

Initiation of insulin adjustment for carbohydrate at onset of diabetes in children using a home-based education programme with a bolus calculator

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Abstract

Improved glycaemic control following diagnosis of type 1 diabetes is associated with improved control in the longer term. This study reports on the experience of a paediatric diabetes service that introduced insulin adjustment for blood glucose and carbohydrate meal content from the first day of diagnosis. This is provided via a newly-designed home education programme, using multiple daily injections of insulin, supported by a bolus calculator blood glucose meter.

Glycaemic control was compared between patients who received the new programme (those diagnosed July 2012 to March 2014) to two historical cohorts: January 2000 to December 2009 and January 2010 to June 2012. The primary outcome was HbA_{1c} at 4–6 months post-diagnosis. Secondary outcomes were HbA_{1c} at 10–12 months post-diagnosis and the percentage of patients achieving HbA_{1c} of <58mmol/mol in the first 12 months.

Twenty-seven children (16 male, mean age 9.7±3.1) completed the new education package beyond 12 months. HbA_{1c} was significantly lower in the 2012–14 cohort when compared to the 2000–09 and 2010–12 cohorts at 4–6 and 10–12 months (mean [95% CI] mmol/mol: 4–6 months 52[47–57] vs 68[65–71] vs 65[61–68]; 10–12 months 57[53–61] vs 72[70–75] vs 71[67–76] p<0.001). In all, 89% of those diagnosed in 2012–14 achieved HbA_{1c} <58mmol/mol within the 12 months post-diagnosis compared with 39% in the 2010–12 cohort and 45% in the 2000–09 cohort (p<0.001).

In conclusion, carbohydrate counting with the use of a bolus calculator blood glucose meter at diagnosis was successfully introduced to a home-based education programme. This approach has improved glycaemic control in the first year of diagnosis, which may have a positive impact on long-term glycaemic control. Copyright © 2016 John Wiley & Sons.

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Key words

children and adolescents; type 1 diabetes; carbohydrate counting; bolus calculator

Background

Glycaemic control in young people with diabetes remains sub-optimal, putting large numbers at risk of long-term complications. In the UK, this has unfortunately failed to be addressed by the widespread use of intensive insulin therapy (multiple daily insulin injections [MDI] and insulin pumps) in routine everyday clinical practice.^{1,2}

A major influence on long-term glycaemic control appears to be the optimisation of blood glucose levels in the immediate period following diagnosis. Optimal glycaemic control close to diagnosis persists several years after diagnosis. This 'tracking' or 'metabolic memory' seems to be enhanced with the use of set pre- and postprandial blood glucose targets.³ Incorporating these targets within a blood glucose meter (as well as insulin:carbohydrate [CHO] ratio

and insulin/glucose sensitivity) in the form of a bolus calculator, allows users to adjust subcutaneous insulin bolus doses injection as part of MDI.

Locally, all new patients diagnosed with type 1 diabetes (T1DM) since 2001 have commenced an MDI regimen using pre-meal rapid insulin and a long-duration analogue. Education and training are delivered at home with <10% of children admitted at diagnosis (mostly for the treatment of diabetic ketoacidosis [DKA]). Insulin pumps are considered after one to three years post-diagnosis: ~50% of our patients currently receive pump therapy. Prior to 2012, our local practice was to initially establish patients on a sliding scale of insulin before introducing the concept of CHO counting at approximately three to six months after diagnosis.

As part of a quality improvement programme to improve clinical

outcomes⁴ we redesigned our new patient programme in 2012. This involved two major changes to our established practice: (1) adjustment of rapid-acting insulin to CHO content; and (2) setting of standardised blood glucose targets. These initiatives were delivered using a commercially available blood glucose bolus calculator, Accu-Chek Aviva Expert®. This glucocentric approach is delivered as soon as possible after diagnosis and certainly over the first week.

This paper follows a cohort of children diagnosed since July 2012 managed under this new approach, and compares their glycaemic outcome with our previous 12-year cohort of children and adolescents diagnosed with T1DM.

Setting

This study utilises data collected from children and adolescents diagnosed with T1DM within NHS Tayside – a mixed urban and rural area in the east of Scotland (population approximately 400 000). Approximately 20–30 young people are diagnosed with T1DM *per annum* and managed by the Diabetes Out There (dot.Tayside) clinical service for young people with diabetes.

Subjects

We followed all patients <18 years old diagnosed with classical T1DM and referred to our service from July 2012 to March 2014. All subjects received our revised new patient programme. Their glycaemic outcome has been compared with two groups: (1) all patients managed by dot.Tayside since January 2000 to December 2009; and (2) all patients managed by dot.Tayside from January 2010 to June 2012.

Methods

New patient education programme. On the first day of diagnosis the patient and their family meet with the dietitian regarding the following:

- Basic dietetic advice – avoidance of sugary foods/drinks, and CHO content of snack sizes.
- Answer any immediate dietetic questions.
- Introduce the idea of CHOs affecting blood glucose.
- Explain to the family that over the next few days we will aim to adjust

insulin to suit what the child or adolescent is eating.

For the 2012–14 cohort, the dietitian made initial contact on day 1 of diagnosis with two home visits arranged at days 1–3 and 4–7. At the initial home visit, the family are asked to keep a three-day food diary with estimation of CHO consumed, blood glucose levels and insulin doses. At the second home visit an insulin:CHO ratio was established using the completed food diary and programmed into a bolus calculator (Accu-Chek Aviva Expert) and the patient and the family used this management approach with MDI (once-daily basal insulin [glargine] and pre-meal rapid-acting insulin [insulin aspart]). If an individual is admitted as inpatient for the management of DKA, the programme starts once the child has been discharged home (usually in three to four days). The overall programme is then followed over the next 6–12 months depending on the aptitude of the patients and their families. A target HbA_{1c} of <58 mmol/mol was set for the first six months after diagnosis.

Bolus calculator and insulin adjustment. All subjects received the Accu-Chek Aviva Expert to enable insulin adjustment with the aim that all families would adjust their pre-meal insulin dose at home by day 7 of diagnosis.

The bolus calculator was set at the outset with pre-prandial blood glucose targets for 00.00–05.30 hours set to 5.5–8.0 mmol/L; for 05.30–19.00 hours they were set to 4.5–7.0 mmol/L; and for 19.00–00.00 hours they were set to 5.5–8.0 mmol/L.

Insulin:CHO ratio was established using a three-day food diary given to the families at the initial home visit and tailored to suit each individual patient's needs. Insulin/glucose sensitivity was calculated using the '100 rule' (100/total daily dose). Insulin was commenced at an initial overall dose of 0.5 units/kg body weight at presentation. Over the next six months appropriate adjustment of all of these parameters was made to optimise glycaemic control depending on review of daily blood glucose measurements, CHO intake and insulin dose administered.

Glycated haemoglobin data. Since 2000, all data are stored on a Scottish national patient management system – SCI-Diabetes. HbA_{1c} (IFCC aligned: mmol/mol) is obtained by capillary blood samples measured using a bedside system (Bio-Rad®). Each patient has a measure at diagnosis and at every visit to the routine outpatients thereafter, resulting in more frequent analysis in the first six months compared with the second six months post-diagnosis. Data were extracted from those currently receiving care from the paediatric diabetes service, i.e. patients who have transitioned to adult services since diagnosis were not included. The denominator for the total number of patients diagnosed during the period covered by the historical cohort was extracted from aggregate figures held by a legacy system (average annual rate was used when these data were incomplete).

Statistical analysis. The primary outcome was HbA_{1c} at 4–6 months. Secondary outcomes included: HbA_{1c} at 10–12 months; the difference between HbA_{1c} at 4–6 and 10–12 months; and the percentage of children achieving target HbA_{1c} (<58 mmol/mol) in the first 12 months following diagnosis. An initial exploratory analysis assessed data completeness and distribution. Owing to small numbers of samples (in the 2012–14 group in particular), months following diagnosis were collapsed into quarterly categories. HbA_{1c} was then compared between year groups using a general linear model (using generalised estimating equations to take into account repeated measures from the same individual). Similarly, univariate analysis of age at diagnosis and sex of patient was completed and retained for the final model if significant at $p < 0.1$. HbA_{1c} levels at 4–6 months and 10–12 months were compared within each year group using paired t-tests (mean HbA_{1c} was calculated for each three-month period for those individuals with more than one HbA_{1c} result). Categorical outcomes were compared using Chi-square. All statistical analyses were conducted using IBM SPSS v21.

As the new patient education redesign was part of a service improvement programme, ethical permission was not required.

Year group	No.	Male No. (%)	Age Mean (SD)	HbA _{1c} (mmol/mol) at diagnosis Mean (SD)	No. of recorded HbA _{1c} levels Median (IQ range)
2000–09	144	64 (44)	7.3 (3.5)	86 (25)	3 (3)
2010–12	67	34 (51)	9.9 (3.4)*	102 (27)*	2 (4)
2012–14	27	16 (59)	9.7 (3.1)*	110 (27)*	4 (6)

SD = standard deviation; IQ range = interquartile range. *Denotes $p < 0.001$ when compared to 2000–09 group.

Table 1. Characteristics of each cohort

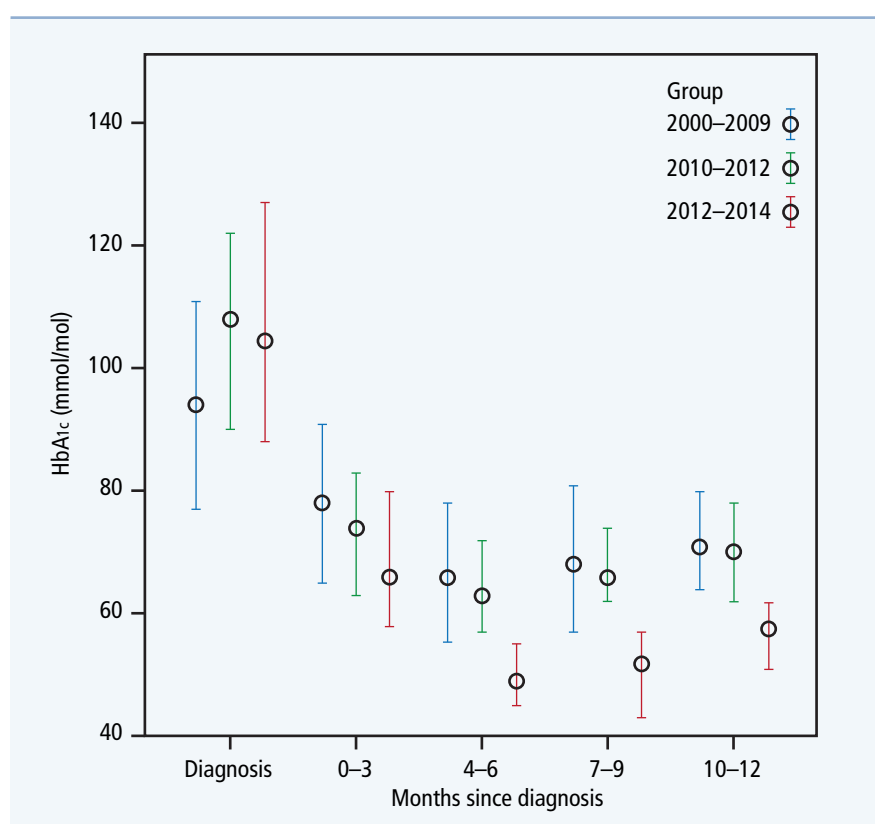


Figure 1. Monthly median and interquartile range (error bars) for HbA_{1c} in the 12 months following diagnosis, by year group

Year group	4–6 months				10–12 months			
	No.	Median (IQ range)	Mean (95% CI)	P value	No.	Median (IQ range)	Mean (95% CI)	P value
2000 to 2009	120	66 (23)	68 (65–71)	–	107	72 (14)	72 (70–75)	–
2010 to 2012	35	63 (15)	65 (61–68)	0.19	22	70 (17)	71 (67–76)	0.46
2012 to 2014	21	49 (20)	52 (47–57)	<0.001	21	58 (12)	57 (53–61)	<0.001

Table 2. Median and mean HbA_{1c} for 4–6 months and 10–12 months following diagnosis

Results

Glycaemic data were available for all children diagnosed with T1DM in NHS Tayside from 2010 onwards. Of the 32 children diagnosed with T1DM between July 2012 and March 2014, 27 (84%) received the new patient education programme. By way of comparison, glycaemic data were available for 67 diagnosed between January 2010 and June 2012 (100% of those diagnosed during this period), and 144 of an estimated 200 children (72%) diagnosed between January 2000 and December 2009 (aggregate data were available for all but two of the years 2000–09). There was no significant difference in gender split between the three groups (see Table 1). Children in the 2010–12 and 2012–14 groups were significantly older than those in the 2000–09 group ($p < 0.001$). Similarly, initial HbA_{1c} was significantly higher in those in the 2010–12 and 2012–14 groups when compared to the 2000–09 group ($p < 0.001$).

All patients had HbA_{1c} measured at diagnosis, with subsequent tests being dispersed throughout the following 12 months. As expected, there is a downward trend in HbA_{1c} in all groups following diagnosis (see Figure 1). The HbA_{1c} was significantly lower in the 2012–14 cohort compared to the 2000–09 and 2010–12 cohorts for HbA_{1c} at 4–6 months and 10–12 months following diagnosis ($p < 0.001$ for both) – see Table 2. Age at diagnosis and sex had no significant effect on HbA_{1c} and so were not retained in the final model.

When comparing HbA_{1c} at 4–6 months with HbA_{1c} at 10–12 months within each of the year groups, paired data were available for 89/144 (62%) in the 2000–09 group, 21/67 (31%) in the 2010–12 group and 16/27 (59%) children in the 2012–14 group. There was a significant rise in HbA_{1c} for the 2012–14 group between the two time points ($p < 0.001$), with no significant difference observed in the 2000–09 and 2010–12 groups.

The proportion of children achieving a target HbA_{1c} at any time in the first 12 months following diagnosis was 24/27 (89%) in the 2012–14 group compared with 26/67 (39%) in the 2010–12 group and 65/144 (45%) in the 2000–09 group ($p < 0.001$).

There were no episodes of severe hypoglycaemia (Grades 2 and 3 according to the International Society for Pediatric and Adolescent Diabetes guidelines⁵) and no episodes of DKA. No patients required admission to hospital after starting their ambulatory new patient education programme. There were no specific issues with the use of the bolus calculator, which was used by all 27 patients in the 2012–14 group.

Discussion

This audit describes the change in HbA_{1c} in the first year following diagnosis of T1DM in patients receiving our revised new patient education programme. This involved insulin adjustment for CHO intake and pre- and postprandial blood glucose targets established using a bolus calculator blood glucose meter (Accu-Chek Aviva Expert). We have demonstrated a clear improvement in glycaemic control throughout the first year following diagnosis when compared to local historical data obtained prior to the new patient education programme.

This comparison of glycaemic control was undertaken between cohorts of new patients diagnosed 2000–09, 2010–12 and 2012–14. The 2010–12 cohort was included as a comparison with the most recent set of patients, as staffing levels and personnel were constant in the years 2010–14. There were twice as many children diagnosed in 2010–12 compared to 2012–14, the cause of which is unknown. Five of the 32 children diagnosed during the 2012–14 period did not receive the new patient education programme. This was due to staff absence during the period April–June 2013, i.e. there was no selection bias in who received the programme. The dataset for those diagnosed prior to 2012 is incomplete owing to natural attrition, e.g. patients moving outwith the area or on to adult services. The lack of paired data between 4–6 months and 10–12 months is disappointing and is a result of non-attendance or re-scheduled appointments to beyond 12 months. The decision to limit this latter window to 12 months following diagnosis was a pragmatic one, based on the date of the analysis (most recent patients diagnosed in March 2014; analysis completed in March 2015).

Key points

- Our approach is a home-based education programme which uses a bolus calculator blood glucose meter to aid insulin calculations for children and adolescents with diabetes, using this to adjust their pre-meal insulin doses from week 1 of diagnosis
- In order to ascertain whether this approach had an impact on glycaemia, we compared HbA_{1c} data obtained within the first year of diagnosis in patients who had undergone the new programme (2012–2014) with historical data (2000–2012)
- Glycaemic control is significantly improved with the introduction of the new patient education programme, reaching near-normal blood glucose levels in the first six months, with a sustained lowering over the first year
- Our approach of intensive insulin adjustment to meals from diagnosis can be adopted within the NHS for people with diabetes

This comparison was not a randomised study but an evaluation of clinical practice over 14 years, where in the last two years a definitive and structured change to the programme has been established and has caused an improvement in glycaemic control. While bias cannot be eliminated in this open-cohort comparison, the use of the same personnel and other educational resources between 2010–12 and 2012–14 suggests that any differences in the glycaemic outcome are influenced to a major degree by the changes adopted in the revised new patient programme.

As a consequence of this improved glycaemic control, there was a significant increase in the proportion of children achieving an HbA_{1c} in the target range (<58mmol/mol). However, for those using the new patient programme there was an observed increase in HbA_{1c} in the latter half of the year. This would suggest that those enrolled in the new programme may need additional support towards the end of their first year post-diagnosis to maintain initial gains.

While the insulin adjustment dose with MDI could be calculated manually, our experience is that this is a difficult undertaking for patients. The bolus calculator (as with insulin pump therapy) allows for the dose to be calculated rapidly at the time of blood glucose testing. This appeared relatively easy for our patients following the education and training delivered in the programme, even from the first few days after diagnosis.

We designed our new patient programme to be delivered in an ambulatory way and this appears to have been accepted by the patients, families and their health professionals. The use of the bolus calculator did not appear to

add to the burden of the diagnosis of diabetes and all patients continue to use the Accu-Chek Aviva Expert to manage their diabetes.

Conclusion

We have successfully introduced insulin adjustment for CHO and preprandial glucose targets using a commercially available bolus calculator with MDI from the onset of diagnosis in a home-based new patient programme. We have observed significant improvements in HbA_{1c} in the first 12 months compared with our previous experience in the preceding decade. We advocate that this intensive approach should be adopted as routine practice. Further follow up of our patient cohort will indicate if this effect is sustained and leads to improvement in overall glycaemic control after several years of diabetes in those patients diagnosed in childhood.

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Declaration of interests

Heather Thom is supported by an educational grant from Roche UK.

Professor Steve Greene has been paid for consulting services and has received grants from several pharmaceutical companies; his full declaration of interests can be found in his biography at <https://discovery.dundee.ac.uk/admin/workspace.xhtml>.

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