3 month treatment with a simple 3-day insulin delivery device in adults with type 2 diabetes

Poettler T¹, Lilly LC², Aberer F¹, Novak E¹, Lanz C¹, Trautmann M³, Warner JL², Pieber TR^{1,4}, Mader JK¹

CONTACT

1
Division of Endocrinology
and Diabetology
Department of
Internal Medicine
Medical University of Graz

Julia Mader

Auenbruggerplatz 15
8036 Graz, Austria
Phone +43 316 385 82383
julia.mader@medunigraz.at
www.medunigraz.at

CeQur Corp

Altsagenstraße 5
6048 Horw, Switzerland
+41 41 500 4862
info@cequr.com

3
Diabetes Research Hamburg
Fueerburg 16a
D-22393 Hamburg, Germany
www.trautmann-diabetes.com

4
JOANNEUM RESEARCH
Forschungsgesellschaft mbH

HEALTH
Institute for Biomedicine and
Health Sciences
Neue Stiftungsstrasse 2
8010 Graz, Austria
health@joanneum.at
www.joanneum.at/health

Background and Aims

- Insulin is a critical therapy for people with type 2 diabetes (T2D)
- 53% of patients with T2D require insulin 6 years after diagnosis
- A large proportion of these patients require basal — bolus therapy to meet glycaemic targets
- The majority of patients in the US are not in good glycaemic control:
 - 71% have an HbA1c >7.0% (>53mmol/mol)
 - 38% have an HbA1c >8.0% (>64mmol/mol)
- Among patients using insulin therapy, 50% report skipping of injections because:
 - injections interfere with daily life
 - injection pain
 - embarrassment
- PAQ was designed as a simple insulin delivery device that could overcome the challenges associated with injectable insulin therapy

Figure 4: Working principle of PAQ. Insulin is filled into an elastomer bladder allowing a constant insulin flow. The flow rate is restricted by capillaries.

Figure 5: PAQ is designed to replace basal-bolus injections by delivery of rapid acting insulin as constant basal rate and bolus insulin on demand.

Endpoints

- HbA1c
- 7-point self-monitoring of blood glucose (SMBG)
- Total daily insulin dose (TDD)
- Body weight
- Patient reported outcomes (PRO)
- Safety:
 - Adverse device effects (ADEs)
 - Hypoglycaemic episodes
 - Application site reactions
- CGM sub-study only:
 - Time in target (70-180mg/dl; 3.9-10mmol/l)
 - Glucose variability

Baseline Characteristics

Patients	28
Age (years)	63 (±7)
Female, n (%)	4 (14)
Caucasians, n (%)	28 (100)
BMI (kg/m ²)	32.3 (4.3)
Diabetes duration (a)	17 ± 8
HbA1c (mmol/mol)	70 (±12)
Total daily dose (U)	58.7 ± 20.7
Basal dose (U)	28.9 ± 9.9
Bolus dose (U)	29.8 ± 16.6
Injections per day, mean (range)	4.3 (2-9)

Table 1: Baseline characteristics of study participants. Data are mean ± SD if not indicated otherwise.

One month of physiologic insulin delivery

4 shots a day for one month
Figure 1: Schematic of injections required in patients on basal bolus insulin therapy (4 insulin injections per day vs. only one insertion every three days on PAQ).

Insulin therapy using multiple injections	Selection of basal rate	Insulin therapy using PAQ
Screening/Baseline	Transition to PAQ	PAQ treatment
1 Week	1-2 Weeks	12 Weeks

Figure 2: Schematic study overview

Figure 3: PAQ insulin delivery device consisting of the Messenger and the Insulin Reservoir.

Primary objective

- To evaluate the performance of PAQ, as measured by HbA1c after 12 weeks of treatment in patients with T2D

Research Design

- Data of two single-arm studies following the same protocol were combined
- 28 adults with T2D and an HbA1c between 7 and 11% on at least 2 insulin injections per day OAD were included in the studies
- Insulin doses were adjusted to reach glucose target levels
- A subgroup of five subjects wore a CGM device for 1 and 2 weeks during baseline and at 8 weeks PAQ treatment

Results

- Twenty-four patients completed the study.
- After 12 weeks of PAQ, HbA1c was significantly decreased ($p=0.0001$). Individual and mean HbA1c changes are displayed in Fig. 6A.
- Compared to baseline, 7-point SMBG was significantly reduced at all time-points (Fig. 6B).
- When transitioned to PAQ, 75% continued on the first basal rate selected.
- TDD increased by 12.1 ± 19.5 U ($p=0.0058$) while body weight remained stable.
- Subjects were satisfied in using PAQ as assessed by PRO (Figure 8A and 8B).

Figure 6: A) Changes in HbA1c and B) 7-point SMBG

Figure 8: Patient reported outcomes A) DTSQ Total Score B) Selected Items on DTSQ

Figure 7: Blinded CGM in 5 subjects. A) during baseline, B) after 8 weeks on PAQ. A significant increase in time in target could be observed.

Acknowledgement

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Adults with T2D were safely transitioned from insulin injections to PAQ and achieved significantly improved glycaemic control without increase of hypoglycemia.