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Variability of Commercial Saw Palmetto–Based Supplements for the Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms

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ABSTRACT Purpose: Some men with mild-to-moderate benign prostatic hyperplasia/lower urinary tract symptoms use saw palmetto supplements to proactively manage their symptoms as an alternative to watchful waiting and/or to avoid prescription medication side effects. This study assessed the potency and authenticity of commercially available saw palmetto–based supplements in the United States.

Materials and Methods: Twenty-eight saw palmetto berry powders, powdered extracts, berry blends, lipid extracts, and multiactive products (lycopene, pumpkin oil, etc) were purchased from major online retailers and retail stores. Total fatty acid content (% weight/weight) and individual fatty acid profile of each product were determined using validated gas chromatography-fatty acid methyl ester methodology and compared with the US Pharmacopeia monograph standards for lipidosterolic extracts of *Serenoa repens*.

Results: Total fatty acid content ranged from 0.796% for a berry powder product to 89.923% for a lipid extract product. None of the berry powders or powdered extracts, 6 of 9 lipid extracts, and 1 multiactive product met criteria for ≥80% total fatty acid content. Only 1 of the 28 products met the US Pharmacopeia criteria for a standardized lipidosterolic extract, defined as total fatty acid content ≥80% and a fatty acid profile indicative of authentic *S. repens* based on the ratios of the lauric acid concentration to 9 other individual fatty acid concentrations.

Conclusions: There is substantial heterogeneity in fatty acid content and profile in saw palmetto supplements. Lipidosterolic extracts of saw palmetto berries standardized to ≥80% fatty acids are most likely to meet established criteria for quality and identity.

Key Words: lower urinary tract symptoms, prostatic hyperplasia, saw palmetto extract, phytotherapy

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INTRODUCTION

Extracts of *Serenoa repens* berries (saw palmetto extracts [SPEs]) are widely used in Europe and the United States by men with benign prostatic hyperplasia (BPH) for the relief of lower urinary tract symptoms (LUTS).[1] Lipidosterolic extracts of *S. repens* (LSESrs) specifically are the most widely studied, both in preclinical and clinical trials.[2] A standardized hexanic extract of *S. repens* has been designated for "well-established use" by the European Medicines Agency, meaning the product has recognized efficacy and acceptable safety for the management of LUTS and has been marketed for ≥30 years.[3] The hexanic

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extract of *S. repens* is among the most commonly prescribed treatments for mild-to-moderate LUTS in Europe[4] and is the only LSESr recommended by the European Association of Urology for LUTS.[5] In Europe, the primary drivers for initiating LSESr monotherapy in patients with BPH/LUTS (in addition to symptom reduction) were patient acceptability, avoidance of sexual side effects, and reduction of inflammation.[6]

Free fatty acids (FA) from LSESrs are incorporated into the prostate cell membrane whereby they alter the 5α-reductase (5-AR) protein structure and disrupt conversion of testosterone to dihydrotestosterone. This results in decreased dihydrotestosterone-dependent signaling, more apoptosis, and less prostatic cellular proliferation.[7-14] There is also a reduction in prostate inflammation from accumulation of FAs from LSESrs that cause a downregulation of proinflammatory genes, as well as reduced $CD45^+$ cell clusters, leukocyte infiltration, and prostaglandin synthesis.[15-17] High concentrations of free FA, including the main components of LSESrs (lauric acid, oleic acid, myristic acid, linoleic acid), are needed to inhibit 5-AR.[11,18] The ratio of the aforementioned FAs to lauric acid, known as the fingerprint for LSESrs, may be critical to efficacy.[4] Several FAs contained within LSESrs, including lauric acid, oleic acid, myristic acid, and linoleic acid, are more potent inhibitors of 5-AR than other FAs, such as palmitic and stearic acids and are, therefore, likely to be more therapeutically relevant.[11,18]

The key to clinical effectiveness of saw palmetto–based supplements is likely a lipidosterolic extraction process that produces the unique FA fingerprint defined by the US Pharmacopeia (USP) as authentic SPE.[4,19] Quality SPEs are manufactured using mature saw palmetto berries and result in a unique FA profile, rich in lauric acid.[20] Both the extraction method and the solvent influence the lipid profile, and it has been recommended that only standardized extracts be used clinically.[21] In the United States, standardized LSESrs are those products that meet the USP criteria for both total FA content (potency) *and* individual FA identity (authenticity).[19] The USP standard for FA content specifies that an LSESr must contain $\geq$80% total FAs by weight.[19] In addition, the USP standard for FA identity specifies that LSESrs must meet acceptable ranges for the ratios of the concentration of lauric acid to the concentrations of 9 other individual FAs[19] (ie, the fingerprint to confirm *S. repens* identity).[4]

In 2021, an international panel of urologists developed several consensus statements regarding the role of LSESr in the management of LUTS in North America.[4] The panel concluded that clinicians in the United States should consider using standardized LSESrs meeting current USP composition criteria for the management of LUTS in appropriate patients. The objective of this study was to assess the potency and authenticity of commercially available saw palmetto–based supplements in the United States by measuring the total FA content and individual FA profiles of 28 products and comparing the results with USP monograph standards for LSESrs.

MATERIALS AND METHODS

Selection Criteria

Commercially available products labeled and sold in the saw palmetto–based supplement category that met specific eligibility criteria were evaluated. Capsules containing saw palmetto berry powder or blends of berry powder and powdered extract were included, as were softgels containing saw palmetto lipid extract. Multiactive products with saw palmetto as the predominant active ingredient were also included to better represent the range of available supplements in the United States. Multiactive products are those that contain other compounds that may improve prostate health, such as lycopene or beta-sitosterol (eg, pumpkin seed oil, stinging nettle, and *Pygeum* bark extracts).[22] Because of consumer awareness about saw palmetto as a prostate health supplement, saw palmetto is often included as a minor component (ie, subtherapeutic levels) in multiactive products to drive purchasing. Thus, the multiactive products selected for study inclusion were chosen based on the labeled amount of saw palmetto (ie, as a predominant ingredient) and/or because they were among the top 5 selling products in their category. Products verified by the dietary supplement quality certification programs of independent organizations (eg, National Sanitation Foundation [NSF], USP) were also included; however, third-party certification was not required.

A total of 28 products were purchased from major online retailers and US retail stores. The products selected included 5 of the top 10 selling brands from online retailers (eg, Amazon, iHerb) and shelf-stocked products from retail stores. Product selection at retail stores was limited; at each store, all saw palmetto–based supplements were purchased that met eligibility criteria and had not previously been purchased. Retail stores included big box chains (eg, Costco, Walmart); grocery chains (excluding specialty stores such as Trader Joe's and Whole Foods); pharmacy chains (eg, Consumer Value Stores, Walgreens); nutritional supplement chains (eg, General Nutrition Centers, Vitamin Shoppe); and independent natural health food stores.

Product labeling information (eg, claimed amount of saw palmetto, recommended daily dose, and complete ingredient list) was recorded for each product. Sample blinding was accomplished by assigning a unique alphanumeric identification code to each product and then repackaging 10 capsules/softgels from each retail product bottle into white high density polyethylene bottles marked with the assigned product identification code. Blinded samples were shipped to an accredited laboratory (Eurofins Food Chemistry Testing, Inc., Madison, WI) for FA analysis. No human/animal subjects were used.

Analytical Methodology

For each of the 28 products, mean fill weights were based on mean content weight of 10 capsules/softgels. Mean fill weights were used for all product FA content calculations.

Fatty acid analysis was based on the USP SPE monograph with minor modifications using validated gas chromatography-FA methyl ester (GC-FAME) methodology.[19,23] Supplement 1 provides detailed sample preparation, analysis, and instrumentation information for GC-FAME analysis. GC-FAME analysis quantified the content of 11 individual FAs by % weight/weight (% w/w) as specified in the USP SPE monograph: caproic, caprylic, capric, lauric, myristic, palmitic, palmitoleic, stearic, oleic, linoleic, and linolenic.[19] The total FA content of each product sample was then calculated as the sum of the 11 individual FA quantities.

Product FA Content

The USP standard for saw palmetto lipid extract is ≥80% total FAs (% w/w),[19] whereas the USP standard for saw palmetto powder is based on individual FA content.[24] Total FAs per unit were calculated by multiplying the mean unit fill weight of each product sample by the percent total FA quantified by GC-FAME analysis. Total FAs per dose were calculated by multiplying the total FAs per unit by the units per dose specified on the product label.

Product FA Identity (Authenticity)

The ratios of the concentration of lauric acid to the concentrations of 9 other individual FAs were calculated to determine the FA fingerprint for each product. The 9 individual FAs used to determine *S. repens* identity include 4 short chain FAs (caproic, caprylic, capric, and myristic) and 5 long chain FAs (palmitic, stearic, oleic, linoleic, and linolenic). Lauric acid ratios for each lipid extract product were compared with minimum and maximum lauric acid ratios specified by the USP standard for identity of saw palmetto lipid extracts.[19]

RESULTS

Product Overview

For presentation of results, the 28 purchased saw palmetto–based supplements were grouped as monotherapy (n = 23) or multiactive (n = 5) products; monotherapy products were further categorized by labeled active ingredient (Figure 1).

Table 1 provides examples of product labels in each category to highlight the diversity of commercially available saw palmetto–based products in the United States.

Individual and Total FA Content

Individual and total FA content (% w/w) of saw palmetto berry blends (berry powder and powdered extract) and berry powders are summarized in Table 2. Total FA content (% w/w) ranged from 0.796% for a berry powder product to 23.745% for a berry blend product. None met the USP standard for lipid extracts of ≥80% total FAs. Only 1 of the berry powder supplements (49DV) met the USP standard for saw palmetto berry powder (USP individual and total FA standards for berry powders are listed in Table 2). Of note, there is no USP standard for berry blend products.

Individual and total FA content of saw palmetto lipid and powdered extract products are summarized in Table 3. Total FA content ranged from 56.970% to 89.923% for the 9 lipid extract products. The single powdered extract product contained only 24.772% total FAs. Six of the 9 lipid extract products that were analyzed met USP criteria for ≥80% total FA content.

Individual and total FA content of multiactive products are summarized in Table 4. Total FA content ranged from 3.435% to 82.985% for the 5 multiactive products. Only 1 multiactive product (SY53) met USP criteria for ≥80% total FA content.

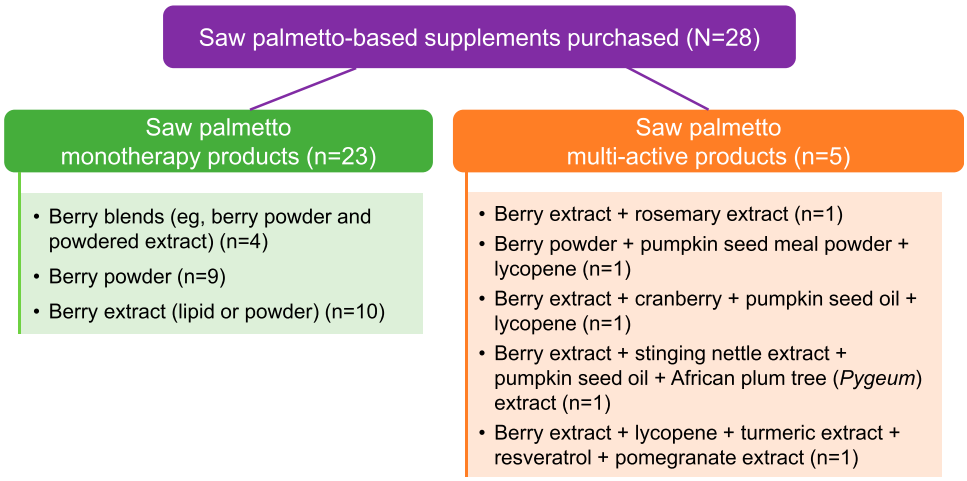

Figure 1. Saw palmetto–based supplements analyzed.

Table 1. *Examples of Saw Palmetto–Based Supplements Available in the United States by Category*

Product Type	Active Ingredient	Amount per Serving	Serving Size
Berry blends (eg, berry powder and powdered extract)			
	• Saw palmetto berries (powder) • Saw palmetto berries (extract, 45% fatty acids)	500 mg	1 capsule
	• Saw palmetto (*Serenoa repens*) berry extract (standardized for 160 mg fatty acids) • Saw palmetto (*S. repens*) (berry)	640 mg 50 mg	1 capsule
Berry powders			
	Saw palmetto berries (powder/45% extract)	1000 mg	2 capsules
	Saw palmetto berries (powder/25% extract)	500 mg	1 capsule
	Saw palmetto powder (*Serenoa serrulata*) (fruit)	450 mg	1 capsule
Berry extracts			
	Supercritical CO_2 saw palmetto berry extract (*S. repens*) standardized to minimum 85% fatty acids	160 mg	1 softgel
	Saw palmetto extract (*S. repens,* berries, 85% fatty acids)	320 mg	1 softgel
Multiactives			
	• Saw palmetto (*S. repens*) extract (fruit) standardized to minimum 85% fatty acids)	320 mg	2 softgels
	• Stinging nettle (*Urtica dioica*) extract (root), beta-sitosterol, pumpkin (*Cucurbita pepo*) oil (seed), African plum tree (*Pygeum africanum*) extract (aerial parts)	475 mg	
	• Saw palmetto berry powder (*S. repens*) • Pumpkin seed meal powder (*Cucurbita* spp.) • Lycopene	500 mg 80 mg 1 mg	2 tablets

Product Identity: Lauric Acid Ratios

Lauric acid ratios for the 7 saw palmetto lipid extract supplements that met USP criteria for ≥80% total FA content are summarized in Table 5. Only 1 of 7 lipid extract supplements (WTS7) met the USP SPE standards for identity as authentic saw palmetto based on lauric acid ratios for all 9 individual FAs. Of note, WTS7 was the only USP-certified product. One product (KJ53) met the USP standard for lauric acid ratios for 8 of 9 individual FAs and was within 10% of the lauric acid ratio range for palmitic acid. However, all other lipid extract supplements with ≥80% total FA content were outside the USP standards for lauric acid ratio ranges by at least ±10% for multiple individual FAs (Table 5).

Table 2. *Individual and Total Fatty Acid Content of Saw Palmetto Berry Blend and Berry Powder Products*

Individual FA (% w/w)	**Berry Blends**				**Berry Powders**								
Common FA Name [Lipid Number]	**GBH7**	**P2D3**	**P649**	**L594**	**98KA**	**JD59**	**P7BH**	**49DV**	**QE9M**	**UP9A**	**3KR4**	**84YF**	**5C6U**	**USP Saw Palmetto Powder Standard[a]**
Caproic [C6:0]	0.518	0.072	0.038	0.330	0.177	0.009	0.080	0.205	0.173	0.087	0.005	0.374	0.104	NLT 0.2
Caprylic [C8:0]	0.202	0.076	0.092	0.665	0.284	0.005	0.064	0.286	0.273	0.196	0.004	0.174	0.204	NLT 0.2
Capric [C10:0]	0.195	0.068	0.066	0.531	0.396	0.000	0.043	0.384	0.380	0.322	0.000	0.179	0.320	NLT 0.2
Lauric [C12:0]	2.963	1.286	0.724	7.737	4.155	0.099	1.580	4.081	4.100	3.652	0.064	2.752	3.668	NLT 2.0
Myristic [C14:0]	1.242	0.627	0.274	3.117	1.580	0.074	0.821	1.548	1.557	1.326	0.064	1.182	1.346	NLT 1.2
Palmitic [C16:0]	0.998	1.904	0.879	2.095	1.283	0.161	1.292	1.257	1.266	2.219	0.186	0.944	2.208	NLT 1.0
Palmitoleic [C16:1]	0.000	0.012	0.000	0.003	0.021	0.000	0.019	0.021	0.020	0.015	0.000	0.000	0.022	—
Stearic [C18:0]	0.237	1.116	0.640	0.467	0.292	0.045	0.585	0.288	0.290	1.151	0.062	0.201	1.144	NLT 0.1
Oleic [C18:1]	3.135	1.716	0.610	7.460	4.142	0.264	2.174	4.081	4.134	3.178	0.500	3.037	3.302	NLT 3.0
Linoleic [C18:2]	1.099	0.206	0.434	1.210	0.709	0.120	0.128	0.695	0.715	0.688	0.311	1.055	0.696	NLT 0.4
Linolenic [C18:3]	0.052	0.051	0.020	0.129	0.090	0.019	0.070	0.094	0.112	0.079	0.017	0.051	0.083	NLT 0.05
Total FA (%)	10.641	7.135	3.776	23.745	13.128	0.796	6.856	12.940	13.021	12.913	1.211	9.949	13.098	NLT 9.0
Total FA/unit (mg)	58.82	41.46	19.51	171.08	59.22	4.25	30.89	61.89	60.30	77.83	6.39	57.11	78.82	
Units/dose	1	1	2	1	4	2	1	5	5	6	2	2	6	

Abbreviations: C, carbon; FA, fatty acid; NLT, not less than; USP, US Pharmacopeia.
Orange shading indicates product was at least ±10% outside the USP standard for saw palmetto powder for an individual FA.
[a]For saw palmetto powders, the USP sets individual FA content (% w/w) criteria.

Table 3. *Individual and Total Fatty Acid Content of Saw Palmetto Lipid Extract and Powdered Extract Products*

Individual FA (% w/w)	Lipid Extract Products									Powdered Extract Product	USP Saw Palmetto Extract Standard
Common FA Name [Lipid Number]	LGL4	KJ53	W3LF	S3FR	EP9K	YPG8	QVF5	XC35	WTS7	F9ZV	
Caproic [C6:0]	0.492	1.173	0.309	0.126	0.054	0.782	0.716	0.073	0.977	0.037	
Caprylic [C8:0]	1.172	2.666	0.593	0.905	0.290	1.541	1.353	0.086	1.739	0.128	
Capric [C10:0]	1.878	2.076	0.800	0.895	0.220	1.197	1.050	0.104	2.452	0.090	
Lauric [C12:0]	24.210	30.026	8.450	14.354	1.990	17.167	15.548	1.243	29.001	0.784	
Myristic [C14:0]	8.934	11.897	3.089	6.206	0.818	6.848	6.254	0.536	10.986	0.489	
Palmitic [C16:0]	8.852	7.588	7.411	10.093	6.620	9.326	9.338	7.378	8.297	11.169	
Palmitoleic [C16:1]	0.132	0.018	0.080	0.411	0.056	0.296	0.331	0.068	0.168	0.027	
Stearic [C18:0]	2.469	1.500	2.027	2.500	2.360	2.270	2.072	3.096	1.696	3.549	
Oleic [C18:1]	25.208	27.872	16.010	47.812	12.721	43.516	47.834	15.793	26.866	7.153	
Linoleic [C18:2]	13.404	4.487	23.150	6.049	28.298	5.939	4.141	28.400	4.456	1.331	
Linolenic [C18:3]	0.668	0.504	2.980	0.573	3.544	0.549	0.509	0.247	0.684	0.016	
Total FA (%)	87.419	89.807	64.901	89.923	56.970	89.429	89.147	57.023	87.323	24.772	NLT 80%
Total FA/unit (mg)	336.56	326.72	349.75	291.80	330.09	258.81	271.90	417.58	285.72	105.31	
Units/dose	1	1	2	2	2	1	2	1	2	2	

Abbreviations: C, carbon; FA, fatty acid; NLT, not less than; USP, US Pharmacopeia.
Green shading indicates product met USP standard for saw palmetto extracts of ≥80% total FA content.

DISCUSSION

This analysis revealed tremendous heterogeneity among the 28 saw palmetto–based supplements that were analyzed, including variation in total FA content (potency) and individual fatty acid identity (authenticity). None of the saw palmetto berry blends or berry powders that were tested met the USP SPE standard for ≥80% total FA content, and only 1 met the USP saw palmetto powder standard for individual FA content. Only 6 of 9 lipid or powder extract products and 1 of 5 multiactive products met the USP SPE standard for ≥80% total FA content. Of the 7 products that met the USP standard for ≥80% total FA content, only 1 met the USP standard for saw palmetto identity. Even within a single supplement category, such as lipid extract products, there was substantial variability in total FA content and individual FA identity.

Although 28 saw palmetto–based supplements were included to evaluate the range of commercially available products in the United States, clinicians should be aware that saw palmetto berry blends, berry powders, and multiactive supplements have *not* been tested in clinical trials for management of BPH/LUTS. The American Urological Association (AUA) guidelines for BPH/LUTS management acknowledged the popularity of saw palmetto–based supplements and other phytotherapies but did not endorse their use,[25] citing a single randomized controlled trial that did not demonstrate a benefit of an LSESr over placebo.[26] However, an extensive global literature review of 190 clinical studies published the same year as the updated AUA guidelines (2021) concluded that monotherapy with 320 mg per day of a standardized LSESr (ie, ≥80% total FA content, authentic *S. repens*) improved LUTS and slowed progression of BPH.[2] For example, a 320 mg softgel standardized to ≥80% FAs would contain ≥256 mg total FAs.

Our findings are consistent with previous analyses of LSESr FA content.[27-29] In 1 analysis of commercially available SPEs, one-third of products tested contained <20% total FAs.[29] A subsequent evaluation of 14 LSESr products that were available either commercially or by prescription in Europe revealed a total FA content ranging from 80.7% for the well-established hexanic extract (Permixon) to 40.7% for a product composed largely of olive oil.[30] Another analysis found 3 of 9 commercial extracts did not meet USP criteria for saw palmetto authenticity.[28]

A 2023 review noted that saw palmetto is one of several phytotherapies prone to adulteration because of increased demand, increased ingredient costs and supply shortages, and economic pressures to reduce

Table 4. *Individual and Total Fatty Acid Content of Multiactive Products*

Individual FA (% w/w)	Multiactive Products					USP Saw Palmetto Extract Standard
Common FA Name [Lipid Number]	**Z5H4**	**8655**	**226M**	**SY53**	**VTZ7**	
Caproic [C6:0]	0.547	0.578	0.399	0.620	0.010	
Caprylic [C8:0]	1.115	1.118	0.748	1.184	0.016	
Capric [C10:0]	0.885	0.886	0.567	0.948	0.018	
Lauric [C12:0]	12.998	14.570	8.711	14.146	0.297	
Myristic [C14:0]	5.157	6.378	3.461	5.807	0.122	
Palmitic [C16:0]	8.324	7.400	4.329	9.193	1.197	
Palmitoleic [C16:1]	0.358	0.025	0.033	0.059	0.000	
Stearic [C18:0]	2.083	1.389	1.210	3.249	0.830	
Oleic [C18:1]	39.426	16.963	13.389	24.211	0.554	
Linoleic [C18:2]	5.096	9.961	9.884	23.200	0.374	
Linolenic [C18:3]	0.497	0.904	0.290	0.367	0.015	
Total FA (%)	76.486	60.173	43.020	82.985	3.435	NLT 80%
Total FA/unit (mg)	617.62	442.27	231.19	775.16	23.03	
Units/dose	1	1	2	1	2	

Abbreviations: FA, fatty acid; NLT, not less than; USP, US Pharmacopeia.
Green shading indicates product met USP standard for saw palmetto extracts of ≥80% total FA content.

consumer cost.[28,30] SPEs are the most expensive phytotherapeutic or dietary oil for several reasons. Growth of the saw palmetto plant is restricted to swampy, remote areas in the Southeastern United States. The annual crop can be affected significantly by rains and hurricanes, making the plants prone to fungal infections and potentially affecting the berry harvest, which is performed manually.[28] Market demand and ingredient shortages have led to use of unripe berries to prepare powders and extracts as well as adulteration of extracts.[23,28] The FA content and composition of a SPE depends on berry maturity.[20] The most common method of lipid extract adulteration is dilution with less expensive plant oils (canola, olive, sunflower).[23,30] FAs of animal origin have also been identified in SPEs.[28]

As noted in the AUA guidelines, use of phytotherapies is popular among patients with BPH/LUTS.[25] Total annual sales in the US prostate health phytotherapy market were estimated at $250 million in 2022, with saw palmetto as the primary ingredient. These patients would benefit from clinician guidance regarding specific supplements that might improve BPH/LUTS. In the United States, where the supplement industry is largely unregulated and subject to economic pressures, clinicians need to understand that high-quality LSESrs exist in a marketplace crowded by low-quality phytotherapeutics that may not be lipid extracts at all or may be adulterated by vegetable or other oils that do not provide the quantity or identify of FAs responsible for the therapeutic effect of LSESrs. Without use of a high-quality, authentic, standardized LSESr product administered at the clinically effective dose of 320 mg/d, the patient is unlikely to experience a clinical benefit.

As with any study, this analysis has some limitations, for example, the limited sample size. In the United States, nearly 1000 saw palmetto–based supplements are commercially available for consumer purchase, but only 28 supplements were included in this analysis. Another limitation is the possibility that more than one of the supplements that had ≥80% total FA content could have also met the USP lauric acid ratio standards for identification as an authentic SPE. Formulation of saw palmetto–based supplements with other ingredients rich in long chain FAs (eg, olive oil, pumpkin seed oil, magnesium stearate, lecithin) can skew the FA profile; in these cases, the lauric acid ratio comparison with USP standards could be limited to evaluation of only short chain FAs (eg, caproic, caprylic, capric, and myristic acids) which are not typically found in most encapsulation excipients. If we

Table 5. *Lauric Acid Ratios for Saw Palmetto Lipid Extract and Multiactive Supplements Containing Not less than 80% Total Fatty Acid Content*

	LGL4	KJ53	S3FR	YPG8	QVF5	WTS7	SY53	USP Lauric Acid Ratio Ranges (min—max) [a]
Short-chain FA lauric acid ratios								
Caproic	49.2	25.6	114.1	22.0	21.7	29.7	22.8	8.5—40.0
Caprylic	20.6	11.3	15.9	11.1	11.5	16.7	11.9	8.5—12.5
Capric	12.9	14.5	16.0	14.3	14.8	11.8	14.9	9.0—16.0
Myristic	2.7	2.5	2.3	2.5	2.5	2.6	2.4	2.2—2.8
Long-chain FA lauric acid ratios								
Palmitic	2.7	4.0	1.4	1.8	1.7	3.5	1.5	2.8—3.9
Stearic	9.8	20.0	5.7	7.6	7.5	17.1	4.4	13.0—26.0
Oleic	1.0	1.1	0.3	0.4	0.3	1.1	0.6	0.6—1.15
Linoleic	1.8	6.7	2.4	2.9	3.8	6.5	0.6	4.0–16.0
Linolenic	36.2	59.6	25.1	31.3	30.6	42.4	38.5	31.5—60.0

Abbreviations: FA, fatty acid; USP, US Pharmacopeia.
Green shading indicates supplement met USP standard for saw palmetto lipid extract identification based on all lauric acid ratio ranges.
Orange shading indicates supplement exceeded USP standard for the lauric acid ratio range by at least ±10%.
Yellow shading indicates supplement was within ±10% of USP standard for the lauric acid ratio range.
[a]USP monograph for saw palmetto lipid extracts provides acceptable lauric acid ratio ranges for both hydroalcoholic and supercritical carbon dioxide extraction. The extraction method is typically not stated on product labels; therefore, the ranges shown here for comparison with the USP standards provide the lowest minimum and highest maximum for either extraction method.

limit the lauric acid ratio comparisons with USP standards to only short chain FAs, then 4 supplements (KJ53, YPG8, QVF5, and SY53) could be designated as having an uncertain *S. repens* FA authenticity profile, rather than an inauthentic FA profile. Finally, selection of within or beyond ±10% for comparison of lauric acid ratios with USP SPE monograph ranges was an arbitrary but reasonable benchmark to evaluate SPE authenticity.

CONCLUSIONS

Urologists and their patients with mild-to-moderate BPH/LUTS who select phytotherapy as a treatment option should be aware that in the United States, few saw palmetto–based supplements meet the USP criteria for standardized LSESrs, including both total FA content (minimum, 80%) and FA identity (authentic *S. repens*). Only 1 of the 28 saw palmetto–based supplements analyzed in this study met the USP criteria for a standardized, authentic LSESr. For a saw palmetto–based supplement to potentially benefit a man with BPH/LUTS, clinicians should recommend only high-quality LSESr products standardized to ≥80% FA.[4] Specifically, clinicians and patients should select only products labeled with the following 3 criteria: (1) saw palmetto berry extract (*S. repens*, not *Serenoa serrulata)*; (2) standardized to ≥80% FAs; (3) dosage regimen of one 320 mg or two 160 mg capsules/softgels per day. Ideally, products should be USP-certified or NSF-certified.

DATA AVAILABILITY STATEMENT

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

CONFLICTS OF INTEREST

Dr. Chughtai is a consultant for Antares, Astellas, BD, BSC, Medeon Biodesign, Olympus, Urovant, and US Nutraceuticals, Inc., d/b/a Valensa International. Dr. Bhojani is a consultant for BSC, Olympus, and Procept BioRobotics. Dr. Zorn is a consultant for BSC, Olympus, Zenflow, Resurge Therapeutics, Clarius, and Procept BioRobotics. Dr. Elterman is a consultant for Astellas, Boston Scientific, Medtronic, Procept BioRobotics, Prodeon, Olympus, Rivermark, Urotronic, and Zenflow.

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