

Original Contributions

A RANDOMIZED, CONTROLLED TRIAL OF THE RECIPROCATING PROCEDURE DEVICE FOR LOCAL ANESTHESIA

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□ **Abstract**—The purpose of this study was to determine whether the new reciprocating procedure device (RPD) is superior to the conventional syringe for the administration of local anesthesia. There were 209 local lidocaine anesthesia procedures randomized between the RPD and the conventional syringe. Outcome measures included administration time, anesthesia pain, procedure pain, and operator satisfaction. The RPD significantly reduced anesthesia administration time by 49% (RPD: 0.68 ± 0.59 min, Syringe: 1.32 ± 1.01 min, $p < 0.001$, 95% confidence interval [CI] for % reduction: 36%–60%), reduced anesthesia pain by 27% (RPD visual analog pain scale score: 4.05 ± 2.64 ; Syringe: 5.55 ± 3.00 ; $p < 0.001$, 95% CI 14%–38%), reduced significant procedure pain by 74% ($p < 0.001$, 95% CI 60%–87%), and improved physician satisfaction by 63% ($p < 0.001$, 95% CI 53%–74%). The RPD markedly reduces the pain associated with lidocaine anesthesia administration, reduces administration time, and maintains the effectiveness of local anesthesia. The RPD is superior to and significantly more effective than the conventional syringe for the administration of local lidocaine anesthesia. © 2008 Elsevier Inc.

□ **Keywords**—syringe; anesthesia; lidocaine; reciprocating procedure device; injection; pain

INTRODUCTION

Local lidocaine anesthesia administered with a syringe and needle remains an important and fundamental com-

ponent of emergency therapy, but pain with lidocaine administration remains a significant patient complaint (1–7). Considerable attention has been directed to the proper syringe and needle technique during local anesthesia (8–11). Buffering the local anesthetic agent as well as the development of alternative delivery methods to lessen the pain associated with local anesthesia have been reported (12–19). Although obviously contributing to the pain experience, poor control of the needle and syringe by the operator during local anesthesia has not been well studied.

The reciprocating procedure device (RPD) incorporates a reciprocating plunger mechanism that permits the index and middle fingers to remain in one position during aspiration and injection while the thumb moves horizontally to the alternative plunger to change the direction of aspiration or injection (Figures 1, 2). Unlike a conventional syringe or the three-ring control syringe, the RPD does not become longer during the aspiration phase (20,21). Due to these mechanical characteristics, the RPD is better controlled by physicians than the conventional syringe, and has been shown to reduce unintended penetration (loss of control of the needle in the forward direction) by 66% and to reduce unintended retraction (loss of control of the needle in the reverse direction) by 68%, resulting in less pain and improved procedure outcomes (20–25). We hypothesized that difficulty con-



Figure 1. Reciprocating procedure device (RPD) for local anesthesia—aspiration. This photograph demonstrates the RPD being used in a one-handed fashion for local anesthesia of the knee before a deep joint aspiration procedure. The smaller plunger is depressed with the thumb for aspiration to be certain the needle is not in a vascular structure; as shown here, the larger plunger is depressed to inject. The free hand is used to stabilize the syringe as shown here, steady the patient, feel the surface anatomy, expose the wound, or operate other devices.

trolling the traditional syringe by the physician operator is a significant component of pain during instillation of local anesthesia, and that the enhanced control of the needle provided by the RPD would result in more rapid, less painful, and more effective local anesthesia and needle procedures.

MATERIALS AND METHODS

Subjects

This project was approved by the institutional review board. Twenty-five physicians (52% attending physicians and 48% resident physicians) performed 209 procedures on patients who required an invasive outpatient procedure for their usual and customary medical care. At the conclusion of the study, the physician operators had far more career experience with the conventional syringe (1533 ± 812.43 local anesthesia procedures) than the RPD (24.6 ± 18.7 local anesthesia procedures, $p < 0.001$).

In each case, patients were individually consented for both the invasive procedure and the institutional review board-approved research protocol. The 209 invasive procedures consisted of local anesthesia followed by deep needle aspiration of the joints for diagnostic purposes (Table 1). In each case, the procedure was randomized to either the conventional syringe or RPD for the local anesthesia portion, and then the subsequent deep needle procedure was performed in a customary manner with

the same type of syringe device (conventional syringe or RPD, respectively). In each group, the proportion of procedures performed by attending physicians vs. resident physicians was similar (approximately 50:50, Table 1, $p > 0.05$).

Syringes

The conventional syringe was a 10-mL Luer-Lok™ BD syringe (Ref 309604, Becton, Dickinson and Company, Franklin Lakes, NJ). To provide an identical 10-mL BD syringe core for valid comparisons, the RPD was prototyped in the University of New Mexico Syringe Laboratory, using an identical 10-mL BD core. Funding for this prototype used non-industry internal resources of the university. Thus, the RPD used in these experiments was an experimental version made of a conventional syringe with a reciprocating mechanism attached, and was similar to but not identical to the commercially available, Food and Drug Administration-approved versions of the RPD, which contain a different syringe core (20,21).

Local Anesthesia

Local anesthesia was achieved with 1% lidocaine solution in the syringe device, which was randomized between the RPD and the conventional syringe. A 1½-inch 25-gauge needle (25 G1-1/2 PrecisionGlide Needle, Becton, Dickinson and Company) was used to first infiltrate



Figure 2. Reciprocating procedure device (RPD) for local anesthesia—injection. This photograph demonstrates the RPD being used in a one-handed fashion for local anesthesia of the knee before a procedure. Once the smaller plunger has been depressed with the thumb for aspiration to be certain the needle is not in a vascular structure, the larger plunger is depressed to inject lidocaine, as shown here. The free hand is used to stabilize the syringe, steady the patient, feel the surface anatomy, expose the wound, or operate other devices.

Table 1. Characteristics of Study Subjects in 209 Local Anesthesia Procedures

| | Conventional Syringe (CS) | Reciprocating Procedure Device (RPD) | Significance | 95% CI for Absolute Difference Between CS and RPD |
|---|---------------------------|--------------------------------------|--------------|---|
| Number of procedures | 115 | 94 | | |
| Patient age | 52.7 ± 12.47 | 51.7 ± 12.8 | $p > 0.05$ | −2.7–4.47years |
| Female | 95/115 (82%) | 73/94 (78%) | $p > 0.05$ | −16%–6% |
| Male | 20/115 (18%) | 21/94 (22%) | $p > 0.05$ | −6%–16% |
| Small joints (PIP, MCP, CMC) | 19/115 (17%) | 10/94 (11%) | $p > 0.05$ | −3%–15% |
| Large to intermediate joints (knee, hip, shoulder, elbow, wrist, ankle) | 96/115 (83%) | 84/94 (89%) | $p > 0.05$ | −15%–3% |
| Procedures performed by attending physicians | 69/115 (60%) | 48/94 (51%) | $p > 0.05$ | −5%–22% |
| Procedures performed by resident physicians | 46/115 (40%) | 46/94 (49%) | $p > 0.05$ | −22%–5% |

PIP = proximal interphalangeal joint; MCP = metacarpophalangeal joint; CMC = carpometacarpal joint.

the skin in an intradermal position, and then gradually deeper into the tissues until the entire volume of lidocaine was infiltrated (Figure 2). Smaller amounts of lidocaine were used for smaller structures. The technique was standardized and required aspiration before injection to be certain that a blood vessel had not been entered (Figure 1), followed by slow injection (Figure 2) and then slow advance of syringe and needle forward while aspirating. The deep needle aspiration procedure was then initiated after the anesthesia had been administered, and each was performed in a standardized manner and in a customary fashion with the same type of syringe device (conventional syringe or RPD, respectively) (26–31). For these post-anesthesia deep aspiration procedures, a 21-gauge needle (21 G1-1/2 PrecisionGlide Needle, Becton, Dickinson and Company) was used in all cases to standardize the pain stimulus associated with the procedure.

Outcome Measures

A non-operating observer timed each local anesthesia procedure, and queried the patient in real time regarding pain during administration of the local anesthesia. Directly after the anesthesia procedure, the observer also queried the physician in terms of satisfaction with the syringe used for anesthesia. To determine effectiveness of the administered anesthesia, the patient was again queried concerning pain during the post-anesthesia procedure. Patient pain was determined with the standardized and validated Visual Analog Pain Scale (VAPS), where 0 cm = no pain and 10 cm = unbearable pain (32,33). The VAPS was obtained twice—immediately after the anesthesia portion and immediately after the deep syringe procedure. Moderate to severe pain was defined as a VAPS ≥ 5 . 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 (34,35).

Statistical Analysis

Data were entered into Excel (Version 5, Microsoft Inc., Redmond, WA), and analyzed in SAS (SAS/STAT Software, Release 9.1, SAS Institute Inc., Cary, NC). An initial sample size of 100 procedures for each treatment group was considered. With this sample size, a two-sided *t*-test at the alpha = 0.05 level has 80% power to detect a mean difference in pain levels of 1 unit on the VAPS scale between procedures using the conventional syringe and the RPD. In this calculation, the within-group standard deviation is estimated to be 2.50, which corresponds to the range for VAPS scores (10) divided by 4. If the standard deviation is set at a more conservative value of 4, then 80% power is obtained for mean differences of 1.60 or greater. Ultimately, our study involved 209 procedures randomly assigned to the two treatment groups, resulting in 115 procedures for conventional syringe and 94 for the RPD. The slight imbalance in sample sizes for the two groups has little practical effect on the power, relative to a sample size of 100 per group.

Differences between treatment groups (i.e., conventional syringe vs. RPD) were determined using either the Satterthwaite *t*-test or Fisher's Exact Test, depending on whether the outcome measure was numerical or categorical. Confidence intervals for differences in means and proportions were obtained using standard two-sample methods. Fieller's method was used to calculate confidence intervals for relative differences in means and percentages between the groups (36). A generalized linear model with a log link was used to assess whether

Table 2. Outcome of 209 Local Anesthesia Procedures Randomized to Either the Conventional Syringe or the Reciprocating Procedure Device (RPD)

| | Conventional Syringe (CS) | RPD | Significance | 95% CI on the % Increase or Decrease for RPD Relative to CS |
|--|---------------------------|-------------|--------------|---|
| Number of procedures | 115 | 94 | | |
| Procedure time (min) | 1.32 ± 1.01 | 0.68 ± 0.59 | $p < 0.001$ | 36%–60% decrease |
| Patient pain during anesthesia (VAPS) | 5.55 ± 2.99 | 4.05 ± 2.64 | $p < 0.001$ | 14%–38% decrease |
| Significant pain (VAPS ≥ 5) | 75/115 (65%) | 36/94 (38%) | $p < 0.001$ | 23%–58% decrease |
| Physician satisfaction (VASS) | 5.41 ± 1.72 | 8.81 ± 0.83 | $p < 0.001$ | 53%–74% increase |
| Patient pain during post-anesthesia procedure (VAPS) | 5.03 ± 3.44 | 2.25 ± 2.55 | $p < 0.001$ | 42%–66% decrease |
| Significant pain during post-anesthesia procedure (VAPS ≥ 5) | 67/115 (58%) | 14/94 (15%) | $p < 0.001$ | 60%–87% decrease |

VAPS = Visual Analog Pain Scale; VASS = Visual Analog Satisfaction Scale.

relative differences between groups varied in procedures performed by attending physicians and resident physicians (37). Linear regression and Pearson correlations were used to assess association between numerical outcomes.

RESULTS

Table 1 shows the patient characteristics and the mix of procedures, which were comparable between the treatment groups. The overall outcomes of the local anesthesia procedures are shown in Table 2. There were 209 local anesthesia procedures randomized to either the conventional syringe or RPD, resulting in 115 procedures for conventional syringe and 94 for the RPD. The RPD resulted in a reduced procedure time compared to the conventional syringe (RPD: 0.68 ± 0.59 min, conventional syringe: 1.32 ± 1.01 min, $p < 0.001$), reduced pain during administration of anesthesia (RPD VAPS score: 4.05 cm ± 2.64; conventional syringe VAPS score: 5.55 cm ± 2.99; $p < 0.001$), and improved physician satisfaction with the anesthesia device (RPD VASS Score: 8.81 cm ± 0.83, conventional syringe VASS score: 5.41 cm ± 1.72, $p < 0.001$). Thus, relative to a conventional syringe, the RPD resulted in a 49% relative reduction in procedure duration ($p < 0.001$, 95% CI 36%–60%), 27% relative reduction in patient pain during anesthesia ($p < 0.001$, 95% CI 14%–38%), and a 63% relative increase in operator satisfaction with syringe performance ($p < 0.001$, 95% CI 53%–74%). Sixty-five percent (75/115) of subjects experienced moderate to severe pain during local anesthesia with the conventional syringe, whereas only 38% (36/94) of subjects experienced moderate to severe pain with the RPD during anesthesia (41% relative decrease; $p < 0.001$, 95% CI 23%–58%).

Pain scores during the post-anesthesia procedures that were performed with either the RPD or conventional

syringe were as follows: RPD VAPS score: 2.25 cm ± 2.55; conventional syringe VAPS score: 5.03 cm ± 3.44; $p < 0.001$, corresponding to a 55% decrease in pain scores ($p < 0.001$, 42%–66%). Fifty-eight percent of subjects (67/115) experienced significant pain (VAPS scores ≥ 5) after conventional anesthesia, whereas 15% (14/94) of subjects experienced VAPS scores ≥ 5 after anesthesia with the RPD (74% relative decrease; $p < 0.001$, 95% CI 60%–87%). Thus, anesthesia administered with the RPD was significantly less painful during administration, and the post-anesthesia procedure with the RPD was also significantly less painful.

Further analysis showed that the effect of the device type on patient pain during anesthesia varied significantly ($p < 0.05$) in procedures performed by resident physicians (13% decrease for RPD vs. conventional syringe, 95% CI 32% decrease to 11% increase) and attending physicians (43% decrease for RPD vs. conventional syringe, 95% CI 28%–55%). On the other outcomes, the relative differences between the treatment groups do not vary significantly ($p > 0.05$) in procedures performed by resident physicians and attending physicians.

Because both anesthesia administration pain and post-anesthesia procedure pain were different with the RPD and conventional syringe, these relationships were explored in more depth by plotting the pain scores during anesthesia against the pain scores during the post-anesthesia procedure, and performing linear regression (Figures 3, 4). As can be seen in Figures 3 and 4, the pain experienced during the administration of anesthesia closely correlated with the pain experienced in the subsequent post-anesthesia procedure for both the conventional syringe and the RPD, indicating that pain during anesthesia predicted pain during the post-anesthesia procedure. However, the slope of the curves, the mean anesthesia pain, and the mean procedure pain were significantly different between the conventional syringe and

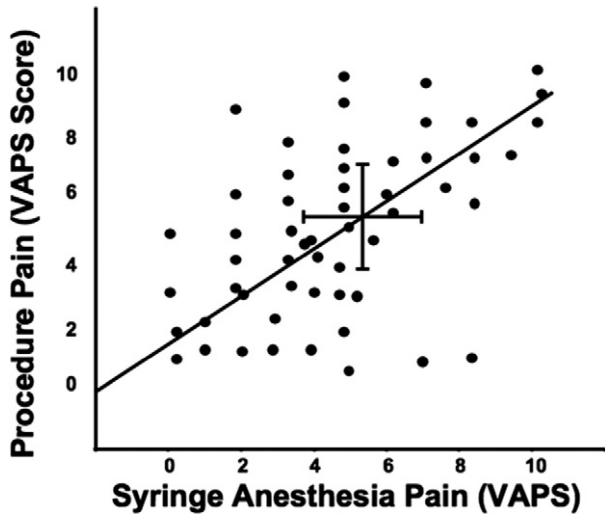


Figure 3. Local anesthesia pain as a predictor of procedure pain—conventional syringe. This figure demonstrates the relationship between pain experienced during the installation of local anesthesia and the effectiveness of that anesthesia, measured in terms of pain experienced during the subsequent procedure. As can be seen, by linear regression methods, pain with local anesthesia (ordinate) predicts pain during the post-anesthesia procedure (abscissa), $r = 0.64$, $p < 0.001$, $n = 115$. The cross indicates the intersection of mean pain (VAPS scores) \pm SD for both anesthesia pain and procedure pain. Note that the slope of the curve and mean pain are considerably more than those of the RPD (Figure 4).

RPD ($p < 0.001$), indicating significantly different device pain response curves.

DISCUSSION

Local lidocaine anesthesia administered with a syringe and needle remains an important and fundamental component of care of the acutely ill or injured patient in the emergency and urgent care environment. Previous efforts at reducing pain during the administration of local anesthesia have concentrated on proper syringe and needle technique, buffering the local anesthetic agent, and alternative methods to the traditional syringe and needle (8–19). Because design inadequacies of the traditional syringe promote poor control of the needle during typical syringe procedures, we hypothesized that inadequate control of the syringe and needle also might be contributing significantly to anesthesia administration pain (21–25).

The present randomized, controlled study demonstrated that administration of local lidocaine anesthesia with the RPD resulted in a 49% relative reduction in the duration of anesthesia administration ($p < 0.001$, 95% CI 36%–60%), 27% relative reduction in patient pain ($p < 0.001$, 95% CI 14%–38%), and a 63% increase in operator satisfaction with anesthesia device performance

($p < 0.001$, 95% CI 53%–74%) (Table 2). Significant patient pain during anesthesia administration was reduced from 65% to 38%, indicating a substantial improvement in preventing pain during administration of local anesthesia. The post-anesthesia needle procedure was also less painful with the RPD compared to the traditionally syringe, further emphasizing the different pain-device relationships with the RPD.

Poor control of the syringe and needle is a major cause of increased patient pain during syringe procedures, including local anesthesia (8–10,21,38–40). The improvement in physician performance in terms of procedure duration and reduced patient pain with the RPD could not be attributed to practice effects, as the physicians had far more practice with the conventional syringe (1533 ± 812.43 local anesthesia procedures) than the RPD (24.6 ± 18.7 local anesthesia procedures, $p < 0.001$). These results suggest that improved physician performance with the RPD in local anesthesia was related to the better intrinsic mechanical control characteristics of the RPD, as has been previously demonstrated (21–25).

An interesting finding in this study is the high degree of pain (62% of subjects) that patients experience during typical lidocaine local anesthesia with a conventional

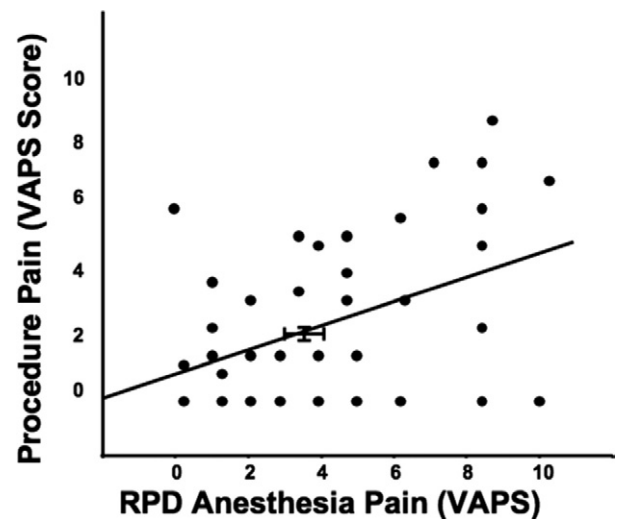


Figure 4. Local anesthesia pain as a predictor of procedure pain—reciprocating procedure device (RPD). This figure demonstrates the relationship between pain experienced during the installation of local anesthesia and the effectiveness of that anesthesia, measured in terms of pain experienced during the subsequent procedure. As can be seen, by linear regression methods, pain with local anesthesia (ordinate) predicts pain during the post-anesthesia procedure (abscissa), $r = 0.41$, $p < 0.001$, $n = 94$. The cross indicates the intersection of mean pain (VAPS scores) \pm SD for both anesthesia pain and procedure pain. Note that the slope of the curve and mean pain are considerably less ($p < 0.001$) than those of the conventional syringe (Figure 3).

syringe (Table 2). This degree of pain is certainly a major reason why pediatric patients do not tolerate local anesthesia with lidocaine well, and if prolonged or multiple sites are necessary, general anesthesia is often employed (4,14,39–49). The problem of pain associated with administration of local anesthesia has been long recognized by clinicians, and considerable attention has been directed at proper syringe and needle technique to reduce this effect (8–11). Most clinicians simply accept that administration of lidocaine will cause pain, and do not alter their individual anesthesia administration technique. However, the problem of pain during administration of local anesthesia is so considerable that transdermal approaches, needleless administration, and computer-assisted injection techniques are areas of intense research and clinical study (7,12–19). A less painful drug delivery device such as the RPD is another logical approach.

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 (Figures 1, 2). The two plungers are mechanically linked in an opposing fashion, 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. This permits the index and middle fingers to remain in one position during both aspiration and injection while the thumb needs to move in only a horizontal plane to the alternative plunger 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.

Unlike a conventional syringe or the three-ring control syringe, the RPD does not become longer during the aspiration phase, which further enhances control of the needle (20,21). These characteristics of stable finger positioning, the exclusive use of the flexor musculature, and the absence of device lengthening during aspiration create a powerful and finely controlled one-handed procedure device (21–25). Recently, clinical trials have demonstrated that the RPD is less painful and is superior to the traditional syringe for arthrocentesis, corticosteroid joint injections, suction needle biopsy, intra-articular hyaluronate injections, and other syringe and needle aspiration procedures performed by physicians (21–25). A one-handed syringe device with enhanced control characteristics where the free hand can be used for device stabilization, anatomic localization, wound exposure, patient restraint, and other necessary tasks is an obvious advantage for emergency procedures, including anesthesia.

LIMITATIONS

Many of the inherent limitations of this type of research were overcome by randomizing patients into intervention groups. However, patients and assessors of outcome could not be blinded and this could have introduced a bias to the results. Furthermore, this study was performed in one Emergency Department setting with a single group of emergency physicians. Further study in other settings must be done to determine whether our results can be more widely generalized.

CONCLUSIONS

The RPD significantly reduces the time required to administer local anesthesia, reduces patient pain during anesthesia, increases operator satisfaction with syringe performance, and significantly reduces the pain of the post-anesthesia procedure. Further study of this new class of reciprocating procedure devices will determine specific indications and future applications of this new technology to the broad field of emergency medicine.

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