Treatment of Low Back Pain: The Potential Clinical and Public Health Benefits of Topical Herbal Remedies

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IN THE UNITED STATES—indeed, throughout the world—low back pain is a major clinical and public health problem. With a lifetime prevalence of about 84% for low back pain and a prevalence of 23% for chronic low back pain (CLBP),¹ low back pain is a major cause of morbidity, especially with respect to work days lost.² In fact, the prevalence of disability as a result of low back pain is 11% to 12%.¹ The economic burden arising from this clinical and public health problem is large and continues to grow. In the United States, for example, total direct costs of healthcare utilization related to low back pain are estimated to be \$96 million a year.³

At present, nonsteroidal anti-inflammatory drugs (NSAIDs) are the major pharmacologic therapies used for the relief of inflammation accompanying CLBP in patients with symptoms that cannot be attributed to a specific disease or spinal abnormality. NSAIDs include traditional NSAIDs, such as naproxen, and cyclooxygenase 2 inhibitors, known as coxibs. In a recently published, comprehensive worldwide meta-analysis⁴ of randomized trials, the vascular and upper gastrointestinal risks of traditional NSAIDs and coxibs were compared and contrasted. The vascular risks of high-dose diclofenac were comparable to those of the coxibs, while high-dose naproxen was associated with less vascular risk than other NSAIDs, including the coxibs. It should be noted that proportional effects on major vascular events were independent of baseline characteristics, including vascular risk factors. All NSAID regimens doubled the risk of heart failure and increased the risk of upper gastrointestinal complications, although coxibs and diclofenac were somewhat less gastrototoxic than ibuprofen and naproxen. Since naproxen is the only drug in this class that provides symptomatic relief of pain and inflammation with no increased vascular risk, it is likely to be more widely used despite the substantial gastrointestinal risks accompanying its use.

In addition to the cardiovascular and gastrointestinal risks they present, traditional NSAIDs and coxibs offer only limited benefits for the treatment of low back pain. A systematic review of randomized trials of patients with acute low back pain and CLBP showed that NSAID use by patients with acute low back pain brought about an average short-term improvement of only 8 points on a 0-to-100 scale compared

to placebo use. NSAID use by patients with CLBP brought about an average short-term improvement of only 12 points compared to placebo use.⁵ Furthermore, no one drug in this class had any greater benefit on pain than any other.⁵ Given this, other remedies for low back pain need to be explored. Two topical herbal remedies, *Capsicum frutescens* (cayenne or capsaicin) and a combination of *Gaultheria procumbens* (wintergreen oil) and *Menthe piperata* (peppermint oil) offer plausible alternative therapies to NSAIDs and coxibs and the potential for a greater benefit-to-risk ratio.

Capsaicin is a powerful local stimulant that, with repeated applications, leads to persistent desensitization to pain.⁶ In some clinical practices, topical capsaicin is used extensively for the treatment of CLBP. The scientific rationale for its use is derived from the results of three randomized placebo-controlled trials, one of acute mechanical back pain and two of chronic nonspecific back pain.⁷ In each of these trials, the use of topical capsaicin produced statistically significant reductions in pain compared with the reductions in pain with the use of placebo. In a subsequent review⁸ of two of the three randomized, placebo-controlled trials of CLBP, capsaicin produced a statistically significant 60% reduction in pain. It should be noted that the risks of topical capsaicin are generally mild and usually limited to local reactions in about one third of the treated patients.⁶

The predominant natural ingredient in wintergreen oil is methyl salicylate, which is a compound closely related to acetylsalicylic acid, or aspirin. When applied to the skin, including tissues at the site of pain, wintergreen oil has analgesic properties. However, due to its aspirin-like qualities, the possibilities and potential, in theory, for bleeding and other side effects must be considered. A combination of wintergreen oil and peppermint oil is commonly used because it is believed to give far better pain relief than either wintergreen oil or peppermint oil alone. In addition, the combination of the two oils may potentiate the individual effects of each oil, thus enabling the use of lower doses of each, which, as a consequence, is likely to produce fewer side effects. At present, wintergreen oil is used far less frequently than capsaicin, at least in part because there are no published randomized trials comparing wintergreen oil or a

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combination of wintergreen oil and peppermint oil to placebo for low back pain. Consequently, the available totality of evidence is wholly insufficient upon which to judge the benefits and risks of these topical remedies. In particular, data are lacking from randomized trials designed *a priori* to test the hypothesis which may be related to perceived concerns about the safety of methyl salicylate.⁹ In fact, however, if 10 ml of a 2.5% formula of wintergreen oil were to be applied all at once to the skin and totally absorbed, the dose would represent the same amount of salicylate present in one 325 mg aspirin tablet.¹⁰ Many methyl salicylate-containing products are available over the counter and self-medication produces very few side effects. There are no safety issues with high quality *Gaultheria procumbens*. The perception of *Gaultheria procumbens* safety issues has arisen from the use of inferior quality or adulterated wintergreen-like oils.

The clinical challenges for healthcare providers who treat CLPB should be viewed as a major challenge to researchers, a challenge to compare the benefits and risks of these potentially promising and safer alternative treatments to conventional therapies. Topical capsaicin and wintergreen oil or a blend of wintergreen and peppermint oils as treatments for CLBP are likely to have far fewer side effects than conventional therapies. To the best of our knowledge, however, none has been directly tested against traditional NSAIDs and coxibs in randomized trials. If wintergreen oil or the blend of wintergreen and peppermint oils were demonstrated to be equivalent or superior to NSAIDs, then the topical agent of greatest efficacy may need to be more widely used in clinical practice. If capsaicin were shown to be less effective than NSAIDs in randomized trials then this result should inform clinical practice. Finally, it is important to discern whether there are additive benefits and/or risks to these oral and topical herbal remedies for CLBP.

Author Disclosure Statement

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UpToDate. He receives royalties for authorship or editorship of three textbooks and, as a co-inventor, for patents, held by Brigham and Women's Hospital, dealing with inflammatory markers and cardiovascular disease. He has an investment management relationship with the West-Bacon Group within SunTrust Investment Services, which has discretionary investment authority. Professor Hennekens does not own any common or preferred stock in any pharmaceutical or medical device company.

References

1. Balagué F, Mannion AF, Pellisé F, Cedraschi C. Non-specific low back pain. *Lancet* 2012;379:482–491.
2. Maetzel A, Li L. The economic burden of low back pain: A review of studies published between 1996 and 2001. *Best Pract Clin Rheumatol* 2002;16:23–30.
3. Mehra M, Hill K, Nicholl D, Schadrack J: The burden of chronic low back pain with and without a neuropathic component: A healthcare resource use and cost analysis. *J Med Econ* 2012;15:245–252.
4. Coxib and traditional NSAID Trialists' (CNT) Collaboration. Vascular and upper gastrointestinal effects of non-steroidal anti-inflammatory drugs: Meta-analyses of individual participant data from randomised trials. *Lancet* 2013;382:769–779.
5. Chou R. Pharmacologic management of low back pain. *Drugs* 2010;70:387–402.
6. Mason L, Moore A, Derry S, et al. Systematic review of topical capsaicin for the treatment of chronic pain. *BMJ* 2004;328:991.
7. Gagnier JJ, van Tulder MW, Berman BM, Bombardier C. Herbal medicine for low back pain. *Cochrane Database Syst Rev* 2006;CD004504.
8. Rubinstein SM, van Middelkoop M, Kuijpers T, et al. A systematic review on the effectiveness of complementary and alternative medicine for chronic non-specific low-back pain. *Eur Spine J* 2010;19:1213–1228.
9. Buckle, Jane. *Clinical Aromatherapy: Essential Oils in Practice*. 2nd ed. New York: Churchill Livingstone 2003; 90–91.
10. Guba R. Toxicity myths: The actual risk of essential oil use. *Int J Aromather* 2000;10:37–49.

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