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NHS
National Institute for Health and Clinical Excellence

Prosthetic intervertebral disc replacement in the cervical spine

1 Guidance

1.1 Current evidence suggests that there are no major safety concerns about the use of prosthetic intervertebral disc replacement in the cervical spine, and there is evidence of short-term efficacy. Clinicians wishing to undertake this procedure should take the following actions.

- Ensure that patients understand the long-term uncertainties about the procedure and the alternative treatment options. In addition, use of the Institute's *Information for the public* is recommended.
- Audit and review clinical outcomes of all patients having prosthetic intervertebral disc replacement in the cervical spine.

1.2 This procedure should only be performed in specialist units where surgery of the cervical spine is regularly undertaken.

2 The procedure

2.1 Indications

2.1.1 This procedure can be used for patients with acute disc herniation or cervical spondylosis. In these conditions, nerve root or spinal cord compression may cause symptomatic radiculopathy or myelopathy.

2.1.2 Conservative treatment options for acute radicular pain include analgesic medication, rest, supervised physical therapy and local injections.

2.1.3 Surgical intervention is reserved for patients with neurological threat, or for patients whose symptoms fail to settle with conservative care. The standard treatment is surgical decompression of the nerve root or spinal cord by cervical discectomy, with or without fusion (using an iliac crest autograft or a variety of preformed spacers or cages). Following cervical discectomy, a proportion of patients re-present with progressive spondylosis requiring surgical treatment at adjacent cervical segments.

2.2 Outline of the procedure

2.2.1 Artificial intervertebral discs have been developed to act as functional prosthetic replacements for intervertebral discs removed at surgery with the aim of reducing adjacent spondylitic change. A number of devices have been developed for the cervical spine. Under general anaesthesia, the patient is placed in the supine position. The anterior cervical spine is exposed, and after standard decompression of the neural elements, an artificial disc prosthesis is placed between the vertebrae.

2.3 Efficacy

2.3.1 Many studies relied on patients' self-reported outcomes to determine the clinical efficacy of prosthetic disc implants.

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This guidance is written in the following context

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for health professionals and people using the NHS in England, Wales and Scotland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

NHS Quality Improvement Scotland

2.3.2 In two randomised controlled trials with follow-up of 6 months and 24 months (n = 13 and n = 9, respectively), neck and arm pain scores and quality of life indices all improved. There was no statistically significant difference in outcomes between patients treated with artificial disc implants and those treated by fusion surgery. One case series of seven patients found significant improvements in arm and neck symptom scores, and neck disability index assessment at 6 months, compared with preoperative values.

2.3.3 The largest case series available reported an improvement in clinical evaluation of motor strength and sensory signs, and reported patient self-evaluation of symptoms as 'excellent' in 65% (32/49) of patients having single-level disc replacement, and 77% (20/26) of patients having surgery at two levels.

2.3.4 The range of motion in the treated spinal segment was reported to be well preserved in those studies that included this outcome measure. One case series reported motion of more than 2 degrees in 93% (43/46) of patients treated. Maintenance of a 5.9-degree range of motion at 12-month follow-up was confirmed by radiographic assessment in the prosthetic disc arm of a randomised controlled trial (n = 27). For more details, refer to the Sources of evidence.

2.3.5 The Specialist Advisors commented that longer-term data were required to compare the results with those of spinal fusion.

2.4 Safety

2.4.1 There were no reported incidents of device failure in 100% (27/27) of patients in the prosthetic disc arm of a randomised control trial, or among 13 patients in a case series. Device migration was noted in 2% (2/103) of patients undergoing prosthetic cervical disc implant in a case series, although no migration was greater than 3.5 mm from the initial implant site, and none were associated with neurological symptoms.

2.4.2 In a large case series of patients undergoing prosthetic implant, reintervention was required in 3% (3/103) of patients (two patients required treatment for residual symptoms, and one patient required evacuation of a haematoma).

2.4.3 Other reported adverse events included transient hoarseness in 13% (2/15) of patients, moderate dysphagia in 4% (1/27) and recurrent laryngeal nerve palsy in 4% (1/27). For more details, refer to the Sources of evidence.

2.4.4 The Specialist Advisors noted that theoretical adverse events included nerve root compression due to device migration and airway obstruction due to anterior displacement. They also noted that device failure may cause spinal cord damage.

Andrew Dillon
Chief Executive
November 2005

Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG143publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

Interventional procedure overview of prosthetic intervertebral disc replacement of the cervical spine, February 2005

Available from www.nice.org.uk/ip265overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0933. *Information for the public* can be obtained by quoting reference number N0934.

The distribution list for this guidance is available at www.nice.org.uk/IPG143distributionlist

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