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Microbial correlates of delayed care for pelvic inflammatory disease

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Abstract

Objective—We studied the microbial correlates of time to care and long term outcomes among pelvic inflammatory disease (PID) patients, as delayed care may increase the risk for reproductive sequelae.

Methods—Mean days of pain prior to care were compared by microbial pathogen (*Chlamydia trachomatis* only, *Neisseria gonorrhoeae* only, *Mycoplasma genitalium* only, co-infection with two or more pathogens, or no pathogens) among 298 women with histologically confirmed endometritis from the PID Evaluation and Clinical Health (PEACH) study. Times to pregnancy and recurrent PID were assessed over a mean of 84 months and compared between women who delayed care (≥ 14 days) and women who sought early care, in the entire cohort and in subsets defined by microbial infection. Analyses were adjusted for age and race, additionally time to pregnancy was adjusted for self-reported baseline infertility.

Results—Patients waited a mean of 7 days before seeking care for symptoms. Time to care was longest among women infected by *C. trachomatis* only (12.3±9.4 days) and *M. genitalium* only (10.9±8.9 days) and the shortest among women infected by *N. gonorrhoeae* only (4.6±5 days) or co-infection (5.6±5.1 days, $p<0.001$). Rates of infertility, recurrent PID, and chronic pelvic pain were frequent overall (17%, 20%, and 36%) and tended to be higher, albeit non-significantly, after delayed care.

Conclusions—Among women with clinically suspected PID, time to care was generally high. *C. trachomatis* and *M. genitalium* positive women had the longest times to care. Although reproductive morbidity was high in this cohort, associations with delayed care were non-significant.

Keywords

Pelvic Inflammatory Disease; Delayed Treatment; *Chlamydia trachomatis*; *Neisseria gonorrhoeae*; *Mycoplasma genitalium*

Introduction

Pelvic Inflammatory Disease (PID), infection and inflammation of the female upper genital tract,¹ is a common condition affecting an estimated 8% to 11% of American women at

some time in their reproductive lives.² Approximately 1 million women will be treated annually for PID in the United States.³ Various organisms have been implicated in the etiology of PID including *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma genitalium* and anaerobic bacteria associated with bacterial vaginosis.³

PID is a disease that can cause serious reproductive morbidity. In a landmark Scandinavian cohort study conducted between 1960 and 1984,^{4,5} of 2500 women with clinically suspected PID, 16% with laparoscopically verified salpingitis versus 2.7% of controls became infertile.^{4,5} In addition, 20% and 25% with salpingitis developed recurrent PID and chronic pelvic pain respectively.^{4,5}

Hillis *et al.* reported that one strong predictor of sequelae following PID is delayed care.⁶ In this case-control study nested within the Scandinavian cohort,⁴ delayed care was associated with a three-fold increase in infertility or ectopic pregnancy among 443 women with one known episode of PID.⁶ Further, the association was strongest among 114 women infected with *C. trachomatis*, with 17.8% of *C. trachomatis* positive women who delayed seeking care experiencing impaired fertility compared to 0% who sought care promptly.⁶ As these associations have not been replicated in a contemporary cohort, and since the distribution of microbes among women with PID appears to have changed over time, our objective was to examine the microbial correlates of time to treatment and long term outcomes among PID patients.

MATERIALS AND METHODS

This study utilized data from the PID Evaluation and Clinical Health (PEACH) study. This was the first randomized clinical trial to compare inpatient and outpatient treatment in preventing long-term complications among 831 women with clinically suspected PID. The methods of subject recruitment, data collection, and follow-up have been reported elsewhere.⁷ Briefly, between March 1996 and February 1999 women aged 14-37 years were recruited from emergency departments, obstetrics and gynecology clinics, sexually transmitted disease clinics, and private practices at 7 primary and 6 secondary sites throughout the eastern, southern, and central regions of the United States. Women who had suspected PID and gave informed consent were eligible for the PEACH study. Eligible women had a history of pelvic discomfort for less than 30 days, findings of pelvic organ tenderness (uterine or adnexal) on bimanual examination, and leukorrhea and/or mucopurulent cervicitis and/or untreated but documented gonococcal or chlamydial cervicitis. The University of Pittsburgh Institutional Review Board approved the study.

A total of 2941 women were screened for study entry, of those 346 (11.8%) did not meet the clinical inclusion criteria for randomization. Women were additionally excluded if they were pregnant (n = 141, 4.8%); had taken antimicrobials within the past 7 days (n = 248, 8.4%); had a history of hysterectomy or bilateral salpingectomy (n = 248, 8.4%); had an abortion, delivery, or gynecologic surgery within the past 14 days (n = 51, 1.7%); had a suspected tubo-ovarian abscess or other condition requiring surgery (n = 191, 6.5%); had an allergy to the study medications (n = 163, 5.5%); were homeless (n = 29, 1%); or had vomiting after a trial of antiemetic treatment (n = 11, 0.4%). A total of 831 women were enrolled in the PEACH study. Our analyses are among 298 women with histologically confirmed endometritis and complete time to treatment data. These women did not differ on important demographic, clinical, and behavioral characteristics compared to women without complete data. Among our cohort, 251 had *N. gonorrhoeae* culture, 271 had *C. trachomatis* polymerase chain reaction (PCR) and 240 had *M. genitalium* PCR results available for analysis.

Women were randomized to either inpatient treatment of intravenous cefoxitin every 6 hours and doxycycline orally twice a day for 14 days; or outpatient treatment consisting of a single intramuscular injection of cefoxitin and oral doxycycline twice a day for 14 days. Because the treatment modality was not associated with reproductive morbidities in the PEACH study,⁸ we do not include them as a covariate in these analyses. Participants were followed-up with in-person visits at 5 and 30 days after treatment. At the 30-day follow-up the gynecological exam was repeated. Telephone follow-ups were conducted by the study nurses every 3 months during the first year after enrollment and then every 4 months until June 2004. At that point information was obtained by self report for 69.1% of the cohort, with a mean follow-up of 84 months.

A pelvic examination and interview were conducted at the baseline visit. The interview collected information on reason for visit, brief pain history, demographics, history of PID/sexually transmitted diseases (STDs), sexual and contraceptive history, reproductive decisions, douching history, pregnancy history, medical and gynecological history and lifestyle habits. Baseline demographic and clinical characteristics used in this analysis included age, race, marriage, education, insurance utilization, microbiological etiology, clinical findings (abnormal vaginal discharge, elevated temperature ($>100.4^{\circ}\text{F}$), elevated white blood cell count (WBC) ($> 10,000\text{mm}^3$), and bilateral adnexal tenderness), smoking, drug use, history of PID, history of bacterial vaginosis, history of *C. trachomatis*, history of *N. gonorrhoeae*, and history of pelvic surgery. Data on prior *M. genitalium* infection was not available. Follow-up interviews collected self-reported information on pelvic pain, pregnancy and births, signs and symptoms of PID, STDs, contraceptive use, pattern of sexual intercourse, and health care utilization.

Gynecological examinations were performed at baseline and 5 and 30 days post treatment. Vaginal smears were gram stained for bacterial vaginosis in a central laboratory by standardized methods described by Nugent *et al.*⁹ Endometrial biopsy specimens were obtained for histological examination including, chlamydial PCR and gonococcal culture. PCR and cultures were performed at a central reference laboratory. For the patients with endometrial biopsies, two reference pathologists separately evaluated at least one section stained with hematoxylin and eosin and at least one stained with methyl green pyronine. Disagreements about the presence or absences of neutrophils and plasma cells were settled by both pathologists reading the slides together and coming to an agreement. Histological endometritis was based on a modification of the criteria proposed by Kiviat *et al.*¹⁰ Endometritis was defined as the presence of at least five neutrophils in the endometrial surface epithelium in the absence of menstrual endometrium and/or at least two plasma cells in the endometrial stroma. Cervical and endometrial specimens were stored and later used to test for *M. genitalium*¹¹ using MgPa-IMW PCR analysis targeting the MgPa gene.¹²

In the current paper, the main outcome variable is delayed care. Sensitivity analyses were conducted to define delayed care in our cohort. Participants were considered to have delayed care if they reported that treatment was sought after having pain between 14 and 30 days ($n = 70$), as women with over 30 days of pain were not included in PEACH. Participants who sought treatment before experiencing 14 days of pain were considered to have sought early care ($n = 228$). The variable was categorized by using the 75th percentile of the distribution of the days until treatment reported during the baseline questionnaire.

Reproductive outcomes included pregnancy, infertility, live birth, recurrent PID, and chronic pelvic pain. Self-reported pregnancy was determined by a positive urine/blood test or physician's diagnosis. Pregnancy was determined among women reporting no birth control or methods considered being unreliable, including withdrawal, rhythm method, vasectomy, or using the following methods rarely or occasionally – diaphragm, condoms, spermicidal

foam/cream/jelly/suppositories, or cervical cap. Infertility was defined by lack of conception (positive urine test or blood test or doctor's diagnosis of pregnancy) despite sexual activity with rare or never use of methods of contraception considered reliable during 12 or more months of follow-up. Frequency of sexual activity did not differ significantly between groups ($P = 0.6180$). Live birth was determined by self-report, and recurrent PID was self-reported and verified whenever medical records were available (45% of cohort). Recurrent PID was confirmed in 76% of medical records. Chronic pelvic pain was defined by two or more consecutive reports of pelvic pain during follow-up. Data from at least 2 follow-up visits were required to determine chronic pelvic pain.

Frequencies of baseline characteristics including age, race, marriage, education, insurance, microbiological etiology, vaginal discharge, temperature, elevated WBC, bilateral adnexal tenderness, smoking, drug use, and gynecological history were compared between patients seeking delayed care or early care, using the X^2 test of proportions.

Delayed care was compared among the following groups; women with *C. trachomatis* identified in the cervix and/or endometrium who had test results that were negative for both *N. gonorrhoeae* and *M. genitalium*, women with *N. gonorrhoeae* identified in the cervix and/or endometrium who had test results that were negative for both *C. trachomatis* and *M. genitalium*, women with *M. genitalium* identified in the cervix and/or endometrium who had test results that were negative for both *C. trachomatis* and *N. gonorrhoeae*, and women with co-infection with two or more of these organisms. A total of 188 women had complete data on all three organisms. Important demographic, behavioral, and clinical characteristics of these women did not differ from women without complete data on all three organisms. Kruskal Wallis test was used to compare the mean time to treatment between microbial pathogens. Cox regression models were used to compare times to pregnancy and times to recurrent PID between groups among the entire cohort and by groups defined by microbial pathogen. All models were adjusted for race and age, and models predicting infertility, pregnancy, and live birth were additionally adjusted for self-reported infertility at baseline. All analyses were conducted using SAS V9.2 (Cary, NC).

RESULTS

Treatment group, age, education, marriage, insurance, vaginal discharge, elevated temperature, history of PID, history of bacterial vaginosis, history of *C. trachomatis*, history of *N. gonorrhoeae*, history of pelvic surgery, and behavioral characteristics did not differ significantly between groups (Table 1). Women with delayed care ($n = 70$) compared to women with early care ($n = 228$) were significantly less likely to be black (68.6% vs. 82%; $p = 0.016$), less likely to have an elevated WBC count (26.3% vs. 43.9%; $p = 0.017$), and less likely to have bilateral adnexal tenderness (74.3% vs. 85.1%; $p = 0.037$).

Time to care varied within our cohort, ranging from 1 to 30 days. Overall, women waited a mean of 7 days before seeking care for symptoms. The mean time to treatment differed significantly between microbial pathogen ($p < 0.0001$), with those who had *C. trachomatis* monoinfection exhibiting the longest time to treatment (12.3 days) followed by patients with *M. genitalium* monoinfection (10.86 days), co-infection patients (5.56 days), and patients with *N. gonorrhoeae* monoinfection (4.56 days; Table 2). Women who tested negative for all three pathogens delayed care for 8.83 days. While these women tested negative for all three of our pathogens, we cannot rule out that they aren't infected with other pathogens which were not tested for or tested negative due to a small pathogen load. Pairwise comparisons revealed that time to care among patients with *C. trachomatis* monoinfection significantly differed from *N. gonorrhoeae* monoinfection and co-infection ($p < 0.05$), but not *M. genitalium* monoinfection. Similarly, *M. genitalium* monoinfection significantly differed

from *N. gonorrhoeae* monoinfection and co-infection ($p < 0.05$), but not *C. trachomatis* monoinfection.

Among women with co-infection, those infected with both *C. trachomatis* and *M. genitalium*, but not *N. gonorrhoeae*, had the longest times to treatment (6.8 ± 5.7 days), followed by infection with both *C. trachomatis* and *N. gonorrhoeae*, but not *M. genitalium*, (5.8 ± 5.6 days), infection with both *N. gonorrhoeae* and *M. genitalium*, but not *C. trachomatis*, (4.7 ± 3.7 days), and co-infection with all three pathogens (2.7 ± 1.7 days). Results were non-significant ($p = 0.6638$). Pairwise comparisons revealed similar but non-significant results.

Women with *C. trachomatis* monoinfection were more likely to delay care than receive early care (23.8% vs. 8.9%; $p = 0.0186$) (Table 3). Women with *M. genitalium* were also more likely to delay care than receive early care (7.1% vs. 2.7%; $p = 0.1551$), although results were non-significant. However, this may be explained by the small sample size and low power. In contrast, women with *N. gonorrhoeae* monoinfection were less likely to delay care compared to those with early care (9.5% vs. 28.8%; $p = 0.0122$).

Although infertility, recurrent PID, and chronic pelvic pain were frequent overall (17%, 20%, & 36%), rates did not significantly differ between women with delayed care and early care. In the entire cohort, there was a non-significant decrease in pregnancy rates (Adj. HR 0.79, 95% CI 0.55-1.13) and increase in recurrent PID (Adj. HR 1.46, 95% CI 0.83-2.58) among women who delayed care. Among *C. trachomatis* patients there was a 6-fold increase in recurrent PID among those who delayed care (Adj. HR 6.11, 95% CI 0.21-187.41), although this was non-significant. A non-significant increase in recurrent PID was also observed among *M. genitalium* (Adj. HR 1.59, 95% CI 0.02-125.52) and *N. gonorrhoeae* (Adj. HR 1.23, 95% CI 0.15-10.05) patients who delayed care. However, the sample size was small for monoinfections, limiting our power and resulting in large confidence intervals.

DISCUSSION

In this cohort of women with mild to moderate PID, times to care varied by pathogen, with the longest times among women with *C. trachomatis* monoinfection, followed by *M. genitalium* monoinfection, and the shortest times among women with *N. gonorrhoeae* monoinfection and co-infection with two or more pathogens. Overall, rates of infertility, recurrent PID, and chronic pelvic pain were high in our cohort.

Our findings demonstrate that women infected with *C. trachomatis* monoinfection had the longest times to care following the onset of pelvic pain. This is similar to Hillis *et al.* who reported that *C. trachomatis* was associated with delayed care (OR 2.1, 95% CI 1.0-4.1).⁶ Our results indicate trends towards decreased pregnancy rates and increased recurrent PID. This is similar to Hillis *et al.* who found that delayed care was associated with impaired fertility (OR 2.8, 95% CI 1.3-6.1).⁶ In contrast to Hillis *et al.* our results were non-significant.

There are several possible explanations for these not entirely concordant results. Our sample size limited the power of our analysis. Further, our population of women is likely a different patient population than the Scandinavian women recruited a generation ago. In addition, endometrial histology was used to confirm PID in our study, whereas 1,844 patients in the Westrom study had laparoscopically confirmed salpingitis.⁵ Although, the use of histologically confirmed endometritis to diagnose PID is an appropriate alternative to laparoscopy,³ not all women with endometritis have salpingitis.¹ Salpingitis may indicate more severe disease and lead to tissue damage, while endometritis may have lesser effects

on tubal pathology.¹ In fact, endometritis was previously reported to not be associated with reproductive morbidity in the PEACH study.¹

Lastly, our studies differed in our definition of delayed care. Hillis *et al.* defined delayed care as 3 or more days of pain before seeking treatment. This cut-point was not appropriate for our population as 76% of patients delayed care for 3 days or more and waited a mean of 7 days before seeking treatment. We ran several sensitivity analyses and using a definition of 3 or more days of pain before seeking care did not change our results.

Our finding that patients with chlamydial or *M. genitalium*-associated PID were more likely to delay care was not surprising. Among women with PID, pelvic pain may be mild or absent,¹⁴ and PID symptoms vary by microbial etiology.^{13,15-17} Chlamydial infections are known to elude detection because they produce few or no symptoms or because the symptoms are non-specific.¹⁸ Further, in chlamydial salpingitis, clinical manifestations are often mild but associated with severe tubal damage.^{15,18} This is in contrast to gonococcal salpingitis which produces more overt and severe symptoms but leads to milder tubal damage.¹⁵

We found that the time to treatment for *M. genitalium* was similar to that of *C. trachomatis*. This finding is consistent with other studies reporting similar symptoms between *C. trachomatis* and *M. genitalium*.^{16,17} This may indicate that among women with PID, those infected with *N. gonorrhoeae* or co-infection present with more overt and severe symptoms, leading to earlier treatment than women with *C. trachomatis* or *M. genitalium*. Indeed we found that the clinical characteristics such as elevated temperature, elevated WBC count, and bilateral adnexal tenderness were lower among women who delayed care compared to those who presented with early care.

The role of individual microbes in the development of sequelae following PID is not well understood. In the PEACH study, approximately 6% of participants had *N. gonorrhoeae* or *C. trachomatis* and 45.9% had persistent endometritis at the 30-day follow-up following baseline treatment with cefoxitin and doxycycline.⁸ Despite demonstrated efficacy of this CDC recommended regimen,¹⁹ there may be several reasons for long term sequelae in some patients. First, as patients with chlamydial or *M. genitalium* infection were more likely to delay care, persistent, low level inflammation may have caused permanent damage to the reproductive tract prior to enrollment. Further *M. genitalium* is resistant to tetracycline and lacks the cell wall target of cefoxitin.¹¹ Not surprisingly, PEACH study patients with endometrial *M. genitalium* were previously reported to suffer treatment failure¹¹ Although the effect of delayed care on sequelae among microbial subgroups was non-significant, rates of sequelae were high.

Our study has several strengths. First, data were obtained from a large, multicentre, prospective randomized clinical trial, with comprehensive demographic, clinical, and obstetric measurements. Further, our findings are generalizable to patients treated for clinically suspected PID. We recognize that timing of treatment was based on self-reported data and that misclassification bias is possible.

Our study demonstrates that among patients with clinically suspected PID, those infected with *C. trachomatis* and *M. genitalium* were more likely to delay care compared to those with gonococcal infection, possibly increasing the likelihood that persistent, low level inflammation may permanently damage the reproductive tract before patients seek care. Our findings could be translated to a population with uncomplicated STI's, where those infected with *C. trachomatis* and *M. genitalium* may be more likely to delay or not seek treatment, putting them at higher risk for PID and its sequelae. Thus continued efforts aimed at early identifications and treatment of asymptomatic, mildly symptomatic, and symptomatic lower

genital tract infections are needed for the prevention and progression to PID and its associated long term morbidities.

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Summary

Among women with pelvic inflammatory disease, times to care were generally high, with the longest times among women with *Chlamydia trachomatis* or *Mycoplasma genitalium* monoinfection.

Table 1

Baseline characteristics of participants presenting for care

Characteristics	Delayed Care (≥ 14 days) N = 70 n (%)	Early Care (< 14 days) N = 228 n (%)	* p-value
Treatment Groups			
Inpatient	31 (44.3)	121 (53.1)	0.198
Outpatient	39 (55.7)	107 (46.9)	
Demographics			
Age			0.423
<25 years	52 (74.3)	158 (69.3)	
25+ years	18 (25.7)	70 (30.7)	
Race/Ethnicity			0.016
African American	48 (68.6)	187 (82)	
White/Hispanic/Other	22 (31.4)	141 (18)	
Married	7 (11.3)	14 (6.7)	0.231
Education			0.732
Less than high school	30 (72.7)	103 (45.2)	
High school or greater	125 (54.8)	40 (57.1)	
Uninsured	36 (58.5)	114 (54.3)	0.599
Clinical Findings			
Abnormal vaginal discharge	47 (24.4)	23 (21.9)	0.634
Temperature (>100.4 F)	3 (4.7)	26 (11.9)	0.095
WBC (> 10,000 mm³)	15 (26.3)	86 (43.9)	0.017
Bilateral adnexal tenderness	52 (74.3)	194 (85.1)	0.037
Gynecological History			
History of PID	16 (23.5)	53 (23.8)	0.968
** History of BV	15 (21.7)	43 (19.5)	0.679
History of <i>C. trachomatis</i>	22 (31.9)	100 (45.1)	0.053
History of <i>N. gonorrhoeae</i>	24 (34.3)	60 (26.8)	0.225
§ History of pelvic surgery	14 (20.0)	51 (22.4)	0.650
Behavioral			
Current smoker	33 (47.1)	113 (49.8)	0.699
Drug use	21 (30)	67 (29.5)	0.938

* Chi-square was used to derive the p-value

** History of bacterial vaginosis (BV)

[§]Self-reported prior pelvic surgeries including but not limited to: Appendix, Bartho cyst, tubal, ovarian, uterine, fiscular, hernia, and coloscopy.

Table 2

Mean time to treatment by organism

Organism	Days of pain Mean±SD	* p-value
<i>C. trachomatis</i> Only (N=23)	12.3±9.35	<.0001
<i>M. genitalium</i> Only (N=7)	10.86±8.90	
<i>N. gonorrhoeae</i> Only (N=45)	4.56±4.97	
** Co-Infection (N=50)	5.56±5.11	
None (N=63)	8.83±8.95	

* Kruskal Wallis test was used to derive the p-value.

** Co-infection – participants with any combination of two or more of the following pathogens: *C. trachomatis*, *N. gonorrhoeae*, or *M. genitalium*

Table 3

Microbial correlates of participants presenting for care 14 days.

Organism	Delayed Care (14 days) * N=48 n (%)	Early Care (< 14 days) * N=140 n (%)	** p-value
<i>C. trachomatis</i> Only (N=23)	10 (23.8)	13 (8.9)	0.0186
<i>M. genitalium</i> Only (N=7)	3 (7.1)	4 (2.7)	0.1551
<i>N. gonorrhoeae</i> Only (N=45)	4 (9.5)	41 (28.8)	0.0122
[§] Co-Infection (N=50)	8 (19.1)	42 (28.8)	0.2090
None (N=63)	17 (40.5)	46 (31.5)	0.4613

* A total of 188 women had data on *C. trachomatis*, *M. genitalium*, and *N. gonorrhoeae* combined.

** Chi-square was used to derive the p-value

[§]Co-infection – participants with any combination of two or more of the following pathogens: *C. trachomatis*, *N. gonorrhoeae*, or *M. genitalium*