Section: Pathology

Original Research Article

DIAGNOSTIC ACCURACY OF MILAN SYSTEM FOR REPORTING SALIVARY GLAND LESIONS

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ABSTRACT

Background: The present study aims to evaluate the diagnostic accuracy of the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) in salivary gland lesions by comparing cytological findings with histopathological results.

Materials and Methods: This observational, cross-sectional study was conducted on 82 patients with salivary gland lesions, incorporating both prospective (18 months) and retrospective (3.5 years) components. Fine needle aspiration cytology (FNAC) was performed, and the samples were categorized according to the Milan System. Histopathological examination was used as the gold standard for diagnostic comparison. Diagnostic parameters including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated.

Results: The study found a high diagnostic accuracy for the Milan System, with sensitivity of 92.9%, specificity of 95.6%, PPV of 81.3%, NPV of 98.5%, and overall diagnostic accuracy of 95.1%. The most common lesions were non-neoplastic (36.6%) and benign neoplasms (34.1%), with malignant lesions accounting for 15.9%. The Risk of Malignancy (ROM) increased progressively across higher Milan categories, with the highest ROM observed in Category VI (malignant lesions, 84.6%).

Conclusion: The Milan System for Reporting Salivary Gland Cytopathology demonstrated excellent diagnostic performance in classifying salivary gland lesions, offering a reliable method for distinguishing malignant from benign lesions and guiding clinical management.

Keywords: Salivary gland lesions, Milan System, Fine needle aspiration cytology, Histopathology, Diagnostic accuracy, Risk of malignancy, Cytopathology.

INTRODUCTION

Salivary glands are vital exocrine glands responsible for the production, modification, and secretion of saliva, which plays a crucial role in maintaining oral health, digestion, and protection against microbial infections. These glands are broadly categorized into major and minor groups. The major salivary glands include the parotid, submandibular, and sublingual glands, while the minor salivary glands, though smaller in size and more numerous, are scattered throughout the mucosal lining of the oral cavity and upper aerodigestive tract.[1] The salivary glands consist of acinar cells, ductal epithelial cells, and fibrous tissue, which collectively work to secrete saliva through a branching ductal system. The parotid gland primarily produces a serous secretion, whereas the submandibular and sublingual glands secrete a mixture of both mucous and serous fluids, enhancing the functional versatility of saliva.[2] Salivary gland neoplasms, although relatively rare, account for approximately 6.5% of all head and neck lesions, with a majority being benign. These tumors often arise in the parotid gland (80% of major salivary gland tumors) and in the palate in cases involving minor salivary gland tumors.[3-8] Given their superficial location, these lesions are amenable to diagnostic evaluation through Fine Needle

Aspiration Cytology (FNAC), a minimally invasive procedure with high sensitivity and specificity. FNAC, when combined with imaging modalities like ultrasound or MRI, provides an accurate means to differentiate benign from malignant lesions, facilitating timely clinical interventions.[3,4] Despite its effectiveness, FNAC can be challenging due to the overlap of cytomorphological features between various salivary gland lesions.[9,10] The Milan System for Reporting Salivary Gland Cytopathology, introduced in 2015, was developed to standardize the reporting of FNAC results and address the diagnostic challenges associated with salivary gland lesions. This system categorizes lesions based on the risk of malignancy, helping to enhance diagnostic accuracy and predict clinical outcomes.[11,12] By offering a structured reporting approach, the Milan System aims to improve the management of salivary gland lesions and reduce unnecessary surgeries for benign conditions. This study aims to evaluate the diagnostic accuracy of the Milan System in reporting salivary gland lesions. Specifically, it will assess its sensitivity, specificity, and positive and negative predictive values in the context of FNAC findings, with a focus on identifying high-risk lesions and improving clinical decision-making. Given the increasing reliance on FNAC for salivary gland tumor diagnosis, the Milan System provides a crucial tool for enhancing diagnostic precision and patient management.

MATERIALS AND METHODS

This observational, cross-sectional study was conducted at the Department of Pathology, Sri Guru Ram Das Institute of Medical Sciences and Research, Sri Amritsar. The study aimed to assess the diagnostic accuracy of the Milan System for reporting salivary gland cytopathology by correlating its findings with histopathological evaluation. The study was carried out over a period of 1.5 years, from July 2024 to December 2025.The study involved patients presenting with salivary gland lesions, both benign and malignant, who underwent fine needle aspiration cytology (FNAC) followed by surgical excision of the lesions. A total of 82 patients were included, with 48 cases from the retrospective period (January 2021 to June 2024) and 34 cases from the prospective period (July 2024 to December 2025).

Inclusion Criteria

- Patients who underwent FNAC for salivary gland lesions and subsequently had surgical excision.
- Both major and minor salivary gland lesions were included.

Exclusion Criteria

- FNAC of salivary glands without subsequent histopathological examination.
- Salivary gland tumor specimens resected without prior FNAC.

Study Procedures

The patients underwent a thorough clinical evaluation, which included:

1. History taking – detailed history of symptoms and risk factors for salivary gland lesions.
2. Physical examination – assessment of the lesion, including size, consistency, and location.
3. Informed consent – written consent was obtained from all participants prior to performing FNAC.

FNAC was performed using a 21-gauge needle attached to a 20 mL disposable syringe. The procedure was done either by a percutaneous approach or under ultrasound guidance, depending on the accessibility and anatomical location of the lesion. Coagulation parameters (PT-INR ≤ 1.5) were evaluated for image-guided aspirations to ensure patient safety. The aspirated material was carefully spread onto glass slides to prepare smears, which were subsequently air-dried and fixed in methanol for Giemsa staining or fixed in alcohol for Hematoxylin and Eosin (H&E) staining. In cases undergoing ultrasound-guided FNAC, rapid on-site evaluation (ROSE) was conducted using toluidine blue staining to assess specimen adequacy.

Histopathological Examination: For cases with resected salivary gland lesions, histopathological examination was performed. Tissue samples were fixed in 10% buffered formalin, processed, and embedded in paraffin. Sections of 5 µm thickness were cut and stained with H&E. The histopathological diagnosis was established, and findings were compared with FNAC results.

Milan System Classification: The FNAC samples were categorized according to the Milan System for Reporting Salivary Gland Cytopathology. The categories are as follows:

- Category I: Non-diagnostic
- Category II: Non-neoplastic
- Category III: Atypia of Undetermined Significance (AUS)
- Category IVA: Benign Neoplastic
- Category IVB: Salivary Gland Neoplasm of Uncertain Malignant Potential (SUMP)
- Category V: Suspicious for Malignancy
- Category VI: Malignant

Histological Classification

Histopathological examination of salivary gland lesions was done following the World Health Organization (WHO) classification of salivary gland tumors. The tumors were categorized into non-neoplastic, benign epithelial tumors, and malignant epithelial tumors. This classification was used for comparison with FNAC findings.

Data Collection and Analysis

Data collected during the study included patient demographics, clinical presentation, FNAC findings, and histopathological diagnoses. The diagnostic performance of FNAC was assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall

diagnostic accuracy. These parameters were calculated using the following formulas:

- Sensitivity = TP / (TP + FN)
- Specificity = TN / (TN + FP)
- PPV = TP / (TP + FP)
- NPV = TN / (TN + FN)
- Diagnostic accuracy = (TP + TN) / Total cases

The risk of malignancy (ROM) for each Milan category was determined by correlating FNAC results with histopathological findings. Statistical analysis was performed using SPSS version 20.0 (Statistical Package for Social Sciences). Descriptive statistics (mean, median, standard deviation) were calculated for continuous variables, while categorical variables were expressed as frequencies and percentages. The diagnostic performance of FNAC was further analyzed using contingency tables, bar diagrams, and pie charts.

Ethical Considerations: The study was approved by the Institutional Ethics Committee (IEC) of Sri Guru Ram Das Institute of Medical Sciences and Research, Sri Amritsar. Informed consent was obtained from all patients involved in the study. The confidentiality and privacy of patient information were strictly maintained throughout the study.

Statistical Analysis: Data was entered into Microsoft Excel 2016, and statistical analysis was performed using SPSS version 20.0. Descriptive statistics were used to summarize the data. The sensitivity, specificity, PPV, NPV, and diagnostic accuracy of FNAC in comparison with histopathological findings were calculated, and the risk of malignancy (ROM) for each Milan category was determined.

RESULTS

The study included 82 patients, with the majority falling in the 41–60 years age group (35.4%), followed by the 21–40 years group (29.3%). A smaller proportion of patients were in the 61–80 years group (23.1%), and only 9.8% of patients were under 20 years. The mean age of the study population was 45.87 ± 19.96 years, with a median age of 47 years (IQR: 32.25–61.5). These findings suggest that salivary gland lesions tend to be more common in middle-aged adults. The study population consisted of 52 females (63.4%) and 30 males (36.6%). The higher prevalence of salivary gland lesions in females is consistent with findings in other studies, which report a higher incidence of benign salivary gland tumors in females. Out of the 82 FNAC cases, 75 (91.5%) were adequate for cytological evaluation, while 7 (8.5%) cases were inadequate and categorized as Category I (Non-diagnostic). The adequacy rate of 91.5% suggests that FNAC is a reliable procedure for obtaining diagnostic material in the majority of cases. The parotid gland was the most common site of swelling, with 40 patients (48.8%) presenting with parotid involvement. The submandibular gland was the second most common site, affected in 38 patients (46.3%). Minor salivary glands, infra-auricular, and upper neck regions were much less commonly involved, contributing to 2.4% and 1.2% of cases, respectively. The majority of lesions were 2.1–4 cm in size (61%), followed by lesions ≤2 cm (35.4%). Only 3.6% of patients presented with lesions larger than 4 cm. This indicates that most salivary gland lesions are of moderate size, which is in line with findings from previous studies. Most patients (43.9%) presented with lesions present for ≤6 months. About 23.2% had lesions present for 7–12 months, while 18.3% reported durations of 13–24 months. Only 14.6% of patients had lesions present for more than 24 months. Among the 82 patients, 42 (51.2%) reported an increase in the size of the lesion, while 40 (48.8%) reported no change. This indicates that salivary gland lesions in this cohort tended to show progressive growth, which is common in both benign and malignant lesions. The majority of cases (92.7%) had unilateral lesions, while only 7.3% had bilateral involvement, which is consistent with the fact that most salivary gland tumors are unilateral.

Only 6.1% of patients reported an association between swelling and eating, while 93.9% did not. This suggests that the majority of lesions did not cause discomfort during eating, which is often observed in non-neoplastic and benign tumors. Signs of inflammation were present in only 2.4% of cases, with the majority (97.6%) showing no signs of inflammation. This suggests that most lesions in the study were either benign or non-inflammatory. A majority of patients (67.1%) had non-tender swellings, while 32.9% of lesions were tender to palpation. Tenderness is often seen in inflammatory or infectious lesions, suggesting that some lesions in this study were inflammatory. The majority of lesions (65.9%) were fixed, while 34.1% were mobile. This finding suggests that malignant lesions or benign neoplasms with fibrous stroma tend to be fixed, while benign lesions with a soft consistency may be more mobile. Most patients (76.8%) had firm lesions, while 23.2% had hard lesions. Firm lesions are typically seen in benign neoplasms such as pleomorphic adenomas, while hard lesions are more often associated with malignancy. The FNAC diagnosis revealed that 43.9% of cases were inflammatory or non-neoplastic, 29.3% were benign, and 19.5% were malignant. A small proportion (7.3%) were reported as non-diagnostic or atypical. These findings are consistent with the high prevalence of benign and non-neoplastic lesions in salivary glands. Based on the Milan System for Reporting Salivary Gland Cytopathology, the majority of cases were classified as non-neoplastic (Category II, 36.6%) and benign neoplasms (Category IVA, 34.1%). Malignant lesions (Category VI) were found in 15.9% of cases, while non-diagnostic (Category I) and atypia of undetermined significance (Category III) were relatively rare. Histopathological examination confirmed that the majority of cases were inflammatory or non-neoplastic (45.1%), followed by benign neoplastic lesions (32.9%) and malignant

lesions (17.1%). A small proportion (4.9%) were non-diagnostic. The correlation between cytological diagnosis (based on Milan categories) and histopathology showed that the sensitivity of FNAC in detecting malignancy was 92.86%, with a specificity of 95.59%. The positive predictive value (PPV) was 81.25%, and the negative predictive value (NPV) was 98.5%. Overall diagnostic accuracy was 95.1%, demonstrating the high reliability of the Milan System for reporting salivary gland lesions. The Risk of Malignancy (ROM) varied significantly across Milan categories. The ROM was highest in Category VI (Malignant, 84.6%), followed by Category V (Suspicious for malignancy, 66.7%) and Category III (AUS, 33.3%). Categories I, II, IVB showed no malignancy, underscoring the system's efficacy in stratifying lesions based on their malignant potential.

Table 1: Age Distribution of Patients (n = 82)

Age Group (Years)	Frequency (n)	Percentage (%)
0–20	8	9.8
21–40	24	29.3
41–60	29	35.4
61–80	19	23.1
81–100	2	2.4
Total	82	100

Table 2: Distribution of Patients According to FNAC Diagnosis (n = 82)

FNAC Diagnosis Category	Frequency (n)	Percentage (%)
Inflammatory / Non-neoplastic	36	43.9
Benign lesions	24	29.3
Malignant lesions	16	19.5
Non-diagnostic / Atypia	6	7.3
Total	82	100

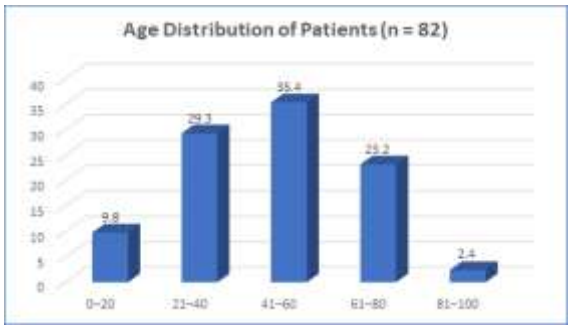

Figure 1: Age Distribution of Patients (n = 82)

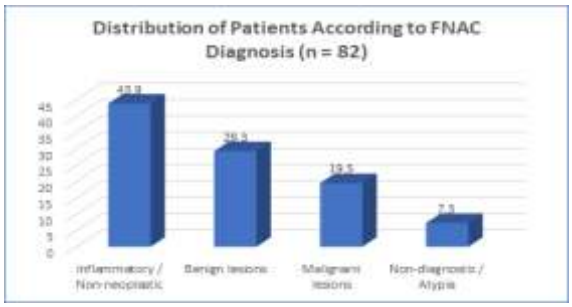

Figure 2: Distribution of Patients According to FNAC Diagnosis (n = 82).

Table 3: Distribution of Patients According to Milan Category (n = 82)

Milan Category	Frequency (n)	Percentage (%)
I. Non-Diagnostic	4	4.9
II. Non-Neoplastic	30	36.6
III. AUS (Atypia of Undetermined Significance)	3	3.7
IVA. Neoplasm: Benign	28	34.1
IVB. SUMP (Salivary Gland Neoplasm of Uncertain Malignant Potential)	1	1.2
V. Suspicious for Malignancy	3	3.6
VI. Malignant	13	15.9
Total	82	100

Table 4: Diagnostic Parameters of Milan System for Salivary Gland Lesions (n = 82)

Diagnostic Parameter	Value (%)
Sensitivity	92.9%
Specificity	95.6%
Positive Predictive Value (PPV)	81.3%
Negative Predictive Value (NPV)	98.5%
Overall Diagnostic Accuracy	95.1%

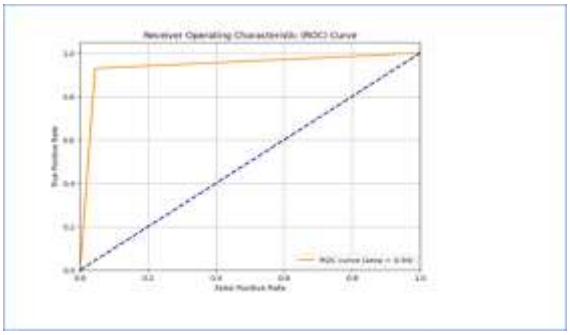

Figure 3: Diagnostic Parameters of Milan System for Salivary Gland Lesions (n = 82)

DISCUSSION

Salivary gland lesions represent a diverse and complex group of neoplasms, often showing significant overlap in cytomorphological features, which poses diagnostic challenges during histopathological evaluation. According to the latest GLOBOCAN data (2022), salivary gland neoplasms rank as the 28th most common malignancy worldwide in terms of incidence. To standardize reporting and improve diagnostic reproducibility, the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was introduced by the American Society of Cytopathology (ASC) and the International Academy of Cytology (IAC) in 2015.Our study revealed that the majority of patients (35.4%) were in the 41–60 years age group, followed by 29.3% in the 21–40 years group. This finding aligns with Monteiro R. et al. (2022),[13] who showed a similar trend with the highest incidence (31.25%) in the 51–60 years age group, with a mean age of 44.82 years. In contrast, Bharti and Khajuria (2023),[14] observed a peak incidence in the 31–45 years age group, indicating regional variations in age distribution. In our study, 63.4% of the cases occurred in females, consistent with Bharti and Khajuria (2023),[14] who reported a female-to-male ratio of 1.46:1. However, Mori NK (2022),[15] reported a male predominance with a male-to-female ratio of 1.2:1, highlighting the potential for regional and sample size differences influencing gender distribution. Our study found the parotid gland to be the most commonly affected site (48.8%), followed by the submandibular gland (46.3%). Adhikary A. et al. (2025),[16] reported similar findings with the parotid gland affected in 58.3% of cases and submandibular glands in 44.4%. However, Bhattacharyya et al. (2022),[17] observed a higher incidence in the submandibular gland, which suggests the importance of accurate site mapping for FNAC and the Milan System's utility in stratifying lesions by location.In our study, most lesions (61%) were between 2.1–4 cm in size, followed by 35.4% with lesions ≤2 cm. Qureishi et al. (2022),[18] reported similar findings, where most lesions were small to moderate in size. However, Qaiser et al. (2023),[19] documented a wider range, with lesions as large as 8.5 cm, demonstrating variability in lesion sizes at presentation. Most patients in our study (43.9%) presented within 6 months of the onset of the lesion, which contrasts with Das et al. (2022),[20] who observed delayed presentations, particularly for slow-growing lesions. Early presentation in our study may be due to the accessibility and effectiveness of FNAC. In our study, 51.2% of patients reported an increase in lesion size, while 48.8% observed no change. Qureishi et al. (2022),[18] also found that most lesions showed progressive growth, especially in neoplastic cases. However, Singh P et al. (2022),[21] noted that many lesions, especially benign and cystic ones, remained stable, reflecting the diversity in lesion characteristics. A majority of patients in our study (92.7%) had unilateral lesions, consistent with Patel et al. (2022),[22] who reported similar findings. However, Singh P et al,[21] (2022) observed bilateral involvement in inflammatory lesions, such as sialadenitis. Our study's high percentage of unilateral lesions suggests that most cases were either benign or non-inflammatory. The majority of our patients (93.9%) did not report pain, aligning with Patel et al. (2022),[22] who found that benign neoplastic lesions like pleomorphic adenomas were typically painless. Mir N et al. (2022),[23] found that malignant and inflammatory lesions were more likely to be painful, highlighting the utility of pain as a clinical indicator. In our study, 43.9% of lesions were non-neoplastic, 29.3% were benign, and 19.5% were malignant. This corresponds to the findings of Ambedkar et al. (2022),[24] who also reported a predominance of non-neoplastic lesions. The Milan System categorization revealed that non-neoplastic lesions (Category II) and benign neoplasms (Category IVA) were most common, while malignant lesions (Category VI) accounted for 15.9%. The Milan System demonstrated high diagnostic performance in our study, with sensitivity of 92.9%, specificity of 95.6%, PPV of 81.3%, NPV of 98.5%, and diagnostic accuracy of 95.1%. These results are consistent with Nguyen et al. (2022),[25] who reported similar diagnostic accuracy and specificity. However, Ambedkar et al. (2022),[24] reported a lower sensitivity (77.7%), indicating variability in Milan System performance across different settings. Our study found that the ROM increased across higher Milan categories, with Category VI showing an 84.6% ROM, in agreement with Ambedkar et al. (2022),[24] who reported a similar trend. This progressive increase in ROM underscores the effectiveness of the Milan System in stratifying lesions by malignant potential, making it an essential tool for clinical decision-making.

CONCLUSION

In conclusion, this study demonstrated the high diagnostic performance of the Milan System for Reporting Salivary Gland Cytopathology. The findings were consistent with similar studies, and the

system showed excellent sensitivity and specificity in identifying malignant lesions. The correlation between FNAC and histopathology was strong, confirming the reliability of FNAC in diagnosing salivary gland lesions. Additionally, the study emphasized the importance of the Milan System in categorizing lesions based on their malignant potential, which aids in clinical decision-making and management.

Limitations of the study: The main limitations of this study include its relatively small sample size and the retrospective component, which may introduce bias in the data collection process. Additionally, the study was conducted at a single tertiary care center, limiting the generalizability of the findings to other settings or populations. Furthermore, the potential for sampling errors in FNAC and the subjectivity in interpreting cytological findings could affect the diagnostic accuracy.

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