AN EVALUATION OF THE EFFICACY OF PREDICTIVE SLIDES IN MITIGATING CROSS-CONTAMINATION RISK IN CYTOPATHOLOGY LABORATORY STAINING METHODS

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Received on : 10-06-2023
Accepted on : 27-12-2023

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ABSTRACT

The utilization of Diff-Quik stain has emerged as a potent assessment tool for triaging potentially malignant specimens. This evaluation procedure not only streamlines the diagnostic process but has also proven to be an effective means of identifying cases that warrant further scrutiny. In particular, the sensitivity of cytodiagnosis in effusions is significantly enhanced through the meticulous preparation of Diff-Quik stained slides. To check efficacy of predictive slides in mitigating cross-contamination risk in cytopathology laboratory staining methods. To evaluate the cytological disparencies in cytology reporting. The Methodology involves the subjection of the collected effusion samples to the Diff-Quik staining process for prompt identification of any cellular abnormalities enabling the early detection of potential malignancies. Due to the high importance of cytodiagnostic procedures with high sensitivity for distinguishing between benign and malignant samples, the application of the Diff-Quik staining process deems to be a pertinent tool in detecting subtle cellular alterations indicative of malignancy. It is imperative to note that the evaluation process using Diff-Quik staining method primarily focuses on minimizing the false negatives, this is to reduce the risk of contamination of subsequent slides. Due to this reduction, the probability of cross-contamination as also been reduced enhancing the validity of the subsequent diagnostic procedures. The preparation of Diff-Quik stained slides not only improves the accuracy of diagnosis but also contributes to the expedition of reporting, which enhances efficient workflow dynamic. In doing so, health care professionals can receive their results in a timely manner enabling them to make prompt decisions. In conclusion, the Diff-Quik staining method has proven to be an effective triage method for the identification of potentially malignant specimens due to its elevated sensitivity for cytodiagnosis and its enhanced efficiency for timely patient care.

KEYWORDS: Diff-quick stain, Malignant specimen, Cytopathology, Laboratory staining methods.

INTRODUCTION

In adherence to the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), there has to be a separation amongst non-gynecologic specimens that exhibit malignancy or highly cellular density. This is to avert the potential risk of cross-contamination amongst the samples. This regulatory requirement was effectively operationalized within the laboratory by the establishment of a meticulous protocol that involves the preparation of a singular air-dried Diff-Quik stained slide for each individual specimen. Each slide was subsequently subjected to be reviewed by a dedicated cytotechnologist (1).

This initial review by the cytotechnologist serves as a crucial step in the triage process. If the sample is potentially malignant or presents with high cellular concentration, it is marked and sent for detailing and interpretation. The cytological findings are then recorded in a comprehensive log. This systemic documentation and preliminary assessment from the initial proactive identification sets the stage for subsequent more in-depth evaluations (2).

The marked cases that were flagged during the cytotechnologist review, that were documented were used to formulate a comprehensive log. The culmination of the log becomes a repository for critical information which aids in the traceability and auditability of each specimen's diagnostic journey. The documentation not only facilitates internal quality control but also provides a valuable resource for retrospect analyses and continued improvement initiatives (2).

A secondary examination is done by a specialized cytopathologist on the marked cases with their

corresponding interpretations. At this stage, a thorough diagnostic process is done by the cytopathologist to critically analyzes each case in its entirety utilizing the individual findings of each specimen. The final diagnosis, backed by the expertise of the cytopathologist, solidifies the outcome of the diagnostic journey for each specimen (2).

Our laboratory is dedicated and committed to the maintenance of continuous high-quality standards to quality assurance with the evolution of the industry's standards for best practices. Due to the dynamic nature of cytology, keeping abreast with contemporary methodologies is imperative. The methodologies implemented was heavily influenced by a survey done by The American Society of Cytopathology Clinical Practice Committee. This comprehensive survey was aimed at uncovering the prevailing practices among cytology practitioners to mitigate the risk of cross-contamination in cytological analyses (3).

In order to stay at the forefront of up-to-date practices, our lab actively rely on the findings by the American society of Cytopathology Clinical Practice Committee's survey. The insights that were derived from the survey informed our laboratory quality assurance initiatives. It also underscores our commitment to adaptability and continuous improvement (3).

The prevention of cross-contamination is paramount in the realm of cytology given its potential to compromise the integrity of diagnostic results. As defined by the CLIA 88, non-gynecologic specimen which exhibits malignancy or increased cellular density requires special attention to mitigate the risk of inadvertent specimen contamination. This meticulous approach aligns with our commitment in delivering reliable diagnosis by upholding regulatory standards (4).

Through a systematic approach involving initial cytotechnologist, meticulous marking of significant cases, comprehensive log documentation and the final evaluation by a specialized cytopathologist, ensures the integrity of each diagnostic journey (2).

METHODS

This investigation spanned a consecutive five-year period, from January 2010 to December 2014, encompassing all fluid cytology cases processed within our laboratory. The primary objective was to assess the procedural accuracy employed during this timeframe. Cytotechnologists (CTs) assigned diagnoses as either negative or positive, with cases lacking suspicious cells categorized as negative. Subsequently, negative cases underwent staining alongside other negatives, utilizing the same stain (5).

However, cases that were highly cellular or malignant were categorized as positive and subjected to separate staining protocols to mitigate the potential risk of cross-contamination. In the cytopathologist conclusive assessment, one thin Prep slide and two hematoxylin and eosin slides, derived from cell-block preparations were crafted. A comparative analysis was then conducted between the CT's initial diagnosis and the cytopathologist final evaluation, with keen focus on identifying disparities between the preliminary and conclusive diagnosis. This systematic approach allowed for a comprehensive evaluation of accuracy of the diagnostic process within the specified time frame (5).

True positive	69
False positive	76
False Negative	71
True Negative	1210
Total	1426
Sensitivity	49%
Specificity	94%
Positive predictive value	48%
Negative predictive value	94%
False positive rate	6%
False negative rate	6%
Accuracy	90%

Table 1: Diagnostic Performance Metrics for Effusion Cytology

2010 to 2014	Case	Reason for discrepancy
Positive to Negative	76	1. Hypercellular sample and reactive mesothelial cell (59) 2. Abundant lymphoid cells (11) 3. Malignant cells present only in DQ (4) 4. Abundant macrophages (2)
Negative to Positive	71	1. Sampling error: 31cases (malignant cells were not present in DQ slide) 2. Interpretation error: 40-19 cases contained enough malignant cells with minimal leomorphism-21 cases scant malignant cell

Table 2: Discrepancy Analysis for Effusion Cytology Cases Between 2010-2014

		In DQ slide could only be identified upon retrospective review
Negative to	69	
Negative	1210	
Total	1420	

Table 2: Discrepancy Analysis for Effusion Cytology Cases Between 2010-2014

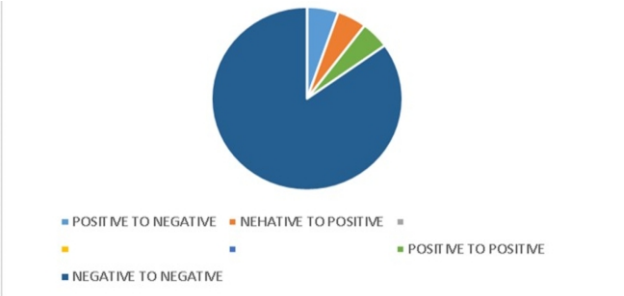

Fig. 1: Comparison of cases between 2010-2014 from Discrepancy Analysis

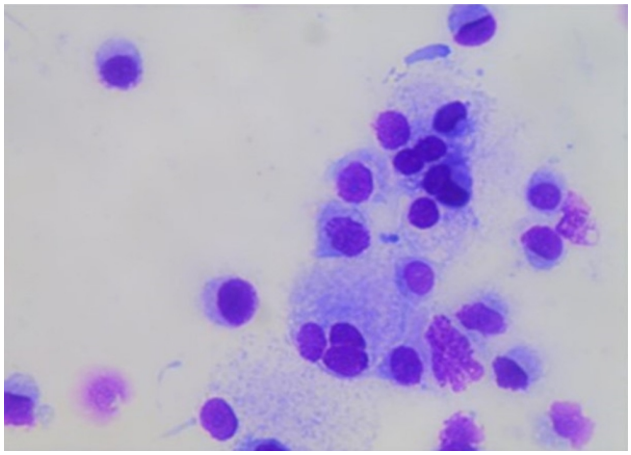

Fig. 2: Diff-Quik Stain Confirming no Malignant Cells Present

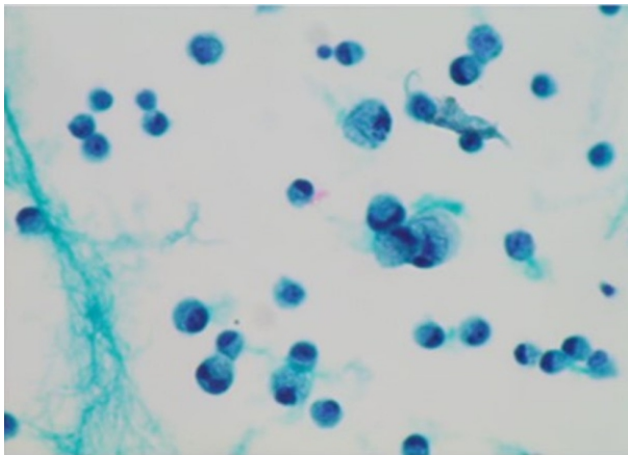

Fig. 3: Diff-Quik Stain Confirming Malignant Cells Present

DISCUSSION

In the comprehensive evaluation of 1426 cases spanning the period from 2010 to 2014, discrepancies emerged in 147 instances, constituting 10.3% of the total cases. Among these discrepancies, 76 cases (5.3%) initially evaluated as positive were later determined to be negative. Conversely, in 71 cases (5%), the initial evaluation was negative, but the final diagnosis was positive (5).

For cases transitioning from a positive to a negative diagnosis, several factors contributed to the observed discordance. Notably, hypercellular samples featuring reactive mesothelial cells accounted for 59 cases, while abundant lymphoid cells, malignant cells exclusively present in the Diff-Quik (DQ) stain, and an abundance of macrophages were contributing factors in 11, 4, and 2 cases, respectively.

Conversely, cases transitioning from a negative to a positive diagnosis highlighted specific challenges. Among the 71 cases, 31 were attributed to sampling errors, wherein malignant cells were not initially present in the DQ slide.5 Interpretation errors played a role in the remaining 40 cases, with 19 containing sufficient malignant cells with minimal pleomorphism and 21 featuring scant malignant cells, only identified upon retrospective review.

Positive-to-positive and negative-to-negative transitions were observed in 69 and 1210 cases, respectively, providing a foundation for assessing the robustness of the diagnostic process. It is noteworthy that false positive cases were deemed less significant, as these errors prompted enhanced caution in specimen handling without compromising diagnostic accuracy.

While a 10.3% discrepancy rate was identified between the initial Diff-Quik Stained predictive slide and final diagnoses, the analysis of transition cases shed light on the nuanced challenges encountered.5 Understanding the specific factors contributing to discrepancies serves as a valuable guide for refining diagnostic protocols and enhancing the overall accuracy of cytological evaluations within the specified timeframe.

CONCLUSION

In conclusion, our study affirms the effectiveness of the preliminary evaluation of effusions using the Diff-Quik stain as a robust method for triaging potentially malignant specimens. The low incidence of discrepancies in Negative/positive cases, coupled with the identification of specific contributing factors, reinforces the reliability of this approach. Furthermore, the preparation of Diff-Quik stained slides emerges as a valuable enhancement,

significantly elevating the sensitivity of cytodiagnosis in effusions. This provides a reliable and effective means of early identification and triage of potentially malignant specimens.5

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How to cite this article:

Siddiqui Z. An Evaluation Of The Efficacy Of Predictive Slides In Mitigating Cross-contamination Risk In Cytopathology Laboratory Staining Methods. Era J. Med. Res. 2023; 10(2): 22-25.