CADTH

CADTH RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS

Hybrid Closed Loop Insulin Delivery Systems: Clinical Effectiveness

Service Line:	Rapid Response Service
Version:	1.0
Publication Date:	September 17, 2019
Report Length:	7 Pages

CADTH

Authors: Kendra Brett, Melissa Walter

Cite As: Hybrid Closed Loop Insulin Delivery Systems: Clinical Effectiveness Ottawa: CADTH; 2019 Sept. (CADTH rapid response report: summary of abstracts).

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to **requests@cadth.ca**

Research Question

What is the clinical effectiveness of hybrid closed-loop insulin delivery systems in patients with type 1 diabetes?

Key Findings

Three randomized controlled trials were identified regarding the clinical effectiveness of hybrid closed-loop insulin delivery systems in patients with type 1 diabetes.

Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were hybrid closed-loop insulin delivery systems and diabetes Type 1 and Type 3c. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2003 and August 29, 2019. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients with insulin-dependent type 1 diabetes Subgroup of interest: patients with type 3c diabetes
Intervention	Hybrid closed-loop insulin delivery systems (e.g., Medtronic MiniMed 670G, Tandem "Control-IQ")
Comparator	Sensor augmented pumps (SAPs); continuous glucose monitoring (CGM); flash glucose monitors (FGMs); closed loops, open loops, hybrid loops; artificial pancreas; self monitoring blood glucose (SMBG); continuous insulin infusion (i.e., insulin pump); multiple daily insulin injections (MDII); any combinations of interventions listed above (e.g., pump plus CGM, pump plus SMBG)
Outcomes	Clinical effectiveness, including: time-in-range, glycated hemoglobin, number of hypoglycemic events requiring assistance, diabetic ketoacidosis, health status (i.e., EuroQol 5D score), hypoglycemia fear survey overall score, and diabetes treatment satisfaction questionnaire overall score

Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials and non-randomized studies.

Three randomized controlled trials[1,2,3] were identified regarding the clinical effectiveness of hybrid closed-loop insulin delivery systems in patients with type 1 diabetes. No relevant health technology assessments, systematic reviews, meta-analyses, or non-randomized studies were identified.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

Two randomized controlled trials[1,2] were identified regarding the clinical effectiveness of the Tandem Control-IQ artificial pancreas system as compared with a sensor augmented pump in adolescents and children with type 1 diabetes. Both studies,[1,2] found that children and adolescents randomized to the Tandem Control-IQ artificial pancreas system had significantly better time-in-range (70-180 mg/dL) and significantly lower average glucose level, and no difference in hypoglycemia exposure compared to those randomized to a sensor augmented pump. One randomized controlled trial[3] was identified regarding the clinical effectiveness of the Medtronic MiniMed 670G hybrid closed-loop system as compared to the Medtronic MiniMed 530G with threshold suspend in patients with type 1 diabetes at a diabetes camp, although the Minimed 670G was not identified by that name in the publication. This study[3] found no difference in time-in-range (70-180 mg/dL) or mean glucose level between the groups. In conclusion, the Tandem Control-IQ artificial pancreas system may provide better glycemic control than a sensor augmented pump in pediatric patients with type 1 diabetes, and the Minimed 670G may not provide improved glucose control compared to a sensor augmented pump.

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

1. Ekhlaspour L, Forlenza GP, Chernavvsky D, et al. Closed loop control in adolescents and children during winter sports: use of the Tandem Control-IQ AP system. *Pediatr Diabetes*. 2019 Sep;20(6):759-768.
PubMed: PM31099946

2. Forlenza GP, Ekhlaspour L, Breton M, et al. Successful at-home use of the Tandem Control-IQ artificial pancreas system in young children during a randomized controlled trial. *Diabetes Technol Ther*. 2019 Apr;21(4):159-169. PubMed: PM30888835

3. Ly TT, Roy A, Grosman B, et al. Day and night closed-loop control using the integrated Medtronic hybrid closed-loop system in type 1 diabetes at diabetes camp. *Diabetes Care*. 2015 Jul;38(7):1205-1211. PubMed: PM26049550

Non-Randomized Studies

No literature identified.

Appendix — Further Information

Randomized Controlled Trials

Study Protocols

4. de Bock M, McAuley SA, Abraham MB, et al. Effect of 6 months hybrid closed-loop insulin delivery in young people with type 1 diabetes: a randomised controlled trial protocol. *BMJ Open*. 2018 Aug;8(8):e020275.
PubMed: PM30104309

5. McAuley SA, de Bock MI, Sundararajan V, et al. Effect of 6 months of hybrid closed-loop insulin delivery in adults with type 1 diabetes: a randomised controlled trial protocol. *BMJ Open*. 2018 Jun;8(6):e020274.
PubMed: PM29886443

Alternative Comparator

6. Paldus B, Lee MH, Jones HM, et al. Glucose control using a standard versus an enhanced hybrid closed loop system: a randomized crossover study. *Diabetes Technol Ther*. 2019 Jan;21(1):56-58.
PubMed: PM30620641

Non-Randomized Studies

Alternative Comparator

7. Stone MP, Agrawal P, Chen X, et al. Retrospective analysis of 3-month real-world glucose data after the MiniMed 670G system commercial launch. *Diabetes Technol Ther*. 2018 Oct;20(10):689-692.
PubMed: PM30160523

8. Cordero TL, Garg SK, Brazg R, et al. The effect of prior continuous glucose monitoring use on glycemic outcomes in the pivotal trial of the MiniMed™ 670G hybrid closed-loop system. *Diabetes Technol Ther*. 2017 Dec;19(12):749-752.
PubMed: PM29148821

No Comparator or Control Group

9. de Bock M, Dart J, Roy A, et al. Exploration of the performance of a hybrid closed loop insulin delivery algorithm that includes insulin delivery limits designed to protect against hypoglycemia. *J Diabetes Sci Technol*. 2017 Jan;11(1):68-73.
PubMed: PM27621143

Uncontrolled Before-and-After Studies

10. Faulds ER, Zappe J, Dungan KM. Real-world implications of hybrid close loop (HCL) insulin delivery system. *Endocr Pract*. 2019 May;25(5):477-484.

PubMed: PM30865545

11. Forlenza GP, Pinhas-Hamiel O, Liljenquist DR, et al. Safety evaluation of the MiniMed 670G system in children 7-13 years of age with type 1 diabetes. *Diabetes Technol Ther*. 2019 Jan;21(1):11-19.
PubMed: PM30585770

12. Salehi P, Roberts AJ, Kim GJ. Efficacy and safety of real-life usage of MiniMed 670G automode in children with type 1 diabetes less than 7 years old. *Diabetes Technol Ther*. 2019 Aug;21(8):448-451.
PubMed: PM31166801

13. Messer LH, Forlenza GP, Sherr JL, et al. Optimizing hybrid closed-loop therapy in adolescents and emerging adults using the MiniMed 670G system. *Diabetes Care*. 2018 Apr;41(4):789-796.
PubMed: PM29444895

14. Garg SK, Weinzimer SA, Tamborlane WV, et al. Glucose outcomes with the in-home use of a hybrid closed-loop insulin delivery system in adolescents and adults with type 1 diabetes. *Diabetes Technol Ther*. 2017 Mar;19(3):155-163.
PubMed: PM28134564

15. Ly TT, Weinzimer SA, Maahs DM, et al. Automated hybrid closed-loop control with a proportional-integral-derivative based system in adolescents and adults with type 1 diabetes: individualizing settings for optimal performance. *Pediatr Diabetes*. 2017 Aug;18(5):348-355.
PubMed: PM27191182

Case Reports

16. Brown S, Raghinaru D, Emory E, Kovatchev B. First look at Control-IQ: a new-generation automated insulin delivery system. *Diabetes Care*. 2018 Dec;41(12):2634-2636.
PubMed: PM30305346

17. Petrovski G, Al Khalaf F, Hussain K, Campbell J. Optimizing a hybrid closed loop system in type 1 diabetes: a case report. *Diabetes Ther*. 2018 Oct;9(5):2173-2177.
PubMed: PM30030688

Review Articles

18. MiniMed 670G hybrid closed-loop system (Medtronic plc.) for managing type 1 diabetes. Plymouth Meeting (PA): ECRI Institute; 2016: **www.ecri.org**. Accessed 2019 Sep 16.