

Randomized Controlled Trial of Sonographic Guided Intra-articular Injections for Knee Osteoarthritis

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ABSTRACT

Purpose: This randomized controlled trial (RCT) evaluated whether sonographic needle guidance influences the clinical outcome of intra-articular injections for osteoarthritis (OA) of the knee.

Method: 92 OA knees indicated for intra-articular triamcinolone injection were randomized (NCT 00651625) to injection by conventional palpation-guided anatomic injection or sonographic image-guided injection enhanced with a one-handed control aspiration-injection syringe (the Reciprocating Procedure Device, RPD®). A one needle, two-syringe technique was used for all patients. The first syringe was used to introduce the needle, anesthetize and dilate the intra-articular space with lidocaine, and aspirate any effusion. After attempting to confirm intra-articular placement, syringe exchange was performed and triamcinolone acetate was injected through the in-dwelling intra-articular needle. Baseline pain, procedural pain and pain at outcome (2-weeks and 6- months) were measured on a Visual Analogue Scale (VAS).

Results: Pain associated with the aspiration-injection procedural pain was reduced by 47.7% (p<0.001). At the 2-week post-injection, sonographic guidance provided incremental outcome improvement over palpation-guided injections consisting of: 41.7% reduction in VAS pain (p<0.025); and an increase in asymptomatic patients (67.4% Sonographic vs. 32.6% Palpation, p<0.03). Follow-up at 6 months found no difference in mean VAS pain scores, but a 1.1 month prolongation of therapeutic effect based on patient-reported duration of benefit (p< 0.01).

Conclusion: Sonographic needle guidance used in conjunction with control syringe technology appears to improve the short-term outcome of intra-articular knee injections. These data are relevant to clinical practice and when designing trials for new intra-articular therapies for osteoarthritis of the knee.

Background

- Literature reports suggest that intra-articular injection of the knee is frequently misdirected outside the intra-articular space, even for experienced clinicians.
- Image-directed procedures and the reciprocating procedure device (RPD®) have been reported to improve needle placement, but their effect on treatment outcome remains an open question. Studies are necessary to determine whether these safety technologies, which add costs, can meaningfully improve important aspects of treatment outcome.

Methods

- 92 subjects with OA of the knee were randomized to either palpation-guided with a conventional syringe OR sonographic guidance with RPD® syringe.
- The RPD®-US technique:
 - Manual palpation, marking of the superficial joint anatomy, and marking the target with a surgical marker.
 - Interrogation of the target joint with ultrasound to define the anatomy, determine the presence of effusion, and confirm the optimal anatomic approach.
 - Removal of gel from the needle entry point, antisepsis with chlorhexidine.
 - Hard copy of image of in-situ needle for documentation
- Use of the one-needle two-syringe technique, where one needle is used and:
 - one syringe is used to introduce the needle, local anesthesia, and aspiration of the joint if necessary.
 - a second syringe is used to inject the treatment, in this case triamcinolone acetamide
 - Real-time ultrasound guidance.
- 0-10 cm Visual Analogue Pain Scales (VAS) during the procedure, and at 2 weeks and 6 months.

RESULTS

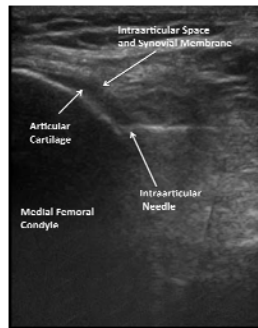


Figure 1. Large Volume Aspiration with the RPD® Safety Syringe. The smaller plunger of this 25 ml RPD® syringe is being depressed gently with the thumb for aspiration - unlike a traditional syringe - resulting in enhanced control and easy aspiration. To inject, the large plunger is depressed.



Figure 2. Ultrasound Image Guidance with RPD® Safety Syringe. Using the bent knee lateral approach, the US probe is held medially parallel to the needle shaft and the target is the medial femoral condyle (see US figure) and is best performed with a 21 gauge 2 inch needle with lidocaine and a syringe exchange.

Figure 3



Figures 3 and 4: Using US-guidance and the RPD® syringe, a needle is introduced into the intra-articular space of the knee, and the space is dilated by injecting lidocaine, thereby anesthetizing the joint and confirming intra-articular positioning (Figure 3). Triamcinolone acetate can then be injected into the intra-articular space with assurance, shown here by the Doppler-enhanced visualization of the triamcinolone being delivered to the joint space (Figure 4).

Figure 4

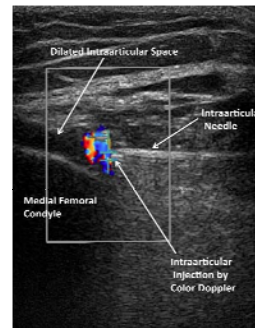


Table 1. VAS Pain During Procedure

	Palpation-guided	Sonographic-guided RPD®	% Difference	95% CI	p-value
# Subjects	46	46			
Baseline Pain 10 cm VAS	7.8± 1.8 cm	7.5± 2.0 cm	-3.8%	-14%, 6.3%	0.45
Procedural Pain 10 cm VAS	4.4± 2.9cm	2.3± 2.4cm	-47.7%	-73%, -23%	0.0003
% Significant Procedural Pain (VAS≥5 cm)	41%	17%	-57.9%	-98.1%, -12.8%	0.009

Table 2. VAS Outcome and Responder Rates

	Palpation-guided	Sonographic-guided RPD®	% Difference	95% CI	p-value
# Subjects	46	46			
Pain @ 2 wks	2.4± 2.1	1.4± 2.1	-41.7%	-78, -5	0.025
Asymptomatic patients at 2 weeks*	32.6%	67.4%	+107%	+44, +157	0.0004
Pain 6 months	6.3 ± 2.9	6.3 ± 2.6	0%	-18, -18	1.0
Asymptomatic patients at 6 months*	5/46	5/46	0%	-125, +125	0.87
Pt-reported benefit duration	3.1 ± 2.1 months	4.2 ± 1.9 months	+ 36%	+8.7, +62	0.01
Time to next procedure	6.0 ± 2.8 months	7.1 ± 3.2 months	+18.3	-2.5,+39.2	0.08

* Asymptomatic patients defined as VAS ≤ 2.0

Summary of Results

- US-RPD Reduced Procedural Pain by 47.7% (p < 0.001).
- US-RPD Reduced Outcome Pain at 2 weeks by 41.7% (p < 0.025)
- US-RPD Increased Responder Rates by 107% (p < 0.001).
- US-RPD Significantly Increased Therapeutic Duration (p<0.01)

Conclusions:

- US-guided injections with the RPD® syringe provide improved therapeutic outcomes, reduce non-responders rates, and prolong the therapeutic effect of intra-articular injections.
- These data suggest that the effectiveness of intra-articular therapies are limited therapeutically by inadequate needle control and inaccurate and/or ineffective intra-articular drug delivery.
- The fact that ultrasound image guidance and accurate needle control improve the outcomes of intra-articular injections may be of importance when planning future clinical trials of intra-articular therapies.