

Integration of new safety technologies for needle aspiration of breast cysts

Randy R. Sibbitt · Dennis J. Palmer ·
Arthur D. Bankhurst · Wilmer L. Sibbitt Jr

Received: 22 March 2008 / Accepted: 3 June 2008
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Abstract

Introduction National and international regulatory agencies and professional societies mandate systematic improvements in both the safety of patients and health care workers (HCW), including the integration of safety technologies into the procedures of obstetrics and gynecology (Ob-Gyn).

Materials and Methods Using national resources for patient safety and literature review, these safety technologies were identified: (1) a safety needle to reduce needle sticks to HCW, and (2) the reciprocating procedure device (RPD) to reduce injuries to patients. These technologies were introduced in a trial fashion into routine breast cyst aspiration, and physician responses were determined.

Results The safety needle presented a number of difficulties associated with the safety sheath, but could be used efficiently for breast cyst aspiration. The RPD safety device functioned well for breast aspiration procedures and was well accepted by physicians.

Conclusions New safety technologies can be successfully evaluated and introduced into the clinic to improve patient and HCW safety during outpatient breast procedures. Since these technologies have been demonstrated to decrease injuries to patients and HCW by 60–70%, serious efforts should be undertaken to systematically integrate safety

technologies into the routine practice, including aspiration of breast cysts.

Keywords Needle · Aspiration · Cyst · Breast · Safety · Complications

Introduction

Needle aspiration of breast cysts is a relatively benign procedure that provides great relief to the patient, and is typically performed by obstetricians and gynecologists (Ob-Gyn), interventional radiologists, family physicians, and breast surgeons [1–16]. Although needle aspiration of the breast is generally considered safe, complications and injuries to the patient do occur and range from 0.1 to 3% and include vasovagal reactions, anxiety, procedural pain, ecchymosis at the puncture site, hematoma, hemothorax, infection, abscess, pneumothorax, respiratory compromise, ischemic necrosis, and tumor seeding [17–27]. Similarly, needlesticks are one of the greatest hazards to healthcare workers (HCW) including Ob-Gyn who perform needle breast aspiration procedures, and the consequences of a needlestick can be career-ending [28–32]. Moreover, injuries to patients and needlestick injuries to HCW have become intense areas for lawsuits, medical malpractice claims, and workman compensation actions [33–39].

The American College of Obstetricians and Gynecologists (ACOG), 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 corresponding national and international regulatory agencies all direct health care entities, including physicians who perform breast procedures, to develop formal mechanisms to improve patient and HCW

R. R. Sibbitt · D. J. Palmer
Division of Interventional Radiology, Department of Radiology,
St. Peter Hospital, Helena, MT, USA

A. D. Bankhurst · W. L. Sibbitt Jr (✉)
Department of Internal Medicine, University of New Mexico
Health Sciences Center, 5th FL ACC, DOIM,
Mail Stop: MSC10-5550, Albuquerque, NM 87131, USA
e-mail: wsibbitt@salud.unm.edu

safety, including systematic integration of new safety technologies [40–49]. Integration of safety technologies has been demonstrated to be one of the most robust methods to decrease injuries to patients and HCW [28–30, 50–68]. Although Ob-Gyn physicians have been leaders in improving operating and delivery room safety, to date few Ob-Gyn departments have systematically integrated safety technologies into their outpatient their syringe and needle procedures; moreover, there is glaring lack of literature on the use of safety technologies specifically in breast aspiration procedures. In the present report, we describe the integration of two safety technologies intended to improve the safety of both the operating Ob-Gyn physician and the patient during aspiration of breast cysts and summarize our experience to date with these new safety technologies.

Materials and methods

Selection of safety devices

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). This study is registered at <http://www.clinicaltrials.gov>. The purpose of this study was to determine the feasibility and practical aspects of using safety technologies for breast cyst aspiration as required by the relevant governing law [39–49]. A total of 221 breast cyst aspirations with the new safety technologies were performed in 46 patients, who were screened by physical examination, mammography, and ultrasound prior to the aspiration procedures. A total of 16 of these patients underwent multiple repeat aspiration procedures due to breast cyst recurrence. Aspirated fluid always underwent cytopathologic analysis. The study design did not attempt to demonstrate actual decreases in serious injuries to patients and reduced needlestick rates to HCW which would have required at least 100,000 cyst aspiration procedures each and was well beyond the scope this study and resources of the institution [28–32, 57, 58]. However, in larger studies safety devices have been demonstrated to significantly reduce injuries to both patients and HCW, thus the legal requirements for these types of feasibility studies in each institution by the governing regulations [39–49]. Identification of the candidate safety technologies for breast aspiration procedures occurred through literature review and through staff interaction with the educational resources of national centers of excellence for patient safety [52–56]. Certain syringe-based needlestick prevention devices were deemed unsuitable—barrel-based needle shields were too awkward and bulky and tended to rotate,

and syringes that internalize the needle and/or needle fitting were actually dangerous if the safety mechanism were inadvertently activated during the syringe procedure while the needle was still in the patient's tissues. Thus, it was deemed that a needle-based safety system rather than a syringe-based system to prevent needle sticks would be most suitable for musculoskeletal procedures and other physician performed syringe procedures. Of needle-based systems, safety needles with an elbow-like sheath were less desirable because they increased the total length of the needle resulting in the syringe and operator's hands being farther away from the tissue target. A BD safety needle with an off-axis rotating safety sheath (305761—25 g 1.5" and 305783—22 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 health care workers (HCW). The BD 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 (Fig. 1). Although the lateral sheath has a large profile, with proper education and physician practice this safety needle permits close approximation to the skin surface as is necessary for syringe and needle procedures. This class of safety devices has been shown to reduce needlesticks to HCW by 70% [28–32, 38, 39, 41, 42, 57, 58].



Fig. 1 Safety needle on the reciprocating procedure device (RPD). A BD safety needle with an off-axis rotating safety sheath was chosen as the safety device to reduce needlestick injuries and is shown here mounted on the RPD safety device. The BD needle comes with two sheaths (*left RPD*), a conventional sheath that is removed to expose and then use the needle (*middle RPD*), and then a lateral rotating sheath that is pushed with the finger and encloses and inactivates the used needle (*right RPD*)



Fig. 2 Reciprocating procedure device (RPD). The RPD safety device for breast cyst aspiration 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. This results in an extremely well controlled and powerful safety device for breast cyst aspiration

In contrast, to improve quality of care and safety for patients during breast aspiration procedures, the safety technology, the reciprocating procedure device (RPD), was chosen (RPD-1, RPD-3, RPD-5, RPD-10, RPD-20, AV-ANCA Medical Devices, Inc, Albuquerque, NM, USA, website: <http://www.AVANCAMedical.com>) (Figs. 1, 2). The RPD is FDA-approved and CE-marked. The RPD is a safety syringe technology that in randomized controlled trials has been shown to improve physician control of needle and syringe, reduce procedure time, reduce patient pain, and improve the outcomes of physician-performed syringe and needle procedures, and is accepted as superior to and safer than the conventional syringe, syringe pistols, syringe handles, and other dedicated procedure syringes [59–68]. The RPD is formed around the core of a conventional syringe barrel and plunger, but has a parallel accessory plunger and an accessory barrel or track to control the motion of the accessory plunger (Figs. 1, 2). The two plungers are mechanically linked by a pulley in an opposing fashion, resulting in a set of reciprocating plungers. Thus, when the accessory plunger is depressed with thumb, the syringe aspirates, and when the dominant plunger is depressed with the thumb, the syringe injects. This permits the index and middle fingers to remain in one position during both aspiration and injection, while the thumb only needs to move in a horizontal plane to the alternative plunger to change the direction of aspiration or injection. The RPD can be fully operated with one hand, but physicians often use two hands for even greater control, and hold the RPD in various ways depending on the procedure requirements. In randomized controlled trials the RPD has been shown to be better controlled and superior to the

conventional syringe, the 3-ring control syringe, syringe pistols, syringe handles, and other dedicated procedure syringes [59, 62]. The RPD has also been shown to be safer than and superior to the conventional syringe for suction needle biopsy, fine needle aspiration of breast (FNA), aspiration of body fluids, intraarticular corticosteroid injection, intraarticular hyaluronate injection, aspiration of head and neck abscess, and local anesthesia [59–68].

Conventional breast cyst aspiration

Conventional aspiration of a breast cyst is usually performed with a traditional syringe [1–16]. The traditional syringe and specialized aspiration devices have a number of mechanical characteristics that induce unintended forward penetration of the needle (loss of control in the forward direction), resulting in most of the complications of breast needle aspiration procedures [17–27, 59, 62].

Method of breast cyst aspiration with the RPD safety device

For breast cyst aspiration with the RPD, the technique is very similar to FNA of the breast, but a larger bore needle; usually a 21 or 22 gauge is used. For breast cyst aspiration the 5, 10 or 20 ml RPD is used (the 5 ml RPD is preferred by individuals with smaller hands) (Fig. 3). The RPD is used to control the needle, administer local anesthesia, and generate vacuum. The skin is prepared with topical chlorhexidine to minimize infection. Prior to aspirating the cyst, 1–2 ml of 1% lidocaine is placed into the RPD, and



Fig. 3 Reciprocating procedure safety device (RPD) for aspiration of a breast cyst or abscess. This photograph demonstrates the RPD safety device being used for aspiration of a large breast cyst. After local anesthesia is administered with the RPD, the smaller plunger is depressed with the thumb for aspiration to generate vacuum and the cyst fluid is aspirated completely into the RPD while the free hand applies pressure to the cyst or operates the ultrasound transducer

with a 22 gauge needle lidocaine is injected intradermally in the skin directly over the breast lesion; the lidocaine is injected deeper until the entire volume of lidocaine is injected up to surface of the lesion avoiding the actual lesion itself. Certain operators do not use local anesthesia. With the RPD emptied of lidocaine and the needle tip at the lesion edge, the thumb moves from the injection plunger to the aspiration plunger that is depressed to the 1–3 ml mark on the RPD to generate gentle vacuum. This low level of vacuum prevents the cyst wall from being pulled against the needle tip and reduces the chance of vacuum-induced hemorrhage which could confuse analysis of the breast fluid, as blood tinged fluids are more likely to be malignant and require cytology [69–73]. The cyst fluid is aspirated completely into the RPD while the free hand operates the ultrasound transducer or applies pressure to the cyst (Fig. 3). If the lesion is suspicious for malignancy then subsequently FNA is performed on the residual wall of the cyst and the entire fluid aspirate is sent down for analysis, usually in the RPD or processed immediately onsite. If the fluid is non-hemorrhagic and the cyst appears benign on ultrasound and mammography, many experts feel that the aspirate should not be sent for cytology, although many physicians send all aspirates for cytology [69–73]. For large cysts greater than 10 or 20 ml in volume, the needle is left intracystically, and RPD syringe exchanges are performed until the cyst is empty. To accomplish a syringe exchange after the first RPD is filled with aspirate, the needle is left in the breast cyst, and while carefully controlling the needle position and holding the needle hub with the fingers, the RPD is carefully rotated off the needle hub. Unlike a conventional syringe, the RPD is asymmetrical during rotation, and this requires deliberate slow rotation. Another empty 10 or 20 ml RPD is carefully rotated onto the needle while holding the needle hub with the fingers, and then the aspiration plunger of the RPD is depressed until the cyst is emptied. Afterwards pressure is applied to the puncture site; subsequently a sterile bandage strip is placed. The technique for aspiration of a breast abscess is identical to aspiration of a breast cyst, but usually a larger gauge needle is employed because fibrin debris may plug the smaller bore needles [12–16]. The RPD has proven to be exceptionally useful in general for safer aspiration of deep abscess [68].

Method of breast cyst sclerotherapy with the RPD safety device

Many patients with breast cysts have the problem of post-aspiration recurrence, and on occasion, these cysts are large and uncomfortable [4, 5, 7, 74]. The breast cysts may be reaspirated, but patients often tire of these repeated procedures [74]. A common practice was injection of air into breast recurrent cysts in hopes of preventing recurrence;

however, injection of air is often ineffective [75]. Another alternative is the use of sclerotherapy to prevent breast cyst recurrence, analogous to sclerotherapy used to prevent cyst recurrence in other organs [76–81]. Most commonly, breast cyst sclerotherapy is performed with sclerosing solutions of 95% ethanol, polidocanol, or tetracycline [76–79]. We feel that 95% ethanol is safest and most established agent for cyst sclerotherapy [77–81]. For breast cyst ablation with sclerotherapy, the cyst fluid is aspirated with the RPD exactly as in the breast cyst aspiration technique, but after aspiration the needle is left in the breast cyst, and while holding the external needle hub of the BD needle with the fingers, the RPD is carefully rotated off the needle hub. A 10 or 20 ml RPD with pre-filled ethanol is attached to the intracystic needle, the needle tip location is again confirmed by US or the aspiration plunger is pressed to create a flashback of cyst fluid into the RPD to confirm intracystic location, and then the cyst is injected with 95% ethanol (1/3–1/2 of the volume of aspirated fluid) by pressing the injection plunger and the ethanol is left in situ. In most cases (except in smaller individuals) the ethanol is not reaspirated, rather the ethanol is left in the cyst, which generally results in more complete cyst resolution. One must be careful to monitor total volume of ethanol (do not exceed 30 ml total ethanol), especially in smaller individuals to avoid ethanol toxicity and do not permit them to drive themselves home. For breast cyst ablation with ethanol sclerotherapy, at least two RPDs are used: one RPD for administering local anesthesia and for aspirating the cyst, and the other RPD for instillation of ethanol.

Results

A total of 221 breast cyst aspiration procedures were performed with the RPD-safety needle combination by 4 physicians. There were no serious complications (pneumothorax, hemothorax, hemorrhage, or infection) in any of the breast cyst aspirations procedures (0 out of 221); nor were there any needlesticks to physicians or other HCW (0%). A total of 34.8% of subjects experienced recurrent cysts and were forced to undergo multiple cyst aspiration procedures. Sclerotherapy was performed in minority of these subjects with recurrent cysts to determine the idiosyncrasies of RPD-safety needle function in this procedure.

Several operating physicians noted that the BD safety needle was cumbersome in certain positions. Thus, physicians had to adjust to the larger profile of BD safety needle caused by the shield, and found that they had to move more deliberately so that their fingers did not snag the shield (Fig. 1). Moreover, the BD safety needle presented several other problems: (1) when ultrasound localization was used the safety sheath often interfered physically with the

ultrasound transducer, and (2) the safety shield would occasionally pinch the skin of patient and cause discomfort. When performing syringe exchanges to drain large cysts or to instill ethanol, the larger hub of the BD safety needle actually provided a mechanical advantage and kept the fingers away from both the needle shaft and the Luer hub, reducing the chance for microbial transmission in either direction. The BD safety needle could be deactivated with one hand while holding pressure on the puncture site; this was a definite advantage. Thus, despite certain difficulties, general cyst aspiration procedures could be performed with the BD safety needle.

The RPD safety device required instruction at first to show how the RPD functioned (“push–push” to aspirate–inject with the RPD rather than the usual “push–pull” with the conventional syringe), but satisfaction with the RPD safety device was high. Aspiration of cyst fluid was achieved much more easily with the RPD and this was immediately evident to all operating physicians. The only difficulty with the RPD was the asymmetry of the device during rotation, and this required deliberate slow rotation to maintain control, but after instruction, all physicians performed this maneuver easily. The RPD was well accepted by physicians who found it to be convenient, safer, and less painful for cyst aspiration. Subsequently, we have successfully performed over 300 aspiration procedures with the RPD safety device (including 221 breast cyst aspirations, and smaller numbers of breast FNA and breast abscess aspiration), and have successfully integrated this safety technology into our routine clinical practices (Fig. 3).

Comments

The present study is one of the first reports of safety devices being systematically evaluated and used for routine outpatient breast cyst aspiration, and fulfills intent and directives of the Joint Commission and other national and international organizations concerned with HCW and patient safety [39–56]. Aspiration of the breast cysts is widely considered as a relatively safe procedure that provides considerable relief to the patient but complications do occur [1–27, 37, 66–69]. Misdiagnosis and delayed diagnosis are ongoing issues, but are reduced by evolving quality control paradigms [69–73]. Since breast cyst aspiration is often performed by the Ob-Gyn physician in the clinic or at the bedside, complications such as pneumothorax, hemothorax, and respiratory compromise are better prevented completely rather than treated in clinic [17–27, 36, 37]. Thus, conscious prevention of injuries to patients during needle procedures is extremely important including safe sterile technique, operator experience, and the consistent, intelligent use of safety technologies [43–52].

The Joint Commission sets yearly goals for patient safety, encouraging and auditing institutions and practices for formal safety procedures including introduction of new methods and technologies to improve patient safety [40]. Patient and HCW safety is also an important issue to the ACOG, federal government, and other national and international agencies with subsequent marked improvements in quality systems and patient outcomes; however, the integration of safety technologies into the clinic are spotty at best, and few departments have formally studied or integrated new patient and HCW safety technologies into their routine outpatient breast procedures [43–52].

The RPD safety device, which can be used for any physician-performed aspiration procedure provides better needle control than the conventional syringe whether operated with one or two hands [59, 62]. The RPD represents a new class of disposable aspiration–injection safety devices that are operated exclusively with the flexor musculature of the hand. The optimal sizes for breast cyst aspiration procedures are the 10 and 20 ml RPD. The RPD has the core of a conventional syringe barrel and plunger, but has a parallel accessory plunger and an accessory barrel to control the motion of the accessory plunger (Figs. 1, 2, 3). The conventional plunger and the accessory plunger are mechanically linked in an opposing fashion by a pulley system, resulting in a set of reciprocating plungers. Thus, when one plunger is depressed with the thumb, the syringe injects and when the accessory plunger is depressed with the same thumb, the syringe aspirates. This permits the index and middle fingers to remain in one position during aspiration and injection, while the thumb only need move laterally to the alternative plunger change the direction of aspiration or injection.

These mechanical characteristics of “push–push” of the plungers instead of “push–pull”, the exclusive of the hand flexor muscles, the lack of mechanical device lengthening during aspiration, enhanced needle control, and the ability to easily generate any level of vacuum or pressure with one hand create a unique patient safety technology [59–68]. The RPD can be fully operated with one hand while the other hand operates an ultrasound transducer or stabilizes and compresses the breast cyst, but physicians often use two hands on the RPD for even greater control, and hold the RPD in various ways depending on the procedure requirements: (1) the standard syringe grip between the index and middle fingers and the thumb operates the plungers (the other free hand used for palpation of the breast lesion or operating an ultrasound transducer), (2) the reverse trumpet grip where the index and middle finger operate the plungers and the thumb and little finger hold the device on the flanges (often used for oblique biopsy angles), (3) the pencil grip, where one hand holds the RPD like a pencil (for precise control) and the other hand

operates the aspiration–injection plungers, or (4) the two-hand standard grip or trumpet grip where the free hand is used to further steady and direct the RPD.

The RPD has been demonstrated to reduce errant operator-associated motion of the needle tip (both unintended forward penetration and unintended retraction) by 60%, a marked improvement in needle control with important patient safety consequences [59, 62]. Clinical trials of the RPD safety technology have consistently demonstrated reduced procedure time, reduced patient pain, greater sample yield, less needle trauma to patient tissues, and reduced complications, including hemorrhage [59–68]. Clinical trials have also demonstrated that the RPD is superior to other syringe biopsy devices including syringes with plunger locks, syringe handles, syringe pistols, the 3-ring control syringe, and other dedicated procedure syringes [59, 62]. Because of the highly favorable safety profile, the RPD is presently used as an example of an advanced safety technology by the Veterans Administration Center for Patient Safety, and has increasingly been adopted by institutions as a safety device for physician-performed syringe procedures [53–56, 59–68]. As of 2008, the RPD costs approximately \$1.50 per device USA, is single use and disposable, is FDA-approved and CE-marked. The RPD is single use and disposable, and consistently reduces needle-associated complications to patients by 40–60% compared to the traditional syringe [59–68].

The present report has a number of limitations. The effectiveness of the safety needle technology could not be assessed in this study because approximately 100,000 subjects are needed to demonstrate a decrease in needle sticks [28–32, 38, 39, 43, 57, 58]. However, larger studies of safety needles in standard injection procedures have shown considerable effectiveness in reducing needle sticks to HCW [4, 6, 76, 77]. Although the BD safety needle could be used for breast cyst aspiration, there is a need for more ergonomic shielding solutions for procedure needles so that the shield does not physically interfere with an ultrasound transducer. The present report also details the successful integration of the new disposable RPD safety device as a platform to perform breast cyst aspiration. The RPD safety device and the BD safety needle for breast cyst aspiration are further low-cost, one-use, disposable tools in the armamentarium of the Ob-Gyn physician and should be considered as synergistic safety technologies for safer, better directed, and less painful breast needle aspiration procedures.

Keys to successful integration of safety technologies include the utilization of national safety resource centers, timely identification of candidate safety technologies, early involvement of staff who would use the safety technology, and trial use by the targeted HCW with final general introduction into the individual clinics. New safety technologies

can be successfully evaluated and introduced into the clinic to improve patient and HCW safety during outpatient breast procedures.

Financial disclosures There was no industry support for this study.

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