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Abstract

MarkPap test for cervical cancer screening

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Background: At ASCO 2001 we introduced a new biomarker driven technology MarkPap(r) for improving visualization of epithelial cell abnormalities on Pap smears. The biomarker is cervical acid phosphatase labeling dysplastic cells. At ASCO 2004, we presented data of two clinical trials. We are presenting results of comparison of the new test with the conventional Pap smear in general population. **Material and Methods:** MarkPap test is available as MarkPap Research Kit (www.markpap.com). The kit was given to cytopathology laboratories with instructions (2-level Screening Procedure and the Criteria for Reading and Interpretation of MarkPap slides) how to use it for cervical cancer screening. Cervical specimens were obtained from women coming for regular Pap test checkup after they signed an IRB approved informed consent. Doctors collected and split specimens into a control (Pap smear first) and a research sample (MarkPap smear). Demography, Pap test results, and disease progress were recorded on CRF up to two years. The study was conducted as a multicenter, recruitment in order of arrival, concurrent control clinical laboratory trial, split-sample, 2-group, assessor blinded study design. Performance measures (Pe, Ps) were the proportion of detected abnormal specimens, and the sensitivity and specificity of screening (standard for validation was the optimized cytologic truth). Statistical analyses were based upon alpha = 0.05, power 80%, 95% Confidence Interval, and minimal clinically meaningful difference of 10%. We compared proportions in paired groups. **Results:** One thousand twenty-three specimens were obtained. Nine hundred sixty-nine were received in pairs. Twenty-two were rejected as non-satisfactory. Among control slides (Ps) 21 were true positive-abnormal comparing to 38 in the new test group (Pe). Superiority of detection was confirmed because delta was below the lower level 95% CI. The equivalence was confirmed because both the upper and lower levels of 95%CI were between plus/minus delta. **Conclusion:** We concluded that the MarkPap test increases sensitivity of detection of abnormal cervical specimens while keeping the specificity equivalent with the conventional Pap test. **Acknowledgment**: Supported in part by NIH SBIR grant 2R44CA086767–02

Author Disclosure

Employment or Leadership	Consultant or Advisory Role	Stock Ownership	Honoraria	Research Funding	Expert Testimony	Other Remuneration