Percutaneous vertebroplasty does not reduce pain and disability from osteoporotic vertebral compression fracture

10.1136/ebmed-2015-110233

Bronek Boszczyk
Nottingham University Hospitals, Nottingham, UK

Correspondence to: Dr Bronek Boszczyk, Nottingham University Hospitals, Nottingham NG7 2UH, UK; bronek.boszczyk@nuh.nhs.uk


Context
Vertebroplasty is a frequently performed procedure stabilising predominantly osteoporotic vertebral fractures through injection of polymethylmethacrylate (PMMA). Recent placebo-controlled (sham) investigations have assessed the efficacy of vertebroplasty. This Cochrane review provides information about the available randomised controlled trials (RCTs) current to November 2014 and is intended for use in clinical and policy decision-making.

Methods
RCTs on adult osteoporotic vertebral fractures published as full articles were considered for inclusion. Comparators were: placebo/sham; supportive care; balloon kyphoplasty or similar procedure; pharmacological treatment; or other form of intervention. Outcome data on pain, disability, quality of life and complications, were extracted and pooled where possible from 11 included trials. Bias was assessed according to the Cochrane Collaboration recommendations.

Findings
Least risk of bias was found in two placebo-controlled RCTs, which yielded moderate quality evidence suggesting that the premise of vertebroplasty providing no clinically significant benefits over placebo. In contrast, six trials comparing vertebroplasty with usual care yielded generally positive findings favouring vertebroplasty, although there was considerable heterogeneity in pooled outcomes.

Commentary
The review denies a role for vertebroplasty in the treatment of osteoporotic vertebral fractures. The disparate results of placebo-controlled studies with sham procedures as compared to studies with unblinded usual care control groups strongly suggests performance and detection biases that undermine confidence in these positive results.

The review is well constructed with one exception, which readers should be aware of when interpreting the results. Data is not comprehensively presented on the actual effective agent—the injected PMMA. Recent Swiss registry results have identified PMMA volume as a primary determinant of clinical benefit in balloon kyphoplasty. Several experimental publications have determined the effective dose of 4–6 mL in the average thoracolumbar vertebra (around 15% of vertebral body volume). However, the exact volume required for effective vertebroplasty remains a matter of debate. This variable is an essential factor when conducting an RCT in order to demonstrate beyond reasonable doubt that the treatment group genuinely received what would be considered a ‘therapeutic’ dose.

The study indicates that trial volumes ranged between 2.8 and 4.1 mL averages. The original publication by Kallmes however does not provide this data and it is not certain that volume was recorded. The lowest average volume of all trials is 2.8 mL. The Cochrane review indicates approximately 3 mL was injected on average. The original protocol of Buchhinder stipulates 3–4 mL injection, however the substantial SD of ±1.2 mL from the original publication, which indicates very minimal volume application in some cases, is not mentioned. A subsequent publication on the same patient group indicates at least 16 patients having received 2.5 mL or less. Unsurprisingly, little clinical difference was seen when comparing groups with volumes under 2.5 mL (the comparison should be with those receiving close to 4 mL for thoracolumbar vertebra).

Both sham RCTs have not demonstrated that the treatment group actually received an adequate augmentation volume and therewith an effective treatment dose. This has been reviewed in detail previously. Pooling the results appears questionable. A published breakdown of levels treated and augmentation volumes applied versus clinical outcome would clarify the validity of these trials. As such, while the review is very thorough and undoubtedly helpful for clinicians, the conclusion that vertebroplasty lacks clinical evidence needs to be read with care.

Implications for practice
The presented review denies vertebroplasty a place in current clinical practice. For researchers conducting clinical trials, this review provides insight into potential design improvements.

Competing interests None declared.

Provenance and peer review Commissioned; internally peer reviewed.

References
Percutaneous vertebroplasty does not reduce pain and disability from osteoporotic vertebral compression fracture
Broniek Bosczczyk

Evid Based Med published online August 31, 2015

Updated information and services can be found at:
http://ebm.bmj.com/content/early/2015/08/30/ebmed-2015-110233

These include:

References
This article cites 6 articles, 0 of which you can access for free at:
http://ebm.bmj.com/content/early/2015/08/30/ebmed-2015-110233

Email alerting service
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Topic Collections
Articles on similar topics can be found in the following collections

Musculoskeletal syndromes (219)
Osteoporosis (55)
Clinical diagnostic tests (440)
Radiology (337)
Pain (neurology) (413)
Injury (154)
Clinical trials (epidemiology) (1594)

Notes
To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/