

(in duplicate 15-days separated to assess test-retest reliability), trait-anxiety scale of the STAI and eight specific questions about glycemic control, compliance and pain were administered. Sociodemographic and clinical data were also collected. Feasibility (item and questionnaire responder rate and time to completion) content validity (item-total correlation and factor analysis), concept validity (correlation with STAI and specific questions) and reliability (test-retest and Cronbach's Alpha) were assessed. **RESULTS:** A 32-items version was developed by an expert panel and administered to 93 (35 Type 1, 58 Type 2) insulin-treated diabetic patients. Ninety-nine% of patients answered all items in 5 minutes (median). Item-total correlation and factor analysis lead to an abridged version with 19 items, maintaining the two original dimensions, and explaining the 47.4% of total variance: FSI; 29.5%, and FST; 17.9%. Test-retest correlation coefficient were 0.85 (FSI) and 0.94 (FST); Cronbach's Alpha were 0.81 (FSI) and 0.89 (FST). FST correlated positively with time treated with insulin ( $p < 0.011$ , type 2); FSI correlated positively with patient reported compliance ( $p = 0.002$ ) and lack of worry in diabetes consequences ( $p = 0.005$ , type 2), and negatively with time treated with insulin ( $p < 0.023$ , type 1). **CONCLUSIONS:** We developed a new-recalibrated version of the Spanish D-FISQ called MIAT-D. Feasibility, dimensionality, content validity and reliability were accurate. Due to the fact of cultural differences and lack of a gold standard for concept validity, this property need to be explored in further studies.

PDB48

#### MANAGEMENT AND TREATMENT ADHERENCE IN TYPE 2 DIABETIC PATIENTS IN SPAIN

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**OBJECTIVES:** Management of Spanish patients with Type 2 diabetes and predictors of adherence to their medication. **METHODS:** Multicenter, naturalistic study of type 2 diabetes patients with a diagnosis longer than one year. Patients were consecutively included in the study among those attending any of the selected 30 Primary Care Centers distributed throughout Spain Sociodemographic and clinical variables were collected. Patients completed the Morisky-Green questionnaire as a measure of adherence. A logistic regression was performed with sociodemographic, clinical, and treatment variables to predict factors of adherence. **RESULTS:** A total of 294 patients were included in the study (mean age = 67.5 yrs; mean duration of diabetes = 9.9 yrs). A total of 6.1% were not receiving anti-diabetic pharmacological treatment, 70.4% received oral(s) therapy, 10.9% were in insulin therapy, and 12.6% a combination of insulin and oral(s) therapy. A total of 58.2% of patients had poor glycemic control (HbA1c > 6.5%). With respect to diabetic complications, 20.4% of patients suffered from microvascular complications only, 11.2% reported macrovascular issues only, while 14.3% suffered from both micro and macrovascular complications. The Morisky-Green questionnaire showed only 47.8% of patients under pharmacological treatment reported a high level of adherence. The logistic regression models showed in that in those patients receiving only insulin, the probability of having a high level of adherence is significantly higher (odds ratio: 2.7) than non-insulin receiving patients. Moreover, when a patient's HbA1c value is lower by one percentage point, the probability of having a high level of adherence is greater (odds ratio: 1.3) compared to the adherence seen at a higher A1c level. **CONCLUSIONS:** Oral agents were the most commonly prescribed anti-diabetic pharmacological agent. Less than half of the

patients reported high adherence to their medication. The level of diabetes control and insulin treatment were found to be associated with adherence although further work should investigate the causal relationship between these variables.

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#### TREATMENT SATISFACTION WITH INSULIN GLARGINE AND INSULIN GLULISINE IN DIABETES MELLITUS—EVALUATED IN AN OBSERVATIONAL STUDY IN GERMANY

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**OBJECTIVES:** Patient reported outcomes (PRO), quality of life (QoL) and clinical efficacy achieved with a combination of insulin glargine (GLA) and insulin glulisine (GLU) were documented in daily practice. **METHODS:** An observational study in Germany documented 1447 type 1 patients (age  $42.6 \pm 14.5$  years) and 5695 type 2 patients (age  $61.8 \pm 10.5$  years) insufficiently controlled under prior intensified insulin therapy who were switched to GLA (mean daily dose at baseline  $21.8 \pm 9.6$  I.U. for type 1 and  $24.4 \pm 13.0$  I.U. for type 2) and GLU ( $28.0 \pm 13.0$  and  $34.4 \pm 23.0$  I.U. respectively) for 89 and 91 days in median respectively. Efficacy was measured by fasting blood glucose (FBG) and HbA1c values. QoL was evaluated with a 5-item-Likert-scales from physician's perspective. PRO was measured with a visual analogue scale (VAS) and a diabetes treatment satisfaction questionnaire (DTSQs) respectively. **RESULTS:** The findings are given for type 1 and type 2 respectively. Mean FBG levels decreased about  $36.4 \pm 48.7$  and  $48.3 \pm 41.6$  mg/dl, HbA1c-values about  $1.0 \pm 1.2$  and  $1.2 \pm 1.0\%$  compared to previous therapy. Sum scores for six categories of QoL in physician's assessment improved from  $14.5 \pm 3.6$  to  $10.1 \pm 3.1$  at follow-up and from  $15.4 \pm 3.7$  to  $10.4 \pm 3.2$ . VAS-scores (0 to 100 scale) improved from  $41.9 \pm 22.0$  to  $19.6 \pm 14.1$  and from  $49.6 \pm 20.9$  to  $22.8 \pm 16.0$ , DTSQs-sum scores from  $20.7 \pm 6.7$  to  $29.3 \pm 5.1$  and from  $19.1 \pm 6.6$  to  $28.4 \pm 5.4$  ( $p < 0.0001$  for all reductions). **CONCLUSION:** In comparison to preceding insulin treatment, basal-bolus therapy with GLA and GLU improved various treatment satisfaction measures from different perspectives in accordance with clinical efficacy.

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#### MYTHS AND REALITIES OF TREATMENT SATISFACTION IN DIABETES

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**OBJECTIVES:** Clinical wisdom assumes that treatment satisfaction (TS) with insulin improves with fewer injections and side effects. We examined the relationships between TS, patient characteristics (age, gender, ethnicity, weight, co-morbidities, diabetes duration) and treatment outcomes (HbA1c, number of daily injections, weight gain, hypoglycemic events). **METHODS:** Baseline and 28 week RCT data comparing efficacy and safety of Biphasic Insulin Aspart 70/30 (BIAsp 70/30, NovoMix® 30/NovologMix® 70/30) vs. insulin glargine in type 2 diabetics ( $n = 240$ ) were analyzed. Subjects completed the Insulin Treatment Satisfaction Questionnaire (ITSQ—overall TS and 5 domains: Lifestyle Flexibility, Hypoglycemic Control, Glycemic Control, Device Satisfaction, Inconvenience of Regimen). Regression analyses examined the relationship between TS, patient/disease characteristic and outcomes. Significant factors were examined together by multivariate regression analyses.