Telecare for Patients With Type 1 Diabetes and Inadequate Glycemic Control

A randomized controlled trial and meta-analysis

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OBJECTIVE — To determine the efficacy of telecare (modem transmission of glucometer data and clinician feedback) to support intensive insulin therapy in patients with type 1 diabetes and inadequate glycemic control.

RESEARCH DESIGN AND METHODS — Thirty-one patients with type 1 diabetes on intensive insulin therapy and with HbA_{1c} >7.8% were randomized to telecare (glucometer transmission with feedback) or control (glucometer transmission without feedback) for 6 months. The primary end point was 6-month HbA_{1c}. To place our findings in context, we pooled HbA_{1c} change from baseline reported in randomized trials of telecare identified in a systematic review of the literature.

RESULTS — Compared with the control group, telecare patients had a significantly lower 6-month HbA_{1c} (8.2 vs. 7.8%, $P = 0.03$, after accounting for HbA_{1c} at baseline) and a nonsignificant fourfold greater chance of achieving 6-month HbA_{1c} ≤7% (29 vs. 7%; risk difference 21.9%, 95% CI −4.7 to 50.5). Nurses spent 50 more min/patient giving feedback on the phone with telecare patients than with control patients. Meta-analysis of seven randomized trials of adult patients with type 1 diabetes found a 0.4% difference (95% CI 0–0.8) in HbA_{1c} mean change from baseline between the telecare and control groups.

CONCLUSIONS — Telecare is associated with small effects on glycemic control in patients with type 1 diabetes on intensive insulin therapy but with inadequate glycemic control.

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The Diabetes Control and Complications Trial (DCCT) and the Stockholm Diabetes Intervention Study (SDIS) showed that intensive diabetes management prevents and decreases the development and progression of the microvascular complications of type 1 diabetes (1,2). Patients in the intensive therapy group in the DCCT visited their study center every week until the target range was achieved and then monthly thereafter. They received weekly telephone contact to adjust their regimens (1). Patients randomized to intensive therapy in the SDIS initially received face-to-face and telephone contact every second week (2). This level of care, and the outcomes that resulted from it in randomized trials (in terms of glycemic control and microvascular complications), have been difficult to implement in clinical practice (3,4) despite strong evidence of its favorable impact on average cost and life expectancy (5,6).

The 2003 American Diabetes Association Position Statement (7) on tests of glycemia in diabetes states that self-monitoring of blood glucose is important to achieve glycemic control in patients with type 1 diabetes. Self-monitoring of blood glucose permits patients to make daily therapeutic decisions to maintain desired blood glucose levels (8,9). In contrast to multifaceted interventions that relied on self-monitoring and include face-to-face advice and support (1,2), there is inconclusive evidence that self-monitoring alone improves outcomes in patients with type 1 diabetes (10,11). Motivated patients who self-monitor and have access to ongoing advice from a health professional may be better able to achieve the results observed in the DCCT and SDIS.

Over the last decade, several studies have addressed the feasibility, safety, and efficacy of substituting diabetes telecare for expensive and logistically challenging face-to-face contact (12–14). Diabetes telecare involves patient transmission of self-monitored blood glucose and feedback (including support and advice) from a diabetes health professional. Whether the provision of telecare can assist in the delivery of intensive advice and support remains unknown.

To study the effect of telecare on the glycemic control of patients with type 1 diabetes on intensive insulin programs who were failing to achieve glycemic control, we conducted a randomized controlled trial. To place our findings in the context of the available evidence, measure

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V.M.M. and Y.C.K. had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Abbreviations: DCCT, Diabetes Control and Complications Trial; IQR, interquartile range; SDIS, Stockholm Diabetes Intervention Study; SDSCA, Summary of Diabetes Self-Care Activities.

the effect of telecare with precision, and ascertain the generalizability of this effect across a wider population, we conducted a systematic review of randomized trials of telecare on glycemic control in patients with type 1 diabetes and performed a meta-analysis of these trials.

RESEARCH DESIGN AND METHODS

—The Mayo Foundation Institutional Review Board approved the study protocol.

Randomized controlled trial

Patients were eligible to participate in this study if they had *1*) documented type 1 diabetes (with C-peptide ≤0.02 nmol/l) of >1 years' duration and 2) inadequate glycemic control (HbA_{1c} ≥7.8%). Patients had completed a 3-day educational program to learn intensive insulin management (15), were using multiple daily insulin injections or insulin pumps, and were receiving usual diabetes care in a diabetes clinic. Patients were excluded if they were pregnant or planning pregnancy.

Randomization procedure. After confirming eligibility and obtaining written informed consent, the study coordinator obtained the patient allocation from the randomization center. A computer generated the allocation sequence using adaptive randomization (16) to minimize differences between the groups in baseline HbA_{1c} (≥9%), glucose goals (80–100 mg/dl [4.4–6.7 mmol/l] or 100–140 mg/dl [5.5–7.8 mmol/l]), and use of a portable insulin pump.

Interventions. We trained all patients enrolled in this study to connect an Accu-link modem to an Accu-Chek Complete glucometer (Roche Diagnostics, Indianapolis, IN) and the phone line and to transmit glucometer data to the research computer. Glucose analysis software on this computer assisted the study nurse with interpretation.

We asked all patients to monitor their blood glucose four times per day, 7 days per week, and to transmit the recorded glucometer data at least every 2 weeks. Patients allocated to the telecare arm received feedback within 24 h of transmission from a study nurse supervised by a clinical endocrinologist. Patients allocated to the control arm did not receive unsolicited feedback, but contacted the study nurse as frequently as necessary. All patients received face-to-face diabetes care at clinic visits every 3 months.

Outcome measures. The primary outcome measure was HbA_{1c} (measured in the same reference laboratory using a high-performance liquid chromatography technique [BioRad, Hercules, CA] by personnel blinded to allocation) 6 months after randomization. Secondary outcome measures included proportion achieving HbA_{1c} ≤7% at 6 months, number and severity of hypoglycemic episodes (as defined in the DCCT [1]), the time the nurse spent in reviewing data and providing patients with feedback, and the time the physicians spent in supervising the study nurse. To assess the impact of the intervention on diabetes self-management, patients completed the valid and reliable Summary of Diabetes Self-Care Activities (SDSCA) questionnaire (17) at baseline and at 6 months after randomization.

Statistical analyses. We estimated the sample size of our study (15 participants per arm) using the distribution of HbA_{1c} at baseline (SD of 1.5%) in the DCCT (1), α of 5%, β of 20%, and an estimated difference in the HbA_{1c} change at the end of 6 months of 1.5% (1 SD). We analyzed all patients in the arms to which they were randomized. To take into account imbalances in HbA_{1c} at baseline, we assessed the effect of treatment (fixed factor) on 6-month HbA_{1c} (dependent variable) after accounting for baseline HbA_{1c} (as covariate) using a general linear model; we also tested whether there was interaction between baseline HbA_{1c} and treatment. We estimated the risk difference for count data (e.g., number of patients achieving HbA_{1c} ≤7%) and its 95% CI using the Wilson method (18). We estimated the median difference in the change in SDSCA scores from baseline to 6 months between the groups and its 95% CI using the bootstrap technique with 10,000 iterations (19) using Resampling Procedures version 1.3 (copyright 2002, D.C. Howell).

The systematic review and meta-analysis

Review protocol. We included randomized controlled trials of telecare (transmission of glucometer data and feedback by health professional) in patients with type 1 diabetes compared to usual care, to other forms of data transmission, or to transmission without feedback. Studies that included other forms of telemedicine without glucometer transmission (i.e., video link and telephone consultation) or mixed patient populations (i.e., type 1 and type 2 diabetes) were not eligible. We conducted electronic searches in Medline, Embase, Cinahl, and HealthStar (from 1982 to June 2003) as well as on the Internet (Google). Working independently and in duplicate, two investigators reviewed all abstracts, selected studies for inclusion, and extracted data about study design and results (HbA_{1c}). Hypoglycemia episodes were incompletely reported, and we do not include those results in this report. We contacted two authors when data needed were missing; one responded with the requested information. Details of excluded studies and the review flowchart are available from the authors.

Meta-analysis

We pooled the standardized mean difference in change of HbA_{1c} from baseline from randomized trials included in the systematic review using random-effects meta-analysis (DerSimonian and Laird method) on Revman 4.2 (Cochrane Collaboration, 2003). We pooled the SD of the change (baseline − end of study) in HbA_{1c} in each group; if these data were unavailable, we pooled the SD of HbA_{1c} at baseline in each group (20). We quantified heterogeneity, the proportion of between-study variability due to study differences (i.e., not due to random error), using the I^2 method (21). A priori, we decided to examine differences in patients studied (enrollment of patients with well-controlled versus poorly controlled diabetes), interventions (frequency of transmission and feedback), length of follow-up (<6 months and ≥6 months), and methods (allocation concealment and loss to follow-up) to try to explain heterogeneity of results.

RESULTS

Study conduct and primary outcomes

Figure 1 describes the flow of the 31 enrolled patients through the study. HbA_{1c} at 6 months was not available for three patients, two in the telecare intervention arm and one in the control arm. Table 1 describes patient characteristics at baseline; there was an imbalance in HbA_{1c}. There was a significant between-group difference in the 6-month HbA_{1c} (telecare 7.8 ± 1.3% vs. control 8.2 ± 1.2%) after

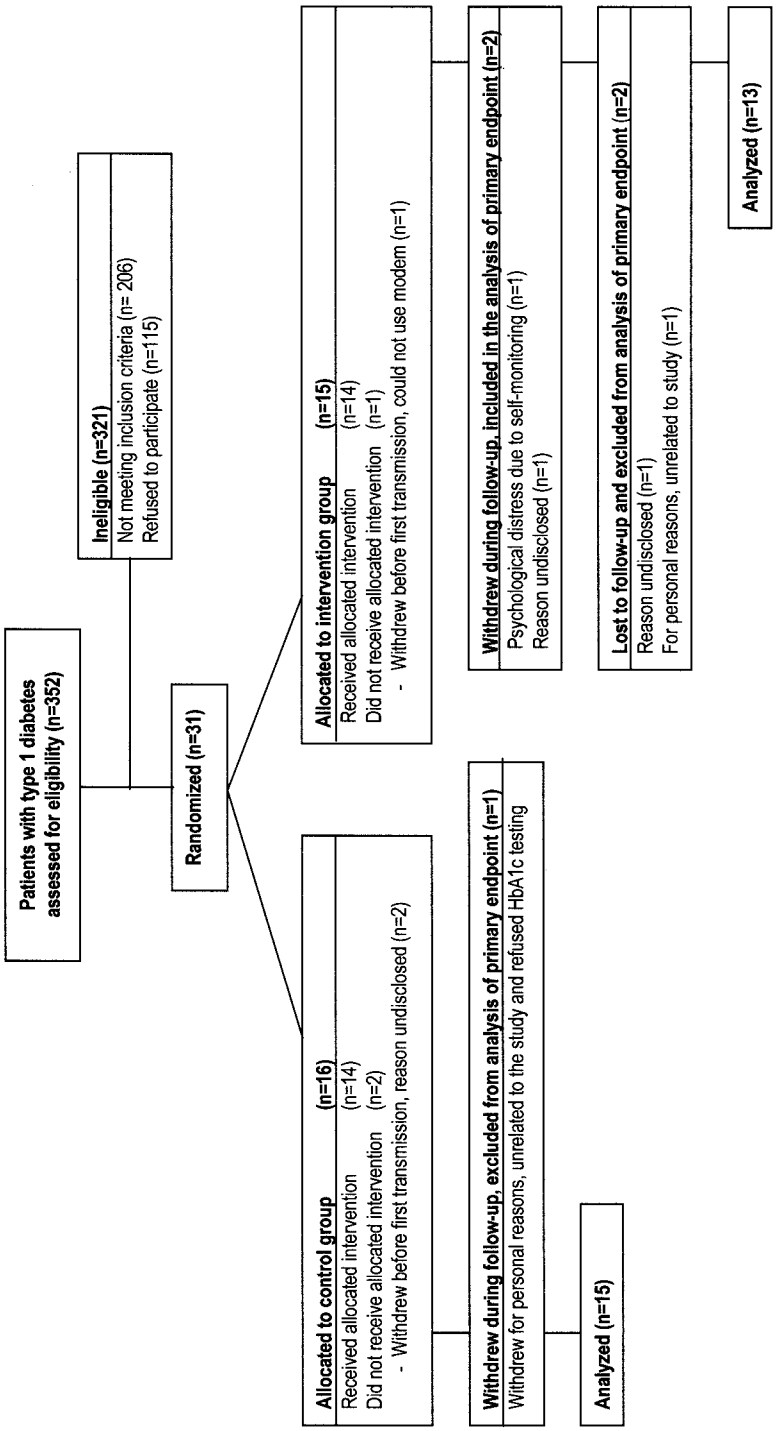

Figure 1—*Flow of patients through the study. Patients who refused participation had a median HbA_{1c} of 8.4% (IQR 7.9–9.4).*

taking into account the difference in HbA_{1c} at baseline ($P = 0.03$). There was no significant interaction between baseline HbA_{1c} and treatment ($P = 0.1$).

Secondary outcomes

Glycemic control. Four of 14 (29%) patients in the telecare intervention arm and 1 of 15 (7%) in the control arm had 6-month $HbA_{1c} \leq 7\%$ (risk difference 21.9%, 95% CI −4.7 to 50.5). There were no episodes of ketoacidosis and three episodes of severe hypoglycemia in each group. After taking into account the difference in insulin doses at baseline, there were no differences in insulin doses (total, basal, and bolus doses) between the groups at 6 months ($P = 0.8$, 0.4, and 0.8, respectively). However, telecare patients had more documented dose changes than the control group during the duration of the study (14 vs. 6, $P = 0.04$); most of these changes occurred during the first 3 months of the study (9 vs. 3, $P = 0.007$).

There was no difference between telecare and control groups in the mean proportion of transmitted values above goal per patient (64%, 95% CI 57–71 vs. 66%, 59–73) and in the mean proportion of transmitted values <60 mg/dl (3.3 mmol/l) per patient (9%, 5–13 vs. 9%, 6–11).

Modem transmissions. During the first 2 months of the trial, patients in the telecare group transmitted a median of six times (interquartile range [IQR] 5–9), whereas the control group transmitted five times (IQR 4–9). During the last 2 months of the trial, telecare patients transmitted five times (IQR 4–8) and control patients 4 times (IQR 3–7). During the first month, patients in both groups monitored 4.1 times per day (95% CI 3.7–4.5). During the last month of the trial, telecare patients self-monitored a mean of 3.6 times per day (95% CI 2.8–4.4) and control patients 3.5 times per day (95% CI 2.9–4).

Self-monitoring. At 6 months, there was a median 10.7% increase from baseline in the blood glucose testing subscale of the SDSCA in the telecare intervention arm and a median 0% change in the control group (median difference in percentage change between telecare and control arms: 10.7%, 95% CI 0–32.1). Patients in both groups reported self-monitoring their blood glucose a median of 6 days per week (IQR 3–7) at baseline and 7 days per week at 6 months (IQR 5–7). Patients in

Table 1 —*Patient characteristics at randomization*

Characteristics	Control	Intervention
n	16	15
Age (years)	44 (32.3–46.8)	41.8 (24.4–52.7)
Sex (% women)	11 (68.8)	10 (66.7)
Diabetes duration (years)	17.2 (10.1–27.1)	16.9 (14.6–27.4)
BMI (kg/m^2)	25.9 (22.3–30.6)	26 (25–28.6)
Creatinine (mg/dl)*	0.9 (0.8–1.1)	1.0 (0.9–1.4)
HbA_{1c}		
Percent	8.8 ± 1.22	9.1 ± 1.3
Distribution (%)	8.3 (7.8–9.7)	8.8 (8.3–9.7)
>10.5%	5 (31.3)	5 (33.3)
Goal range		
80–120 mg/dl (4.4–6.7 mmol/l)	9 (56.3)	9 (60)
100–140 mg/dl (5.5–7.8 mmol/l)	7 (43.7)†	6 (40)
Insulin pump	5 (31.3)	5 (33.3)
Hypoglycemic unawareness	7 (43.8)	5 (33.3)
Daily insulin units		
Total dose	47 ± 19	50 ± 14
Total basal dose	25 ± 12	26 ± 10
Total bolus dose	23 ± 10	25 ± 6

Data are means ± SD, *n* (%), or median (IQR).*To convert to Système International (SI) units (μmol/l), multiply values by 88.4; †one patient had a glucose goal range of 90–150 mg/dl (5–8.3 mmol/l).

both groups reported self-monitoring their blood glucose four times per day a median of 4 days per week (IQR 3–7) at baseline and 5 days per week at 6 months (IQR 3–7). There were no differences in the change in scores (6 month − baseline) of the SDSCA between the two groups for the general diet, specific diet, exercise, foot care, smoking status subscales, and adherence to insulin doses.

Clinician review and feedback time measures. The clinical endocrinologists spent a median of 9 min per patient (IQR 3–17) reviewing data transmission with the study nurse and 0 min (IQR 0–6) reviewing data from control patients. The nurse spent as a median of 76 min reviewing data from each telecare patient during the 6 months of the study (IQR 43–107) and 12 min (IQR 9–22) reviewing data from control patients. Finally, the nurse spent a median of 68 min (IQR 36–119) providing feedback to telecare patients and 18 min (IQR 13–31) providing feedback to control patients. In other words, during the 6 months of the trial, the average telecare patient spent a total of 1 h on the phone discussing diabetes care with a nurse who had reviewed data for 2.4 h (10 min of which with a clinical endocrinologist); the average usual care patient spent only 17 min on the phone with a nurse who had reviewed data for 30 min. We found a significant correlation (Pearson 0.56, $P < 0.001$) between nurse feedback time and the number of documented insulin dose changes.

Systematic review and meta-analysis of the literature

Two reviewers working independently considered six trials published in seven manuscripts (22–28) eligible for review, with perfect interobserver agreement (Table 2). One additional eligible study was presented as a poster at the 63rd Scientific Sessions of the American Diabetes Association in June 2003 (29). Meta-analyses of these eight studies (including the trial reported in this work) showed that telecare was not significantly different from usual care (pooled HbA_{1c} change from baseline: 0.2%, 95% CI −0.2 to 0.6%) (Fig. 2). We could not explain heterogeneity with any of our hypotheses stated a priori. One-third of the variability in the pooled estimate came from between-study differences ($I^2 = 34\%$) that were completely accounted for by excluding the only randomized controlled trial in children with type 1 diabetes (I^2 after exclusion of this study = 0%). The result from this latter study was significantly different from the pooled HbA_{1c} change from baseline from the studies of adults with type 1 diabetes ($P = 0.02$), which was 0.4%, 95% CI 0–0.8. The result was similar after excluding the randomized controlled trial of telecare in pregnant patients with type 1 diabetes (0.5%, 95% CI 0.05–0.9).

CONCLUSIONS — In this randomized trial of telecare versus modem transmission in patients with type 1 diabetes on an intensive insulin regimen but failing to achieve glycemic control (as judged by their HbA_{1c} levels), we found telecare to have a small impact on glycemic control. We saw a trend in enhanced adherence to self-monitoring (greater in the telecare group) and better glycemic control in both groups. The main difference in care delivery between the two groups was in the health professional's time. Greater nurse feedback time was associated with more insulin dose changes, and significantly more insulin dose changes occurred in the telecare group.

Strengths and limitations of our study

Our study has several strengths. This is the first study to offer modem transmission to the control group to isolate the effect of clinician feedback in the telecare context. It is also a randomized trial conducted with adequate allocation concealment and in accordance with the intention-to-treat principal. We focused our attention on the difficult group of patients with type 1 diabetes on intensive insulin therapy who were failing to achieve recommended glycemic goals despite intense education and usual specialist diabetes care. Limitations include a follow-up period limited to 6 months, loss of 3 of 31 patients to follow-up, the imbalance in baseline HbA_{1c}, and the borderline statistical significance of our results.

Our study in the context of the available evidence for telecare

Our study is unique in that we asked patients in the control group to regularly transmit their glucose levels, thus controlling for modem transmission per se. Our study shares the limitations of previous studies, which include enrolling a small sample, following them for a brief period (maximum follow-up was 12 months in two studies [26,29], 6 months in four others, and 3 months in another one [24]), and losing about 10% of patients to follow-up.

Table 2 —*Systematic review of the literature*

Study	Patients	Intervention	Control	Face-to-face consultations	Study design	Outcome
Pediatric patients						
Marrero et al., 1995 (26)	106 type 1 diabetic pediatric patients on multiple daily insulin injections with inadequate control.	Modem transmission every 2 weeks, with clinician feedback (algorithm triggered).	No scheduled inter-visit contacts or data transmission.	Every 3 months.	Parallel RCT. No report of loss to follow-up. Outcome: HbA_{1c} at 6 and 12 months.	Telecare: Mean HbA_{1c} (nl 6.5–8.0%) changed from 9.4% to 9.6 (6 months) and to 10.0 (12 months). Control: Changed from 9.9% to 9.7 (6 months.) and to 10.3 (12 months.). Difference: NS
Pregnant patients						
Wojcicki et al., 2001 (27)	32 pregnant type 1 diabetic patients using intensive insulin therapy and with inadequate control.	Nightly modem transmission, with daily clinician feedback.	No scheduled inter-visit contacts or data transmission.	Every 3 weeks.	Parallel RCT. Two patients were excluded from analysis because of illness after randomization. Outcome: HbA_{1c} at 6 months.	Telecare: Mean HbA_{1c} (nl NR) changed from 7.9% to 6.8. Control: Changed from 8.1% to 6.7. Difference: NS
Adult patients						
Ahring et al., 1992 (24)	42 type 1 diabetic patients not using intensive insulin therapy and with inadequate control.	Modem transmission every week, with clinician feedback	No scheduled inter-visit contacts or data transmission.	At baseline, 6 weeks, and 12 weeks.	Parallel RCT. Two patients lost to follow-up from each arm. Outcome: HbA_{1c} at 3 months.	Telecare: Mean HbA_{1c} (nl 4.5–9.0%) changed from 10.6% to 9.2. Control: Changed from 11.2% to 10.2. Difference: NS
Gómez et al., 2002 (28)	10 type 1 diabetic patients with inadequate glycemic control.	Modem transmission every 2 weeks, with clinician feedback within the 24 h following each transmission.	No scheduled inter-visit contacts or data transmission.	Every 6 months.	Crossover RCT (period duration of 6 months). No data reported on loss to follow-up. Outcome: HbA_{1c} at 6 months.	Telecare: Median HbA_{1c} (nl NR) changed from 8.4% to 7.9. Control: Changed from 8.1% to 8.2. Difference: NS
Bierdmann et al., 2002 (22,23)	48 type 1 diabetic patients using intensive insulin therapy and with inadequate control.	Modem transmission at least every 2 weeks, with clinician feedback every 2 to 4 weeks.	Face-to-face visits at least every month.	Every 2 months.	Parallel RCT. Five patients lost to follow-up at 4 months. Outcome: HbA_{1c} at 4 months (data at 8 months available for only 21 patients).	Telecare: Mean HbA_{1c} (nl NR) changed from 8.3% to 6.9. Control: Changed from 8.0% to 7.0. Difference: NS
Chase et al., 2003 (25)	70 type 1 diabetic patients with some receiving intensive insulin therapy and with a wide range of glycemic control.	Every 2 weeks, with clinician feedback.	No scheduled inter-visit contacts or data transmission.	Every 3 months (omitting the mid-third month visit in the intervention group).	Parallel RCT. Seven patients were excluded from analysis (five from the intervention arm because of failure to transmit data and three from the control arm for failure to attend the 3-month visit). Outcome: HbA_{1c} at 6 months.	Telecare: Mean HbA_{1c} (nl 3.2–6.2%) changed from 9.0% to 8.6. Control: Changed from 8.9% to 8.6. Difference: NS
Welch et al., 2003 (29)	52 type 1 diabetic patients with poor glycemic control.	Every 2 to 4 weeks, with clinician feedback.	No scheduled inter-visit contacts or data transmission.	Every 3 months.	Parallel RCT. Of 52 patients, 18 (10 from the control arm) and 28 (16 from the control arm) were lost to follow-up at 6 and 12 months, respectively. Outcome: HbA_{1c} at 6 and 12 months.	Telecare: Mean HbA_{1c} changed from 8.9% to 8.6 (6 months) and to 8.5 (12 months). Control: Changed from 9.1% to 8.9 (6 months) and to 9.0 (12 months). Difference: NS at 6 and 12 months.
Montori et al., 2004 (present study)	31 type 1 diabetic patients using intensive insulin therapy and with inadequate control.	Modem transmission at least every 2 weeks, with clinician feedback.	Modem transmission at least every 2 weeks, with clinician feedback on demand.	Every 3 months.	Parallel RCT. Three patients lost to follow-up (two from the intervention arm). Outcome: HbA_{1c} at 6 months.	Telecare: Mean HbA_{1c} (4.0–6.1%) changed from 9.1% to 7.8. Control: Changed from 8.8% to 8.2. Difference (after adjusting for baseline difference in HbA_{1c}): $P = 0.03$.

nl, normal range; NR, not reported; RCT, randomized controlled trial.

The strongest inference about the true magnitude of telecare effect on glycemic control comes from our meta-analysis. Taken together, the literature on telecare among adult patients with type 1 diabetes effectively rules out larger effects of ≥1% in HbA_{1c}. The results are consistent with a small significant effect on diabetes control, but this inference is dependent on a post hoc subgroup analysis that one could question.

Implications for research, policy, and practice

Clinicians and policymakers have limited information (summarized here) about the efficacy of telecare in patients with type 1 diabetes. Given the wide CIs that include negligible treatment effects in spite of pooling all of the available evidence, stronger inferences about effectiveness would require additional studies.

While it is possible for telecare to replace usual care for some patients (25), particularly those with limited access to health professionals, the available evidence does not inform us about the patient subgroups most likely to benefit. A recently published randomized trial of intensive insulin therapy versus usual care among young patients with type 1 diabetes documented greater improvement in HbA_{1c} from intensive treatment (including intensive face-to-face advice and support) in the subgroup of patients least competent in self-management (30). It is plausible that delegation of routine diabetes support to nonphysician clinicians (31) and to telecare to replace routine face-to-face visits among patients with adequate self-management skills who are doing well may free up resources (e.g., clinical encounter appointment slots with a diabetologist) to deliver intensive advice and support to patients with limited self-management skills and who are not doing well.

Summary

In summary, telecare (the transmission of glucometer data followed by nurse-mediated feedback and support) augmenting usual care among patients with type 1 diabetes and inadequate glycemic control had a small effect on glycemic control compared with the transmission of glucometer data without feedback in the context of usual care. A meta-analysis of the available evidence on telecare in patients with type 1 diabetes was consis-

Figure 2—*Meta-analysis of randomized trials of telecare versus usual care in patients with type 1 diabetes. To convert the pooled standardized mean difference (SMD) to usual HbA_{1c} units, multiply by 1.5 (the SD in the DCCT trial).*

tent with the findings of our trial and effectively ruled out larger treatment effects (change in $HbA_{1c} \geq 1\%$). Taken together, the evidence is insufficient to recommend telecare or to identify a subgroup of patients most likely to benefit from this technology.

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