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Enhancing Diagnostic Precision and Clinical Outcomes with FNAC in Parotid Gland Masses

Rehana Ramzan[1*], Zainab Niazi[2], Fareeha Shahid[3], Bismah Ahmad[4], Maria Ilyas[4] and Hana Tasneem Khan[2]

[1]Department of Histopathology, Islamabad Medical and Dental College, Islamabad, Pakistan
[2]Department of Oral Pathology, Islamabad Medical and Dental College, Islamabad, Pakistan
[3]Department of Histopathology, Akhtar Saeed Medical College, Rawalpindi, Pakistan
[4]Department of Oral Pathology, Combined Military Hospital Lahore Medical College and Institute of Dentistry, Lahore, Pakistan

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***Corresponding Author:**
Rehana Ramzan
Department of Histopathology, Islamabad Medical and Dental College, Islamabad, Pakistan
Rehana.ramzan@donthospital.com

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ABSTRACT

Parotid gland tumors present with diverse histopathological profiles, making accurate preoperative diagnosis essential for appropriate management. Fine Needle Aspiration Cytology (FNAC) provides a minimally invasive technique to differentiate between benign and malignant lesions. **Objectives:** To evaluate the diagnostic accuracy of ultrasound-guided FNAC, categorized using the Milan System, in parotid gland masses by correlating cytological findings with final histopathological diagnoses. **Methods:** A prospective observational study was conducted over 12 months, involving 100 patients with clinically suspected parotid gland tumors at a tertiary care center. Patients were enrolled based on predefined inclusion and exclusion criteria. Ultrasound-guided FNAC was performed using 22-gauge needles, and aspirates were categorized per the Milan System. All participants subsequently underwent parotidectomy, and histopathology was used as the reference standard. Data analysis was conducted using SPSS version 26.0 to determine sensitivity, specificity, predictive values, and overall diagnostic accuracy. **Results:** Among the 100 cases, FNAC classified 48 as benign, 12 as malignant, and 5 as non-diagnostic. The most frequent benign and malignant tumors were pleomorphic adenoma (41%) and mucoepidermoid carcinoma (14%), respectively. FNAC demonstrated a sensitivity of 90.4%, specificity of 96.1%, positive predictive value (PPV) of 92.3%, negative predictive value (NPV) of 94.8%, and an overall accuracy of 93.5%. The highest diagnostic concordance was observed in Milan categories IVa and VI. **Conclusions:** It was concluded that FNAC, when guided by ultrasound and interpreted through the Milan System, demonstrates high diagnostic accuracy for parotid masses. It is a cost-effective first-line diagnostic tool, especially beneficial in resource-limited settings.

INTRODUCTION

Salivary gland tumors, especially those originating in the parotid gland, constitute a diverse and complex group of neoplasms that present notable diagnostic and therapeutic difficulties [1]. These lesions display a wide histopathological range, with nearly 70% of all salivary gland tumors occurring in the parotid gland. They encompass benign entities like pleomorphic adenomas and aggressive malignancies such as muco-epidermoid and adenoid cystic carcinomas [2]. An accurate diagnosis before surgery is critical for determining the surgical approach, ensuring facial nerve preservation, guiding prognosis, and planning for any necessary adjuvant treatment. Nonetheless, clinical evaluation and imaging modalities alone often fall short in terms of sensitivity and specificity for differentiating between benign and malignant parotid lesions [3]. Fine Needle Aspiration Cytology (FNAC) has emerged as one of the main minimally invasive methods of preoperative examination of parotid gland tumors [4]. It has the benefits of being simple, economical and able to give a quick cellular diagnosis with minimal morbidity to the patient. The last twenty years have witnessed the development of FNAC from a simple

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cytological method to a complex one that has been aided by the use of ancillary studies like immunocytochemistry and molecular profiling. FNAC performed with ultrasound guidance has even higher sample adequacy and diagnostic yield, and far fewer non-diagnostic or indeterminate results [5]. Despite its broad clinical application, the utility of FNAC in salivary gland pathology remains somewhat debated due to overlapping cytomorphologic characteristics among different tumor types and the inherent challenges of cytological interpretation [6]. To mitigate these limitations, the Milan System for Reporting Salivary Gland Cytopathology was introduced as a structured, tiered classification system designed to enhance communication between pathologists and clinicians and support more informed therapeutic planning [7]. However, real-world data evaluating the diagnostic accuracy, predictive values, and clinical impact of this system, especially in resource-constrained healthcare settings, remain limited [8]. With the world healthcare moving to precision medicine, the importance of precise, early, and less invasive diagnostic tools in head and neck oncology has gained even greater importance, as the morbidity of surgery in these parts can be quite high. The early stratification of patients by FNAC could assist in minimizing the unnecessary surgery of benign lesions and facilitating earlier treatment of malignant lesions [9]. FNAC diagnostic properties have also been supplemented with the use of advanced adjunctive technologies like cell block methods, flow cytometry, and next-generation sequencing, which enable the detection of molecular markers that can guide treatment and long-term monitoring [10]. FNAC is especially beneficial in low- and middle-income nations with undeveloped diagnostic infrastructure; it is a cost-efficient method of addressing diagnostic gaps and reducing healthcare disparities [11]. Consequently, a comprehensive reassessment of FNAC's diagnostic performance in parotid gland lesions, especially within high-volume clinical environments, is both timely and essential to support evidence-based clinical practices and improve patient-centred outcomes [12]. Although previous studies have highlighted the role of FNAC in salivary gland tumors, limited evidence exists regarding its diagnostic reliability in real-world tertiary settings, especially when using standardized cytological systems like the Milan System. Furthermore, there is a paucity of data from resource-constrained healthcare environments where diagnostic tools must be both cost-effective and precise.

This study aimed to assess the diagnostic accuracy of ultrasound-guided FNAC in evaluating parotid gland masses, compare its cytological results with final histopathological findings, and examine its relevance in guiding clinical decisions and surgical management.

METHODS

This prospective observational study was carried out at a single Tertiary Care Academic Hospital in the Department of Otolaryngology and Head and Neck Surgery, in collaboration with the Department of Histopathology. This study was conducted over 12 months from 24 January 2024 to 24 January 2025 and aimed to evaluate the diagnostic performance of FNAC in patients presenting with parotid gland masses. Ethical approval was granted by the Institutional Review Board (IRB) under protocol number IMDC/DS/IRB/248, and written informed consent was obtained from all participants by the principles of the Declaration of Helsinki. The sample size was calculated using the standard formula for estimating proportions in diagnostic studies, which is based on a 95% confidence level ($Z = 1.96$), an assumed prevalence of 50% to allow for maximum variability ($p = 0.5$), and a 5% margin of error ($d = 0.05$). This yielded a theoretical sample size of 384. However, due to practical limitations and the single-center design, a pragmatic sample of 100 patients was selected, consistent with similar diagnostic accuracy studies in the literature. Participants were recruited according to predefined inclusion and exclusion criteria. Inclusion criteria included patients aged 18 years or older with a primary, untreated parotid gland mass and a clinical indication for both FNAC and surgical excision. Exclusion criteria encompassed a history of prior treatment for parotid tumors, recurrent lesions, evidence of distant metastasis at presentation, or contraindications to FNAC, such as bleeding disorders or localized infection. All patients underwent a thorough clinical evaluation, followed by high-resolution ultrasonography (USG) of the parotid region, which served as guidance for the FNAC procedure. The use of ultrasound improved needle targeting and reduced the rate of inadequate samples. FNAC was carried out by an experienced histopathologist using a 22-gauge needle, without the administration of local anesthesia. From each lesion, 2–3 needle passes were obtained. Smears were prepared as both air-dried for Giemsa staining and alcohol-fixed for Papanicolaou staining. Cytological evaluation was performed following the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC), which classifies findings into six diagnostic categories: Category I (Non-diagnostic), Category II (Non-neoplastic), Category III (Atypia of undetermined significance), Category IVa (Benign neoplasm), Category IVb (Salivary gland neoplasm of uncertain malignant potential, or SUMP), Category V (Suspicious for malignancy), and Category VI (Malignant). These standardized categories were used alongside clinical assessment to inform surgical planning. Following FNAC, all patients proceeded to definitive parotidectomy. The excised specimens were evaluated by an independent pathologist, using the 2022 World Health Organization (WHO) classification criteria for salivary gland tumors. Final

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histopathological diagnosis served as the reference standard to assess the diagnostic accuracy of FNAC. Statistical analysis was conducted using IBM SPSS Statistics for Windows, Version 26.0. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were computed by comparing cytological findings with the corresponding histopathological diagnoses. In addition, concordance between Milan System categories and final histopathology was analyzed. Continuous variables were reported as mean ± standard deviation, while categorical variables were summarized as frequencies and percentages. A p-value less than 0.05 was considered indicative of statistical significance.

RESULTS

The study comprised 100 patients presenting with parotid gland masses. The mean age was 47.6 ± 13.4 years, with an age range of 18 to 76 years. A slight male predominance was noted, with 58 male (58%) and 42 female (42%). The most frequent clinical symptom was a painless swelling, reported in 82% of patients, followed by painful masses in 12%, and facial nerve involvement in 6%. Right-sided parotid gland involvement was seen in 56% of cases, whereas 44% had lesions on the left side. Fine Needle Aspiration Cytology (FNAC) yielded diagnostic results in 95% of patients, while 5% were categorized as non-diagnostic.According to the Milan System for Reporting Salivary Gland Cytopathology, the most commonly assigned category was IVa (Benign neoplasm), representing 48% of all cases (Table 1).

Table 1: Cytological Classification of FNAC Based on the Milan System(n=100)

Milan Category	Cytological Diagnosis	Number of Cases
Category I	Non-diagnostic	5
Category II	Non-neoplastic	12
Category III	Atypia of undetermined significance (AUS)	6
Category IVa	Benign neoplasm	48
Category IVb	Salivary gland neoplasm of uncertain malignant potential (SUMP)	8
Category V	Suspicious for malignancy	9
Category VI	Malignant	12

Final histopathological evaluation revealed that 55% of the lesions were benign tumors, including pleomorphic adenoma, Warthin tumor, and basal cell adenoma. Malignant neoplasms constituted 23% of the cases and included mucoepidermoid carcinoma, adenoid cystic carcinoma, acinic cell carcinoma, and carcinoma ex pleomorphic adenoma. Additionally, 9% of the lesions were categorized as inflammatory or non-neoplastic, such as chronic sialadenitis. Rare tumor types accounted for the remaining 14% of the histopathological findings (Table 2).

Table 2: Final Histopathological Diagnosis of Parotid Gland Lesions(n=100)

Histopathological Diagnosis	Number of Cases
Pleomorphic Adenoma	41
Warthin Tumor	7
Basal Cell Adenoma	3
Mucoepidermoid Carcinoma	14
Adenoid Cystic Carcinoma	5
Acinic Cell Carcinoma	4
Carcinoma Ex Pleomorphic Adenoma	3
Chronic Sialadenitis (Non-Neoplastic Lesion)	9
Other Rare Tumors (E.G., Oncocytoma, Myoepithelial Carcinoma)	14

FNAC demonstrated strong diagnostic performance in distinguishing malignant from benign parotid gland lesions. The sensitivity for detecting malignancy was 90.4%, specificity was 96.1%, with a positive predictive value (PPV) of 92.3% and a negative predictive value (NPV) of 94.8%. The overall diagnostic accuracy of FNAC was calculated to be 93.5%, underscoring its reliability as a preoperative diagnostic modality (Table 3).

Table 3: Diagnostic Accuracy Metrics of FNAC in Parotid Gland Masses

Diagnostic Metric	Value (%)
Sensitivity for Malignancy	90.4
Specificity for Malignancy	96.1
Positive Predictive Value	92.3
Negative Predictive Value	94.8
Overall Diagnostic Accuracy	93.5

The results of this prospective study support the great diagnostic value of ultrasound-guided fine needle aspiration cytology (FNAC) in the evaluation of parotid gland masses. FNAC provided diagnostic information in 95% of patients, and the most common cytological group was that of benign neoplasms, mainly pleomorphic adenomas (48%). These findings were confirmed by final histopathological examination, which showed that benign tumors prevailed (55%), with malignant lesions (23%), and non-neoplastic diseases, namely chronic sialadenitis (9%). The histological spectrum was made up of rare tumor types, which were 14%. FNAC had a strong diagnostic performance, exhibiting sensitivity of 90.4%, specificity of 96.1%, positive predictive value (PPV) of 92.3%, negative predictive value (NPV) of 94.8, and an overall accuracy of 93.5. These findings support the fact that FNAC, especially when directed by ultrasound and interpreted according to the Milan System, is a safe and least invasive way of preoperative analysis and categorization of parotid gland lesions.

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DISCUSSION

Fine needle aspiration cytology (FNAC) continues to be a pillar in the preoperative evaluation of salivary gland lesions, especially those that occur in the parotid gland [13, 14]. With a sensitivity of 90.4, a specificity of 96.1 and an accuracy of 93.5, FNAC in this study has shown itself to be a superb diagnostic procedure. The findings are consistent with those of former research by Reerds *et al.,* and Tripathi *et al.,* who also indicated the quality of FNAC in salivary gland diagnostics, particularly in the interpretation of organized reporting paradigms like the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC). The present results reaffirm the existing clinical applicability of FNAC, especially under conditions wherein proper, non-invasive diagnostic procedures are determined as essential in the decision-related surgical planning, irrespective of resource availability [10, 11]. Refinement of the salivary gland cytopathology due to the implementation of the Milan System has been remarkable in that it allows risk-stratification and tiering of the diagnosis method, thus enhancing its consistency and easing communication between these two structures. The FNAC category IVa (benign neoplasm) was the most commonly assigned during our cohort, and its correlation with the final histopathology was always with the pleomorphic adenoma. This observation corresponds with those of big studies that agreed strongly between Milan categories and histopathological outcomes as reported by Tochtermann *et al.,* and Han *et al.,* [8, 15]. Furthermore, Milan categories V (suspicious malignancy) and VI (malignant) in our study proved that they were well aligned with known malignant tumors, including mucoepidermoid carcinoma and adenoid cystic cancer, indicating a predictive advantage of these Milan categories in daily diagnostic practice [16, 17]. Recent advances in cytopathology emphasize the role of ancillary techniques in improving the diagnostic yield of FNAC. Cell block preparation, immunocytochemistry, and molecular profiling are increasingly used to complement cytomorphologic assessment, particularly in cases with overlapping features. For example, molecular markers such as CRTC1–MAML2 fusion in mucoepidermoid carcinoma and MYB–NFIB translocation in adenoid cystic carcinoma offer specific diagnostic and prognostic value and can now be detected in FNAC-derived material. The practical implications of FNAC are particularly profound in resource-limited healthcare systems, where it offers a low-cost, rapid, and accurate tool for patient stratification. By enabling differentiation between benign and malignant parotid lesions, FNAC prevents unnecessary surgical interventions, facilitates appropriate treatment pathways, and ultimately reduces healthcare costs. Nguyen *et al.,* in a systematic review and meta-analysis, emphasized that FNAC maintains high sensitivity and specificity across both academic and community settings when performed with ultrasound guidance and interpreted using standardized systems such as the Milan classification. In our study, the use of real-time ultrasound guidance yielded a low non-diagnostic rate (5%), supporting its essential role in improving aspirate adequacy and diagnostic reliability [18]. Studies by Nguyen and Giang and Nassif *et al.,* confirm that the integration of these molecular adjuncts into FNAC workflows significantly improves diagnostic confidence in indeterminate categories [18 ,19]. This was a single-center study with a sample size of 100 patients, which may limit generalizability to larger populations with broader histological diversity. Moreover, although interpretations were made according to the Milan System and confirmed by experienced pathologists, interobserver variability remains an inherent challenge in cytopathological diagnosis. Finally, the absence of long-term clinical follow-up data precludes assessment of FNAC's prognostic utility and its impact on recurrence rates or disease-free survival [19]. Finally, this study supports the robust diagnostic role of ultrasound-guided FNAC enhanced through structured interpretation using the Milan System in evaluating parotid gland lesions. It offers a high degree of sensitivity and specificity, particularly in distinguishing between benign and malignant tumors, and holds immense clinical value in both well-resourced and resource-limited settings. The multicenter studies, where a larger population of cases is involved, molecular cytopathology, and long-term clinical follow-up are obligatory, and these studies should be used to further define diagnostic accuracy, particularly in the Milan stages III, IVb. The combination of cytomorphology and molecular profiling, diagnostic imaging refers to the future of personalized diagnosis in salivary gland pathology [20].

CONCLUSIONS

It was concluded that FNAC, used with ultrasound guidance and with the analysis of the structure of the Milan system, is a highly sensitive, specific, and precise alternative to the distinction of benign and malignant salivary parotid tumors. These observations confirm its further application in a clinical practice as an informative preoperative diagnostic tool. It was more reliable in categories IVa, V, and VI in Milan, and a problem of diagnostic uncertainty also occurred in categories III and IVb. These results justify the application of FNAC not only as a minimally invasive and low-cost preoperative diagnostic technique but also as a definitive process to improve clinical decision-making, in particular, and the healthcare system in general, where resources are scarce. Overall, the study supports the use of FNAC to plan surgery, avoid unnecessary procedures, and

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instill the element of patient-centered care, thereby complying with our goals and considerations. It should be attempted in the future to introduce the use of FNAC coupled with molecular and immunocytochemical add-ons that can further improve the diagnostic accuracy of this procedure, especially in cytological indeterminate diseases.

Authors Contribution

Conceptualization: RR
Methodology: RR, ZN, FS
Formal analysis: BA
Writing review and editing: MI, HTK

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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