# ARTICLE ORIGINAL/ORIGINAL ARTICLE

# COMPARISON of QUALITY of LIFE in a GROUP of LEBANESE TYPE 1 DIABETICS on INSULIN PUMP and THOSE on MULTIPLE DAILY INJECTIONS

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ABSTRACT • AIM: The aim of the study is to investigate the differences in the quality of life (QOL) in Lebanese youths with type 1 diabetes using continuous subcutaneous insulin infusion (CSII) and those using multiple daily injections (MDI) treatment modalities.

METHODS: A descriptive, cross-sectional, comparative matched design was used. The sample included 36 adolescents and young adults on one of two treatment modalities (CSII or MDI) and matched for age, gender, and level of education. QOL was measured with the Indiana Diabetes Quality of Life for Youth and latest HbA1C level was recorded.

RESULTS: The CSII group had significantly lower HbA1C levels (p < 0.001), and reported better health perception (p = 0.029), more satisfaction with life (p = 0.002), less impact of the disease (p = 0.002), and fewer worries about their disease (p = 0.029), compared to the MDI group. The overall quality of life score was also significantly better in the CSII group than in the MDI group (p = 0.001).

CONCLUSIONS: Findings suggest that CSII is associated with better glycemic control and QOL in the Lebanese youth population with type 1 diabetes.

Keywords: Type 1 diabetes, insulin pump, quality of life, multiple daily injections

# INTRODUCTION

Youth is a time of rapid physiologic and emotional change, and can be very stressful. Diabetes may have an added negative effect on the adolescent's physical, social and psychological well-being and quality of life (QOL), which in turn may lead to low adherence to treatment and poor glycemic control [1].

The effectiveness of treatment for type 1 diabetes is measured in terms of both the glycemic control achieved and the QOL of the individual [2]. By having a better QOL, the adolescent with diabetes is more likely to adhere

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Bayrakdar A, Noureddine S, Farhood L, Nasrallah MP. Comparaison de la qualité de vie d'un groupe de Libanais diabétiques de type 1 traités soit par pompe à insuline soit par multiples injections quotidiennes. J Med Liban 2014; 62 (1): 22-26.

RÉSUMÉ • OBJECTIF: Le but de cette étude est d'examiner les différences de qualité de vie entre de jeunes Libanais atteints de diabète de Type 1 qui utilisent la pompe à insuline et ceux qui utilisent plusieurs injections sous-cutanées d'insuline.

MÉTHODES: Une recherche descriptive transversale a comparé 36 adolescents et jeunes adultes diabétiques. Divisés en deux groupes, utilisant soit la pompe à insuline, soit les multiples injections quotidiennes, ils ont été appariés selon leur âge, sexe et niveau d'éducation. L'instrument de qualité de vie utilisé est l'*Indiana Diabetes Quality of Life for Youth* et le dernier taux d'hémoglobine glycosylée (HbA1C) a été comparé entre les deux groupes.

RÉSULTATS: Ceux utilisant la pompe avaient un taux de HbA1C inférieur (p < 0,01), une meilleure perception de leur santé (p = 0,029), étaient plus satisfaits de la vie (p = 0,002), moins négatifs par rapport à leur maladie (p = 0,002) et se faisaint moins de soucis à propos de leur diabète (p = 0,029). Leur score de qualité de vie était aussi meilleur que le groupe à multiples injections (p = 0,001).

Conclusion : Ces résultats suggèrent que la pompe à insuline est associée à un meilleur contrôle de la glycémie et une meilleure qualité de vie chez les jeunes Libanais atteints de diabète de type 1.

Mots-clés : diabète de type 1, pompe à insuline, qualité de vie, multiples injections quotidiennes

to the treatment, thus having improved metabolic status.

In Lebanon, the insulin pump or continuous subcutaneous insulin infusion (CSII) was introduced in 2003 for type 1 diabetes [3] and the number of patients using CSII estimated at 85 subjects at the time of the study, is rapidly increasing. Advantages of using CSII include fewer insulin injections than MDI, with the potential to enhance treatment adherence in children and adolescents, and the decrease in the variation of blood glucose level throughout the day [4].

Investigators who studied the effect of the CSII treatment on the QOL of youths with type 1 diabetes reported inconsistent results. One small study from Lebanon found an overall good QOL [3]. Boland *et al.* [5] found that patients on CSII treatment reported significantly better coping with the disease than those using multiple

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daily injections (MDI) treatment (p = 0.05). Better general and mental health were also found in patients with type 1 diabetes receiving CSII compared to those on MDI in a randomized crossover trial [6]. Moreover, parents of children with type 1 diabetes reported in a qualitative study that the pump provided better glucose control, easier disease management, and more flexible meal times, as well as more freedom and spontaneity in the daily lives of everyone in the family [7]. On the other hand, other investigators found no significant differences or improvement in QOL of youths using the CSII compared to those using the MDI mode [8-13].

The differences found in the results of the studies could be due to their different population age groups, sample inclusion and exclusion criteria, tools used to measure QOL, and the various research designs used [14]. Considering the conflicting results in the studies above, and the paucity of similar data in Lebanon, the purpose of this paper is to compare the QOL in Lebanese youths with type 1 diabetes mellitus (DM) using CSII with those using MDI treatments.

The hypothesis tested was: Patients using CSII treatment will experience 1/ less disease impact of diabetes, 2/ better life satisfaction, and 3/ fewer worries about their disease than patients using MDI treatment.

# MATERIALS AND METHODS

# Design

A descriptive, cross-sectional, comparative matched design was used in this study. Due to the limited number of patients on insulin pump, a convenience sample of 40 adolescents with type 1 diabetes (20 per group) was recruited from one university affiliated hospital and a chronic care center that are major referral centers for patients with type 1 diabetes. Inclusion criteria included: age 12 to 24 years and diagnosis of type 1 diabetes for at least two years. Patients using the insulin pump were chosen to be on CSII for at least six months. Exclusion criteria included co-morbidities known to influence QOL like: retinopathy, nephropathy, neuropathy, cardiovascular disease, hypertension, peripheral vascular disease, substance abuse and any disability that limits physical activity. There were only 19 patients using the CSII who met the inclusion criteria. One patient on the pump had no interest in participating in the study, which resulted in a final sample size of 36; 18 using CSII and 18 MDI treatment. The two groups were matched according to age, gender, and level of education since these characteristics may influence the impact of diabetes.

# Data collection

Data was collected using a self-administered survey. The Diabetes Quality of Life Questionnaire for Youth (DQOLY) by Ingersoll and Marrero [15] was used to measure quality of life. The instrument includes 51 items divided into three subscales: *Diabetes Life Satisfaction*, *Disease Impact*, and *Disease Related Worries*. Items are

scored on a 5-point Likert scale: 1 (very dissatisfied or never) to 5 (very satisfied or all the time). Summative scores ranged from 17 to 85 on the Diabetes Life Satisfaction scale, 23 to 115 on the Disease Impact scale and 11 to 55 on the Disease Related Worries scale. On the Impact and Worries scales, higher scores indicate lower QOL. On the Satisfaction scale, higher scores indicate better QOL. For this study, reverse coding was done to the Satisfaction scale, so that higher scores would indicate lower QOL. Also, in the tool a question asks participants to rate their overall health on a scale of 1 (poor) to 4 (excellent). Reliability testing of the DQOLY showed Cronbach's alphas of 0.85, 0.83 and 0.82 for the Life Satisfaction, Disease Impact and Disease Related Worries scales, respectively. The three scales were also found to be related, with significant correlations between -0.45 and -0.58 [15]. Content validity of the DQOLY was established by the independent review of a panel of four experts in pediatric diabetes [15].

The questionnaire was translated into Arabic by a professional translator and then back translated to English by a nurse not familiar with the study. The two English versions were compared and found to be linguistically equivalent. The questionnaire was also evaluated for cultural appropriateness to the Lebanese population by an endocrinologist and a diabetes nurse educator who approved its cultural appropriateness and did not suggest any modifications. Questions about the participants' demographics, their caregivers, the breadwinner of the house, and other illnesses, the participants' use of any medications besides insulin, were added. Patients using the insulin pump were asked how they felt about it and those who were not using the pump were asked whether or not they would consider using it.

The study was approved by the Institutional Review Board of the university and the recruitment sites. A list of all patients on the pump was obtained from the diabetes educators and patients who met the study criteria were selected. Verbal approval of the patients' physicians was obtained. The patients were contacted by phone and invited to participate in the study. Individual meetings were scheduled at the participants' homes, where the study was explained and an informed consent obtained; for participants younger than 18 years, parental consent and child assent were obtained. The questionnaires were filled by the participants, with the primary investigator available for any questions. Also data on the most recent HbA1C level was collected.

## Statistical analysis

The data were analyzed using the Statistical Package for the Social Sciences. Alpha was set at 0.05. Means, standard deviations (SD) and frequencies were calculated to describe the sample characteristics. Cronbach's alpha was calculated for the overall DQOLY and its subscales. Student *t* test and chi square analyses were done to compare the two treatment groups on demographic and clinical variables. The hypothesis was tested using paired *t* tests.

Pearson r correlation coefficient was calculated between the HbA1C levels, health perception and DQOLY scores.

#### **RESULTS**

### **Baseline characteristics**

The sample included 36 patients, 20 males and 16 females. Seven patients were from the American University of Beirut Medical Center and 29 from the Chronic Care Center. Differences in demographic and clinical variables between the two groups are shown in tables I and II. The age range was 15 to 24 years, with a mean of  $19.2 \pm 2.6$  years. Duration of diabetes ranged from 2 to 20 years with a mean of  $9.1 \pm 5.1$  years. Time since using the pump ranged between 1 and 5 years with a mean of  $2.9 \pm 1.3$  years. No significant differences were found except for the recruitment site. Significantly more patients on the pump were recruited from the Chronic Care Center than the hospital. Moreover, the level of education of the primary caregiver tended to be higher in the CSII group compared to that in the MDI group. For both groups, the majority of participants had university education and the mother was the primary caregiver

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TABLE I  COMPARISON of the PUMP (N = 18) and MDI (N = 18) GROUPS on DEMOGRAPHIC and CLINICAL CHARACTERISTICS for CATEGORICAL VARIABLES USING Chi <sup>2</sup>							
Variable	Pump N (%)	MDI N (%)	Chi <sup>2</sup>	p value (2-sided)			
RECRUITMENT SITE  Medical center  Chronic care center	6 (33) 12 (67)	1 (6) 17 (94)	4.43	0.035			
Gender Male Female	10 (56) 8 (44)	10 (56) 8 (44)	0.00	1.000			
Nationality Lebanese Others	16 (89) 2 (11)	18 (100) 0 (0)	2.12	0.146			
LEVEL OF EDUCATION Intermediate Secondary/ Technical degree University	1 (6) 6 (33) 11 (61)	1 (6) 6 (33) 11 (61)	0.00	1.000			
OCCUPATION None or student Business Secretary/clerical Professional	16 (88) 1 (6) 1 (6) 0 (0)	16 (88) 0 (0) 1 (6) 1 (6)	2.00	0.572			
CoMorbidities None Yes	18 (100) 0 (0)	17 (94) 1 (6)*	1.03	0.310			
OTHER MEDICATIONS No Yes	17 (94) 1 (6)**	18 (100) 0 (0)	1.03	0.310			
MDI: multiple daily injections  *Patient had hypercholesterolemia **Patient was on didrogesterone							

## **Study outcomes**

Table II shows the results of the hypothesis testing and the group differences in HbA1C levels and health perception. Last measured HbA1C ranged from 6.1% to 12.4% with a mean of 8.2%. Scores on the DQOLY dimensions ranged between 74 and 177; impact scores ranged between 36 and 77; worries between 12 and 39; and satisfaction between 20 and 62. The CSII group reported significantly more satisfaction with life, fewer worries about the disease and less impact of the disease compared to the MDI group. The overall QOL was also significantly better in the CSII group than in the MDI group. The CSII group had a significantly better overall health perception and significantly lower HbA1C levels than the MDI group  $(7.4 \pm 0.9 \text{ versus } 8.9 \pm 1.4 \text{ respectively}, p < 0.001)$ .

Pearson r correlations showed a significant relation between the HbA1C levels and the overall DQOLY score (r = 0.34, p = 0.045). Only the satisfaction scale was significantly correlated with HbA1C (r = 0.40, p < 0.05).

In order to better understand the specific areas that had the most significant differences between the two groups, *t* test was done for each item of the DQOLY. Patients in the pump group perceived significantly more flexibility and less restriction with their diet, less interference of diabetes with their work, school, and social life, as well as less burden of the disease on their families compared to those in the MDI group. In addition, they were more willing to tell others that they have diabetes than those in the MDI group.

Of the participants using the insulin pump, 17/18 reported positive feelings about it while one was undecided. Of the MDI participants, 10/18 reported that they

TABLE II*  DEMOGRAPHIC CHARACTERISTICS for CONTINUOUS VARIABLES, HEALTH RELATED and QOL SCORES in the WHOLE SAMPLE & COMPARISON BETWEEN the PUMP and MDI GROUPS USING TWO-SIDED t -TEST						
VARIABLE	Total N = 36	Pump N = 18	MDI N = 18	p value		
Age (years)	19.2 ± 2.6	19.2 ± 2.6	19.2 ± 2.6	1.0		
Duration of disease (years)	9.1 ± 5.1	8.7 ± 4.8	9.5 ± 5.5	0.62		
Time since using PUMP (years)		2.9 ± 1.3				
Last HbA1C (%)	8.2 ± 1.4	$7.4 \pm 0.9$	8.9 ± 1.4	< 0.001		
OVERALL HEALTH PERCEPTION	$3.0 \pm 0.7$	$3.3 \pm 0.5$	$2.8 \pm 0.8$	0.029		
Worry	$20.9 \pm 6.7$	18.8 ± 4.8	$23.1 \pm 7.6$	0.029		
SATISFACTION	$33.7 \pm 10.6$	$30.0 \pm 9.0$	37.5 ± 11.0	0.002		
IMPACT	52.0 ± 11.3	$46.8 \pm 8.2$	57.3 ± 11.6	0.002		
DQOLY SCORE	$106.7 \pm 26.3$	$95.6 \pm 20.0$	117.8 ± 28.0	0.001		
*Data is presented as mean ± SD  QOL: Quality of Life DQOLY: Diabetes Quality Of Life Youth						

would consider using the insulin pump for the following reasons: it makes life easier (55.6%), provides better control (22.2%), reduces injections and allows more freedom in the diet, (each reported by 11.1% of the MDI group). Reasons for not considering using the pump included: being used to insulin injections (50%), not knowing about the pump, the continuous presence of the machine and the pump being a constant reminder of the disease (each reported by 12.5% of the MDI group).

#### DISCUSSION

This is the first case-controlled study that examined QOL in Lebanese youth with Type 1 DM. Results showed that the CSII group had significantly lower HbA1C levels, better overall health perception and QOL, more satisfaction with life and less impact of the disease, and tended to report fewer worries than the MDI group. Hence the study hypothesis was supported.

Some researchers who compared QOL between patients on the pump and those using MDI found no significant difference [5, 8-13]. Two of the above studies used preschoolers [11] and school children up to 13 years of age [9], whereas others used a wide age range [8, 13] in contrast to the current study which used a homogeneous group of adolescents and young adults.

The findings of the current study were compared with those that used the DQOLY. In a randomized trial of 23 children, there was no difference on any of the QOL subscales, except for more treatment satisfaction (30.6  $\pm$  3.7 vs. 21.9  $\pm$  3.8, p < 0.001). The nonsignificant differences may be explained by the novelty effect of the pump treatment, since it was introduced only 3.5 months before the study to the patients [9]. Patients usually need time to adjust to the pump, thus the effect on QOL needs time to materialize. In the current study, minimum time on the pump was one year, allowing patients time to adjust, which may explain the higher QOL scores in the pump group.

The second study [5] that used the DQOLY had a sample size of 75, yet failed to find significant differences between the two groups. Differences in socioeconomic status of the two groups were not addressed, which could have affected the results. QOL was also measured only up to 12 months after pump therapy, which may have not been enough to identify group differences. In the current study, pump use averaged three years.

The third group of investigators [10] studied 103 children and adolescents and found no significant differences between the groups. Although a matched design was not used, there was significantly better HbA1C level in the pump group and a significant relationship between the health question and the three QOL subscales as was found in the current study. Similarly, a recent controlled study of 62 adolescents failed to find a difference in DQOLY or in the level of parental stress [12]. Surprisingly, the HbA1C was not different between the CSII and MDI groups, and above the American Diabetes

Association target levels in both groups.

A number of factors may account for the significant results in our study. The use of a matched design may have reduced the effect of select confounders. Moreover, clinical variables that might influence QOL, namely comorbidities and duration of diabetes, did not differ between the two groups. The vast majority of the sample included students, thus one may assume that they share similar lifestyles and so the differences between the two groups are genuine and likely to be explained by treatment type.

The higher socioeconomic status of the pump group as reflected in the higher proportion of university graduates among caregivers and breadwinners compared to the MDI group, and the higher proportion of professionals among the breadwinners, could account for the difference in the QOL between the two groups. However, it is worth noting that although the insulin pump is expensive, it is covered by the National Security Social Fund, making it accessible across the different socioeconomic groups. Furthermore, the Chronic Care Center provides comprehensive diabetes care and education at no charge to all Lebanese with type 1 diabetes, making the availability and support system for pump use accessible to even the lower socioeconomic group.

The main physiologic advantage of the pump, namely better glycemic control evidenced by the significantly lower HbA1C levels in the pump group, translated into a better perceived health in that group and better QOL. Furthermore, in this study, the pump group showed significant advantage over the MDI group for each of the QOL subscales. The areas that accounted for these differences related to diet, activities, social life and the perception of disease burden on the patient and family. The pump afforded the patients more freedom and flexibility in their lifestyle, a finding supported by previous investigators [8]. The significantly different items can be explained in relation to the lifestyle of the sample, which included adolescents and young adults who were mostly students, and in whom acceptance by peers is of paramount importance [16]. Fulfillment of this need requires an active lifestyle and freedom from restrictions by illness and its treatment. Item analysis reflected less dietary restriction, less perceived interference of the illness with school/work, and less illness burden on the family in the pump group, in addition to more acceptances of the illness and less impact on going out with friends, compared to the MDI group. Thus the insulin pump is quite beneficial in meeting the developmental needs of this age group. Although there were no significant differences in the items that measured the physical status of the participants, the lower HbA1C levels in the pump group reflect better glycemic control, which means fewer disease complications.

Some limitations are evident in this study. Random allocation to the treatment groups was not done, therefore the possibility of a selection bias cannot be ruled out. Nevertheless, matching the two groups on age, gender, and education limited the confounding variables. The

homogeneous convenience sample of small size limits the representativeness to the Lebanese population with type 1 patients. Nevertheless, the sample recruitment sites cater to a large section of this population, especially those using insulin pumps. The DQOLY addresses the psychological and social dimensions of QOL more than the physical dimension. Questions about physical health did not address specific symptoms, especially hypoglycemia. A question about hypoglycemia in the original DQOL was deleted upon testing the instrument with adolescents, as it did not correlate with the total variance of the scale [15]. Nevertheless, items that ask about whether diabetes interferes with school, work, activities and leisure do indirectly address the physical dimension of the QOL. Moreover, the significant group difference in HbA1C implies better physical health in the pump group. Lastly, the type of MDI was not assessed in this study. It is possible that the use of older insulin regimens may have affected negatively the DQOLY in the MDI group, and thus exaggerated the benefits of the pump. Nonetheless, a study using a large sample size of 1,341 adults addressed specifically the issue of MDI type and found no difference in DQOL between glargine- or NPH-based regimens, and found that both were inferior to CSII [17].

Given the nature of T1 diabetes and how intimately its therapeutic modality is linked to lifestyle, it may not be possible to use a randomized design to compare quality of life in CSII and MDI patients. Nonetheless, a large trial targeting the adolescent age group, and controlling the methodologic discrepancies reported in the literature is needed. Future studies need also to assess symptoms and physical outcomes like frequency of hypoglycemic episodes, incidence of diabetic ketoacidosis and long-term complications, in relation to QOL in the patients using various treatments.

In conclusion, the data suggest that the insulin pump can lead to improved metabolic control and a better quality of life in the Lebanese youth population with type 1 diabetes.

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DECLARATION OF COMPETING INTERESTS: The authors declare that they have no conflict of interest.

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