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RESULTS OF ADVANCED HYBRID CLOSED LOOP (TOUCHCARE NANO SYSTEM) IN TYPE 1 DIABETES PATIENTS IN ARGENTINA

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Introduction: Automated insulin delivery (also known as a closed-loop system) has shown potential to improve glycaemic control and quality of life in people with type 1 diabetes mellitus (DM1).

Objectives: To evaluate glycaemic outcomes in Argentine patients with well-controlled DM1 from different baseline treatments, using a structured initiation protocol for the TouchCare® Nano closed loop insulin patch pump (AHCL).

Materials and Methods: In this multi-centre, prospective, open-label, single-arm, prospective study, we invited patients with DM1 and HbA1c below 8.5% with different baseline treatments to participate. All participants followed a structured initiation protocol with four steps. The main outcome of this study was the change in the following parameters: time in range (TIR) 70-180 mg/dL, time in the tight range (TITR) 70-140 mg/dL, time below range (TBR) 70 mg/dL and HbA1c from baseline to the study phase. The TRIM-D questionnaire was administered at baseline and at the end of the study. Paired Student's t-test was used for statistical analysis and a value of $p<0.05$ was considered statistically significant.

Results: 20 participants were recruited and 18 completed the 16-week study. 12 (66.7%) were female, mean age was 21.7 years (7-46±12.6), previous treatments were: 26% (7) minimed 670, 22% (6) MDI, and the rest other non-HCL pumps. TIR increased from 61.58% ± 15.19 at baseline to 70.98% ±6.97 at 12 weeks ($p<0.011$). TITR increased from 37.89% ±16.2 at baseline to 48.32% ±7.55 at 12 weeks ($p<0.010$). After use of the AUTO MEAL function, TIR increased to 72.93% ±8.27 and TITR increased to 50.88% ±9.1 at week 16. As for TBR, there was no significant difference from 1.99% ±1.59 at baseline to 2.24% ±1.09 in the study phase ($p<0.12$). HbA1c decreased from 7.27% ±0.69 at baseline to 6.83% ±0.69 at the end of the study ($p<0.03$). At the end of the study, 69% of patients achieved the recommended TIR and 56% achieved the recommended TITR. The TRIM-D questionnaire showed an increase in satisfaction with the comfort and ease of treatment, including an improvement in the comfort of daily life and a decrease in the frequency of interference with other activities. No episodes of severe hypoglycemia or DKA were reported.

	Baseline		4 weeks		8 weeks		12 weeks		16 weeks		P1 value	P2 value
Variable	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Base vs.12w**	**12w vs. 16w**
HbA1c	7.27%	0.69	-	-	-	-	-	-	6.83%	0.69	0.0303	-
Auto Bolus	-	-	4.8	3.38	5.02	3.84	6.15	4.11	19.51	11.1	0.001	<0.0001
TIR 70-180	61.598	15.19	72.76	8.68	70.67	9.56	70.98	6.97	72.93	8.27	0.0114	0.3253
TAR 180	26.34	10.19	16.21	4.81	16.34	5.15	17.28	4.53	17.08	6.1	0.0011	0.8781
TAR 250	10.12	8.1	7.56	4.64	9.36	6.93	8.27	3.48	6.98	3.65	0.2369	0.1469
TBR 70	1.99	1.57	2.5	2.12	2.69	2.39	2.59	2.19	2.24	1.09	0.1579	0.3471
TBR 54	0.53	0.85	1.02	1.01	0.94	1.23	0.87	1.36	0.77	1.29	0.0450	0.8037
TITR 70-140	37.89	16.22	50.58	7.94	48.79	10.45	48.32	7.55	50.88	9.12	0.0104	0.1844
Average sensor glucose	163.68	22.61	148.5	14	151.2	17.87	151.7	12.3	148.6	12.51	0.0122	0.313
% time in auto mode	-	-	96.88	5.23	80.12	33.43	93.93	13.26	92.52	22.48	-	0.6347

Table 1

Variable	TIR Value	Initial		1 month		2 months		3 months		4 months		p
		n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	
Range 70-140	<50%	13	77.2	12	66.7	8	44.4	11	31.1	8	44.4	0.2093
	>50%	5	27.8	6	33.3	10	55.6	7	38.9	10	55.6	
Range 70-180	<70%	12	66.7	9	50	8	44.4	7	38.9	6	33.3	0.1979
	>70%	6	33.3	9	50	10	55.6	11	61.1	12	68.7	

Table 2

Conclusions: Patients with DM1, receiving various treatments and who initiated the TouchCare® Nano closed-loop patch pump system following a structured initiation protocol, improved their glycaemic metrics and achieved the internationally recommended glycaemic control targets of TIR >70%, TITR >50%, TBR <5% and HbA1c of <7%.