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Title Innovative medical devices for diabetes management

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Aim

To assess the effectiveness and impact in the context of the Emilia-Romagna Health Service (Italy) of innovative medical devices such as Continuous Subcutaneous Insulin Infusion (CSII), Continuous glucose monitoring (CGM), and Sensor-Augmented insulin Pumps (SAP) for patients with type 1 or 2 diabetes mellitus undergoing multi-daily injective (MDI) insulin therapy.

Conclusions and results

CSII is a medical device that allows continuous insulin infusion in subcutaneous tissue. CGM - proposed as an alternative to self-monitoring of blood glucose performed several times a day. It carries out frequent measurements of glycaemic levels, allowing capture of the glycaemic profile of a diabetic patient. SAP, a semi–integrated (open loop) system for the management of the diabetes, integrates a CSII pump and a CGM device.

The main expected benefits are better glycaemic control, reduction in hypoglycaemic episodes and improvement in quality of life. International guidelines and HTA reports agree upon the lack of robust evidence supporting the use of the three devices, advising a restricted use to the most suitable patients, which should be identified through explicit and shared criteria. A recent good quality systematic review (Yeh et al. 2012) included randomised controlled trials with small numbers of patients, a short duration (maximum 52 weeks), evaluating only short-term clinical outcomes (glycaemic control, hypoglycaemic episodes, body parameters, quality of life) and no clinical outcomes related to micro- or macro-vascular complications.

The evidence on CSII pumps compared to MDI therapy shows a slight difference in glycosylated haemoglobin (HbA1c) levels - considered not significant from a clinical point of view - and in global quality of life for type 1 adults diabetic patients, while no difference both in glycaemic parameters and in quality of life is shown in paediatric patients with type 1 diabetes and in adult patients with type 2 diabetes.

Data on CGM devices, drawn from studies on a mixed population of patients with type 1 diabetes, children/adolescents and adults, show a statistically significant difference - judged as clinically not significant – in glycaemic parameters (HbA1c, time in hyperglycaemia) in favour of CGM versus SMBG. Data from four studies show that there is a statistically and clinically significant difference of HbA1c and time spent in hyperglycaemia in favour of SAP in mixed populations of paediatric and adult patients with type 1 diabetes. The presumed clinical impact on long-term micro- and macro-vascular outcomes of innovative devices for diabetes is not confirmed by presently available data. Moreover, no shared criteria to identify patients who could benefit most from these devices are available.

Methods

The short report methodology consists of identifying primarily up-to-date and good quality systematic reviews. A bibliographic research of primary studies is performed only if good quality systematic reviews are lacking. Given the quantity and quality of the available secondary literature, a search for primary studies was judged unnecessary.

Written by

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