EFFICACY OF INSULCLOCK IN PATIENTS WITH POORLY CONTROLLED TYPE 1 DIABETES MELLITUS: A PILOT, RANDOMIZED, CLINICAL TRIAL

F. Gomez-Peralta[1], C. Abreu[1], S. Gomez-Rodriguez[1], M. Cruz-Bravo[1], C. María-Sánchez[1], G. Poza[1], L. Ruiz-Valdepeñas[2].

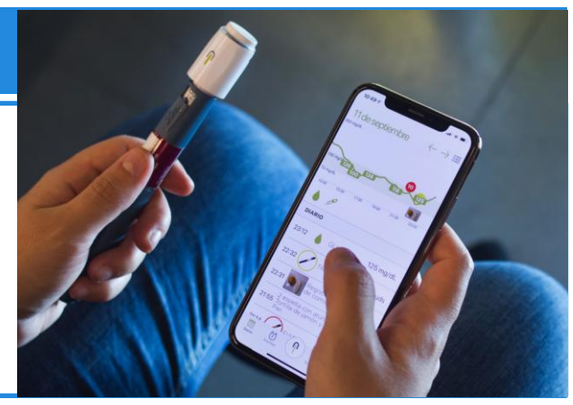
[1] Endocrinology and Nutrition Unit, Hospital General de Segovia, SEGOVIA, Spain

[2] Research and Development Unit, Insulcloud S.L. (B87131454), Bilbao, Spain.

Background

Insulclock® is an electronic device designed to improve treatment adherence and insulin injection tracking. The system includes several alarms and reminders for patients, regarding time of injection and temperature of conservation of the insulin. It also includes an app as a diabetic diary, where all the information is registered automatically, including SMBG, insulin injections and food intake. The information could be shared with caregivers and healthcare providers.[1]

This is the first pilot study to measure the clinical impact of this system in patients with T1DM.



Methods

This randomized, single-center, pilot study assessed glycemic control, missed and mistimed insulin doses and QoL after four weeks of *Insulclock* use in patients with uncontrolled T1DM and compared these outcomes with or without receiving reminders and app alerts (Active or Masked groups, respectively).

Participants self-administered rapid insulin with Humalog Kwikpen® pens coupled to *Insulclock* according to routine clinical practice. By means of acoustic and visual alarms, participants received information for a correct injection technique (an alert if injection time was <6 seconds) or to prevent stacking insulin (an alert if a previous injection was done within the 2 previous hours). Participants wore the masked Freestyle Libre Pro (Abbott Diabetes Care, Witney, Oxon, UK) for 14 days for CGM. Twenty-one participants were recruited and sixteen completed the study: ten in the Active group and six in the Masked group.

Statistical analyses Continuous variables were described by the mean, SD, median, IQR and extremes (Min, Max). Categorical variables were described by number and percentage. Comparisons between two independent groups for continuous variables were performed using the Student's *t*-test for unpaired data or the Chi-square test for categorical variables. The level of statistical significance was set at $p < 0.05$.

Table 1. Demographic and clinic characteristics of patients at baseline.

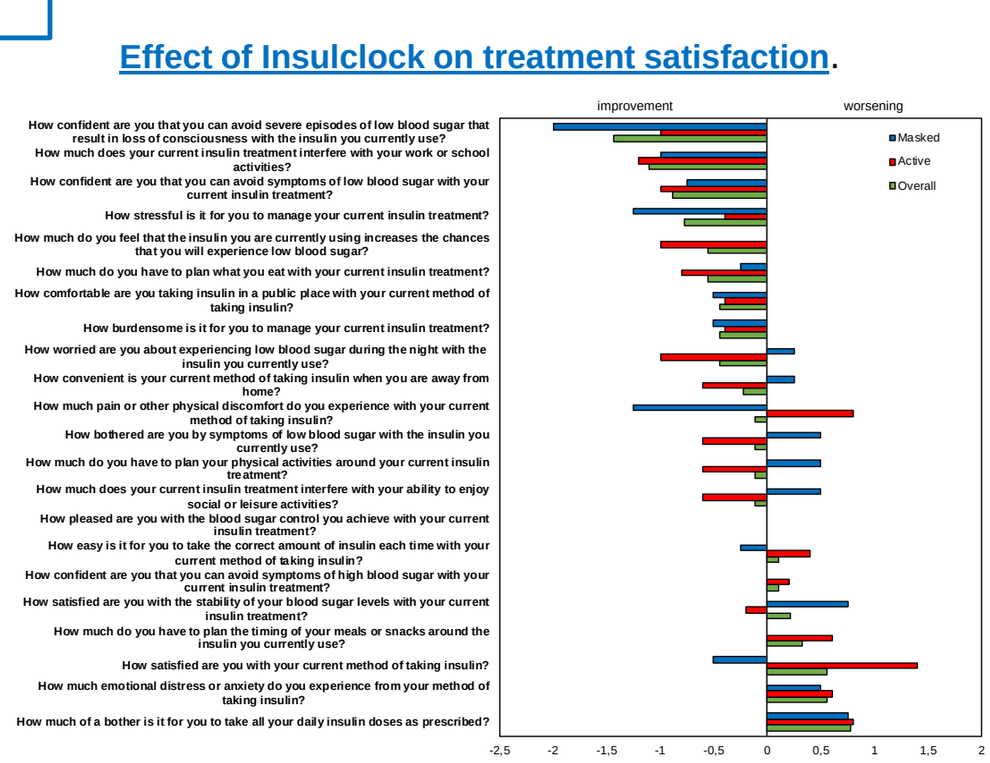
	Total	Active Insulclock	Masked Insulclock	P-value
Age (years)	40.1 (13.9)	43.1 (13.8)	35.2 (13.8)	0.285
Sex (male), n (%)	9 (56.3%)	5 (50.0%)	4 (66.7%)	0.515
Duration of diabetes (years)	20.4 (11.9)	20.9 (12.5)	19.5 (11.9)	0.828
Weight (kg)	69.4 (10.6)	65.2 (9.5)	75.1 (10.1)	0.085
BMI (kg/m^2)	24.8 (3.9)	23.2 (3.0)	27.0 (4.2)	0.070
Microvascular complications, n (%)				
Retinopathy	6 (37.5)	4 (40.0)	2 (33.3)	
Nephropathy	2 (12.5)	2 (20.0)	0 (0)	
Neuropathy	5 (31.3)	3 (30.0)	2 (33.3)	
SBP (mmHg)	121.9 (18.4)	118.0 (8.3)	126.8 (27.5)	0.515
DBP (mmHg)	75.0 (10.3)	72.4 (9.7)	78.3 (11.5)	0.434
Insulin (IU/kg)				
Long-acting	0.39 (0.21)	0.31 (0.09)	0.50 (0.27)	
Rapid-acting	0.41 (0.22)	0.34 (0.13)	0.50 (0.27)	

Data are expressed as mean (SD), except for sex and microvascular complications (%). BMI, Body Mass Index; SBP, systolic blood pressure; DBP, diastolic blood pressure. Statistical significance between groups was determined using either the Student's t-test or the Chi-square test for continuous or categorical variables, respectively.

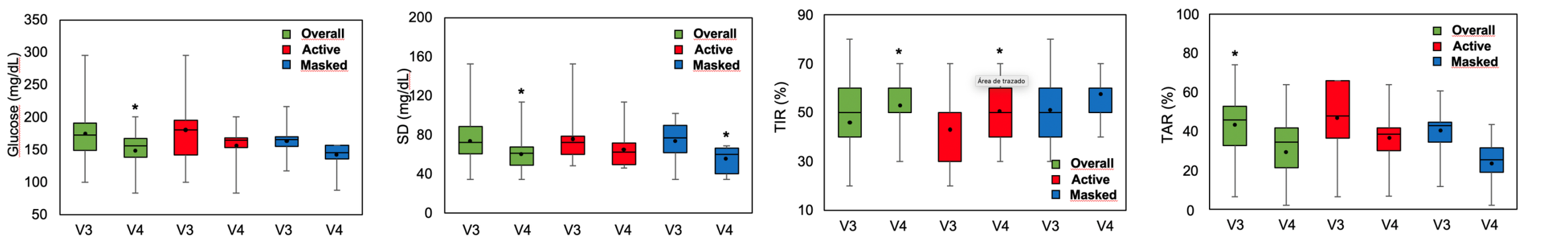
Results

Insulclock use was associated with a decrease in mean glucose (-27.0 mg/dL [1.5 mmol/L]; $p = 0.013$), glucose standard deviation (SD) (-14.4 mg/dL [0.8 mmol/L]; $p = 0.003$), and in time above range (TAR) (-12.5%, $p = 0.0026$), and an increase in time in range (TIR) (+7%; $p = 0.038$) in the overall population. The use of app information and alerts in the Active group was associated with an increase in TIR (+8%; $p = 0.026$). We observed a reduction in the number of missed insulin doses per month of -3.9 ($p = 0.1352$) and -5.4 ($p = 0.032$) in mistimed doses in the overall population. Most of the items of The Insulin Treatment Satisfaction Questionnaire (ITSQ) improved after four weeks of *Insulclock* use, and those related to the treatment interference in work/school activities and the potential of treatment to avoid hypoglycemic episodes showed statistical significance.

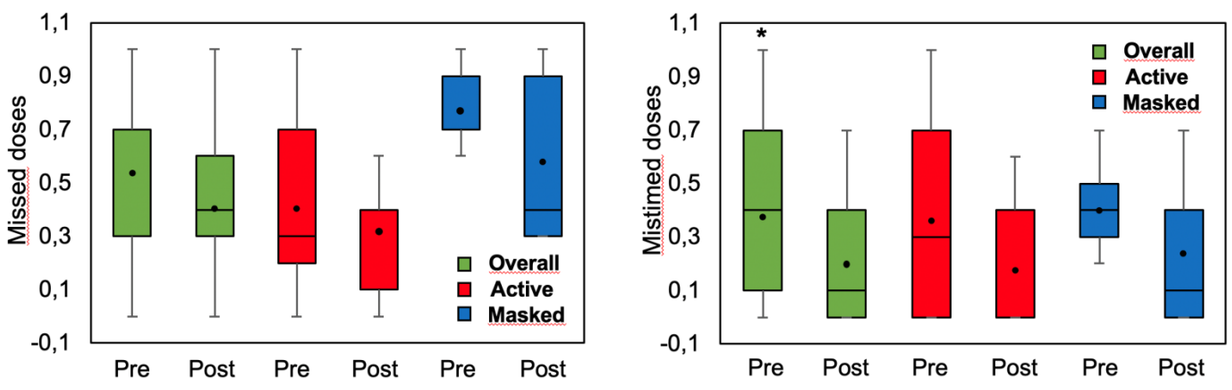
Effect of Insulclock on treatment satisfaction.



Glycaemic control



Adherence



Conclusions

This pilot study points out an **improvement in glycemic control, adherence and quality of life in T1DM patients using Insulclock**, supporting the development of clinical trials powered to confirm such a clinical benefit.

1.- Gomez-Peralta F et al. Insulclock: A novel insulin delivery optimization and tracking system. Diabetes Technol Ther 2019; 21: 209–214.

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