Water versus gel lubricant for cervical cytology specimens

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Practice recommendations

- Gel should be considered a viable option in obtaining Pap smears to ease insertion, minimize discomfort, and perhaps help maintain regular interval sampling compliance. Physicians choosing to use gel should be careful to apply only a thin layer to the outer blades of the speculum.
- Because approximately two thirds of false-negative smears are related to inadequate sampling, be sure to obtain cells from the transformational zone, where cancer is known to develop.

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The medical literature generally recommends moistening the speculum with water for performance of a Papanicolaou (Pap) test, because gel lubricants interfere with specimen analysis and assessment of vaginal secretions.[1,2] After an extensive literature search, we found little information that identified or substantiated the type or frequency of interference or distortion in analysis or assessment with regard to gel lubricants on cervical cytologic evaluation. The only study of gel lubricant use that we found recommended further study because surprisingly few Pap smears are rendered inadequate despite the high prevalence of gel use.[3]

Due to these findings and the lack of literature substantiating interference or distortion with gel lubricants, we investigated whether there is a difference in Pap smear obscuration rates with gel-lubricated vs water-lubricated speculum samples.

METHODS

Target population

The target population consisted of all women who received Pap smears between 1995 and 1999 at the University of Tennessee Health Sciences Center HealthPlex Family Medicine Residency Program in Memphis, Tennessee. Pap smears

TABLE

Lubricant use and cytology findings

	Total no.	Water lubricant, % (n)	Gel lubricant, % (n)	No lubricant, % (n)
Lubricant use reported	615	62 (379)	13 (81)	25 (155)
Adequate sample	611	99.2 (376)	98.8 (80)	100 (155)
Inadequate sample	4	0.08 (3)	1 (1)	0 (0)
Not obscured	588	96.8 (367)	93.8 (76)	93.5 (145)
Obscured	27	3 (12)	6.2 (5)	6.5 (10)
By blood	16	58 (7)	20 (1)	80 (8)
By other*	11	42 (5)	80 (4)	20 (2)

*Defined as obscuration by nonblood contaminant(s).

were obtained by resident physicians in the Department of Family Medicine, University of Tennessee Health Science Center. The specific technique used by the residents was left to their discretion and each was asked to describe the usual use of lubricants.

More than 4169 Pap smears were identified via *Current Procedural Terminology* codes (A88141, A88155, A88164, and/or A88167). Of these, 649 charts were selected by using every sixth record. From those selected, 615 contained adequate information to be included in the study.

Data collection

We gathered medical record data by using a retrospective review of medical records, including the medical record number, date of birth, date of service, provider performing pelvic examination or obtaining cervical cytology smear, identification of the laboratory processing and reporting each cytology report, and insurance coverage (Medicare, private, self-payer, and TennCare/Medicaid). Cervical cytology report information retrieved included sample adequacy (satisfactory or unsatisfactory), whether the sample was identified as obscured, and whether obscuration was caused by blood.

We also collected data from the medical record on potential confounders, including socioeconomic status (determined by insurance source) and reproductive status (currently pregnant, menopausal, or posthysterectomy). Medical records containing incomplete documentation of any portion of the review criteria were excluded.

Analysis

Statistical analysis was completed with SAS 8.1. Simple χ^2 analysis was used where appropriate to demonstrate associations. A stepwise regression model was considered, but none of the χ^2 statistics were significant, which eliminated the need for a modeling procedure.

RESULTS

Of the 615 participants, 50 were pregnant, 49 were menopausal, and 42 had undergone a hysterectomy. By matching clinicians' survey responses to the cytology specimens they collected, we determined that 379 were acquired with water, 81 with gel, and 155 without lubricant.

We reviewed cytology reports for the documented level of adequacy, the presence of any

obscuration, and the type of obscuration (see **Table** for cytology findings). All 27 obscured and 4 inadequate specimens (5% of the 615 cytology reports reviewed) were reported among women who were pregnant, menopausal, or posthysterectomy. Menopausal women accounted for 89% (24) of obscured specimens and 100% (4) of inadequate specimens. Within the menopausal group, 63% (15) of the specimens were obscured by blood and 37% (9) were obscured by "other." The term "other" was not defined further or explained on any cytology report. The 5 laboratories reporting obscuration by "other" were contacted, and all reported that this term defines obscuration by nonblood contaminants. Pregnant women accounted for 7% (2) of the obscured specimens, with 1 obscured by blood and 1 obscured by "other." Women identified as posthysterectomy contributed 4% (1) of the obscured specimens; it was reported as obscured by "other."

Reports identifying obscured or inadequate specimens and socioeconomic status were also cross-tabulated against type of lubricant used in consideration for possible bias. The outcome showed no identified indication.

No statistically significant difference was found in the likelihood of specimen obscuration or adequacy vs inadequacy between water, gel, or no lubricant. The occurrence of obscuration was lower with the use of water lubricant (3.2%) than with gel lubricant (6.2%) or no lubricant (6.5%). However, this difference was not statistically significant ($P<.20$).

DISCUSSION

The purpose of this study was to identify any differences in the occurrence of contamination or distortion of cervical cytology test results between water and gel as the lubricant. With a sample size that allowed us to detect an absolute difference as small as 7%, we found no significant difference between the use of gel or water lubricant in the likelihood of cell obscuration or inadequacy. These findings did not support current data reported in several publications and may explain the lack of publications describing specific adverse gel effects on sampling collection.

Inadequate specimens in postmenopausal women

The number of obscured and inadequate specimens found within the group of women who had reached menopause was not unexpected because of hormonal changes in cervical cells and the physical structure of the uterus. Although not unexpected, it is of concern that this group includes many older women who constitute an underscreened subgroup who frequently forego routine cervical cancer screening unless they have gynecologic problems.[4]

In recognizing the need for this group to obtain testing and maintain routine screening compliance, minimizing discomfort related to cervical cell acquisition procedure should be a primary consideration. Because lubricant minimizes friction and optimizes the ease of speculum insertion, gel can be considered an effective choice for these women.

Sampling errors

Nationally, approximately two thirds of false-negative smears are related to inadequate sampling, and the primary sampling error is the failure to obtain cells from the transformational zone, where cancer is known to develop.[5,6] The high percentage of specimen adequacy (99% for the water and gel groups and 100% for the no-lubricant group) found during this study may be attributed to the homogeneity in clinical training of the participating residents.

Although different labs evaluated cytology specimens (depending on the payment source), all providers who performed cervical cell acquisition were considered influenced by similar training. Also, all of our residents are taught that when gel lubricant is used, a thin coat is to be placed only on the external speculum blade surfaces.

Limitations of this study

The size of the study population was limited by medical record completeness and the response

rate for physician surveys. A larger study might have found a difference, although it is questionable whether such a difference would be statistically significant.

Reliance on a survey of the usual type of lubricant may be less accurate than direct observation; however, direct observation was not practical in our setting. The adequacy and quality of cytology specimens also could have been affected by cervicitis, vaginitis, interval from last menstrual period, and use of hormone therapy, but these conditions would not be expected to affect the patients of physicians using one type of lubricant more than those using another.

In addition, we were limited in designing the study by the lack of comparison literature. As with other studies of this size, further research is recommended, with additional clinicians and study populations to reinforce and elaborate on the current findings.

Conclusions

A thin coat of water-soluble gel on the external vaginal speculum blade surfaces did not compromise the adequacy or interpretation of cervical cytology. Gel should be considered an option in obtaining Pap smears to ease insertion, minimize discomfort, and perhaps help maintain regular interval sampling compliance. Physicians choosing to use gel should be careful to apply only a thin layer to the outer blades of the speculum.

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