
Percutaneous Stentoplasty (Vertebral Body Stenting) for the Treatment of Osteoporotic Vertebral Fractures

Synthes Submission for the NICE Multiple Technology Appraisal on Osteoporotic Vertebral Fractures

Date of submission 8th February 2012
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1. Executive Summary

The symptomatic vertebral compression fracture can negatively impact health and quality of life by causing substantial pain and severe disability. This pathology has been associated with decreased life expectancy and increased morbidity. It is characterised by a collapse of the vertebral body which leads to a spinal deformity due to a reduction in the vertebral body height. It is estimate that the number of patients diagnosed with an osteoporotic vertebral compression fracture is about 20,908 each year in the UK (See Epidemiology, Section 2.2.1). However, only between 2 and 5% of those undergo surgical intervention (i.e. vertebroplasty or balloon kyphoplasty with or without stent) with the vast majority being treated conservatively.

Conservative management focuses on the alleviation of symptoms with analgesic medications and spinal support. Even the highest standard of conservative management does not allow for a restoration of spinal alignment and thus cannot prevent kyphotic deformity. Therefore, conservative management will never prevent the progression of the deformity and individuals managed in this way are more likely to have new fractures as the condition progresses (See Description of pathology, Chapter 2.2). Height restoration and realignment of the vertebral bodies are important factors to prevent progression of the deformity and commensurate deterioration of quality of life. Surgical techniques such as vertebroplasty, balloon kyphoplasty and stentoplasty (Vertebral Body Stenting) can be an option to alleviate pain and restore height as well as the normal curvature of the spine. Surgical treatment usually leads to an immediate pain relieve and allows for an early remobilisation and return to normal activity for patients. Vertebroplasty, balloon kyphoplasty and stentoplasty consist in inserting solidifying cement into the vertebral body through a minimal invasive surgical procedure (See Mechanism of action, Section 2.4.2). Vertebroplasty is mainly applied for fracture stabilization and pain relief. Balloon kyphoplasty allows for a correction of functional kyphotic deformity and height restoration through the insertion of an inflatable balloon. However, with this approach there was still loss of vertebral body height and realignment after balloon deflation. Therefore further improvement in clinical management was required.

The Stentoplasty system, developed by Synthes, involves the implantation of Vertebral Body Stents (VBS, 2 implants per level). The stent mounted on the balloon aims at keeping the restored height and thus overcoming the problem of partial height loss after removal of the balloon. The VBS stent is expanded inside the collapsed vertebra and offers height restoration and height conservation while at the same time offering a cavity for injection of highly viscous PMMA based bone cement approved for use in vertebroplasty or balloon kyphoplasty procedures (See Clinical Effectiveness, Chapter 3). The VBS system is intended for the reduction of painful vertebral compression fractures and/or creation of a void in cancellous bone in the spine for the treatment of levels ranging from Th5-L5. It is indicated for painful osteoporotic vertebral compression fractures (Genant Grade 2 and Grade 3), without posterior wall involvement i.e. (See Indication, Section 2.4.3).

Extensive mechanical and biomechanical testing has been performed to characterize the mechanical behaviour and performance of the Synthes VBS System, as well as its ability to be used for the reduction of fractures and creation of a void in cancellous bone (See Summary of Vertebral Body Stenting biomechanical studies, Paragraph 3.2). The preclinical testing of the VBS System was designed to evaluate all relevant loading conditions that may impact the device to demonstrate a reasonable assurance of safety. These biomechanical tests demonstrated a significant decrease of height loss after balloon deflation using VBS compared to balloon kyphoplasty. For instance, VBS was able to significantly maintain the pre-fracture height and avoid a loss of reduction which has been measured with balloon deflation in kyphoplasty.

Synthes has initiated a multicenter randomised controlled trial which is still ongoing. It compares the VBS system with balloon kyphoplasty. The primary endpoints are VAS and restoration of vertebral body height (beck index). First results are expected to be available at the end of 2013 (See Ongoing clinical trial, Paragraph 3.4). Until now there have been one prospective case series, three retrospective case series and one multi-centre case series published (See Clinical Effectiveness, Chapter 3). These studies account for a total of 209 patients with 148 being osteoporotic patients. The outcomes measured in these studies were pain, functional status, vertebral body height and angular deformity, progression of adjacent level vertebral fractures, cement leakage and stent opening.

In all these studies, the use of VBS showed positive clinical results and demonstrated a significant level of pain relief and functional improvement. Overall, VAS and ODI score were reduced by 6.4 points and 41.7% respectively at 12 months. In addition, a substantial improvement of the vertebral body height to 15.3% at 12 months was also demonstrated, as well as a good kyphosis correction to 4.5° at 12 months (See Clinical Effectiveness, Chapter 3). The risk of adjacent vertebral fracture was estimated to be 9%, which seems similar or somewhat lower than the rates reported in the literature for vertebroplasty and balloon kyphoplasty. In addition, a rate of 3% of symptomatic cement leakage has been reported, mainly causing radiculopathy. However, this rate was assessed using older version of the cement sold by Synthes (Vertecem). This cement was replaced in the meantime by a newer formula (Vertecem V+) which has a significantly higher viscosity. We believe that this new cement should significantly reduce the leakage rate.

Considering the first clinical results of VBS (both published and unpublished) we consider VBS to be a safe and effective surgical technique to treat osteoporotic vertebral compression fractures with a low rate of adverse events.

Finally, the cost of treating one patient with painful vertebral fracture is largely driven by the costs of hospitalisation, analgesia usage, community care and procedural costs (eg, operator fees and equipment costs for vertebroplasty and balloon kyphoplasty or stentoplasty). However, there is some evidence that balloon kyphoplasty and stentoplasty may shorten hospital length of stay compared to hospitalised patients treated conservatively (See Cost-effectiveness, Chapter 4).