OBJ LIMITED
Active transdermal drug delivery

Trial Summary| Tetracaine

Effect of Dermaportation on Time of Onset of Anaesthesia after Tetracaine Gel in Healthy Human Volunteers

Objective

Topical anaesthetics are widely used to relieve distress in children and adults during venepuncture and minor dermatological procedures. However, the speed of onset of anaesthesia is relatively slow i.e. between 60 min for lidocaine and prilocaine (Emla®) and 30 min for tetracaine formulations (Ametop®). The present clinical pilot study investigates the efficacy of Dermaportation to hasten the therapeutic effect of a commercially available tetracaine gel.

Method

Healthy adult volunteers (5 females, 2 males) participated in the study (ethical approval granted by the HREC of Curtin University). The study was carried out under the Guidelines of the National Health and Medical Research Council of Australia.

A 200 mg aliquot of Ametop® gel (4% tetracaine; Smith and Nephew) was applied to each of four arm sites, 2 per each upper arm. Two active and two passive Dermaportation coils (OBJ Limited, Perth, Australia) randomised over the arms. The distribution was double-blind. Dermaportation was applied for 20 min. The coils were then removed, the sites wiped clean with tissue paper and functional testing initiated.

Touch sensitivity was measured with an electronic von Frey device (Somedic). Three testing sessions were conducted, i.e. at 10 min before Ametop administration (pre-test), at 0, and 20 min post Ametop® administration. The volunteers were instructed to close their eyes during the trials.

The *von Frey* probe was held perpendicular to the upper arm, and gently pushed against the skin at each administration site. The subjects were instructed to verbally acknowledge whenever they noticed the touch with the von Frey probe. The force measured at the touch detection point was registered electronically. For each application site, three successive trials per session were conducted and averaged.

Result

The touch sensitivity before the start of the administration of tetracaine was similar for the passive and active treatment sites. Twenty minutes after the end of the Ametop® administration, Dermaportation treated sites were less sensitive to the mechanical von Frey stimulation than the passively treated sites (Frey 20min post: $F_{1,16} = 5.85$; $p < 0.05$). Figure 1 shows that the touch threshold increases with each session, demonstrating successful anaesthesia.

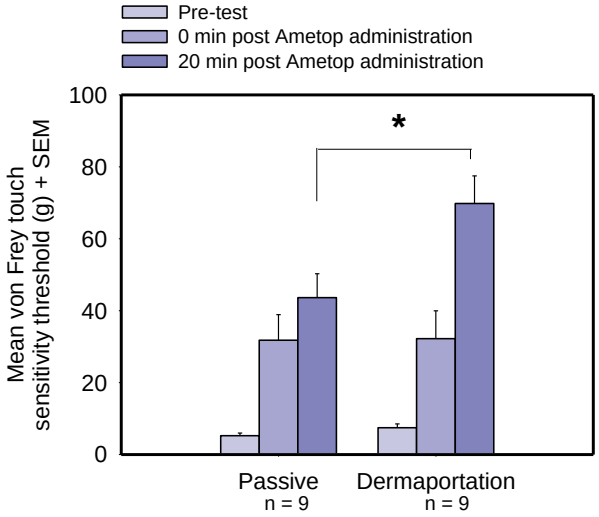

Figure 1: *Effects of passive or Dermaportation induced transdermal delivery of tetracaine (Ametop®) on touch sensitivity thresholds measured via an electronic von Frey system, before, immediately after, and 20 min post topical administration. The topical administration time was 20 min.*

Summary

Ametop® gel is a commercially available topical local anaesthetic product, with a recommended application period of at least 30 min prior to any procedure. In the current study we did not investigate skin puncture, due to ethical constraints, but focused on touch sensitivity thresholds for measuring differences between passively and Dermaportation delivered Ametop® within subjects. The results of measuring the threshold force at which the volunteers noticed a tactile stimulus (von Frey) showed that, even with a small subject number and one seventh of the standard dose, the Dermaportation treated sites were more numb than the passively treated sites 20 min post Ametop® administration.

Dermaportation reduced the time of onset of topical anaesthesia in healthy human volunteers.

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