



Single versus multi-dose antibiotic prophylaxis for pelvic organ prolapse surgery with graft/mesh



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ABSTRACT

Objective: To compare the risk of postoperative infections in women who receive single-dose versus multi-dose prophylactic antibiotic regimen during prolapse surgery with mesh/graft.

Study design: Retrospective cohort study of 460 women who underwent prolapse surgery with mesh/graft. We compared women who received a single-dose prophylactic antibiotic regimen to those who received a multi-dose regimen. The primary outcome was the presence of any postoperative infection, defined as the presence of any of the following infections: urinary tract infection (UTI), fever, wound or trocar site infection, mesh infection or pelvic abscess. Associations between prophylactic antibiotic regimen and postoperative infections were estimated using univariable and multivariable analysis.

Results: Rate of any postoperative infection was similar between the single- and multi-dose groups (19% vs. 16%, $p = 0.50$). Rate of UTI was significantly higher in the single-dose compared to the multi-dose group (13% vs. 7%, $p = 0.03$). On multivariable analysis, after controlling for vaginal route of surgery, the odds of UTI was not significantly different between groups (OR 0.59, 95% CI 0.27, 1.26).

Conclusion: A single-dose antibiotic regimen is sufficient for prophylaxis against postoperative infections in women undergoing prolapse surgery with graft/mesh.

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Introduction

Approximately one-third of surgeries performed for pelvic organ prolapse are augmented with graft or mesh material [1]. The United States Food and Drug Administration (FDA) lists infections as one of the most frequent adverse events reported after mesh-augmented prolapse surgery [2]. Infections reported after prolapse repair using mesh or graft include urinary tract infection (UTI) with reported rates of 3.5–31% [3–6], wound infections (3–6%) [3,6], vaginal infections (0–18.4%) [4,7], mesh infections (1%) [8], and pelvic infections and abscess (1–2%) [9,10].

Antibiotic prophylaxis is widely accepted as a means of decreasing postoperative infectious morbidity and is recommended for surgery in women undergoing prolapse surgery with mesh. Based on data from the vaginal hysterectomy and orthopedic literature [11,12], the American Urologic Association (AUA) recommends antimicrobial prophylaxis for 24 h or less at the time of “vaginal urologic surgery” and “surgery involving

implanted prosthesis” [13]. The American College of Obstetrics and Gynecology (ACOG) recommends a single dose of perioperative antibiotic for “urogynecology procedures, including those involving mesh” [14]. However, the optimal duration of antibiotics prophylaxis for women undergoing prolapse surgery is not known. Studies comparing single- to multi-dose antibiotic prophylaxis regimens in women undergoing prolapse surgery with mesh are lacking and it is unclear if these women have any additional benefit from multi-dose as compared to single-dose regimens.

The aim of this study was to compare the risk of postoperative infections in women who receive single-dose versus multi-dose prophylactic antibiotic regimens during prolapse surgery augmented with mesh/graft.

Material and methods

Following approval by the institutional review board at the University of Pennsylvania, we conducted a retrospective cohort study of women who had undergone prolapse surgery between January 2008 and March 2012 in the University of Pennsylvania Health System. Eligible subjects were identified by Current Procedural Terminology codes for prolapse surgeries in which mesh or graft could have been used (anterior colporrhaphy, posterior colporrhaphy, combined anterior–posterior colporrhaphy,

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combined anterior–posterior colporrhaphy with enterocele repair, insertion of mesh for repair of pelvic floor defect, vaginal repair of enterocele, extra-peritoneal vaginal colpopexy, intra-peritoneal vaginal colpopexy, abdominal sacrocolpopexy, laparoscopic sacrocolpopexy). We were purposefully broad in our search to minimize missing any cases. Inclusion criteria were surgical repair of prolapse with mesh or graft as documented on the operative report, administration of perioperative antibiotics, and follow up of at least 6 weeks after surgery. We excluded women with prolapse surgery in which mesh was only used for anti-incontinence procedure such as sling, incomplete documentation regarding antibiotic administration, women with less than 6-weeks postoperative follow up, and women who underwent concomitant non-gynecologic surgery.

Preoperative data recorded included age, body mass index, race, parity, smoking status, hormone use, medical co-morbidities, preoperative prolapse stage, and preoperative post-void residual volume. Surgical and perioperative data including surgical approach, procedures performed, length of surgery, antibiotic choice and regimen, were also recorded. Surgical approach was classified as abdominal (robotic or open) or vaginal. A co-incident vaginal procedure was defined as a vaginal procedure (such as sling or posterior repair) in a patient who had undergone abdominal prolapse surgery. Postoperative information on duration of indwelling catheter, number of voiding trials, prescription of antibiotic prophylaxis for prolonged indwelling catheter, and postoperative complications were extracted.

Women received either a single- or multi-dose perioperative antibiotic regimen at the time of surgery based on the surgeon's usual practice. A single-dose regimen was defined as the administration of a dose of antibiotics within 1 h of incision and no other antibiotic given in the postoperative period except in the presence of a diagnosed infection. Patients who received one additional dose of antibiotics in cases that exceed 4 h in length were included within the single-dose group. A multi-dose regimen was defined as administration of a dose of antibiotics within 1 h of incision followed by additional doses in the postoperative period in the absence of a clinically diagnosed infection.

Our primary outcome was the presence of any postoperative infection, defined as the presence of any one of the following: UTI, fever, wound or trocar site infection, mesh infection, or pelvic abscess. A UTI was defined as the documentation of irritative voiding symptoms such as dysuria, worsening urgency, frequency, or nocturia requiring antibiotics treatment in the 6-week period following surgery. Urinalysis and urine culture data were collected when available. Postoperative fever was defined as documentation of a temperature greater than 101 F OR a temperature greater than 100.4 on two occasions at least 4 h apart, excluding the first 24 h postoperative, within 6 weeks of surgery [15]. The diagnosis of a wound or trocar site infection was based on documentation of examination findings by a physician or nurse and antibiotic treatment for wound infection within the 6-week postoperative period. The diagnosis of mesh infection was based on the documentation of signs of local tenderness at the site of mesh insertion with or without the presence of redness or purulent discharge within the 6-week postoperative period [16].

We compared demographic data between the single- and multi-dose groups using Pearson chi-squared tests for categorical variables and student's *t*-tests or Wilcoxon rank sum test as appropriate for continuous variables. The odds ratio of postoperative infections in the two groups was estimated using univariable and multivariable logistic regression analysis. Baseline characteristics that were significantly different between the two groups were included in our multivariable model as potential confounders. All reported *p*-values were two-sided and *p*-values < 0.05 were considered statistically significant. All data analyses were

performed in STATA 10.1 (Stata Corp., College Station, TX). Prior studies have reported that UTI is the commonest infection in women undergoing prolapse surgery with mesh. The rate of UTI in women undergoing prolapse surgery and who had received a single dose of antibiotics is approximately 10% [6,7,18]. Our retrospective sample would allow us to detect a three-fold reduction in the rate of UTI between the single- and multi-dose groups with power of 80% at a significance level of 0.05.

Results

During the study period, 489 women underwent graft/mesh-augmented prolapse surgery by one of four attending surgeons and met our eligibility criteria. We excluded 4 women due to missing data on antibiotic regimen, 6 were excluded due to less than 6-weeks follow up, and 19 women underwent concomitant non-gynecologic surgery, resulting in 460 records for analysis. Of these, 306 (67%) received a multi-dose regimen and 154 (33%) received a single-dose regimen.

Antibiotics administered included cefazolin alone (77%) or cefazolin plus gentamicin or metronidazole (5%). Women allergic to penicillin or cephalosporins received gentamicin and/or clindamycin (11%), vancomycin (3%), levofloxacin (1%), or doxycycline (<1%). The median number of doses in the multi-dose group was 3 administered during the first 24 h after surgery (range 2–4). Antibiotic dosing regimens (single or multi-dose) administered were based on the surgeon's usual practice and preference. Surgeons 1 and 2 preferred a multi-dose regimen and 88 and 87%, respectively, of their cases received a multi-dose regimen. A hospital-wide policy resulted in a change of practice in December 2011 when they switched uniformly to a single-dose regimen. Surgeons 3 and 4 preferred a single-dose regimen and 90% cases of surgeon 3 and 100% cases of surgeon 4 received a single-dose regimen. In both groups, all patients who were discharged with indwelling foley catheters received prophylactic antibiotics.

Baseline demographic data are presented in Table 1. Age, body mass index, tobacco use, baseline post-void residual, and co-morbid conditions were not significantly different between the two groups. The differences in route of surgery and duration of indwelling catheter reflect individual surgeon practice patterns. Women in the single-dose group had a higher overall prolapse stage, were more likely to have undergone a vaginal or co-incident vaginal procedure for prolapse or incontinence (82% vs. 26%, *p* < .001) and had an indwelling catheter for a significantly longer duration (4.2 ± 4.1 vs. 2.7 ± 2.4 days, *p* < .001) than the multi-dose group. However, the number of voiding trials was similar between the two groups.

Any postoperative infection

Overall, 79/460 (17%) of women were diagnosed with any postoperative infection. The rate of any postoperative infection was similar in women who underwent vaginal and co-incident vaginal procedures compared to those who underwent abdominal procedures alone (20% v, 15%, *p* = 0.18). The risk of postoperative infection was not associated with preoperative prolapse stage or duration of indwelling catheter. The rate of any postoperative infection was similar in the single- and the multi-dose group (19% vs. 16%, *p* = 0.50) (Table 2). The odds of any postoperative infection were not significantly lower than for the multi-dose compared to the single-dose groups (Odds ratio 0.84, 95% CI (0.51, 1.39)).

Urinary tract infection

The commonest reported infection was a UTI (41/460, 9%). Positive urinalysis and urine cultures were documented in 29/41

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