

Efficacy of Insulin Pump Therapy on Diabetes Treatment Satisfaction and Glycemic Control Among Patients with Type 1 Diabetes Mellitus in Saudi Arabia: A Prospective Study

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ABSTRACT

Introduction: The aim of this study was to explore the impact of insulin pump therapy on diabetes treatment satisfaction and glycemic control among patients with type 1 diabetes mellitus (T1DM) in Saudi Arabia.

Methods: A 6-month, prospective study was conducted among 47 patients (aged 17–24 years) with T1DM who attended the Insulin Pump Clinic at Prince Sultan Military Medical City, Riyadh, Saudi Arabia, between April 2014 and November 2014. The respondents were purposively and conveniently selected and were interviewed using the Arabic version of the Diabetes Treatment Satisfaction Questionnaire at baseline, 3, and 6 months. Demographics and

clinical variables including hemoglobin A1c (HbA1c) were also collected.

Results: The mean (\pm standard deviation) age of the study cohort was 19.1 ± 1.93 years. Seventeen patients were male (36.2%) and 30 were female (63.8%). Compared to baseline, significant positive differences were found in treatment satisfaction among female patients and patients with long-standing T1DM at 6 months. Frequency of hyperglycemia and hypoglycemia declined significantly in female patients at 6 months and in patients who had a shorter duration of T1DM. Furthermore, significant positive differences were found in HbA1c levels among female patients and among those who had a shorter duration of T1DM compared to baseline. Both female and male patients and those with a shorter duration of T1DM showed a significant decline in insulin necessity at 6 months when compared to baseline.

Conclusion: Although multiple daily injections is a feasible preference for insulin supply, insulin pumps should also be considered for patients with T1DM as it appears to increase patients' treatment satisfaction, decrease the frequency of hypoglycemia, hyperglycemia, and reduce HbA1c levels.

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INTRODUCTION

Type 1 diabetes mellitus (T1DM) is a chronic disease, generally diagnosed in children and adolescents, which needs strict multidisciplinary treatment over the patient's lifetime. Over the last few eras, the incidence of T1DM has been increasing in many regions of the world [1, 2]. Studies have reported that the incidence of T1DM in Saudi Arabia has also increased over the last 30 years [3]. The incidence of T1DM in Saudi Arabian children and adolescents is 109.5 per 100,000, which is higher than in many developed countries [4, 5].

The imperative purpose of treatment of T1DM in children and adolescents is to keep up near-normoglycemia through intensive insulin therapy, to preclude serious complications, and to avoid long-standing macrovascular and microvascular complications, while facilitating as close to a normal life as possible [6]. Effective and regular insulin therapy must therefore be delivered on the basis of the patient's necessities, choices, resources, and the family for the best management of T1DM [6, 7].

Scientific and technological developments in insulin pump therapy—or continuous subcutaneous insulin infusion (CSII) such as strategy and functionality, advanced features for calculating insulin doses, providing insulin and examining data the extensive dissemination of accrued knowledge and the desire to succeed glycemic levels as near to the normal level as possible, have resulted in a substantial rise in insulin pump use around the world [8–10]. Compared to multiple daily injections (MDI), insulin pump treatment is a

more valuable, more effective, and safer method for maintaining glycemic control, minimizing diabetes-associated complications, providing higher flexibility in daily life, and a better quality of life [8–10].

Despite advances in medical technology and research documenting their clinical effectiveness having led to the increased use of insulin pump therapy worldwide, the use of insulin pumps in Saudi Arabia is relatively limited, and there is also limited evidence regarding their impact on glycemic control and diabetes treatment satisfaction. Therefore, the present study aimed to explore the impact of insulin pump therapy on treatment satisfaction and glycemic control among patients with T1DM.

METHODS

Study Design, Setting, and Sampling

A 6-month, prospective study was conducted in 47 patients (aged 17–24 years) with T1DM registered at the Insulin Pump Clinic, Prince Sultan Military Medical City (PSMMC), Riyadh, Saudi Arabia, between April 2014 and November 2014. The respondents were purposively and conveniently selected, and eligible patients (see below) were given individual patient numbers.

Inclusion and Exclusion Criteria

Patients with T1DM, aged 17–24 years, treated with MDI therapy for the last 12 months, and Saudi nationals were included in the study. Patients who had a history of psychopathology, cognitive impairment, and those already under insulin pump treatment were excluded.

Compliance with Ethics Guidelines

This study was conducted in accordance with the Helsinki Declaration of 1964, as revised in 2013, and the protocol of this study was approved by the research ethics committee of the PSMMC. Patients were informed about the purpose and methods of the research both verbally and in written form. Written consent was obtained from patients before the completion of study measurement.

Insulin Pump Training

Prior to commencing the insulin pump therapy, all eligible patients received pre-insulin pump education and a general introduction to pump therapy for the Paradigm[®] Veo[™] system (Medtronic MiniMed, Northridge, CA, USA). All the information used in the training program, including pamphlets, were in the patients' national language (Arabic). In addition, initial insulin pump training for those transitioning from MDI therapy and carbohydrate counting sessions were given. After initiation of insulin pump therapy, all patients were in daily contact with the same pump trainer for the first week, then 3–7 appointments were given for the first month, and then monthly follow-up visits were scheduled within the insulin pump clinic (Diabetes Treatment Center, PSMMC) for the stabilizing of insulin pump therapy.

Study Measurements

An Arabic version of the Diabetes Treatment Satisfaction Questionnaire (DTSQ), specifically designed to measure diabetes treatment satisfaction, was used. This instrument aims to assess changes in patient satisfaction related to therapy modifications, and is also useful for

comparing the level of satisfaction in patients using different treatment strategies.

The DTSQ is an accurate instrument for measuring treatment satisfaction in patients with T1DM [11]. The DTSQ contains eight health concepts: six questions address general satisfaction with a score from 0 (very dissatisfied) to 6 (very satisfied). The entire score is a sum of the six separate item scores. A higher overall score specifies a higher satisfaction with diabetes treatment [11]. Two questions connected to the occurrence of hyperglycemic and hypoglycemic events are assessed independently. Both questions are measured with a score from 0 (never experienced) to 6 (most of the time) [11]. Clinical variables including hemoglobin A1c (HbA1c) and diabetes treatment satisfaction were collected at baseline, 3, and 6 months. HbA1c readings were collected from the patients' records which are analyzed in the central lab at PSMMC (COBAS INTEGRA 400 plus/800 analyzers).

Hyperglycemia and Hypoglycemia

All patients involved in the study were advised to record finger stick blood glucose readings at least 6–7 times daily and to record these in a standard self-monitoring blood glucose diary that was reviewed and documented to report any hypoglycemic or hyperglycemia readings. Hyperglycemia was defined as any blood glucose value >180 mg/dL (>10 mmol/L) while hypoglycemia was defined as any blood glucose value ≤ 70 mg/dL (≤ 3.9 mmol/L),

Statistical Analysis

Data analysis was performed using Excel 2010 (Microsoft Corporation, Seattle, WA, USA) and SPSS version 16 (SPSS Inc., Chicago, IL, USA). In

addition to descriptive analysis, *t* tests and Tukey's post hoc tests were used to look for differences among the groups. A *P* value of <0.05 was considered statistically significant.

RESULTS

Out of the 56 patients recruited, nine failed to show up at 3 months after the baseline visit or failed to show at the last visit (6 months) and were excluded from the study. A total of 47 adolescents continued until the end of the study and were included in the analysis. The demographic variables of the study population are shown in Table 1. The mean [\pm standard deviation (SD)] age of the study cohort was 19.1 ± 1.93 years. Seventeen patients were male (36.2%) and 30 were female (63.8%). The mean (\pm SD) duration of diagnosis of T1DM was 8.13 ± 5.3 years. The majority of the patients were in <20 years age group (70.2%) and more than 55% of the patients had long-standing diabetes (≥ 7 years).

Table 1 Demographic variables of the study population

Variable	Frequency	%
Gender		
Male	17	36.2
Female	30	63.8
Age		
<20 years	33	70.2
≥ 20 years	14	29.8
Education		
Secondary	32	68.1
College	15	31.9
Duration of T1DM		
≤ 7 years	21	44.7
>7 years	26	55.3

T1DM type 1 diabetes mellitus

The treatment satisfaction of the study population is shown in Fig. 1. Compared to baseline, a significant positive difference was found in treatment satisfaction in female patients at 6 months ($P < 0.05$). Similarly, patients with long-standing T1DM expressed significant improvement in treatment satisfaction at 6 months ($P < 0.05$).

Compared to baseline, frequency of hyperglycemia was significantly reduced among female patients and patients who had a shorter duration of T1DM at 6 months ($P < 0.05$; Table 2). Similarly, frequency of hypoglycemia was also significantly reduced among female patients and patients who had a shorter duration of T1DM at 6 months when compared to baseline ($P < 0.05$; Table 2). However, no significant differences were observed between genders and duration of T1DM ($P > 0.05$). Compared to baseline positive improvements were observed in necessity of insulin dose among both genders and those with a shorter duration of T1DM ($P < 0.05$). No notable differences were found for body weight within the study population (Table 2).

Positive differences were found in the HbA1c levels of both genders, among different patient age groups, and among patients with different duration of T1DM. However, compared to baseline, significant positive differences were found in HbA1c levels among female patients and those who had a shorter duration of T1DM ($P < 0.05$; Fig. 2).

DISCUSSION

In the present prospective study, we found that insulin pump treatment generally increased treatment satisfaction among the study population when compared to MDI treatment. This is in agreement with previous studies, where insulin pump therapy has been shown

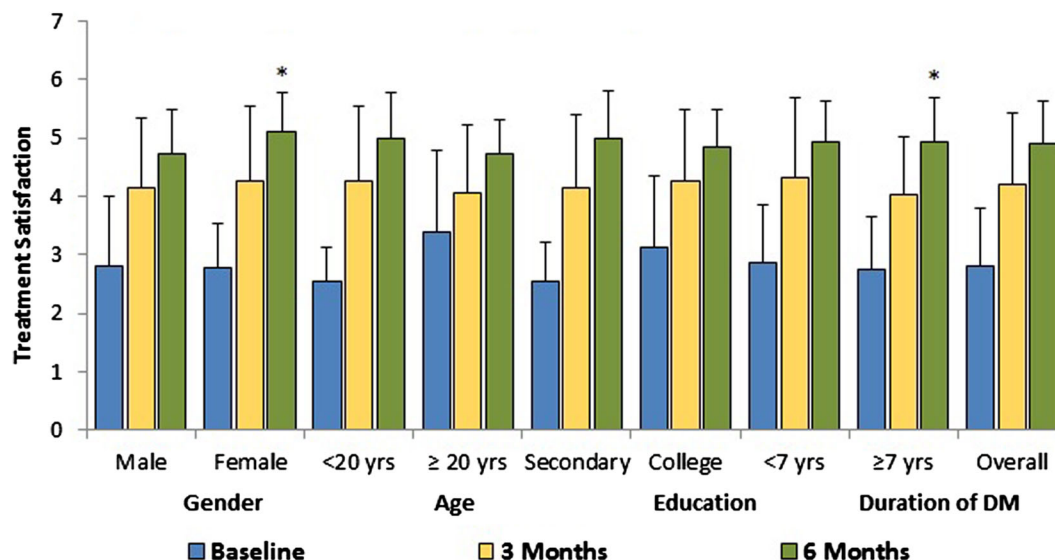


Fig. 1 Impact of insulin pump therapy on treatment satisfaction. Values are presented as mean \pm standard deviation. Groups compared by *t* test and Tukey's post hoc test. * $P < 0.05$ considered significant. DM diabetes mellitus, yrs years

to have better treatment satisfaction, probably associated with the insulin pumps' higher portability and improved comfort of insulin dosing [12, 13]. The suspension of insulin infusion permits for better control over insulin supply and adjustment of insulin dosing according to the activity level [12, 13]. It should be noted that in our study we found a significant increase in treatment satisfaction among female patients compared to baseline. In contrast to our finding, other studies have found that lower treatment satisfaction is correlated with being female, using insulin, and having diabetic complications [14]. This challenge involves the body image concerns of young adults. Female patients do not like the concept of being tethered to the pump via tubing for the entire day, and they do not want to worry about where to wear the pump on their clothing. On the other hand, some female patients who are more private about their diabetes do not like the visibility of a pump, and they do not like having to describe the pump to others [15]. Similarly, female patients

who are using an insulin pump indicated higher levels of body frustration and self-consciousness, while younger patients report feeling different, lower levels of treatment satisfaction, and consider pumps to be unfashionable [15]. However, the positive findings among our study group may due to the fact that Saudi girls always use the abaya (a full-length, sleeveless outer garment) which covers the whole body except the face, feet, and hands. This dress code may help girls in Saudi Arabia to overcome the above-stated reasons for not wearing insulin pump, when compared to the Western world.

It is essential to state here that we found positive decrease in HbA1c levels among both genders, patients of different ages, and patients with different duration of T1DM. However, no significant differences were observed among these different variables except for female patients and for those with a shorter duration of T1DM. There is also a debate concerning the long-standing usefulness of insulin pump therapy to lower HbA1c levels and increase

Table 2 Impact of insulin pump therapy on frequency of hyperglycemia, hypoglycemia, insulin dose, and body weight

Variables	Frequency of hyperglycemia			Frequency of hypoglycemia		
	Baseline	3 months	6 months	Baseline	3 months	6 months
Gender						
Male	2.30 ± 1.25	2.13 ± 1.21	2.04 ± 1.26	2.48 ± 0.94	2.04 ± 0.87	1.91 ± 0.99
Female	2.42 ± 0.92	1.88 ± 1.07	1.83 ± 1.52*	2.63 ± 0.92	2.20 ± 0.84	1.50 ± 1.40*
Age						
<20 years	2.39 ± 1.27	1.91 ± 1.20	1.64 ± 1.44	2.64 ± 1.05	1.97 ± 0.84	1.55 ± 1.09
≥20 years	2.29 ± 0.46	2.21 ± 0.95	2.06 ± 1.36	2.36 ± 0.49	2.57 ± 0.75	2.04 ± 1.50
Education						
Secondary	2.48 ± 1.22	2.04 ± 1.16	2.15 ± 1.4	2.56 ± 1.08	1.89 ± 0.89	1.52 ± 1.15
College	2.20 ± 0.89	1.95 ± 1.14	1.65 ± 1.35	2.55 ± 0.68	2.50 ± 0.68	1.95 ± 1.35
Duration of T1DM						
<7 years	2.62 ± 0.85	1.92 ± 1.09	1.86 ± 1.3*	2.85 ± 0.78	2.23 ± 0.90	1.62 ± 1.32*
≥7 years	2.05 ± 1.28	2.10 ± 1.22	2.00 ± 1.41	2.19 ± 0.98	2.05 ± 0.80	1.81 ± 1.16
Overall total	2.36 ± 1.09	2.00 ± 1.14	1.70 ± 1.25	2.55 ± 0.92	2.15 ± 0.85	1.70 ± 1.25
Variables	Insulin dose (IU/kg)			Body weight (kg)		
	Baseline	3 months	6 months	Baseline	3 months	6 months
Gender						
Male	1.31 ± 0.13	1.20 ± 0.20	1.01 ± 0.23*	63.1 ± 6.77	63.2 ± 5.66	64.1 ± 4.99
Female	1.26 ± 0.25	1.17 ± 0.22	1.00 ± 0.16*	57.2 ± 9.32	57.8 ± 6.35	58.7 ± 6.26
Age						
<20 years	1.27 ± 0.23	1.16 ± 0.24	1.03 ± 0.19	60.0 ± 8.89	60.4 ± 6.40	61.3 ± 6.14
≥20 years	1.31 ± 0.11	1.23 ± 0.06	0.95 ± 0.19	60.2 ± 8.27	60.6 ± 7.10	61.3 ± 6.64
Education						
Secondary	1.31 ± 0.15	1.16 ± 0.26	1.04 ± 0.21	60.5 ± 7.81	61.3 ± 5.32	62.2 ± 5.04
College	1.25 ± 0.25	1.22 ± 0.11	0.95 ± 0.17	59.5 ± 9.70	58.3 ± 7.92	60.2 ± 7.50
Duration of T1DM						
<7 years	1.31 ± 0.11	1.14 ± 0.25	0.99 ± 0.22*	58.8 ± 6.47	59.6 ± 4.78	60.7 ± 4.40
≥7 years	1.25 ± 0.28	1.23 ± 0.13	1.02 ± 0.15	61.6 ± 10.6	61.5 ± 8.26	62.1 ± 7.90
Overall total	1.28 ± 0.20	1.18 ± 0.21	1.00 ± 0.19	60.1 ± 8.62	60.5 ± 6.55	61.3 ± 6.22

Values are presented as mean ± standard deviation. Groups compared by *t* test and Tukey's post hoc test

T1DM type 1 diabetes mellitus

* $P < 0.05$ considered significant

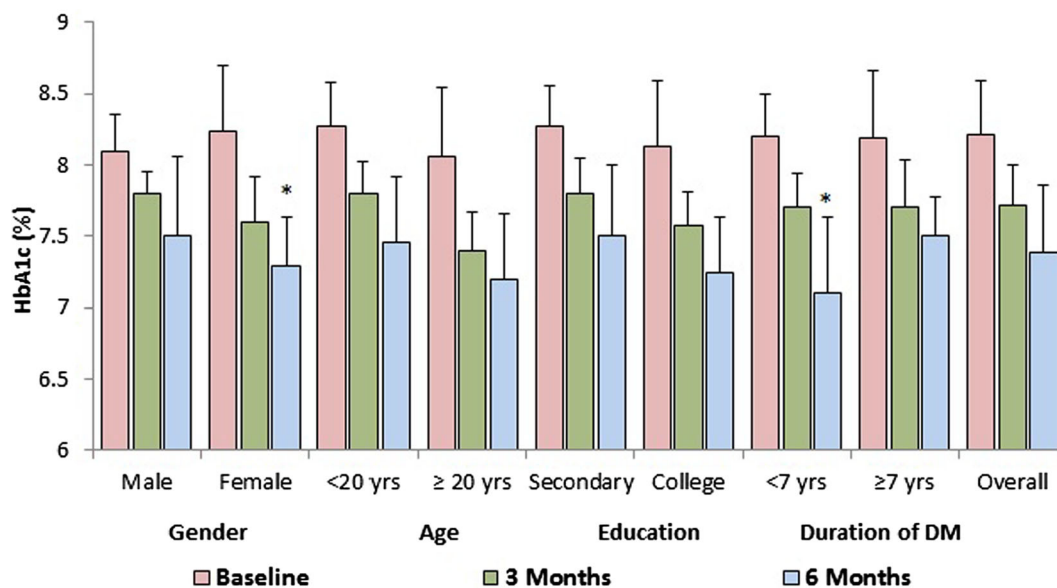


Fig. 2 Impact of insulin pump therapy on glycemic control. Values are presented as mean \pm standard deviation. Groups compared by *t* test and Tukey's post hoc test.

* $P < 0.05$ considered significant. *DM* diabetes mellitus, *HbA1c* hemoglobin A1c, *yrs* years

glycemic control among patients with T1DM. Findings of various studies differ with respect to the capability of insulin pump to sustain lower glycemic levels during the first 6–12 months [16]. A recent seven-year follow-up study reported that the mean difference in HbA1c levels between insulin pump and non-insulin pump users was 0.6% [17]. This level of change is clinically significant, since the diabetes control and complications trial (DCCT) has described reductions in microvascular complications of 21–49% with every 1% reduction in HbA1c. Another study has observed equal improvement in HbA1c for both male and female patients after 6 months of insulin pump therapy, but after 12 months they observed improvement only for male patients [18]. Furthermore, they found that the mean HbA1c level at initiation of insulin pump therapy was 8.7% and declined to a nadir of 7.5% 6-month post-initiation. This increased over time (range 7.8–8.2%) but remained lower than the pre-insulin pump HbA1c level. Also,

shorter duration of diabetes prior to CSII initiation, presence of an emotional disorder, a record of missed clinic appointments, and being a current and active smoker were predictors of higher HbA1c on CSII [8]. On the other hand, several findings including the DCCT have confirmed that, compared to MDI treatment, CSII can deliver better glycemic control with a lower risk of severe hypoglycemia and lower weight gain [19, 20]. In contrast to the above studies, a pilot trial in 2003 in patients aged 12–35 years reported that there was no significant difference in glycemic control between CSII and MDI treatments from the onset of diabetes [21]. It is clear that a tighter HbA1c goal may have been easier to accomplish with CSII, thereby distinguishing in efficiency between the two treatment approaches. Regarding insulin doses, we found that female patients and those who have shorter duration of diabetes mellitus had lower insulin necessity compared to baseline; this is a common finding in many other studies [20, 22, 23].

Importantly, our study found that the frequency of hypoglycemic events was generally lower at 6 months among the study population when compared to the baseline. Furthermore, significant decreases were found among female patients and those who had a shorter duration of T1DM. Insulin pump therapy has the benefits of providing both lower doses of insulin and variable basal doses. As a result, it may offer a lower risk of hypoglycemia among patients with T1DM. Numerous studies have suggested that the risk of hypoglycemia is reduced among the insulin pump users [24]. Despite the general benefits, insulin pumps are not applicable for all patients, costing several thousand Riyals for the pump itself and incurring further costs for monthly supplies [24–26].

The major limitations of this study include a relatively small sample size, a limited number of risk factors investigated, limited social and demographic factors examined, and the fact that the study was performed at a single center. Furthermore, there was no control group with which to compare the study group and so the results may not be generalizable to real-world situations. More studies on a larger scale are needed to address these limitations. Despite the limitations, the study delivers valuable data for insulin pump therapy and treatment satisfaction among patients with T1DM in Saudi Arabia.

CONCLUSIONS

While MDI is a feasible option for insulin delivery, the use of insulin pumps should also be considered for patients with T1DM as it was shown to increase patient treatment satisfaction, decrease the frequency of hypoglycemia and hyperglycemia, and reduce HbA1c levels.

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Conflict of interest. Ayman A. Al Hayek, Asirvatham A. Robert, Mohamed A. Al Dawish, Rim B. Braham, Hanouf S. Goudeh, and Fahad Al Sabaan declare no conflict of interest.

Compliance with ethics guidelines. This study was conducted in accordance with the Helsinki Declaration of 1964, as revised in 2013, and the protocol of this study was approved by the research ethics committee of the PSMCC. Patients were informed about the purpose and methods of the research both verbally and in written form. Written consent was obtained from patients before the completion of study measurement.

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