International Journal of Research in Medical Sciences
*Gulia M et al. Int J Res Med Sci. 2024 Jul;12(7):2318-2322*
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20241877

**Original Research Article**

# Reporting of serous effusions in accordance with Indian Academy of Cytology guidelines in a tertiary care centre: a 1-year study

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**Received:** 12 June 2024
**Revised:** 25 June 2024
**Accepted:** 26 June 2024

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## ABSTRACT

**Background:** The objective of the present study was to categorize serous effusions in accordance with the Indian Academy of Cytology (IAC) guidelines, evaluate the characteristics of various types of serous effusions using cytological findings, and determine the risk of malignancy within different diagnostic categories.
**Methods:** The study conducted at a tertiary care teaching hospital focused on patients with pleural, and peritoneal effusions/ascitic fluid, using retrospective data from patient records. Samples sent to the pathology department for cytopathological analysis over a one-year period after obtaining approval from institutional ethics committee (IEC). The statistical methods used included descriptive statistics and frequency analysis to examine the different cell types and characteristics present in the effusions. Risk of malignancy was calculated for each category. A Chi-square test was used to assess the relationship between different diagnostic categories, with a p value of <0.05 indicating statistical significance.
**Results:** The findings of the study indicate that out of a total of 161 cases, there were 127 (78.88%) male patients and 34 (21.12%) female patients, resulting in a male to female ratio of 18:5. Ascitic fluid was present in 103 cases (64%) and pleural fluid in 58 cases (36%). The majority of cases, 148 (91.92%), fell into the benign category, followed by 5 cases (3.10%) in category 3, 3 cases (1.86%) in category 5, 2 cases (1.24%) in category 4, and 3 cases (1.86%) in category 1. A statistically significant p value of 0.04 was found among the different diagnostic categories.
**Conclusions:** The IAC has specific guidelines and recommendations for reporting serous effusion cytology to ensure accurate and consistent interpretation of results. In conclusion, reporting serous effusion cytology according to IAC guidelines is essential for accurate diagnosis, prognostic information, quality assurance, communication with the healthcare team, and promoting research and education in the field. Adhering to these guidelines ensures standardized reporting practices and improves patient care outcomes.

**Keywords:** IAC, Risk of malignancy, Serous effusion

## INTRODUCTION

The classification systems in diagnostic cytopathology serve a crucial purpose in providing a standardized language for pathologists and clinicians to communicate effectively about cytological findings. These systems help ensure consistency in diagnoses and facilitate better patient care by allowing for accurate interpretation and comparison of results across different laboratories and medical facilities. The first significant success story is the Bethesda system for reporting of cervical cytology, which highlights the necessity and practical value of such systems once more.[1] Although serous fluid is one of the most common specimens processed by cytopathology laboratories, a uniform reporting terminology and system was lacking until recently.

In clinical practice, particularly oncology, effusion always suggests an underlying pathology and is a crucial diagnostic sample.[2] In 2020, the Indian Academy of Cytologists (IAC) established guidelines and categories for reporting serous effusion cytology. The IAC guidelines are categorically divided into three main groups – essential, optimal and optional.[3] Following the guidelines of the IAC helps in standardising the approach to classify serous effusions which helps in improving the consistency and reliability of results across the different laboratories and healthcare providers. Further it reduces the risk of errors and misdiagnosis and helps in predicting the course of the disease.

The study of effusions in cytology goes beyond just morphology. Following the microscopic examination, additional procedures such as special staining, cell block preparation, immunohistochemistry, and molecular analysis including PCR, Sanger sequencing, and next generation sequencing can be performed. Cytology has been reported to have high sensitivity for the diagnosis of malignancy in serous effusions. Nevertheless, a diagnostically gray area, including atypia and suspicious for malignancy cases, exists worldwide, similarly to other areas of cytology with clarity in the definition of inadequate and benign samples.[4] The classification system defines the diagnostic criteria, achieves better communication with clinicians and between pathologists in a worldwide spectrum and, finally, setting clinical management guidelines based on risk of malignancy assessment for each diagnostic category.[5,6]

The objective of the present study was to categorize serous effusions in accordance with the IAC guidelines, evaluate the characteristics of various types of serous effusions using cytological findings, and determine the risk of malignancy within different diagnostic categories.

## METHODS

The study conducted at Adesh Medical College and Hospital focussed on patients with pleural, and peritoneal effusions/ascitic fluid, using data from patient records. Samples sent to the pathology department for cytopathological and histopathology analysis over a one-year period from January 2023 to December 2023 were reviewed after obtaining approval from the institutional review committee (IRC) and institutional ethics committee (IEC). Patient's consent was obtained before the study.

### *Type of the study design*

It was a cross sectional study.

### *Inclusion criteria*

Patients presenting to the institute with pleural and peritoneal effusions for which the fluid was tapped under ultrasound guidance in the department of radio-diagnosis and sent to the pathology department for cytopathological study were included.

### *Exclusion criteria*

Patients with fluid samples tapped at another institute were excluded.

The specimen's overall appearance was observed and processed through centrifugation, resulting in the preparation of 3 slides that were stained with giemsa, pap stain, and haematoxylin and eosin. Special stains (AFS and PAS) were also applied as needed. Cases were then assigned to one of the five diagnostic categories of IAC.[3]

The statistical methods used included descriptive statistics and frequency analysis to examine the different cell types and characteristics present in the effusions. Risk of malignancy was calculated for each category. A Chi-square test was used to assess the relationship between different diagnostic categories, with a p value of <0.05 indicating statistical significance.

## RESULTS

The study shows that out of total of 161 cases, 127 (78.88%) were males and 34 (21.12%) were females with M:F ratio of 18:5.

Figure 1 shows that most of the cases 37 (23%) were in the age group of 41-50 years, followed by 36 (22.36%) cases in 51-60 years, 34 (21.11%) cases in 61-70 years, 22 (13.66%) cases in 31-40 years and 15 (9.31%) cases in 71-80 years, 9 (5.6%) cases in 21-30 years, 5 (3.1%) cases in 11-20 years, followed by 2 (1.24%) cases in 81-90 years and only 1 (0.62%) case was seen in age group 1-10 years.

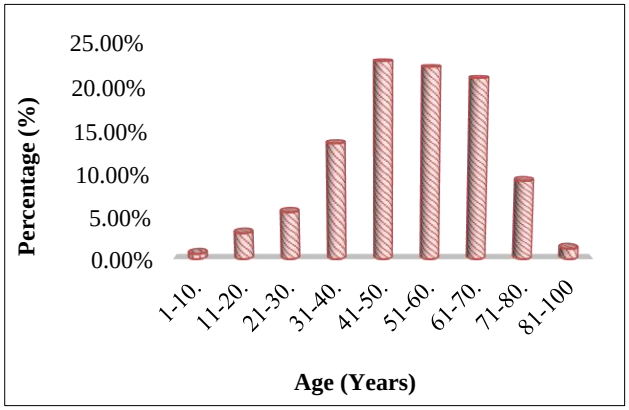


**Figure 1: Age wise distribution of cases.**

Out of 161 cases, ascitic fluid consisted of 103 specimen (64%) and pleural fluid consisted of 58 specimen (36%) (Figure 2).

Out of 161 specimens, 94 (58.4%) samples were clear and 67 (41.6%) were turbid. 37 specimens (23%) showed

presence of coagulum and in 124 specimens (77%) coagulum was absent. Clot was present in 25 specimens (15.53%) and absent in 136 specimens (84.47%). Out of 161 specimens, maximum were pale yellow in colour 122 (75.77%), reddish coloured 27 (16.77%), deep yellow 5 (3.12%), transparent 3 (1.86%) and least 1 (0.62%) each of brown, dark yellow, green and white coloured.

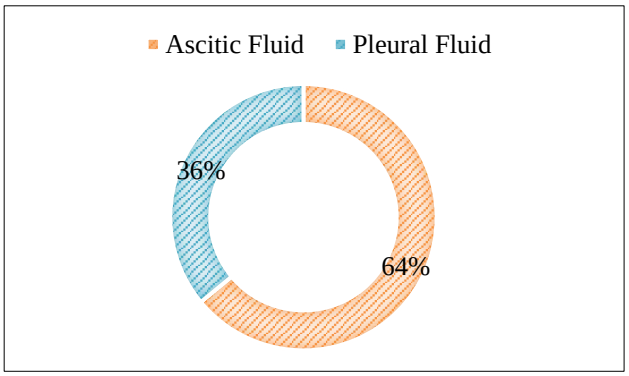


**Figure 2: Type of specimen.**

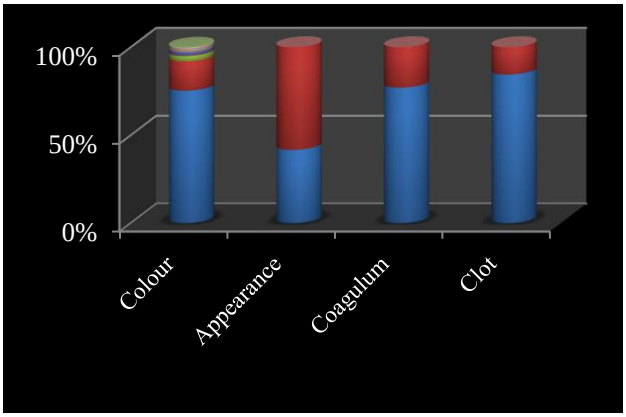


**Figure 3: Appearance, coagulum±, clot± and colour of specimen.**

Figure 4 shows that out of 161 cases, benign category comprised majority of cases 148 (91.92%), followed by category 3 with 5 cases (03.10%), category 5 having 3 (1.86%) cases, category 4 with 2 cases (1.24%) and 3 (1.86%) cases in category 1.

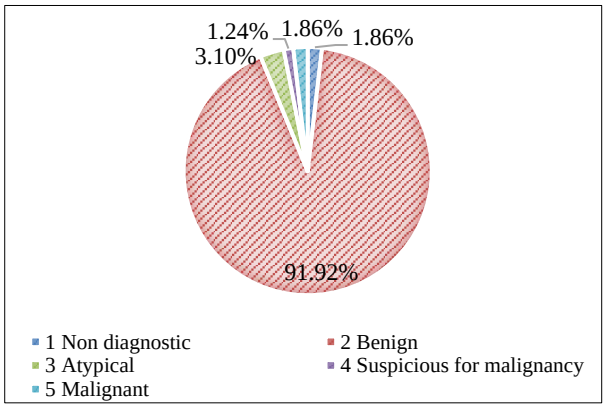


**Figure 4: Categorisation of cases according to IAC categories.**

Table 1 displays the breakdown of serous effusion, highlighting lymphoid cells as the most prevalent cell type, followed by reactive mesothelial cells, neutrophils, and eosinophils.

**Table 1: The differential cell count in serous effusion.**

| Predominant cell type | Number (%) |
|---|---|
| **Lymphocytes** | 121 (75.15) |
| **Neutrophils** | 34 (21.13) |
| **Mesothelial cells** | 3 (1.86) |
| **Eosinophils** | 1 (0.62) |
| **Atypical cells** | 10 (0.62) |
| **Degenerated cells** | 1 (0.62) |
| **Total** | 161 (100) |

**Table 2: Estimated risk of malignancy in different IAC categories.**

| Diagnostic category | No. of cases | Follow up | Malignant | Benign | ROM (%) |
|---|---|---|---|---|---|
| **1** | 3 | 3 | 1 | 2 | 33.3 |
| **2** | 148 | 14 | 1 | 13 | 7.14 |
| **3** | 5 | 4 | 2 | 1 | 50 |
| **4** | 2 | 2 | 2 | - | 100 |
| **5** | 3 | 3 | 3 | - | 100 |

P value of 0.04 was obtained between the different diagnostic categories which is considered as statistically significant.

## DISCUSSION

The current research aimed to classify serous effusion (both pleural and ascitic fluid) into 5 specific diagnostic categories as outlined by the IAC.

In the research by Kundu et al, most of the effusions observed were pleural, followed by peritoneal and pericardial effusions. This is consistent with the findings of the study by Deep. In contrast, our study found that the majority of samples consisted of ascitic fluid, followed by pleural fluid.[8,9]

In the present study, out of 161 cases, benign category comprised majority of cases 148 (91.92%), followed by category 3 with 5 cases (03.10%), category 5 having 3

(1.86%) cases, category 4 with 2 cases (1.24%) and 3 (1.86%) cases in category 1. The estimated risk of malignancy calculated for each category from 1-5 was 33.3%, 7.14%, 50%, 100% and 100% respectively. Category 2, which consisted of the majority of cases in our study, is consistent with findings from other studies.[7-9]

The study conducted by Jha et al showed that 4.26% of cases fell under category 1, 83.77% were in category 2, 5.2% in category 3, 3.25% in category 4, and 8.22% in category 5.[7] ROM for categories I-V was 21.42%, 14.9%, 33.3, 90% and 96.4% respectively.[7]

A study by Kundu et al, examined total of 1340 samples with 2.6%, 71.2% ,1.3%, 4.4% and 20.5% samples with rate of malignancy (ROM) as 20%, 16.7%, 50%, 94.4% and 100% for category 1-5 respectively.[9]

Based on the study conducted by Deep et al, the findings show that 84.2% of cases were classified as category 2 (benign), followed by category 5 (5.84%), category 4 (5.84%), category 3 (2.63%), and category 1 (1.46%). The ROM calculated for category 1 in the study was 0%, with all follow-up cases ultimately determined to be benign lesions.[8] ROM was 4.4%, 50%, 50% and 100% respectively for categories 2-5.[8]

The ROM are the lowest for category 1 and the highest for category 5, which is consistently seen across all studies.[7-9]

In the present study, non-diagnostic category smears were pauci-cellular or haemorrhagic with proteinaceous background. These cases did not show any definitive cytological features to suggest a specific diagnosis. The study conducted by Jha et al and Kundu et al observed similar results.[7,9] Additional clinical correlations, repeated cytology, and further investigations were needed to confirm the diagnosis in these instances.[7,9]

Category 2, which accounted for majority of cases primarily consisted of cyto-preparatory smears showing a predominant inflammatory infiltrate. This infiltrate mainly consisted of lymphoid cells, with a few cases exhibiting a mixed population of lymphoid cells and neutrophils, and rarely eosinophils. Reactive mesothelial cells were also present as part of the accompanying cell population. Additionally, a small subset of cases contained benign epithelial cells, histiocytes, and macrophages. The majority of cases in this category were determined to be benign, likely attributed to inflammatory processes such as infection or irritation. In cases where the presence of inflammatory cells is uncertain or worrisome further investigations may be necessary to arrive at the final diagnosis. The underlying causes of benign serous effusions include organ failure, autoimmune diseases, infectious diseases, cirrhosis, low levels of albumin, and peritoneal dialysis.[10] Special stains should be used to rule out infectious causes such as tuberculosis or fungal infection in pleural effusions that are rich in lymphocytes and neutrophils, with or without necrosis.[7] Eosinophilic pleural effusion can be attributed to infections, drug allergies, malignancies, and benign asbestos-related conditions.[11]

Category 3 indicates cases where the smears have low cellularity with occasional cells showing atypical-pleomorphic features, such as abnormal nuclei with a high nuclear to cytoplasmic ratio. These findings may suggest the presence of abnormal cells that do not fit into typical categories, requiring further investigation and monitoring. The presence of atypical cells, NOS (category 3) and atypical cells suspicious for malignancy (category 4), have the possibility to be reclassified into definitive benign or malignant categories with further sampling or additional testing hence it is highly recommended to conduct a repeat cytology for cases falling into categories 1, 3, and 4.[9]

In the present study, three cases in category 5 were analyzed. The primary site examined was the ovary, with a diagnosis of serous carcinoma and secondary deposits in the peritoneal cavity. Another case involved breast carcinoma metastasizing to the lungs, and the third case involved pleural effusion originating from primary lung cancer. Reactive mesothelial cell proliferation was identified as the cause of the false positive cases in category 5 by Jha et al.[7] Therefore, conducting a cell block with immunohistochemical analysis of epithelial (EMA, CD15, CK7, and CK20) and mesothelial cell markers (calretinin, D2-40, WT1, desmin) could be beneficial in making a diagnosis.[8] In the study by Deep et al, the most common cause of malignancies in pleural effusion were from lung and breast as observed in other studies.[8-10]

A comparable reporting system, known as the International TIS, is utilized for reporting serous fluid cytopathology, categorizing findings into five groups: non-diagnostic (ND), negative for malignancy (NFM), atypia of unknown significance (AUS), suspicious for malignancy (SFM), and malignant (MAL).[12]

The diagnostic categories for serous effusion cytology in the Indian system (IAC) and international system (The Bethesda System) are similar in many ways, but there are also some key differences. Overall, while there are some differences in the diagnostic categories of serous effusion cytology between the Indian and international systems, the fundamental principles of categorizing and communicating cytology findings remain similar. It is important for healthcare professionals to be aware of and understand the specific guidelines and terminology used in the system they are working with to ensure accurate interpretation and communication of cytology results.

***Limitations***

The limited sample size may not accurately represent the entire population and may not be applicable to other setting. The data captured at a single point in time, may not be able to show changes over time which could limit the

ability to assess trends or patterns in the reporting of serous effusions.

## CONCLUSION

In conclusion, our study found that the reporting of serous effusions in our tertiary care centre was largely in accordance with the guidelines set by the IAC. However, there were some areas for improvement identified, including the need for more consistent documentation of clinical history and increased utilization of immunohistochemistry for accurate diagnosis. Further efforts towards standardization and quality control in reporting practices are recommended to improve patient care and outcomes.

*Funding: No funding sources*
*Conflict of interest: None declared*
*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Gulia M, Gulia SP, Mittal SS, Rana S, Tathagat, Aaryan. Reporting of serous effusions in accordance with Indian Academy of Cytology guidelines in a tertiary care centre: a 1-year study. Int J Res Med Sci 2024;12:2318-22.