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Syringe and Needle Size, Syringe Type, Vacuum Generation, and Needle Control in Aspiration Procedures

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Abstract

Purpose—Syringes are used for diagnostic fluid aspiration and fine needle aspiration biopsy (FNA) in interventional procedures. We determined the benefits, disadvantages, and patient safety implications of syringe and needle size on vacuum generation, hand force requirements, biopsy/fluid yield, and needle control during aspiration procedures.

Materials and Methods—Different sizes (1, 3, 5, 10, and 20 ml) of the conventional syringe and aspirating mechanical safety syringe, the reciprocating procedure device (RPD), were studied. 20 operators performed aspiration procedures with the following outcomes measured: 1) vacuum (Torr), 2) time to vacuum (seconds), 3) hand force to generate vacuum (Torr-cm²), 4) operator difficulty during aspiration, 5) biopsy yield (mg), and 6) operator control of the needle tip position (mm).

Results—Vacuum increased tissue biopsy yield at all needle diameters ($p < 0.002$). 20 ml syringes achieved a vacuum of -517 Torr, but required significantly more strength to aspirate, and

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resulted in significant loss of needle control ($p<0.002$). The 10 ml syringe generated only 15% less vacuum (-435 Torr) than the 20 ml, and required much less hand strength. The mechanical syringe generated identical vacuum at all syringe sizes with less hand force ($p<0.002$), and provided significantly enhanced needle control ($p<0.002$).

Conclusions—To optimize patient safety and control of the needle and maximize fluid and tissue yield during aspiration procedures, a two-handed technique and the smallest syringe size adequate for the procedure should be used. If precise needle control or one-handed operation is required, a mechanical safety syringe should be considered.

Keywords

Syringe; Safety; Aspiration; Complications; FNA; Needle

Introduction

Aspiration of body fluids and fine needle aspiration biopsy (FNA) with suction provided by a syringe are important diagnostic procedures in interventional medicine [1–9]. In the field of FNA, there is considerable controversy regarding the use of capillary action with vacuum versus vacuum provided by syringe, and if vacuum is used, the optimal size of syringe for aspiration procedures with operators usually recommending larger syringes sizes - a 10 ml, 20 ml, or even larger devices [9–14]. For fluid aspiration procedures, the syringe is sized according the amount of fluid anticipated, or in the case of a syringe as a needle introducer is sized in the 3 ml to 10 ml range. However, the size of the aspiration syringe is left to the discretion of the physician, and the choice of syringe size is often based on the experience, training, and prejudices of the operator [1–8].

The choice of syringe size should be based on the known effects of syringe size on the strength of vacuum generation, the force required to generate a specific level of vacuum, the difficulty to generate vacuum, the volume of fluid to be aspirated or the required biopsy yield, needle control, and patient safety considerations [1–13]. Although biopsy or fluid yield is important, patient safety and the known complications of needle aspiration must be considered, including hemorrhage, hematoma, pneumothorax, and respiratory arrest [15–21]. The Joint Commission, the Needlestick Safety and Prevention Act, the Occupational Safety and Health Administration (OSHA), the Patient Safety and Quality Improvement Act of 2005, and Veterans Administration National Center for Patient Safety and relevant national and international organizations concerned about safety all urge physicians to maximize patient safety during invasive procedures, including integration of safety technologies [22–28].

Patient safety in needle procedures include maintenance of a sterile field using disposable medical supplies if possible, exclusion of patient drug allergies, careful attention to anesthesia protocols, recognition and correction of coagulation status, correct patient/operative site confirmation, pre-puncture interrogation of the target with the imaging modality to define operative anatomy, post-procedure observation and care, compulsive labeling, custody, and processing of the biopsy sample, careful needle control during and after the procedure, and prompt recognition of complications [22–28]. In the present randomized-controlled study trial, we compared a conventional syringe to a mechanical procedure syringe and examined the effect of syringe size on aspiration procedures including hand force required to aspirate, biopsy yield, vacuum generation capabilities, and control of the needle tip, all which have direct relevance to patient safety.

Materials and Methods

Subjects

This project was in compliance with the Helsinki Declaration and was approved by the institutional review board (IRB). Subject confidentiality and privacy was protected according to the Health Insurance Portability and Accountability Act (HIPAA). This clinical trial is registered at *clinicaltrials.gov*; the registration number is NCT00651625. After informed consent, 20 operators who regularly perform diagnostic aspiration procedures were asked to perform a protocol of aspiration procedures with the various sizes and types of procedure syringes and needles with the following outcomes measured 1) quantitative levels vacuum (negative pressure) measured in Torr (mm Hg) 2) time to achieve a certain degree of vacuum, 3) hand force required to pull the plunger to achieve a certain degree of vacuum, 4) difficulty in generating maximum vacuum with the various sizes, and 5) ability of the operator to control the needle tip position while aspirating. The operators were experienced with the conventional syringe, and novices to the mechanical syringe. Each operator performed each syringe maneuver with each variable 10 times with the order of each maneuver randomized to eliminate the possibility of a consistent bias and to minimize the impact of any training effect.

Syringes

The conventional syringes were the 1 ml, 3 ml, 5 ml, 10 ml, and 20 ml Luer-Lot BD syringe (Ref 309604, Becton Dickinson & Co., Franklin Lakes, NJ 07417). This syringe was used in both a one-handed and two-handed technique. The mechanical syringe, the reciprocating procedure device (RPD) (Figure 1), was also provided in the 1 ml, 3 ml, 5 ml, 10 ml, and 20 ml sizes (RPD) (RPD-1, RPD-3, RPD-5, RPD-10, RPD-20, AVANCA Medical Devices, Inc, 600 Central Ave SE, Ste 232, Albuquerque, New Mexico, 87102, USA. tele: 505. 243.4600 website: www.AVANCAMedical.com) [29,30]. The mechanical syringe was used in a one-handed fashion. The RPD mechanical syringe has two barrels, two plungers, and a mechanical linkage between the plungers – a pulley system – that permit the plungers to reciprocate. Thus, the index and middle fingers do not change position, only the thumb moves from one plunger to the other to move between aspiration and injection. This creates an extremely stable aspiration-injection device that can easily generate vacuum or pressure [29,30].

Vacuum Generation

Vacuum (negative pressure) was measured in each syringe with a digital pressure meter with male Luer fittings (DPM-2000 Digital Pressure Meter, BC Group, Chicago, IL). A female:female luer adaptor was used to attach the male luer lock fitting of the syringes to the male luer lock fitting of the pressure meter. Vacuum (negative pressure) was measured in Torr (mm Hg) and as expressed at Torr below ambient pressure. For certain experiments Torr was measured as a function of time or as a function of displacement of the plunger of the aspirating syringe. Four different needles were used to determine the effect of needle diameter on vacuum generation, a 27 gauge 1 inch needle, a 25 gauge 1.5 inch needle, a 21 gauge 6 cm needle, and a 22 gauge 10 cm needle (BD, 1 Becton Drive, Franklin Lakes, NJ 07417, website: <http://www.bd.com>). For the needle experiments a low dead space female luer adapter with a silicone rubber port was attached to the pressure meter, and the silicone rubber seal was penetrated by the needle so that vacuum at the needle tip could be directly measured. 10 measures were made at each needle gauge and plunger displacement and time course determined to maximum vacuum attained at each plunger displacement, each corresponding to the volume measures on the syringe barrel.

The Effect of Vacuum and Needle Diameter on Biopsy Yield

Fine needle biopsy in *ex vivo* liver was performed using 3 different gauges of biopsy needles with or without vacuum as follows: 22 gauge (22ga × 15 cm, Disp Chiba Biopsy Needle, Cook, Bloomington, IL) and 17 and 19.5 gauge (Percut 17 ga X 15 cm Biopsy Needle, Cat No. N715, and 19.5 ga X 10 cm Percut Cut-Biopsy Needle, Cat No. N910, EZEM, Inc, Westbury, NY) with 1) vacuum and no vacuum using a 10 conventional syringe, and 2) vacuum and no vacuum using the 10ml RPD syringe. Needle biopsies were performed by a single operator in a randomized fashion between each needle size with and without vacuum until 10 biopsies with each needle size with and without vacuum were performed. Using these needles, the needle tip was placed through the hepatic capsule, the stylet removed, and the syringe device attached. Biopsies were performed with no vacuum (0 Torr) or maximum vacuum (approximately -441 Torr). After each individual biopsy procedure, the biopsy needle was removed, air was placed into the mechanical or conventional syringe, and the sample expelled and weighed in a digital precision balance and the result expressed in milligrams (mg) of tissue.

Force Required to Generate Vacuum

Force required to pull the plunger of a conventional syringe or push the aspiration plunger of a mechanical syringe to a particular degree of vacuum was calculated by the measured vacuum (pressure) multiplied times the cross sectional surface area of the inner barrel of the syringe device (**surface area** = πr^2), where $r = 1/2$ the inner diameter of the barrel. Force was expressed in Torr-cm².

Difficulty in Generating Vacuum

The difficulty in generating maximum vacuum was determined by the ability of the operator to generate maximum vacuum with a particular device size using one hand, and was expressed as a percentage of individuals able to generate maximum vacuum for each syringe and RPD size.

Precise Measurement of Syringe and Needle Control by the Physician

The clinically validated quantitative needle-based displacement procedure model was used to precisely measure syringe and needle control by the individual physician (Figure 2) [29,30]. In this measurement system, a layer of 1.3 cm thick open cell flexible polystyrene foam simulates the target tissue. A rigid polystyrene marker is placed on the needle to a preset indelible mark on the needle, and then the needle is advanced into the target surface until the needle tip is at the desired location and polystyrene marker is touching the surface. The physician operator then performs the aspiration procedure. Loss of control in the forward direction (penetration) pushes the polystyrene marker posteriorly on the needle past the indelible mark, permitting precise measurement in mm of loss of control in the forward direction. Each operator performed 10 procedures with each size of the conventional syringe with one hand, 10 procedures each with each size of the conventional syringe with two hands, and 10 procedures with each size of the RPD with one hand, randomized equally between the 1, 3, 5, 10, and 20 ml devices.

Statistical Analysis

Data were entered into Excel (Version 5, Microsoft, Seattle, WA), and analyzed in SAS (SAS/STAT Software, Release 6.11, Cary, NC). Differences in categorical data were determined with Fisher's Exact Test and differences in parametric data with the t-test, while differences between multiple parametric data sets were determined with Fishers Least Significant Difference Method. Corrections were made for multiple comparisons. Correlations between parametric data were determined with logistic regression and between

non-parametric data with Spearman correlation and Kendall rank method. Corrections were made for multiple comparisons.

Results

The effects of device size on vacuum generation are shown in Figures 3 and 4. The relationship of vacuum to volume displacement of the plunger was non-linear and asymptotic for larger syringe and RPD sizes (20 ml, 10 ml, and 5 ml), and near linear for the smaller syringes and RPDs (3 ml, 1 ml). As can be seen in Figures 3 and 4, the conventional syringe and RPD generated statistically identical vacuum: plunger displacement curves for each syringe size ($p>0.9$). Thus, size for size the conventional syringe and the RPD mechanical syringe generated the identical vacuum at the same level of plunger displacement. The maximum vacuum possible with each the syringe and RPD was dependent on syringe size: the 20 ml syringe and RPD (-517 ± 12 Torr maximum vacuum), the 10 ml (-441 ± 11 Torr maximum vacuum), the 5 ml (-334 ± 8 Torr maximum vacuum), the 3 ml (-250 ± 7 Torr maximum vacuum), and the 1 ml (-120 ± 6 Torr maximum vacuum). Thus, syringe and RPD size had a significant effect on the strength of vacuum generated, with the 20 ml syringe and RPD each generating a maximum vacuum of approximately -517 Torr.

However, the 10 ml syringe and 10 ml RPD both generated about -441 Torr vacuum, which was only 15% less than the -517 Torr generated by the corresponding 20 ml devices (Figures 3 and 4). Thus, a flattening of the vacuum:volume displacement of the plunger curves occurred at the 10 ml displacement in both the 10 ml and the 20 ml devices where there was a sharp asymptote after which further plunger displacement resulted in only a minimal increase in vacuum (15%) despite an additional 10 ml (100%) of plunger displacement (100%). Therefore, there is a diminishing return in terms of vacuum generation where vacuum levels off asymptotically after the 10 ml plunger displacement with very little additional vacuum generation to 20 ml plunger displacement. Between different sizes of syringes, the strength of vacuum at the same plunger volume displacement was identical; thus, the 20 ml syringe and RPD syringe both generated approximately -250 Torr at the 3 ml mark, as did the 10 ml, 5 ml, and 3 ml devices. Similarly, each generated approximately -334 Torr at the 5 ml plunger displacement mark. The strength of vacuum was solely determined by the volume displacement of the plunger at all syringe and RPD sizes; therefore, larger syringes only generate more maximum vacuum than smaller syringes when the volume displacement of the plunger is greater.

The effects of needle diameter and vacuum on biopsy yield are shown in Table 1. The use of vacuum markedly increased the yield of biopsy material (75% to 150%, depending on needle size) ($p<0.01$). In addition, larger needles provided much more biopsy specimen than did smaller diameter needles (Table 1). The syringe and the RPD each provided essentially the same biopsy yield, consistent with the largely identical vacuum generation characteristics as shown in Figures 3 and 4. The effect of needle diameter on vacuum generation at the needle tip is shown in Figure 5, and was essentially identical for both the syringe and the RPD ($P>0.5$). Larger needle sizes (21 g and 22 g) permitted almost instantaneous generation of vacuum at the needle tip (approximately one second to maximum vacuum); however, small needle diameters (25 g and 27 g) delayed the development of maximum vacuum at the needle tip, not fully equalizing for approximately 3 to 3.5 seconds (Figure 5).

The actual force required to pull a plunger on a mechanical syringe to a particular level of vacuum is shown in Figure 6 and, like vacuum generation, was identical between the conventional syringe and the RPD size by size ($p>0.5$). The relationship between the level

of vacuum and force required to distract the plunger was largely linear within a specific size of syringe or RPD, but demonstrate markedly different and unique slopes between each individual syringe and RPD size (Figure 6). Importantly, the force to generate a predefined level of vacuum was markedly different between the various device sizes with vacuum being developed with minimal force with the smaller devices, but requiring much more force with the larger devices. For example, to generate the maximum vacuum in a 3 ml syringe or RPD (approximately -253 Torr) requires a force of 800 Torr-cm² to maintain the plunger at the 3 ml volume displacement mark; in contrast to generate the same vacuum (approximately -253 Torr) with a 20 ml syringe at the 3 ml plunger displacement mark requires 4.25 times more force (3400 Torr-cm²). Similarly, although the 20 ml syringe or RPD can develop a 15% greater maximum vacuum than the corresponding 10 ml device, the 20 ml devices require almost double the force (185%) – 7600 Torr-cm² versus 4150 Torr-cm² to generate this vacuum (Figure 6). Therefore, a larger degree of vacuum is achieved only by using markedly more force to generate this vacuum. The force required to generate equivalent levels of vacuum of a small syringe with a large syringe are 2 to 5 times larger, requiring greater hand and arm strength, and thus, more force on the syringe.

To measure individual difficulty in generating vacuum, we determined the ability of 20 operators to generate maximum vacuum with each size of the conventional syringe and each size of the RPD biopsy device using one-hand, which is often used during aspiration procedures, and is a validated measure of difficulty in operating a particular syringe device [29,30]. Figure 7 demonstrates the difficulty of generating the same level of vacuum with the different sizes of syringe and RPD. As can be seen, 100% (20/20) of individuals could generate maximum vacuum with one hand using either the 1 ml syringe or the 1 ml RPD ($p=0.5$). However, with the 10 ml syringe only 20% of subjects (4/20) could generate maximum vacuum (-441 Torr), while 100% of subjects (20/20) could generate the same maximum vacuum (-441 Torr) using the 10 ml RPD ($p<0.0001$). Notably, 0% of subjects (0/20) could generate maximum vacuum with 20 ml syringe using one hand, while 95% (19/20) could generate the same maximum vacuum (-517 Torr) with the RPD ($p<0.001$).

Thus, although the RPD and conventional syringes generate identical vacuum size-by-size, it is far easier to generate the same vacuum with the RPD than with the conventional syringe because of the mechanical advantage provided by the pulley mechanism. Because it is easier to generate vacuum in smaller size syringes than larger syringes and in the RPD relative to the conventional syringe, it would be predicted that both syringe and needle control would be better with smaller syringes and the RPD during aspiration than large conventional syringes. Increasing syringe size had a potent negative effect on the control of the conventional syringe whether used with one hand ($r = 0.97$, slope = 2.14, 95% CI 1.54 to 2.76, $p < .002$) and when used with two hands ($r = -0.98$, slope = 2.16, 95% CI 1.51 to 2.84, $p < .002$) with the worst control being with the 20 ml syringe whether used with one or two hands ($p<0.005$) (Figure 8).

In contrast, because the RPD can generate the same level of vacuum as a syringe but can achieve this more easily, control of the RPD is superior to that of the conventional syringe at all syringe sizes (Figure 8, $p < 0.01$). In direct syringe to syringe comparisons, the curves in Figure 8 demonstrate that the RPD syringe operated with one hand provides significantly better needle control (18.9% less unintended forward penetration) than the conventional syringe operated with two hands (mean unintended penetration across all sizes; RPD syringe = 7.02 ± 1.08 mm; Conventional Syringe: 8.66 ± 1.03 mm, $p < 0.001$) The difference in control between the RPD and conventional syringe was even greater comparing the conventional syringe with one hand (mean unintended penetration 13.2 ± 3.0 mm) to the RPD syringe with one hand (mean unintended penetration 7.02 ± 1.08 mm) with the RPD reducing unintended forward penetration by 46.9% ($p < 0.001$).

Discussion

Needle aspiration procedures to obtain body fluids or tissue, including FNA, that use a syringe for application of vacuum remain important diagnostic procedures in radiology, endocrinology, otolaryngology, cytopathology, cardiology, and obstetrics [1–14]. Diagnostic fluid aspiration has not changed from the basic technology of syringe and needle since inception. In terms of biopsy, core biopsy techniques have become increasingly popular, however, FNA techniques have not been supplanted by core biopsy; rather FNA and related aspiration techniques continue to be important diagnostic procedures throughout medicine [3–14]. Some experts recommend no syringe-generated vacuum at all - the so-called - fine needle non-aspiration biopsy (FNNA); however, it has been demonstrated that with FNNA cytopathologic yield is less in many tissues and often provides inadequate tissue in benign or fibrous lesions, forcing an open biopsy for a definitive diagnosis [31–34].

The recommendations for the syringe size appropriate for FNA with suction vary widely between experts, but generally the 10 ml and 20 ml conventional syringes are recommended [1–14]. Certain types of needle biopsy, such as chorionic villus sample (CVS) will not work at all without suction applied with a syringe [9]. The quantity of biopsy material obtained by FNA or cutting needle biopsy also varies widely between different sizes of syringe and needle with the effect of needle diameter dominating over syringe size [9–14,31,32]. The present study compared FNAA to FNA with 17, 19.5, and 22 gauge biopsy needles, and found that suction with FNA increased biopsy yield in milligrams by 155%, 75%, and 77% respectively compared to FNNA, thus, in terms of tissue yield, there is no question that FNA provides more tissue than FNNA (Table 1). Thus, although FNNA is certainly an established and reasonable alternative biopsy method, because of reduced tissue yield with FNNA, especially in benign lesions, many experts recommend performing both FNA and FNNA in the same individual for best diagnostic sensitivity [1–14].

Needle aspiration procedures are safer than the equivalent open techniques; however, serious complications do occur from needle biopsies and can be fatal [15–18]. Needle biopsy and fluid aspiration procedures, depending on the target organ, can result in pain, bruising, arterial puncture, hematoma, exsanguination, pneumothorax, hemothorax, infection, cardiac perforation, airway compromise, and death, resulting in lawsuit and increased health care costs [15–21]. Thus, needle and syringe techniques, although much safer than open techniques are not without risk – and as the Joint Commission and other safety advocates emphasize, technologic advances that permit better control of the procedure device improve outcomes are important to integrate into medicine to improve patient safety [22–31,35]. Better control of the syringe device during aspiration procedures has been shown to improve outcomes in syringe aspiration procedures and reduce pain and serious complications, including hemorrhage [29,30,35].

The present study demonstrates that syringe size has a potent effect on control of the needle with smaller syringes having better control and larger syringes poorer control (Figure 8); however, larger syringes provide more vacuum than smaller syringes (Figures 1 and 3). Sandrucci et al felt that vacuum was very important to FNA techniques, and recommended even more powerful vacuum generated with larger syringes up to 60 ml [13]. In contrast, Cochrane et al found that the 20 ml syringe was superior in terms of sample yield [9]. Similarly, Cannon et al demonstrated that different sized syringes can generate different levels of vacuum, and found that the 20 ml syringe provided the best overall biopsy sample yield [10]. In contrast, Yankelevitz et al reported that the same vacuum could be obtained with a 10 ml and 50 ml syringe, and felt that the 20 ml syringe was a good compromise to accommodate dead space in the needle [11]. In practice, most operators use a 10 ml or 20 ml syringe for FNA and similarly, most syringe pistols, handles, and guns accommodate either

a 10 ml or 20 ml syringe [14]. Thus, there remains some controversy concerning the vacuum generation characteristics of the different syringe sizes [9–14].

The present study specifically investigated the vacuum generation characteristics of different sizes of two commonly used aspiration devices: the conventional syringe and the RPD mechanical syringe (Figures 1–5). As can be seen, for both the conventional and mechanical syringe, there were marked differences in maximum vacuum generation characteristics between the different syringe sizes. Each device size evinced a characteristic volume displacement-vacuum curve with increasingly non-linearity as syringe size increased (Figures 3 and 4). The 20 ml syringe and 20 ml RPD generated the greatest vacuum of approximately -517 Torr, which is consistent with many recommendations for using a 20 ml device for FNA [9–14]. However, the degree vacuum generated by the 10 ml devices was only 15% less (-441 Torr) than the 20 ml device (-517 Torr) due to an asymptotic relationship of plunger volume displacement to vacuum, thus, creating, a marginal advantage (15%) of using a 20 ml compared to 10 ml vacuum suction device (Figures 3 and 4). This indicates that using a 20 ml and greater device size for suction biopsy has a strong diminishing returns aspect due to the flat asymptotic portion of the plunger displacement-vacuum generation curve which levels off asymptotically at 10 ml with very little gain in vacuum with further plunger displacement past 10 ml.

Although the plunger-displacement - vacuum generation curves were unique to each syringe or RPD size, the curves of the different syringe devices were related intimately to each other in terms of a specific vacuum generated for a certain volume displacement of the plunger. For example, when the plunger was displaced to the 1 ml mark on the 1, 3, 5, 10, and 20 ml syringe and RPD sizes, all syringe devices generated identical vacuum (approximately -120 Torr). Similarly, when the plunger was displaced to the 5 ml mark on the 5, 10, and 20 ml syringe and RPD sizes, all syringe devices generated identical vacuum (approximately -334 Torr). Therefore, all syringe devices, 1 ml through 20 ml, generate identical vacuum at the same volume displacement of the plunger.

This aspect is important clinically: if the plunger of the 20 ml syringe or RPD is not displaced fully to the 20 ml mark, there is no advantage of using the 20 ml device compared to the smaller 10 ml syringe or RPD device (Figures 3 and 4). As an example, many operators use a 10 ml or 20 ml syringe or RPD for biopsy of the breast or thyroid -but only apply gentle vacuum to the 3 or 4 ml mark. The present study demonstrates there is no vacuum advantage by using the larger 10 ml or 20 ml devices with this technique, rather, a 3 ml or 5 ml syringe or RPD could be used to generate identical vacuum, but with functional advantages, as the 3 ml and 5 ml syringes and RPDs are shorter, smaller, and more easily controlled (Figures 7 and 8).

Different sizes of needles amongst other factors are important in terms of tissue yield during suction biopsy procedures [9,10,14, 31–34]. The present study demonstrated that increases in needle size produce predictable increases in tissue yield, and that application of vacuum also markedly increases tissue yield (Table 1). As can be seen in Figure 5, needle size also had a marked affect on vacuum generation as a function of time, but not on maximum vacuum. Importantly, small needle diameters (27 gauge and 25 gauge) commonly used for FNA required considerably more time to reach maximum vacuum at the needle tip as compared to larger needles (22 gauge and 21 gauge) commonly used for cutting needle (for example Chiba needle) biopsy (Figure 5). The implications are that when using smaller needle diameters (25 and 27 gauges) that it might be wise to wait several seconds until the vacuum at the needle tip has maximized before performing a suction biopsy maneuver in order to take full advantage of maximum vacuum at the needle tip.

Although the 10 ml or 20 ml syringe and RPD are favored by most operators for suction biopsy because greater vacuum and sample can be achieved, the effect of these larger devices sizes on control of the biopsy device and safety have not been fully discussed in the literature [1–31]. Better control of the procedure device has been shown to improve outcomes in syringe aspiration procedures and reduce complications, including hemorrhage; and control of the needle tip is extremely important in FNA where complications can be severe or even fatal [15–30]. Thus, the present study also investigated the effect of syringe size on the operator control of the needle and syringe while generating specific levels of vacuum. As can be seen in Figure 8, operating the conventional syringe while generating maximum caused considerable loss of control in the forward direction ($p<0.001$). The ability of the operator to control the syringe and needle decreased progressively as syringe size increased from 1 ml to 20 ml with the 20 ml syringe being the worst controlled. Controlling the syringe with 2 hands or the use of the RPD mechanical syringe with one hand, markedly improved control of the needle and syringe, with the RPD being statistical superior to the conventional syringe whether used with one or two hands (Figure 7).

Thus, although larger syringe sizes can generate more maximum vacuum, they are also increasingly difficult to control, and result in exaggerated unintended forward penetration (loss of control in the forward direction) that has been associated with the serious complications of syringe and needle procedures [29,30,35]. Thus, if a 20 ml syringe must be used, 2 hands should be used whenever possible, or, if one-handed operation or enhanced control of the needle is required, a safety mechanical like the RPD should be considered. The increasing inability to control the needle and syringe with increasing syringe size might be due to the increasing difficulty to pull the plunger back to achieve full vacuum.

Indeed, the 20 ml device required almost twice the force as did the 10 ml to achieve maximum vacuum (Figures 6 and 7). Moreover, it was difficult for operators to pull back the larger sizes of syringe plunger to maximum vacuum, with the majority of operators unable to easily perform this maneuver. In contrast, virtually all subjects were able to achieve maximum vacuum while controlling the needle with the 10 ml and 20 ml RPD mechanical syringe because of the mechanical advantage provided by the pulley mechanism (Figures 1, 6, 7). The Society of Interventional Radiology, the Joint Commission, the Needlestick Safety and Prevention Act, the Occupational Safety and Health Administration (OSHA), the Patient Safety and Quality Improvement Act of 2005, and the Veterans Administration National Center for Patient Safety all encourage the systematic evaluation and integration of new safety methods and technologies to improve health care worker and patient safety, including syringe and needle aspiration procedures such as FNA [22–28].

There are limitations to this study. Although certain of the authors presently use the RPD mechanical syringe in their own practice which would present a practice bias, to minimize possible bias in this study, the operators that performed the syringe procedures were complete novices to the mechanical syringe, although experienced with the conventional syringe. The selection of operators inexperienced with the mechanical syringe created a consistent bias against the mechanical syringe, reducing differences with the conventional syringe, but it is unlikely this would have influenced the results of the study. This is also an ex-vivo lab study that does not include the use of these devices in an actual clinical setting (i.e., no patients were biopsied). Patient safety is being extrapolated from the needle control demonstrated and may not truly translate to the clinical setting although studies in other aspiration procedures indicate that improved needle control does translate to less procedural pain, improved outcomes, and fewer complications, including hemorrhage [30,35,36].

Further, other alternatives are available for aspiration other than a conventional or mechanical syringe. To better generate vacuum, syringe pistols, syringe guns, handles, and

dedicated biopsy syringes have been developed [14,29,30]. A serious problem with these devices is 1) unintended forward penetration of the needle during aspiration, a dangerous characteristic associated with increased procedural complications, including increased procedural pain and hemorrhage, 2) the expense of the device, which can be as much as \$100 per device, and 3) the tendency to reuse these devices unsterilized between patients, an unacceptable practice that contributes to infectious complications [29,35,42–47]. Another alternative is the vacuum syringe, where the plunger is locked in position by a spacer or plunger lock or the use vacuum bottle or vacuum tube [14,29,42–47]. A problem with these devices is expense, difficulty in transitioning from no vacuum and to vacuum at the needle tip, difficulty in release of vacuum so that the sample is not sucked from the needle into the syringe barrel, and difficulties in expelling the sample [29,42–47].

Another alternative to direct use of a mechanical syringe is the use of tubing between the syringe and needle, so that the needle can be held in one hand and the syringe in other or, alternatively, an assistant can generate vacuum or a vacuum syringe can be attached to the tubing [48]. However, if there is one operator, one still has to generate vacuum with one hand which is difficult with larger conventional syringes and easier with the mechanical syringe as the present study demonstrates. Furthermore, using the tubing technique, the inner diameter of the tubing and length of tubing are critical in terms of deadspace that typically ranges from 1.5 ml to 3 ml in pressure tubing; deadspace decreases vacuum achievable with each syringe size [49]. Using tubing with a 10 ml syringe in our laboratory, 1 ml, 2 ml, and 3 ml of tubing deadspace reduces vacuum achievable by 13%, 20%, and 32% respectively. Using tubing with a 20 ml syringe, 1 ml, 2 ml, and 3 ml of tubing deadspace reduces vacuum achievable by 3%, 8%, and 12% respectively. Vacuum intensity is probably not important for vascular access or fluid aspiration procedures, but it is important for biopsy [14,31,38,48,50]. Thus, if the tubing technique is used, low deadspace tubing and/or a 20 ml syringe device should be used to minimize the effect of deadspace on vacuum intensity.

The RPD mechanical syringe, also known as the reciprocating syringe, is formed around the core of a traditional syringe barrel and plunger, but has an extra plunger and barrel (Figure 1) [29,30]. The two plungers are mechanically linked in an opposing fashion by a pulley system, resulting in a set of reciprocating plungers. Thus, when the aspiration plunger is depressed with thumb, the RPD aspirates, and when the injection plunger is depressed with the thumb, the RPD injects. The characteristics of stable finger positioning, one-handed operation, the exclusive use of the flexor musculature, enhanced finger flanges with better hand grip, the shock-absorbing qualities of the reciprocating mechanism, and the absence of device lengthening permit enhanced needle control and safer, more accurate aspiration and injection procedures [29,30]. Mechanical syringes been demonstrated to decrease the complications of syringe and needle procedures, including hemorrhage, by 35–60% [29,30, 35]. Because of enhanced safety, reduced pain, and ability to aspirate and inject with one hand, mechanical syringes are recognized by National Center for Patient Safety as a patient-safety technology [29,30,35–41].

The present report demonstrates that larger syringes can generate significantly more vacuum than smaller syringes, but this increase in vacuum is marginal (15%) and is associated with loss of control of the syringe and needle in the forward direction resulting in unintended forward penetration that has been associated with the complications of syringe and needle procedures [29,30,35]. Thus, if larger syringes (10 or 20 ml) are used they should either always be operated with two hands throughout the procedure, or if one-handed use, enhanced control of the needle are required, a mechanical syringe such as the RPD should be considered to make aspiration easier and to improve needle control. Further, if maximum vacuum is not required for a particularly procedure, smaller syringe devices should be used to generate the same vacuum while reducing the force required and improving needle

control. This study also demonstrated that when smaller diameters of needles are used (25 gauge or 27 gauge) maximum vacuum at the needle tip is delayed by several seconds, thus, the operator should pause for a few seconds after generating vacuum before performing the biopsy to permit vacuum equilibration at the needle tip. Similarly when vacuum is released, the operator should pause for several seconds to permit the vacuum in the syringe device to return to ambient pressure so that the sample is not aspirated back into the barrel of the biopsy syringe device.

In summary, aspiration syringes have unifying physics that permit predictable generation of vacuum, but also create predictable loss of needle control and increasing difficulty in generating vacuum with larger syringe sizes. For greatest needle control, the smallest size syringe appropriate for the aspiration procedure should be utilized (usually a 5 ml or 10 ml syringe), two-hands should always be used on the syringe device when generating vacuum during an aspiration procedure, and if one-handed operation, reduced patient pain, a larger 10 or 20 ml device, or enhanced needle control are desired, a mechanical syringe should be considered.

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Figure 1. Different Sizes of Reciprocating Procedure Device (RPD)

The RPD mechanical syringe (1 ml, 3 ml, 5 ml, 10 ml, and 20 ml RPD) device 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. Linear Displacement Method for Measuring Syringe and Needle Control

A rigid polystyrene marker is placed on the needle to a preset indelible mark on the needle, and then the needle is advanced into the target surface until the needle tip is at the desired location and polystyrene marker is touching the surface. The physician operator then performs the aspiration procedure. Loss of control in the forward direction (penetration) pushes the polystyrene marker posteriorly on the needle past the indelible mark, permitting precise measurement in mm of loss of control in the forward direction.

Figure 3. Vacuum Generation with the Conventional Syringe

Vacuum in Torr (mm Hg) are shown as a function of plunger displacement and syringe size. As can be seen each syringe size has its unique vacuum - plunger displacement curve with the 20 ml syringe generating the greatest vacuum. However, along each curve, the plunger displacement to a particular volume generates the identical vacuum regardless of syringe size.

Figure 4. Vacuum Generation with the Reciprocating Procedure Device (RPD)

Vacuum in Torr (mm Hg) are shown as a function of plunger displacement and RPD size.

As can be seen each RPD size has its unique vacuum - plunger displacement curve with the 20 ml device generating the greatest vacuum; however, the curves generated with the RPD are identical to those with the conventional syringe - thus the RPD and conventional syringe are identical in vacuum-generation characteristics.

Figure 5. Vacuum Generation as a Function of Needle Diameter

Vacuum in Torr (mm Hg) are displayed as a function of time with 4 different needle diameters (measured in gauge) using a 20 ml RPD to generate vacuum. As can be seen, smaller diameters of needles have a lag time of several seconds before generation of maximum vacuum.

Figure 6. Vacuum Generation as a Function of Force

Vacuum in Torr (mm Hg) are displayed as a function of force required to displace the plunger to various volumes. The solid line represents the near-linear relationship of vacuum to force for each syringe or RPD size. The fine dotted lines demonstrate the force required to generate maximum vacuum with a particular syringe size. The bold dotted lines indicate the corresponding force necessary to generate the same level of vacuum with the 20 ml RPD or syringe. As can be seen, it requires much more force to generate the same level of vacuum with larger syringes.

Figure 7. Operator Difficulty Generating Maximum Vacuum

Vacuum in Torr (mm Hg) are displayed as a percentage of individuals able to generate maximum vacuum (fine dotted horizontal lines) with a particular syringe or RPD size. The conventional syringe is the bold dotted line, and the RPD the solid bolded line. As can be seen, it is much easier for operators to generate high level of vacuum with the RPD compared to a conventional syringe due to the pulley mechanism of the RPD.

Figure 8. Needle Control as a Function of Syringe Size

The undesirable characteristic of unintended forward penetration (loss of control of the needle in the forward direction) for each syringe size during aspiration procedures with the conventional syringe used with one hand is shown. The 1 ml device corresponds to a vacuum of -120 Torr, 3 ml -250 Torr, 5 ml -334 Torr, 10 ml -441 Torr, and 20 ml -517 Torr. Control of the conventional syringe was improved if vacuum was generated and the device controlled with two hands ($p < 0.002$), but most improved in terms of needle control with the RPD mechanical syringe ($p < 0.002$).

Table 1

Biopsy Yield as a Function of Needle Diameter and Vacuum

Needle Diameter (gauge)	Fine Needle Non-Aspiration Biopsy (FNNA) Biopsy Yield (mg) (no vacuum -0 Torr) n = 10	Fine Needle Aspiration Biopsy (FNA) Biopsy Yield (mg) (vacuum-441 Torr) n = 10	Increase in Biopsy Yield	95% Confidence Interval	Significance
17 Gauge - 10 ml Syringe	9.3± 3.1 mg	23.7± 5.0 mg	155%	113% to 197%	P 0.0001
17 Gauge - 10 ml mechanical syringe	9.5± 3.0 mg	24.1± 6.1 mg	153%	106% to 201%	P 0.0001
19.5 Gauge - 10 ml Syringe	5.1± 1.9 mg	8.9± 2.1 mg	75%	38% to 111%	P 0.002
19.5 Gauge - 10 ml mechanical syringe	5.0± 2.1 mg	9.1± 1.9 mg	82%	44% to 120%	P 0.002
22 Gauge - 10 ml Syringe	1.6± 0.6 mg	2.8± 0.7 mg	75%	37% to 113%	P 0.002
22 Gauge - 10 ml mechanical syringe	1.6± 0.7 mg	2.9± 0.6 mg	81%	43% to 119%	P 0.002