National Institute for Health and Clinical Excellence

Continuous subcutaneous insulin infusion for the treatment of diabetes (review)

Royal College of Nursing

Introduction

With a membership of over 395,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

Response to the Assessment Report on the health technology appraisal of Continuous subcutaneous insulin infusion for the treatment of diabetes (review)

The Royal College of Nursing welcomes the opportunity to review this document.

In general we agree with the interpretation of the evidence. The Health Technology Assessment Report appears to be a comprehensive reflection of the evidence base.

In addition to the evidence considered, the systematic review by Winckley et al (2006) in the British Medical Journal (BMJ) may be worth referring to with regard to the findings which found psycho-educational interventions were significantly more effective in children than adults and therefore may indicate a different approach to structured education for pump therapy in children.

We would like to comment on how the clinical results should be interpreted in the context of current clinical practice as detailed below:

A clear selection criteria is emerging which is applicable nationally and should be used across board.

There would probably be a need to develop main centres initially for CSII in order to gain sufficient level of experience. This, however, would require funding to support it.

September 2007

With respect to the incidence of diabetes of 26.5 per 100,000 as at 2003/04 in comparison to 17 per 100,000 in 1985-1990, in our view, this increase in incidence of diabetes coupled with the increase in intensity of management supports the need for a review of workforce requirements.

The potential for 1% reduction in HbA1c (43/46 studies showed a reduction) and 0.5% from psycho-educational interventions (Winckley et al 06 systematic review) – means children in the UK will have a much better chance of achieving the HbA1c target of 7.5%.

If pump therapy use is expanded, considerable educational needs for both the patient and Health care professional will need to be addressed. It is our understanding that Leeds offers the only pump course which specifically addresses the needs of Children and young people.

There would therefore, be a need to encourage and raise awareness of the importance of structured education pre-pump use, especially basal dose adjustment and SMBG.

The literature found no evidence of increased risk of DKA in CSII but Hanas data shows this may be an emerging finding. This may indicate a learning need which goes beyond merely providing information and may require more active involvement and problem solving and skilful facilitation from an experienced team to really aid understanding of the speed and severity of which DKA can occur in pumps compared to basal bolus regime using long acting insulin.

There is a need to address the difficulty of lunch time injection at school so that more children are able to use a basal bolus regime as many were on BD insulin regimes to avoid difficulties with injecting at school which is not acceptable.

The need to address health care professionals' negative attitude and perceptions of CSII is fundamental to maintaining the confidence of children and families and enabling them to make informed choices regarding treatment options.

Doyle (2004) CSII better than analogue in children. Clinical experience indicates the ability to finely tune the basal rate in the middle of the night and early morning is more effective than analogue insulins.

Adjusting and setting basal rates, choice of food bolus available to more accurately match type and amount of food and the need for more immediate action to prevent DKA requires more support and education and will not be covered in a structured education programme such as DAFNE.

Basal rate at 6-9am is often double the amount between 24-6am due to dawn phenomenon.

The impact which hypos have on IQ (Gold and Frier 95) with deficits found mostly in children diagnosed under 5yrs supports clinical experience that children under 5 years should be offered insulin pump therapy from diagnosis.

We would suggest that a child on less than 20u/day should be considered for pumps.

Fear of hypos affects the family not just child (Clarke 98) and is the most likely reason for not achieving recommended HbA1c targets therefore psycho-educational interventions which address this should be available as part of routine care.

The evidence for using pumps in children is growing particularly in younger children. There are difficulties managing injections in school (so pumps are considered to be comparatively easier). Also IQ deficits, chronic fear of hypos, better moods being a universal comment all these issues contribute to a compelling case for pumps from diagnosis.

Young children have a lot to gain from early initiation of CSII and should be offered at diagnosis.

Metabolic memory means early aggressive treatment should be mandatory (Ihnat 2007-09-09).

We would agree with the view that 35% of parents said change did not go as well as anticipated – this also fits with clinical experience. We would suggest that families should be informed of this prior to pump start. In some areas, 10 days to 3/12 was identified as the time required to feel comfortable with CSII.

QoL Barnard et al (2007) - currently no QoL gains from CSII in current evidence base but this may indicate a lack of evidence rather than evidence of no benefit.

It was interesting to note the non health benefits - better moods in children treated with CSII was an almost universal comment.

An important point made regarding use of the CORE model was that the main driver is HbA1c when in fact Quality of life gains from a reduced fear of hypo would have to be only relatively minor to make CSII cost effective.

With regards to lack of tolerance to wearing a pump – Saline pump starts are useful in children and young people as they benefit from a concrete experience of wearing the pump – gaining insight into questions and responses from other people as well as managing their dressing and undressing etc.

The indications for CSII in section 1.9 are an improvement. In the capital costs, the report lists £10 as the cost of meter. We understand that in one PCT meters are provided free to patients by the manufacturing companies either through the practice nurse or Diabetes Centre, so in that instance, there is no direct cost to the NHS. Patients who are being assessed for CSII will be under the care of a specialist diabetes team, therefore, have easy access to the meters. The cost to the NHS is from the test strip usage 4-8 tests per day. It is not clear if this practice is the same across board and should be taken into consideration in determining the cost of meters.

Pump use have been reported to be successful. In one instance a patient was reported to have been on the pump for 3 years. The patient went on it because of recurrent DKA and prolonged admissions and the outcome since being on the pump has been reported to be very successful.

We are aware that in Worcestershire, they have a county wide pump panel with the PCT commissioner. They have a pathway that patients have to have undertaken which includes trying both Glargine o.d. and Detemir o.d or b.d. This has been reported to be very useful in helping to manage patients' expectations and ensuring equity across the PCT.

Conclusion

CSII offers some benefits to some groups of patients, such as independence and better management of their condition. If pump therapy use is expanded, considerable educational needs for both the patient and Health care professional will need to be addressed.

There would be a need to encourage and raise awareness of the importance of structured education pre-pump use, especially basal dose adjustment and SMBG.

References

Winckley, K; Landau, S; Eisler, I & Ismail, K (2006). *Psychological interventions to improve glycaemic control in patients with type 1 diabetes*: systematic review and meta-analysis of randomised controlled trials. BMJ July 2006, 333; 65