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Research Article

Maternal Outcome in Diabetic Pregnant Women-Impact of an Intervention Programme

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A B S T R A C T

Gestational diabetes mellitus is a substantial and growing health concern. It has serious, long term consequences for both baby and mother. Early detection and intervention can greatly improve outcomes for women with this condition. Studies have revealed higher incidence of preterm labor, pre-eclampsia, nephropathy, birth trauma, caesarean section, postoperative wound complications, fetal wastage from early pregnancy loss or congenital anomalies, macrosomia, shoulder dystocia, stillbirth, growth restriction, and hypoglycaemia etc. Therefore the present study using quasi-experimental time series non-equivalent control group design was conducted on 110 sample subjects, 56 in experimental group and 54 in control group, in a selected hospital of Kashmir (J&K, India) to determine the effectiveness of antenatal intervention on maternal parameters of diabetic pregnant women in order to improve their outcome. The study revealed a significant difference in maternal outcome of experimental group of diabetic pregnant women as compared to control group of diabetic pregnant women.

Keywords: Diabetic Pregnant Woman, Intervention Programme, Maternal Parameters, Maternal Outcome

Background

Diabetes Mellitus complicating pregnancy is a common risk factor contributing to perinatal, neonatal and infant morbidity and mortality. About 1-14 percent of all pregnancies are complicated by diabetes mellitus and 90 percent of them are gestational diabetes mellitus (GDM). Nearly 50% of women with GDM will become overt diabetes (type-II) over a period of 5-20 years.[1]

Diabetes is a systematic disorder of carbohydrate, protein and fat metabolism, characterized by hyperglycaemia. In mothers who experience vascular changes as a result of diabetic complication, there may be compromised utero-placental circulation. This decreases the amount of oxygen available to the fetus and may contribute to intra-uterine growth retardation, small for gestational age and low birth weight. Preterm birth is related to fetal hypoxia. The maternal mortality rate is approximately 0.5%, however this rate is still five times that of non-diabetic pregnancies.[2]

The prevalence of both obesity and Gestational Diabetes Mellitus (GDM) is rising worldwide. The complications of diabetes affecting the mother include preterm labor, pre-eclampsia, nephropathy, birth trauma, caesarean section, and postoperative wound complications etc. Fetal complications include fetal wastage from early pregnancy loss or congenital anomalies, macrosomia, shoulder dystocia, stillbirth, growth restriction and hypoglycaemia etc. The presence of obesity among diabetic patients compounds this complications.[3]

Gestational diabetes mellitus is characterised by glucose intolerance of variable severity that begins or is first diagnosed during pregnancy and usually resolves not long after delivery.[4] Though in most cases, diabetes disappears after delivery, recent research has shown that the number of women with the condition who go on to get full blown diabetes is increasing. Around 25% cases get type 2 diabetes within 15 years. Indians are in the high risk group.[5]

Although diabetes in pregnancy has previously been regarded as benign, some studies have recently reported that the consequences of not treating gestational diabetes causes increased perinatal morbidity associated with hyperglycaemia in pregnancy. Fortunately these complications seem to be lessened and outcome for women with this condition and her baby improved by screening, early detection and management of this condition.[6]

Greco et al.[7] reported that gestational diabetes is a major risk factor to affect the pregnancy outcome. Women need to be identified and screened by making them to have plasma tests done for glucose levels at fasting, post prandial and glucose tolerance. Detected cases of diabetics should be provided with verbal and written information about hygiene, diet, weight reduction, exercise, regular monitoring of blood sugar, weight, blood pressure and fetal monitoring.

Growther et al. [8] reported that the early detection, prompt treatment of gestational diabetes with modified diet and weight control improves the pregnancy outcome.

Hare[9] reported that pregnant women with diabetes need to undergo screening, early detection and management of this condition, regular checkups to have watch on their glycaemia levels. Regular blood and urine glucose monitoring are the major management goals to prevent from diabetic complications to her and her growing fetus. In the long run, it has improved the neonatal and infant outcome.

In a case control study of maternal recreational physical activity and risk of gestational diabetes,[10] reported that the risk got reduced by 49- 78% in mothers who climb stairs daily than those who do not. The risk was also found reduced depending on the number of hours spend performing recreation, distance walked, pace of walking and energy expended.

Gribble et al.[11] while studying the value of urine screening for glucose at each prenatal visit reported that it is easy way to keep watch on pregnancy and make it safe from diabetic complications by detecting it early and by timely care of pregnant women.

Major et al.[12] reported that women who receive nutrition counseling and follow a diet that adequately meets the needs of their pregnancy by restricting carbohydrates to 35-40% of daily calories decreases maternal glucose concentration and maternal and fetal outcomes.

Wang Thomas[13] and Beth Lewis[14] has shown the effect of exercise during pregnancy on maternal outcome. They indicated brisk walking, jogging, home maintenance, kaegle's exercise and reported the safety of these exercises during pregnancy in reducing risks of weight gain, preeclampsia, gestational diabetes, duration of labour and rates of caesarean section.

Favourable outcome of diabetic pregnancy requires multidisciplinary approach involving the obstetrician, endocrinologist, neonatologist, nurse, nutritionist and social worker with commitment and active participation by the woman. Her compliance to frequent prenatal visits, strict adherence to dietary regimen, regular self monitoring of blood pressure and blood glucose level, frequent laboratory evaluation and intensive fetal surveillance helps in improvement in her pregnancy outcome. Therefore, preventive measures against gestational diabetes should start during the intrauterine period and continue from early childhood throughout life. In this respect, detection of Gestational Diabetes Mellitus (GDM), defined as carbohydrate intolerance of variable severity with onset or first recognition during the present pregnancy becomes an important public health issue.

The pregnancy outcome in high risk mothers could be improved by providing adequate prenatal care in terms of health education for early detection of risks and preventing complications.

Antenatal care to women during pregnancy includes preventive services, risk approach, prenatal advice, specific health protection, mother-craft class for psychological preparation etc.[15p572] As indicated in above studies thus there is a need for antenatal intervention program would come out with better outcome of pregnancy than those who receive routine prenatal care. This program was a comprehensive interventional package including information about GDM (written and verbal), antenatal and dietary advises, demonstrations (testing and monitoring of weight, blood pressure, blood sugar, exercises). Support at home is an important factor which needs to be emphasized antenatal intervention program thus researcher has decided to call their husbands or significant others and counsel them; give them an information booklet which would help them in taking daily care and care during critical period.

Objectives

- To assess the physical and physiological parameters of diabetic pregnant women at baseline (16 weeks of gestation) before implementation of intervention programme (pre-test) among both experimental and control group.
- To assess the physical and physiological parameters of

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diabetic pregnant women at various weeks of gestation among experimental group after implementation of intervention programme (post-tests).

- To assess the physical and physiological parameters of diabetic pregnant women at various weeks of gestation among control group (post-tests).
- To compare the pre test values of physical and physiological parameters of diabetic pregnant women with their post tests done at various weeks of gestation.
- To compare the maternal outcome of diabetic pregnant women of experimental group with that of control group of diabetic pregnant women.
- To associate maternal outcome of diabetic pregnant women with their demographic variables.

Hypotheses

H_1: There is significant change in the physical and physiological parameters of diabetic pregnant women on post tests as compared to their pretest at 0.05 level of significance.

H_2: There is significant difference in the maternal outcome of diabetic pregnant women of experimental group as compared to control group of diabetic pregnant women at 0.05 level of significance.

H_3: There is significant association between maternal outcome of diabetic pregnant women and their selected demographic variables at 0.05 level of significance.

Review of Literature

Di Simone et al.[16] studied insulin plasma levels in pregnant patients with impaired glucose tolerance and its relationship with pregnancy outcome in UK. They found that these mothers had delivered still births (13.3%), had undergone premature labour (8.97%) and caesarean rates were 17%. Babies (17.5%) had Apgar score below 7, low birth weight (65.49%), born before 36 weeks (5.43%) and between 32-35 weeks (3.54%)

Caruso et al.[17] studied insulin secretion in patients with gestational diabetes and its relationship with pregnancy outcome. They revealed that perinatal outcome was positive in women taking regular insulin and controlled meals in breaks. The women delivered full term (87.2%), normal birth weight (66.9%), had fewer babies (1.2%) with congenital defects.

Coetzee and Levitt[18] conducted a study on pregnant women with diabetes to observe their neonatal outcome. They reported high rates of low birth weight and prematurity (33.25%) among women with uncontrolled blood sugar and still births were found high in mothers (14%) who were detected diabetics after 24 weeks of gestation.

Catalano et al.[19] conducted a study in South Africa to find out weight gain in diabetic pregnant women. They reported that extra gain in weight of >18Kg in women with diabetes has shown adverse perinatal outcome. 25.6% of these women had delivered prematurely, 58.9% women were hypertensive. About 34.82% had delivered big babies. There were reports of still birth (5.13%), congenital anomalies (7.64%) and preterm small babies (6.94%).

Fraser et al.[20] compared prevalence and neonatal outcome of gestational diabetes among Bedouins of Jewish population in South Israel and revealed that prevalence was found high (45.12%) in population with background family diabetics. They further reported adverse outcome among women with late recognition of diabetes (26.6%), higher rates of still births (31.9%), congenital anomalies (61.2%) perinatal deaths (25.4%) and asphyxiated babies (45%).

Hawthrone et al.[21] studied outcome of diabetic pregnancy in New Castle General Hospital and reported that 34.6% infants were born with birth weight of less than normal, congenital anomolies was revealed in 13% and abortions were found in 9.53%.

Gazzolo et al.[22] studied Doppler velocimetry and behavioural state development in relation to perinatal outcome in pregnancies complicated by gestational diabetes in Canada. They reported that 31.83% women had to undergo emergency caesarean section before 37 weeks of gestation and 46.51% of the neonates had birth weight less than 2500g. They had shown higher rates of congenital anomalies (35.21%), perinatal deaths (31.2%) and asphyxiated babies (28.9%).

China et al.[23] studied obstetric and neonatal outcome among women in Switzerland with gestational diabetes in Singapore and reported that 58.62% women needed assisted vaginal delivery by application of forceps, 6.08% delivered still births and 32.1% mothers delivered babies by caesarean section. The neonatal complications included hypoglycaemia (22.05%), congenital anomalies (4.06%), Apgar score of less than 7 (12.64%), prematurity (15.34%) and infections (13.18%).

Dutta[24] studied effect of diabetes during pregnancy with perinatal and neonatal outcome in a city hospital of Orrisa and revealed that diabetes during pregnancy was found associated with preterm labour (20%), preeclampsia (25%) and polyhydramnios (25-50%). Other associated risks included abortions, infections, maternal distress and fetal hazards like congenital malformations and perinatal loss.

Crowther et al. *[Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS)]*[25] conducted a randomized clinical trial to determine whether treatment of women with gestational diabetes mellitus reduced the risk of perinatal complications. The researchers randomly assigned gestational diabetic women between 24 and 34 weeks'

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gestation to two groups. Intervention group of 490 women were to receive dietary advice, blood glucose monitoring, and insulin therapy as needed and other 510 women to routine care called it routine care group. It was found by them that the rate of serious perinatal complications like fetal deaths, shoulder dystocia, bone fracture, nerve palsy was significantly lower among the infants of intervention group than among the infants of the routine-care group whereas admission to the neonatal nursery, jaundice requiring phototherapy, induction of labor, were found more in intervention group, although the rates of cesarean delivery were similar. At three months, post-partum, data revealed 0 lower rates of depression and higher scores of improved health status, in the intervention group.

Rosenberg et al[26] examined associations between obesity, diabetes and three adverse pregnancy outcomes i.e. primary caesarean delivery, preterm birth and Low Birth-Weight (LBW) among 329988 singleton births of 4 ethnic groups i.e; Asians, Hispanics, Whites and Blacks from birth files in New York city. Their data revealed that chronic and gestational diabetes were significant risks for a primary caesarean and for preterm birth in all women where as chronic diabetes as risk for low birth weight was higher in Asians, Hispanics and Whites and had lower risk for Blacks. It was further revealed by them that obesity and diabetes were independently associated with adverse pregnancy outcomes thus they require life style modification.

Langer, Oded et al.[27] conducted a study in USA on 4001 women with gestational diabetes (GDM) to investigate the relationship between pre-pregnancy weight, treatment modality (diet or insulin), level of glycemic control and pregnancy outcome. Their findings revealed that obese women who achieved targeted levels of glycemic control when treated with insulin had comparable pregnancy outcome but when treated with diet therapy who achieved targeted levels of glycemic control had a 2-to 3-fold higher risk for adverse pregnancy outcome when compared with overweight and normal weight women with well-controlled GDM whereas normal weight women treated with diet therapy who achieved targeted levels of glycemic control had good outcomes. It was concluded that the women with GDM who failed to achieve established levels of glycemic control had significantly higher adverse pregnancy outcomes in all 3 maternal weight groups.

Bell et al.[28] studied trends and prevalence and outcome of pregnancy in women with preexisting type I and II diabetes in England and reported higher rates of still birth (22%), abortions (13.8%), preterm (54%) and low birth weight (48.7%). The women who gained excess weight and required emergency hospitalization were 16.8%.

Garcia-Patterson et al.[29] did a randomized trial on 512 women in Poland to evaluate the effect of light exercise on gestational diabetes. They reported birth of normal weight babies (57%), full term (75.41%) and very few congenital defects (3.1%).

Metzge[30] presented the findings of a study conducted by The Australian Carbohydrate Intolerance Study (ACHOIS) trial group during the Fifth International Workshop Conference on Gestational Diabetes Mellitus. ACHOIS had carried out a randomized clinical trial to assess whether treating women with gestational diabetes reduced the risk of perinatal complications. 1000 pregnant women with gestational diabetes at 24-28 weeks of gestation were randomly assigned to receive dietary advice, blood glucose monitoring, insulin therapy or routine care. Serious perinatal outcomes were reduced from 4% to 1% in pregnant women treated for gestational diabetes. However, rate of admission to the neonatal nursery was high in intervention group.

Mattoo[31] conducted a study in Delhi to evaluate the effectiveness of a planned health education programme on knowledge, skill, stress and glycaemia level, maternal and neonatal outcome of mothers with gestational diabetes and compared them with a control group of mothers with gestational diabetes. In her planned health education programme, she included brisk walking for 30-45 minutes, dietary prescription and health teachings and reported that knowledge was gained significantly in experimental group who also showed reduced glycaemia levels (86.4%) than control group (13.6%). There was spontaneous onset of labour with vaginal delivery of full term, alive and normal weight babies more in experimental group whereas control group had more preterm deliveries. She reported higher rates of caesarean births, polyhydramnios, perineal injury, big baby and congenital abnormality in control group as compared to experimental group.

Materials and Methods

A quasi experimental research approach with time series non-equivalent pre-test-post–test-control group design was used to study 110 pregnant women with diabetes at Antenatal Clinic (ANC) of Sheri-Kashmir Institute of Medical Sciences (SKIMS), Srinagar. Sample was selected randomly with 56 subjects in experimental group and 54 subjects in control group. Criteria for selecting the sample subjects were pregnant women irrespective of gravidity and socioeconomic status, between 16-20 weeks of gestation, who were diagnosed as diabetic. Women with normal gestation and who were not registered were not included in the study. The interview-schedule was used to collect data about demographic variables and nutritional status; assessment proforma was used to assess physical and physiological parameters; and observation checklist was used to assess maternal outcome of subjects. Records were also analyzed to collect data. Instruments like weighing machine, BP apparatus, fetoscope were also used while

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conducting physical examination. Data was collected from March 2012 to August 2012.

Antenatal intervention programme consisted of written and verbal information about diabetes in pregnancy, antenatal and dietary advises and demonstrations (testing and monitoring of weight, blood pressure, blood sugar, checking fetal movement, exercises). The initial/ baseline assessment was done for both experimental and control group of study subjects at 16 weeks of gestation. Antenatal intervention programme was administered systematically only on experimental group during 16th weeks of gestation. Each woman was provided with Self Care Activity Compliance Checklist and was advised to fill it up when she performs any activity. Physical and physiological parameters of diabetic pregnant women of both experimental and control group was assessed during 24th, 28th, 32nd and 36th weeks of gestation and maternal outcome was observed based on assessment of maternal parameters. It was planned to analyze and interpret the data using appropriate descriptive and inferential statistics .

Result

Section I: Demographic Variables of Subjects

Data presented in Table 1, shows that the experimental group and control group were similar in all the demographic characteristics. The mean age of subjects was 24.02±3.12 years in experimental group and 25.36 ±4.18 years in control group. 50% of subjects from both the groups belonged to age group of 20-30 years and 43-44%of subjects belonged to age group of above 30 years. Maximum number of subjects from both groups belonged to middle socio economic class, had moderate exposure to smoke, average nutritional status, and were primigravidae.

Section II: Assessment of physical and physiological parameters at various weeks of gestation among experimental and control group of diabetic pregnant women

These physical and physiological parameters include body weight, haemoglobin, blood pressure, fasting blood sugar, fundal height and fetal heart rate presented in Table 2&3.

Table 1.Distribution of subjects among Experimental Group and Control Group according to Demographic Variables

N=110

S. No.	Demographic variables	Experimental Group (N=56)	Control Group (N=54)	p-value
1.	**Age (mean±SD)**	24.02±3.12	25.36±4.18	
	Less than 20 years	4 (7.14%)	3 (5.55%)	0.124
	20-30 years	28 (50%)	27 (50%)	
	More than 30 years	24 (42.85%)	24 (44.44%)	
2.	**Socio Economic Status**			
	High	3 (5.35%)	4 (7.40%)	0.332
	Middle	33 (58.92%)	30 (55.55%)	
	Low	20 (35.71%)	20 (37.03%)	
3.	**Exposure to Smoke**			
	Mild	16 28.57%)	10 (18.51%)	0.219
	Moderate	38 (67.85%)	43 (79.62%)	
	Severe	02 (3.57%)	01 (1.85%)	
4.	**Nutritional Status**			
	Good	10 (17.85%)	13 (24.07%)	
	Average	31 (55.35%)	31 (57.40%)	
	Fair	15 (26.78%)	10 (18.51%)	
5.	**Gravidity**			
	Primigravida	40 (71.42%)	40 (74.07%)	0.312
	Secondgravida	14 (25%)	10 (18.51%)	
	Multigravida	02 (3.57%)	04 (7.40%)	
	Grand multigravida	00 (0.00)	00 (0.00)	

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Table 2.Mean of maternal parameters of Experimental Group at Various Weeks of Gestation in Terms of Subject's body weight, haemoglobin, blood pressure, fasting blood sugar, fundal height and fetal heart rate

n=56

Maternal Parameters	Various weeks of gestation				
	16 weeks ($\bar{X}$±SD)	24 weeks ($\bar{X}$±SD)	28 weeks ($\bar{X}$±SD)	32 weeks ($\bar{X}$±SD)	36 weeks ($\bar{X}$±SD)
Body weight (in Kg)	65.07±7.90	68.35±8.26	70.57±8.09	72.92±8.20	75.21±8.26
Haemoglobin (g%)	11.03±0.88	11.32±0.84	11.54±0.74	11.54±0.74	12.06±0.76
Systolic Blood pressure	113.21±7.22	122.29±6.15	118.5±8.37	124±6.99	124.29±7.41
Diastolic Blood pressure	77.14±4.6	78.28±5.9	78.92±6.12	81.71±6.24	82.14±6.86
Fasting Blood sugar	183.71± 50.44	140.5± 30.58	122.71± 14.85	114.57± 10.20	107.57±12.51
Fundal Height	16.57±0.92	23.57±1.31	28.57±0.95	32.92±0.83	35.71±0.46
Fetal heart rate	142±1.72	142.36±1.63	142±1.63	141.79±1.83	143.29±3.27

Table 3.Mean of maternal parameters of Control Group at Various Weeks of Gestation in Terms of Subject's weight, haemoglobin, fasting blood sugar, blood pressure, fundal height and fetal heart rate

n=54

Maternal Parameters	Various weeks of gestation				
	16 weeks ($\bar{X}$±SD)	24 weeks ($\bar{X}$±SD)	28 weeks ($\bar{X}$±SD)	32 weeks ($\bar{X}$±SD)	36 weeks ($\bar{X}$±SD)
Body weight (in Kg)	58.11±7.24	61.83±6.82	64.33±6.22	66.94±5.64	69.22±5.80
Haemoglobin (g%)	10.97±0.45	11.62±0.37	11.30.32	11.28±0.49	11.55±1.69
Systolic Blood pressure	113.78±6.68	113.56±6.84	115.78±6.95	116.89±8.7	120±8.32
Diastolic Blood pressure	73.33±6.37	76±5.26	76.22±6.68	79.33±5.6	80.67±7.62
Fasting Blood sugar	248.56± 55.18	217.56± 51.92	199.89±49.23	180.33±39.04	155.89±39.66
Fundal Height	23.88±1.39	23.4516	27.77±0.64	33.67±0.42	36.11±0.32
Fetal heart rate	143.78±2.24	143.56±2.10	144±1.35	144±1.35	148.74±5.9

Table 2, presents the mean of maternal parameters of experimental group from 16-36 weeks of gestation. The mean body weight of experimental group of subjects was 68.07±7.90(16 weeks) to 75.21±8.26 (36 weeks); mean haemoglobin was 11.03±0.88, 11.32±0.84, 11.54±0.74, 11.54±0.74, 12.06±0.76 at 16,24,28,32,36 weeks of gestation respectively. Mean systolic and diastolic pressure was within normal limits throughout the gestation period. Mean fasting blood sugar was 183.71± 50.44 at 16 weeks, 140.5±30.58 at 24 weeks, 122.71±14.85 at 28 weeks, 114.57±10.20 at 32 weeks and 107.57±12.51 at 36 weeks of gestation. Mean fundal height varied normally at various weeks of gestation. Mean fetal heart rate was within normal range at various weeks of gestation.

Table 3, presents the mean of maternal parameters of control group of diabetic subjects from 16-36 weeks of gestation. The mean body weight of control group of subjects was 58.11±7.24 (16 weeks) to 69.22±5.80 (36 weeks); mean haemoglobin was 10.97±0.45, 11.62±0.37, 11.3±0.32, 11.28±0.49, 11.55±1.69 at 16,24,28,32,36 weeks of gestation respectively. Mean systolic and diastolic pressure was within normal limits throughout the gestation period. Mean fasting blood sugar was high throughout and was 248.56±55.18 at 16 weeks, 217.56±51.92 at 24 weeks, 199.89±49.23 at 28 weeks, 180.33±39.04 at 32 weeks and 155.89±39.66 at 36 weeks of gestation. Mean fundal height varied normally at various weeks of gestation. Mean fetal heart rate was within normal range at various weeks of gestation.

Section III: Comparison of physical and physiological parameters of experimental and control group between various weeks of gestation

All the physical and physiological parameters of experimental and control group were assessed separately at baseline (16 weeks of gestation) as pretest and were compared with

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parameters of 24 weeks (post-test I), 28 weeks (post-test II), 32 weeks (post-test III) and 36 weeks (post-test IV). Their comparison is presented in table 4&5. To test the significance of change 't' test was computed and following null hypothesis was formulated.

Ho1: There is no significant change in the physical and physiological parameters of diabetic pregnant women on post tests as compared to their pretest at 0.05 level of significance.

Table 4, presents the comparison of parameters among experimental group of diabetic pregnant women between pre-test (16 weeks assessment before implementation of intervention) and post-test I (24 weeks of gestation), post -test II (28 weeks of gestation), post test III (32 weeks of gestation), post-test IV (36 weeks of gestation).

Mean body weight between pretest and post-test I did not show any significant difference where as there was significant difference in mean body weight between pretest and post test II (0.0128; $p<0.05$), between pre-test and post-test III (0.0006;$p<0.01$), between pre-test and post-test IV (0.0001; $p<0.01$).

Mean haemoglobin between pre-test and post-test I did not show any significant difference where as there was significant difference in mean haemoglobin between pre-test and post-test II (0.0226; $p<0.05$), between pre-test and post-test III (0.0034; $p<0.01$), between pre-test and post-test IV (0.0001; $p<0.01$).

Mean systolic blood pressure showed significant difference between pre-test and all 4 post-tests ($p<0.01$). Mean diastolic blood pressure showed no significant difference between pre-test and post-tests (I&II) where as there was significant difference in mean diastolic blood pressure between pre-test and post-test III (0.0029; $p<0.05$) and between pre-test and post-test IV (0.0023; $p<0.05$).

Regarding mean fasting blood sugar and mean fundal height, there was highly significant difference between pre-test and all 4 post-tests ($p<0.01$). Mean fetal heart rate showed no significant difference between pre-test and post-tests (I, II & III) where as there was significant difference in mean fetal heart rate between pre-test and post-test IV (0.0702; $p<0.05$). Thus null hypothesis was rejected. And research hypothesis was accepted which shows effectiveness of intervention programme on experimental group.

Table 5, presents the comparison of parameters among control group of diabetic pregnant women between pre-test (16 weeks assessment) and post-test I (24 weeks of gestation), post-test II (28 weeks of gestation), post-test III (32 weeks of gestation), post-test IV (36 weeks of gestation).

Mean body weight between pre-test and post-test I did not show any significant difference where as there was significant difference in mean body weight between pretest and post-test II (0.0014; $p<0.05$), between pre-test and post-test III and IV (0.0001; $p<0.01$).

Mean haemoglobin between pre-test and post-test I and IV did not show any significant difference where as there was significant difference in mean haemoglobin between pre-test and post-test II(0.0023; $p<0.05$), between pre-test and post-test III(0.0190; $p<0.05$).

Mean systolic blood pressure did not show any significant difference between pre-test and post-tests (I,II & III) where as there was significant difference between pre-test and - IV (0.0038; $p<0.05$). Mean diastolic blood pressure showed no significant difference between pre-test and post-tests (I&II) where as there was significant difference in mean diastolic blood pressure between pre-test and post-test III (0.0006; $p<0.01$) and between pre-test and post-test IV (0.0003 $p<0.01$).

Regarding mean fasting blood sugar and mean fundal height, there was significant difference between pre-test and all 4 post-tests ($p<0.05$ and 0.01). Mean fetal heart rate showed no significant difference between pre-test and post-tests (I, II &III) where as there was significant difference in mean fetal heart rate between pre-test and post-test IV (0.0002; $p<0.01$) .

Section IV: Comparison of maternal outcome between experimental group and control group of subjects

Maternal outcome was assessed and scored on the basis of measurement of physical and physiological parameters during 24th, 28th, 32nd and 36th weeks of gestation and during intra partum period. The variables were categorized in three subcategories and were then compared between experimental and control group of subjects. During pregnancy, it was assessed in terms of gain in weight (normal-weight gain of 11-15 Kg; average-weight gain of 9-10.9 Kg; below normal->15/<9 Kg), gain in haemoglobin (normal-12-16g%; average-10-11.9g%; below normal<10g%), control over blood pressure (good<120/ 80mmHg; average-120-130/ 80-90mmHg; fair->130/ 90mmHg), control over blood sugar (good-70-126mg/ dl; average-126-140mg/ dl; fair->140mg/ dl), fetal distress (absent/ mild distress/ severe distress), need for blood transfusion (no, 1-2 transfusions,>2 transfusions), any emergency hospitalization (no. once/twice,>twice) and during intra-partum period it was assessed in terms of mode of delivery (normal vaginal, assisted, caesarean) gestational age (full term/ preterm/ very preterm). To test the significance of difference, chi square and odds ratio was computed and following null hypothesis was formulated.

Ho2: There is no significant difference in the maternal outcome of diabetic pregnant women of experimental group as compared to control group of diabetic pregnant women at 0.05 level of significance.

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Table 4.Comparison of Pretest and Posttests among Diabetic Pregnant Women of experimental group

n=56

Tests	Pre-test	Post-test 1			Post-test 2			Post-test 3			Post test 4		
Weeks of Gestation	16 Weeks	24 Weeks			28 Weeks			32 Weeks			36 Weeks		
Parameters	$\bar{X}\pm SD$	$\bar{X}\pm SD$	't'value	'p'value	$\bar{X}\pm SD$	't'value	'p'value	$\bar{X}\pm SD$	't'value	'p'value	$\bar{X}\pm SD$	't'value	'p'value
Body Weight	65.07±7.90	68.35±8.26	1.5185	0.1347	70.57±8.09	2.5738	0.0128*	72.92±8.20	3.6481	0.0006**	75.21±8.26	4.6944	0.0001**
Haemoglobin	11.03±0.88	11.32±0.84	1.2614	0.2126	11.54±0.74	2.3471	0.0226*	11.70±0.75	3.0662	0.0034**	12.06±0.76	4.6874	0.0001**
Systolic BP	113.21±7.22	122.29±6.15	5.0660	0.0001**	118.5±8.37	2.5324	0.0143*	124±6.99	5.6815	0.0001**	124.29±7.41	5.6670	0.0001**
Diastolic BP	77.14±4.6	78.28±5.9	0.8063	0.4236	78.92±6.12	1.2303	0.2339	81.71±6.24	3.1194	0.0029*	82.14±6.86	3.2033	0.0023*
Fasting B Sugar	183.71±50.44	140.5±30.58	3.8763	0.0003**	122.71±14.85	6.1388	0.0001**	114.57±10.20	7.1094	0.0001**	107.57±12.51	7.7527	0.0001**
Fundal height	16.57±0.92	23.57±1.31	23.1390	0.0001**	28.57±0.95	48.0151	0.0001**	32.92±0.83	69.8233	0.0001**	35.71±0.46	98.4641	0.0001**
FHR	142±1.72	142.36±1.63	0.8039	0.4250	142±1.63	0.0000	1.0000	141.79±1.83	0.4425	0.6599	143.29±3.27	1.8475	0.0702*

*significant at 0.05level, **significant at 0.01level

Table 5.Comparison of Pretest and Posttests among Diabetic Pregnant Women of Control group

n=54

Tests	Pre-test	Post-test 1			Post-test 2			Post-test 3			Post-test 4		
Weeks of Gestation	16 Weeks	24 Weeks			28 Weeks			32 Weeks			36 Weeks		
Parameters	$\bar{X}\pm SD$	$\bar{X}\pm SD$	't'value	'p'value	$\bar{X}\pm SD$	't'value	'p'value	$\bar{X}\pm SD$	't'value	'p'value	$\bar{X}\pm SD$	't'value	'p'value
Weight	58.11±7.24	61.83±6.82	1.9434	0.0574	64.33±6.22	3.3861	0.0014*	66.94±5.64	4.9994	0.0001**	69.22±5.80	6.2230	0.0001**
Haemoglobin	10.97±0.45	11.62±0.37	5.7975	0.0001**	11.3±0.32	3.1995	0.0023*	11.28±0.49	2.4212	0.0190*	11.55±1.69	1.7233	0.0908
Systolic BP	113.78±6.68	113.56±6.84	0.1196	0.9053	115.78±6.95	1.0781	0.2860	116.89±8.7	1.4733	0.1467	120±8.32	3.0291	0.0038*
Diastolic BP	73.33±6.37	76±5.26	1.6794	0.0991	76.22±6.68	1.6269	0.1098	79.33±5.6	3.6758	0.0006**	80.67±7.62	3.8402	0.0003**
Fasting B Sugar	248.56±55.18	217.56±51.92	2.1260	0.0383*	199.89± 49.23	3.4199	0.0012*	180.33±39.04	5.2450	0.0001**	155.89±39.66	7.0861	0.0001**
Fundal height	16.55±0.84	23.88±1.39	23.4516	0.0001**	27.77±0.64	55.2075	0.0001**	33.67±0.42	94.7221	0.0001**	36.11±0.32	113.0694	0.0001**
FHR	143.78±2.24	143.56±2.10	0.3723	0.7112	144±1.35	0.4371	0.6639	144±1.35	0.4371	0.6639	148.74±5.9	4.0839	0.0002**

*significant at 0.05level, **significant at 0.01level

Table 6.Comparison of maternal outcome between Experimental and Control Group

N=110

Maternal outcome variables	Categories	Experimental Group(N=56)	Control Group (N=54)	Odds Ratio (OR)	p-value
Gain in weight	Normal	52 (92.86%)	36 (66.67%)	Reference	0.015
	Average	0	0	6.5	
	Below Normal	4 (7.14%)	18 (33.33%)		
Gain in haemoglobin	Normal	34 (60.71%)	28 (51.85%)	Reference	0.075
	Average	22 (39.29%)	26 (48.15%)	3.42	
	Below Normal	0	0		
Control over Blood Pressure	Normal	36 (64.29%)	48 (88.89%)	Reference	0.052
	Average	8 (14.29%)	0	0.08	
	Below Normal	12 (21.43%)	6 (11,12%)	0.375	
control over blood sugar	Good	52 (92.86%)	18 (33.33%)	Reference	0.001**
	Average	4 (7.14%)	12 (22.22%)	8.67	
	Fair	0	24 (44.45%)	69.73	
Fetal Distress	Absent	48 (85.71%)	24 (44.45%)	Reference	0.003**
	Mild Distress	8 (14.29%)	24 (44.45%)	6	
	Severe Distress	0	6 (11.10%)	13.72	
Need for blood transfusion	No	56 (100%)	54 (100%)		
	1-2 transfusions	0	0		
	>2 transfusions	0	0		
Emergency Hospitalization	No	48 (85.71%)	36 (66.67%)	Reference	0.149
	Once/ Twice	8 (14.29%)	2 (2.22%)	2	
	>Twice	0	6 (11.11%)	9.48	
Mode of delivery	Normal vaginal	44 (78.57%)	30 (55.56%)	Reference	0.079
	Assisted	0	6 (11.11%)	10.5	
	Caesarean	12 (21.43%)	18 (33.33%)	2.2	
Gestational age	Full term	48 (85.71%)	36 (66.67%)	3	0.121
	Preterm	08 (14.29%)	18 (33.33%)		
	Very preterm	0	0		

**Significant at 0.01 level, * significant at 0.05 level

Table 6, indicates that normal weight gain was more among experimental group subjects (OR=6.5) than their control subjects ($p<0.05$). Gain in haemoglobin was normal in maximum number of experimental group subjects, whereas there were equal number of subjects in both groups who had average gain in haemoglobin level.

The mean blood pressure was found normal among experimental group subjects who followed therapeutic diet, adhered to advises and exercises etc as compared to the control group subjects who had high blood pressure levels ($p<0.05$).

Majority of subjects in experimental group (92.86%) had good control over blood sugar as compared to subjects in control group (33.33%). Fair control over blood sugar was found in 44.45% of control subjects whereas it was not evident in experimental group of subjects (OR=69.73). There was significant absence of fetal distress among experimental group of subjects (OR=13.72) than their control subjects ($p<0.05$). Study subjects in both experimental and control group did not need any blood transfusion. The need for emergency hospitalization did not show any significant difference between experimental and control group subjects.

Subjects did not show any significant difference in the mode

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of delivery and gestational age between their experimental and control group subjects. Majority of babies were born by normal vaginal delivery, without distress, full term, in both groups but caesarean births, babies with distress, was more in babies born in subjects of control group who also delivered 33.33% preterm babies. This indicates that exposure subjects to intervention was effective on experimental group who delivered babies normally and full term. Diabetic subjects did not show any significant difference in the gestational age between the experimental and control group.

As these findings indicate that there is difference in maternal outcome between experimental group and control group subjects thus depicts that intervention was effective. The researcher rejects the null hypothesis showing that there is difference in maternal outcome between experimental group and control group subjects.

Section V: Association of maternal outcome with demographic variables of diabetic pregnant women

Multivariate Logistic Regression was done to associate maternal outcome with demographic variables of diabetic pregnant women i.e; age, Socio-Economic Status (SES), nutritional Status and gravidity. To test the significance of association, following null hypothesis was formulated:

Ho3: There is no significant association between maternal outcome of diabetic pregnant women and their selected demographic variables at 0.05 level of significance.

Findings have indicated significant association ($p<0.05$) of:

- Gain in weight with age group of 20-30 years (0.013*) and with good nutritional status (0.023*).
- Mode of delivery with socio-economic status (0.025*).
- Gestational age with socio-economic status (0.010*) and gravidity (0.042*).

The study indicated no significant association of pregnancy outcome variables like control over blood pressure, control over blood sugar, fetal distress, need for blood transfusion, and emergency hospitalization with age, socio economic status, nutritional status and gravidity of subjects.

Thus null hypothesis was partially accepted and partially rejected.

Discussion

Maximum number of subjects from both groups belonged to middle socio economic class, had moderate exposure to smoke, average nutritional status, and were primigravidae**.** Malik and Mir[32] conducted a prospective study in Srinagar to identify preventable factors of perinatal mortality in high risk pregnancy obtained similar observations. Present study indicated that high percentage of subjects had average nutritional status. Amin and Imtiyaz[33] have studied correlation of maternal factors like age, literacy, income, type of family, Hb level and antenatal care on the nutritional status of pregnant women and have found that majority of women had average nutritional status.

The mean body weight and mean haemoglobin of experimental group of subjects increased normally, mean systolic and diastolic pressure was within normal limits throughout the gestation period. Mean fasting blood sugar was controlled from 16-36 weeks of gestation. Mean fetal heart rate was within normal range at various weeks of gestation. Spong[34] evaluated pregnancy outcome for 8,293 pregnant women including first time mothers in US at multiple sites. She reported normal weight gain, and gain in haemoglobin among 17.5% and 32.5% women respectively who attended counselling sessions during pregnancy.

The mean body weight and mean haemoglobin of control group of subjects were increasing normally, mean systolic and diastolic pressure was within normal limits throughout the gestation period. Mean fasting blood sugar was high throughout.Mean fetal heart rate was within normal range at various weeks of gestation. Mean fasting blood sugar was high throughout.Mean fundal height varied normally at various weeks of gestation. Mean fetal heart rate was within normal range at various weeks of gestation. Mattoo[31] while studying effectiveness of educational program on gestational diabetic women. She also studied similar parameters and found range in physical and physiological parameters of diabetic pregnant women in both groups almost in same range.

In comparison of parameters among experimental group of diabetic pregnant women between pretest and post-test I, II, III and IV. Mean body weight, mean haemoglobin, mean blood pressure, mean fasting blood sugar showed significant difference between pretest and their post tests ($p<0.05$). Mean fetal heart rate showed no significant difference between pretest and post tests (I, II & III) where as there was significant difference in mean fetal heart rate between pretest and post test IV. Mattoo[31] while studying effectiveness of educational program on gestational diabetic women found similar comparison in all physical and physiological parameters.

In comparison of parameters among control group of diabetic pregnant women between pretest and post test I, II, III and IV. there was significant difference in mean body weight, mean haemoglobin mean blood pressure and mean fetal heart rate in pretest and some post test whereas there was no significant difference in pretest and some post tests in these parameters. Regarding mean fasting blood sugar and mean fundal height, there was significant difference between pretest and all 4 posttests ($p<0.05$ and 0.01). Mean fetal heart rate showed no significant difference between pretest and post tests (I, II & III) where

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as there was significant difference in mean fetal heart rate between pretest and post test IV (0.0002; p<0.01). Mattoo[31] found similar comparison in all physical and physiological parameters.

In comparing maternal outcome between experimental and control group of subjects, normal weight gain was more among experimental group subjects than their control subjects (p<0.05). The findings are consistent with the study of Thangaratinam et al.[35] who studied the effect of dietary and lifestyle interventions in pregnancy on maternal and fetal weight. Similar results were shown by Mattoo[31], Catalano et al.[19]

Gain in haemoglobin was normal in maximum number of experimental group subjects, whereas there were equal number of subjects in both groups who had average gain in haemoglobin level. Similar observations were reported in the findings of a study on weight gain patterns during pregnancy conducted at Srinagar by Kousar.[36] She reported that increase in weight and haemoglobin was highest in mothers who had adequate intake of calories and proteins.[37] reported that haemoglobin in gestational diabetic mothers had shown significant increase after iron supplementation. These findings are supported by Dempsey[10] who studied effect of dietary habits, exercise, rest and follow ups on prevention of maternal complications among a group of 875 pregnant women with Gestational Diabetic Mellitus (GDM). His findings revealed statistically significant change in maternal weight, haemoglobin, blood pressure and glycaemia levels after implementation of intervention.[25] in their study on 545 diabetic pregnant women found that comprehensive antenatal care with education has reduced high glycaemia levels, increased haemoglobin and improved fetal growth. The findings of study conducted by Mattoo[31] are also consistent with findings of present study. She reported that GDM mother's glycaemia level at 30, 32, 34 and 36 weeks after administration of planned health education programme was found normal in experimental group as compared to control group (p<0.05). She reported increase in mean weight, decrease in mean blood pressure and mean blood sugar in experimental group.[18] Conducted a study on pregnant women with diabetes to observe their neonatal outcome. They reported high rates of low birth weight and prematurity (33.25%) among women with uncontrolled blood sugar and still births were found high in mothers (14%) who were detected diabetics after 24 weeks of gestation.

The mean blood pressure was found normal among experimental group subjects who followed therapeutic diet, adhered to advises and exercises etc as compared to the control group subjects who had high blood pressure levels (p<0.05). Mathews and Mahendra[38] conducted a study in Karnataka on 545 diabetic pregnant women and found that comprehensive antenatal care with education has reduced high glycaemia levels, increased haemoglobin and improved fetal growth. Kramer and Mc Donald[39] reported that exercises in pregnant women have controlled the weight gain and blood pressure who studied aerobic exercise for women during pregnancy. Chandra and Agarwal[40] who studied nutritional aspect of women with special reference to pregnancy and reported fetal distress and birth of premature distressed baby more in women with inadequate dietary intake who needed emergency hospitalization for blood transfusions and due to fetal distress.

Majority of subjects in experimental group had good control over blood sugar as compared to subjects in control group. There was significant absence of fetal distress among experimental group of subjects (OR=13.72) than their control subjects (p<0.05). These findings are supported by study of Mattoo[31] who reported that gain in weight and haemoglobin had shown no significant difference between experimental and control group whereas more number of experimental group of Gestational Diabetic Mellitus (GDM) women (86.4%) attained normal blood pressure and glycaemia levels thus fetal distress was not evident in them and they had significantly shown better maternal outcome during labour.[23] studied obstetric and neonatal outcome among women in Switzerland with gestational diabetes in Singapore and reported that 58.62% women needed assisted vaginal delivery by application of forceps, 6.08% delivered still births and 32.1% mothers delivered babies by caesarean section.

Study subjects in both experimental and control group did not need any blood transfusion. The need for emergency hospitalization did not show any significant difference between experimental and control group subjects. Similar observations were made by Gupta et al.[41]

Di Simone et al.[16] studied insulin plasma levels in pregnant patients with impaired glucose tolerance and its relationship with pregnancy outcome in UK. They found that these mothers had delivered still births (13.3%), had undergone premature labour (8.97%) and caesarean rates were 17%. Babies (17.5%) had Apgar score below 7, low birth weight (65.49%), born before 36 weeks (5.43%) and between 32-35 weeks (3.54%)

Siega et al.[42] did a systematic review of maternal weight gain according to the Institute of Medicine Recommendations: birth weight, fetal growth, and postpartum weight retention and reported statistically significant difference among study and control group in terms of gain in haemoglobin, control over blood pressure, fetal distress and overall maternal outcome.

The findings of Mattoo[31] also are consistent with findings

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of present study. She studied effectiveness of planned health education program among women with Gestational Diabetic Mellitus (GDM) on knowledge, stress, glycaemia level, maternal and perinatal outcome. She reported that GDM mother's glycaemia level at 30, 32, 34 and 36 weeks (after administration of planned health education programme-PHEP at 28 weeks of gestation) was found normal in experimental group as compared to control group ($p<0.05$). She reported increase in mean weight (66.37-68.91Kg), mean haemoglobin (11.3-11.9 g%); decrease in mean blood pressure (116.2/ 76.2-118.7/ 78.2mmHg) and mean blood sugar (90.1-87.9mg/dl) in experimental group. Mean fundal height and mean fetal heart rate was similar in both groups (not significant) which again agree with the findings of present study.

Subjects did not show any significant difference in the mode of delivery and gestational age between their experimental and control group subjects.Berkowitz et al.[43] reported delivery of full term baby with normal birth weight ($p<0.05$) among diabetic women who had followed regular antenatal plan. Similar observations were made by China et al.[23] and Coetzee and Levitt[18] when they investigated the neonatal outcome in maternal diabetes. Similar observations were made by Bell[28] who conducted a study in UK to find out effects of maternal body mass index on the neonatal outcome and obstetric complications in women with gestational diabetes and reported that the babies were born by caesarean section (34.21%) and by assisted delivery (18.7%) and about 10.65% were soon admitted in neonatal nursery for observation or for treatment as the baby's condition was poor.

Findings have indicated significant association ($p<0.05$) of gain in weight with age group of 20-30 years (0.013*) and with good nutritional status (0.023*); mode of delivery with socio-economic status (0.025*) and gestational age with socio-economic status (0.010*) and gravidity (0.042*). Kousar[36] reported that only maternal age and dietary calorie intake were found to have significant effect on weight gain ($p<0.001$). It was reported that 26% mothers belonged to <20 years of age and had the lowest weight gain of 7.08+1.85Kg. As the age advanced the weight gain also increased being 7.83+2.01Kg in the 21-25 years age group and 9.16+2.05Kg in the 26-30 years age group. With regard to socio economic class, maximum weight gain has been seen in mothers belonging to SES class I i.e.; 10.6+2.6Kg; and the least weight gain in mothers who belonged to SES class IV i.e;7.09+0.18Kg. The present study findings are also endorsed by China et al.[23] Mattoo[31] who had shown significant association of socio-economics status with mode of delivery. Present study indicates that the neonates born to subjects with good nutritional status had good condition during early *neonatal period* of 24 hours. The data reveals no significant association of early neonatal outcome with age, socio economic status and gravidity of subjects. The findings of the study conducted by Catalano et al.[19] are also consistent with the findings of present study. They found that weight gain is significantly associated with age of diabetic pregnant women.

The study indicated no significant association of pregnancy outcome variables like control over blood pressure, control over blood sugar, fetal distress, need for blood transfusion, and emergency hospitalization with age, socio economic status, nutritional status and gravidity of subjects. Berkowitz et al.[43] while studying maternal characteristics and neonatal outcome and gestational diabetes, reported that younger women developed diabetic complications and had adverse effect on the perinatal outcome though their findings too are not-significant. Similar results were observed in studies conducted by Carr et al.[44], Johnson et al.[45] who too found no association of age, SES, nutritional staus and gravidity with control over blood pressure.

Conclusion

On comparing physical and physiological parameters of experimental group and control group subjects between pretest and post tests at various weeks of gestation, it is evident that the mean weight and haemoglobin of experimental group was more, mean systolic/ diastolic blood pressure and mean fasting blood sugar of experimental group was less on post tests as compared to their pretest value. This indicates the effectiveness of intervention program.

Since there was significant difference in only two of the pregnancy outcome variables between experimental and control group, it indicates that nurses are not able to address to the problems of diabetic pregnant women in highly crowded antenatal clinics and cannot counsel them, which may be probably due to posting of one staff nurse in antenatal clinic who remains busy in immunizing and giving iron infusions.

The findings revealed significant association of gain in weight in subjects with good nutritional status in subjects from middle socio economic status. Thus dietary counseling during pregnancy is essential aspect to improve pregnancy outcome.

It was found that subjects with high socio economic status delivered babies more by caesarean section than low socio economic subjects which may be related to their sedentary life style. Subjects with middle socio economic status delivered live and full term babies more than low socio economic subjects which may be probably due to good nutritional status in middle class. Primigravida subjects delivered more full term babies than multigravida subjects which indicates that high parity leads to delivery of baby who is preterm and has low birth weight.

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The study indicated no significant association of control over blood pressure/ blood sugar, absence of fetal distress, need for blood transfusion and emergency hospitalization with age, socio economic status, nutritional status and gravidity of subjects thus it clearly indicates that probably these socio-demographic characteristics of subjects do not influence their maternal outcome.

Implications

Prenatal intervention enabled subjects of experimental group to attain desirable pregnancy outcome. Exposure of diabetic subjects to intervention was effective on experimental group who delivered babies normally, full term and without distress. It is found that pharmacological regimen alone do not improve the pregnancy outcome but should be supported with verbal information, discussion, and written information, teaching about diet modification, and self monitoring of weight, blood pressure and blood sugar.

The findings of the present study revealed that pregnancy outcome of diabetic pregnant women were improved by intervention program. Continuous assessment, reinforcement of care and counseling of diabetic pregnant women during antenatal period motivates them to comply with better and therapeutic dietary regimes, follow health promoting antenatal advises and avoid health inhibiting points so that they give birth to a healthy and full term baby who enjoys the healthful life ahead. Therefore there is great need to educate and counsel the women during prenatal period with special emphasis on risk factors of pregnancy which can have bearing on their pregnancy outcome.

Nurses shall be the role models for mothers while demonstrating and providing information. Nurses should provide counselling and health education to women on each visit and whenever required. Continuous assessment of these women should be part of nursing care at antenatal clinics and antenatal wards.Nurses can prepare information booklet to be provided to educated group for self learning whereas for mothers with low education or no schooling, teaching can be adopted with the use of teaching aids like flip chart, posters, flash cards, slide.

During the antenatal education programmes nurses should place emphasis on involvement of husbands or significant others in care giving, demonstrations and in counseling sessions so that high risk women receive special attention at home on diet, sleep, hours of work and get sufficient periods of rest. This makes woman relaxed and encourages her for follow up.

Conflict of Interest: None

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