NICE guidance

Non-rigid stabilisation techniques for the treatment of low back pain

Interventional procedures guidance
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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 IPG183 and IPG185.

1 Guidance

1.1 Current evidence on the efficacy of non-rigid stabilisation techniques for the treatment of low back pain shows that these procedures are efficacious for a proportion of patients with intractable back pain. There are no major safety concerns. Therefore, these procedures may be used provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options.

2 The procedure

2.1 Indications and current treatments

2.1.1 Chronic low back pain commonly may result from minor abnormalities of spinal movement as a result of degenerative change affecting intervertebral discs and/or spinal facet joints.

2.1.2 Conservative treatments include advice and education, posture and exercise training, manual therapies, analgesics, non-steroidal anti-inflammatory drugs and acupuncture. For patients with severe, life-limiting chronic low back pain that is

refractory to conservative interventions, surgery may be appropriate, such as spinal fusion procedures or insertion of prosthetic intervertebral discs.

2.2 Outline of the procedure

2.2.1 Non-rigid (flexible, dynamic) lumbar spine stabilisation involves insertion of implants aiming to support and partially restrict spinal segment movement, and minimise abnormal loading in adjacent segments.

2.2.2 With the patient under general or epidural anaesthesia, a posterior approach via a midline incision or minimal access techniques is used. Adjacent vertebrae across one or more segments are linked by a non-rigid connector system (usually pedicle screws and an artificial ligament or flexible rod) to restrict painful intervertebral movements.

2.2.3 Adjunct laminectomy and/or discectomy may be done where appropriate.

2.2.4 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 non-randomised comparative study of 218 patients treated by posterior lumbar interbody fusion (n=78), posterolateral fusion (n=75) or Graf ligamentoplasty (n=65) reported that additional surgery for adjacent-level segment disease was reported in 6 patients, 5 patients and 1 patient respectively at 37- to 45-month follow-up (no significant difference reported between groups).

2.3.2 A non-randomised comparative study of 45 patients (18 non-rigid stabilisation versus 27 fusion) reported that additional surgery was required for adjacent-level disc lesion, disc herniation or spinal stenosis in 1 patient in the non-rigid

stabilisation group and 5 patients in the fusion group at mean follow-ups of 71 and 75 months respectively (significance not stated).

2.3.3 A case series of 101 patients reported that 15% (15 out of 101) of patients required a total of 18 further procedures by 1-year follow-up, of which 10 were revision surgery (including decompression, extension of segmental fixation or removal of a synovial facet cyst) for increased back pain, radiculopathy or increased instability.

2.3.4 The non-randomised comparative study of 45 patients (18 non-rigid stabilisation versus 27 fusion) reported adjacent-segment disc deterioration at the L2 to L3 level confirmed by X-ray in 7% and 36% of patients at mean follow-ups of 71 months and 75 months respectively ($p<0.05$).

2.3.5 A non-randomised comparative study of 26 patients treated by dynamic stabilisation (n=11) or rigid stabilisation (n=15) reported changes from baseline in mean lumbar spine range of motion of 14.4° to 18.3° and 23.6° to 12.7° respectively at 6-week follow-up ($p=0.05$, $p=0.02$ respectively).

2.3.6 A non-randomised comparative study of 103 patients treated by non-rigid stabilisation (n=46) or rigid stabilisation (n=57) reported reductions in pre-operative back pain (measured on a visual analogue scale [VAS] from 0 to 10; higher score indicates greater pain) from 7.3 to 1.4 and from 7.4 to 2.1 respectively (mean follow-ups of 9.3 and 10.6 months respectively; p=not significant).

2.3.7 The non-randomised comparative study of 103 patients reported improvement in disability (measured on the Oswestry Disability Index [ODI] scale 0% to 100%; higher scores indicate greater disability) from 35.2 pre-operatively to 12.1 at a mean follow-up of 9.3 months in the non-rigid stabilisation group and from 37.8 pre-operatively to 13.6 at a mean follow-up of 10.6 months in the rigid stabilisation group (significance not stated).

2.3.8 The case series of 101 patients reported a significant decrease in mean leg pain (measured on a VAS from 0 to 100) from 80.3 at baseline to 25.6 at 1-year follow-up ($p<0.01$).

2.3.9 The Specialist Advisers listed key efficacy outcomes as relief of pain, ODI, return

to work, patient satisfaction and quality of life, and low rates of adjacent segment disease and revision.

2.4 Safety

2.4.1 Dural tears were reported in 12% (12 out of 101) of patients in a case series. Eleven of the tears were repaired intraoperatively, of which 1 continued to leak and required subsequent surgical closure.

2.4.2 The non-randomised comparative study of 103 patients (46 non-rigid stabilisation versus 57 rigid stabilisation) reported screw fracture in 1 patient in the non-rigid stabilisation group at 3 months.

2.4.3 The case series of 101 patients reported 1 patient in whom the vertebral pedicle fractured during screw insertion. The pedicle screw was not placed and a hemilaminectomy was done.

2.4.4 The case series of 83 patients reported 2 patients with screw misplacement (1 patient required revisional surgery) and 7 cases of screw loosening (confirmed by X-ray).

2.4.5 The Specialist Advisers considered theoretical adverse events to include paralysis, vessel or visceral injury, increase in lordosis, nerve root entrapment, screw malpositioning leading to sciatica or nerve damage, weakness and numbness, screw breakage leading to construct failure, and infection.

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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.