Chapter 2
BPH: VARIATIONS IN SEXUAL INTERACTIONS & ACTIVITY WITH PROSTAQUIL™

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INTRODUCTION

BPH (Benign Prostatic Hypertrophy) is associated to urinary outflow obstruction, weak urine stream, hesitancy, urinary frequency and urgency, nocturia, incomplete emptying, terminal dribbling, overflow or urge incontinence and different levels of urinary retention.
Diagnosis is clinical but cystoscopy, ultrasound, urodynamics or other imaging studies may be used to quantify the problem and to exclude concomitant problems, including cancer.
With a prostate volume >30 mL and a high *American Urological Association Symptom Score* the prevalence of BPH (age range 55-74, in subjects without cancer) is around 19%. If voiding criteria (maximum urinary flow rate <10 mL/sec and a post-void residual urine volume >50 ml) are considered the prevalence is only 4%.
The prevalence of BPH increases from 8% between 31 and 40 years to 40-50% between 51 and 60 and to >80% in men older than 80 years. At the moment, there is no definitive treatment (1). The treatment is symptomatic; 5-alfa reductase inhibitors, alfa blockers and surgical options are used. Symptoms may affect a large number of subjects therefore costs are high. Several options may be considered. Initial mild, symptoms may benefit from milder drug, supplementary management with Saw Palmetto (SP) or other supplements.

In most preparations of SP, fatty acids inhibit 5alfa-reductase opposing the conversion of testosterone to dihydrotestosterone. Most formulations for BPH use saw palmetto (80-90% essential fatty acids and phytosterols). Strong evidence (1) supports the use of SP to treat signs/symptoms of BPH (i.e. frequency). Prostaquil™ (capsules, 100 mg) includes Py-

geum Extract, Saw palmetto oil, zinc and pumpkin seed oil. Pygeum has been used for fever, malaria, wound care, stomach pain, kidney disease and as an appetite stimulant. Pharma standard extracts of Pygeum, have been succesfully used for BPH.

This registry evaluated the management of initial symptoms of BPH in subjects using Prostaquil™ (Alchem, India) in a supplement registry (150 days). The focus of this part of the registry was on **sexual interactions.**

Patients-Methods: subjects with BPH were included. The target of the registry was the supplementary management of initial, mild symptoms in subjects not using other drugs, who did not have previous surgical procedures or urinary retention and no significant infections in the 3 years before the registry.

STANDARD MANAGEMENT (SM) in subjects without surgical indications, with initial symptoms, is based on avoidance of anticholinergic, sympathomimetics and opioids.
Alfa-adrenergic blockers (terazosin, doxazosin, tamsulosin, alfuzosin) improve voiding; 5 alfa-reductase inhibitors (finasteride, dutasteride) tend to reduce prostate size.
In the treatment of BPH a combination of drugs is more effective than single treatments. Regular voiding, avoiding long periods sitting, regular exercise, regular hydration, avoiding caffeine and spices, a diet with decreased sugar and NaCl are adviced. Prostaquil™ (Alchem) was used at the dosage of 2 capsules in the evening. The product includes Pygeum extract (100 mg) and Saw palmetto oil (35 mg). The evaluation for these patients was based on two major parameters: the variation in urinary volumes in 150 days of follow up and the efficacy of sexual interactions (self evaluation).

REGISTRY. Two registry groups were progressively formed: a Prostaquil™ group using also SM (according to the Merck Manual) and a group using SM for BPH (association of two products, one alfa adrenergic blocker and one 5 alfa-reductase inhibitor) as suggested by the urologists.
The treatment was decided only by the urologists without interaction from the registry observers.

Types of evaluation: the initial volume vas measured early in the afternoon (2-4 pm). The urinary volume – flowing with-

out significant efforts – was measured. After this measurement a 18 G urinary catheter was used to empy the bladder of its residual volume. All measurements are in ml.

Also **a questionnaire** was used to evaluate progress in **sexual interaction**s considering the previous 150 days and the 150 days of the registry.
Sexual interactions (in a simplified evaluation form) were arbitrarily considered as effective, completed or satisfactory (yes/not) without scoring.

Table 2.1. Registry groups.

Group	Prostaquil™	Controls
Number	14	17
Days of follow up	155;4	156;6
Age	62:3	63;4.2
PSA <4 ng/mL	3.1;0.2	3.11;0.2
Creatinin levels	Normal	Normal
Prostatic volume (normal <30 mL)	39.4;5.5	39.3;3.1

RESULTS

The two resulting groups (Table 2.1) were comparable for age, symptoms distribution and ultrasound findings (prostate volume and residual urinary volume).
The days of follow up were comparable.
No side effects or tolerability problems were observed and compliance was optimal with more than 96% of the capsules correctly used.
Spontaneous emptying was significantly increased with Prostaquil™ and the final residual volume was minor at 150 days ($p<0.05$).

Table 2.2 shows the 40% increase in spontaneous flow volume (vs 12% in controls; $p<0.05$). Prostaquil™ produced an almost 15% decrease in residual volume ($p<0.5$).
The total volumes, as expected, were not changed. The volume changes are shown in **Figure 2.1**.

Table 2.3 shows the sexual interactions variations: Prostaquil™ appears to be more effective considering completed interactions and global satisfaction.
No urinary bacterial contamination was observed.

Table 2.2. The main observation urinary volumes.

	Prostaquil™		**Controls**	
Volumes	*Inclusion (ml)*	*150 days (ml)*	*Inclusion (ml)*	*150 days (ml)*
Volume 1 *spontaneous urination*	63.;8.3	88.6;9	64;7	72;5
Volume 2 *residual vescical urinary volume*	155;4	132;5	151;5	149;8
Total volume	218;6	220;6	215;4.3	221;5.9

Table 2.3. Sexual interaction questionnaires in the 150 days before inclusion and in the 150 days of the registry.

	Prostaquil™		**Controls**	
	5 months before	*in 24 weeks*	*5 months before*	*in 24 weeks*
Interactions	*Inclusion*	*150 days*	*Inclusion*	*150 days*
Effective	16.3;1.1	24.3;1	16.1:1.1	18.3;1.6
Completed	15.2;0.9	22.1;1	14.4;1.2	15.8;1.4
Satisfactory	11.3;1.1	21.5;1	12;1.1	13.3;1.2

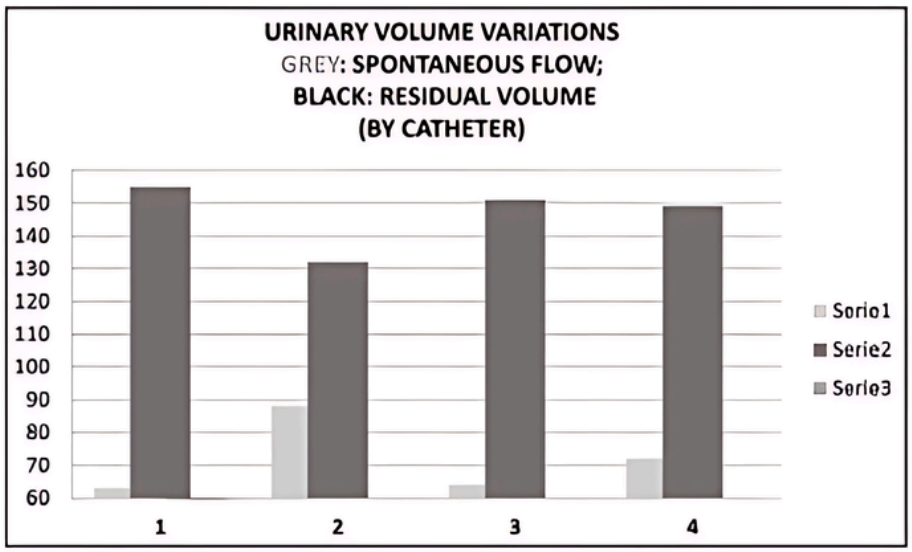

Figure 2.1. Variations in urinary volumes (ml): the spontaneous flowing urinary volume (grey) is increased in 150 days (2) with Prostaquil™. The residual volume (catheter, black) proportionally decreases at 150 days. The variations in the control group were significantly lower (4) with a minimal change in spontaneous flow.

DISCUSSION

Subjects with newly diagnosed BPH and mild symptoms may try self-management of symptoms with a non-prescription supplement as the first step. Pygeum and Saw Palmetto-derived compounds are a good and safe option, recognized, for long-term management and considered effective and safe.

Long-term treatment with 5-alfa reductase inhibitors or alfa blockers may expose patients to significant side effects and potential interactions with other drugs.

Finasteride significantly worsens ejaculatory function. Doxazosin and finasteride may cause significant worsening in erectile function and other sexual problems (including libido reduction). Also depression, and anxiety have been observed.

Other rare side effects include breast tenderness and enlargement (gynecomastia), and allergic reaction. Finasteride is also associated with intraoperative floppy iris syndrome and cataract formation.

At present, there is very limited potential for the medical treatment of BPH. There are minor possibility of self-medication for patients with initial, limited and controllable symptoms.

Most studies focus on interventional/surgical treatments that generate much higher profits. Studies on medical treatment are relatively old and limited.

Studies on drug interactions are also limited. Medical treatment is generally considered a poor option by most specialists as urologists are not interested in managing BPH with drugs or supplements that may be a significant option particularly in countries where medical services are basic or when there is no medical coverage.

The sexual aspects related to treatments and the potential advantage of Pygeum have not been studied with adequate attention. A number of evaluations have studied Pygeum in BPH. Standardized preparations may be useful to control urinary symptoms in BPH.

In conclusion, Prostaquil™, a new generation pharma standard supplement – including Pygeum – may be an important option for self-management in most uncomplicated patients with BPH improving voiding and sexual functions.

References

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