CME/SAM

ASC/SIL Ratio for Cytotechnologists

A Surrogate Marker of Screening Sensitivity

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Upon completion of this activity you will be able to:
- describe the differences between routine (full) review of negative gynecologic cytology cases and rapid prescreening.
- discuss the utility of the atypical squamous cell/squamous intraepithelial lesion (ASC/SIL) ratio for cytotechnologists.

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Abstract

The atypical squamous cell/squamous intraepithelial lesion (ASC/SIL) ratio has been used as a surrogate quality control tool for specificity and uncertainty for cytopathologists. Whether this ratio is useful for cytotechnologists is not known.

During an 8-month period, the sensitivity of screening for 11 cytotechnologists was determined using rapid prescreening. The ASC/SIL ratio for each cytotechnologist was correlated with the screening accuracy for each.

Screening sensitivity varied from 50.5% to 97.7%, and the ASC/SIL ratio varied from 0.87 to 4.49. The mean screening sensitivity for cytotechnologists with ASC/SIL ratios less than 1.5 was significantly less than that of cytotechnologists whose ASC/SIL ratio was more than 3.0 (67% vs 95%; P = *.021).*

In the absence of more accurate quality control data, an ASC/SIL ratio less than 1.5 for a cytotechnologist may be a surrogate marker for inadequate screening sensitivity.

Atypical squamous cells (ASC) is the most common gynecologic cytologic abnormality, constituting around 5% of Papanicolaou test results.[1-3] It reflects a diagnosis of uncertainty and is used as an intralaboratory and interlaboratory comparison tool for quality control purposes.[1-3] However, since the diagnosis of ASC is dependent on the laboratory patient population, a higher rate can occur if there is a larger proportion of high-risk patients. In response to this, the ASC/squamous intraepithelial lesion (SIL) ratio was introduced as a quality control measure that was less dependent on the patient population, because the ASC and SIL rates would both increase in a laboratory with more high-risk patients.[1-6] The ASC/SIL ratio can be calculated for the entire laboratory or for individual cytopathologists and has served as a surrogate marker for the level of certainty and for specificity. Current recommendations are for a laboratory or cytopathologist to maintain a ratio of less than 2:1 or 3:1, although these recommendations are based on survey data rather than actual measurements of sensitivity or specificity. Whether there is a lower limit to this ratio that corresponds to decreased sensitivity is not known.

In addition, despite being used for quality control purposes for more than 10 years, little has been done to use ASC/SIL ratios as a quality control measure for cytotechnologists. Whether the ASC/SIL ratio of individual cytotechnologists correlates with their screening sensitivity or specificity is not known. To address this, we compared the ASC/SIL ratio of 11 cytotechnologists with the screening sensitivity and specificity as determined using rapid prescreening (RPS).

Materials and Methods

RPS for an 8-month period was performed as previously described.[7] In brief, from November 2006 to June 2007, RPS was routinely performed by 11 cytotechnologists on all routine conventional Papanicolaou (Pap) smears (n = 26,931) received at the Cytopathology Laboratory, McGill University Health Center, Montreal, Canada. Because the usual practice in our laboratory is that all Pap smears from high-risk cases, such as those from the colposcopy and oncology clinics, never undergo RPS and are instead always reviewed by a pathologist even if screened as "negative," all such cases were excluded from the current study. In other words, all cases included in the current study relate to a routine screening population.

The cases included in the study underwent RPS in a manner similar to that previously reported[8,9] with the following modifications. The majority of screeners spend between 15 and 30 minutes to rapidly prescreen 1 set of approximately 20 slides each day, allowing 45 to 90 seconds to screen each slide. One half of the screeners use the Turret method, and the others use the Whole or the Step method, depending on their preference. For the Whole technique, the screener reads the slide in horizontal direction; for the Step technique, the slide is read in a stair-wise fashion; for the Turret technique, the screener runs the slide in horizontal and vertical (Greek bar) sense alternately. The great majority of screeners do not perform the RPS first thing in the morning; the period of the day devoted to RPS is variable from one screener to another. The current study evaluates real-life RPS performance done without restriction.

All RPS diagnoses were recorded as abnormal/review (R) or negative (N) on a standardized worksheet, without making any marks on the slide or paperwork. The threshold for R was ASC. After the cases were rapidly prescreened, they were fully screened without knowledge of the RPS diagnosis, making sure that the full screener was not the same as the RPS screener. Once a diagnosis was made on the full screening, the final and RPS diagnoses were compared. In cases in which both reviews were labeled N, the results were finalized by the cytotechnologist. Cases labeled R by both screeners or N by RPS but R by full screening were referred to a pathologist for final diagnosis. Cases labeled R by RPS but N by full screening were referred back to the rapid prescreener to review the slide and dot suspected abnormal cells; these were also referred to a pathologist. The final diagnosis of the pathologists was used as the "gold standard" for calculating sensitivity and specificity of RPS and full screening. Four pathologists diagnosed all cases during the study period; all 4 had subspecialty training in cytopathology.

Data on the ASC/SIL ratios (of individual cytotechnologists) were retrieved from the computerized data base of the cytopathology laboratory during this same period. Of note, the data used relate to the "raw" diagnosis that the cytotechnologists made themselves when screening the slides based on their own interpretation (ie, before changes made by pathologists who made the final diagnoses). The SIL component (by individual cytotechnologists) included low-grade SIL, SIL difficult to classify, and high-grade SIL or above. Because of software limitations, the ASC component (by individual cytotechnologists) included ASC, ASC cannot exclude high-grade SIL, and atypical glandular cells (AGC). Inclusion of the AGC along with ASC in the calculation of the ASC/SIL has also been used by others.[5] In this study, the rates of ASC, ASC cannot exclude high-grade SIL, and AGC (at final diagnosis, after review by pathologists) were 2.5%, 0.3%, and 0.2%, respectively; thus, inclusion of AGC in this calculation increased the atypical rate by 7%.

Of note, the numbering of the cytotechnologists (in the text and tables) was kept the same as in previously published studies from the laboratory with the same group of cytotechnologists (despite the absence of cytotechnologist 8 during the current study) to facilitate comparison of the current data with data from previously published studies.

Statistical analysis was performed using a 2-tailed Mann-Whitney *U* test as appropriate. A significance level of *P* less than .05 was used.

Results

A total of 26,931 smears were rapidly prescreened and evaluated. Screening sensitivity, specificity, and the ASC/SIL ratio are summarized in **Table 1**. Screening sensitivity varied from 50.5% to 97.7%, specificity from 97.1% to 99.6%, and the ASC/SIL from 0.87 to 4.49.

Table 1
ASC/SIL Ratio, Corrected Screening Sensitivity, and Specificity for 11 Cytotechnologists*

Cytotechnologist No.	ASC/SIL Ratio	Corrected Sensitivity (%)†	Specificity (%)†
1	1.34	51.1	99.5
2	4.49	95.1	97.5
3	2.32	77.3	97.6
4	1.36	50.5	99.6
5	0.87	87.2	99.3
6	4.32	93.5	99.4
7	2.86	80.1	97.5
9	1.81	97.7	99.1
10	3.85	96.3	97.8
11	1.21	79.4	99.7
12	3.05	96.2	97.1
Total	2.2	82.2	98.6
Median	2.3	87.2	99.1
Mean	2.5	82.2	98.5

ASC, atypical squamous cells; ASCUS, atypical squamous cells of undetermined significance; SIL, squamous intraepithelial lesions.
* The screener numeration is the same as in our previous studies[8,9] for easier comparison. Cytotechnologist 8 was not active during the present study period.
† For ASCUS and above.

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For statistical analysis, the ASC/SIL ratios were grouped according to cytotechnologists with ASC/SIL ratios of less than 1.5, 1.5 to 3.0, and more than 3.0 **Table 2** and **Table 3**. The mean screening sensitivity for cytotechnologists with ASC/SIL ratios less than 1.5 was significantly less than that of cytotechnologists whose ASC/SIL ratio was more than 3.0 (67% vs 95%; $P = .021$). Inversely, the specificity of the cytotechnologists whose ASC/SIL ratio was less than 1.5 was significantly higher than that of cytotechnologists whose ASC/SIL ratio was more than 3.0 (99.5% vs 98.0%; $P = .021$).

Table 2
Sensitivity (%) Grouped by ASC/SIL Ratio*

	ASC/SIL Ratio		
	<1.5	1.5-3.0	>3.0
	51.1	77.3	95.1
	50.5	80.1	93.5
	87.2	97.7	96.3
	79.4		96.2
Mean	67.1	85.0	95.3

ASC, atypical squamous cells; SIL, squamous intraepithelial lesions.
* Each value, except the mean values, is the screening sensitivity for 1 of 11 cytotechnologists.

Table 3
Specificity (%) Grouped by ASC/SIL Ratio*

	ASC/SIL Ratio		
	<1.5	1.5-3.0	>3.0
	99.5	97.6	97.5
	99.6	97.5	99.4
	99.3	99.1	97.8
	99.7		97.1
Mean	99.5	98.1	98.0

ASC, atypical squamous cells; SIL, squamous intraepithelial lesions.
* Each value, except the mean values, is the screening specificity for 1 of 11 cytotechnologists.

Discussion

The most commonly used quality control method at present in North America for gynecologic cytology is the 10% full rescreening of randomly selected Pap tests that were originally interpreted as negative. However, because only a fraction (ie, 10%) of the cases are reexamined, it is an ineffective strategy because the best possible theoretical pick-up rate would be that fraction itself (ie, 10%). An alternative method would be to perform a second full screening of all negative smears; this is, however, not practical in high-volume laboratories.

A more practical approach is rapid rescreening of all negative cases using 30 to 120 seconds per slide; this is a recommended quality control measure in the United Kingdom and has received widespread acceptance in Europe and Australia.[10-12] Rapid rescreening has, however, the drawbacks that the rapid screener is aware of the previous interpretation (ie, it was a negative case) and there are no means of monitoring its effectiveness. These drawbacks are eliminated by using a variation of rapid rescreening, that is, RPS[13,14]; it involves rapidly screening all slides before their full screening. Because the cases that are rapidly screened have not been triaged, the rapid prescreeners often detect abnormalities on the slides, making this activity more interesting than the rapid rescreening (for which all abnormal slides detected by full screening are triaged out before rapid rescreening). Because the screening of the slide is performed so quickly for an RPS, it might seem counterintuitive that it would work, but it does, as shown consistently by different investigators under different circumstances.[7-9,13-15] The results of RPS prove the adage that 2 heads (or 4 eyes) are better than 1 (or 2)!

Although the ASC/SIL ratio is a well-known quality control method in gynecologic cytology, there are several limitations to its use. First, the most commonly cited recommendations for appropriate ASC/SIL ratios derive from survey data without any corresponding information concerning specificity or sensitivity. As a result, the recommendations allow a laboratory to compare its ASC/SIL ratio with those of other laboratories, but no information concerning the sensitivity or specificity that the ratio corresponds to is given. Second, the ASC/SIL ratio has been primarily used as a quality control measure for cytopathologists and the laboratory in general. To date, little if any information is available concerning the use of this measure in the evaluation of a cytotechnologist's performance. The data in this study are the first to directly address both of these issues.

Our data show that this ratio can be useful in evaluating the performance of cytotechnologists. It is no surprise that cytotechnologists with lower ASC/SIL ratios were more specific in their diagnoses than those with higher ASC/SIL ratios. However, it was surprising that this increased specificity came at the price of such a large decrease in their screening sensitivity and where this threshold appeared to be. Specifically, when cytotechnologists with an ASC/SIL ratio of 1.5 to 3.0 were compared with those with an ASC/SIL ratio of less than 1.5, the difference in specificity was only 1.4% (98.1% vs 99.5%, respectively). However, this very small difference in specificity was accompanied by a decrease in sensitivity of 18% (85% to 67%). In our opinion, this decrease in sensitivity is simply too great to justify the small improvement in specificity. As a result, in the absence of additional data concerning the screening sensitivity of individual cytotechnologists, our data suggest that maintaining an ASC/SIL ratio of more than 1.5 might be the best way to ensure that the sensitivity of screening is acceptable. In addition, further improvements in sensitivity (85% to 95%) appear to be possible with ratios of more than 3.0, with only a 0.1% decrease in specificity.

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There are several important limitations to this study. First, it is important to stress that these results are specific to cytotechnologists and may not necessarily apply to cytopathologists or the laboratory in general.[16-18] It is very likely that the optimum ASC/SIL ratio for the laboratory is very different from the optimum ASC/SIL ratio for cytotechnologists. Most commonly, a laboratory depends on its cytotechnologists to maintain adequate sensitivity and on its cytopathologists to maintain adequate specificity. For practical purposes, the main impact of the cytopathologist on the output of the laboratory is to correctly downgrade cases sent by the cytotechnologists to negative and, thus, improve the specificity of the laboratory. It is entirely possible that well-trained cytopathologists may be able to correctly downgrade a sufficient number of cases to make the laboratory's ASC/SIL ratio significantly less than that of the cytotechnologists. Nevertheless, these results imply that trying to make cytotechnologists responsible for specificity by stressing a low ASC/SIL ratio for cytotechnologists has significant limitations. Directors of cytopathology laboratories who give instructions to cytotechnologists to keep their ASC rate "under control" may be sacrificing significant sensitivity if the ASC rate becomes too low.

Second, we stress that the ASC/SIL ratio is a surrogate marker for sensitivity and specificity and, as such, has limitations to its use. For example, although cytotechnologists with ASC/SIL ratios of more than 3.0 had a mean screening sensitivity that was higher than those with ASC/SIL ratios less than 1.5, this correlation is not perfect; in fact, the cytotechnologist with the highest screening sensitivity had an ASC/SIL ratio between 1.5 and 3.0. Why this particular cytotechnologist is able to keep a high specificity at the same time as a high sensitivity is unknown. That cytotechnologist has 20 years' experience (range for the other cytotechnologists, 7-31 years) and fully screened a total of 2,249 slides during the study period (range for the other cytotechnologists, 1,510-3,159); these factors, therefore, do not seem to be significant. Also, in a previous study,[7] we showed that screeners' sensitivity in gynecologic cytology seemed unrelated to the experience level of individual cytotechnologists or to their workloads at the levels examined. Finally, the daily tasks of that cytotechnologist are similar to those performed by the other cytotechnologists. Although it cannot be proven, we postulate that the performance of that particular cytotechnologist has to do with natural aptitudes, analogous to other disciplines; simply put, some people are better than others at performing certain tasks. Therefore, rare cytotechnologists may have the optimal combination of cytotechnology skills to achieve high screening sensitivity and fine-tuned diagnostic skills allowing them to maintain a high specificity at the same time; for such a cytotechnologist, these guidelines may not necessarily apply. However, to identify such individuals, one cannot rely on the ASC/SIL ratio, but instead must measure the screening sensitivity and specificity of individual cytotechnologists directly using the RPS technique.[7]

Third, in this study AGC was included in the calculation of the atypical rate. If AGC cases were not included, the ASC/SIL ratios would be slightly less. Since AGC increased the atypical rate by 7%, the ASC/SIL ratios that would correspond to 1.5 and 3.0 would be approximately 1.4 and 2.8 if AGC were not included.

But how do these numbers really affect the laboratory? What does "keeping your cytotechnologists under control" really mean? The total abnormality rate (ASC + SIL) for this laboratory is 2.8%, so that in every 1,000 slides there are 28 abnormal cases. The cytotechnologists with an ASC/SIL ratio of more than 3.0 successfully find 27 of 28 abnormal cases (the additional case is found through RPS) and refer a total of 19 additional cases that need to be downgraded by cytopathologists. The cytotechnologists with an ASC/SIL ratio between 1.5 and 3.0 identify 24 of 28 abnormal cases and refer an additional 18 cases that need to be downgraded. The cytotechnologists with an ASC/SIL ratio of less than 1.5 only identify 19 of the 28 abnormal cases but only refer 5 additional cases that need to be downgraded. As a result, the cytopathologists who work with cytotechnologists with ASC/SIL ratios greater than 1.5 will have to review about 50% more cases, but the result is that the laboratory identifies 18% to 28% more abnormal cases. In our opinion, the increase in sensitivity is more than worth the additional work.

Although there seems to be a clear lower limit to ASC/SIL ratios for cytotechnologists, is there an upper limit? The cytotechnologists with an ASC/SIL ratio more than 3.0 had a sensitivity of 95%. Screening sensitivities greater than this are difficult to demonstrate, although, of course, are possible. Among the 11 cytotechnologists involved in the current study, none had an ASC/SIL ratio greater than 4.5. Therefore, the optimal ASC/SIL ratio for cytotechnologists might range as high as 5.0; this, however, remains to be validated by other laboratories. Nevertheless, it is important to note that even as the ASC/SIL ratios increase above 3.0, the decrease in specificity is extremely small. There is a much greater loss in specificity going from less than 1.5 to 3.0 than from 3.0 to 4.5. Thus, it seems that cytotechnologists with ASC/SIL ratios greater than 3.0 are not really referring that many additional cases that need to be downgraded.

This study used RPS to assess sensitivity and specificity. The power and advantage of this technique is illustrated in this study, which allowed us to precisely measure sensitivity and specificity in a routine laboratory setting. However, similar results can be achieved by using histologic follow-up as recently outlined in a study by Thrall et al[19] looking at the impact of using the more restrictive definition

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of ASC according to the Bethesda System 2001 compared with the previous Bethesda classification, which originally included "ASCUS [atypical squamous cells of undetermined significance], favor reactive." In their study, they showed that the increased specificity of an ASCUS diagnosis as outlined in the Bethesda 2001 classification came at the cost of a decreased sensitivity for some women with significant SILs, such as cervical intraepithelial neoplasia 2/3.

A similar approach may also be useful in the evaluation of other measures of quality, such as the positive human papillomavirus rate for ASC. By itself, this variable depends on a variety of factors, including the sensitivity and specificity of screening in identifying cases of ASC. Without any additional information, it is difficult to know if an increase in the positive human papillomavirus rate is being achieved by increasing specificity or by decreasing sensitivity. If this rate were measured in conjunction with the sensitivity as determined by RPS, the effect on sensitivity and specificity could then be determined.

Finally, in this study, all of the missed cases were identified by RPS. An alternative method to achieve excellent sensitivity, keep the ASC/SIL ratio of the cytotechnologists low, and reduce the number of cases referred to the pathologists for review is to not allow cytotechnologists to refer that many cases and instead routinely use excellent RPS to identify all cases that are missed in the initial screening. Indeed, in another study using RPS in the routine laboratory setting, the authors were able to achieve a sensitivity of 87%, even though the sensitivity after the initial screening was only 65%.[15] In addition, this method allows accurate measurement of the sensitivity and specificity of individual cytotechnologists and cytopathologists and of the laboratory as a whole. As such, we strongly recommend RPS as the only meaningful way to measure sensitivity in the routine laboratory setting and believe it is a much more powerful quality assessment method than ASC/SIL ratios.

We have shown that the ASC/SIL ratio for individual cytotechnologists is a good surrogate marker for the screening sensitivity of cytotechnologists. In the absence of more detailed information such as that obtained by directly measuring screening sensitivity by RPS, our data suggest that the ASC/SIL ratio of cytotechnologists should be kept greater than 1.5 to ensure adequate screening sensitivity.

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