Real-World Use of Permixon® in Benign Prostatic Hyperplasia – Determining Appropriate Monotherapy and Combination Treatment

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ABSTRACT

Introduction: Benign prostatic hyperplasia (BPH) is a major health concern for aging men. The resulting lower urinary tract symptoms may have a profound effect on a patient’s quality of life and it is recognized that patient acceptability of treatment is key to decreasing the human and economic burden of the condition. Alpha-adrenergic antagonists (alpha-blockers), 5-alpha-reductase inhibitors (5-ARIs), and phytotherapy as monotherapy or in combination, form the mainstay of medical treatment.

Methods: The Adelphi Permixon Study, a cross-sectional study of representative consulting patients with BPH in two European countries, was undertaken to examine the reasons for choice of medication. Physicians completed patient record forms, and data were analyzed for clinical outcomes and their relationship with the choice of appropriate therapy.

Results: Patients receiving combination therapies for BPH are likely to be older and are more likely to be retired than those on monotherapy. Combination therapy is adopted in the real-world setting as first-line therapy on a not-infrequent basis. The analyses demonstrated an association between choice of Permixon® (Pierre Fabre Medicament, Castres, France) as appropriate monotherapy or in combination with alpha-blockers, and the following: BPH severity; treatment of general urinary symptoms, including storage and voiding symptoms; improvement of urinary flow rate; lack of a risk of sexual problems; and reduction of inflammation. Permixon combination with an alpha-blocker is associated with benefits in terms of speed of onset of action, reduction of inflammation, and a positive benefit regarding sexual problems when compared with use of alpha-blocker monotherapy.

Conclusion: In the real clinical world, Permixon is considered an appropriate treatment for BPH as both monotherapy and in combination with alpha-blockers. Prescribing Permixon
in combination with alpha-blockers can be demonstrated to provide benefits beyond use of either therapy alone.

**Keywords:** Alpha-blockers; Appropriate treatment; BPH; Combination therapy; Patient acceptability; Permixon; Phytotherapy; Real-world

**INTRODUCTION**

Benign prostatic hyperplasia (BPH), a nonmalignant enlargement of the prostate, can lead to voiding and storage lower urinary tract symptoms (LUTS). However, not all LUTS are necessarily directly associated with BPH [1]. The true incidence of BPH is, therefore, difficult to assess, but may be up to 40% in men over 40, and 90% in those over 80 years of age [2]. BPH is a benign proliferation of the prostatic stromal and epithelial cells leading to formation of palpable nodules and enlargement of the prostate gland. This increase in size may eventually compress the urethral canal leading to physical symptoms of urinary hesitancy and frequency, dysuria, sexual dysfunction, increased risk of urinary infection, and sometimes retention. These clinical manifestations of BPH may also lead to anxiety and depression [3].

Mild LUTS may not in themselves cause sufficiently aggravating symptoms to warrant intervention and a policy of “watchful waiting” (WW) can be adopted. This will include continued patient consultation with medical assessment and monitoring, patient reassurance and education, plus advice for self-management and lifestyle changes. Progression to serious symptoms, such as retention, is infrequent [4], but deterioration from mild-to-moderate symptoms will occur within most patients over a 5-year period from diagnosis, with approximately one-third progressing to minimally invasive therapies or surgery [5–8]. The remaining two-thirds will require medication. Alpha-adrenergic antagonists (alpha-blockers), 5-alpha-reductase inhibitors (5-ARIs), and phytotherapy as monotherapy or in combination, form the foundation of medical treatment [9, 10].

The pharmacologic use of phytotherapeutic agents (plants and herbs) for the treatment of LUTS associated with BPH has been growing steadily [11–14]. Such agents are used both as monotherapy and in combination with other medications. Permixon® (Pierre Fabre Medicament, Castres, France), a lipido-sterolic extract of *Serenoa repens*, belongs to this group of compounds and has been extensively studied for the pharmacotherapeutic management of LUTS/BPH [15–18].

Adelphi Real World (ARW) conducted this holistic observational study on the pharmacological treatment of BPH to understand the reasons physicians chose a particular therapy. The study, undertaken in France and Spain, was designed to describe the profile, management, and factors influencing the choice of therapy by physicians. The analyses discussed in this paper concentrate upon the use of alpha-blockers, 5-ARIs, and Permixon as monotherapy or in combination, all regarded as mainstays of therapeutic management of BPH in both France and Spain.

**METHODS**

**Study Design**

The ARW Permixon Study was conducted in January and February 2011, with urologists and primary care physicians (PCPs), and their patients recruited in France and Spain. The study method was based upon the ARW “Disease Specific Programme” approach. The full methodology for this approach, including limitations, has been outlined previously [19]. Physicians completed a patient record form (PRF) for consulting BPH