

Natural Treatment of BPH

A practical experience report on ProstaMed®

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Urination problems, the frequent urge to urinate, and the tiresome need to get up during the night often affect men still in the “prime of life”. Nowadays, benign prostatic hyperplasia (BPH) can be considered a widespread disease. Half of all 50-year-old men have prostate problems – a proportion that increases substantially with increasing patient age (1). Sufferers often interpret the symptoms as “normal signs of ageing” and accept them. The family doctor can do a great deal to improve their quality of life.

Introduction

The treatment options range from phytopharmaceuticals to synthetic alpha-1 blockers and 5 α -reductase inhibitors. However, phytotherapy, in particular, enjoys a good standing in the treatment of BPH. In the past, several studies proving that phytopharmaceuticals are highly effective in BPH have been published (2). One of the most important phytopharmaceuticals is without doubt saw palmetto extract, as contained in ProstaMed®.

The different substances in the lipophilic fraction of saw palmetto extract allow the various symptoms of BPH to be treated at two levels: firstly, ProstaMed produces a specific antiandrogenic effect by inhibition of 5 α -reductase (3) and by inhibition of dihydrotestosterone (DHT) receptor binding (4). Secondly, ProstaMed brings about dose-dependent inhibition of cyclooxygenase and 5-lipoxygenase, which leads to a consistent lowering of their metabolite levels, achieving an anti-oedematous and anti-inflammatory effect (5).

A practical experience survey documenting experience and the value of BPH treatment with ProstaMed was carried out recently among Swiss general practitioners and internal specialists in independent practice. This report

summarises the most important results.

Observation of experience

The interviews for this practical experience report were carried out between May 2003 and June 2004 among 85 doctors in independent practice in Switzerland. 364 men with a mean age of 65 years, and with previously untreated Alken stage I and II benign prostatic hyperplasia, were followed up and documented. As is usual in practical surveys, the rhythm of observations, the treatment and the intervals between appointments followed the normal routine of the practice or were left at the doctors' discretion. ProstaMed was prescribed and dosed in accordance with the recommendations in the summary of product characteristics.

At the start of treatment and after eight weeks, the severity of the prostatic hyperplasia was recorded using the IPS score (*Table*), and further information collected related to the index measuring quality of life due to urinary problems as well as an assessment of ProstaMed in terms of effectiveness, tolerability and onset of effect. Naturally, all adverse events were documented.

Results

Effectiveness

At the start of treatment, the mean IPS score for all patients was 16.2, corresponding to moderate benign prostatic hyperplasia symptoms. After only eight weeks, a statistically significant 35 per cent reduction in the score was achieved. It is

interesting that the symptomatic improvement took place regardless of the baseline score. A subanalysis examined the effect of ProstaMed as a function of symptom severity (Figure 1). For this purpose, the patients were subdivided into three groups – 0 to 7 points corresponded to mild symptoms, 8 to 19 to moderate symptoms and 20 to 35 to

severe symptoms. The symptoms in all three patient groups underwent a statistically significant reduction - by 42 per cent, 38 per cent and 30 per cent respectively. The good effect even in patients with severe symptoms is interesting. It was possible to reduce their IPS score from an average of 23 points to 16 points.

Table: IPS score (International Prostate Symptom score)

How often during the last 4 weeks...	Not at all	Less than one in 5 times	In less than half of cases	In about half of cases	In more than half of cases	Nearly all the time
1. did you feel as if you were not able to empty your bladder completely?	0	1	2	3	4	5
2. did you have to pass water again within 2 hours of your last urination?	0	1	2	3	4	5
3. did you notice that the urine stream was interrupted several times?	0	1	2	3	4	5
4. did you have difficulty making urination last longer?	0	1	2	3	4	5
5. did you notice a weak urine stream?	0	1	2	3	4	5
6. did you have to press down or strain to be able to urinate?	0	1	2	3	4	5
	Not at all	Once	Twice	3 times	4 times	5 times or more
7. did you have to get up to urinate each night, on average?	0	1	2	3	4	5
	Total IPS score = _____			Sum of points from questions 1 - 7		

Due to the onset of effect within four weeks in 82.7 per cent of patients and the effective reduction in the IPS score, the investigators involved rated the effectiveness of ProstaMed as

very positive overall – 35 per cent considered the effect very good, 53 per cent good and only 12 per cent inadequate. It was also possible to significantly improve the index measuring quality of life due to

urinary problems (Figure 2). At the start of the treatment, the patients felt somewhat dissatisfied with their urinary problems, whereas after eight weeks they were overwhelmingly satisfied.

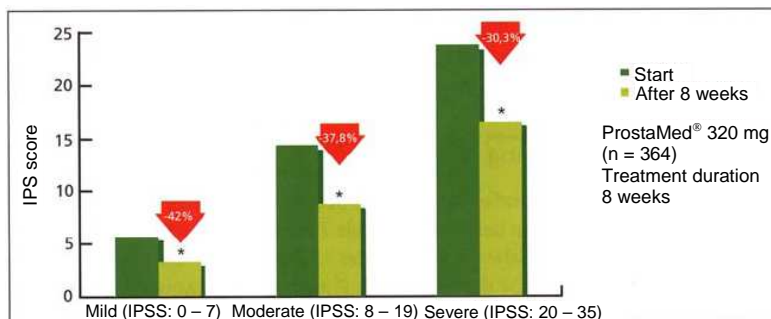


Figure 1: Reduction in the IPS score on ProstaMed®, regardless of the baseline score.

Tolerability

A single adverse reaction was reported during the observation – occasional belching. Otherwise, the treatment was rated as very good by the doctors and patients alike (Figure 3), and 86.5 per cent of patients wished to continue the treatment.

Discussion

The objective of the practical experience report was to gather data on the effectiveness and tolerability

of ProstaMed® in everyday practice. It goes without saying that the validity of a practical experience report is limited and that it cannot replace a well-founded study in which the use of the treatment is laid down by a trial protocol. Compared with the results from clinical trials, the results of this practical observation provide an important starting point for the use of ProstaMed in everyday practice.

With the 30 per cent reduction in irritative and obstructive symptoms, measured using the IPS score, and the significant

improvement in the quality of life index, the results obtained with ProstaMed meet the requirements of a modern BPH treatment. They also concord with current studies of saw palmetto extract, which show a similar reduction in the IPS score (2). Even in comparison with other conventional treatment options such as finasteride, a 5 α - reductase inhibitor, ProstaMed demonstrates comparable effectiveness, with a low side effect rate (6).

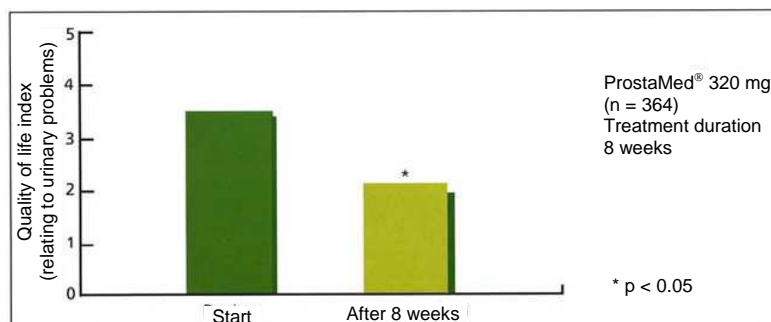


Figure 2: Improvement in the quality of life index (0 = excellent, 6 = very poor)

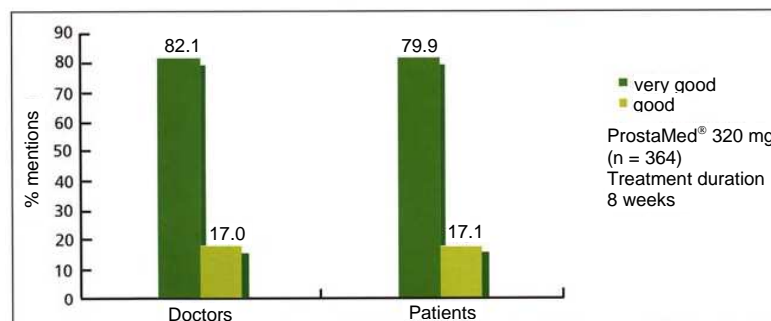


Figure 3: Assessment of the tolerability of ProstaMed® by doctors and patients

It is interesting that eight weeks of treatment with ProstaMed brought about a mean therapeutic success equivalent to that achieved with six months of treatment (7) or one year of treatment (6) in long-term studies. Most of the results discussed here, from the largest study of saw palmetto extract conducted to date in Switzerland, are therefore in harmony with the results of controlled clinical trials. This also shows that compliance is

ensured in practical observations.

ProstaMed is therefore suitable for the effective treatment of mild and moderate BPH, with a low side effect rate. ProstaMed is reimbursable by health insurance companies within the basic insurance cover and is therefore part of the standard arsenal of BPH treatment. A particularly cost-effective option, it addresses current efforts to curb the rise in health service costs.

The most important results

This practical observation included 364 patients with an average IPS score of 16.2. On treatment with ProstaMed, their score fell significantly (p < 0.05) by 35 per cent to 10.5. The effectiveness of ProstaMed was rated as good to very good by both patients and doctors, and 82.7 per cent of patients reported an onset of effect after only four weeks.

Tolerability proved to be very good. Throughout the observation period, only one adverse event connected with the test medication was reported – occasional belching. •

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Declaration of interest: The practical survey was financed by Bioforce AG.