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L'Evolutione della  
Diabetologia alla luce del  
Piano Nazionale Diabete

XX CONGRESSO  
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“Automonitoraggio della glicemia oggi”

*Nuove Tecnologie*

# Dal 1969 al 2012.....





## Documento per la formulazione e l'implementazione di un Piano Strategico Nazionale sulla malattia diabetica

In particolare va ricordata la parte relativa alla scelta del glucometro dove si riportano *“le caratteristiche che devono essere tenute presenti e che possono condizionare la scelta di uno strumento rispetto ad un altro in relazione al tipo di paziente (stile di vita, limitazioni manuali o visive,....) nella cura a domicilio e che devono garantire a) praticità d'uso e alla fenotipizzazione del paziente, b) accuratezza e precisione; c) controllo di qualità”*.

Inoltre viene evidenziato che, nel confrontarsi con nuove apparecchiature, è necessario sempre considerare gli aspetti organizzativi assieme alla appropriatezza delle procedure diagnostiche e terapeutiche, enfatizzando il concetto secondo cui al corretto utilizzo della strumentazione si deve sempre affiancare un corretto apprendimento sia dell'operatore che del paziente e un appropriato utilizzo di competenze.

## Self-Adjustment of Insulin Dose Using Graphically Depicted Self-Monitoring of Blood Glucose Measurements in Patients with Type 1 Diabetes Mellitus

Andreas Reichel, M.D.,<sup>1</sup> Hannes Rietzsch, M.D.,<sup>1</sup> Barbara Ludwig, M.D.,<sup>1</sup> Katrin Röthig,<sup>1</sup>  
Annette Moritz, Ph.D.,<sup>2</sup> and Stefan R. Bornstein, M.D.<sup>1</sup>

### *Methods:*

A 24-week crossover study was performed in 25 patients with type 1 diabetes mellitus using CSII and SMBG. Patients were randomized either to entering blood glucose data into handwritten logbooks or to using the Accu-Chek SmartPix information management system (IMS) coupled with instructions from a training manual to aid interpretation of the IMS readings. Patients analyzed these chart readings every 2 weeks, and outpatient visits were scheduled for both arms every 6 weeks.

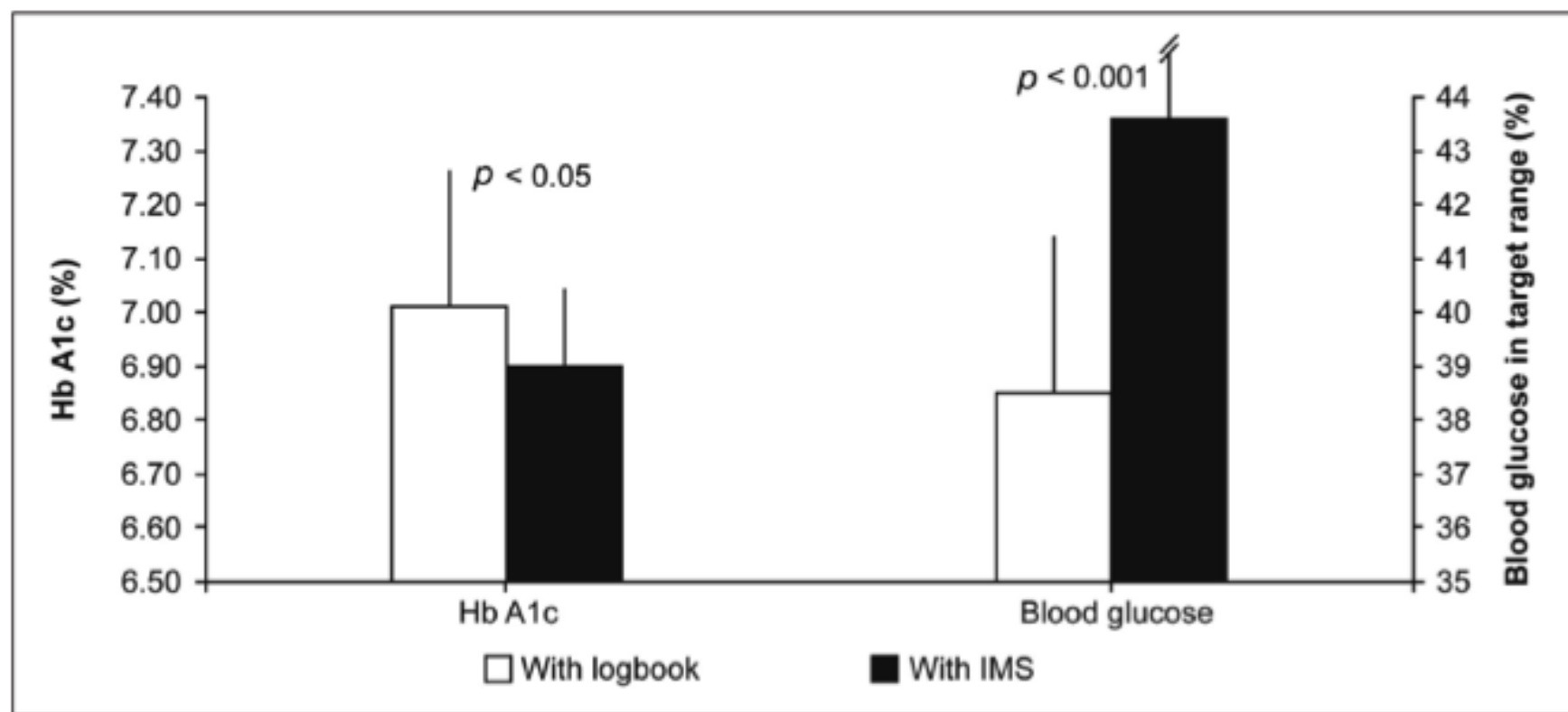


Figure 3. Differences between groups in HbA1c levels and proportion of patients achieving glycoemic targets. Error bars represent the standard deviation.



## Improving Self-Monitoring of Blood Glucose among Adults with Type 1 Diabetes: Results of the Mobile<sup>TM</sup> Study

Jane Overland · Jessie Abousleiman · Andriana Chronopoulos · Natasha Leader ·  
Lynda Molyneaux · Christopher Gilfillan

**Introduction:** The objective of this study was to determine whether people with type 1 diabetes are more likely to self-monitor their blood glucose (SMBG) as recommended by their diabetes health care professional using the Accu-Chek Mobile<sup>TM</sup> (F. Hoffmann-La Roche AG, Basel, Switzerland) monitoring system compared to the Freestyle Optium<sup>TM</sup> (Abbott, North Chicago, IL, USA).

**Methods:** Thirty-five participants with type 1 diabetes participating in a randomized cross-over study were assigned to monitor their blood glucose levels for a 3-month period using the Accu-Chek Mobile or the Freestyle Optium monitoring system and then to cross-over to the alternative device. After completion of the 6-month cross-over period, participants were invited to select their meter of choice and were followed for a further 3 months.

## Improving Self-Monitoring of Blood Glucose among Adults with Type 1 Diabetes: Results

**Table 2** Monitoring frequency (SMBG/week), glycemic control (HbA1c), satisfaction with treatment (DTSQ), confidence in treating diabetes (CIDS score), and diabetes distress (PAID score) at baseline and during the 3-month cross-over periods that participants were randomized to use the Accu-Chek Mobile™ meter vs. the Freestyle Optium™ meter

At completion of the 6-month randomized cross-over phase, all participants were invited to be followed in a 3-month extension study. The monitoring frequency of the participants who indicated a preference for the Accu-Chek Mobile meter ( $n = 25$ ) remained significantly higher during the 3-month extension phase than at baseline [median 17 [interquartile range (IQR) 8–29] SMBG estimates/week vs. median: 7 (IQR: 3–16) SMBG estimates/week;  $P = 0.0002$ ].

These participants also had a small but statistically significant improvement in their glycemic control [average HbA1c:  $8.7 \pm 1.1\%$  ( $70.1 \pm 11.3$  mmol/mol) at 9 months vs.  $9.1 \pm 1.2\%$  ( $75.3 \pm 13.3$  mmol/mol) at baseline;  $P = 0.04$ ].

diabetes treatment satisfaction questionnaire (change version), *HbA1c* glycosylated hemoglobin, *PAID* problem areas in diabetes management, *SMBG* self-monitoring of blood glucose

Results expressed as mean (SD) or <sup>a</sup> median (IQR)

<sup>b</sup>  $F = 6.2$ ,  $P = 0.003$

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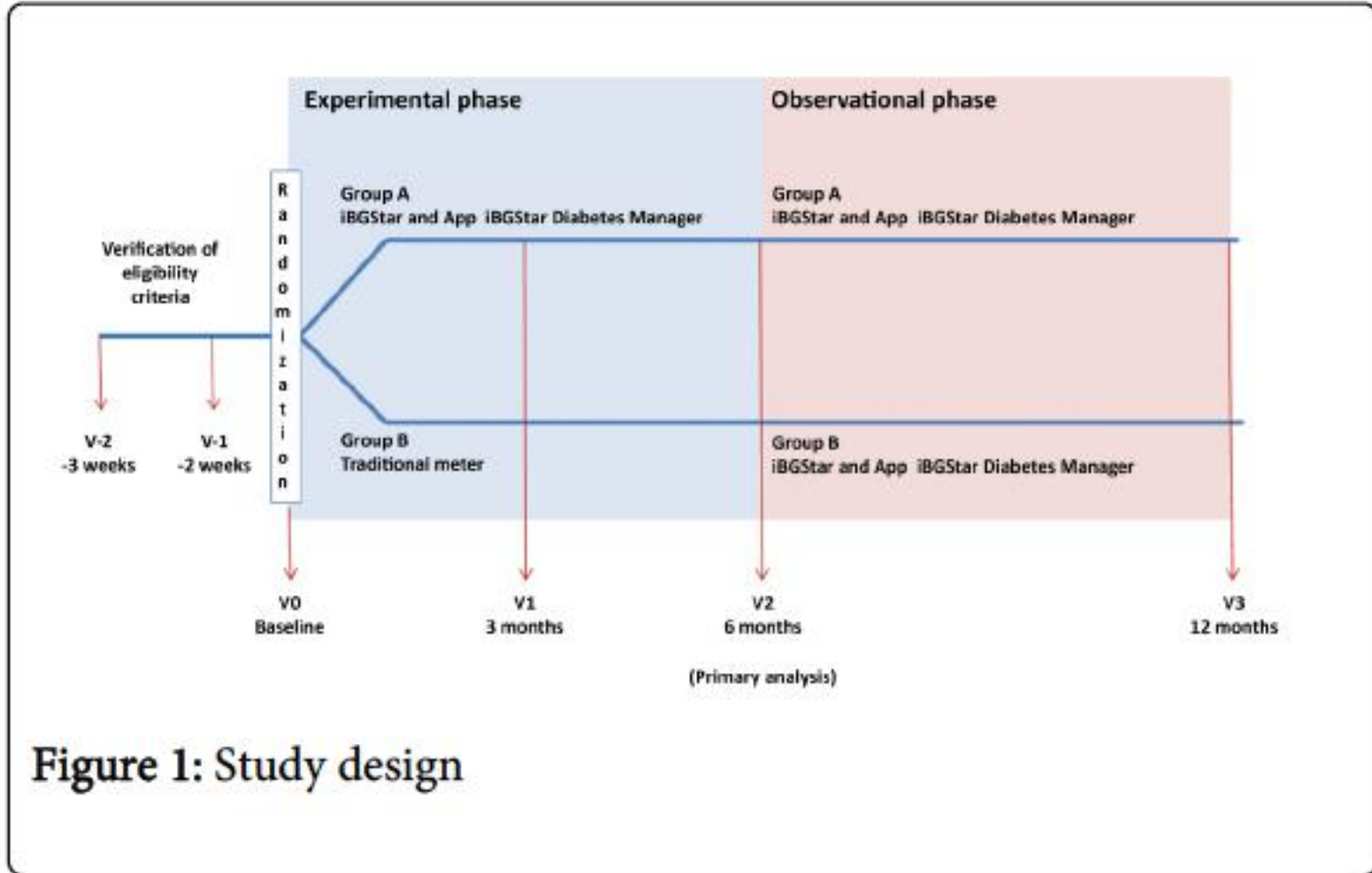
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**Figure 1: Study design**



## **Criteria for evaluation:**

### **Primary evaluation criteria**

The objective of this study was to test **the superiority of iBGstar™ as a component of the diabetes treatment vs. traditional blood glucose self-monitoring system for reducing HbA1c levels after 6 months in young patients with type 1 diabetes.**

The co-primary study objective was to test **the superiority of iBGstar™ as a component of the diabetes treatment vs. usual blood glucose self-monitoring system for improving the compliance to SMBG (proportion of patients performing at least 30% of the recommended SMBG tests) after 6 months.**

### **Secondary evaluation criteria:**

As secondary efficacy objectives, the study aimed to evaluate the co-primary end-points at 12 months and all the following parameters at 6 and 12 months:

Percentage of patients with HbA1c  $\leq 7.5\%$ ;

Variation in the average number of weekly SMBG;

Quality of life: ADDQOL (young adults 18-24 years) and DQOL-Y (adolescents 14-17 years) after 6 months;

Patient satisfaction with SMBG meter assessed by VAS;

Number and type of overall contacts between centers and patients during 6 months.

### **Safety:**

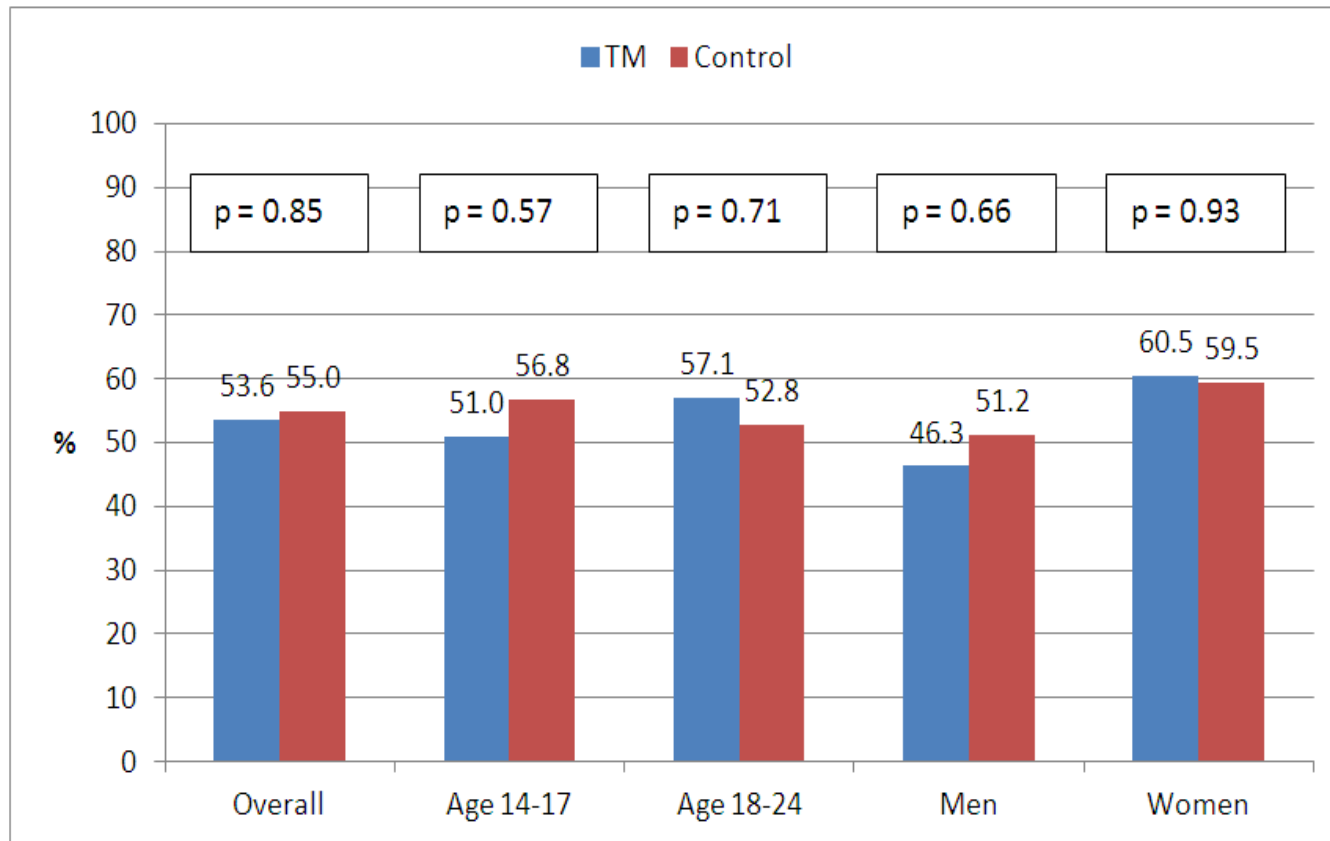
Incidence of hypoglycemia (grade 1 and grade 2) during 6 and 12 months;

Incidence of adverse events during 6 and 12 months.

<b>Characteristics</b>		<b>Total</b>	<b>Group A</b>	<b>Group B</b>	<b>p-value</b>
<b>N</b>		182	92	90	
<b>Age (years±Std)</b>		17.7±3.0	17.6±3.1	17.8±3.0	0.56
<b>n (%)</b>					
<b>Age</b>	14-17	101 (55.49)	54 (58.70)	47 (52.22)	0.38
	18-24	81 (44.51)	38 (41.30)	43 (47.78)	
<b>Gender</b>	Female	89 (48.9)	45 (48.9)	44 (48.9)	1.00
	Male	93 (51.1)	47 (51.1)	46 (51.1)	
<b>Living status</b>	Lives alone	6 (3.3)	3 (3.3)	3 (3.3)	0.6
	Lives with family	175 (96.1)	89 (96.7)	86 (95.6)	
	Other	1 (0.6)	0 (0.0)	1 (1.1)	
<b>Occupational status</b>	Employed	23 (12.6)	9 (9.8)	14 (15.6)	0.44
	Unemployed	24 (13.2)	11 (12.0)	13 (14.4)	
	Housewife	1 (0.5)	1 (1.1)	0 (0.0)	
	Student	134 (73.4)	71 (77.1)	63 (70.0)	
<b>Ethnic group</b>	Other	6 (3.3)	2 (2.2)	4 (4.4)	0.6
	Black	3 (1.6)	2 (2.2)	1 (1.1)	
	White	173 (95.1)	88 (95.6)	85 (94.5)	

Characteristics	Total	Group A	Group B	p-value	
	n (%)				
<b>Diabetes duration</b>	8.8 ± 4.6	8.6 ± 4.5	9.0 ± 4.7	0.65	
<b>HbA1c</b>	10.05 ± 1.40	9.91 ± 1.32	10.20 ± 1.47	0.1811	
<b>Number of HbA1c measurements collected during the last 12 months</b>	3.7 ± 1.1	3.6 ± 0.9	3.7 ± 1.2	0.48	
<b>% patients with at least 1 severe hypoglycemic episode (grade 2) in the last 12 months</b>	15.9	17.4	14.4	0.59	
<b>Number of severe hypoglycemic episodes (grade 2) in the last 12 months</b>	1.6 ± 6.7	2.0 ± 7.6	1.1 ± 5.6	0.51	
<b>% patients with at least 1 episodes of ketoacidosis in the last 12 months</b>	6.0	5.4	6.7	0.73	
<b>Number of episodes of ketoacidosis in the last 12 months</b>	0.2 ± 0.9	0.1 ± 0.4	0.2 ± 1.2	0.7	
<b>Education to carbohydrate counting</b>	No	105 (57.7)	54 (58.7)	51 (56.7)	0.21
	Yes	74 (40.7)	38 (41.3)	36 (40.0)	
	NA	3 (1.6)	0 (0.0)	3 (3.3)	

# Compliance to SMBG at six months



# Results of the experimental phase

	Group A (N=92)				Group B (N=90)				A vs. B	p-value A vs. B	p-value A Pre- post	p-value B Pre- post
	BASELINE*	3 MONTHS *	6 MONTHS *	Mean chang e 0-6**	BASELINE *	3 MONTHS *	6 MONTHS *	Mean chang e 0-6**	Mean differenc e 0-6**	p** (6 vs. 0)	p** (6 vs. 0)	p** (6 vs 0)
HbA1c (%)	9.9 (1.3)	9.3 (1.6)	9.5 (1.4)	-0.44 (0.13)	10.2 (1.5)	9.9 (1.7)	9.8 (1.6)	-0.32 (0.13)	-0.12 (0.18)	0.51	<b>0.0008</b>	<b>0.02</b>
SMBG weekly (N)	8.8 (5.3)	8.4 (5.7)	16.0 (12.1)	+7.2 (1.2)	8.5 (5.3)	7.9 (5.5)	16.1 (10.8)	+7.7 (1.3)	-0.5 (1.8)	0.78	<b>&lt;0.0001</b>	<b>&lt;0.0001</b>
<u>ADDQoL:</u>												
Average score	62.2 (9.1)	NA	61.0 (13.5)	-1.5 (1.5)	61.2 (13.5)	NA	62.2 (12.5)	+1.2 (1.5)	-2.7 (2.1)	0.19	0.30	0.41
ADD_I	0.8 (1.0)	NA	1.0 (0.8)	+0.1 (0.1)	0.8 (0.8)	NA	0.9 (1.0)	+0.1 (0.1)	+0.05 (0.2)	0.81	0.33	0.52
ADD_II	-1.1 (0.9)	NA	-1.1 (0.9)	-0.03 (0.2)	-1.2 (0.9)	NA	-1.2 (0.9)	-0.02 (0.2)	-0.01 (0.2)	0.95	0.16	0.15
<u>DQOLY</u>												
Average score	26.8 (12.4)	NA	25.8 (12.1)	+0.4 (1.6)	27.9 (10.5)	NA	25.9 (9.8)	-0.8 (1.6)	+1.2 (2.3)	0.60	0.78	0.65
<u>impact</u> of diabetes (23 items)	28.0 (12.3)	NA	27.3 (13.9)	-0.5 (1.5)	25.3 (9.9)	NA	25.1 (10.1)	+1.0 (1.6)	-1.4 (2.2)	0.52	0.77	0.54
<u>sg</u> about diabetes (11 items)	20.1 (15.7)	NA	21.9 (17.3)	+0.8 (2.2)	20.7 (15.1)	NA	20.1 (13.6)	+2.0 (2.2)	1.1 (3.1)	0.72	0.38	0.71
<u>satisfaction</u> with treatment (10 items)	25.1 (15.5)	NA	27.3 (15.1)	+4.5 (2.9)	29.8 (19.6)	NA	26.7 (15.5)	-3.8 (2.9)	8.3 (4.1)	<b>0.05</b>	0.13	0.19
<u>satisfaction</u> with life (7 items)	35.8 (16.4)	NA	35.1 (17.7)	-0.2 (2.7)	41.0 (16.3)	NA	34.9 (15.5)	-5.8 (2.9)	5.6 (4.0)	0.17	0.95	<b>0.05</b>
<u>health</u> perception (1 item)	2.2 (0.8)	NA	2.2 (0.8)	0.0 (0.1)	2.3 (0.6)	NA	2.3 (0.8)	0.0 (0.1)	0.0 (0.2)	0.90	0.91	0.94
VAS	63.6 (21.6)	NA	75.8 (17.4)	12.4 (2.5)	63.5 (24.5)	NA	69.6 (18.9)	5.7 (2.5)	6.7 (3.5)	<b>0.05</b>	<b>&lt;0.0001</b>	<b>0.02</b>



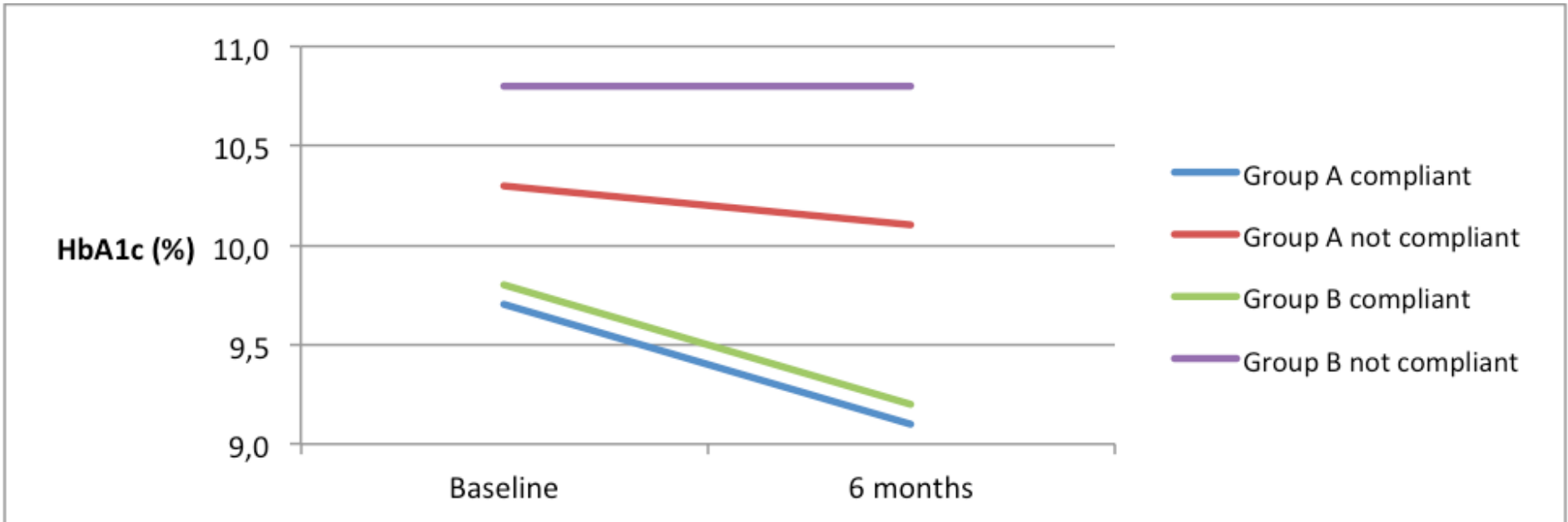
# Efficacy parameters from baseline to 6 months, by age

		Group A (N=92)				Group B (N=90)				A vs. B	p-value A vs. B	p-value Group A Pre-post	p-value Group B Pre-post
		BASE- LINE	3 MONTHS	6 MONTHS	Mean change 0-6	BASE- LINE	3 MONTHS	6 MONTHS	Mean change 0-6	Mean difference 0-6	p* (6 vs. 0)	p** (6 vs. 0)	p** (6 vs 0)
<b>HbA1c (%)</b>	14-17	10.1 (1.3)	9.6 (1.9)	9.8 (1.6)	-0.39 (0.17)	10.3 (1.3)	9.9 (1.5)	9.8 (1.4)	-0.45 (0.18)	+0.06 (0.25)	0.82	<b>0.02</b>	<b>0.02</b>
	18-24	9.6 (1.2)	9.0 (1.1)	9.1 (1.0)	-0.50 (0.19)	10.1 (1.7)	9.9 (2.0)	9.9 (1.9)	-0.16 (0.19)	-0.34 (0.27)	0.21	<b>0.01</b>	0.39
<b>SMBG weekly (N)</b>	14-17	8.6 (5.8)	8.2 (6.2)	16.0 (13.6)	+7.4 (1.8)	8.8 (6.1)	8.8 (5.3)	17.6 (10.4)	+8.8 (1.9)	-1.5 (2.6)	0.57	< <b>0.0001</b>	< <b>0.0001</b>
	18-24	9.1 (4.4)	8.7 (4.8)	16.0 (9.6)	+6.9 (1.6)	8.1 (4.4)	7.0 (5.7)	14.4 (11.1)	+6.3 (1.6)	+0.6 (2.3)	0.80	< <b>0.0001</b>	<b>0.0002</b>
<b>VAS</b>	14-17	60.6 (21.7)	NA	75.6 (20.2)	+15.0 (3.4)	60.1 (25.0)	NA	68.8 (18.2)	+7.2 (3.6)	+7.8 (4.9)	0.12	< <b>0.0001</b>	<b>0.05</b>
	18-24	67.9 (21.0)	NA	76.1 (13.0)	+8.7 (3.5)	67.1 (23.6)	NA	70.4 (19.9)	+4.3 (3.3)	+4.4 (4.8)	0.37	<b>0.02</b>	0.19

# Efficacy parameters from baseline to 6 months, by gender

		Group A				Group B				A vs. B	p-value A vs. B	p-value A Pre- post	p-value B Pre- post
	Gender	BASELINE	3 MONTHS	6 MONTHS	Mean change 0-6	BASELINE	3 MONTHS	6 MONTHS	Mean change 0-6	Mean difference 0-6	p* (6 vs. 0)	p** (6 vs. 0)	p** (6 vs. 0)
HbA1c (%)	M	9.9 (1.1)	9.4 (1.5)	9.6 (1.5)	-0.32 (0.16)	10.2 (1.5)	9.9 (1.6)	10.1 (1.6)	-0.16 (0.16)	-0.16 (0.22)	0.48	<b>0.04</b>	0.30
	F	10.0 (1.5)	9.3 (1.7)	9.4 (1.4)	-0.55 (0.20)	10.2 (1.5)	9.9 (1.9)	9.6 (1.7)	-0.49 (0.21)	-0.06 (0.29)	0.83	<b>0.008</b>	<b>0.02</b>
SMBG weekly (N)	M	8.9 (4.9)	7.9 (6.2)	15.6 (14.1)	+6.7 (1.9)	8.8 (5.7)	8.6 (7.2)	16.6 (11.4)	+7.7 (1.9)	-1.1 (2.7)	0.69	<b>0.0006</b>	<b>0.0001</b>
	F	8.7 (5.7)	8.9 (5.1)	16.4 (9.6)	+7.7 (1.6)	8.1 (4.9)	7.2 (5.2)	15.7 (10.2)	+7.6 (1.6)	+0.1 (2.3)	0.96	< <b>0.001</b>	< <b>0.001</b>
DQOLY satisfaction with life (7 items)	F	39.3 (17.7)	NA	37.5 (18.1)	-1.0 (3.4)	47.6 (14.2)	NA	35.1 (14.3)	-12.5 (4.4)	+5.5 (13.5)	<b>0.02</b>	0.77	<b>0.008</b>
VAS	M	59.0 (21.6)	NA	73.9 (19.4)	+15.1 (3.4)	63.5 (25.2)	NA	66.0 (19.8)	+2.1 (3.4)	+13.0 (4.8)	<b>0.009</b>	< <b>0.0001</b>	0.54
	F	68.3 (20.7)	NA	77.8 (15.1)	+9.7 (3.5)	63.5 (24.0)	NA	73.6 (17.2)	+9.6 (3.5)	0.0 (4.9)	1.00	<b>0.007</b>	<b>0.008</b>

# Change in HbA1c levels by compliance to SMBG at 6 months



# 6 Months

## ○ **HbA1c**

- No significant between-group difference in HbA1c levels change was found.
- In both groups, HbA1c levels were reduced (-0.4% in Group A and -0.3% in Group B);
- Reduction in HbA1c levels in Group A as compared to Group B were more marked in males and subjects aged 18-24 years.

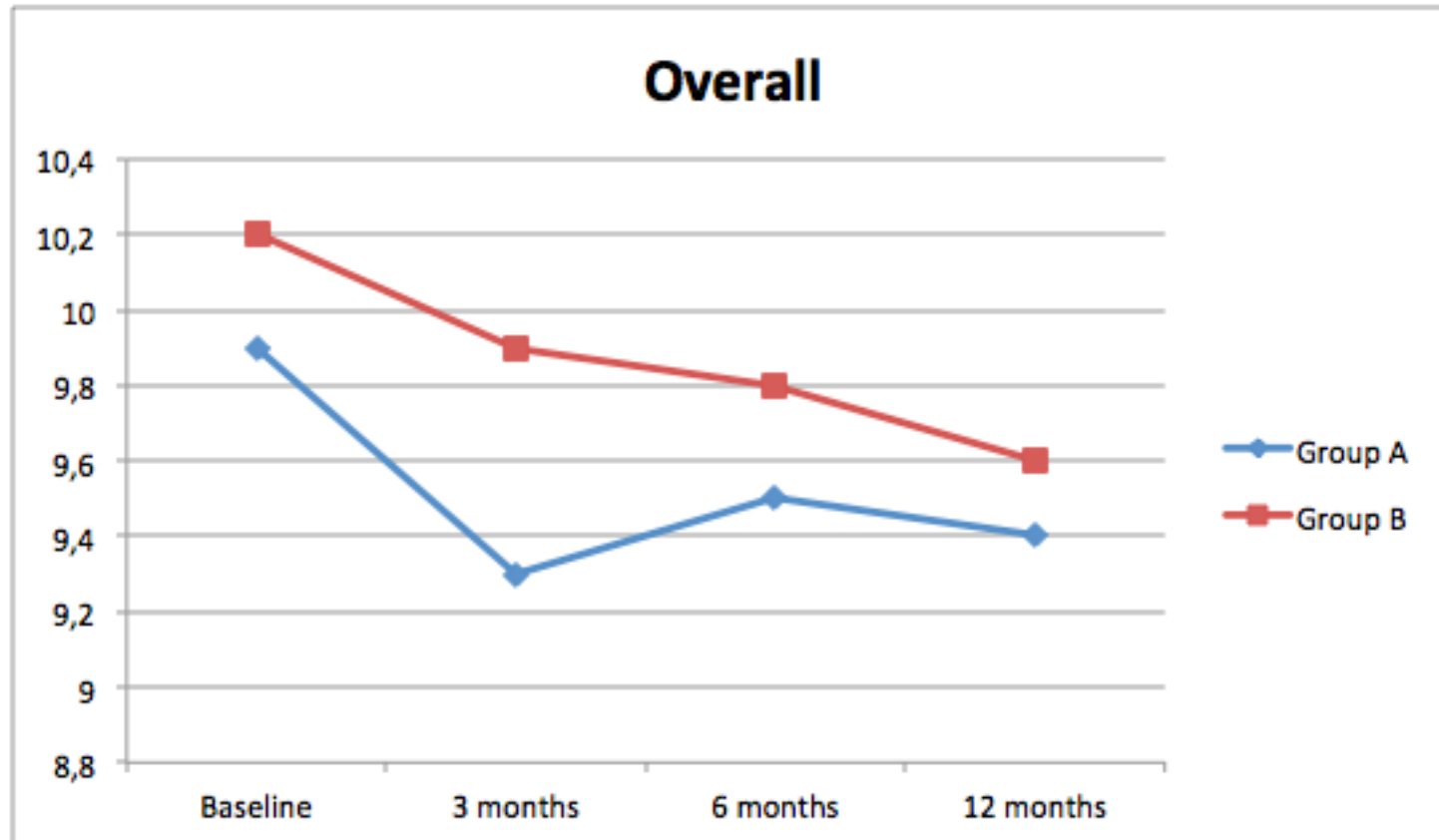
## ○ **Compliance**

- 53.6% of patients in Group A and 56.0% in Group B could be defined compliant to SMBG, without a statistically significant between group difference.
- Compliance was reached more frequently in females than in males, without difference between study groups.
- Number of weekly number of SMBG increased from  $8.8 \pm 0.9$  to  $16.0 \pm 0.9$  in Group A and from  $8.5 \pm 0.9$  to  $16.2 \pm 0.9$  in Group B. Between-group comparison did not show statistically significant difference while the pre-post improvements were statistically significant within both groups.

## ○ **Satisfaction**

- Higher benefits in the subscales of DQOLY-satisfaction with life and satisfaction with treatment were found in Group A as compared to Group B.
- VAS score was increased significantly more in Group A than in Group B (+12.4 (2.5) vs. +5.7 (2.5);  $p=0.05$ ). Analysis stratified by gender showed that the between-group satisfaction strongly differed in male patients in favor of the experimental glucose meter, while no difference was found in female subjects.

# HbA1c at 12 months in the overall population



**Table 13 HbA1c at 12 months in the overall population**

	Estimated mean change (95% CI)	p-value
Delta HbA1c 6-12M Group A	-0.07 (-0.35;0.20)	0.60
Delta HbA1c 6-12M Group B	-0.31 (-0.59;-0.03)	0.03
Delta HbA1c 0-12M Group A	-0.50 (-0.77;-0.23)	0.0003
Delta HbA1c 0-12M Group B	-0.63 (-0.91;-0.35)	≤0.0001
Delta HbA1c 6-12M Group A vs. Group B	0.24 (-0.16;0.63)	0.24
Delta HbA1c 0-12M Group A vs. Group B	0.13 (-0.26;0.52)	0.52



# 12 Months

## **HbA1c**

Between 6 and 12 months after randomization, HbA1c levels remained stable in Group A (-0.07%), while they further decreased by -0.31% in Group B after switching to the experimental meter. No between-group difference in HbA1c levels was found at the end of the study ( $p=0.24$ ), but the change from 0 to 12 months was clinically relevant and statistically significant in both groups (Group A: -0.50;  $p=0.0003$  and Group B: -0.63;  $p<0.0001$ ).

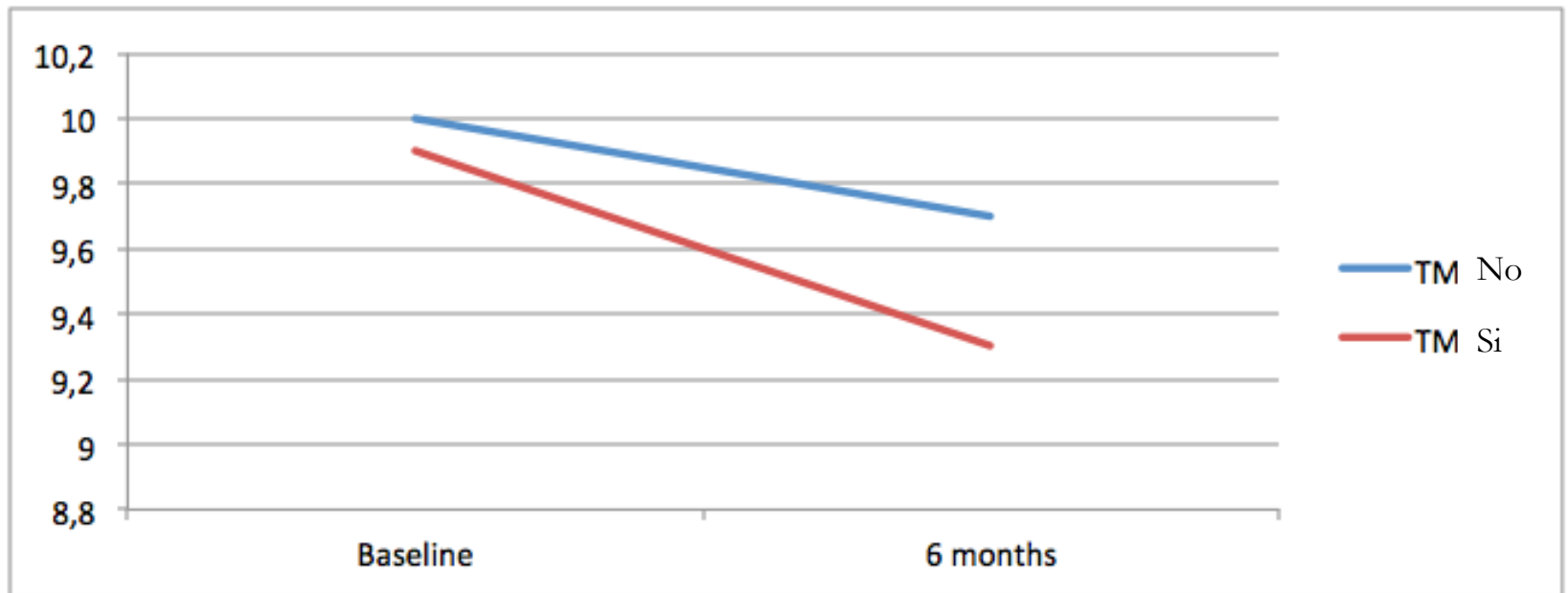
## **Compliance**

After 12 months, the proportion of patients compliant to SMBG was slightly decreased compared to that obtained after 6 months, but no between-group difference was found. However, the proportion of women compliant to SMBG in Group B was substantially higher, though statistical significance was not reached.

Also in terms of within-group comparisons, the percentage reductions from 6 to 12 months were not statistically significant. An exception was represented by women in the Group A, showing a statistically significant reduction at 12 months compared to 6 months (60.5% vs. 40.5%;  $p=0.05$ ).

**Figure 5**

**Change in HbA1c levels (additional analyses), by use of telemedicine (TM) contacts (email, SMS, and/or phone calls) during 6 months (Group A only)**



# iNew Trend Study Conclusion

The study documented that quality of life was unchanged after six months. It is important to underline that increasing the frequency of self-monitoring blood glucose is not a determinant of poorer quality of life.

On the other hand, the VAS significantly improved in both group. In men, VAS was substantially influenced by the glucose meter, while in women this improvement was independent from the assigned device. Furthermore, VAS significantly increased in the subgroup aged 14-17 years, but only in patients allocated to the experimental glucose meter.

glucose.

Improvements in HbA1c were obtained increasing the number of weekly measurements from around 8 to 16, i.e. from 1.1 to 2.3 measurements/day.

# Conclusioni

La disponibilità di molteplici dispositivi per l'autocontrollo domiciliare ad elevato e differenziato contenuto tecnologico ci permette di incontrare al meglio le differenti caratteristiche cliniche ed i differenti bisogni dei pazienti avviati all'autocontrollo glicemico.

L'identificazione del “giusto glucometro, per il giusto paziente, soprattutto in alcune classi di pazienti,

è elemento fondamentale per ottenere e mantenere un adeguata compliance all'SMBG,

una ottimale soddisfazione sul proprio trattamento e aumentare, quindi, la motivazione per i nostri pazienti all'ottimale gestione del proprio diabete