Continuous glucose monitoring with real-time measurement devices has added benefit

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Patients with insulin-dependent diabetes can better control their HbA1c value with a combination of blood glucose self-monitoring (BGSM) and continuous interstitial glucose monitoring (CGM) using a real-time measurement device (real-time CGM) than with BGSM alone without severe or serious hypoglycaemia occurring more frequently.

Data were lacking for most other outcomes and research questions, or the study results were not statistically significant, or they did not provide a clear picture. This was the result of a final report published on 21 May 2015, which the German Institute for Quality and Efficiency in Health Care (IQWiG) had produced, commissioned by the Federal Joint Committee (G-BA).

Better glycaemic control hoped for

Patients using intensive insulin therapy usually have to measure their blood-glucose levels four to six times daily to adjust their insulin dose. This method not always ensures optimal control of blood-glucose levels. Real-time CGM is hoped to improve glycaemic control. The devices not only show current glucose concentration, but also the trend of glucose levels so that patients can take action to avoid hypo- and hyperglycaemia. Better glycaemic control is also hoped to prevent or delay long-term complications from damage to small arterial vessels.

Some devices combine this real-time CGM with an insulin pump. One of

the combination devices additionally has an automated low-glucose suspend (LGS) function: This pump suspends insulin delivery when the glucose level falls below a certain threshold to prevent hypoglycaemia.

Vast majority of studies on type 1 diabetes

IQWiG investigated 15 randomized controlled trials with a minimum duration of 24 weeks as to whether proof, indications or hints of greater benefit or harm of real-time CGM in comparison with other methods of measurement can be derived from them. The vast majority of the 1952 study participants in total had type 1 diabetes.

The following patient-relevant outcomes were included: all-cause mortality, cardiovascular mortality, cardiovascular morbidity, blindness, renal impairment, amputation, ketoacidotic or hyperosmolar coma, hypoglycaemia and HbA1c values (in joint consideration), symptoms of chronic hyperglycaemia, other adverse events, and health-related quality of life. In children and adolescents as well as in pregnant women, additional patient-relevant outcomes such as developmental disorders or miscarriages were investigated.

Improvement in HbA1c value without increase in severe or serious hypoglycaemia

The joint consideration of severe or serious hypoglycaemia and HbA1c values showed: The HbA1c value can be improved without increasing the occurrence of severe or serious hypoglycaemia in comparison with the control group. Depending on the age group (over/under the age of 18 years) and the severity of the hypoglycaemia, the certainty of conclusions was between a hint and proof.

There was a hint of harm of real-time CGM in the outcome "skin

reactions" both in adults and in children and adolescents. In health-related quality of life, the few clinically relevant study results provided no consistent picture so that no hint of advantage or disadvantage can be derived from them. For all other outcomes, no conclusion on greater benefit or harm of the combination of real-time CGM and BGSM versus BGSM alone can be derived either because there were no statistically significant differences or because data were lacking.

Real-time CGM variants: no hints

In the comparison of different variants of real-time CGM, particularly of continuous versus intermittent real-time CGM, there was no hint of greater benefit or harm for any of the outcomes investigated - again partly due to the lack of statistically significant differences and partly due to the lack of data.

The same applies for the question whether real-time CGM in combination with BGSM and LGS function has greater benefit or harm than BGSM alone: The only relevant study on this comparison provided no statistically significant differences between the treatment options for any of the relevant outcomes.

More information: www.iqwig.de/download/D12-01_E … surement-devices.pdf

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