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# A Prospective, Randomized, Double-Blind, Placebo Controlled Trial to Evaluate 4% Liposomal Lidocaine Cream on Pain and Anxiety During Venipuncture in Pediatric Patients Who Present to the ED

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# A Prospective, Randomized, Double-Blind, Placebo Controlled Trial to Evaluate 4% Liposomal Lidocaine Cream on Pain and Anxiety During Venipuncture in Pediatric Patients who Present to the Emergency Department

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## Study Objectives:

Pain reduction or elimination in pediatric patients is a national standard of care. Most hospitals apply a topical anesthetic to potential venipuncture locations to alleviate pain and anticipatory anxiety of the procedure. Unfortunately, available topical anesthetics formulations require 30-60 minutes application dwell time prior to venipuncture and vasoconstrictive effects may differ between creams. Liposomal lidocaine cream has been shown to reduce or eliminate pain after dwelling for 30 minutes. However, in children who present with an acute illness, 30 minutes can be an unacceptable wait time. The effectiveness of applying liposomal lidocaine cream under occlusion for 15 minutes in urgent venipuncture has never been studied. The objective was to determine if a liposomal lidocaine cream that dwells for 15 minutes, versus the recommended 30 minutes, decreases pain and anxiety in pediatric patients.

## Methods:

A prospective, randomized, double blind, placebo control study design was used in which subjects were randomly assigned to receive either liposomal lidocaine or placebo cream. The study population included pediatric patients ages 5-18 years old, meeting the study criteria and who presented to one site of a multi-site, academic, community Emergency Department (ED). Once subjects were consented and enrolled in the study, the liposomal lidocaine or a placebo cream was applied for 15 minutes under occlusion. A 100mm Visual Analogue Scale (VAS) was used to measure both perceived and observed level of parental and patient anxiety before, during and after the venipuncture. A 6-point validated FACES pain scale and heart rate (as an indirect measure) was used to rate patient level of pain during venipuncture. History of previous venipuncture, difficulty of venipuncture, and uniformity of topical ointment application were documented.



## Results:

A total of 120 subjects were enrolled in the study, resulting in 57 subjects enrolled into each group, and six subjects who were treatment failures. Baseline characteristics did not differ ( $p > 0.05$ ) between children in the study and placebo groups. However, one interesting difference that approached significance was that children in the study group had experienced more venipuncture needlesticks in the past two years ( $M = 6.8, SD = 15.0$ ) than the placebo group ( $M = 2.8, SD = 3.7, t(63) = -1.97, p = 0.054$ ). The relative risk of a painful venipuncture stick was 1.2, or 20% greater (95% confidence interval 0.77 to 1.90) in the placebo group than the study group. There were no significant differences in mean levels of patient, parent or observer ratings of procedural anxiety, or patient heart rate or the patient's mean rating of venipuncture pain between the study and placebo groups ( $p > 0.05$ ). There were no significant differences in mean pain ratings ( $p > 0.05$ ) when data were grouped by patient age ranges ( $< 7$  years, 7-11 years, 12-18 years).

## Conclusions:

Application of liposomal lidocaine prior to venipuncture did show a small reduction in relative risk of patient perceived venipuncture pain, but did not reduce the mean level of patient perceived pain during venipuncture. No differences in mean levels of procedural anxiety rating, patient heart rate, or mean venipuncture pain rating was observed between study groups.