

National Osteoporosis Society Submission

7 February 2012

NICE Multiple Technology Appraisal - Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures

Introduction

In 2011 the National Osteoporosis Society Helpline received nearly 100 enquires about percutaneous vertebroplasty/percutaneous balloon kyphoplasty. The main issues we hear from patients about these procedures concern pain (“will it help with the awful pain I have?”), posture (“will it improve my spinal curvature”), how they work (“why does pain improve?”) and their potential risks.

During January 2012 a survey was conducted with members of the National Osteoporosis Society on their experience of vertebral fracture. It also sought their views on the potential for percutaneous vertebroplasty/percutaneous balloon kyphoplasty to be used in treating such fractures. Quotes in this submission are from survey respondents, who include patients and carers affected by vertebral fracture. Many of the issues we hear about on the helpline are echoed in the responses we have received: pain, height loss and potential risks of the procedures. In addition to the physical effects of fracture, respondents have highlighted the ways in which vertebral fractures have affected their personal lives, including:

- ability to work (“I was forced to retire from my nursing work; I had to give up my job as a teacher”)
- ability to care (“I couldn't dress myself without help from my husband for four months”; my husband is blind so I am responsible for all of the housework and jobs around the house. Since (my fractures) I have not had the ability to do these jobs”)
- emotional wellbeing (“my daughter feels very guilty at not being able to help; I could no longer keep my diagnosis of osteoporosis with spinal fractures a 'secret' at work, and expected to have to retire”).

It is recognised that not all fractures come to the attention of clinicians, but it is apparent from the survey that healthcare professionals are not identifying patients presenting with pain as having potentially suffered a vertebral fracture.

- “It was assumed that my pain was muscular; the first three fractures were not diagnosed until months after the event; the doctors thought I had just pulled muscles - I was in agony.”

Identifying how these patients can benefit from effective treatment (whether current standard treatment or vertebroplasty/percutaneous balloon kyphoplasty) also needs to be addressed.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

Advantages

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

The technology should help with the short and medium term relief of pain from incident vertebral fractures. It should reduce suffering and improve quality of life for these individuals.

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(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology.

Pain relief, and the impact it will have on their quality of life, is a key benefit patients hope to gain from the technology:

- “If it reduced the pain, then the benefits would be enormous, as it is the pain that is so debilitating and restrictive, in every day life”
- “I am virtually housebound from the pain, and small tasks like housework are impossible. I am 32 years old; it has affected my life completely.”

Height loss and spinal deformity are of concern for patients with vertebral fractures. The technology could potentially relieve physical symptoms and levels of disability associated with vertebral fractures. It could also improve the mental health and quality of life of those affected:

- “Not to lose any more height which would help digestion as can only have very small meals. Have lost two stone in 18 months.”
- “Kyphosis has affected my swallowing in that it takes me over an hour just to eat one course with the result this restricts social activities, such as eating out.”
- “Height loss (5.5 inches) has resulted in all sorts of every day to day problems through not being able to look up in advance where I am going or reaching items from above eye level”
- “My body shape has completely changed and I struggle to find clothes to fit. I cannot bear to look at myself in the mirror as I look old and bent over.”

Disadvantages

Please list any problems with or concerns you have about the technology.

The risk of complications from the procedure:

- adverse effects due to implantation of balloon or leakage of cement
- increased risk of new vertebral fractures in the adjacent vertebra.

Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

Yes. Many patients feel they do not have the information available to make an informed decision. They can be influenced by the information they receive from health professionals or other patients, in addition to whether they have had a good/bad experience with the procedure.

Are there any groups of patients who might benefit more from the technology than others?

Patients with significant symptoms (acute back pain, soon after vertebral fracture) which are not responding to standard therapy

Are there any groups of patients who might benefit less from the technology than others?

It is less clear whether there is any benefit in those with persistent or chronic back pain due to fracture.

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Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

Please list any current standard practice (alternatives if any) used in the UK.

In the UK current standard treatment would involve:

- analgesia, stepped according to level of pain
- limited bed rest and physiotherapy (heat, TENS, gentle exercise)
- bracing
- facet joint injection

In very severe cases a course of sub-cutaneous or nasal calcitonin, or infusion of iv bisphosphonates might be given.

If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them.

Improvement in pain and quality of life may be better in some patients with the technologies when compared to existing treatment. If the technology is effective, the symptoms usually settle more quickly.

The technology has advantages over conventional analgesia, which may result in side effects or, in some patients, be ineffectual.

- "Pain relief was ineffective. The side effects were horrific."
- "Do not like being on a pain patch but intolerant of oral medication."
- "The pain relief made me very ill ...and was sick every half hour. Didn't help with the pain."
- "I don't sleep very well and constant pain killers affect me badly so I have to have a break."

If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them.

- "Side effects which may not be fully known."
- "Worry that it might make the back worse and go wrong and become more disabled."

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

The technology is linked with very positive beneficial effects on patients' symptoms in observational studies. However, controlled trials do not confirm (other than kyphoplasty in one study) any definite benefits of the intervention over a sham procedure. Some of the negative outcomes from trials may relate to inclusion of patients who would be less likely to respond.

Availability of this technology to patients in the NHS

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What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

The technology would provide an option for the management of patients with severe osteoporosis and vertebral fractures who are not responding to conventional therapy and in whom quality of life may be significantly affected:

- “Patients could discuss the procedure with specialist.”
- “It would offer treatments which otherwise would not be available.”
- “HOPE”

What implications would it have for patients and/or carers if the technology was not made available to patients on the NHS?

This would reduce the management options that comprise the potential treatment strategy for what can be a painful and debilitating syndrome:

- “Would be a disadvantage to patients not able to fund private treatment.”
- “Less treatments meaning those who have the financial means are better treated than those who do not.”
- “It is not just the length of life that counts, but the quality of it. It will be sad if people like me can't have the surgery because we can't afford a private operation. Also, in any case, I have far more trust of treatment on the NHS than in private clinics.”

Are there groups of patients that have difficulties using the technology?

- Patients unable to receive local or general anaesthesia.
- Patients living in areas where there was no local service.