Original Article

Application of Milan system for reporting of salivary gland pathology and risk stratification: An institutional experience

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Abstract:

Background: Fine-needle aspiration cytology (FNAC) is a sensitive technique for diagnosing salivary gland pathologies. Milan system of reporting salivary gland cytopathology (MSRSGC) is an evidence-based system of reporting which has been introduced to improve reporting and communication between cytopathologist and clinician by introducing standardized categories with specified treatment protocols.

Aims and Objectives: The aim of the present study is to find the diagnostic accuracy and risk of malignancy (ROM) in various categories when MSRSGC is applied.

Materials and Methods: A single-institute-based 3-year retrospective study was done. All salivary gland lesions were reclassified according to MSRSGC. ROM, diagnostic specificity, sensitivity and accuracy of FNAC of salivary gland lesions were calculated.

Results: A total of 133 cases were included in the study. Overall, the most common diagnosis was found to be pleomorphic adenoma comprising 61 (42.8%) of all cases. Adenoid cystic carcinoma was the most commonly diagnosed malignancy comprising of 6 (4.5%) of all lesions. Cases were further divided into Milan categories, namely nondiagnostic, nonneoplastic, atypia of undetermined significance, benign neoplasm, neoplasm of undetermined malignant potential, suspicious of malignancy and malignancy comprising 5 (3.7%), 29 (21.8%), 77 (57.8%), 4 (3%), 3 (2.2%), 1 (0.7%) and 14 (10.5%) cases, respectively, with ROM of 0, 14.28%, 33.33%, 5.71%, 66.66%, 100% and 80%, respectively. Sensitivity, specificity and diagnostic accuracy to separate benign from malignant lesions were 80%, 89.80% and 87.50%, respectively.

Conclusion: FNAC of the salivary gland lesions is a safe and reliable diagnostic procedure. The Milan system of reporting is a risk stratification system which can improve the overall effectiveness of reporting and care of patients.

Keywords: Cytopathology, Milan system, risk stratification, salivary gland

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INTRODUCTION

Fine-needle aspiration cytology (FNAC) of salivary glands is a useful tool which is used extensively and effectively for initial evaluation, diagnosis and subsequent management of salivary gland lesions.[1] FNAC aids in easy distinction between neoplastic and nonneoplastic (NN) lesions of salivary glands.[2,3]

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Salivary gland lesions show wide overlap of cytomorphological features, especially when differentiating benign from low-grade tumors.[4] Salivary gland tumors show heterogenity leading to difficulty in exact categorization of these tumors.[5] The accuracy of cytology for categorizing and diagnosing various neoplasms is different in various studies and ranges

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from 48% to 94%.[1,6-8] Cytology guides the clinician for conservative management of benign lesions and low-grade tumors thus reducing unnecessary surgical intervention.[9,10]

An attempt to categorize these lesions has been done in different studies in the past.[11,12] Until now, there was no uniform, category-based grading system for the reporting of salivary gland lesions. "The Milan system for reporting salivary gland cytopathology" (MSRSGC) was introduced to standardize the reporting of salivary gland cytology.[9] The present study was done to find the effectiveness of FNAC to differentiate benign and malignant lesions and to assess the risk of malignancy (ROM) in various diagnostic categories when the Milan system of reporting is applied.

MATERIALS AND METHODS

A 3-year retrospective study was conducted in a rural care tertiary hospital. A total of 133 cases of FNAC of salivary gland lesions for the period of 2017–2019 were reviewed. Patient clinical details, FNAC smears and histological slides where available were retrieved from the departmental records. Based on the cytological details, the salivary gland lesions were reviewed and classified according to MSRSGC categories by two independent observers into Category 1: nondiagnostic; Category 2: NN; Category 3: atypia of undetermined significance (AUS); Category 4a: neoplasm: benign; Category 4b: neoplasm: salivary gland neoplasm of undetermined malignant potential (SUMP); Category 5: suspicious of malignancy (SM); and Category 6: malignant in an unbiased manner without referring to the previous diagnosis. Histological correlation was available in 62 cases.

The statistical analysis was performed using the IBM SPSS statistics version 21 for Windows (IBM Corporation, North Castle Drive, Armonk, New York, USA). The number of false positives, false negatives, true positives and true negatives was assessed by comparing cytological diagnosis to that of histological diagnosis. The specificity, sensitivity and diagnostic accuracy of FNAC were then calculated to differentiate benign and malignant lesions of the salivary gland. The overall risk of neoplasm and ROM was calculated for each category of MSRSGC by using the following formulas:

Overall risk of neoplasm = number of cases which turned out to be neoplastic (benign + malignant) on histopathology in each category/total number of cases in each category on cytology.

Overall risk of neoplasm = number of cases which turned out to be malignant on histopathology (benign + malignant) in each category/total number of cases in each category on cytology.

RESULTS

A total of 133 cases of FNAC were performed in a period of 3 years. The age of patients ranged 18–85 years, and the mean age was 44.83 years. The male: female ratio was 2.6:1. The most commonly involved salivary gland was parotid gland (74.4%) followed by submandibular (21%) and minor salivary glands (4.5%), as shown in Table 1. The male-to-female ratio was found to be 2.6:1.

The cytological diagnosis offered in different cases is shown in Table 2. Benign neoplasm was the largest category and comprised 77 cases (57.8%) followed by NN category comprising 29 cases (21.8%). The nondiagnostic, AUS, SUMP, SM and malignant category comprised 5 (3.7%), 4 (3%), 3 (2.2%), 1 (0.7%) and 14 (10.5%) cases, respectively. Overall, the most common diagnosis was found to be pleomorphic adenoma (PA) comprising 61 (42.8%) of all cases. In malignant cases, adenoid cystic carcinoma was the

Table 1: Site-wise distribution of involved salivary gland

Involved salivary gland	Number of cases (%)
Parotid gland	99 (74.4)
Submandibular gland	28 (21)
Minor salivary glands	6 (4.5)

Table 2: Cytological diagnosis and distribution according to proposed Milan system

Milan category	Cases	Diagnosis
I: ND	5	
II: NN	29	Chronic sialadenitis - 14 Sialadenosis - 5 Acute sialadenitis - 3 Granulomatous sialadenitis - 2 Lymphoepitheial lesion - 2 Benign cyst - 1
III: AUS	4	
IVA: Neoplasm: Benign	77	PA - 61 Warthin's tumor - 12 Basal cell adenoma - 1 Oncocytoma - 2 Lipoma - 1
IVB: Neoplasm: SUMP	3	
V: SM	1	
VI: Malignant	14	Ca ex pleomorphic adenoma - 1 Poorly differentiated carcinoma - 1 Adenoid cystic carcinoma - 6 Adenocarcinoma NOS - 1 MEC - 2 Myoepithelial carcinoma - 1 Acinic cell carcinoma - 1 PLGA - 1

NOS: Not otherwise specified, MEC: Mucoepidermoid carcinoma, PLGA: Polymorphous low-grade adenocarcinoma, PA: Pleomorphic adenoma, AUS: Atypia of undetermined significance, NN: Nonneoplastic, SUMP: Salivary gland neoplasm of undetermined malignant potential, SM: Suspicious of malignancy, ND: Nondiagnostic

most commonly diagnosed malignancy comprising 6 cases constituting 4.5% of all salivary gland lesions. Among the NN category cases, chronic sialadenitis was the most common diagnosis comprising 14 (48.2%) cases.

Histological follow-up was available in 62 (46.6%) cases. On follow-up, the number of concordant and discordant cases was noted. In the discordant category, further categorization into benign and malignant neoplasms was done [Table 3]. In nondiagnostic category, histological follow-up was available in three out of total of five cases. The final diagnosis offered in these cases after histological examination was benign cyst, chronic sialadenitis and Warthin's tumor, respectively. In NN category, out of a total of 29 cases, histopathology was available in seven cases. Five of these seven cases were found to have a concordant diagnosis. Among the discordant cases, one was diagnosed as PA and other as mucoepidermoid carcinoma (MEC) [Figure 1].

In Category 3 - AUS, four cases were placed according to cytology. Three cases were present for histological follow-up and were diagnosed as PA, myoepithelioma and adenoid cystic carcinoma, respectively [Figure 2].

In Category 4a of benign neoplasms, a total 77 cases were included with histological follow-up of 35 cases. Thirty-three out of these cases were concordant. Two cases were found to be discordant and were diagnosed as adenoid cystic carcinoma and polymorphous low-grade adenocarcinoma (PLGA). While in Category 4b (SUMP), only three cases were present. Histopathological follow-up was available in all three cases, and these comprised one case each of PA, myoepithelial carcinoma [Figure 3] and adenoid cystic carcinoma [Figure 4].

In the Category 5 - SM, one case was present which was diagnosed as carcinoma expleomorphic adenoma on histopathological examination. While Category 6 comprised 14 cases with histopathological follow up in ten cases. Two out of these ten cases were discordant and were given a final diagnosis of PA in both cases.

The risk of neoplasm and ROM were calculated for each MSRSGC categories [Table 4]. The overall risk of neoplasm was found to be least in NN category (28.57%) followed by nondiagnostic category (33.33%). The risk of neoplasm was found to be 100% in all the other categories. However, the overall ROM was found to be the highest in SM category (100%) followed closely by malignant category (80%). The rest of categories showed ROM of

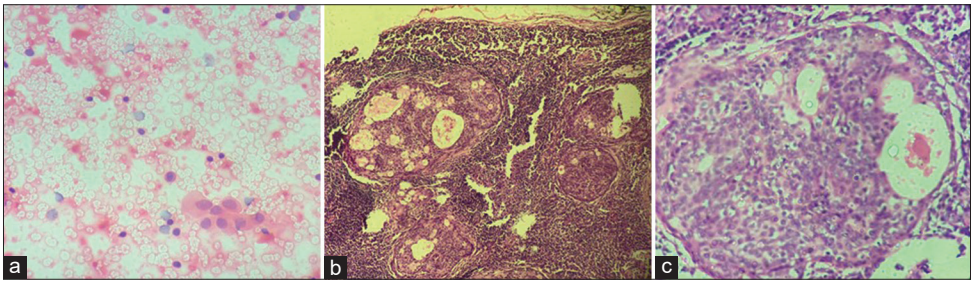

Figure 1: (a) Category 2. Nonneoplastic – fine-needle aspiration smear showing few squamous cells in a mucoid background (H&E, ×100). (b and c) Histological follow-up revealed mucoepidermoid carcinoma (H&E, ×100; H and E, ×400)

Table 3: Cytohistological correlation and categorization according to the proposed Milan system

Number of cases - cytology	Histology follow up	Milan category	Concordant cases	Discordant cases	
				Benign diagnosis	Malignant diagnosis
6	3	1 - ND	-	Benign cyst Chronic sialadenitis Warthins	
29	7	2 - NN	5	PA	MEC
4	3	3 - AUS	-	PA Myoepithelioma	Adenoid cystic carcinoma
77	35	4A - BN	33		Adenoid cystic carcinoma PLGA
3	3	4B - SUMP	-	Cellular PA	Adenoid cystic carcinoma Myoepithelial carcinoma
1	1	5 - SM	-		Carcinoma ex pleomorphic adenoma
14	10	6 - Malignant	8	PA (2)	

SM: Suspicious of malignancy, AUS: Atypia of undetermined significance, NN: Nonneoplastic, SUMP: Salivary gland neoplasm of undetermined malignant potential, MEC: Mucoepidermoid carcinoma, PLGA: Polymorphous low-grade adenocarcinoma, PA: Pleomorphic adenoma, ND: Nondiagnostic, BN: Benign neoplasm

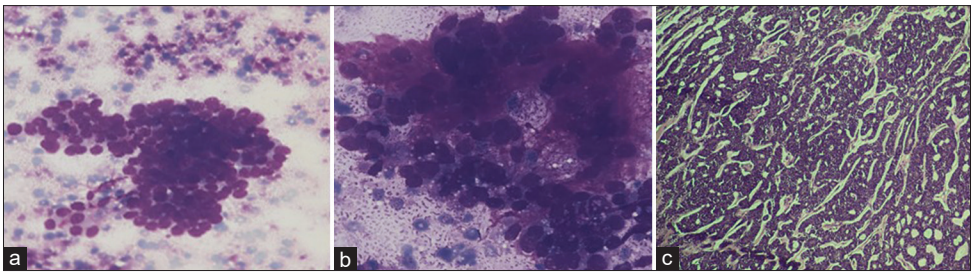

Figure 2: (a and b) Category 3 - AUS: Fine-needle aspiration smear showing few clusters of small monotonous cells showing nuclear atypia surrounding hyaline-like material with the absence of hyaline globules (MGG, ×100; MGG, ×400). (c) On histological follow-up diagnosed as adenoid cystic carcinoma (H&E, ×100)

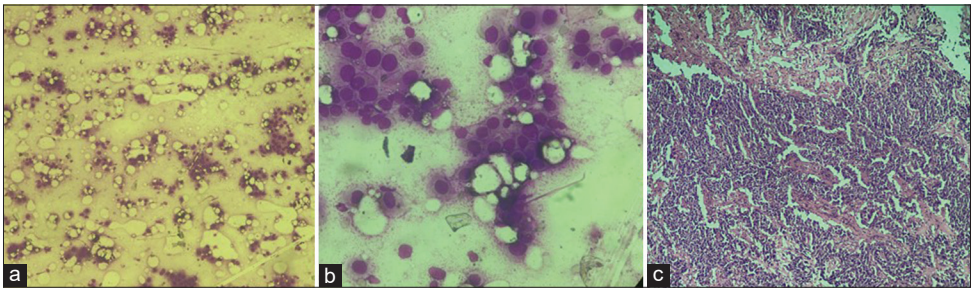

Figure 3: (a and b) Fine-needle aspiration smear showing few plasmacytoid cells with focal nuclear atypia. The case was placed under Category 4b - SUMP (L&G, ×40; L&G, ×400). (c) On histological follow diagnosed as myoepithelial carcinoma (H&E, ×100)

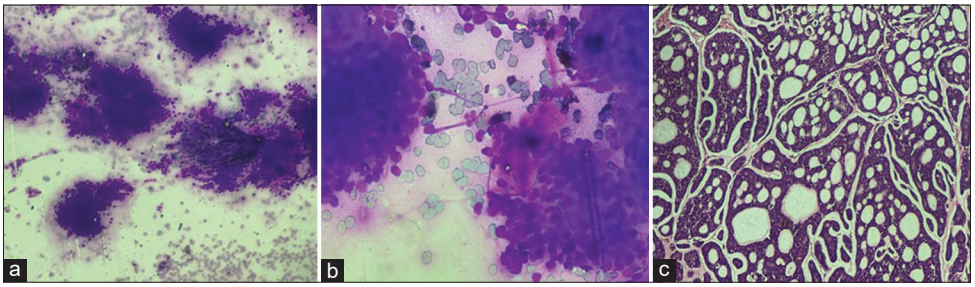

Figure 4: (a and b) Category 4b - SUMP: Fine-needle aspiration showing a cellular smear comprising of small monotonous cells revealing nuclear atypia surrounding hyaline-like material (MGG, ×100; MGG, ×400). (c) Histological follow-up revealed an adenoid cystic carcinoma (H&E, ×100)

Table 4: Overall risk of neoplasm and risk of malignancy

Milan category	Overall risk of neoplasm (%)	Overall risk of malignancy (%)
1 - ND	1/1 (33.33)	0
2 - NN	2/7 (28.57)	1/7 (14.28)
3 - AUS	3/3 (100)	1/3 (33.33)
4A - BN	35/35 (100)	2/35 (5.71)
4B - SUMP	3/3 (100)	2/3 (66.66)
5 - SM	1/1 (100)	1/1 (100)
6 - Malignant	10/10 (100)	8/10 (80)

ND: Nondiagnostic, BN: Benign neoplasm, SM: Suspicious of malignancy, AUS: Atypia of undetermined significance, NN: Nonneoplastic, SUMP: Salivary gland neoplasm of undetermined malignant potential

0% in nondiagnostic, 14.28% in NN, 33.33 in AUS and 5.71 in benign neoplasm categories.

Sensitivity, specificity and diagnostic accuracy of salivary gland cytology to separate benign lesions from malignant lesions when compared to histopathology was found to be 80%, 89.80% and 87.50%, respectively.

DISCUSSION

The salivary gland FNAC has outperformed over-frozen sections as it is safe, minimally invasive and cost-effective diagnostic procedure.[10,13,14] By this method, the NN lesions can be diagnosed accurately before surgery and thus preventing patient from undergoing unnecessary invasive procedures.[14,15]

In our study, salivary gland lesions were found to be more common in males as compared to females, with a male: female ratio of 2.6:1. Most commonly involved salivary gland was parotid gland followed by submandibular and minor salivary glands. These findings were similar to studies done by Rohilla and Kala *et al*.[4,16]

MSRSGC is a new system introduced for reporting and classification of salivary gland lesions. It aims to

provide better and standardized communication between clinicians and cytopathologists for effective patient management. The Milan system is an evidence-based six tier system which aims to provide ROM and clinical management strategy for each category.[11] This system divides FNAC's into six categories which are nondiagnostic, NN, AUS, benign neoplasm, SUMP, suspicious for malignancy and malignant with ROM different for each category as reported in different studies. In our study, also the salivary gland lesions were classified into the above-mentioned categories and ROM was calculated for each category.

Category 1 cases which are nondiagnostic and had insufficient diagnostic material without any sufficient information. This category included five cases (4.4%). In all these lesions, mainly fluid was aspirated, cellularity was low and smears showed only occasional cystic macrophages and inflammatory cells. Three cases were available for follow-up and histology. These cases were reclassified into one case each of benign cyst, chronic sialadenitis and Warthin's tumor. In such cases, various authors have suggested multiple passes from different planes and FNAC under ultrasound guidance when required, to overcome the drawback of diagnostic difficulty caused due to less cellularity on smear.[13,17]

The NN category (category 2) includes benign, reactive, inflammatory and metaplastic processes without the presence of any atypical features.[18] Our study included a total 29 (21.8%) cases. The most common diagnosis in this category was chronic sialadenitis (48.27%). These cases revealed benign clusters of ductal cells with scant acinar cells in a background of lymphocytes. Similar results were obtained in the study done by Kala *et al.* and Karuna *et al.*[4,19] Histological follow-up was available in seven cases following which two cases were reclassified, one into PA while the other into MEC. Cystic lesions form an important area of diagnostic pitfall as these can include a wide range of lesions, namely benign cysts comprising of simple retention cyst, mucocele, lymphoepithelial cyst along with benign tumors such as Warthins tumor, cystic PA and malignant cystic lesions such as MEC and acinic cell carcinoma.[16,20] The possible reason for false diagnosis in our study in this category is the same. FNAC of both these cases revealed mucoid and cystic areas without the presence of much cellular component and so both of these cases were diagnosed as benign cysts. The ROM of this category was calculated to be 14.28%, similarly various studies have shown a ROM ranging from 0% to 20%.[1,3,5,6,10,11,16] Our findings are in concordance with these findings.

The Category 3 - AUS includes cases with limited atypical features where a malignancy cannot be completely ruled out. In our study, these comprised of four cases, and histopathological follow-up was available in three cases. Out of three cases, two were diagnosed as one case each of PA and myoepithelioma, respectively, on histopathology. These cases showed focal areas of high cellularity and few reactive changes, and hence, the cases were placed in this category. One case was assigned a diagnosis of adenoid cystic carcinoma on histopathological follow-up. This was attributed to the presence of basaloid cells showing atypia, but with the absence of hyaline globules which led to the placement of this case into category AUS. The goal of introducing this category is to reduce the number of false negatives in NN category. This category should however comprise of <10% of all salivary gland FNAC samples according to the Milan system.[21] In our study, this category comprised 3% of total salivary gland lesions and ROM was found to be 33.3%. In various studies, ROM for this category was found to be 10%–35%, and our findings were in concordance with these studies.[1,3-6,10,11,16]

The benign neoplasm category had 77 (57.89%) cases in our study, and histological follow-up was available in 35 cases. PA followed by Warthin's tumor was the most common diagnosis in this category. This was similar to a study by Kala *et al.*[4] PA usually reveals metachromatic fibrillary chondromyxoid stroma with frayed margins in the background with clusters of round to plasmacytoid epithelial cells, thus rendering an easy diagnosis. Warthin's tumor, however, shows abundant lymphoid cells accompanied by oncocytic cells in a thin dirty to mucoid background. This category has been found to have a higher diagnostic accuracy according various reported studies.[9,11] However, in few cases, differentiating between benign and low-grade malignant neoplasms may be difficult. This is due to overlapping morphological features and heterogeneity of these tumors.[20] In our study, two cases from this category were reclassified on histological follow-up. One case turned out to be adenoid cystic carcinoma and another PLGA. In the first case, cytology revealed myxoid material with ductal cells. Typical hyaline globules were however not seen hence diagnosed as PA on cytology. In another case, there was the presence of extrafibrillary matrix, and only mild atypia was observed in epithelial cells. This led to the false diagnosis of PA. The ROM of this category is expected to be low, less than 5 percent as reported by Rossi *et al.*, and these cases are managed by conservative surgical resection or follow-up in few cases.[9] In our study, the ROM was found to be 5.71% and was found to be concordant with various studies which reported the ROM to be 0%–13%.[1,3-6,10,11,16]

The second category under neoplastic group is SUMP. This category includes aspirates where the features of diagnosis of a neoplasm are present, but a specific entity cannot be designated and malignancy cannot be ruled out. Out of 3 (2.25%) cases in this category, one was reclassified on histopathology. The presence of plasmacytoid cells and atypical features with absence of necrosis lead to a diagnosis of SUMP on cytology. Subsequently, this case turned out to be myoepithelial carcinoma on histology. The other case showed occasional hyaline globules with few clusters of small monotonous cells embedded in hyaline stroma were seen. It was diagnosed as adenoid cystic carcinoma on histological follow-up. In another case, smears showed very high cellularity of ductal and myoepithelial cells and scant matrix was observed thereby placed in SUMP. On histology, this case was diagnosed as cellular PA. In our study, the ROM of this category was found to be 67%. The ROM for this category has been found out to be ranging from 35% to 100% in various studies, and most commonly low-grade malignancies are included in this category.[1,3-6,10,11,16]

Category 5 lesion - SM are suggestive of a malignancy but not all criteria for a specific diagnosis are present. It is usually found that aspirates in this category are either deficient in quantity or in the quality of cytomorphological features of abnormal cells.[9] Similarly, in our study, there were high-grade features suggestive of malignancy, but exact differentiation and definite diagnosis could not be contemplated. A single case (0.75%) was placed in this category which revealed chondromyxoid material with basaloid and plasmacytoid cells and ductoacinar structures with focal atypia. On histology, the case was diagnosed as carcinoma ex PA. The ROM for this category was calculated to be 100%. This category has been found to have a wide range of ROMs by different authors ranging from 0% to 100%.[1,3-6,10,11,16]

Category 6 consists of cases with diagnostic features of malignancy. The aim of introducing this category is to sub classify tumors, especially into low grade and high grade because the approach to management of these cases are different. In our study, it comprised a total of 14 (10.52%) cases with histological follow-up available in ten cases. Adenoid cystic carcinoma 6 (4.51%) cases, followed by MEC 2 (1.5%) cases was found to be the most common diagnosis. This finding was in concordance with study by Kala *et al.* while in other studies by Rohilla *et al.* and Katta *et al*., MEC was the most common malignant lesion. Cytological smears of adenoid cystic carcinoma may show variable cellularity of small basaloid cells depending on the histological subtypes of this tumor. However, the presence variable-sized homogenous, acellular, nonfibrillary extracellular matrix globules which are surrounded by cells usually points to the diagnosis of this tumor. FNAC of MEC predominantly shows three types of cells including squamoid, intermediate, and mucus secreting cells with a dirty to mucoid background. The number of these cells and cystic component vary according to the differentiation of the tumor. Two cases of this category were falsely diagnosed as malignant and turned out to be PA on histopathological examination. This can be attributed to high cellularity with few reactive changes and scattered atypical cells in one of the cases. In another case, false diagnosis was likely due to the presence of dense inflammation and degenerated cells. These cells can cause an over interpretation of malignancy in some cases. The ROM for this category was found to be 80% and is in concordance to various studies where ROM for this category has been found to be ranging from 57% to 100%.[1,3-6,10,11,16]

By incorporating MSRSGC for diagnosing salivary gland lesions, a sensitivity, specificity and accuracy of 80%, 89.80% and 87.50%, respectively, were obtained in our study. Similar results were obtained in a study by Rohilla *et al.* and Rajwanshi *et al*.[13,16] These findings were found to be superior and better when compared to other studies utilizing conventional methods for reporting salivary gland lesions.[4,5]

CONCLUSION

The MSRSGC is a newly introduced system which helps to stratify these lesions, escalate standardized and uniform communication and lower the nondiagnostic reporting rates. The system conveys specific ROM, thereby helping the clinician to plan the therapeutic approach in patients and hence improves overall care.

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Conflicts of interest
There are no conflicts of interest.

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