NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transaxial interbody lumbosacral fusion for low back pain

As a person gets older, the discs between the vertebrae (back bones) can deteriorate. This can cause severe pain and disability and surgery may be needed.

This procedure is done through a small cut at the base of the spine. Part or all of the damaged disc is removed. An artificial implant and bone graft material are inserted into the remaining disc space. It aims to join the 2 back bones together to stop the painful joint moving.

The National Institute for Health and Care Excellence (NICE) is looking at transaxial interbody lumbosacral fusion for low back pain. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are 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 developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please 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 we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 19 April 2018

Target date for publication of guidance: July 2018

1 Draft recommendations

1.1 Evidence on the safety of transaxial interbody lumbosacral fusion for low back pain shows that there are serious but well-recognised complications. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 This procedure should only be done by a surgeon with specific training in the procedure, who should carry out their initial procedures with an experienced mentor.

1.3 Clinicians are encouraged to enter data onto the British Spine Registry.

2 The condition, current treatments and procedure

The condition

2.1 Chronic low back pain may result from degenerative changes in the intervertebral discs or spinal facet joints.

Current treatments

2.2 Conservative treatments include pain relief, non steroidal anti-inflammatory medication and manual therapy (see NICE's guideline on low back pain and sciatica). For people with severe, life-limiting, chronic low back pain that does not respond to conservative treatments, surgery may be appropriate. This may include bony fusion of vertebrae (to immobilise segments of the vertebral column thought to be responsible for back pain, using either a posterior or anterior approach) or inserting a prosthetic intervertebral disc (which preserves lumbar mobility to reduce the risk of degenerative changes in adjacent intervertebral disc spaces). Other surgical alternatives include non‑rigid stabilisation techniques.

The procedure

2.3 Transaxial interbody lumbosacral fusion is done with the patient under general anaesthesia. A small incision is made lateral to the coccyx and a guide-pin introducer is inserted under fluoroscopic guidance. Air insufflation may be used to improve visualisation of the rectum during fluoroscopy. The guide-pin introducer is advanced over the sacrum's midline anterior surface towards the L5–S1 space. A reamer is then passed over the guidewire to the endplate of S1. As with conventional spinal fusion, the disc is

removed through the canal created by the reamer. A mixture typically consisting of commercially available bone graft material, patient's own bone extracted from the surgical site and blood is prepared in the operating theatre and injected into the disc space. A special rod is screwed between the L5 and S1 vertebrae along the canal created by the reamer to maintain segmental height and alignment. Using a posterior approach, pedicle or facet joint screws may be used to provide extra stabilisation.

2.4 The potential benefits of the transaxial approach include faster recovery and less postoperative morbidity compared with conventional spinal fusion surgery.

3 Committee considerations

The evidence

3.1 To inform the committee, 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 8 sources, which was discussed by the committee. The evidence included 2 systematic reviews, 1 non-randomised comparative study, 3 case series and 2 case reports, and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: pain reduction, improvement in Oswestry Disability Index scores, and quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: bowel perforation, damage to adjacent structures, revision surgery, bleeding, and infection.

3.4 This guidance is a review of NICE's interventional procedures guidance on transaxial interbody lumbosacral fusion.

Committee comments

3.5 The committee noted that there was a risk of bowel perforation because of this procedure and that in patients who had this complication, many needed a colostomy.

3.6 The committee was told that most patients having the procedure also have posterior fusion surgery at the same time.

3.7 The committee was told that the technique has evolved over time and much of the evidence reviewed by the committee was from an older version of the device.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee
March 2018

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