Ametop Alone vs. Ametop and Vapocoolant Spray to Reduce Pain on IV Insertion in Pediatric Patients

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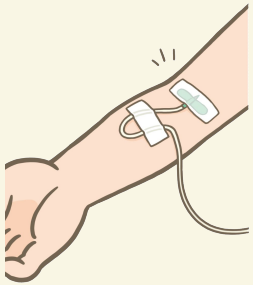
Background



Intravenous (IV) Insertion:

Medical procedures can cause distress in pediatric patients.

Ametop Gel:

Provides numbing before needle insertion.

May be insufficient for sensitive individuals.

Vapocoolant Spray:

Offers immediate cooling and numbing.

May improve pain relief when combined with Ametop Gel.

Introduction

Research:

Performed randomized trial with FPS-R assessments

Procedures:

- Control group: Ametop alone
- Study group: Ametop + Spray

Impact:

Provide better medical care for pediatric patients

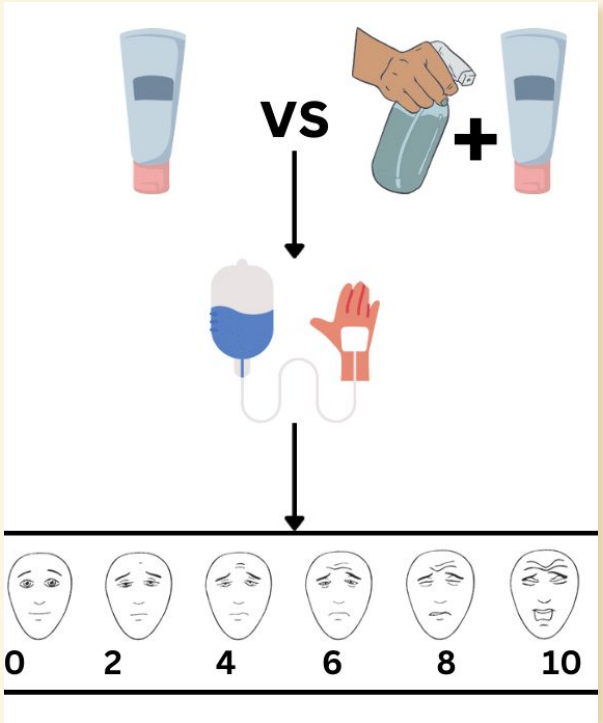
Objectives

Main Objective:

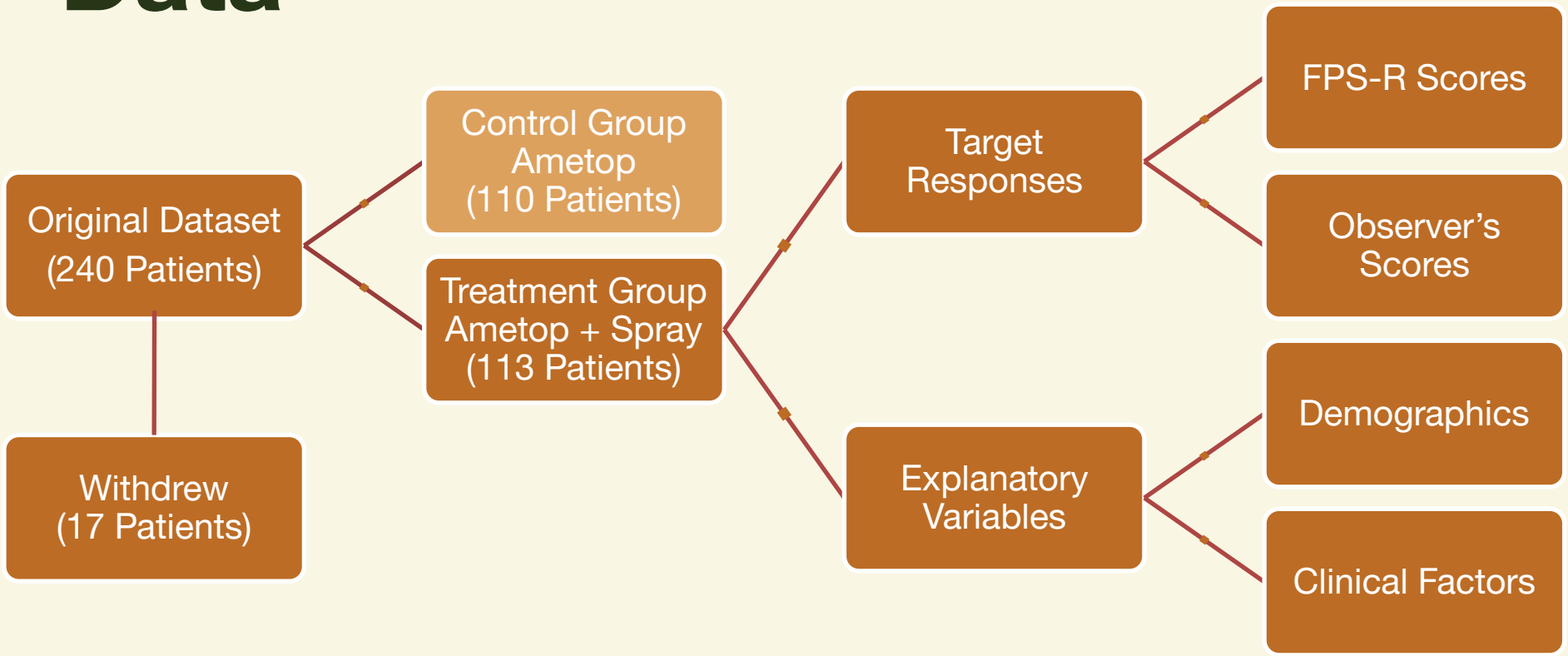
- Ametop alone vs. Ametop + vapocoolant spray to reduce pain in IV insertion

Secondary Objectives:

- How the spray influences pain levels differently across age groups
- How the spray influences the number of IV Attempts
- Side effects of Ametop

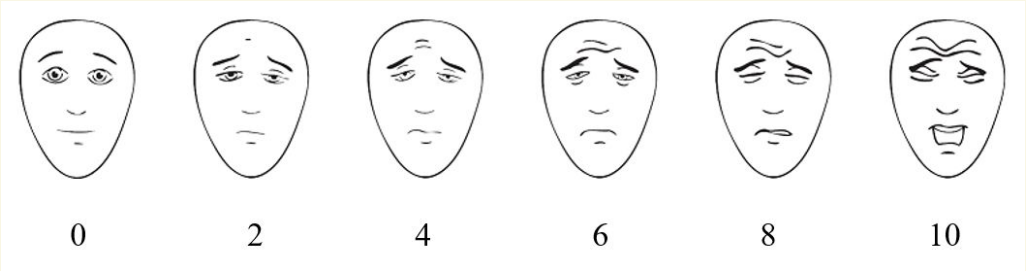


Data


Original Dataset
(240 Patients)
Withdrew
(17 Patients)
Control Group
Ametop
(110 Patients)
Treatment Group
Ametop + Spray
(113 Patients)
Target
Responses
Explanatory
Variables
FPS-R Scores
Observer's
Scores
Demographics
Clinical Factors

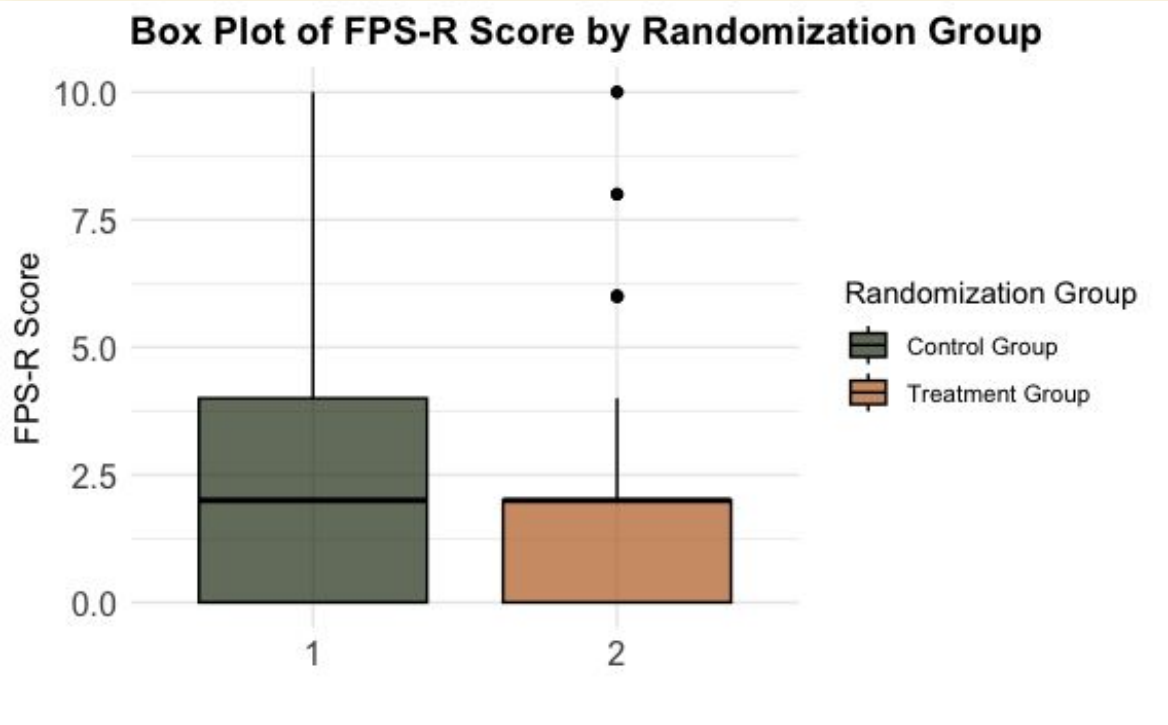
Data Explanation

- **FPS-R Scores (Pain Level)**
  - Patients rated their pain on the FPS-R scale from 0 (no pain) to 10 (worst pain possible)
- **Age** (5 - 16 years old)
- **Number of IV Attempts**
  - The number of attempts required to successfully insert the IV



Exploratory Data Analysis

Main Objective



Statistical Analysis

Main Objective

Main Objective: Ametop vs. Ametop + Vapocoolant Spray

- Two-sample T-test
  - H_0 : The mean FPS-R scores are the same for the two groups
  - H_a : The mean FPS-R scores are lower on the study group (Ametop + spray) than the control group (Ametop)

  - Normality assumption from CLT

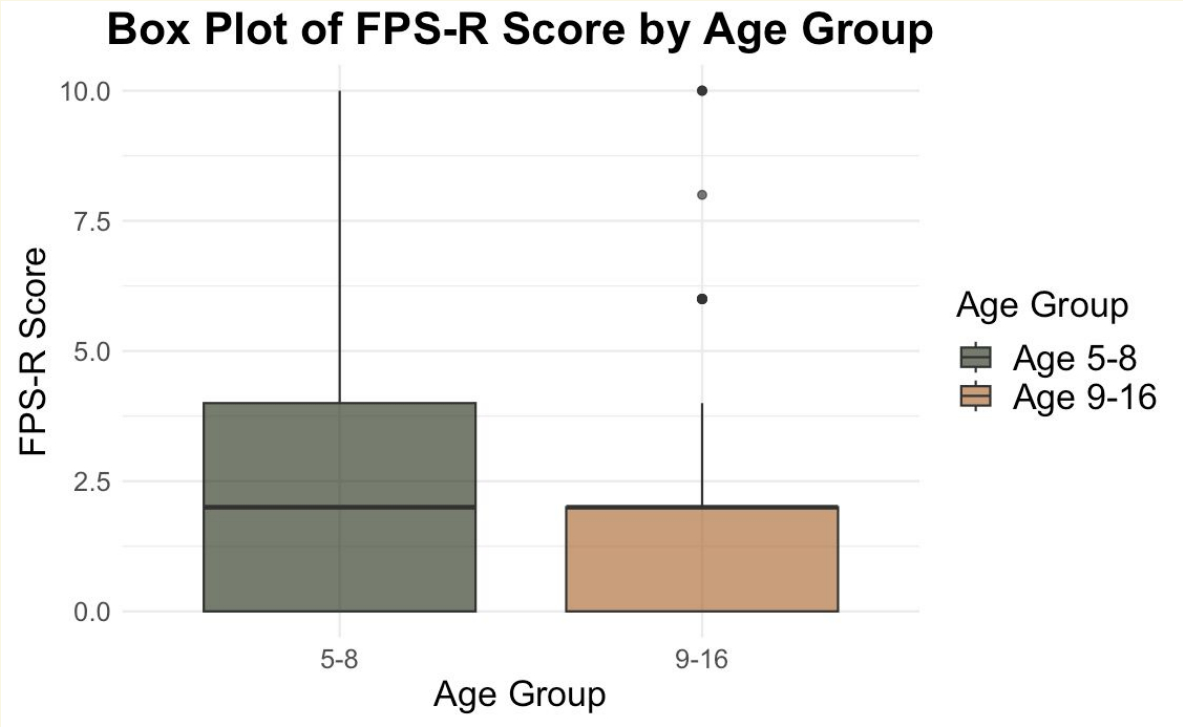
Result

Main Objective

P-value	Significance level	Conclusion
0.02258	0.05	The addition of vapocoolant spray may reduce discomfort in pediatric patients.

Exploratory Data Analysis

Secondary Objective: Age Influence on Pain Level



Exploratory Data Analysis

Secondary Objective: Age Influence on Pain Level

Age group	Count
5-8	114
9-16	109

Age Groupings:

1) Two groups to compare which age group where we should use the spray on. Using 3, 4, or more age group splits might unnecessarily complicate things.
2) We chose the age groups 5-8 and 9-16 because there are more young children than older ones in the study. Thus, this grouping would have roughly equal sample sizes.

Statistical Analysis

Secondary Objective: Age Influence on Pain Level

- Linear regression
  - H_0 : There is no effect of age, randomization group, or the interaction between age and randomization group on the FPS-R scores
  - H_a : There is an effect of age, randomization group, or the interaction between age and randomization group on the FPS-R scores

- Model's assumptions are verified through QQ plot and residual plot

Result

Secondary Objective: Age Influence on Pain Level

Age Group	Group	FPS-R Score Fitted Values
5-8	Control	3.129
5-8	Study	2.154
9-16	Control	2.125
9-16	Study	1.738

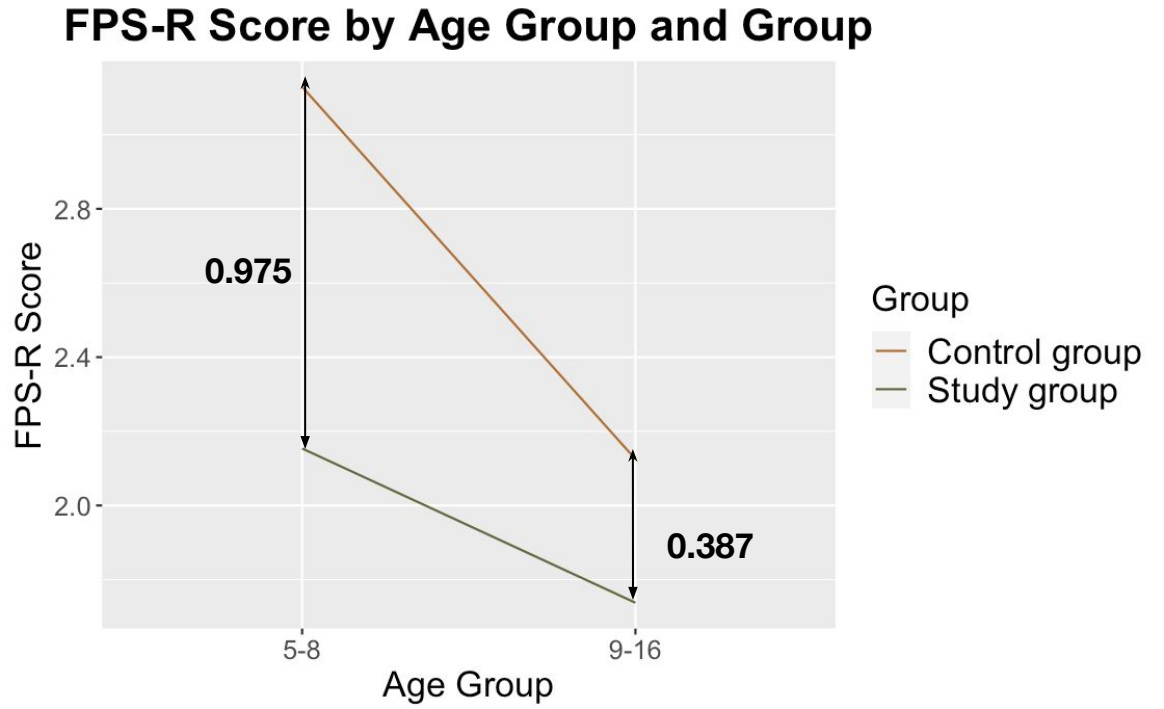
0.975

0.387

- The addition of spray decreases the pain level by 0.975 for age-group 5-8.
- The addition of spray decreases the pain level by 0.387 for age-group 9-16.

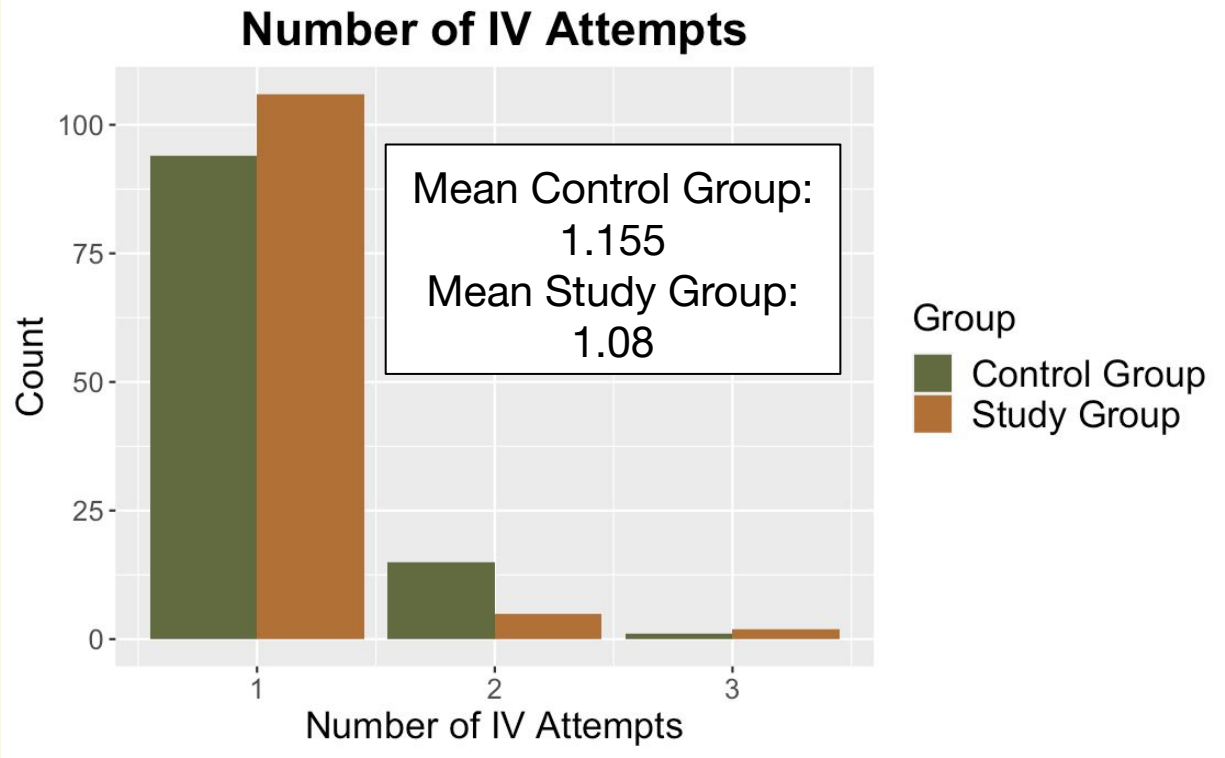
Result

Secondary Objective: Age Influence on Pain Level



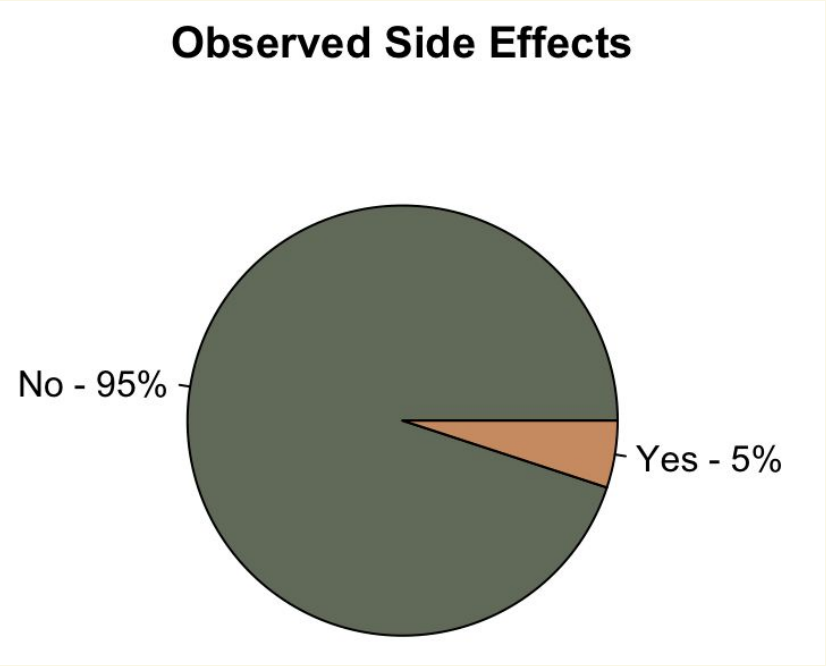
Result

Secondary Objective: Difference of number of IV attempts on control & study group



Result

Secondary Objective 2: Side effect



Side effects (Yes - 5%)

Category count

Category	Count
Pain	1
Puffiness	1
Redness only	6
Redness + Itching	4

Conclusion

Adding vapocoolant spray is beneficial

- Ametop + spray is likely more effective to reduce discomfort in pediatric patients than ametop alone.
- Ametop + spray is likely more effective to reduce discomfort in younger children (ages 5-8) than in older children (ages 9-16).
- Ametop + spray does not increase the number of IV attempts.

Ametop causes some mild side effects

- 5% of patients experienced side effects, which may indicate the need for another medical procedure for some individuals.

Reference

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