

Patient Pain and Tissue Trauma During Syringe Procedures: A Randomized Controlled Trial

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ABSTRACT. Objective. To investigate the relationship of needle control to tissue trauma and hemorrhage during syringe procedures.

Methods. Forty-seven subjects with a palpable knee effusion underwent needle and syringe aspiration. Subjects were randomized to the conventional syringe or a safety technology, the reciprocating procedure device (RPD). This trial was registered at clinicaltrials.gov. Pain was measured with the Visual Analog Pain Scale (VAPS). Cell count, crystal examination, culture, and aspirated fluid volume were determined. Red blood cell (RBC) counts were used to measure blood in aspirated fluid.

Results. Patient pain during the syringe procedure significantly predicted blood (RBC) in aspirated fluid ($r = 0.53$, $p = 0.001$). When compared to the conventional syringe, the RPD safety device reduced blood in aspirated fluid by 66.7% (RBC, $10^3/\text{ml}$: RPD 8.9 ± 11.4 ; syringe 26.7 ± 90.2 ; $p < 0.01$), reduced patient pain by 73.9% (VAPS: RPD 1.68 ± 2.34 ; syringe 6.44 ± 2.86 ; $p < 0.01$), and improved fluid aspirate yield by 132% (aspirate volume: RPD 20.9 ± 19.7 ml; syringe 9.00 ± 6.58 ml; $p < 0.01$).

Conclusion. Inadequate control of needle and syringe during physician-performed syringe procedures is an important cause of trauma to patient tissues resulting in hemorrhage, increased patient pain, and decreased aspirate yield. The RPD — a safety device that improves needle control and decreases needle trauma to tissues — reduces hemorrhage and improves the safety, outcome, and aspirate yield of physician-performed syringe procedures. (First Release April 15 2008; *J Rheumatol* 2008;35:1124–9)

Key Indexing Terms:

SYRINGE
SYNOVIAL

PROCEDURE
INJECTION

ARTHROCENTESIS
RECIPROCATING DEVICE

Rheumatologists, orthopedic surgeons, and other medical specialties use a syringe and needle to aspirate body fluids, inject medications, and provide vacuum to obtain tissue biopsies¹⁻⁶. When performing these syringe procedures, occasionally on aspiration there is frank blood in the aspirate that is euphemistically referred to by the proceduralist as a “traumatic tap”⁷⁻¹⁹. The causes of a traumatic tap are thought to be due to misdirection or poor control of the needle or to various host factors, but the consequences to the patient can be serious or even fatal⁷⁻¹⁹. Clinical trials have demonstrated that the conventional syringe, especially when transitioning from injection to aspiration, is difficult to precisely control, causing both unintentional forward penetration and unintentional retraction, resulting in erratic needle

control and increased patient pain^{20,21}. Poor control of the syringe and needle can result in a prolonged procedure time, increased patient pain, a failed procedure, unintended perforation of a blood vessel or other organ, poor sample yield, and delayed diagnosis⁷⁻²⁵.

We hypothesized that a traumatic tap is typically induced by misdirection or loss of control of the syringe and needle, resulting in exaggerated tissue trauma, increased hemorrhage, and increased patient pain. We also hypothesized that a new safety technology, the reciprocating procedure device (RPD), that reduces errant motion of the syringe and improves needle control²⁰⁻²⁶ would reduce tissue trauma, hemorrhage, patient pain, and the incidence of a traumatic tap.

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MATERIALS AND METHODS

Subjects. This project was in compliance with the Helsinki Declaration and was approved by the institutional review board (IRB). Patient confidentiality and privacy were protected according to the Health Insurance Portability and Accountability Act. In each case, patients individually consented both to the syringe procedure and to the IRB-approved research protocol. Our study is registered at clinicaltrials.gov. Entry criteria included: (1) a palpable knee effusion; (2) a planned arthrocentesis for therapeutic and/or diagnostic purposes; and (3) ability to give informed consent. Exclusion criteria included the use of anticoagulants or antiplatelet drugs, the presence of a hemorrhagic diathesis, and a history of recent trauma. Patients were ran-

domized to the conventional syringe or RPD-safety device treatment groups by flipping a coin. Thirteen physicians (2 attendings and 11 residents) performed 47 arthrocentesis procedures on 44 individual patients who required a diagnostic or therapeutic arthrocentesis of the knee for their usual and customary medical care. All resident physician procedures were supervised by the attendings. The study group included knee effusions in the following numbers and conditions: 26 rheumatoid arthritis, 6 reactive arthritis, 5 osteoarthritis, 1 systemic lupus erythematosus, 3 gout, and 6 other miscellaneous disorders between the 2 groups. Distributions of conditions were similar in both groups ($p = 0.63$). Patient age [conventional: 45.8 ± 16.6 yrs, RPD: 47.8 ± 15.2 yrs, 95% confidence interval (95% CI) -16.6% to 25.1% difference; $p = 0.67$], proportion of women [conventional: 22/25 (88%), RPD: 17/22 (77.3%), 95% CI -70% to 96% ; $p = 0.328$], percentage of procedures performed by attendings [conventional: 9/25 (37%); RPD: 8/22 (33%), 95% CI 20.2% – 55% ; $p = 0.97$], and years of experience of the physicians per individual procedure (conventional: 16.8 ± 12.3 yrs, RPD: 16.9 ± 12.3 yrs, 95% CI -56.3% to 57.5% difference; $p = 0.978$) were comparable between the 2 groups. Arthrocentesis of the knee was performed in a customary fashion after 2% local lidocaine anesthesia^{1–4,22–25}. Local anesthesia was achieved with 2% lidocaine solution using a 1.5-in, 25-gauge needle, first to infiltrate the skin in an intradermal position, and then gradually deeper into the tissues until the entire volume of lidocaine was infiltrated. Subsequently, the arthrocentesis was performed with a 22-gauge, 1.5-in needle mounted on the RPD or conventional syringe, respectively. Since entry criteria to our study included the presence of a palpable

effusion, the lateral suprapatellar approach (that is, introducing the needle into the distended suprapatellar bursa from the lateral side) was the standard approach, performed while simultaneously compressing the patella and medial bursa side to distend the opposing lateral bursal compartment. “Visible blood” in synovial fluid was defined as synovial fluid with any visible evidence of blood including trace blood, a streak of blood, pink or red tinted fluid, or grossly hemorrhagic fluid. Aspirated synovial fluid volume was recorded, then the fluid was sent to the laboratory for culture, cell count, and crystal examination.

Needles and syringes. BD safety needles with an off-axis rotating safety sheath (305761- 25-g, 1.5-in and 305783- 22-g, 1.5-in BD Eclipse™ Needle, Becton Dickinson, Franklin Lakes, NJ, USA) were used for local anesthesia and the needle aspiration procedure, respectively. The conventional syringe was a 10-ml Luer-Lok™ BD syringe (Ref. 309604, Becton Dickinson). The reciprocating procedure device (RPD) was a Luer-Lok 10-ml device (RPD-10, Avanca Medical Devices, Albuquerque, NM, USA). Both devices are presently available in other sizes as well, but the 10-ml device was used to standardize the device size for our study. The RPD is formed around 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^{20–26}. The 2 plungers are mechanically linked in an opposing fashion, 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 (Figure 1). This permits the index and middle fingers to



Figure 1. One-handed use of the reciprocating syringe for arthrocentesis. The reciprocating syringe is being used one-handed for aspiration and drainage of a knee effusion. Larger plunger is depressed with thumb for injection and the smaller plunger for aspiration. As shown, smaller plunger is depressed for continuous aspiration. The free hand is used to feel anatomy, steady the extremity or syringe, apply pressure to the effusion, or operate an ultrasound transducer. Here, the free hand is being used to steady the extremity and to apply tactile pressure to the effusion to assist in fully draining the knee effusion.

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. These characteristics of stable finger positioning and the exclusive use of the intrinsic flexor musculature create a powerful and finely controlled one-handed procedure syringe.

Outcome data of clinical procedures. Patient pain during the aspiration procedure was determined with the standardized and validated Visual Analog Pain Scale (VAPS) where 0 cm = no pain and 10 cm = unbearable pain^{27,28}. Operator satisfaction with the syringe after the procedure was determined with the Visual Analog Satisfaction Scale (VASS) where 0 cm = completely dissatisfied with the performance of the procedure syringe and 10 cm = completely satisfied with the performance of the procedure syringe^{29,30}. Final clinical outcomes were determined (1) directly at the conclusion of the procedure; (2) by review of the synovial fluid results; and (3) by a telephone call to the patient at 2 weeks after the procedure.

Statistical analysis. Data were entered into Excel (Version 5, Microsoft, Seattle, WA, USA), and analyzed in SAS (SAS/STAT Software, Release 6.11, SAS Institute, Cary, NC, USA). 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 Fisher's least significant difference method. Corrections were made for multiple comparisons. Correlations between parametric data were determined with logistic regression and between nonparametric data with Spearman correlation and Kendall rank method.

RESULTS

The pain the patient experienced as measured by VAPS during the aspiration procedure was significantly associated with visually evident blood ($r = 0.53$, $p < 0.001$, Spearman), red blood cell/white blood cell (RBC/WBC) ratio ($r = 0.56$, $p = 0.0007$, Spearman) and absolute RBC counts ($r = 0.53$, $p = 0.001$, Spearman; Figure 2). Physician satisfaction with

the procedure device was independently associated with reduced patient pain ($r = 0.54$, slope = -0.29 ± 0.07 , 95% CI -0.43 to -0.16 , $p < 0.001$, linear regression).

Table 1 shows results of fluid aspiration comparing the conventional syringe to the RPD safety device. More procedures (approximately 65%) were performed by physicians in training (residents and fellows) under attending supervision in both groups than were performed by attendings (approximately 35%). WBC counts were similar between the 2 groups ($p = 0.67$); however, absolute RBC, RBC/WBC ratio, visible blood in the synovial fluid, anesthesia pain, procedure pain, and significant pain (VAPS score ≥ 5) were significantly greater with the conventional syringe compared to the RPD. The RPD safety device increased aspirated fluid volume by 132% ($p = 0.012$), reduced absolute RBC by 66.7% ($p < 0.001$), reduced RBC/WBC by 62.3% ($p < 0.001$), reduced trace or obvious bloody fluid by 71.6% ($p < 0.001$), reduced procedure pain scores (VAPS) by 73.9% ($p < 0.001$), decreased significant pain (VAPS ≥ 5) by 78.8% ($p < 0.001$), and increased operator satisfaction by 52.8% ($p < 0.001$).

DISCUSSION

One of the euphemisms of medicine is the description of the result of an aspiration procedure as a "traumatic tap" or "bloody aspirate" — with little direct discussion of how the trauma or bleeding occurred⁷⁻²⁵. It is usually understood between physicians that a syringe procedure resulting in a traumatic tap or bloody aspirate was painful for the patient,

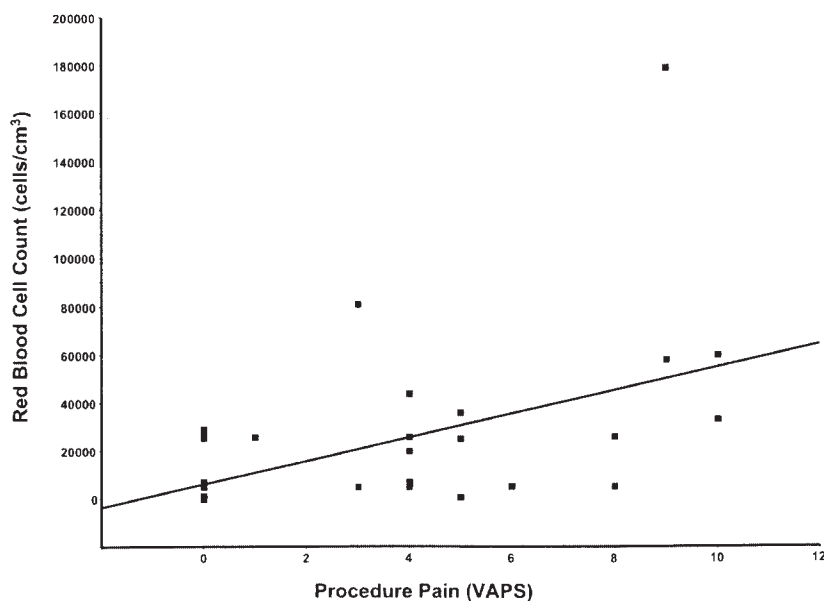


Figure 2. Hemorrhage and patient pain during syringe and needle aspiration procedures. Graph shows the significant relationship ($r = 0.53$, $p = 0.001$) of hemorrhage (absolute red blood cell counts, RBC) in aspirated body fluid and the pain a patient experiences during the procedure as measured by the visual analog pain score (VAPS). As can be seen, when a patient experiences increased pain during a syringe and needle procedure, there is increased needle-induced tissue trauma resulting in hemorrhage (increased absolute RBC) in aspirated fluid.

Table 1. The outcome of 47 aspiration procedures of the knee.

	Conventional Syringe	RPD Safety Device	Percentage Difference	p	95% CI
No. procedures	25	22			
Fluid volume, ml	9.00 ± 6.58	20.9 ± 19.7	+132	0.012*	38.8–225
White blood cell count (1000/ml)	13.4 ± 20.4	11.8 ± 11.4	-11.9	0.67*	-61.9–85.7
Red blood cell count (1000/ml)	26.7 ± 90.2	8.9 ± 11.4	-66.7	< 0.001***	-35.4 to -107
RBC/WBC ratio	51.2 ± 94.0	19.1 ± 70.2	-62.3	< 0.001***	-15.0 to -101
Visible trace or gross blood (%)	16/25 (64.0)	4/22 (18.2)	-71.6	< 0.001**	-27.6 to -101
Patient pain during anesthesia (VAPS)	6.84 ± 2.23	4.36 ± 2.34	-36.3	< 0.001*	-16.7 to -55.8
Patient pain during procedure (VAPS)	6.44 ± 2.86	1.68 ± 2.34	-73.9	< 0.001*	-49.8 to -98.0
Significant pain (VAPS ≥ 5) (%)	17/25 (68.0)	3/22 (13.6)	-80.0	< 0.001**	-39.9 to -105
Physician satisfaction (VASS)	6.04 ± 1.34	9.23 ± 0.53	+52.8	< 0.001*	42.7–62.9

* t-test; ** Fisher exact test; *** Rank order test. RPD: reciprocating procedure device; VAPS: Visual Analogue Pain Scale

but usually there is little acknowledgment that the physician's direction and control of the needle were directly responsible for both the trauma to patient tissues and the pain the patient experienced. It is recognized that intrinsic patient factors (hemorrhagic diathesis, anticoagulants, antiplatelet drugs, vascular malformations, local infarction, tumor, variant anatomy, and previous trauma) can result in a hemorrhagic aspirate even under the best of circumstances¹⁻¹⁹. However, a traumatic tap often occurs outside of these circumstances and is most likely related to the physician's choice of anatomic entry point, the specific device used, and the experience, skill and judgment of the individual controlling the syringe device. In our study, these physician-operator variables were equivalent between both treatment groups.

We hypothesized that the pain a patient experienced during a syringe and needle procedure was due in part to direct needle trauma to patient tissues caused by inadequate control of the syringe and needle. Since direct needle trauma to tissues is difficult to measure *in vivo*, the study used surrogate measures of trauma, including visible blood in the aspirated fluid, absolute RBC, RBC/WBC ratios, and patient pain. To reduce confounding factors, patients taking anticoagulants, taking antiplatelet drugs, with a hemorrhagic diathesis, or who experienced recent trauma were excluded from the study.

Figure 2 demonstrates the significant relationship between absolute RBC and the pain a patient experiences during an aspiration procedure (absolute RBC $r = 0.53$, $p < 0.001$). Although there are obviously other factors that increase the pain that a patient experiences during a syringe and needle procedure (for example, not using anesthesia, large needle bore diameter, obvious misdirection of the needle, errant motion of the needle, anxiety, needle phobia, and others), at least a substantial portion of the pain is likely due to direct needle trauma to pain-sensitive tissues, including periosteum, periarticular tissues, and synovial membrane^{4,19,25}. After needle trauma, these pain-sensitive tissues

may bleed, causing the increased red blood cells noted in the aspirated fluid^{1-12,19}. Previous clinical trials have demonstrated that a conventional syringe is often poorly controlled during physician-performed syringe and needle procedures, especially when aspirating or repetitively aspirating and injecting^{20,21}. Our study provides further evidence of the intrinsic failings of the traditional syringe, demonstrating increased hemorrhage and pain associated with use of the conventional syringe in aspiration procedures (Table 1).

If poor syringe and needle control were contributing to the observed increases in tissue trauma, and inducing hemorrhage and patient pain observed with the conventional syringe, then an intervention that improves the control of the syringe and needle should reduce hemorrhagic taps, reduce RBC in aspirated fluid, and reduce patient pain^{4,20-25}. The RPD is a safety technology designed to ergonomically function with the native musculature of the hand to improve control of the needle in both the injection and aspiration phases of syringe procedures^{20,21}. Because of these enhanced control characteristics, the RPD has been shown to be faster, safer, and less painful for physician-performed syringe and needle procedures, including general body-fluid aspiration procedures, arthrocentesis, intraarticular injection of corticosteroid, needle and syringe administration of local anesthesia, intraarticular injection of hyaluronate, and needle aspiration biopsy²⁰⁻²⁶. Thus, if poor control of the needle and syringe were contributing to "hemorrhagic taps," needle-induced tissue trauma, bleeding into body fluid, and increased patient pain, the RPD safety device should reduce these complications.

Table 1 shows the effect of the RPD on outcome in syringe and needle aspiration procedures. As can be seen, relative to the conventional syringe, the RPD significantly reduced pain scores (VAPS scores) by 73.9%, reduced significant pain (VAPS scores ≥ 5) by 80.0%, reduced RBC/WBC ratio by 62.3%, and reduced absolute RBC counts by 66.7% (all $p < 0.02$). In addition, the RPD was associated with a 132% increase in aspirated fluid volume

and a 71.6% reduction in visible hemorrhage in aspirated fluid ($p < 0.02$; Table 1). Physician satisfaction was also significantly higher with the RPD than with the conventional syringe (Table 1), and physician satisfaction was highly associated with reduced patient pain ($r = 0.54$, slope = -0.29 ± 0.07 , 95% CI -0.43 to -0.16 , $p < 0.001$).

Our study has certain limitations: (1) only knee aspirations were studied; (2) only the 10-ml device was studied; (3) only needle trauma that caused hemorrhage could be measured by the RBC counts; (4) needle trauma that did not cause blood in aspirated fluid would not be detected by our study except as the observed increased in procedural pain; (5) the subjects had a mix of different rheumatologic diagnoses; and (6) multiple operators performed the procedures. While these last 2 are cited as criticisms, they could also be considered strengths, in that the techniques are consistent in many hands. Physicians in training (residents and fellows) under attending supervision performed approximately 65% of all procedures in our study; their lack of skill likely contributed to increased levels of tissue trauma and increased hemorrhage we observed. However, regardless of experience, both attendings and residents significantly improved their syringe performance and needle control with the RPD, resulting in reduced tissue trauma, pain, and hemorrhage (Table 1). Moreover, like previous studies, ours further supports the concept that the conventional syringe is often inadequately controlled by physicians during needle and syringe procedures, resulting in poorer outcomes¹⁹⁻²⁵. Because of the usual lack of significantly large blood vessels or susceptible soft tissues in joints, arthrocentesis rarely results in life-threatening hemorrhage or fatal outcomes. However, misdirection or loss of control of the needle in the shoulder, wrist, hip, temporomandibular joint, or axial skeleton can result in unintended arterial puncture, hemorrhage, aneurysm, thrombosis, pneumothorax, nerve injury, and other serious complications^{1-4,17,20-25,31-33}.

Similarly, the complications of other physician-performed syringe procedures directed at non-musculoskeletal target organs can be catastrophic⁵⁻¹⁸. In poorly directed and poorly controlled syringe procedures in the musculoskeletal system (usually by resident physicians), we have personally observed significant morbidity, including local hemorrhage, painful hematoma formation, patient emotional distress and suffering, and several weeks of decreased function, requiring additional medical attention, analgesics, local measures, and increased healthcare costs. Thus, the complications of any syringe and needle procedure can be serious, and should not be trivialized^{10,31-33}.

The RPD, a control-type syringe safety device, is formed around the core of a conventional syringe barrel and plunger, but has a parallel accessory plunger or plunger equivalent and an accessory barrel or track to control the motion of the accessory plunger²⁰⁻²⁶. The 2 plungers are mechanically linked in an opposing fashion, resulting in a

set of reciprocating plungers. 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. When actually using the RPD, physicians are rather inventive and actually hold the RPD in a variety of positions according to the procedural needs, including the conventional syringe grip, the pencil syringe grip, 2-hand grip, 1-hand grip, and the 1 or 2-handed reverse trumpet grip. In all these grips, the flexor musculature of the hand is used to both aspirate and inject, quite different from any other syringe device. These characteristics of stable finger positioning and the exclusive use of the intrinsic flexor musculature create a powerful and finely controlled 1-handed procedure syringe^{20,21}.

The Needlestick Safety and Prevention Act, the Joint Commission, and the Occupational Safety and Health Administration, and similar regulatory bodies in Europe and Canada, direct healthcare entities, including rheumatology services, to improve both patient and health worker safety, including integration of safety technologies³⁴⁻³⁷. Presently, a conventional syringe costs \$0.10 to \$0.35 US, a conventional safety syringe \$0.25 to \$0.55 US, and the RPD \$1.45 to \$1.65 US (in comparison, methylprednisolone acetate costs about \$5.00/40 mg, hyaluronate costs approximately \$150/dose US, and a major complication of a syringe procedure \$5,000 to \$10,000 US). Thus, regardless of the device, syringes are the least costly aspect of a syringe and needle procedure¹⁰. Of the 3 syringe technologies, only the RPD has been demonstrated to decrease patient pain and reduce the complications of physician-performed syringe and needle procedures, including hemorrhage^{1-25,31-33}. Since physicians use only about 5% of all the syringes in a healthcare system (the bulk being used by nursing and pharmacy), yet are responsible for over 85% of all the serious syringe and needle injuries to patients, use of the RPD, a relatively inexpensive safety technology, may both make economic sense and improve the quality of rheumatologic care^{5-19,34-37}. Our study further shows that inadequate control of needle and syringe during physician-performed syringe procedures is an important cause of needle trauma to patient tissues, resulting in an increased incidence of hemorrhage, increased patient pain, and decreased aspirate yield, and demonstrates that all of these adverse events can be reduced with the RPD, a safety device that replaces the conventional syringe in physician-performed procedures, including arthrocentesis.

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