



Research Article

Systematic Review on Safety and Efficacy of Saw Palmetto as a Health Supplement for Prostate Health in Adult Males

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Abstract:

Background and AIM:

Saw palmetto is a medicinally active herbal plant found in the Southeast of the United States. Saw palmetto extracts are extracted from the *Serenoa repens* fruits are consumed by the people globally as a health supplement. It is also useful for treating enlarged prostate drums, urinary tract infections and improved development of hair. It reduces inflammation as well. Increased sex desire and fertility are other applications. Some studies have also indicated that Saw palmetto effectively treats benign prostatic hyperplasia. Saw palmetto has several other advantages, such as hair loss prevention, treating the infection of the urinary system, preserving prostate health, reducing inflammation. In systematic reviews, information from the different studies can often be collected using statistical approaches to draw new statistical inferences from the pooled data. There is no need to incorporate meta-analysis in all systematic evaluations although systematic reviews do contain all methodological analysis. In simple terms, a systematic review is the entire process of selecting, evaluating, and combining every relevant evidence, whereas meta-analysis is the statistical combination of data obtained from a systematic investigation.

Methodology:

PUBMED database records were detected, Recordings were done after deletion of duplicates. Full articles of text eligibility were checked. Publishing chosen: Adult males with prostate disease, Saw palmetto efficiency: Saw palmetto's prostate condition and safety: condition of prostate.

Result:

We discovered 218 papers after performing the review research using PUBMED, which comprised meta-analysis, RCTs, systematic reviews, and reviews. Articles that were duplicated and/or lacked information on safety and/or efficacy were deleted. Data was gathered from four systematic reviews with a total patient count of 10,601 and seven randomised controlled trials (RCTs) with a total patient count of 2042. The patients were 65 years old on average. *Serenoa repens* were found to be just as effective as tamsulosin 0.2-0.4 mg and finasteride 5 mg in treating BPH. When compared to placebo, *Serenoa repens* improved the urine symptoms score, symptoms, and flow measure. *Serenoa repens* was associated with 0.64 fewer voids each night (95 percent CI -0.98 to -0.31; P=0.001) and a 2.75 mL/s (95 percent CI 0.57 to 4.93; P=0.01) increase in Qmax (N=1 study). *Serenoa repens* improved the International Prostate Symptom Score and Quality of Life in men with benign prostatic hyperplasia, as well as decreased urinary tract problems and flow measurements. *Serenoa repens* has such a low risk of side effects, with only a few small ones. *Serenoa repens* is a better choice than tamsulosin or finasteride for hair loss.

Conclusion:

According to the findings of the review study, extracts from the Saw Palmetto plant, *Serenoa repens*, aids in the improvement of urinary incontinence and flow measurements in males with benign prostatic hyperplasia. Also, Saw palmetto is a safe drug with favourable safety profile.

Keywords: Benign prostatic hyperplasia, Saw Palmetto, *Serenoa repens*, Sabal Serrulate, Dwarf Palm, Lower urinary tract symptoms

Introduction:

A literature review is a greater overview of basic research on a given study topic that finds, chooses, assesses, and synthesises each relevant high-quality research material to answer the question. It provides a comprehensive overview of scholarly literature related to a certain study subject or issue. A large study is more thorough than a standard literature review, which examines a very much smaller corpus of research findings and presents them from the perspective of a single author. Assessments have their roots in medicine and are now utilised in Evidence-Based Therapy and proof behavioral-practice-research to inform decision-making.^(1,2) Systematic reviews typically combine data from several research papers using statistical approaches, and then utilise the pooled data to draw new statistical findings. Meta-analysis is the term for this. Although not all systematic reviews must include meta-analysis, systematic reviews do contain all meta-analyses. A systematic review is the complete process of choosing, analysing, and incorporating all available evidence in layman's words, whereas meta-analysis is the statistical approach of combining data from a literature review.^(3,4)



Figure:1 Cultivation of Saw palmetto plants

Saw palmetto is a herbal plant which possess medicinal properties and is found in South Eastern United States. The extract of Saw palmetto is collected from the fruit of *Serenoa repens* and is taken as health supplement by people worldwide. Additionally, it is used to treat swollen prostate gland, urinary infections and for better hair growth. It also lowers inflammation. Other uses include increasing sexual drive and fertility⁽⁵⁾. Certain studies found that it is also effective against benign prostatic hyperplasia.

There are certain other benefits of using Saw palmetto like hair loss prevention, for treatment of urinary tract infection, maintaining prostate health, decrease inflammation and to regulate testosterone level⁽⁶⁾.

SP extract has also been reported to aid with the symptoms of benign prostatic hypertrophy, a condition in which the prostate gland grows out of control. BPH is more common in older persons and should be treated as soon as possible to avoid negative health repercussions.⁽⁷⁾ Several studies have shown that consuming a 320 microgram doses of Saw palmetto each day for two months before prostate surgery lowers recovery time and aids in the management of complications such as blood loss.⁽⁸⁾

However, there are contradictory reports which states that use of Saw palmetto extract is not significantly effective against reducing symptoms of benign prostate hyperplasia and has side effects⁽⁹⁾. Also, it causes excessive bleeding during and after surgery⁽¹⁰⁾.

Previous reports also concluded that Saw palmetto also hampers the process of blood

coagulation by making it slower. Saw palmetto causes higher chances of contusion and bleeding in people those who take it along with other medicines⁽¹¹⁾. Various in vitro studies conducted suggested the possible mechanism of action of Saw palmetto but clinical proof of the application is missing. By considering above mentioned facts about the reviews of Saw palmetto we went on to analyse the results and research regarding the beneficial and adverse effects of Saw palmetto.⁽¹²⁾



Figure:2 Saw palmetto extract capsules

Saw palmetto is a natural substance that comes from the *Serenoa repens* tree's fruit. It's general uses include treatment of swollen prostate, improvement of urinary function and boosting

hair growth. Other uses of Saw palmetto includes increasing sexual drive and fertility and to bring down inflammation. Saw palmetto is found in the south eastern United States⁽¹³⁾.

Most benefits and uses of Saw Palmetto:

- a. Prevent hair loss
- b. Improves urinary tract function
- c. May support prostate health
- d. May decrease inflammation
- e. May help regulate testosterone level⁽¹⁴⁾

Saw palmetto extract is being used to relieve the symptoms of benign prostatic hyperplasia, a condition in which the prostate gland expands. BPH generally affects people of older age and if left untreated it could be followed by lower urinary tract signs which hampers the quality of life. Saw palmetto could be used for treating these disorders. Saw palmetto might also possess anticancer effects. Saw palmetto can be used for treating prostate cancer⁽¹⁵⁾.

Uses & Effectiveness:

Possibly Effective for-

According to multiple studies, using 320 milligrams of Saw palmetto each day for 2 months before prostate surgery can dramatically minimise the length of the procedure, blood loss, and other complications that may emerge after surgery, resulting in a reduction in overall hospital time.⁽¹⁶⁾

Possibly ineffective in terms of -

Prostate enlargement (BPH). Saw palmetto is not considerably effective in lowering BPH symptoms, according to the majority of high-quality, credible research. Saw palmetto appears to have no effect on the want to go to the toilet at night or on the relieve of painful urination.⁽⁷⁾

Special Precautions and Warnings:

Surgery: Saw palmetto could hamper blood coagulation by slowing it down. Saw palmetto may cause excessive bleeding during and after surgery. It's best if you don't take Saw Palmetto for at least two weeks before your surgeries.⁽⁸⁾

Interactions:

Anticoagulant/antiplatelet medications (drugs that slow blood coagulation):

Blood coagulation has been demonstrated to be slowed by Saw palmetto. People who use Saw palmetto with drugs that reduce clotting may be at

an increased risk of contusion and bleeding.⁽⁹⁾

Dosing:

- 1) Recommended dose of Saw palmetto for treating Benign Prostatic Hyperplasia is 160 mg BD or 320 mg OD⁽⁸⁾.
- 2) Consume 320 milligram of Saw palmetto extracts twice a day for two months before a prostate procedure (TURP)⁽¹⁶⁾

Aim and Objectives

Aim:

The AIM is Systematic Review on Safety and Efficacy of Saw palmetto as a Health Supplement for Prostate Health in Adult Males

Objectives:

To assess the safety and efficacy of SAW PALMETTO as Health Supplement for Prostate Health in Adult Males Subjects.

Methodology

Materials and methods:

The goal of this systematic study was to answer two questions.

- 1) Is Saw palmetto effective in treating benign prostatic hyperplasia?
- 2) Is Saw palmetto safe to use?^[21]

Search Strategy:

Data searches were carried out up to March 2021 in PubMed to identify eligible studies published from inception through to February 2021. Search terms included 'Serenoa repens', 'Saw palmetto', 'Sabal serrulata' and 'Dwarf palm'. The analysis confined our search to published studies in English only. Reference lists of identified articles and published reviews were also hand searched.

Eligibility Criteria:

We included studies that assessed the efficacy and/or safety of Saw palmetto at a daily dosage of 320 mg in patients with LUTS/BPH. Study designs considered eligible for review included Systematic reviews of RCTs, Meta-analyses and RCTs, if they included data on the selected outcomes. Studies on corpses, in vitro research, and studies in populations other than human adult males were all eliminated, as were studies on corpses, in vitro studies, and studies in populations other than

human adult males. There was no minimum length of follow-up required to include studies.

Study Selection and Data Extraction:

Two reviewers looked over the literature search results and categorised studies as potentially eligible for inclusion based on titles and abstracts first, then complete texts second. Disagreements about the importance of individual studies were resolved in a debate with a third reviewer. During the talks, the study team came to an agreement on the final list of papers for data extraction. Data on the trial environment and design, study population, treatment aspects (dose and duration), and outcomes were extracted, as described below.

Outcomes Assessed:

The following information from the studies were recorded:

- (1) Drug dose and dosage patients received
- (2) Type of study and patient count
- (3) Health condition/Purpose of use
- (4) Age of patients involved
- (5) Comparator used
- (6) The International Prostate Symptom Score, quality of life, maximal flow rate, void per night, Urinary Symptom Score, and flow metrics have all changed over time.
- (7) Safety was assessed in terms of ADRs and AEs^[42,43,44,45]

Plan of Study:

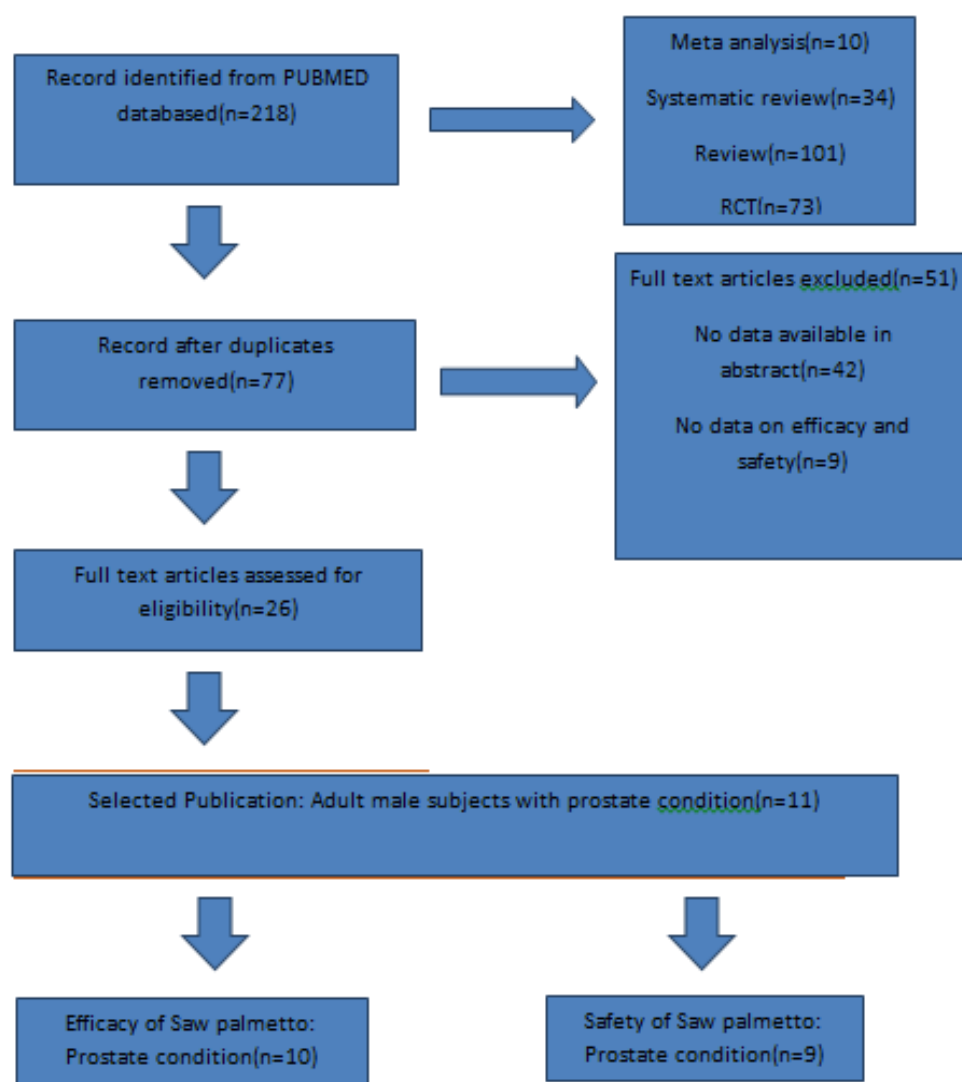


Figure.3: PRISMA flow diagram

Observation and Results**Step 1.**

Literature was searched on PubMed with following terms (synonyms words for Saw palmetto).

❖ **Meta-Analysis**

When we search on PubMed with the keyword, Saw palmetto, *Serenoa repens*, Sabal serrulate and Dwarf palm a total number of 10 Meta-Analysis as show in Table no.1.1

Table:1.1

Search Term	No. of Publications	Date of Search
Saw Palmetto	03	16 March 2021
<i>Serenoa repens</i>	03	16 March 2021
Sabal Serrulate	03	18 March 2021
Dwarf Palm	01	18 March 2021

❖ **Systematic Review**

When we search on PubMed with the keyword, Saw palmetto, *Serenoa repens*, Sabal serrulate and Dwarf palm a total number of 34 Systematic review as show in Table no.1.2

Table:1.2

Search Term	No. of Publications	Date of search
Saw Palmetto	13	19 March 2021
<i>Serenoa repens</i>	10	20 March 2021
Sabal Serrulate	10	23 March 2021
Dwarf Palm	01	23 March 2021

❖ **Review**

When we search on PubMed with the keyword, Saw palmetto, *Serenoa repens*, Sabal serrulate and Dwarf palm a total number of 101 Review as show in Table no.1.3

Table:1.3

Search Term	No. of Publications	Date of search
Saw Palmetto	40	25 March 2021
<i>Serenoa repens</i>	27	28 March 2021
Sabal Serrulate	32	2 April 2021
Dwarf Palm	02	5 April 2021

❖ **Randomized Controlled Trial**

When we search on PubMed with the keyword, Saw palmetto, *Serenoa repens*, Sabal serrulate and Dwarf palm a total number of 73 RCTs as show in Table no.1.4

Table:1.4

Search Term	No. of Publications	Date of search
Saw Palmetto	29	7 April 2021
<i>Serenoa repens</i>	22	12 April 2021
Sabal Serrulate	22	16 April 2021
Dwarf Palm	00	16 April 2021

Step 2.

Removed duplicate publications.❖ **Systematic review**

Out of 34 systematic reviews, 14 were selected after removing 20 duplicates as show in table no.2.1

Table:2.1

Search Term	No. of Publications	Date of search
Saw Palmetto	09	19 April 2021
<i>Serenoa repens</i>	02	19 April 2021
Sabal Serrulate	02	19 April 2021
Dwarf Palm	01	19 April 2021

❖ **Review**

Out of 101 review articles, 34 articles were selected after removing 67 duplicates as show in table no.2.2

Table:2.2

Search Term	No. of Publications	Date of search
Saw Palmetto	33	20 April 2021
<i>Serenoa repens</i>	00	20 April 2021
Sabal Serrulate	00	20 April 2021
Dwarf Palm	01	20 April 2021

❖ **Randomized Controlled Trial**

Out of 73 RCTs, 29 were selected and 44 duplicates removed as show in table No.2.3

Table:2.3

Search Term	No. of Publications	Date of search
Saw Palmetto	29	22 April 2021
<i>Serenoa repens</i>	00	22 April2021
Sabal Serrulate	00	22 April2021
Dwarf Palm	00	22 April2021

Step 3.**Following articles were searched and then sorted (included or excluded):**

77 articles selected out of which 51 articles were excluded. Reason for Exclusion: Non-English text; No data/information available in abstract/full text; No data on Efficacy/ Safety as show in table no.3

Table no:3

PMID	Type of Publication	Purpose (Health condition)	Inclusion/Exclusion	Reason for Exclusion
26612980	Randomized Controlled Trials	At rest and during activity, the acute efficacy of a fat-loss item on substrate utilisation, hunger perception, emotional functioning, and rate of perceived effort.	Exclusion	No data available in abstract

24450252	Randomized Controlled Trials	Does adding <i>Serenoa repens</i> to tamsulosin make it more effective in treating benign prostatic enlargement?	Inclusion	
23259358	Randomized Controlled Trials	Analysis of the CAMUS randomised trials on the effect of raising Saw palmetto fruit extract dosage on serum prostate particular antigen.	Exclusion	No data available in full text.
23063633	Randomized Controlled Trials	The CAMUS trials looked at the safety and hazard of saw palmetto.	Inclusion	
21954478	Randomized Controlled Trials	Increased doses of Saw Palmetto extract have an effect on lower urinary tract problems.	Inclusion	
23017510	Randomized Controlled Trials	In a trial of phytotherapy in males with urinary incontinence, relationships between participants' worldwide prostate symptom score, benign prostatic hyperplasia (bph hyperplasia impact index alterations, and general assessment of change were examined.	Inclusion	
25038794	Randomized Controlled Trials	Short-term antibiotic treatment with prulifloxacin (unidrox) in combination with Saw palmetto extracts, lactobacillus sporogens, and arbutin for secondary bacterial prostatitis (lactorepens).	Exclusion	No data available in abstract
24399119	Randomized Controlled Trials	The IDIProst platinum study found that an increase in sexual function is linked to a higher quality of life, irrespective of urinary better coordination.	Exclusion	No data on efficacy and safety
27711089	Randomized Controlled Trials	<i>Serenoa repens</i> extracts including selenium and lycopene, as well as bromelain and methylsulfonylmethane extract, have been shown to enhance levofloxacin efficacy in people with chronic microbial prostatitis.	Exclusion	No data available in abstract
31527377	Randomized Controlled Trials	A dual randomised research used a mixture of vaccinium macracarpon, lyciumbarbarum L., and probiotics (Bifiprost) to protect secondary bacterial prostatitis.	Exclusion	No data on efficacy
23642948	Randomized Controlled Trials	Prostate EZE Max: An herbal remedies formulation for the management of symptoms of benign prostatic hyperplasia (bph is the subject of a phase II randomized dual	Exclusion	No data available in abstract

		placebo-controlled clinical investigation.		
28403589	Randomized Controlled Trials	A randomised clinical research looked at the efficacy of combining palmitoylethanolamide or alpha-lipoic acid in persons with chronic prostatitis/chronic pelvic symptoms.	Exclusion	No information in full abstract.
24231216	Randomized Controlled Trials	Duloxetine's Effectiveness in a Multidrug Therapy for Chronic Prostatitis/Chronic Urinary Pain Syndrome.	Exclusion	No information in full abstract.
30027406	Randomized Controlled Trials	Results of a randomised biopsy investigation on the effects of Serenoa repens hexanic extracts on prostatic inflammatory.	Exclusion	No information in full abstract.
23083656	Randomized Controlled Trials	The CAMUS Trial found links between changes in pelvic pain and sleep disruption over period.	Inclusion	
26306400	Randomized Controlled Trials	Efficacy of Serenoa repens (PermixonW 160 mg) Hexanic Extract on Inflammatory Biomarkers in the Therapy of Lower Urinary Tract Classic Symptoms with BPH.	Inclusion	
21554128	Randomized Controlled Trials	Investigators for a Botanical Therapies Clinical Trial for BPH are being sought.	Inclusion	
23383975	Randomized Controlled Trials	In a double-blind dosage escalation clinical trial with Saw Palmetto, participants in the study made therapy designation guesses.	Inclusion	
30488800	Randomized Controlled Trials	A Comparison Analysis of Two Various Treatments in Persistent Prostatitis/Chronic Pelvic Persistent Pain: Flower Pollen Extraction in Association with Nutrients (Deprox 500®) Vs Serenoa repens	Exclusion	No data available in full text.
23383667	Randomized Controlled Trials	Benefits of Serenoa repens, Selenium, and Lycopene (Profluss®) upon inflammatory associated with Male Infertility results of the multicenter Italian trial "FLOG" (Flogosis and Profluss in Prostate gland and Genital Disorder).	Exclusion	No data available in full text.
25154739	Randomized Controlled Trials	Management of LUTS/BPH with Serenoa repens, Lycopene, and Selenium vs. Tamsulosin This multicentre, double-blind, randomised trial in Italy compared	Exclusion	No information in full abstract.

		solo and combination therapies (PROCOMBTrial).		
29569389	Randomized Controlled Trials	<i>Serenoa repens</i> + selenium + lycopene vs. tadalafil milligrammes for the therapy of urinary incontinence owing to benign prostatic blockage: a Phase IV, outdoor, non-inferiority clinical trial (SPRITE study).	Exclusion	No information in full abstract.
24938176	Randomized Controlled Trials	Re-evaluation of 4 controlled clinical research indicate that a fixed dose combo Pros 160/120 of sabal + urtica compounds improves dysuria in males with LUTS indicative of Hyperplasia.	Exclusion	No information in full abstract.
23298508	Randomized Controlled Trials	A two-year research comparing the efficacy of finasteride or <i>Serenoa repens</i> as in treatment of alopecia.	Exclusion	No information in full abstract.
28604133	Randomized Controlled Trials	A preliminary investigation into the use of topical cetirizine there in treatment of hyperandrogenism.	Exclusion	No information in full abstract.
25614155	Randomized Controlled Trials	Tamsulosin Plus vs. Tamsulosin <i>Serenoa repens</i> in Combination with Tamsulosin for the Therapy of BPH in Men: A 12-month Random Open Labeling Study	Inclusion	
24399120	Randomized Controlled Trials	<i>Serenoa repens</i> extracts is used in conjunction with quinolones to help treat bacterial prostate. A lengthy observational original study early findings.	Exclusion	No information in full abstract.
26891611	Randomized Controlled Trials	Saw Palmetto with Symptom Control During Prostate Cancer Radiotherapy.	Inclusion	
30880074	Randomized Controlled Trials	<i>Serenoa repens</i> Extraction Safety and Effectiveness in Chinese Patients with BPH. A Multicenter, Randomized, Double-blind, Placebo Controlled Test	Inclusion	
26648251	Systematic Review (dwarf palm)	Dupuytren's contraction of the fingers is treated by surgery.	Exclusion	No information in full abstract.
31952967	Systematic Review (Sabal serrulate)	A Systematic Overview and Networking Meta-analysis of Randomised Nocebo Clinical Studies of <i>Serenoa repens</i> Vs Placebo Versus Apex predator for the Therapy of Lower Urinary Tract Symptomatology Prostatic Dilatation.	Inclusion	
23235581	Systematic	<i>Serenoa repens</i> is used to treat	Inclusion	

	Review	prostatitis hyperplasia in men.		
31002161	Systematic Review (Saw palmetto)	Fitoterapia en Urología. Evidencia científica actual de su aplicación en hiperplasia benigna de próstata y adenocarcinoma de prostate.	Exclusion	No information in full abstract.
33313047	Systematic Review	Is it a friend or a foe to take a natural hair nutrient? A Study Conducted of Saw Palmetto on Alopecia.	Exclusion	No information in full abstract.
32274957	Systematic Review	A Comes To the topic and Meta-Analysis using Serenoa repens or Tamsulosin there in Prevention of Male Infertility.	Inclusion	
29196903	Systematic Review	A Comprehensive Search of the Concurrent Utilisation Prescription Medications and Natural Medicinal Remedies in Aging Adults.	Exclusion	No information in full abstract.
31451276	Systematic Review	Dietary and benign prostatic hypertrophy.	Inclusion	
11772128	Systematic Review	Herb Medications and Prescription Drug Complications.	Exclusion	No information in full abstract.
28723522	Systematic Review	Safety profile of Serenoa repens (Permixon) Hexanic Lipidosterolic Compound with in Treating of Lower Uti Problems Review ” or Meta-analysis of Controlled Studies Owing to Prostate Cancers.	Exclusion	No information in full abstract.
29694707	Systematic Review (Serenoa repens)	Literature review and conceptual of randomised controlled trials including observational research on the benefits and risks of a hexanic preparation of Serenoa repens (Permixon) for the cure of pelvic pain associated with male infertility.	Inclusion	
12137626	Systematic Review	<i>Serenoa repens</i> is used to treat benign prostatic hyperplasia in men.	Inclusion	
25692375	Review (dwarf)	PRECICE intramedullary limb lengthening system.	Exclusion	No information in full abstract.
32060633	Review (saw palmetto)	Medical care for pelvic pain linked with male infertility focuses on swelling.	Exclusion	No information in full abstract.

31680216	Review	For the management of hair loss, herbal remedies are used.	Exclusion	No information in full abstract.
32066284	Review	Overview of male patterned baldness treatment options.	Exclusion	No information in full abstract.
33003518	Review	Nutritional Factors and Nutrients Affecting PSA Intensities in Prostate cancer Patients and Increased Mortality: A Comprehensive Review Based on Randomized Clinical Trials.	Exclusion	No information in full abstract.
26816707	Review	Phytotherapy: emerging therapeutic option in urologic disease.	Exclusion	No information in full abstract.
25703069	Review	So what would we understand about the use of natural medicine in the treatment of benign prostatic hypertrophy?	Inclusion	
22512478	Review	A Overview of Human and Animal Models on Nature Products for the Treatment of Male Infertility: New Pharmacology Agents	Exclusion	No information in full abstract.
30046855	Review	Einflussmedikamentöser BPS Therapieauf die sexuelleFunktion.	Exclusion	No information in full abstract.
22139685	Review	Focusing on Metabolism Enzymes and Carriers in Medicinal Interactions.	Exclusion	No information in full abstract.
23295239	Review	Novel agents in treatment of BPH.	Exclusion	No information in full abstract.
31577095	Review	Prevention and management of BPH and prostate cancer with nutraceuticals.	Exclusion	No information in full abstract.
24527031	Review	Cyclosporine and Herbal Supplement Interactions.	Exclusion	No information in full abstract.
25112532	Review	The effect of modern extraction methods on the pharmacology character of Serenoa repens extract used to treat urinary complaints.	Exclusion	No information in full abstract.
30980598	Review	A look at herbal treatments for alopecia areata.	Exclusion	No information

				in full abstract.
23202286	Review	Nutrition and benign prostatic hyperplasia.	Exclusion	No information in full abstract.
25312251	Review	The Function of Inflammatory in (BPH)-Related Lower Urinary Tract Problems and Its Possible Effects on Medical Management.	Inclusion	
22236736	Review	Herbal and Modern Drug Interactions a review of the Therapeutic Evidence.	Exclusion	No information in full abstract.
21798388	Review	What Should I Tell The patient Regarding Saw Palmetto in the Treatment of Male Infertility?	Inclusion	
22883375	Review	An summary of reviews on nutritional supplements for bph.	Inclusion	
31807332	Review	For bph, saw palmetto (<i>Serenoa repens</i>) extract is used.	Inclusion	
23432584	Review	A Three Therapeutic Way to Addressing Prostatitis Hyperplasia with <i>Serenoa repens</i> , Lycopene, and Selenium	Inclusion	
28436684	Review	Current Data and Therapeutic Significance in Naturopathy for <i>Serenoa repens</i> with Lower Urinary Symptoms/Prostate gland.	Inclusion	
24290486	Review	Online Sources of Herbal Product Information.	Exclusion	No information in full abstract.
25165780	Review	Benign Prostatic Hyperplasia (BPH) with Phytotherapy A quick look at the product.	Inclusion	
23472485	Review	An summary of systematic Reviews on the negative impacts of herbal remedies.	Exclusion	No information in full abstract.
26608588	Review	A bibliometric analysis of research literature on plants for the therapy of androgenetic alopecia published in Scopus.	Exclusion	No information in full abstract.
27232207	Review	Urinary complaints suggesting of male infertility can be managed with <i>Serenoa repens</i> , selenium, & lycopene.	Inclusion	
30790614	Review	The impact of phytotherapies on testosterone, reproductive cells, and prostatic indicators beyond tribulus (<i>Tribulus terrestris</i> L.)	Exclusion	No information in full abstract.

22257149	Review	Drug Interactions with Herbal Medicines.	Exclusion	No information in full abstract.
24188663	Review	Chemoprevention of Prostate Cancer.	Exclusion	No information in full abstract.
22588833	Review	Phenotyping Study to Identify the Effects of Phytopharmaceuticals on the In Vivo Behavior of Human Cyp450 Enzymes.	Exclusion	No information in full abstract.
Reason for Exclusion: Non-English text; No data/information available in abstract/full text; No data on Efficacy/ Safety.				

Step 4.

Following publications were selected.

Adult male subjects with prostate condition.

26 articles were sorted on the basis of inclusion criteria and following 11 articles were selected as show in table no.4

Table: 4

PMID	Type of Publication	No. of subjects	Health condition (Purpose of use)	Data Efficacy Safety	
32274957	Systematic Review	1080	A Systemic Review as well as Meta-Analysis using <i>Serenoa repens</i> in the therapy of BPH.	Yes	Yes
23235581	Systematic Review	582	<i>Serenoa repens</i> is used to treat benign prostatic enlargement in men.	Yes	Yes
23083656	Randomized Controlled Trials	339	The CAMUS Trial found links among improvements in pelvic pain and disturbed sleep over period.	Yes	No
26306400	Randomized Controlled Trials	206	Benefits of <i>Serenoa repens</i> (PermixonW 160 mg) Hexanic Extraction on Inflammatory Biomarkers in the Therapy of Lower Urinary Tract Symptoms with BPH.	Yes	Yes
23063633	Randomized Controlled Trials	369	The CAMUS trials looked at the safety and toxicology of saw palmetto.	No	Yes
21954478	Randomized Controlled Trials	369	Increased doses of Saw Palmetto extracts have an effect on lower urinary problems.	Yes	No
12137626	Systematic Review	3139	Regarding male infertility, <i>Serenoa repens</i> is used.	Yes	Yes
24450252	Randomized Controlled Trials	265	Does adding <i>Serenoa repens</i> into tamsulosin make it more effective in treating benign prostatic hyperplasia.	Yes	Yes
29694707	Systematic Review	5800	Large study and meta-analysis of randomized trials and observational research on the effectiveness and safety of such a hexanic extracts of <i>Serenoa</i>	Yes	Yes

			repens (Permixon) for the treating of pelvic pain coupled with benign prostatic hypertrophy.		
25614155	Randomized Controlled Trials	140	A One-Year Randomized Open Label Study compared Tamsulosin Plus Serenoa repens to Tamsulosin mostly in Prevention of Benign Prostatic Hyperplasia among Korean Men.	Yes	Yes
30880074	Randomized Controlled Trials	354	Serenoa repens Extract Effectiveness in Chinese Patients with Benign Prostatic Hypertrophy: A Multicenter, Rct, Dual, Dummy Control Trial.	Yes	Yes

Step 5.

Above mentioned Publications were studied for finding Safety and Efficacy of Saw Palmetto.

Efficacy of Saw Palmetto: Prostate Condition

10 articles depicting efficacy of Saw palmetto as show in

Table no.5.1

Table:5.1

PMID	Type of Publication	No. of subjects	Age	Duration of use	Dosage and use		Efficacy
					Saw palmetto	Comparator	
32274957	Systematic Review	1080	55-80 yrs	6 months	320 mg OD	Tamsulosin 0.4 mg OD	Same effect as Tamsulosin
23235581	Systematic Review	582	40-90 yrs	4-72 weeks	320 mg, 640 mg, 960 mg	Placebo	Not effective even at double and triple dose
26306400	Randomised controlled trials	206	45-85 yrs	90 days	160 mg BID	Tamsulosin 0.4 mg OD	Effective anti-inflammatory agent
21954478	Randomised controlled trials	369	45 + yrs	72 weeks	320 mg, 640 mg, 960 mg	Placebo	No effect greater than placebo
12137626	Systematic Review	3139	40-88 yrs	48 weeks	160 mg BID	Placebo Finasteride 5mg OD	Mild To Moderate Improvement in symptoms
24450252	Randomised controlled trials	265	Mean age 65 yrs	6 months	320 mg OD	Tamsulosin 0.4 mg OD	Equally Effective
29694707	Systematic Review	5800	Mean age 65 yrs	3 months	320 mg OD	Placebo	Positive effects over placebo
25614155	Randomised controlled trials	140	50-80 yrs	12 months	320 mg OD	Tamsulosin 0.2 mg OD	Tamsulosin + <i>Serenoa repens</i> more effective than Tamsulosin alone
30880074	Randomised controlled trials	354	50-70 yrs	24 weeks	320 mg OD	Placebo	Effective in improving symptoms
23083656	Randomized Controlled	339	45+ yrs	72 weeks	320 mg OD	Placebo	No significant improvement in

	Trials						sleep behaviour.
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Safety of Saw Palmetto: Prostate Condition

9 articles depicting safety of saw palmetto as show in
Table no.5.2

Table no.5.2

PMID	Type of Publication	No. of subjects	Age	Duration of use	Dosage and use		Safety
					Saw palmetto	Comparator	
32274957	Systematic Review	1080	55-80 yrs	6 months	320 mg OD	Tamsulosin 0.4 mg OD	Favourable safety profile
23235581	Systematic Review	582	40-90 yrs	4-72 weeks	320 mg, 640 mg, 960 mg	Placebo	Adverse effects were mild, not significant.
26306400	Randomised controlled trials	206	45-85 yrs	90 days	160 mg BID	Tamsulosin 0.4 mg OD	Safer than Tamsulosin
23063633	Randomized Controlled Trials	369	45 + yrs	18 months	320 mg, 640 mg, 960 mg	Placebo	At doses up to three times the typical level, there was no evidence of harm.
12137626	Systematic Review	3139	40-88 yrs	48 weeks	160 mg BID	Placebo Finasteride 5mg OD	Low ADRs as compared to Finasteride
24450252	Randomised controlled trials	265	Mean age 65 yrs	6 months	320 mg OD	Tamsulosin 0.4 mg OD	No significant ADRs
29694707	Systematic Review	5800	Mean age 65 yrs	3 months	320 mg OD	Placebo	Low incidence of ADRs
25614155	Randomised controlled trials	140	50-80 yrs	12 months	320 mg OD	Tamsulosin 0.2 mg OD	20% had drug related ADRs
30880074	Randomised controlled trials	354	50-70 yrs	24 weeks	320 mg OD	Placebo	No serious side effects, Safe

After conducting the review study by using PUBMED we have found out 218 articles which included meta-analysis, RCTs, systematic reviews and review. Duplicate articles and articles with no information on safety and/or efficacy were removed. Data was gathered from four systematic reviews with a total patient count of 10,601 and seven randomised controlled trials with a total patient count of 2042. The average age of the patients was 65. Serenoa repens was shown to be similarly

efficacious in curing BPH when compared to tamsulosin 0.2-0.4 mg and finasteride 5 mg. When compared with placebo, Serenoa repens improved the urine symptoms score, symptoms, and flow measure. The usage of Serenoa repens improved the World Prostate Measuring The data and Quality of Life in males with benign prostatic hyperplasia, as well as decreased urinary tract symptoms and outflow measurements. Serenoa repens has anti-inflammatory effects as well. Safety profile of *Serenoa repens* is favourable

with mild adverse effects which were not significant. When compared with tamsulosin or finasteride, *Serenoa repens* is safer.

Discussion

In this systematic review on safety and efficacy of saw palmetto as a health supplement for prostate health in adult males. We have conducted 218 articles available at PubMed. In the considered articles, 10 articles are meta-analysis, 34 articles are systematic review, 101 articles are review articles and 73 articles are Randomized Controlled Trials. Among all the above articles 141 articles are found to be duplicates so rest of 77 articles are considered for systematic review of safety and efficacy of saw palmetto as a health supplement for prostate health in adult males.

Out of the selected 11 article 10 support the efficacy of Saw palmetto and 9 support the safety of Saw palmetto in prostate hyperplasia to be used as health supplement. The trend of article supporting efficacy of the Saw palmetto is 90.90% in which 12,274 patients are under study. The article supporting the efficacy of Saw palmetto is mainly of Randomised Control Trial and Systematic review article. Number of patient under the study in the article considered in systematic reviews are 9691 and these study are of plain placebo control and Tamsulosin and Finasteride placebo control and trend for the effect over placebo is 50% and trend of same effect in systematic review is 50%. And number of patient under study Randomized Controlled Trials 1673 and these studies are tamsulosin & plain placebo control and trend of study for the effect over placebo is 33.3% and no effect is 16.04% same as placebo is 33.03% and 16.04% subject combination are more effective than tamsulosin

alone the trend of article supporting safety the drug is 81.9% in which 11,935 patients are under study. The article supporting safety of saw palmetto which are reviewed are Randomized Controlled Trials & systematic review. The number of patient under study in systematic review article are 10,601 and these study are plain placebo control Tamsulosin and Finasteride placebo control and trend of after safety than placebo in systematic review article is 75% and mild ADR is 25% were as in Randomized Controlled Trial the number of patients are in study is 1334 and these study are Placebo and tamsulosin placebo control and the trend of study for better safety than tamsulosin is 20% same & good safety is 60% and in single study 20% of patient suffered ADRs.

Conclusion

According to the findings of the review study, extract from the Saw Palmetto plant, *Serenoa repens*, aids in the improvement of lower urinary tract symptoms and flow measurements in males with benign prostatic hyperplasia. According to this study, *Serenoa repens* had the same efficacy as tamsulosin and finasteride in curing BPH in terms of IPSS, QoL, LUTS improvement, and flow measures. *Serenoa repens* and Tamsulosin combined therapy is more successful than Tamsulosin alone. When compared to tamsulosin and finasteride, *Serenoa repens* is a safer medicine with fewer side effects. *Serenoa repens* has only mild adverse effects which are not significant and no severe adverse effects up to 3 times the usual dose.

Conflict Of Interest- None Declared

Funding-Self Funding

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How to cite this article: ., S., Sarma, S. N., Siwach, D., Hasan, A., Mittal, P., Paul, P., & Paul, P. (2022). Systematic Review on Safety and Efficacy of Saw Palmetto as a Health Supplement for Prostate Health in Adult Males. *Journal of Current Medical Research and Opinion*, 5(06), 1252-1270. <https://doi.org/10.52845/CMRO/2022/5-6-3>