562

Biomedical and patient reported outcomes from the PRO solo multi-national, multi-centre clinical trial

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Background and aims: Patch pumps provide increasing choice in insulin delivery therapy as people with diabetes look to technologies to help them achieve their diabetes goals. Patient Reported Outcomes (PROs) help to understand device burden alongside benefit, as well as impact on everyday living, acceptance of therapy regimens and drivers of self-management behaviours. This study aimed to investigate biomedical outcomes as well as the effect on PROs of the newly introduced Accu-Chek Solo micropump system compared to treatment by multiple daily injections (MDI) and an established patch pump.
Materials and methods: 181 participants were enrolled in a three-armed, randomized, controlled multinational, multi-centre trial. Individuals with type 1 diabetes naïve to insulin pump therapy (39.0 ±11.9 years old, 44% females, 15.0 ±10.8 years since diagnosis of diabetes, HbA1c **63.9**±**5mmol/mol (**8.0 ± 0.6%) used either the Accu-Chek Solo micropump system (**ACS**), MDI or Insulet Omnipod (IO) for 6 months, followed by 3 months where all used ACS. The Diabetes Technology Questionnaire (DTQ, at baseline, 3, 6 and 9 months) was the primary endpoint. Time in target range, glycaemic variability and number of insulin boluses as well as indications for commencement of insulin pump therapy were assessed according to a pre-defined analyses plan.
Results: At six months, DTQ change score was significantly higher in ACS group (105.9 ± 2.66 SD) compared to MDI (94.8±2.63) (p=0.001) but no significant differences were identified between ACS and IO participants. ACS participants achieved a greater improvement in time in range at 26 weeks (from baseline) than either MDI or IO participants (ACS: mean BG data 54.2% ±12.9 improved to 58.2% ±19.9 compared to MDI 48.1% ±11.6 to 49.6 ±11.5 or IO 52.8% ±22.7 to 48.9% ±20.6, p=0.001. Glycaemic variability was similarly reduced from 77.0 ±15; to 75.0 ±17.0mg/dL; however it increased in the IO group slightly from 68.1 ±10.2 to 68.9 ±10.0mg/dL. A slight reduction was also observed in the MDI group (71.7 ±15.0 to 70.2 ±13.1mg/dL). Participants in the ACS and IO groups experienced a greater bolus frequency increase than the MDI groups (baseline ACS mean boluses = 4.0 ±1.0 per day rising to 4.5 ±1.4 at 26 weeks; IO 4.0 ±1.1 rising to 4.8 ±2.9) compared to MDI (baseline mean = 3.9 ±1.2, unchanged at 26 weeks). The primary indication for commencement of pump therapy (stated by *n*=124, 69%) was because HbA1c goals were not being met, followed by participants' desire for the therapy (n=31, 17%).
Conclusion: PROs are increasingly relevant as drivers of self-management behaviours and subsequent clinical outcomes, including HbA1c. Participants switching from MDI therapy to the ACS micropump system experienced a significant and meaningful positive impact regarding sustained improvement in reported outcomes, with no differences between the ACS and IO users. Results indicate improved biomedical outcomes for participants in pump user groups compared to MDI and non-inferiority of the novel ACS patch pump to the well-established IO pump. Patient preferences are important parameters when deciding the best therapy for each individual user.
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