A HOSPITAL BASED PROSPECTIVE STUDY TO EVALUATE THE SENSITIVITY AND SPECIFICITY OF FNAC DIAGNOSIS IN SALIVARY GLAND NEOPLASMS AT TERTIARY CARE CENTER

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Abstract
Background: Fine needle aspiration cytology (FNAC) plays a role in preoperative diagnosis of any salivary gland mass lesions. The objective of this study was to evaluate the sensitivity and specificity in various salivary gland neoplasms, which helps in the appropriate therapeutic management. Materials and Methods: The present study included 300 FNAC cases of salivary gland lesions, both prospective and retrospective in our institute during 2-year study period. The study included all salivary gland FNACs diagnosed and performed during the defined period; however, recurrent cases were excluded from the study. The cases were retrieved from the register of cytology division and analyzed according to Milan System of classification of salivary gland cytopathology. Risk of malignancy for each cytological category was calculated based on malignant histopathological diagnosis divided by the total number of cases in the corresponding category. The overall diagnostic accuracy, the sensitivity, specificity, positive predictive value, and negative predictive value were calculated. Results: Our study showed that total 300 FNACs were performed. Of all the FNACs undertaken, 180 (60%) were from male patients and 120 (40%) were from female patients. The age of the patient ranged from 5 to above 80 years, and peak age of incidence was in 5th to 6th decades of life. The sensitivity, specificity of FNAC for diagnosing neoplastic salivary gland lesions were 93.48% and 100%. Positive predictive value, negative predictive value and diagnostic accuracy of FNAC for diagnosing neoplastic salivary gland lesions were 100%, 66.67% and 94.23% respectively. Conclusion: We concluded that FNAC has a high diagnostic accuracy and helps in early appropriate therapeutic management, whether it is local excision for a benign neoplasm or radical surgery for a malignant neoplasm or alternate treatment. Though there are few diagnostic pitfalls, fine needle aspiration should always be encouraged for initial assessment of all salivary gland swellings.

INTRODUCTION

Fine needle aspiration cytology (FNAC) as a technique of obtaining diagnostic material dates back to 19th century when surgeons Stanley and Earle performed aspiration on a liver mass at St Bartholomew’s hospital, London.¹,² Fine needle aspiration cytology was first introduced in 1920s by Dudgeon and Patrick at St Thomas hospital, London and Martis and Ellis at Memorial hospital, New York.³ Menetrier was the first to use the aspiration technique to investigate lung cancer. The use of 21-gauge needle was described by Guthrie and Martis. Ellis and Stewart carried out this technique in a large scale at the Memorial hospital, New York. Modern fine needle aspiration cytology, cytological morphological criteria and the differential diagnosis of the major tumor entities were defined by Joseph Zajicek’s Scandinavian school of cytopathology.⁴ In 1980 Fine needle sampling without aspiration was introduced by Zaidela et al which was successfully used in salivary gland tumors.⁵ Fine-needle aspiration cytology (FNAC) as a diagnostic procedure is well established and used to evaluate palpable lesions.⁶,⁷ It is the initial investigative applied to establish a diagnosis before any surgical intervention.⁸ It is widely used, safe and relatively non-traumatic procedure that can immediately provide important information. It is easily applicable for locations such as the salivary...
glands, in particular the major salivary glands and to a lesser extent the minor salivary glands.\textsuperscript{[7]} The lesions of salivary glands are commonly encountered clinical problems and range from non neoplastic lesions like inflammation (sialadenitis) and cysts, commonest benign tumour like pleomorphic adenoma to malignant lesions of variable malignant potential.\textsuperscript{[8]} Fine needle aspiration cytology (FNAC) of the salivary glands is an accepted, sensitive and specific technique in the diagnosis of both neoplastic and non-neoplastic lesions.\textsuperscript{[9]} Lesions of the salivary glands frequently are evaluated by this technique and the usefulness of salivary gland FNA relates to the fact that it is easy to perform, is minimally invasive, smear evaluation is immediate, and the procedure can be repeated several times to obtain more tissue for diagnosis or special studies.\textsuperscript{[10,11]} The diagnostic accuracy of FNAC of salivary glands reported varies between 86\% to 98\%.\textsuperscript{[12,13]} The sensitivity ranges from 62\% to 97.6\% and specificity is higher from 94.3\% to 100\%.\textsuperscript{[14,15]} The objective of this study was to evaluate the sensitivity and specificity in various salivary gland neoplasms, which helps in the appropriate therapeutic management.

**MATERIALS AND METHODS**

The present study included 300 FNAC cases of salivary gland lesions, both prospective and retrospective in our institute during 2-year study period. Histopathological correlation was done wherever available and possible. The study included all salivary gland FNACs diagnosed and performed during defined period; however, recurrent cases were excluded from the study. The cases were retrieved from register of cytology division and analyzed according to Milan System\textsuperscript{16} of classification of salivary gland cytology into following diagnostic categories: nondiagnostic, nonneoplastic, atypia, benign, neoplasm of uncertain malignant potential (NUMP), suspicious for malignancy, and malignant.

After explaining the procedure to the patients, the nodule of interest was palpated and fixed with the help of thumb and index finger. Under aseptic precautions, Fine needle aspiration was done using 21-gauge needle and 5 ml syringe applying negative pressure. The material was aspirated and smeared onto clean glass slides. Minimum of 4-5 smears were prepared in the present study. Smears were wet fixed using 95\% ethyl alcohol for Haematoxylin and eosin (H&E) stain and Papanicalaou stain, and air dried for Leishman stain. The histopathological specimens when available were fixed overnight in 10\% formalin, processed using automatic tissue processor, Leica TP20 stained with routine H & E stain. The stained cytological and histopathological slides were studied under light microscope, analyzed and correlated. Exclusion criteria included all cases where the aspirate was inadequate and or smears were acellular/hemorrhagic.

Cytological diagnosis was correlated with histopathological diagnosis whenever, excised salivary gland specimens were available. Risk of malignancy for each cytological category was calculated based on malignant histopathological diagnosis divided by the total number of cases in corresponding category. The overall diagnostic accuracy, the sensitivity, specificity, positive predictive value, and negative predictive value were calculated.

**RESULTS**

Our study showed that total 300 FNACs were performed. Of all the FNACs undertaken, 180 (60\%) were from male patients and 120 (40\%) were from female patients. The age of the patient ranged from 5 to above 80 years, and peak age of incidence was in 5th to 6th decades of life. The parotid gland was most frequently involved (70\%) and this was followed by submandibular and minor salivary gland with equal frequency of involvement (14\%) and minority (2\%) cases were reported in sublingual salivary gland.

On FNAC the lesions were broadly categorized into non neoplastic and neoplastic lesions. Out of 300 patients, majority of cases, 170 (56.66\%) were neoplastic lesions and 130 (43.33\%) were non neoplastic lesions [Table 1].

Out of 300 cases, histopathology correlation was available for 104 cases. Among the 104 histopathologically diagnosed cases, 12 (11.54\%) cases were non-neoplastic and 92 (88.46\%) cases were neoplastic [Table 2]. Among the 92 neoplastic lesions, 62 (60\%) cases were benign and 30 (28.46\%) cases were malignant.

Out of 300 cases in present study, histopathology was available for 104 cases, and among which 86 cases were true positive for neoplastic lesions on FNAC. The sensitivity, specificity of FNAC for diagnosing neoplastic salivary gland lesions were 93.48\% and 100\%. Positive predictive value, negative predictive value and diagnostic accuracy of FNAC for diagnosing neoplastic salivary gland lesions were 100\%, 66.67\% and 94.23\% respectively [Table 3].

<table>
<thead>
<tr>
<th>Types of Lesions</th>
<th>No. of Patients</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non neoplastic</td>
<td>130</td>
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<tr>
<td>Neoplastic</td>
<td>170</td>
<td>56.66%</td>
</tr>
<tr>
<td>Total</td>
<td>300</td>
<td>100%</td>
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Table 1: Distribution of non-neoplastic and neoplastic lesions on FNAC
Table 2: Histopathologically diagnosed Non-Neoplastic and Neoplastic Lesions

<table>
<thead>
<tr>
<th>Lesions</th>
<th>No. of Patients</th>
<th>Percentage (%)</th>
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</thead>
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<tr>
<td>Non-Neoplastic</td>
<td>12</td>
<td>11.54%</td>
</tr>
<tr>
<td>Neoplastic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benign</td>
<td>62</td>
<td>60%</td>
</tr>
<tr>
<td>Malignant</td>
<td>30</td>
<td>28.46%</td>
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<tr>
<td>Total</td>
<td>104</td>
<td>100</td>
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Table 3: Cyto-histopathological correlation of Lesions

<table>
<thead>
<tr>
<th>FNAC</th>
<th>Histopathology (HPE)</th>
<th>Non-Neoplastic</th>
<th>Neoplastic</th>
<th>Total</th>
</tr>
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<tr>
<td>Non-Neoplastic</td>
<td></td>
<td>12</td>
<td>2</td>
<td>4</td>
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<tr>
<td>Benign Neoplasms</td>
<td></td>
<td></td>
<td>60</td>
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<tr>
<td>Malignant Neoplasms</td>
<td></td>
<td></td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>12</td>
<td>62</td>
<td>30</td>
</tr>
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</table>

FIGURE 1: (a) Inadequate cytology shows few cyst macrophages and cyst fluid; 10 × Pap smear. (b) Nonneoplastic cytology, Pap smear 10 × shows benign salivary acini and lymphocytes in the background. H and E 10 × of same case shows chronic sialadenitis. (c) Benign cytological category, Pap smear 10 × shows grayish blue matrix material and epithelial cells clusters. H and E 40 × shows chondromyxoid stroma with epithelial cell trabeculae. (d) Atypia of undetermined significance, Pap smear 40 × shows cyst macrophages and mucinous material; this could be mucocele or low-grade mucoepidermoid carcinoma, corresponding H and E 40 × shows low-grade Mucoepidermoid carcinoma.

FIGURE 2: (a) Suspicious of malignancy cytology: MGG smear 40 × reveals atypical cell, H and E 40 × of the same case shows squamous cell carcinoma. (b) Malignant cytology: Pap smear 10 × and H and E 40 × show adenoid cystic carcinoma.

DISCUSSION

Salivary gland tumours comprise 3% to 6% of all head and neck neoplasms in adults with an incidence of 1 to 3 per 100,000 people per year. Fine needle aspiration cytology (FNAC) of the salivary gland is a widely used and commonly accepted, sensitive and specific technique in the diagnosis of both neoplastic and non-neoplastic lesions of the salivary gland. This has proved to be a very important diagnostic tool in the diagnosis of salivary gland lesions, mainly due to its safe procedure, cost-effectiveness, lower rate of complications and aids the clinician in therapeutic management. The main goal of FNA is to determine if a mass is inflammatory and/or reactive, benign or malignant neoplasm and if possible, to render a specific diagnosis, especially typing the neoplastic lesions. Cytology study will definitely distinguish between salivary and non-salivary lesions, benign and malignant lesions, so also specific and nonspecific inflammation. Because of heterogeneity of numerous lesions, cytomorphological features are overlapping. Hence, many a times it poses problem in the definitive diagnosis.

In present study, majority of the salivary gland lesions were seen in male patients. There was male preponderance with male to female ratio of 1.14:1. Similar observation was made by Upasana et al., Jain C et al., Gandhi S et al.,[21] (1.43:1).

Our study showed parotid gland was most frequently involved site for benign as well as malignant lesions, whereas literature reported minor salivary gland as most frequent site for malignant tumors. This was followed by the involvement of submandibular gland and minor salivary gland. In our study, malignant tumors were most common finding, whereas various other studies reported benign neoplasm as most common finding. This could be due to our center being a tertiary cancer care center. Neoplastic lesions were more common than non-neoplastic lesions in the present study, which was a similar finding seen in study done by Upasana et al who found of 82.5% neoplastic cases and of 17.5% non-neoplastic lesions. However the study done by Jain C et al.,[22] showed a higher frequency of non-
neoplastic lesions (54.27%) than neoplastic lesions (45.31%). Out of 300 cases, histopathology correlation was available for 104 cases. Among the 104 histopathologically diagnosed cases, 12 (11.54%) cases were non-neoplastic and 92 (88.46%) cases were neoplastic. Among the 92 neoplastic lesions, 62 (60%) cases were benign and 30 (28.46%) cases were malignant. Similar observation was seen in the study done by Upasana P et al, who found that 75 (86.2%) were concordant and 12 (13.8%) were discordant. In study by Jain C et al, had 30 cases available for histopathological correlation, 26 (86.6%) were concordant and 4 (13.4%) were discordant. In the study done by Gandhi S et al, had 30 cases among which 26 (86.6%) were concordant and 4 (13.4%) were discordant.

CONCLUSION
We concluded that FNAC has a high diagnostic accuracy and helps in early appropriate therapeutic management, whether it is local excision for a benign neoplasm or radical surgery for a malignant neoplasm or alternate treatment. Though there are few diagnostic pitfalls, fine needle aspiration should always be encouraged for initial assessment of all salivary gland swellings. FNAC of the salivary gland tumours showed that it is advantageous for both the patients and the clinicians because of its immediate results, accuracy, lack of complications and its economy.

REFERENCES