Effectiveness and cost-effectiveness of acute hospital-based spinal cord injuries services: systematic review

A-M Bagnall\textsuperscript{1*}
L Jones\textsuperscript{1}
G Richardson\textsuperscript{2}
S Duffy\textsuperscript{1}
R Riemsma\textsuperscript{1}

\textsuperscript{1} NHS Centre for Reviews and Dissemination, University of York, UK
\textsuperscript{2} Centre for Health Economics, University of York, UK

* Corresponding author

**Executive summary**

*Health Technology Assessment 2003; Vol. 7: No. 19*
Objectives

The review aims to examine the following four questions:

1. the effectiveness and cost-effectiveness of spinal fixation surgery
2. immediate versus delayed referral to a spinal injuries unit (SIU)
3. how many people with a new spinal cord injury (SCI) are discharged from hospital without ever being transferred to an SIU
4. the effectiveness and cost-effectiveness of steroids for people with SCI.

Methods

Search strategy

Three separate search strategies were devised to find studies about:

- spinal fixation surgery
- referral, transfer and discharge of spinal cord injured patients
- steroid use for people with SCI.

Inclusion and exclusion criteria

Participants

People of any age with a complete or partial interruption of spinal cord function resulting from trauma.

Interventions

Q1 – surgical spinal fixation compared with any other treatment
Q2 – immediate versus delayed referral to SIU
Q3 – transferral to SIU, non-transferral to SIU
Q4 – steroids versus any other intervention.

Outcomes

All reported clinical outcomes were recorded. Outcomes such as radiological evaluation were given less emphasis.

Study design

Q1a – controlled studies
Q1b – controlled studies
Q2 – controlled studies or large case series
Q3 – any published data
Q4 – randomised controlled trials (RCTs) and systematic reviews.

Data extraction and quality assessment strategy

Quality of studies was assessed, according to criteria set out in NHSCRD’s Report 4, and data were extracted by one reviewer and checked by the second. Quality scores were not assigned to studies, but the results of quality assessment are discussed in the text.

Methods of analysis/synthesis

Data from included studies were summarised within each research question category. For dichotomous data, relative risks were calculated with 95% confidence intervals. Pooled relative risks were calculated as appropriate. For continuous data, mean differences with 95% confidence intervals were calculated and, if data were pooled, weighted mean differences were calculated.

Statistical heterogeneity was assessed. Where pooling was not sensible, data were summarised narratively, giving prominence to studies with the least biased designs.

Results

Question 1a. Spinal fixation versus no fixation

Sixty-eight studies were found: many were poorly reported or of poor validity. Most were retrospective observational studies and many included people with spinal injury but without SCI. The decision on whether to operate often
depended on the severity of the injury. In many studies, results of surgery with and without fixation were reported together. Heterogeneity was seen in many results which did not seem to be explained by severity of injury, types of surgery performed, country of study, year of publication or sample size.

It is unclear whether fixation surgery is associated with neurological improvement. Neurological deterioration did not differ between groups. There was significantly less mortality in the fixation group. Fixation surgery was more likely to be associated with device failure (which is not surprising) and wound infection, and less likely to be associated with instability of the spine. Data on urinary status and length of stay were equivocal. Fixation was associated with increased functional ability (to walk), shorter time to mobilisation and possibly increased independence in daily living activities.

It is unclear whether early fixation is more likely to lead to neurological improvement, shorter duration of hospitalisation or improved urinary status than late fixation.

**Question 1b. Fixation surgery in spinal injury units (SIUs) compared with non-SIU hospitals**

Only four studies were found. No significant differences were seen.

**Question 2. Delayed referral to a SIU**

All 28 studies were retrospective observational studies. In most, study details were poorly reported and there was doubt over the comparability of groups at baseline and on confounding factors. Times of referral and transfer were not reported separately.

Evidence suggested an effect in favour of the SIU group for neurological improvement. No differences were seen between early and late referrals. There was no difference in functional outcome between groups. Data on death rates in early versus late referrals and SIU versus non-SIU groups were equivocal.

Rates of most complications did not differ significantly between the two groups. The SIU group were less likely to develop pressure sores; this effect may have been time dependent. Delayed referral patients were more likely to experience a wide variety of complications.

Data from one study showed that patients treated in SIUs were less likely to need assistance with many activities of daily living. The study also found that patients in the SIU cohort spent more hours out of the house per week and were more likely to be in paid employment.

Patients receiving treatment in SIUs were more likely to have experienced shorter lengths of stay in hospital. Evidence suggested that patients undergoing early referral experienced shorter acute hospitalisation times.

**Question 3. How many people with a new SCI are discharged from hospital without ever being transferred to an SIU?**

No relevant published studies of any design were found. Primary research should be commissioned and published.

**Question 4. Steroids**

The evidence suggested that treatment with high-dose methylprednisolone within 8 hours of injury resulted in greater motor function recovery (of around four points, measured by standard clinical examination) compared with placebo. However, the practical relevance of this improvement was not stated. No effect was seen when all patients treated with methylprednisolone within 24 hours were compared with those treated with placebo.

Greater pinprick sensation was shown in all patients in the methylprednisolone group at 6 months but this beneficial effect was not evident at 1 year. Comparison of a 10-day regimen of high-dose with low-dose methylprednisolone found no differences between groups except that wound infection was higher in the high-dose group.

**Economics**

No studies were identified that considered both costs and the impact on patient outcomes of a given intervention. We were therefore unable to present any useful cost information which may have helped to improve the decision-making process.

**Conclusions**

Only retrospective observational studies were found which assessed spinal fixation surgery or delayed referral to SIUs. In most studies
there was doubt over the comparability of groups, at baseline and on confounding factors. Although there was evidence to suggest some benefits of fixation surgery and also a benefit of immediate referral to SIUs compared with delayed or no referral, owing to the limitations of the data these should be interpreted with caution.

In general, there was little investigation of the implications of the interventions from the point of view of the patients, relatives or partners. Primary qualitative research should be carried out among users to understand what outcomes are important, and patients should be involved in study design.

Data on effectiveness of spinal fixation surgery is high in quantity but low in quality. Spinal fixation does not appear to offer advantages in terms of neurological improvement, length of hospital stay or urinary status. Spinal fixation patients experienced less mortality, spinal instability or psychological problems. They were more likely to be mobile in a shorter time and independent in activities of daily living than non-fixation groups. They were more likely to experience wound infection, device failure and loss of spine flexibility. Not enough data were found to assess whether surgery is most beneficial when carried out in SIUs. Further research of higher quality is required in this area.

Patients undergoing immediate referral to SIUs may experience better outcomes than patients whose referral is delayed, or who are treated elsewhere. Owing to the questionable comparability of groups in the majority of studies, the evidence to support this conclusion is weak. Well-designed prospective observational studies with appropriately matched controls are needed.

High-dose methylprednisolone steroid therapy may be effective in promoting some degree of neurological recovery if given within 8 hours of injury. There is a need for more RCTs of pharmacological therapy for acute SCI.

We found no published studies of any design which would help to answer the question of how many people with acute SCI are discharged from hospital without ever being transferred to an SIU. Primary research involving audit of selected hospital records or a search of national hospital activity data should be commissioned and published.

The search strategy did not identify any full economic evaluations, that is, no study considered the costs as well as the impact on patient outcomes of a given intervention. Future research should include full economic evaluations, possibly alongside a large RCT, which fully consider the costs and consequences of implementing interventions.

**Publication**

How to obtain copies of this and other HTA Programme reports.

An electronic version of this publication, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (http://www.hta.ac.uk). A fully searchable CD-ROM is also available (see below).

Printed copies of HTA monographs cost £20 each (post and packing free in the UK) to both public and private sector purchasers from our Despatch Agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per monograph and for the rest of the world £3 per monograph.

You can order HTA monographs from our Despatch Agents:

– fax (with credit card or official purchase order)
– post (with credit card or official purchase order or cheque)
– phone during office hours (credit card only).

Additionally the HTA website allows you either to pay securely by credit card or to print out your order and then post or fax it.

Contact details are as follows:

HTA Despatch Email: orders@hta.ac.uk
C/o Direct Mail Works Ltd Tel: 02392 492 000
4 Oakwood Business Centre Fax: 02392 478 555
Downley, Havant PO9 2NP, UK Fax from outside the UK: +44 2392 478 555

NHS libraries can subscribe free of charge. Public libraries can subscribe at a very reduced cost of £100 for each volume (normally comprising 30–40 titles). The commercial subscription rate is £300 per volume. Please see our website for details. Subscriptions can only be purchased for the current or forthcoming volume.

Payment methods

Paying by cheque
If you pay by cheque, the cheque must be in pounds sterling, made payable to Direct Mail Works Ltd and drawn on a bank with a UK address.

Paying by credit card
The following cards are accepted by phone, fax, post or via the website ordering pages: Delta, Eurocard, Mastercard, Solo, Switch and Visa. We advise against sending credit card details in a plain email.

Paying by official purchase order
You can post or fax these, but they must be from public bodies (i.e. NHS or universities) within the UK. We cannot at present accept purchase orders from commercial companies or from outside the UK.

How do I get a copy of HTA on CD?

Please use the form on the HTA website (www.hta.ac.uk/htacd.htm). Or contact Direct Mail Works (see contact details above) by email, post, fax or phone. HTA on CD is currently free of charge worldwide.

The website also provides information about the HTA Programme and lists the membership of the various committees.
The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS.

The research reported in this monograph was commissioned by the HTA Programme on behalf of the Specialist Commissioning Groups in the East of England, London and the South to inform policy development. This Technology Assessment Report brings together evidence on key aspects of the use of the technology concerned.

The research reported in this monograph was funded as project number 01/28/01.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme, the Specialist Commissioning Groups in the East of England, London and the South or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for any recommendations made by the authors.

Criteria for inclusion in the HTA monograph series
Reports are published in the HTA monograph series if (1) they have resulted from work commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in Health Technology Assessment are termed ‘systematic’ when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA Programme Director: Professor Kent Woods
Series Editors: Professor Andrew Stevens, Dr Ken Stein, Professor John Gabbay, Dr Ruairidh Milne, Dr Chris Hyde and Dr Rob Riemsma
Managing Editors: Sally Bailey and Sarah Llewellyn Lloyd

The editors and publisher have tried to ensure the accuracy of this report but do not accept liability for damages or losses arising from material published in this report.