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Long-term real-world outcomes of hybrid closed-loop therapy in adults with type 1 diabetes in the UK

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Abstract:

Background and aims: The National Health Service (NHS) England adult hybrid-closed loop (HCL) pilot provided access to HCL for people attending adult diabetes services with a diagnosis of type 1 diabetes (T1D), managed with an insulin pump and intermittently scanned continuous glucose monitoring, with an HbA1c $\geq 8.5\%$ (69 mmol/mol). We aimed to assess longitudinal changes in glycaemic and patient-reported outcomes in this population.

Materials and methods: Anonymized clinical data were submitted to a secure web-based tool within the NHS network in a platform designed by the Association of British Clinical Diabetologists. HbA1c, sensor glucometrics, diabetes distress scale (DDS) score and Gold score (hypoglycemia awareness) changes between baseline and follow-up were assessed. Analysis was performed using SPSS 28.0.

Results: Over a median follow-up of 20.4 months (IQR 15.6-22.8), 150 adults from 12 centers with paired baseline and follow-up HbA1c data available were included [64.7% female; 90.7% White; median age 38 years (IQR 29-51) and diabetes duration 20 years (IQR 13-27)]. Baseline HbA1c was $9.3 \pm 1.2\%$ (78.5 ± 13.2 mmol/mol) and reduced by 1.6% (95% CI -1.4, -1.7; $P < 0.001$) (-17.1 mmol/mol [95% CI -15.4, -18.9]; $P < 0.001$) at follow-up. Time in range (TIR) (3.9-10.0 mmol/L) increased from 37.7% at baseline to 62.1% at follow-up ($P < 0.001$). Gold score decreased by 0.6 (95% CI -0.3, -0.9; $P < 0.001$) and DDS score reduced by 1.4 (95% CI -1.0, -1.7; $P < 0.001$). One fifth (17.3%, 26/150) achieved HbA1c $< 7.0\%$ (53 mmol/mol) at follow-up. At baseline, 2.7% of our cohort met the internationally recommended target of $> 70\%$ TIR, increasing to 36.3% (41 of 113) at follow-up ($P < 0.001$). Gold ≥ 4 was reported in 23.7% at baseline vs. 7.9% at follow-up ($P = 0.004$). Changes in glycaemic and patient-reported outcomes are shown in Table 1.

Conclusion: HCL therapy is associated with long-term improvements in HbA1c, TIR, hypoglycaemia and diabetes-related distress in adults with T1D in the real world.

Table 1. Baseline and follow-up HbA1c, continuous glucose monitoring metrics and patient-reported outcome measures

	N	Baseline	Follow-up	Change (95% CI)	P
HbA1c, mmol/mol	150	78.5 ± 13.2	61.4 ± 10.7	-17.1 (-15.4, -18.9)	<0.001
HbA1c, %	150	9.3 ± 1.2	7.7 ± 1.0	-1.6 (-1.4, -1.7)	<0.001
Time above range, level 2 (> 13.9 mmol/L), % †	150	34.2 ± 18.3	19.9 ± 9.8	-20.8 (-17.8, -24.3)	<0.001
Time above range, level 1 ($10.1-13.9$ mmol/L), % †	107	25.5 ± 11.5	22.8 ± 8.7	-2.7 (0.06, -5.4)	0.06
Time in range (3.9-10.0 mmol/L), % †	113	37.7 ± 15.9	62.1 ± 13.5	24.4 (21.5, 27.3)	<0.001
Time below range, level 1 (3.0-3.9 mmol/L), % †	111	2.0 ± 2.6	1.1 ± 1.6	-0.9 (0.4, -1.4)	0.001
Time below range, level 2 (< 3.0 mmol/L), % †	114	0.9 ± 1.4	0.2 ± 0.5	-0.7 (1.0, -0.6)	0.005
Coefficient of variation, % †	87	38.1 ± 8.8	34.4 ± 7.8	-3.7 (-1.4, -6.0)	0.002
Gold score	76	2.4 ± 1.7	1.8 ± 1.3	-0.6 (-0.3, -0.9)	0.001
Diabetes distress scale score	55	3.2 ± 1.4	1.8 ± 0.9	-1.4 (-1.0, -1.7)	<0.001

Data are mean \pm SD. †Data derived from intermittently scanned continuous glucose monitoring (ICGM) at baseline and real-time CGM at follow-up.

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