Introduction
This Evidence Note summarises the published clinical and cost-effectiveness evidence on spinal fusion, disc replacement and interspinous distraction devices in the lumbar spine for adult patients with mechanical low back pain or degenerative spondylolisthesis. Mechanical low back pain describes pain in the joints, discs and/or connective tissues of the lower spine for which no specific cause has been found. Degenerative spondylolisthesis describes one vertebra slipping forward over another as a result of aging. It is one of a set of degenerative conditions affecting the lumbar spine, which may be collectively described as degenerative disc disease or degenerative spondylosis. A number of reports were found on this broader disease category (without having comprehensively searched for it) of uncertain generalisability to the specific condition of degenerative spondylolisthesis. Only the most recent, robust and relevant evidence has been included. This Evidence Note does not cover the condition spinal stenosis without degenerative spondylolisthesis. Neither does it consider the comparison of all surgery with conservative management; nor specific techniques for fusion surgery with each other.

Health technology description

Spinal fusion
Spinal fusion is surgery to join together two vertebrae using a bone graft, in order to stop motion between them. There are a variety of techniques for spinal fusion, which can be instrumented or not; and anterior, posterior, circumferential or lateral. In instrumented fusion, as well as the bone graft, a cage, screw, hook or rod is implanted.

Disc replacement
Disc replacement entails partially or fully removing a damaged intervertebral disc, and inserting an artificial disc.

Key points
- In mechanical low back pain which has persisted despite optimal conservative management, there is evidence that spinal fusion can be of benefit.
- In chronic low back pain, spinal fusion is unlikely to be cost effective versus intensive rehabilitation over a 2-year time horizon; however there is some indication that it could become cost effective over a longer term time horizon.
- In degenerative spondylolisthesis, there is evidence that spinal fusion as an adjunct to decompression leads to better clinical outcomes than decompression alone.
- Evidence for clinical effectiveness of disc replacement and interspinous distraction devices was minimal. It was neither specific to degenerative spondylolisthesis, nor necessarily generalisable to mechanical low back pain.
- No cost-effectiveness evidence was identified on spinal fusion, disc replacement or interspinous distraction devices in the treatment of degenerative spondylolisthesis.

Interspinous distraction devices
Interspinous distraction devices are implants used for dynamic stabilisation of the spine, which restrict motion to the range which does not cause pain. Published evidence was found on the Wallis® (Zimmer Spine) and X-STOP® (Medtronic Spine) devices.

Epidemiology

Mechanical low back pain
In Scotland, around 8% of adult patients consulted either a general practitioner (GP) or practice nurse for back pain in the year 2009–2010; with a pattern of increasing consultations with age. Annual prevalence among adults in the United Kingdom (UK) is estimated at one-third, of whom around 20% consult their GP. Symptoms generally resolve spontaneously.
In persistent or recurrent low back pain, defined as lasting between 6 weeks and 12 months, the National Collaborating Centre for Primary Care and Royal College of General Practitioners advise providing information to promote self-management, and offering treatment alternatives of an exercise programme, manual therapy or acupuncture.1

Degenerative spondylolisthesis
Specific prevalence data were not found for degenerative spondylolisthesis.

Clinical effectiveness

Mechanical low back pain

Spinal fusion
A National Collaborating Centre for Primary Care guideline from 2009 on early management of persistent non-specific low back pain recommended consideration of a referral for an opinion on spinal fusion for those whose severe pain persists following an optimal package of physical and psychological care, and who would consider having surgery.1 This was based on results from two well-conducted systematic reviews (Ibrahim 2008 [containing Brox 2003; Fairbank 2005; Fritzell 2001] and Mirza 2007 [containing Brox 2003; Brox 2006; Fairbank 2005; Fritzell 2001]). The systematic review by Ibrahim (2008) included a meta-analysis, which showed benefit of spinal fusion surgery over physical therapy and cognitive therapy on the Oswestry disability index (mean difference=4.87; 95% confidence interval [CI] 1.62 to 8.12; p=0.003).

No evidence was found on disc replacement or interspinous distraction devices for mechanical low back pain.

Degenerative spondylolisthesis

Spinal fusion
A Cochrane systematic review from 2008 of surgery for degenerative lumbar spondylolisthesis (containing Fritzell 2001; Brox 2003) reported conflicting results from the two included studies.3 A trial of fusion versus physiotherapy showed superior outcomes for spinal fusion, in terms of independent observer rating, patient rating, pain (visual analogue scale), disability (Oswestry scale), and return to work.3 Whereas a trial of fusion versus rehabilitation reported comparable outcomes on each of these measures.3

A North American Spine Society guideline from 2008 on the diagnosis and treatment of degenerative lumbar spondylolisthesis recommended adding spinal fusion to surgical decompression to improve clinical outcomes, based on fair quality evidence from two systematic reviews (Mardjetco 1994; Martin 2007) and three studies (Bridwell 1993; Herkowitz 1991; Matsudaira 2005).4 Satisfactory long-term results were reported for decompression and fusion in patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis, based on poor quality evidence from three studies (Kornblum 2004; Booth 1999; Postacchini 1992).4

A study of 101 patients with degenerative spondylolisthesis receiving posterior lumbar interbody fusion with pedicle screws found no difference in post-operative clinical results between younger (<70 years; mean 59 years) and older groups (70+ years; mean 74 years).5

Disc replacement
The comparative evidence on disc replacement was not specific to degenerative spondylolisthesis. The National Institute for Health and Clinical Excellence (NICE) interventional procedure guidance from 2009 reported improved short-term outcomes and similar longer term outcomes in symptomatic degenerative disc disease of the lumbar spine for disc replacement versus spinal fusion, on the Oswestry disability index and quality of life score measured by the Short Form–36 questionnaire (SF–36).6 NICE recommended that the procedure should only be undertaken following the failure or contraindication of conservative management.6

A Cochrane systematic review from 2008 of surgery for degenerative lumbar spondylosis was unable to draw firm conclusions from the preliminary results of two trials of disc replacement versus fusion (containing McAfee 2003; Zigler 2003/Delamater 2003).3

Interspinous distraction devices
Comparative evidence was found for the Wallis® and X-STOP® devices only; but this was not specific to degenerative spondylolisthesis. The effectiveness of the Wallis® device was examined in the Medical Services Advisory Committee health technology assessment on lumbar non-fusion posterior stabilisation devices which reported on an average quality single non-randomised trial (Senegas 2002) of 80 patients undergoing discectomy for recurrence of herniated disc.7 Reduction in pain was greater among those receiving a Wallis® implant after discectomy than discectomy alone on the visual analogue scale (74% versus 52%; raw data and statistical significance not reported).7 Improvement in functional status using the Oswestry disability index was also greater among those receiving a
Wallis® implant (relative change 1.28; statistical significance not reported).⁷

There was less analgesic use after surgery in the group receiving the Wallis® implant (42.5% versus 20% no longer taking analgesics; statistical significance not reported).⁷ There was no difference between groups in the reoperation rate (Relative risk =1.00; 95% CI 0.22 to 4.66).⁷

A Cochrane systematic review from 2008 of surgery for degenerative lumbar spondylosis found one trial (Zucherman 2004) of the X-STOP® interspinous spacer device versus non-surgical control in 200 patients with spinal stenosis.³ This reported less secondary surgery (odds ratio [OR]=0.26; 95% CI 0.09 to 0.73) and less moderate or severe pain (OR=0.14; 95% CI 0.07 to 0.29) with the X-STOP®.³

Cost effectiveness

Mechanical low back pain

A cost-utility analysis comparing spinal fusion with intensive rehabilitation in chronic low back pain reported an incremental cost-effectiveness ratio of £48,588 (95% CI £279,883 to £372,406) at 2 years follow up.⁸ These results indicated that spinal fusion may not be cost effective at 2 years. However sensitivity analyses suggest that if the benefit observed at 2 years was maintained for a further 2 years, then spinal fusion could be cost effective according to commonly accepted thresholds.

Degenerative spondylolisthesis

No evidence was found on the cost effectiveness of spinal fusion, disc replacement or interspinous distraction devices in degenerative spondylolisthesis.

Safety

Each of the procedures examined for this Evidence Note entails surgery under anaesthetic, with the attendant risks. A specific risk of lateral spinal fusion is lower limb dyasiaesthesia from nerve damage.⁹ Further theoretical risks of lateral spinal fusion include cerebrospinal fluid leak, infection and failure of the spine to fuse.⁹ NICE interventional procedure guidance from 2009 in symptomatic degenerative disc disease of the lumbar spine noted that fewer adverse events were reported for disc replacement than spinal fusion.⁶ A small study of the Wallis® device after discectomy compared with discectomy alone found similar rates of minor complications, and no major adverse events.⁷ For the X-STOP® device, minor complications such as respiratory distress, wound swelling and pain were reported in up to 8% of patients; and major complications such as malpositioned implants in up to 3%.⁷ Blood loss was less with the X-STOP® than spinal fusion because the procedure is less invasive.⁷

Conclusion

Evidence has been found that spinal fusion can be of benefit in mechanical low back pain and degenerative spondylolisthesis. In chronic low back pain, spinal fusion is unlikely to be cost effective versus intensive rehabilitation over a 2-year time horizon; however longer follow up may reverse this position. Further research is required to establish the clinical effectiveness of disc replacement and interspinous distraction devices in mechanical low back pain and degenerative spondylolisthesis.

Equality and Diversity

Healthcare Improvement Scotland is committed to equality and diversity in respect of the six equality groups defined by age, disability, gender, race, religion/belief and sexual orientation.

The Evidence Note process has been assessed and no adverse impact across any of these groups is expected. The completed equality and diversity checklist is available on www.healthcareimprovementscotland.org

About Evidence Notes

For further information about the Evidence Note process, see www.healthcareimprovementscotland.org

To propose a topic for an Evidence Note, email evidencenotes.qis@nhs.net

References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network (formally eLibrary) http://www.knowledge.scot.nhs.uk, or by contacting your local library and information service.
Acknowledgements

Healthcare Improvement Scotland would like to acknowledge the helpful contribution of the following, who gave advice on the content of this Evidence Note:

- Mr Niall Craig, Consultant Orthopaedic Surgeon, NHS Grampian
- Mr Douglas Somerville, Consultant Orthopaedic Surgeon, NHS Highland

Healthcare Improvement Scotland Development Team

- Joanne Abbotts, Author/Health Services Researcher
- Karen Macpherson, Senior Health Services Researcher
- Carolyn Sleith, Information Scientist
- Susan Downie, Medical Writer
- Doreen Pedlar, Project Co-ordinator
- Marina Logan, Team Support Administrator

© Healthcare Improvement Scotland 2011
ISBN 1-84404-926-4

References


