

Health Technology Appraisal- Continuous subcutaneous insulin infusion for the treatment of diabetes (review)



Submission on behalf of British Dietetic Association (BDA)

Following consultation with the BDA membership, around 40 diabetes specialist dietitians highlighted common themes which are summarised below. This is thought to be a representative sample from across the country, encompassing the majority of dietitians involved in CSII therapy.

Geographical Variation

There was a wide variation in interpretation of current NICE guidelines; with some centres funding all patients for pumps, others funding only selected requests, some a certain number each year and others refusing most patients.

Carbohydrate Counting & Structured Education

Carbohydrate counting has been identified as an essential component for effective management of CSII therapy. This enables patients to adjust bolus insulin according to the amount of carbohydrate eaten. Many centres report that education around carbohydrate counting and insulin dose adjustment is essential prior to commencement of pump therapy. The length of time between this training and initiation of CSII was not specified, but members suggested 4-6 months as giving sufficient time for these new skills to be implemented effectively.

Pros and cons to carb counting on a one-to-one basis and as part of group education were common themes. However, the consensus suggested it did not matter how carb counting was taught, as long as it was carried out prior to commencing CSII. Many members suggested effective training around carb counting and insulin dose adjustment had prevented several patients requiring CSII. Some centres find this training difficult to implement within current funding levels.

The members were aware that patients with type 1 diabetes must have access to structured type 1 education. An audit at the Royal Free demonstrated around 30% of patients requesting CSII no longer required it 4 months after completing structured education – a cost saving to the PCT. However, ensuring patients have received this prior to commencing pump therapy is proving difficult in many areas, partly due to the backlog of patients. Having this as a prerequisite (at this point in time) to CSII, would delay many patients from improving glycaemic control. There will always be patients who for various reasons are not able to attend structured education (eg paediatric patients, those requiring translators), so flexibility within the guidelines is required.

All members felt that MDI therapy should be optimized by attendance on a type 1 structured education programme or with detailed 1;1 education around carb counting and insulin dose adjustment before CSII is considered. A clearly laid out care pathway; such as that at Bristol (Appendix 1) would clarify the process.

Specialist Clinics

A specialist secondary care clinic was felt necessary to manage patients with CSII. It was generally felt that helping patients optimise glycaemic control required health care professionals (HCP) who were used to managing pumps and the problems associated with them. None of the membership felt patients should receive pump care in a primary care setting. The membership felt that a successful pump management team should comprise a Specialist Dietitian, Specialist Nurse and Consultant with interest and experience in CSII.

Education of Health Care Professionals

Members felt accredited independent courses were necessary to train HCP in pump therapy. There was some discussion as to benefits of more experienced centres providing a 'hub and spoke' model to improve care, communication and education. Areas such as the Midlands have a PAN Birmingham group meeting regularly for transfer of information, education, sharing of resources and the development of protocols, enabling the less experienced centers to improve standards of care. Regional groups within Strategic Health Authorities could provide this across the country.

Patient Contracts

Patient contracts were common across the country. These included what was expected from both the patient and HCP. These often included a trial of an initial 6 months on CSII, to assess the benefit to the patient. Many centres are aware that it is very easy for patients to be left on pump therapy, despite having sub-optimal control. Contracts will facilitate the assessment of these patients in the medium/long term. As new therapy becomes available patients currently funded will need to be reviewed to ensure they are achieving their targets in the most effective and cost efficient way. For example, many patients who are currently funded have not attended structured education programmes.

Data Collection/National Register

A centralised collection of data, including quality of life assessment, glycaemic control and reasons for pump therapy would be a useful resource in planning future CSII requirements/auditing effectiveness.

Subgroups

Current guidance fails to take into account subgroups that may benefit. The membership felt the following groups might fall into this category:

Paediatric patients

Dietitians reported children feeling stigmatized by needing to inject insulin at school. Many children had to be removed from their normal group of friends to take their insulin. CSII would remove this stigma as the child would be able to self manage.

Patients experiencing frequent DKA

2 cases were reported of CSII used in adolescents requiring monthly (or more) hospital admissions secondary to DKA. No admissions had been seen in these patients once CSII had been initiated.

High intensity sport/exercise

Patients involved in sport at high levels of performance have benefited from the flexible basal rates CSII offers. One adolescent basketball player reported far fewer hypos following CSII.

Gastroparesis

A significant improvement within this group of patients has been widely reported, as demonstrated by the attached case series given as an oral presentation at Diabetes UK APC 2006 (see Appendix 2).

Labile blood glucose levels

Members suggested that many patients have benefited from a more reliable absorption of insulin, therefore preventing the extremes of glycaemia seen in some patients. Erratic blood sugar levels are often not reflected by HbA1c levels.

Shift work/Improved quality of life

The flexibility of variable basal patterns is useful in patients working different shift patterns. For patients experiencing reduced QoL secondary to diabetes, CSII can also be beneficial, however these patients may need psychological input prior to CSII, as members have reported cases where CSII has reduced QoL further.

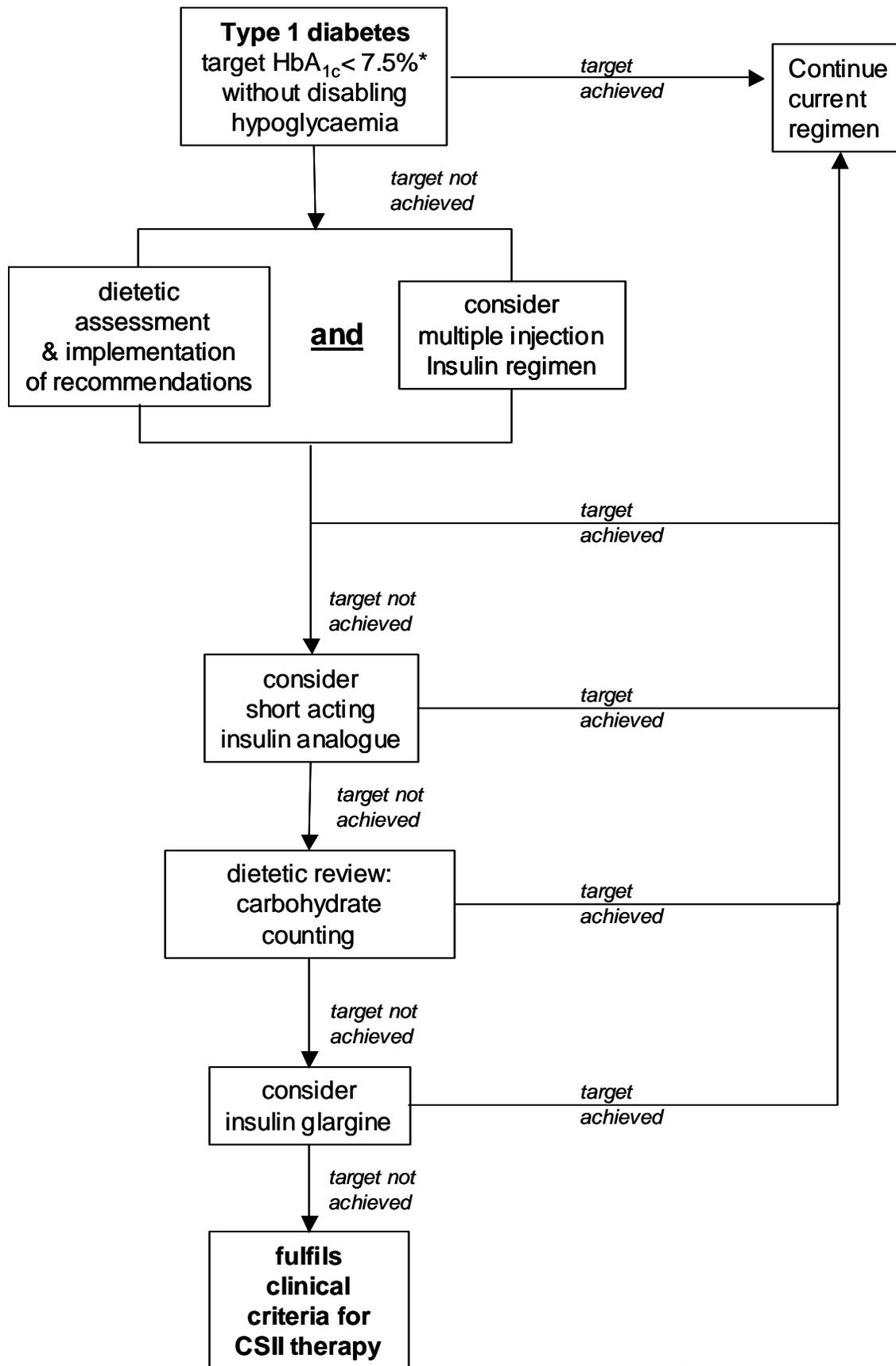
Medical conditions affecting glycaemic control

Various medical treatments are known to affect glycaemic control. This can lead to glycaemic instability in certain conditions. One such example is the use of steroid therapy in those who have had renal transplants. See case studies (Appendix 3) for further details.

Implementation

Ensuring patients receive adequate dietetic intervention prior to and whilst receiving CSII is essential to optimize glycaemic control. A recent DUK report identified serious shortcomings in dietetic staffing levels across the country, with many recently vacated posts being frozen/cut. A recommendation from NICE as to the minimal level of input required by an 'average' patient (pre and during CSII) would help ensure equity of care provision across the country.

Patient selection protocol (1)



* <6.5% if patient has microalbuminuria

Intensive management with CSII can prevent hospital admissions of patients with gastroparesis

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Introduction: Gastroparesis is a difficult management problem that can have a significant impact on quality of life (QOL) and due to glycaemic instability it often leads to repeated hospital admissions.

A combination of hyperglycaemia, multiple motor and sensory abnormalities of the upper gut results in variable absorption of nutrients which leads to difficulties in controlling blood glucose levels with multiple dose injections (MDI). Individualized insulin delivery via continuous subcutaneous insulin infusion (CSII) may provide greater glycaemic stability in this group, which in turn may prevent acute complications and the necessity for in-patient management.

Aims: Prevent hospital admissions and improve QOL by stabilizing glycaemic control in patients with gastroparesis by conversion from MDI onto CSII.

Methods: Seven female patients mean Age 32 years SD +/- 6.8 (range 24 -41) with a mean duration of type 1 diabetes of 20 years SD +/- 6.3 (range 12 -29) and symptomatic gastroparesis were converted from MDI onto CSII. All were on an optimized MDI regimen, which incorporated an average total daily insulin (TDI) of 44 units SD +/- 18.5 (range 24-78). Despite no educational deficits all had sub-optimal glycaemic control (mean HbA1c 10.5% SD +/- 1.3 (range 8.8 -12.2)), and erratic control which incorporated frequent episodes of hypoglycaemia, often requiring third party assistance, 5 describing total unawareness. Further autonomic complications included, 1 oesophageal, 3 bowel, 2 postural hypotension and 2 neurogenic bladder. Other established complications included, 5 retinopathy, 3 nephropathy (1 requiring dialysis), 2 hypertension, and 4 painful peripheral neuropathy. **One hundred and seventy-four in-patient days in the preceding twelve months prior to CSII initiation were recorded.** All reported low mood and 3 were treated with antidepressants.

Results: Mean duration of treatment with CSII was 15.7 months SD +/- 20.4 (range 2-60) and resulted in a reduction in the mean value of HbA1c by 1.9% and in TDI to a mean of 41.5 units SD +/- 9.2 (range 34.6-57.9). Hypoglycaemia was reported as infrequent and accountable and all episodes were associated with awareness. There was improvement of gastroparesis related symptoms and weight increased on average by 6.6 kg (mean BMI 23.3 SD +/- 3.5 (range 17-27.5)). Well being and QOL was heightened with one patient discontinuing antidepressants. **In-patient episodes related to glycaemic management or gastroparesis have not been required since conversion onto CSII.**

Conclusion: CSII is an effective means of overcoming glycaemic instability caused by gastroparesis. Hospital admissions are reduced, symptom impact and QOL issues improve

Reference

Morrison, G, Hill, K, Purewal, TS, Weston, PJ 2006, Can CSII effectively maintain glycaemic stability in patients with gastroparesis? *Case report orals- Clinical cases, Diabetic Medicine*, vol. 23 (supplement 2) p 1-30 (A18)

Case Studies

Miss N (38 year old) – Diagnosed with T1 diabetes in 1989.

No recorded complications, 1 episode of severe hypoglycaemia many years previous

- Requested CSII Nov 2006 due to fear of hypoglycaemia, and BG levels increasing mid-afternoon despite optimised MDI with carb counting. – Prior to pump therapy HbA1c levels 8.5-9% due to fear of hypos
- Commenced CSII Jan 2007. Awaiting first HbA1c value, but BG readings 3-8 mmol/L, expected to be lower than previous
- Miss N is now confident to reduce her blood glucose levels. She is aware occasional hypos can occur as part of tight glycaemic control, and can now manage these effectively. Quality of life has improved significantly, allowing Miss N more freedom and to feel in control

Mrs C (56 year old) – Diagnosed with T1 diabetes in 1991.

No recorded complications

- Self-funded CSII in 2001 for variable blood glucose control and hypoglycaemia. Average HbA1c pre-pump 9.9% (8.7-11.8%)
- Average HbA1c post pump 8.2%
- Diagnosed with thyrotoxicosis in May 2005, including Grade 3 Thyroid Eye Disease – required prednisolone and azathioprine – maintained average HbA1c of 8% during 2 years of treatment. CSII allowed a rapid increase in insulin to counter the insulin resistant effects of steroid therapy, including a 200% increase over a 24 hour period in basal insulin. Without CSII, it is probable this patient would have been admitted to hospital due uncontrolled diabetes.
- Prior to CSII, Mrs C was reluctant to leave the house alone for fear of hypos. She now shops and attends hospital visits alone.