

The Effect of Vaginal Speculum Lubrication on the Rate of Unsatisfactory Cervical Cytology Diagnosis

Anne-Marie E. Amies, MD, Leslie Miller, MD, Shu-Kuang Lee, MS, and Laura Koutsky, PhD

OBJECTIVE: Nonlubricated plastic specula can adhere to the vaginal introitus and cause discomfort with pelvic examination. We wanted to see if application of water-soluble gel lubricant to the plastic vaginal speculum would change the unsatisfactory cervical cytology diagnosis rate.

METHODS: Five public health family planning clinic sites were randomized to either water-soluble gel or water only as lubricant during speculum examination for cervical cytology collection. The pathologists were unaware of the assignment of lubricant use. The cumulative rates of cervical cytology diagnoses were calculated for 6 months before, 6 months during, and 6 months after the intervention.

RESULTS: From July 1998 through December 1999, 8534 Papanicolaou smears were collected, with 1440 using gel lubrication from January 1999 through June 1999. Rates of unsatisfactory smears for lubricant use clinics were 1.4% during use of lubricant and 1.4% without use (odds ratio [OR] 1.0; 95% confidence interval [CI] 0.6, 1.8). Rates of unsatisfactory smears for lubricant use versus nonlubricant use clinics during the gel intervention period were 1.4% versus 1.3% (OR 1.1; 95% CI 0.6, 2.0). There were no significant differences for the rates of atypical squamous cells of undetermined significance, low-grade squamous intraepithelial lesion, high-grade squamous intraepithelial lesion, or atypical glandular cells of undetermined significance within or between lubricant and nonlubricant clinics for each 6-month period. There were no cases of invasive cancer.

CONCLUSION: The use of a small amount of water-soluble gel lubricant on the outer inferior blade of the plastic vaginal speculum does not change cervical cytology results in a young, reproductive-age population. (Obstet Gynecol 2002;100:889–92. © 2002 by The American College of Obstetricians and Gynecologists.)

From the Department of Obstetrics and Gynecology, University of Washington School of Medicine; and Department of Epidemiology and Biostatistics, University of Washington, Seattle, Washington.

LK and S-KL received funding support from the National Institutes of Health (grants CA34493 and AI38383).

The authors thank the Public Health Seattle King County Family Planning Program for its invaluable assistance.

Cervical cancer screening has dramatically decreased the rate of invasive cervical cancer. In patients screened every year from age 20 to age 64, the incidence of cervical cancer is 93% lower than in the unscreened population.¹ A review of the histories of women who have died from cervical cancer revealed that 57% had not had a Papanicolaou smear in the 5 years before diagnosis, if ever.² Investigation into why women do not present for screening cervical cytology or for colposcopic examination showed that fear of pain was a reason cited by 87% of young, reproductive-age women.³ Water-soluble gel lubrication of instruments to ease insertion has been shown to decrease pain with cystoscopy.^{4,5} Little has been published on the topic of vaginal speculum discomfort. One study used the subjects' rating of pain with speculum insertion as a baseline measure for the subsequent reported pain with surgical termination of pregnancy.⁶ In that study, women reported pain of speculum insertion averaged 17 on a scale of 1–100, half the pain of cervical dilation. This suggests that speculum discomfort may be clinically important. The use of gel lubrication versus water only to decrease pain during speculum examination has not been studied.

Gynecology textbooks either have no mention of speculum lubrication or discourage the use of lubrication besides tap water during speculum examination. The reason for this admonition is often not cited, although some voice concern about possible interference with cytologic interpretation of the Papanicolaou smear.^{7–11} A single retrospective review of 205 Papanicolaou smears, of which 96.5% were collected using gel lubricant, reported that even with a thin gel overlay adequate cytology interpretation was possible.¹² To evaluate the use of lubricant gel, we proposed randomizing our clinics to evaluate the effect on cytology results.

MATERIALS AND METHODS

Approval for the study was granted by the institutional review board of the University of Washington. The study was conducted from July 1998 through December 1999 at five Public Health Seattle King County family

Table 1. Cytology Diagnoses Between Lubricant and Nonlubricant Clinics During Intervention

Cytology diagnosis	Lubricant used, January–June 1999 [n = 1440 (%)]	No lubricant, January–June 1999 [n = 1466 (%)]	Odds ratio (95% confidence interval)
Unsatisfactory	20 (1.4)	19 (1.3)	1.1 (0.6,2.0)
ASCUS	56 (3.9)	59 (4.0)	1.0 (0.7,1.4)
LGSIL/HGSIL/AGCUS	62 (4.3)	66 (4.5)	1.0 (0.7,1.4)
Atypical endometrials	2 (0.1)	1 (0.1)	
Normal/BCC	1300 (90.4)	1321 (90.2)	Reference

ASCUS = atypical squamous cells of undetermined significance; LGSIL = low-grade squamous intraepithelial lesion; HGSIL = high-grade squamous intraepithelial lesion; AGCUS = atypical glandular cells of undetermined significance; BCC = benign cellular changes.

planning clinics. The clinics were randomized by drawing names from an envelope labeled for assignment to either water-soluble gel lubricant or no lubricant except tap water for all speculum examinations for cervical cytology specimen collection during the intervention period. The sites then performed all speculum examinations for cervical cytology specimen collection as allocated from January 1999 through June 1999. All women undergoing collection of Papanicolaou smears were included. All sites did not routinely use water-soluble gel lubricant on the speculum before and after the study period. Women at lubricant study sites were informed of the study by a poster in the clinic examination rooms and given the option to decline speculum lubricant.

The two clinics randomized to lubricant use were provided with HR Lubricating Jelly (Carter Wallace Inc., New York, NY). The lubricant ingredients include water, propylene glycol, hydroxypropyl methylcellulose, carbomer 934P, methylparaben, propylparaben, and sodium hydroxide. Clinicians were instructed to apply a dime-sized amount of gel lubricant on the distal end of the outer surface of the inferior blade of the plastic speculum to lubricate the introitus from January 1, 1999 to June 30, 1999. The clinics randomized to nonlubricant use were asked to use only tap water if lubricant was needed during the same period.

Cervical cytology samples were collected from the ectocervix using the Ayers spatula, followed by a cytobrush. The cells were then applied to a single glass slide, fixed with alcohol, and allowed to air dry. The labora-

tory vendor and cytology supplies were the same for the entire study period. The laboratory and cytopathologists were not alerted regarding lubricant use for specimen collection. The cumulative 6-month totals of normal and abnormal cervical cytology diagnoses were collected by site for the 6 months preceding intervention (July through December 1998), the 6 months during intervention (January through June 1999), and the 6 months after intervention (July through December 1999). The percentages of normal, abnormal, and unsatisfactory cytology rates were compared within clinics and between clinics for each 6-month period. Data were collected from the clinic charts of the patients with unsatisfactory cytology diagnoses to evaluate the etiologies for the unsatisfactory smears. Specific questions asked included pathology diagnosis, age, day of menstrual cycle, type of contraceptive used, presence of sexually transmitted disease, and cytology history. Multivariate logistic regression (SPSS for Windows 8.0; SPSS Inc., Chicago, IL) was used to examine associations between lubricant use and cytology diagnosis 1) during the gel intervention period for all clinics, which were divided into two categories (clinics that used lubricant and clinics that did not) (Table 1), and 2) before and after the gel intervention period versus during the intervention period for the two clinics where gel was used. This model was adjusted by clinic (Table 2). We calculated that 1150 Papanicolaou smears in each arm were necessary to detect an odds ratio of 2.0 or doubling of the unsatisfactory diagnosis with a power of 80% and an α error of .05.

Table 2. Cytology Diagnoses Within Lubricant Clinics During Lubricant Use Versus Before and After Lubricant Use

Cytology diagnosis	Lubricant used, January–June 1999 [n = 1440 (%)]	No lubricant used, July–December 1998 and July–December 1999 [n = 2919 (%)]	Odds ratio (95% confidence interval)
Unsatisfactory	20 (1.4)	40 (1.4)	1.0 (0.6,1.8)
ASCUS	56 (3.9)	114 (3.9)	1.0 (0.7,1.4)
LGSIL/HGSIL/AGCUS	62 (4.3)	100 (3.4)	1.3 (0.9,1.8)
Atypical endometrials	2 (0.1)	0 (0.0)	
Normal/BCC	1300 (90.4)	2665 (91.3)	Reference

Abbreviations as in Table 1.

RESULTS

Results of a review of MEDLINE during January 1998 back to 1966 using the key words "gel," "speculum," "lubrication," "Pap smear," "cervical cytology," and "pelvic exam" revealed only one study¹² assessing the effect of gel lubrication on Papanicolaou smear interpretation. A total of 8534 Papanicolaou smears were collected from all five clinics during the entire study period. From July 1, 1998 to December 31, 1998 and from July 1, 1999 to December 31, 1999, 5628 Papanicolaou smears were obtained, with 2919 from the lubricant-assigned clinics and 2709 from the non-lubricant-assigned clinics. During the intervention period from January 1, 1999 to June 30, 1999, 2906 Papanicolaou smears were obtained, with 1440 from the lubricant-assigned clinics and 1466 from the non-lubricant-assigned clinics. All but six patients consented to lubricant use. Comparison of the lubricant clinics with the control clinics revealed similar patient socioeconomic status (63.8% versus 65.2% below the poverty level), ethnicity (40.7% versus 27.5% non-white), and years of experience of providers (15.2 versus 16.7).

The percentages of unsatisfactory, atypical squamous cells of undetermined significance (ASCUS), low-grade squamous intraepithelial lesion (SIL), high-grade SIL, and atypical glandular cells of undetermined significance (AGCUS) smears for the lubricant use clinics did not significantly differ from those of the control clinics during the intervention period (Table 1). The rates of unsatisfactory, ASCUS, low-grade SIL, high-grade SIL, and AGCUS diagnoses within the lubricant use clinics for the 6 months during versus 6-month periods before and after use of lubricant did not significantly differ (Table 2). There were only three atypical endometrial cell Papanicolaou smears collected during the 6-month study period, two with lubricant (0.1%) and one without (0.1%). There were no cases of invasive cancer. The rate of absent endocervical cells was significantly less with the use of lubricant within the lubricant use clinics (8.1% versus 12.1% [odds ratio 0.6; 95% confidence interval 0.5, 0.8]). During the entire study period one lubricant clinic had persistently elevated rates of absent endocervical cells (12.72% from January 1, 1999 through June 30, 1999; 17.23% for the preceding 6 months, and 23.82% for the following 6 months). Investigation into the clinical practice at this site revealed a provider who was not using the cytobrush on any patient suspected to be pregnant. Because the unsatisfactory rate was lower during the lubricant study period, it is unlikely that the higher rate of absent endocervical cells was due to lubricant use.

Review of the unsatisfactory Papanicolaou smear de-

scriptive sections of the cytology reports revealed no reported gel overlay or drying artifact causing difficulty with interpretation. Unsatisfactory reports revealed excess inflammation, excess blood, or scanty cells for the etiology of the unsatisfactory diagnosis. The average age of patients in the lubricant group with unsatisfactory cytology was 22.7, versus 22.5 in the control group. Oral contraceptive pill or medroxyprogesterone usages for patients with unsatisfactory diagnoses were 50.0% and 53.8% for the lubricant and control populations, respectively. During the lubricant intervention period, 25% of the lubricant patients with unsatisfactory smears reviewed had positive cultures for chlamydia, whereas no members of the nonlubricant group with unsatisfactory smears had chlamydia diagnosed.

DISCUSSION

The Bethesda system requires that Papanicolaou preparations must include enough cells to cover 10% of a slide.¹³ If 75% of the epithelial cells are obscured by blood, inflammation, or artifact, the slide is considered unsatisfactory. Multiple variables have been studied and have been shown to affect the rate of unsatisfactory smears, including: presence of menses, hormonal contraceptive use,¹⁴ genital atrophy,¹⁵ use of the cytobrush,¹⁶ experience of the provider,¹⁷⁻²⁰ individual cytopathologist variation, and laboratory variation.²¹

Because fear of pain may be a reason women do not seek Papanicolaou screening, efforts should be made to try to minimize the pain associated with examination without compromising the quality of the Papanicolaou smear as a screening tool for cancer. Our results show that the use of a small amount of water-soluble lubricant on the outer inferior blade of the plastic vaginal speculum did not significantly increase the rate of unsatisfactory cervical cytology smear diagnoses in our young, reproductive-age population. This finding suggests that lubrication may be used cautiously when indicated during speculum examination when obtaining cervical cytology.

Our study did not evaluate the pain level women experienced with speculum insertion or other variables potentially important to reported or experienced pain like parity, anxiety, history of sexual abuse, or infection. We did not directly address the effect of water-soluble lubricant formulation with bacteriostatic preservatives on gonorrhea and chlamydia culture or normal saline and potassium hydroxide slide evaluation of vaginal discharge. Our population is young and not in the highest-risk group for cervical carcinoma, and we also used the standard smear cytology preparation and not the liquid cytology preparation. Our study did not assess if

there is an upper limit of gel that may interfere with cytology interpretation, but our results indicate that using a dime-sized amount of water-soluble gel lubricant did not change the cytology results.

Because lubricant use did not impede the interpretation of Papanicolaou smears, it is most likely safe to conduct further studies to assess whether lubricant use can decrease pain or discomfort associated with speculum examination. Comparison of the comfort with metal and plastic speculums would be instructive. Further investigation should be done to assess the use of lubricant during the evaluation and diagnosis of vaginal and cervical infections to verify that any woman undergoing speculum exam could be offered a sterile water-soluble lubricant to ease speculum examination.

REFERENCES

1. Eddy DM. Screening for cervical cancer. *Ann Intern Med* 1990;113:214–26.
2. Janerich DT, Hadjimichael O, Schwartz PE, Lowell DM, Meigs JW, Merino MJ, et al. The screening histories of women with invasive cervical cancer, Connecticut. *Am J Public Health* 1995;85:791–4.
3. Kahn JA, Chiou V, Allen JD, Goodman E, Perlman SE, Emans SJ. Beliefs about Papanicolaou smear and compliance with Papanicolaou smear follow-up in adolescents. *Arch Pediatr Adolesc Med* 1999;153:1046–54.
4. Brekkan E, Ehrnebo M, Malmstrom PU, Norlen BJ, Wirbrant A. A controlled study of low and high volume anesthetic jelly as a lubricant and pain reliever during cystoscopy. *J Urol* 1991;146:24–7.
5. Goldfischer ER, Cromie WJ, Karrison TG, Naskiewicz L, Gerber GS. Randomized, prospective, double-blind study of the effects on pain perception of lidocaine jelly versus plain lubricant during outpatient rigid cystoscopy. *J Urol* 1997;157:90–4.
6. Miller L, Jensen MP, Stenchever MA. A double-blind randomized comparison of lidocaine and saline for cervical anesthesia. *Obstet Gynecol* 1996;87:600–4.
7. Kawada C. Gynecologic history, examination, and diagnostic procedures. In: Decherney AH, Pernol ML, eds. *Current obstetric and gynecologic diagnosis and treatment*. 8th ed. East Norwalk, Connecticut: Appleton & Lange, 1994:613–32.
8. Cunningham FG, Gant NF, Leveno KJ, Gilstrap LC III, Hauth JC, Wenstrom KD. *Williams obstetrics*. 21st ed. New York: McGraw-Hill, 2001:227.
9. Stenchever MA. History, physical examination, and preventive health care. In: Stenchever MA, Droegemueller W, Herbst AL, Mishell DR Jr, eds. *Comprehensive gynecology*. 4th ed. St. Louis: Mosby, 2001:144.
10. Keye WR Jr. Gynecologic history, examination and diagnostic procedures. In: Scott JR, DiSaia PJ, Hammond CB, Spellacy WN, eds. *Danforth's obstetrics and gynecology*. 7th ed. Philadelphia: Lippincott-Raven, 1997:604.
11. American College of Obstetricians and Gynecologists. *Cervical cytology: Evaluation and management of abnormalities*. ACOG technical bulletin no. 183. Washington: American College of Obstetricians and Gynecologists, 1993.
12. Casselman CW, Crutaner RA, Jadsingh IH. Use of water-soluble gel in obtaining the cervical cytologic smear. *Acta Cytol* 1997;41:1861–2.
13. Kurman RJ, Solomon D. *The Bethesda system for reporting cervical/vaginal cytologic diagnoses: Definitions, criteria, and explanatory notes for terminology and specimen adequacy*. New York: Springer-Verlag, 1994:7–8.
14. Vooijs GP, van der Graaf Y, Elias AG. Cellular composition of cervical smears in relation to the day of the menstrual cycle and the method of contraception. *Acta Cytol* 1987;31:417–26.
15. Waddell CA. The influence of the cervix on smear quality. I: Atrophy. An audit of cervical smears taken post-colposcopic management of intraepithelial neoplasia. *Cytopathology* 1997;8:274–81.
16. Taylor PT, Andersen WA, Barber SR, Covell JL, Smith EB, Underwood PB. The screening Papanicolaou smear: Contribution of the endocervical brush. *Obstet Gynecol* 1987;70:734–7.
17. Wilson JD, French R, Branch T, Sutton J. Inadequate cervical cytology: The need to audit individual smear takers' inadequate rates. *Cytopathology* 1999;10:107–11.
18. Woodman CBJ, Yates M, Ward K, Williams D, Tomlinson K, Luesley D. Indicators of effective cytological sampling of the uterine cervix. *Lancet* 1989;2:88–90.
19. Kane BR, Berger MS, Lisney M. Pap smear adequacy: The role of clinician experience. *Fam Med* 1997;29:315–7.
20. Vooijs GP, Elias A, van der Graaf Y, Poelen-van de Berg M. The influence of sample takers on the cellular composition of cervical smears. *Acta Cytol* 1986;30:251–7.
21. Ciatto S, Cariaggi MP, Minuti AP, Confortini M, Palli D, Pas L, et al. Interlaboratory reproducibility in reporting inadequate cervical smears: A multicentre multinational study. *Cytopathology* 1996;7:386–90.

Address reprint requests to: Anne-Marie Amies, MD, University of Washington Medical Center, Department of Obstetrics and Gynecology, Box 356460, 1959 NE Pacific Street, Seattle, WA 98195; E-mail: aamies@u.washington.edu.

Received March 14, 2002. Received in revised form July 15, 2002. Accepted August 1, 2002.