Original Article

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Impact of a Comprehensive Nursing Intervention Package on the Glycemic Control of Women with GDM

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Abstract

Gestational diabetes mellitus (GDM) is associated with many maternal and foetal complications. Many of these complications can be prevented by controlling the blood sugar level. The purpose of the study is to evaluate the effectiveness of a comprehensive nursing intervention package (CNIP) which focus on improving the self-care abilities of women with GDM on the glycemic control. ***Materials and methods:*** The study used a pretest-posttest control group design. Eighty women with GDM, at 24-32 weeks of gestation, attending a tertiary care university teaching hospital in South India were randomized to experimental and control group (40 each). FBS, PPBS and insulin dose measured before the intervention, at two weeks, in the week prior to delivery, third postnatal day and six weeks postpartum were compared between experimental and control group using t-test. ***Results:*** The PPBS level and insulin dose of the experimental group were significantly lower than the control group ($p<0.001$) in the week prior to delivery. The mean gain in insulin dose from pretest to the week prior to delivery was significantly lower in the experimental group than the control group (4.25+/-5.3 vs. 13.6+/-7, $t(78)=6.7$; $p<0.001$).The frequency of hypoglycemia during pregnancy [2 (5%) vs. 9 (22.5%); $p<0.05$] were also lower in the experimental group than the control group. ***Conclusion:*** The findings of the study are suggestive of the effectiveness of CNIP in improving the glycemic control of women with GDM. Nursing interventions focusing on enhancing self-care will be cost-effective approach as it may be beneficial in reducing the need for insulin in women with GDM.

Key words: Comprehensive Nursing Intervention Package; Gestational Diabetes Mellitus; Glycemic Control; Insulin Dose.

Introduction

Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (ADA) [1]. High blood sugar level increases the risk for many maternal and fetal complications. Maternal complications of GDM include pregnancy induced hypertension including pre-eclampsia [2,3,4], infections [3], hydramniose [4], premature rupture of membranes [3], preterm labour[2], placental abruption[2,3] and

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higher rate of operative delivery [2,3]. Fetal complications include macrosomia [2,4,5], preterm birth [2,5], shoulder dystocia [2], birth trauma[2], congenital anomalies[4], IUGR[5], hypoglycemia[5], polycythemia[4], hypocalcemia[4,5] and hyperbilurubinemia[4,5]. Women with GDM are at an increased risk of developing diabetes in the future[6]. The incidence of diabetes and metabolic syndrome is found to be about 37 % and 60% respectively in women with GDM at five years following delivery[12]. Exposure to hyperglycemia during pregnancy increases the risk for DM, obesity and metabolic syndrome in the offspring[8]. Type 2 diabetes was diagnosed at younger ages among those exposed to hyperglycemia in utero[9]. Increased risk of developing diabetes in the offspring is up to 20%[10].

The prevalence of GDM varies worldwide and among different racial and ethnic group within a country, and it may range from 2-14%[1]. Many studies have shown that Native American, Asian, Hispanic, and African-American women are at higher risk for GDM than non-Hispanic white women [11]. A systematic review of the trends of prevalence of GDM among the Asian countries over the past 20 revealed evidence of increasing GDM in China, Hong Kong, Thailand and India [12]. In India an increasing trend in the prevalence is observed from 2% in 1982 to 7.62% in 1991[13]. Some of the lowest and highest rates of GDM are documented in India and it range from 3.8 to 21% in different parts of the country, depending on the geographical locations and diagnostic methods used [14]. The prevalence of GDM is found to be higher in urban areas and in southern part of India [13,14,16].

Developing and allocating appropriate resources for the effective management of GDM are of critical importance not only for the perinatal management but also for the postpartum diabetes prevention strategies. A randomized control trial conducted on 1000 women with GDM show that women who received treatment with dietary advice, blood glucose monitoring and insulin therapy as needed had significantly lower incidence of serious perinatal morbidity and better health related quality of life [17]. The treatments to lower blood glucose level alone or with special obstetric care are found to lower the risk of adverse perinatal complications [18]. The perinatal outcome of pregnancies complicated by diabetes depends on the glycemic levels during pregnancy[19]. So the aim of management of GDM is to maintain blood glucose levels within normal limits so as to achieve better maternal and fetal outcomes.

GDM is usually managed with diet modification, glucose monitoring and insulin therapy. More than 50% of the women diagnosed with GDM require insulin therapy [20]. The clients may need repeated hospitalization for the adjustment of insulin dose as well as the prevention and management of complications. This makes the treatment of GDM expensive. Blood glucose levels are influenced by lifestyle factors like diet and physical activity. The studies conducted on the dietary management of GDM show that diet composed of adequate carbohydrate and with high fiber and low glycemic index (GI) foods improve maternal glucose tolerance, gestational weight gain and birth weight of the offspring [21]. Using a low GI diet was found to lower the need for insulin[22]. In women with GDM physical activity and exercise are found to improve glycemic control and reduce need for insulin [23,24]. The women with GDM are usually treated as outpatients. Life style factors which influence GDM like diet, physical activity etc happens outside the hospital premises. Educational programmes led by nurses for the women with GDM have shown to improve the health behaviors and pregnancy outcomes [25].

The present study is an attempt to device a cost-effective nursing intervention for the women with GDM incorporating the benefit of diet and exercise. The CNIP is developed as a set of multi-component interventions which center on improving the self-care abilities related to diet, exercise and other self-care activities. The purpose of this paper is to present the effect of the CNIP on the glycemic control of women with GDM which is tested by comparing the glycemic control between experimental and control group.

Materials and Methods

An experimental approach with pretest post-test control group design was used for the study. The setting of the study was the Obstetric unit of a selected tertiary care University teaching hospital in South India. The period of data collection was from February 2012 to December 2013.

Sampling

Sample size was estimated based on the result of the pilot study conducted on 20 women with

GDM and it was 40 in each group. For the purpose of random allocation, 80 chits were prepared, 40 each for experimental and control group. As a pregnant woman with GDM who meet the inclusion criteria was identified a chit was drawn and allocation was done accordingly. Attrition of the subjects was compensated by replacing it with new ones till the required number in each group was obtained.

All the women with GDM between 18 to 39 years, gestational age between 24-32 weeks and without any other complications were included for the study. Ability to read and write Malayalam or English and consent to be contacted over phone were also set as inclusion criteria. Diagnosis of GDM before 12 weeks, uncontrolled hyperglycemia and women receiving oral hypoglycemic agents were excluded.

Comprehensive Nursing Intervention package

The independent variable of the study was the Comprehensive Nursing Intervention Package (CINP) which refers to an intervention package developed by the investigator for women with GDM. The CNIP focus on enhancing their self-care abilities related to diet, exercise and other self-care measures and thereby improving glycemic control and there by achieve a better perinatal outcome.

The CNIP includes exercise package, dietary package and other self-care activities. Exercise package comprises of post prandial exercise which consists of self-paced walking and arm exercises to be performed in the first postprandial hours. The dietary package aims at improving the diet by making modifications in the existing diet practice. It focuses on splitting diet, carbohydrate counting and following a low GI diet while eating a balanced diet. Other self care activities include monitoring of daily fatal movement and maintaining DFMC chart, monitoring for the signs and symptoms of complications, maintaining blood sugar chart and regular follow up. Teaching on GDM and interventions of the package, self-care guide, self-care log, telephonic support and follow up are part of the intervention.

Data collection

Ethical clearance was obtained from Institutional Ethics Committee of Amrita Institute of Medical Science and Research Centre, Kochi. Detailed explanation of the purpose of the study and nature of participation was explained to all the potential participants. A detailed patient information sheet was given to them and were given time to ask doubts. Participation in the study was confirmed for those who were willing to participate and meet the criteria for participation. A written informed consent was obtained from all the participants enrolled for the study.

Background information was obtained with the help of a semi-structured interview schedule on recruitment. The data on FBS, PPBS, insulin dose and any significant clinical data collected from the client's record were documented in a flow sheet. Both groups received routine care which includes blood sugar testing and follow-up by obstetrician once every two weeks. Insulin dose were adjusted based on the blood sugar values. As part of CNIP, women in the experimental group were given teaching on GDM and the interventions in the package. Teaching sessions were delivered in a group of two to three women with GDM in a room adjacent of the outpatient department. A self-care guide on the contents taught was given to them. They were given a log book to record the diet intake, exercise done and fetal movements daily which is reviewed in the follow up session after two weeks when they were helped to evaluate own self-care activities and to decide on modifications to be made. A blood sugar chart was given to the women to record the data on FBS, PPBS levels and insulin dose. In the first two weeks of the intervention the women in the experimental group were contacted twice a week over phone to review the diet and exercise and to clarify any doubts. Second session of teaching was given during follow up session after two weeks content of which include review the first session, care after delivery, breastfeeding and newborn care. They were also allowed to contact the investigator over phone to clear any doubts. Adherence to the package was ensured by evaluating the log book.

Blood sugar level measured at two weeks, in the week prior to delivery, third postnatal day and 6 weeks postpartum were considered as the posttest.

Results

Section 1. Background data

The mean age of the experimental group and control group were 29.8+/-5.2 and 30.1+/-4.7 years respectively. All the women were in the age group of 20 to 39 years. The mean gestational age of

Table 1: Distribution of the experimental and control group based on the clinical data

Sl. No.	Clinical variables	Experimental group (n=40)		Control group(n=40)		p-value
		F	%	F	%	
1.	Order of pregnancy					
	First	16	40	16	40	1
	Second and above	24	60	24	60	
2.	Gestational age at diagnosis of GDM					
	Before 20 weeks	9	22.5	10	25	
	20-24 weeks	17	42.5	15	37.5	0.899
	After 24 weeks	14	35	15	37.5	
3.	Gestational age when insulin treatment started					
	Before 20 weeks	3	7.5	2	5	
	20 -24 weeks	12	30	12	30	0.969
	After 24 weeks	16	40	15	37.5	
	Not on insulin	9	22.5	11	27.5	

Table 2: Distribution of the experimental and control group based on the risk factors of GDM

Risk factors	Experimental group (n=40)		Control group(n=40)		p-value
	F	%	F	%	
a. Family history of DM	24	60	21	52.5	0.499
b. Family history of GDM	5	12.5	7	17.5	0.531
c. Age over 30years	19	47.5	21	52.5	0.655
d. Overweight (BMI more than 26)	5	12.5	6	15	0.745
e. PCOD	2	5	1	2.5	0.556
f. Sedentary lifestyle	7	17.5	5	12.5	0.531
Past obstetrical history (n=24)					
g. History of GDM	6	15	7	17.5	.762
h. Birth of child with birth weight more than 4kg	1	2.5	1	2.5	1
i. History of abortion or still birth	3	7.5	3	7.5	1
j. History of preterm birth	2	5	3	7.5	0.644

Table 3: OGTT values of the experimental and control group

	Mean=/-SD			
	Experimental group (n=40)	Control group(n=40)	t-value	p-value
FBS	94.08+/-7.9	94.21+/-6.7	.081	.935
1st hour PPBS	219.5+/-37.5	217.7+/-32.5	.217	.829
2nd hour PPBS	162.8+/-17.4	161+/-15.2	.472	.638
3rd hour PPBS	126.35+/-23	124.2+/-22	.397	.693

recruitment of the experimental group was 28.3+/-2.7 weeks and the control group was 28.9+/-2.5 weeks. The clinical data, risk factors of GDM and diagnostic oral glucose tolerance test values of the sample is given in table 1, 2 and 3 respectively and it shows that groups were homogenous in relation these variables which may have influence on the glycemic control.

Section 2: Glycemic control

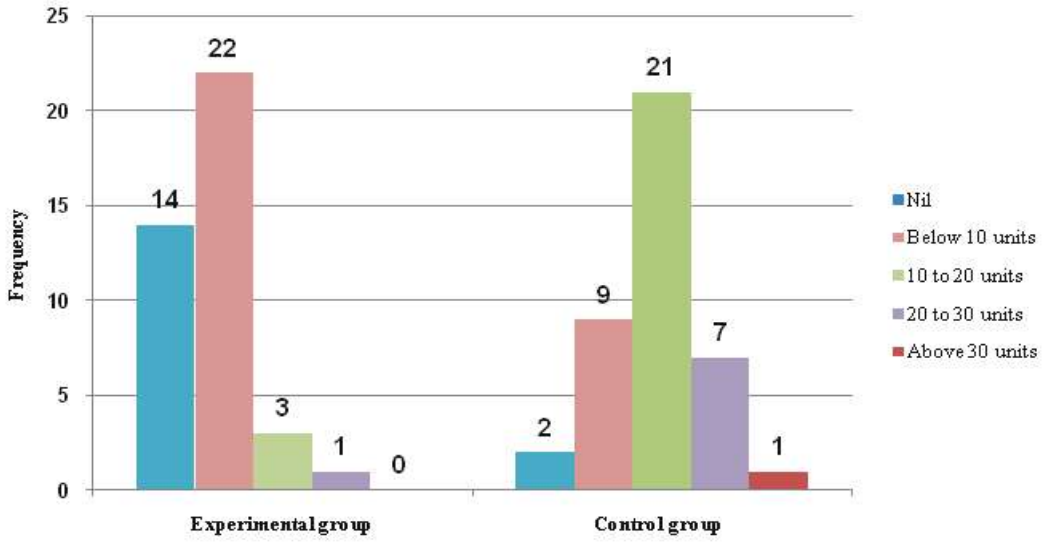
The hypothesis tested to identify the effect of CNIP on glycemic control was *'There will be no significant difference in the glycemic control (FBS, PPBS, insulin dose, and gain insulin dose) between the experimental and control group'*. The comparison of FBS, PPBS and insulin dose is presented in table 4. There was no significant difference in the FBS, PPBS or insulin dose between groups in the pretest. The PPBS level of the experimental group was significantly lower than the control group, when measured two weeks after the intervention (111.25+/-16.4 vs.138.1+/-14.7, t (78) = 7.686; p<0.001) and in the week prior to delivery (101+/_14.7 vs. 129+/-13.5, t=9.114; p<0.001). In the week prior to delivery the experimental group had significantly lower insulin dose (15.25+/-11.6 vs. 23.15+/-10.9, t(78)=3.138; p=0.002).

Table 4: Comparison on FBS, PPBS & insulin dose between the experimental and control group

	Mean +/- SD		t-value	p-value
	Experimental group	Control group		
Pre test				
FBS	90.7 ±9.1	93.7+9.4	1.456	0.149
PPBS	134.38 ±19.3	136.23+14.5	0.485	0.629
Insulin dose	11 ±8.4	9.55+7.5	0.816	0.417
Post test 1 (after two weeks)				
FBS	89.7 ±5.8	91.1+6	1.036	0.304
PPBS	111.25 ±16.4	138.1+14.7	7.686	<0.000**
Insulin dose	12.6 ±8.9	13.55+8	0.503	0.617
Post test 2 (week prior to delivery)				
FBS	86.33±6.6	89.23±9.4	1.595	0.115
PPBS	101.03±14.7	129.85±13.5	9.114	<0.000***
Insulin dose	15.25±11.6	23.15±10.9	3.138	0.002**
Post test 3 (Postnatal day 3)				
FBS	87.08±8.6	92.9±9.6	2.857	0.005*
PPBS	115.53±21	123.08±25.5	1.446	0.152
Post test 4 (6 weeks post partum)				
FBS	85.7±5.7	87.8±6.8	1.499	0.138
PPBS	120±43	126.23±15.3	1.417	0.160

The gain insulin dose from pretest to the week prior to delivery was less than 10 units in majority of the experimental group whereas in the control group majority had gain more than 10 units (Figure 1). The mean gain in insulin dose in the experimental group was also significantly lower than the control group (4.25+/-5.3 vs. 13.6+/-7, t(78)=6.7; p<0.001). The experimental group had less number of

Fig. 1: Distribution of the experimental and control group based on the gain in insulin dose



hypoglycemic episodes during pregnancy than the control group [2 (5%) vs. 9 (22.5%); p<0.05].

Discussion

Results of the study support the effectiveness of the CNIP in improving the PPBS levels during pregnancy and reducing the need for insulin in women with GDM. CNIP is a set of multi-component interventions which focused on improving the self-care abilities related to diet, exercise and other self-care measures. Though evidence for similar intervention could not be identified in the accessed literature, many individual components of the package were found to be effective in improving the glycemic control.

A systematic review and meta-analysis of randomized clinical trials analyzed the efficacy of dietary interventions on maternal or newborn outcomes in GDM among nine eligible RCTs, including 884 women aged 31.5 years (28.7-33.2) with 27.4 weeks (24.1-30.3) of gestation. The outcomes were compared among low glycemic index (GI) (n = 4; 257 patients), total energy restriction (n = 2; 425 patients), low carbohydrates (n = 2; 182 patients), and others (n = 1; 20 patients). A low GI diet was associated with less frequent insulin use and lower birth weight than control diets, suggesting that it is the most appropriate dietary intervention to be prescribed to patients with GDM [26]. A low GI diet was recommended as part of CNIP. Energy or carbohydrate restriction was not advised. Women were rather asked to split the total carbohydrate per day. The insulin use of the experimental group was lower than the control group.

Another RCT on the effect of a low GI diet on blood glucose found that glycemic control improved on both diets, but more postprandial glucose values were within target on low GI (58.4% of n=1891) than control (48.7% of n=1834; p<0.001) [27]. In the present study though both group had glycemic levels within normal limits and the experimental group had PPBS levels significantly lower than the control group. Nutrition education and maintenance of food record in the form of diet log were part of the intervention. An experimental study conducted in Finland among 54 women at risk of GDM found that intensive dietary therapy in the form of dietary advice improve the quality of diet [28].

Exercise package in the CNIP incorporate self-paced walking and arm exercises to be performed in the postprandial hours. As GDM is associated with insulin resistance and glucose intolerance, the blood sugar level in the postprandial hours tend to be high. Exercise promotes contraction stimulated glucose transport across the muscles and increases glucose uptake by 35 fold, thereby reducing the blood glucose levels and help to achieve better control of diabetes [29].

Experimental studies which evaluated the effect of light exercise during postprandial hours found that it improve the PPBS levels [23,30] and insulin requirement in women with GDM [23]. In another study the effectiveness of a structured low-intensity walking protocol on capillary glucose control among women with GDM found that there was an acute drop of capillary glucose concentration from pre- to post-exercise of 2.0mmol/ L and the walking group had significantly lower mean glucose concentrations in the fasted state and one hour after meals and insulin injected less frequently than the control group [24].

In the present study also the experimental group had low PPBS level and less insulin prescribed in the week prior to delivery. But no difference was observed in the FBS levels. A probable explanation for not having an effect in the FBS level may be the intense glucose monitoring and medical treatment both group were receiving. The insulin dose was adjusted to maintain blood sugar within normal limits. Here both the groups maintained blood sugar level within the normal limits.

Exercising during postprandial hours helps to improve blood glucose control at the same time reducing the risk for hypoglycemia. In addition to this, most of the women were not engaged in exercise previously and later half of pregnancy is not a right time to start intense exercise therapy. Light exercises during postprandial hours are feasible and easily tolerated even by women who haven't exercised before.

Measures to ensure compliance was incorporated in the CNIP. A log book was given to the women to record diet taken and exercise done daily. Telephonic follow up was done twice a week in the initial two weeks to encourage and motivate them adhere to the self-care measures and to maintain the self-care log. Twenty four hour dietary recall was also done over phone to review diet and to ensure that they follow the dietary prescription. Two weeks after the first session a follow up session was arranged during which the women were made to evaluate their self-care activities and they were helped to identify the areas to improve. The dietary recall obtained during telephonic follow up was also used for evaluation and providing suggestions for change in the follow up sessions. Evidence from literature suggest that

telephone based interventions are effective in improving health behaviours and lifestyle[31].

A significant difference was observed in the hypoglycemic episode between the groups. The dietary intervention in the package includes splitting of diet, low GI foods and carbohydrate counting. Splitting the diet into three major meals and three to four snacks helps to distribute the glycemic load, which would have prevented the fluctuations in the blood glucose levels. Following a low GI diet is found to be associated with reduction in hypoglycemia [32]. Carbohydrate counting is also associated with less hypoglycemic episodes [33]. In addition to this the exercise was done in the postprandial hours which again reduce the risk for hypoglycemia. Thus the dietary as well as exercise interventions in the package together could have contributed to less number of hypoglycemic episodes in women in the experimental group.

The studies discussed above show that each intervention in the package are effective in improving glycemic control. CNIP is a combination of these interventions which would have augmented its effectiveness to achieve a better glycemic control.

Conclusion

The findings of the study are suggestive of the effectiveness of the Comprehensive Nursing Intervention Package in improving the glycemic control of the women with GDM in terms of PPBS levels and insulin need. The intervention focuses on improving the self-care abilities of the women and there by achieving glycemic control. By reducing the need for insulin CNIP provides a cost effective option for the women with GDM. These findings warrant the need of an active role of nurse in the care of women with GDM, to educate them and to empower them for self-care and thereby improving the glycemic control. As the intervention has created awareness and brought lifestyle change in a group who is at risk for developing diabetes in the future it has role in the primary preventions of diabetes also.

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