Impact of insulin pump therapy on glycemic control , and body mass index on Type 1 diabetes mellitus, Tripoli Libya.

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Abstract

Background:

Diabetes mellitus is a chronic disease characterized by hyperglycemia that leads after many years to chronic micro vascular and macro vascular complications .Type 1 diabetes is a life-threatening chronic condition requiring continuous and life-long management that can be stressful for patients and their caregivers.

Objectives: is to evaluate the effectiveness of insulin pump therapy on glycemic control , and body mass index in Type 1 DM.

Patients and Method: this is retrospectively studied the profiles of 73patients were on insulin pump therapy (28 males and 45 females) attending insulin pump clinic at the National Diabetes& Endocrinology center in Tripoli, Libya, from the period of first January 2014 to last December 2017. Data collected included demographic, clinical,HBA1C level ,and body mass index before, at six months, and after one year of nsulin pump therapy use .

Results:61.5% were females ;mean age of patients was 29.08± 8.68 years . The mean duration of diabetes was 11.14±6.54 years. 50.7% of them were students, 83.6% were University students . The most of patients , 91.8% have no complications of diabetes. The mean HbA1C values improved from 8.29 ± 1.55 at initiation of the insulin pump therapy, to 7.27 ± 1.08 at the end of 6 months ,and to 7.35 ± 1.30 at the end of one year, with p value of 0.000 .also The Mean body weight has no change from the start of therapy to the end of one year study (from 25.07 ± 4.54 at start to 25.18 ± 4.74 at end of 6 months to 26 ± 5.14 at end of study with p value 0.000

4-Conclusion: the impact of insulin pump therapy was positive in maintaining a good glycemic control in most of participants, and unchanged in the body mass index.

Key words: Insulin pump therapy, Type 1 diabetes mellitus,HbA1C, Body mass index(BMI).

Introduction

flexibility in timing and amounts of nutritional intake and physical activity , allowing for wide variations in lifestyle .In addition , use of rapid acting insulin makes coverage of the

early-morning glucose rise (dawn phenomenon)possible ,eases sick day management , and matches nutrient absorption more physiologically ,thereby reducing the risk of hypoglycemia .

A review of controlled trials in patients with type 1 diabetes showed that with CSII therapy, the mean blood glucose concentrations and glycosylated hemoglobin (HbA1C) values were either slightly lower than or comparable to those of MDI[7]. Therefore, the presenting study was undertaken to evaluate the effect of insulin pump therapy on the glycemic control and body mass index.

Continuous subcutaneous insulin infusion or insulin pump therapy ,has been used to treat diabetes since the late 1970[1-3].The beneficial effects of intensive glycemic control in reducing the risk of chronic complications in type 1diabetes were firmly established in the Diabetes Control and Complications Trial (DCCT)[4],and The UK Prospective Diabetes Study (UKPDS)[5]. Both continuous subcutaneous insulin infusion (CSII) and multiple daily injection (MDI) therapy are effective means of implementing intensive diabetes management. The theoretical advantage of insulin pump therapy is its ability to mimic physiological insulin release and meet physiological insulin needs in people with insulin deficiency[6] .The basal and bolus functions of the pump allow separate determination and adjustment of both these insulin requirements and also allow

Patients and methods

Settings and design

This study was conducted at insulin pump clinic in National Diabetes &

Endocrinologycenterat Tripoli, an educational center located in the capital and providing diabetes care for most of the western region of Libya for adult and adolescent diabetic patients. This is a

descriptive, case series , retrospective study that reviewed the medical records of 73 type I diabetic participants using insulin pump ,and followed at insulin pump clinic from periodoffirst January2014 to last December 2017.The following information was obtained from the participants records which included Sociodemographic data such as age ,sex, Address ,marital stat , level of education and occupation, duration and complication of Diabetes .and Anthropometric data such as height and Weight ,and BMI was calculated as the Ratio of Weight in KG to the square of Height in meter, And HbA1c level. all these results were collected at the start of pump initiation were used as the baseline value ,and 6 month and end of year.

Device used

Seventy three patients used Medtronic Mini Med Veopumpwhich is a single device with the character of low suspend technique when augmented with real-time Continuous glucose monitoring (sensor) device .The smart pump contains Bolus Wizard calculator which has the property of tracking insulin preventing its accumulation in the body .Rapid acting insulin was used during this study (LISPRO or ASPART).

Statistical analysis

SPSS (statistical package for social sciences) software version 16 was used to analyze the collected data; mean, standard deviation and percentages used for descriptive, And Analytical statistics: compare mean , ANOVA test, in depended test used .p value <0.05 considered significant

Results

demographic characteristics

73 patients 61.6% of them were females figure 1. , 65.8%were between 15-30 years old with mean age 29.08±8.68years. table 1 , 47.9% have diabetes for more than 10 years, and only 8.2% have diabetes complication such as diabetic nephropathy , retinopathy, neuropathy. More than half 67.1% of patients lives in Tripoli, half of them 50.7% were student, 83.6%have university education level.
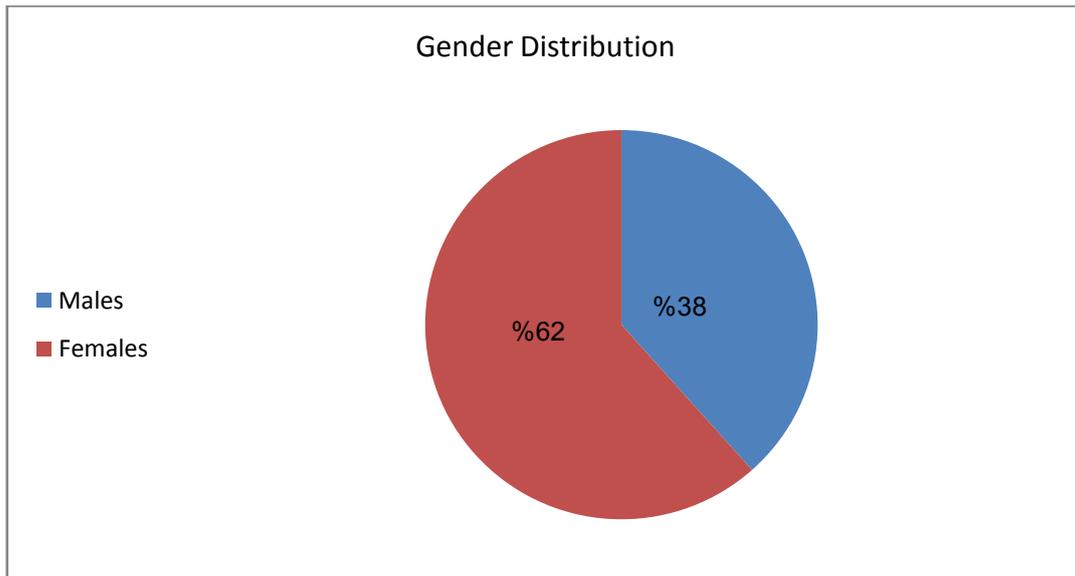
Figure 1. Gender of study sample

Table 1 : Demographic characteristics of the study sample. No =(73).

character	Frequency (%)
Age Mean age 29.08±8.68 years	
<30 years	48 (65.8%)
>30 years	25 (34.2%)
Education Level	
University	61 (83.6%)
Secondary	12(16.4 %)
Occupation	
Student	37 (50.7%)
Employee	12 (16.4%)
House wife	9 (12.3%)
Free job	7 (9.6%)
Doctor	7 (9.6%)
Marital Status	
Single	52 (71.2%)
Married	17 (23.3 %)

Divorced	2 (2.7%)
Widow	2 (2.7%)
Address	
Tripoli	49 (67.1%)
Outside Tripoli	24 (32.8%)
Duration of diabetes	
Mean duration of diabetes 11.14±6.54 years	
1-5 years	11(15.1%)
6-10years	27(37%)
< 10 years	35(47.9%)
Associated disease	
No associated disease	67(91.8%)
Have associated disease	6(8.2%)

Impact of insulin pump therapy

Table 2. showed that HbA1C values improved significantly after beginning of insulin pump therapy decreasing from (8.29 ± 1.55 % ,to 7.27 ± 1.08% , to7.35 ± 1.30 %)p value of 0.001, and also the Mean body index change significantly from the start of therapy to end of year study (from 25.07 ± 4.54 kg/m^2 , to 25.18 ± 4.74kg/m^2, to 26.45 ± 4.14kg/m^2)respectively P value 0.000.

Table 2 :Mean of HBA1C , and BMI. No=(73)

Character	Mean±SD
HbA1 before Insulin pump	8.29 ± 1.55%
HbA1 at 6 months	7.27 ± 1.08%
HbA1 at one year	7.35 ± 1.30%
P value	0.000
BMI before Insulin pump	25.07 ± 4.54 kg/m^2
BMI at 6 months	25.18 ± 4.74 kg/m^2
BMI at one year	26.45 ± 4.14 kg/m^2
P value	0.000

Table 3. revealed that, The   mean of HbA1c was no significant difference seen between both gender from before started insulin pump therapy to end of years study (P= 0.261P=,0.659 P=0.872) respectively.

figure 2.Alsothe Researchers   notice that there was no statically significant relation. between age group , educational level , duration of diabetes and associated disease, and   means   of   HbA1C

Table 3.comparisons of meansHbA1 according to character of patients N =(73).

| Character	HbA1 before Insulin pumpMean ± SD	HbA1 at 6 months Mean ± SD	HbA1 at one year Mean ± SD
Gender			
Male	8.0±1.2 %	7.19± 1.03%	7.40 ± 1.46%
Female	8.45 ± 1.72 %	7.32 ± 1.12%	7.33 ± 1.24%
Pvalue	0.261	0.659	0.872
Age			
<30	8.38 ± 1.61%	7. 33± 1. 51%	7. 53 ± 1.36%
> 30	8.19± 1.45%	7.14± 0.96%	6.98± 1.12%
P value	0.636	0.797	0.311
Education			
Secondary	9.50 ± 1.44%	7.75 ± 1.17%	7.86 ± 1. 40%
University	8.05 ± 1.47%	7. 17 ± 1.05%	7.26 ± 1.27%
Value P	0.003	0.110	0.205
Duration of diabetes			
1-5 years	8.59 ± 1.05%	7.78 ± 1.42%	7.88 ± 1.22%
6-10 years	8.36 ± 1.55%	7.27 ± 0.91%	7.28 ± 1.40%
>10 years	8.14±1.69%	7.11±1.07%	7.21±1.25%
P value	0.681	0.241	0.383
			Associated disease
No associated disease	8.31±1.54%	7.27±1.03%	7.39±1.32%
Have associated disease	8.08±1.77%	7.29±1.64%	7.01±1.07%
P value	0.730	0.959	0.524

In Table 4. showed that, The mean of body mass index was increased in females from 25.67 kg/m^{2}to 26.58 kg/m^{2}during period of study with (p = 0.113,p= 0.039, p=0.009) respectively. there was statically no difference figure 3..And an increase in the in the Age group less than thirty years old from 24.41±4.07 kg/m^2 to 25.44±4.98 kg/m^2, and decreased from 26.02±5.35 kg/m^2 to 25.22±5.14 kg/m^2 in Ages more than 30 years with pvalue of(0.262, 0.401,&0.862) respectively statically no difference . Educational levelthere was no significant change in mean of body mass index with p value=(0.494,0.949,0.845) respectively. But   the patients with duration of diabetes from one to five years show increased of mean BMI from 25.05±4.51 kg/m^2,to 26.44± 5.68 kg/m^2. and decreased in group duration six to ten from 25.35 ± 4.70 kg/m^2 to24.50 ± 4.45 kg/m^2 statically significant no relation. The   associated disease no significant changed in their body mass index .

Table 3.comparisons of means HbA1 according to character of patients N =(73) .

Character	BMI before Insulin pump Mean ± SD	BMI at 6 months Mean ± SD	BMI at one year Mean ± SD
Gender			
Male	23.9±4.47 kg/m^2	23.60±3.92 kg/m^2	23.1±3.47 kg/m^2
Female	25.67±4.50 kg/m^2	26.09±4.97 kg/m^2	26.58±5.21 kg/m^2
Pvalue	0.113	0.039	0.009
Age			
<30	24.41±4.07 kg/m^2	24.69±4.26 kg/m^2	25.44±4.98 kg/m^2
> 30	26.02±5.35 kg/m^2	26.04±5.66 kg/m^2	25.22±5.14 kg/m^2
P value	0.262	0.401	0.862
Education			
Secondary	24.17 ± 4.85 kg/m^2	25.27± 5.64 kg/m^2	25.36± 4.81 kg/m^2
University	25.17± 4.50 kg/m^2	25.17± 4.61 kg/m^2	25.36± 4.81 kg/m^2
Value P	0.494	0.949	0.845
Duration of diabetes			
1-5 years	25.05±4.51 kg/m^2	25.60± 5.52 kg/m^2	26.44± 5.68 kg/m^2
6-10 years	25.35 ± 4.70 kg/m^2	25.19± 5.19 kg/m^2	24.50 ± 4.45 kg/m^2

>10 years	24.73±4.56 kg/m^2	25.06±4.27 kg/m^2	25.79±5.15 kg/m^2
P value	0.874	0.953	0.528
			Associated disease
No associated disease	25.23±4.63 kg/m^2	25.41±4.80 kg/m^2	25.43±4.83 kg/m^2
Have associated disease	22.55±2.63 kg/m^2	22.83±3.60 kg/m^2	25.33±6.53 kg/m^2
P value	0.167	0.206	0.966
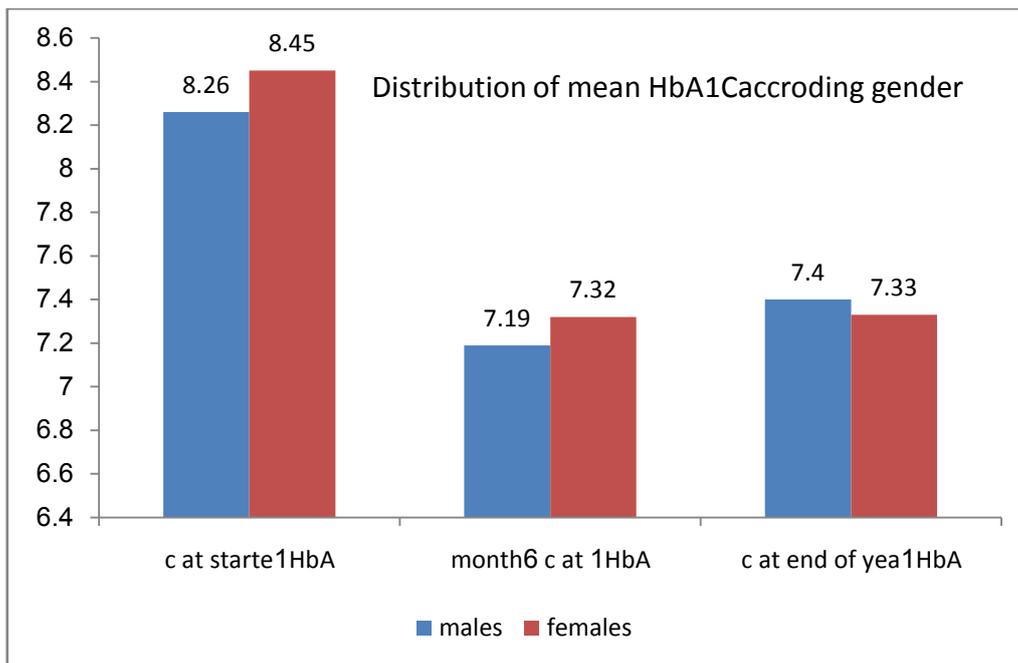
.Figure 2.Demonstratingof frequency mean HbA1 according gender

Distribution of Mean of BMIaccording gender

BMI at starte
- males: 23.9
- females: 25.6

month6 BMI at
- males: 23.6
- females: 26

BMI at end of year
- males: 23.1
- females: 26.5

■ males ■ females
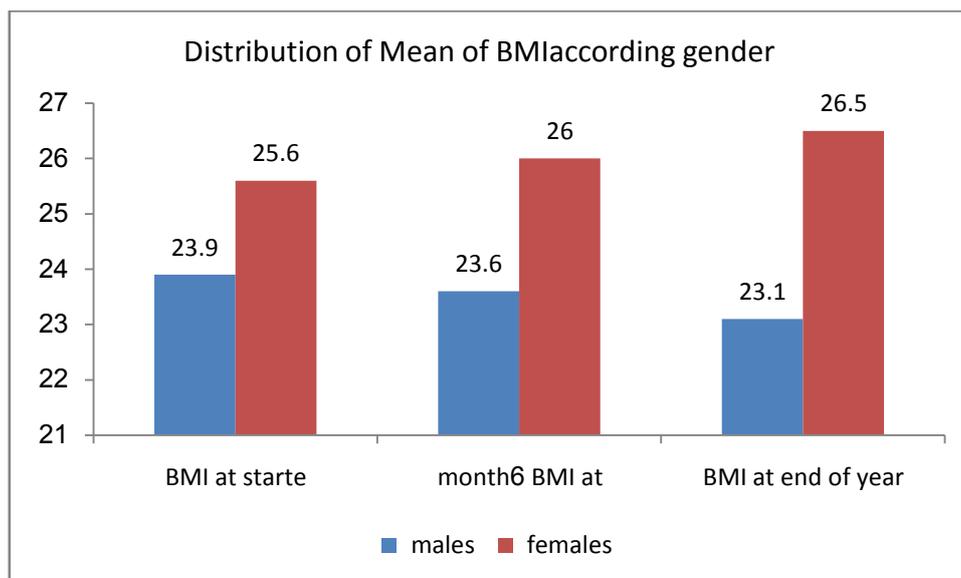
Figure 3. Demonstrating of frequency mean BM1 according gender

Discussion

This is the first experience in adult type 1 diabetes with insulin pump therapy in National Diabetes &Endocrinology Center. The Results showed that most of our patient swithage between 15- 30 years old , mean age 29 years ; females more than males with 47.9% have diabetes for more than 10 years , means 11.14 years ; these results not compared with previous studies which was done at same National Diabetes Center Tripoli[8], on small group 32 patients showed most age between 2-22 years mean age 15 years ;no gender difference with 94.39% have diabetes for 1-14 years mean 6.9 years, and another study[9], which was done at Germany on larg group, in which mean age 12.4 years , mean diabetes duration

5.2 years .. This means large difference between mean agesat starting pump therapy and mean for diabetes duration in our results and these different centers for pump therapy. The mean of HbA1C improved from a mean baseline value of 8.29% to 7.27% and 7.35 % at 6 and 12 months of therapy respectively .The improvement in the HbA1c was sustained through the 12 months duration. Disclosed result in star 3 study[9] was 8.3% to 7.5%, and Some studies also demonstrated that the initial lowering of HbA1C with CSII was sustainable for more than 1 year.[10,11].The improved glucose control in our pump therapy-treated patients might have been the result of several factors. Besides tailoring insulin delivery to an individual's requirement on a 24-hour basis,

factors other than the pump technology itself could also have contributed to the improvement. The availability of a multidisciplinary diabetes care team with the required skills and experience in pump therapy is critically important[12,13].Long-term support and guidance should also be available to address questions and promptly resolve problems unique to special circumstances[14] . Proper selection of candidates for pump therapy is also vitally important. They need to be familiar with various aspects of self-careand to maintain close contact with members of the diabetes care team. In addition, they have to be taught carbohydrate counting and other practical issues, including insulin replacement, timely

Conclusion,

our experience has show edthat insulin pump therapy results in a significant reduction in HbA1c by about 1% . So pump therapy is suitable for those T1 diabetic patients who cannot achieve diabetes treatment goals by MDI therapy.Theslightly increased in the Body mass index, necessitate therefore to increase the Education program about insulin

replacement of tubing, proper care of the needle insertion site, and procedures to follow in case of pump malfunction. [15,16]. The badly controlled diabetes is well known to be associated with lowly nutrition. In this study we found, The mean body mass index had increased slightly from $25.07 kg/m^2$ in starting to $25.18 kg/m^2$ and $26.17 kg/m^2$ at 6, and 12 months respectively in the previous study[8] reported slightly improved in their body mass index from $21.2 kg/m^2$ to $22 kg/m^2$,indicating that calorific intake has increased which a common side effect of pump therapy . Some investigators reported also a deterioration in metabolic control after 6 months of pump therapy[17]

pump use, and further studies are needed on a larger scale.

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