Use of continuous insulin infusion pumps in young children with type 1 diabetes: a systematic review
Churchill JN, Ruppe RL, Smaldone A

CRD summary
The authors concluded that continuous subcutaneous insulin infusion was a safe and effective method of insulin delivery in young children. The authors’ conclusions appeared to be based on studies with a weaker methodological design rather than the studies with high validity, and as such should be treated with caution.

Authors' objectives
To compare effectiveness of continuous subcutaneous insulin infusion (CSII) and multiple daily injections of insulin therapy in reducing glycosylated haemoglobin (HbA1c) and episodes of severe hypoglycaemia in children aged six years or less.

Searching
MEDLINE and CINAHL were searched from 1996 to March 2008. Search terms were reported.

Study selection
Randomised controlled trials (RCTs) or quasi-experimental trials that compared multiple daily injections to CSII in children aged six years or less with type 1 diabetes were eligible for inclusion. Studies needed to last for at least six months and measure HbA1c and episodes of hypoglycaemia. Secondary outcomes eligible for inclusion were quality of life measures.

Included studies assessed CSII compared to two to three insulin injections daily or to pre-treatment levels. Study duration was six or 12 months. Length of follow up ranged from six months to four years after the start of CSII. Average age of participants ranged from one to 6.4 years. Length of time since diagnosis of type 1 diabetes ranged from six months to two years. One study included only participants with poor glycaemic control. HbA1c was assessed using the Bayer DCA 2000+ in all studies except one. Definition of hypoglycaemia varied between studies. A range of standardised scales was used to assess quality of life and parental stress.

Two reviewers independently assessed the studies for review.

Assessment of study quality
Methodological quality of included studies was assessed according to study design, blinding, withdrawals/dropouts, definition of outcome measures and documentation of hypoglycaemic episodes, tools for measuring HbA1c, defined study objectives, clearly defined interventions and use of intention-to-treat analyses. Each criterion was awarded 1 if present and 0 if absent, which gave a maximum score of 7.

Two reviewers independently assessed study quality. Disagreements were resolved through discussion.

Data extraction
The authors did not state how data were extracted for the review.

Methods of synthesis
The studies were combined in a narrative synthesis.

Results of the review
Seven studies were included for the review (n=176): three RCTs (n=78); and four quasi-experimental before-and-after studies (n=98). Sample sizes ranged from nine to 65. Two studies scored 6 on the validity assessment, one scored 5, one scored 4 and three scored 3. Loss to follow up was less than 20% in all studies. In two RCTs, the CSII group received
more frequent and closer contact with the diabetes team than than the other group.

**Episodes of Hypoglycaemia**: Two RCTs reported no difference between CSII and multiple daily injections in severe hypoglycaemia. In all other studies, CSII reduced the number of hypoglycaemic episodes by nearly 50%. However, this drop was not statistically significant. In two RCTs (n=59) there was a small but statistically significant increase in episodes of mild to moderate hypoglycaemia.

**Glycaemic control**: Two RCTs (n=41) did not find any significant improvement in HbA1c compared to multiple daily injections. One RCT reported significant improvements in HbA1c compared to multiple daily injections at three months (p<0.05), but not at six months. All four before-and-after studies (n=98) showed significant improvements in HbA1c compared to baseline levels (p ranged from <0.05 to 0.001). In one study, improvements were maintained at four years (n=6, p<0.001).

**Quality of Life**: Three studies (n=55) reported significant improvements in diabetes-related quality of life in parents compared to baseline levels. In one study, mothers' diabetes-related quality of life improved significantly compared to parents in the multiple daily injections group.

**Authors' conclusions**

CSII was a safe and effective method of insulin delivery in young children.

**CRD commentary**

The review addressed a clear question with well-defined inclusion criteria. The search was restricted to two databases and so some important data may have been missed. It appeared that there was no search for unpublished data and it was unclear whether the search was restricted by language. Therefore, publication and language bias could not be ruled out. Study selection and validity assessment were conducted independently in duplicate; it was unclear whether similar steps were taken in the data extraction process. Therefore, reviewer error and bias could not be definitively ruled out. A suitable validity assessment was performed and the studies were found to be of mixed quality. The decision to combine the studies in a narrative synthesis was appropriate given the variety of study designs included for the review. The authors' conclusions appeared to be based on studies with a weaker methodological design rather than the studies with high validity, and as such should be treated with caution.

**Implications of the review for practice and research**

**Practice**: The authors stated that insulin pump therapy should be considered the treatment of choice for young children with type 1 diabetes where parents were motivated, able to understand the pump technology, monitor blood glucose and work with the multi-disciplinary team.

**Research**: The authors stated that longer-term multicentre RCTs of CSII in young children were needed to assess metabolic control and long-term outcomes, such as delay in onset of complications, neurocognitive outcomes and family stress.

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Record Status
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