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An analysis of Medtronic MiniMed 670G insulin pump use in clinical practice and the impact on glycemic control, quality of life, and compliance

Maxwell E. Horowitz [a], *William A. Kaye* [b], *Gary M. Pepper* [c], *Kathryn E. Reynolds* [c], *Shital R. Patel* [c], *Kort C. Knudson* [c], *Geetanjali K. Kale* [c], *Maria E. Gutierrez* [c], *Leslie A. Cotto* [c], *Barry S. Horowitz* [b,*]

[a] *Mount Sinai Morningside-West, New York, NY, United States*
[b] *Metabolic Research Institute, Inc., West Palm Beach, FL, United States*
[c] *Palm Beach Diabetes and Endocrine Specialists, P.A., West Palm Beach, FL, United States*

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ABSTRACT

Aims: This study evaluated the use of the Medtronic MiniMed 670G system in adults with type 1 diabetes mellitus from a large endocrinology practice and its impact on glycemic control, quality of life (QoL), compliance and safety.

Methods: 84 participants completed one site visit for data collection. Percentage of time in range (TIR: 70–180 mg/dL), hyperglycemia or time above range (TAB) (>180 mg/dL), hypoglycemia or time below range (TBR) (<70 mg/dL), HbA1c, average blood glucose (ABG), and other metrics were evaluated at the last visit using the system (LVMM) and compared between the last visit on previous insulin therapy (LVPT).

Results: The mean percentage of TIR at the LVMM was 74.0 ± 12.1%, with an increase of 27.1% ($p < 0.001$) in TIR from the LVPT. The mean percentage of TAR was 22.9 ± 11.8% and the mean percentage of TBR was 3.2 ± 5.1%.

Conclusions: The use of the Medtronic MiniMed 670G system in our practice resulted in a TIR above the recommended target with a high degree of treatment satisfaction and compliance in adults with type 1 diabetes. Furthermore, the system may be a reasonable choice for patients struggling with significant amounts of hypoglycemia.

1. Introduction

The Medtronic MiniMed 670G system is the first commercially available, licensed hybrid closed loop system used for continuous delivery of basal insulin and administration of insulin boluses for the management of type 1 diabetes mellitus. Meta-analyses have shown a significantly higher proportion of time spent in near normoglycemic range with hybrid

* Corresponding author.at: 1515 North Flagler Drive, Suite 440, West Palm Beach, FL 33401, United States.
E-mail addresses: bhorowitz@metabolic-institute.com (M.E. Horowitz), wkaye@pbdes.com (W.A. Kaye), gpepper@pbdes.com (G.M. Pepper), kreynolds@pbdes.com (K.E. Reynolds), spatel@pbdes.com (S.R. Patel), kknudson@pbdes.com (K.C. Knudson), gkale@pbdes.com (G.K. Kale), mgutierrez@pbdes.com (M.E. Gutierrez), lcotto@pbdes.com (L.A. Cotto), bhorowitz@metabolic-institute.com (B.S. Horowitz).

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closed loop systems compared to conventional pump therapy [1] and to any other insulin treatment [2]. Smaller trials have revealed lower mean glucose and HbA1C levels [3,4].

The Medtronic MiniMed 670G system was evaluated in a single arm non-randomized pivotal trial. HbA1c decreased and patients spent significantly more time in near normoglycemic range (TIR). In addition, none of the participants experienced severe hypoglycemia or DKA and the majority of participants trusted the system and felt comfortable using it [5]. A prospective observational study of patients utilizing the system found a significant correlation between auto mode utilization and HbA1c, but 46% of participants stopped using auto mode by 12 months and only 32% were in auto mode > 70% of the time [6].

While pivotal trials and prospective randomized controlled studies (RCTs) are important with regard to evaluating outcomes measures such as efficacy, these studies can also have problems such as selection bias. Research assessing whether the improved outcomes associated with technological advances translate from clinical trials to real-life use is important, especially with the continuity of care that is afforded by the same health care provider in private practice as opposed to academic centers. This retrospective analysis evaluated the use of the Medtronic MiniMed 670G system in a patient population of adults with type 1 diabetes mellitus from an adult endocrinology practice and examine its impact on glycemic control, quality of life (QoL), and patient compliance with the device

1.1. *Subjects*

Participants were males or females 18 years of age or older with a documented history of type 1 diabetes mellitus. Participants were required to have been using the Medtronic MiniMed 670G system for at least three months. The 84 participants included in this study are patients in our endocrinology practice followed by our endocrinologists who, in the course of their therapy for type 1 diabetes, transitioned to the Medtronic 670G system from previous therapies for a variety of reasons, including unacceptable glycemic control, hypoglycemia, convenience, etc. The decision to transition patients from their previous pump or multiple daily injections (MDI) therapy was made by the endocrinologist in our practice caring for the patient in conjunction with the patient. The time spent with our education staff was typical for a patient in our practice transitioning to a new insulin pump and was uniform among the participants in the study.

2. Materials and methods

2.1. *Study design*

Participants completed one site visit during which consent was signed for retrospective data collection from their electronic medical record (EMR), including their pump data. All measures included were part of standard clinical practice. The previous type of insulin therapy was determined. In addition, participants completed the Diabetes Treatment Satisfaction Questionnaire (DTSQ) [7], Diabetes-Dependent Quality of Life (ADDQoL) questionnaire [8], and "Pump QoL vs. Previous Therapy" questionnaire (PQPT) at this visit (Fig. 1).

2.2. *Assessments*

The primary efficacy measure for this study is glycemic control while using the Medtronic MiniMed 670G system. Data regarding several pump metrics from the last office visit prior to the single study visit in which the participant was enrolled (LVMM) were collected from the EMR: percentage of time in near normoglycemic range (TIR: 70–180 mg/dL), percentage of time in hyperglycemia or time above range (TAR) (>180 mg/dL) and hypoglycemia or time below range (TBR) (<70 mg/dL), and average blood glucose (ABG) level. These were compared to that of the last visit on previous insulin therapy (LVPT), which was also collected from the participant's EMR. TIR was uniformly calculated for 2 weeks at all data points for all participants. In addition, HbA1c, fructosamine, and glycomark were obtained from the EMR and compared between the participant's LVPT and LVMM.

The secondary efficacy measures are QoL, compliance, and safety while using the Medtronic MiniMed 670G system. DTSQ, ADDQoL, and PQPT were completed by each participant. Percentage of patients who continued to use the device in auto mode was assessed, including the percentage who continued to use the sensor. In addition, percentage of participants discontinuing the pump, sensor, and/or auto mode was assessed, including the reason for cessation. Adverse events experienced that were previously recognized with the use of this device such as skin irritation, rash, hyperglycemia, and incidence of diabetic ketoacidosis (DKA) were assessed. Hypoglycemia was assessed from pump data as percent of time of ABG between 50 and 70 mg/dl and <50 mg/dl as opposed to the ADA hypoglycemia classification levels which are not obtainable from the system[9].

2.3. *Statistical Methods*

Data analyses were performed with IBM SPSS statistics software version 26 (IBM SPSS, Chicago, IL, 2019). For demographic data, means and ranges were determined for age, years since the diagnosis of type 1 diabetes mellitus, and time using the Medtronic MiniMed 670G system. For data from the LVMM and the LVPT, means and standard deviations were determined for percentage of TIR, percentage of TAR, percentage of TBR, ABG, HbA1c, fructosamine, glycomark, percent time using auto mode, percent time using the sensor, total daily dose of insulin, percent basal and bolus, insulin-to-carbohydrate ratio, sensitivity, and active insulin time. Paired samples statistics were used to compare mean measures at the time of the LVMM to that of the LVPT. To evaluate QoL, means were determined for the DTSQ, ADDQoL, and PQPT questionnaires.

3. Results

3.1. *Demographics*

34 male and 50 female participants were included in this study (Table 1). The mean participant age was 51 (range 21–

1. Compared to my previous insulin therapy (previous pump or multiple daily injections), the control of my diabetes is better since using the Medtronic 670 pump.

(A) Strongly Disagree (B) Disagree (C) Neutral (D) Agree (E) Strongly Agree

2. Compared to my previous insulin therapy (previous pump or multiple daily injections), it is easier to manage my diabetes since using the Medtronic 670 pump.

(A) Strongly Disagree (B) Disagree (C) Neutral (D) Agree (E) Strongly Agree

3. Compared to my previous insulin therapy (previous pump or multiple daily injections), I am happier managing my diabetes since using the Medtronic 670 pump.

(A) Strongly Disagree (B) Disagree (C) Neutral (D) Agree (E) Strongly Agree

4. Compared to my previous insulin therapy (previous pump or multiple daily injections), I am more compliant managing my diabetes since using the Medtronic 670 pump.

(A) Strongly Disagree (B) Disagree (C) Neutral (D) Agree (E) Strongly Agree

5. Compared to my previous insulin therapy (previous pump or multiple daily injections), my overall quality of life is better since using the Medtronic 670 pump.

(A) Strongly Disagree (B) Disagree (C) Neutral (D) Agree (E) Strongly Agree

Fig. 1 – "Pump QoL vs. Previous Therapy" (PQPT) questionnaire created by Metabolic Research Institute, Inc.

Table 1 – Demographic Characteristics.

Demographic Characteristics	
Sex (M, F)	34,50
Years of age (Mean, Range)	51, 21–77
Years since diagnosis of DMI (Mean, Range)	32, 2–71
Months using Medtronic MiniMed 670G(Mean, SD)	24,8
Previous Insulin Therapy	
Animas OneTouch Ping	6
Multiple Daily Injections (MDI)	9
Medtronic MiniMed 530G	37
Medtronic MiniMed 630G	18
Paradigm Revel 523	2
Paradigm Revel 723	11
Tandem Tslim	1

77). The mean time since the diagnosis of type 1 diabetes mellitus was 32 years (range 2–71 years) and the mean time using the Medtronic MiniMed 670G system was 24 ± 8 months. Of these 84 participants, all of them continued using the pump, 77 continued using the sensor and 72 continued to use the sensor in auto mode. 12 participants did not continue use in auto mode due to specific reasons and of these 7 discontinued sensor use altogether (Table 2). For the 72 participants who continued sensor use in auto mode, the mean time using the Medtronic MiniMed 670G system was 25 ± 8 months.

Table 2 – Reasons for Auto Mode Discontinuation.

Reason for Discontinuation of Auto Mode	
Chemotherapy	1*
Insurance did not cover sensor	4*
Personal preference for manual mode	
Tried auto mode and preferred to adjust manually	2
Found manual mode easier to use vs. auto mode	1
Pregnancy	1
Sensor inconvenience	
Inconvenient with exercise	1
Inconvenient with work	1*
Inconvenient with travel	1*

* Discontinued sensor use all together.

3.2. *Efficacy*

In examining the primary efficacy measures of the 77 participants continuing to use the sensor, the mean percentage of TIR at the LVMM on the Medtronic MiniMed 670G system was 74.0 ± 12.1% (Table 3). The mean percentage of TAR was 22.5 ± 11.3% and the mean percentage of TBR was 3.2 ± 5.3%. ABG was 165.6 ± 25.9 mg/dL in the 72 participants who had LVMM data and mean HbA1c was 7.4 ± 0.8% (58 mmol/mol) in all 84 participants who had LVMM data. Mean fructosamine was 398.6 ± 91.9 umol/L in the 61 participants who had LVMM data and mean glycomark was 7.1 ± 4.8 mcg/mL in the 44 participants who had LVMM data.

While 72 participants continued using the sensor in auto mode, 71 of the 84 participants (85%) had adequate CGM data at LVPT for comparison. The mean percentage of TIR at the LVPT was 46.3 ± 18.8% while that at the LVMM was 73.4 ± 13.0%. This represents a significant increase in percentage of TIR of 27.1% ($p < 0.001$). The mean percentage of TAR at the LVPT was 47.4 ± 20.4% while that at the LVMM was 23.5 ± 11.7%, representing a significant decrease of 23.9% ($p < 0.001$). The mean percentage of TBR at the LVPT was 6.2 ± 7.9% while that at the LVMM was 2.9 ± 4.7%, representing a significant decrease of 3.3% ($p = 0.004$). These data are shown in Fig. 2. To evaluate whether the range of duration of time on the system had an impact upon the results, we analyzed the TIR data by tertile of duration of time on the system, both with equal numbers of participants in each tertile and purely by tertile of duration of time on the system. In either analysis, there was no significant difference in the tertiles between each other or between the overall analysis (data on file).

There was no significant change in HbA1c in the 82 of the 84 participants who had adequate data for comparison. The mean HbA1c at the LVPT was 7.4 ± 1.0% (57 mmol/mol) while that at the LVMM was 7.5 ± 0.9% (58 mmol/mol), representing an increase of 0.1% ($p = 0.337$). A subgroup analysis was performed examining HbA1c<7.5% (58 mmol/mol) and greater than or equal to 7.5% (58 mmol/mol) at the LVPT. For those with HbA1c greater than or equal to 7.5%, the mean HbA1c at the LVPT was 8.5 ± 0.8% (69 mmol/mol) while that at the LVMM was 8.0 ± 0.9% (64 mmol/mol), representing a significant decrease of 0.5% ($p = 0.007$). For those with HbA1c<7.5% (58 mmol/mol), the mean HbA1c at the LVPT was 6.8 ± 0.5% (51 mmol/mol) while that at the LVMM was 7.2 ± 0.7% (55 mmol/mol), representing a significant increase of 0.4% ($p < 0.001$). Of note, when examining time in hypoglycemia (<70 mg/dL), participants with LVPT HbA1c<7.5% (58 mmol/mol) had a significant reduction from 7.4% to 2.6% ($p = 0.001$), whereas the reduction in participants with LVPT HbA1c greater than or equal to 7.5% (58 mmol/mol) was from 4.1% to 3.6% ($p = 0.758$).

Table 3 – Primary Efficacy Measure Endpoint Data.

Primary Efficacy Measure Endpoint Data	
TIR (Mean ± SD)	74.0 ± 12.1%
TAR (Mean ± SD)	22.9 ± 11.3%
TBR (Mean ± SD)	3.2 ± 5.3%
HbA1c (Mean ± SD)	7.4 ± 0.8% (57 mmol/mol)
ABG (Mean ± SD)	165.6 ± 25.9 mg/dL
Fructosamine (Mean ± SD)	398.6 ± 91.9 umol/L
Glycomark (Mean ± SD)	7.1 ± 4.8 mcg/mL

In the 65 of 84 participants who had adequate data for comparison, ABG at the LVPT was 176.5 ± 38.4 mg/dL while that at LVMM was 165.7 ± 23.2 mg/dL, representing a significant decrease of 10.8 mg/dL ($p = 0.008$). In the 52 of 84 participants who had adequate data for comparison, the mean fructosamine at the LVPT was 450.3 ± 121.6 umol/L while that at LVMM was 397.9 ± 94.7 umol/L, representing a significant decrease of 52.4 umol/L ($p < 0.001$). In the 39 of 84 participants who had adequate data for comparison, the mean glycomark at the LVPT was 6.5 ± 4.8 mcg/mL while that at the LVMM was 7.1 ± 5.0 mcg/mL, representing an increase of 0.6 mcg/mL ($p = 0.099$).

3.3. *QoL*

QoL while using the Medtronic Minimed 670G system was evaluated using the DTSQ, ADDQoL, and PQPT. DTSQ is scored with a minimum score of 0 and a maximum score of 36. The mean score for the DTSQ in this study was 29.9 ± 5.0, indicating a high degree of diabetes treatment satisfaction. ADDQoL-I is scored with a minimum score of −3 and a maximum score of 3. The mean score for the ADDQoL-I in this study was 1.8 ± 0.9, indicating a "very good" rating of present QoL. ADDQoL-II is scored with a minimum score of −3 and a maximum score of 1. The mean score for the ADDQoL-II in this study was −1.9 ± 1.0, indicating QoL would be "much better" if the participant did not have diabetes. ADDQoL-III is scored with a minimum score of −9 and a maximum score of 3. The mean score for ADDQoL-III in this study was −2.4 ± 1.6, indicating QoL based on a variety of metrics would be "much better" if the participant did not have diabetes. Lastly, PQPT is scored with a minimum score of −2 and a maximum score of 2. The mean score in this study was 0.9 ± 1.0, indicating that participants "agree" that their QoL based on several metrics is better on their current diabetes therapy with the Medtronic Minimed 670G system compared to their previous therapy.

3.4. *Compliance*

Compliance while using the Medtronic Minimed 670G system was evaluated by assessing the percentage of participants

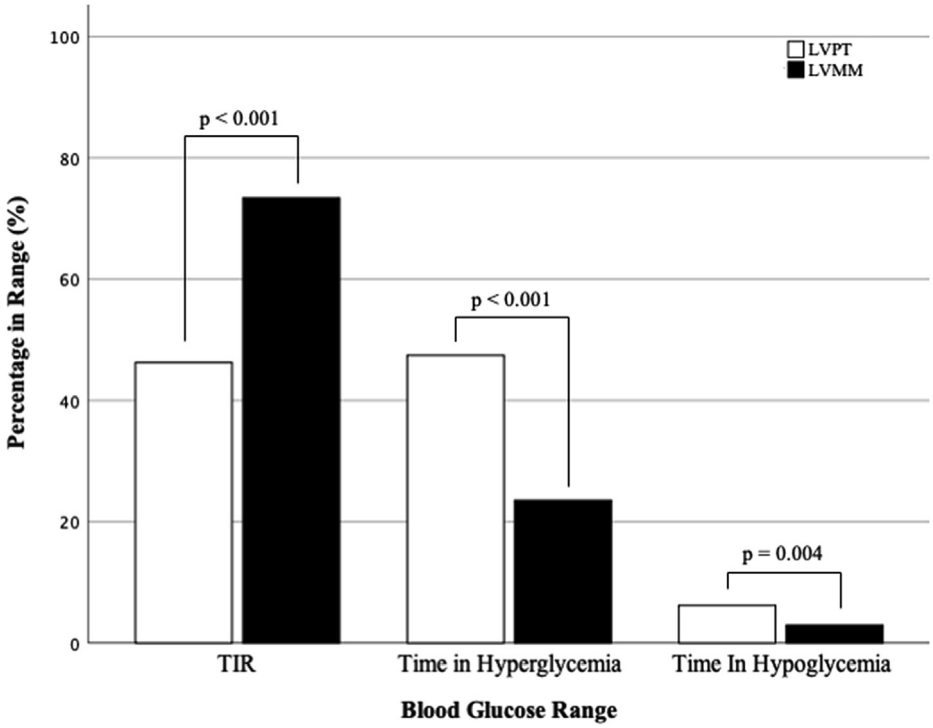

Fig. 2 – Primary efficacy endpoint of blood glucose ranges. The changes of Time in Range (TIR), time in hyperglycemia, and time in hypoglycemia between the last visit on previous insulin therapy (LVPT) and the last visit using the Medtronic Minimed 670G system (LVMM).

who continued to use the sensor as well as those who continued to use the system in auto mode. 77 of the 84 participants continued to use the sensor and the mean percentage time using the sensor in this population was 81.5 ± 13.1%. As mentioned previously, 72 of the 84 participants (86%) continued use in auto mode while 12 participants did not (Table 2). For those continuing use in auto mode, the mean percentage of time in auto mode was 81.6 ± 16.5%.

3.5. *Pump parameters*

In comparing secondary efficacy pump measures, the mean TDD of insulin at the LVPT was 50.2 ± 26.7 U while that at the LVMM was 51.2 ± 28.5 U, representing an increase of 1.0 U ($p = 0.535$). The mean percentage of basal insulin use at the LVPT 53.5 ± 15.0% while that at the LVMM was 47.7 ± 12.0%. Concurrently, the mean percentage of bolus insulin use at the LVPT was 46.5 ± 15.0% while that at the LVMM was 52.3% ± 12.0%. These represent a significant decrease of basal insulin percentage and a significant increase of bolus percentage of 5.8% ($p < 0.01$). The mean ICR at the LVPT was 8.4 ± 3.8 g/U while that at the LVMM was 6.9 ± 3.9 g/U, representing a significant decrease of 1.5 g/U ($p < 0.001$). The mean sensitivity at the LVPT was 46.6 ± 20.2 mg/dL/U while that at LVMM was 46.8 ± 21.8 mg/dL/U, representing an increase of 0.2 mg/dL/U (0.846). Lastly, the mean active insulin time at the LVPT 3.5 ± 0.9 h while that at the LVMM was 3.6 ± 0.6 h, representing an increase of 0.1 h ($p = 0.595$).

3.6. *Safety*

In evaluating safety while using the Medtronic Minimed 670G system, no adverse events of skin irritation, rash, or incidence of DKA occurred. However, as discussed previously, there were percentages of time where participants experienced hyperglycemia or TAR and hypoglycemia or TBR. The mean percentage of TAR or ABG > 180 mg/dL was 22.9 ± 11.8%. In subgroup analysis, the percentage of time in ABG 180–250 mg/dL was 18.7 ± 8.0% and that in ABG > 250 mg/dL was 4.4 ± 5.3%. The mean percentage of TBR or ABG < 70 mg/dL was 3.2 ± 5.1%. In subgroup analysis, the percentage of time in ABG 50–70 mg/dL was 2.8 ± 4.8% and that in ABG < 50 mg/dL was 0.6 ± 1.5%.

4. Discussion

In a group of 84 patients with type 1 diabetes mellitus from a large endocrinology practice using the Medtronic Minimed 670G system, the mean percentage of TIR was 74.0%, which is in line with results from previously done RCTs analyzing this system and clinically impactful for patient care. This exceeds the minimum target guideline of 70% for adults with type 1 or type 2 diabetes mellitus as described in an analysis of clinical targets for CGM data interpretation [10] and the national average of 70.2% for patients on the system (Data on File, Medtronic, Northridge, CA, 2020). The percentage of TIR is also of great significance given the findings of a 2019

study examining validation of TIR as an outcome measure, which found a mean percentage of TIR of 52% in participants undergoing intensive treatment for type 1 diabetes mellitus [11]. The study also found a significant increase in the percentage of TIR with the use of the system compared to previous insulin therapy.

In evaluating HbA1c with the use of the Medtronic MiniMed 670G system compared to previous insulin therapy, there was no significant change in HbA1c in the participants who had adequate data for comparison as well as for the group of those participants who had remained on the sensor in auto mode. Of interest, the glucose management indicator (GMI), a measure estimating approximate HbA1c based on ABG level from continuous glucose monitoring (CGM) [12], was calculated for further evaluation of HbA1c at LVPT and LVMM. The mean GMI at the LVPT was 7.5 ± 0.9% while that at the LVMM was 7.3 ± 0.6%, representing a decrease of 0.2% ($p = 0.011$). This small improvement in GMI could imply a glycation issue as a possible explanation of the actual HbA1c data.

While a decrease in HbA1c might be expected with the significant increase in TIR and decrease in the mean percentage of time in hyperglycemia that was seen, there are several potential explanations as to why this was not the case. First, this was not a treat-to-target study, but a real-world study where the endocrinologists in our practice caring for their patients made adjustments in pump parameters based on goals that were individualized for each patient. In addition, the Medtronic MiniMed 670G system algorithm targets a blood glucose of 120 mg/dL. Furthermore, participants were already relatively well-controlled at the LVPT prior to switching to the Medtronic MiniMed 670G system. Finally, those with higher HbA1c values at baseline had a reduced percentage of time in hyperglycemia, while those with lower HbA1c values had a reduced percentage of time in hypoglycemia, indicating improvement in parameters specific to each subgroup.

The data from three separate QoL questionnaires indicates that participants in the study were generally very satisfied with the Medtronic MiniMed 670G system (DTSQ and ADDQoL) and also found QoL to be better than their previous therapy (PQPT). The QoL results are further supported by the high rate of compliance in time using the sensor and remaining in auto mode. In examining the reasons for discontinuation (Table 2), half of the participants who discontinued auto mode did not do so voluntarily, with a lack of coverage by insurance or a current medical issue preventing its use. Of the remaining six participants, three discontinued due to preference for using the sensor in manual mode and three discontinued due to inconvenience. This indicates that there were no significant issues with the functionality of the device, site issues or the participants' ability to use it.

In contrast, pediatric studies with the system have indicated that children, adolescents, and young adults have more significant issues than adults with ability, compliance and motivation in controlling their diabetes and may require more assistance and support [13]. Furthermore, in the one year prospective study of children and adults by Lal et al. [6], which had a high discontinuation rate for a variety of reasons, there was a significant correlation between A1c and time in auto mode for those remaining on the system. As with our study, this implies that patients achieving a high TIR with this system may be highly motivated and a potentially self-selecting group.

In examining the secondary efficacy measures, there was no significant change in TTD of insulin. However, there was an increase in bolus insulin requirements with a greater bolus to basal ratio with use of the Medtronic MiniMed 670G system, as well as a concomitant significant decrease in ICR. This is a phenomenon that we have seen clinically when patients are transitioned to the system and it is recommended in the Protocol For Hybrid Closed Loop Therapy (Medtronic, Northbridge, CA, 2019) that ICR typically may need to be strengthened. While it is possible that some participants were over-basaled and/or under-bolused on their previous insulin therapy, it also may be likely that due to the pump algorithms for delivering basal insulin, bolus requirements are increased when transitioning to the system.

This study found no major adverse events such as DKA or site issues, indicating a high degree of safety while using the Medtronic MiniMed 670G system. While hyperglycemia and hypoglycemia occurred as is typical of managing patients with type 1 diabetes mellitus, the incidence of each was significantly reduced with the system. Moreover, subgroup analysis indicates minimal percentages of time in the extreme ranges of hyperglycemia and hypoglycemia. It is highly clinically relevant, that while patients with already good glycemic control may have no change or an actual increase in A1c as noted above, this appears to be associated with a reduction of time below range and may therefore be a reasonable choice for patients struggling with significant amounts of hypoglycemia.

Being a retrospective analysis of data from patients in our practice, this study does have several limitations, such as not having an active comparator group. Also, a pre-specified time for being on the system would have been preferred, but this would have been somewhat difficult to choose as the follow up varied among the participants. In addition, not all of the participants had evaluable data for comparison. The comparison between LVMM and LVPT must therefore be interpreted judiciously. Finally, the PQPT questionnaire is not a validated assessment of QOL, but was developed by the authors to derive some comparison of QOL on the system to previous treatment.

5. Conclusions

In summary, the results of this study indicate that the use of the Medtronic MiniMed 670G system in our practice resulted in a TIR above the recommended target with a high degree of treatment satisfaction and compliance in adults with type 1 diabetes. Furthermore, the system may be a reasonable choice for patients struggling with significant amounts of hypoglycemia.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Author Contributions

MEH and BSH were responsible for writing the original article. MEH was responsible for data collection, statistical analysis and table and figure creation. BSH, WAK, GMP, KER, SRP, KCK, GKK, MEG and LAC were the physicians of the participating participants and assisted in the editing of the manuscript. BSH is the guarantor for this original article and, as such, had full access to all of the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis.

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Disclosures

The authors have no conflicts of interest. The funding source was not involved in the study design, data collection, interpretation, statistical analysis, manuscript preparation, or the decision to submit the manuscript for publication.

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