Preprocedural checklist for regional anesthesia: impact on the incidence of wrong site nerve blockade (an 8-year perspective)


ABSTRACT

Background The term “Wrong-Site Surgery (WSS)” is commonly associated with surgical procedures; however, The Joint Commission (TJC) considers any invasive procedure, not just a surgical procedure, performed on the wrong side, at the wrong site, or on the wrong patient to be a WSS. For anesthesia providers, this means that a wrong-site nerve block (WSNB) also constitutes a WSS and would be considered a sentinel event by TJC. In an attempt to combat WSNB, the American Society of Regional Anesthesia and Pain Medicine published guidelines in 2014 recommending the use of a preprocedural checklist before performing regional blocks. The effectiveness of such a checklist, however, to reduce the occurrence of WSNB has not yet been demonstrated. We hypothesized that the introduction of a preprocedural checklist specific for regional anesthesia would be associated with a lower rate of WSNB procedures.

Methods A retrospective review was performed to compare the incidence of WSNB 2 years before, to 6 years after the implementation of a preprocedural checklist specific to regional anesthesia.

Results Prior to checklist implementation, 4 WSNB events occurred during 10 123 procedures (3.95 per 10 000 (95% CI 1.26 to 9.53)). Following implementation, WSNB events occurred during 35 890 procedures (0 per 10 000 (95% CI 0 to 0.84)); p=0.0023.

Conclusions Implementation of a regional anesthesia specific preprocedural checklist was associated with a significantly lower incidence of WSNB procedures. While prospective controlled studies would be required to demonstrate causation, this study suggests that for regional anesthesia procedures, a preprocedural checklist may positively impact patient safety.

INTRODUCTION

The term “Wrong-Site Surgery” (WSS) is frequently used to describe a surgical procedure performed on the wrong-side, at the wrong-site, on the wrong-person, or in which an incorrect procedure is performed.1 What is often underappreciated, however, is that this type of medical error is not exclusive to surgical procedures. According to The Joint Commission (TJC) “any invasive procedure that exposes patients to more than minimal risk, including procedures performed in settings other than the OR (operating room)” that is performed on the wrong patient, on the wrong side, or at the wrong site also constitutes a WSS.2 While TJC specifically mentions procedures performed in endoscopy units and interventional radiology suites, anesthesia-related procedures such as a peripheral nerve block (PNB) would also be included since these procedures are invasive and have more than minimal inherent risk for a patient.

Although some may consider wrong-site nerve blockade (WSNB) to have less serious consequences than a wrong-site surgical procedure, TJC considers any wrong-site invasive procedure to be a sentinel event, “regardless of the type of procedure or the magnitude of the outcome.”3 For clarification, a sentinel event is defined as a serious adverse patient safety event that signals the need for immediate institutional investigation and response. Sentinel events are routinely evaluated as a part of TJC’s institutional accreditation review. In addition, the National Quality Forum has labeled wrong-site invasive procedures a “never event,” meaning they should never occur.

Historically, wrong-site surgical procedures have received significantly more attention than WSNB, both in the lay press and the medical literature. Over the last few decades, wrong-site surgical procedures have been the target of a considerable number of initiatives aimed at decreasing or eliminating their occurrence, including the enactment of the Universal Protocol by TJC in 2004.4 Surprisingly, WSNB appears to be far more common than wrong-site surgical procedures. The most commonly cited incidence for wrong-site surgical procedures is 1 in 112 994, which was calculated using data from 30 hospitals across Massachusetts over a 20-year period. During this time period, 25 wrong-site surgical procedures occurred in almost 3 million surgical procedures.3 However, this statistic does not include the 15 reported spine surgeries that were performed on the wrong side or at the wrong level. When these are included, the incidence becomes 1 in 70 659.5 In contrast, the reported incidence of WSNB in regional anesthesia ranges from 1.28 to 3.63 per 10 000 procedures (1 in 2755 to 1 in 7812).6 Although the actual incidence for both types of serious safety events is likely higher due to underreporting, these data suggest that WSNB events occur at a rate that is 10-fold higher than that of wrong-site surgical procedures.

In an effort to directly combat WSNB, a task force appointed by the American Society of Regional Anesthesia and Pain Medicine published...
recommendations in 2014 regarding a preprocedural checklist specific to regional anesthesia. While the use of a checklist prior to surgical procedures has been shown to significantly influence various surgical outcomes including mortality, the utility of a preprocedural checklist for decreasing the rate of WSNB has not been established.

The aim of this study was to investigate the impact that a preprocedural regional anesthesia-specific checklist may have on the rate of WSNB by directly comparing the incidence of WSNB events occurring both before and after implementation. The hypothesis, defined a priori, was that the incidence of WSNB would be significantly lower following checklist implementation.

METHODS

Institutional review board (IRB) approval was obtained prior to study initiation and the need for informed consent was formally waived (Wake Forest University Health Sciences, #00048477, 02/15/2018). The study period of interest ran from July 1, 2009 to June 30, 2017 (fiscal years 2010–2017, with a fiscal year defined as July 1–June 30). The study was conducted across two sister institutions, both under the umbrella of Wake Forest Baptist Health in Winston Salem, North Carolina, USA. These included a tertiary care hospital, level-one trauma center and academic training facility (Wake Forest Baptist Medical Center) and a predominantly outpatient surgical center (Davie Medical Center), where total joint replacement surgeries are also performed, which opened during fiscal year 2014.

The primary outcome was the incidence of WSNB, calculated per 10 000 regional anesthesia PNB procedures, occurring both prior to a specific intervention and afterwards. The intervention of interest, which occurred on July 1, 2011, was the implementation of a preprocedural checklist to be performed prior to all regional anesthesia procedures (figure 1). For purposes of the study, this date delineated the preintervention group (fiscal years 2010–2011) from the postintervention group (fiscal years 2012–2017). All PNB procedures performed during the time-period of interest were included in the analysis, regardless of whether they were performed for analgesia or anesthesia. However, neuraxial procedures (both epidural and subarachnoid procedures) were not included.

The rates of WSNB in the preintervention and postintervention groups were compared using a Fisher’s exact test and 95% CI were subsequently determined. Data analysis was performed using SAS, V9.4 (SAS Institute, Cary, North Carolina, USA).

The number of WSNB procedures that occurred per fiscal year (numerator) over the study period was determined through query of institutionally maintained safety databases, which are used to categorize and track adverse events. From the start of the study period (fiscal year 2010) through September of 2011, the institutional database used for adverse event reporting was Patient Safety Net (University Health System Consortium). Starting in October 2011 and continuing through the end of the study period, RL solutions was used. While these databases were accessed retrospectively, the filing of safety events occurred in real-time by front-line providers involved in the adverse event, and each patient safety event was both recorded and investigated at the time of its occurrence.

The number of nerve block procedures performed per fiscal year (denominator) encompassed PNBs performed for either surgical anesthesia or for postoperative analgesia. Paravertebral and truncal blocks were included, but neuraxial blocks (subarachnoid and epidural) were excluded. Both billing codes and procedural documentation in the electronic health record (EHR) were used, but because conversion to a new EHR occurred during the study period, some assumptions and estimates related to annual block totals for some years were required, as described below.

For fiscal years 2014–2017, the total number of nerve block procedures performed annually, both those intended for analgesia and for surgical anesthesia, were calculated through a query of the current EHR (Epic; Epic Systems, Verona, Wisconsin, USA). In addition, this time period was used to calculate the ratio of blocks performed for analgesia to blocks performed for anesthesia. Because the prior EHR used during fiscal years 2010–2012, was no longer accessible for data mining, billing records were used to determine the annual number of Current Procedural Terminology (CPT) codes, specific to PNB procedures, submitted annually during this time period. Since blocks for surgical anesthesia could not be captured from billing data for 2010–2012 (anesthetic blocks are billed by time-units rather than CPT code), the total annual block numbers during these years were estimated by applying the analgesic to anesthetic nerve block ratio calculated from the 2014–2017 dataset. The EHR transition occurred during fiscal year 2013, resulting in billing and data lapses that prevented an accurate determination of the number of nerve block procedures performed during this fiscal year. The number of nerve block procedures for 2013 was then estimated as the average of nerve block procedures performed during fiscal years 2012 and 2014.

RESULTS

Both the total number of nerve block procedures performed annually and the annual incidence of WSNB occurring from 2010 to 2017 are depicted in figure 2. The ratio of analgesic to anesthetic nerve block procedures performed during fiscal years 2014–2017 was 3.61 to 1.

In the 2-year period prior to the intervention (fiscal years 2010 and 2011), a total of 10 123 nerve blocks were performed. Over this same time period, four WSNB procedures occurred, resulting in a calculated incidence of WSNB of 3.95 per 10 000 procedures (95% CI 1.26 to 9.53).

In the 6-year period following the implementation of the preprocedural checklist specific to regional anesthesia procedures 2012–2017, a total of 35 890 nerve blocks were performed. During this time period, a total of zero WSNB occurred, resulting in a calculated incidence for WSNB of 0 per 10 000 procedures (95% CI 0 to 0.84).

The preintervention and postintervention rates of WSNB were significantly different with p value of 0.0023.

DISCUSSION

Despite the amount of attention that WSS has received over the last two decades, the breadth of previously published literature/research on the subject of WSNB is surprisingly limited. While there have been a few reports that have quantified the overall incidence of WSNB in regional anesthesia, and an extensive review article on WSNB that included recommendations for potential prevention, only the study by Hudson and colleagues investigated the potential impact that a checklist or timeout policy could have on the incidence of WSNB. In their study, the authors reported a pre-timeout WSNB incidence of 1.39 per 10 000 procedures compared with a post-timeout WSNB incidence of 0.7 per 10 000 procedures. Although the frequency of WSNB procedures in this study did appear to decrease after an institutional timeout was enacted, the authors stated that “there was no association between the number of wrong-site blocks and the existence of the (timeout) policy.” Based on their statement,
it must be assumed that there was not a statistical difference between the preintervention and postintervention incidences of WSNB, although no p value was given.

In contrast, our study was able to demonstrate an association between the existence of a preprocedural checklist for regional anesthesia and a lower incidence of WSNB. One potential reason why our results differ from prior studies might be related to checklist compliance. Previously, it has been suggested that the implementation of a checklist, by itself, might not be enough to prevent medical errors. In order to be most effective and prevent patient safety errors, a checklist needs to be implemented and it must be used both consistently and completely. This statement is supported by the results of Hudson and colleagues, where two of the three WSNB procedures that occurred after the

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**Figure 1** Our organization’s regional anesthesia Pre-Procedural Timeout checklist.

<table>
<thead>
<tr>
<th>RAAPM Patient Responsibilities</th>
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<tbody>
<tr>
<td>State your name, date of birth, surgery, and the side</td>
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<tr>
<th>RAAPM RN Responsibilities</th>
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<tbody>
<tr>
<td>▶ Alert Surgical Team of remaining surgical workflow issues</td>
</tr>
<tr>
<td>▶ Ensure completeness of the Surgical Consent Document</td>
</tr>
<tr>
<td>▶ Withhold sedation until after time out</td>
</tr>
<tr>
<td>▶ Confirm patient wristband information</td>
</tr>
<tr>
<td>▶ Confirm NPO, DNR and antibiotic status of patient</td>
</tr>
<tr>
<td>▶ State medication allergies and recent anticoagulation status</td>
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<thead>
<tr>
<th>RAAPM Resident / Fellow Responsibilities</th>
</tr>
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<tbody>
<tr>
<td>▶ Ensure completeness of the Anesthesia Evaluation Document</td>
</tr>
<tr>
<td>▶ Ensure completeness of the Anesthesia Consent Document</td>
</tr>
<tr>
<td>▶ Mark the site(s) with an “O” prior to needle placement.</td>
</tr>
<tr>
<td>○ Lateral shoulder for upper extremity blocks</td>
</tr>
<tr>
<td>○ Lateral thorax for neuraxial, PVB, TAP, rectus blocks</td>
</tr>
<tr>
<td>○ Lateral hip for lower extremity blocks</td>
</tr>
<tr>
<td>▶ State each regional block to be performed and its side</td>
</tr>
<tr>
<td>▶ Pause between each regional block</td>
</tr>
<tr>
<td>▶ Re-initiate the time out if you leave the bedside</td>
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<thead>
<tr>
<th>RAAPM Attending Responsibilities</th>
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<tbody>
<tr>
<td>▶ View the complete and up-to-date Surgical Consent Document</td>
</tr>
<tr>
<td>▶ Perform medical direction</td>
</tr>
<tr>
<td>▶ Give handoff when contacted by OR anesthesia attending</td>
</tr>
</tbody>
</table>
were reported in the state of Minnesota, which is one of several including WSNB, continue to occur. In 2017, 36 WSS events list/timeout also appear to be a key reason why cases of WSS, that is not in the patient’s best interest, to consistently use the information openly, to speak up if/when they observe something teamwork-based training that emphasized the need to share communication were introduced concurrently. In addition, all surgical standardized processes for both patient hand-offs and commun-
tution’s operating rooms. Multiple other checklists as well as resource management techniques and tools throughout the insti-
stitution, implementation of the regional anesthesia check
list was part of a much broader initiative to incorporate crew
associations, when other studies could not, is more complex and
potential for confounding, and it is, therefore, not possible to
determine causality between the presence of the checklist and
WSNB procedures.
Although determining checklist compliance over our study
period was not possible due to EHR transition, it is important
to note that any retrospective method of quantifying checklist
compliance is unlikely to reflect true checklist fidelity. In a prior
prospective study of 142 surgical procedures, the “documented”
compliance rate for the use of a surgical checklist was 100%.
However, an observer auditing the thoroughness of the check-
list process found that none of the cases actually executed all
the items on the checklist. Inconsistencies in using a checklist timeout also appear to be a key reason why cases of WSS,
including WSNB, continue to occur. In 2017, 36 WSS events
were reported in the state of Minnesota, which is one of several
states that mandate reporting of adverse events. This was the
highest annual number of events reported over the last 10 years,
and it is notable that spinal injections and preprocedural injec-
tions were the most common type of WSS. Root cause analyses
of these adverse events found that site marking was omitted 41%
of the time, site marking (when done) was not visually confirmed
11% of the time, and source documentation was not referenced
during the timeout 19% of the time.
A second potential reason why our study found a positive
association, when other studies could not, is more complex and
less tangible and that is culture. It must be noted that at the study
institution, implementation of the regional anesthesia check-
list was part of a much broader initiative to incorporate crew
resource management techniques and tools throughout the insti-
tution’s operating rooms. Multiple other checklists as well as
standardized processes for both patient hand-offs and commu-
nication were introduced concurrently. In addition, all surgical
services employees (1600+ individuals) received structured
teamwork-based training that emphasized the need to share
information openly, to speak up if/when they observe something
that is not in the patient’s best interest, to consistently use the
patient safety tools, and the importance of creating/maintaining
a culture of safety. This training has continued to be provided on
a monthly basis for all new employees.
Creating a culture of safety is of significant importance as it
not only helps to ensure that the checklist is used consistently
and correctly, it also helps to foster a shared sense of mission so
that providers hold each other accountable and work toward the
common goal of patient safety. In fact, culture has been recog-
nized as being equally as important as the actual checklist to the
success of the landmark Keystone intensive care unit project in
which catheter-related blood stream infections were significantly
reduced after implementation of a checklist.
In regards to the preprocedural checklist and processes in place
at our institution there are a few things that warrant further elab-
oration. First, regional anesthesia procedures can be performed
prior to surgical site making as long as the laterality and proce-
dure specified on the surgical consent matches the details of
the case posting in the EHR as well as the patient’s stated expecta-
tions. For this reason, our checklist does not call for verification
of surgical site marking prior to nerve blockade. However, if
there are any discrepancies between the consent, case posting,
or patient expectations, these must be rectified by the surgical
team prior to proceeding. Second, it should be noted that
directly involving the patient in the timeout process is viewed as
a critically important step, as demonstrated by the requirement
that they state their name, date of birth, procedure, and side at
the beginning of the timeout process. For non-English speaking
patients, an interpreter is routinely used to accomplish this task
and these are available both in-hours and remotely by video
conference 24 hours a day. For cognitively impaired patients or
pediatric patients, the legal guardian is allowed to assume the
role of the patient and to verify the required information.
This study has a number of limitations that warrant discus-
sion. First, the retrospective design of the study introduces the
potential for confounding, and it is, therefore, not possible to
determine causality between the presence of the checklist and
a lower rate of WSNB procedures. While a prospective study
would do so, performing such a study would likely be extremely
difficult, if not impossible, given the rarity with which WSNB

Figure 2 Graphic representation of preintervention and postintervention annual numbers of peripheral nerve blocks and the number of wrong-side nerve blocks occurring annually.
procedures occur. In addition, randomizing patients to a study arm in which a checklist of some sort is not used would likely be seen as unsafe/unethical given TJC’s requirements and the Universal Protocol.

Second, some assumptions were required to calculate annual block totals. It was assumed that regional anesthesia volume and the ratio of analgesic to anesthetic nerve blocks were relatively consistent across years, and it should be recognized that the number of nerve block procedures for years 2010 through 2013 are, therefore, best approximations. However, given the large difference in WSNB incidence between the preintervention and postintervention time periods in this study, as well as the large sample size, it is unlikely that estimating block totals for these fiscal years significantly affected the outcome. In addition, regardless of the method used to calculate block totals, the retrospective nature of the study would have introduced the potential that not all block data would be appropriately identified.

Third, it is possible that not all WSNB events occurring during the study period were captured. While events could have been missed during data collection, in general, serious patient safety events like WSNB procedures are captured in real time and trigger an extensive investigation to determine their root cause, design an action plan, and to implement process change. This robust incident review process makes it highly unlikely that any events were missed during data collection. However, given the perceived stigma of being involved in this, or any other kind, of serious patient safety event, it is conceivable that events occurred (both in the preintervention and postintervention time periods) and were not reported.

It is also important to note that it was not feasible to capture near miss WSNB events in this study. Certainly one of the potential mechanisms by which a preprocedural checklist may prevent WSNB events from occurring is by identifying and stopping errors before harm reaches the patient. While it would have been interesting to explore the association between the presence of the checklist and the rate of near miss events, this was unfortunately not possible given the study design.

Finally, during data analysis, we chose to include all PNBs and to exclude neuraxial procedures. Although some previous studies have elected to exclude bilateral blocks, under the assumption that they are unlikely to be performed on the wrong side, we chose to include them as it is still possible that bilateral blockade could be performed on the wrong patient or that the wrong block(s) could be performed. On the other hand, we elected to not include neuraxial blocks (spinals and epidurals) in the analysis. While the same argument could be made for neuraxial procedures, the scope of this study was peripheral nerve blockade.

Of note, all four WSNB procedures that occurred in the preintervention period were PNBs performed on the wrong side. Two of the events in fiscal year 2011, a combined femoral catheter and single-injection sciatic nerve block performed for a total knee arthroplasty and an ankle block performed for an incision and drainage of a foot wound, occurred despite a timeout being performed. The ankle block patient had wounds on both feet, which potentially contributed to the error. However, in both instances, the attending anesthesiologist was not present for the timeout. In the third event during fiscal year 2011, no timeout was performed prior to the procedure. While the safety database query revealed that a WSNB occurred in April of 2010, additional details surrounding the event, other than it occurred on the wrong side, were not available.

In conclusion, the implementation of a preprocedural regional anesthesia-specific checklist at our institution was associated with a significant reduction in the rate of wrong side nerve block procedures and should be strongly considered as a key component of creating a culture of safety aimed at improving patient safety and reducing serious safety events.

Competing interests None declared.

Ethics approval Institutional review board (IRB) approval was obtained prior to study initiation and the need for informed consent was formally waived (Wake Forest University Health Sciences, # 00048477)

REFERENCES