

Fine tuning the control of diabetes

**The 0.12 formula for the management
of type 1 diabetes**

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Today's workshop

- 2 Case scenarios
- I will review the current formulae available to fine tune the management of type 1 diabetes
- Identify the 3 important factors that help us to manage type 1 diabetes
- **The 0.12 formula and its potential role in managing type 1 diabetes.**
- Discussion around the management of diabetes using the two case scenarios

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Case scenario 1

- Sebastian, newly diagnosed type 1 diabetic, presented at the age of 22 months with osmotic symptoms, BS of 24.6 mmol/L and blood ketones of 2 mmol/L
- Weight 13kgs, Clinically very well. Normal BP, normal perfusion, Normal electrolyte, and Normal blood gases.

How would you manage him?

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Case scenario 2

- Suleman, aged 11, diagnosed in Pakistan with type 1 diabetes at the age of 2 and coeliac in September last year in the UK.
- On the basal bolus regimen of Lantus 26 units and Novorapid 7, 7, 7. No carb. counting, non compliant.
- Presented January 2014 with severe DKA. Previous similar episode in Sept. 2013 .
- Ph: 7.0, BE -29, Bic: 4.5, BS 44mmol/L BK: 5.9 mmol/L. U&Es, Cr Normal, Agitated, but alert, not vomiting. BP and perfusion are normal. not significantly dehydrated. Weight 29 kgs

How would you manage him?

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Why better control!!

DCCT (Diabetes Control and Complications Trial) Study Findings:

- Intensive blood glucose control reduces risk of
 - Eye disease, by 76%
 - Kidney disease by 50%
 - Nerve disease by 60%

EDIC (Epidemiology of Diabetes Interventions and Complications) Study Findings

- Intensive blood glucose control reduces risk of
 - Any cardiovascular disease event by 42%
 - Nonfatal heart attack, stroke, or death from cardiovascular causes by 57%

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Why better control!!

- The Good control of diabetes is essential to minimise the risk of complications
- For each 1% reduction in HbA1c there is 20-25% reduction in the risk of the long term complications

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Background

- **Formulae Calculating Insulin Sensitivity / Correction Factor (CF)**
 - the 1500 rule pioneered by Paul Davidson:
 - » $1500/\text{TDD} - 83/\text{TDD}$ (total daily dose of insulin)
 - 1500 became 1800 from which the 100 rule was derived.
 - Subsequently further adjustment made (1076 – 2200)
- **Formulae calculating Carbohydrate to Insulin Ratio (CIR)**
 - Walsh and Roberts' 450 rule was introduced in 1994 and later modified to the 500 rule, and the 300 rule for paed
 - $\text{CIR} = 450/\text{TDD}$

In 1998 Steed developed the rule-of-3 for the carbohydrate insulin ratio

 - $\text{CIR} = 3 \times \underline{\text{body weight (lb)}}/\text{TDD}$

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Clinical studies

Davidson and Colleagues 2003 (167 pump patients)

- Correlated the 1500 rule and the rule-of-3 and looked at insulin pump settings
- Retrospective study that calculated the TDD as a mean of 6 days prior to their visit of best HbA1c (<7%) with a mean basal rate of 48% of TDD
- They derived modification of both formulae
- **Insulin sensitivity = $1717/\text{TDD}$**
- **$\text{CIR} = 2.8 \times \text{weight (lbs)} / \text{TDD}$.**
- Neither of which has been subsequently validated
- Glucose control was not intensely established. It relied on low HbA1c as a reflection of good control

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Clinical studies

Kings and Armstrong (2007<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2769604/>)

- 30 pump patients on CGM were studied to calculate CIR and CF with a mean basal rate of 38% of TDD
- The CIR was determined from the amount of rapid acting insulin needed to return the glucose to +/- 20% of premeal level within 4 hours.
- **$CIR = 217/TDD + 3$**
- To determine the CF, the premeal insulin bolus was reduced by 25% to cause hyperglycaemia by 4 hours later. Then the CF was calculated by the amount of rapid acting insulin required to return the glucose to 80-120 mg/ dl within four hours of the bolus.
- **Insulin sensitivity = $1076/TDD$**

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Clinical studies

Walsh and colleagues (2010<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2956816/>)

- They analysed the data of 1020 pump patients selecting 396.:
 - 85% of glucose data were entered directly from a meter
 - **At least 28 days of consecutive data (average 74) with at least 20 glucose readings (average 316)**
- The pumps then were divided into tertiles 132 each based on mean glucose and the lowest mean of 8mmol/L then was used to derive the formulae
- Their mean basal rate was 48% of the TDD
- **Insulin sensitivity = 1960/TDD or 109/TDD**
- **CIR = 2.6 x weight (lb) / TDD or 5.7 x weight (kg) / TDD**

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Available formulae

Formulae calculating Insulin Sensitivity Factor

- Insulin sensitivity = $1500/\text{TDD}$ (Davidson)
- Insulin sensitivity = $1717/\text{TDD}$ (Davidson and colleagues)
- Insulin sensitivity = $1076/\text{TDD}$ (King and Armstrong)
- Insulin sensitivity = $1960/\text{TDD}$ (Walsh and Colleagues)

Formulae calculating Carb/Insulin Ratio (CIR)

- $\text{CIR} = 450/\text{TDD}$ (Walsh and Roberts)
- $\text{CIR} = 3 \times \text{body wt (lb)} / \text{TDD}$ (Steed)
- $\text{CIR} = 2.8 \times \text{body wt (lb)} / \text{TDD}$ (Davidson and Colleagues)
- $\text{CIR} = 2.6 \times \text{body wt (lb)} / \text{TDD}$ (Walsh and Colleagues)
- $\text{CIR} = 217/\text{TDD} + 3$ (King and Armstrong)

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How reliable !!!

- **Currently all formulae rely on the Total Daily Dose of Insulin which is 3 times inaccurate:**
 - rarely would an individual use the same daily dose of insulin
 - The TDD includes the basal insulin while the carb insulin ratio is concerned with bolused insulin only.
 - In any diabetic with HbA1c of more than 8% the TDD cannot be accepted as a true body need
- **All formulae have no physiological background.**
 - **For the insulin sensitivity figures between 1076 and 1960 (60 -109) have been suggested**
 - **For CIR the proposed figures are not practical**

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Case scenarios

Case 1

- Sebastian newly diagnosed type 1 diabetic, presented at the age of 22 months with osmotic symptoms and BS of 24.6 mmol/L and blood ketones of 2 mmol/L
- Weight 13kgs, Clinically very well. Normal BP, normal perfusion, Normal electrolyte, and Normal blood gases.

How would you manage him?

Case 2

- Suleman aged 11, diagnosed in Pakistan with type 1 diabetes at the age of 2 and coeliac in the UK 4 months ago.
- On the basal bolus regimen of Lantus 26 units and Novorapid 7, 7, 7. No carb. counting, non compliant.
- Presented January 2014 with severe DKA. Previous similar episode in Sept. 2013 .
- Ph: 7.0, BE -29, Bic: 4.5, BS 44mmol/L BK: 5.9 mmol/L. U&Es, Cr Normal, Agitated, but alert, not vomiting. BP and perfusion are normal. not significantly dehydrated. Weight 29 kgs

How would you manage him?

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OUR APPROACH

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Important factors

- **Insulin Sensitivity Factor:**

Is the effect of 1 unit of insulin on the blood sugar of the diabetic over the duration of its effect.

Helpful for the correction of high blood sugar

- **Carbohydrate Insulin Ratio:**

Is the amount of carbohydrate that is metabolised by 1 unit of insulin injected S/C over the duration of its effect.

Helpful in giving freedom and flexibility to patients

- **Glucose Sensitivity Factor: (0.12 formula)**

Is the amount of carbohydrate in grams needed to raise the blood sugar in diabetics by 1 mmol/L without the effect of insulin.

Helpful to calculate the carbohydrate dose of hypoglycaemia

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Important features

$$\text{GSF} \times \text{ISF} = \text{CIR}$$

$$\text{ISF} = \text{CIR} / \text{GS}$$

$$\text{GS} = \text{CIR} / \text{ISF}$$

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The 0.12 Formula

Glucose sensitivity (the origin of the 0.12 formula)

- Glucose is in all body fluid which form 65% of body weight
- $1\text{mmol/L} = 18\text{mgs/dl}$
- $1\text{mmol/L} = 180\text{mgs/L} = 0.18\text{gram/L}$ so

To raise the blood sugar by 1 mmol/L (in type 1 diabetic)
we need to give 0.18 gram of sugar for every litre of body fluid

- $0.18 \times \text{Body weight} \times 0.65 = \underline{0.12 \times \text{body weight (Kg)}}$

0.12 is the amount of carb. in grams needed for each 1 kg body weight to raise the blood sugar by 1 mmol/L

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The 0.12 Formula

Example: 20 kg. child with CIR ratio of 1:10

- His glucose sensitivity according to the formula is:
 $0.12 \times 20 = 2.4$ grams (Say **2.5**)
If we know 2.5 gram carb raise his blood sugar by 1 mmol/L then 10 gram (his carb ratio) will raise it by $(10 / 2.5) = 4$ mmol/L.
- what is the Insulin sensitivity?
If 1 unit of insulin is needed for 10 grams of carb and we know that 10 grams of carb will increase BS by 4 mmol/L then 1 unit given without 10 gram of carb should drop blood sugar by 4 mmol/L
- Insulin sensitivity: $10/2.5 = 4$ mmol/L

$$\text{GSF (4)} \times \text{ISF (2.5)} = \text{carb ratio (10)}$$

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Case scenario 1

Our management of Sebastian

- Given 2 units of S/C insulin ($0.05 \times 13 \times 4$) BS:
 - Baseline: 24.6 mmol/L
 - 1 hour: 18.3 mmol/L
 - 2 hours: 11.8 mmol/L
 - 3 hours: 7.6 mmol/L
 - 4 hours: 3.2 mmol/L
- His insulin sensitivity is calculated therefore to be 10 -12 mmol/L (21/2)
- His glucose sensitivity $13 \times 0.12 = 1.5$
- His carb ratio is 1: 18

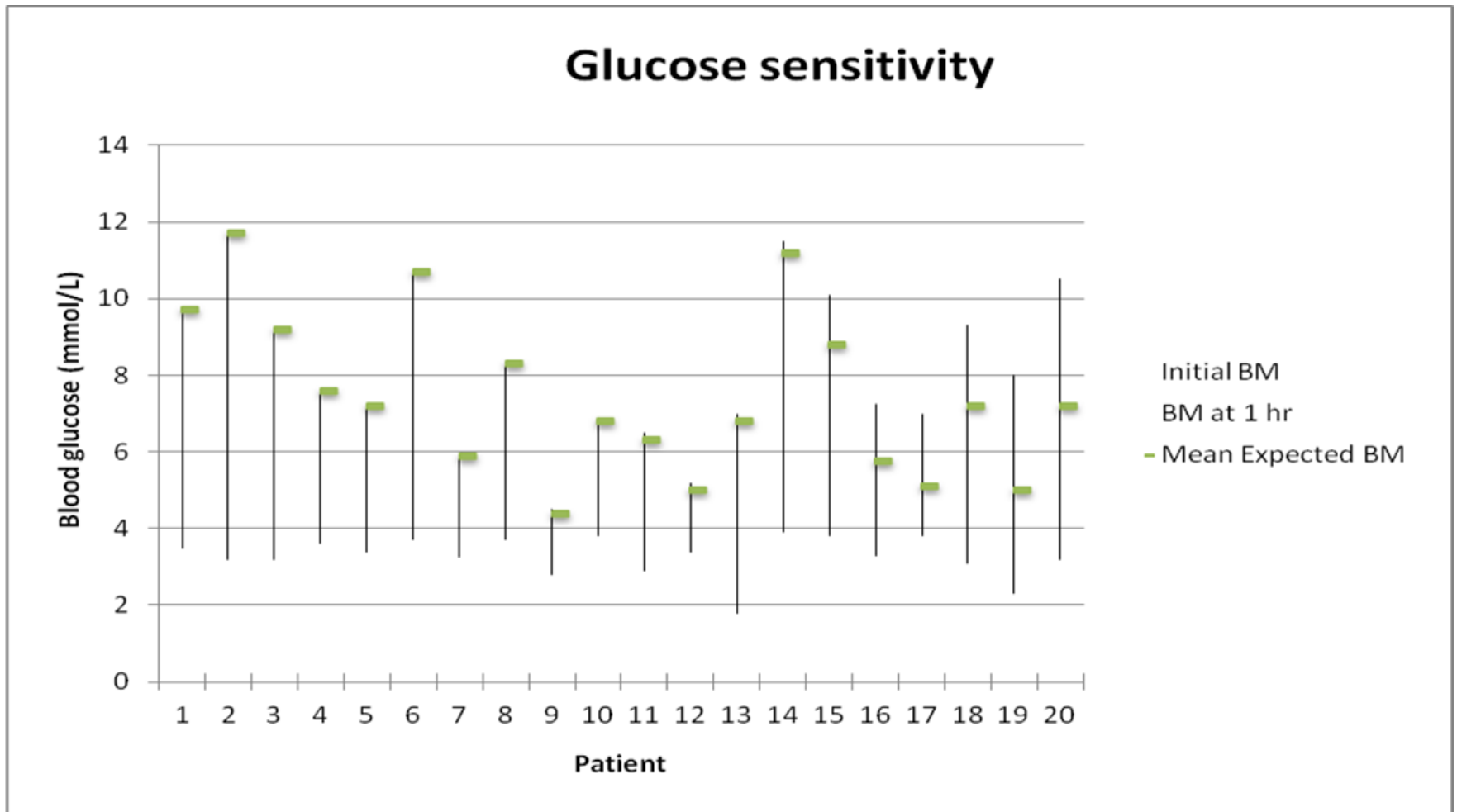
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Case scenario 2

Our management of Suleman

- Given IV Normal saline maintenance fluid and given 6 units of S/C Insulin ($0.05 \times 29 \times 4$). Blood sugar dropped
 - Baseline: 44 mmol/L
 - 1h: 38mmol/L
 - 2h: 34mmol/L
 - 3h: 31mmol/L
 - 4h: 26mmol/L
- **Insulin Sensitivity: $18/6 = 3$**
- **Glucose sensitivity $0.12 \times 29 = 3.5$**
- **Carbohydrate Insulin ratio $3 \times 3.5 = 10.5$**

Testing the 0.12 formula



Testing the 0.12 formula

