MITIGATING PROCEDURAL PAIN DURING VENIPUNCTURE IN THE PEDIATRIC POPULATION: A RANDOMIZED FACTORIAL STUDY

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Disclosure

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- Objectives:
  - Learners will describe methods for alleviation of procedural pain during venipuncture in children.
  - Learners will report statistically significant findings from the research study presented.
  - Learners will identify areas for further study in the mitigation of procedural pain during venipuncture in children, especially ethnic considerations.

- The authors report no conflict of interest and have no financial interest in the products presented here. No financial support nor sponsorship was received for this research study.

Problem

- Venipuncture pain is one of most distressing and painful healthcare experiences for children (Hands et al., 2009; Jeffs et al. 2011; Ortiz et al., 2012; and Walco, 2008).

- Evidence suggests that a significant number of children receive less than optimal management of procedure-related pain (Birnie, et al. 2014; Chidambaran & Sadhasivam, 2012; Helgadottir, 2000; Stinson et al., 2008).

Problem

- In a systematic review, Stinson et al. (2008) concluded that many of the approaches to pain management in children "…have not been rigorously evaluated, and there is limited evidence for their effectiveness" (p. 55).

Purpose

- To determine the efficacy of three interventions on the experience of pain associated with venipuncture in a group of pediatric patients

Research Questions

- Is there a difference in the perceived pain associated with a venipuncture procedure in a group of pediatric patients based on the preparatory intervention used during the procedure?
- Is the effectiveness of the preparatory intervention used to reduce perceived pain during a venipuncture procedure influenced by age, sex, or ethnic group?

Methods

- **Design**

  randomized factorial design

	Toddlers (18-35 months)	Preschoolers (3-5 years)	School-Aged (6-12 years)	Adolescent (13-17 years)
LMX 4% Only	20	20	20	20
Buzzy® Only	20	20	20	20
Buzzy® & LMX 4%	20	20	20	20

- Randomization into groups with purposeful sampling based on age, sex, and ethnic group

Methods

Setting and Sample

- Patients recruited from the Children's Center of a comprehensive, regional hospital in the Southeastern United States:
  - Pediatric unit
  - Pediatric intensive care unit
  - Pediatric outpatient unit

Methods

- Approved by the hospital's Institutional Review Board
- Parental or caregiver consent was obtained
- Assent was obtained for children age 7 years and greater

Inclusion Criteria

- Between the ages of 18 months and 17 years
- First needle stick during this admission
- Parent or primary caregiver present at the time of needle stick
- Developmentally appropriate for age
- English as primary language, parent and child

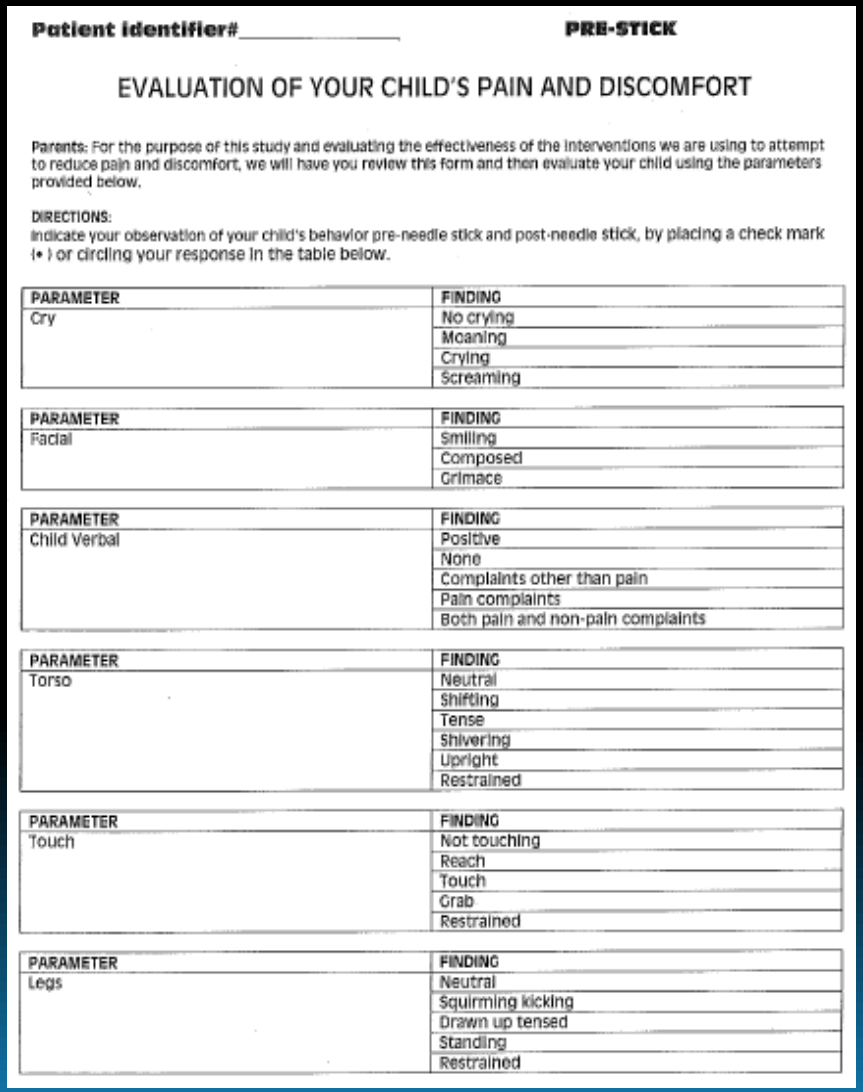
Exclusion Criteria

- Previous needle stick during this admission
- Previous experience with Buzzy® or LMX 4%
- Known chronic illness (i.e. sickle cell disease, diabetes, cystic fibrosis)
- Infusaport in place
- Sedated, unconscious or hemodynamically unstable

Pain Measures

- Parent/caregiver made observational assessment for all age groups using:

Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)



Patient identifier#_____ **PRE-STICK**

EVALUATION OF YOUR CHILD'S PAIN AND DISCOMFORT

Parents: For the purpose of this study and evaluating the effectiveness of the interventions we are using to attempt to reduce pain and discomfort, we will have you review this form and then evaluate your child using the parameters provided below.

DIRECTIONS:
Indicate your observation of your child's behavior pre-needle stick and post-needle stick, by placing a check mark (•) or circling your response in the table below.

PARAMETER	FINDING
Cry	No crying
	Moaning
	Crying
	Screaming

PARAMETER	FINDING
Facial	Smiling
	Composed
	Grimace

PARAMETER	FINDING
Child Verbal	Positive
	None
	Complaints other than pain
	Pain complaints
	Both pain and non-pain complaints

PARAMETER	FINDING
Torso	Neutral
	Shifting
	Tense
	Shivering
	Upright
	Restrained

PARAMETER	FINDING
Touch	Not touching
	Reach
	Touch
	Grab
	Restrained

PARAMETER	FINDING
Legs	Neutral
	Squirming kicking
	Drawn up tensed
	Standing
	Restrained

Pain Measures

- School Aged and Adolescents self-reported pain using:

Wong Baker FACES® Pain Rating Scale (WBFPRS)

Methods

- All participants were placed in a position of comfort.
  - Treatment room used for those less than 13 years of age.
- A distraction technique that was age appropriate was used for all participants

Procedure

- Hospital policy followed for venipuncture procedure
- Pediatric nurses caring for the patient carried out the procedure
- LMX4% and/or Buzzy® used per manufacturer's recommendations
- CHEOPS and WBFPRS completed pre- and post-procedure
- Unsuccessful 1st venipuncture attempted were withdrawn from the study

Results

Participants enrolled .....258 participants

Lost to attrition.....85

- 67 unsuccessful first venipuncture attempt
- 3 parents/guardians changed their mind or left before study
- 2 children withdrew themselves
- 6 protocol violations (i.e., pre-treatment scales were not completed)
- 7 were withdrawn for other reasons (i.e., no venipuncture was ordered).

Final number of participants….. 173 children

Results

Table 1. Demographics

	Group 1 (LMX4)		Group 2 (Buzzy®)		Group 3 (Buzzy® + LMX4)		Total	
	n	%	n	%	n	%	n	%
Ethnic Groups	**66**	**100**	**55**	**100**	**52**	**100**	**173**	**100**
Non-Hispanic White	41	62.1	30	54.5	30	57.7	101	58.4
Minority Children	25	37.9	25	45.5	22	42.3	72	41.6
Gender	**66**	**100**	**55**	**100**	**52**	**100**	**173**	**100**
Female	31	45.5	25	47.0	21	40.4	77	44.5
Male	35	53.0	30	54.5	31	59.6	96	55.5
Developmental Level	**66**	**100**	**55**	**100**	**52**	**100**	**173**	**100**
Toddler	14	21.2	11	20.0	10	19.2	35	20.2
Pre-School	14	21.2	10	18.2	10	19.2	34	19.7
School Age	24	36.4	20	36.4	21	40.4	65	37.6
Adolescent	14	21.2	14	25.5	11	21.2	39	22.5

Results

Table 2. Analysis of Variance Among Groups

	Sum of Squares	df	Mean Square	F	Sig.
CHEOPS Post-Pre:					
• Between Groups	24.699	2	12.350	1.830	.164
• Within Groups	1140.621	169	6.749		
• Total	1165.320	171			
WBFPRS Post-Pre:					
• Between Groups	33.487	2	16.743	1.467	.235
• Within Groups	1152.667	101	11.413		
• Total	1186.154	103			

Figure 1. Estimated Difference in Pre-and Post- CHEOPS by Ethnic group and Treatment Group

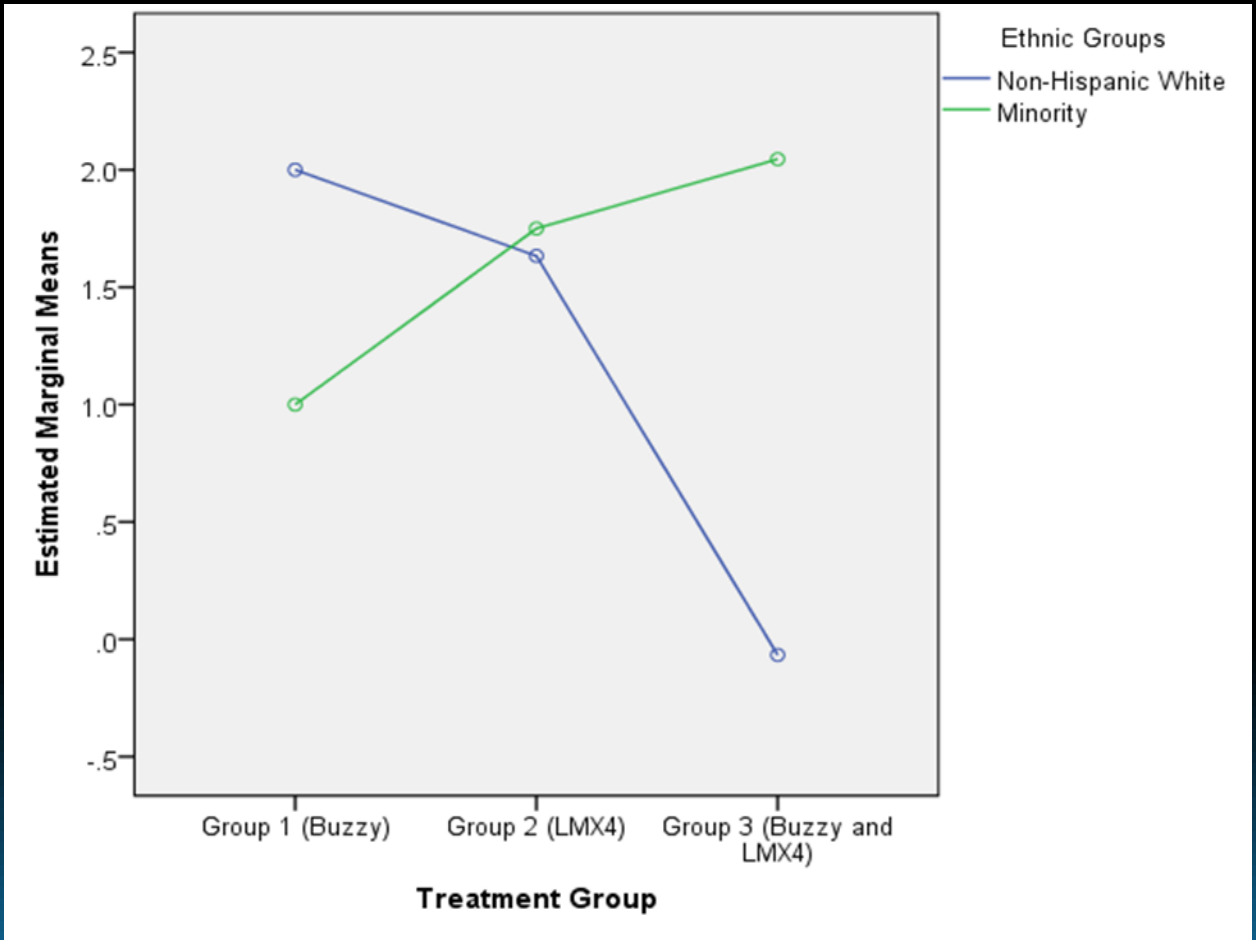
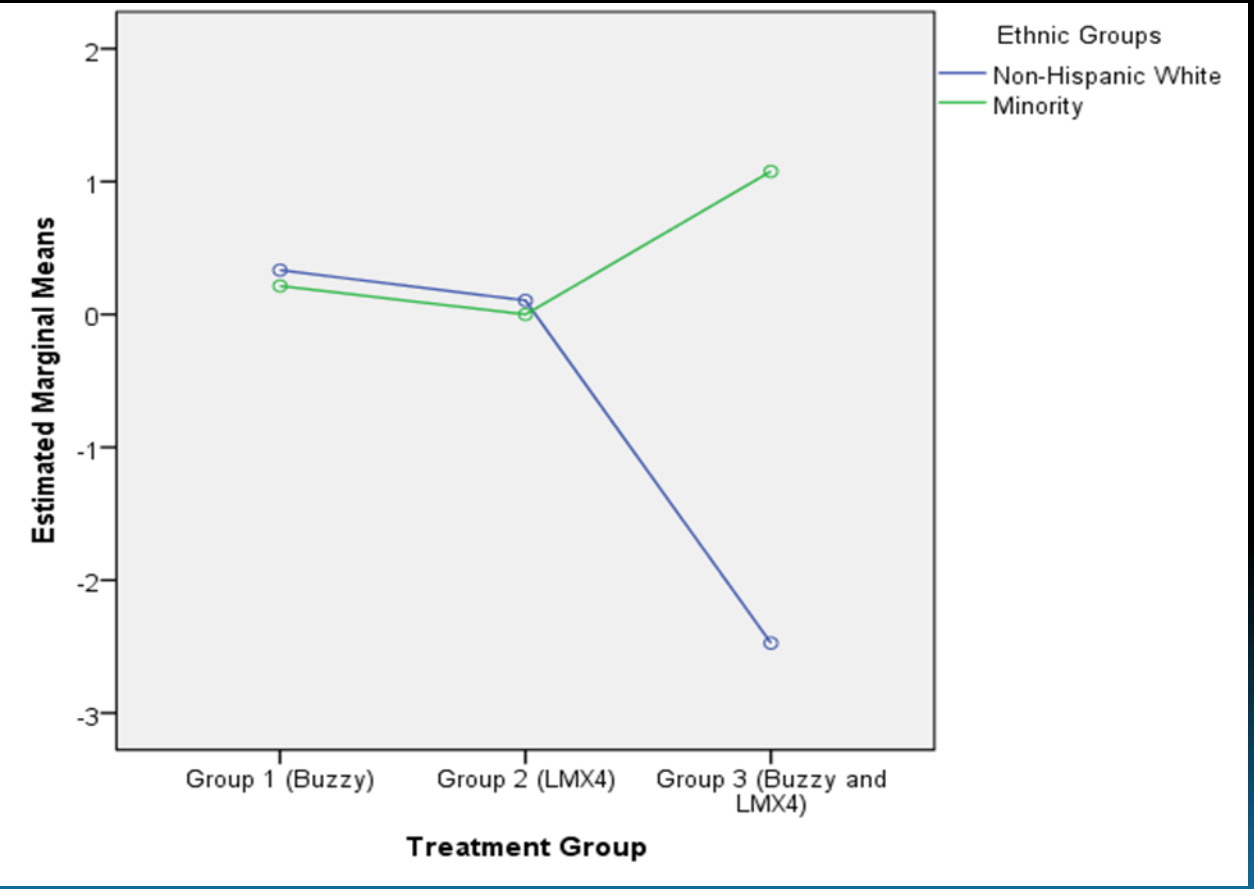


Figure 2. Estimated Difference in Pre-and Post- WBFPRS by Ethnic Group and Treatment Group



Discussion

Question 1: Is there a difference in the perceived pain associated with a venipuncture procedure in a group of pediatric patients based on the preparatory intervention used during the procedure?

No statistically significant differences amongst the 3 Groups:

p = 0.164 for CHEOPS and p = 0.235 for WBFPRS

- **Consistent with 2 studies comparing Buzzy® to vapocoolant spray:**
  - **Baxter et al. (2009) – adults, Buzzy® as effective as the spray**
  - **Baxter el al. (2011) – children, Buzzy® as effective as the spray**

- **Inal and Kellici (2012) identified value of a quick-acting method to reduce pain when time is of the essence performing a venipuncture procedure**.

Discussion

Question 2: Is the effectiveness of the preparatory intervention used to reduce perceived pain during a venipuncture procedure influenced by age, sex, or ethnic group?

There was a statistically significant interaction of ethnicity with treatment demonstrated in both the CHEOPS (p=.006) and WBFPRS (p=.04) scores and only in Group 3.

- **Concurrent interventions produced a significant effect in reducing pain in Non-Hispanic white children in Group 3 when compared with Groups 1 & 2.**

- **Cumulative effect ?**
- **Placebo effect of "more is better"?**

Discussion

More important question: Why the concurrent interventions did not reduce pain in minority children in the study?

- **Rahim-Williams et al. (2012)** posed that "….evaluating ethnic differences in experimental pain models may not only provide information about underlying mechanisms but may also predict or explain group differences in clinical pain… [and] … may have translational merit" (p. 523).

- **Lu, Zeltzer, and Tsao (2013)** reported ethnic differences in terms of pain intensity, pain unpleasantness, and anticipatory anxiety even after controlling for age, sex, and socioeconomic status.

Discussion

Parents/guardians perceived the pain (CHEOPS) experienced by toddlers and pre-schoolers to be greater than pain experienced by school age children and adolescents (p = 0.005).

- Previous studies have reported that younger children demonstrate more behaviors associated with pain and distress than older children (**Bournaki, M. C., 1997; Goodenough et al., 1999; McCarthy et al., 2010**).

- It should be noted that a parent/guardian may have been reacting to the behavior of the child rather than the actual pain. Several studies have noted difficulty in differentiating pain from distress and anxiety (**Cohen, 2008**).

Limitations

- Only one child life specialist on staff.
- Varying levels of experience by nurses performing needle-stick procedures
  - Impact on the success rate on first attempt
  - Impact on the discomfort experienced by study participants.
- The crying and smiling faces on the WBPFRS can be interpreted as happiness and sadness rather than pain.
- CHEOPS is validated for use by clinicians rather than parents

Conclusions

- Mechanical vibration (Buzzy®) appears to be as effective as a topical anesthetic in children regardless of age group or sex.

Conclusions

- Findings from the study:
  - Support the importance of ethnic group when assessing the experience of pain
  - Suggests that ethnic groups should be considered when considering the approach to the mitigation of pain during a procedure

- Further exploration of ethnic influences regarding procedural pain in children is of utmost importance.

Questions?

This research study is in memory of Becky Robertson, BSN, RN, CPN.

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