NICE guidance

Prosthetic intervertebral disc replacement in the cervical spine

Interventional procedures guidance
Published: 19 May 2010

www.nice.org.uk/guidance/ipg341

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 IPG143.

1 Guidance

1.1 Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

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

1.3 NICE encourages further research into prosthetic intervertebral disc replacement in the cervical spine. Research outcomes should include long-term data on preservation of mobility, occurrence of adjacent segment disease and the avoidance of revision surgery.

2 The procedure

2.1 Indications and current treatments

2.1.1 Degenerative cervical disc disease may present with symptoms of pain and

stiffness in the neck, and pain, paraesthesia, numbness or weakness of the limbs.

2.1.2 Conservative treatment options include rest, analgesic medication, physical therapy and local injections. In patients who are refractory to conservative treatment or at risk of permanent neurological damage, decompression of nerve roots or the spinal cord by cervical discectomy may be offered, with or without vertebral body fusion using a bone graft or cage.

2.2 Outline of the procedure

2.2.1 Prosthetic intervertebral discs are implants that can be inserted between the vertebrae as an alternative to fusion using bone grafts or cages. They are designed with the aim of preserving the mobility of the diseased intravertebral segment, and therefore reducing the risk of adjacent segment degeneration in the long term.

2.2.2 With the patient under general anaesthesia and in the supine position, the anterior cervical spine is exposed. After standard decompression of the neural elements, and partial or full removal of the damaged disc, the artificial disc prosthesis is placed into the intervertebral space. More than one disc can be replaced during the same procedure.

2.2.3 Various devices can be used for this procedure.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A randomised controlled trial (RCT) of 541 patients reported that improvement from baseline in mean Neck Disability Index (NDI) score (10-item questionnaire scored out of 100; higher scores indicate greater disability) was significantly greater in patients treated with prosthetic cervical disc insertion (55.7 to 20.7

points) compared with fusion (56.4 to 26.8 points) at 3-month follow-up (p=0.004), but this difference was not significant at 6-, 12- or 24-month follow-up.

2.3.2 An RCT of 463 patients reported a greater improvement from baseline in mean NDI score in patients treated with a prosthetic cervical disc (51.4 to 16.2 points) than in those treated by fusion (50.2 to 19.2 points) at 24-month follow-up (p=0.025).

2.3.3 A case series of 54 patients, who received 77 prosthetic cervical discs between them, reported no heterotopic ossification in 34% (26 out of 77) of implants, bridging ossification but with preservation of prosthesis movement in 10% (8 out of 77), and complete fusion of the level in 9% (7 out of 77) at 1-year follow-up.

2.3.4 RCTs of 541, 463 and 209 patients all reported that baseline quality of life measurements (using Short Form-36 physical and mental health components) improved significantly at 24-month follow-up in patients treated by either prosthetic cervical disc insertion or fusion, but that differences between groups were not statistically significant (absolute figures not stated).

2.3.5 The Specialist Advisers listed key efficacy outcomes as NDI score, arm and neck pain score measured by visual analogue scale, Short Form-36 score, technical success and revision rate, range of movement and reduction in rate of adjacent level disease after 5 to 10 years.

2.4 Safety

2.4.1 Revision surgery was required in 0% (0 out of 276) of patients treated with a prosthetic cervical disc and 2% (5 out of 265) of patients treated by fusion at 2-year follow-up in the RCT of 541 patients (p=0.028). The rate of supplemental fixation in the neck (not otherwise defined) requiring additional surgery was significantly lower among patients treated with a prosthetic disc (0% [0 out of 276]) than those treated by fusion (3% [9 out of 265]; p=0.003).

2.4.2 Cerebrospinal fluid leak during decompression surgery occurred in 2% (1 out of 43) of patients treated with prosthetic cervical discs at 2 levels in a non-RCT of

146 patients (subsequent management and sequelae not described).

2.4.3 A case report described fracture of the posterior central parts of the caudal C6 and the cranial C7 vertebrae during the procedure. Bleeding occurred during the procedure, caused by bony fragments avulsed from the fracture compressing the posterior longitudinal ligament and the thecal sac (bleeding controlled and disc inserted without further complication).

2.4.4 The Specialist Advisers listed possible adverse events as implant migration or loosening, paraplegia, disc extrusion following trauma, segmental kyphosis and inadequate decompression. They considered theoretical adverse events to include infection, fusion of prosthesis, need for explantation surgery, disc debris causing inflammatory response, wear to the disc and osteolysis.

3 Further information

Sources of evidence

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

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-6339-3

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.