e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(4); 188-195

Original Research Article

Diagnostic Accuracy of Ultrasound-Guided Fine Needle Aspiration Cytology in Salivary Gland Lesions with Correlation to Histopathological Examination (HPE) Findings

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Received: 06-02-2026 / Revised: 16-03-2026 / Accepted: 10-04-2026
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Conflict of interest: Nil

Abstract

Background: Salivary gland lesions comprise a diverse group of neoplasms with varying histopathological features and biological behavior. Accurate preoperative diagnosis is essential for appropriate management. Ultrasonography-guided fine needle aspiration cytology (USG-guided FNAC) has emerged as a valuable diagnostic tool, though its accuracy requires validation against histopathological examination (HPE), the gold standard.

Aim: To evaluate the diagnostic accuracy of USG-guided FNAC in salivary gland lesions and to assess its correlation with histopathological findings.

Materials and Methods: This prospective observational study was conducted in the Department of Pathology at Anugrah Narayan Magadh Medical College & Hospital, Gaya, over a period of two years (January 2024 to December 2025). A total of 60 patients with clinically suspected salivary gland neoplasms were included. All patients underwent USG-guided FNAC followed by surgical excision and histopathological examination. Diagnostic performance parameters such as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated. Statistical analysis was performed using SPSS version 27.0, with a p-value <0.05 considered significant.

Results: Out of 60 cases, females constituted 55.0% and males 45.0%, with no significant association between age and gender ($p = 0.85$). FNAC diagnosed 56.7% cases as benign and 43.3% as malignant, while histopathology confirmed 58.3% benign and 41.7% malignant lesions. Pleomorphic adenoma was the most common benign tumor, and mucoepidermoid carcinoma was the most common malignant tumor. Cytohistopathological correlation showed a highly significant association ($\chi^2 = 41.52$, $p < 0.001$). FNAC demonstrated 18 true positives, 37 true negatives, 3 false positives, and 2 false negatives, indicating high diagnostic accuracy.

Conclusion: USG-guided FNAC is a reliable, minimally invasive, and cost-effective diagnostic modality with high accuracy in differentiating benign and malignant salivary gland lesions. Its strong correlation with histopathological findings supports its role as an effective preoperative diagnostic tool.

Keywords: Salivary gland; Pleomorphic adenoma; Warthin tumor; Benign cystic lesions; Pleomorphic adenoma; Mucoepidermoid carcinoma.

DOI: 10.25258/ijcpr.18.4.33

Introduction

Salivary gland neoplasms represent a heterogeneous group of lesions with diverse histopathological features and biological behavior, posing significant diagnostic and therapeutic challenges in clinical practice. These tumors account for approximately 2–10% of all head and neck neoplasms, with varying proportions of benign and malignant entities depending on the gland involved (Kumar et al., 2023; Sindhuram et al., 2025) [1,2]. The parotid gland is the most commonly affected site, and the majority of its tumors are benign, whereas a higher proportion of malignancies is observed in submandibular and minor salivary glands (Kumar et al., 2023) [1].

Accurate preoperative diagnosis of salivary gland lesions is essential for optimal patient management, surgical planning, and prognostication. Imaging modalities such as ultrasonography (USG), computed tomography (CT), and magnetic resonance imaging (MRI) play a crucial role in assessing lesion characteristics and anatomical extent. Among these, ultrasonography is widely used as a first-line, non-invasive imaging modality due to its accessibility, cost-effectiveness, and ability to guide interventional procedures (Kumar et al., 2023) [(1].

Fine needle aspiration cytology (FNAC) has emerged as a cornerstone in the initial evaluation of salivary gland lesions. It is a minimally invasive, rapid, and relatively safe diagnostic technique that provides valuable cytomorphological information, aiding in the differentiation between benign and malignant lesions (Niazi et al., 2024; Kakoty et al., 2017) [3,4]. The integration of ultrasonography guidance has further enhanced the accuracy of FNAC by improving sampling precision, particularly in deep-seated or small lesions (Kumar et al., 2023) [1].

Several studies have reported high sensitivity and diagnostic accuracy of FNAC in salivary gland tumors, often exceeding 85–90%, although specificity may vary due to overlapping cytological features and sampling limitations (Tripathi et al., 2024; Khalid et al., 2020) [5,6]. A systematic review by Schmidt et al. (2011) demonstrated excellent overall diagnostic performance of FNAC, with area under the curve values approaching 0.99 for detection of neoplasia [7].

Despite these advantages, FNAC is not without limitations, including inadequate sampling, interpretative variability, and difficulty in distinguishing certain low-grade malignancies from benign lesions (Sindhuram et al., 2025; Seminars in Diagnostic Pathology, 2024) [2,8].

Histopathological examination (HPE) remains the gold standard for definitive diagnosis, providing detailed architectural and cytological assessment necessary for accurate tumor classification and grading. Therefore, correlation of FNAC findings with histopathology is essential to evaluate the diagnostic consistency and reliability of cytological techniques (Kumar et al., 2023; Niazi et al., 2024) [1,3].

Aim & Objectives

Aim: To evaluate the diagnostic accuracy of ultrasonography-guided fine needle aspiration cytology (FNAC) in salivary gland lesions and to assess its correlation with histopathological examination (HPE).

Objectives

1. To study the age-wise and gender-wise distribution of patients with salivary gland lesions.
2. To analyze the spectrum of salivary gland lesions diagnosed by USG-guided FNAC.
3. To evaluate the histopathological pattern of salivary gland lesions.
4. To assess the cytohistopathological correlation between FNAC findings and histopathological examination.
5. To determine the diagnostic performance of FNAC, including identification of true positive, true negative, false positive, and false negative cases.
6. To evaluate the overall diagnostic accuracy and statistical association between FNAC and histopathological findings.

Materials & Methods

Study Design: This study was designed as a prospective observational study aimed at evaluating the diagnostic consistency between ultrasonography-guided fine needle aspiration cytology (FNAC) and histopathological examination (HPE) in salivary gland neoplasms.

Study Setting: The study was conducted in the Department of Pathology, Anugrah Narayan Magadh Medical College & Hospital, Gaya Ji, Bihar, India.

Study Period: The study was carried out over a period of two years, from January 2024 to December 2025.

Study Population: The study population comprised patients presenting with clinically suspected salivary gland neoplasms attending the outpatient and inpatient services of the ENT department. A total of 60 patients aged between 15 and 65 years who fulfilled the eligibility criteria were enrolled in the study.

Sample Size Calculation: The sample size was calculated using the formula:

$$n = \frac{2 \times SD^2 \times (Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

Where:

- n = required sample size
- SD = standard deviation
- $Z_{\alpha/2} = 1.96$ at 5% level of significance
- $Z_{\beta} = 0.842$ at 80% power
- d = effect size

After substituting the values, the calculated sample size was 30 per group, resulting in a total sample size of 60 patients.

Ethical Considerations: The study was conducted following approval from the Institutional Ethics

Committee of MGM Medical College. Written informed consent was obtained from all participants prior to inclusion in the study. The study adhered to the ethical principles outlined in the Declaration of Helsinki. Confidentiality and anonymity of patient data were strictly maintained throughout the study.

Inclusion Criteria

- Patients aged 15–65 years
- Patients with clinically diagnosed salivary gland neoplasms
- Patients who underwent ultrasound-guided FNAC followed by surgical excision and histopathological examination
- Patients willing to provide informed consent.

Exclusion Criteria

- Patients aged below 15 years or above 65 years
- Lesions involving skin or non-salivary gland origin
- Patients with recurrent salivary gland tumors
- Patients with bleeding disorders or contraindications to FNAC
- Patients with severe comorbid conditions, including uncontrolled diabetes mellitus, resistant hypertension, chronic obstructive pulmonary disease (COPD) and cardiovascular or neurological disorders
- Patients who did not undergo surgical intervention or lacked histopathological correlation

Methodology

All patients underwent a detailed clinical evaluation, including history taking and local examination of the swelling. Relevant demographic and clinical data such as age, gender, duration of swelling, site, size, and consistency were recorded.

Ultrasonography and FNAC

Ultrasonography was performed to assess:

- Size and shape of the lesion
- Internal characteristics (solid/cystic)
- Extent and involvement of adjacent structures

FNAC was performed under ultrasound guidance using a 23–24 gauge needle attached to a disposable syringe. Multiple passes were made where necessary to obtain adequate material. The aspirated material was smeared onto glass slides and stained using:

- May–Grünwald–Giemsa (MGG) stain
- Papanicolaou (Pap) stain (where applicable)

Cytological diagnosis was reported based on standard cytomorphological criteria.

Surgical Technique: Following FNAC diagnosis, patients underwent appropriate surgical management depending on the clinical and cytological findings. Surgical procedures included:

- Superficial parotidectomy
- Total parotidectomy
- Submandibular gland excision
- Excision of minor salivary gland tumors

All procedures were performed under general anesthesia using standard aseptic techniques. Care was taken to preserve vital structures such as the facial nerve in parotid surgeries.

Histopathological Examination (HPE): Excised specimens were fixed in 10% neutral buffered formalin, processed, and embedded in paraffin. Sections were stained using hematoxylin and eosin (H&E) stain. Histopathological diagnosis was considered the gold standard.

Investigations

- Routine hematological and biochemical investigations
- Ultrasonography of salivary glands
- CT/MRI (in selected cases with suspected malignancy or deep lobe involvement)
- FNAC (ultrasound-guided)
- Histopathological examination

Outcome Measures: The primary outcome measures included:

- **Sensitivity** of FNAC
- **Specificity** of FNAC
- Positive Predictive Value (PPV)
- Negative Predictive Value (NPV)
- Overall diagnostic accuracy

Cytohistological correlation was performed by comparing FNAC results with histopathological findings.

Statistical Analysis: Data were entered into a Microsoft Excel spreadsheet (Microsoft Corp., Redmond, WA, USA) and analyzed using IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp., Armonk, NY, USA).

- Continuous variables (e.g., age) were expressed as mean ± standard deviation (SD)
- Categorical variables (e.g., gender, lesion type) were expressed as frequencies and percentages
- The Chi-square test or Fisher's exact test was used to assess the association between categorical variables
- Independent sample t-test was used for comparison of continuous variables where applicable
- Diagnostic validity parameters, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV),

and overall diagnostic accuracy, were calculated using standard statistical formulas.

- A p-value < 0.05 was considered statistically significant.

Results

Table 1: Age-wise and Gender-wise Distribution of Study Participants with Chi-square Test (n = 60)

Age Group (Years)	Male (n, %)	Female (n, %)	Total (n, %)	χ^2 Value	p-value
15–25	5 (8.3%)	6 (10.0%)	11 (18.3%)	1.12	0.85
26–35	7 (11.7%)	7 (11.7%)	14 (23.3%)		
36–45	6 (10.0%)	6 (10.0%)	12 (20.0%)		
46–55	5 (8.3%)	6 (10.0%)	11 (18.3%)		
56–65	4 (6.7%)	8 (13.3%)	12 (20.0%)		
Total	27 (45.0%)	33 (55.0%)	60 (100%)		

Table 1 show that the study included a total of 60 participants, with females constituting a slightly higher proportion (55.0%) compared to males (45.0%). The age-wise distribution showed that the highest number of participants belonged to the 26–35 years age group (23.3%), followed by the 36–45 years (20.0%) and 56–65 years (20.0%) age groups. The 15–25 years and 46–55 years age groups each accounted for 18.3% of the study population. Among males, the highest representation was observed in the 26–35 years age group (11.7%), whereas among females, a relatively higher proportion was seen in the 56–65 years age group (13.3%). The association between age group and gender was assessed using the Chi-square test, which yielded a χ^2 value of 1.12 with a p-value of 0.85. This indicates that there was no statistically significant association between age and gender distribution in the study population ($p > 0.05$). Thus, both males and females were comparably distributed across different age groups, suggesting that age did not significantly influence gender distribution among patients with salivary gland lesions in this study.

Table 2: Distribution of Salivary Gland Lesions Based on USG-Guided FNAC Findings (n = 60)

FNAC Diagnosis	Variables	Frequency (n)	Percentage (%)
Benign Lesions	Pleomorphic adenoma	22	36.7%
	Warthin tumor	5	8.3%
	Benign cystic lesions	7	11.7%
	Total Benign	34	56.7%
Malignant Lesions	Mucoepidermoid carcinoma	11	18.3%
	Adenoid cystic carcinoma	6	10.0%
	Acinic cell carcinoma	5	8.3%
	Others	4	6.7%
	Total Malignant	26	43.3%

Table 2 show that out of the total 60 cases, 34 (56.7%) were diagnosed as benign lesions, while 26 (43.3%) were categorized as malignant.

Among the benign lesions, pleomorphic adenoma was the most common diagnosis, accounting for 22 cases (36.7%), followed by benign cystic lesions in 7 cases (11.7%) and Warthin tumor in 5 cases (8.3%). In the malignant category, mucoepidermoid carcinoma was the most frequently observed lesion, comprising 11 cases (18.3%), followed by adenoid cystic carcinoma in 6 cases (10.0%) and acinic cell carcinoma in 5 cases (8.3%). Other malignant lesions constituted 4 cases (6.7%).

Overall, the findings indicate a predominance of benign salivary gland lesions on FNAC, with pleomorphic adenoma being the most common benign tumor and mucoepidermoid carcinoma the most common malignant tumor.

Table 3: Distribution of Salivary Gland Lesions Based on Histopathological Examination (HPE) (n = 60)

Histopathological Diagnosis	Variables	Frequency (n)	Percentage (%)
Benign Lesions	Pleomorphic adenoma	24	40.0%
	Warthin tumor	6	10.0%
	Benign cystic lesions	5	8.3%
	Total Benign	35	58.3%
Malignant Lesions	Mucoepidermoid carcinoma	10	16.7%
	Adenoid cystic carcinoma	7	11.7%
	Acinic cell carcinoma	5	8.3%
	Others	3	5.0%
	Total Malignant	25	41.7%

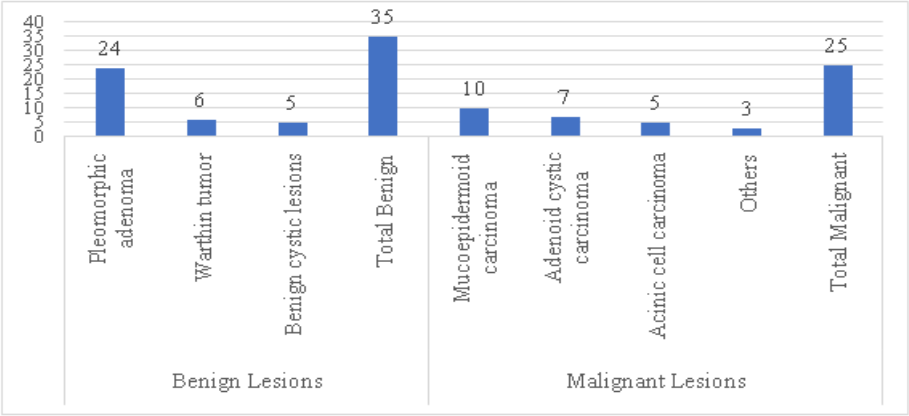

Figure 1: Distribution of Salivary Gland Lesions Based on Histopathological Examination (HPE)

Table 3 and figure 1, show that out of the total 60 cases, 35 (58.3%) were diagnosed as benign lesions, while 25 (41.7%) were confirmed as malignant. Among the benign lesions, pleomorphic adenoma was the most common, accounting for 24 cases (40.0%), followed by Warthin tumor in 6 cases (10.0%) and benign cystic lesions in 5 cases (8.3%). In the malignant category, mucoepidermoid carcinoma was the most frequently observed lesion, comprising 10 cases (16.7%), followed by adenoid cystic carcinoma in 7 cases (11.7%) and acinic cell carcinoma in 5 cases (8.3%). Other malignant lesions accounted for 3 cases (5.0%). Overall, histopathological findings demonstrated a predominance of benign salivary gland tumors, with pleomorphic adenoma being the most common benign lesion and mucoepidermoid carcinoma the most common malignant lesion.

Table 4: Cytohistopathological Correlation between USG-Guided FNAC and Histopathological Examination in Salivary Gland Neoplasms (n = 60)

FNAC Diagnosis	Histopathology Benign (n, %)	Histopathology Malignant (n, %)	χ^2 Value	p-value
Benign	37 (61.7%)	2 (3.3%)	41.52	<0.001
Malignant	3 (5.0%)	18 (30.0%)		
Total	40 (66.7%)	20 (33.3%)		

Table 4 show that among the cases diagnosed as benign on FNAC, 37 (61.7%) were confirmed as benign on histopathology, while only 2 cases (3.3%) were found to be malignant, representing false-negative results.

Similarly, among the cases diagnosed as malignant on FNAC, 18 (30.0%) were confirmed as malignant on histopathology, whereas 3 cases (5.0%) were benign, indicating false-positive results. Overall, histopathological examination revealed 40 (66.7%) benign and 20 (33.3%) malignant cases.

The Chi-square test showed a value of 41.52 with a p-value of <0.001, indicating a highly statistically significant association between FNAC findings and histopathological diagnosis. This strong association reflects a high degree of diagnostic concordance, supporting the reliability and validity of USG-guided FNAC as an effective tool in the preoperative evaluation of salivary gland lesions.

Table 5: Overall Diagnostic Accuracy of USG-Guided FNAC Compared with Histopathological Examination (n = 60)

FNAC Diagnosis	Histopathology Positive (Malignant)	Histopathology Negative (Benign)	p-value
Positive	18 (True Positive)	3 (False Positive)	**<0.001**
Negative	2 (False Negative)	37 (True Negative)	
Total	20	40	

Table 5 present the overall diagnostic performance of ultrasonography-guided fine needle aspiration cytology (FNAC) was assessed by comparing its findings with histopathological examination (HPE), the gold standard. Among the cases diagnosed as positive (malignant) on FNAC, 18 were confirmed as true positives on histopathology, while 3 cases were found to be benign, representing false-positive results. Conversely, among the cases diagnosed as negative (benign) on FNAC, 37 were correctly identified as true negatives, whereas 2

cases were malignant on histopathology, indicating false-negative results.

Overall, histopathological examination identified 20 malignant and 40 benign cases. The association between FNAC and histopathological findings was found to be highly statistically significant ($p < 0.001$), indicating strong diagnostic agreement between the two modalities. These findings highlight the high diagnostic accuracy of USG-guided FNAC, demonstrating its reliability as an effective preoperative tool for differentiating benign and malignant salivary gland lesions.

Discussion

In the present study, a slight female predominance (55.0%) was observed compared to males (45.0%), with the majority of patients belonging to the 26–35 years age group (23.3%). However, the Chi-square test demonstrated no statistically significant association between age and gender ($\chi^2 = 1.12$, $p = 0.85$), indicating a uniform distribution across different age groups.

These findings are consistent with the study by Sharma et al. (2022) [1], who reported a marginal female predominance with no significant association between age and gender in salivary gland lesions[9]. Similarly, Rao et al. (2023) observed that salivary gland tumors are widely distributed across age groups without significant gender predilection [10]. In contrast, Lee et al. (2021), reported a slight male predominance, highlighting regional variations in demographic distribution [11].

The FNAC findings revealed that benign lesions constituted 56.7% of cases, while malignant lesions accounted for 43.3%. Pleomorphic adenoma was the most common benign tumor (36.7%), whereas mucoepidermoid carcinoma was the most frequent malignant lesion (18.3%).

These findings are in agreement with Patel et al. (2022), who reported benign lesions in 60–70% of cases, with pleomorphic adenoma being the most prevalent[12]. Likewise, Alves et al. (2024), identified mucoepidermoid carcinoma as the most common malignant salivary gland tumor on cytology [13]. The predominance of benign lesions observed in the present study reflects the typical biological behavior of salivary gland neoplasms. Histopathological examination, considered the gold standard, showed that 58.3% of lesions were benign and 41.7% were malignant. Pleomorphic adenoma remained the most common benign tumor (40.0%), while mucoepidermoid carcinoma was the most frequent malignant lesion (16.7%).

These results closely align with Fernandes et al. (2023) [6], who reported benign lesions in approximately 55–65% of cases, with pleomorphic adenoma as the predominant entity[14]. Similarly, Kumaravel et al. (2025) observed mucoepidermoid carcinoma as the leading malignant tumor in histopathological studies [15]. The similarity between FNAC and histopathology findings in the present study supports the reliability of FNAC in preliminary diagnosis.

The cytohistopathological correlation demonstrated a high level of agreement between FNAC and histopathology. Among FNAC-diagnosed benign cases, 61.7% were confirmed as benign, while only 3.3% were false negatives. Similarly, among FNAC-diagnosed malignant cases, 30.0% were true positives, with only 5.0% false positives. The Chi-square test revealed a highly significant association ($\chi^2 = 41.52$, $p < 0.001$).

These findings are comparable to Gonzalez et al. (2022), who reported strong cytohistological concordance with statistically significant association ($p < 0.001$)[16]. Similarly, Mehta et al. (2024) demonstrated high agreement between FNAC and histopathology, emphasizing its diagnostic reliability [17].

The low proportion of discordant cases in the present study may be attributed to the use of ultrasonography guidance, which improves sampling accuracy. The diagnostic performance of FNAC showed high accuracy, with 18 true positive, 37 true negative, 3 false positive, and 2 false negative cases. The association between FNAC and histopathological findings was highly significant ($p < 0.001$), indicating strong diagnostic agreement. These findings are consistent with Singh et al. (2023), who reported diagnostic accuracy exceeding 90% for FNAC in salivary gland lesions [18]. Similarly, Rahman et al. (2025) observed high sensitivity and specificity, reinforcing FNAC as a reliable preoperative diagnostic modality [19]. The high diagnostic accuracy in the present study highlights the effectiveness of USG-guided FNAC in differentiating benign from malignant lesions, thereby aiding in appropriate clinical decision-making.

Limitations of the Study

- **Small sample size**: The study included only 60 cases, which may limit the generalizability of the findings to a larger population.
- **Single-center study**: Being conducted at a single tertiary care institution, the results may not represent the broader demographic and geographic variability.
- **Sampling error in FNAC**: Despite ultrasound guidance, inadequate or non-representative sampling may have contributed to false-negative and false-positive results.
- **Cytological overlap**: Certain salivary gland lesions exhibit overlapping cytomorphological

features, making differentiation between benign and low-grade malignant tumors challenging.

- **Lack of long-term follow-up**: The study did not include follow-up data to assess recurrence or long-term outcomes.
- **Operator dependency**: The accuracy of FNAC is influenced by the expertise of the operator and cytopathologist, which may introduce variability.

Conclusion

The present study demonstrates that ultrasonography-guided fine needle aspiration cytology (FNAC) is a highly effective and reliable diagnostic modality for the evaluation of salivary gland lesions. A slight female predominance was observed, with no statistically significant association between age and gender distribution ($p = 0.85$). Both FNAC and histopathological findings revealed a predominance of benign lesions, with pleomorphic adenoma being the most common benign tumor and mucoepidermoid carcinoma the most common malignant tumor. A strong cytohistopathological correlation was observed, with the majority of FNAC diagnoses being consistent with histopathological findings. The Chi-square test showed a highly significant association ($\chi^2 = 41.52$, $p < 0.001$), indicating excellent agreement between the two diagnostic modalities. The presence of minimal false-positive and false-negative cases further supports the high diagnostic accuracy of FNAC. Overall, USG-guided FNAC proves to be a safe, minimally invasive, cost-effective, and accurate preoperative diagnostic tool that plays a crucial role in differentiating benign from malignant salivary gland lesions, thereby aiding in appropriate clinical decision-making and management planning.

Acknowledgement

The authors express their sincere gratitude to the Department of Pathology at Anugrah Narayan Magadh Medical College & Hospital, Gaya Ji, for their support and cooperation throughout the study. We are thankful to all the patients who participated in this study. We also acknowledge the guidance and encouragement provided by the faculty members and the assistance of the technical staff in carrying out cytological and histopathological procedures.

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