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CYTOMORPHOLOGICAL SPECTRUM OF SALIVARY GLAND LESIONS WITH APPLICATION OF THE MILAN REPORTING SYSTEM: A PROSPECTIVE STUDY FROM A TERTIARY CARE CENTRE IN RAJASTHAN, INDIA

Pathology

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ABSTRACT

Salivary gland lesions comprise a diverse group of non-neoplastic and neoplastic conditions with overlapping cytomorphological features, making accurate preoperative diagnosis challenging. Fine needle aspiration cytology (FNAC) is a minimally invasive and cost-effective diagnostic technique, while the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) provides a standardized, risk-based reporting framework. This prospective study, conducted over one year at Jhalawar Medical College, evaluated the cytomorphological spectrum of salivary gland lesions, classified cases according to the MSRSGC, and assessed the diagnostic accuracy of FNAC using histopathology. A total of 155 patients underwent FNAC with May-Grünwald-Giemsa and Papanicolaou staining. The mean age was 45.81 ± 17.51 years, with a male-to-female ratio of 1.3:1. The parotid gland was the most commonly involved site (51.0%). Category IVA (benign neoplasm) was the predominant MSRSGC category (49.0%), with pleomorphic adenoma (25.8%) and Warthin tumor (23.2%) being the most frequent lesions. Malignant lesions accounted for 14.2% of cases. Histopathological correlation, available in 38 cases, showed 84.2% concordance, with FNAC demonstrating 83.3% sensitivity, 100.0% specificity, and 97.4% overall accuracy. FNAC, interpreted using the MSRSGC, is a reliable and accurate tool for the preoperative evaluation and risk stratification of salivary gland lesions.

KEYWORDS

Fine-needle aspiration; Salivary gland neoplasms; Milan System; Pleomorphic adenoma

INTRODUCTION

Few areas in head and neck pathology are as diagnostically demanding as salivary gland disease. With more than 40 distinct tumour entities recognised in the 2017 WHO classification (Ihrler et al., 2018), many sharing overlapping cytomorphological features, arriving at a correct preoperative diagnosis requires careful correlation of clinical, radiological, and cytological data. Salivary gland tumours account for 2–6.5% of all head and neck tumours, (Brennan et al., 2010) yet their histological heterogeneity is disproportionately large for their prevalence.

FNAC has become the standard first-line tissue investigation in this region. Faster, safer, and better tolerated than incisional biopsy, it avoids the risk of facial nerve injury inherent to open parotid surgery, minimises tumour seeding, and provides meaningful preoperative guidance. Reported sensitivity and specificity range from 62–97.6% and 94.3–100%, respectively, (Rohilla et al., 2017), a wide spread that reflects both the technique's strengths and its dependence on aspirate quality and cytopathologist experience.

For years, the absence of a unified reporting vocabulary complicated cross-institutional comparison and left clinicians uncertain how to act on cytological impressions. The MSRSGC, proposed in 2015 by the American Society of Cytopathology and International Academy of Cytology, (Faquin et al., 2018; Rossi et al., 2017) addressed this gap through a six-tier system, Non-Diagnostic (I), Non-Neoplastic (II), Atypia of Undetermined Significance (III), Benign Neoplasm (IVA), Salivary Gland Neoplasm of Uncertain Malignant Potential (IVB/SUMP), Suspicious for Malignancy (V), and Malignant (VI), each carrying a defined risk of malignancy and management recommendation.(Rossi et al., 2017)

We report our experience applying the MSRSGC prospectively to 155 consecutive salivary gland aspirates at Jhalawar Medical College, a tertiary centre in rural Rajasthan, with the aims of mapping the local cytomorphological spectrum, validating FNAC against histopathology, and assessing the system's practical utility in this setting.

MATERIALS AND METHODS

Study Design

This was a prospective, hospital-based, cross-sectional study conducted over one year in the Department of Pathology, Jhalawar Medical College, Jhalawar, Rajasthan, following Institutional Ethics Committee approval (IEC No. 100, dated 24.07.2020). Written informed consent was obtained from each participant.

Patient Selection

All patients with clinically palpable, superficial salivary gland swellings that yielded adequate aspirate were enrolled. Cases were excluded if aspiration yielded only haemorrhagic or scanty material after two passes, or if the patient declined to consent.

FNAC Procedure

Aspirations were performed under aseptic precautions using a 24-gauge needle on a 5 mL syringe, without local anaesthesia. Air-dried smears were stained by the May-Grünwald-Giemsa (MGG) method; ethanol-fixed smears (95%) were processed by the Papanicolaou technique. Ziehl-Neelsen staining was added in cases where granulomatous inflammation was suspected. Smears with fewer than 60 lesional cells or obscuring preparation artefacts were categorised as non-diagnostic.(Faquin et al., 2018)

Classification and Correlation

Every case was assigned an MSRSGC category at sign-out. When surgical excision followed, the histopathological report was retrieved and compared with the FNAC impression; each pair was classified as concordant or discordant. A 2×2 contingency table was constructed, with histopathology as the reference standard and FNAC categories V and VI combined as positive for malignancy. Sensitivity, specificity, PPV, NPV, and overall accuracy were derived by standard formulae. Categorical associations were examined using the chi-square test (significance threshold $p < 0.05$). Data were analysed using IBM SPSS Statistics version 22.

RESULTS

Clinico-demographic Profile

Over the study year, 155 patients were enrolled. Ages ranged from 18 to 75 years (mean 45.81 ± 17.51). Presentation peaked in the 21–40 years bracket (36.1%), with progressively fewer cases in the 41–60 years (29.0%) and over-60 (27.7%) groups; only 11 patients were aged 20 or younger. Males outnumbered females (87 vs 68; M:F = 1.3:1). Swellings had been present for a mean of 13.13 ± 6.71 months (range 1–24), reflecting the characteristically slow evolution of most lesions. FNAC yielded adequate material in 93.5% of aspirates (n = 145). Demographic and clinical details are summarised in Table 1.

Table 1: Clinico-demographic and Clinical Profile of Study Patients (n = 155)

Parameter	Category	n (%)
Age Group (years)	≤20 years	11 (7.1%)
	21–40 years	56 (36.1%)
	41–60 years	45 (29.0%)
	>60 years	43 (27.7%)
	Mean ± SD	45.81 ± 17.51 years (Range: 18–75)

Gender	Male	87 (56.1%)
	Female	68 (43.9%)
	M:F Ratio	1.3:1
Gland Involved	Parotid	79 (51.0%)
	Submandibular	61 (39.4%)
	Minor Salivary Glands	15 (9.7%)
Laterality	Right	77 (49.7%)
	Left	74 (47.7%)
	Bilateral	4 (2.6%)
Symptom Duration	Mean ± SD	13.13 ± 6.71 months Range: 1–24)
FNAC Adequacy	Adequate	145 (93.5%)
	Inadequate	10 (6.5%)

Site Distribution

Parotid lesions accounted for 51.0% (n = 79), followed by submandibular (39.4%, n = 61) and minor salivary glands (9.7%, n = 15). Right- and left-sided involvement were nearly equal (49.7% vs 47.7%); bilateral lesions were seen in only four cases (2.6%).

Cytological Diagnoses and MSRSGC Categories

Pleomorphic adenoma was the single most frequent diagnosis, 40 cases (25.8%), followed by Warthin tumor at 36 (23.2%). Non-neoplastic lesions included sialadenitis (n = 20, 12.9%) and cystic lesions (n = 19, 12.3%). Mucoepidermoid carcinoma led among malignancies with 21 cases (13.5%), and adenoid cystic carcinoma accounted for 16 (10.3%). Only three cases received an AUS designation (1.9%). When assigned MSRSGC categories: 76 cases fell under IVA, 39 under II, 22 under VI, 15 under V, and 3 under III. Mucoepidermoid carcinoma cases split across Category V (n = 11) and VI (n = 10); adenoid cystic carcinoma across V (n = 4) and VI (n = 12), reflecting genuine cytological uncertainty in a subset. Category distribution correlated strongly with cytological diagnosis ($p < 0.001$). Full data are in Table 2.

Table 2: Distribution of Cytological Diagnoses and Milan System Categories (n = 155)

Cytological Diagnosis	Milan Category (MSRSGC)	n	%
Cystic Lesion	II – Non-Neoplastic	19	12.3
Sialadenitis	II – Non-Neoplastic	20	12.9
Atypical Cells	III – AUS	3	1.9
Pleomorphic Adenoma	IVA – Benign Neoplasm	40	25.8
Warthin Tumor	IVA – Benign Neoplasm	36	23.2
Mucoepidermoid Carcinoma*	V (n=11) + VI (n=10)	21	13.5
Adenoid Cystic Carcinoma*	V (n=4) + VI (n=12)	16	10.3
Total	**II=39, III=3, IVA=76, V=15, VI=22**	**155**	**100.0**

Chi-square test applied. p <0.001, Significant
****MEC: Category V (n=11), VI (n=10); AdCC: Category V (n=4), VI (n=12).***

Gland-wise Distribution

Warthin tumor showed the most pronounced gland predilection, 75.0% (27/36) arose in the parotid. Sialadenitis, conversely, was predominantly submandibular (70.0%, 14/20), consistent with the longer, more tortuous course of Wharton's duct. Pleomorphic adenoma spread more evenly: 18 parotid, 16 submandibular, 6 minor gland cases. No malignancy arose from minor salivary glands in our series. The association between gland site and diagnosis was statistically significant ($p = 0.008$); details are in Table 3.

Table 3: Gland-wise Distribution of Cytological Diagnoses (n = 155)

Cytological Diagnosis	Minor SG (n)	Parotid (n)	Submandibular (n)	Total (n)	%
Cystic Lesion	3	10	6	19	12.3
Sialadenitis	3	3	14	20	12.9
Atypical Cells	0	1	2	3	1.9
Pleomorphic Adenoma	6	18	16	40	25.8
Warthin Tumor	3	27	6	36	23.2
Mucoepidermoid Carcinoma	0	12	9	21	13.5
Adenoid Cystic Carcinoma	0	8	8	16	10.3
Total	**15**	**79**	**61**	**155**	**100.0**

Chi-square test applied. p =0.008, Significant

Histopathological Correlation

Surgical excision was available in 38 of 155 cases (24.5%). On histopathology, the most common diagnoses were: pleomorphic adenoma (n = 11), cystic lesion (n = 6), abscess (n = 5), sialadenitis (n = 5), Warthin tumor (n = 4), mucoepidermoid carcinoma (n = 3), adenoid cystic carcinoma (n = 3), and one atypical/inconclusive case. Of the 38 paired assessments, 32 were concordant (84.2%) and 6 discordant (15.8%). The clinically significant mismatch was one false-negative, pleomorphic adenoma on FNAC later confirmed as mucoepidermoid carcinoma on histopathology. Three cystic lesions on cytology proved to be pleomorphic adenoma on excision, and two aspiration-diagnosed abscesses were likewise reclassified. No false-positive malignant call was made. Case-level concordance data are presented in Table 4.

Table 4: Summary of FNAC vs. HPE Concordance (n = 38 cases)

FAC Diagnosis	HPE Diagnosis	n	Concordance
Pleomorphic Adenoma	Pleomorphic Adenoma	6	Concordant
Pleomorphic Adenoma	Mucoepidermoid Carcinoma	1	Discordant (False Negative)
Warthin Tumor	Warthin Tumor	4	Concordant
Cystic Lesion	Cystic Lesion	6	Concordant
Cystic Lesion	Pleomorphic Adenoma	3	Discordant
Sialadenitis	Sialadenitis	5	Concordant
Abscess	Abscess	5	Concordant
Abscess	Pleomorphic Adenoma	2	Discordant
Basaloid Neoplasm	Adenoid Cystic Carcinoma	3	Concordant
Mucoepidermoid Carcinoma	Mucoepidermoid Carcinoma	2	Concordant
Atypical/Inconclus.	Atypical/Inconclusive	1	Concordant
Total Concordant		**32**	**84.2%**
Total Discordant		**6**	**15.8%**
TOTAL		**38**	**100.0%**

Diagnostic Performance

Among six histologically confirmed malignancies, five were correctly identified on FNAC (TP = 5; FN = 1); none of the 32 non-malignant cases attracted a false-positive malignant label (FP = 0; TN = 32). Sensitivity was 83.3%, specificity 100.0%, PPV 100.0%, NPV 97.0%, and overall diagnostic accuracy 97.4%. The 2×2 contingency table and all derived parameters, with supporting formulae, are given in Table 5.

Table 5: 2×2 Contingency Table and Diagnostic Performance Parameters of FNAC (n = 38)

	HPE Malignant	HPE Non-malignant	Total
FNAC Positive (Malignant)	TP = 5	FP = 0	5
FNAC Negative (Non-malignant)	FN = 1	TN = 32	33
Total	**6**	**32**	**38**
Diagnostic Parameter	**Formula**	**Calculation**	**Value**
Sensitivity	TP/(TP+FN)	5/6	83.3%
Specificity	TN/(TN+FP)	32/32	100.0%
Positive Predictive Value (PPV)	TP/(TP+FP)	5/5	100.0%
Negative Predictive Value (NPV)	TN/(TN+FN)	32/33	97.0%
Overall Diagnostic Accuracy	**(TP+TN)/Total**	**37/38**	**97.4%**

TP = True Positive; FP = False Positive; FN = False Negative; TN = True Negative; PPV = Positive Predictive Value; NPV = Negative Predictive Value.

DISCUSSION

Our series of 155 salivary gland aspirates from a tertiary hospital in rural Rajasthan produced findings that broadly mirror those of comparable Indian studies, while offering specific data on MSRSGC distribution and FNAC accuracy in an underserved regional setting.

Patient Profile

At a mean age of 45.81 years, our cohort was somewhat older than in Pujani *et al*.(Pujani et al., 2018) (mean 37.2 years), possibly reflecting delayed specialist referral, a recurrent challenge in rural healthcare.

The symptom duration of 13.13 months reinforces this interpretation; patients tolerated their swellings for over a year before presenting. Male preponderance (M:F = 1.3:1) was consistent across comparable series, including Pujani *et al*. (1.4:1)(Pujani et al., 2018) and Kala *et al*.,(Kala et al., 2019) though gender did not statistically influence lesion type in our data. Parotid predominance (51.0%) aligns with published epidemiology, while the relatively high proportion of submandibular cases (39.4%) likely reflects obstructive sialadenitis referrals from primary care, a pattern we have observed clinically over the study period. FNAC adequacy at 93.5%, matching published figures from Sandhu *et al*.(Sandhu et al., 2017) confirmed technical consistency across our aspirations.

Parotid predominance at 51.0% is broadly in line with Kakoty *et al*. (62% parotid)(Kakoty et al., 2017) and Katta *et al*. (66.67% parotid);(Katta & Chaganti, 2019) our somewhat lower parotid proportion and higher submandibular representation likely reflects the concentration of obstructive submandibular pathology in our referral base. Bilateral lesions were rare (2.6%) and were predominantly seen in cases of sialadenosis and Warthin tumor, both known to occur bilaterally.

Morphological Spectrum

Pleomorphic adenoma (25.8%) and Warthin tumor (23.2%) together formed nearly half the series, a finding consistent across virtually every published FNAC series globally. Warthin tumor's near-exclusive parotid predilection in our data (75.0% of cases) mirrors its known pathogenesis: development from entrapped heterotopic salivary duct tissue within intraparotid lymph nodes. Sialadenitis showed the opposite pattern, predominantly submandibular (70.0%), owing to the tortuous anatomy of Wharton's duct, which favours stone formation and ascending infection. Accurate identification of these inflammatory and cystic conditions on cytology carries direct therapeutic impact. In our setting, a confident non-neoplastic FNAC diagnosis spares patients a general anaesthetic and an operation, both of which carry meaningful risk and cost.

Malignant lesions constituted 14.2% of the series. Mucoepidermoid carcinoma led at 13.5%, followed by adenoid cystic carcinoma at 10.3%, the two most prevalent salivary malignancies in the 2017 WHO classification.[18] No minor gland malignancy was identified, though this likely reflects referral patterns rather than true anatomical rarity. Atypical cases were few (1.9%), suggesting that most of our aspirates were interpretable to a definitive or near-definitive level.

Milan System Performance

Category IVA dominated at 49.0%, consistent with Pujani *et al*. (43.3%)(Pujani et al., 2018) and Kala *et al*. (33.4%).(Kala et al., 2019) The robust chi-square association ($p < 0.001$) between Milan category and cytological diagnosis confirmed internal coherence of the classification in our dataset. One practical observation: 11 of 21 mucoepidermoid carcinoma cases were placed in Category V rather than VI. This is diagnostically honest, low-grade mucoepidermoid carcinoma, particularly in its cystic form, can yield mucin-predominant aspirates with limited atypia that fall short of the certainty required for a Category VI call. Accommodating this uncertainty within a structured tier, rather than forcing a binary benign/malignant verdict, is one of the MSRSGC's most valuable contributions to clinical communication.

Diagnostic Accuracy

Perfect specificity (100.0%) and PPV (100.0%) are the most clinically consequential findings from our performance analysis, no patient in this series was subjected to unnecessarily radical surgery on the basis of a false-positive malignant diagnosis. This matters especially in parotid surgery, where an incorrect malignant call might lead to facial nerve sacrifice. Sensitivity at 83.3% is acceptable, though it was limited by a single false-negative case: a cystic pleomorphic adenoma appearance on FNAC that histopathology returned as mucoepidermoid carcinoma. Such misclassification is well documented in the literature; cystic low-grade mucoepidermoid carcinoma, when aspirated, yields mucin-rich fluid with sparse intermediate cells, a pattern that closely mimics cystic degeneration in pleomorphic adenoma. Our NPV of 97.0% supports conservative management decisions when cytology is reassuringly benign. These parameters compare favourably with Pujani *et al*. (sensitivity 81.8%, specificity 100.0%, accuracy 96.9%)(Pujani et al., 2018) and Kakoty *et al*. (sensitivity 90.91%, specificity 96.42%).(Kakoty et al., 2017)

Discordances beyond the false-negative involved cystic lesions and abscesses incorrectly classified as pleomorphic adenoma. Both are explainable: cystic pleomorphic adenoma may yield predominantly fluid when the solid component is not sampled, and a secondarily infected parotid tumour may present an inflammatory aspirate masking the underlying neoplasm. Clinical correlation, particularly treating any long-standing, firm parotid swelling with suspicion despite a seemingly benign aspirate, remains indispensable.

LIMITATIONS

Histopathological follow-up in only 24.5% of cases is the primary limitation, a constraint common to studies from institutions where many patients with benign FNAC diagnoses decline or cannot access surgery. The small HPE-confirmed subgroup (n = 38) reduces the precision of sensitivity estimates, particularly for rare categories. Ancillary techniques, immunocytochemistry, FISH, molecular profiling, were unavailable; their incorporation in future studies would likely reduce both false-negative and AUS rates.

CONCLUSION

Across 155 prospectively enrolled salivary gland aspirates, FNAC proved safe, technically reliable, and diagnostically accurate. Benign lesions dominated, with pleomorphic adenoma and Warthin tumor together comprising nearly half the series. Site-specific predilections, Warthin tumor for the parotid, sialadenitis for the submandibular gland, were clearly evident. Malignant lesions were confined to major glands and accounted for 14.2%. Where surgical follow-up was available, FNAC achieved 84.2% concordance with histopathology, with perfect specificity and a negative predictive value of 97.0%. The MSRSGC provided a coherent, clinically meaningful risk-stratification framework across all lesion types. We recommend routine integration of FNAC with MSRSGC reporting into the standard diagnostic workup for salivary gland swellings, including at tertiary centres in resource-limited settings.

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