Safety and Efficacy Report

Arnica

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Homeopathic medicine is becoming increasingly popular both in this country and abroad. It is based on the premise that “similia similibus curantur,” i.e., an agent that causes certain symptoms in a healthy person can be used to treat those same symptoms when administered in a diluted, “potentized” form.1 Samuel Hahnemann, a German physician, expanded this principle into a system of medicine in the nineteenth century. Though homeopathic remedies are generally viewed with disdain by most physicians, some have recently enjoyed more widespread use. Arnica montana, marketed as SinEcch by Alpine Pharmaceuticals (San Rafael, Calif.), is used by many plastic surgeons to limit postoperative edema and ecchymosis. In their advertising literature, the company provides a large number of testimonials from plastic surgeons who use the product and feel that it is effective.

A. montana is an herb that is a member of the Compositae family and is native to the mountains of Siberia and Central Europe. The primary stem of the plant branches into two or three smaller stems, with a flower, similar to a daisy, on each of them. The flowers bloom from June to August and can cause sneezing, so arnica has also been called sneezewort. Other names for it include leopard’s bane, wolf’sbane, mountain tobacco, and mountain snuff. The A. montana used for medicinal purposes is an extract of dried flowers from the plant.

Arnica has been used extensively in folk medicine since the sixteenth century, especially in Russia. It is the classic homeopathic remedy for trauma of various kinds and was often used by mountain climbers to relieve sore muscles and minimize bruising from falls. It has also been used for myocarditis, cardiac insufficiency, arteriosclerosis, angina pectoris, and many other unproven applications.2

More recently, a number of studies have been carried out evaluating the efficacy of arnica. Tveiten et al.3 performed a limited randomized, double-blind, placebo-controlled trial evaluating the efficacy of arnica in limiting muscle soreness. Their study group included 36 individuals running in the Oslo marathon in 1990. Muscle soreness was evaluated immediately after the marathon and on the subsequent 3 days. Their data suggested a benefit in the arnica-treated runners, particularly 2 and 3 days after the race, though the differences were not statistically significant. They repeated the study in 1995 with 46 runners and found a statistically significant improvement in soreness immediately after the race, but not at other time points.4 To further evaluate this effect, Vickers et al.5 carried out a randomized, double-blind, placebo-controlled trial of arnica in 519 individuals participating in long-distance races. The majority (57 percent) participated in the London marathon. In this more definitive trial, no statistically significant benefit to arnica was noted in terms of relieving muscle soreness.

The ability of arnica to reduce the incidence of postoperative complications in several clinical situations has also been studied. Kaziro6 and Pinsent et al.7 evaluated arnica in separate randomized, double-blind trials evaluating whether arnica could limit postoperative complications after tooth extractions. Kaziro evaluated 118 patients and utilized controls treated with metronidazole and placebo. In his study, metronidazole was the only modality that significantly limited postoperative pain and swelling, and arnica was ineffective. In Pinsent et
al.’s study involving 59 patients, the arnica-treated group did experience somewhat less pain and possibly less bleeding. Hart et al. performed a double-blind, placebo-controlled, randomized clinical trial of arnica in patients undergoing total abdominal hysterectomy. Seventy-three patients completed their protocol. No statistical differences could be identified between treated and untreated patients in terms of infection, hospital stay, and postoperative pain. Jeffrey and Belcher performed a double-blind, randomized, placebo-controlled trial of arnica in 37 patients undergoing endoscopic carpal tunnel release. They demonstrated a statistically significant degree of pain reduction in treated patients 2 weeks after treatment, though no difference was noted in swelling, in grip strength, or in pain 1 week after surgery.

Several additional studies have evaluated the question of whether arnica can diminish the incidence of bruising and hematomas. Campbell evaluated bruising in volunteers subjected to experimental trauma in two separate trials involving 15 and 20 individuals. Their data suggested some benefit to arnica at limiting bruising, though the results were not statistically evaluated due to the small size of the studies. Ramelet et al. performed a randomized, prospective, double-blind, placebo-controlled multicenter trial to evaluate whether arnica could reduce the incidence of postoperative hematomas after vein stripping procedures in 130 consecutive patients. No statistically significant difference was noted in the arnica-treated group. Michael Kulick presented a randomized, prospective, double-blind, placebo-controlled trial of arnica in a series of 29 liposuction patients at the 2002 American Society for Aesthetic Plastic Surgery meeting. He demonstrated a statistically significant reduction in bruising and swelling in the arnica-treated group. Another randomized, prospective, double-blind, placebo-controlled trial in 29 rhytidectomy patients presented at the 2002 American Academy of Facial and Reconstructive Plastic Surgery meeting demonstrated a statistically significant decrease in bruising on postoperative days 1 and 7, though not on days 5 and 10.

In addition to efficacy, a significant concern with any drug is its safety. Most homeopathic medications have not been subjected to rigorous safety testing, though the dose of the active agents in homeopathic preparations is exceptionally small. In fact, it has been questioned whether there is enough of the agent present to have any effect, good or bad, in homeopathic arnica preparations. Though there have not been reports of significant toxicity related to the clinical use of arnica, significant deleterious effects could theoretically occur. At high doses, arnica can cause significant toxicity, including gastroenteritis, muscular weakness, cardiotoxicity, bleeding, and even death.

One of the most significant concerns relative to the use of arnica by plastic surgeons has to do with arnica’s potential impact on anticoagulant/antiplatelet activity, which could increase the risk of postoperative bleeding. Nevertheless, Baillargeon et al. did not demonstrate any alteration in bleeding time or other coagulation assays in healthy volunteers to whom arnica was administered. It is possible that it could influence the activity of other drugs that influence coagulation, such as warfarin. Heck et al. concluded that more scientifically controlled studies are necessary to assess these potential effects.

In the September 1, 2002, issue of Plastic and Reconstructive Surgery, David Glasson, F.R.A.C.S. questioned the Journal’s acceptance of an advertisement for A. montana. Mr. Glasson’s contention was that claims related to the efficacy of the product were unproven by the scientific literature. Though J. William Little, M.D., in his response, provided the justification for inclusion of the advertisement, Mr. Glasson’s comments regarding arnica’s efficacy are, most likely, accurate. Ernst and Pittler reviewed many of the above-mentioned studies in their systematic analysis of the clinical efficacy of arnica in 1998 and concluded that existing evidence could not support the claim that homeopathic arnica is efficacious beyond a placebo effect. Though additional information has been presented and published since the time of their publication, definitive evidence of efficacy has not been provided. Several studies suggest arnica is effective, while others have provided contradictory results.

One of the difficulties in examining endpoints such as pain, swelling, and bruising is that measurements are often somewhat subjective. Such few quantitative data make a clear definition of limited effects on populations of patients more difficult. A subtle benefit induced by arnica would be very difficult to definitively and reproducibly demonstrate in
studies involving the relatively small numbers of individuals considered in most studies to date. Though current data may be inconclusive, arnica may ultimately be proven to be an efficacious agent at limiting postoperative swelling and bruising, as the manufacturers claim. It is encouraging, for the time being, that significant toxicity has not been reported, despite increasingly widespread use of the agent.

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REFERENCES