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Evaluation of pain-alleviating strategies during allergy shots (subcutaneous immunotherapy): a randomized controlled pilot study

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Key words

Allergic pediatric patients; Buzzy device; pain interventions; ShotBlocker; subcutaneous immunotherapy.

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Impact statement

Evaluated distraction devices and ethyl chloride spray for reducing needle pain during SCIT in children. No significant differences found, suggesting need for further research due to small sample size.

Summary

Background. *Subcutaneous immunotherapy (SCIT) is a potential disease-modifying therapy effective for treatment of various allergic disorders. Pain and fear are common concerns of children, which can pose stress and result in negative experiences. The purpose of this study was to evaluate and compare the effectiveness of three marketed distraction devices and ethyl chloride spray (a routinely used topical anesthetic agent for painful procedures), the current clinical standard of care in reducing the perception of needle pain during SCIT administration in children.* ***Methods.*** *40 children, aged 4-17 years, receiving SCIT with use of one of three alternative pain therapies or with standard practice were enrolled. Participants were randomly assigned to one of the pain-modifying interventions. The three interventional groups were ShotBlocker® (Bionix, Toledo, OH, USA), Buzzy® I (Pain Care Labs, Atlanta, GA, USA) (vibration only), and Buzzy® II (vibration with ice). Control group was ethyl chloride spray. The study consisted of two visits during SCIT administration process.* ***Results.*** *Of these 40 children, 12 received the ShotBlocker, 8 received the Buzzy I, 11 received the Buzzy II, and 9 received ethyl chloride spray (control group).* ***Conclusions.*** *There were no significant differences found between each of the distraction devices and between the control group. Type II error/false negative finding cannot be ruled out because of a small sample. Therefore, we cannot conclude that no true difference exists between each distraction device and the control group simply because of occurrence of a non-significant P-value in our study.* ***Study registration.*** *Protocol ID: 1353562; ClinicalTrials.gov ID: NCT04181632.*

Introduction

Allergic diseases have reached epidemic proportions globally, affecting nearly 30% of the world's population (1). Subcutaneous immunotherapy (SCIT) is a potentially disease-modifying therapy that is effective for the treatment of patients with allergic diseases (2). Studies in general have found that allergen-specific immunotherapy is more effective than the standard of care including pharmacotherapy, and SCIT remains the gold standard of treatment (3). Pain and swelling are common adverse reactions of SCIT and can affect its tolerability in many children (4). Needle procedure-related fear may result in increased avoidance behavior and attempts to eliminate any possible exposure to needles (5). Thus, receiving repeated injections could develop into negative experiences for both child and legal guardian during SCIT administration and possibly affect compliance.

To determine the relevancy of this issue, we reviewed the charts of 150 current SCIT patients in our pediatric clinic and found 141 of them use at least one pain-relieving intervention (95%). This led us to believe that most SCIT pediatric patients desire pain relief during SCIT injections.

The Buzzy® device (Pain Care Labs, Atlanta, GA, USA) and ShotBlocker® (Bionix, Toledo, OH, USA) are two non-pharmacological methods used during painful interventions (6) and for common needle-related medical procedures (4, 7). In these methods, according to the door control theory, the pain signals of the injection are blocked temporarily, and the "doors" leading to the central nervous system are closed (7). Studies and reviews evaluating pharmacological and nonpharmacological interventions for needle-related pain have increased considerably over the past decade (8); however, there are limited data on the comparative effectiveness in children receiving SCIT. The purpose of this study was to evaluate and compare these two marketed pain devices with ethyl chloride spray, a routinely used topical anesthetic agent for painful procedures, in reducing the perception of needle pain during SCIT administration in children.

Materials and methods

A randomized controlled pilot study included 40 participants aged 4 to 17 years presenting for SCIT administration in our clinic. The standardized dosage protocol outlined in the second and third updates of Allergen Immunotherapy: a Practice Parameter (9, 10) was used for environmental allergen and venom immunotherapy. As suggested in these updates, a consistent, uniform color-coded labeling system for dilutions was used. It consisted of the highest concentration (maintenance dose) labeled as a red vial, the next highest yellow, and then green and blue, respectively.

Patients were enrolled and randomly assigned to one of four color-coded study groups (three intervention/experimental groups and one comparison/control group). The study consisted of pain-reduction therapies received during one routine nurse visit for SCIT administration. This clinical trial was approved by our hospital's Institutional Review Board and conducted in accordance with the declaration of Helsinki.

Interventional groups

1. ShotBlocker #1-25 (red).
2. Buzzy I (vibration only) #26-50 (green).
3. Buzzy II (vibration with ice) #51-75 (blue).

Control group

4. Ethyl chloride/PainEase® spray (Gebauer Company, Cleveland, OH, USA) #76-100 (light blue).

Study procedures

Visit 1

Children aged 4 to 17 years presenting to the allergy clinic to receive SCIT were screened by the principal investigator or co-investigator for study inclusion and exclusion criteria. The investigator and the research coordinator provided the legal guardian and child with an overview of the study design, the risk and benefits assessment, and study requirements. Parents were advised that oral pain medication was an exclusion for the randomization visit. After obtaining legal guardian written consent and child assent, the child was considered enrolled in the study. A subject ID was assigned. A visible mark placed on the child's allergy injection chart indicated the child was ready to be randomized at their next routine allergy injection visit.

Inclusion criteria

- Children aged 4 to 17 years on SCIT.
- A minimum of three injections prior to enrollment at visit 1.
- Child accompanied by legal guardian.

Exclusion criteria

- Children with a known pain or sensory disorder.
- Developmental delay lacking necessary cognitive ability.
- Administration of any form of pain analgesic within 8 hours of randomization at visit 2.

Visit 2

The allergy nurse interviewed the legal guardian using a questionnaire that collected demographic, health, and treatment information. The principal investigator provided randomized subject assignments. Study staff were blinded to the envelopes containing the four group assignments that were coded by number and color. The subject was presented with a bag containing the envelopes and blindly selected one determining the distraction method to be utilized. The Wong-Baker FACES Pain Rating Scale is a validated tool utilized to assist in self-evaluation of pain in children aged 3 to 18 (11). The subject was introduced to the scale and asked to circle the face that most closely matched their current level of pre-injection pain.

Application of the distraction method

The nurse applied the assigned distraction method to the injection site per the manufacturer's guidelines before administering the first injection to the child. Immediately following the first SCIT injection, the child was asked to circle the face on the Wong-Baker FACES Pain Rating Scale that most closely matched their post-injection level of needle pain. The guardian circled the number on the Numeric Pain Rating Scale that most closely matched their perception of their child's post-injection needle pain level.

Data analysis

Quantitative component data collected and evaluated for this study included the following patient participant demographic information: age, race, and sex; randomized interventions used; diagnoses including allergic rhinitis, asthma, and atopic dermatitis; immunotherapy dose; antihistamine and pain medication

utilization; patient and parental pain scores; and any adverse reactions.

Quantitative component data collected for this study were entered into Microsoft Excel spreadsheets and analyzed using Excel functions. Target population demographic characteristics were analyzed using descriptive statistics by the principal investigator with the level of significance set at < 0.05.

All information collected as part of the evaluation of the impact of this study was aggregated data from the project participants and did not include any potential patient identifiers. Participant confidentiality was assured by coding participants using individual identification numbers for analysis activities occurring outside of the electronic health record. This information was stored in accordance with the policies and procedures of our organization's Institutional Review Board. The Excel files containing codified data without protected health information were stored in password-protected files at our hospital on a password-protected desktop computer in a locked office space accessible only by the principal investigator and study designees. The risks to patients participating in this project were no different from the risks of patients receiving standard care.

Continuous variables were summarized as median (range) and mean (standard deviation), while categorical variables were reported as frequency (percentage). Unadjusted comparisons of patient characteristics and outcomes between each distraction device and the control group were made using a Kruskal-Wallis rank sum test (continuous and ordinal variables) or Fisher's exact test (categorical variables). P-values less than 0.05 were considered statistically significant, and all statistical tests were two-sided. Statistical analyses were performed using R Statistical Software (version 4.0.3; R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 40 children who received SCIT were included in this randomized controlled pilot study. Of these 40 children, 12 received the ShotBlocker, 8 received the Buzzy I, 11 received the Buzzy II, and 9 received ethyl chloride spray (control group). Both the overall needle pain rating by the children after their allergy injection and the overall parental perception of needle pain are displayed by each of the four interventions (**figure 1**). The overall summary of patient characteristics is shown in **table I**. The median age overall was 13 years, and 62% of the patients were male.

Table II shows the comparison of patient characteristics between the ShotBlocker group and the control group. Similar-

Figure 1 *- Patient allergy shot pain scores.*

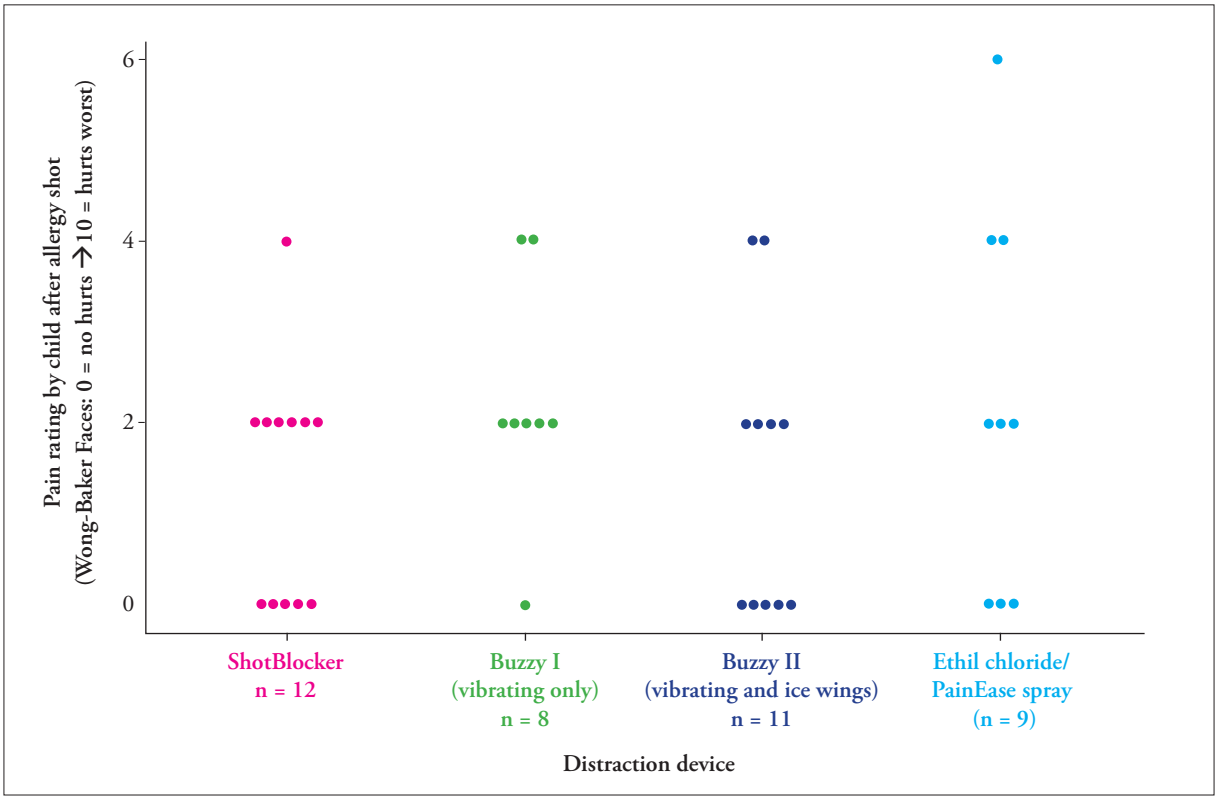

Table I *- Patient characteristics overall.*

Characteristic	Overall (n = 40)
Distraction device	
ShotBlocker	12 (30%)
Buzzy I (vibration only)	8 (20%)
Buzzy II (vibration and ice wings)	11 (28%)
Ethyl chloride/PainEase spray	9 (22%)
Age (years)	
Median (range)	13 (7-19)
Sex	
Male	25 (62%)
Female	15 (38%)
Race	
White	22 (55%)
Black	7 (18%)
Hispanic	6 (15%)
Mixed/other	5 (12%)
Asthma	11 (28%)
Atopic dermatitis	5 (12%)
Length of time receiving allergy shots (years)	
< 1 year	8 (20%)
1-2 years	19 (48%)
3-5 years	13 (32%)
Number of allergy shots received	
1-2	15 (38%)
3-4	20 (50%)
≥ 5	5 (12%)
Dosage for allergy shot (mL)	
< 0.5	15 (38%)
0.5	20 (50%)
> 0.5	5 (12%)
Type of allergy shot	
Environment	32 (80%)
Venom	8 (20%)
Has had symptoms after allergy shot	14 (35%)
Reaction type	
None	26 (65%)
Local	6 (15%)
Systemic	8 (20%)
Antihistamines	20 (50%)

ly, the comparison between the Buzzy I group and the control group is shown in **table III**, and the comparison between the Buzzy II group and the control group is shown in **table IV**. There were no significant differences found between any of the distraction devices and the control for age, sex, race, asthma, atopic dermatitis, length of time receiving allergy shots, number of allergy shots, vial color, allergy shot dosage, type of allergy shot, symptoms after allergy shot, reaction type, and antihistamine use.

Table V displays the pain outcomes comparison between the ShotBlocker and control groups, the Buzzy I and control groups, and the Buzzy II and control groups. While the mean pain ratings by both the children and the legal guardians were lower in two of the intervention groups (ShotBlocker and Buzzy II) compared with the standard care group (ethyl chloride spray), these differences were not significant (all $p > 0.34$).

Discussion and conclusions

Subcutaneous immunotherapy is an effective disease-modifying therapy for the treatment of allergic diseases. The injections may cause pain that could interfere with administration and possible adherence. This pilot study compared two distraction devices with a topical analgesic control group. To provide adequate power to compare devices, the goal was to enroll 100 children. The COVID-19 pandemic limited enrollment. Of the 48 patients enrolled, data were collected on 40 because of non-completion of visit 2. Our inclusion criteria required a minimum of three previous injection visits. Since the average length of SCIT for the enrollees was longer than 1 year, our cohort studied patients with established compliance. This pilot study suggested that the ShotBlocker resulted in the lowest mean child-reported pain score of 1.33, followed closely by the Buzzy II with a mean of 1.45 compared with 2.22 in the control group and 2.25 in the Buzzy I group. The same pattern was seen in the guardian scores.

Finally, we conducted a brief literature review of articles published on related topics to compare the results of this study with those existing in the medical literature (12-18). Although we identified several studies evaluating the pain-alleviating strategies used by various intramuscular injections, most of the studies (conducted in the last decade) compared with ours showed some degree of improvement in pain tolerance with the use of various distraction devices including Buzzy. We believe that the difference in their outcome *versus* ours was related to the following factors: 1) most of these studies examined the intramuscular injection *versus* the subcutaneous route in our study; 2) most of the reviewed studies were done on children receiving one to two immunizations *versus* a minimum of three subcutaneous immunotherapy injections; 3) although glycerin-related discomfort, burning, and pain sensation were not confounding factors in our study because of the similar glycerin concentration in all

injections, this could be a differentiating factor in comparison with non-glycerinated immunization injections.

Study limitations

First, considering the small sample size of our study, we cannot conclude that no true difference exists between each distraction device and the control group simply because of the occurrence of a non-significant P-value in our study. A type II error/false negative finding cannot be ruled out because of a small sample. Second, although our minimum age criterion for enrollment was 4 years, we were unable to enroll enough younger subjects because of parental/subject refusal to proceed because

Table II *- Patient characteristics by distraction device (ShotBlocker vs standard care).*

Characteristic	Ethyl chloride/PainEase spray (n = 9)	ShotBlocker (n = 12)	P-value
Age (years)			0.91
Median (range)	14 (8-17)	14 (8-19)	
Sex			0.66
Male	6 (67%)	6 (50%)	
Female	3 (33%)	6 (50%)	
Race			1.00
White	5 (56%)	6 (50%)	
Black	2 (22%)	3 (25%)	
Hispanic	1 (11%)	2 (17%)	
Mixed/other	1 (11%)	1 (8%)	
Asthma	2 (22%)	4 (33%)	0.66
Atopic dermatitis	1 (11%)	1 (8%)	1.00
Length of time receiving allergy shots (years)			0.056
< 1 year	2 (22%)	2 (17%)	
1-2 years	0 (0%)	8 (67%)	
3-5 years	7 (78%)	2 (17%)	
Number of allergy shots			0.90
1-2	4 (44%)	5 (42%)	
3-4	5 (56%)	7 (58%)	
Dosage for allergy shot (mL)			0.97
< 0.5	4 (44%)	4 (33%)	
0.5	3 (33%)	7 (58%)	
> 0.5	2 (22%)	1 (8%)	
Type of allergy shot			0.61
Environment	6 (67%)	10 (83%)	
Venom	3 (33%)	2 (17%)	
Has had symptoms after allergy shot	2 (22%)	4 (33%)	0.66
Reaction type			1.00
None	7 (78%)	8 (67%)	
Local	1 (11%)	2 (17%)	
Systemic	1 (11%)	2 (17%)	
Antihistamines	5 (56%)	6 (50%)	1.00

they did not want any pain-relieving methods or devices other than "what they were used to," *i.e.*, ethyl chloride spray. This led us to limit our subjects to those who were willing to accept all forms of methods/devices resulting in decreased sample size in the younger population.

In conclusion, to our knowledge, this is the first study that compared the efficacy of these pain-alleviating devices with ethyl chloride spray for children receiving SCIT. The data were inconclusive, so additional data collection including larger numbers of patients and perhaps an improved study design may be warranted. It may

Table III *- Patient characteristics by distraction device (Buzzy I vs standard care).*

Characteristic	Ethyl chloride/PainEase spray (n = 9)	Buzzy I (vibration only) (n = 8)	P-value
Age (years)			0.19
Median (range)	14 (8-17)	12 (7-14)	
Sex			1.00
Male	6 (67%)	5 (62%)	
Female	3 (33%)	3 (38%)	
Race			1.00
White	5 (56%)	4 (50%)	
Black	2 (22%)	2 (25%)	
Hispanic	1 (11%)	2 (25%)	
Mixed/other	1 (11%)	0 (0%)	
Asthma	2 (22%)	3 (38%)	0.62
Atopic dermatitis	1 (11%)	2 (25%)	0.58
Length of time receiving allergy shots (years)			0.055
< 1 year	2 (22%)	2 (25%)	
1-2 years	0 (0%)	5 (62%)	
3-5 years	7 (78%)	1 (12%)	
Number of allergy shots			0.13
1-2	4 (44%)	2 (25%)	
3-4	5 (56%)	3 (38%)	
≥ 5	0 (0%)	3 (38%)	
Dosage for allergy shot (mL)			0.80
< 0.5	4 (44%)	3 (38%)	
0.5	3 (33%)	3 (38%)	
> 0.5	2 (22%)	2 (25%)	
Type of allergy shot			1.00
Environment	6 (67%)	6 (75%)	
Venom	3 (33%)	2 (25%)	
Has had symptoms after allergy shot	2 (22%)	4 (50%)	0.34
Reaction type			0.49
None	7 (78%)	4 (50%)	
Local	1 (11%)	2 (25%)	
Systemic	1 (11%)	2 (25%)	
Antihistamines	5 (56%)	4 (50%)	1.00

Table IV *- Patient characteristics by distraction device (Buzzy II vs standard care).*

Characteristic	Ethyl chloride/PainEase spray (n = 9)	Buzzy II (vibration and ice wings) (n = 11)	P-value
Age (years)			0.82
Median (range)	14 (8-17)	13 (7-17)	
Sex			1.00
Male	6 (67%)	8 (73%)	
Female	3 (33%)	3 (27%)	
Race			0.62
White	5 (56%)	7 (64%)	
Black	2 (22%)	0 (0%)	
Hispanic	1 (11%)	1 (9%)	
Mixed/other	1 (11%)	3 (27%)	
Asthma	2 (22%)	2 (18%)	1.00
Atopic dermatitis	1 (11%)	1 (9%)	1.00
Length of time receiving allergy shots (years)			0.12
< 1 year	2 (22%)	2 (18%)	
1-2 years	0 (0%)	6 (55%)	
3-5 years	7 (78%)	3 (27%)	
Number of allergy shots			0.45
1-2	4 (44%)	4 (36%)	
3-4	5 (56%)	5 (45%)	
≥ 5	0 (0%)	2 (18%)	
Dosage for allergy shot (mL)			0.80
< 0.5	4 (44%)	4 (36%)	
0.5	3 (33%)	7 (64%)	
> 0.5	2 (22%)	0 (0%)	
Type of allergy shot			0.28
Environment	6 (67%)	10 (91%)	
Venom	3 (33%)	1 (9%)	
Has had symptoms after allergy shot	2 (22%)	4 (36%)	0.64
Reaction type			0.78
None	7 (78%)	7 (64%)	
Local	1 (11%)	1 (9%)	
Systemic	1 (11%)	3 (27%)	
Antihistamines	5 (56%)	5 (45%)	1.00

Table V *- Patient pain outcomes by distraction device.*

Pain outcome	Ethyl chloride/PainEase spray (n = 9)	ShotBlocker (n = 12)	P-value
Wong-Baker pain rating by child after shot			0.34
Median (range)	2 (0-6)	2 (0-4)	
Mean (SD)	2.22 (2.11)	1.33 (1.30)	
Parental perception of pain rating			0.53
Median (range)	2 (0-4)	1 (0-4)	
Mean (SD)	1.44 (1.33)	1.17 (1.19)	
Pain outcome	**Ethyl chloride/PainEase spray (n = 9)**	**Buzzy I (vibration only) (n = 8)**	**P-value**
Wong-Baker pain rating by child after shot			0.84
Median (range)	2 (0-6)	2 (0-4)	
Mean (SD)	2.22 (2.11)	2.25 (1.28)	
Parental perception of pain rating			0.48
Median (range)	2 (0-4)	2 (0-4)	
Mean (SD)	1.44 (1.33)	1.88 (1.46)	
Pain outcome	**Ethyl chloride/PainEase spray (n = 9)**	**Buzzy II (vibration and ice wings) (n = 11)**	**P-value**
Wong-Baker pain rating by child after shot			0.42
Median (range)	2 (0-6)	2 (0-4)	
Mean (SD)	2.22 (2.11)	1.45 (1.57)	
Parental perception of pain rating			0.63
Median (range)	2 (0-4)	1 (0-5)	
Mean (SD)	1.44 (1.33)	1.27 (1.49)	

be of value to compare the devices with a non-treatment control group, if participants were willing to refrain from pain relief. The data reported above indicate that the use of the ShotBlocker lowered pain perception in children compared with the other interventions. However, ShotBlocker, Buzzy I, and Buzzy II were non-inferior to ethyl chloride. Areas of additional study include the effect of allergen extract concentration and duration of SCIT on the efficacy of these distraction devices. Regardless, all studied interventions may be useful in counseling patients and families prior to and during SCIT administration for pain relief.

Fundings

None.

Contributions

EY: conceptualization, investigation, methodology, writing - review & editing. JP: data curation, investigation, methodology, project administration, supervision, writing - original draft. TD, KG, KW: data curation, investigation, methodology.

Conflict of interests

The authors declare that they have no conflict of interests.

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