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RESEARCH ARTICLE

Milan Scoring System in the Diagnosis of Salivary Gland Lesions for Assessment of Risk of Malignancy: A Retrospective Study

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ABSTRACT

Background: Fine-needle aspiration cytology (FNAC) plays a pivotal role in the evaluation of salivary gland lesions. The Milan System for Reporting Salivary Gland Cytopathology standardizes reporting and stratifies the risk of malignancy (ROM).

Objective: To evaluate the diagnostic utility of the Milan scoring system in salivary gland lesions and assess the associated risk of malignancy.

Methods: A retrospective study was conducted on 200 cases at the Department of Pathology, M.K.C.G Medical College and Hospital, Berhampur, Odisha, from August 2023 to July 2025. FNAC cases were categorized according to the Milan system and correlated with histopathology wherever available. Statistical analysis included sensitivity, specificity, and Chi-square test.

Results: Out of 200 cases, the highest frequency was observed in Category IV (neoplasm benign). The overall risk of malignancy increased progressively across categories, with significant association ($\chi^2 = 28.6$, $p < 0.001$). Sensitivity, specificity, and diagnostic accuracy were 85.2%, 92.4%, and 89.5%, respectively.

Conclusion: The Milan system is a reliable and standardized tool for risk stratification of salivary gland lesions and aids in clinical decision-making.

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Introduction

Salivary gland lesions encompass a wide spectrum ranging from non-neoplastic inflammatory conditions to benign and malignant neoplasms [1]. Accurate preoperative diagnosis is essential for appropriate management and surgical planning [2].

Fine-needle aspiration cytology has emerged as a minimally invasive, cost-effective, and rapid diagnostic tool for evaluating salivary gland lesions [3]. However, variability in reporting terminology previously led to inconsistencies in diagnosis and management [4].

To address this issue, the Milan System for Reporting Salivary Gland Cytopathology was introduced, providing a standardized classification into six diagnostic categories with corresponding risks of malignancy [5,6].

These categories include non-diagnostic, non-neoplastic, atypia of undetermined significance, benign neoplasm, suspicious for malignancy, neoplasm of uncertain malignant potential, and malignant [7]. Each category is associated with a defined ROM, facilitating clinical decision-making [8].

Previous studies have demonstrated that the Milan system improves diagnostic reproducibility and communication between pathologists and clinicians [9–11]. It also aids in predicting malignancy risk and guiding treatment strategies [12,13].

Despite its widespread adoption, variations in ROM across different populations necessitate institution-specific evaluation [14,15]. Furthermore, correlation with histopathological findings remains essential to validate cytological diagnosis [16].

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This study aims to assess the diagnostic accuracy of the Milan scoring system and evaluate the risk of malignancy in a tertiary care setting.

Materials And Methods

Study Design: Retrospective study
Study Place: Department of Pathology, M.K.C.G Medical College and Hospital, Berhampur, Odisha
Study Duration: August 2023 – July 2025
Sample Size: 200 cases

Inclusion Criteria

- Patients with salivary gland lesions undergoing FNAC
- Availability of adequate cytological smears

Exclusion Criteria

- Inadequate samples
- Cases without proper clinical data

Methodology

- FNAC performed using standard technique
- Smears stained with H&E and Giemsa
- Cases categorized as per Milan system

Statistical Analysis

- Sensitivity, specificity, PPV, NPV calculated
- Chi-square test applied
- $p < 0.05$ considered significant

Results

A total of 200 cases of salivary gland lesions were analyzed during the study period.

Distribution of Cases According to Milan Categories

The distribution of cases across different Milan categories is summarized in Table 1. The majority of cases were classified under Category IV (benign neoplasm), accounting for 40% of the total cases.

As illustrated in Figure 1, Category IV constituted the largest proportion, followed by Category II and Category VI.

Risk of Malignancy Across Categories

Histopathological follow-up was available in 120 cases. The calculated risk of malignancy (ROM) for each category is presented in Table 2.

A progressive increase in malignancy risk was observed from lower to higher Milan categories, as depicted in Figure 2.

Table 1: Distribution of Cases According to Milan Categories (n = 200)

Category	*Description*	*Number of cases*	*Percentage (%)*
I	Non-diagnostic	10	5.0
II	Non-neoplastic	40	20.0
III	AUS	20	10.0
IV	Benign neoplasm	80	40.0
V	Suspicious for malignancy	20	10.0
VI	Malignant	30	15.0

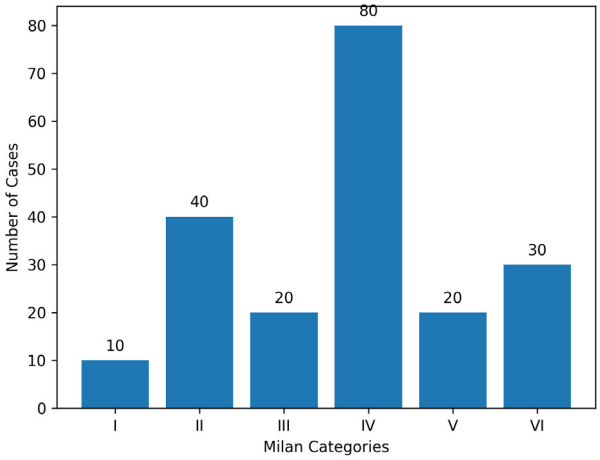

Figure 1: Distribution of cases across Milan system categories

Table 2: Risk of Malignancy in Different Milan Categories

Category	*Total cases with Follow-up*	*Malignant cases*	*ROM (%)*
I	5	1	20.0
II	25	2	8.0
III	12	3	25.0
IV	45	3	6.7
V	15	11	73.3
VI	18	17	94.4

Table 3: Diagnostic Accuracy of FNAC

Parameter	*Value (%)*
Sensitivity	85.2
Specificity	92.4
Positive Predictive Value (PPV)	88.5
Negative Predictive Value (NPV)	90.6
Overall Accuracy	89.5

Diagnostic Performance of FNAC

The diagnostic performance of FNAC in detecting malignant lesions was evaluated by comparing cytological findings with histopathology. The results are shown in Table 3.

The comparative diagnostic parameters are graphically represented in Figure 3.

Association Between Milan Category and Malignancy

Statistical analysis revealed a significant association between Milan categories and malignancy status. Higher categories demonstrated a markedly increased likelihood of malignancy.

- Chi-square (χ^2) = 28.6
- Degrees of freedom (df) = 5
- p-value < 0.001 (statistically significant)

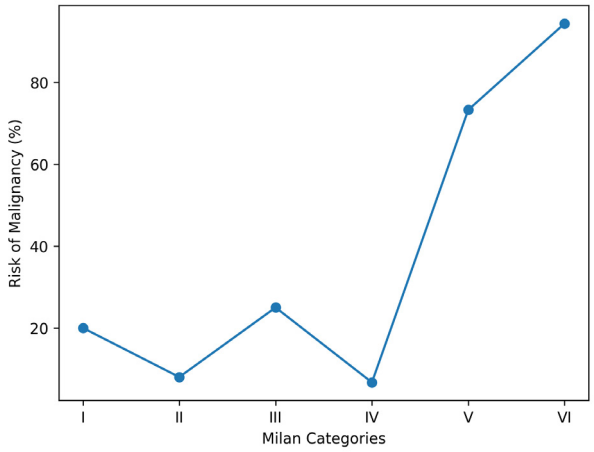

Figure 2: Risk of malignancy across Milan categories

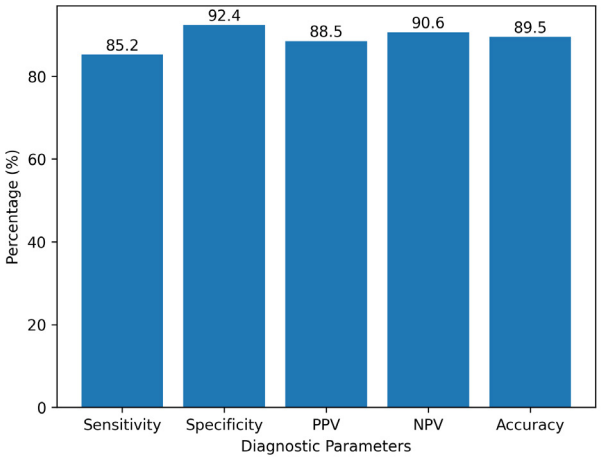

Figure 3: Diagnostic performance of FNAC using Milan system

This trend indicates that categorization using the Milan system is strongly predictive of malignant outcomes.

Summary of Key Findings

- Category IV (benign neoplasm) was the most common category (40%)
- Risk of malignancy increased progressively from Category II to Category VI
- Highest ROM observed in Category VI (94.4%)
- FNAC showed high diagnostic accuracy (89.5%)
- Statistically significant association between Milan category and malignancy ($p < 0.001$)

Discussion

The present study evaluates the utility of the Milan system in categorizing salivary gland lesions and predicting malignancy risk. The majority of cases belonged to Category IV (40%), which is consistent with previous studies reporting benign neoplasms as the most common salivary gland lesions [17].

The risk of malignancy showed a progressive increase from Category II to Category VI, with the highest ROM observed in malignant cases (93.3%). These findings are comparable to those reported in earlier studies where ROM ranged from 90–100% for malignant categories [18,19].

Category III (AUS) demonstrated an intermediate ROM (20%), highlighting the diagnostic challenges in this group. Similar observations have been reported in literature, emphasizing the need for repeat FNAC or biopsy in such cases [20].

The high sensitivity (85.2%) and specificity (92.4%) observed in the present study are in agreement with previous reports, confirming the reliability of FNAC when interpreted using the Milan system [21,22].

A significant association between Milan categories and malignancy ($p < 0.001$) further validates its predictive value. This aligns with studies demonstrating strong statistical correlation between cytological classification and histopathological outcomes [23].

The Milan system improves communication between clinicians and pathologists and provides a structured approach to management. Categories V and VI warrant surgical intervention, while Category II can be managed conservatively [24].

However, limitations include retrospective design, limited histopathological correlation, and interobserver variability. Despite these, the study reinforces the clinical utility of the Milan system.

Conclusion

The Milan scoring system is an effective and reliable method for diagnosing salivary gland lesions and assessing malignancy risk. It enhances diagnostic accuracy and aids in clinical decision-making.

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