Chapter 4
PROSTAQUIL™ IN BPH (BENIGN PROSTATIC HYPERTHROPHY); A 6 MONTHS REGISTRY. PRELIMINARY OBSERVATIONS

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This study evaluates the long-term (6-month) supplementary management with Prostaquil™ in patients with benign prostatic hypertrophy (BPH). This study extends to 6 months the observations of our previously published study (an 8-week registry).
The aim of this more extended *'SAFETY'* registry was the evaluation of the symptomatic relief produced by Prostaquil™ in the management of the most common initial symptoms of benign prostatic hyperthrophy (BPH) in otherwise healthy subjects. Prostaquil™ (Alchem) was used at the dosage of 200 mg/day.
This new product includes Pygeum extract (100 mg, produced) and Saw palmetto oil (35 mg).
The two comparable resulting management groups were:
1. standard management group;
2. the supplement group.
These groups are comparable at almost 6 months of follow up.

RESULTS

After almost 6 months no side effects or tolerability problems were observed and the compliance was considered optimal with more than 96% of the capsules correctly used.
At 8 weeks, 3 and 5 months (while waiting for the final 6-month results), urinary emptying, frequency, intermittency, urgency, weak flow, straining, nocturia were all significantly improved with Prostaquil™ ($p<0.05$).
The improvement - globally and evaluating any single item - was significantly superior to the improvement observed in controls ($p<0.05$) using only standard management.

The quality of life in the supplement group at 5 months was also significantly better in comparison with controls ($p<0.05$).
The prostatic volume and the urinary residual vescical volume was significantly improved (as reported in another presentation:
(BPH: VARIATION IN PROSTATE VOLUME AND VESCICAL VOLUME; EFFECTS OF PROSTAQUIL™) in the supplement group.

As indicated also in another specific study, there was a significant improvement in sexual interactions in the supplement group in comparison with the standard management (BPH: VARIATIONS IN SEXUAL INTERACTIONS & ACTIVITY WITH PROSTAQUIL™).
Furthermore, another substudy has evaluated the possible interactions of Prostaquil™ with other drugs, particularly antiplatelet agents and anticoagulants that are commonly and frequently used by subjects with BPH (PROSTAQUIL™ SAFETY STUDY: NON-INTERFERENCE WITH ANTICOAGULANTS & ANTIPLATELET AGENTS).
This study has shown that the supplementation with Prostaquil™ is safe and does not interfere with these common treatments in cardiovascular patients.
The costs of management with Prostaquil™ were decreased as the need for other management methods, tests and consultations also significantly reduced with the supplement.

In conclusion, the most common symptoms of BPH are controlled by Prostaquil™ a new standardized supplement including Pygeum and Saw palmetto oil with a very important safety and tolerability profile.
The safety study is now under the final evaluation extended at 6 months that will be discussed in the presentation.

References

1. Belcaro G et al. Supplementary management of benign prostatic hypertrophy with Prostaquil™. An 8-week registry. Minerva Gastroenterol Dietol. 2015 Oct 22. [Epub ahead of print].