

M. A. Foy BM, FRCS

Orthopaedic Surgeon,
Great Western Hospital Swindon, UK

Medico-legal editor

e-mail: foyfrcs5@gmail.com



Sentinel and never events in spinal surgery

INTRODUCTION

What is a sentinel event? The Joint Commission define it as: “any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient not related to the natural course of a patient's illness”.¹ Two recent publications look at sentinel events in cervical and lumbar spine surgery from a national database in the USA.^{1,2} In the UK in the 21st century we talk about ‘never’ events i.e. events that should never occur during the provision of medical care. NHS England³ lists 25 of these, only three are surgical; wrong site surgery, wrong implant/prosthesis and retained foreign object. Application of the World Health Organization surgical safety checklist³ is intended to minimise or abolish the occurrence of such events in the operating theatre. Some of the other never events can apply to surgical patients during their episode of hospital care e.g. maladministration of drugs, issues with nursing care of the elderly and frail, and anaesthetic errors.

The issue that challenges surgeons and the legal profession when such events occur (and where it appears that all reasonable precautions have been taken to avoid their occurrence) is whether that sentinel/never event constitutes a breach of the duty of care owed to the patient by the treating surgeon/hospital and if so, what is the effect of that breach.

INCIDENCE AND LITERATURE REVIEW

The reviews of Marquez-Lara et al^{4,5} present a very large cohort of patients reviewed over a long period. In the lumbar spine⁴ they looked at 543 146 lumbar spine surgeries carried out between 2002 and 2011 from the Nationwide Inpatient Sample (NIS) database. Revision procedures were excluded from the analysis. There were 414 (0.08%) sentinel events. They were:

1. Wrong site surgery: 3 per 10 000 cases (0.03%)
2. Vascular injury: 2 per 10 000 cases (0.02%)
3. Nerve injury: 2 per 10 000 cases (0.02%)
4. Retention of foreign object: 1 per 10 000 cases (0.01%)
5. Bowel/peritoneal injury: 6 per 100 000 cases (0.006%)

Wrong site surgery and retained foreign object are ‘never’ events according to NHS England. Overall, sentinel events occurred more frequently with posterior decompression, posterolateral fusion and posterior interbody fusion. Mortality increased by a factor of 20 (0.07% to 1.46%) if a sentinel event occurred. Wrong site surgery was more common with posterior surgery while vascular and visceral injury occurred more commonly with anterior surgery.

In the cervical spine⁵ the NIS database provided 251 318 procedures over the same period. There were 123 sentinel events (0.05%):

1. Nerve injury: 0.3 per 1000 cases (0.03%)

2. Wrong site surgery: 0.1 per 1000 cases (0.01%)
3. Oesophageal perforation: 0.04 per 1000 cases (0.004%)
4. Retention of foreign object: 0.03 per 1000 cases (0.003%)
5. Vascular injury: 0.003 per 1000 cases (0.0003%)

Hospital resource utilisation and peri-operative outcomes markedly varied between the different groups. Those who experienced a sentinel event had a longer period of hospitalisation (4.3 ± 8.0 versus 1.9 ± 2.6 days, $p < 0.001$) and greater total hospital costs. In addition, sentinel events were associated with a significantly greater incidence of post-operative aspiration, dysphagia, neurological complications, re-intubation, and surgical site infections ($p < 0.001$). Again, the incidence of mortality was nearly 10 times greater (8.1 versus 0.9 per 1000 cases, $p < 0.001$) among affected patients.

The specific issue of wrong site surgery was discussed by Longo et al.⁶ Their literature review of 12 selected papers on the subject found that the frequency of wrong level exposures ranged from 0.1% to 15%. A number of prevention strategies were discussed. As Hadjipavlou and Marshall⁷ pointed out: “this [wrong site exposure] does not usually cause harm as long as it is recognised.” They also pointed out that: “The harm caused by wrong site surgery can vary from trivial to serious.” In medical negligence cases, where the wrong level has been operated on, there is often debate and disagreement about the effect of partial removal of a healthy, probably non-symptomatic disc on the outcome for the patient. Wrong site surgery was more common in the lumbar than the cervical spine. We were surprised when we surveyed members of the British Association of Spinal Surgeons (BASS) in 2007 and found quite a wide variation in the use of intra-operative x-ray screening amongst members of the Association.⁸ Twelve per cent of surgeons used screening intermittently and only 54% always used screening for discectomy/decompression. However, Mody et al⁹ and Hsiang¹⁰ showed that obtaining intra-operative radiographs does not always guarantee that the correct level will be operated on. It seems to the author of this article that if the wrong level is operated on and no radiographs have been taken then the action is indefensible, while if radiographs have been taken there may be some semblance of a defence on the basis of anatomical variation, patients’ body habitus or technical issues.

CASES FOR CONSIDERATION

Case 1

A 35 year old man was undergoing a second revision decompression for an L4/5 disc prolapse. The treating surgeon considered whether to fuse the spine at the same time but decided against it. During the procedure one of the jaws of the pituitary rongeur used in the procedure broke and lodged in the disc space. It proved to be irretrievable despite use of image

intensification. The surgeon decided after 45 minutes that to pursue the matter further was likely to cause injury to the dura and neurological structures and therefore chose to leave it *in situ* in the belief that it would probably not migrate. It subsequently moved, although did not cause any neurological injury. The patient sought a second opinion from another surgeon who advised revision surgery with a posterior lumbar interbody fusion (PLIF) and removal of the broken rongeur tip. The original surgeon was sued for leaving the broken tip in the disc space. Expert evidence was obtained by both sides and it was agreed that the original surgeon had taken all reasonable efforts to remove the rongeur and given his concerns about causing further injury by pursuing matters further it was reasonable to leave it *in situ*. It was concluded that although the rongeur tip had migrated it appeared (on serial CT scans) to have stabilised in position, and while reasonable, it was not mandatory to remove it and proceed to a PLIF. The argument was also put forward by the claimants' solicitors that the rongeur had broken because it had been used incorrectly by the original surgeon. This involved expert evidence from product specialists/engineers. This aspect of the case was not pursued when it became clear that the expert spinal surgical evidence indicated that there was no case on breach of duty.

Case 2

A 45 year old woman underwent a C5/6 anterior cervical discectomy and fusion (ACDF) for C6 radiculopathy. During the surgery there was damage to the spinal cord which resulted in a central cord syndrome. While not paralysed she had significant ongoing disability as a result of the spinal cord injury. She continued with some radiculopathy, but given the spinal cord injury, this was not considered to be of great import. The radicular pain was felt to be slightly better than prior to surgery. She was followed up in the Orthopaedic Spinal outpatient clinic on a number of occasions and serial radiographs were taken. She was told that the appearances were satisfactory. She subsequently decided to sue the surgeon for negligence because of the injury to the spinal cord and the ongoing disability that resulted from it. Expert opinion was sought on the matter around two years after the original operation. Expert opinion was that the patient had been appropriately counselled on the risks of surgery, which included the risk of spinal cord injury and while unfortunate there was nothing to suggest that it had occurred as a result of negligence. However, on reviewing the series of MRI scans and radiographs it became apparent that the surgery had in fact been carried out not at the intended C5/6 level, but at C6/7. Therefore the patient had never had the opportunity to benefit from the surgery given that it had been carried out at the wrong level. It was not clear whether the failure to inform the patient that the wrong level had been operated on was due to serial incompetence during the various post-operative reviews or for other reasons. In the circumstances the defendant felt that there was no other option but to admit breach of duty and settle the claim.

Case 3

A 36 year old woman underwent an L5/S1 discectomy for sciatica. The operation proceeded uneventfully and the sciatica resolved immediately.

In the post-operative period her rehabilitation was hampered by abdominal pain. This was initially ignored but worsened and 72 hours after surgery she was seen by a general surgeon who diagnosed peritonitis and carried out an exploratory laparotomy. At surgery a jejunal injury was found. It was believed to have been caused by anterior penetration of the annulus during discectomy with resulting jejunal biopsy. Following the abdominal surgery the patient made a good recovery and returned to her legal practice. The original operating surgeon was sued for causing the jejunal injury. There was much discussion between the spinal experts on whether this sentinel event constituted negligence. It was eventually agreed that it probably did not as this was a very rare but recognised risk of discectomy. The operating surgeon was criticised for not being more alert to the potential complication in the first 48 hours, but as laparotomy was the likely outcome in any event, and there was a satisfactory outcome from it the case was dropped.

CONCLUSIONS

There is a strong possibility that if a sentinel or 'never' event occurs it will lead to the surgeon in charge of the patients care (or the Trust/Health authority) being the subject of litigation. As can be seen from the cases discussed above, even after such events it is not guaranteed that such actions will be successful. It behoves the surgeon to take all necessary precautions to prevent such events from occurring, be aware of the rare complications that can accompany this type of surgery and recognise and deal with them expeditiously and to be honest and frank with the patient if such problems arise.

REFERENCES

1. **The Joint Commission.** Sentinel Event Statistics – March 31, 2006. <http://www.jointcommission.org/SentinelEvents/Statistics/> (date last accessed 4 September 2014).
2. **NHS England.** The Never Events List 2013-14. <http://www.england.nhs.uk/wp-content/uploads/2013/12/nev-ev-list-1314-clar.pdf> (date last accessed 4 September 2014).
3. **World Alliance for Patient Safety.** WHO surgical checklist & implementation manual (2008). http://www.who.int/patientsafety/safesurgery/ss_checklist/en/ (date last accessed 4 September 2014).
4. **Marquez-Lara A, Nandyala SV, Hassanzadeh H, et al.** Sentinel Events in Lumbar Spine Surgery. *Spine (Phila Pa 1976)* 2014;(Epub ahead of print) PMID: 24480954.
5. **Marquez-Lara A, Nandyala SV, Hassanzadeh H, et al.** Sentinel events in cervical spine surgery. *Spine (Phila Pa 1976)* 2014;39:715-720.
6. **Longo UG, Loppini M, Romeo G, Maffulli N, Denaro V.** Errors of level in spinal surgery: an evidence-based systematic review. *J Bone Joint Surg [Br]* 2012;94-B:1546-1550.
7. **Hadjipavlou AG, Marshall RW.** Wrong site surgery: the maze of potential errors. *Bone Joint J* 2013;95-B:434-435.
8. **Shaw MJ, Pearce M, Foy MA, Fogg AJ.** X-ray screening in spinal surgical practice in the United Kingdom. *J Bone Joint Surg [Br]* 2008;90-B_SUPP III:530.
9. **Mody MG, Nourbakhsh A, Stahl DL, et al.** The prevalence of wrong level surgery among spine surgeons. *Spine (Phila Pa 1976)* 2008;33:194-198.
10. **Hsiang J.** Wrong-level surgery: a unique problem in spine surgery. *Surg Neurol Int* 2011;2:47.