

by the patient preference to different characteristics of ESA treatments. Patients had to complete a questionnaire at baseline and around 6-month. Questionnaire was developed using a CBC analysis method with the following hypothesis: 1) 7 ESA characteristics; 2) from 2 to 3 levels per characteristics; 3) each possible answer includes 1 level for 2 characteristics; 4) 2 choices per question; 5) and 6) 7 questions per CBC questionnaire. The number of combinations between all characteristics and levels was 288, and 20 questionnaires have been generated in order to mix all possible treatment characteristics and levels. Patients only had to answer one questionnaire and a randomization has been used to obtain equal number of respondents for each questionnaire. CBC analysis was planned and performed for subgroup of patients already receiving ESA or not. **RESULTS:** A total of 790 patients were included, 609 questionnaires were analyzed at baseline. Fifty-five percent of patients were already treated by ESA, among them the most important characteristic was the planned frequency of administration for 31%, followed by the importance of the treatment efficacy for 20%, the pain at injection site for 11%. But when asking a direct question to patient on which characteristic was the most important, 82% of them answered treatment efficacy, 5% for pain at injection site and frequency of injection. Similar results were found for ESA naïve patients. **CONCLUSIONS:** The CBC analysis revealed that frequency of injections is underestimated by patients and should be taken into account by physicians when choosing an ESA treatment.

PUK16

ONE MONTH AFTER TREATMENT INITIATION NOCTURIA PATIENTS SLEPT SIGNIFICANTLY LONGER AND BETTER ON TREATMENT THAN PLACEBO PATIENTS

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OBJECTIVES: To explore how fast patients treated for nocturia (waking up at night one or more times to void) reported improvement in initial period of undisturbed sleep and sleep quality. **METHODS:** A 3 month randomized, controlled, double-blind study at 39 centers in US and Canada comparing treatment versus placebo in patients with ≥ 2 voids/night. The initial period of undisturbed sleep was based on patient reported sleep/void diary. Self reported sleep quality was assessed by two VAS scales: 1) quality of last night's sleep, and 2) feeling refreshed in the morning. **RESULTS:** Following 1 week of Desmopressin treatment patients on both placebo and drug had an increase in undisturbed sleep (women: 81/105 min; men 30/71 min (placebo/treatment, respectively)). After 1 month treatment patients slept statistically significantly longer (women 95 /131 min, $p=0.02$; men 56/99 min, $p<0.001$), increasing to a 3 month treatment contrast of 49 minutes (women) and 39 minutes (men) and with a mean total period of undisturbed sleep of 5.2 hours (women) and 4.3 hours (men). Patient self reported sleep quality on a 10 point scale increased after 1 week (women 1.2 vs. 1.6; men 0.5 vs. 0.7) growing to significant treatment difference in women ($p= 0.03$) and numerical difference in men after 3 months (women 1.8 vs. 2.3; men 1.3 vs. 1.7). Self reported feeling of being "refreshed in the morning" increased after 1 week (women 1.1 vs. 1.5; men 0.5 vs. 0.7) and was statistically significant versus placebo at month 3 (women 1.7 vs. 2.2, $p=0.04$; men 0.85 vs. 1.34, $p=0.01$). **CONCLUSIONS:** Treatment increased patients self reported initial period of undisturbed sleep already after one week and was significantly different from placebo from month 1 and onwards. Patients experienced a consequent improvement in sleep quality and feeling refreshed in the morning.

PUK17

PATIENTS WITH NOCTURIA – INCREASING TIME TO FIRST VOID IMPROVES SLEEP QUALITY

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OBJECTIVES: Traditionally, treatment of nocturia (waking up at night one or more times to void) has been focused on a reduction in number of voids. However, a serious consequence of nocturia is fragmentation of sleep. Research has shown that the initial hours of sleep is fundamental for obtaining the necessary amount of slow wave sleep (SWS). **METHODS:** Data from two randomized, placebo-controlled trials (US/Can) with 646 adult patients with nocturia (≥ 2 voids/night determined via 3-day voiding diary) was used. Patients were to rate three sleep quality questions on a 10-point visual analogue scale during the three months of treatment (baseline, Day 4, Week 1, Month 1, 2 and 3): 1) How do you feel right now? 2) Feeling refreshed in the morning? and 3) Quality of last night's sleep? A threshold of 4 hours to time to first void (TTFV) (i.e. initial undisturbed sleep) were explored in terms of improved scores in the sleep quality questions, by comparing patients in the following 4 groups: 1) Poor sleep: TTFV <4 hours at all visits (baseline and post-baseline); 2) Improved somewhat: Baseline TTFV <4 hours and at least 1 post-baseline TTFV ≥ 4 hours; 3) Improved: Baseline TTFV <4 hours, all post-baseline TTFV ≥ 4 hours; and 4) Over threshold at baseline: Baseline TTFV ≥ 4 hours. **RESULTS:** The change from baseline in all three sleep quality questions were statistically and clinically improved for group 2 (Improved somewhat) and even further improved for group 3 when comparing with group 1, with significant differences already occurring at week 1. The differences widened over the study period. The magnitude of improvement was consistently higher for females compared to males. **CONCLUSIONS:** In conclusion, more than 4 hours of undisturbed sleep is associated with rapid and clinically meaningful improvements in sleep quality for nocturia patients and could be used as a future treatment goal.

PUK18

PSYCHOMETRIC ANALYSES OF PATIENT-REPORTED OUTCOME INSTRUMENTS FOR AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE

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OBJECTIVES: Patient-reported disease burden in Autosomal Dominant Polycystic Kidney Disease (ADPKD) has not been rigorously documented. This study provides initial evaluation of the psychometric properties of two new ADPKD-targeted instruments: ADPKD Impact Scale (ADPKD-IS) and ADPKD Urinary Impact Scale (ADPKD-UIS). **METHODS:** US-English versions of ADPKD-IS and ADPKD-UIS were administered to 702 adults with ADPKD as part of an observational study. Confirmatory factor analysis (CFA) was conducted to test the fit of previously developed conceptual frameworks. Next, item response theory (IRT) and classical psychometrics were examined, including item- and scale-level reliability and convergent validity (with the SF-12v2 and Brief Pain Inventory – Short Form (BPI-SF)). **RESULTS:** CFA results for both instruments demonstrated good fit between data and conceptual frameworks (ADPKD-IS domains of physical impact, fatigue, and emotional impact and ADPKD-UIS domains of urinary urgency burden, urinary frequency burden, and nocturia burden): ADPKD-IS = confirmatory fit index (CFI)/nonnormed fit index (NNFI) > 0.95, root mean square error of approximation (RMSEA) < 0.06; ADPKD-UIS = CFI/NNFI > 0.99, RMSEA < 0.08. IRT- and item-level analyses revealed no misclassified items with their intended scales or problems with skew or inappropriate heterogeneity of variance throughout the response scale. Internal consistency reliability for all domains ranged from the mid .80s to mid .90s. Convergent validity of the ADPKD-IS/ADPKD-UIS domains was supported by correlations with the SF-12 (PCS/MCS) and BPI-SF domains (mid .40s to mid .60s). **CONCLUSIONS:** The ADPKD IS/ADPKD-UIS instruments demonstrated prespecified psychometric criteria. Whereas longitudinal evaluation of these measures is needed, the current study provides encouraging results for these new ADPKD-specific measures of patient burden.

PUK19

CONTENT VALIDITY OF THE ACTIONABLE BLADDER SYMPTOM SCREENING TOOL (ABSST) IN NON-DIABETIC FEMALES WITH OVERACTIVE BLADDER (OAB) AND URGENCY URINARY INCONTINENCE (UUI)

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OBJECTIVES: To assess the content validity of the Actionable Bladder Symptom Screening Tool (ABSST), previously validated in patients with multiple sclerosis (MS) associated neurogenic detrusor overactivity (NDO), in women with overactive bladder (OAB) and urgency urinary incontinence (UUI). The ABSST is an 8-item questionnaire which assesses bladder symptoms along with their impact. **METHODS:** Cognitive interviews were conducted with non-diabetic female gynecology patients suffering from OAB and UUI to 1) understand how subjects describe experiencing OAB and UUI and, 2) assess subjects' comprehension of the ABSST. Interviews were audio-recorded, transcribed verbatim, and analyzed using Atlas.ti. **RESULTS:** Ten subjects were interviewed; 6 Caucasian, mean age was 49.2 ± 13.7 , and 7 full- or part-time employed. All 10 subjects had clinician-confirmed and self-reported OAB (average duration 6.9 ± 4.7 years). Mean ABSST score was 4.2 out of 8. Subjects understood the 5 symptom items (frequencies of urinary urgency, urgency incontinence, nocturia, and total micturition, and intensity of urinary urgency) and the 3 impact items (social limitations, embarrassment, and work limitations) as intended including instructions, and response options. Subjects confirmed that the symptoms were relevant and important. Although only a few subjects spontaneously reported experiencing the symptom impacts, 6 subjects acknowledged embarrassment was important and 7 subjects reported experiencing work limitations. **CONCLUSIONS:** Overall, subjects found the ABSST items relevant and easy to understand. Participants found the symptom items were more relevant than the impact items. Possible explanations may be that these gynecology patients are a younger, healthier group compared to the MS sample, and have adapted to and coped with their conditions thereby lessening the perceived impacts of OAB and UUI. Nonetheless, the ABSST was understood well and was reported to be comprehensive and relevant to their experiences with OAB and UUI symptoms.

PUK20

IMPACT OF MIRABEGRON TREATMENT AND SYMPTOM SEVERITY ON WORK PRODUCTIVITY AND ACTIVITY IMPAIRMENT IN PATIENTS WITH OVERACTIVE BLADDER

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OBJECTIVES: Mirabegron, a novel selective beta-3 adrenergic agonist, has recently been approved in the United States for the treatment of overactive bladder (OAB). This study aimed to assess the impact of mirabegron on Work Productivity and Activity Impairment (WPAI) and the associations between WPAI outcomes and OAB symptom severity. **METHODS:** Data were obtained from a 12-week phase III randomized trial (NCT00662909) comparing mirabegron 50mg and placebo for OAB treatment. WPAI outcomes were measured using the WPAI-Questionnaire for OAB, including employment and total activity impairment (TAI) for all patients, and absenteeism, presenteeism and total work productivity impairment (TWPI) for employed patients. OAB severity measures included