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Original article

Efficacy and Safety of Insulin Pump Therapy in Children and Adolescents with Type 1 Diabetes Mellitus

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ABSTRACT

Continuous subcutaneous insulin infusion (CSII) pump represents a treatment option that can aid in achieving an important goal to reduce the most frequent complications associated with treatment; hypoglycemic and hyperglycemic episodes, which have also a great impact on life quality of patients. This study was conducted to report the effect and safety of insulin pump therapy on glycemic control, hypoglycemia and diabetic ketosis (DKA) rates in Libyan type 1 diabetic (T1D) patients. A descriptive and retrospective study which included patients treated and followed up at Tripoli University Hospital. Fifty-seven T1D patients used CSII pump enrolled in this study. Assessment of hypoglycemia, DKA, measuring the glycosylated hemoglobin (HbAlc) values at time of diagnosis (prior to CSII) and at time of study conduction. Mean age was 12.72 year ± 3.8 SD. Mean duration of diabetes was 7.28 years ± 3.9 SD. The baseline mean HbA1c was 8.58 ± 1.73% during Multiple Daily Injections (MDI) at pre-pump and 7.76 ± 1.33% post initiation of CSII (p = 0.001), with higher proportion of patient's post-pump treated had good metabolic control with HbA1c compared to pre-pump infusion 23, 40.4% and 16, 28.1%, respectively. Both the incidence of ketoacidosis and severe hypoglycemic episodes was improved compared with MDI pre-pump significantly during CSII (P<0.001). This study supports that CSII is an effective alternative in managing T1DM. In addition, therapy with insulin pump in children with diabetes is very efficient and safe with obvious reduction of HbA1c and significantly diminished rates of DKA and hypoglycemia.

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INTRODUCTION

The Diabetes Control and Complications Trial (DCCT) demonstrated that, in patients with Type 1 Diabetes (T1D), tight metabolic control achieved with intensive insulin therapy is superior to conventional treatment in reducing the risk of long-term microvascular complications [1]. One of the most significant innovations in diabetes technology in the last 50 years has been Continuous Subcutaneous Insulin Infusion (CSII) pump and Continuous Glycemic Control (CGM). CSII is intensive insulin therapy, which attempts to mimic physiological insulin release by administration of 24-hour adjustable basal rates and flexible mealtime bolus doses [2]. CSII is a viable alternative to MDI therapy for patients with T1D who are capable, motivated, and trained to use insulin pumps. In addition, insulin-pump therapy can improve glycemic control in patients with T1D because it can reduce the within-day and between-day glycemic variability that

noted with insulin injections [3-5]. Recent evidence from the T1D Exchange clinic registry shows that during childhood mean glycosylated hemoglobin (HbA1c) remains above the target of 7.5% for all age groups, with a peak of 9.2% in the late teenage years [6]. Several meta-analyses of randomized controlled trials of glycemic control comparing CSII with multiple daily insulin injections (MDI) have established that the Mean Glycosylated Hemoglobin Value (MHbA1c) is significantly lower with CSII pump [7-11]. The incidence of DKA in adolescents in DCCT was 4.7/100 patient years in the conventional arm and 2.8/100 patient years in the intensive arm [12]. According to pediatric follow-up studies, the frequency of DKA does not increase with pump therapy [13-14].
In addition, the advantage of CSII therapy is its ability to mimic physiological insulin release, which may provide a more efficient supply of insulin to the tissues and minimize the risk of hypoglycemic events [15]. A retrospective study showed that CSII pump is safe, effective and a superior alternative to multiple daily insulin (MDI) [16-17]. Our aim of this study was to evaluate the efficacy of insulin pump report on glycemic control and recurrence of DKA in Libyan T1D patients.

METHODS

Study design and setting

A cross-sectional study was conducted using a questionnaire involving 57 children diagnosed with T1D and they initiated insulin pump therapy during 2018–2021 at Pediatric Department of Tripoli University Hospital. Socio-demographic characteristics of patients include age, gender, school class, duration of T1DM and history of any associated disease has been documented. In addition, clinical assessment and laboratory analyses were measured, which included: height was measured in m, weight in kg, and body mass index (BMI), HbA1c.

Data collection

We reviewed data of 57 patients enrolled in this study; demographic variables such as age, gender, educational level, and past medical history related to their condition from file record. Furthermore, we documented other relevant clinical variables such as weight, height, Body Mass Index (BMI) and laboratory results as HbAlc values at diagnosis, prior to, and at time of conduct this study. In addition, number of DKA episodes prior and after use of insulin pump, hypoglycemia and the impact on life quality of patients. Written consent obtained from all patients/parents.

Statistical analysis

The collected data was analysed using the SPSS, version 25.0 statistical software. The quantitative variables reported as means and standard deviations or medians ranges. When distributions approximated the normal curve, parametric tests employed using the chi-square test of association for categorical variables and the independent samples t-test for continuous data. The change in HbA1c was analysed using a paired t-test of the difference in HbA1c and DKA episodes between the post-pump and prior-pump.

RESULTS

In this study, 21 males and 36 females were enrolled with type 1 diabetes with age ranged between 6 and 21 years old (mean of 12.72 year±3.8 SD). 40.4% of them were less than 12 years old. The mean duration of diabetes was 7.28 years ± 3.9 SD. 27 (47.4%) of patients had a duration of diabetes of between 5 and 10 years and 19 (33.3%) for less than 5 years (figure 1). In addition, mean age at diabetes diagnosis was 5.43 years ± 3.2 SD.
Regarding the indications for CSII therapy initiation, the most common indications are the glycemic variability, poor glycemic control and hypoglycemic episodes.

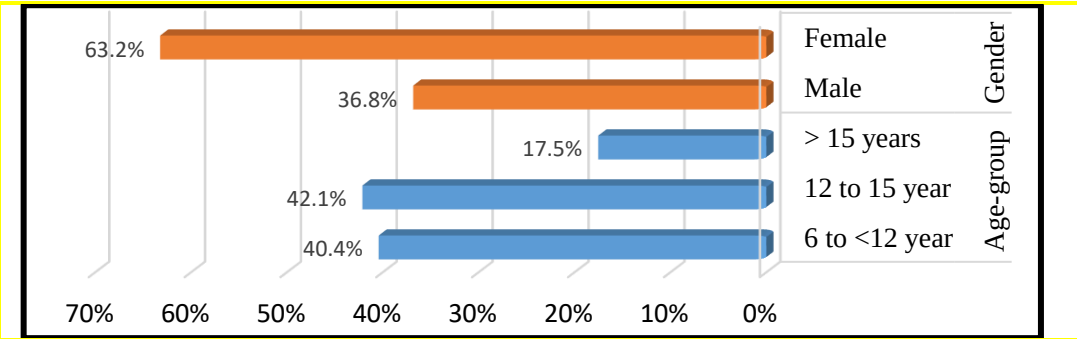

Figure 1. Distribution of participants according to age and gender

Insulin regimen prior to pump therapy; the majority of patients (80.7%) were being treated with flexible insulin regime ((Rapid Acting Insulin (Novorapid or Apidra or Humalog) and long-acting basal insulin (Lantus or Levemir) with carbohydrate counting and eleven patients (19.3%) with short acting insulin (Actripid) and Isophane (NPH, Intermediate insulin). Fifty-eight episodes of diabetic ketoacidosis (DKA) occurred in 35 (60.7%) patients prior to the initiation of insulin pump therapy with baseline mean HbA1c level was 8.58 ± 1.73 (Table 1).

Table 1. Clinical characteristics of the patients at insulin pump therapy initiation

Variables		N	%
Age at T1D Diagnosis	< 6 years old	6	10.5%
	6 -10 years old	47	82.5%
	> 10 years old	4	7.0%
Insulin regimen prior to insulin pump therapy	Regular insulin + NPH insulin	11	19.3%
	Rapid insulin + long-acting basal insulin	46	80.7%
Occurrence of DKA in a year prior to insulin pump therapy initiation	History of admission with DKA	35	60.7%
	No history of admission with DKA	22	39.3%

At the time of pump therapy initiation, the mean age of the participants was 11.46 years ± 3.39 SD. The results showed a significant difference in overall HbA1c, twenty-three patients (40.4%) showed HbA1c 7.76 ± 1.33 compared to before CSII pump (16, 28.1%), (p = 0.001) and 31.6% with HbA1c between 7.5 - 8.4% (Table 2).

Table 2. HbA1c values before and after insulin pump therapy introduction.

Variables		HbA1c (%) before insulin pump therapy		HbA1c (%) after insulin pump therapy		p-value
		N	%	N	%	
HbA1c (%) Mean ± SD		8.57 ± 1.71		7.76 ± 1.33		
Glycaemic control HbA1c (%)	< 7.5%	16	28.1%	23	40.4%	0.001
	7.5 -8.4%	12	21.1%	18	31.6%	
	8.5 -9.9	15	26.3%	12	21.1%	
	>10%	14	24.6%	4	7.0%	

HbA1c improvement observed more in male than in female gender group but it was statistically not significant. Furthermore, according the age group, HbA1c decreased in all age groups and more in age group > 15 years (figure 2,3).

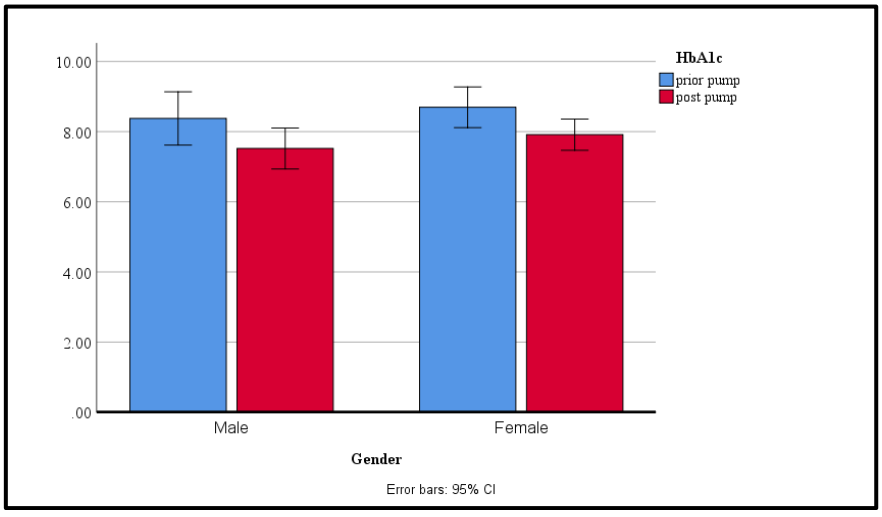

Figure 2: HbA1c in all patients according to gender

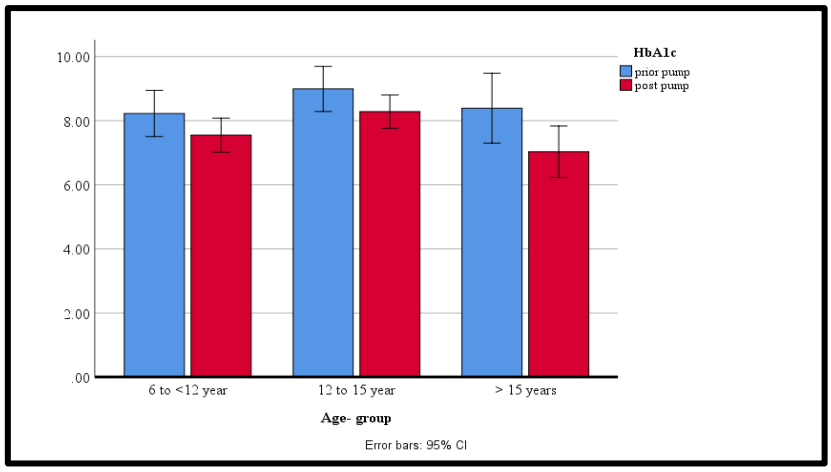

Figure 3 HbA1c in all patients according to the age

Data related to the diabetes duration exhibited that HbA1c showed a more decrease with group of diabetes duration more than 10 years after use of insulin pump (figure 4).

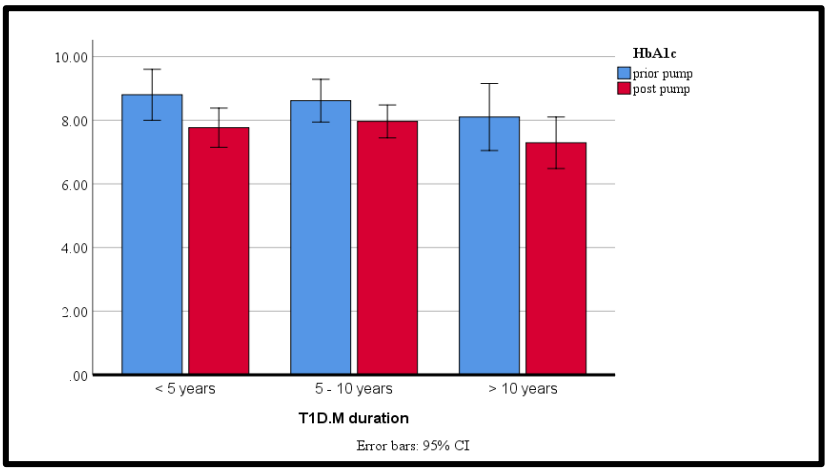

Figure 4. HbA1c in all patients according to diabetes duration

Regarding the parent education finding, we documented that 33 (57.7%) of fathers and 27 (47.4%) of mothers have studied secondary/technical education, followed by a university degree or above as Master or Ph.D. in (31.6%, 35%) of fathers and mothers, respectively. Furthermore, we noted that HbA1c is less in the group of mothers with university education level prior to initiation of insulin pump whereas it is noted after insulin pump in mothers and fathers with primary school education levels but statistically not significant (Figure 5).

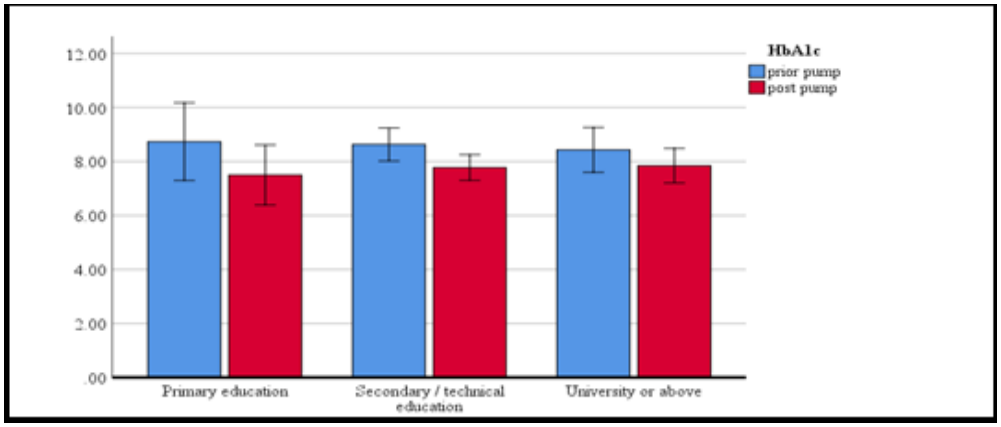

Figure 5: The HbA1c in all patients according to parent's education levels

Diabetic ketoacidosis was more frequent prior to insulin pump period compared with after insulin pump, 35 episodes (60.7%) were identified in 25 patient's vs 10 episodes of DKA (12.3%) were identified in 10 patients, after insulin pump therapy respectively, p = 0.001. In addition, DKA episodes was significantly common in females before and after insertion of the pump (table 3).

Table 3. Patients who developed diabetic ketoacidosis before and after receiving a insulin pump infusion in relation to gender and HbA1c

Variables	Prior insulin pump infusion			Post insulin pump infusion		
	DKA episodes		No DKA	DKA episodes		No DKA
	35 patients (60.7%)		22 patients (39.3%)	10 patients (17.5%)		(47 patients (82.5%)
Gender	12 males	23 females	-----	2 Males	8 females	------
HbA1c Prior insulin pump therapy initiation Mean±SD	8.75±1.61		8.33±1.92	9.27±0.78		8.48±1.81
HbA1c Post insulin pump therapy initiation Mean±SD	8.03±1.42		7.39±1.14	8.13±1.36		7.72±1.34

The total number of hypoglycemic episodes during (MDI) pre-pump were 57, in which 29 were severe episodes that were common in females. These episodes decreased significantly to only 3 severe episodes of hypoglycemia during CSII therapy (P <0.001) (table 4).

Table 4. Patients who developed hypoglycemia before and during insulin pump infusion in relation to gender

Gender	Prior insulin pump infusion		Post insulin pump infusion	
	Severe Hypoglycaemia episodes		Hypoglycaemia episodes	
	29 patients (50.9%)		3 patients (5.3%)	
	9 males	20 females	1 male	2 females

DISCUSSION

Glycosylated hemoglobin testing is still worldwide-standardized test for the diagnosis and the assessment of diabetes management, as it is a strong predictor for long-term diabetes complications. The development of insulin analogs, more sophisticated insulin delivery systems (e.g. insulin pumps), continuous glucose monitoring (CGM), and more recently, integrated systems as sensor-augmented insulin pumps and closed-loop control systems demonstrate greatly enhanced the feasibility of maintaining glucose levels within a prespecified target range [18]. Different studies have shown that CSII improves glycemic control and increases patient's quality of life, without increasing the incidence of hypo or hyperglycemic episodes [19-21]. At the time of insulin pump insertion, 38 (66.7%) of them had T1D duration longer than 5 years and we observed that insulin pump therapy improves glycemic control with a difference in HbA1c pre and post-insulin pump (p = 0.001). In literature, many studies documented significant improvement of HbA1c after the insertion of insulin pump therapy in T1D patients with different percentage [22-25].

A meta-analysis studies in comparing CSII treatment with MDI only demonstrated a reduction in HbA1c between 0.4% and 0.5% in both adults and children [26,27]. Regarding DKA, still it is one of the most common, costly, and dangerous acute complication in patients with T1D. We found that DKA decreased with use of CSII from prior to insulin pump period compared to after insulin pump, 60.7% vs 12.3%, respectively, p = 0.001. Dogan et al [28] demonstrated that 70% of DKA episodes in CSII patients related to technical problems as kinking of the tubing and leakage of insulin at the infusion site. In addition, analyzing data from pediatric CSII patients from different European countries showed that the frequency of DKA was 6.6/100 patient years [29] and was less in another observational study, with frequency of 4.7 DKA episodes/100 patient years during a 5-yr follow-up of CSII users [30]. Our results indicated that DKA episodes was common in girls either pre and post insertion insulin pump which is similar to literature where documented that recurrent DKA to be twice as common in females [31-33].

In literature, many studies reported reduced frequency of severe hypoglycemia events was achieved in patients after the use of CIIS pump [34-40]. Other randomized studies on children have been reported, no difference in severe hypoglycemia [41-43].

CONCLUSION

Therapy with insulin pump in children with diabetes was very efficient and safe in achieving therapeutic goal of T1D with decrease of (HbA1c). In addition, in our study, we confirm that the use of CSII therapy is improve the glycemic control and significantly diminished rates of DKA and sever hypoglycemia.

Acknowledgment

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Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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فعالية وسلامة العلاج بمضخة الأنسولين لدى الأطفال والمراهقين المصابين بداء السكري من النوع الأول

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[3]قسم طب الأطفال، مستشفى سبها، سبها، ليبيا

المستخلص

يمثل العلاج بمضخات الإنسولين (بالتسريب المستمر للأنسولين تحت الجلد CSII) خيارًا علاجيًا يمكن أن يساعد في تحقيق هدف مهم وهو تقليل المضاعفات الأكثر شيوعًا والمرتبطة بعلاج الداء السكري مثل نوبات انخفاض مستوي السكر (الجلوكوز) في الدم وارتفاع السكر في الدم، والتي لها أيضًا تأثير كبير على نوعية حياة المرضى. أجريت هذه الدراسة لمعرفة تأثير وسلامة العلاج بمضخة الأنسولين على التحكم في الداء السكري وهبوط السكر في الدم ومعدلات حدوث الحماض الكيتوني السكري(DKA) لدى المرضى الليبيين من الأطفال المصابين بداء السكري من النوع الأول(T1D) هي دراسة وصفية واسترجاعية شملت المرضى الذين يتم علاجهم ومتابعتهم في قسم الأطفال بمستشفى طرابلس الجامعي. سبعة وخمسون مريضاً من مرضى T1D والمستخدمين لمضخة الانسولين مسجلين في هذه الدراسة. وتتضمن الدراسة تقييم نوبات انخفاض مستوي السكر (الجلوكوز) في الدم ،معدلات حدوث الحماض الكيتوني السكريDKA ، وقياس قيم الهيموجلوبين السكري الغليكوزيلاتي (HbAlc) في وقت التشخيص قبل استخدام مضخة الانسولين وفي وقت إجراء الدراسة. كان متوسط العمر 12.72 سنة ± 3.8 SD ومتوسط مدة الإصابة بمرض الداء السكري كان 7.28 سنة ± 3.9 SD ، كان متوسط الهيموجلوبين السكري الغليكوزيلاتي HbA1c هو 8.58 ± 1.73٪ أثناء فترة العلاج بالحقن اليومي المتعدد (MDI) في مرحلة ما قبل استخدام المضخة و7.76 ± 1.33٪ بعد العلاج بمضخة الانسولين CSII (P =0.001)، مع وجود نسبة أعلى من المرضى الذين تم علاجهم بالمضخة كان لديهم تحكم في الداء السكري جيد مع HbA1cمقارنة بنوع العلاج قبل استخدام مضخة النسولين 23- 40.4% و 16- 28.1%، على التوالي . معا معدلات حدوث الحماض الكيتوني السكري والنوبات الشديدة في انخفاض مستوي السكر (الجلوكوز) في الدم تحسنت بصورة كبيرة بالعلاج بمضخة الانسولين CSII مقارنة مع فترة العلاج بالحقن اليومي المتعددP <0.001 (MDI). تدعم هذه الدراسة أن استخدام مضخة النسولين CSII هو بديل فعال في علاج النوع الأول من الداء السكريT1DM ، بالإضافة لذلك فإن العلاج بمضخة الأنسولين للأطفال المصابين بداء السكري فعال وآمن للغاية مع انخفاض واضح في نسبة الهيموجلوبين السكري الغليكوزيلاتي HbA1c وانخفاض كبير في معدلات حدوث الحماض الكيتوني السكري وفي حدوث نوبات انخفاض مستوي السكر (الجلوكوز) في الدم.

الكلمات الدالة. مرض الداء السكري من النوع الأول، الهيموجلوبين السكري الغليكوزيلاتي، مضخة الأنسولين، الحماض الكيتوني السكري ، انخفاض مستوي السكر (الجلوكوز) في الدم.