

# Needle-Free Jet Injection of Local Anesthetic Predicts Lower Pain Scores for Clubfoot Tenotomy Compared to Topical Anesthetic: A Randomized Control Trial

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## INTRODUCTION:

Topical anesthetic cream for in-office clubfoot tenotomy may be preferred to avoid a painful needle stick in an awake infant. There are also concerns that swelling after local anesthetic injection may prevent palpation of the Achilles tendon with inability to safely perform the tenotomy in an awake infant. The purpose of this study was to evaluate the pain response during tenotomy with topical anesthetic cream compared to needle-free injection of local anesthetic with a jet injector.

## METHODS:

Clubfoot Tenotomy Trial (ClubTT): a prospective, multicenter, double-blind randomized control trial enrolled idiopathic clubfoot patients aged  $\leq 6$  weeks. After serial Ponseti casting, patients with residual equinus were randomized to receive local anesthesia for tenotomy: TOPICAL (4% liposomal lidocaine cream with saline jet injection) or JET (placebo cream with 1% lidocaine jet injection). Participants, care providers, and investigators were blinded to randomization groups. Pain was assessed with the Faces, Legs, Activity, Consolability (FLACC) score, categorized as mild (1-3), moderate (4-6), or severe (7-10). Patient temperament was assessed. During the casting and tenotomy visits, FLACC score, heart rate, and oxygen saturation were collected at specific time points.

## RESULTS:

After exclusions, 94 were randomized: TOPICAL (n=49) and JET (n=45). There were no differences in demographics (ethnicity, race, sex, age) or clinical factors (Dimeglio score, laterality, number of casts, temperament). At tenotomy, mean FLACC scores were lower in the JET injection group (8.4 vs 9.5,  $p=0.039$ ) and a smaller proportion of JET injection group patients had FLACC scores in the severe category (73.3% vs 95.9%,  $p=0.002$ ). An ordinal regression model demonstrated that the JET injection group was more likely to have a lower FLACC score at tenotomy (OR 14.3,  $p=0.004$ ), controlling for age, sex, laterality, study site, Dimeglio, and average baseline FLACC scores. There were no adverse events.

## DISCUSSION AND CONCLUSION:

Local anesthesia via topical cream resulted in severe pain during tenotomy in >95% patients. Jet injection of local anesthetic increased the odds of a lower FLACC score by 14X and decreased the incidence of severe pain. Providers should consider a jet injection system for local anesthesia to reduce the risk of severe pain during in-office clubfoot tenotomy.

