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Review article

Stentoplasty effectiveness and safety for the treatment of osteoporotic vertebral fractures: A systematic review

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ABSTRACT

To assess the effectiveness and safety of stentoplasty in people with osteoporotic vertebral body fractures. A systematic search of databases including MEDLINE, EMBASE and Cochrane library, between others, was conducted to June 9, 2014. Clinical trials and observational studies that included alive adults with osteoporotic vertebral body fractures and the comparators were the intervention himself, vertebroplasty or balloon kyphoplasty were selected. Quality of evidence was graded according to the GRADE approach. Two review authors independently selected studies, assessed risk of bias and extracted data. Forty-two citations were identified during the search. After removing duplicates, five studies were included: two clinical trials and three observational studies. Stentoplasty, showed higher rate of adverse events related to material ($P = 0.043$) and cuff pressure ($P = 0.014$) in comparison to kyphoplasty. There was no difference between two procedures in terms of reduction of kyphosis, time of exposure to radiation or postoperative loss of cement. Stentoplasty in comparison to vertebroplasty, showed an improvement of restoration of vertebral height ($P = 0.042$), kyphosis correction and volume of bone cement. No differences were found between two procedures in terms of loss of vertebral body volume. Based on observational studies, stentoplasty improved vertebral height, pain and functional disability at 6 and 12 months follow-up, and corrected the angle vertebral fractures in patients with osteoporotic vertebral body. Stentoplasty was presented as a safe procedure in short-medium term, with a low complication rate, a reduced loss of cement and new vertebral body fractures lower rates. Stentoplasty improves vertebral height, reduces the pain and functional disability and correct the vertebral angle in patients with osteoporotic vertebral body fracture with minimum adverse events. Stentoplasty is comparable to kyphoplasty in terms of correction of kyphosis, time of exposure to radiation and cement postoperative loss, and comparable to vertebroplasty in terms of restoration of vertebral height correction and bone cement volume.
Level of evidence: Level II systematic review.

1. Introduction

Vertebral compression fractures (VCFs) are the most common type of osteoporotic fractures [1] and increases exponentially with age. It is estimated that VCFs occur in approximately 26% of women aged 50 years or older [2]. In VCFs, one or more vertebrae are compressed, leading to a reduction in height and potentially also to abnormal curvature of the spine (kyphosis). In 66% of cases, the VCFs can lead to sever acute and chronic pain, impaired mobility and reduced quality of life caused by the loss of vertebral body height [3]. Therefore, the goal of treatment is to relieve pain and postural impairment caused by loss of vertebral body height without replacing [4,5]. Non-invasive treatment (such as pain medication, bed rest and back braces) focuses on alleviating symptoms and supporting the spine. However, in patients whose severe pain does not resolve with conservative management, surgical spinal stabilization is necessary [6,7]. The initial surgical treatment of VCFs was percutaneous vertebroplasty, a minimally invasive surgical procedure in which bone cement is injected into a fractured vertebra under radiological guidance using fluoroscopy [8]. Vertebroplasty stabilizes the column while increasing patient mobility and reduces the pain associated with the fracture. However, this procedure does not correct the deformity and kyphosis spinal compression associated with morbidity [9–11]. Balloon kyphoplasty (BK) is a variation of this approach in which an inflatable balloon

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tamp is placed in the collapsed vertebra before cement injection in order to create a virtual cavity allowing low-pressure cement injection [12,13]. A potential advantage of this procedure is that it may partially correct the reduction in vertebral height, however the degree of height restoration may be none or minimal after deflating the balloon [14,15].

Stentoplasty has been proposed as a new minimally invasive therapeutic option for patients with VCFs. In this approach a small balloon catheter surrounded by a metal stent is inserted into the vertebral body in order to maintain the vertebral height of the cavity into which bone cement is then injected. The expanded stent provides mechanical stability and keeps open the created cavity, preventing the collapse of the vertebral body while the balloons are folded and removed [6]. The average time for completion of the procedure is about 45 minutes. The patient can be incorporated as soon as tolerated and is free to resume physical activity as a function of the intensity of pain. One of the goals of vertebral body stenting was to improve patient safety and reduce the risk of cement leakage by formation of a cavity for cement application, as occurs with balloon kyphoplasty. This procedure could allow vertebral fractures to be fully corrected and to stop the loss of restored vertebral body height after balloon deflation. However, clinical outcomes of evidence for this procedure are variable and contradictory and the advantage of vertebral body stenting remains unclear, so the optimal treatment of this patient population is still debated. The aim of this study is to determine the clinical effectiveness and safety of stentoplasty as a treatment for patients with osteoporotic VCFs as himself, as in comparison to vertebroplasty or balloon kyphoplasty.

2. Methodology

A systematic search of databases including MEDLINE, EMBASE and Cochrane library, The Cochrane Central Register of Controlled Trials (CENTRAL), University of York Centre for Health technology Assessment (INAHTA), Clinicaltrials.gov and UK National Research Register was conducted with a cut-off date of June 9, 2014. The search strategies combined MeSH (Medical Subject Headings), Emtree terms and text words to define the population, index test (stentoplasty), comparator and outcomes (PICO format). Searches were not limited by language, date or publication type except letters from publishers. Additionally, reference lists of the final selection of articles were checked manually to identify other relevant papers. Clinical trials (randomized or not) and observational studies involving more than 15 patients and including alive people of any age and either sex with painful osteoporotic vertebral body fractures and the comparators were the intervention himself, vertebroplasty or balloon kyphoplasty were selected. Studies which also included participants with non-osteoporotic vertebral fractures of other aetiologies (e.g. fractures associated with trauma, myeloma or metastatic cancer) were included if data relating to participants with osteoporotic fractures could be extracted separately, or if the proportion of participants with non-osteoporotic fractures was extremely small ($n < 5$). Studies in animals models, preclinical and biological studies, narrative reviews, editorials, surveys, conference papers or series of individual cases and studies with modifications of the standard stentoplasty were excluded from the review. Titles and abstracts of all retrieved articles were scanned for inclusion by two reviewers with reference to a third reviewer when there was any doubt about their eligibility for reaching consensus. Primary outcomes were pain/analgesic use, incapacity/back-specific functional status, mortality and complications. Vertebral body height and angular deformity, incidence of new vertebral fractures, and cement leakage were considered as secondary outcomes. Only studies which reported data relating to at least one of the primary or secondary outcomes listed were eligible for inclusion in the review. Full paper articles were retrieved for further assessment and if there was doubt regarding inclusion from the title and abstract, the full article was obtained for clarification. The quality of the included studies was critically assessed by the same two reviewers using a tool based on the criteria proposed by Stevenson et al for non-experimental studies, and by the Cochrane Collaboration for controlled trials. All information was extracted from the articles selected by two independent reviewers using predesigned forms specifically for this. A qualitative and quantitative (if it was possible) synthesis was performed from the results provided by those studies that met the inclusion criteria and P values < 0.05 as statistically significant, were considered with confidence intervals at 95%. The method used for determining the level of evidence for the outcome variable was described by GRADE (GRADE tables available electronic annex).

3. Results

Forty-two citations were identified during the search. After removing duplicates and applying the exclusion criteria, five studies were finally included [16–20] (Fig. 1): two clinical trials [16,20] (one non-randomized [16]) and three observational prospective [18,19] and retrospective studies [17]. Clinical trials compared stentoplasty with percutaneous balloon kyphoplasty [20] and stentoplasty with percutaneous vertebroplasty ($n = 29$) [16]. None of included studies compared results of stentoplasty with conservative treatment or non-surgical management. Table 1 shows the included studies description.

Included studies accounted a total of 213 symptomatic patients (77.4% women and 22.5% men) between 35 and 94 years of age (mean 71.5 years). All included patients had persistent local midline back pain refractory to conservative treatment for indeterminate time and back pain related to the site of the fracture on magnetic resonance imaging (MRI), only one study [16] included patients with pain refractory to conservative treatment for at least 6 weeks. Description of population in included studies is presented in Table 2. Only one study [20] defined osteoporotic fractures as fractures that occurred spontaneously or as a result of minimal trauma from day-to-day activities, but did not it in terms of bone mineral density. The remainder appeared to assume the presence of osteoporosis from the presence of VCF in the absence of any other known fracture aetiology. The procedures were performed through a percutaneous transpedicular approach with two stents placed below the collapsed vertebral endplate as seen on a fluoroscopic view, except one [17] that did not inform about used method. The included studies varied in terms of internal validity. The potential sources of bias in case of included clinical trials were the lack of clarity about the method of both assignment to treatment groups and concealment of allocation, as only one of them [20] was reported as randomized. Because of the radio-opaque nature of the cement used for stentoplasty, vertebroplasty or kyphoplasty, it is impossible to blind the assessors of radiographic outcomes (vertebral body height, kyphotic angle and incident fracture) to treatment allocation. However, there is no other reason why blinded assessors should not have been used to collect data relating to other outcomes (detection bias).

3.1. Stentoplasty versus percutaneous balloon kyphoplasty

Only one controlled trial compared the stentoplasty clinical and radiological results with balloon kyphoplasty ($n = 65$, 100 fractures) [20] (Table 3). There was no difference between the two procedures in terms of reduction of kyphosis (low quality), time of exposure to radiation or postoperative loss of cement