

Title Page

TITLE:

**ONE-STOP THYROID NODULE CLINIC WITH SAME DAY FINE NEEDLE
ASPIRATION CYTOLOGY IMPROVES EFFICIENCY OF CARE.**

Running Head: Surgeon performed US-FNAC

Authors:

Rajeshbhai Patel FRACS ^a, Anita Skandarajah MD, FRACS ^{a b}, Alexandra Gorelik
MSc ^c, Matthew J Shears MBBS ^a, Robert Tasevski MSc, FRACS ^{a b}, Julie A Miller
FRACS ^{a b}

Departments and Institution:

^a Endocrine Surgery Unit, The Royal Melbourne Hospital, Melbourne, Australia

^b Department of Surgery, University of Melbourne, Melbourne , Australia

^c Melbourne Epicentre, The Royal Melbourne Hospital, Melbourne, Australia

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Corresponding Author:

Rajeshbhai Patel

Whangarei Hospital, Maunu Road, Private Bag 9742, Whangarei, 0148, New Zealand

rajesh1280@gmail.com

phone: +6494304100

Fax: +6494304115

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Abstract

Introduction

Thyroid nodules are a common presenting complaint for endocrine surgeons; many require ultrasound-guided fine needle aspiration cytology (US-FNAC). In an attempt to streamline our service, we introduced same-day surgeon-performed US-FNAC in 2014.

Methods

Three groups were defined: (A) retrospective group with FNAC performed in radiology prior to August 2014, (B) prospective radiology FNAC group, and (C) prospective surgeon-performed group. Demographics, nodule characteristics, pathology and management plans were recorded. The number and dates of hospital attendances were extracted from the medical record.

Results

Over 4 years 635 patients underwent 757 FNAC. There were 438 patients in Group A, 78 in Group B, and 119 in Group C. Patient demographics and nodule size were

similar between groups. Those undergoing FNAC in endocrine surgery clinic required 2 visits prior to receiving a diagnosis and management plan, compared to 3 visits for those performed in radiology. Non-diagnostic rates between three groups were 6.5%, 7.4% and 5.4% ($p = 0.842$) whilst malignant FNAC results occurred in 3%, 4% and 8% ($p = 0.015$) respectively. Median time from US-FNAC to definitive management plan was 42, 41 and 14 days ($p < 0.001$). The introduction of the one-stop clinic resulted in a 41% reduction of patients attending the radiology department for FNAC.

Conclusion

Surgeon-performed US-FNAC decreases the time from FNA request to definitive plan and reduces the number of patient visits, providing more efficient care. Patients referred to the endocrine surgery clinic with thyroid nodules have thyroid cancer more frequently than patients referred to radiology.

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Introduction

Thyroid nodules are the most common reason for referral to an endocrine surgeon, and their incidence is increasing.¹ The time between referral and diagnosis is a time of heightened anxiety for patients. Fine-needle aspiration cytology with ultrasound guidance (US-FNAC) is the gold standard diagnostic test to differentiate benign from malignant thyroid nodules.²⁻⁴

Specialist evaluation of thyroid nodules at many public hospital endocrine surgery clinics involves three outpatient appointments: (1) clinical evaluation in endocrine surgery clinic, (2) referral to radiology for US-FNAC, and finally (3) appointment back in endocrine surgery clinic for delivery of results and formation of

a management plan. This sequence is inefficient for the health care system and inconvenient for the patient.

We have previously shown that surgeon performed US-FNAC is just as accurate as radiology-performed US-FNAC.⁵ These findings have been replicated in other studies.⁶⁻¹⁰ In 2014, we introduced a service offering same-day surgeon-performed US-FNAC to patients requiring thyroid biopsy. The subsequent follow up appointment facilitates delivery of results and the management plan, and the extra appointment in radiology is eliminated. This “one-stop thyroid nodule evaluation clinic” has not previously been described in the Australian public hospital setting.

We aimed to evaluate the impact of surgeon-performed thyroid US-FNAC on the time from the initial FNAC request to formation of a management plan, the number of patient visits, and the burden on the radiology department from US-FNAC.

Methods

With institutional ethics approval, we studied all patients undergoing US-FNAC in our public hospital during a four-year period from August 2011 to August 2015. Surgeon-performed US-FNAC in the thyroid clinic was introduced in August 2014. All patients were offered a same-day FNA biopsy or to return to radiology on another day. Three groups were defined: (A) Retrospective group with FNAC performed by the radiology department prior to August 2014, (B) prospective radiology FNAC group, August 2014-August 2015 and (C) prospective one-stop surgeon performed

US-FNAC, August 2014-August 2015. Patient demographics, nodule characteristics (size, number), cytology, and management plans were extracted from patient charts. For operated patients, histopathology results were documented. The number and dates of hospital attendances (clinic and radiology) were recorded.

Timeliness of care was calculated, in particular the number of days between FNAC being requested and FNAC being performed, as well as the number of days from FNAC request to the patient receiving results and formation of a management plan.

Patients in all three groups were excluded from analysis if there was a planned 6 or 12 month US-FNAC, if US-FNAC was requested from the emergency department, if there was insufficient data available, or if patients did not attend follow up clinics.

Patients were given an appointment to attend for results after FNA was performed. If patients failed to attend, another appointment was sent by post. In addition, referring GP's were sent copies of cytopathology reports.

Surgeon performed US-FNAC procedure

One of three endocrine surgeons performed, or supervised a fellow performing, each US-FNAC. All three surgeons had taken a thyroid US/FNA course, and had experience with thyroid ultrasound FNAs. The fellow took the course at the beginning of the year. We followed the American Thyroid Association guidelines to determine which nodules underwent FNAC.² After history, physical examination, and review of

existing images, patients requiring thyroid FNAC were given written and verbal information about the FNAC, with the opportunity to ask questions. Patients were asked if they wanted the FNAC on the same day as the clinic or at another appointment at the radiology department. We established a dedicated clinic room with a portable BK Medical Flex Focus Ultrasound System (model 1202, BK Ultrasound, Denmark) with a high frequency linear array transducer (6-18MHz). A cytology scientist attended, and prepared slides and assessed for specimen adequacy in clinic. Patients were positioned supine, with a pillow behind the shoulders, and the neck extended. After US assessment of the thyroid and identification of nodules requiring FNAC, skin was cleaned with alcohol-based skin preparation and a 25 gauge x 1.25" needle with no syringe attached was used to perform FNAC. The needle was visualized entering the nodule with real time US. Representative images were saved and stored. By advancing and withdrawing the needle a few millimeters and rotating the needle within the nodule, cellular material enters the needle and hub via capillary action. Aspiration with a syringe was used only in cases when material did not appear via capillary action alone. Once material appeared in the hub of the needle, the needle was withdrawn and handed to the cytology scientist. The cytologist then expelled the material onto a glass slide and created a smear by sliding a second slide across it. One slide was allowed to air dry, whilst the other was wet-fixed in 95% alcohol. The cytology technician visually inspected slides for specimen adequacy by holding the slide in front of a light box and assessing the amount of material present, presence of tissue fragments, colloid content and blood. If the technician reported a specimen as

inadequate, another needle pass was performed. A small adhesive dressing was placed on the puncture site if necessary.

All FNAC results were reported according to the Bethesda classification for thyroid cytology.¹¹

Statistical analysis

Stata 12 (StataCorp, TX, USA) statistical package was used. Fishers exact test for categorical data and Kruskal-Wallis for continuous data. A p value <0.05 was considered statistically significant.

Results

Six hundred and thirty five patients underwent 757 US-FNAC during the study period. There were 438 patients in group A, 78 group B and 119 in group C, who underwent 513, 98 and 146 US-FNAC respectively. In group A, 29 patients were excluded from the timeliness analysis. Twenty-seven patients had planned 6 or 12 months follow up and two had 'urgent' requests from the emergency department. In group B, 9 patients were excluded because of planned 6 months follow up. In group C, 8 patients were excluded from the timeliness of care analysis, as they failed to attend the follow up appointment.

Within group C, Surgeon-performed FNAC, 99.2% (118/119) of patients preferred same day biopsy rather to attending radiology on another day.

Demographics and nodule size

Gender and age was not statistically different between the three groups. For groups A, B and C, the percentage female was 77.6%, 74.4% and 83.0% respectively. The mean age for each group was 58, 54 and 50 years. (Table 1) The nodule size was not statistically different between groups; the median size was 21, 23 and 20mm respectively.

FNAC results

A total of 757 US-FNAC were performed. Seven hundred and nineteen were thyroid nodule biopsies and 33 were lymph node FNAC. Within group C, we also performed biopsies on 2 thyroglossal duct cysts, one submandibular gland, and one facial lipoma. (Table 2) Non-diagnostic sample rates (Bethesda I) were 6.5, 7.4 and 5.4% in groups A, B, and C, respectively ($p=0.842$). Malignant FNAC in the three groups were 3%, 5% and 8%, respectively ($p=0.015$). All Bethesda groups are shown in Table 3.

Within group C, 7 patients had insufficient FNAC results. All of these patients underwent repeat FNAC within two-weeks, or were assessed as low risk and had repeat FNAC in 6 months..

Anticoagulation and Complications

Radiology patients were asked to cease anticoagulation prior to biopsy. Amongst the surgical patients, anticoagulation therapy was not considered a contra-indication for FNAC, and biopsies were performed on all group C patients with indications for FNAC, regardless of medication use. There were no haematomas, infections, or other complications in any Group C patients. Complication data for patients biopsied in radiology were not available.

Timeliness of care

For groups A and B, (the radiology groups,) the median time from 'FNA request to FNA performed' was 23 and 21 days respectively. For group C, this time was zero days, because the request date and performed date were the same day (in the clinic). The median time from 'FNA request to FNA results and management plan' was 42, 41 and 14 days between the three groups ($p < 0.001$). (Table 4)

Discussion

Ultrasound guided FNAC is considered the gold standard in the work up of thyroid nodules.² Danese et al, in a study with over 4000 patients has shown US-FNAC to be more accurate with a lower false negative rate compared to palpation FNAC.³ Traditional US-FNAC was the domain of the radiologist, however, surgeon-performed US-FNAC has been shown to be just as accurate.^{5-10, 12-15} In a recent meta-

analysis of head and neck US-FNAC, Ganguly et al has shown that the overall inadequacy rate for clinicians is 10.8%, radiologists 9.0% and cytopathologists 4.3%.

¹⁶ In our cohort where a surgeon-performed US-FNAC is performed in conjunction with the presence of a cytology scientist, the inadequacy rate was 5.4%, supporting previous data that surgeon-performed US-FNAC is safe and accurate, with an acceptable non-diagnostic rate.

In our study, malignant FNAC results were diagnosed statistically more frequently in the surgeon-performed US-FNAC cohort (8.5%) compared to the combined retrospective and prospective radiology cohort (3.2%). It is possible there may be a different threshold for biopsy between surgeons and radiologists but this was not evaluated. However, this could also represent a referral bias. Patients with concerning ultrasound findings may be more likely to be referred directly to the surgical clinic, rather than to radiology. However, this is only a hypothesis. Malignant FNAC results in one large surgeon-performed US-FNAC study were 6.9%. ⁸

Timeliness of care has not been extensively published in the surgical literature. In one study from Singapore, Wei Xiang Gu et al, in a retrospective study of 112 patients compared the time taken for cytological diagnosis between surgeon-performed US-FNAC and radiological US-FNAC. The mean time to establish diagnosis in the surgeon-performed US-FNAC was 1 working day, whilst in the radiology group it was 25 working days. However, this study did not focus on when the patient was informed of the diagnosis.¹⁷ Our study showed that the median time between first clinic visit and review of results was 14 days, limited by availability of

clinic appointments. This reduction in patient 'waiting time' is likely to decrease patient anxiety. Lodewijk et al demonstrated that anxiety and stress levels decrease when results are given to patients after thyroid FNAC. In their study, they performed thyroid FNAC and provided same day results to 39 patients. They compared anxiety levels before and after the same day delivery of results.¹⁸ This decrease was more pronounced with benign results compared to malignant. Many non-thyroid studies (breast, prostate) have also shown that patients who wait longer for results suffer increased anxiety.^{19,20} This anxiety is usually the greatest just after the biopsy is performed and also leading up to when the result is to be delivered.

Many studies have shown that a more timely biopsy reduces delays to surgery. Our study was not looking at this factor in particular, as many patients do not require surgery. We have previously shown that surgeon-performed US-FNAC leads to faster time to surgery in thyroid cancer patients, compared to radiology performed US-FNAC.⁵

Diagnostic head and neck 'one stop clinics' have been proposed in the United Kingdom, as per the NICE guidelines (2004). In order to streamline the evaluation of patients with head and neck lumps, the guidelines recommended a surgeon, radiologist and cytopathologist staff the clinics. These clinics often allow the patient to have a diagnosis on the same day.²¹ However, these guidelines have been criticized for not being evidence based, and not having the weight to justify a dedicated clinic with a surgeon, radiologist and a pathologist.²²

Ganguly et al, in their systematic review, examined the impact of having a cytopathologist present to examine the prepared slide immediately, which is an area of controversy. In 16 studies that had a cytopathologist present at the time of biopsy the inadequacy rate was 6.0%, compared to 54 studies in which there was no onsite assessment, where the inadequacy rate was 10.3%. Furthermore, in the presence of a cytologist technician instead of a cytopathologist, the inadequacy rate was 11.2%.¹⁶ Although our rates are far lower, with a cytology scientist, the presence of a cytopathologist with access to same-day provision of results is being considered as a future direction for our thyroid one-stop clinic.

The introduction of surgeon-performed US-FNAC has had a significant impact on radiology throughput. Prior to the introduction of the thyroid one-stop clinic, 11.2 patients/month had thyroid US-FNAC in the radiology department. After the introduction, there was a 40% drop, to 6.6 patients/month. The concept of the one-stop thyroid nodule clinic was strongly supported by our radiology colleagues, who were struggling to keep up with demand.

Although the surgeon-performed US-FNAC demonstrates a number of advantages over radiology performed US-FNAC, the radiologist still has an integral role in the multidisciplinary management of the patient with a thyroid nodule. All diagnostic thyroid US and follow up US are still done in the radiology department. We are not proposing that endocrine surgeons completely replace the radiologist, but rather, complement the radiologist in the evaluation of thyroid nodules with an

efficient and safe office-based procedure that ultimately saves patient time and radiology resources.

Conclusion

Surgeon-performed US-FNAC decreases the time from FNAC request to definitive plan and reduces the number of patient visits, providing more efficient care.

Intuitively, fewer overall patient visits would save health dollars, but health economics was not evaluated. The higher incidence of thyroid cancer amongst patients with thyroid nodules referred to directly to surgical clinic, rather than radiology, likely reflects appropriate triage by referring doctors.

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Table 1: Patient demographics and nodule size

		Group A	Group B	Group C	p value
Time (months)		39	12	12	
Patients		438	78	119	
FNAC		513	98	146	
Gender	Female	340 (77.6%)	58 (74.4%)	100 (83.0%)	0.276
	Male	98 (22.4%)	20 (25.6%)	19 (16.9%)	
Age	Mean (Range)	58 (22-92)	54 (22-90)	50 (18-81)	
Nodule size (mm)	Median (IQR)	21 (15-32)	23 (14-33)	20 (13-30)	0.340

IQR- interquartile range

Table 2: FNAC distribution

	Group A Radiology retrospective	Group B Radiology prospective	Group C Surgeon- performed FNAC
Thyroid	494	95	130
Lymph node	18	3	12
Other†	1	0	4
Total	513	98	146

† thyroglossal duct cysts, lipomas, submandibular gland

Table 3: Thyroid FNAC results

Bethesda		Group A Radiology Retrospective	Group B Radiology Prospective	Group C Surgeon- performed FNAC	p value
I	Non-diagnostic	6.5%	7.4%	5.4%	0.842
II	Benign	85.9%	79.0%	76.2%	0.015
III	AUS/FLUS	1.4%	6.3%	4.6%	0.005
IV	Follicular/Hurthle neoplasm	2.4%	1.1%	3.9%	0.461
V	Suspicious for malignancy	0.8%	1.1%	2.5%	0.607
VI	Malignant	2.8%	5.3%	8.5%	0.015

Table 4: Timeliness of care

	Radiology Retrospective	Radiology Prospective	Surgeon performed FNAC	p value
Patient numbers	409	69	111	
Time frame (months)	39	12	12	
FNA request to FNA performed (days) median (IQR)	23 (12.3-41.5)	21 (8.4-36.4)	0	<0.01
FNA request to results and management plan (days) median (IQR)	42 (27.4- 62.5)	41 (26.5-62.0)	14 (7-21)	<0.001

IQR – interquartile range