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Original Research Article

Study to Assess the Performance and Safety of Exocool Pain Numbing Device on Pain Due to Vaccination and Intravenous Cannulation in Children

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Abstract

Exocool™ system is a Novel pain Numbing device used for providing a painless experience to sharp prick of injection needles using cryo-numbing mechanisms which numb the site of the application within 8-10 seconds without the use of any chemical or therapeutic agents. Exocool system finds a wide area of application from cosmetic procedures, paediatrics centres, vaccination centres, pathology labs, clinics, and at home. This study is a Randomized, controlled, two-arm, Parallel, sham-controlled trial to study the efficacy of pain-numbing devices and to measure the patients and caregiver satisfaction with the device during intravenous cannulation. Children aged 4-18 years were considered in the study. A total of 60 subjects participated in the study. A majority of study participants (80%) rated the cool device as satisfactory and which indicated that they liked the device. The results show that Exccool device has significant and satisfactory analgesia actions for intravenous cannulation among children (4-18yrs). This study revealed that Exocool Pain Numbing is an effective pain management intervention for children in vaccination and intravenous cannulation.

Keywords: Pain, Cannulation, Children, Device.

Introduction

One Half of patients admitted to hospitals or visit clinics for treatment experience painful Intravenous, Intramuscular, and other invasive needles injections for diagnosis, treatment, and prevention of disease or infection. Particularly, Venous cannulation is considered a common and painful procedure during hospitalization. Children have preoccupied psychological conditions like needle phobia (Fear of needles), and anxiety which results in a negative impact on subsequent healthcare engagement [1,2]. Commonly, Adverse events related to vaccination like pain at injection sites and needle fear among children are neglected. There is a need for healthcare professionals to adopt pain management strategies in their clinical settings to manage needle-associated pain in childhood immunization [1,3].

However, existing procedures like the use of medicine or chemical agents such as EMLA cream or amethocaine cream have been effectively used to anesthetize the skin prior to painful procedures in children. but it requires sufficient time and requires staff to assess the site for applying cream and to do occlusive dressing [4].

Exocool™ system is a Novel pain Numbing device used for providing a painless

experience to sharp prick of injection needles using cryo-numbing mechanisms which numb the site of the application within 8-10 seconds without the use of any chemical or therapeutic agents. Exocool system finds a wide area of application from cosmetic procedures, paediatrics centers, vaccination centers, pathology labs, clinics, and at home.

Exocool device has a metal tip that is made up of a biocompatible Aluminium alloy which is safe, friendly, and ideal to be used for on kinds of skin conditions. It works using a Cryo-numbing mechanism which uses cold temperatures below to numb the body site. The effective numbing effects require 4-6 seconds for sensitive skin and 8-10 seconds for normal skin. For better use and effective application, it is recommended to store the device in a deep freezer at a temperature below -12°C.

Among Children and teenagers, Wong-Baker Faces Pain Rating Scale and the Visual Analogue Scale (VAS) is widely used as self-reporting appropriate instrument for measuring pain based on their behavioral pattern to pain [5].

Study Objectives

The primary aim of our study is to assess the safety and efficacy of the Exocool Device in reducing the intensity of Pain during intravenous cannulation in children compared to the Sham device.

A secondary aim was to evaluate patient and caregiver satisfaction and their willingness to use the device in the future.

The tertiary aim is to assess the adverse events of intravenous cannulation using the Exocool device and Sham device.

Materials and Methods

This study is a Randomized, controlled, two-arm, Parallel, sham-controlled to assess the safety and efficacy of the Exocool Device in reducing the intensity of Pain during intravenous cannulation in children. Subjects with Group A provide with Active Exocool Pain Numbing Device and Group B provide with Sham Device. The primary outcome is to measure pain intensity reduction using a pain assessment score. Subjects were randomly allocated to Group A and Group B and groups in a 1:1 ratio. All subjects were assessed and treated on the first day of the injection administered. The procedure was fully explained to the participants they were asked to sign the informed consent form.

All assessments were performed at baseline, and injections were administered during the treatment period and the follow-up course. Any adverse events occurring during the study were recorded throughout the study. The ethical approval for the study was granted by Independent Ethics Committee and Pharexcel Consulting Private Limited. After the approval from IEC, Voluntary Written informed consent was obtained from the subject(s) and their legal representative before the start of the trial. The study was followed and conducted based on Ethics Committee notifications as per the GCP guidelines issued by the Central Drugs Standard Control Organization (CDSCO) and ethical guidelines for biomedical research on human subjects issued by the Indian Council of Medical Research (ICMR).

Take the device out of the freezer, and secure the lid on top of the device to extend its effectiveness at room temperature. Once the lid is on the device, press the button to check the color of the light to ensure it's ready for use.

If the light is blue - it indicates that the device is simply too cold to be used and there is a risk of cryo-burn (cold burn). Please keep the device outside the deep freezer for some minutes and wait until the light turns green color. If the light is red - it indicates that the device needs more cooling before using it. If the light is green - the device is at associate optimum temperature and is prepared to be used. Thoroughly sanitize the metal tip and the area of the skin where the injection is going to be administered.

Once the metal tip and the skin are sanitized, please apply Exocool's metal tip on the area where the injection is going to be administered. Apply for 8-10 seconds on normal skin. Sanitize the metal tip again, and put the device & its lid back into the freezer for further use.

At the time of cannulation the patient and caregiver were separately asked to rate the pain score from zero to ten, and assess the Pain using the VAS scale patient and carer The level of satisfaction was determined by the five-point Likert Scale (really liked it, liked it, neither liked nor disliked it, didn't like it, really didn't like it) and whether they would use the device again were assessed and also adverse events immediate or delayed pain, erythema, sustained blanching, urticaria, and pruritus in a 4-point scale were assessed.

Study Setting and Population

The study was conducted at Arpitha Children Clinic Sanjay Nagar, Bangalore, Karnataka, India children aged 4-18years were considered in the study. A total of 60 subjects have participated in the study (30 in each Group) Group A- Exocool Pain Numbing Device Group B- Sham DEVICE

A subject having an allergic reaction to metal and cold sensation, confirmed needle phobia, a Child with hemophilia or bleeding disorder, Eczema/skin damage at the injection site, or Children with behavioral/developmental disorder were not eligible for enrollment

Data analysis

The baseline characteristics containing categorical data (gender, medical history) and continuous data, such as age and disease course were reported with descriptive statistics in frequencies or percentages, and t-tests (paired & unpaired) and $\chi 2$ tests were carried out to sociodemographic variables and other indicators.

To determine the difference between variables before and after treatment in the same group, a paired t-test was carried out. An unpaired t-test was carried out to compare the intergroup differences between the two independent groups. With 95% confidence intervals, a p-value of less than 0.05 (two-sided) is considered statistically significant.

Follow-up assessments are done 3 times, Baseline (after usage of a device), 24hr after using the device, 7th day after using the device

Results

Among the 60 study participants, Children 4-18yrs were screened and then enrolled for study after satisfying the inclusion-exclusion criteria. An identification number was given by the investigator to each subject at enrollment into the study

Mean baseline data of VAS Score

The mean Pain Assessments score among the study subjects in Group A after using the Exocool pain numbing device was found to be 2.07±1.11, after 24hr of initial use of the device the score was found to be 0.90±0.99, after the 7th day of initial use of the device was found to be 0.53±0.51.

The Mean Pain assessments among the study subjects Group A (Exocool Pain Numbing Device) Caregiver report after using the device was found to be 2.10±1.06, after 24 hr after using the device was found to be0.83±0.91, 7 the day after using the device was found to be 0.33±0.48.

The mean Pain Assessments in Group B (Sham Device) after using the device were found to be6.23±1.77, 24 hr after using the device is found to be3.03±1.87, 7th day was found to be 0.50±0.51. The Average Mean Pain assessments in Group B (Sham Device) Caregiver report before using the device was found to be 6.13±1.72, 24 hr after using the device was found to be 2.97±1.79, 7th day was found to be0.60±0.50.

Mean data of wong bakers scale

The Average mean of the Wong-Baker Faces Scale in Group A (Exocool Pain numbing Device) after using the device was

found to be1.73±1.26. The Average Mean Wong-Baker Faces Scale in Group B (Sham Device) subjects after using the device were found to be 5.27±2.55.

Local site reaction

Local site reaction was assessed at Baseline (After using the Device), 24 hr after using the device, and on the 7th day after using the device, on the 7th day the local site reaction was 0%.

Table 1: local site reaction in group A (exocool pain numbing device) and group B (sham device)

SI.No	Reaction	Group A				Group B			
		24 hr after using the device							
		No reaction	Mild	Moderate	Severe	No reaction	Mild	Moderate	Severe
1.	Edema	93%	6.6%	0%	0%	86%	6.6%	6.6%	0%
2.	Erythema	100%	0%	0%	0%	93.3%	3.3%	3.3%	0%
3.	Sustained blanching	93.3%	6.6%	0%	0%	100%	0%	0%	0%
4.	Urticaria	100%	0%	0%	0%	100%	0%	0%	0%
5.	Pruritus	100%	0%	0%	0%	100%	0%	0%	0%

Likert scale for device – satisfaction questionnaire

80% and 20% of subjects in Group A (EXOCOOL PAIN NUMBING DEVICE) reported Excellent and Very good on the usage of the device which is useful to provide pain relief at the time of injection or cannulation according to patient satisfaction score (Likert scale score) whereas, In Group B (SHAM DEVICE) 0% of the subjects reported excellent and very good and 76% and 23% of the subjects reported very poor and worst.

Discussion

The painful procedures associated with needles have preoccupied fear and anxiety among the children. This study shows that Exocool has effective analgesia for vaccination and intravenous cannulation in children. Pain scores reported by the subject show significantly lower pain with the use of Exocool pain-numbing device as compared to the Sham Device. The findings of this study were more promising than the given inconclusive success rates or difficulties with the topical numbing techniques previously studied [6,7]. However, topical local anesthetics cream has a successive in reducing the injection site pain during administrations of various vaccines, including diphtheria pertussis-tetanus (DPT), polio, 19 diphtheria-tetanus-acellular pertussis-inactivated polioviruses, Haemophilus influenzae type b conjugate, hepatitis B, measles-mumps-rubella (MMR), and influenza virus vaccine [3,8]. The Exocool device has a significant advantage compared to that of conventional topical creams which includes the marked reduction of time with effective analgesia is achieved (10 seconds versus 30-60 minutes of topical anesthetic) and cost-saving from not needing to use occlusive dressing on the injection site.

The procedure of applying the topical cream is often done by staff who are not involved in the cannulation and may apply the cream in a suboptimal location, which may not be on the vein. If the chosen vein for cannulation was not suitable or unsuccessful in the attempt, then the device can be immediately applied to another site. Children may be very sensitive to topical creams and may develop adverse events like erythema, edema itching, and rash.8 Exoocool device has a long-lasting battery, standing for 2500+ checks. The Exocool device has simple and easy handling and this makes it more attractive and successful

in providing pain-less effects on the skin, Patient satisfaction after using the Exocool device was an impressively high score of (80%) Likert scores indicating that majority of patients ' Really liked' or 'liked' the device, with 0 SAE reported.

Applying local topical anesthesia cream may generate fear and anxiety related to the anticipation of the possible cannulation into their vein among the children. But in Exocool, cryo-numbing mechanisms numb the site of the application within 8-10 seconds without the use of any chemical or therapeutic agents.

One of the main disadvantages of cooling the skin over the vein which is about to get cannulated is vasoconstriction of the vein. But this is not a significant disadvantage as the vein is more assessable to the naked eye and palpates after application of the device. Among the children, the preoccupied fear or anxiety about cannulation may influence an unfavorable Likert rating of the device. The ratings given by caregivers may have an influence on their personal experiences and may potentially introduce bias to observations of their child's reaction [4].

Our study results have demonstrated a low occurrence of complications with only edema of the skin and sustained blanching of the skin being reported. However, the Exoocool device has no potential to cause morbidity or fatal Reaction associated with cold burns if not used appropriately with attention to the recommended instructions for use.

Conclusion

The Exocool numbing device was found to have sufficient safety and efficacy profile with satisfactory analgesia for intravenous cannulation in children (4-18yrs). This study revealed that Exocool Pain numbing is an effective pain management intervention for children in vaccination and intravenous cannulation.

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