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Original Research Paper

Pathology

EVALUATION OF ACCURACY OF MILAN SYSTEM FOR REPORTING SALIVARY GLAND CYTOPATHOLOGY AND RISK STRATIFICATION

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ABSTRACT **Introduction:** Salivary gland tumours comprise around 3–10% of head and neck neoplasms. Fine-needle aspiration (FNA) is the first line investigation for preoperative diagnosis of salivary gland lesions and for identifying the malignant potential of a tumour but because of its intratumoral heterogenecity, diversity and morphological overlap challenging the cytopathologist "The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was introduced to provide diagnosis and better management according to the risk of malignancy (ROM) in different categories. **Methodology:** A total of 100 specimen were evaluated cytologically and histopathologically. The histopathological findings were compared with the pre-operative cytology of the FNAC specimens. The risk of malignancy (ROM) and the overall risk of malignancy (OROM) were also calculated. **Results:** Amongst the non-neoplastic lesions, Chronic sialadenitis was the most common. Pleomorphic adenoma (47.9%) and Mucoepidermoid carcinoma (11.26%) were the most common benign and malignant salivary gland neoplasms respectively. According to the MILAN system, the risk of malignancy was 20%, 6.6%, 50%, 3.3%, 50%, 100% and 100% in category I, II, III, IVA, IVB , V and VI respectively. The overall risk of malignancy was 14.2%, 4.5%, 25%, 2.2%, 33.3%, 75% and 50% in category I, II, III, IVA, IVB, V and VI respectively. A sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of 84.6%, 100%, 100%, 96.29% and 96.9% respectively. **Conclusion:** The current investigation validates the diagnostic value of MSRSGC and helps guide the treatment of salivary gland diseases in clinical practice.

KEYWORDS : Risk of malignancy, fine needle aspiration, salivary gland tumours, benign, malignant

INTRODUCTION

Fine-needle aspiration cytology (FNAC) of salivary gland is used world-wide for the diagnosis and management of salivary gland tumors. (1)

In addition, FNAC of salivary gland has the potential to restrict the need for surgery of non-neoplastic salivary lesions, thereby reducing the possible risk of intraoperative tumours implantation and facial nerve damage.(2-4)

It provides a minimally invasive, safe, cost-effective and accurate technique that is extremely useful in identification of benign lesion also.

Apart from this, FNAC is a useful tool to differentiate between primary vs metastatic lesions specially head and neck malignancies and thus helping in deciding the treatment plan. (5)

The probability of malignancy of salivary gland neoplasms increases with gland size. Since certain neoplasms are quite frequent, they may simulate a distinct mass of non-neoplastic disease of the salivary gland. The average risk of malignancy for this group, which is categorized as non-neoplastic, is between 0% and 20%. Owing to the frequent suspicion of malignancy, it is imperative that salivary gland FNA be performed on the same patient population. It may also occur simultaneously as the neoplastic lesion. Careful clinicoradiological correlation is required to prevent false negative FNA. The incidence of malignancy rises from 20% to 25% in the parotid gland, to 40%-50% in the submandibular gland, and to 50%-81% in the sublingual glands and minor salivary glands (6-9). These tumor have a propensity to spread quickly, thus early identification and intervention are essential. (10,11,12)

Salivary glands' complex tissue composition and varied form make cytology reporting more challenging. (13-17). The intricacy of salivary gland cytology has been exacerbated by the absence of a consistent risk classification reporting system. The bulk of published data support the value of FNA in the diagnosis of disorders of the salivary glands, notwithstanding notable limitations. A number of investigations reveal excellent sensitivity and specificity. (18-21).

The ability of FNA to distinguish between benign and malignant salivary gland lesions is highly accurate. However, its accuracy in identifying neoplasm subtypes varies. (22-27). A standardized reporting system called the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was developed to get over the aforementioned restrictions and improve communication between clinicians and pathologists. A thorough diagnostic method, the MSRSGC divides cytology results for salivary gland diseases into seven levels. There are appropriate management techniques and a corresponding risk of malignancy (ROM) for each category [28-30]. Furthermore, the MSRSGC has undergone three updates: (a) clarifying the definition of specimen adequacy; (b) a specimen containing only mucus being defined as "atypia of undetermined significance" for the possibility of

mucoepidermoid carcinoma (MEC); (c) the creation of the SUMP category to accommodate for the diagnostic gray zone of rare and morphologically overlapping neoplasms from benign to low-grade malignancy.[28]

The main aim of the MSRSGC is to develop a system that is easy to use and will enhance and establish consistent communication between cytopathologists and clinicians. (31,32) This study was conducted to assess the utility of MSRSGC categorization on FNA specimens of salivary gland lesions. Further, the risk of malignancy (ROM) in non-neoplastic and neoplastic cases of salivary gland was stratified to guide for further ancillary test and management plan. We also aimed to confirm the validity and diagnostic accuracy of MSRSGC by histopathological follow up.

Methodology

This was a prospective/observational study conducted in the department of Pathology, B R D Medical College, Gorakhpur, U.P over a period of 1 year (March 2023 to April 2024). The study was approved by the institutional ethical committee. The study was carried out on the patients of all salivary gland swellings coming to outpatient department and admitted. In this study the salivary gland lesions were classified by using MSRGS categories. The histological reports and clinical follow up wherever available were compared.

All patients presenting with salivary gland swelling were explained about the procedure in detail and written informed consent was obtained for the same. Detailed clinical examination was performed on all the patients and required variables were recorded. Patients were explained about the procedure. Aspiration was performed under aseptic conditions. All salivary gland swelling including parotid, submandibular, sublingual or minor salivary gland lesion were aspirated via percutaneous or sometimes intraorally with a 22-23 gauze needle with or without ultrasound guidance wherever needed. The needle was inserted into the lesion and to and fro movement was performed. The material was then aspirated. It was later spread over clean labelled slides and smears were prepared. This procedure was repeated at different sites varying from 2-6 slides smeared with aspirate for H&E and Pappanicolaou stain smear. Slides for wet smears were fixed in 95% alcohol, while the other were air dried.

The cytological features were evaluated and then cases were reclassified according to MSRGS as follows-

Table 1- The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC)

Diagnostic category	Diagnosis
I	Non-diagnostic (ND)
II	Non-neoplastic (NN)
III	Atypia of Undetermined Significance (AUS)
IV	Neoplasm
A	Benign neoplasm
B	Salivary gland Neoplasm of Uncertain Malignant Potential (SUMP)
V	Suspicious For Malignancy
VI	Malignant (M)

Statistical Analysis

All relevant data was collected and appropriate statistical tools were applied to analyse the data. Analysis was done by data sorting method, classified by tabulation and presentation by pie charts and histograms

RESULTS

Out of 100 cases of salivary gland lesion, 7 (7%) cases were non-diagnostic, 22 (22%) were non-neoplastic, 4(4%) were atypia of undetermined significance and 44(44%) were benign neoplasms. Amongst the non-neoplastic lesions, the incidence of Chronic sialadenitis was highest i.e. 8(36.3%), followed by Acute sialadenitis 6(27.2%), Sialadenosis 3(13.7%), Mucocele 3(13.7%) and Granulomatous sialadenitis 2(9.10%). Amongst the Benign Neoplastic lesions, Pleomorphic adenoma 34(47.9%) was the most common followed by Warthin tumour 7(9.86%). Out of 16 malignant cases, Mucoepidermoid carcinoma 8(11.26%) was the most common followed by Adenoid cystic carcinoma 4(5.64%).

Most of the participants were 41-50 years (27%) of age followed by 22% belonging to the 31-40 year age group. 53% of the participants were males (Table 2). Majority of the cases were present in parotid gland (47%) followed by submandibular gland (39%) (Table 2). Among the cases available for histopathology, 4, 14, 1, 29, 1, 0 and 0 benign cases respectively belonged to category I, II, III, IVA, IVB, V and VI. Similarly, 1,1,1,1,13,8 malignant cases belonged to category I, II, III, IVA, IVB, V and VI respectively. Out of 100 cases evaluated cytologically, histopathology was available for 65 cases. Among those histopathologically evaluated, from the category I, 3 were pleomorphic adenoma, 1 was Warthin's tumour and 1 was diagnosed as low grade MEC. Amongst the category II cases, 15 were available for histological follow-up out of which 14 cases were confirmed as benign and were in concurrence with the FNA diagnosis while 1 was diagnosed as high grade MEC on histopathological examination. Of the 4 cases assigned to category III, 2 were available for histopathological follow up, among which 1 was found to be pleomorphic adenoma while the other was diagnosed as carcinoma ex pleomorphic adenoma on histopathological examination. From the category IVA, 30 were available for histopathological follow up, among which 29 were in concordance with the FNA diagnosis while 1 was diagnosed as adenoid cystic carcinoma. In category IVB, 2 were available for histopathology, out of which 1 was diagnosed as adenoid cystic carcinoma while 1 was diagnosed as basal cell adenoma on histopathological examination. In case of category V, 3 were available for histopathological follow up and all were confirmed as malignant. 2 cases of MEC, one case of adenoid cystic carcinoma were available for histopathological follow up. Among the category VI, 8 were available for histopathology and all were confirmed as malignant neoplasms. (Table 3)

According to the MILAN system, the risk of malignancy was 20%, 6.6%, 50%, 3.3%, 50%, 100% and 100% in category I, II, III, IVA, IVB , V and VI respectively. The overall risk of malignancy was 14.2%, 4.5%, 25%, 2.2%, 33.3%, 75% and 50% in category I, II, III, IVA, IVB, V and VI respectively. A sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of 84.6%, 100%, 100%, 96.29% and 96.9% respectively (Table 5). 52 true negative, 11 true positive and 2 false negative cases were observed in the study. There were no cases of a false positive.

Table 2: Clinicopathological Profile Of Salivary Gland FNACs

S. No	Feature	Categories	No. of cases	Percentage
1	Age	1-10	7	7
		11-20	6	6
		21-30	13	13
		31-40	22	22
		41-50	27	27
		51-60	13	13
		>61	12	12
2	Gender	Male	53	53
		Female	47	47

3	Site	Parotid gland Submandibular gland Other minor salivary gland	63 30 7	63 30 7

Table 3 : Cytohistological correlation with definitive histological diagnosis of lesion of salivary gland

Category	Cytology number of cases	Cytological diagnosis	HPE number of cases	Histopathological diagnosis
I Non-Diagnostic	7		5	Pleomorphic Adenoma (N=3) Warthin's tumor (N=1) Low grade MEC (N=1)
Ii Non-Neoplastic	22	Chronic Sialadenitis (N=8) Acute Sialadenitis (N=6) Sialadenosis (N=3) Mucocele (N=3) Granulomatous sialadenitis (N=2)	15	Chronic Sialadenitis (N=7) Acute Sialadenitis (N=4) Sialadenosis (N=1) Mucocele(N=2) High grade MEC N=1)
Iii Atypia Of Undetermined Significance	4		2	Pleomorphic Adenoma (N=1) Carcinoma ex Pleomorphic Adenoma (N=1)
Iva Benign Neoplasm	44	Pleomorphic Adenoma (N=33) Warthin's tumour (N=7) Basal cell adenoma (N=3) Lipoma (N=1)	30	Pleomorphic Adenoma (N=23) Warthin's tumour (N=4) Basal cell adenoma (N=2) AdCC (N=1)
Ivb Salivary Gland Neoplasm Of Uncertain Malignant Potential	3		2	AdCC(N=1) Basal cell adenoma(N=1)
V Suspicious For Malignancy	4		3	MEC(N=2) AdCC(N=1)
Vi Malignant Neoplasm	16	Mucoepidermoid carcinoma (N=9) Adenoid cystic Carcinoma(N=3) Salivary duct carcinoma(N=1) Acinic cell carcinoma(N=1) Squamous cell carcinoma (N=2)	8	Low grade MEC (N=3) AdCC (N=3) Salivary duct carcinoma(N=1) SCC(N=1)
Total		100		65

Table 4: Comment on discordance of cytological diagnosis

Category	Cytological diagnosis	Histopathological diagnosis	Comment on discordance
I: Non-diagnostic	Non-diagnostic	Pleomorphic adenoma Warthin's tumour Low grade mucoepidermoid carcinoma	Inadequate cellularity
II: Non-Neoplastic	Granulomatous sialadenitis	High-grade mucoepidermoid carcinoma	Paucicellularity and necrotic background on cytology
III: Atypia of undetermined significance	AUS	Pleomorphic adenoma	Presence of bizarre atypical cells on cytology
IVA: Benign neoplasm	Pleomorphic adenoma	Adenoid cystic carcinoma	Presence of few atypical cells on cytology
IVB: SUMP	SUMP	Basal cell adenoma	Close differential of adenoid cystic carcinoma due to hyaline globules and high N:C ratio

Table 5 : Overall Result evaluating accuracy of MILAN system

Result	Percentage (%)
Sensitivity	84.6%
Specificity	100%
Positive predictive value	100%
Negative predictive value	96.29%
Diagnostic Accuracy	96.9%

DISCUSSION

We observed that among the 100 cases reported using MILAN system, 7%, 22%, 4%, 44%, 3%, 4% and 16% belonged to category I, II, III, IVA, IVB, V and VI respectively. Pujani et al (33) observed that amongst 150 cases, 4.6%, 42%, 2%, 43.3%, 1.3%, 1.3% and 5.3% belonged to category I, II, III, IVA, IVB, V and VI respectively. In a study by Kala et al (1), it was observed that, 6.1%, 38.2%, 2.7%, 33.4%, 2.0%, 2.4% and 15% belonged to category I, II, III, IVA, IVB, V and VI respectively. In the present study, the malignant cases were 16% which is comparable to Kala et al (1) and Amita et al (34). In the present study highest number of cases are belong to the age group of 31-50 years of age i.e, 49%, which is similar to the study of Pujani et al(33) in which the highest number of cases are also between the age of 31-50 years of age i.e, 46%. While the study done by Kala et al has highest number of cases in the age group of 21-40 years of age i.e., 46.1%.

In the present study the Male: Female ratio of the cases is 1.12:1 i.e 53% are male while 47% are females, which is similar to studies of Kala et al (1) with M:F ration of 1.1:1 having 52.6% male and 47.4% females and Pujani et al (33) with M:F ratio of 1.6:1 having 58.66% male and 41.33% female. In the present study, the most common salivary gland involved was parotid

gland i.e 63%, followed by 30% submandibular gland and 7% were involved in minor salivary glands. The result is in accordance with the studies done by Pujani et al (33) and Rohilla et al (35). The ratio remaining the same with the studies of Maleki et al and Vishwanathan et al but the percentages are slightly higher than the other studies.

In our study risk of malignancy for category I is 20% which is in accordance with studies done by Kala et al(1) and Wu et al(36). Risk of malignancy for category II is 6.6% which is in accordance with studies done by Layfield et al(37) and Vishwanathan et al.(38) Risk of malignancy for category III is 33.3% which is in concurrence with studies done by Higuchi et al(39) and Wu et al(36). Risk of malignancy for category IVA is 3.3% which is comparable to studies done by Kala et al(1) and Wu et al(36). Risk of malignancy for category IVB is 50% which is in accordance with the studies of Pujani et al (33) and Wu et al(36). Risk of malignancy for category V is 100% which is similar to studies of Pujani et al(33) and Wu et al (36). Risk of malignancy for category VI is 100% which is again similar to studies done by Pujani et al (33) and Wu et al(36). We observed that the overall risk of malignancy is 14.2%, 4.5%, 25%, 2.2%, 33.3%, 75% and 50% for category I, II, III, IVA, IVB, V and VI respectively. This result is in accordance with Vishwanathan et al (38) and Pujani et al (33) except for category I which is 4.1% in the study done by Vishwanathan et al and 0% in case of Pujani et al study.

In the present study the sensitivity and specificity are 84.6% and 100% respectively which are comparable to the studies of Pujani et al (33) with a sensitivity of 81.8% and specificity of 100%, Amita et al (34) with a sensitivity of 89.4% and specificity of 100%.The sensitivity observed by Rohilla et al (79.4%) and Vishwanathan et al (79%) are lower than our study. The specificity of Chen et al (70.4%) is lower than our study. We observed a positive predictive value of 100% which is in concordance with the studies of Pujani et al (33) and Amita et al (34). The negative predictive value of our study is 96.29% which is in concordance with the studies of Pujani et al (33)and Higuchi et al(39). In the present study, we observed a diagnostic accuracy is 96.9% which is in accordance with the study of Higuchi et al (39) (97%) and is higher than the study of Chen et al (80.1%) and Kala et al (90%).

CONCLUSION

The current investigation validates the diagnostic value of MSRSGC and helps guide the treatment of salivary gland diseases in clinical practice. Despite the heterogeneity of salivary gland lesions and their morphologically overlapping characteristics, this system will meet the needs of cytopathologists and clinicians because, in addition to the advantages of risk stratification and range of motion, it proposed a six-category scheme that classifies salivary gland FNAC and reduces the likelihood of false-negative and false-positive cases.

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