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Original Research Article

A THREE-YEAR RETROSPECTIVE STUDY OF THE CYTOPATHOLOGICAL SPECTRUM AND HISTOPATHOLOGICAL CORRELATION OF SALIVARY GLAND LESIONS AND CLASSIFICATION ACCORDING TO THE MILAN SYSTEM

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ABSTRACT

Background: Fine needle aspiration cytology (FNAC) is a minimally invasive and useful procedure for evaluating salivary glands lesions worldwide. Diverse morphological patterns in salivary gland lesions make diagnosis challenging at times hence the Milan system of reporting was introduced to overcome this difficulty.

Material and Methods: This is a three-year retrospective study from January 2023 to January 2026 conducted on 49 cases of salivary gland lesions and smears were stained with May-Grünwald Giemsa stain, Haematoxylin & Eosin and Papanicolaou stains. Smears of old cases were retrieved from records and reclassified according to Milan system for reporting salivary gland cytology. Histopathological comparison was done wherever possible and sensitivity, specificity, positive predictive value, negative predictive value, diagnostic accuracy of FNAC for diagnosing benign and malignant lesions and risk of malignancy for each category was calculated.

Results: 49 salivary gland lesions were included in the study with most common age group being 61-70 years (23.28%) and male to female ratio of 2:1. Acute and chronic sialadenitis (10.2% each) were the most common non-neoplastic lesions and Pleomorphic adenoma (16.32%) was the most common benign lesion. The commonest malignancy was mucoepidermoid carcinoma (8.16%). Histopathology was received for 30 cases. Statistical analysis revealed the Sensitivity, Specificity, Positive predictive value, Negative predictive value and Diagnostic accuracy as 79.3% ,100%, 100%, 93.75% and 94.73% respectively.

Conclusion: FNAC is a simple and cost-effective procedure with high sensitivity, specificity and accuracy which makes it a reliable diagnostic tool for rapid and early diagnosis of salivary gland lesions.

Keywords: Salivary gland lesions, Pleomorphic adenoma, Mucoepidermoid carcinoma, Milan system.

INTRODUCTION

Salivary glands are the organs that produce and secrete saliva. These include three major (parotid, submandibular, sublingual) and numerous minor glands throughout the mouth and oropharynx.[1] Fine needle aspiration cytology (FNAC) is a minimally invasive useful procedure for evaluating lesions of salivary glands worldwide. It has advantage over incisional biopsy and frozen section due to its low cost, minimum morbidity, rapid turn-around time, high accuracy in diagnosing various non neoplastic and neoplastic lesions and differentiating benign from malignant.[2,3,4] Thus, it helps in eliminating unnecessary surgeries for non-neoplastic lesions and planning further treatment strategy in neoplastic cases.[3,5] Various studies have shown high sensitivity (62 to 97%), specificity (80 to 100%), and accuracy

(86 to 98%) of FNAC in salivary gland neoplasms.[6-10] Despite this, diverse morphological patterns and overlapping features of various salivary gland lesions make accurate diagnosis challenging at times hence making the management difficult.

To overcome this, the American Society of Cytopathology (ASC) and the International Academy of Cytology (IAC) proposed a six tiered international classification system called Milan system for reporting of salivary gland cytopathology (MSRSGC)in 2015. It is a standard and uniform reporting system which provides the diagnostic criteria, risk stratification and plan of management of various categories. This study was conducted to observe the cytomorphological spectrum of various salivary gland lesions in IRPGIMSR and NRCH, New Delhi and reclassify them according to Milan system.

MATERIALS AND METHODS

his is a three year retrospective study from January 2023 to January 2026 conducted on all cases of salivary gland lesions coming for Fine needle aspiration to department of pathology, IRPGIMSR and NRCH, New Delhi and included a total of 49 cases. As this was a retrospective study, the informed consent was waived. However, patient confidentiality is strictly maintained. Patients of all ages and gender were included in the study and clinically evaluated by detailed history and examination. Aspirations were performed from different sites of the salivary gland swelling by the standard procedure using a 23-gauge needle and 10-ml syringe. Air-dried smears were stained with May-Grünwald Giemsa (MGG) stain and alcohol fixed smears were stained with Haematoxylin and Eosin (H&E) and Papanicolaou(Pap) stains. Smears of old cases were retrieved from the records and were reclassified according to Milan system of reporting salivary gland cytology 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. We compared the histopathological findings with the FNAC diagnosis wherever possible and calculated sensitivity, specificity, positive predictive value, negative predictive value, diagnostic accuracy of FNAC for diagnosing benign and malignant lesions and risk of malignancy for each category. The statistical analysis was performed by correlating the cytological diagnosis with histopathological findings to calculate sensitivity, specificity, PPV, NPV and diagnostic accuracy. The cases with available histopathological correlation were included in the statistical analysis.

RESULTS

A total of 49 salivary gland lesions were examined cytologically during the study period, 69.4% were males, and 30.6% females with a male to female ratio of 2:1. Most patients were in their 6th decade with mean age of 65 years [Table1]. The most frequent site of involvement was the parotid gland (61.22%) [Table 2]. The cases were distributed according to the MSRSGC categories. The majority of cases belonged to category II (non-neoplastic-30.6%), followed by category IV a (benign-26.53%) of Milan. Acute and chronic sialadenitis (10.2%each) were the most common nonneoplastic lesion and Pleomorphic adenoma (16.32%) was the most common benign lesion. The commonest malignancy was mucoepidermoid carcinoma (8.16%) [Table2]. Out of 49 cases, histopathology was received for 30 cases. Among these, 23 cases had the similar diagnosis as in cytology [Table 3]. The risk of malignancy for each category was calculated [Table 3]. For the statistical analysis, Milan categories V and VI were considered to be malignant, while II and IVa were benign. The categories I, III and IVb were excluded from statistical calculation. Statistical analysis revealed the Sensitivity, Specificity, Positive predictive value, Negative predictive value and Diagnostic accuracy as 79.3% ,100%, 100%, 93.75% and 94.73% respectively.

Table 1: Age and gender distribution of the salivary gland lesions

Age group	No. of cases(%)	Male(%)	Female(%)
0-10	1(2.04)	0	1(2.04)
20-Nov	0	0	0
21-30	2(4.08)	1(2.04)	1(2.04)
31-40	6(12.24)	5(10.20)	1(2.04)
41-50	8(16.32)	6(12.24)	2(4.08)
51-60	8(16.32)	7(14.9)	1(2.04)
61-70	18(36.73)	10(20.40)	8(16.33)
71-80	5(10.2)	4(8.16)	1(2.04)
81-90	1(2.04)	1(2.04)	0
Total	49(100%)	34(69.4%)	15(30.6%)

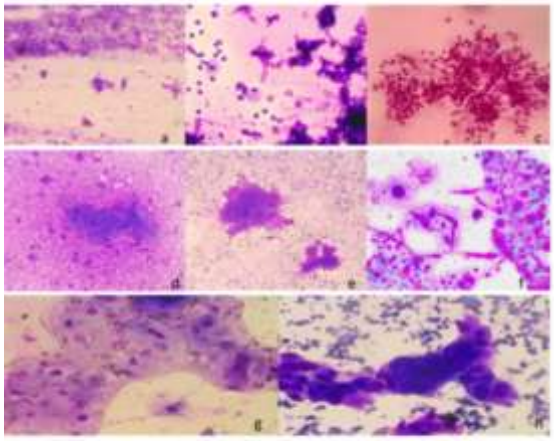
Table 2: Distribution of lesions based on salivary gland involved, cytology diagnosis and categorization according to Milan system (n=49)

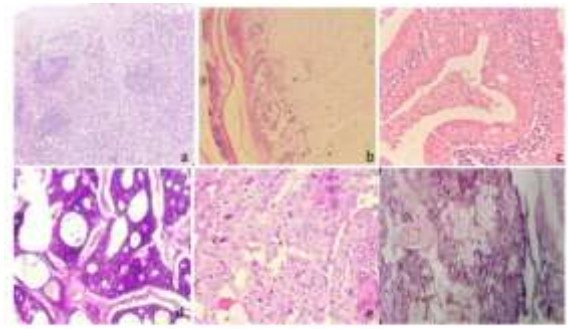
Diagnostic categories of Milan System	FNAC Diagnosis	Parotid (%)	Submandibular (%)	Minor (%)	Total (%)
I.Non-diagnostic(10.2%)	Inadequate cellularity	1	0	1	2(4.08)
	Acinar cells only	0	1	1	2(4.08)
	Cystic lesion	0	0	1	1(2.04)
II.Non-neoplastic (30.6%)	Sialadenosis	1	1	0	2(2.04)
	Acute Sialadenitis	1	4	0	5(10.2)
	Chronic Sialadenitis	3	2	0	5(10.2)
	Lymphoepithelial cyst	1	0	0	1(2.04)
	Retention cyst	0	0	2	2(4.08)
III. Atypia of undetermined significance [AUS] (2.04%)	Paucicellular with chondromyxoid stroma	1	0	0	1(2.04)
IV. Neoplasm - A. Benign (26.53%)	Pleomorphic adenoma	6	2	0	8(16.32)
	Warthins tumor	2	1	0	3(6.12)
	oncocytoma	1	0	0	1(2.04)
	sialolipoma	1	0	0	1(2.04)
IV. Neoplasm – B. Salivary gland neoplasm of uncertain malignant potential (SUMP) (2.04%)	SUMP with basaloid features	0	0	1	1(2.04)
V. Suspicious for malignancy (6.12%)	Possibility of Malignant epithelial lesion	1	0	0	1(2.04)
	Possibility of Metastatic deposits	2	0	0	2(4.08)
VI.Malignant (22.45%)	Mucoepidermoid Carcinoma	3	1	0	4(8.16)
	Adenoid cystic carcinoma	0	0	1	1(2.04)
	Acinic cell carcinoma	1	0	0	1(2.04)
	Metastasis -squamous cell ca - NHL	3 2	0 0	0 0	3(6.12) 2(4.08)
	TOTAL	30(61.22%)	12(24.5%)	7(14.3%)	49(100%)

Table 3: Comparison of FNAC with histopathology (30 cases)

	FNAC Diagnosis	No. of cases	No. of HPE cases	HPE Finding	Risk of Malignancy (%)
I. 5	Inadequate cellularity	2	1	Pleomorphic adenoma	0%
	Acinar cells only	2	1	sialadenosis	
	Cystic lesion	1	0	-	
II. 15	Sialadenosis	2	0	-	0%
	Acute sialadenitis	5	0	-	
	Chronic sialadenitis	5	3	Chronic sialadenitis	
	Lymphoepithelial cyst	1	1	Warthins tumor	
	Mucus Retention cyst	2	1	mucocele	
III. 1	Paucicellular with chondromyxoid stroma	1	1	Pleomorphic adenoma	No. of cases in Milan category
IVA. 13	Pleomorphic adenoma	8	8	Pleomorphic adenoma	0%
	Warthins tumor	3	3	Warthins tumor	
	oncocytoma	1	1	oncocytoma	
	sialolipoma	1	0		
IVB. 1	SUMP with basaloid features	1	1	Adenoid cystic carcinoma	100%
V. 3	Possibility of malignancy	1	1	Acinic cell carcinoma	100%
	Possibility of metastasis	2	2	MEC	
VI.11	MEC	4	3	MEC	54.54%
	Adenoid cystic carcinoma	1	1	Adenoid cystic carcinoma	
	Acinic cell carcinoma	1	0	-	
	Metastasis				

	- Squamous cell ca - NHL	3 2	1 1	Squamous cell ca NHL	





DISCUSSION

The present study evaluate the cytomorphological spectrum of salivary gland lesion using FNAC and assesses its diagnostic accuracy by applying the Milan system for reporting salivary gland cytology with histomorphological correlation in available cases. Salivary gland lesions can be classified into nonneoplastic, benign and malignant and show wide variation in clinical features and morphological pattern. FNAC aims at distinguishing these lesions and further subtyping wherever possible thus aiding the clinician to plan better management for the patient and avoid unnecessary surgery. The present study included 49 cases of salivary gland lesions. The mean age in our study was 65 years which was not similar to the findings of Rohilla M et al,[7] (43.7 years), Naz et al,[11] (42 years) and Ghartimagar et al,[12] (40.01 years). However in studies by Balmiki Datta et al,[16] and Vaidya S et al,[17] mean age was 35 years and 38 years respectively. The higher mean age observed in the study may be attributed to better accessibility to healthcare for elderly patients in our set up. There were 34 males and 15 females with male to female ratio of 2:1 similar to Ambedkar et al,[13] (1.7:1) and Rohilla M et al,[7] (1.7:1). However in study by Ghartimagar et al,[12] females were affected more than males with male to female ratio of 1:1.36, whereas Naz et al,[11] showed equal distribution in both males and females (1:1). The male predominance observed in the present study is consistent with most published literature and reflects regional and lifestyle related failures. Most frequent gland involved in our study was parotid gland (61.22%) followed by submandibular gland (24.5%) and minor salivary glands (14.3%). Ghartimagar et al,[12] Vaidya S et al,[17] Koirala S et al,[18] and Balmiki Datta et al,[16] showed similar findings. Literature also shows that Parotid gland is the most common gland affected by salivary gland neoplasms.[19] The larger volume of parotid tissue and its higher susceptibility to both inflammatory and neoplastic processes may be attributed to parotid predominance. According to MSRSGC Category I (Non-diagnostic) consists of lesions which have insufficient cellular material that is less than 60 lesional cells, nonneoplastic acinar cells only, non-mucinous cyst fluid only and poorly prepared slides with artifacts (air drying, obscuring blood, poor staining etc). Our study showed 10.2 % non-diagnostic cases which is similar to Naz et al,[11] (4.3%). Studies by Tochtermann et al,[14] Balmiki Datta et al,[16] and Sandhu V K et al,[15] showed 8%, 8.7% and 11.7% non-diagnostic cases respectively. A repeat FNAC or USG guided FNAC can be done to reduce false negative outcomes. Category II (Non-neoplastic) constitutes highest 30.6% lesions in our study which is similar to studies by Ambedkar et al,[13] (45.5%) and Sandhu VK et al.[15] (41.17%). Acute sialadenitis [Fig.1.a] was the commonest among them. This may be because it presents with pain and fever for which patient seeks early medical consultation. Retention cyst was the least common [Fig.1.b]. Out of the 5 cases of Chronic sialadenitis on cytology, histopathology was received for 3 cases which had similar diagnosis[Fig.2.a] . Correct identification of non neoplastic lesions is crucial to avoid unnecessary surgical intervention as it can be managed conservatively. Category III (Atypia of undetermined significance) involves lesions with limited cellular atypia which lacks qualitative and quantitative features for diagnosing a neoplasm. The percentage of this category in our study was 2.04% which is similar to study done by Ambedkar et al,[13] (1.29%). FNAC yielded myxoid stroma only which later on in histopathology was diagnosed as Pleomorphic adenoma [Fig.2.b]. AUS reflects inherent limitation of FNAC in cases of low cellularity or partial sampling and thus highlights the importance of close clinical and radiological correlation.

The percentage of Category IVa (Benign neoplasm) was 26.53% in our study. Pleomorphic adenoma (16.32%) was the commonest [Fig.1.c] followed by

Warthin's tumour (6.12%)[Fig.1.d]. Similar findings were noted in many other studies.[11-13,15-18]

Literature also states that pleomorphic adenoma is the most common benign salivary gland neoplasm followed by Warthin's.[19] Out of 13 cases in IVa category histopathology was received for 12 cases and all were in concordance with cytopathological findings i.e 8 Pleomorphic adenoma , 3 Warthin's tumour [Fig.2.c] and 1 oncocytoma. 100% cytohistopathological concordance in benign neoplasm in the present study confirms the reliability of FNAC in diagnosing benign salivary gland tumors.

Category IV b (Salivary gland neoplasm of uncertain malignant potential) includes cases with cytomorphologic features diagnostic of neoplasm but indefinite for a specific tumour type to distinguish it between benign and malignant. In our study we received only 1 case of SUMP on cytology which showed basaloid features [Fig.1.e] which on histopathology was reported as Adenoid cystic carcinoma [Fig.2.d]. Although limited in number SUMP remains clinically significant, as these lesions warrant surgical excision due to their substantial risk of malignancy. Category V (Suspicious for malignancy) shows features that are highly suggestive of but not unequivocal for malignancy. The percentage of this category in our study was 6.12% while Balmiki Datta et al,[16] showed 1.80% and Ambedkar et al,[13] showed 1.29% such cases in their study. On cytology 1 case was reported as Possibility of malignant epithelial lesion [Fig.1.g] and 2 cases as Possibility of metastatic deposits which later on histopathology were reported as Acinic cell carcinoma [Fig.2.e] and Mucoepidermoid carcinoma [Fig.2.f] respectively. This is the grayzone of FNAC interpretation where limited atypical cytomorphological features necessitate histopathological examinationfor confirmation.

In Category VI, we received 11 Malignant cases (22.45%) on cytopathology with Mucoepidermoid carcinoma [Fig.1.h] being the commonest (4;8.16%). Similar findings were seen in study conducted by Ambedkar et al,[12] (3.8%), Koirala S et al,[18] (7.46%) and Ghartimagar et al,[11] (62.5%). Literature also states Mucoepidermoid carcinoma to be most common salivary gland malignant neoplasm.[19] Out of the 4 cases, histopathology was done for only 3 which showed concordance with FNAC diagnosis. The other malignancy on cytology was Adenoid cystic carcinoma [Fig.1.f] for which histopathology was received and confirmed the diagnosis. The risk of malignancy for each category (I,II,III,IVa,IVb,V,VI) in our study was calculated to be 0,0,0,0,100,100 and 54.5 % respectively which showed wide variation from Milan and studies by Ambedkar et al,[13] and Balmiki et al.[16] The reason for low ROM in our study may be attributed to incomplete HPE, follow up and sample size. The Sensitivity, Specificity, Positive predictive value, Negative predictive value and Diagnostic accuracy in our case was 79.3% ,100%, 100%, 93.75% and 94.73% respectively which was nearly similar to Rohilla M et al,[7] (79.4%,98.3%,96.4%,89.2% and 91.4% respectively), Balmiki Datta et al,[16] (75%, 100 %, 100%,95% and 95.65% respectively) and Vaidya S et al,[17] (81.82%, 100 %, 100%, 95.9% and 96.55% respectively). The slight variation from other studies may be due to variation in the number of cases.

Limitations: Factors affecting final diagnosis such as aspiration site (as in solid cystic tumors), smearing and staining quality. Immunohistochemistry and molecular studies were not available. Histopathology was not available for maximum cases because surgeries were withheld during COVID period. The retrospective nature of the study and limited histopathological follow up may have influenced risk of malignancy calculation(ROM). Despite these limitations, the study provides valuable insight into the application of Milan system in routine cytopathological evaluation of salivary gland lesions.

CONCLUSION

FNAC is a simple and cost-effective procedure with high sensitivity, specificity and accuracy making it a reliable diagnostic tool for early diagnosis of salivary gland lesions, especially for developing countries. However, due to heterogeneity and diversity of these lesions, a standard and uniform reporting system called Milan system is helpful which provides universal reporting protocol and better understanding of lesion in relation to risk stratification and their clinical management. This also reduces descriptive ambiguity and false positive interpretation on FNAC. Using standardized reporting protocol like the Milan system for reporting for salivary gland enhances the communication between pathologist and clinician and facilitates appropriate patient management.

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