Fine-Needle Aspiration Biopsy of Salivary Gland Lesions in a Selected Patient Population

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Objective: To report the role of selective use of preoperative fine-needle aspiration biopsy (FNAB) in patients with major salivary gland lesions at a tertiary care cancer center.

Design: Retrospective review of FNAB results compared with final histologic diagnosis as the criterion standard.

Setting: An academic tertiary care cancer center.

Patients: A consecutive series of 258 patients who underwent FNAB of major salivary gland lesions between 1996 and 2000, of whom 169 had surgical resection.

Main Outcome Measures: Predictive value, sensitivity, specificity, and accuracy.

Results: FNAB was performed in 169 (37%) of 463 salivary gland lesions undergoing surgical procedures. A total of 126 lesions were in the parotid gland and 44 in the submandibular gland. Seventy-nine lesions (46%) were malignant. There were 150 FNAB specimens (89%) that were satisfactory for evaluation. The FNAB diagnosis of malignant or suspicious lesion had positive and negative predictive values of 84% and 77%, respectively. Ten of 20 false-negative FNAB results were low-grade lymphoma on final histologic assessment. Fine-needle aspiration biopsy diagnosis of a benign neoplasm had positive and negative predictive values of 83% and 88%, respectively. A cytopathologic diagnosis of a nonneoplastic lesion was predictive in only 47% of cases. Fifteen (47%) of 32 lymphocyte-predominant FNAB specimens were lymphoma on final histologic assessment. Ten (20%) of 49 patients with history of a solid, non–head and neck malignancy had evidence of distant metastasis to the salivary gland by histologic and/or cytopathologic assessment.

Conclusions: An FNAB diagnosis of malignant or neoplastic major salivary gland disease is generally predictive of final histologic diagnosis. The predictive value of a negative FNAB finding is low, and should not supersede clinical suspicion. Cytologic findings of a lymphocyte-predominant lesion should prompt further workup to rule out lymphoma.

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The patient population at a tertiary care cancer center generally includes a large number of patients with prior malignancy and patients referred for management of salivary gland masses that are suspicious for malignant disease. Fine-needle aspiration biopsy is used in the evaluation of a selected group of salivary gland masses at our institution. The aim of this study was to report the accuracy of preoperative FNAB of major salivary gland lesions used selectively in a tertiary cancer referral center. We reviewed the experience at the Memorial Sloan-Kettering Cancer Center (MSKCC) over a 5-year period. Results of salivary gland FNAB were compared with histologic findings after resection to define the accuracy of this diagnostic procedure in a selected patient population.

## METHODS

A total of 463 patients treated at the MSKCC between January 1, 1996, and December 31, 2000, who had FNAB and/or surgical excision or biopsy of previously untreated major salivary gland lesions were identified using institutional computer databases. All FNABs were performed at MSKCC or cytopathology slides from other institutions were officially interpreted by an MSKCC cytopathologist. Surgical excision or biopsy was performed by 1 of 7 staff members of the Head and Neck Service. Medical records were reviewed to retrospectively collect clinical and pathology data. Patients with a history of previously treated salivary gland neoplasm who had possible recurrent disease at the primary site were excluded from the analysis.

Demographic, clinical, cytopathology, and histopathology data were entered into a computer database (Microsoft Excel 2000; Microsoft Corp, Redmond, Wash). Details of cytopathologic interpretation, including specimen quality, cell types identified, cytologic impression, specific cytologic diagnosis, and specific histologic diagnosis, were recorded.

Cytopathologic and histologic findings were categorized as malignant, suspicious, benign neoplastic, or nonneoplastic. Sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) of FNAB were calculated using histologic diagnosis of the surgical specimen as the criterion standard. All cases in which cytopathology did not correlate with histology were rereviewed by a cytopathologist (O.L.) to identify whether specimen quality or sampling error may have contributed to this lack of correlation.

### RESULTS

A total of 463 salivary gland surgical procedures were performed during the study period, of which 169 (37%) also had a preoperative FNAB (group A). This group forms the basis of this study (Table 1). A separate cohort of 89 patients had an FNAB without undergoing surgical excision of the salivary gland mass (group B), so that a total of 258 salivary gland FNAB specimens were evaluated during the study period.

One hundred eight (64%) FNABs were performed at MSKCC, while the remaining 61 (36%) were performed elsewhere prior to referral to our service. One hundred fifty FNAB specimens were satisfactory for evaluation (89%), while the remaining 19 FNAB specimens (11%) were unsatisfactory for evaluation on initial review on the basis of insufficient cells or excessive artifact. The rate of unsatisfactory FNAB specimens was similar for those performed at MSKCC (13%) and those reviewed at MSKCC (8%).

Seventy-nine (46%) of 170 lesions were malignant. Distribution of histologic diagnoses of parotid (n = 127) and submandibular lesions (n = 43) is summarized below and in Table 2.

<table>
<thead>
<tr>
<th>Histologic Diagnosis</th>
<th>Parotid Lesions</th>
<th>Submandibular Lesions</th>
<th>Total No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acinic cell carcinoma</td>
<td>3 (5)</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Adenoid cystic carcinoma</td>
<td>2 (3)</td>
<td>1 (6)</td>
<td>3</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>14 (23)</td>
<td>7 (39)</td>
<td>21</td>
</tr>
<tr>
<td>Malignant mixed</td>
<td>5 (8)</td>
<td>1 (6)</td>
<td>6</td>
</tr>
<tr>
<td>Melanoma</td>
<td>7 (11)</td>
<td>1 (6)</td>
<td>8</td>
</tr>
<tr>
<td>Mucoepidermoid</td>
<td>7 (11)</td>
<td>4 (22)</td>
<td>11</td>
</tr>
<tr>
<td>Myoepithelial carcinoma</td>
<td>1 (2)</td>
<td>1 (6)</td>
<td>2</td>
</tr>
<tr>
<td>Poorly differentiated carcinoma</td>
<td>3 (5)</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Salivary ductal carcinoma</td>
<td>7 (11)</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Squamous cell carcinoma</td>
<td>6 (10)</td>
<td>1 (6)</td>
<td>7</td>
</tr>
<tr>
<td>Other malignant</td>
<td>6 (10)</td>
<td>2 (11)</td>
<td>8</td>
</tr>
<tr>
<td>Total Malignant</td>
<td>61</td>
<td>18</td>
<td>79</td>
</tr>
<tr>
<td>Benign</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemangioma</td>
<td>2 (3)</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Lipoma</td>
<td>1 (2)</td>
<td>1 (4)</td>
<td>2</td>
</tr>
<tr>
<td>Hyperplastic lymph node</td>
<td>12 (18)</td>
<td>2 (8)</td>
<td>14</td>
</tr>
<tr>
<td>Monomorphic adenoma</td>
<td>4 (6)</td>
<td>1 (4)</td>
<td>5</td>
</tr>
<tr>
<td>Oncocytoma</td>
<td>6 (9)</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Pleomorphic adenoma</td>
<td>26 (39)</td>
<td>8 (32)</td>
<td>34</td>
</tr>
<tr>
<td>Sialadenitis</td>
<td>1 (2)</td>
<td>11 (44)</td>
<td>12</td>
</tr>
<tr>
<td>Warthin tumor</td>
<td>10 (15)</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Other benign</td>
<td>4 (6)</td>
<td>2 (8)</td>
<td>6</td>
</tr>
<tr>
<td>Total Benign</td>
<td>66</td>
<td>25</td>
<td>91</td>
</tr>
</tbody>
</table>

**Table 1. Demographic Data**

<table>
<thead>
<tr>
<th>Age, mean (range), y</th>
<th>57 (13-87)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, No. (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>92 (54)</td>
</tr>
<tr>
<td>Female</td>
<td>78 (46)</td>
</tr>
<tr>
<td>Site of lesion, No. (%)</td>
<td></td>
</tr>
<tr>
<td>Parotid</td>
<td>126 (74)</td>
</tr>
<tr>
<td>Submandibular</td>
<td>44 (26)</td>
</tr>
<tr>
<td>Size of lesion, median (range), cm</td>
<td>2.0 (0.3-8.0)</td>
</tr>
</tbody>
</table>

**Table 2. Histologic Diagnoses of Salivary Gland Lesions**

**Table 3. Histologic Diagnosis Parotid Lesions Submandibular Lesions**

<table>
<thead>
<tr>
<th>Histologic Diagnosis</th>
<th>Parotid Lesions</th>
<th>Submandibular Lesions</th>
<th>Total No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benign neoplastic</td>
<td>61 (48%)</td>
<td>18 (43%)</td>
<td></td>
</tr>
<tr>
<td>Nonneoplastic</td>
<td>49 (39%)</td>
<td>11 (26%)</td>
<td></td>
</tr>
<tr>
<td>17 (13%)</td>
<td>14 (33%)</td>
<td></td>
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</tr>
</tbody>
</table>
lesions in general (either benign or malignant) corre-
related with histologic diagnosis of a neoplastic lesion in 
94% of cases. It is noteworthy that patients with an FNAB 
specimen with no evidence of neoplastic cells actually 
had a neoplastic lesion, either benign or malignant, in 
more than one half of such cases (53%) on final histo-
logic assessment.

A total of 20 patients had false-negative FNAB di-
agnoses for malignancy. Ten (50%) of these 20 patients 
had low-grade lymphoma diagnosed by open biopsy. Lymph-
cocytes were present in the FNAB specimen in all cases 
of lymphoma. The remaining 10 false-negative FNAB find-
ings included 3 cases of malignant mixed tumor, 2 mu-
coepidermoid carcinomas, 2 acinic cell carcinomas, 1 
metastatic melanoma, 1 metastatic neuroendocrine car-
cinoma, and 1 squamous cell carcinoma. In 4 of these 
cases, the FNAB was interpreted as a benign neoplastic 
lesion and 1 case was interpreted as a branchial cleft cyst. 
After rereview of the cytopathology slides, sampling er-
eror was evident in 5 cases.

Ten benign neoplasms diagnosed on final histo-
logic assessment had no neoplastic cells identified with 
FNAB, including 3 oncocytomas, 2 Warthin tumors, 2 
pleomorphic adenomas, 1 hemangioma, 1 lipoma, and 
1 benign lymphoepithelial lesion.

Ten specimens with false-positive FNAB findings, 
interpreted as cytologically suspicious or malignant, were 
benign neoplasms (n=6), sialadenitis (n=3), or a lymph 
ode (n=1) by histologic examination. In 3 of the 6 be-
ign neoplasms, the correct diagnosis was part of the di-
ferential diagnosis offered.

The accuracy of cytologic diagnosis according to fi-
nal histologic assessment is summarized in Table 4. The 
type of lesion, ie, malignant, benign neoplastic, or non-
neoplastic, was suggested by the FNAB in most cases. No-
table exceptions included lymphoma and malignant mixed 
tumor.

A more clinically meaningful approach is evaluat-
ing the value of specific FNAB diagnoses in correctly 
predicting final histologic diagnosis (Table 5). This table
includes the subset of specimens in which the cytologist was able to offer a specific diagnosis or considered the FNAB finding to be malignant or suspicious (n=105). Cytopathologic impression of malignancy or benign neoplasm was predictive in most cases. The cytopathologic diagnosis of a benign lymph node, however, was actually lymphoma on final histologic assessment in 50% of those cases.

Thirty-two cytopathology specimens, including 24 parotid and 8 submandibular lesions, contained lymphocytes or inflammatory cells with no salivary epithelium present. These were associated with lymphoma in 15 patients (47%). In only 5 of these cases were atypical lymphocytes or lymphocytes suspicious for lymphoma detected by routine cytopathology. The remaining 17 patients had 9 hyperplastic lymph nodes, 2 cases of sialadenitis, 1 oncocytoma, 1 Warthin tumor, 1 hemangioendothelioma, 1 acinic cell carcinoma, and 1 metastatic neuroendocrine carcinoma.

When the analysis was limited to FNAB specimens containing salivary epithelium, the positive and negative predictive values for detecting malignancy were 82% and 85%, respectively. While the NPV was higher in this subgroup than the overall study population, malignant cells were still not detected in 15% of FNABs from patients with malignant masses. While the PPV of suspicious or malignant cells in a lymphocyte predominant FNAB was 100%, the NPV was only 57%.

Forty-eight patients (28%) had a documented diagnosis of malignancy within 10 years before presentation. Malignant salivary gland lesions were found in 31 (65%) of these 48 patients compared with 48 (39%) of 122 patients with no history of malignant disease (χ² = .005).

Ten (77%) of 13 patients with history of a head and neck malignancy had metastases (8 parotid, 2 submandibular) from their index primary tumor, including 4 of 5 patients with cutaneous squamous cell carcinoma, 4 of 5 patients with cutaneous melanoma, 1 patient with Merkel cell carcinoma, and 1 of 2 patients with oral cavity squamous cell carcinoma. Three of 7 patients with a history of lymphoma had recurrent lymphoma, while 3 of these patients had primary salivary gland malignancies.

Twenty-five patients had a history of a non–head and neck solid malignant tumor, and 3 of these patients had metastases to the salivary gland on final histologic assessment (gastric adenocarcinoma, neuroendocrine carcinoma, and lung adenocarcinoma). Nine (36%) of these 25 patients had a diagnosis of a new malignancy, a rate similar to that of patients with no history of malignant tumors.

Among the 89 patients in group B, who had FNAB but no surgical excision, 46 patients (52%) had a documented prior malignancy. Seven of 24 patients with a history of a non–head and neck, solid malignant tumor had cytopathologic evidence of distant metastases, including 3 lung carcinomas, 1 breast carcinoma, 1 prostate leiomyosarcoma, 1 renal cell carcinoma, and 1 pancreatic adenocarcinoma. Considering all patients from groups A and B with a prior history of a non–head and neck, solid malignant tumor, 10 (20%) of 49 patients had evidence of distant metastasis to the salivary gland by either histologic and/or cytopathologic assessment.

The cytopathologic interpretation of FNAB specimens from the remaining 82 patients in group B without evidence of distant metastases included 12 (15%)
FNAB specimens unsatisfactory for evaluation, 18 (22%) benign salivary tumor, 3 (4%) suspicious for neoplasm, 6 (7%) primary salivary malignancy, 5 (6%) metastatic carcinoma, 4 (5%) lymphoma, 11 (13%) lymph node, 16 (20%) negative for malignant cells, 1 (1%) cyst, and 6 (7%) inflammatory. These findings were not confirmed by histologic evaluation.

Our experience with selective use of FNAB for salivary gland masses in a tertiary care cancer center revealed a relatively high PPV of cytopathologic findings of suspicious or malignant cells. The NPV was only 77%, implying that even in the absence of suspicious or malignant cells, a patient with a “benign” FNAB result may have a malignancy in 23% of cases. Similarly, cytopathologic findings of neoplastic cells, either benign or malignant, predicted a neoplastic lesion on final histologic assessment in 94% of cases. The NPV, however, was only 47%. This means that more than half of FNAB specimens with no neoplastic cells were actually neoplastic lesions on final histologic assessment.

Reported predictive value of salivary gland FNAB has varied widely between studies. A study by Al-Khafaji et al1 with a patient population similar to the present study reported PPV and NPV of 85% and 84%, respectively. This study also reported correct identification of 10 of 10 cases of lymphoma based on FNAB, although the lymphoma grade and type was not specified. Other studies with a lower proportion of malignant lesions have reported a wide range of predictive values. Atula et al2 reported PPV and NPV for parotid malignancy of 70% and 87%, respectively. The same group reported PPV and NPV of submandibular masses of 50% and 86%, respectively.4 Zurrida et al8 however, reported both high PPV and NPV of 100% and 90%, respectively.

Most studies of salivary gland FNAB have reported results in terms of sensitivity and specificity. Diagnostic sensitivity of cytopathology in detecting malignant disease was 73% in this study. The implication of this finding is that if FNAB were used as a screening tool in this patient group, 27% of malignant lesions would have been missed. These values fall within the wide range of sensitivity reported in other studies, from values as low as 27% up to 97%.2-10 The reasons for such a wide range of reported sensitivity and predictive values is unclear, but may be related to technical factors, such as experience of the physician performing the FNAB, and the availability of immediate and expert cytopathologic examination to assess adequacy of the specimen.

Specificity of a cytologic diagnosis of suspicious or malignant cells was 87% in this study. Specificity reported in most studies has been similarly high, in the range of 84% to 100%.2-10 Sensitivity and specificity of 82% and 86%, respectively, were reported from another tertiary care cancer center with a patient population similar to ours.1

The false-negative FNAB findings included a variety of lesions. A common reason for false-negative FNAB findings is sampling error. In particular, malignant mixed tumors are heterogeneous lesions, and frequently contain both benign and malignant features. Similarly, low-grade mucoepidermoid carcinomas are difficult to diagnose by cytopathologic evaluation alone because of the heterogeneous cellular population and scant cellularity.

The potential for false-negative FNAB findings has been highlighted in several studies. Atula et al3 reported on 187 patients who underwent parotid FNAB with histologic confirmation. Only 52% of malignant lesions were correctly diagnosed by cytopathologic assessment. In particular, diagnosis of mucoepidermoid carcinoma, adenoid cystic carcinoma, lymphoma, and squamous cell carcinoma was frequently missed by FNAB alone. Similar to our study, 59% of FNAB specimens without neoplastic cells were neoplastic lesions on final histologic assessment. Another study published by Atula et al3 revealed false-negative FNAB results in 10 of 14 submandibular malignancies, including 5 lymphomas and 3 adenoid cystic carcinomas. Zurrida et al6 reported false-negative FNAB findings in 9 (29%) of 31 parotid malignancies, including several mucoepidermoid, acinic cell, adenoid cystic, and myoepithelial carcinomas. Al-Khafaji et al1 reported 13 false-negative FNAB findings out of 76 malignant tumors (17%). These included several cases of low-grade mucoepidermoid carcinoma, squamous cell carcinoma, acinic cell carcinoma, and malignant mixed tumors.

This study highlights the difficulty in diagnosing low-grade lymphoma based on FNAB alone. Low-grade lymphomas accounted for half of the falsely negative FNAB results in our experience. A mixed population of benign inflammatory cells and malignant lymphocytes, as well as lack of cellular atypia, makes this diagnosis difficult by cytology. Similar findings have been described in several reports. Zurrida et al6 reported correct identification of only 2 of 7 cases of parotid lymphoma by FNAB, and both of these were high-grade lymphoma. The difficulty in diagnosis of lymphoma by FNAB is not unique to the salivary glands. Pilotti et al11 in a study of lymph node FNABs, included 88 cases of lymphoma. Sixteen (100%) of 16 cases of high-grade lymphoma were correctly identified by FNAB; however, only 23 (64%) of 36 cases of low-grade lymphoma were identified.

The patients in the present study underwent open biopsy for definitive diagnosis of lymphoma. Although several studies have reported high rates of diagnosis and subclassification of lymphomas by FNAB and flow cytometry,12,13 accurate classification of a low-grade lymphoma usually requires an open biopsy to obtain adequate tissue samples.

The high rate of malignant lymphoma in patients with FNAB specimens containing many lymphocytes was a striking finding in this study. Forty-seven percent of these cases were lymphomas on final histologic assessment. Chai et al12 reported similar findings in a study of salivary gland FNABs with prominent lymphoid component. The large number of lymphomas may, in part, reflect a selection bias in our institution.

Our philosophy regarding salivary gland FNAB has been to use this investigation in selected clinical scenarios. These include evaluation of poorly defined salivary gland masses, suspected nonsalivary pathology (eg, lymphoma), and suspected recurrent or metastatic disease to the salivary gland. Fine-needle aspiration biopsy
has also been used, at the surgeon’s discretion, to confirm malignant disease in order to counsel patients regarding extent of surgical resection and possible neck dissection. The selection criteria for patients who received FNAB in this study are difficult to precisely define, but were generally performed for the above reasons. Only 37% of all patients undergoing salivary gland resection underwent preoperative FNAB during the study period. The rate of malignant disease in this group was 46%, compared with 33% of patients who had resection without preoperative FNAB. This reflects the higher clinical suspicion for malignant lesions in patients who underwent preoperative FNAB.

We do not advocate routine use of FNAB in the evaluation of well-defined parotid masses, because it generally does not alter the surgical plan or extent of resection. More important, if interpreted out of context, a false-negative FNAB finding may dissuade the patient and surgeon from pursuing an indicated surgical procedure.

Management of the facial nerve is based on preoperative facial nerve function and intraoperative findings. In most cases, a functioning facial nerve or its branches are not sacrificed unless grossly invaded by tumor. A preoperative FNAB does not help with this determination. However, the cytologic diagnosis of a malignant lesion may allow for improved preoperative counseling of the possibility of facial nerve weakness and rehabilitation.

When interpreting FNAB results from salivary gland masses, one must keep in mind the limitations of FNAB. A cytologic diagnosis of a malignant or benign neoplastic lesion is, in general, predictive of final histologic diagnosis, although 16% of malignant cytopathologic impressions were benign on final histology in this study. A negative FNAB specimen, one without neoplastic or malignant cells, does not reliably rule out a malignant or neoplastic lesion. An FNAB specimen with predominantly lymphocytes without salivary epithelium was frequently associated with low-grade lymphoma on final histologic diagnosis even when suspicious or malignant cells were not identified, and this finding should prompt further workup for lymphoma. The possibility of salivary epithelial tumor cannot be ruled out by a lymphocyte predominant FNAB.

The findings in this study supports the use of FNAB in several clinical scenarios: (1) evaluation of patients with prior history of head and neck skin or upper aerodigestive malignancy; (2) evaluation of patients with prior history of non–head and neck solid tumors; and (3) evaluation of suspected nonsalivary pathology, with the caveats that a negative FNAB finding by itself does not rule out lymphoma or other neoplastic diseases, and that a lymphocyte predominant cytology specimen should be interpreted by the clinician as suspicious for lymphoma.

Selective use of FNAB of major salivary gland masses yielded a PPV of 84% and an NPV of 77%. Lymphocyte-predominant FNAB specimens were found to have a low predictive value and, by themselves, cannot reliably iden-

**CONCLUSIONS**

Tify low-grade lymphoma. Such an FNAB finding should prompt further workup for lymphoma, and the possibility of a primary salivary tumor should also be considered. Fine-needle aspiration biopsy has a useful role in the evaluation of salivary gland masses in patients with a history of head and neck malignancy, including cutaneous malignancy, a history of a non–head and neck solid malignant tumor, or a history of lymphoma to rule out recurrent or metastatic disease. When FNAB is used to rule out lymphoma, the difficulty in diagnosing low-grade lymphoma by FNAB should be recognized. Fine-needle aspiration biopsy may also be a useful diagnostic tool in the preoperative counseling of patients with salivary gland masses. Regardless of the situation in which FNAB is used, a negative FNAB finding should not supersede clinical judgment in the management of a clinically suspected malignant or neoplastic lesion of the major salivary glands.

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**REFERENCES**