INAHTA Briefs

Issue 2010/102

Title **Clinical Effectiveness and Cost-Effectiveness of Continuous Subcutaneous Infusion for Diabetes: Systematic Review and Economic Evaluation**

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Reference Volume 14.11. ISSN 1366-5278. www.hta.ac.uk/project/1622.asp

Aim

To examine the clinical and cost effectiveness of using continuous subcutaneous insulin infusion (CSII) to treat diabetes; to update the previous assessment; and to take account of developments in alternative therapies, in particular the long-acting analogue insulins.

Conclusions and results

Based on the totality of evidence, using observational studies to supplement the limited data from randomized trials against best multiple daily injection (MDI), CSII provides some advantages over MDI in type 1 diabetes mellitus (T1DM) for both children and adults. However, no evidence indicated that CSII is better than analogue-based MDI in type 2 diabetes mellitus (T2DM) or in pregnancy. Further trials with larger numbers and longer durations comparing CSII and optimized MDI in adults, adolescents, and children are needed. In addition, a trial should compare CSII versus MDI with similar provision of structured education in both arms. A trial is also needed for pregnant women with pre-existing diabetes, to investigate using CSII to the best effect. The 74 studies used for analysis included 8 randomized controlled trials (RCTs) of CSII versus analogue-based MDI in either T1DM or T2DM, 8 new (since the last NICE appraisal) RCTs of CSII versus NPH-based MDI in T1DM, 48 observational studies of CSII, 6 studies of CSII in pregnancy, and 4 systematic reviews. The following benefits of CSII were highlighted: better control of blood glucose levels, as reflected by glycated hemoglobin (HbA1c) levels, with the size of improvement depending on the level before starting CSII; reduction in swings in blood glucose levels, and in problems due to the dawn phenomenon; fewer problems with hypoglycemic episodes; reduction in insulin dose per day, (partly off-setting the cost of CSII); improved quality of life, including reduced chronic fear of severe hypoglycemia; more flexibility of lifestyle (no need to eat at fixed intervals), more freedom of lifestyle and easier participation in social and physical activity; and benefits for the patients' family. The submission from INPUT emphasized the quality of life gains from CSII, as well as improved control and fewer hypoglycemic episodes. Also, there was a marked discrepancy between the improvement in social quality of life reported by successful pump users, and the lack of convincing health-related quality of life gains reported in the trials. With regard to economic evaluation, the main cost of CSII is for consumables, eg, tubing and cannulas, and is about 1800 to 2000 pounds sterling (GBP) per year. The cost of the pump, assuming 4-year life, adds another GBP 430 to GBP 720 per annum. The extra cost compared with analogue-based MDI averages GBP 1700.

Recommendations

See Executive Summary link at www.hta.ac.uk/project/1622.asp.

Methods

See Executive Summary link at www.hta.ac.uk/project/1622.asp.

Further research/reviews required

1) The need for adequate trials of CSII against analogue-based MDI has not been met. We need further trials with larger numbers and longer durations, comparing CSII and optimized MDI in adults, adolescents, and children. Duration is important because maximum benefit from CSII might not be obtained for many months. Conversely, we need to know if initial benefits in HbA1c level are sustained. 2) A trial of CSII versus MDI is needed with similar provision of structured education in both arms. Without such trials, we cannot be sure whether the benefits observed with CSII are due to the CSII itself, or to better self-management of diabetes resulting from increased patient education. See Executive Summary link at www.hta.ac.uk/project/1622.asp.

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ISSN 1654-501X