NICE guidance

Minimally invasive fusionless posterior-approach surgery to correct idiopathic scoliosis in children and young people

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg765

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.

1 Recommendations

1.1 Minimally invasive fusionless posterior-approach surgery to correct idiopathic scoliosis in children and young people should be used only in research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research should include:

- patient selection in terms of age, skeletal maturity, and site and degree of scoliosis
- the technique and device (including version) used
- patient-reported outcomes
- potential damage from local inflammatory processes (including metallosis) and systemic metal poisoning
- long-term movement in the thoracic spine
- long-term complications for the lifetime of the device.

Why the committee made these recommendations

The evidence on efficacy and safety for the procedure is limited. There are only a few studies, which are small and provide no long-term data.

The procedure aims to preserve movement in the spine but there is no evidence about

whether this is beneficial. Also, different versions of the device have been used in different studies, and there is limited evidence for the current version.

There are also safety concerns about:

- potential build-up of metal in the body (metallosis) and metal poisoning from titanium in the device
- bone destruction (osteolysis) where the device is attached to the spine.

This procedure is only recommended for use in research because, overall, there is not enough good quality evidence on its safety and efficacy.

2 The condition, current treatments and procedure

The condition

2.1 Scoliosis is a 3-dimensional change to the spine in the coronal, sagittal and axial planes. It causes the bones of the spine to twist or rotate so that the spine curves sideways. Scoliosis curves most commonly occur in the thoracic spine, but can also occur in the lumbar spine. Occasionally, they occur in both the thoracic and lumbar spine.

2.2 Adolescent idiopathic scoliosis (AIS) is the most common type of scoliosis in children and young people. It is progressive and the exact cause is unknown. Mild to moderate spinal curvature does not cause any health problems but can cause cosmetic concerns. Severe spinal curvature with secondary rib changes can also cause significant pain and lung problems.

Current treatments

2.3 Treatment of AIS depends on several factors, including skeletal maturity, location of the spinal curve, speed of curve progression and size of the curve. Conservative treatments for mild to moderate AIS include routine

surveillance (spinal imaging to monitor progression) and physical therapy. For severe AIS, interventions include casting or bracing (for curves of more than 25 degrees) or spinal fusion surgery (for curves of more than 40 degrees) with various instrumented metallic fixation techniques and grafting to fuse vertebrae. Minimally invasive growth modulating and fusionless surgical techniques to correct idiopathic scoliosis include vertebral body stapling, vertebral body tethering, magnetically controlled growing rods and sublaminar polyester bands. These are also used for AIS in some people. The aim is to correct the scoliosis, prevent progression, restore balance, and reduce pain and morbidity.

The procedure

2.4 Minimally invasive fusionless posterior-approach surgery to correct idiopathic scoliosis is intended to treat AIS in selected people aged 8 years to 17 years whose bones have not fully matured. It is mainly used to correct flexible single curves (a thoracic major curve, or a thoracolumbar or lumbar major curve) with a Cobb angle of up to 60 degrees that reduces to 30 degrees or less on lateral side-bending radiographs, and thoracic kyphosis of less than 55 degrees (as measured from T5 to T12).

2.5 The procedure is done under general anaesthesia and fluoroscopic guidance using a posterior unilateral approach. The concave side of the spinal curve is exposed through an incision around the apex of the curve. Two pedicle screws are inserted into the vertebral bodies through the pedicle above and below the apex of the spinal curvature to serve as anchor points. A ratchet rod with an extender and 2 polyaxial joints (that allow a degree of spinal motion) is then fixed to the spine with pedicle screws that are implanted around the apex of the curve. Distraction during surgery is applied with a manual instrument to expand the rod and to straighten the spine. After the procedure, people are allowed to weight bear during everyday activities.

2.6 About 2 to 3 weeks after surgery, people are advised to exercise daily. This is to allow the rod additional unilateral elongation so there may be further gradual straightening of the spine while the person continues to

grow. Because the procedure does not involve any spinal fusion, spinal motion is preserved. This minimises length of hospital stay and recovery time.

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 4 sources, which was discussed by the committee. The evidence included 2 retrospective case series, 1 retrospective cohort study and 1 prospective cohort study. It is presented in the summary of key evidence section in the interventional procedures overview. The committee also considered data available from the US Food and Drug Administration website. 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: correction of the scoliosis, maintenance of spinal mobility and quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: osteolysis, pain, infection, metallosis and damage to adjacent structures.

Committee comments

3.4 The committee noted that, currently, the rod used in the intervention is intended to be left in place for life.

3.5 The committee was informed that there is more than 1 version of the device and that the technology is evolving.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation