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Blood glucose self-monitoring: No benefit for noninsulin-dependent patients with type 2 diabetes

Insufficient trials -- no conclusions possible on diabetes-related diseases

This release is available in German.

Contrary to the widely-held belief, there is no proof that non-insulin-dependent patients with type 2 diabetes benefit from glucose self-monitoring. Moreover, it remains unclear whether an additional benefit is displayed by the blood test compared to the urine test or vice versa, in other words, whether one or other of the tests might offer an advantage to patients. The current data are quantitatively and qualitatively inadequate: the few trials that are suitable for investigating these questions have not included or have insufficiently reported many outcomes important to patients. Owing to their short duration, it is also not possible to draw any conclusions on the long-term benefit of glucose self-monitoring. This is the conclusion of the final report of the Institute for Quality and Efficiency in Health Care (IQWiG), published on 14 December 2009.

Self-monitoring is well established in insulin-dependent patients

Anyone who injects insulin should check their blood glucose level regularly, so that they can regulate the insulin dose according to need - this is an established procedure for patients with type 1 or type 2 diabetes. However, it is unclear whether people with type 2 diabetes, who manage without insulin, also benefit from blood glucose self-monitoring. The Federal Joint Committee (G-BA) therefore commissioned IQWiG to assess the patient-relevant benefit of urine glucose and blood glucose self-monitoring when treating diabetes type 2 without insulin.

Self-monitoring should also contribute towards changes in lifestyle

Besides drug therapy, lifestyle, especially diet and exercise, also plays an important role in the treatment of type 2 diabetes. Many experts assume that blood glucose self-monitoring helps

patients in adapting their lifestyle, because the measured values enable them to see the direct effect of diet and physical activity and then to take suitable measures. The result should be that their blood glucose is better controlled and acute and long-term complications are reduced - at least this is the assumption.

Currently, there are two options for self-monitoring blood glucose. The kidneys excrete glucose via urine when the glucose level in the blood is too high. Patients can test for hyperglycaemia by carrying out a urine dipstick test. However, hypoglycaemia cannot be detected in this way. It can only be reliably detected by blood glucose monitoring: a small sample of blood is taken and placed on a test strip. In each case patients require thorough instruction in handling the test strips correctly and in being able to interpret the blood and urine test results and take appropriate action.

6 trials included in the assessment

In order to examine whether the above-mentioned assumptions can be scientifically proven, IQWiG searched for comparative trials with and without self-monitoring. Self-monitoring could also be a component of a complex education and treatment programme, such as are often offered to patients with diabetes mellitus. These trials were included if the participants in the treatment and control groups received the same treatment regimen - the only difference being that one group was with self-monitoring and the other without.

Overall, IQWiG and its external experts found 6 randomized controlled trials that were suitable for investigating the impact of medical interventions on the course of the disease. In all the included trials, education was a component in the therapy strategy. All 6 trials investigated the benefit of blood glucose self-monitoring; no suitable clinical comparisons were identified on urine glucose self-monitoring. The duration of the included trials was between 6 and 12 months, in other words, none of them were designed to investigate the long-term benefit of self-monitoring.

Not possible to draw conclusions on important outcomes

However, data on criteria that were important for the patient-relevant benefit were not even collected in these trials. This applies in particular to concomitant and late complications caused by diabetes, such as sight loss or cardiac disease. Other outcomes, such as quality of life and patient satisfaction, were in fact investigated in a few trials but inadequately reported, so that the results cannot be accepted as reliable. Yet even the few available data did not display any advantage for self-monitoring.

According to IQWiG and its external experts, therefore, the quality of trials on glucose self-monitoring is still inadequate overall. What is lacking are trials of longer duration that enable the long-term effects of glucose self-monitoring to be evaluated. Even the Canadian Agency for Drugs and Technologies in Health (CADTH) has complained in its most recent assessment of blood glucose self-monitoring that there is a lack of long-term trials.

No evidence of better results in blood glucose control

Blood glucose self-monitoring provides a snapshot of the blood glucose level. Depending on the measured value, patients can then take appropriate measures, for example, by eating something. However, blood glucose self-monitoring is not suitable for determining the quality of metabolic control. The HbA1c value is used for this. It is an indicator for long-term blood glucose control and serves as the "memory" for the blood glucose level. High HbA1c values in diabetes indicate poor metabolic control.

All trials included in the assessment additionally investigated the impact of blood glucose self-monitoring on the HbA1c value. The joint analysis revealed that blood glucose self-monitoring actually does assist in lowering blood glucose. However, the difference was marginal compared to the group that did not carry out self-monitoring. It was inside the range that is acceptable within the context of drug approval for describing a new drug as "not inferior" compared to existing drugs. No health advantage from this difference can therefore be anticipated.

Advantage for hypoglycaemia not proven

Furthermore, the HbA1c value alone has no validity in assessing the benefit of glucose self-monitoring, since the more the blood glucose level drops, the greater the risk of hypoglycaemia. In this case, hypoglycaemia is not merely unpleasant, but can also represent a serious complication in individual cases. For this reason, it is always necessary to assess changes in the HbA1c value in relation to the occurrence of hypoglycaemia. The available trials on blood glucose self-monitoring were inappropriate for this, however. Thus, an advantage of hypoglycaemia is not proven. In addition, it remains unclear whether glucose self-monitoring has contributed towards patients being able to make changes to their lifestyle.

Overall, IQWiG and its external experts come to the conclusion, therefore, that a benefit of blood glucose self-monitoring cannot be proven from the available trials. Due to a lack of trials on urine glucose self-monitoring, no conclusions can be drawn from a comparison of urine and blood tests, either.

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Commenting procedure

IQWiG published the preliminary results in the form of the preliminary report in June 2009 and interested parties were invited to submit comments. When the comments stage ended, the preliminary report was revised and sent as a final report to the contracting agency, the Federal Joint Committee, in October 2009. Documentation of the written comments and minutes of the oral debate are published in a separate document simultaneously with the final report. The report was produced in collaboration with external experts.