Original Article

Effects of therapeutic patient education program on glycemic control and quality of life among children and adolescents with type 1 diabetes mellitus in Fez city, Morocco

Hanaâ Ait-Taleb Lahsen[1,2], Mohammed El Amine Ragala[1,3], Hanane El Abed[1,2], Btissame Zarrouq[3,4], Karima Halim[1,3]

[1]Department of Biology, LSNAMOPEQ, Faculty of Sciences Dhar El Mahraz Fsdm, Sidi Mohamed Ben Abdellah University, [2]High Institute of Nursing and Technical Health Professions, Fez ISPITS, [3]Department of Biology, High School Teachers-Training College (Ecole Normale Superieure), Sidi Mohamed Ben Abdellah University, [4]Laboratory of Epidemiology and Research in Health Sciences, Sidi Mohamed Ben Abdellah University, Fez, Morocco

Abstract

Context: Type 1 diabetes mellitus (T1DM) is a chronic disease, mainly observed in children or youth, with a significantly increased incidence in young children. Structured therapeutic patient education (TPE) is a must to help them manage their disease effectively and lead a healthy lifestyle.

Aims: This study aimed to assess the effects of a structured TPE program on glycemic markers and quality of life (QOL) of T1DM children and adolescents in Fez city, Morocco.

Settings and Design: It is a quasi-experimental study.

Materials and Methods: One hundred T1DM children and adolescents, aged 8–18, participated in a TPE intervention at the pediatric department in a hospital center in Fez, Morocco. Glycemic markers were measured and QOL was assessed by a validated questionnaire.

Statistical Analysis Used: Parametric and nonparametric tests were used and statistical significance determined by $P < 0.05$.

Results: At 3 months' follow-up, both global and dimensional QOL mean scores improved significantly ($P \leq 0.0001$), whereas glycosylated hemoglobin (HbA1c) decreased (10.28% vs. 10.62%), tough with no statistical significance ($P = 0.160$). Furthermore, a significant improvement was observed in the maximum preprandial (2, 11 g/L [1.51–2.58] vs. 2, 37 g/L [1.81–3.21], $P = 0.001$) and postprandial blood glucose levels (2, 50 g/L [1.90–3.27] vs. 2, 95 g/L [2.07–3.99], $P = 0.001$) after 3 months; with no significant change in their minimum.

Conclusion: Although this TPE intervention was more effective in improving patients' QOL than their HbA1c, it is worth striving to implement regular TPE programs for T1DM pediatric patients and adjust them to achieve a better patients' glycemic markers levels.

Keywords: Adolescent, child, diabetes mellitus, patient, quality of life, type 1

Address for correspondence: Prof. Hanaâ Ait-Taleb Lahsen, No. 31, Lottissement Bennis, Quartier Raha, Av. Ibn Al Athir, Fez, Morocco.
E-mail: hanaa.aittaleblahsen@usmba.ac.ma

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INTRODUCTION

Type 1 diabetes mellitus (T1DM) is a chronic disease mainly observed in children or young adults. Over 1.2 million children and adolescents (0–19 years) worldwide have T1DM (estimated at 43.3 thousands in Morocco) in 2021, with an incidence increasing each year (estimated at 5.1 thousands in Morocco) and significant excess mortality in the 1st years after diagnosis, largely attributed to acute metabolic complications of diabetes: Ketoacidosis and hypoglycemia.[1-5] The treatment, essentially centered on a daily management of insulin therapy, diet and physical activity, should be systematically initiated, as from diagnosis, by a team of specialists, with the integration of the therapeutic education of the child and his family.[4,6,7] Hence, therapeutic patient education (TPE) becomes a must, an integral part and the key to successful management of diabetes and have definitely of a beneficial effect on glycemic control and on psychosocial outcomes of T1DM children and adolescent.[7-13] With such a structured disease self-management, the child and his family will avoid serious and multiple complications, as well as behavioral, emotional, and social problems without compromising his quality of life (QOL) and wellbeing.[12,14]

TPE must be distinguished from simple patient information or traditional education.[15] It is based on structured and diversified educational sessions incorporating, in addition to knowledge and skills related to diabetes, the psychological patient components.[8]

In this regard, to be effective, educational interventions must be, among other things, based on clear theoretical psycho-educational principles based on cognitive-behavioral techniques, and be considered as a continuous process of self-management support individualized and psychosocial support, involving the continued responsibility of parents and other careers.[13,16]

In chronic diseases, TPE should be conducted on a four steps model: (1) Educational diagnosis of the patient needs, (2) Definition, in priority order, of the skills required to manage the disease in order to plan an individual program, (3) Implementation of the educational program with appropriate educational methods, and (4) Evaluation of the program's process and outcomes.[17-20]

This study aimed to implement a TPE program for T1DM children and adolescents, as there's no one in the Moroccan context, and assess if this intervention will improve their glycemic markers and disease-related QOL.

MATERIALS AND METHODS

Study design

The present work was designed as a quasi-experimental study aiming to assess the effect of a structured education intervention for children and adolescents with T1DM by comparing their glycemic markers and QOL on pre and post intervention. Measurements were obtained before intervention (baseline t0) and at 3 months follow-up after (follow-up t1).

Participants' recruitment and sampling

Children and adolescents with T1DM were recruited, from January to July 2022, during their appointments for consultation in the hospital's pediatric department (Prefectural hospital center). Were eligible to participate in this study all patients with T1DM, aged 8–18 years, diagnosed with T1DM for a minimum of 6 months, able to understand and speak Arabic language and giving a written informed consent. The exclusion criteria were as follows: Type 2 diabetes, age <8 years, significant verbal inability communication and comorbidity. Out of a total of 419 children and adolescents attending their appointments in the pediatric department during the study period, 120 gave written informed consent and were included using a convenience sampling nonprobabilistic method, as there was not any exhaustive primary list of these patients. The minimal sample size was calculated as 80 patients, through GPower tool, using the data from a pilot study which yielded a glycated hemoglobin level of 9.31% ±0.44% before and 9.15% ±0.35% after educational intervention, based on an alpha error <0.05 and a statistical power of 95%.[21] After giving their consent to participate in the study and after having undergone an educational diagnosis (first stage of TPE), 20 patients withdrew. Eventually, 100 patients accepted and actually participated in the educational intervention.

Intervention

There is no structured TPE program for T1DM children and adolescents in Morocco. Therefore, patients included in the intervention (n = 100) participated in an original TPE program developed following the four steps model of D'Ivernois and Gagnayre (2008).[18]

The first stage of this model, the educational diagnosis, was a fundamental educational assessment to know the patients and identify their needs, potentialities, expectations, and receptivity to the proposal of the personalized TPE program.[18] T1DM children's and adolescents' educational needs, determined as part of this assessment stage were used to plan a personalized

educational program and define the skills that best meet these participants' needs and concerns.[22] Those skills revolve around two main categories namely self-care and adaptation[23] and were broken down into educational objectives[24] which formed the framework of Referential skills [Table 1].

The 100 patients assigned to the intervention participated in a TPE program of three group sessions (one session per week), 90 min each, with 2–11 patients per group, based on their age and the predefined referential skills. The first session focused on the pathophysiology of T1DM and how to perform self-monitoring measures and insulinotherapy. Session 2 was dedicated to the detection and treatment of short term complications (hypoglycemia and diabetic ketoacidosis) and how to prevent or identify earlier the long-term ones. The third and last session' topics were diabetes diet and positive attitudes toward T1DM and the related emotional troubles and concerns. In addition of the 100 T1DM children and adolescents participating in this study, their parents and careers attended the three sessions.

The three group sessions were mainly conducted by a nurse educator trained in TPE, one of the authors, with pediatric dietetician nurse collaboration. The TPE intervention took place in a nursing center located in the same hospital.

The educational intervention is based on Bandura's social cognitive theory, regularly used in pediatric diabetology, which revolves around the concept of self-efficacy feeling related to the individuals' beliefs in their own abilities to adopt the right behaviors and perform particular performances. This feeling's sources are active experience based on personal control of the tasks to be performed, vicarious experience based on observation which leads to social modeling of the knowledge and skills shown by various models like peers, verbal persuasion generating beliefs of ability to successfully perform the desired behavior and positive emotional states leading to good performance of the desired behavior.[25,26]

Thus, to stimulate learning among these young participants, active teaching methods adapted to their age were used.

Measures and data collection

For the 100 patients included in the TPE intervention, sociodemographic data were collected at baseline. Glycemic markers and health-related QOL (HRQOL) were assessed at baseline and 3 months following the TPE intervention. Glycosylated hemoglobin (HbA1c) was measured and minimum and maximum values of pre- and postprandial blood glucose were assessed by a review of patient records on their diabetes log book for the last 2 weeks before the measurement.

Table 1: Referential skills for children and adolescents with type 1 diabetes mellitus

Educational objectives	Specific objectives	Teaching methods
Being able to explain his diabetes		
Explain the pathophysiology of type 1 diabetes	Locate some organs (liver, pancreas, kidneys, heart, etc.) in the human body Explain the pancreas role in the insulin production Explain the relationship between insulin and blood sugar Differentiate between the different types of diabetes Identify the type 1 diabetes causes and complications	Brainstorming Power point presentation with drawings and pictures
Explain T1D self-monitoring measures	Measure capillary blood glucose Look for sugar and acetone in the urine	Simulation
Explain how to take treatment	Differentiate between types of insulin and their action mechanisms Perform an insulin injection	Simulation
Being able to react in a crisis		
Know how to detect hypo and hyperglycemia	Identify the different signs of hypo and hyperglycemia Identify the factors responsible for hypo and hyperglycemia	Brainstorming Powerpoint presentation with drawings and pictures
Manage a hypo and hyperglycemia crisis	Take the needed measures in a hypo or hyperglycemia crisis	Role-play
Be able to adapt his diet to the treatment constraints		
Explain the principles of a diet for T1D	Differentiate food groups Justify the need to diversify his diet and distribute carbohydrates over the day Identify situations justifying a change in carbohydrate intake: Physical activity, etc.	Brainstorming Powerpoint presentation with drawings and pictures Group discussions
Being able to express his emotions and his experience with the disease		
Expressing his troubles and difficulties in connection with T1D	Explain his feelings about monitoring Identify difficulties when taking the treatment Express concerns about new food constraints Explain his emotions at school	Group discussions

HRQOL was measured using a validated questionnaire, the Pediatric QOL Inventory PedsQL 3.0, specific HRQOL module developed for T1DM (with User License Agreement from Mapi Research Trust) with good internal consistency, reliability, and validity.[27] The PedsQL 3.0 T1DM module has five scales with 28 items: (1) Diabetes symptoms (11 items), (2) treatment I barriers (4 items), (3) treatment II adherence (7 items), (4) worry (3 items), and (5) communication (3 items). Each participant was asked how much of a problem each item has been during the past 1 month. A five-point Likert response scale was used (0 = never a problem and 4 = almost always a problem). Then, items were reverse-scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, and 4 = 0), which combine to produce a total diabetes score. Higher scores indicate better HRQOL. Scale scores were computed as the sum of the items divided by the number of items answered.[27]

Data analysis

The socio-demographic, glycemic and QOL data analysis was performed using the Statistical Package for the Social Sciences IBM SPSS Statistics 25 (IBM Corp., Armonk, NY).

Data are expressed as either means ± standard deviation and 95% confidence interval (CI), for the normally distributed variables (HbA1c and QOL mean total score), or median and interquartile range (25^{th}–75^{th}) for the nonnormally distributed ones (minimum and maximum values of pre- and postprandial blood glucose, QOL diabetes, treatment I and II, worry, and communication mean scores).

Changes in glycemic markers and HRQOL variables from baseline to 3 months in the TPE intervention were assessed by parametric and nonparametric tests based on normality tests. To assess the effect of TPE intervention on HbA1c values and QOL mean total score within the same intervention group, the paired samples Student's *t*-test was applied. To assess the TPE intervention effect achieved on minimum and maximum values of pre- and postprandial blood glucose, QOL diabetes, treatment I and II, worry and communication mean scores, the related samples Wilcoxon signed-ranks test was applied. Statistical significance was assumed at a two-tailed $P < 0.05$.

Ethical considerations

Based on a study protocol, ethical approval was granted from the University Hospital Ethics Committee of Sidi Mohamed Ben Abdellah Fez University (Protocol code: 14/22, date of approval: January 2022). Besides that, T1DM children and adolescents participating in this study were recruited after receiving both oral and written information about the study. As the participants are minors, written formal consent was obtained from their parents and careers. Researchers had ensured that the internationally recognized ethical principles for research involving human subjects were respected throughout this research, and all methods were carried out per the relevant guidelines and regulations.

RESULTS

One hundred children and teenagers participated in a structured TPE intervention between February and July 2022, half male and half female, 92% living in the urban area, with a mean age of 11.90 (±2.4) and a mean year with TD1M of 4.16 years (±3.12). Only 44% of these participants had a regular physical activity and 1% of them were not educated at school because of the related disease troubles [Table 2].

All the participants follow an insulin therapy regimen with two injections (morning and evening).

The response's rate 3 months after the TPE intervention was 99.9% ($n = 99$). Glycemic markers and HRQOL were assessed at baseline T0 and 3 months T1 following the TPE intervention [Tables 3 and 4].

Glycemic markers

Regarding HbA1c values [Table 3], there was no statistically significant change after 3 months of TPE intervention compared to T0 baseline (10.28% vs. 10.62%, $P = 0.160$). However, there was a significant improvement in the maximum preprandial (2, 11 g/L [1.51–2.58] vs. 2, 37 g/L [1.81–3.21], $P = 0.001$) and postprandial

Table 2: Participant's baseline sociodemographic characteristics (*n*=100)

	Percentage
Age (years), mean±SD	11.90±2.4
Years with T1DM, mean±SD	4.16±3.12
Sex	
Male	50.0
Female	50.0
Urban/rural area	
Urban area	92.0
Rural area	8.0
Study level	
Primary school	62.0
Secondary school	37.0
Not educated	1.0
Physical activity	
Yes	44.0
No	56.0

Categorical variables are expressed in percentage and continuous variables in mean±SD. SD=Standard deviation, T1DM=Type 1 diabetes mellitus

Table 3: Participants' glyquemic marquers assessed at baseline T0 and 3 months following the TPE intervention T1 (*n*=100)

Glycemic markers	T0 (Before TPE intervention)	T1 (3 months after TPE intervention)	*P*
HbA1c (%)	10,62 +/- 2.56	10,28 +/- 2.47	0.160[a]
Preprandial maximum blood glucose (g/l)	2,37 (1.81-3.21)	2,11 (1.51-2.58)	0.001[b]
Preprandial minimum blood glucose (g/l)	1,01 (0.78-1.31)	0,93 (0.75-1.31)	0.257[b]
Postprandial maximum blood glucose (g/l)	2,95 (2.07-3.99)	2,50 (1.90-3.27)	0.001[b]
Postprandial minimum blood glucose (g/l)	1,13 (0.85-1.54)	1,19 (0.90-1.54)	0.665[b]

Data are expressed as means +/- standard deviation for the normally distributed variables (HbA1c), or as median and interquartile range (25^{th}-75^{th}) for the non normally distributed ones (min and max of preprandial and postprandial blood glucose). [a]Paired samples Student's *t*-test. [b]Wilcoxon signed-ranks test

Table 4: Participants' HRQOL assessed at baseline T0 and 3 months following the TPE intervention T1 (*n*=100)

QOL	T0 (Before TPE intervention)	T1 (3 months after TPE intervention)	*P*
QOL global mean score	52,96 (+/-8,78)	63,41 (+/- 7,79)	0.000[a]
QOL Diabetes symptoms mean score	50.00 (45.45-54.54)	56.82 (52,27-61,36)	0.000[b]
QOL treatment I barriers mean score	56,25 (43.75-62.50)	62,50 (62.50-68.75)	0.000[b]
QOL treatment II adherence mean score	42,86 (35.71-50.00)	50,00 (46.43-53.57)	0.000[b]
QOL worry mean score	41,67 (33.33-50.00)	50,00 (50.00-58.33)	0.000[b]
QOL communication mean score	33,33 (25.00-50.00)	50,00 (50.00-58.33)	0.000[b]

Data are expressed as means +/- standard deviation for the normally distributed variables (QOL total mean score), or as median and interquartile range (25^{th}-75^{th}) for the non normally distributed ones (QOL Diabetes symptoms, traitement I barriers, treatment II adherence, worry and communication mean scores). [a]Paired samples Student's *t*-test. [b]Wilcoxon signed-ranks test

blood glucose levels (2, 50 g/L [1.90–3.27] vs. 2, 95 g/L [2.07–3.99], $P = 0.001$) after 3 months; with no significant change in their minimum (respectively $P = 0.257$ and $P = 0.665$).

Health-related quality of life

It was measured using PedsQL 3.0 questionnaire. For both global and dimensional QOL, mean scores improved significantly after 3 months of TPE intervention ($P \leq 0.0001$) [Table 4]. Thus, comparing baseline measurements T0 with those after 3 months T1, participants showed a better overall mean QoL score ($P \leq 0.0001$), showing less disease-related problems. Similarly, the mean Diabetes QoL score improved ($P \leq 0.0001$), indicating less pronounced symptoms. In the same way, there were less treatment barriers or adherence issues at T1 for the participants, since mean Treatment I and II QoL scores improved significantly ($P \leq 0.0001$). Regarding the Worry QoL dimension, its mean score increased, as well as the mean communication QoL score ($P \leq 0.0001$), showing less illness-related worries and communication problems.

DISCUSSION

This study purpose was to implement a TPE program for T1DM children and adolescents and assess if this intervention will improve their glycemic markers and HRQOL. The results showed a small and statistically not significant improvement in HbA1c levels for participants at 3 months after the TPE intervention. Same was observed in other studies where there was no change achievement in overall HbA1c after patient education.[8,28-32] This disappointing not effective change in glycemic control may be due to one or more influences such as short term assessment of HbA1c, which may not reflect the education program impact; biopsychosocial effects of puberty; and questions regarding timing of the intervention and readiness to change for some T1DM children and young people.[29,30]

However, in their integrative review of the quality and outcomes of diabetes education programs for children and adolescents, Colson *et al*. state that 40% ($n = 12$ of 30) of the studies measuring HbA1C as an evaluation criteria of the education programs, an improvement in glycemic control in pediatric diabetes was observed.[33] For the others glycemic markers in this study, there was a significant improvement only in the maximum pre- and postprandial blood glucose levels, with no significant change in their minimum.

In contrast to the unobserved effect of TPE intervention on HbA1c, QOL assessed by PedQL 3.0, in its global mean scores, as well as the dimensions' ones have improved significantly 3 months after the TPE intervention. The improvement meet the widely reported structured education programs' positive impact on patients QOL.[28-31] This suggests that children and adolescents with T1DM derive great benefit from therapeutic education to reduce the disease's symptoms, to better adhere to treatments and face their barriers, to better deal with their concerns and communicate with caregivers and others about their illness.

Besides, in addition of intensifying glycemic control, therapeutic programs should focus also on interventions reported to be effective in reducing diabetes-specific family

conflict proved to diminish the overall QOL of children and youth with T1DM.[34]

Limitations and future research directions

In our study, the TPE intervention for children and adolescents with T1DM was in our context the first structured education program that incorporates the educational approach's stages recommended by D'Ivernois and Gagnayre (2008).[18] However, despite its encouraging results, there are some limitations. Indeed, in this study, a control group was not included, which could have neutralized any bias in the change in results unrelated to therapeutic education. However, it was not possible to consider a control group in the same structure, as almost all the recruited patients wanted to benefit of TPE. Similarly, the short-term follow-up in our study may not have been long enough for a significant change in HbA1c levels.

Hence, further researches could include a control group from another hospital structure and provide for a longer duration of follow-up.

CONCLUSION

In this study, although there was no significant effect on HbA1c levels, the TPE achieved an effective improvement in QOL and other glycemic markers which suggests that structured patient education has the potential to help children and adolescents with T1DM to acquire the right skills and better manage their disease. Nevertheless, it should be emphasized that these interventions must be regular to maintain the gains in terms of better glycemic control and QOL.

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Conflicts of interest

There are no conflicts of interest.

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