

Integration of Patient Safety Technologies Into Sclerotherapy for Varicose Veins

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The American College of Surgeons, the Joint Commission, the Needlestick Safety and Prevention Act, and the Occupational Safety and Health Administration, all direct surgical departments, including vascular surgeons who supply sclerotherapy services, to develop formal mechanisms to improve the safety of the patient and health care worker (HCW), including integration of new safety technologies. The purpose of the present study was to identify and evaluate new safety technologies for outpatient sclerotherapy for chronic venous disease. Using national resources for patient safety and literature review, the following safety technologies were identified: (1) a safety needle to reduce inadvertent needlesticks to workers, and (2) the reciprocating procedure device (RPD) to reduce iatrogenic injuries to patients. Both devices were evaluated in the clinic, and physician responses were determined. Although the safety sheath of the needle was somewhat

bulky and could interfere with the ultrasound transducer, sclerotherapy could be performed with it. The RPD safety device required instruction 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 the RPD permitted better needle control and more precise injections. The RPD was well accepted by physicians who found it to be convenient, safer, and less painful. Subsequently, the involved services successfully integrated these safety technologies into their routine clinical practices. As recommended by the Joint Commission, safety technologies can be successfully evaluated and introduced into the clinic to improve patient and HCW safety during physician-performed syringe and needle procedures, including sclerotherapy.

Keywords: varicose vein; varicosity; sclerotherapy; injection; syringe; safety; foam; sclerosing; phlebology

Sclerotherapy is the injection of a caustic solution (a sclerosant) into a varicose vein so as to cause localized destruction of the venous intima and obliteration of the vessel.¹⁻⁵ Sclerotherapy by direct injection is primarily used by specialty surgeons to treat small varicose veins, reticular veins, and spider veins.³⁻⁶ Larger vein sclerotherapy is usually accomplished indirectly by the placement of a catheter to inject foam sclerosant or by alternative

radiofrequency or direct surgical methods.⁶⁻²² Although sclerotherapy for chronic venous disease is generally well tolerated, serious complications can occur, including grave patient injury and subsequent malpractice litigation; thus, patient safety during sclerotherapy is always an important consideration.²³⁻⁵⁹ The operating physician can also be injured during a sclerotherapy session, most commonly by needlestick, an occupational hazard for surgeons that can be career-ending.⁶⁰⁻⁶⁵

The American College of Surgeons, the Joint Commission, the Needlestick Safety and Prevention Act, and the Occupational Safety and Health Administration (OSHA), all direct surgical services, including sclerotherapy and phlebology services, to develop formal mechanisms to improve the safety of the patient and health care worker (HCW), including

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integration of new safety technologies.⁵⁹⁻⁷⁸ Improvement in the safety design of medical instruments through safety engineering is one of the most robust methods to improve patient safety, prevent iatrogenic injuries to patients, and reduce needlesticks to HCW, including physicians.⁶⁸⁻⁸³ To date, safety technologies in surgery are not standardized, thus, individual institutions and departments are granted considerable latitude regarding choice of individual technologies.⁵⁹⁻⁸³ Recently, safety needles and safety syringes have become available that improve patient and HCW safety and reduce iatrogenic injuries.^{60-65,84-98} To date few phlebology services have formally integrated these types safety technologies into their sclerotherapy procedures; furthermore, there is a substantial absence of literature on the use of safety technologies in phlebology and sclerotherapy.¹⁻⁵⁸ In the present report, we describe the integration of 2 safety technologies into sclerotherapy and summarize our experience to date with these new safety devices.

Methods and Materials

Selection of Safety Devices

This project was in compliance with the Helsinki Declaration and was approved by the institutional review board. Patient confidentiality and privacy was protected according to the Health Insurance Portability and Accountability Act. This study is registered at www.clinicaltrials.gov. All products used in this study were commercially available and approved by the Food and Drug Administration. The purpose of the study, as encouraged by the Joint Commission, OSHA, and the Needlestick Safety and Prevention Act was to determine the feasibility of using proven safety technologies in sclerotherapy and determine problems and advantages of various of the technologies.⁵⁹⁻⁶¹ Identification of the candidate safety technologies occurred through literature review and through staff interaction with the educational resources of national centers of excellence for patient safety.⁸⁰⁻⁸³ 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 needlesticks would be most suitable for sclerotherapy 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 target vein. A BD safety needle with an off-axis rotating safety sheath (305761 25 g 1.5 in. and 305783 22 g 1.5 in. BD Eclipse Needle, BD, 1 Becton Drive, Franklin Lakes, NJ 07417, Web site: <http://www.bd.com>) was chosen as the safety device to reduce needlestick injuries to HCWs. The BD needle comes with 2 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 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 needle sticks to HCW by 70%.^{60-65,84-88}

In contrast, to improve quality of care and safety for patients during sclerotherapy procedures, the safety technology, the reciprocating procedure device (RPD), was chosen (RPD-1, RPD-3, RPD-5, RPD-10, AVANCA Medical Devices, Inc, Albuquerque, NM, Web site: www.AVANCAMedical.com; Figures 1 and 2). 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.⁸⁹⁻⁹⁸ The RPD is formed around the core of a conventional syringe barrel and plunger, but it has a parallel accessory plunger and an accessory barrel or track to control the motion of the accessory plunger (Figures 1 and 2). The 2 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 in order to change the direction of aspiration



Figure 1. The reciprocating procedure device (RPD) in aspiration prior to injecting foam sclerosant.

The RPD (also known as the *reciprocating syringe*) is in the aspiration phase, where the thumb is on the smaller aspiration plunger. The 5-mL 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. The 2 plungers are mechanically linked in an opposing fashion by a pulley system or gears, resulting in a set of reciprocating plungers. Thus, when the accessory plunger is depressed with the thumb, the syringe aspirates, and when the dominant plunger is depressed with the thumb, the syringe injects. The free hand can be used for palpation as shown here or can be used to stabilize the syringe further, steady the extremity, or operate other devices such as an ultrasound transducer. A flashback of blood is required to ensure intravascular positioning of the needle tip prior to injecting sclerosant.

or injection. The RPD can be fully operated with 1 hand, but physicians often use 2 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.^{89,92} The RPD has also been shown to be



Figure 2. The reciprocating procedure device (RPD) injecting foam sclerosant.

The 5-mL RPD is in the injection phase, where the thumb is on the larger injection plunger. The free hand can be used for palpation as shown here or can be used to stabilize the syringe further, steady the extremity, or operate other devices such as an ultrasound transducer. A flashback of blood ensured intravascular positioning of the needle tip and thus, the sclerosant could be injected safely.

safer than and superior to the conventional syringe for suction needle biopsy, fine needle aspiration of breast, aspiration of body fluids, intra-articular corticosteroid injection, intra-articular hyaluronate injection, aspiration of head and neck abscess, and local anesthesia.⁸⁹⁻⁹⁸

Conventional Direct Injection Sclerotherapy

Conventional sclerotherapy is usually performed with a traditional syringe and needle.¹⁻¹⁶ The traditional syringe and specialized aspiration devices have a number of mechanical characteristics that induce unintended forward penetration or retraction of the needle (loss of control in the forward or

reverse directions), resulting in mistargeting of the blood vessel and secondary complications of sclerotherapy.^{17-58,89,92}

Use of the RPD for Foam Sclerotherapy for Reticular and Varicose Veins

As is standard, air is injected into the sclerosant solution via a 3-way stopcock and 2 syringes, 1 of the syringes being the RPD (Figure 3).^{4,12-16,99-101} Usually, a 5-mL RPD and 1.0% or 3% sodium tetradecyl sulfate solution (STS; AngioDynamics, Queensbury, NY) is used for this purpose. For safety, a 27 or 25 gauge needle on the RPD is placed in the larger reticular and small varicose veins at a 45° angle with the bevel up using visual or ultrasound guidance, the aspiration plunger is depressed so that a flash back of blood is obtained, assuring intravenous positioning (Figure 1), and then the sclerosant foam is injected (Figure 2). The surgeon holds the ultrasound transducer in one hand, and operates the RPD with the other. When not using ultrasound and directly injecting veins, the RPD is held with 2 hands for greater control, with one hand cradling the RPD and stretching the skin, and the other operating the aspiration-injection plungers (Figure 4). With this technique, using the RPD, needle control is markedly improved and the possibility of extravascular injection or hemorrhage from needle trauma is significantly reduced.

Use of the RPD for Sclerotherapy of Spider Veins

For sclerotherapy of spider veins a 30 gauge needle on a 1-mL or 3-mL RPD is used (Figure 4). A cradled 2-hand grip controls the RPD with one hand cradling the RPD and stretching the skin, and the other operating the aspiration-injection plungers. The needle is bent at a 45° angle, with the bevel up, and countertraction is applied with the free hand, and the needle is inserted parallel to the vessel and the skin surface. As the vessel is entered, aspiration can be performed first for blood flashback or the sclerosant can be directly and gently injected. Because of the larger finger flanges and the better grip provided by the RPD, the RPD provides better needle control than the conventional syringe whether direct injection or aspiration then injection is performed. The slight reduction of pressure and



Figure 3. The reciprocating procedure device (RPD) preparing foam sclerosant.

The 5-mL or 10-mL RPD is attached to a 3-way stopcock and a conventional syringe. The sclerosant is mixed 3:1 or 4:1 with air or carbon dioxide and violently agitated by cycling between the RPD and syringe until completely homogenized sclerosant foam is obtained.

blanching that occurs with injection also confirms intravascular positioning. When more concentrated solutions are used in larger veins, aspiration is always performed prior to injection to ensure correct placement of the needle within the vein before injection to prevent extravasation.

Use of the RPD for Sclerotherapy of Incompetent Perforating Veins

A 1-mL or 3-mL RPD containing 1 mL of 1% STS is fitted with a 20 gauge disposable BD safety needle. The skin at the site is cleaned with chlorhexidine, the needle is inserted into the vein, the aspiration plunger is depressed, and a little blood is aspirated into the syringe to confirm that the tip of the needle is within the vein. About 0.1 mL of sclerosant is injected to clear the needle. The RPD is then held firmly against the legs, the patient lies back, and the leg is raised to empty the vein. The ring and index finger of the free hand are pressed on the vein above and below the needle, and about 1½ inches apart, to localize the effect of the injection. 0.5 to 1 mL of the



Figure 4. The reciprocating procedure device (RPD) injecting foam sclerosant in a spider vein.

The 1-mL RPD is in the injection phase, where the thumb is on the larger injection plunger. The free hand can be used for palpation as shown here or can be used to stabilize the syringe further, steady the extremity, or operate other devices such as an ultrasound transducer. With this small needle size, the sclerosant can be directly injected although some operators use a flashback of blood to ensure intravascular positioning of the needle tip and thus, safe injection of the sclerosant.

STS is injected into the isolated, almost empty, segment of vein and the needle removed and pressure applied. The sclerosant is retained in the isolated segment of the vein by the compressing fingers of the left hand for about 30 seconds.

Use of the RPD for Local Anesthesia Prior to Microphlebectomy and Thrombectomy

Local anesthesia can be effectively and less painfully administered with the RPD and a BD safety needle.⁹⁴ Typically, a 1 inch or 1.5 inch 27 or 25 gauge needle is affixed to a 3 mL or 5 mL RPD filled with

1% lidocaine with epinephrine and the area for microphlebectomy or thrombectomy is anesthetized.^{9,18-22} Using the 3 mL or 5 mL RPD the 27 or 25 gauge needle is used to first infiltrate the skin in an intradermal position, and then gradually deeper into the tissues, aspirating prior to injecting to be certain that a blood vessel has not been entered.

Results

When using the BD safety needle, a number of problems occurred: (1) the safety versions of BD safety needle with smaller diameters (≥ 27 gauge) were difficult to acquire, thus only 25 gauge and larger diameter BD safety sclerotherapy needles were available for analysis; (2) the safety sheath was bulky and sometimes interfered with direct visualization of veins or interfered physically with the ultrasound transducer; (3) the locking fittings of the safety needle sheath protruded and sometime pinched the patient's skin and caused discomfort; and (4) there was a tendency for physicians to remove the safety sheath. However, the safety needle could be inactivated with one hand, while pressure could be applied to the sclerotherapy site; this was a definite advantage. Thus, the BD safety needle had certain limitations, but sclerotherapy could be performed with it.

The RPD safety sclerotherapy 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 blood prior to injection to assure intravascular positioning of the needle tip was achieved much more easily with the RPD, and this was immediately evident to all operating physicians. The RPD was well accepted by physicians who found it to be convenient, safer, and less painful. Subsequently, the involved services have successfully integrated this safety technology into their routine clinical practices.

Discussion

Although sclerotherapy for chronic venous disease is generally well tolerated, serious complications may occur.^{12,25-29} Complications range from 0.1% to 10% and include bruising, hematoma, venous netting, hyperpigmentation, persistent pain, deep venous

thrombosis, pulmonary embolus, extravascular injection of sclerosant, blistering, intraarterial injection of sclerosant, embolia cutis medicamentosa, tissue necrosis, tissue infarction, ischemic gangrene, limb amputation, deformity, sensorimotor neuropathy, chronic ulceration, compartment syndrome, headache, scotoma, transient ischemic attack, stroke, bacterial cellulitis, necrotizing fasciitis, cardiac arrest, death, and subsequent malpractice litigation.²⁵⁻⁵⁸ Certain of these complications are not related to surgical technique and are caused by variant anatomy or exaggerated systemic response to the sclerosant.⁵⁰⁻⁵⁴ Others, especially infection, are operator induced and clearly preventable, being associated with poor technique, inadequate local antisepsis, inadequate HCW hand washing, the inappropriate use of reusable equipment, and loss of protective skin due to extravasation with tissue necrosis.¹⁰⁰⁻¹⁰³ Severe complications are associated with needle mistargeting and injecting outside of the venous lumen and include blistering, tissue necrosis, tissue infarction, chronic ulceration, ischemic gangrene, limb amputation, deformity, sensorimotor neuropathy, and compartment syndrome.²⁵⁻⁵⁵ These complications are particularly challenging, and are better prevented completely rather than treated post hoc.⁵⁶⁻⁵⁸ The operating physician can also be injured during a sclerotherapy session, most commonly by needlestick, an occupational hazard for surgeons that can be career-ending.^{60-62,83-88}

In this context, 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.⁵⁹ Patient and HCW safety is also an important issue to the American College of Surgeons and the Veterans Administration National Center for Patient Safety who have stimulated marked improvements in safety procedures to prevent patient injuries.^{67-71,77-83} In sclerotherapy, one such patient-safety technology is the use of ultrasound to interrogate venous anatomy and identify perforating veins and valve competence before the sclerotherapy and to directly visualize the needle tip in real time to assure intravenous positioning when injecting sclerosant, markedly improving patient safety.⁵⁸ However, other common patient and HCW safety technologies such as safety needles and safety syringes have not been formally studied or extensively integrated by specialties that perform sclerotherapy.^{29,41-49} Such safety technologies have

been demonstrated to reduce injuries to patients and HCW by 40% to 70%; thus, there is every reason to consider using these established safety technologies in sclerotherapy.¹⁰⁴⁻¹⁰⁶

One such patient-safety technology is the RPD, also known as the reciprocating syringe, which is formed around the core of a traditional syringe barrel and plunger, but has an extra plunger and barrel (Figures 1 and 2). The 2 plungers are mechanically linked in an opposing fashion by a pulley system, 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 in order to change the direction of aspiration or injection. This also permits the powerful and exquisitely well-controlled flexor musculature of the hand and forearm to be used for both injection and aspiration.

The RPD does not become longer during the aspiration phase, unlike a conventional syringe or the 3-ring control syringe, and this mechanical effect enhances control of the needle tip. During a physician-performed syringe procedure, the RPD reduces unintended forward penetration and unintended retraction of the needle tip by 60% (6 to 12 mm) resulting in enhanced patient safety, reduced tissue trauma, reduced pain, improved needle targeting, and reduced rates of complications, including hemorrhage.⁸⁹⁻⁹⁸ These characteristics of stable finger positioning, the exclusive use of the flexor musculature, and the absence of device lengthening create a powerful and finely controlled one-handed procedure device. The physician must be trained with the RPD and get used to the “push-push” mechanics of the plungers instead of the usual “push-pull” with the conventional syringe; however, both inexperienced physicians and clinical masters with the conventional syringe perform significantly better with the RPD because the device is mechanically superior and safer than a conventional syringe.^{89,92} Physicians who use ultrasound hold the ultrasound transducer with one hand and operate the RPD with the other hand.

Clinical trials have demonstrated that the RPD is safer, less painful, better controlled, and superior to the traditional syringe for aspiration of body fluids, precise anatomic injection of pharmaceuticals,

safer administration of local anesthetics, and aspiration of body tissues.⁸⁹⁻⁹⁸ Because of its enhanced safety, reduced pain, and ability to use one hand, the RPD is also being used for not only sclerotherapy, but for fine needle aspiration biopsy, emergency procedures, cyst and abscess aspiration, administration of botulinum toxin, regional nerve blocks, administration of local anesthesia, and musculoskeletal procedures.⁸⁹⁻⁹⁸ As of 2008, the RPD costs approximately US\$ 1.50 per device (www.AVANCA Medical.com); thus, the RPD is used primarily for physician-performed syringe and needle procedures like sclerotherapy and not for nursing and pharmacy where 95% of syringes are consumed. Physicians induce the majority of serious deep needle injuries to patients with the conventional syringe, and the use of the better controlled and safer RPD has been demonstrated to decrease the complications of syringe and needle procedures, including hemorrhage, by 35% to 60%.⁸⁹⁻⁹⁸

The safety needle studied here could be used for sclerotherapy, but there were a number of problems, including (1) safety needles with smaller diameters (≥ 27 gauge) typically used for cosmetic procedures were difficult to acquire, (2) the safety sheath was bulky and sometimes interfered with visualization of veins or interfered physically with the ultrasound transducer; (3) the locking fittings of the safety needle sheath protruded and sometimes pinched the patient's skin causing discomfort; and (4) there was a tendency for physicians to remove the safety sheath. Thus, the safety needle had certain limitations, but sclerotherapy could be performed with it and the needle could be inactivated with one hand. Because safety needles reduce needlesticks to HCW by 70%, these devices should be used wherever possible to protect operating surgeons and their staff.^{60-65,84-88}

The present report has a number of limitations. There is a need for more ergonomic shielding solutions for sclerotherapy needles so that the shield does not physically interfere with the procedure. In addition, there is a need for ergonomically shielded needles of smaller diameters that are typically used in many cosmetic procedures. Furthermore, the effectiveness of the safety needle technology (reduced needlesticks) could not be assessed in this study because very large numbers of sclerotherapy sessions (greater than 50 000) would be required to demonstrate a decrease in needlestick rates.^{60-65,84-88} Similarly, thousands of sclerotherapy procedures would be required to demonstrate a statistical reduction in the

serious complications of sclerotherapy that was clearly beyond the scope the present feasibility study.²⁵⁻⁵⁸ Despite this, larger studies of safety needles and the RPD safety device in syringe procedures have shown considerable effectiveness in reducing needle sticks and injuries to patients thus the use of these devices are to be encouraged.^{46-49,53,58,59}

In summary, the present study demonstrates, as recommended by the American College of Surgeons, the Joint Commission, the Needlestick Safety and Prevention Act, and the Occupational Safety and Health Administration, that safety technologies can be successfully evaluated and introduced into the clinic to improve patient and HCW safety during physician performed syringe and needle procedures, including sclerotherapy.

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