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Original article

Efficacy and Safety of Insulin Pump During the Fasting Month of Ramadan among Patients in Libya

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ABSTRACT

Background and aims. *Insulin pump has proved to be an effective way to administer insulin in patient with type 1 diabetes mellitus and it's the most effective way to control blood glucose level with the lowest rate of hypoglycemia. However, no data are available to assess its efficacy and safety in fasting diabetics. The present study aims to assess the efficacy and safety of insulin pump during fasting in Ramadan.* ***Methods****. This was a prospective observational single center non randomized study. Patients with type I diabetes who received insulin through insulin pump (n= 21). Variables such as, weight changes, biochemical profile, HbA1c, and lipid profile were evaluated before and after Ramadan.* ***Results****. Most patients on insulin pump were able to complete their fasting during Ramadan (average 2 fast breaking per patient)) with minimal episodes of hypoglycemia and severe hyperglycemia requiring hospitalization. No significant difference was found in biochemical profiles of patients on insulin pump who were fasting during the month of Ramadan as compared to pre-Ramadan.* ***Conclusion****. The insulin pump proved to be effective and safe in fasting patient during Ramadan in Libya.*

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INTRODUCTION

Ramadan is the 9th month of the Muslim calendar when the Holy Quran was sent down from heaven.Fasting during Ramadan is one of the five pillars of Islam. It is mandatory for adult and adolescent Muslims to fast Ramadan. Depending on the geographical location and season, the duration of the daily fast may range from a few to 20 hrs. During fasting, Muslims abstain from food and drinks from dawn to dusk for about 29-30 days [1]. It's estimated that around 40-50 million individuals with diabetes worldwide fast during Ramadan [2]. Fasting of patients with diabetes is usually discouraged. The population -based epidemiology of diabetes and Ramadan study conducted in 13 Islamic countries showed that 43% of patients with type 1 diabetes and 79% of patients with type 2 diabetes fast during Ramadan.Also, it shows 4.7-fold increase in the incidence of severe hypoglycemia in patient of type 1 diabetes. Moreover, this study showed a 3-fold increase in episodes of severe hyperglycemia which is the main reason for the increased risk of diabetic ketoacidosis [2]. Fasting is associated with improvement in several hemostatic risk markers for cardiovascular disease including reduction in plasma triglyceride and plasma LDL cholesterol level, as well as improvement in insulin sensitivity and leptin. Similar beneficial effects of fasting have been reported in diabetic individuals [3].

Fasting during the day influences the control of diabetes because of changes in meal times and the type of food eaten therefore there is high risk of developing acute complications like hypoglycemia or ketoacidosis during fasting. The major risk of diabetics who fast during Ramadan is hypoglycemia [4]. Recently, glycemic therapeutic options for diabetes have expanded, with the introduction of new therapeutic agent and new technologies, some of these have been used during Ramadan and have shown a potential therapeutic benefit. Insulin pump has proved to be an effective way to administer insulin in patient with type 1 diabetes mellitus and it's the most effective way to control blood glucose level with the lowest rate of hypoglycemia.

In Libya many children and adolescent with diabetes insist to fast including those on insulin pump. However, there is no data available for the safety and efficacy of insulin pump during Ramadan in Libya. Therefore, the current study was undertaken to investigate the safety and efficacy of insulin pump therapy in Libyan diabetic patients during the fasting month of Ramadan.

METHODS

A prospective observational study was conducted on diabetic children and adolescent using insulin pump who wish to fast the month of Ramadan in 1435 alhijre year (June/July 2014). A total of20 patients wishing to fast Ramadan, of them17 patients used Medtronic pump and 4 patients used *Accua check combo* pump, and appropriate consent was taken. All patients were followed in pump clinic at Tripoli diabetic center.

The outcome variables included: body weight, BMI, HbA1c, total basal insulin dose differences, lipid profile, numbers of hypoglycemic episodes, numbers of hyperglycemic episodes requiring hospitalization, and numbers of days breaking fast. All patients visited the clinic prior to the month of Ramadan to adjust their basal insulin doses to minimize confounder.

Advice was given in the diabetic clinic to follow a healthy diet and followed a minimum activity level during fasting& they were instructed to check blood glucose 3-4 times during fasting hours. They were educated how to correct hyperglycemia with a correction bolus without breaking their fasting. Advice was given to break their fast if they have severe hypoglycemia and instructed to stop the pump for 2 hours. If they had a blood sugar of 75mg and to breakfast if this happens in early morning hours. Patients were trained on temporary basal pump programming and carbohydrate counting. The results of the outcome variables were compared between the ones who complete the fast and those who break their fast.

Data analysis was performed by statistical package for the social sciences program version 17, and were expressed in mean ± standard deviation SD. A *P* of less than0.05 was considered to be the cut off value of significance. Statistics analysis was performed using the non-parametric statistic. Wescott test was done for all the variables for it is significant.

RESULTS

A total of 20 children and adolescents were included in the study.9 Of them (45%) were females and 11(55%) were males, with mean age of 17±4 years (Figure1).

Table1. Sex of the patients

Sex of the patient	number	%
Male	11	55
Female	9	45
total	20	100

Table 2 shows that 55% of the patients could complete their fasting during Ramadan, while 22%fast 28 days, 15% fast 26 days, and 8% fast 24 days (table 2).

Table 2. Percent of patients fast per days

Number of days	*% of patient fasted*
29	***55***
28	***22***
26	***15***
24	***8***

Mild hypoglycemia were major causes of breaking the fast. About 2 out of 20 patients needed to break their fasting for one day because of mild hypoglycemia (FBS≤75mg). While, one patient suffered from severe hypoglycemia. Approximately, 3 out of 20 patients had episodes of hyperglycemia (serum blood sugar of >300mg), no diabetic ketoacidosis episode was reported while 3 patients had both hypoglycemia and hyperglycemia that (table 3).

Table 3. Causes of break fasting among cases

cause	number	%
None	11	55
Hypoglycemia	3	15
Hyperglycemia	3	15
Both	3	15
Total	20	10

The mean HbA1c for those patients who able to complete their fast was7.75 ± 0.94 before Ramadan and 7 .21 ± 0.82 after Ramadan. While, in those patients who break their fast was 7.58 ± 0.72 before Ramadan and 7.54± 1.06 after Ramadan. At the beginning of Ramadan, the weight of the patients in higher who complete one month fasting (mean 68.9±16.29) than those who break their fast (mean of 61±9.47) (table 2, figure4). There was mild weight reduction in both groups after Ramadan, but statistically not significant. There are no significant differences were seen in serum LDL, cholesterol before and after Ramadan in both group (table 2).

Table4. Weight and biochemical profile pre and post Ramadan among break fasting and not break fasting

Parameters	Patients groups	Pre Ramadan	Post Ramadan	P value
Weight (Kg)	Not break fasting Break fasting	68.9 ± 16.29 61 ± 9.47	68±15.8 60.78 ± 9.7	0.142 0.480
Hb1Ac	Not break fasting Break fasting	7.75 ±0.94 7.58 ±0.72	7.21 ± 0.82 7.54 ± 1.06	0.074 0.833
Total cholesterol	Not break fasting Break fasting	1.59 ±11.94 1.55 ±5.02	1.59 ±11.76 1.55 ± 0.33	0.059 0.78
LDL	Not break fasting Break fasting	8.1 ± 9.2 79.33 ± 5.81	8.1 ± 9.2 79.77 ± 5.1	1 0.655

DISCUSSION

In the past, fasting during Ramadan has not been recommended for type I diabetics because of the risk of hyperglycemia or hypoglycemia. However, current evidence has proved with proper education that, a proper adjustment of the insulin doses, it is safe for adult diabetics, to fast during Ramadan [2,7-12]. The management of children with diabetes who choose to fast during Ramadan is a challenge for pediatrician as the majority of guidelines and data on safety and metabolic impact of fasting are based on practice and studies on adult population.

In the current study, the majority of our patients completed the full month of fasting, 3 patients had mild hypoglycemia and non-had diabetic ketoacidosis irrespective of high blood sugar. Therefore, the present study showed the patients on insulin pump experienced a less episodes of hypoglycemia and hyperglycemia.

Studies about insulin pump usage during Ramadan fasting are sparse. An earlier study done by Benbarka et al [5], was conducted on 63 patients found that out of49 fasting patients, about 11 patients decided not to fast, in compare to 49 who fasted (24males and 25 females), with mean age of 22±7 years.

Thirty patients (61.2%) fasted the whole month of Ramadan in the current study were presented with hypoglycemia and was the major cause of breaking fast. No sever hypoglycemia was reported by any involved patients. The present study shows a higher hypoglycemic episode. This might be explained by the good metabolic control as reflected by HbA1c 7 or less, while those who had a higher HbA1c more than 7.5 usually they complete the fast and this mild hyperglycemia protect them from hypoglycemia during Ramadan fasting. In our population sample, there was mild weight reduction which was statistically none significant with a p value of 0.375. However, there was increased weight in majority of

patients on intensive insulin therapy [6]. The serum level of LDL, cholesterol and triglyceride in both groups were the same in the pre- and after- Ramadan. This can be explained by that hyperlipidemia is a reflection of chronic hyperglycemia and fasting does not elevate the blood lipid level [7-12].

Unusual hyperglycemia was reported in 15% of our pump group requiring broken their fast but no diabetic ketoacidosis was reported. The mean was calculated for all the variables which showed that there were no significant changes occurred during Ramadan for all variables, and this mean that diabetic children and adolescent on insulin pump could fast in Ramadan safely biochemically and physically

This study had some limitation, the patients did not keep along of their carbohydrate intake during this month which would be helpful in analyzing reasons for hypoglycemia or hyperglycemia in some patients. The other limitation of this study was that the daily activities and dietary habits were not documented, however the patients were instructed to keep a minimum activity level. Furthermore, the sample size of this study was even small to produce worthful result.

CONCLUSION

current findings shows that insulin pump therapy is an effective way in controlling diabetes during the fasting month of Ramadan, and fasting is feasible in patients with type IDM using an insulin pump with adequate diabetic control. More researches with larger patient population are need to be done to conclude an absolute benefit of the insulin pump over the other ways to manage diabetes during Ramadan.

Disclaimer

The article has not been previously presented or published, and is not part of a thesis project.

Conflict of Interest

There are no financial, personal, or professional conflicts of interest to declare.

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