

## PS 70

### Glucose measurement and insulin injection devices

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#### Pump compatibility of insulin aspart compared to insulin lispro with respect to catheter complications and dermal/subcutaneous irritations in type 1 diabetes patients with insulin pump therapy (CSII)

T. Siegmund<sup>1</sup>, S. von Amelunxen<sup>1</sup>, M. Kaiser<sup>2</sup>, P.-M. Schumm-Draeger<sup>1</sup>; <sup>1</sup>3rd. Med. Department, Klinikum Munich GmbH, Munich, <sup>2</sup>Novo Nordisk, Mainz, Germany.

**Background and Aims:** Rapidly absorbed insulin analogues, such as insulin Lispro or insulin Aspart have demonstrated similar results considering efficacy and safety in patients with type 1 Diabetes (T1D) undergoing CSII therapy. The purpose of this study was to compare the pump compatibility of these two different insulin preparations with respect to occurrence of catheter complications and dermal/subcutaneous irritations around the catheter insertion sides.

**Materials and Methods:** In this single-center, randomized, double-blind, 2-period crossover study 20 patients with T1D on CSII therapy were randomized to two 4-week treatment periods on either type of insulin. Each patient received a standardised questionnaire after every 4-week period including 5 categories: 1. pain/burning during bolus administration, 2. inflammation at the insertion side, 3. dermal redness at the insertion side, 4. dermal/subcutaneous indurations and 4. catheter occlusions. Every category was divided into 4 degrees of severity leading to the insulin specific side-effect scores (0 points: no complications, 1 point: mild, 2 points: moderate, 3 points: strong) which were then used for statistical analysis. At the end of the study all patients were asked which insulin preparation they would prefer before the order of the insulins was cleared.

**Results:** Insulin Aspart showed an overall significant ( $p < 0.005$ ) lower side-effect score ( $1.5 \pm 1.5$  points) than insulin Lispro ( $7.1 \pm 3.6$  points). Considering the different categories, insulin Aspart showed significantly less side effects within the categories pain/burning ( $p < 0.005$ ), inflammation ( $p < 0.004$ ) and dermal redness ( $p < 0.001$ ). The categories dermal/subcutaneous indurations ( $p = 0.188$ ) and catheter occlusions ( $p = 0.375$ ) did not reach statistical significance. From the patients point of view 68.4% would have chosen insulin Aspart, 15.8% would have chosen insulin Lispro, 15.8% had no preference.

**Conclusion:** Insulin Aspart shows a lower side-effect score considering pump compatibility with respect to occurrence of catheter complications and dermal/subcutaneous irritations compared to insulin Lispro and was overall better tolerated in patients with T1D undergoing CSII therapy. Patients suffering from these complications may benefit from using insulin Aspart.

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#### Insulin infusion set survival comparing Novolog with Humalog

B. Buckingham, J. Block, P. Clinton, E. Kunselman, D. Wilson; Pediatric Endocrinology, Stanford University, Palo Alto, United States.

**Background:** There is a common perception amongst our pump patients that infusion sets last longer with more stable diabetes control and less infusion site reactions when Novolog is used rather than Humalog.

**Methods:** To test this hypothesis, 18 subjects were assigned in a double-blind, cross-over study to use either Novolog or Humalog for 1 week without changing the infusion set. The sequence of insulin use was randomized. Insulin was supplied by the pharmacy in generic bottles labeled insulin "A" or "B". Subjects used a "Silhouette" infusion set, and were asked to continue to use the same set until there was: 1) a blood glucose of  $> 300$  mg/dl that failed to decrease by 50 mg/dl one hour following a correction dose, 2) serum ketones  $> 0.6$  mmol/l associated with a blood glucose  $> 250$  mg/dl, 3) more than 5 mm of redness or firmness at the infusion site 4) or study end (1 week). All subjects wore a Minimed continuous glucose sensor (CGMS) while their study infusion sets were functioning.

**Results:** The mean ( $\pm$ SD) duration for infusion set survival using Novolog was  $4.9 \pm 1.8$  days and for Humalog was  $5.1 \pm 1.8$  days ( $p = \text{NS}$ ). In each group there were 8 subjects (44%) who used their infusion sets for the full 7 days (6 subjects had both infusion sets last 7 days). Six sets infusing Humalog were removed for hyperglycemia and a failed correction dose (mean duration 3.4 days), and 2 sets infusing Novolog failed for the same reason (mean duration 3.6 days). Three sets infusing Humalog were

removed for erythema, induration, and/or pain (mean duration 4.2 days) and 6 sets infusing Novolog were removed for the same reason (mean duration 3.6 days). During the 7 study days, 26% of infusion set sites had erythema  $> 5$  mm compared to 8% of CGMS sites, and 10% of infusion sites had induration  $> 5$  mm compared to 0% of CGMS sites. Infusion set catheters were stained with dithizone and all catheters had evidence of insulin precipitation in the tubing. Subjects were unable to correctly identify which insulin they were using.

**Conclusion:** We could not demonstrate a difference between Novolog and Humalog in infusion set survival.

Support: Novo Nordisk

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#### Insulin treatment satisfaction and fear of self-injection: a comparison of the InnoLet insulin doser and standard vial/syringe

C. Ory<sup>1</sup>, A. Vanderplas<sup>1</sup>, L. Nicklasson<sup>2</sup>, W. Lyness<sup>3</sup>, E. Chang<sup>1</sup>, K. Stockl<sup>1</sup>; <sup>1</sup>Health Informatics and Outcomes Research, Prescription Solutions, Costa Mesa, <sup>2</sup>Health Economics and Pricing, Novo Nordisk Pharmaceuticals, Princeton, <sup>3</sup>Clinical Research, Novo Nordisk Pharmaceuticals, Princeton, United States.

**Background and Aims:** InnoLet insulin injection device is specifically designed to overcome practical and psychological obstacles that prevent many patients from effectively managing their insulin treatment. InnoLet is a disposable insulin injection device with a large easy-to-read dial, large push button for injection, and audible clicks for each unit injected. The objective of this study was to evaluate insulin treatment satisfaction, including fear of self-injection, associated with use of the InnoLet insulin doser vs. standard vial/syringe.

**Materials and Methods:** In a prospective, randomized, open-label, two-period (each 12 weeks), crossover study, 260 patients were enrolled (age  $\geq 18$  yrs, with type 1 or 2 diabetes, and receiving NPH or regular or 70/30 insulin for at least 6-months). Patients were excluded if they had a baseline  $\text{HbA}_{1c} > 10\%$ , were unable to read/write English, were unable to administer their own injections, were pregnant/lactating, were using antipsychotic medications, or had a history of alcohol abuse or cognitive impairment. Patients were randomized to use either vial/syringe or InnoLet for 12 weeks, and then switched to the alternate treatment for 12 weeks. At the end of each treatment period, patients completed the Insulin Treatment Satisfaction Questionnaire (ITSQ) and Fear of Self-Injection Questionnaire. The ITSQ consisted of 25-items on a 7-point Likert scale which were transformed to six subscales ranging from 0-100; higher scores represented greater satisfaction. The Fear of Self-Injection Questionnaire consisted of 8-items on a 4-point Likert scale; higher scores represented greater fear.

**Results:** Of the entire cohort, 165 (64%) patients completed the study. Of these, 91 (55%) were in the vial/syringe-to-InnoLet treatment group, 50% were female and mean age was  $60 \pm 11$  years. No significant differences in baseline characteristics were observed in either treatment group. Of the 165 patients, 164 patients completed all six ITSQ subscales and 160 patients completed the entire Fear of Self-Injection Questionnaire in both treatment periods. There was a significant difference in ITSQ scores between the delivery systems. While using the InnoLet system, patients scored higher on all six ITSQ subscales, which included convenience of regimen, lifestyle flexibility, glycemic control, hypoglycemic control, and insulin delivery device satisfaction (Wilcoxon,  $p < 0.001$ ). Patients reported significantly lower fear of self-injection after using InnoLet vs. vial/syringe (Mean  $\pm$  SEM:  $9.4 \pm 0.2$  vs.  $11.0 \pm 0.4$ ;  $p < 0.0001$ ).

**Conclusion:** The InnoLet<sup>®</sup> may offer greater patient acceptance, improved treatment satisfaction and reduced fear of self-injection. These findings may be clinically significant, given the potential health gains that can be obtained through improved diabetes self-management.

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#### Which needle length for injecting insulin

G. Kreugel<sup>1</sup>, H. J. M. Beijer<sup>2</sup>; <sup>1</sup>Endocrinology, University Hospital Groningen, Groningen, <sup>2</sup>Faculty of Health Care, Hogeschool Utrecht, The Netherlands.

**Background and Aims:** In the Netherlands most patients with diabetes mellitus that are treated with insulin, use an insulin pen for insulin administration. The injection technique can influence the absorption rate of insulin. Diabetes nurses created transmural guidelines about injecting insulin. It was not clear what would be the correct advice concerning the length of the needles. The aim of this study is to compare the effect of insulin injections using a 5 mm insulin needle with insulin injections using a longer needle,