

## EFFECTS OF *SERENOA REPENS* ALCOHOL EXTRACT ON BENIGN PROSTATE HYPERPLASIA

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### ABSTRACT

An increasing tendency has recently emerged for the use of phytotherapeutic agents as alternative to commercial pharmacological agents for the treatment of benign prostate hyperplasia (BPH). The purpose of this study is to evaluate the effects of *Serenoa repens* alcohol extract treatment on BPH patients' symptoms and major parameters during one-year follow-up.

The study was performed on 70 men aged 40 - 79 years (mean 60.58) with symptomatic BPH that were divided into a group of 40 patients treated with *Serenoa repens* extract (SRT) and a control group of 30 patients that received no treatment and were observed only. The following parameters were determined at the time of diagnosis (baseline), and after 6 and 12 months: prostate size, serum prostate-specific antigen (PSA) and uroflowmetry parameters including maximum flow rate (MFR), average flow rate (AFR) and post-voiding residual volume (PVRV). In addition, the relevant patient symptoms were evaluated using the International Prostate Symptom Score (IPSS) system.

The patients in the SRT group showed a statistically significant increment of the average MFR and AFR values and reduction of PV relative to the control group ( $p < 0.05$ ). The significant differences between the proportion of patients with prostate volume  $> 40$  ml in the SRE treated group vs. control group was observed ( $p < 0.05$ ). The mean IPSS score was highly significantly reduced in the SRT group ( $p < 0.01$ ).

The mild improvements of the urine flow, prostate size and IPSS score during 12 months treatment with the *Serenoa repens* extract indicate possible efficiency of this phytotherapeutic agent in patients with BPH.

**Key words:** benign prostate hyperplasia, phytotherapeutics, *Serenoa repens* extract

### INTRODUCTION

Benign prostatic hyperplasia (BPH) is very common disorder and is responsible for significant morbidities in male population over 45 years old [1-3].

Numerous studies have shown that BPH is a progressive condition which can have a significant

negative impact on patients' quality of life and if left untreated, can lead to acute urinary retention and chronic renal insufficiency [4-7]. Until about 25 years ago, surgical prostate resection was the only therapeutic opportunity. At that period, pharmacotherapy including  $\alpha$ -adrenergic antagonists ( $\alpha$ -blockers) and 5- $\alpha$  reductase inhibitors

gradually became the major treatment option for BPH [8]. Although administration of those medications is usually well tolerated, the side effects sometimes become significant or unacceptable for some patients and their efficacy is not always satisfactory [9].

Largely from that reason, an increasing tendency has recently emerged for the use of phytotherapeutic agents as alternative to the commercial pharmacological agents for BPH treatment. The extract of the North American dwarf palm tree *Serenoa repens* is a phytopharmaceutical product that is most commonly used for the treatment of urological symptoms associated with benign prostatic hyperplasia [10]. Moreover, the commercial preparations of this phytotherapeutic agent are increasingly becoming a treatment option, they have a long history of research and relatively well determined mechanisms of action [11-16].

The purpose of this study is to evaluate the effects of *Serenoa repens* alcohol extract on BPH patients' symptoms and major parameters during a one-year follow-up.

## MATERIALS AND METHODS

Seventy men aged 40 - 79 years (mean 60.58) with symptomatic BPH were recruited for a one-year follow-up, clinical study. The enrolled patients were assigned either by monotherapy with *Serenoa repens* alcohol extract (SRT group, n=40) or received no treatment and were observed by watchful waiting only, serving as a control group (n=30). The patients from the SRT group were treated with 320 mg/day of commercial *Serenoa repens* alcohol extract (Prostamol Uno, Berlin-Chemie AG).

During the 12-month evaluation period, each patient was examined at the time of the diagnosis (baseline), and after 6 and 12 months. The standard clinical and laboratory examinations were performed including the prostate size i.e. volume (PV) estimation with transabdominal ultrasonography and serum prostate-specific antigen (PSA) determination. Uroflowmetry parameters that were measured were: Maximum flow rate (MFR) and Average flow rate (AFR), both expressed as ml/sec. The post-voiding residual volume (PVR) or the residual urine were measured in milliliters. The relevant patient symptoms were evaluated using the International Prostate Symptom Score (IPSS) system. All diagnostic and patient evaluation procedures were performed following the established clinical

practice at the Urology Clinic and according to the European Association of Urology (EAU) Guidelines [17].

The patients of both groups that did not complete the study by any cause were excluded from the calculations. The missing values of any parameter were dealt with by the last observation carried forward method. The null hypothesis was that the investigated herbal supplement treatment does not offer improvement of symptoms and major parameters in BPH patients during 12 month follow-up.

The numerical variables that showed normal distribution were compared between the groups with the unpaired Student's independent samples t-test. The differences among the independent parameter means derived from the data with skewed distribution were compared between the groups with non-parametric Mann-Whitney test. The comparison of the categorical variables between the two investigated groups of patients was calculated with the Chi-square test.

All statistical tests used were two-tailed;  $p$ -values  $\leq 0.05$  and  $\leq 0.01$  were considered significant and highly significant, respectively. Data processing was performed using XLSTAT 2016 and Microsoft Excel 2016.

## RESULTS

Of the 70 evaluable patients with diagnosed BPH, 40 were continuously treated with *Serenoa repens* alcohol extract during 12 months, while 30 patients received no treatment (watchful waiting) and served as a control group.

The values obtained with the uroflowmetry (MFR, AFR and PVR), laboratory testing (PSA), transabdominal ultrasonography (PV) and patient evaluation (IPSS) in both SRT-treated and in the control group at baseline, as well as after 6 and 12 months, were represented in **Table 1** and **Figure 1**.

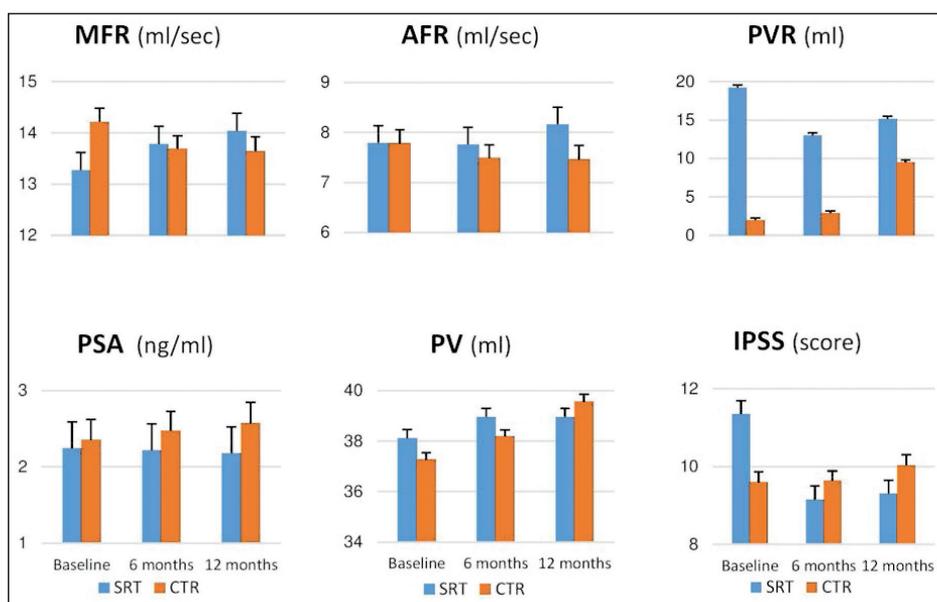
Error bars represents  $\pm$  S.E. Abbreviations: SRT, *Serenoa repens* treated group; CTR, control group - watchful waiting; MFR, maximum flow rate; AFR, average flow rate; PV, prostate volume; PVR, post voiding residual volume; PSA, prostate-specific antigen; PV, prostate volume; IPSS, International Prostate Symptom Score.

**Table 2** provides the group mean changes in the analyzed clinical and laboratory parameters in both patient groups at 6 and 12 months regarding the corresponding baseline values, as well as the statistical significance expressed by the calculated  $p$ -values.

**Table 1.** Mean values of the analyzed parameters in both patient groups from baseline to 6 and 12 months

Parameter	SRT group (n=40)			Control group (n=30)		
	Baseline	6 months	12 months	Baseline	6 months	12 months
MFR (ml/sec)	13.27 ± 0.93	13.78 ± 0.88	14.03 ± 0.91	14.22 ± 1.06	13.69 ± 1.11	13.65 ± 1.17
AFR (ml/sec)	7.79 ± 0.48	7.75 ± 0.46	8.16 ± 0.51	7.79 ± 0.57	7.50 ± 0.55	7.46 ± 0.61
PVR (ml)	19.20 ± 4.86	13.00 ± 4.38	15.13 ± 4.77	2.00 ± 1.19	2.90 ± 1.64	9.50 ± 3.63
PSA (ng/ml)	2.24 ± 0.34	2.22 ± 0.35	2.17 ± 0.35	2.35 ± 0.27	2.48 ± 0.25	2.57 ± 0.28
PV (ml)	38.11 ± 1.94	38.95 ± 2.05	38.95 ± 2.17	37.27 ± 2.50	38.18 ± 2.63	39.57 ± 2.73
IPSS (score)	11.35 ± 0.34	9.15 ± 0.53	9.30 ± 0.55	9.60 ± 0.46	9.63 ± 0.52	10.03 ± 0.57

The values are expressed as mean ± S.E.

**Figure 1.** Value means in both patient groups at baseline and at 6 and 12 months.**Table 2.** Comparison of the analyzed parameters differences in both patient groups after 6 and 12 months follow-up

Parameter	SRT group (n=40)		Control group (n=30)		Difference between the two groups <i>p</i>
	Mean change from baseline to 6 months	Mean change from baseline to 12 months	Mean change from baseline to 6 months	Mean change from baseline to 12 months	
MFR (ml/sec)	0.51 ± 0.40	0.76 ± 0.38	-0.53 ± 0.29	-0.57 ± 0.30	0.011 *
AFR (ml/sec)	-0.03 ± 0.24	0.37 ± 0.14	-0.29 ± 0.14	-0.32 ± 0.17	0.002 *
PVR (ml)	19.20 ± 4.86	13.00 ± 4.38	2.00 ± 1.19	2.90 ± 1.64	0.063
PSA (ng/ml)	-0.03 ± 0.09	-0.07 ± 0.11	0.12 ± 0.12	0.22 ± 0.10	0.060
PV (ml)	+0.84 ± 0.24	+0.84 ± 0.35	+0.92 ± 0.28	+2.30 ± 0.50	0.016 *
IPSS (score)	-2.20 ± 0.41	-2.05 ± 0.47	0.03 ± 0.22	0.43 ± 0.31	0.00011 *

The values are expressed as mean change ± S.E.; \*, statistically significant ( $P < 0.05$ )

### Uroflowmetry

Patients in the *Serenoa repens* treated group showed a statistically significant increase of the average MFR and AFR values over 12 months of treatment relative to the control group where the opposite tendency was registered, nevertheless the values were clinically negligible. The post

voiding residual volume was not statistically significantly different between the treated and the control group.

### PSA

Serum PSA levels were similar at baseline, as well as after 6 and 12 months of follow-up. The

mean PSA values were not significantly different between the two groups ( $p>0.05$ ).

### Prostate size

Both treated and control groups showed a very small, but gradual increase of the prostate volume during the 12-months follow-up, although this seems to be of limited, if any, clinical importance. However, this PV increasing tendency was milder in the SRT group and the difference between the two investigate groups is statistically significant ( $p<0.05$ ). There were significant differences between the proportion of patients with prostate volume  $>40$  ml was 37.50% in the *Serenoa repens* treated group vs. 46.67% in the control group (Chi-square test,  $p<0.05$ ).

### Urinary symptom scores

The mean IPSS score was significantly reduced in the *Serenoa repens* treated group from baseline to 6 and 12 months, but not in the control patient group. The observed differences were statistically highly significant and may reflect a clinically noticeable improvement in the patients treated with *Serenoa repens* alcohol extract.

## DISCUSSION

Patients with symptomatic BPH are usually treated with  $\alpha$ -blockers as a first-line therapy option. However, the patients with mild symptoms and in those who are not anxious by their symptoms might be managed with watchful waiting (i.e. active surveillance), according to the American Urology Association [18]. In our study, we have enrolled a population of 70 patients that fulfill the above recommendation for watchful waiting and divided them into two groups: SRT group treated with commercial *Serenoa repens* extract and a control groups with no medical treatment. Clinical and laboratory examinations were performed at the beginning of the study, and 6 and 12 months later.

We observed that the parameters measured by uroflowmetry (MFR, AFR and PVR) were either insignificantly changed during the 1-year follow-up or no differences were found between the SRT and the control groups of patients. Similarly, the serum PSA levels remain nearly unaffected regarding to baseline values in both SRT and control groups, which is comparable to some previous studies. In a recent randomized, placebo-controlled, double blind multi-centered CAMUS trial conducted on 369 men with BPH,

*Serenoa repens* extract does not affect serum PSA levels more than placebo [19].

On the contrary, the prostate size increase during the 1-year follow-up and the proportion of patients with prostate volume  $>40$  ml was significantly higher in the control groups than in the SRT group indicating a measurable effect on this important BPH parameter.

We observed significant reduction of the mean IPSS score in the *Serenoa repens* extract treated patients, which is even more prominent considering the initially registered higher IPSS score at baseline in the SRT group. This indicates that there is clinically evident improvement in the patients' symptoms related to BPH in the treated patients. Although the changes in the validated urological symptom scores in SRT group were highly significant ( $p<0.01$ ) regarding the control group, no patient had a clinically important improvement ( $\geq 3$  points) on the IPSS score scale.

Our results are consistent with some of the previously published studies in which noticeable reduction of the lower urinary tract symptoms associated with BPH and significant improvement of life quality with less decrease in sexual function was detected [20]. The clinical responses to phytotherapy with *Serenoa repens* extracts are found to be very promising in other studies, too [21, 22]. Some authors describes the improvement in erectile function and decreasing complications following transurethral resection of the prostate, especially bleeding [23]. EAU guidelines state that this herbal extracts significantly reduce nocturia in comparison with placebo [17]. On the contrary, some authors described that *Serenoa repens* extracts have not shown more effectiveness than placebo in the treatment of BPH [24-26]. However, more recent data favor the use of *Serenoa repens* extracts in milder BPH cases with promising results [27].

The mechanisms of pharmacological action of *Serenoa repens* extracts in BPH have not been fully understood yet, though they have been extensively studied. The current research indicates that active components of this extract lead to inhibition of  $5\alpha$ -reductase and have anti-androgenic, anti-inflammatory, anti-proliferative and anti-edematous effects on the prostate cells [15]. At molecular level, binding to the receptors in the lower urinary tract, including the  $\alpha 1$ -adrenergic receptors, muscarinic acetylcholine receptors, 1,4-dihydropyridine receptors and vanilloid receptors was observed [28]. In addition, it seems that the anti-inflammatory effects *Serenoa repens* extracts

are mediated by modulation of the expression of inflammation related-genes, while anti-androgenic effects are primarily due to the inhibition of type 1 and type 2 isoenzymes of 5 $\alpha$ -reductase [12, 13]. It should be noted that the extraction methods also have an impact on the pharmacological action in BPH and this may be one of the major reasons for studies' inconsistencies [14, 29].

No serious adverse events or interactions with co-administered drugs have been described during the use of *Serenoa repens* extracts and this phytotherapy is associated with less sexual dysfunction-related side effects than the usual drug therapy for BPH as tamsulosin or finasteride [30].

A limitation of the present study is that it was not randomized considering the current protocol's opportunity to observe only the patients with BPH under strict inclusion and exclusion criteria. Larger studies with longer follow-up are needed to further evaluate the potential efficiency of this phytotherapeutics for BPH as an alternative to the established pharmaceutical agents and to evaluate the possible side effects due to the long-term use.

## CONCLUSION

In our clinical study, the patients treated with *Serenoa repens* extract (320 mg/day) showed a significant increase of the uroflowmetry parameters, but this seems to be of marginal clinical importance. The levels of serum PSA remained virtually unchanged in both groups during the follow-up. We found that the prostate size increase and the proportion of patients with prostate volume >40 ml was significantly lower in the SRT group than in the control groups during the 1-year follow-up. The mean IPSS score was noticeably reduced in the *Serenoa repens* treated group, which reflects the lower urinary tract symptoms.

The mild improvements of the urine flow, prostate size and IPSS score during 12 months treatment with the SRE indicate possible efficiency of this phytotherapeutic agent in patients with BPH.

## REFERENCES

- Hoke GP, McWilliams GW. Epidemiology of benign prostatic hyperplasia and comorbidities in racial and ethnic minority populations. *Am J Med.* 2008; 121(8 Suppl 2):S3-10. doi: 10.1016/j.amjmed.2008.05.021.
- Patel ND, Parsons JK. Epidemiology and etiology of benign prostatic hyperplasia and bladder outlet obstruction. *Indian J Urol.* 2014; 30(2):170-6. doi: 10.4103/0970-1591.126900.
- Vuichoud C, Loughlin KR. Benign prostatic hyperplasia: epidemiology, economics and evaluation. *Can J Urol.* 2015; 22 Suppl 1:1-6.
- Jacobsen SJ, Girman CJ, Lieber MM. Natural history of benign prostatic hyperplasia. *Urology.* 2001; 58(6 Suppl 1):5-16; discussion 16.
- Fitzpatrick JM. The natural history of benign prostatic hyperplasia. *BJU Int.* 2006; 97 Suppl 2:3-6; discussion 21-2. doi: 10.1111/j.1464-410X.2006.06097.x.
- Barkin J. Benign prostatic hyperplasia and lower urinary tract symptoms: evidence and approaches for best case management. *Can J Urol.* 2011; 18 Suppl:14-9.
- Alcaraz A, Carballido-Rodriguez J, Unda-Urzaiz M, et al. Quality of life in patients with lower urinary tract symptoms associated with BPH: change over time in real-life practice according to treatment--the QUALIPROST study. *Int Urol Nephrol.* 2016; 48(5):645-56. doi: 10.1007/s11255-015-1206-7.
- Elterman DS, Barkin J, Kaplan SA. Optimizing the management of benign prostatic hyperplasia. *Ther Adv Urol.* 2012; 4(2):77-83. doi: 10.1177/1756287212437361.
- Fourcade RO, Lacoïn F, Roupret M, et al. Outcomes and general health-related quality of life among patients medically treated in general daily practice for lower urinary tract symptoms due to benign prostatic hyperplasia. *World J Urol.* 2012; 30(3):419-26. doi: 10.1007/s00345-011-0756-2.
- Ryu YW, Lim SW, Kim JH, et al. Comparison of tamsulosin plus serenoa repens with tamsulosin in the treatment of benign prostatic hyperplasia in Korean men: 1-year randomized open label study. *Urol Int.* 2015; 94(2):187-93. doi: 10.1159/000366521.
- Di Silverio F, Monti S, Sciarra A, et al. Effects of long-term treatment with *Serenoa repens* (Permixon) on the concentrations and regional distribution of androgens and epidermal growth factor in benign prostatic hyperplasia. *Prostate.* 1998; 37(2):77-83. doi: 10.1002/(SICI)1097-0045(19981001)37:2<77::AID-PROS3>3.0.CO;2-I.
- Bayne CW, Donnelly F, Ross M, et al. *Serenoa repens* (Permixon): a 5 $\alpha$ -reductase

- types I and II inhibitor-new evidence in a coculture model of BPH. *Prostate*. 1999; 40(4):232-41. doi: 10.1002/(SICI)1097-0045(19990901)40:4<232::AID-PROS4>3.0.CO;2-0.
13. Latil A, Libon C, Templier M, et al. Hexanic lipidosterolic extract of *Serenoa repens* inhibits the expression of two key inflammatory mediators, MCP-1/CCL2 and VCAM-1, in vitro. *BJU Int*. 2012; 110(6 Pt B):E301-7. doi: 10.1111/j.1464-410X.2012.11144.x.
  14. Scaglione F, Lucini V, Pannacci M, et al. Comparison of the potency of 10 different brands of *Serenoa repens* extracts. *Eur Rev Med Pharmacol Sci*. 2012; 16(5):569-74.
  15. Sirab N, Robert G, Fasolo V, et al. Lipidosterolic extract of *Serenoa repens* modulates the expression of inflammation related-genes in benign prostatic hyperplasia epithelial and stromal cells. *Int J Mol Sci*. 2013; 14(7):14301-20. doi: 10.3390/ijms140714301.
  16. European Medicines Agency (2015) Committee on Herbal Medicinal Products (HMPC). Assessment report on *Serenoa repens* (W, Bartram) Small, fructus EMA/HMPC/137250/2013. Available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Herbal-HMPC\\_assessment\\_report/2014/12/WC500179593.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Herbal-HMPC_assessment_report/2014/12/WC500179593.pdf). Accessed May 2017.
  17. Gratzke C, Bachmann A, Descazeaud A, et al. EAU Guidelines on the Assessment of Non-neurogenic Male Lower Urinary Tract Symptoms including Benign Prostatic Obstruction. *Eur Urol*. 2015; 67(6):1099-109. doi: 10.1016/j.eururo.2014.12.038.
  18. AUA Practice Guidelines Committee. AUA guideline on management of benign prostatic hyperplasia (2003). Chapter 1: Diagnosis and treatment recommendations. *J Urol*. 2003; 170(2 Pt 1):530-47. doi: 10.1097/01.ju.0000078083.38675.79.
  19. Andriole GL, McCullum-Hill C, Sandhu GS, et al.; CAMUS Study Group. The effect of increasing doses of saw palmetto fruit extract on serum prostate specific antigen: analysis of the CAMUS randomized trial. *J Urol*. 2013; 189(2):486-92. doi: 10.1016/j.juro.2012.09.037.
  20. Fagelman E, Lowe FC. Saw Palmetto Berry as a Treatment for BPH. *Rev Urol*. 2001 Summer; 3(3):134-8.
  21. Kim SW. Phytotherapy: emerging therapeutic option in urologic disease. *Transl Androl Urol*. 2012; 1(3):181-91. doi: 10.3978/j.issn.2223-4683.2012.05.10.
  22. Argirović A, Argirović D. Does the Addition of *Serenoa Repens* to Tamsulosin Improve Its Therapeutical Efficacy in Benign Prostatic Hyperplasia? *Vojnosanit Pregl*. 2013; 70(12):1091-6.
  23. Geavlete P, Multescu R, Geavlete B. *Serenoa repens* extract in the treatment of benign prostatic hyperplasia. *Ther Adv Urol*. 2011; 3(4):193-8. doi: 10.1177/1756287211418725.
  24. Bent S, Kane C, Shinohara K, et al. Saw palmetto for benign prostatic hyperplasia. *NEJM*. 2006; 354(6):557-66. doi: 10.1056/NEJMoa053085.
  25. Barry MJ, Meleth S, Lee JY, et al. Effect of increasing doses of Saw palmetto extract on lower urinary tract symptoms. *JAMA*. 2011; 306(12):1344-51. doi: 10.1001/jama.2011.1364.
  26. MacDonald R, Tacklind JW, Rutks I, et al. *Serenoa repens* monotherapy for benign prostatic hyperplasia (BPH): an updated Cochrane systematic review. *BJU Int*. 2012; 109(12):1756-61. doi: 10.1111/j.1464-410X.2012.11172.x.
  27. Ooi SL, Pak SC. *Serenoa repens* for Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia: Current Evidence and its Clinical Implications in Naturopathic Medicine. *J Altern Complement Med*. 2017 Apr 24. doi: 10.1089/acm.2016.0302.
  28. Suzuki M, Ito Y, Fujino T, et al. Pharmacological effects of saw palmetto extract in the lower urinary tract. *Acta Pharmacol Sin*. 2009; 30(3):227-81. doi: 10.1038/aps.2009.1.
  29. De Monte C, Carradori S, Granese A, et al. Modern extraction techniques and their impact on the pharmacological profile of *Serenoa repens* extracts for the treatment of lower urinary tract symptoms. *BMC Urol*. 2014; 14:63. doi: 10.1186/1471-2490-14-63.
  30. Agbabiaka TB, Pittler MH, Wider B, et al. *Serenoa repens* (saw palmetto): a systematic review of adverse events. *Drug Saf*. 2009; 32(8):637-47. doi: 10.2165/00002018-200932080-00003.

## ЕФЕКТИТЕ НА АЛКОХОЛНИОТ ЕКСТРАКТ ОД *SERENOA REPENS* ВРЗ БЕНИГНАТА ПРОСТАТНА ХИПЕРПЛАЗИЈА

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### Резиме

Во последните години забележана е растечка тенденција на употреба на фитотерапевтиците како алтернатива на комерцијалните фармаколошки агенси при третманот на бенигната простатна хиперплазија (БПХ). Целта на оваа студија е да ги евалуира ефектите на алкохолниот екстракт од *Serenoa repens* врз симптомите кај пациентите со БПХ и врз основните параметри во текот на едногодишно клиничко следење.

Истражувањето е извршено врз 70 мажи со возраст во опсег од 40 - 79 години (просек 60,58) со симптоматска БПХ кои беа поделени во две групи: група СРТ составена од 40 пациенти третирани со екстракт од *Serenoa repens* и контролна група од 30 пациенти кои не примаа терапија, односно беа исклучиво клинички следени. Следните параметри беа определувани при поставувањето на дијагнозата (појдовна точка), како и 6, односно 12 месеци подоцна: волумен на простатата, серумскиот простатно-специфичен антиген (PSA), како и урофлоуметриските параметри кои вклучуваа максимална брзина на проток на урината (MFR), просечна брзина на проток (AFR) и волуменот на застапаната урина по празнењето на мочниот меур (PVRV). Покрај тоа, релевантните симптоми кај пациентите беа евалуирани користејќи го интернационалниот систем на бодување на симптомите на простатата (IPSS).

Кај пациентите од СРТ-групата е регистрирано статистички значајно зголемување на просечните вредности на MFR и AFR и намалување на PV во однос на тие кај контролната група. Забележани се сигнификантни разлики меѓу застапеноста на пациентите со волумен на простатата >40 ml кај СРТ-групата, наспроти контролната група. Просечните IPSS-бодови беа високо сигнификантно намалени кај СРТ-групата.

Умереното подобрување на протокот на урината, волуменот на простатата и на IPSS-бодовите во текот на 12-месечниот третман со екстракт од *Serenoa repens* укажуваат на возможна ефективност на овој фитотерапевтски агенс кај пациентите со БПХ.

**Клучни зборови:** бенигна простатна хиперплазија, фитотерапевтици, екстракт на *Serenoa repens*