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Case Study

SAFETY AND EFFICACY OF A NUTRACEUTICAL FORMULATION-REPROGUARD IN THE MANAGEMENT OF PROSTATE-ASSOCIATED SYMPTOMS

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ABSTRACT

The prostate gland is essential to male reproductive health and is influenced by age, inflammation, and lifestyle factors that may contribute to conditions such as prostatitis, benign prostatic hyperplasia (BPH), and prostate cancer. Nutraceuticals with antioxidant, anti-inflammatory, and androgen-modulating properties have emerged as supportive strategies for maintaining prostate health. This Phase I pilot study evaluated the preliminary efficacy and safety of a multi-ingredient nutraceutical formulation containing *Urtica dioica*, β-sitosterol, lycopene, zinc sulphate, *Camellia sinensis*, vitamin D_3, and *Punica granatum* in male patients diagnosed with *Sukrasthamba* and *Dourbalya*. The open-label study was conducted over 30 days in ten participants aged 21–40 years. Clinical assessments were performed at baseline, day 15, and day 30. The treatment demonstrated favourable overall clinical outcomes, with 80% of patients showing very good improvement, 10% moderate improvement, and 10% mild improvement. No patients showed lack of response, and no adverse events or dropouts were reported, indicating good tolerability and acceptability. These findings suggest that the nutraceutical formulation is safe and potentially effective in managing prostate-associated symptoms.

INTRODUCTION

The prostate plays a vital role in men's reproductive health, yet it is often overlooked until mild to severe symptoms appear. As men age, the prostate becomes particularly vulnerable to physiological changes that may affect urinary function, overall comfort, and long-term well-being. Three of the most common prostate-related conditions are prostatitis, benign prostatic hyperplasia (BPH), and prostate cancer. Although these conditions differ in cause, clinical impact, and long-term risk, all can significantly affect quality of life.

Prostatitis, an inflammation of the prostate gland, most commonly affects middle-aged adults. It occurs less frequently in men over 50 years of age and is rare in young adults [1-6].

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Although overall prevalence estimates range from 2% to 14% [7], recent epidemiological data remain limited, partly due to patients' reluctance to seek medical evaluation or undergo diagnostic assessment. Clinically, prostatitis is often associated with pelvic discomfort, genital or lower back pain, and frequent or painful urination. Its onset may be triggered by infection, stress, or other factors that disrupt normal prostate function [8,9]. Prostatitis and benign prostatic hyperplasia (BPH) are distinct conditions; however, accumulating evidence suggests that a history of prostatitis may contribute to the development of BPH, particularly in ageing men [10]. Age-related fluctuations in systemic sex hormones including androgens, oestrogens, and progesterone can influence prostatic growth and function. Inflammatory mediators are also implicated in the development of BPH and in its potential progression toward prostate cancer [11]. In addition, external factors such as dietary habits and lifestyle-related disorders may further exacerbate these changes [12,13]. Hormonal alterations have also been strongly linked to tumorigenesis. Age-related imbalances in androgens, oestrogens, and

progesterone may promote cellular proliferation, inhibit apoptosis, and contribute to the establishment of a pro-inflammatory microenvironment within the prostate [14]. These effects are further amplified by dihydrotestosterone (DHT), which participates in oncogenic pathways primarily through activation of androgen receptor signalling, thereby reinforcing tumour-promoting processes[15]. Benign prostatic hyperplasia (BPH) becomes increasingly prevalent in men aged 50 years and older and is commonly associated with lower urinary tract symptoms (LUTS). BPH is considered a multifactorial condition rather than a disease driven by a single causative factor [13]. It is characterized by non-cancerous enlargement of the prostate gland, leading to urethral narrowing and impaired bladder function. Typical symptoms include frequent and urgent urination, weak urinary stream, incomplete bladder emptying, and nocturia [16]. These symptoms can be both frustrating and disruptive, prompting many men to seek supportive or preventive strategies to maintain prostate health and urinary comfort. Importantly, persistent or long-standing BPH may carry additional risks. A meta-analytical observational study reported an increased incidence of both prostate and bladder cancer among individuals with BPH [17], suggesting that chronic prostatic enlargement may represent a precancerous condition in certain cases. Age-related prostate enlargement may further increase prostate cancer risk, as ageing cells can evade apoptosis and progressively accumulate genetic mutations. Moreover, age-dependent prostatic hyperplasia appears to become less androgen-sensitive over time [18], potentially altering disease progression and treatment responsiveness.

Severe cases of prostatitis and BPH have also been linked to erectile dysfunction (ED) [19- 21]. This association is most commonly observed in men aged 60–80 years; however, younger individuals (≥35 years) with severe or chronic forms of prostatitis or BPH may also experience sexual dysfunction. In addition, certain medical and surgical treatments for BPH have been reported to negatively affect erectile function [21]. Given these concerns, milder management strategies including dietary supplements and lifestyle-based interventions may serve as supportive or preventive options, particularly in early-stage BPH or as adjuncts to conventional therapy. Such approaches may help delay disease progression and potentially reduce the risk of BPH transitioning into a cancerous state. Prostate-specific antigen (PSA) testing is considered in selected high-risk individuals with persistent or severe prostatitis or BPH. Because these conditions can elevate PSA levels above normal ranges, careful clinical evaluation is required to exclude underlying prostate cancer [22, 23].

The most serious condition affecting the prostate is prostate cancer, which typically develops later in life. Although disease progression varies from slow-growing to highly aggressive forms, maintaining overall prostate health and remaining attentive to early changes are essential components of long-term wellness.

Figure 1: Global 5-year prevalence of prostate cancer per 100,000 males (ages 35–85+), 2022.

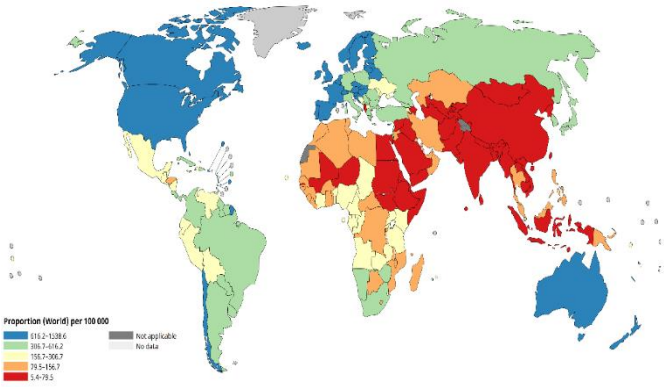


Figure 1 illustrates the estimated 5-year prevalence of prostate cancer worldwide, expressed as the number of prevalent cases per 100,000 males aged 35–85+ in 2022. Countries are colour-coded according to prevalence ranges defined by the International Agency for Research on Cancer (IARC). The highest prevalence values (dark blue; 616.2–1538.6 per 100,000) are predominantly observed in high-income regions, including North America, Australia, and parts of Northern and Western Europe. Intermediate prevalence levels (light blue to orange; 79.5–616.2 per 100,000) are seen across Latin America, Eastern Europe, and parts of Asia, while the lowest prevalence (red; 5.4–79.5 per 100,000) is concentrated in many countries in South Asia, the Middle East, and parts of Africa. Countries shown in grey represent areas where data were unavailable or not applicable [24]. Overall, the map highlights substantial geographic variation in prostate cancer burden, reflecting differences in population age structure, PSA screening practices, access to healthcare, and cancer detection and reporting systems. These disparities underscore the importance of regional epidemiological context when considering prevention strategies and therapeutic development. Because prostatitis, BPH, and prostate cancer share overlapping symptoms and are influenced by inflammation, hormonal balance, and age-related changes, proactive prostate support is increasingly recognized as an important component of men's health. Within this context, targeted nutritional supplementation may play a valuable role in supporting healthy prostate function, comfort, and long-term vitality.

The nutraceutical capsule under discussion contains *Urtica dioica* (UD) polyphenols, β-sitosterol, lycopene, green tea catechins, zinc, vitamin D_3, and pomegranate extract, each of which has been individually studied for potential roles in supporting prostate health. Among these, *Urtica dioica*, commonly known as stinging nettle, is naturally distributed across Asia, Europe, Australia, and the United States [25]. Its leaf extract contains a diverse array of phytochemicals, including hydroxycinnamic acid derivatives, flavonoids, anthocyanins [26], essential oils, organic acids, tannins, carotenoids, vitamins[27], as well as certain phytosterols and polysaccharides[28]. UD has demonstrated antioxidant, anti-inflammatory, antimicrobial, antidiabetic, antiproliferative, anticancer, and analgesic activities [29-31]. Preclinical toxicological studies in mice reported no observable adverse effects at tested doses[26,32], supporting its safety for human use. Reflecting this, regulatory authorities such as the Food Safety and Standards Authority of India (FSSAI) recognize UD as a permitted botanical ingredient with defined safe-use limits in food and nutraceutical applications. Importantly, UD has been widely investigated for its effects on benign prostatic hyperplasia (BPH) and lower urinary tract symptoms (LUTS), with multiple studies confirming its pharmacological efficacy in these conditions [27, 28, 33]. Following UD, β-sitosterol has also been extensively studied for prostate health. Clinical evidence shows that it improves LUTS and urinary flow in BPH patients [34-37]. Mechanistically, β-sitosterol may inhibit 5-α-reductase, reduce androgen receptor (AR) activity, and lower the International Prostate Symptom Score (IPSS) and inflammatory cytokines[38]. Additionally, it downregulates DNMT and HDAC, which can prevent abnormal prostate cell growth and contribute to prostate cancer prevention[39,40]. Lycopene, a potent antioxidant, enhances cell signalling, protects cells from oxidative damage, and supports detoxification processes [41]. Studies in prostate cancer cell lines indicate that lycopene can inhibit cell proliferation and interfere with androgen activation and signalling, mechanisms closely linked to prostate cancer development [42,43]. Similarly, zinc plays a vital role in prostate metabolism, and supplementation may reduce prostate size by modulating inflammation and BPH progression[44,45]. Low zinc concentrations are consistently observed in prostate tissue following prostate cancer diagnosis, suggesting that restoring zinc levels could offer therapeutic benefits [46]. Catechins from green tea (*Camellia sinensis*) have also been proposed to alleviate LUTS in BPH patients [47]. Clinical studies indicate that green tea supplementation may reduce prostate cancer risk, with treated individuals showing a markedly lower incidence compared to placebo[48]. Mechanistically, catechins inhibit 5-α-reductase, thereby decreasing dihydrotestosterone (DHT) levels and modulating androgen-driven prostate growth[49]. Beyond plant-derived compounds, certain vitamins such as vitamin D_3 also influence prostate health. Its biologically active form binds to the vitamin D receptor (VDR) expressed in prostate cells, modulating androgen-related growth signalling, regulating smooth muscle contraction, and suppressing inflammatory responses all key factors in BPH development[50]. Clinical evidence suggests that adequate vitamin D_3 consumption is associated with a decreased prevalence of BPH [44]. *Punica granatum* (Pomegranate), specifically its seeds, has been used in Ayurveda for its medicinal properties. It helps balance the body's doshas and alleviate symptoms like excessive thirst (*Trsna*), burning sensations (*Daha*), and fever (*Jvara*). These effects are particularly helpful for conditions involving inflammation or infection [51]. Phytochemical analysis revealed the presence of ellagic acid, ellagitannins, gallic acid, and punicalagin, compounds that have been reported to exhibit antioxidant, anticancer, anti-inflammatory, and antibacterial activities [52]. Pomegranate is part of a biologically active botanical formulation that reduces oxidative DNA damage, suppresses NF-κB-driven inflammation, and enhances endothelial nitric oxide signalling. It also modulates IGF-1/Akt/mTOR pathways, which are involved in prostate senescence, benign prostatic hyperplasia, and prostate carcinogenesis [53]. Together with other ingredients *Urtica dioica*, β-sitosterol, lycopene, zinc, green tea catechins, and vitamin D_3, *Punica granatum* may support prostate wellness. These ingredients work through complementary antioxidant, anti-inflammatory, and androgen-modulating pathways. This may improve urinary symptoms, reduce prostate enlargement, and promote long-term prostate health. While these individual effects are supported by research, the combined formulation has not been clinically tested. This Phase-I pilot study aimed to explore the formulation's effects and safety over 30 days.

MATERIALS AND METHODS

Clinical Validation of a Nutraceutical Capsule

Study Design and Ethical Approval

This study was a prospective, Phase I, open-label, single-centre, community-based pilot clinical study designed to evaluate the efficacy of a nutraceutical capsule composed of *Urtica dioica*, β-sitosterol, lycopene, zinc, green tea catechins, vitamin D_3, and *Punica granatum*. The trial was conducted under the supervision of the Contract Research Organization (CRO), Ashram Siddha Research Institute. The study protocol (Protocol Number: RG-104-04-24) was reviewed and approved by the Institutional Ethics Committee for Clinical Research of the CRO, as constituted under Rule 7 and registered under Rule 8

of the Central Drugs Standard Control Organization (CDSCO), operating under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. The study complied with the ethical guidelines for biomedical research on human participants as per the 2006 AYUSH-ICMR guidelines. In accordance with the Declaration of Helsinki, written informed consent was obtained from all participants prior to enrolment, and they were thoroughly briefed on the study's purpose, procedures, potential risks, and benefits.

Study Population

The trial was conducted in the city Salem, Tamil Nadu, India, where the estimated prevalence rates of *Sukrasthamba* (Obstruction), *Dourbalya* (nervous disorder) associated with loss of libido, erectile dysfunction., exceeds 30% of the local population. The study was conducted over a 30-day period, from April 8, 2024, to May 7, 2024. Participants were recruited through an open-label, non-randomized, community-based process.

Selection Criteria

Inclusion and exclusion criteria were determined based on comprehensive clinical examinations and reviews of medical histories. A total of ten participants, aged above 20 years and below 40 years and presenting with the specified clinical symptoms namely *Sukrasthamba* (Obstruction), *Dourbalya* (nervous disorder), were enrolled in the trial. Individuals above 45 years of age or those with a history of osteoarthritis, drug or alcohol abuse, night or shift work, diabetic complications, psoriatic arthritis, or endocrine disorders were excluded from the study. Additionally, participants were withdrawn from the trial if their symptoms worsened or if they developed any serious condition requiring urgent medical attention.

Intervention

The investigational product administered in this study was a nutraceutical capsule formulated with *Urtica dioica* tender leaf extract, 40% β-sitosterol, 6% lycopene, Zinc Sulphate of Grade IP, Dry leaf extract of *Camellia sinensis*, vitamin D_3 stabilized at 100 IU/mg, and 10% *Punica granatum* seed extract.

Table 1: Composition of Reproguard Formulation

S.No.	Name of Ingredient	Botanical Name/ Chemical Name	Category
1	Urtica	*Urtica dioica* L.	Herbal ingredient
2	β-Sitosterol	β-Sitosterol	Phytosterol
3	Lycopene	Lycopene	Carotenoid
4	Zinc Sulphate	Zinc sulphate	Mineral
5	Green Tea	*Camellia sinensis var. sinensis*	Herbal ingredient
6	Vitamin D_3	Cholecalciferol	Vitamin
7	Pomegranate	*Punica granatum* L.	Herbal ingredient

Participants were instructed to take one to two tablets orally, twice daily in the morning and evening, with lukewarm water, for the duration of the study. In addition to the daily tablet supplement, all participants received lifestyle counselling that included personalized dietary recommendations, physical activity guidance, and general health education to support therapeutic outcomes and encourage self-management of their condition. Compliance monitoring was conducted on patients to ensure adherence, participants were instructed to complete weekly adherence diaries to record daily intake.

Clinical Assessment and Evaluation

Comprehensive clinical evaluations were conducted on Day 1 (baseline) and Day 30 (end of study) by qualified Siddha and Ayurveda practitioners. Detailed case records were maintained for each participant throughout the study. Diagnostic assessments were carried out in accordance with traditional Siddha diagnostic protocols which involves the eightfold diagnostic method *Envagai Thaervu, Tridosha Naadi* a pulse diagnosis to assess the balance of *Vata, Pitta,* and *Kapha,* and *Saptha Dhatu Thaervu* meaning evaluation of the seven body tissues. These assessments provided a holistic understanding of the participants' health status and were used to monitor progress during the study. The primary outcome measure was defined as a minimum 10% reduction in presenting symptoms, as reported by the participants and confirmed by the clinical judgment of the attending physicians. This reduction was considered a clinically significant indicator of therapeutic success. Participants received detailed information about the study, including potential side effects, expected benefits, the right to withdraw at any time, and procedures for follow-up and referral, all communicated in their native language to ensure complete understanding. As depicted in Figure 2, the study cohort consisted of 10 Males while 5 patients were aged 21-30 years and 5 patients aged 31–40 years. The efficacy of the nutraceutical supplement

was evaluated over a one-month period by monitoring improvements in symptoms.

RESULTS

A total of ten male patients diagnosed with *Sukrasthamba* (obstruction) and *Dourbalya* (nervous disorder), presenting with loss of libido and erectile dysfunction, were enrolled in this clinical study evaluating a nutraceutical intervention. Patient assessment was based on demographic characteristics, duration of illness, and improvement in major clinical symptoms over a one-month treatment period. The results are summarized according to the data presented in the tables and figures. In terms of age distribution, five patients (50%) were aged 21–30 years, while the remaining five (50%) were 31–40 years. The mean age of participants was 31.7 years, indicating a slightly higher representation of middle-aged males. No participants were below 21 years, and only one patient was above 40 years.

The chronicity of prostate-related symptoms among the patients was evenly distributed, with 50% experiencing acute onset (within 3 months) and 50% experiencing chronic onset (lasting more than 3 months). Among the acute cases, 20% were aged 21–30 years, while 30% were aged 31–40 years. Conversely, in chronic cases, 30% were in the 21–30 years age group and 20% in the 31–40 years age group. This distribution indicates that, in this study sample, middle-aged patients were slightly more likely to present with acute symptoms, whereas younger patients tended to have a more prolonged, chronic course of prostate-related complaints. The findings indicate that age may influence the duration and pattern of symptom presentation, thereby allowing comparative evaluation across different stages of disease progression. The limited variability across groups further reflects the uniformity of sample selection and reliability of the recorded data.

Figure 2: Chronicity of the Disease Among Patients (n = 10)

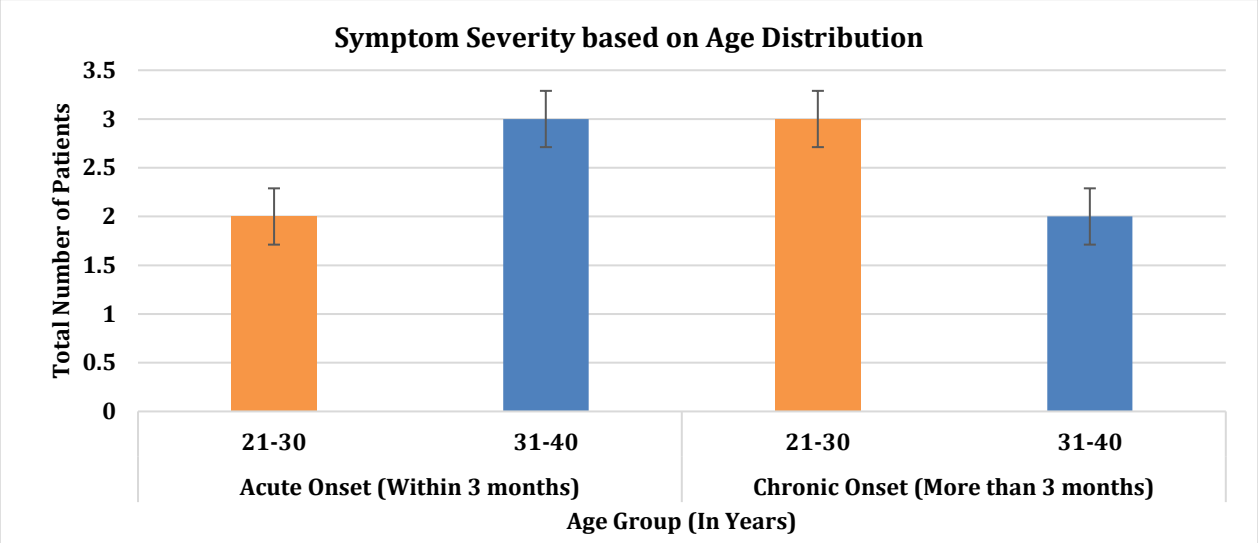


Figure 3 and table 2 and 3 provides the extent of symptom improvement evaluated at 15 days and 30 days in two age groups (21–30 years and 31–40 years) for three major clinical parameters: *Sukrasthamba, Dourbalya* (nervous weakness and fatigue), and loss of libido with erectile dysfunction. At 15 days, patients in the 21–30 years age group showed a mean improvement score of 5, which reduced slightly to 4 at 30 days. Similarly, patients aged 31–40 years demonstrated a mean score of 5 at 15 days and 4 at 30 days. Overall, both age groups exhibited comparable improvement patterns, corresponding to a 75% improvement in *Sukrasthamba* symptoms by the end of the treatment period. In the 21–30 years group, improvement scores were 4 at 15 days and 3 at 30 days, indicating moderate and sustained improvement. In contrast, the 31–40 years group showed higher scores, with 6 at 15 days and 5 at 30 days, reflecting a greater degree of symptomatic relief. Percentage-wise, improvement in *Dourbalya* was 75% in the younger group and 83% in the older group. For symptoms related to libido and erectile function, patients aged 21–30 years demonstrated improvement scores of 4 at 15 days and 3 at 30 days, corresponding to a 75% improvement. Patients in the 31–40 years age group showed higher scores, with 6 at 15 days and 5 at 30 days, resulting in an 84% improvement, indicating a comparatively better response in this age group. Across all three symptom domains, both age groups exhibited progressive and clinically meaningful improvement over the one-month intervention period. While improvements in *Sukrasthamba* were comparable between age groups, patients aged 31–40 years consistently demonstrated greater improvement in *Dourbalya* and sexual dysfunction–related symptoms. The trend observed in the bar diagram reflects early improvement at 15 days, followed by sustained benefit at 30 days, suggesting a stable therapeutic response over time.

Table 2: Symptom-Specific Improvement in Clinical Outcomes

Age Group (In Years)	Improvements in symptoms *Sukrasthamba*, Oligospermia		Improvements in symptoms *Dourbalya* (General weakness) and fatigue		Improvements in symptoms loss of libido, erectile dysfunction	
	15 Days	30 Days	15 Days	30 Days	15 Days	30 Days
21-30	5	4	4	3	4	3
31-40	5	4	6	5	6	5

Figure 3: Combined One-Month Improvement in *Sukrasthamba, Dourbalya* (Nervous Weakness), Fatigue, Loss of Libido, and Erectile Dysfunction Among Patients (n = 10)

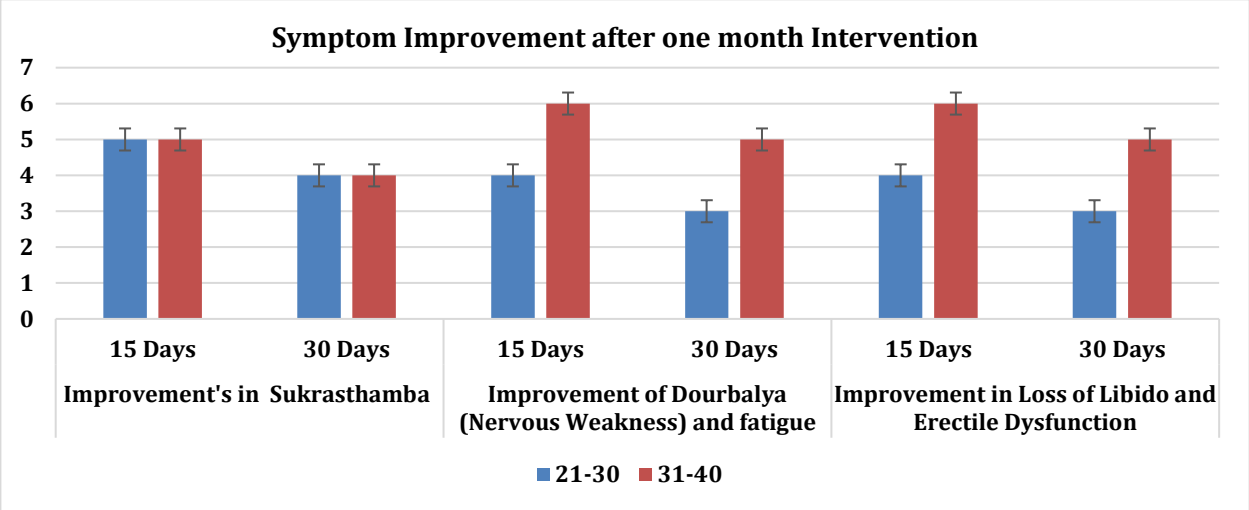
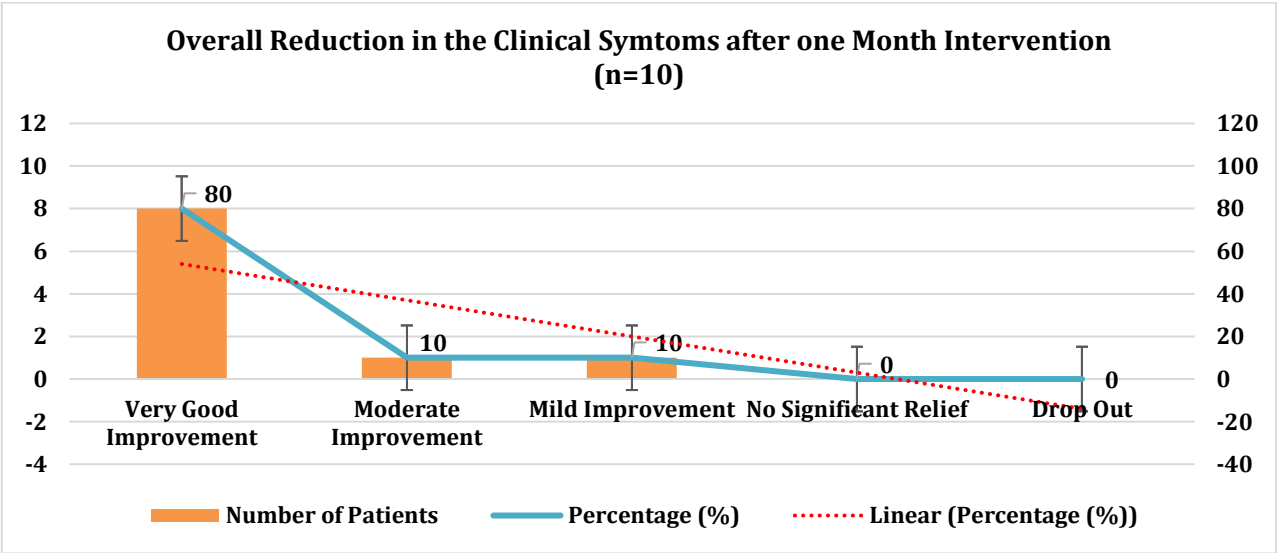


Table 3: Percentage of Improvement in the clinical symptoms (n=10)

Age Group	Percentage (%) of Improvement in *Sukrasthamba*	Percentage (%) Improvement in *Dourbalya* (Nervous Weakness) and Fatigue	Percentage (%) of Improvement in Loss of Libido and Erectile Dysfunction
21-30	75	75	75
31-40	75	83	84

The overall clinical outcomes of treatment are depicted in figure 4. Out of ten patients, eight patients (80%) showed very good improvement, one patient (10%) showed moderate improvement, and one patient (10%) showed mild improvement. Notably, no patients exhibited no significant relief, and there were no dropouts during the study period. This highlights the good acceptability, safety, and therapeutic effectiveness of the treatment protocol in managing prostate associated symptoms

Figure 4: Overall Reduction in Clinical Symptoms After Intervention (n = 10)



DISCUSSION

The prostate is a vital male reproductive gland that undergoes physiological changes with age and can be influenced by lifestyle factors such as sedentary behaviour and metabolic disorders [4,8,9]. Chronic or recurrent prostatitis has been associated with the development of benign prostatic hyperplasia (BPH)[10], a condition whose progression may depend on factors such as age, overall health, and the duration and severity of the disease[11-13,18]. Over time, in certain cases, prolonged BPH may contribute to pathological changes that increase the risk of malignant transformation, potentially leading to prostate cancer[17]. Given the progressive nature of BPH and its potential complications, strategies to support prostate health are of significant interest. Several nutraceuticals and bioactive compounds have been suggested to exert beneficial effects through antioxidant, anti-inflammatory, and androgen-modulating mechanisms, potentially improving urinary symptoms, reducing prostate enlargement, and supporting long-term prostate function[25-27,41,42,46]. The present study evaluates a nutraceutical formulation consisting of *Urtica dioica* (UD), β-sitosterol, Lycopene, Zinc Sulphate, *Camellia sinensis*, vitamin D_3, and *Punica granatum* as a potential dietary supplement for prostate wellness. These agents are believed to act complementarily, targeting multiple pathways involved in prostate health. In the context of traditional medicine, male patients diagnosed with *Sukrasthamba* and *Dourbalya* often present with symptoms such as loss of libido and erectile dysfunction. This Phase I pilot study was designed to assess the preliminary effects and tolerability of the multi-ingredient formulation over a 30-day intervention period in this population. The findings demonstrated meaningful symptomatic improvement across multiple clinical domains, with consistent trends observed across different age groups and varying disease chronicity, suggesting potential benefits for both prostate function and associated reproductive symptoms.

The study population showed an equal distribution of patients in the 21–30 years and 31–40 years age groups, with a mean age of 31.7 years. This distribution allowed comparative assessment across younger and middle-aged males, a demographic commonly affected by functional prostate-related and sexual health complaints. The absence of participants below 21 years and minimal representation above 40 years suggests that the findings are most applicable to early and mid-adulthood, a period often associated with lifestyle-related and stress-induced symptomatology. The equal distribution of acute and chronic disease onset highlights the heterogeneous nature of symptom presentation. Notably, middle-aged patients were slightly more likely to present with acute symptoms, whereas younger patients tended to exhibit a chronic course. This pattern may reflect differences in symptom perception, healthcare-seeking behaviour, or adaptive coping mechanisms across age groups. Importantly, the balanced distribution enabled evaluation of therapeutic response across different stages of disease progression. Improvement in *Sukrasthamba* was comparable across both age groups, with a consistent 75% improvement by the end of one month. The similarity in response suggests that obstructive symptoms may be equally reversible in younger and middle-aged patients when addressed in a timely manner. The slight reduction in mean improvement scores from day 15 to day 30 likely reflects stabilization rather than regression, indicating sustained benefit following early symptomatic relief. In contrast, *Dourbalya* (nervous weakness and fatigue) showed a clear age-related difference in response. Patients aged 31–40 years demonstrated higher improvement scores and percentages (83%) compared to younger patients (75%). This may suggest that middle-aged individuals, who often experience greater baseline fatigue and stress-related symptoms, derive proportionally greater benefit from intervention. The sustained improvement at 30 days indicates ongoing functional recovery rather than transient symptom suppression. A similar pattern was observed in loss of libido and erectile dysfunction, with the 31–40 years age group showing greater improvement (84%) than the younger group (75%). This difference may be related to variations in baseline symptom severity, which could influence the extent of observable improvement. Improvements in nervous weakness were also noted alongside changes in ED; however, this association does not necessarily imply a direct relationship and may reflect overlapping responses to treatment rather than a causal link.

The overall clinical outcome further reinforces the efficacy of the intervention. A substantial proportion of patients (80%) experienced very good improvement, while the remaining patients showed moderate to mild improvement. The absence of non-responders and dropouts suggests good tolerability, acceptability, and compliance, which are critical factors in long-term management of functional and chronic conditions. The convergence of subjective symptom relief, consistent improvement across multiple domains, and favourable overall outcomes suggests a holistic therapeutic benefit rather than isolated symptom control. The early onset of improvement by day 15, followed by sustained benefit at day 30, indicates a stable and progressive response pattern. The findings of this study suggest that early intervention may yield meaningful benefits

irrespective of disease chronicity, while age may influence the magnitude of improvement in fatigue and prostate associated conditions.

CONCLUSION

The findings of this Phase I pilot study indicate that the evaluated multi-ingredient nutraceutical formulation may provide effective support for prostate health and associated reproductive functions in males presenting with *Sukrasthamba* and *Dourbalya*. The intervention was well tolerated and produced consistent improvement across various symptom-related parameters within a short intervention period. Comparable improvement in obstructive prostate symptoms across age groups suggests that early intervention may be beneficial regardless of disease chronicity. Enhanced improvements in fatigue and sexual dysfunction observed among middle-aged participants highlight the potential influence of age and baseline symptom severity on treatment response. The absence of adverse events and high patient compliance further support the suitability of this formulation as a supportive therapeutic option. The results indicate that the evaluated nutraceutical formulation is safe, well tolerated, and effective in alleviating prostate-associated symptoms, thereby serving as a reliable approach to prostate wellness.

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REFERENCES

1. Mehik A, Hellström P, Lukkarinen O, Sarpola A, Järvelin MR. Epidemiology of prostatitis in Finnish men: a population-based cross-sectional study. BJU International. 2000; 86(4): 443-448.
2. Clemens JQ, Meenan RT, O'Keeffe Rosetti MC, Gao SY, Calhoun EA. Incidence and clinical characteristics of National Institutes of Health type III prostatitis in the community. Journal of Urology. 2005; 174(6): 2319-2322.
3. Gao DJ, Guo YS, Yu HY, Wang YJ, Cui WG. Prevalence and related factors of prostatitis-like symptoms in young men. Zhonghua Nan Ke Xue. 2007; 13(12): 1087-1090.
4. Krieger JN, Lee SWH, Jeon J, Cheah PY, Liong ML, Riley DE. Epidemiology of prostatitis. International Journal of Antimicrobial Agents. 2008; 31(Suppl 1): 85-90.
5. Bajpayee P, Kumar K, Sharma S, Maurya N, Kumar P, Singh R, Lal C. Prostatitis: prevalence, health impact and quality improvement strategies. Acta Poloniae Pharmaceutica. 2012; 69(4): 571-579.
6. Lee KC, Cho IR. Chronic prostatitis/chronic pelvic pain syndrome in adolescents compared with that in young adults. Investigative and Clinical Urology. 2017; 58(4): 267-270.
7. Mandar R, Korrovits P, Rahu K, Rahu M, Sibul EL, Mehik A, Punab M. Dramatically deteriorated quality of life in men with prostatitis-like symptoms. Andrology. 2020; 8(1): 101-109.
8. Schaeffer AJ, Landis JR, Knauss JS, Propert KJ, Alexander RB, Litwin MS, et al. Demographic and clinical characteristics of men with chronic prostatitis: the National Institutes of Health chronic prostatitis cohort study. Journal of Urology. 2002; 168(2): 593-598.
9. Cyril AC, Jan RK, Radhakrishnan R. Pain in chronic prostatitis and the role of ion channels: a brief overview. British Journal of Pain. 2022; 16(1): 50-59.
10. Gandaglia G, Briganti A, Gontero P, Mondaini N, Novara G, Salonia A, et al. Role of chronic prostatic inflammation in the pathogenesis and progression of benign prostatic hyperplasia. BJU International. 2013; 112(4): 432-441.
11. Elkahwaji JE. Role of inflammatory mediators in the development of prostatic hyperplasia and prostate cancer. Research and Reports in Urology. 2012; 4: 1-10.
12. Ellem SJ, Risbridger GP. Aromatase and regulating the estrogen: androgen ratio in the prostate gland. Journal of Steroid Biochemistry and Molecular Biology. 2010; 118(4-5): 246-251.
13. Corona G, Vignozzi L, Rastrelli G, Lotti F, Cipriani S, Maggi M. Benign prostatic hyperplasia: a new metabolic disease of the aging male and its correlation with sexual dysfunctions. International Journal of Endocrinology. 2014; 2014: 329456.
14. Bosland MC, Mahmoud AM. Hormones and prostate carcinogenesis: androgens and estrogens. Journal of Carcinogenesis. 2011; 10: 33.
15. Marks LS, Mostaghel EA, Nelson PS. Prostate tissue androgens: history and current clinical relevance. Urology. 2008; 72(2): 247-254.
16. Bruskewitz RC. Quality of life and sexual function in patients with benign prostatic hyperplasia. Reviews in Urology. 2003; 5(2): 72-80.

17. Dai X, Fang X, Ma Y, Xianyu J. Benign prostatic hyperplasia and the risk of prostate cancer and bladder cancer: a meta-analysis of observational studies. Medicine. 2016; 95(18): e3493.
18. Banerjee PP, Banerjee S, Brown TR, Zirkin BR. Androgen action in prostate function and disease. American Journal of Clinical and Experimental Urology. 2018; 6(2): 62-72.
19. Chung SD, Keller JJ, Lin HC. Association between chronic prostatitis/chronic pelvic pain syndrome and erectile dysfunction: a case-control study. BJU International. 2012; 110(5): 726-730.
20. De Nunzio C, Roehrborn CG, Andersson KE, McVary KT. Erectile dysfunction and lower urinary tract symptoms. European Urology Focus. 2017; 3(4-5): 352-363.
21. Zhang Y, Zang N, Xiang Y, Lin F, Liu X, Zhang J. Erectile dysfunction prevalence and impact of prostate conditions among US adults: NHANES 2001–2004. Frontiers in Endocrinology. 2025; 15: 1412369.
22. Meigs J, Barry M, Giovannucci E, Rimm E, Stampfer M, Kawachi I. High rates of prostate-specific antigen testing in men with evidence of benign prostatic hyperplasia. American Journal of Medicine. 1998; 104(6): 517-525.
23. Duskova K, Vesely S. Prostate specific antigen: current clinical application and future prospects. Biomedical Papers of the Medical Faculty of Palacky University in Olomouc. 2015; 159(1): 18-26.
24. World Health Organization, International Agency for Research on Cancer. GLOBOCAN 2022: Global 5-year prevalence of prostate cancer per 100,000 males (ages 35–85+). Lyon (France): IARC; 2022 [cited 2026 Feb 7]. Available from: https://gco.iarc.fr/
25. Taylor K. Biological flora of the British Isles: Urtica dioica L. Journal of Ecology. 2009; 97(6): 1436-1458.
26. Dar SA, Ganai FA, Yousuf AR, Balkhi MUH, Bhat TM, Sharma P. Pharmacological and toxicological evaluation of Urtica dioica. Pharmaceutical Biology. 2013; 51(2): 170-180.
27. Abi Sleiman M, Younes M, Hajj R, Salameh T, Abi Rached S, Abi Younes R, et al. Urtica dioica: anticancer properties and other systemic health benefits from in vitro to clinical trials. International Journal of Molecular Sciences. 2024; 25(13): 7501.
28. Ghorbanibirgani A, Khalili A, Zamani L. Efficacy of stinging nettle (Urtica dioica) in patients with benign prostatic hyperplasia: a randomized double-blind study. Iranian Red Crescent Medical Journal. 2013; 15(1): 9.
29. Bhusal KK, Magar SK, Thapa R, Lamsal A, Bhandari S, Maharjan R, et al. Nutritional and pharmacological importance of stinging nettle (Urtica dioica L.): a review. Heliyon. 2022; 8(6): e09691.
30. Dhouibi R, Affes H, Salem MB, Hammami S, Sahnoun Z, Zeghal KM, Ksouda K. Screening of pharmacological uses of Urtica dioica and other benefits. Progress in Biophysics and Molecular Biology. 2020; 150: 67-77.
31. Taheri Y, Quispe C, Herrera-Bravo J, Sharifi-Rad J, Ezzat SM, Merghany RM, et al. Urtica dioica-derived phytochemicals for pharmacological and therapeutic applications. Evidence-Based Complementary and Alternative Medicine. 2022; 2022: 4024331.
32. Mahboubi M. Urtica dioica in the management of benign prostate hyperplasia. Natural Products Journal. 2020; 10(5): 535-542.
33. Safarinejad MR. Urtica dioica for treatment of benign prostatic hyperplasia: a randomized double-blind placebo-controlled crossover study. Journal of Herbal Pharmacotherapy. 2005; 5(4): 1-11.
34. Berges RR, Windeler J, Trampisch HJ, Senge TH, β-Sitosterol Study Group. Randomized placebo-controlled double-blind clinical trial of β-sitosterol in patients with benign prostatic hyperplasia. Lancet. 1995; 345(8964): 1529-1532.
35. Klippel KF, Hiltl DM, Schipp B, German BPH-Phyto Study Group. Multicentric placebo-controlled double-blind clinical trial of β-sitosterol for treatment of benign prostatic hyperplasia. British Journal of Urology. 1997; 80(3): 427-432.
36. Wilt TJ, Ishani A, MacDonald R, Stark G, Mulrow CD, Lau J, Cochrane Urology Group. Beta-sitosterols for benign prostatic hyperplasia. Cochrane Database of Systematic Reviews. 2011; (5): CD001043.
37. Saeidnia S, Manayi A, Gohari AR, Abdollahi M. The story of beta-sitosterol: a review. European Journal of Medicinal Plants. 2014; 4(5): 590-609.
38. Cabeza M, Bratoef E, Heuze I, Ramírez E, Sánchez M, Flores E. Effect of beta-sitosterol as inhibitor of 5-alpha reductase in hamster prostate. Proceedings of the Western Pharmacology Society. 1998; 46: 153-155.
39. Patra SK, Patra A, Dahiya R. Histone deacetylase and DNA methyltransferase in human prostate cancer. Biochemical and Biophysical Research Communications. 2001; 287(3): 705-713.
40. Macoska JA. Use of beta-sitosterol for the treatment of prostate cancer and benign prostatic hyperplasia. American Journal of Clinical and Experimental Urology. 2023; 11(6): 467-475.

41. Ilic D, Forbes KM, Hassed C. Lycopene for the prevention of prostate cancer. Cochrane Database of Systematic Reviews. 2011; (11): CD008007.
42. Wertz K, Siler U, Goralczyk R. Lycopene: modes of action to promote prostate health. Archives of Biochemistry and Biophysics. 2004; 430(1): 127-134.
43. Van Breemen RB, Sharifi R, Viana M, Pajkovic N, Zhu D, Yuan L, et al. Antioxidant effects of lycopene in men with prostate cancer or benign prostatic hyperplasia. Cancer Prevention Research. 2011; 4(5): 711-718.
44. Das K, Buchholz N. Benign prostate hyperplasia and nutrition. Clinical Nutrition ESPEN. 2019; 33: 5-11.
45. Ebaid H, Bashandy SA, Hassan I, Al-Tamimi J, Haredy SA, Imbabi T, et al. Preventive effect of zinc sulfate against olanzapine-induced testicular toxicity in male rats. Biological Trace Element Research. 2025; 203(7): 3764-3778.
46. Costello LC, Franklin RB. Role of zinc in normal prostate function and metabolism and its implications in prostate cancer. Archives of Biochemistry and Biophysics. 2016; 611: 100-112.
47. Bettuzzi S, Brausi M, Rizzi F, Castagnetti G, Peracchia G, Corti A. Chemoprevention of prostate cancer by green tea catechins in men with high-grade prostate intraepithelial neoplasia. Cancer Research. 2006; 66(2): 1234-1240.
48. Morán E, Budía A, Broseta E, Boronat F. Phytotherapy in urology: scientific evidence in benign prostatic hyperplasia and prostate adenocarcinoma. Actas Urologicas Espanolas. 2013; 37(2): 114-119.
49. Grant P, Ramasamy S. Update on plant-derived anti-androgens. International Journal of Endocrinology and Metabolism. 2012; 10(2): 497-502.
50. Adorini L, Penna G, Fibbi B, Maggi M. Vitamin D receptor agonists target static, dynamic and inflammatory components of benign prostatic hyperplasia. Annals of the New York Academy of Sciences. 2010; 1193(1): 146-152.
51. Government of India. Punica granatum. Vol. II. New Delhi; Ministry of Health and Family Welfare, Department of AYUSH; 2001. p. 53-55.
52. De Silva MB, Brimson JM, Tencomnao T. Punica granatum L. In: Medicinal Properties and Molecular Mechanisms of Thai Traditional Herbs. Bangkok; Publisher name; 2025. p. 83.
53. Kroeger N, Belldegrun AS, Pantuck AJ. Pomegranate extracts in the management of men's urologic health: scientific rationale and clinical data. Evidence-Based Complementary and Alternative Medicine. 2013; 2013: 701434.

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