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Conventional cytology reporting versus revised Milan system reporting (2023) in salivary gland lesions: A cross-sectional study

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Abstract

Background: Fine needle aspiration cytology (FNAC) is a widely accepted first-line diagnostic tool for evaluating salivary gland lesions because it is minimally invasive, rapid, cost-effective, and reliable. However, conventional cytology reporting lacks standardized terminology, resulting in variability in interpretation and communication. The revised Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) 2023 provides uniform diagnostic categories with associated risk of malignancy and management recommendations. This study compared conventional cytology reporting with the revised Milan System (2023) in salivary gland lesions.

Aim: To compare conventional cytology reporting with the revised Milan System reporting (2023) in salivary gland lesions.

Materials and Methods: This cross-sectional observational study was conducted in the Department of Pathology, Rohilkhand Medical College and Hospital, Bareilly. A total of 58 salivary gland FNAC cases were included after applying the inclusion and exclusion criteria. All cases were reported using the conventional cytology reporting system and simultaneously categorized according to the revised Milan System (2023). Histopathological correlation was performed wherever surgical specimens were available. Diagnostic categorization, risk stratification, and cytohistological concordance were evaluated. Statistical analysis was performed using SPSS version 26.0, with a p-value <0.05 considered statistically significant.

Results: Most patients belonged to the 21–40 years age group. Benign lesions predominated on conventional reporting. According to the revised Milan System, most cases were categorized as benign neoplasm and non-neoplastic lesions. Histopathological correlation, available in 15 cases, showed an overall cytohistological concordance of 80%, with the highest concordance observed in benign neoplasm and malignant categories. Diagnostic variability was mainly seen in atypia of undetermined significance and salivary gland neoplasm of uncertain malignant potential categories.

Conclusion: The revised Milan System (2023) provides a standardized and clinically relevant framework for reporting salivary gland cytology, improving diagnostic reproducibility, risk stratification, and communication between cytopathologists and clinicians.

Keywords: Salivary gland; Fine needle aspiration cytology; Milan System; Cytology; Histopathology

1. Introduction

Fine needle aspiration cytology (FNAC) is widely accepted as an important diagnostic tool in the evaluation of salivary gland lesions because of its simplicity, rapidity, cost-effectiveness, and minimally invasive nature. Salivary gland lesions

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comprise a heterogeneous group of inflammatory, reactive, benign, and malignant conditions with overlapping clinical and cytomorphological features, making accurate diagnosis challenging in routine pathology practice.[1,2] FNAC plays a critical role in preoperative assessment and assists clinicians in planning appropriate management strategies while minimizing unnecessary surgical interventions.[3,4] Despite its utility, conventional cytology reporting of salivary gland lesions has historically suffered from lack of uniformity and standardization, leading to significant variability in diagnostic interpretation and communication among cytopathologists and treating clinicians.[5,6] Descriptive reporting terminology such as "benign," "malignant," or "suspicious" often lacked defined diagnostic criteria and failed to provide clear risk stratification or management recommendations. This variability contributed to inconsistent diagnostic reproducibility and uncertainty in clinical decision-making.[7,8]

The diagnostic accuracy of FNAC in salivary gland lesions varies depending upon lesion type, adequacy of aspirated material, cystic degeneration, sampling technique, and expertise of the cytopathologist.[9] Previous studies have reported sensitivity ranging from 84% to 97% and specificity ranging from 84% to 100% for salivary gland FNAC.[10,11] Inflammatory lesions and reactive conditions may occasionally mimic neoplastic processes, while certain benign neoplasms may demonstrate atypical features resulting in diagnostic ambiguity. Such challenges emphasized the need for a structured reporting system capable of categorizing lesions according to defined diagnostic criteria and associated risk of malignancy.

In response to these challenges, organ-specific cytology reporting systems were gradually developed to improve standardization and enhance communication between pathologists and clinicians. These included the Bethesda System, Japanese Guidelines, Temple Classification, and British reporting systems. The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was introduced as an evidence-based international consensus reporting framework that linked diagnostic categories with estimated risk of malignancy and recommended clinical management pathways.[12] The Milan system categorized salivary gland cytology into six major diagnostic groups including Non-Diagnostic, Non-Neoplastic, Atypia of Undetermined Significance (AUS), Neoplasm including Benign Neoplasm and Salivary Gland Neoplasm of Uncertain Malignant Potential (SUMP), Suspicious for Malignancy, and Malignant categories.[13,14]

The revised Milan System reporting 2023 further refined the original classification by incorporating updated diagnostic criteria, improved risk stratification, and expanded guidance for ancillary investigations including immunocytochemistry and molecular testing. The revised system aimed to reduce interobserver variability and improve cytohistological correlation. [15,16] the standardized framework also improved communication between clinicians and pathologists by providing clinically meaningful diagnostic categories linked with evidence-based management recommendations.

Histopathological correlation remains essential for evaluating the diagnostic performance of cytology reporting systems. Correlation of cytological findings with subsequent histopathology provides important information regarding diagnostic accuracy, sensitivity, specificity, and predictive values. [17,18]

The present study was therefore undertaken to compare conventional cytology reporting with revised Milan System reporting 2023 in salivary gland lesions and to evaluate the utility of the Milan system in improving diagnostic categorization, risk stratification, and cytohistological correlation in routine pathology practice.

Aim

To compare the conventional cytology reporting with revised Milan system reporting (2023) in salivary glands lesions.

Objectives

- To evaluate salivary gland lesions as per conventional reporting.
- To categorize the lesions based on The Milan system reporting 2023.
- To compare diagnostic categories in both the systems.
- To correlate the result of cytology findings with histopathology wherever possible.

2. Material and methods

2.1. Study Design, Place and Duration

A Cross-sectional study was carried out on 58 cases at Department of Pathology, Rohilkhand Medical College and Hospital, Bareilly, UP for One year (April 2024 - March 2025).

2.1.1. Inclusion Criteria

Patients of all age groups with salivary gland lesions referred for cytology in the Department of Pathology.

2.1.2. Exclusion Criteria

- Patients with bleeding disorders.
- Any associated lesion of the overlying skin.
- Patients undergoing of radiotherapy and chemotherapy.
- Patients reported as lesions other than salivary gland.

2.2. Ethical Approval

The study was conducted after obtaining approval from the Institutional Ethics Committee of Rohilkhand Medical College and Hospital, Bareilly, UP. Informed consent was obtained from all patients before FNA procedure.

2.3. Procedure

Detailed clinical history, including age, sex, site of the lesion, duration of swelling, pain, associated symptoms, and radiological findings (wherever available), was recorded. FNAC was performed under aseptic precautions using a 22–24-gauge needle attached to a 10 mL disposable syringe. Aspirated material was smeared onto clean glass slides, and air-dried smears were stained with Leishman-Giemsa (LG) stain. Biopsy or excision specimens, wherever available, were fixed in 10% neutral buffered formalin, processed routinely, and stained with Hematoxylin and Eosin (H and E).

All cases were initially reported using the conventional descriptive cytology reporting system and simultaneously categorized according to the 2023 Revised Milan System for Reporting Salivary Gland Cytopathology (MSRSGC). Histopathological correlation was performed wherever tissue specimens were available, and cytohistological concordance along with diagnostic parameters was evaluated wherever feasible.

2.4. Statistical Analysis

The data collected were analysed using SPSS software (version 23.0). Appropriate statistical tests were applied to assess the significance of the associations between variables. A p-value of less than 0.05 was considered statistically significant.

3. Results

A total of 58 salivary gland FNAC cases were evaluated in the present study using both conventional cytology reporting and revised Milan System reporting 2023. Comparative assessment demonstrated that the revised Milan system provided improved diagnostic categorization, better risk stratification, and enhanced cytohistological correlation compared with conventional descriptive reporting methods.

Table 1 Age Distribution of Study Participants (n = 58)

Age Group (Years)	Number of Cases	Percentage (%)
0–20	10	17.24
21–40	22	38.93
41–60	16	27.59
61–80	10	16.24
Total	58	100.00

Table 1 depicts the majority of study participants belonged to the 21–40 years age group, accounting for 38.93% of cases, followed by the 41–60 years age group comprising 27.59% of cases. Participants aged 0–20 years and 61–80 years each represented 16.24% of the study population.

Table 2 Distribution of Salivary Gland Lesions According to Conventional Cytology Reporting (n = 58)

Conventional Cytology Diagnosis	Number of Cases	Percentage (%)
No Opinion Possible	1	1.72
Benign Lesions	31	53.45
Inflammatory / Reactive Lesions	13	22.44
Benign / Indeterminate Salivary Neoplasms	5	8.61
Malignant Lesions	8	13.78
Total	58	100.00

Table 2 depicts that Benign lesions constituted the predominant category on conventional cytology reporting, accounting for 53.45% of cases. Inflammatory and reactive lesions represented 22.44% of cases, while malignant lesions comprised 13.78%. Benign or indeterminate salivary gland neoplasms accounted for 8.61% of cases, whereas only 1.72% of cases were categorized as non-diagnostic with no definitive cytological opinion possible.

Table 3 Distribution of Cases According to the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) (n = 58)

Milan Category	Number of Cases	Percentage (%)
Category I – Non-Diagnostic	1	1.72
Category II – non-neoplastic	21	36.21
Category III – AUS	3	5.17
Category IV-A – Benign Neoplasm	21	36.21
Category IV-B – SUMP	7	12.07
Category V – Suspicious for Malignancy	2	3.45
Category VI – Malignant	3	5.17
Total	58	100.00

Table 3 depicts he majority of salivary gland lesions were classified under Category II (Non-Neoplastic) and Category IV-A (Benign Neoplasm), each accounting for 36.21% of cases. Category IV-B (SUMP) constituted 12.07% of cases, while Categories III (AUS) and VI (Malignant) each represented 5.17%. Categories I (Non-Diagnostic) and V (Suspicious for Malignancy) were the least frequent, accounting for 1.72% and 3.45% of cases, respectively.

Table 4 Cytohistological Correlation According to the Milan System (n = 15)

Milan Category	Concordant Cases	Discordant Cases	Total Cases	Concordance Rate (%)
II – non-neoplastic	3	0	3	100.0
III – AUS	0	1	1	0.0
IV-A – Benign Neoplasm	6	0	6	100.0
IV-B – SUMP	2	2	4	50.0
VI – Malignant	1	0	1	100.0
Total	12	3	15	80.0

Table 4 depicts that among the 15 cases with available histopathological correlation, 12 cases (80.0%) demonstrated concordance between Milan System categorization and final histopathological diagnosis, while 3 cases (20.0%) were discordant. Complete concordance was observed in Categories II (Non-Neoplastic), IV-A (Benign Neoplasm), and VI

(Malignant). Diagnostic variability was primarily observed in Category IV-B (SUMP) and Category III (AUS), reflecting the inherent cytomorphological uncertainty associated with these categories. Overall, the Milan System demonstrated a high degree of cytohistological agreement and provided reliable risk-based stratification of salivary gland lesions.

3.1. Concordant cases

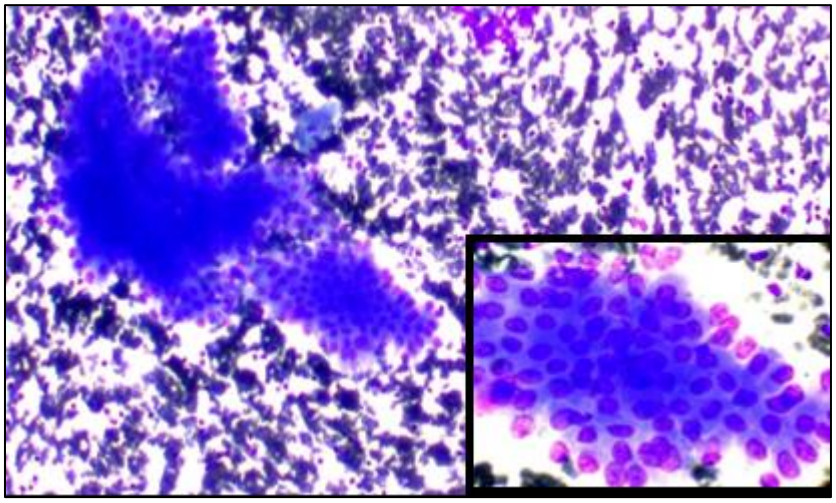

Figure 1 Leishman -Giemsa-stained smears show oncocytic epithelial cell clusters with granular cytoplasm in a background of abundant lymphoid cells and proteinaceous debris, suggestive of Warthin's Tumor-Category IV A (Low power 100x). Inset shows high power view of oncocytic cells forming papillae (400x)

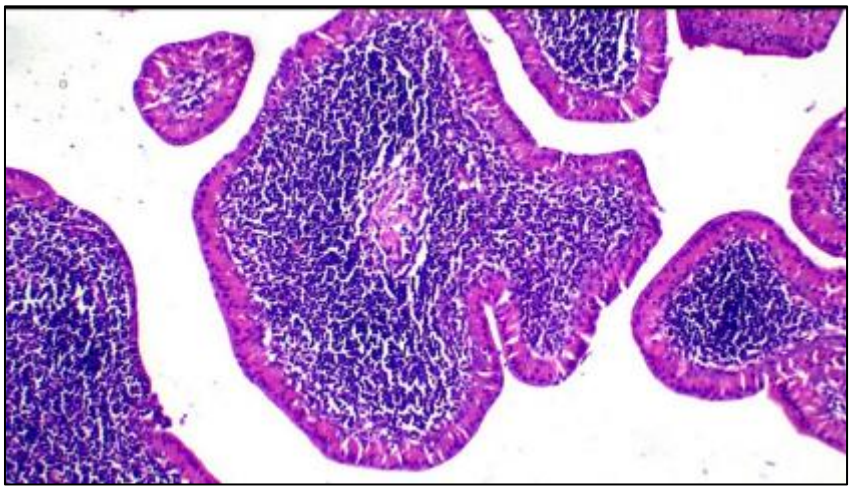

Figure 2 Haematoxylin and Eosin-stained section shows papillary structures lined by bilayered oncocytic epithelium with dense lymphoid stroma forming germinal centres, consistent with Warthin's tumor – Category IV A(Low power 100x)

3.2. Discordant cases

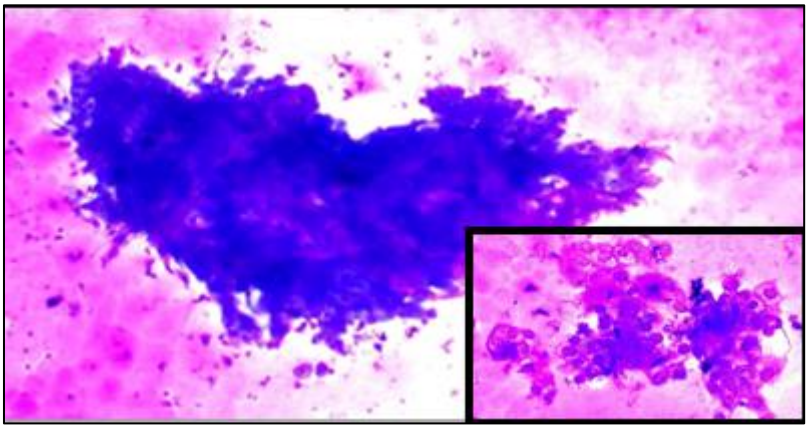

Figure 3 Leishman -Giemsa-stained smears show epithelial/myoepithelial cells with mild–moderate atypia and focal architectural complexity in a mucoid background, insufficient for definitive benign or malignant categorization, suggestive of Category VI-B (SUMP). (Low Power 100x). Inset, high power view showing papillae and sheets of suspicious cells showing moderate nuclear membrane(400x)

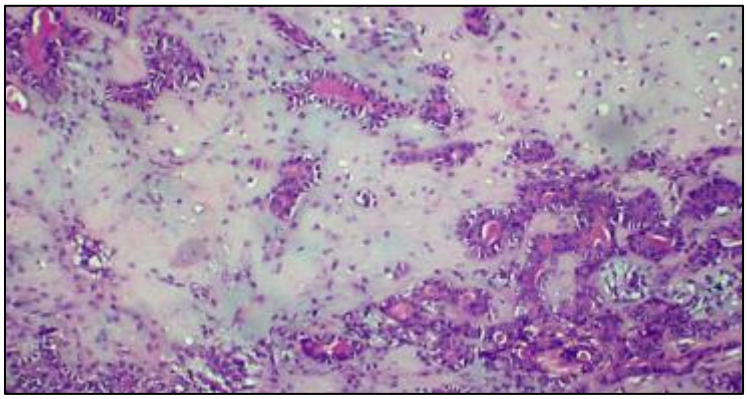

Figure 4 Haematoxylin and Eosin-stained section examined shows tubules and cords of epithelial and myoepithelial cells with chondromyxoid and myxoid stromal background, Consistent with Pleomorphic Adenoma. (Low power 100x)

3.3. Discordance

Cytological diagnosis was SUMP and histological diagnosis was Pleomorphic adenoma. Thus, a discordance was found due to degenerative changes in cells, mimicking malignancy.

4. Discussion

Fine-needle aspiration cytology (FNAC) is a rapid, minimally invasive, and cost-effective diagnostic modality for evaluating salivary gland lesions. However, the wide morphological diversity of these lesions, overlapping cytological features, cystic degeneration, and metaplastic changes make accurate diagnosis challenging. [19,20] The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was introduced to provide standardized reporting, improve diagnostic consistency, and facilitate risk-based clinical management. [21,22]

In the present study, the majority of patients belonged to the 21–40 years age group accounting for 38.93%, followed by the 41–60 years age group which constituted 27.59%, indicating that salivary gland lesions are most commonly encountered in middle-aged adults. Similar age distributions have been reported by Boccato P et al.[10], Jain et al.[23], and Paris et al.[24], who observed that salivary gland lesions occur predominantly during the third to fifth decades of life, with benign tumors being more common in this age group.

Conventional cytology reporting demonstrated that benign lesions constituted the largest diagnostic category accounting for 53.45%, followed by inflammatory/reactive lesions represented 22.41% and malignant lesions comprised 13.80%. Pleomorphic adenoma was the most frequently diagnosed lesion, consistent with previous studies by Zbären et al.[11], Colella et al.[25], and Schmidt et al.[26], who reported pleomorphic adenoma as the commonest salivary gland neoplasm and demonstrated a high diagnostic accuracy of FNAC for benign salivary gland lesions.

Application of the revised Milan System provided a more structured classification of salivary gland lesions. Categories II (Non-Neoplastic) and IV-A (Benign Neoplasm) each accounted for 36.21% of cases, while Category IV-B (SUMP) constituted 12.07%. Categories III (AUS) and VI (Malignant) each represented 5.17% of cases, whereas Categories I (Non-Diagnostic) and V (Suspicious for Malignancy) were least frequent. Similar category distributions have been reported by Rossi et al.[18], Wei et al.[15], and Rohilla et al.[21], who found that the majority of salivary gland FNAC specimens were classified into the Non-Neoplastic and Benign Neoplasm categories, with relatively few cases falling into the indeterminate or malignant categories.

A major advantage of the Milan System is its standardized reporting format, which links each diagnostic category with an estimated risk of malignancy and appropriate clinical management. Compared with conventional descriptive reporting, it reduces interpretative ambiguity and improves communication between cytopathologists and clinicians. Similar observations have been emphasized by Faquin et al.[19], Viswanathan et al.[22], and Baloch et al.[16], who concluded that the Milan System improves interobserver reproducibility, facilitates uniform reporting, and provides clinically meaningful risk stratification for patient management.

Histopathological correlation was available in 15 cases, of which 12 showed concordance, giving an overall concordance rate of 80%. Complete concordance was observed in Categories II, IV-A, and VI, while discordance was mainly observed in Categories III (AUS) and IV-B (SUMP), reflecting the inherent diagnostic difficulty associated with atypical and indeterminate lesions. Similar observations have been reported by Rohilla et al.[21], Song et al.[17], and Kocjan[29], who also demonstrated excellent concordance in benign and malignant categories but lower concordance in AUS and SUMP because of overlapping cytomorphological features and sampling limitations.

The findings of the present study support the clinical utility of the revised Milan System for Reporting Salivary Gland Cytopathology as a reliable and standardized reporting framework. The system successfully categorized the majority of lesions into clinically meaningful groups, demonstrated high cytohistological concordance in benign and malignant categories, reduced interpretative ambiguity, and facilitated risk-based stratification of salivary gland lesions. Adoption of the Milan System in routine cytopathology practice may therefore improve diagnostic consistency, enhance multidisciplinary communication, and contribute to more effective patient management.

5. Conclusion

The revised Milan System reporting 2023 provides a standardized, reproducible, and clinically relevant framework for evaluation of salivary gland cytology specimens. Compared with conventional descriptive reporting, the Milan system improves diagnostic stratification, cytohistological correlation, and communication between cytopathologists and clinicians.

Implementation of the revised Milan System in routine cytopathology practice may improve diagnostic accuracy, facilitate risk-based management, and reduce interpretative variability in salivary gland lesions.

Limitations

The present study was conducted at a single tertiary care center with a relatively limited sample size. Histopathological correlation was not available in all cases, which may have influenced assessment of diagnostic accuracy and risk stratification.

Recommendations

Larger multicentric studies with extended histopathological follow-up are recommended to further validate the diagnostic performance and clinical utility of the revised Milan System reporting 2023 in salivary gland cytopathology.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict-of-interest to be disclosed.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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