The ASC/SIL Ratio for Cytopathologists as a Quality Control Measure

A Follow-up Study

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Abstract

Monitoring the relative frequency of the interpretations of atypical squamous cells (ASC) and squamous intraepithelial lesions (SIL) has been proposed as a quality control measure. To assess its value, an ASC/SIL ratio was calculated every 6 months for 3.5 years, and confidential feedback was provided to 10 cytopathologists (CPs). By using simple regression analysis, we analyzed the initial and final ASC/SIL ratios for individual CPs and for the entire group. The ratio was below the upper benchmark of 3:1 for all but 1 CP during every 6-month period. The ratio for all CPs combined showed a downward trend (from 2.05 to 1.73). The ratio for 6 CPs decreased, and for two of them the decrease was statistically significant. One CP showed a statistically significant increase in the ASC/SIL ratio. The decrease for some CPs likely reflects the salutary effect of confidential feedback and counseling.

Atypical squamous cells (ASC) is the most common epithelial abnormality reported in Papanicolaou (Pap) test results.[1-3] Currently, the Bethesda System for reporting Pap test results defines ASC as cells showing cytologic changes suggestive of squamous intraepithelial lesion (SIL) but with insufficient evidence, qualitative or quantitative, for a definite diagnosis of SIL.[4] Because ASC is essentially a diagnosis of uncertainty, many laboratories monitor their ASC rates for quality control purposes to ensure that this interpretation is not overused. To control for differences in the frequency of cervical dysplasia in different populations, the ratio of ASC to SIL interpretations has been adopted as the preferred measure, especially for interlaboratory comparisons.[1-3] Several benchmarks have been proposed and widely adopted: one is an upper benchmark of 3[5]; another, used primarily for interlaboratory comparisons, includes upper and lower (95th and 5th) percentiles.[6]

In a previous study, Juskevicius et al[7] showed that measuring the ASC/SIL ratio of individual cytopathologists (CPs) and providing it to them periodically in a confidential communication is a useful quality control measure. It allows individual CPs to assess their ratio compared with that of the laboratory as a whole and against the 3:1 benchmark. We found no correlation between a CP's years of experience or annual gynecologic cytology case load and his or her ASC/SIL ratio. We did find a statistically significant decrease in the ASC/SIL ratio for our laboratory in a 3-year period during which CPs received feedback on their individual ratios. We could not be sure, however, whether the decrease in the ratio was due to the confidential feedback we provided, because there was at least one confounding factor: during that period, our laboratory converted from conventional Pap smears to liquid-based preparations. It was possible that the decrease in the ASC/SIL

ratio during that time was due at least in part to this improved method for slide preparation.

Our aim in the present study was to extend our analysis for an additional 3.5-year period, after the conversion to liquid-based slide preparation had already been completed.

Materials and Methods

A summary of the cytologic interpretations made by 10 CPs on gynecologic cytology specimens was retrieved from the laboratory information system. This summary included data sorted by principal diagnostic category, eg, negative for intraepithelial lesion, ASC, low-grade SIL, or high-grade SIL. The ASC/SIL ratios for each of 10 CPs and the entire laboratory were calculated every 6 months for a 42-month period (3.5 years) between July 1, 2000, and December 31, 2003. The study periods were divided as follows: 1, July 1 to December 31, 2000; 2, January 1 to June 30, 2001; 3, July 1 to December 31, 2001; 4, January 1 to June 30, 2002; 5, July 1 to December 31, 2002; 6, January 1 to June 30, 2003; and 7, July 1 to December 31, 2003. During this time, between 83% and 93% of the annual volume of gynecologic cytology specimens examined in our laboratory was prepared using the ThinPrep method (Cytyc, Marlborough, MA). There were no significant changes in the terminology used for reporting results, cytotechnology or cytopathology staff, approach to reviewing cases, or provider mix.

The ASC/SIL ratio was obtained by dividing the sum of all ASC cases by the sum of all SIL cases. SIL for this purpose included low-grade SIL, high-grade SIL, SIL difficult to grade, and carcinoma. The CPs were periodically informed of their ratio (along with the laboratory average for that period) in a confidential communication. CPs whose ratio exceeded the upper benchmark obtained confidential face-to-face counseling by the laboratory director.

Regression analysis was used to estimate the trends in ASC/SIL ratios over time, and rates of change per 6-month period were calculated. The trend for the whole laboratory was derived by using 2 approaches: pooling the ASC and SIL frequencies over CPs before constructing ratios and averaging the ratios, giving equal weight to each CP.

Because there was little change in the cytopathology staffing between this study and a previous study[7] that examined the immediately preceding consecutive periods, we combined the data from both studies to show trends during the span of 6.5 years.

Results

Table 1 shows the ASC/SIL ratios for the CPs and for the entire laboratory for 7 consecutive 6-month periods. The ratio was always less than 3:1 for the laboratory as a whole. All CPs had an ASC/SIL ratio below the upper benchmark of 3:1 during all periods, with 1 exception (CP5). CP5 had ratios above the benchmark during 6 periods, and a ratio below the benchmark during 1 period.

Table 2 shows the trends for the 3.5-year period. The laboratory as a whole showed a downward trend in its ASC/SIL ratio **Figure 1**, which was more pronounced when the ratio was calculated as an average of the CPs' individual ratios than when test frequencies were pooled; however, neither rate of change for the study period was statistically significant.

Six CPs showed a downward trend in their ratios, while 4 showed an upward trend. Of the 6 CPs with negative rates of change, 2 (CP5 and CP6) had statistically significant changes **Figure 2**.

Of the CPs who showed an upward trend, only 1 (CP4) had a statistically significant increase in the ASC/SIL ratio, which, nevertheless, always remained below 3.

Table 1
ASC/SIL Ratios for 10 Cytopathologists During Seven Consecutive Six-Month Periods

	Period						
Cytopathologist	**1**	**2**	**3**	**4**	**5**	**6**	**7**
1	1.13	2.40	1.93	2.11	0*	1.81	1.87
2	2.00	0*	1.37	1.30	1.48	1.22	1.64
3	1.92	2.37	2.54	1.90	1.86	2.28	1.86
4	1.36	1.55	1.33	1.69	1.47	1.70	1.89
5	4.64	3.90	4.66	4.13	2.83	3.64	3.21
6	2.85	1.96	2.34	1.48	1.28	1.36	0*
7	2.42	1.85	2.13	1.72	1.47	2.10	1.92
8	0.88	0.99	0.90	0.57	0.95	1.37	0.88
9	2.29	3.42	1.70	2.17	0*	0*	0*
10	0*	0*	0*	1.33	1.26	1.29	1.66
Pooled	2.05	1.89	2.03	1.66	1.51	1.87	1.73
Averaged	2.17	2.31	2.10	1.84	1.58	1.86	1.87

ASC, atypical squamous cells; SIL, squamous intraepithelial lesion.
* No gynecologic cytology specimens were examined by the cytopathologist during this period.

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Table 2
Rates of Change and *P* Values for ASC/SIL Ratios

Cytopathologist	Rate of Change	*P*
1	0.04	.07
2	–0.07	.31
3	–0.04	.54
4	0.07	.04
5	–0.24	.05
6	–0.30	.02
7	–0.06	.35
8	0.03	.57
9	–0.21	.63
10	0.10	.29
Pooled	–0.05	.16
Averaged	–0.08	.07

Figure 3 shows combined data from the present study, which covered 7 six-month periods, with data from a previously published study of 6 six-month periods directly preceding the time of the present study, for a span of 6.5 years.

Discussion

Because ASC is essentially a diagnosis of uncertainty, it is reasonable, as a quality control measure, for a laboratory to monitor its ASC/SIL ratio and that of its individual CPs to see if it (or any individual CP) may be using the ASC interpretation too frequently. To this end, useful benchmarks exist. These include a proposed upper limit (3:1)[5] and nationwide percentile rankings for ASC/SIL ratios based on large surveys of laboratories compiled by the College of American Pathologists.[6]

In a previous article, the experience in our laboratory monitoring the ASC/SIL ratio for 3 years was reported.[7] As in the present study, CPs in the prior study were notified periodically, in a confidential communication, of their individual ASC/SIL ratio and that of the laboratory as a whole. During that 3-year period, there was a statistically significant decrease in the ASC/SIL ratio for the entire laboratory and for some CPs. It was tempting to conclude that the decrease we observed resulted from periodic feedback (with focused counseling). That study period, however, coincided with the conversion from conventional smears to liquid-based preparation of gynecologic cytology specimens in our laboratory. It was unclear how much of the decrease in the ASC/SIL ratio was due to feedback and how much to an improvement in the quality of the preparation itself. The importance of the present study lies in the absence of any confounding factors. During the present follow-up period, there were no significant changes in the slide preparation method, terminology for reporting results, cytotechnology staff, cytopathology staff, or provider mix.

The laboratory and all CPs, with 1 exception, began this study period with an ASC/SIL ratio below 3:1. During the subsequent 3.5-year period and in the absence of confounding factors, we

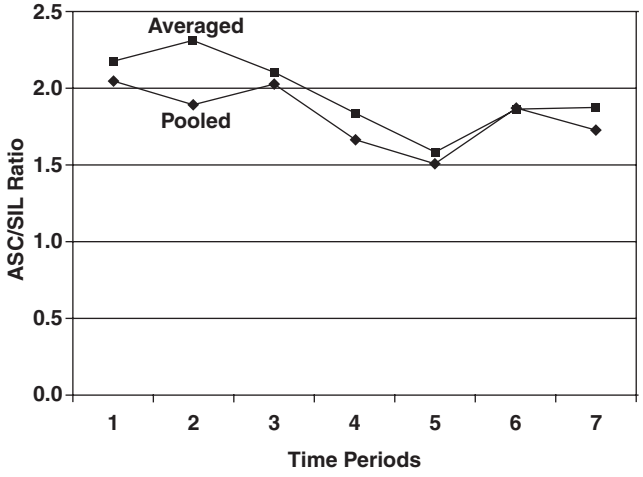

Figure 1 The atypical squamous cells (ASC)/squamous intraepithelial lesion (SIL) ratio for the entire laboratory for 7 consecutive periods.

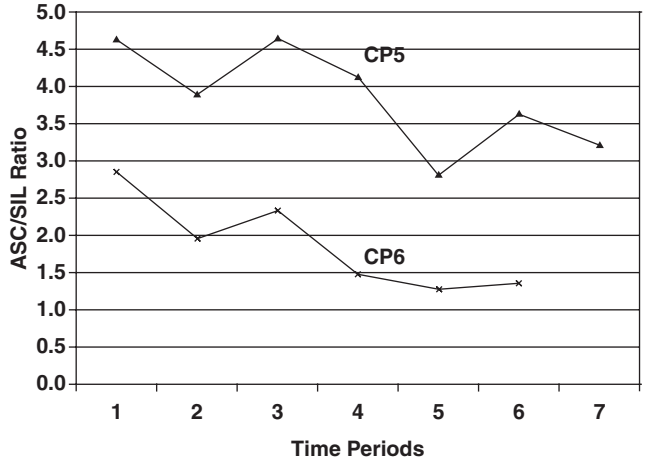

Figure 2 Data for 2 cytopathologists (CPs; CP5 and CP6) whose atypical squamous cells (ASC)/squamous intraepithelial lesion (SIL) ratios decreased significantly over time.

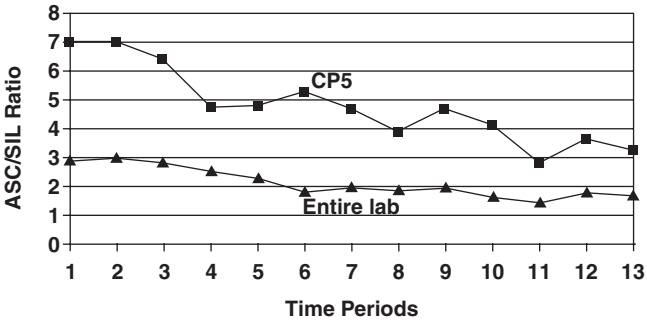

Figure 3 The atypical squamous cells (ASC)/squamous intraepithelial lesion (SIL) ratio for the entire laboratory and 1 outlier during a 6.5-year period (combined data from the present study and the study by Juskevicius et al[7]). CP5, cytopathologist 5.

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found that the ASC/SIL ratio of the laboratory and most CPs trended downward. The decrease was statistically significant for 2 CPs, including the one whose ratio was the highest. However, there was variability: the ASC/SIL ratios of 4 CPs increased rather than decreased, and the increase was significant for 1 CP.

What can we conclude from these results? Does periodic feedback influence the frequency with which CPs use the ASC interpretation? We believe that, for some CPs, the answer is yes. CP5, an outlier, has likely made significant modifications in his or her approach to diagnosis as a result of feedback, bringing the ASC/SIL ratio down from 7.0 to 3.2 (Figure 3). In this case, the decrease took 5 years to occur, but changes in diagnostic threshold may not be easy for all CPs to effect quickly, particularly significant changes like those of CP5. It might be that monitoring the ASC/SIL ratio will prove most useful for identifying outliers and enabling them to take steps to rein in overuse of the ASC interpretation.

To more conclusively prove that feedback can reduce the ASC/SIL ratio of CPs, it would be necessary to do a controlled study, particularly of outliers, some of whom are provided feedback and some of whom are not. Short of such a controlled study, we cannot exclude, for example, the possibility that ASC/SIL ratios trend downward of their own accord, for at least some limited period, regardless of feedback.

We cannot exclude the possibility that feedback can also cause *an increase* in the ASC/SIL ratio for some CPs. It is possible that, on finding that they had a relatively low ratio, some CPs in this study modified their thresholds to align their ratio closer to the (higher) laboratory average ratio. One effect that feedback might have, then, is a normalization of individual ratios to the laboratory average. In this regard, one can argue that an appropriate lower benchmark for the ASC/SIL ratio exists—that a very low ratio might, in fact, be too low.[6]

It is important to point out that the ASC/SIL ratio, although a measure of a CP's uncertainty, is not a measure of a CP's diagnostic accuracy. Accuracy cannot be determined from an ASC/SIL ratio, but only by comparison with an external standard, such as a biopsy or human papillomavirus (HPV) test result. For this reason, it is important for laboratory directors to use judgment in how they assess the overall performance of an outlier such as CP5. Overall performance evaluation ideally takes into consideration not just the ASC/SIL ratio but also other information such as biopsy and HPV correlation data. When the diagnostic accuracy of CP5 was, in fact, measured using receiver operating characteristic (ROC) curve analysis derived from histologic correlation, we found that the accuracy of CP5 was not significantly different from that of other CPs.[8] There may, indeed, be little correlation between a measure of uncertainty, like the ASC/SIL ratio, and a measure of accuracy, like histologic correlation data or the rate of a positive test result for high-risk HPV.[9] We recommend, therefore, that, whenever possible, CP performance evaluations include, in addition to ASC/SIL ratios, some measure(s) of accuracy.

We conclude that monitoring the ASC/SIL ratio of a laboratory and its individual CPs is a useful quality control measure. Confidential feedback likely leads to a diminution in the ASC/SIL ratio for some CPs, particularly those whose ratio exceeds the upper benchmark. Feedback may even result in an increase in the ratio for CPs whose ratio is below average. For the majority of CPs, whose ratio conforms to established benchmarks, the benefit of feedback may be its positive reinforcement and the stabilization of an already appropriate ratio.

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