

# Chlamydial cervicitis: testing the practice guidelines for presumptive diagnosis

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## Abstract

**Objective:** To test the recommendation from the Canadian guidelines for sexually transmitted diseases (STDs) that mucopurulent endocervical discharge and 10 or more polymorphonuclear leukocytes (PMNs) per high-power field of a Gram-stained endocervical smear or, when Gram staining is not possible, the presence of endocervical discharge and one of edema, erythema or induced mucosal bleeding of the cervix can be considered diagnostic for chlamydial cervicitis.

**Methods:** A total of 596 consecutive women attending 2 family planning clinics for routine care underwent vaginal speculum examination and were tested for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. PMN counts from Gram-stained endocervical smears and the presence or absence of putative indicators of chlamydial infection were recorded.

**Results:** The prevalence of chlamydial cervicitis was 6.2% (37/596), and no women tested positive for *N. gonorrhoeae*. Presumptive diagnosis of chlamydial cervicitis based on the guidelines criteria of mucopurulent endocervical discharge and 10 or more PMN per high-power microscopic field had a sensitivity and specificity of 18.9% and 97.0% respectively, a positive predictive value of 29.2% and a positive likelihood ratio (LR) of 6.2 ( $p = 0.003$ ). Presumptive diagnosis based on endocervical discharge with edema, erythema or induced mucosal bleeding of the cervix had a sensitivity and specificity of 43.2% and 80.0% respectively, a positive predictive value of 12.5% and a positive LR of 2.2 ( $p = 0.002$ ). In the presence of bacterial vaginosis or vaginitis, the LR for the criteria of mucopurulent endocervical discharge and 10 or more PMN per high-power field was 5.4 ( $p = 0.04$ ), whereas the LR was 4.3 ( $p = 0.10$ ) if bacterial vaginosis and vaginitis were absent.

**Conclusions:** In this setting, the practice of making a presumptive diagnosis of chlamydial cervicitis on the basis of the criteria given in the Canadian STD guidelines was not supported.

## Résumé

**Objectif :** Vérifier la recommandation tirée des lignes directrices canadiennes sur les maladies transmissibles sexuellement (MTS) selon laquelle un écoulement endocervical mucopurulent combiné à un résultat de 10 leucocytes polymorphonucléaires ou plus présents par champ à fort grossissement d'un frottis endocervical à coloration de Gram ou, lorsque la coloration de Gram est impossible, la présence d'un écoulement endocervical et d'oedème, d'érythème ou de saignement provoqué de la muqueuse du col, peuvent être considérés comme un diagnostic de cervicite à *Chlamydia*.

**Méthodes :** Au total, 596 femmes qui se sont présentées consécutivement à 2 cliniques de planification familiale pour des soins de routine ont subi un examen vaginal effectué au moyen d'un spéculum et ont subi un test de dépistage du *Chlamydia trachomatis* et du *Neisseria gonorrhoeae*. On a consigné le nombre de leucocytes polymorphonucléaires provenant de frottis endocervicaux soumis à une coloration de Gram et la présence ou l'absence d'indicateurs hypothétiques d'infection à *Chlamydia*.



## Evidence

## Études

From the Departments of  
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Epidemiology and  
Biostatistics, and ‡Pathology,  
McMaster University,  
§the Regional Virology and  
Chlamydiology Laboratory,  
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‡ See related article page 65

**Résultats :** La prévalence de cervicités à *Chlamydia* s'est établie à 6,2 % (37/596) et aucune femme n'a donné de résultat positif au test de dépistage du *N. gonorrhoeae*. Le diagnostic présomptif de cervicite à *Chlamydia* fondé sur les critères des lignes directrices relatifs à la présence d'un écoulement endocervical mucopurulent et de 10 leucocytes polymorphonucléaires ou plus par champ microscopiques à fort grossissement avait une sensibilité et une spécificité de 18,9 % et de 97,0 % respectivement, une valeur prédictive positive de 29,2 % et un rapport de vraisemblance positif de 6,2 ( $p = 0,003$ ). Un diagnostic présomptif fondé sur un écoulement endocervical accompagné d'oedème, d'érythème ou de saignement provoqué de la muqueuse du col avait une sensibilité et une spécificité de 43,2 % et 80,0 % respectivement, une valeur prédictive positive de 12,5 % et un ratio de vraisemblance positif de 2,2 ( $p = 0,002$ ). En présence de vaginose ou de vaginite bactérienne, le coefficient de vraisemblance des critères que constituent l'écoulement endocervical mucopurulent et la présence de 10 leucocytes polymorphonucléaires ou plus par champ à fort grossissement était de 5,4 ( $p = 0,04$ ), tandis que le coefficient de vraisemblance était de 4,3 ( $p = 0,10$ ) en l'absence de vaginose et de vaginite bactérienne.

**Conclusions :** Dans ce contexte, la pratique qui consiste à poser un diagnostic présomptif de cervicite à *Chlamydia* fondé sur les critères énoncés dans les lignes directrices canadiennes sur les MTS n'a pas été appuyée.

Chlamydial infections cause a spectrum of illness in women, including pelvic inflammatory disease and its sequelae: tubal factor infertility, ectopic pregnancy and chronic pelvic pain.<sup>1</sup> Evidence has been accumulating that points to early recognition and treatment of chlamydial infections as crucial steps in preventing complications and sequelae.<sup>2,3</sup> At least half of cases of tubal factor infertility<sup>4,5</sup> could be prevented if chlamydial infections could be eliminated, and approximately 40% of ectopic pregnancies are attributable to chlamydial pelvic inflammatory disease.<sup>6</sup> The effectiveness and efficiency of selective (rather than universal) screening of women for chlamydial cervicitis was demonstrated in a previous Canadian study,<sup>7</sup> and this approach has been advocated in recently published guidelines of the Canadian Task Force on the Periodic Health Examination.<sup>1</sup>

Because infection is not associated with specific clinical features, historical and clinical characteristics that might aid in the presumptive diagnosis of *Chlamydia trachomatis* infection have been of great interest, especially when immediate treatment is desirable in low resource settings or when return for treatment after diagnostic testing is not feasible. Canadian guidelines for STDs currently recommend that a presumptive diagnosis of chlamydial infection be made on the basis of the presence of mucopurulent or purulent endocervical secretions and 10 or more polymorphonuclear leukocytes (PMN) per high-power field of a Gram-stained endocervical smear.<sup>8</sup> The guidelines recommend that if Gram staining is not available a presumptive diagnosis of mucopurulent cervicitis due to *Neisseria gonorrhoeae* and *C. trachomatis* should be made if endocervical discharge and at least one of edema or erythema in an area of ectopy or induced mucosal bleeding is present.<sup>8</sup>

In one study the presence of yellow mucopurulent endocervical secretions and 10 or more PMN per high-power field in a Gram-stained cervical smear had 91% sensitivity and 74% specificity in detecting chlamydial infection;<sup>9</sup> however, other studies have not validated these results in US women. Moscicki and associates<sup>10</sup> suggested that a threshold value of 5 PMN, rather than 10, would be more sensitive for diagnosing cervicitis. Nugent and Hillier<sup>11</sup> could not confirm the usefulness of the guideline's cutoff of 10 PMN in pregnant women and suggested a cutoff value of 30 in this group.

Despite the lack of validation and the presumed inability of most physicians to have Gram staining performed in their offices, Canadian practice guidelines published in 1995 recommended these criteria for the presumptive diagnosis of chlamydial cervicitis.<sup>8</sup> To test the accuracy of the guidelines, we analysed Gram-stained endocervical smears obtained from (but not reported for) a group of participants in a previously published study on selective screening for chlamydial cervicitis,<sup>7</sup> as well as descriptions of endocervical discharge from these patients.

## Methods

### Sample selection

The present study was based on data from 596 of the first 617 women 16 years of age or older who were screened for *Chlamydia* and from whom Gram-stained endocervical smears were obtained for a previously reported study conducted from January 1989 to April 1990.<sup>7</sup> The women were attending 2 family planning clinics for



routine care, which included a pelvic examination. Potential participants were excluded if they had used antibiotics within the previous 21 days, were known to be pregnant or were menstruating. After giving written informed consent (on a form approved by the McMaster University Ethics Review Committee), the participants completed a self-administered questionnaire on demographic information and sexual, gynecologic, and obstetric history and symptoms. Clinic staff reviewed the completed questionnaire with the client to clarify ambiguities and obtain missing data. Twenty-one Gram-stained endocervical specimens were unsuitable for reading;<sup>9</sup> therefore, our analysis was based on 596 of the first 617 women who participated in the other study.

### **Patient evaluation and data collection**

Fifteen physicians, uniformly trained before the study to reduce interobserver variation, performed the gynecologic examinations, collected the specimens and recorded the results on a standardized form. Discharge from the endocervical os on a white-tipped swab was described in terms of translucence (opaque or clear), colour (yellow or white) and consistency (mucoid or watery). Mucopurulent endocervical discharge was defined as the presence of yellow endocervical mucus on a white swab.<sup>9</sup> Erythema and edema was scored as present or absent, and induced mucosal bleeding was reported if bleeding occurred with cervical swabbing. All specimens were collected according to a standard protocol, and the physicians did not know the results of other tests. Swabs for microbiologic culture and Gram staining were collected after the cervix had been cleaned of excess mucus with a large cotton swab. A swab from the posterior vaginal fornix and an endocervical swab were smeared on separate glass slides and air dried for Gram staining. Three endocervical swabs were obtained, one each for *C. trachomatis* culture, chlamydial enzyme immunoassay (EIA) and *N. gonorrhoeae* culture.

### **Laboratory methods**

All specimens were transported on wet ice to the laboratory within 24 hours of collection. *C. trachomatis* was isolated by means of cyclohexamide-treated McCoy cells and iodine staining in a microculture system with one blind passage after 72 hours.<sup>12</sup> For the isolation of *N. gonorrhoeae*, the specimen was inoculated onto a plate of modified NYC selective culture medium, and standard methods were followed.<sup>12</sup> Swabs were assayed by the Chlamydiazyme EIA kit (Abbott Laboratories, North Chicago, Ill.), and positive specimens were retested by means of a confirmatory blocking assay (Abbott Laboratories), which identified false positives.<sup>7</sup> A saline-diluted

wet preparation for *Trichomonas vaginalis*<sup>13</sup> and a Gram-stained vaginal smear for bacterial vaginosis and hyphae<sup>14</sup> were analysed. No tests for herpes simplex viral identification were performed.

Samples unsuitable for Gram staining either contained more than 100 epithelial cells per high-power field, which indicated that the sample might have been taken from the vagina rather than the endocervix, or lacked a sufficient number of cells for evaluation.<sup>9</sup> The mean PMN count per 1000 $\times$  oil-immersion microscopic field of a Gram-stained endocervical smear was based on the PMN counts in 5 nonadjacent fields with a thin, homogeneous layer of cervical mucus.<sup>9</sup> The reliability of categorizing PMN counts at a cutoff of 10 per microscopic field was good, as checked by the 2 microscopists who evaluated the slides. The value of kappa, the proportion of possible interobserver agreement above agreement due to chance, was good (0.51), and the raw agreement was 83.3%.<sup>15</sup> The 2 microscopists were blinded to the results of testing for *Chlamydia*.

### **Statistical methods**

A case of chlamydial infection was defined as a positive result from either culture or blocked EIA for samples obtained at the cervix. The data were analysed by means of the continuity-corrected  $\chi^2$  or Fisher's exact test as appropriate, with a probability of a type I error of 0.05 (2-tailed). The positive likelihood ratio (LR) was defined as the odds that a positive result on the diagnostic test would be expected in a patient with, as opposed to without, the target disorder.<sup>16</sup> For example, the positive LR (2.0) for the odds that a PMN count of 30 or more on a Gram-stained cervical smear would appear in a patient with chlamydial cervicitis was calculated as 6/37 (0.16) divided by 47/559 (0.08) (Table 1, line 4).

The accuracy of the STD guidelines for the presumptive diagnosis of chlamydial cervicitis was also tested for an association with bacterial vaginosis or vaginitis. Women were included in this analysis if data were available on the presence or absence of bacterial vaginosis, yeast or trichomonal vaginitis ( $n = 396$ ).

## **Results**

### **Sample description**

The mean age of the 596 women was 21.5 years (standard deviation 3.1). A history of STD was reported by 135 (22.7%) of 594 women who answered this question, and 328 (55.0%) of the 596 women reported a new sexual partner in the preceding year. Most of the women were being seen for an annual pelvic examination. Thirty-seven (6.2%) of the women tested positive for *C. trachomatis*.

The results were positive by culture only for 10 women and by blocked EIA only for 11; both tests were positive for the remaining 16 women. Questioning revealed intermenstrual bleeding in 68 (11.4%), increased urination frequency in 62 (10.4%), dysuria in 139 (23.3%) and yellow vaginal discharge in 49 (8.2%) of the 596 women. Endocervical secretion, described as either yellow, opaque or mucoid, was present in 250 (41.9%) of the 596 women on vaginal speculum examination. In 48 (19.2%) of those 250 women, the endocervical discharge was described as yellow. Redness of the cervix was noted in 130 (22.0%) of 592 women, swelling of the cervix in 23 (3.9%) of 592 women and induced mucosal bleeding in 166 (27.9%) of 596 women. *N. gonorrhoeae* was not isolated at the cervix of any women, and intracellular gram-negative diplococci were not identified in any Gram-stained endocervical smears. Trichomoniasis and bacterial vaginosis were present in 1 (0.2%) of 565 and 60 (14.4%) of 417 women, respectively. Yeast was present in 57 (10.1%) of 565 women.

**Diagnostic accuracy of PMN count and mucopurulent endocervical discharge**

Table 1 shows rates of chlamydial infection for various PMN cutoff values. A cutoff of 20 PMN showed the strongest (LR = 2.1) and the only significant ( $p = 0.008$ ) association with chlamydial infection. In a test of the guidelines recommendation to use the combination of PMN count and mucopurulent endocervical discharge, the cutoff of 10 PMN had a sensitivity of 18.9% and a specificity of 97.0%; the positive predictive value was

29.2% and the LR 6.2 (Table 2). Using higher cutoff values for PMN (20 or 30) increased the positive predictive values and the LRs. According to the guidelines recommendation to diagnose chlamydial cervicitis in the presence of mucopurulent endocervical discharge and PMN of 10 or more, 24 women would have been candidates for treatment; however, only 7 of these actually tested positive for chlamydial infection.

**Diagnostic accuracy of endocervical discharge with edema, erythema or induced mucosal bleeding of the cervix**

According to the criteria of endocervical discharge and one of edema, erythema or induced mucosal bleeding of the cervix — the combination recommended in the guidelines for presumptive diagnosis of chlamydial infection when Gram staining is not available — 16 of 37 cases of chlamydial infection were correctly identified (sensitivity 43.2%), and 447 of 559 negative cases were identified (specificity 80.0%). The positive predictive value was 12.5%, the negative predictive value 95.5% and the LR 2.2 ( $p = 0.02$ ). On this basis, 128 women would have been treated, of whom only 16 actually had infections.

**Vaginal conditions and presumptive diagnosis of cervicitis**

For 396 women, data were available on the presence or absence of bacterial vaginosis, yeast and trichomonal vaginitis. Table 3 shows the results of testing the guide-

**Table 1: Association with chlamydial infection of different cutoff values for counts of polymorphonuclear leukocytes (PMN) per high-power field (HPF) in Gram-stained endocervical smears\***

PMN/HPF	Positive for <i>Chlamydia</i> <i>n</i> = 37	Negative for <i>Chlamydia</i> <i>n</i> = 559	Sensitivity, %	Specificity, %	PPV,† %	NPV,‡ %	LRS	<i>p</i>
≥ 5	15	185	40.5	66.9	7.5	94.4	1.2	0.45
≥ 10	15	140	40.5	75.0	9.7	95.0	1.6	0.06
≥ 20	12	82	32.4	85.3	12.8	95.0	2.1	0.008
≥ 30	6	47	16.2	91.6	11.3	94.3	2.0	0.19

\*Based on data for 596 women attending 2 family planning clinics where the prevalence of chlamydial cervicitis was 6.2%.  
 †Positive predictive value.  
 ‡Negative predictive value.  
 §Positive likelihood ratio.

**Table 2: Association with chlamydial infection of different cutoff values for PMN counts per HPF in Gram-stained endocervical smears among women with mucopurulent endocervical discharge (MED)**

Indicator of cervicitis*	Positive for <i>Chlamydia</i> <i>n</i> = 37	Negative for <i>Chlamydia</i> <i>n</i> = 559	Sensitivity, %	Specificity, %	PPV, %	NPV, %	LR	<i>p</i>
≥ 10 PMN/HPF + MED	7	17	18.9	97.0	29.2	94.8	6.2	0.003
≥ 20 PMN/HPF + MED	7	11	18.9	98.0	38.9	94.8	9.6	< 0.001
≥ 30 PMN/HPF + MED	4	5	10.8	99.1	44.4	94.4	12.0	0.001

\*Based on data for 596 women attending 2 family planning clinics among whom the prevalence of chlamydial cervicitis was 6.2%.



lines in women with vaginitis or bacterial vaginosis and those without. In women with either of these conditions, the LR for the guidelines criteria of mucopurulent endocervical discharge and PMN of 10 or more was 5.4 ( $p = 0.04$ ); the LR was 4.3 among women who had neither of these conditions ( $p = 0.10$ ). However, according to the guidelines criteria of visual indicators without PMN count, the LR was higher (2.7,  $p = 0.006$ ) among the women without vaginitis or bacterial vaginosis than among those with a vaginal condition (LR 1.5,  $p = 0.32$ ) and in the overall sample (LR 2.2,  $p = 0.02$ ).

## Discussion

Our findings agree with those previously reported in the US<sup>10,11</sup> and indicate that a cutoff value of 10 PMN per high-power field on a Gram-stained cervical smear is not clinically useful in the presumptive diagnosis of chlamydial cervicitis. In our sample, the LR values for PMN cutoffs of 10, 20 and 30 in the presence of a mucopurulent endocervical discharge were 6.2 ( $p = 0.003$ ), 9.6 ( $p < 0.001$ ) and 12.0 ( $p = 0.001$ ) respectively. If the PMN count had not been available and the alternative criteria of endocervical discharge combined with edema, erythema or induced mucosal bleeding of the cervix had been used for presumptive treatment, the LR would have been 2.2 ( $p = 0.02$ ). Nugent and Hillier<sup>11</sup> found that using the presence of yellow discharge on an endocervical swab as the criterion for mucopurulent cervicitis yielded a higher LR (2.2) than cutoff values of 10 PMN (LR 1.2) or 30 PMN (LR 1.8). Moscicki and associates<sup>10</sup> reported that the PMN threshold of 5 was more sensitive (91%) than cutoff values of 10 (47%) and 15 (79%); however, the LR for the cutoff of 15 (3.5) was greater than the LR for the cutoff values of 5 (2.6) and 10 (2.2).

Brunham and associates<sup>9</sup> did not assess the influence of trichomonal or candidal vaginitis on PMN count in cervical mucus because of the small number of women in their study who were infected with those organisms; however, they suggested that specimens be carefully collected to exclude vaginal epithelial cells and vaginal flora. Our results have also shown that the guidelines criteria, which rely on a PMN count of 10 or more, are more accurate in the presence of vaginitis or bacterial vaginosis. The dependence of accuracy on the presence or absence of vaginal conditions represents another drawback of using the PMN count for the presumptive diagnosis of chlamydial cervicitis.

Presumptive diagnostic criteria that do not rely on microscopic information are more practical for physicians to use in the office setting. Several studies have indicated that visual and historical indicators are effective in predicting the probability of chlamydial infection in women. Cervical signs such as the presence of endocervical discharge, cervical edema, erythema or induced mucosal bleeding are independent predictors of infection.<sup>17-19</sup> Age between 14 and 24 years,<sup>17</sup> having a partner with urethritis<sup>18</sup> and having a recent new sexual partner<sup>19</sup> are also independent predictors. In our setting, if testing for *Chlamydia* had been limited to women with cervical induced mucosal bleeding, suspicious discharge, increased urination frequency, intermenstrual bleeding or a new sexual partner in the previous year, 75.4% of the sample would have been screened, and 93.3% of all cases of chlamydial infection would have been detected, without any microscopic information.<sup>7</sup> This selective screening rule was shown to be effective and efficient in this low-prevalence setting and was validated in a student health clinic.<sup>7</sup>

Situations do arise when there is concern that a woman is not likely to return for treatment once a laboratory has

**Table 3: Association with chlamydial infection of different cutoff values for PMN counts per HPF in Gram-stained endocervical smears among women with mucopurulent endocervical discharge and vaginitis or bacterial vaginosis\***

Indicator of cervicitis	Positive for <i>Chlamydia</i>	Negative for <i>Chlamydia</i>	Sensitivity, %	Specificity, %	PPV, %	NPV, %	LR	<i>p</i>
<b>Vaginitis or bacterial vaginosis present</b>								
	<i>n</i> = 11	<i>n</i> = 79						
≥ 10 PMN/HPF + MED	3	4	27.3	94.9	42.9	90.4	5.4	0.04
≥ 20 PMN/HPF + MED	3	2	27.3	97.4	60.0	90.6	10.8	0.01
≥ 30 PMN/HPF + MED	1	2	9.0	97.5	33.3	88.5	3.6	0.33
Visual indicators† + MED	5	24	45.5	69.6	17.2	90.1	1.5	0.32
<b>Vaginitis and bacterial vaginosis absent</b>								
	<i>n</i> = 17	<i>n</i> = 289						
≥ 10 PMN/HPF + MED	2	8	11.8	97.2	20.0	94.9	4.3	0.10
≥ 20 PMN/HPF + MED	2	5	11.8	98.3	28.6	95.0	6.8	0.05
≥ 30 PMN/HPF + MED	1	1	5.9	99.7	50.0	94.7	17.0	0.10
Visual indicators + MED	8	50	47.0	82.7	13.8	96.3	2.7	0.006

\*Based on data from 396 women for whom information from vaginal fluid assessment for bacterial vaginosis, yeast and trichomonal vaginitis was available (part of a sample of 596 women attending 2 family planning clinics among whom the prevalence of chlamydial cervicitis was 6.2%).

†Endocervical discharge plus edema, erythema or induced mucosal bleeding of the cervix.



confirmed the diagnosis of chlamydial infection. In these cases, presumptive diagnosis and treatment may appear to be the preferred course. However, treatment based on a presumptive diagnosis of chlamydial cervicitis may be less cost-effective than treatment based only on confirmed diagnosis. A cost-effectiveness analysis comparing laboratory confirmation of *Chlamydia* with presumptive diagnosis reported that, all things being equal, presumptive treatment with single-dose azithromycin would result in a higher cost per case of pelvic inflammatory disease prevented than treatment with the same agent based on laboratory confirmation (US\$3502 v. US\$792).<sup>20</sup> However, the study did not mention what rate of return for treatment was assumed.

Generally speaking, guidelines should be developed and applied with caution. The diagnostic accuracy of criteria to predict infection may depend on the prevalence of the infection and the relative proportions of symptomatic and asymptomatic individuals in the population. Several studies have demonstrated that the sensitivity of chlamydial testing drops as the prevalence of infection and the proportion of those tested who are symptomatic decrease.<sup>21-23</sup> Presumptive diagnosis also has implications for reinfection, since treatment of sexual partners may not be concurrent, if it occurs at all. Guidelines that rely on the use of a microscope or Gram staining in the physician's office are likely to fail if neither is commonly available. The results of this study suggest that guidelines for presumptive diagnosis, like all practice guidelines, should be undergoing quality control for validity and practicability. It has been suggested that a randomized clinical trial is the most desirable way to assess whether implementation of the guidelines results in the expected outcomes.<sup>24</sup>

The 1995 Canadian STD guidelines criteria for presumptive diagnosis of chlamydial cervicitis appear to have been based on the 1984 results of Brunham and associates,<sup>9</sup> who used Gram-stained endocervical smears from Seattle women attending an STD clinic. It is interesting to note that by 1993, STD guidelines in the US were no longer recommending the use of the PMN count in the presumptive diagnosis of *C. trachomatis*.<sup>25</sup>

Future research may reveal criteria for presumptively diagnosing chlamydial infection that yield positive outcomes; however, the existing evidence suggests that treatment based on laboratory diagnosis is the most effective and efficient strategy for managing mucopurulent cervicitis.

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