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A Prospective Observational Study of Salivary Gland Tumors: Clinical Presentation, Histopathology, and Diagnostic Correlation

Bhagyashree Jena[1], Monalisa Patsani[2], Arunima Kar[3*], Subhalaxmi Rautray[2], Smruti Swain[4], Subrat Behera[5]

[1]Junior Resident, Department of ENT, SCB Medical College and Hospital, Cuttack, India
[2]Associate Professor, Department of ENT, SCB Medical College and Hospital, Cuttack, India
[3]Assistant Professor, Department of ENT, SCB Medical College and Hospital, Cuttack, India
[4]Professor and HOD, Department of ENT, SCB Medical College and Hospital, Cuttack, India
[5]Professor and HOD, Department of ENT, Maharaja Jajati Keshari Medical College and Hospital, Jajpur, Odisha, India

***Address for Correspondence:** - Dr. Arunima Kar, Assistant Professor, Department of ENT, SCB Medical College and Hospital, Cuttack, India
E-mail: arunimakar92@gmail.com

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ABSTRACT

Background: Salivary gland tumours are uncommon and histologically diverse, making preoperative diagnosis challenging because of their variable clinical presentation. Accurate differentiation between benign and malignant lesions is essential for appropriate treatment planning. Therefore, this prospective study aimed to evaluate the clinical presentation, histopathological spectrum, and diagnostic accuracy of fine-needle aspiration cytology (FNAC) and imaging modalities in salivary gland tumours at a tertiary care center to improve evidence-based diagnostic and surgical decision-making.

Methods: A tertiary care center conducted this prospective observational study from 2022 to 2024. We conducted clinical, radiographic, and cytological evaluations on 500 people who reported pain and/or enlargement of their salivary glands. To link the findings of the fine-needle aspiration cytology (FNAC) with the histological examination, the Milan System was employed. Diagnostic accuracy calculations and descriptive statistics are both parts of statistical analysis.

Results: Of the cases, 43 (8.6%) had tumors in the salivary glands. The area primarily impacted was the parotid gland. Of the total number of cases, 60.5% were benign tumors; the most prevalent of these was mucoepidermoid carcinoma, followed by pleomorphic adenoma. Of the three diagnostic methods used, FNAC, CECT, and ultrasonography yielded the most accurate results (90.6%).

Conclusion: Combined clinical, cytological, and radiological evaluation particularly FNAC with Milan reporting provides reliable preoperative assessment of salivary gland tumors, facilitating optimal surgical planning.

Key-words: Salivary gland neoplasms; Fine-needle aspiration cytology; Histopathological correlation; Diagnostic accuracy; Milan System for Reporting Salivary Gland Cytopathology; Prospective observational study

INTRODUCTION

Despite making up less than 5% of all head and neck tumours, salivary gland tumours are incredibly diverse in their malignant potential, clinical behaviour, and histopathology, making them a formidable diagnostic and therapeutic obstacle [1-3].

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Although parotid glands are the most frequently affected, submandibular, sublingual, and minor lesions in salivary glands can develop these tumours as well [4–10].

In order to improve surgical planning and prognosis, it is crucial to accurately differentiate benign from malignant salivary gland tumours before surgery. Because slow-growing malignant tumours can seem like benign lesions, clinical appearance alone is often not enough to diagnose them [3,7]. Hence, imaging techniques, fine-needle aspiration cytology (FNAC), and histological examination are all part of the diagnosis process. Recent standardisation of FNAC reporting by the Milan System for Reporting Salivary Gland Cytopathology has increased

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risk categorisation and clinicopathological association [2,8,9]. For the purpose of identifying tumour size and cancerous features, modern imaging techniques, especially contrast-enhanced computed tomography (CECT), are invaluable [6].

Data from prospective Indian cohorts is still scarce, especially on diagnostic accuracy and clinicopathological linkages, despite an increase in literature from Western populations [11–13]. In order to improve surgical and diagnostic decision-making based on evidence, this study gathered data from a tertiary care center to prospectively assess the clinical presentation, histopathological spectrum, and diagnostic performance of FNAC and imaging modalities in salivary gland tumours.

MATERIALS AND METHODS

Study Design and Setting- Patients presenting with disorders of the salivary glands were extensively evaluated in this prospective observational study. The prospective nature of the study enabled real-time data collection, standardized evaluation, and follow-up of enrolled participants while minimizing recall bias. The study was conducted in the Department of Otorhinolaryngology and Head and Neck Surgery (ENT & HNS), S.C.B. Medical College and Hospital, Cuttack, Odisha, India, a tertiary care referral hospital serving both rural and urban populations. The study was carried out over a period of two years, from July 2022 to June 2024. The study population comprised patients presenting to the ENT outpatient department or admitted with symptoms suggestive of salivary gland pathology.

Inclusion Criteria

- Patients presenting with salivary gland swelling, abscess, and/or pain.
- Patients who provided written informed consent to participate in the study.

Exclusion Criteria

- Patients who refused to provide informed consent.
- Patients who could not be followed up adequately during the study period.

Sample Size- A total of 500 patients fulfilling the inclusion criteria and presenting with salivary gland swelling and/or pain were enrolled consecutively during the study period. All eligible patients presenting to the study hospital during the study period were included in this prospective observational study.

Variables and Data Collection- Data were collected using a structured and pre-designed proforma to ensure uniformity and completeness. Demographic variables included age, gender, and geographic region within Odisha. Clinical variables comprised presenting symptoms and their duration, history of associated pain or abscess, past medical history, and relevant family history of salivary gland disorders. Investigative variables included radiological investigations such as ultrasonography (USG) and computed tomography (CT), where indicated, cytological assessment by fine-needle aspiration cytology (FNAC), FNAC reporting according to the Milan System for Reporting Salivary Gland Cytopathology, and histopathological examination (HPE) of surgically excised specimens, wherever applicable. Additional variables included history of potential risk factors, such as substance abuse and other relevant exposures associated with salivary gland tumours, as well as the surgical modalities employed in the management of salivary gland lesions.

Bias Control- Selection bias was minimized by enrolling all consecutive eligible patients during the study period. Diagnostic bias was reduced through the use of standardized radiological and cytological reporting systems, including the Milan System for Reporting Salivary Gland Cytopathology for FNAC.

Statistical Analysis- All data were entered into Microsoft Excel and analyzed using the Statistical Package for the Social Sciences (SPSS). Descriptive statistics were used to summarize demographic and clinical characteristics, with continuous variables expressed as mean ± standard deviation or median (interquartile range), and categorical variables as frequencies and percentages. Comparative analyses between groups were performed using appropriate statistical tests based on data distribution. The diagnostic performance of radiological modalities was evaluated by calculating sensitivity, specificity, and other relevant diagnostic indices using histopathological findings as the reference standard, wherever applicable. A p-value of <0.05 was considered statistically significant.

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Ethical Considerations- Written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the principles of the Declaration of Helsinki and relevant national ethical guidelines. Ethical approval was obtained from the Institutional Ethics Committee (IEC) of S.C.B. Medical College and Hospital, Cuttack, before the commencement of the study.

RESULTS

Table 1 presents the Fundamental features of the research participants. Histopathological confirmation of salivary gland tumours was found in 43 (8.6%) of 500 individuals who reported swelling and/or pain in these glands. The affected individuals were mostly middle-aged, with an average age of 44.3 years. There were 1.07 males for every 1.28 females, or 62.8% of the total. Histological analysis revealed a considerable malignancy burden, with 60.5% of tumours being benign and 39.5% being malignant.

Table 1: Baseline Characteristics of Study Population (n = 500)

Variable	Observation
Total patients with salivary gland swelling/pain	500
Confirmed salivary gland tumors	43 (8.6%)
Mean age (years)	44.3
Male	16 (37.2%)
Female	27 (62.8%)
Benign tumors	26 (60.5%)
Malignant tumors	17 (39.5%)

Tumour and symptom distribution is seen in Table 2. Most commonly affected was the parotid gland (67.4% of cases), then the submandibular region (23.3% of cases), the sublingual region (7.0%), and finally the soft palate (2.3%). In most cases, swelling was the first sign of the disease. Most reports of pain were from tumours located in the parotid and submandibular regions. Tumours of the parotid gland were the only ones to cause neurological symptoms and trismus; tumours of the sublingual and soft palate, on the other hand, typically manifested as painless swellings.

Table 2: Distribution of Salivary Gland Tumors and Associated Symptoms (n = 43)

Gland	Tumors	Swelling	Pain	Tingling	Trismus
Parotid	29	29	6	2	2
Submandibular	10	10	3	0	0
Sublingual	3	3	2	0	0
Soft palate	1	1	0	0	0
Total	43	43	11	2	2

Here is a summary of the duration of symptoms and substance usage in Table 3. On average, symptoms persisted for 8.2 months; the highest duration was observed in cases with parotid tumours, which lasted 8.7 months. While 16.3% of cases had a history of substance exposure, the most common of which was tobacco, no association was established between parotid tumours and alcohol use.

Table 3: Duration of Symptoms and Substance Exposure among Patients with Salivary Gland Tumours

Parameter	Parotid	Submandibular	Sublingual	Soft Palate	Overall
Mean duration of symptoms (months)	8.7	7.9	6.0	3.0	8.2
History of substance exposure, n (%)					7 (16.3)

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Tobacco	2	2	0	1	5
Smoking	0	1	1	1	3
Alcohol	0	1	1	0	2

Histopathological spectrum is shown in Table 4. Malignant and benign tumours were equally prevalent in the submandibular gland as they were in the parotid gland. Every tumour found in the sublingual gland was cancerous. The most common benign tumour was pleomorphic adenoma, while the most common malignancy was mucoepidermoid carcinoma.

Table 4: Histopathological Distribution of Salivary Gland Tumours (n = 43)

Histopathological Parameter	Parotid	Submandibular	Sublingual	Soft Palate	Total
Benign tumours	20	5	0	1	26
Malignant tumours	9	5	3	0	17
Specific histological tumour types					
Pleomorphic adenoma	15	4	0	1	20
Warthin's tumour	5	1	0	0	6
Mucoepidermoid carcinoma	7	4	3	0	14
Adenoid cystic carcinoma	2	1	0	0	3

Diagnostic precision and patient care are the topics of Table 5. The diagnostic accuracy was 90.6% for FNAC, CECT, and ultrasonography, in that order. According to the final histology, most patients were categorised as Milan Category IVA. Malignant tumours necessitated extensive excision and neck dissection, and surgical treatment was tailored according to the tumour type and gland involved.

Table 5: Diagnostic Performance, Milan Cytology Classification and Surgical Management of Salivary Gland Tumours

Parameter	Finding	p-value
Diagnostic accuracy (%)		
Ultrasonography	83.7	0.117
CECT	88.3	0.006
FNAC	90.6	0.103
Milan System for Reporting Salivary Gland Cytopathology	Number of cases	
Category II (Non-neoplastic)	1	
Category IVA (Benign neoplasm)	28	
Category IVB (SUMP)	3	
Category VI (Malignant)	11	
Surgical management	Procedure performed	
Parotid (Benign)	Superficial/Partial parotidectomy, Enucleation	
Parotid (Malignant)	Total parotidectomy	
Submandibular (Benign)	Partial or total gland excision	
Submandibular (Malignant)	Total excision ± neck dissection	
Sublingual (Malignant)	Gland excision + neck dissection	
Soft palate (Benign)	Local excision	

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DISCUSSION

In this prospective series of 43 histologically confirmed salivary gland tumors among 500 patients with salivary swelling (8.6%), we observed a predominance of parotid involvement (67.4%), female preponderance (62.8%), a mean age of 44.3 years, and a benign:malignant ratio of ~1.5:1. These epidemiologic features broadly align with contemporary reports in both Indian and international cohorts, which consistently report the parotid as the most common site and pleomorphic adenoma as the predominant benign tumor [1–4].

The relatively high malignant proportion (39.5%) and the observation that all sublingual tumors were malignant mirror classical descriptions that sublingual and minor salivary glands have greater malignant propensity [5,14]. Our finding of mucoepidermoid carcinoma as the commonest malignancy and adenoid cystic carcinoma as less frequent is concordant with multiple recent reviews and regional series [6,10,11].

Clinically, universal presentation with swelling and variable pain parallels other series; parotid tumors more often produced neural/functional complaints (tingling, trismus) consistent with facial nerve proximity [3,7]. The mean symptom duration (overall 8.2 months; parotid 8.7 months) underscores the indolent natural history of many salivary neoplasms and echoes prior Indian studies reporting delayed presentation attributable to socioeconomic and access barriers [7,13].

Regarding diagnostics, FNAC demonstrated the highest accuracy in our cohort (90.6%), followed by CECT (88.3%) and USG (83.7%). These results are comparable to recent institutional validations of the Milan reporting system and contemporary FNAC performance analyses, which report high specificity with variable sensitivity for malignancy; the Milan system also improves risk stratification and clinicopathologic correlation [2,4,8,9]. CECT's statistically significant performance in distinguishing benign from malignant lesions supports current recommendations to combine imaging with cytology for preoperative planning [6,7].

Our substance-exposure signal (16.3% reporting tobacco/smoking/alcohol) is modest and concordant with heterogeneous global data that suggest tobacco may be a risk cofactor for selected salivary neoplasms but is not a dominant etiologic driver [1,15].

The study is single center with a modest tumor sample (n=43), limiting power for subgroup statistical tests and outcome inference. Selection bias is possible as only symptomatic patients presenting to ENT were captured; molecular and long-term outcome data were not available.

Multi-center prospective registries with standardized Milan reporting, high-resolution imaging protocols and incorporation of molecular markers would refine risk stratification. Future studies should examine prognostic implications of diagnostic discordance and evaluate machine-learning augmented imaging/ FNAC interpretation to improve preoperative prediction.

CONCLUSIONS

Salivary gland tumours comprise a heterogeneous group of lesions with diverse clinical and histopathological presentations, necessitating accurate preoperative evaluation for appropriate management. In the present study, the parotid gland was the most commonly affected site, with pleomorphic adenoma being the predominant benign tumour and mucoepidermoid carcinoma the most frequent malignant tumour. Fine-needle aspiration cytology (FNAC), particularly when interpreted using the Milan System for Reporting Salivary Gland Cytopathology, demonstrated high diagnostic utility and correlated well with histopathological findings. Radiological imaging, especially contrast-enhanced CT, further improved preoperative assessment and surgical planning. Histopathological examination remained the gold standard for definitive diagnosis. A multidisciplinary approach integrating clinical examination, imaging, cytology, and histopathology facilitates timely diagnosis, appropriate surgical management, and improved patient outcomes.

CONTRIBUTION OF AUTHORS

Research concept- Bhagyashree Jena, Monalisa Patsani, Arunima Kar

Research design- Bhagyashree Jena, Monalisa Patsani, Subhalaxmi Rautray

Supervision- Smruti Swain, Subrat Behera

Materials- Bhagyashree Jena, Arunima Kar, Subhalaxmi Rautray

Data collection- Monalisa Patsani, Arunima Kar, Subhalaxmi Rautray

Data analysis and interpretation- Smruti Swain, Subrat Behera

Literature search- Monalisa Patsani, Arunima Kar,

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Writing article- Bhagyashree Jena, Subhalaxmi Rautray
Critical review- Smruti Swain, Subrat Behera
Article editing- Bhagyashree Jena, Subhalaxmi Rautray
Final approval- Smruti Swain, Subrat Behera

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