

Transaxial interbody lumbosacral fusion for severe chronic low back pain

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg620

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG387.

1 Recommendations

- 1.1 Evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic 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. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 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 should 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, lifestyle-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 Patient commentary was sought but none was received.

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.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).