A Randomized Study To Evaluate The Efficacy Of Insulclock® Pen Device In Insulin-treated Patients With Uncontrolled Type 2 Diabetes

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Introduction

- Poor adherence to diabetes treatment is common and associated with increased risk of morbidity.
- Insulin pen devices have been reported to improve patient satisfaction and treatment adherence compared to the traditional vial/syringe.
- Insulclock® is a small electronic device plugged onto insulin pen to track information via Bluetooth to smart-phone technology on date, time and dosage of injections and with an alarm system to reduce insulin omissions.

Study Objectives

- To determine if Insulclock® system results in improved treatment adherence compared to conventional insulin pen device.
- To determine if the Insulclock® system results in higher treatment satisfaction compared to a conventional insulin pen device.
- To determine changes in HbA1c compared to conventional insulin pen device.

Methods

We performed a randomized, cross-over design study in patients with type 2 diabetes (T2D) on basal insulin (n: 82).

Patients on basal insulin ± oral agents with HbA1c between 7.0% and 12.0% were randomized to a 12-week 'intervention' phase (reminders) or to a 12-week 'control' phase without device feedback.

Basal insulin was titrated every 2 weeks to a target fasting and premeal glucose between 70-130 mg/dl.

Study outcomes included differences between groups on glycemic control, treatment adherence and satisfaction (DTSQc survey)

Results

Insulclock® System Flow

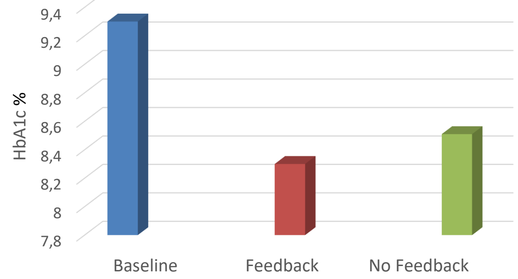
Changes in HbA1c and FBG

Variable	Mean (SD)
Baseline HbA1c, %	9.23 (1.53)
HbA1c change from baseline with feedback%	-0.09 (2.02)
HbA1c change from baseline without feedback, %	-0.72 (2.00)
Baseline BG (mg/dL)	201.41 ± 79.34
Average FBG with feedback, mg/dL	141.42 ± 33.71
Average FBG without feedback, mg/dL	149.25± 46.51

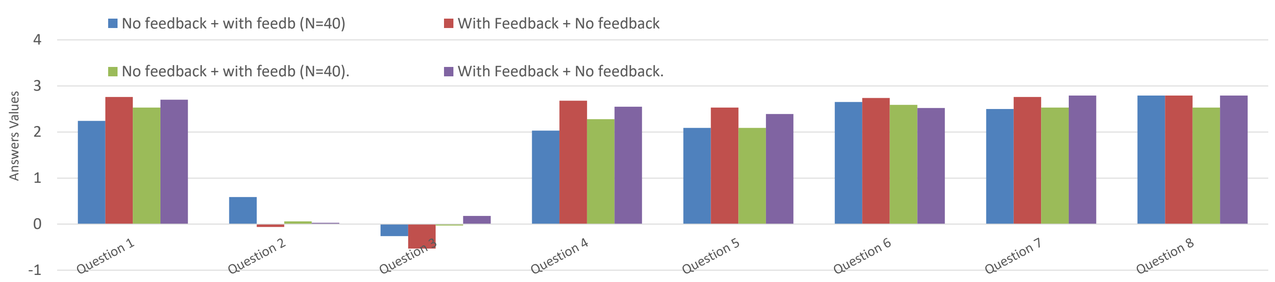
Demographics and Clinical Characteristics

Variable	Overall (N=80)
Age, years	55.73 ± 11.05
Sex, No. (%)	
. Female	44 (55)
. Male	36 (45)
Race, No. (%)	
. Black	73 (91)
. Hispanic	3 (3.8)
. White	4 (5.0)
Annual income, No. (%)	
. Over $20,000	27 (34)
. Under $20,000	53 (66)
Weight, kg	93.70 ± 25.14
BMI , kg/m²	32.40 ± 7.57
Diabetes duration, Median (Q1, Q3),years	10.0 (5.0, 15.0)
HbA1C, %	9.23 ± 1.53

Change in A1c from Baseline



DTSQc Satisfaction Questionnaire



Summary and Conclusions

- HbA1c improved significantly from baseline, with a reduction of 0.9 % in the intervention and 0.7% in the control group.
- Insulclock® improved glycemic control (estimated reduction in mean daily blood glucose (BG), fasting BG, and pre-meal BG of 6.03 (95% CI: [-3.21, 15.3]), 6.66 (95% CI: [-1.72, 15.04]), and 5.57 (95% CI: [-6.15, 17.31]) mg/dl, respectively, based on linear mixed models
- There were no differences in treatment adherence or on the rate of hypoglycemia.
- Patients were equally satisfied with the device during intervention and control phase (DTSQc 15.5±3.7 and 15.2±3.1, respectively).
- In conclusion, the use of Insulclock® resulted in improved glycemic control and overall good satisfaction in insulin treated patients with T2D.

Acknowledgement

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