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Research

Improving Wake-Up Times for Spine Surgery Using New OR Team Checklist Protocol and Communication

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Abstract

Introduction: Prolonged post-anesthesia wake-up times present a threat to patient safety. Shorter wake-up times allow for intraoperative physical exams and potential to re-operate quickly in case of detected neurologic deficits, which may allow for a better neurologic outcome. Furthermore, shorter wake-ups may reduce length of hospital stay, lowering healthcare costs.

Methods: We studied how a standardized spine deformity surgery checklist and new OR team communication impacted post-anesthesia wake-up times after scoliosis surgery. We used a Kruskal-Wallis one-way ANOVA to compare 17 wake-up times recorded prior to using the new surgery checklist and teamwork protocol to 468 wake-up times recorded over three years after implementation of the new protocol. We used a Pearson correlation coefficient to analyze how wake-up times varied based on surgical duration with the new protocol.

Results: After one year of the new protocol, wake-up times reduced from an average of 16.6 minutes to an average of 7.6 minutes. Wake-up times further declined to an average of 6.0 minutes by years two and three of the new protocol, with significant reductions in these years ($p=0.024$ and $p=0.030$, respectively). Improvements to the protocol were made over time in response to outliers. Nearly 75% of wake-up times were less than five minutes with the new protocol. Wake-up times recorded using the new protocol showed a significant weak positive correlation with surgical duration ($r=0.092$, $p=0.047$).

Conclusion: The standardized surgery checklist and new team communication promotes significantly shorter post-anesthesia wake-up times, irrespective of surgical duration. While using a comprehensive surgery checklist may take a few more minutes up front, that time is saved at the end with shorter wake-up time, creating net time savings while improving safety. Key steps to promoting a shorter intraoperative wake-up include: 1) using a bispectral index monitor (BIS) with a goal in the 50s, 2) standardized target anesthetic dosing parameters, 3) eliminated anesthetic drug variability, 4) every-thirty-minute timeouts to monitor patient status, and 5) sub-three-minute pre-surgery wake-up time goals verbalized to the OR team.

***Keywords:** Surgery Checklist, Teamwork, Anesthesia Wake-Up Times, Scoliosis*

Introduction

Prolonged wake-up times from anesthesia present a potential threat to patient safety, especially after complex procedures such as scoliosis and other spine surgeries. Even though neuromonitoring is usually performed during these surgeries, the most important sign of normal neurologic function is seeing the patient moving their arms and legs after surgery. Identifying neurologic deficits within a few minutes in the operating room (OR) allows for emergent imaging and potentially performing a revision surgery in the same OR with all instruments still sterile and the surgeon still available. This can increase the chance for the patient to have a better final outcome.

Wake-up time is actually "waste." Longer wake-up times extend hospital stay by prolonging surgical duration, which positively correlates with stay times in the surgical intensive care unit (ICU) [1]. This extended stay is associated with higher rates of comorbidities, blood transfusions, complications, and transfer to non-residential care facilities [1]. Average healthcare costs increase by $18,916 for patients with longer lengths of stay [1]. Shorter hospital stays from faster wake-ups also reduce hospital acquired infections, pressure ulcers, and other adverse events [1]. Still worse, delayed recovery of spontaneous breathing and protective respiratory reflexes compromise a patient's health post-anesthesia [2].

Wake-up times can vary dramatically due to perioperative factors such as age, gender, BMI, genetics, and medications [2]. Several studies have shown that older male patients with a higher BMI are more likely to experience a prolonged wake-up time [2]. Pre-existing metabolic conditions, such as hypoglycemia, electrolyte imbalance, hyperglycemia, hypertension, liver disease, and hypoxia have also been shown to increase wake-up times [2]. Surgical factors also influence wake-up times. Delayed awakening was observed more frequently in patients undergoing GI surgery [2]. Hypothermia, intraoperative hemorrhage, embolism, and cerebral hypoxia also contribute to delayed wake-up times [2]. Desflurane anesthesia prolongs anesthesia in upper GI surgeries [3], as does midazolam in geriatric patients [4]. Spinal anesthesia (SA) is associated with significantly lower operative time and total anesthesia time, favoring lower wake-up times [5]. However, SA is associated with longer PACU stay [5], emphasizing the need for lower post-anesthesia wake-ups. While there are many comorbid conditions that can't be controlled by the surgical team, our goal was to eliminate variation in the anesthesia and surgery process to minimize wake-up times for safety and efficiency benefits.

Usage of a bispectral index (BIS) monitor is key to objectively monitoring the patient's anesthetic status to allow for a short wake-up. The BIS monitor is a device for tracking brain activity under anesthesia. Output values range from 0-100, with zero representing no brain activity, and 100 representing an alert state; values between 40-60 are typical during surgery. In this study, BIS values were maintained in the 50s, except during rod insertion. Excessively low BIS values increase the time for patients to reach an alert state, presenting a safety hazard if those patients are unable to be evaluated intraoperatively for neurologic deficits. An added benefit of BIS monitor usage is the potential to detect intraoperative generalized tonic-clonic seizures [6]. Propofol, a well-accepted intraoperative treatment for seizures, rarely can provoke seizure progression [7]. While BIS monitoring does not replace EEG for the monitoring of seizure progression, a sudden increase in BIS values can be indicative of seizure activity, followed by a rapid decrease in BIS values during the postictal state [8].

Standardization of OR protocols is critical for stabilizing highly variable outcomes such as wake-up times. Surgery checklists offer a prime opportunity for such "standard work". In 2008, the World Health Organization (WHO) began the "Safe Surgery Saves Lives" program, marking the widest scale implementation of a surgical safety checklist. The program implemented a 19-step checklist with the goal of improving communication and overall quality of care during surgeries. Post-implementation, complications dropped from 11.0% to 7.0% ($p<0.001$) and mortality rates dropped from 1.5% to 0.8% ($p=0.003$) [9]. Since then, numerous studies have looked at standardization in medicine. Studies in cardiology indicate checklists can reduce minor errors in arterial switch operations and promote teamwork in the cardiac ICU [10]. In laser airway surgery, checklist usage improved vocalization and completion of critical safety steps [11]. In assessing skin lesion images using mobile teledermoscopy, checklists were shown to improve the accuracy and overall quality [10]. Furthermore, 94% of ophthalmologists consider checklists to be of value [10], and a study of 144 ENT procedures showed a near perfect compliance rate with a checklist workflow [12]. However, many of these studies are limited by small sample sizes and none studied the effect of a surgery checklist on postoperative wake-up times.

No checklist is effective without teamwork. Teamwork in the OR is limited by ineffective communication, which serves as a common source of errors and complications [13]. Implementing Formula 1 and aviation techniques to surgery ICU handoffs was shown to reduce technical errors and improve team dynamics [14]. Additionally, preoperative briefing between surgeons, anesthesia providers, and nurses has been shown to significantly increase implementation of change principles [15]. In a multi-site trial using the scoliosis surgery checklist used in this study, there was a significant improvement in team dynamics [16]. Following this study, the Scoliosis Research Society (SRS) used the same checklist items and developed a shorter version, the "SRS Spinal Deformity Surgery Team Checklist", using a Delphi method [17]. One of the items the team of reviewing surgeons chose to keep in the SRS checklist was "Moving both upper and lower extremities before leaving OR (if feasible)".

This checklist was published on the SRS website and circulated to the entire SRS membership worldwide in August 2022.

While many acknowledge the value of procedure-specific checklists and improved team communication, it is often hard to drive adoption, especially if there is a perception that the checklist and extra team communication may cost more time. Here, we demonstrate that an OR protocol integrating a surgery checklist with consistent team dynamics can significantly lower postoperative wake-up times to enhance patient safety. We show that a comprehensive OR checklist can actually save time, rather than cost extra time, which may help drive checklist adoption and thereby improve patient safety, efficiency, and healthcare costs.

Methods

Overview

Between 2018-2021, wake-up times were recorded from 485 scoliosis surgeries among two hospitals. Wake-up times in 2018, "Year 0" of new protocol, were recorded before implementation of a surgery checklist and improved team communication, and wake-up times in 2019-2021, "Years 1-3" of new protocol, were recorded after these changes. These times were taken as the difference in time points between incision closure and 1) successful extubation and 2) lower extremity movement.

New OR Protocol

Before each surgery during the preoperative OR timeout, the surgeon vocalized the team goal to achieve a sub-three-minute wake-up time with an intraoperative BIS goal in the 50s. During each surgery, a standardized scoliosis surgery checklist was followed. Propofol and sufentanil were the primary anesthetics after skin incision, with targeted dosages of 100 mcg/kg/min and 0.1 mcg/kg/hr, respectively. When sufentanil was unavailable, fentanyl was used at 1.0 mcg/kg/hr. A BIS monitor was used to track the depth of anesthesia. Intraoperative mini-timeouts were scheduled every thirty minutes to reassess estimated blood loss (EBL), mean arterial pressure (MAP), BIS reading, anesthetic dosing, pulse pressure variation (PPV), body temperature, urine output, and face, arm, hand and leg checks. Of note, these mini-timeouts were also implemented several months prior to Year 1 of the new protocol, though these timeouts were not verbalized preoperatively up front or enforced consistently prior to Year 1. Underbody warmers were placed on the Jackson OR table with over-patient blankets and OR room and patient temperature monitoring, since patient temperature is linked to drug metabolism. Wake-up times were recorded in a checklist software as the time difference between the turn from prone to supine and the completion of both extubation and lower extremity movement, although both times were also tracked independently. This "Spinal Deformity Surgery Team Checklist" can be viewed on the SRS website. A summary of this protocol can be viewed in Table 1.

Statistical Analyses

A non-parametric Kruskal-Wallis test was used to assess for significant differences between wake-up times in each year of the study. Kolmogorov-Smirnov and Shapiro-Wilk normality tests were used to verify the data were non-normal, and the Levene statistic was used to verify homogeneity. The Pearson correlation coefficient was calculated to determine the strength of correlation between wake-up times and surgical duration after checklist and teamwork implementation. All statistical analyses were conducted in IBM SPSS v29.0.1.0. with 95% confidence intervals. The intra-operative checklist and process timer used in this study was 3Greens.com.

Results

Impact of New Protocol on Wake-Up Times

After the first year of the new protocol, wake-up times reduced by an average of 56.3%, from 16.6 minutes in Year 0 to 7.6 minutes in Year 1 (Figure 2). Thereafter, wake-up times were reduced by an average of 1.6 minutes between Year 1 and Year 2, down to 6.0 minutes, and remained stable between Years 2 and 3 (Figure 2). The standard deviation in wake-up times reduced from 38.9 in Year 0 to 12.7 in Year 1 and then steadily decreased to 9.2 by the end of Year 3 (Table 3). Wake -up times ranged from 1-164 minutes in Year 0 to 1-112 minutes thereafter (Table 3, Figure 4). Wake-up times showed significant reductions between Year 0 and Years 2 and 3, as well between Year 1 and Year 2 and between Year 1 and Year 3 (Table 4). Nearly 75% of wake-up times were less than five minutes after implementation of the new protocol (Figure 3).

Long wake-ups triggered mini-huddles and subsequent protocol changes in some cases. During Year 1, one long wake-up appeared to be due to using a higher rate of sufentanil (^ in Figure 1, Table 2). Following this long wake-up, target rates for propofol and sufentanil were introduced, with goals to meet those standard rates within the first hour of operation in order to achieve a BIS level in the 50s.

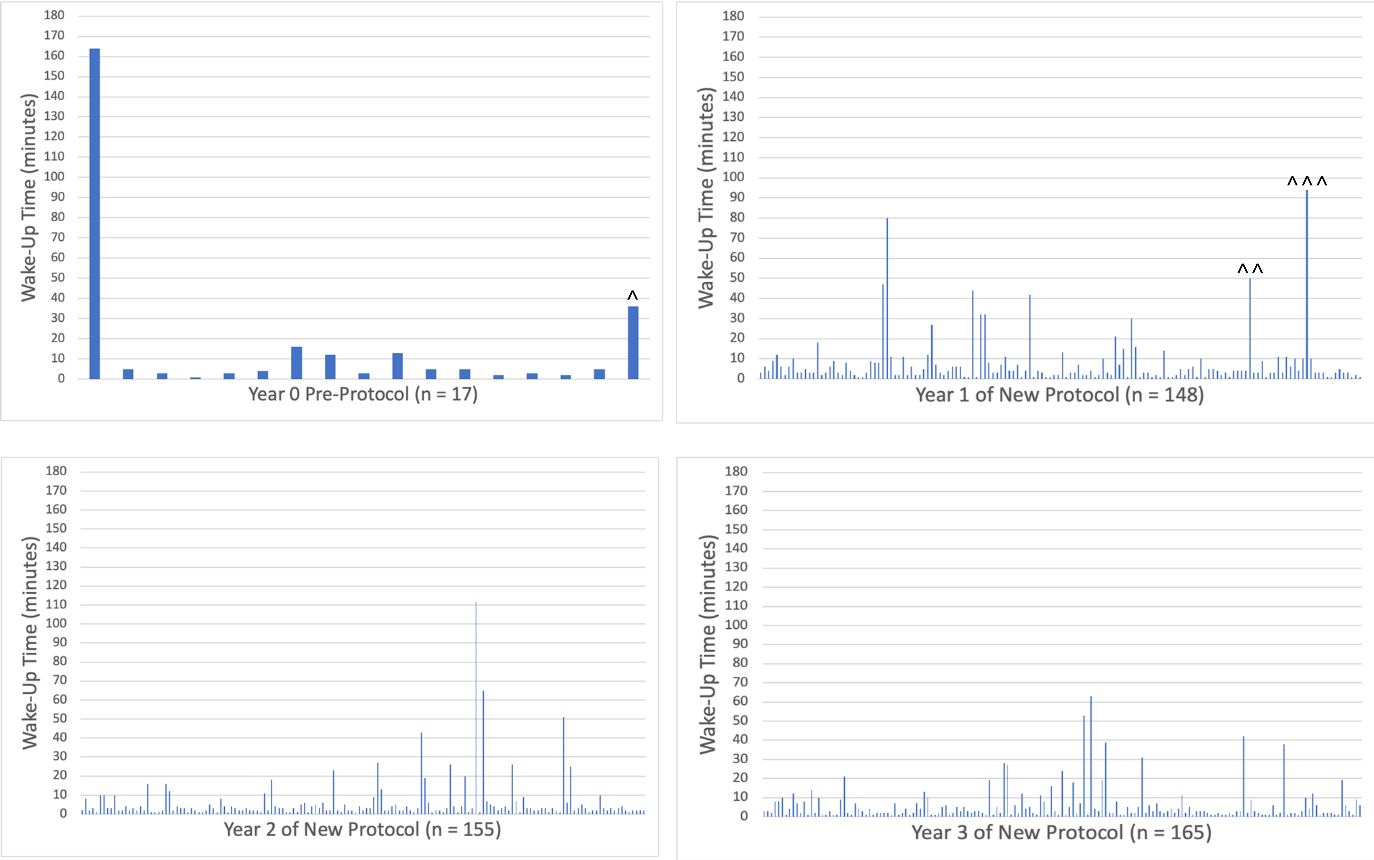

Figure 1. *Wake-Up Times by Year.*

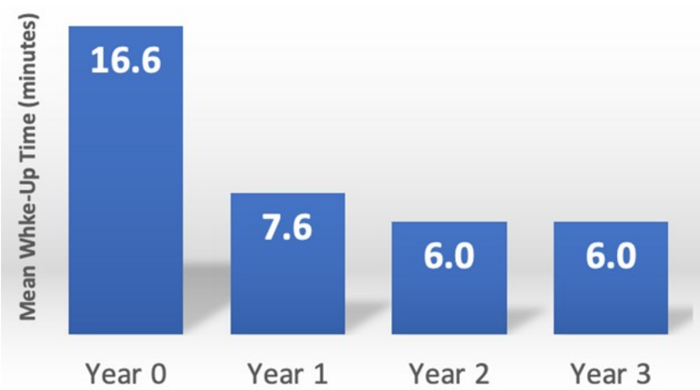

Figure 2. *Mean Wake-Up Times by Year.*

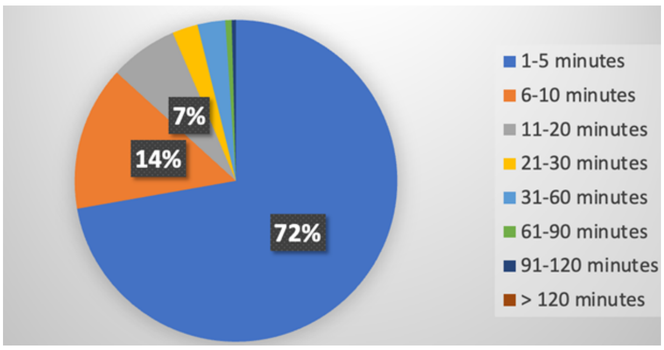

Figure 3. *Post-Protocol Breakdown.*

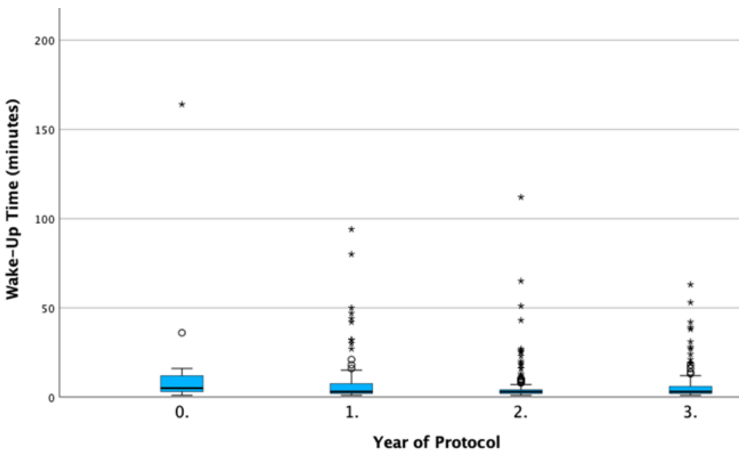

Figure 4. *Variability in Wake-Up Times.*

We also introduced intraoperative accountability with the every-thirty-minute mini-timeouts, which included the anesthetic drug rates, BIS, body temperature and other parameters. Verbal reminders by the surgeon to the anesthesia team when the scoliosis rods were about to be inserted was added to the protocol to ensure the narcotic was turned off at that time so MAP could be raised into the 80s for spinal cord perfusion. There were also two cases of prolonged wake-ups associated with the usage of medications unspecified in the new protocol; one case involved usage of methadone (^^ in Figure 1, Table 2) and another involved administration of a ketamine drip (^^^ in Figure 1, Table 2). It was decided that neither of these medications should be used, nor any other medication, unless first checking with the surgical team. Occasionally a single-dose of ketamine was used for patients who had significant preoperative narcotic use. In Years 2 and 3, the use of Precedex and Dilaudid at the end of surgery caused some longer wake-ups, providing further support for adhering to the medications specified in the protocol whenever possible. Overall, we created a culture of continuous quality improvement based on mutual respect and doing what was right for the patient on the OR table, and also for future patients we will be serving together.

Wake-Up Times Based on Surgical Duration

A significant weak positive correlation ($r = 0.092$, $p = 0.047$) was found between wake-up time and surgery time after the implementation of the checklist and teamwork workflow (Table 5). Surgical duration in this period varied from as low as 60 minutes to as high as 570 minutes. However, mean wake-up times remained stable around six minutes throughout this time frame.

Table 1. New Protocol Overview.

Preoperative Steps		**Intraoperative Steps**		**Postoperative Steps**	
Standard Work Steps	*Teamwork Steps*	*Standard Work Steps*	*Teamwork Steps*	*Standard Work Steps*	*Teamwork Steps*
Set room temp to 69F before patient enters room	Welcome new team members and introduce by name	Perform q30 minute mini-timeouts	Encourage open communication and perform verbal read-backs to ensure completion of key steps	Mark time of turning from prone to supine	Conduct a team debrief to compare wake-up time goal to the achieved wake-up time
Underbody warmer placed on Jackson table	Discuss checklist and teamwork goals	Turn off sufentanil at time of rod insertion and raise MAP to 80s	Create a mutual sense of accountability to adhere to steps outlined in the checklist	Mark time of moving bilateral lower extremities and time of extubation	Elicit team member feedback and revise protocol appropriately
Goals		*Goals*		*Goals*	
Achieve a 3-5 minute intraoperative wake-up, keep patient warm, maintain BIS level in the 50s, achieve propofol and sufentanil target rates, perform q30 minute intraoperative mini-timeouts		Perform frequent patient checks using dedicated time set aside in the OR to review positioning, EBL, BIS level, MAP, PPV, and body temperature		Measure quality outcomes, identify areas for improvement, and revise methods as part of an iterative process.	

Table 2. Wake-Up Time Notable Outliers.

Year of Protocol	Wake-up Time (minutes)	Reason for Prolonged Wake-Up
0 (^)	36	Administration of methadone
1 (^^)	50	Usage of 0.3 mcg/kg/hr sufentanil instead of 0.1 mcg/kg/hr
1 (^^^)	94	Administration of a ketamine drip

Table 3. Wake-Up Time Descriptives.

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean Lower Bound	95% Confidence Interval for Mean Upper Bound	Minimum	Maximum
0	17	16.59	38.926	9.441	-3.43	36.60	1	164
1	148	7.58	12.744	1.048	5.51	9.65	1	94
2	155	6.05	12.126	.974	4.12	7.97	1	112
3	165	6.04	9.226	.718	4.62	7.45	1	63
Total	485	6.88	13.378	.607	5.69	8.07	1	164

Table 4. Wake-Up Time Comparison.

Sample 1-Sample 2	Test Statistic	Std. Error	Std. Test Statistic	Sig.
2-3	-3.363	15.492	-.217	.828
2-1	38.834	15.917	2.440	.015
2-0	79.944	35.384	2.259	.024
3-1	35.470	15.680	2.262	.024
3-0	76.580	35.278	2.171	.030
1-0	41.110	35.467	1.159	.246

Table 5. Correlation Between Wake-Up Time and Surgical Duration.

		Wake-Up Time (minutes)	Surgical Duration (minutes)
Wake-Up Time (minutes)	Pearson Correlation	1	.092*
	Sig. (2-tailed)		.047
	N	468	468
Surgical Duration (minutes)	Pearson Correlation	.092*	1
	Sig. (2-tailed)	.047	
	N	468	468

Discussion

Setting a three-minute wake-up time goal pre-surgery for the purpose of patient safety, providing up-front BIS goals and target anesthetic dosing, and implementing every-thirty-minute "mini-huddles" for accountability are critical for motivating and enabling team members to achieve a shorter wake-up. Providing OR team members with evidence-based reasons for the importance of short wake-ups can incentivize team members to achieve a short wake-up goal. Fostering a culture where we can learn from each other and leverage each other's training and experience to make things better for the patient and for the team created a collaborative, rather than a confrontational, environment.

The surgeon in this study reinforced the need for conducting an early neurological exam, having the ability to re-operate in sterile OR conditions, and having the ability to easily raise MAP for rod insertion, all critical for optimizing patient safety. Ensuring all team members' names were on the "white board", having room introductions for all team members prior to timeout, and referring to OR team members by name throughout the operation increased their sense of value and accountability for carrying out key checklist steps. Holding each other accountable and alert with thirty-minute mini-timeouts during surgery to review patient positioning and other key metrics, such as BIS and drug dosing rates, was one of the changes made during the three-year process that improved wake-up times. Eliminating medications such as ketamine drips and methadone also helped to decrease variability. Furthermore, early in the process it was learned that anesthesia providers tend to run the patients "deeper" to avoid criticism from surgeons if the patients moved. This preconceived notion surprised the surgeon but made sense as the reason for their behavior. When the surgeon made it clear that they would not be angry if the patient moved, and that it was more important for patient safety to keep them in the right BIS parameters for a rapid wake-up, it created a new team trust that helped in the adoption of the new methods.

In fact, throughout the last five years of using this protocol, there have been no disruptive wake-up events during surgery, no patient recall, and no patients with difficult pain management after surgery as a result of the new process.

A common concern for running patients at a higher BIS is that these patients will experience higher levels of postoperative pain. Several studies explored the correlation between BIS level and postoperative pain, with some finding those run at lower BIS levels experience less postoperative pain [18], and others finding no significant difference between postoperative pain and higher BIS levels [18]. Although patients run at higher BIS levels may experience higher pain levels postoperatively, we did not observe this to be an issue during our use of the new protocol. Once motor function has been assessed after wake-up, additional pain medications can be administered to keep the patient comfortable, but that was rarely needed in the operating room before PACU. In addition, the benefits of early detection of neurologic deficits via faster post-anesthesia wake-up times outweigh the slight risks of initial postoperative pain, should it even occur.

Consistent dosing of propofol and sufentanil and eliminating excess drug usage provides each patient with the opportunity for a short wake-up. The primary drugs administered during scoliosis surgery were propofol and sufentanil, which are general anesthetics and narcotics, respectively. The surgery checklist used in this study explicitly specified target usage of 100 mcg/kg/min of propofol and 0.1 mcg/kg/hr of sufentanil. It was noted during our study that some patients required higher levels of these drugs, particularly during skin incision and initial exposure, but thereafter, dosing could be decreased to the target values. As previously mentioned, we noted a prolonged wake-up in the first year of the new protocol associated with 0.3 mcg/kg/hr of sufentanil. By establishing target values for propofol and sufentanil to our pre-surgical checklist and intraoperative mini-timeouts, the chances of wake-up times prolonging by account of higher than target drug administration was greatly lowered, especially when combined with sharing the BIS scores every thirty minutes with the team.

Additionally, lower doses of propofol and sufentanil allow for easier blood pressure regulation within 20% of a patient's baseline MAP. Initially, MAP was maintained in the 70s, but is raised into the 80s to increase spinal perfusion pressure for rod insertion [5]. As a part of the protocol, the narcotic, usually sufentanil, is turned off during rod insertion; having less medications on board at the time of rod insertion makes it easier to raise the MAP. The administration of additional drugs during surgery can create a deepened anesthetic state, thus prolonging wake-up times. As noted earlier, we observed prolonged wake-ups associated with ketamine drip and methadone usage. These cases reinforce the need for adhering to standardized protocols proven to promote short wake-up times; they also reinforce the importance of letting anesthesia providers know that they should not feel pressure to administer higher doses or additional drugs to avoid a negative reaction from the surgeon, and that any new drugs to be considered should first be discussed with the surgeon and team.

Using intraoperative mini-timeouts every thirty minutes allows the OR team to set aside dedicated time for evaluating patient anesthetic status and ensure proper measures are taken to lower wake-up. In this study, thirty-minute timers were set by the checklist software to remind the OR team to check the patient's face, extremities, EBL, PPV, MAP, BIS reading, body temperature, and drug dosing. These factors provide information on patient perfusion, intubation level, electrical activity, and drug buildup. Without the accountability of a timer, there is less incentive to pay attention to these critical factors that can prolong wake-up times. Awareness of these metrics can allow for intraoperative adjustment of anesthetic depth, allowing for shorter wake-up times. We also believe consistent use of the mini-timeouts allowed wake-up times to show little correlation with surgical duration (Table 5). Longer durations under anesthesia are expected to produce prolonged wake-up times due to extended exposure to anesthetizing drugs; however, by regularly monitoring the patients' depth under anesthesia and dosing parameters, drug buildup can be minimized and allow for short wake-up times, irrespective of surgical duration.

One key outcome from this safety and quality improvement effort is that the protocol, as well as the measurement of wake-up times and other outcomes, occurs in a cooperative manner between the anesthesia physician, nurse anesthetist (CRNA), student registered nurse anesthetist (SRNA), surgeon and remaining OR team, including the circulating nurse. As discovered in Perera's study on improving team dynamics with the use of the checklists and teamwork, our teams have experienced the same finding [16] - the team prefers the new way of doing things. The CRNAs at both hospitals have chosen to include training for the checklists and anesthesia protocol in their documents shared with other anesthesia staff, and also use it to train their SRNAs, who have disclosed it has been helpful for their education.

We recognize having a single surgeon among two hospitals limits the generalizability of our study. Notably, there were numerous data outliers, but all were included in the analyses. In several instances, speculated reasons for these outliers were documented in the checklist OR notes as learning aids. The evolution in the protocol from these outliers likely accounts for further reduced wake-up times in later years. Additionally, the pre-protocol sample size was small, but the large reduction in wake-up times post-protocol and continued reduction during the protocol years adds value to our study. Finally, there may have been additional medications administered in addition to the two primary anesthetics, propofol and sufentanil, such as midazolam, fentanyl, morphine, ketamine, methadone, and dilaudid.

While we observed several instances of longer wake-up times associated with ketamine and methadone usage, we believe standardization of the primary anesthetics in the protocol is responsible for the results, as well as restricting the use of other medications as much as possible.

Prospective, multi-center studies are warranted to evaluate our standard work and teamwork protocol in more diverse settings. Similar outcomes with a variety of OR teams and surgical specialties would add tremendous value to our protocol. Additionally, we would like to assess the effects of shorter wake-up times on postoperative recovery outcomes, including pain scores, nausea, and length of PACU and hospital stay. The Alert, Verbal, Pain, Unresponsive (AVPU) Scale and the Glasgow Coma Scale would allow for a postoperative evaluation in the PACU, and scores could be correlated to wake-up time values. The Quality of Recovery (QoR) Scoring Index could supplement this assessment by allowing patients to rate their recovery based on commonly experienced postoperative complications [19].

Finally, we would like to formally assess OR team member satisfaction with the checklist workflow and enhanced team communication using Likert scales and other tools. Anesthesia providers, surgeons, and other OR team members would rate their satisfaction with various aspects of their job before and after experiencing the new protocol. As previously described, anesthesia providers often feel pressured to run patients at deeper levels of anesthesia in order to prevent patients from flinching during the operation. Much of this pressure stems from deeply ingrained healthcare stereotypes that surgeons will negatively react to a patient moving during an operation. Surgeons can also have stereotypes and a lack of knowledge about what truly is happening on the other side of the drape. In our study, we have torn down the "drape" between the anesthesia and surgical teams so that we are indeed one team working towards one goal - to get our precious patient through the surgery successfully and safely, and learn something new so we can do even better next time. This has created a safer, more positive work environment for all of us, and has provided a great environment to train new staff. As a result, we will never go back to the old way.

Conclusion

Prolonged post-anesthesia wake-up times can jeopardize patient safety and hospital efficiency. Standard work and teamwork create a sense of mutual accountability in the operating room, which favors shorter wake-up times. We demonstrated that consistent use of a scoliosis surgery checklist and strong team-based care led to a 59.2% reduction in wake-up times after a year of implementation. Setting short wake-up time goals preoperatively, maintaining a BIS goal in the 50s, standardizing anesthetic dosing parameters, eliminating anesthetic drug variability through standard work, and using every thirty-minute timeouts to monitor patient status are essential for ensuring consistently low wake-up times.

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Disclosures

Ethical Considerations: Our study was classified as non-human studies research by the Institutional Review Board at the Jerry Wallace School of Osteopathic Medicine at Campbell University on October 16th, 2023.

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Author Contributions

GE analyzed the data and created the tables and figures. GE and LH wrote the manuscript. LH, KT, AS, KS, and KD collected the data. CF, GB and GE obtained IRB approval. All authors reviewed the manuscript.

Conflict of Interest

The authors have no conflicts of interest to declare.

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