Comparison of the Conventional Pap Smear and GluCyte™ Thin-Layer Preparation with Cervical Biopsy as the Gold Standard

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ABSTRACT
INTRODUCTION: The study was performed in order to compare the relative sensitivity of a new lower cost manual liquid based-thin-layer preparation to conventional Pap smears using the cervical biopsy as the standard for comparison.

MATERIALS AND METHODS: Patients were selected based upon Pap smears previously screened in positive by conventional cytology or suspect for cervical cancer in the city of Barueri. Results from GluCyte™ liquid based preparation, another conventional Pap smear, and biopsy were compared in this study. Patients had colposcopic examination and a new sample from the uterine cervix was obtained using the Roven Cervex Brush. A new conventional smear was made and the brush consisting of residual material was sent to the lab in the Synamed Preservative Vial. The Pap test samples were processed utilizing the GluCyte™ method and both samples (conventional and liquid based) were stained using the conventional Pap staining method. When the biopsy was performed, it was at the same time to the lab and procured in the routine manner.

The liquid based and conventional smears were identified and randomly mixed, blinded, and read by three expert cytologists. The results of conventional and liquid based cytology smears were compared to evaluate the diagnostic agreement between the cytology preparations and the biopsies.

RESULTS: In 100 patients, 99 biopsies were performed. From these cases, 27 were low grade and 3 high grade. The study showed that the conventional cytology had an agreement in 61% of the biopsies. Synamed GluCyte™ liquid based-thin-layer preparations yielded results that coincided with biopsy results in 81% of the cases.

CONCLUSION: The report suggests the GluCyte™liquid based method is more sensitive than the conventional cytology in comparison with biopsies as the gold standard for diagnosis of cervical cancer. More randomized studies comparing the two methods and biopsies are being performed.

INTRODUCTION
Over the past decade there has been an abundance of literature supporting the benefits of liquid based cytology methods over the conventional Pap technique. However, the current commercially available methods are too expensive for many impoverished areas of the world. One new alternative is the GluCyte™ Liquid Based Thin-Layer Preparation system. This technique offers both a manual method and an automated system for specimen preparation. The increased sensitivity of the manual method over the conventional Pap is the focus of this study.

MATERIALS AND METHODS
The study is comprised of one hundred patients with previous conventional cytology that is positive or suspect for cervical cancer. At the time of colposcopy, a conventional Pap smear was performed and the cervical brush tip was removed and placed into the Synamed preservative vial and sent to the laboratory for processing using the GluCyte™ method. Both preparations were stained using the Papanicolaou technique, and the slides were randomly mixed, blinded and diagnosed by three experienced cyto cytologists.

RESULTS
One hundred patient samples were evaluated and compared in the study. Agreement between the two cytology methods on all cases was 76%. In one of these cases had corresponding biopsies that were used as the gold standard. Of these biopsies, there were 5 HSIL, 27 LSIL, and 29 negative diagnostic interpretations. Table 1 shows the correlation between the conventional method and the biopsy. Table 2 shows the correlation between the GluCyte™ method and the biopsy.

Table 1

<table>
<thead>
<tr>
<th>Biopsy</th>
<th>HSIL</th>
<th>LSIL</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional</td>
<td>19</td>
<td>12</td>
<td>2</td>
<td>33</td>
</tr>
<tr>
<td>GluCyte</td>
<td>9</td>
<td>0</td>
<td>0</td>
<td>9</td>
</tr>
</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th>Biopsy</th>
<th>HSIL</th>
<th>LSIL</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>GluCyte</td>
<td>24</td>
<td>6</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>Conventional</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>5</td>
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</table>

REFERENCES

Lipid-based cervical cytologic smear study and conventional Papanicolaou smear: A meta-analysis of prospective studies comparing cytologic diagnoses and sample adequacy.

CONCLUSIONS

The study suggests that the GluCyte™ method is the more sensitive and specific method for cytology evaluation when compared to cases that have biopsy confirmed abnormalities as the gold standard. The low cost of equipment and training of laboratory personnel makes the GluCyte™ method an appealing screening technique for patients at high risk of developing cervical cancer.

GluCyte™ Processing Rack

LSIL GluCyte™ Preparation

BSIL GluCyte™ Preparation

Lipid-based cervical cytologic smear study and conventional Papanicolaou smear: A meta-analysis of prospective studies comparing cytologic diagnoses and sample adequacy.

Lipid-based cytologic smear and conventional smear: The comparison of lipid-based cytology smear and conventional smear over two 12-month periods.

Cost is a barrier to widespread use of liquid-based cytology for cervical cancer screening in Korea.