

## A Lean Neck Mass Clinic Model: Adding Value to Care

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**Objectives/Hypothesis:** To demonstrate that ultrasound-guided fine needle aspiration (USFNA) with on-site cytopathologic analysis eliminates unnecessary diagnostic testing, return visits, and repeat procedures and optimizes quality of care.

**Study Design:** Retrospective cohort.

**Methods:** Sixty-one new patients (28 female; 33 male; age range = 19–85 years) were seen in our dedicated neck mass clinic over a 1-year period. All patients underwent USFNA of masses located in neck levels I–VI (n = 40), parotid gland (n = 20), or parapharyngeal space (n = 1). Each patient underwent two USFNA passes followed by on-site cytopathologic analysis with additional passes if required for diagnosis.

**Results:** Diagnosis was made in 93.4% (n = 57) of patients, allowing for counseling and treatment planning at the first visit. To obtain a diagnosis, more than half (57.4%, n = 35) of our patients required additional passes, which implies that they would have required an additional visit without on-site cytopathologic analysis. Treatment included observation in 42.6% (n = 26) of patients, surgery in 32.8% (n = 20) of patients, and nonsurgical treatment (chemotherapy, radiation, other) in 24.6% (n = 15) of patients. The average time from check-in to checkout including the clinic visit, biopsy, and treatment counseling was 103 minutes, and the average round trip mileage traveled per patient was 127.6 miles.

**Conclusions:** The adult neck mass is a commonly encountered scenario in otolaryngology. For the patient, this can be a stressful situation in which timely and accurate diagnosis is critical. A dedicated lean neck mass clinic model with USFNA and on-site cytopathologic analysis can be both an efficient part of one's practice and a valuable addition to patient care.

**Key Words:** Neck mass, fine needle aspiration, ultrasound.

**Level of Evidence:** 4

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### INTRODUCTION

Early diagnosis and management is critical for successful treatment in patients who present with neck masses as a sequela of malignancy. For patients with benign disease who present with a neck mass, early diagnosis can also be very valuable at alleviating concerns and anxiety. As there is no gold standard diagnostic algorithm for these patients, our team orchestrated a new lean neck mass clinic model with the hope of improving care for this patient population.

Lean management principles are largely attributed to Taiichi Ohno and were initially used at Toyota manufacturing in Japan. The goal of lean management is to remove waste from a process so that all remaining work is value-added while serving a customer's needs.<sup>1,2</sup> Utilizing lean principles, we describe our dedicated neck mass clinic

and demonstrate that in-office ultrasound-guided fine needle aspiration (USFNA) with immediate on-site cytopathologic analysis eliminates unnecessary diagnostic testing, return visits, and repeat procedures and optimizes quality of care.

### MATERIALS AND METHODS

This study was performed as a retrospective cohort with University of Michigan Institutional Review Board approval (HUM00087331). A total of 117 new patients were seen in our lean neck mass clinic over a 1-year period. Patients were excluded if they were given a diagnosis prior to presentation, had imaging and/or ultrasound characteristics that were diagnostic negating need for USFNA, or if they did not undergo USFNA for other reasons (n = 48). A total of 61 new patients (28 female; 33 male; age range = 19–85) met inclusion criteria. Patients were not required to hold any medication prior to their office visit, including anticoagulants. All included patients underwent a history, head and neck physical examination, review of any prior imaging, and USFNA of masses of at least 5 mm located in neck levels I–VI (n = 40), parotid gland (n = 20), or parapharyngeal space (n = 1). Each patient underwent two USFNA passes followed by on-site cytopathologic analysis. The patients underwent additional passes with repeat cytopathologic analysis if required with the goal of preliminary diagnosis at the same visit. On-site core needle biopsy was performed if there was concern for lymphoma based on history and physical, particularly if the patient complained of B symptoms, or if the cytopathologist requested additional tissue to make a diagnosis and/or treatment plan based on fine needle aspiration (FNA; n = 6).

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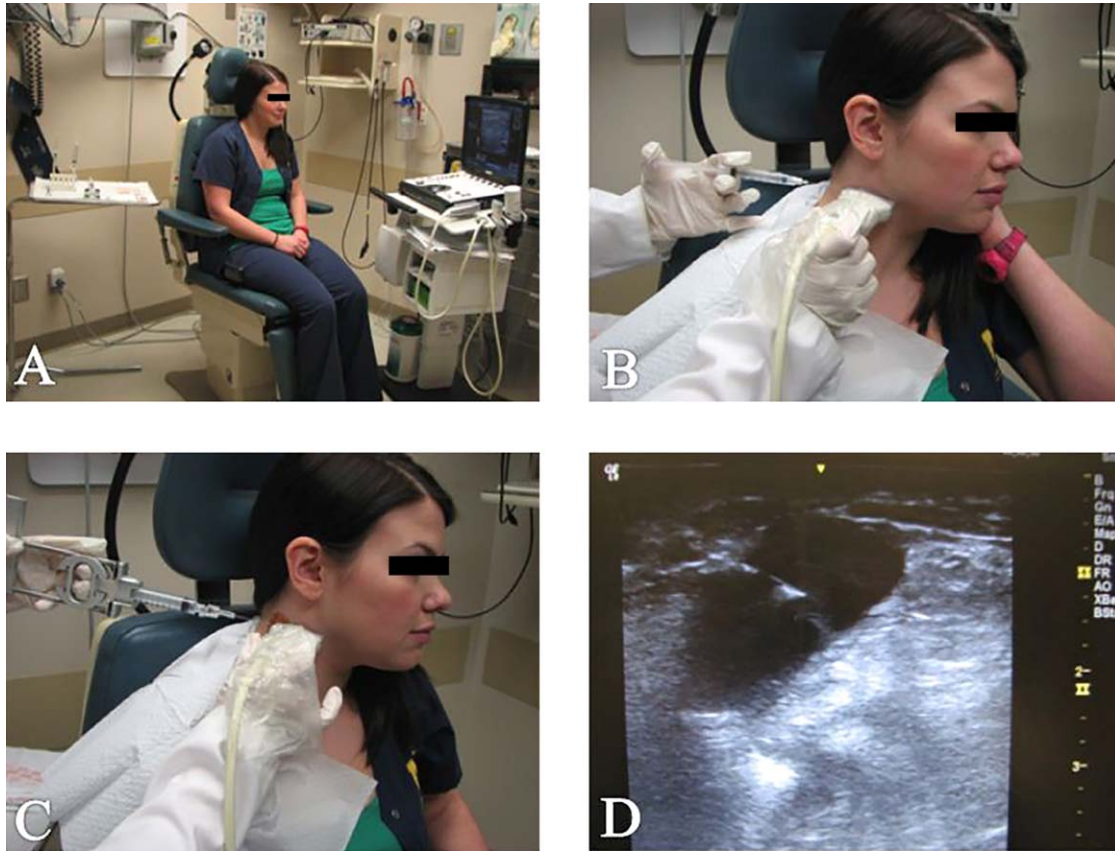


Fig. 1. (A) Examination room setup for a right-sided neck mass. Note that sharp instruments are out of patient sight, which may help ease anxiety. The patient is asked to visualize the ultrasound screen, which assists with access. (B) After ultrasound examination, the expected trajectory is marked and local anesthetic is injected. (C) A 22-gauge needle is used to perform the fine needle aspiration with negative pressure. (D) The needle is visualized under ultrasound guidance and multiple micropasses are made within the mass to improve diagnostic yield before releasing the plunger and withdrawing the needle. [Color figure can be viewed in the online issue, which is available at [www.laryngoscope.com](http://www.laryngoscope.com).]

All office-based USFNA procedures were performed by one staff otolaryngologist with expertise in head and neck oncology as well as American College of Surgeons Thyroid and Parathyroid Ultrasound certification. Ultrasound was performed with Doppler as appropriate to further delineate any vascular involvement. The lesions were visualized on ultrasound and marked appropri-

ately, and then local anesthetic (1% lidocaine with 1/100,000 epinephrine) was injected into the presumed FNA trajectory. Next, a 22-gauge needle was used to aspirate the mass under ultrasound guidance and the mass was documented. Two passes were performed (Fig. 1). The specimens were then immediately handed off to the on-site cytopathologist or cytotechnician for immediate

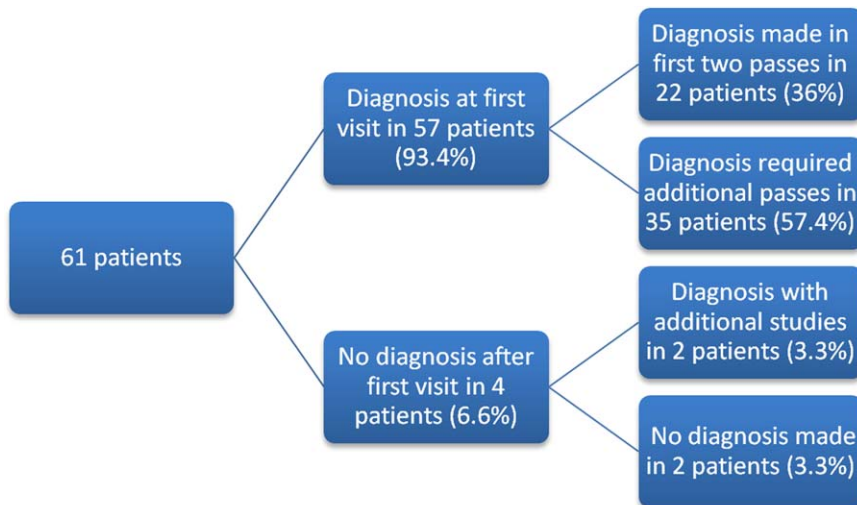


Fig. 2. How a diagnosis was obtained for the 61 patients who visited our neck mass clinic. Diagnosis was made in 93.4% (n=57) of patients at their first visit; more than half (57.4%, n=35) of these patients required additional passes, which implies that they would have required an additional visit without on-site cytopathologic analysis. Of the four patients who did not receive a diagnosis after the first visit, two obtained a diagnosis after additional studies, and no diagnosis was made in the other two. [Color figure can be viewed in the online issue, which is available at [www.laryngoscope.com](http://www.laryngoscope.com).]

TABLE I.  
Breakdown of Patient Characteristics, Clinic Findings, and Outcomes.

Age, yr	Sex	Location	Additional Passes?	Diagnosis at First Visit?	Diagnosis	Outcome
81	F	Parotid	Y	Y	Warthin tumor	Observation
68	M	Level IV	Y	N	None (reactive lymphadenopathy)	Observation
48	M	Level II	N	Y	Benign salivary gland tissue	Observation
53	M	Level II	Y	Y	Squamous cell carcinoma	Nonsurgical treatment
28	F	Anterior neck	N	Y	Thyroglossal duct cyst	Observation
24	F	Level I	N	Y	Reactive lymphadenopathy	Observation
61	F	Level I	N	Y	Sialoceles	Observation
24	M	Level V	Y	Y	Lymphoma	Nonsurgical treatment
66	F	Level I	Y	Y	Reactive lymphadenopathy	Observation
56	M	Level I	Y	Y	Reactive lymphadenopathy	Observation
77	M	Level II–IV bilateral	N	Y	Lymphoma	Nonsurgical treatment
39	F	Level II–IV	N	Y	Pleomorphic adenoma	Surgical treatment
63	M	Level II	N	Y	Squamous cell carcinoma	Surgical treatment
80	M	Level II	Y	Y	Merkel cell carcinoma	Surgical treatment
89	M	Levels I–V	Y	Y	Lymphoma	Nonsurgical treatment
57	M	Level II	Y	Y	Squamous cell carcinoma	Surgical treatment
63	M	Level II	Y	Y	Poorly differentiated carcinoma	Nonsurgical treatment
51	M	Levels I–V	Y	Y	Infection/tuberculosis	Nonsurgical treatment
59	F	Level VI	Y	Y	Nodular hyperplasia	Observation
63	M	Parotid	Y	Y	Squamous cell carcinoma	Surgical treatment
70	M	Level I	Y	N	None (sialadenitis)	Further workup, nonsurgical treatment
39	M	Parotid	N	Y	Simple cyst	Surgical treatment
94	F	Parotid	N	Y	Low-grade oncocytic neoplasm	Observation
68	F	Level I	Y	Y	Reactive lymphadenopathy	Observation
72	F	Parotid	N	Y	Pleomorphic adenoma	Surgical treatment
30	F	Parotid	Y	Y	Parotid cyst	Surgical treatment
59	M	Level II	N	Y	Squamous cell carcinoma	Nonsurgical treatment
70	M	Parotid	N	Y	Parotid cyst	Observation
25	M	Level V	N	Y	Reactive lymphadenopathy	Observation
69	F	Level II	Y	Y	Squamous cell carcinoma	Nonsurgical treatment
66	F	Level V	N	Y	Reactive lymphadenopathy	Observation
66	F	Parotid	Y	Y	Warthin tumor	Surgical treatment
44	F	Level I	Y	Y	Reactive lymphadenopathy	Observation
50	M	Parapharyngeal	Y	N	None (paraganglioma)	Further workup, observation
47	M	Parotid	N	Y	Pleomorphic adenoma	Surgical treatment
77	M	Parotid	Y	Y	Granulation	Observation
65	M	Parotid	N	Y	Warthin tumor	Observation
77	F	Level II	N	Y	Warthin tumor	Observation
30	M	Parotid	Y	Y	Pleomorphic adenoma	Surgical treatment
67	F	Level I	Y	Y	Low-grade malignancy	Surgical treatment
67	F	Level II	Y	Y	Venous malformation	Observation
53	M	Level II	Y	Y	Squamous cell carcinoma	Nonsurgical treatment
66	M	Level III	Y	Y	Paraganglioma	Observation
60	F	Parotid	Y	Y	Low-grade neoplasm	Surgical treatment
20	F	Level II	Y	Y	Reactive lymphadenopathy	Observation
47	M	Level II–IV	Y	Y	Squamous cell carcinoma	Nonsurgical treatment
64	M	Parotid	N	Y	Warthin tumor	Nonsurgical treatment
63	M	Level V	Y	Y	Pleomorphic lipoma	Surgical treatment

TABLE I.  
(Continued)

Age, yr	Sex	Location	Additional Passes?	Diagnosis at First Visit?	Diagnosis	Outcome
67	M	Parotid	N	Y	Low-grade neoplasm	Observation
67	F	Parotid	N	Y	Low-grade neoplasm	Surgical treatment
50	M	Level V	N	Y	Simple cyst	Observation
85	F	Parotid bilateral	N	Y	Warthin tumor	Observation
29	M	Level II	N	Y	Branchial cleft cyst	Surgical treatment
19	M	Level I	Y	N	None (schwannoma)	Further workup, surgical treatment
51	F	Parotid	N	Y	Pleomorphic adenoma	Surgical treatment
52	F	Parotid	Y	Y	Warthin tumor	Observation
63	F	Level V	Y	Y	Lymphoma	Nonsurgical treatment
33	M	Level V	Y	Y	Lymphoma	Nonsurgical treatment
41	F	Level VI	N	Y	Papillary thyroid carcinoma	Surgical treatment
29	F	Parotid	N	Y	Pleomorphic adenoma	Surgical treatment
58	F	Level II–IV bilateral	Y	Y	Noncaseating granuloma	Nonsurgical treatment

F = female; M = male.

processing and reviewed in person or via telecommunication with an off-site cytopathologist. Repeat passes were performed if the specimen was inadequate as necessary. The cytopathologist reported their preliminary diagnosis to the surgeon to be shared with the patient followed by counseling and planning if appropriate.

## RESULTS

Diagnosis was made in 93.4% (n = 57) of patients, allowing for counseling and treatment planning at the first visit (Fig. 2). To obtain a diagnosis, more than half (57.4%, n = 35) of our patients required additional passes, which implies that they would have required an additional visit without on-site cytopathologic analysis. On-site core needle biopsy was performed in 8.7% (n = 6) of patients if lymphoma was highest on the differential diagnosis or if additional tissue was required for diagnosis and/or treatment planning. All patients with a parotid mass received a diagnosis at the first visit. Of the four patients who did not receive a diagnosis at the first visit and required additional workup, three had neck masses (n = 2 level I, n = 1 level IV) and one had a parapharyngeal space mass.

The average time from check-in to checkout including the clinic visit, biopsy, and treatment counseling was 103 minutes. The average round trip mileage traveled per patient was 127.6 miles. Treatment included observation in 47.5% (n = 29) of patients, surgery in 31.1% (n = 19) of patients, and nonsurgical treatment (chemotherapy ± radiation) in 21.3% (n = 13) of patients (Table I). There were no major complications reported in any patient, including infection, hematoma, or neuropathy.

Of the 19 patients who had surgical therapy, 16 patients had their diagnosis confirmed on final pathology. The other three patients all had low-grade salivary gland neoplasms on their USFNA. After surgical excision, these were further stratified as an oncocytoma

(n = 1), basal cell adenoma (n = 1), and low-grade mucoepidermoid carcinoma (n = 1).

## DISCUSSION

Our clinical model provides a standardized algorithm that promotes expedient diagnosis, counseling, and formation of a treatment plan. By reducing time to diagnosis and the need for return visits, this model decreases wait times for new referrals and allows the surgeon to see more new patients. Additionally, office-based ultrasound and ultrasound-guided procedures have been proven to be a cost-effective tool for the head and neck surgeon.<sup>3</sup> In-office USFNA often avoids the need for further imaging for diagnosis or alternatively, guides further imaging for treatment planning if needed.

Although USFNA has a higher sensitivity and specificity when compared to conventional FNA with palpation alone, it historically fails to provide an adequate sample or has indeterminate cytologic findings in 10% to 20% of cases.<sup>4,5</sup> On-site cytopathologic review can immediately assess the adequacy of a specimen and improve diagnostic yield. A study by Moberly et al. compared methods of review for USFNA and found that the diagnostic rate was increased and the rate of adequate specimens obtained showed a positive trend when a cytopathologist was present at the time of biopsy.<sup>6</sup> With immediate cytologic analysis, the surgeon has the ability to communicate with the cytopathologist regarding differential diagnosis and concerns based on history, physical, and ultrasound characteristics that may also enhance diagnostic yield.

The patient benefits most greatly from this practice model. Prior to the opening of this clinic, a patient presenting with a neck mass would be referred to any available new head and neck patient slot with any number of otolaryngology providers. Their workup from that point would be entirely provider specific and may have included history and physical only, further radiologic imaging,

pathology- or radiology-performed FNA, physician-performed FNA, or physician-performed USFNA without on-site cytopathologic analysis. Patients almost always required at least two to three visits for diagnosis and counseling. Some providers also routinely performed operative excisional biopsy after a nondiagnostic FNA.

Patients specifically benefit from reduced time to diagnosis, as most patients are given a preliminary diagnosis on the day of their first visit. There is improved diagnostic accuracy with USFNA with on-site cytopathology, which decreases the need for repeat procedures and leads to decreased patient discomfort overall. There is reduced risk to the patient in our model for several reasons. First, they avoid radiation from additional imaging. Second, they avoid the anesthetic risk from an excisional biopsy. Third, because we do not require the patient to hold anticoagulation for USFNA, their risk of thromboembolic events is reduced. Lastly, because cytotechnicians can immediately assess the quality of an FNA sample, repeat passes do not require additional anesthetic, and patients have reported less pain than with traditional FNA. Patients incur less cost, as this model requires fewer trips to our facility for which they must pay for transportation, meals, and parking, and have a reduced need for radiologic studies and diagnostic operative intervention, both of which can cost a patient thousands of dollars. Patients benefit emotionally, as they are rarely left waiting for a diagnosis, leading to less anxiety in the weeks between office visits. They also are provided with counseling at their first visit, which either provides them with reassurance or assists them in early planning.

## CONCLUSION

The adult neck mass is a commonly encountered scenario in otolaryngology. For the patient, this can be a stressful situation in which timely and accurate diagnosis is critical. A dedicated lean neck mass clinic model with USFNA and on-site cytopathologic analysis can be both an efficient part of one's practice and a valuable addition to patient care.

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