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TREATMENT STRATEGIES, PATTERNS OF DRUG USE AND TREATMENT DISCONTINUATION IN MEN WITH LUTS SUGGESTIVE OF BENIGN PROSTATIC HYPERPLASIA – THE TRIUMPH PROJECT (1)

Aims of Study

Benign prostatic hyperplasia (BPH) is common in elderly men. Patients with BPH can be free of any symptoms. They often suffer however from lower urinary tract symptoms (LUTS) related to difficulties in voiding or storage. Based on the severity of the symptoms patients either receive no treatment, pharmacological treatment or prostate surgery. We aimed to describe the treatment strategies, the adherence to pharmacological treatment and to investigate whether the type of main LUTS/BPH complaints predicts early treatment discontinuation.

Methods

Within the GP research database (IPCI) in the Netherlands we identified all males aged 45 years or older with at least 6 months of valid database history and newly diagnosed with LUTS/BPH during 1995-2000. Within this cohort we searched for all cases of prostate surgery and calculated the incidence rate for prostate surgery. Pharmacological treatment was assessed between the date of LUTS/BPH diagnosis and the end of study period. Patterns of drug use were described in terms of switching, adherence and early treatment discontinuation. Patients were considered to have discontinued treatment early if they received only one episode of treatment taking up less than 20% of the follow-up time. Adherence to therapy was defined as the duration of an episode divided by the time-interval between the start of that episode and the start of the next. Logistic regression analysis was used to study the association between the type of main urinary complaints at the start of pharmacological treatment and the risk of early treatment discontinuation. In accordance with the ICS standardization report on the terminology of lower urinary tract function (2), urinary complaints were classified in 3 categories: storage symptoms, voiding symptoms and post micturition symptoms. If the reason for starting pharmacological treatment was only indicated as "BPH" or "prostatism" and no specific complaints were listed, the patients were classified as having "prostatism symptoms". Adjustment was made for possible riskfactors such as age, dosing regimen, chronic disease score (CDS) and PSA measurement. The CDS is based on the use of drugs as a proxy for long-term diseases, allowing for the construction of an overall index of chronic disease status (3-4).

Results

Of the 2214 men with incident LUTS/BPH, 1075 (49%) received pharmacological treatment and 238 (11%) underwent prostate surgery. The overall incidence of prostate surgery was 62/1000 men-years (95%CI: 54.4-70.2). The incidence increased with age from a low incidence of 20.7/1000 men-years (95%CI:4.1-66.3) at the age of 45-49 years to a high incidence of 106/1000 men-years (95%CI:81.5-137) at the age of 75-79 years.

The majority of the patients received their first pharmacological treatment within 1 year after diagnosis. The average adherence to α-blockers was 67% (95%CI:66-68%), to 5α-reductase inhibitors 73% (95%CI:69-77%) and to combination therapy 71% (95%CI:49-93%). Switching occurred in 12% of the patients. Of the treated population, 280 patients (26%) discontinued treatment early mainly due to symptom improvement (19%), adverse events (28%) and/or persistence of complaints (24%).

The probability of early discontinuation was higher in patients with complaints of mainly voiding symptoms (OR_{adj} 3.39 (95%CI:1.90-6.05)), mainly post-micturition symptoms (OR_{adj} 2.41 (95%CI:1.17-4.96)) or mainly storage symptoms (OR_{adj} 1.83 (95%CI:1.14-2.92) as compared to patients complaining of the combination of storage, voiding and/or post micturition symptoms. Normal PSA measurement as compared to no PSA measurement

being done (OR_{adj} 1.48;95%CI:1.07-2.04) was associated with early discontinuation. Older age(> 60 years) and a higher chronic disease score were associated with a lower risk for early treatment discontinuation. In the univariate analysis, a once daily dosing regimen as opposed to multiple dosing a day was associated with a reduced risk for early treatment discontinuation (OR 0.72;95%CI:0.53-0.98) but this association was no longer statistically significant when adjusting for all riskfactors (OR_{adj} 0.75 (95%CI:0.55-1.04)).

Conclusions

Forty-nine% of the LUTS/BPH are pharmacologically treated. Adherence differed slightly between treatments. The risk for early treatment discontinuation was highest in patients younger than 60 years without co-morbidity, with normal PSA values as opposed to having had not PSA measurement at all and with voiding symptoms as main complaint. Patients complaining of the combination of storage, voiding and post micturition symptoms have more severe or more bothersome LUTS/BPH what may contribute to the lower rate of early treatment discontinuation. Men complaining of LUTS/BPH who turn out to have a normal serum PSA value might find reassurance in this result and be less motivated to continue treatment. Further studies are needed to test this hypothesis.

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