Self-Monitoring of Blood Glucose in Noninsulin-Treated Diabetes

A Systematic Review

Swedish Council on Health Technology Assessment

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Summary and Conclusions of the SBU Report:

Self-Monitoring of Blood Glucose in Noninsulin-Treated Diabetes

A Systematic Review

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People with diabetes use test strips as a means to check their blood glucose levels. Systematic self-monitoring of blood glucose is necessary for successful insulin therapy aimed at controlling glucose. However, in patients with noninsulin-treated type 2 diabetes, the benefit of systematic self-monitoring has been called into question.

This report reviews the scientific evidence for systematic self-monitoring of blood glucose with test sticks in patients with type 2 diabetes, but who are not receiving insulin therapy. The Swedish National Board of Health and Welfare commissioned the report to use as a basis for their national guidelines on diabetes care. SBU is producing three additional reports within the framework of the National Board of Health and Welfare's guidelines on diabetes – patient education in managing diabetes, intensive glucoselowering therapy in diabetes, and dietary treatment of diabetes.

Conclusions

The scientific evidence does not show any benefits from systematic self-monitoring of blood glucose (SMBG) with test sticks in people with noninsulin-treated type 2 diabetes. Examples of specific situations where people with noninsulin-treated type 2 diabetes may have reason to use test sticks include symptoms of hypoglycemia, particularly in patients being treated with sulfonylurea agents and meglitinides. Self-monitoring may also be needed for other purposes, eg, educational purposes in conjunction with changes in therapy or acute disease.

A more restrictive use of test sticks in this patient group would reduce costs and would not increase medical risks.

SBU's Summary

Background and Purpose

Type 2 diabetes is common. The prevalence in the adult population is approximately 4%, about half of whom are receiving insulin therapy. The risk of complications in diabetes is strongly associated with long-term control of blood glucose. Several different options are available to monitor glucose levels. The most common, and the most studied, methods involve SMBG with the use of test sticks and an electronic meter, and measurement of HbA_{1c}. HbA_{1c} is a blood test that is often performed in conjunction with visiting a physician or nurse. It provides information on the average glucose levels in the blood during the 6 weeks immediately prior to testing. Self-monitoring of blood glucose is a way to help patients learn more about their blood glucose levels.

Self-monitoring of blood glucose has several potential purposes. It can be used to address a specific need, eg, suspected hypoglycemia, or to help patients understand how physical activity and diet affect their blood glucose levels. Monitoring can also be more systematic. Systematic monitoring usually involves measuring blood glucose before and after meals for one or more days per week to observe variations in blood glucose levels throughout the day. This information could enable changes in lifestyle and pharmacotherapy, with the long-term goal being to improve glucose control.

The basic premise of this report is that test sticks for SMBG, which are free-of-charge to patients, represent a substantial cost to health care. Hence, it is important to determine the patient benefits and cost-effectiveness of using test sticks in SMBG.

Limitations

The report focuses on systematic self-monitoring of blood glucose in patients with noninsulin-treated type 2 diabetes. We did not investigate systematic SMBG during insulin therapy since this is assumed to be necessary to adequately control glucose, a prerequisite for successful insulin therapy.

Questions

- Does self-monitoring of blood glucose with test sticks in patients with noninsulin-treated type 2 diabetes reduce the risks for delayed complications, improve long-term control of blood glucose, and enhance quality of life?

- Are the risks for severe hypo- and hyperglycemia reduced?

- Is systematic SMBG cost effective?
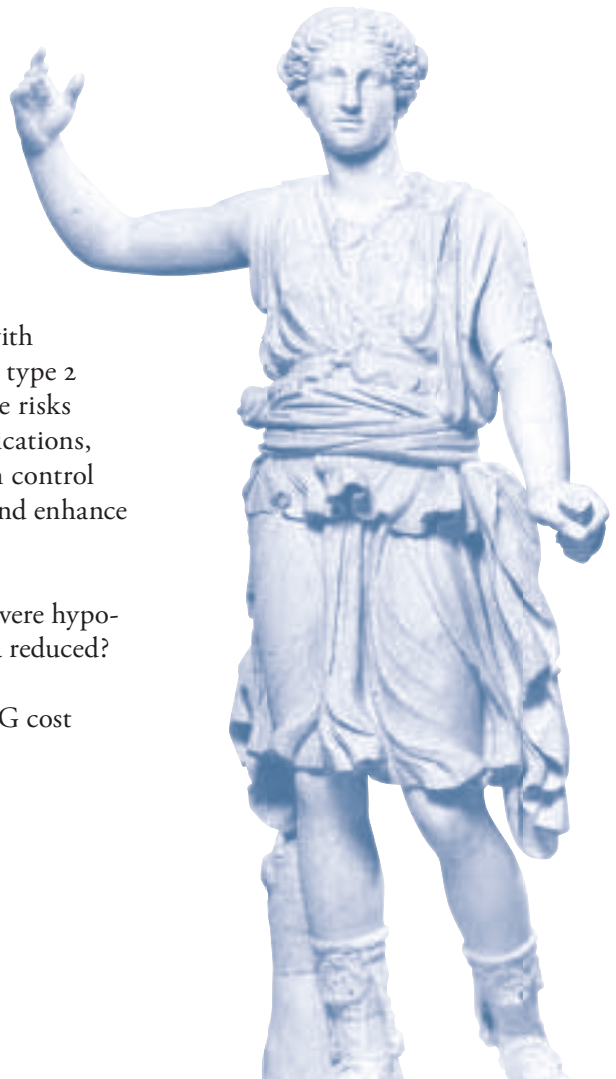
Target Groups

The report is intended to serve as a basis for national guide-lines on diabetes care issued by the Swedish National Board of Health and Welfare and targets healthcare professionals responsible to care for people with diabetes. It also targets politicians and administrators in decision-making positions in health care. This report may also provide valuable information to patients and their families.

Methods

SBU uses thorough and systematic methodology to search bibliographic databases for relevant literature on the issue being studied. Included studies are assessed individually for quality, and specially designed methodology is used to summarise key information in table format. Findings are graded to reflect the strength of the evidence, and the assessment aims to cover medical, economic, social, and ethical perspectives.

Fact Box 1 Study Quality and Strenght of Evidence.

Study quality refers to the scientific quality of an individual study and its ability to provide a valid answer to a specific question.

Strength of the evidence refers to a judgment of the total strength of all scientific evidence and its ability to provide a valid answer to a specific question. SBU uses GRADE, an international grading system for the body of evidence. Study design is a key element in the overall judgment of each outcome measure. Other factors that can weaken or strengthen the power of the evidence are: risk of bias, inconsistency of results, indirectness of evidence, data precision, risk of publication bias, and other aspects, eg, effect size and the dose-response relationship.

Grading the strength of the evidence – four levels:

Strong scientific evidence (⊕⊕⊕⊕) is equivalent to high quality of the body of evidence according to GRADE.

Moderately strong scientific evidence (⊕⊕⊕○) is equivalent to moderate quality of the body of evidence according to GRADE.

Limited scientific evidence (⊕⊕○○) is equivalent to low quality of the body of evidence according to GRADE.

Insufficient scientific evidence (⊕○○○) is equivalent to very low quality of the body of evidence according to GRADE.

The stronger the evidence, the less likely it is that the results presented will be affected by new research findings within the foreseeable future.

Conclusions
SBU's conclusions represent our overall judgment of benefits, risks, and cost effectiveness.

Results

Effects on quality of life are inconsistent in studies of SMBG with test sticks in people with noninsulin-treated type 2 diabetes (Insufficient scientific evidence ⊕○○○).

It cannot be determined whether systematic SMBG with test sticks in people with noninsulin-treated type 2 diabetes reduces the risks for severe hypoglycemia (Insufficient scientific evidence ⊕○○○).

The use of systematic SMBG with test sticks in people with noninsulin-treated type 2 diabetes shows, after 6 months, a small improvement in HbA_{1c} compared to the control group (Limited scientific evidence ⊕⊕○○). None of the randomised trials lasted more than 1 year.

Cost effectiveness cannot be evaluated as regards systematic SMBG with test sticks in people with noninsulin-treated type 2 diabetes (Insufficient scientific evidence ⊕○○○).

Table 1 Summary of findings on self-monitoring of blood glucose.

Outcomes	Number of patients (no of studies & study design)	Mean value in standard group (min–max)
Diabetes complications	–	–
Severe hypoglycemia	1 299 (2 RCTs[*])	0 cases
Quality of life[***]	709 (3 RCTs)	–
HbA$_{1c}$ after >1 year	–	–
HbA$_{1c}$ 6 months	2 207 (7 RCTs)	6.6%–8.4%

[*]   Four RCTs (n=2 086) addressed hypoglycemia, but in two of these
      studies the occurrence of severe hypoglycemia was negated.
[**]   Since incidence in the included populations is very low, the studies
      would need to be substantially larger. A possible absolute effect would
      be very small in this population.
[***] No, or very minor, effects on quality of life. The findings were conflicting
      since the effects in two studies pointed in opposite directions.

CI = Confidence interval; RCT = Randomised controlled trial

Absolute effect (95% CI)	Quality of evidence	Comments and study limitations
–	–	Not studied
–	Insufficient ⊕○○○	Imprecision –2** Indirectness –1
–	Insufficient ⊕○○○	Imprecision –1 Inconsistency –1 Risk of bias –1
–	Insufficient ⊕○○○	No studies retrieved
0.26 percentage points lower (−0.37, −0.16)	Limited ⊕⊕○○	Risk of bias –1 Indirectness –1

We included 7 studies with 2 207 patients in total. All of these studies were appraised to have moderately strong quality, but variation within this grading category was wide. Three studies bordered on low quality.

The included studies differ on several points. The populations differed with respect to several characteristics, eg, medication, mean age, and average number of years diagnosed with diabetes. Few patients older than 75 years of age were included.

We found substantial variation in the definition of systematic SMBG used in the different studies, illustrated in part by wide variation in the average consumption of test sticks (<1 to >5 test sticks per day). Participants in the control groups did not monitor their own blood glucose. Two of the studies reported 12-month follow-up, while the remainder reported 6-month follow-up.

Small Reduction in HbA$_{1c}$

Systematic monitoring of blood glucose with test sticks revealed a small reduction in HbA$_{1c}$; around 0.26 percentage points (95% CI −0.37 to −0.16) after 6 months in patients with noninsulin-treated type 2 diabetes. Sensitivity analyses show that this effect is only marginally influenced if we exclude one or two of the studies, irrespective of which.

Evidence is insufficient to comment on risks for hypo- or hyper-glycemia. Four studies (2 086 patients) reported that the prevalence of hypoglycemia had been studied. Only two of these clearly reported there were no cases of severe hypoglycemia. None of the studies reported on any cases of hyperglycemia that required hospitalisation.

Effects on Quality of Life

Three studies reported on the effects of SMBG on quality of life. The results were conflicting, in that one study reported higher, one study reported lower, and one study reported the same quality of life in the SMBG groups and control groups respectively.

Conclusion

This systematic review suggests that the main effect of systematic SMBG is a small decrease in HbA_{1c} (0.26 percentage points). The clinical importance of this reduction is not clear. In comparison, the most common oral drugs for diabetes, metformin and glibenclamide reduce HbA_{1c} by around 1.0 to 1.5 percentage points. No other clinically important effects were found from SMBG, but evidence was judged to be insufficient as regards the other outcome measures (quality of life, severe hypoglycemia, and hyperglycemia requiring hospital-isation). A small effect on these cannot be ruled out.

Health Economics

We studied three health economic questions related to systematic self-monitoring of blood glu-cose with test sticks in people with noninsulin-treated type 2 diabetes.
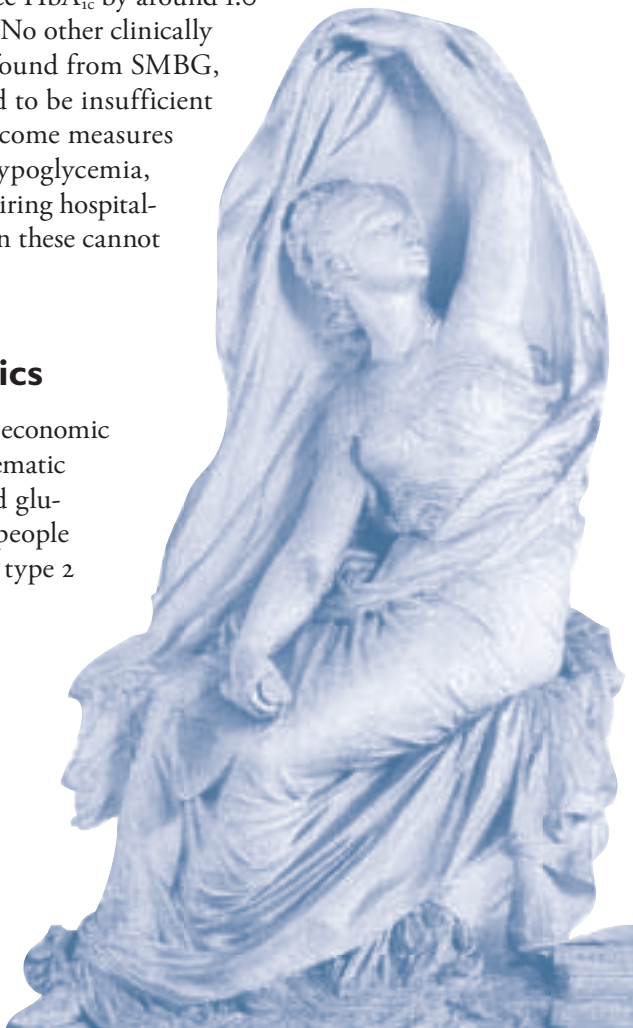
1) Is the Method Cost Effective?
The health-economic data are conflicting. Three studies were identified, all of which were based on highly uncertain assumptions. Cost effectiveness cannot be evaluated.

2) How Much does Sweden Spend on Test Sticks for Systematic Self-Monitoring of Blood Glucose in People with Noninsulin-Treated Type 2 Diabetes?
According to our estimates based on statistics from the Swedish Prescription Drug Registry, the costs for people on oral anti diabetics alone is approximately 100 million Swedish kronor (SEK) per year, and the costs for those not on diabetic drugs is almost SEK 30 million. The total cost in Sweden for acquiring test sticks for SMBG exceeds SEK 600 million per year, ie, the greatest expenditure is for people receiving insulin therapy.

3) What are the Opportunity Costs?
Our estimate, based on an assumed reduction in the use of test sticks, suggests that resources on the order of SEK 50 to 90 million per year could be freed if package sizes were smaller or fewer packages were prescribed.

Consequence Analysis

The scientific evidence does not show that people with non-insulin-treated type 2 diabetes derive any explicit benefit from systematic SMBG involving the use of test sticks. This finding suggests that a more restrictive use of test sticks in this patient group would reduce costs without increasing medical risks.

Examples of specific situations where there may be reasons to use test sticks in people with noninsulin-treated type 2 diabetes would include cases of symptomatic hypoglycemia, particularly in patients treated with sulfonylurea and meglitinides. Self-monitoring might also be needed for other purposes, eg, educational purposes in conjunction with changes in therapy and in acute disease.

Some patients may view restrictions as a problem. They might feel insecure if not allowed to use test sticks freely and might feel negatively toward physicians who limit this type of monitoring. It is important for patients to be well informed and understand that the need for testing from a safety perspective is relatively small in noninsulin-treated type 2 diabetes.

Another consequence of more restrictive use of test sticks would be the need for smaller packaging: 10 to 20 test sticks per package rather than 50.

Knowledge Gaps

- Studies have not investigated monitoring when needed compared to no monitoring.

- It is not clear whether the small improvement in HbA_{1c} could change after a longer period. Studies lasting more than one year are not available.

- Possible educational effects of systematic monitoring, eg, on exercise and diet, have not been studied.

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SBU Evaluates Health Care Technology

Below is a brief summary of the mission assigned to SBU by the Swedish Government:

- SBU shall assess healthcare methods by systematically and critically reviewing the underlying scientific evidence.

- SBU shall assess new methods as well as those that are already part of established clinical practice.

- SBU's assessments shall include medical, ethical, social and economic aspects, as well as a description of the potential impact of disseminating the assessed health technologies in clinical practice.

- SBU shall compile, present and disseminate its assessment results such that all parties concerned have the opportunity to take part of them.

- SBU shall conduct informational and educational efforts to promote the application of its assessments to the rational use of available resources in clinical practice, including dental care.

- SBU shall contribute to the development of international co-operation in the field of health technology assessment and serve as a national knowledge centre for the assessment of health technologies.

Self-Monitoring of Blood Glucose in Noninsulin-Treated Diabetes

SBU's report on self-monitoring of blood glucose in noninsulin-treated diabetes builds on a systematic, critical review of the scientific literature in the field.

The report is one in a series of reports published by SBU (Swedish Council on Technology Assessment in Health Care).

This document presents the summary and conclusions of the full report, which has been approved by SBU's Board of Directors and Scientific Advisory Council.