NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of direct C1 lateral mass screw procedure for cervical spine stabilisation

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in February 2005.

Procedure names

- Direct lateral mass screw placement.
- Polyaxial screw and rod fixation of cervical spine.
- Internal fixation of C1/2 using lateral mass screws

Specialty societies

Specialist advice was sought from:

- British Association of Spinal Surgeons
- British Cervical Spine Society
- Society of British Neurological Surgeons
- British Scoliosis Society
- Society for Back Pain Research.

Description

Indications

Atlantoaxial instability (excessive movement between the first and second vertebrae of the neck) can be caused by trauma, malignancy, inflammatory or congenital defects. They can present as local spinal pain, but if the spinal cord is compressed symptoms such as clumsiness, lack of coordination, difficulty walking, high cervical paralysis or death may occur. Treatment is by stabilisation of the C1 on to the C2 vertebrae.

Current treatment and alternatives

Traditional methods of atlantoaxial fusion involves the use of wires and bone grafts, but they require external support in the post-operative period, including the use of halo devices. Rigid fixation by transarticular screws between C1 and C2 have been

described which do not require external fixation but this procedure is not appropriate for every case. This new procedure has been developed which achieves rigid fixation between C1 and C2 by the use of a screw placed in each bone and connection of these screws with rods and a plate.

What the procedure involves

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 a rod 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.

Efficacy

The primary endpoint in the literature concerning direct C1 lateral mass screw procedures for atlantoaxial instability is successful fusion. In two case series of 37 and 160 patients and one case report where fusion was intended (no implant excision), immobilisation of the C1–C2 section was achieved in all patients.

In a case series clinical and neurological recovery was documented in all patients, although assessment measures were not described, and in a case report the patient was described as pain free and neurologically intact at 6 months follow-up.

A case series investigating a lateral mass and plate system showed 6% (9/157) of patients could not be completed due to inadequate exposure of the atlantoaxial region.

Safety

In two case series there were no reports of implant rejection (0/157) or failure (0/37). No injury or laceration of the vertebral artery was recorded in case series or case reports where safety outcomes were reported.

Sensory loss in the distribution of the C2 nerve was reported by 11% (18/157) of patients undergoing screw and plate fixation. 3% (1/37) of patients suffered a deep wound infection. In one case series six screws were found to be penetrating more than 4 mm from the anterior cortex of C1 but with no clinical complications; also, one screw was found to be broken at 18 months follow-up.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to direct C1 lateral mass screw procedure. Searches were conducted via the following databases, covering the period from their commencement to 20/12/2004MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with fracture or instability of the cervical spine.
Intervention/test	Direct screws to lateral mass of C1 and fixation with rods to C2.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on two case series and two case reports.

Existing reviews on this procedure

No systematic reviews or evidence based guidelines were located on this topic during literature searching.

Table 1 Summary of key efficacy and safety findings on direct CI lateral mass screw procedure

Abbreviation used: ICA – internal carotid artery			
Study Details	**Key efficacy findings**	**Key safety findings**	**Comments**
Harms J (2001)(1) Case series Germany n = 37 Fracture = 20, symptomatic odontoid os = 6, rheumatoid arthritis = 4, rotary subluxation=3, osteoarthritis C1–C2 = 2, congenital malformation = 2 Age = 49 yrs, Male = 51% Follow up 0 months to 2 years (median 6 months) Neutral alignment and flexion extension assessed by radiographs and CT angiograms 2 cases undertaken without fusion	**Device durability** There were no cases of implant failure **Success of stabilisation** All cases demonstrated radiographic evidence of solid fusion, where this was attempted. **Excision of the device** Two patients underwent reduction and instrumentation between C1 and C2 but without fusion. Both successfully had the apparatus removed at a second operation at 3 or 4 months following the initial operation	**Device acceptability** There were no instances of neurologic deterioration postoperatively or during follow-up **Procedure safety** There were no instances of dural laceration or injury to the vertebral artery in the 37 cases in the series 3% (1/37) of patients suffered a deep wound infection, which responded to subsequent debridement and IV antibiotics	No assessment of symptom scores reported. Two cases (5%) were lost to follow-up. One patient died before 6 month follow-up. The mean follow-up time is not determinable. The poly axial screws inserted can be used as part of a modular system for fixation to the occiput or the sub axial cervical spine.

Abbreviation used: ICA – internal carotid artery			
Study Details	**Key efficacy findings**	**Key safety findings**	**Comments**
Stulik J (2005) Case series Czech republic n=18 Patients treated with the Harms technique for fixation of C1-C2. 4 patients had temporary fixation without bone grafts. Male =56%, Age= 55 years. Follow up = 6 months	**Operative parameters** Mean operative time was 81 minutes (range 35 to 155). Mean intraoperative blood loss was 560 ml (range 50 to 1500) **Fixation success** At 6 months follow up bony fusion was achieved in 100% (14/14) of cases where this was the aim of the procedure. Also the C1-C2 segment was found to be stable in all 18 patients at 12 weeks. **Excision of the device** All four patients who underwent temporary fixation between C1 and C2 but without fusion reported restricted motion in rotation of about 10 to 25% after explant of the instrumentation.	**Complications** 6% (4/72) of screws into the C1 and C2 did not reach the anterior cortical bone as planned. 4% (3/72) of screws protruded through the bone, but no clinical complications were reported. Overall 4% (3/72) screws were malpositioned during the procedure.	English abstract only of Czech paper Patients included in series had a range of conditions from fractures of C 1 or C2 atlantoaxial instability, and rotary dislocations. Authors report shorter operating time and less blood loss with greater experience but data not provided. No outcomes are compared to baseline. No details given of how patients were recruited for the series. There was a ‘drop out’ rate of 18% (4/22) of cases that underwent the procedure but were not included in the analysis. No reason for exclusion is given.

Abbreviation used: ICA – internal carotid artery			
Study Details	**Key efficacy findings**	**Key safety findings**	**Comments**
Goel A (2002)(2) Case series India n = 160 The first 14 cases were those for whom conventional fixation methods had failed or were not suitable; the remainder are consecutive cases with atlantoaxial instability Age = 27 years, Male = 57%, Significant trauma =17%, Congenital atlantoaxial instability = 83%, Quadriparesis = 98%, kinaesthetic sensation affected = 30%, spinothalamic sensations effected = 29% Bone graft between C1–C2. Metal screws inserted to guideholes in lateral mass of the atlas and axis, a 2 cm diameter shaped double compression stainless steel plate Follow-up 42 months (mean)	**Procedure success** In 6% (9/157) of cases, inadequate exposure of the atlantoaxial region prevented the completion of the screw and plate procedure and an alternative fixation technique was employed **Fixation** All 157 patients showed signs of clinical and neurological recovery 'in varying degrees' Immobilisation of the C1–C2 section was successful in all cases	**Operative safety** There was no procedure-related morbidity or mortality relating to the procedure in 157 cases **Adverse events** There was no case of implant rejection Sensory loss in the distribution of the C2 nerve was reported by 11% (18/157) of patients Six screws were found to be protruding from the anterior cortex by more than 4 mm (total number of screws used in the series not reported but assume in region of 640 screws). No clinical complications due to excessive screw length were reported. One screw was observed to have broken at 18 month follow-up in one case. No bleeding occurred that would suggest vertebral artery damage	No objective measures of efficacy are reported. The intervention used a slightly different fixation technique to the other studies presented in this overview, with screws placed through a metal plate, rather than rods attached to ends of polyaxial screws. All patients had radiographic assessment, but CT sagittal reconstruction was carried out in 68 cases, and MRI in 74 cases. No reason was stated for selection for these investigations. Three patients died from unrelated causes during or soon after surgery and are not included in follow-up assessment. Procedure does not prevent the growth of the neck in children.

Abbreviation used: ICA – internal carotid artery			
Study Details	**Key efficacy findings**	**Key safety findings**	**Comments**
Currier BL (2004)(3) Review – Case report USA No demographic or clinical details of the case are presented (unpublished data)	None presented	**Operative complication** The internal carotid artery is at risk from a screw placed in to the lateral mass of the atlas in cases where it runs close to the anterior aspect of the site of insertion	Discussion of surgical technique. Majority of data from bio-mechanical studies on cadaveric spine specimens.
Resnick D K (2002)(4) Case report USA 54-year-old woman with type II fracture of the odontoid fitted with rigid collar, complaining of worsening neck pain at 6 weeks. Radiographic evidence of 5 mm of dorsal displacement and angulation of the odontoid peg. C1–C2 pedicle screw fixation, with rods connected to multiaxial screws, following a modified Gallie fusion and an allograft iliac crest bone graft placed between the lamina of C1 and the spinous process of C2 Follow-up 6 months	**Postoperative assessment** X-rays showed good alignment of the spine and satisfactory screw position **Follow up assessment** At 6 weeks post surgery no movement was noted on flexion or extension X-rays At 6 months post surgery the patient was pain free and was neurologically intact	Not reported	Case report of patient not suitable for transarticular screw fixation. No objective assessment of clinical parameter either pre or post operatively. Technique is technically less demanding than for transarticular screw placement. Authors comment that the biomechanical and clinical successes of this procedure are yet to be determined.

Validity and generalisability of the studies

• No studies provided statistical comparison of efficacy outcomes between baseline and follow-up.

• There may be different safety and efficacy profiles for rod or plate fixation.

• Few details are provided of case series inclusion criteria.

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

• A highly specialist technique to be used with image intensification or computer guidance.

• Adverse events from this procedure, are haemorrhage from venous plexus, and screw failure or loosening. Less common but more serious complications may include injury to the vertebral artery (less likely than with transarticular screw fixation), and spinal cord injury through screw misplacement.

• Suggested audit criteria include those relating to peri-operative complications.

• The uptake of this procedure is likely to the limited to a few specialist centres, and training on replica bones is advised.

Issues for consideration by IPAC

• Indications for this procedure are not consistent.

• Little in vivo data available

References

(1) Harms J, Melcher RP. Posterior C1-C2 fusion with polyaxial screw and rod fixation.[see comment]. Spine 2001; 26(22):2467-2471.

(2) Goel A, Desai KI, Muzumdar DP. Atlantoaxial fixation using plate and screw method: a report of 160 treated patients. Neurosurgery 2002; 51(6):1351-1356.

(3) Currier BL, Yaszemski MJ. The use of C1 lateral mass fixation in the cervical spine. Current Opinion in Orthopedics 2004; Vol. 15(3):-191.

(4) Resnick DK, Benzel EC. C1-C2 pedicle screw fixation with rigid cantilever beam construct: case report and technical note. Neurosurgery 2002; 50(2):426-428.

Appendix A: Additional papers on direct C1 lateral mass screw procedure for cervical spine stabilisation not included in the summary tables

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Goel A, Laheri V. (1994) "Plate and screw fixation for atlanto-axial subluxation". *Acta Neurochirurgica* 129(1–2), 47–53.	30 cases 17 months follow-up	Same cases as reported in Goel (2002)	All patients had improvement or stabilisation in neurological status. No patient has had recurrent instability requiring further operation. No evidence of screw loosening or failure.

Appendix B: Literature search for direct lateral mass screw procedure.

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

1 polyaxial screw$.tw. (10)
2 bone screw$.tw. (512)
3 exp Bone Screws/ (8766)
4 rod screw$.tw. (25)
5 lateral mass screw$.tw. (70)
6 exp Internal Fixators/ (2048)
7 exp Orthopedic Fixation Devices/ (35591)
8 orthop$edic fixation device$.tw. (9)
9 vertex.tw. (2774)
10 (rod adj2 system$).tw. (366)
11 CD horizon.tw. (4)
12 cross?link.tw. (1378)
13 atlantis.tw. (80)
14 wire fix$.tw. (613)
15 or/1-14 (40383)
16 lateral mass.tw. (260)
17 15 and 16 (138)
18 jefferson$.tw. (661)
19 ((C1 or C2 or axi$ or atlant$ or atlas$ or cervical) adj2 subluxation).tw. (676)
20 ((C1 or C2 or axi$ or atlant$ or atlas$ or cervical) adj2 fracture$).tw. (1754)
21 ((C1 or C2 or axi$ or atlant$ or atlas$ or cervical) adj2 instab$).tw. (830)
22 ((C1 or C2 or axi$ or atlant$ or atlas$ or cervical) adj2 injur$).tw. (3015)
23 ((C1 or C2 or axi$ or atlant$ or atlas$ or cervical) adj2 stabl$).tw. (155)
24 exp Spinal Fusion/is [Instrumentation] (1907)
25 exp Spinal Fractures/ (4452)
26 or/18-25 (11819)
27 exp atlas/ or exp axis/ or exp atlanto-axial joint/ or exp atlanto-occipital joint/ (3916)
28 exp Fracture Fixation/ (29966)
29 27 and 28 (250)
30 26 or 29 (11899)
31 17 and 30 (73)
32 limit 31 to human (73)
33 from 32 keep 1-73 (73)