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SUPPORTIVE CLINICAL REFERENCES, ABSTRACTS AND JOURNAL ARTICLES

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Eplasty. 2018 Feb 7;18: e6. eCollection 2018.

Vapocoolant Anesthesia for Cosmetic Facial Rejuvenation Injections: A Randomized, Prospective, Split-Face Trial

Zeiderman MR, Kelishadi SS, Tutela JP, Rao A, Chowdhry S, Brooks RM[1], Wilhelmi BJ

Background: Minimally invasive cosmetic procedures are the most commonly performed aesthetic techniques by plastic surgeons. Patients are interested in a pain-free experience. Surgeons desire patient satisfaction and time-efficient utilization of office staff and resources. Clinical evidence exists for use of vapocoolant technology to reduce pain associated with IV cannulation in the pediatric population and in hemodialysis patients. Applying vapocoolant technology to facial rejuvenation is a novel approach to decrease pain associated with neurotoxin or filler injection.

Methods: A prospective randomized study was conducted testing 15 subjects receiving filler injections and another 15 patients receiving neurotoxin injections using a split-face model. The vapocoolant spray tested consisted of a 95/5 ratio of 1,1,1,3,3 Pentafluoropropane and 1,1,1,2 Tetrafluoroethane. Within each group, subjects received in random order either the injectable corresponding to their group alone as a control or the injectable used in conjunction with the vapocoolant spray. Therefore, each patient randomly received injection (filler or neurotoxin) alone versus injection (filler or neurotoxin) plus vapocoolant on an equivalent half of his or her face. An independent examiner recorded from each patient on a scale of 1-10 perceived pain for injection alone versus injection plus vapocoolant spray. Male and female English speaking/literate volunteers aged 22-65 whom were either naive to or had prior exposure to neurotoxin or filler injections were studied. Subjects enrolled in other clinical studies or having consumed any narcotic medications within 48 hours of participation were excluded.

Results: Vapocoolant spray at the time of cosmetic facial injections lead to a 59% decreased percent change in perceived pain score with neurotoxin injections (range 0-100% change) and 64% decreased percent change in perceived pain score with filler injections (range 0-100% change). These results were statistically significant. See attached histograms.

Conclusion: Vapocoolant spray reduces pain associated with facial rejuvenation procedure.

PMCID: PMC5809626
PMID: 29484087

PMID: 29484087 Pain Management Nursing, 2017 Nov 16

Patient and Health Care Provider Responses from a Prospective, Double-Blind, Randomized Controlled Trial Comparing Vapocoolant Spray versus Placebo Spray in Adults Undergoing Venipuncture in the Emergency Department.

Tracy Barbour, Sharon O'Keefe, RN, BSN, Sharon E. Mace, MD, FACEP, FAAP

Abstract:
Painful medical procedures are common. Topical anesthetics are easily applied, rapid onset, inexpensive, and avoid injection pain and needlestick injury. The aims of this study, using patient and health care provider questionnaires, were to answer the following questions: (1) Does vapocoolant spray decrease venipuncture pain? (2) Would patients be satisfied with and use a vapocoolant spray in the future? (3) Would providers be satisfied with and use a vapocoolant spray in the future? Adults (18-80 years) in a hospital emergency department (ED) were randomly assigned to sterile water placebo spray (S) (N = 50) or vapocoolant spray (V) (N = 50) before venipuncture. Questionnaires were completed by patients undergoing venipuncture (N = 100) and the health care providers (N = 100) who performed the venipuncture (total questionnaires = 200) as part of a prospective, double-blind, randomized controlled trial comparing the efficacy and safety of vapocoolant spray compared with placebo spray in patients undergoing venipuncture in the ED. Patient and venipuncture variables were not significantly different for the two groups (S vs. V). Responses to the questionnaires were significantly different for the S versus V groups for both the patients and the health care providers. Patient questionnaires: Did you have less pain with spray? S 14%, V 76% ($p < .001$). Compared with previous blood draws, the spray was much more painful/more painful: S 10%, V 6%; same: S 76%, V 16%; less painful/much less painful: S 14%, V 78% ($p < .001$). How satisfied were you with the spray? Satisfied/very satisfied: S 20%, V 74% ($p < .001$). Would you use this spray in future? Yes S 20%, V 80% ($p < .001$). Provider results: The patient had less pain with the use of the spray: S 14%, V 78% ($p < .001$). How satisfied were you with the use of the spray? Satisfied/very satisfied: S 12%, V 82% ($p < .001$). Would you use this spray in the future? Yes S 24%, V 84% ($p < .001$). The use of a vapocoolant spray in adult ED patients undergoing venipuncture significantly decreased venipuncture pain, was associated with high patient and provider satisfaction, and both patients and providers would use a vapocoolant spray in the future for venipuncture and other painful procedures.

DOI: http://dx.doi.org/10.1016/j.pmn.2017.09.006

Scandinavian Journal of Pain, October 2017, Volume 17, 8-15

Prospective, double blind, randomized, controlled trial comparing vapocoolant spray versus placebo spray in adults undergoing intravenous cannulation

Mace, Sharon E.

HIGHLIGHTS:

· Vapocoolant spray significantly decreased the pain of intravenous cannulation.
· There were no complications or adverse events.
· Minor side effects that occurred in a few patients resolved quickly.
· No visible skin abnormalities were present 5 - 10 min after spray application.

Abstract:

OBJECTIVES: Painful diagnostic and therapeutic procedures are common in the health care setting. Eliminating, or at least, minimizing the pain associated with various procedures should be a priority. Although there are many benefits of providing local/topical anesthesia prior to performing painful procedures, ranging from greater patient/family satisfaction to increased procedural success rates; local/topical anesthetics are frequently not used. Reasons include the need for a needlestick to administer local anesthetics such as lidocaine and the long onset for topical anesthetics. Vapocoolants eliminate the risks associated with needlesticks, avoids the tissue distortion with intradermal local anesthetics, eliminates needlestick pain, have a quick almost instantaneous onset, are easy to apply, require no skills or devices to apply, are convenient, and inexpensive. The aims of this study were to ascertain if peripheral intravenous (PIV) cannulation pain would be significantly decreased by using a vapocoolant (V) versus sterile water placebo (S) spray, as determined by a reduction of at least ≥1.8 points on numerical rating scale (NRS) after vapocoolant versus placebo spray, the side effects and incidence of side effects from a vapocoolant spray; and whether there were any long term visible skin abnormalities associated with the use of a vapocoolant spray.

RESULTS: Patient demographics (age, gender, race), comorbidity, medications, and vital signs; and PIV procedure variables (e.g., IV needle size, location, number of IV attempts, type and experience of healthcare provider performing the IV) were not significantly different for the two groups. Median (interquartile range) PIV pain was 4 (2, 7) (S) and 2 (0, 4) (V) ($P < 0.001$). Skin checklist revealed minimal erythema: S 0% ($N = 0/150$), V: 2.7% (4/150), which resolved within 5 min, and no blanching, skin pigmentation changes, itching, edema, or ecchymosis. Photographs at 5–10 min revealed no visible skin changes in any patient ($N = 300$), vapocoolant ($N = 150$) or placebo groups ($N = 150$). Complaints ($N = 26$) were coolness/cold feeling S 8.7% ($N = 13$), V 7.3% ($N = 11$), coolness/numbness S 0% ($N = 0$), V 0.7% ($N = 1$), and burning S 0.7% ($N = 1$), V 0 (0%). Patient acceptance of the vapocoolant spray was high: 82% (123/150) of the patients stated they would use the spray in the future, while only 40.7% (61/150) of the placebo group stated they would use the placebo spray in the future.

CONCLUSIONS AND IMPLICATIONS: Vapocoolant spray significantly decreased peripheral intravenous cannulation pain in adults versus placebo spray and was well tolerated with minor adverse effects that resolved quickly. There were no significant differences in vital signs and no visible skin changes documented by photographs taken within 5–10 min postspray/PIV.

https://www.ncbi.nlm.nih.gov/pubmed/28850378
CDC - VACCINE ADMINISTRATION *General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)*
Revised April 2017 (Page 90)

Methods for Alleviating Discomfort and Pain Associated with Vaccination

Comfort measures, such as distraction (e.g., playing music or pretending to blow away the pain), cooling of the injection site(s), topical analgesia, ingestion of sweet liquids, breastfeeding, swaddling, and slow, lateral swaying can help infants or children cope with the discomfort associated with vaccination (*35-37*). Pretreatment (30-60 minutes before injection) with a 5% topical lidocaine-prilocaine emulsion might decrease the pain of vaccination by causing superficial anesthesia (*38,39*). Evidence indicates that this cream does not interfere with the immune response to MMR (*40*). Topical lidocaine-prilocaine emulsion should not be used on infants aged <12 months who are receiving treatment with methemoglobin-inducing agents (e.g., acetaminophen, amyl nitrate, nitroprusside, dapsone) because of the possible development of methemoglobinemia (*41*). Use of a topical refrigerant (vapocoolant) spray immediately before vaccination can reduce the short-term pain associated with injections and can be as effective as lidocaine-prilocaine cream (*42*). Evidence does not support use of antipyretics before or at the time of vaccination; however, they can be used for the treatment of fever and local discomfort that might occur following vaccination. Studies of children with previous febrile seizures have not demonstrated antipyretics to be effective in the prevention of febrile seizures (*43*).

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html

Practical Dermatology March 2017

A Prospective, Blinded Placebo-Controlled Evaluation of Pain Control Using A Vapocoolant Spray During Minor Office Procedures

Duraes EFR, Kortyka S, Moore F, Walzman JT, Zins JE, Mlynek K

Background: Vapocoolant sprays (skin refrigerants) are topical anesthetics that are known to efficiently reduce pain in a variety of clinical settings. This study investigated the efficacy of a skin refrigerant (Gebauer's Pain Ease®) in pain reduction during acrochordon removal in the office setting in a prospective, randomized patient blinded fashion.

Methods: A total of 34 healthy patients with bilateral acrochordons were recruited to assess the differences in pain level between skin refrigerant spray and placebo spray. Only patients with mirror image lesions were included. Lesions were alternatively sprayed with either the vapocoolant or placebo spray. Patients were randomized and blinded to the type of spray they received. They were asked to grade the pain level on a validated pain scale after each excision. Wilcoxon signed rank test was used to compare the pain level reported.

Results: Patients had a mean age of 60±13 years; 14(41.2%) were males and 20(58.8%) were females. The mean pain for Groups 1 (Vapocoolant) was 1.4 points (95% CI:-2.2, - 0.7) lower than for Group 2 (Control). Significantly lower pain was observed in Group 1 (p=0.001). In the sensitivity analysis, results from the paired t-test showed similar findings (p=0.001).

Conclusion: Vapocoolant sprays are convenient and effective tools to alleviate pain during acrochordon removal. Ease of administration, rapid anesthesia onset and low cost make the spray an excellent option for minor surgical procedures in outpatient setting.

http://practicaldermatology.com/2017/03/evaluating-a-vapocoolant-spray-call-for-case-reports/

Am J Emerg Med. 2016 May;34(5):845-50. doi: 10.1016/j.ajem.2016.01.039. Epub 2016 Feb 13.

Topical ethyl chloride to reduce pain associated with venous catheterization: a randomized crossover trial.

Fossum K[1], Love SL[1], April MD[2].

Author information

Abstract

OBJECTIVE: To compare pain associated with venous catheterization after administration of topical ethyl chloride vs placebo among emergency department health care providers.

METHODS: We conducted a randomized, double-blind, placebo-controlled, crossover trial among a convenience sample of health care provider volunteers in a tertiary care urban emergency department. We randomly allocated subjects to initial treatment (ethyl chloride vs sterile water aerosol spray) and catheterization site (left or right antecubital fossa). After venous catheterization placement and discontinuation, subjects underwent a 5-minute washout period. All subjects then underwent venous catheterization in the contralateral antecubital fossa after administration of the alternative agent. We measured all outcomes after discontinuation of the second catheter. The primary outcome was difference in pain verbal numeric rating scale score (0-10) between the 2 agents. Secondary outcomes included preferred agent (binary) and future willingness to use agent on patients (5-point Likert scale).

RESULTS: Thirty-eight health care providers were recruited; all completed the study. Median pain verbal numeric rating scale scores were 4 (interquartile range, 2-5) for placebo vs 2 (1-4) for ethyl chloride. The effect size for pain reduction with ethyl chloride compared with placebo was 2 (95% confidence interval, 0.5-2; P = .001). Most subjects (68.4%) preferred ethyl chloride to placebo. Five-point Likert scale scores measuring willingness to use preferred product on future patients were higher by 2 (95% confidence interval, 1-3) among subjects preferring ethyl chloride vs placebo.

CONCLUSIONS: We found that topical ethyl chloride yields a greater reduction in pain associated with venous catheterization compared with topical placebo.

TRIAL REGISTRATION: ClinicalTrials.gov NCT02499965.

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PMID: 26971823 DOI: 10.1016/j.ajem.2016.01.039

Indexed for MEDLINE

Am J Emerg Med. 2016 May;34(5):798-804. doi: 10.1016/j.ajem.2016.01.002. Epub 2016 Jan 7.

Prospective, randomized, double-blind controlled trial comparing vapocoolant spray vs placebo spray in adults undergoing venipuncture.

Mace SE[1].

Author information

Abstract

INTRODUCTION: Topical anesthetics are used to decrease procedural pain such as venipuncture. Advantages of vapocoolants include rapid onset, ease of application, low cost, and lack of associated pain of injection and other needlestick-related risks. We hypothesized that the pain of venipuncture would be reduced by at least 1.8 points on a 10-point numerical rating scale after application of a vapocoolant compared with placebo.

METHODS: We conducted a prospective, randomized, double-blind controlled trial of vapocoolant vs placebo spray in 100 adults (ages 18-80) requiring venipuncture in a hospital emergency department or observation unit. The primary efficacy outcome was the difference in pain scores immediately after venipuncture, measured on a 10-point verbal numeric rating scale from 0 (none) to worst (10). Safety outcomes included local adverse effects (edema, erythema, blanching) and changes in vital signs (VS).

RESULTS: Patient characteristics and venipuncture procedure were not significantly different for the 2 groups. The median (interquartile range) pain of venipuncture was 3 (1.2-5) in the placebo group and 1 (0-3) in the vapocoolant group, $P < .001$. Skin checklist revealed the following: vapocoolant-minimal blanching 4%, minimal erythema 18% which resolved within 5 minutes; placebo-no visible skin changes. Photographs at 5 to 10 minutes revealed no visible skin changes in any patient. There were 2 complaints: "very wet and cold on skin" (placebo) and "felt burning on skin" (vapocoolant).

CONCLUSION: The vapocoolant significantly decreased venipuncture pain in adults compared with placebo and was well tolerated with minor adverse effects that resolved quickly. There were no significant differences in VS and no visible skin changes documented at the site by photographs taken within 5 to 10 minutes postspray/venipuncture.

TRIAL REGISTRATION: ClinicalTrials.gov NCT01712776.

PMID: 26979261 DOI: 10.1016/j.ajem.2016.01.002

Skin Sterility After Application of a Vapocoolant Spray Part 2.

Mlynek K[1], Lyahn H, Richards B, Schleicher W, Bassiri Gharb B, Procop G, Tuohy M, Zins J.

Abstract

INTRODUCTION:

Refrigerant sprays have been used for pain relief at the time of minor office procedures. However, their sterility remains in question. This study investigates the microbiologic effect of this vapocoolant when sprayed after 70 % isopropyl alcohol skin preparation.

MATERIALS AND METHODS:

In 50 healthy volunteers, three skin culture samples were collected: Group 1 prior to alcohol application; Group 2 after preparation with alcohol, and Group 3 after preparation with alcohol followed with vapocoolant spray. Samples were cultured in a blinded fashion and analyzed after 5 days of incubation. Gram staining was performed when cultures were positive.

RESULTS:

Bacterial growth was found in 98 % of samples prior to any skin preparation. This was reduced to 54 % after alcohol use (Group 2). Spraying with the skin refrigerant further reduced bacterial growth to 46 % (Group 3). The results showed a significant reduction in the number of positive bacterial cultures following skin preparation with alcohol and when alcohol prep was followed by vapocoolant spray ($p < 0.001$) compared to initial cultures. No statistical difference was observed between Groups 2 and 3 ($p = 0.74$).

CONCLUSIONS:

The use of the vapocoolant spray does not compromise the sterility of the skin following alcohol prep. Both 70 % isopropyl alcohol antiseptic preparation and skin preparation followed by vapocoolant spray significantly reduce skin colonization when compared to unprepared skin ($p < 0.001$).

PMID:] https://www.ncbi.nlm.nih.gov/pubmed/26044395

Summer; 23(2):71-6.

Microcirculatory effect of topical vapocoolants.

Galdyn I[1], Swanson E[2], Gordon C[2], Kwiecien G[3], Bena J[4], Siemionow M[5], Zins J[3].

Abstract

BACKGROUND:

Vapocoolant sprays are commonly used to minimize pain following minor interventions such as venipuncture, shave biopsy or needle insertion. Although these sprays have been widely used in clinical practice, little is known about their effect on microcirculation or cutaneous blood flow.

OBJECTIVE:

To evaluate the real-time effect of a topical vapocoolant using a well-established, rat cremaster muscle microcirculatory model, allowing direct measurement of changes in vessel diameter, capillary density and leukocyte behaviour.

METHODS:

Fifty rats were divided into a control and four experimental groups: group 1: 4 s spray with vapocoolant at 18 cm distance; group 2: 10 s spray at 18 cm distance; group 3: 4 s spray at 8 cm distance; and group 4: 10 s spray at 8 cm distance. Vessel diameters, capillary density and leukocyte behaviour were monitored for 1 h thereafter. Muscle was harvested for immunohistochemistry analysis of proangiogenic markers (vascular endothelial growth factor and von Willebrand factor), leukocyte behaviour markers (E-selectin, vascular cell adhesion molecule, intercellular adhesion molecule), pimonidazole-hypoxia staining and ApopTag (Millipore, USA) staining for apoptosis. Gene expression for inflammatory markers (interleukin [IL]-1β, IL-2, IL-4, IL-6, IL-10, tumour necrosis factor-alpha and interferon-gamma) was evaluated using polymerase chain reaction and myeloperoxidase assay for inflammation was performed.

RESULTS:

The use of refrigerant spray decreased vessel diameter and capillary density initially, although none of these decreases were statistically significant. Polymerase chain reaction showed no significant changes. The myeloperoxidase assay showed statistically significant increase in myeloperoxidase activity in groups 2, 3 and 4. Immunohistochemistry was negative for angiogenic and proinflammatory markers.

CONCLUSIONS:

The lack of statistically significant changes in vessel diameter and inflammatory markers corroborated the safety on microcirculation.

PMID: 26090345 [PubMed] PMCID: PMC4459411 [Available on 2016-06-01]

Oral and Maxillofacial Surgery Cases. June 2015; 1(2):29-39 DOI: http://dx.doi.org/10.1016/j.omsc.2015.05.004

Topical refrigerant spray for pediatric venipuncture for outpatient surgery.

Thomas Schlieve, DDS, MD, Michael Miloro, DMD, MD

Abstract

HIGHLIGHTS:

1. Pediatric anesthesia is a challenge because of poor cooperation from anxious children.
2. The pain of injections in the child may prevent the ability to obtain intravenous access in the outpatient setting and prevent the ability to perform the planned surgical procedure(s).
3. A simple technique using topical refrigerant spray can remove the pain associated with obtaining intravenous access.
4. This simple procedure is well tolerated, and no failures have been observed in the pediatric population undergoing outpatient surgery.
5. This technique should be used by all oral and maxillofacial surgeons.

Anxiety in the pediatric patient population is a problem for outpatient anesthesia because of poor patient compliance during the initiation of the anesthetic technique. A variety of techniques have been used in the outpatient surgery and emergency department settings to improve cooperation in the pediatric age group or those with developmental and cognitive delay. These adjunctive techniques include the growing popularity of the use of eutectic mixtures of local anesthetic cream, nitrous oxide, oral premedication and intramuscular injections. A highly effective technique to use during intravenous catheter insertion is the use of a refrigerant spray, ethyl chloride, to cause a transient local hypoesthesia of the skin at the venipuncture site. This technique is not associated with any significant contraindications or adverse reactions, and it should be considered for both pediatric and adult patients in the oral and maxillofacial surgery practice.

DOI: http://dx.doi.org/10.1016/j.omsc.2015.05.004

Nurs Manage. 2014 Dec; 45(12):21-2. DOI: 10.1097/01.NUMA.0000457135.64967.fd. No abstract available.

So much to gain for nurses who ease the pain.

Papa A.

PMID: 25412376 [PubMed - in process]

Dermatol Surg. 2014 Oct; 40(10):1103-7. DOI: 10.1097/01.DSS.0000452654.29636.56.

Skin sterility after application of a vapocoolant spray.

Schleicher WF[1], Richards BG, Huettner F, Ozturk C, Zuccaro P, Zins JE.

Abstract

BACKGROUND:

Refrigerant sprays have been widely used to reduce pain in the office setting. However, more recently, their use has been limited by both concern regarding flammability and questions of bacterial contamination.

OBJECTIVE:

We investigated the microbiological effect of 1,1,1,3,3 pentafluoropropane and 1,1,1,2-tetrafluoroethane when sprayed after povidone-iodine application in 50 volunteers.

MATERIALS AND METHODS:

In 50 volunteers, 3 cultures were taken (1) at time 0 before antiseptic application, (2) after povidone-iodine topical antiseptic, and (3) after spraying with vapocoolant. Cultures at 3 time intervals were analyzed in a blinded fashion, and Gram stains obtained when cultures were positive.

RESULTS:

Bacterial growth was found in 98% of cultures taken before antiseptic was applied (Group 1), in 28 cultures (56%) after povidone-iodine was applied, and in 24 cultures (48%) after spraying with vapocoolant. There was a statistically significant difference found between Group 1 (no antiseptic) and both Group 2 (after antiseptic but before vapocoolant) and Group 3 (after vapocoolant) ($p < .001$).

CONCLUSION:

The topical antiseptic povidone-iodine significantly reduces skin colonization when compared with unprepared skin ($p < .001$). The vapocoolant 1,1,1,3,3 pentafluoropropane and 1,1,1,2-tetrafluoroethane is sprayed on skin prepared with povidone-iodine; there is no statistically significant increase in bacterial colonization.

PMID: 25229779 [PubMed – indexed for MEDLINE]

https://www.ncbi.nlm.nih.gov/pubmed/25229779

Pediatr Emerg Care. 2013 Jan; 29(1):8-12. DOI: 10.1097/PEC.0b013e31827b214b.

Cryotherapeutic topical analgesics for pediatric intravenous catheter placement: ice versus vapocoolant spray.

Waterhouse MR[1], Liu DR, Wang VJ.

Topical refrigerant spray for pediatric

Abstract

OBJECTIVES:

Intravenous catheter placement is one of the most common sources of pain for children in inpatient settings. We sought to compare the efficacy of 2 cryotherapeutic treatments for this procedure: vapocoolant spray versus topical ice pack.

METHODS:

We prospectively enrolled 95 patients, aged 9 to 18 years, in a pediatric emergency department who required intravenous (IV) catheters as part of their treatment. Subjects were randomly assigned to receive vapocoolant spray or topical ice pack for 3 minutes, before IV catheter placement. Subjects completed visual analog scale (VAS) scores for 3 time points: baseline, pretreatment with ice or spray, and IV insertion. The principal investigator and 2 physicians viewing video recordings of the procedure also completed VAS scores for observed pain levels. Visual analog scale scores were compared using the Wilcoxon rank sum test.

RESULTS:

Although median VAS scores were similar, the change in VAS from baseline was of greater magnitude in the Pain Ease group, indicating that it may be more effective. More subjects in the Pain Ease group (76%) felt their treatment worked well, compared with 49% in the ice group. Physician-assigned VAS scores were lower and less variable than those of subjects. Most IV insertions were successful (83%).

CONCLUSIONS:

Vapocoolant spray may be more effective than ice as an analgesic for IV insertion. Subjects were more satisfied with vapocoolant spray. Neither agent caused a decrease in successful IV insertion rates.

PMID: 23283254 [PubMed – indexed for MEDLINE]

PMCID: PMC3985604

https://www.ncbi.nlm.nih.gov/pubmed/23283254

Journal of Athletic Training, 2012 May; 47(3)Supplement: S-92

Cold Perception, Surface, Subcutaneous and Intramuscular Temperatures Provided by Gebauer's Ethyl Chloride® Topical Vapocoolant Spray.

Martin KM, Merrick MA.

CONTEXT:

Vapocoolant sprays rapidly cool the skin, providing brief local anesthesia for injections and intravenous cannulation as well as management of minor sports injuries and spray & stretch. Temperature effects in humans and effects of commonly used nozzle types, spray distances or spray durations have never been previously reported.

OBJECTIVE:

To describe cold perception and temperature effects of Ethyl Chloride

DESIGN:

Crossover design

SETTING:

Research laboratory

PATIENTS OR OTHER PARTICIPANTS:

Convenience sample of 10 healthy participants (age=21.9 ± 2.4yr)

INTERVENTIONS:

Ethyl Chloride was applied to the proximal forearm in 8 experimental conditions on different days with at least 48hrs between. Conditions were determined using a 2x2x2 repeated measures factorial based on clinical use instructions. Independent variables were: nozzle type (mist & stream), spray duration (4 & 10 sec [or until skin blanching]) and spray distance (7.6cm [3in] & 17.8cm [7 in]). Treatment order was determined using a balanced Latin Square.

MAIN OUTCOME MEASURES:

Ambient and interface temperature were measured using surface thermocouples. Subcutaneous and 1cm intramuscular temperature were measured using sterile implantable thermocouples inserted via cannulae. Temperatures were recorded at 1sec intervals for 500sec. Cold severity perception was measured via 10cm Visual Analog Scale. Data were analyzed via repeated measures MANOVA with Sidak adjusted pairwise comparisons with ˜ = 0.05.

RESULTS:

Ambient (25.5 ± 0.5°C, p=0.52) and baseline temperatures (surface 30.3 ± 1.18°C), SubQ 33.3 ± 0.9°C, IM 33.5 ± 1.1°C, p=0.68) did not differ across conditions. Averaged across conditions, interface

temperature was -8.9 ± 1.3°C, SubQ temperature was 30.7 ± 1.1°C and IM temperature was 32.3 ± 0.6°C. For interface temperature, a nozzle X distance X duration interaction effect occurred (p=0.007). Pairwise comparisons showed (mist, 7in, 4sec) did not produce interface temperatures below freezing (3.05 ± 1.6°C) and was warmer than other conditions (ranged -6.27°C to -14.00°C). A main effect for nozzle (p=0.004) showed that stream (-10.94 ± 0.9°C) was colder than mist (-6.89 ± 0.6°C). A main effect for distance (p=0.007) showed that 3in (-10.55 ± 0.7°C) colder than 7in (-7.27 ± 0.7°C). A main effect for duration (p<0.001) showed 4sec (-6.65 ± 0.9°C) was warmer than spraying until skin blanched (-11.18 ± 0.5°C). Subcutaneously, a single main effect for spray duration (p=0.037) showed 4sec (31.37 ± 0.4°C) was warmer than spraying until the skin blanched (30.12 ± 0.7°C). No effect was observed intramuscularly (p=.912). For cold perception, a main effect for distance (p= 0.015) showed 3in (4.9/10 ± 0.3) feels colder than 7in (3.75/10 ± 0.5). A main effect for duration (p<0.001) showed spraying until the skin blanched (5.34/10 ± 0.4) feels colder than 4sec (3.3/10 ± 0.4).

CONCLUSIONS:

Other than (mist, 7in, 4sec), Ethyl Chloride cools skin to well below freezing without causing skin injury. Temperature changes at SubQ (~-2.8°C) and IM (~-1.1°C) are small, short lived and may not be clinically meaningful.

Journal of Athletic Training, 2012 May; 47(3)Supplement: S-91

Cold Perception, Surface, Subcutaneous and Intramuscular Temperatures Provided by Gebauer's Pain Ease® Topical Vapocoolant Spray.

Merrick MA, Martin KM.

CONTEXT:

Vapocoolant sprays rapidly cool the skin, providing brief local anesthesia for injections and intravenous cannulation as well as management of minor sports injuries and spray & stretch. Temperature effects in humans and effects of commonly used nozzle types, spray distances or spray durations have never been previously reported.

OBJECTIVE:

To describe cold perception and temperature effects of Pain Ease

DESIGN:

Crossover design

SETTING:

Research laboratory

PATIENTS OR OTHER PARTICIPANTS:

Convenience sample of 10 healthy participants (age =22.3 ± 1.9yrs)

INTERVENTIONS:

Pain Ease was applied to the proximal forearm under 8 experimental conditions on different days at least 48hrs apart. Conditions were determined using a 2x2x2 repeated measures factorial based on clinical use instructions. Independent variables were: nozzle type (mist & stream), spray duration (4 & 10 seconds) and spray distance (7.6cm [3 in] & 12.7cm [5 in]). Order of testing was determined using a balanced Latin Square.

MAIN OUTCOME MEASURES:

Ambient and interface temperature were measured using surface thermocouples. Subcutaneous and 1cm intramuscular temperatures were measured using sterile implantable thermocouples inserted via cannulae. Temperatures were recorded at 1sec intervals for 500sec. Cold severity perception was measured via 10cm Visual Analog Scale. Data were analyzed via repeated measures MANOVA with Sidak adjusted pairwise comparisons with α=0.05.

RESULTS:

Ambient (25.9 ± 0.4°C, p=0.79) and baseline temperatures (surface 31.1 ± 0.4°C, SubQ 34.0 ± 0.4°C, IM 34.5 ± 0.4°C, p=0.68) did not differ across conditions. Interface temperature fell to -11.4 ± 1.1°C and

re-warmed within 4-5 minutes. SubQ temperature fell to 28.1 ± 1.0°C. IM temperature fell to 33.1 ± 0.5°C. A main effect was observed for spray duration on cold perception (4sec = 3.9/10, 10sec = 5.9/10, $p<0.001$) and on lowest temperature at all 3 depths (surface 4sec = -9.4 ± 0.7°C, 10sec = 13.4 ± 0.4°C, $p=0.001$; SubQ 4sec = 30.5 ± 0.6°C, 10sec = 25.7 ± 0.5°C, $p<0.001$; IM 4sec = 33.5 ± .3°C, 10sec = 32.7 ± 0.3°C, $p=0.05$). A main effect for nozzle was observed on cold perception (stream = 4.1/10, mist = 5.7/10, $p=0.003$) and on lowest temperature at only surface (stream = -7.5 ± 0.6°C, mist = -15.4 ± 0.7°C, $p<0.001$) and SubQ depths (stream = 29.3 ± 0.5°C, mist = 26.9 ± 0.6°C, $p=0.03$). All 3 subjects receiving mist nozzle/5in/10sec had adverse skin reactions consistent with mild frostbite and the condition was terminated. Temperatures for it were -17.9 ± 1.4°C.

CONCLUSIONS:

Pain Ease cools skin to well below freezing regardless of application technique. This does not produce skin injury except in a single condition (mist, 5in, 10sec). Temperature changes at SubQ (~-5.9°C) and IM (~ -1.4°C) are small, short lived and may not be clinically meaningful. Mist nozzle produces much colder temperatures and feels colder regardless of spray distance or duration. Spraying for 10sec feels colder and is colder than 4sec. Spraying for 10 seconds with the mist nozzle should not be used clinically.

J Bone Joint Surg Am. 2012 Jan 18; 94(2):118-20. DOI: 10.2106/JBJS.K.00229.

Skin sterility after application of ethyl chloride spray.

Polishchuk D[1], Gehrmann R, Tan V.

Abstract

BACKGROUND:

Ethyl chloride topical anesthetic spray is labeled as nonsterile, yet it is widely used during injection procedures performed in an outpatient setting. The purpose of this study was to investigate the sterility of ethyl chloride topical anesthetic spray applied before an injection. Our a priori hypothesis was that application of the spray after the skin has been prepared would not alter the sterility of the injection site.

METHODS:

We conducted a prospective, blinded, controlled study to assess the effect of ethyl chloride spray on skin sterility. Fifteen healthy adult subjects (age, twenty-three to sixty-one years) were prepared for mock injections into both shoulders and both knees, although no injection was actually performed. Three culture samples were obtained from each site on the skin: one before skin preparation with isopropyl alcohol, one after skin preparation and before application of ethyl chloride, and one after ethyl chloride had been sprayed on the site. In addition, the sterility of the ethyl chloride was tested directly by inoculating cultures with spray from the bottles.

RESULTS:

Growth occurred in 70% of the samples obtained before skin preparation, 3% of the samples obtained after skin preparation but before application of ethyl chloride, and 5% of the samples obtained after the injection site had been sprayed with ethyl chloride. The percentage of positive cultures did not increase significantly after application of ethyl chloride ($p = 0.65$). Spraying of ethyl chloride directly on agar plates resulted in growth on 13% of these plates compared with 11% of the control plates; this difference was also not significant ($p = 0.80$).

CONCLUSIONS:

Although ethyl chloride spray is not sterile, its application did not alter the sterility of the injection sites in the shoulder and knee.

PMID: 22257997 [PubMed – indexed for MEDLINE]

https://www.ncbi.nlm.nih.gov/pubmed/22257997

Int J Med Sci. 2011; 8(7):623-7. Epub 2011 Oct 12.

Vapocoolant spray vs lidocaine/prilocaine cream for reducing the pain of venipuncture in hemodialysis patients: a randomized, placebo-controlled, crossover study.

Çelik G[1], Özbek O, Yılmaz M, Duman I, Özbek S, Apiliogullari S.

Abstract

OBJECTIVE:

Patients undergoing hemodialysis are repeatedly exposed to stress and pain from approximately 300 punctures per year to their arteriovenous fistula. This study was designed to measure pain associated with venepuncture during AVF cannulation and to compare the effectiveness of ethyl chloride vapocoolant spray, topical eutectic mixture of local anesthetics (EMLA) cream and placebo in controlling pain caused by venepuncture of arteriovenous fistula patients undergoing chronic hemodialysis.

METHODS:

This randomized, placebo-controlled, crossover study, included 41 patients undergoing conventional hemodialysis three times a week. First intervention was conducted as baseline pain assessment (control). In the three consecutive dialysis sessions, every patient randomly received 1) ethyl chloride vapocoolant spray, 2) EMLA, or 3) placebo cream before venepuncture. Pain perception was recorded by patients immediately after cannulation on a 0-100 mm visual analogue scale (VAS). $P<0.05$ was considered as significant.

RESULTS:

VAS scores presented a marked inter-individual variation during venepuncture. EMLA application resulted in significantly lower total pain scores compared to control and all other interventions ($p<0.05$). No patient experienced severe pain with EMLA or vapocoolant. The patients reported less moderate and severe pain with EMLA, and vapocoolant spray compared to control and placebo interventions. Moderate and severe pain scores were similar between EMLA and vapocoolant spray ($p>0.05$).

CONCLUSION:

Venipuncture for AVF cannulation causes mild to moderate pain in hemodialysis patients. Although local application of EMLA is more effective than in preventing venepuncture pain, ethyl chloride vapocoolant is as effective as EMLA for preventing mild to moderate puncture pain in patients undergoing hemodialysis.

PMID: 22022215 [PubMed – indexed for MEDLINE] PMCID: PMC3198258

J Plast Reconstr Aesthet Surg. 2010 Sep; 63(9):1443-6. DOI: 10.1016/j.bjps.2009.07.045. Epub 2009 Aug 27.

Botulinum toxin injection pain relief using a topical anesthetic skin refrigerant.

Engel SJ[1], Afifi AM, Zins JE.

Abstract

BACKGROUND:

This study was performed to determine if pretreatment application of a topical anesthetic skin refrigerant reduced discomfort during botulinum toxin injection.

METHODS:

Twenty patients were assigned to four groups determined by side of the face pretreated with skin refrigerant and side receiving the first injection. On a Visual Analog Scale of 0-10 patients rated discomfort levels after injections in the glabellar complex with and without pretreatment.

RESULTS:

Mean discomfort rating for the pretreated side was 3.1, while the mean discomfort rating for the non-pretreated side was 4.5. Discomfort was not affected by the side sprayed (p=0.33) nor by administering the injection to the sprayed side first (p=0.37). The paired t-test revealed a significant difference between discomfort levels on the pretreated and non-pretreated sides (p=0.038) yielding a 95% confidence interval of (-2.71, -0.09).

CONCLUSIONS:

Topical anesthetic skin refrigerant significantly reduces discomfort in a cost-effective manner for reported by patients undergoing botulinum injections.

PMID: 19716355 [PubMed – indexed for MEDLINE]

Pediatrics. 2009 Aug; 124(2):e203-9. DOI: 10.1542/peds.2007-3466. Epub 2009 Jul 13.

Reducing immunization discomfort in 4- to 6-year-old children: a randomized clinical trial.

Berberich FR[1], Landman Z.

Abstract

OBJECTIVE:

The goal was to test a multifaceted distraction method designed to reduce injection-associated pain in school-aged children.

METHODS:

A clinical trial evaluated 41 children, 4 to 6 years of age, who were given 3 standard prekindergarten immunizations; 21 were assigned randomly to an office routine control group, whereas 20 received a multifaceted, discomfort-reducing intervention. The intervention added verbal suggestions of diminished sensation and a visual focusing activity to the use of ethyl chloride, an established pain-reducing measure. The distraction materials used for the intervention consisted of topical ethyl chloride spray, an improvised, plastic, multipronged arm gripper, and a vibrating instrument descending on the contralateral arm, which provided the focusing task and visual distraction.

RESULTS:

According to patient and parent Faces Pain Scale-Revised scores and nonblinded, video-taped observations scored according to the face-legs-activity-crying-consolability method, the intervention group showed highly significant reductions in pain and discomfort, compared with the control group (patient self-report, $P < .0013$; parent report, $P < .0002$; observation score, $P < .0001$).

CONCLUSION:

This multifaceted distraction intervention reduced significantly the pain and discomfort of childhood immunizations in children 4 to 6 years of age.

PMID: 19596729 [PubMed – indexed for MEDLINE]

J Emerg Nurs. 2009 Jul; 35(4):379-82. DOI: 10.1016/j.jen.2009.02.015. Epub 2009 Apr 14. No abstract available.
http://pediatrics.aappublications.org/content/early/2009/07/13/peds.2007-3466

Reducing pain in pediatric procedures in the emergency department.

Ramponi D[1].

PMID: 19591743 [PubMed – indexed for MEDLINE]
http://www.jenonline.org/article/S0099-1767(09)00121-4/abstract

Ophthal Plast Reconstr Surg. 2009 May-Jun; 25(3):173-7. DOI: 10.1097/IOP.0b013e3181a145ca.

Reduction of pain and anxiety prior to botulinum toxin injections with a new topical anesthetic method.

Weiss RA[1], Lavin PT.

Abstract

PURPOSE:

To evaluate the safety and efficacy of vapocoolants (topical skin refrigerants) to induce skin anesthesia and relieve patient anxiety and pain prior to cosmetic botulinum injections.

METHODS:

A paired (split-face) design was used in 52 patients where patient side (left vs. right) was randomized to receive either vapocoolant spray or no treatment control to test the study hypothesis of better anesthetic efficacy of vapocoolant spray versus no treatment control.
A pain and anxiety questionnaire was administered before, during, and after the injections.

RESULTS:

A considerable percentage of patients either expected pain (35% of naïve patients expected moderate pain) or had experienced pain from their prior treatment (35% had experienced moderate pain). Among naïve patients, 15% had moderate or severe anxiety and among experienced patients, 31% had moderate anxiety. Pain was a factor in delaying the scheduling of cosmetic botulinum toxin treatments in 19% of naïve patients and 31% of experienced patients. Pain reported from actual injections was higher than what was anticipated prior to treatment. There was a significant reduction in pain at injection sites treated with vapocoolant ($p < 0.001$, paired t test). Overall, 67% of all patients reported that the vapocoolant method had less pain than no anesthesia and 54% preferred vapocoolant for their next treatment. Overall, 6% of all patients would schedule their next botulinum toxin treatment sooner if vapocoolant were available.

CONCLUSIONS:

Vapocoolants represent a safe and effective means to reduce patient discomfort and anxiety before and during botulinum toxin type A treatments for glabellar area indications.

PMID: 19454924 [PubMed - indexed for MEDLINE]

CMAJ. 2008 Jul 1;179(1):31-6. DOI: 10.1503/cmaj.070874.

The effect of vapocoolant spray on pain due to intravenous cannulation in children: a randomized controlled trial.

Farion KJ[1], Splinter KL, Newhook K, Gaboury I, Splinter WM.

Abstract

BACKGROUND:

Established noninvasive pharmacologic means of alleviating pain and anxiety in children undergoing intravenous cannulation are time-consuming, and thus impractical for routine use in the emergency department. Vapocoolant sprays provide transient skin anesthesia within seconds of application. We compared the effect of a new vapocoolant spray to placebo on pain due to intravenous cannulation in children.

METHODS:

In this double-blind randomized controlled trial, which we conducted between June 1 and Sept. 12, 2006, 80 children aged 6-12 years received either vapocoolant spray or placebo before cannulation. Children rated their pain using a 100-mm colour visual analogue scale. Secondary outcomes included success rate on first attempt at cannulation and pain ratings by the children's parents, nurses and child life specialists.

RESULTS:

We found a modest but significant reduction in pain with the use of vapocoolant spray (mean difference 19 mm, 95% confidence interval [CI] 6-32 mm; $p < 0.01$). Cannulation on first attempt was more often successful with the use of vapocoolant spray (85.0%) than with placebo (62.5%) (mean difference 22.5%, 95% CI 3.2%-39.9%; $p = 0.03$). The number needed to treat to prevent 1 cannulation failure was 5 (95% CI 3-32). Parents ($p = 0.04$), nurses ($p = 0.01$) and child life specialists ($p < 0.01$) considered the children's pain to be reduced with the use of vapocoolant spray.

INTERPRETATION:

The vapocoolant spray in our study quickly and effectively reduced pain due to intravenous cannulation in children and improved the success rate of cannulation. It is an important option to reduce childhood procedural pain in emergency situations, especially when time precludes traditional interventions.

PMID: 18591524 [PubMed - indexed for MEDLINE] PMCID: PMC3267474

CDC MMWR Recommendations and Reports, December 1, 2006: 55(RR15); 1-48

Recommendations of the Advisory Committee on Immunization Practices (ACIP).

Kroger AT, Atkinson W, Marcuse E, Pickering L.

SUMMARY:

This report is a revision of General Recommendations on Immunization and updates the 2002 statement by the Advisory Committee on Immunization Practices (ACIP) (CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices and the American Academy of Family Physicians. MMWR 2002;51[No. RR-2]). This report is intended to serve as a general reference on vaccines and immunization. The principal changes include 1) expansion of the discussion of vaccination spacing and timing; 2) an increased emphasis on the importance of injection technique/age/body mass in determining appropriate needle length; 3) expansion of the discussion of storage and handling of vaccines, with a table defining the appropriate storage temperature range for inactivated and live vaccines; 4) expansion of the discussion of altered immunocompetence, including new recommendations about use of live-attenuated vaccines with therapeutic monoclonal antibodies; and 5) minor changes to the recommendations about vaccination during pregnancy and vaccination of internationally adopted children, in accordance with new ACIP vaccine-specific recommendations for use of inactivated influenza vaccine and hepatitis B vaccine. The most recent ACIP recommendations for each specific vaccine should be consulted for comprehensive discussion. This report, ACIP recommendations for each vaccine, and other information about vaccination can be accessed at CDC's National Center for Immunization and Respiratory Diseases (proposed) (formerly known as the National Immunization Program) website at: http//:www.cdc.gov/nip

UNDER: VACCINE ADMINISTRATION-
METHODS FOR ALLEVIATING DISCOMFORT AND PAIN ASSOCIATED WITH VACCINATION:

Comfort measures, such as distraction (e.g., playing music or pretending to blow away the pain), ingestion of sweet liquids, breast feeding, cooling of the injection site, and topical or oral analgesia, can help infants or children cope with the discomfort associated with vaccination (*77,78*). Pretreatment (30--60 minutes before injection) with 5% topical lidocaine-prilocaine emulsion can decrease the pain of vaccination by causing superficial anesthesia (*79,80*). Evidence indicates that this cream does not interfere with the immune response to MMR (*81*). Topical lidocaine-prilocaine emulsion should not be used on infants aged <12 months who are receiving treatment with methemoglobin-inducing agents because of the possible development of methemoglobinemia (*82*).

Acetaminophen has been used among children to reduce the discomfort and fever associated with DTP vaccination (*83*). However, acetaminophen can cause formation of methemoglobin and might interact

with lidocaine-prilocaine cream if used concurrently (*82*). Use of a topical refrigerant (vapocoolant) spray immediately before vaccination can reduce the short-term pain associated with injections and can be as effective as lidocaine-prilocaine cream (*84*).

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm

The FDA has determined that each of the Gebauer family of skin refrigerants is substantially equivalent (SE) to each other in terms of efficacy. Therefore, this clinical study is relevant to all Gebauer skin refrigerants.

Ethyl Chloride Reduces Pain and Anxiety Associated with Minor Outpatient Procedures

Victoria Chazin, PhD[1], Gary Pekoe, PhD[1], Sandra Amoils, MD[2], Patrick Nunan, MD[3], Neil Niren, MD[4], Timothy Kremcheck, MD[5], Clyde Henderson, MD[6]

The use of Ethyl Chloride (EC), a vapocoolant intended for topical application, has been shown to be an effective cutaneous anesthetic (Travell, 1955). Ethyl Chloride has been shown to block skin pain associated with needle insertion or minor surgical procedures such as lancing boils or incision and drainage of small abscesses. Ethyl Chloride briefly lowers the skin temperature below 10° C, thus conveying the anesthetic effect. However, Ethyl Chloride is not as widely used in the management of pain associated with these procedures as might be expected. This may be due to a lack of physician focus on pain management in these procedures, or a lack of awareness of the effectiveness of the product.

A recent evaluation (Reis and Holubkov, 1997) examined the effectiveness of Fluori-Methane (a nonflammable alternative to Ethyl Chloride) and a topical cream (EMLA) in reducing immunization pain associated with childhood vaccinations. **The concern was that the lack of pain management contributes to poor compliance with regard to vaccinations and health care appointments kept by this patient population. This study was a follow-up to the 1955 study that showed that Ethyl Chloride provided cutaneous anesthesia in seconds at a fraction of EMLA's cost (Travell, 1955).** The 1997 study indicated that Fluori-Methane is inexpensive and more effective at reducing immediate injection pain when compared with distraction alone, and equally as effective and faster-acting than EMLA cream, and the data suggest that Fluori-Methane could be used to improve patient and parent compliance in this patient group. This conclusion could be extrapolated to the adult population, where lack of compliance could be less documented, whereas the lack of required immunizations in school-aged children is more easily quantifiable.

This evaluation was designed to determine if the use of Ethyl Chloride in adult patients before a procedure would reduce the pain or the anxiety or anticipation of pain associated with injections or minor procedures. If this is true, it should increase patient compliance and augment better doctor/patient relationships in this population. In this evaluation, 98 patients visiting dermatologists, orthopedists, podiatrists, and family medicine physicians filled out a questionnaire after being treated with Ethyl Chloride before an injection or other minor invasive procedure.

METHODS

Subjects

Ninety-eight patients undergoing wart removal, injections, blood draws, punch biopsies or fluid aspirations were identified by nurses at five medical practice offices in the greater Cincinnati and Pittsburgh areas, and asked to participate in this study. Before a patient saw the doctor, they were given a one page sheet of "Instructions For The Patient" which stated that they were being asked to anonymously evaluate a topical vapocoolant spray (Ethyl Chloride, The Gebauer Company, Cleveland, OH) to be used on them before their procedure. The instructions also informed the patient that, after their visit with the doctor, they would be asked to fill out a survey about their experience. Patients received compensation in the form of a gift certificate to a local shopping mall for their time and effort. Every effort was made to not bias the patient about the painblocking effects of the vapocoolant spray prior to receiving the injection or procedure and filling out the survey.

Vapocoolant Procedure

Prior to the use of Ethyl Chloride, the site of the skin procedure to be anesthetized was cleaned as normal before an injection and the procedure syringe made ready. The Ethyl Chloride spray container was held upside down and the spray continuously applied for approximately three to five seconds to the site from a distance of 12 inches. The skin was not to be "frosted." The area was wiped with alcohol one time quickly just as the material evaporated, and followed immediately with the injection or procedure.

Patient Response Measurement

The main focus of the survey was on the actual pain of the procedure plus the patient's fear and anxiety anticipating the procedure. Patients rated the levels of discomfort associated with their procedure, and then were asked how their experience that day compared to what they had anticipated feeling. They were also asked to compare how they felt before the first use of Ethyl Chloride and how they would feel if they knew they were to receive it before a future procedure. Additionally, the survey asked about the patient's experiences related to the known cold- and numbness-inducing aspects of Ethyl Chloride. One section of the survey dealt with patient compliance, and whether or not Ethyl Chloride would play a role in that aspect of the doctor/patient relationship. Patients were also asked if they would specifically ask for their doctor again, and if they would recommend their doctor and Ethyl Chloride to their friends and relatives. Lastly, a section of patient demographics was included in the survey.

Data Analysis

The patient individual responses were tabulated, however, no formal statistical analyses were applied to the data.

RESULTS

Subject Demographics

Age*	15-20 yrs	21-30 yrs	31-40 yrs	41-50 yrs	51-60 yrs	Over 60
	7.1% (7/98)	13.3% (13/98)	25.5% (25/98)	30.6% (30/98)	13.3% (13/98)	9.2%

1 patient did not answer this question

RESULTS continued

Income*	$0-25,000	$25,000-$50,000	Over $50,000
	14.3% (14/98)	29.6% (29/98)	52% (51/98)

*4 patients did not answer this question

Education	High School	College	Grad School
	28.6% (28/98)	53.1% (52/98)	16.3% (16/98)

*2 patients did not answer this question

Gender	Female	Male
	68.4% (67/98)	31.6% (31/98)

Physicians	Family Practice	Orthopedics	Podiatry	Dermatology
	31 patients	27 patients	20 patients	20 patients

Procedures	Injection	Wart/mole Removal	Blood Draw	Biopsy	Other*
	48% (47/98)	9.2% (9/98)	29.6% (29/98)	5.1% (5/98)	8.2% (8/98)

*Other: Fluid aspiration, stitch removal, boil drainage, etc.

Topical Sensations with Ethyl Chloride

Of the 98 patients studied, 100% experienced a feeling of cold from the spray. 25% categorized the cold as pleasant, 5% as unpleasant, and 69% as neither pleasant nor unpleasant. Not one patient categorized the cold as painful. The majority of these patients (68%) experienced the cold for less than 60 seconds, 28% felt it lasted for 1-5 minutes and 4% said it lasted longer than 5 minutes.

Of the 98 patients studied, 58% experienced a feeling of numbness from the spray. 40% categorized the numbness as pleasant, 7% as unpleasant, and 46% as neither pleasant nor unpleasant. Not one patient categorized the numbness as painful. The majority of these patients (53%) experienced the numbness for less than 60 seconds, 35% felt it lasted for 1-5 minutes and 12% said it lasted longer than 5 minutes.

	Pleasant	Painful	Unpleasant	Neither pleasant nor painful
How Cold Felt	25.5% (25/98)	0% (0198)	5.1% (5/98)	69.4% (68/98)
How Numbness Felt*	40.4% (23/57)	0% (0/57)	7% (4/57)	45.6% 926/57)

*4 patients did not answer this question

Duration:

	Less than 60 sec.	1-5 min.	Longer than 5 min.
Felt Cold 100% (98/98)	68.4% (67/98)	27.6% (27/98)	4.1% (4/98)
Felt Numbness 58.2% (57/98)	52.6% (30/57)	35.1% (20/57)	12.3% (7/57)

Pain Response

When asked about the discomfort from the procedure itself, only 7% of patients said that they experienced pain, 45% said they felt no discomfort and the other 40% categorized any discomfort from their procedure as mild to moderate.

As to the procedure, 65% of patients reported that they experienced less pain than expected from their procedure, while 31% reported that their pain was the same as anticipated and only 3% reporting that they experienced more pain than they had anticipated.

Pain Expectation*	Less than expected	Worse than expected	Same as expected
	65.3% (64/98)	3.1% (3/98)	30.6% (30/98)

*1 patient did not answer this question

Of the 98 patients surveyed, 44 had the same procedure performed previously. Thirty-two of these 44 patients did not have the Ethyl Chloride applied on the previous occasion. When asked how today's procedure went as compared to last time without the Ethyl Chloride, almost 60% of patients stated that they experienced less pain this time with the application of Ethyl Chloride. 31% said they experienced no difference while one patient said more pain was experienced this time.

# of patients that had procedure before	#of patients that did not have EC used then
44.9% (44/98)	72.7% (32/44)

The experience of these 32 patients as compared to last time (no EC previously vs. EC this time)*

Experienced less pain than last time	No difference in pain	More pain than last time
59.4% (19/32)	31.3% (10/32)	3.1% (1/32)

*2 patients did not answer this question

Anxiety

The most striking result from the survey was that 79% of patients who expressed anxiety in regards to the pain associated with their procedure, stated that they would have less fear or anxiety the next time knowing that ethyl chloride would be used before the procedure.

72% of patients replied that they would ask for ethyl chloride to be used before their next procedure, and 90% said they would recommend Ethyl Chloride to their friends and family. 67% of patients said they would be more likely to ask for the same doctor knowing that he or she uses Ethyl Chloride and 99% said they would recommend their doctor to their friends and relatives. Almost 90% (87/98) of patients stated that they would not cancel an appointment in the future due to nervousness or anxiety knowing that Ethyl Chloride would be used.

DISCUSSION

Ethyl Chloride has been proposed as an effective topical vapocoolant anesthetic for use in minor office procedures such as injections or other invasive procedures involving the skin. This study was undertaken to examine Ethyl Chloride's effectiveness as a cutaneous anesthetic, as well as its influence on patient anxiety associated with these minor, yet painful, procedures. One concern is that physicians are not sensitive to patients' reactions to the pain associated with these procedures, and thus do not pretreat with a topical anesthetic agent such as Ethyl Chloride. This can lead to a decrease in patient compliance, where patients with an aversion to pain would cancel, not show up, or not schedule office visits in anticipation of the pain. This has been proposed and demonstrated with a very similar product in pediatric patients with regard to vaccinations (Reis & Holubkov, 1997).

The results of this study show that Ethyl Chloride is an effective topical anesthetic, as only 7% of the patients reported feeling any pain associated with the procedures. When this is coupled with the fact that 65% of the patients experienced less pain than expected from their procedure, it appears that Ethyl Chloride was very effective in these patients.

One would expect that Ethyl Chloride, due to its action to lower the skin temperature, would have a chilling as well as numbing effect on the area. The patients were queried as to whether this was an uncomfortable sensation, so it could be determined as to whether Ethyl Chloride, while acting as an effective anesthetic, would produce some untoward sensations that would discourage the patient from asking for it again. The results show that while 100% of the patients identified the spray as cold, and 58% described it as numbing, none of the patients described the product as painful. Only 5% described the cold as unpleasant, while 7% described the numbness as unpleasant. Therefore, Ethyl Chloride can be viewed as creating an insignificant degree of discomfort when applied. This correlates well with the data showing that 90% of the patients would recommend Ethyl Chloride's use to their friends, and 72% would ask for Ethyl Chloride again themselves.

Anxiety or fear about the pain associated with a particular procedure, even one as simple as an injection, can severely interfere with patient compliance. This evaluation showed that 65% of patients experienced less pain than anticipated and 79% of the patients stated that they would be less anxious about the procedure the next time if they knew Ethyl Chloride would be used.

While one cannot state this to predict a 79% increase in future compliance, it does indicate that fear associated with a future procedure has been ameliorated, and one would expect more of these patients to comply in the future. In fact, almost 90% stated that they would not cancel a future appointment due to fear knowing that Ethyl Chloride would be used. It was also shown that of patients who had the same procedure performed previously (but without Ethyl Chloride being applied first), 59% experienced less pain than the last time. **Overall, this evaluation demonstrates that Ethyl Chloride used before minor outpatient procedures, greatly decreases the patient's discomfort related to that procedure and reduces the anxiety associated with that procedure. This most likely will increase patient compliance.**

REFERENCES

Reis, EC and Holubkov, R. Vapocoolant spray is equally effective as EMLA cream in reducing immunization pain in school-aged children. Pediatrics 1997:100, 1-6.

Travell, J. Factors affecting pain of injection. JAMA 1955:158:368-371.

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Drug Saf. 1997 Apr; 16(4):279-87.

A risk-benefit assessment of topical percutaneous local anaesthetics in children.

Russell SC[1], Doyle E.

Abstract

Since its introduction, eutectic lidocaine-prilocaine cream ('EMLA')1 has been found to be an effective topical an aesthetic agent, with a high degree of efficacy, particularly for venepuncture and venous cannulation, and an impressive tolerability profile. Reports of adverse effects are remarkable for their rarity. The only problems that are likely to be encountered are oral ingestion of the cream (which may lead to anaesthesia of the oropharynx and possible toxicity secondary to rapid absorption of local anaesthetic from oral mucous membranes) and methaemoglobinaemia following repeated applications in neonates and infants. Analysis of the risks and benefits associated with its use comes down heavily in favour of the preparation. More recently, a preparation of tetracaine (amethocaine) has been marketed as a gel. Its advantages are a faster onset, and longer duration, of action than 'EMLA'. Although less widely used, it too has an impressive tolerability record. Concerns over the potential for anaphylactic type reactions due to its ester structure have not been realised in clinical practice. Of the other available preparations, lidocaine (lignocaine), applied iontophoretically, is unlikely to become popular because of the complexity of administration. A paste made of tetracaine, epinephrine (adrenaline) and cocaine (TAC) appears to be a far more toxic preparation on theoretical grounds, and this has been borne out in clinical practice; it is not as well tolerated as 'EMLA' or tetracaine gel. Ethyl chloride, although not a local anaesthetic, can safely provide cutaneous analgesia in children in circumstances when it is impractical to wait for a local anaesthetic preparation to take effect.

PMID: 9113495 [PubMed - indexed for MEDLINE]

Pediatrics. 1997 Dec; 100(6):E5.

Vapocoolant spray is equally effective as EMLA cream in reducing immunization pain in school-aged children.

Cohen Reis E[1], Holubkov R.

Abstract

BACKGROUND:

Untreated immunization pain causes undue distress and contributes to under immunization through physician, and possibly parental, resistance to multiple simultaneous injections.

OBJECTIVE:

To compare the efficacies of two pain management methods in reducing immediate immunization injection pain and distress in school-aged children.

DESIGN:

A randomized, controlled clinical trial of eutectic mixture of local anesthetics (EMLA) cream and vapocoolant spray.

PATIENTS:

Children aged 4 to 6 years and scheduled to receive diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) during health supervision visits.

INTERVENTIONS:

Enrolled children were randomized to one of three treatment groups: 1) EMLA cream + distraction; 2) vapocoolant spray + distraction; or 3) distraction alone (control). The specific pharmacologic pain control interventions consisted of EMLA cream (2.5% lidocaine, 2.5% prilocaine [Astra Pharmaceutical Products, Inc., Westborough, MA] $15. 00/patient; applied 60 minutes before injection) and vapocoolant spray (Fluori-Methane [Gebauer Company, Cleveland, OH] $0. 50/patient; applied via spray-saturated cotton ball for 15 seconds immediately before injection).

MAIN OUTCOME MEASURES:

The blinded investigator (BI) measured (by edited videotape) cry duration and the number of pain behaviors using the Observational Scale of Behavioral Distress. Pain visual analog scales (linear and faces scales) were completed by the child, parent, nurse, and the BI.

RESULTS:

Sixty-two children, aged 4.5 +/- 0.4 years (mean +/- SD) were randomized. The three treatment groups had similar subject characteristics. All pain measures and cry duration were similar for EMLA and vapocoolant spray. Both EMLA and spray were significantly better than control. Results for spray vs control: cry duration (seconds): 8.5 +/- 21.0 vs 38.6 +/- 50.5; number of pain behaviors: 1.2 +/- 1.9 vs. 3.1 +/- 2.1; child-scored faces scale: 2.0 +/- 2.4 vs. 4.1 +/- 2.3; parent-scored faces scale:

1.6 +/- 1.6 vs. 3.0 +/- 1.7; nurse-scored faces scale: 1.6 +/- 1.2 vs. 3.1 +/- 1.4; and BI-scored faces scale: 1.0 +/- 1.5 vs. 2.4 +/- 1.4.

CONCLUSIONS:

When combined with distraction, vapocoolant spray significantly reduces immediate injection pain compared with distraction alone, and is equally effective as, less expensive, and faster-acting than EMLA cream. As an effective, inexpensive, and convenient pain control method, vapocoolant spray may help overcome physician and parent resistance to multiple injections that lead to missed opportunities to immunize.

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Analgesia for venous cannulation: a comparison of EMLA (5 minutes application), lignocaine, ethyl chloride, and nothing.

Selby IR[1], Bowles BJ.

Abstract

Three commonly available local anaesthetics were compared, in a controlled trial, for use before venous cannulation. The pain of application of the local anaesthetic, the pain of cannulation, and the rate of successful cannulations were compared. The value of EMLA cream applied for 5 min was questioned. Venous cannulation with a 20G venflon was found to be significantly more painful than the application of any of the local anaesthetics ($P < 0.01$). Lignocaine 1%, injected subcutaneously, and ethyl chloride spray significantly reduced the pain of venous cannulation ($P < 0.01$). The use of lignocaine did not result in significantly more failed cannulations than the control group. It was concluded that local anaesthesia should be used before venous cannulation, even for 20G cannulae.

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Ethyl chloride and venepuncture pain: a comparison with intradermal lidocaine.

Armstrong P[1], Young C, McKeown D.

Abstract

One hundred and twenty unpremedicated patients undergoing gynaecological surgery were randomly allocated to one of three equal treatment groups to assess the effectiveness of ethyl chloride in producing instant skin anaesthesia to prevent the pain of venepuncture from a 20 G cannula. They received either no anaesthetic, 0.2 ml one per cent lidocaine plain intradermally or a ten-second spray of ethyl chloride at the cannulation site. Ethyl chloride produced skin anaesthesia that significantly reduced the pain of venepuncture. However, it was not as effective as intradermal lidocaine. It had no effect on vein visualisation or ease of cannulation. Ethyl chloride can be recommended as a method of producing instant skin anaesthesia.

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