feeder study baseline). These changes were maintained or further improved during the open-label extension, such that significant improvements (p < 0.001 vs. feeder study baseline) were observed for darifenacin 7.5/15 mg in the same eight KHQ domains after a further 24 months of treatment. Darifenacin was well tolerated and the overall long-term safety profile was consistent to that observed in the 12 week phase III studies. CONCLUSIONS: Darifenacin significantly improves QoL in patients with OAB, with improvements maintained for 2 years during open-label treatment.

**PUK29**

**DEVELOPMENT AND VALIDATION OF A COMPREHENSIVE SYMPTOM CHECKLIST IN URINARY INCONTINENCE**

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**OBJECTIVE:** To develop and validate a unique tool specific to urinary incontinence (UI) symptoms covering all types of incontinence among both men and women. METHODS: An Advisory Committee (AC) of 5 urologists was set up, involved at all stages of questionnaire development and validation. A test questionnaire was developed by AC with content validity being assessed simultaneously on 3 men, 4 women suffering from UI and 3 clinicians. Clinicians were asked to comment items’ relevance and comprehensiveness; patients completed the scale and were asked to provide general comments regarding the scale and detailed comments regarding each element. The scale was redrafted and tested on 25 other patients. A longitudinal, multi-centre, anonymous, observational study was carried out to validate the scale. The scale was administrated by 21 urologists to 258 stable patients (206 UI sufferers and 52 not UI sufferers) until June 15th 2005. Patients filled in the scale, the ICIQ-SF and a diary twice at one-week interval and clinicians completed a medical form at baseline.

**RESULTS:**

- The test scale contained 11 items covering urge, SUI, dysuria and pollakiuria. After initial cognitive debriefing and comments regarding each element, the scale was redrafted and tested on 25 other patients. A longitudinal, multi-centre, anonymous, observational study was carried out to validate the scale.
- The scale was administrated by 21 urologists to 258 stable patients (206 UI sufferers and 52 not UI sufferers) until June 15th 2005. Patients filled in the scale, the ICIQ-SF and a diary twice at one-week interval and clinicians completed a medical form at baseline.
- RESULTS: The test scale contained 11 items covering urge, SUI, dysuria and pollakiuria. After initial cognitive debriefing and comments regarding each element, the scale was redrafted and tested on 25 other patients. A longitudinal, multi-centre, anonymous, observational study was carried out to validate the scale. The scale was administrated by 21 urologists to 258 stable patients (206 UI sufferers and 52 not UI sufferers) until June 15th 2005. Patients filled in the scale, the ICIQ-SF and a diary twice at one-week interval and clinicians completed a medical form at baseline.
- RESULTS: The test scale contained 11 items covering urge, SUI, dysuria and pollakiuria. After initial cognitive debriefing and comments regarding each element, the scale was redrafted and tested on 25 other patients. A longitudinal, multi-centre, anonymous, observational study was carried out to validate the scale.
- RESULTS: The test scale contained 11 items covering urge, SUI, dysuria and pollakiuria. After initial cognitive debriefing and comments regarding each element, the scale was redrafted and tested on 25 other patients. A longitudinal, multi-centre, anonymous, observational study was carried out to validate the scale.

**CONCLUSIONS:** The list was updated according to comments collected during 8 semi-structured clinicians interviews. Clinicians were asked about the relevance, comprehensiveness, and ability of the listed activities to capture changes. They also reported how their patients managed to control the risk of leakage. Twenty SUI women were asked to assess the relevance, importance, and applicability of each effort, to reword the list and to describe with their own words how they control the risk of leakage. The scale was finalised according to their comments.

**RESULTS:** A list of 72 daily life efforts provoking leakages was set from 15 UI specific scales and 21 studies selected from the literature. The clinician interviews allowed to group similar concepts and to establish a shortlist containing the 15 most relevant efforts. Answer choices covered the occurrence of leakage, and various behaviour adaptation such as seeking help, taking precautions, muscular control, and avoiding situations. After validation of format, items, wording, and answer choices, by the patients, the pilot scale was produced.

**CONCLUSION:** This self-reported scale allows SUI patients to accurately describe their control on leakage risk in daily life efforts. This highly specific instrument will allow clinicians to better assess the true impact of therapeutic options on patients’ life, in both clinical research and clinical practice. The scoring procedure and its properties will be assessed in a specific validation study.

**PUK30**

**BENIGN PROSTATE HYPERPLASIA: RELATION BETWEEN IPSS, SPI AND QUALITY OF LIFE IPSS ITEM SCORES**

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**OBJECTIVES:** The International Prostatic Symptom Score (IPSS) evaluates the frequency of symptoms associated with lower urinary tract symptoms (LUTS). An eighth question (q8) evaluates the patient’s overall satisfaction dealing with his urinary tract status but does not study in detail his bothersomeness. The SPI score (Symptom Problem Index) evaluates the patient’s overall satisfaction dealing with his urinary tract status but does not study in detail his bothersomeness. The scores were also weakly related to SPI (r = 0.57). The question on quality of life corresponded to maintenance or avoidance of activities causing leakages, the additional benefit of therapeutic options might be important to capture. Our objective was to develop a new specific and sensitive endpoint to evaluate treatment effects in Stress Urinary Incontinence (SUI) in clinical trials. METHODS: A comprehensive list of efforts provoking leakages was established from a systematic literature review and 30 clinician interviews. The list was updated according to comments collected during 8 semi-structured clinicians interviews. Clinicians were asked about the relevance, comprehensiveness, and ability of the listed activities to capture changes. They also reported how their patients managed to control the risk of leakage. Twenty SUI women were asked to assess the relevance, importance, and applicability of each effort, to reword the list and to describe with their own words how they control the risk of leakage. The scale was finalised according to their comments.

**RESULTS:** A list of 72 daily life efforts provoking leakage was set from 15 UI specific scales and 21 studies selected from the literature. The clinician interviews allowed to group similar concepts and to establish a shortlist containing the 15 most relevant efforts. Answer choices covered the occurrence of leakage, and various behaviour adaptation such as seeking help, taking precautions, muscular control, and avoiding situations. After validation of format, items, wording, and answer choices, by the patients, the pilot scale was produced. **CONCLUSION:** This self-reported scale allows SUI patients to accurately describe their control on leakage risk in daily life efforts. This highly specific instrument will allow clinicians to better assess the true impact of therapeutic options on patients’ life, in both clinical research and clinical practice. The scoring procedure and its properties will be assessed in a specific validation study.