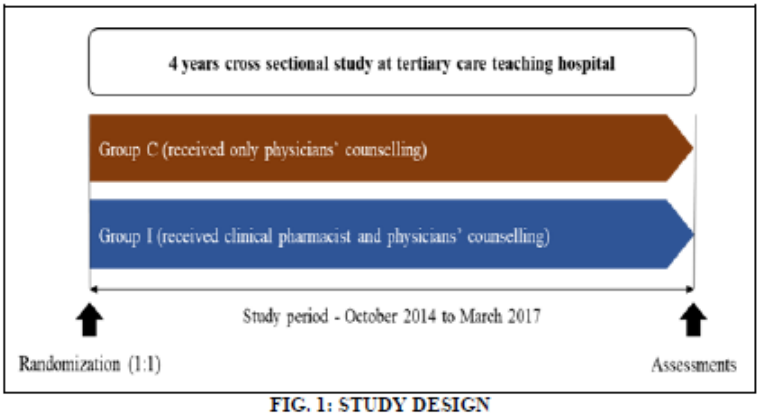

FIG. 1: STUDY DESIGN

Patients: Registered pregnant women with ≥ 24 weeks of gestation diagnosed to have GDM residing within 5 km of study area aged more than 18 years who were willing to participate in the study were recruited. Pregnant women with endocrinal complications, renal complications, pregnancy complications, prior type 2 diabetes mellitus, multiple gestations and having significant difficulties to cooperate were excluded from the study.

Sample Size Calculation: Considering the prevalence of GDM as 20%, standard error as 10%, the minimum effect sample size was calculated as 250 women presenting with GDM in each group.

Assessments: Those who were eligible along with their family members were briefed about the nature of the study, the intervention and the procedure involved in the study. The knowledge about GDM was assessed using the questionnaire which comprised of 18 questions and emphasized on dietary habits, exercise program, random blood sugar level monitoring, treatment, insulin intake, medications, adverse drug reactions, complication in mother as well as fetus and birth outcomes. The interpretation of knowledge was done based on the scores obtained *i.e.*, those who answered correctly were interpreted as having adequate knowledge and were graded with score of one for each question.

Dhyani et al., IJPSR, 2018; Vol. 9(11): 4968-4973. E-ISSN: 0975-8232; P-ISSN: 2320-5148

The sum of total points was calculated and these total scores were converted in terms of percentage and the grading was done as having excellent knowledge if the percentage was ≥ 75, good knowledge if the percentage was 51 to 75, average knowledge if the percentage was 26 to 50, and poor knowledge if the percentage was ≤ 25.

Study Procedure: Subjects were randomized by SNOOZE method, where patients were provided with sealed opaque envelopes and asked to choose the envelope. After incorporation of baseline data intervention patients were counselled in local languages. Demographic data such as age, religion, education, occupation, place of residence (civilization), socioeconomic status, history of diabetes mellitus, family history, current treatment, past medical history, personal history and dietary habits were collected. Clinical pharmacists provided structured counselling on the management of GDM; socioeconomic factors in the management of GDM; importance of monitoring blood glucose levels; insulin administration by using various educational strategies such as (1) pamphlets, (2) flipcharts and (3) demonstration; importance of physical exercise; adherence to the management of GDM and importance of regular follow up. Pregnant women with GDM in control group only underwent routine counselling by physician or nurse.

Ethics Approval: Prior to the commencement, the study was approved by Institutional Ethics Committee and pregnant women with GDM based on the criteria set by Diabetes in Pregnancy Study group India (DIPSI) were screened for eligibility. The study was registered under Clinical Trials Registry India Number- CTRI/2017/01/007622. Permission to conduct this study was obtained from KLE University's Institutional Ethics Committee Belagavi, Karnataka, India.

Statistical Analysis: The categorical data was expressed in terms of rates, ratios and percentages. The comparison between groups for demographic characteristics was done using Fishers exact test or chi-square test. Continuous data was expressed as mean ± standard deviation and the comparison was done using independent sample t-test. A probability (p value) of ≤ 0.05 at 95% confidence interval was considered as statistically significant. The data was analyzed using SPSS statistical software version 20.0.

RESULTS:

Descriptive Analysis: A total of 500 women provided written consent to participate in the study and these women were randomized into group C (n=250) and group I (n=250). The overall age of the women ranged between 22 years to 44 years with mean age of 28 years. About 38% of women in group C and 59% of women in group I were aged between 26 years to 30 years **Table 1**. The BMI in 67.60% of the women who belonged to group C was between 19.8 kg/m^2 to 26.0 kg/m^2 compared with 66.40% of the women in group I **Table 2**. Most of the patients (52.4%) had primary education in group C compared with 62% in group I **Table 3**. When distributed based on religion, most of the patients belonged to Hindu in both group C (50.80%) and group I (58.8%; **Fig. 2**) and majority of them were working (group C, 59.6% and group I, 55.6%; **Fig. 3**) and resided in slum area (group C, 38.8% in group C and group I, 47.60%; **Table 4**).

TABLE 1: DISTRIBUTION OF STUDY POPULATION ACCORDING TO AGE DISTRIBUTION

Age group (years)	Group C	Group I
Total number of patients*	250	250
Mean ± SD#	27.73 ± 2.57	27.31 ± 2.24
20 to 25	50 (20.0%)	55 (22.0%)
26 to 30	168 (67.2%)	170 (68.0%)
31 to 35	29 (11.6%)	25 (10.0%)
36 to 40	2 (0.8%)	0
> 40	1 (0.4%)	0

*p=0.526; #p=0.052; Group C, control group; Group I, interventional group

TABLE 2: DISTRIBUTION OF STUDY POPULATION ACCORDING TO BODY MASS INDEX

Body mass index, kg/m^2	Group C	Group I
Total number of patients*	250	250
< 19.8	4 (1.6%)	1 (0.4%)
19.8 to 26.0	169 (67.6%)	166 (66.4%)
> 26.0	77 (30.8%)	83 (33.2%)

*p=0.391; Group C, control group; Group I, interventional group

TABLE 3: DISTRIBUTION OF STUDY POPULATION ACCORDING TO EDUCATION

Education	Group C	Group I
Total number of patients*	250	250
Collegiate	17 (6.8%)	18 (7.2%)
Illiterate	45 (18.0%)	41 (16.4%)
Postgraduation	16 (6.4%)	15 (6.0%)
Primary	131 (52.4%)	155 (62.0%)
Secondary School Leaving Certificate	41 (16.4%)	21 (8.4%)

*p=0.069; Group C, control group; Group I, interventional group

Dhyani et al., IJPSR, 2018; Vol. 9(11): 4968-4973. E-ISSN: 0975-8232; P-ISSN: 2320-5148

TABLE 4: DISTRIBUTION OF STUDY POPULATION BASED ON PLACE OF RESIDENCE

Place residence	Group C	Group I
Total number of patients	250	250
Rural	58 (23.2%)	46 (18.4%)
Slum	97 (38.8%)	119 (47.6%)
Urban	95 (38.0%)	85 (34.0%)

Group C, control group; Group I, interventional group

Pre- and Post- Intervention Knowledge Assessment: Prior to the intervention that is counselling by research scholar in group C, most of the pregnant women had average knowledge about GDM in 52.8% and 62.4% of patients in group C and group I, respectively **Fig. 4**.

Knowledge about GDM were notably improved post intervention in group I with 33.2% showed good knowledge and 7.6% had excellent knowledge compared with 24.4% and 3.2% of the women in group C respectively **Table 5**.

TABLE 5: CHANGE IN KNOWLEDGE POST INTERVENTION

Knowledge	Group C	Group I
Total number of patients*	250	250
Excellent	8 (3.2%)	19 (7.6%)
Good	61 (24.4%)	83 (33.2%)
Average	130 (52.0%)	118 (47.2)
Poor	51 (20.4%)	30 (12.0%)

*p=0.003; Group C, control group; Group I, interventional group

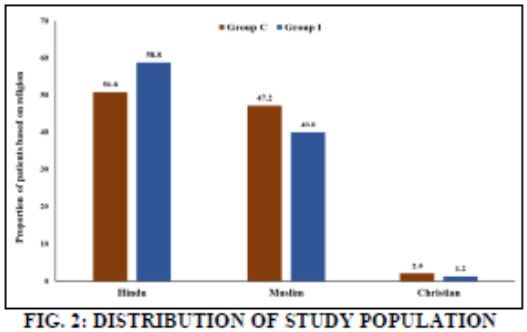

FIG. 2: DISTRIBUTION OF STUDY POPULATION ACCORDING TO RELIGION. Group C, control group; Group I, interventional group

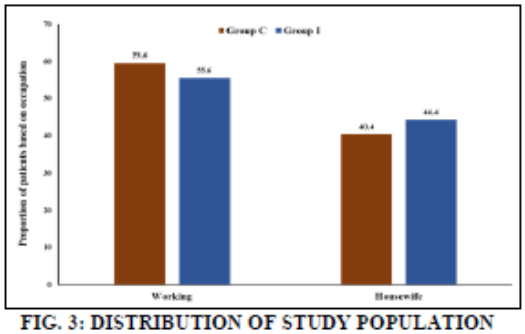

FIG. 3: DISTRIBUTION OF STUDY POPULATION ACCORDING TO OCCUPATION. Group C, control group; Group I, interventional group

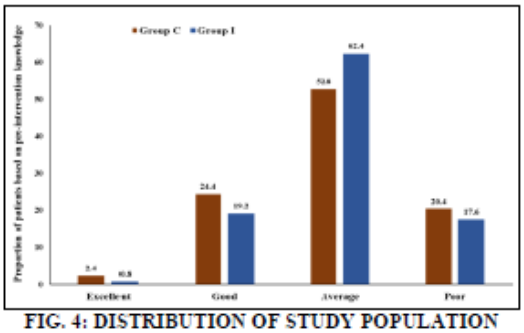

FIG. 4: DISTRIBUTION OF STUDY POPULATION ACCORDING TO PRE-INTERVENTION KNOWLEDGE. Group C, control group; Group I, interventional group

DISCUSSION: This cross-sectional study was designed to measure the impact of clinical pharmacist counselling in GDM women. Our results showed greater enhancement of knowledge about GDM in pregnant women who belonged to interventional group. Our results suggest that women need to be targeted for better education in order to reduce the risk of GDM.

Increase rate of GDM in Indian women is certainly a major concern, given the adverse events associated with it. However, despite the availability of guidelines for screening and management in the general population, management of GDM is still challenging [12, 13]. The challenges include, lack of consensus among the physicians regarding the timing of oral glucose tolerance test after delivery,

Dhyani et al., IJPSR, 2018; Vol. 9(11): 4968-4973. E-ISSN: 0975-8232; P-ISSN: 2320-5148

ineffective communication among physicians, patients, and primary care providers [12]. Due to these challenges, GDM patients fail to control their glucose levels through lifestyle modifications and end up in using insulin [14].

Previous reports suggest that interventions such as self-management are effective in improving glycaemic control, lowering health-care costs, and improving the quality of life in patients with GDM [15, 16]. However, self-management of GDM are associated with certain unavoidable challenges, such as, lack of information in communities and sometimes cultural perspectives are barriers to GDM care. Hence, many women remain sedentary during pregnancy because of these perceived barriers. This condition requires a certain level of expertise, knowledge, and experience to manage [17, 18]. Increase in patient compliance and proper educational interventions may promote better pregnancy outcomes [12, 13] which is affordable and easily accessible at the primary, secondary, and tertiary levels of health care in India [2]. Existing studies showed knowledge gaps, and inefficient approach to GDM management, which eventually contribute to suboptimal patient outcomes [10, 13]. Moreover, performance implication of clinical pharmacists for the management of GDM are seldom investigated.

It is well accepted that processes of care influence the diabetes outcomes and many processes are considered indicators of quality of diabetes care [12]. Thus, achieving optimal processes of care is postulated to be a key element in the care of patients with diabetes [15], for example, a model has been proposed by Brown *et al*., [17] to explain this association between socioeconomic status and health outcomes in patients with diabetes. It suggests that health outcomes (which show the effects of care on the health status of patients) [18] are influenced by distal factors, such as individual (*i.e.,* cultural background) or community characteristics, as well as by more proximal factors such as health behaviours, access to health care, and processes of care (*i.e.*, what is done to care for a patient) [19, 20].

The pharmacists are trained to provide patient care and possess knowledge of pharmacotherapy and experience in medication management. The collaboration between pharmacists and women health providers are essential when managing high-risk patients. This collaboration allows patients the option to remain in their original medical home. Clinical pharmacists may provide services that are culturally and linguistically appropriate throughout each stage of pregnancy and follow-up [21, 22]. Hence, clinical pharmacists' intervention may contribute to the better management of GDM though. The WINGS study demonstrated that a collaborative approach between pharmacists, physicians and patients may yield better management of GDM [2]. The relationship established between the providers, pharmacist, and patients aligns well with the patient-centered medical home model. A recent study in the pregnant women from Jordan, also demonstrated that clinical pharmacist assisted services in the management of pregnancy hyperglycemia, fundamentally and significantly improve the knowledge and control the disease [23].

Counselling helps achieving the personalized therapeutic goal of each individual patient. Evidences suggest that integrated pharmaceutical care by clinical pharmacist results in reduction of glycemic control of diabetic patients. Hence, in a developing country like India, where there is an increase in the number of diabetic populations observed in recent years. Like every cross-sectional study, this study was not different and has some limitations, first being the number of populations studied and data collections.

Further, this study was carried out in a specific region, hence generalizability of results may be an issue. Nevertheless, it was a pretty long duration study, hence the results can play a role of precursor for focused sequential studies to find out more regarding the importance of clinical pharmacists in the management of GDM in India. Further, it was evident that even short pharmaceutical care programs provide important information related to patient counselling, disease characteristics, drugs and lifestyle modifications *etc*., hence, the findings of our study, may have substantial impact.

CONCLUSION: Overall the present study highlights poor knowledge about GDM among the pregnant women in study area and intervention in the form of counselling by the pharmacist enhances the knowledge. This prompt need for the education through counselling on GDM to the pregnant

women, which may help to create awareness about this condition through the healthcare providers and pharmacists.

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AUTHORS' CONTRIBUTIONS: NSM designed this study, VD, MSG, SK, and interpreted the data, performed data analysis, and wrote the manuscript. All Authors state that they had complete access to the study data that supports the publication.

CONFLICT OF INTEREST: The author(s) declare(s) that they have no conflicts of interest to disclose.

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Original Article

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Awareness of gestational diabetes mellitus among pregnant women attending a tertiary health center

Vineeta Dhyani, Niranjana S. Mahantashetti[1], M. S. Ganachari, Sanjay Kambar[2], Vikrant Ghatnatti[3]

Abstract:

BACKGROUND AND OBJECTIVES: Awareness of gestational diabetes mellitus (GDM) among pregnant women is poor. However, increasing awareness may help in diagnosis and prevention of maternal and fetal complications. Hence, this study was aimed at evaluating the knowledge in diagnosed GDM pregnant women.

METHODOLOGY: This cross-sectional study was conducted from October 2014 to March 2017. A total of 500 registered pregnant women diagnosed to have GDM residing within 5 km of the study area aged more than 18 years who were willing to participate in the study were enrolled in the study. The participants were provided with the questionnaire which was designed to assess their knowledge about GDM.

RESULTS: The age of the women ranged from 22 to 44 years with mean age as 27.53 ± 2.42 years and median age as 27 years. The most common age group was 26–30 years which comprised 67.6% of the women. Maximum women had primary education (61%) and were Hindus (54.8%). Most of the women were working (54.8%), resided in slum areas (43.2%), and had body mass index (BMI) between 19.8 and 26 kg/m^2 (67%). The mean BMI level was 28.07 ± 4.11 kg/m^2. The mean blood sugar levels at diagnosis ranged between 88 and 300 mg/dL and the mean blood sugar level was 201.36 ± 38.67 mg/dL and the median blood sugar level was 190 mg/dL. Majority of the women, that is, 57.6% of the women, had an average knowledge about GDM while 21.8% of the women had good knowledge, 1.6% had excellent, and 19% had poor knowledge. The mean knowledge score was 6.51 ± 3.41. The mean percentage of the knowledge was 36.14% ± 18.94%. Statistically significant association was noted between knowledge about GDM with maternal age and educational status, religion, and occupation ($P < 0.050$), but the GDM knowledge was independent of that found between place of residence ($P = 0.715$) and family history of DM ($P = 0.661$).

CONCLUSION: There is poor knowledge about GDM in the study area. Hence, there is need to create awareness of this condition through counseling and use of mass media.

Keywords:

Antenatal care, gestational diabetes mellitus, knowledge, pregestational diabetes mellitus

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Introduction

India ranked second globally for the number of adults with diabetes mellitus (DM) while China being the first.[1] Gestational DM (GDM) is one of the subtypes of diabetes, characterized by glucose intolerance first detected during pregnancy.[2] The prevalence of pre-GDM (PGDM) and GDM varies with ethnicity. The South Asian race is at a higher predisposition for both type 2 DM and GDM.[3-4] A recent community-based study in South India reported 17.8% of the women residing in urban area with GDM, 13.8% women residing in semi-urban, and 9.9% women residing in rural areas using 2 h 75 g postglucose value ≥ 140 mg/dL.[5-6]

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Diabetes complicates up to 20% of all pregnancies worldwide, including PGDM and GDM.[7] PGDM is at risk of preeclampsia in the antepartum period whereas the infants born to the mother with GDM may be at risk for macrosomia, hypoglycemia, jaundice, respiratory distress syndrome, polycythemia, and hypocalcemia.[8] Furthermore, GDM is attributable to increased risk of cardiovascular outcomes, stillbirth, early childhood obesity, and adverse maternal outcomes, such as increased rates of preeclampsia and cesarean and operative births. Based on recent literature, it is suggested that gestational diabetes and fetal macrosomia are independent risk factors for shoulder dystocia.[9]

Data suggest that educational strategies on GDM need to be encouraged and implemented, especially for young, fertile women of all ethnicities. Early counseling of families has been recommended by the Fifth International Workshop-Conference on GDM to avoid excessive material and fetal weight gain.[10] Educational programs have been recommended that emphasize reduced fat and energy intake, regular physical activity, and regular clinic visits.[11]

This study was conducted to evaluate the awareness of GDM among pregnant women attending a tertiary care center of North Karnataka.

Methodology

This cross-sectional study was conducted under the Department of Pharmacy Practice, Jawaharlal Nehru Medical College, KLE University, Belagavi, Karnataka, from October 2014 to May 2017. The sample size of the study was calculated by the inverse random sampling formula to reject the null hypothesis. An attrition rate of 15% was considered. Those registered pregnant women diagnosed to have GDM residing within 5 km of study area aged more than 18 years, and those who were willing to participate in the study were recruited for the study. Pregnant women with endocrinal complications and renal complications, pregnancy complications, prior type 2 DM, multiple gestations, and having significant difficulties to cooperate were excluded from the study. Before the commencement, the study was approved by the institutional ethics committee; this study was also registered with Indian CTRI-CTRI/2017/01/007622. Pregnant women with ≥24 weeks of gestation diagnosed to have GDM based on DIPSI criteria and were screened for eligibility. Those who were eligible were briefed about the nature of the study and the intervention, procedure involved in the study along with their family members. Those who were willing to participate and provide written informed consent were enrolled.

The selected participants were interviewed to obtain the demographic data such as age, religion, education, occupation, place of residence socioeconomic status, history of DM, family history, current treatment, medical history, personal history, and dietary habits. These findings were recorded in a predesign and pretested pro forma.

Further, the participants were provided with the questionnaire in local language which was designed to assess the knowledge regarding the GDM. The questionnaire comprised 18 questions and emphasized about dietary habits, exercise program, random blood sugar monitoring, treatment, insulin intake, medications, adverse drug reactions, complication in mother as well as fetus, and birth outcomes. The assessment was done by a research scholar based on the responses obtained from the questions. The interpretation of knowledge was done based on the scores obtained, that is, those who answered correctly were interpreted as having adequate knowledge and were graded with a score of 1 for each question. Finally, the sum of total points was calculated and these total scores were converted into percentage and the grading was done as having excellent knowledge if the percentage was ≥75, good knowledge if the percentage was between 51 and 75, average knowledge if the percentage was between 26% and 50%, and poor knowledge if the percentage was ≤25%.

Statistical analysis

The data were entered into a Microsoft Excel spreadsheet and were analyzed using SPSS statistical software version 20.0. The categorical data were expressed as rates and ratios, and Fisher's exact test and Chi-square test were used for calculating percentages and comparison. Continuous data were expressed as mean ± standard deviation and the independent sample *t*-test was used for the calculation of comparison. $P \leq 0.05$ as 95% confidence interval was termed as statistically significant.

Results

During the study, a total of 500 women provided written consent to participate in the study and filled the questionnaire. The age of the women ranged from 22 to 44 years with mean age as 27.53 ± 2.42 years and median age as 27 years. The most common age group was 26–30 years comprised 67.6% of the women [Graph 1]. Maximum women had primary education (61%) and were Hindus (54.8%). Most of the women were working (54.8%) and resided in slum areas (43.2%) [Table 1]. Most of the women had body mass index (BMI) between 19.8 and 26.00 kg/m^2 (67%) [Graph 2]. The mean BMI level was 28.07 ± 4.11 kg/m^2 with median levels being 27.41 kg/m^2. The minimum BMI recorded was 17.80 kg/m^2 and

maximum BMI was as high as 42.98 kg/m². The mean blood sugar levels at diagnosis ranged between 88 and 300 mg/dL, the mean blood sugar level was 201.36 ± 38.67 mg/dL, and median blood sugar level was 190 mg/dL.

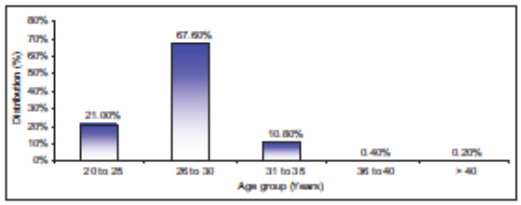
Table 1: Demography characteristics

Demography characteristics	Findings	Distribution (*n*=500)	
		Number	Percentage
Education	Illiterate	76	15.2
	Primary	305	61
	SSLC	39	7.8
	Collegiate	53	10.6
	Postgraduation	27	5.4
	Total	500	100
Religion	Hindu	274	54.8
	Muslim	218	43.6
	Christian	8	1.6
	Total	500	100
Occupation	Working	274	54.8
	House wife	218	43.6
	Total	500	100
Place of residence	Rural	104	20.8
	Slum	216	43.2
	Urban	180	36
	Total	500	100

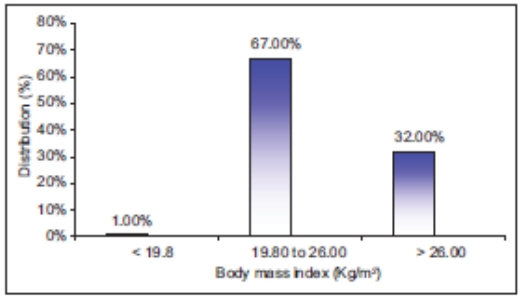
Table 2: Distribution of study population according to the Knowledge about GDM

Questions	Distribution (*n*=500)	
	Number	Percentage
Gestational diabetes is a condition diagnosed during ___Phase of life?	234	46.8
Gestational diabetes may be treated with?	234	46.8
Women are more likely to develop gestaional diabetes if the are?	234	46.8
In uncontrolled gestational diabetes, the blood sugar is?	234	46.8
Which of the following is true ?	234	46.8
The normal range for fasting blood sugar for pregnant women is?	234	46.8
Butter is mainly?	234	46.8
Rice is mainly?	234	46.8
The presence of ketones in the urine is a?	234	46.8
Which one of the following possible complications is usually not associated with diabetes?	234	46.8
A woman with gestational diabetes on insulin who finds her blood sugar constantly high should probably?	234	46.8
When a woman with gestational diabetes on insulin becomes ill and unable to eat the prescribed diet?	234	46.8
If you feel the beginnings of a low blood sugar reaction, you should?	234	46.8
Low blood sugar is caused by?	158	31.6
A woman with gestational diabetes should?	135	27
Exercisign when a woman has gestational diabetes?	215	43
After a baby is born, a mother who has had gestational diabetes?	177	35.4
With gestational diabetes, a baby may be?	137	27.4

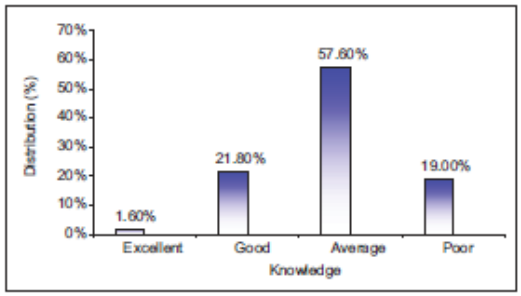
Majority of the women, that is, 57.6% of women, had average knowledge about the GDM while 21.8% of the women had good knowledge, 1.6% had excellent, and 19% had poor knowledge [Graph 3]. Most of the women answered accurately for the question numbers 1–14 (46.8% of the women each), that is, effect of exercise on GDM (60%). Maximum women answered wrong for the question number15 (27%) [Table 2], that is, a woman with gestational diabetes should take moderate exercise such as walking, exercise more than a woman who do not have gestational diabetes, rest more than a woman who do not have gestational diabetes [Table 2]. The mean knowledge score was 6.51 ± 3.41 and median score was 6 with range null being minimum and 17 being



Graph 1: Age distribution of the study population



Graph 2: Body mass index



Graph 3: Knowledge about gestational diabetes mellitus

maximum. The mean percentage of the knowledge was 36.14% ± 18.94% and median knowledge percentage was 33.33%. None of the women answered all the questions correctly. Further 16 (3.2%) women could not answer even one question correctly [Table 2]. Maximum women had knowledge about the condition of gestational diabetes, its treatment, causes, blood sugar levels, and dietary intake (46.8%). However, the participants were unaware about what should be the lifestyle modification with regard to the daily exercise and effect of GDM on newborn weight.

Statistically significant association was noted between knowledge about GDM with age and educational status, religion, and occupation ($P < 0.050$). However, no association was found between place of residence ($P = 0.715$) and family history of DM ($P = 0.661$) with GDM knowledge. Significantly higher number of participants aged between 36 and 40 years had excellent knowledge about GDM (71.43%) compared to 20.95% of the women aged 20–25 years who had poor knowledge and to 59.05% of the women aged 20–25 years who had average knowledge [Table 3]. According to the age, awareness of disease also increases in pregnant women with GDM.

Discussion

The present study highlights poor knowledge in the study area about GDM and a small proportion of women with (21.8%) good knowledge. The knowledge levels of GDM observed in the present study were very much in agreement with a similar study by Shriraam *et al*. in Chennai who reported that 17.5% women had good knowledge, 56.7% had fair knowledge, and 25.8% of women were observed to have inadequate knowledge about GDM. The median knowledge score was observed to be 7. However, the proceeding study use different sets of questionnaire which comprised 12 questions, every correct response was given a score of 1 and each women's score was calculated out of 12. A score of 0–4 was considered as poor knowledge, 5–8 as fair, and 9–12 as good knowledge of GDM, while in the present study, the questionnaire comprised 18 questions. In the present study, 46.8% of the women had awareness of GDM consistent with a study by Shriraam *et al*. in Chennai where 85% of the participants had awareness of GDM compared to 46.8% in our study.

A similar study by Shriraam *et al*. in Chennai showed that majority of population of women was known

Table 3: Association of demographic characteristics with knowledge

Variables	Subgroups	Knowledge levels							
		Poor		Average		Good		Excellent	
		No	Percentage	No	Percentage	No	Percentage	No	Percentage
Age group (Years)	20 to 25	22	20.95	62	59.05	21	20	0	0
	26 to 30	67	20	196	58.51	72	21.49	0	0
	31 to 35	6	11.54	28	53.85	15	28.85	3	5.77
	36 to 40	0	0	2	28.57	0	0	5	71.43
	40 or more	0	0	0	0	1	100	0	0
	Total	95	19	288	57.6	109	21.8	8	1.6
Education	Primary	51	18.48	169	61.23	52	18.84	4	1.45
	SSLC	3	13.64	14	63.64	5	22.73	0	0
	Collegiate	12	27.27	29	65.91	3	6.82	0	0
	Postgraduation	5	22.73	6	27.27	10	45.45	1	4.55
	Illiterate	24	17.65	70	51.47	39	28.68	3	2.21
	Total	95	19	288	57.6	109	21.8	8	1.6
Religion	Hindu	58	21.17	154	56.2	56	20.44	6	2.19
	Muslim	37	16.97	133	61.01	46	21.1	2	0.92
	Christian	0	0	1	12.5	7	87.5	0	0
	Total	95	19	288	57.6	109	21.8	8	1.6
Occupation	Housewife	67	21.47	170	54.49	69	22.12	6	1.92
	Working	28	14.89	118	62.77	40	21.28	2	1.06
	Total	95	19	288	57.6	109	21.8	8	1.6
Place of residence	Rural	19	18.27	64	61.54	19	18.27	2	1.92
	Slum	38	17.59	123	56.94	53	24.54	2	0.93
	Urban	38	21.11	101	56.11	37	20.56	4	2.22
	Total	95	19	288	57.6	109	21.8	8	1.6
Family History	Present	36	16.59	128	58.99	49	22.58	4	1.84
	Absent	59	20.85	160	56.54	60	21.2	4	1.41
	Total	95	19	288	57.6	109	21.8	8	1.6

to the condition of GDM and DM. Awareness of GDM diagnosis time, diet, and exercise as a treatment option for GDM and of the probability of untreated GDM posing a risk to the unborn child was also high among the study women. The knowledge about the risk factors for GDM and the course of GDM and that the women diagnosed with GDM are at an increased risk for future type 2 diabetes was low. However, in our study, participants knew the condition of gestational diabetes, its treatment, causes, blood sugar levels, and dietary intake (46.8%). However, the participants were unaware of what should be the lifestyle modification with regard to daily exercise and effect of GDM on newborn weight. This difference can be explained by the different civilizations of the study area, that is, most of the women in the study from Chennai involved literate participants and in this study considerable subset of participants had poor educational status with (1.6%) of women having primary education to slum area (43.2%) where health-seeking behavior, awareness of health is lacking.

In this study, positive association was noted between knowledge about GDM with age, educational status, occupation, and religion. This finding was consistent with a similar study by Shriraam *et al.* in Chennai, but the authors reported a positive association of knowledge with only age and educational status. However, the association between GDM knowledge with occupation and religion needs further evaluation as only small subset of women belonged to Christianity.

Conclusion

The present study highlights poor knowledge about the GDM in the study area. There is a need to create awareness of this condition through regular screening, using mass media. Furthermore, there is a need for educating the health-care workers and doctors as both have an important role in creating awareness among antenatal women.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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Annexure VIII

INFORMED CONSENT FORM

Form No._____

Informed consent form

Pharmacists as Educators in optimizing Identification and Management of Gestational Diabetes Mellitus and its outcomes in newborns –An interventional study

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Researcher:-Vineeta Dhyani

+917204345879

E-mail:vaneeta.dhyani@gmail.com

Participant's Name:-_____**Date:-**_____

Date of Birth:-_____ **Age:-**_____

Address:-_____

Qualification:-_____**Annual income:-**_____

Please read following before putting your signature

1) I confirm that, I have read and understood/have been explained about the information in the participant (patient) information sheet concerning this study. My questions concerning this study have been answered by **Vineeta Dhyani.**
2) I understand that my participation is voluntary in the study and I am free to withdraw at any time, without giving any reason and without my medical care/legal rights being affected.
3) I understood and permit the above researcher/Ethics committee/regulatory authorities to look into my health records, both for current study and further research that may be conducted in relation to it even if i stop taking part in the study.
4) I understand that my identity will be confidential and will not be revealed in any information related to scientific purpose or published

Form No._____

5.) I agree not to restrict the use of any of my information or results that arises from this study provided; such a use is only for scientific purpose.

6.) I have been given a copy of the information sheet and consent form to keep, by signing this form; I have not given up my legal rights.

7.) I agree to take part in the study

Participant's Name:- _____

Signature/ thumb impression:-_____

Name of LAR/Impartial witness:-_____

Signature/ thumb impression:-_____

Name of Gynaecologist:-_____

Signature:-_____

MARATHI ICF

Form No.:-_____

KLE UNIVERSITY

माहितीपूर्ण संमती फॉर्म

गर्भावस्थेतील मेलिटस प्रकारचा मधुमेह ओळखणे व त्याचे व्यवस्थापन, आणि नवजात शिशूंमधील त्याचे परिणाम सुव्यवस्थित करण्याच्या संदर्भात शिक्षकांच्या भूमिकेत औषधतज्ञ – एक हस्तक्षेपी अभ्यास

संशोधक:- विनीता ध्यानी
+917204345879
ई-मेल:-vaneeta.dhyani@gmail.com

सहभागीचे नाव:-_____ दिनांक:-_____

जन्मदिनांक:-_____ वय:-_____

रुग्णाची पत्ता:-_____

पात्रता:-_____ **रुग्णाची वार्षिक उत्पन्न:** -_____

कृपया तुमची स्वाक्षरी करण्यापूर्वी खालील मजकूर वाचा

1) मी या अभ्यासाबाबतचे सहभागीसाठीचे माहितीपत्रक वाचले असून ते मला समजले आहे , आणि मी भाग घेतल्यास मी काय करणे आवश्यक आहे आणि माझ्याबाबतीत काय होईल , हे मला समजले आहे. अभ्यासाबाबतच्या माझ्या प्रश्नांची उत्तरे Vineeta Dhyani यांनी दिली आहेत:

2) मला कल्पना आहे की मी या अभ्यासामधून केव्हाही , कोणतेही कारण न देता आणि माझ्या नेहमीच्या निगा व व्यवस्थापनावर काहीही परिणाम न होता माघार घेऊ शकेन.

Form No.:-_____

3) मला कल्पना आहे की मी जरी अभ्यासामध्ये भाग घेण्याचे थांबवले , तरी संशोधकांना आणि अधिकार्यांना सध्याच्या अभ्यासासाठी तसेच पुढे केले जाऊ शकेल अशा पुढील संशोधनासाठी माझ्या आरोग्य नोंदी पाहण्यासाठी माझ्या परवानगीची आवश्यकता लागणार नाही.

4) मला कल्पना आहे की माझी माहिती इतर कोणालाही उघड केली जाणार नाही.

5) माझी माहिती किंवा या अभ्यासाचे निष्कर्ष यांचा उपयोग जर फक्त शास्त्रीय कारणांसाठीच होणार असेल, तर अशा उपयोगावर कोणतीही बंधने न घालण्याचे मी मान्य करत आहे.

6) मला या माहिती पत्रकाची व संमती प्रपत्राची एक प्रत माझ्याकडे ठेवण्यासाठी देण्यात आली आहे , या प्रपत्रावर स्वाक्षरी करून मी माझे कोणतेही कायदेशीर हक्क सोडून दिलेले नाहीत.

7) मी या अभ्यासात भाग घेण्याचे मान्य करत आहे.

सहभागीचे नाव:-_____

स्वाक्षरी/अंगठ्याचा ठसा:-_____

निष्पक्ष साक्षीदाराचे नाव:-_____

Form No.:-_____

स्वाक्षरी/अंगठ्याचा ठसा:-_____

स्त्रीरोग तज्ञाचे नाव:-_____

स्वाक्षरी:-_____

संशोधकांचे नाव:-_____

स्वाक्षरी:-_____

KANNADA ICF

Form no:-_____

ಮಾಹಿತಿ ನೀಡುವ ಅಂಗೀಕಾರದ ರೂಪ

ನವಜಾತ ರಲ್ಲಿ ಗುರುತಿನ ಮತ್ತು ಗರ್ಭಧಾರಣೆ ಮಧುಮೇಹ ಮೆಲ್ಲಿಟಸ್ ನಿರ್ವಹಣೆ ಮತ್ತು ಅದರ ಪರಿಣಾಮಗಳ ನರಳೀಕರಿಸುವಲ್ಲಿ ವಿಧ್ಯಾಭ್ಯಾಸ ಎಂದು ಔಷಧಿಕಾರರು -ಆಯ್ನ್ ಮಧ್ಯಂತರ ಅಧ್ಯಯನ

ಭಾಗವಹಿಸುವವರ ಹೆಸರು: -_____ ದಿನಾಂಕ: -_____

ಜನ್ಮ ದಿನಾಂಕ : -_____ ವಯಸ್ಸು : -_____

ವಿಳಾಸ:-_____

ಕ್ವಾಲಿಫಿಕೇಷನ್ : -_____ವಾರ್ಷಿಕ ಆದಾಯ :_____

ನಿಮ್ಮ ಸಹಿ ಹಾಕುವ ಮೊದಲು ಕೆಳಗಿನ ಓದಿ

1) ನಾನು ಈ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಸ್ಪರ್ಧಿ (ರೋಗಿಯ) ಮಾಹಿತಿ ಹಾಳೆಯಲ್ಲಿ ಬಗ್ಗೆ ವಿವರಿಸಲಾಗಿದೆ / ಓದಲು ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ, ದೃಢೀಕರಿಸಿ. ಈ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ನನ್ನ ಪ್ರಶ್ನೆಗಳನ್ನು Vineeta Dhyani ಉತ್ತರಿಸಲಾಗುವುದಿಲ್ಲ.

2) ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆ ಅಧ್ಯಯನದಲ್ಲಿ ವ್ಯಯಕ್ತಿಕವಾಗಿದ್ದು ಮತ್ತು ಯಾವುದೇ ಕಾರಣ ನೀಡದೆ ಮತ್ತು ವೈದ್ಯಕೀಯ ಅರೈಕೆ ಇಲ್ಲದೆ, ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಿಂದಕ್ಕೆ ಪಡೆಯಬಹುದು ಎಂದು ಅರ್ಥ / ಕಾನೂನು ಹಕ್ಕುಗಳನ್ನು ಪ್ರಭಾವಿತರಾಗುವುದರಿಂದ.

Form no:-_____

3) ನಾನು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿದ ನಿಲ್ಲಿಸಿದಾಗಲೂ ಸಹ ಇದು ಸಂಬಂಧಿಸಿದಂತೆ ನಡೆಸಲಾಗುವುದು ಎಂದು ಅಧ್ಯಯನವು ಮತ್ತು ಹೆಚ್ಚಿನ ಸಂಶೋಧನೆಗಾಗಿ ಎರಡೂ ಅರ್ಥ ಮತ್ತು ನನ್ನ ಆರೋಗ್ಯ ದಾಖಲೆಗಳ ನೋಡಬೇಡಿ ಮೇಲೆ ಸಂಶೋಧಕ / ನೈತಿಕತೆಯ ಸಮಿತಿ / ನಿಯಂತ್ರಕ ಅಧಿಕಾರಿಗಳು ಅನುಮತಿ.

4) ನನ್ನ ಗುರುತನ್ನು ರಹಸ್ಯ ಇರುತ್ತದೆ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಕಾರಣಗಳಿಗೆ ಸಂಬಂಧಿಸಿದ ಅಥವಾ ಪ್ರಕಟಿಸಿದ ವೈಯಕ್ತಿಕ ಮಾಹಿತಿಯನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ ಎಂದು ಅರ್ಥ

5) ನಾನು ಒದಗಿಸಿದ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಕಾಣಿಸಿಕೊಳ್ಳುವ ನನ್ನ ಮಾಹಿತಿ ಅಥವಾ ಫಲಿತಾಂಶಗಳು ಯಾವುದೇ ಬಳಕೆಯನ್ನು ನಿರ್ಬಂಧಿಸಲು ಒಪ್ಪುತ್ತದೆ; ಇಂತಹ ಬಳಕೆಗೆ ಮಾತ್ರ ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶವಾಗಿದೆ.

6) ನಾನು ಈ ನಮೂನೆಗೆ ಸಹಿ ಮೂಲಕ ಇರಿಸಿಕೊಳ್ಳಲು ಮಾಹಿತಿ ಹಾಳೆ ಮತ್ತು ಒಪ್ಪಿಗೆ ರೂಪ ಪ್ರತಿಯನ್ನು ನೀಡಲಾಗಿದೆ; ನನ್ನ ಕಾನೂನು ಹಕ್ಕುಗಳನ್ನು ಬಿಟ್ಟುಕೊಡುವುದಿಲ್ಲ.

7) ನಾನು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಳ್ಳುತ್ತೇನೆ

ಭಾಗವಹಿಸುವವರ ಹೆಸರು: - _____

ಸಹಿ / ಹೆಬ್ಬೆಟ್ಟಿನ ಗುರುತು : -_____

ಗೃಹದೇವತೆ / ನಿಷ್ಪಕ್ಷಪಾತಿ ಸಾಕ್ಷಿಯ ಹೆಸರು : -_____

ಸಹಿ / ಹೆಬ್ಬೆಟ್ಟಿನ ಗುರುತು : -_____

Form no:-_____

ಸ್ವೀರೋಗತಜ್ಞ ಹೆಸರು: -_____

ಸಹಿ: -_____

ಸಂಶೋಧಕ ಹೆಸರು: -_____

ಸಹಿ: -_____

ANNEXURE –IX

PATIENT INFORMATION SHEET ENGLISH

Form No. .....

PAIENT INFORMATION SHEET

Pharmacists as Educators in optimizing Identification and Management of Gestational Diabetes Mellitus and its outcomes in newborns –An interventional study

Introduction:-

You are invited to participate in a interventional study .The purpose of this information leaflet is to explain exactly what is involved in participating in the study and to give you an opportunity to think whether you want to participate or not.Your clinical pharmacist will explain to you everything that is not clear to you and answer all your questions.Please do not hesitate to ask about anything you want to discuss in more detail before agreeing to participate in the study.which compares the benefit of the Proposed study helps patients with Gestational Diabetes mellitus to return as quickly as possible to fulfill and to reduce the chances.We want to know whether pharmaceutical care of patients can provide better and effective quality of life.

Purpose of study:-

Pharmaceutical care is the responsible provision of medicine therapy for the purpose of definite outcome that improve patient quality of life, which is an interdisciplinary approach and indispensable element of patient centered health care and requires to change the traditional professional attitude, it implies on actively participate patients in making decision regard to pharmacotherapy, encouraging positive lifestyle changes, to improve medication adherence, medication education and disease management for patients.

Why have you been chosen to take part in the study:-

GDM is defined as "Gestational diabetes mellitus (GDM) is a condition that develops during pregnancy when the body is not able to make enough insulin. The lack of insulin causes the blood glucose (also called blood sugar) level to become higher than normal.Criteria for the diagnosis were initially established more than 40 years ago with minor modifications this criteria is used till today. These criteria are not designed to identify pregnant women who are at an increased risk for adverse pregnancy outcomes but rather women who are at a high risk for the development of diabetes after pregnancy

What does it mean to participate?

Your participation is entirely voluntary; to help you make your decision, please read this information sheet. You are free to discuss the content of this document with a member of your family. You may take much time as you like to consider whether take or not to take part in the study. If you chose not to take part, your current and future care will not be affected. If you agree to take part you are free to withdraw from the study at any time without loss of benefits.

Once you understand what is involved in the study and you wish to participate, you will be requested to sign the consent form. If you have a question or query at any time during the research study you should feel free to ask us and obtain answers to your questions. You are not giving any of your legal rights by volunteering for this research study or by signing this consent form.

To participate in the study means that you have given your consent to be a part of this study for a duration of two years during which the following will be required from you.

During the study:-

You will be assessed for your Gestational Diabetes Meliteus by using details from your medical records, if you found eligible, you will be assigned to one of the two groups. (1) Served with pharmaceutical care and another one (2) served with usual care. Both groups are the beneficial for the patients.The allocation to one or another group will be done by computerized sample randomization technique. Thus, each person will have 50:50 chances of being assigned to either of the two groups (like the flip of a coin). If you assigned to the intervention group, you will receive an educational session on medication management, disease management and lifestyle modification during this session we will provide you patient information leaflets (PIL). The material will be free of cost.

Further contact after completion of baseline data collection:-

After the hospital visit or follow-up we will ask you some question about your health, daily activity and lifestyle. Subsequently, we will also collect your routine information from the hospital record and your follow-up in OPD.

Benefits from the study:-

Pharmaceutical care is a patient oriented care, which is a beneficiary approach, Provided by clinical pharmacist for improving patient's health By participating in the study you may become more aware of your Gestatinal Diabetes status and how you can look after it in the future by making positive lifestyle and other changes.

What are the risks in participating in the study:-

We do not expect that you will incur any risk by participating in the study. There is no invasive procedure involve in this study.

Who has reviewed the study?

This study has been reviewed by the Institutional Ethics Committee, which has responsibility for scrutinizing proposal for medical research on human. The reviewing committee has raised no objection from the point of view of medical ethics.

Inquiries/Questions:-

If you have any question about research, develop a research related problem or note a change in your condition, you should contact VINEETA DHYAN Mob.No. +917204345879. Should you have any Question regarding your rights as a research participant, you may contact the Institutional Review Board.

"Thank you for taking to read this information sheet. If you wish to take part in this study, Please sign and date the consent from given to you, you will be given a copy of the information sheet and your signed consent form."

Participant initials……

PATIENT INFORMATION SHEET MARATHI

Form:-_____

गर्भकालीन मधुमेह के प्रबंधन तथा पहचान और नवजात शिशुओं में उसके परिणामों के अनुकूलन में शिक्षकों के रूप में फार्मासिस्ट-एक हस्तक्षेप अध्ययन

प्रस्तावना:-

आपण ही माहिती हस्तपत्रक एक मध्यवर्ती अभ्यास उद्देश मध्ये सहभागी होण्यासाठी आमंत्रित केलेले अभ्यास सहभागी आहे नक्की काय हे स्पष्ट करण्यासाठी आणि आपण सहभागी किंवा नैदानिक फार्मासिस्ट करण्यासाठी स्पष्ट होईल इच्छिता किंवा नाही हे विचार करण्यासाठी एक संधी देणे आहे तुम्हांला समजत नाही आहे आणि आपल्या सर्व प्रश्न. आपल्याला अभ्यास सहभागी मान्य आधी अधिक तपशील चर्चा करायची काहीही विचाराल अजिबात संकोच करू नका प्रस्तावित अभ्यास लाभ गर्भधारणेचे मधुमेह इन्शूलिनच्या कमतरतेमुळे रक्तामध्ये व लघवीमध्ये साखर आढळणे असलेल्या रुग्णांना र औषध काळजी जीवन चांगले आणि प्रभावी गुणवत्ता प्रदान करू शकता की नाही हे जाणून घेऊ इच्छित पूर्ण करण्यासाठी आणि शक्यता आम्ही रुग्णांना औषध काळजी जीवन चांगले आणि प्रभावी गुणवत्ता प्रदान करू शकता की नाही हे जाणून घेऊ इच्छित.

अभ्यास उद्देश: -

फार्मास्युटिकल काळजी एक इंटरडिसीप्लीनरी दृष्टिकोन आणि धीर केंद्रीत आरोग्य हक्क घटक आहे आणि पारंपारिक व्यावसायिक वृत्ती बदलण्यासाठी करणे आवश्यक आहे जे जीवन रुग्ण गुणवत्ता सुधारण्यासाठी निश्चित परिणाम हेतूने औषध थेरपी जबाबदार तरतूद आहे, ते सक्रियपणे रुग्णांना सहभागी वर सुचवते रुग्णांना औषधोपचार निष्ठा , औषधोपचार शिक्षण आणि रोग व्यवस्थापन सुधारण्यासाठी , सकारात्मक जीवनशैली बदल प्रोत्साहन , औषधोपचार थेरपी निर्णय संबंधित बनवून .

तुम्हाला या अभ्यासात भाग घेण्यासाठी का त्रनवडण्यात आले आहे:-

" गर्भधारणेचे मधुमेह इन्शूलिनच्या कमतरतेमुळे रक्तामध्ये व लघवीमध्ये साखर आढळणे अशी व्याख्या केली जाते शरीर पुरेसे मधुमेहावरील रामबाण उपाय करू शकत नाही तेव्हा गर्भधारणेच्या दरम्यान विकसित एक अशी स्थिती आहे . मधुमेहावरील रामबाण उपाय अभाव निदान सुरुवातीला किरकोळ बदल या निकष आज पर्यंत वापरले जाते 40 पेक्षा अधिक वर्षांपूर्वी स्थापन करण्यात आली आहे रक्तातील ग्लुकोजच्या (देखील म्हणतात रक्तातील साखर) पातळी कमी .निकष जास्त होण्यासाठी होतो. या मानदंडाशी गर्भधारणा झाल्यानंतर मधुमेह विकासासाठी उच्च धोका असतो गर्भवती प्रतिकूल गर्भधारणा निकालाची एक वाढीव धोका असतो महिला उलट महिला ओळखण्यासाठी डिझाइन करण्यात आलेल्या आहेत.

Form:-_____

भाग घेण्याचा काय अथा आहे?

आपले सहभाग पूर्णतः ऐच्छिक आहे; आपण आपल्या निर्णय घेण्यात मदत करणे, ही माहिती पत्रक वाचले करा. आपण आपल्या कुटुंबाचा एक सदस्य हे दस्तऐवज सामग्री चर्चा मुक्त आहेत. आपल्याला अभ्यास मध्ये भाग घेणे घेऊन किंवा नाही विचार करायला म्हणून आपण जास्त वेळ लागू शकतो. आपण भाग घेणे नाही निवडले, तर आपल्या वर्तमान आणि भविष्यातील काळजी परिणाम होणार नाही. आपण भाग घेणे सहमत असल्यास आपण फायदे बिनबाद कोणत्याही वेळी अभ्यास मागे मुक्त आहेत.

आपल्याला अभ्यास सहभागी आहे ते समजून आणि आपण सहभागी होऊ इच्छित असाल एकदा, आपण संमती फॉर्म साइन इन करण्याची विनंती केली जाईल. तुम्ही संशोधन अभ्यास करत असताना, कोणत्याही वेळी एखादा प्रश्न किंवा क्वेरी असल्यास, आपण आपल्या प्रश्नांची उत्तरे आम्हाला विचारू प्रास मोकळ्या पाहिजे. आपण या संशोधन अभ्यास प्रपिावर किंवा ही संमती फॉर्म साइन इन करून आपला कायदेशीर अधिकार कोणत्याही देत नाहीत.

सर्वेक्षणात भाग घेण्यासाठी आपण खालील आवश्यकता जाईल दरम्यान दोन वर्षे कालावधीसाठी या अभ्यास एक भाग असल्याचे करण्याची आपली संमती दिली आहे याचा अर्थ असा.

अभ्यासा रम्यान:-

तुमच्या वैद्यकीय नों ीदंमधील मात्रहती वापरुन तुमचे तुमच्या गभाावस्थेतील मेत्रलटस प्रकारच्या मधुमेहासाठी मूल्यमापन केले जा ल. तुम्ही पाि ठरल्यास तुम्हाला खालील ोनपैकी एका गटात त्रन ेत्रशत केले जा ल: (1) औषधशास्त्रीय त्रनगा क्र ली जा ल, आत्र् ुसरा (2) नेहमीप्रमा्े त्रनगा क्र ली जा ल. ोन्ही गट रुग्ाांसाठी लाभ ायक आहेत.

एका ककवा ुसर् या गटामध्ये त्रन ेत्रशत करण्याचे काम संग्कीकृत या ृत्रच्छकर् पधतीतीने केले जा ल. अशा रीतीने प्रत्येक व्यक्तीला ोन्हीपैकी कोत्याही एका गटान सामील केले जाण्याची शक्यता 50:50 असेल (ना्ेफेकीप्रमा्े).

तुम्हाला जर "हस्तक्षेप" गटात त्रन ेत्रशत करण्यात आले, तर तुम्हाला औषधांचे व्यवस्थापन, रोगाचे व्यवस्थापन आत्र् जीवनशैलीतील ब ल यावर एक त्रशक्ष् सि क्र ले जा ल. या सिामध्ये आम्ही तुम्हाला रुग्त्रवषयक मात्रहतीची पिके (पी आय एल) पुरवू. हे मोफत असेल.

बेसलाईन माहितीच्या संकलनाच्या समाप्तीनंतर पुढील संपर्क-

रुग्णालयाच्या भेटीनंतर किंवा पाठपुराव्यानंतर आम्ही तुम्हाला तुमचे आरोग्य, दैनंदिन कार्ये आणि जीवनशैलीबाबत काही प्रश्न विचारु. त्याच्यानंतर आम्ही रुग्णालयातील नोंदींमधून आणि पाठपुराव्यासंबंधीच्या ओपीमधून तुमची नित्याची माहितीसुद्धा गोळा करु.

Form:-_____

अभ्यासामधून होणारे लाभ-

औषधशास्त्रीय निगा ही रुग्णलक्ष्यी निगा असते, हालाभदायकदृष्टिकोनआहे; तू रुग्णाचे आरोग्य सुधारण्यासाठी वैद्यकीय औषधतज्ञाकडून दिली जाते, आणि ती तुम्हाला मोफत उपलब्ध असेल. या अभ्यासात भाग घेतल्यामुळे तुम्हाला तुमचा गर्भावस्थेतील मधुमेहाच्या स्थितीबाबत, आणि भविष्यात जीवनशैलीमध्ये व इतर सकारात्मक बदल करुन तुम्ही त्याची कशी काळजी घेऊ शकाल, याबाबत आणखी ज्ञान होऊ शकेल.

अभ्यासामध्ये भाग घेण्याचे कोणते धोके आहेत-

या अभ्यासात भाग घेतल्यामुळे तुम्हाला कोणताही धोका असेल असे आम्हाला अपेक्षित नाही . या अभ्यासात कोणत्याही आक्रमक पद्धती अंतर्भूत नाहीत.

अभ्यासाचा आढावा कोणी घेतला आहे?

या अभ्यासाचा आढावा संस्थात्मकनीतिमत्तासमितीनेघेतला आहे,जिच्यावर मानवांवरील वैद्यकीय संशोधनाचा प्रस्ताव तपासण्याची जबाबदारी आहे .आढावा समितीने वैद्यकीय नीतिमत्तेच्या संदर्भात कोणतेही आक्षेप घेतलेले नाहीत.

चौकशा/प्रश्न:-

तुम्हाला या संशोधनाबाबत काही प्रश्न असले, किंवा एखादी संशोधनाशी संबंधित समस्या निर्माण झाली, किंवा तुमच्या स्थितीमध्ये काही बदललक्षातआला, तर तुम्ही विनीता ध्यानी यांच्याशी मोबाई क+917204345879 वर संपर्क साधावा . तुम्हाला संशोधन सहभागी म्हणून तुमच्या असलेल्या हक्कांबाबत प्रश्न असल्यास तुम्ही संस्थात्मक आढावा मंडळाशी संपर्क साधू शकता.

"हे माहितीपत्रक वाचण्यासाठी वेळ काढल्याबद्दल तुमचे आभार. तुम्हाला या अभ्यासात भाग घ्यायचा असेल तर कृपया तुम्हाला दिलेल्या संमती प्रपत्राबर स्वाक्षरी करुन दिनांक लिहा या माहितीपत्रकाची आणि स्वाक्षरी केलेल्या संमती प्रपत्राची एक प्रत तुम्हाला दिली जाईल"

सहभागीची आस्वाक्षरे.....

PATIENT INFORMATION SHEET KANNADA

Form No.:-_____

ನವಜಾತ ರಲ್ಲಿ ಗುರುತಿನ ಮತ್ತು ಗರ್ಭಧಾರಣೆ ಮಧುಮೇಹ ಮೆಲ್ಲಿಟಸ್ ನಿರ್ವಹಣೆ ಮತ್ತು ಅದರ ಪರಿಣಾಮಗಳ ಸರಳೀಕರಿಸುವಲ್ಲಿ ವಿಧ್ಯಾಭ್ಯಾಸ ಎಂದು ಔಷಧಿಕಾರರು -ಆಯ್ನ್ ಮಧ್ಯಂತರ ಅಧ್ಯಯನಪರಿಚಯ

ಪರಿಚಯ: -

ನೀವು ಈ ಮಾಹಿತಿಯನ್ನು ಚಿಗುರೆಲೆಯು ಒಂದು ಮಧ್ಯಂತರ ಅಧ್ಯಯನ .ಉದ್ದೇಶ ಭಾಗವಹಿಸಲು ಆಮಂತ್ರಿಸಲಾಗಿದೆ ಅಧ್ಯಯನದಲ್ಲಿ ತೊಡಗಿಸಿಕೊಂಡಿದೆ ನಿಖರವಾಗಿ ವಿವರಿಸಲು ಮತ್ತು ನೀವು ಭಾಗವಹಿಸಲು ಅಥವಾ ವೈದ್ಯಕೀಯ ಔಷಧಿ ಅಲ್ಲ.ವಿವರಿಸಲು ಬಯಸುವ ಎಂಬುದನ್ನು ಯೋಚಿಸುವುದು ಅವಕಾಶ ನೀಡುವುದು ನಿಮಗೆ ಸ್ಪಷ್ಟವಾಗಿಲ್ಲ ಮತ್ತು ಎಲ್ಲಾ ನಿಮ್ಮ ಪ್ರಶ್ನೆಗಳನ್ನು. ದಯವಿಟ್ಟು ನೀವು ಅಧ್ಯಯನ. ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಳ್ಳುವ ಮುನ್ನ ಹೆಚ್ಚಿನ ವಿವರ ಚರ್ಚಿಸಲು ಬಯಸುತ್ತೇನೆ ಏನು ಬಗ್ಗೆ ಕೇಳಲು ಹಿಂಜರಿಯಬೇಡಿ ಉತ್ತರಿಸಲು ನೀವು ಎಲ್ಲವನ್ನೂ ಪ್ರಸ್ತಾಪಿತ ಅಧ್ಯಯನದ ಪ್ರಯೋಜನ ಗೆಸ್ಟೇಶನಲ್ ಡಯಾಬಿಟಿಸ್ ರೋಗಿಗಳಿಗೆ ಸಹಾಯ ಹೋಲಿಸುತ್ತದೆ ಮೆಲ್ಲಿಟಸ್ ರೋಗಿಗಳ ಔಷಧೀಯ ಪಾಲನೆ ಜೀವನದ ಉತ್ತಮ ಮತ್ತು ಪರಿಣಾಮಕಾರಿ ಗುಣಮಟ್ಟದ ಒದಗಿಸುತ್ತದೆ ಎಂಬುದನ್ನು ತಿಳಿಯುವ ಪೂರೈಸಲು ಮತ್ತು ಅವಕಾಶಗಳು. ನಾವು ಕಡಿಮೆ ಸಾಧ್ಯವಿದ್ದಷ್ಟು ಮರಳಲು.

ಅಧ್ಯಯನದ ಉದ್ದೇಶ: -

ಔಷಧೀಯ ಪಾಲನೆ ಒಂದು ಅಂತರ ಶಾಸ್ತ್ರೀಯ ವಿಧಾನದಲ್ಲಿ ಮತ್ತು ರೋಗಿಯ ಕೇಂದ್ರಿತ ಆರೋಗ್ಯ ಅನಿವಾರ್ಯ ಅಂಶ ಮತ್ತು ಸಾಂಪ್ರದಾಯಿಕ ವೃತ್ತಿಪರ ವರ್ತನೆ ಬದಲಾಯಿಸಲು ಅಗತ್ಯವಿರುವ ರೋಗಿಯ ಜೀವನ ಗುಣಮಟ್ಟ ಸುಧಾರಿಸುವ ನಿರ್ದಿಷ್ಟ ಫಲಿತಾಂಶವನ್ನು ಉದ್ದೇಶದಿಂದ ಔಷಧ ಚಿಕಿತ್ಸೆಯ ಜವಾಬ್ದಾರಿ ಒದಗಿಸುವಿಕೆ, ಇದು ಸಕ್ರಿಯವಾಗಿ ರೋಗಿಗಳು ಭಾಗವಹಿಸಲು ಮೇಲೆ ಸೂಚಿಸುತ್ತದೆ ರೋಗಿಗಳಿಗೆ ಔಷಧಿಗಳನ್ನು ನಿಷ್ಠೆ, ಔಷಧಿಗಳನ್ನು ಶಿಕ್ಷಣ ಮತ್ತು ರೋಗ ನಿರ್ವಹಣೆ ಸುಧಾರಿಸಲು, ಧನಾತ್ಮಕ ಜೀವನಶೈಲಿಯ ಪ್ರೋತ್ಸಾಹ, ಔಷಧೀಯ ನಿರ್ಧಾರ ಸಂಬಂಧಿಸಿದಂತೆ ಮಾಡುವಲ್ಲಿ.

ನೀವೇಕೆ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಆಯ್ಕೆ ಮಾಡಲಾಗಿದೆ: -

ಜಿಡಿಎಂ "ಗೆಸ್ಟೇಶನಲ್ ಡಯಾಬಿಟಿಸ್ ಮೆಲ್ಲಿಟಸ್ (ಜಿಡಿಎಮ್) ವ್ಯಾಖ್ಯಾನಿಸಲಾಗಿದೆ ದೇಹದ ಸಾಕಷ್ಟು ಇನ್ಸುಲಿನ್ ಮಾಡಲು ಸಾಧ್ಯವಿಲ್ಲ ಯಾವಾಗ ಗರ್ಭಾವಸ್ಥೆಯಲ್ಲಿ ಬೆಳವಣಿಗೆ ಒಂದು ಸ್ಥಿತಿ ಇದೆ. ಇನ್ಸುಲಿನ್ ಕೊರತೆ ರೋಗ ಆರಂಭದಲ್ಲಿ ಸಣ್ಣ ಪುಟ್ಟ ಮಾರ್ಪಾಡುಗಳನ್ನು ಈ ಮಾನದಂಡಗಳನ್ನು ಇಂದು ತನಕ ಬಳಸಲಾಗುತ್ತದೆ ಹೆಚ್ಚು 40 ವರ್ಷಗಳ ಹಿಂದೆ ಸ್ಥಾಪಿಸಲಾಯಿತು ರಕ್ತದ ಗ್ಲೂಕೋಸ್ (ಸಹ ಕರೆಯಲಾಗುತ್ತದೆ ರಕ್ತದ ಸಕ್ಕರೆ) ಮಟ್ಟದ ಸಾಮಾನ್ಯ. ಮಾನದಂಡಗಳನ್ನು ಹೆಚ್ಚಿನ ಕಾರಣವಾಗುತ್ತದೆ. ಈ ಮಾನದಂಡಗಳನ್ನು ಗರ್ಭಧಾರಣೆಯ ನಂತರ ಮಧುಮೇಹ ಅಭಿವೃದ್ಧಿಗೆ ಹೆಚ್ಚಿನ ಗಂಡಾಂತರ ಗರ್ಭಿಣಿ ಪ್ರತಿಕೂಲ ಗರ್ಭಧಾರಣೆ ಫಲಿತಾಂಶಕ್ಕಾಗಿ ಹೆಚ್ಚಿನ ಅಪಾಯ ಮಹಿಳೆಯರ ಆದರೆ ಮಹಿಳೆಯರು ಗುರುತಿಸಲು ವಿನ್ಯಾಸಗೊಳಿಸಲಾಗಿದೆ.

Form No.:-_____

ಏನು ಭಾಗವಹಿಸಲು ಅರ್ಥವೇನು?

ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ವೈಯಕ್ತಿಕವಾಗಿದ್ದು; ನಿಮ್ಮ ನಿರ್ಧಾರ ಸಹಾಯ, ಈ ಮಾಹಿತಿಯನ್ನು ಶೀಟ್ ಓದಿ. ನಿಮ್ಮ ಕುಟುಂಬದ ಸದಸ್ಯ ಈ ಡಾಕ್ಯುಮೆಂಟ್ ವಿಷಯ ಚರ್ಚಿಸಲು ಉಚಿತ. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಟೇಕ್ ಇಲ್ಲವೋ ಪರಿಗಣಿಸಲು ಇಷ್ಟ ಎಂದು ನೀವು ಹೆಚ್ಚು ಸಮಯ ತೆಗೆದುಕೊಳ್ಳಬಹುದು. ನೀವು ಭಾಗವಹಿಸಲು ನಿರ್ಧರಿಸಿತು, ನಿಮ್ಮ ಪ್ರಸ್ತುತ ಮತ್ತು ಭವಿಷ್ಯದ ಕಾಳಜಿ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ. ನೀವು ಭಾಗವಹಿಸಲು ಒಪ್ಪಿದಲ್ಲಿ ಪ್ರಯೋಜನಗಳನ್ನು ನಷ್ಟವಿಲ್ಲದೆಯೇ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂಪಡೆಯಲು ಉಚಿತ.

ನೀವು ಅಧ್ಯಯನ ಸೇರಿಕೊಂಡಿರುತ್ತದೆ ಎಂಬುದನ್ನು ಅರ್ಥ ಮತ್ತು ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸುವ ಒಮ್ಮೆ ಸಮ್ಮತಿಯ ನಮೂನೆಗೆ ಸಹಿ ಮಾಡುವಂತೆ ಕೋರಲಾಗುವುದು. ನೀವು ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಒಂದು ಪ್ರಶ್ನೆ ಅಥವಾ ಪ್ರಶ್ನೆಗೆ ಹೊಂದಿದ್ದರೆ ನೀವು ನಿಮ್ಮ ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರಗಳನ್ನು ನಮಗೆ ಕೇಳಲು ಮತ್ತು ಪಡೆಯಲು ಹಿಂಜರಿಯಬೇಡಿ. ನಿಮ್ಮನ್ನು ಈ ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಸ್ವ ಇಚ್ಛೆಯಿಂದ ಅಥವಾ ಈ ಸಮ್ಮತಿ ನಮೂನೆಯನ್ನು ಸಹಿ ಮೂಲಕ ನಿಮ್ಮ ಹಕ್ಕುಗಳನ್ನು ನೀಡುವ ಇಲ್ಲ.

ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಕೆಳಗಿನ ನೀವು ಅಗತ್ಯವಿದೆ ಯಾವ ಸಂದರ್ಭದಲ್ಲಿ ಎರಡು ವರ್ಷಗಳ ಅವಧಿಯವರೆಗೆ ಈ ಅಧ್ಯಯನದ ಒಂದು ಭಾಗವಾಗಿದೆ ಎಂದು ನಿಮ್ಮ ಒಪ್ಪಿಗೆ ನೀಡಿದ್ದಾರೆ ಎಂದು ಅರ್ಥ.

ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ: -

ನೀವು ಅರ್ಹತೆ ಪಡೆದಿದ್ದರೆ, ನೀವು ಎರಡು ಗುಂಪುಗಳ ಒಂದು ನಿಯೋಜಿಸಲಾಗುವುದು, ನಿಮ್ಮ ವೈದ್ಯಕೀಯ ದಾಖಲೆಗಳು ವಿವರಗಳು ಬಳಸಿಕೊಂಡು ನಿಮ್ಮ ಗೆನ್ಪೇಶನಲ್ ಡಯಾಬಿಟಿಸ್ ಮೆಲ್ಲಿಟಸ್ ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ. (1) ಔಷಧೀಯ ಪಾಲನೆ ಬಡಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಇನ್ನೊಂದನ್ನು (2) ಸಾಮಾನ್ಯ ಆರೈಕೆ ಬಡಿಸಲಾಗುತ್ತದೆ. ಎರಡೂ ಗುಂಪುಗಳು ಒಂದು ರೋಗಿಗಳು. ದಿವಿಂಗಡಣೆಗೆ ಉಪಯುಕ್ತವಾಗಿದ್ದಾರೆ ಅಥವಾ ಇನ್ನೊಂದು ಗುಂಪು ಗಣಕೀಕೃತ ಮಾದರಿ ಯಾದೃಚ್ಛಿಕ ತಂತ್ರಜ್ಞಾನದಿಂದ ಮಾಡಲಾಗುವುದು. ಆದ್ದರಿಂದ, ಯಾವುದೇ ವ್ಯಕ್ತಿ (ಒಂದು ನಾಣ್ಯದ ಫ್ಲಿಪ್ ಹಾಗೆ) ಎರಡು ಗುಂಪುಗಳ ಎರಡೂ ನಿಗದಿಪಡಿಸಲಾಗಿದೆ ಎಂಬ 50:50 ಅವಕಾಶಗಳನ್ನು ಹೊಂದಿರುತ್ತದೆ. ನೀವು ಹಸ್ತಕ್ಷೇಪ ಗುಂಪಿಗೆ, ನೀವು ನೀವು ರೋಗಿಯ ಮಾಹಿತಿಯನ್ನು ಚಿಗುರೆಲೆಗಳು ಒದಗಿಸುತ್ತದೆ ಈ ಅಧಿವೇಶನ (ಪಿಐಎಲ್) ಸಮಯದಲ್ಲಿ ಔಷಧಿ ನಿರ್ವಹಣೆ, ರೋಗ ನಿರ್ವಹಣೆ ಹಾಗೂ ಜೀವನಶೈಲಿ ಬದಲಾವಣೆ ಮೇಲೆ ಶೈಕ್ಷಣಿಕ ಅಧಿವೇಶನದಲ್ಲಿ ಸ್ವೀಕರಿಸುತ್ತೀರಿ. ವಸ್ತು ಉಚಿತವಾಗಿ ಇರುತ್ತದೆ.

ಬೇಸ್ಲೈನ್ ಮಾಹಿತಿ ಒಟ್ಟುಗೂಡಿಸಲು ನಂತರ ಇನ್ನಷ್ಟು ಸಂಪರ್ಕಗಳು: -

ಆಸ್ಪತ್ರೆಗೆ ಭೇಟಿ ನಂತರ ಅಥವಾ ಅನುಸರಣಾ ನಾವು ನಿಮ್ಮ ಆರೋಗ್ಯ, ದೈನಂದಿನ ಚಟುವಟಿಕೆ ಮತ್ತು ಜೀವನಶೈಲಿ ಬಗ್ಗೆ ಕೆಲವು ಪ್ರಶ್ನೆ ಕೇಳುತ್ತೇವೆ. ತರುವಾಯ, ನಾವು ಆಸ್ಪತ್ರೆಯ ದಾಖಲೆ ಮತ್ತು ಒ.ಪಿ.ಡಿ. ನಿಮ್ಮ ಅನುಸರಣಾ ನಿಮ್ಮ ವಾಡಿಕೆಯ ಮಾಹಿತಿಯನ್ನು ಸಂಗ್ರಹಿಸುತ್ತದೆ.

Form No.:-_____

ಅಧ್ಯಯನದಿಂದ ಪ್ರಯೋಜನಗಳು: -

ಔಷಧೀಯ ಪಾಲನೆ ನಿಮ್ಮ ಗೆಸ್ಟ್ರೋಶನಲ್ ಡಯಾಬಿಟಿಸ್ ಮೆಲ್ಲಿಟಸ್ ಸ್ಥಿತಿ ಬಗ್ಗೆ ಅಧಿಕ ಮಾಡಬಹುದು ಅಧ್ಯಯನದಲ್ಲಿ, ಮತ್ತು ನೀವು ಧನಾತ್ಮಕ ಮೂಲಕ ಭವಿಷ್ಯದಲ್ಲಿ ಇದು ನಂತರ ನೋಡಲು ಹೇಗೆ ಮೂಲಕ ರೋಗಿಯ ಆರೋಗ್ಯವನ್ನು ಸುಧಾರಿಸುವ ವೈದ್ಯಕೀಯ ಔಷಧಿ ನೀಡಿದ್ದಾರೆ ಫಲಾನುಭವಿ ವಿಧಾನ ಇದು ರೋಗಿಯ ಆಧಾರಿತ ಆರೈಕೆ, ಆಗಿದೆ ಜೀವನಶೈಲಿ ಮತ್ತು ಇತರ ಬದಲಾವಣೆಗಳನ್ನು.

ಅಧ್ಯಯನ ಭಾಗವಹಿಸುವ ಅಪಾಯಗಳನ್ನು ಯಾವುವು: -

ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವ ಮೂಲಕ ಯಾವುದೇ ಅಪಾಯ ಅನುಭವಿಸುತ್ತವೆ ಎಂದು ಅಪೇಕ್ಷಿಸುವುದಿಲ್ಲ. ಯಾವುದೇ ಆಕ್ರಮಣಶೀಲ ವಿಧಾನ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಒಳಗೊಂಡಿರುತ್ತವೆ ಇಲ್ಲ.

ಯಾರು ಅಧ್ಯಯನ ಪರಿಶೀಲಿಸಿದೆ?

ಈ ಅಧ್ಯಯನವು ಮಾನವನ ಮೇಲೆ ವೈದ್ಯಕೀಯ ಸಂಶೋಧನಾ ಪ್ರಸ್ತಾವನೆಯನ್ನು ಪರಿಶೀಲನೆ ಜವಾಬ್ದಾರಿಯನ್ನು ಹೊಂದಿರುವ ನೈತಿಕ ಸಮಿತಿಯ, ಪರಿಶೀಲಿಸಿದಾಗ. ಪರಾಮರ್ಶೆ ಸಮಿತಿ ವೈದ್ಯಕೀಯ ನೀತಿಶಾಸ್ತ್ರದ ದೃಷ್ಟಿಯಿಂದ ಅಕ್ಷೇಪಣೆ ಎತ್ತಿದ್ದರು.

ವಿಚಾರಣೆಯಲ್ಲಿ / ಪ್ರಶ್ನೆಗಳು: -

ನೀವು ಸಂಶೋಧನೆ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆ ಇದ್ದರೆ, ಸಂಶೋಧನಾ ಸಂಬಂಧಿಸಿದ ಸಮಸ್ಯೆಗಳು ಅಭಿವೃದ್ಧಿ ಅಥವಾ ನಿಮ್ಮ ಪರಿಸ್ಥಿತಿಯ ಬದಲಾವಣೆ ಗಮನಿಸಿ, ನೀವು ಸಂಪರ್ಕಿಸಬೇಕು ವಿನುತಾ ಧ್ಯಾನ್ Mob.No. +917204345879. ಒಬ್ಬ ಸಂಶೋಧನಾ ಭಾಗಿಯಾಗಿ ನಿಮ್ಮ ಹಕ್ಕುಗಳ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆ ಇರಬೇಕು, ನೀವು ಸಾಂಸ್ಥಿಕ ವಿಮರ್ಶಾ ಸಮಿತಿ ಸಂಪರ್ಕಿಸಬಹುದು.

"ಈ ಮಾಹಿತಿಯನ್ನು ಶೀಟ್ ಓದಲು ತೆಗೆದುಕೊಳ್ಳುವ ಧನ್ಯವಾದಗಳು. ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಬಯಸಿದಲ್ಲಿ ನೀವು ನೀಡಿದ, ನೀವು ಮಾಹಿತಿ ಹಾಳೆ ಮತ್ತು ನಿಮ್ಮ ಸಹಿ ಸಮ್ಮತಿಯ ನಮೂನೆಯ ಒಂದು ಪ್ರತಿಯನ್ನು ನೀಡಲಾಗುವುದು, ಸೈನ್ ಮತ್ತು ಒಪ್ಪಿಗೆ ಇಲ್ಲಿಯವರೆಗೆ ದಯವಿಟ್ಟು. "

ಪಾಲ್ಗೊಳ್ಳುವವನಮೊದಲಕ್ಷರಗಳನ್ನು:-_____

ANNEXURE X

- **Pre-post -Knowledge assessment GDM questioners.**

Tick the right ☐

A. Basic knowledge about GDM

1.Gestational diabetes? Pre Post

Is present during pregnancy	**Y/N** **Y/N**
May lead to permanent diabetes in later life	**Y/N** **Y/N**
Disappears once the baby is born	**Y/N** **Y/N**
I don't know	**Y/N** **Y/N**

2. Gestational diabetes may be treated with? Pre Post

Diet	**Y/N** **Y/N**
Diet and exercise	Y/N Y/N
Insulin	Y/N Y/N
Tablets	Y/N Y/N
I don't know	Y/N Y/N

3. Women are more likely to develop gestational diabetes if they are?Pre Post

Overweight	**Y/N**	**Y/N**
Have had more than three children	Y/N	Y/N
Are from India or other country	Y/N	Y/N
I don't know	Y/N	Y/N

4. In uncontrolled gestational diabetes, the blood sugar is? Pre Post

Normal	**Y/N**	**Y/N**
Increased	Y/N	Y/N
Decreased	Y/N	Y/N
I don't know	Y/N	Y/N

5. Which of the following is true? Pre Post

It does not matter if gestational diabetes is not fully controlled	**Y/N**	**Y/N**
It is best to show slightly raised blood sugar in order to avoid low blood sugar	Y/N	Y/N
Poor control of diabetes could result in a greater chance of complications for a pregnancy and baby	Y/N	Y/N
I don't know	Y/N	Y/N

6. The normal range for fasting blood sugar for pregnant women is? Pre Post

Less than 95 mg/dL (5.3 mmol/L)	**Y/N**	**Y/N**
Less than 120 mg/dL (6.7 mmol/L)	Y/N	Y/N
less than 140 mg/dL (7.8 mmol/L),	Y/N	Y/N

I don't know	Y/N	Y/N

Knowledge about diet/food values

7. Butter is mainly? **Pre** **Post**

Protein	**Y/N**	**Y/N**
Fat	Y/N	Y/N
Carbohydrate	Y/N	Y/N
I don't know	Y/N	Y/N

8. Rice is mainly? **Pre** **Post**

Protein	**Y/N**	**Y/N**
Fat	Y/N	Y/N
Carbohydrate	Y/N	Y/N
I don't know	Y/N	Y/N

Knowledge about management of GDM

9. The presence of ketones in the urine is a?

Pre **Post**

Good sign	**Y/N**	**Y/N**
Bad sign	Y/N	Y/N
Usual finding in diabetes	Y/N	Y/N

I don't know	Y/N	Y/N

10. Which one of the following possible complications is usually not associated with diabetes? Pre
Post

Changes in vision	**Y/N**	**Y/N**
Changes in the kidney	Y/N	Y/N
Changes in the lung	Y/N	Y/N
I don't know	Y/N	Y/N

11. A woman with gestational diabetes on insulin who finds her blood sugar constantly high should probably? Pre
Post

Stop taking insulin	**Y/N**	**Y/N**
Increase her insulin	Y/N	Y/N
Decrease her insulin	Y/N	Y/N
Consult her healthcare provider	Y/N	Y/N
I don't know	Y/N	Y/N

12. When a woman with gestational diabetes on insulin becomes ill and unable to eat the prescribed diet? Pre
Post

She should immediately stop taking insulin	**Y/N**	**Y/N**

She must continue to take insulin	Y/N	Y/N
She should use oral anti-diabetes drugs instead of insulin	Y/N	Y/N
Consult her healthcare provider	Y/N	Y/N
I don't know	Y/N	Y/N

13. If you feel the beginnings of a low blood sugar reaction, you should?

	Pre	**Post**
Immediately take some insulin	**Y/N**	**Y/N**
Immediately lie down and rest	Y/N	Y/N
Immediately eat or drink something sweet	Y/N	Y/N
I don't know	Y/N	Y/N

14. Low blood sugar is caused by? **Pre** **Post**

Too much insulin	**Y/N**	**Y/N**
Too little insulin	Y/N	Y/N
Too little food	Y/N	Y/N
Too little exercise	Y/N	Y/N
I don't know	Y/N	Y/N

15. A woman with gestational diabetes should? **Pre** **Post**

Take moderate exercise such as walking	**Y/N**	**Y/N**
Exercise more than a woman who does not have gestational diabetes	Y/N	Y/N
Rest more than a woman who does not have gestational diabetes	Y/N	Y/N

I don't know	Y/N	Y/N

16. Exercising when a woman has gestational diabetes? Pre Post

Lowers blood sugar	**Y/N**	**Y/N**
Allows a woman to eat more	Y/N	Y/N
Raises blood sugar	Y/N	Y/N
Prevents excessive weight gain	Y/N	Y/N
I don't know	Y/N	Y/N

17.After a baby is born, a mother who has had gestational diabetes? Pre Post

Doesn't need to worry about diabetes any more	**Y/N**	**Y/N**
Should get a follow-up glucose test at her 6-week check up	Y/N	Y/N
May need to have regular checks as she gets older	Y/N	Y/N
I don't know	Y/N	Y/N

18.**With gestational diabetes, a baby may be? Pre Post**

Larger than usual	**Y/N**	**Y/N**
Smaller than usual	Y/N	Y/N
Born early	Y/N	Y/N

Admitted to a special care nursery	Y/N	Y/N
I don't know	Y/N	Y/N

PART-I (Socio Demographics Data)

1.) Age of the patient

<25 years	
25-29 years	
30-34 years	
≥35 years	

2.) Educational level

Illiterate	
Primary	
SSLC	
Collegiate	
Post-graduation/professional	

3.) Religion

Hindu	
Muslim	
Christian	
Other	

4.) Occupational status

Student	
Housewife	
Office job	
Self employed	
Others	

5.) Working pattern

In school	
In industry	
In hospital	
Other job	

6.) Civilization

Urban	
Urban slum	
Rural	

7.) Monthly income of the family	
8.) Total number of family members	
9.) a.)Monthly per capita income	
b.)SES:I/II/III/IV	

Part-II(Female specific)

10.) Family history of diabetes

Grand parents
Parents
Siblings
Others

11.) Current treatment of diabetes

Diet and exercise
Insulin

12.) When was your last menstrual period?

13.) Have you used birth control measures?
Combination of both

14.) Haveyou been pregnant before this?

Yes
No

a.)If yes how many times
b.)How many live births

15.) Have you ever had gestational diabetes mellitus in previous pregnancy?

Yes
No

16.)any history of tuberclusis / cardiac disease /liver disease /urinary tract infections?

Yes
No

Part-III (Family history):

17.) Does anyone in your family have diabetes?

Yes
No
If yes, specify no of member, type of Diabetes and its duration –

18.)Do any women in your family have Gestational diabetes mellitus?

Yes
No
If yes,specify no of member, detected at gestation age and its treatment and its outcome on maternal and fetal-

PART-IV (Personal Health Habits)

19.) Do you have any history of tobacco use?

Yes
No
If yes , specify the quantity

PART-V(Physical Activity and Nutritional History)

20.)a.) Do you participate in regular physical activity or exercise ?

Yes
No

b.)If yes , what type?

Walking

Running
Yoga
Others /specify

21.) How long you are active?(Duration of physical activity /Exercise)

<15 minutes
15-30minutes
30-45 minutes
45-60minutes
>60

22.) a.) Do you have meal plan?

Yes
No
If yes specify: Diet details

23.)Which type of diet you use?

Vegetarian
Non –vegetarian
Ovo-vegetarion

Components of cost of Gestational diabetes mellitus

1.) Consulted doctor during pregnancy

None	
Once	
Twice	
More than 2 times	

2.) Total amount spent

Consultation	
Lab investigation	
Medication	

3 a.) Do you follow Doctor's advice for GDM management?

Yes	
No	

b.) Reason for not following Doctor's advice

No knowledge	
No resources	
No time	
Other	

4) Because of cost, do you?

Skip medication	

Skip lab investigations
Skip consulation

5.) To Doctor advice which component you are following and to what extent?

Therapy	80-100%	60-80%	40-50%	<50%	NA
Drug					
Diet					
Exercise					

6.)Whose advice was effective?

Doctor
Nurse
Pharmacist
Why was it effective?

7.)Which component of advice was effective?

Oral	
Demo	
Flip	
Phemplet	
Video clipping	
Booklet	
Phone calls/ messages	

8.)a.) During your pregnancy, whether admitted to hospital for Gestational diabetes mellitus or its complication

Yes
No

b.) If yes how many times

Once
Twice
3>2 times
Total cost incurred due to hospitalization:

9.) Hospital preferred for Gestational diabetes mellitus?

Government
Private

10.)Who is responsible for finances of your Gestational diabetes mellitus?

Health insurance
Employer
Relative
Self –Pay

11.) Do you take loans for your expenses?

Yes
No

12.) a.)Do you have health insurance?

Yes
No

b.) If yes, monetary re-imbursement from insurance

Full
Partial

13.) a.)Do you need some one to help in yourGestational diabetes mellitus?

Yes
No

b.) Is your care giver economically productive?

Yes
No

c.) Your care giver feel burdened?

Yes
No

d.) Do you practice self-care?

Yes	
No	
1.) NEONATAL DETAILS	
2.) PERINATAL MORTALITY	**YES** ☐ **NO** ☐

3.) Gestational age

31-34 wk	☐
34-35 wk	
35-36 wk	☐
36-37 wk	☐

4.) Birth weight

1.5-**2 kg**	☐
2.1-2.5 k	☐
2.6 -3 kg	☐
3.1 -3.5 kg	☐

GDM outcome in newborn

Outcome	Yes/no
Perinatal Mortality	
Macrosomia	
LGA births	
Shoulder dystocia	
Neonatal ICU admission	
Congenital abnormalities	
Birth trauma	
Hyperbilirubinemia	
Respiratory distress syndrome	

SGA births
Neonatal hypoglycaemia
Others

EAFLETS EVALUATION FORM

- **Tick the appropriate boxes.✔**

Readability	**Easy** ☐	**Difficulty** ☐	**Fair**☐	**Cannot read** ☐
Understanding	Easy☐	Difficulty☐	Fair☐	Cannot read☐
Design and layout	Easy ☐	Difficulty☐	Fair☐	Cannot read☐
Printing	Easy ☐	Difficulty☐	Fair☐	Cannot read☐
Content	Easy ☐	Difficulty☐	Fair☐	Cannot read☐

ANNEXURE-XI

PHEMPLET KANNADA

KLES
DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE
NEHRU NAGAR, BELGAUM-590010

GESTATIONAL DIABETES MELLITUS

(GDM)

Gestational Diabetes

High blood glucose levels in mother

Brings extra glucose to baby

Causes baby to put on extra weight

(Diabetes During Pregnancy)

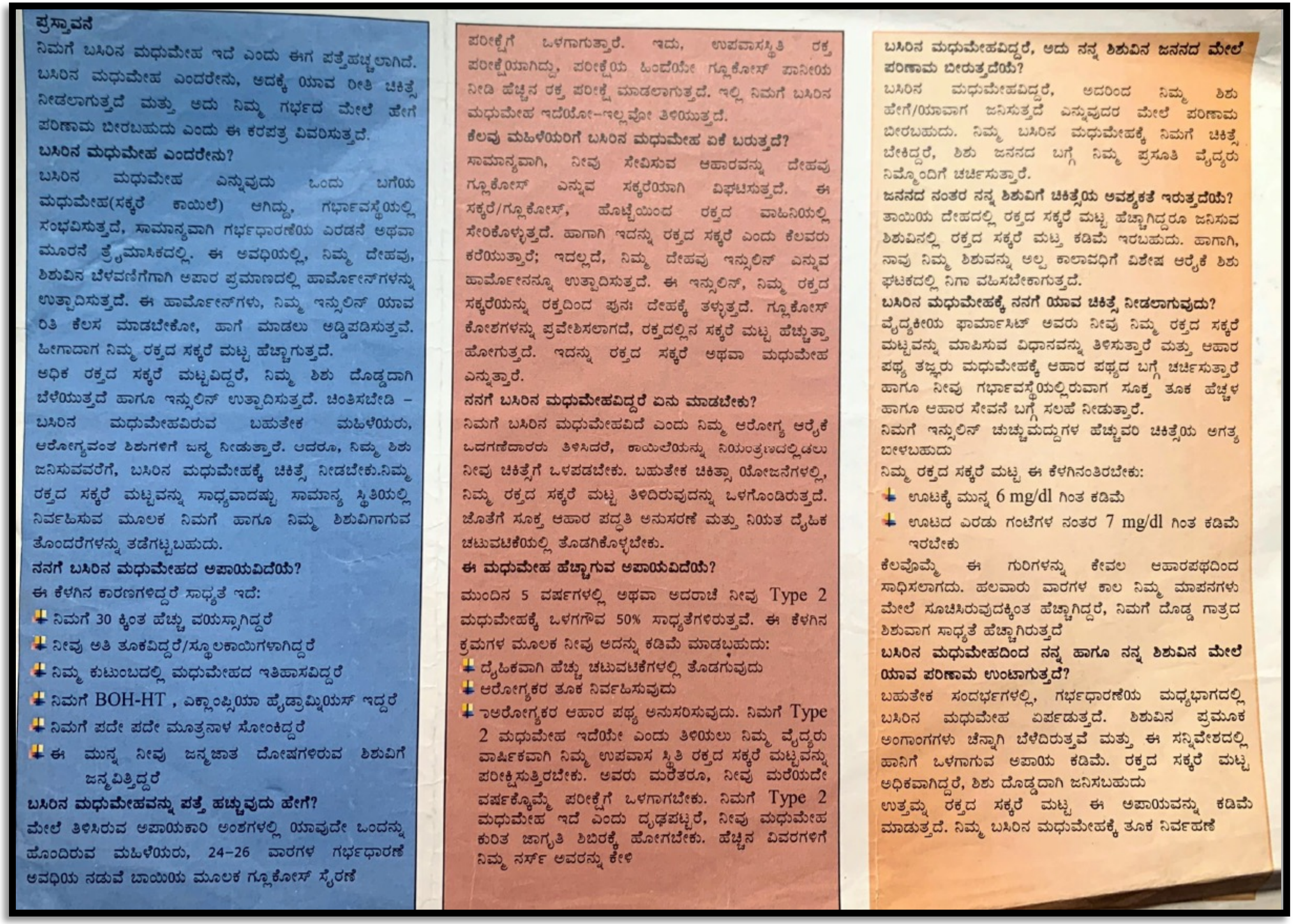
DEPARTMENT OF PHARMACY PRACTICE

KLES Dr. Prabhakar Kore Hospital

& MRC, Nehru Nagar, Belagavi.

Tel: 2473777, ext.1768

FOR FURTHER INFORMATION
PLEASE CONTACT:
DEPARTMENT OF PHARMACY
PRACTICE
KLES Dr. Prabhakar Kore Hospital
& MRC, Nehru Nagar, Belagavi.
Tel:2473777, ext. 1768



ಪ್ರಸ್ತಾವನೆ

ನಿಮಗೆ ಬಸಿರಿನ ಮಧುಮೇಹ ಇದೆ ಎಂದು ಈಗ ಪತ್ತೆಹಚ್ಚಲಾಗಿದೆ. ಬಸಿರಿನ ಮಧುಮೇಹ ಎಂದರೇನು, ಅದಕ್ಕೆ ಯಾವ ರೀತಿ ಚಿಕಿತ್ಸೆ ನೀಡಲಾಗುತ್ತದೆ ಮತ್ತು ಅದು ನಿಮ್ಮ ಗರ್ಭದ ಮೇಲೆ ಹೇಗೆ ಪರಿಣಾಮ ಬೀರಬಹುದು ಎಂದು ಈ ಕರಪತ್ರ ವಿವರಿಸುತ್ತದೆ.

ಬಸಿರಿನ ಮಧುಮೇಹ ಎಂದರೇನು?

ಬಸಿರಿನ ಮಧುಮೇಹ ಎನ್ನುವುದು ಒಂದು ಬಗೆಯ ಮಧುಮೇಹ(ಸಕ್ಕರೆ ಕಾಯಿಲೆ) ಆಗಿದ್ದು, ಗರ್ಭಾವಸ್ಥೆಯಲ್ಲಿ ಸಂಭವಿಸುತ್ತದೆ, ಸಾಮಾನ್ಯವಾಗಿ ಗರ್ಭಧಾರಣೆಯ ಎರಡನೆ ಅಥವಾ ಮೂರನೆ ತ್ರೈಮಾಸಿಕದಲ್ಲಿ. ಈ ಅವಧಿಯಲ್ಲಿ, ನಿಮ್ಮ ದೇಹವು, ಶಿಶುವಿನ ಬೆಳವಣಿಗೆಗಾಗಿ ಅಪಾರ ಪ್ರಮಾಣದಲ್ಲಿ ಹಾರ್ಮೋನ್‌ಗಳನ್ನು ಉತ್ಪಾದಿಸುತ್ತದೆ. ಈ ಹಾರ್ಮೋನ್‌ಗಳು, ನಿಮ್ಮ ಇನ್ಸುಲಿನ್ ಯಾವ ರಿತಿ ಕೆಲಸ ಮಾಡಬೇಕೋ, ಹಾಗೆ ಮಾಡಲು ಅಡ್ಡಿಪಡಿಸುತ್ತವೆ. ಹೀಗಾದಾಗ ನಿಮ್ಮ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟ ಹೆಚ್ಚಾಗುತ್ತದೆ.

ಅಧಿಕ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟವಿದ್ದರೆ, ನಿಮ್ಮ ಶಿಶು ದೊಡ್ಡದಾಗಿ ಬೆಳೆಯುತ್ತದೆ ಹಾಗೂ ಇನ್ಸುಲಿನ್ ಉತ್ಪಾದಿಸುತ್ತದೆ. ಚಿಂತಿಸಬೇಡಿ – ಬಸಿರಿನ ಮಧುಮೇಹವಿರುವ ಬಹುತೇಕ ಮಹಿಳೆಯರು, ಆರೋಗ್ಯವಂತ ಶಿಶುಗಳಿಗೆ ಜನ್ಮ ನೀಡುತ್ತಾರೆ. ಆದರೂ, ನಿಮ್ಮ ಶಿಶು ಜನಿಸುವವರೆಗೆ, ಬಸಿರಿನ ಮಧುಮೇಹಕ್ಕೆ ಚಿಕಿತ್ಸೆ ನೀಡಬೇಕು.ನಿಮ್ಮ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟವನ್ನು ಸಾಧ್ಯವಾದಷ್ಟು ಸಾಮಾನ್ಯ ಸ್ಥಿತಿಯಲ್ಲಿ ನಿರ್ವಹಿಸುವ ಮೂಲಕ ನಿಮಗೆ ಹಾಗೂ ನಿಮ್ಮ ಶಿಶುವಿಗಾಗುವ ತೊಂದರೆಗಳನ್ನು ತಡೆಗಟ್ಟಬಹುದು.

ನನಗೆ ಬಸಿರಿನ ಮಧುಮೇಹದ ಅಪಾಯವಿದೆಯೆ?

ಈ ಕೆಳಗಿನ ಕಾರಣಗಳಿದ್ದರೆ ಸಾಧ್ಯತೆ ಇದೆ:

- ನಿಮಗೆ 30 ಕ್ಕಿಂತ ಹೆಚ್ಚು ವಯಸ್ಸಾಗಿದ್ದರೆ
- ನೀವು ಅತಿ ತೂಕವಿದ್ದರೆ/ಸ್ಥೂಲಕಾಯಿಗಳಾಗಿದ್ದರೆ
- ನಿಮ್ಮ ಕುಟುಂಬದಲ್ಲಿ ಮಧುಮೇಹದ ಇತಿಹಾಸವಿದ್ದರೆ
- ನಿಮಗೆ BOH-HT , ಎಕ್ಲಾಂಪ್ಸಿಯಾ ಹೈಡ್ರಾಮ್ನಿಯಸ್ ಇದ್ದರೆ
- ನಿಮಗೆ ಪದೇ ಪದೇ ಮೂತ್ರನಾಳ ಸೋಂಕಿದ್ದರೆ
- ಈ ಮುನ್ನ ನೀವು ಜನ್ಮಜಾತ ದೋಷಗಳಿರುವ ಶಿಶುವಿಗೆ ಜನ್ಮವಿತ್ತಿದ್ದರೆ

ಬಸಿರಿನ ಮಧುಮೇಹವನ್ನು ಪತ್ತೆ ಹಚ್ಚುವುದು ಹೇಗೆ?

ಮೇಲೆ ತಿಳಿಸಿರುವ ಅಪಾಯಕಾರಿ ಅಂಶಗಳಲ್ಲಿ ಯಾವುದೇ ಒಂದನ್ನು ಹೊಂದಿರುವ ಮಹಿಳೆಯರು, 24–26 ವಾರಗಳ ಗರ್ಭಧಾರಣೆ ಅವಧಿಯ ನಡುವೆ ಬಾಯಿಯ ಮೂಲಕ ಗ್ಲೂಕೋಸ್ ಸೈರಣೆ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗುತ್ತಾರೆ. ಇದು, ಉಪವಾಸಸ್ಥಿತಿ ರಕ್ತ ಪರೀಕ್ಷೆಯಾಗಿದ್ದು, ಪರೀಕ್ಷೆಯ ಹಿಂದೆಯೇ ಗ್ಲೂಕೋಸ್ ಪಾನೀಯ ನೀಡಿ ಹೆಚ್ಚಿನ ರಕ್ತ ಪರೀಕ್ಷೆ ಮಾಡಲಾಗುತ್ತದೆ. ಇಲ್ಲಿ ನಿಮಗೆ ಬಸಿರಿನ ಮಧುಮೇಹ ಇದೆಯೋ–ಇಲ್ಲವೋ ತಿಳಿಯುತ್ತದೆ.

ಕೆಲವು ಮಹಿಳೆಯರಿಗೆ ಬಸಿರಿನ ಮಧುಮೇಹ ಏಕೆ ಬರುತ್ತದೆ?

ಸಾಮಾನ್ಯವಾಗಿ, ನೀವು ಸೇವಿಸುವ ಆಹಾರವನ್ನು ದೇಹವು ಗ್ಲೂಕೋಸ್ ಎನ್ನುವ ಸಕ್ಕರೆಯಾಗಿ ವಿಘಟಿಸುತ್ತದೆ. ಈ ಸಕ್ಕರೆ/ಗ್ಲೂಕೋಸ್, ಹೊಟ್ಟೆಯಿಂದ ರಕ್ತದ ವಾಹಿನಿಯಲ್ಲಿ ಸೇರಿಕೊಳ್ಳುತ್ತದೆ. ಹಾಗಾಗಿ ಇದನ್ನು ರಕ್ತದ ಸಕ್ಕರೆ ಎಂದು ಕೆಲವರು ಕರೆಯುತ್ತಾರೆ; ಇದಲ್ಲದೆ, ನಿಮ್ಮ ದೇಹವು ಇನ್ಸುಲಿನ್ ಎನ್ನುವ ಹಾರ್ಮೋನನ್ನೂ ಉತ್ಪಾದಿಸುತ್ತದೆ. ಈ ಇನ್ಸುಲಿನ್, ನಿಮ್ಮ ರಕ್ತದ ಸಕ್ಕರೆಯನ್ನು ರಕ್ತದಿಂದ ಪುನಃ ದೇಹಕ್ಕೆ ತಳ್ಳುತ್ತದೆ. ಗ್ಲೂಕೋಸ್ ಕೋಶಗಳನ್ನು ಪ್ರವೇಶಿಸಲಾಗದೆ, ರಕ್ತದಲ್ಲಿನ ಸಕ್ಕರೆ ಮಟ್ಟ ಹೆಚ್ಚುತ್ತಾ ಹೋಗುತ್ತದೆ. ಇದನ್ನು ರಕ್ತದ ಸಕ್ಕರೆ ಅಥವಾ ಮಧುಮೇಹ ಎನ್ನುತ್ತಾರೆ.

ನನಗೆ ಬಸಿರಿನ ಮಧುಮೇಹವಿದ್ದರೆ ಏನು ಮಾಡಬೇಕು?

ನಿಮಗೆ ಬಸಿರಿನ ಮಧುಮೇಹವಿದೆ ಎಂದು ನಿಮ್ಮ ಆರೋಗ್ಯ ಆರೈಕೆ ಒದಗಣೆದಾರರು ತಿಳಿಸಿದರೆ, ಕಾಯಿಲೆಯನ್ನು ನಿಯಂತ್ರಣದಲ್ಲಿಡಲು ನೀವು ಚಿಕಿತ್ಸೆಗೆ ಒಳಪಡಬೇಕು. ಬಹುತೇಕ ಚಿಕಿತ್ಸಾ ಯೋಜನೆಗಳಲ್ಲಿ, ನಿಮ್ಮ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟ ತಿಳಿದಿರುವುದನ್ನು ಒಳಗೊಂಡಿರುತ್ತದೆ. ಜೊತೆಗೆ ಸೂಕ್ತ ಆಹಾರ ಪದ್ಧತಿ ಅನುಸರಣೆ ಮತ್ತು ನಿಯತ ದೈಹಿಕ ಚಟುವಟಿಕೆಯಲ್ಲಿ ತೊಡಗಿಕೊಳ್ಳಬೇಕು.

ಈ ಮಧುಮೇಹ ಹೆಚ್ಚಾಗುವ ಅಪಾಯವಿದೆಯೆ?

ಮುಂದಿನ 5 ವರ್ಷಗಳಲ್ಲಿ ಅಥವಾ ಅದರಾಚೆ ನೀವು Type 2 ಮಧುಮೇಹಕ್ಕೆ ಒಳಗಾಗುವ 50% ಸಾಧ್ಯತೆಗಳಿರುತ್ತವೆ. ಈ ಕೆಳಗಿನ ಕ್ರಮಗಳ ಮೂಲಕ ನೀವು ಅದನ್ನು ಕಡಿಮೆ ಮಾಡಬಹುದು:

- ದೈಹಿಕವಾಗಿ ಹೆಚ್ಚು ಚಟುವಟಿಕೆಗಳಲ್ಲಿ ತೊಡಗುವುದು
- ಆರೋಗ್ಯಕರ ತೂಕ ನಿರ್ವಹಿಸುವುದು
- ಆರೋಗ್ಯಕರ ಆಹಾರ ಪಥ್ಯ ಅನುಸರಿಸುವುದು. ನಿಮಗೆ Type 2 ಮಧುಮೇಹ ಇದೆಯೇ ಎಂದು ತಿಳಿಯಲು ನಿಮ್ಮ ವೈದ್ಯರು ವಾರ್ಷಿಕವಾಗಿ ನಿಮ್ಮ ಉಪವಾಸ ಸ್ಥಿತಿ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟವನ್ನು ಪರೀಕ್ಷಿಸುತ್ತಿರಬೇಕು. ಅವರು ಮರೆತರೂ, ನೀವು ಮರೆಯದೇ ವರ್ಷಕ್ಕೊಮ್ಮೆ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಬೇಕು. ನಿಮಗೆ Type 2 ಮಧುಮೇಹ ಇದೆ ಎಂದು ದೃಢಪಟ್ಟರೆ, ನೀವು ಮಧುಮೇಹ ಕುರಿತ ಜಾಗೃತಿ ಶಿಬಿರಕ್ಕೆ ಹೋಗಬೇಕು. ಹೆಚ್ಚಿನ ವಿವರಗಳಿಗೆ ನಿಮ್ಮ ನರ್ಸ್ ಅವರನ್ನು ಕೇಳಿ

ಬಸಿರಿನ ಮಧುಮೇಹವಿದ್ದರೆ, ಅದು ನನ್ನ ಶಿಶುವಿನ ಜನನದ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುತ್ತದೆಯೆ?

ಬಸಿರಿನ ಮಧುಮೇಹವಿದ್ದರೆ, ಅದರಿಂದ ನಿಮ್ಮ ಶಿಶು ಹೇಗೆ/ಯಾವಾಗ ಜನಿಸುತ್ತದೆ ಎನ್ನುವುದರ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರಬಹುದು. ನಿಮ್ಮ ಬಸಿರಿನ ಮಧುಮೇಹಕ್ಕೆ ನಿಮಗೆ ಚಿಕಿತ್ಸೆ ಬೇಕಿದ್ದರೆ, ಶಿಶು ಜನನದ ಬಗ್ಗೆ ನಿಮ್ಮ ಪ್ರಸೂತಿ ವೈದ್ಯರು ನಿಮ್ಮೊಂದಿಗೆ ಚರ್ಚಿಸುತ್ತಾರೆ.

ಜನನದ ನಂತರ ನನ್ನ ಶಿಶುವಿಗೆ ಚಿಕಿತ್ಸೆಯ ಅವಶ್ಯಕತೆ ಇರುತ್ತದೆಯೆ?

ತಾಯಿಯ ದೇಹದಲ್ಲಿ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟ ಹೆಚ್ಚಾಗಿದ್ದರೂ ಜನಿಸುವ ಶಿಶುವಿನಲ್ಲಿ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟ ಕಡಿಮೆ ಇರಬಹುದು. ಹಾಗಾಗಿ, ನಾವು ನಿಮ್ಮ ಶಿಶುವನ್ನು ಅಲ್ಪ ಕಾಲಾವಧಿಗೆ ವಿಶೇಷ ಆರೈಕೆ ಶಿಶು ಘಟಕದಲ್ಲಿ ನಿಗಾ ವಹಿಸಬೇಕಾಗುತ್ತದೆ.

ಬಸಿರಿನ ಮಧುಮೇಹಕ್ಕೆ ನನಗೆ ಯಾವ ಚಿಕಿತ್ಸೆ ನೀಡಲಾಗುವುದು?

ವೈದ್ಯಕೀಯ ಫಾರ್ಮಾಸಿಸ್ಟ್ ಅವರು ನೀವು ನಿಮ್ಮ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟವನ್ನು ಮಾಪಿಸುವ ವಿಧಾನವನ್ನು ತಿಳಿಸುತ್ತಾರೆ ಮತ್ತು ಆಹಾರ ಪಥ್ಯ ತಜ್ಞರು ಮಧುಮೇಹಕ್ಕೆ ಆಹಾರ ಪಥ್ಯದ ಬಗ್ಗೆ ಚರ್ಚಿಸುತ್ತಾರೆ ಹಾಗೂ ನೀವು ಗರ್ಭಾವಸ್ಥೆಯಲ್ಲಿರುವಾಗ ಸೂಕ್ತ ತೂಕ ಹೆಚ್ಚಳ ಹಾಗೂ ಆಹಾರ ಸೇವನೆ ಬಗ್ಗೆ ಸಲಹೆ ನೀಡುತ್ತಾರೆ.

ನಿಮಗೆ ಇನ್ಸುಲಿನ್ ಚುಚ್ಚುಮದ್ದುಗಳ ಹೆಚ್ಚುವರಿ ಚಿಕಿತ್ಸೆಯ ಅಗತ್ಯ ಬೀಳಬಹುದು

ನಿಮ್ಮ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟ ಈ ಕೆಳಗಿನಂತಿರಬೇಕು:

- ಊಟಕ್ಕೆ ಮುನ್ನ 6 mg/dl ಗಿಂತ ಕಡಿಮೆ
- ಊಟದ ಎರಡು ಗಂಟೆಗಳ ನಂತರ 7 mg/dl ಗಿಂತ ಕಡಿಮೆ ಇರಬೇಕು

ಕೆಲವೊಮ್ಮೆ ಈ ಗುರಿಗಳನ್ನು ಕೇವಲ ಆಹಾರಪಥ್ಯದಿಂದ ಸಾಧಿಸಲಾಗದು. ಹಲವಾರು ವಾರಗಳ ಕಾಲ ನಿಮ್ಮ ಮಾಪನಗಳು ಮೇಲೆ ಸೂಚಿಸಿರುವುದಕ್ಕಿಂತ ಹೆಚ್ಚಾಗಿದ್ದರೆ, ನಿಮಗೆ ದೊಡ್ಡ ಗಾತ್ರದ ಶಿಶುವಾಗ ಸಾಧ್ಯತೆ ಹೆಚ್ಚಾಗಿರುತ್ತದೆ

ಬಸಿರಿನ ಮಧುಮೇಹದಿಂದ ನನ್ನ ಹಾಗೂ ನನ್ನ ಶಿಶುವಿನ ಮೇಲೆ ಯಾವ ಪರಿಣಾಮ ಉಂಟಾಗುತ್ತದೆ?

ಬಹುತೇಕ ಸಂದರ್ಭಗಳಲ್ಲಿ, ಗರ್ಭಧಾರಣೆಯ ಮಧ್ಯಭಾಗದಲ್ಲಿ ಬಸಿರಿನ ಮಧುಮೇಹ ಏರ್ಪಡುತ್ತದೆ. ಶಿಶುವಿನ ಪ್ರಮುಖ ಅಂಗಾಂಗಗಳು ಚೆನ್ನಾಗಿ ಬೆಳೆದಿರುತ್ತವೆ ಮತ್ತು ಈ ಸನ್ನಿವೇಶದಲ್ಲಿ ಹಾನಿಗೆ ಒಳಗಾಗುವ ಅಪಾಯ ಕಡಿಮೆ. ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟ ಅಧಿಕವಾಗಿದ್ದರೆ, ಶಿಶು ದೊಡ್ಡದಾಗಿ ಜನಿಸಬಹುದು

ಉತ್ತಮ್ಮ ರಕ್ತದ ಸಕ್ಕರೆ ಮಟ್ಟ ಈ ಅಪಾಯವನ್ನು ಕಡಿಮೆ ಮಾಡುತ್ತದೆ. ನಿಮ್ಮ ಬಸಿರಿನ ಮಧುಮೇಹಕ್ಕೆ ತೂಕ ನಿರ್ವಹಣೆ

PHEMPLET ENGLISH

What happens after my baby is born?

- Your **baby will stay with you unless he or she needs extra care.**
- **Breastfeeding is best for babies**, and there's no reason why you shouldn't breastfeed your baby if you have gestational diabetes. Whichever way you choose to feed your baby, you should start
- Feeding him or her as soon as possible after birth, and then every 2–3 hours to help your baby's blood glucose stay at a safe level.
- Your baby should have his or her blood glucose level tested a few hours after birth to make sure that it is not too low. Your baby may need to be looked after in a neonatal unit if he or she is unwell, needs close monitoring or treatment, needs help with feeding or was born prematurely.
- Gestational diabetes usually gets better after birth and therefore you are likely to be advised to stop taking all diabetes medications immediately after your baby is born. Before you go home, your blood glucose level will be tested to make sure that it has returned to normal. You should have a test to check your blood glucose level after an **overnight fast or a GTT about 6–8 weeks after your baby is born.** It is important that you attend, as a small number of women continue to have diabetes after pregnancy.

FOR FURTHER INFORMATION
PLEASE CONTACT:
DEPARTMENT OF PHARMACY PRACTICE
KLES Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi.
Tel:2473777, ext. 1768

What effects will GDM have for me and my baby?
In most cases, GDM will be picked up in the middle of pregnancy. The baby's major organs are well developed at this stage of the pregnancy and are not at risk of damage. Raised blood glucose levels may result in a large baby (macrosomia).
Good blood glucose control reduces the risk of this. If you need tablets and/or insulin treatment in addition to diet and weight management to treat your GDM, you will be given an appointment to see the Obstetrician.
What should I do if I can't meet the blood glucose target?
If you have two or more readings above your target it is **very important** to ring the Clinical Pharmacist **VineetaDhyani**
PH.NO +917204345879 and leave them a message asking them to call you back.
Will GDM go away after the pregnancy?
To make sure your blood glucose levels have returned to normal, you will have a fasting plasma blood glucose test 6 weeks after the birth of your baby. The test will be done at your General Practice (GP).
Will I have GDM in further pregnancies?
You will be treated as though you have GDM in all further pregnancies and you should contact the **Clinical Pharmacist- Vineeta Dhyani on Tel:+917204345879** when your pregnancy is confirmed.
What extra care will I need during pregnancy?
If you are diagnosed with gestational diabetes, you will be under the care of a specialist healthcare team and will be advised to have your baby in a consultant-led maternity unit that has a neonatal unit. Your healthcare team will usually include a doctor specializing in diabetes, an obstetrician, a specialist diabetes nurse, a specialist diabetes midwife and a dietician and Clinical Pharmacist.
You should start receiving extra antenatal care as soon as your gestational diabetes is diagnosed. Having gestational diabetes will mean more clinic visits at the hospital.

KLES
DR. PRABHAKAR KORE HOSPITAL
MEDICAL RESEARCH CENTRE
NEHRU NAGAR, BELGAUM-590010

KLE's Dr. Prabhakar Kore Hospital And MRC

GESTATIONAL DIABETES MELLITUS
(GDM)

Gestational Diabetes
High blood glucose levels in mother
Brings extra glucose to baby
Causes baby to put on extra weight

(Diabetes During Pregnancy)

DEPARTMENT OF PHARMACY PRACTICE
KLES Dr. Prabhakar Kore Hospital
& MRC, Nehru Nagar, Belagavi.
Tel: 2473777, ext.1768

1

Introduction

Now you have been diagnosed with Gestational Diabetes mellitus (GDM) this leaflet explains what GDM is, how it is treated and how it may affect your pregnancy.

What is GDM?

Gestational Diabetes mellitus (GDM) is a type of diabetes that occurs during pregnancy, usually during the second or third trimester of the pregnancy, when your body makes large amounts of hormones to help your baby grow. These hormones keep your insulin from working the way it should. When this happens, your blood sugar rises.

High blood sugar will cause your baby to grow large and make insulin. Don't worry–most women with gestational diabetes have healthy babies. Still, the gestational diabetes has to be treated until your baby is born. Keeping your blood sugar as near normal as possible will prevent problems for you and your baby.

Am I riskfor Gestational Diabetes?

- You could be at risk: you are >30 yrs old
- You are overweight/obese
- You have a family history of diabetes
- You have had a baby weighing over 9 kg
- You have had BOH-HT,eclampsia hydramnious
- You have had persistent Urinary Tract Infection
- You have earlier given birth to still born baby or with congenital anomaly.

How is GDM Diagnosed?

Women with one of the above risk factors have an Oral Glucose Tolerance Test at 24-26 weeks pregnant. This was the fasting blood test followed by a glucose drink and further blood test that you had done which has shown you have GDM.

2

Why do some women get gestational diabetes mellitus?

Usually, the body breaks down much of the food you eat into a type of sugar, called glucose. Because glucose moves from the stomach into blood, some people use the term blood sugar; instead of glucose your body makes a hormone called insulin that moves glucose out of the blood and into the body. The glucose cant get into the cells, so the amount of glucose in the blood gets higher and higher. This is called blood sugar or diabetes.

Is there a risk of the diabetes Developing?

You have a 50% risk of developing Type 2 Diabetes over the next 5 years and beyond. You can reduce the risk by:

- Being more physically active
- Trying to achieve a healthy weight
- Maintaining a healthy diet Your General Practitioner (GP) should check your fasting blood glucose level annually to see if you have developed Type 2 Diabetes. If this doesn't happen, you should contact your GP surgery and remind them that you need ablood test. If you are diagnosed with Type 2 diabetes, then you should be referred to a Diabetes Groupeducation session; please ask your practice nurse for more details.

What should I do if I have gestational diabetes mellitus?

If your health care provider tells you that you have gestational diabetes mellitus. You need to follow a treatment plan to keep the treatment under control. Most treatment plan includes knowing your blood sugar level. Eating a healthy Diet, getting regular physical activity.

3

Is there a risk of the diabetes Developing?

You have a 50% risk of developing Type 2 Diabetes over the next 5 years and beyond. You can reduce the risk by:

- Being more physically active
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- Maintaining a healthy diet Your General Practitioner (GP) should check your fasting blood glucose level annually to see if you have developed Type 2 Diabetes. If this doesn't happen, you should contact your GP surgery and remind them that you need ablood test. If you are diagnosed with Type 2 diabetes, then you should be referred to a Diabetes Groupeducation session; please ask your practice nurse for more details.

Will GDM effect how I deliver my baby?

GDM may affect when/how your baby is delivered. If you need treatment for your GDM the Obstetrician will discuss your baby delivery options with you.

Will my baby need any treatment after Delivery?

Sometimes the baby is born with a low blood glucose level in response to the mother's raised blood glucose levels. We may need to monitor your baby in the Special Care Baby Unit for a short period

what treatment will I receive for GDM?

You will be taught how to monitor your blood glucose levels by the Clinical Pharmacist and seen by the Diabetes Dietitian for a dietary assessment and you will be given advice on appropriate weight gain and diet in pregnancy.

You may need an additional treatment with insulin injections.

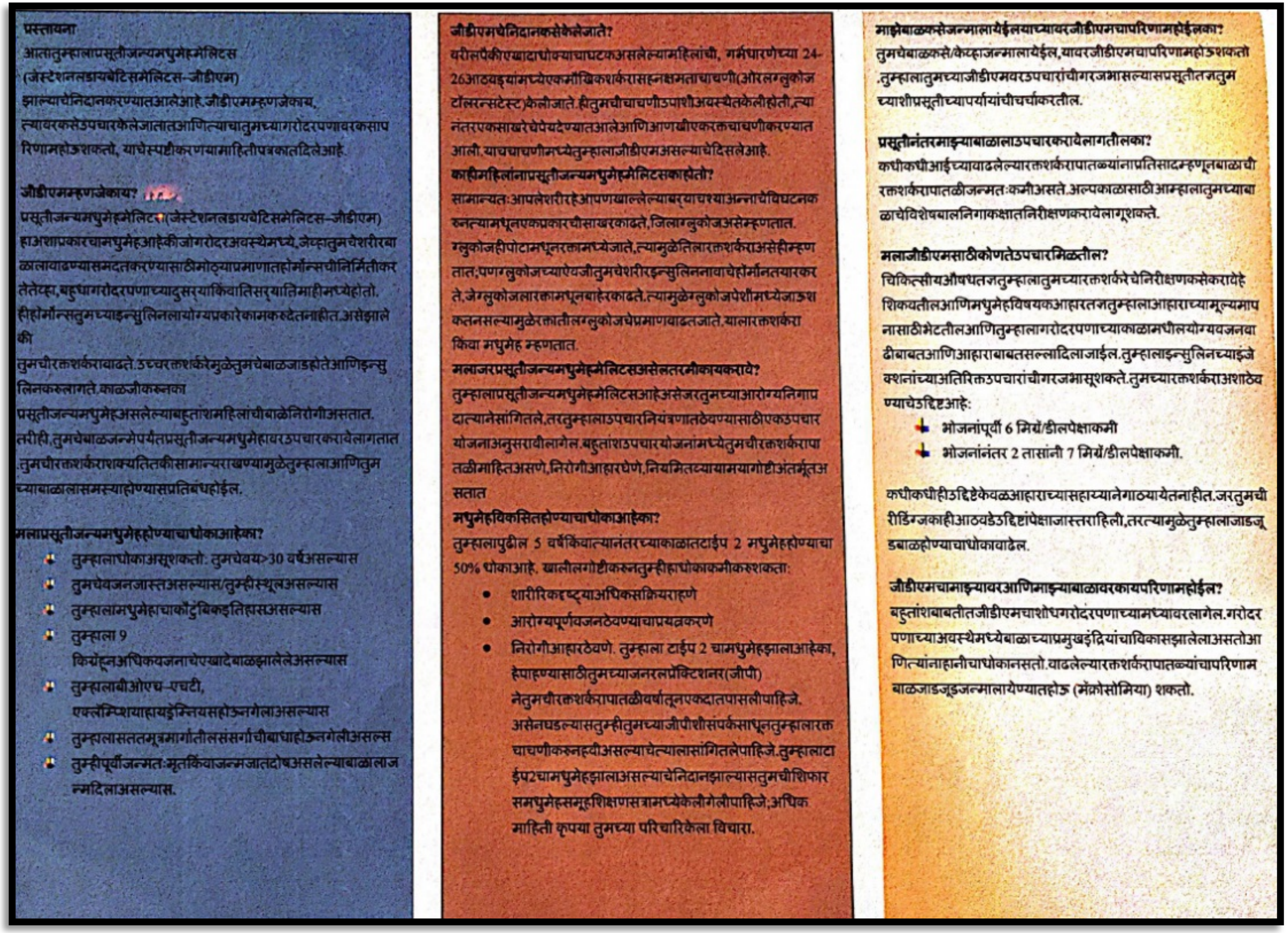
The target is for your blood glucose levels to be

- Less than 6 mg/dl before meals
- Less than 7mg/dl two hours after meals.

Sometimes these targets cannot be achieved by diet alone. If your readings are abovethe targets for a number of weeks, it will increase your risk of having a large baby.

4

PHEMPLET MARATHI



प्रस्तावना

आतातुम्हालाप्रसूतीजन्यमधुमेहमेलिटस
(जेस्टेशनलडायबेटिसमेलिटस–जीडीएम)
झाल्याचेनिदानकरण्यातआलेआहे.जीडीएमम्हणजेकाय,
त्यावरकसेउपचारकेलेजातातआणित्याचातुमच्यागरोदरपणावरकसाप
रिणामहोऊशकतो, याचेस्पष्टीकरणयामाहितीपत्रकातदिलेआहे.

जीडीएमम्हणजेकाय?

प्रसूतीजन्यमधुमेहमेलिटस(जेस्टेशनलडायबेटिसमेलिटस–जीडीएम)
हाअशाप्रकारचामधुमेहआहेकीजोगरोदरअवस्थेमध्ये,जेव्हातुमचेशरीरबा
ळालावाढण्यासमदतकरण्यासाठीमोठ्याप्रमाणातहोर्मोन्सचीनिर्मितीकर
तेतेव्हा,बहुधागरोदरपणाच्यादुसऱ्याकिंवातिसऱ्यातिमाहीमध्येहोतो.
हीहोर्मोन्सतुमच्याइन्सुलिनलायोग्यप्रकारेकामकरुदेतनाहीत.असेझाले
की
तुमचीरक्तशर्करावाढते.उच्चरक्तशर्करेमुळेतुमचेबाळजाडहोतेआणिइन्सु
लिनकरुलागते.काळजीकरुनका
प्रसूतीजन्यमधुमेहअसलेल्याबहुतांशमहिलांचीबाळेनिरोगीअसतात.
तरीही,तुमचेबाळजन्मेपर्यंतप्रसूतीजन्यमधुमेहावरउपचारकरावेलागतात
.तुमचीरक्तशर्कराशक्यतितकीसामान्यराखण्यामुळेतुम्हालाआणितुम
च्याबाळालासमस्याहोण्यासप्रतिबंधहोईल.

मलाप्रसूतीजन्यमधुमेहहोण्याचाधोकाआहेका?

- तुम्हालाधोकाअसूशकतो: तुमचेवय>30 वर्षेअसल्यास
- तुमचेवजनजास्तअसल्यास/तुम्हीस्थूलअसल्यास
- तुम्हालामधुमेहाचाकौटुंबिकइतिहासअसल्यास
- तुम्हाला 9 किग्रॅहूनअधिकवजनाचेएखादेबाळझालेलेअसल्यास
- तुम्हालाबीओएच–एचटी, एक्लॅम्पिशयाहायड्रॅम्नियसहोऊनगेलाअसल्यास
- तुम्हालासततमूत्रमार्गातीलसंसर्गाचीबाधाहोऊनगेलीअसल्स
- तुम्हीपूर्वीजन्मतःमृतकिंवाजन्मजातदोषअसलेल्याबाळालाज न्मदिलाअसल्यास.

जीडीएमचेनिदानकसेकेलेजाते?

यरीलपैकीएखादाधोक्याचाघटकअसलेल्यामहिलांची, गर्भधारणेच्या 24-
26आठवड्यांमध्येएकमौखिकशर्करासहनक्षमताचाचणी(ओरलग्लुकोज
टॉलरन्सटेस्ट)केलीजाते.हीतुमचीचाचणीउपाशीअवस्थेतकेलीहोती,त्या
नंतरएकसाखरेचेपेयदेण्यातआलेआणिआणखीएकरक्तचाचणीकरण्यात
आली.याचचाचणीमध्येतुम्हालाजीडीएमअसल्याचेदिसलेआहे.

काहीमहिलांनाप्रसूतीजन्यमधुमेहमेलिटसकाहोतो?

सामान्यतःआपलेशरीरहेआपणखाल्लेल्याबऱ्याचश्याअन्नाचेविघटनक
रुनत्यामधूनएकप्रकारचीसाखरकाढते,जिलाग्लुकोजअसेम्हणतात.
ग्लुकोजहीपोटामधूनरक्तामध्येजाते,त्यामुळेतिलारक्तशर्कराअसेहीम्हण
तात;पणग्लुकोजच्याऐवजीतुमचेशरीरइन्सुलिननावाचेहोर्मोनतयारकर
ते.जेग्लुकोजलारक्तामधूनबाहेरकाढते.त्यामुळेग्लुकोजपेशींमध्येजाऊश
कतनसल्यामुळेरक्तातीलग्लुकोजचेप्रमाणवाढतजाते.यालारक्तशर्करा
किंवा मधुमेह म्हणतात.

मलाजरप्रसूतीजन्यमधुमेहमेलिटसअसेलतरमीकायकरावे?

तुम्हालाप्रसूतीजन्यमधुमेहमेलिटसआहेअसेजरतुमच्याआरोग्यनिगाप्र
दात्यानेसांगितले,तरतुम्हालाउपचारनियंत्रणातठेवण्यासाठीएकउपचार
योजनाअनुसरावीलागेल.बहुतांशउपचारयोजनांमध्येतुमचीरक्तशर्करापा
तळीमाहितअसणे,निरोगीआहारघेणे,नियमितव्यायामयागोष्टीअंतर्भूतअ
सतात

मधुमेहविकसितहोण्याचाधोकाआहेका?

तुम्हालापुढील 5 वर्षेकिंवात्यानंतरच्याकाळातटाईप 2 मधुमेहहोण्याचा
50% धोकाआहे. खालीलगोष्टीकरुनतुम्हीहाधोकाकमीकरुशकता:

- शारीरिकदृष्ट्याअधिकसक्रियराहणे
- आरोग्यपूर्णवजनठेवण्याचाप्रयत्नकरणे
- निरोगीआहारठेवणे. तुम्हाला टाईप 2 चामधुमेहझालाआहेका, हेपाहण्यासाठीतुमच्याजनरलप्रॅक्टिशनर(जीपी) नेतुमचीरक्तशर्करापातळीवर्षातूनएकदातपासलीपाहिजे. असेनघडल्यासतुम्हीतुमच्याजीपीशीसंपर्कसाधूनतुम्हालारक्त चाचणीकरुनहवीअसल्याचेत्यालासांगितलेपाहिजे.तुम्हालाटा ईप2चामधुमेहझालाअसल्याचेनिदानझाल्यासतुमचीशिफार समधुमेहसमूहशिक्षणसत्रामध्येकेलीगेलीपाहिजे;अधिक माहिती कृपया तुमच्या परिचारिकेला विचारा.

माझेबाळकसेजन्मालायेईलयाच्यावरजीडीएमचापरिणामहोईलका?

तुमचेबाळकसे/केव्हाजन्मालायेईल,यावरजीडीएमचापरिणामहोऊशकतो
.तुम्हालातुमच्याजीडीएमवरउपचारांचीगरजभासल्यासप्रसूतीतज्ञतुम
च्याशीप्रसूतीच्यापर्यायांचीचर्चाकरतील.

प्रसूतीनंतरमाझ्याबाळालाउपचारकरावेलागतीलका?

कधीकधीआईच्यावाढलेल्यारक्तशर्करापातळ्यांनाप्रतिसादम्हणूनबाळाची
रक्तशर्करापातळीजन्मतःकमीअसते.अल्पकाळासाठीआम्हालातुमच्याबा
ळाचेविशेषबालनिगाकक्षातनिरीक्षणकरावेलागूशकते.

मलाजीडीएमसाठीकोणतेउपचारमिळतील?

चिकित्सीयऔषधतज्ञतुम्हालातुमच्यारक्तशर्करेचेनिरीक्षणकसेकरावेहे
शिकवतीलआणिमधुमेहविषयकआहारतज्ञतुम्हालाआहाराच्यामूल्यमाप
नासाठीभेटतीलआणितुम्हालागरोदरपणाच्याकाळामधीलयोग्यवजनवा
ढीबाबतआणिआहाराबाबतसल्लादिलाजाईल.तुम्हालाइन्सुलिनच्याइंजे
क्शनांच्याअतिरिक्तउपचारांचीगरजभासूशकते.तुमच्यारक्तशर्कराअशाठेव
ण्याचेउद्दिष्टआहे:

- भोजनांपूर्वी 6 मिमो/डीलपेक्षाकमी
- भोजनांनंतर 2 तासांनी 7 मिमो/डीलपेक्षाकमी.

कधीकधीहीउद्दिष्टेकेवळआहाराच्यासहाय्यानेगाठ्यायेतनाहीत.जरतुमची
रीडिंग्जकाहीआठवडेउद्दिष्टांपेक्षाजास्तराहिली,तरत्यामुळेतुम्हालाजाडजू
डबाळहोण्याचाधोकावाढेल.

जीडीएमचामाझ्यावरआणिमाझ्याबाळावरकायपरिणामहोईल?

बहुतांशबाबतीतजीडीएमचाशोधगरोदरपणाच्यामध्यावरलागेल.गरोदर
पणाच्याअवस्थेमध्येबाळाच्याप्रमुखइंद्रियांचाविकासझालेलाअसतोआ
णित्यांनाहानीचाधोकानसतो.वाढलेल्यारक्तशर्करापातळ्यांचापरिणाम
बाळजाडजूडजन्मालायेण्यातहोऊ (मॅक्रोसोमिया) शकतो.

ANNEXURE -XII

CERTIFICATE

KLEU's COLLEGE OF PHARMACY
BELGAUM

INDO – UK SYMPOSIUM

Certificate

This is to certify that Mr./Miss./Mrs./Dr./Prof. Vineeta Dhyani has participated as a Participant in "INDO – UK SYMPOSIUM ON RESEARCH PERSPECTIVES IN VASCULAR COMPLICATIONS OF DIABETES" held on 16th October 2012.

Prof [Dr.] F.V.Manvi
Dean Faculty of Pharmacy,
KLE University, Belgaum

Prof [Dr] A.D.Taranalli
Principal,
KLEU College of Pharmacy, Belgaum

International Conference on
Maternal and Newborn Health Research
– A KLE Centenary Event
March 5 - 6, 2016

This is to certify that Ms Vineeta Dhyani

Address ....KLEUs College of Pharmacy, Belgaum

has participated in the International Conference

held on March 5th - 6th , 2016 at KLE University's J N Medical College, Belgaum, Karnataka, INDIA.

CERTIFICATE

Dr M S Ganachari
Organising Secretary, ICMNHR 2016 &
Deputy Registrar,
KLE University, Belgaum

Dr (Mrs) M S Mahantashetti
Organising Chairman, ICMNHR 2016 &
Principal, KLE University's
J N Medical College, Belgaum

Dr Shivaprasad S Goudar
Convenor, ICMNHR 2016
Professor of Physiology & Research Coordinator
Women's and Children's Health Research Unit
J N Medical College, Belgaum

APPI National Seminar 2015

KLE University's

Accredited 'A' Grade by NAAC & placed in Category "A" by MHRD (GoI)

Jawaharlal Nehru Medical College, Belagavi

"Fighting the Obesity Epidemic – Need of the hour"

Organized by : The Association of Physiologists and Pharmacologists of India (APPI), Belgaum Branch

Sponsored by : Indian Council of Medical Research (ICMR), Medical Council of India (MCI)

Endorsed by : The Physiological Society of India (PSI), South Asian Association of Physiologists (SAAP)

This is to certify that Ms. Vineeta Dhyani

has participated as *DELEGATE / ~~ORGANIZING COMMITTEE MEMBER~~* in APPI National Seminar 2015 held on Saturday 29th August 2015 at J N Medical College, Belagavi.

Karnataka Medical Council has granted "TWO (02) Credit Hours" for his/her participation Vide Letter No. K.M.C./C.M.E./511/2015 dated 27-06-2015.

CERTIFICATE

Dr. (Mrs) N. S. Mahantshetti	Dr. M.S. Ganachari	Dr. Seema V Kamaraddi	Dr. Uma B. R.
Principal, JNMC, Belagavi	Organizing Chairman	Organizing Secretary	Zonal Chairman KMC-CME Accreditation Committee

KLE UNIVERSITY
EMPOWERING PROFESSIONALS

CERTIFICATE

(Formerly known as KLE Academy of Higher Education & Research, Belgaum)
(Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Placed in Category 'A' by MHRD, Govt. of India
Nehru Nagar, Belgaum - 590 010, Karnataka State, India
Ph. : 0831-2444444 FAX : 0831-2493777 Web: http://www.kleuniversity.edu.in E-mail: info@kleuniversity.edu.in

UNIVERSITY DEPARTMENT OF EDUCATION FOR HEALTH PROFESSIONALS

This is to certify that

Dr./Mr./Mrs. VINEETA - DHYANI

has participated in the Workshop entitled

SPSS 22, Research Methodology and Biostatistics

on _____ organised by KLE UNIVERSITY

DEPARTMENT OF EPI. BIOSTATISTICS as a Delegate / ~~Resource Person~~.

Dr. JYOTI NAGMOTI
DIRECTOR, UDEHP

Dr. V. D. PATIL
REGISTRAR

ADVANCED ACADEMIC TRAINING PROGRAMME IN PHARMACY PRACTICE

KLE UNIVERSITY

KLES

December 2015

CERTIFICATE

This is to certify that Mr./Miss./Mrs./Dr./Prof. VINEETA DHYANI has participated as Delegate/faculty in "Advanced Academic Training programme in Pharmacy Practice" held from 8th to 12th December 2015 at KLEU's College of Pharmacy, Belagavi.

Prof. (Dr.) V.P. Rasal
Principal
(Chief Co-ordinator)

Prof. (Dr.) M. S. Ganachari
Head - Dept. of Pharmacy Practic
(Programme Co-ordinator)

Department of Pharmacy Practice
KLEU's College of Pharmacy, Belgaum

RESEARCH SOCIETY FOR THE STUDY OF DIABETES IN INDIA
RSSDI
KARNATAKA CHAPTER

11th Annual Conclave of
Research Society for the Study of Diabetes in India
Karnataka Chapter KRSSDI Belagavi-2015

This is to certify that

Dr.Vineeta Dhyani

bearing Registration No. ..... Registered with Karnataka *Medical Council from* Belagavi *has participated as Delegate in*

11th Annual Conclave of Research Society for the Study of Diabetes in India, Karnataka Chapter KRSSDI Belagavi-2015 held on 19th & 20th December 2015, at KLE Centenary Convention Centre, Belagavi.

Karnataka Medical Council has granted **FOUR (04)** Credit Hours for this CME
Vide Letter No. K.M.C./ C.M.E./ 1013/ 2015, dated : 21-11-2015

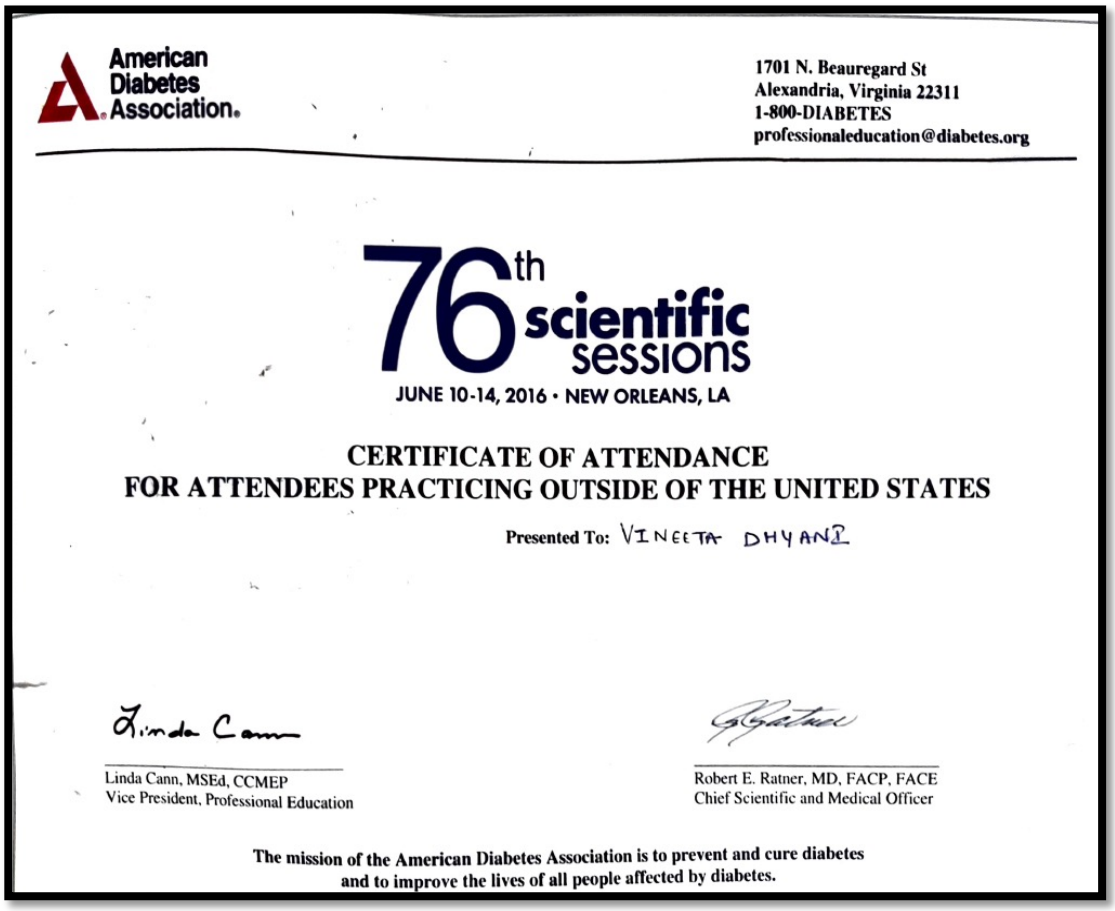
Dr. K. R. Narasimha Setty
Chairman, RSSDI
Karnataka Chapter

Dr. Uma B. R.
KMC-CME Zonal Chairman
Karnataka

Dr. M. V. Jali
Organizing Chairman
KRSSDI Belagavi-2015

Dr. V. A. Kothiwale
Organizing Secretary
KRSSDI Belagavi-2015

Dr. R. B. Nerli
Chairman, Scientific Committee,
KRSSDI Belagavi-2015



American Diabetes Association.

1701 N. Beauregard St
Alexandria, Virginia 22311
1-800-DIABETES
professionaleducation@diabetes.org

76th scientific sessions

JUNE 10-14, 2016 • NEW ORLEANS, LA

CERTIFICATE OF ATTENDANCE
FOR ATTENDEES PRACTICING OUTSIDE OF THE UNITED STATES

Presented To: VINEETA DHYANI

Linda Cann

Linda Cann, MSEd, CCMEP
Vice President, Professional Education

Robert E. Ratner, MD, FACP, FACE
Chief Scientific and Medical Officer

The mission of the American Diabetes Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

ANNEXURE –XIII

PHOTOGRAPHS

Photograph 1: Patient Counseling

Photograph:2 Health Education : GDM

Photograph: 3 Paatient Demographics