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ORIGINAL PAPER

Observational Database Serenoa Repens (DOSSER): Overview, analysis and results

A multicentric SIUrO (Italian Society of Oncological Urology) Project

Alessandro Bertaccini [1], Marco Giampaoli [1], Riccardo Cividini [1], Gian Luca Gattoni [2], Roberto Sanseverino [3], Tommaso Realfonso [3], Giorgio Napodano [3], Andrea Fandella [4], Elisa Guidoni [4], Domenico Prezioso [5], Raffaele Galasso [5], Carmine Cicalese [5], Vincenzo Scattoni [6], Angelo Armenio [7], Giario Conti [8], Matteo Corinti [8], Roberta Spasciani [8], Giovanni Liguori [9], Nikolitsa Lampropoulou [9], Giuseppe Martorana [1]

[1] Clinica Urologica, Policlinico Sant'Orsola-Malpighi, Università di Bologna; [2] Web-Master SIUrO; [3] UOC-Urologia Ospedale "Umberto 1°" Nocera Inferiore; [4] Casa di Cura Giovanni XXIII - Monastier di Treviso; [5] Dipartimento di Scienze Ginecologiche, Ostetriche, Urologiche e Medicina della Riproduzione Università degli studi di Napoli; [6] Div. Urologia, Istituto Scientifico H. San Raffaele, Milano; [7] Ospedale Buccheri La Ferla, Palermo; [8] Ospedale S. Anna, Como; [9] Clinica Urologica Università degli Studi di Trieste - Ospedale di Cattinara, Italy.

Summary

Objective: *Men affected with Benign Prostate Hyperplasia (BPH) and Lower Urinary Tract Symptoms (LUTS) are demonstrating to require an increasing amount of attention from Urologists and Primary-care Physicians. Over the years, common urological medications were based on either α-blockers and/or 5α-reductase inhibitors.During the last decade the phytotherapeutic drugs are gaining a more often central role in the BPH and LUTS managements. In particular, clinical usage of the extract of the dried ripe fruit of serenoa repens with a dosage of 320 mg per day, has shown its clinical efficacy and its superiority. Purpose of this multicentric observational retrospective study was to evaluate all the urological aspects (clinical, biochemical, instrumental and pathological) of patients affected by BPH and LUTS, with a PSA < 10 ng/ml, a previous negative prostatic biopsy and in therapy with a daily dose of 320/640 mg of serenoa repens.*

Patients and Methods: *The study was conducted in 8 different centers throughout Italy from September 2010 to November 2011. Data and information of 298 men with an average of 63 years (mean PSA of 5.4 ng/ml and mean prostate gland volume of 57 cc), affected by non-acute urinary symptoms caused by BPH, a dosed PSA level inferior to 10 ng/ml, a previous negative prostate biopsy and in therapy with serenoa repens alone or associated to an α-blocker, were retrospectively inserted in an extensive on-line SIUrO Database. Comprehensive questionnaires were filled in for each patient at 3 and 6 months of follow-up. Each questionnaire contained various sections, each of them composed by several items: dosed PSA levels, uroflowmetry, International Prostate Symptoms Score (IPSS), International Index of Erectile Function (IIEF-5), trans-rectal ultrasound (TRUS) patterns, digital rectal examinations (DRE) aspects, previous prostate bioptical results (histology) and side effects.*

Results: *PSA levels weren't subjected to an increase, revealing a stabilizing or downward trend. Percentage of patients with PSA below the level of 4 ng/mL was lower at the end of the study. The overall changes in the uroflowmetry were similar and parallel both in the group with only serenoa repens intake and in the group with serenoa repens plus α-blocker. The mean medium flow and the mean maximum flow had a slightly increase along the observation time. There was a substantial decreasing in the amount of patients presenting severe prostatic symptoms. Patients reported through the IIEF-5 score a sexual activity substantially unchanged after 6 months of follow-up. The serenoa repens intake resulted in an improvement of the "inflammatory-like reports", in terms of ultrasound patterns, DRE and bioptical features.*

Conclusions: *serenoa repens demonstrated its efficacy reducing dysuria with minimal side effects. Further prospective studies might confirm its stabilization or lowering role on PSA levels in this cohort of patients and its possible clinical anti-inflammatory action.*

KEY WORDS: *Serenoa repens; Phytotherapy; BPH; LUTS; Prostate; Inflammation.*

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Introduction

Men affected with Benign Prostate Hyperplasia (BPH) and the Lower Urinary Tract Symptoms (LUTS), which accompany this condition, are demonstrating to require an increasing amount of attention from Urologist and Primary-care Physicians (1). BPH is estimated to present in 70% of men aged ≥ 70 years (2). In order to treat those widespread conditions, the common urological medications were based on either α-blockers and/or 5α-reductase inhibitors (3).

Along the centuries, since human being started to practice Medicine, plants and plants-derived drugs have always held an important role in treating clinical conditions. Even in the modern era, after the huge spread of synthetized drugs, the use of phytotherapeutic agents is increased in many medical areas also due the good compliance showed by the patients.

Over the last decade there has been an increase in the use of plant-derived drugs and such agents, which have undergone several clinical testing, are gaining a more often central role in the BPH and LUTS managements (4-5). Amongst the various phytotherapeutic agents, the most popular and widely employed is the extract of the dried ripe fruit of *Serenoa repens* (also named Sabal Serrulata) (6). In particular, clinical usage of *Permixon®* (*Pierre Fabbre Mèdicament, Castres, France*) with a dosage of 320 mg per day, has shown its clinical efficacy and its superiority compared with others brand in order to relieve LUTS and BPH symptoms in several clinical trials (7-11).

Although the definitive molecular mechanism was not clearly identified, several in vitro studies underlined the efficacy of *Serenoa repens* extract as 5α-reductase non-competitive inhibitor (12) and they also suggested that has anti-estrogenic, anti-inflammatory and proapoptotic effects in cultured cells (13).

In a recent review of the *Cochrane Collaboration* (14) the authors concluded that *Serenoa repens* provides mild to moderate improvements in urinary symptoms and in flow measures (15). Thus the anti-androgenic, anti-proliferative and anti-inflammatory complementary activities of *Serenoa repens* could constitute an additional help to treat symptomatic BPH patients where both "*irritation*" and "*obstruction*" are involved (16).

Purpose of this multicentric observational retrospective study was to evaluate all the urological aspects (clinical, biochemical, instrumental and bioptical) of patients affected by BPH and LUTS who were taking a daily dose of 320 mg of *Serenoa repens*, through the compilations of extended questionnaires afterward submitted to an on-line complex and estensive database.

Patients and methods

a) Patients

The study was conducted in 8 different centers throughout Italy, from September 2010 to November 2011, They actively participated to the recruitment and database data collecting.

Men of all ages affected by non-acute urinary symptoms caused by BPH were retrospectively recruited. The criteria of inclusions were a PSA level inferior to 10 ng/ml, a previous negative prostate biopsy and therapy with *Serenoa repens* alone or associated to an α-blocker.

Patients were excluded if they had a positive history in their family of prostate cancer, they had undergone to a previous pelvic surgery, if they were chronically assuming anti-inflammatory drugs or/and a 5α-reductase inhibitor, and if they were affected by previous prostate cancer, diabetes mellitus, chronic inflammatory diseases or neurological diseases.

b) Study design

We retrospectively analyzed the data acquired from 298 patients who were taking a daily dose of *Serenoa repens*. The whole amount of data was collected through the use of standardized questionnaires which were normally used during the clinical practice along a period of 6 months of observation. Patients who were either taking only *Serenoa repens* or *Serenoa repens* associated with an α-blocker were included in order to evaluate either the exclusive effects of *Serenoa repens* either its additional effects on an α-blocker.

Of 298 patients included in on-line database, 296 used *Permixon®* as their *Serenoa repens* daily intake.

c) Assessments

Each questionnaire contained different items inherent PSA levels, uroflowmetry, urinary symptoms, erectile function, trans-rectal ultrasound (TRUS) patterns, digital rectal examination (DRE) aspects and previous prostate bioptical results.

PSA levels characteristics included the measurements of total and free PSA. In the uroflowmetry paragraph, were reported the voided volume, the maximum flow value, the medium flow value and the presence of intermittence in the flow. Urinary symptoms were evaluated through the use of the International Prostate Symptoms Score (IPSS-short form) composed by 7 questions each of them to be rated on a 0 to 5 scale based on the severity of the symptoms. The International Index of Erectile Function (IIEF-5) was applied to measure the sexual function. The IIEF-5 consisted of 5 questions, each of them to be rated on a 0 to 5 scale from worst to best. On the questionnaires were reported the principal aspects of the TRUS: capsule profiles, focal lesions, calcifications and seminal vesicles. Any abnormal DRE findings were reported in the questionnaires.

Lastly, histological results of previous prostate mappings were included specifying if there were any bioptical cores positive for acute or chronic inflammation (Figures 1a, 1b); any patient found positive for prostate neoplasm was dropped out from the study.

Results

For the basal step of the study (day 0) 298 patients were retrospectively included in the 8 different urological centers. At the 3 months and 6 months check-up, the respective lost patients to follow-up were 56 and 69 corresponding respectively to 18.8% and 23.1%. Only 3 patients presented collateral effects, 2 of them complained dermatological symptoms and one was affected by diarrhea. The mean patient age was 63 years (Table 1).

Table 1.

General and withdrawals.

	Baseline	3 Months	6 Months
Total patients	298	242	229
Lack of efficacy	0	0	0
Side effects	0	2	1
Lost to follow-up		56 (18,8%)	69 (23,1%)

Table 2.

PSA.

	Baseline	6 Months
Patients with PSA dosed	282	207
Mean total PSA (CI 95%)	5,39 (5,15-5,63)	4,38 (4,18-4,67)
Patients with PSA total < 4ng/ml	71 (25,2%)	108 (48,43%)

At baseline 282 values of dosed PSA were reported while at 6 months 207 total PSA levels were reported. At baseline the mean PSA total was of 5.39 ng/mL (CI 95% 5,15 - 5,63) while after six month of *Serenoa repens* was of 4.38 ng/mL (CI 95% 4,18 - 4,67). A the final follow-up an increased percentage of patients with a PSA below the level of 4 ng/mL was observed (Table 2).

For the uroflowmetry analysis the patients were divided

Table 3.

Uroflowmetry.

	Baseline (Only Serenoa r. N=134) (Serenoa r. + α-blocker N=42)	3 Months (Only Serenoa r. N=73) (Serenoa r. + α-blocker N=38)	6 Months (Only Serenoa r. N=108) (Serenoa r. + α-blocker N=35)
Voided volume (mean)			
Serenoa repens	288,17 (CI 95%: 269,01 - 307,32)	266,88 CI 95%: 246,50 - 302,43)	301,31 (CI 95%: 301,70 - 345,61)
Serenoa repens + α-blocker	256,12 (CI 95%: 221,20 - 279,46)	288,17 (CI 95%: 234,29 - 296,14)	266,57 (CI 95%: 240,07 - 296,95)
Average flow rate (mean)			
Serenoa repens	7,05 (CI 95%: 6,96 - 8,03)	8,94 (CI 95%: 8,49 - 10,17)	7,78 (CI 95%: 7,79 - 9,03)
Serenoa repens + α-blocker	10,48 (CI 95%: 5,07 - 16,68)	7,05 (CI 95%: 7,30 - 9,39)	8,63 (CI 95%: 7,82 - 9,68)
Maximum flow rate (mean)			
Serenoa repens	13,64 (CI 95%: 12,80 - 14,57)	13,47 (CI 95%: 12,38 - 15,14)	14,35 (CI 95%: 12,92 - 14,13)
Serenoa repens + α-blocker	12,9 (CI 95%: 12,03 - 14,39)	13,64 (CI 95%: 12,38 - 15,30)	14,24 (CI 95%: 13,14 - 16,07)
Patients with intermittent urinary flow (%)			
Serenoa repens	38,81%	17,81%	20,37%
Serenoa repens + α-blocker	23,81%	18,42%	14,29%

Table 4.

IPSS (International Prostate Symptoms Score).

	Baseline (Only Serenoa r. N=134) (Serenoa r. + α-blocker N=42)	6 Months (Only Serenoa r. N=108) (Serenoa r. + α-blocker N=35)
Voided volume (mean)		
Serenoa repens	15,84 (CI 95%: 14,95 - 18,22)	11,69 CI 95%: 8,58 - 11,61)
Serenoa repens + α-Blocker	14,17 (CI 95%: 11,15 - 16,26)	10,38 (CI 95%: 7,41 - 12,16)
Patients with absent of/light symptoms (score 0-7)		
Serenoa repens	19,57%	29,41%
Serenoa repens + α-blocker	22,22%	37,50%
Patient with mild symptoms (score 8-19)		
Serenoa repens	43,16%	57,52%
Serenoa repens + α-blocker	52,38%	52,08%
Patient with severe symptoms (score 20-35)		
Serenoa repens	37,37%	13,07%
Serenoa repens + α-blocker	25,40%	10,42%

Table 5.

IIEF (International Index of Erectile Function).

	Baseline (Only Serenoa r. N=134) (Serenoa r. + α-blocker N=42)	6 Months (Only Serenoa r. N=108) (Serenoa r. + α-blocker N=35)
Mean IIEF		
Serenoa repens	17,75 (CI 95%: 14,78 - 17,54)	17,17 CI 95%: 15,63 - 18,18)
Serenoa repens + α-blocker	18,00 (CI 95%: 15,90 - 19,23)	18,08 (CI 95%: 16,77 - 20,14)

Table 6.

TRUS, DRE, Biopsies.

	Baseline	6 Months
Patients undergone to TRUS	244	106
Inflammatory findings	45,10%	29,20%
Suspect US-lesions	12,30%	1,90%
Ectasic seminal vesicles	30,30%	17,90%
Prostate gland volume	57,4 cc	56,4 cc
Patients undergone to DRE	272	185
Presence of palpable nodules	9,60%	4,30%
Patients undergone to prostatic mapping	237	65
Patients with 2 or more cores positive for inflammation	20,70%	1,50%

in two groups depending on the association with an α-blocker to the *Serenoa repens* therapy. After six months of treatment the overall changes in the uroflowmetry were similar and parallel in the two groups.

The mean of medium flow and the mean of maximum flow showed an increase along the observation time. However the "*Serenoa repens alone*" group showed a better increase in the mean void volume while the group with the combined therapy had a worsening.

The intermittence in the flow had an acceptable response with therapies but the "*Serenoa repens alone*" treatment group revealed a two-fold rate improvement (38.81% to 20.37% against 23.81 to 14.29%). The group of patients who were taking the *Serenoa repens* plus α-blocker showed a more rapid improvement in the maximum flow (Table 3).

After 6 months a similar decrease in the mean IPSS was observed in both groups.

There was a decrease in the amount of patients presenting severe prostatic symptoms and a concomitant increase in the number of patients with absent/light symptoms. Both kind of therapies showed similar effects (Table 4).

Actual patients's sexual lives, observed on the basis of IIEF-5, weren't affected either by the "*Serenoa repens alone*" treatment or the association of *Serenoa repens* and α-blocker (Table 5).

The *Serenoa repens* intake resulted in a reduction of the "*inflammatory findings*", in terms of ultrasound, DRE and bioptical aspects without any changes in the glandular volume (Table 6).

Discussion

Although the DOSSER study shows several limits due its retrospective nature and its lack of a control group, it is the only multicentric observational study, of our knowledge, which allows us to evaluate the clinical data of this peculiar cohort of patients (patients with LUTS, BPH and a previous negative prostate biopsy).

We reported a good patients' compliance in term of follow-up; drop out rate at 6 month follow up was 23.1%. *Serenoa repens*, either alone or in association with an α-blocker, demonstrated to have a few side effects according to other studies (17).

Even in studies with placebo arms, adverse effects generally occurred in similar numbers in patients receiving either *Serenoa repens* or placebo, indicating that the drug is well tolerated and safe compared to alternative treatment options (8-11).

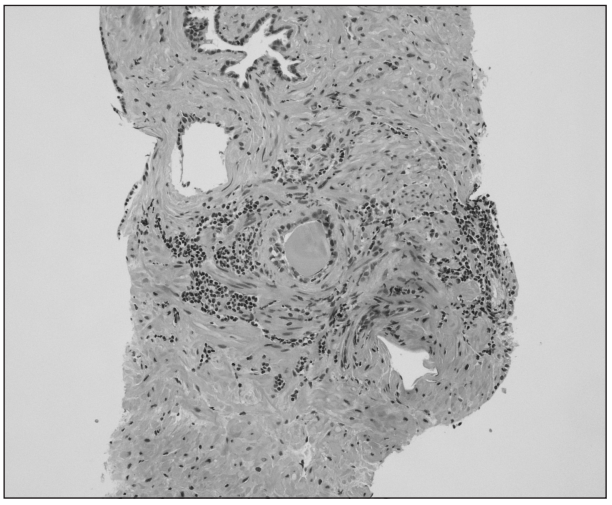
Although several studies indicated that PSA levels remained unchanged in patients treated with *Serenoa repens* (8, 18-20), we reported a decrease in the mean serum total PSA of 1.01 ng/ml and an increase in the percentage of patients with a PSA below 4 ng/ml. Because the role of the PSA as a marker for the screening of prostate cancer has been questioned in several trials, it would be interesting to evaluate with future studies the role of *Serenoa repens* in order to distinguish both BPH and inflammatory derived PSA raisings.

Serenoa repens may be therefore not only equivalent to 5α-reductase inhibitors but also to α-blockers in terms of efficacy, durability and speed of treatment effect. In fact a meta-analysis based on several clinical trials of *Serenoa repens* revealed that the maximum urinary flow improved with the use of the drug compared with a placebo (21-22). With the analysis of our database we experienced the same improvement in the uroflowmetry parameters. *Serenoa repens*, compared with the association of *Serenoa repens* plus α-blocker, revealed similar efficacy after 6 months in terms of maximum and mean flow. The α-blocker showed only a more rapid action to increase the maximum flow (at 3 months observation).

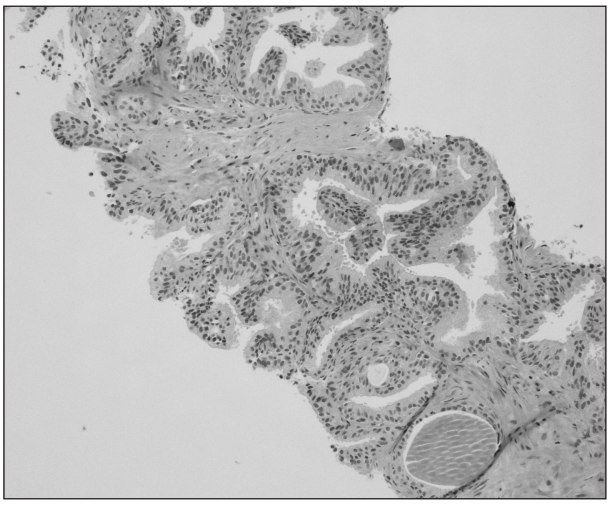
Patients' quality of life reported through the IPSS appeared to receive a benefit from *Serenoa repens*. Mean IPSS decreased during the 6 months of therapy and patients with severe scores showed to have a more notable relief (23).

The sexual life quality, evaluated through the IIEF-5 usage, didn't show any change during the follow up, nevertheless it could be supposed a worsening due the psychological rebound related to the likelihood of repeating a prostate biopsy and a PSA dosage.

Figure 1.



Prostate tissue with moderate chronic inflammatory infiltrate and post-inflammatory atrophy of the prostatic glands (Magnification 100x).



Prostate tissue with hyperplastic glands and focal high grade prostate intraepithelial neoplasia (PIN). (Magnification 100x).

(Images provided courteously provided by Dott. Michelangelo Fiorentino, Sant'Orsola-Malpighi Hospital, Bologna)

The demonstrated anti-androgenic, anti-inflammatory and anti-proliferative proprieties of *Serenoa repens* (24) are confirmed by our transrectal ultrasound (TRUS), clinical and bioptical findings.
Both percentages of ultrasound inflammatory aspects and of suspect lesions decreased after 6 months of *Serenoa repens* treatment such as the presence of palpable nodules at DRE. Finally patients who underwent to prostate mapping showed a lowering in the number of cores positive for inflammation.
Along with other investigations, dosages of IL-6, IL-8, VES and PCR were included in the SIUrO database, however the low numbers of the reported data didn't allow an analysis of those biochemical aspects.
Furthermore the low number of patients taking a daily dose of 640 mg of *Serenoa repens*, didn't allow us any evaluation of the possible differences in clinical aspects.

Conclusions

Serenoa repens comfirmed its efficacy in reducing dysuria with minimal side effects. Further prospective studies might confirm its role in the stabilization or lowering of PSA levels and its possible clinical anti-inflammatory action without affection of quality of life in patients affected by LUTS and chronic prostatitis.

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Correspondence

Alessandro Bertaccini, MD
Clinica Urologica, Policlinico Sant'Orsola-Malpighi,
Università di Bologna
via Palagi 9 - Bologna, Italy
Alessandro.Bertaccini@gmail.com

Marco Giampaoli, MD
Clinica Urologica, Policlinico Sant'Orsola-Malpighi,
Università di Bologna, Bologna, Italy
giampaoli.marco85@gmail.com

Riccardo Cividini, MD
Clinica Urologica, Policlinico Sant'Orsola-Malpighi,
Università di Bologna, Bologna, Italy
ric684@gmail.com

Gian Luca Gattoni
Web-Master SIUrO
mail@lucagattoni.com

Roberto Sanseverino, MD
UOC-Urologia Ospedale "Umberto 1°", Nocera Inferiore, Italy
roberto.sanseverino@libero.it

Tommaso Realfonso, MD
UOC-Urologia Ospedale "Umberto 1°", Nocera Inferiore, Italy
tomrea@libero.it

Giorgio Napodano, MD
UOC-Urologia Ospedale "Umberto 1°" , Nocera Inferiore, Italy
giorgio.napodano@gmail.com

Andrea Fandella, MD
Casa di Cura Giovanni XXIII, Monastier di Treviso, Italy
afandella@alice.it

Elisa Guidoi, MD
Casa di Cura Giovanni XXIII , Monastier di Treviso, Italy
afandella@urologia-andrologiagiovanni23.it

Domenico Prezioso, MD
Dipartimento di Scienze Ginecologiche, Ostetriche,
Urologiche e Medicina della Riproduzione
Università degli Studi di Napoli, Napoli, Italy
dprezioso@libero.it

Raffaele Galasso, MD
Dipartimento di Scienze Ginecologiche, Ostetriche,
Urologiche e Medicina della Riproduzione
Università degli Studi di Napoli, Napoli, Italy
rgalasso1973@libero.it

Carmine Cicalese, MD
Dipartimento di Scienze Ginecologiche, Ostetriche,
Urologiche e Medicina della Riproduzione
Università degli Studi di Napoli, Napoli, Italy

Vincenzo Scattoni, MD
Div. Urologia, Istituto Scientifico H. San Raffaele, Milano, Italy
scattoni.vincenzo@hsr.it

Angelo Armenio, MD
Ospedale Buccheri La Ferla, Palermo, Italy
armix2002@libero.it

Giario Conti, MD
Matteo Corinti, MD
Roberta Spasciani, MD
SC Urologia Ospedale S. Anna, Como, Italy

Giovanni Liguori, MD
Nikolitsa Lampropoulou, MD
Clinica Urologica Università degli Studi di Trieste
Ospedale di Gattinara, Trieste, Italy

Giuseppe Martorana, MD
Clinica Urologica, Policlinico Sant'Orsola-Malpighi,
Università di Bologna, Bologna, Italy
giuseppe.martorana@unibo.it