

## Reduction of Risk on Newly Detected Gestational Diabetes Mellitus by Multi Model Intervention- A Hospital Based Study

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### ABSTRACT

Gestational diabetes mellitus is one of the most common complications of pregnancy, and it is associated with significant maternal and fetal morbidity. GDM can be controlled by the multi model intervention which is the holy grail of health care. It is the key to patient adherence – a prerequisite to achieve better outcomes. It is easy to recognize an engaged patient – they do what their health care providers recommends ...what their health care team knows what is right for them. The aim of the present study was to evaluate the effectiveness of patient engagement package on glycemic control in Gestational Diabetes Mellitus. Prospective interventional study was conducted at a Government Hospital, Tambaram. Antenatal mothers (n = 212) with GDM were randomized into study group (n = 104) and Control groups (n = 108). Power analysis and nonprobability-purposive sampling technique were applied to analyze sample size and sample selection, respectively. Quasi-experimental time-series design was adopted. The study group received patient engagement package which includes Counseling on diet, exercises, and regular monitoring of blood glucose level, Insulin therapy based on the blood glucose level and regular dose of Iron, folic acid and Calcium tablets and adjunct therapy as Yoga which includes Yogic sukshma vyayama(20 -25 mts), Nadishodana pranayama(5-10 mts) and Dhyanam(5 mts).They were instructed to follow up the visits regularly in the antenatal outpatient department.The Control group (n = 108) received only the standard care. Fasting and postprandial blood glucose levels were continuously monitored from 24<sup>th</sup> week to till delivery. At 24<sup>th</sup> week statistically no significant difference was found between mean and standard deviation of blood glucose level of Gestational Diabetes Mellitus in study group and control group (  $t=0.29$   $p=0.76$  ).Statistically positive improvement was found between study group and control group in the post test which was done at 28<sup>th</sup>,32 and 36<sup>th</sup> week and the “t” values were respectively  $t=3.41$   $p=0.001^{***}$ ,  $t=4.82$   $p=0.001^{***}$ ,  $t=6.34$   $p=0.001^{***}$  which was having very high significance at  $p= 0.001^{***}$  in blood glucose level of Gestational Diabetes Mellitus. Our findings show that multi model intervention brings marked reduction in blood glucose level of Gestational Diabetes Mellitus and yoga can be used as an adjunct therapy to control and maintain the blood glucose level of Gestational Diabetes Mellitus. If patient engagement package practiced regularly by the antenatal mothers with Gestational Diabetes Mellitus will provide beneficial effect in terms of reduction in the fasting, postprandial blood glucose.

### INTRODUCTION

Pregnancy induces progressive changes in maternal carbohydrate metabolism. As pregnancy advances insulin resistance and diabetogenic stress due to placental hormones necessitate compensatory increase in insulin secretion. When this compensation is inadequate, Gestational Diabetes develops. ‘Gestational Diabetes Mellitus is defined as carbohydrate intolerance with onset or recognition during pregnancy.[1] The incidence of Gestational Diabetes Mellitus ranges from 2-4% of all pregnancies, but varies widely in different population. In addition, women with a diagnosis of GDM have a 35–50% chance of reoccurrence in future pregnancies and a 40–60% increased risk of developing type 2 diabetes within 10 years whereas the children of these women also have an elevated risk of developing obesity and diabetes in their lifetime[2]. Thus, there is an important need for excellent treatment and preferably prevention strategies for GDM in women. Moreover, maternal metabolic control during pregnancy may positively impact women’s risk of later

onset of type 2 diabetes and the risk of obesity and type 2 diabetes in their children, making prevention or treatment of GDM additionally important [3].National Institute of Diabetes (2007) reports that out of every 100 pregnant women in the United states,3-8 women get Gestational Diabetes and it occurs approximately 1 in 2,014 or 0.05% or 1,35,000 people in USA. The prevalence of GDM in the low risk group of adolescent or teenage pregnancies ranges from 1.2% to 1.8%. The prevalence of GDM in high risk populations generally ranges from 3.3% to 6.1%. Totally in worldwide 7% of all pregnancies are complicated by GDM, resulting in more than 2,00,000 cases annually.[4] Gestational Diabetes Mellitus (GDM) poses are largely associated with increased blood glucose levels, placing both mother and child at high risk. Treatment for reducing maternal glucose level will be helpful in controlling the risk factors associated with GDM.[5] GDM can be controlled by the Patient engagement which is the holy grail of health care. Multi model intervention *is a person’s sustained participation in managing their health in a way*

Table 1: Comparison of pre and posttest mean score of fasting and postprandial blood glucose level of GDM between study group and control group ( N=212)

Blood Glucose	Weeks	Groups				Student independent t-test
		Study group (n=104)		Control group (n=108)		
		Mean	SD	Mean	SD	
Fasting blood sugar level	Week 24	122.99	21.28	123.88	22.09	t=0.29 p=0.77
	Week28	106.31	22.96	123.86	17.77	t=6.23 p=0.001***
	Week32	102.37	22.03	117.57	18.88	t=5.40 p=0.001***
	Week36	90.27	16.41	113.40	17.62	t=9.88 p=0.001***
Post prandial blood sugar level	Week 24	160.45	36.74	157.14	34.93	t=0.67 p=0.50
	Week28	140.14	34.78	158.54	30.34	t=4.10 p=0.001***
	Week32	127.01	30.13	154.25	35.94	t=5.96 p=0.001***
	Week36	117.13	26.50	146.16	36.19	t=6.64 p=0.001***

\*\*\* Very high significance at  $p < 0.001$

Table 2: Comparison of pretest and posttest mean score of fasting and postprandial blood glucose level of GDM among study group (n=104)

Blood Glucose	Pretest (week24)		Week28		Week32		Week36		Repeated measures ANOVA F-test	post hoc comparison using bonferonni t-test
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
Fasting blood glucose	122.99	21.28	106.31	22.96	102.37	22.03	90.27	16.41	F=25.70 p=0.001***	W24Vsw28,32,26 W28Vsw24,32,36
Postprandial blood glucose	160.45	36.74	140.14	34.78	127.01	30.13	117.13	26.50	F=34.97 p=0.001***	W32Vsw24,28,36 W36Vsw24,28,32

\*\*\* Very high significance at  $p < 0.001$

Table 3: Comparison of pretest and posttest mean score of fasting and postprandial blood glucose level among control group (n=108)

Blood Glucose	pretest (Week24)		Week28		Week32		Week36		Repeated measures ANOVA F-test
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Fasting blood glucose	123.88	22.09	123.86	17.77	117.57	18.88	113.40	17.62	F=7.73 p=0.001***
Postprandial blood glucose	157.14	34.93	158.54	30.34	154.25	35.94	146.16	36.19	F=2.89 p=0.04*

\*Significant at  $p < 0.05$ , \*\*\* Very high significance at  $p < 0.001$

that creates the necessary self-efficacy to achieve physical, mental and social well-being. This means that healthcare delivery must entice a person to actively participate over the long-term while fostering health related self-efficacy which yields meaningful physical, mental or social benefit. In only this way can healthcare organizations depend on the active and sustained participation required to improve clinical outcomes.[6] The purpose of this study was to evaluate the effectiveness of patient engagement package on glycemic control in Gestational Diabetes Mellitus. In the present study, patient Engagement package was compared with standard-care for blood glucose level in patients with GDM by evaluating the fasting and postprandial blood glucose level at 24<sup>th</sup>, 28<sup>th</sup>, 32<sup>nd</sup>, 36<sup>th</sup> week.

## MATERIAL AND METHODS

From June 2010 to June 2011, 212 antenatal mothers with Gestational Diabetes Mellitus who had attended the antenatal outpatient department at government hospital, Tambaram were evaluated. In our prospective interventional study, quantitative approach and quasi-experimental time-series design were adopted. Sample Size was detected using power analysis. Based on the inclusion and exclusion criteria, non-probability purposive sampling technique was employed for selecting samples. Samples were matched with regard to blood sugar levels at a Government Hospital, Tambaram, India. Of 220 antenatal mothers with GDM, the study group included 110 mothers and the Control group had 110 mothers.

Inclusion Criteria included those with a history of GDM between 24 and 28 weeks of gestation. Exclusion criteria involved those with polyhydramnios, multiple pregnancy, pregnancy induced hypertension, complicated pregnancy, cardiac problems, obesity, and mother who practice yoga and exercise. After assessing the initial values ,6 Mothers from study group and 2 mothers from control group have withdrawn from their study

The study protocol was approved by the ethical committee of Institutional review board and Institutional ethical committee of SRM University, Kattankulathur, Chennai, Tamilnadu, India. To execute the study the researcher obtained official written permission from Directorate of Medical and rural health Services, Chennai, Joint Director of health services Kancheepuram and Chief Senior Civil surgeon Medical Officer from Government General Hospital, Tambaram .Informed written consent was obtained from the samples and their care takers related to the study purpose, type of data, nature of commitments, participation and procedure.

Method of data collection: On the first day of contact, the investigator has collected the information about socio demographic variables and Obstetrical variables from all the selected antenatal mothers with Gestational diabetes Mellitus of Study and control group by structured interview schedule. The investigator had spent 10 to 15 minutes per sample to collect that information. Then the investigator have assessed the Fasting and postprandial blood glucose for both study and control group at 24<sup>th</sup> week. Control group were received the standard care from 24<sup>th</sup> week to till delivery from the Hospital.

In study group after completion of initial assessment at 24<sup>th</sup> week they received multi model intervention which includes Counseling on diet, exercises, and regular monitoring of blood glucose level, Insulin therapy based on the blood glucose level and regular dose of Iron, folic acid and Calcium tablets and Yoga as an adjunct therapy which includes Yogic sukshma vyayama(20 -25 mts), Nadishodana pranayama(5-10 mts) and Dhyanam(5 mts) from 24<sup>th</sup> week to till delivery.

They were instructed to follow up the visits regularly in the antenatal outpatient department.

To perform yoga intensively the antenatal mothers with Gestational Diabetes Mellitus were grouped about 22 in each session and were briefed and demonstrated about the steps of Yoga.After that along with the investigator instruction mothers were performed yoga in groups for 6 days continuously.To support the practice, booklet contained general instruction of Gestational Diabetes Mellitus and the steps of yoga were given at the end of the session. After 6 days of intense practice of yoga by the study participants, investigator has assessed the correct practice of yoga with the checklist. Practice scores were assessed and more than 80% of the scores were eligible to continue the study.The doubts were clarified by the investigator. After the intensive training, yoga was done by the study participants daily at home for 30-40 minutes a day, from 24 weeks of gestation to till the end of the pregnancy. Group session weekly once was conducted as a reassessment and reinforcement from 24<sup>th</sup> week to till delivery. Investigator by participatory observation assessed the correct practice of the yoga with the check list in every group session. Posttest was done to assess the fasting and postprandial blood glucose of Gestational Diabetes Mellitus for study group at 28<sup>th</sup>, 32 and 36<sup>th</sup> week (4 weeks once).

**RESULTS**

Statistically no significant difference was found in the distribution of demographic, obstetrical variables of mothers those who were participated for the study between study and control group. Table 1 illustrates that the pretest score for fasting and postprandial blood glucose level is high in both the Groups. However, the posttest score of the study group significantly decreased than that of the Control group at the level of p 0.001.Statistical significance was calculated using Student independent t-test

The above table depicts that at 24<sup>th</sup> week before Yoga, fasting blood glucose mean score is 122.99, After 12

Table 4: Comparison of percentage of reduction in fasting and postprandial blood glucose level of Gestational Diabetes Mellitus between study and control group (N=212)

Gro ups	Clinical parameters	Week 24		Week 36		Difference		Mean difference with 95% CI	% of difference from baseline with 95% CI
		Mean	SD	Mean	SD	Mean	SD		
groupStudy (n=104)	Fasting blood glucose	122.99	21.28	90.27	16.41	32.72	17.85	32.72 (29.25-36.19)	↓26.6% (23.8%-14.5%)
	Postprandial blood glucose	160.45	36.74	117.13	26.50	43.32	30.17	43.32 (37.45-49.18)	↓26.9% (23.3%-30.6%)
Control (n=108)	Fasting blood glucose	123.88	22.09	113.40	17.62	10.48	15.28	15.28 (7.57-13.40)	↓2.35 (6.11%-10.8%)
	Postprandial blood glucose	157.14	34.93	146.16	36.19	10.98	26.47	10.98 (5.93-16.03)	↓6.9% (3.8%-10.2%)

Table 5: Effectiveness of multi model intervention on fasting and postprandial bloodglucose level of GDM Study group (N=212)

Clinical parameters	Study group	Control group	Benefit
Blood Glucose_Fasting	26.00%	2.35%	23.65%
Blood Glucose_PP	26.90%	6.9%	20.00%

weeks of intensive practice of Yoga at 36<sup>th</sup> week it was 90.27 mg/dl. Post prandial mean score before yoga at 24<sup>th</sup> week 160.45 mg/dl, after yoga at 36<sup>th</sup> week 117.13 mg/dl. So this reduction in the fasting and postprandial blood glucose level was having very high significance at  $p=0.001$ . It was assessed using Repeated measures analysis of variance F-test. Between weeks like 24<sup>th</sup> week and 28<sup>th</sup> week differences was calculated using bonferroni t-test.

The above table reveals that statistically significance difference was found between pre and posttest mean score of fasting blood glucose ( $F=7.73p=0.001^{***}$ ), Post prandial blood glucose ( $F=2.89p=0.04^*$ ) of the mothers with gestational Diabetes Mellitus.

The above table conclude that mean difference with 95% CI is greater extent in study group than the control group in all the clinical parameters of Gestational Diabetes Mellitus.

All the tables illustrates the effectiveness of multi model intervention on fasting and postprandial blood glucose of Gestational Diabetes Mellitus among Mothers with Gestational diabetes Mellitus. In Study group the percentage of benefit was more than the control group. This result strongly reports that there is a significant difference in the pre and posttest level of clinical parameters of Gestational diabetes Mellitus between study group and control group.

## DISCUSSION

Diabetes poses a major health problem globally and is one of the top five leading causes of death in most developed countries. A substantial body of evidence suggests that it could reach epidemic proportions particularly in developing and newly industrialized countries (King H, Aubert RE, Herman WH, 1998). Indeed, by the year 2025, three-quarters of the world's 300 million adults with diabetes will be in developing countries and almost a third in India and China alone (Fall CH, 2001). The prevalence of diabetes in India is showing a sharp upswing as is evident from secular trends from different parts of the subcontinent and studies of migrant Indians (King H, Zimmet P, 1988). The World Health Organization has estimated that in 1995, 19.4 million individuals were affected by diabetes in India and these numbers are expected to increase to 57.2 million by the year 2025 i.e. one-sixth of the world total. The revised figures are 80.9 million by the year 2030 (Bjork S, Kapur A, King H, et al, 2003). These numbers also include GDM, and should alert Health care team to the need to direct special attention to this population, especially in developing countries. The prevalence of diabetes is increasing globally and these numbers include women with GDM. GDM is considered as a transient abnormality of glucose intolerance during pregnancy. Women with GDM are at increased risk of diabetes in future as are their children and the following subsequent generations. The primary prevention is likely to reverse or halt this trend.

Pregnancy affects both the maternal and fetal metabolism and even in non-diabetic Women exerts a Diabetogenic effect. Among Pregnant women 2 to 17.8 develop GDM (Negrato.CA., Mattar, 2012). There is a growing evidence that Yoga may offer Cost-effective Intervention for mother with GDM (Innes KE, Vincent HK, 2007). This article Critically analyzed the effect of Yoga on Blood glucose level in Mother with GDM. Results of this study showed that there was a significant reduction in the Blood glucose level after the Intensive Practice of Yoga for every 4 weeks and there was a marked reduction in the Blood glucose level after 12 weeks of Intensive and Continuous Practice of Yoga. Statistically the result shows for a Yoga group the Mean Fasting Blood glucose level before Yoga at 24 week was 122.99 Mg/dl and After Yoga at 28 weeks it was 106.31 Mg/dl, at 32 weeks 102.37 Mg/dl, and at 36<sup>th</sup> week 90.27 Mg/dl, which was highly statistically significant at 'p' value 0.001<sup>\*\*\*</sup>. The Mean Postprandial Blood glucose level Before Yoga at 24 week was 160.45 Mg/dl and After Yoga at 28 weeks it was 140.14 Mg/dl, at 32 weeks 127.01 Mg/dl, and at 36<sup>th</sup> week 117.13 Mg/dl which was highly significant at 'p' value 0.001<sup>\*\*\*</sup>.

The study findings are consistent with study conducted by Malhotra.v., Singh.s, 2005 on the Beneficial effect of Yoga on Diabetes results indicate that there was significant decrease in Fasting Blood glucose level from basal 208.3 +/- 20.0 to 171.7 +/- 19.5 Mg/dl. So the study concluded that Yoga asana may be used as an adjunct with diet and drugs in the Management of Type 2 Diabetes.

Yang K, Bernardo L.M et al., 2011, conducted study on the Utilization of 3 Month Yoga programme for adults at High risk for type 2 Diabetes He reported that the Yoga group Experienced improvements in Weight, Blood pressure, insulin, Triglycerides and Exercise Self efficacy. All the Participants Assigned to the Yoga intervention completed Yoga Programme With out any Complication and expressed high satisfaction with the programme (99.2%).

Barakat R, Cordero.Y, 2012, conducted a Randomized Controlled study on Exercise during Pregnancy Improves Maternal glucose screening at 24 to 28 weeks. The aim of the study was to asses the influence of an Exercise programme performed by healthy pregnant women on Maternal glucose was studied and there was a significant differences were found between study groups on the 50gms MGS values corresponding to the Experimental group (103.8 mg/dl) were better than those of the Control group (126.9 mg/dl). So the study concluded that the moderate physical activity programme performed during pregnancy improves maternal glucose tolerance.

## CONCLUSION

There is a growing evidence that yoga may offer cost-effective intervention for mother with GDM. Yoga can

help women get through their pregnancy with minimal discomfort. It also helps during birth and post-delivery stages. A positive outcome of these study findings indicate that the Sukshma vyayamas, Pranayama and Meditation practiced together, it brings marked reduction in all the clinical parameters of Gestational Diabetes Mellitus and yoga can be used as a adjunct therapy to control and maintain clinical parameters of Gestational Diabetes Mellitus. If yoga can be practiced regularly along with medication, diet control and follow-up by the antenatal mothers with Gestational Diabetes Mellitus will provide beneficial effect in terms of reduction in the fasting, postprandial blood glucose and urine sugar level, appropriate weight gain and positive maternal, fetal and neonatal outcome and good level of satisfaction on yoga. The Researcher concludes that the antenatal mothers with Gestational Diabetes Mellitus can practice yoga because "Ensuring healthy baby is every woman's dream" and Yoga helps to achieve that dream

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