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Prophylactic Antibiotic Use in Female Patients With Pelvic Floor Reconstructive Surgery: A Retrospective Comparative Effectiveness Study

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Abstract

Problem: The purpose of this project was to determine the most effective prophylactic antibiotic to decrease the number of patients who have urinary tract infections (UTIs) after pelvic floor reconstructive surgery in a gynecological reconstructive surgery practice.

Methods: This was a retrospective chart review from 2015-2017 that included 732 subjects from a single practice. All patients underwent pelvic floor reconstructive surgery, with or without a midurethral sling placed. Patients also had a catheter and vaginal packing postoperatively. Patients who had a culture-proven UTI within the six-week postoperative period were noted.

Results: There were less UTIs ($\chi 2 = 12.119$, df = 1, P = .000) in the fluoroquinolone cohort than in the other antibiotic cohort. Additionally, it was found that there was a statistically significant increase in the prevalence of UTIs in those who had amoxicillin clavulanic acid (Augmentin) vs. those who had levofloxacin (Levaquin) ($\chi 2 = 13.102$, df = 2, P = .001). Vulvovaginal candidiasis reported symptom findings also proved significant, as the Augmentin cohort had more complaints than any other antibiotic group ($\chi 2 = 30.010$, df = 10, P = .001).

Implications: The project findings reinforced the need for prudence when considering prophylactic antibiotic use in the postoperative period. While more research is needed to explore antibiotic treatment options further, the data collected and analyzed provided novel evidence to guide the decrease of unwanted UTIs in this population. Most notably, this project proved Augmentin is not the ideal choice for UTI prophylaxis in this

population because of the high number of proven UTIs found, and the statistically high prevalence of vulvovaginal candidiasis-related complaints.

Dedication and Acknowledgements

I would like to dedicate this project to my loving husband, Micah, and my parents Ron and Sherry Walter. Without them, I would not have completed this journey. Their love, comfort, and encouragement has truly meant everything to me.

I am extremely grateful for the support of Dr. Sara Wood, Dr. Nancy Magnuson, Dr. Roxanne Vandermause, Dr. Andrew Futterman, and Dr. Annah Bender. Their feedback and guidance throughout this process has greatly impacted the success of the project and significance of our findings.

Introduction

Approximately 200,000 women undergo surgery for pelvic floor reconstruction each year (Boyles, Weber, & Meyn, 2003). Over 10 percent of women are expected to seek surgical intervention for pelvic floor prolapse or incontinence by the age of 80 (Sutkin, Alperin, Meyn, Wiesenfeld, Ellison, & Zyczynski, 2010). The most common morbidity associated with pelvic floor reconstructive and incontinence surgery is urinary tract infections (UTIs) (Sutkin et al., 2010). Pelvic floor reconstructive surgery requires manipulation of instruments at and near the urethra. While the bladder and urethra are clean, the vagina and anus are not; all structures are close in proximity, leading to potential contamination, offering support to the relevance of this topic. Another factor that impacts UTIs in this population is the risk for incomplete bladder emptying postoperatively. Whether by denervation of the bladder secondary to a hysterectomy, postoperative swelling, narcotics and anesthetics, or midurethral sling placement, women may develop urinary retention, which increases their chances of developing a UTI (Sutkin et al., 2010).

Lastly, the use of a catheter raises the risk of a UTI postoperatively. Seventy to eighty percent of complicated UTIs in the United States annually are associated with indwelling urinary catheters, which accounts for one million UTIs per year (Flores-Mireles, Walker, Caparon, & Hultgren, 2015). Female patients undergoing pelvic floor reconstructive surgery may have a catheter placed in surgery that remains indwelling for several days postoperatively. For this reason, prophylactic antibiotics are often prescribed to prevent UTI occurrence in the postoperative period (defined as *six weeks*).

The purpose of this project was to determine the most effective prophylactic antibiotic to decrease the number of patients who have UTIs after pelvic floor reconstructive surgery in a gynecological reconstructive surgery practice. This retrospective chart review yields data on female pelvic floor reconstructive surgery patients who have a catheter, and compares effectiveness of prophylactic treatment of fluoroquinolones versus other antibiotics.

Literature Review

The literature review process relied on several search engines, including Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane, PubMed, National Center for Biotechnology Information (NCBI), and EBSCOhost for pertinent evidence-based research data. The peer-reviewed articles were examined to support data found. There were many keywords that demonstrated their use in the search for empirical literature, including UTIs, postoperative complications, pelvic floor reconstructive surgery, fluoroquinolones, prophylactic use of antibiotics, vaginal surgery, anti-incontinence surgery, midurethral sling surgery, catheter-associated urinary tract infections, and antibiotic resistance. The data collected was largely from the past five years. Limitations in the amount of data found required broadening the search, including references dating back to 2003.

Inclusion criteria determined for targeting the researched population for this project include the following: (a) adult, female participants, (b) who have undergone at least one of the following, cystocele repair with anterior colporrhaphy, rectocele repair with posterior colporrhaphy, enterocele repair with posterior colporrhaphy, or sacrospinous colpopexy. Patients must also (c) have a catheter (transurethral catheter or

suprapubic tube), (d) and vaginal packing. Criterion that exclude potential patients are (a) those that had any mesh removed at the time of pelvic floor reconstructive surgery, and (b) those who exclusively had a colpoperineorrhaphy. Patients with prior histories of recurrent UTIs, those who are postmenopausal, and patients who additionally have a urethral sling were also noted, as those variables may impact results. All UTIs were proven by straight cath culture in order to be included in the evidence. Secondary endpoints that were collected include: self reports of vulvovaginal candidiasis (vaginal yeast) infections, confirmed clostridium difficile cases, and how many days from surgery those incidents occurred.

The theoretical framework for this project was based on a model developed by Marita G. Titler that provides foundation and establishes necessary guidance. Titler developed the IOWA Model which guided the evidence-based research performed and supports its use appropriately in practice (Brown, 2014). The steps to this framework are: (1) determine the issue/problem, (2) decide on a plan, (3) create a team, (4) identify evidence, (5) analyze the evidence, (6) determine conclusions from the evidence, (7) navigate change, (8) decide if change is applicable to practice, (9) implement the change, and (10) disseminate results (Brown, 2014). The need for structure to direct the course of this project prompted a search for an ideal framework. The IOWA model presents ten clear elements that propelled the project from inception through completion.

The focused problem for this project is the prevalence of UTIs postoperatively. Identification of antibiotic effectiveness in preventing UTIs is the second element from the selected framework. This quality improvement project was conducted by a women's health nurse practitioner, with the support of an assembled team that included a

urogynecologist/gynecological reconstructive surgeon, a doctor of science in nursing/family nurse practitioner, an OB/GYN resident physician, and a doctor of philosophy in nursing. A thorough review of literature, collection of data, analysis, and establishment of conclusions took place prior to determining change implementation, and circulation of the findings.

Review of the current literature revealed a lack of evidence on the project topic. In regard to occurrences of postoperative UTIs, data varied substantially. Findings from extant research in this area are equivocal. There are no consistent conclusive results that have an answer to the purpose of this project.

According to Mueller et al. (2016), in examining postoperative patients after pelvic floor reconstructive surgery, an observational study concluded that 66% of postoperative complications occurred in the first two weeks after surgery and 46% of those complications were UTIs. The research included a sample size of 396 women; 125 of the women had postoperative complications (Mueller et al., 2016). Guldberg et al. (2014) studied a larger population of 2,151 women after having surgery for urinary incontinence, rather than pelvic floor reconstructive surgery. The findings showed that within the first 60 days postoperatively, 26% of patients who had a history of UTIs redeemed an antibiotic prescription for a possible UTI (Guldberg et al., 2014). Only 11% of preoperative non-users of antibiotics to treat UTIs, which was a total of 182 patients, received a prescription for antibiotics for a possible UTI during the 60 days immediately following surgery. This evidence supports the plan to note all patients with prior UTIs.

A journal article published in 2008 reviewing relevant randomized controlled trials (RCTs) evaluated the UTI prevalence after pelvic floor operations. The findings

from the review of nineteen studies gathered that incidences of UTIs for those receiving placebos after pelvic floor surgery ranged from 10-64%. (Falagas, Athanasiou, Iavazzo, Tokas, & Antsaklis, 2008). Alternatively, the UTI occurrence was 0-15% in those who received cephalosporins, which was identified as being the optimal regimen in UTI prevention after pelvic floor surgery (Falagas et al., 2008). Falagas et al. (2008) also concluded rates of UTIs were 13.6% higher in those treated with ampicillin/sulbactam, 27.2% with ciprofloxacin, 10-22.7% with metronidazole, 20% with metronidazole plus ampicillin, and 28% higher with cotrimoxazole. A study by Swartz et al. (2010), reported that there was no significant difference in UTI occurrence after midurethral sling surgery in those who received prophylactic antibiotics (3 days of cephalexin, fluoroquinolone, or doxycycline), and those who received no antibiotic. Although there was not a urine culture for every recorded UTI, the results revealed no difference ($P = 0.03$), except that there were more low-grade adverse events relating to antibiotic use in those in the prophylactic antibiotic cohort (Swartz et al., 2010).

While the information accumulated may cause presumptions, it is important to acknowledge some of the weaknesses in the literature. Many of the studies are examining different types of surgeries, including generalized pelvic floor surgery, anti-incontinence surgery, and reconstructive vaginal surgery. All the variations of what surgery was performed, how it was performed, who performed it and who it was performed on are all considerations that have significance. Likewise, not all the UTIs reported in the documentation were confirmed by urine culture. Some of the reported UTIs were based on self-report and others were assumed from urinalysis for bacteria, nitrates, and leukocyte esterase. While symptoms such as urinary frequency, urgency, and burning on

urination may be present, that is not definitive of an infection. Abnormal urinalysis results can appear as a result of the collection technique and, by controlling these variables, firm evidence can result. Furthermore, not all patients studied had a catheter, or had a catheter for at least 7 days.

In this review, antibiotics and their strengths and weaknesses were researched and observed more closely. A randomized controlled trial assessing nitrofurantoin (Macrobid) prophylaxis in catheterized patients after pelvic reconstructive surgery with 159 participants concluded that prophylactic Macrobid daily does not reduce the risk for postoperative UTIs (Dieter et al., 2014). Dieter et al. (2014) looked at the three weeks immediately following surgery; results indicated 22% of the 81 patients receiving Macrobid and 13% of the 78 patients given the placebo had UTIs, either suspected or culture-proven. Conversely, Jackson et al., (2013) found that a three-day course of prophylactic Macrobid after surgery for midurethral sling placement was significant (P = .04) to decrease postoperative UTIs. The randomized, double-blinded, placebo-controlled, multicenter trial enrolled 149 subjects and measured UTI prevalence by meeting certain symptomatology; UTIs were not culture-proven (Jackson et al., 2013). Moreover, another study looked at 449 subjects, 211 randomized to Macrobid, and 224 randomized to placebo, after pelvic organ prolapse and/or urinary incontinence surgery with suprapubic catheterization (Rogers et al., 2004). Findings included a significant decrease in culture-proven UTIs in those who received Macrobid (P = 0.002) at the time of suprapubic tube removal, but not at the 6-8-week postoperative check-up (Rogers et al., 2004).

Sutkin et al. (2010) concluded that prolonged duration of catheterization (≥10 days after surgery) is significant to cause UTIs, despite antibiotic prophylaxis. In a retrospective chart review of 394 women who had undergone surgery for pelvic floor prolapse or stress incontinence, it was found that there was a significantly higher prevalence of UTIs in the six-week postoperative period the longer there was a catheter in, or clean intermittent self-catheterization (CSIC) was practiced (Sutkin et al., 2010).

While many limitations have been acknowledged, there are also strengths present. By recognizing sensitivities, a better understanding of the functioning of antibiotics can be assessed to provide sufficient prophylactic outcomes for patients. The data collected has suggested that postoperative complications, including UTIs, will likely materialize shortly after surgery, rather than weeks out; this evidence can be compared to future data collection to determine relevance. With the nature of pelvic floor reconstructive surgery, the anatomical location of the urethra and its adjacency to other contaminated structures pose increased risk to the patients' likelihood of developing a UTI.

Methods

The purpose for this project is based on the postulate that comparing postoperative antibiotic effectiveness will result in action to reduce the number of postoperative UTIs. The approach was a retrospective design that, by utilizing evidence-based practice and data collection, has the potential to implement change. The goal of achieving the greatest outcome for the population researched, with the least amount of adverse effects possible, is of highest priority. The setting for the project was a healthcare facility in Saint Louis, Missouri. Approximately two years of data collectively was synthesized from a convenience sample of 732 female patients who underwent pelvic

floor reconstructive surgery in the years 2015 through 2017. All patients included had pelvic floor reconstructive surgery, and also may or may not have a midurethral sling placed for stress urinary incontinence. Patients also had a temporary catheter (transurethral or suprapubic) and vaginal packing postoperatively. Patients that have additionally undergone any type of mesh removal, and those having only a colpoperineorrhaphy, were not included in the dataset.

Institutional Review Board training for the facility setting and for the University of Missouri Saint Louis was obtained. Data collection occurred from the electronic health records (EHR) system as a retrospective medical record review; every patient was assigned a number to de-identify personal information. A master log with patient names and assigned numbers was protected and maintained at the healthcare facility. Data collected included: age of subject at time of surgery, type of reconstructive surgery the subject underwent, postoperative antibiotic prescribed, length of time the catheter was in, if they had a proven UTI infection during the postoperative period, how many days after surgery the UTI occurred, the bacteria responsible for the UTI, the antibiotics resistance and susceptibility, if the patient is postmenopausal, if the patient has a prior history of UTIs, and if the patient has a urethral sling. All data collected was compiled on a spreadsheet for analysis. The data was then converted into an SPSS spreadsheet and tests including frequencies and chi-squares were performed to analyze the information.

Results

Several outcomes were identified through this process. When comparing effectiveness of antibiotics for UTI prophylaxis, it became clear that certain antibiotics were more adequate. Out of 732 patients, 315 took a fluoroquinolone (Levaquin = 312;

Ciprofloxacin = 3), 414 took either Augmentin (n = 326), Bactrim (n = 38), or Macrobid (n = 50), and 3 subjects received no antibiotic. Only 4 subjects who took a fluoroquinolone got a UTI. Twenty-seven subjects got a UTI after taking one of the other antibiotics; this finding was statistically significant ($\chi 2 = 12.119$, df = 1, P = .000). Augmentin users had the highest prevalence of postoperative UTIs (n = 23). This finding was also statistically significant at $\chi 2 = 11.378$, df = 1, P = 0.001. When then comparing Augmentin to those taking fluoroquinolones, the same significant result was found. After breaking down the analysis to the two largest antibiotic groups prescribed in the practice, further outcomes were explored between the Augmentin and Levaquin cohorts (see Appendix A). The Levaquin users (n = 312) had 4 UTIs and the Augmentin users (n = 326) had 23 UTIs. This finding was statistically significant ($\chi 2 = 13.102$, df = 2, P = .001). Further examination of the demographics of the Levaquin and Augmentin cohorts can be found in Appendix A.

Other parallels explored included examining the possible correlation between proven UTIs and postmenopausal status, prior history of UTIs, having a current mid-urethral sling, having a hysterectomy as part of their surgery, and the length of time the catheter was in. Of note, there was significance in those with prior histories of UTIs, those with a mid-urethral sling, and those with a catheter in longer than 10 days (see Appendix B). When considering the length of time the catheter was in, only 11 UTIs occurred within 10 days of surgery, whereas 20 UTIs were confirmed in those who had the catheter longer than 10 days. Of the 31 UTIs identified, Escherichia coli was the responsible bacteria for 10 of the infections (32.3%). Then, after acknowledging the most frequent UTI-causing bacteria, it led to the analysis of the most resistant and susceptible

antibiotic choices for the UTIs. The three antibiotics that the 31 infections were most frequently susceptible to were Tobramycin (n = 28), Gentamicin (n = 29), and Cefepime (n = 26). Of the antibiotics that were prescribed postoperatively, here is the bacteria susceptible[s] vs. resistant[r] breakdown: Levaquin (n = 24[s]/2[r]), Augmentin (n = 15[s]/3[r]), Bactrim (n = 17[s]/5[r]), Macrobid (n = 21[s]/2[r]), and Ciprofloxacin (n = 23[s]/5[r]). Conversely, the antibiotics with the highest frequency of resistance were Ampicillin (n = 12) and Tetracycline (n = 7).

Lastly, the self-reports of vulvovaginal candidiasis infections requiring medicinal treatment and the incidents of clostridium difficile were investigated. Of the population researched, there were no confirmed cases of clostridium difficile. There were however 48 subjects treated for a vulvovaginal candidiasis infection. Of the 48 yeast episodes, there was a statistical finding of $\chi 2 = 30.010$, df = 10, P = .001 of those who had taken Augmentin postoperatively (see Appendix D).

Discussion

The findings from this study suggested that fluoroquinolone use for the prophylactic treatment of UTIs is superior to other antibiotics. More specifically, Levaquin is a preferred treatment, in regard to the prevention of UTIs and shows a fairly small risk for vulvovaginal candidiasis infections, when compared to Augmentin. Although other antibiotics were included, as well as 3 subjects that received no antibiotic, the proportion of subjects given Augmentin and Levaquin was far greater. Then, comparing those two cohorts, we must take into consideration the potential differences in the populations that could contribute to these findings. When matching the populations side-by-side, it was evident only few differences were found.

When considering the implications these results have on practice, it is important to weigh the risks vs benefits of the antibiotic options. While Levaquin had a significantly lower rate of postoperative UTIs, it does have a black box warning for tendon rupture (Tanne, 2008). Evidence from this study points to the superiority of Levaquin, but other risks must be calculated when prescribing is considered. Augmentin was identified as having a poor ability to prevent UTIs and a high incidence of vulvovaginal candidiasis complaints, leading to the inference that it may not be the ideal postoperative treatment of choice either. It would be beneficial to conduct future research comparing the Bactrim and Macrobid more closely, because this project had limited patients on these antibiotics. However, from the narrow cohorts investigated, the drawbacks seemed low.

Conclusion

This project demonstrated that there are both advantages and disadvantages to varying antibiotics in the postoperative period. In order to establish the greatest care for this patient population, clinicians must place emphasis on the preventative abilities of individual antibiotics relating to UTIs, as well as the negative effects of each medication. The evidence needs to be compiled and considered when making changes or maintaining current treatment regimens. This study showed a large difference in the prevention capabilities between Levaquin and Augmentin, but data was limited on Ciprofloxacin, Macrobid, and Bactrim. While acknowledging the robust data from the fluoroquinolone class, it must also be noted that this is not the only data to consider when prescribing a prophylactic antibiotic to a patient. The black box warning, however rare, is cautionary and must also be weighed when choosing the proper treatment for an individual.

The findings support the need to amend the prescribing patterns to avoid Augmentin and consider more frequent prescribing of Bactrim and Macrobid. Discriminating amongst the high and low risk factors to prevent postoperative UTIs in this population is also key. It would be appropriate to consider using Levaquin in populations found to be at a higher risk for a postoperative UTI, including those with a prior history of UTIs and those who plan to have a midurethral sling/suprapubic tube placed for stress urinary incontinence.

Ultimately, much light was shed on the pitfalls of some antibiotic choices, most notably Augmentin, and leads to the need for further research to identify the optimal choice for UTI prevention in the pelvic floor reconstructive surgical patient.

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Appendices

Appendix A

Fluoroquinolones vs. Other Antibiotics - Cohort Comparison			
Variables	Fluoroquinolones	Other Antibiotic	P-Value
Postmenopausal	243/315 (77.1%)	312/414 (75.4%)	.576
Midurethral Sling/SPT	153/315 (48.6%)	186/414 (44.9%)	.326
Hysterectomy	157/315 (49.8%)	204/414 (49.3%)	.880
History of UTIs	78/315 (24.8%)	108/414 (26.1%)	.684
Catheter >10 days	93/315 (29.5%)	111/414 (26.8%)	.419
The p-value was set to <.05.			

Levaquin vs. Augmentin - Proven UTI Crosstabulation			
Antibiotic	Proven UTI		Total
	Yes	No	
Other	4	90	94
Levaquin	4	308	312
Augmentin	23	303	326
Total	31	701	732

Chi-Square Tests - Levaquin vs. Augmentin			
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	13.102[a]	2	.001
Likelihood Ratio	14.512	2	.001
Number of Valid Cases	732		

Levaquin vs. Augmentin - Cohort Comparison			
Variables	Levaquin	Augmentin	P-Value
Postmenopausal	240/312 (76.9%)	243/326 (74.5%)	.716
Midurethral Sling/SPT	151/312 (48.4%)	141/326 (43.3%)	.270
Hysterectomy	157/312 (50.3%)	162/326 (49.7%)	.734
History of UTIs	76/312 (24.4%)	75/326 (23.0%)	.009*
Catheter >10 days	93/312 (29.8%)	78/326 (23.9%)	.030*
These are individual chi-squares. The p-value was set to <.05. *Denotes significant finding			

Appendix B

Association of UTIs with Postoperative Antibiotics and Other Factors		
Variable	Chi-Square	P-Value
Prior History of UTIs (n = 17)	14.603	< .0001*
Catheter in Longer than 10 days (n = 20)	21.402	< .0001*
Current Midurethral Sling (n = 22)	7.824	.005*
Post-op Antibiotic = Augmentin (n = 23)	11.378	.001*
Postmenopausal (n = 25)	.390	.532
Surgery Included a Hysterectomy (n = 15)	.019	.891
These are individual chi-squares. The df was 1 for each of these crosstabulations. The p-value was set to <.05. *Denotes significant finding		

Appendix C

Transurethral vs. Suprapubic - Cohort Comparison			
Variable	Transurethral n = 392 (53.6%)	Suprapubic N = 340 (46.4%)	P-Value
Age (Years)	61 (29-86)	59 (28-85)	.466
Postmenopausal	307/392 (78.3%)	249/340 (73.2%)	.109
Prior history of UTIs	100/392 (25.5%)	87/340 (25.6%)	.981
Incidence of UTIs	9/392 (2.3%)	22/340 (6.5%)	.005*
Catheter > 10 days	2/392 (0.5%)	203/340 (59.7%)	< .0001*
These are individual chi-squares. The p-value was set to <.05. *Denotes significant finding			

Appendix D

Vulvovaginal Candidiasis Crosstabulation			
Postoperative Antibiotic	Vaginal Yeast Infection		Total
	Yes	No	
Levaquin	7	305	312
Augmentin	39	287	326
Bactrim	0	38	38
Ciprofloxacin	0	3	3
Macrobid	2	48	50
Total	48	684	732

Chi-Square Tests - Vulvovaginal Candidiasis Infections			
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	30.010[a]	10	.001
a. 12 cells (66.7%) have expected count less than 5. The minimum expected count is .00.			