

Summary and conclusions

The SBU assessment of available knowledge

Good control of the blood glucose level is vital to avoid diabetes complications. In type 1 diabetes and sometimes in type 2 diabetes, intensive insulin therapy is required, which involves multiple daily injections. The most common complication associated with this therapy is low blood glucose (hypoglycaemia), which can have serious consequences. An alternative to injections for intensive insulin therapy is continuous insulin delivery using a pump, also known as continuous subcutaneous insulin infusion (CSII).

Conclusions

- ▶ Insulin pumps for diabetes are commonly used today, especially in the treatment of children and adolescents. However, there is a considerable lack of knowledge regarding the effects of insulin pump therapy on illness and mortality. This lack of knowledge also extends to the use of insulin pumps in combination with continuous glucose monitoring, so called sensor-augmented pump therapy (SAP). More well-performed long-term studies of all patient groups with diabetes are required.
- ▶ People with diabetes are considerably more satisfied with SAP than with intensive injection therapy and self-monitoring of blood glucose with test strips. Being satisfied with the treatment may be important in terms of achieving better blood glucose control. Available knowledge is less clear when it comes to treatment satisfaction with insulin pumps only.
- ▶ There is limited or insufficient knowledge regarding the effect of insulin pumps or SAP on quality of life, ketoacidosis and severe hypoglycaemia.

- ▶ The intervention cost of insulin pump therapy is SEK 11,000 more per patient and year compared to injection therapy. For adults, insulin pumps are used predominantly when injection therapy fails to achieve the treatment goals; it is rarely the first-choice treatment. The higher cost must be contrasted with the short- and long-term benefits from a well-functioning diabetes therapy. Individual assessment is therefore warranted pending new studies.
- ▶ For children of preschool age, insulin pumps tend to be the first-choice treatment when diabetes is diagnosed. This can be particularly important when it is difficult to inject sufficiently small doses or there is fear of needles.
- ▶ The most important measure for long-term glucose control is HbA_{1c}, which is also closely linked to diabetes complications. Insulin pump therapy has shown some improvement in HbA_{1c} in the short term. Studies on SAP indicate additional improvement in HbA_{1c}. If future studies with longer follow-up periods show continued improvement, the risk of diabetes complications would be reduced.

Surrogate measures (such as HbA_{1c}, C-peptide and glucose variability) are not evidence-graded, but are described in the report. In addition, HbA_{1c} is reported in Appendix 3.

Study of practice

There are no comprehensive statistics on the use of insulin pumps either alone or in combination with continuous subcutaneous glucose monitoring (SAP) in Sweden. In order to chart practice of the use of these methods in specialist care more closely, a major study of practice was conducted that involved all the diabetes clinics in Sweden.

Economic aspects

Insulin pump therapy costs SEK 11 000 more per patient and year than intensive injection therapy. Since approximately 10 000 patients are treated with insulin pumps in Sweden today, it would currently amount to an additional cost of about SEK 110 million per year. If insulin pump therapy is combined with continuous glucose monitoring (SAP), the annual additional cost increases by around another SEK 28 000 per patient. In order to calculate whether insulin pump therapy and SAP are cost-effective methods compared to injection therapy and self-monitoring of blood glucose

with test strips, the increased treatment costs need to be considered in relation to the long-term effects on health.

Ethical and social aspects

Diabetes is a disease that requires considerable patient effort both day and night in a very different way from most other illnesses. Other values than the medical effects must therefore be taken into account. The methods of administering insulin and monitoring blood glucose have considerable impact on the individual patients and their families.

Patient benefit (Table 1.1 Summary table)

Outcomes		Number of studies/ participants	Results	Scientific evidence
Insulin pumps for diabetes compared to intensive injection therapy				
Adults with type 1 diabetes (results based on a systematic review)				
Severe hypoglycaemia (short-term effect)		8/762	No difference	⊕⊕○○ ¹
Adults with type 2 diabetes (results based on a systematic review)				
Severe hypoglycaemia (short- and long-term effect)		3/279	No difference	⊕⊕○○ ¹
Sensor-augmented pump therapy (SAP) for diabetes compared to intensive injection therapy and self-monitoring of blood glucose with test strips				
School-age children and adolescents with type 1 diabetes				
Treatment satisfaction (long-term effect)	Children's estimation	1/130	Higher for SAP	⊕⊕⊕○ ¹
	Parents' estimation	1/118	Higher for SAP	⊕⊕⊕○ ¹
Adults with type 1 diabetes				
Treatment satisfaction	Short-term effect	1/83	Higher for SAP	⊕⊕○○
	Long-term effect	1/334	Higher for SAP	⊕⊕⊕○
Severe hypoglycaemia	Long-term effect	1/329	No difference	⊕⊕○○
Insufficient scientific evidence ⊕○○○				

For type 1 diabetes, there is insufficient scientific evidence for insulin pumps and SAP in preschool children; insulin pumps in school-age children and adolescents as well as SAP except for treatment satisfaction; insulin pumps in adults except for severe hypoglycaemia as well as SAP except for severe hypoglycaemia and treatment satisfaction. For type 2 diabetes, there is insufficient scientific evidence for SAP in adults and for insulin pumps except for severe hypoglycaemia. The same applies to insulin pumps and SAP for diabetes in children under one year of age and in pregnant women with diabetes.

¹ Reduction according to GRADE: -1 for risk of bias, -1 indirectness, +1 for effect size

² Reduction according to GRADE: -1 for risk of bias, -1 indirectness

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TABLES IN ENGLISH

- Table 2.1 Intervention cost (in Swedish kronor) of insulin pumps (CSII) and multiple daily injections (MDI), per patient and year, [page 20](#)
- Table 2.2 Intervention cost (in Swedish kronor) of SAP and daily injections in combination with self-monitoring with test strips, per patient and year, [page 22](#)
- Table 2.3 Cost-effectiveness studies comparing SAP with daily injections in combination with self-monitoring with test strips in adult patients with type 1 diabetes, [page 23](#)
- Table 3.1 Characteristics and quality assessment of original studies for insulin pump therapy in children and adolescents with type 1 diabetes, [page 36](#)
- Table 3.2 Outcome results of included studies for insulin pump therapy vs multiple daily injections (MDI) in children and adolescents with type 1 diabetes, [page 38](#)
- Table 4.1 Characteristics and quality assessment of original studies for insulin pump therapy in pregnant women with type 1 diabetes, [page 42](#)
- Table 4.2 Outcome results of included studies for CSII in pregnant women with type 1 diabetes, [page 42](#)
- Table 5.1 Characteristics and quality assessment of systematic reviews of insulin pump therapy for adults with type 1 or type 2 diabetes, [page 44](#)
- Table 5.2 Results of systematic reviews of insulin pump therapy for adults with type 1 or type 2 diabetes, [page 45](#)
- Table 6.1 Characteristics and quality assessment of original studies for SAP in children with type 1 diabetes, [page 48](#)
- Table 6.2 Outcome results of included studies for SAP vs MDI and SMBG in children with type 1 diabetes, [page 52](#)
- Table 7.1 Characteristics and quality assessment of original studies for SAP in adults with type 1 diabetes, [page 54](#)
- Table 7.2 Outcome results of included studies for SAP vs MDI and SMBG in adults with type 1 diabetes, [page 56](#)
- Table 8.1 Summary of findings, insulin pump therapy for type 1 diabetes, [page 60](#)
- Table 8.2 Summary of findings insulin pump therapy for type 2 diabetes, [page 63](#)
- Table 8.3 Summary of findings, SAP therapy for type 1 diabetes, [page 64](#)
- Table 9.1 Description of included studies on insulin pump therapy, [page 69](#)
- Table 9.2 Description of included studies on sensor augmented pump therapy (SAP), [page 73](#)
- Table 12.1 HbA1c (%) for children and adults with type 1 diabetes, [page 86](#)

REFERENCES, [page 65](#)