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Title **A Randomized Controlled Trial to Compare Minimally Invasive Glucose Monitoring Devices to Conventional Monitoring in the Management of Insulin-Treated Diabetes Mellitus (MITRE)**

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Aim

To evaluate the clinical efficacy, acceptability, and economic impact, in the long and medium term, of two minimally invasive, continuous glucose monitors in poorly controlled, insulin-requiring people with diabetes.

Conclusions and results

The percentage change in HbA1c from baseline to 18 months was the primary indicator of long-term efficacy in this study. The percentage change in HbA1c from baseline to 6 months and baseline to 12 months assessed efficacy in the medium term. The change to 3 months assessed the short-term effects. No differences between any of the groups were found in the percentage changes in HbA1c at any of the assessment times. Likewise, no differences were found in the percentage of participants achieving what was defined as a clinically important change of 12.5% in HbA1c percent at each of the assessment times. Although not significant, the Glucowatch group produced the smallest change in HbA1c and the lowest numbers achieving a clinically meaningful change at all time points. The findings on change in HbA1c, in the group studied, indicated no advantage from having a continuous glucose monitoring device. The economic analysis showed no advantage pertaining to the groups that received continuous blood glucose monitoring devices. Using health economic tools, a lower cost and higher benefit was found in the attention control arm during the trial period. A comparison of the use and acceptability of devices indicated that, overall, the Glucowatch was used less (20% vs 57% by 18 months), had more side effects, was found to interfere more with daily activities, and was perceived as being more difficult to use compared to the Continuous Glucose Monitoring System (CGMS).

Recommendations

The findings indicate that continuous glucose monitors, as assessed in this study, do not improve clinical outcomes in individuals with poorly controlled, insulin-requiring diabetes. In terms of health economics, no benefits accrued from use of the two continuous glucose monitoring devices assessed in the study. The findings also indicate differences in the acceptability to participants of the two devices. On acceptability grounds alone, the data suggest that the Glucowatch technology assessed in this study will not be frequently used by individuals with diabetes.

Methods

See Executive Summary link at www.hta.ac.uk/project/1306.asp.

Further research/reviews required

The findings emphasize the importance of examining acceptability. Devices may demonstrate clinical value, but if potential users find them unacceptable – or choose not to use them – then it is unlikely that they could be introduced into routine clinical care.

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