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A COMPARATIVE STUDY OF CONVENTIONAL CYTOLOGY REPORTING AND THE MILAN SYSTEM FOR REPORTING SALIVARY GLAND CYTOPATHOLOGY

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Abstract
Background: Fine-needle aspiration cytology (FNAC) is widely used for the evaluation of salivary gland lesions, but conventional reporting often lacks uniform terminology and clear risk stratification. The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was introduced to address these limitations. ***Aim:*** To compare conventional cytology reporting with the Milan System in the evaluation of salivary gland FNAC. ***Materials and Methods:*** This hospital-based comparative study included 130 salivary gland FNAC cases. All cases were reported using conventional cytology and re-categorized according to MSRSGC. Histopathological correlation was available in 92 cases and was considered the gold standard. Diagnostic performance parameters and risk of malignancy (ROM) were calculated. ***Results:*** Benign neoplasms were the most common lesions. The Milan System showed a progressive increase in risk of malignancy from Category II to Category VI. Compared to conventional reporting, MSRSGC demonstrated higher sensitivity (87.0% vs 73.9%), specificity (92.5% vs 85.1%), and overall diagnostic accuracy (90.2% vs 82.6%), with a statistically significant difference. ***Conclusion:*** The Milan System is superior to conventional cytology reporting as it provides standardized reporting, reliable risk stratification, and improved diagnostic accuracy, thereby facilitating better clinical decision-making in salivary gland lesions.

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

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INTRODUCTION
Salivary gland swellings are frequently encountered in ENT and head-and-neck practice and represent a diagnostically diverse group of conditions ranging from inflammatory/obstructive lesions to benign and malignant neoplasms. Fine-needle aspiration cytology (FNAC) is widely accepted as a first-line investigation because it is minimally invasive, rapid, cost-effective, and helpful for pre-operative triage and planning. Despite these advantages, salivary gland cytology is well known to be challenging: tumour heterogeneity, cystic change, metaplastic alterations, sampling limitations, and overlapping cytomorphology across multiple entities can reduce diagnostic certainty and create variability in reporting.

Traditionally, many laboratories have used "conventional" (non-standardized) reporting styles—often descriptive impressions or locally preferred terminologies such as "benign lesion," "suggestive of pleomorphic adenoma," "suspicious," or "malignant." While clinically familiar, this approach can lead to inconsistent use of diagnostic labels and inconsistent communication of uncertainty between cytopathologists and clinicians. An international survey conducted during the development of a unified reporting approach highlighted substantial variation in diagnostic thresholds, adequacy criteria, terminology for indeterminate categories, and expected management—strengthening the argument for a standardized system in salivary gland FNAC.1

To overcome these limitations and improve clinical communication, the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was developed as an evidence-based, internationally endorsed reporting framework. The key strength of MSRSGC is that it provides well-defined diagnostic categories and links each category to an implied Risk of Malignancy (ROM) and general management recommendations, thereby allowing clinicians to make ROM-based decisions more consistently. In other words, MSRSGC shifts reporting from variable

narrative impressions toward structured risk stratification—similar in philosophy to other standardized cytology systems—so that cytology reports are more reproducible and actionable across different centres and observers.2

Following its introduction, several institutional and multi-institutional validation studies assessed how MSRSGC performs by correlating cytology categories with histopathology (follow-up surgical diagnosis) and calculating ROM category-wise. Large retrospective series have shown that reclassifying cases into MSRSGC categories enables consistent ROM estimation, highlights the clinical significance of indeterminate groups such as AUS (Atypia of Undetermined Significance) and SUMP (Salivary gland neoplasm of Uncertain Malignant Potential), and improves overall communication to the treating team.3 Multi-institutional evidence is particularly important because it demonstrates that the system can function across different practice environments and not only within a single laboratory's local reporting culture.4

Evidence from the Indian setting has also supported the usefulness of MSRSGC in routine practice. Studies have reported that applying Milan categories provides clearer clinicopathological communication and allows ROM-based interpretation that is easier to incorporate into decision-making (repeat FNAC, imaging correlation, or surgery depending on clinical context), which is valuable in high-volume centres where FNAC is frequently used for initial diagnosis. Beyond single-centre studies, systematic reviews and meta-analyses have strengthened the evidence base for MSRSGC by pooling data across published studies and evaluating malignancy risk stratification and diagnostic performance. Meta-analytic data support the overall effectiveness of Milan categories in predicting neoplasia and malignancy and provide pooled ROM estimates that guide both reporting benchmarks and quality assurance.5 More recently, meta-analysis focusing on prospective studies has further suggested that MSRSGC performs well in real-world cytopathology practice and that ROM values from prospective cohorts are generally concordant with reference expectations, supporting reliability of the system even when applied prospectively.6

In this context, a comparative evaluation of conventional cytology reporting versus MSRSGC is clinically relevant. Such comparison helps determine whether structured Milan reporting improves (i) uniformity of terminology, (ii) risk-based categorization, (iii) cyto-histopathological correlation, and (iv) overall clinical decision-making for patients with salivary gland lesions—thereby potentially improving patient counselling and appropriate management.6,7

Aim

To compare conventional cytology reporting with the Milan System for Reporting Salivary Gland Cytopathology in the evaluation of salivary gland lesions.

Objectives

1. To categorize salivary gland FNAC cases using both conventional cytology reporting and the Milan System.
2. To assess and compare the diagnostic utility and risk stratification provided by the two reporting systems.

MATERIALS AND METHODS

Study design

A hospital-based observational comparative study was conducted to compare conventional FNAC reporting with the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) in patients presenting with salivary gland swellings.

Study setting

The study was carried out in the Department of Pathology in collaboration with the Department of ENT and General Surgery at a tertiary care teaching hospital.

Sample size

Sample size calculation

Sample size was calculated to ensure adequate malignant cases for estimating sensitivity of FNAC reporting with acceptable absolute precision.

$$n_{malignant} = \frac{Z^2_{\alpha/2} \times Se(1 - Se)}{d^2}$$

Where:

- (Z_{\alpha/2} =1.96) for 95% confidence
- (Se) = anticipated sensitivity
- (d) = absolute precision (allowable error)

Assuming:

- anticipated sensitivity $Se = 0.85$
- allowable error $d = 0.13$

$$n_{malignant} = \frac{(1.96)^2 \times 0.85 \times 0.15}{(0.13)^2} = \frac{3.84 \times 0.1275}{0.0169} \approx 29 \text{ malignant cases}$$

Expected malignancy proportion among salivary gland FNAC is 25% then total sample:

$$N = \frac{n_{malignant}}{0.25} \approx \frac{29}{0.25} \approx 116$$

Adding 10% for inadequate smears/loss to follow-up:

$$N_{final} \approx 116 + 12 \approx 128$$

Final sample size taken: 130 cases.

Study population

All patients with salivary gland swelling (parotid/submandibular/sublingual/minor salivary gland) referred for FNAC during the study period.

Sampling technique

Consecutive sampling

Eligibility criteria

Inclusion criteria

- Patients of any age and gender with clinically/radiologically suspected salivary gland lesion
- Patients who underwent FNAC of the salivary gland swelling
- Cases with available histopathology (biopsy/excision) and/or adequate follow-up where applicable

Exclusion criteria

- Inadequate clinical details / non-salivary swellings
- Recurrent lesions with prior definitive diagnosis
- Smears that remain inadequate even after repeat FNAC
- Patients unwilling for FNAC or without consent

Data collection

A structured proforma was used to record:

- Demographic details: age, sex
- Clinical details: site, duration, pain, facial nerve symptoms, fixation, etc.
- Imaging findings (USG/CT/MRI if available)
- FNAC findings and category
- Histopathology diagnosis (gold standard) wherever available

FNAC procedure and smear processing

- FNAC was performed under aseptic precautions using 22–23G needle with 10 mL syringe (with/without aspiration depending on lesion and operator preference).
- For deep lesions, USG-guided FNAC was done when required.
- Multiple passes were taken as needed.
- Smears were prepared and stained as:
    - May–Grünwald–Giemsa (MGG) for air-dried smears
    - Papanicolaou (Pap) and/or H&E for alcohol-fixed smears
- Cell block preparation was done where sufficient material was available.

Reporting methods (index tests)

1) Conventional reporting

Each FNAC was first reported using the routine conventional format used in the department:

- Non-neoplastic / inflammatory
- Benign neoplasm (e.g., pleomorphic adenoma, Warthin tumour)
- Suspicious / indeterminate
- Malignant / suggestive of malignancy

2) Milan System reporting (MSRSGC)

The same FNAC cases were then categorized into MSRSGC:

- Category I: Non-diagnostic
- Category II: Non-neoplastic
- Category III: Atypia of Undetermined Significance (AUS)
- Category IVa: Benign neoplasm
- Category IVb: SUMP
- Category V: Suspicious for malignancy
- Category VI: Malignant

Blinding - Milan categorization was done independently by a cytopathologist blinded to histopathology (and ideally blinded to the first report), and discrepancies were resolved by consensus.

Reference standard

- Histopathology of biopsy/excision specimen was considered the gold standard wherever available.
- For cases without surgery, clinical–radiological follow-up (minimum 6 months) was used to support benign/non-neoplastic diagnosis (mention clearly in limitations).

Statistical analysis

Data entered in MS Excel and analysed using SPSS. Categorical variables: presented as frequency and percentage. Continuous variables: mean ± SD / median (IQR) as appropriate. Association between reporting category and histopathology: Chi-square test / Fisher's exact test. Agreement between conventional reporting and MSRSGC: Cohen's kappa (κ). Diagnostic accuracy indices (sensitivity, specificity, PPV, NPV) with 95% confidence intervals. $p < 0.05$ considered statistically significant.

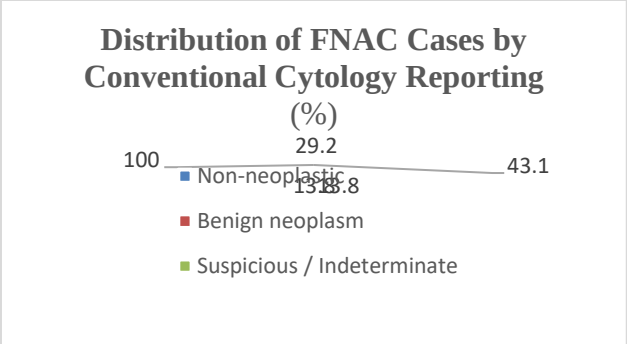
RESULTS

A total of 130 salivary gland FNAC cases were included in the study. All cases were reported using conventional cytology reporting and subsequently categorized according to the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC). Histopathological correlation was available in 92 cases (70.8%).

Table 1: Distribution of FNAC Cases by Conventional Cytology Reporting (n = 130)

Conventional cytology diagnosis	Number	Percentage (%)
Non-neoplastic	38	29.2
Benign neoplasm	56	43.1
Suspicious / Indeterminate	18	13.8
Malignant	18	13.8
Total	**130**	**100**

Graph 1: Distribution of FNAC Cases by Conventional Cytology Reporting (n = 130)



Interpretation:

Benign neoplasms constituted the largest group (43.1%). However, 27.6% of cases were reported as suspicious or malignant, reflecting the limited risk stratification and diagnostic ambiguity inherent to conventional reporting.

Table 2: Distribution of FNAC Cases According to Milan System (MSRSGC) (n = 130)

Milan category	Number	Percentage (%)
I – Non-diagnostic	6	4.6
II – Non-neoplastic	34	26.2
III – AUS	10	7.7
IVa – Benign neoplasm	48	36.9
IVb – SUMP	12	9.2
V – Suspicious for malignancy	8	6.2

VI – Malignant	12	9.2
Total	**130**	**100**

Interpretation:
MSRSGC provided structured categorization, clearly separating indeterminate lesions into AUS and SUMP categories and thereby improving diagnostic clarity compared to conventional reporting.

Table 3: Histopathological Diagnosis of Correlated Cases (n = 92)

Histopathological diagnosis	Number	Percentage (%)
Non-neoplastic	24	26.1
Benign neoplasm	44	47.8
Malignant neoplasm	24	26.1
Total	**92**	**100**

Interpretation:
On histopathology, benign neoplasms were most common, while **26.1%** of cases were malignant, emphasizing the need for accurate pre-operative risk stratification.

Table 4: Risk of Malignancy (ROM) for Milan Categories Based on Histopathology (n = 92)

Milan category	Cases with HPE	Malignant cases	ROM (%)
I – Non-diagnostic	4	1	25.0
II – Non-neoplastic	22	1	4.5
III – AUS	8	2	25.0
IVa – Benign neoplasm	34	2	5.9
IVb – SUMP	10	4	40.0
V – Suspicious for malignancy	6	5	83.3
VI – Malignant	8	8	100

Interpretation:
There was a progressive increase in risk of malignancy from Category II to Category VI, validating the risk-based design of the Milan System.

Table 5: Diagnostic Performance of Conventional Reporting and Milan System for Detection of Malignancy (n = 92)

Diagnostic parameter	Conventional reporting (%)	Milan System (%)
Sensitivity	73.9	87.0
Specificity	85.1	92.5
Positive predictive value	70.8	83.3
Negative predictive value	87.9	94.0
Overall accuracy	82.6	90.2

p-value: 0.03

Interpretation:
The Milan System demonstrated significantly better diagnostic performance than conventional reporting in identifying malignant salivary gland lesions ($p < 0.05$)

DISCUSSION

Fine-needle aspiration cytology (FNAC) plays a pivotal role in the initial evaluation of salivary gland lesions; however, diagnostic complexity and heterogeneous morphology often limit the effectiveness of conventional cytology reporting. In the present study, benign neoplasms constituted the majority of cases on conventional reporting (43.1%), while 27.6% were categorized as suspicious or malignant, reflecting a significant proportion of diagnostically ambiguous cases. Similar diagnostic uncertainty using conventional reporting has been reported by multiple authors, emphasizing the need for standardized reporting systems to improve clinical communication and management decisions.8,9

Application of the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) in this study resulted in more structured categorization of cases, with benign neoplasms accounting for 36.9%, non-neoplastic lesions for 26.2%, and indeterminate categories (AUS and SUMP) together comprising 16.9% of cases. These findings are comparable to those reported by Kala et al. and Wu et al., who demonstrated that MSRSGC effectively redistributes equivocal cases into defined indeterminate categories, thereby reducing diagnostic ambiguity.10,11 This stratification is clinically relevant because it allows tailored management strategies rather than a binary benign–malignant interpretation.

Histopathological correlation, available in 92 cases, showed that 26.1% of lesions were malignant. When risk of malignancy (ROM) was calculated for each Milan category, a progressive increase in ROM was observed from Category II (4.5%) to Category VI (100%). Notably, Category IVb (SUMP) demonstrated a ROM of 40%, while Category V (suspicious for malignancy) showed a ROM of 83.3%. These values are in close agreement with published ROM ranges reported in large validation studies and meta-analyses, reinforcing the reliability of the Milan System in predicting malignancy risk.12,13 The relatively low ROM observed in Category IVa (5.9%) further supports accurate identification of benign neoplasms using MSRSGC.

In the present study, diagnostic performance analysis revealed that the Milan System outperformed conventional reporting in the detection of malignancy, with higher sensitivity (87.0% vs 73.9%), specificity (92.5% vs 85.1%), and overall diagnostic accuracy (90.2% vs 82.6%). The difference in diagnostic performance was statistically significant (McNemar test, p = 0.03). Similar improvements in diagnostic accuracy with MSRSGC have been documented by Farahani and Baloch, who reported superior malignancy risk stratification compared with non-standardized reporting methods. This improvement is particularly important in clinical practice, as higher sensitivity minimizes missed malignancies, while higher specificity reduces unnecessary surgical interventions.

The findings of the present study are also consistent with Indian and international studies that highlight the clinical value of MSRSGC in providing reproducible, risk-based reporting that enhances multidisciplinary decision-making.14 In resource-limited settings, where FNAC remains the primary diagnostic modality for salivary gland lesions, structured systems like MSRSGC offer significant advantages by optimizing patient triage and reducing diagnostic variability.

Overall, the present study demonstrates that while conventional cytology reporting remains useful for initial evaluation, the Milan System offers clear advantages in terms of standardized terminology, risk stratification, and diagnostic accuracy. These benefits align with recommendations from recent systematic reviews and expert consensus statements advocating routine adoption of MSRSGC in salivary gland cytopathology practice.15,16

CONCLUSION

The present study demonstrates that the Milan System for Reporting Salivary Gland Cytopathology is superior to conventional cytology reporting in the evaluation of salivary gland FNAC. The Milan System provides standardized terminology, clear risk stratification, and better correlation with histopathology, thereby reducing diagnostic ambiguity. It showed higher sensitivity, specificity, and overall diagnostic accuracy for detecting malignancy when compared to conventional reporting. Hence, routine adoption of the Milan System in salivary gland cytology reporting is recommended to improve diagnostic consistency and guide appropriate clinical management.

REFERENCES

1. Rossi ED, Baloch Z, Pusztaszeri M, Faquin WC. The Milan System for Reporting Salivary Gland Cytopathology: analysis and suggestions of initial survey. Cancer Cytopathol. 2017; 125:757-766.
2. Rossi ED, Faquin WC. The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC): an international effort toward improved patient care. Cancer Cytopathol. 2018;126(9):756-766.
3. Kala C, Kala S, Khan L. Milan System for Reporting Salivary Gland Cytopathology: an experience with the implication for risk of malignancy. J Cytol. 2019;36(3):160-164.
4. Wu HH, Alruwaii FI, Zeng B, Cramer HM, Lai CR, Hang JF, et al. Application of the Milan System for Reporting Salivary Gland Cytopathology: a retrospective 12-year bi-institutional study. Am J Clin Pathol. 2019;151(6):613-621.
5. Farahani SJ, Baloch Z. Retrospective assessment of the effectiveness of the Milan system for reporting salivary gland cytology: a systematic review and meta-analysis of published literature. Diagn Cytopathol. 2019; 47:67-87.
6. Lagerstam H, Kalfert D, Maleki Z, Kholová I. How the Milan System for Reporting Salivary Gland Cytopathology works in cytopathology practice: meta-analysis of prospective studies and comparison with retrospective studies. Cancer Cytopathol. 2024;132(7):447-457.
7. Rossi ED, Faquin WC, Baloch ZW, et al. The Milan system for reporting salivary gland cytopathology: a comprehensive review of the literature. Diagn Cytopathol. 2020;48(10):880-889.
8. Rossi ED, Baloch Z, Pusztaszeri M, Faquin WC. The Milan System for Reporting Salivary Gland Cytopathology: analysis and suggestions of initial survey. Cancer Cytopathol. 2017;125(10):757-766.
9. Griffith CC, Pai RK, Schneider F, et al. Salivary gland tumor cytopathology: a pattern-based approach to diagnosis. Arch Pathol Lab Med. 2015;139(11):1491-1503.
10. Kala C, Kala S, Khan L. Milan System for Reporting Salivary Gland Cytopathology: an experience with the implication for risk of malignancy. J Cytol. 2019;36(3):160-164.
11. Wu HH, Alruwaii FI, Zeng B, Cramer HM, Lai CR, Hang JF. Application of the Milan System for Reporting Salivary Gland Cytopathology: a retrospective 12-year bi-institutional study. Am J Clin Pathol. 2019;151(6):613-621.

12. Farahani SJ, Baloch Z. Retrospective assessment of the effectiveness of the Milan system for reporting salivary gland cytology: a systematic review and meta-analysis. Diagn Cytopathol. 2019;47(2):67-87.
13. Wang Z, Zhao H, Guo H, An C. Application of the Milan System for Reporting Salivary Gland Cytopathology: a systematic review and meta-analysis. Cancer Cytopathol. 2022;130(11):849-859.
14. Amita K, Rakshith G, Shankar SV, et al. Evaluation of accuracy of Milan System for Reporting Salivary Gland Cytopathology: an Indian institutional study. J Cytol. 2020;37(1):15-20.
15. Rossi ED, Faquin WC, Baloch ZW. The Milan system for reporting salivary gland cytopathology: a comprehensive review. Diagn Cytopathol. 2020;48(10):880-889.
16. Lagerstam H, Kalfert D, Maleki Z, Kholová I. How the Milan System for Reporting Salivary Gland Cytopathology works in cytopathology practice: meta-analysis of prospective studies. Cancer Cytopathol. 2024;132(7):447-457.