Use of PaQ®, a Simple 3-Day Basal/Bolus Insulin Delivering Device, Reduces Barriers to Insulin Therapie in Patients with Type 2 Diabetes

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ABSTRACT

PaQ® (CeQur SA) is a simple to use patch-on device which provides set basal rates and bolus insulin on demand. PaQ® was designed to minimize barriers to insulin therapy. In addition to feasibility of use, safety and efficacy (reported elsewhere), this study analyzed the impact of the use of PaQ® on patient reported outcomes (PRO) including; barriers against insulin treatment, diabetes related distress and negative attitudes towards insulin therapy in twenty patients with type 2 diabetes (T2D) on a stable multiple daily injections (MDI) insulin regimen. This single center, open label, single arm study was comprised of three 2-week periods; baseline (MDI), transition from MDI to PaQ®, and PaQ® treatment. Three validated questionnaires were completed at the end of the baseline and PaQ® treatment periods; Barriers to Insulin Treatment – Questionnaire (BIT), Problem Areas In Diabetes - Scale (PAID) and Insulin Treatment Appraisal Scale (ITAS). Nineteen patients (age 59±5 y, T2D duration 15±7 y, 21% female, A1C 7.7±0.7%) completed the questionnaires at the two measurement points. There was a strong and significant effect of PaQ® in the mean BIT total score (2.5 to 2.1, difference (D)=0.4±0.6; p=.01, effect size (d)= 0.70). Patients perceived less hardship from insulin therapy (overall improvement d=0.35), less stigmatization by insulin injection (overall improvement d=0.28) and less fear of hypoglycemia (overall reduction d=0.29). Diabetes related distress was slightly reduced (PAID 21.7 to 21.0, D=0.7 ±6.7, p = 0.79, d= 10). A non-significant reduction was also seen in the mean ITAS score (42.80 to 40.80, D=2.0 ±6.5, p=.20, d=31). The study is limited by both the uncontrolled design and small sample size. However, the results and the moderate to large effects sizes suggest that the use of PaQ® has beneficial and clinically relevant effects to overcome barriers to and negative appraisal of insulin treatment, without increasing other diabetes related distress.

PaQ® device

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INTRODUCTION

PaQ® (CeQur SA) is a simple to use patch-on device which provides set basal rates and bolus insulin on demand. PaQ® replaces daily basal and prandial insulin injections. In this study patients went from taking 4 to 8 injections per day to receiving 1 injection (cannula placement) every 3 days. This makes the handling of insulin treatment in daily routine much easier and therefore PaQ® has the potential to reduce barriers to and negative appraisal of insulin therapy. In addition to its feasibility of use, safety and efficacy, this study analyzed the impact of the use of PaQ® on patient reported outcomes (PRO): 1) barriers against insulin treatment, 2) negative attitudes towards insulin therapy and 3) diabetes related distress in patients with type 2 diabetes (T2D) on a stable multiple daily injections (MDI) insulin regimen.

METHODS

This single center, open label, single arm study was comprised of three 2-week periods: baseline (MDI), transition from MDI to PaQ®, and PaQ® treatment. Three validated questionnaires were completed at the end of the baseline and PaQ® treatment periods:

- The Barriers to Insulin Treatment – Questionnaire (BIT) assesses psychological barriers against insulin treatment. It allows the calculation of a total score (a higher score signifies more barriers) as well as the calculation of 5 sub-scales measuring different psychological aspects of performing an insulin therapy: "Fear of injections and self-testing", "Expectations regarding positive insulin-related outcomes", "Expected hardship from insulin therapy", "Stigmatization by insulin injections" and "Fear of hypoglycemia". All scales are ranging from 0 -10 (minimum to maximum barrier or benefit, respectively).
- The Insulin Treatment Appraisal Scale (ITAS) consists of 16 negative and 4 positive statements which also form the dimensions of the scale (positive and negative appraisal). For calculating the total score, the coding of the positive items was inversed to acquire a homogenous interpretation. The total scale ranges from 0 – 100, the higher the score the more negative the appraisal).
- The Problem Areas In Diabetes –Scale (PAID) measures diabetes related distress and has a scale range from 0 - 100, with a higher score indicating higher distress.

Non parametric significance tests were used for pre-post comparisons (Wilcoxon -Test). Effect sizes are represented as Cohen's *d* (number of standard deviations).

RESULTS

Nineteen type 2 diabetic patients completed the questionnaires at the two measurement points (see table 1).

- There was a strong and significant effect of PaQ® on the mean BIT total score (see figure 1), thus overall barriers to insulin therapy were reduced significantly after 2 weeks' use of PaQ®. The changes in the 5 sub-scales before and after the PaQ® use are shown in figure 2. The effect sizes on the total BIT-scale and the five sub-scales are depicted in figure 3. The total score showed a large effect size (Cohen's *d* > 0.5) 4 of 5 sub-scales had medium effects (between d>0.2 and d<0.2). After the use of the PaQ®, patients experienced less hardship from insulin therapy, reported less fear of hypoglycemia, and felt less stigmatized due to insulin therapy.
- Negative appraisal of insulin treatment, assessed by the ITAS, was also reduced (figure 4), but reduction was not significant.
- Diabetes related distress as measured by the PAID, was reduced after the PaQ® use (figure 5). Although reduction of diabetes related distress was not significant, PAID results suggest that there is a trend towards a reduction in diabetes related distress.
- As the effect sizes show (figure 6) the improvement of the total ITAS score was rather due to a reduction of negative attitudes towards insulin therapy than to an increase of positive attitudes towards insulin treatment. Compared to the BIT-scale the effect sizes on the others scales are much smaller. Improvement of the PAID-score showed only a small effect size.

CONCLUSION

PaQ® was designed to reduce the known barriers to insulin therapy. The data from this study suggests barriers to insulin treatment can be significantly reduced with the use of PaQ®. The effect sizes of the sub-scales indicate that reduction of "hardship of insulin therapy", "less feelings of stigmatization" and "less fear about hypoglycemia" seemed to be most important in overall reduction of Barriers to Insulin Treatment. Reduction of "hardship of insulin treatment" and "feeling of stigmatization" might be explained by the fact that the use of PaQ® replaced on average 5.2 daily insulin injections. It is unclear what led to "less fear of hypoglycemia", although a hypothesis came from post study interviews where several study participants credited the constant insulin delivery for improved control. Negative appraisal of insulin treatment was reduced after the use of PaQ®, but more positive views on insulin treatment were not observed. Diabetes related distress was slightly reduced, suggesting that PaQ® use was not associated with an increased burden of living with diabetes. The study is limited by both, the uncontrolled design and small sample size. However, the results and the moderate to large effects sizes suggest that the use of PaQ® has beneficial and clinically relevant effects to overcome barriers to and negative appraisal of insulin treatment, without increasing other diabetes related distress.
Future studies will elucidate whether PaQ®'s ability to reduce barriers to insulin treatment will result in improved glycemic control.

Characteristic	Number
Mean age ± SD (yrs.)	59.0 ±5.0
Mean diabetes duration ± (yrs.)	17.0 ±7.0
% female	21%
Mean A1c ± SD (%)	7.7 ±0.7
Mean total insulin dose ± SD (U)	60.4 ± 19.0
Mean number of insulin injections – range	5.2 (min - max 4 - 8)
Mean BIT score ± SD	2.5 ±1.2
Mean ITAS score ± SD	42.8 ±9.0
Mean PAID score ± SD	21.7 ±19.0

Table 1: Sample Characteristics

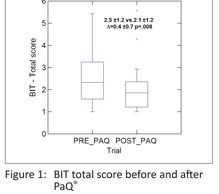

Figure 1: BIT total score before and after PaQ®

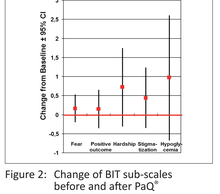

Figure 2: Change of BIT sub-scales before and after PaQ®

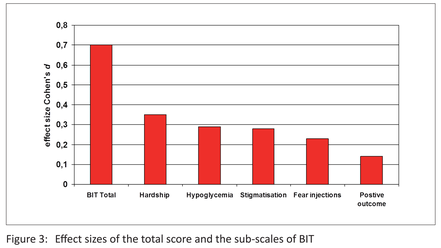

Figure 3: Effect sizes of the total score and the sub-scales of BIT

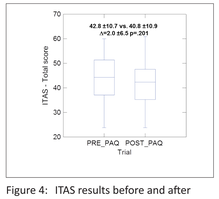

Figure 4: ITAS results before and after PaQ®

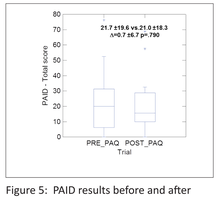

Figure 5: PAID results before and after PaQ®

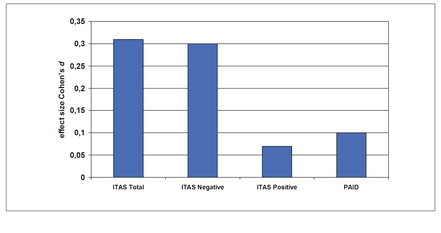

Figure 6: Effect sizes of the total score and the sub-scales of ITAS and the PAID score