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REVIEW ARTICLE

Antibiotic prophylaxis for selected gynecologic surgeries[☆]

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ABSTRACT

Background: Antibiotic prophylaxis for surgery is commonly used and is recommended by multiple organizations. **Objective:** To critically review gynecology-specific data regarding surgical antibiotic prophylaxis in selected benign gynecologic surgeries. **Search strategy:** MEDLINE and Cochrane databases were searched from inception to July 2010. **Selection criteria:** Randomized controlled trials of benign vaginal, cervical, transcervical, abdominal, or laparoscopic procedures other than hysterectomy comparing prophylactic antibiotic use with placebo or with another antibiotic. Outcomes of interest were postoperative infections, additional treatments, and adverse events. **Data collection and analysis:** In total, 19 trials met the inclusion criteria. Studies were individually assessed for methodologic quality, then grouped by procedure and evaluated for evidence quality. **Main results:** There was no difference in infectious outcome for loop electrosurgical excision, hysteroscopic ablation, or laparoscopy, although evidence quality was poor. Fair evidence supports antibiotic prophylaxis for suction curettage or laparotomy. There were insufficient data regarding vaginal surgery prophylaxis. **Conclusion:** Antibiotic prophylaxis may be beneficial in first-trimester suction curettage and laparotomy. No advantage was found for loop electrosurgical excision, hysteroscopy, or laparoscopic gynecologic surgery. Newer procedures and vaginal surgery lack research and merit study.

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1. Introduction

Antibiotic prophylaxis for gynecologic surgery has become a widely accepted practice for reducing post-surgical complications such as wound infections, vaginal cuff cellulitis, endometritis, urinary tract infections (UTIs), and foreign-body infections. Intravenous medications given shortly before the start of surgery are recommended by many hospitals, accrediting bodies, and national organizations. Indeed, some complications, including UTIs, are being evaluated as markers of quality and qualifiers for payment by insurers and other governing bodies. Although prophylaxis is generally thought to be

safe, unnecessary administration of antibiotics is undesirable because it can result in antibiotic-resistant bacteria, unnecessary cost, adverse reactions, and changes in natural flora [1].

As with any widely accepted practice, antibiotic prophylaxis bears periodic scrutiny regarding the supporting evidence. The collective guidelines available from the American College of Obstetricians and Gynecologists (ACOG) [1] and the Surgical Infection Prevention Project [2] do not necessarily provide uniform guidance to gynecologic surgeons. A recent study indicated that compliance with prophylaxis is incomplete and that local hospital-based guidelines may supersede national guidelines [3]. Furthermore, with the advent of many new surgeries, including minimally invasive procedures and mesh-based surgery, data regarding prophylaxis for these procedures are not well known and merit review.

The aim of the present study was to review the gynecology-specific literature regarding antibiotic prophylaxis to determine the quality of evidence underpinning current guidelines and to identify areas for future study.

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2. Materials and methods

The Society of Gynecologic Surgeons Systematic Review Group (SGS-SRG) comprises practicing gynecologists and is assisted by experts in systematic-review methodology. The antibiotic prophylaxis subgroup of the SGS-SRG created a protocol defining population, interventions, comparators, and outcomes (PICO) to evaluate antibiotic prophylaxis in non-hysterectomy gynecologic surgery for benign conditions.

The population of interest was women undergoing vaginal, cervical, transcervical, abdominal, or laparoscopic benign gynecologic procedures excluding hysterectomy. The focus was on non-hysterectomy procedures in order to avoid redundancy with an ongoing (as of September 2012) systematic review by the Cochrane Collaboration regarding prophylactic antibiotics for hysterectomy [4]. The intervention was prophylactic antibiotic use compared with placebo or with another antibiotic, of any dose, route of administration, or perioperative timing. The outcomes of interest were clinically diagnosed or treated postoperative surgical and non-surgical site infections and adverse effects related to antibiotic use.

MEDLINE and the Cochrane Central Register of Controlled Trials were searched from inception to July 16, 2010, for English-language randomized controlled trials (RCTs). Search terms were determined by group discussion and review of literature terminology, and included “antibiotic prophylaxis,” “premedication,” and specific gynecologic procedures. A list of the medical subject headings used is available on request. Additional studies were identified from references of relevant review articles. Unpublished articles or abstracts were not identified, and study authors were not contacted.

The yield of citations was screened, and potentially eligible articles were then reviewed in full text to determine whether inclusion criteria were met. Data extraction of included articles was performed in duplicate. The extraction form was piloted by subgroup members before it was finalized. Extraction forms identified the PICO variables and study design details such as characteristics and discrepancies between groups, outcome definition, whether power was calculated and met, and applicability of study findings. Using a system modified from the Agency for Healthcare Research and Quality [5], extractors graded the quality of each study as good, fair, or poor, based on the likelihood of bias. Bias was assessed for factors including funding, blinding of patients/investigators, and loss of patients to follow-up. The best measurement of postoperative infection—the primary outcome for the present review—was identified in each study. The quality of an outcome within a study was assessed and the overall study quality downgraded if there were limitations specific to the outcome. Discrepancies between extractors were resolved by discussion among all subgroup members.

Evidence profiles for each procedure were created and the quality of the evidence was graded following the GRADE approach, based on individual study quality, consistency across studies, directness (applicability/generalizability of the population and intervention), and sparseness of data [6]. The net effect of antibiotic prophylaxis was classified as favoring antibiotic use, failing to show a difference between groups, or favoring the alternative (including placebo). Decisions were made by discussion and consensus among all members for specific topic subgroups.

3. Results

The literature search identified 2525 citations, of which 2301 were excluded based on title and abstract. Of the 224 full-text articles reviewed, 205 were excluded for not meeting PICO criteria (Fig. 1). Nineteen articles were included in the present systematic review (Supplementary Material S1).

3.1. Cervical surgery (loop electrosurgical excision procedure)

Two studies on cervical surgery—specifically, loop electrosurgical excision procedure (LEEP)—met the inclusion criteria [7,8]. Both were graded fair quality. Foden-Shroff et al. [7] compared oral ofloxacin for 5 days after LEEP with placebo in an evenly divided group of 500 women. Need for antibiotics to treat vaginal discharge in the 2 weeks after surgery was used as an indicator of infection. Women were queried on medication adverse effects. The study was limited by poor follow-up and lack of demographic information. Also, the definition of infection was not specific because discharge alone does not necessarily indicate infection. There was no difference in infection rate between the groups (13.2% ofloxacin vs 10.3% placebo; $P=0.39$); placebo was favored owing to adverse effects (11.6% ofloxacin vs 7.4% placebo; $P=0.21$).

The other LEEP study, performed in Hong Kong, compared a group using a vaginal pessary containing 100 mg of tetracycline and 50 mg of amphotericin B—placed twice daily for 14 days, starting on the day of the procedure [8]—with a control group that did not receive any treatment after LEEP. The investigators chose vaginal bleeding requiring medical attention as a surrogate for postoperative infection. Patients were monitored for 3 weeks after the procedure. The study did not find a significant difference between the groups in terms of self-reported vaginal bleeding, discharge, lower abdominal pain, fever, or hospital admission. The study was graded as fair quality because the number of patients who returned for follow-up was smaller than the power analysis specified (137 in the treatment group and 153 in the control group). In addition, the control group was not given a placebo pessary, which alone could confound bleeding or discharge symptoms.

The overall quality of the evidence regarding antibiotic prophylaxis for LEEP was graded very low; the quality of evidence for measures of adverse effects was graded low. The sparseness and the indirectness of the evidence further detracted from the quality. In both studies, participants were given antibiotics for extended courses after surgery, which is currently unacceptable by US accreditation standards for prophylaxis [9]. There was no difference in infection with antibiotic use, and the adverse effect profile favored placebo.

3.2. Transcervical surgery (hysteroscopic ablation)

Only 1 study met PICO criteria for transcervical surgery. Bhattacharya et al. [10] randomized 55 women undergoing hysteroscopic resection or laser ablation of the endometrium to either amoxicillin/clavulanate or no antibiotic at induction. The primary outcome was bacteremia by blood culture but signs of infection were also reported. The study was stopped early, and thus did not reach power, after an interim safety analysis found a significant difference in bacteremia between the groups (2% vs 16%; $P<0.02$). However, there were no differences for clinical outcomes such as fever, pain, discharge, evaluation by a general practitioner, or treatment with antibiotics over 2 weeks post-surgery. Based on this sparse evidence, we suggest not using antibiotic prophylaxis for women undergoing hysteroscopic endometrial ablation.

3.3. Suction curettage (for products of conception)

Eight randomized trials on antibiotic prophylaxis for first-trimester suction curettage and 1 randomized trial involving second-trimester dilation and evacuation were identified [11–19]. No trials of dilation and curettage without products of conception met the inclusion criteria.

3.3.1. Tetracyclines

Five studies investigated tetracycline use [11–15]. In the 3 placebo-controlled studies, the definitions of infection were similar

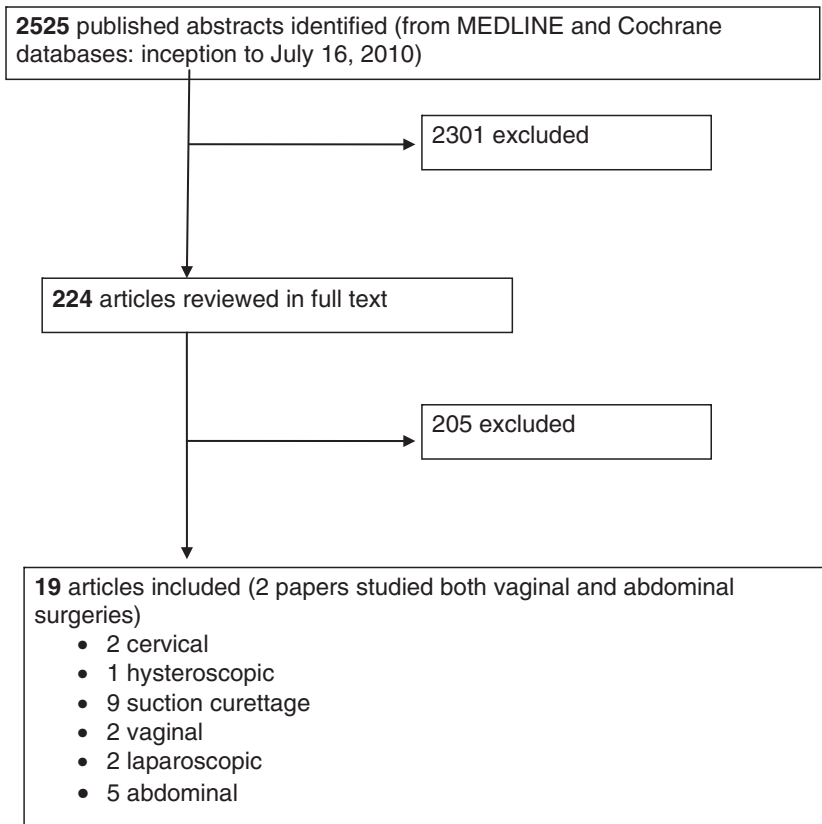


Fig. 1. Flow diagram of the selection and systematic review of studies on prophylactic antibiotics for select benign gynecologic surgeries.

and based on physical examination findings, including lower abdominal pain, tenderness, purulent leukorrhea or vaginal bleeding, leukocytosis, and fever [11–13]. Postoperative follow-up was 2–5 weeks across the studies. Prieto et al. [11] randomized 345 women to preoperative intravenous doxycycline or placebo for first-trimester suction curettage. Postabortion infection rates were 6.6% for doxycycline and 5.8% for placebo, which was not significantly different. The intervention was not blinded, therefore allowing for bias.

Heisterberg and Gnarpe [12] randomized patients to lymecycline or placebo for 14 days, starting the morning of surgery. Ninety women were randomized but only 55 were analyzed because of loss to follow-up or protocol deviation. Infection rates were 8.3% for antibiotics and 22.6% for placebo ($P > 0.2$). The high rate of post-surgical infection was made more likely because the inclusion criteria required a history of pelvic inflammatory disease (PID). Limitations included small sample size with high loss of participants to follow-up. The outcome was dependent on participant recall of nonspecific symptoms, which may have introduced further bias.

Levallois and Rioux [13] had the largest sample size for this procedure, with 1077 women randomized to either doxycycline or placebo. They tested women for chlamydia cervicitis prior to the procedure and separately analyzed 1002 women who were negative. A regimen of 100 mg of oral doxycycline given 1 hour preoperatively and 200 mg administered 30 minutes postoperatively was associated with a significant reduction in postoperative infection compared with placebo (from 3% to 0.3%; $P = 0.001$). Participants who received antibiotics more commonly reported nausea and vomiting.

Two studies compared different doxycycline regimens [14,15]. Lichtenberg and Shott [14] randomized 800 women to doxycycline for 3 or 7 days after first-trimester suction curettage. There was no significant difference in infection rates between the regimens but, because of loss to follow-up, the study did not meet its sample size

requirement. The other study was a placebo-controlled comparison of doxycycline taken the night before versus the morning of dilation and evacuation [15]. This was chiefly an assessment of adverse effects, and nausea and vomiting were more severe when doxycycline was taken on the morning of surgery.

3.3.2. Erythromycin

One study investigated the use of oral erythromycin taken twice daily for 7 days for PID prevention after first-trimester abortion [16]. The final analysis included 378 women, which met the sample size requirements for power. Post-surgical PID occurred in 10.5% of the erythromycin group and 15.9% of the placebo group, which was not significantly different ($P = 0.129$).

3.3.3. Clindamycin

Larsson et al. [17] performed a multi-institutional study investigating clindamycin vaginal cream after first-trimester abortion. The study was industry sponsored and the role of the pharmaceutical manufacturer was unspecified. Patients were instructed to follow-up if they experienced complications. Of the 1665 patients who were randomized, 389 (23%) were excluded for reasons such as loss to follow-up ($n = 157$ [40%]), preoperative chlamydia infection ($n = 31$ [8%]), and antibiotic treatment outside the protocol ($n = 72$ [19%]). The rate of postoperative infection was 4.5% in the clindamycin group and 4.8% in the placebo group ($P = 0.68$).

3.3.4. Ceftriaxone

Henriques et al. [18] performed an RCT of ceftriaxone versus the “standard of care” for each patient’s apparent risk of infection following first-trimester termination. Women were categorized as high risk if they had a history that indicated prior PID or sexually transmitted infection. Then, in both risk groups, women were randomized to

either ceftriaxone or “standard” treatment. The standard treatment was determined based on each patient’s assessed risk; low-risk women were not given any antibiotics, whereas high-risk women were treated with intravenous ampicillin and metronidazole preoperatively, followed by oral metronidazole and pivampicillin 3 times per day for 4 days. There was a significant difference in the rates of post-surgical infection in the low-risk population: 0.7% in the ceftriaxone group and 3.6% in the no-prophylaxis group ($P < 0.05$). In the high-risk population, there was no difference in infection between those receiving ceftriaxone and those receiving standard of care (3.7% vs 4.7%; $P > 0.05$). The group of low-risk women who received ceftriaxone reported a significantly higher rate of diarrhea compared with controls. All other potential adverse effects were similar between the groups.

3.3.5. Metronidazole

Heisterberg and Petersen [19] compared metronidazole with placebo for the prevention of PID following first-trimester elective termination. Of 119 women randomized, 100 were included in the analysis; 8 were lost to follow-up, and the remaining cases involved protocol deviation. Women in the treatment group received 400 mg of oral metronidazole 1 hour before, then 4 and 8 hours after surgery. Women in the placebo group received similarly timed tablets. All follow-up was completed 2 weeks postoperatively. Rates of infection were 3.9% in the treatment group and 20.4% in the placebo group ($P < 0.025$).

Moderate-quality evidence supports the use of a tetracycline for infection prophylaxis in first-trimester suction curettage. There is also moderate- and high-quality evidence to support the use of ceftriaxone and metronidazole, respectively, to reduce postabortion infection. Although gastrointestinal adverse effects occur more often in women receiving prophylaxis, the benefits of reducing post-procedure infectious morbidity warrant the risk. The optimal regimen remains unclear because the small number of RCTs used variable regimens for dosage, route, and particular antibiotic. Tetracycline, ceftriaxone, or metronidazole may be appropriate choices.

3.4. Vaginal surgery (excluding hysterectomy)

Two studies addressing antibiotic prophylaxis in vaginal surgery met the inclusion criteria [20,21]. Houang et al. [20] performed a double-blind, randomized, placebo-controlled trial of various gynecologic surgeries, including abdominal surgery without entry into the vagina (discussed later) and vaginal surgery without entry into the peritoneal cavity. Participants were randomized to 1 of 3 preoperative antibiotic regimens (placebo vs ampicillin-sulbactam vs ampicillin-metronidazole). Follow-up was 6 weeks. In addition to pelvic or vaginal infection, the authors attempted to identify UTIs. Infection rates were not different among the study arms for vaginal surgery without entry into the peritoneum. Only 30 patients were randomized and no power analysis was performed, so type II error is a possibility.

Schiøtz and Guttu [21] studied postoperative UTIs and bacteriuria in 135 women undergoing “vaginal plastic surgery.” Another subgroup who underwent “routine gynecologic laparotomy” [21] are discussed later. This was a randomized, double-blind, placebo-controlled trial but included women who had an indwelling Foley catheter for 24 hours. The authors observed a benefit of methenamine over placebo for UTI prevention when both surgical approaches were collectively analyzed. However, the subgroup of patients undergoing vaginal surgery ($n = 55$) was not separately analyzed. Eleven (7.6%) women in the entire study had adverse events: 8 had nausea (5 methenamine, 3 placebo) and 3 had a rash (1 methenamine, 2 placebo) ($P > 0.05$ for all).

Only 2 trials met PICO criteria for review and it was felt that there was insufficient information available to guide decision making.

3.5. Laparoscopic surgery (excluding hysterectomy)

Two RCTs were identified that evaluated antibiotic use in benign gynecologic laparoscopic procedures excluding hysterectomy [22,23]. Kocak et al. [22] randomized 450 women to either a single preoperative dose of a first-generation cephalosporin ($n = 200$) or no antibiotics ($n = 250$). Indications for surgery included infertility, endometriosis, tubal ligation, and chronic pelvic pain. The technique of randomization was not detailed but the percentage of women listed for each indication was exactly the same in the 2 groups. The physicians caring for the women postoperatively were not blinded. There were no differences between the groups for each infectious outcome.

Cormio et al. [23] randomized 356 patients undergoing laparoscopy to amoxicillin-clavulanate or cefazolin at anesthesia induction. Surgeries included ovarian cystectomy, myomectomy, adnexectomy, and endometriosis. One patient in the amoxicillin-clavulanate group became febrile. The outcomes were not significantly different between the groups.

In both studies extracted, the rate of infection was low (0%–5.5%), supporting a minimal need for antibiotics in general. Based on these 2 studies, it was concluded that antibiotic prophylaxis for laparoscopic surgery does not provide a significant benefit.

3.6. Laparotomy (excluding hysterectomy) without entry into vagina or bowel

Five studies investigating antibiotic prophylaxis in abdominal gynecologic surgeries excluding hysterectomy [20,21,24–26] met the present PICO criteria. The largest and highest-quality study reported a benefit of perioperative antibiotics; in this 3-armed, double-blind, placebo-controlled trial [24], 1350 women undergoing mini-laparotomy tubal ligation were randomized to tetracycline, ampicillin, or placebo for 5 days postoperatively. Participants were assessed 2 and 7 days after surgery for infection (defined as temperature higher than 100.4 °F) or signs of inflammation (erythema, discharge, pain, swelling, or dehiscence). There was a significantly lower incidence of infection with tetracycline than with placebo (1.8% vs 5.8%; $P = 0.025$). There was no significant difference in infection rates between ampicillin and placebo, or ampicillin and tetracycline.

Two studies found no difference in infection rates between groups receiving antibiotics and those receiving placebo. In the study by Houang et al. [20], for abdominal surgery without entry into the vagina, 79 women were randomized to sulbactam-ampicillin, metronidazole-ampicillin, or placebo. The authors found no difference in fever or wound infection between the groups. “No significant side effect” was seen but adverse events were not otherwise described. Bhatia et al. [25] performed a small quasi-randomized (assignment was based on hospital number) study of 26 women undergoing retropubic urethropexy. Three of 12 patients who did not receive antibiotics developed wound abscesses, whereas no abscesses developed among the patients who received cefazolin. Statistical analysis of infection rates was not reported. The authors also reported a “fever index” calculation [27], which was significantly different between the groups but is of unclear clinical utility.

Periti et al. [26] compared 2 cephalosporins. The authors randomized women undergoing cesarean delivery, abdominal or vaginal hysterectomy, or myomectomy via exploratory laparotomy. The present review included only the 36 myomectomy patients, whose results were reported separately. Although this was a small subset of patients, no significant difference in infection rates was seen between women treated with cefazolin and those who received cefotaxime. In their methenamine trial, Schiøtz et al. [21] reported a significantly lower rate of UTIs and asymptomatic bacteriuria in the study population.

Overall, data for laparotomy without hysterectomy were limited. The study by Akhter et al. [24] was remarkable because of its sound study design and large sample size but the procedure performed is only questionably generalizable to other, more extensive surgeries. Adverse events were described in only 1 study, in which no difference was observed between the study and the control populations. The evidence indicates that there is a benefit to using perioperative antibiotics for women undergoing abdominal gynecologic surgery excluding hysterectomy without entry into the vagina or bowel.

4. Discussion

Optimization of surgical outcomes is a priority for physicians, patients, medical institutions, and accrediting bodies. Despite the widely accepted practice of antibiotic prophylaxis for surgery, the few RCTs identified in the present systematic review on antibiotic prophylaxis for non-hysterectomy gynecologic procedures highlight low-quality evidence for many practices. In some cases, such as vaginal surgery, the data were too weak to provide a clear answer. Newer procedures also lack data. It is a common finding that accepted practices may still merit re-examination and further study.

In 2009, ACOG published clinical guidelines regarding prophylactic antibiotics for gynecologic surgery [1]. The guidelines are comprehensive in their coverage of the wide range of gynecologic procedures that exist. Although the guidelines can be extremely helpful to gynecologic surgeons, they incorporate a range of study designs, include studies from other fields, and are based on group consensus and expert opinion [1]. The aim of the present paper was to critically evaluate the evidence regarding benign gynecologic surgeries using a pre-established PICO for study inclusion. In contrast to the variety of studies referenced in the ACOG guidelines, the present review included only RCTs of gynecology-specific surgical procedures. We believe that it is informative and relevant to gynecologic surgeons to know that the existing evidence regarding prophylactic antibiotic use for the majority of gynecologic procedures remains poor. Only 19 studies meeting the inclusion criteria for the 6 routes of gynecologic surgery were identified, of which 3 are also cited in the ACOG guidelines. Careful review of the 55 references cited by ACOG showed no further high-quality studies ($n=16$) that would have met the criteria because these remaining Level I studies examined other procedures such as intrauterine device placement or were from other fields such as colorectal surgery [1].

Given the paucity of high-quality evidence from studies on gynecologic surgery, evidence from similar fields and procedures may be extrapolated to fill these gaps. For example, studies from colorectal surgery, general surgery, and urologic surgery offer some applicability to gynecologic pelvic surgery. As a field, it may be wise to consider whether this practice should be temporary or whether studies specific to women undergoing these procedures should be carried out to provide best guidance. Early adaptation in gynecology of procedures considered substantially equivalent to those in other fields has previously led to concerns for patient safety [28]. Lesser-studied procedures and those unique to gynecology, such as advanced laparoscopic or robotic surgery in women and mesh placement in prolapse surgery, still merit consideration for study, given the lack of data found for these surgeries.

The strengths of the present study were the systematic review techniques used in a group with methods and domain experience [29,30], and the lack of conflicts of interest. A comprehensive and detailed search of relevant published RCTs was used to collect the data, and the review was limited to gynecology studies. Multiple experienced gynecologic surgeons assessed the studies, and group consensus was used to assure uniformity.

There were limitations to the present study. As with any systematic review, the information collected was shaped by the available evidence, which may reflect publication bias. There was a limited

number of RCTs for most surgeries, and they were mostly of poor quality. Insufficient evidence precluded a clear answer for vaginal surgery. The results were influenced by lack of consistency in the definition of infection between studies, and the timing and delivery of “prophylaxis” were also variable. Several studies used prolonged postoperative courses of medication, which would not be categorized as prophylaxis using current US standards. There was limited opportunity to discuss the best choice of antibiotic because few studies compared antibiotics, and some studies used medications not currently available in the USA. Questions also arose about the applicability of studies that were published some time ago because certain practices are now obsolete, such as prolonged hospitalization after short laparoscopic procedures. Practice variations between different countries may also limit the relevance of the results. Notably, the study was also limited with regard to the type of surgery performed, including advanced laparoscopic procedures and pelvic reconstruction surgery involving the use of graft material, because no RCTs examining perioperative antibiotics in these surgeries were identified.

In conclusion, the present systematic review summarizes the highest-quality evidence available in the English-language gynecology literature on antibiotic prophylaxis. We expect that the information presented can be used to inform future research and providers seeking to give best care to their patients. We recommend further clinical studies on prophylactic antibiotics for procedures such as vaginal surgery without hysterectomy, advanced laparoscopic and robotic surgery, and surgery involving grafts.

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.ijgo.2012.06.023>.

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Conflict of interest

The authors have no conflicts of interest.

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