Increasing Cytotechnologist Workload Above 100 Slides per Day Using the BD FocalPoint GS Imaging System Negatively Affects Screening Performance

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Abstract

Studies examining the effects of increased workload on the performance of individual cytotechnologists are limited. Using FocalPoint GS, the performance of 3 cytotechnologists was evaluated. The study consisted of 3 phases. In phase I, cytotechnologists were asked to screen at their usual pace. In phase II, cytotechnologists were asked to screen as fast as possible without feeling that the quality of their work was diminished. In phase III, cytotechnologists were asked to screen at least 15% more than their daily workload from phase II. Productivity was increased by decreasing the percentage of cases that underwent full manual review (from 38% to 19%) and by decreasing the time spent on each slide (from 5.5 min to 3.7 min). Overall, the total abnormal rate decreased by 31.9% from phase I to phase III of the study. In addition, the false-negative fraction increased significantly, from 1% to 6.9%. Our results indicated a negative association between increased cytotechnologist daily workload with FocalPoint GS and CT screening performance. Workloads were increased by decreasing the time spent reviewing 10 fields of view and the percentage of cases that underwent full manual review.

The FocalPoint GS imaging system (FPGS; BD Diagnostics, Burlington, NC) was recently approved by the US Food and Drug Administration (FDA) to assist in primary gynecologic cytology screening. It is a fully integrated computer imaging system designed to assist cytotechnologists in the primary screening of SurePath Papanicolaou (Pap) tests (BD Diagnostics). It consists of an image processor and automated reviewing stations. The FPGS image processor scans the entire slide and locates 10 fields of view (FOVs) containing cells of interest for each slide. The cytotechnologists evaluate each FOV to identify any potential abnormalities. If the FOVs do not contain any potential abnormalities and the slide was satisfactory for evaluation, the cytotechnologists may elect to sign out the case as negative without further review unless the slide is being selected for directed quality control rescreening. Manual review of the entire slide is required if one or more of the following conditions is met: (1) any potential abnormalities were identified in any of the FOVs, (2) no endocervical or transformation zone component is identified in any of the FOVs, (3) specimen adequacy cannot be determined, or (4) a technical processing failure is identified by the instruments. Several studies have shown that FPGS significantly improved the detection of squamous abnormalities.1-3

Many laboratories in the United States have implemented automated assisted primary screening for gynecologic cytology to increase cytotechnologist productivity to combat the shortage of the cytotechnologist workforce. Productivity is usually measured in terms of the number of slides screened during an 8-hour day. The FDA approval of the system included the acceptance of a higher daily screening limit of 170 slides in no less than 8 hours compared with 100 slides approved for manual screening.4 A recent study using the ThinPrep imaging
system (TIS; Hologic Corp, Marlborough, MA) demonstrated that screening performance is negatively affected, with an increase in cytotechnologist workload. To our knowledge, no similar studies exist to date that have evaluated cytotechnologist performance at progressively increasing screening rates with FPGS. In the current study, we examined the screening performance of 3 cytotechnologists whose workload was systematically increased progressively using FPGS.

Materials and Methods

This study was approved by the institutional review board of Yale University, New Haven, CT. The average annual Pap test volume of our laboratory was approximately 80,000, including 80% SurePath, 20% ThinPrep, and less than 1% conventional preparation. The laboratory employed 13 cytotechnologists with experience ranging from 5 to more than 30 years. All liquid-based Pap tests were image assisted using either FPGS or TIS.

The current study was conducted over a 6-week period and limited only to SurePath Pap tests. It involved 3 cytotechnologists with experience ranging from 6 to 16 years, with a mean of 10 years. While participating in the study, the 3 participant cytotechnologists were exempted from all other laboratory duties and their time was entirely devoted to this study, with the exception of checking patient demographics and clinical information on the requisition sheets and the working drafts generated by the laboratory information system. The latter activity required an average of 30 seconds per slide.

The study was conducted in 3 phases. Each phase consisted of a total of 10 working days. In phase I, the cytotechnologists were asked to screen at their usual speed and not to change their usual screening habits. The purpose of phase I was to establish a baseline performance for comparison. In phase II, the cytotechnologists were encouraged to screen as fast as possible without feeling that the quality of their work was compromised. In phase III, the cytotechnologists were asked to screen with a speed at least 15% higher than their average speed in phase II. We chose 15% because it represented the minimum increase in productivity from phase I to phase II. At the beginning of the study, the cytotechnologists were not aware of the study design but were informed that it was a study assessing screening productivity. Furthermore, the participant cytotechnologists were not given any directions or advice regarding how to attain higher speeds or how to alter their screening patterns. All Pap tests underwent 100% rescreening by the remaining cytotechnologists who were not involved in the study.

The daily and hourly screening rates of each participant cytotechnologist for each phase were recorded. In addition, we recorded the rate of total abnormal findings, which was defined as atypical squamous cells (ASC) or higher for each cytotechnologist. We calculated the rate of ASC, low-grade squamous intraepithelial lesion (LSIL), and high-grade squamous intraepithelial lesion (HSIL). We also estimated the false-negative fractions (FNFs) and false-positive fractions (FPFs) of each cytotechnologist for each phase. The FNFs were estimated based on cases initially interpreted as negative and reclassified as squamous intraepithelial lesions or higher. The equation for calculating the FNF was “false-negative cases/(false-negative cases + true-positive cases).” The FPF was estimated based on cases initially interpreted as ASC or higher and reclassified as negative by both the review cytotechnologists and pathologists. The equation for calculating the FPF was “false-positive cases/(false-positive cases + true-negative cases).”

Statistical analysis was performed using Minitab version 16 software (Minitab, State College, PA). The Student t test was used to compare the productivity of participant cytotechnologists among different phases. The Z test was used to compare the rates of total abnormal findings and different categories among different phases. A P value of .05 or less was considered statistically significant.

Results

The total number of SurePath Pap tests screened by the 3 participant cytotechnologists during the study period was 8,709. Table 1 summarizes the number of slides screened by individual cytotechnologists and at different phases of the study. Statistically significant differences were found between phase I and phase II findings (P = .03), between phase II and phase III findings (P = .04), and between phase I and phase III findings (P = .01). Table 2 summarizes the average productivity of each phase during the study period. Compared with phase I, the average productivity of all cytotechnologists was 30.1% and 48.7% higher for phase II and III, respectively; the differences were statistically significant (P = .03, P = .008; Table 2). Compared with phase II, the average productivity of all cytotechnologists was also significantly higher during phase III (by 14.7%, P = .017; Table 2). Each cytotechnologist spent an average of 7 hours for screening each day; the average screening time per slide decreased from 5.5 to 3.7 minutes, representing a 33% reduction (P = .031; Table 3).

Table 1

<table>
<thead>
<tr>
<th>Cytotechnologist</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>822</td>
<td>937</td>
<td>1,119</td>
</tr>
<tr>
<td>2</td>
<td>815</td>
<td>1,054</td>
<td>1,197</td>
</tr>
<tr>
<td>3</td>
<td>664</td>
<td>993</td>
<td>1,108</td>
</tr>
<tr>
<td>Total</td>
<td>2,301</td>
<td>2,984</td>
<td>3,424</td>
</tr>
</tbody>
</table>
The differences between phase II and III ($P = .05$) were statistically significant, but differences between phase I and II were not significant ($P > .05$; Table 3).

Cases that underwent imaging that also had full manual review decreased from phase I (38%) to phase III (19%). Table 4 summarizes the total abnormal rate for each phase of the study. Two participant cytotechnologists reported a significant decrease in the total abnormal rates. On the other hand, the remaining cytotechnologist reported an increase in the total abnormal rates; however, the difference was not statistically significant. Overall, the total abnormal rate decreased by 31.9% from phase I to phase III of the study.

Table 5 compares the overall performance of the 3 cytotechnologists during phase I and III of the study. Productivity was increased by decreasing the percentage of cases that underwent full manual review (from 38% to 19%) and by decreasing the time spent on each slide (from 5.5 to 3.7 min). The decrease in the total abnormal rate from phase I to III was probably attributed to a substantial decrease in the rate of ASC and, to a lesser degree, the rate of LSIL. No significant difference was found in the detection of HSIL between the 2 phases. In addition, the FNF increased significantly from 1% to 6.9% (Table 5).

A weakness of our study that must be addressed is the fact that we did not include ASC cases in the calculation of FNF, but they were included in the total abnormal rate and in

Table 2
Productivity of Cytotechnologist During the 3 Phases of the Study

<table>
<thead>
<tr>
<th>Cytotechnologist</th>
<th>Phase I Slides/d</th>
<th>Phase I Slides/h</th>
<th>Phase II Slides/d</th>
<th>Phase II Slides/h</th>
<th>Phase III Slides/day</th>
<th>Phase III Slides/h</th>
<th>Increase from Phase I to III, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>82.2</td>
<td>10.9</td>
<td>93.7</td>
<td>12.5</td>
<td>111.9</td>
<td>14.9</td>
<td>36.1</td>
</tr>
<tr>
<td>2</td>
<td>81.5</td>
<td>10.8</td>
<td>105.4</td>
<td>14.1</td>
<td>119.7</td>
<td>16.0</td>
<td>46.8</td>
</tr>
<tr>
<td>3</td>
<td>66.4</td>
<td>8.8</td>
<td>99.3</td>
<td>13.2</td>
<td>110.8</td>
<td>14.8</td>
<td>66.8</td>
</tr>
<tr>
<td>Mean</td>
<td>76.7</td>
<td>10.2</td>
<td>99.5</td>
<td>13.3</td>
<td>114.1</td>
<td>15.2</td>
<td>48.7</td>
</tr>
</tbody>
</table>

* Method for calculating workload (fields of view only = 0.5 slide, full manual review = 1.0 slide, fields of view + manual review = 1.5 slide).

Table 3
Mean Time Spent Per Slide During the 3 Phases of Study

<table>
<thead>
<tr>
<th>Cytotechnologist</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Absolute Time Decrease, min*</th>
<th>Relative Decrease, %*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5.1</td>
<td>4.5</td>
<td>3.8</td>
<td>1.4</td>
<td>26.5</td>
</tr>
<tr>
<td>2</td>
<td>5.2</td>
<td>4.0</td>
<td>3.5</td>
<td>1.6</td>
<td>31.9</td>
</tr>
<tr>
<td>3</td>
<td>6.3</td>
<td>4.2</td>
<td>3.8</td>
<td>2.5</td>
<td>40.1</td>
</tr>
<tr>
<td>Mean</td>
<td>5.5</td>
<td>4.2</td>
<td>3.7</td>
<td>1.8</td>
<td>32.8</td>
</tr>
</tbody>
</table>

* From phase I to phase III.

Table 4
Total Abnormal (ASC or Above) Rate During the 3 Phases of Study

<table>
<thead>
<tr>
<th>Cytotechnologist</th>
<th>Phase I, No./Total (%)</th>
<th>Phase II, No./Total (%)</th>
<th>Phase III, No./Total (%)</th>
<th>Relative Changes, %*</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>115/822 (14.0)</td>
<td>125/937 (13.3)</td>
<td>189/1,119 (16.9)</td>
<td>20.7</td>
<td>.079</td>
</tr>
<tr>
<td>2</td>
<td>171/815 (21.0)</td>
<td>107/1,054 (10.2)</td>
<td>103/1,197 (8.6)</td>
<td>–59.0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>3</td>
<td>70/664 (10.5)</td>
<td>62/993 (6.2)</td>
<td>69/1,108 (6.2)</td>
<td>–40.9</td>
<td>.002</td>
</tr>
<tr>
<td>Mean</td>
<td>356/2,301 (15.5)</td>
<td>294/2,384 (9.9)</td>
<td>361/3,424 (10.5)</td>
<td>–31.9</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

ASC, atypical squamous cells; CA, carcinoma; HSIL, high-grade squamous intraepithelial lesion; LSIL, grade squamous intraepithelial lesion; NS, not significant.
the FPF (Table 5). It was not the practice of the department at the
time (2009-2010) to include ASC cases in the calculation of
FNF, and the required data were not available for recal-
culation. Subsequently the method of FNF calculation changed
and is reflected in later data (second half of 2011).

Discussion

The use of computer-assisted primary screening is now
quite entrenched in gynecologic cytology. The main benefits
are increased accuracy, efficiency, and productivity in a cost-
effective manner. These improvements are most beneficial
to high-throughput laboratories, which experience increasing
volume and workload. Among the 3 devices currently
approved by the FDA for computer-assisted primary screen-
ing of Pap tests, the FocalPoint Slide Profiler (BD Diagnos-
tics) scores, sorts, and ranks both conventional and SurePath
Pap slides according to the probability and degree of abnor-
mality of the slide; up to 25% of the slides that scored below a
certain threshold are eligible for archiving without any manual
review. The remaining 2 are the TIS and FPGS Imaging Sys-
tem, which use location-guided screening technology.

The increase in productivity as a result of implementa-
tion of location-guided imaging systems depends largely on
the speed with which slides are screened. A workload study
documenting cytotechnologist screening rates was conducted
by BD Diagnostics using the FPGS imaging system. Based
on the observations of 16 cytotechnologists from 4 sites, the mean
daily rates ranged from 93 to 173 slides, with low to high rates
ranging from 48 to 240 slides. Because none of the cytotech-
nologists worked more than a mean 5 hours, these rates were
obtained by extrapolation to represent 8 hours of daily screen-
ing. For example, the reported highest daily rate of 240 slides
was extrapolated from a cytotechnologist who evaluated a total
of 948 slides and screened a mean of only 4.3 hours per day.
Nonetheless, the FDA has approved a daily maximum cytolog-
year screening workload of 170 slides, in no less than an 8-hour
work day, using FPGS. This does not supersede the Clinical
Laboratory Improvement Amendment (CLIA) requirement of
100 slides in no less than an 8-hour day per 24-hour period.

The FDA recently clarified how to calculate workload limits
for imaged slides. Briefly, a value of 0.5 is assigned to any
slide that is reviewed on an imaging system using FOVs only,
whereas a value of 1.0 is assigned to any slide that has under-
gone full-slide manual review; slides with both FOV and full-
slide manual review are counted as 1.5 slides. Based on these
values, the total should not exceed the CLIA limit of 100 slides
in no less than an 8-hour day.

Aside from the BD Diagnostics study, only a few studies
in the literature have evaluated workload and the use of FPGS.
These studies have demonstrated a significant decrease in the
mean screening time per slide when using the FPGS imag-
ing system. According to an early Italian study, the mean
screening time per slide was 6 minutes with conventional
manual screening and 4 minutes through FOV analysis plus
rapid manual rescreening; the mean difference was more
than 2 minutes. Recently, our laboratory also observed a
14% decrease in the screening time, from 6.8 minutes per
slide to 5.5 minutes per slide, after implementing FPGS with
increased detection of ASC of undetermined significance and
LSIL cases and a substantial decrease in estimated FNF.
However, our average daily rate per cytotechnologist was 79
slides, approximately 50% lower than the maximum workload
approved by the FDA for the FPGS system.

In the current study, the baseline daily rate for all 3
cytotechnologists was approximately 77 slides and was com-
parable with the overall average daily rate (79 slides) for the
entire laboratory before the study (data not shown). During
phase 3 of the study, the increase in daily rate ranged from
36% to 67% with a mean of 49%. All 3 cytotechnologists
screened more than 100 slides per day during phase 3. On the
other hand, the percentage of cases that underwent full manual
review decreased from 38% to 19% from phase 1 to phase 3.
An overall 32% decrease in total abnormal rate was noted
from phase 1 to phase 3.

Our findings were comparable with those of Elsheikh
et al, who examined the effect of increasing workload
on the cytotechnologist performance using the TIS. The
authors observed that the productivity of 3 cytotechnologists
increased by 36%, from an average of 87 to 118 slides per
day, whereas the percentage of cases that underwent full man-
ual review decreased from 25% to 20% and the total abnormal
rate decreased from 10% to 8%. The authors concluded that
an increased cytotechnologist workload of more than 100
slides per day with the TIS resulted in a significantly reduced
screening performance. Our findings also echoed the findings
by Ellis et al, who compared individual screening sensitiv-
ity of manual screening of SurePath slides with individual
workload. The authors observed that the sensitivity for a daily
workload of 23 slides or less was significantly higher than that
for a daily workload of more than 23 slides (98.3% vs 95.7%).
In a more recent study, Renshaw and Elsheikh observed
that screening sensitivity correlated negatively with epithelial cell
abnormality (ECA)–adjusted workload (number of slides
screened/day × laboratory ECA rate) with the TIS.

In the current study, 2 participant cytotechnologists
experienced a 40% and 60% decrease in total abnormal rate,
whereas 1 cytotechnologist experienced a small but nonsig-
nificant increase in total abnormal rate. Although the overall
FPFs were similar between phase 1 and phase 3, the FPF of
the cytotechnologist who demonstrated a small increase in
the total abnormal rate increased from 1.2% during phase
1 to 3.4% during phase 3; the difference was statistically
significant \((P = .004; \text{data not shown})\). It can be inferred that cytotechnologists were likely making errors at the initial triage stage, i.e., during the screening of the 10 FOVs and not at the subsequent full-slide manual review.

Another consideration is that a minority of cytotechnologists can screen more than 100 slides per day successfully. In the routine laboratory setting, it would be difficult to set up different screening rates for certain cytotechnologists and ensure through quality assurance that they continue to perform adequately at these higher screening rates. In the interest of patient safety, it is best to have a universal guideline for all cytotechnologists that limits screening to 100 slides per day.

Roberts at al\(^{10}\) observed that the majority of the false-negative cases occurred because of the failure of the cytotechnologists to identify the presence of abnormalities in at least 1 of the 22 FOVs when using the TIS. Another study also pointed out that the most diagnostically abnormal cells were not always present in the 22 FOVs selected by the TIS.\(^{11}\) The latter finding may also be applicable to FPGS.

The total abnormal rate decreased because of a decrease in the rate of ASC, undetermined significance, and, to a lesser extent, LSIL. The FNF was markedly increased, mostly because of increased LSILs missed by participant cytotechnologists. Our data suggest that the cytotechnologists appeared to struggle in identifying ASC and LSIL at higher screening rates. No statistical difference was seen in detecting HSIL at higher screening rates; however, this is likely because of a statistical limitation of the small sample size. Elsheikh et al\(^{5}\) only observed a decrease in the reporting of ASC and HSIL but not LSIL with higher screening rate with the TIS.

Although the participating cytotechnologists were not explicitly asked about the strategies they used to increase productivity throughout the 3 phases, we postulated that the most likely method was by decreasing the percentage of cases that underwent manual review. This was supported by the fact the overall percentage of cases that underwent full manual review decreased from 38% to 19% from phase 1 to phase 3.

One major limitation is the small scale of the current study, which only involved 3 cytotechnologists and fewer than 9,000 samples. Another major limitation is the short period of phase 3. It is possible that the cytotechnologists were still trying to find ways to adapt to the increasing workload. In addition, because of the short period of phase 3, the cytotechnologists were not provided with feedback on the quality of their performance. Lastly, the cytotechnologists were aware that their cases were to undergo 100% rescreening, which might have influenced their performance.

In conclusion, our results suggested that a negative correlation existed between the increased daily workload and the screening performance of cytotechnologists. A workload of 100 or more slides was associated with lower sensitivities in identifying squamous abnormalities. Productivity was increased by reducing the proportion of cases that underwent full-slide review and by reducing the average time spent on reviewing the 10 FOVs.

\textbf{References}


