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NHS
National Institute for Clinical Excellence

Prosthetic intervertebral disc replacement

1 Guidance

1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement appears adequate to support the use of this procedure. However, there is little evidence on outcomes beyond 2–3 years and collection of long-term data is therefore particularly important.

1.2 Clinicians wishing to undertake prosthetic intervertebral disc replacement should take the following actions.

- Ensure that patients understand the uncertainty about the procedure's long-term efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
- Audit and review clinical outcomes of all patients having prosthetic intervertebral disc replacement.

1.3 Publication of longer-term efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Prosthetic intervertebral disc replacement is an alternative to the established operations of discectomy and spinal fusion in patients with:

- herniated lumbar intervertebral disc
- degenerative disc disease in lumbar spine
- post-laminectomy syndrome in the lumbar spine
- lower back pain refractory to conservative treatment for more than 6 months.

2.2 Outline of the procedure

2.2.1 Artificial intervertebral discs consist of two metallic endplates separated by a more pliable inner core. The implantation of the prosthetic discs involves a major operation through an incision below the umbilicus. The diseased disc is partially or fully excised (depending on the prosthesis used). The vertebral endplates and surrounding spinal ligaments are preserved and help to maintain implant stability. Single or multiple discs can be replaced during the same operation.

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2.3 Efficacy

2.3.1 Two studies reported good or excellent clinical results in 63% (29/46) and 79% (83/105) of patients. The percentage of patients able to return to work was reported to be 67% (31/46) and 87% (91/105), respectively, but a third study with 93 patients found no increase in patients returning to work. This same multi-centre study reported on leg pain and found a statistically significant improvement in patients at 12 months compared with baseline, and in one case series, lower back pain was improved in 65% (30/46) of patients. A recent randomised controlled trial of 304 patients with degenerative disc disease randomised to receive either a prosthetic disc or spinal fusion found significantly more patients improved in their Oswestry Disability Index score at 24 months in the prosthetic disc group (62% of them improved) compared with the group of patients treated by spinal fusion (49% of them improved). For more details, refer to the Sources of evidence (see right).

2.3.2 The Specialist Advisors expressed concern about the lack of good-quality, long-term evidence. They stressed the importance of training.

2.4 Safety

2.4.1 Complication rates in the studies ranged from 16% (8/50) to 45% (9/20). The wide variation may, in part, be explained by differing definitions of complications. These included implant-related problems such as migration and dislocation. Re-operation rates varied between 3% (3/93) and 24% (12/50). The randomised controlled trial of 304 patients reported major neurological events by 24 months in 5% (10/205) of patients receiving an artificial disc, compared with 4% (4/99) of patients undergoing spinal fusion. For more details, refer to the Sources of evidence (see right).

2.4.2 The Specialist Advisors listed the potential complications as pain, spinal infection, vascular damage and damage to the pre-sacral plexus that may cause problems such as retrograde ejaculation.

2.5 Other comments

2.5.1 It was noted that this is a major surgical procedure that requires skill in the anterior approach to the spine.

2.5.2 This procedure has potential advantages over alternative treatments; however, it also has the potential for serious complications.

2.5.3 Prostheses vary considerably and newer ones may have different outcomes to those previously reported.

Andrew Dillon
Chief Executive
November 2004

Information for the Public

The Institute 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, in English and Welsh, from www.nice.org.uk/IPG100publicinfo

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, January 2004

Available from: www.nice.org.uk/ip126overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0749. *Information for the Public* can be obtained by quoting reference number N0750 for the English version and N0751 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at www.nice.org.uk/IPG100distributionlist

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National Institute for Clinical Excellence
MidCity Place, 71 High Holborn, London WC1V 6NA, website: www.nice.org.uk

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