Standardization of thyroid fine needle aspiration procedure and outcomes within an endocrine surgery department

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Background: Fine needle aspiration (FNA) biopsy is an essential procedure for thyroid nodules. Although, the efficacy of surgeon-performed thyroid FNA biopsies has been demonstrated in the literature, there are insufficient data regarding how to establish an efficient program with a low insufficiency rate within a group practice.

Methods: An endocrine surgery thyroid FNA biopsy program was established in 2000 by one surgeon, with training of additional partners during fellowship and upon recruitment. The results within 18 years were analyzed. The FNA biopsies were performed by endocrine surgeons under ultrasound guidance without on-site pathologist review.

Results: A total of 5,469 FNA biopsies were performed by 7 surgeons. The total number of FNA biopsies performed by each surgeon varied between 291–1,378. FNA biopsies were performed in 2 passes using 22-gauge needles under constant suction. The overall insufficiency rate was 4.3%, with individual surgeon rates ranging between 2.7% and 7.2%. The insufficiency rate for the whole team ranged between 3.3% and 5% when examined in 5-year blocks.

Conclusions: This study shows that an establishment of a highly efficient thyroid FNA biopsy program within a group practice is possible with a structured endocrine surgical training and adoption of a standard technique.

Keywords: Thyroid; fine needle biopsy; endocrine surgeon; technique

Introduction

Thyroid nodules are detected in up to 70% of the patients undergoing a neck ultrasound (1-3). Fine needle aspiration (FNA) biopsy is an essential procedure to rule out malignancy, which is present in 5–10% (4-6). The performance of thyroid FNAs by endocrine surgeons is a new concept, but simplifies otherwise a multidisciplinary process and facilitates triage to surgery if required (4,7,8). As a result, these patient benefits have been recognized and various surgical series with an adequate sampling rate, ranging between 92–100%, have been reported in the literature (4,8-12). Previous studies have focused on a comparison of surgeon versus radiologist-performed thyroid FNA in regards to adequacy (6,8), the impact of trainees on sufficiency rates (13-15) and the effect of an on-
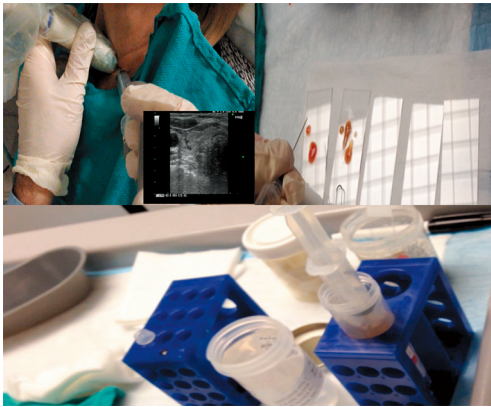
Figure 1 Demonstration of the fine needle aspiration (FNA) technique used in the study. Under ultrasound guidance, by inserting the needle in plane of the transducer, the nodules were biopsied in 2 passes. Then the aspirates were laid on a total of 4 slides and also washed in a CytoLyt solution. An onsite cytopathologist review was not performed.

site cytopathologist to avoid insufficient biopsies (11,16,17).

In modern medical practice, departments have to function as a unit, with standardization of skills and outcomes. The challenges of departmental units include the fact that a learning curve is involved with invasive procedures and that the group includes surgeons at various stages in their careers, and hence with different skill levels. With increasing institutional and patient expectations for standardized and consistent outcomes, it is important to streamline a high-volume procedure, such as thyroid FNAs within group practices.

To our knowledge, the performance analysis of a group, rather than individuals, has not been performed for thyroid FNAs. This is a complex dynamic task, as it requires setting up a certain benchmark goal, anticipation of failures related to the learning curve of individuals and utilization of a feedback circuit that should involve a continuous quality measurement and perfection of the group performance in a progressive fashion. Our group has been a pioneer in surgeon-performed ultrasound in endocrine surgery for the past 20 years. The aim of this study is to analyze the experience and process for standardization of surgeon-performed thyroid FNAs within this group practice.

We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/gs-20-630).

Methods

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional/regional/national ethics/committee/ethics board of Cleveland Clinic (IRB# 18-041) and individual consent for this retrospective analysis was waived. An endocrine surgery thyroid FNA program was established in 2000 by one surgeon (AS). A target of less than 10% insufficiency rate was set as a goal. Upon determination that the senior surgeon's insufficiency rate was less than 10%, this technique was then taught to additional junior partners during their endocrine surgery fellowship at the program or upon recruitment from other training programs. Outcomes were periodically reviewed for each surgeon, to ensure achievement of the <10% insufficiency goal, as part of a continuous quality improvement process. The insufficiency rates were communicated back to each surgeon as a quality metric. The results of this practice within 18 years were analyzed from an IRB-approved departmental database.

The decision for thyroid FNA was made based on the American Thyroid Association 2009 and 2015 guidelines on the management of thyroid nodules (18,19). The FNAs were performed by individual endocrine surgeons under ultrasound and without on-site pathologic review. The patients were positioned on the exam table in a semi Fowler position, with the neck extended and the head and torso raised to 30 degrees. After the nodules were recognized on ultrasound and patients consented for FNA, a 10-mm syringe with a 22-gauge needle were used to biopsy the nodules under ultrasound guidance and continuous application of suction using a pistol. About 10 thrusts were made with the needle for each pass and pressure applied to the skin after biopsy. Two passes were performed for each nodule. The aspirates were sprayed on a total of 4 slides, smears created and fixated in alcohol. The residual aspirate from each syringe was also washed in a CytoLyt solution and sent for cytology (*Figure 1*). To eliminate confusion in interpreting the results, cystic nodules were excluded, with only solid nodules analyzed in the study.

As it is known that there could be inter-observer differences in the evaluation of thyroid nodules between cytopathologists (20), the FNA slides were reviewed and decided upon by a group of cytopathologists and not by an individual cytopathologist.

Table 1 The number of total biopsies performed versus insufficient samples reported on cytopathology per individual surgeons in the study

Surgeon	Number of biopsies performed	Number of insufficient biopsies	Rate of insufficiency (%)
Senior	783	21	2.68
Surgeon #1	1,378	56	4.06
Surgeon #2	291	21	7.21
Surgeon #3	928	54	5.81
Surgeon #4	1,304	45	3.45
Surgeon #5	482	27	5.60
Surgeon #6	303	12	3.96
Total	5,469	236	4.31
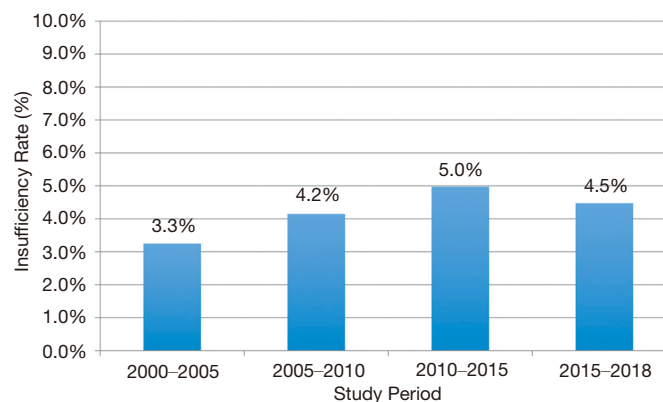
Figure 2 Bar graphs showing the insufficiency rate of the whole group divided into 5-year periods.

Statistical analysis

The data were obtained from an IRB-approved database. Statistics were performed using descriptive analysis with JMP Version 13.1 (SAS Institute, Inc, Cary, NC).

Results

A total of 5469 FNAs performed by 7 endocrine surgeons. The number of FNAs performed by each surgeon varied between 291–1,378. The overall insufficiency rate was 4.3%, with individual surgeon rates ranging between 2.7% and 7.2% (*Table 1*). Over the course of the study, the insufficiency rate ranged between 3.3% and 5% when examined in 5-year blocks for the whole team (*Figure 2*). A typical learning curve was not observed for most surgeons, suggesting that this task was mastered in fellowship training (*Figure 3*). For one surgeon who was trained upon recruitment, an insufficiency rate of 12% in the first 100 FNAs dropped to 6% in the

second 100 FNAs, suggesting a learning curve of 100 FNAs to optimize sufficiency above 90%.

All biopsies were performed using 2 passes applying continuous suction with 22-gauge needles. Complications included bleeding into 2 nodules in 2 patients. None of these patients required blood transfusions or emergency surgery.

Discussion

To our knowledge, this is the first study that evaluates a group practice to see if thyroid FNAs could be standardized to consistently achieve a target sufficiency rate by both the whole group and each member. Our results show that a technique that yields satisfactory outcomes can be mastered by a team and sustainable performance metrics be accomplished. A prerequisite for this model to be successful is a continuous periodic assessment of performance by
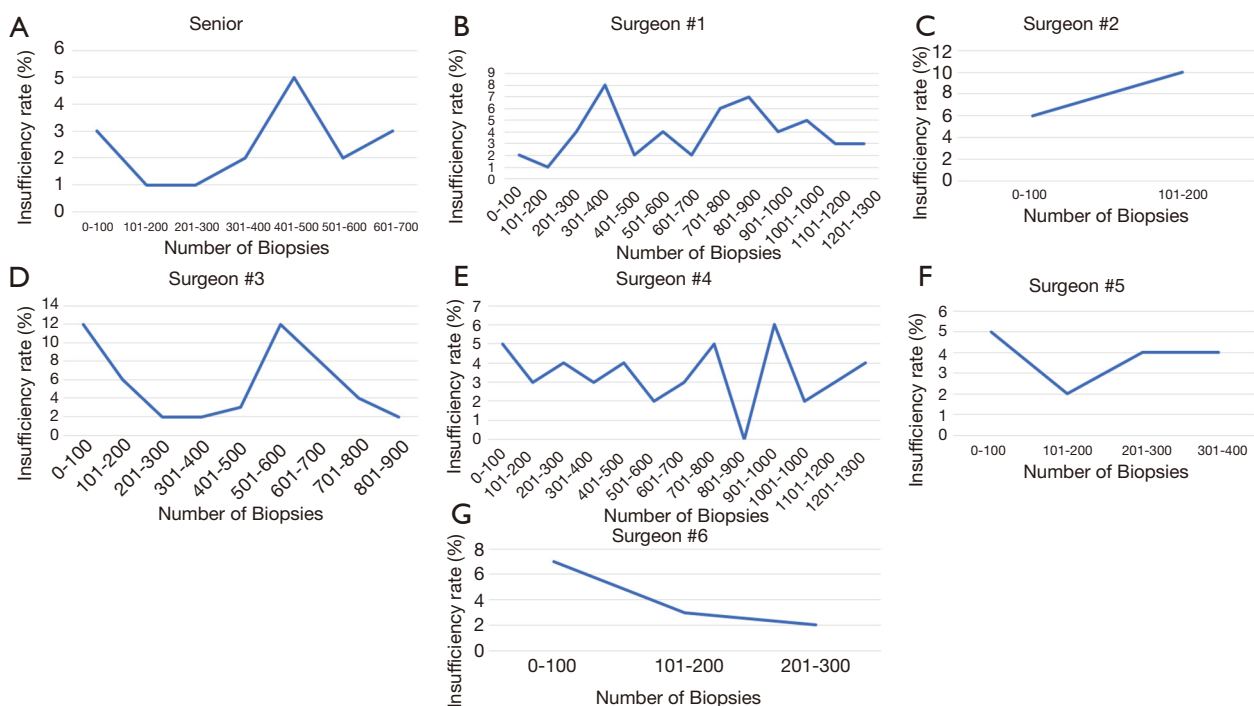
Figure 3 Line graphs showing the insufficiency rate for each surgeon, analyzed in 100 FNA-blocks.

using pre-determined metrics (sufficiency rate of >90%) and provision of regular feedback to individual surgeons about their performance. This standardization enabled the maintenance of ≥95% overall sufficiency rate for the whole group when examined in 5-year blocks. We believe that this proficiency-based performance model could be applied to other interventional procedures in a group practice and would be analogous to evidence-based practice to optimize outcomes.

Upon increasing surgeon experience with ultrasound, opportunities to increase efficiency of patient care in the management of thyroid nodules have been recognized. Many studies have confirmed the efficacy of surgeon-performed thyroid nodule FNA (3,4,6,8,10,14,15). Our recent study has further suggested the benefits of this practice to the assessment of lymph nodes (9). Although traditionally performed by radiologists, thyroid FNA has been successfully acquired by surgeons. A number of studies have confirmed an equivalency of the results when compared with those of radiologists (6,7,21). In a study performed by Al-Azawi *et al.* (8), the inadequacy rate of thyroid FNAs done by radiologists versus surgeons was 9.3 % and 5.3 %, respectively.

There is disagreement in the literature regarding the optimal

technique for performing thyroid FNAs (11,16,17,22-26). Needle sizes that have been advocated range between 22 and 27 gauges in various reports (11,13,16,24,26-29). There is also controversy regarding whether suction should be applied or not during the procedure (22,24,26). Furthermore, whether a cytopathologist should be on site or not is another topic of controversy (11,16,23). Finally, the number of passes and slides are also controversial (7,13-15,17,23,29-33). What these controversies suggest, as a bottom line, is that there are many techniques that could yield a high sufficiency for thyroid FNAs. In our study, 2 passes with 22-G needles using constant suction under ultrasound guidance without an on-site cytopathology achieved a low insufficiency rate that could be reproduced within a group practice in a consistent and sustainable fashion. We suggest other groups to employ the same operational process for an evidence-based standardization of a given technique. However, the individual members should be ready to modify their technique based on regular feedback about target metrics.

An interesting finding of our study was that a typical pattern of learning curve was not demonstrated when results of each surgeon were analyzed chronologically. We believe that this is related to two factors. First, the skill can be mastered during fellowship training. The insufficiency rate

of the majority of surgeons was <10% in the first 100 FNAs in the current study. For one surgeon who was trained upon recruitment, 100 FNAs was necessary for the learning curve to achieve insufficiency rate below 10%. Hence, we suggest the routine incorporation of thyroid FNAs, along with surgical ultrasound, to endocrine surgical fellowship programs. Second, we speculate that with accumulating experience, more challenging nodules (i.e., smaller, deeply located, etc.) are targeted by individual surgeons, which lead to a horizontal sufficiency rate over time. Our findings contrast with those showed by two studies (13,15) that reported improved sufficiency rates with increasing experience.

In summary, this report shows that an establishment of a highly efficient thyroid FNA program for a surgical group practice is possible with a structured endocrine surgical training and adoption of a standard technique. The maintenance of efficiency requires a periodic quality review of outcomes and acquisition of a standard FNA technique with known acceptable outcomes. The most appropriate management of thyroid nodules regarding organizational set up (i.e., FNAs performed by endocrinologists, radiologists, pathologists versus surgeons) is beyond the scope of this paper.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at http://dx.doi.org/10.21037/gs-20-630

Data Sharing Statement: Available at http://dx.doi.org/10.21037/gs-20-630

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/gs-20-630). EB serves as an unpaid editorial board member of *Gland Surgery* from Aug 2020 to Jul 2022.

The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional/regional/national ethics/committee/ethics board of Cleveland Clinic (IRB# 18-041) and individual consent for this retrospective analysis was waived.

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