Medical University of Graz

Feasibility of Use and Performance of PaQ®

A Simple 3-Day Basal / Bolus Insulin Delivery Device in Patients with Type 2 Diabetes

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Background

- 43 % of treated T2D patients are not in good glycemic control[1]
- Majority of patients on insulin need basal AND bolus insulin to reach glycemic targets[2]
- Among patients using insulin therapy, 50 % report skipping injections because:
  - injections interfere with daily life
  - injection pain
  - embarrassment[3]

PaQ® insulin delivery device

PaQ® (CeQur SA) is a simple patch-on device that provides set basal rates and bolus insulin on demand

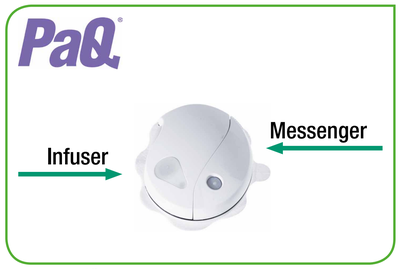

Figure 1: PaQ® insulin delivery device consisting of the infuser and the messenger

It consists of

Infuser

- 5 set basal rates (20, 24, 32, 40, 50 U / 24 hours) – w/o programming
- Bolus dose at push of a button (2 U / push)
- Needs to be replaced every 3 days

Messenger

- Messenger notifies the user:
  - How long PaQ® has been on
  - When to change
- Reusable (3 months)

PaQ® Feasibility Study

Design

- Single center, single arm, patient controlled
- No dose optimization or treat to target

Inclusion criteria

- Patients with T2D
- HbA1c ≤ 9 %
- Stable regimen of basal / bolus insulin ± OADs

Primary Objective

- To assess patient's ability to use PaQ®
- Study schedule (Figure 2)
- Patient training (Figure 3)

Patient characteristics

Table 1: Patient characteristics (baseline)

20 patients with T2D (18 completers)*	
Female	21 %
Age	59 ± 5 years
HbA1c	7.7 ± 0.7 %
BMI	32 ± 6 kg / m²
Diabetes duration	15 ± 7 years
Total daily insulin dose	60 ± 19 U
Number of daily injections	5 (4 – 8)

* 1 p. discontinued during baseline, 1 p. discontinued during transition

Results

Ability to use PaQ®

- 100 % of the patients were able to assemble, fill, prime and use PaQ®
- 100 % could correctly understand signals emitted from PaQ® and responded adequately
- 149 reservoirs were applied
- Reservoir was exchanged every 2.6 (± 0.8) days
- 83 % were "very satisfied" and 17 % were "satisfied" with the time it took to learn how to use PaQ®

Transition from MDI to PaQ®

- Selected basal rate was the same as or less than subjects' baseline basal dose
- Transition from MDI to PaQ® was achieved within 6 to 9 days
  - in 14 patients with 1st basal dose selected
  - in 5 patients with transition to a 2nd basal dose

Hypoglycemia (BG ≤ 70 mg/dl)

- Baseline period, MDI (n = 19) 12 patients (69 %)
- Transition period, PaQ® (n=19) 8 patients (42 %)
- Treatment period, PaQ® (n=18) 8 patients (44 %)
- No severe hypoglycemia occurred during the study

Continuous glucose monitoring (CGM)

- Blinded CGM data during PaQ® therapy revealed a trend towards improved glycemic control
- Mean change in average 24 hour glucose exposure of –190.3 mg/dL (p = 0.18) compared to baseline
- The reduction in glucose exposure occurred overnight and during the day
- CGM revealed no episodes of severe hypoglycemia
- The improved glucose exposure was consistent with a mean change in A1c of –0.3 ± 0.4 %

Total daily insulin dose during baseline (MDI) and treatment period (PaQ®)

Table 2: Insulin doses during baseline (MDI) and treatment (PaQ®) period

	Basal Dose (U)	Bolus Dose (U)	TDD (U)
Baseline period (n = 19)	30 (9)	31 (14)	60 (19)
Treatment period (n = 18)	29 (7)	29 (14)	57 (15)

The values are mean +/-SD

- Mean TDD for all patients at the end of PaQ® therapy (57 ± 15 U) was not different from baseline (60 ± 19 U)

Self-monitored blood glucose (SMBG)

Table 3: Changes in self-monitored glucose values during PaQ® therapy

	Breakfast		Lunch		Dinner		Bedtime
	Pre	Post	Pre	Post	Pre	Post	
Δ Mean	–10.7	–13.0	8.6	–2.6	–2.7	10.6	–17.9
SD	28	34	41	36	27	61	45
p-value	0.12	0.13	0.39	0.76	0.67	0.48	0.12

The values are mean +/-SD

- Changes in SMBG (mg/dL) during PaQ® therapy showed a trend toward better glycemic control compared to baseline (pre- and post- breakfast, bedtime)

Conclusions

- **Easy to assemble and use after 1 hour of training**
- **Device delivered daily basal and bolus insulin requirements**
- **Safe to use**
- **High patient satisfaction and acceptance**
- **MDI treated patients with T2D were easily and safely transitioned from MDI to PaQ®.**
- **Despite similar TDD during MDI and PaQ® study periods, there was a trend toward improved glycemic control with PaQ® therapy**
- **Future studies will assess longer-term PaQ® efficacy and safety**

References

1 Cheung, BMY et al. Am J Med. 2009; 122 : 443–53.
2 Rury R. Holman, et al. NEJM 361;18. October 29, 2009
3 Peyrot, M et al. Diabetes Care 2010; 33 : 240–245, 2010

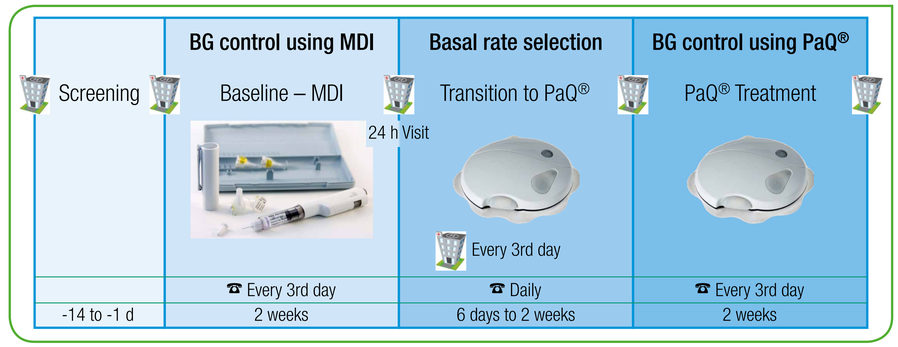

Figure 2: Study schedule. The study included a 2-week baseline phase, a 6 –14 days transition period and a 2 week treatment period

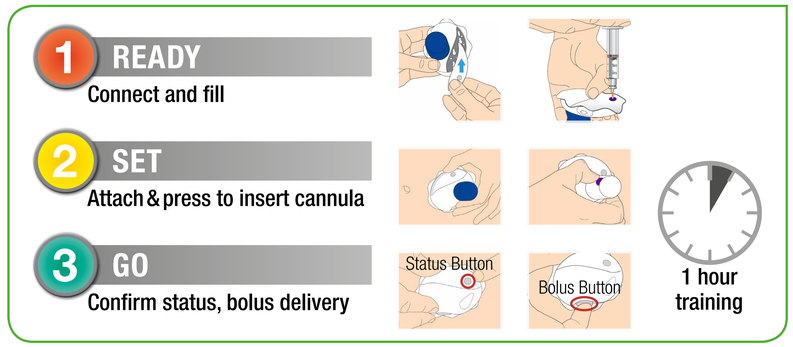

Figure 3: 1 hour patient training