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Image-Directed Fine Needle Aspiration Biopsy of the Thyroid with Safety-Engineered Devices

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Abstract

Purpose—The purpose of the present study was to integrate safety-engineered devices into outpatient fine needle aspiration (FNA) biopsy of the thyroid in an interventional radiology practice.

Materials and Methods—The practice center is a tertiary referral center for image directed FNA thyroid biopsies in difficult patients referred by the primary care physician, endocrinologist, or otolaryngologist. As a departmental quality of care and safety improvement program, we instituted integration of safety devices into our thyroid biopsy procedures, and determined the effect on outcome (procedural pain, diagnostic biopsies, inadequate samples, complications, needlesticks to operator, and physician satisfaction) before institution of safety devices (54 patients) and after institution of safety device implementation (56 patients). Safety devices included 1) a patient safety technology - the mechanical aspirating syringe (reciprocating procedure device), and 2) a healthcare worker safety technology (anti-needlestick safety needle).

Results—FNA of thyroid could be readily performed with the safety devices. Safety-engineered devices resulted in a 49% reduction in procedural pain scores ($p<0.0001$), a 56% reduction in significant pain ($p<0.002$), a 21% increase in operator satisfaction ($p<0.0001$), and a 5% increase in diagnostic specimens ($p=0.5$). No needlesticks to healthcare workers or patient injuries occurred during the study.

Conclusions—Safety-engineered devices to improve both patient and healthcare worker safety can be successfully integrated into diagnostic FNA of the thyroid while maintaining outcomes and improving safety.

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Key Terms

Fine Needle; FNA; Biopsy; Aspiration; Thyroid; Safety

Introduction

Fine needle aspiration biopsy (FNA) and fine needle non-aspiration biopsy (FNNA or capillary action biopsy) remain important diagnostic procedures for lesions of the thyroid, although core biopsy is used preferentially in certain centers (1–10). Because of the simplicity, safety, rapid diagnosis, effectiveness, reduced costs, specificity and sensitivity, FNA of the thyroid will remain important for diagnosis for the foreseeable future both as a primary and supportive diagnostic modality (1–20). Our practice center is a tertiary referral center for difficult patients many of whom have failed non-aspiration biopsy (FNNA) referred by the primary care physician, endocrinologist, or otolaryngologist for an image-directed biopsy in order to avoid an open biopsy. Because FNA routinely yields larger biopsy samples than FNNA, especially in benign lesions, in these difficult patients we exclusively utilize FNA with aspiration by a syringe to consistently provide adequate sample (16–18).

Although FNA of the thyroid is considered safe, complications do occur (11, 19,20). Complications range from 0.01% to 2% and include vasovagal reactions, anxiety, pain, ecchymosis at the puncture site, hematoma, respiratory compromise, infection, abscess, recurrent laryngeal nerve paralysis, thyroid ischemic necrosis, thyroid storm, pneumothorax and tumor seeding (19–47). FNA can also be dangerous for the operating physician with contaminated needle stick rates ranging from 2.2%–46.3% per physician year (48–50). The Joint Commission, the Needlestick Safety and Prevention Act, the Occupational Safety and Health Administration (OSHA), and corresponding national and international agencies all direct health care entities, including physicians who perform procedures to develop formal mechanisms to improve patient and health worker safety including the introduction of safety-engineered devices (51–55). We hypothesized that integration of safety devices into our practice could be accomplished without a detrimental effect on patient outcome or diagnostic sample yield.

METHODS

Subjects

This project was in compliance with the Helsinki Declaration and was approved by the institutional review board (IRB). Patient confidentiality and privacy was protected according to the Health Insurance Portability and Accountability Act (HIPAA). Four operating physicians performed FNA thyroid biopsy procedures on 110 patients who required an outpatient thyroid biopsy for their usual and customary medical care. FNAs were performed first in 54 patients with conventional non-safety devices, and then after implementation of the safety program, in 56 patients with safety-engineered devices.

Safety-Engineered Devices

Identification of the candidate safety technologies for FNA occurred through literature review and through staff interaction with the educational resources of national centers of excellence for patient safety (56–59). A safety needle with an off-axis rotating safety sheath (305761- 25 g 1.5" BD Eclipse™ Needle, BD, 1 Becton Drive, Franklin Lakes, NJ 07417, website: <http://www.bd.com>) was chosen as the safety device to reduce needle stick injuries to healthcare workers (Figures 1 and 2). This safety needle comes with two sheaths, a

conventional sheath that is removed to expose and then use the needle, and then a lateral rotating sheath that is pushed with the finger and encloses and inactivates the used needle (Figure 2). This class of safety devices has been shown to reduce needle sticks to health care workers by 75% (54,55,60,61).

In contrast, to improve the safety for patients during FNA a mechanical syringe was chosen (RPD-10, AVANCA Medical Devices, Inc, Albuquerque, New Mexico, USA. website: www.AVANCAMedical.com) (Figures 1 and 3). Mechanical syringes have been shown to improve physician control of needle and syringe, reduce procedure time, reduce patient pain, reduce complications\ including hemorrhage, and improve the outcomes of physician-performed syringe and needle procedures (63–70). Mechanical syringes are routinely used for therapy of thyroid cysts (3). The mechanical syringe is formed around the core of a conventional syringe barrel and injection plunger, but has a parallel aspiration plunger and an accessory barrel or track to control the motion of the injection plunger (Figures 1 and 3). The two plungers are mechanically linked by a pulley in an opposing fashion, resulting in a set of reciprocating plungers. Thus, when the aspiration plunger is depressed with thumb, the syringe aspirates, and when the injection plunger is depressed with the thumb, the syringe injects. A mechanical syringe can be fully operated with one hand while the other hand operates an ultrasound transducer or palpates or stabilizes the lesion. The conventional syringe was the 10 ml Luer-Lok™ BD syringe (Ref 309604, BD, 1 Becton Drive, Franklin Lakes, NJ 07417, website: <http://www.bd.com>). Operators did not practice with either device before use.

FNA of the thyroid

The intended biopsy site was first palpated and interrogated with ultrasound to determine the location and depth of the thyroid nodule or cyst (9–11). The skin was then prepared with topical chlorhexidine to minimize the possibility of introduced infection, and to remove any residual ultrasound gel at the intended puncture site (11,19,20). The needle was never passed through a layer of ultrasound gel on the skin since this gel produces a serious obscuring precipitation on Wrights staining. Subsequently, using sterile technique the 1% lidocaine was injected with a 25 g 1.5 inch needle at the intended site of the FNA intradermally in the skin directly over the thyroid nodule. Using ultrasound guidance, a deeper injection of 1% lidocaine was performed onto the thyroid capsule (which is pain sensitive) avoiding the thyroid parenchyma itself. The analgesic duration of local anesthesia after the initial injection persisted long enough to complete multiple passes and a repeat injection was rarely, if ever, needed. By visualization using ultrasound the needle was quickly introduced into the nodule with a series of advance-withdraw motions, the excursions of which were carefully maintained within the target over a brief time; 2–5 seconds while gentle vacuum was applied (using the 2 to 5 ml mark on the 10 ml syringe or mechanical syringe). With the conventional syringe to generate vacuum, the plunger was pulled back with free hand while the syringe hand controlled the syringe and needle. The mechanical syringe was controlled with one hand and vacuum generated by pressing the aspiration plunger with the thumb of the same hand (Figure 3). The free hand was used to further stabilize and direct the mechanical syringe or to operate the US transducer. After several rapid passes, vacuum was released by carefully releasing the plunger before removing the needle from the patient in order to prevent the aspirate being pulled into the syringe barrel. After extracting the needle from the biopsy site, the needle was removed from the syringe or mechanical syringe, air was aspirated into the syringe, the needle was reattached, and the needle placed above the specimen slide. The sample was then expelled by pressing the plunger of the syringe or the injection plunger of the mechanical syringe. The expelled sample was then air-dried, and alcohol fixed for Romanowsky and Papanicolaou staining, respectively. If fluid was obtained it was prepared for liquid based preparations. At least three passes and samples

were obtained in each biopsy site, and more if the sample was judged to be clinically inadequate.

Outcome Measures

All needlesticks to health care workers during and after the procedure were mandatory reported to the Employee Health Office. All FNA samples were analyzed blindly by an experienced cytopathologist and were rated as "diagnostic", "non-diagnostic" or "inadequate" indicating that a repeat FNA or other diagnostic procedure was indicated. Procedural pain with the syringe devices were determined with the 10 cm Visual Analogue Pain Scale (VAS) where 0 cm = completely dissatisfied with the performance of the procedure syringe and 10 cm = completely satisfied with the performance of the procedure syringe (70,71). Operator satisfaction with the syringe devices was determined with the Visual Analogue Satisfaction Scale (VASS) where 0 cm = completely dissatisfied with the performance of the procedure syringe and 10 cm = completely satisfied with the performance of the procedure syringe (70,71).

Statistical Analysis

Data were entered into Excel (Version 5, Microsoft, Seattle, WA), and analyzed in SAS (SAS/STAT Software, Release 9.1, Cary, NC). Differences in characteristics of the two patient groups (safety-engineered devices, conventional syringe) were determined using Fisher's exact test. Differences between the two treatment groups (i.e. conventional syringe versus safety-engineered devices) were determined using a two-sample test on the difference between group means or percentages, depending on whether the outcome measure was numerical or categorical. The standard error of the difference in means or percentages was obtained using generalized estimating equations (GEE) to account for multiple responses on the same patient. A modification Fieller's method to accommodate multiple responses was used to calculate confidence intervals for relative differences in means and percentages between treatment groups.

RESULTS

Use of Safety-Engineered Devices

When using the safety needle the physicians immediately encountered problems of the safety sheath physically interfering with the positioning of the ultrasound transducer, interfering with the positioning of the needle on the neck, and interfering with the repetitive motions necessary for FNA thyroid biopsy. Thus, all four operating physicians initially had difficulty accommodating to the safety needle, and initially removed the safety sheath or switched to a non-safety needle. The essential problem was mechanical interference between the edge of the ultrasound probe and the leading sheath of the safety needle. This interference could be minimized or prevented by rotating the sheath out of the plane of the ultrasound probe or by using a longer needle that moved the interfering sheath away from the probe. Thus, with practice, all operators were able to perform FNA with the safety needle. Physicians initially had to accommodate to the "push-push" to aspirate-inject with the mechanical syringe, compared to the "push-pull" of the conventional syringe. With practice physicians could facily perform FNA with the mechanical syringe.

Outcomes with Safety-Engineered Devices

There were no needlesticks to physicians or serious injuries to patients during the study (Table 1). Safety-engineered devices significantly reduced procedural pain scores by 49% ($p<0.0001$), reduced significant pain by 56% ($p<0.002$), and resulted in a 21% increase in physician satisfaction ($p<0.0001$). Diagnostic specimen outcomes were maintained with a

minor 5% increase in diagnostic biopsies and a 28% reduction in inadequate or non-diagnostic aspirates, neither of which reached statistical significance ($p = 0.5$ for both). Physician satisfaction with the safety-engineered devices was high (Table 1).

Disposal of Used Safety-Engineered Devices

After use, both the mechanical syringe and the safety needles had adequately narrow profiles to be directly disposed of in a standard sharps container. If very small sharps containers are used, the inactivated safety needle could be removed and placed in the sharp container, and the mechanical syringe without the needle placed in a regular non-sharps biohazard receptacle.

Discussion

Although initial core biopsy of the thyroid is preferred in some centers, the vast majority of proceduralists and cytopathologists consider initial FNA as the method of choice for evaluating isolated thyroid nodules (1–20). Relative to isolated core biopsies FNA is easier to perform, faster, less traumatic, provides a diagnosis more rapidly and is more cost effective (2–4). Thus, despite the popularity of isolated core biopsies in some radiology centers, FNA will remain an important and useful diagnostic technique in the evaluation of the thyroid for the foreseeable future (1–20).

Despite the relative safety of FNA of the thyroid, especially compared to open procedures, there remain hazards to the patient (hematoma, infection, respiratory compromise, vasovagal reaction, thyroid necrosis) and hazards to the physician operator, principally the danger of inadvertent needlestick (19–51). The Joint Commission, the Needlestick Safety and Prevention Act, and the Occupational Safety and Health Administration (OSHA) direct hospitals, clinics, and physician services, including services that provide thyroid biopsy, to develop formal mechanisms to improve patient and health worker safety, including but not limited to integration of new safety technologies (52–55). The Joint Commission sets yearly goals for patient safety, and encourages and audits institutions for formal safety procedures and plans and quality measures, including introduction of new safety methods and technologies (52). Unfortunately, to date, there are few if any published studies of the integration of safety-engineered devices into biopsy of the thyroid.

The present study investigated whether safety-engineered devices for FNA of the thyroid can be successfully evaluated and introduced into the diagnostic clinic to improve patient and surgeon safety while maintaining high-quality FNA samples and achieving an acceptable level of physician acceptance. The candidate safety technologies, safety needles and mechanical syringes, were first identified by literature review, analysis of randomized controlled trials, and use of national patient safety resources (54–70). Use of safety-engineered devices for FNA of the thyroid required certain alterations in technique, but maintained high-quality cytopathologic specimens while providing protection from needlesticks and enhanced patient safety.

FNA and the related technique FNNA biopsy are the methods of choice, rather than core biopsies or cutting needle biopsy, for the initial evaluation of isolated nodules of the thyroid (19,20). FNA is performed with vacuum provided by a syringe while FNNA is performed without vacuum (8–19). Both techniques utilize a combination of traumatic mechanical filling and capillary action to bring the biopsy material into the needle; FNA further uses vacuum to more completely fill the entire shaft of needle with material (8–19). Proponents of FNNA of the thyroid maintain that the samples obtained by FNNA are less distorted and have less blood; proponents of FNA of the thyroid claim that the long-term tract record of FNA is better, that sample volume is greater, and the incidence of inadequate samples are

less, especially in benign lesions (1–20). Most studies demonstrate that the two methods are essentially equivalent in the thyroid, although FNA may be superior in benign lesions where cellular yield tends to be inadequate (8–20). Since the two techniques are compatible with one another and simple to use sequentially, many experts recommend using both FNA and FNNA on the same patient to improve diagnostic accuracy and sensitivity and assure adequate sample (19,20). Our practice center is a tertiary referral center for difficult patients many of whom have failed non-aspiration biopsy (FNNA) referred by the primary care physician, endocrinologist, or otolaryngologist for an image-directed biopsy in order to avoid an open biopsy. Because FNA routinely yields larger biopsy samples than FNNA, especially in benign lesions, in these difficult patients we exclusively utilize FNA with aspiration by a syringe to consistently provide adequate sample (16–18).

The cytopathologic adequacy of the present study for diagnostic FNA samples in this difficult referral population is consistent with adequacy levels reported in the literature of 70% to 92% with FNA with syringe aspiration and 81% to 92% with FNNA without aspiration (Table 1) (1–20). Thus, it was possible to integrate proven safety technologies - safety needles and the mechanical syringe into the FNA procedure - while still maintaining high quality cytological sampling (Table 1). As mentioned for thyroid biopsy, we prefer FNA with gentle vacuum to FNNA, principally because of our difficult referral population and a consistently higher yield of tissue of FNA with syringe suction especially in benign lesions (13,15,16).

However, the safety technologies in this study can also be used for FNNA. The syringe method for FNNA is where the needle is mounted on a syringe and the syringe is used as a handle - not to generate vacuum - and is usually held in the pencil grip (8–20). A mechanical syringe can substitute for the conventional syringe and can be gripped in the pencil grip similarly to the conventional syringe. During FNNA the mechanical syringe removes the fingers physically from the proximity of the needle, reduces the chance of contaminating the needle and thus introducing infection, and reduces the chances of an accidental needle stick. The syringe method of FNNA also permits the use of a needle on a stable, controllable platform, rather than using the bare needle with the fingers. This method of using a syringe or mechanical syringe also facilitates rapidly moving from FNA to FNNA and back again in the same individual, thus permitting both FNA and FNNA to be performed in the same procedure.

Needlesticks to the operating physician have been considered an inevitable occupational hazard that can drastically change careers and can even be fatal (48–50). However, needlestick can be prevented. The Joint Commission, the Needlestick Safety and Prevention Act and the Occupational Safety and Health Administration (OSHA) direct hospitals, clinics, and surgical services, including services that provide interventional services, to develop formal mechanisms to improve patient and health worker safety, including but not limited to integration of new safety technologies (52–54). Needle procedures are dangerous for physician operators with contaminated needlestick or sharp injury rates ranging from 2.2%–46.3% per physician year (48–51). Although only a discrete piece of an overall safety and quality improvement program, judicious introduction and evaluation of safety-engineered devices may have a significant effect on the overall patient and healthcare worker safety within an institution (48–51,55,60,61). The use of safety needles reduces the incidence of occupational needle sticks by 40% to 70% (from 20/100,000 to 6/100,000 needles sticks) (48–51,55,60,61). Thus, there are compelling reasons to use safety needles in FNA procedures as long as the safety devices do not interfere with the mechanics of the procedures, and the cytopathology results are equivalent. The present study demonstrates this.

FNA of the thyroid is considered a relatively safe procedure for the patient (19,20). Complications of FNA, although rare, range from 0.01% to 2% and include vasovagal reactions, procedure pain, ecchymosis at the puncture site, hematoma, respiratory compromise, infection, abscess, recurrent laryngeal nerve paralysis, thyroid ischemic necrosis, fibrosis, thyroid storm, pneumothorax, and tumor seeding along the needle track (19–47). The complications of FNA are due to a complex mix of inherent patient characteristics, needle technique, procedural antisepsis, the use of non-safety devices, blind vs. image-directed needle placement, and variable control and direction of the needle by the operating physician (19–47,63). In clinical trials safety needles and mechanical syringes have been demonstrated to improve operator control of the syringe and needle, reduce tissue trauma, reduce procedural pain, reduce procedure time, improve sample yield, reduce the incidence of hemorrhage, and reduce needle-associated injuries by 40% to 70% (48–51, 55, 60,61,63–70). The present study demonstrates that safety needles and mechanical syringes that improve operator control of the needle and syringe can be successfully integrated into FNA of the thyroid while maintaining excellent cytopathological quality.

There are several limitations to this study. First, although blinding of an operator to hand-held surgical instrument is difficult if not impossible, the operators in this study were not blinded to the mechanical syringe and safety needle that could have induced a consistent bias. Second, the present study incorporated a sequential study design where outcomes of traditional methods for FNA were first studied, then the safety interventions were implemented, and changes or improvements in FNA outcomes contrasted between the two methods (Table 1). A randomized trial design would have had less potential for a consistent bias, and thus the sequential, rather than randomized design of the present study is a weakness. However, the sequential study design used here is typical of patient safety-improvement programs as actually implemented in hospitals and large-healthcare organizations, where an outcome is first measured, a safety intervention is then implemented, and the outcome changes and improvements after the intervention are measured (72,73). Thus, although not randomized, the present safety study design parallels patient safety improvement programs most commonly recommended and implemented in actual clinical practice (74,75).

The present study demonstrates that safety-engineered devices including safety needles and mechanical syringes can be evaluated and introduced into FNA of the thyroid to improve the safety of both patients and surgeons while maintaining and improving diagnostic outcomes.

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Figure 1. Safety Needle on a Mechanical Syringe

A safety needle with an off-axis rotating safety sheath is shown mounted on the mechanical syringe. This safety needle comes with two sheaths (left), a conventional sheath that is removed to expose and then use the needle (middle), and then a lateral rotating sheath that is pushed with the finger and encloses and inactivates the used needle (right). The mechanical syringe injects when the thumb presses the dominant plunger and aspirates when the accessory plunger is pushed. The index and middle fingers do not change position on the finger flanges when transitioning from injection to aspiration.

Figure 2. Safety-Engineered Devices being used for Fine Needle Aspiration (FNA) Biopsy of the Thyroid

This photograph demonstrates the mechanical syringe being used for local anesthesia of the thyroid capsule followed by FNA of the thyroid. The smaller plunger is depressed with the thumb for aspiration to generate vacuum for FNA, and after multiple passes through the thyroid lesion, the small plunger is then released to remove vacuum prior to pulling needle from skin to prevent the sample from being sucked into the barrel. The larger plunger is depressed to expel the sample onto a cytological slide or processing solution.

Figure 3. Inactivation of the Safety Needle

After the FNA needle has been irrigated to remove the biopsy sample, the safety needle is immediately inactivated by swinging the locking safety sheath over the contaminated needle.

Table 1

Effect of Safety Devices in Fine Needle Aspiration Procedures of the Thyroid

	Conventional Non-Safety Syringe	Safety- Engineered Devices	Percent Difference	95% Confidence Interval	Statistical Significance
Number of Procedures	54	56			
Procedural Pain (10 cm VAS Pain Score)	4.3±2.8 cm	2.2±2.2 cm	-49% (-1.1±2.5 cm)	-71% to -27%	0.0001
Significant Procedural Pain (10 cm VAS ≥ 5 cm)	41% (22/54)	18% (10/56)	-56%	-94% to -14%	0.002
Procedural Complications	0/54	0/56	0%	Not applicable	1.0
Diagnostic Biopsies	85% (46/54)	89% (50/56)	+5%	-10% to +20 %	0.50
Inadequate or Non-Diagnostic Biopsy samples	15% (8/54)	11% (6/56)	-28%	-116% to +59 %	0.50
Needlesticks to Operator	0/54	0/56	0%	Not applicable	1.0
Physician Operator Satisfaction (10 cm VAS)	6.9±1.3	8.3±1.3	+21% (+1.4±1.4 cm)	+13% to +27 %	0.0001