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Treatment Satisfaction and Quality of Life for an Integrated Continuous Glucose Monitoring/Insulin Pump System Compared to Self-Monitoring Plus an Insulin Pump

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Abstract

Background:

Little is known about how the most advanced technology affects treatment satisfaction and health-related quality of life (HRQOL) in adults with diabetes. This study was designed to assess treatment satisfaction and HRQOL among users of an integrated real-time (RT) continuous glucose monitoring (CGM)/continuous subcutaneous insulin infusion (CSII) system compared with those using self-monitoring of blood glucose (SMBG) with CSII.

Methods:

Participants were 311 adult respondents to an Internet survey, 162 using RT-CGM/CSII, 149 using SMBG + CSII (median age 43 years; type 1 diabetes 94%; diabetes duration >15 years 61%; median insulin use 15 years). Respondents completed instruments assessing glucose monitoring system and insulin delivery system convenience, interference, burden, glucose control efficacy, cost satisfaction, overall satisfaction, and treatment preference, as well as quality of life (diabetes-related worries, social burden, and psychological well-being). Real-time CGM/CSII users also assessed specific elements of the RT-CGM/CSII system. Group differences were assessed using analysis of covariance controlling for respondent characteristics.

Results:

The RT-CGM/CSII group gave significantly better ratings than the SMBG + CSII group for their glucose monitoring system's glucose control efficacy, overall satisfaction, desire to switch, and willingness to recommend, and significantly worse ratings for interference with daily activities. The RT-CGM/CSII group gave significantly better ratings than the SMBG + CSII group for their insulin delivery system's convenience and glucose control efficacy, overall satisfaction, desire to switch, and willingness to recommend. Real-time CGM/CSII users gave positive ratings of all system features.

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Abbreviations: (BGMS) blood glucose monitoring system, (BGMSRQ) blood glucose monitoring system rating questionnaire, (CGM) continuous glucose monitoring, (CSII) continuous subcutaneous insulin infusion, (DMS) data-management software, (HRQOL) health-related quality of life, (IDSRQ) insulin delivery system rating questionnaire, (MDI) multiple daily injection, (PRO) patient-reported outcome, (RCT) randomized controlled trial, (RT) real time, (SDU) standard deviation unit, (SMBG) self-monitoring of blood glucose, (UAQ) user acceptance questionnaire

Keywords: continuous glucose monitoring, continuous subcutaneous insulin infusion, health-related quality of life, patient satisfaction

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Abstract cont.

Conclusions:

Users of the integrated RT-CGM/CSII system reported more benefits of treatment, higher treatment satisfaction and quality of life, and greater preference for this system than SMBG + CSII users.

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Introduction

Technology for monitoring glucose and delivering insulin has advanced dramatically in recent years, culminating in the development of systems integrating real-time (RT) continuous glucose monitoring (CGM) and continuous subcutaneous insulin infusion (CSII). Some studies have assessed clinical outcomes of CGM or CSII, but to date, only one study compared a RT-CGM/CSII system with an alternative blood glucose monitoring/insulin delivery system [self-monitoring of blood glucose (SMBG) + CSII].[1]

Continuous glucose monitoring appears to have an advantage over SMBG for time spent in normoglycemia.[2] Also, patients using CGM devices that displayed blood glucose (BG) data had reduced glycemic excursions compared to patients using "blinded" CGM devices,[3] and patients using CGM with an alert feature (that could indicate when a low BG level was impending or had occurred) had hypoglycemic episodes of shorter duration than patients using CGM without an alert feature.[4] Continuous subcutaneous insulin infusion therapy appears to have advantages over multiple daily injection (MDI) therapy, including lower hemoglobin A1c levels and lower rates of severe hypoglycemia in most studies,[5–9] but not in all.[10,11] The one study that compared a RT-CGM/CSII system with SMBG + CSII suggested that CGM systems could improve glucose control in CSII patients, but only when they are used consistently.[1]

Ideally, advanced technology devices such as RT-CGM/CSII should have benefits not only in terms of clinical outcomes, but also for patient-reported outcomes (PROs) such as treatment satisfaction and health-related quality of life (HRQOL). Health-related quality of life is a critical outcome in its own right, and treatment satisfaction affects patient acceptance. Studies reporting that CGM systems improved clinical outcomes only when they were used consistently[1,3,12] make clear the critical role of patient acceptance in realizing the benefits of any new treatment or technology. We found only one small randomized controlled trial (RCT) comparing PRO for RT-CGM/CSII with an alternative treatment system (MDI + SMBG).[13] This study reported that several PRO were significantly more positive in the RT-CGM/CSII arm, including insulin delivery system BG control efficacy and satisfaction, and BG monitoring system BG control efficacy and interest in switching to another BG monitoring system. No PRO was significantly more positive in the MDI + SMBG arm.

The present study is the first to compare PRO in two groups of patients using CSII therapy: a group using RT CGM/CSII and a group using SMBG + CSII. The two groups were chosen because they represent the treatment systems used by patients engaged in the most technologically advanced intensive insulin therapy. The study was designed to answer the following questions: (1) how does satisfaction with one's BG monitoring system differ between the two groups of patients, (2) how does satisfaction with one's insulin delivery system differ between the two groups of patients (differences may be the result of synergistic effects of the integrated system even though both groups are using CSII), (3) how does HRQOL differ between the two groups of patients, and (4) for those using the RT-CGM/CSII system, what is the level of acceptance for each component of the system?

Patients and Methods

The study was an Internet survey of patients using one of two treatment systems. One group used a new device (the Paradigm® 722 System, Medtronic MiniMed) that combines an insulin pump with RT-CGM and CareLink data-management software (DMS). The glucose-monitoring device communicates readings to the insulin

pump, and the insulin pump incorporates glucose readings, insulin delivery memory, and patient-entered carbohydrate consumption estimates into a recommended bolus dose (Bolus Wizard). The other group used CSII with SMBG.

Procedure

The sampling frame for respondent selection was the Medtronic diabetes database consisting of patients who expressed interest in using the Paradigm 722 System and met Medtronic qualification criteria for using the Paradigm 722 System. Respondent demographic data were obtained from this database. Potential respondents were adults (aged 18 or older). Two subsamples were defined: (1) patients using a nonsensor-augmented insulin pump and making three or more daily BG checks and (2) patients who had been using the Paradigm 722 System pump for 3–6 months and who were previously using either MDI and SMBG or a nonsensor-augmented insulin pump and SMBG.

Potential respondents were contacted by email and offered an incentive of $25 to participate. Volunteers were accepted on a first-come-first-served basis, and the panels were closed when sample targets (175–200) were met. The study goal was to obtain 150 qualified subjects in each group; this would yield power of 0.80 to identify group differences of 0.3 standard deviations at the .05 probability level.

Quorum institutional review board approved the study protocol. The project was conducted during November and December 2007. Final samples reported in this paper were composed of those whose answers on the screening portion of the questionnaire confirmed that they met the criteria for inclusion in one of the study subsamples.

Measures

Respondents completed the blood glucose monitoring system rating questionnaire (BGMSRQ).[13] The BGMSRQ was based on the insulin delivery system rating questionnaire (IDSRQ),[13,14] consisting of a subset of the IDSRQ items with the same response options; however, the instructions identified the rating target as the respondent's BG monitoring system rather than the respondent's insulin delivery device. Measures included convenience, interference, BG burden, BG control, overall satisfaction, desire to switch BG monitoring system, willingness to recommend current BG monitoring system, and comparison of current and prior BG monitoring system (the latter indicating treatment preference).

Respondents also completed the IDSRQ.[14] Ratings of the insulin delivery system included convenience, interference, blood glucose burden, BG control, overall satisfaction, desire to switch insulin delivery system, willingness to recommend current insulin delivery system, and comparison of current and prior insulin delivery system (the latter indicating treatment preference). The HRQOL dimensions included diabetes worries, diabetes social burden, positive well-being, and negative well-being.

Respondents using the RT-CGM/CSII system completed three user acceptance questionnaires (UAQs).[13] Each UAQ consisted of questions about elements of the RT-CGM/CSII treatment system (i.e., the DMS, RT-CGM, and CSII elements). Response options were a seven-point scale (strongly agree to strongly disagree). The UAQ for DMS included measures of system operation, using data displays, and overall assessment. The UAQ for RT-CGM contained measures of comfort, sensor operation, using data displays, alarms, and overall assessment. The UAQ for CSII contained measures of comfort, pump operation, alarms, Bolus Wizard, and overall assessment.

All BGMSRQ, IDSRQ, and UAQ measures were scored so the minimum score was 0 and the maximum score was 100, with higher scores representing more of the characteristic represented in the scale's name. The UAQ measures were scored so that higher scores represent more positive ratings; 50 represents a neutral score (neither positive nor negative). Multi-item scales were calculated as the mean of component items.

Statistical Analysis

Reliability (inter-item agreement) of multi-item scales was assessed by Cronbach's alpha. One-way analysis of variance assessed unadjusted differences in mean scores between study groups. Analysis of covariance with covariates (gender, marital status, age, insurance type, type and duration of diabetes, years using insulin) assessed adjusted differences between study groups. One-sample *t* tests assessed whether mean RT-CGM/CSII users' UAQ scores differed from neutral ratings (neutral = 50). Paired (correlated) *t* tests assessed whether RT-CGM/CSII system users rated system components differently. Effect sizes were measured in terms of pooled standard deviation units (SDUs) and reported in terms of meeting the one-half standard deviation criterion for a "minimally detectable difference," the smallest difference that an individual would be able to detect.[15] Effects of this size are classified as "moderate" to "large."[16]

No adjustments were made for multiple comparisons. All analyses were conducted with SPSS 14.

Results

Subjects

The study population consisted of 311 participants who met all inclusion/exclusion criteria and completed the study protocol, with 149 in the SMBG + CSII group and 162 in the RT-CGM/CSII group. In the RT-CGM/CSII group, 102 had switched from using SMBG with MDI and 60 had switched from using SMBG with CSII.

Data on respondent characteristics are presented in **Table 1**. One-third (33%) of the respondents were married, and 59% were female. Age ranged from 18 to 71 years, with a median of 43. Most (63%) respondents had preferred provider organization or exclusive provider organization insurance coverage. Most (94%) respondents had type 1 diabetes and diabetes of duration over 15 years (60%), with a median of 15 years taking insulin. The RT-CGM/CSII group was significantly less likely to be single and had a lower duration of diabetes.

Table 1.
Respondent Characteristics by Treatment Group[a]

Measure	SMBG + CSII (*N* = 149)	RT-CGM/CSII (*N* = 162)	*p*[b]
Age (years)	41.0 ± 12.4	43.6 ± 12.3	.062
Gender[c]			.167
Female	62.8% (93)	54.9% (89)	—
Male	37.2% (55)	45.1% (73)	—
Marital status			.012
Married	32.6% (50)	32.7% (53)	—
Single	30.2% (45)	17.3% (28)	—
Other	36.2% (54)	50.0% (81)	—
Insurance			.099
Preferred or exclusive provider organization	58.4% (87)	67.9% (110)	—
Other	41.6% (62)	32.1% (52)	—
Diabetes type			.060
Type 1	96.6% (144)	91.4% (148)	—
Type 2	3.4% (5)	8.6% (14)	—
Duration of diabetes[c]			.010
<2 years	0% (0)	4.5% (6)	—
2–5 years	4.5% (5)	9.7% (13)	—
6–10 years	12.6% (19)	14.2% (22)	—
11–15 years	17.1% (19)	16.4% (74)	—
>15 years	65.8% (73)	55.2% (74)	—
Duration of insulin use (years)	18.0 ± 11.5	18.9 ± 14.5	.607

[a] Cell entries are mean ± standard deviation or % (*N*).
[b] Probability by analysis of variance or chi-square.
[c] Number of responses do not sum to sample size because of missing values.

Measures

The reliability of all study measures was good. For the BGMSRQ the range of alphas was 0.85–0.95 (median = 0.87). For the IDSRQ the range of alphas for the ratings of the insulin delivery system was 0.92–0.94 (median = 0.92). For HRQOL the range of alphas was 0.77–085 (median = 0.81). For the UAQ the range of alphas for DMS was 0.70–0.93 (median = 0.92). For CGM the range was 0.80–0.90 (median = 0.89). For CSII the range was 0.74–0.96 (median = 0.84).

Group Comparisons

Preliminary analyses indicated that there were few significant differences in BGMSRQ or IDSRQ measures between RT-CGM/CSII users who switched from MDI or from CSII; therefore, all analyses pool the responses of these two subgroups except as noted.

Blood Glucose Monitoring System

Results are presented in **Table 2**. For analyses unadjusted for respondent demographic and disease characteristics, the RT-CGM/CSII group gave significantly better ratings than the SMBG + CSII group for 4 of 8 BG monitoring system measures (BG control, overall satisfaction, switch, recommend) and significantly worse ratings for interference; the differences for BG control, switch, and recommend were more than 0.5 SDU. In the RT-CGM/CSII group, the mean score for comparison of current and prior BG monitoring system was 89.4 ± 17.1, which indicates that that this group rated CGM significantly ($p < .001$) better than SMBG (results not shown in table). The difference from the neutral rating (50, indicating that CGM and SMBG are equal) was more than 0.5 SDU.

When study group comparisons were adjusted for respondent demographic and disease characteristics, results were substantively the same as the unadjusted results.

Insulin Delivery System

Results are presented in **Table 2**. For analyses unadjusted for respondent demographic and disease characteristics, the RT-CGM/CSII group gave significantly better ratings than the SMBG + CSII group for 5 of 8 insulin delivery

system measures (convenience, blood glucose control, overall satisfaction, switch, recommend); none were more than 0.5 SDU. In the RT-CGM/CSII group, the mean score for comparison of current and prior insulin delivery system among those who had switched to RT CCM/CSII from free-standing CSII was 85.2 ± 21.3; the integrated CSII device was rated significantly ($p < .001$) better than the free-standing CSII device (results not shown in table). The difference from the neutral rating (50, indicating that the devices are equal) was more than 0.5 SDU.

When study group comparisons were adjusted for respondent demographic and disease characteristics, results were substantively the same as the unadjusted results.

Health-Related Quality of Life

Results are presented in **Table 2**. For analyses unadjusted for respondent demographic and disease characteristics, the RT-CGM/CSII group gave significantly better ratings than the SMBG + CSII group for 1 of 4 measured

Table 2.
Respondent Ratings of Blood Glucose Monitoring System, Insulin Delivery System, and Quality of Life by Treatment Group[a]

Category measure	SMBG + CSII (Unadjusted)	RT-CGM/CSII (Unadjusted)	SMBG + CSII (Adjusted)	RT-CGM/CSII (Adjusted)
BG monitoring system				
Convenience	62.4 ± 24.2	57.8 ± 22.8	61.8	58.2
Interference	17.5 ± 24.8[b]	30.6 ± 23.5	18.3[b]	30.0
BG burden	21.5 ± 33.9	22.3 ± 34.5	21.8	22.1
BG control	49.0 ± 24.4	69.1 ± 20.8[b,c]	48.2	69.8[b,c]
Cost satisfaction	50.6 ± 36.3	46.2 ± 40.8	50.2	46.5
Overall satisfaction	52.9 ± 26.2	62.5 ± 22.8[b]	52.2	64.4[b]
Switch BG monitoring system	58.3 ± 27.6	33.2 ± 24.4[b,c]	58.9	32.3[b,c]
Recommend BG monitoring system	69.2 ± 23.2	80.6 ± 21.6[b,c]	68.7	81.1[b,c]
Insulin delivery system				
Convenience	70.7 ± 20.4	78.6 ± 16.9[b]	70.8	78.5[b]
Interference	25.1 ± 23.2	22.5 ± 20.4	25.5	22.9
BG burden	24.5 ± 33.6	18.2 ± 31.0	24.6	18.3
BG control	63.1 ± 22.2	68.7 ± 19.7[d]	62.8	69.0[d]
Cost satisfaction	44.4 ± 35.6	46.6 ± 35.1	44.6	46.5
Overall satisfaction	66.7 ± 22.5	73.4 ± 21.8[d]	66.9	73.2[d]
Switch insulin delivery system	38.4 ± 27.3	24.7 ± 21.9[d]	38.0	24.9[b]
Recommend insulin delivery system	82.9 ± 20.8	87.5 ± 17.8[e]	82.6	87.9[e]
Quality of life				
Worries	48.4 ± 19.4	45.4 ± 18.4	48.7	45.1
Social burden	30.9 ± 18.7	32.4 ± 18.2	31.1	32.4
Positive well-being	55.6 ± 17.7	56.2 ± 17.0	55.4	56.4
Negative well-being	47.5 ± 21.1	42.2 ± 20.2[e]	47.1	42.7

[a] Cell entries are mean (± standard deviation); adjusted means obtained by analysis of covariance with covariates from **Table 1** set to mean values.
[b] $p < .001$ (more positive perception).
[c] Effect size more than 0.5 pooled SDUs.
[d] $p < .01$ (more positive perception).
[e] $p < .05$ (more positive perception).

components of quality of life (negative well-being); the difference was less than 0.5 SDU. When the analysis was adjusted for respondent demographic and disease characteristics, this difference was no longer statistically significant ($p = .073$).

User Acceptance for Real-Time Continuous Glucose Monitoring/Continuous Subcutaneous Insulin Infusion

Respondents' assessments of the specific features of each component of the RT- CGM/CSII system are presented in **Table 3**. On all UAQ measures, the DMS, the CGM device, and the CSII device were rated significantly ($p < .001$) different from neutral in the positive direction. Twelve of 13 measures were more than 0.5 SDU higher than a neutral rating; only CGM comfort was not. Overall ratings of CGM ($p = .008$) and CSII ($p < .001$) were significantly higher than the overall rating of DMS; overall ratings of CSII ($p < .001$) were significantly higher than the overall rating of CGM.

Table 3.
User Acceptance for Integrated Real-Time Continuous Glucose Monitoring/Continuous Subcutaneous Insulin Infusion

Category (*N*) measure	Mean ± standard deviation	SDU[a]	*p*[b]
DMS (109)			
System operation	69.0 ± 30.2	0.63	<.001
Using displays	64.3 ± 22.3	0.64	<.001
Overall assessment	70.3 ± 26.0	0.78	<.001
CGM (154)			
Comfort	59.2 ± 21.2	0.43	<.001
Sensor operation	62.3 ± 18.4	0.67	<.001
Using displays	74.6 ± 16.7	1.47	<.001
Alarms	69.9 ± 18.5	1.08	<.001
Overall assessment	79.6 ± 21.5	1.37	<.001
CSII (154)			
Comfort	72.2 ± 18.7	1.19	<.001
Pump operation	81.6 ± 16.0	1.98	<.001
Alarms	70.4 ± 17.4	1.17	<.001
Bolus Wizard	76.6 ± 24.2	1.10	<.001
Overall assessment	88.8 ± 15.3	2.54	<.001

[a] Difference of mean from neutral rating in SDUs.
[b] One-sample *t* test for difference from neutral rating (mean not equal to 50, two tailed).

Discussion

The integrated RT-CGM/insulin pump system was associated with statistically significant advantages over SMBG + CSII. Overall, respondents preferred RT-CGM/CSII over SMBG + CSII, and respondents using RT-CGM/CSII were more satisfied with their BG monitoring and insulin delivery devices, were more likely to recommend their system than respondents using SMBG + CSII, and were less likely to want to switch to another treatment system. Many of the statistically significant differences met the criterion for a "minimally detectable difference" (an effect size of "moderate" to "large").

Blood Glucose Monitoring System

Continuous glucose monitoring was rated as significantly superior to SMBG for half of the group comparisons, including all the overall assessments (satisfaction, desire to switch, and willingness to recommend). The advantage in overall satisfaction/willingness to recommend was due primarily to the large advantage for CGM in perceived glucose control efficacy, which was more than enough to offset a smaller but statistically significant disadvantage in interference. The latter finding might reflect the relative simplicity of SMBG. Earlier studies in children found moderately high satisfaction with one CGM system[17] and much lower satisfaction (and declining use over time) with a system no longer in the market that used a different technology.[18] Skin irritation, excessive alarms, and inaccurate readings were the most common reasons given for declining use.

It would seem that the system investigated in the present study represents a viable alternative to the systems studied earlier, although it is not possible to make direct comparisons due to differences in the assessment measures and subject populations (adults versus children) in the different studies.

Insulin Delivery System

The RT-CGM/CSII group gave higher ratings to their pump device than those using the pump with SMBG for several insulin delivery system measures (convenience, glucose control efficacy, overall satisfaction, and interest in switching devices). Moreover, those who had switched from SMBG + CSII to RT-CGM/CSII rated the latter as being better. These differences might be the result of a halo effect for those using the RT-CGM/CSII system (i.e., a tendency for participants using this system to generalize perceived CGM benefits to the CSII component of the RT-CGM/CSII system). Alternatively, these differences

may reflect synergistic effects of combining CSII with CGM, e.g., the pump can be used more easily and effectively when continuous glucose information is transmitted directly from the CGM device to the pump.

Health-Related Quality of Life

Those using the RT-CGM/CSII system reported more favorable HRQOL than those using SMBG + CSII on only one measure: negative well-being; but this difference was not significant after adjustment for respondent characteristics. Thus our results suggest that using the RT-CGM/CSII system results in neither improvement nor deterioration in the components of quality of life measured in this study. While it is possible that the greater treatment satisfaction reported by RT-CGM/CSII users in this study is not accompanied by greater HRQOL, it is also possible that the quality of life measures included in this study were not sensitive to the quality of life effects of RT-CGM/CSII use.

User Acceptance

Respondents gave positive ratings to the specific features of the components of the integrated RT-CGM/CSII. These include the operation and use of displays for all three components (DMS, CGM, CSII). Respondents gave positive ratings for ease of use and clinical benefits to the alarms of both CGM and CSII and to the Bolus Wizard feature of the pump device. These findings support those of an earlier study that use of the bolus calculator (a feature of the system evaluated in the current study) was associated with a high level of patient satisfaction.[2]

Our finding that patients were very satisfied with all aspects of the CGM system differs from a report of low levels of satisfaction among children using another system, with frequent reports of skin irritation, excessive alarms, and inaccurate readings.[18] Differences between our findings and those of the earlier study could be a result of several factors, including the technical and operation features of the systems, the training received, and differences between child and adult patients.

One drawback with the RT-CGM/CSII treatment system examined in this study is the fact that only 67% of respondents in this group reported using the data management system. This represents a substantial opportunity for improved clinical outcomes.

Study Strengths and Limitations

This study is the first to assess treatment satisfaction and HRQOL for treatment systems used by patients engaged in the most technologically advanced intensive insulin therapy. The study included large samples of patients using each treatment system, used validated instruments to study both the BG monitoring and insulin delivery components, and incorporated detailed assessments of all components of the integrated RT-CGM/CSII system.

The major study limitation is the fact that the treatment groups were not created by random assignment. We used several strategies to control for potential bias that might result. First, the sampling frames for both groups were defined by interest in using the integrated RT-CGM/insulin pump system, yielding a common inclusion criterion. It is possible that those who did not receive this system were disappointed (resulting in worse ratings of their treatment system), but this is a problem with all open-label studies, including RCTs.[19] Like studies with conventional random assignment to treatment arm, participants indicated their willingness to use either treatment system, and the treatment they received was based on an external decision rather than their preference. We also attempted to compensate for potential sources of bias by controlling for several respondent characteristics, but it is not possible to control for all potentially relevant characteristics.

A second limitation is that the group using the integrated RT-CGM/insulin pump system did not include those who might have used the system and then terminated its use due to negative perceptions of the system (those who would be identified as "early terminators" in a clinical trial). Including such "early terminators" in the current study might have reduced the differences between RT-CGM/CSII users and SMBG + CSII users reported here.

Finally, in this study it was not possible to compare patient-reported benefits of the RT-CGM/CSII system with objective measures of those benefits (e.g., effects on glucose levels), because we had no data on these objective measures, so we do not know whether the perceived benefits correspond to the actual benefits. Other studies have shown a strong association between clinical outcomes and associated perceived benefits.[20,21]

In spite of these limitations, the study did identify differences in treatment system perceptions between current users of SMBG + CSII and RT-CGM/CSII.

Clinical Implications

The primary clinical implication of this study is that a RT-CGM/CSII system combining an insulin pump with RT-CGM and DMS may result in patients' perceiving more benefits of treatment and higher treatment

satisfaction and be preferred over treatment systems that do not incorporate RT-CGM and DMS. These findings suggest that patients can and will use the integrated RT-CGM/insulin pump system under real-world conditions (rather than in a clinical trial setting). In combination with studies demonstrating that use of such a system could improve clinical outcomes,[1,3] our findings provide reason for optimism about the potential value of this development in diabetes management technology.

Research Implications

The study did not examine all possible combinations of "low-tech" and "high-tech" treatment system components (i.e., SMBG + MDI and CGM + MDI). While many patients use SMBG + MDI, few patients use CGM + MDI, and there were not enough of the latter in the sampling frame to include in the study. As more MDI patients switch from SMBG to CGM, it will become possible to include such patients in naturalistic studies such as the one reported here. Ultimate determination of the contribution of the insulin delivery system and BG monitoring components to study outcomes would require a four-group (2 x 2 factorial) RCT examining all possible combinations of these components. This would allow us to determine the independent contribution of CGM and CSII separately and in combination to improvement over "low-tech" treatment (SMBG with MDI).

A number of research questions still need to be answered, including (1) how many patients would use the integrated RT-CGM/CSII treatment system if it were available to them, (2) whether the benefits of this system are larger/smaller for particular patient segments, and (3) whether patients are able to use this system consistently over the long term. Answers to these questions will allow clinicians, payers, and patients to make the necessary decisions about how to use this new advance in diabetes management technology.

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