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Original Research

Post-Operative Pain After Orthopedic Surgery: A Comparative Study Between the United States and Ethiopia

Laura E. Jackson, Ph.D., Meghan Lemons, MS-3., Haley Albers, MS-3, Kameron King, MS-3, Joey Maksoud, MS-3, Michael Braman, MS-3, Collin Freking, MS-3, Johnathan Dallman, M.D., Damon Mar, Ph.D., Abiy Haile, M.D., Solomon Mengistu, M.D., Archie Heddings, M.D.

ABSTRACT

Introduction. Post-operative pain management varies across healthcare systems and cultural contexts. While opioids are central in the United States, many countries rely on non-opioid strategies due to limited access or cultural norms. Authors of this study compared pain management strategies and outcomes among orthopedic trauma patients at academic centers in the United States and Ethiopia.

Methods. A retrospective cohort study was conducted of patients undergoing orthopedic trauma surgery at Tikur Anbessa Specialized Hospital (Ethiopia) and the University of Kansas Health System (United States) between May and October 2022. Visual Analog Scale (VAS) pain scores at 24 and 48 hours post-operatively, analgesic use, and demographics were analyzed.

Results. Ethiopian patients often were more male, younger, and had lower body mass indexes and fewer comorbidities (e.g., obesity, diabetes, smoking) than United States patients. Despite receiving fewer analgesics and no post-operative nerve blocks, Ethiopian patients reported lower VAS pain scores at both 24 and 48 hours. In the United States cohort, patients with nerve blocks had lower pain scores than those without; however, both groups reported higher scores than Ethiopian patients. In the United States, pain scores correlated positively with the number of analgesics administered.

Conclusions. Ethiopian patients reported better pain control despite fewer interventions, suggesting that systemic, demographic, and cultural factors may strongly influence post-operative pain experiences. These findings underscore the importance of context-sensitive approaches to pain management and highlight the need for further research to inform equitable, effective strategies across diverse settings.

INTRODUCTION

Post-operative pain management remains a global challenge. In the United States, opioids have traditionally served as the cornerstone of post-surgical analgesia. However, growing concerns about adverse effects and dependency risks have driven a shift toward multimodal, opioid-sparing strategies.[1-6]

Opioid prescribing practices vary widely across countries, shaped by healthcare infrastructure, regulations, and cultural norms.[6] For example, Young et al.[7] found that American patients were prescribed significantly higher morphine milligram equivalents than patients in the Netherlands and Haiti. Similarly, Ayres et al.[8] reported that Romanian patients, who received no opioids, experienced more pain in the first 24 hours post-operatively but less pain in the second 24 hours compared to American patients receiving opioids.

In many low- and middle-income countries (LMICs), limited access to medications and interventions such as regional nerve blocks or intravenous opioids necessitates reliance on lower-intensity strategies. These disparities create opportunities for natural comparisons between high-resource and resource-limited settings. Cultural coping mechanisms and patient expectations may further shape how pain is perceived and reported.[8]

Such global differences highlight the importance of understanding how systemic and cultural factors influence pain experiences. As high-use countries move toward alternatives to opioid-centric models, examples from LMICs demonstrate that effective pain control is possible without opioids. Religious beliefs, patient expectations, clinician-patient relationships, and health literacy are among the factors that can shape pain perception, expression, and management.

In this study, we compared post-operative pain management strategies and outcomes among orthopedic trauma patients at two academic medical centers: one in Ethiopia and one in the United States. This collaboration between the University of Kansas Health System and Tikur Anbessa Specialized Hospital sought to explore cross-national practices, enhance understanding of global pain management, and identify context-specific strategies for resource-limited settings. We hypothesized that American patients would receive more opioids but report worse pain control, given prior evidence linking higher opioid use with increased pain sensitivity, cultural expectations, and opioid-induced hyperalgesia.[8]

METHODS

Study Design. This retrospective cohort study compared post-operative pain management among orthopedic trauma patients treated at two academic medical centers: The University of Kansas Health System (Kansas City, KS, USA) and Tikur Anbessa Specialized Hospital (TASH; Addis Ababa, Ethiopia). TASH, Ethiopia's primary referral hospital, has limited opioid availability (e.g., tramadol, morphine), and use in orthopedic patients is minimal due to supply constraints and restrictive prescribing practices. Post-operative nerve blocks are not routinely administered.[6] Surgeries were performed between May 1 and October 31, 2022. Institutional review board (IRB) approval was obtained from both institutions, and informed consent was waived due to use of de-identified data. The institutions were chosen based on an established academic partnership, providing a unique opportunity to compare orthopedic trauma care and post-operative pain management across distinct resource and cultural contexts.

American data were extracted from the Healthcare Enterprise Repository for Ontological Narration (HERON), a de-identified

electronic health record platform using Current Procedural Terminology (CPT) and International Classification of Diseases (ICD-10) codes.[9] Ethiopian data were prospectively collected during patient care and entered into Research Electronic Data Capture® (REDCap®), hosted at the University of Kansas Medical Center.[10,11]

Inclusion Criteria. Eligible participants were ≥18 years anunderwent surgical fixation for traumatic fractures, including acetabulum, bimalleolar, trimalleolar, clavicle, distal radius, femoral head/neck/shaft, pelvis, pelvic ring, pilon, proximal humerus, tibia with fibula, or tibial plateau. Patients with multiple qualifying injuries were categorized as polytrauma. Exclusion criteria included non-operative management, pregnancy, or incomplete post-operative pain score documentation.

Data Collection. Variables included demographics (age, sex, body mass index [BMI]), injury characteristics (fracture type, mechanism of injury, time from injury to admission), and comorbidities (obesity, diabetes, smoking, alcohol use). Pain management variables included opioid and non-opioid medications, route of administration, opioid doses (converted to morphine milligram equivalents [MMEs]), and use/timing of peripheral nerve blocks.

Pain Score Measurement. Pain was measured using the Visual Analog Scale (VAS; 0 = no pain, 10 = worst imaginable pain).[12] When multiple scores were recorded within a 24-hour window, the mean was used for 0-24- and 24-48-hour intervals.

Statistical Analysis. Categorical variables were summarized as frequencies and percentages; continuous variables as means and standard deviations. Normality was assessed with the Shapiro-Wilk test. Group comparisons used Chi-square or Fisher's exact tests for categorical variables and independent *t*-tests or Wilcoxon rank-sum tests for continuous variables, depending on distribution. Analyses were conducted in R version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria), with significance set at $\alpha = 0.05$. To evaluate whether analgesic intensity was associated with pain, Pearson correlations were computed between the total number of analgesics administered (opioid and non-opioid, unweighted by dose) in the first 24 and 48 hours and corresponding VAS pain scores. Linearity was checked with scatterplots, and both variables were tested for normality. Correlations were stratified by cohort (Ethiopia vs. United States).

RESULTS

Patient Demographics. Of 357 patients, 122 were Ethiopian and 235 American. Ethiopian patients were younger, more often male, and had lower mean weight and BMI compared with Americans (all p <0.001; Table 1).

Comorbidities and Pain Scores. Obesity (37.9% vs. 1.6%) and diabetes (17.0% vs. <1%) were more prevalent in Americans. Smoking rates differed significantly, but alcohol abuse did not. In the American cohort, neither obesity nor diabetes was associated with higher post-operative pain scores at 24 or 48 hours.

Mechanisms of Injury. Falls were the most common mechanism in Americans (54%), followed by motor vehicle accidents (26%). Among Ethiopians, motor vehicle accidents were most common (44%), followed by falls (26%). Less frequent causes included gunshot wounds (19 vs. 11), assaults (11 vs. 6), crush injuries (6 vs. 4), pathologic fractures (0 vs. 4), recreational injuries (0 vs. 21), and other/unknown causes.

Time to Admission. Ethiopian patients had longer average delays from injury to hospital admission (16.8 ± 56.0 days vs. 6.0 ± 8.8 days), though this was not statistically significant (p = 0.23). The wide variability in Ethiopia likely reflects delayed presentation and limited access to care.

Injury Types. Distal radius and trimalleolar fractures were more common in Americans, while tibia/fibula and femoral shaft fractures predominated in Ethiopians.

Post-Operative Pain and Analgesia. Pain management differed markedly. No Ethiopian patient received a peripheral nerve block, compared with 48.9% of Americans. Among Americans who did, pain scores were unexpectedly higher (24h: 5.2 ± 2.9; 48h: 6.4 ± 2.6) than Ethiopians. To standardize comparisons, analyses excluded patients with blocks. Without blocks, American patients reported significantly higher pain scores than Ethiopians at both 24h (5.5 ± 2.7 vs. 4.8 ± 1.7, p = 0.004) and 48h (6.6 ± 2.5 vs. 2.8 ± 1.6, p <0.001; Table 2). Notably, Ethiopian pain scores declined from 24 to 48h, while American scores increased.

Analgesic Use. Analgesic profiles differed (Table 3). Ethiopians received primarily tramadol (99%), with diclofenac (37%) and paracetamol (2%). Americans received fentanyl (69%), paracetamol (47%), oxycodone (41%), hydromorphone (28%), and ketorolac (2%). Mean doses (±SD) were Ethiopians: tramadol 50 mg (0.0), diclofenac 72 mg (8.6), paracetamol 1000 mg (0.0); Americans: paracetamol 833 mg (182.6), fentanyl 47 mcg (74.3), oxycodone 9 mg (3.2), hydromorphone 1.2 mg (2.1), ketorolac 23 mg (10.3).

Dosing Patterns. Ethiopian tramadol was almost always scheduled TID (96-98% across 48h). Diclofenac was BID (51%) or PRN (49%). American paracetamol schedules varied (BID 23%, TID 32%, QID 4% in first 24h; mostly QID in second 24h, 72%). Fentanyl use was inconsistent initially but escalated, with most patients requiring ≥3 doses in the second 24h (93%). Oxycodone and hydromorphone were usually scheduled 2-4 times daily. Ketorolac was given BID in the first 24h and TID-QID thereafter.

Correlations Between Analgesia and Pain. In Ethiopia, the number of analgesics did not correlate with pain scores. In contrast, Americans receiving more analgesics reported higher pain, with significant positive correlations at 24h ($r = 0.502$, p <0.001) and 48h ($r = 0.203$, p = 0.039).

Table 1. Summary of Ethiopian and American orthopedic fracture patient demographics.

Demographics	Ethiopian Participants, n = 122	American Participants, n = 235	*P* value
Female/Male	21/101	122/113	p <0.001
Age (Years)	34.9 ± 15.3	47.7 ± 17.6	p <0.001
Body Mass Index (kg/m2)	22.2 ± 2.7	29.3 ± 8.0	p <0.001

Note: Gender is represented as counts and compared between groups using a Chi-square test. Means and standard deviations are reported for age and body mass index (BMI). Age and BMI were compared using *t*-test or Wilcoxon rank sum tests as appropriate.

Table 2. Comparison of post-operative visual analog scale (VAS) pain scores between Ethiopian and American orthopedic fracture patients who did not receive a peripheral nerve block.

Pain Score	Ethiopian Participants, n = 122	American Participants, n = 235	*P* value
24 hours	4.8 ± 1.7	5.5 ± 2.7	p = 0.004
48 hours	2.8 ± 1.6	6.6 ± 2.5	p <0.001

Note: Means and standard deviations are reported, and comparisons between groups were made using independent *t*-tests.

Table 3. Post-operative analgesics administered to Ethiopian and American orthopedic patients in the first 24 and 48 hours after surgery. Means and standard deviations are reported for doses. Frequencies and percentages are presented for medication use.

Ethiopian Participants			
Analgesic (dose)	**1st 24h, n (%)**	**2nd 24h, n (%)**	**n (%)**
Tramadol (mg)	BID: 5 (4) TID: 116 (96)	BID: 2 (2) TID: 118 (98)	121 (99)
Diclofenac (mg)	PRN: 22 (49) BID: 23 (51)	PRN: 9 (20) BID: 36 (80)	45 (37)
Paracetamol (mg)	PRN: 2 (100)	-	2 (2)
American Participants			
Analgesic (dose)	**1st 24h, n (%)**	**2nd 24h, n (%)**	**n (%)**
Paracetamol (mg)	BID: 56 (23) TID: 78 (32) QID:107 (4) >QID: 6 (3)	BID: 15 (6) TID: 52 (21) QID: 180 (72)	118 (47)
Fentanyl (mcg)	BID: 53 (21) TID: 67 (27) QID: 59 (24) >QID: 69 (28)	BID: 41 (17) TID: 83 (33) QID: 41 (17) >QID: 83 (33)	172 (69)
Hydromorphone (mg)	BID: 110 (44) TID: 46 (19) QID: 57 (23) >QID: 34 (14)	BID: 58 (24) TID: 87 (35) QID: 58 (24) >QID: 43 (18)	69 (28)
Oxycodone (mg)	BID: 94 (38) TID: 74 (30) QID: 59 (24) >QID: 19 (8)	BID: 64 (26) TID: 53 (21) QID: 71 (29) >QID: 60 (24)	102 (41)
Ketorolac (mg)	BID: 249 (100)	TID: 124 (50) QID: 124 (50)	6 (2)

Abbreviations: PRN, as needed; BID, two times daily; TID, three times daily; QID, four times daily; >QID, more than four times daily.

DISCUSSION

This cross-national analysis highlights that post-operative pain outcomes are influenced by more than pharmacologic intensity. Demographics, mechanisms of injury, systemic factors, and cultural expectations all shaped how pain was perceived, reported, and treated. These findings underscore why universal pain management strategies may not translate equally across settings.

Ethiopian patients were significantly younger, more male, and leaner than American patients. These differences align with trauma patterns in LMICs, where occupational exposure, reliance on public transport, and weaker safety enforcement disproportionately affect younger men.[13-15] Such demographic factors may shape both pain thresholds and reporting behaviors, reflecting broader social and economic influences. Mechanisms of injury also diverged: Americans more often sustained falls, recreational, and pathologic fractures, while Ethiopians experienced motor vehicle accidents, gunshot wounds, and crush injuries; patterns consistent with occupational and societal risks.

BMI differences further highlight physiologic contributors to pain. Obesity-related inflammation can exacerbate chronic pain and impair recovery,[16,17] whereas low BMI may signal malnutrition and poor bone healing. Both extremes alter bone density and fracture risk, potentially shaping pain outcomes.[18] Time to surgery also differed; Ethiopians had longer delays, possibly reducing acute nociceptive pain before surgery, while Americans underwent earlier fixation during peak inflammatory response.[19]

Analgesic strategies varied markedly. Nerve blocks, used only in the United States, provided modest benefit but did not equalize pain outcomes. This challenges assumptions about their universal efficacy and suggests cultural expectations, prior opioid exposure, and care environments modulate their effect.[20,21] Similarly, the positive correlation between number of analgesics and pain in Americans, but not Ethiopians, likely reflects reactive prescribing rather than true efficacy. These findings highlight that escalating medications does not necessarily improve outcomes without addressing underlying pathology or patient expectations.[22]

Limitations. This study has limitations. We did not account for preoperative analgesic use or psychological factors such as preoperative anxiety, both of which may affect post-operative pain. Cohorts also differed in demographics and comorbidities, including age, sex, BMI, obesity, and diabetes. The retrospective design precludes causal inference, and variability in care protocols (e.g., nerve blocks, medication regimens) introduces confounding. Cultural influences on pain reporting are difficult to quantify; however, psychological factors, such as preoperative anxiety, likely contributed, as prior studies have documented differences in anxiety prevalence across settings.[23,24] Finally, reliance on 24-hour mean VAS scores limited temporal granularity. Despite these limitations, the trends align with prior research on opioid-induced hyperalgesia, cultural influences, and demographic effects on recovery.[16,19,22,23,25]

CONCLUSIONS

Despite not receiving post-operative nerve blocks, Ethiopian patients reported consistently lower pain scores than American patients, even when the latter received blocks. While fracture types also differed; distal radius and trimalleolar more common in Americans, tibia/fibula and femoral shaft more common in Ethiopians; these contrasts cannot fully explain the differences observed. Instead, system-level, cultural, and physiologic factors likely play a central role.

Future research should examine how multimodal, non-opioid strategies perform across diverse environments, particularly in resource-limited settings. Attention to surgical timing, patient expectations, and the contextual effectiveness of nerve blocks will be key to developing equitable, culturally attuned approaches to post-operative pain management.

ARTICLE INFORMATION

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Corresponding Author: Laura Jackson, Ph.D., ljackson18@kumc.edu, (785) 331-8899.

Author Affiliations: The University of Kansas School of Medicine-Kansas City, Kansas City, Kansas, USA (Jackson, Lemons, Mar); Department of Orthopedic Surgery, The University of Kansas School of Medicine-Kansas City, Kansas City, Kansas, USA (Dallman Mar, Heddings); Department of Orthopedic Surgery, Saint Paul's Millennium Medical College- Gulele Sub-City, Addis Ababa, Ethiopia (Haile, Mengistu)

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Original Research

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Adverse Events Reported Following RSV Prefusion F Protein Vaccines Administration Among Approved Populations: A Cross-Sectional Study

Tyler McLaughlin, MS-3, Dulcinea Rakestraw, Ph.D., MPH, Hayrettin Okut, Ph.D., Elizabeth Ablah, Ph.D.

ABSTRACT

Introduction. Respiratory syncytial virus (RSV) is a major cause of lower respiratory tract infections among children and older adults. Two RSV prefusion F protein (RSVpreF) vaccines currently are approved for adults aged 60 years and older. However, little is known about the adverse events reported among individuals in this age group who have received an RSVpreF vaccine. The purpose of this study was to compare adverse events reported by nonpregnant adults (≥60 years old) who received an RSVpreF vaccine.

Methods. This study included individuals who reported a vaccine-related adverse event to the Vaccine Adverse Event Reporting System (VAERS). Data abstracted from VAERS were recoded into standardized adverse event categories for analysis.

Results. A total of 2,321 individuals were included. The three most frequently reported adverse event categories were neurologic, musculoskeletal, and constitutional symptoms. Recipients of Arexvy™ (Respiratory Syncytial Virus Vaccine, Adjuvanted) reported more injection site reactions compared with those who received Abrysvo™ (Respiratory Syncytial Virus vaccine). There were no adverse event categories that were more commonly reported among Abrysvo™ recipients compared with Arexvy™ recipients.

Conclusions. The adverse events observed in this study were consistent with findings from previous Phase II/III trials. The higher frequency of injection site symptoms among Arexvy™ recipients may be attributable to the adjuvant included in Arexvy™ but absent in Abrysvo™. Overall, these findings indicate that both vaccines provide safe protection against RSV for older adults, with minimal side effects, in a population that previously had no vaccination option.

INTRODUCTION

Respiratory Syncytial Virus (RSV) is a major cause of lower respiratory infections among children and older adults.[1,2] In the United States, RSV leads to approximately 1.6 million outpatient pediatric visits each year.[2,3] Older adults also remain at high risk for severe RSV disease due to waning immunity and comorbid conditions.[4] Among this population, RSV is associated with an estimated 10,000 deaths annually, 267 hospitalizations per 100,000 people, and 1.4 million outpatient visits.[5,6] The true burden likely is even greater, as RSV is under-detected when clinicians do not routinely test for it, particularly in older adults.[5]

Historically, RSV treatment strategies have centered on secondary and tertiary prevention, including supportive care, ribavirin, monoclonal antibodies, RSV intravenous immunoglobulin (RSV-IVIG), glucocorticoids, and bronchodilators.[7] Ribavirin, however, is known to cause teratogenic and other adverse effects and is therefore reserved for select cases.[8] Likewise, monoclonal antibodies and RSV-IVIG generally are limited to "high-risk" individuals such as immunocompromised patients, premature infants, and older adults with significant comorbidities.[1,7] Most available treatment approaches provide symptomatic relief but do not prevent infection.

A major advance occurred on May 3, 2023, when the United States Food and Drug Administration (FDA) approved two RSV prefusion F (RSVpreF) protein vaccines (Arexvy™ [Respiratory Syncytial Virus Vaccine, Adjuvanted] and Abrysvo™ [Respiratory Syncytial Virus vaccine]). for adults aged 60 years and older, offering a new primary prevention tool for at-risk populations.[9-11] These vaccines target the RSVpreF protein, which had historically been difficult to isolate and purify.[2,12,13]

Clinical trials for these vaccines reported common adverse events such as injection site pain, muscle pain, joint pain, headache, fatigue, and nausea.[14] Rare but more serious events, including inflammatory neurological conditions like Guillain-Barré syndrome, also were observed.[14] However, real-world data on adverse events reported by individuals who received an RSVpreF vaccine remain limited. Therefore, authors of this study aimed to compare adverse events among nonpregnant adults aged 60 years or older who received an RSVpreF vaccine.

METHODS

Participants. This study included individuals who reported a vaccine-related adverse event to the Health and Human Services Vaccine Adverse Event Reporting System (VAERS).[15] VAERS is an open reporting system that allows anyone to submit post-vaccination adverse events using free-text entries. Eligible participants were adults aged ≥60 years who received one of the two RSVpreF vaccines and reported at least one adverse event between August 1, 2023, and January 31, 2024. Exclusions included missing age, age <60 years, pregnancy, receiving an inappropriate vaccine based on guidelines, or incomplete required information.

Instrument. Extracted variables included demographics (e.g., age, sex), vaccine details (e.g., vaccine name and brand), and adverse event information (e.g., symptoms, disability, vaccination problems). Demographics were used to confirm eligibility, while vaccine details and event characteristics allowed comparison of adverse event profiles between the two RSVpreF vaccines.

Procedures. The study was approved by The University of Kansas Medical Center (KUMC) Institutional Review Board (IRB) and followed STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.[16]

De-identified VAERS data were downloaded and stored in REDCap® (CTSA Award # UL1TR002366), electronic data capture tools hosted at The KUMC.[17,18] Because VAERS relies on unstructured free-text reporting, adverse events were recoded into standardized categories based on the affected system. Coding was completed by one researcher and reviewed by four others, with consensus reached through discussion. Categories included vaccine information (e.g., vaccine name, inappropriate administration) and adverse event types (e.g., constitutional symptoms, cardiovascular issues, injection site reactions).

Statistical Analysis. Data were analyzed using SAS® version 9.4 (SAS Institute Inc., Cary, NC). Categorical variables were summarized as frequencies and percentages. Continuous variables were described using means and standard deviations (SD) or medians and interquartile ranges (IQRs), depending on distribution. Associations between categorical variables were tested using likelihood-ratio Chi-square tests in 2×2 tables. Statistical significance was set at $p < 0.0015$ after Bonferroni correction.

RESULTS

A total of 2,764 individuals initially met study criteria. After review, 443 were excluded: 198 lacked age information in their VAERS report, 197 received a vaccine outside the recommended age range or received the incorrect vaccine, and 48 were identified as pregnant after data abstraction. The final sample included 2,321 participants. Of these, 28.5% (n = 662) were male, 71.2% (n = 1,654) were female, and 0.2% (n = 5) did not report sex. Ages ranged from 60 to 102 years, with a mean age of 73 years (SD 7.2). Most participants received Arexvy™ (69.8%, n = 1,620), while 30.2% (n = 701) received Abrysvo™.

The most frequently reported adverse event categories were neurologic (31.6%, n = 733), musculoskeletal (29.1%, n = 676), and constitutional symptoms (28.4%, n = 658; Table 1). Vaccine administration problems, such as incorrect dose, reconstitution issues, or administration errors, accounted for 8.9% (n = 206) of reports. Serious neuroinflammatory events, including Guillain-Barré syndrome, were reported in 0.9% (n = 20) of cases. Mortality was 0.7% (n = 15).

Patients who received Arexvy™ reported injection site symptoms more frequently (29.4%, 477/1,620; χ^2_1=27.7; $p < 0.0001$; Table 2) than those who received Abrysvo™ (18.9%, 133/701; χ^2_1=27.7; $p < 0.0001$; Table 2). Patients who received Abrysvo™ did not report any specific adverse event more often than those who received Arexvy™.

Table 1. Adverse events reported by participants ≥ 60 years.

Reported Adverse Event	Percent (Frequency)
Allergic reaction	3.5% (80)
Autoimmunity	0.5% (11)
Cardiovascular adverse event	8.0% (185)
Clotting problem	0.8% (18)
Constitutional symptoms	28.4% (658)
Death	0.7% (15)
Ear adverse event	1.6% (36)
Edema	10.3% (238)
Genitourinary adverse event	1.2% (27)
GI adverse event	15.8% (367)
Hematological adverse event	0.7% (7)
Infection	2.7% (62)
Injection site symptoms	26.3% (610)
Liver adverse event	0.3% (6)
Metabolic adverse event	0.7% (17)
Musculoskeletal adverse event	29.1% (676)
Nasal adverse event	3.1% (72)
Neurologic adverse event	31.6% (733)
Ocular adverse event	2.5% (59)
Oral adverse event	3.6% (84)
Other	23.8% (552)
Psychiatric adverse event	6.1% (142)
Renal adverse event	0.6% (14)
Respiratory adverse event	9.7% (226)
Serious cardiovascular adverse event	0.4% (9)
Serious neuroinflammatory adverse event	0.9% (20)
Serious neurologic adverse event	0.9% (20)
Serious respiratory adverse event	0.2% (5)
Skin adverse event	19.3% (448)
Vaccine administration problem	8.9% (206)

Table 2. Adverse events reported by vaccine received in adults ≥60 years.

Reported Adverse Event	Abrysvo™	Arexvy™	Chi-square (df)	*P* value
Allergic reaction	4.6% (n = 32)	3.0% (n = 48)	3.8 (1)	0.0521
Autoimmunity	0.7% (n = 5)	0.4% (n = 6)	1.2 (1)	0.2694
Cardiovascular adverse event	8.7% (n = 61)	7.7% (n = 124)	0.7 (1)	0.3923
Clotting problem	1.0% (n = 7)	0.7% (n = 11)	0.6 (1)	0.4204
Constitutional symptoms	27.3% (n = 191)	28.8% (n = 467)	0.6 (1)	0.4380
Death	0.7% (n = 5)	0.6% (n = 10)	0.1 (1)	0.7910
Ear adverse event	1.3% (n = 9)	1.7% (n = 27)	0.5 (1)	0.4932
Edema	9.3% (n = 65)	10.7% (n = 173)	1.1 (1)	0.3051
Genitourinary adverse event	0.6% (n = 4)	1.4% (n = 23)	3.1 (1)	0.0798
GI adverse event	17.4% (n = 122)	15.1% (n = 245)	1.9 (1)	0.1668
Hematological adverse event	0.4% (n = 3)	0.9% (n = 14)	1.3 (1)	0.2578
Infection	3.0% (n = 21)	2.5% (n = 41)	0.4 (1)	0.5237
Injection site symptoms	18.9% (n = 133)	29.4% (n = 477)	27.7 (1)	<0.0001*
Liver adverse event	0.1% (n = 1)	0.3% (n = 5)	0.5 (1)	0.4696
Metabolic adverse event	0.6% (n = 4)	0.8% (n = 13)	0.4 (1)	0.5475
Musculoskeletal adverse event	28.0% (n = 196)	29.6% (n = 480)	0.7 (1)	0.4163
Nasal adverse event	3.4% (n = 24)	3.0% (n = 48)	0.3 (1)	0.5567
Neurologic adverse event	35.52% (n = 249)	29.9% (n = 484)	7.2 (1)	0.0072
Ocular adverse event	2.7% (n = 19)	2.5% (n = 40)	0.1 (1)	0.7346
Oral adverse event	4.6% (n = 32)	3.2% (n = 52)	2.6 (1)	0.1085
Other	23.1% (n = 162)	24.07% (n = 390)	0.3 (1)	0.6164
Psychiatric adverse event	5.9% (n = 41)	6.2% (n = 101)	0.1 (1)	0.7218
Renal adverse event	0.6% (n = 4)	0.6% (n = 10)	0.02 (1)	0.8939
Respiratory adverse event	11.0% (n = 77)	9.2% (n = 149)	1.8 (1)	0.1825
Serious cardiovascular adverse event	0.6% (n = 4)	0.3% (n = 5)	0.9 (1)	0.3511
Serious neuroinflammatory adverse event	1.7% (n=12)	0.5% (n = 8)	8.5 (1)	0.0036
Serious neurologic adverse event	0.7% (n = 5)	0.9% (n = 15)	0.3 (1)	0.6108
Serious respiratory adverse event	0.3% (n = 2)	0.2% (n = 3)	0.2 (1)	0.6329
Skin adverse event	17.8% (n = 125)	19.9% (n = 323)	1.4 (1)	0.2377
Vaccine administration problem	7.7% (n = 54)	9.4% (n = 152)	1.7 (1)	0.1915

*Indicates a statistically significant result (p <.0015). df, Degrees of freedom.

DISCUSSION

In this study, adverse events were grouped by organ system as well as broader categories, such as constitutional symptoms, injection site symptoms, and vaccine administration problems, that emerged during data abstraction. Because VAERS reports consist of unstructured free-text entries, recoding was necessary to standardize symptom categories and enable meaningful analysis. This approach differs from clinical trials, which tracked a narrower set of predefined adverse events such as headache, injection-site pain, and fever.[19,20]

Of all vaccine recipients, about two-thirds reported being female and almost a third reported being male, which aligns with prior research showing that men are less likely to seek medical care or visit their primary care physician.[21,22] These demographic differences highlight the need for continued counseling of both elderly on the importance of RSV vaccination.

Neurologic adverse events, including headache, dizziness, and paresthesia, were the most reported symptoms. This is consistent with a Phase II trial of adults aged 18-40 years, where headache was the most frequently reported systemic adverse event (42-52%).[19] Similar findings were reported in a Phase III trial of adults aged ≥60 years, in which 27% of participants reported a systemic adverse event, most commonly headache (13%).[20]

In our study, 26.3% of patients reported injection-site symptoms. By comparison, the Phase II trial reported local reactions in 39-71% of participants,[19] and the Phase III trial reported local reactions in 12%.[20] Differences in symptom grouping and sample size may account for variability between this study's findings and those of the clinical trials.

Recipients of Arexvy™ reported injection-site symptoms more frequently than those who received Abrysvo™. This difference may reflect the presence of an adjuvant in Arexvy™, which is absent in Abrysvo™.[23,24] Adjuvants enhance immunogenicity by stimulating a stronger inflammatory response,[24] but they also are associated with increased reactogenicity, the physical manifestations of that response.[25]

In our study, vaccine administration problems accounted for 8.9% of reports, including administration errors, expired vaccines, or improper reconstitution. These events are not captured in controlled clinical trials but may arise in routine practice, underscoring the need for quality-control measures as RSV vaccines become more widely used. Serious adverse events were uncommon, representing 2.3% of all reports in our study. Neuroinflammatory conditions such as Guillain-Barré syndrome were reported by 0.9%, with no observed differences between vaccines. Mortality also is rare in our finding. Continued monitoring is warranted as vaccine uptake expands.

Overall, RSVpreF vaccines demonstrated a safety profile consistent with Phase II/III trials and offer important primary prevention for elderly populations who previously had no vaccine option.[19,20] Future research should aim to better characterize vaccination rates across demographic groups, identify barriers to uptake, and, ideally, benefit from a centralized database that includes all vaccine recipients, not only those who submit VAERS reports.

Limitations. This study differed from earlier clinical trials in that VAERS includes a much wider range of adverse events, necessitating grouped symptom categories. While this improved data usability, it limited the ability to assess the frequency of individual specific adverse events. As a cross-sectional study, causal relationships between the vaccines and reported adverse events cannot be established. Only individuals who submitted VAERS reports were included; therefore, the overall incidence of adverse events in the vaccinated population cannot be determined. VAERS reports may be incomplete, especially when submitted by individuals without medical training, and severe symptoms may overshadow mild ones, further contributing to incomplete reporting.

CONCLUSIONS

The most frequently reported adverse events among RSVpreF vaccine recipients were neurologic symptoms, musculoskeletal symptoms, and constitutional complaints. Recipients of Abrysvo™ were not more likely to report any specific adverse event compared with Arexvy™ recipients, whereas Arexvy™ recipients more commonly reported injection-site symptoms, likely related to the adjuvant. These findings are consistent with Phase II/III clinical trials and indicate that both vaccines provide safe and important protection for elderly adults, a group that previously had no primary prevention option for RSV. Given RSV's long-standing role as a major cause of lower respiratory infections in the United States, the availability of safe vaccines represents an important advancement in protecting older adults.

ARTICLE INFORMATION

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Corresponding Author: Tyler McLaughlin,The University of Kansas School of Medicine-Wichita, Wichita, Kansas, 1010 N Kansas St., Wichita, KS, 67214, Tyler.jay25@gmail.com.

Author Affiliations: The University of Kansas School of Medicine-Wichita, Wichita, Kansas (McLaughlin); Department of Family Medicine, The University of Kan-sas School of Medicine-Wichita, Wichita, Kansas (Rakestraw); Department of Population Health, The University of Kansas School of Medicine-Wichita, Wichita, Kansas (Okut, Ablah).

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Brief Report | Quality Improvement

Improving Prophylactic Antibiotic Selection for Type 3 Open Fractures in the Trauma Setting

Matthew G. Van Engen, M.D., Isaac C. Talbert, M.D., William M. Clune, MS-3, Parker R. Zimmerman, M.D., Vafa Behzadpour, M.D., Seth A. Tarrant, M.D., Rosalee E. Zackula, M.A., Bernard F. Hearon, M.D., Bradley R. Dart, M.D.

ABSTRACT

Introduction. The purpose of this quality improvement study was to implement a standardized prophylactic antibiotic protocol for type 3 open fractures and to evaluate changes in both subjective comfort and objective knowledge of open fracture management among trauma team personnel.

Methods. A simplified protocol for antibiotic selection in open fractures was developed and implemented at two regional Level 1 trauma centers. We used pre-intervention surveys to assess participants' ability to select the preferred antibiotic regimen for open fracture clinical scenarios and their comfort with open fracture management. The intervention consisted of instructional posters displayed in trauma bays showing the Gustilo classification for open fractures and the approved prophylactic antibiotic regimen for each fracture type. After a six-week intervention period, unmatched post-education survey responses were compared with pre-intervention responses using Fisher's Exact Test or the Fisher-Freeman-Halton Exact Test, with significance set at $p < 0.05$.

Results. Participants included 16 orthopedic residents and 18 trauma staff members. The proportion of respondents who reported being very comfortable selecting antibiotics for type 3 open fractures increased from 6% to 68% ($p < 0.001$). Correct identification of the preferred antibiotic regimen across three clinical scenarios involving type 3 open fractures increased by an average of 58%, with all improvements reaching statistical significance ($p < 0.001$).

Conclusions. Implementation of a simplified antibiotic prophylaxis protocol, reinforced with instructional posters in the emergency department, significantly improved participants' knowledge and confidence in antibiotic selection for type 3 open fractures. These findings support the adoption of standardized treatment algorithms in trauma care settings.

INTRODUCTION

Open fractures, often the result of high-energy mechanisms, are defined as a bony fragment communicating with the outside environment as the result of soft tissue disruption.[1] The severity of injury has a direct correlation with the risk of post-operative surgical site infection (SSI).[2] Gustilo developed a well-recognized classification system which is widely used in the orthopaedic literature to describe these open fractures and which is the basis for prophylactic antibiotic regimens used for open fractures in the trauma setting.[3,4]

Early antibiotic administration has a well-recognized impact in reducing post-operative SSI in open fractures.[5,6] In this regard, the official recommendation of the American Academy of Orthopaedic Surgeons is for the first dose of antibiotics to be given as soon as feasibly possible, or within three hours of injury.[5,6] Various antibiotic regimens exist for open fracture management, particularly Gustilo type 3 open injuries. Traditionally, a first-generation cephalosporin and an aminoglycoside have been the standard of care, with penicillin added for grossly contaminated farm-related injuries.[4]

At local trauma centers, orthopaedic residents, general surgery residents, and nursing staff reported uncertainty about appropriate antibiotic regimens for type 3 open fractures, particularly when multiple antibiotics were included in a single protocol. This confusion prompted a literature review, which revealed opportunities to improve staff performance and patient outcomes. For example, Redfern et al.[7] showed non-inferior rates of deep SSI with piperacillin/tazobactam for initial antibiotic prophylaxis in type 3 open fractures when compared with previous multi-antibiotic regimens. Similarly, Siebler et al.[8] demonstrated an effective approach for ensuring timely antibiotic administration in patients with open fractures.

Based on these findings, we aimed to improve prophylactic antibiotic selection at our local trauma centers among all health care professionals treating patients with open fractures, with a particular focus on residents in training. The objectives of this quality improvement (QI) study were (1) to implement a simplified, standardized antibiotic protocol for type 3 open fracture management in the trauma setting and (2) to assess changes in both subjective comfort and objective knowledge of open fracture management among orthopaedic residents and non-orthopaedic trauma staff, including general surgery attendings, general surgery residents, and emergency department personnel such as physician assistants and nurses.

METHODS

This study was conducted during the 2021 academic year as a QI initiative by a five-member team of orthopaedic residents, one from each post-graduate year group. The project was approved by the residency program director and deemed by the The University of Kansas Medical Center's institutional review board (IRB) to be a QI study designed to improve trauma personnel compliance with best practices for selecting prophylactic antibiotics in patients with open fractures.

Classic QI methodology was applied to define, measure, analyze, improve, and control prophylactic antibiotic administration for type 3 open fractures in the trauma setting. The residency QI program methods and previous studies have been described in detail elsewhere.[9]

Development of a standardized antibiotic regimen for open fracture management was modeled after a previously successful protocol implemented at another academic medical center.[8] Antibiotic selection and dosing for the current protocol were determined in collaboration with infectious disease specialists and pharmacists from both regional Level 1 trauma centers.

Orthopaedic residents at all levels of training and non-orthopaedic trauma staff members, including general surgery trauma attendings, general surgery residents, physician assistants, and nursing personnel, were recruited to participate in this QI initiative. Participant comfort with and baseline knowledge of open fracture management were assessed using a 10-question paper pre-intervention survey.

The primary intervention consisted of two educational posters: one displaying the Gustilo open fracture classification system and another outlining the standardized open fracture treatment protocol (Figure 1). Each poster was displayed in the trauma bays at both trauma centers for six weeks. Informal discussions about antibiotic prophylaxis and fracture classification occurred among orthopaedic residents and some non-orthopaedic participants, though these were not considered an essential component of the educational intervention. Following the six-week exposure period, post-intervention survey responses were collected. Pre- and post-surveys were unmatched and anonymous.

A

Gustilo Classification	Injury Description
Type I Fracture	Open fracture with clean wound <1 cm long
Type II Fracture	Open fracture with laceration > 1 cm but <10 cm long Moderate soft tissue damage
Type III A Fracture	Open fracture with laceration >10 cm long Extensive soft tissue damage Segmental or highly comminuted fracture Traumatic amputation
Type III B Fracture	Same as Type 3A fracture but with additional periosteal stripping and bone exposure requiring flap coverage
Type III C Fracture	Any open fracture with vascular injury requiring repair

B

OPEN FRACTURE ANTIBIOTIC PROTOCOL

	Preferred Therapy	Severe Penicillin or Cephalosporin allergy
Type 1 or 2 fracture	Cefazolin 2g IV (<120kg) Cefazolin 3g IV (>120kg)	Clindamycin 900mg
Type 3 fracture (clean)	Piperacillin/Tazobactam 4.5g IV over 4 hours	Levofloxacin 500mg IV
Type 3 fracture (contaminated)	Piperacillin/Tazobactam 4.5g IV over 4 hours	Levofloxacin 500mg IV PLUS Metronidazole 500mg IV
Known MRSA Colonization	Add vancomycin 15 mg/kg q12h	

ORTHOPEDIC SURGERY RESIDENCY PROGRAM OPEN FRACTURE ANTIBIOTIC PROTOCOL
ADAPTED FROM UNIVERSITY OF NEBRASKA

KU WICHITA

Figure 1. (A) Gustilo classification for open fractures and (B) open fracture prophylactic antibiotic protocol by Gustilo fracture type. Traumatic amputation may be considered type III C open fractures.

Questionnaire responses were manually entered into the Research Electronic Data Capture (REDCap®) system.[10,11] Responses were compared with the Fisher-Freeman-Halton Exact test or Fisher's Exact test using IBM SPSS Statistics, version 29. Significance level to determine statistical difference was set at $p < 0.05$. This QI report was prepared in keeping with the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines.[12]

RESULTS

A total of 34 participants completed both the pre- and post-education surveys. The study cohort consisted of 16 orthopaedic surgery residents and 18 other trauma staff members, with nine participants from each trauma center. Pre- and post-survey comparisons are presented in Table 1.

Before the intervention, most respondents (68%, 23/34) strongly agreed or agreed that they experienced confusion when administering prophylactic antibiotics for open fractures. Awareness of an existing antibiotic prophylaxis protocol increased significantly from 29% (10/34) in the pre-survey to 100% (34/34) in the post-survey ($p < 0.001$). Agreement that an antibiotic prophylaxis algorithm would be very helpful also increased, from 53% (18/34) before the intervention to 82% (28/34) afterward ($p = 0.023$).

Participant comfort levels in managing open fractures improved markedly following implementation of the protocol. Those who reported feeling *very comfortable* increased from 9% to 71% ($p < 0.001$) for type 1 or 2 fractures and from 6% to 68% ($p < 0.001$) for type 3 fractures. While comfort levels improved among both orthopaedic residents and other trauma staff, the increase was greater in the orthopaedic resident cohort (Figure 2).

Knowledge assessment results are summarized in Table 1. Overall, the average increase in correctly identifying the preferred antibiotic regimen across all clinical scenarios was 49%, with post-survey accuracy ranging from 68% to 100%. The largest improvement was observed in the type 3 open fracture scenario involving a gunshot wound with perforated bowel and pelvic involvement, where correct identification of piperacillin/tazobactam increased from 15% to 82% ($p < 0.001$). Participants correctly identifying the preferred regimen in all three type 3 open fracture scenarios increased by an average of 58%, with all improvements reaching statistical significance ($p < 0.001$).

Knowledge improvement in the type 1 open fracture scenario was not statistically significant, as most participants (88%) had already correctly identified cefazolin as the antibiotic of choice in the pre-survey.

No clinical outcome measures, such as time to antibiotic administration or patient infection rates, were assessed in this study.

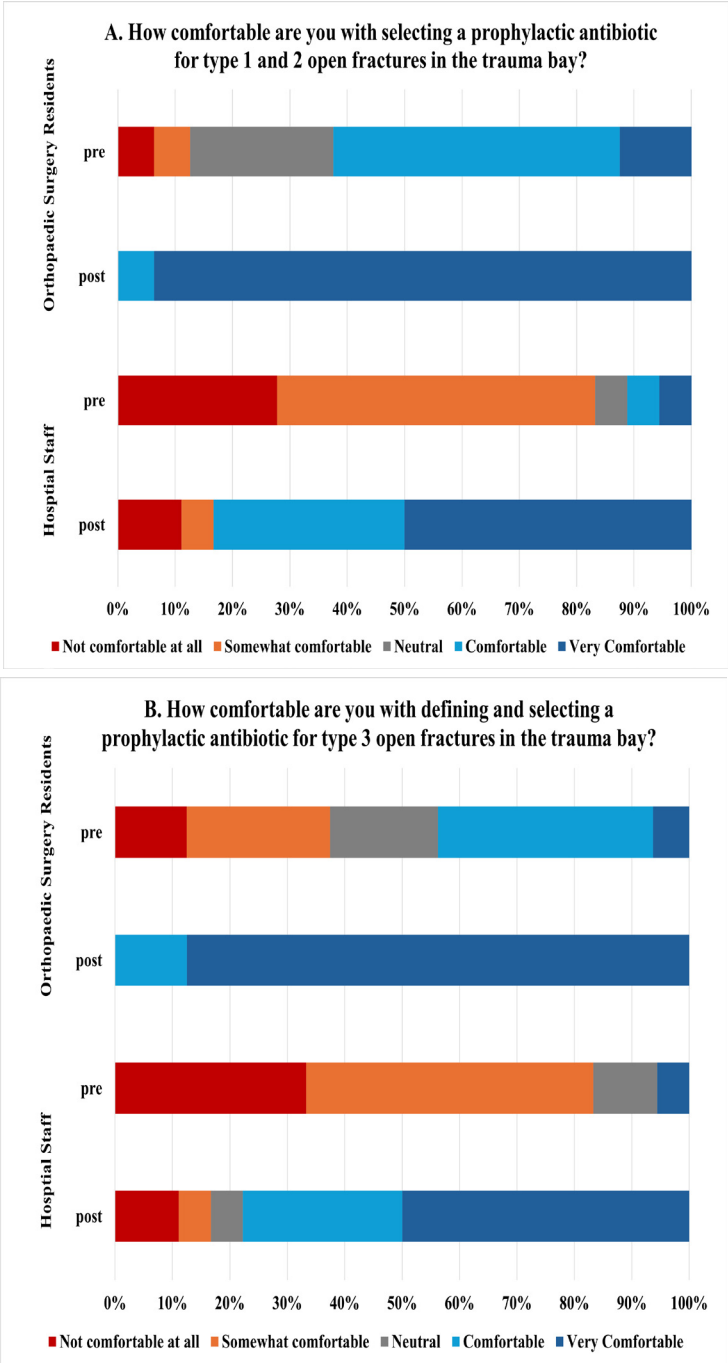

Figure 2. Changes in pre- and post-education comfort level among orthopaedic surgery residents and hospital trauma staff selecting prophylactic antibiotics for (A) type 1 and 2 and (B) type 3 open fractures.

DISCUSSION

The present QI initiative significantly improved participants' awareness of the antibiotic protocol for open fracture management and increased their comfort level in selecting prophylactic antibiotics. Knowledge of the correct antibiotic for specific open fracture clinical scenarios also improved. The simplified antibiotic regimen and educational posters displayed in the emergency departments showed to be an effective strategy for enhancing open fracture care at the regional Level 1 trauma centers.

While participants demonstrated competence in selecting prophylactic antibiotics for type 1 open fractures, pre-intervention survey results revealed deficiencies in knowledge regarding higher-grade open fractures. These findings align with those of Lin et al.,[13] who reported moderate adherence to antibiotic prophylaxis guidelines for Gustilo type 1 and 2 open fractures, but low adherence for type 3 injuries. This knowledge gap among trauma personnel may contribute to delays or omissions in selecting the recommended prophylactic antibiotic regimen for severe open fractures.

Prompt administration of antibiotics in open fracture management is a well-established measure for reducing postoperative SSIs. For instance, Siebler et al.[8] reported a significant reduction in time to antibiotic administration following implementation of a standardized protocol. Although the present study did not evaluate time to antibiotic administration or other patient outcome data, the observed improvements in knowledge and comfort with open fracture management suggest that similar QI strategies could yield clinical benefits.This study is limited by its small sample size, which makes it statistically underpowered, its single geographic region setting, and the absence of clinical outcome measures due to its focus on participant knowledge and confidence in antibiotic prophylaxis. Additionally, participant bias may have influenced the study results.

CONCLUSIONS

This QI initiative significantly increased subjective comfort with and objective knowledge of prophylactic antibiotic management for type 3 open fractures among trauma staff members at two Level 1 trauma centers. Future efforts to assess time to antibiotic administration and post-operative infection rates at both trauma centers may be helpful to evaluate the clinical impact of this QI intervention.

Table 1. Unmatched comparison of pre- and post-education anonymous survey responses.

Question	Response	Pre-survey	Post-survey		
		n (%)	n (%)	$\chi 2$ (*df*)	*P* value
Respondent	Orthopaedic resident	16 (47.1)	16 (47.1)	0.0 (2)	>.999
	Other trauma staff (hospital #1)	9 (26.5)	9 (26.5)		
	Other trauma staff (hospital #2)	9 (26.5)	9 (26.5)		
Have you experienced confusion regarding antibiotic prophylaxis for open fracture management in the trauma bay which ultimately delayed time to antibiotic administration	Strongly disagree	2 (5.9)			
	Disagree	3 (8.8)			
	Neutral	6 (17.6)			
	Agree	10 (29.4)			
	Strongly agree	13 (38.2)			
Are you aware of a protocol for antibiotic prophylaxis for open fracture management in the trauma bay?	Yes	10 (29.4)	34 (100.0)	37.1 (1)	<.001*
	No	24 (70.6)	0 (0)		
How helpful would an antibiotic prophylaxis algorithm be for open fracture management in the trauma bay?	Not helpful at all	0 (0)	0 (0)	7.4 (3)	0.023
	Somewhat helpful	1 (2.9)	0 (0)		
	Neutral	1 (2.9)	0 (0)		
	Helpful	14 (41.2)	6 (17.6)		
	Very helpful	18 (52.9)	28 (82.4)		
Comfort Level					
How comfortable are you with selecting a prophylactic antibiotic for type 1 and 2 open fractures in the trauma bay?	Not comfortable at all	6 (17.6)	2 (5.9)	31.9 (4)	<.0001
	Somewhat comfortable	11 (32.4)	1 (2.9)		
	Neutral	5 (14.7)	0 (0)		
	Comfortable	9 (26.5)	7 (20.6)		
	Very Comfortable	3 (8.8)	24 (70.6)		
How comfortable are you with defining and selecting a prophylactic antibiotic for type 3 open fractures in the trauma bay?	Not comfortable at all	8 (23.5)	2 (5.9)	34.3 (4)	<0.001
	Somewhat comfortable	13 (38.2)	1 (2.9)		
	Neutral	5 (14.7)	1 (2.9)		
	Comfortable	6 (17.6)	7 (20.6)		
	Very Comfortable	2 (5.9)	23 (67.6)		
Knowledge Assessment					
A patient presents with a trimalleolar ankle fracture with a 1 cm open laceration over the fracture site. What antibiotic prophylaxis should be administered?	**Cefazolin**	30 (88.2)	34 (100.0)	4.3 (2)	0.114
	Ceftriaxone	0 (0)	0 (0)		
	Piperacillin/Tazobactam	2 (5.9)	0 (0)		
	Cefazolin + Gentamicin	2 (5.9)	0 (0)		
A patient presents with a segmental tibia fracture and 2 cm laceration over the fracture site. What antibiotic prophylaxis should be administered?	**Piperacillin/Tazobactam**	3 (8.8)	23 (67.6)	28.5 (3)	<0.001
	Cefazolin	21 (61.8)	11 (32.4)		
	Cefazolin + Gentamicin	7 (20.6)	0 (0)		
	Ceftriaxone	3 (8.8)	0 (0)		
Which antibiotic has non-inferior rates of surgical site infections when compared to cefazolin + gentamicin when being used for clean type 3 open fractures?	**Ceftriaxone**	15 (44.1)	32 (94.1)	20.2 (3)	<0.0001
	Ancef	13 (38.2)	2 (5.9)		
	Amoxicillin	1 (2.9)	0 (0)		
	Cefuroxime	5 (14.7)	0 (0)		

Note: Fisher-Freeman-Halton Exact test, unless otherwise specified. *Fisher's Exact test.
Correct responses to the knowledge assessment items are shown in bold.
Overall average increase, pre- to post-intervention, for correct responses was 48.8%.

Table 1. Unmatched comparison of pre- and post-education anonymous survey responses. *Continued*

		Pre-survey	Post-survey		
Question	**Response**	**n (%)**	**n (%)**	*χ2 (df)*	***P* value**
What antibiotic has non-inferior rates of surgical site infections when compared to cefazolin + gentamicin + penicillin when being used for grossly contaminated type 3 open fractures in the setting of farm injury or standing water?	Penicillin + Doxycycline	3 (8.8)	0 (0)	24.2 (4)	<0.001
	Ceftriaxone	7 (20.6)	1 (2.9)		
	Cefepime	7 (20.6)	0 (0)		
	Piperacillin/Tazobactam	12 (35.3)	31 (91.2)		
	Cefazolin + Piperacillin/Tazobactam	5 (14.7)	2 (5.9)		
What antibiotic should be administered for a gunshot wound with perforated bowel and bony pelvic involvement?	Cefazolin + gentamycin	4 (11.8)	0 (0)	32.0 (3)	<0.001
	Metronidazole + penicillin	8 (23.5)	1 (2.9)		
	Piperacillin/Tazobactam	5 (14.7)	28 (82.4)		
	Ceftriaxone + Metronidazole	17 (50.0)	5 (14.7)		

Note: Correct responses to the knowledge assessment items are shown in bold.
Overall average increase, pre- to post-intervention, for correct responses was 48.8%.

ARTICLE INFORMATION

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Corresponding Author: Bernard F Hearon, M.D., 929 N. Saint Francis, Room 4076, Wichita KS, 67214. bhearon@cox.net.

Author Affiliations: Department of Orthopaedic Surgery, The University of Kansas School of Medicine Wichita, Wichita, Kansas (Van Engen, Talbert, Zimmerman, Behzadpour, Tarrant, Hearon, Dart); The University of Kansas School of Medicine Wichita, Wichita, Kansas (Clune); Office of Research, The University of Kansas School of Medicine Wichita, Wichita, Kansas (Zackula).

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Keywords: *antibiotic prophylaxis, continuing medical education, open fracture, quality improvement*

Brief Report

KANSAS JOURNAL of MEDICINE

Influence of Oscillation Drilling on Screw Purchase: A Biomechanical Pilot Study

Parker R. Zimmerman, M.D., Cole D. Daharsh, BSBME, Lindsey E. Mendenhall, BSBME, Rosalee E. Zackula, M.A., Randall L. Lais, M.D., Bradley R. Dart, M.D.

ABSTRACT

Introduction. Oscillation drilling (OD) commonly is used in orthopaedic surgery to minimize soft tissue damage and control drill advancement, thereby reducing the risk of "plunging" through cortical bone. However, its effect on screw purchase compared to forward drilling (FD) remains unstudied. The purpose of this study was to compare maximal insertional torque (MIT), a proxy for screw purchase, following OD and FD in a synthetic bone model.

Methods. Pilot holes were drilled into synthetic femoral shaft models using OD and FD with three drill bit sizes (2.0 mm, 2.6 mm, and 3.2 mm). Corresponding self-tapping stainless-steel screws (2.7 mm, 3.5 mm, and 4.5 mm) were inserted into the pilot holes. MIT was measured during screw insertion using an axial torsion testing device, with five trials per condition.

Results. For 2.7 mm screws, mean MIT was 195.8 ± 47.0 N·cm (FD) versus 232.8 ± 11.8 N·cm (OD); for 3.5 mm screws, 336.8 ± 100.6 N·cm (FD) versus 357.4 ± 150.7 N·cm (OD); and for 4.5 mm screws, 943.5 ± 551.8 N·cm (FD) versus 1089.2 ± 232.2 N·cm (OD). No statistically significant differences in MIT were found between FD and OD across screw sizes ($p = 0.85$), although MIT increased significantly with the 4.5 mm screws ($p < 0.001$).

Conclusions. OD and FD produced comparable screw purchase across screw sizes, suggesting that either technique may be used without compromising fixation strength in orthopaedic applications.

INTRODUCTION

Drills used in orthopaedic surgery typically offer forward drilling (FD), oscillation drilling (OD), and reverse modes. OD frequently is employed to reduce soft tissue entanglement and to provide greater control over drill advancement, thereby minimizing the risk of "plunging" through cortical bone. Despite its widespread use, the biomechanical effects of OD on screw fixation remain underexplored in the orthopaedic literature, which has focused primarily on thermal necrosis, drill speed or feed rate, and predrilling.[1,2] One study using K-wires reported greater heat generation during OD compared with FD,[3] but no published studies to date have directly compared OD and FD in the context of screw insertion.

Screw purchase, the mechanical stability of a screw in bone, depends on factors such as pilot hole size, screw thread diameter, core diameter, and screw pitch. Maximal insertional torque (MIT) is a validated surrogate for screw purchase.[4,5] Authors of the present study examined the influence of pilot hole drilling technique (OD vs FD) on MIT across different screw sizes. We hypothesized that screw purchase would not differ significantly between drilling modes. Testing was conducted in a synthetic bone model using standard orthopaedic screws and drill bits.

METHODS

Study Design and Materials. Authors of this biomechanical study compared MIT of screws inserted into pilot holes created by OD versus FD in a synthetic femoral shaft model. Three drill bit sizes (2.0 mm, 2.6 mm, and 3.2 mm) were paired with self-tapping stainless steel cortical screws (2.7 mm, 3.5 mm, and 4.5 mm, respectively), all 34 mm in length (Stryker Corp., Kalamazoo, MI). The synthetic femoral shaft analogue (Sawbones®, Vashon Island, WA) featured a 7 mm cortical shell and 16 mm intramedullary canal, resulting in a 30 mm outer diameter, dimensions consistent with midshaft femoral models used in prior screw purchase studies.[5]

Biomechanical Test Procedure. Pilot holes were drilled at a constant speed (revolutions per minute) alternating between OD and FD, using standard orthopaedic principles. Five screws of each size were inserted bicortically (2 mm beyond the far cortex) through a washer simulating a fracture plate to allow maximal screw head compression and prevent countersinking.[6] Insertions were performed at 10 revolutions per minute under a constant 22.2 N downward load. MIT was recorded using an ElectroForce 3220 axial torsion system (TA Instruments, New Castle, DE) in accordance with ASTM F543-23 testing standards.

Data Analysis. A total of 30 trials (five OD and five FD per screw size) were conducted. Due to budgetary constraints and small sample size, no power analysis was performed. Statistical analyses included ANOVA with bootstrapping to assess the effects of screw size and drilling technique on prevailing torque, stratified by screw size, with bivariate comparisons conducted using Bonferroni post-hoc tests. Missing data were not imputed. Analyses were conducted using IBM SPSS (Statistical Package for the Social Sciences) version 29 (IBM Corp., Armonk, NY), with data compiled in Microsoft Excel (Microsoft Corp., Redmond, WA). Statistical significance was set at $p < 0.05$.

RESULTS

Prevailing Torque. Figure 1 shows the average prevailing torque by screw size and drilling technique. Torque measures with the FD technique appeared linear. Mean values ranged from 113.5 Newton-centimeters [N-cm; 95% confidence interval (CI) was (65.2, 148.9) with 999 bootstrap samples] for the 2.7 mm screws to 281.6 N-cm [95% CI (181.5, 381.7) with 1,000 bootstrap samples] for the 4.5 mm screws. Increasing torque by screw size also was noted for the OD technique; however, OD was not

available for the 4.5 mm screws due to equipment limitations. No statistical differences were observed between FD and OD (t_{19} = 0.122; p = 0.904).

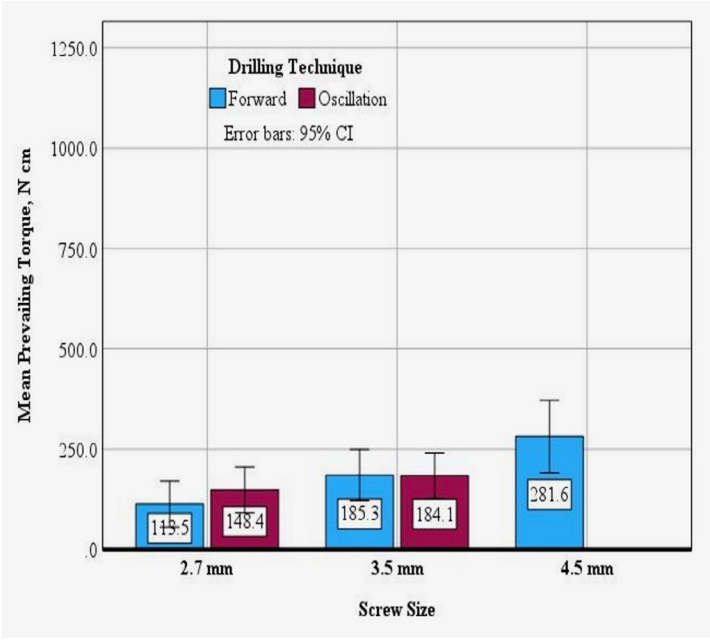

Figure 1. Mean prevailing screw torque by screw size and drilling technique.

Results from analysis of variance (ANOVA) for prevailing torque by screw size and drilling mode showed significant differences by screw size (F_2 = 5.995, p = 0.011). Results by drilling mode were F_1 = 0.368, p = 0.553, with an interaction effect of F_2 = 0.422, p = 0.525. Adjusted *R* squared was 0.296, such that approximately 1/3 of the data variability were accounted for with this model. Post-hoc tests indicated significant torque differences occurred between the 2.7 mm screws and the 4.5 mm screws where the mean difference was 150.7 N-cm [p = 0.016; the 95% CI, based on 604 bootstrap samples, was (37.9, 262.3)].

Maximal Insertional Torque (MIT). Figure 2 shows the average MIT by screw size and drilling technique. MIT measures increased by screw size and were larger for OD than for FD. Mean values ranged from 195.8 N-cm [95% CI (151.2, 229.2) with 1,000 bootstrap samples] for the 2.7 mm screws with the FD technique to 1089.2 N-cm [95% CI (881.3, 1215. 6) with 1,000 bootstrap samples] for the 4.5 mm screws with OD. Comparisons for OD and FD showed no statistically significant differences (t_{19} = 0.192, p = 0.850). However, MIT variability was notably higher for 4.5 mm screws with FD where the standard deviation was 551.8. Most of these latter trials exceeded the Bose ElectroForce torque capacity (680 N-cm) and required a calibrated torque wrench to determine MIT. Failure modes included screw head stripping (53%) and screw-bone interface stripping (40%).

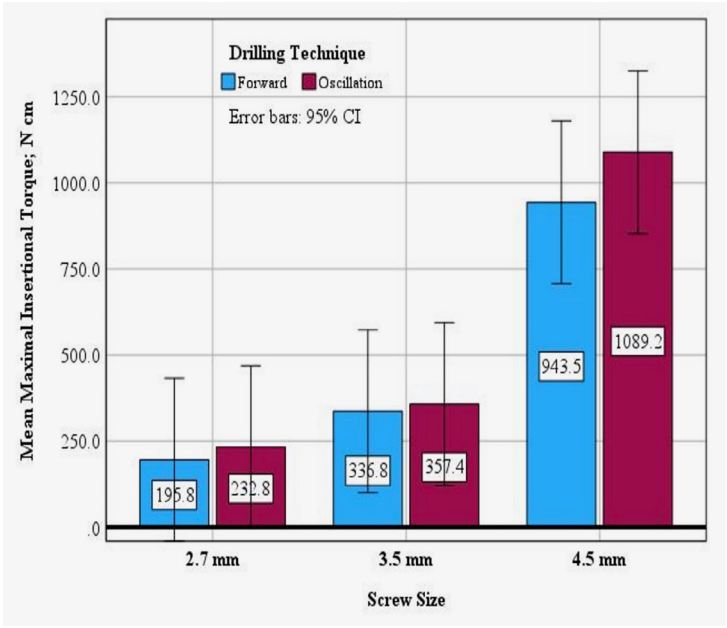

Figure 2. Mean maximal insertional torque (MIT) by screw size and drilling technique.

DISCUSSION

Our findings show that OD and FD to be biomechanically equivalent for screw purchase in a synthetic bone model, supporting our hypothesis that these drilling modes may be used interchangeably in orthopaedic surgery without compromising fixation strength. While prior studies have focused on heat generation during OD with K-wires and drill bits,[2,3] our findings suggest that any thermal effects do not impair screw purchase. The significant influence of screw size on purchase is consistent with prior work from our institution,[5] reflecting greater thread engagement with larger screws. Trends in prevailing torque data further supported the equivalence of OD and FD, despite equipment limitations encountered with the largest screw size.

Limitations. This study has several limitations. High variability in the 4.5 mm trials (SD up to 551.8 N·cm) and equipment limits (680 N·cm capacity) underestimated MIT and prevented prevailing torque capture for these screws. The use of a manual torque wrench introduced additional variability, while offset holes resulted in premature screw stripping (53%) and interface stripping (40%), potentially biasing results. Future studies could address these issues with a redesigned fixture for offset clamping and a servo-hydraulic frame with higher torque capacity, though this may reduce sensitivity. The synthetic bone model lacked cancellous bone and biologic variability, limiting clinical translation. Finally, the small sample size (n = 5 per test condition) and absence of a formal power analysis restrict generalizability, despite the use of bootstrapping.

Clinical Relevance. These findings suggest that OD and FD provide comparable screw purchase across the tested screw sizes, offering surgeons flexibility in drilling technique without compromising fixation strength. This may be particularly relevant for surgical training, where OD can be advantageous in preventing soft tissue entanglement or drill plunge.

CONCLUSIONS

OD and FD were biomechanically equivalent for screw purchase in this synthetic bone model, indicating that either technique may be used without compromising fixation strength. Larger studies using biologic models and improved biomechanical fixtures are needed to validate these findings.

ARTICLE INFORMATION

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Corresponding Author: Bradley R. Dart, M.D., 929 N. Saint Francis, Room 4076, Wichita KS, 67214. bradleydart@gmail.com.

Author Affiliations: Department of Orthopaedic Surgery, The University of Kansas School of Medicine Wichita, Wichita, Kansas (Zimmerman, Lais, Dart); Emerging Technologies and Composites Lab, National Institute for Aviation Research, Wichita State University, Wichita, Kansas (Daharsh, Mendenhall); Office of Research, The University of Kansas School of Medicine Wichita, Wichita, Kansas (Zackula); Advanced Orthopaedic Associates, PA, Wichita, Kansas (Lais, Dart).

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***Keywords**: biomechanics, bone screws, orthopedic fixation device, torque*

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Case Report

End-Stage Renal Disease, Peritoneal Dialysis, and Blastomycosis: A Rare Intersection with Life-Limiting Implications

Joseph Odeyemi, M.D., Adam M. Sandid, Jessica Emoto, M.D., Ramya Banda, M.D., Maria Mallick, M.D., Maha A. Assi, M.D.

INTRODUCTION

Blastomycosis is a fungal infection primarily caused by *Blastomyces dermatitidis*, typically acquired through inhalation.[1] It is endemic to the Ohio and Mississippi River valleys, the Great Lakes region, and the southeastern and south-central United States; however, recent epidemiologic trends indicate a dramatic expansion in its geographic range.[2,3] Pneumonia is the most common clinical presentation, although dissemination to other organs can occur.[1] Peritoneal involvement is uncommon, and diagnosis may be delayed due to nonspecific symptoms and an initial suspicion of bacterial infection.[4-7]

Fungal peritonitis in patients on peritoneal dialysis (PD) is a rare but serious complication, accounting for only 3-6% of all PD-associated peritonitis cases.[8] Most cases are caused by *Candida* species, while *Blastomyces* peritonitis has been reported only in a few instances.[4-8] We describe a rare case of *Blastomyces*-associated peritonitis in a patient on PD, highlighting diagnostic and therapeutic challenges and underscoring the importance of clinical awareness as endemic patterns shift.

CASE REPORT

A 66-year-old man with end-stage renal disease on daily PD and type 2 diabetes mellitus, residing in Kansas, presented with progressively worsening peri-umbilical abdominal pain. He had no recent antibiotic use or travel history. On examination, he exhibited abdominal tenderness with rebound and had a scrotal wound. He was afebrile but had a leukocytosis of 18.1 $\times 10^9$/L. Contrast-enhanced abdominal computed tomography (CT) revealed diffuse mild small bowel dilatation without a definite transition point, concern for small bowel wall necrosis, portal venous gas within the liver, and a small volume of ascites.

Peritoneal fluid analysis showed a white blood cell (WBC) count of 2,660 cells/mm^3 with 94% neutrophils, consistent with PD-related peritonitis. He was transitioned to hemodialysis (HD) due to abnormal CT findings, concern for inadequate peritoneal filtration, and anticipation of a complicated clinical course. Empiric intravenous piperacillin-tazobactam and vancomycin were initiated, along with intraperitoneal ceftazidime and oral nystatin for antifungal prophylaxis.

Over the next two days, the patient developed encephalopathy and hypotension, requiring intensive care unit (ICU) transfer for vasopressor support and bilevel positive airway pressure ventilation. A repeat CT scan showed resolution of portal venous gas and improved small bowel perfusion, though mild residual dilatation suggestive of ileus persisted. Repeat peritoneal fluid analysis revealed a decreased WBC count of 752 cells/mm^3 with 93% neutrophils. His ileus was managed conservatively with nasogastric decompression. Subsequent peritoneal fluid WBC counts continued to decline (Figures 1 and 2), and both blood and peritoneal fluid bacterial cultures remained negative (samples had been obtained after initiation of empiric antibiotics).

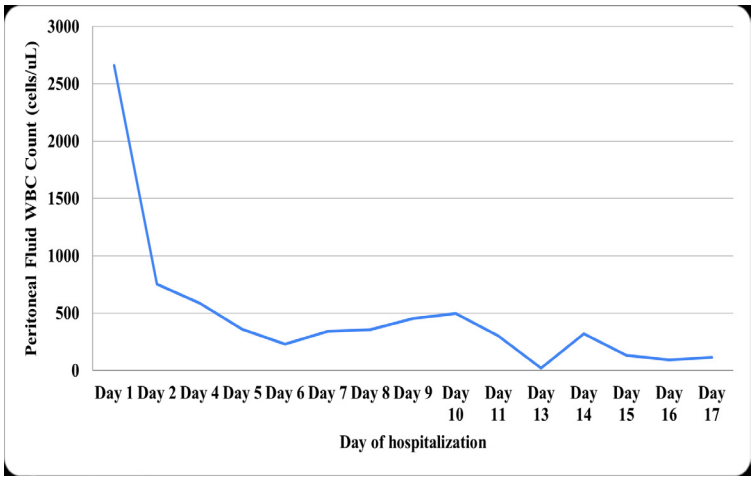

Figure 1. Trends in peritoneal fluid total white blood cell count during hospitalization.

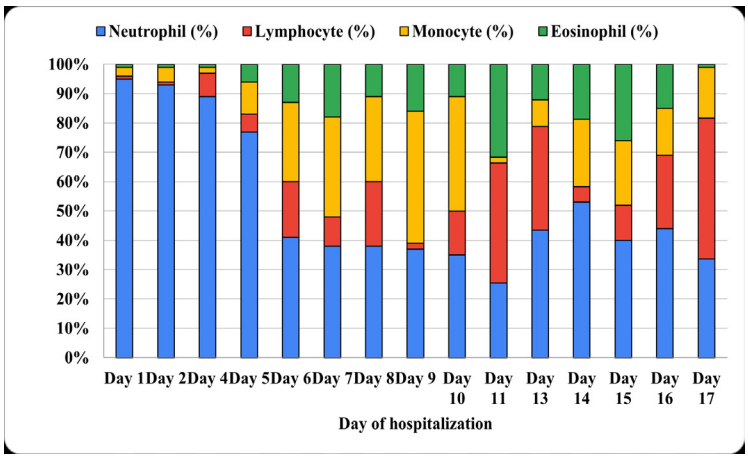

Figure 2. Peritoneal fluid white blood cell differentials during hospitalization.

Wound cultures from the scrotal lesion grew extended-spectrum beta-lactamase–producing *Klebsiella* species and *Morganella morganii*, prompting a change in antibiotics to meropenem. The patient's leukocytosis and peritoneal fluid findings improved. However, because inflammatory markers failed to normalize, his PD catheter was removed 18 days after admission. He was discharged home to complete a two-week course of intravenous ertapenem.

He was readmitted a few days later with recurrent abdominal pain and fever. Fungal culture results from the initial peritoneal fluid sample subsequently returned positive at four weeks for *Blastomyces dermatitidis*. He was started on intravenous amphotericin B for fungal peritonitis. The patient declined

further HD and hospitalization and was discharged home with hospice services. In alignment with his wishes, he agreed to continue oral antifungal therapy with itraconazole while under hospice care.

DISCUSSION

This case highlights the importance of considering fungal pathogens, including rare organisms such as *Blastomyces dermatitidis*, in PD-associated peritonitis, particularly when signs and symptoms persist despite broad-spectrum antibiotic therapy. Patients may present with both bacterial and fungal peritonitis simultaneously, as illustrated in this case. This scenario is especially likely when peritoneal fluid cell counts, and leukocytosis initially improve with antibiotics. Empiric antimicrobial therapy, along with supportive measures such as transition to HD and management of ileus, may temporarily suppress inflammation, contributing to an apparent but misleading clinical improvement. A neutrophilic predominance in peritoneal fluid is not uncommon in fungal peritonitis and has been reported in cases with up to 65% neutrophils.[4-5] However, the change in neutrophil proportion from 94% on day 1 to 33% on day 17, accompanied by a rise in lymphocytes from 1% to 47% with persistent symptoms, should raise suspicion for an alternate pathogen.

The indolent growth of *Blastomyces*, often requiring up to four weeks for culture positivity, can significantly delay diagnosis and treatment. In such cases, earlier ordering of fungal cultures, serum or urine antigen testing, and serologic assays may expedite diagnosis and guide timely management.[9] The sensitivity of antigen testing is approximately 89% in disseminated blastomycosis and is higher in urine than in serum.[9] However, specificity is about 79% because of cross-reactivity with histoplasmosis, coccidioidomycosis, and paracoccidioidomycosis.[9] Consequently, *Blastomyces* urinary antigen testing can serve as a useful screening tool.[4] In one reported case, urinary antigen levels exceeded the quantitation limit (>14.7 ng/mL) after the diagnosis was confirmed by PD fluid culture.4 In our patient, the diagnosis of *Blastomyces* peritonitis was made before transition to hospice care; therefore, further diagnostic testing was not pursued.

Although awareness of endemic exposures remains valuable, the shifting geographic distribution of fungal pathogens has made this factor less reliable.[2-3] *Blastomyces* classically has been associated with the Ohio and Mississippi River valleys, the Great Lakes region, and parts of the southeastern United States.[2-3] However, recent data indicate expanding endemicity and emerging clusters in regions such as Kansas, where this patient resided.[10] This trend challenges clinicians to recognize that geographic exposure history alone may no longer predict risk and underscores the need for broader clinical suspicion, even in areas previously considered low-risk. Delayed recognition of fungal pathogens can lead to clinical deterioration and poorer outcomes.

Blastomyces-associated peritonitis represents a manifestation of disseminated blastomycosis.[11] According to the Infectious Diseases Society of America (IDSA) guidelines, patients with comorbidities or acute illness requiring ICU-level care, such as in this case, are classified as having moderate to severe disease.[11] For such patients, the IDSA recommends induction therapy with amphotericin B for 1-2 weeks or until improvement, followed by at least 12 months of oral itraconazole.[11] For mild to moderate disease, oral itraconazole alone for 6-12 months may suffice.[11] In cases of suspected fungal peritonitis or refractory or relapsing PD-associated peritonitis, prompt PD catheter removal and transition to HD are recommended.[12]

Patients with immunocompromising conditions, including end-stage renal disease and diabetes mellitus, are more susceptible to severe blastomycosis.[13] Diabetes has been identified as an independent risk factor for aggressive disease, likely due to impaired neutrophil function and delayed immune response.[13,14] In this patient, comorbidities likely contributed to the atypical presentation, rapid clinical decline, and poor outcome. The delayed identification of the fungal etiology also postponed initiation of effective antifungal therapy.

CONCLUSIONS

Prognosis in fungal peritonitis remains guarded, especially in patients with significant comorbidities or delayed diagnosis.[15] Previously reported cases have shown high early in-hospital mortality (<30 days).[4,5] Although the patient agreed to continue oral antifungal therapy, he declined further HD and opted for hospice care. This case underscores the importance of patient-centered care and shared decision-making in guiding both therapeutic interventions and end-of-life choices. His decision highlights the essential role of transparent communication in managing complex, life-limiting infections and reinforces the need to align treatment with patient values and goals.

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Corresponding Author: Joseph Odeyemi, M.D., Department of Internal Medicine, The University of Kansas School of Medicine Wichita, 1010 N Kansas St, Wichita KS, 67214. jodeyemi@kumc.edu.

Author Affiliations: Department of Internal Medicine and Pediatrics, The University of Kansas School of Medicine Wichita, Wichita, Kansas (Odeyemi, Emoto); Johns Hopkins University, Krieger School of Arts and Sciences (Sandid); Internal Medicine, The University of Kansas School of Medicine Wichita, Wichita, Kansas (Banda, Mallick); Infectious Disease Consultants of Kansas (Assi).

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***Keywords**: blastomycosis, peritoneal dialysis, peritonitis*

KANSAS JOURNAL of MEDICINE

Case Report

Intraductal Papillary Neoplasm of the Biliary Tract: A Rare Pre-Malignant Diagnosis

Devan Crow, MS-4, Mitchell Misfeldt, M.D., Shelby Fishback, M.D., Rex Parker, M.D., Vanessa L. Williams, M.D.

INTRODUCTION

Intraductal papillary neoplasm of the biliary tract (IPNB) is a rare premalignant lesion of the biliary tree and a precursor of cholangiocarcinoma.[1] It is analogous to intraductal papillary mucinous neoplasm of the pancreas (IPMN-P), which has established guidelines for standardized surveillance.[2] Compared with IPMN-P, IPNB carries a higher risk of progression to invasive cholangiocarcinoma.[3,4]

IPNB arises from the bile duct epithelium and exhibits papillary or villous morphology. Imaging typically demonstrates ductal dilatation with papillary frond-like filling defects or intraductal masses.[5-7] Magnetic resonance imaging (MRI) is important for identifying malignant transformation, with features such as mass-like ductal thickening, restricted diffusion, and progressive delayed enhancement.[8] MRI combined with endoscopic retrograde cholangiopancreatography (ERCP) and tissue sampling is recommended for early diagnosis and surgical resection.[1]

Diagnosis remains challenging due to nonspecific clinical features and overlap with other biliary disease. Recognition of the characteristic imaging findings is essential for timely diagnosis and management.

CASE REPORT

A 46-year-old woman presented to the emergency department with a one-week history of right flank pain, nausea, and vomiting. She had recently completed a course of antibiotics for a urinary tract infection. On physical examination, she appeared ill and had right upper quadrant tenderness. Laboratory evaluation revealed leukocytosis and elevated alkaline phosphatase, while serum lipase and urinalysis were within normal limits.

Initial contrast-enhanced computed tomography (CT) demonstrated marked intra- and extra-hepatic biliary ductal dilatation, most pronounced in the posterior right hepatic lobe (Figure 1). Same-day MRI with magnetic resonance cholangiopancreatography (MRCP) confirmed the dilatation but revealed no discrete intraductal or obstructing mass (Figure 2A, B). Given these findings, the patient was evaluated by gastroenterology and interventional radiology. ERCP demonstrated a dilated common bile duct (Figure 3A). A subsequent transhepatic cholangiogram with biliary drain placement was performed (Figure 3B). Cytology from brushings revealed high-grade dysplasia, raising concern for invasive carcinoma.

The patient ultimately underwent right hepatectomy with Roux-en-Y hepaticojejunostomy. Final pathology confirmed IPNB with high-grade dysplasia and multiple microscopic foci of periductal invasive carcinoma. Her postoperative course was complicated, requiring prolonged hospitalization, after which she initiated chemotherapy for IPNB with invasive carcinoma.

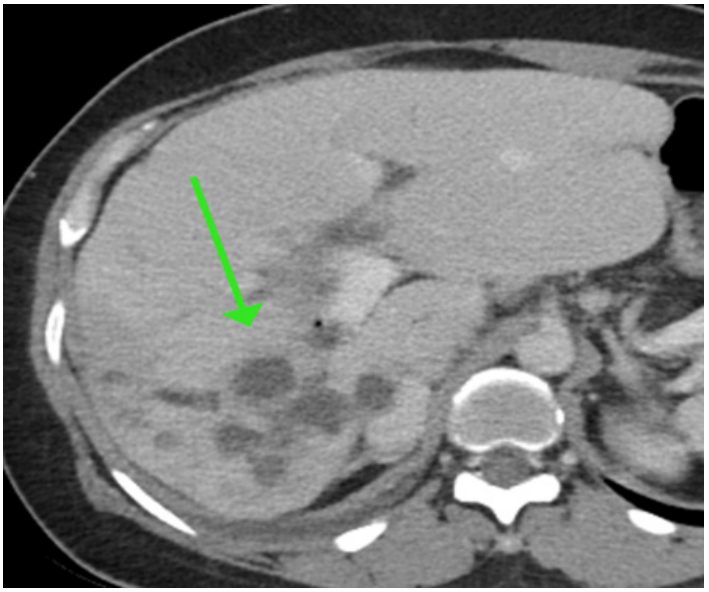

Figure 1. Axial CT image of the abdomen with contrast demonstrates marked biliary ductal dilatation (arrow) in the posterior right hepatic lobe without discrete obstructing or intraductal mass from IPNB.

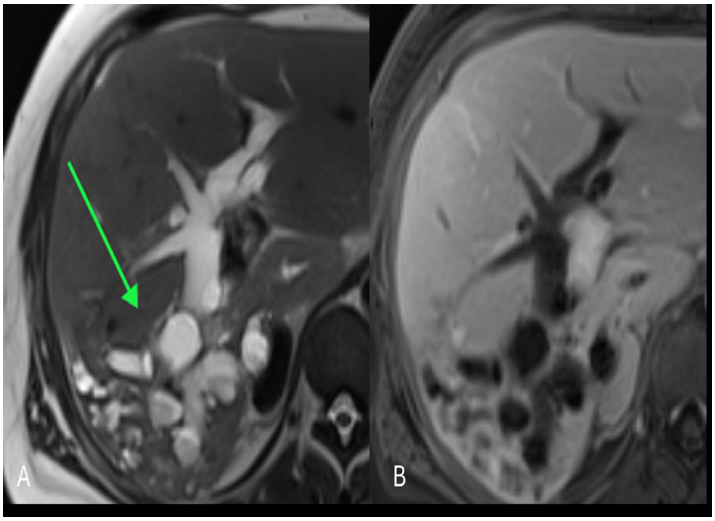

Figure 2. MRI abdomen with and without contrast. (A) Axial T2 image demonstrates marked intrahepatic biliary ductal dilatation (arrow) in the posterior right hepatic lobe from IPNB; (B) Axial postcontrast T1 fat saturated image without enhancing intraductal mass or filling defect.

DISCUSSION

IPNB is a neoplasm arising from the bile duct epithelium with papillary or villous morphology.[1,5] It is a slow-growing lesion that can undergo malignant transformation to cholangiocarcinoma and is histologically classified as low- to intermediate-grade dysplasia, high-grade dysplasia, or IPNB with associated invasive carcinoma.[9] Patients may present with abdominal pain, cholangitis, or obstructive jaundice with elevated alkaline phosphatase.[1,7,9] Although more common in Asian populations, IPNB accounts for only 7-11% of bile duct tumors in Western countries, with risks

factors including primary sclerosing cholangitis, choledochal cysts, and Gardner syndrome.[1]

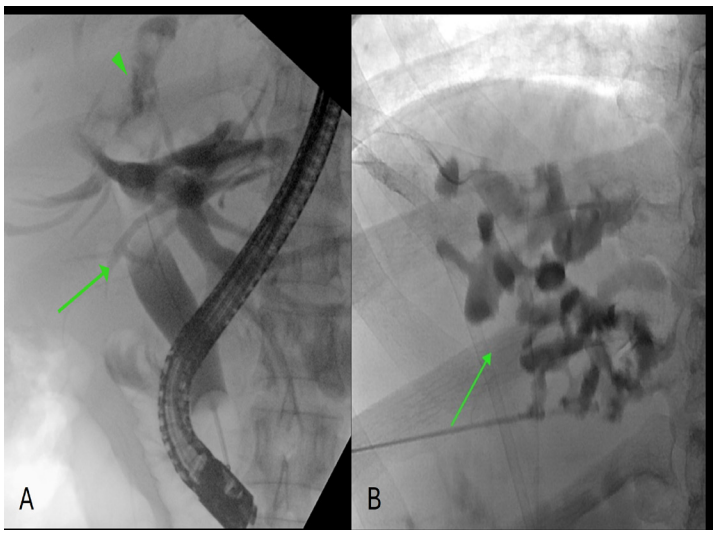

Figure 3. (A) ERCP image demonstrates marked extrahepatic (arrow) and intrahepatic (arrowhead) biliary ductal dilatation from IPNB; (B) Percutaneous right transhepatic cholangiogram with marked intrahepatic biliary ductal dilatation (arrow) without discrete mass from IPNB.

Imaging findings vary depending on mucin production and intraductal tumor size, location, and morphology. Ultrasound and CT often reveal nonspecific biliary ductal dilatation with or without intraductal masses or papillary filling defects, while MRI/MRCP is more sensitive for detection.[9,10] ERCP frequently is used in conjunction with cross-sectional imaging to evaluate mucin production and obtain tissue samples. Four radiologic patterns of IPNB have been described: (1) intraductal mass with aneurysmal bile duct dilatation both upstream and downstream from the lesion; (2) intraductal mass with upstream dilatation; (3) multiple intraductal masses with aneurysmal upstream dilatation and variable downstream dilatation; and (4) diffuse bile duct dilatation without a discrete mass.[1,5,9,11] Diffusion-weighted imaging further enhances the detection of invasive carcinoma, particularly with periductal infiltration.[8,10]

In our case, imaging demonstrated diffuse biliary ductal dilatation without a discrete mass, and pathology confirmed IPNB with microscopic foci of invasive carcinoma. Although microscopic invasive carcinoma was found after tissue sampling, no imaging findings suggestive of cholangiocarcinoma were identified on MRI. Even without overt malignant imaging features, IPNB is a premalignant lesion that requires close surveillance with MRI/MRCP and ERCP with tissue sampling. Diagnosis often is challenging due to its nonspecific presentation and overlap with other biliary diseases, such as ascending cholangitis.

CONCLUSIONS

In summary, IPNB is the rare biliary counterpart of the more common pancreatic IPMN. Because patients with IPNB are at increased risk of malignant transformation to invasive cholangiocarcinoma, recognition of its imaging features is important for early diagnosis and timely treatment.

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Corresponding Author: Vanessa L. Williams, M.D., Department of Radiology, The University of Kansas School of Medicine-Kansas City, Kansas City, Kansas, vwilliams4@kumc.edu.

Author Affiliations: The University of Kansas School of Medicine-Kansas City, Kansas City, Kansas (Crow); Department of Radiology, The University of Kansas School of Medicine-Kansas City, Kansas City, Kansas (Misfeldt, Fishback, Parker, Williams).

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Evaluating the Evidence: Public Awareness of the Association Between Alcohol and Cancer in the US

Alishka Rojas-Addari, MS-4, Nola D. Tran, MS-4, Mary L. Wallace, MS-3, Samuel Ofei-Dodoo, Ph.D., MPA, M.A., CPH

Manuscript Citation: Fokom Domgue J, Yu R, Hawk E, Shete S. Public Awareness of the Association Between Alcohol and Cancer in the US. JAMA Oncol. 2025 1;11(7):789-791. PMID: 40440050.[1]

Type of Investigation: Cross-sectional, population-based survey study.

Question: What proportion of the United States adult population are aware of the association between alcohol consumption and cancer risk and what sociodemographic, behavioral, and cancer beliefs are associated with this awareness?

METHODS

Design. Cross-sectional, population-based survey from the 2022 data from Health Information National Trends Survey (HINTS), a nationally representative survey of United States adults.

Outcome. The primary outcome was awareness of the association between alcohol and cancer risk based upon responses to the question, "*Have you ever heard or read that alcohol increases the risk of cancer*?" Responses were categorized, as "*Yes*, *No*, or *Don't know*." Covariates included sociodemographic, health, behavioral, and cancer belief-related variables.

Population. The population was U.S. adults ≥18 years who answered questions on alcohol-cancer awareness in the 2022 HINTS. A total of 5,937 respondents were included in the study.

Statistical Analysis. Survey-weighted statistical analyses were used to summarize the characteristics of the study population and prevalence of awareness of the association between alcohol and cancer. Survey-weighted multinomial logistic regression analysis was used to examine factors associated with awareness of the association between alcohol and cancer. The significance level was set at $p < 0.05$, and results were reported as adjusted odds ratios with 95% confidence intervals.

Follow-Up. There was no follow-up during this study.

RESULTS

Among 5,937 respondents, 50.7% were women, 17.0% Hispanic, 5.7% non-Hispanic Asian, 10.9% non-Hispanic Black, 61.3% non-Hispanic White, and 5.0% non-Hispanic other. Overall, 67.3% had no more than some college education, 10.1% reported a personal history of cancer, and 30.6% believed cancer prevention is not possible. Awareness that alcohol increases cancer risk was reported by 40.6% of respondents, while 39.1% were unaware and 20.4% were unsure. Awareness was lowest among non-Hispanic Black respondents (30.0%), those with no more than some college education (35.2%), and those who believed cancer prevention is not possible (31.5%). In adjusted analyses, non-Hispanic Black respondents (OR 0.59; 95% CI 0.42-0.84), individuals with lower education (OR 0.62; 95% CI 0.45-0.85), and those who believed cancer prevention is not possible (OR 0.60; 95% CI 0.47-0.78) had significantly lower odds of awareness, whereas respondents with a cancer history had higher odds (OR 1.61; 95% CI 1.21-2.13).

Study Conclusion. The authors concluded that implementing the updated Surgeon General's recommendation to include health warning labels on alcohol-containing beverages is needed to reduce the alcohol-related cancer burden in the United States.[2] They also advocated for stronger public health strategies and improved clinician-patient communication regarding these risks. Although the guidelines have been revised, awareness of the association between alcohol and cancer among United States adults still has substantial room for improvement.

Commentary. Fokom et al.[1] examined public awareness of the association between alcohol use and cancer risk across sociodemographic, behavioral, and cancer belief-related factors in the United States adult population. The authors reported adherence to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist.[3] The STROBE checklist is designed to improve the quality and transparency of reporting in observational studies, including cross-sectional, cohort, and case-control designs. It outlines 22 essential items that should be addressed in a manuscript and helps authors critically evaluate their research. Each item includes subcomponents with recommendations for how it should be presented.

The assessment of STROBE adherence showed that the authors included several elements that strengthened the study, such as descriptions of how quantitative variables were handled in the analyses, details about data sources, and clarification of outcomes, predictors, and potential confounders (Supplemental, available online at journals.ku.edu/kjm). However, several reporting deficiencies also were identified. For example, Fokom et al.[1] did not include an abstract, nor did the title specify the study design. The Methods section lacked information on potential sources of bias, while the Results section omitted reasons for non-participation, unadjusted estimates, category boundaries, and handling of missing data. The Discussion section did not provide a comprehensive interpretation of findings or address external validity.

Given that the HINTS data are derived from probability-based sampling involving stratification, clustering, and unequal probabilities of selection,[4] the Preferred Reporting Items for Complex Sample Survey Analysis (PRICSSA) guidelines would have been more appropriate or used in conjunction with STROBE. These guidelines are recommended for all publicly available HINTS datasets.[5] Using PRICSSA would have enhanced transparency

can play a key role in raising awareness and potentially reducing alcohol-related cancer burden.

Strengths. The authors' use of a nationally representative survey (HINTS) enhanced the generalizability of their findings,

Table. Itemized List of Each PRICSSA Item, a Detailed Description of Each Item, and Example Text of Each Item That Could Be Used in a Manuscript.

PRICSSA item	Description	Page
1.1 Data collection dates	Describe the survey®s data collection dates (e.g., range) to provide historical context that could affect survey responses and nonresponse.	1
1.2 Data collection mode(s)	Describe the survey®s data collection mode(s). Data collection mode can affect survey responses (e.g., to sensitive questions), including nonresponse, and a survey®s data collection mode may change over time (e.g., during the COVID-19 pandemic).	No
1.3 Target population	State the target population the survey was designed to represent and describe all weighted estimates with respect to this target population.	1
1.4 Sample design	Describe the survey®s sample design, including information about stratification, cluster sampling, and unequal probabilities of selection.	No
1.5 Survey response rate(s)	State the survey®s response rate and how it was calculated.	No
2.1 Missingness rates	Report rates of missingness for variables of interest and models and describe any methods (if any) for dealing with missing data (e.g., multiple imputation).	No
2.2 Observation deletion	State whether any observations were deleted from the dataset. If observations were deleted, provide a justification. Note: It is best practice to avoid deleting cases and use available subpopulation analysis commands no matter what variance estimation method is used.	No
2.3 Sample sizes	Include unweighted sample sizes for all weighted estimates.	No
2.4 Confidence intervals/standard errors	Include confidence intervals or standard errors when reporting all estimates to inform the reliability/ precision of each estimate.	1-2
2.5 Weighting	State which analyses were weighted and specify which weight variables were used in analysis.	1
2.6 Variance estimation	Describe the variance estimation method used in the analysis and specify which design variables (e.g., PSU/stratum, replicate weights) were used.	No
2.7 Subpopulation analysis	Describe the procedures used for conducting subpopulation analyses (e.g., Stata®s "subpop" command, SAS®s "domain" command).	No
2.8 Suppression rules	State whether or not a suppression rule was followed (e.g., minimum sample size or relative standard error).	No
2.9 Software and code	Report which statistical software was used, comprehensively describe data management and analysis in the manuscript, and provide all statistical software code.	1
2.10 Singleton problem (as needed)	Taylor Series Linearization requires at least two PSUs per stratum for variance estimation. Sometimes an analysis is being performed and there is only a single PSU in a stratum. There are several possible fixes to this problem, which should be detailed if the singleton problem is encountered.	No
2.11 Public / restricted data (as needed)	If applicable, state whether the public use or restricted version of the dataset was analyzed.	1
2.12 Embedded experiments (as needed)	If applicable, provide information about split sample embedded experiments (e.g., mode of data collection or varying participant incentives) and detail whether experimental factors were accounted for in the analyses.	No

by ensuring detailed reporting of survey design variables, weighting procedures, and variance estimation.[5]

Assessment Instrument. Evaluation of the study using the PRICSSA guidelines is shown in the Table. Several key reporting elements were missing, including information on data collection mode, sample design, survey response rates, and handling of missing data. In addition, details on variance estimation and unweighted sample sizes were not provided. Failure to account for these complex design features may hinder reproducibility, bias parameter estimates, and increase the likelihood of Type I error.[4]

CONCLUSIONS

While this study has limitations, it draws attention to a meaningful public health gap. The observed disparity in awareness across the educational and racial groups shows a need for targeted education, and the need for real implications for policy and clinical practice. Health professionals and public health campaigns and the application of survey weights ensured appropriate representation across key demographic groups. The authors incorporated multiple relevant covariates, including sociodemographic and belief-based factors, providing a comprehensive analytical framework. Additionally, the results are timely and relevant, aligning with the release of the 2025 Surgeon General's guidance on alcohol and cancer risk.[2]

Limitations. The cross-sectional design limits causal inference. Potential selection bias may be present due to non-response and missing data that were not fully addressed. The outcome measure relatively was simplistic and may not have captured the nuances of participants' awareness. Although the authors claimed to have followed the STROBE guidelines, adherence was incomplete. While they used survey-weighted multinomial logistic regression to examine factors associated with awareness of the alcohol-cancer link, they did not report model performance measures, leaving uncertainty about how well the model fit the data.

COMPLIANCE WITH ETHICAL STANDARDS

Conflict of Interest. Dr Hawk reported receiving personal fees from multiple cancer centers for serving on external advisory boards, consulting, and co-chairing committees, as well as from Guardant Health for advising on blood-based cancer detection tests. He also reported institutional and federal grants related to cancer prevention and early detection, with partial salary support from an endowed chair position. No other disclosures were reported.

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Corresponding Author: Samuel Ofei-Dodoo, Academic and Student Affairs, The University of Kansas School of Medicine-Wichita, Wichita, Kansas, 1010 N Kansas St., Wichita, KS, 67214, sofeidodoo@kumc.edu.

Author Affiliations: The University of Kansas School of Medicine-Wichita, Wichita, Kansas (Rojas-Addari, Tran, Wallace); Department of Internal Medicine, The University of Kansas School of Medicine-Wichita, Wichita, Kansas (Ofei-Dodoo).

Conflict of Interest Disclosure: Samuel Ofei-Dodoo currently is the current Editor-in-Chief for the *Kansas Journal of Medicine*.

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