BPH AND IPSS SCORES EVALUATED AFTER 6 MONTHS ACCORDING TO THE TYPE OF DISEASE MANAGEMENT

Marionneau N, Myon E, Charles T
Pierre Fabre, Boulogne-Billancourt, France

OBJECTIVES: Benign prostatic hyperplasia (BPH) occurs frequently in middle-aged and elderly men. Recent epidemiologic data suggest that 50% of men aged 50 years are concerned. Because of the growing elderly population in the industrialised countries, the management of the disease is becoming a major public health problem. A wide variety of medical treatment is available, and the financial burden associated to it is increasing. This is a public health problem with a number of diagnostic, therapeutic and economic facets. The severity of the problem is assessed by the score obtained on the IPSS, a well known and recognised questionnaire. METHODS: More than 700 patients with BPH diagnosed for less than 3 months will be included in the CHOQ program by 250 general practitioners. Every 6 months, and for at least 3 years, the patient and his partner will fill out a quality of life questionnaire. This questionnaire is composed of a generic instrument that assesses the general health condition, and 5 specific instruments that investigate the consequences of the BPH on sexuality, sleeping and urinary symptoms.

RESULTS: Using a follow-up cohort study, we isolated two groups presenting a recently diagnosed BPH: the first patient population was kept under watchful waiting (n = 101) versus a second patient population undergoing treatment with Serenoa repens (n = 112). For the patients under watchful waiting, the IPSS score was respectively 11.8 (5.7) and 10.9 (6.7) upon patient inclusion and after 6 months. This difference is not statistically significant. However, for the patients treated with Serenoa repens, the IPSS score was respectively 14.3 (6.6) and 11.9 (5.7) upon patient inclusion and after 6 months. The noted difference is statistically significant (p < 0.0001). CONCLUSIONS: Patients suffering from a recently diagnosed BPH and treated with Serenoa repens thus showed a statistically significant improvement as demonstrated by the IPSS score.

Benign Prostatic Hyperplasia: Cross Evaluation of the GP-Patient IPSS

Perrin P1, Marionneau N2, Ruffion A1, Myon E1, Taieb C1
1Lyon Sud Hospital, Pierre Bénite, France; 2Pierre Fabre, Boulogne-Billancourt, France

OBJECTIVES: To compare the results obtained with the IPSS administered by GP (GP-IPSS) versus a self administered questionnaire (patient-IPSS). METHODS: A total of 338 recently diagnosed BPH patients were involved in the analyses. For each of them, their GP (General Practitioner) filled an GP-IPSS questionnaire in according to their knowledge of their patients. The patient completed the patient-IPSS questionnaire himself and send it back to data management center through a prepaid envelope to avoid patient’s answers to be viewed by the GP. Bland & Altman method was chosen to visualize individual difference and to quantify the bias. RESULTS: On average GP overestimated by 1.3 points [0.9–1.7] 95% the IPSS compared to patient self evaluation. Individual discrepancies reached 3 points or more among 42% of patients. The results of GP-IPSS were significantly higher at 6 months, 12 months and 18 months taking into account Bonferroni correction. CONCLUSIONS: There was a statistically significant bias between GP’s administered IPSS and self administered IPSS. We recommend to always keep the same IPSS administration’s mode during the course of a clinical trial.

Estimation and Analysis of Direct Medical Cost of Secondary Hyperparathyroidism (SHPT) in Dialysis Patients

Rosillon D1, Ducarme X2, Lins RL1, Standaert B1
1SGS Biopharma, Ware, Belgium; 2ZNA Stuivenberg, Antwerp, Belgium

Secondary hyperparathyroidism (SHPT) is frequently observed in dialysis patients leading to costly to treat health complications. METHODS: To assess whether direct medical costs significantly vary with SHPT conditions. METHODS: Direct medical cost and resource use data were retrospectively collected from patient medical files and invoices of 73 dialysis patients over maximum period of 2 years prior to death in 3 dialysis centres in Belgium. Total collection period was segmented into two SHPT condition episodes defined by PTH values ≤ or >300 pg/mL, using linear interpolation lines between subsequent PTH measurements. Costs were retrieved from hospital invoices, including start and stop date of each bill and cost category (hospitalisations, medications, dialysis, laboratory tests, honoraria, and other). To overcome problems of incomplete invoices, an invoice coverage factor was developed comparing available invoices with health care resource utilisation from medical files. Periods with insufficient coverage were discarded. Resource use and costs were attributed to each individual PTH condition episode. Statistical modeling: Because of heavily skewed cost data, incomplete data sets, the need to adjust cost results for time to death and centre effect, mixed models on non-transformed and log-transformed costs and General Linear Model (GLM) with a gamma response probability distribution and a loglink function were used. RESULTS: Results expressed as mean cost per day show that periods with elevated PTH-values lead to higher costs compared to normal periods (average cost-difference per day: approximately €50; p < 0.05). Results will further be discussed regarding distribution of residuals, and hypothesis testing. To assess robustness of results, three sensitivity analyses were performed: analysis on subjects having experienced both PTH conditions before death; analysis over different observation periods using 6 months incremental time periods; cost depreciation factor. CONCLUSIONS: The statistical method allowed obtaining robust and valuable cost estimates for different SHPT conditions.

Exploring Neurogenic Detrusor Overactivity Within an Overactive Bladder Population

Bridge S1, Solanki J1, Lister S2
1Pfizer Ltd, Tadworth, Surrey, UK; 2CompuFile Ltd, Woking, Surrey, UK
### Abstracts

**PUK20**

**BENIGN PROSTATE HYPERPLASIA: MUST BOTHERSOMENESS OF SYMPTOMS BE PRIVILEGED?**

Perrin P1, Marionneau N2, Cucherat M3, Taeib C4, Myon E5

1Lyon Sud Hospital, Pierre Bénite, France; 2Pierre Fabre, Boulogne-Billancourt, France; 3University Teaching Hospital (CHU), Pierre Bénite, France

**OBJECTIVES:** The IPSS evaluates the frequency of lower urinary tract symptoms (LUTS). The SPI score (Symptom Problem Index) evaluates the degree of discomfort associated with each question on the IPSS. Our objective is to quantify the degree of bothersomeness induced by each BPH symptom.

**METHODS:** A cohort of 907 male patients with BPH diagnosed or receiving treatment for Parkinson's disease, stroke, multiple sclerosis or spinal cord injury. Data was analysed by age, gender and OAB symptoms.

**RESULTS:** The cohort contained 13,482 OAB patients, representing a prevalence of 1.7% of the population (n = 815,054) of whom 61% (n = 8150) were women and 43% were aged over 65. In total, 1314 (10%) patients had a neurological disease, this increased to 16% (948 patients) in those over 65. Incontinence was experienced by 29% (n = 384) of those with a neurological disease but in only 18% of the complete cohort. Those with neurological disease also more commonly experienced urinary frequency. **CONCLUSION:** This study suggests that there is value in assessing patients who present with OAB symptoms for early signs of underlying neurological conditions. It is important to identify neurological disease as the cause of detrusor overactivity. This will help clinicians understand the aetiological factors behind the condition and also help in its overall management.

**PUK21**

**INDUCED BOTHERSOMENESS IN THE ANALYSIS OF THE IPSS QUESTIONNAIRE**

Marionneau N1, Perrin P2, Charles T3, Myon E4, Cucherat M5

1Pierre Fabre, Boulogne-Billancourt, France; 2Lyon Sud Hospital, Pierre Bénite, France; 3University Teaching Hospital (CHU), Pierre Bénite, France

**OBJECTIVES:** The International Prostatic Symptom Score (IPSS) evaluates urinary disorders symptoms frequency associated with benign prostatic hyperplasia, but does not take into account the bothersomeness that they induce. The Symptom Problem Index (SPI) evaluates the degree of discomfort associated with each question on the IPSS. Our objective is to quantify the degree of bothersomeness induced by each BPH symptom.

**METHODS:** A cohort of 907 male patients with BPH was monitored by French General Practitioners (GP). The IPSS and SPI questionnaires were self-administered. The IPSS and SPI scores were evaluable for 722 patients. The relationship between SPI and IPSS was investigated through the correlation between the 2 scores and by the construction of quadratic curve estimations for each symptom. The degree of bothersomeness that each symptom induces was explored by the Area Under the Curve (AUC) corresponding to an IPSS item score equal to or greater than 2 points. **RESULTS:** The mean IPSS score was 12.6 +/- 6.4, the mean SPI score was 12.2 +/- 6.5. The correlation coefficient between the IPSS and SPI scores was 0.70; the scores from the 2 rating scales showed a very high variability. Induced bothersomeness varied from 0 to 23% according to the symptom evaluated. Nocturia seems to be the most important symptom taking into account the bothersomeness it caused. Despite weak urinary stream was the most frequent symptom in this cohort, it was only involved in 4% of induced bothersomeness. **CONCLUSIONS:** The two questionnaires do not collect the same information. The concept of induced bothersomeness allows a more refined analysis of the extent of bothersomeness associated with each question on the IPSS. If we accept the hypothesis that bothersomeness is the main parameter that leads to a treatment decision, the joint use of the IPSS and SPI seems appropriate.

**PUK22**

**PATIENT SATISFACTION: INTERNATIONAL DEVELOPMENT, TRANSLATABILITY ASSESSMENT AND LINGUISTIC VALIDATION OF THE OAB-S, AN OVERACTIVE BLADDER TREATMENT SATISFACTION QUESTIONNAIRE**

Conway K1, Plaut EC2, Kopp Z3, Abrams P4, Brubaker L5

1Mapi Research Institute, Lyon, France; 2Mapi Values, Boston, MA, USA; 3Pfizer Inc, New York, NY, USA; 4Bristol Urological Institute, Bristol, UK; 5Loyola University Medical Center, Maywood, IL, USA

**OBJECTIVE:** The Overactive Bladder Treatment Satisfaction Questionnaire (OAB-S) is a self-administered instrument assessing treatment satisfaction in patients with overactive bladder. The OAB-S has been developed for worldwide use; moreover, its conceptual equivalence and cultural adaptability across countries were considered early in the development process. To date, the OAB-S is available in five languages including US-English, US-Spanish, UK-English, Spain-Spanish and German. **METHODS:** The cultural and linguistic equivalence of the OAB-S was ensured at different stages of the development and the translation processes: 1) the OAB-S was simultaneously developed in US-English and US-Spanish and tested for face and content validity; 2) the pre-final original questionnaire underwent a translatability assessment, an international critical review with the objective of suggesting re-formulations in the pre-final version considering the context and constraints of other languages and cultures; 3) finally, the OAB-S was translated into the three remaining lan-