Effects of Lubricants Used at Speculum Examination on Conventional and ThinPrep Smear Results

Nilgün Güdücü¹, Herman İşçi², Alexandra Lieb³, Salim Karavelioğlu⁴, Zehra N Kavak⁵

ABSTRACT
Aims and objectives: We conducted a retrospective study to compare the rate of satisfactory conventional and ThinPrep smears with and without lubricant use.

Materials and methods: We reviewed smear test results of 5,126 patients retrospectively. Both conventional and ThinPreps were included.

Results: Overall, there was no difference between the two groups for satisfactory smear results. There was also no difference between smear groups in postpartum and postmenopausal patients. Lubricant use decreased satisfactory smear rate in ThinPrep smears (81.9% and 85.5%, p = 0.038). When ThinPrep smears were taken without lubricants, a statistically significantly higher rate of cervical dysplasia (2.5% and 3.6%, p = 0.023), nonspecific infection (64.9% and 69.2%, p = 0.001), trichomonas infection (0.3% and 0.9%, p = 0.004), and bacterial vaginosis (2.7% and 5.9%, p = 0.001) were detected.

Conclusion: Lubricants affect satisfactory smear results only in ThinPrep smears. Detection of cervical dysplasias, bacterial vaginosis, and trichomonas infections were higher when lubricants were not used.

Keywords: Cervical dysplasia, Infection, Lubricants, Smear, Speculum, ThinPrep.

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INTRODUCTION
Papanicolaou (Pap) smear test is a successful screening test that has reduced mortality rate of invasive cervical cancer more than 70% in developed countries where it is a standard part of preventive healthcare policies.¹ In developed countries, about 60% of women who lost their lives due to invasive cervical cancer had no Pap smear tests in the past 5 years prior to diagnosis.² One of the factors that decrease compliance with cervical screening programs is the pain felt during gynecological examinations, especially at speculum insertion.³ There is no hesitation to use lubricants at transvaginal ultrasonography and bimanual examination to reduce the discomfort, but classic gynecological teaching is reluctant to use lubricants at speculum insertion. Improper use of lubricants at speculum examination to decrease pain and improve compliance may interfere with processing and interpretation of both conventional and ThinPrep Pap smear tests.⁴ ⁵ This may further increase the false-negative rate of Pap smear test that approached 50% in some studies.⁶ The aim of this study was to compare the rates of satisfactory conventional and ThinPrep smears with and without lubricant use.

MATERIALS AND METHODS
A retrospective review of the cytology reports performed by two gynecologists working for more than 10 years in our outpatient gynecology clinic covered a total of 5,126 cases between October 2009 and April 2013. The practice of Dr 1 is to introduce the metal speculum always with lubricants and the practice of Dr 2 is to introduce the metal speculum without any lubricants. The other physicians of our clinic use lubricants according to the presenting case and cytology reports of these clinicians were excluded. We compared the cytology reports of the two physicians for the effects of lubricants on Pap smear tests. Specimens were collected by a Cytobrush. Each report was again separated as conventional and

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period (smear test within 2 months after delivery) during specimen collection were noted as confounding variables. Patients who have had hysterectomy were excluded. The study protocol was in confirmation with the ethical guidelines of Helsinki Declaration.

Statistical analyses were performed using the NCSS (National Council for the Social Studies) 2007 and PASS (power analysis and sample size) 2008 statistical software (Utah, USA). Data showing anthropometric parameters were presented as mean±standard deviation. Parameters showing normal distribution were compared with Student T test, other parameters were compared with Pearson Chi-squared test.

**RESULTS**

Mean age of the patients was 40.04 ± 11.68 years (17–95). Table 1 shows that patients whose smears were taken without lubricant use had a statistically significantly higher rate of cervical dysplasia (2.5% and 3.6%, p = 0.023), nonspecific infection (64.9% and 69.2%, p = 0.001), trichomonas infection (0.3% and 0.9%, p = 0.004), and bacterial vaginosis (2.7% and 5.9%, p = 0.001). There was no difference between the two groups for satisfactory smear results.

Table 2 shows satisfactory smear results in postpartum and postmenopausal women. Overall, there was no difference between the two groups in this patient population. There was no difference between the two groups for satisfactory smear results but patients who had ThinPrep smears without lubricant use had statistically significantly more satisfactory smear results when compared to patients with lubricant use (85.5% and 81.5% respectively, p = 0.038).

**DISCUSSION**

In this study, we found statistically significantly more satisfactory smear results in ThinPrep smears taken without lubricant use but in conventional smears, there was no difference between the two groups. Investigations to date have demonstrated that lubricants changed the smear results,4–6,8–10 but other studies reported contradictory results11–17 Not only did physician applied lubricants cause interpretation errors, but also, vaginal creams, douching, spermicides, foreign-bodies, and over-the-counter lubricants used personally were reported to interfere with the results.10,17

In this study, the physician applied a small amount of lubricant on both blades of the speculum and he introduced it without contaminating the external cervical os for many years, but when the residents, nurses, or clinicians with different levels of experience are involved, the results may change. A previous study reported higher unsatisfactory smear results with residents.7 Other studies searched for the improper use of lubricant, overlaying the lubricant to both blades,10 only superior blade,9 or only inferior blade12 were searched; in all cases, the satisfactory smear results did not change with lubricant use.

Lubricants were proposed to interfere with processing of ThinPrep smears by adhering to and plugging the semipermeable membrane of the filter, this may prevent transfer of cells to the slide.10 Previous studies comparing lubricant use in ThinPrep smears reported both higher interpretation error and also no difference between the two groups.

In low risk populations, the rate of atypical squamous cells of undetermined significance (ASCUS) should be less than 5%.19 Our population was a low risk population and cervical dysplasia rate was similar to those of previously reported studies.5 Prevalence of cervical intraepithelial lesions increased in the presence of endocervical cells.20 In our study, rate of cervical dysplasia was higher in the group that did not use lubricant, but in previous studies, there was no difference between the groups.5,12

Patients who are in the postmenopausal or postpartum period may especially have more discomfort during speculum examination due to vaginal dryness. Previous studies reported beneficial effect of lubricants during examination in postmenopausal patients but not in premenopausal patients.21 These patients may benefit from

| Table 1: Comparison of patients with and without lubricant use during smear test |
|---------------------------------|-------------|--------|--------|--------|
| **Lubricant used** | **Lubricant not used** | **Total** | **p value** |
| **Cervical dysplasia** | **n (%)** | **n (%)** | **n (%)** |
| AGUS | 4 | 1 | 5 | 0.10 |
| ASC-H | 6 | 2 | 8 | 0.2 |
| ASC-US | 45 | 1.6 | 50 | 2.1 | 95 | 1.9 |
| HGSIL | 5 | 0.2 | 6 | 0.3 | 11 | 0.2 |
| LGSIL | 10 | 0.4 | 21 | 0.9 | 31 | 0.6 |
| Normal | 2,719 | 97.5 | 2,253 | 96.4 | 4,972 | 97.0 | 0.023* |
| Conventional | 1,809 | 64.9 | 1,461 | 62.5 | 3,270 | 63.8 | 0.082 |
| ThinPrep | 980 | 35.1 | 876 | 37.5 | 1,856 | 36.2 |
| Infection | 1,810 | 64.9 | 1,618 | 69.2 | 3,428 | 66.9 | 0.001** |
| Satisfactory smear | 2,358 | 84.5 | 2,017 | 86.3 | 4,375 | 85.3 | 0.076 |
| Postmenopausal | 389 | 13.9 | 351 | 15 | 740 | 14.4 | 0.277 |
| Postpartum | 299 | 10.7 | 55 | 2.4 | 354 | 6.9 | 0.001** |
| Trichomonas | 8 | 0.3 | 22 | 0.9 | 30 | 0.6 | 0.004** |
| Bacterial vaginosis | 74 | 2.7 | 137 | 5.9 | 211 | 4.1 | 0.001** |

Pearson’s Chi-squared test

*p < 0.05, **p < 0.01

AGUS, atypical glandular cells; ASC-US, atypical squamous cells of undetermined significance; ASC-H, atypical squamous cells-HGSIL cannot be excluded; LGSIL, low-grade squamous intraepithelial lesion; HGSIL, high-grade squamous intraepithelial lesion.
lubricant use. According to our results, there was no difference between the two groups in satisfactory smear results in these two special groups. Satisfactory smear results decreased to half in postmenopausal women when compared to the whole population, this is in contrast to a previously reported study. 5

In our study, the rate of infection was higher in the group where lubricants were not used, but a previous study reported contradictory results 5 and another study found no difference between the groups. 11

The strength of this study was the performance of sampling only by two physicians, this decreased the risk of sampling error due to experience, but there was no randomization and two different sampling practice without randomization might create another bias. Another strength was the large number of participants. To the best of our knowledge, ThinPrep and conventional smear were compared for the effects of lubricants by only one study previously. This increased the contribution of this article to the literature.

One of the limitations of this study is its retrospective nature, we cannot be sure about the use of lubricants and vaginal medications by patients prior to obtaining the samples.

In conclusion, lubricants affect satisfactory smear results only in ThinPrep smears. Detection of cervical dysplasias, bacterial vaginosis, and trichomonas infections were higher when lubricants were not used.

References
1. Ries LG, Eisner MP, Kosary CL, et al., ed. SEER Cancer Statistics Review, 1975–2001. Bethesda (Md): National Cancer Institute. Atlanta (Ga): American Cancer Society. Cancer Facts and Figures 2004; 2004 http://seer.cancer.gov/csr/1975_2001/.
2. Janerich DT, Hadjimichael O, Schwartz PE, et al. The screening histories of women with invasive cervical cancer, connecticut. Am J Public Health 1995;85(6):791–794. DOI: 10.2105/AJPH.85.6.791.
3. Kahn JA, Chiu V, Allen JD, et al. Beliefs about papanicolaou smears and compliance with papanicolaou smear follow-up in adolescents. Arch Pediatr Adolesc Med 1999;153(10):1046–1054. DOI: 10.1001/ archpedi.153.10.1046.
4. Holton T, Smith D, Terry M, et al. The effect of lubricant contamination on Thin-Prep (Cytyc) cervical cytology liquid-based preparations. Cytopathology 2008;19(4):236–243. DOI: 10.1111/j.1365-2303.2007.00525.x.
5. Köşüş A, Köşüş N, Duran M, et al. Effect of liquid-based gel application during speculum examination on satisfactory level of smear examination. Arch Gynecol Obstet 2012;285(6):1599–1602. DOI: 10.1007/s00404-011-2198-x.
6. Charoenkwan K, Ninunanahaeminda K, Khunamornpong S, et al. Effects of gel lubricant on cervical cytology. Acta Cytol 2008;52(6):654–658. DOI: 10.1159/000325617.
7. Paterson ME, Peel KR, Joslin CA. Cervical smear histories of 500 women with invasive cervical cancer in yorkshire. BMJ 1984;289(6449):896–898. DOI: 10.1136/bmj.289.6449.896.
8. Zardawi IM, Catterall N, Duncan J, et al. Effects of gel lubricant on conventional and liquid-based cervical smear results. Acta Cytol 2003;47:704–705.
9. Martinez-Giron R, Martinez-Torre S, Fernandez-Garcia C. Vaginal lubricant gel as an artefact on a pap smear. Diagn Cytopathol 2011;39(6):431. DOI: 10.1002/dc.21437.
10. Feit TD, Mowry DA. Interference potential of personal lubricants and vaginal medications on Thin-Prep pap tests. J Am Board Fam Med 2011;24(2):181–186. DOI: 10.3122/jabfm.2011.02.100086.
11. Hathaway JK, Pathak PK, Maney R. Is liquid-based pap testing affected by water-based lubricant? Obstet Gynecol 2006;107(1):66–70. DOI: 10.1097/01.AOG.0000192512.03576.da.
12. Amies AM, Miller L, Lee SK, et al. The effect of vaginal speculum lubrication on the rate of unsatisfactory cervical cytology diagnosis. Obstet Gynecol 2002;100(5, Part 1):889–892. DOI: 10.1097/00006250-200211000-00011.
13. Griffith WF, Stuart GS, Gluck KL, et al. Vaginal speculum lubrication and its effects on cervical cytology and microbiology. Contraception 2005;72(1):60–64. DOI: 10.1016/j.contraception.2005.01.004.
14. Allan GM, Korownyk C, Ivers N. Papanicolaou tests: does lubricant reduce the quality or adequacy? Can Fam Physician 2011;57:309.
15. Harmi M, Jones KA. Using lubricant for speculum insertion. Obstet Gynecol 2010;116(2, Part 1):415–417. DOI: 10.1097/AOG.0b013e3181e750f1.
16. Smith-McCune K, Tuveson JL, Rubin MM, et al. Effect of replen gel used with a diaphragm on tests for human papillomavirus and other lower genital tract infections. J Lower Gen Tract Dis 2006;10(4):213–218. DOI: 10.1016/j.lgt.2005.01.004.
17. Wied FL, Bibbo M, Keebler CM, et al. Compendium on diagnostic cytology. 8th ed., Chicago, Illinois, USA: International Academy of Cytology; 1997. pp. 36–37. 7274.
18. Gilson M, Desai A, Cardoza-Favarato G, et al. Does gel affect cytology or comfort in the screening papanicolaou smear? J Am Board Fam Med 2006;19(4):340–344. DOI: 10.3122/jabfm.19.4.340.
19. McGrath CM. ASCUS in papanicolaou smears. Problems, controversies, and potential future directions. Am J Clin Pathol 2002;117(1):62–75. DOI: 10.1309/RREK-8L6M-D2KC-HWLH.
20. Davy D, Austin RM, Birdsong G, et al. ASCCP patient management guidelines: pap test specimen adequacy and quality indicators. Am J Clin Pathol 2002;118(5):714–718. DOI: 10.1309/6GBF-EGH8-WXDE-ANGX.
21. Uygur D, Guler T, Yayci E, et al. Association of speculum lubrication with pain and papanicolaou test accuracy. J Am Board Fam Med 2012;25(6):798–804. DOI: 10.3122/jabfm.2012.06.120021.

Table 2: Comparison of patients with and without lubricant use during smear test for satisfactory smear results

| Satisfactory smear | Lubricant used | Lubricant not used | p value |
|--------------------|---------------|-------------------|--------|
| Yes (n = 220)      | 73.6%         | 69.1%             | 0.491  |
| No (n = 79)        | 26.4%         | 30.9%             |        |
| Yes (n = 176)      | 45.2%         | 39.6%             | 0.121  |
| No (n = 213)       | 54.8%         | 60.4%             |        |
| Yes (n = 1,555)    | 86.0%         | 86.8%             | 0.492  |
| No (n = 254)       | 14.0%         | 13.2%             |        |
| Yes (n = 803)      | 81.9%         | 85.5%             | 0.038* |
| No (n = 177)       | 18.1%         | 14.5%             |        |

Pearson’s Chi-squared test *p < 0.05