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Using insulin pump with a remote control system in patients with diabetes improves glycemic control and enhances patient satisfaction

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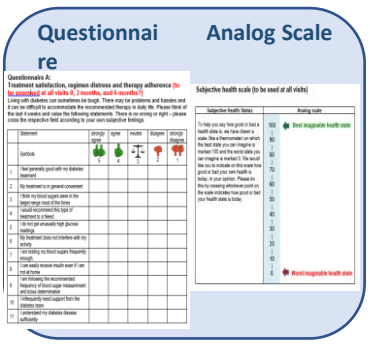
Background & Objective

Efficacy of insulin pump therapy in the management of T1DM is confirmed. Compliance with diabetes management tasks implies a considerable burden for young patients. The Accu-Check Combo system (ACCS) has advanced features to ease insulin delivery especially offering the use of a remote control. The aim of the study is to assess the effect of ACCS use on glycemic control and patient satisfaction in adolescent patients and young adults (age 12-30). We also aim to explore the suitability of the system for younger school children who may need assistance of parents or guardians.

Questionnaire / Analog Scale



Methods

The study is prospective and is undertaken in two centers. The primary study group included adolescent patients (12-17) and young adults (18-30). The secondary study group comprises school children aged 6-11. Relevant treatment parameters and patient satisfaction questionnaires were recorded at baseline and in 2 follow-up visits at 12 and 24 weeks. The intended size of the study (n=40) provides sufficient power (85%) to detect a mean individual decrease in HbA1c of 0.5%. Non-parametric Wilcoxon signed rank test was employed to analyze results. The effect on HbA1c was further analyzed by regression analysis in order to explore potential determinants of the therapeutic effect.

Results

43 patients were enrolled. Primary group n=28 (mean age 16, 12-28) and secondary n=15 (mean age 9, 6-11). Analysis data sets comprised 24 and 14 patients in the primary and secondary group. The development of parameters and of questionnaire results from baseline over visit1 to visit2 for the primary study group are summarized in Table 2. There was a mean decrease of HbA1c 1.05% (p<.0001) baseline to visit 2. There were significant increases in *general treatment satisfaction*, with the *perceived handling ease*, and with *subjective compliance*
There was a slight (6%) but significant decrease in average daily insulin (p=0.03). Regression analysis (Table 2a and Table 2b) revealed that patients with high baseline HbA1c profited most from the new system (p=0.0012). Also higher treatment satisfaction at visit 2 went along with better HbA1c decrease (p=0.0264). Results for the secondary study group (Table 3) were largely in parallel but partly failed statistical significance due to the lower sample size.
Safety: For the 3 months before baseline there were 15 and 12 reports of DKA and hypoglycemic events in the total group, respectively. For period 1 (baseline to visit1) there was one report of hypoglycemia, and for period2 (visit 1 to visit 2) no safety events were reported.

IN SHORT

Results Primary Group

- Mean decrease of HbA1c 1.05% (p<.0001) baseline to visit 2
- Significant increases in *general treatment satisfaction*, with the *perceived handling ease*, and with *subjective compliance*
- Slight (6%) but significant decrease in average daily insulin (p=0.03)
- Patients with high baseline HbA1c profited most from the new system (p=0.0012)
- Higher treatment satisfaction at visit 2 went along with better HbA1c decrease (p=0.0264)

Results for the *secondary study group* were largely in parallel.

Conclusion:

- Use of ACCS led to substantially improved glycemic control
- Improvement in particular for those with high baseline HbA1c
- Better HbA1c emerged from insulin-in-time and not by higher dose
- Satisfaction with the new system helped for better effects
- Use of ACCS led to favorable

Study scheme

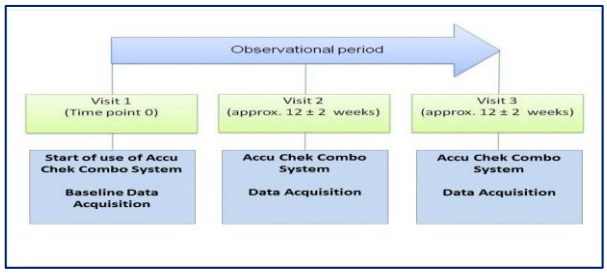


Table 1

Study Groups at Baseline	Primary Study Group Age 12 - 30 N=24		Secondary Study Group Age 6 - 11 N=14	
	Mean	Std	Mean	Std
Demography				
SEX [% female]	70.8	-	64.3	-
AGE [years]	16.0	4.0	9.0	1.7
WEIGHT [kg]	52.9	11.7	31.6	12.2
HEIGHT [cm]	156.1	8.3	130.3	12.6
BMI [kg/m²]	21.5	4.1	18.0	3.6
BMI PERCENTILE [%]	62.7	21.2	48.7	36.7
ETHNICITY [% UAE]	75.0	-	42.9	-
Status				
% married	4.2	-	-	-
% school	75.0	-	100.0	-
% college	16.7	-	-	-
% employed	8.3	-	-	-
Diabetes				
HbA1c [%]	9.7	1.7	8.7	1.9
DURATION DIABETES [y]	6.3	5.1	2.8	2.0

Table 2

Primary Study Group N=24 Age 12-30 y

	Baseline		Visit 1		Visit 2		
	Mean	STD	Mean	STD	Mean	STD	p-value [1]
Parameter							
HbA1c	9.7	1.7	8.5	1.3	8.6	1.2	0.00009
Average Daily Insulin	48.5	17.7	45.5	17.0	46.3	15.9	0.030
Average Blood Glucose	-	-	211.3	58.0	199.4	59.8	-
BPsys	113.7	9.4	113.4	10.2	114.9	9.9	0.239
BPdia	68.7	8.2	67.3	8.1	68.0	8.4	0.949
BMI	21.5	4.0	22.0	4.1	21.6	4.6	0.923
Subjective Perception of Therapy [2]							
Satisfaction Analog scale	56.3	12.5	70.2	13.5	75.7	12.6	0.00001
Satisfaction Questionnaire	61.7	18.8	73.9	16.4	79.3	10.5	0.00336
Subjective Handling Ease	44.8	16.7	64.1	20.9	75.3	17.3	0.00006
Subjective Compliance	47.4	16.5	60.7	13.7	70.6	10.5	0.00003

[1] p-value for development from baseline to visit 2 by Wilcoxon signed rank test
[2] Analog scale 0-100 = worst to best; the questionnaire ratings (1-5) were rescaled to 0 – 100;

2a

Regression: change in HbA1c*

N=24	Regression Coefficient	P-value
HbA1c at baseline	-0.49	0.002
SEX (female=1)	-0.58	0.21
AGE [years]	-0.06	0.35
Average Daily Insulin Period2	-0.002	0.91

Multiple regression analysis: dependent variable change HbA1c from baseline to visit2

2b

Regression: change in HbA1c*

N=24	Regression Coefficient	P-value
V2 Satisfaction Questionnaire	-0.04	0.019
V2 Subjective Handling Ease	0.03	0.142
V2 Subjective Compliance	-0.02	0.543

* Multiple regression analysis: dependent variable change in HbA1c from baseline to visit2

Table 3

Secondary Study Group N=14 Age 6-11 y

	Baseline		Visit 1		Visit 2		
	Mean	STD	Mean	STD	Mean	STD	p-value [1]
Parameter							
HbA1c	8.7	1.9	7.7	0.8	7.7	0.9	0.09
Average Daily Insulin	33.5	20.7	28.6	16.1	30.1	14.5	0.10
Average Blood Glucose	.	.	182.2	29.0	174.0	37.5	.
BPsys	102.7	10.1	105.9	10.4	108.4	18.2	0.46
BPdia	62.3	8.9	63.6	9.9	62.8	8.2	0.90
BMI	18.0	3.6	19.0	3.8	18.9	3.9	0.0046
Subjective Perception of Therapy [2]							
Satisfaction Analog scale	60.0	16.2	78.6	8.6	80.7	9.2	0.0005
Satisfaction Questionnaire	58.0	16.2	85.7	11.6	83.0	10.5	0.0005
Subjective Handling Ease	46.4	22.2	67.0	14.4	63.4	12.5	0.084
Subjective Compliance	58.6	15.5	75.0	12.0	69.1	15.1	0.197

[1] p-value for development from baseline to visit 2 by Wilcoxon signed rank test
[2] Analog scale 0-100 = worst to best; the questionnaire ratings (1-5) were rescaled to 0 – 100;

Discussion

The study demonstrates using a system with remote control can markedly improve glycemic control. Reduction of insulin dose proves that improvement was achieved by insulin-in-time rather than increasing the insulin dose. A further remarkable finding was that the best improvement was seen for patients with the most unfavorable baseline HbA1c values. It is further reassuring that no DKA and only one hypoglycemic event was reported during the use of ACCS.

Personal satisfaction, ease of handling and perceived therapy compliance advanced markedly with the new system. The fact that patient satisfaction also correlated with improved glycemic control underlines that 'soft' measures, like good instruction and education to work with the new system also may contribute to better therapy compliance.

Conclusion

The use of a pump system with remote control led to improvement of glycemic control. Patient satisfaction advanced significantly and the safety developed favorable.

The handling of insulin delivery through a remote control may at first sight appear as a smaller technical improvement – however, this study underlined that this improvement may represent, for young patients, a major step forward to enable due therapy adherence.