NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Percutaneous insertion of craniocaudal expandable implants for vertebral compression fracture

A vertebral compression fracture occurs when the main part of one of the bones in the spine (the vertebral body) is crushed. This can be caused by injury, osteoporosis (weakening of the bones) or the spread of cancer into the spine. In this procedure, metal implants are inserted through the skin and into the crushed vertebra. The implants are expanded to the desired size and surrounded with bone cement. The aim is to improve symptoms caused by the compression fracture.

The National Institute for Health and Care Excellence (NICE) is examining percutaneous insertion of craniocaudal expandable implants for vertebral compression fracture and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about percutaneous insertion of craniocaudal expandable implants for vertebral compression fracture.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.
- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 22 July 2016

Target date for publication of guidance: November 2016

1. Draft recommendations

1.1. The evidence on percutaneous insertion of craniocaudal expandable implants for vertebral compression fracture raises no major safety concerns. Evidence on its efficacy is adequate. Therefore this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit.

1.2. Patient selection and treatment should be done by a specialist multidisciplinary team that includes a radiologist and a spinal surgeon.

1.3. The procedure should be limited to patients whose pain is refractory to more conservative treatment.

2. Indications and current treatments

2.1. Vertebral compression fractures usually occur when the front of the vertebral body collapses, and may be caused by trauma, cancer or osteoporosis.

2.2. Pain is the most common symptom in patients with vertebral compression fractures. Fractures can also cause progressive spinal deformity with abnormal curvature (kyphosis). This can lead to increased risk of further fracture at adjacent levels and progressive malalignment, deformity and pain.

2.3. Treating vertebral compression fractures aims to reduce pain, improve function and minimise the incidence of new fractures. Non-invasive treatment (such as pain medication, bed rest, and back braces) focuses on relieving symptoms and supporting the spine.

2.4. Surgery such as percutaneous vertebroplasty and balloon kyphoplasty may be considered in patients whose condition is refractory to medical therapy and when there is continued vertebral collapse and severe pain. Sometimes more invasive surgery with vertebral body realignment and instrumented fusion (bone grafts and spinal rods) may be needed.

3. The procedure

3.1. Percutaneous insertion of craniocaudal expandable implants for vertebral compression fracture aims to restore vertebral height and

augment the fractured vertebral body to relieve pain and increase mobility.

3.2. Vertebral craniocaudal expandable implants are inserted under general, regional or local anaesthesia. With the patient in a prone position, using fluoroscopic guidance, trocars are inserted through the vertebral pedicles into the vertebral body, which is then cannulated. Unexpanded implants, mounted on a bespoke instrument, are placed inside the vertebral body and expanded to restore vertebral height. High-viscosity bone cement is injected into and around each implant, filling the space in the surrounding bone.

4. Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview ***[add URL]***.

4.1. In a randomised controlled trial (RCT) of 300 patients treated by a vertebral craniocaudal expandable implant (n=153) or by balloon kyphoplasty (n=147), procedure success at 12 months was 94% (120/127) in the implant group and 98% in the balloon kyphoplasty group (no statistically significant difference between groups; Bayesian credible interval −3%, 9% to 2%). Procedure success was defined as a reduction in pain by 15 mm or more from baseline on the 100 mm visual analogue scale (VAS), maintenance of function (did not worsen by 10 or more points) or improvement in function from baseline on the 100-point Oswestry disability index (ODI), and no device-related serious adverse events.

4.2. In the RCT of 300 patients treated by a vertebral craniocaudal expandable implant (n=153) or by balloon kyphoplasty (n=147),

there was a statistically significant improvement from baseline in the mean VAS scores for pain (0–100 mm, from no pain to worst imaginable pain) in both groups at follow-up. In the implant group, the mean VAS score changes (± standard deviation, SD) from baseline were: −59.8±28.9 (n=140) at 30 days, −68.6±25.9 (n=135) at 6 months and −70.8±26.3 (n=127) at 12 months. In the balloon kyphoplasty group, the mean VAS score changes from baseline were −61.1±26.9 (n=135) at 30 days, −65.2± 27.4 (n=126) at 6 months and −71.8±23.5 (n=126) at 12 months. No statistically significant differences between groups were seen at follow-up. In a retrospective matched-paired comparative study of 52 patients treated by a vertebral craniocaudal expandable implant (n=26) or by balloon kyphoplasty (n=26), the mean VAS scores (±SD) improved in both groups from 87.6±12.8 before the procedure to 10.8±20.8 at 6 months in the implant group and from 83.1±14.9 to 24.6±11.0 in the balloon kyphoplasty group (p value within group not reported). VAS scores 6 months after the procedure were statistically significantly different between groups (p<0.0001).

4.3. In the RCT of 300 patients treated by a vertebral craniocaudal expandable implant (n=153) or by balloon kyphoplasty (n=147), the mean ODI score (0–100, from no disability to maximum disability) changes from baseline were −31.4±21.9 (n=140) at 30 days, −37.7±20.1 (n=135) at 6 months and −38.1±19.8 (n=127) at 12 months in the implant group. In the balloon kyphoplasty group, the mean ODI score changes from baseline were −34.6±20.4 (n=135) at 30 days, −38.4±20.4 (n=126) at 6 months and −42.2±21.7 (n=126) at 12 months. There was a statistically significant improvement in ODI scores within groups but not between groups (level of statistical significance not reported).

4.4. In an RCT of 185 patients treated by a vertebral craniocaudal expandable implant (n=92) or by balloon kyphoplasty (n=93), there was a statistically significant improvement in the mean short-form (SF)-36 (physical functioning domain) scores in both groups from 32±11 before the procedure to 65.8±15.6 at 1 year in the implant group and from 28±12 to 68±19.8 in the balloon kyphoplasty group (p=0.001 for both groups compared with baseline, but no statistically significant difference between groups at 1-year follow-up, p=0.72). There was also a statistically significant improvement in the mean SF-36 (mental health domain) scores in both groups, from 42±10 before the procedure to 64±11 at 1 year in the implant group and from 41±9 to 62±9.7 in the balloon kyphoplasty group (p=0.001 for both groups compared with baseline but no statistically significant difference between groups at 1-year follow-up, p=0.64).

4.5. In an RCT of 300 patients treated by a vertebral craniocaudal expandable implant (n=150) or by balloon kyphoplasty (n=150), there was a statistically significantly greater increase in vertebral body height after the procedure in the implant group than in the kyphoplasty group ($p<0.05$). In the implant group, vertebral height was restored by more than 50% in 85% of patients, by less than 50% in 12% of patients and there was no change in 3%. In the balloon kyphoplasty group, vertebral height was restored by more than 50% in 58% of patients, by less than 50% in 26% of patients and there was no change in 16%. In the retrospective matched-paired comparative study of 52 patients treated by a vertebral craniocaudal expandable implant (n=26) or by balloon kyphoplasty (n=26), there was a statistically significant increase in anterior and mid-vertebral height (mean±SD) in both groups after the procedure. This increased from 21.06 ± 2.77 mm before the procedure to 22.41± 7.14 mm after the procedure (anterior) and from 18.36±

5.64 mm to 20.89± 6.00 mm (mid) in the implant group, and from 21.68 ± 2.08 mm to 25.09± 2.54 mm (anterior) and from 21.97± 1.78 mm to 25.29± 2.10 mm (mid) in the balloon kyphoplasty group ($p<0.001$ for the within-group comparison). At 6 months vertebral height had not changed much from after the procedure in both groups: in the implant group, anterior vertebral height was 22.28 ± 6.85 mm and mid-vertebral height was 21.19± 6.08 mm, and in the balloon kyphoplasty group, anterior vertebral height was 24.56± 2.27 mm and mid-vertebral height was 24.91± 2.08 mm. In a prospective case series of 32 patients, the mean (±SD) Beck index (anterior edge height divided by posterior edge height) changed from 0.75± 0.14 before the procedure to 0.77± 0.14 at 12 months.

4.6. In the RCT of 185 patients treated by a vertebral craniocaudal expandable implant (n=92) or by balloon kyphoplasty (n=93) there was a statistically significant decrease in mean (±SD) wedge angle only in the implant group, from 13.7±7 degrees before the procedure to 7.80±6 degrees after the procedure ($p=0.009$). The mean wedge angle in the balloon kyphoplasty group decreased from 14.9±8 degrees to 11.5±7 degrees ($p=0.067$). Wedge angles after the procedure were not statistically significantly different between groups ($p=0.11$). In the prospective case series of 32 patients, there was a statistically significant decrease in the mean (±SD) vertebral kyphotic angle and in the mean Cobb angle from 9.0± 5.8 degrees before the procedure to 8.3± 5.6 degrees at 3 days and 8.3± 5.5 degrees at 12 months. For the mean (±SD) Cobb angle there was a statistically significant decrease from 12.3± 16.4 degrees before the procedure to 10.8± 16.4 degrees at 3 days and 10.8± 16.3 degrees at 12 months ($p<0.05$ for the comparisons at 12 months versus baseline).

4.7. In the RCT of 185 patients treated by a vertebral craniocaudal expandable implant (n=92) or by balloon kyphoplasty (n=93), there was residual kyphosis of 5 degrees or more at the final observation in 84% (69/82) of spines in the implant group and in 100% (86/86) of spines in the balloon kyphoplasty group (p<0.001).

4.8. The specialist advisers listed the following key efficacy outcomes: radiological parameters such as restoring and maintaining vertebral body height, alignment and sagittal balance, and functional outcome measures.

5. Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview ***[add URL]***.

5.1. Death was reported in 2 patients in a prospective case series of 32 patients treated by a vertebral craniocaudal expandable implant. One death was caused by heart failure 4 months after the procedure and the other was caused by metastatic pancreatic cancer 8 days after the procedure.

5.2. Cement extravasation measured immediately after the procedure and assessed on X-ray by an independent laboratory was reported in 55% (98/177) of vertebra levels in patients treated by a vertebral craniocaudal expandable implant and in 58% (103/178) of levels in patients treated by balloon kyphoplasty in an randomised controlled trial (RCT) of 300 patients treated by an implant (n=153) or by balloon kyphoplasty (n=147). There was no statistically significant difference between the groups; Bayesian credible interval (BCI) −3% (−13% to 8%). However, in a secondary analysis, cement

extravasation was reported statistically significantly less frequently in the implant group than in the balloon kyphoplasty group (17% [30/177] of levels compared with 26% [46/178] of levels, difference in BCI −9% [−17% to −0.33%]). Cement leaks were reported statistically significantly less frequently in the implant group (3% [4/133] of vertebras) than in the balloon kyphoplasty group (10% [12/122] of vertebras; p≤0.05) in an RCT of 185 patients treated by a vertebral craniocaudal expandable implant (n=92) or by balloon kyphoplasty (n=93). Intracanal leaks were reported in none of the patients treated by the implant and in 2% (2/86) treated by balloon kyphoplasty. Cement leaks identified by CT scan were reported in 14% (11/77) of patients in a retrospective case series of 77 patients treated by a vertebral craniocaudal expandable implant. All patients had post-traumatic fractures. One patient had nerve root pain caused by the cement leaking along a secondary fracture line in the pedicle (see section 5.4).

5.3. Dural tear was reported in 1 patient in a case series of 57 patients. It occurred during the initial pedicle access with the Jamshidi needle. It was treated with Gelfoam and there were no residual or permanent sequelae.

5.4. Adjacent level fracture was reported in 21% (28/134) of the as-treated population in the implant group and in 22% (29/130) of the as-treated population in the balloon kyphoplasty group in the RCT of 300 patients treated by an implant (n=153) or by balloon kyphoplasty (n=147). There was no statistically significant difference between the groups; BCI −1% (−11% to 8%). In the same study, a fractured pedicle was reported in 1 patient in the implant group. It was associated with the use of the implant in the setting of sclerotic bone. This resulted in back pain at the time of discharge, which was treated with analgesics. New fractures were

reported in 12% (3/26) of patients in the implant group and in 54% (14/26) of patients in the balloon kyphoplasty group in a retrospective matched-paired comparative study of 52 patients. The difference between the groups was statistically significant, $p<0.0001$. Adjacent fractures were reported in 8% (2/26) of patients in the implant group and in 35% (9/26) of patients in the balloon kyphoplasty group.

5.5. Pain after the procedure was reported in 1 patient in the implant group in the RCT of 300 patients treated by an implant (n=153) or by balloon kyphoplasty (n=147).

5.6. Skin infection that started in hospital was reported in 1 patient in the retrospective case series of 77 patients. The infection was probably caused by contamination from an oral infection and was treated with antibiotics.

5.7. Haematoma was reported in 1 patient in a different prospective case series of 32 patients treated by a vertebral craniocaudal expandable implant; revision was not needed.

5.8. Minor loss of height of the stabilised L2 vertebral body in an osteoporotic fracture was reported in 1 patient in the second prospective case series of 32 patients. The Beck Index changed after the procedure from 1.0 to 0.96 and the Cobb angle changed from 11 degrees to 13 degrees. The visual analogue scale score remained unchanged.

5.9. Collapse of the disc above the operated vertebral body as a result of the trauma which caused the initial fracture was reported in 1 patient in the first prospective case series of 32 patients.

5.10. Device migration was reported in 1 patient in the retrospective case series of 77 patients; this reflected a technical problem that occurred with an instrument prototype.

5.11. In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: incorrect placement of the implant, implant tilt in osteoporotic bone and endplate fracture so that vertebral body height was not restored. They considered that the following were theoretical adverse events: failure to deploy the implant correctly and implant-related problems such as failure to raise the endplates.

6. Committee comments

6.1. The committee noted that several different devices are available for this procedure.

6.2. The committee noted that most of the evidence is for use in osteoporotic vertebral fractures and that there was very little evidence for using the procedure in traumatic or metastatic fractures.

7. Further information

7.1. For related NICE guidance, see the NICE website.

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