Original Article

Cytomorphological Spectrum and Classification of Salivary Gland Lesions According to Milan System of Reporting

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Abstract

Background: Salivary gland lesions comprise a diverse group of non-neoplastic, benign, and malignant conditions with overlapping cytomorphological features. Fine-needle aspiration cytology (FNAC) is widely used as a minimally invasive first-line diagnostic tool for the evaluation of these lesions. The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) provides a standardized reporting framework with defined risk of malignancy (ROM) and management recommendations. The aim is to evaluate salivary gland lesions using FNAC and classify them according to the Milan System to determine their diagnostic significance. **Material and Methods:** This retrospective observational study was conducted in the Department of Pathology of a tertiary care centre over a period of three years from January 2022 to January 2025. A total of 50 salivary gland FNAC cases were included. Archived FNAC smears stained with MGG, PAP, and H&E were reviewed along with available histopathological sections and clinical records. Cases were categorized according to the Milan System for Reporting Salivary Gland Cytopathology. Cytohistopathological correlation and ROM were assessed wherever histopathology was available. Statistical analysis was performed using SPSS software. **Results:** Benign neoplasms (Category IVa) constituted the largest group comprising 24 (48%) cases, followed by non-neoplastic lesions accounting for 13 (26%) cases. Pleomorphic adenoma was the most common benign neoplasm, while chronic sialadenitis was the predominant non-neoplastic lesion. Categories III and IVb demonstrated higher ROM ranging from 33% to 50%, whereas Categories V and VI showed a ROM of 100%. FNAC demonstrated a sensitivity of 78.6%, specificity of 97.2%, positive predictive value of 91.6%, negative predictive value of 92.8%, and overall diagnostic accuracy of 93.3%. **Conclusion:** The Milan System proved to be a practical and effective framework for standardized reporting of salivary gland cytology. FNAC demonstrated high specificity and diagnostic accuracy, reaffirming its utility as a reliable first-line diagnostic modality for salivary gland lesions.

Keywords: Fine-needle aspiration cytology; Milan System; Salivary gland lesions; Risk of malignancy; Pleomorphic adenoma.

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Introduction

Salivary gland lesions comprise a wide spectrum of non-neoplastic, benign, and malignant conditions with varied clinical presentations and biological behavior.[1] These lesions often present as painless swellings and may demonstrate overlapping clinical and radiological features, making preoperative diagnosis challenging.[2] Accurate distinction between inflammatory, benign neoplastic, and malignant lesions is essential for appropriate patient management and surgical planning.[3]

Fine-needle aspiration cytology (FNAC) has emerged as a valuable first-line diagnostic modality in the evaluation of salivary gland lesions.[4] It is a minimally invasive, rapid, safe, and cost-effective technique that aids in differentiating neoplastic from non-neoplastic lesions and helps guide therapeutic decisions.[5] FNAC can reduce unnecessary surgical interventions in non-neoplastic conditions while facilitating timely management of malignant lesions.[6] However, the heterogeneous architecture of salivary gland tumors, cystic changes, overlapping cytomorphological features, and occasional sampling errors continue to pose diagnostic difficulties.[7]

To overcome variability in reporting and improve communication between cytopathologists and clinicians, the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was introduced in 2018.[8] The system provides a standardized reporting framework comprising six diagnostic categories, each associated with a defined risk of malignancy (ROM) and recommended clinical management.[9,10] The Milan system has contributed to improved reproducibility and uniformity in reporting salivary gland cytology and has gained widespread acceptance in routine diagnostic practice.[11-14]

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Despite increasing utilization of the Milan system, limited data are available from Indian tertiary care settings regarding the cytomorphological spectrum of salivary gland lesions and the applicability of the Milan classification in routine clinical practice. Hence, the present study was undertaken to evaluate salivary gland lesions using FNAC and classify them according to the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) to determine their diagnostic significance. The objectives of the study were to analyse the cytomorphological features of salivary gland lesions on FNAC, categorize the lesions according to the Milan system, and assess the distribution of Milan categories along with the risk of malignancy using available histopathological correlation.

Materials and Methods

This retrospective observational study was conducted in the Department of Pathology at a tertiary care centre over a period of three years from January 2022 to January 2025. The study included a total of 50 cases of salivary gland lesions that underwent fine-needle aspiration cytology (FNAC) during the study period. The study population comprised all patients presenting with salivary gland swellings who underwent FNAC evaluation.

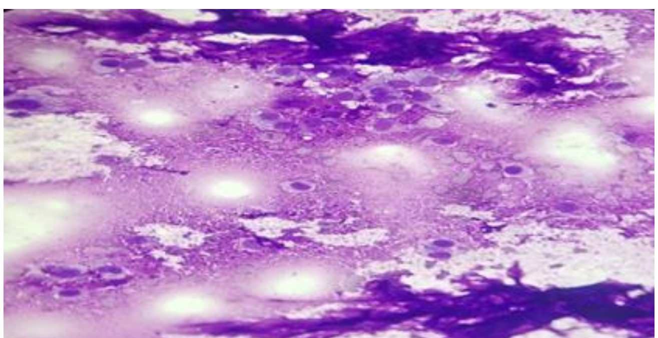

Figure 1: Pleomorphic Adenoma (40x MGG)

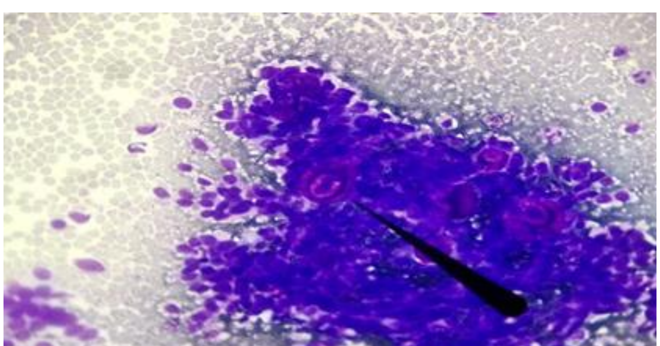

Figure 2: Adenoid cystic carcinoma showing basaloid tumor cells surrounding hyaline globules (40x MGG)

All salivary gland FNAC smears received in the Department of Pathology during the study period with adequate cellularity and relevant clinical details were included in the study, irrespective of availability of histopathological follow-up. Cases with poorly cellular or inadequate aspirates and cases with incomplete clinical information were excluded from the study. Clinical details including age, sex, site of lesion, and provisional clinical diagnosis were retrieved from pathology records and documented using a standardized proforma.

Archived FNAC smears and histopathology slides, wherever available, were reviewed retrospectively. FNAC smears stained with May–Grünwald–Giemsa (MGG), Papanicolaou (PAP), and Hematoxylin and Eosin (H&E) stains were independently re-evaluated by cytopathologists. Cytomorphological assessment included evaluation of cellularity, architectural patterns, cytoplasmic and nuclear features, background components, and the presence of mucin, cystic change, or necrosis. All cases were categorized according to the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) into Categories I to VI, including subcategorization into IVA and IVB wherever applicable.

Histopathological slides available for operated cases were reviewed to assess cytohistopathological concordance. Risk of malignancy (ROM) for each Milan category was calculated based on histopathological follow-up. Statistical analysis was performed using Microsoft Excel and Statistical Package for the Social Sciences (SPSS) software. Descriptive statistics were used for data analysis, and the Chi-square test was applied wherever appropriate. A p-value of <0.05 was considered statistically significant.

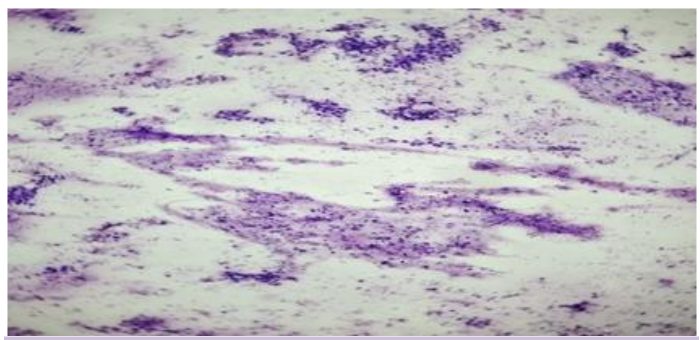

Figure 3: Mucoepidermoid carcinoma (20x & 40x MGG)

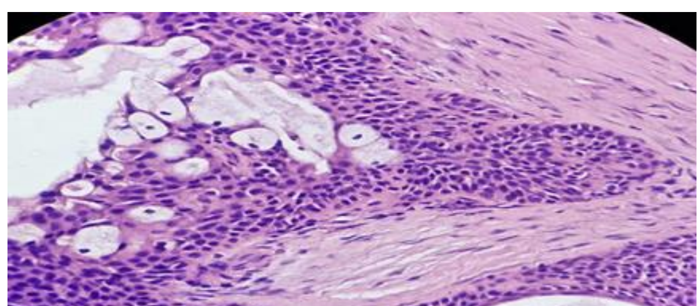

Figure 4: Histopathology of Mucoepidermoid carcinoma with perineural invasion (H&E 20x)

Results

A total of 50 salivary gland lesions were categorized according to the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC). The most common category was benign neoplasm (Category IVa), comprising 24 (48%) cases, followed by non-neoplastic lesions (Category II) accounting for 13 (26%) cases. Non-diagnostic lesions (Category I), atypia of undetermined significance (AUS) (Category III), and malignant lesions

(Category VI) each constituted 3 (6%) cases. Salivary gland neoplasm of uncertain malignant potential (SUMP) (Category IVb) and suspicious for malignancy (Category V) each accounted for 2 (4%) cases. [Table 1]

Table 1: Distribution of Salivary Gland Lesions According to the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC)

Milan Category	n (%)
Non-diagnostic (Category I)	3 (6%)
Non-neoplastic (Category II)	13 (26%)
Atypia of undetermined significance (AUS) (Category III)	3 (6%)
Benign neoplasm (Category IVa)	24 (48%)
Salivary gland neoplasm of uncertain malignant potential (SUMP) (Category IVb)	2 (4%)
Suspicious for malignancy (Category V)	2 (4%)
Malignant (Category VI)	3 (6%)
Total	50 (100%)

Among Category I lesions, two cystic lesions and one normal salivary gland tissue case showed benign histopathological findings with a ROM of 0%. In Category II, chronic sialadenitis was the most frequent diagnosis with 6 cases, followed by acute sialadenitis and parotitis with 3 cases each, while sialadenosis accounted for 1 case. Histopathological correlation available in chronic sialadenitis cases was concordant with cytological diagnosis, yielding a ROM of 0%. In Category III (AUS), two mucinous cyst cases were benign on histopathology, whereas one case showing salivary duct cyst on FNAC was diagnosed as mucoepidermoid carcinoma on histopathology, resulting in a ROM of 33%. [Table 2]

Table 2: Cytohistopathological Correlation and Risk of Malignancy (ROM) According to Milan Categories I–III

Milan Category	Primary FNAC Diagnosis	No. of Cases	Histopathology Available, n	Histopathological Diagnosis	ROM (%)
Category I (Non-diagnostic), n=3	Normal salivary gland tissue	1	1	Normal salivary gland tissue	0
	Cystic lesion	2	2	Benign cystic lesion	
Category II (Non-neoplastic), n=13	Chronic sialadenitis	6	3	Chronic sialadenitis	0
	Acute sialadenitis	3	0	—	
	Parotitis	3	0	—	
	Sialadenosis	1	0	—	
Category III (AUS), n=3	Mucinous cyst	2	2	Benign cystic lesion	33
	Salivary duct cyst	1	1	Mucoepidermoid carcinoma	

Among Category IVa lesions, pleomorphic adenoma was the predominant diagnosis accounting for 22 cases, while basal cell adenoma constituted 2 cases. Histopathological correlation showed concordance in pleomorphic adenoma cases, whereas both basal cell adenoma cases were diagnosed as pleomorphic adenoma on histopathology, with an overall ROM of 0%. In Category IVb (SUMP), one case diagnosed as low-grade mucoepidermoid carcinoma was confirmed on histopathology, while one case had no histopathological follow-up, resulting in a ROM of 50%. Both Category V cases diagnosed cytologically as malignant epithelial lesion were confirmed as metastatic squamous cell carcinoma on histopathology, yielding a ROM of 100%. Similarly, all Category VI malignant cases showed malignant histopathological outcomes with a ROM of 100%. [Table 3]

Table 3: Cytohistopathological Correlation and Risk of Malignancy (ROM) According to Milan Categories IV–VI

Milan Category	Primary FNAC Diagnosis	No. of Cases	Histopathology Available, n	Histopathological Diagnosis	ROM (%)
Category IVa (Benign neoplasm), n=24	Pleomorphic adenoma	22	15	Pleomorphic adenoma	0
	Basal cell adenoma	2	2	Pleomorphic adenoma	
Category IVb (SUMP), n=2	Salivary gland neoplasm with predominant oncocytic cells	1	0	-	50
	Low-grade mucoepidermoid carcinoma	1	1	Mucoepidermoid carcinoma	
Category V (Suspicious for malignancy), n=2	Malignant epithelial lesion	2	2	Metastatic squamous cell carcinoma	100
Category VI (Malignant), n=3	Mucoepidermoid carcinoma	1	1	Mucoepidermoid carcinoma	100
	Adenoid cystic carcinoma	1	1	Adenoid cystic carcinoma	
	Salivary duct carcinoma	1	1	Mucoepidermoid carcinoma	

The diagnostic performance of FNAC in salivary gland lesions demonstrated a sensitivity of 78.6%, specificity of 97.2%, positive predictive value (PPV) of 91.6%, negative predictive value (NPV) of 92.8%, and an overall diagnostic accuracy of 93.3%, indicating high reliability of FNAC in distinguishing benign from malignant salivary gland lesions. [Table 4]

Table 4: Diagnostic Performance of FNAC in Salivary Gland Lesions

Parameter	Value (%)
Sensitivity	78.6
Specificity	97.2
Positive Predictive Value (PPV)	91.6
Negative Predictive Value (NPV)	92.8
Diagnostic Accuracy	93.3

Discussion

Salivary gland lesions encompass a heterogeneous group of inflammatory, benign, and malignant entities with overlapping cytomorphological features, making accurate preoperative diagnosis challenging. In the present study, benign neoplasms constituted the largest category, accounting for 48% of cases, followed by non-neoplastic lesions (26%). Pleomorphic adenoma was the most common benign neoplasm, while chronic sialadenitis represented the predominant non-neoplastic lesion. Similar findings were reported by Mahadev et al., in which benign neoplasms accounted for 43.01% and non-neoplastic lesions for 41.93% of cases, with pleomorphic adenoma and sialadenitis being the most frequent diagnoses in their respective categories.[15] Likewise, Jha et al. observed Category IVA lesions as the predominant Milan category comprising 48.97% of cases, followed by Category II lesions constituting 27.4%, findings closely comparable to the present study.[16]

Application of the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) in the present study provided a standardized approach for risk stratification and cytohistopathological correlation. The risk of malignancy (ROM) in Categories I, II, and IVA was 0%, which was comparable to the low ROM reported by Mahadev et al.

The indeterminate categories, namely Category III (AUS) and Category IVB (SUMP), demonstrated higher ROM ranging from 33% to 50% in the present study, reflecting the inherent diagnostic ambiguity associated with these categories.[15] Similar observations were reported by Jha et al., who documented a ROM of 100% for Category III lesions, emphasizing the need for careful interpretation and close clinicoradiological correlation in indeterminate lesions.[16] In the present study, one AUS case showing chondromyxoid stroma on FNAC was diagnosed as mucoepidermoid carcinoma on histopathology, highlighting the potential for overlap between benign and malignant salivary gland lesions.

Categories V and VI in the present study demonstrated a ROM of 100%, indicating excellent predictive value for malignancy in cytologically suspicious and malignant lesions. Comparable findings were observed by Mahadev et al. and Jha et al., both of whom reported high ROM in these categories, supporting the diagnostic reliability of the Milan system in identifying malignant salivary gland lesions.[15,16] However, occasional discordance between cytological and histopathological diagnosis has been reported in the literature, particularly in cystic and low-grade tumors, due to overlapping cytomorphological features and sampling limitations. Such diagnostic pitfalls underscore the importance of adequate sampling, meticulous cytomorphological evaluation, and integration of clinical and radiological findings.

The diagnostic performance of FNAC in the present study demonstrated high specificity (97.2%) and overall diagnostic accuracy (93.3%), with sensitivity of 78.6%, findings that are comparable to those reported by Jha et al., who documented specificity and diagnostic accuracy of 97.01% and 87.37%, respectively.[16] These findings support FNAC as a reliable and minimally invasive diagnostic modality for salivary gland lesions. Furthermore, the Milan System provides a robust and standardized reporting framework that enhances diagnostic consistency, facilitates communication between pathologists and clinicians, and assists in appropriate patient management. Nevertheless, cautious interpretation and clinicoradiological correlation remain essential, particularly in indeterminate categories associated with higher ROM.

The strengths of the present study include the application of the standardized Milan System for Reporting Salivary Gland Cytopathology (MSRSGC), detailed cytohistopathological correlation, and assessment of risk of malignancy (ROM), which enhance the clinical relevance and diagnostic utility of the findings. The study also demonstrated high specificity and diagnostic accuracy of FNAC in salivary gland lesions. However, the study was limited by its retrospective design, relatively small sample size, and incomplete histopathological follow-up in all cases, particularly in non-neoplastic and indeterminate categories, which may have influenced the calculated ROM and overall diagnostic performance.

Conclusion

The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) proved to be a practical and effective framework for categorizing salivary gland FNACs, providing standardized diagnostic stratification and aiding clinical management. Benign neoplasms, particularly pleomorphic adenoma, constituted the majority of lesions in the present study, while malignant categories demonstrated strong cytohistopathological concordance with a risk of malignancy (ROM) of 100%. The indeterminate categories (III and IVb) showed relatively higher ROM, highlighting the importance of cautious interpretation and the need for further clinicoradiological and histopathological evaluation in such cases. Overall, FNAC demonstrated high diagnostic accuracy, specificity, and reliability, reaffirming its role as a valuable first-line diagnostic modality in the evaluation of salivary gland lesions.

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Conflicts of interest

There are no conflicts of interest.

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