



Glycemic control metrics in a cohort of hospitalized patients with type 1 diabetes using hybrid closed-loop and advanced hybrid closed-loop systems

Ana María Gómez Medina^{a,b,*}, Diana Cristina Henao-Carrillo^{a,b}, Carlos Yepes^{a,b}, Julio Silva^{a,b}, Javier Alberto Gómez González^{a,b}, David Cortes^{a,b}, Sofia Robledo^b, Gabriela Mejía^b, Martín Rondon^c

^a Endocrinology Unit, Hospital Universitario San Ignacio, Carrera 7 # 45-62, Colombia

^b Faculty of Medicine, Pontificia Universidad Javeriana, Carrera 7 # 40-62, Colombia

^c Department of Epidemiology, Pontificia Universidad Javeriana, Carrera 7 # 40-62, Colombia

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ABSTRACT

Aims: To describe Hybrid closed-loop (HCL) and advanced hybrid closed-loop (AHCL) performance in the hospital setting based on the continuous glucose monitoring (CGM) metrics description.

Methods: This was an observational study from a cohort of patients with T1D using HCL/AHCL with history of hospitalization. CGM metrics were analyzed during the hospital stay. CGM metrics sub-analysis of the population with active Automated Mode (AM) and SmartGuard (SG) during hospitalization and/or surgical procedure was performed.

Results: Twenty-four patients were included (50 % women; mean age, 49 years [inter-quartile range (IQR), 39–62 years]). During hospitalization 70.8 % patients achieved %Time in Range (TIR) between 70 and 180 mg/dL ≥ 70 %. The overall %TIR was 75.5 % (IQR, 67.3–81.5 %), % time below range (TBR) < 70 mg/dL was 2.1 % (IQR, 0.7–5.4 %) and %TBR < 54 mg/dL was 0 % (IQR, 0–5.4 %). Users of the AHCL with active SG achieved a non-significant higher %TIR during hospitalization (79 % [73.8.88 %] vs. 76 % [72.81 %], $p = 0.312$) and had a shorter stay (3[IQR, 2.4] vs. 6 days[IQR, 5.7], $p = 0.045$) compared to the users of the HCL with AM active. No device-related serious adverse events occurred for users of either system.

Conclusions: HCL/AHCL systems with active AM/SG in patients with T1D in the hospital environment leads to % TIR > 70 % in ranges of 70–180 mg/dL in patients without increasing hypoglycemia.

1. Introduction

During hospital stay, several factors, such as hyperglycemia, hypoglycemia, and high glycemic variability favor alterations in glucose levels. Such factors are associated with adverse outcomes during hospitalization, including increased risk of infections, increased costs, and increased mortality [1–3]. Hybrid closed-loop (HCL) and advanced hybrid closed-loop (AHCL) systems, are currently available for the outpatient treatment of individuals with type 1 diabetes (T1D) which allow achieving glycemic control objectives alongside the reduction of frequency of hypoglycemic episodes. Therefore, it has become more

likely that the hospital staff will face the management of patients with T1D who use this technology [4]. However, evidence regarding the safety of HCL and AHCL systems in hospital environments for patients with T1D is limited.

The HCL and AHCL systems [5–7] comprise an insulin infuser, a transmitter, and an algorithm that can adjust insulin infusion according to the information produced by continuous glucose monitoring (CGM). The Minimed 670 is a HCL system, utilizes an insulin pump programmed with an algorithm to administer micro boluses of insulin for basal insulin requirements based upon glucose values transmitted from a CGM [8]. The Minimed 780G is an AHCL system adjust basal insulin with self-

Abbreviations: HCL, hybrid closed-loop; AHCL, advanced hybrid closed-loop; TIR, time in range; T1D, type 1 diabetes; CGM, continuous glucose monitoring; AM, automated mode; SG, smart guard; IQR, inter-quartile range; TBR, time below range; SD, standard deviation.

* Corresponding author at: Endocrinology Unit, Hospital Universitario San Ignacio, Carrera 7 # 45-62, Colombia.

E-mail addresses: anagomez@javeriana.edu.co (A.M. Gómez Medina), d-henao@javeriana.edu.co (D.C. Henao-Carrillo), cayepes@husi.org.co (C. Yepes), silvaljd@javeriana.edu.co (J. Silva), jalbertogomezg@javeriana.edu.co (J.A. Gómez González), david-cortes@juanncorpas.edu.co (D. Cortes), s.robledo@javeriana.edu.co (S. Robledo), gabriela.mejiap@javeriana.edu.co (G. Mejía), martin.rondon@javeriana.edu.co (M. Rondon).

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correcting boluses every 5 min and provides the option of setting different glucose targets, 100, 110 or 120 mg/dL, as well as the temporary target of 150 mg/dL [9]. Recently, a case series, including four patients with different reasons for hospital admission, in whom the HCL system was successfully used was published [8]. Controlled clinical studies have reported the safety and efficiency of using closed-loop systems compared to using standard treatment in patients diagnosed with type 2 diabetes and hospitalized in the general ward, which significantly increased the time in range (TIR) between 100 and 180 mg/dL without increasing the risk of hypoglycemia [10–12]. However, there are no publications of clinical intervention studies in the population with T1D.

The American Diabetes Association and the American Association of Clinical Endocrinologists support the continuation of HCL and AHCL systems in hospitals whenever the patient and the clinical staff agree that continued use is safe and appropriate [13]. However, the removal of devices, such as insulin infusers and CGM systems for diabetes treatment, is a common practice during hospitalization [14], because the nursing and non-endocrinology attending physician staff are not trained in the use this technology. This is possibly related to the lack of information regarding the safety of HCL and AHCL systems in hospitals where acute illnesses, medications, and invasive procedures challenge glyce-mic control [8] and the absence of recommendations that allow the implementation of the use of these devices during the hospital stay. The objective of this study is to describe the performance of this technology in hospitals based on CGM metrics.

2. Methods

An observational study was conducted in a prospective cohort of patients diagnosed with T1D using the HCL (MiniMed 670G, Medtronic, Northridge, CA, USA) and AHCL (Minimed 780G, Medtronic, Northridge, CA, USA) systems through follow-up at the San Ignacio University Hospital in Bogotá, Colombia. We included patients aged over 18 years with a history of hospitalization for medical pathology in a general ward or elective surgery between March 2020 and February 2023. Women who were pregnant or had childbirth, and patients who refused to sign the informed consent were excluded. The Ethics Committee of the San Ignacio University Hospital and the Pontificia Universidad Javeriana approved the study.

The patients included belong to a cohort of patients who were being followed up by an interdisciplinary group at our institution. All patients received standardized training in our institution at the beginning of the device use. This training protocol has been described in a previous publication [15]. The device was programmed according to recommendations. A target of 120 mg/dL and 110 mg/dL were decided for two AHCL users and target of 100 mg/dL was decided for the rest of the patients included. All users were programed with active insulin for 2 h [16]. All patients were instructed to continue the use of HCL/AHCL in the event of hospitalization if it was approved by the treating physician. During ambulatory follow-up, history of hospitalization for any cause was systematically asked.

Baseline demographic data, weight, body mass index, total daily insulin dosage, glycosylated hemoglobin level measured by high-performance liquid chromatography and creatinine level were retrieved from the medical history. Patients uploaded CGM data 14 days before hospital admission and during hospitalization using a virtual platform (CareLink Pro® version 4.0C, Medtronic MiniMed, Inc, Northridge, CA, USA). Once a hospitalization event was identified, CGM data was obtained retrospectively. During hospitalization, food was provided according to the usual schedule of patients managed in the general ward, based on the usual clinical practice of each institution. The place of hospitalization was determined by the patient and/or the insurance company. The patients were autonomous in handling the device and administering their prandial boluses according to the configuration of the device. No device programming adjustments were

made during hospitalization or prior to the surgical procedure and the use of Automatic Mode (AM) and Smart Guard (SG) was recorded. After the procedure, the patient resumed the administration of prandial boluses once the diet was restarted. Safety endpoints were severe hypoglycemia < 40 mg/dL (<2.2 mmol/L) and clinically significant hyperglycemia 360 mg/dL (>2.0 mmol/L) with ketonemia, as determined by capillary measurements, infection at the cannula insertion site, or device dysfunction during hospital stay.

For continuous variables, normality was assessed using the Shapiro Wilk test. Mean and standard deviation (SD) or median and interquartile ranges (IQR) were reported for variables that did not meet the normality criteria, according to the characteristics of the variables. For categorical variables, frequencies and percentages were reported. CGM data TIR between 70 and 180 mg/dL, time below range (TBR) (<54 and < 70 mg/dL), time above range (>180 mg/dL), and coefficient of variation were recorded. Baseline glyce-mic control objectives (14 days before hospital admission) as well as objectives during the hospitalization period were analyzed. In the analysis of the CGM data, it was included from 00:00 to 24:00 h on the day of admission and the day of discharge. Ten patients were hospitalized for elective surgery and the respective CGM data were analyzed during the surgical procedure. For comparing the different groups, the Mann–Whitney test was used for comparing medians and the exact Fisher test for comparing proportions. Subgroup analyses were performed according to the AM and SG use for each device. The confidentiality and privacy of data was protected by maintaining the collection formats under secure access. STATA version 16.0 was used for the analysis.

3. Results

31 incident cases were identified. Six patients were excluded due to device removal during hospitalization as indicated by the attending physician, and one patient due to loss of CGM data during hospitalization. A total of 24 patients (50 % were women; mean age, 49 [IQR, 39–62] years) were included in the analysis (Table 1). The most frequent microvascular complication was diabetic neuropathy (50 %), followed by diabetic retinopathy (41.7 %). Regarding adherence, all patients used the AM or SG > 80 % of the time before hospitalization. The mean hospital stay was 4.5 ± 3.7 days.

The main causes of hospitalization were elective surgery (n = 8), infection (n = 5), coronary heart disease (n = 2), and other causes, such as decompensation due to asthma attacks, abdominal pain, and drug-related toxicity (n = 9). One patient was hospitalized due to hyperglycemia without ketoacidosis and another was hospitalized due to severe hypoglycemia. 70.8 % patients achieved TIR between 70 and 180 mg/dL ≥ 70 % during hospitalization and the overall %TIR was 75.5 % (IQR, 67.3–81.5 %), %TAR > 180 mg/dL of 17.7 % (IQR, 11.6–20.5 %), TAR > 250 mg/dL 1.5 % (IQR 0–4.6 %), TBR < 70 mg/dL of 2.1 % (IQR, 0.7–5.4 %) and TBR < 54 mg/dL of 0 % (0–5.4 %).

Fig. 1 shows the glyce-mic control metrics during the stay in the general ward and/or surgical procedures according to the type of device used. Among the 16 patients hospitalized for medical pathology in the general ward, the %TIR between 70 and 180 mg/dL was 76.5 % (IQR, 69.4–82 %) with %TBR < 70 mg/dL of 1.5 % (IQR, 0.2–4.5 %), and %TBR < 54 mg/dL of 1.0 % (IQR, 0–1.3 %) (Table 2). No events of severe hypoglycemia or diabetic ketoacidosis during hospitalization were observed.

During elective surgery the average duration was 3.9 h. The %TIR between 70 and 180 mg/dL was 72.5 % (IQR, 57–81.5 %) with a %TBR < 70 mg/dL of 7.0 % (IQR, 2.0–8.5 %) and a %TBR < 54 mg/dL of 0.5 % (IQR, 0–0.5 %), with no significant differences between HCL and AHCL (Table 2). Only one patient reported transient sensory loss during the surgical procedure. No sensor signal loss was reported during surgical procedure with the use of electrocautery. No serious adverse events related to the device were observed.

Of the 24 patients, 18 used the devices with AM and SG turned on

Table 1

Characteristics of the patients included in the study according to the type of device used.

Characteristics	Total n = 24		HCL n = 13		AHCL n = 11		p
Age in years, median (IQR)	49	(39–62)	47	(41–52)	62	(38–62)	0.504 ^a
Female, n (%)	12	(50)	9	(69.2)	3	(27.3)	0.100 ^b
Time to diabetes in years, mean (SD)	27.3	(13.3)	31.2	(12.6)	22	(12.9)	0.107 ^a
Time of HCL/AHCL use in months, mean (SD)	9	(4.4)	9.7	(3.6)	8.3	(5.2)	0.440 ^a
Cardiovascular disease, n (%)	7	(29.2)	2	(15.4)	5	(45.5)	0.182 ^b
Anthropometric data							
Weight in kg, mean (SD)	65.6	(13.4)	69	(12.9)	61.5	(13.3)	0.176 ^a
Body mass index, mean (SD)	24.2	(4.2)	26.1	(3.9)	22	(3.4)	0.014 ^a
Baseline paraclinical data							
HbA1c%, mean (SD)	7.9	(1.2)	7.7	(0.6)	8.2	(1.6)	0.307 ^a
Creatinine mg/dL, mean (SD)	1.0	(0.5)	0.9	(0.4)	1.2	(0.7)	0.203 ^a
Metabolic control metrics before hospitalization							
GMI, mean (SD)	6.9	(0.4)	6.9	(0.4)	6.9	(0.3)	0.894 ^a
% Sensor use, % (SD)	86	(14.8)	83	(12.8)	89	(16.7)	0.121 ^a
% AM/SG, % (SD)	71.4	(38.2)	57.1	(39.7)	85.7	(32.8)	0.013 ^a
%TIR (70–180 mg/dL), median (IQR)	71.5	(66.5–78.2)	69	(65–76)	75	(70.7–81.0)	0.055 ^a
%TAR (>180 mg/dL), median (IQR)	19	(15.8–21.5)	21	(17–24)	18	(0–20)	0.052 ^a
%TAR (>250 mg/dL), median (IQR)	4.5	(1.0–9.0)	4	(2–9)	5	(0.5–7.5)	0.503 ^a
%TBR (<70 mg/dL), median (IQR)	2	(1–3.2)	2	(1–4)	1	(1–2.5)	0.302 ^a
%TBR (<54 mg/dL), median (IQR)	0	(0–2)	0	(0–2)	0	0	0.200 ^a
%CV, median (IQR)	34.3	(28.7–38.8)	37.6	(32.5–39.8)	28.7	(28–38.4)	0.160 ^a
TDD, mean (SD)	43	(18.7)	44	(16.9)	41.9	(21.4)	0.788 ^a

HCL, hybrid closed-loop system; AHCL, advanced hybrid closed-loop system; HbA1c, glycosylated hemoglobin; IQR, interquartile range; TIR, time in range; TAR, time above range; TBR, time below range; ICU, intensive care unit; CV, coefficient of variation; TDD: Total daily dose of insulin.

^a Kruskal–Wallis rank sum test;

^b Fisher's exact test for count data.

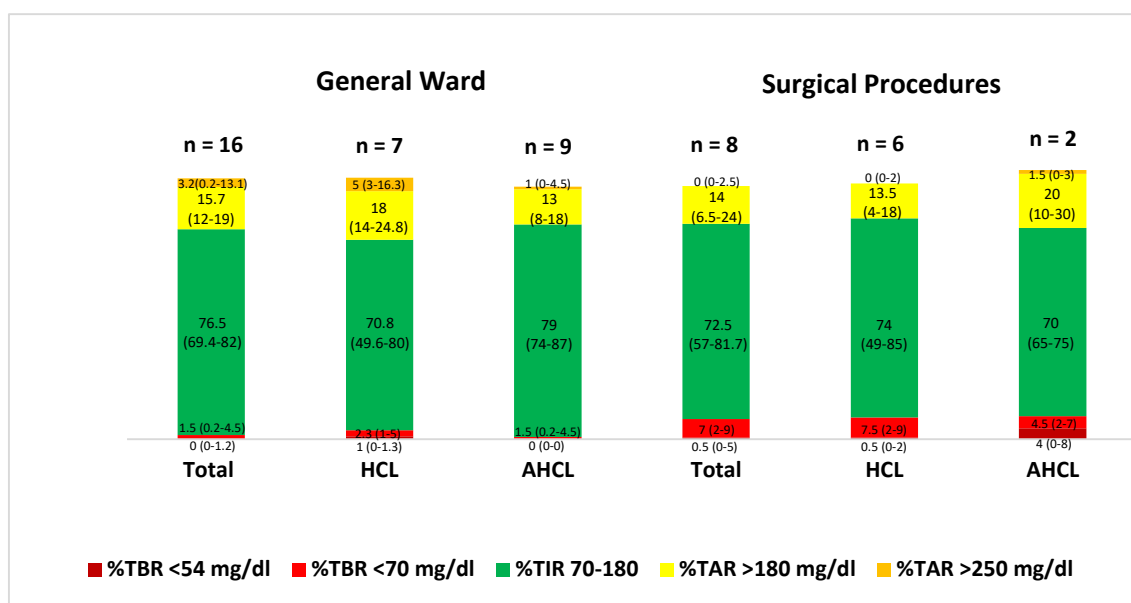


Fig. 1. Glycemic control metrics during stay in general ward and surgical procedures according to the type of device used.

during the hospital stay and the elective surgical procedure. Therefore, a comparative analysis was performed between the two devices (Fig. 2). The use of AHCL with SG turned on showed a higher %TIR in patients hospitalized in General Ward compared to the use of HCL with active AM (79 % [73.5–89.3 %] vs. 73.4 % [68.0–80.0 %], $p = 0.196$). During surgery, users of HCL and AHCL systems who used the AM and SG did not show events < 54 mg/dL (Table 3). Hospital stay was shorter for AHCL with SG users compared to HCL with AM users (3 days [IQR, 2–4 days] vs. 6 days [IQR, 5–7 days], $p = 0.045$).

4. Discussion

An automated system aimed at administering insulin in response to

glucose levels can simplify the management of hyperglycemia in the hospital. This study showed that the use of HCL and AHCL systems in patients with T1D in a real-life hospital setting allows to safely maintain %TIR. The use of AHCL with active SG was associated with a higher %TIR (without increasing hypoglycemia) and a shorter hospital stay compared with the use of HCL with active AM. Despite the limited evidence available, data from this study suggest that use of HCL and AHCL systems with active AM or SG should be continued during hospitalization associated with cooperative effort between patient and medical staff.

Implementation of standardized protocols for glycemic management in hospitalized patients with T1D requires constant monitoring, frequent capillary glucose measurements, and insulin administration with meals,

Table 2

Glycemic control metrics during the stay in the general ward and surgical procedures according to the type of device used.

Metrics	Hospitalization in General Ward n = 16							Surgery n = 8						
	Total		HCL n = 7		AHCL n = 9		p ^a	Total		HCL n = 6		AHCL n = 2		p ^a
%TIR (70–180 mg/dL), median (IQR)	76.5 (69.4–82.0)		70.8 (49.6–80.0)		79.0 (74.0–87.0)		0.100	72.5 (57.0–81.5)		74.0 (49.0–85.0)		70.0 (65.0–75.0)		0.738
%TAR (>180 mg/dL), median (IQR)	15.7 (12–19)		18.0 (14.0–24.8)		13.0 (8.0–18.0)		0.123	14.0 (6.5–24.0)		13.5 (4.0–18.0)		20.0 (10.0–30.0)		0.502
%TAR (>250 mg/dL), median (IQR)	3.2 (0.2–13.1)		5.0 (3.0–16.3)		1.0 (0.0–4.5)		0.204	0 (0–2.5)		0.0 (0.0–2.0)		1.5 (0.0–3.0)		0.702
%TBR (<70 mg/dL), median (IQR)	1.5 (0.2–4.5)		2.3 (1.0–5.0)		0.8 (0.0–2.0)		0.165	7.0 (2.0–8.5)		7.5 (2.0–9.0)		4.5 (2.0–7.0)		0.499
%TBR (<54 mg/dL), median (IQR)	0 (0–1.2)		1.0 (0–1.3)		0 (0–0)		0.144	0.5 (0.0–5.0)		0.5 (0.0–2.0)		4.0 (0.0–8.0)		0.859

HCL, hybrid closed-loop system; AHCL, advanced hybrid closed-loop system; HbA1c, glycosylated hemoglobin; IQR, interquartile range; TIR, time in range; TAR, time above range; TBR, time below range; ICU, intensive care unit; CV, coefficient of variation. ^aKruskal–Wallis rank sum test.

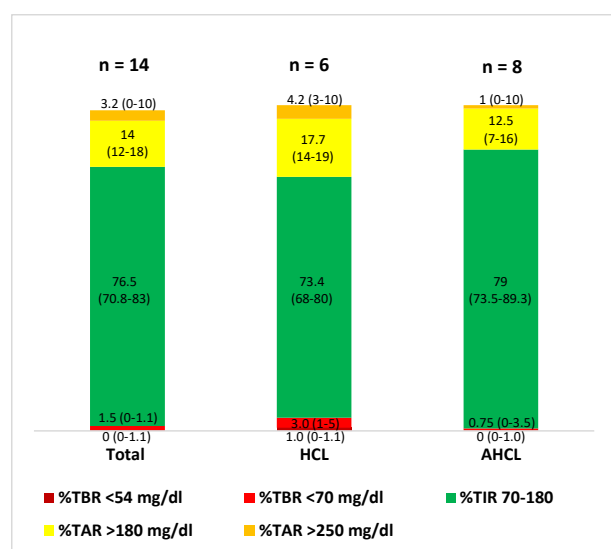


Fig. 2. Glycemic control metrics during stay in general ward according to patients with automatic mode and/or active smart guard.

thus increasing the workload of hospital staff and reducing adherence to these protocols [12]. Consequently, this may favor hyperglycemia, hypoglycemia, and increased glycemic variability, which are associated with adverse outcomes during hospitalization [1–3]. However, the use of HCL and AHCL systems could reduce the burden on health personnel, adherence to insulin administration and measurement of glucose levels in real time, improving glycemic control during the hospital stay. Previous studies including patients with type 2 diabetes have compared closed-loop systems achieving a higher %TIR (100–180 mg/dL) compared to the standard protocol, with no increase in hypoglycemic time over a 72-h period [12].

Recent guidelines suggest “in someone who is well, and may be in hospital for a short elective procedure or investigation, it may be appropriate to let the hybrid closed-loop continue to control their glucose” [17]. However, no consensus was reached on the use of AM or

SG in patients using HCL/AHCL during hospitalization [13,17]. However, in this study, patients using HCL or AHCL with active AM or SG showed a better glycemic profile during hospitalization. Another study has reported that the improvement of %TIR without an increase in hypoglycemia is constant within the user population of closed-loop systems in the general ward and the patients requiring hemodialysis during hospitalization [18]. However, further studies are required to determine additional benefits to glycemic control of HCL and AHCL systems in the hospital. Similarly, guidelines should be developed for the management of these devices in the hospital and in surgical settings.

Reports suggest that discontinuation of device use during hospitalization, such as CGM and HCL, in 85 % of cases was related to device malfunction [14]. However, in this study, no patient reported device malfunction requiring device removal. According to Markov et al., care-related interruptions occurred most frequently owing to diagnostic imaging, followed by surgeries and procedures [14]. In this study eight patients continued HCL/AHCL use during the elective surgical procedure without any observed device malfunction. Similarly, Herzig et al. showed in a controlled clinical study that the use of a closed-loop system favored achieving glycemic control objectives in the perioperative period with a %TIR between 100 and 180 mg/dL >70 % without increasing hypoglycemia, equipment malfunction or serious adverse events [19]. This suggests the safety of the use of HCL and AHCL systems during scheduled surgical procedures. However, studies with a larger population and on its use during procedures of longer duration and complexity are required.

The current recommendations for the use of AID systems in the hospital do not include specific recommendations regarding HCL/AHCL systems and even recommend their removal in surgical procedures longer than 2 h and recommend insulin infusion adjustments according to the glucose level in short procedures (<2 h). However, in this cohort, the patients continued the administration of insulin with HCL/AHCL during surgical procedures with a mean duration of 3.9 h, achieving a safe TIR without hypoglycemia and without loss of the sensor. Although additional studies are required, these findings suggest that current recommendations regarding the use of HCL/AHCL systems may change in the future.

Unlike the patients from controlled clinical trials, the patients in this cohort were hospitalized in institutions of different complexity. During

Table 3

Glycemic control metrics during stay in the general ward and during the surgical procedures according to the type of device used in patients using Automatic Mode and active Smart Guard.

Metric	Hospitalization in General Ward							Surgery						
	Total n = 14		HCL n = 6		AHCL n = 8		p ^a	Total n = 4		HCL n = 3		AHCL n = 1		p ^a
%TIR (70–180 mg/dL), median (IQR)	76.5	(70.8–83.0)	73.4	(68.0–80.0)	79.0	(73.5–89.3)	0.196	71.5	(43.5–85.0)	78.0	(22.0–92.0)	65.0		0.654
%TAR (>180 mg/dL), median (IQR)	14.0	(12.0–18.0)	17.7	(14.0–19.0)	12.5	(7.0–16.0)	0.136	24.0	(9.0–53.5)	18.0	(0–77.0)	30.0		0.654
%TAR (>250 mg/dL), median (IQR)	3.2	(0–10.0)	4.2	(3.0–10.0)	1.0	(0–10.7)	0.327	1.0	(0–2.5)	0	(0–2.0)	3.0		0.157
%TBR (<70 mg/dL), median (IQR)	1.5	(0–5.0)	3.0	(1.0–5.0)	0.75	(0–3.5)	0.266	2.0	(1.5–5.0)	2.0	(1.0–8.0)	2.0		1.000
%TBR (<54 mg/dL), median (IQR)	0	(0–1.1)	1.0	(0–1.1)	0	(0–1.0)	0.390	0	(0–0)	0	(0–0)	0.0		Nan

HCL, hybrid closed-loop system; AHCL, advanced hybrid closed-loop system; HbA1c, glycosylated hemoglobin; IQR, interquartile range; TIR, time in range; TAR, time above range; TBR, time below range; ICU, intensive care unit; CV, coefficient of variation.

^a Kruskal–Wallis rank sum test.

hospitalization, no adjustments were performed to the initial programming of the devices, none of the patients showed serious adverse events related to the devices, and only six patients discontinued the use of AM during hospitalization. The hospital stay of AHCL users with active SG was significantly shorter. However, given the small sample size and the lack of analysis of the many factors that contribute to length of hospital stay, further studies are required to suggest that the use of AHCL contributes to shorter stay. There are limitations that should be considered. Among them are the retrospective design of the study, the low number of patients with surgical interventions, lack of assessment of satisfaction with the device by the nursing staff and the patient. In addition, a large percentage of patients with %TIR > 70 % and high adherence to the use of HCL/AHCL systems were included, which limits the application of these findings in other populations. Also, for patients whose AM/SG function was disabled, intraoperative glucose levels and the method of insulin delivery during surgery were not available.

5. Conclusion

There is little evidence about the use of HCL and AHCL systems in a hospital setting. However, this study shows that the use of this technology in patients with T1D in a real-life hospital environment maintained the %TIR between 70 and 180 mg/dL without increasing hypoglycemia both in the general ward and during surgical procedures. In addition, the use of AHCL with active SG was associated with a higher %TIR without increasing hypoglycemia and a shorter hospital stay compared to the use of HCL with active AM. However, further studies are required to determine whether the use of this technology is able to impact outcomes such as hospital stay, morbidity, and mortality among hospitalized patients.

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: AMG reports speaker fees from Novo Nordisk, Sanofi, Elli Lilly, Boehringer Ingelheim, Abbott and Medtronic. DCH reports speaker fees from Novo Nordisk, Sanofi and Abbott.

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