



Journal club: 6 December 2012

Attendees: Mr A.Khan, Miss A.Fishlock, Mr G.Hannant, Miss Z.Sun, Dr A.Howard, Mr G.Rudol, Miss K.Lowery, Mr M.Blomfield
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Theme: Spine: Spinal surgery – Timing of operative management in spinal trauma

Cengiz SL, Kalkan E, Bayir A, Ilik K, Basefer A. Timing of thoraco-lumbar spine stabilization in trauma patients; impact on neurological outcome and clinical course. A real prospective (rct) randomized controlled study. *Arch Orthop Trauma Surg* 2008;128:959-66.

Reviewer: Miss A.Fishlock

Summary

1. Purpose

This study aimed to evaluate the optimal timing of stabilisation for patients with spinal injuries. It compared the neurological recovery in patients with thoraco-lumbar spine fractures after surgical decompression and stabilisation performed early (within 8 hours) and late (3-15days) following spinal cord injury.

2. Methods

27 patients, M (18) and F (9) were included in the study. Ages ranged from 23 and 68 years (mean 41.4 +/- 14.71 years). Patients presented with an initial neurological deficit due to acute thoraco-lumbar spinal injury at the T8-L2 level. Patients were excluded if they were clinically unstable, had a severe multi system injury or were unsuitable to undergo acute surgery. The decision to treat surgically was based on the unstable fracture pattern or neurological deficit. Methylprednisolone was given to all patients at presentation. Patients were randomly separated into 2 groups; twelve within the 'early' group and fifteen within the 'late' group. Patients were assessed for neurological deficit and improvements scored using the ASIA standardised system. Neurological status was evaluated at presentation, preoperatively, and at the time of discharge/transfer

3. Results

Results demonstrated that patients who had 'early' surgery had a significantly shorter admission, had less systemic complications and demonstrated enhanced neurological improvement. The level of the injury did not influence the outcome in either group.

4. Conclusions

The conclusion drawn for this study was that early stabilisation of throco-lumbar spine fractures within 8 hours after trauma appears to be favourable. With improved neurological recovery, decreased length of admission and reduction in systemic complications

5. Critique

Strengths

- The same independent neurosurgeon carried out a blind assessment of the patients at formalised time periods, therefore helping to reduce variability in assessment.
- A formal scoring system was utilised (ASIA).
- Treatment was standardised, including pre-operative steroids and the surgical procedure.

Methodological Concerns

- Only 27 patients included in the study, with each group consisting of only 12 and 15 patients respectively. There was also a large age range, and much fewer female patients included (perhaps demonstrating the epidemiological spread of this type of injury).
- Neurology following spinal injury can often be progressive, and if this is the case urgent decompression is required. Therefore patients cannot be truly randomised into immediate or delayed group.
- The patients are not truly randomised in this study, indeed the timing of surgery was actually dictated by the day of presentation, therefore taking a prospective pragmatic approach to 'randomisation'.
- Patients with the most severe type of injury may have been excluded from this study as patients with severe multi system injury were excluded. This was likely to include polytrauma patients, therefore excluding potentially the most unstable patients.
- There was no standardised time-frame for follow-up. Indeed, all patients were followed-up for a median on 14.5 (15-20) months. However the neurology may continue to improve, even after this time.
- Although the study demonstrates that the change in motor index scores from preoperative to postoperative assessment was statistically, the study does not evaluate if the functional outcome improved. This surely must be the most important outcome for the patients.

Final Thought

Overall it was felt that this was a good paper, but not likely to change practice. If patients have a thoracolumbar injury and they have evolving neurology they require surgery imminently. Surgery should be performed when it is clinically deemed necessary and appropriate.

Rahimi-Movaghar V, Saadat S, Vaccaro AR, Ghodsi SM, Samadian M, Sheykhmozaafari A, Safdari SM, Keshmirian B. The efficacy of surgical decompression before 24 hours versus 24 to 72 hours in patients with spinal cord injury from T1 to L1 – with specific consideration on ethics: a randomized controlled trial. *Trials* 2009;10:77.

Reviewer: Miss A.Fishlock

Summary

1. Purpose

This article proposed a study to investigate the efficacy of surgical decompression before 24 hours versus 24 to 72 hours in patients with spinal cord injury from T1 to L1. The researchers hoped that the study would assist in contributing to the question of the efficacy of the timing of surgery in traumatic thoraco-lumbar SCI.

2. Methods

The study was to a prospective, randomised clinical trial recruiting 328 selected spinal cord injury patients with traumatic thoraco-lumbar spinal cord injury. They were to be assigned to either a)

early surgery (<24 hours), or b) late surgery (24-72 hours). Patients in the late surgery group would be provided with supportive care up (pressure support, immobilisation, and analgesia) until the surgery occurred. Patients were to be followed up 12 months post trauma.

3. Results

No results are available as this paper was published in a clinical trials journal.

4. Conclusions

No conclusion can be drawn as this is a research proposal, published in a clinical trials journal.

5. Critique

Strengths

- Formalised inclusion and exclusion criteria
- Power calculation has been made
- Excellent follow up planned
- Formal clinical assessment tool used ASIA and NASCIS

Methodological Concerns

- It was clear that the calculation on sample size demonstrated that a large n number (328 patients) would be required to achieve any power.
- The study states that it is a randomised controlled trial, however it would appear that the study plans to prospectively analyse, retrospective data.
- There are a number of ethical issues raised in this study. Firstly, if a patient has a potential chance of improvement by early surgery, it is acceptable to deny a patient this surgery purely for research purposes. It was argued that as the advantages of early decompression are not clear, then it is acceptable to delay surgery.
- Furthermore, as this study was to be done in Iran, many patients do not present to a hospital where early surgical intervention might be possible, due to lack in resources. Also this journal club thought that it was unethical to not treat patients if they presented to a hospital with staff and resources available to perform early decompression.

Final Thought

Overall, it was felt that this was a very well proposed study, but ethical issues are still difficult to accept.