Summary and Overall Assessment (Knowledge Base Insulin Pump and CGM)

Introduction

This evaluation is based on the Swedish Dental and Pharmaceutical Benefits Agency (TLV) commission from the government to conduct health technology assessments of medical devices. An evaluation at the national level can shed light not only on the individual care providers, but also on society as a whole through the utilisation of the ethical platform. It is very important that decisions and recommendations do not rely only on the principle of cost-effectiveness, but also take into account the other prevailing principles, namely the principles of human dignity and of need and solidarity, in accordance with the Health and Medical Services Act (1982:763).

Method and target group

The TLV has been commissioned by the government to evaluate the cost-effectiveness of insulin pumps. We have expanded this commission to also apply to continuous glucose monitoring (CGM) and sensor-augmented insulin pump therapy (SAP), which involves the insulin pump being combined with CGM. We have received help from the Swedish Council on Health Technology Assessment (SBU) with the scientific data on the effect of insulin pumps and CGM, and have also been assisted by the Royal Institute of Technology (KTH) in testing the insulin pumps. In addition to this we have attached a number of experts to the case. The ambition was to construct a health economic model ourselves, but this turned out not to be possible.

Disease severity

The TLV assesses that the severity of the disease is moderate to high in children and adults with type 1 diabetes who have insufficient glycaemic control. However, this varies between patients.

Patient benefit

Insulin pumps

Based on the scientific data available concerning the benefit to patients, together with long-term, extensive proven experience in Sweden, it can be concluded that insulin pumps and SAP provide a treatment effectiveness that is in the same order of magnitude as intensive insulin treatment with injections, which is the relevant alternative for comparison. The uncertainty is, however, great.

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For certain groups of patients, who have problems with, for example, fluctuating glucose levels and hyper- or hypoglycaemia despite optimised insulin therapy, the use of an insulin pump is beneficial in comparison with intensive insulin therapy with injections. These benefits are also thought to occur in the case of insulin pump treatment of patients with low BMI (and low insulin doses), the dawn phenomenon, repeated episodes of diabetic coma, unconsciousness caused by hypoglycaemia or severe diabetic gastroparesis. The same applies to children.

However, it is very important to evaluate the use of insulin pumps and reassesses whether a patient is receiving any benefit (including quality of life benefits) from the insulin pump and discontinue with it if there is no beneficial effect.

Continuous glucose monitoring (CGM)

Based on the available scientific data concerning the benefit to patients, together with the experience that exists in Sweden, it can be concluded that there are significant gaps in our knowledge of CGM and that the clinical experience of this method is shorter (<10 years) that is the case for insulin pumps. The treatment effectiveness of CGM appears to be in the same order of magnitude as blood glucose measurement with test strips. The uncertainty is, however, very large.

Treatment with CGM has advantages for patients who have a particularly large problem with recurrent serious hypoglycaemia (that the patient cannot deal with themselves), inability to detect the warning signs of hypoglycaemia, for children who need to have their blood glucose tested very frequently (>10/day) and for patients who have inexplicably high HbA1c levels or fluctuating blood glucose.

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Cost-effectiveness

In order to undertake a satisfactory health economic evaluation, both the cost and the effectiveness sides must be surveyed and supported by data of a sufficiently high quality.

In its report, the SBU has worked out the average annual cost of treatment with insulin pumps and CGM, compared to treatment with injections and measurement with test strips. The SBU emphasises that the cost is high for the various treatments, but have not investigated the effectiveness side in their cost analysis. As such, this analysis does not show whether the treatments are cost-effective or not. The cost analysis that has been conducted by the SBU provide a solid basis from which to further develop a cost-effectiveness analysis.

According to the SBU, there are eight cost-effectiveness analyses comparing insulin pumps and injection treatment that are of a good scientific quality. However, the SBU is of the opinion that these analyses have used a reduction in the change in HbA1c values that is too large. They do, however, indicate that certain patients experience an improvement in their quality of life on insulin pump treatment.

According to the SBU, there is on one relevant cost-effectiveness analysis that compares an insulin pump combined with CGM with injection treatment and glucose measurement with test strips. The study builds on American data and healthcare costs that are not directly comparable with Swedish circumstances, this result in a great deal of uncertainty. The results from the sensitivity analysis that best reflect Swedish circumstances show that the cost per quality-adjusted life year (QALY) is about SEK 675,000 for treatment with SAP. The TLV is of the opinion that the cost per QALY is high, but that there is a great deal of uncertainty about the transferability to Swedish circumstances.

Regarding comparisons between CGM and glucose measurement with test strips, there are two model analyses that maintain sufficient quality according to the SBU. These two analyses are both based on the American data and healthcare costs, which leads to a great deal of uncertainty with regard to their results for a Swedish setting. According to these studies, treatment with CGM leads to a cost of between SEK 300,000 and 660,000 per QALY. The TLV is of the opinion that the cost per QALY is moderate to high, but that there is a great deal of uncertainty about the transferability to Swedish circumstances.

Follow-up and evaluation
We have identified a need to update the clinical guidelines for diabetes, and also to include guidelines for SAP and GGM, which are currently lacking.

Follow-up of these aids is very important, especially follow-up of the impact on quality of life. Consequently, the SBU is of the opinion that there needs to be additional controlled trials that are of a high quality, have a longer follow-up time and cover all groups of diabetes patients in order to be able to comment on the effects. According to the TLV's experts, this type of comparison would require thousands of patients to be monitored over the course of up to 10 years. Therefore, we cannot expect to be in possession of such data within a reasonable length of time. However, if the follow-up takes place in the right way, and the registry achieves a high degree of coverage, we will gain this information gradually, even if it takes the form of the results of controlled trials.

Overall assessment
With regard to insulin pumps, there is a lack of relevant cost-effectiveness analyses. Thus, we cannot comment on the cost-effectiveness.

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The organisations responsible for healthcare may therefore decide whether or not the method will be introduced for those patients who fulfil the treatment targets without these aids.

However, it is important to follow-up and evaluate their use. If a patient does not receive any beneficial effect (including improvements in their quality of life) the use of these aids should be stopped.