Abstract:

Background:

Although exceedingly rare, Wrong Site Surgery (WSS) remains a persistent problem in the United States. The incidence is thought to be 2-3 per 10,000 craniotomies and about 6-14 per 10,000 spine surgeries. In July 2004 the Joint Commission mandated the Universal Protocol (UP) for all accredited hospitals.

Objective:

Assess the effect of UP implementation on the incidence of neurosurgical WSS at the University of Illinois College of Medicine at Peoria / Illinois Neurological Institute.

Methods:

The Morbidity and Mortality Database in the Department of Neurosurgery was reviewed to identify all recorded cases of WSS since 1999. This was compared to the total operative load (excluding endovascular procedures) of all attending Neurosurgeons to determine the incidence of overall WSS. A comparison was then made between the incidences before and after UP implementation.

Results:

Fifteen WSS events were found with an overall incidence of 0.07% and Poisson 95% confidence interval of 8.4-25. All but one of these were wrong level spine surgeries (14/15). There was only one recorded case of wrong side surgery and this occurred after implementation of the UP. A statistically greater number of WSS events occurred before (n=12) as compared with after (n=3) UP implementation ($p<0.001$).

Conclusions:

A statistically significant reduction in overall WSS was seen after implementation of the UP. This reduction can be attributed to less frequent wrong level spine surgery. There was no case of wrong procedure or patient surgery and the one case of wrong side surgery occurred after UP implementation.

Running Title: Results of Universal Protocol Implementation

Keywords:
checklist
Neurosurgery
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wrong site surgery
Sentinel Event

Joint Commission

Abbreviations:

WSS: Wrong Site Surgery

UP: Universal Protocol

JC: Joint Commission

Introduction:

Although exceedingly rare, Wrong Site Surgery (WSS) remains a persistent problem in the United States. The consequences can be as minor as pain from an additional incision to death or permanent morbidity from an unnecessary procedure. The Joint Commission (JC) defines a WSS as a sentinel event and from a medico-legal perspective, a WSS event is extremely difficult to successfully defend. Goodkin et al reviewed 68 cases of wrong level spine surgery and found the majority of cases were settled out of court and only 13 were successfully defended.[1]

In a response to prevent WSS, the American Academy of Orthopaedic Surgeons promoted a "Sign Your Site" campaign in 1997.[2] This was followed by the North American Spine Society's guidelines in 2001 on preventing WSS through their sign, mark, and x-ray campaign.[3] In July 2003 the JC released the Universal Protocol (UP) for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery. The following year, it became mandatory for all accredited hospitals, ambulatory care, and office-based surgery facilities.[4]

The true incidence of WSS is largely unknown due to underreporting. In non-spine surgeries, it is thought to be approximately 1 in 113,000 operations.[5] Among Neurosurgeons, the incidence is thought to be 2-3 cases per 10,000 craniotomies and about 6-14 cases per 10,000 spine surgeries.[6] The Illinois Adverse Health Care Events Reporting Law of 2005 mandates all hospitals in Illinois report adverse events to the Illinois Department of Public Health. These events include wrong side surgery, surgery on the wrong body part, and surgery on the wrong patient.[7] The JC keeps a national database of sentinel events and has found a general trend of increased WSS events reported per year.[8] It remains unclear whether this represents a true increase in the incidence or an increase in reporting.[9] The effectiveness of the UP remains

unknown and to the authors' knowledge, there are no studies showing a decrease in the incidence of WSS since the implementation of the UP.

Methods:

Since 1991, the Department of Neurosurgery at the University of Illinois College of Medicine at Peoria has held a monthly or biweekly Morbidity and Mortality Conference. The decision on which patients to discuss was left to the attending surgeon or any member of the surgical team. All patients that were discussed had the details of their case recorded in a database.

After obtaining IRB approval, the Morbidity and Mortality Conference Database was searched for all incidents of WSS from 1999 to 2011. WSS was defined as wrong side surgery, surgery on the wrong body part, wrong procedure, and surgery on the wrong patient. The incidence of WSS was calculated as the ratio of the number of WSS events to the total number of surgical procedures (excluding endovascular procedures) of all Illinois Neurological Institute attending Neurosurgeons performed for that time period. All WSS events prior to 1999 were not included in this paper because there was no data regarding the total number of surgical procedures prior to 1999. Fisher's Exact test was performed to determine statistical significance. In order to determine the incidence of WSS for spinal procedures and cranial procedures, all surgeries from 1999 to 2011 were classified into either cranial, spinal, or other surgeries. The total number of spinal and cranial WSS were then divided by their respective total number of surgeries to determine their respective incidences.

Results:

A total of 15 WSS events occurred from 1999 to 2011. Twelve occurred prior to the implementation of the UP and three occurred afterwards. *(Table 1)* The total operative volume from January 1st, 1999 to June 30th, 2004 (prior to the UP) was 7,286 procedures and from July 1st, 2004 to December 31st, 2011 (after the UP) was 15,457 procedures. *(Table 2)* Fisher's Exact test found a statistically significant difference between the two groups ($P < 0.001$). The incidences and Poisson 95% confidence intervals (in parenthesis) of all WSS events, WSS events prior to the UP, and WSS events after the UP were; 0.07% (8.4-25), 0.16% (6.2-21), and 0.02% (0.62-8.8).

Of the 15 WSS events, 14 were due to wrong level spine surgery. One wrong side cranial surgery was reported and this occurred after the implementation of the UP. There was no reported wrong patient/procedure surgery or wrong side spine surgery. The incidence of spinal WSS was 14 per 11,173 patients (0.13%) and cranial WSS was 1 per 3974 patients (0.03%). Twelve of the 14 wrong level spine surgeries required an additional level of fusion. Intraoperative x-rays were obtained prior to decompression in 8 cases, not obtained in 5 cases, and unknown in 1 case. The cause of the error in the cases where an x-ray was obtained was due to misinterpretation of the x-ray by the surgeon and/or radiologist. The WSS error was discovered prior to the end of the case in 12 out of 15 cases and required an additional surgery in the remaining 3 cases *(Table 3)*.

Discussion:

Checklists have gained increasing attention in the medical community due in part to their success in the aviation industry. In his book, *The Checklist Manifesto*, Dr. Atul Gawande relates the story of a crash in 1935 involving a test flight of a Model 299, the precursor to the B-17 bomber. An investigation into the accident found no mechanical errors, but that the pilot was unable tojavac manage all the complexities of the aircraft. One newspaper dubbed it "too much airplane for one man to fly". Instead of requiring additional training of pilots, Boeing created a pilot's checklist to be used prior to takeoff. The results of the checklist were so impressive that Boeing was able to secure a contract with the United States Army during World War II to sell approximately 13,000 B-17 bombers.[10]

Within the medical community, surgical checklists have been shown to improve patient outcomes. A prospective cohort study involving checklists prior to placement of central lines found a statistically significant decrease in catheter-related bloodstream infections.[11] In 2008, the World Health Organization created a 19-point Surgical Safety Checklist designed to reduce surgical complications and death. This checklist was incorporated into a prospective international study involving eight hospitals in eight different cities, four of which were in developing countries and the remaining four in developed countries. After collecting data on 3733 patients before and 3955 patients after introduction of the Surgical Safety Checklist, the

authors found a statistically significant decrease in death (1.5% to 0.8%) and inpatient complications (11.0% to 7.0%). Upon further analysis of the results, the majority of the benefits appear to have occurred in the hospitals in developing countries. In addition, the authors admit they are unable to determine the impact of the Hawthorne effect on their results.[12]

Checklists in Neurosurgery

Recently, the neurosurgical community has seen an increased use in surgical checklists. To help manage aneurysm perforation during endovascular coiling, Taussky et al created a checklist of steps to take if aneurysm perforation is suspected.[13] In an effort to reduce ventriculostomy related infections, the University of Florida Department of Neurosurgery devised a checklist in 2006 that was mandated for residents performing bedside ventriculostomy procedures. They were able to reduce their infection rate from 9.2% to less than 1%. The authors state that their success was not simply due to the checklist, but also because of the commitment of the nurses, physicians, and Intensive Care Unit staff.[14] However, the authors made no mention of whether they switched to antibiotic impregnated catheters, which have been shown in multiple prospective randomized controlled trials to reduce the rate of external ventricular drain associated infections.[15,16,17]

To test the feasibility of checklists in Movement Disorder Surgery, Connolly et al created a checklist to be used in their Deep Brain Stimulation Surgeries. In a prospective series of 13 patients, they found a mean of two errors per case. The amount of time added to the case was minimal and appeared to improve from the beginning to the end of their study. Unfortunately, there was no control group to determine whether the change in errors was statistically significant or clinically meaningful.[18]

Checklists for Wrong Site Surgery

While there are a number of studies on the use of checklists to reduce infection, very little has been published on the success of checklists to reduce WSS. In a review of 35 wrong side craniotomies, Cohen and his colleagues found the common factor in every case was human error.[19] In order to reduce the impact of human error, the Veteran's Health Administration developed the Medical Team Training Program, which places emphasis of conducting

preoperative briefings and postoperative debriefings, both guided by a checklist to improve communication and patient safety in the OR. The authors found a statistically significant decrease in adverse events, which they defined as wrong patient, side, site, implant, or procedure in patients observed in 2001-2006 to those observed in 2006-2009.[20] In 2010, Lyons published the experience of the Department of Neurosurgery at the Mayo Clinic in Arizona eight years after implementation of their operative checklist. There were no WSS events reported in the 6345 patients treated over that time period. Unfortunately, there was no data regarding the incidence of WSS prior to the checklist.[21]

Wrong Level Spine Surgery

Of the 15 WSS cases recorded in the present study, all but one was due to a wrong level spine surgery. The results of a 30-question survey sent to members of the American Association of Neurological Surgeons in 2006 show that 50% of surgeons have performed one or more wrong level spine surgery in their career.[22] According to the JC, several factors contribute to WSS, including; emergency cases, unusual physical characteristics (i.e. morbid obesity, congenital deformity, etc.), unusual time pressures to start or complete the procedure, unusual equipment or set-up in the operating room, and multiple surgeons or procedures involved in the single case.[23] Numerous authors have recommended the use of intraoperative radiographs to localize the correct level prior to decompression.[24,25,26] In a prospective study evaluating the accuracy of anatomical localization, Ammerman and colleagues found anatomic localization was only accurate in 85 out of 100 lumbar diskectomies when compared to localization with an x-ray.[27] Some have published their experience using fiduical markers placed at the correct level pre-operatively by an interventional radiologist.[28,29] It remains unknown whether this would be practical or economically feasible outside of a few select cases. Unfortunately, obtaining a x-ray during surgery does not guarantee correct level surgery as evident by 8 of the 14 wrong level spine surgeries in the present series. Out of the 8 wrong level surgeries with x-rays, four were obese (two of which were morbidly obese), 3 were overweight and bordering on obese (BMI=28-29), and one had a normal BMI. Two patients had a transitional vertebrae between L5 and S1 (one overweight and one obese) and the remaining three non-obese patients were reported to have poor quality images that were thought to have caused the error.

In their original review in 1997, the North American Spine Society obtained information on eleven single level spine surgeries performed on the wrong level. Of those eleven cases, ten were incorrectly performed on the level above.[30] Ebraheim and colleagues performed a prospective study in 1999 comparing the accuracy of anatomic localization to that of lateral radiographs in 80 posterolateral lumbar fusions. Anatomic localization was correct in 76 surgeries (95%) and in the remaining four cases, two were incorrectly localized at the level above and two the level below.[31] In the current series, the level above was incorrectly decompressed in 8 of 11 wrong level surgeries in the lumbar spine (all via a posterior approach). This contrasts with the level below being incorrectly decompressed in 3 of 3 wrong level surgeries in the cervical spine (all via an anterior approach). Although there has been very little published on this subject, one may speculate that the anatomy of the posterior lumbar spine and surgical approach for a posterior lumbar decompression/fusion may pre-dispose a surgeon to erroneously operate on the level above more often than the level below. Conversely, the anatomy of the anterior cervical spine and surgical approach for an anterior cervical diskectomy and fusion may pre-dispose a surgeon to erroneously operate on the level below more often than the level above. Larger studies with a greater sample size are needed to determine the validity of this theory.

Wrong Site Surgery Incidence

Among patients in the current series; 14 per 11,173 patients had spine surgery at the wrong level and 1 per 3974 patients had cranial surgery on the wrong side with an incidence of 0.13% and 0.03% respectively. The overall rate of WSS was found to be 0.07% (15 incidents per 22,743 procedures). Compared to Orthopaedic Surgeons, this is higher than the incidence reported by James et al in 2012 of 0.007% (71 incidents per 1,045,097 procedures). It should be noted that the authors admit their study may underestimate the percentage of WSS cases because they only obtained information during the case collection period of surgeons who were seeking certification by the American Board of Orthopaedic Surgery. The surgeons may be more vigilant towards preventing WSS because of their upcoming certification examination.[32] According to the JC, WSS cases in 2006 were most often caused by Orthopaedic and General Surgery (20% of cases, each). Neurosurgery, in comparison, is the 6th highest specialty and caused 6% of WSS cases in 2006.[33] This discrepancy in a lower percentage of WSS cases, but

higher incidence of WSS among Neurosurgeons can likely be attributed to the fact that Orthopaedic Surgeons outnumber Neurosurgeons and the percentage of all WSS may not accurately represent the incidence of WSS per surgical specialty. Further studies are needed to determine the true incidence of WSS among various subspecialties.

Limitations

There are several limitations to this study. First, it is subject to the limitations of a retrospective review. Second, the conclusions reached rely on the accuracy of the Morbidity and Mortality Database. While there was a fair bit of uniformity in how the conference was run, the selection of which patients to discuss was left to the discretion of the attending surgeon and members of the surgical team. However, it should be noted that both of these issues was operant before and after the implementation of the UP. Third, the low incidence of wrong side surgery and lack of wrong patient or wrong procedure surgeries will not allow any conclusions to be made regarding these adverse events except that they are exceedingly rare events. Lastly, a number of institutional changes aside from the UP have been made from 1999 to 2011 that may have contributed to the reduction of WSS events including 1) a switch to an electronic picture archiving and communication system for all patient images in 2005 making intraoperative localization imaging much simpler and more reliable and, 2) a gradual cultural shift in the operating room towards a team-based approach with all parties involved taking responsibility for prevention of WSS. All these factors make it impossible to determine what role, if any, the UP had in decreasing the rate of WSS.

Some have speculated that the reason there has not been an appreciably decrease in WSS since the implementation of the UP is procedural non-compliance. Dr. Richard Croteau, Executive Director for Patient Safety Initiatives at the JC found that when analyzing root causes of WSS from 1995 to 2006, there has been an increase in percentage of cases that have problems with procedural compliance.[32] In the current study, compliance with the UP was found to contribute to one of the three cases of WSS after implementation of the UP. All three cases had documented evidence of the time out being performed prior to incision and two of three cases had the correct site marked prior to incision. In the case of the wrong side surgery in 2010, the time out was performed, but the case was performed emergently and the correct side was not

marked prior to surgery.

DeVine et al performed a systematic review of all relevant literature on WSS and they stated in their evidence summary "There is no evidence to support the JC checklist, North American Spine Society checklist, or any other preventative measure with respect to their effectiveness in preventing a WSS."[24] A recent review of the self-reported rate of WSS among cases submitted by Orthopaedic Surgeons to the American Board of Orthopaedic Surgery from 1999 to 2011 found no statistically significant difference between the WSS rate before and after the UP implementation.[3] While the data from the current study does show a decrease in wrong level spine surgery since the implementation of the UP, there were no cases of wrong procedure or patient surgery and the one case of wrong side surgery occurred after the UP was implemented. One might argue that a wrong spine level event is more often one of inaccurate intraoperative localization than it is of inappropriate preoperative identification of the targeted level. If such is the case, it is difficult to attribute significant reduction in wrong spine level events to the implementation of the UP. Rather, the reduction is likely a manifestation of a dramatic cultural change in the operating room that has led to more vigilant assurance by all parties that the appropriate procedure is being done on the correct patient.

Conclusions:

This is the first study to show a statistically significant decrease in neurosurgical WSS since the implementation of the UP. This decrease can be attributed entirely to the reduction in wrong level spine surgery as there was no case of wrong side, procedure, or patient surgery. Larger, prospective studies are needed to determine 1) whether the reduction in WSS is directly attributable to implementation of the UP and 2) if the inevitable perioperative delays and subsequent costs associated with the UP are justified in efforts to prevent an exceedingly uncommon event.

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