Sensor-Augmented Pump Therapy and Continuous Glucose Monitoring (CGM) were topics of significant focus at this year’s American Diabetes Association Scientific Sessions, which were held from June 24-28, 2011 in San Diego, California. Listed below are highlights from several of the studies presented at the meeting.

Sensor-Augmented Pump Therapy for A1C Reduction (STAR 3) Study: Results from the 6-Month Continuation Phase

Richard M. Bergenstal, William V. Tamborlane, Andrew Ahmann, John B. Buse, George Dailey, Stephen N. Davis, Carol Joyce, Tim Peoples, Bruce A. Perkins, John B. Welsh, Steven M. Willi, Michael A. Wood

- STAR 3, a 1-year randomized clinical trial (RCT), compared sensor-augmented insulin pump therapy (SAPT) to multiple daily injection (MDI) therapy in 485 subjects with type 1 diabetes.
- This study reports the results of the 6-month, single crossover (MDI to SAPT) continuation phase of STAR 3. Aims were to examine the durability of the effects of SAPT for up to 18 months and to evaluate the effects of switching to SAPT in subjects whose metabolic control with MDI had been optimized.
- In the RCT, baseline A1C levels were 8.3% in both groups but, at study end, A1C values were significantly lower in the SAPT group (7.5%) versus in the MDI group (8.1%) (p<0.001).
- A total of 443 subjects completed the RCT and 420 (95%) enrolled in the continuation phase. A1C remained reduced during the continuation phase in the SAPT group. After device training and 3-month use of the SAPT system, A1C decreased to 7.6% in the crossover group (p<0.001). The A1C decrease from the end of the 1-year RCT (at month 12) in the crossover group was significant at both 15 and 18 months, and among both adult and pediatric subgroups (p<0.05).
- Increased sensor wear was significantly associated with greater A1C reductions in the crossover group (p<0.001).

“Glycemic benefits of SAPT persist for at least 18 months. Both adult and pediatric subjects transitioning from MDI to SAPT experienced rapid and safe A1C reductions in the STAR 3 study continuation phase.”

Patient-Reported Outcomes in the Sensor-Augmented Pump Therapy (SAPT) for A1C Reduction (STAR 3) Trial

Richard R. Rubin, Mark Peyrot, STAR 3 Study Group

- In STAR 3, the first large RCT comparing SAPT to optimal conventional therapy (MDI with SMBG) in adults and children (n=485) over 12 months, the authors examined patient-reported outcomes (PRO) with study participants and pediatric caregivers. The authors assessed within and between treatment arm PRO changes from baseline.
- Adult health-related quality of life (HRQOL) (SF-36 Physical Component Summary [PCS] and Mental Component Summary [MCS]): PCS scores improved in the SAPT arm only (p<0.05), with no MCS change in either arm and no between-arm PCS or MCS difference in change (all p>0.05).
- Child and Caregiver HRQOL (PedsQL Physical Health Summary [PhysHS] and Psychosocial Health Summary [PsychHS]): PhysHS child and caregiver scores did not change in either arm (p>0.05) with no between-arm difference in change. Child PsychHS scores improved in both arms (p<0.05), with no between-arm difference in change. Caregiver PsychHS scores improved in the SAPT arm only (p<0.05).
- Fear of hypoglycemia (Hypoglycemia Fear Survey Worry [HFSW] and Behavior [HFSB] subscales): HFSW and HFSB scores improved in adults, children, and caregivers in the SAPT arm only, with greater improvement in SAPT than MDI in adults and caregivers (all p<0.05).
- Treatment satisfaction (Insulin Delivery System Rating Questionnaire [IDSRQ]): All IDSRQ subscale measures improved in SAPT adults, and key measures (Convenience, Efficacy, and Overall Preference) also improved in SAPT children and caregivers (all p<0.001). All significant between-arm differences in IDSRQ subscale change favored SAPT; SAPT arm improvement was greater for key measures (Convenience, Efficacy, Overall Preference) in adults, children, and caregivers (all p<0.001).

“In the first large study of SAPT compared to optimal conventional therapy, SAPT had significant PRO advantages over MDI with SMBG, especially for treatment satisfaction in adults, children, and caregivers, hypoglycemia fear in adults and caregivers, and HRQOL in caregivers.”
Insulin Pump Adjustments and Glycemic Outcomes in the Pediatric Cohort of the STAR 3 Study

- STAR 3 was a 1-year trial comparing sensor-augmented pump therapy (SAPT) to multiple daily injection (MDI) therapy in type 1 diabetes. Pediatric subjects with high vs. low end-of-study A1C values may have used or adjusted the pump in different ways.
- At baseline, the mean A1C value of the 78 subjects aged 7-18 years in the SAPT group was 8.3 ± 0.6%; by 12 months, A1C decreased to 7.9 ± 0.9% (p<0.001). Quarterly attributes of subjects with the lowest and highest A1C values at 1 year were compared.
- Subjects with low A1C values used lower total daily doses of insulin (TDD), more boluses per day, and smaller boluses than those with high A1C values (p<0.05). They had fewer sensor glucose (SG) values >180 mg/dL, but a similar number <70 mg/dL. There were more severe hypoglycemic (SH) episodes in subjects with high A1C, but the difference over the entire year was not statistically significant (p=0.061). Most pump setting adjustments occurred in the first 3 months.

“This analysis of STAR 3 data suggests that promoting behaviors that allow pediatric SAPT patients to give smaller and more frequent insulin boluses may help to optimize glycemic outcomes.”

Patient- or Physician-Driven Continuous Glucose Monitoring (CGM) Improves Control and Quality of Life (QoL) in Poorly-Controlled Type 1 Diabetic Patients on Intensified Insulin Therapy: A One-Year Multicenter Study
Pauline Schaepelynck, Laure Rocher, Helene Hanaire, Lucy Chaillous, Eric Renard, Agnes Sola, Alfred Penfornis, Nadia Tubiana-Rufi, Veronique Sulmont, Regis Radermecker, Guillaume Charpentier, Jean-Pierre Riveline

- Benefits of real-time CGM have been clearly shown in patients with type 1 diabetes (T1D) in 3 to 6-month studies. The aim of this study was to assess the effect of two approaches of 1-year use of CGM in poorly-controlled patients with T1D.
- The study was a 1-year, open, multicenter trial. Patients were randomly assigned into 3 groups: Group 1 (G1) (CGM prescribed on patient demand), Group 2 (G2) (CGM prescribed by physician recommendation), and Group 3 (G3) (conventional SMBG). The primary outcome was the change in the A1C level at 1 year. The secondary outcomes were the standard deviation (SD) of glucose levels, hypoglycemia, and QoL.
- 178 patients completed the study. At 1 year, the A1C level similarly improved in both CGM groups, and was significantly reduced when compared to the control group: G1 vs. G3: -0.52% (p=0.0006), G2 vs. G3: -0.47%, (p=0.0008), G1 + G2 vs. G3: -0.50% (p<0.0001). SD of glucose was also reduced by 11.9 mg/dL in G1 + G2 vs. G3 (p=0.018) and by 15.1 mg/dL in G2 vs. G3 (p=0.049). Occurrence of hypoglycemia was similar in the 3 groups.
- Patient satisfaction (DQoL) and physical health (SF-36) scores improved in both CGM groups at 1 year (respectively p=0.004 and p=0.04). The frequency of CGM use was significantly correlated to the improvement of A1C (p=0.05). In addition, A1C levels were more improved in patients on a pump (G1 + G2 vs. G3: -0.67%) versus patients on multiple injections (G1 + G2 vs. G3: - 0.23%).

“Long-term use of CGM resulted in a sustained and significant improvement of metabolic control and QoL in poorly-controlled T1D patients on intensified insulin therapy. The use of CGM ‘on patient demand’ is as effective as a ‘physician-prescribed’ use strategy.”