

| | |
|-------------------|--|
| Title: | Artificial intervertebral disc replacement (Total disc arthroplasty) February/March 2006 |
| Agency: | Medicare Services Advisory Committee (MSAC) Commonwealth Department of Health and Aged Care GPO Box 9848 Canberra ACT 2601 Australia |
| Reference: | MSAC application 1090, Assessment report, ISBN 1 74186 036 9, ISSN 1443-7120, http://www.msac.gov.au |

Aim

To assess the safety, effectiveness and cost-effectiveness of artificial intervertebral disc replacement (AIDR) and under what circumstances public funding should be supported for the procedure.

Conclusions and results

Safety

The safety of cervical AIDR was assessed from one RCT comparing cervical AIDR and cervical spinal fusion, 11 case series and one HTA report. The trial reported no statistically significant differences in the total number of adverse events experienced by participants treated with cervical AIDR (n=27) or cervical spinal fusion (n=28) (RR=0.93, 95% CI: 0.63, 1.36).

The safety of lumbar AIDR was assessed from two multicentre RCTs comparing lumbar AIDR and lumbar spinal fusion, 15 case series, two systematic reviews and three HTAs. One trial reported no significant differences in the rates of adverse events between participants treated with lumbar AIDR (n=205) or lumbar spinal fusion (n=99) (RR=0.98; 95% CI: 0.86, 1.11).

The long-term (>5 years) comparative safety of AIDR and fusion is unknown.

Effectiveness

Evidence for the effectiveness of cervical AIDR versus cervical spinal fusion was derived from one RCT. The trial reported similar outcomes for patients undergoing cervical AIDR or fusion, however, the trial enrolled few participants, did not report full data, had short-term follow-up (24 months), and participants, investigators and outcome assessors were not blinded to treatment.

Evidence for the effectiveness of lumbar AIDR versus lumbar fusion was derived from two RCTs. Both trials reported improved health outcomes for participants undergoing lumbar AIDR compared with lumbar fusion, however both trials had short-term follow-up (24 months), and participants, investigators and outcome assessors were not blinded to treatment.

Cost-effectiveness The incremental cost of cervical AIDR was estimated to be \$9,438 (range \$8,413 to \$13,346) per separation.

The incremental cost of lumbar AIDR was estimated to be \$1,054 per separation when all methods of fusion were included.

Recommendations

Interim public funding should be supported at this time for single level AIDR in patients with single level intra lumbar disc disease in the absence of osteoporosis and prior fusion at the same level who have failed conservative therapy. In the absence of adequate evidence of effectiveness, public funding for AIDR in the cervical spine should not be supported.

Method

MSAC conducted a systematic review of literature via Medline, Embase, the Cochrane Library, CINAHL, Biological Abstracts and the Australasian Medical Index from 1966 to February 2005.