NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous vertebroplasty for palliation of painful spinal metastases

Cancer from elsewhere in the body can spread to the spine (spinal metastases), causing severe pain and weakness in the vertebrae (bones of the spine). This may lead to instability or fractures and spinal cord compression.

In this procedure a needle-like probe containing an electrode is inserted into the spinal metastases. It produces an electrical current that heats the cancer cells and destroys them (radiofrequency ablation). The aim is to shrink the spinal metastases to relieve pain and other symptoms (palliation). During the same procedure, bone cement is injected into the resultant cavity (percutaneous vertebroplasty) or a balloon is put into the vertebral cavity to lift the bone into position and then cement is injected (balloon kyphoplasty).

NICE is also looking at transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the <u>draft guidance for consultation</u>. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

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After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a <u>resolution process</u> before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 11 November 2022

Target date for publication of guidance: April 2023

1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous vertebroplasty for palliation of painful spinal metastases is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out <a href="https://www.what.governance.com/what.governance.com/what.governance.com/what.governance.com/what.governance.com/what.governance.com/what.governance.governance.com/what.governance.gove
- 1.2 For auditing the outcomes of this procedure, the main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- 1.3 Patient selection should be done by a multidisciplinary team. The procedure should only be done by clinicians with training and expertise in kyphoplasty or vertebroplasty techniques.

2 The condition, current treatments and procedure

The condition

2.1 Spinal metastases can affect quality of life by causing severe pain, functional impairment, vertebral fractures, nerve root impingement, spinal cord compression and hypercalcaemia.

Current treatments

2.2 Treatment for spinal metastases is always palliative. It aims to reduce pain, improve and maintain function, provide mechanical stability, and prevent further local tumour progression. Current treatment options include a combination of medical therapies (such as analgesics, systemic therapies including osteoclastic inhibitors such as bisphosphonates and denosumab, chemotherapy or

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hormone therapy), orthotic support, radiation therapy (external beam radiotherapy or stereotactic body radiotherapy), and minimally invasive localised percutaneous procedures such as cryoablation, photodynamic therapy, microwave ablation, and radiofrequency ablation. These techniques may also be used with kyphoplasty or vertebroplasty to improve structural or mechanical stabilisation after tumour ablation. Open surgery (or surgery combined with radiotherapy) may be suitable for some people with spinal cord compression and vertebral fractures.

The procedure

- 2.3 Radiofrequency ablation is a procedure for palliative treatment of spinal metastases. It is usually done in a day-case setting using a transpedicular or parapedicular approach under general anaesthesia or local anaesthesia with sedation. The approach is either percutaneous, endoscopic or surgical.
- 2.4 Under imaging guidance (fluoroscopy, CT or MRI) a radiofrequency probe is inserted into the spinal tumour. The radiofrequency probe is attached to a radiofrequency generator, which creates high frequency alternating current pulses that heat and destroy the tumour. This creates a cavity in the vertebral body. In this procedure, percutaneous vertebroplasty or balloon kyphoplasty is done at the same time with the aim of preventing subsequent fractures in the treated vertebrae.
- 2.5 Radiofrequency ablation is not usually done if the spinal metastases are close to neurological structures because of the risk of neurological injury.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 1 prospective case series, 5 retrospective cohort studies and 1 case report. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in pain, reduction in use of analgesics (especially opioids) and health-related quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: cement leakage, infection, and thermal damage to adjacent structures, including neurological damage.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- The committee was informed that the procedure can produce rapid relief of pain.
- 3.6 Different types of radiofrequency ablation devices are used in this procedure, including bipolar and monopolar electrodes.
- The committee were advised that this procedure is primarily used for lytic lesions.

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- 3.8 The committee noted that evidence on the additional benefit of radiofrequency ablation as an adjunct to kyphoplasty or vertebroplasty is limited.
- The committee encourages submission of data to an appropriate register.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
October 2022

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