A Randomized Trial of Vertebroplasty for Osteoporotic Spinal Fractures


ABSTRACT

Background Vertebroplasty is commonly used to treat painful, osteoporotic vertebral compression fractures.

Methods In this multicenter trial, we randomly assigned 131 patients who had one to three painful osteoporotic vertebral compression fractures to undergo either vertebroplasty or a simulated procedure without cement (control group). The primary outcomes were scores on the modified Roland–Morris Disability Questionnaire (RDQ) (on a scale of 0 to 23, with higher scores indicating greater disability) and patients' ratings of average pain intensity during the preceding 24 hours at 1 month (on a scale of 0 to 10, with higher scores indicating more severe pain). Patients were allowed to cross over to the other study group after 1 month.

Results All patients underwent the assigned intervention (68 vertebroplasties and 63 simulated procedures). The baseline characteristics were similar in the two groups. At 1 month, there was no significant difference between the vertebroplasty group and the control group in either the RDQ score (difference, 0.7; 95% confidence interval [CI], –1.3 to 2.8; P=0.49) or the pain rating (difference, 0.7; 95% CI, –0.3 to 1.7;...
P=0.19). Both groups had immediate improvement in disability and pain scores after the intervention. Although the two groups did not differ significantly on any secondary outcome measure at 1 month, there was a trend toward a higher rate of clinically meaningful improvement in pain (a 30% decrease from baseline) in the vertebroplasty group (64% vs. 48%, P=0.06). At 3 months, there was a higher crossover rate in the control group than in the vertebroplasty group (43% vs. 12%, P<0.001). There was one serious adverse event in each group.

Conclusions Improvements in pain and pain-related disability associated with osteoporotic compression fractures in patients treated with vertebroplasty were similar to the improvements in a control group. (ClinicalTrials.gov number, NCT00068822 [ClinicalTrials.gov].)

Source Information
From the Mayo Clinic, Rochester, MN (D.F.K., L.A.G.); the University of Washington, Seattle (B.A.C., P.J.H., J.A.T., L.S., B.G., J.G.J.); Nuffield Orthopaedic Centre NHS Trust, Oxford (D.J.W., S.O.), Gartnavel General Hospital, Glasgow (R.E.), the University of Bristol, Bristol (W.H.), Nottingham University Hospital NHS Trust, Nottingham (D.J.A.-W.), and Western General Hospital, University of Edinburgh, Edinburgh (S.H.R.) — all in the United Kingdom; and St. George Hospital, University of New South Wales, Sydney (T.H.D.).

Address reprint requests to Dr. Kallmes at the Department of Radiology, Mayo Clinic, 200 First St. SW, Rochester, MN 55905, or at kallmes.david@mayo.edu.

Full Text of this Article

This article has been cited by other articles:


http://content.nejm.org/cgi/content/short/361/6/569?query=TOC