

# Continuous subcutaneous glucose monitoring for diabetes

SBU ALERT REPORT | EARLY ASSESSMENT OF NEW HEALTH TECHNOLOGIES

OCTOBER 2013 | WWW.SBU.SE/201304

# Summary and conclusions

#### The SBU assessment of available knowledge

Good control of the blood glucose level is vital to avoid diabetes complications. Blood glucose can be monitored by the patient using test strips (Self Monitoring of Blood Glucose, SMBG) or via a subcutaneous sensor (Continuous subcutaneous Glucose Monitoring, CGM). In type 1 diabetes, frequent blood glucose monitoring is required daily to achieve good glucose control.

### Conclusions

- There is a considerable lack of knowledge regarding the benefits of continuous glucose monitoring, compared to self-monitoring of blood glucose with test strips, when it comes to illness and mortality. More high-quality, controlled studies with a longer follow-up period are required for all patient groups with diabetes.
- Persons with diabetes are considerably more satisfied with continuous glucose monitoring, particularly in combination with insulin pump therapy (sensor-augmented pump therapy, SAP), than with modern therapy, which involves multiple daily injections and self-testing with test strips. Being satisfied with the treatment may be significant in terms of achieving better blood glucose control.
- There is limited or insufficient knowledge regarding the effect of continuous glucose monitoring, either alone or in combination with insulin pump therapy on quality of life, severe hypoglycaemia and ketoacidosis.
- The intervention cost of long-term use of continuous glucose monitoring is significantly higher compared to self-testing with test strips
  SEK 28,000 more per patient and year. However, the additional cost is significantly lower if continuous glucose monitoring is only used for a short period, for example, to adjust

insulin doses. As there is a lack of knowledge concerning the benefits of continuous glucose monitoring, it is not possible to assess its cost-effectiveness. The higher cost must be contrasted with the short- and long-term benefits from a well-functioning diabetes therapy. Individual assessment of suitable treatment is therefore warranted pending new studies.

- ➤ Although continuous glucose monitoring is used in Sweden, diabetes clinics are reluctant to offer the method, particularly to adults. It is used by few patients and predominantly for short periods, generally in patients with recurrent hypoglycaemia. For infants and children of pre-school age, continuous glucose monitoring can make life considerably easier, because they often need to take 10–15 blood glucose measurements per day.
- ➤ The most important measure for long-term glucose control is HbA1c. Poor glucose control is closely linked to diabetes complications. Therapy using continuous glucose monitoring improves HbA1c in the short term. This applies if the method is used consistently, ie a minimum of six days per week. Studies on SAP indicate additional improvement in HbA1c. 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 continuous glucose monitoring either alone or in combination with insulin pump therapy (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**

Continuous glucose monitoring costs approximately SEK 28,000 more per year and patient than self-monitoring of blood glucose using test strips. The additional cost depends on how many test strips can be reduced with continuous glucose monitoring compared to test strips alone. If continuous glucose monitoring is used in combination with insulin pump therapy (SAP), the annual additional cost increases by approximately another SEK 11,000 per patient. In order to calculate whether continuous glucose monitoring and SAP are cost-effective methods compared to injection therapy and test strips, the increased treatment costs need to be considered in relation to the long-term effects on the health of patients.

#### 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 administrating 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
Continuous subcutaneous glucose monitoring (CGM) for diabetes compared to self-monitoring of blood glucose with test strips (SMBG)				
Real-time CGM: School-age children and	adolescents with type 1 diab	oetes		
Treatment satisfaction (short-term effect) from a parental perspective		1/146	Higher for CGM	$\oplus \oplus \bigcirc \bigcirc^1$
Quality of life (short-term effect)	Children's estimation	2/325	No difference	$\oplus \oplus \bigcirc \bigcirc^1$
	Parents' estimation	2/325	No difference	$\oplus \oplus \bigcirc \bigcirc^1$
Quality of life (long-term effect)	Children's estimation	1/107	No difference	$\oplus \oplus \bigcirc \bigcirc^1$
	Parents' estimation	1/154	No difference	⊕⊕⊖O¹
Sensor-augmented pump therapy (SAP) for diabetes compared to intensive injection therapy and SMBG				
School-age children and adolescents with type 1 diabetes				
Treatment satisfaction (long-term effect)	Children's estimation	1/130	Higher for SAP	$\oplus \oplus \oplus \bigcirc$
	Parents' estimation	1/118	Higher for SAP	$\oplus \oplus \oplus \bigcirc$
Adults with type 1 diabetes				
Treatment satisfaction	Short-term effect	1/83	Higher for SAP	$\oplus \oplus \bigcirc \bigcirc$
	Long-term effect	1/334	Higher for SAP	$\oplus \oplus \oplus \bigcirc$
Severe hypoglycaemia	Long-term effect	1/329	No difference	$\oplus \oplus \bigcirc \bigcirc$
Insufficient scientific evidence $\oplus 000$				

For type 1 diabetes, there is insufficient scientific evidence for real-time CGM and SAP in preschool children; school-age children and adolescents except for treatment satisfaction and quality of life and SAP except for treatment satisfaction; real-time CGM in adults and SAP except for severe hypoglycaemia and treatment satisfaction. The same applies to real-time CGM and SAP for diabetes in children under one year of age, pregnant women, adults with type 2 diabetes as well as to retrospective CGM for diabetes in all the patient groups.

<sup>1</sup>Reduction according to GRADE: -1 for risk of bias, -1 for indirectness.

#### Project group

Unn-Britt Johansson (Professor), Ragnar Hanås (Associate Professor), Per-Olof Olsson (PhD), Anna Lindholm Olinder (PhD), Martina Persson (PhD)

#### SBU

Sophie Werkö (Project Director), Stella Jacobson (Assistant Project Director), Emelie Heintz (Health Economist), Derya Akcan (Information Specialist), Anna Attergren Granath (Project Administrator), Thomas Davidson (Health Economist, Co-reader)

**Scientific reviewer** Kerstin Berntorp (Associate Professor)

SBU Alert report no 2013-04 www.sbu.se/en • registrator@sbu.se

#### For more on this report, please visit www.sbu.se/201304e

TABLES IN ENGLISH

- Table 2.1 Intervention cost (in Swedish kronor) of continuous glucose monitoring and self monitoring with test strips, per patient and year, page 21
- Table 2.2 Cost-effectiveness studies comparing continuous glucose monitoring (CGM) and self monitoring with test strips (SMBG) in adult patients, page 23
- Table 2.3 Intervention cost (in Swedish kronor) of SAP and multiple daily injections in combination with self monitoring with test strips, per patient and year, page 24
- Table 2.4 Cost-effectiveness studies comparing SAP with daily injections (MDI) in combination with self monitoring of blood glucose (SMBG) in adult patients with type 1 diabetes, page 25
- Table 3.1 Characteristics and quality assessment of original studies for retrospective CGM in children with type 1 diabets, page 38
- Table 3.2 Outcome results of included studies for retrospective CGM vs SMBG in type 1 diabetes, page 40
- Table 3.3 Characteristics and quality assessment of original studies for real-time CGM in children with type 1 diabetes, page 40
- Table 3.4 Outcome results of included studies for real-time CGM vs SMBG in type 1 diabetes, page 44
- Table 4.1 Characteristics and quality assessment of systematic reviews of retrospective CGM for adults with type 1 diabetes, page 48
- Table 4.2 Results of systematic reviews of retrospective CGM in adults with type 1 diabetes, page 50
- Table 4.3 Characteristics and quality assessment of systematic reviews of real-time CGM for adults with type 1 diabetes, page 50

- Table 4.4 Results of systematic reviews of realtime CGM in adults with type 1 diabetes, page 51
- Table 4.5 Characteristics and quality assessment of original studies of real-time CGM for adults with type 1 diabetes, page 51
- Table 4.6 Characteristics and quality assessment of original studies of retrospective CGM for adults with type 1 or type 2 diabetes, page 52
- Table 4.7 Characteristics and quality assessment of original studies of real-time CGM for adults with type 2 diabetes, page 53
- Table 5.1 Characteristics and quality assessment of original studies for SAP vs MDI and SMBG in children with type 1 diabetes, page 54
- Table 5.2 Outcome results of included studies for SAP vs MDI and SMBG in children with type 1 diabetes, page 56
- Table 6.1 Characteristics and quality assessment of original studies for SAP vs MDI and SMBG in adults with type 1 diabetes, page 58
- Table 6.2 Outcome results of included studies for SAP vs MDI and SMBG in adults with type 1 diabetes, page 60
- Table 7.1 Summary of findings, retrospective CGM vs SMBG for type 1 diabetes, page 62
- Table 7.2 Summary of findings, real-time CGM vs SMBG for type 1 diabetes, page 62
- Table 7.3 Summary of findings SAP vs MDI and SMBG for type 1 diabetes, page 64
- Table 8.1 Included studies, page 68
- Table 10.1 HbA1c (%) for children and adults with type 1 diabetes, page 90

REFERENCES, page 65