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A RANDOMIZED CONTROLLED TRIAL COMPARING TREATMENT REGIMENS FOR ACUTE PAIN FOR TOPICAL OLEORESIN CAPSAICIN (PEPPER SPRAY) EXPOSURE IN ADULT VOLUNTEERS

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ABSTRACT

Objective. Several topical therapies have been proposed to treat acute pain from exposure to oleoresin capsaicin (OC). The purpose of this study was to determine the most beneficial topical treatment for relieving contact dermatitis pain caused by OC exposure. **Methods.** We performed a single-blind, randomized human experiment evaluating the effectiveness of five different regimens for the treatment of topical facial OC exposure. Forty-nine volunteer, adult law enforcement trainees were exposed to OC during a routine training exercise and were randomized to one of five treatment groups (aluminum hydroxide–magnesium hydroxide [Maalox], 2% lidocaine gel, baby shampoo, milk, or water). After initial self-decontamination with water, subjects rated their pain using a 10-cm visual analog scale (VAS) and then every 10 minutes, for a total of 60 minutes. Subjects were blinded to previous VAS recordings. A two-factor analysis of variance (ANOVA) (treatment, time) with repeated measures on one factor (time) was performed using a 1.3-cm difference as clinically significant. **Results.** Forty-four men and five women, with an average age of 24 years, participated in the study. There was a significant difference in pain with respect to time ($p < 0.001$), but no significant interaction between time and treatment ($p > 0.05$). There was no significant difference in pain between treatment groups ($p > 0.05$). **Conclusion.** In this study, there was no significant difference in pain relief provided by five different treatment regimens. Time after exposure appeared to be the best predictor for decrease in pain.

PREHOSPITAL EMERGENCY CARE 2008;12:432–437

INTRODUCTION

Background

Oleoresin capsaicin (OC), or pepper spray, is a common form of self-defense in our society and has been used by law enforcement agencies since the 1970s.¹ Every year, numerous people are exposed to this toxin both purposefully and inadvertently. Law enforcement agencies

routinely utilize OC to control and subdue combative, dangerous, or aggressive suspects. Emergency medical providers are often required to assess and treat personnel who have been exposed to OC. The most common OC exposure is sprayed contact to the facial epithelia, exposed mucous membranes, and eyes.

Clinical effects of OC include inflammation and irritation of exposed mucous membranes and epithelia. Exposure to the mucous membranes of the mouth, nasal passages, and gastrointestinal system results in an immediate burning sensation. Airway exposure leads to an acute inflammatory process resulting in mucus production, severe coughing and sneezing, irritation, and a burning sensation in the nose and mouth, which may lead to bronchospasm, especially in individuals with underlying pulmonary disease.^{2,3} Ocular exposure induces severe lacrimation, involuntary closure of the eyelids, temporary blindness, and possibly corneal abrasions.⁴ Finally, dermal exposure produces redness and pain in exposed areas, which may persist for several hours.⁵

Despite the widespread use of OC, there are no widely accepted antidotes for OC exposure. Currently, the prevailing treatment is purely symptomatic and entails copious water irrigation. However, many topical remedies have been suggested in the literature, including vegetable oil,^{6,7} corticosteroids,^{6,7} rubbing alcohol,^{7,8} baking soda paste,⁷ vinegar,^{7–9} milk,^{10,11} lidocaine gel,^{7,8,12} and antacids.^{13,14} Also, unpublished anecdotal experience from a military law enforcement academy points to improvements in pain after applying baby shampoo to affected areas.¹⁵ The efficacy of these various treatments remains primarily anecdotal, with little research comparing these methods. To our knowledge, no studies have compared the effectiveness of proposed modalities in the literature for acute pain from OC exposure (milk, lidocaine gel, aluminum hydroxide–magnesium hydroxide [Maalox], baby shampoo, and water). Further information about the most efficacious treatment would be helpful to alleviate undue pain and suffering for patients presenting after exposure.

The purpose of this study was to determine if there is a beneficial treatment for contact dermatitis caused by OC (pepper spray) exposure beyond the standard of water decontamination. Our research hypothesis was that there would be differences in the amount of pain relief over time provided by antacid, milk, lidocaine

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gel, and baby shampoo when compared with tap water in adult volunteers who were exposed to facial OC in a simulated “real-world” exposure.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, single-blind, randomized human experiment evaluating the efficacy of five different regimens for the treatment of topical facial capsaicin exposure. This study protocol received approval from the Brooke Army Medical Center’s institutional review board. This study was performed at a law enforcement academy in August 2005.

Selection of Participants

Fifty volunteers were recruited from two consecutive classes of military law enforcement trainees. These subjects are required to undergo routine topical facial capsaicin exposure as part of their law enforcement training. Subjects consented to participate during the pepper spray educational lectures on the day prior to exposure. Enrollment in the study was purely voluntary, and refusal to participate had no effect on final grades or graduation requirements. An ombudsman aided in recruitment and answered questions to avoid any concerns of coercion from instructors or researchers. Exclusion criteria included age <18 years or >60 years, opioid or other analgesic medication use within eight hours before the study, pregnancy, or a prior known allergy to capsaicin, lidocaine, Maalox, baby shampoo, or milk. Subjects were also excluded if open wounds, blisters, or dermatologic disorders of the face or neck were present.

Interventions

The law enforcement training includes an educational session about pepper spray effects, followed by exposure on the following day. Law enforcement trainees are exposed to pepper spray and then undergo 2 minutes of situational training that involves exertion and confrontation of aggressive individuals. OC exposure occurred under guidelines set by the training academy and included 2-second sprays from a pepper spray canister at a predetermined distance from sprayer to subject. Subjects were subjected to a second spray if they closed their eyes before initiation of the initial spray. OC was delivered by a commercially available standard-duty aerosol spray canister widely used by law enforcement agencies nationwide (Cap-stun 5.5% OC spray, Zarc International, Minonk, IL). This aerosol contains 5.5% OC (0.92% capsaicinoids), 64% isopropyl alcohol carrier agent, and 30.5% isobutene/propane propellant.

After the exposure and 2 minutes of training, subjects were allowed to self-decontaminate using tap water and then were immediately randomized to one of five treatment groups (antacid [Maalox—magnesium hydroxide-aluminum hydroxide], lidocaine gel [2% lidocaine gel], milk [grade A, pasteurized, homogenized, whole milk], baby shampoo [Johnson & Johnson’s “No More Tears” baby shampoo], or tap water [control]). All treatments were stored and administered at the ambient temperature. Treatment groups consisted of soaked cloths in the substance, and the subjects were allowed to put the cloth over their face or use it as a wipe for painful areas. Subjects were instructed to close their eyes prior to placing the washcloth on their face and were allowed to obtain freshly soaked cloths at their discretion. Trainees refusing participation in the study were treated with tap water, as is standard for this academy training exercise. Additional treatment after completion of the study period was left to the judgment of supervising physicians. Pain/discomfort was measured using the visual analog scale (VAS).

Data Collection and Processing

Demographic data (weight, height, age, gender, allergies, and ethnicity) were recorded during the pepper spray educational lectures on the preceding day when the subjects consented to participate. Pain/discomfort ratings utilizing the VAS were obtained by two emergency medicine physicians and one resident initially and every 10 minutes, for a total of 60 minutes. Subjects were not shown prior pain/discomfort rating data when completing each VAS. At the conclusion of 60 minutes, a final pain/discomfort rating was obtained.

Outcome Measures

The primary outcome measure was a change in pain as measured by the VAS.

Data Analysis

In this study, the independent variables were treatment, of which there were five (antacid, lidocaine gel, milk, baby shampoo, and tap water), and time (before exposure, and every 10 minutes for one hour during treatment). The dependent variable was pain measured on a VAS. The null hypothesis was that there would be no difference in pain with respect to treatment. The alternative hypothesis was that one or more treatments would reduce pain. We estimated the mean \pm standard deviation (SD) or range of the VAS pain scores to be 8.5 ± 0.5 based on the recollection of a sample of ten to 20 subjects. We used a two-factor analysis of variance (ANOVA) (treatment, time) with repeated measures on one factor (time), followed by one-tailed t-tests corrected for multiple comparisons.

Sample Size Estimation/Power Analysis

Ten post hoc comparisons are appropriate for this design, so we made a maximum Bonferroni correction of $p = 0.05 / 10 = 0.005$. We performed the power analysis on the post hoc test. A 1.3-cm improvement was chosen by the authors as clinically significant based on previous literature,^{16,17} as well as on clinical estimation. This is an effect size of 1.3 with a $SD \pm 0.5$. We used a look-up table based on employing the method of Kraemer and Thiemann¹⁸ to obtain an initial estimate of the sample size, which was confirmed with 1,000 iterations of a Monte Carlo simulation until the power was between 80% and 85% with a level of confidence of 95%. According to this method, nine subjects per group (45 total) were needed to detect a 2-SD or 1.0-cm difference.

RESULTS

Fifty subjects initially volunteered, 44 men and six women. One woman was excluded subsequent to enrollment after she remembered a possible allergy to antacid. This resulted in a total of 49 subjects for whom data were collected. The average age of our subjects was 23.6 years (range 18–36 years). The average weight of our subjects was 174.5 lb (range 115–281 lb). There was a significant difference in pain with respect to time ($p < 0.001$) in all groups (Fig. 1). But all the treatment groups behaved similarly with respect to time. There was no significant difference in pain between the treatment groups ($p > 0.05$). Ninety-five percent confidence intervals (CIs) are included as error bars on outlying data points in Figure 1 to give the reader an appreciation of the graphical representation of significance. Individual responses by treatment group are depicted in Figures 2 through 6.

Limitations and Future Studies

This study has some limitations worth discussion. First, we allowed subjects to self-decontaminate with tap water before applying any study treatment. We feel this method is most likely to mimic the actions taken in true exposures, but acknowledge that this initial decontamination may have confounded larger differences between potential treatments. During study development, it seemed unreasonable to apply potential treatments without first attempting a minimal decontamination maneuver to remove the irritant. Despite brief decontamination with water, all subjects had severe pain at enrollment.

Although participants were blinded to their treatment groups, it is possible that participants could deduce which treatment they were provided based on the properties (color, texture, viscosity) of the substance. In discussions with subjects after completion of the study, we were surprised that most subjects were unsure of which treatment they had been given.

Some of our subjects exposed to OC described ocular pain as significant. Our study provided only tap water during self-decontamination as treatment for ocular pain. It is possible that untreated ocular pain may have masked small differences in the treatment of dermal pain that our study was not powered to detect. Our contamination methods were chosen to mimic a real-world exposure to capsaicin and to best test these commonly used treatment strategies. Since real exposures most frequently include both dermal and ocular exposures, the concurrent eye pain is a fact of exposure. If the benefits of the tested treatments are so easily masked by concurrent ocular pain, any potential benefit they provide is unlikely to be clinically relevant for treatment in real exposures. The treatment of ocular pain associated with capsaicin exposure should be a focus of future studies.

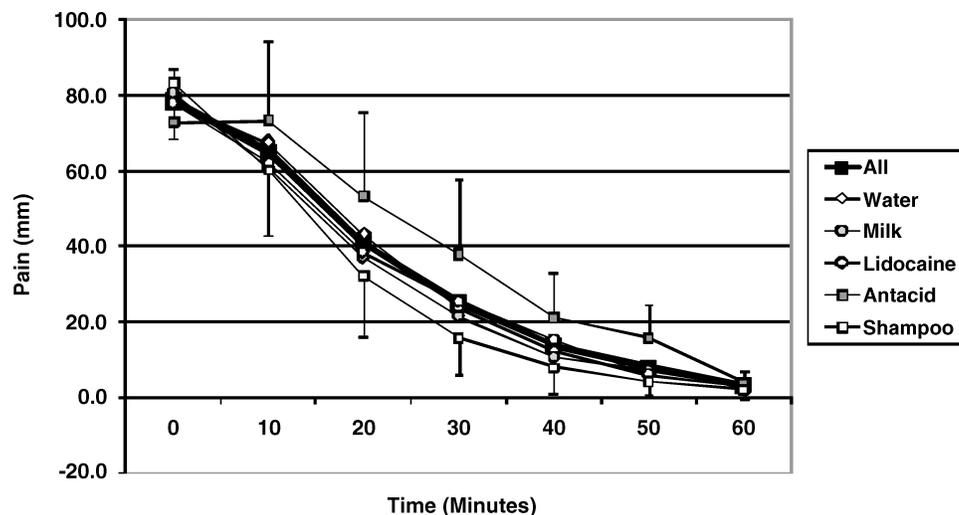


FIGURE 1. Average recorded pain on the visual analog scale (mm) over time for each respective treatment group. Ninety-five percent confidence intervals are included as error bars on outlying data points to give the reader an appreciation of the graphical representation of significance.

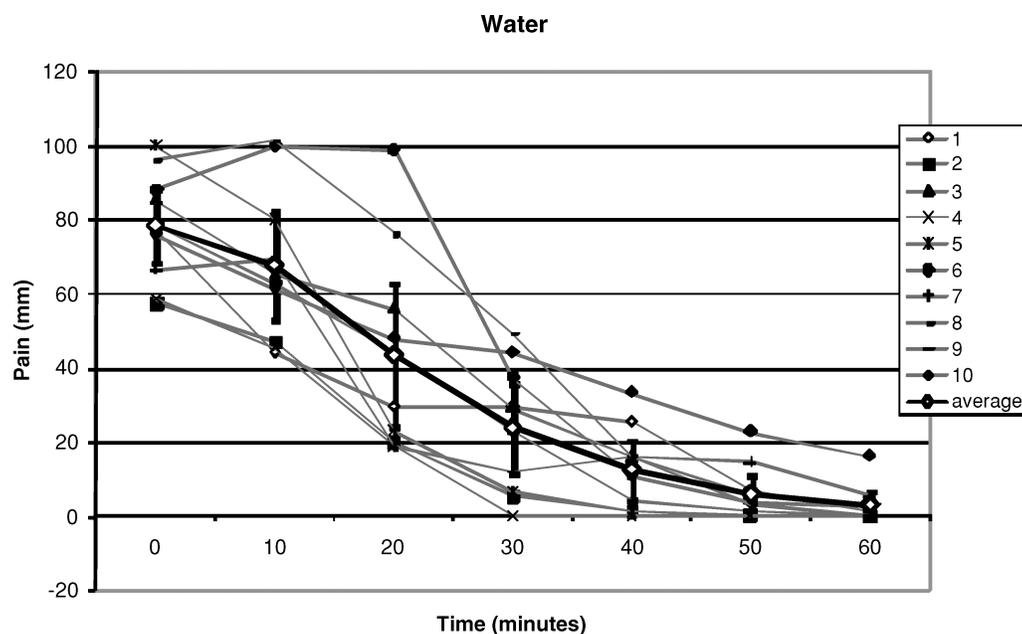


FIGURE 2. Recorded pain (mm) on the visual analog scale over time for each respective patient receiving water as treatment. The black line is the mean trendline.

Tolerance to the effects of capsaicin can develop, and could affect results in studies subjecting participants to multiple exposures. The subjects in this study had no previous exposure to capsaicin sprays, and thus differences due to tolerance are unlikely to have affected our results.

Late in the data collection, we found that our VAS line was 7.5 cm, because of a photocopying error. All study subjects were evaluated utilizing this shorter VAS line. Because the protocol was near complete, and all previous subjects had been evaluated using

this shorter VAS line, we chose to continue using the same length VAS line to maintain consistency. A ratio was used to convert our recorded results to those of a 10-cm scale. Although this shorter VAS may have caused the calculated 10-cm scale pain scores to be off by 1–2 mm, it is unlikely that the variation in VAS masked a clinically significant difference between treatments.

Finally, in retrospect, comparing the numeric rating scale with the VAS may have been beneficial because pain was so severe at the beginning of the study.

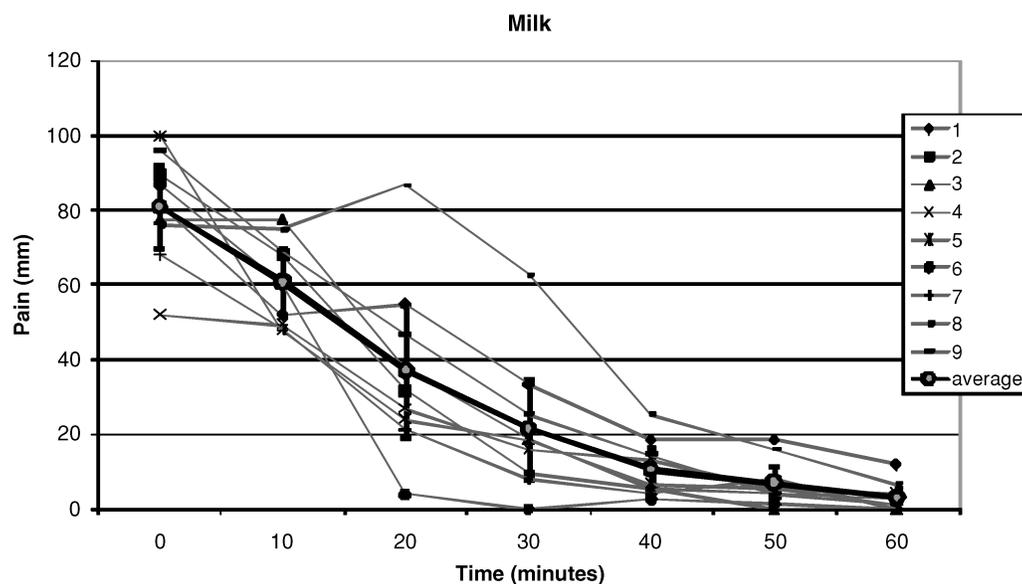


FIGURE 3. Recorded pain (mm) on the visual analog scale over time for each respective patient receiving milk as treatment. The black line is the mean trendline.

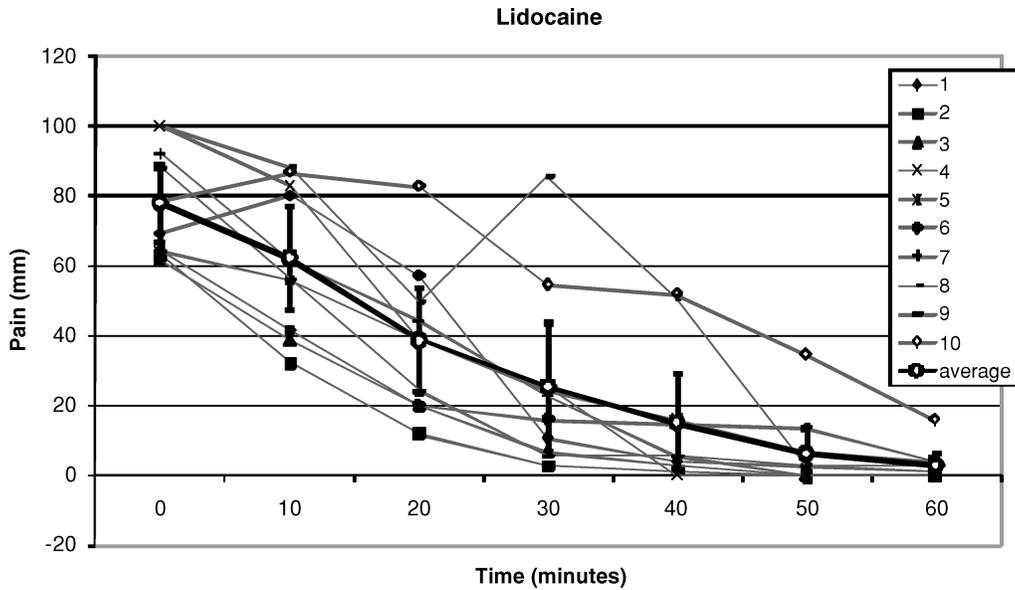


FIGURE 4. Recorded pain on the visual analog scale (mm) over time for each respective patient receiving lidocaine as treatment. The black line is the mean trendline.

DISCUSSION

To our knowledge, this is the first prospective randomized clinical trial that evaluates various proposed treatments for dermal exposure to OC. Oleoresin capsaicin (OC) is a thick, dark reddish-brown liquid concentrate of all the active ingredients of the *Capsicum* plant and is obtained by extracting dried, ripe fruit of *Capsicum* chili peppers. Capsaicin has profound irritant potency. The minimum tolerated exposure of OC is less than that of more classic tear gases, CS (o-chlorobenzylidene) and

CN (chloroacetophenone). Although CS is more potent, an equivalent dose of OC is less toxic than that of the classic tear gases.¹⁹ The increased potency and better safety profile of OC have made it the preferred incapacitating agent of civilians and law enforcement alike. Emergency physicians are frequently called upon to treat the painful effects of OC spray. The results of this study will help to guide the emergency physician to the best potential treatment options for these dermal exposures.

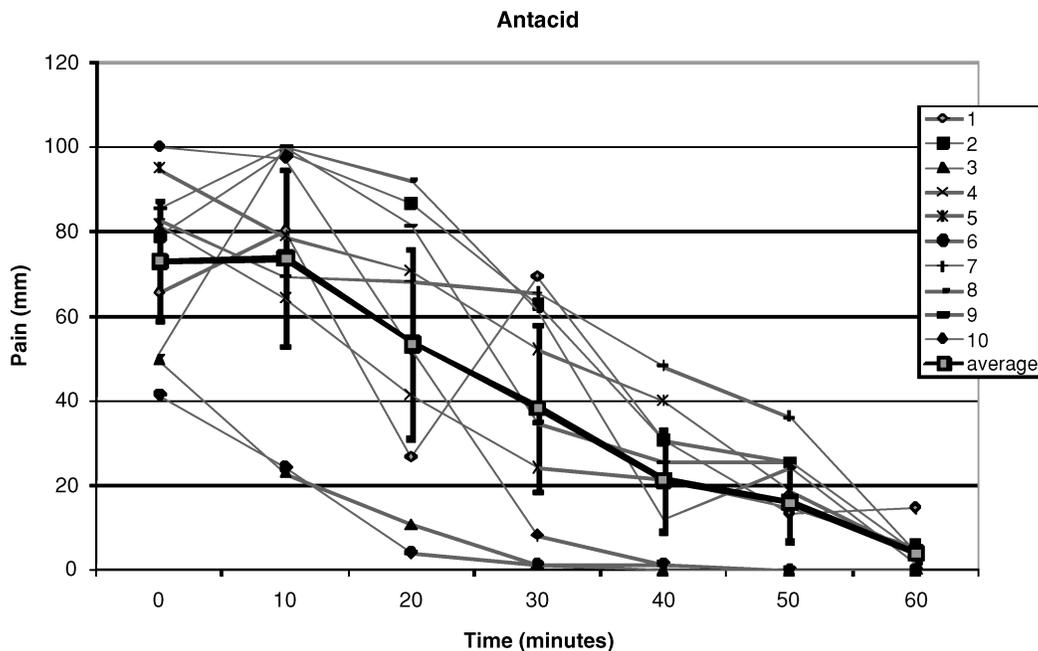


FIGURE 5. Recorded pain on the visual analog scale (mm) over time for each respective patient receiving antacid as treatment. The black line is the mean trendline.

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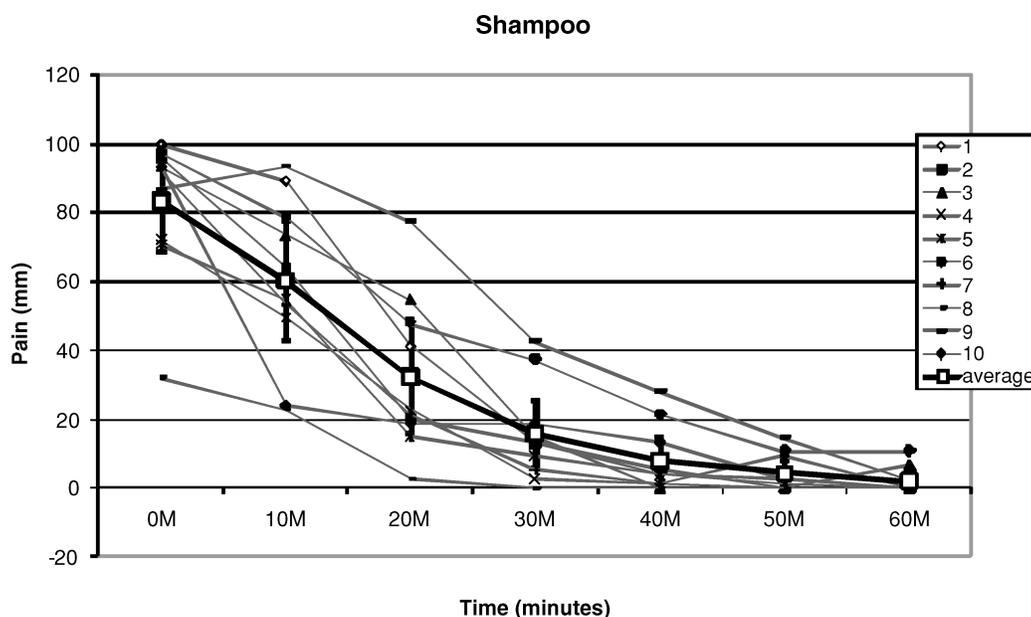


FIGURE 6. Recorded pain on the visual analog scale (mm) over time for each respective patient receiving shampoo as treatment. The black line is the mean trendline.

Interestingly, a number of our subjects volunteered that the best pain relief was obtained by minimizing stimulation to the exposed area. Although streaming air from fans and application of fresh treatment towels to the affected area provided temporary relief, some subjects described recurrent severe pain with the cessation of these stimuli. This recurrent pain after stimulation led some subjects to prefer minimizing stimulus to the affected areas, stating that this method ultimately decreased cumulative pain. This observation that a single stimulus (rubbing or touching affected areas) caused an exacerbation of the pain sensation, while constant repetitive stimulation (streaming air from fans) seemed to momentarily decrease pain, could provide an area for future research.

Despite several small studies in the literature proposing anecdotal treatments for topical OC (pepper spray) exposure, our results revealed no significant difference in pain between our treatment groups (water, milk, Maalox, baby shampoo, and viscous lidocaine). All treatment groups behaved similarly with respect to time, hinting that time is the most important factor in the resolution of pain from topical OC exposure. Based on the results of our study, we cannot recommend use of these potential antidotes. Copious water decontamination and, possibly, oral analgesics should remain the preferred method of pain control after topical OC exposure.

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