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A Practice Change to Eliminate Prophylactic Antibiotics for Elective Percutaneous Nephrostomy Tube Exchanges in Low-Risk Outpatients: A Retrospective Review on Risk for Infection

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A B S T R A C T

The purpose of this project was to determine if evidence-based practice change related to antibiotic administration criteria for outpatients receiving percutaneous nephrostomy tube exchanges implemented by a medical center's Vascular and Interventional Radiology department impacted hospital admission rates for infection in these patients. The 2017 practice change was based on 2010 guidelines from the Society of Interventional Radiology (SIR), stating that outpatients with a low risk of acquiring infection did not need to receive a perioperative antibiotic, as evidence has shown prophylactic therapy has no significant effect on infection rates for this population. Using a retrospective review design, 1 year of data before and after the practice change were collected and analyzed using the repeated measures generalized estimating equation (GEE) model with a binomial output by Liang & Zeger. Fisher's exact test was used to evaluate demographic variables by level of risk of infection. Data included 493 procedural events for 126 outpatients. The mean number of events per patient was 3.91 (SD: 4.15; median: 2; interquartile range: 3). Admission and infection criteria within thirty days of the event and infection risk factors were collected for each patient. Age, sex, and race were the variables that had a significant relationship with risk level of infection. Due to sample size, the GEE model could not be run using risk level (high/low) to predict admissions before or after the practice change. The relationship between the number of risk factors (0-5) and the odds of admission for infection was the same regardless of the practice change (before: odds ratio [OR] = 2.17, 95% confidence interval [CI] = 1.19-3.95; after: OR = 1.9, 95% CI = 1.12-3.22, $p_{interaction}$ = .67). For every increase in a patient's number of risk factors, the odds of developing an infection would be expected to increase by almost 90% (OR = 1.9, 95% CI = 1.27-2.84). Although it was not possible to determine efficacy of the practice change, the predictive analysis indicated that risk level is a significant predictor of admission for infection regardless of antibiotic therapy. The results suggest that demographic indicators should be considered when determining appropriate therapies for this procedure; however, research studies should evaluate this relationship with larger samples to design specific recommendations. Our project results support the 2010 SIR antibiotic prophylaxis guidelines and their more recently updated antibiotic parameter guidelines from 2018.

Introduction

Prudent use of antibiotics in appropriate health care situations has the potential to reduce occurrences of infections and adverse events related to antibiotic resistance. In 2010 alone, the United States spent approximately eleven billion dollars on antibiotic-

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related expenditures, with most of this sum related to outpatient settings and pharmacies (Suda et al., 2018).

During the earlier stages of implementation, antibiotic stewardship was initially directed toward the acutely ill, but it has now expanded beyond this scope to include patients with chronic illnesses (Sloane, Huslage, Kistler & Zimmerman, 2016). Frequent antibiotic administration is associated with patients with chronic illnesses, particularly macrolides (Iizumi, Battaglia, Ruiz & Perez Perez, 2017). In recent years, approximately more than 10% of patients living in a nursing home are actively receiving systemic antibiotics, with the average resident being given a new prescription approximately every 80 days (Sloane, Huslage, Kistler & Zimmerman, 2016).

There are several reasons for a patient with renal disease to undergo a fluoroscopically guided percutaneous nephrostomy (PCN) tube placement, including malignant obstruction, surgical complications, neurogenic bladder, or calculus (Maneevese, Sabir & Ahrar, 2018). The placement of a PCN tube allows renal function to continue, even in the setting of ureteral malignancy or other postrenal impairment (Vargas-Cruz et al., 2017). In addition to having a high risk of infection, patients who undergo regular PCN exchanges frequently have an advanced stage of cancer as their primary diagnosis (Sountoulides, Mykoniatis & Dimasis, 2014). The median life expectancy for patients with end-stage cancer who undergo any form of palliative urinary diversion does not typically exceed 1 year (Sountoulides, Mykoniatis & Dimasis, 2014). Patients who require PCNs to maintain a patent ureteral conduit typically undergo a catheter exchange approximately every 60 days, as the evidence suggests that this time frame is optimal for decreasing infection rates and minimizing frequent hospital charges (McDevitt, Acosta-Torres, Zhang et al., 2017).

Patients undergoing PCN exchange develop an infection for a variety of reasons. PCN tubes that are in place for a long duration are often colonized with a biofilm layer of bacteria along the lumen of the indwelling catheter. It is theorized that one route of infection could be the physical manipulation of the colonized PCN tube during the catheter exchange or the catheter being advanced into the kidney (Sutcliffe, Briggs, Little, McCarthy, Wigham et al., 2015).

In 2010, the Society of Interventional Radiology (SIR) published a guideline specifying that patients who regularly undergo elective PCN exchange procedures do not need a perioperative antibiotic (Venkatesen et al., 2010), unless they clinically qualify as being high risk or having an active obstruction. Based on this guideline, the Vascular and Interventional Radiology department at the Medical University of South Carolina implemented a practice change in May 2017 to withhold perioperative antibiotics in outpatients receiving elective PCN exchanges, who were considered to be at low risk of infection.

Specific Aim

The purpose of this project was to evaluate the practice change and to develop local evidence to support prophylactic antibiotic administration on criteria-based infection risk factors. Infection rates in patients who received a PCN exchange after the practice change were compared with infection data from patients receiving PCN exchanges before the practice change. The patients who were positive for an infection were also separated by those who received outpatient treatment for their infection and those and were admitted to the facility as inpatient for management of their infection. Antibiotic administrations before and after the practice change were also compared.

Literature review

Evidence findings from the literature analysis and synthesis in support of withholding prophylactic antibiotics for patients with a lower risk of infection can be summarized with several common themes, particularly related to outdated studies with small sample sizes and trends in modern health care of evolving antibiotic-resistant microbiome. Historically, the field of interventional radiology (IR) evolved in the 1960s from diagnostic radiology and surgery; experts in this field continue to maintain many surgery-derived guidelines (Matsumoto, Shigemura & Yamamichi et al., 2012; Venkatesan et al., 2010). Given this contemporary timeline, the literature search included articles from the last 10 years. Several landmark studies that were published almost thirty years ago, that were consistently cited in the more recent articles, also were included in the analysis (Appendix A), given their clinical relevance.

Obtaining more recent evidence, from the previous 10 years, related to the effect of antibiotic prophylaxis administration on PCN exchange infection rates remains a considerable challenge. Evidence-based studies that are considered landmark research on the topic were published over 20 years ago. One retrospective study (Maneevese, Sabir & Ahrar, 2018) of 216 patients undergoing PCN tube placements indicated that the previously noted risk factors did not statistically correlate to occurrences of PCN-related catheter-associated urinary tract infections. More recent articles continue to provide support for the practice change but emphasize that this matter and other guidelines should be clinically re-evaluated for relevancy (Matsumoto et al., 2012; Murtha et al., 2017).

PCN Infections

There are no clinically standard definitions or criteria specifically related to classifying PCN infections, other than adhering to the clinical guidelines related to sepsis and systemic inflammatory response syndrome (SIRS) protocol (Siddiq et al., 2012). In 2016, an international task force convened to define updated clinically accepted sepsis guidelines, who defined sepsis as a life-threatening organ dysfunction caused by a dysregulated host response to infection and that the statement “severe sepsis” was a redundant term (Singer et al., 2016). Given the diversity of clinical definitions, estimates of sepsis and mortality rates are difficult to accurately calculate, but the rate for hospital admission for sepsis is 13% of total admissions (Murtha et al., 2017). Mortality for inpatients with sepsis is about 10%, and mortality for those with septic shock jumps to over 40%, which results in about $20 billion in health care spending per year (Murtha et al., 2017).

Infection Criteria

Fever and chills are generally used in IR as the clinical standards in documenting a suspected infection in a postprocedural PCN patient signs and symptoms, based on the original SIRS criteria guidelines (Venkatesen et al., 2010). Per Singer et al. (2016), clinicians have reported the SIRS criteria method of measurement to be insufficient in determining a seemingly subjective precursor to sepsis (Singer et al., 2016). This stems from the concern that an elevated white blood cell (WBC) count, temperature, and tachycardia also can be associated with the more general term of “inflammation” (Singer et al., 2016). To substitute the SIRS criteria, the 2016 sepsis task force proposed usage of the Sepsis-related (or Sequential) Organ Failure Assessment (SOFA) score. This scoring system is recommended by the American Medical Association to be used as a method of determining risk of sepsis in critical care patients, but when looking at patients outside of the intensive care unit, the use of the SOFA score and SIRS criteria showed no statistical difference in predictive validity of hospital mortality because of sepsis (Singer et al., 2016). The simplified Quick SOFA score (respiratory rate >22/min, altered mentation, systolic blood pressure 100 mmHg) also is suggested as possible replacement to using

SIRS criteria, but the results are not as robust (Singer et al., 2016). When evaluating the application to the clinical setting of IR procedures using moderate sedation, the altered mentation score, and Glasgow Coma Scale to calculate the SOFA and quick SOFA scores could be inaccurate.

PCN Complications

One of the primary complications from PCN placement is displacement, with studies citing rates of approximately 15% (Huang, Asher, Richter et al., 2015). Complications may include dislodgement, urine leakage, and unintentional retraction. Improper positioning of the PCN catheter pigtail can result in decreased urine output, hematuria, pain, and fever (Huang et al., 2015). If symptoms continue, the patient might return to IR to be fluoroscopically evaluated, and if the catheter loop is abnormally smaller in diameter in comparison to previous imaging, a new PCN catheter is replaced and repositioned using a guidewire in the tract to improve renal outflow (Huang et al., 2015).

PCN placements for nephrolithotomy have a higher risk of infection, given that these are typically placed in an emergent setting, before being transported to the operating room for the nephrolithotomy procedure. In one study, 27.4% of patients (n = 45) developed SIRS, and 20 cases (12.2%) of fever were recorded (Yang, Liu, Hu, Wang, & Jiang, 2017). In this sample, the larger the size of the stone and the higher the urine WBC count, the greater risk of developing SIRS. Higher serum albumin levels, high WBC counts in the urine, and increased stone size also were associated with postoperative fever.

Antibiotic Administration

Given the financial and societal costs associated with frequent and systemic administration of broad-spectrum antibiotics, there is ongoing research in decreasing the risk of bacterial infections associated with the urinary tract, in addition to PCN-related infections. PCN catheters typically become colonized after placement, but signs or symptoms of infection, such as a fever or chills, are frequently inconsistent. The repeated administration of a systemic antibiotic in the setting of a cyclic decrease in “colonization resistance” could result in an increased chance of antibiotic resistance through unwanted pathogens reducing the diversity of the microbiome (Munro, 2015; Cronan et al., 1989b). One study suggested that the use of antibiotic-impregnated nephrostomy catheters coated with either chlorhexidine or minocycline/rifampin could be effective in decreasing microbial activity, as this practice has demonstrated promising results when applied to in vitro therapies (Vargas-Cruz et al., 2017). Administration of probiotics after a procedure and antibiotic administration also is a consideration, through the theory of restoring the regular microbiome of the patient and reducing the chance of developing antibiotic resistance (Munro, 2015).

Methods

The institutional review board (IRB) of the academic health center and concurrent agreement from the university determined that IRB approval was not needed to evaluate patient data in this retrospective study. A retrospective quasiexperimental design was used to evaluate the impact of antibiotic therapies on admission for infection rates among low-risk outpatients for events from May 2016 to May 2018. There were three primary questions: (1) what were the infection rates after the practice change compared with before the practice change, (2) was the practice change effectively implemented, and (3) did demographic variables of age, gender, and ethnicity and type of health insurance have a relationship with the risk level of infection.

Sample

The population data analyzed for this project were from patients who electively receive PCN exchanges as scheduled outpatients, organized by the level of risk of acquiring a postprocedure infection. Low risk was initially categorized as patients who had no history of urinary tract infections, diabetes, physical obstruction, renal transplant, or hypertension (Cochran et al., 1991; Cronan et. al, 1989a; Pabon-Ramos, Dariushnia, Walker et al., 2016; Venkatesen et al., 2010). Prior the procedure, the clinical determination of risk level was made from conducting a history and physical of the patient, while considering the department's antibiotic prophylaxis guidelines, to determine whether a prophylactic antibiotic should be administered (Gilbert & Guimaraes, 2016). The practice change protocol was implemented in May 2017 and added to Medical University of South Carolina IR procedural handbook in the July 2017 version (Appendices B and C), which provides the department's protocol in an evidence-based manual (Nelson, Gilbert & Guimaraes, 2017).

Measures

Collected patient data ranged from May 1, 2016 to May 1, 2018. One patient and their sole respective PCN event was removed from the data set because of a data error. After being exported to the statistical software for analysis, a duplicate test was run, and two duplicate events were removed. The final data set used for analysis included 126 patients and 493 PCN exchange events.

Practice Change Variables

In total, 213 of the reviewed events took place before the practice change, and 280 of the events took place after the practice change. The variables of practice change (before and after), antibiotic (given or not given), type of antibiotic (name of antibiotic), and infection criteria were not fixed variables, as they changed based on date of procedure event and the therapy received.

Infection Criteria

The following items from patients were collected if they occurred within 30 days after the procedure event: temperature less than 36°C or greater than 38°C, WBC >10,000/mcL, positive urine culture, and positive blood culture.

Temperature

Temperatures greater than 38°C or lower than 36°C were included in the data within 30 days of the event. There were only nine events of an abnormal temperature in the data set.

White Blood Cell Count

WBC counts over 10,000/mcL were included within the data analysis if they were documented within 30 days of the event. Neutropenia can be concerning for an infection; however, most patients in the data set had a history of being immunocompromised because of their medical history, or medical therapy. Given most patients in this data set had a relatively low WBC count, it was unclear whether their lower values were attributed to their medical history or medical therapy and could not be an accurate predictor of acute infection.

Table 1
Events with positive urine cultures[1] within 30 days of procedure[2]

Criteria	Number of events	Criteria	Number of events
Coagulase-negative *Staphylococcus* NOT methicillin resistant	2	*Enterococcus faecalis* and *Pseudomonas aeruginosa*	1
Mixed Gram-negative and Gram-positive organisms	7	ESBL-producing *Klebsiella pneumoniae*	2
Mixed Gram-negative and Gram-positive organisms and *Pseudomonas aeruginosa* isolate	2	ESBL-producing *Klebsiella pneumoniae* and *Pseudomonas aeruginosa*	2
Enterococcus faecalis	4	*Escherichia coli* and *Proteus mirabilis*	1
ESBL-producing *Escherichia coli*	1	Escherichia coli and Gram-negative rods	1
Gram-negative rods isolated	1	*Klebsiella pneumoniae*	2
Proteus mirabilis	1	*Klebsiella pneumoniae* and *Enterococcus faecalis*	1
Pseudomonas aeruginosa	7	Coagulase-negative *Staphylococcus* NOT methicillin resistant and *Pseudomonas aeruginosa*	1
Citrobacter freundii and *Enterococcus faecalis*	1	*Proteus mirabilis* and *Escherichia coli*	1
Gram-positive cocci	5	*Serratia marcescens* and *Citrobacter freundii*	1
Escherichia coli and *Enterobacter cloacae*	1	*Stenotrophomonas maltophilia*	1
Escherichia coli	2	Mixed Gram-positive organisms	3
Methicillin-resistant *Staphylococcus aureus*	2	Mixed Gram-positive and *Pseudomonas aeruginosa*	1
Aerococcus urinae	1	Organism(s) unknown[3]	6
Carbapenem-resistant *Enterobacter cloacae*	1		
Enterobacter cloacae	2	**Total**	**64**

PCN = percutaneous nephrostomy; ESBL = extended spectrum beta-lactamase.
Frequencies are presented for categorical measures.
[1] Positive urine culture is defined as having >100,000 bacterial growth.
[2] Criteria were collected within 30 days of PCN exchange date.
[3] The specific organism was unknown, as results at outside hospital or clinic were unavailable.

Urine Cultures

Urine cultures were recorded as positive if the bacteria count was over 100,000 colony forming units/mL. The organisms most frequently noted in the positive urine cultures were mixed Gram-negative and Gram-positive organisms, *Pseudomonas*, *Escherichia. coli*, Gram-positive cocci, *Klebsiella*, and *Enterococcus*. Several of the bacteria types were multidrug resistant. There were multiple events where culture results did not provide the specific organism(s). In six of the positive urine cultures, the organism was unknown, as the source of testing was an outside hospital or clinic. Table 1 provides the number and organisms for positive urine cultures.

Blood Cultures

Positive blood culture results were collected within the 30-day time frame after the procedure. There were seven events with positive blood cultures; five of these events also had positive urine cultures and were followed by admission for infection; the other two patients did not have positive urine cultures and they were not admitted. All of these events were associated with six different patients who had been assigned to the high-risk category of acquiring a PCN infection. Table 2 provides results of the blood cultures by risk level.

Demographics of Sample

Ages of the 126 patients in the sample set ranged from 21 to 91 years, with a mean of 60.4 years ± 15.2 with 66 males (52%) and 60 females (48%). A total of 72 patients identified as white/Caucasian (57%) and 54 identified as nonwhite/Caucasian (43%). The nonwhite demographic included 49 patients who were identified in the electronic medical record (EMR) as black/African American, two Asian patients (4 events), and one Native American/Alaskan patient (1 event).

Admission and Diagnostic Data

Admission data collected from the EMR included the following variables: date of admission for infection and the clinician's diagnosis of reason for admission. If the reason for admission was attributed to a positive urinary tract infection (UTI) because of the PCN exchange, it was documented in the admission for infection. Documentation regarding outpatient treatment for infection also was documented as a separate variable. Any information gleaned from the telephone/email notes in the EMR regarding an outside hospital admission for infection or outpatient treatment of a UTI was included in the admission and diagnostic variables. Figure E in Appendix E provides a diagram of the potential clinical pathways for an outpatient undergoing a PCN exchange, based on their risk factors, perioperative therapies, and event of postprocedure infection.

Analysis

Data were analyzed using descriptive and inferential statistics. The descriptive statistics analyses were conducted using Microsoft Excel and SPSS (Version 25, Armonk, NY). Data from the preprocedure and postprocedure change were compared using a generalized estimating equations (GEE) model with a repeated measures regression analysis with a binomial output in SAS (Version 9.4, Cary, NC) (Liang & Zeger, 1986). This model was chosen because unlike the logistic regression and analysis of variance models, it accounts for reoccurring events that vary in number for each individual patient, and observations are nested within the clustered events.

Table 2
Blood culture results by bacteria and risk level of patient

Blood culture results	High-risk patients[1]	Low-risk patients[2]
Coagulase-negative *Staphylococcus*	2	0
Alpha-hemolytic *Streptococcus*, not *Pneumococcus/Enterococcus*	1	0
Staphylococcus aureus, non–methicillin resistant	1	0
Gram-positive cocci in clusters	1	0
Gram-negative rods, *Bacillus*, not *anthracis*	1	0
Positive per OSH, results unknown	1	0
Total number of positive blood cultures	**7**	**0**

PCN = percutaneous nephrostomy; OSH = outside hospital.
[1] Positive blood culture was present in a patient with a high risk (having 2-5 risk factors) of having a PCN-related infection.
[2] Low-risk patients have 0-1 of the risk factors of PCN-related infection.

Table 3
Population demographics by risk level

Demographics	Overall (n = 126)	Low risk (n = 37)	High risk (n = 89)	p-value
Age (mean years ± SD)	60.42 ± 15.24	56.84 ± 17.89	61.91 ± 13.83	p < .01
Gender				.007
Male	66 (52%)	12 (32%)	54 (61%)	
Female	60 (48%)	25 (68%)	35 (39%)	
Race				.08
White/Caucasian	72 (57%)	26 (70%)	46 (52%)	
Nonwhite[1]	54 (43%)	11 (30%)	43 (48%)	
Primary insurance				.82
Medicare	76 (60%)	21 (57%)	55 (62%)	
Medicaid	19 (15%)	5 (14%)	14 (16%)	
Private insurance	20 (16%)	8 (21%)	12 (13%)	
Military insurance	3 (2%)	1 (3%)	2 (2%)	
No insurance	8 (6%)	2 (5%)	6 (7%)	

SD = standard deviation.
Frequency and percentages are presented for categorical measures. Means and standard deviations are presented for continuous measures. p-values were derived from Fisher's Exact test for categorical measures and *t*-tests for continuous measures. Low risk was defined as having 0 to 1 risk factors and high risk was defined as having 2 to 5 risk factors.
[1] Nonwhite category includes 49 black/African American patients, 4 Asian patients, and 1 Native American/Alaskan patient.

Initially, the risk factors for this project were to only include the three used in the landmark study by Cochran et al. (1991), which indicated that risk level was determined by the presence of one of the three risk factors of type II diabetes, previous UTI, or history of neoplasm or obstruction. Early into the project's statistical analysis, it was noted that 19 patients had none of these original three risk factors, which would not have been a sufficient sample for review. However, the guidelines developed by the SIR (Venkatesen et al., 2010) provide the following risk factors in their guidelines: "advanced age, diabetes, bladder dysfunction, indwelling catheter, earlier manipulation, ureter intestinal anastomosis, bacteriuria, and stones." No statement is provided in SIR's guidelines regarding whether having one risk factor designates them as "high risk" (Venkatesen et al., 2010). To better address the risk factors described in the guidelines, the two other factors of hypertension and renal transplant were included in the data (Bahu et al., 2013; Cochran et al., 1991; Pabon-Ramos, Dariushnia & Walker, 2016). The "low-risk" level was extended to encompass patients who had either 0 to 1 risk factor, and the "high-risk" level was adjusted to include 2 to 5 risk factors.

Results

Table 3 displays patient characteristics overall and by risk category. The mean age of patients in the data set was 60.4 ± 15.2 years. Age was greater in the high-risk group than in the low-risk group (61.9 years vs. 56.8 years, $p < .01$, $|t| = 1.715$). Sex was associated with higher level of risk with more males in the high-risk than in low-risk group (61% vs. 32%, $p < .01$, $\chi^2 = 8.357$). There were 54 (43%) nonwhite patients (i.e., black/African American, Asian, Native American) versus 72 (57%) white patients; there was a trend toward significance between race and a higher chance of having an infection ($p < .08$, $\chi^2 = 3.686$). Most of the patients from both risk levels had Medicare as their primary type of insurance, with 57% of low-risk patients and 62% of high-risk patients. There was no significant relationship between risk and insurance type ($p < .82$, $\chi^2 = 1.382$).

The five risk factors contributing to high/low risk are provided in Table 4. All of the risk factors had a p-value of <.01 with the presence of the risk factor being more prevalent in the high-risk group compared with the low-risk group. Eighty-two (65%) of the patients had a history of a previous UTI, with 67 of them being in the high-risk category. The risk factor of neoplasm/obstruction had the highest concentration of high-risk patients, which was 70 (79% of the high risk patients). Sixty-four patients (57%) had a history of hypertension and were in the high-risk category. All 16 of the patients with a transplant were in the high-risk group. All five of the risk factors were significant in determining the risk level.

Admission for PCN-Related Infection Within 30 Days of PCN Exchange

Over the entire time period of collected data, the total amount of UTI-associated admissions within 30 days of a procedural event was 33 (7%). Twenty-nine (6%) of these events were attributed to high-risk patients, and four (1%) of these events were attributed to

Table 4
Frequencies by risk factors

Risk factors	Overall (n = 126)	Low risk (n = 37)	High risk (n = 89)	p-value
Type II diabetes				P < .01
Yes	28 (22%)	1 (3%)	27 (30%)	
No	98 (77%)	36 (97%)	62 (70%)	
Previous UTI				p < .01
Yes	82 (65%)	15 (41%)	67 (75%)	
No	44 (35%)	22 (59%)	22 (25%)	
Neoplasm/obstruction				p < .01
Yes	84 (67%)	14 (38%)	70 (79%)	
No	42 (33%)	23 (62%)	19 (21%)	
Hypertension				p < .01
Yes	66 (52%)	2 (5%)	64 (57%)	
No	60 (48%)	35 (95%)	25 (28%)	
Renal transplant				p < .01
Yes	16 (13%)	0 (0%)	16 (18%)	
No	110 (87%)	37 (100%)	73 (82%)	

Frequency and percentages are presented for categorical measures. p-values were derived from Fisher's Exact test for categorical measures. Low risk was defined as having 0 to 1 risk factors and high risk was defined as having 2 to 5 risk factors.

Table 5
Generalized estimating equation–derived odds ratios for admitted infections by high-/low-risk categories and continuous number of risk factors

Exposure	Admitted for PCN-related infection	No admission for PCN-related infection	Crude OR (95% CI)	Adjusted OR (95% CI)
Low risk[1]	4 (1%)[6]	111 (23%)	1.0 (ref)	p < .00
High risk[2]	29 (6%)	349 (71%)	2.16 (0.59–7.89)	3.19 (1.02–10.44)
Number of risk factors: all[3]	33 (7%)	460 (93%)	–	1.90 (1.27–2.84)
Before practice change[4]	15 (3%)	200 (41%)	–	2.17 (1.19–3.95)
After practice change[5]	18 (4%)	260 (53%)	–	1.90 (1.12–3.22)

CI = confidence interval; OR = odds ratio; PCN = percutaneous nephrostomy.
[1] Patients with 0 to 1 of the 5 risk factors are at low risk of infection.
[2] Patients with 2 to 5 of the 5 risk factors are at high risk of infection.
[3] Continuous variables of number of risk factors before stratification by whether practice change had yet been implemented.
[4] PCN exchange events that took place prior to implementation of practice change.
[5] PCN exchange events that took place after implementation of practice change.
[6] n and % are derived from total of 493 events in the data set.

low-risk patients. The number of events that were followed by treatment as an outpatient within the 30-day period was 35 (7%). Five (1%) of these events were associated with patients with a low risk of infection, and 30 (6%) events were associated with high-risk patients. The average number of days between the procedure event and admission for infection was 0.09 days. The average amount of time between the date of event, collected positive urine culture, and elevated WBC was 0 days. Our results support the evidence that when an inflammatory response to the PCN exchange is likely to present, it characteristically occurs within 72 hours after the day of the procedure (Robles & Miller, 2017). If a patient who has undergone an outpatient routine PCN exchange is clinically diagnosed with a PCN-related infection, they are either treated for their UTI as an outpatient or they are admitted to the hospital for inpatient therapy. The following analyses consider the predictive odds of risk level and practice change on patients undergoing routine exchanges and whether they received PCN-related infection treatment as an outpatient or by being admitted as an inpatient.

After adjusting for the demographic variables of gender, WBC >10K, and age, the GEE model evaluated whether the risk of level of infection (low risk or high risk) was a predictor of admission for infection. The odds ratio (OR) for the high-risk patients was 3.19, although the confidence interval (CI) was wide (95% CI = 1.02 – 10.44). There was a strong, significant association when using a continuous form of risk factors (OR = 1.9, 95% CI = 1.27 – 2.84), indicating that for every increase in the number of risk factors, the OR of being admitted for infection increased by almost 90 percent.

When the same analysis was stratified by before or after practice change, there was no significant interaction present (before practice change: OR = 2.17, 95% CI = 1.19-3.95; after practice change: OR = 1.9, 95% CI = 1.12 - 3.22, $p_{interaction} = 0.67$, Table 5).

Patients Treated as Outpatients for UTI Within 30 Days of Routine PCN Exchange

For patients who had a PCN-related infection that received outpatient management, the same adjusted GEE model's output indicated that level of risk (high or low) was not associated with outpatient infections (OR = 1.72, 95% CI = 0.59-5.03); the same was true when using the continuous form of the number of risk factors (OR = 1.35, 95% CI = 0.92-1.96).

When the same analysis was stratified by before or after practice change, the OR for the before practice change segment was nearly significant at 2.52 (95% CI = 0.93-6.8), whereas the OR for after practice change group was only 1.04 (95% CI = 0.66-1.64). The p-value for the interaction term between number of risk factors and the indicator for before or after practice change was 0.08. Table 6 provides the parameter estimates for outpatient analysis from the GEE model.

Outpatient Treatment for UTI and Admission for UTI Combined

The same test was adjusted to include patients with a PCN-related infection who were either treated as outpatients or were admitted for treatment as the combined dependent variable, with the low- or high-risk level of infection as the independent variable; the results indicated a significant relationship (OR = 2.4, 95% CI = 1.01 to 5.72). When using the number of risk factors as a continuous independent variable, the OR was 1.55 (95% CI –1.15 to 2.10).

After stratifying the data by before or after practice change, a relationship between the combined inpatient- and outpatient-treated infections and risk factors before the practice change was noted to be significant (OR = 2.17, 95% CI = 1.18-4.00), but there was no significant relationship between the infections and risk factors after the practice change (OR = 1.36, 95% CI = 0.93-2.00, $p_{interaction} = 0.52$, Table 7).

Antibiotic Administration

The repeated measures model was used again, but the variables were changed to evaluate for implementation of the practice change on antibiotic usage. The dependent variable was changed to whether a perioperative antibiotic was given, and the independent

Table 6
Analysis of generalized estimating equation–derived odds ratios for outpatients by high-/low-risk categories and continuous number of risk factors

Exposure	Outpatient treatment for PCN-related infection	No outpatient infection	Crude OR (95% CI)	Adjusted OR (95% CI)
Low risk[1]	5 (1%)[5]	110 (22%)	1.0 (ref)	p < .00
High risk	30 (6%)	348 (71%)	1.72 (0.55–5.33)	1.72 (0.59–5.03)
Number of risk factors: all[2]	35 (7%)	458 (93%)	–	1.35 (0.92–1.96)
Before practice change[3]	10 (2%)	205 (42%)	–	2.52 (0.93–6.80)
After practice change[4]	25 (5%)	253 (51%)	–	1.04 (0.66–1.64)

CI = confidence interval; OR = odds ratio; PCN = percutaneous nephrostomy.
[1] Low risk of infection is defined as having 0 to 1 of the 5 risk factors.
[2] Continuous variable of 0–5 risk factors of PCN-related infection before being stratified by the practice change variable.
[3] Before practice change was implemented.
[4] After practice change was implemented.
[5] n and % calculated based on total number of events in data set (493).

Table 7
Analysis of generalized estimating equation–derived odds ratios for combined inpatients and outpatients[1] by high-/low-risk and continuous number of risk factors

Exposure	Diagnosed and treated for infection	No infection	Crude OR (95% CI)	Adjusted OR (95% CI)
Low risk[2]	8 (2%)[6]	107 (22%)	1.0 (ref)	–
High risk	54 (11%)	324 (66%)	2.03 (0.80–5.17)	2.40 (1.01–5.72)
Number of risk factors: all[3]	62 (13%)	431 (87%)	–	1.55 (1.15–2.10)
Before practice change[4]	22 (5%)	193 (39%)	–	2.17 (1.18–4.00)
After practice change[5]	40 (8%)	238 (48%)	–	1.36 (0.93–2.00)

CI = confidence interval; OR = odds ratio; PCN = percutaneous nephrostomy.
[1] Dependent variable of positive UTIs for inpatient and outpatient was combined for analysis.
[2] Low risk of infection is defined as having 0 to 1 of the 5 risk factors.
[3] The continuous variable of 0–5 risk factors of PCN-related infection before being stratified by the practice change variable.
[4] Before practice change was implemented.
[5] After practice change was implemented.
[6] n and % values calculated based on total number of events in data set (493).

variable remained as risk level (low or high). After adjusting for the covariates of gender, age, and WBC>10K, the OR was 1.09 (95% CI = 0.56-2.12). After stratifying by practice change (before and after), the OR for before the practice change was 1.17 (95% CI = 0.85-1.58) and after the practice change was 1.56 (95% CI = 1.19-2.04).

The same model was run again, using the remainder of the risk factors as independent variables. With history of type II diabetes, the OR was 2.88 (95% CI = 1.54-5.39). For the before practice change segment, the OR was 2.65 (95% CI = 1.11-6.32). The OR for after practice change was 3.02 (95% CI = 1.34-6.80).

The remainder of the risk factors were examined as an independent variable in separate models. There was no significant association between the risk factors of prior UTI, neoplasm/obstruction, hypertension, or renal transplant and antibiotic usage (Table 8).

Discussion

Although the sample size was small, the analyses suggest that implementation of the practice change did not have an effect on admission for infection rates or outpatient infection rates. These results contribute to the evidence and support the evidence-based guidance that administering a prophylactic antibiotic to routine exchange patients with a low risk of acquiring a PCN-related infection has no marked effect on their chance of acquiring an infection (Cochran et al., 1991; Venkatesen et al., 2010). When the data were stratified by before and after practice change, the number of risk factors present was a significant predictor of antibiotic therapy.

We expected that there would be an increase in the likelihood of infection based on having a higher number of risk factors, but it was

Table 8
Analysis of generalized estimating equation–derived odds ratios for antibiotic usage by low-/high-risk and continuous number of risk factors

Exposure	Antibiotic given n = 337[1]	No antibiotic given n = 156[2]	Crude OR (95% CI)	Adjusted OR (95% CI)
Risk level				
Low risk[3]	75 (15%)[7]	40 (4%)	1.0 (ref)	p < .00
High risk[4]	262 (53%)	116 (23%)	1.09 (0.58–2.06)	1.09 (0.56–2.12)
Before practice change[5]	–	–	–	1.17 (0.86–1.58)
After practice change[6]	–	–	–	1.56 (1.19–2.04)
Type II diabetes				
Presence	91 (18%)	18 (4%)	2.71 (1.46–5.03)	2.88 (1.54–5.39)
No presence	246 (50%)	138 (28%)	–	–
Before practice change	–	–	–	2.65 (1.12–6.32)
After practice change	–	–	–	3.02 (1.34–6.80)
Previous UTI				
Presence	265 (53%)	115 (23%)	1.36 (0.76–2.41)	1.29 (0.73–2.28)
No presence	72 (15%)	41 (8%)	–	–
Before practice change	–	–	–	0.88 (0.33–2.37)
After practice change	–	–	–	1.33 (0.70–2.55)
Neoplasm/other obstruction				
Presence	231 (47%)	112 (23%)	0.83 (0.46–1.50)	0.80 (0.44–1.45)
No presence	106 (22%)	44 (9%)	–	–
Before practice change	–	–	–	0.79 (0.33–1.92)
After practice change	–	–	–	0.95 (0.49–1.83)
Hypertension				
Presence	203 (41%)	82 (17%)	1.32 (0.76–2.30)	1.44 (0.82–2.55)
No presence	134 (27%)	74 (15%)	–	–
Before practice change	–	–	–	1.32 (0.55–3.13)
After practice change	–	–	–	1.85 (0.95–3.61)
Renal transplant				
Presence	55 (11%)	9 (2%)	3.04 (1.46–6.33)	2.88 (1.38–6.03)
No presence	282 (57%)	147 (29%)	–	–
Before practice change	–	–	–	1.44 (0.60–3.50)
After practice change	–	–	–	3.80 (1.29–11.18)

CI = confidence interval; OR = odds ratio; PCN = percutaneous nephrostomy.
[1] Number of events (procedures) where an antibiotic was administered.
[2] Number of events where an antibiotic was not administered.
[3] Low risk of infection is defined as having 0 to 1 of the 5 risk factors.
[4] High risk of infection is defined as having 2-5 of the 5 risk factors.
[5] Continuous variable of 0–5 risk factors of PCN-related infection stratified by practice change.
[6] Continuous variable of 0-5 risk factors of PCN-related infection stratified by practice change.
[7] n and % values calculated based on total number of events in data set (493).

surprising to see a high OR of 1.9, indicating that for each additional categorical risk factor, there was a 90 percent increase in the odds of being admitted for infection. In addition, certain risk factors did show more clinical significance than others, in terms of being associated with administration of an antibiotic. The results of the final model provided ORs that showed no significance before the practice change and significance after the practice change. This indicated that after the practice change, there were greater odds of being given an antibiotic for every increase in the number of risk factors that patients had in their history. However, we cannot make a statement of significance regarding the risk level (low or high) being a predictor of antibiotic therapy, because the sample size was too small. An adequately powered research study could be used to explore this association.

The relationship between a patient's number of risk factors and odds of admission for infection was the same regardless of whether the procedure took place before or after the practice change.

Gender/Sex

Our findings indicated that several clinical demographics had a relationship on risk level of infection, to include higher levels of age, male gender, and nonwhite ethnicity. As 91% (n = 115) of the patients were residents of South Carolina (Appendix D), these demographics were compared with census data for additional insight. The percentage of high-risk male patients was 43% (n = 54), and the percentage of high-risk female patients was 27% (n = 35). Overall, there were more male patients (n = 66) in the sample size than females (n = 60), but this difference was only a slightly higher value. In adult inpatients admitted to acute care, male sex was noted to be an independent predictor (OR = 2.76) of catheter-associated bacteriuria (Conway, Liu, Harris, & Larson, 2017). In this sample, 52 (41%) male patients had a history of neoplasm or obstruction compared with 32 females (25%), indicating a relationship between gender and neoplasm/obstruction ($p < .01$). As bladder cancer and prostate cancer are the leading causes of urological malignancies during their advanced stages (Sountoulides, Mykoniatis & Dimasis, 2014), both have a high rate of upper urinary tract obstruction, requiring placement of a PCN or ureteral stent. Other malignant obstructions may be due to colorectal cancer, retroperitoneal tumors, and gynecological malignancies (Bahu et al., 2013; Sountoulides, Mykoniatis & Dimasis, 2014). As prostate cancer is sex specific, 183,529 males receive this diagnosis per year in the United States (The Centers for Disease Control and Prevention, 2015). Although the specific reason for them having this risk factor was not specified in the data set, it is possible that the prevalence of higher rates of cancer in the male sample had an effect on the analysis.

Race

The United States Census Bureau (2017) estimated the following race demographics for the State of South Carolina: 63.8% white and nonwhite (37.15%). Our dataset's racial demographics were similar to the census data, with a higher percentage of white patients (57%) compared with nonwhite patients (43%). Race is associated with overall higher rates of infection in the literature. In a retrospective cohort study consisting of hospital discharge data from 7 states in the country (Mayr, Yende, Linde-Zwirble et al., 2010), there was a 43.7% higher rate of hospitalization infection among black patients, in comparison with white patients (47.3; 95% CI, 47.1-47.4; 34.0; 95% CI, 33.9-34.0; $p < .001$), and blacks had a 67% higher rate of hospitalization for severe sepsis than white patients. Among black patients admitted for infection, there was a higher rate of diabetes (23.6%) and chronic kidney disease (3.5%) compared with white patients admitted for infection (17.8% and 2.6%, respectively). From the same analysis, it was noted that black patients also had a higher rate of postoperative infection rates compared with white patients (adjusted OR = 1.27, 95% CI = 1.15-1.42; $p < .001$). It is not fully understood whether the source of these disparities stem from varied levels of preventative care, complex social determinants, management of chronic illnesses, or inconsistent thresholds of admission criteria (Mayr et al., 2010).

Age

As the health care system in this country faces the challenge of providing effective care to an aging population, we must consider the changing perspective of chronic illness management and increased cancer survival rates. Although the ideal aspiration of conducting PCN exchanges is to transition the patient to eventually no longer needing them (Nelson et al., 2017), this is not always achievable, given the setting of advanced or metastatic illness (Sountoulides, Mykoniatis & Dimasis, 2014). The average age of all patients in the data set was 60.42 (±15.24; $p < .01$), which was only marginally lower than the average age of high-risk patients (62 years ± 13.83) and higher than the average low-risk age of 56.84 (±17.89). The age variable served as a covariate in the inferential analysis, indicating that age likely does have a relationship with risk of admission for infection.

Risk Factors

The results showed that all five of the factors were independently associated with whether an antibiotic was given to a patient or not. Several of these risk factors may contribute to an increased chance of being immunocompromised, or they can negatively affect the clearance of the renal collecting system (Bahu et al., 2013; Venkatesen et al., 2010). In patients with a history of cancer who underwent nephrostomy exchanges, the use of prophylactic antibiotics did not have a significant effect in preventing asymptomatic bacteriuria or pyelonephritis (Bahu et al., 2013). This suggests the risk factor of cancer may result in these patients having an increased chance of infection (Bahu et al., 2013) that cannot be managed with the present antimicrobial therapies. The presence of type II diabetes was a predictor of antibiotic administration in our model, and the guidelines from SIR indicate that it is a risk factor, but one study suggests that its presence had no significant effect on rates of infection (Bahu et al., 2013). In the same chart review, previous history of UTI was also found to be a risk factor for development of pyelonephritis in patients receiving a PCN exchange (Bahu et al., 2013). Patients undergoing a urinary tract procedure have a 2.70 OR of acquiring a catheter-associated bacteriuria (Conway et al., 2016) as an inpatient, and our results support that independent risk factors and even the number of risk factors present could also affect the chances of acquiring an infection. The results from the GEE-derived model support the evidence that patients with a higher number of these independent risk factors have an increased chance of admission for infection after routine PCN exchange (Bahu et al., 2013; Venkatesen et al., 2010).

The disparity gaps prevalent in the demographic data and in the literature suggest that these factors should be considered when providing care, particularly with vulnerable populations. In addition, management of these patient's chronic risk factors is also enmeshed within their present socioeconomic condition (Mayr et al., 2010). Addressing the social disparities that are present among high-risk groups would likely require intervention from a local level initiative. Clinical interventions could involve more effective management of chronic illnesses and comorbidities, improved adherence to vaccination schedules, mindful consideration of host immunity, and use of effective medical therapies (Mayr et al., 2010).

Limitations

This project had several limitations, particularly regarding the sample size and quality of data. By conducting a retrospective analysis, we understood that the quality level of the data was less likely to be controlled. Although the sample size of 493 events was similar to our predicted estimate of the size of the final data set, several of the variables' sample sizes were too small to be used sufficiently in a statistical analysis. Many of the predictive models run gave results that indicated there was a clinical significance in the data, but a larger sample size may have revealed statistical significance. It was a challenge to collect the most feasibly accurate and complete infection criteria possible, given the limitations to clinical data access outside of this institution's network. Initially, it was planned that clinical data and collected culture results would be used to designate the presence of infection. Most of these variables did not include a sufficient sample size for them to be effectively included in the predictive segment of the analysis.

Separating the PCN exchange data from similar procedures in the EMR was a more complicated process than initially anticipated. Some variance between the PCN exchange events was anticipated, where other interventions could have taken place mid procedure. If a patient was scheduled for a PCN exchange and the PCN was then removed or converted to a different kind of catheter or stent, this event was not included in the data set.

Conclusions

Our results continue to support the previous evidence and guidelines on the topic of antibiotic administration for patients receiving PCN exchanges. Most of the evidence that supports SIR's 2010 guidelines and the society's recently published updates on parameters for prophylactic antibiotics (Chehab et al., 2018) is from over 2 decades ago. Since then, more recent researchers have stated the need for increased review of antibiotic administration guidelines within a more current clinical environment (Bahu et al., 2013; Murtha et al., 2017).

The OR of 1.56 and the precise CI for the stratified data after the practice change analysis indicate that after implementation of the policy change, risk level was more likely to affect whether or not a perioperative antibiotic was given. The analysis indicated that there was an association between risk factors and the increased likelihood of a patient either being admitted or receiving outpatient treatment for a PCN-related infection. The elevated ORs indicate that subjects with a history of type II diabetes had a significant relationship with being given a perioperative antibiotic.

Although the results from this quality improvement project are limited in terms of influence, we believe the evidence bolsters the importance of prudent evaluation of clinical interventions. Our results also highlight the need for personalized approaches, taking into account a patient's age, gender, race, and risk factors when evaluating for antibiotic administration for PCN exchanges.

Supplemental data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jradnu.2019.07.004.

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