NICE guidance

Direct C1 lateral mass screw for cervical spine stabilisation

Interventional procedures guidance
Published: 14 December 2005

www.nice.org.uk/guidance/ipg146

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.

1 Guidance

1.1 Current evidence on the safety and efficacy of direct C1 lateral mass screw for cervical spine stabilisation appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 This procedure should be performed only in specialist units where surgery of the cervical spine is routinely undertaken.

2 The procedure

2.1 Indications

2.1.1 Atlantoaxial instability (excessive movement between the first and second cervical vertebrae) can be caused by trauma, malignancy and inflammatory or congenital defects. It can present with local pain, but if the spinal cord is compressed it can cause clumsiness, lack of coordination, difficulty walking and, rarely, paralysis or death. Treatment is by stabilisation of the C1 (atlas) on to the C2 (axial) vertebra.

2.1.2 Traditional methods of atlantoaxial fusion involve using wires and bone grafts, but these require external support in the postoperative period, including halo devices. Methods of rigid fixation with transarticular screws between C1 and C2 have been described. These do not require external fixation, but are not appropriate for every patient.

2.2 Outline of the procedure

2.2.1 Under general anaesthesia, the patient is placed in the prone position and standard posterior exposure of the cervical spine is performed. Screws are inserted into the lateral masses of C1 and fixed by rods corresponding to screws in the lateral masses or pedicles of C2. The posterior arch of bone compressing the spinal cord may be removed. An onlay graft of bone permits a permanent fusion between C1 and C2.

2.3 Efficacy

2.3.1 The primary endpoint in the literature was successful fusion. In two case series of 37 and 160 patients and one case report, immobilisation of C1 on C2 was achieved in 196 patients (in the remaining 2 patients the intent was not to procure fusion, see sources of evidence for more information).

2.3.2 In a case series of 157 patients, clinical and neurological recovery was documented in 100% but assessment measures were not described.

2.3.3 A case series investigating a lateral mass and plate system reported that 6% (9 of 157) of procedures could not be completed because of inadequate exposure of the atlantoaxial region. For more details, refer to the sources of evidence.

2.3.4 The specialist advisors considered this to be a variation on existing fusion techniques.

2.4 Safety

2.4.1 In two case series of 157 and 37 patients, there were no reports of implant failure. No vertebral artery injuries occurred in the 3 case series (n=212) or in the 1 case report where safety outcomes were reported.

2.4.2 In a case series, sensory loss in the distribution of the C2 nerve root was reported by 11% of patients (18 of 157) undergoing screw and plate fixation. In the

same series, 6 screws were found to be penetrating more than 4 mm from the anterior cortex of C1 but with no clinical complications. One screw was found to be broken at 18 months' follow-up. In another case series, deep wound infection was reported in 3% of patients (1 of 37). For more details, refer to the sources of evidence.

2.4.3 The specialist advisors stated that potential adverse events include haemorrhage from the vertebral venous plexus and screw failure or loosening. Less common but more serious complications may include injury to the vertebral artery, and spinal cord injury caused by screw misplacement.

2.5 Other comments

2.5.1 It was recognised that the evidence on this procedure was limited, but it was considered sufficient in the context of the conditions requiring treatment.

2.5.2 These recommendations are based on evidence from studies using 2 different techniques: the plate system and the more recent polyaxial screw and rod systems.

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

4 Update information

Minor changes since publication

January 2012: Minor maintenance.

ISBN: 978-1-4731-6418-5

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.