

Does a water-based lubricant affect Pap smear and cervical microbiology results?

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Griffith WF, Stuart GS, Gluck KL, Heartwell SF. Vaginal speculum lubrication and its effects on cervical cytology and microbiology. *Contraception* 2005;72(1):60-4.

Research question

Does water-based lubricant affect results of Papanicolaou smears and detection of sexually transmitted infections?

Type of article and design

This was a randomized, single-blind, controlled trial.

Relevance to family physicians

Vaginal speculum examination is routinely performed by most family physicians, most commonly to obtain a Pap smear or to test for sexually transmitted infections, mainly *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. The most common reason cited by women for not having routine speculum examination is pain during the examination.¹ Whether or not lubrication will decrease discomfort during the speculum examination has never been tested, but several women have indicated to one of the authors (M.P.) that speculum examinations with lubrication are more comfortable. However, although lubrication might make the speculum examination more comfortable, most family physicians are reluctant to use lubrication because they have been told that it alters cytology and microbiology results.²⁻⁴

Overview of study and outcomes

The study was performed at the University of Texas Southwestern Medical Center at Dallas Maple Plaza Women's Health Center between July 2003 and February 2004. The clinic is 1 of 8 federally funded university family-planning clinics, servicing a homogenous, reproductive-aged, and predominantly low-socioeconomic Hispanic patient population. Patient demographic information and laboratory results were received in monthly aggregates without patient identification information. All patients undergoing Pap smear or endocervical DNA probe assay for *C trachomatis* and *N gonorrhoeae* were included in the study; therefore, repeat clinical visits by individual patients could occur. No exclusion criteria were listed in the article. The study was exempt from the university's Institutional Ethics Review Board. The authors did not state whether or not patients were informed that the trial was taking place and if they could decline participation. The 8 months of the study period were randomized

into equal numbers of control and experimental months. During the experimental months, all patients undergoing vaginal speculum examinations had the speculum lubricated with water-soluble gel lubricant. During the control months, water-moistened vaginal speculums were used. Pap smears were performed with Ayre spatulas followed by cytobrush, and the cells were applied to single glass slides, fixed with isopropyl alcohol, and allowed to air dry. Patients tested for *C trachomatis* and *N gonorrhoeae* were tested using DNA probe assay. Both cytopathology and microbiology laboratories were blinded to lubricant use. The expertise of the clinicians (nurse practitioners, residents, medical students, and nursing students supervised by faculty) was consistent during the study period. The study compared the number of unsatisfactory cytology results and the number of *C trachomatis* infections detected between water-lubricant (control) and gel-lubricant (experimental) months. Because of the small number of *N gonorrhoeae* infections detected, statistical comparisons could not be calculated.

The χ^2 and student *t* tests were used to determine if demographic characteristics differed between control and experimental months. The χ^2 test was used to determine the odds ratio (OR) for unsatisfactory cytology reports and number of positive test results for *C trachomatis* infections between experimental and control months.

Results

The total number of clinic visits during the trial period was 9500 (4901 during the experimental months and 4599 during the control months). No difference in demographic characteristics between the control and experimental groups was demonstrated. The total number of Pap smears collected was 3460 (1828 in the experimental months and 1632 in the control months). Results of 20 (1.1%) Pap smears were unsatisfactory during the experimental months and 24 (1.5%) were unsatisfactory during the control months (OR 0.74, 95% confidence interval [CI] 0.41 to 1.35). This statistically insignificant result is consistent with those of other experiments.^{5,6}

A total of 5535 combination microbial DNA probe assays for endocervical *C trachomatis* and *N gonorrhoeae* infections were collected (2909 during experimental months and 2626 during control months). During experimental months, 44 (1.5%) assays returned positive results for *C trachomatis*; during control months, 38 (1.5%) assays returned positive results for *C trachomatis* (OR 1.05, 95% CI 0.67 to 1.62). Because there were only 3

positive results for *N gonorrhoea* in the control months and 0 in the experimental months, statistical calculations for *N gonorrhoea* DNA probe assays could not be made.

Analysis of methodology

This study was a well-conducted randomized trial in a federally funded family-planning facility. The study participants included all patients who presented for Pap tests or DNA probe assays for *C trachomatis* or *N gonorrhoeae*. Although there were various service providers—including nurse practitioners, residents, medical students, and nursing students overseen by faculty—which might have resulted in inconsistent sampling techniques, distribution of service provider expertise did not change by month during the study period. Monthly randomization of lubricant or nonlubricant assignment for speculum insertion was chosen over individual patient randomization and permitted the inclusion of all patients. The study sampling method, therefore, could not account for repeat testing during the study period by individuals. Repeat testing of the same patient would not likely affect test results unless the Pap test and DNA probe swabs could not be obtained successfully from the individual. Because the rates of unsatisfactory tests were no different in each group, repeat testing did not appear to be a factor. Both the Pap smear and DNA probe assay laboratories were blinded to the monthly randomization assignment, and the study revealed no differences in the test results during the intervention and nonintervention months, with an OR of 0.74 for unsatisfactory cervical cytology and an OR of 1.05 for *C trachomatis* detection. The results for *N gonorrhoeae* could not be compared because of the low incidence rate of the infection in the sample population.

Application to clinical practice

The mix of disciplines and varying expertise among service providers did not indicate a significant change in satisfactory or unsatisfactory results during the monthly randomization assignment, which suggests that results would likely be similar in most physician offices. Although the single study site and patient characteristics could affect the generalizability of results, use of water-based gel lubricant or water-moistened vaginal speculum and the effect on test results is consistent with other Pap testing studies,^{5,6} which show no increase in unsatisfactory results. This study addressed concerns raised by Amies et al⁶ about the effects of water-based gel lubricants on sexually transmitted infection test results and found no significant difference in the detection of *C trachomatis* infections. The effect of water-based gel lubricant on the detection of *N gonorrhoea* could not be studied because the incident rate in this population did not provide sufficient cases for analysis. 🌿

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BOTTOM LINE

- This study shows that the use of water-based gel lubricant on the vaginal speculum does not appear to affect the rate of unsatisfactory Papanicolaou test results compared with water-moistened speculums alone, which is consistent with the findings published in other studies.^{5,6} The use of a water-based lubricant at the request of or for the comfort of the patient would appear to be acceptable.
- The effect of water-based gel lubricant on tests for sexually transmitted infection, in particular *Chlamydia trachomatis*, does not appear to be of concern. The effect of water-based lubricant on *Neisseria gonorrhoea* testing was not answered by this study; this testing needs to be undertaken in a population with a higher incident rate for the infection.
- Readers are encouraged to search for studies that continue to confirm the results reported in this study and, in particular, studies that measure comfort level between water-based gel lubrication of the vaginal speculum compared with water-moistened vaginal speculums during the procedure.

POINTS SAILLANTS

- Cette étude fait valoir que l'utilisation d'un gel lubrifiant à base d'eau sur le spéculum vaginal ne semble pas influencer le taux de résultats insatisfaisants des tests de Papanicolaou par rapport à un spéculum seulement humecté d'eau, ce qui corrobore les constatations publiées dans d'autres études^{5,6}. L'utilisation d'un lubrifiant à base d'eau à la demande de la patiente pour son confort semblerait acceptable.
- L'effet du recours à un gel lubrifiant à base d'eau sur les tests de dépistage des infections transmises sexuellement, en particulier à la *Chlamydia trachomatis*, ne semble pas causer d'inquiétudes. Cette étude ne s'est pas penchée sur les effets du lubrifiant à base d'eau dans les tests de dépistage des *Neisseria gonorrhoeae*; ces tests doivent être effectués dans une population où le taux d'incidence de cette infection est plus élevé.
- On encourage les lecteurs à chercher des études qui continuent de confirmer les résultats rapportés dans la présente étude et, en particulier, celles qui mesurent la différence dans le degré de confort entre l'utilisation de gel lubrifiant à base d'eau sur le spéculum vaginal et l'humectation avec de l'eau durant l'intervention.

Competing interests

None declared

References

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