Original Research Article

Implications of inter observer variability in cervical smear reporting

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ABSTRACT

Background: In spite of the Bethesda system 2001 (TBS 2001), formulating strict guidelines for reporting cervical smears, intra observer and inter observer variations are unavoidable and can be considered an inherent part of the reporting system. The implications of this variation are in the quality of performance of the reporting laboratory and in the patient management. Rescreening is a tool to reduce the variations and improve the quality of both the laboratory staff and laboratory as such. Rescreening by two or more experienced observers has helped in identifying new cases better. The present study aims to rescreen cervical smears by two independent observers, to compare the results of the two independent observers and to understand the implications of this variability on the quality of cervical smear reporting.
Methods: 1000 consecutive cervical smears were rescreened by two experienced cyto-pathologists independently. Their findings were charted out and analyzed statistically for kappa value.
Results: Initial reporting had identified 20 cases of neoplastic nature. First observer identified, in addition, 6 new cases and second observer identified 12 new cases. The inter observer variability of 6 cases showed a kappa value of 0.89.
Conclusions: Rescreening is a safe way of picking up missed cases. Rescreening by two or more observers is better in identifying new cases. This helps in improving the quality of reporting personnel and the laboratory as well as in improving patient care.

Keywords: Cervical smear, Inter observer variability, Kappa value, Rescreening

INTRODUCTION

Screening for cervical cancers has been the most successful and one of the best implemented programs of the previous century. In spite of a long history starting from Dr George Papanicolaou's observations and recommendations on cervical smears, reporting on cervical smears is often associated with disparities.[1] Many recommendations for proper reporting have been put forth. However, none were complete enough to be universally accepted. Finally, the recommendations of the Bethesda system 2001 (TBS 2001), of cervical smear reporting came closest to being complete in including the

"grey zones".[2] This system has been revised and the universally accepted format at present is TBS 2014 with a few additional points in the glandular cells category. Intra-observer variability as well as inter-observer variability is a well-known and accepted fact.[3-6] Implications of this variability are grave, since this is a screening programme for early detection of cervical neoplasms.

With this background, the present study was undertaken:

- To rescreen cervical smears by two independent observers

- To compare the results of the two independent observers and
- To understand the implications of this variability on the quality of cervical smear reporting.

METHODS

A total of 1000 consecutive Papanicolaou (PAP) stained cervical smears were included in this study. These were already screened by a cyto technician and reported by a pathologist using TBS 2001. The selection of cases was irrespective of their previous diagnosis.

All these smears were rescreened by two equally experienced observers, independently, at 10x objective, taking a maximum of 6 minutes per smear. The history provided to both observers was whether the patient was in reproductive age group or was post-menopausal. Hysterectomy status was also mentioned. The findings were tabulated, compared and analyzed for inter-observer agreement. Statistical method followed was calculation of k value by studying the inter-observer variability.

- Observed value = true positives+ true negatives / total no of cases*100
- Expected value= row total * column total/grand total of cases
- k value= (observed value - expected value)/ (100 - expected value).

RESULTS

In our institution, cervical smears are first screened by a cyto technician and then reported by a cyto pathologist.

Present study was undertaken to analyze the reporting quality of our lab, i.e. as a quality control measure. As a part of the study, 1000 consecutive cases were selected regardless of the previous diagnosis.

Table 1: The new cases identified by the 2 independent observers.

Initial	I observer	II observer
Obscuring factors	3 ASCUS	6 ASC H
Obscuring factors	2 ASCH	3 ASCH
Obscuring factors	1 HSIL	1 HSIL
ASCUS	ASCUS	ASCH
ASCH	ASCH	HSIL/SCC

The initial reporting of these 1000 cervical smears showed 20 cases of neoplastic nature. These included the atypical squamous cells including, atypical squamous cells of undetermined significance (ASCUS) and atypical squamous cells- high grade (ASCH) and the high-grade lesions, including high grade squamous intraepithelial lesion and squamous cell carcinoma (HSIL/SCC).

When all the 1000 cases (i.e. 100% rescreening) were reviewed by two experienced cyto-pathologists, it was found that one observer had identified 6 new cases and the other observer had identified 12 new cases (Table 1).

There was, thus, an inter-observer variability of 6 between the two observers (Table 2). This was statistically analyzed and the overall k value calculated as 0.89, indicating a high concordance rate. The result was compared to other similar studies (Table 3).

Table 2: Category of the lesions at initial reporting, rescreening by the first and the second observers, and the inter-observer variability.

Category	Initial	I Observer	II Observer	Inter-observer variability*
NILM	686	686	686	
Inflammatory/bloody smears	294	291	287	4
ASCUS	5	8	11	3
ASCH	6	8	10	2
HSIL/SCC	9	10	11	1
Total	1000	1000	1000	10

*Overall inter observer variability was 10. However, variability in reporting neoplastic lesions, including ASC group, was 6.

Table 3: Comparison of kappa statistics between various studies.

Lesions	La Ruche et al[9#]	Schiffman et al[5!]	Remya et al[3*]	Present study
ASCUS-ASCH	0.33	0.64(0.62-0.67)		0.67
HSIL/SCC	0.53	0.51(0.46-0.55)		0.67
Overall			0.61	0.89

*Only overall kappa value was reported by Remya et al. # La Ruche et al considered ASC lesions together and ! Schiffman et al also included LSIL in the low-grade lesions.

DISCUSSION

As, is a well-known fact, cervical smear reporting shows intra and inter observer variation.[3,4] TBS guidelines have helped in reducing the differences. The latest revision, TBS 2014, has also put forth many guidelines, especially, regarding reporting of glandular cells.[2] In spite of all this, variability in reporting is common and affects patient management. It is also an important quality determining factor for the reporting laboratory. [5-7]

Most studies that have been carried out, report maximum variations in the atypical squamous cell (ASC) category.[8-14] This has been attributed to many reasons amongst which, are the time allotted by screener for each smear, educational qualification of screeners, experience of screeners etc.[2,6,12] It has been observed by some authors that the experience of the observer and the grade of the lesions affects the reporting variability, i.e. more the experience of the observer the better is the pick-up rate. So also, higher the grade i.e. HSIL/ SCC show higher reporting reproducibility. Also, the rate of shedding of cells and preservation of their morphology render their interpretation subjective.[4,5]

Many studies have compared the reporting reproducibility on liquid based preparations against conventional smears. These have reported discrepancies in reporting ASC lesions on an equivocal basis irrespective of the methodology of smear preparation.[15-17]

PAPNET (automation in cytology) may have helped in speeding up the cervical smear reporting and increased the pick-up rates of atypical lesions, but, studies comparing PAPNET (automation) and conventional screening have reported similar variations in reporting of ASC lesions. It has been stated that PAPNET is no better than conventional rescreening and shows similar intra and inter observer variability.[18]

In the present study, 1000 consecutive conventional PAP smears, which were already reported, were rescreened by two observers, independently, using TBS 2001 guidelines. Each smear was studied for 6 minutes by each observer.[7] During re-screening, one observer could pick 6 new cases and the second observer identified 12 new cases. The observations of both the observers were charted as shown in Table 1. First observer identified 3 new cases against a background of obscuring factors, while second observer identified 10 new cases in the same inadequate smears. An initial diagnosis of ASCUS and ASC H was interpreted as ASC H and HSIL/SCC by the second observer. The discrepancy was seen to be more in reporting ASC lesions (Table 2). After the study both observers discussed the differences and it was found that a few of the cases identified by the second observer were, in fact, pertaining to the reparative category according to TBS 2001. These were omitted from the final report. Only those cases which were strictly following the TBS guidelines for reporting lesions of

neoplastic nature were signed out as review reports and these were informed to the treating Gynecologist for further management of the patients.

These observations were statistically analysed and an overall kappa value calculated. This was then compared with similar studies (Table 3). It was found that on rescreening for a longer duration (6 minutes), atypical cells, either single or in small clusters, could be identified in a severely inflammatory or a bloody background.

CONCLUSION

Hence, to conclude, inter and intra observer reproducibility in reporting cervical smears is not 100%, even when strict TBS guidelines are followed. Rescreening is an excellent quality control measure in any laboratory handling cervical smears. The accuracy can be enhanced by rescreening by two or more observers independently. Reproducibility increases with time allotted for rescreening, and experience of the observers. However, a discussion on the discrepancies between the observers is mandatory to resolve discordant report, and, the final revised report should be informed to the treating Gynecologist to manage the patients accordingly.

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