Available online on 15.03.2019 at http://jddtonline.info

Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

Drug utilization pattern of gestational diabetes mellitus in pregnant women and complication of gestational diabetes mellitus in mother and newborn in a secondary care hospital: A retrospective study

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ABSTRACT

The present study was a retrospective study, carried out by total of 100 cases in the Obstetric And Gynaecology department of a secondary care hospital, Tiruppur, Tamil Nadu. There were 100 pregnant women who had gestational diabetes. Increasing gravida (secondary gravida G_2 -44%) shows more prevalence of GDM than primi (34%).Body Mass Index , family history of diabetes and previous history of GDM shows more significance in occurring GDM. Among 100 population, 45% patients receiving insulin with medical nutritional therapy (MNT) ,30% patients receiving medical nutritional therapy (MNT) alone , 11% patients receiving medical nutritional therapy (MNT) with metformin, 3% patients receiving medical nutritional therapy (MNT) with Oral Hypoglycaemic Agents (OHA) and insulin , 3% patients receiving insulin alone and 8% patients didn't receiving any therapy. Overall 96% of women with GDM had one or more complications and 4% had no complication. From this , 35.89% patients shows caesarean delivery with recurrent GDM, followed by 10.25% patients shows caesarean delivery with polyhydramnios, 15.38% patients shows caesarean delivery with Pregnancy Induced Hypertension (PIH).Overall 74% of new-borns had one or more complications and 27% had no complication. 24.32% patients shows macrosomia with neonatal hypoglycaemia, 16.21% patients shows macrosomia with preterm birth, 13.52% patients shows macrosomia with hyperbilirubinemia. Our study concludes that the complications arise from GDM to both mother and new-borns can be resolved and minimised by proper diagnosis and appropriate treatment during the pregnancy.

Keywords: Gestational Diabetes Mellitus, Drug Utilization Pattern, Complications, Oral Glucose Tolerence Test

Article Info: Received 08 Feb 2019; Review Completed 27 Feb 2019; Accepted 28 Feb 2019; Available online 15 March 2019

Cite this article as:

Ganesan V, Junitha R, Nino Mariyam A, Drug utilization pattern of gestational diabetes mellitus in pregnant women and complication of gestational diabetes mellitus in mother and newborn in a secondary care hospital: A retrospective study, Journal of Drug Delivery and Therapeutics. 2019; 9(2):86-92 **http://dx.doi.org/10.22270/jddt.v9i2.2438**

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INTRODUCTION

GDM is a condition of elevated blood glucose level generally detected during pregnancy and become normal soon-after delivery, resulting with immediate and long-term effects to both mother and child. It usually begins during the 24th week of pregnancy as a consequence of the body's inability to make and use all the insulin it needs during the gestation period . Gestational diabetes mellitus can have significant impact on birth outcomes, especially babies having macrosomia [1]. According to the Centres for Disease Control and Prevention [CDC] (2011), there is a higher prevalence of gestational diabetes mellitus among African Americans, Hispanic/Latino American, and American Indians than other ethnicities. Also, the age-adjusted incidence for gestational diabetes among all races and ethnicities increases with the body mass index [2].

The prevalence rate of GDM in reproductive age women is similar to the rate of impaired glucose tolerance in the general population. Over the next 2-3 decades 80 million women in the reproductive age will be affected by diabetes in the world. Twenty million women expected to be affected in India. Ethnically Indian women are considered more risks to develop diabetes and the relative risk of developing diabetes mellitus in Indian women are 11.3 times more compared to western countries women [3] .The prevalence is high across the Asian countries and studies about perinatal consequences of these diseases are important from these countries [4] . Screening is usually carried out around 24 – 28 weeks of gestational age. But GDM can manifest at any stage of pregnancy. The factors that can influence the pregnant women to develop GDM in all trimesters include age, Body Mass Index (BMI) , positive family history of diabetes, previous history of GDM, multiparity and irregular menstrual history[5] . Indeed the hyperglycaemia resolves in postpartum it causes caesarean delivery, preterm delivery Macrosomia, hyperbilirubinemia, hypoglycaemia, shoulder dystocia and respiratory distress syndrome. GDM affects

mother as well as their child, at the age of 5 years, offspring of GDM mothers are larger and have transformed glucose metabolism compared to offspring of non GDM mothers[6]. The prevalence of childhood type-2 diabetes for past 30 years is attributable to increasing exposure to maternal diabetes during pregnancy [7]. Women with GDM are at increased risk and it may lead to have preeclampsia and cardiovascular complications[8,9]. In long term, GDM women are more prone (20 – 50%) to develop type 2 diabetes mellitus in five years after delivery[10].

Gestational diabetes mellitus has significant impact on birth outcomes. Children who are born to mothers with gestational diabetes mellitus are likely to have health-related complications later in life and are at risk of infant death[11]. Nearly all infants born to gestational diabetes mothers are at risk of developing macrosomia[12]. Gestational diabetes mellitus has significantly been linked with complication during pregnancy period such as high caesarean sections, preeclampsia, and urinary tract infection in both neonate and the mother[13]. Women who have had gestational diabetes mellitus during their first pregnancy are at higher risk of developing gestational diabetes in their subsequent pregnancies. Also, evidence suggests that 30 to 50 percent of women diagnosed with gestational diabetes mellitus will go on to develop type 2 diabetes mellitus in future[14]. The long-term consequences of gestational diabetes mellitus is the risk of developing cardiovascular disease, hypertension and stoke if left on treated [15]. There is a significant link with macrosomia, neonatal hypoglycaemia, and jaundice. In infant, the most common birth outcome caused by gestational diabetes mellitus is macrosomia[16,17,18,19]. This is an excessive weight gain of the foetus due to gestational diabetes mellitus[20]. The children of mothers who developed gestational diabetes mellitus during pregnancy are at higher risk of obesity and type 2 diabetes mellitus in the future[21].

Diet and exercise are important elements in the treatment of GDM. Insulin and certain oral hypoglycaemic drugs can be used, separately or combined, to achieve normoglycemia[22,23]. Oral anti-diabetic drugs are not recommended to treat GDM since these drugs are causing potential teratogenicity and cross the placenta resulting with neonatal hyperinsulinism and Hypoglycaemia[24,25].

In conclusion, gestational diabetes mellitus has many consequences for both the mothers and the babies. Primary prevention such as preventing obesity before pregnancy, maintain a healthy diet, and counselling are needed before a woman gets pregnant. Secondary prevention such as screening for gestational diabetes mellitus should be done to expected mothers. This will help to further guide expected mothers to improve their nutrition exercise, and reduce weight among mothers who are at risk. Finally, urgent care is need for those mothers who are diagnosed with gestational diabetes in order to reduce complications for both the mothers and the neonates

METHOD

A retrospective study was conducted at department of OBG in 500 bedded tertiary care hospital Trippur India for a period of one and half year (nov 2016-may 2018). The study protocol was review and formally approved by ethical committee. A total 100 participate attending the antenatal clinic were included in the study. We screened pregnant women who had risk factor for gestational diabetes including age 47% patient in 20-25 year, recurrent GDM 68%, BMI (52%), caesarean (85.8%, PIH(7.6%) and hypoglycaemia (24.32%) macrosomia (13.52%), hyperbilirubinemia (13.52%) in neonate. In this study relates to the complication of neonates and mother with treatment schedule. In patient women including those having medical history of hypertension , diabetes mellitus , asthma, family history of diabetes, history of PCOS, where included in the study .Pregnant women on anti-retroviral therapy (ART), pregnant women without diabetes were excluded.

Initial screening was done by a glucose challenge test with 50g glucose. If the 1-hour blood glucose level exceeds 130mg/dl, then a 3- hour oral glucose tolerance test (OGTT) with100g glucose was performed and diagnosis was established according to WHO criteria for screening of GDM and American Diabetes Association criteria. The following are the values which the American Diabetes Association considers to be abnormal during the 100g OGTT;{Fasting plasma glucose level>105mg/dl(5.8mmol/L), 1hr plasma glucose level>190mg/dl (10.6mmol/L), 2hr plasma glucose level >165mg/dl (9.2mmol/L) and 3hr plasma glucose level >145mg/dl (8mmol/L).Women with elevated fasting values at the time of the three-hour oral glucose -tolerance test were immediately started on insulin therapy. Data was statistically analysed using Microsoft excel with statistical package. Qualitative data were expressed as percentage of patient.

RESULT

Age Wise Classification

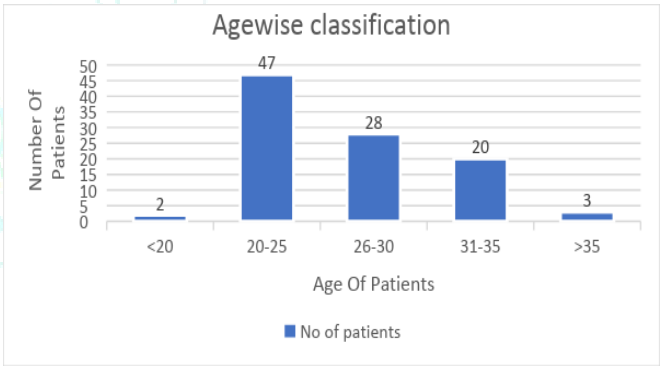

Figure 1: Age wise distribution of patients (n=100)

Menstrual history wise classification

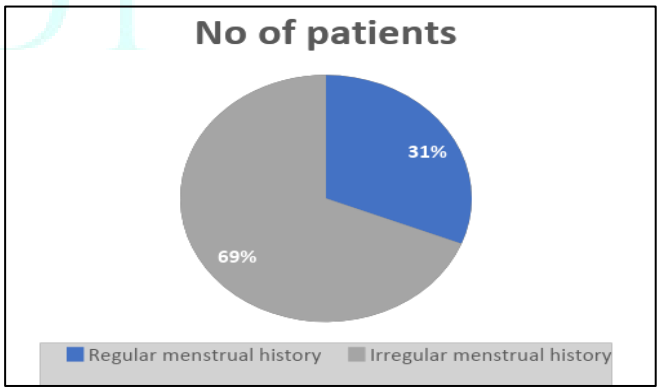

Figure 2: Menstrual history wise distribution of patients (n=100)

Family history wise distribution

Table 1: Family history wise distribution of patients (n=100)

Family background	No of patients	% of patients
Father With DM	8	8%
Mother With DM	5	5%
Not Known	87	87%

Obstetric History

Table 2: Obstetric history wise distribution

Obstetric history	No of patients	% of patients
G1	34	34%
G2	44	44%
G3	13	13%
G4	3	3%
G5	3	3%
>G5	3	3%

Aborted History

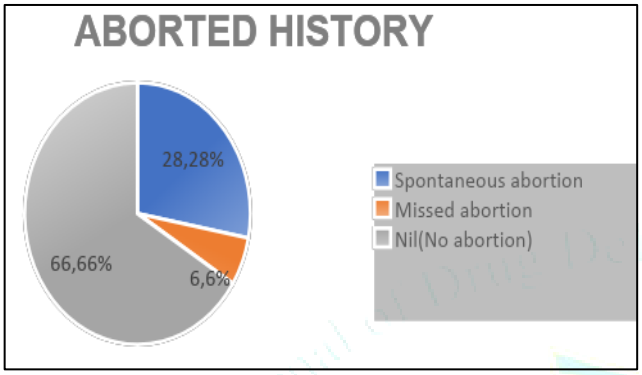

Figure 3: Abortion history wise classification of patients (n=100)

BMI ratio of patients

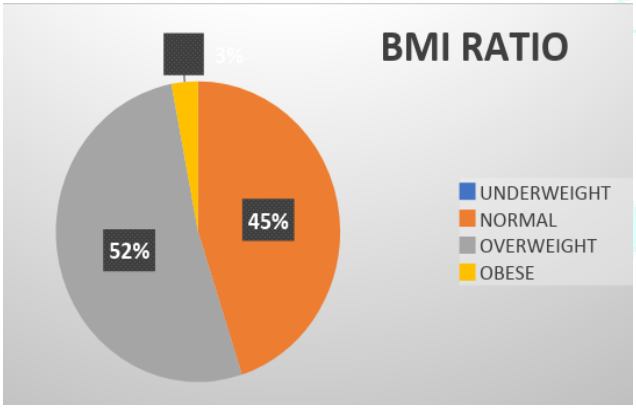

Figure 4: BMI ratio wise distribution of patients (n=10)

Trimester of pregnancy which the GDM occurs

Table 3: Patient data distribution on the basis of trimester which GDM occurs

Trimester	No of patients	% of patients
1st	3	3%
2nd	46	46%
3rd	36	36%
No Information	15	15

Mode of delivery

Table 4: Mode of delivery

Mode of delivery	No of patients	% of patients
Carrying	26	26%
Caesarean Section	60	60%
Assisted Vaginal Delivery	9	9%
Normal Vaginal Delivery	1	1%
Abortion/Intrauterine Death/Still Birth	4	4%

Screening of GDM

Table 5: Screening of GDM

Screening of GDM	No of patients	% of patients
Preliminary Tests (RBS,FBS,PPBS)	99	99%
Pre Test (GCT)	68	68%
OGTT	26	26%
No Test	1	1%

Treatment Plan

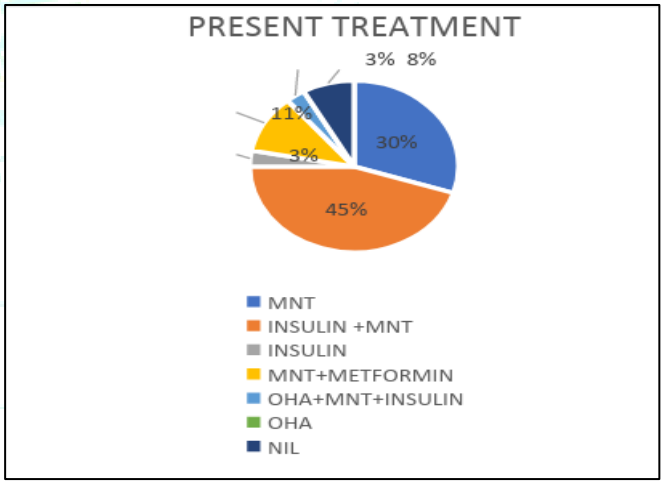

Figure 5: Current Treatment Plan

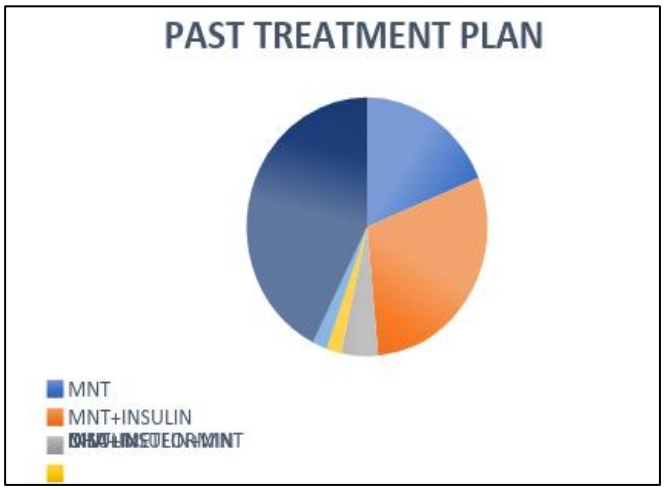

Figure 6: Past Treatment Plan

Maternal Complications

Table 6: Maternal Complication

Complications	No of patients	% of patients
Nil complication	4	4%
1 complication	30	30%
2 complication	39	39%
3 complication	24	24%
4 complication	3	3%

Neonatal Complications

Table 7: Neonatal Complication

Complication	No of patients	% of patients
No complications	27	27%
1 complication	34	34%
2 complication	37	37%
3 complication	2	2%

Two Complication Occurs-Maternal

Table 8: Two Complication occur -Maternal

Complications	No of patients	% of patients
LSCS+RECURRENT GDM	14	35.89%
LSCS+POLYHYDRAMINOSIS	4	10.25%
LSCS+PIH	6	15.38%
LSCS+ABORTION	1	2.56%
LSCS+UTI	1	2.56%
LSCS+PROM	3	7.69%
LSCS+PROTEINURIA	1	2.56%
MISCARRAGE+RECURRENT GDM	1	2.56%
ABORTION +AVD	1	2.56%
POLYHYDRAMINOSIS+MISCARRAGE	1	2.56%
UTI+ABORTION	1	2.56%
PIH+AVD	1	2.56%
PIH+UTI	1	2.56%
PIH+PROTEINURIA	1	2.56%
UTI+POLYHYDRAMINOSIS	1	2.56%
PIH+RECURRENT GDM	1	2.56%

TWO COMPLICATION OCCURS – NEONATAL

Table 9: Two Complication occurs-Neonatal

Complications	No of patients	% of patients
Macrosomia +neonatal hypoglycemia	9	24.32%
Macrosomia+infection	3	8.10%
Macrosomia +preterm birth	6	16.21%
Macrosomia +hyperbilirubinemia	5	13.52%
Macrosomia+respiratory distress	4	10.81%
Macrosomia+jaundice	1	2.70%
Hypoglycemia +preterm birth	2	5.40%
Hypoglycemia+hyperbilirubenemia	2	5.40%
Respiratory distress +preterm birth	2	5.40%
Respiratory distress +jaundice	1	2.70%
Preterm birth +hyperbilirubenemia	1	2.70%
Perinatal mortality+macrosomia	1	2.70%

COMPLICATION IN MOTHER WITH TREATMENT SCHEDULE

Table 10: Complication in mother with treatment schedule

Maternal complications	Nonpharmacological + Pharmacological	Non pharmacological
Caesarean	8.21%	21.53%
PIH	6%	11%
Preeclampsia	1.02%	0.51%
PROM	1.53%	2.05%
Hypoglycaemia	0.51%	0.51%
Ketoacidosis	0%	0%
Increased proteinuria	1.02%	1.02%
Miscarriage/abortion	2.05%	5.12%
Polyhydramnios	1.02%	5.64%
Shoulder dystocia	0%	0%
Assisted vaginal delivery	4.10%	1.02%
Future type 2 DM /Recurrent DM	2.05%	15.86%
UTI	1.53%	5.12%

COMPLICATION WITH TREATMENT IN NEWBORN

Table 11: Complication with treatment in new born

Neonatal complications	Pharmacological	Non pharmacological	Nonpharmacological + Pharmacological
Congenital abnormalities	0%	0%	0%
Neonatal hypoglycaemia	6.03%	12.06%	0.86%
Macrosomia	9.48%	27.58%	0.86%
Neonatal mortality	0.86%	2.58%	0.86%
Birth trauma	0%	0%	0%
Still birth	1%	0%	0.00%
Preterm birth	5.17%	11.20%	0%
Infection	0.86%	1.72%	0%
Jaundice	2.58%	0%	0%
Hyperbilirubinemia	1.72%	6.03%	0%
Respiratory distress	4.31%	4.31%	0%

DISCUSSION

Drug Utilization study is being conducted widely and it is been carried out in different heath care sectors. Such studies are helpful to determine the behaviour of the use of medicines in a society. A survey based on prescription is considered to be one of the most effective methods to determine the prescribing approach of physicians. A study conducted by Caitlin A et al with a large sample size concluded that the additional investigation is mandatory during Anti Diabetic drug use in pregnancy for safety and efficacy of such drugs on maternal outcomes [26] .The present study is an attempt to study and evaluate the drug utilization pattern of Gestational Diabetes Mellitus in pregnant women and complication of Gestational Diabetes Mellitus in mother and new born in secondary care hospital. A total number of 100 patients case sheet were analysed during one year and 6 months on the secondary care hospital Tirupur, Tamil Nadu, India from November 2017 To August 2018.

The present study aims to the drug utilisation pattern of Gestational Diabetes Mellitus, so that it found that out of 100 patients the current therapy follows as 45% patients receiving insulin with medical nutritional therapy (MNT) , followed by 30% patients receiving medical nutritional therapy (MNT) alone , 11% patients receiving medical nutritional therapy (MNT) with metformin, 3% patients receiving medical nutritional therapy (MNT) with Oral Hypoglycaemic Agents (OHA) and insulin , 3% patients receiving insulin alone and 8% patients didn't receiving any therapy. And past therapy follow as follows as 30% patients receiving insulin with medical nutritional therapy (MNT), followed by 19% patients receiving medical nutritional therapy (MNT) alone, 5% patients receiving insulin alone, 2% patients receiving medical nutritional therapy (MNT) with metformin, 2% patients receiving medical nutritional therapy (MNT) with Oral Hypoglycaemic Agents (OHA) and insulin and 43% patients didn't receiving any therapy. The present study shows that the drugs are prescribed according to the National Institute Of Challenge And Excellence (NICE) guidelines, Indian national guidelines management for GDM and GDM management according to Tamil Nadu health care and welfare committee. The patients receiving other drugs for the conditions other than are 26 patients receiving labetalol for pregnancy induced hypertension (PIH), 4 patients receiving etroxin for hypothyroidism, 4 patients receiving magnesium sulphate regimen for Pregnancy Induced Hypertension and 66 patients doesn't receive any other medications.

In age group classification, there were 47% patients in the age group 20-25 years being the largest age group affected, followed by 28% in the age group 26-30, 20% in the age group 31-35, 3% in the age group greater than 35 and 2% in the age group less than 20%. Advancing age is considered to be a main risk factor for GDM. By the menstrual history wise classification 69% patients have regular menstrual history and 31% have irregular menstrual history. Among the population, the family history distribution observed that group with history of DM on father about 8% patients and mother about 5% and not known cases are of 87%. Among the 100 patients observed that secondary gravida G_2 shows more prevalence of 44%, followed by 34% primi G_1 (first pregnancy), G_3-13% and 3% on both G_4,G_5 and greater than G_5 group. It was found that 66% patients had no history of abortion, 28% patients had history of spontaneous abortion, and 6% patients had history of missed abortion cases. The high prevalence of history of miscarriage and abortion because these are one of the major maternal complication of the GDM patients. Out of 100 cases of pregnant women having gestational diabetes mellitus, 68% patients having newly diagnosed GDM and 32% of patients have been observed with recurrent GDM. A previous study reported that the of the risk factors reviewed Age, BMI, and prior history of GDM were the predictive factor for GDM in the current pregnancy[27]. As regard to the Body Mass Ratio (BMI),the present study report that GDM was found to be significantly more prevalence among women with BMI ratio 25-30 kg/m^{2}patients of about 52%, followed by 45% of prevalence in normal body mass index and greater than 30 kg/m^2 patients are of 3% . Increase in the body mass index ratio had a great influence on the occurrence of gestational diabetes mellitus. Of the among population, the women diagnosed GDM in her second trimester is high 46% patients, followed by 36% in the third trimester and 3% patient were diagnosed in the first trimester. As the studies states, the probability of GDM occurs proportional to the increase in the trimester. More probability of occurring GDM was after half of the second trimester. 15% patients didn't have information about the trimester which the GDM occurs or diagnosed. Faezch kians et al reported that approximately 40% of pregnancy diabetes cases will turn into diabetes over

the coming years and controlling the risk factors can reduce the incidence of diabetes in pregnancy[28].

In this present study, 74 cases are delivered and 26 cases are carrying. Out of 74 cases the mode of delivery are assign to be 85.8% patients with caesarean, 12.3% patients with assisted vaginal deliveries and 1.45% patients with normal vaginal deliveries and 5.7% patients meet up with abortion. The screening test of GDM divides into preliminary test comprises of RBS,PPBS,FBS,Pre test as Glucose Challenge Test (GCT) And Oral Glucose Tolerance Test (OGTT) This study observed that 99% patients undergoes screening tests and 1% patient didn't have any screening tests. Among these 68 patients undergoes pre test ie, Glucose Tolerance Test (GCT) and 26 patients were undergoes Oral Glucose Tolerance Test (OGTT). These diagnostic criteria compliance with WHO diagnostic criteria for screening of GDM. A earlier study reported the necessity of observation and quantification of maternal outcome with GDM and thus proper measures were taken to reduce the complications during delivery and the neonatal period[29] . Also this present study aims to the complication of GDM in mother and new born. Overall, 96% of women with GDM had one or more complications and 4% had no complication. As showed in table and figure 39% patients had 2 number of complications , followed by 30% patients had one complication, 24% patients had 3 number of complications and 3% had 4 number of complications. It found that two complication was of higher prevalence and among 39 patients, 35.89% patients shows caesarean delivery with recurrent GDM, followed by 10.25% patients shows caesarean delivery with polyhydramnios, 15.38% patients shows caesarean delivery with PIH, 7.69% patients shows caesarean delivery with premature rupture of membrane (PROM), 2.56% patient shows caesarean delivery with abortion, 2.56% patient shows caesarean delivery with proteinuria, 2.56% patient shows miscarriage and recurrent GDM, 2.56% patient shows polyhydramnios with miscarriage,2.56% patient shows UTI with abortion, 2.56% patient shows PIH with Assisted Vaginal Delivery (AVD), 2.56% patient shows PIH with UTI, 2.56% patient shows PIH with proteinuria, 2.56% patient shows UTI with polyhydramnios . Overall 74% of new born had one or more complications and 27% had no complication. As showed in table and figure 37% patients had 2 number of complications , followed by 34% patients had one complication, and 2% patients had 3 number of complications. It found that two complication is of higher prevalence and among 37 patients, 24.32% patients shows macrosomia with neonatal hypoglycaemia, followed by 8.10% patients shows macrosomia with infection, 16.21% patients shows macrosomia with preterm birth, 13.52% patients shows macrosomia with hyperbilirubinemia, 10.81% patients shows macrosomia with respiratory distress, 5.40% patients shows hypoglycaemia with preterm birth, 5.40% patients shows hypoglycaemia with hyperbilirubinemia, 5.40% patients shows respiratory distress with preterm birth, 2.70% patient shows macrosomia with jaundice, 2.70% patient shows respiratory distress with jaundice, 2.70% patient shows preterm birth with hyperbilirubinemia, 2.70% patient shows perinatal mortality with macrosomia. Linder K Schleger et al conducted a study and reported that foetal macrosomia was a common adverse infant outcome of GDM if unrecognised and untreated in time[30].

When neonatal complication compares with current drug therapy, the results shows that in neonatal hypoglycaemia, the higher prevalence shown in non pharmacological treatment is about 12.06%, followed by pharmacological treatment about 6.03% and lesser is 0.86% in non pharmacological with pharmacological treatment. In macrosomia, the higher prevalence shown in non pharmacological treatment was about 27.58%, followed by pharmacological treatment about 9.48% and lesser was 0.86% in non pharmacological with pharmacological treatment. Neonatal mortality, the higher prevalence shown in non pharmacological treatment is about 2.58%, followed by 0.86% in both pharmacological treatment and non pharmacological with pharmacological treatment. Still birth is shown in pharmacological treatment about 1%. The higher prevalence of preterm birth shown in non pharmacological treatment is about 11.20%, followed by pharmacological treatment about 5.17%. The higher prevalence of infection shown in non pharmacological treatment is about 1.72%, followed by pharmacological treatment about 0.86%. Other major neonatal complication such as jaundice and hyperbilirubinemia shown higher in the newborns of about 0% and 6.03% in non pharmacological treatment and 2.58% and 1.72% in pharmacological treatment. The prevalence of respiratory distress is about 4.31% in both non pharmacological and pharmacological treatment. There was no congenital abnormalities among the neonates should be observed.

In this present study compares the maternal complication with treatment, it observed that the complication caesarean delivery was higher in non pharmacological treatment about 21.53%, followed by non pharmacological with pharmacological treatment about 8.21% and lesser in pharmacological therapy about 0.51%. Also Assisted Vaginal Delivery (AVD) is high in non pharmacological with pharmacological treatment about 4.10%, followed by non pharmacological treatment of about 1.02%. PIH observes was higher in non-pharmacological treatment about 11% ,followed by non pharmacological with pharmacological treatment about 6% and lesser in pharmacological therapy about 1%.Preelampsia was higher in non pharmacological with pharmacological treatment about 1.02% ,followed by non pharmacological treatment with about 0.51% and lesser in pharmacological therapy about 0%.PROM was higher in non pharmacological treatment about 2.05% ,followed by non pharmacological with pharmacological treatment about 1.53% and lesser in pharmacological therapy about 0%. The prevalence of complication hypoglycaemia was 0.51% in both pharmacological with non pharmacological and non pharmacological treatment schedule. There is no ketoacidosis and shoulder dystocia observed in the patients. The prevalence of complication increased proteinuria was 1.02% in both pharmacological with non pharmacological and non pharmacological treatment schedule. Maternal complication miscarriage and abortion is higher in non pharmacological treatment about 5.12%, followed by non pharmacological with pharmacological treatment about 2.05% and lesser in pharmacological therapy about 1.0%. The UTI was higher in non pharmacological treatment about 5.12%, followed by non pharmacological with pharmacological treatment about 1.53%. The chance of Future type 2 DM or recurrent DM was 15.86 in non pharmacological treatment, followed by2.05% in non pharmacological treatment with pharmacological treatment. Caroline A et al study found that treatment of GDM in the form non pharmacological and insulin therapy for controlling glycaemic level and results the reduction of caesarean delivery rate[31].

CONCLUSION

The present study concludes that the our study site (secondary care hospital) follows the drug utilisation pattern according to the guidelines of NICE (National Institute of Challenge And Excellence) for management of GDM, Indian

National Guidelines For Management Of GDM and Guidelines For GDM by Tamil Nadu Health Care And Welfare. GDM shows formidable treat to both mother and children. The treatment schedule consist of first line therapy as MNT (Medical Nutritional Therapy) ie Non pharmacological therapy, then MNT with insulin (Non pharmacological with pharmacological), followed by MNT with insulin and metformin (OHA) or MNT with metformin. But in some cases only pharmacological therapy is prescribed alone as insulin. The screening criteria for GDM were conducted in the hospital, as per the WHO criteria for screening and diagnosis of GDM. The GDM shows complication in both mother and new born. In that caesarean delivery, chance of future diabetes mellitus or recurrent GDM, Pregnancy Induced Hypertension, miscarriage / abortion, Premature Rupture Of Membrane, chance of getting infections etc for mother and neonatal hypoglycaemia, macrosomia, respiratory distress, hyperbilirubinemia, jaundice, septic attack, chance of having type 2 DM on future. On comparing treatments with complications of GDM it was found to be, the prescribing pattern of pharmacological with nonpharmacological treatment shows safe and effective than other prescription contains pharmacological or non pharmacological treatment alone. Controlling risk factors and screening for early detection are mandatory for better maternal and foetal health.

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