URINARY DISORDERS, EVOCATIVE OF BPH

Studying the degree of satisfaction of patients with urinary disorders, evocative of BPH

A pragmatic, European cohort (France, Italy, and Portugal) of 420 patients presenting with urinary disorders, evocative of BPH, was followed up for 6 months. RESULTS: A total of 175 patients were evaluated. Satisfaction was expressed as the differential between the expectation of the patients recorded before the start of treatment and the status declared at 6 months. In addition a binary (yes/no) question regarding general satisfaction was used as the primary evaluation criterion. We observed positive satisfaction in 61.7% of subjects in terms of the “effort or force needed to start urinating”, 54.35% for “sensation of not emptying the bladder after urinating” and 50% for the “need to urinate”. We observed negative satisfaction in 68.18% of subjects with respect to the progression of “getting up in the night to urinate”. At 6 months, the response to the general satisfaction question confirms these initial results—nearly 98% of subjects were satisfied with their BPH. We did not see any significant differences between the 3 treatment groups. CONCLUSIONS: The individualized expectation of the patient will undoubtedly be one of the major preoccupations of the next few decades. Medical treatment for BPH is accompanied by a satisfaction that is compatible with long term compliance with the treatment by the patient.

Patients with urinary disorders, evocative of BPH: What are their expectations?

OBJECTIVES: The individualised expectations of the patient will undoubtedly be one of the major preoccupations of the few decades to guarantee optimal treatment through compliance. METHODS: A pragmatic, European cohort (France, Italy, and Portugal) of 420 patients presenting with urinary disorders, evocative of BPH, was followed up for 6 months. A questionnaire regarding expectations was handed out at the first consultation. RESULTS: A total of 317 patients were evaluated. The symptoms that 30.7% of patients wished to see improved with the highest priority were “getting up in the night to urinate”, then for slightly less than 20%, “sensation of not emptying the bladder after urinating”. Amongst the symptoms that were the least concerned about were “the effort or force needed to start urinating” for 23% of responders, then “sensation of not emptying the bladder after urinating” for 16% and the “size and force of the stream of urine”. “Getting up in the night” was the principal complaint in all 3 countries (38% in France, 26 and 25% in Italy and Portugal), similarly “the effort or force needed to start urinating” is the symptom that preoccupies the patients the least in France and Italy; the “size and force of the stream of urine” preoccupies the Portuguese the least. Nearly 90% of the Italians claimed that they would only be satisfied if they never had to get up in the night again, (35% for the French, 50% for the Portuguese). Overall, 60% of the subjects questioned said that they would be satisfied if they were “markedly” improved. CONCLUSIONS: The expectation of patients in the treatment of BPH is very important, and undoubtedly difficult to satisfy entirely. These results are probably due to the fact that our population was composed of patients that had been diagnosed recently.

Methodological considerations when assessing work productivity (WP) and activities of daily living (ADL) outcomes in multinational clinical trials in women with heavy and/or prolonged menstrual bleeding (HPMB) Treated with estradiol valerate/dienoestrol (E2/V/DNG)

METHOD OBJECTIVES: To evaluate the effect of E2/V/DNG, an oral contraceptive, on WP (presenteeism) and ADL outcomes in HPMB suffers using an appropriate analytical strategy. METHODS: A post-hoc analysis of patient-reported outcomes from a multicenter, randomized, placebo-controlled trials in North America and Europe/ Australia that evaluated the efficacy of E2/V/DNG in women with HPMB. Data were collected using a modified Work Productivity and Activities Impairment questionnaire. WP and ADL outcomes were measured on a 10-point Likert scale. The analytical strategy was developed to determine and apply the most appropriate statistical methodology given the data and methodological challenges, including highly-skewed, incomplete, multi-country data, unbalanced enrolment across countries, and the auto-regressive nature of the outcomes. The analyses progressed from descriptive statistics to Bayesian regression in several sequential steps. The underlying model chosen for Bayesian analysis was simultaneous equation modeling to incorporate temporal aspects and potential cross-country heterogeneity. RESULTS: The data set included 416 patients (E2/V/DNG, n = 265; placebo, n = 151) across 12 countries. In all analytical approaches, E2/V/DNG vs. placebo treatment showed significantly positive effects on WP and ADL at a magnitude of a one-point change on the Likert scale (based on linear regression analysis). In Bayesian analyses, Gamma distribution yielded a better model fit (DIC = 2129.01 vs. 2460.12 for normal distribution [presenteeism] and DIC = 2313.33 vs. 2640.36 [ADL]). The average treatment effect on presenteeism for Gamma distributed models was −0.82 (95% CI: −1.37, −0.34) at treatment day 84 and −1.06 (95% CI: −1.67, −0.56) at treatment end (EOT; day 196). The average treatment effect on ADL was −1.07 (95% CI: −1.70, −0.32) at day 84 and −1.09 (95% CI: −1.63, −0.62) at EOT. CONCLUSIONS: E2/V/DNG has a statistically significant and positive impact on presentation and ADL impairment. The robustness of these findings was confirmed by the application of several methodological approaches, with Bayesian analyses appropriately dealing with identified methodological challenges.