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Saw Palmetto

Updated: April 2, 2020.

OVERVIEW

Introduction

Saw palmetto is a popular herbal medication and extract derived from the fruit of the low growing, small palm, Serenoa repens, which has fan shaped leaves and is native to Florida and the Southeast United States. Currently, saw palmetto is used mostly for symptoms of benign prostatic hypertrophy. Saw palmetto has been implicated in rare cases of clinically apparent liver injury, but its specific role in causing liver injury remains uncertain.

Background

Saw palmetto (saw pal met' toe) is a widely used herbal derived from the fruit of the low growing bushy palm of the same name (Serenoa repens). Native Americans used saw palmetto fruit both as a food as well as an herbal remedy with multiple uses, including as a sedative, diuretic, sleeping aid, expectorant and cough suppressant, aid to lactation, infertility, indigestion and urinary problems. Currently, saw palmetto is one of the most widely used herbal medications and is used largely for symptomatic benign prostatic hypertrophy. Saw palmetto is available in multiple formulations including liquid extracts, tablets, capsules, and as an herbal tea. The active components of palmetto extracts are believed to be the volatile oils and free fatty acids which have activity in inhibiting 5-alpha-reductase and the conversion of testosterone to dihydrotesterone, which has been demonstrated in vitro, but not in human studies. In short term clinical trials, saw palmetto appeared to be beneficial in improving symptoms of prostatic hypertrophy, but it had no effects on prostate size or serum prostatic specific antigen (PSA) levels. In longer term studies, the benefit of saw palmetto in improving urinary symptoms of benign prostatic hypertrophy was less clear. Saw palmetto is available in multiple over-the-counter preparations often in combination with other herbals or dietary supplements, and most commonly for symptoms of urinary hesitancy, urgency or burning. Side effects of saw palmetto are uncommon and mild and may include dizziness, headache, nausea, vomiting, constipation and diarrhea. In most randomized controlled clinical trials, side effects were no more frequent with saw palmetto than with placebo therapy.

Hepatotoxicity

Chronic therapy with saw palmetto has not been linked to serum enzyme elevations and prospective trials found little or no evidence of liver injury from its administration. However, there have been rare case reports of clinically apparent liver injury attributed to saw palmetto, although in some instances, other possible causes of liver disease were present. In the reported cases, the latency to onset was within 1 to 2 weeks of starting therapy, and clinical features resembled acute viral hepatitis with a hepatocellular pattern of serum enzyme elevations and resolution within 1 to 3 months. Immunoallergic and autoimmune features were not present.

Likelihood score: D (possible, rare cause of clinically apparent liver injury).

Mechanism of Injury

Saw palmetto extracts have many components, but none of them has been shown to be particularly hepatotoxic. The rare cases of liver injury reported with saw palmetto use have had idiosyncratic features. Saw palmetto has few herb-drug interactions and is not affected by inducers or inhibitors of the cytochrome P450 enzyme system.

Outcome and Management

Hepatotoxicity from saw palmetto is very rare and cases have been self-limiting upon stopping the herbal. There have been no instances leading to fatalities, liver transplantation, chronic hepatitis, or vanishing bile duct syndrome. Studies of rechallenge have not been reported.

Other Names: Cabbage palm, Sabal

Drug Class: Herbal and Dietary Supplements

PRODUCT INFORMATION

REPRESENTATIVE TRADE NAMES

Saw Palmetto – Generic

DRUG CLASS

Herbal and Dietary Supplements

SUMMARY INFORMATION

Fact Sheet at National Center for Complementary and Integrative Health, NIH

CHEMICAL FORMULA AND STRUCTURE

DRUG	CAS REGISTRY NUMBER	MOLECULAR FORMULA	STRUCTURE
Saw Palmetto	84604-15-9	Herbal mixture	Not applicable

ANNOTATED BIBLIOGRAPHY

References updated: 02 April 2020

Zimmerman HJ. Unconventional drugs. Miscellaneous drugs and diagnostic chemicals. In, Zimmerman, HJ. Hepatotoxicity: the adverse effects of drugs and other chemicals on the liver. 2nd ed. Philadelphia: Lippincott, 1999: pp. 731-4.

(Expert review of hepatotoxicity published in 1999; saw palmetto is not discussed).

Seeff L, Stickel F, Navarro VJ. Hepatotoxicity of herbals and dietary supplements. In, Kaplowitz N, DeLeve LD, eds. Drug-induced liver disease. 3rd ed. Amsterdam: Elsevier, 2013, pp. 631-58.

(Review of hepatotoxicity of herbal and dietary supplements [HDS]; saw palmetto is listed as nonhepatotoxic).

Saw palmetto. In, PDR for Herbal Medicines. 4th ed. Montvale, New Jersey: Thomson Healthcare Inc. 2007: pp. 725-9.

(Compilation of short monographs on herbal medications and dietary supplements).

Hamid S, Rojter S, Vierling J. Protracted cholestatic hepatitis after the use of Prostata. Ann Intern Med. 1997;127:169–70. PubMed PMID: 9230022.

(65 year old man developed jaundice and pruritus 2 weeks after starting an herbal preparation that contained saw palmetto [bilirubin 8.2 mg/dL, ALT 1364 U/L, Alk P 179 U/L, AMA positive, anti-HCV positive, HCV RNA negative], with resolution 3 months after stopping).

Wilt TJ, Ishani A, Stark G, MacDonald R, Lau J, Mulrow C. Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review. JAMA. 1998;280:1604–9. PubMed PMID: 9820264.

(A systematic review of literature on efficacy of saw palmetto for benign prostatic hypertrophy identified 18 trials involving 2939 men and found overall evidence for its efficacy in improving urinary symptoms; side effects were mild, infrequent and similar in frequency with placebo).

De Smet PAGM. Herbal remedies. N Engl J Med. 2002;347:2046–56. PubMed PMID: 12490687.

(Review of status and difficulties of herbal medications including lack of standardization, federal regulation, contamination, safety, hepatotoxicity and drug-herb interactions; specific discussion of 4 herbs with therapeutic promise: ginkgo, hawthorn, saw palmetto and St. John's wort).

Stedman C. Herbal hepatotoxicity. Semin Liver Dis. 2002;22:195–206. PubMed PMID: 12016550.

(Review and description of patterns of liver injury, including discussion of potential risk factors, and herb-drug interactions; saw palmetto is not discussed).

Schiano TD. Hepatotoxicity and complementary and alternative medicines. Clin Liver Dis. 2003;7:453–73. PubMed PMID: 12879994.

(Comprehensive review of herbal associated hepatotoxicity; saw palmetto is not listed as causing hepatotoxicity).

Russo MW, Galanko JA, Shrestha R, Fried MW, Watkins P. Liver transplantation for acute liver failure from drug-induced liver injury in the United States. Liver Transpl. 2004;10:1018–23. PubMed PMID: 15390328.

(Among ~50,000 liver transplants reported to UNOS between 1990 and 2002, 270 [0.5%] were done for drug induced acute liver failure, including 7 [5%] for herbal medications, none attributed to saw palmetto).

Bent S, Kane C, Shinohara K, Neuhaus J, Hudes ES, Goldberg H, Avins AL. Saw palmetto for benign prostatic hyperplasia. N Engl J Med. 2006;354:557–66. PubMed PMID: 16467543.

(Controlled trial of saw palmetto [160 mg twice daily] vs placebo for one year in 225 men with symptomatic benign prostatic hypertrophy found no difference in symptoms, urinary flow rate, prostate size, quality of life or side effects).

Jibrin I, Erinle A, Saidi A, Aliyu ZY. Saw palmetto-induced pancreatitis. South Med J. 2006;99:611–2. PubMed PMID: 16800417.

(55 year old reformed alcoholic developed pancreatitis after intermittent use of saw palmetto for 4 years [bilirubin not mentioned, ALT 1232 U/L, Alk P 184 U/L, amylase 2152 U/L], with resolution within a few days of stopping herbal).

Singh YN, Devkota AK, Sneeden DC, Singh KK, Halaweish F. Hepatotoxicity potential of saw palmetto(Serenoa repens) in rats. Phytomedicine. 2007;14:204–8. PubMed PMID: 16854576.

(Treatment of rats for 4 weeks with concentrations of saw palmetto 5 times that recommended in humans did not result in serum ALT elevations, evidence of oxidative stress or hepatic histological abnormalities).

Avins AL, Bent S, Staccone S, Badua E, Padula A, Goldberg H, Neuhaus J, et al. A detailed safety assessment of a saw palmetto extract. Complement Ther Med. 2008;16:147–54. PubMed PMID: 18534327.

(Detailed analysis of side effects in a controlled trial of saw palmetto [Bent 2006] vs placebo found no overall difference in rates of side effects, no evidence of hepatotoxicity, no change in ALT, AST or bilirubin levels or serious hepatic adverse events in saw palmetto treated subjects).

García-Cortés M, Borraz Y, Lucena MI, Peláez G, Salmerón J, Diago M, Martínez-Sierra MC, et al. Rev Esp Enferm Dig. 2008;100:688–95. [Liver injury induced by "natural remedies": an analysis of cases submitted to the Spanish Liver Toxicity Registry]. Spanish. PubMed PMID: 19159172.

(Among 521 cases of drug induced liver injury submitted to Spanish registry, 13 [2%] were due to herbals but none attributed to saw palmetto).

Chalasani N, Fontana RJ, Bonkovsky HL, Watkins PB, Davern T, Serrano J, Yang H, Rochon J; Drug Induced Liver Injury Network (DILIN). Causes, clinical features, and outcomes from a prospective study of drug-induced liver injury in the United States. Gastroenterology. 2008;135:1924–34. PubMed PMID: 18955056.

(Among 300 cases of drug induced liver disease in the US collected between 2004 and 2008, 9% of cases were attributed to herbal medications, but none were linked to saw palmetto).

Tacklind J, MacDonald R, Rutks I, Wilt TJ. Serenoa repens for benign prostatic hyperplasia. Cochrane Database Syst Rev. 2009;(2):CD001423. PubMed PMID: 19370565.

(Systematic review of medical evidence of efficacy of saw palmetto as therapy of symptoms of benign prostatic hypertrophy; in controlled trials, there was no difference in adverse event rates between saw palmetto and placebo arms).

Navarro VJ. Herbal and dietary supplement hepatotoxicity. Semin Liver Dis. 2009;29:373–82. PubMed PMID: 19826971.

(Overview of the regulatory environment, clinical patterns, and future directions in research with HDS; saw palmetto is not listed as a potentially hepatotoxic HDS).

Jacobsson I, Jönsson AK, Gerdén B, Hägg S. Spontaneously reported adverse reactions in association with complementary and alternative medicine substances in Sweden. Pharmacoepidemiol Drug Saf. 2009;18:1039–47. PubMed PMID: 19650152.

(Review of 778 spontaneous reports of adverse reactions to herbals to Swedish Registry found 17 to saw palmetto, but none related to liver injury).

Lapi F, Gallo E, Giocaliere E, Vietri M, Baronti R, Pieraccini G, Tafi A, et al. Acute liver damage due to Serenoa repens: a case report. Br J Clin Pharmacol. 2010;69:558–60. PubMed PMID: 20573093.

(58 year old man developed abdominal pain and fatigue 1 week after starting saw palmetto in a dose of 900 mg daily [bilirubin 2.0 mg/dL, ALT 1237 U/L, GGT 456 U/L], resolving within 10 days of stopping).

Reuben A, Koch DG, Lee WM; Acute Liver Failure Study Group. Drug-induced acute liver failure: results of a U.S. multicenter, prospective study. Hepatology. 2010;52:2065–76. PubMed PMID: 20949552.

(Among 1198 patients with acute liver failure enrolled in a US prospective study between 1998 and 2007, 133 [11%] were attributed to drug induced liver injury of which 12 [9%] were due to herbals, but none were attributed to saw palmetto).

Stickel F, Kessebohm K, Weimann R, Seitz HK. Review of liver injury associated with dietary supplements. Liver Int. 2011;31:595–605. PubMed PMID: 21457433.

(Review of current understanding of liver injury from herbals and dietary supplements focusing upon herbalife and hydroxycut products, green tea, usnic acid, Noni juice, Chinese herbs, vitamin A and anabolic steroids: saw palmetto is not discussed).

Teschke R, Wolff A, Frenzel C, Schulze J, Eickhoff A. Herbal hepatotoxicity: a tabular compilation of reported cases. Liver Int. 2012;32:1543–56. PubMed PMID: 22928722.

(A systematic compilation of all publications on the hepatotoxicity of specific herbals identified 185 publications on 60 different herbs, including one case report attributed to saw palmetto [Lapi 2010]).

Bunchorntavakul C, Reddy KR. Review article: herbal and dietary supplement hepatotoxicity. Aliment Pharmacol Ther. 2013;37:3–17. PubMed PMID: 23121117.

(Systematic review of literature on HDS associated liver injury mentions that saw palmetto has been rarely linked to instances of hepatotoxicity).

Avins AL, Lee JY, Meyers CM, Barry MJ; CAMUS Study Group. Safety and toxicity of saw palmetto in the CAMUS trial. J Urol. 2013;189:1415–20. PubMed PMID: 23063633.

(Analysis of the adverse events that arose in a controlled trial of saw palmetto vs placebo in 369 men with symptoms of benign prostatic hypertrophy found no differences in rates of adverse events; ALT elevations occurred in 12-14% of saw palmetto vs 11-17% of placebo recipients).

Björnsson ES, Bergmann OM, Björnsson HK, Kvaran RB, Olafsson S. Incidence, presentation and outcomes in patients with drug-induced liver injury in the general population of Iceland. Gastroenterology. 2013;144:1419–25. PubMed PMID: 23419359.

(In a population based study of drug induced liver injury from Iceland, 96 cases were identified over a 2 year period, including 15 [16%] due to HDS, none of which were attributed to saw palmetto).

Navarro VJ, Barnhart H, Bonkovsky HL, Davern T, Fontana RJ, Grant L, Reddy KR, et al. Liver injury from herbals and dietary supplements in the U.S. Drug-Induced Liver Injury Network. Hepatology. 2014;60:1399–408. PubMed PMID: 25043597.

(Among 85 cases of HDS associated liver injury [not due to anabolic steroids] enrolled in a US prospective study between 2004 and 2013, saw palmetto was not implicated in any of the cases).

Brown AC. Liver toxicity related to herbs and dietary supplements: Online table of case reports. Part 2 of 5 series. Food Chem Toxicol 2017; 107 (Pt A): 472-501.

(Description of an online compendium of cases of liver toxicity attributed to HDS products, lists a single report of hepatotoxicity from saw palmetto [Lapi 2010]).

Asher GN, Corbett AH, Hawke RL. Common herbal dietary supplement-drug interactions. Am Fam Physician. 2017;96:101–7. PubMed PMID: 28762712.

(Review of herb-drug interactions of the most commonly used herbal supplements, mentions that saw palmetto has not been shown to have effects or to be affected by P450 substrates, inducers or inhibitors).

Vinarov AZ, Spivak LG, Platonova DV, Rapoport LM, Korolev DO. 15 years' survey of safety and efficacy of Serenoa repens extract in benign prostatic hyperplasia patients with risk of progression. Urologia. 2019;86:17–22. PubMed PMID: 29741118.

(Among 30 patients with benign prostatic hypertrophy treated with saw palmetto [320 mg once daily] for up to 10 years, there was no progression of symptoms and no reported adverse side effects that could be attributed to the herbal supplement).

Ye Z, Huang J, Zhou L, Chen S, Wang Z, Ma L, Wang D, et al. Efficacy and safety of Serenoa repens extract among patients with benign prostatic hyperplasia in China: a multicenter, randomized, double-blind, placebo-controlled trial. Urology. 2019;129:172–9. PubMed PMID: 30880074.

(Among 354 Chinese patients with benign prostatic hypertrophy treated with saw palmetto [160 mg] or placebo twice daily for 24 weeks, urinary symptoms and peak urinary flow improved more with the herb treatment, while adverse event rates were similar and there were no serious adverse events or mention of ALT elevations or liver related side effects).