Efficacy of self-monitoring of blood glucose in patients with type 2 diabetes mellitus managed without insulin: a systematic review and meta-analysis

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Read the related commentary by Sonia Butalia and Doreen M Rabi on pages e114–16.

ABSTRACT

Background: Self-monitoring of blood glucose levels is commonly performed by patients with diabetes mellitus. However, there is debate surrounding the clinical utility and cost-effectiveness of this practice among patients with type 2 diabetes managed without insulin. We conducted a systematic review and meta-analysis to determine the effect of self-monitoring versus no self-monitoring, and the optimal frequency of self-monitoring, in this population.

Methods: MEDLINE, EMBASE, BIOSIS Previews, CINAHL and PsycINFO were searched for randomized controlled trials (RCTs) and observational studies published in English from January 1990 to March 2009. Additional citations were obtained through searches of the Internet and conference proceedings, and from stakeholder feedback. Two reviewers independently selected studies, extracted data and performed an assessment of the methodologic quality of the studies. Key outcomes of interest were hemoglobin A_{1c} (HbA_{1c}) concentration, hypoglycemia, quality of life, long-term complications of diabetes and death. Where appropriate, we pooled data using random-effects meta-analysis.

Results: We identified 1624 citations through the literature search and selected 25 articles for inclusion. We observed a statistically significant improvement in the HbA_{1c} concentration across RCTs that compared self-monitoring of blood glucose levels with no self-monitoring among patients taking oral antidiabetes drug therapy (weighted mean difference −0.25%, 95% confidence interval −0.36% to −0.15%). Subgroup analysis indicated that results from RCTs that provided patients with education on how to interpret and apply self-monitoring test results were similar to those from RCTs that did not. On the basis of limited evidence, self-monitoring of blood glucose levels did not demonstrate consistent benefits in terms of quality of life, patient satisfaction, prevention of hypoglycemia or long-term complications of diabetes, or reduction of mortality. There was insufficient evidence pertaining to the optimal frequency of self-monitoring.

Interpretation: Self-monitoring of blood glucose levels was associated with a modest, statistically significant reduction in hemoglobin A_{1c} concentrations, regardless of whether patients were provided with education on how to interpret and use the test results. Further studies are required to determine whether self-monitoring reduces the risk of long-term complications of diabetes and to identify patients most likely to benefit from self-monitoring.

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Diabetes mellitus is associated with serious long-term complications and premature death.[1,2] In 2004/05, diabetes was diagnosed in about 5.5% (1.8 million) of Canadians 20 years of age and older.[3] Type 2 diabetes accounts for about 90% of all cases of diabetes.[4] Maintaining a hemoglobin A_{1c} (HbA_{1c}) concentration of 7% or less is recommended for all patients with diabetes to reduce the risk of long-term complications.[2]

Self-monitoring of blood glucose levels may contribute to glycemic control by allowing for adjustments in diet, physical activity and pharmacotherapy in response to test results. Although the need for self-monitoring in patients taking insulin is well established,[2] the utility of the practice in patients with type 2 diabetes managed without insulin is controversial.[5–8] Nevertheless, use of self-monitoring is highly prevalent in this population. In a recent study, people covered by the Ontario Public Drug Program whose diabetes was managed without insulin submitted claims for 1.3 blood glucose test strips per day on average in 2006. This resulted in a total annual cost of $69 million, or 63% of the Ontario Public Drug Program's total expenditures on test strips.[9] Apart from the economic costs, self-monitoring of blood glucose may be associated with patient discomfort and inconvenience. Hence, evidence-based information is needed to guide optimal use of this technology in patients with type 2 diabetes who do not use insulin.

Existing systematic reviews in this area have reported marginal advantages of self-monitoring of blood glucose levels in terms of controlling HbA_{1c}, but they have not usually assessed other outcomes of interest such as hypoglycemia, long-term complications of diabetes or quality of life.[10–16] Furthermore, previous reviews have not accounted for differences across trials in the degree to which participants were educated on how to interpret and act on test results of self-monitoring. This is a key limitation, since people using test strips must be able to act appropriately in response to abnormal readings if self-monitoring is to be effective. We therefore conducted a systematic review and meta-analysis to determine the effect of self-monitoring versus no self-monitoring, and the optimal frequency of self-monitoring, in patients with type 2 diabetes managed without insulin. We also assessed the effect of patient education regarding self-interpretation and application of test results on HbA_{1c} concentrations and other clinical outcomes. This research was conducted as part of a larger initiative aimed at optimizing the use of this health technology (www.cadth.ca/index.php/en/compus/blood-glucose).

Methods

This systematic review was conducted according to a protocol developed a priori.[17] Here, we summarize key methodologic aspects of the review.

Literature search. MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, BIOSIS Previews, CINAHL and PsycINFO were searched for studies published in English from January 1990 to March 2009. We restricted the search to studies published after 1990 to increase the likelihood that study conditions and practices for diabetes management were reflective of current practices. We also conducted parallel searches for studies in the Cochrane Library and Centre for Reviews and Dissemination databases. The search strategy comprised both controlled vocabulary, such as Medical Subject Headings, and key words. The main search concepts were "blood glucose test strips" and "type 2 diabetes mellitus." We obtained additional citations through searching the Internet and conference proceedings and from stakeholder feedback. (See online Appendix A for the complete literature search.)

Eligibility criteria. We included English-language full-text articles and conference abstracts of randomized controlled trials (RCTs) and observational studies (i.e., cohort, case–control and time series) that compared self-monitoring of blood glucose levels with no self-monitoring, or that compared different frequencies of self-monitoring, in adults or children with type 2 diabetes managed without insulin. To ensure a valid assessment of the efficacy of self-monitoring in this patient population over a clinically relevant timeframe, we excluded studies that did not report outcomes by type of diabetes or type of therapy, were of less than 4 weeks' duration, or demonstrated substantial differences between treatment groups in terms of management practices other than self-monitoring of blood glucose levels.

Outcomes. Outcomes of interest included measures of glycemic control; hypoglycemia; body weight; body mass index; hyperosmolar, hyperglycemic, nonketotic coma; generic and diabetes-specific health-related quality of life; patient satisfaction with diabetes care and treatment; efficacy of patient self-management of diabetes; and long-term complications of diabetes. In this article, we present results for HbA_{1c} concentration, hypoglycemia, health-related quality of life, patient satisfaction and long-term complications of diabetes. Results for other outcomes are presented elsewhere.[18]

Data extraction. Two reviewers (2 of BM, KC, CY, AL) independently extracted data from each included article using a form designed a priori.[18] The following information was extracted: data for all relevant outcomes; study characteristics (e.g., inclusion and exclusions criteria); characteristics of participants (e.g., age, duration of diabetes); and sources of funding. Disagreements were resolved by consensus or a third reviewer. Authors of the included studies were contacted if data were missing.

Quality assessment. The 2 reviewers also independently assessed each included study's methodologic quality using modified Scottish Intercollegiate Guidelines Network-50 instruments for RCTs and cohort studies.[19] This information was used in a sensitivity analysis to test the effect of removing poor-quality studies. Disagreements in quality assessment were resolved by consensus or a third reviewer.

Data analysis. We pooled data across RCTs using Review Manager version 5.0 (Cochrane Collaboration) with random-effects meta-analysis.[20,21] The decision to use the random-effects model was based on clinical heterogeneity of patient characteristics (e.g., baseline HbA_{1c} concentration) and of trial design (e.g., testing frequency). We conducted sensitivity analyses to test the effect of removing studies of poor quality, and the effect of removing studies that presented pooled results for patients taking oral antidiabetes drug therapy (e.g., metformin, sulfonylureas) and for patients taking no pharmacotherapy. Subgroup analyses were conducted based on the provision of education on how to interpret and act on test results, medication class, frequency of self-monitoring, duration of self-monitoring and patient characteristics. We assessed heterogeneity using the I^2 statistic[22] and publication bias using Egger's test. We did not pool data from observational studies because of a high degree of methodologic heterogeneity.

Results

Study selection. Of the 1624 citations identified through the literature search, we reviewed 324 as full-text articles. Twenty-six articles, representing 9 RCTs and 13 observational studies, were selected for inclusion (Fig. 1).[8,23–47] In 2 instances, data from the same clinical trial were presented in multiple full-text articles: Farmer and colleagues,[31] Simon and colleagues,[39] French and colleagues[23] and Farmer and colleagues[46] reported results from the Diabetes Glycaemic Education and Monitoring (DiGEM) trial, whereas the study by Siebolds and colleagues[38] was an extension of the trial initially reported by Schwedes and colleagues.[25] Data from one observational study[44] were not extractable.

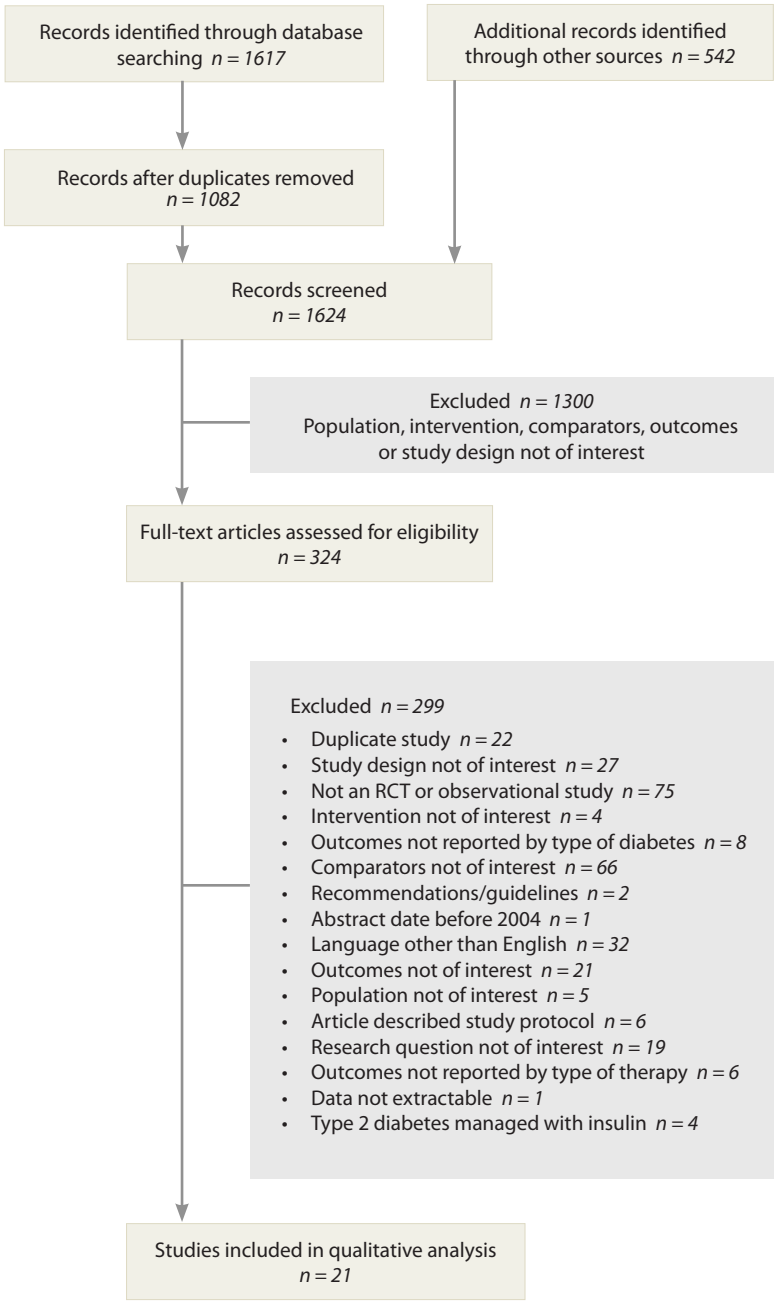

Figure 1: Selection of randomized controlled trials and observational studies on the efficacy of self-monitoring of blood glucose levels in patients with type 2 diabetes mellitus managed without insulin.

Because we sought to isolate the effect of self-monitoring of blood glucose levels from other strategies for managing diabetes in patients with type 2 diabetes who do not use insulin, we excluded

a number of studies included in past systematic reviews of self-monitoring. Appendix B (online) presents the reasons for excluding a selection of these studies.

Among the included RCTs, 2 compared one frequency of self-monitoring with another frequency;[29,43] 7 compared self-monitoring with no self-monitoring.[8,24,25,31,34,35,38,45] The DiGEM trial had 3 study groups: self-monitoring in combination with education on how to interpret and act on results, self-monitoring with usual care, and no self-monitoring.[23,31,39,46] There was considerable variability across trials in the extent to which participants used oral antidiabetes drug therapy. In 2 studies, all of the participants used such therapy,[24,43] whereas in the remaining 7 RCTs, some participants used oral antidiabetes drug therapy while others used no antidiabetes pharmacotherapy.[8,23,25,29,31,34,35,38,39,45,46] The proportion of participants who used oral antidiabetes drug therapy in these studies, where reported, ranged from 9%[35] to 98%.[8] Only 1 RCT reported subgroup data on participants who did not use antidiabetes pharmacotherapy.[31]

Study characteristics and methodologic quality. Sample sizes ranged from 28[34] to 689 patients[24] in the included RCTs, and from 115[36] to 12 786[27] in the observational studies. Study duration ranged from 6 to 12 months for the RCTs, and from 3 months[42] to 6.5 years[33] for the observational studies. The per-protocol frequency of self-monitoring in the RCTs varied from 1 strip per week[29,43] to 6 strips per day for 6 days per week,[8] although actual use was significantly lower in most cases.

Four RCTs[31,35,43,45] were rated as being of good methodologic quality, and four[8,24,25,34] as poor quality (online Appendix C). One RCT[29] was reported as an abstract and could not be assessed for quality. The reasons for assigning ratings of poor quality were inadequate descriptions of procedures for randomization and allocation concealment, high dropout rates, and failure to conduct an intention-to-treat analysis. All included observational studies were rated as being of poor quality except for 2 time-series studies,[26,40] which could not be assessed for quality (online Appendix D).

Meta-analysis of studies involving patients using oral antidiabetes drug therapy

Effect of self-monitoring on HbA_{1c} concentration. Seven RCTs (n = 2270) reported the effect of self-monitoring of blood glucose levels versus no self-monitoring on change in HbA_{1c} concentration from baseline.[8,24,25,31,34,35,45] The meta-analysis yielded a statistically significant difference in HbA_{1c} in favour of self-monitoring (weighted mean difference −0.25%, 95% confidence interval [CI] −0.36% to −0.15%) (Fig. 2A, Table 1). Results were similar when we restricted the analysis to good-quality studies,[31,35,45] or to studies in which all participants used oral antidiabetic drug therapy (Table 1).[24,31,45] There was no evidence of publication bias (Egger's regression test; p = 0.29).[48]

We conducted a subgroup analysis based on whether study participants were instructed on how to interpret and apply results from self-monitoring (Fig. 2B). The pooled differences in HbA_{1c} concentration were similar regardless of whether trials implemented such an educational component (Table 1). In the DiGEM trial, the only RCT that directly compared the effect of self-monitoring combined with an educational component and self-monitoring combined with usual care, no statistically significant difference in HbA_{1c} concentration was found between study groups (mean difference 0.03%, 95% CI −0.15% to 0.21%).[31]

We conducted additional subgroup analyses to determine whether the HbA_{1c} estimate was affected by differences across studies in the frequency or duration of self-monitoring, baseline HbA_{1c} concentration, time since diabetes diagnosis and type of oral antidiabetes drug therapy used (Table 1). Results were similar to those from the overall analysis across all subgroups, although the pooled estimate across the 2 trials[25,34] that used an average frequency of self-monitoring of more than twice daily was somewhat higher than the pooled estimate across trials testing lower frequencies (mean difference −0.47%, 95% CI −0.79% to −0.15%). We found no statistically significant effect of self-monitoring on HbA_{1c} concentration in the only RCT that enrolled newly diagnosed patients (mean difference −0.40%, 95% CI −0.96% to 0.16%).[35]

The only RCT comparing one frequency of self-monitoring with another that reported HbA_{1c} found no significant difference at 6 months between a frequency of once per week compared with 4 times per week.[43]

Results from the observational studies were mixed with respect to the effect of self-monitoring of blood glucose on HbA_{1c} levels (Table 2).[27,28,32,36,37,40–42] In general, mean HbA_{1c} levels were lower in patients performing self-monitoring than in those not performing self-monitoring, and higher daily frequencies of self-monitoring were associated with incremental reductions in HbA_{1c} concentration. However, effect sizes varied considerably across studies.

Effect of self-monitoring on other outcomes. The pooled relative risk for overall hypoglycemia across 3 RCTs reporting this outcome[24,31,45] (n = 1752) was significantly higher with self-monitoring than with no self-monitoring

(rate ratio [RR] 1.99, 95% CI 1.37 to 2.89) (Table 3); however, the rate of overall hypoglycemia was significantly lower (RR 0.73, 95% CI 0.55 to 0.98).[35,45] There were no statistically significant differences in severe or nocturnal hypoglycemia (Table 3). However, Barnett and colleagues reported a statistically significant reduction in the number of symptomatic hypoglycemic events reported by patients using a sulfonylurea drug who performed self-monitoring compared with those who did not perform self-monitoring (RR 0.57, 95% CI 0.38 to 0.85).[45]

Five RCTs reported the effect of self-monitoring on health-related quality of life and patient satisfaction (Table 4).[23,24,35,38,39] There were no statistically significant differences between self-monitoring and no self-monitoring in terms of patient scores on the Well-being Questionnaire,[23,38] the Diabetes Treatment Satisfaction Questionnaire[23,25] or the overall EuroQol-5D score. In the DiGEM trial, quality of life measured using the EuroQol-5D was significantly lower in the study arm in which patients used self-monitoring and received intensive

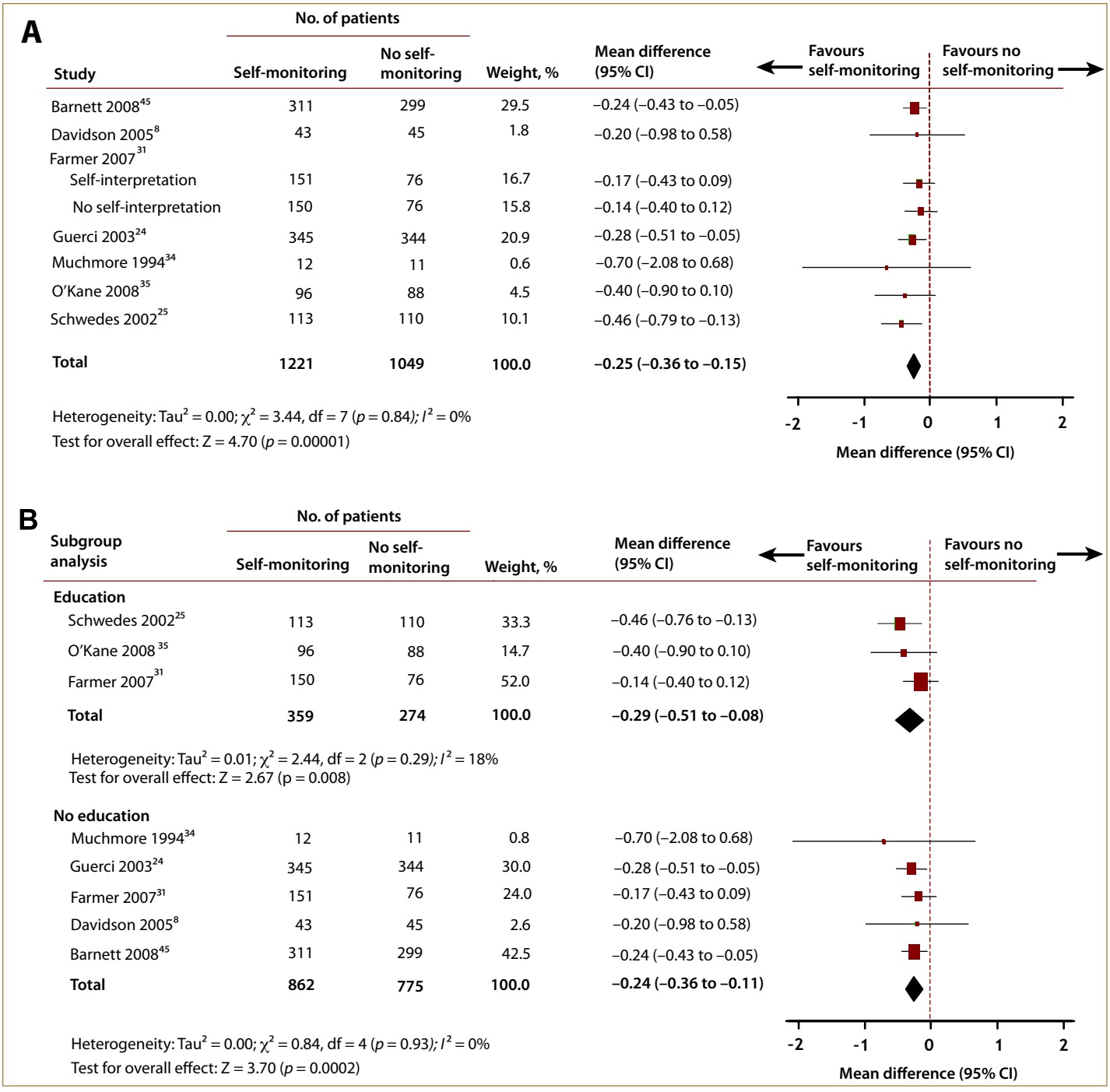

Figure 2: Effect of self-monitoring of blood glucose levels versus no self-monitoring on hemoglobin A_{1c} concentration (change from baseline) in adults with type 2 diabetes managed without insulin. **(A)** Overall pooled estimate of effect from 7 randomized controlled trials. **(B)** Results of subgroup analysis based on whether patients were provided with education on how to interpret and apply self-monitoring test results.

education than in the arm in which patients did not use self-monitoring (mean difference −0.072, 95% CI −0.127 to −0.017); this effect was due primarily to increased levels of anxiety and depression.[39] However, results from 2 studies reporting subscale scores from the Well-being Questionnaire were conflicting with respect to the effect of self-monitoring on depression.[35,38]

Two observational studies[30,33] that compared the effect of self-monitoring with no self-monitoring reported mixed results for mortality. A retrospective cohort study involving patients with newly diagnosed diabetes reported that self-monitoring was associated with significantly decreased risks of all-cause mortality and non-fatal diabetes-related events at 6.5 years.[33] Conversely, a prospective cohort study involving patients with previously diagnosed diabetes reported no change in all-cause mortality at 10 years associated with self-monitoring.[30]

Meta-analysis of studies involving patients not using oral antidiabetes drug therapy

One RCT subgroup analysis[31] and 2 observational studies[27,32] compared self-monitoring with no self-monitoring in patients managed without antidiabetes pharmacotherapy. In the subgroup of participants in the DiGEM trial not taking antidiabetes agents, HbA_{1c} concentrations did not differ significantly between those using self-monitoring test strips and those not using them, regardless of whether users received intensive education in combination with self-monitoring.[31] In contrast, a large retrospective cohort study reported statistically significant differences in HbA_{1c} favouring self-monitoring.[27]

Table 1: Effect on hemoglobin A_{1c} (HbA_{1c}) concentrations reported in RCTs comparing self-monitoring of blood glucose levels with no self-monitoring, or various frequencies of self-monitoring, among adults with type 2 diabetes managed without insulin

Analysis	No. of studies (sample size)	Weighted mean difference (95% CI), %	I^2 value, %
Self-monitoring versus no self-monitoring			
Overall	7 RCTs[8,24,25,31,34,35,45] (n = 2270)	−0.25 (−0.36 to −0.15)	0
Sensitivity and subgroup analyses			
Good-quality RCTs only	3 RCTs[31,35,45] (n = 1247)	−0.21 (−0.34 to −0.08)	0
Studies in which all participants used oral antidiabetes drugs	3 RCTs[24,31,45] (n = 1628)	−0.24 (−0.36 to −0.11)	0
Education regarding application of test results			
Education	3 RCTs[25,31,35] (n = 710)	−0.28 (−0.47 to −0.08)	17.8
No education	5 RCTs[8,24,31,34,45] (n = 1712)	−0.22 (−0.34 to −0.10)	0
*Average frequency of self-monitoring**			
< 1 test per day	3 RCTs[8,24,31] (n = 1230)	−0.20 (−0.35 to −0.06)	0
1–2 tests per day	2 RCT[35,45] (n = 794)	−0.26 (−0.44 to −0.07)	0
> 2 tests per day	2 RCTs[25,34] (n = 246)	−0.47 (−0.79 to −0.15)	0
Duration of self-monitoring			
6 months	5 RCTs[8,24,25,35,45] (n = 1794)	−0.28 (−0.41 to −0.15)	0
> 6 months	3 RCTs[31,34,35] (n = 660)	−0.19 (−0.36 to −0.01)	0
Relation of diabetes to use of self-monitoring			
Previously diagnosed	6 RCTs[8,24,25,31,34,45] (n = 2086)	−0.25 (−0.35 to −0.14)	0
Newly diagnosed	1 RCT[35] (n = 184)	−0.40 (−0.96 to 0.16)	NA
Glycemic control at baseline			
HbA1c < 8.0%	1 RCT[31] (n = 453)	−0.16 (−0.34 to 0.03)	NA
HbA1c ≥ 8.0%	6 RCTs[8,24,25,34,35,45] (n = 1817)	−0.30 (−0.43 to −0.17)	0
Type of oral antidiabetes drug			
Sulfonylurea	1 RCT[45] (n = 610)	−0.24 (−0.43 to −0.05)	NA
Various	2 RCTs[24,31] (n = 1018)	−0.24 (−0.40 to −0.07)	0
Frequency of self-monitoring			
Once per week v. 4 times per week	1 RCT[43] (n = 178)	−0.08 (−0.41 to 0.25)	NA

CI = confidence interval, NA = not applicable, RCT = randomized controlled trial.
*Average daily use of blood glucose test strips is based on actual testing frequency, when reported. Otherwise, it was assumed that participants adhered to testing frequencies outlined in the study protocol.

A second retrospective cohort study reported a 0.35% reduction in HbA_{1c} ($p < 0.001$) for every additional test strip dispensed per day among new users of self-monitoring, but not among patients who had used self-monitoring for at least 3.5 years.[32]

Interpretation

Our systematic review identified 7 RCTs that compared self-monitoring of blood glucose levels with no self-monitoring in patients with type 2 diabetes managed without insulin. The meta-analysis indicated that self-monitoring was associated with a statistically significant improvement in HbA_{1c} concentration of 0.24% among patients receiving oral antidiabetes drug therapy, a result that is consistent with findings from previous systematic reviews.[10–14,16] However, the clinical relevance of this effect is questionable in light of published minimal clinically important differences in HbA_{1c}.[49,50] Among patients who were not using antidiabetes pharmacotherapy, the improvement in HbA_{1c} was even smaller and statistically nonsignificant.

We did not pool data from the observational studies because of the presence of substantial methodologic variation. Compared with RCTs, results from observational studies are more likely to be affected by selection bias, because patients who perform more frequent self-monitoring may also be more likely to engage in lifestyle and health care utilization behaviours that lead to better glycemic control. This may explain, at least in part, why some observational studies have reported larger HbA_{1c} benefits than RCTs have.[27,40]

We also examined whether self-monitoring of blood glucose levels was more effective when used in conjunction with patient education regarding the interpretation of results and appropriate responses.[11,15,51] We found that results from studies that provided such education were similar to those from studies that did not. This is consistent with the results of the DiGEM trial, which also reported no significant difference in glycemic control between patients instructed in self-interpretation and those who were directed to have a health professional interpret results from self-monitoring.[31] However, the apparent lack of benefit from patient education could also be related to study factors such as poor compliance with the study protocol, or the lack of a specific algorithm for patients and clinicians to use self-monitoring test results to make therapeutic decisions.

According to the Diabetes in Canada Evaluation Study, the average HbA_{1c} concentration among patients with type 2 diabetes in Canada is 7.5%, and only 20% of patients have a concentration in excess of 8.5%.[52] Of the 7 RCTs included in our meta-analysis, 6 enrolled patients with a mean baseline HbA_{1c} concentration of 8.1% to 10.5%. Therefore, our results may be more applicable to patients with poorly controlled diabetes. The DiGEM study, the only RCT that included patients with a baseline HbA_{1c} of less than 8.0%, reported a statistically nonsignificant benefit of self-monitoring.[31]

Improvements in quality of life among patients using self-monitoring are typically attributed to a greater level of self-efficacy and control.[53,54] Pain, discomfort and inconvenience associated with self-monitoring may reduce

Table 2: Mean differences in hemoglobin A_{1c} (HbA_{1c}) concentrations reported in retrospective cohort studies comparing self-monitoring of blood glucose levels with no self-monitoring, or various frequencies of self-monitoring, among adults with type 2 diabetes managed without insulin

Analysis	No. of studies (sample size)	Mean difference in HbA1c concentration (95% CI), %
Self-monitoring v. no self-monitoring		
≥ 1 strip per day v. no self-monitoring	1 R. cohort[27] ($n = 8735$)	−0.68 (−0.77 to −0.59)
< 1 strip per day v. no self-monitoring	1 R. cohort[27] ($n = 10243$)	−0.21 (−0.30 to −0.12)
Prescription of 2–4 strips per week v. no prescription of strips	1 R. cohort[36] ($n = 115$)	−0.20 (−0.77 to 0.37)
Prescription of 0.56 strips per day v. no prescription of strips	1 R. cohort[41] ($n = 299$)	−0.13 (−0.28 to 0.02)
Self-monitoring v. no self-monitoring among patients with baseline HbA_{1c} ≥ 10%	1 time-series[40] ($n = 133$)	−0.63 (−1.14 to −0.12)
Frequency of self-monitoring		
Once per day v. less than once per day	1 R. cohort[27] ($n = 6594$)	−0.47 (−0.57 to −0.37)
Increase of 1 strip per day		
Patients using oral antidiabetes drug therapy	1 R. cohort[37] ($n = 1795$)	0.09 ($p = 0.54$)
Patients using sulfonylurea agent	1 R. cohort[42] ($n = 216$)	0.02 ($p > 0.50$)
New users of test strips	1 R. cohort[32] ($n = 5546$)	−0.42 ($p < 0.001$)
Prevalent users of test strips	1 R. cohort[32] ($n = 7409$)	−0.16 ($p < 0.001$)
Increase of 10 test strips per week	1 R. cohort[28] ($n = 5862$)	−0.06 ($p = 0.38$)

CI = confidence interval, R. cohort = retrospective cohort.

quality of life.[53–58] In our analysis, we found no significant differences between self-monitoring and no self-monitoring in terms of overall health-related quality of life, patient satisfaction or patient well-being, although evidence for these outcomes was sparse and analysis was complicated by the use of different scales. Analysis of subscales related to psychological well-being demonstrated discrepant findings across studies with respect to the effect of self-monitoring on anxiety and depression. The available data on the effects of self-monitoring on quality of life and patient satisfaction are thus inconclusive. Further studies using standardized instruments are required to determine the benefits, if any, of self-monitoring on these outcomes.

The relative risks for severe and nocturnal hypoglycemia were not significantly affected by self-monitoring, but the risk of overall hypoglycemia was significantly higher with self-monitoring than with no self-monitoring. This was likely due to greater detection of asymptomatic hypoglycemia.[10,14,24,45] Interestingly, the number of events of overall hypoglycemia was significantly lower with self-monitoring. The reason for this counterintuitive result is unclear, although it may be that increased detection of hypoglycemia with self-monitoring soon after initiation of self-monitoring (which results in a higher relative risk) ultimately produces behavioural changes that reduce future hypoglycemic events (resulting in a lower rate ratio). The finding by Barnett and colleagues that rates of symptomatic hypoglycemia were lower among patients given a sulfonylurea agent who performed self-monitoring than among those who received the pharmacotherapy alone[45] may indicate that self-monitoring prevents asymptomatic hypoglycemia from progressing. However, this is a highly subjective outcome that is likely prone to ascertainment bias. Further studies using more rigorous methods are therefore required to confirm this possible benefit of self-monitoring.

Data regarding long-term clinical outcomes were infrequently reported in observational studies, and no such data were reported in RCTs. Given the high likelihood of selection bias in observational studies, further RCTs of adequate size and duration are required to determine whether self-monitoring reduces long-term complications of diabetes in patients with type 2 diabetes who do not use insulin.

Strengths and limitations. In this review, we systematically evaluated the available evidence from RCTs and observational studies related to self-monitoring of

Table 3: Effect on overall, severe and nocturnal hypoglycemia reported in RCTs comparing self-monitoring of blood glucose levels with no self-monitoring, or various frequencies of self-monitoring, among adults with type 2 diabetes managed without insulin

Analysis	No. of studies (sample size)	Effect estimate (95% CI)	I^2 value, %
Self-monitoring v. no self-monitoring			
Overall hypoglycemia	3 RCTs[24,31,45] (*n = 1752*)	RR 1.99 (1.37 to 2.89)	33.8
	2 RCTs[35,45] (*n = 794*)	Rate ratio 0.73 (0.55 to 0.98)	0
Severe hypoglycemia	3 RCTs[25,31,45] (*n = 1752*)	RR 0.17 (0.01 to 4.12)	NA
Nocturnal hypoglycemia	1 RCT[45] (*n = 610*)	RR 0.41 (0.11 to 1.58)	NA
Frequency of self-monitoring (once per week v. 4 times per week)			
Overall hypoglycemia	1 RCT[43] (*n = 202*)	RR 0.28 (0.11 to 0.73)	NA
Severe hypoglycemia	1 RCT[43] (*n = 202*)	No events	NA

CI = confidence interval, NA = not applicable, RR = relative risk, RCT = randomized controlled trial.

Table 4: Mean differences in patient satisfaction with diabetes treatment, well-being and quality of life reported in RCTs comparing self-monitoring of blood glucose levels with no self-monitoring among adults with type 2 diabetes managed without insulin

Analysis	No. of studies (sample size)	Weighted mean difference (95% CI), %
Treatment satisfaction (DTSQ)	2 RCTs[23,24] (n = 562)	–0.26 (–1.38 to 0.86)
Well-being (WBQ-12)	1 RCT[23] (n = 339)	–0.85 (–2.27 to 0.56)
Well-being (WBQ-22)	1 RCT[38] (n = 223)	1.83 (–0.05 to 3.71)
Quality of life (EQ-5D)		
Self-monitoring overall	1 RCT[39] (n = 453)	–0.06 (–0.13 to 0.02)
Self-monitoring with education	1 RCT[39] (n = 302)	–0.029 (–0.084 to 0.025)
Self-monitoring without education	1 RCT[39] (n = 301)	–0.072 (–0.127 to –0.017)

CI = confidence interval, DTSQ = Diabetes Treatment Satisfaction Questionnaire, EQ-5D = EuroQol-5D, RCT = randomized controlled trial, WBQ = Well-being Questionnaire

blood glucose levels in patients with type 2 diabetes managed without insulin across a wide range of outcomes, over numerous clinically relevant subgroups and through a number of detailed sensitivity analyses. In particular, we assessed the effect of patient education on the efficacy of self-monitoring, a factor that is commonly cited as being central to obtaining benefits from use of the technology.

Despite these strengths, certain limitations of our analysis warrant mention. We may have overlooked potentially relevant studies by excluding non–English-language articles in the literature search. However, a number of reviews on methodology have suggested that this practice has minimal impact on the results of systematic reviews and meta-analyses.[59–62] Furthermore, previous systematic reviews in this area did not identify additional RCTs published in a language other than English;[10–14,16] hence, the likelihood of bias arising from the imposed language restriction is minimal. Another limitation is the relatively low statistical power to detect differences within some subgroups; however, it is reassuring that the HbA_{1c} point estimates across subgroups were generally similar.

Possible limitations in the internal validity and generalizability of the RCTs included in this review should be noted. The lack of blinding may have resulted in overestimation of benefits of self-monitoring, because participants randomly assigned to self-monitoring may have been more motivated to perform other behaviours that resulted in better glycemic control. However, it could be argued that any effects of self-monitoring in terms of increased patient motivation are important ancillary benefits that may also be realized in clinical practice; hence, they do not necessarily limit the internal validity of studies. Perhaps more importantly, only 1 RCT[45] described a treatment algorithm in which results of self-monitoring were used to adjust antidiabetes treatments. The remaining studies either based therapeutic decisions on HbA_{1c} levels[8,24,31,35] or did not specify how treatments were modified in response to self-monitoring test results.[25,34] Furthermore, the degree to which participants acted appropriately in response to test results was not documented in studies, even when education regarding interpretation and application of test results was provided. Therefore, the benefits of self-monitoring, particularly in combination with patient education, may have been underestimated. However, results of qualitative research indicate that self-monitoring results are not often reviewed by physicians;[63] hence, the manner in which self-monitoring was used in the RCTs included in our review may not be entirely unreflective of clinical practice.

The remaining limitations stem from the paucity of studies addressing key issues pertaining to self-monitoring in patients with type 2 diabetes who do not use insulin. Much of the evidence of the efficacy of self-monitoring of blood glucose levels relates to HbA_{1c} levels rather than prevention of complications related to diabetes. Whether HbA_{1c} concentration is an adequate surrogate outcome for clinically relevant outcomes in patients with type 2 diabetes is controversial, especially in terms of the risk for cardiovascular events.[64,65] There was also insufficient evidence regarding optimal frequency or timing of self-monitoring. Although some studies implemented patient education about how to interpret test results, there was considerable heterogeneity in both the format and intensity of education and cointerventions provided. Therefore, specific educational components that are of value in conjunction with self-monitoring could not be identified. Finally, patients with type 2 diabetes managed without insulin represent a heterogeneous clinical population. Therefore, certain subgroups (e.g., patients undergoing significant changes in medication regimen) may be more likely than others to benefit from self-monitoring. Further studies are needed to adequately define the place of self-monitoring in these subgroups.

Conclusion. Our findings suggest that self-monitoring of blood glucose levels is associated with modest improvements in glycemic control among patients with type 2 diabetes managed without insulin. The provision of education to help patients translate results from self-monitoring into appropriate responses appeared to result in no greater benefit than self-monitoring without education, although studies may have been limited in their ability to adequately assess the effects of education. The limited evidence regarding health-related quality of life and patient satisfaction indicated no benefit of self-monitoring on these outcomes. There was insufficient evidence to determine the effect of self-monitoring on long-term complications and mortality, or to define an optimal testing frequency. Additional high-quality RCTs of sufficient size and duration are required to determine whether self-monitoring reduces the burden of diabetes complications, and to identify the patient subgroups and clinical scenarios in which self-monitoring is most likely to provide benefit.

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oversight for the extraction, analysis and interpretation of the data. Brendan McIntosh wrote the first draft of the manuscript. Chris Cameron, Sumeet Singh and Marshall Dahl assisted in drafting the manuscript. All of the authors critically reviewed the manuscript and approved the final version submitted for publication. Sumeet Singh is the corresponding author and guarantor for the research.

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