NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Vertebral body tethering for idiopathic scoliosis in children and young people

Scoliosis is the abnormal sideways curving of the spine, which in most cases has an unknown cause (idiopathic). It usually develops in childhood and early adolescence and can lead to deformity of the chest wall. In this procedure, under general anaesthesia, screws are put into the vertebral bodies (bone discs that make up the spine). A cord is fixed (tethered) to the screws and pulled taut, restricting growth on the long side. This allows the spine to grow faster on the short side so that the curve is gradually corrected. The aim is to correct the scoliosis before the person reaches adulthood and their spine stops growing.

NICE is looking at vertebral body tethering for idiopathic scoliosis in children and young people.

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draft guidance for consultation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 The draft guidance may change after this consultation.

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• meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 1 March 2022

Target date for publication of guidance: June 2022

1 Draft recommendations

- 1.1 Evidence on the safety of vertebral body tethering for idiopathic scoliosis in children and young people is limited but raises concerns of serious complications. Evidence on its efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out <u>what only in research means on the NICE interventional procedures guidance page</u>.
- 1.2 Further research should include randomised controlled trials or analysis of registry data.
- 1.3 This procedure should only be done in specialist centres by spinal surgeons with specific training in anterior spinal surgery.

2 The condition, current treatments and procedure

The condition

- 2.1 Scoliosis causes the bones of the spine to twist or rotate so that the spine curves sideways. Scoliosis curves most commonly happen in the upper and middle back (thoracic spine). It can also develop in the lower back and, occasionally, happens in both the upper and lower parts of the spine.
- 2.2 Idiopathic scoliosis is the most common type of scoliosis. It is a progressive condition, and its exact cause is unknown. There are 3 types of idiopathic scoliosis: infantile idiopathic scoliosis, juvenile idiopathic scoliosis and adolescent idiopathic scoliosis.

Current treatments

2.3 Treatment of idiopathic scoliosis depends on a number of factors, including age, severity and location of the spinal curve, and the pattern and progression of the curve. In many cases, idiopathic

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scoliosis is mild (a curve of less than 25°) and does not need treatment other than close monitoring and physical therapy. For moderate scoliosis (a curve between 25° and 45°) and severe scoliosis (a curve greater than 45°), treatment options include casting, bracing and surgery (such as spinal fusion andgrowing rods).

The procedure

- 2.4 Vertebral body tethering is a nonfusion spinal treatment for idiopathic scoliosis. The aim is to preserve the flexibility of the spine and modulate its growth on the concave and convex sides, so slowly correcting the scoliosis.
- 2.5 In this procedure, under general anaesthesia, screws are placed into each vertebra on the convex side of the spine. The screws are connected by a flexible cord. Tension is then applied to the cord to partially correct and tether the convex side of the spine and so restrict its growth. Thoracic tethers are usually done through a thoracoscopic or open approach and lumbar tethers need a miniopen approach. After surgery, the cord continues to restrict growth on the convex side while allowing faster growth on the concave side, so potentially producing further correction of the scoliosis.
- 2.6 The technique exploits a known reaction of bone to being stretched or being compressed. This response is known as the Heuter– Volkmann law and notes that bone growth increases when stretched and decreases when compressed. In scoliosis this response can be used on a curved spine if the bones still have significant growth potential.

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 1 meta-analysis, 3 non-randomised comparative studies, 6 case series and 1 case report. It is presented in the summary of key evidence section in the interventional procedures overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improvement in quality of life and lung function, reduction in scoliotic curve, and maintenance of spinal mobility.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, infection, tether rupture, and need for further surgery.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was informed that:
 - This procedure is indicated for patients with progressive scoliosis who still have significant growth potential.
 - This procedure does not preclude a subsequent posterior spinal fusion if indicated.
 - This procedure may be done when more conservative treatment such as bracing has failed.
 - There is more than 1 device available for this procedure.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

March 2022

ISBN: