IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Self-monitoring of urine or blood glucose in diabetes mellitus type 2[1]

Executive Summary

[1] Translation of the executive summary of the final report "Urin- und Blutzuckerselbstmessung bei Diabetes mellitus Typ 2" (Version 1.0; Status: 14.10.2009). Please note that this translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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Self-monitoring of urine or blood glucose in diabetes mellitus type 2

Executive summary

Research question

The aims of the planned investigation can be summarized as follows:

- to assess the benefit of self-monitoring of blood glucose (SMBG) as an integral component of every blood glucose lowering therapy strategy compared to a strategy without self-monitoring of blood glucose
- to assess the benefit of self-monitoring of urine glucose (SMUG) as an integral component of every blood glucose lowering therapy strategy compared to a strategy without self-monitoring of urine glucose
- to assess the benefit of self-monitoring of urine glucose as an integral component of every blood glucose lowering therapy strategy compared to self-monitoring of blood glucose as an integral component of every blood glucose lowering therapy strategy

in patients with diabetes mellitus type 2 who are not receiving insulin therapy. The focus was on patient-relevant outcomes.

The intervention "glucose self-monitoring" as such was assessed explicitly. Structured education and treatment programmes as an entity were not assessed if glucose self-monitoring represented only one of several components in a complex intervention.

In addition to the benefit assessment, the results of epidemiological studies were to be described in terms of the link between long-term glucose self-monitoring and morbidity and mortality.

Methods

The methods in this assessment were published in advance in a report plan. The report plan version 1.0 for this commission was published on the Internet on 11 October 2005. Work on the commission was interrupted in the middle of 2006 and re-started in June 2008. During that period, a comprehensive revision of the original report plan became necessary. The amendments were published on the Internet on 20 August 2008 in the form of a new, preliminary report plan version 1.1 dated 7 August 2008. Comments could be submitted on this version until 17 September 2008 (hearing). Those submitting comments were invited to an oral debate on 22 October 2008 to discuss any unclear aspects arising from the written comments on the report plan. Comments and documentation of the oral debate are published on the Internet in a separate document ("Documentation and appraisal of comments on the

report plan"). Following the submission of comments, a revised report plan was published (version 2.0 dated 29 January 2009).

The preliminary assessment, the preliminary report, was published on the Internet on 23 June 2009. All interested parties, institutes and organizations, including private individuals, professional associations and industry, could submit comments on this preliminary report until 21 July 2009 (hearing). Those submitting comments were invited to an oral debate on 18 August 2009 to discuss any unclear aspects arising from the written comments. In addition, the preliminary report was externally reviewed. This final report also contains the amendments that arose from the submission of comments and from the external review.

The benefit assessment was conducted on the basis of randomized controlled trials (RCTs). A systematic literature search was conducted in MEDLINE, EMBASE, CINAHL, and Cochrane databases. The time period up till June 2009 was covered. In addition, literature indexes of relevant secondary publications (systematic reviews, HTA reports) and publicly accessible study registries were searched. RCTs with a duration of at least 24 weeks were included in which glucose self-monitoring by patients with diabetes mellitus type 2 who were not receiving insulin was compared to an intervention without glucose self-monitoring. The literature screening was carried out by 2 reviewers independently of each other. After assessing study quality, the results of the individual trials classified according to outcomes were compared and described.

Results

Search results

The systematic literature search identified 15 publications that reported data from 10 potentially relevant trials. Of these, 2 trials that contained relevant subgroups (patients without insulin therapy) could not be included as data for these subgroups were not made available by the authors (Wing 1986, Oria-Pino 2006). Due to missing relevant outcomes, a further 2 trials were not included in the assessment (Allen 1990, Gallichan 1994). The Scherbaum 2008 trial compared different intensities of SMBG and did not include any intervention without SMBG; thus, it was only included for effect modifiers at different monitoring frequencies. As a result, 5 trials were included in the assessment (ASIA, DIGEM, DINAMIC1, ESMON, SMBG). For the DINAMIC 1 study, the unpublished study report was made available upon request, and was also taken into account

In all 5 trials, SMBG was compared versus no SMBG. There were no relevant trials available on SMUG. The 5 included trials had a duration of between 6 and 12 months and thus none of them were designed to investigate the long-term benefit of SMBG. Therefore, the report's conclusions are based exclusively on results from trials of a comparatively short duration.

Study and publication quality

No relevant trials were available on the majority of the pre-defined outcomes. This applied particularly to the following outcomes: hyperglycaemic-related symptoms, all-cause mortality, cardial morbidity and mortality, cerebral morbidity and mortality, vascular non-cardial and non-cerebral morbidity and mortality, blindness and retinal changes affecting sight, terminal kidney failure with dialysis required, amputation (minor and major amputations), inpatient treatment for any reason and hyperosmolar and ketoacidotic coma.

Reported outcomes

In some trials there was information on hypoglycaemia in conjunction with blood glucose monitoring and change in medication, on other adverse events, on change in body weight, and on health-related quality of life and patient satisfaction. However, even for these outcomes, the reporting of results was inadequate in some cases.

Hypoglycaemia and data on HbA1c value as a criterion for blood glucose lowering therapy and change in drug therapy

Overall, the quantity of data on hypoglycaemia was insufficient, particularly data on non-severe hypoglycaemia. Thus, only severe hypoglycaemia could be included in the assessment. However, severe hypoglycaemia was only assessed in 3 of the included trials and also occurred very rarely (a total of 1 event). Overall, there was a statistically significant, but clinically non-relevant, difference in the HbA1c value between the groups: on average the HbA1c value in the SMBG group was reduced by 0.23% points more than in the group without SMBG (95% CI: [0.12; 0.34]). In a sensitivity analysis, which included only the 3 trials with a low bias potential, the HbA1c difference was 0.18% (95% CI: [0.05; 0.31]). The change in medication showed no difference between the intervention groups. In summary, there was no proof of benefit of SMBG in the joint evaluation of the 3 outcomes.

Other adverse events

Adverse events (other than hypoglycaemia) were only reported separately for the 2 groups in one of the included trials, DINAMIC1. No statistically significant difference was shown between the interventions. There was also no statistically significant difference between the interventions in study discontinuations due to adverse events or in serious adverse events, which were also reported only in the DINAMIC1 trial for both groups. However, the number of events was very low in each case.

Overall, on the basis of admittedly insufficient data, there was no proof of harm from SMBG compared to an intervention without SMBG.

Body weight

Body weight was documented in the course of the trial in 4 out of 5 included trials. All trials showed a slight reduction in weight on average. The difference between the treatment groups was overall not statistically significant.

Health-related quality of life

Data on health-related quality of life were found in 3 trials. In the DIGEM trial, 2 different measurement instruments (W-BQ12[2] and EQ-5D[3]) were used, whereas ESMON and SMBG used the W-BQ22 instrument. The bias potential for this outcome was high in all trials. In the DIGEM trial, no statistically significant difference in quality of life between the interventions could be established using W-BQ12; the data on EQ-5D were in part contradictory and could not be analysed. The ESMON trial described increased depression in SMBG patients, whereas a decrease in depression was described for these patients in the SMBG trial.

Overall, the data yielded no proof of benefit of or harm from SMBG on health-related quality of life.

Patient satisfaction

Patient satisfaction was investigated in 3 trials, with all trials using the DTSQ[4] questionnaire to collect data. None of the trials showed a statistically significant difference in patient satisfaction between the treatment groups.

Overall, no proof of benefit of or harm from SMBG could be derived from investigations into patient satisfaction.

Results from epidemiological studies

Overall, 2 relevant epidemiological studies were identified in which the link between SMBG and mortality and morbidity was investigated. Both the studies displayed results with differing orientation, and have little validity. Overall, the epidemiological studies yielded no proof of a link between SMBG and mortality or morbidity.

Conclusions

There is no proof of benefit of either SMBG or SMUG in patients with diabetes mellitus type 2 who are not receiving insulin. Furthermore, there is no proof of additional benefit of SMBG

[2] Well-Being Questionnaire
[3] European Quality of Life - 5 Dimensions
[4] Diabetes Treatment Satisfaction Questionnaire

compared to SMUG or vice versa. There were no relevant trials reported with sufficient transparency on SMUG.

Results of epidemiological studies on the link between long-term glucose self-monitoring and morbidity and mortality

The epidemiological studies on this topic yielded no proof of a link between SMBG or SMUG and morbidity and mortality.

Keywords: self-monitoring of blood glucose, self-monitoring of urine glucose, diabetes mellitus type 2, systematic review

The full report (in German) is available on www.iqwig.de/index.559.html