

RAPID APPRAISAL

Name of Trial: Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial

Reference: BMJ. 2008; published online 17 April doi: 10.1136/bmj.39534.571644.BE

Question: Does self monitoring of blood glucose in newly diagnosed type 2 diabetics affect patients' glycaemic control and feelings towards their treatment?

Summary: The use of blood glucose self monitoring in newly diagnosed type 2 diabetics did not affect patients' glycaemic (HbA_{1c}) control compared to no self monitoring. There were no significant differences seen between the groups with treatment satisfaction or attitudes, but on the depression subscale of the well-being questionnaire, a higher proportion experienced depression in the self monitoring group. No other differences were seen between the groups with respect to hypoglycaemia incidence, body mass index and use of oral hypoglycaemic drugs. This small, twelve month study adds to data already available; the routine use of self monitoring of blood glucose in patients with non-insulin treated type 2 diabetics is not recommended.

Did the study ask a clearly focussed question?

Yes – Self monitoring of blood glucose in type 2 diabetes is widely undertaken in primary care, with poor evidence to justify routine introduction. This study was designed to investigate the effects of the self monitoring of blood glucose on newly diagnosed type 2 diabetic patients' HbA_{1c} levels, and also on attitudes to and perceptions of their treatment. The primary outcomes were differences between groups in HbA_{1c} levels, psychological indices and the incidence of hypoglycaemia. Secondary endpoints were differences in body mass index (BMI) and the use of oral hypoglycaemic drugs.

Was the study design appropriate?

Yes – This was a prospective, randomised controlled trial, assessing the effects of self monitoring compared to no monitoring (control) over one year. Patients were eligible if they were less than 70 years old and were newly diagnosed with type 2 diabetes. They were excluded if they had secondary diabetes, used insulin, previously used blood glucose self monitoring, had a major illness within the preceding six months or had chronic kidney or liver disease or alcohol misuse. A total of 184 patients were randomised to self monitoring (n = 96) or control (n = 88). The study was funded by the Northern Ireland research and development office. The blood glucose meters were supplied free of charge by the manufacturers (Johnson and Johnson).

The study had a > 90% power to detect a 1% difference in HbA_{1c} between the two groups at the 0.05 level. Analysis was performed on the intention to treat population, with missing data imputed.

Were participants appropriately allocated to intervention and control groups?

Yes – After assessment, patients were randomised using a randomly generated allocation code in

sealed envelopes (although this is not generally considered an ideal randomisation method).

Baseline characteristics were similar in the two groups, with a slight dominance of men in both groups (57% and 64% in the monitoring and control groups, respectively). Patients in the self monitoring group were given a single glucose monitor and educated in how to use it. They were requested to monitor four fasting and four post-prandial capillary blood glucose measurements every week, and advised on how to respond to any high/low readings. Patients in the control group were requested not to acquire or use a meter for the duration of the study.

Were participants, staff and study personnel 'blind' to participants study group?

No – As the intervention was self monitoring, it was not possible to blind all those involved. However, the authors state that laboratory tests were performed in the hospital laboratory, where staff were blinded to the treatment allocation.

Were all of the participants who entered into the trial accounted for at its conclusion?

Yes – A total of 184 patients were randomised on an intention to treat basis, with none lost to follow up. Two patients in each group withdrew from the study but were included in the final analysis.

Were the participants in all groups followed up and data collected in the same way?

Yes – Both groups of patients went through an identical multi-disciplinary, structured educational programme, and were reviewed every three months for one year. At each of these visits, their diabetes care was fully reviewed and additionally, the self monitoring group received ongoing support and education in the interpretation of and response to their blood glucose results. An identical treatment algorithm was used for the management (pharmacological and dietary) of glycaemia in both groups, based on the HbA_{1c} targets.

Was the study large enough?

Probably – The power calculation was given, however the number of patients required in each group to achieve this are not presented, but independent calculations suggest that a minimum of 85 patients in each group would have been required. As a general observation, 184 patients is a relatively small number of patients, considering the prevalence of type 2 diabetes in the wider UK population.

How are the results presented and what is the main result?

Primary endpoints

The primary endpoint of HbA_{1c} fell in both groups, but there were no significant differences between groups at any time point. At 12 months, the mean (standard deviation) values in the monitoring and control groups were 6.9 (0.8)% vs 6.9 (1.2)%, $p = 0.69$; 95% confidence interval for difference -0.25% to 0.38%.

Psychological indices were measured by patients completing a three-monthly 'diabetes treatment satisfaction questionnaire' and a 'well-being questionnaire'. Patients in the self monitoring group scored 6% higher on the depression subscale of the well-being questionnaire, (i.e. were more depressed), at 12 months ($p = 0.01$). The authors do not state whether this is clinically significant. There were no significant differences between the groups on any of the other subscales; the percentage change associated with monitoring on psychological variables, was 5.86 ($p = 0.07$) for anxiety and 4.16 ($p = 0.15$) for positive wellbeing.

There was no significant difference between the two groups in the incidence of hypoglycaemia, with four and six patients in the self monitoring and control groups, respectively, reporting hypoglycaemia.

There was a high level of compliance in the self monitoring group, with 63/96 patients carrying out over 80% of the requested blood glucose readings.

Secondary endpoints

There was no significant difference in the use of oral hypoglycaemic drugs or BMI between the two groups at any time point.

How precise are the results?

This was a small, well structured study, with comparable baseline characteristics in both patient groups. The 95% confidence intervals provided for the HbA_{1c} endpoint between the two groups were -0.25% to 0.38% and this gives a reasonable estimate of precision. It is unlikely, for example, that a clinically important difference such as >0.5% would have been missed by this study.

Can the results be applied to the local population?

Yes – The study participants were newly diagnosed type 2 diabetic men and women under

70 years (86.7% of recruited patients proceeded to randomisation). The patients were recruited from hospital outpatient diabetes clinics in Northern Ireland. There is no mention of ethnicity, which would have been valuable due to the higher diabetes incidence in certain ethnic populations.

The NICE type 2 diabetes guideline² suggests that patients with poorly controlled blood glucose levels are more likely to experience clinical complications. NICE recommends that in such patients, HbA_{1c} levels should be measured every 2 – 6 months. NICE goes on to state that self-monitoring of glucose should be taught if the need/purpose is clear and agreed with the patient, but should not be considered as a stand-alone intervention.² The participants in this study are representative of type 2 diabetic patients in whom routine self-monitoring of blood glucose may not be warranted.

Does self monitoring of blood glucose in newly diagnosed type 2 diabetics affect patients' glycaemic control and feelings towards their treatment?

The use of blood glucose self monitoring in this patient group did not affect patients' glycaemic (HbA_{1c}) control. A previous larger study ($n = 2,855$)³ showed an increase in distress, worry and depressive symptoms with the frequency of blood testing but in the ESMON study, there were no significant differences between the groups with respect to treatment satisfaction or attitudes. However, on the depression subscale of the well-being questionnaire, a higher proportion experienced depression in the self monitoring group. No other differences were seen between the groups.

This study was a relatively small study and therefore would not be expected to change practice alone. However, when considered alongside the DiGEM study (covered in a previous Rapid Appraisal; suggesting routine monitoring was not required in well-controlled, non-insulin-dependent type 2 diabetic patients and regular HbA_{1c} measurements should be used to monitor blood glucose control),⁴ the argument is strengthened for reviewing recommendations to patients in general practice. An economic evaluation of the DiGEM study concluded that self monitoring of blood glucose was unlikely to be cost effective in addition to standardised usual care.⁵ This ESMON study demonstrated that a small cohort of newly diagnosed type 2 diabetics showed no improvement in glycaemic control when they participated in self monitoring of blood glucose compared to those who did not. Those who did self-monitor appeared to experience higher levels of depression.

Further information is available in the RDTC's Drug Update No.50:⁶ Self-monitoring of blood glucose and Rapid Appraisal (No.19) of the DiGEM study.³

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KEY: RCT - randomised controlled trial, G – guidelines, R – review, CT – controlled trial

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