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ORIGINAL ARTICLE

Is Automated Insulin Delivery System Therapy Safe and Effectıve in Children Under 7 Years Old?

Minimed™ 780G Under 7 Years Old Children

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What is already known on this topic?
The experience and knowledge under seven years regarding the use of automated insulin delivery systems are insufficient.

What this study adds?
It was shown in this study for the first time that MinimedTM 780G can be used under seven years of age by comparing MinimedTM 780G with the MinimedTM 640G and multiple dose therapy.

ABSTRACT

Objective: This study aims to evaluate the off-label use of the MiniMed™ 780G system in children under seven years old.
Methods: Children under seven years with type 1 diabetes (T1D) using MiniMed™ 780G were retrospectively compared with children of similar age and gender using MiniMed™ 640G and multiple-dose insulin (MDI) therapy with continuous glucose monitoring systems (CGMs). CGM metrics, total daily insulin dose (TDI), and HbA1c levels were evaluated retrospectively at baseline and at the 3rd, 6th, and 12th months.
Results: At the initiation of MiniMed™ 780G therapy, the mean age was 5,25±1,22 years (range: 2,8–6,8 years). Glucose management indicator (GMI) and HbA1c remained lower in the MiniMed™ 780G group at the 3rd, 6th, and 12th months compared to baseline (p=0,009 and p<0,001, respectively), Time Above Range (TAR) was significantly lower at the 3rd, 6th, and 12th months (p=0,018, 0,017, 0,04, respectively), and Time in Range (TIR) was higher at the 3rd and 12th months (p=0,026 and 0,019, respectively) compared with the other groups. No instances of ketoacidosis or severe hypoglycemic events were observed in any of the children during the follow-up period.
Conclusions: The absence of significantly higher levels of hypoglycemia compared to other groups at any time point, along with a significant decrease in TAR across all time points, a significant increase in TIR at the 3rd and 12th months, and a significant decrease in HbA1c and CV, indicates that the MiniMed™ 780G system is both safe and effective for children under seven years old.

Keywords: Automated delivery system, diabetes, diabetes mellitus, endocrinology, predictive low glucose suspension

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INTRODUCTION

The incidence of type 1 diabetes (T1D) continues to rise, with 18% of new diagnoses occurring in children aged nine and younger[1]. Treatment of T1D in young children is challenging since they often experience marked day-to-day and within-day variability in glucose levels and high variability in insulin requirements compared with older children with T1D[2]. Current glycemic goals by the American Diabetes Association (ADA) and the International Society of Pediatric and Adolescent Diabetes (ISPAD) recommend that young children maintain a HbA1c level < 7,0% when possible and without risk of severe hypoglycemia[3]. However, recent data from the SWEET found that 69% of children under six years have HbA1c higher than 7%, suggesting this age group would benefit from increased attention and interventions to support diabetes management[4]. Diabetes management is complicated by rapid physical and neurological development, difficulty verbalizing thoughts and feelings, frequent and unpredictable physical activity, picky eating, and behavioral challenges and fears[5]. The fear of nighttime hypoglycemia is common, and only a minority of young children's hypoglycemia appears to be recognized with self-monitoring blood glucose measurements[6]. Apart from hypoglycemia, a 6-year longitudinal study suggested that gray and white matter volumes and cognitive scores are affected by hyperglycemia in early-onset T1D[7].

Diabetes technologies, insulin pumps, and continuous glucose monitoring systems (CGMs) are evolving tools for diabetes management, and the use of such technologies in young children has significantly increased in recent years[8]. Recent data from the T1D Exchange indicate that CGMs use in children under 6 years old has increased by 45% from 2016 to 2022[9], and insulin pump use nearly doubled, with the highest use rates in the youngest patients[10]. Hybrid closed-loop systems, which automatically adjust insulin delivery according to glucose levels aside from mealtime boluses, are relatively novel in young children. There are results from observational and randomized studies for MiniMed™ 780G systems in children over seven years suggesting that an algorithm that automatically doses basal insulin based on sensor glucose (SG) levels improves TIR without increasing or even decreasing the time spent below range (TBR)[11-13].

MiniMed™ 780G improved glycemic control safely in a 12-week study period in toddlers and preschoolers, simultaneously diminishing parental diabetes distress[14]. In another study involving 11 patients aged between 2 and 6 years, the use of MiniMed™ 780G for 6 months resulted in an increase in TIR without any risk of hypoglycemia[15].

This is the first safety study comparing the off-label use of MiniMed™ 780G in children aged 2-7 years throughout one year patients with T1D using MiniMed™ 640G pump, and MDI+CGMs.

MATERIALS AND METHODS:

This retrospective nonrandomised study recruited children between 2 and 7 years of age diagnosed with T1D for more than one year and who were on MiniMed™ 780G insulin pump, MiniMed™ 640G insulin pump and MDI + CGM therapy at least 12 months. HbA1c, insulin dose and CGM metrics of all the patients were downloaded from patient charts and

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Medtronic Carelink Personal Software, Libreview, and Dexcom Clarity Diabetes Management Software reports retrospectively. In our clinic as a standardised insulin pump therapy management, clinicians and diabetes nurses monitored the safety of the treatment on a weekly basis (via phone call and WhatsApp), and pump settings [Target glucose, insulin carbohydrate ratio (ICR), AIT] were adjusted as required in the first month of pump initiation an monthly after the first month. In MDI+CGM patients ICR and sensitivity factor and CGM reports are monitored monthly (via phone call and WhatsApp).

T1D patients who start on MiniMed™ 780G, MiniMed™ 640G pump therapy or CGM alone receive complete carbohydrate counting training standardised according to ISPAD guidelines[16,17]. In patients under 7 years of age; MiniMed™ 780G insulin pump is initially used in manual mode for 2 weeks followed by auto mode. The target blood glucose is set to 120 mg/dl, and the active insulin time to 3 hours initially.

In MiniMed™ 640G insulin pump therapy, target blood glucose is set to 100 mg/dl, predictive low glucose suspend to 60mg/dl, low and high alarm to 60 mg/dl and 180 mg/dl, and active insulin time to 3 hours at the beginning.

MDI+CGM patients receive the standardised education for CGM including the use of arrows, alarm settings and target glucose levels according to the CGMs consensus[18].

Outcomes measured included CGMs metrics according to the international recommendations[19]. Safety endpoints included serious adverse events, such as severe hypoglycemia and diabetic ketoacidosis. Clinical and glycemic data are reported using descriptive statistics expressed as mean (standard deviation [SD]) and/or median (interquartile range).

Statistical Analysis: IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp was used for the statistical analyses. A normality test was performed for the distribution. Shapiro-Wilk test was used in groups that included 30 or fewer children; otherwise, Kolmogorov-Smirnov test was used to determine distribution. One-way ANOVA test was used to compare MiniMed™ 780G, MiniMed™640G, and MDI+CGMs therapy groups in normally distributed variables, and the independent t-test was used in non-parametric variables. The Mann-Whitney U test was used to compare two independent groups using variables that were not distributed normally. Wilcoxon test was used in variables that didn't distribute normally to compare pre-treatment with 3-6-12. months TAR, TIR, TBR, HbA1c, and other variables in the same group, and a paired t-test was used as a non-parametric equivalent. $p<0,05$ was accepted as statistically significant.

Ethical committee approval was obtained from the University the study rolled on. The study was conducted in accordance with the Helsinki Declaration, which was revised in October 2013. Informed consent was obtained from all parents or caregivers of children recruited in the study.

RESULTS:

Thirty-three children with T1D; age, diabetes duration, total daily insulin dose and Hb A1c matched were retrospectively analyzed. Eleven were using the MiniMed™ 780G insulin pump, eleven MiniMed™640G insulin pump, and eleven MDI+CGMs. Among the 33 participants, 14 (42%) were female, the mean age was 5,18±1,39 (2-6,9) years, and the duration of diabetes was 3,51±1,54 years.

The mean age at the initiation of the MiniMed™ 780G, MiniMed™ 640G insulin pump was 5,25±1,22 (2,8-6,8) years and 4,1±2,13 (2-6,5) years, respectively. In the MDI+CGMs group, the mean age was 5,59±1,19 (3,3-6,7) years. Baseline mean TDI dose was 10,6±4,34 (4,5-17,6) U/day in MiniMed™ 780G group (manuel mode), 13,9±6 (3,5-24,2) in MiniMed™ 640G group, and 14,8±6,72 (4,5-25) in MDI+CGMs group (Table 1).

In the MiniMed™ 780G group, SmartGuard™ usage in all children exceeded 85% after the initial two weeks of use in manual mode, as intended (93,73%, 96,45%, and 87,91% at 3, 6, and 12 months, respectively). GMI and HbA1c remained significantly lower within the group

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over time (0,01 and <0,001, respectively); marked decreases were observed within three months after auto-mode switched on **(Table 2).**
In the MiniMed™ 780G group, TAR was lower at the 3rd, 6th, and 12th months when compared to Minimed 640G and MDI+CGM (p= 0,02; 0,02; 0,04, respectively); TIR was higher at the 3rd and 12th months when compared to the other 2 groups (p=0,03 and 0,02). TIR increased by 8,4% (70% to 75,9%), TAR decreased by 10,4% (23,67% to 21,2%), and TBR decreased by 12,1% (3,3% to 2,9%) in twelve months of MiniMed™ 780G pump group **(Figure 1)**. CV and HbA1c were lower at 12 months (p=0,01 and 0,02) **(Figure 2)**; average blood glucose (BG) was lower at 6th and 12th months (p= 0,02 and 0,01) compared to the other groups **(Table 3).** All CGM metrics in Table 3.

DISCUSSION

Type 1 diabetes presents numerous morbidities that significantly impact the lives of children. Initiating the most effective therapy as early as possible can mitigate complications[20]. The MiniMed™ 780G insulin pump appears to be the most effective therapy for achieving this goal[21]. However, there is a notable lack of studies investigating the effectiveness and safety of such devices in children under seven years old. Additionally, glucose control in this age group is challenging due to the variability of insulin requirements[2]. This paper aimed to show the effectiveness and reliability of the MiniMed™ 780G insulin pump in children aged 2 to 7 years.
Pulkkinen et al. investigated 35 children aged between 2 to 6 years old receiving MiniMed™ 780G treatment. In their study, TIR showed an 8,3% increase with an 8,6% decrease in TAR during the 12 weeks under MiniMed™ 780G treatment. Similar results were reported in their extended follow-up study, though they focused on time in tight range. Time in Range (TIR) increased from 58,3% initially to 66,2% in the sixth month, and these values were sustained during an 18-month follow-up. However, TIR remained below 70% throughout the investigation, with the most significant increase observed in the first three months. They concluded that TIR values below 70% might be attributable to the younger age group and lower baseline TIR values compared to other studies[14,22]. Tornese et al. also investigated MiniMed™ 780G in a similar age group, showing an 8,5% increase in TIR along with a significant decrease in TAR[23]. A further study conducted by Abraham et al. found that TIR increased from 64,1% at baseline to 74,7% in the fifth week[15]. In our study, similar to the aforementioned studies, TIR increased by 6,67% in the third month, which remained consistent throughout the 12 months. It demonstrated statistically significantly higher values than the MiniMed™ 640G and MDI+CGMs groups in the third and sixth months, and this difference persisted during the follow-up period.
TAR and TBR serve as additional indicators of treatment success. Similar to studies conducted by Pulkkinen and Tornese, TAR showed a significant decrease during follow-up in our study[22,23]. Additionally, TAR was significantly lower than in the other treatment groups, except initially. However, TBR did not significantly decrease in MiniMed™ 780G compared to MiniMed™ 640G and MDI+CGMs. Furthermore, no instances of severe hypoglycemia or ketoacidosis were observed in any case. This suggests that the MiniMed™ 780G insulin pump is as safe as the MiniMed™ 640G insulin pump and MDI+CGMs, as indicated by TBR and TAR in this vulnerable age group.

Pulkkinen et al. showed that CV didn't decrease significantly during the follow-up period[21]. In contrast to Pulkkinen, Tornese et al. found a significant decrease in CV during their study period[23]. Our study is the first study that compares CV between three different treatment groups. Similar to Pulkkinen et al., CV didn't change during the follow-up in our research but was significantly lower in the MiniMed™ 780G group compared to the other treatment groups.

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Pulkkinen et al. found that HbA1c decreased significantly over 18 months. However, during the follow-up period, they observed a temporary increase in HbA1c between the sixth and twelfth months, which was attributed to the lifting of COVID-19 restrictions, particularly an increase in infections during that period[22]. In our study, HbA1c decreased significantly during the 12-month follow-up in the MiniMed™ 780G group. It was significantly lower in the MiniMed™ 780G group, with the most remarkable change observed in the third month compared to the other treatment modalities. GMI, derived from the term of estimated A1c (eA1c), had been created to assess more accurately and make more personalized glucose management[24]. Tornese et al.[23] investigated the GMI and found that the change in the GMI was insignificant. Seget also published their 2023 study with a significant decrease in the GMI[25]. Unfortunately, numerous studies have indicated that the GMI alone might not be used in this regard. Instead, it is advised to be used with HbA1c value to estimate hypoglycemia risk. An increased gap between HbA1c and GMI is associated with an increased risk of hypoglycemia[25]. Moreover, if higher HbA1c values persist despite lower GMI, the risk of diabetes-associated complications will increase[26]. Although a larger gap between GMI and HbA1c was observed in the MiniMed™ 780G and MiniMed™ 640G groups initially, it decreased during follow-up in our study. However, in the MDI+CGMs group, this gap persisted over time. HbA1c levels in the MiniMed™ 780G group significantly decreased during follow-up, reaching even lower levels than GMI in the twelfth month. In contrast, in the MiniMed™ 640G group, HbA1c did not differ over time. Considering that lower HbA1c values than GMI and lower HbA1c indicate lower diabetes-associated complications, the MiniMed™ 780G insulin pump is more effective and safe than the MiniMed™ 640G insulin pump and MDI+CGMs in this age group.

The instructions for determining minimum and maximum Total Daily Insulin (TDI) doses are outlined in the MiniMed™ 780G insulin pump manual. The manufacturer has set the minimum TDI at eight daily units[27]. In the study by Pulkkinen, TDI was a minimum of 8U/day[22]. In Tornese's study, the minimum TDI was 6U initially under manual mode, 6,6U after auto-mode, and 7,2U in the 3rd month[23]. In our study, the minimum TDI was under 8U. Initially in manual mode one patient had a TDI dose as 4,5 U/day but increased to 6,4 units in automode.

"**Limitations of the study**

1. Low number of patients; more patients are necessary to make more accurate decisions.

2. Retrospective study design

CONCLUSION

In our study, we observed that the MiniMed™ 780G was superior to both the MiniMed™ 640G and MDI+CGMs in terms of metabolic control (achieving HbA1c < 7% and Time in Range > 70%) over a one-year follow-up period in children 2-7 yrs.

AUTHOR CONTRIBUTIONS

Nihal Gul Uslu: Conceptualization, Formal analysis, Investigation, Methodology, Visualization, Writing – original draft (lead)
Deniz Ozalp Kizilay: Writing – review & editing, Visualization
Gunay Demir: Data curation, Resources
Yasemin Atik Altinok: Data curation, Resources
Sukran Darcan: Supervision, Writing – review & editing
Samim Ozen: Supervision, Writing – review & editing

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Damla Goksen: Project administration, Resources, Supervision (lead), Writing – review & editing (lead)

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Table 1: Baseline characteristics all the patients of T1D			
	MiniMed™ 780G	MiniMed™ 640G	MDI+CGMs
Total daily insulin dose	10,6 (4,5-17,6)	13,9 (3,5-24,2)	14,8 (4,5-25)
Diabetes duration (years)	2,85±1,65 (1,1-6,3)	5,18±1,83 (1,75-7,75)	2,51±1,15 (1,1-4,42)
Age at pump/CGMs initiation (years)	5,25±1,22 (2,8-6,8)	4,1±2,13 (2-6,5)	5,59±1,19 (3,3-6,7)
CGMs: Continuous glucose monitoring system, **MDI:** Multiple dose insulin treatment;, SD score, standard deviation score			

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Table 2: Comparison between 0-3-6-12. month values extracted from MiniMed™ 780G.					
	MiniMed™ 780G				
	0.month Initiation "Manuel Mode"	3. month	6. month	12. month	p
TAR (%)	23,67±12,72	18,44±7,33	20±5,92	21,2±8,93	0,91
180-250	17,64±7,02	15,91±5,13	17,18±6,1	18,09±5,43	0,56
>250	4,73±6,77	3,55±2,70	6,82±11,5	3,55±3,39	0,41
TIR (%)	**70,00±16,01****	**76,67±7,11****	72,45±15,61	75,90±7,71	0,891
TBR (%)	4,67±3,14	4,78±2,86	3,64±2,42	5,46±2,13	0,27
54-70	2,82±2,4	3,27±2,01	2,91±1,81	2,45±1,29	0,50
<54	0,45±0,69	1,27±2,1	0,64±0,81	0,45±0,52	0,42
CV (%)	36,13±5,62	37,13±4,35	36,46±3,58	34,3±2,14	0,38
GMI (%)	7,27±1,19	6,56±0,22	6,64±0,21	6,71±0,38	**0,01**
HbA1c (%)	8,8±1,7	6,64±0,47	6,71±0,4	6,51±0,38	**<0,001**
SmartGuard™ (%)	-	93,73±12,96	96,45±3,45	87,91±29,3	
TDI (U/day) (min-max)	4,5-17,6	8,2-20,3	7,7-25,9	9,3-33,2	0,08
AIT (hours)	3	3	3	3	
Meal per day	4,4±1,1	4,8±2	5,9±1,4	6,1±2,1	0,08
Amount of carb	128,6±33,5	136,1±45,4	154,8±28,6	154,5±33,2	0,09

Significant difference regarding GMI and HbA1c was observed during the one-year follow-up. The most remarkable improvement was between 0 to 3 months.
Although TIR didn't show any significant increase when 12 months statistically examined together, it was significantly changed between initial time to 3rd month **(p<0,001)**.
AIT: Active Insulin Time, **CGMs:** Continuous Glucose Monitoring system; **CV:** Coefficient of Variation; **GMI:** Glucose Management Indicator; **MDI:** Multiple dose insulin treatment; **TAR:** Time Above Range; **TBR:** Time Below Range; **TDI:** Total Daily Insulin Dose, **TIR:** Time In Range

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Table 3: Comparison between MiniMed™ 780G and MiniMed™ 640G and CGMs+multi-dose SC insulin users.

	0-month			p*	3-month			p*	6-month			p*	12-month			p*
	MiniMed™ 780G	MiniMed™ 640G	MDI+ CGMs		MiniMed™ 780G	MiniMed™ 640G	MDI+ CGMs		MiniMed™ 780G	MiniMed™ 640G	MDI+ CGMs		MiniMed™ 780G	MiniMed™ 640G	MDI+ CGMs	
TAR (%)	23,7 ±12,7	32,4 ±12,7	33,6 ±19,8	0,11	18,4 ±7,3	36,5 ±17,9	34,3 ±15,5	**0,02***	20± 5,9	39± 18,7	36,6 ±19,4	**0,02***	21,2 ±8,9	31,3 ±10,7	37,2 ±19,4	**0,04***
180-250	17,6 ±7	25,6 ±10,5	21,6 ±9,5	0,14	15,9 ±5,1	28,1 ±14,4	25,5 ±7,6	**0,02***	17,2 ±6,1	28,7 ±13,7	25,1 ±11,3	0,05	18,1 ±5,4	23,5 ±6,8	20,7 ±6,6	0,15
>250	4,7± 6,8	6,8± 5,3	12,3 ±11,7	0,11	3,6± 2,7	8,4± 5,8	8,6± 8,8	0,12	6,8± 11,5	10,3 ±7,7	11,5 ±11,7	0,56	3,6± 3,4	7,82 ±4,22	16,5 ±18,5	**0,03***
TIR (%)	70±16	63,8 ±13,8	64,7 ±19,7	0,24	76,7 ±7,1	59,6 ±17,5	63,6 ±15,1	**0,03***	72,5 ±15,6	57,3 ±17,9	60,5 ±19,1	0,12	75,9 ±7,7	64,7 ±9,7	59,1 ±18,7	**0,02***
TBR (%)	4,7± 3,1	3,8± 2,4	1,6± 1,1	0,06	4,8± 2,9	3,7± 2,8	2,4± 2,3	0,18	3,6± 2,4	3,7± 2,6	3±2,2	0,75	5,5± 2,1	4±3,1	3,7± 3	0,94
54-70	2,8± 2,4	3,1± 1,9	2,4± 2,5	0,75	3,3± 2	3,1± 2,3	2,3± 2,1	0,51	2,9± 1,8	3±1,8	2,9± 2,2	0,99	2,5± 1,3	3,2± 1,9	3,6± 2,9	0,48
<54	0,5± 0,7	0,7± 0,8	0	**0,03***	1,3± 2,1	0,6± 0,9	0,1± 0,3	0,13	0,6± 0,8	0,7± 0,9	0,1± 0,3	0,1	0,5± 0,5	0,8± 1,5	0,2± 0,4	0,29

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CV (%)	36,1 ±5,6	36,4 ±5,3	36,3 ±5,5	0, 98	37,1 ±4,4	35,4 ±5,7	34,8 ±5,1	0, 7	36,5 ±3,6	36,5 ±5,4	35,8 ±5,5	0, 92	34,3 ±2,1	37± 3,8	39,7 ±4,9	**0, 01 ***
GMI (%)	7,3± 1,2	6,4± 2,2	5,2± 3,4	0, 15	6,6± 0,2	7,1± 6,4	6,4± 2,4	0, 47	6,6± 0,2	7,3± 0,5	6,6± 2,3	0, 46	6,7± 0,4	6,1± 2,1	6,5± 2,2	0, 63
HbA 1c (%)	8,8± 1,7	7,5± 1,1	7,5± 1,3	0, 22	6,6± 0,5	7,2± 0,8	7,2± 1,3	0, 68	6,7± 0,4	7,3± 0,7	7,6± 1,6	0, 18	6,5± 0,4	7,4± 0,5	7,6± 1,3	**0, 02 ***
Average BG (mg/dl)	161, 3±25 ,8	166, 4±27 ,6	-	0, 91	152, 4±2 4,5	173, 7±2 7,9	-	0, 16	151, 6±3 0,7	180, 9±2 1,9	-	**0, 02 ***	152, 5±2 8,2	179, 6±1 4,6	-	**0, 01 ***
TDI (U/day) (min - max)	10,6 (4,5-17,6)	13,9 (3,5-24,2)	14,8 (4,5 -25)	0, 25	12,8 (8,2 - 20,3)	15,1 (4-25,6)	15,7 (5-26)	0, 55	13,9 (7,7 - 25,9)	16 (6,2 - 24,9)	18,9 (5,2 -22)	0, 2	15,9 (9,3 - 33,2)	17,6 (5,8 - 29,4)	21,4 (13-34)	0, 26
Amount of bolus insulin (U)	6,7± 2,9	9,2± 4,5	-	0, 18	8±2	10,4 ±4,9	-	0, 28	8,8± 2,3	11± 4,2	-	0, 18	9,9± 2,8	11,8 ±5,1	-	0, 39
Auto - correction insulin (U)	-	-	-	-	1,1± 0,9	-	-	-	2,1± 1,6	-	-	-	2,6± 2,2	-	-	**-**
Basal insulin (U)	4±2, 7	4,2± 2	-	0, 55	4,8± 3	4,5± 2,4	-	0, 97	5,1± 2,9	5±2, 3	-	0, 53	6,1± 4,1	5,9± 2,2	-	0, 55
Meal per day	4,4± 1,1	6,6± 1,9	-	**0, 01 ***	4,8± 2	5,9± 1,2	-	0, 12	5,9± 1,4	6,1± 1,7	-	0, 97	6,1± 2,1	5,9± 1,5	-	0, 77
Amount of carb	128, 6±33 ,5	144, 9±38 ,2	-	0, 28	136, 1±4 5,4	143, 7±4 2,9	-	0, 62	154, 8±2 8,6	149, 2±3 5,7	-	0, 6	154, 5±3 3,2	158, 6±3 8,8	-	0, 67

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Average SG (mg/dl)	145,1±20	153,7±15,1	162,7±32,4	0,27	139,8±13	158,5±21,1	161,7±23,6	0,78	141,3±13,7	164,7±22,4	163,5±29	**0,02***	142,6±14,2	156,9±16,3	169,6±42,9	0,83

BG: Blood Glucose; **carb:** carbohydrate; **CGMs:** Continuous Glucose Monitoring system; **CV:** Coefficient of Variation; **GMI:** Glucose Management Indicator; **SC:** Subcutaneous; **SG:** Sensor glucose; **MDI:** Multiple dose insulin treatment**; TAR:** Time Above Range; **TBR:** Time Below Range; **TDI:** Total Daily Insulin Dose; **TIR:** Time In Range
***: p<0,05:** Statistically significant.

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Figure 1: TIR, TAR, and TBR changes of the groups
780G: Minimed™ 780G; **640G:** Minimed™ 640G; **MDI+CGM:** Multiple Dose Insulin + Continuous Glucose Monitoring; **TAR:** Time Above Range; **TBR:** Time Below Range; **TIR:** Time In Range

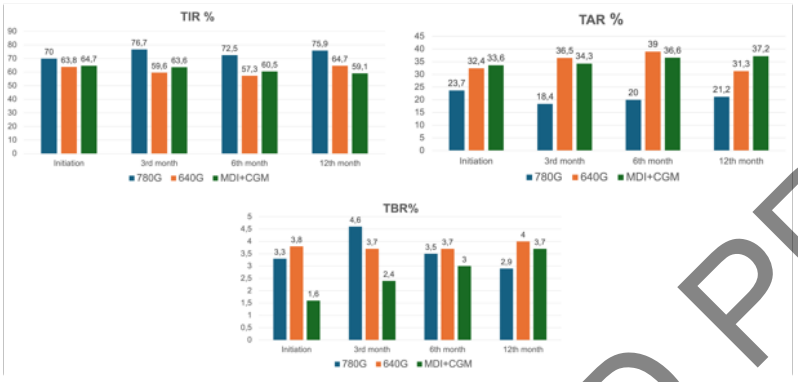
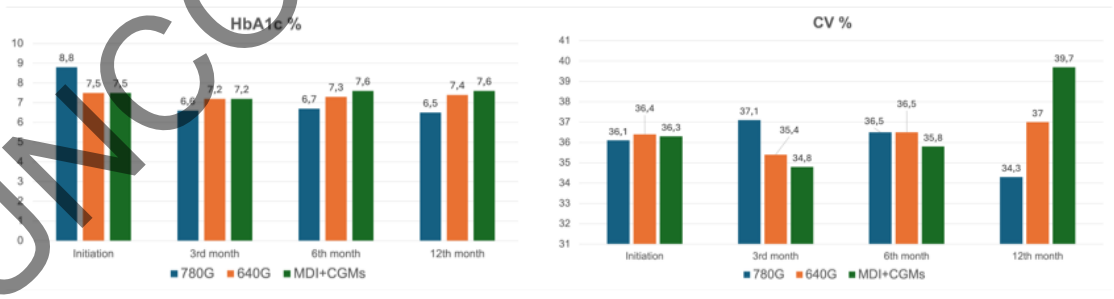


Figure 2: HbA1c and CV changes of the groups
780G: Minimed™ 780G; **640G:** Minimed™ 640G; **CV:** Coefficient of Variation; **MDI+CGM:** Multiple Dose Insulin + Continuous Glucose Monitoring



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