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Closed-Loop Therapy in Diabetic Pregnancies

1. **Cost-effectiveness of advanced hybrid closed loop therapy compared to standard insulin therapy for type 1 diabetes in pregnancy: an economic evaluation of the CRISTAL trial.**

   Item Type: Journal Article

   Authors: Azahaf S.;Beunen K.;Van Wilder N.;Ballaux D.;Vanhaverbeke G.;Taes Y.;Aers X.P.;Nobels F.;Van Huffel L.;Marlier J.;Lee D.;Cuypers J.;Preumont V.;Siegelaar S.E.;Painter R.C.;Laenen A.;Gillard P.;Mathieu C.;Luyten J. and Benhalima, K.

   Publication Date: 2025

   Journal: eClinicalMedicine 81(pagination), pp. Article Number: 103106. Date of Publication: 01 Mar 2025

   Abstract: Background: A multicentre, randomised controlled trial (the CRISTAL trial), demonstrated the safety and efficacy of MiniMedTM 780G advanced hybrid closed loop (AHCL) therapy during pregnancy, showing improved glycaemic control overnight, less hypoglycaemia, and improved treatment satisfaction compared to standard insulin therapy (SoC, mainly open-loop insulin pump therapy). This study aimed to assess the cost-effectiveness of AHCL, which has a higher initial cost, compared to SoC in pregnant women with type 1 diabetes (T1D). Method(s): A decision tree model was developed to estimate the cost-effectiveness of AHCL compared to SoC in pregnant women with T1D, covering pregnancy to birth and postpartum hospital discharge (a time horizon of 28 weeks). Total

costs per strategy (in 2024 euros,) were calculated from a healthcare payer perspective. The base-case analysis derived prevalence of pregnancy complications and hospitalisations directly related to diabetes management from the CRISTAL trial. Uncertainty was analysed by exploring multiple scenarios and sensitivity analyses. Finding(s): In the base-case analysis, the cost of using AHCL during pregnancy was estimated at 13,988.75 (95% CI: 12,240 to 16,062) compared to 14,221.33 (95% CI: 12,380 to 16,420) for SoC, indicating cost-savings of 232.57 per individual, alongside the demonstrated clinical benefits of AHCL. The primary cost driver was the AHCL device cost. This cost was offset by savings from shorter and less frequent hospital admissions (mainly due to severe hypoglycaemia and dysregulated diabetes) in the AHCL group compared to SoC. In our probabilistic sensitivity analysis, AHCL was dominant in 73% of the simulated cost-effectiveness pairs. Interpretation(s): AHCL might be cost-saving compared to SoC for pregnant women with T1D. However, more robust data are needed to assess the potential impact of AHCL therapy on pregnancy and long-term health outcomes. Funding(s): Diabetes Liga Research Fund and Medtronic.Copyright © 2025 The Author(s)

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2. **Case series of a hybrid closed loop therapy system used in pregnancy.**

Item Type: Journal Article

Authors: Brigham T.L.;Klein M.P.;SnellBergeon J.K. and Polsky, S.

Publication Date: 2025

Journal: Acta Diabetologica (pagination), pp. Date of Publication: 2025

Abstract: Aims: The effectiveness of Hybrid Closed-Loop (HCL) therapy is rarely studied in type 1 diabetes (T1D) pregnancies. Method(s): T1D pregnancies (n = 15) managed off-label during gestation using a commercially available HCL system, Tandem Control IQ, were retrospectively reviewed for baseline characteristics, continuous glucose monitoring (CGM), insulin pump use, insulin doses, and gestational health outcomes. Analyses for unadjusted descriptive statistics of baseline characteristics, glycemic parameters, and gestational health outcomes were performed (mean +/- standard deviation (SD) or median with interquartile range (IQR) for continuous variables). Control IQ was used prior to pregnancy by 12 of the 15 cases, with 3 initiating use during gestation. Result(s): On average, targets were met for pregnancy-specific Time-In-Range (psTIR, 63-140 mg/dL for > 70%) during most of gestation, pregnancy-specific Time-Below-Range (psTBR, Result(s): On average, targets were met for pregnancy-specific Time-In-Range (psTIR, 63-140 mg/dL for > 70%) during most of gestation, pregnancy-specific Time-Below-Range (psTBR, 140 mg/dL for 140 mg/dL), and TBR (140 mg/dL), and TBR (Conclusion(s): Tandem Control IQ HCL therapy

used with assistive techniques in 15 T1D pregnancies was associated with improved glycemic levels from the first clinic visit onward.Copyright © Springer-Verlag Italia S.r.l., part of Springer Nature 2025.

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3. **Mixed Methods Randomized Controlled Trial Comparing Quality of Life for Pregnant Women With Type 1 Diabetes Using Hybrid Closed-Loop to Sensor-Augmented Pump Therapy.**

Item Type: Journal Article

Authors: Buschur E.O.;Reedy J.;Berget C.;Barnard J.G.;Garcetti R.;Nease E.;Bartholomew A.;Johnson C.;Driscoll K.A.;Dungan K.M.;SnellBergeon J.K.;Pyle L.L. and Polsky, S.

Publication Date: 2025

Journal: Endocrine Practice (pagination), pp. Date of Publication: 2025

Abstract: Objective: Type 1 diabetes in pregnancy is challenging. This study explores how assisted hybrid closed-loop therapy (HCL) versus sensor-augmented pump therapy (SAPT) impacts quality of life in pregnancy. Method(s): We interviewed 22 of 24 participants randomized to HCL or SAPT in the Pregnancy Intervention with a Closed-Loop System study. Participants completed questionnaires about hypoglycemia fear and device satisfaction and trust. Result(s): Quality of life was similar among women with type 1 diabetes using HCL (n = 12) and SAPT (n = 12) throughout pregnancy and early postpartum. Hypoglycemia fear was not statistically different between groups but improved in the HCL group in the second trimester versus baseline. Glucose monitoring satisfaction and trust increased during pregnancy in the HCL group but decreased in the SAPT group. Women trusted their mode of insulin delivery despite stress and frustration with fluctuating glucose and risks of hyperglycemia to their fetuses. Women who preferred less involvement with their management preferred HCL, whereas those desiring more involvement preferred SAPT. Conclusion(s): These similarities demonstrate that open communication is needed between provider and patient to determine perceived benefits versus burdens of HCL use in pregnancy, especially in the United States where available HCL systems lack pregnancy-specific algorithms and Food and Drug Administration approval for pregnancy use.Copyright © 2025 AACE

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C%2FAN%3E%3CDT%3EArticle+In+Press%3C%2FDT%3E

4. **Approach to the Patient using Diabetes Technology in Pregnancy.**

Item Type: Journal Article

Authors: Dickens L.T. and Gonzalez, M. G.

Publication Date: 2025

Journal: The Journal of Clinical Endocrinology and Metabolism (pagination), pp. Date of Publication: 07 Jan 2025

Abstract: Diabetes in pregnancy increases risk for complications for the pregnant patient and neonate. Tight glycemic control to maintain glucose levels as close to non-diabetic ranges as possible can lower risk for these complications. Achieving strict glycemic targets can be challenging and technologies including continuous glucose monitors (CGM) and hybrid closed loop (HCL) insulin pumps have the potential to improve diabetes control and pregnancy outcomes. The aim of this review is to present and appraise the current data about use of these technologies in pregnancy. In pregnancies with type 1 diabetes (T1D), CGM can improve glycemic control and reduce risk for neonatal complications. International consensus guidelines recommend >70% time in pregnancy target range (TIR) of 63-140 mg/dL (3.5-7.8 mmol/L) and there is data to suggest higher TIR in pregnancies with T1D can reduce risk for neonatal complications including fetal overgrowth and pregnancy complications like preeclampsia. Recent randomized controlled trials have demonstrated improved glycemic outcomes with use of HCL insulin pumps in pregnancy with T1D, though the results vary depending on the system used and available glycemic targets. In pregnancies with type 2 diabetes (T2D) and GDM, retrospective data suggests CGM can improve glycemia but there is limited data about outcomes or optimal CGM targets. Studies have reported glycemic measures for pregnancies without diabetes which may serve as a guide for further outcomes studies of T2D and GDM. Access to diabetes technology and the necessary healthcare systems to support use of these devices may be barriers that contribute to healthcare disparities.

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5. **Changes to insulin pump settings throughout pregnancy for individuals using assisted hybrid closed-loop therapy versus sensor-augmented pump therapy.**

Item Type: Journal Article

Authors: King, Jocelynn;Buschur, Elizabeth;Garcetti, Rachel;Pyle, Laura;Sakamoto, Casey;Snell-Bergeon, Janet;Nease, Emily;Bartholomew, Anna;Dungan, Kathleen and Polsky, Sarit

Publication Date: Apr ,2025

Journal: Journal of Diabetes & its Complications 39(4), pp. 109000

Abstract: AIMS: We compared changes in insulin pump settings and insulin distribution throughout pregnancy and early postpartum for participants with type 1 diabetes using sensor-augmented pump therapy (SAPT) or hybrid closed-loop (HCL) therapy without a pregnancy-specific glucose target. METHODS: In this investigator-initiated trial 23 participants were randomized at 14-18 weeks gestation to HCL therapy or SAPT until 4-6 weeks postpartum. We compared the changes to insulin pump settings and insulin delivery between groups using mixed-effects models. RESULTS: There were no significant differences in total daily insulin dose between HCL and SAPT groups from preconception through 4-6 weeks postpartum. However, the proportion of total insulin coming from bolus insulin was higher for the HCL group in month 9 (70.9 % HCL vs 57.9 % SAPT, p = 0.014). The HCL group had a lower total daily basal dose compared to SAPT in months 9 and 10 (p : There were no significant differences in total daily insulin dose between HCL and SAPT groups from preconception through 4-6 weeks postpartum. However, the proportion of total insulin coming from bolus insulin was higher for the HCL group in month 9 (70.9 % HCL vs 57.9 % SAPT, p = 0.014). The HCL group had a lower total daily basal dose compared to SAPT in months 9 and 10 (p CONCLUSION: More bolus insulin and less basal insulin were used by the HCL group compared to the SAPT group, at least in part due to pump settings that contribute to more bolus insulin delivery. Copyright © 2025 Elsevier Inc. All rights reserved.

6. **Automated insulin delivery during the first 6 months postpartum (AiDAPT): a prespecified extension study.**

Item Type: Journal Article

Authors: Lee, Tara T. M.;Collett, Corinne;Bergford, Simon;Hartnell, Sara;Scott, Eleanor M.;Lindsay, Robert S.;Hunt, Katharine F.;McCance, David R.;Reynolds, Rebecca M.;Wilinska, Malgorzata E.;Sibayan, Judy;Kollman, Craig;Hovorka, Roman and Murphy, Helen R.

Publication Date: Mar ,2025

Journal: The Lancet Diabetes & Endocrinology 13(3), pp. 210–220

Abstract: BACKGROUND: Clinical guidelines in the UK and elsewhere do not specifically address hybrid closed loop (HCL) use in the postpartum period when the demands of caring for a newborn are paramount. Our aim was to evaluate the safety and efficacy of HCL use during the first 6 months postpartum compared with standard care. METHODS: In this prespecified extension to a multicentre, randomised controlled trial, pregnant women with type 1 diabetes at nine UK sites were followed up for 6 months postpartum. Eligible participants (AiDAPT participants recruited after the implementation of the postpartum protocol amendment approval, those still pregnant or within six months of delivery at the time of amendment implementation and still using HCL or continuous glucose monitoring [CGM] therapy) continued their randomly assigned treatment, either standard insulin therapy with CGM or HCL therapy (CamAPS FX system version 0.3.1, CamDiab, Cambridge, UK). Participants were randomised in a 1:1 ratio with stratification by clinical site using randomly permuted block sizes of 2 or 4. The primary outcome was the between-group difference in percentage time in range ([TIR] 3.9-10.0 mmol/L [70-180mg/dL]), measured during the periods of month 0 up to 3, months 3 to 6, and over 6 months postpartum. The study is registered at ClinicalTrials.gov (ISRCTN56898625) and is complete. FINDINGS: Of the 124 AiDAPT trial participants, 66 (53%) were ineligible for inclusion in the postpartum extension, and 57 participants consented to continue their treatment per original random allocation. The mean age was 31 years (SD 4), and all participants had early pregnancy HbA1c 59.4 mmol/mol (SD 10.5 [7.6% SD 1.0%]). In the 6 months postpartum, mean time with glucose levels within the target range was higher in the HCL group compared with the standard care group (72% [SD 12%] vs 54% [17%]), with an adjusted treatment difference of 15% (95% CI 7 to 22). Results for hyperglycaemia (>10.0 mmol/L) and mean CGM glucose also favoured HCL (-14% [95% CI -23% to -6%] and -1.3 mmol/L [-2.3 to -0.3], respectively). Hypoglycaemia rates were low, with no between-group differences (2.4% vs 2.6%). There were no treatment effect changes depending on postpartum period (0 up to 3 months vs 3 to 6 months) and no unanticipated safety problems. INTERPRETATION: Participants in the HCL group maintained 70% TIR during the first 6 months postpartum, supporting continued use of HCL rather than standard insulin therapy for people with diabetes once they have given birth. FUNDING: National Institute for Health Research, Juvenile Diabetes Research Foundation, and Diabetes Research & Wellness Foundation. CGM devices were provided by Dexcom at a discounted price.

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extension+study.&aulast=Lee&pid=%3Cauthor%3ELee+TTM%3BCollett+C%3BBergford+S%3BHartnell+S%3BScott+EM%3BLindsay+RS%3BHunt+KF%3BMcCance+DR%3BReynolds+RM%3BWilinska+ME%3BSibayan+J%3BKollman+C%3BHovorka+R%3BMurphy+HR%3C%2Fauthor%3E%3CAN%3E39884300%3C%2FAN%3E%3CDT%3EJournal+Article%3C%2FDT%3E

7. **Switching to insulin lispro U-200 in a pregnant woman using a 780G advanced hybrid closed-loop led to a rapid improvement in glucose metrics.**

Item Type: Journal Article

Authors: Mendoza, Lilian C.;Cohen, Ohad;Smaniotto, Vittorino and Corcoy, Rosa

Publication Date: Apr ,2025

Journal: Diabetes Research & Clinical Practice 222, pp. 112047

Abstract: Maintaining tight glucose levels during pregnancy is crucial and challenging. We describe a pregnant woman with type 1 diabetes and obesity, treated with an advanced hybrid closed-loop MiniMed 780G since pre-pregnancy, who displayed a sustained improvement in her glucometrics after switching to lispro U-200. Copyright © 2025 Elsevier B.V. All rights reserved.

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8. **Use of continuous glucose monitoring and hybrid closed-loop therapy in pregnancy.**

Item Type: Journal Article

Authors: Benhalima K. and Yamamoto, J. M.

Publication Date: 2024

Journal: Diabetes, Obesity and Metabolism 26(S7) (pp 74-91), pp. Date of Publication: 01 Dec 2024

Abstract: Continuous glucose monitoring (CGM) has led to a paradigm shift in the management of pregnant women with type 1 diabetes (T1D), with improved glycaemic control, less hypoglycaemia and fewer pregnancy complications. Data on CGM use in pregnant women with type 2 diabetes (T2D) are limited. A large randomized controlled trial (RCT) on CGM use in people with T2D in pregnancy is ongoing. Small studies on CGM use in women with gestational diabetes (GDM) have suggested improved glycaemic control and better qualification when insulin is needed. However, none of these studies was powered to evaluate pregnancy outcomes. Several large RCTs are ongoing in women with GDM. In addition to CGM, other technologies, such as advanced hybrid closed-loop (AHCL) systems

have further improved glycaemic management in people with T1D. AHCL therapy adapts insulin delivery via a predictive algorithm integrated with CGM and an insulin pump. A large RCT with the AHCL CamAPS FX demonstrated a 10% increase in time in range compared to standard insulin therapy in a pregnant population with T1D. Recently, an RCT of an AHCL system not approved for use in pregnancy (780G MiniMed) has also demonstrated additional benefits of AHCL therapy compared to standard insulin therapy, with improved time in range overnight, less hypoglycaemia and improved treatment satisfaction. More evidence is needed on the impact of AHCL therapy on maternal and neonatal outcomes and on which glycaemic targets with CGM should be used in pregnant women with T2D and GDM. We review the current evidence on the use of CGM and AHCL therapy in pregnancy.

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9. **Comparing advanced hybrid closed loop therapy and standard insulin therapy in pregnant women with type 1 diabetes (CRISTAL): a parallel-group, open-label, randomised controlled trial.**

Item Type: Journal Article

Authors: Benhalima, Katrien;Beunen, Kaat;Van Wilder, Nancy;Ballaux, Dominique;Vanhaverbeke, Gerd;Taes, Youri;Aers, Xavier-Philippe;Nobels, Frank;Marlier, Joke;Lee, Dahae;Cuypers, Joke;Preumont, Vanessa;Siegelaar, Sarah E.;Painter, Rebecca C.;Laenen, Annouschka;Gillard, Pieter and Mathieu, Chantal

Publication Date: Jun ,2024

Journal: The Lancet Diabetes & Endocrinology 12(6), pp. 390–403

Abstract: BACKGROUND: Advanced hybrid closed loop (AHCL) therapy can improve glycaemic control in pregnant women with type 1 diabetes. However, data are needed on the efficacy and safety of AHCL systems as these systems, such as the MiniMed 780G, are not currently approved for use in pregnant women. We aimed to investigate whether the MiniMed 780G can improve glycaemic control with less hypoglycaemia in pregnant women with type 1 diabetes. METHODS: CRISTAL was a double-arm, parallel-group, open-label, randomised controlled trial conducted in secondary and tertiary care specialist endocrinology centres at 12 hospitals (11 in Belgium and one in the Netherlands). Pregnant women aged 18-45 years with type 1 diabetes were randomly assigned (1:1) to AHCL therapy (MiniMed 780G) or standard insulin therapy (standard of care) at a median of 10.1 (IQR 8.6-11.6) weeks of gestation. Randomisation was done centrally with minimisation dependent on baseline HbA1c, insulin administration method, and centre. Participants and study teams were not masked to group allocation. The primary outcome was proportion of time spent in the pregnancy-specific target glucose range (3.5-7.8 mmol/L), measured by continuous glucose monitoring (CGM) at 14-17 weeks, 20-23 weeks, 26-29 weeks, and 33-36 weeks. Key secondary outcomes were overnight time in target range, and time below glucose range (, insulin administration method, and centre. Participants and study teams

were not masked to group allocation. The primary outcome was proportion of time spent in the pregnancy-specific target glucose range (3.5-7.8 mmol/L), measured by continuous glucose monitoring (CGM) at 14-17 weeks, 20-23 weeks, 26-29 weeks, and 33-36 weeks. Key secondary outcomes were overnight time in target range, and time below glucose range (FINDINGS: Between Jan 15, 2021 and Sept 30, 2022, 101 participants were screened, and 95 were randomly assigned to AHCL therapy (n=46) or standard insulin therapy (n=49). 43 patients assigned to AHCL therapy and 46 assigned to standard insulin therapy completed the study. At baseline, 91 (95.8%) participants used insulin pumps, and the mean HbA1c was 6.5% (SD 0.6). The mean proportion of time spent in the target range (averaged over four time periods) was 66.5% (SD 10.0) in the AHCL therapy group compared with 63.2% (12.4) in the standard insulin therapy group (adjusted mean difference 1.88 percentage points [95% CI -0.82 to 4.58], p=0.17). Overnight time in the target range was higher (adjusted mean difference 6.58 percentage points [95% CI 2.31 to 10.85], p=0.0026), and time below range overall (adjusted mean difference -1.34 percentage points [95% CI, -2.19 to -0.49], p=0.0020) and overnight (adjusted mean difference -1.86 percentage points [95% CI -2.90 to -0.81], p=0.0005) were lower with AHCL therapy than with standard insulin therapy. Participants assigned to AHCL therapy reported higher treatment satisfaction. No unanticipated safety events occurred with AHCL therapy. INTERPRETATION: In pregnant women starting with tighter glycaemic control, AHCL therapy did not improve overall time in target range but improved overnight time in target range, reduced time below range, and improved treatment satisfaction. These data suggest that the MiniMed 780G can be safely used in pregnancy and provides some additional benefits compared with standard insulin therapy; however, it will be important to refine the algorithm to better align with pregnancy requirements. FUNDING: Diabetes Liga Research Fund and Medtronic.

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10. **Advanced Hybrid Closed-Loop Therapy Compared With Standard Insulin Therapy Intrapartum and Early Postpartum in Women With Type 1 Diabetes: A Secondary Observational Analysis From the CRISTAL Randomized Controlled Trial.**

Item Type: Journal Article

Authors: Beunen, Kaat;Gillard, Pieter;Van Wilder, Nancy;Ballaux, Dominique;Vanhaverbeke, Gerd;Taes, Youri;Aers, Xavier-Philippe;Nobels, Frank;Van Huffel, Liesbeth;Marlier, Joke;Lee, Dahae;Cuypers, Joke;Preumont, Vanessa;Siegelaar, Sarah E.;Painter, Rebecca C.;Laenen, Annouschka;Mathieu, Chantal and Benhalima, Katrien

Publication Date: Nov 01 ,2024

Journal: Diabetes Care 47(11), pp. 2002–2011

Abstract: OBJECTIVE: To determine efficacy and safety of intrapartum and early postpartum advanced hybrid closed-loop (AHCL) therapy compared with standard insulin therapy in pregnant women with type 1 diabetes (T1D). RESEARCH DESIGN AND METHODS: CRISTAL was a double-arm, open-label, randomized controlled trial performed in Belgium and the Netherlands that assigned 95 pregnant participants with T1D 1:1 to a MiniMed 780G AHCL system (n = 46) or standard insulin therapy (n = 49). This prespecified, secondary observational analysis focused on differences in glycemic control and safety outcomes between participants from the original AHCL group who continued AHCL intrapartum (n = 27) and/or early postpartum (n = 37, until hospital discharge) and those from the original standard insulin therapy group using standard insulin therapy intrapartum (n = 45) and/or early postpartum (n = 34). RESULTS: Of the 43 and 46 participants in the AHCL and standard insulin therapy groups, respectively, completing the trial, 27 (62.8%) in the AHCL group continued AHCL and 45 in the standard insulin therapy group (97.8%) continued standard insulin therapy intrapartum. Compared with standard insulin therapy, intrapartum AHCL was associated with more time in range 3.5-7.8 mmol/L (71.5 +/- 17.7% vs. 63.1 +/- 17.0%, P = 0.030) and numerically lower time above range >7.8 mmol/L (27.3 +/- 17.4% vs. 35.3 +/- 17.5%, P = 0.054), without increases in time below range : Of the 43 and 46 participants in the AHCL and standard insulin therapy groups, respectively, completing the trial, 27 (62.8%) in the AHCL group continued AHCL and 45 in the standard insulin therapy group (97.8%) continued standard insulin therapy intrapartum. Compared with standard insulin therapy, intrapartum AHCL was associated with more time in range 3.5-7.8 mmol/L (71.5 +/- 17.7% vs. 63.1 +/- 17.0%, P = 0.030) and numerically lower time above range >7.8 mmol/L (27.3 +/- 17.4% vs. 35.3 +/- 17.5%, P = 0.054), without increases in time below range CONCLUSIONS: AHCL is effective in maintaining tight glycemic control intrapartum and early postpartum and can be safely continued during periods of rapidly changing insulin requirements. Copyright © 2024 by the American Diabetes Association.

%3BAers+XP%3BNobels+F%3BVan+Huffel+L%3BMarlier+J%3BLee+D%3BCuypers+J%3BPreumont+V%3BSiegelaar+SE%3BPainter+RC%3BLaenen+A%3BMathieu+C%3BBenhalima+K%3C%2Fauthor%3E%3CAN%3E39331059%3C%2FAN%3E%3CDT%3EJournal+Article%3C%2FDT%3E

11. **Use of Automated Insulin Delivery in Pregnancies Complicated by Type 1 Diabetes.**

Item Type: Journal Article

Authors: Chillakanti, Mahima;Young, Elaine;Hopcroft, April;Bellini, Natalie;Smith, Jennifer and Isaacs, Diana

Publication Date: Oct ,2024

Journal: TouchREVIEWS in Endocrinology 20(2), pp. 110–118

Abstract: Background: Diabetes during pregnancy is associated with significant maternal and foetal health risks. Insulin requirements also change during pregnancy. This necessitates careful and effective management of diabetes. Although commonly used in clinical practice, the US Food and Drug Administration (FDA)-approved algorithms for automated insulin delivery (AID) systems do not have pregnancy-specific glycaemic targets. This review aims to evaluate the safety and efficacy of AID systems in reaching glycaemic targets in pregnant women with type 1 diabetes (T1D). Methods: In this retrospective case review, six pregnant women with T1D used three types of AID systems. Two patients used Omnipod 5, two patients used Control-I Q and two patients used Do-I t-Yourself (DIY) Loop. Results: Across trimesters, the two patients using Omnipod 5 had an average time in range (TIR) of 68 and 82%. Patients using Control-I Q had an average TIR of 77 and 69%. Both the patients using DIY Loop had an average TIR of 85%. Hypoglycaemia occurrence was minimal. Additionally, four of the six patients had uncomplicated vaginal deliveries in their third trimester, and four of the six patients achieved guideline-r ecommended TIR targets. Birth complications for the other two patients were resolved shortly after birth. Throughout the pregnancies, insulin needs approximately doubled. Conclusions: AID systems can achieve near-desired glycaemic targets with minimal hypoglycaemia in pregnant women with T1D. Randomized controlled trials are needed to confirm these findings and to win FDA indications in pregnancy. Copyright © Touch Medical Media 2024.

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12. **Use of Advanced Hybrid Closed-Loop System during Pregnancy: Strengths and Limitations of Achieving a Tight Glycemic Control.**

Item Type: Journal Article

Authors: Giannoulaki P.;Kotzakioulafi E.;Nakas A.;Kontoninas Z.;Evripidou P. and Didangelos, T.

Publication Date: 2024

Journal: Journal of Clinical Medicine 13(5) (pagination), pp. Article Number: 1441. Date of Publication: 01 Mar 2024

Abstract: Background: Pregnant women with type 1 diabetes mellitus (T1DM) face an elevated risk of complications for both themselves and their newborns. Experts recommend strict glycemic control. The advanced hybrid closed-loop (AHCL) system, though not officially approved for pregnant T1DM patients, is promising for optimal glycemic control. Method(s): We collected CGM metrics, HbA1c levels, insulin pump settings, and doses from a 33-year-old pregnant woman with 23-year history of T1DM from the 6th week of gestation to birth. She was initially on continuous insulin pump therapy with CGM and switched to the AHCL system (MiniMedTM 780G, Medtronic, Northridge, CA, USA) between weeks 13 and 14. Result(s): The AHCL system improved glycemic control from weeks 14 to 26, achieving international guidelines with TIR = 72%, TAR = 24%, TBR = 4%. At week 30, TIR was 66%, TAR 31%. By altering diet and adding 'fake carbohydrates', she maintained TIR >= 70%, TBR Result(s): The AHCL system improved glycemic control from weeks 14 to 26, achieving international guidelines with TIR = 72%, TAR = 24%, TBR = 4%. At week 30, TIR was 66%, TAR 31%. By altering diet and adding 'fake carbohydrates', she maintained TIR >= 70%, TBR Result(s): The AHCL system improved glycemic control from weeks 14 to 26, achieving international guidelines with TIR = 72%, TAR = 24%, TBR = 4%. At week 30, TIR was 66%, TAR 31%. By altering diet and adding 'fake carbohydrates', she maintained TIR >= 70%, TBR Conclusion(s): The use of the AHCL system holds significant promise for improving glycemic control in pregnancy. Optimal glycemic control with MiniMedTM 780G in pregnancy requires accurate carbohydrate counting, specific timing of insulin doses in relation to meal consumption and dietary choices that reduce the glycemic load of meals continue to be crucial factors in achieving optimal glycemic control during pregnancy using the MiniMedTM 780G system. Further research and clinical studies are needed to explore the full potential of these advanced systems in managing T1DM during pregnancy and optimizing maternal and neonatal outcomes.Copyright © 2024 by the authors.

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13. Automated closed-loop insulin delivery for the management of type 1 diabetes during pregnancy: the AiDAPT RCT

Item Type: Journal Article

Authors: Lee, Tara TM;Collett, Corinne;Bergford, Simon;Hartnell, Sara;Scott, Eleanor M.;Lindsay, Robert S.;Hunt, Katharine F.;McCance, David R.;Barnard-Kelly, Katharine;Rankin, David;Lawton, Julia;Reynolds, Rebecca M.;Flanagan, Emma;Hammond, Matthew;Shepstone, Lee;Wilinska, Malgorzata E.;Sibayan, Judy;Kollman, Craig;Beck, Roy;Hovorka, Roman, et al

Publication Date: 2024

Journal: National Institute for Health and Care Research
Abstract: BACKGROUND: There are over 2000 pregnancies annually in women with type 1 diabetes in the UK. Despite recent improvements in diabetes technology, most women cannot achieve and maintain the recommended pregnancy glucose targets. Thus, one in two babies experience complications requiring neonatal care unit admission. Recent studies demonstrate that hybrid closed-loop therapy, in which algorithms adjust insulin delivery according to continuous glucose measurements, is effective for managing type 1 diabetes outside of pregnancy, but efficacy during pregnancy is unclear. OBJECTIVE: To examine the clinical efficacy of hybrid closed-loop compared to standard insulin therapy in pregnant women with type 1 diabetes. DESIGN: A multicentre, parallel-group, open-label, randomised, controlled trial in pregnant women with type 1 diabetes. SETTING: Nine antenatal diabetes clinics in England, Scotland and Northern Ireland. PARTICIPANTS: Pregnant women with type 1 diabetes and above-target glucose levels, defined as glycated haemoglobin A1c of >= 48 mmol/mol (6.5%) in early pregnancy. INTERVENTIONS: A hybrid closed-loop system compared to standard insulin delivery (via insulin pump or multiple daily injections) with continuous glucose monitoring. OUTCOME MEASURES: The primary outcome is the difference between the intervention and control groups in percentage time spent in the pregnancy glucose target range (3.5-7.8 mmol/l) as measured by continuous glucose monitoring from 16 weeks' gestation until delivery. Secondary outcomes include overnight time in range, time above range (> 7.8 mmol/l), glycated haemoglobin A1c, safety outcomes (diabetic ketoacidosis, severe hypoglycaemia, adverse device events), psychosocial functioning obstetric and neonatal outcomes. RESULTS: The percentage of time that maternal glucose levels were within target range was higher with closed-loop than standard insulin therapy: 68.2 +/- 10.5 in closed-loop and 55.6 +/- 12.5 in the control group (mean-adjusted difference 10.5 percentage points, 95% confidence interval 7.0 to 14.0; p p p p LIMITATIONS: Our results cannot be extrapolated to closed-loop systems with higher glucose targets, and our sample size did not provide definitive data on maternal and neonatal outcomes. CONCLUSIONS: Hybrid closed-loop therapy significantly improved maternal glycaemia during type 1 diabetes pregnancy. Our results support National Institute for Health and Care Excellence guideline recommendations that hybrid closed-loop therapy should be offered to all pregnant women with type 1 diabetes. FUTURE WORK: Future trials should examine the effectiveness of hybrid closed-loop started before pregnancy, or as soon as possible after pregnancy confirmation. TRIAL REGISTRATION: This trial is registered as ISRCTN56898625. FUNDING: This award was funded by the National Institute of Health and Care Research (NIHR) Efficacy and Mechanism Evaluation (EME) programme (NIHR award ref: 16/35/01) and is published in full in Efficacy and Mechanism Evaluation; Vol. 11, No. 7. See the NIHR Funding and Awards website for further award information. Dexcom supplied the continuous glucose monitoring systems used by AiDAPT intervention- and control-arm participants at reduced cost. Copyright ©

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14. **Technology advances in diabetes pregnancy: right technology, right person, right time**

Item Type: Journal Article

Authors: McLean, Anna;Maple-Brown, Louise and Murphy, Helen R.

Publication Date: Oct ,2024

Journal: Diabetologia 67(10), pp. 2103–2113

Abstract: This review outlines some of the extraordinary recent advances in diabetes technology, which are transforming the management of type 1 diabetes before, during and after pregnancy. It highlights recent improvements associated with use of continuous glucose monitoring (CGM) but acknowledges that neither CGM nor insulin pump therapy are adequate for achieving the pregnancy glucose targets. Furthermore, even hybrid closed-loop (HCL) systems that are clinically effective outside of pregnancy may not confer additional benefits throughout pregnancy. To date, there is only one HCL system, the CamAPS FX, with a strong evidence base for use during pregnancy, suggesting that the pregnancy benefits are HCL system specific. This is in stark contrast to HCL system use outside of pregnancy, where benefits are HCL category specific. The CamAPS FX HCL system has a rapidly adaptive algorithm and lower glucose targets with benefits across all maternal glucose categories, meaning that it is applicable for all women with type 1 diabetes, before and during pregnancy. For women of reproductive years living with type 2 diabetes, the relative merits of using non-insulin pharmacotherapies vs diabetes technology (dipeptidyl peptidase-4 inhibitors, glucagon-like peptide-1 receptor agonists and sodium-glucose cotransporter 2 inhibitors) are unknown. Despite the urgent unmet need and potential benefits, studies of pharmacotherapy and technology use are extremely limited in pregnant women with type 2 diabetes. Copyright © 2024. The Author(s).

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15. **Real-world data on the Minimed 780G advanced hybrid closed-loop system use during type 1 diabetes pregnancy: One centre observational study.**

Item Type: Journal Article

Authors: Munda A.;Kovacic C. and Pongrac Barlovic, D.

Publication Date: 2024

Journal: Journal of Diabetes and its Complications 38(8) (pagination), pp. Article Number: 108795. Date of Publication: 01 Aug 2024

Abstract: Aim The efficacy of hybrid closed-loop systems (HCLs) in managing glycemic control in pregnant women with type 1 diabetes remains inadequately characterized. We evaluated the use of the Medtronic Minimed 780G HCLs. Method(s): The retrospective observational study analyzed the glycemic and perinatal outcomes of pregnant women using the HCLs, followed at our tertiary centre. Independent t-tests were employed to compare data among trimesters based on pre-pregnancy HbA1c. The associations between glycemic parameters and perinatal outcomes were explored using Spearman rho. Result(s): Among the 21 women (age: 33.5 +/- 4.2 years, diabetes duration: 21.2 +/- 7.6 years, pre-pregnancy HbA1c 7.0 +/- 1.1 % (52.9 +/- 11.9 mmol/mol)) time in range (pTIR, 63-140 mg/dl; 3.5-7.8 mmol/l) increased progressively throughout pregnancy (trimesters: first: 64.0 +/- 9.0 %; second:71.3 +/- 11.8 %; third: 75.7 +/- 8.1 %). Simultaneously, mean sensor glucose decreased (trimesters: first: 130 +/- 10.4 mg/dl (7.2 +/- 0.6 mmol/l); second: 120.9 +/- 13.4 mg/dl (6.7 +/- 0.7 mmol/l); third: 117.3 +/- 9.1 mg/dl (6.5 +/- 0.5 mmol/l)). Although a majority of women achieved the target pTIR until the third trimester, this did not consistently prevent the delivery of a large-for-gestational-age baby. Notably, one ketoacidosis event occurred, and there were no reported instances of severe hypoglycemia. Conclusion(s): Use of the Minimed 780G HCLs enabled the attainment of recommended pregnancy glycemic targets for most women with type 1 diabetes in a real-world setting.Copyright © 2023

16. **Demarcating the benefits of hybrid closed loop therapy in pregnant women with type 1 diabetes.**

    Item Type: Journal Article

    Authors: Murphy, Helen R. and Scott, Eleanor M.

    Publication Date: Jun ,2024

    Journal: The Lancet Diabetes & Endocrinology 12(6), pp. 368–369

    URL: https://libkey.io/libraries/2828/openurl?genre=article&sid=OVID:medline&id=pmid:38697181&id=doi:10.1016%2FS2213-8587%2824%2900104-9&issn=2213-8587&isbn=&volume=12&issue=6&spage=368&pages=368-369&date=2024&title=The+Lancet+Diabetes+%26+Endocrinology&atitle=Demarcating+the+benefits+of+hybrid+closed+loop+therapy+in+pregnant+women+with+type+1+diabetes.&aulast=Murphy&pid=%3Cauthor%3EMurphy+HR%3BScott+EM%3C%2Fauthor%3E%3CAN%3E38697181%3C%2FAN%3E%3CDT%3EJournal+Article%3C%2FDT%3E

17. **Randomized Trial of Assisted Hybrid Closed-Loop Therapy Versus Sensor-Augmented Pump Therapy in Pregnancy.**

    Item Type: Journal Article

    Authors: Polsky S.;Buschur E.;Dungan K.;Garcetti R.;Nease E.;Malecha E.;Bartholomew A.;Johnson C.;Pyle L. and SnellBergeon, J.

    Publication Date: 2024

    Journal: Diabetes Technology and Therapeutics 26(8), pp. 547–555

    Abstract: Objective: Examine gestational safety, glycemic and health outcomes, of a hybrid closed-loop (HCL) system without pregnancy-specific glucose targets. Research Design: This was a pilot feasibility investigator-initiated, two-site, single-blind, randomized controlled trial of sensor-augmented pump therapy (SAPT) versus HCL therapy in type 1 diabetes pregnancies. Participants were enrolled in the first trimester and randomized at 14-18 weeks of gestation and used SAPT or HCL until 4-6 weeks postpartum. We compared continuous glucose monitoring (CGM) metrics, severe hypoglycemia (SH), diabetic ketoacidosis (DKA), adverse skin reactions, and pregnancy outcomes between groups. Result(s): Baseline characteristics were similar between groups (n = 11 HCL and n = 12 SAPT). There was no SH or DKA episode after randomization. Time spent Result(s): Baseline characteristics were similar between groups (n = 11 HCL and n = 12 SAPT). There was no SH or DKA episode after randomization. Time spent Result(s): Baseline characteristics were similar between groups (n = 11 HCL and n = 12 SAPT). There was no SH or DKA episode after randomization. Time spent Result(s): Baseline characteristics were similar between groups (n = 11 HCL and n = 12 SAPT). There was no SH or DKA episode after randomization. Time spent Result(s): Baseline characteristics were similar between groups (n = 11 HCL and n = 12 SAPT). There was no SH or DKA episode after randomization. Time spent Result(s): Baseline characteristics were similar between groups (n = 11 HCL and n = 12 SAPT). There was no SH or DKA episode after randomization. Time spent Conclusion(s): CGM within group differences were seen for time Conclusion(s): CGM within group differences were seen for time Copyright © Mary Ann Liebert, Inc.

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18. **Real-World Evidence of Off-Label Use of Commercially Automated Insulin Delivery Systems Compared to Multiple Daily Insulin Injections in Pregnancies Complicated by Type 1 Diabetes.**

Item Type: Journal Article

Authors: Quiros, Carmen;Herrera Arranz, Maria Teresa;Amigo, Judit;Wagner, Ana M.;Beato-Vibora, Pilar I.;Azriel-Mira, Sharona;Climent, Elisenda;Soldevila, Berta;Barquiel, Beatriz;Colomo, Natalia;Duran-Martinez, Maria;Corcoy, Rosa;Codina, Mercedes;Diaz-Soto, Gonzalo;Marquez Pardo, Rosa;Martinez-Brocca, Maria A.;Rebollo Roman, Angel;Lopez-Gallardo, Gema;Cuesta, Martin;Garcia Fernandez, Javier, et al

Publication Date: Aug ,2024

Journal: Diabetes Technology & Therapeutics 26(8), pp. 596–606

Abstract: Aims: To compare glycemic control and maternal-fetal outcomes of women with type 1 diabetes (T1D) using hybrid closed loop (HCL) versus multiple daily insulin injections (MDI) plus continuous glucose monitoring. Methods: Multicenter prospective cohort study of pregnant women with T1D in Spain. We evaluated HbA1c and time spent within (TIR), below (TBR), and above (TAR) the pregnancy-specific glucose range of 3.5-7.8 mmol/L. Adjusted models were performed for adverse pregnancy outcomes, including baseline maternal characteristics and center. Results: One hundred twelve women were included (HCL n = 59). Women in the HCL group had a longer duration of diabetes and higher rates of prepregnancy care. There was no between-group difference in HbA1c in any trimester. However, in the second trimester, MDI users had a greater decrease in HbA1c (-6.12 +/- 9.06 vs. -2.16 +/- 7.42 mmol/mol, P = 0.031). No difference in TIR (3.5-7.8 mmol/L) and TAR was observed between HCL and MDI users, but with a higher total insulin dose in the second trimester [+0.13 IU/kg.day)]. HCL therapy was associated with increased maternal weight gain during pregnancy (betaadjusted = 3.20 kg, 95% confidence interval [CI] 0.90-5.50). Regarding neonatal outcomes, newborns of HCL users were more likely to have higher birthweight (betaadjusted = 279.0 g, 95% CI 39.5-518.5) and macrosomia (ORadjusted = 3.18, 95% CI 1.05-9.67) compared to MDI users. These associations disappeared when maternal weight gain or third trimester HbA1c was included in the models. Conclusions: In a real-world setting, HCL users gained more weight during pregnancy and had larger newborns than MDI users, while achieving similar glycemic control in terms of HbA1c and TIR.

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World+Evidence+of+Off-Label+Use+of+Commercially+Automated+Insulin+Delivery+Systems+Compared+to+Multiple+Daily+Insulin+Injections+in+Pregnancies+Complicated+by+Type+1+Diabetes.&aulast=Quiros&pid=%3Cauthor%3EQuiros+C%3BHerrera+Arranz+MT%3BAmigo+J%3BWagner+AM%3BBeato-Vibora+PI%3BAzriel-Mira+S%3BCliment+E%3BSoldevila+B%3BBarquiel+B%3BColomo+N%3BDuran-Martinez+M%3BCorcoy+R%3BCodina+M%3BDiaz-Soto+G%3BMarquez+Pardo+R%3BMartinez-Brocca+MA%3BRebollo+Roman+A%3BLopez-Gallardo+G%3BCuesta+M%3BGarcia+Fernandez+J%3BGoya+M%3BVega+Guedes+B%3BMendoza+Mathison+LC%3BPerea+V%3C%2Fauthor%3E%3CAN%3E38417014%3C%2FAN%3E%3CDT%3EJournal+Article%3C%2FDT%3E

19. **MiniMedTM 780G Advanced Hybrid Closed-Loop System Study in Pregnant Women with Type 1 Diabetes.**

Item Type: Journal Article

Authors: Guibert, Clara;Amoura, Lamia;Rakotoarisoa, Luc;Plat, Francoise;Sonnet, Emmanuel;Lablanche, Sandrine;Treglia, Clemence;Sarde, Elisa;Leca, Viviane;Rimareix, Frederique;Melki, Vincent;Baucher, Franciane;Betari, Bouchra;Meyer, Laurent and Kessler, Laurence

Publication Date: Dec ,2023

Journal: Diabetes Technology & Therapeutics 25(12), pp. 893–901

Abstract: Background: Evaluate the impact of the MiniMed TM 780G advanced hybrid closed-loop (AHCL) system on the glucose profile of pregnant women with type 1 diabetes (T1D) and maternal-neonatal complications. Methods: From April 2021 to September 2022, pregnant women with T1D treated with the AHCL system were included in an observational multicenter retrospective study. Continuous glucose monitoring parameters were analyzed monthly during pregnancy as well as maternal-neonatal complications. Results: Thirteen pregnant women, including a twin pregnancy (age: 33 +/- 3 years, hemoglobin A1c [HbA1c]: 7.3% +/- 0.7%, insulin doses: 0.72 +/- 0.21 U/kg/day) were analyzed. At delivery, gestational age was 37 +/- 2 weeks. During first 2 weeks of pregnancy, time in range (TIR, 63-140 mg/dL) was 46% (34-55) and increased to 54% (51-59) (P P P 70% throughout pregnancy. Time below the range 70% throughout pregnancy. Time below the range P P P P = 0.005). The reported carbohydrate amount increased from 167 +/- 363 g/d during early pregnancy to 243 +/- 106 g/d (P Conclusion: The AHCL system provided good glucose control during pregnancy and recommendation targets were reached during the nocturnal period only. The maternal and neonatal complications remained high.

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265%3C%2FAN%3E%3CDT%3EJournal+Article%3C%2FDT%3E

20. **Listening to Women: Experiences of Using Closed-Loop in Type 1 Diabetes Pregnancy.**

Item Type: Journal Article

Authors: Lawton J.;Kimbell B.;Closs M.;Hartnell S.;Lee T.T.M.;Dover A.R.;Reynolds R.M.;Collett C.;BarnardKelly K.;Hovorka R.;Rankin D. and Murphy, H. R.

Publication Date: 2023

Journal: Diabetes Technology and Therapeutics 25(12), pp. 845–855

Abstract: Introduction: Recent high-profile calls have emphasized that women's experiences should be considered in maternity care provisioning. We explored women's experiences of using closed-loop during type 1 diabetes (T1D) pregnancy to inform decision-making about antenatal rollout and guidance and support given to future users. Method(s): We interviewed 23 closed-loop participants in the Automated insulin Delivery Among Pregnant women with T1D (AiDAPT) trial after randomization to closed-loop and *20 weeks later. Data were analyzed thematically. Result(s): Women described how closed-loop lessened the physical and mental demands of diabetes management, enabling them to feel more normal and sleep better. By virtue of spending increased time-in-range, women also worried less about risks to their baby and being judged negatively by health care professionals. Most noted that intensive input and support during early pregnancy had been crucial to adjusting to, and developing confidence in, the technology. Women emphasized that attaining pregnancy glucose targets still required ongoing effort from themselves and the health care team. Women described needing education to help them determine when, and how, to intervene and when to allow the closed-loop to operate without interference. All women reported more enjoyable pregnancy experiences as a result of using closed-loop; some also noted being able to remain longer in paid employment. Conclusion(s): Study findings endorse closed-loop use in T1D pregnancy by highlighting how the technology can facilitate positive pregnancy experiences. To realize fully the benefits of closed-loop, pregnant women would benefit from initial intensive oversight and support together with closed-loop specific education and training. Clinical Trial Registration number: NCT04938557.Copyright © Julia Lawton, et al., 2023.

URL: https://libkey.io/libraries/2828/openurl?genre=article&sid=OVID:embase&id=pmid:37795883&id=doi:10.1089%2Fdia.2023.0323&issn=1520-9156&isbn=&volume=25&issue=12&spage=845&pages=845-855&date=2023&title=Diabetes+Technology+and+Therapeutics&atitle=Listening+to+Women%3A+Experiences+of+Using+Closed-Loop+in+Type+1+Diabetes+Pregnancy&aulast=Lawton&pid=%3Cauthor%3ELawton+J.%3BKimbell+B.%3BCloss+M.%3BHartnell+S.%3BLee+T.T.M.%3BDover+A.R.%3BReynolds+R.M.%3BCollett+C.%3BBarnard-Kelly+K.%3BHovorka+R.%3BRankin+D.%3BMurphy+H.R.%3C%2Fauthor%3E%3CAN%3E2029196217%3C%2FAN%3E%3CDT%3EArticle%3C%2FDT%3E

21. **Automated Insulin Delivery in Women with Pregnancy Complicated by Type 1 Diabetes.**

Item Type: Journal Article

Authors: Lee T.T.M.;Collett C.;Bergford S.;Hartnell S.;Scott E.M.;Lindsay R.S.;Hunt K.F.;McCance D.R.;BarnardKelly K.;Rankin D.;Lawton J.;Reynolds R.M.;Flanagan E.;Hammond M.;Shepstone L.;Wilinska M.E.;Sibayan J.;Kollman C.;Beck R.;Hovorka R., et al

Publication Date: 2023

Journal: New England Journal of Medicine 389(17), pp. 1566–1578

Abstract: Background Hybrid closed-loop insulin therapy has shown promise for management of type 1 diabetes during pregnancy; however, its efficacy is unclear. Methods In this multicenter, controlled trial, we randomly assigned pregnant women with type 1 diabetes and a glycated hemoglobin level of at least 6.5% at nine sites in the United Kingdom to receive standard insulin therapy or hybrid closed-loop therapy, with both groups using continuous glucose monitoring. The primary outcome was the percentage of time in the pregnancy-specific target glucose range (63 to 140 mg per deciliter [3.5 to 7.8 mmol per liter]) as measured by continuous glucose monitoring from 16 weeks' gestation until delivery. Analyses were performed according to the intention-to-treat principle. Key secondary outcomes were the percentage of time spent in a hyperglycemic state (glucose level >140 mg per deciliter), overnight time in the target range, the glycated hemoglobin level, and safety events. Results A total of 124 participants with a mean (+/-SD) age of 31.1+/-5.3 years and a mean baseline glycated hemoglobin level of 7.7+/-1.2% underwent randomization. The mean percentage of time that the maternal glucose level was in the target range was 68.2+/-10.5% in the closed-loop group and 55.6+/-12.5% in the standard-care group (mean adjusted difference, 10.5 percentage points; 95% confidence interval [CI], 7.0 to 14.0; PCopyright © 2023 Massachusetts Medical Society.

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22. **At-Home Use of a Pregnancy-Specific Zone-MPC Closed-Loop System for Pregnancies Complicated by Type 1 Diabetes: A Single-Arm, Observational Multicenter Study.**

Item Type: Journal Article

Authors: Levy C.J.;Kudva Y.C.;Ozaslan B.;Castorino K.;O'malley G.;Kaur R.J.;Levister C.M.;Church M.M.;Desjardins D.;McCradySpitzer S.;Ogyaadu S.;Trinidad M.C.;Reid C.;Rizvi S.;Deshpande S.;Zaniletti I.;Kremers W.K.;Pinsker J.E.;Doyle F.J. and Dassau, E.

Publication Date: 2023

Journal: Diabetes Care 46(7), pp. 1425–1431

Abstract: OBJECTIVE There are no commercially available hybrid closed-loop insulin delivery systems customized to achieve pregnancy-specific glucose targets in the U.S. This study aimed to evaluate the feasibility and performance of at-home use of a zone model predictive controller-based closed-loop insulin delivery system customized for pregnancies complicated by type 1 diabetes (CLC-P). RESEARCH DESIGN AND METHODS Pregnant women with type 1 diabetes using insulin pumps were enrolled in the second or early third trimester. After study sensor wear collecting run-in data on personal pump therapy and 2 days of supervised training, participants used CLC-P targeting 80-110 mg/dL during the day and 80-100 mg/dL overnight running on an unlocked smartphone at home. Meals and activities were unrestricted through-out the trial. The primary outcome was the continuous glucose monitoring percentage of time in the target range 63-140 mg/dL versus run-in. RESULTS Ten participants (HbA1c 5.8 +/- 0.6%) used the system from mean gestational age of 23.7 +/- 3.5 weeks. Mean percentage time in range increased 14.1 percentage points, equivalent to 3.4 h per day, compared with run-in (run-in 64.5 +/- 16.3% versus CLC-P 78.6 +/- 9.2%; P = 0.002). During CLC-P use, there was significant decrease in both time over 140 mg/dL (P = 0.033) and the hypoglycemic ranges of less than 63 mg/dL and 54 mg/dL (P = 0.037 for both). Nine participants exceeded consensus goals of above 70% time in range during CLC-P use. CONCLUSIONS The results show that the extended use of CLC-P at home until delivery is feasible. Larger, randomized studies are needed to further evaluate system efficacy and pregnancy outcomes.Copyright © 2023 by the American Diabetes Association.

23. **Expert Guidance on Off-Label Use of Hybrid Closed-Loop Therapy in Pregnancies Complicated by Diabetes.**

Item Type: Journal Article

Authors: Szmuilowicz E.D.;Levy C.J.;Buschur E.O. and Polsky, S.

Publication Date: 2023

Journal: Diabetes Technology and Therapeutics 25(5), pp. 363–373

Abstract: Automated insulin delivery (AID) systems have established benefits in terms of glycemic control, health outcomes, and quality of life and are strongly recommended for people with type 1 diabetes outside of pregnancy. While evidence for use of investigational AID systems during pregnancy is promising, data and guidance are still needed regarding use of commercially available systems during pregnancy. Unfortunately, none of the hybrid closed-loop (HCL) systems that are currently available in the United States have glucose targets that are as aggressive as pregnancy glycemic targets, none have a pregnancy-specific algorithm, and none are approved for use during pregnancy. As such, any use of these systems during pregnancy is considered off-label in the United States and would be "assisted"by provider/user techniques. Despite these limitations, many women conceive while using clinically available HCL systems and may be hesitant to cease use during pregnancy. Achievement of strict pregnancy glycemic targets can be difficult, and it is conceivable that selective off-label use of clinically available HCL systems in some women could lead to improved glycemia. We herein offer expert guidance based on clinical experience and available case reports on how to identify appropriate candidates for HCL therapy in pregnancy, how to counsel pregnant women with diabetes on the potential risks and benefits of HCL therapy during pregnancy, and how to manage commercially available systems off-label throughout gestation in an assisted HCL approach.Copyright © 2023 Mary Ann Liebert, Inc.

24. **The role of technology in the care of diabetes mellitus in pregnancy: an expert review.**

Item Type: Journal Article

Authors: Thayer S.M.;Williams K.J. and Lawlor, M. L.

Publication Date: 2023

Journal: AJOG Global Reports 3(3) (pagination), pp. Article Number: 100245. Date of Publication: 01 Aug 2023

Abstract: Diabetes mellitus is one of the most commonly encountered pregnancy complications and is associated with multiple adverse perinatal outcomes. Technology has progressed to address the unique challenges patients face in managing diabetes mellitus in pregnancy. Technology has bolstered diabetes mellitus education with smartphone applications focused on nutrition counseling and carbohydrate intake advice. Continuous glucose monitors and insulin infusion systems have shown benefit by simplifying glycemic monitoring and insulin administration. Improvements in glycemic control and perinatal outcomes have been seen with continuous glucose monitor use when compared with intermittent blood glucose monitoring, and more pregnant people are using insulin pumps instead of multiple daily insulin injections. Hybrid closed-loop systems are emerging and are able to integrate continuous glucose monitoring and insulin pump technologies while maximizing automated features in the nonpregnant population, but these have not been endorsed for use in pregnancy yet. Applying telehealth practices has been associated with high patient satisfaction among those with diabetes mellitus in pregnancy, and leveraging remote patient monitoring through telehealth platforms and short-range wireless technologies can reduce the burden of patient visits. As technology becomes more integrated into routine management of diabetes mellitus in pregnancy, practitioners should emphasize individualized counseling and device selection to ensure patient autonomy and safety.Copyright © 2023

25. **What's new in the management of type 1 diabetes in pregnancy?.**

Item Type: Journal Article

Authors: Lee T.T. and Murphy, H. R.

Publication Date: 2022

Journal: British Journal of Hospital Medicine (London, England : 2005) 83(12), pp. 1–10

Abstract: Type 1 diabetes in pregnancy is associated with an increased risk of complications for both mother and fetus. However, managing glycaemia during pregnancy to reduce these risks is challenging, owing to changes in insulin resistance with advancing gestation, as well as increased daily variation in insulin pharmacokinetics. These factors can add significant psychological and daily self-care burden to mothers during what may already be an anxious time. Increasingly, diabetes technologies are being used during pregnancy to improve and facilitate diabetes self-care. While these can be empowering for people with type 1 diabetes, careful consideration is required in relation to how and when these can be continued safely in the inpatient setting (including acute antenatal admissions, labour and delivery) and when extra support is required from adequately trained healthcare professionals. This article describes current forms of diabetes technologies used and the latest national guidance relating to the care of type 1 diabetes in pregnancy.

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26. **AiDAPT: automated insulin delivery amongst pregnant women with type 1 diabetes: a multicentre randomized controlled trial - study protocol.**

Item Type: Journal Article

Authors: Lee T.T.M.;Collett C.;Man M.S.;Hammond M.;Shepstone L.;Hartnell S.;Gurnell E.;Byrne C.;Scott E.M.;Lindsay R.S.;Morris D.;Brackenridge A.;Dover A.R.;Reynolds R.M.;Hunt K.F.;McCance D.R.;BarnardKelly K.;Rankin D.;Lawton J.;Bocchino L.E., et al

Publication Date: 2022

Journal: BMC Pregnancy and Childbirth 22(1) (pagination), pp. Article Number: 282. Date of Publication: 01 Dec 2022

Abstract: Background: Pregnant women with type 1 diabetes strive for tight glucose targets (3.5-7.8 mmol/L) to minimise the risks of obstetric and neonatal complications. Despite using diabetes technologies including continuous glucose monitoring (CGM), insulin pumps and contemporary insulin analogues, most women struggle to achieve and maintain the recommended pregnancy glucose targets. This study aims to evaluate whether the use of automated closed-loop insulin delivery improves antenatal glucose levels in pregnant women with type 1 diabetes. Methods/design: A multicentre, open label, randomized, controlled trial of pregnant women with type 1 diabetes and a HbA1c of >=48 mmol/mol (6.5%) at pregnancy confirmation and 7.8 mmol/l), standard CGM metrics, HbA1c and psychosocial functioning and health economic measures. Safety outcomes include the number and severity of ketoacidosis, severe hypoglycaemia and adverse device events. Discussion(s): This will be the largest randomized controlled trial to evaluate the impact of closed-loop insulin delivery during type 1 diabetes pregnancy. Trial registration: ISRCTN 56898625 Registration Date: 10 April, 2018.Copyright © 2022, The Author(s).

27. **Carbohydrate Intake and Closed-Loop Insulin Delivery System during Two Subsequent Pregnancies in Type 1 Diabetes.**

Item Type: Journal Article

Authors: Munda A.;Kovacic C. and Pongrac Barlovic, D.

Publication Date: 2022

Journal: Metabolites 12(11) (pagination), pp. Article Number: 1137. Date of Publication: 01 Nov 2022

Abstract: Carbohydrate intake is one of the main determinants of glycemic control. In pregnancy, achievement of tight glycemic control is of utmost importance; however, data on the role of hybrid closed-loop systems (HCLs) in pregnancy are scarce. Therefore, we aimed to assess glycemic control achieved through the use of HCLs, and its association with carbohydrate intake in type 1 diabetes pregnancy. We included data from women with a sensor-augmented pump (SAP) during their first pregnancy and HCL use during the subsequent pregnancy. Student's paired t-test was used to compare data between both pregnancies. Six women were identified, with age 30.2 +/- 3.6 vs. 33.0 +/- 3.6 years, diabetes duration 23 +/- 5 vs. 26 +/- 5 years, and baseline HbA1c 6.7 +/- 0.7% (50.1 +/- 7.7 mmol/mol) vs. 6.3 +/- 0.6% (45.2 +/- 6.5 mmol/moll) in the first and second pregnancies, respectively. Time with glucose in the range 3.5-7.8 mmol/L was 69.1 +/- 6.7 vs. 78.6 +/- 7.4%, p = 0.045, with the HCLs compared to SAP. Higher meal frequency, but not the amount of carbohydrate consumption, was associated with more time spent in the target range and lower glycemic variability. HCLs and meal frequency were associated with better glycemic control in a small series of pregnant women with type 1 diabetes. Whether this translates to better perinatal outcomes remains to be seen.

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28. **A Systematic Review of Collective Evidences Investigating the Effect of Diabetes Monitoring Systems and Their Application in Health Care.**

Item Type: Journal Article

Authors: Kamusheva, Maria;Tachkov, Konstantin;Dimitrova, Maria;Mitkova, Zornitsa;Garcia-Saez, Gema;Hernando, M. Elena;Goettsch, Wim and Petrova, Guenka

Publication Date: 2021

Journal: Frontiers in Endocrinology 12, pp. 636959

Abstract: Introduction: Diabetes monitoring systems (DMS) are a possible approach for regular control of glucose levels in patients with Type 1 or 2 diabetes in order to improve therapeutic outcomes or to identify and modify inappropriate patient behaviors in a timely manner. Despite the significant number of studies observing the DMS, no collective evidence is available about the effect of all devices. Goal: To review and consolidate evidences from multiple systematic reviews on the diabetes monitoring systems and the outcomes achieved. Materials and methods: Internet-based search in PubMed, EMBASE, and Cochrane was performed to identify all studies relevant to the research question. The data regarding type of intervention, type of diabetes mellitus, type of study, change in clinical parameter(s), or another relevant outcome were extracted and summarized. Results: Thirty-three out of 1,495 initially identified studies, involving more than 44,100 patients with Type 1, Type 2, or gestational diabetes for real-time or retrospective Continuous Glucose Monitoring (CGMS), Sensor Augmented Pump Therapy (SAPT), Self-monitoring Blood Glucose (SMBG), Continuous subcutaneous insulin infusion (CSII), Flash Glucose Monitoring (FGM), Closed-loop systems and telemonitoring, were included. Most of the studies observed small nominal effectiveness of DMS. In total 11 systematic reviews and 15 meta-analyses, with most focusing on patients with Type 1 diabetes (10 and 6, respectively), reported a reduction in glycated hemoglobin (HbA1c) levels from 0.17 to 0.70% after use of DMS. Conclusion: Current systematic review of already published systematic reviews and meta-analyses suggests that no statistically significant difference exists between the values of HbA1c as a result of application of any type of DMS. The changes in HbA1c values, number and frequency of hypoglycemic episodes, and time in glucose range are the most valuable for assessing the appropriateness and effectiveness of DMS. Future more comprehensive studies assessing the effectiveness, cost-effectiveness, and comparative effectiveness of DMS are needed to stratify them for the most suitable diabetes patients' subgroups. Copyright © 2021 Kamusheva, Tachkov, Dimitrova, Mitkova, Garcia-Saez, Hernando, Goettsch and Petrova.

29. **Case series of a hybrid closed-loop system used in pregnancies in clinical practice.**

Item Type: Journal Article

Authors: Polsky S. and Akturk, H. K.

Publication Date: 2020

Journal: Diabetes/Metabolism Research and Reviews 36(3) (pagination), pp. Article Number: e3248. Date of Publication: 01 Mar 2020

Abstract: Background: Hybrid closed-loop (HCL) therapy is rarely studied in pregnancy. We present three cases of women with type 1 diabetes who used the Medtronic 670G HCL system for most or all of gestation. Method(s): The Medtronic 670G system has a manual mode (no automated insulin delivery) and an auto mode (AM, HCL therapy). Women in this case series used AM off-label in gestation. Result(s): Case 1 started HCL therapy in the second trimester, her sensor glucose time spent 10 mmol/L improved thereafter. Case 1 had average sensor glucose (ASG) levels of 6.4 +/- 2.4 mmol/L in the first trimester, 7.0 +/- 2.7 mmol/L in the second trimester before HCL use, 7.1 +/- 2.1 mmol/L in the second trimester after HCL use, and 6.8 +/- 1.9 mmol/L in the third trimester. Case 1 continued AM during operative delivery and post-partum. Cases 2 and 3 used HCL therapy throughout gestation but with inconsistent time in AM. When they increased time in AM their glycaemic indices improved. Case 2 had ASG of 9.5 +/- 3.4, 8.6 +/- 2.9, and 7.9 +/- 2.5 mmol/L in the first through third trimesters, respectively. Case 3 had ASG of 11.1 +/- 4.8 and 3.9 to 10 mmol/L in the first and second trimesters, respectively. Case 2 continued HCL therapy post-partum, Case 3 did not. Conclusion(s): CareLink Clinical Software only reports the non-pregnant time in range. Nonetheless, this represents the first report of HCL therapy in pregnancy with a system approved by the Food and Drug Administration in non-pregnant populations.Copyright © 2019 John Wiley & Sons Ltd

30. **Women's Experiences of Day-and-Night Closed-Loop Insulin Delivery During Type 1 Diabetes Pregnancy.**

Item Type: Journal Article

Authors: Farrington C.;Stewart Z.;Hovorka R. and Murphy, H.

Publication Date: 2018

Journal: Journal of Diabetes Science and Technology 12(6), pp. 1125–1131

Abstract: Aims: Closed-loop insulin delivery has the potential to improve day-to-day glucose control in type 1 diabetes pregnancy. However, the psychosocial impact of day-and-night usage of automated closed-loop systems during pregnancy is unknown. Our aim was to explore women's experiences and relationships between technology experience and levels of trust in closed-loop therapy. Method(s): We recruited 16 pregnant women with type 1 diabetes to a randomized crossover trial of sensor-augmented pump therapy compared to automated closed-loop therapy. We conducted semistructured qualitative interviews at baseline and follow-up. Findings from follow-up interviews are reported here. Result(s): Women described benefits and burdens of closed-loop systems during pregnancy. Feelings of improved glucose control, excitement and peace of mind were counterbalanced by concerns about technical glitches, CGM inaccuracy, and the burden of maintenance requirements. Women expressed varied but mostly high levels of trust in closed-loop therapy. Conclusion(s): Women displayed complex psychosocial responses to day-and-night closed-loop therapy in pregnancy. Clinicians should consider closed-loop therapy not just in terms of its potential impact on biomedical outcomes but also in terms of its impact on users' lives.Copyright © 2018 Diabetes Technology Society.

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31. **Day-and-night closed-loop insulin delivery in a broad population of pregnant women with type 1 diabetes: A randomized controlled crossover trial.**

Item Type: Journal Article

Authors: Stewart Z.A.;Wilinska M.E.;Hartnell S.;O'Neil L.K.;Rayman G.;Scott E.M.;Barnard K.;Farrington C.;Hovorka R. and Murphy, H. R.

Publication Date: 2018

Journal: Diabetes Care 41(7), pp. 1391–1399

Abstract: OBJECTIVE Despite advances in technology, optimal glucose control remains elusive and neonatal complications remain ubiquitous in type 1 diabetes (T1D) pregnancy. Our aim was to examine the safety, efficacy, and longer-term feasibility of day-and-night closed-loop insulin delivery. RESEARCH DESIGN AND METHODS We recruited 16 pregnant women (mean [SD]: age 32.8 [5.0] years, T1D duration 19.4 [10.2] years, HbA1c 8.0% [1.1], and BMI 26.6 [4.4] kg/m2) to an open-label, randomized, crossover trial. Participants completed 28 days of closed-loop and sensor-augmented pump (SAP) insulin delivery separated by a washout period. Afterward, participants could continue to use the closed-loop system up to 6 weeks postpartum. The primary end point was the proportion of time with glucose levels within the target range (63-140 mg/dL). RESULTS The proportion of time with glucose levels within target was comparable during closed-loop and SAP insulin delivery (62.3 vs. 60.1% [95% CI 24.1 to 8.3]; P = 0.47). Mean glucose and time spent hyperglycemic >140 mg/dL also did not differ (131.4 vs. 131.4 mg/dL [P = 0.85] and 36.6 vs. 36.1% [P = 0.86], respectively). During closed-loop, fewer hypoglycemic episodes occurred (median 8 [range 1-17] vs. 12.5 [1-53] over 28 days; P = 0.04) and less time at) to an open-label, randomized, crossover trial. Participants completed 28 days of closed-loop and sensor-augmented pump (SAP) insulin delivery separated by a washout period. Afterward, participants could continue to use the closed-loop system up to 6 weeks postpartum. The primary end point was the proportion of time with glucose levels within the target range (63-140 mg/dL). RESULTS The proportion of time with glucose levels within target was comparable during closed-loop and SAP insulin delivery (62.3 vs. 60.1% [95% CI 24.1 to 8.3]; P = 0.47). Mean glucose and time spent hyperglycemic >140 mg/dL also did not differ (131.4 vs. 131.4 mg/dL [P = 0.85] and 36.6 vs. 36.1% [P = 0.86], respectively). During closed-loop, fewer hypoglycemic episodes occurred (median 8 [range 1-17] vs. 12.5 [1-53] over 28 days; P = 0.04) and less time at) to an open-label, randomized, crossover trial. Participants completed 28 days of closed-loop and sensor-augmented pump (SAP) insulin delivery separated by a washout period. Afterward, participants could continue to use the closed-loop system up to 6 weeks postpartum. The primary end point was the proportion of time with glucose levels within the target range (63-140 mg/dL). RESULTS The proportion of time with glucose levels within target was comparable during closed-loop and SAP insulin delivery (62.3 vs. 60.1% [95% CI 24.1 to 8.3]; P = 0.47). Mean glucose and time spent hyperglycemic >140 mg/dL also did not differ (131.4 vs. 131.4 mg/dL [P = 0.85] and 36.6 vs. 36.1% [P = 0.86], respectively). During closed-loop, fewer hypoglycemic episodes occurred (median 8 [range 1-17] vs. 12.5 [1-53] over 28 days; P = 0.04) and less time at Copyright © 2018 by the American Diabetes Association.

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Search Strategy

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2	"closed-loop therapy".kw.	12
3	1 or 2	175818
4	exp Pregnancy in Diabetics/ or exp Diabetes, Gestational/	29472
5	(diabet* adj3 pregnan*).tw,kw.	12519
6	(GDM or gestational diabetes).tw,kw.	25882
7	4 or 5 or 6	42040
8	3 and 7	103
9	limit 8 to (english language and yr="2020 -Current")	62
10	from 9 keep 1-4,6-11,13,17,20-23,28-30,34,36,39-40,45,56,59	26

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1	closed-loop therapy.tw,kw.	223
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3	exp maternal diabetes mellitus/	61967
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5	(GDM or gestational diabetes).tw,kw.	40472
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7	1 and 6	11
8	from 7 keep 1-7,10-11	9
9	closed-loop.tw,kw.	20930
10	6 and 9	85
11	limit 10 to english language	82
12	from 11 keep 2-4,6-7,14,18-19,22-25,29-30,40,42-43,56,63,65	20
13	"Hybrid closed-loop therapy".kw.	7
14	6 and 13	3