PROTOCOL TITLE: Will Patients Perceive a Vapocoolant Spray to be Effective in Reducing Pain and Increasing Satisfaction with Insertion at an Intravenous Site?

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1.0 INTRODUCTION

1.1 Abstract

The primary purpose of this study is to determine if by offering a vapocoolant (cold spray) to Nuclear Medicine outpatients prior to having an intravenous catheter (IV) inserted will increase patient satisfaction of IV insertion as well as determine if pain of insertion is decreased. Furthermore, this study will examine the patients' willingness to use a vapocoolant spray with future IV insertions and potentially reduce anxiety when an IV insertion is required.

1.2 Relevant Literature and Data Rationale

Patients requiring intravenous (IV) access are faced with the necessity of an invasive and uncomfortable procedure. Approximately 25 million people in the United States and 90% of all hospitalized patients require IV catheter insertion. (Levitt, F.C. & Ziemba-Davis, M., 2013).

Pain management during medical care, in addition to being recognized as a basic human right, impacts a patient's satisfaction. (Hogan, M., Smart, S., Shah, V., & Taddio, A., 2014). The Joint Commission standards endorsed by the American Pain Society require health care providers to assess and manage pain. The standard of care for managing pain associated with invasive procedures is to anticipate and ameliorate pain to the greatest degree possible. (Levitt et al., 2013).

Research studies have been conducted to determine the least painful method of anesthetizing a peripheral IV site in addition to studying patient's perception of the anesthetizing agent. One study found that the use of 1% lidocaine intradermally before insertion of IV catheter was the most effective technique in reducing IV catheter insertion discomfort (Winfield, C., Knicely, C., Jensen, C., Taylor, S., Thomas, K., Burns, S., & Quatrara, B., 2013) however this particular method requires a physician order for lidocaine injection, can become costly and subjects the patient to an additional needle stick. The advantage of utilizing a vapocoolant spray has been researched and found to likely reduce pain during intravenous cannulation and are not likely to make cannulation more difficult nor cause serious adverse events. (Griffith, R., Jordon, V., Herd, D., Reed, P., & Dalziel, S., 2016).

This study is necessary to further support the use of a vapocoolant spray as a tool in managing pain or the perception of pain prior to IV cannulation insertion.

2.0 STUDY OBJECTIVES

2.1 Primary Objective

The Nuclear Medicine department at Aultman Hospital seeks to address the issue surrounding pain and satisfaction associated with the invasive procedure of starting an intravenous catheter (IV) for the injection of radiopharmaceutical

and/or medications needed to complete nuclear images and provide for viable scans. The primary purpose of this study is to determine if by applying a vapocoolant (cold spray) at the IV insertion site on Nuclear Medicine outpatients will increase the satisfaction with IV insertion as well as determine if pain of insertion is decreased. Furthermore, this study will examine the patients' perception in using a vapocoolant spray as a way to improve upon the traditional method of starting IV's that do not offer pain management prior to their insertion. A sterile water mist will be used as the comparator spray to add validity to the standard of care arm.

Research Questions:

For the purpose of this study, the following questions will be addressed:

1. Will patients perceive a vapocoolant spray to be more effective in reducing pain prior to IV cannulation insertion over saline spray?
2. Will the use of a vapocoolant spray increase satisfaction with insertion at an intravenous site over that of a sterile water spray?

2.2 Secondary Objective

The broader implication to this study is to bring awareness to both caregivers and patients alike that there are options for pain management when IV insertions are needed and/or required. Furthermore, vapocoolant sprays are already being utilized for pain management in accessing port-a-cath sites in our Radiology department therefore this study could use the same spray as is indicated for its use in accessing IV insertion sites.

3.0 SUBJECT SELECTION

3.1 Inclusion Criteria

Patients who voluntarily agree to participate in the study and are scheduled for a Nuclear Medicine Stress Test at Aultman Heart Center.

3.2 Exclusion Criteria

Patients will be excluded from this study for the following reasons:

1) If this is the first time the patient has ever had an intravenous catheter (IV).

2) Any patient under the age of 18 and/or any patient over the age of 85.

3). Those who are or may be pregnant.

4) Any woman who is breastfeeding.

5) Any patient who has taken any narcotic, sedative, and/or as needed anti-anxiety medication within the last 8 hours of the intravenous catheter insertion.

6). Any persons who are non-English speaking.

7). Any persons who are decisionally impaired.

8). Any persons who are illiterate.

9). Any patient who has had a known hypersensitivity and/or allergy to Ethyl Chloride.

10). Any persons who have been diagnosed with Raynaud's Syndrome and/or Carpal Tunnel Syndrome.

4.0 SUBJECT ENROLLMENT

The study population for this research is a convenience sample of patients who have been ordered to undergo a Nuclear Medicine Stress Test at Aultman Hospital Heart Center. Upon arrival to the Nuclear Medicine department the patient must check in at the front desk for his/her scheduled exam. The patient will need to fill out the necessary documents required by the nuclear medicine department to perform the stress test imaging. In addition to the patient will be given a letter to make them aware that a research study is being conducted within the department. (See Attachment 1-Explanation of Research Study). This letter is only intended to inform the patient that a research study is being conducted this is not intended to be used for the consent process. When it is time for the patient's exam the researcher will take the patient back to the injection room where an explanation for the exam and need for IV access will be explained.

The researcher of the study will have information from the patient's health record that will indicate a patient's age and gender. The researcher will automatically exclude any persons who do not meet the age requirement in addition to asking the patient if this is the first time they have ever had an intravenous catheter placed. Also at this time the researcher will determine if the patient is able to speak and read English as well as determine if the patient is decisionally aware. The patient will be asked additional questions to determine the patient's inclusion/exclusions to participate in the research study. (See Attachment 2- Inclusion/Exclusion Criteria Checklist). If the patient does not meet the criteria set forth for the study the patient will be told that they do not qualify at that time and that their nuclear exam will continue as ordered without the use of the research interventional spray being used in the study and they will get an IV using the method currently in practice. If a patient is eligible to participate in the study the researcher will make the patient aware of their eligibility and again explain the use of a vapocoolant spray vs. a placebo spray prior to IV insertion. The researcher will explain to the patient why the study is being conducted and allow the patient adequate time to decide on whether to participate in the study. If the patient chooses to participate in the study they will be asked to read and sign/date the HRRB approved research consent form. (See Attachment 3- Consent Form). Subjects will be given ample time to consider participation and have all of their questions addressed.

5.0 STUDY DESIGN AND PROCEDURES

5.1 Design/Study Type

This is a single blind interventional study with a post design using a convenience sample of patients undergoing a Nuclear Medicine Stress Test at Aultman Heart Center.

5.2 Selection of Instruments

A questionnaire will be filled out by the researcher while asking the patient questions prior to and after IV insertion. (See Attachment 4- Patient Questionnaire and Researcher Documentation Form). The patient will be provided with a visual diagram of a 0-10 pain scale and a 1-5 satisfaction Likert Scale. (See Attachment 5- Visual Pain and Satisfaction Scale).

5.3 Description of Intervention

This study will have both an experimental group and a control group.

5.3.1 Interventional Products

The control group will receive a placebo mist spray of sterile water. The product chosen for this is known as Nature's Tears Eye mist and is manufactured by Bio-Logic Aqua Research Technologies International Inc. This product was used as a placebo in a similar study. (Mace, S.E., 2016). This product is marketed to be used for the eyes and face but for the purpose of this study we will use it off label for its preservative and chemical free, non-allergenic, sterile properties. "With Nature's Tears EyeMist, the assembly process begins with a plastic, aluminized barrier bag which is attached to a plastic applicator nozzle. The rigid aluminum canister, with bag and nozzle in place, is then pressurized with nitrogen, an inert chemical that comprises 80% of the air we breathe. Nitrogen has a greater capacity to pressurize than oxygen or air, retards freezing, and microbes cannot live in nitrogen. The unit is then sealed with a rubber gasket. In the extremely unlikely event that the gasket fails, the unit would depressurize and simply not work. As long as the seal is intact, the contents remain clean and sterile." (Bio Logic Aqua Research Technologies International Inc, 2010.) The product has a four-year shelf life. (Bio Logic Aqua Research Technologies International Inc. 2010.) The experimental group will receive a spray that is manufactured by the Gebauer Company and is known as Ethyl Chloride Mist Spray Can P/N 0386-0001-02. This spray was selected because of its current use and patient preference in accessing port-a-catheter sites. The mist spray is indicated for temporary control of pain associated with injections, starting IV's and venipuncture, minor surgery and minor sports injuries. (Gebauer's Ethyl Chloride Spray, 2016).

The Nature's Tears Eye mist and Ethyl Chloride sprays used will be unidentifiable by the patients in the study. The Radiology department at Aultman hospital has agreed to cover the cost for the sprays needed in this study. The Gebauer Company indicates that each spray can may be used up to 50 times therefore for the purpose of this study it is estimated that 2 cans will be needed. The Bio-Logic Aqua Research Technologies

corporate office has agreed to send 2 cans of their Nature's Tears Eye mist at no charge.

5.3.2 Product Handling and Storage

The manufacturer of Nature's Tears Eye Mist MDS report (see Attachment 7) indicates that the can should be stored at room temperature and should not be stored at temperature's greater than 50ºC (120ºF). (Biologic Aqua Technologies, 2013). For the purpose of this study the Nature's Tear Mist spray will be refrigerated to "mimic" a cold spray. There are no documented contraindications that refrigeration would affect the sterility or application of the spray. The refrigerator is located in the Nuclear Medicine department's "Hot Lab" that is monitored by temperature control and is in a locked room. The Gebauer Company's Safety Data Sheet (SDS) (see Attachment 6) indicates that the ethyl chloride spray should be stored in cool, dry well ventilated area. Protect against physical damage. Do not subject to temperatures above 120°F (50°C). Do not store near high frequency ultrasound equipment or non-explosion proof electrical equipment. (Gebauer Company, 2013.) This product will be stored in a locked cabinet located in the Nuclear Medicine Department's scan room which is temperature controlled at 72°F.

5.3.3 Intervention Administration

The researcher will access a peripheral IV site using the hospital protocol on inserting IV catheters. The researcher will select an IV site; the patient's skin will be cleansed prior to the intervention spray being applied per hospital protocol. The researcher will then spray the intervention spray made by the Gebauer Company according to the manufacturer's recommendations which is to spray the Ethyl Chloride aerosol can for 4 to 10 seconds from a distance of 3 to 9 inches (8-23 cm). Do not spray longer than 10 seconds. Spray the area for the time recommended or until the skin just turns white; do not frost the skin. With skin, taut, quickly introduce the needle because the numbing effect of ethyl chloride only lasts for a few seconds to a minute. (Gebauer's Ethyl Chloride Spray, 2016). Reapplication of the spray to the area when it has been too long or is no longer "numb" is also indicated by the manufacturer but for the purpose of this study the patient will only have the application applied once. For the control group the patient's skin will be prepared per hospital protocol then the researcher will apply the Nature's Tears Eye Mist to the area for 4-10 seconds prior to IV access.

5.4 Data Collection

The questionnaire (See Attachment 4- Patient Questionnaire and Researcher Documentation Form) will include the following questions prior to the use of the intervention:

1.) Using the visual analog scale provided how would you rate your pain the last time you remember having an IV inserted?

2.) Using a 0-5 Likert scale please rate how satisfied you were the last time you remember having an IV inserted?

3.) Do you think it is important to control the pain of starting an IV?

Once the IV has been placed the researcher will ask the patient the following questions:

1.) Using the same 0-10 pain scale how would you rate this IV insertion?
2.) Using the same 1-5 satisfaction scale how satisfied were you with this IV insertion?
3.) Would you choose to have a spray used again if you needed to have an IV inserted in the future?

The researcher will document the patient responses as well as the angiocatheter size, angiocatheter location, numbers of IV start attempts, the time that the intervention was applied and what interventional spray was used. (See Attachment 4- Patient Questionnaire and Researcher Documentation Form). This information will be coded and will be used to analyze study results post intervention. The presence of adverse events will be monitored and documented for 120 minutes following the IV insertion.

6.0 STUDY ADMINISTRATION

6.1 Description of Study Process

This study will be conducted using patients who are ordered to undergo a Nuclear Medicine Stress Test. These patients will only be seen in this department the day that the stress test exam is performed. The anticipated time it will take to gather the patient's information, conduct the recruitment and consent portion of the study is approximately 30 minutes per patient. This study will use a convenience sample of patients over a 4-month period. The target goal is 30 patients; however, researchers may recruit up to 80 patients.

Once the determination has been made by the researcher that the patient is a candidate for the study the patient has consented they will be assigned to either the control group or experimental group through a computerized randomization sheet. Both the control group and experimental group will be equally represented. Once the IV has been placed regardless of what intervention was used the patient will then be asked by the researcher the questions as stated above.

The participants will only have the intervention used on a first attempt IV access. If the participant has to have additional attempts by the researcher to start an IV, their study will automatically be excluded.

6.2 Data Quality and Confidentiality

The information obtained during this study will remain confidential and will be stored in a file cabinet with a key lock. Jennifer Miller and Laura Wagner the Sub- investigators of this study under the supervision of the Principle Investigator Dr. Mitryan Kar will be responsible for the following:

1). Explaining the study to potential participants along with conducting the consent process with the patient.

2). Asking related questions to consented participants regarding the research information obtained during the conduction of this study.

3). The medical review of patient health information determine eligibility.

4). Administration of the vapocoolant spray and placebo spray prior to IV access.

5). Performing IV access on study participants

6). Identifying any adverse reaction to the intervention being used. All adverse events will be reported to and managed by the Principle Investigator.

These responsibilities performed only by the Sub Investigators will ensure that there will be no threat to the validity of the study being performed and its study results. Data for this study will be kept only as long as the study is being conducted and analyzed for results. Once this information has been obtained all records will be discarded in accordance with hospital policy and applicable regulations. Within the consenting process the patient will be made aware that their information will be kept confidential and that the patient has the right to end their participation in the study at any point.

6.3 Regulatory and Ethical Considerations

6.3.1 Risk Assessment

Adverse events with these products are uncommon. The interventional products being used have been tested and studied for any adverse reactions. Sterile water can will be cooled in a refrigerator to “mimic” a cooling sensation when applied to the patient’s skin. The only foreseeable risk would be the perceived “cold” by the patient. Because the sterile water is sterile there is no risk to contamination of the skin after the researcher has applied the aseptic technique for accessing an intravenous catheter. The Gebauer Company, the manufacturer of the interventional vapocoolant ethyl chloride spray has indicated that it is extremely rare to have an adverse reaction to the ethyl chloride however cutaneous sensitization may occur. Freezing can occasionally alter skin pigmentation. A study has been published in the Journal of Hospital Infection titled the “Effects of vapocoolant spray on skin sterility prior to intravenous cannulation” which concluded that vapocoolant spray does not recontaminate the skin after disinfection, and should pose no increased risk of infection when used as an anesthetic agent prior to intravenous cannulation. (Evans, J.G., Taylor, D.M., Hurren, F., Ward, P., Yeoh, M., & Howden, B.P., 2015).

The Gebauer Company list precautions when using the ethyl chloride spray specifically stated as: Do not spray in eyes. Inhalation of ethyl chloride should be avoided as it may produce narcotic and general anesthetic effects, and may produce deep anesthesia or fatal coma with respiratory or cardiac arrest. Ethyl chloride is flammable and should never be used in the presence of an open flame or electrical cautery equipment. When used to produce local freezing of tissues, adjacent skin areas should be protected by an application of petroleum. The thawing process may be painful, and freezing may lower local resistance to infection and delay healing. (Gabauer's Ethyl Chloride Spray, 2016).

The sub investigators for the study will monitor the patient for any potential reaction to the ethyl chloride spray. The most common reaction being temporary skin color changes at the spray site. Furthermore, the sub investigators will monitor for the very rare but severe allergic reactions that could occur including rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; decreased urination; symptoms of liver problems (eg, dark urine; loss of appetite; pale stools; stomach pain; unusual nausea or tiredness; yellowing of the skin or eyes). (Gebauer's Ethyl Chloride Spray, 2016). (See Attachment 6- The Gebauer Company's Safety Data Sheet (SDS).

6.3.2 Potential Benefits of Study Participation

The benefit to the patient who receives the intervention prior to IV cannulation can result in the possible reduction in pain during the IV access and/or the perception thereof. Knowledge gained from this research may help guide treatment guidelines in the future.

6.3.3 Informed Consent/Assent and HIPPA Authorization

In order to protect human rights this study will be conducted in full conformance with principles of "Declaration of Helsinki" and good clinical practice. This study will comply with all protocols set forth for research at Aultman Health Foundation under the guidance of the HRRB.

7.0 SAFETY MANAGEMENT

7.1 Adverse Events and Collection/Reporting

The patients in this study will remain in the department for at least 2 hours following IV insertion to ensure that the sub investigators of the study have adequate time to monitor the patient pre-and post interventional spray specifically the use of the ethyl chloride spray to ensure no reaction has and/or will occur as it relates to the use of ethyl chloride. In the case that an adverse reaction would occur the Principle Investigator of the study Dr. Mitryan Kar would be contacted to assess and treat the patient for the reaction in question.

7.2 Data Safety Monitoring Plan

The Principle Investigator will be responsible for oversight of this project. All Investigators will be trained on reporting and oversight of regulatory

requirements. Data and outcomes produced by this research study will be monitored by the HRRB office on a regular basis. Data review will occur after the first three (3) patients and every 30 patients thereafter. The study will be registered on clinicaltrials.gov, with regular updates as required by regulations.

8.0 STATISTICAL CONSIDERATIONS

Analysis for this study is a descriptive statistic of a covariance using pre-procedure perception as the covariance. A power analysis was completed and determined that a minimum sample with a level of significates of 0.5 moderate effect size is 30 subjects. Our goal for this study is to exceed that sample size and have up to 80 participants. Statistical assistance will be sought to assure accurate data input and complete data results.

9.0 OUTCOMES AND SIGNIFICANCE

The intention of this study is to measure whether the use of a vapocoolant spray as an intervention increases the patient's satisfaction of IV insertion and decrease the patient's pain and/or perception thereof. This interventional study aims to show that the use of a vapocoolant spray prior to IV cannulation insertion will not only yield positive feedback from patients undergoing Nuclear Medicine scans but that such an intervention could change the traditional methods used for starting IV's in hospitalized patients. Furthermore, this study can be used to compare the use of a vapocoolant spray versus current practice which is not using a vapocoolant spray on IV insertions. This comparison will lead to awareness in pain management for IV insertions as well as determine if such a spray is cost effective and necessary.

10.0 REFERENCES

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11.0 APPENDICES

11.1 Attachment 1-Explanation of Research Study

11.2 Attachment 2- Inclusion/Exclusion Criteria Checklist

11.3 Attachment 3- Consent Form

11.4 Attachment 4- Patient Questionnaire and Researcher Documentation Form

11.5 Attachment 5- Visual Pain and Satisfaction Scale

11.6 Attachment 6- The Gebauer Company's Safety Data Sheet (SDS).

11.7 Attachment 7- Bio Logic Aqua Research Technologies International Inc. Monitor Safety Data Sheet (MSDS).