

Comparisons of Hybrid Closed Loop Systems in the under 5 age group

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Agenda

- A retrospective analysis of 14 children and young people under the age of 5 years old – Omnipod 5 HCL v's CAMAPS HCL system
- Case study representation of an under 1 year old – using the Tandem T Slim Pump – in control IQ
- Sharing our learning points
- Looking forward
- Areas for enhancing practice

The hard truth

Rawshani A, Sattar N, Franzen S, et al. Excess mortality and cardiovascular disease in young adults with type 1 diabetes in relation to age at onset: a nationwide, register-based cohort study. Lancet 2018;392:477–486

“Children who develop diabetes in their first years of life risk exposure to many decades of hyperglycaemia, hence having a high risk of early complications and premature death.”

Comparison of glycaemic outcomes in children under 5 years using CAMAPS FX app or Omnipod 5 Hybrid Closed Loop (HCL systems)

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Introduction:

Limited data comparing under 5's using HCL Systems

Aim and Objective:

Retrospective observational study comparing 6-month outcomes in CYP <5 years for CamAPS FX (CamAPS) vs Omnipod 5 System (OP5)

Methodology: retrospective cohort study of 14 CYP (CamAPS n=7; OP5 n=7).

Primary outcomes (90-day CGM data):

- Time in range (TIR, 3.9-10mmol/L)
- Time in tight range (TITR, 3.9-7.8mmol/L)
- Time above range (TAR, >10mmol/L)
- Time above range (TAR2, >13.9mmol/L)
- Time below Range (TBR <3.9mmol/L)

Secondary Outcomes: Sensor/Automode usage and meal/carb entries

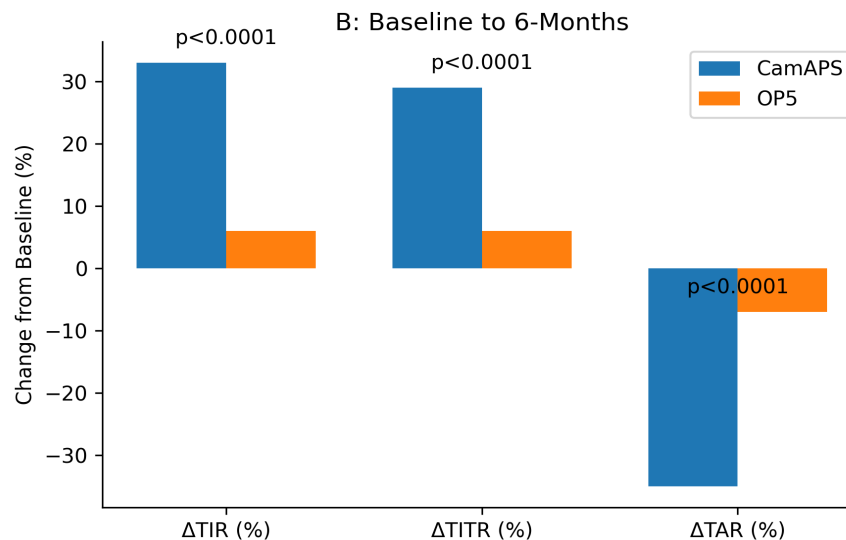
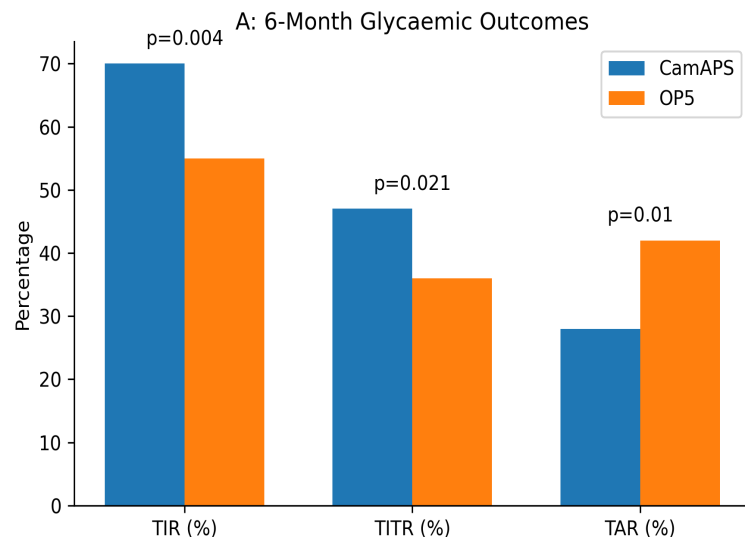
Baseline

Baseline	OP5	CamAPS	P Value
Average age (yrs)	4.5	2.3	p=0.001
Total Daily Dose	15.4	7.5	p=0.008
Units per kg	0.6	0.7	p=0.455
Ethnicity	1.7	1.7	p=0.999
SES*	1.6	1.4	p=0.429
Gender (male)	4	3	p=0.658

*SES= Socioeconomic status

Baseline	OP5	CamAPS	P Value
TIR (%)	48	36	p=0.060
TITR (%)	30	18	p=0.020
TAR (%)	49	62	p=0.140
TAR2 (%)	24	33	p=0.274
TBR (%)	2.7	1.1	p=0.060

Results



Secondary Outcomes

No differences at 6 months:

- Percentage sensor use
- Automode use
- Carbohydrates per kg
- Meal entries per day

6 months	OP5	CamAPS	Δ	P Value
TIR (%)	55	70	15	p=0.004
TITR (%)	36	47	11	p=0.021
TAR (%)	42	28	-14	p=0.010
TAR2 (%)	16	7	-9	p=0.001
TBR (%)	3.1	3.4	0.3	p=0.998

B to 6 m	OP5	CamAPS	Δ	p Value
TIR (%)	7	33	26	p<0.0001
TITR (%)	6	29	23	p<0.0001
TAR (%)	-7	-34	-27	p<0.0001
TAR2 (%)	-8	-26	-18	p=0.003
TBR (%)	0.4	2.2	1.8	p=0.170



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Conclusions & future direction

Conclusions:

- In CYP <5 years, CamAPS is associated with better glycaemic outcomes over 6 months when compared to OP5.
- Data hints at clinically meaningful differences between HCL algorithms in CYP <5 years.
- All used Dexcom G6 (no issues with CGM results comparability)

Limitations:

- N=14
- Retrospective analysis
- Baseline differences, however, these favoured the OP5 group (higher TDD and age)
- No HCL specific settings assessed
- Number of contacts not assessed
- No HbA1c

Future Direction:

- 12 months data with larger cohort
- Assess HCL settings (target levels, carbohydrate ratios, active insulin time).
- Assess educational input
- Assess QOL of caregivers
- Education: review methods/time and follow up that was used across both groups



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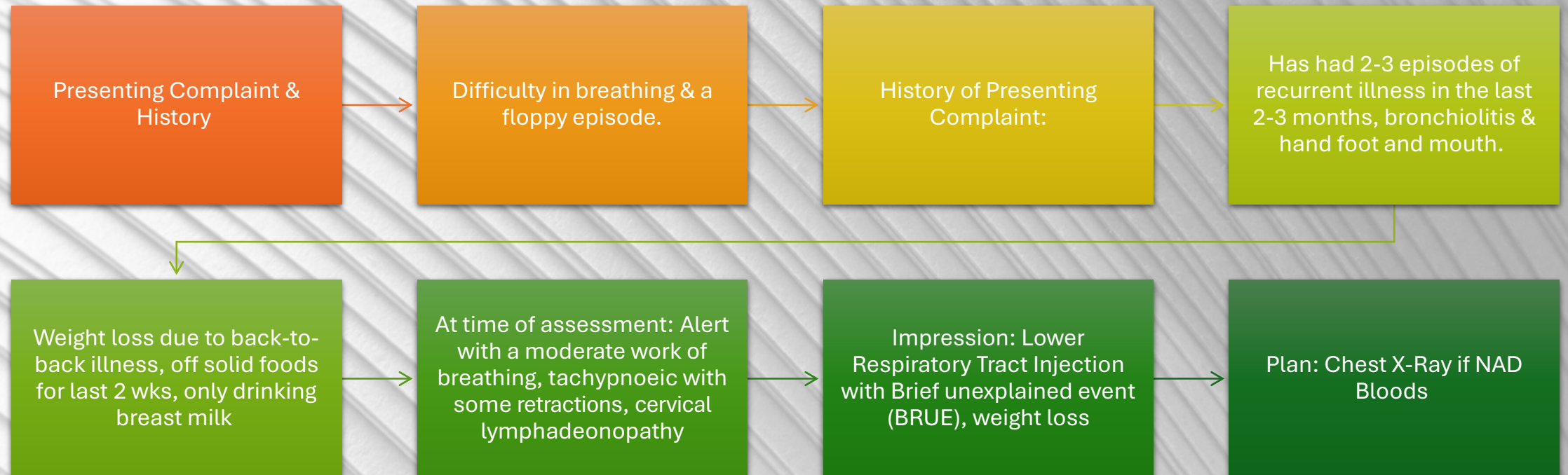
So which pump did we use with the next under 5-year-old?

Omnipod
5

CamAPS
FX

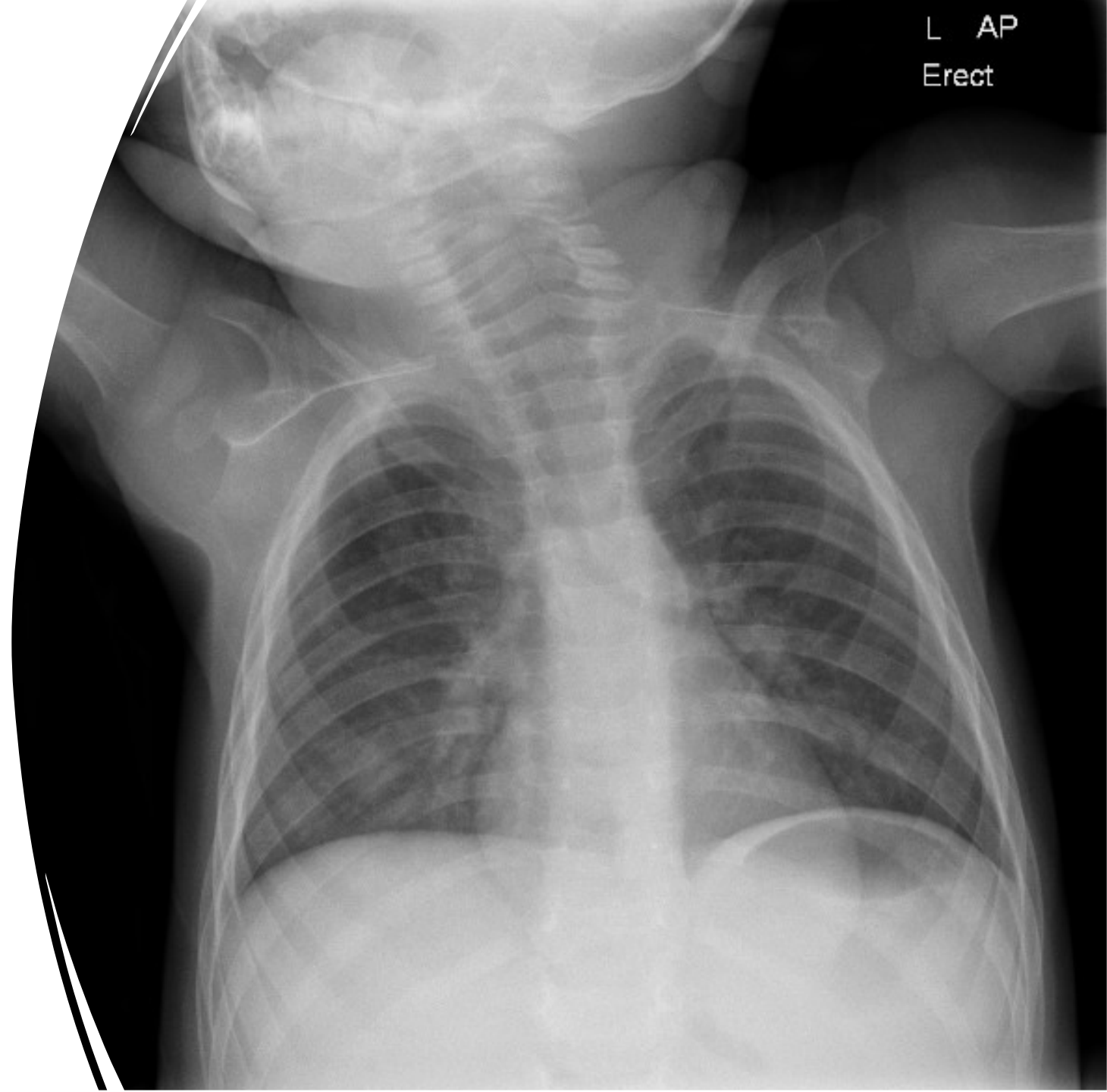
Tandem
T-Slim

Presentation to ED



Chest X-Ray

- Rotated film with suboptimal inspiration
- Poss focus of consolidation towards R lower zone
- Otherwise perihilar bronchial wall thickening
- No significant effusion or pneumothorax.



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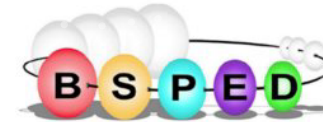
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Presentation, Red Flags & Initial Investigations

- **Initial observations & investigations:**
- Blood Gas (at time of taking Bloods and inserting cannula)
- **pH 7.163**
- **Base Excess -22.6**
- **HC03 10.1**
- **Glucose 31mmol/L**
- Lactate 1.6
- **Ketones 6.3mmol/L**
- **Weight Loss** (previously 9.0 kg at prev admission to ED, now 8.7kg – Growth chart on next slide)

Managed as per BSPED DKA protocol

- Switched surgical sliding scale allowed to eat and drink
- Enables assessment of insulin requirement



British Society for
Paediatric Endocrinology
and Diabetes

Integrated care pathway for the management of children and young people with

Diabetic Ketoacidosis

Children and young people with a pH 7.2- 7.29 &/or bicarb < 15 have MILD DKA

Children and young people with a pH less than 7.1-7.19 &/or bicarb < 10 have MODERATE DKA

Children and young people with a pH less than 7.1 &/or bicarb < 5 have SEVERE DKA

Insulin Requirements on Sliding Scale

Pre pump 11.92 units/day (1.37 units/kg/day)

Intercurrent illness – not resolved – discussion with General Paediatrics initiated

During time on insulin sliding scale – initial pump options and continuous glucose monitoring were explored.

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Discussion: Pump Options for <1 year old

- Child is small (often little subcutaneous fat due to some weight loss)
- Size of subcutaneous Cannula
- Size of CGMS Sensor
- Placement of Cannulas – risk of contamination ? Dressings/ Skin integrity
- Size of Pump
- Requirement of a phone? Connectivity
- Download/Cloud based data sharing
- Confidence & Competence in the Specialist Team
- Lack of expert knowledge within the ward environment
- Risk/Benefits
- Dynamic scenarios
- Bespoke management
- Language barriers?
- Pump Failure whilst on ward – Risk Assessment

HCL system	Smartguard	Tandem Control IQ	CamAPS FX	Omnipod 5
Pump	Medtronic 780G	Tandem T:Slim	Dana RS/Dana I Ypsomed compatible pump	Omnipod 5 (with OP5 handset)
CGM	Medtronic Guardian3 and 4	Dexcom G6 or G7 (v 7.7)	Dexcom G6/Libre 3	Dexcom G6 (with own phone and Clarity App)
Licens	80 years TDD 5-350 units/day Weight 10-300kg Rapid acting insulins	> 6 years TDD 10—100 units/day Weight 25-140kg Rapid acting insulins	>1 year Pregnancy TDD 5-350 units/day Weight 10-300kg Rapid & ultra rapid insulins	> 2 years TDD 5u – 200u/d (to get 3 day pod wear) Rapid acting insulins
Parameter for AID	Parameters from last 2-6 days Adaptive algorithm Ongoing learning	Personal profile (basal rates/ICR/ISF) Uses weight and TDD input by user to determine algorithm parameters	Uses weight and TDD input by user to determine algorithm parameters Ongoing learning	Target glucose is only factor affecting insulin delivery. Aggressiveness of algorithm is learnt from TDD history of previous 4-5 pods
Basal insulin	Basal insulin adjusted every 5 mins	Basal insulin adjusted if SG predicted to exit target range	Extended boluses given every 10-12 mins	Adaptive basal rate given as microboluses every 5 mins
Autocorrec tions	If SG>6.7mmol/l and max auto-basal	If SG predicted > 10mmol/l, 60% correction bolus, 1 per hour	Automatic correction boluses delivered as modulation of basal rate	Automatic correction boluses delivered as modulation of basal rate

HCL system	Smartguard	Tandem Control IQ	CamAPS FX	Omnipod 5
Bolus	Manual bolus No Extended boluses Uses programmed ICR	Manual bolus Extended bolus possible for 2hrs Uses programmed ICR & ISF	Remote bolus (phone app) No Extended boluses Uses programmed ICR	Remote bolus (handset) SmartBolus feature accounts for glucose AND TREND <i>Ensure reverse correction is on</i> No extended boluses Uses programmed ICR and ISF
Target	Default 5.5 mmol/l 6.1 or 6.7 mmol/l	6.25-8.9 mmol/l	Personalised target 4.4 -11.0 mmol/l Default 5.8 mmol/l Customise across 24 hrs	Personalised target 6.1-8.3mmol/l in up to 8 time segments
Adjustable parameters that affect algorthim	ICR, AIT Target glucose	Basal profiles, ICR, ISF, weight ?? Target glucose	ICR, weight, add meals Target glucose	Target glucose, AIT ICR & ISF (for meals)
Overrides	Temp target 8.3 mmol/l & no autocorrections but does alter aggressiveness of the algorthim	Exercise 7.8-8.9 mmol/l (v 7.7) 30min-8hrs Sleep target – 6.36-6.7 mmol/l	Ease off – reduces delivery by ~ 30% Boost – increases delivery by 30-50%	Activity – raised target to 8.3, reduces insulin deliver by ~50% and limits microbolus corrections
Reverts to manual mode	Loss of CGM data Sensor integrity concerns Max basal limit reached	Loss of CGM data Max insulin delivery reached	Loss of CGM data Loss of connection with pump	Loss of CGM data/warm up – Max deliver reached In LIMITED mode will deliver programmed basal OR learnt basal – whichever is lowest.
Data platform	Carelink	Glooko & Tandem Source	Glooko + Phone req	Glooko + Phone req

Tandem T Slim- Control IQ now

- Control IQ + -
- Body weight 9-200kg
- Total Daily Dose 5-200 unit
- Age indication >2 years
- CE mark for people with Type 2 diabetes
- Temp basal rate can be used (but Control IQ can continue to modulate)
- Libre 3+
- Possibility of lower ISF

How does Control-IQ technology work?

Control-IQ technology is designed to help increase time in range (3.9-10.0 mmol/L)* using Dexcom G6 continuous glucose monitoring (CGM) values to predict glucose levels 30 minutes ahead and adjust insulin delivery accordingly, including delivery of automatic correction boluses (up to one per hour).†

		 Control-IQ technology	 Sleep Activity	 Exercise Activity
  Delivers	Delivers an automatic correction bolus if sensor glucose is predicted to be above ____ mmol/L	10.0	--	10.0
 B Increases	Increases basal insulin delivery if sensor glucose is predicted to be above ____ mmol/L	8.9	6.7	8.9
 B Maintains	Maintains active Personal Profile settings when sensor glucose is between ____ - ____ mmol/L	6.25-8.9	6.25-6.7	7.8-8.9
 B Decreases	Decreases basal insulin delivery if sensor glucose is predicted to be below ____ mmol/L	6.25	6.25	7.8
 0 Stops	Stops basal insulin delivery if sensor glucose is predicted to be below ____ mmol/L	3.9	3.9	4.4

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- Tandem Source = Secure cloud-based platform for the T-Slim X2 insulin pump
- Connects the pump, Smartphone App + Healthcare = Seamless data flow
- Enables remote bolusing
- Enables software updates – via the Tandem Source App to the cloud
- Integrated management
- Smart phone NOT essential

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Education & Teaching – its intense....

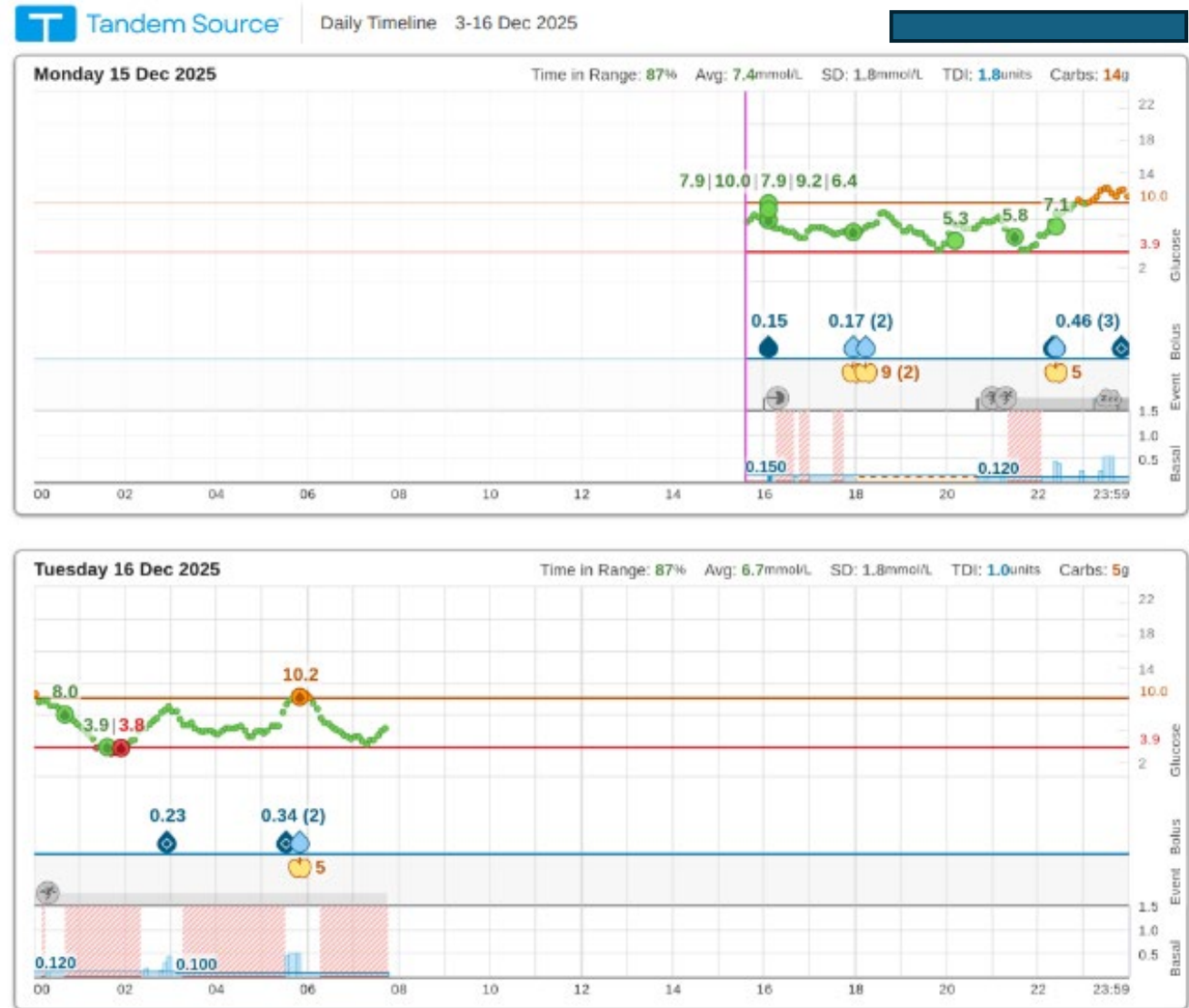
- Contacts – on ward/education
- Initiation of pump
- Cannula changes (every 48 hours – to enable quicker acquisition of skills, whilst minimising length of stay)
- How to give a bolus, check a bolus has been given, hypos, survive & thrive
- Carb counting accuracy
- Basics – injections
- Since discharge – many contacts

First Download from day 1 of being on Control IQ

- Findings: - hypos +++

Dr Krone "a sleepless night"

- What do you think might have been a solution?



Tuesday - 16 Dec 2025

Time in Range: 88%

Avg: 7.4mmol/L SD: 2.0mmol/L

TDI: 4.5units

Carbs: 50g



Wednesday - 17 Dec 2025

Time in Range: 85%

Avg: 8.2mmol/L SD: 1.8mmol/L

TDI: 4.8units

Carbs: 53g



On going management and challenges

- Huge number of contacts/telephone calls out of hours/review
- Intercepting hypos
- Options that we have found work well – Glucojuice & Neat Ribena – interception of hypos



- **Low Glucose levels:**

- hypo guidance chart
- Wait 20 minutes before retreating
- No 10g snack after treated

- **High Glucose Levels:**

Glucose mmol/L	Arrow	Treatment	Choose only one	
		Glucose (grams)	Glucojuice	Ribena Undiluted
4.0 - 6.0	↓↓↓	3	11	11
	↓↓	2	8	9
	↓	1	5	6
Less than 4.0	↓↓↓	3	14	14
	↓↓	3	11	11
	↓	2	8	9
	→	1	5	6
	↗	1	3	3
	↘	1	3	3

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On going learning – Via UCLH

Tips

- 30% basal for all CYP under 7 years
- Under 2's – use 150 rule breakfast
- 200 rule lunch
- 200 rule dinner
- Insulin Sensitivity Factor 95 and looking to move to 83
- Very often programme basal overnight to 0 – the algorithm will kick in if it needs to!

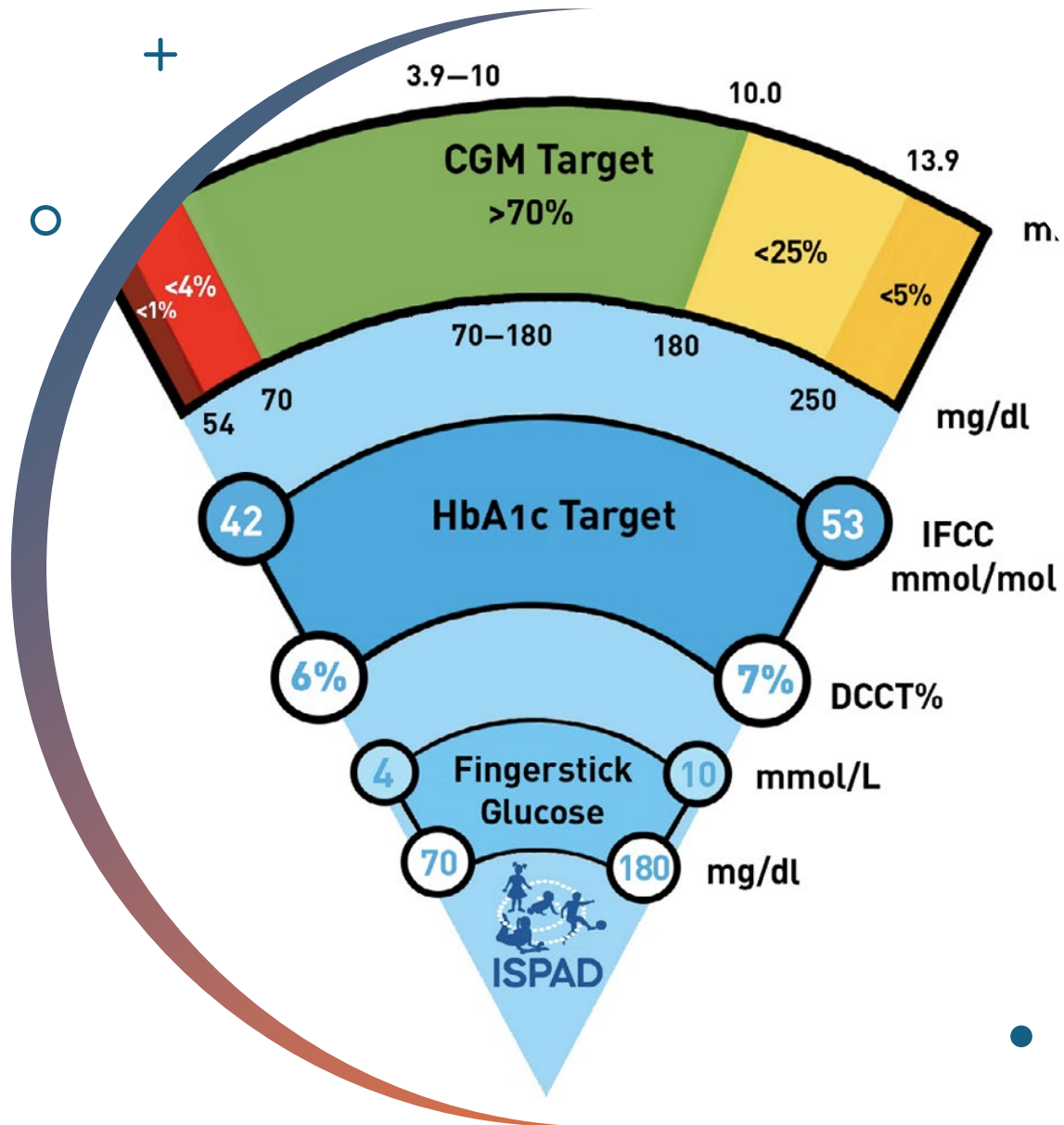
Why do we need to continue to invest time?

- “Children who develop diabetes in their first years of life risk exposure to many decades of hyperglycaemia, hence having a high risk of early complications and premature death.”

Rawshani A, Sattar N, Franzen S, et al. Excess mortality and cardiovascular disease in young adults with type 1 diabetes in relation to age at onset: a nationwide, register-based cohort study. *Lancet* 2018;392:477–486

Another reason to invest time and effort...

Age-dependent risk of dysglycaemia, especially hyperglycaemia, negatively affects the developing brain.”



What are the targets? Future goals? Hypo targets?

- Time in Tight Range
- 3.9 to 7.8 mmol/L
- Target of >50%

Start AID As Early As Possible

Effect of 48 months of closed-loop insulin delivery on residual C-peptide secretion and glycemic control in newly diagnosed youth with type 1 diabetes

Study design & participants

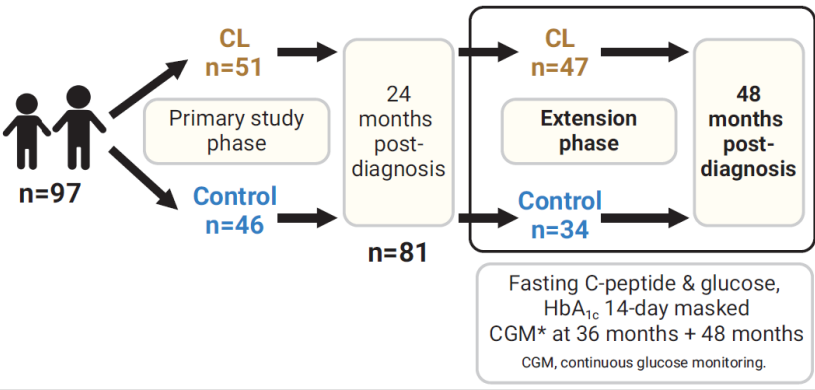
Aim: evaluate effect of **long-term intensive metabolic control** with hybrid closed-loop on residual C-peptide secretion and glucose control in **newly diagnosed children & young people** with type 1 diabetes



- Age 10 to 16.9 years
- After 24-month primary study phase
- Optional extension phase until 48 months post-diagnosis

Hybrid closed-loop (CL) compared to standard insulin therapy (Control) until 48 months post-diagnosis

Intervention



Results

No difference in fasting C-peptide corrected for fasting glucose at 48 months between groups.

Glycemic outcomes favor CL :

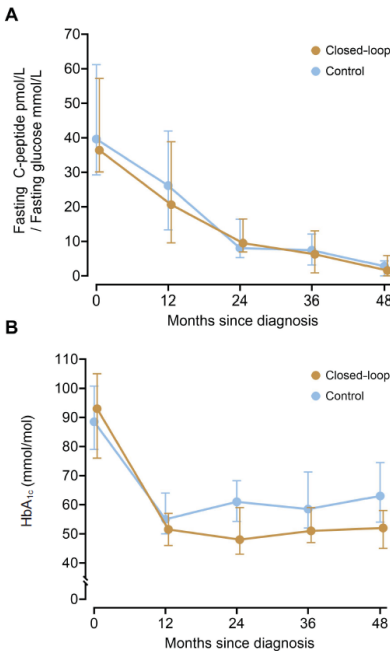
- **Time in target glucose range***
↑ **12 percentage points**
- **HbA_{1c}**
↓ **10mmol/mol (0.9%)**
- **Time below range***
↔ **0.5 percentage points**

Conclusion:

Improved glycemic control was sustained over 48 months after diagnosis with closed-loop insulin delivery compared to standard therapy in youth with type 1 diabetes. This did not appear to confer a protective effect on residual C-peptide secretion.

*Sensor-based glucose metrics were calculated from 14 days of masked data from Abbott FreeStyle LibrePro Flash Glucose Monitoring System.

Longitudinal C-peptide and HbA_{1c}



Panel A: Longitudinal fasting C-peptide adjusted for fasting plasma glucose. Panel B: Longitudinal glycated hemoglobin (HbA_{1c}). The 1 bars represent interquartile ranges.

TIR at 2 years
61% vs 50%

HbA_{1c} at 2 years
54 vs 59

AID is better than CGM but its not enough on it own

Our next youngest patients

- 15 months (male) weight 10.4kg (presentation in DKA)
- 10-month-old (female) 7.4kg (well at diagnosis)
- Smoother transition to Pump therapy (following period on sliding scale insulin + some basal insulin)
- Management plans for ward staff -Unified approach
- Team approach – settings/prescribing/strategies/risk assessments
- Just look at the download.....

Download 10 month (week 2)



Routine from Sara (BCH Family SW) Triple P

1. **Exposure Matters** – Keep trying, even if it's tough.
2. **Make it Fun** – Challenge or game.
3. **Small Bites, Big Gains** – Small changes gradually
4. **Set a Routine** – Same time, same place every day for consistency.
5. **Lead by Example** – Monkey see, monkey do
6. **Don't Force, Encourage** – Choice not a chore
7. **Use Rewards** – Celebrate small milestones – stickers, wall chart.
8. **Settled Family Environment for Eating** – Eat as a family
9. **Reduce Decision Fatigue** – Have a clear, structured plan each day.
10. **Play the Long Game** – Small, consistent improvements lead to big results.

Summary & Moving forward

- Remember hypos will occur – quite often at early initiation
- Don't forget that parents/carers need to know the basics – injection therapy, finger prick testing/when to calibrate
- Talk to the team – gather ideas/whats best/risk assessment/resources needed for success
- Tap into the expertise around you and seek to learn (its pretty niche)
- Keep positive it's a dynamic process
- Always talk through the data if not sure (with family & other HCP)
- Celebrate the success and praise the hard graft (families and teams alike)

Some of the under 5's squad

Huge thanks



References

Works Cited

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Advanced Practitioner 360
Feedback - LOUISE COLLINS



Questions?

Anonymous Feedback