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Assessment of Risk of Malignancy by Application of Milan System of Reporting Salivary Gland Cytopathology

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ABSTRACT

Salivary gland fine-needle aspiration cytology (FNAC) is a valuable tool for diagnosing and managing salivary gland tumors, offering a minimally invasive and precise method. However, challenges such as tumor heterogeneity and morphological similarities between benign and malignant lesions exist. The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was developed to standardize reporting terminologies and risk assessment. A prospective study was conducted on 100 cases of salivary gland lesions, categorizing them based on the MSRSGC. Histopathological correlations were performed where available and diagnostic accuracy metrics were calculated. The majority of cases were in the 21-40 age group, predominantly affecting the parotid gland. Cytological-histopathological correlation showed variable accuracy across different lesion types. The diagnostic accuracy of FNAC was 87.00%, with sensitivity and specificity at 65.22% and 93.5% respectively. The risk of malignancy varied across MSRSGC categories, with the AUS category presenting a 100% risk. Pleomorphic adenoma was the most prevalent lesion, with notable misdiagnoses observed. The MSRSGC provides valuable risk stratification for salivary gland lesions, aiding in treatment decisions and patient counseling. Despite challenges, FNAC remains effective in distinguishing between benign and malignant lesions, demonstrating comparable diagnostic accuracy to previous studies. Standardized reporting systems like the MSRSGC contribute to improved consistency and reliability in diagnosing salivary gland lesions.

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Key Words

Fine-needle aspiration cytology, risk of malignancy, salivary gland lesions, the Milan system

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INTRODUCTION

Salivary gland fine-needle aspiration cytology (FNAC) is a globally utilized method for diagnosing and managing salivary gland tumours. This technique offers a minimally invasive, safe, cost-effective and precise method that is highly valuable for identifying a significant portion of salivary gland nodules as benign. As a result, it reduces the need for unnecessary invasive surgeries in patients with benign conditions. Furthermore, it provides guidance for the subsequent management strategy. The list[1,2,3,4] Multiple studies have consistently demonstrated the high accuracy of fine-needle aspiration cytology (FNAC) in distinguishing between neoplastic and non-neoplastic lesions, as well as benign and malignant neoplasms. The sensitivity of FNAC ranges from 86-100%, while the specificity ranges between 90% and 100%[5,6,7,8,9,10]. In addition, FNAC serves as a valuable tool for distinguishing between primary and metastatic lesions, particularly in cases of head and neck malignancies. This aids in the determination of the appropriate treatment plan[11]. Although salivary gland fine-needle aspiration cytology (FNAC) is a valuable and accurate tool for cytopathologists, it does present some challenges. These challenges include the wide variety and heterogeneity of salivary gland tumours, the morphological similarities between different malignant tumours, and even between benign and malignant tumours[12,13,14,15]. The accuracy of subclassifying neoplasms using FNAC varies significantly across different studies, ranging from 48-94%[1,6,13,16]. The cytomorphological features of basaloid cell component, oncocytoid changes, squamous metaplasia and cystic component pose a diagnostic challenge in FNAC. Several studies suggest utilising morphological pattern-based analysis to create a risk stratification method for classifying salivary gland neoplasms. This approach aims to determine the risk of malignancy (ROM) and provide guidance for additional ancillary tests and management plans[3,17,18]. Nevertheless, these studies exhibit significant disparity in the range of ROM across various categories, spanning from 6-100%, thereby lacking a unified consensus approach[17,19,20].

Another significant limitation is the inconsistency in the terminology used to report salivary fine needle aspiration cytology (FNAC). Different reporting formats have been utilized, ranging from a two-tiered scheme to six or more[16,21]. While certain individuals have attempted to classify based on histological category, others have explored alternative terminology such as atypical, suspicious and malignant[17,22]. The wide range of classifications made it challenging for the clinician to interpret the report and determine the appropriate management based on range of motion (ROM). Therefore, a standardized terminology for reporting salivary gland cytopathology was developed. The American Society of Cytopathology and International Academy of Cytology have recently introduced a hierarchical international classification system known as the "Milan System for Reporting Salivary Gland Cytopathology" (MSRSGC). This system offers a framework for clinical management based on the risk of malignancy in various categories[23,24]. The Multi-tiered System for Reporting and Grading of Cytology (MSRSGC) is a classification system that offers a consistent terminology and range of motion (ROM) for each category. This system helps to eliminate the uncertainty that is frequently encountered when interpreting Fine Needle Aspiration Cytology (FNAC). The present study was retrospectively conducted to reclassify the salivary gland lesions based on the previous FNAC diagnosis and to assess the range of motion in different categories.

MATERIALS AND METHODS

This is a prospective study conducted on all 100 cases of salivary gland lesions coming to Department of Pathology, Sri Aurobindo Medical College and PG Institute-Indore (M.P.) for FNAC. Patients of all ages, all genders were included in the study. Histopathological correlation was done wherever available. Smears of all the cases were air dried Giemsa stained and classified according to MSRSGC into six categories including nondiagnostic, non-neoplastic, atypia of undetermined significance, neoplasm (benign or salivary gland neoplasm of uncertain malignant potential), suspicious for malignancy and malignant. The risk of malignancy and diagnostic accuracy was assessed. Number of false positive, false negative, true positive and true negative were identified. Sensitivity, specificity, positive predictive value and negative predictive value were calculated.

RESULTS AND DISCUSSIONS

The (Table 1) presents the distribution of cases based on age, sex and the site of lesion in a sample population. In terms of gender, 58% were male and 42% were female. Regarding age groups, the majority of cases fell within the 21-40 age bracket, comprising 55% of the sample, followed by the 41-60 age group at 21%, with smaller proportions in the 0-20, 60-70 and over 70 categories at 10%, 12% and 1% respectively. In terms of the site of lesion within the salivary glands, the majority involved the parotid gland (61%), followed by the submandibular gland (27%) and other minor glands (12%). This data provides insight into the demographic and anatomical distribution of cases within the studied population. (Table 2) illustrates the correlation between cytological and histopathological cases. Among the cytological diagnoses, non-diagnostic cases amounted to 5, with 3 of them correlating with

Table 1. Distribution of cases according to age, sex and site of lesion

Variables	Frequency	Percentage
	Gender	
Male	58	58
Female	42	42
	Age group	
0-20		
	10	10
21-40		
	55	55
41-60		
	21	21
60-70		
	12	12
>70	01	01
	Salivary gland involved	
Parotid	61	61
Submandibular		
	27	27
Other minor glands	12	12

Table 2. Correlation between cytological and histopathological cases

Cytological diagnosis	No. of cases	No. of cases with histological correlation
Non diagnostic	05	03
Sialadenosis	10	08
Chronic Sialadenitis	06	06
Retention cyst	04	02
Pleomorphic adenoma	43	35
Basal cell adenoma	05	04
Oncocytoma	01	01
Warthins tumor	04	03
Lymphoepithelial cyst mucocele	02	01
Neoplasm of uncertain malignant potential	02	01
Suspicious of malignancy	03	02
Mucoepidermoid carcinoma	07	05
Acinic cell carcinoma	02	01
Ca ex pleomorphic adenoma	01	NIL
Epithelial myoepithelial carcinoma	01	NIL
Squamous cell carcinoma	01	01
Metastatic carcinoma	01	01
Lymphoma	02	02

Table 3. Categorisation of cases according to Milan system for reporting of salivary gland cytopathology along with risk of malignancy.

Category	No. of cases	Risk of malignancy
Non diagnostic I	05	1/3(33.3%)
Non neoplastic II	21	2/17(11.7%)
AUS III	01	1/1(100%)
Neoplasm IV Benign		
SUMP		
	53	3/43 (6.9%)
	02	1/1 (100%)
Suspicious of malignancy V	03	1/1(100%)
Malignant VI	15	10/10(100%)
Total	100	1/3(33.3%)

Table 4. Statistical comparison of the present study

	Present study (%)
Diagnostic accuracy	87.00
Sensitivity	65.22
Specificity	93.5
PPV	96.87
NPV	46.62
PPV- Positive predictive value, NPV- Negative predictive value	

Table 5. Comparison of risk of malignancy of various categories of Milan system of Study Participants

Category	Present Study
Non diagnostic (%)	33.3
Non neoplastic (%)	11.7
AUS	100
Neoplasm Benign SUMP	
	6.9
	100
Suspicious for malignancy (%)	100
Malignant (%)	100

histological findings. Sialadenosis had 10 cases, out of which 8 showed histological correlation, while chronic sialadenitis had 6 cases, all of which matched histological results. Similarly, retention cysts had 4 cases, with 2 demonstrating histopathological correlation. Pleomorphic adenoma had the highest frequency with 43 cases, of which 35 had corresponding histopathological findings. Basal cell adenoma had 5 cases, 4 of which correlated with histology, while oncocytoma and Warthin's tumor each had 1 case, all of which matched histopathological findings. Lymphoepithelial cyst mucocele had 2 cases, with 1 correlating with histology and neoplasm of uncertain malignant potential had 2 cases, 1 of which matched histopathological findings. Suspicious of malignancy had 3 cases, 2 of which showed histological correlation. Mucoepidermoid carcinoma had 7 cases, 5 of which were confirmed histologically, while acinic cell carcinoma had 2 cases, 1 of which matched histological results. Carcinoma ex pleomorphic adenoma and epithelial myoepithelial carcinoma each had 1 case with no corresponding histological correlation. Squamous cell carcinoma and metastatic carcinoma had 1 case each, both of which correlated with histological findings and lymphoma had 2 cases, both with histological correlation. This data offers insight into the alignment between cytological diagnoses and their histopathological confirmation. (Table 3) presents the categorization of cases according to the Milan system for reporting of salivary gland cytopathology, along with the associated risk of malignancy. The categories include Non diagnostic (I) with 5 cases, of which 1 out of 3 (33.3%) had a risk of malignancy. Non-neoplastic (II) comprised 21 cases, with 2 out of 17 (11.7%) presenting a risk of malignancy. Category AUS (Atypical of Undetermined Significance) III had 1 case, with a 100% risk of malignancy. Neoplasm (IV) Benign included 53 cases, with 3 out of 43 (6.9%) and 1 out of 1 (100%) showing risks of malignancy for SUMP (Salivary Gland Neoplasm of Uncertain Malignant Potential) and others respectively. Suspicious of malignancy (V) had 3 cases, all of which showed a 100% risk of malignancy. Finally, Malignant (VI) category encompassed 15 cases, all with a 100% risk of malignancy. In total, out of 100 cases, 1 out of 3 (33.3%) presented a risk of malignancy. This table offers a comprehensive overview of the categorization of salivary gland cytopathology cases along with their respective risks of malignancy based on the Milan system.

In the present study, the diagnostic accuracy was recorded at 87.00%, indicating the overall effectiveness of the diagnostic methods employed. Sensitivity, representing the ability to correctly identify positive cases, stood at 65.22%, while specificity, the capacity to accurately detect negative cases, was notably higher

at 93.5%. The Positive Predictive Value (PPV), indicating the probability of true positive cases among all positive results, reached 96.87%, underscoring the reliability of positive diagnoses. However, the Negative Predictive Value (NPV), reflecting the likelihood of true negative cases among all negative results, was relatively lower at 46.62%. These metrics collectively illustrate the performance and accuracy of diagnostic procedures within the scope of the present study.

(Table 5) compares the risk of malignancy across various categories of the Milan system within the study participants. In the Non diagnostic category, 33.3% of cases were associated with a risk of malignancy. For the Non neoplastic category, the risk was lower at 11.7%. AUS (Atypical of Undetermined Significance) category presented a 100% risk of malignancy. Within the Neoplasm Benign (SUMP) category, 6.9% of cases were associated with a risk of malignancy, while the rest were benign. Cases categorized as Suspicious for malignancy and Malignant both demonstrated a 100% risk of malignancy. This table highlights the varying levels of malignancy risk across different diagnostic categories within the Milan system as observed in the study participants. FNAC is widely used by clinicians as an initial diagnostic tool because it is easy to perform and provides rapid diagnosis. This technique is characterized by its minimal invasiveness, rapidity and cost-effectiveness, making it highly efficient for use in outpatient settings[6,25].

The clinical utility of FNAC extends beyond neoplastic conditions. Additionally, it holds significant worth in the identification of inflammatory, infectious and degenerative ailments. This method is primarily suitable for superficial lesions. Accurate and conclusive FNAC results rely on samples that are representative of the lesion being examined, contain sufficient cells and other tissue components and are properly prepared and processed. However, this technique is subject to certain limitations. Primarily, the reliability and precision of the results are heavily contingent upon the quality of the samples and smears. Pathological processes often exhibit heterogeneity and the small samples obtained through fine needle procedures may not accurately represent the overall condition. Certain lesions are primarily identified based on their micro architectural patterns, which may not be adequately captured in cytological preparations. Insufficient samples are a difficulty encountered during fine-needle aspiration cytology (FNAC). This may be attributed to the lesion's small size, deep location, or the presence of dense fibrosis or sclerosis within the lesion. Moreover, the presence of overlapping morphological characteristics and the heterogeneity in cytomorphology within the same lesions pose challenges in accurately identifying and subcategorizing a specific salivary gland lesion. Accurate diagnosis of the lesions relies on the presentation, clinical history and effective communication between clinicians and pathologists. In order to enhance the quality of care and consistency in diagnosing salivary gland lesions, a category-based system called the Milan system was implemented. Griffith *et al*. proposed an adequacy criterion stating that the presence of epithelial cells should be observed in more than four high power fields[16]. Currently, the Milan system suggests a minimum of 60 lesional cells for diagnosing salivary lesions[26].

Cystic lesions are another factor contributing to false negative cases. A cyst lesion can be classified as nonneoplastic, benign, or malignant. Examples of nonneoplastic cysts include retention cysts, while benign cysts can include warthins tumours. On the other hand, malignant cysts can include mucoepidermoid carcinomas. Aspirating only fluid in these cases can result in a diagnostic pitfall. The aspirated fluid exhibits a low cell count, making the diagnosis in such instances particularly arduous and demanding. After aspirating the fluid from a cystic lesion, it is important to palpate the area to identify any solid regions. A subsequent attempt should then be made to aspirate from these solid areas. Additionally, guided FNAC can be beneficial in such instances to extract a sample from the specific region. During the current investigation, two cystic lesions were initially misdiagnoses as retention cysts based on cytology, but were later determined to be low grade mucoepidermoid carcinomas upon histopathological examination. One of these cases was reclassified as AUS category according to the Milan system due to the presence of a small number of atypical cells with very low cellularity. The current study exhibited a male to female ratio of 3:2, which is consistent with previous research[26,27]. The parotid gland was the most frequently affected, followed by the submandibular gland and minor salivary glands. Kala and Sonal *et al.*[26,28,30] reported similar findings. The current study exhibits a sensitivity of 65.22% and specificity of 93.5%, with a diagnostic accuracy of 87% in distinguishing between benign and malignant lesions. This is analogous to other studies conducted by Manju Kumari *et al*. Zubair *et al*. Santosh *et al*. and Katta *et al*.[30,29,30,31].

The most prevalent lesions in this study are sialadenosis (47.61%, 10/21), pleomorphic adenoma (81.13%, 43/53) and mucoepidermoid carcinoma (46.66%, 5/15) among the non-neoplastic, benign and malignant conditions. The prevalence of chronic sialadenitis was consistent with previous research findings. However, the prevalence of

mucoepidermoid carcinomas was greater compared to previous research findings[32,33]. The current study observed the highest number of cases in category IV (55%), followed by category II (21%) and category VI (15%), which aligns with the findings of previous studies conducted by Manju *et al*. Sheetal *et al.* and Yogambal *et al*.[30,26-37]. Pleomorphic adenoma is characterized by a chondromyxoid background, but it can be challenging to diagnose due to similarities with hyaline globules or basement membrane-like material. In our study, two cases each of basal cell adenoma and adenoid cystic carcinoma were mistakenly identified as pleomorphic adenoma. Two instances of pleomorphic adenoma and adenoid cystic carcinoma were erroneously identified as basal cell adenoma. The AUS category is used for lesions that exhibit minimal atypia and cannot definitively exclude a neoplastic process. The incidence of cases diagnosed as Atypical Salivary Gland Neoplasms (AUS) is anticipated to be less than 10% of all Fine Needle Aspiration (FNA) procedures performed on salivary glands. In this particular study, the group in question had a solitary case, which accounted for only 1.1% of the total.

On histopathology, the ROM (Rate of Malignancy) of this category was 100%, which is higher because there was only one case in this category and it was confirmed to be malignant on histopathology. This variation in the range of the reported ROM (0-73%) in previous studies could have influenced the results of the present study. However, it is worth noting that the ROM reported in the study conducted by Manju *et al*. and Kala *et al*.[32,29] was consistent with our findings. Esther *et al.* presented an updated version of the Milan Classification System for Salivary Gland Tumours. The purpose of this update is to highlight potential diagnostic challenges and differential diagnoses. The goal is to establish a standardized and practical reporting system that takes into account the risks of malignancy[26]. The current study demonstrated that the risk of cancer, the precision of diagnosis and the ability of FNAC to distinguish between benign and malignant salivary gland lesions at our institution were similar to those reported in other studies, as indicated in (Table 5 and 6).

CONCLUSION

The Milan system of reporting salivary gland cytopathology offers risk stratification by assessing the likelihood of malignancy. This information is valuable for determining patient counseling and treatment decisions. It minimizes both the occurrence of false positive and false negative cases in FNAC.

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