

Spring 2018

Vapocoolant Spray's Effect on Peripheral Inserted Venous Catheter Pain in Adult Patients

Zachary Krol
zwk4@zips.uakron.edu

Fiona Flaherty
fmf3@zips.uakron.edu

Ryan Williams
rjw84@zips.uakron.edu

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Recommended Citation

Krol, Zachary; Flaherty, Fiona; and Williams, Ryan, "Vapocoolant Spray's Effect on Peripheral Inserted Venous Catheter Pain in Adult Patients" (2018). *Honors Research Projects*. 716.

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Vapocoolant Spray's Effect on Peripheral Inserted Venous Catheter Pain in Adult Patients

Fiona Flaherty, Ryan Williams, Zachary Krol

University of Akron

Abstract

Intravenous (IV) cannulation is required to administer medications and fluids to patients. In addition, it is also a recognized source of pain and anxiety in over one-half of all patients requiring IV insertion (Page & Taylor, 2010). Pain management is within nurses' scope of practice, therefore it's important to identify effective pain management strategies. The purpose of this study is to determine the effect that a topical vapocoolant spray has on pain in pre-operative adults during IV cannulation. The gate control theory of pain will guide this randomized, experimental study of a convenience sample of adults in an outpatient endoscopic floor at a Northeast Ohio level one-trauma center. Participants are randomly assigned to groups based on even weeks of the month (control group) and odd weeks (experimental group). Participants will rate pain at pre- and post- procedures on visual analog scales. Independent two sample t-tests will be used to determine group differences. In relation to our research investigation, we analyzed both groups' answers to one question: "How painful was the needle stick?" on a scale of 1-10, 10 being most painful. The reported pain score of the non-spray group was 3.33, compared to the spray group mean of 2.86. These averages are rather close in value, suggesting no significant difference in perceived pain level with the use of the vapocoolant spray prior to IV insertion.

Introduction

As nurses, the ability to start intravenous (IV) infusion lines with minimal pain and discomfort in patients is important since our scope of practice includes effective pain management. This is especially important for the pre-operative population when IV lines serve the purpose of injecting medication for anesthesia during surgery and administering necessary fluid therapy. They may also be used to provide medication to treat pain and nausea. IV-related insertion pain can be a consequence that can adversely affect patient experience and the patient-nurse relationship. Patients frequently report pain as a side effect of IV cannulation, which may increase anxiety in hospitalized patients (Jacobsen, 2006). Preoperational anxiety is a concern that occurs in more than half of all patients that go into surgery (Nigussie, Belachew, & Wolancho, 2014). Decreasing patient's pain from IV cannulation could increase patient satisfaction while decreasing the negative physiologic pain effects, which include disruption of the body's normal functioning, activation of the sympathetic nervous system, release of various hormones, and disruption to homeostasis (Sessle, 2011). So, it becomes important not to increase or add to pre-operative anxiety or pain with IV cannulation. In the United States, over 100 million surgical procedures are performed annually (Winfield et al., 2013). Since IV insertion is performed for nearly all surgical procedures, there is a need to make the process painless.

Researchers have examined the effects of intradermal anesthetics, such as the application of lidocaine, on pain and anxiety in pre-operative patients. Brown (2003) compared the application of lidocaine prior to IV insertion and found that IV cannulations were less painful with the use of lidocaine. However, few have investigated the effect of cold, topical sprays on IV pain. The following research question will be answered: In adult pre-operative patients during IV cannulations, how does the application of a vapocoolant, topical spray affect pain score? Our

group will be working under Dr. Brian Radesic and Angelo Donatelli, a Doctor of Nursing Practice (DNP) student, to study the effect of the application of a vapocoolant, topical spray on IV pain score during the pre-operative period. Data will be collected over the timeline of three months and include subjects with a variety of cultural, ethnic, and lifestyle backgrounds.

Review of Literature

Researchers have examined pain of IV cannulations in children (Waterhouse, Liu, & Wang, 2013), hemo-dialysis patients (Celik, Ozbek, Yilmaz, Duman, & Apiliogullari, 2011), and adult patients in various settings including; emergency department patients (Hijazi, Taylor, & Richardson, 2008), patients in an international travel clinic (Mawhorter, Daugherty, Ford, Hughes, Metzger, & Easley, 2001), outpatient procedures (Deguzman, O'Mara, Sulo, Haines, Blackburn, & Corazza, 2012), and inpatient procedures (Brown, 2003). All have found that IV cannulations cause stress, anxiety, and pain, regardless of patient demographics. Researchers have also studied the effects of different interventions on pain in patients during IV cannulation. These interventions include the use of ice on the skin (Waterhouse et al., 2013), lidocaine injection prior to IV cannulation (Brown, 2003), Eutectic Mixture of Local Anesthetics (EMLA) cream composed of 2.5% lidocaine and 2.5% prilocaine (Mawhorter et al., 2001), topical lidocaine (ELA-MAX) cream composed of 5% lidocaine (Luhmann, Hurt, Shootman, & Kennedy, 2004), and a topical vapocoolant spray (Celik et al., 2011). Although ice application, compared to no ice, during IV cannulation decreased pain score in 47% of patients, when compared with a topical vapocoolant spray, ice was shown to be less effective (Waterhouse et al., 2013). In general, researchers have found that lidocaine injection prior to IV cannulation, application of EMLA cream, application of ELA-MAX cream, and a topical vapocoolant spray each decrease pain and anxiety during IV cannulations. In addition, they found the application of

a topical vapocoolant spray to be the most effective when considering cost and time management (Page, & Taylor, 2010).

Several interventions have limitations, for example, lidocaine injections lowered IV insertion pain, but at the same time may have contributed to pain and anxiety, because the lidocaine was also injected (Beck, Zbierajewski, Barber, Engoren, & Thomas, 2011) and possibly an additional reason for pain and anxiety. Topical EMLA and ELA-MAX creams decreased IV insertion pain and anxiety by numbing the skin and are not invasive, but they may take 30-45 minutes to have effect on IV cannulation pain (Kleiber, Sorenson, Whiteside, Gronstal, & Tannous, 2002) which is precious time in the pre-op surgical areas. It is also important to note that lidocaine and prilocaine can be contraindicated for patients with heart problems. The vapocoolant sprays were determined to be just as effective as the local anesthetics (Hijazi et al., 2008), as well as more cost-effective and instantaneous because its action takes a matter of seconds to numb the area (Hijazi et al., 2008). This research study aims to determine the effect of topical vapocoolant sprays on pain score in adult patients on an outpatient endoscopy floor.

Theoretical Framework

The gate control theory of pain proposes that a nonpainful stimuli (i.e., massage, heat, ice) interrupts the transduction of signal from a painful stimulus (Deardorff, 2016). The spinal cord is the center for pain signal transduction. When a painful stimulus is encountered, a signal is sent from the affected nerve to the spinal cord, which transmits the signal to the brain so the body responds appropriately. In the gate control theory of pain, “the sensitivity of the nociceptive system can be decreased or increased and this ‘gate control’ can occur at peripheral, spinal, and supraspinal levels. The resulting changes in pain sensitivity can be rapidly reversible or

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persistent, highly localized or widespread” (Treede, 2016). Decreased sensitization to the reception of pain signals in the brain may then reduce the pain that a person experiences. The gate control theory of pain suggests that the introduction of a nonpainful stimuli may interrupt the transmission of a painful signal to the brain. The gate control theory of pain states that, “nociceptive (pain arising from nerve cells) and non-nociceptive signals are summated within the substantia gelatinosa (spinal cord). If nociceptive signals outweigh non-nociceptive signals, a pain signal is propagated” (Kirkpatrick et al., 2015). For example, if an individual were to hit their arm on a door, natural responses would be to rub the affected area. The rubbing of the affected area introduces a cutaneous stimulation that interferes with the amount of pain the person is experiencing. Rather than only interpreting the pain from the affected area, the nervous system will now also interpret the cutaneous stimulation that is being received from the rubbing. Since there are a limited number of pathways that stimuli can be transmitted through, introducing a nonpainful stimulus forces some of the pathways to interpret the nonpainful stimulus, rather than interpreting the painful stimulus. The introduction of this nonpainful stimulus decreases the amount of pain the individual is experiencing by forcing the body to interpret a secondary stimulus instead of the pain. If the individual were to stop rubbing their arm, suddenly they may feel more pain due to the fact that there are more gates, or nerve pathways, open to interpret the pain faster. The rubbing may strategically close these gates. Since the sprays work by numbing the local area and use the cold as a distraction, the study is guided by the gate control theory of pain.

IV cannulation creates a superficial-sharp pain as a result of direct trauma to the skin due to nociception; the body's response to painful stimulus. The purpose of this study is to examine the effect of a vapocoolant spray on pain score during IV cannulation. The brain modulates pain

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signals by controlling endorphins which stop the transmission of substance P, a “peptide neurotransmitter which modulates sensitivity to pain” (Felipe, Herrero, Obrien, Palmer, Doyle, Smith, & Hunt, 1998). This is applicable to our study because the same principle is being used with the vapocoolant spray. The cooling effects and stimulation of the spray activate the gate control theory and slow the reception of painful stimuli. Based on this theory, it is anticipated the application of a vapocoolant spray prior to IV cannulation will decrease the pain score experienced by the participant during IV cannulation.

Methods

Design

This experimental investigation is testing the effect of a 95% Pentafluoropropane/5% Tetrafluoroethane topical vapocoolant spray on pain score in pre-operative patients during IV cannulation. Study protocol has been approved by the hospital Institutional Review Board (IRB). This secondary analysis study proposal was submitted and approved by the University of Akron IRB. Gabauer Company provided the vapocoolant spray. The company provided no other support, nor did it influence the design, conduct or reporting of the study.

Site and Population

The site of this experiment is an outpatient endoscopic floor in a Northeast Ohio level one-trauma center located at a 532-bed, urban, teaching hospital. Inclusion criteria include: ability to speak, write, and read English, between the ages of 18 to 85, and scheduled for an outpatient endoscopic procedure between December 2016 and April 2017. Exclusion criteria includes: Raynaud's, PVD, allergy to aerosol, cold intolerance, frostbite history, frail/thin skin, diabetes mellitus, renal dialysis, pregnant, in-patient population, patient refusal, and product allergy.

Sampling Procedures and Recruitment

The consenting process will consist of written and verbal explanations (see appendix A). Subjects will sign a privacy release, giving access to medical records for data collection. Informed consent will be documented by receiving the subject's initials on each sheet of the consent form and signature at the end of the consent form. During the even weeks of the months, the subjects who consent will be assigned to the control group and receive standard care. During the odd weeks of the months subjects who consent will be assigned to the experimental group.

Data Collection

After obtaining informed consent, research team members will collect all demographic data, medical history, and comorbidities from pre-screening assessments in patient charts, to determine eligibility. All data collected during the pre-screening for eligibility will be destroyed via the shredding cabinet if subjects are ineligible to participate in the study. For the study, a total of 128 patients is needed to achieve the effect size of 0.5 for this study, or 64 patients in each study group.

Subjects complete pre- and post- questionnaires (see Appendix B) that will measure a baseline of previous PIVC experience and pain during IV cannulations. The questionnaire has multiple questions and uses a zero to ten pain scale; zero being no pain and ten being the most severe pain. Data collection will be obtained by a research team member.

Measures

Pain is measured with a visual analogue scale (VAS). It has established validity and reliability in a study to measure sensory intensity and affective magnitude of both chronic and experimental pain (Price, McGrath, Rafii, & Buckingham, 1983). The scale asks participants to rate their pain on a scale from zero to ten, zero being no pain at all and ten being severe pain.

Data Analysis

Data was analyzed based on level of variable measure with nominal level data analyzed with descriptive statistics to describe the sample and pain variable. Summed ordinal, interval, and ratio level data will be analyzed with inferential statistics. An independent sample t-test will determine group differences on demographics prior to the intervention, which will describe group differences and similarities. After the intervention, an independent sample t-test will determine group differences of pain score with statistical significance set at $<.05$

Time Line for Completion

This honors nursing research project is working with a University of Akron DNP student Angelo G. Donatelli, and is sponsored by Dr. Radesic, Brian DNP, MSN, CRNA, who is the Director of The University of Akron's Nurse Anesthesia Program, and Assistant Director of School of Nursing. Our proposal to the Honors College and UA IRB was approved at the beginning of the spring semester in January 2017. We chose to enroll in the senior honors project independent study in Fall 2017, and/or Spring 2018. Data collection for this project occurred between December 2016 and April 2017 and was subject to further instruction from the lead researcher, Angelo G. Donatelli. After we collected data on the first 128 patients, we were granted access to the data for analysis. During this time period we analyzed the necessary data for our honors project and record the findings.

Results

One hundred twenty-eight patients were randomly divided into either the control group, or experimental spray group. Placement in either group was determined by the week of the month. Sixty-four eligible patients that were consented during an even week of the month were placed in the control group. Sixty-four eligible patients that were consented during an odd week of the month

were placed in the experimental group. It is worth noting that the two groups differed in age, gender, IV cannulation site, cannula size, and staff member inserting cannula. Reported pain for most patients in both groups was low (Table two) and did not significantly differ between the two groups ($P=0.179$, and $t= - 1.35$). The mean reported pain level for patients in the control group was 3.33, while the mean reported pain level for the experimental group was 2.86 (Table one). After reviewing the collected data, no significant pain reduction could be proven in patients receiving the vapocoolant spray prior to IV cannulation, as opposed to patients receiving no treatment.

Discussion

The results of the patients' surveys following IV insertion showed that the control group and experimental group did not differ significantly in a difference of pain. The pain for both groups were reported on a visual analogue scale of one to ten (1-10). The experimental group had an average reported pain of 2.86, while the control group had an average reported pain of 3.33. The significant differing between these two results is rather very little. Therefore, from this study it is hard to assess if there is any clinical evidence to suggest that the vapocoolant spray provides any therapeutic comfort for the patients.

This finding was an unexpected finding due to the information synthesized from the literature review, in which there was overwhelming evidence that any intervention was better than no intervention at all. In a study with over 1,000 patients on the application of ice as a prior intervention, it showed that 47% of the sample showed a significant relief of pain from that intervention (Waterhouse et al., 2013). Following up with that, the same study indicated that a topical vapocoolant spray was more effective than ice (Waterhouse et al., 2013). With those conclusions alone, it was safely assumed that the vapocoolant spray in this study would produce

differing results from the control group. However, with only 47% of the sample indicating that a less effective intervention was better than no intervention at all, it is likely that this current study under review has too small of a sample size.

The theoretical framework that coincides with this study was the gate control theory, which is that one non-painful stimulus may interrupt the pain transmission of a painful stimulus. In theory this is very sound. Although common subjective data seen with patients receiving the vapocoolant spray were that there was slight discomfort in how cold the intervention was. This may indicate that although a cold stimulus is considered a non-painful stimulus in this study, it may still be a discomforting stimulus. In other words, this study may be trading one discomforting stimuli for another. Therefore, further testing should be conducted that has a controlled and narrower patient population, a larger sample size, and fewer nurses conducting IV insertions. It would be highly beneficial if it could just be a single nurse that conducts future IV insertions with this type of study.

Conclusion

Our secondary analysis involved 128 total subjects, 64 in the control group and 64 in the experimental group. The experimental group received an application of the vapocoolant spray prior to IV cannulation, while the control group underwent standard treatment and did not receive the vapocoolant spray. Upon conclusion of the IV insertion all subjects were asked to complete a brief questionnaire about their IV experience. In relation to our research investigation, we analyzed both groups' answers to one question: "How painful was the needle stick?" on a scale of 1-10, 10 being most painful. The reported pain score of the non-spray group was 3.33, compared to the spray group mean of 2.86. These averages are rather close in value, suggesting no significant difference in perceived pain level with the use of the vapocoolant spray

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prior to IV insertion. One limitation to this secondary analysis was the low sample size. A larger sample size would decrease the risk of variability and provide an accurate analysis. Additionally, data collection was limited to nurse availability.

In regards to the implications for the future of nursing practice, additional studies need to be collected with vapocoolant sprays, or a similar topical, cold spray. Subject-reported pain levels are inconclusive, and do not support the hypothesis that the application of a topical cold spray prior to IV cannulation decreases pain score during the procedure. Future studies could research separate potential effects of the application of a cold spray prior to IV insertion, aside from pain. This would include patient anxiety, as well as the nurse's confidence.

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Table One

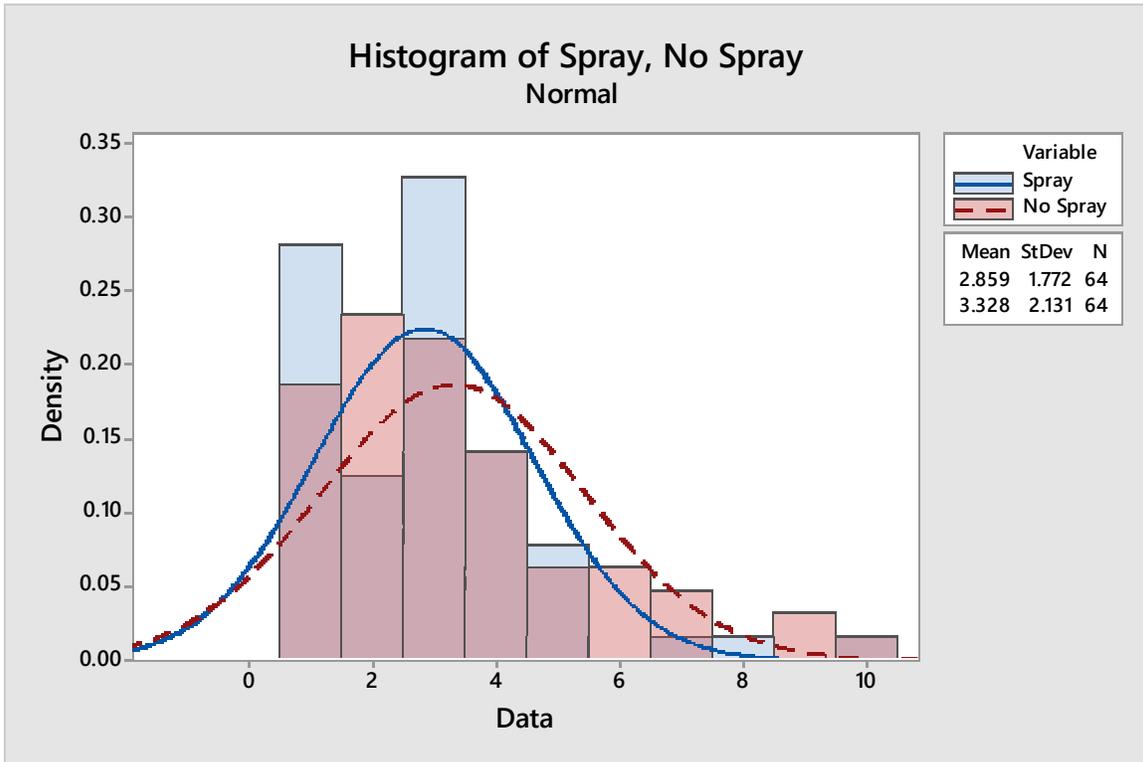


Table Two**Two-Sample T-Test and CI: Spray, No Spray****Method**

μ_1 : mean of Spray
 μ_2 : mean of No Spray
 Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
Spray	64	2.86	1.77	0.22
No Spray	64	3.33	2.13	0.27

Estimation for Difference

Difference	95% CI for Difference
-0.469	(-1.155, 0.217)

Test

Null hypothesis $H_0: \mu_1 - \mu_2 = 0$
 Alternative hypothesis $H_1: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
-1.35	121	0.179

Appendix A

Title: Exploring Patient Satisfaction and Nurse's Peripheral Intravenous Catheter (PIVC) Insertion Using a Vapocoolant

Principle Investigator: Angelo G. Donatelli MSN, CRNA

Other Investigators: Julie Imani MSN, CNS, OCN, Brian Radesic DNP, MSN, CRNA, Richard Kucera MSN, CRNA

Institutional affiliations: The University of Akron and Cleveland Clinic Akron General

Doctors and nurses want to know more about how our care affects patients. One way to learn this is by asking patients to take part in research studies. Angelo G. Donatelli MSN, CRNA, is leading this study.

You are being invited join in this research study because you are going to have an IV started today. Before you agree to take part, you need to know what this study is about. The purpose of this study is to understand how starting an IV affects the patient. In this study we want to know if using a cold spray before the needle stick makes a difference. Some study patients will receive the standard IV start used in the endoscopy unit. Other study patients will receive a cold spray before the IV start. The study patients will be placed into one of these two groups. You will be asked to answer questions about your IV experiences. The questions will have answers for you to circle your responses. One goal of this study is to improve patient satisfaction with the IV start. This study will want to know if the cold spray helps the nurse start the IV.

Joining this study is voluntary. If you do not wish to join in the study, you will still receive the standard therapy used by your physician in the treatment of your disease or condition.

Appendix B

Patient IV Experience Questionnaire

Pre-IV start questions

1. Have you ever had an IV before? Yes No I don't know

If you answered yes, please continue. Otherwise you are finished with this questionnaire.

2. Think about your most recent IV start. Please rate your satisfaction with the needle stick?

1	2	3	4	5	6	7	8	9	10
Very Satisfied					Very Dissatisfied				

3. Circle how many needle sticks it took to place your most recent IV.

1	2	3	more than 3	I don't recall
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4. With your most recent needle stick, please circle which one of the following was used to lessen the pain from the needle stick:

Cold spray	Numbing Cream	Can't recall	Other _____
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5. If a product was used to lessen the pain, rate how satisfied you were with this product (or with the result)?

1	2	3	4	5	6	7	8	9	10
Very Satisfied					Very Dissatisfied				

Post IV start questions: No spray group

1. Was there anything that could have made the IV start today better? (Choose all that apply)
 - Something was used to decrease the pain of the needle
 - Nothing because it was ok
 - Nothing because it always hurts
 - Other _____

2. How painful was the needle stick?

1 2 3 4 5 6 7 8 9 10

No Pain Worst Pain

3. How did the pain from the needle stick affect your satisfaction with your IV experience?

1 2 3 4 5 6 7 8 9 10

No Affect Major Affect

Post IV start questions: Spray group

1. Did the cold spray lessen the pain for the needle stick today?

1	2	3	4	5	6	7	8	9	10
No Affect					Major Affect				

2. How painful was the needle stick?

1	2	3	4	5	6	7	8	9	10
No Pain					Worst Pain				

3. How did the pain from the needle stick affect your satisfaction with your IV experience?

1	2	3	4	5	6	7	8	9	10
No Affect					Major Affect				