

Use of advanced carbohydrate counting and an automated bolus calculator in clinical practice: the BolusCal[®] training concept

Merete Meldgaard, Camilla Damm-Frydenberg, Ulla Vesth, Kirsten Nørgaard and Signe Schmidt

Department of Endocrinology, Copenhagen University Hospital Hvidovre, Denmark

Background: BolusCal[®] is a newly developed training concept for patients with Type 1 diabetes (T1D) on a basal-bolus regime. The training, which is provided by a diabetes nurse and a dietician, consists of a 4-hour group session followed by a 1-hour follow-up and includes training in advanced carbohydrate counting and the use of an automated bolus calculator.

Aims: The aim of this article is to describe the BolusCal training concept and to report changes in HbA1c and body mass index (BMI) as well as resources spent 12 months after implementing the BolusCal training concept in routine clinical practice.

Methods: During 14 months in 2012–2013, 86 patients with T1D participated in a BolusCal training course. We retrospectively collected patient data from electronic medical records.

Results: From training course participation to 12 months, HbA1c decreased from 66 to 57 mmol/mol (8.2–7.4%) ($p < 0.001$). BMI did not change. Within the first 6 months the number of follow-up consultations ranged from 0 to 9 (median 3).

Conclusions: Our newly developed training concept for patients with T1D has been successfully implemented in routine practice. Twelve months after the training, patients achieved significant and clinically relevant improvements in HbA1c whereas BMI remained stable. In general, patients needed only few follow-up consultations. Following our initial positive experience with the BolusCal training concept, we are now training other health care professionals in providing the training concept to T1D patients within Denmark and throughout Europe.

Key words: Advanced carbohydrate counting, bolus calculation, automated bolus calculator, Type 1 diabetes, structured education programme, clinical practice, BolusCal[®] training concept

Introduction

The diabetes control and complications trial showed that intensive management of blood glucose (BG) has the potential to significantly reduce the development and slow the progression of micro-vascular complications in Type 1 diabetes (T1D).¹ A decade later, the dose adjustment for normal eating (DAFNE) study demonstrated that flexible intensive insulin therapy with multiple daily injections of insulin adjusted to BG level, carbohydrate (CHO) intake and exercise have beneficial effects on glycaemic control and diabetes-related quality of life.^{2,3} In line with these findings, treatment guidelines recommend intensive insulin therapy and matching meal insulin to BG level, CHO intake and anticipated activity in patients with T1D.^{4,5} Achieving optimal glycaemic control requires, however, a high level of daily self-management and up to 64% of T1D patients estimate insulin bolus sizes incorrectly.^{6–9}

In Denmark, treatment and advice given to patients with T1D have varied over the years. Until the 1980s,

patients were taught to follow a diet with fixed CHO content matching a fixed insulin dose, which often was taken twice daily. It was difficult to take variations in appetite and activity into account. In the following years the treatment approach changed and focus on limiting the CHO content in the diet was diminished. With the introduction of rapid-acting insulin analogues in the late 1990s, even greater flexibility in diabetes diets became an option, but treatment recommendations varied: some health care providers (HCP) still prescribed fixed doses of insulin for each meal whereas others let patients eat as the general population as long as appropriate insulin was taken with the meal – often on a trial-and-error basis. Subgroups of HCPs started training T1D patients on a basal-bolus regimen in advanced carbohydrate counting (ACC) and since 2010 the Danish national treatment guidelines have recommended ACC for all T1D patients.⁵

At the outpatient diabetes clinic at Copenhagen University Hospital Hvidovre, we manage the therapy

of approximately 800 patients with T1D. One-hundred and eighty of these are insulin pump users and the large majority of the remainder follow a basal-bolus regimen. Nurses who have completed a special training course and are approved by the administrative consultant have permission to adjust insulin doses.

In 2010–2011 we performed a 16-week, randomised controlled clinical trial in 51 adults with T1D in poor metabolic control on a basal-bolus regimen to investigate the effects of ACC and the use of an automated bolus calculator (ABC).¹⁰ The study had two intervention arms: in one arm patients were trained in ACC using mental arithmetic and in the other intervention arm, patients were trained in ACC using the ABC.

For the study, we developed a training concept (BolusCal[®]) inspired by the British DAFNE programme.² Considering the patients' busy lives and the department's limited resources, we wanted to test whether a 3-hour group session with a 1-hour individual follow-up session 2 weeks later could improve glycaemic control and patient satisfaction. HbA1c improved significantly by -0.8% in patients counting CHOs and calculating insulin doses by mental arithmetic and by -0.7% in patients counting CHOs and using the ABC for insulin dose calculations (between-group difference insignificant). Diabetes treatment satisfaction improved in all patients but was significantly greater in patients using the ABC.¹⁰

Based on the positive outcome of this pilot study, we decided to offer the BolusCal training and the ABC to all patients with T1D on a basal-bolus regimen with analogue insulin attending our clinic. Since 2012, we have held six to seven courses per year with 10–12 patients attending each course.

The aim of this retrospective study was to evaluate the effects of the combined use of ACC and an ABC when implemented as part of routine clinical practice by use of the BolusCal training concept on HbA1c and body mass index (BMI). In addition, we wanted to assess

HCP resources spent on training patients in the new treatment approach.

Methods

To assess changes in HbA1c and BMI 6 and 12 months after participation in BolusCal training and to estimate resources spent on training patients in ACC and ABC use, we retrospectively collected data from electronic patient medical records. Comparisons between baseline, 6-month and 12-month data were conducted using the paired *t*-test. Effect of sex and previous ACC experience was evaluated using the unpaired *t*-test.

Advanced carbohydrate counting

ACC is a method for calculating the size of an insulin bolus, which is the amount of rapid-acting insulin needed to cover CHO intake and bringing BG to target.^{9,11,12} The components of the ACC include the carbohydrate:insulin ratio (CIR), the insulin sensitivity factor (ISF), the current BG, the target BG, the insulin resistance factor, insulin on board (IOB) and the amount of CHO to be consumed (Fig. 1).

CIR is the amount of CHO needed to counteract the effect of one unit of rapid-acting insulin and ISF is the decrease in BG level caused by one unit of rapid-acting insulin. As a starting point, CIR and ISF can be estimated from the 500 rule and the 100 rule, i.e. 500 and 100 divided by the patient's total daily insulin dose. Both factors may vary over the day, so differentiated CIRs and ISFs may subsequently be calculated based on worksheets filled in by the patient. The insulin resistance factor is 1 on normal days, > 1 when the patient is insulin-resistant, e.g. on sick days and < 1 when the patient is insulin sensitive, e.g. in relation to physical activity. IOB is active insulin present from a previous bolus and should be subtracted to avoid hypoglycaemic episodes. The BG target is set according to patient preferences, HbA1c, degree of retinopathy and treatment goals.

$$\text{insulin bolus} = \frac{\text{current BG} - \text{target BG}}{\text{ISF}} + \frac{\text{grams CHO}}{\text{CIR}} \times \text{insulin resistance factor} - \text{IOB}$$

The insulin resistance factor is 1 on normal days, >1 when the patient is insulin resistant e.g. on sick days, and < 1 when the patient is insulin sensitive e.g. physical active.

Example:

If a patient has BG 12.4 mmol/l, target BG 6.0 mmol/l, ISF 1.7 mmol/l and CIR 8 g CHO/unit, eats 45 g of CHO, and estimates the insulin resistance factor to 0.9 due to physical activity, the insulin bolus equation will be:

$$\frac{12.4 \text{ mmol/l} - 6.0 \text{ mmol/l}}{1.7 \text{ mmol/l}} + \frac{45 \text{ g}}{8 \text{ g}} \times 0.9 = 8.46 \text{ units, rounded to 8 units}$$

Figure 1 Illustration of the principles of advanced CHO counting. BG, blood glucose; ISF, insulin sensitivity factor; CHO, carbohydrate; CIR, carbohydrate:insulin ratio; IOB, insulin on board

Last but not least the patient requires knowledge of measuring, calculating and estimating the CHO content of meals as well as a general understanding of diabetes.^{9,11,12}

Figure 1 depicts the ACC equation and gives an example of insulin bolus calculation. If the patient only needs to correct a BG out of target, the CHO part is skipped, and if the BG is already in target, the correction part is skipped.

A prerequisite for successful ACC is an appropriate basal insulin dose. The long-acting insulin should cover the patient's basal insulin needs. The basal insulin dosage can be evaluated by looking into the patient's diabetes diary or by asking the patient to fast for alternating periods of the day while registering BG values.

Although ISF and CIR often are rounded to facilitate the mental arithmetic, calculations are still very challenging to many patients.^{9,13,14} To assist patients, ABCs have recently been developed.^{8,10,15–19}

The automated bolus calculator

The ABC is a BG meter with an integrated bolus calculator that assists the patient in the complicated calculations of ACC. Patient-specific factors including CIR, ISF, BG target, insulin resistance factor and insulin action time are programmed into the ABC.

To get meal and/or correction bolus advice, the patient measures a BG, enters the estimated grams of CHO in the meal and activates the ABC's health event to adjust for insulin resistance according to physical activity, health status, level of stress and menstrual cycle, if needed. The patient can increase or decrease the suggested bolus size before confirming the dose and injecting insulin. The ABC subtracts IOB from the bolus advice, which reduces the risk of hypoglycaemia if the patient re-boluses within the insulin action time. If the BG is <3.0 mmol/l the ABC gives advice on the amount of CHO that should be eaten to reach the BG target. If the BG is below the BG target but >3.0 mmol/l, the ABC will subtract insulin from the meal bolus advice, such that the patient reaches the BG target.

The ABC data can be reviewed via the statistics function and can also be downloaded and emailed to the HCP. Further, the device can be set to give reminders for BG measuring, insulin injection and clinic visits.

The BolusCal training concept

The aim of the BolusCal training concept

The aim is to teach the patients how to count CHO, use the ABC and improve knowledge about their diabetes treatment so that they feel empowered to make qualified treatment decisions and reach their individual treatment goals.

Teaching approach

Ten to twelve patients are booked for a 4-hour group-teaching course, which contains both theoretical and practical training. The teaching is based on theory and examples from T1D everyday life and the patients

are invited to contribute with their own experiences. We emphasise that we will help the patients individually with their specific diabetes-related problems and together try to find appropriate practical solutions. PowerPoint and hand-outs for personal notes support the training.

Training in CHO estimation

The training includes identifying CHO in food, factors affecting the absorption of CHO, reading CHO tables,²⁰ estimating CHO content from food labels and introduction of applications (APPs) for smartphones, which can support the calculation of CHO.^{20–23}

The patients participate in a practical session including the use of scales (Figure 2). They weigh the amount of, e.g. oatmeal, bread, potatoes, rice and pasta they would normally eat and calculate the CHOs in these portions. They note the grams of CHO on a worksheet to get familiar with filling in worksheets, which are used at follow-up sessions. Finally, they get tips to estimate the weight of food or snacks without a scale.

Work sheets

The work sheets are very important tools in the optimisation of ACC, and further the worksheets are the foundation of the calculations of the differentiated CIR and ISF. Patients are asked to fill in worksheets for at least 3 days with BG measurements before every meal/snack, 4 hours after meals/snacks (which may correspond to the next meal) and before bedtime. If the patients skip a meal they should still measure BG every 4 hours because these values are useful for evaluation of the basal insulin dose. To avoid overlap of insulin boluses, patients are asked to separate meals/snacks by four hours and only take correction insulin at mealtimes, if possible, while filling out the worksheets (Figure 3).

To get the most precise values for calculating the differentiated CIR and ISF, the patients are carefully instructed to register BG, food intake (measured in grams), the



Figure 2 Practical exercise in advanced CHO counting



Figure 3 Using smartphone APPs while filling in worksheet. ©Photographer Susanne Østergaard, who granted permission to use the photos in this article

amount of CHO, insulin dose suggested by the ABC, insulin dose taken, health condition, activity level, work day and symptoms of hypoglycaemia, if BG is not measured. If the patients know that certain foods affect their BG in a special way, they are encouraged to make extra worksheets including this particular food.

Device setup and training

During the training session, the patients program the ABC with their CIR(s) and ISF(s). Then they measure their first BG and use the ABC to calculate an insulin bolus for a fictive meal. The possibility of entering extra CHO without measuring BG, when eating multiple portions or overeating after hypoglycaemia, is mentioned. If the patients' total daily dose of insulin is ≤ 30 units, we recommend the use of an insulin pen that gives half units and accordingly set the ABC to round to half units instead of whole units.

General diabetes training

The patients are trained in insulin action profiles, variations in insulin absorption and sensitivity, timing of insulin dosing, best practices in injection technique and BG measurement. In addition, they are encouraged to increase or decrease the long-acting insulin according to health status, planned activity, female hormonal cycle and to follow the precautions associated with drug and alcohol intake.

Individual follow-ups

Two weeks after the course, each patient comes to an individual follow-up with the same nurse and the dietician who taught the course. The ABC is downloaded to the computer and the nurse looks for patterns in BG values to see if the basal insulin and the ISF are correctly adjusted. The nurse discusses the findings with the patient, takes the patient's experiences in consideration and makes the necessary adjustments. They clarify whether the patient uses the device correctly, e.g. confirming bolus advises, using the health options for physical activity, sick days, etc. To keep track of BG levels the patient is introduced to the ABC statistics functions and the possibility of downloading data. Meanwhile the dietician reviews the worksheets to see whether the patient counts CHOs correctly. The dietician then calculates the differentiated CIR. The nurse and dietician make a common conclusion and supervise the patient in implementing the suggested changes in the ABC. The patient's special challenges with diabetes are addressed and specific advice is given.

Further follow-ups depend on the patient's needs and the demand for further adjustments. Follow-ups can be scheduled with the dietician, the nurse or both – in the clinic, by telephone consultations or by email. When the patient is confident with the concept and the ABC is adjusted correctly the patient returns to regular quarterly visits with their usual HCPs.

Results

From 1 January 2012 to 28 February 2013, 86 patients with T1D treated with a basal-bolus regimen participated in a BolusCal training course at Copenhagen University Hospital Hvidovre, Denmark. At the time of course attendance, mean participant age was 42 years (SD = 12 years, range 20–66 years), 56 (67%) were female, mean diabetes duration was 15 years (SD = 9 years, range 2–44 years). Twelve per cent of the patients had an HbA1c < 53 mmol/l (7.0%) at baseline. Forty-six per cent of the patients were CHO-counting naïve, whereas the remaining patients had previous experience with CHO counting or were current users of the method.

Table 1 summarises HbA1c and BMI data at baseline, 6 and 12 months. HbA1c decreased from 66 to 58 mmol/mol (8.2–7.5%) ($p < 0.001$) after 6 months and to 57 mmol/mol (7.4%) after 12 months, which was also

Table 1 HbA1c and BMI at baseline, 6 and 12 months.

	Mean	SD	Range
HbA1c baseline	66 mmol/mol (8.2%)	11 mmol/mol (1.0%)	41–100 mmol/mol (5.9–10.5%)
HbA1c 6 months	58 mmol/mol (7.5%)*	9 mmol/mol (0.8%)	38–84 mmol/mol (5.6–9.8%)
HbA1c 12 months	57 mmol/mol (7.4%)*	7 mmol/mol (0.6%)	42–79 mmol/mol (6.0–9.4%)
BMI baseline	25.4 kg/m ²	3.7 kg/m ²	17.8–38.4 kg/m ²
BMI 6 months	25.8 kg/m ²	3.9 kg/m ²	19.6–37.8 kg/m ²
BMI 12 months	25.8 kg/m ²	3.8 kg/m ²	19.7–35.6 kg/m ²

* Significant difference ($p < 0.001$) compared with baseline value.

significantly different from the baseline value ($p < 0.001$) but not different from the 6-month value ($p = 0.532$). After 12 months, 26% of the patients had an HbA1c < 53 mmol/l (7.0%). There was no difference in change in HbA1c between patients with and without previous experience with ACC and there were no sex-differences.

At 12 months, 72% of patients were using the ABC consistently and 5% were using the device on and off. The group of non-users included four patients who had switched to CSII-therapy within 1 year after BolusCal course attendance.

Within the first 6 months following the training course, the number of consultations per patient with a nurse, a dietician or a doctor ranged from 0 to 9 with a median number of 3. Most frequently a nurse met the patients. Only a minority of consultations were conducted per email or telephone

Discussion

The purpose of this 12-month retrospective cohort study was to evaluate the effects of the combined use of ACC and an ABC when implemented as part of routine clinical practice using the BolusCal training concept. We found significant reductions in HbA1c, from 66 to 57 mmol/mol (8.2–7.4%) ($p < 0.001$) after 12 months. BMI was stable during the 12-month observation period. Within the first 6 months following the training course, the total number of consultations per patient ranged from 0 to 9 with a median number of 3.

The decrease in HbA1c is significant and clinically relevant. The positive finding is particularly impressive considering that 12% of the patients had an HbA1c < 53 mmol/l (7.0%) before the training.

BMI did not change in the year following the BolusCal training although patients could eat freely. Several patients lowered their insulin dose in relation to activity instead of eating extra CHOs, and this could have had a stabilising effect on their BMI. The training in CHO estimation may also have been a weight-related eye opener, and during the follow-up sessions several patients were surprised about the amount of CHO in wholemeal buns.

Despite the relatively big change from experience-based insulin dosing to the BolusCal training concept, patients in general needed very few follow-ups. The majority of patients found it fairly easy to implement the new method. We experienced that challenges often were related to assessing the impact of physical activity and therefore they needed few follow-ups. Some patients found calculating the amount of CHOs in the meals difficult because of poor mathematical skills or because they often were dining out. A few patients lacked time or motivation to complete the worksheets correctly, in these situations it was impossible for us to make ISF and ICR calculations, and a new follow-up with new worksheets had to be scheduled. A couple of patients were unfamiliar with the use of technologies and found

it difficult to learn to use the ABC and accordingly the training in the use of the ABC had to be repeated at the individual follow-ups. Depending on the challenges met by the patients, follow-ups varied in number and content. Most follow-ups were with the nurse alone, but there were also a considerable number of follow-ups with the dietician and nurse together.

The DAFNE study group trained their patients for 5 days and achieved a reduction of 11 mmol/mol (1.0%) in HbA1c after 6 months, which narrowed to 6 mmol/mol (0.5%) reduction after 12 months.² We invested 4 hours of training with a dietician and nurse and a mean of three follow-up consultations to achieve a reduction in HbA1c of 9 mmol/mol (0.8%) after 12 months. In our opinion these resources are well spent.

The BolusCal training concept is a complex intervention consisting of three major elements: ACC, the ABC and general diabetes training. It is impossible for us to evaluate whether one element has greater impact than the others. On a pilot basis, we provided patients who were already using ACC with the ABC before BolusCal training course attendance, but we found that the patients did not get the full benefit of the ABC until after completing the training course. During the follow-up consultations, patients spontaneously shared their experiences. We did not record their feedback systematically and the following is only a sample of distinctive patient reports. A few patients told us that after a while, they thought that they had learned how to manage their diabetes, so they decided to measure less BGs and use ACC with mental calculations instead of the ABC. However, as they realised that their BG values increased, they started using the ABC again. Many patients told us that they had the impression that their BGs were more stable and they had fewer hypoglycaemia episodes after ABC start. Patients, who previously used smartphone APPs for bolus calculations that did not take IOB into account, reported being pleased with the ABC.

After 1 year 72% of the patients were still using the ABC consistently and 5% were using it on and off. As a patient said: 'I do not need to use my energy on calculating the bolus dose; I can focus on what I want to achieve'.

The first follow-up was scheduled about 2 weeks after the training course. The time was chosen to stimulate patients to implement the new treatment method directly and to be able to quickly identify problems and optimise ABC settings without patients losing patience and motivation. We learned that when the nurse and dietician have joint follow-up consultations, it saves the patient from having to repeat the same issues. On our side we felt that joint follow-up sessions gave us a better and common understanding of the issues. We have learned more about each other's work areas and methods and this knowledge we use to identify problem areas we did not recognise earlier and to involve the other individual competencies better in other consultations. However, when we implemented the BolusCal training concept in the clinic, it was challenging to give all our colleagues

the necessary practical experience with the new concept due to a small number of patients in the start-up phase.

As with other concepts, the strength of the BolusCal training concept is in the weakest link. If the patient has poor BG measuring and/or injection techniques, counts the CHOs incorrectly, overeats after hypoglycaemia without bolusing, takes insulin after meals rather than before or forgets it, BG will still reach magical heights. To achieve optimal glycaemic control a high level of daily self-management is required, even with ACC and an ABC. Therefore, to us, the real magic is when we see the patient reflecting on the BG results, taking responsibility and finding personal solutions to the challenges of living with T1D.

The positive results obtained at Hvidovre University Hospital will hopefully benefit other patients as well since we so far have trained 250 HCPs from clinics all over Denmark in providing the BolusCal training concept at their sites. Further, we have introduced our concept in Norway, the Netherlands, Portugal and Switzerland.

Conclusions

Our newly developed training concept for patients with T1D has been successfully implemented in routine practice. Twelve months after the training, patients achieved significant improvements in HbA1c from 66 to 57 mmol/mol (8.2–7.4%) whereas BMI remained stable. The median number of follow-up consultations was 3. The implementation of the concept requires only few resources.

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