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Comparison of the SurePath™ liquid-based Papanicolaou smear with the conventional Papanicolaou smear in a multi-site direct-to-vial study

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KEYWORDS

SurePath™ • conventional slide • Papanicolaou (Pap) smear • cytology • liquid-based • thin-layer • cervicovaginal smear

ABSTRACT

BACKGROUND

Split-sample clinical trials for liquid-based Papanicolaou (Pap) smears demonstrated that the liquid-based Pap smear was a safe and effective replacement for the conventional Pap smear. However, clinical intended use of liquid-based technology employs direct-to-vial collection methods. The current study compared the cytologic detection rates of the liquid-based Pap smear with conventional Pap smears in a direct-to-vial study performed at three clinical sites.

METHODS

Data from 58,580 prospective SurePath™ slides and 58,988 historic conventional slides were collected. Results were statistically compared with regard to disease prevalence and adequacy to include biopsy follow-up data for conventional and SurePath tests.

RESULTS

The SurePath method was found to provide a statistically significantly greater detection rate for clinically important categories of high-grade squamous intraepithelial lesion (HSIL+) and low-grade squamous intraepithelial lesion (LSIL+) (64% and 107%, respectively; $P < 0.00001$ for

each lesion) compared with conventional slides. The clinical significance of increased cytologic detection using SurePath was supported by biopsy data that essentially demonstrated concordance with regard to biopsy interpretation for HSIL+ ($P = 0.9105$ at Site 1; $P = 1.0000$ at Site 2; and $P = 1.0000$ at Site 3) and LSIL+ ($P = 0.6966$ at Site 1; $P = 0.8052$ at Site 2; and $P = 1.00$ at Site 3). The detection rate of atypical squamous cells of undetermined significance (ASCUS+) was found to be significantly increased (75.12%; $P < 0.00001$). A statistically significantly lower proportion of unsatisfactory slides using the SurePath test compared with conventional slides was noted (-58%; $P < 0.00001$). The ASCUS/LSIL+ ratio was found to be reduced overall when using SurePath (-28.9%), regardless of whether the study sites were combined or considered individually. The rate of false-negative results noted with SurePath (10.43%) and conventional slides (12.97%) was essentially equivalent.

CONCLUSIONS

The SurePath Pap smear was found to outperform conventional slides in the detection of HSIL+ and LSIL+ cytologic lesions of the cervix and reduced the number of unsatisfactory diagnoses. The HSIL+ advantage for SurePath is not limited to HSIL but appears to extend to carcinoma as well. Cancer (Cancer Cytopathol) 2004. © 2004 American Cancer Society.

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