Anaesthesia Reports 2025, 13, e70003 doi:10.1002/anr3.70003

Case Report

Hybrid closed loop technology in emergency surgery in a person with type 1 diabetes

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Summary

Management of type 1 diabetes is constantly evolving. Hybrid closed loop technology is replacing multiple dose insulin and continuous subcutaneous insulin infusions as the preferred manner for managing type 1 diabetes in the community. Currently, there are no case reports or clinical guidelines to instruct practitioners on the safe peri-operative use of hybrid closed loop technology for patients requiring emergency surgery. In our case report we present the case of a 15-year-old male patient who required emergency surgery and wanted to continue the benefits of his hybrid closed loop technology in managing his diabetes peri-operatively. In addition, we discuss the strategies we used to overcome the issue of the continuous glucose monitor misreading paracetamol as glucose. Finally, we present the rationale for the guidance of safe peri-operative use of hybrid closed loop technology. This may allow other patients to benefit from continuation of hybrid closed loop technology during emergency surgery.

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Accepted: 4 February 2025
Keywords: hybrid closed loop; insulin, type 1 diabetes mellitus; paracetamol; perioperative; surgery
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Introduction

Type 1 diabetes affects approximately 0.5% of the population within Europe and North America. Type 1 diabetes is characterised by an absolute lack of insulin and people with type 1 diabetes are dependent on exogenous insulin. The management of type 1 diabetes in the community has evolved over the last decade [1]. It used to be almost exclusively managed with multiple dose insulin (MDI) regimens, but with the miniaturisation of pump technology, the continuous subcutaneous insulin infusion (CSII) has become a popular alternative. More recently, with improvements in continuous glucose monitors (CGM) and wireless technology, hybrid closed loop (HCL) systems have been developed and are now the preferred method for managing type 1 diabetes [2]. This is because these systems maintain at least 60% of the daily time in range [1]. Hybrid closed loop systems, otherwise known as automated insulin delivery, deliver subcutaneous short-acting insulin via the insulin pump, but the rate is dictated by a CGM, which is connected by Bluetooth technology [3–5].

Continuous glucose monitor technology is also evolving. The devices measure the interstitial glucose concentration, rather than the capillary glucose concentration. Using enzymes located at the tip of the needle and specific electrochemical methodology, the sensor detects and measures the interstitial glucose concentration. There are several different types of CGM, for example, the Freestyle Libre® (Abbot, Maidenhead, UK), Guardian® (Medtronic, Watford, UK) or the G6® (Dexcom, Camberley, UK). In all the monitors above, the enzymatic reaction, the voltage applied and the presence or absence of a

permselective membrane, means that certain non-glucose molecules as well as glucose molecules can influence the measurements recorded by the CGM sensors. Known interfering substances include endogenous substances, such as oxygen, bilirubin, alcohol and ascorbic acid; and exogenous medicines including ACE inhibitors, paracetamol, salicylic acid, hydroxyurea, heparin and atenolol [6, 7]. The amount required to cause significant interference is debated. For example, taking a large dose of vitamin C (1 g every 3–4 h) led to the CGM device over-reading the glucose by approximately 0.5 $mmol.l^{-1}$ [6]. However, given the rapid urinary clearance of vitamin C, it remains unknown how long this transient rise remains in the interstitial fluid into which the CGM device is inserted. Some of the newer CGM devices have a permselective membrane which selectively prevents the transfer of various non-glucose molecules reaching the tip of the needle. This reduces the risk of aberrant substances interfering with the CGM results. Both CGM devices and blood glucose monitors are prone to erroneous readings, with issues in relation to both reproducibility and accuracy, and this may prevent concordant data. It is anticipated that the recent recommendations on updating the error grid for continuous glucose monitors will mitigate this and allow better estimation for accuracy and reproducibility of future devices [8].

During surgery, it is imperative that exogenous insulin is continued in people with type 1 diabetes, therefore anaesthetists and peri-operative diabetes teams need to ensure that patients receive sufficient insulin to prevent hyperglycaemia and diabetic ketoacidosis, whilst avoiding hypoglycaemia [9].

Peri-operative guidelines are now available for the safe management of the CSII [3–5, 9]. General guidance includes: short starvation period; review by diabetes healthcare professional before admission; siting the pump away from the diathermy due to the potential of electromagnetic interference; use of bipolar diathermy where possible; use of a Teflon® needle, rather than a steel needle for the subcutaneous injection; advising the patent to aim for a capillary blood glucose zone of 6–10 $mmol.l^{-1}$ and ensuring the anaesthetist has a contingency plan in the event of pump malfunction [3–5, 9].

As HCL technology is relatively new, formal guidelines for its peri-operative continuation are yet to be created. However, using principles primarily gained from the peri-operative use of the CSII, limited guidance is available for patients requiring elective surgery [3–5, 9]. Options include disconnecting the insulin pump from the patient and commencing a variable rate intravenous insulin infusion (VRIII), changing the insulin pump so that it administers a fixed rate of subcutaneous insulin akin to the peri-operative use of CSII or continuation of HCL technology with additional precautions. Additional precautions are required as the use of HCL technology in the peri-operative period is complicated by five additional factors which affect either the CGM device or the connectivity:

1. The lag period between interstitial glucose and blood glucose affecting the reliability of the reading from the CGM;
2. Poor perfusion of the interstitial space affecting the reliability of the reading from the CGM;
3. Inadequate specificity of the CGM devices to detect and measure purely glucose molecules;
4. Electromagnetic interference with the Bluetooth technology;
5. Compression of the CGM leading to erroneous results [3–5, 9–11].

The peri-operative use of HCL technology has so far only been described in elective surgery, rather than in the emergency setting [3–5]. We describe the peri-operative management of a 15-year-old male patient, with a BMI of 35 $kg.m^{-2}$, whose type 1 diabetes was managed with HCL technology. He required emergency surgical fixation of a tibial tuberosity fracture. Both he and his mother wanted optimal control of his diabetes, a minimal length of hospital stay and optimal pain management.

Report

The patient had a 3-year history of type 1 diabetes mellitus. Following diagnosis, he was initially managed with a multiple dose insulin regimen, but his management was sub-optimal despite extra support from his parent and the specialist diabetes team. This had repercussions on his education, day-to-day living and his blood glucose control. Consequently, he was transferred to a Medtronic 780 g HCL system using Fiasp® insulin and Guardian 4® sensors (Medtronic, Watford, UK), achieving a recent HbA1c of 54 $mmol.mol^{-1}$. He had recently started lisinopril for proteinuria but had normal creatinine clearance and was able to take non-steroidal anti-inflammatory drugs.

He was admitted via the emergency department to the paediatric ward with a right tibial tuberosity avulsion fracture sustained while playing dodgeball. The patient was seen by the paediatric diabetes specialist nurse and was prepared for surgery the following morning. A new Teflon® cannula was inserted and transparent tape was placed over the Guardian 4® sensor and transmitter to reduce the risk of disconnection.

Shared decision-making with the patient, his mother, the paediatric diabetes specialist nurse and the anaesthetic team determined the peri-operative management of his diabetes. As it was anticipated that he would only miss one meal (breakfast), the options included continuation of the HCL with setting a temporary elevated target, using the CSII mode of the pump or setting up a variable rate intravenous insulin infusion. The risks and benefits of each strategy were discussed. It was agreed that the HCL would be continued with CGM and frequent capillary blood glucose (CBG) monitoring. He fasted overnight and was prioritised first on the operating list.

On the morning of surgery, the HCL technology was altered to achieve a temporary target glucose of 8.3 $mmol.l^{-1}$. At the pre-operative briefing, the team was informed of the HCL and the necessity to reduce electromagnetic interference. It was also discussed that due to his elevated BMI, tracheal intubation and controlled ventilation would be best. He was anaesthetised in theatre to minimise transfers and the risk of disconnections. The pump was positioned on the pillow to ensure access and the CGM was on the patient's upper arm and protected from pressure. Both were well away from the surgical site. Before induction his capillary blood glucose was checked and it correlated well with the CGM. Induction was performed using propofol 200 mg and fentanyl 150 μg. Rocuronium 25 mg was administered before tracheal intubation. He was then ventilated with oxygen, air and sevoflurane. Multimodal analgesia was provided with intravenous paracetamol 1 g, diclofenac 50 mg, an additional 100 μg of fentanyl and dexamethasone 3.3 mg. Local anaesthetic infiltration was performed by the surgeon. We administered antibiotic prophylaxis with teicoplanin 800 mg and gentamicin 160 mg. The surgery involved evacuating the fracture haematoma from the knee, K-wiring the intra-articular fragment, before fixing the fracture with three partially-threaded cannulated screws. Surgical time was 115 min. Point-of-care capillary blood glucose monitoring was performed at a 30-min intervals to ensure optimal glycaemic control was maintained throughout the surgery. Before administration of the intravenous paracetamol, there was reasonable concordance between the capillary blood glucose and the reading from the CGM (7.7 and 9.7 $mmol.l^{-1}$, respectively). Fifteen minutes after administering paracetamol, the discrepancy increased to 4.5 $mmol.l^{-1}$, with the point-of-care capillary blood glucose concentration being 8.5 $mmol.l^{-1}$, whilst the CGM read 13.0 $mmol.l^{-1}$. The greatest discrepancy occurred 35 min after administration of the paracetamol when the capillary blood glucose was 8.2 $mmol.l^{-1}$, while the CGM reading was 14.4 $mmol.l^{-1}$. The readings from the two monitors then converged again, with the capillary point-of-care blood glucose reading remaining constant. The paediatric diabetes specialist nurse remained available for telephone support but was not required. Maintenance of anaesthesia and tracheal extubation were uneventful. Postoperatively, the patient was pain free and hungry. After eating lunch, the temporary target function was stopped. Despite the patient's desire to be discharged on the same afternoon, this happened on the following day due to the need for in-patient physiotherapy and tuition in the use of crutches.

Discussion

This case demonstrates two important points. First, it is possible to enable patients to choose to continue to have their diabetes managed using HCL technology during emergency surgery. Second, by altering the temporary target glucose and by measuring the CBG every 30 min, paracetamol can be safely administered without the fear of the HCL device administering dangerous amounts of insulin.

The patient was able to experience the benefits of continued use of HCL technology throughout his emergency surgery due to the effective team working between the anaesthetic team, the diabetes team and the theatre team. The paediatric diabetes specialist nurse had the foresight to ensure he had the correct consumables. This allowed us to avoid a VRIII with its inherent risks, which include a prolonged length of stay, insufficient point-of-care capillary blood glucose monitoring leading to inadequate titration and subsequent dysglycaemia and diabetic ketoacidosis caused by errors in transitioning from the HCL. Whilst emergency surgery for people with type 1 diabetes previously routinely necessitated VRIII, it is now increasingly acknowledged that provided certain individual, surgical, organisational and physiological criteria are met, modification of an MDI regimen or CSII is superior and is preferred [4, 5]. The care outlined in our case report demonstrates that provided these criteria are met, continuation of HCL technology for emergency surgery is possible and can also help to achieve patient-centred goals, including minimal hospital stay and good glycaemic control.

Currently, the literature suggests hourly point-of-care monitoring with capillary blood glucose when using HCL technology in the intra-operative period [3–5]. Because of the potential for paracetamol molecules to interact with the Medtronic sensor (as there is no permselective membrane) and be interpreted as glucose molecules, we performed CBG testing every 30 min. The wide discrepancy noted between the capillary blood glucose and the CGM justified this decision. Whilst no intervention was required, it enabled the anaesthetic team to remain assured that the patient was safe at all times. The safety of the patient was

Table 1 Elements and their rationale for the safe peri-operative use of hybrid closed loop technology in patients requiring expedited or elective surgery.

Element	Rationale
Short starvation period [5, 9]	It is necessary to ensure that the individual has minimal physiological trespass and can resume eating immediately postoperatively
Shared decision making to discuss risks and benefits of the options [3, 5, 9]	Continued use of HCL has risks and the person with diabetes needs to be an active partner in their care
Ability to be reviewed pre-operatively by a diabetes specialist [3, 5, 9]	The diabetes specialist can advise on the necessary adjustments and ensure the correct consumables are available
Ability to set the glucose target for a temporary target above normal [3]	It is prudent to set a higher temporary glucose target to mitigate the risk of hypoglycaemia
Physiologically stable with good tissue perfusion and no evidence of sepsis or DKA [3, 5]	Continuation of CGM requires good interstitial perfusion
Planned operation has no major fluid shifts [3, 5]	Continuation of CGM requires good interstitial perfusion
Ability to be prioritised on the operating list [5, 9]	Need to ensure minimal starvation and ability to resume normal diet and insulin regimen
Ability for a Teflon needle to be sourced [3, 5, 9]	To reduce risk of burns from diathermy a Teflon needle is required
Ability to site CGM away from pressure and the diathermy arc [3, 5]	Excess pressure and electromagnetic interference can cause HCL malfunction
Ability to protect the devices from electromagnetic interference (no MRI) [3, 5]	Electromagnetic interference can cause CGM malfunction
Ability to minimise the risk of disconnection of pump and CGM [3]	Transfers can lead to disconnection
Ability to observe insulin pump, catheter and cannula site [3]	Need to ensure continuous administration of insulin and no kinking or disconnection
Recognition that certain drugs will cause the CGM to be misread [5]	Certain medicines can be misread as glucose and cause inappropriately high rate of infusion
Ability to do CBG at 30-min intervals	Due to concerns about CGM malfunction and interference, regular testing is required to provide assurance that person with diabetes is safe
Contingency plan if HCL technology fails and becomes unsafe [5]	Should HCL technology malfunction, there is a need to provide alternative sources of exogenous insulin to prevent DKA
Ability for the person with diabetes/carers/diabetes team to resume responsibility for HCL technology in the immediate postoperative period [3, 5]	Once the person with diabetes is awake, the settings will need to be resumed to normal

HCL, hybrid closed loop; DKA, diabetic ketoacidosis; CBG, capillary blood glucose; CGM, continuous glucose monitoring; MRI, magnetic resonance imaging.

further enhanced by activating the temporary target to 8.3 mmol.l^{-1} from 5.5 mmol.l^{-1} and measuring the CBG at 30-min intervals. This meant that even if the CGM erroneously over-read the glucose, excess insulin would not be infused, or the insulin pump could be over-ruled, if the actual CBG was low. Thus, the risk of inappropriately high insulin infusion causing iatrogenic hypoglycaemia was mitigated. As the use of HCL technology becomes more common, anaesthetists will need to become proficient in their peri-operative use to enable people under their care to be able to benefit from the continuation of this technology. Table 1 summarises the rationale for elements of safe peri-operative use of HCL technology in those requiring emergency and elective surgery [3, 5, 9]. Widespread adoption of these principles will enable health care practitioners to ensure that other patients are also given choice as to how their diabetes is managed during procedures where it is anticipated that only one meal will be missed. This will allow patients using hybrid closed loop technology to avoid the risks of the VRIII and maintain optimal glycaemic control.

Further research is required to establish which other anaesthetic and analgesic medicines interact with CGM sensors and the degree of interference caused. This will enable diabetes teams and people with diabetes to make informed judgements when deciding the best intra-operative target.

Acknowledgements

This case report was published with the written consent of the patient's mother. No external funding. PO, NL, HA and KD report no conflict of interest.

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