

Full Length Research Paper

Pilot project for education of gestational diabetes mellitus (GDM) patients – Can it be beneficial?

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The objective of this issue is to assess the effectiveness of an educational program on patients with gestational diabetes mellitus (GDM). The study design is a case-control study that includes 30 pregnant women, mild GDM; between 19 and 41 years of age, without severe complications of diabetes. The women were divided into two groups – passing education Group I (n=15), and Group II (n=15), not passing education. A 1-month education was conducted. The clinical data and metabolic control for the two groups were evaluated. Group II shows better improvement in comparison with Group I, and also mild improvement in the blood glucose level. The patients' quality of life improves with about 1.0 point at average according to the applied questionnaire. This is the first time that the education is being done by pharmacists to patients with GDM at pharmacy conditions. The results prove that the educational approach has the potential to improve patient's quality of life.

Key words: Gestational diabetes mellitus, education, pharmaceutical care.

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance of different severity with onset or first recognition during pregnancy (Metzger and Counstan, 1998). Gestational diabetes affects 2-10% of pregnancies (Crowther et al., 2005). It usually manifests itself in the latter half of pregnancy and is characterized by carbohydrate intolerance of variable severity (Georgiou et al., 2008). GDM is not only associated with increasing pregnancy morbidity but also with the increasing possibility for subsequent diabetes in the mother. It is proven that the prevalence of GDM is proportional to the frequency of Type 2 diabetes within a given population (American College of obstetricians and gynaecologists, 2001) GDM is characterized by insulin levels that are insufficient to meet insulin demands. There are three general causes that can cause GDM: 1)

autoimmune β -cell dysfunction, 2) highly penetrant genetic abnormalities that lead to impaired insulin secretion, and 3) β -cell dysfunction that is associated with chronic insulin resistance (Metzger and Counstan, 1998). It was proven that the proper identification and management of GDM are associated with a decrease in mortality and morbidity in infants. With appropriate therapy, the likelihood of intrauterine fetal death is not detectably higher than in the general population (Metzger Counstan, 1998). The on time treatment of GDM leads to reduction of serious perinatal morbidity and also to improvement of mother's quality of life. The goal of treatment is to reduce the risks of GDM for mother and child by keeping blood glucose levels equal to those of pregnant women who don't have such a disease. The highest risk of complications is established when there is an increase of the initial level of pre-prandial blood sugar OR= 3.0 (with 95% CI between 1.55–5.81) and when there is an increase of the postprandial glucose OR=1.4 (with 95% CI between -1.06 – 1.97) (Todorova et al., 2007).

Scientific evidence shows that “controlling glucose levels can result in less serious fetal complications and increased maternal quality of life and insulin administered twice daily during the third trimester to mothers who have

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Abbreviations: GDM, Gestational diabetes mellitus; GCT, glucose challenge test; OGTT, oral glucose tolerance test; BMI, body mass index; QOL, quality of life.

even a mild degree of hyperglycaemia will reduce fetal size, and in particular fetal adiposity” (Hillier et al., 2008). The proper management GDM includes special meal plans and scheduled physical activity and of course-daily blood glucose testing. The further steps may require insulin injections (American Diabetes Association, 2008).

In 1989, in St Vincent, Italy was signed the St Vincent declaration, a joint initiative of the International Diabetes Federation European region and the World Health Organization (WHO) European regional office. It is a program for strategic action to reduce the human and economic burden of diabetes in Europe and has been adopted by most of the European governments. The St Vincent initiative has few target areas, which seek to improve the quality of life of people with diabetes and to promote education of patients so to prevent diabetes complications. Patient education is very important and a team approach, including physicians, pharmacists and nurses, is beneficial (International Diabetes Federation, 2004). A major part of GDM management involves educating patients about diet, exercise, self-monitoring and insulin treatment. The pharmacist can support the team involved in caring for GDM patients, of course they cannot replace the current care (Evans and Patry, 2004)

That is why the aim of this study is to assess the role of the pharmacist as a health-care educator and to assess the effectiveness of patient’s education for pregnant women with gestational diabetes.

MATERIALS AND METHODS

The study design is a case-control study that includes 30 pregnant women, mild GDM; between 19 and 40 years of age, without severe complications of diabetes.

The study population includes pregnant women attending antenatal clinic with gestational diabetes February 2010 - May 2010. Women, suspected to have GDM were subjected to 2 h 75 g glucose challenge test (GCT). Those with sugar level around 140 mg/dl (7.8 mmol/L) or above (n=35) were requested for oral glucose tolerance test (OGTT) recommended by WHO, scheduled on another day. A total of 35 women were informed about the study design and the procedures and 30 of them were recruited to the study. They provided an informed consent. Complete medical history including menstrual cycle, previous medical history and family history was collected by an interview. The following including criteria are used: age above 18 years, one-fetus pregnancy, GDM, insignificant additional disease without organ damage, without infectious diseases.

The women were divided into two groups – passing education Group I (n=15), and Group II (n=15), not passing education. The assignment was based on the principle of random numbers through custom random number generator. The divided into 2 groups patients did not have the option to switch study groups.

A 1-month education was conducted. The clinical data and metabolic control for the two groups were evaluated.

Settings

The educational program continued 4 weeks. There were specified the most suitable conditions for both the patients and the pharmacists that allowed good interaction. It was provided at the pharmacy they are attending. The education course was presented to Group I. The educational course included the following teaching

units:

1. The essence of GDM;
2. The complication of improper disease management;
3. Proper diet regimen (based on the Sample GDM diet menu of the Endocrinology clinic of Minneapolis).

The first unit acquainted each of the women from Group I with the aim of the educational program, provided general concept about GDM and about self-monitoring and emphasized on the active patient participation in the treatment. The personal information of each of the patients was collected, concerning the duration of the disease, the prescribed drug treatment if any, the frequency of the hypoglycaemic and hyperglycaemic incidents. At the end of the first unit, each of the patients was supplied with written materials on the essence of GDM. The goal was to learn the seriousness of GDM.

The main topic discussed during the second teaching unit was complication of improper management. The educator explained the complications of GDM and discussed with every woman the effects on the fetus.

The main topic discussed during the third teaching unit was proper diet regimen (based on the GDM diet menu of the Endocrinology clinic of Minneapolis, USA). At the end of the session the patients were supplied with the Sample GDM diet menu. Each of the patients was supplied with written materials on proper nourishing for diabetic patients and physical activity.

The educational materials used during the program included: a set of one-page written materials that illustrate the most important aspects of every educational lecture, provided to the patient after every session; questionnaire cards for distribution among the participants as a standardized procedure for assessment of their knowledge acquired in the beginning and at the end of the education; individual food and activity record for the self-monitored data (food, total grams of carbs, comments and activities, Insulin treatment); the education was performed by the authors and by 5 pre-graduating students that have passed their exam in Pharmaceutical care. Additional training was given to them to be prepared for the role of educators. There was a 3-day intensive training course provided by an endocrinologist, pharmacists and a therapist. The training course included a brief review of the disease, complications, risks, exercise and fetus protection and ended with a role-playing of various situations that can happen in the pharmacy.

In the beginning and at the end of the educational process a patient quality of life (QOL) questionnaire and a questionnaire for assessment of the knowledge acquired were applied. The Education questionnaire includes 7 questions, assessing the knowledge of the patient about their disease, their insulin therapy, what is hypoglycaemia, their knowledge on proper diet, physical exercise and finally their knowledge about the complication from GDM for them and the fetus. The answers were coded: with 1- “yes”; with 2 - “no” and with 3 – “don’t know”.

The QOL questionnaire answers were coded as it follows: 5 –“all the time”; 4-“most of the time”; 3-“most half of the time”; 2-“less than half of the time”; 1-“part of the time” and 0 – “never”. At the end of the program the clinical data and the metabolic control for the two groups (GCT and OGTT) were evaluated.

All data were processed through SPSS 17.0 software. Chi-square test and paired t test were used as data analysis. A chi-square test is used in order to prove that there is no relationship between the variables. A paired t-test is used to be proven the changes after the education. A p value less than 0.05 are considered significant

RESULTS

Patient demography

A summary of patient demographic data is presented in

Table 1. Main characteristics of the participants with their demographic data and blood glucose values.

Demographics	Group I (n ₁ =15)	Group II (n ₂ =15)	Significance (p<0.05)
Age (years)	33.93 ± 5.587	30.07 ± 6.10	NS
Living conditions:			
Living alone	26.70%	26.70%	<0.001
Living with her family	73.30%	66.70%	
Living with other people		6.70%	
Gravidity	1.87±0.64	1.8±0.676	
Body mass index	22.90±3.938	21.23±2.904	<0.001
Gestation at first visit (weeks)	10.73±1.751	11.40±1.121	<0.001
28-week GCT (mmol/l)	7.94±0.304	7.93±0.306	<0.001
28-week OGTT (mmol/l)	8.05±0.396	7.95±0.304	<0.001
final GCT (mmol/l)	7.53±0.717	7.68±0.305	<0.001
final OGTT (mmol/l)	7.53±0.717	7.96±0.445	<0.001

Data are expressed as mean ± SD.

Table 2. Main results from the education process.

Question	Before education		After education		Group I (n ₁ =15)		Group II (n ₂ =15)	
	Group I (n ₁ =15)	Group II (n ₂ =15)	Group I (n ₁ =15)	Group II (n ₂ =15)	t	Significance p<0.05	t	Significance p<0.05
What is diabetes	2.20±0.561	2.07±0.704	1.13±0.352	1.93±0.594	5.87	p<0.001	0.435	p=0.67
Insulin therapy	1.73±0.458	2.00±0.00	1.00±0.00	1.80±0.414	6.205	p<0.001	1.871	p=0.082
Hypoglycemia	3.00±0.00	2.87±0.352	1.07±0.258	2.60±0.737	29	p<0.001	1.468	p=0.164
Hyperglycemia	3.00±0.00	2.87±0.352	1.07±0.258	2.73±0.594	29	p<0.001	1.00	p=0.334
Diet	1.87±0.352	2.13±0.352	1.00±0.00	2.07±0.458	9.539	p<0.001	1.00	p=0.334
Physical exercise	1.87±0.352	2.13±0.352	1.13±0.352	2.07±0.458	6.205	p<0.001	1.00	p=0.334
Complications	1.93±0.458	2.13±0.352	1.07±0.258	2.00±0.378	6.5	p<0.001	1.00	p=0.334

Table 1. The average age of Group I is 33.93 ± 5.587, while the average age for Group II is 30.07 ± 6.10 that is important as older maternal age (over the age of 30) is one of the common risk for developing of GDM. The two groups fall within the "normal" category according to their body mass index (BMI). BMI was determined (weight in kg / height in m²) using measurements obtained after removal of footwear and outdoor clothing. According to the patient's history there is no family history of diabetes (Table 1).

Blood glucose results

The results from the initial tests GCT and OGTT for the two groups show high blood glucose concentrations for the two groups. There is significance difference between the results from the initial tests and final tests for Group I (GCT: t=2.418, p=0.030; OGTT: t=3.035, p=0.009), while there is no significant difference for Group II (GCT:

t=1.716, p=0.108; OGTT: t=- 0.099, p=0.923). The women that have passed the education units show better improvement in comparison with Group II. That means that in some cases - depending on the severeness of the disease, the age, disease history, BMI and many other factors - the education can be beneficial for the management of GDM (Table 1).

Education

During the 1-month education and its end, improvement in the patient's knowledge about their disease and complications was observed (Table 2). There was significant improvement for Group I on all the topics, assessed by the questionnaire, but the considerable increase of knowledge was achieved on the essence of hypoglycaemia and hyperglycemia – 1.93, followed by the essence of diabetes – 1.07 and the proper diet – 0.87.

Table 3. Changes in the quality of life after education.

Condition	Before education		After education		t	Group I (n ₁ =15)		Group II (n ₂ =15)	
	Group I (n ₁ =15)	Group II (n ₂ =15)	Group I (n ₁ =15)	Group II (n ₂ =15)		Significance p<0.05	t	Significance p<0.05	
Happy and in good mood	2.20±1.32	2.33±1.234	3.13±1.125	2.47±1.125	-2.606	p=0.021	-1.468	p=0.164	
Calm	3.00±0.00	3.07±0.258	3.53±0.516	2.93±0.458	-4.0	p=0.001	-3.5	p=0.004	
Vital and active	2.27±0.594	2.33±0.488	3.27±0.458	2.20±0.561	-5.916	p<0.001	1.00	p=0.334	
Woke up fresh and rested	2.40±0.507	2.13±0.516	3.00±0.00	2.07±0.594	-4.583	p<0.001	1.00	p=0.334	
Daily routine full with interesting things	1.13±0.352	1.33±0.617	2.20±0.862	1.73±1.033	-4.298	p=0.001	-1.468	p=0.164	

The behavioural parameters studied performed significant changes for Group I as they are summarized in Table 3. The results from the twice-applied questionnaire assessing the quality of life of the patients in the beginning and in the end of the educational programme show that the five main indices have been improved with on the 1.0 unit for Group I (Table 3). The greater increase is observed in the positive changes in the daily routine – 1.07 for Group I, followed by number of days when the patient “woke up fresh and rested” with 1.00 and patient being happy and good mood – 0.93. It could be considered that the educational process affects both the physical and the psychological well-being and thus it is beneficial for the global patient’s quality of life.

DISCUSSION

It is of great importance to diagnose and manage gestational diabetes earlier in order to be minimized the risks for the fetus (Georgiou et al., 2008). The advanced pharmacy practitioner in diabetes management is a relatively new approach. The role of the pharmacist in it, integrates drug management, patients’ compliance assessment, blood glucose monitoring, skills training, prospective and retrospective drug utilization review, adverse drug reaction and toxicity screening and education of the patients (Valentine et al., 2003). These skills in fact are not new for the pharmacist but their introduction, as systematized approach in everyday practice should correspond to the local circumstances. To match the context of the pharmaceutical care, defined by the APA as “Patient-centered, outcomes-oriented pharmacy practice that requires the pharmacist to work in concert with the patient to promote health, to prevent disease and to assess, monitor, initiate and modify medication use”, is a real challenge for the management of diabetes and GDM, especially for Bulgaria (American Pharmaceutical Association, 2011). Despite the relatively small sample size, this study shows the role of education program for improvement of patient’s outcomes. The results confirm the necessity of individual approach in the selection of therapeutic strategy for the women with

GDM. As the St Vincent declaration assumed, it has to improve the quality of life of people with diabetes and to promote education of patients to prevent diabetes complications. According to the St. Vincent declaration the aim of the treatment of GDM is the achievement of child birth similar to the child birth by women without diabetes (International Diabetes Federation, 2004) In this project are involved all healthcare givers, including the pharmacists in order to be achieved these goals.

Recent clinical outcome studies have made diabetic patients a target for primary care and pharmacist initiatives, so to be improved their quality of life. (Douglas et al., 2000; Dixon, 2002; Campbell et al., 1990; Mensing et al., 2002) This conclusion presumes that there should not be any risk of complication for the mother and for the fetus or the probability for that should be minimized by proper management of the disease (Kimmerle et al., 1995).

Conclusion

This study proves that the educational approaches is a necessary step for better management of a chronic disease in order to minimize the risk from complications and the pharmacists are capable to perform it. The GDM education can be performed in pharmacy conditions, the patients are ready to attend such an education and the results show improvement in their knowledge about their disease, complication, and proper diet and insulin therapy. The results from the study confirm the need for consistent patients’ education, using variety of educational models, as an essential part of the diabetes care that will result in improvement of patient’s QOL.

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