Original Research Article

UJ Urologia Journal

Urologia Journal
1–6

DOI: 10.1177/03915603251408298
journals.sagepub.com/home/urj
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Prostate health supporting by a novel nutraceutical compound with antioxidant property: Results from a pilot study

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Abstract

In recent years, healthcare strategies have increasingly emphasized a holistic and comprehensive approach in patient management that extends beyond the treatment of isolated physical symptoms. In this context, the use of nutraceuticals has gained interest as a complementary approach, particularly in managing chronic conditions and age-related disorders, such as lower urinary tract symptoms (LUTS) due to benign prostate hyperplasia (BPH). A new dietary supplement, contains a blend of bio-active compounds (Drolessano®)—including lycopene, sulforaphane, silymarin, glutathione, escine, tryptophan, and green tea extract—has been introduced in Italian pharmacopeia as food supplements in urological and andrological diseases. Here, we aim to assess the effects of Drolessano® on serum prostate-specific antigen (PSA) levels and urinary symptoms in individuals with BPH. Fifty-five men presenting with elevated PSA values and mild lower urinary tract symptoms (International Prostate Symptom Score [IPSS] < 7) were recruited in this pilot study. All enrolled patients underwent Drolessano® one tablet daily for 6 months. PSA concentrations and IPSS scores were recorded at baseline (T0), at 3 months (T1), and at the end of the treatment period (T2). Data at the follow-up has been compared with those at baseline. Patients enrolled experienced a statistical significance average PSA declined from 4.8 to 3.7 ng/mL ($p < 0.003$), as well as in improvement of quality of life, tested by patient reported outcomes. The supplement was generally well tolerated, and no serious adverse effects were reported during the study period. These preliminary data suggest that Drolessano® may offer a supportive benefit in the management of BPH, particularly with respect to reducing PSA levels and improvement quality of life. Otherwise, controlled trials with larger sample sizes are needed to substantiate these findings and to better understand the underlying mechanisms of action.

Keywords

prostate, prostate-specific antigen, antioxidants, nutraceuticals, silymarin

Received: 31 July 2025; accepted: 30 November 2025

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Introduction

Patient health management has transcended traditional boundaries, embracing a holistic approach that integrates the physical, psychological and social dimensions of well-being. This paradigm shift reflects the growing recognition of the complex interplay between various health aspects and the importance of addressing them collectively to improve patient care and outcomes. In this context, the field of nutraceuticals is increasingly recognized as a crucial element in the quest for optimizing health and wellness, particularly in the treatment of chronic conditions and health issues related to aging.[1,2] Drolessano® is a new dietary supplement recently introduced in Italian pharmacopeia.[2] It is free from gluten and lactose. Drolessano® embodies this holistic approach to health maintenance. Formulated with a potent blend of antioxidants and bioactive compounds, including lycopene from Solanum lycopersicum, sulforaphane from Brassica oleracea, silymarin from Silybum marianum, reduced glutathione, escin from Aesculus hippocastanum, tryptophan, and extracts of Camellia sinensis (green tea), Drolessano® is designed to leverage the synergistic effects of these ingredients to promote overall health and counteract the physiological processes associated with aging.[3] The actions of these components are multiple. Drolessano® has been designed to act in a synergistic manner. Silymarin and glutathione exert an hepatoprotective action and silymarin exhibits also anti-inflammatory effects.[4,5] Escin has a strong anti-inflammatory and anti-oedemic effect through different mechanism including a direction on glucocorticoid receptors and, probably, bradykinin modulation.[6] A certain anti-inflammatory effect has been described also for sulforaphane and lycopene.[7,8] The latter compound has been also associated with reducing prostate cancer risk.[9] Trypthophan is a useful compound in reducing symptoms associated with patient's discomfort including insomnia or mood changes.[10] The components of Drolessano® may partially help in the modulation of both nociceptive and neuropathic pain.[6,11,12] The aim of this study is to describe the action of Drolessano® in patients with elevated PSA levels and mild urinary symptoms.

Materials and methods

Study protocol

This study has been planned as pilot study. Drolessano® was administrated daily, for 6 months, in patients with increased PSA levels and with mild lower urinary tract symptoms (LUTS). PSA levels and LUTS were monitored at baseline (T0), 3 (T1) and 6 (T2) months after the treatment start.

Inclusion and exclusion criteria

We enrolled all patients with the following criteria: >45 years old; PSA > 4.00 ng/ml; clinical and instrumental diagnosis of benign prostatic hyperplasia; mild urinary symptoms evaluated using the International Prostate Symptom Score (IPSS < 7); able to respect the study protocol. All patients with the following criteria were excluded: diagnosis of prostate carcinoma; severe urinary symptoms (IPSS > 7); reported allergy to one or more of Drolessano® components.

Questionnaires, urological examination, and instrumental examination

The validated Italian versions of the IPSS, was self-administered to each patient at the arrival to the urological institution. All patients underwent urological examinations and ultrasound evaluation according to the international guidelines. In all patients with a suspicion of prostate carcinoma a multiparametric MRI (mpMRI) of the prostate have been performed. In case of positive findings at mpMRI confirmed by prostate biopsy the patient has been excluded from the study. Patient-Reported Outcomes (PROs) have been also used to evaluate the improvement of quality of life and health being status after the treatment.

Drug adherence

At the end of the study, the adherence to the treatment was calculated using a formula based on the number of tablets consigned at the time of admission and on the number of tablets returned unused at the end of the study.

Statistical analysis and ethical considerations

The statistical analysis aimed to evaluate whether Drolessano® effectively reduces PSA levels and LUTS over time. PSA levels were measured at the beginning of the study (T0), after 3 months (T1), and after 6 months (T2). We also assessed urinary symptoms using the International Prostate Symptom Score (IPSS). A χ^2 test or Fisher exact test was used for categorical variables. All statistical analyses were performed using SPSS software, with significance set at $p < 0.05$. We requested the ethics committee's view. According to the Italian bylaw, the authorization is not required because the nutraceutical compounds are not included into the pharmacological regulation. However, the study was conducted according in line with Good Clinical Practice guidelines and with the ethical principles of the Declaration of Helsinki. Before the beginning of the study, all participants signed the written informed consent. No placebo run-in period was performed.

Results

During the study period, 67 patients were enrolled. Twelve patients (17.9%) were lost during the follow-up and excluded from the analysis, while 55 patients (82.1%) completed the study (mean age 55.4 ± 5.6 years). Table 1 shows all anamnestic, clinical and laboratory characteristics of all enrolled patients at baseline.

Table 1. Clinical, instrumental, and laboratory patient's data at the enrollment time.

Patients characteristics	Mean (SD[a] or %)
Age	55.4 ± 5.6
Educational qualification	
Primary school	-
High school	41 (74.5)
University	14 (25.5)
Sexually active (past month)	55 (100)
Start of LUTS history (months)	26.2 ± 7.39
Symptoms score at baseline (mean)	
IPSS[b]	6.9 ± 0.3
Laboratory	
PSA (ng/ml)	4.8 ± 2.1
Instrumental examinations	
Abdomen ultrasonography	
Prostate volume (ml^3)	63 ± 21.8
Uroflowmetry	
Qmax (ml/s)	11 ± 1.5
Voided volume (ml)	345 ± 89.3
Post-void residual volume (ml)	91 ± 31.6

SD[a]: Standard Deviation; IPSS[b]: International Prostate Symptoms Score.

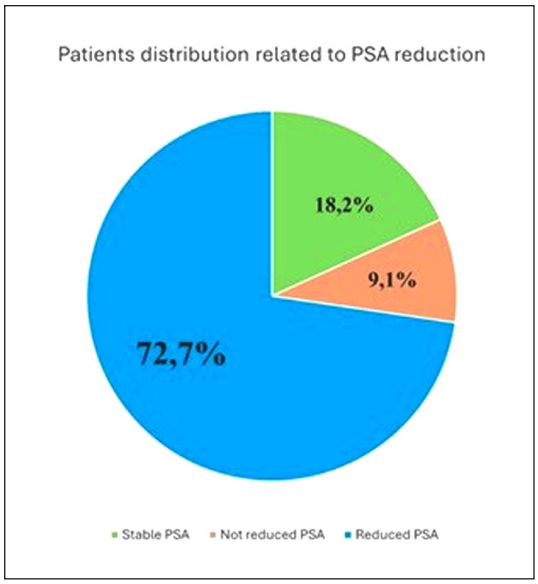

Figure 1. The figure shows the patients' distribution related to PSA reduction.
PSA: prostate-specific antigen.

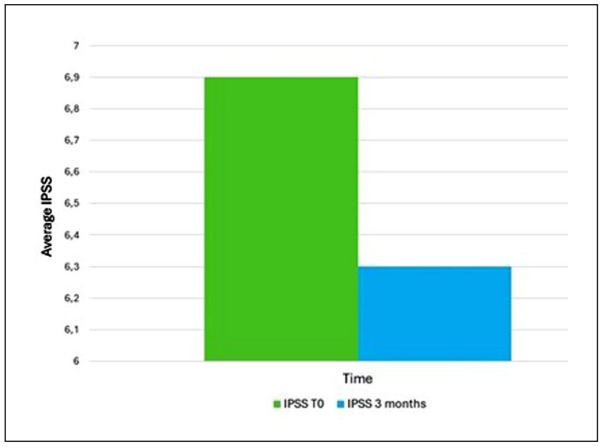

Figure 2. The figure shows the IPSS changes at 3 months.
IPSS: International Prostate Symptom Score.

Laboratory and questionnaires results

A significant reduction in PSA levels in 40 out of the 55 treated patients treated has been reported at the follow-up evaluation. The baseline average PSA level in all patients was 4.8 ng/ml. After treatment, the average PSA level in patients decreased to 3.7 ng/ml, indicating an average reduction of 1.1 ng/ml. Particularly, in 40 patients (72.7%), PSA levels decreased significantly. The average reduction in PSA for this group was 1.5 ng/ml, from an initial average of 4.8 ng/ml to an average of 3.3 ng/ml. In 10 patients (18.2%), PSA levels remained stable with no significant changes. In five patients (9.1%), PSA levels did not decrease and showed no appreciable changes. The reduction in PSA observed in the 40 patients who responded positively to the treatment was statistically significant ($p = 0.021$). Although this reduction in IPSS scores is more modest compared to the reduction in PSA levels, it still indicates an improvement in urinary symptoms and a higher quality of life for the patients. The distribution of results also highlighted that the treatment was well-tolerated by patients, with no reports of serious side effects. The stability of PSA levels in the 10 patients and the absence of reduction in the remaining five suggest that while Drolessano® is effective in most cases, individual variables may influence the treatment response. These data are summarized in Figure 1. Additionally, an improvement in IPSS was observed in all patients. The initial average IPSS was 6.9, and after treatment, the global average IPSS decreased to 6.3 (Figure 2). Patients experienced a statistical significant improvement of quality of life, tested by patient reported outcomes (PROs).

Discussion

Clinical considerations

The shift toward a more holistic and comprehensive approach in contemporary healthcare represents a necessary evolution in patient management. This approach recognizes the complexity of human health, where physical disorders are often intertwined with psychological, social, and emotional factors. Traditionally, medicine has focused on treating symptoms rather than the individual as a whole. However, in recent years, there has been a transition toward more inclusive health assessments that consider the patient's overall well-being to achieve optimal health outcomes.[13] In this context, dietary supplements like Drolessano® emerge as

significant elements complementing conventional medicine. Drolessano®, with its rich formulation of antioxidants and bioactive compounds, aims to leverage the synergistic effect of its ingredients to improve prostate and overall health. This discussion will explore in detail the mechanisms through which Drolessano®'s components may contribute to PSA reduction and prostate health improvement.[3] The holistic approach to health focuses not only on the physical aspect but also on the psychological and social ones. This is particularly relevant for patients with urological and andrological disorders, who often experience a significant impact on their quality of life due to physical difficulties and the anxiety associated with such conditions.[14] For example, benign prostatic hyperplasia (BPH) can cause bothersome urinary symptoms that negatively affect daily life and the patient's psychological well-being.[15] Additionally, anxiety regarding the potential progression of the disease to prostate carcinoma can further aggravate emotional distress.[16] Supplements like Drolessano® offer a complementary approach that can improve these multifaceted aspects of health. The formulation of Drolessano® is designed to address not only physical symptoms through the reduction of PSA and inflammation but also to enhance psychological well-being by reducing anxiety and improving sleep quality, thanks to compounds like tryptophan.[17–19]

Efficacy of antioxidants and bioactive components

Lycopene. Lycopene, a carotenoid found primarily in tomatoes, has been extensively studied for its effects on prostate health. Several studies have shown that lycopene can inhibit the progression of prostate disease by reducing oxidative stress and inflammation.[9] Another study highlighted that lycopene interferes with the proliferation of prostate cells and reduces DNA damage.[20]

Sulforaphane. Sulforaphane, a compound found in cruciferous vegetables like broccoli, is known for its potent anti-inflammatory and antioxidant properties.[21] It can modulate gene expression and enzyme activity, reducing inflammation and oxidative damage in prostate cells.[22] In vitro and in vivo studies have shown that sulforaphane can reduce PSA levels and improve prostate health by preventing the progression of BPH and prostate carcinoma.[23]

Silymarin. Silymarin, a flavonoid extracted from milk thistle, is renowned for its hepatoprotective and anti-inflammatory properties.[4] Recent studies have suggested that silymarin may also have beneficial effects on prostate health. Its ability to reduce systemic inflammation can contribute to lowering PSA levels in patients with BPH.[12] Specifically, silymarin can inhibit the proliferation of prostate cells and enhance immune function, thereby reducing inflammatory markers associated with increased PSA levels.[12,24]

Reduced glutathione. Glutathione is a powerful antioxidant that protects cells from oxidative stress and damage. Its ability to maintain cellular integrity and prevent DNA damage is crucial for prostate health.[5] Studies have shown that glutathione supplementation can reduce PSA levels and improve prostate function by reducing oxidative stress and inflammation.[25]

Escin. Escin, derived from horse chestnut, is known for its anti-inflammatory and vasoprotective properties. It improves blood circulation and reduces inflammation, two factors that can positively influence prostate health.[6,11,26] Although escin has not been specifically studied for its ability to reduce PSA, its anti-inflammatory properties may help reduce prostate inflammation, a key factor in elevated PSA levels in patients with BPH.[11,27]

Green tea extracts. Green tea extracts, rich in polyphenols and catechins, have shown beneficial effects on prostate health. Catechins, in particular, are known for their anti-inflammatory and antioxidant properties.[28,29] Studies have demonstrated that regular consumption of green tea can reduce the risk of developing BPH and prostate cancer, as well as lower PSA levels in patients with prostate disorders. Green tea catechins can inhibit the growth of prostate cells and reduce inflammation, thereby contributing to the decrease in PSA levels.[30,31]

Synergy between components

The combination of these bioactive components in Drolessano® exploits the synergistic effect to maximize benefits for prostate health. While each component has individually shown positive effects on prostate health and PSA reduction, their combination can amplify these effects through complementary mechanisms.[12] For instance, the combination of lycopene and sulforaphane can provide more robust antioxidant protection,[23,32] while escin and silymarin can work together to reduce systemic inflammation and improve blood circulation.[33,34] Interesting findings have shown that several nutraceutical components have a favorable synergistic effect in other prostatic diseases.[35,36] By integrating these components, Drolessano® aims to offer a comprehensive approach to improving prostate health, addressing both the physical and psychological aspects of well-being.

Conclusions

Our study has demonstrated that Drolessano®, a dietary supplement formulated with a combination of powerful antioxidants and bioactive compounds, can significantly reduce PSA levels in patients with benign prostatic hyperplasia and no suspicion of prostate carcinoma. The average reduction in PSA from 4.8 to 3.7 ng/ml in the 40

patients who responded positively to the treatment was statistically significant. This reduction, observed in approximately 72.7% of the treated patients, underscores the efficacy of Drolessano® in improving prostate health. In addition to the reduction in PSA, the study found a mild improvement in the IPSS in all patients. Although this reduction is more modest compared to the PSA reduction, it still represents an improvement in urinary symptoms and, consequently, a better quality of life for the patients. These results support the use of Drolessano® as part of an integrated therapeutic approach for managing benign prostatic hyperplasia. The holistic approach of the treatment not only addresses physical symptoms but also considers the psychological and social well-being of patients, thus improving their overall quality of life. The improvement in urinary symptoms, associated with the reduction in PSA, suggests that Drolessano® may play an important role in managing patients with benign prostatic hyperplasia, especially those with mild to moderate symptoms and no suspicion of prostate carcinoma. However, it is important to recognize the limitations of our study. The sample size is relatively small and does not include a control group, which may limit the applicability of the results. Additionally, the study duration was limited to 6 months; longer studies could provide more information on the long-term efficacy and safety of Drolessano®. Further researches with randomized controlled trials and larger study are necessary to confirm these findings and to further explore the mechanisms through which Drolessano® exerts its beneficial effects. It is also advisable to investigate the potential role of individual variables, such as age, diet, and overall health status, that may influence the treatment response. In conclusion, preliminary data suggest that Drolessano® may be a useful complement to existing therapeutic options for managing benign prostatic hyperplasia. Treatment with Drolessano® has not only shown to significantly reduce PSA levels but also improve urinary symptoms, thus contributing to better quality of life for patients. These results encourage further studies to consolidate the role of Drolessano® in clinical practice and to deepen the understanding of its benefits and mechanisms of action.

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Ethical considerations

Not required.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Sequence information

Not applicable.

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