

An Update on Wrong-Site Spine Surgery

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Abstract

Study Design: Broad narrative review of current literature and adverse event databases.

Objective: The aim of this review is to report the current state of wrong-site spine surgery (WSSS), whether the Universal Protocol has affected the rate, and the current trends regarding WSSS.

Methods: An updated review of the current literature on WSSS, the Joint Commission sentinel event statistics database, and other state adverse event statistics database were performed.

Results: WSSS is an adverse event that remains a potentially devastating problem, and although the incidence is difficult to determine, the rate is low. However, given the potential consequences for the patient as well as the surgeon, WSSS remains an event that continues to be reported alarmingly as often as before the implementation of the Universal Protocol.

Conclusions: A systems-based approach like the Universal Protocol should be effective in preventing wrong-patient, wrong-procedure, and wrong-sided surgeries if the established protocol is implemented and followed consistently within a given institution. However, wrong-level surgery can still occur after successful completion of the Universal Protocol. The surgeon is the sole provider who can establish the correct vertebral level during the operation, and therefore, it is imperative that the surgeon design and implement a patient-specific protocol to ensure that the appropriate level is identified during the operation.

Keywords

wrong-site surgery, wrong-site spine surgery, wrong level, wrong patient, wrong side

Introduction

Wrong-person, wrong-procedure, and wrong-site surgery still remains a common sentinel event reported by the Joint Commission on Accreditation of Healthcare Organizations (JC). These events remain a concern 15 years after the JC mandated the Universal Protocol (UP) in 2004. In addition to increased health care costs and potential legal action, this medical error can lead to patient morbidity and negatively affect long-term outcomes.

Historical Perspective

The American Academy of Orthopedic Surgeons (AAOS) launched the Sign Your Site campaign in 1998. This initiative encouraged surgeons to clearly mark their initials on the correct site as part of their preoperative process in an attempt to reduce wrong-site surgery errors.^{1,2} In 2004, the JC introduced the UP that provides guidelines for the fundamental elements of a prevention protocol that include requirements for marking the surgical site, confirmation of patient identity, confirmation of

the intended procedure, and a review of these details among the surgical team during a final time-out immediately prior to the start of the surgery.³ The World Health Organization (WHO) advanced the “Safe Surgery Saves Lives” initiative in 2008 that included the WHO Surgical Safety Checklist.⁴

Despite these patient safety initiatives, wrong-site surgery remains a real concern. The JC ranked wrong-site surgery as the second most frequently reported sentinel event between 1995 and 2005, with 455 of 3548 (12.8%) events.⁵ Despite the required implementation of the UP by JC-accredited hospitals in 2004, wrong-site surgery remained the second most

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frequently reported event in 2014.⁶ The JC sentinel event database reported 1072 wrong-site surgeries among its 8275 reported sentinel events (12.9%) from 2004 to June 2014. The most recent summary data of sentinel events reviewed by the JC reported 336 wrong-site surgeries among its 2563 reported (13.1%) from 2015 through 2017.⁷

There are limitations to this data and how it can be interpreted. These events are voluntarily reported and likely represent only a small portion of actual occurrences. Therefore, no clear conclusions can be made about the actual relative frequency of events or trends over time using the database and most studies do not allow for the calculation of an event rate. The exact incidence of wrong-site surgery is not known; however, patient safety experts would maintain that one wrong-site surgery is too many.

There have been 2 quality systematic reviews performed in the past decade regarding wrong site surgery. In 2010, a systematic review determined an estimated rate of wrong-site surgery varied widely ranging from 0.09 to 4.5 per 10 000 surgeries performed and that no literature existed to substantiate the effectiveness of the JC UP in decreasing the rate of wrong-site surgery.⁵ In 2015, a Cochrane systematic review was performed to evaluate the effectiveness of interventions for reducing wrong-site surgery.⁸ After identifying over 3000 references, only 1 article was identified that met the criteria for review that analyzed the incidence of wrong-site surgery before and after the implementation of the JC UP. Vachhani et al⁹ reported a statistically significant reduction in overall wrong-site surgery after implementation of the UP.⁹ They reported 15 wrong-site surgery events. All but one (14/15) were wrong-level spine surgeries. Only 1 case of wrong-side surgery was recorded, and it was after implementation of the UP. They reported a statistically greater number of wrong-site surgery events (12) in comparison with after (3) UP implementation. However, the Cochrane review reanalyzed the Vachhani et al data and evaluated the annual incidence rates of wrong-site surgery. The annual incidence rates suggested that a strong downward trend in the incidence of wrong-site surgery existed *prior* to the UP implementation and thus, the effect of the intervention in this study is unclear. The Cochrane review concludes that confounding factors influencing the rates of wrong-level spine surgery in this study may include increasing use of intraoperative imaging and techniques such as fiducial marking, which is something that is not an inherent stipulation of the UP.

Wrong-site surgery is rather unique as it pertains to spine surgery. Because of this, the term “wrong-site spine surgery” (WSSS) has been adopted to describe this event.^{5,10} Although the UP offers a systems-based prevention method for identifying the proper patient, procedure, and region of the spinal column, this approach cannot be relied on to establish the correct vertebral level during the surgical procedure.

Current Trends in Wrong-Site Spine Surgery

The American Board of Orthopaedic Surgery database was queried from 1999 to 2010 in a study to compare the incidence

of wrong site surgery before July 2005 with incidence after this date.¹¹ There were 44 wrong-site surgical procedures out of 609 715 cases reported (0.0072%) from 1999 to 2005. There were 27 wrong-site surgical procedures out of 435 382 cases reported (0.0062%) from 2006 to 2010. This difference was not significant. The same analysis was performed after surgical procedures involving the spine were excluded revealing 24 wrong-site surgical procedures out of 568 438 (0.0042%) from 1999 to 2005 and 11 wrong-site surgical procedures out of 398 873 (0.0028%) from 2006 to 2010. Although this difference was also not statistically significant, the rate of nonspine wrong-site surgery fell 35% after institution of the UP, suggesting a trend. A total of 897 spine surgeons submitted 324 085 spinal procedures from 1999 to 2010. Thirty-one surgeons (3.5%) reported a wrong-level spine surgery for an estimated rate of 0.041%. Of the 26 wrong-level spine surgeries reported, 14 occurred in the lumbar spine, 8 involved the cervical spine, and 2 involved the thoracic spine. None of the reports indicated that neglecting to obtain intraoperative images was the cause of the wrong-level event. However, 11 reports stated that the imaging was not interpreted correctly. Reasons cited included morbid obesity, moving the retractors after localization without adequately marking the appropriate level, and unrecognized movement of tubular retractors during minimally invasive surgery. A higher frequency of wrong-level surgery in lumbar procedures has been confirmed in another review on wrong-level spine surgery.¹²

Mesfin et al¹³ reported results of an observational study assessing formal WSSS training of spine surgery fellows in North America during the 2013–2014 academic year. A total of 152 spine fellows were polled, with a response from 46 (30.3%). Among the fellows who responded, 14 (30.4%) had already experienced WSSS.

The Minnesota Department of Health releases an Adverse Health Events report annually. In the most recent report dated February 2018, the overall analysis for the year 2017 revealed an increase in wrong site surgical events.¹⁴ There were 36 wrong-site surgery events, which was the highest surgically related adverse event. Spine surgeries were the most common type of procedures involved in wrong-site surgery. However, despite the increase in the event total, given the 3.1 million surgeries and invasive procedures performed, the overall incidence remained very low. The report concluded that verification of the surgical site for spine surgery remains a challenge, particularly in identifying the correct spinal level intraoperatively. However, in this reporting year, 43% of WSSS events were wrong-side events (ie, right vs left). This sentinel event, which should be identified and confirmed with a systems-based approach like the UP, still remains a concern.

While the AAOS Sign Your Site initiative, JC-mandated UP, and WHO Surgical Safety Checklist guidelines are specific in content, implementation of these guidelines can vary widely across institutions, hospitals, and surgery centers. Even when protocols are implemented, adherence may not be consistent within a given system. This helps explain why wrong-site surgery continues to occur.

Prevention

Systems-based prevention can be effective for confirming the proper patient, following the proper planned procedure, and identifying the proper anatomical site or region. Adherence to the planned protocol should minimize these types of wrong-site surgery errors. However, the prevention systems cannot be relied on to establish the correct spine level during surgery. The spine surgeon is the sole health care provider with access to and knowledge of all pertinent information necessary to identify the correct level of surgery. This requires appropriate training on interpreting the pre- and intraoperative imaging studies, correlating the imaging with surgical anatomy and addressing the pathology at the appropriate level. The surgeon has the primary responsibility for the implementation of a patient-specific protocol to avoid WSSS. Several reports have been published with recommendations to aid in the identification of the appropriate spinal level during the pre- and intraoperative period.^{10,15-17} These localizing techniques involve utilizing a metallic marker on an anatomical landmark during the exposure of the spine, and reliably interpreting some form of imaging intraoperatively. Ultimately, prevention relies on proper education beginning at the resident and fellow level of training regarding the pitfalls in avoiding WSSS, and it appears that formal education regarding this potentially avoidable complication is limited.¹³

Conclusion

WSSS is an adverse event that remains a potentially devastating problem, and although the incidence is difficult to determine, the rate is very low. However, given the potential consequences for the patient as well as the surgeon, WSSS remains an event that continues to be reported alarmingly as often as before the implementation of the UP, and most would consider one event too many. A systems-based approach like the UP should be effective in preventing wrong-patient, wrong-procedure, and wrong-sided surgeries if the established protocol is implemented and followed consistently within a given institution. However, wrong-level surgery can still occur after successful completion of the UP. The surgeon is the sole provider who can establish the correct vertebral level during the operation, and therefore, it is imperative that the surgeon design and implement a patient-specific protocol to ensure that the appropriate level is identified during the operation. We recommend intraoperative imaging during exposure and marking of a fixed anatomic structure with a metallic instrument and comparing that image with routine preoperative studies to confirm the correct site for spine surgery. The type of imaging used varies and is dependent on the region of the spine, highlighting the fact that patient-specific protocols developed during the preoperative planning should be documented and implemented by the surgeon. This should become a routine part of the preoperative planning. Finally, training to perform this task needs to become part of the curriculum during residency and fellowship.

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