

# Diagnostic Accuracy of Fine Needle Aspiration Cytology in Evaluation of Parotid Gland Neoplasms

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## ABSTRACT

**Objective:** To analyze Fine Needle Aspiration Cytology's diagnostic accuracy in Parotid Gland Neoplasms by taking the Post-Operative Histopathology Results as a Gold Standard.

**Study Design:** Prospective Longitudinal Study.

**Place and Duration of the Study:** Department of Ear, Nose, Throat, Head and Neck Surgery, Dow University of Health Sciences, Dr Ruth K.M Pfau Civil Hospital, Karachi, Pakistan, from Sep 24 to May 25.

**Methodology:** Analysis was performed on 123 patients who underwent parotidectomy due to a parotid gland lump. The study included all participants who were between the ages of 18 and 75 and who had a suspicion of a parotid gland tumor. The exclusion criteria included any patient with a history of previous parotid gland surgery, autoimmune disease, chronic granulomatous condition, or any inflammatory condition of the parotid gland.

**Results:** Among the 123 patients enrolled, benign tumors were observed in 89 cases (72.4%), whereas malignant tumors were identified in 34 cases (27.6%). When preoperative fine needle aspiration cytology results were compared to the final histopathology, the FNAC revealed diagnostic accuracy of 92.68%, sensitivity of 85.29%, specificity of 95.51%, positive predictive value of 87.88%, and negative predictive value of 94.44%.

**Conclusion:** Our study suggests that FNAC has good sensitivity and specificity and is a relatively accurate method in diagnosing parotid gland neoplasms. Thus, it can be a useful resource for preoperative counselling on the characteristics of the neoplasms and their outcomes as well.

**Keywords:** Diagnostic accuracy, Fine Needle Aspiration Cytology, Parotid Neoplasms, Parotidectomy, Sensitivity and Specificity.

**How to Cite This Article:** Ali SF, Shaikh IA, Rahim D, Ain Q, Rai D, Siddiqui AH. Diagnostic Accuracy of Fine Needle Aspiration Cytology in Evaluation of Parotid Gland Neoplasms. *Pak Armed Forces Med J* 2026; 76(Suppl-1): S218-S223. DOI: <https://doi.org/10.51253/pafmj.v76iSUPPL-1.13590>

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## INTRODUCTION

A vast variety of unusual morphological and pathological neoplasms are included in salivary gland tumors, and their histology is incredibly varied.<sup>1</sup> They make up 0.6% of all cancers in the human body and 3% of all tumors in the head and neck. Around 80% of salivary gland tumors are benign and most commonly occur in the parotid gland. Less frequently occurring percentages are seen in submandibular and sublingual salivary gland tumors.<sup>2</sup> Pleomorphic adenoma and Warthin tumors are the most frequent benign parotid gland tumors, although malignant parotid gland tumors are less prevalent. The most prevalent type is mucoepidermoid carcinoma.<sup>3</sup> Swelling or bulk in the subauricular region can be caused by both benign and malignant tumours, making diagnosis difficult. As a result, these must be identified during the preoperative phase.<sup>4</sup>

Before surgery, fine-needle aspiration cytology

(FNAC) is a crucial diagnostic technique and a recommended procedure used to rule out a parotid tumor.<sup>5</sup> Because of its superficial nature and ease of accessibility, FNAC has become a preferred approach for diagnosing salivary gland tumors preoperatively.<sup>6</sup> Additionally, this method is affordable, easy to use, painless, and well tolerated. It also effectively differentiates between benign and malignant parotid tumors.<sup>7</sup> A precise FNAC diagnosis has important therapeutic implications and assists doctors in making patient care decisions. It also plays a key role in deciding whether surgery should be avoided in non-neoplastic diseases and defining the extent of surgery in benign or malignant lesions.<sup>8</sup> However, cytopathologic examination might be difficult and exacerbated by common pitfalls. The diagnostic validity of FNAC is determined by the aspirate's quality and yield, as well as the cytopathologist's skill. The fact that salivary gland tumours are a heterogeneous group with widely different histopathologic features adds to the diagnostic challenges.<sup>9</sup> Furthermore, some writers argue that preoperative FNAC has minimal impact on clinical

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Received: 22 Jun 2025; revision received: 25 Aug 2025; accepted: 26 Aug 2025

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care because most parotid masses require surgery in the end as well as owing of its false positives and false negatives, the usefulness of FNAC in its interpretation is still debatable.<sup>2</sup> While FNAC is frequently used for the diagnosis of parotid gland neoplasms, there is inconsistency in its reported diagnostic accuracy. The cytopathologist's experience, the quality of the sample that was acquired, and the particulars of the neoplasm can all have an impact on this variability. Similarly, a study conducted in Aga Khan University Hospital by Dhanani *et al.*, reported that the Diagnostic Accuracy of FNAC was found out to be 95.8% with sensitivity, specificity, positive and negative predictive value of 88.9%, 97.9 %, 93% and 96.7% respectively.<sup>10</sup> However, still, the data provided by the studies conducted in Pakistan, especially in public sector tertiary care hospital is very limited.

The rationale for conducting this study is to analyze the diagnostic accuracy of FNAC in the diagnosis of parotid gland neoplasms in our population. Test is comparatively easy, cheap, non-invasive, and also no hospitalization nor general anesthesia is required for the same. If the results of my study show good diagnostic accuracy, then this non-invasive test will be recommended in future as first line of investigation, which will aid the surgeons in performing parotid gland excision. Moreover, since the cytopathologist's expertise and experience, in addition to the aspirate's quality, affect the FNAC's accuracy. Therefore, in order to illustrate the level of expertise within our institution and pinpoint any gaps, this research will involve an evaluation of diagnostic outcomes connected with the cytopathologist's performance.

### METHODOLOGY

This was a prospective longitudinal study conducted in Department of ENT, Head and Neck Surgery, DUHS, DMC, Dr. Ruth K.M Pfau Civil Hospital, Karachi, Pakistan, from Sep 24 to May 25, after the approval of the synopsis both by College of Physicians and Surgeons Pakistan and IRB department of the Institute (IRB-3474/DUHS/APPROVAL/2024/233).

The sample size is calculated using WHO Diagnostic Accuracy Sample size calculator by taking the statistics of Sensitivity as 88.9 %<sup>10</sup> and Specificity of 89.63 %, <sup>11</sup> and Prevalence of the disease 67.50% (6) with a confidence level of 95%, margin of error 5%, and 10% inflation to cater for non-response and missing information. Thus, according to all the above-

stated statistics, our sample size for the patients is calculated to be 123 patients. The sampling technique was non-probability, convenient sampling.

**Inclusion Criteria:** Patients aged between 18 years and 75 years present with suspicion of parotid gland neoplasm.

**Exclusion Criteria:** Patients who had preexisting chronic granulomatous condition, preexisting autoimmune disease, any preexisting inflammatory condition of parotid gland, or a history of prior surgery of the parotid gland.

This study was based on patient records, FNAC results, and subsequent histopathology findings from our database, which remained the main emphasis of the data collection process. We enrolled the patients who had infra-auricular mass with or without local pain and confirmed on ultrasound, as well after which their FNAC was done using a 23-gauge needle; smears were fixed in alcohol and stained with Papanicolaou and Giemsa. Cytology was interpreted by experienced cytopathologists, after which their surgery was done, and final histopathological report was made. Data was analyzed using Statistical Package for Social Sciences Version 26. Mean $\pm$ SD were calculated for continuous variables like age. Percentages and frequencies were estimated for categorical variable gender, benign and malignant parotid neoplasm. ROC curve analysis was performed to determine the area under the curve, sensitivity, and specificity. The *p*-value of less than 0.05 was considered significant.

### RESULTS

A total of 123 cases were reviewed, with the distribution of histological diagnoses: 68 (55.3%) were female, and 55(44.7%) were male, with an average age of 38.9 $\pm$ 9.5 years. The most common tumor was Pleomorphic Adenoma 83(67.5%), a benign neoplasm. Mucoepidermoid Carcinoma (15.4%) was the most frequently observed malignant tumor. Acinic Cell Carcinoma (4.9%) and Adenoid Cystic Carcinoma 6(4.9%) were also present in a smaller proportion. Rare cases included Lymphoma, Monomorphic Adenoma, Sialadenitis, Warthin Tumor, and Squamous Cell Carcinoma ( $\leq$ 1.6%) each. Benign tumors accounted for 89(72.4%) of cases, with an 81(91.0%) FNAC concordance rate. Malignant tumors constituted 34(27.6%) of cases, with a 26(76.5%) FNAC concordance rate. (Table-I).

Table-II presented that FNAC provided an accurate diagnosis in 26(89.65%) of true positive cases.

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A 3(10.35%) inaccuracy rate was observed among true positive cases, indicating a small margin of diagnostic error, while a total of 106(86.2%) of the true negative cases were accurately diagnosed by FNAC. 17(13.8%) of the true negative cases had discrepancies between FNAC and final histological findings.

**Table-I: Histological and Cytological Diagnosis of Patients With Parotid Gland Tumors (n=123)**

Diagnosis	Histology	Concordant	Discordant
Frequency (%)			
Benign	89(72.4)	81(91.0)	8(9.0)
Malignant	34(27.6)	26(76.5)	8(23.5)

**Table-II: True Positives With Inaccurate Results of Patients With Parotid Gland Tumors**

Frequency (%)	
True Positive	
Accurate	26(89.65)
Inaccurate	3(10.35)
True negative	
Accurate	81(95.29)
Inaccurate	4(4.71)

**Table-III: True negative, True Positive, False negative, and False Positive with discordance in histology diagnosis of patients**

	FNAC	Histopathology
True negative(n=4)	Pleomorphic adenoma (n=2)	Sialadenitis (n=2)
	Tuberculosis(n=1)	Pleomorphic adenoma (n=1)
	Warthin tumor(n=1)	Basal Cell adenoma (n=1)
True Positive (n=3)	Mucoepidermoid carcinoma (n=1)	Acinic cell Carcinoma(n=1)
	Mucoepidermoid carcinoma (n=1)	Acinic cell Carcinoma(n=1)
	Mucoepidermoid carcinoma (n=1)	Adenoid Cystic Carcinoma(n=1)
False Positive (n=4)	Mucoepidermoid carcinoma (n=4)	Pleomorphic adenoma (n=4)
False negative(n=5)	Pleomorphic adenoma (n=4)	Lymphoma(n=1) Ex-Pleomorphic Carcinoma(n=1) Mucoepidermoid carcinoma(n=1) Squamous cell carcinoma(n=1)
	Sialadenitis (n=1)	Lymphoma(n=1)

The most frequent discordance among true negatives was pleomorphic adenoma misdiagnosed as sialadenitis. In true positives, acinic cell carcinoma and adenoid cystic carcinoma were misclassified as mucoepidermoid carcinoma.

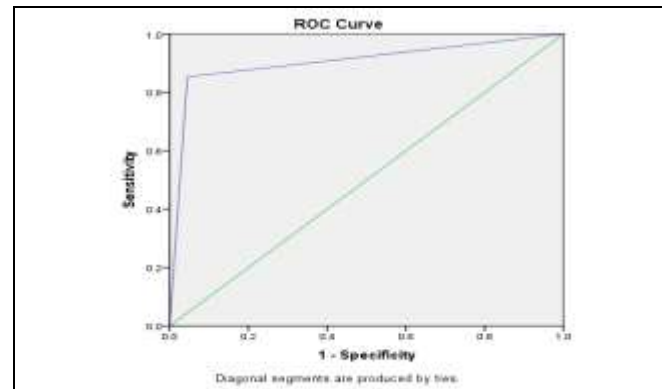
When FNAC was compared with Histopathological results sensitivity of 85.29% was observed. The specificity was 95.51%, and the positive predictive and negative predictive, diagnostic accuracy values were 87.88%, 94.44%, and 92.68%, respectively.

The area under the curve (AUC) for FNAC in detecting disease was 0.904. The 95% confidence interval (CI: 0.830 to 0.978), indicates a high level of diagnostic accuracy, which is significant,  $p < 0.001$ . An AUC of 0.904 suggests that FNAC has excellent diagnostic performance in identifying tumors.

**Table-IV: Comparison Of FNAC and Histological Results With Preoperative Cytology Results (n=123)**

FNAC diagnosis	Histological diagnosis		
	Benign	Malignant	Total
Benign	85(69.11%)	5(4.06%)	90
Malignant	4(3.25%)	29(23.58%)	33
Total	89	34	123

T. N=True Negative, F. N=False Negative, F. P=False Positive, T. P=True Positive



**Figure-1: Receiver operating Characteristic curves (ROC)for the use of (FNAC) to Determine benign and Malignant Disease**

## DISCUSSION

In this study, the presence of false positives (n=4) and false negatives (n=5) in low quantities is also in resemblance with the reported literature. However, there is still the possibility of misclassification, emphasizing the need for further confirmatory tests in ambiguous cases. In total, 16 cases exhibited discrepancies between FNAC and histology, indicating the challenge of distinguishing between morphologically similar tumors. These discrepancies highlight the challenge of distinguishing certain tumor types using FNAC alone. From a surgical standpoint, the majority of parotid tumors are removed for both

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therapeutic and diagnostic reasons, even in cases when FNAC indicates a benign lesion.

Altin *et al.*, had reported that fine needle aspiration cytology is a crucial diagnostic tool for treating a variety of head and neck lesions. The authors also asserted that it is a better diagnostic technique and is safe and accurate in terms of diagnosis and consequences, respectively.<sup>11</sup> However, Fikova *et al.*, contend that due to the increased frequencies of false positives and false negatives and the eventual need for surgery, it has little bearing on clinical care. The accuracy of FNAC in distinguishing between benign and malignant tumors was assessed in this study. About 72.4% of the 123 parotid lesions that were removed were benign, with a total of 89 of those lesions. Thirty-four malignant lesions, 27.6% of the total, were removed. These results are consistent with those found in recent studies, which show that the incidence of benign lesions is 80–85% and that of malignant lesions is 15–20%.<sup>12</sup>

Tripathi *et al.*, accounted for 89 cases of benign tumours (72.4%), of which 81(91.0%) were concordant with FNAC findings. Of the cases, 34(27.6%) had malignant tumors, and the FNAC concordance rate was 26(76.5%). In both cases, the rate is close to what is present in the published literature.<sup>13</sup> The overall discordance rate was higher for malignant tumors 8(23.5%) compared to benign tumors 8, (9.0%), indicating a greater challenge in diagnosing malignancies using FNAC alone, which is also comparable with the research of Dostalova *et al.*,<sup>14</sup> However, to overcome this discordance rate Varazzani *et al.*, implied an extensive 10 years long retrospective study with 5 year follow up to establish the importance of using preoperative MRI, as findings like irregular margins, infiltration of neighboring tissues (subcutis, parapharyngeal space or nerves), and hypo intensity in T2 sequences suggest the presence of a malignant lesion.<sup>15</sup>

In a study by Jering *et al.*, 4 out of 5 false negatives were pleomorphic adenoma, which were later found out to be malignant, because Pleomorphic adenoma is the most common neoplastic lesion of parotid gland, so cytologists might be deceived by this sometimes and report malignant tumours as benign in cytology.<sup>16</sup> In a true negative 1 case of basal cell adenoma was misdiagnosed as Warthin Tumor, as both mentioned tumours belong to monomorphic adenoma group, so sharing some of the common cytological characteristics. Moreover, it is also

reported in literature by Chowdhary *et al.*, that Basal cell adenoma can sometimes be misdiagnosed as Pleomorphic adenoma due to small round basal cells with scanty stroma simulating cellular Pleomorphic adenoma.<sup>17</sup>

FNA results that were inconclusive were mostly caused by Mucoepidermoid carcinoma. (Table-III). So, Carcinoma was responsible for half of the inconsistent outcomes. This subgroup's modest alterations and varied appearance make FNA difficult. Moreover, histology is necessary for a conclusive diagnosis of cancer. However, due to its high prevalence and very well-defined and consistent shape, pleomorphic adenoma can still be recognized reliably.<sup>11</sup>

Several investigations on the effectiveness of FNAC in evaluating parotid gland masses have been conducted, with a wide variety of sensitivities and specificities. A study undertaken in Turkey by Hanege *et al.*, showed that the specificity, sensitivity, positive predictive value, negative predictive value, and accuracy of FNAC were 98 percent, 90 percent, 86 percent, 98 percent, and 97 percent, respectively, when patients diagnosed with malignant and benign cytology were evaluated.<sup>3</sup> Likewise, another comparative study by Chauhan *et al.*, between preoperative FNAC results and postoperative biopsy results, suggests that FNAC is 73% specific and 97% sensitive in diagnosing parotid gland tumors.<sup>7</sup> Similarly, a study by Kasinathan *et al.*, which reported sensitivity and specificity of 68.96% and 89.63%, respectively, as well as positive and negative predictive values of 54.05% and 94.23%, supports the idea that FNAC is an effective diagnostic tool.<sup>18</sup> Another study by Vidyalakshmi *et al.*, on FNAC revealed that its sensitivity and specificity for benign tumors were 100 and 71%, respectively, whereas for malignant tumors, they were 64 and 93%.<sup>19</sup> Overall FNAC sensitivity and specificity for parotid gland lesions given by Kulkarni *et al.*, were 90.3% and 100%, respectively, with 100% and 57.1% for positive and negative predictive values.<sup>20</sup> A latest study by Mayer *et al.*, claimed that FNAC is 88.9% sensitive, 97.9 % specific in diagnosing parotid gland tumors, thus, has significantly reduced surgeries due to timely diagnosis.<sup>21</sup> The positive and negative predictive values were 93% and 96.7%, respectively, with the diagnostic accuracy of FNAC 95.8%.<sup>10</sup> Our results are also in accordance with the above-mentioned studies, with diagnostic accuracy of 92.68%, sensitivity of



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85.29%, specificity of 95.51%, positive predictive value of 87.88%, and negative predictive value of 94.44%.

Our study has a few limitations. The small number of patients may have impacted our results; in particular, the small number of malignant tumors and their discordance rate with FNAC raises some questions. Nonetheless, our findings can offer a perspective and pointer to further research in this area. Finally, follow-up and tumor recurrence rates were not included in our analysis. Therefore, Future larger multicenter studies with a large sample size are still needed to further advocate for FNAC in preoperative diagnosis.

## CONCLUSION

According to our research, FNAC is a reasonably accurate technique for identifying parotid gland neoplasms and has good sensitivity and specificity. It can therefore be a helpful tool for

preoperative counseling regarding the features of the neoplasms and their prognoses.

**Conflict of Interest:** None.

**Funding Source:** None.

## Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

SFA & IAS: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

DR & QA: Data acquisition, data analysis, approval of the final version to be published.

DR & AHS: Critical review, concept, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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