A prospective time-series quality improvement trial of a standardized analgesia protocol to reduce postoperative pain among neurosurgery patients

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OBJECTIVE The inclusion of the pain management domain in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey now ties patients' perceptions of pain and analgesia to financial reimbursement for inpatient stays. Therefore, the authors wanted to determine if a quality improvement initiative centered on a standardized analgesia protocol could significantly reduce postoperative pain among neurosurgery patients.

METHODS The authors implemented a 10-month, prospective, interrupted time-series trial of a quality improvement initiative. The intervention consisted of a multimodal, interdepartmental, standardized analgesia protocol with process improvements from preadmission to discharge. All neurosurgical-floor patients participated in the quality improvement intervention, with data collected on a systematically randomly sampled subset of 96 patients for detailed analysis. Patient-reported numeric rating scale pain on the first postoperative day (POD) served as the primary outcome.

RESULTS Implementation of the analgesia protocol resulted in improved preoperative and postoperative documentation of pain ($p < 0.001$) and improved use of multimodal analgesia, including use of NSAIDs ($p < 0.009$) and gabapentin ($p < 0.027$). This intervention also correlated with a 32% reduction in reported pain on the 1st POD for all neurosurgical patients (mean pain scale scores 4.31 vs 2.94; $p = 0.000$) and a 43% reduction among spinal surgery patients (mean pain scale scores 5.45 vs 3.10; $p = 0.036$). After controlling for covariates, implementation of the protocol was a significant predictor of lowered postoperative pain ($p = 0.05$) on the 1st POD. This reduction in pain correlated with protocol compliance ($p = 0.028$), and a significant decrease in the monthly number of naloxone doses suggests improved safety (mean dose $\pm$ SD 1.5 ± 1.0 vs 0.33 ± 0.5 ; $p = 0.04$). Furthermore, a significant and persistent reduction in the pain management component of the HCAHPS scores suggests a durability of results extending beyond the life of the study (72.1% vs 82.0%; $p = 0.033$).

CONCLUSIONS The implementation of a standardized analgesia protocol can significantly reduce postoperative pain among neurosurgical patients while increasing safety. Given the current climate of patient-centered outcomes, this study has broad implications for the continuum of care model proposed in the Affordable Care Act.

Clinical trial registration no.: NCT01693588 (clinicaltrials.gov)

<http://thejns.org/doi/abs/10.3171/2015.10.JNS15698>

KEY WORDS quality; analgesia; postoperative pain; postsurgical pain

ABBREVIATIONS BMI = body mass index; EHR = electronic health record; HCAHPS = Hospital Consumer Assessment of Healthcare Providers and Systems; NRS = numeric rating scale; OME = oral morphine equivalent; PDSA = Plan-Do-Study-Act; POD = postoperative day; PROMIS = Patient Reported Outcomes Measurement Information System.

SUBMITTED March 28, 2015. **ACCEPTED** October 7, 2015.

INCLUDE WHEN CITING Published online March 11, 2016; DOI: 10.3171/2015.10.JNS15698.

UNCONTROLLED postoperative pain is associated with an increased risk for pulmonary and cardiovascular complications, is the most common cause for delayed discharge and unexpected readmissions after ambulatory surgery, and is responsible for prolonged convalescence after surgery.^{3,20,25,39,42,44} Additionally, high levels of postoperative pain are associated with an increased risk of chronic pain.^{25,42}

Recently, patients' perceptions of postoperative pain and analgesia have become critical components of health care evaluations, and these evaluations are increasingly being tied to reimbursements. This is evident in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey.¹⁴ The HCAHPS survey directly questions a patient's need for analgesics while admitted, how often their pain was "well controlled," and how often the hospital staff did "everything they could to help with pain."¹⁴ Prior studies have demonstrated that a patient's HCAHPS domain of pain and analgesia satisfaction is highly correlated with their global satisfaction with a hospitalization.¹⁹

After discovering that the pain domain HCAHPS scores for our department were consistently below the national median, we implemented a quality improvement trial to address postoperative pain. While several examples of analgesia protocols were present in the literature, none used an interdepartmental approach, focused on all phases of care, or used quality improvement methodologies. Therefore, using a conceptual health model of pain, we developed a multimodal, interdepartmental, standardized analgesia protocol that followed neurosurgical patients from preadmission to discharge. Our primary outcome goal was a significant reduction in patients' average postoperative pain score on the 10-point numeric rating scale (NRS). Secondary goals were to determine that a standardized protocol could be safely implemented and to determine which factors predicted postoperative pain in neurosurgical patients. We hypothesized that by using quality improvement methodologies, a standardized analgesia protocol could be developed and implemented by a multidisciplinary team and could increase patient satisfaction in the domain of pain treatment and analgesia during hospitalization for neurosurgical surgery.

Methods

Our institution is an 852-bed, academic tertiary referral center with approximately 4000 neurosurgical discharges annually. To assess the efficacy of our quality improvement initiative, a prospective interrupted time-series trial was conducted. The study consisted of a 4-month preintervention surveillance period (October 2012 through January 2013) followed by a 6-month postintervention phase (February through July 2013). Systematic random sampling was used to identify every 10th postoperative neurosurgical patient admitted preintervention and every 17th patient postintervention. Exclusion criteria were age younger than 18 years, nonoperative patients, use of methadone within the last 6 months, pregnancy, or inability to communicate their pain level in English. Ninety-six of 160 patients screened were enrolled in the study, a recruitment

rate of 60%, with a 100% completion rate of enrolled patients. The reasons for screening failure were refusal to participate in the study ($n = 28$), discharge prior to the study coordinator arriving ($n = 19$), inability to provide informed consent ($n = 5$), use of methadone ($n = 4$), lack of English proficiency ($n = 2$), and other reasons ($n = 6$). The study was approved by the University of Florida institutional review board. It is registered with the ClinicalTrials.gov database (<http://clinicaltrials.gov>), and its registration no. is NCT01693588.

Intervention

An interdepartmental committee composed of neurosurgery, anesthesiology, acute pain service, nursing, and pharmacy personnel was formed. This committee developed an initial driver diagram¹⁶ and aggregated best practices from other institutions and the current literature. Interviews of residents, fellows, and nurses revealed specific barriers to pain control such as the following: 1) poor communication between anesthesiology and neurosurgery teams regarding postoperative analgesia, 2) variation of analgesia prescribing among neurosurgical faculty, 3) resident fears of obscuring the neurological examination with excessive opioids, 4) inconsistent notification of residents by nurses for uncontrolled postoperative pain, and 5) delayed responses of physicians to requests for analgesia escalation by nursing staff.

Therefore, an "analgesia bundle" was designed to address all points of a patient's hospitalization (Table 1). Appendix A presents a more detailed intervention protocol. The bundle included preoperative process improvements, intraoperative analgesia standardization, improved recognition of postoperative pain, and a standardized postoperative analgesia protocol (Appendix B) and analgesia escalation protocol (Appendix C). Using our electronic health record (EHR) system, we developed an automated daily list of all patients with at least 1 pain score equal to or greater than 7 on the NRS within the prior 24 hours. This information was then distributed to neurosurgery and nursing staff in the form of a run chart. The pain control committee used this data to guide multiple Plan-Do-Study-Act (PDSA) cycles.¹⁵

Data Collection

Analgesics use was categorized as follows: acetaminophen, antiepileptics/antidepressants adjuvant agents (gabapentin, pregabalin), anxiolytics (e.g., benzodiazepines), NSAIDs, and opioids. Daily oral morphine equivalents (OMEs) were totaled using our pharmacy's equal analgesic conversion algorithm. To control for preexisting pain, anxiety, and depression, all subjects received 5 question batteries from the Patient Reported Outcomes Measurement Information System (PROMIS). The PROMIS batteries were Pain Behavior Bank, Physical Function Bank, Anxiety Bank, Depression Bank, and Sleep Disturbance Bank. PROMIS uses computer-adaptive testing and item-response theory to minimize responder burden and improve accuracy, which was necessary in patients with extreme pain.^{1,4,5,7,10,13,21,36,37} The question selection was by maximum posterior weighted information and stopping

TABLE 1. Intervention performed during the analgesia initiative

1	Preop improvements
1.1	Increased documentation of preop pain using NRS
1.2	Improved documentation of preop anxiety & depression
1.3	Improved documentation of preop analgesic usage
1.4	Scripting of expected pain counseling & inclusion in preop visit
2	Intraop
2.1	Preop dosing of spinal surgery patients w/ gabapentin
2.2	Improved use of multimodal analgesia (acetaminophen, NSAIDs, ketamine, gabapentin)
2.3	Standardization of analgesia use among neuroanesthesiologists
3	Postop pain recognition
3.1	Online training of nurses on pain recognition
3.2	Set goal of "6-must be fixed." In all patients w/ pain level >6, action must be taken
3.3	Nursing staff were informed to first maximize all PRN medications prior to notifying residents & fellows for uncontrolled pain
3.4	Automatically import last 24-hr pain scores into the daily rounding notes for neurosurgery
4	Postop pain control
4.1	Developed a standardized analgesia protocol for neurosurgery patients based on surgery type
4.2	Inclusion of the analgesia protocol into the standard order set for postop neurosurgery patients
4.3	Developed a safe analgesia escalation protocol
4.4	Developed a trigger for consulting Acute Pain Services
4.5	Develop a pain note for neurosurgery that aided in calculation of preop OMEs
4.6	Education of residents and fellows on pain management

PRN = as needed.

conditions were a minimum of 4 and a maximum of 8 responses per battery. PROMIS batteries were scored using a graded response model and reported t-scores were based on a large national sample.

The main process measure was compliance with the entire analgesia protocol. Other process measures included analgesics use on postoperative Days 1 and 3 (POD1, POD3), use of patient-controlled analgesia, and documentation of pre- and postoperative pain scores. A postoperative survey adapted from the Brief Pain Survey and the Short-Form McGill Pain Questionnaire^{18,28,29,41,45,46} assessed time to administration of pain medication, perception of physicians' and nurses' sympathy, and perceptions of analgesia regimen effectiveness (Appendix D).

Pain was assessed every 4 hours using the 10-point NRS. These scores were aggregated for a POD1 and POD3 score and functioned as the primary outcome. A successful reduction was defined as a statistically significant 1.06-point decrease in the average NRS on POD1. Secondary outcome measures were the POD3 scores and HCAHPS pain management domain. Length of stay and naloxone use data were documented as a countermeasure.

Education

Physicians underwent 3 hours of live training on the protocol. Intervention refinements from PDSA cycles were implemented via email. The initiative was disseminated to nurses via quality teams and an online mandatory training module with a posttest. All nurses completed the training and achieved an acceptable posttest score of at least 80%. Education of hospital administration and Quality Department staff was performed via regular updates through the hospital's Medical Executive Pain Committee. Educational presentations are available upon request from the first author.

Statistical Analysis

Based on pain and psychometric literature, a minimum clinically important difference of half the standard deviation of the preintervention POD1 pain scores (1.06) was determined a priori.^{1,2} Sample size was based on a mean change in the NRS of 1.0 (SD 1.5; α error 5%; 90% power). Baseline characteristics were compared with repeated 2-tailed independent sample t-tests if continuous and a chi-square test if ratios. Data are reported as mean $\pm$ SD. A univariate linear regression model (SPSS V22.0.0; IBM Corp.) was created to determine factors' association with postoperative pain. Treatment group (pre- or postintervention) was our primary predictor, and candidate variables included surgery type, age, sex, body mass index (BMI), history of depression, history of anxiety, each of the 5 PROMIS batteries, and preoperative medication use (acetaminophen, antiepileptics/antidepressants, anxiolytics, NSAIDs, and opioids, including OMEs) as covariates. The Hosmer-Lemeshow test was used to assess model fit. A p value < 0.05 was considered significant. A multivariate regression with a stepwise elimination routine was used to determine best predictors of POD1 pain with rational exceptions. The statistical criterion for entry into and staying in the model was $p \leq 0.3$. The model for POD3 pain was identical but included POD1 pain as a candidate variable. Finally, a repeated measure, mixed linear model was developed with POD1 and POD3 as the outputs and the same covariates.

Results

Prior to the intervention, no standardized analgesia strategy existed for neurosurgical patients; rather, each physician followed personal preference. Accordingly, analgesics were not included in the standard postoperative order sets. Informal interviews revealed that residents were often hesitant to adequately treat patients' pain for fear of obscuring the neurological examination. In the 8 quarters preceding the initiative, HCAHPS survey results showed that only $72.1\% \pm 6.4\%$ of neurosurgical-floor patients felt they were "always helped with their pain" and only $56.6\% \pm 6.9\%$ felt their "pain was always controlled." Both of these numbers place us below the national median when compared with other neurosurgery programs. Therefore, we implemented a quality improvement intervention to address postoperative pain control.

The cornerstone of the intervention was a standardized analgesia protocol based on the World Health Organiza-

tion analgesic ladder. Postoperative analgesia regimens were created for supratentorial craniotomy, suboccipital craniotomy, spine surgery without fusion, and spine surgery with fusion (Appendix B). Next, a rational analgesia escalation algorithm was developed by Pharmacy and Acute Pain Service (Appendix C). These protocols were approved by the neurosurgery faculty and incorporated into the electronic postoperative order sets. Other interventions, as detailed in Table 1 and Appendix A, were implemented on or about February 1, 2013. The Pain Control Committee met monthly to review the project, and PDSA cycles were implemented as necessary.

When comparing the pre- and postintervention sample populations ($n = 48$ each), no difference was found between them in age, sex, type of surgery (cranial vs spinal), or BMI (Table 2). PROMIS computer adaptive testing surveys were used to control for premorbid pain, physical dysfunction, anxiety, and depression. No differences in preoperative pain behaviors ($p = 0.075$), pain-related interference in daily life ($p = 0.567$), or pain-related physical dysfunction ($p = 0.198$) were noted. Although no difference existed between the two groups regarding a medical

history of depression ($p = 0.238$) or anxiety ($p = 0.809$), after the intervention, patients reported a slightly higher preadmission depression inventory score (46.3 ± 11.1 vs 53.5 ± 11.7 ; $p = 0.003$) and anxiety scale score (49.8 ± 10.9 vs 56.8 ± 10.5 ; $p = 0.002$) on the PROMIS batteries. Therefore, these were controlled for in the final analysis. No difference existed between the percentage of patients using opioids ($p = 0.212$), acetaminophen ($p = 0.657$), benzodiazepines ($p = 0.412$), NSAIDs ($p = 0.386$), or gabapentin ($p = 0.355$) before or after the intervention. However, among the patients who did use opioids, the preintervention group tended to use a high, 24-hour OME (mean 94.8 ± 48.9 mg/day vs 48.9 ± 48.9 mg/day; $p = 0.007$). Again, this was controlled for in the final analysis.

Implementation of the Pain Control Protocol

Institution of a pain management initiative correlated with increased documentation of preexisting pain and recognition of postoperative pain. Documentation of preoperative pain in the medical record increased from 12.5% to 47.9% ($p = 0.000$) (Table 3), and documentation of pain in the daily postoperative rounding notes in-

TABLE 2. Preoperative patients' characteristics*

Characteristic	Preintervention	Postintervention	p Value
Time			
October 2012 through January 2013	48		
February 2013 through August 2013		48	
Sex			0.067
M	29 (60.4)	20 (41.7)	
F	19 (39.6)	28 (58.3)	
Mean age, yrs	56.2 ± 16.7	55.9 ± 16.2	0.926
Mean BMI, kg/m ²	28.4 ± 7.1	29.1 ± 7.6	0.662
Surgery			1.00
Craniotomy	18 (37.5)	17 (35.4)	
Spine	30 (62.5)	31 (64.6)	
Mental health			
History of depression	9 (18.8)	15 (31.3)	0.238
History of anxiety	10 (20.8)	12 (25)	0.809
Preop analgesia use			
Opioids	23 (47.9)	16 (33.3)	0.212
Mean 24-hr OME, mg/day	94.8 ± 48.9	48.9 ± 48.9	0.007
Acetaminophen	16 (33.3)	13 (27.1)	0.657
Anxiolytics (e.g., benzodiazepines)	10 (20.8)	6 (12.5)	0.412
NSAIDs	5 (10.4)	9 (18.8)	0.386
Antiepileptics/antidepressants (gabapentin, pregabalin)	4 (8.3)	7 (14.6)	0.355
PROMIS, mean score			
Pain Behavior Scale	56.0 ± 10.4	59.2 ± 5.8	0.075
Pain Interference Scale	60.2 ± 12.1	61.5 ± 9.6	0.567
Physical Dysfunction Scale	34.4 ± 8.3	36.7 ± 8.4	0.198
Sleep Scale	55.2 ± 10.5	59.6 ± 10.3	0.049
Depression Scale	46.3 ± 11.1	53.5 ± 11.7	0.003
Anxiety Scale	49.8 ± 10.9	56.8 ± 10.5	0.002

* Data are given as number (%) of patients unless otherwise indicated, and mean values are presented $\pm$ SD.

creased from 8.3% to 100% following the intervention ($p = 0.000$).

Significant changes in peri- and intraoperative analgesia were driven by a consensus discussion by the neuroanesthesia faculty. The approach focused on consistent use of multimodal analgesia and attention to continuation of preexisting therapy with long-acting opiates. Patients receiving some form of multimodal pain therapy beyond the intraoperative administration of intermediate-acting narcotics increased from 81% to 92% ($p = 0.23$) across all neurosurgeries. The use of gabapentin and acetaminophen increased from 6% to 25% and 67% to 88%, respectively ($p = 0.025$ for gabapentin and $p = 0.029$ for acetaminophen). Gabapentin use increased particularly in spine surgery patients. The proportion of patients who received long-acting opiates perioperatively increased from 40% to 67% ($p = 0.014$). Although not statistically significant, there was an increase from 25% to 46% ($p = 0.055$) in the percentage of patients prescribed at least 1 adjunctive analgesic after the rollout of the initiative.

Inclusion of the standardized analgesia protocol in the neurosurgery postoperative order set also had significant effects on prescriber habits. Monthly compliance with all aspects of the analgesia protocol increased from 0% to 35.4% postintervention, with a maximal compliance of 80% noted in the 3rd postintervention month (Fig. 1A). It must be noted that if a patient failed on any single measure, they were not counted as compliant. Despite this

partial compliance with the total protocol, physicians were much more likely to use at least 2 or more classes of analgesia after the protocol implementation. Postintervention, the use of NSAIDs increased from 8.3% to 31.3% ($p = 0.009$) and use of gabapentin increased from 12.5% to 33.3% ($p = 0.027$). While not statistically significant, acetaminophen use also trended upward (56.3% vs 75%; $p = 0.055$). Preintervention, no patient was prescribed intravenous acetaminophen, which was commonly used afterward. Interestingly, there was no significant change in the mean 24-hour OME after the intervention (55.7 ± 100.6 mg/day vs 63.2 ± 58.5 mg/day; $p = 0.655$), nor was there an increase in the use of patient-controlled analgesics (37.5% vs 29.2%; $p = 0.390$).

Although the time between patients' requests for analgesia and administration of the medication among floor patients was brief preintervention, this showed no significant changes postintervention. The percentage of patients who felt that less than 5 minutes had elapsed between requesting medication and its administration remained constant (52.2% vs 48.8%; chi-square, $p = 0.712$). Additionally, the percentage of patients who felt the longest time for analgesic delivery was less than 10 minutes (67.4% vs 58.2%; chi-square, $p = 0.782$) remained unchanged.

It appears that gains made in this study were due to improved pain control rather than changes in patients' perceptions of medical staff. Patients' perception of caregiver sympathy was assessed through postoperative surveys. However, the percentage of patients who either "strongly agree" or "agree" with the statement "My doctor is always sympathetic to my pain" (91.7% vs 91.7%; $p = 1.00$) did not change. Similarly, no change was seen when asking about nursing sympathy (93.8% vs 91.6%; $p = 0.452$).

Postoperative Pain Decreased Following Implementation of the Pain Control Protocol

In general, implementation of the analgesia protocol correlated with reduced pain on POD1. A univariate linear regression of 16 candidate variables demonstrated that increasing age ($p = 0.016$), having a cranial surgery as opposed to spinal surgery ($p = 0.000$), and being admitted to the hospital after the analgesia protocol ($p = 0.004$) (Table 4) were most predictive of a lower aggregate POD1 pain score. Controlling for all other variables, patients reported a 31.8% reduction in POD1 pain on the 10-point NRS scale after implementation of the protocol ($p < 0.0001$) (Table 4, Fig. 1B). Patients recovering from spine surgery had the largest improvement, with a 43.1% drop in NRS pain scores (5.45 vs 3.10; $p < 0.036$). Patients recovering from cranial surgery only had a 20.9% reduction but most likely suffered a floor effect, since their baseline pain scores were roughly half that of spinal surgery patients both before and after the intervention (2.78 vs 5.45) (Table 4).

Modifiers of postoperative pain included age. For each additional year of age, patients reported 0.03 fewer points on the average POD1 NRS. Factors having no effect included BMI, sex, any of the PROMIS indices, and history of depression, anxiety, or preoperative OME. Similarly, the greatest predictor of lower POD3 pain was having a cranial procedure ($p = 0.018$). Otherwise, the greatest predictors of lower POD3 pain were a low POD1 NRS pain

TABLE 3. Process improvement measures*

Measure	Preintervention	Postintervention	p Value
Pain documented in HPI	6 (12.5)	23 (47.9)	0.000
Pain documented in daily note	4 (8.3)	48 (100)	0.000
POD1, no. of patients	48	48	
Acetaminophen	27 (56.3)	36 (75)	0.055
Benzodiazepine	5 (10.4)	10 (20.8)	0.170
NSAID	4 (8.3)	15 (31.3)	0.009
Baclofen	9 (18.8)	5 (10.4)	0.386
Gabapentin	6 (12.5)	16 (33.3)	0.027
PCA use	18 (37.5)	14 (29.2)	0.390
Mean OME, mg/day, $\pm$ SD	55.7 $\pm$ 100.6	63.2 $\pm$ 58.5	0.655
Compliance w/ protocol	0 (0)	17 (35.4)	0.000
POD3, no. of patients	19	22	
Acetaminophen	4 (21.1)	11 (50.0)	0.050
Benzodiazepine	4 (21.1)	8 (36.4)	0.466
NSAID	1 (5.3)	4 (18.2)	0.393
Muscle relaxant	8 (42.1)	3 (13.6)	0.133
Gabapentin	3 (15.8)	9 (40.9)	0.176
PCA use	0	2 (9.1)	0.490
Mean OME $\pm$ SD	72.29 $\pm$ 70.7	39.17 $\pm$ 36.5	0.062

HPI = history of presenting illness; PCA = patient-controlled analgesia.

* Data given as number (%) unless otherwise indicated.

FIG. 1. Protocol process and outcome measures. **A:** Protocol compliance and POD1 pain scores. **B:** Aggregate NRS pain scores for all surgeries and specifically for craniotomies and spinal surgeries. *** $p < 0.0001$. **C:** Monthly postoperative NRS pain scores pre- and postintervention for craniotomies and spinal surgeries. **D:** Weekly aggregate pain scores for all patients admitted to the neurosurgery, orthopedic, or general surgery services. **E:** HCAHPS scores: pain management summary scores by quarter. **F:** T-chart showing the number of days between consecutive naloxone doses. A T-chart is a specialized control chart used for monitoring rare adverse events. Each point on the x-axis is a sequential administration of naloxone to a floor patient with times since previous administration represented on the y-axis.

score ($p = 0.0033$), a lower BMI ($p = 0.032$), and a lower PROMIS depression inventory ($p = 0.006$). All other variables showed no significant influence (Table 4).

A repeated measure, mixed linear model was developed with POD1 and POD3 pain scores as the outputs; covariates included type of surgery, age, pain intervention group, preoperative OME, BMI, and PROMIS depression inventory. Patients' pain did not change significantly between POD1 and POD3 ($p = 0.787$); this most likely resulted from the discharge of patients with adequate analgesia. When including both POD1 and POD3 pain scores in the model, having cranial surgery ($p = 0.001$) and being in the postintervention group ($p = 0.046$) were significant predictors of decreased postoperative pain.

The observed decline in monthly aggregate POD1 NRS pain scores appears to begin with implementation of the

analgesia protocol (time = 0) (Fig. 1A and C). Furthermore, the monthly aggregate POD1 showed a strong negative correlation with protocol compliance in cranial patients (-0.441 ; $n = 10$; $p = 0.202$), spinal surgery patients (-0.515 ; $n = 10$; $p = 0.128$), and all surgical patients (-0.686 ; $n = 10$; $p = 0.028$) (Fig. 1A and C). The possibility exists that these results could have been due to secular trends (e.g., hospitalwide improvements in pain management) concurrent with this initiative. Therefore, 307,945 NRS pain scores were collected from all postoperative neurosurgery ($n = 140,035$), general surgery ($n = 77,789$), and orthopedic surgery patients ($n = 90,121$). Neurosurgery pain scores were compared with general surgery and orthopedic pain scores by week. After controlling for age ($p < 0.0001$) and BMI ($p < 0.0001$), a univariate linear regression revealed a significant department and time interaction, with the neu-

TABLE 4. Outcome measures*

Measure	Preintervention	Postintervention	p Value
POD1, no. of patients	48	48	
Aggregate pain score	4.31 (3.7–4.9)	2.94 (2.04–3.85)	0.000
Cranial surgery patients' scores	2.78 (1.79–3.77)	2.20 (1.08–3.32)	0.21
Spinal surgery patients' scores	5.45 (4.64–6.25)	3.10 (2.37–3.83)	0.036
POD3, no. of patients	18	20	
Aggregate pain score	3.22 (1.972–4.465)	2.39 (1.382, 3.391)	0.058
Cranial surgery patients' scores	1.54 (–0.991 to 4.076)	1.39 (–0.300 to 3.080)	0.402
Spinal surgery patients' scores	4.89 (3.838–5.949)	3.38 (2.451–4.314)	0.043
How much relief has your pain treatments or medication provided? (0%–100%)	74.3 (66.7–81.93)	66.3 (58.30–74.22)	0.663
Mean length of stay, days (CI)	2.98 (2.21–3.75)	2.87 (2.10–3.65)	0.851
Naloxone doses/mo, $\pm$ SD	1.5 $\pm$ 1.0	0.33 $\pm$ 0.5	0.039
Median days btwn naloxone doses	12	64	—

* Data given as mean pain score (95% CI) unless otherwise indicated.

rosurgery NRS pain scores being significantly lower than scores for other services after the start of the intervention ($p < 0.0001$) (Fig. 1D).

Finally, during the intervention and after its completion, the HCAHPS pain domain responses for this patient population were also assessed as an externally measured and nationally standardized method of assessing inpatient analgesia. However, it must be noted that HCAHPS scores were collected quarterly from 50 randomly selected, anonymous patients and did not correlate directly with the study population. The normalized national percentage of patients that either “agree” or “strongly agree” with their pain management increased from 64.3% preintervention to 72.8% postintervention (t-test, $p = 0.007$). This resulted in departmental scores at or near the national median and coincided with the implementation of the analgesia initiative (Fig. 1E). Furthermore, this trend has continued well after the close of the study, suggesting persistent institutional change. Additionally, the percentage of patients who were always “helped with their pain” increased significantly from 72.1% to 82.0% postintervention ($p = 0.033$). While there was no statistical change in the percentage of patients reporting their pain was “always controlled,” this HCAHPS question was trending in a favorable direction (56.5% vs 63.2%; $p = 0.14$).

As a countermeasure, the number of naloxone doses was tracked. This medication is only given in this population for treatment of altered mental status believed to be associated with opioid overdose. Given its low frequency, this indicator was documented among all postoperative neurosurgical-floor patients during the study period. Following implementation of the pain protocol, the rate of naloxone dose administration fell from 1.5 doses per month to 0.33 doses per month ($p = 0.04$) (Table 4). Additionally, the median number of days between naloxone doses increased from 12 to 64 after the intervention (Fig. 1F).

Lessons From Implementation

Significant resistance to implementation was encountered

from neurosurgery residents. Although all neurosurgery faculties had approved the protocol, many residents were unsure if repercussions would exist if a faculty member's previous preferences were ignored. Reinforcing the Just Culture Model combatted this misconception.⁹ This paradigm does not punish a practitioner for a patient harm event if this practitioner was following a best practices protocol; rather, it coaches the individual if errors were made and alters the protocol to improve safety if needed. Second, the few instances of overmedication were closely scrutinized. Because of this increased emphasis, it was assumed that these events were occurring with increased frequency, although the inverse was true as demonstrated in our findings (Table 4, Fig. 1E). One failure of this initiative was an EHR note that guided residents through calculating a patient's OME and suggested logical escalations according to the protocol. Despite several revisions, this note remained too cumbersome to gain widespread adoption among the residents. Finally, our EHR did not clearly show nurses which analgesia tiered patients were receiving, thus preventing them from suggesting dose escalations. Improvements to the electronic medical record order displays were a frequent focus of the PDSA cycles.

Discussion

In this study we demonstrated that a literature-based, standardized analgesia protocol could be implemented among postoperative patients despite a wide range of faculty opinions regarding analgesia. This protocol resulted in improved documentation, improved response to postoperative pain, and improved use of multimodal analgesia. Furthermore, it correlated with a 32% reduction in aggregate pain scores among all patients on POD1, and this effect was most significant among spinal surgery patients, who had a 43% reduction in postoperative pain. This observed decline correlated with an increase in protocol compliance and a significant decrease in the number of administered naloxone doses. Furthermore, HCAHPS scores

recorded since the completion of the formal initiative suggest durability beyond the life of the study.

These findings are consistent with and extend those from previous reports. Uncontrolled postoperative pain is both prevalent and undertreated, with 20% to 30% of all surgical patients experiencing moderate to severe postoperative pain.^{8,30} A review of inpatient neurosurgical patients at another institution found that 18% of patients complained of excruciating pain, while 37% of patients complained of severe pain.³³ Similar to this study, published work shows that among neurosurgery patients, factors that predict postoperative pain include type of surgery,^{17,26} premonitory pain,²⁶ and depression.

This study supports improved analgesia among patients with multimodal therapy. Prior neurosurgical literature demonstrates that narcotics have been the predominant method of pain management after craniotomy.^{23,33,38,40} Unfortunately, because of their effects on mental status, these agents are typically used sparingly. However, a Cochrane Review showed that combining acetaminophen with codeine provides increased pain control and extends the duration of analgesia.⁴³ Given the disadvantages of opioids and the relative advantages of nonopioid agents, it is surprising that very few studies of neurosurgery patients have promoted the use of multimodal analgesia.

In a meta-analysis of 17 lumbar surgery studies, patients receiving NSAIDs in addition to opioids had lower pain scores and consumed fewer opioids than the group receiving opioids alone, with no difference in the incidence of adverse effects.²⁴ In 1 small, randomized controlled trial, craniotomy patients receiving both cyclooxygenase-2 inhibitors and narcotics had significantly lower pain, decreased length of stay, and decreased narcotics use compared with narcotics use alone.³⁴

The implementation of an analgesia protocol is not new. In patients with end-stage renal disease, implementation of the WHO analgesia ladder decreased mean pain scores by 6 points on a 10-point scale.² A multimodal analgesia regimen implemented among total hip arthroplasty patients found reduced postoperative pain in a 4-day postoperative period.²⁷ Finally, 2 randomized controlled trials showed that a single-agent protocol of more than 300 mg of oral gabapentin prior to lumbar discectomy reduced postoperative pain and decreased fentanyl use.^{31,32} In contrast to the current study, these studies only addressed a single class of agents and lacked modern quality improvement methodologies.

One published quality improvement intervention compared patient-controlled analgesia to an oral, multimodal analgesia protocol that included NSAIDs and acetaminophen in spinal surgery patients.³⁵ Similar to the current study, these authors found that patients used significantly fewer opioids, had less pain, and fewer side effects associated with opioids; however, this study only used historical controls.³⁵ Other examples of multimodal pain management protocols in nonsurgical patients have shown decreased use of inappropriate pain medications,⁶ standardized care, decreased length of time to extubation, decreased hospital length of stay, decreased cost, and decreased nursing time.^{11,12} Whereas other studies have altered the analgesia agents used to treat postoperative pain,

this was the first study, to our knowledge, to address patient pain pre-, intra, and postoperatively. Furthermore, to our knowledge, this is the first report that used the combined efforts of surgery, anesthesia, nursing, pharmacy, and quality improvement methodologies.

Several potential limitations resulting from this study's time-series design must be acknowledged. First, nurses collected pain scores and were aware of the initiative; this could have potentially influenced patient-reporting practices, resulting in response bias. However, self-reported, anonymous patient questionnaires showed similar trends in magnitude and temporal correlation with the nurse-collected data. Next, the recruitment of patients with lower pain scores in the postintervention group could have resulted in allocation bias. Therefore, systematic random sampling was used to limit convenience sampling, and a recruitment rate of 60% is similar to published analgesia literature. Furthermore, we used PROMIS computer adaptive testing to ease responder burden and lessen responder fatigue, making it more likely to capture this population. Contamination bias was curtailed by limiting initiative implementation to a 1-week period among all departments. This study design also is susceptible to secular trends, but a comparison of neurosurgery pain scores to those of orthopedic and general surgery patients during the same time period mitigates this concern. Finally, improved analgesia could have resulted from the Hawthorne effect or improvements in performance because clinicians were aware of the study goals. Unfortunately, a balanced, incomplete block design was not feasible in this study. However, the HCAHPS scores (Fig. 1E) demonstrate persistent improvements in pain management nearly 2 years after the end of the formal study, which lasted only 6 months. If the results were only from the influence of being observed, this effect would have returned to baseline at the close of the study.

The greatest strengths of this study are its pragmatism and generalizability. All measures implemented are achievable in other institutions with very little capital outlay. To our knowledge, this is one of the first studies to use rigorous quality improvement methodology and a strong multidisciplinary approach to directly address an observed underperformance in the HCAHPS pain domain. This study suggests that among neurosurgery patients, a quality improvement initiative with interdepartmental cooperation and standardization of analgesia can decrease postoperative pain, promote multimodal analgesia therapy, and decrease adverse events associated with opioids in a large institution. Since immediate postoperative pain is one of the strongest predictors of developing chronic pain among outpatients, this study has broad implications for the continuum of care model proposed in the Affordable Care Act.²²

Acknowledgments

This study received funding from the W. Martin Smith Interdisciplinary Patient Quality and Safety Awards Program.

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Disclosures

The authors report no conflict of interest concerning the materi-

als or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Titsworth, Guin, Bushwitz, Hurley, Seubert. Acquisition of data: Abram, Herman, West, Davis, Bushwitz, Seubert. Analysis and interpretation of data: Guin, Bushwitz, Seubert. Critically revising the article: Titsworth, Abram, Guin, Herman, Bushwitz, Hurley, Seubert. Reviewed submitted version of manuscript: all authors. Administrative/technical/material support: Davis.

Supplemental Information

Online-Only Content

Supplemental material is available with the online version of the article.

Appendices A–D. <http://thejns.org/doi/suppl/10.3171/2015.10.JNS15698>.

Previous Presentations

Portions of this work were presented in abstract form at the Annual Meeting of the Congress for Neurological Surgeons, Boston, Massachusetts, October 18–22, 2014.

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