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SCIENTIFIC LETTERS

Health-related quality of life in children with type 1 diabetes and advanced hybrid closed-loop systems

Análisis de calidad de vida relacionada con la salud en niños con diabetes tipo 1 y terapia con sistemas híbridos de asa cerrada

Dear Editor:

The goal of treatment of type 1 diabetes (T1D) is to achieve optimal glycaemic control to prevent acute and chronic complications of the disease without compromising the quality of life of children and their families.[1] However, achieving adequate metabolic control is challenging and requires significant engagement of the family. Despite technological advances, such as continuous glucose monitoring (CGM) and continuous subcutaneous insulin infusion (CSII) systems, T1D has a significant impact on daily life for patients and their immediate circles, increasing the risk of mental health problems.[2]

Hybrid closed loop systems (HCLSs) consist of an insulin infusion system (or pump), a CGM device and a control algorithm that allows the delivery of variable doses of insulin determined by the algorithm based on the interstitial glucose levels, which reduces to some degree the burden that the disease places on the caregivers (Appendix A).

The objective of our study was to analyse whether there was an improvement in health-related quality of life (HRQoL) of children and parents after initiation of the HCLS.

We conducted a retrospective and prospective study in children with T1D who started treatment with HCLS in a secondary care hospital. The assessment of HRQoL consisted in the administration of the first questionnaire specifically developed for children and adolescents with T1D validated in Spanish (DISABKIDS).[3] We retrieved data from the questionnaire completed by the parents and also the questionnaire completed by patients if they were aged more than 8 years, administered at baseline before initiation of the HCLS and again after a minimum of 6 months. We also collected clinical data through the retrospective review of the patients' health records and the software of the CGM and CSII systems (LibreView, CareLink and Glooko). The main outcomes under study were the questionnaire scores and the measured CGM-derived metrics and glycated haemoglobin (HbA1C). The study was approved by the competent research ethics committee and we obtained informed consent for all participants.

The DISABKIDS questionnaire assesses mental (independence and emotion), social (inclusion and exclusion) and physical (limitation and treatment) dimensions of HRQoL and was developed for assessment of children and adolescents with chronic diseases. We used the diabetes-specific module, which consists of 2 scales: impact and treatment. The former assesses the emotional impact of daily glycaemic control and dietary restrictions. The treatment scale deals with the constant need to plan treatment and carrying equipment. The score reflects a better quality of life the closer it is to 100 (range, 0–100). The questionnaires also include 3 items that assess decompensations in the past year.

The study included 25 patients (56% male). The mean age at diagnosis of T1D was 6.5 years (SD 3.5). Most patients used the Minimed 780G-Guardian 4 system (Medtronic) and 4 the Tandem t:slim X2-Dexcom G6 system (Novalab).

Table 1 presents the CGM-derived metrics and HbA1C values before and after initiation of the HCLS: there was an increase in the number of patients who met the criteria for adequate glycaemic control established by the International Consensus of Time in Range (2019),[4] in addition to a significant increase of the time in range, with a decrease in the time with levels between 181 and 250 mg/dL and a reduction in the mean glucose level. Fig. 1 presents the scores of parents and children in the pre- and post-HCLS DISABKIDS questionnaires.

We observed improvement in patient CGM-derived metrics and parental HRQoL, which was consistent with previous studies.[5,6] However, we did not find significant differences in the HRQoL scores in the children, which were also lower compared to previous reports.[3] This could be due to the lower age of patients in our study, as in many cases responsibility for the management of diabetes had yet to be transferred to the patient (self-care), so the burden of diabetes management still fell primarily to the family.

We did not find statistically significant differences between the scores of patients who met the criteria of adequate control and those who did not. This finding is concerning, as patients with poor glycaemic control may perceive their health status as ''good'' despite a lack of objective indicators to corroborate it (glucose or HbA1C levels), which in turn may affect their adherence to treatment.

The main limitations of our study were the small sample size and the limited duration of treatment with a HCLS. Notwithstanding, it evinced an improvement in CGM-derived metrics as well as in HRQoL in the family. We believe that the HRQoL of patients with T1D and their families should

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Table 1 Summary of clinical and glucose level data before and after initiation of hybrid closed-loop system.

Variable (n = 25)	Pre-HCLS (mean ± SD)	Post-HCLS (mean ± SD)	*P*	Targets established in consensus[4]
Age (years)	10 ± 3.5	11.5 ± 3.4		
Insulin dose (U/kg/day)	0.7 ± 0.3	0.8 ± 0.2	.07	
Mean glucose (mg/dL)	153.8 ± 16.8	145.6 ± 13.5	.04	<154[b]
SD	52.0 ± 11.8	48.6 ± 9.2	.13	–
CV (%)	33.3 ± 5.5	32.9 ± 4.6	.78	<36
GMI (%)	7.0 ± 0.4	6.7 ± 0.4	.05	<7[b]
Time < 54 mg/dL (%)	0.2 ± 0.5	0.4 ± 0.8	.52	<1%
Time 54–69 mg/dL	1.9 ± 1.8	2.2 ± 1.4	.45	<4%
Time 70–180 mg/dL (%)	69.7 ± 12.7	75.7 ± 8.6	.04	>70%
Time 181–250 mg/dL (%)	23.9 ± 8.9	18.0 ± 6.3	.01	<25%
Time >250 mg/dL (%)	6.0 ± 9.4	4.0 ± 3.2	.29	<5%
HbA1C (%)	6.8 ± 0.7	6.8 ± 0.5	.82	<7[b]
Met adequate glycaemic control criteria[a]	28%	60%	.045	

CV, coefficient of variation; GMI, glucose management indicator; HCLS, hybrid closed loop glucose monitoring and insulin delivery system; HbA1C, glycated haemoglobin; SD, standard deviation.
[a] Adequate control criteria proposed by Battelino et al.[4]
[b] Standard care in diabetes-2023 (American Diabetes Association).

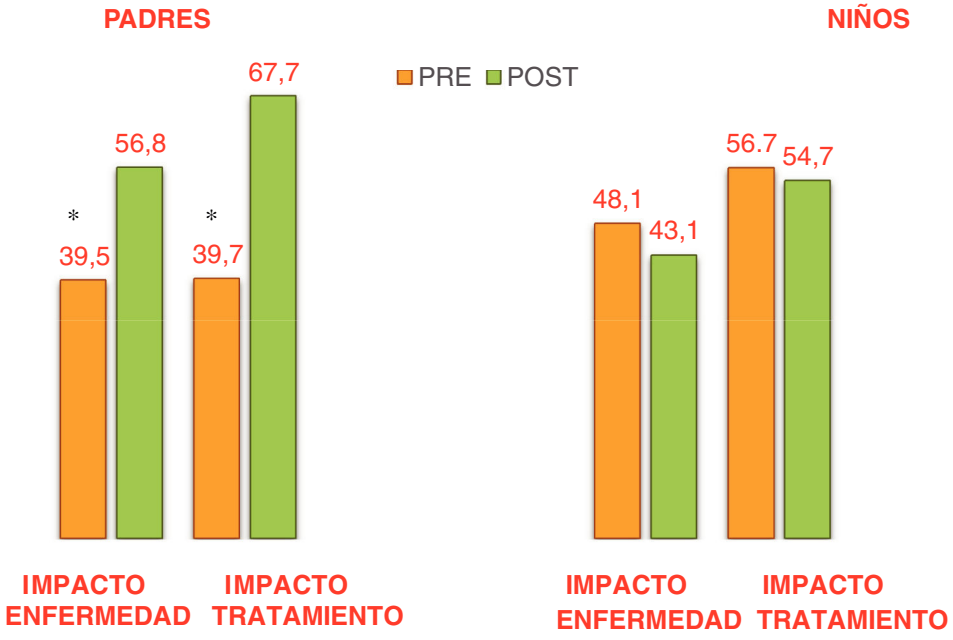

Figure 1 Scores in the DISABKIDS health-related quality of life questionnaire before and after initiation of HCLS (time elapsed from initiation of HCLS, 18.9 ± 10.5 months).
PRE, Pre-HCLS; POST, Post-HCLS.
*PRE-POST difference: $P < .05$.

be assessed routinely, and the diabetes-specific module of the DISABKIDS questionnaire can be a suitable tool for the purpose.

Conflicts of interest

Belén Huidobro Fernández has received fees for participating in conferences organised by Air Liquid and for attending courses organised by Medtronic. All other authors have no conflicts of interest to disclose.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.anpedi.2023.12.003.

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Primary Sjögren syndrome: Only diagnose what is known

Síndrome de Sjögren primario: solo se diagnostica lo que se conoce

Dear Editor:

Sjögren syndrome (SjS) is a systemic autoimmune disease (SAD) characterised by lymphocytic infiltration of exocrine glands (mainly salivary and lachrymal), asthenia and tissue and organ destruction of variable degree. It can be primary or secondary, and affects 10% to 18% of patients with other autoimmune diseases, such as lupus, rheumatoid arthritis or systemic sclerosis.

It is one of the most frequent SAD. Primary SjS has an incidence of 6 to 10 per 100.000 people and a prevalence of 40 to 70 per 100.000 people. It is more frequent in women (ratio 6–9:1) between 30 to 50 years. Only 1% of the patients have pediatric-onset.[1] Its low frequency in paediatrics and the scarce number of publications in Spanish might explain that a number of paediatricians are not familiar with this disease, which motivated us to review the clinical and laboratory characteristics of the 9 patients diagnosed with JSjS in our hospital between 2011 and 2023 (Table 1)

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The disease was more frequent in women (8/9), and the mean age at diagnosis was 12.3 years. Five out of nine patients were asymptomatic at the time of diagnosis and were referred due to the presence of autoantibodies found during the workup performed for variety of reasons. Among these patients, one had a history of self-limited episodes of mild bilateral parotid swelling that was not considered relevant by the family. Two out of nine patients had xerophtalmia, which was the reason for referral in one of them; one recurrent parotitis and one arthritis associated with thrombotic thrombocytoenic purpura (TTP). When the history taken at admission was reviewed, she reported xerostomia of several months for which se had not sought medical care. Table 1 details other minor symptoms in the patients.

In regards to laboratory tests, 8/9 tested positive for anti-SSA/Ro antibodies, 7/9 for rheumatoid factor (RF), 7/9 for antinuclear antibodies (ANA) and 5/9 for anti-SSB/La antibodies. Two patients had cytopenias at disease onset, one of them secondary to TTP.

Table 1 presents the results of the ophthalmological evaluation and the salivary gland ultrasound (SGU). Fig. 1 shows the changes observed in the SGUS.

Juvenile SjS is an olygosymptomatic disease: although only 2 of the 9 patients referred xeropthalmya, 6 had keratoconjunctivitis sicca, and while only 5 had abnormal sonographic features, all 9 had focal lymphocytic sialoadenitis.

The presentation of JSjS is different from the presentation in adults, and currently there are no validated classification criteria available for the paediatric population. The predominant feature in adults is dryness (xerostomia