

Self-monitoring in Type 2 diabetes: a randomized trial of reimbursement policy

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Accepted 23 April 2006

Abstract

Aim Self-monitoring of blood glucose is often considered a cornerstone of self-care for patients with diabetes. We assessed whether provision of free testing strips would improve glycaemic control in non-insulin-treated Type 2 diabetic patients.

Methods Adults with Type 2 diabetes, excluding those with private insurance or using insulin, were recruited through community pharmacies and randomized to receive free testing strips for 6 months or not; all patients received similar baseline education and a glucose meter. Primary outcome was change in HbA_{1c} over 6 months.

Results We randomized 262 patients (131 intervention and 131 control subjects). Mean age was 68.4 years (SD 10.9), 48% were male, mean duration of diabetes was 8.2 years (SD 7.2), 97% used oral glucose-lowering agents and mean baseline HbA_{1c} was 7.4% (SD 1.2). After 6 months, we observed no difference in HbA_{1c} between intervention and control patients, after adjusting for baseline HbA_{1c} [adjusted difference 0.03, 95% confidence interval (CI) -0.16, 0.22; $P = 0.78$]. A per protocol analysis of study completers (152/262; 60%) yielded similar results. Intervention patients reported testing 0.64 days per week more often than control subjects (95% CI 0.18, 1.10; $P = 0.007$), although testing was not associated with better glycaemic control (Pearson $r = -0.10$, $P = 0.12$).

Conclusions Reducing financial barriers by providing free testing strips did not improve glycaemic control in patients with Type 2 diabetes not using insulin. Our results question the value of policies that reduce financial barriers to testing supplies in this population.

Diabet. Med. 23, 1247–1251 (2006)

Keywords adult diabetes, glycaemic control, health policy, self-monitor blood glucose

Introduction

Self-monitoring is generally considered a cornerstone of self-care for patients with diabetes [1–3]. Presumed benefits include the avoidance of hypoglycaemia and improved glycaemic control, although the precise benefits of testing in patients with Type 2 diabetes are unclear and the evidence associating testing with better glycaemic control is weak and conflicting [4–7].

Conversely, the cost of self-monitoring is substantial, both to individuals and to healthcare systems [8–10]. Test strips are priced at about \$1 (CDN) (€0.70) each and consume a large proportion of cost of care for diabetes [9,10], despite limited evidence of benefit [4–7]. Health policies that reduce financial barriers to unproven interventions could lead to significantly increased costs without any net clinical benefits [4,6,11].

We therefore conducted a randomized controlled trial to determine the clinical and behavioural impact of simply providing free testing supplies to patients with Type 2 diabetes, vs. the usual policy of patients paying ‘out-of-pocket’ for their testing supplies.

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Methods

Study subjects had Type 2 diabetes of at least 1 year's duration, were ≥ 30 years old and not on insulin. We excluded pregnant patients and those with gestational diabetes, as well as patients with private insurance coverage for testing supplies. We excluded those using insulin because the use of self-monitoring for patients on insulin is considered 'essential' according to practice guidelines [12] and because these patients were, at the time of study inception, eligible for financial support for testing strips through a provincial programme.

Subjects were recruited through a network of 38 community pharmacies. As the study involved assessments of health behaviours that might be susceptible to a Hawthorne effect, we employed a partial disclosure informed consent procedure. Ethical approval was obtained from the Health Research Ethics Board of the University of Alberta and by the Regina Health District Research Ethics Board.

On initial screening, subjects completed baseline measures, including HbA_{1c} at local laboratories. Eligible subjects were randomized to receive free testing strips for 6 months or not. All subjects were then invited back to the pharmacy for meter training, with each subject receiving a free meter (Glucometer Elite XL®; Bayer Diagnostics, Toronto, Ontario, Canada). To standardize the training and recommendations for all subjects, study pharmacists were instructed to recommend the following: (i) on oral glucose-lowering agents, average seven tests per week; (ii) on diet alone, once daily, three or four times per week. All patients were invited back for scheduled follow-up visits at 3 and 6 months for reinforcement of testing procedures. At each of the initial and 3-month visits, intervention subjects received a 3-month supply of testing strips (i.e. 100 strips). Control subjects received only the free meter with training and reinforcement at each study visit.

Our primary outcome was change in HbA_{1c} over 6 months. It is widely considered that an improvement in HbA_{1c} of $> 0.5\%$ is 'clinically important' [13]. We provided patients with requisitions for HbA_{1c} samples. These were then frozen, shipped and analysed at a single central laboratory, using the Bio-Rad Variant II Haemoglobin Testing system, accurate to within 0.4% (Dynacare Kasper Medical Laboratories, Edmonton, Alberta, Canada). Investigators were blinded to allocation status and HbA_{1c} measurements.

Our secondary outcome assessed self-monitoring behaviours using the Summary of Diabetes Self-Care Activities [14,15]. Respondents rate the number of days per week that they performed each self-care activity. The average of the two self-monitoring questions represented the self-monitoring score; a difference of 1.0 on this scale represents, on average, someone who tests at least 1 day a week more frequently [14–15].

The primary analysis was the comparison of 6-month HbA_{1c} values between study arms, using analysis of covariance, adjusting for baseline HbA_{1c}. We planned *a priori* secondary analyses of subgroups stratified above or below HbA_{1c} of 8.0%. Our primary analyses were based on an intention-to-treat framework, whereby missing values at the end of follow-up were imputed with each patient's baseline values. Because our losses to follow-up were greater than expected, we also conducted 'on-treatment' (per-protocol) analyses for subjects with complete data.

We estimated that 120 subjects per study arm were needed to detect an absolute difference in HbA_{1c} of 0.5%, assuming a common SD of 1.4% [16], a two-tailed $\alpha = 0.05$ and power of 80%. We planned for 300 patients to account for an anticipated 30% loss to follow-up and to allow for potential subgroup analyses.

Results

Community pharmacists screened 458 potentially eligible patients. Of those who were excluded on screening, the primary reason was insurance coverage for testing supplies ($n = 182$, 40%) (Fig. 1). We randomized 262 patients (131 intervention and 131 control subjects). This was fewer than we had planned, as we were forced to stop enrolment because of changes in provincial reimbursement policy—specifically, all patients with Type 2 diabetes became eligible for reimbursement for the cost of their testing supplies. Effectively, this policy change meant that no one in the province was eligible for our study.

The mean age of the participants was 68.4 years (SD 10.9), 48% were male, mean duration of diabetes was 8.2 years (SD 7.2). Intervention and control patients were comparable, although the former were older (70 vs. 67 years; $P = 0.04$) and had a lower body mass index (29.1 vs. 31.7 kg/m², $P = 0.001$) than the latter (Table 1). The mean baseline HbA_{1c} was 7.4% (SD 1.2) and did not differ between groups.

Following randomization, 106 (40%) subjects, 47 (36%) from the intervention group and 59 (45%) from the control group, did not complete their scheduled 6-month follow-up visit, when outcomes would have been ascertained (Fig. 1). Of those not completing, 87 (82%) withdrew, 17 (16%) were lost to follow-up and two (2%) died. The major reason for study withdrawal was loss of interest ($n = 29$, 33%). We found no clinical or socio-demographic differences between completers and non-completers (data not shown).

We observed no difference in the 6-month HbA_{1c} between intervention and control subjects; adjusted for baseline HbA_{1c}, the difference was 0.03 [95% confidence interval (CI) -0.16 , 0.22; $P = 0.78$] (Table 2). When we considered only those subjects with complete data, the difference in 6-month HbA_{1c}, adjusted for baseline, was 0.02 (95% CI -0.29 , 0.33; $P = 0.90$). Similar results were observed in posthoc analyses based on baseline glycaemic control or controlling for differences in age and body mass index. In all comparisons, the 95% CIs explicitly exclude a clinically important difference (in either direction) of 0.5% for HbA_{1c}.

Intervention patients who received free strips self-reported testing on average 0.64 days (95% CI 0.18, 1.10; $P = 0.007$) per week more often than control subjects (Table 2). In subjects with complete data, the difference in self-monitoring scores between the intervention and control groups was 1.00 (95% CI 0.29, 1.71; $P = 0.006$), which is interpreted as testing one additional day per week. There was no association between the changes in self-reported frequency of testing and HbA_{1c} (Pearson $r = -0.10$, $P = 0.12$).

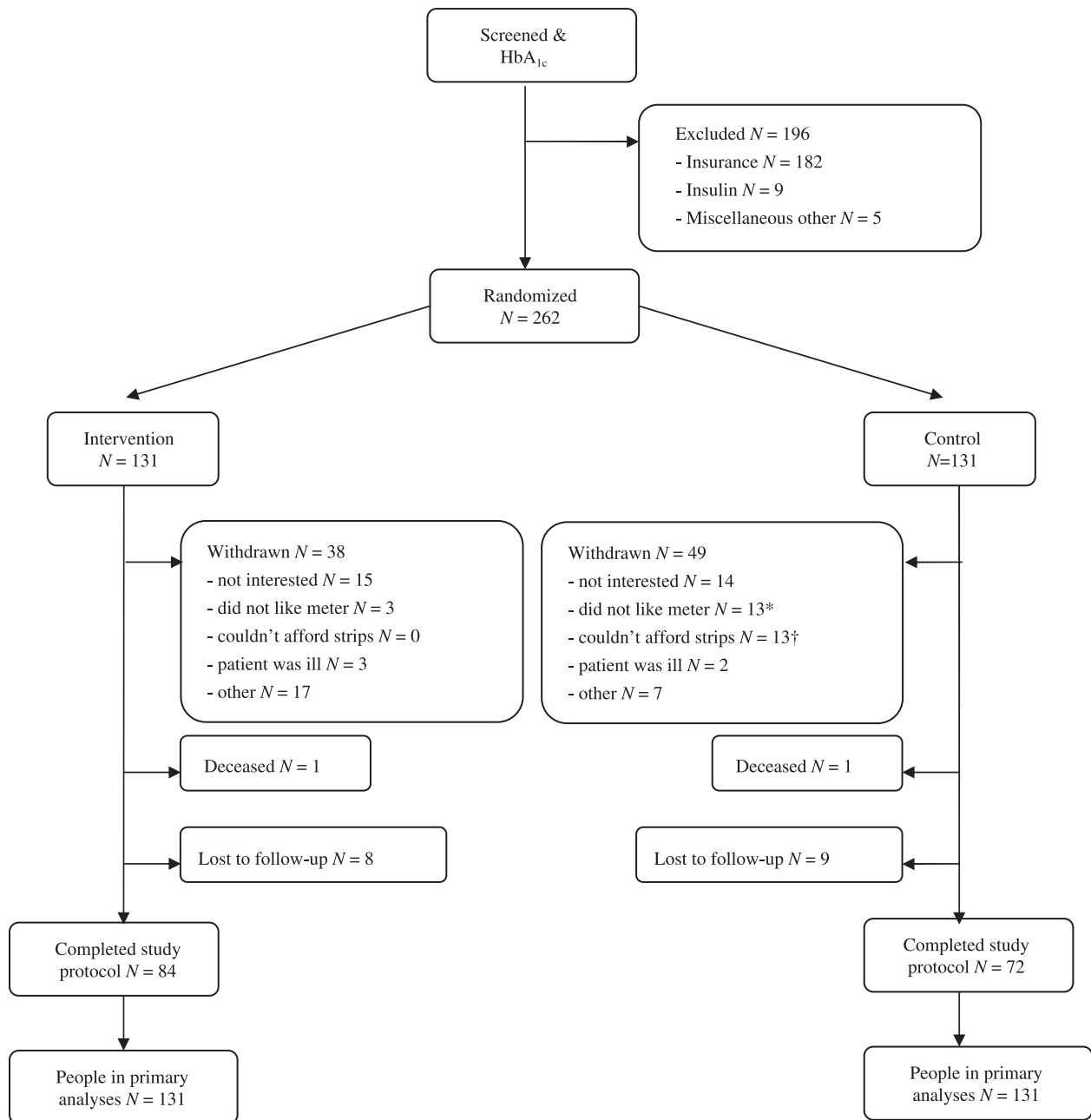


Figure 1 Patient enrolment and disposition. * $P = 0.03$. † $P = 0.001$.

Discussion

In this randomized controlled trial we found that the provision of free testing supplies to those with non-insulin-treated Type 2 diabetes was not associated with clinically important improvements in glycaemic control over 6 months. Patients in the intervention group self-reported using testing strips slightly more often, but this did not lead to better glycaemic control.

The value of self-monitoring in Type 2 diabetes is complicated by a tangled web of perspectives. Some patients with diabetes

embrace self-monitoring, as it gives them a sense of control [6,17–19]. Guidelines promote self-monitoring because clinicians, even those schooled in evidence-based medicine, advocate a practice that ‘makes sense’ (albeit without established evidence of benefit and which is very expensive) [4,6,9,11]. The lack of evidence has prompted some prominent opinion leaders to suggest that self-monitoring for people with Type 2 diabetes not receiving insulin is a ‘waste of money’ [11].

The paucity of evidence supporting self-monitoring has been recognized [4–7], leading to a number of recent studies [13,20–

Variable	Intervention (N = 131)	Control (N = 131)
Age (years)	69.8 (10.0)	67.0 (11.7)*
Sex (male)	64 (49%)	62 (47%)
Married or living with partner	69 (53%)	80 (61%)
Annual household income = \$40 000 (CDN)	37 (28%)	39 (30%)
High school education	75 (57%)	82 (63%)
Body mass index (kg/m ²)	29.1 (5.8)	31.7 (6.8)†
Duration of diabetes (years)	8.6 (7.3)	7.7 (7.0)
Oral agents for diabetes	127 (97%)	126 (96%)
Been to diabetes educational clinic	95 (72%)	97 (74%)
Years since last visit to diabetes educational clinic	4.2 (4.9)	4.7 (5.4)
Number of visits to doctor in the last 6 months	4.4 (3.5)	4.5 (3.7)
Number of visits to doctor for diabetes in the last 6 months	2.3 (2.0)	2.5 (2.9)

*P = 0.035.

†P = 0.001.

Mean ± SD or number (%).

Table 1 Baseline characteristics of study patients

Table 2 Analysis of HbA_{1c} and self-testing frequency

Comparison	Intervention (N = 131)	Control (N = 131)
HbA _{1c} mean (SD) intention-to-treat analysis	(N = 131)	(N = 131)
Baseline	7.5 (1.6)	7.3 (1.2)
6-month	7.3 (1.5)	7.1 (1.2)
Adjusted difference (95% CI)	0.03 (-0.16, 0.22)	
P-value (ANCOVA)	0.78	
HbA _{1c} mean (SD) per-protocol analysis	(N = 84)	(N = 72)
Baseline	7.6 (1.7)	7.4 (1.3)
6-month	7.2 (1.6)	7.1 (1.2)
Adjusted difference (95% CI)	0.02 (-0.29, 0.33)	
P-value (ANCOVA)	0.90	
SDSCA, mean (SD) intention-to-treat analysis	(N = 131)	(N = 131)
Baseline	3.4 (2.4)	3.4 (2.4)
6-month	4.1 (2.5)	3.5 (2.5)
Adjusted difference (95% CI)	0.64 (0.18, 1.10)	
P-value (ANCOVA)	0.007	
SDSCA, mean (SD) per-protocol analysis	(N = 84)	(N = 72)
Baseline	3.6 (2.3)	3.5 (2.4)
6-month	4.7 (2.3)	3.6 (2.5)
Adjusted difference (95% CI)	1.00 (0.29, 1.71)	
P-value (ANCOVA)	0.006	

SDSCA, Summary of Diabetes Self-care Activities [14]; higher scores mean more frequent self-monitoring (range: 0–7); a difference of 1.0 indicates, on average, testing 1 day per week more frequently.

25]. Mounting evidence suggests that simply measuring blood glucose alone is ineffective [11]. Efficacy studies suggest self-monitoring has some small-to-modest effect on glycaemic control, limited to subgroups of patients who actively incorporate results into lifestyle modification and diabetes management [7,20,22]. Most health policies, however, simply pay the cost of testing supplies without linking such reimbursement to ongoing education and evaluation [4–7]. Evidence supporting such policies is even less compelling [4,8,11,15,25,26]. Our

results, along with others [8], suggest it may be possible to achieve substantial savings without compromising glycaemic control in Type 2 diabetes.

We recognize a potential volunteer bias in our study, with most subjects having relatively good glycaemic control at baseline (though this may well reflect the distribution of HbA_{1c} in the community with Type 2 diabetes), thereby limiting any potential improvement. Current guidelines [1] recommend self-monitoring for the entire population that we enrolled and any non-restrictive reimbursement policy for testing supplies would cover all of these patients. It is particularly ironic that our study was prematurely terminated due to a change in reimbursement policy which provided increased financial coverage for all potentially eligible study subjects.

As with most previous studies [13,22], we anticipated considerable losses to follow-up. Non-completers were similar to completers and the consistency of our main and sensitivity analyses increases confidence in our conclusion. We recognize that we determined changes in glycaemic control over a relatively short time for a chronic condition. The duration of our study is, however, comparable to Phase III and IV clinical trials required for regulatory approval of new glucose-lowering agents, which consider short-term changes in HbA_{1c} as a surrogate measure equated with lifelong clinical benefits. Insurance and reimbursement policies that continue to fund interventions that fail to meet standards of evidence-based medicine may lead to a ‘policy steal’, siphoning scarce healthcare resources away from those interventions known to be effective and cost-effective such as antihypertensive or lipid-lowering therapies [6,27].

In conclusion, we observed that reducing financial barriers to self-monitoring by providing free testing strips did not lead to improved glycaemic control in patients with Type 2 diabetes who do not use insulin. Our results have implications with respect to reimbursement policies for testing supplies, suggesting that universal coverage policies may, indeed, be a ‘waste of money’

[11] relative to investments in proven effective treatments and services for patients with diabetes.

Competing interests

Financial support was provided by unrestricted grants from the Canadian Diabetes Association (in honour of the late John Heinen), the Institute of Health Economics and Aventis Canada. This work was also supported by a New Emerging Team (NET) grant sponsored by the Canadian Diabetes Association, the Heart and Stroke Foundation of Canada, The Kidney Foundation of Canada, the Canadian Institutes for Health Research. These funding organizations played no role in the design or conduct of the study or the preparation of this manuscript.

Acknowledgements

J.A.J. holds a Canada Research Chair in Diabetes Health Outcomes and is a Health Scholar with the Alberta Heritage Foundation for Medical Research (AHFMR). S.R.M. is a Population Health Investigator with AHFMR and a New Investigator of the Canadian Institutes of Health Research. We thank the community pharmacists that participated in this study who identified and tracked study subjects, and EPICORE at the University of Alberta for data management.

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