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File: ■ Saw Palmetto (*Serenoa repens*)

- Metabolomics
- Fatty Acid Analysis
- Quality Control

HC 071463-511

Date: December 31, 2014

RE: Two Different Types of Analytical Methods Used to Compare Phytochemical Contents of an International Variety of Saw Palmetto Products

Booker A, Suter A, Krnjic A, et al. A phytochemical comparison of saw palmetto products using gas chromatography and ¹H nuclear magnetic resonance spectroscopy metabolomic profiling. *J Pharm Pharmacol*. June 2014;66(6):811-822.

Saw palmetto (*Serenoa repens*) is native to the southeastern United States and has been traditionally used for bronchitis, colds, and urinary tract problems in both men and women. The most common contemporary use of saw palmetto is in the treatment of benign prostatic hyperplasia (BPH). Multiple clinical trials have reported its efficacy in BPH symptom treatment, as well as for related sexual dysfunction. Saw palmetto fatty acids are thought to be the compounds associated with reported bioactivity.

Metabolomics refers to the measurement and comparison of global profiles of compounds, proteins, or other aspects of biological function. Principal component analysis (PCA) defines components of a large data set that account for the variation in data. When plotted, this analysis can allow variation due to different amounts or presence of compounds to be detected.

Commercial saw palmetto products employ various extraction processes, resulting in divergence from standard content and inconsistent efficacy. In addition, product content often varies from manufacturers' claims. This investigative study used ¹H nuclear magnetic resonance (NMR) spectroscopy and metabolomics-based PCA to analyze 57 saw palmetto products, in addition to gas chromatograph (GC) analysis of fatty acid content; this study also assessed these analytical techniques for the quality control measurement of saw palmetto products.

In total, this study procured 57 samples from Canada, Finland, Germany, the Netherlands, United Kingdom, South Korea, Spain, Switzerland, and the United States. The supplements were hard or soft gel capsules, tablets, or tinctures, and 29 of them were composed of only saw palmetto extracts; the other 28 contained additional ingredients such as vitamins, herbal extracts, or minerals. This study analyzed 46 products with GC for fatty acid content, 34 were analyzed with ¹H NMR, and 26 were examined with both methods. GC utilized hexane and

heptane extracted material, while ^1H NMR was done on 150 mg of either methanol or chloroform extracts.

The GC fatty acid analysis was done based on the total of nine saw palmetto fatty acids: lauric acid, capric acid, caprylic acid, myristic acid, palmitic acid, linolenic acid, oleic/linoleic acid, and stearic acid. Fatty acid doses were calculated using the lowest recommended daily dosage stated for the product. It was noted that in daily dose recommendation and amount of botanical extract listed in the doses, a large amount of variation was observed among the products; daily fatty acid consumption (based on lowest dosage recommendation) ranged from 8.43 mg to 1473 mg, according to the analysis. Those supplements containing only saw palmetto had an average daily dosage of fatty acid content of 230.5 ± 127.2 mg (range of 30.89 mg to 1473.2 mg), and supplements with other ingredients averaged 261.0 ± 247.5 mg of fatty acids (range of 8.34 mg to 1173.02 mg) per daily dosage.

Those supplements with saw palmetto alone procured from Switzerland and South Korea had a comparable amount of fatty acids, while a supplement from Spain had 13.3 times more fatty acid per daily dosage than the sample with the lowest amount. Additionally, the amount of fatty acids in the supplements was anywhere from a tenth to 4.6 times more than the amount stated on the label by the manufacturer. All but four saw palmetto-only supplements met the *European Pharmacopoeia* standard of 20% lauric acid; three of these samples contained elevated oleic and linoleic acid, with 1 supplement showing very high concentrations of linolenic acid, suggesting possible adulteration of the latter.

Using ^1H NMR metabolomic analysis, the results showed that three samples did not group with samples of other supplements; differences in extraction methods and divergent ingredients are likely explanations, as the colors differed also. Upon more detailed analysis, fatty acids accounted for most of the differences and may be concentrated due to extraction methods or additives. The sample most distanced from the others in the PCA contained a unique ingredient (polyoxethylene glycol).

It is mentioned that monographs advise a saw palmetto dosage of 320 mg of extract containing 70-95% fatty acids (224-304 mg fatty acids daily). According to this analysis, nine samples with just saw palmetto extract were in agreement with this dosage range. Of the supplements with just saw palmetto extract, five samples provided higher quantities of fatty acids, and five samples had lower amounts than this range. Of those samples that contained additional ingredients, 16 delivered higher quantities of fatty acids, and 11 provided lower values. It is suggested that these discrepancies in fatty acids per daily dosage may cause problems with efficacy.

The authors conclude that the agreement of fatty acid content and concentration in many samples is indicative of consistent mixture of fruit maturity and harvest locations. Limitations of GC include a lack of measurement of other bioactive compounds, while PCA lacks the ability to detect small differences in extraction or preparation processes. In conclusion, this study employed metabolomics as a useful tool in assessing both botanical supplement quality and potential adulteration.

—Amy C. Keller, PhD

Referenced article can be found at <http://onlinelibrary.wiley.com/doi/10.1111/jphp.12198/pdf>.

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