Investigation of urology intraoperative events leading to root cause analysis at national VA medical centers

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PEARD LM, TEPLITSKY S, ANNABATHULA A, GUNNAR W, MILLS P, HARRIS A. Investigation of urology intraoperative events leading to root cause analysis at national VA medical centers. *Can J Urol* 2023;30(2):11467-11472.

Introduction: *Adverse events in urologic procedures are poorly studied. This study analyzes the Veterans Health Administration (VHA) Root Cause Analysis (RCA) data for patient safety adverse events during urologic procedures performed in a VHA operating room (OR).*

Materials and methods: *The VHA National Center for Patient Safety RCA database was queried for fiscal years 2015-2019 using urologic terms including vasectomy, prostatectomy, nephrectomy, cystectomy, cystoscopy, lithotripsy, ureteroscopy, urethral, TURBT, etc. RCAs for events outside a VHA OR were excluded. Cases were categorized based on type of event.*

Results: *Sixty-eight RCAs were identified for 319,713 urologic procedures. The most common pattern identified was equipment or instrument issue, including broken scopes or smoking light cords, with 22 cases. Eighteen RCAs involved a sentinel event, including 12 retained surgical items (RSI) (surgical sponge, retained guidewire) and 6 wrong site surgeries (WSS) (incorrect laterality, wrong procedure) representing a serious safety event rate of 1 in 17,762 procedures. In addition, 8 RCAs pertained to medical or anesthesia events (incorrect dosing, postoperative myocardial infarction), 7 to pathology errors (missing or mislabeled specimen), 4 to incorrect patient information or consent, and 4 to surgical complications (hemorrhage, duodenal injury). In 2 cases there was inappropriate work up. One case caused a delay in treatment, one case had an incorrect count, and one case identified lack of credentialing.*

Conclusions: *RCAs of patient safety adverse events occurring during urologic OR procedures highlight the need for targeted quality improvement projects to prevent WSS events, prevent RSI events, and maintain properly functioning equipment.*

Key Words: root cause analysis, quality improvement, urology, adverse events

Introduction

It has been suggested medical errors represent the third leading cause of death in the United States, but these deaths often remain unmeasurable outside of confidential forums.[1] In the late 1990s, the patient safety movement arose from a reaction to a series of highly-publicized medical failures.[2] The publication "To Err is Human" by the Institute of Medicine in 1999 further highlighted the prevalence of errors in medicine leading toward mortality.[3] However, instead of placing blame on the mistakes of medical professionals, the publication focused on how systemic changes may lead to increased patient safety by reducing medical errors.

Root cause analysis (RCA) was initially developed in the psychology literature.[2] In its essence, RCA is a retrospective analysis aiming to break down an event into its "basic and causal factor(s) that underlie variation in performance."[2,4] RCA has since become a staple in hospitals and other healthcare settings to identify problems and develop solutions.[2] Through the use of RCA, the Veterans Health Administration (VHA) has previously implemented system changes and shown an overall decrease in adverse events

Accepted for publication March 2023

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in operating rooms in 2010-2017 compared to 2001-2006 and 2006-2009, highlighting the efficacy of these interventions. However, there is little urology-specific literature describing the use of RCA in the setting of urologic procedures.

Our objective was to characterize events leading to RCA in urologic operating rooms (OR) across national Veterans Affairs (VA) Medical Centers to enhance understanding of common themes leading to adverse events and of appropriate use of RCA in this setting.

Materials and methods

The VA National Center for Patient Safety (NCPS) utilizes RCA to identify systemic issues and identify prevention strategies based on adverse events.[5,6] In addition to being implemented on a national level, the NCPS is involved in providing training in RCA at local hospitals.[7] When an RCA of an adverse event is conducted at a local VA, a detailed report including a narrative review of each event is submitted to the NCPS for review.[7] Additionally, after an incident occurs, the patient safety manager assigns the case a Severity Assessment Code (SAC). SAC scores range from 1-3 and are based on the event's severity and likelihood of occurrence. "SAC Potential" refers to the potential for harm, while "SAC Actual" refers to the actuality of harm.[8] A score of 3 in either category requires an RCA to be performed within 45 days of the initial report.[9] Each RCA is also classified by a Severity score. Severity scores range from 1 to 4 with 1 meaning no injury, 2 meaning moderate injury, 3 meaning major injury, and 4 meaning catastrophic injury or death.[8]

A dataset of surgical RCAs submitted to the VA NCPS between fiscal years 2015 to 2019 (10/1/14-8/30/19) start of fiscal year 2015 to August 2019 was created using the search terms urology, -gic, -gist, vasectomy, prostatectomy (including TURP, RRP, LRP, PVP), nephrectomy, cystectomy, cystoscopy, lithotripsy, kidney stone, ureteroscopy, ureter, -al, urethral, TURBT, bladder/prostate cancer, and Gleason. Cases were manually reviewed and all cases that did not pertain to an event in a urology operating room were excluded from analysis. The cases were then categorized by similarity and divided based on the type of event. SAC and severity scores were also recorded.

Lastly, we compiled a list of proposed changes or outcomes resulting from each RCA. We categorized all outcomes into five categories: "Pre or postoperative policy or procedural changes," "Intraoperative procedural changes," "Nursing or technologist policy changes," "Institutional policy," and "Physician policy." Common factors related to each outcome were then identified.

Results

The total number of OR urology procedures between fiscal years 2015 and 2019 was 62,632. Urology procedures ranged by fiscal years from 14.8%-15.5% of total OR procedures, representing 15.0% for entire study period. The Serious Safety (Sentinel) Event Rate during the study was 1/17,762 urology procedures. From fiscal year 15-19, the VHA experienced 132 wrong site surgeries and 142 retained surgical item procedures.[10] Urology procedures represented 6/132 (4.5%) of wrong site surgeries and 12/142 (8.5%) of retained surgical item events.

Of the RCAs pertaining to Urology, sixty-eight cases meeting search and inclusion criteria were identified, Table 1. After review, eleven themes emerged, including "Wrong Case of Inappropriate Work up," "Pathology," "Equipment or Instrument Issue," "Medical Event or Anesthesia," "Retained Foreign Body," "Incorrect Patient Information or Consent," "Surgical Complications," "Wrong Site Surgery," "Credentialing," "Incorrect Count," and "Delay in Treatment."

The most common pattern identified was "Equipment or Instrument Issue," accounting for 22 cases (32.4%), Figure 1. Examples included not having sterile flexible ureteroscopy available after the patient was asleep, no biopsy forceps available for bladder biopsy, expired ureteral stent placed, dirty or cracked scopes, leg stirrup that fell off of bed during procedure, and smoking light cords. Twelve events (17.6%) were categorized as "Retained Foreign Body." Items included retained portions of guidewires, surgical sponges, a Floseal syringe, a blade from a Thomson retractor, portion of Jackson Pratt drain, and a blade handle. Eight events (11.8%) were categorized under "Incorrect Medication or Medical Event." Examples included incorrect dosing of medication, injection of isopropyl alcohol instead of contrast during retrograde pyelography, code team not allowed to enter OR during code event, and a ST-elevation myocardial infarction during transurethral resection of the prostate. Seven events (10.3%) pertained to "Pathology" errors. This category included events such as missing specimens, mislabeled specimens, an incorrect pathological diagnosis of urothelial carcinoma leading to radical cystectomy that was later revised to prostate adenocarcinoma, and a case of urothelial tissue found in a different patient's eyelid biopsy specimen container.

TABLE 1. **Summary of all events leading to root cause analysis**

Category	Description	# of cases
Equipment or instrument issue	Instrument needed for procedure not available	3
	Broken or dirty scope and no additional scope available	4
	Light or electrical cord burning drapes and/or patient	7
	Expired stent opened and placed	1
	Dirty instrument opened	4
	Leg stirrup broken and fell off bed	1
	Robot equipment malfunction	1
	Fragment of resectoscope broke off during procedure	1
Retained foreign body	Retained surgical sponge	1
	Retained portion of guidewire	3
	Retained Floseal matrix syringe	1
	Retained blade from Thompson retractor	1
	Retained fragment of a Stone Cone device	1
	Retained JP drain	1
	Retained blade handle	1
	Retained other item	2
	Retained portion of ureteral stent	1
Incorrect medication or medical event	Wrong epinephrine dose given	1
	Blood transfusion not given when requested	1
	Multiple intubation attempts leading to swelling of airway and respiratory compromise in PACU	1
	Isopropyl alcohol used for pyelogram instead of contrast	1
	Patient code perioperatively	2
	Patient with critical hyperkalemia preoperatively, operative team not notified	1
	Myocardial infarction postoperatively	1
Pathology	Specimen not sent to pathology or missing	5
	Incorrect initial pathologic diagnosis	1
	Specimens labeled with incorrect patient information	1
Wrong site surgery	Incorrect laterality	4
	Spinal cord stimulator battery identified and dissected instead of bladder Interstim battery	1
	Prostate biopsy performed instead of cystoscopy	1
Incorrect patient information or consent	Patient given discharge instructions under different patient's name	1
	Patient with dementia consented for surgery, no family notified	1
	Procedure performed without consent	1
	Wrist band with incorrect patient information	1
Surgical complications	Renal artery injury during ureteroscopy	1
	Intraabdominal bladder rupture during TURP	1
	Duodenal mucosal injury and postoperative hemorrhage during radical nephrectomy	1
	Postoperative hemorrhage from testicular artery following radical orchiectomy	1
Inappropriate work up	Patient taken to OR for large inguinal hernia, diagnosed as hydrocele intraoperatively	1
	Bladder tumor missed on preoperative work up for TURP	1
Credentialing	Attending surgeon for ureteral stent did not have credentials in facility	1
Incorrect count	Missing needle during count unable to be found in OR or on Xray	1
Delay in treatment	Diagnosis of testicular torsion delayed due to lack of ultrasound in ED resulting in orchiectomy	1

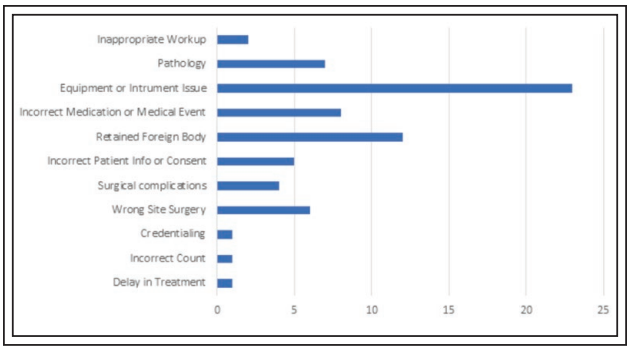

Figure 1. Distribution of events leading to RCA.

There were six (9.0%) "Wrong Site Surgeries." These included a wrong side ureteral stent placement, wrong ureter identified and transected during revision of ureteroenteric anastomosis, spinal cord stimulator dissected instead of Interstim bladder stimulator, and a prostate biopsy performed in a patient scheduled for cystoscopy. Four cases (5.9%) were categorized as "Incorrect Patient Information or Consent." For example, a transurethral resection of bladder tumor was performed without consent, a patient was sent postoperative instructions for a different patient, and an identification wrist band was placed with the incorrect patient information and not noted until postoperative day one. There were four cases (5.8%) identified as "Surgical Complications." Examples include a renal artery injury during ureteroscopy, postoperative bleeding from the testicular artery after radical orchiectomy, bowel evisceration, and an unrecognized bladder perforation during transurethral resection of the prostate. Two cases (2.9%) were categorized as "Inappropriate Work up." For example, a TURP was scheduled and patient was noted to have large bladder tumor intraoperatively, which had been previously seen on an ultrasound ordered by the primary care physician multiple months prior. An inguinal hernia repair was scheduled in a patient with a hydrocele. One case (1.5%) identified a lack of credentialing on the part of the attending physician, one case (1.4%) resulted in a delay of treatment for a testicular torsion, and one case (1.4%) stemmed from an incorrect count.

Of the 68 RCAs, 37 received a SAC Actual score of 1, 18 received a score of 2, and 13 received a score of 3, Figure 2a. Five of the RCAs received a SAC Potential score of 1, 23 received a 2, and 40 received a SAC Potential score of 3. Twenty-six RCAs received a Severity score of 1, 15 received a score of 2, 16 received a score of 3, and 11 received a score of 4, Figure 2b.

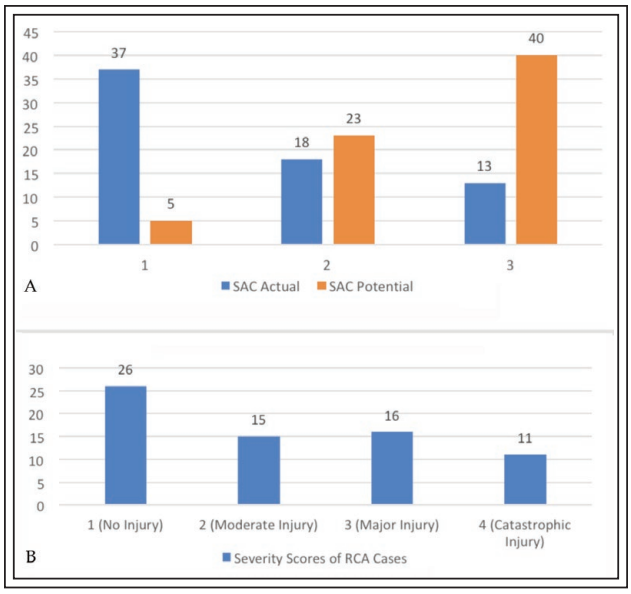

Figure 2. Distribution of SAC scores, actual and potential **(a)** and severity scores **(b)** across RCAs.

Regarding outcomes resulting from each RCA, 32 (47.1%) were related to "Pre or Postoperative policy or procedural changes". The next most common category was "Intraoperative procedural changes" which accounted for 21 (30.9%) of the RCAs. "Nursing or technologist policy changes" accounted for 6 (8.8%), "Institutional policy" changes accounted for 5 (7.4%), and "Physician policy" changes accounted for 2 (2.9%). No outcomes were associated with the remaining 2 RCAs included.

Discussion

Our study identified events leading to RCA in urologic operating rooms using a robust nationwide database. The most common events leading to RCA by a large margin stemmed from equipment errors. Other common errors included retained foreign bodies, mistakes involving pathology, and medication errors. Of note, this study identified the most common errors, such as missing equipment, retained foreign bodies, and misplaced pathology, are by in large, preventable as well as identifiable and therefore excellent and appropriate candidates for RCA and intervention on a systemic level.

In the urologic literature, RCA has been applied to specific clinical situations. For example, in a series of 15 patients, Paller et al applied RCA to analyze health system factors contributing to late presentation of metastatic prostate cancer.[7] RCA has been also

used as an educational tool for urology residents to analyze and learn from adverse events.[11] In a study by Harris, Ziemba, and Bylund, urology residents used RCA to analyze events such as fascial dehiscence, neonatal urosepsis, superior mesenteric artery ligation, pyelonephritis following ureteroscopy, and surgical site infection as examples. However, the urologic data analyzing and reporting medical errors is limited. In surgery, the VHA data has been used to specifically analyze "wrong surgery" events, i.e. wrong patient or wrong side operations, and characterize upstream and downstream causes of events identified during RCA.[12] Interestingly, wrong patient prostatectomies were the fourth most common event in the study, following spine surgery, cataract operations, and excisions of skin lesions, and several other urologic procedures were mentioned, such as wrong side orchiectomies and wrong patient TURBTs.[12] To our knowledge there are no studies in the current literature describing the overall most common medical errors in the setting of urologic surgery, particularly at this national level.

The data collected by the VA NCPS concerning RCAs has been utilized in a wide range of publications in other specialties.[5,7,13] In a similar study to the present, Aboumrad et al used this data to analyze themes with RCAs involving an oncology provider.[13] The most common theme identified was "care delay," including delay and diagnosis and more commonly delay in treatment, which encompassed coordination of follow up and office-patient communication. The second most common theme was "chemotherapy errors," including wrong medications and equipment malfunction. Although in a very different practice setting, this is fairly consistent with our data, highlighting that preventable errors including equipment issues are common.

Neily et al presented another similar cohort of 32 patients using NCPS data specific to anesthesia care.[14] At 28%, the most common type of event was "medication errors." The other themes were largely anesthesia-specific, but they also reported 8% of the events included "consent issues." Although in a similar practice setting to our data (the operating room), they reported only 3 cases (8%) of equipment issues in their qualitative analysis. Although types of events in both this study and the current study are specialty specific, similar overarching themes did emerge.

Another analysis of cases from the NCPS specific to gastrointestinal scopes and tube placement procedures noted the most common adverse event was "retained item."[15] This is consistent with Joint Commission data that cites unintended retained foreign objects as the most commonly reported sentinel event in 2017 and 2018.[4] Retained foreign bodies accounted for 17.1% of the cases in this study, making it the second most common theme. The use of this VA NCPS data in the setting of urologic operating rooms enriches the current data available as well as provides the first analysis looking at adverse events across the field of urology nationally.

With an ever-increasing emphasis on patient safety since the 1990s, there has been an emergence of "just culture."[16] The concept of "just culture" carries the outlook mistakes arise from a fault in organization or system design rather than the individual. This has risen above an alternate "punitive approach," which identifies an incident and the individual at fault resulting in punishment of said individual. A "just culture" requires an environment welcoming open communication and reporting of errors without fear of punishment.[16] Root cause analysis in an objective format is a central tool in creating this culture of honest communication and error reporting.[17] This is particularly critical in the operating room setting, where our patients are at their most vulnerable and the potential for serious and potentially fatal error is high. Surgery, including urology, has been slow to adopt and teach event analysis in a blame free environment. Continued work aims to standardize the RCA process across hospital units and systems to improve implementation.[18] This study presents examples of appropriate events for RCA on a local level, giving urologists a framework for events warranting RCA in their individual institutions. By continuing to develop this "just culture" within the field of urology through honest error reporting and appropriate analysis and intervention, we can take the first steps toward safer surgeries.

There are several limitations to this study. Case reporting was voluntary, introducing potential bias. Additionally, we were limited to events specific to the operating room setting. Expanding our data to urologic patients in various practice settings, including the office and inpatient practice, would enrich the data for application across the field of urology. Although the sample size is small at 62 cases, this data remains the largest report of adverse events concerning adult urology to our knowledge and is representative of serious errors in VAs across the country. This allows national trends to be highlighted that are applicable across geography rather than identifying weaknesses at a single institution, so we can focus on areas for improvement on a national level. However, the data is limited to the VA healthcare system and may not be generalizable other settings, such as private and academic hospitals.

Conclusions

This qualitative study describes the examples of events leading to root cause analyses using a national database. The most common events leading to RCA were equipment and instrument issues, almost all of which are potentially preventable. By identifying these themes, we can better target efforts improving quality and safety in urologic operating rooms. □

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