NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

Scoliosis means the spine is curved to the side. It usually starts in childhood and there is usually no known cause (idiopathic). In some people, it can worsen during times of rapid growth, which can cause a severe curve of the spine and can cause problems with the ribs. This can result in significant cosmetic and lung problems, and chronic pain.

In this procedure, under a general anaesthetic, a self-adjusting rod is inserted along the spine through a small cut (minimally invasive) in the back (posterior approach). It is attached to the spine using screws. The rod is lengthened during the operation to straighten the spine. Afterwards, people are given exercises to do to help continue lengthening the rod. The aim is to correct the spinal curve without the need to fuse bones in the spine (fusionless), which is a major operation, and to keep flexibility in the spine.

NICE is looking at minimally invasive fusionless posterior-approach surgery to correct idiopathic scoliosis in children and young people.

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

This document contains the draft guidance for consultation. 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 The draft guidance may change after this consultation.

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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 resolution process 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: 21 February 2023

Target date for publication of guidance: July 2023

1 Draft 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.

1.3 Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

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
- destruction of bone (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 for correction of flexible single curves (a thoracic major curve or thoracolumbar major curve) measuring up to 60 degrees.

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 self-adjusting 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 self-adjusting 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 this device 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.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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