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Original article

Pregnancy outcome and glycemic control in women with type 1 diabetes: A retrospective comparison between CSII and MDI treatment

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ABSTRACT

Aim: Present study was aimed to evaluate glycemic control and maternal–fetal outcome in pregnant type 1 diabetic patient treated with continuous subcutaneous insulin infusion (CSII) or multiple daily injections of insulin (MDI).

Patients and methods: A retrospective observational study included thirty-four pregnant type 1 diabetic patients. Patients were divided into two group, CSII treated group ($n = 14$) and MDI treated group ($n = 20$). The HbA1c level and maternal–fetal outcome were evaluated in both the treatment group. Outcome parameters such as glycemic control (HbA1c), hypoglycemic events, time and mode of delivery and labor results (abortion, premature labor, perinatal mortality, neonatal weight, Apgar score, neonatal hypoglycaemia, presence of congenital abnormalities) were analyzed.

Results: Pregnancy outcome and glycemic control in pregnant type 1 diabetic patients treated with CSII and MDI were evaluated and compared. Two groups were compared for their epidemiological parameters, although patients on CSII treatment had longer duration of diabetes compared to MDI treated group. Reduction in HbA1c level was higher in CSII treated patients at first (CSII: 0.9% vs MDI: 0.46%), second (CSII: 1.58% vs MDI: 0.78%) and third trimester (CSII: 1.74% vs MDI: 1.09%) of pregnancy compared to MDI treated patients. Duration of pregnancy and new born baby weight were founded similar in both group. Moreover, the rate of abortion, preterm labor, cesarean section and hypoglycemia in new born were founded less in CSII treated group compared to MDI treated group and Apgar score was significantly ($p < 0.05$) higher in CSII treated group compared to MDI treated group.

Conclusion: Results of present study revealed that the CSII gives better glycemic control and pregnancy outcome in pregnant type 1 diabetic patients compared to MDI treatment. CSII also decreases the daily insulin requirement compared MDI.

1. Introduction

Before the discovery of insulin, a woman with type 1 diabetes mellitus (DM) had almost no chance of successful delivery of a healthy baby, and rate of maternal mortality was higher by 25%. The maternal mortality rate decreased dramatically after introduction of insulin treatment, but the rate of pregnancy losses remained high for several decades [1]. Optimizing glycemic control during pregnancy is extremely important to reduce both maternal and fetal complications, resulting in a major improvement in pregnancy outcome. The management of diabetes in pregnancy is a sensitive subject matter, spanning multiple disciplines such as medicine, obstetrics, dietetics, midwifery and other specialties [2].

The raised in hemoglobin A1c (HbA1c) levels associate with adverse perinatal outcomes [3–5]. Many of clinical studies have confirmed that good control over diabetes with intensive insulin therapy, starting before conception and maintained during pregnancy, can reduce both maternal and perinatal complications [6].

Recently, continuous subcutaneous insulin infusion (CSII) or insulin pump therapy has been used as an alternative to multiple-dose insulin injection (MDI). It is documented that both CSII and MDI offer the advantage of frequent dose adjustment, which lead to optimize glycemic control. However, data exist concerning the

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use of these different methods of insulin administration (CSII or MDI) during pregnancy is inadequate [7–9] in terms of normalizing blood sugar level, reducing hypo and hyperglycemia, and pregnancy outcome in type 1 diabetes with treatment of CSII.

CSII with the use of personal portable insulin pump is at the moment the most advanced way of insulin delivery in type 1 diabetes patients. Many of recent research has been proven superiority of CSII over the MDI regimen in controlling diabetes, CSII use resulted the lowering HbA1c levels with decreasing incidence of hypoglycemia as compared to MDI [10,11]. However, there are several limitations to insulin pump use, including high costs and requirement of appropriately developed patients' ability to operate the device on their own. Thus, our study was aimed to evaluate and compare the pregnancies outcome of CSII and MDI treated pregnant type 1 diabetes mellitus patients.

2. Patients and methods

A retrospective observational study was carried out from February 2010 to April 2012 at a Dia Care – Diabetes Care & Hormone Clinic, Ahmedabad, Gujarat, India. The study was approved by institutional ethics committee and all participants provided informed consent prior to study enrollment.

A total 34 pregnant women with type 1 diabetes were selected based on age, BMI index and duration of diabetes. Thirty four patients were categorized into two groups, out of 34 patients, 20 were being treated with MDI using rapid acting insulin analogs, while 14 were being treated with CSII based on either aspart or lispro. Patient in both groups had started their respective treatment at least three or six month before conception. The aim of treatment was to maintain blood sugar level during pregnancy as per American Diabetes Association (ADA) recommendation.

Insulin pumps were lent to randomly selected patients, based on availability of insulin pump at the time of patient's visit. Admittingly, this random selection process was subjective by some independent factors as well as level of patient's education as those who were unable to handle or operate pump on their own were not offered pump treatment.

All patients were under care of the Dia Care team, consisting of a diabetologist, obstetrician, diabetes educator, dietician and pump educator. All patients received dietary counseling and were provided with glucose meters. Episodes of severe hypoglycemia were noted according to severity. HbA1c level of patients were measured at baseline visit and thereafter at every three month.

Patients were classified according to White's classification and parameters such as mother's age, body mass index (BMI) and duration of diabetes were noted [10]. The following parameters such as HbA1c levels, hypoglycemic events, time and mode of delivery and labor results (miscarriage, premature labor, perinatal mortality, neonatal weight, Apgar score, neonatal hypoglycaemia, presence of congenital abnormalities) were analyzed in study.

The statistical analysis was performed with PRISM 5 software, using non-parametric tests for independent samples (Mann–Whitney's test) and χ^2 or Fischer exact test to assess the differences in distribution (proportions) of qualitative parameters and $p < 0.05$ was considered statistically significant.

3. Results

Baseline characteristic of study participants are shown in Table 1. Mean age and BMI did not differ significant between groups and duration of diabetes was almost similar in both the study groups. The number of patients with chronic complications including retinopathy, nephropathy or both was almost similar in both groups. Patients were categorized according to Whites classification (Table 1).

Table 1
Characteristics of the study group (mean ± SD).

	CSII ($n = 14$)	MDI ($n = 20$)	p-Value
Age (years)	31.34 ± 5.11	30.2 ± 4.17	0.44
BMI (km/m^2)	25.91 ± 2.56	26.19 ± 2.17	0.68
<25	7	7	0.38
25–30	6	12	0.43
>30	1	1	0.48
Duration of diabetes	8.5 ± 3.51	8.35 ± 2.6	0.95
Patient's categorization by white's classification			
Class	CSII ($n = 14$)	MDI ($n = 20$)	
A. Diabetes treated with diet or drugs	0	0	
B. Age of onset > 20 years, and duration > 10 years	3	11	
C. Age of onset 10–19 years, or duration 10–19 years	9	6	
D. Age of onset < 10 years, and duration > 20 years or retinopathy	0	1	
R. Proliferative retinopathy	1	0	
F. Nephropathy	1	1	
R.F. Proliferative retinopathy and nephropathy	0	1	

The effect of CSII or MDI treatment on HbA1c level in T1D pregnant women was presented in Fig. 1. Significant ($p < 0.05$) reduction in HbA1c level was noted at first, second and third trimesters in both the studied groups when compared to baseline. The reduction in HbA1c was higher in CSII treated group in all three trimester compared to MDI treated group, but there was no significant difference in HbA1c level measured in consecutive pregnancy trimesters between CSII or MDI treated group.

Data of obstructive outcomes are presented in Table 2. Mean duration of pregnancy, incidence if premature labor, cesarean section and new born birth weight were similar in both the treatment group. One case of abortion was noted in CSII treated group and two cases of abortion were noted in MDI treated group. Apgar score was higher in CSII treated group compared to MDI treated group. When comparison within CSII treated group no significant difference in outcomes of pregnancy were observed between patients who started CSII treatment before three or six months of conceptions.

4. Discussion

Risk of congenital malformations, perinatal mortality, obstetric complications and neonatal morbidity is increased during pregnancy in women with type 1 diabetes mellitus [12–14]. A

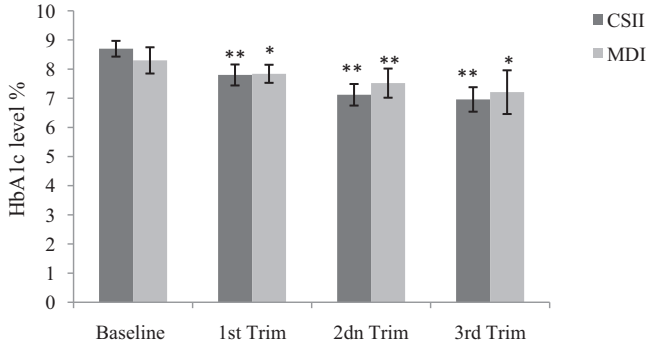

Fig. 1. Effect of CSII and MDI on HbA1c level (%). Data are expressed as mean ± S.D., $^*P < 0.05$ and $^{**}P < 0.001$ when compared to baseline.