Self-monitoring of blood glucose in type 2 diabetes: a new look at published trials

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To the Editor: Published randomised controlled trials (RCTs) of self-monitoring of blood glucose (SMBG) in type 2 diabetes have not reached a consistent conclusion with regard to the benefit of using SMBG, especially in non-insulin-treated patients. As a consequence, there is worldwide variability in the use of glucose test strips and policies on reimbursement [1].

We analysed 18 relevant RCTs [2–19], some of which had not been included in previous meta-analyses [20–25]. Why do these trials not provide a reliable answer? The main reason appears to be conceptual. SMBG per se is a diagnostic procedure and not an intervention. Clinical trials, though, compare different types of intervention vs outcome. Hence, the 18 RCTs did not simply compare the same treatment protocol plus/minus SMBG but compared intervention strategies, which differed in many aspects, i.e. SMBG-guided disease management strategies. Each of the

RCTs studied a different strategy for SMBG-guided disease management. As a consequence, the clinical outcomes of the different trials can hardly be combined in a meta-analysis. This renders safe conclusions virtually impossible.

An SMBG-guided disease management strategy should include some type of algorithm enabling the patient to translate SMBG readings into changes of diet, daily exercise and/or of dose of glucose-lowering medication. Next there should be some guidance for patients during their first months of using SMBG, and, finally, decisions on medication and advice from nurses or doctors should also make use of documented SMBG results. For this advice, some rules or an algorithm on how to translate blood glucose profiles into medical advice should exist in the context of a RCT.

We have analysed the RCTs for the SMBG-based disease management strategy employed. Unfortunately, information on this crucial point is quite brief in most reports. Only seven of the 18 study protocols included an algorithm or some guideline to teach patients how to respond to elevated SMBG readings, whether they were fasting or postprandial (Table 1). Reinforcement of patient education by guidance during the study ranged from one visit in 6 months to initially weekly meetings, to continuous support via the Internet. Six trials did not report a procedure for consideration of documented SMBG data for making medical treatment decisions by doctors or nurses; a further two trials apparently evaluated fasting but not postprandial values (Table 1).

We conclude that most RCTs of SMBG in type 2 diabetes do not provide a sufficiently detailed description of the SMBG-guided disease management strategy used, even though it is this intervention strategy that is analysed in the trial. As judged from the information provided, there is

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Table 1 SMBG-based disease management strategies in published RCTs

Study (RCT) [reference no.]	Patient self-management of glycaemia: algorithm for how to respond to BG level ^a		Patient guidance during study		Treatment guidelines for nurse/doctor using SMBG data ^a		HbA _{1c} (%)
	High FBG	High pp BG	Method of contact	Frequency	FBG	BG profile	
Allen et al. [2]	Yes	No	Hospital visits	Monthly for 6 months	Yes	No	12.4±3.3
Brown et al. [3]	No	No	Meetings in official buildings	Weekly for 3 weeks, biweekly for 6 weeks, monthly for 3 months	No	No	11.81±3.00
Cho et al. [4]	No	No	Internet + hospital visits	Every 3 months for 30 months	Yes	Yes	7.7±1.5
Davidson et al. [5]	Yes	Yes	Meeting with the dietitian	Five times in 12 weeks	Yes	Yes	8.5±2.2
Estey et al. [6]	No	No	Meeting with a nurse	Every 2 weeks	No	No	6.3±1.1
Farmer et al. [7]	Yes	Yes	Telephone calls	Four in 10 weeks	Yes	No	7.53±1.12
Fontbonne et al. [8]	No	No	Home visit	One in 10 weeks	Yes	No	7.41±1.02
Guerci et al. [9]	No	No	Hospital visits	At months 1, 3, 6 and 9	Yes	Yes	8.2±0.3 ^b
Jaber et al. [10]	No	No	Hospital visits	At months 1, 3, 6 and 9	Yes	Yes	7.28±0.88
Johnson et al. [11]	No	No	Pharmacy visits	Every 2 months for 6 months	Yes	Yes	-0.36±0.29 ^{c,h}
Jones et al. [12]	No (?)	No (?) ^b	Hospital visits	Every 6 weeks for 24 weeks	No	No	9.0±1.3
			Hospital visits	Every 2–4 weeks for 4 months	Yes	Yes	11.5±2.9
			Pharmacy visits	After 3 and 6 months	No	No	7.5±1.6
			Centre visits	About four in 1 year	No	No	7.78 ^d /8.30 ^e
			Non-medical contact (mail or phone)	Monthly			
Kibriya et al. [13]	Yes	Yes	Hospital visits	Every 3 months for 18 months	Yes	Yes	8.19±1.37
Kwon et al. [14]	No	No	Hospital visits	At 0 and 12 weeks	Yes	Yes	7.59±1.43
			Internet	At least weekly for 12 weeks			
Miles et al. [15]	No	No	Hospital visits	Four times in 3 months	Yes	Yes	10.3±2.6
Moreland et al. [16]	No (?)	No (?) ^b	Centre visits	After 3 and 6 months	No	No	9.3±1.2
	No	No	Centre visits	After 3 and 6 months	No	No	9.1±1.2
Muchmore et al. [17]	Yes	Yes	Group meetings	Weekly for 12 weeks, every 4 weeks for 16 weeks	Yes	Yes	10.29±0.33 ^b
			Meeting with dietitian	Two times			8.8±1.9
			Meeting with nurse educator	Three times			-0.13±1.28 ^c
Schwedes et al. [18]	Yes	Yes	Hospital visit	Every 4 weeks for 24 weeks	Yes ^g	Yes ^g	-0.04±1.31 ^c
Wing et al. [19]	Yes	Yes	Meeting	Weekly for 12 weeks, monthly for 6 months, after 9 and 12 months	Yes	Yes	8.75±0.48 ^b

HbA_{1c} values are means±SD; ^a ‘Yes’ means positively stated, ‘No’ means ‘probably no’ as concluded from the description of methods; ^b Manual for patients; ^c Change; ^d Responder; ^e Non-responder; ^f Subgroup; ^g Plus diary for metabolic control; ^h SEM instead of SD; BG, blood glucose; FBG, fasting blood glucose; pp, postprandial

great variation in the SMBG-guided intervention strategies employed: this limits the usefulness of combining all RCTs in a meta-analysis of ‘benefit’ from SMBG.

Future trials of SMBG in type 2 diabetes should define precisely the intervention strategy employed, and in particular how patients and nurses/doctors should make use of fasting and postprandial SMBG readings. Appropriate use of SMBG data by the patient may be improved by practical lessons that allow the patient to recognise the impact of high- vs low-glycaemic meals and of moderate physical activity, such as 30 min brisk walking. It is not enough to learn the rules and signs: practical lessons to learn how to control the steering wheel and use the pedals to keep metabolic control on track are also needed.

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