USE OF AN AUTOMATED BOLUS CALCULATOR BY A TELEMEDICINE SYSTEM FOR THE MANAGEMENT OF INSULIN THERAPY IN TYPE 1 DIABETES PATIENTS

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INTRODUCTION

To obtain optimal glycaemic control in Type 1 Diabetes (T1D) patients on multiple daily injections (MDI), adjustments of insulin dose at meal times must be made by taking into account several parameters as blood glucose levels, the insulin/carbohydrate ratio, the carbohydrate intake at each meal. A bolus advisor system (Accu-Chek® Aviva Connect) developed for the establishment of the insulin dose to be administer, takes into account all above parameters.

Aim of this randomized trial was to evaluate the efficacy of a bolus advisor system on glycaemic control and patients compliance to Self-Monitoring of Blood Glucose (SMBG), using a telemedicine system.

MATERIALS AND METHODS

A total of 24 consecutive patients affected by T1D aged 18-65 years with disease duration > 1 year, were enrolled in the study.

HbA1c and patients compliance, assessed as average number of daily measurements and as total measurements, were evaluated at entry into the trial and at 3 and 6 months follow-up.

As secondary end-points the number of hypoglycaemic events and the total results above target range were evaluated. Paired t test (two tailed) and analysis of variance were used to evaluate differences in HbA1c at different time points.

DEMOGRAPHIC AND CLINICAL FEATURES OF T1D PATIENTS

	Carbs Counting (treated group)	No Carbs Counting (control group)	All patients	p-value
Age range (years) (mean ± SD)	36.62±9.39	37.55±7.15	37.04±8.27	0.7905
Disease duration (years) (mean ± SD)	16.15±14.26	12.91±9.25	14.67±12.09	0.5243
Gender Female Male	7/13 6/13	6/11 5/11	13/24 11/24	0.9727
HbA1c (%) (mean ± SD)	7.65±0.87	7.55±0.98	7.6±0.9	0.7766
BMI (kg/m²) (mean ± SD)	23.2±3.28	22.98±1.98	23.1±2.71	0.8491
Daily insulin requirement (IU/kg/day) (mean ± SD)	0.45±0.23	0.58±0.17	0.51±0.21	0.1570

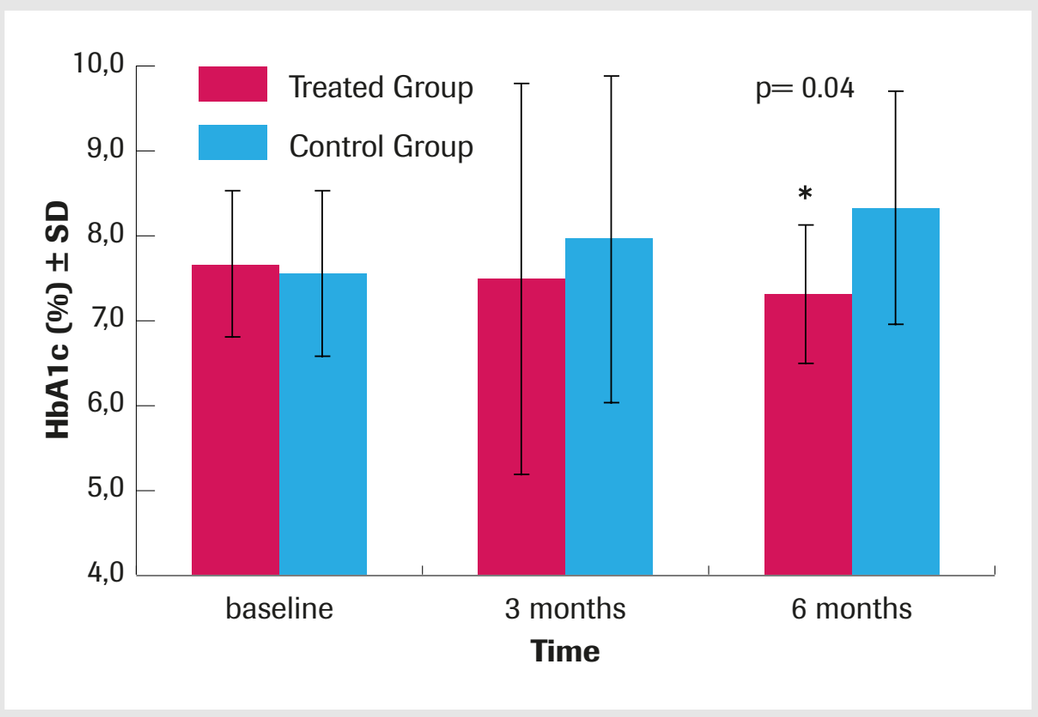
RESULTS

HbA1c at entry was 7.65% ±0.87 (SD) in patients using this bolus advisor system with bolus calculator and data transmission by App on a Smartphone activated and 7.55% ± 0.98 (SD) in the control group with bolus advisor turned off and on standard education for insulin management (p:NS).

After 3 months follow-up there was a tendency for an improvement in HbA1c in the active group vs. control group (7.49%±1.04 vs. 7.99%±2.04, respectively, p:NS).

After 6 months of observation, a significant reduction in HbA1c was observed in the active group vs. control subjects (7.32%±0.82 vs. 8.32±1.38 P=0.04).

A major compliance to SMBG assessed as mean number of daily measurements (P=0.03) and as total of the measurements for each quarter (P=0.02) was observed in active group vs. control group.



Variable	Visit	Difference	Lower 95% CL	Upper 95% CL	p-value
HbA1c	0-3 Months 3-6 Months	0,527 1,008	-0,583 0,258	1,637 1,759	0.3360 **0.04**
BMI	0-3 Months 3-6 Months	-0,122 0,580	-0,608 -0,242	0,364 1,403	0,6050 0,1564
Insulin requirement	0-3 Months 3-6 Months	0,047 0,066	-0,060 -0,034	0,154 0,165	0,3674 0,1823
Average glucose values (mg/dL)	0-3 Months 3-6 Months	3,224 -3,005	-32,690 -25,458	39,139 19,447	0,8518 0,7812
SD Average glucose values	0-3 Months 3-6 Months	1,520 0,143	-11,397 -13,988	14,436 14,274	0,8063 0,9833
Compliance SMBG Average Number Daily Measurements	0-3 Months 3-6 Months	-0,942 -1,765	-2,125 -3,428	0,241 -0,102	0,1116 **0,0387**
Total Measurements	0-3 Months 3-6 Months	0,853 0,396	0,472 0,178	1,543 0,880	0,5800 **0,0253**
Number of hypoglycaemic events	0-3 Months 3-6 Months	1,413 0,791	0,620 0,238	3,221 2,622	0,3890 0,6846
Total Results above target range	0-3 Months 3-6 Months	1,232 0,532	0,511 0,205	2,970 1,381	0,6254 0,1826

CONCLUSIONS

In conclusion, this bolus advisor system is a friendly wirelessly meter that helps to improve glycaemic control with the achievement of glycemic targets and the improvement of patients compliance to SMBG.