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Continued Use of an Integrated Meter with Electronic Logbook Maintains Improvements in Glycemic Control Beyond a Randomized, Controlled Trial

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ABSTRACT

Background: Blood glucose monitoring is an important component of diabetes self-management for individuals with insulin-treated diabetes. Although patient-maintained logbooks are routinely used, glucose values may be inaccurately recorded or not recorded at all. Electronic logbooks may help overcome such problems. We conducted a randomized, controlled trial (RCT) to compare glycemic control in insulin-treated participants using integrated glucose meters and electronic logbooks (Electronic Group) with participants using conventional meters and paper logbooks (Paper Group), and to determine persistence of glycemic improvements during long-term observational follow-up.

Methods: After a 4-week run-in, adult and pediatric participants ($n = 205$) with stable hemoglobin A_{1C} (A1C) $\geq$8.0% were randomized, and their logbook data and A1C were monitored every 4 weeks for 16 weeks. After the RCT, patients selected their monitoring systems and resumed usual care. The four resulting subgroups, defined by whether patients continued or changed monitoring systems, were reassessed after 26–65 weeks.

Results: During the RCT, mean A1C decreased −0.27% in the Paper Group and −0.35% in the Electronic Group. Repeated-measures analysis revealed that the mean decrease was significantly greater in the Electronic than the Paper Group ($P = 0.022$). From randomization through observational follow-up, participants consistently using integrated meters/logbooks had an A1C decrease of −0.36% ($P = 0.008$), whereas participants using conventional meters/logbooks throughout or switching meters returned to pre-enrollment A1C levels.

Conclusions: Compared to conventional monitoring systems, use of an integrated meter and electronic logbook resulted in modest, but significant and sustained, improvement in A1C in insulin-treated patients with suboptimal glycemic control during an RCT and observational follow-up.

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INTRODUCTION

LARGE PROSPECTIVE CLINICAL TRIALS have shown that intensive treatment of diabetes can reduce the risk of chronic complications.[1–5] Despite advances in pharmacologic therapies and monitoring technologies, glycemic control is suboptimal in the United States, with over 60% of people with diabetes having hemoglobin A_{1C} (A1C) values above 7.0%.[6,7]

Self-monitoring of blood glucose (SMBG) improves glycemic control in individuals with poorly controlled insulin-treated diabetes,[8–11] and increased monitoring frequency has been linked to lower A1C values.[10,12–20] Although SMBG with patient-maintained logbooks is routinely used, glucose values and other data may be inaccurately recorded.[21–23] SMBG meters with electronic logbooks or electronic diaries promote adherence and pattern recognition and may overcome the problems associated with written logbooks.[22]

The OneTouch® UltraSmart® System (LifeScan, Milpitas, CA) is an integrated glucose meter and electronic logbook capable of capturing user comments regarding food intake, health status, exercise, and insulin doses. The meter accurately stores blood glucose (BG) results and automatically converts them into meaningful charts and graphs that can be displayed on the meter directly, thus helping patients and their health care professionals (HCPs) determine the impact of medications and life-style. We conducted a randomized, controlled trial (RCT) comparing the use of this integrated meter/logbook with conventional meters and paper logbooks for their ability to improve glycemic control. In addition, to determine whether any glycemic improvements noted in the RCT could be sustained outside the confines of a clinical trial, we performed an observational follow-up measurement of A1C approximately 11 months after the end of the RCT.

RESEARCH DESIGN AND METHODS

Participants

Investigators from seven centers (nine clinical sites) in the United States recruited adult and pediatric (<21 years old) patients with type 1 or insulin-treated type 2 diabetes. Inclusion criteria included a regimen of two or more daily injections or continuous subcutaneous insulin infusion; suboptimal (A1C ≥8%) but stable glycemic control, defined as A1C at week 4 within ±1% of that at enrollment (week 0); and BG monitoring frequency of two or more times daily. Exclusion criteria included previous use of OneTouch UltraSmart; risk of hypoglycemia as a contraindication to improving glycemic control; a regimen of premixed, fixed-ratio combination insulins with an unwillingness to use self-mixed insulins; and active use of meter downloading and computer-based data management software. Institutional protocol approval and informed consent/assent were obtained.

Study design and procedures

RCT. Enrollment in the RCT commenced on August 8, 2003. At enrollment [Study Visit (SV) 1, week 0], participants were informed of the purpose of the study, and blood was drawn for A1C analysis. During a 4-week run-in, participants continued using their current BG meters (14 different meters were used) with written logbooks. At SV2 (week 4), participants were randomly assigned to continue using their current meters and paper logbooks (Paper Group), or to use the integrated glucose meter/logbook (Electronic Group). A stratified, blinded randomization process ensured balance of participants in each group according to age category (adult vs. pediatric) and baseline A1C. Participants in the Paper Group received re-education in the use of their meter and a new meter if their current meter was not functioning properly, whereas participants in the Electronic Group were trained in the use of the integrated meter/logbook, including how to access the "Graph of All Results" and "Average by Time of Day" screens in the electronic log, along with instructions to review these screens with their HCPs. Participants received equivalent time for education, and all necessary supplies for SMBG, regardless of meter assignment. The HCP determined participant glucose monitoring regimens and treatment decisions independent of study protocol. Participants returned

monthly for four visits through week 20 (SV6). At each visit, the participant's meter was downloaded, blood was drawn for central A1C analysis, and the logbook (electronic or paper), current treatment, and SMBG regimen were reviewed. Individualized counseling was provided, and treatment recommendations regarding life-style, monitoring regimens, and insulin adjustments were made. All patients and HCPs were blinded to the results of meter downloads and A1C determinations until the end of the RCT.

Observational follow-up. At the last RCT visit (SV6), participants in the Paper Group were offered the integrated meter and electronic log system. Participants from both groups returned to usual medical center or community care, and all were given the choice of monitoring systems. Glucose monitoring strips were no longer provided. Patients who had been enrolled at sites with 30 or more participants, and who had completed SV6, were recruited to participate in an observational follow-up visit (SV7). The follow-up visit occurred 26–65 weeks (median 45.9 weeks) after the end of the RCT, at which time blood was drawn for central A1C measurement. Meter choices made by patients during the observational period were self-reported at this follow-up visit and verified by the HCP. The last participant completed the observational follow-up on June 2, 2005.

Outcome measures

The primary outcome for both the RCT and observational follow-up was A1C determination after randomization. Additional outcomes of the RCT included SMBG frequency, magnitude of daily glycemic excursions, and occurrence of measured hypoglycemia after enrollment. Meter downloads provided data on frequency of SMBG; daily glycemic excursions (calculated by subtracting the lowest BG from the highest BG measurement within a given day); and the rate of measured hypoglycemia, defined as any BG result <60 mg/dL (<3.3 mmol/L).

Statistical analysis

RCT. A1C analysis included all randomized participants who completed at least one post-randomization study visit. All analyses were conducted using SAS (version 8.2 for Windows, SAS Institute, Inc., Cary, NC). Means ± SD are presented unless otherwise noted. All statistical tests were two-sided with an α level of 0.05 to determine significance. Comparisons included paired and unpaired t tests, χ^2 analysis, and nonparametric tests, where appropriate. A1C data were analyzed using repeated-measures analysis of variance with baseline A1C, defined as the value observed at the time of randomization (SV2), as the covariate.

Observational follow-up. Patient data were divided into four subgroups based on their original randomization into the Paper and Electronic Groups and whether they continued using the meter they were randomized to or switched to a different meter. For each subgroup, average A1C at the observational follow-up visit (SV7) was calculated, as was the average A1C for the patients in that subgroup at each of the other visits. A1C data were analyzed using paired t tests.

RESULTS

RCT

Participant disposition and study design appear in Figure 1. The Paper ($n = 92$) and Electronic ($n = 113$) Groups had similar demographic characteristics, including gender distribution, type of diabetes, ethnicity, age, years since diagnosis, years of SMBG, and monitoring frequencies (Table 1). The Paper and Electronic Groups had similar mean A1C values at enrollment (SV1; 9.13 ± 0.91% vs. 9.06 ± 1.29%) and similar mean reductions from enrollment to randomization (SV2; −0.17 ± 0.45% vs. −0.17 ± 0.40%). From randomization through the end of the RCT, mean A1C decreased −0.27% in the Paper Group and −0.35% in the Electronic Group (Fig. 2). Repeated-measures analysis showed that the mean decrease over this time period was significantly greater in the Electronic Group than in the Paper Group ($P = 0.022$). An analysis of pediatric patients ($n = 70$) showed similar results favoring participants in the Electronic Group ($P = 0.024$).

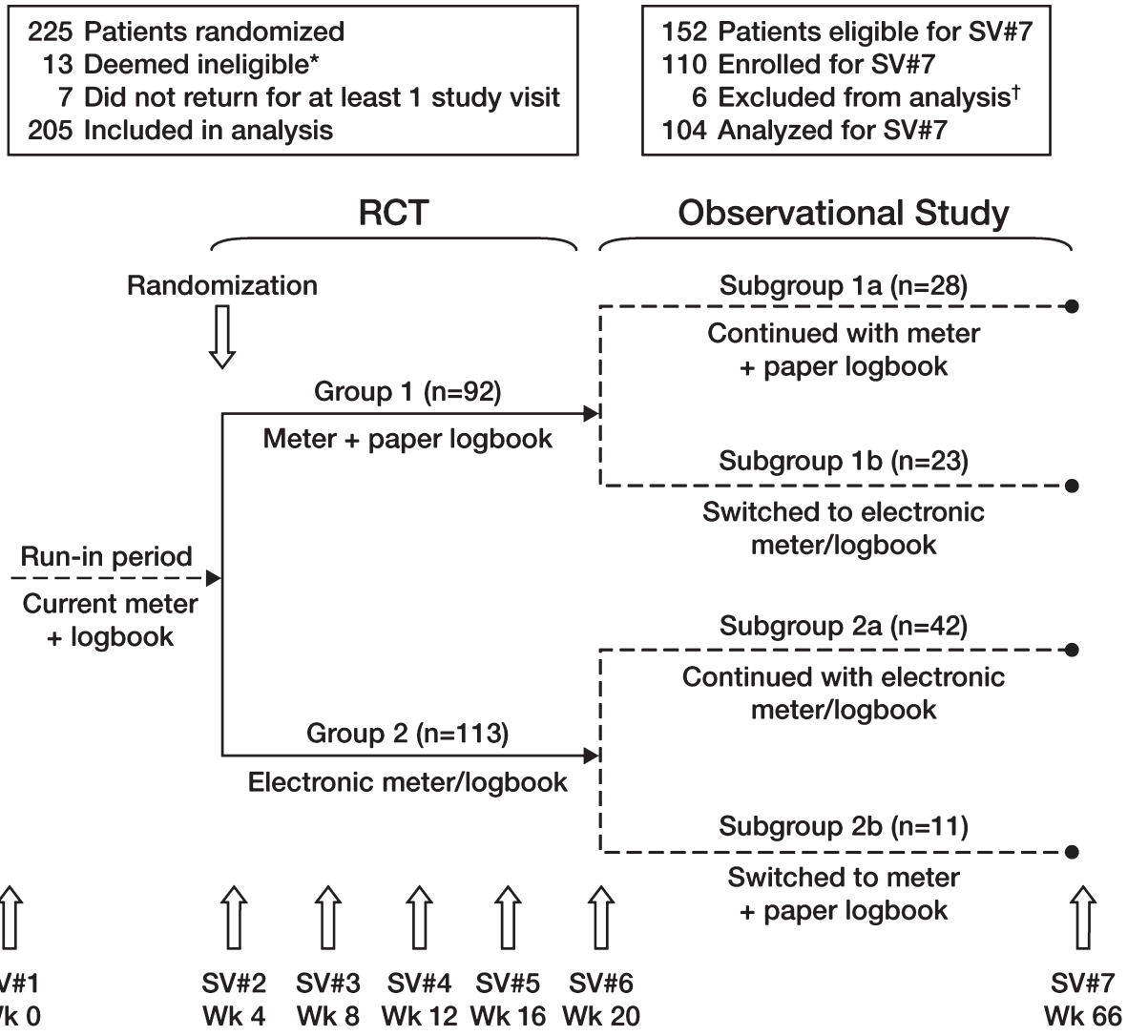

FIG. 1. Design of the RCT and observational follow-up. *A1C at SV2 more than 1.0% different from A1C at SV1. †One became pregnant; five enrolled in another study involving unknown medications that may have affected BG values.

At enrollment, the reported SMBG frequency was similar in the two groups, with 58% in the Paper Group and 59% in the Electronic Group monitoring four or more times per day. From randomization through the end of the RCT, the documented average daily SMBG frequency was significantly greater in the Electronic Group (4.0 ± 1.5 times per day) than in the Paper Group (3.5 ± 1.5 times per day) with 48% of the Electronic Group compared to 30% of the Paper Group monitoring four or more times daily ($\chi^2 = 8.92$, $df = 3$, $P = 0.03$).

Mean Amplitude of Glycemic Excursions (MAGE) did not differ significantly between groups, with daily glycemic excursions generally exceeding 200 mg/dL. However, the rate of measured hypoglycemic events was significantly lower in the Paper Group than in the Electronic Group (1.0 vs. 1.5 events per week, $P < 0.0001$), although no episodes of severe hypoglycemia were reported in either group.

Observational follow-up

Disposition of the 104 patients who returned for SV7 appears in Figure 1; there were no significant baseline inter-subgroup differences (Table 1). Mean A1C at randomization (SV2) was similar in the four subgroups (Table 1). Between SV2 and SV7, mean A1C decreased by

Table 1. Baseline Demographic Characteristics for Participants According to Group Assignment and by SV7 Subgroup

	Paper group (n = *92*)	*Subgroup 1a* (n = *28*)	*Subgroup 1b* (n = *23*)	*Electronic group* (n = *113*)	*Subgroup 2a* (n = *42*)	*Subgroup 2b* (n = *11*)
Age (years)	35.0 ± 18.7	32.5 ± 18.6	32.6 ± 19.0	35.7 ± 19.7	32.9 ± 18.6	28.8 ± 18.5
Gender (male)	42 (45.7%)	10 (35.7%)	12 (52.2%)	49 (43.4%)	17 (40.5%)	3 (27.3%)
Diagnosis						
Type 1	73 (79.4%)	22 (78.6%)	20 (87.0%)	90 (79.6%)	38 (90.5%)	9 (81.8%)
Type 2	19 (20.6%)	6 (21.4%)	3 (13.0%)	23 (20.4%)	4 (9.5%)	2 (18.2%)
Duration of diabetes (years)	14.0 ± 10.0	11.9 ± 9.4	14.4 ± 10.1	13.3 ± 10.3	12.5 ± 10.3	13.2 ± 10.4
Frequency of SMBG (times/day)	3.8 ± 1.2	3.6 ± 1.0	3.9 ± 1.3	3.9 ± 1.4	3.9 ± 1.2	3.8 ± 1.3
A1C (%)	9.13 ± 0.91	9.05 ± 1.01	9.32 ± 0.87	9.06 ± 1.29	8.96 ± 0.96	9.21 ± 1.44

Data are mean ± SD values or number (%) as indicated.

−0.36 ± 0.13% ($P = 0.008$) in those who continued using the integrated meter/logbook from the RCT through the follow-up visit (Group 2a), but increased in the other three groups, +0.32 ± 0.20% in those who used conventional meters and logbooks throughout (Group 1a, $P = 0.118$), +0.04 ± 0.28% in those who switched from electronic to conventional meters and logbooks (Group 2b, $P = 0.899$), and +0.01 ± 0.19% in those who switched from conventional to electronic meters/logbooks (Group 1b, $P = 0.964$). The difference between those who used conventional meters and logbooks throughout (Group 1a) and those who used integrated meters/logbooks throughout (Group 2a) was statistically significant (Fig. 3, $P = 0.006$). A similar trend in mean A1C differences was observed between pediatric patients who used conventional meters and paper logbooks throughout and those who used integrated meters/logbooks throughout ($P = 0.053$). Between the end of the RCT and the follow-up visit (SV6 to SV7), A1C increased in all four groups: +0.35 ± 0.18% in Group 1a ($P = 0.058$), +0.41 ± 0.25% in Group 1b ($P = 0.122$), +0.11 ± 0.11% in Group 2a ($P = 0.317$), and +0.29 ± 0.28% in Group 2b ($P = 0.326$).

Of the 65 patients who used the electronic logbook (Groups 1b and 2a), 33 reported reviewing screens with their HCP. Between the end of the RCT and SV7, the A1C increase in patients who did not review screens with their HCP was greater than in those who did review screens (+0.42 ± 0.21% vs. +0.02 ± 0.09%, $P = 0.052$) (Fig. 4).

DISCUSSION

These results demonstrate that, both during an RCT and during an observational follow-up period of routine care without the added support of a trial, use of an integrated meter/logbook was associated with improved glycemic control when compared with use of conventional meters and paper logbooks. Participants using the integrated meter/logbook monitored more frequently, which may have motivated positive behavioral changes or provided additional information on which they could take action to improve glycemic control. The automated formatting of accurate data may have resulted in better decision-making by participants or HCPs. Among participants who used the integrated meter/logbook, those who reviewed their screens with their HCPs tended toward better glycemic control than those who did not, suggesting that active engagement with the electronic logbook may have been beneficial.

While significant, both the difference between the two groups at the end of the RCT and the absolute reductions in A1C from baseline were modest. This was not surprising, considering the modest nature of the intervention and the relatively short length of the RCT. The participants included in this trial, with high initial A1C levels, may have been particularly challenged in their ability to change behaviors without significant intervention.[24] However, as shown in several landmark clinical trials, any reduction in A1C reduces the risks of complications.[1–5,25]

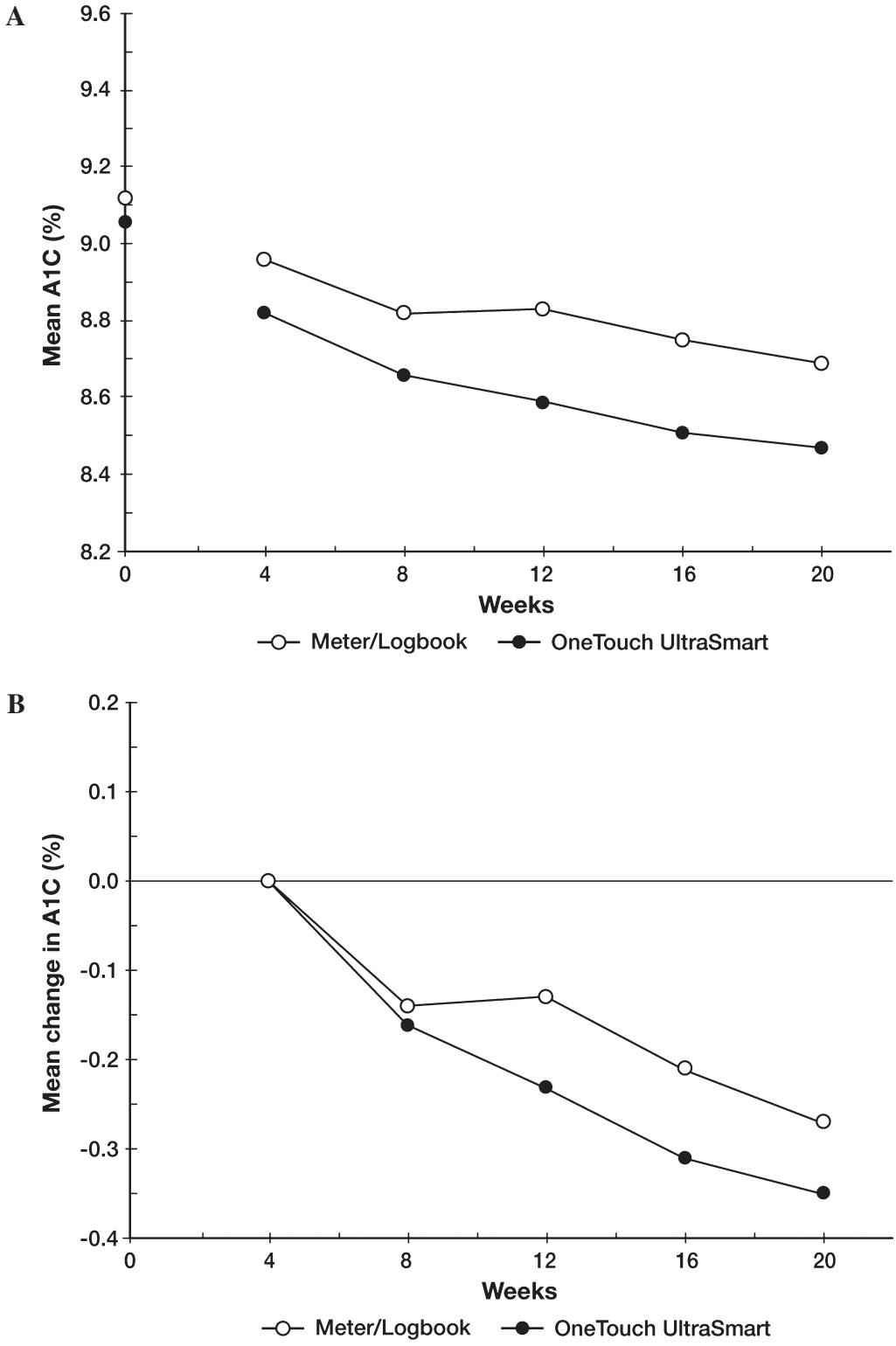

FIG. 2. (**A**) Mean A1C at each study visit during the RCT. Participants were enrolled at SV1 (week 0) and randomized at SV2 (week 4). In the Paper Group, there were 92 patients at SV1 and SV2, 90 at SV3, 84 at SV4, 86 at SV5, and 86 at SV6. In the Electronic Group, there were 113 patients at SV1, 111 at SV2, 110 at SV3, 108 at SV4 and SV5, and 107 at SV6. (**B**) Mean decrease in A1C during the RCT from time of randomization (SV2).

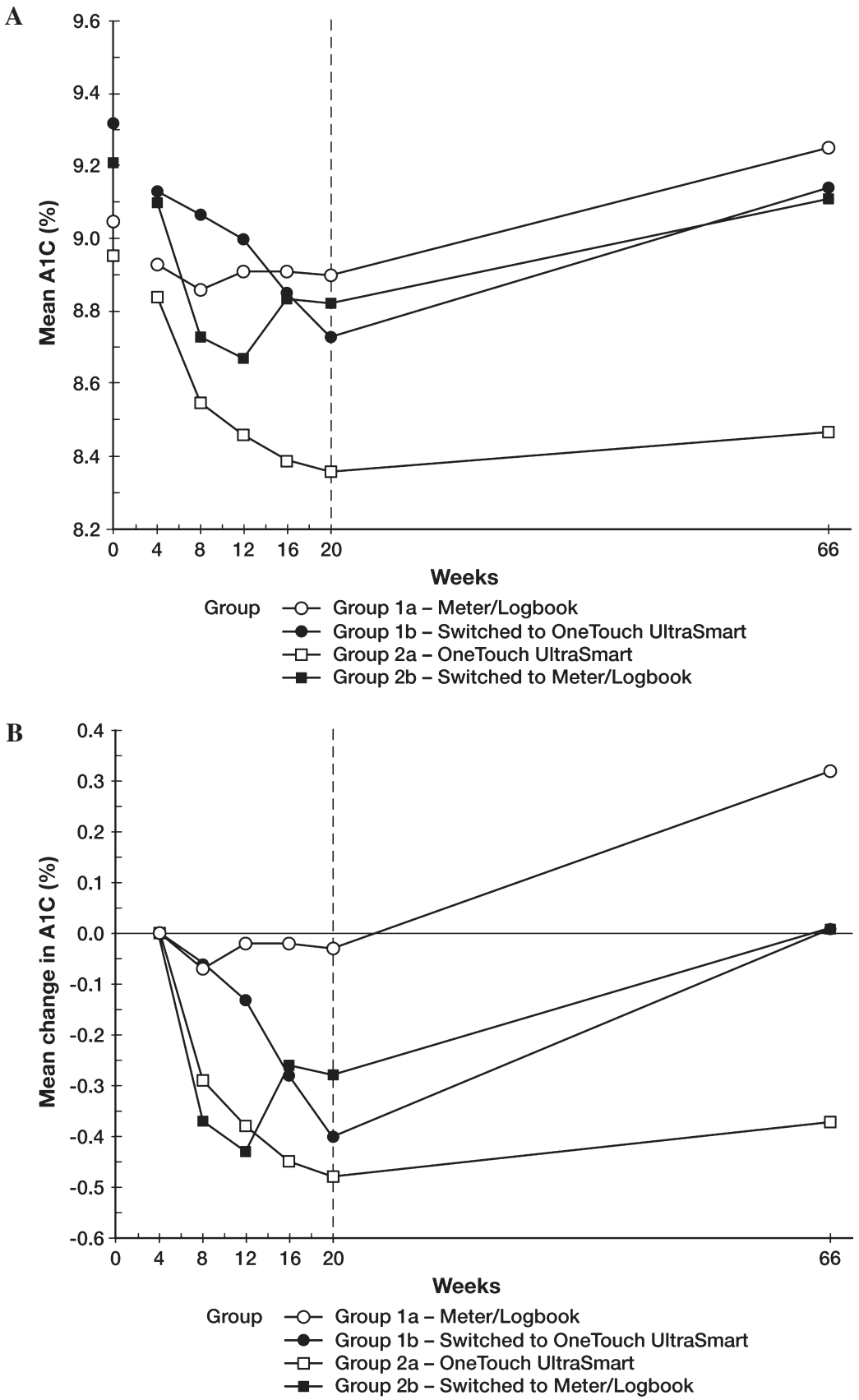

FIG. 3. (**A**) Mean A1C for patients completing the observational follow-up, by subgroup. Two patients, one each from Groups 1a and 1b, were not present for SV4, and two patients, one each from Groups 1b and 2a, were not present for SV5. The follow-up study visit occurred between weeks 46 and 85 (median week 65.9). (**B**) Mean decrease in A1C from time of randomization (SV2).

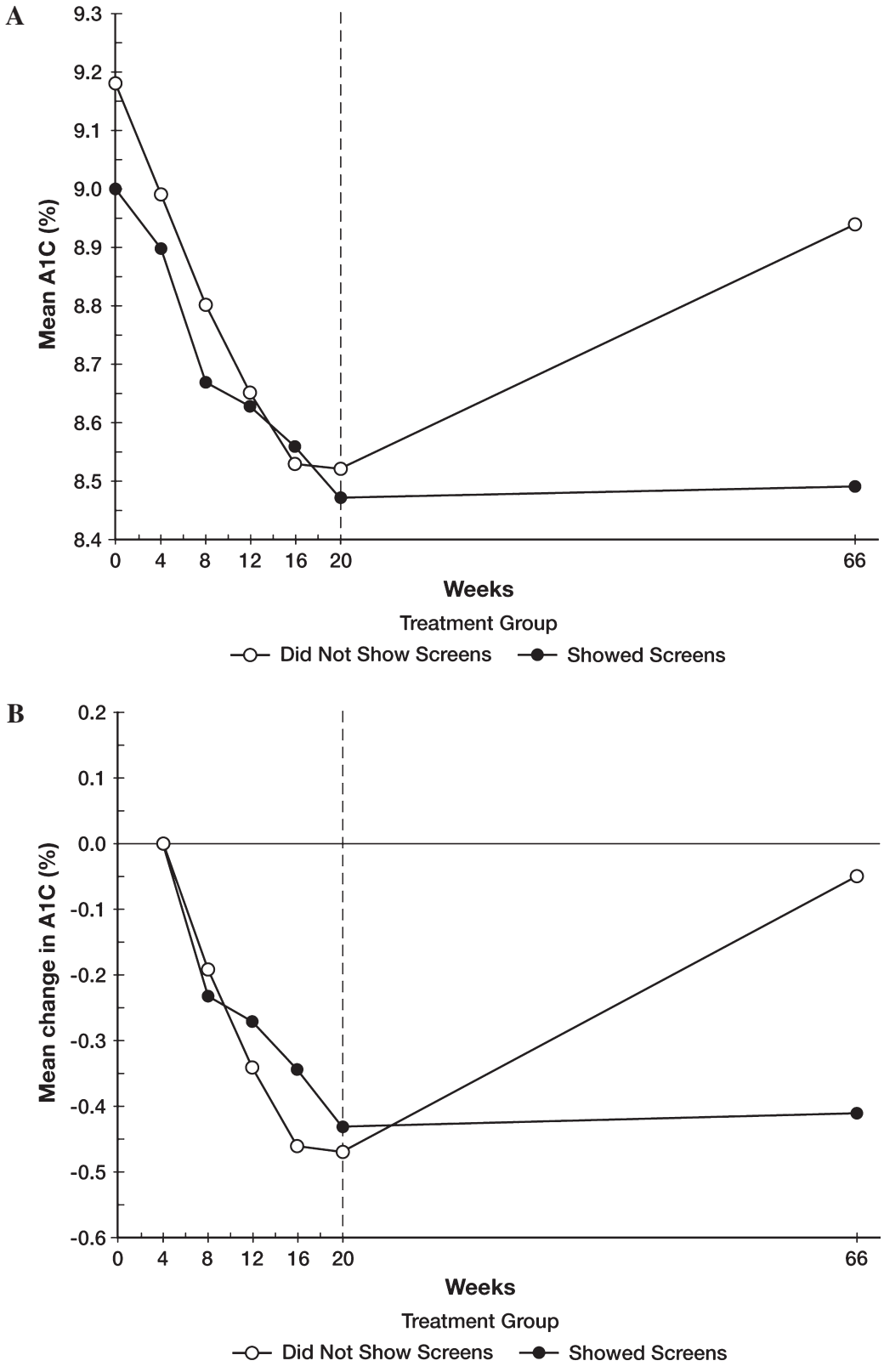

FIG. 4. (**A**) Mean A1C for patients using the integrated meter/logbook through SV7 (Groups 1b and 2a) who reported reviewing screens or not reviewing screens with their HCPs. The follow-up study visit occurred between weeks 46 and 85 (median week 65.9). (**B**) Mean decrease in A1C from time of randomization (SV2).

The Paper Group's reduction in A1C during the run-in period and RCT may be related to positive behavior changes associated with being observed in a clinical trial and receiving additional support and free monitoring supplies, as has been consistently observed in other glucose monitoring trials.[24,26,27] However, when patients return to usual care following a clinical trial, they tend to relapse into old habits, and glycemic benefits disappear.[5] This tendency was observed during the non-trial, observational period, as patients in three of the four subgroups returned to pre-trial A1C levels, whereas patients who continued with the integrated meter/logbook maintained their significant A1C reduction from baseline. The greater divergence of the Paper and Electronic Groups after the RCT suggests a glycemic advantage from using an electronic logbook. In addition to the ease with which BG data are displayed in the electronic logbook, it may also reduce patient burden by removing the need to maintain a written logbook.

The issuance of a new device to a single arm of the study (the Electronic Group) may have exaggerated the glycemic benefit attributed to this group during the RCT. This effect, however, would not likely have been maintained over an extended period in a real-world setting, contrary to what was observed during follow-up. Furthermore, patients who switched to electronic meters/logbooks after the RCT experienced an increase in A1C to pre-trial levels during the follow-up period. Unlike participants initially randomized to the Electronic Group, those who switched to integrated meters/logbooks during the observational period did not receive standardized training, instruction to review screens with their HCPs, or monthly reinforcement, indicating that appropriate training and engagement with the electronic logbook may be a requisite for achieving or sustaining improved glycemic control with any new technology.

Routine meter downloading and analysis are complex and labor and time intensive. Although downloaded results may aid in treatment guidance, most HCPs do not routinely download glucose meter data.[28] Accordingly, the protocol for the RCT did not allow routine downloading of results in either arm, and the beneficial effect on glycemic control observed in the Electronic Group was likely associated with the data available to patients and/or the HCPs in the absence of downloading. Similar benefits may have been attainable by downloading conventional meters to appropriate diabetes management software during the RCT. However, although meter downloading was permitted during the observational follow-up period, only participants who continued to use the integrated meter/logbook maintained their improvement in glycemic control.

This study warrants additional comments regarding limitations. The length of the RCT was relatively short, and A1C levels in both groups were still declining at the last study visit (SV6), suggesting the possibility of a more robust effect in a longer study, particularly one with monthly follow-up. In addition, because of the nature of this trial, neither patients nor their HCPs could be fully blinded to group assignment, possibly leading to unintended bias. Next, the greater reduction in A1C in the Electronic Group may have yielded a greater number of measured hypoglycemic episodes. Alternatively, the increased detection of hypoglycemic episodes in the Electronic Group may have resulted from more frequent BG monitoring and greater ascertainment of events rather than from an actual increase in events relative to the Paper Group. Finally, the choice to continue with or switch monitoring systems during the observational period was left to the patients and their HCPs, introducing the possibility of selection bias.

In conclusion, these results demonstrate that insulin-treated participants using integrated meters and electronic logbooks were able to improve glycemic control when compared to participants using conventional meters and paper logbooks. Moreover, patients using integrated meters and electronic logbooks were able to maintain significant glycemic improvements during long-term follow-up in a real-world setting, beyond the controlled conditions of a clinical trial. Sustained improvements in glycemic control will likely serve to preserve health and reduce the risks of future complications; additional studies are needed to confirm these findings.

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