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GYNECOLOGY

A prospective assessment of pelvic infection risk following same-day sexually transmitted infection testing and levonorgestrel intrauterine system placement

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BACKGROUND: Misperceptions persist that intrauterine device placement is related to pelvic infections and *Chlamydia* and gonorrhea testing results are needed prior to placement.

OBJECTIVE: We sought to evaluate the relationship of *Chlamydia* and gonorrhea screening to pelvic infection for up to 2 years following placement of the levonorgestrel 52-mg intrauterine system.

STUDY DESIGN: A total of 1751 nulliparous and multiparous females 16 to 45 years old enrolled in a multicenter trial designed to evaluate the efficacy and safety of a new levonorgestrel intrauterine system for up to 7 years. Participants had *Chlamydia* screening at study entry and yearly if they were age \leq 25 years. Women also had baseline gonorrhea screening if testing had not been performed since starting their current sexual relationship. Those who changed sexual partners during the trial had repeated *Chlamydia* and gonorrhea testing. Intrauterine system insertion could occur on the same day as screening. Participants did not receive prophylactic antibiotics for intrauterine system placement. Investigators performed pelvic examinations after 12 and 24 months and when clinically indicated during visits at 3, 6, and 18 months after placement and unscheduled visits. Pelvic infection included any clinical diagnosis of pelvic inflammatory disease or endometritis.

RESULTS: Most participants (n = 1364, 79.6%) did not have sexually transmitted infection test results available prior to intrauterine system placement. In all, 29 (1.7%) participants had positive baseline testing for a sexually transmitted infection (*Chlamydia*, n = 25; gonorrhea, n = 3; both, n = 1); 6 of these participants had known results (all with *Chlamydia* infection) prior to intrauterine system placement and received treatment before enrollment. The 23 participants whose results were not known at

the time of intrauterine system placement received treatment without intrauterine system removal and none developed pelvic infection. The incidence of positive *Chlamydia* testing was similar among those with and without known test results at the time of intrauterine system placement (1.9% vs 1.5%, respectively, P = .6). Nine (0.5%) participants had a diagnosis of pelvic infection over 2 years after placement, all of whom had negative *Chlamydia* screening on the day of or within 1 month after intrauterine system placement. Infections were diagnosed in 3 participants within 7 days, 1 at 39 days, and 5 at ≥ 6 months. Seven participants received outpatient antibiotic treatment and 2 (diagnoses between 6–12 months after placement) received inpatient treatment. Two (0.1%) participants had intrauterine system removal related to infection (at 6 days and at 7 months after placement), both of whom only required outpatient treatment.

CONCLUSION: Conducting *Chlamydia* and gonorrhea testing on the same day as intrauterine system placement is associated with a low risk of pelvic infection (0.2%). Over the first 2 years of intrauterine system use, infections are infrequent and not temporally related to intrauterine system placement. Pelvic infection can be successfully treated in most women with outpatient antibiotics and typically does not require intrauterine system removal. Women without clinical evidence of active infection can have intrauterine system placement and sexually transmitted infection screening, if indicated, on the same day.

Key words: *Chlamydia*, contraception, endometritis, gonorrhea, intrauterine device, intrauterine system, levonorgestrel, Liletta, pelvic infection, pelvic inflammatory disease

Introduction

Although the intrauterine device (IUD) is one of the most effective methods of reversible contraception,¹ some health care providers remain concerned that IUD use increases the risk of pelvic

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0002-9378/\$36.00 © 2016 Elsevier Inc. All rights reserved. http://dx.doi.org/10.1016/j.ajog.2016.05.017 infection.²⁻⁴ Misconceptions about IUD use and infection are entrenched in common practice throughout the world,^{5,6} leading some providers to believe that infection risk is high and that sexually transmitted infection (STI) screening is needed prior to IUD placement.⁷ When providers require unnecessary tests for STI and make patients wait for IUD placement, barriers to effective contraception are created.

Research over the past 2 decades has begun to clarify the relationship among pelvic infection risk, STI, and IUD placement. Pelvic infection rates are very low among a screened population, including when the IUD is placed without test results.⁸⁻¹² Even when *Chlamydia* or gonorrhea infection is present, the risk of pelvic infection is low with IUD insertion.¹³ Despite this evidence, we lack large, rigorously conducted, prospective trials performed in the United States with direct subject evaluation to evaluate pelvic infection rates shortly after and remote from insertion. Information from such studies can further elucidate risks and perhaps remove obstacles to immediate IUD insertion.



We recently reported the initial results of a Comprehensive Contraceptive Efficacy and Safety Study (ACCESS) of an intrauterine system (IUS) for regulatory approval of Liletta (Odyssea Pharma SPRL, Liège, Belgium; an Allergan affiliate).¹⁴ We conducted this large prospective study with the intent of IUS placement occurring with a same-day screen and insert model, meaning that participants would not have to wait for test results to return before IUS placement occurred. This report summarizes STI prevalence and pelvic infection rates in a large cohort of US women with multiple evaluations over a 2-year period.

Materials and Methods

This report represents a planned secondary analysis of data from the ACCESS IUS multicenter, phase III, open-label clinical trial of Liletta (Medicines360, San Francisco, CA; and Allergan, Irvine, CA), a levonorgestrel (LNG) 52-mg IUS. Details on the methods of this study have been reported previously.¹⁴ Briefly, investigators at 29 clinical sites in the United States invited healthy, nonpregnant, sexually active, nulliparous and parous females aged 16-45 years (inclusive) with regular menstrual cycles and who desired a hormonal IUS for contraception to participate. Although only monogamous women could enroll, they could change partners during the study and continue to participate. We excluded women with a history of pelvic inflammatory disease (PID) without a subsequent intrauterine pregnancy and those with a known cervical infection (cervicitis on examination or known positive Chlamydia or gonorrhea testing) or vaginal infection (trichomoniasis and symptomatic Candida or bacterial vaginosis) unless successfully treated and considered clinically cured for at least 7 days prior to study entry. A central or local institutional review board for each center approved the study. All participants signed written informed consent before study participation. Registration is Clinicaltrials.gov number NCT0099 5150.

At the screening visit, an investigator performed a pelvic examination that included determination of active vaginal, cervical, and pelvic infection. All participants had Chlamydia testing at the screening visit and those who had no gonorrhea testing since starting their current sexual relationship also had gonorrhea testing. Enrollment and IUS placement could occur on the same day as the screening procedures without Chlamydia or gonorrhea testing results. Investigators applied an antiseptic solution to the vagina and cervix prior to IUS placement. Up to 2 placement attempts could occur within 30 days of signing consent. Investigators followed up participants who had a failed insertion only if an adverse event occurred during the placement attempt.

Follow-up visits occurred at 1, 3, and 6 months after IUS placement and every 6 months thereafter to assess adverse events, changes in sexual partner, medical history, concomitant medication use, and whether the IUS was still the primary method of contraception. Investigators performed a full pelvic examination annually or at any visit for which a reported symptom warranted an examination, and an abbreviated limited examination to confirm IUS presence at all other visits. Starting at month 9, telephone contacts occurred 3 months after each clinic visit to ask the same questions as at study visits. During the trial, participants who reported a change in sexual partner had Chlamydia and gonorrhea testing in accordance with the US Centers for Disease Control and Prevention (CDC) recommendations.¹⁵ All STI evaluations were performed by endocervical swab, vaginal swab, or urine nucleic acid amplification testing. Investigators treated participants with a positive Chlamydia or gonorrhea test from the screening evaluation or during the study with antibiotic regimens consistent with published CDC sexually transmitted disease treatment guidelines without requirement for IUS removal.¹⁵

Data are presented on infection outcomes for 2 years post-IUS placement using descriptive statistics. We also performed a survival analysis to calculate the pelvic infection rate at 2 years. We used Fisher exact testing for comparisons of proportions. Only those participants with successful IUS placement are included in all analyses. Pelvic infection included any clinical diagnosis of endometritis or PID by a study or nonstudy health care provider during clinical trial participation. Investigators at each study site assessed pelvic infection severity (mild, moderate, severe, life-threatening) in accordance with Food and Drug Administration standards for clinical trials and the relationship to the IUS or to the placement or removal procedure.

Results

Of the 1751 women enrolled, 1714 (97.9%) had successful placement and are included in this analysis. Demographic characteristics appear in Table 1. Overall, 1553 (90.6%), 1401 (81.7%), and 1157 (67.3%) participants continued IUS use at 6 months, 1 year, and 2 years, respectively.

Almost all women (n = 1687, 98.4%) had *Chlamydia* testing at screening (Table 2); the 27 missed tests included unsatisfactory specimens or protocol violations. These 27 participants all had successful IUS placements on the same day as the screening evaluation. Of these participants, 26 had *Chlamydia* tests performed within 1 month (n = 24) or at 3 months (n = 2). The 1 other participant did not attend any visits after IUS placement and withdrew consent on study day 88. Investigators performed gonorrhea testing in 1401 (81.7%) of women at screening.

Most women (n = 1364, 79.6%) did not have STI test results available prior to IUS placement. In all, 29 (1.7%) participants had positive baseline testing for STI including 25 (1.5%) with positive Chlamydia testing, 3 (0.2%) with positive gonorrhea testing, and 1 (0.1%) with both. Only 6 of these 29 participants (all with positive Chlamydia testing) had known results and treatment prior to placement. One participant with a positive Chlamydia test had a missed test at screening with a positive result at 1 month. All 29 participants with positive STI testing received outpatient antibiotic treatment, none had the IUS removed, and none developed a pelvic infection. The incidence of positive *Chlamydia* testing was similar among participants with and without known test results at the time of IUS placement (1.9% vs 1.5%, respectively, P = .6). STI testing during 2 years of follow-up was performed when indicated with low rates of positivity (Table 2).

Site investigators reported pelvic infection in 9 (0.5%) participants over 2 years. Using survival analysis, the overall pelvic infection rate through 2 years remained similar at 0.6%. Eight of these participants had negative Chlamydia testing at screening and 1 had an unsatisfactory specimen with a negative test at 1 month postinsertion. Seven had negative gonorrhea testing at screening and 2 had no gonorrhea testing. Site investigators classified 3 infections as mild and 6 as severe. Seven participants received outpatient antibiotic treatment and 2 participants, both classified as having severe infections, initially received inpatient treatment. Pelvic infections occurred within 7 days in 3 participants (all with negative Chlamydia and gonorrhea testing at screening), at day 39 for 1 participant, and >6 months following IUS placement for the other 5 participants (Figure). Six (66.7%) of the 9 infections occurred after day 30, and 8 of 9 cases occurred during the first year for a 1-year pelvic infection rate of 0.47% (95% confidence interval, 0.14-0.79%). Six of the 9 participants with infection had negative Chlamydia and gonorrhea testing around the time of the diagnosis; the other 3 were empirically treated without testing.

Two participants opted to have the IUS removed in relation to a diagnosis of pelvic infection. Both had successful treatment with outpatient antibiotics for the infection; 1 participant diagnosed by the investigator with a mild infection 1 day after placement chose to have her IUS removed 5 days later and the other participant diagnosed by the investigator with a severe infection on study day 215 had her IUS removed 7 days later.

TABLE 1

Demographics of study population and contraceptive method at enrollment for women in phase III study who had successful placement of levonorgestrel intrauterine system (N = 1714)

Variable	n (%) or mean \pm SI
Age, y	27.3 ± 5.7
<25 y	621 (36.2)
Ethnicity	
Hispanic or Latina	251 (14.6)
Race ^a	
American Indian or Alaska Native	21 (1.2)
Asian	67 (3.9)
Black or African American	225 (13.2)
Native Hawaiian or other Pacific Islander	6 (0.4)
White	1342 (78.5)
Multiple races indicated	49 (2.9)
Body mass index, kg/m ^{2a}	$\textbf{26.9} \pm \textbf{6.8}$
Obese, \geq 30.0	433 (25.3)
Partner status	
Lives with partner	1003 (58.5)
Parity	
Nulliparous	986 (57.5)
Marital status	
Never married	1081 (63.1)
Married	478 (27.9)
Divorced	123 (7.2)
Separated	29 (1.7)
Widowed	3 (0.2)

Comment

ACCESS IUS included a broad range of US women, more than half of whom were nulliparous. The trial allowed same-day IUS placement, meaning that providers could obtain STI testing at the time of IUS placement. Nearly 80% of participants had IUS placement without knowledge of STI testing results. Those with positive testing had STI treatment without the need for IUS removal, and no participant who had same-day placement and was then found to have a positive STI screen developed pelvic infection. All those who developed pelvic infection shortly after placement had negative STI testing. The ACCESS IUS population had a higher *Chlamydia* rate (1.5%) than the general US population (0.5%) with similar gonorrhea rates $(0.2\% \text{ and } 0.1\%, \text{ respectively}).^{16}$ Still, all participants with a positive *Chlamydia* or gonorrhea test received outpatient antibiotic treatment without removal of the IUS and none developed pelvic infection.

The other key finding in this large prospective study is that pelvic infection is not more common in the first few weeks after IUS placement. A meta-analysis published in 1992 with almost 23,000 parous women (74% of whom received a

TABLE 2

Sexually transmitted infection testing at baseline and throughout 2 years of follow-up in women who received levonorgestrel 52-mg intrauterine system (N = 1714)

	Chlamydia testing		Gonorrhea testing	
	No. tested	Positive results	No. tested	Positive results
Baseline				
Results not known prior to IUS placement ^a	1364	20 (1.5%)	1081	4 (0.4%)
Results known prior to IUS placement	323	6 (1.9%)	320	0
Mo 1	97	8 (8.2%)	83	0
Mo 3	84	3 (3.6%)	81	0
Mo 6	133	6 (4.5%)	131	1 (0.8%)
Mo 12	558	10 (1.8%)	438	0
Mo 18	188	3 (1.6%)	175	2 (1.1%)
Mo 24	354	10 (2.8%)	257	0

Sexually transmitted infection testing included *Chlamydia* and gonorrhea testing at baseline. Testing during study follow-up included *Chlamydia* testing for all women <25 y of age and *Chlamydia* and gonorrhea testing for all participants who reported new sexual partner since their last visit.

Scheduled study visits during first 2 y of trial occurred at mo 1, 3, 6, 12, 18, and 24.

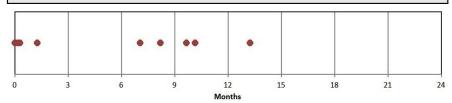
IUS, intrauterine system.

^a One subject at baseline had positive test for both *Chlamydia* and gonorrhea.

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copper IUD) suggested an increased risk of pelvic infection in the first 3 weeks following IUD placement.¹⁷ That study presented global data from clinical research centers in Europe, Asia, Africa, as well as North, Central, and South America. The study population had little or no STI screening before or after IUD placement. In our current study, we found that although 3 participants did have an infection diagnosed during this time frame (all with negative initial STI screening), more (6) participants had a pelvic infection diagnosed remote from IUS placement during 2 years of study follow-up. These differences may arise from several possible sources. First, our current study universally used antiseptic prior to IUS placement and this point is unclear from the meta-analysis. Second, this study included LNG IUS whereas the meta-analysis included primarily copper IUD users. LNG IUS users have lower rates of discontinuation for PID than copper users, although this difference appears to become pronounced after

TIGONE	
Days of diagnosis of pelvic infection over 2 years of use of levono	raestrel
Days of diagnosis of pervic infection over 2 years of use of revolu	n good of
intrauterine system	



Days of pelvic infection diagnosis over course of 2 years for 9 pelvic infections that occurred during study follow-up.

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2 years of use.¹⁸ Third, we designed our current study to enroll a low-risk population for pelvic infection although participants could change partners throughout the trial; our study population may be lower risk than those women in studies used for the meta-analysis. Lastly, it is possible that our study investigators may have evaluated women differently than providers in studies included in the meta-analysis. Women may have pain or other symptoms suggestive of pelvic infection around the time of IUS placement and some clinicians may have a low threshold for making a diagnosis of infection with the caveat of "better safe than sorry."

The American Congress of Obstetricians and Gynecologists and CDC recommend that STI screening, when needed, can be performed on the same day as IUD placement without the need to wait for a negative result prior to placement.^{19,20} The recommendations also include antibiotic treatment of any positive STI tests without IUD removal. Despite these national recommendations, misperceptions continue within the medical community. A survey of US obstetrician-gynecologists published in 2002 found two-thirds of providers recommended against IUD use in women with a history of STI and 81% recommended against an IUD for a woman with a history of PID.⁴ A 2014 survey of US obstetrician-gynecologists found continued misunderstanding of evidence and recommendations as two-thirds considered nulliparous women inappropriate IUD candidates and 16% stated that pelvic infection is a major risk of IUD use.²¹ Multiple evaluations of provider practices in the last 5 years have shown in California, Colorado, and nationally that 58–86% of providers require \geq 2 visits to obtain an IUD, with the California survey demonstrating the primary reason of STI screening results being available prior to placement.²²⁻²⁴ Same-day placement of intrauterine contraceptives significantly increases utilization. A study in a primarily low-income, Medicaid-insured population found that only 54% of women desiring an intrauterine contraceptive received one with a 2-visit requirement.25

We found that pelvic infection in a sexually active population screened for STI is rare, not clustered at the time of IUD insertion, and remains low over 2 years of use. Only 2 (0.2%) of the 1714 participants had the IUS removed for a pelvic infection over 2 years. For this study, we had a low threshold for reporting a pelvic infection, counting any diagnosis regardless of whether or not the principal investigator at the study site agreed with the diagnosis. Because the differentiation of endometritis and PID is subjective, we included all cases as equal. The annual incidence of PID in the United States ranges from 0.2% among privately insured women to 1.1% in new US military recruits.^{26,27} The 1-year pelvic infection rate in this study of 0.47% is within this range. Investigators in the CHOICE study reported a 6-month pelvic infection rate of 0.46% among IUD users in St Louis County, Missouri, despite a much higher baseline rate of *Chlamydia* infection.¹² Interestingly, CHOICE investigators reported no pelvic infections among 1552 LNG IUS users.

We believe these findings are generalizable to the US population, even though some of the study entry criteria, as necessary for a phase III study, limit the population. For example, women enrolled in the study had to have no history of PID without a subsequent intrauterine pregnancy or no known cervical or vaginal infection unless successfully treated and considered clinically cured for at least 7 days. Although participants needed to be monogamous at study entry, they could continue in the study using the IUS if they changed partners, similar to intrauterine contraceptive use in the general population. The Chlamydia positivity rate was slightly higher than the general population and the demographics match those of the US census in regard to race and ethnicity.²⁸ Overall, we do not believe any limitations negate the findings that sameday STI testing and IUS insertion are safe.

Our study adds to the existing literature that the pelvic infection rate with IUS use is very low, even in women who do not have STI testing results available at the time of IUS placement. Based on the consistent findings across studies, women without clinical evidence of active infection, such as purulent cervical discharge or uterine tenderness, can have IUS placement and STI screening, if indicated, on the same day.

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