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Diagnostic Accuracy of Ultrasonography in Diagnosis of Parotid Gland Lesions Using Fine-Needle Aspiration Cytology as The Gold Standard

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ABSTRACT

Objective: To determine the diagnostic accuracy of ultrasound by using ultrasound-guided FNAC as the gold standard for diagnosing parotid salivary gland conditions.

Methods: A prospective observational study was conducted at the Radiology department of Islamabad Diagnostic Centre from January 2022 to December 2022. Patients of all ages and genders with suspected major salivary gland conditions were included. All patients underwent ultrasonography and FNAC after providing informed consent and receiving an explanation of the procedure. Following local anesthesia, a needle was inserted under ultrasound guidance to aspirate tissue samples. The aspirated material was labeled, handled, and transported for laboratory analysis. Data were collected using a self-designed form, and data analysis was carried out using SPSS version 20.

Results: A total of 47 cases were evaluated, with a mean participant age of 47.31 years. Of all participants, 57.4% were males, and 42.6% were females. Among the cases with benign FNAC results, 19 were correctly identified as benign in histopathology (True Positives, TP), while 2 were incorrectly classified as malignant (False Positives, FP). Conversely, for the cases with malignant FNAC results, 6 were falsely identified as benign (False Negatives, FN), and 20 were correctly classified as malignant (True Negatives, TN). Sensitivity was found to be 76%, and specificity was 95%. The positive predictive value (PPV) was 90%, and the negative predictive value (NPV) was 76%. The overall accuracy of ultrasound-guided FNAC was calculated to be 82%.

Conclusion: Ultrasonography has proven to be an effective, non-invasive, and reliable diagnostic tool for assessing parotid gland pathology. It demonstrated a strong capability in accurately distinguishing between benign and malignant cases, with high sensitivity and specificity.

Keywords: Parotid gland, pathology, ultrasonography, FNAC, sensitivity, specificity.

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Introduction

The parotid gland, one of the major salivary glands, plays a crucial role in maintaining oral health and facilitating digestion. A variety of pathological conditions, including tumors, cysts, and inflammatory lesions, can affect the parotid gland. The diagnostic accuracy of ultrasound in parotid gland lesion has significant clinical implications. Patients can benefit from accurate and non-invasive imaging, however minimally invasive procedure i.e. ultrasound guided FNAC is still needed.

Salivary gland tumors make up about 2% to 5% of all head and neck tumors.[1,2] The majority of these tumors originate

in the major salivary glands, with roughly 80% occurring in the parotid glands.[1,2] It constitutes a diverse and varied collection of neoplasms with intricate clinicopathologic features and distinct biological tendencies. This diversity adds complexity to the process of diagnosing these conditions.3 Salivary gland neoplasms are known for their extensive range and histological diversity even within the same tumor. Clinical evaluation and diagnostic results are essential factors in the decision-making process for selecting the most suitable diagnosis and treatment for salivary gland tumors.[3] Many non-neoplastic conditions, benign tumors, and malignant growths in the salivary gland can exhibit either a significant or minor cystic element. It is crucial to differentiate between these conditions because the management of patients can vary significantly depending on the specific diagnosis.[3,4]

However, the modern era necessitates prompt and precise diagnosis.[5] Fine Needle Aspiration Cytology (FNAC) and Ultrasonography (USG) are two diagnostic methods that have garnered significance in recent times because of their swift, reproducible, and accurate characteristics.[5] While FNAC is generally safe, it is not entirely free of risks. Infection, bleeding, and swelling at the biopsy site are potential complications. These risks are typically low but can occur, especially in cases where the procedure is not performed by an experienced practitioner or if the patient has an underlying bleeding disorder.[6] Another significant possible complication involves the inadvertent introduction of infection or neoplastic cells into adjacent tissue planes when the needle is passed through them to access the targeted area for aspiration.[6] This underscores the importance of carefully evaluating whether a fine-needle aspiration is required to inform treatment decisions or if definitive treatment can be pursued without the need for fine-needle aspiration.[6] Although imaging diagnosis are crucial in the preoperative assessment of parotid gland tumors, as they offer valuable insights into the tumor's precise location within the gland and its connections with nearby structures.[7] Distinguishing between benign and malignant growths before surgery and understanding the histological subtype of parotid tumors are of utmost significance in the process of surgical planning.[7]

However, ultrasonography of the primary salivary glands (sUS) is an emerging diagnostic approach for assessing the involvement of major salivary glands.[8,9] It is well-tolerated, non-invasive, cost-effective, radiation-free, widely available in rheumatological outpatient settings,[8] and safe for patients with bleeding disorders. Though, its reliability significantly depends on the operator's proficiency. Furthermore, ultrasonography has the potential to accurately categorize parotid gland lesions, which in turn can be helpful in making decisions about whether a biopsy is required. Radiologist–performed ultrasound is increasingly integrated into head and neck surgery as a supplement to the physical examination.[10] This study aims to bridge diagnostic gaps at the local level by determining the diagnostic accuracy of ultrasonography for major salivary gland conditions, potentially improving the quality of diagnoses and patient care by taking FNAC as gold standard.

Methodology

A prospective observational study was carried out at the Radiology department of Islamabad diagnostic centre after taking ethical approval form ERB committee of the University. Study was conducted during a period of one year from June 2022 to May 2023. Patients presenting with clinical symptoms or imaging findings suggestive of major salivary gland conditions of either age and gender were included. Patients with contraindications to FNAC, history of coagulopathy or bleeding disorders, severe local infection overlying the target area, history of allergy to local anesthesia or medications used in the procedure, patients with a known diagnosis of a major salivary gland malignancy and patients who were unwilling for the ultrasound-guided Fine-Needle Aspiration Cytology (FNAC) procedure were excluded. All the patients underwent ultrasonography and ultrasound guided FNAC, after obtaining informed consent and explaining the procedure to the patient, each patient was well positioned to access the salivary gland effectively.

The ultrasound imaging process by using (machine name) was done selecting the appropriate probe, applying gel, and employing the scanning techniques to visualize the gland and any lesions. Furthermore, the local anesthesia was administered to the targeted area, ensuring patient comfort during the procedure of FNAC. The Syringe needle of 3cc or 5cc was inserted under ultrasound guidance to aspirate the tissue or fluid samples. The aspirated material was handled, labeled, and transported for laboratory analysis. After FNAC, patients were monitored for any immediate complications, and appropriate post-procedure care was provided. All data were collected using a self-designed proforma. Data analysis was conducted using SPSS version 20. To determine the sensitivity, specificity (SP), negative predictive value (NPV), and positive predictive value (PPV) of Fine-Needle Aspiration Cytology (FNAC) with

histopathology as the gold standard, 2x2 tables were employed to represent the calculations.

Results

In this analysis of the diagnostic accuracy of ultrasonography was assessed with Fine Needle Aspiration Cytology (FNAC) as the gold standard. The mean age of the participants was 47.31 years, with a standard deviation of 14.42 years. Regarding gender distribution, the majority of the participants were male, accounting for 57.4% of the sample, while females comprised 42.6%. The average tumor size is measured at 27.80 mm in length and 21.82 mm in width as per ultrasonography. (Table I)

Table I: Descriptive statistics of demographic characteristics. (n=47)

Variables		Statistics
Age	Mean	47.31 years
	SD	14.42 years
	Minimum	24 years
	Maximum	68 years
Gender	Male	27(57.4%)
	Female	20(42.6%)
Site of lesion	Left	23(48.9%)
	Right	24(51.1%)
Tumor size average		27.80 X 21.82 mm

Among the ultrasonography findings, the majority of cases were categorized as "Suspicious for malignancy," representing 36.2% of the total sample. Pleomorphic adenoma and Warthin tumor were also prominent, accounting for 19.1% and 12.85% of cases, respectively. Additionally, there were cases of malignant findings (6.4%), abscess (8.5%), benign tumors (4.3%), infections with inflammation (4.3%), lymph nodes (4.3%), and normal results (4.3%). On the other hand, when examining FNAC cytology findings, the largest category was "Pleomorphic adenoma," representing 36.2% of cases, followed by malignant cases at 29.8%. Other findings included Warthin tumor (6.4%), low-grade salivary malignancies (6.4%), and various inflammatory conditions, including acute inflammation, chronic inflammation TB, and abscess, each at 4.3%. There were also cases of normal histology (4.3%) and lymph nodes (4.3%). (Table II)

Among the benign ultrasonography cases, 19 were correctly identified as benign in FNAC cytology (True Positives, TP), while 2 were incorrectly classified as malignant (False Positives, FP). Conversely, for the malignant FNAC cases, 6 were falsely identified as benign (False Negatives, FN), and 20 were correctly classified as malignant (True Negatives, TN). The diagnostic performance metrics calculated from these findings are as follows: Sensitivity, was found to be 76%, specificity, was high 95%. The PPV was 90%, while NPV was 76%. The overall Accuracy (ACC) of the ultrasonography was calculated at 82%. (Table III)

Table II: Ultrasonography and FNAC cytology findings. (n=47)

Variables		Statistics	
Ultrasonography findings	Abscess	4	8.5%
	benign tumor	2	4.3%
	Infection + inflammation	2	4.3%
	Lymph node	2	4.3%
	Malignant	3	6.4%
	Normal	2	4.3%
	Pleomorphic adenoma	9	19.1%
	Suspicious for malignancy	17	36.2%
	Warthin tumor	6	12.85
Total		**47**	**100.0%**
FNAC cytology findings	Abscess	2	4.3%
	Acute inflammation	2	4.3%
	chronic inflammation TB	2	4.3%
	Low grade salivary malignancy	3	6.4%
	Lymph node	2	4.3%
	Malignant	14	29.8%
	Normal	2	4.3%
	Pleomorphic adenoma	17	36.2%
	Warthin tumor	3	6.4%
Total		**47**	**100.0%**

Table III: Diagnostic accuracy of ultrasonography by taking FNAC cytology as gold standard. (n=72)

Ultrasonography	FNAC cytology	
	Benign	**Malignancy**
Benign	19 TP	2 FP
Malignancy	6 FN	20 TN

Sensitivity: TP/(TP+FN) x100 = 76%. Specificity: TN/(FP+TN) x100 = 95%, **PPV:** TP/(TP+FP) x100 = 90%. **NPV:** TN/(FN+TN) x100 =76%. **ACC:** P+TN/(TP+TN+FP+FN) x100 =82%

Discussion

Major salivary gland lesions often require accurate diagnostic evaluation to determine the appropriate management strategy. Ultrasonography is noninvasive and easily available basic valuable tool in this regard, but its diagnostic accuracy compared to fine-needle aspiration cytology and histopathology as the gold standard, remains a subject of interest and investigation. This study aims to

assess the diagnostic accuracy of ultrasonography in the diagnosis of major salivary gland lesions and its concordance with FNAC cytological findings. In this study mean age of the participants was 47.31 years, the majority of the participants were male, 57.4%, while females comprised 42.6%. In the comparison of this study Kasinathan B et al[11] reported that 31 individuals participated in their study, with average age of these participants 41±16.08 years, and according to gender distribution among the study participants was nearly equal, with a ratio of 1:1.066, indicating a slight predominance of females in the population. In another study demonstrated that the patients' ages ranged from 22 to 62 years, with a median age of 42 years and male to female ratio was 1.2:1.0 females.[12] The gender difference may be attributed to variances in study sample size and sample selection criteria when compared to other studies.

In this study among the benign looking cases on ultrasonography, 19 were correctly identified as benign in FNAC cytology (True Positives, TP), while 2 were incorrectly classified as malignant (False Positives, FP). Conversely, for the malignant ultrasonography cases, 6 were falsely identified as benign (False Negatives, FN), and 20 were correctly classified as malignant (True Negatives, TN). Sensitivity, was found to be 76% and specificity 95%. The PPV was 90% and NPV was 76%. In the comparison of this study Krupa K et al[13] indicated that contrast-enhanced ultrasonography holds promise as a valuable tool for preoperative diagnosis of salivary gland lesions. Similar to the findings of Wang et al.[14] ultrasound imaging typically depicts benign parotid gland lesions with a smoothly regular outline and either a consistent or inconsistent internal structure. Conversely, highly malignant tumors often present an irregular and diverse internal structure, often accompanied by the involvement of cervical lymph nodes. In contrast, low-grade malignant tumors may share similarities with benign lesions on ultrasound.[14] Our findings were also supported by the Soni R et al[15] as ultrasonography identified 30 benign lesions, with 25 of them confirmed as benign and 5 as malignant. Additionally, 5 cases were initially classified as malignant, with 4 of them confirmed as malignant and one as benign.

The ultrasound achieved an 83% accuracy rate for diagnosing benign lesions with (96% sensitivity and 44% specificity), and an 85% accuracy rate for diagnosing malignant lesions (50% sensitivity of 50% and 95% specificity). However partially concurring with the study by Wu and colleagues, who noted limited ultrasound diagnostic accuracy in identifying malignant lesions.[16] In the line of this series Garg K et al[16] carried out study to assess the precision of different methods employed in diagnosing salivary gland tumors and they concluded that sonography demonstrated the greatest sensitivity and precision when contrasted with fine needle aspiration cytology and clinical evaluation.[17] Other investigations similarly noted that ultrasound sensitivity, specificity, and diagnostic precision for salivary gland lesions were quite satisfactory.[17,18] Ultrasonography is a straightforward approach for diagnosing salivary gland conditions. It can be conducted as an outpatient procedure, is well-tolerated by the majority of patients, doesn't necessitate anesthesia, and provides immediate results. While there are certain limitations associated with making precise predictions about specific lesions, combining ultrasonography (USG) of salivary gland lesions with a comprehensive clinical history and physical examination can provide valuable insights to assist the surgeon in arriving at an accurate diagnosis and planning the subsequent course of treatment.

Therefore, it is advisable to employ USG as the primary means for the initial assessment of all salivary gland lesions before resorting to open biopsy. However, it's important to note that the definitive and reliable diagnosis is ultimately established through histopathology. The study conducted on a limited sample size might not have provided a sufficiently extensive basis for forming all-encompassing conclusions. Additionally, the ultrasound reports were produced by different radiologists and pathologists, each possessing varying levels of expertise. To establish a more precise assessment of the validity of ultrasonography, it is advisable to conduct larger-scale studies on this topic.

Conclusion

Ultrasonography observed to be as an effective, noninvasive, and reliable diagnostic tool for assessing initial parotid gland pathology. Its capability in correctly identifying benign and malignant cases, with a high sensitivity and specificity. But, considering false positive and false negative findings on ultrasound and the overall satisfactory accuracy of ultrasound guided FNAC, highlights its practicality in clinical practice for diagnosing parotid gland conditions, making it a valuable and accessible option for clinicians.

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