

## DOES ASPIRIN HEAL LEG ULCERS?

**TITLE:** Randomised trial of oral aspirin for chronic venous leg ulcers

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**Background.** The pathogenesis of venous ulceration is unclear. Thrombocytosis and mean platelet volume have been implicated in some cases, and case reports have suggested the efficacy of aspirin in patients with increased platelet hyperaggregability and venous disease.

**Clinical question.** Does aspirin heal chronic venous leg ulcers?

**Population studied.** Twenty outpatients in a British dermatology unit were enrolled; referral pattern was not specified. Patients were excluded if the ulcer diameter was less than 2 cm, if they were already taking aspirin, anticoagulants, or nonsteroidal anti-inflammatory drugs (NSAIDs), or if lower extremity arterial dopplers showed an ankle-to-brachial ratio (ABR) of less than 0.9 (an ABR lower than 0.9 suggests the presence of significant peripheral arterial disease). Other medical history was not described. The similarity of the population studied to routine family practice patients is unclear.

**Study design and validity.** The study design was excellent. A double-blind, randomized, placebo-controlled trial was used to ascertain the value of adding 300 mg of enteric coated aspirin to standard therapy with standardized compression bandages. The patients were followed for 4 months.

**Outcomes measured.** At 0, 2, and 4 months, patients were assessed visually for erythema, eczema, hemosiderin,

atrophy blanch, and dermatoliposclerosis using a simple 0 to 3 scale; the examiners were unaware of treatment group. Infection was excluded by cultures and C-reactive protein at each visit. Ulcer size was recorded by duplicate tracing, and ulcers were photographed at each visit.

**Results.** Of patients taking aspirin, 38% healed completely and 52% improved, compared with 0% and 26%, respectively, of patients taking placebos ( $P < .007$ ). The presence or absence of bacterial infection, number and duration of ulcers, history of deep venous thrombosis, and ulcer diameter at entry did not significantly influence healing rate. No side effects of treatment were noted in this small sample.

**Clinical recommendation.** This report provides strong evidence that aspirin is a useful adjunct in the treatment of chronic venous ulcers with a diameter  $>2$  cm in patients without evidence of arterial disease. The small sample size limits analyses of contributory factors, but it should not cast too much doubt on the central findings. A small sample is more of an issue in studies that report no differences because of the lack of statistical power to demonstrate a difference. A more significant issue is the applicability of the results to family practice patients. This report does not describe the referral pattern, previous treatments, confounding conditions, or specifics of patients' activities and other individual characteristics, all of which might influence the effectiveness of the aspirin. In this case, however, the possible therapy is well known, simple, inexpensive, and relatively benign, and the results are clinically impressive. Aspirin is worth trying for patients who fit the study's inclusion criteria.

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