SAR Journal of Dentistry, Oral Surgery and Medicine

Abbreviated Key Title: *SAR J Dent Oral Surg Med*
Home page: http://sarmedjournals.com/

ISSN 2707-7772 (P)

Original Research Article

Interpreting the Meaning of Pain Severity Scores in Children Using Buzzy and Distracting Cards- A Randomized Clinical Trial

Dr. Palagari Lakshmi Prasanna[1], Dr. Peddengatagari Suresh[2], Dr. K. Srinivasan MDS[3*]

[1]Assistant Professor, Department of Pedodontics and Preventive Dentistry, Govt Dental College and Hospital (RIMS), Kadappa, AP State, India
[2]Professor and HOD, Department of Periodontics, Govt Dental College and Hospital (RIMS), Kadappa, AP State, India
[3]Associate Professor, Department of Pedodontics and Preventive Dentistry, CKS Theja Institute of Dental Science and Research, Tirupati, India

***Corresponding Author**
Dr. K. Srinivasan

Article History: | Received: 11.03.2021 | Accepted: 16.04.2021 | Published: 30.04.2021|

Abstract: ***Context*:** Pain is the most common cause of needle Phobia. To overcome this, many advanced injection techniques have been implemented. The most recent and advanced technique was using a small vibrating device to the conventional injection technique. In the Buzzy device, a noninvasive device is used in children that combine vibration and cold modalities to block pain sensation. ***Objective*:** The present study investigates the efficacy of three interventions methods (Buzzy, distracting cards and magic glove) in managing pain and fear in children during the operative procedure. ***Design*:** A prospective clinical study. ***Setting*:** Private hospital and Private dental clinic. ***Subjects*:** The purposive sample composed of (n=180) participants aged six to14 years and their parents. The study's participants were randomly assigned to two groups. The Intervention Group included (n=90). Among them established pain distraction (Buzzy more Distraction cards group (n=45) and distraction cards group (n=45) by the researchers. On the other hand, the control group was included in the same number (n=90), and no strategy was used. ***Tools:*** The pain levels were evaluated with the *Numerical Pain Rating Scale.* ***Statistical Analysis:*** The obtained data were compared and statistically analyzed using SPSS version 22. The following descriptive analysis, like Student's t-test and ANOVA (Univariate Analysis of Variance), was applied to determine the significant difference between them. ***Results*:** Pain and fear were similar in the two groups in which a pain management strategy was applied. Pain and fear were more significant when no strategy was adopted. ***Conclusion*:** The study results suggest that the Buzzy more Distraction cards method effectively decreased children's pain levels than the control group, according to observer-report and parent-report.

Keywords: Buzzy device; Distraction card; Children; Fear; pain measurement.

INTRODUCTION

According to the American Pain Society, pain represents the fifth vital sign; therefore, evaluating its intensity should be part of patient assessment and documentation [1].

Stedman's medical dictionary defines pain1 as 'an unpleasant sensation associated with actual or potential tissue damage and mediated by specific nerve fibres to the brain, where its conscious appreciation may be modified by various factors [2].

Medical and procedures induce anxiety, fear, and behavioural distress in children and their families, further intensifying their pain and interfering with the procedure [3].

The cannula's Insertion is often complicated in children who are afraid of needles or have a bad experience; fear activates the sympathetic nervous system, thereby provoking peripheral vasoconstriction [4].

Adequate local anaesthesia is the most critical pillar upon which modern dentistry stands [5].

Injections of local anaesthesia are one of the effective methods to reduce pain. Nevertheless, injection of local anaesthetic itself is an excellent source of patient fear [6].

Pharmacologic and non-pharmacologic methods are used for pain management in children. Non-pharmacologic methods are noninvasive and inexpensive methods [7].

When selecting the non-pharmacologic methods, it is required to consider a child's age, cognitive competence, culture, behavioural factors, coping skills, personal differences, and pain type [7].

Buzzy® and ShotBlocker® have been reported to be two valuable devices in reducing pain [8].

Buzzy, which is composed of a bee-shaped gadget producing vibrations and cooling through freezable wings. The effect of Buzzy is based on the gate-control theory discovered by Melzack and Wall in 1965, which suggests that barriers can control the flow of pain information employing the activation of nociceptive fibres [9].

In this case, the purpose of the cold and the vibrations is to block pain signals ' transmission.

The distraction methods' primary objective is to return child focus from frightening circumstances that increase the child's anxiety level during management to non-frightening and preferably pleasant objects or events [10].

Numerous tools used to measure pain are described in the literature, such as questionnaires and physiological responses. In recent years, pain scales have gained a more significant proportion in research and clinical settings, such as the Visual Analogue Scale (VAS), Face Pain Scale (FPS), Numerical Rating Scale (NRS), and Verbal Rating Scale (VRS) [11].

In the present study, the pain levels were evaluated using the Numerical Pain Rating Scale [15, 16].

The numerical rating scale (NRS) is one of the simplest and most frequently used instruments in clinical practice to measure children's pain intensity in children eight years and older.

Several studies have described promising non-pharmacologic acute pain control in children, whether the present technique works for every child, and there is a paucity of data in the literature for such a pain-relieving technique that we have used in the study. Considering these aspects, we felt the need to conduct this study.

AIMS

Evaluate the Buzzy System's efficacy in reducing pain during an operative procedure in children compared to routine technique (magic gloves) used in the ambulatory where the study took place.

Study Objectives

1. Primary objective.

a. To study nonpharmacological measures' effectiveness (buzzy device and distraction card) to reduce pain and anxiety in children between 6 and 14 years old.

2. Specific Objectives.

a. To describe the socio-demographic characteristics of the study population.

b. Evaluate the parent/caregiver's satisfaction concerning the Buzzy System's distractive techniques and their willingness to use them again for future procedures.

RESEARCH METHODOLOGY

Research Hypotheses

It was hypothesized that; the buzzy device with distraction cards will have a positive effect on reducing pain and increasing parent's satisfaction during venipuncture and dental operative procedure in the respondent.

Research design: This study was a randomized, cross- over, single-blinded design.

Trial design and study setting and Study Period: The present study was conducted at two different settings, a private hospital and a private dental clinic. The study period was from Dec 2020 to Jan 2021.

Research methodology: This study protocol was developed per the Standard Protocol Items: Recommendations for Interventional Trials recommendations [13].

Subjects: The purposive sample composed of (n=180) participants and their parents. The study's participants were randomly assigned to two groups. The Intervention Group included 90 participants. The researchers established pain distraction (Buzzy more Distraction cards group) 45 participants and distraction cards group 45 participants. On the other hand, the control group was included in the same number (n=90).

Inclusion Criteria

a. Children aged between 6 years old and 14 years old [21].
b. Children required a venipuncture procedure.
c. Children required infiltration LA for the dental treatment procedure. At least one caregiver/parent distracted the child with the distraction cards (in the Intervention Group).

Exclusion Criteria

a. A break or abrasion on the skin or nerve damage or limited sensation where the needle-related procedure will be performed.
b. Absence of a caregiver/parent during the procedure
c. Children unable to quantify or express their pain (e.g., severe cognitive deficit).
d. Lack of parental consent.
e. Participants use an analgesic within the last 6 hours.
f. Participants with known behavioural management problems, previous experience with Buzzy®, anaesthetic or similar creams, sedated, hemodynamically unstable, developmental delay, or pathologies.

Sample Size Determination

Based on the previous studies [14] and using pain as the primary outcome variable, an alpha level of 5% for a power of 90%, and a type I error of 0.05, it was necessary to compare 21 children per group. Anticipating that some children would probably drop out of the study increased the sample size by 25%. Therefore, the total number of children enrolled was 45 patients per group using the following formula [15]:

$$n = \frac{(Z_\alpha + Z_\beta)^2 \times \sigma^2}{d^2}$$

Where?
Z- a constant
Z_α - set by convention according to the accepted α error and whether it is a one-sided or two-sided effect.
Z_β)- set by convention according to the power of the study.
σ^2- standard deviation (estimated)
d^2- the difference in the effect of two interventions which is required (estimated effect size).

Tools of data collection:

Three tools were developed for collecting data.

Tool I: Structured Interview Schedule: It was developed by the research team after reviewing the related literature and collecting data related to the parents and children.

This tool included Two parts:

- Part A: social-demographic Variables of Respondents such as Age (years), Gender, Birth order and Operative procedures (Table-1).
- Part B: social-demographic Variables of Parents of Studied groups of buzzy intervention Respondents such as age (years), Caregiver attending the procedure, Parents' educational level and Residence (Table 2 & 3).

Tool II: Criterion measured

The criterion measures used in the study was the level of pain measured by the Numerical rating scale (NRS); (for Experimental Group and control group). Adopted from Hockenberry and Wilson [15] and Song et al., [16].

The Numeric Rating Scale (NRS-11) is an 11-point scale for patient self-reporting of pain. It is based solely on the ability to perform daily living activities (ADLs) and can be used for adults and children ten years old or older (Table-4).

It consisted of a line divided by numbered points ranged from (0-10) consisting of six cartoon faces that range from a neutral expression (0-happy/no pain) to a screaming face (10 hurts more than).

Rating Pain Level: 0: No Pain;1-3: Mild Pain (nagging, annoying, interfering little with ADLs);4-6: Moderate Pain (interferes significantly with ADLs);7-10: Severe Pain (disabling; unable to perform ADLs).

This scale was selected because it is more commonly used in clinical practice and is a reliable and valid pain intensity measure.

Tool III: Parents` satisfaction

(Likert-scale Rating): Adapted from Friedel et al., [18] it was used to assess parents' satisfaction regarding the cold device (Buzzy System), this scale formed of 4 variables (Table-3):

1. My child was comforted using the buzzy system during the procedure.
2. It was a positive experience.
3. I think the buzzy system is easy to use.
4. I would like to use the buzzy system in the future for tests carried out on my son/daughter. The Likert scale consists of 4 statements and was based on five points 1:no, 2: probably not, 3: do not know, 4: yes, 5: definitely.

Study instrument (Buzzy system) [17]: used in this study, associates three different components and modulations of pain (Figure-1):

a. Cryotherapy effect: by a changeable cold liquid device that the bee-shaped device.

b. Vibration: a mechanical effect formed by applying a bee-shaped device a few centimetres from the needle entry point.
c. Distraction: reasoning method: distracting the child with (distraction cards) (Figure-2).

Validity and reliability of study tools

Content validity was ascertained by a group of experts, three Dental and Medical Specialties, respectively. Their opinions were elicited regarding the tools format layout, consistency, scoring system. Modifications for the tools were done according to the experts' judgment on the clarity of sentences, appropriateness of the content, and items' sequence. The experts were agreed on the intervention but recommended minor language skills changes that would make the information clearer. Reliability of all items of the tools was done. The reliability test was established by using the Cronbach alpha to assess internal consistency construct validity. Cronbach alpha r= 0.86.

Ethical Considerations: All children and their parents were informed about the study's aim, its benefits to obtain their acceptance to participate. The researchers informed them that the study's participation is voluntary; they have the right to withdraw from the study at any time, without giving any reason, and their responses would be held confidentially. The secrecy and privacy of all the data will be assured. Written or verbal consent were obtained from those who welcome to participate in the study.

A pilot Study: Power analysis was approved on 10% of the total sample (n=180) children and their parent to test the study tools' clearness and applicability as well as an approximation of the time needed to complete each study tool. Those who contributed to the pilot study were later excluded in the study as there were no modifications to the tools.

Procedure [19, 20]

After obtaining the consent, the study's aim was explained to children and their parents under study. The researchers started to collect data from the children and their parent in the selected setting.

Each child was interviewed individually to determine his level of pain during the treatment procedure. The age group's choice was based on scientific literature, which asserts that children in this age range were incredibly responsive to distraction technique [21].

The procedure was explained for the children in both groups. In one of the Intervention Group, a combination of a Buzzy® with directed distraction (BDG) method of reducing pain opted during the Invasive procedure.

In the other, the Intervention Group, children were involved in distraction cards (DG) techniques during the Invasive procedure. The Buzzy® is a device in the shape of a bee whose body vibrates with cold gel wings (cooled in a freezer).

The researcher placed the buzzy with the frozen wings on children's skin by attaching it to the arm or manually holding it in place, as close as possible above the needle insertion site (about 5-10 cm above the insertion site).

Children were requested to focus on the sensations of the-Buzzy rather than look at the needle insertion procedure. A 30 to 60 s rest was selected between the fixing of the device before the procedure. The buzzy device remained on till the end of the procedure. Finally, the researchers assessed pain using the appropriate pain and anxiety assessment tool, which took 3 to 5 minutes.

The parents were asked to interact with their children using distraction cards, a small number of cartoon images. The parents' evaluated was the level of satisfaction with the distraction device method of pain control in the child and their desire to use it again in the future, with the appropriate parent's satisfaction assessment tool.

The buzzy component contains 20 g of ice and can be removed and kept in the freezer between procedures. Each pair of wings can stay frozen for about 10 min at room temperature and could be used up to 10 times.

Distraction Cards [19]

The distraction cards consisted of 5 x8 cm graphic cards with various pictures and shapes. The children were allowed to examine the cards, and then the researcher asked the children what they could see on the cards. Distraction with the cards began immediately before the invasive procedure and continued until the procedure had been completed.

Standard Care (Control Group) [19]:

In the control group in the study setting, no type of distraction or device (CG) were implemented. The-magic glove technique is traditionally used. The children in the control group were permitted to keep their family nearby. The Invasive routine procedure was applied, and the level of pain in each child was evaluated using appropriate pain and anxiety assessment tools.

Before starting the procedure, the researcher gently rubbed the area where the needle was positioned to free it from the pain. The child, imagining that the researcher is placing the glove and feeling the massage's influence on his site and his body, would feel certain numbness in the same area where the sensitivity is lowered.

Statistical Design

Analysis of data was done per the objectives. Statistical analysis was performed using SPSS version 20.0 software.

Descriptive statistics were performed for sample characteristics calculating (percentage, mean and standard deviation).

The inferential statistics calculating (analysis of variance ANOVA (F) and independent t-test) was performed to compare groups in categorical variables.

When the p-value was less than 0.05, it was considered significant, and less than 0.001 was considered highly significant.

RESULTS

Demographics and clinical characteristics

A total of 200 children were enrolled between December 2020 and January 2021, Of the 200 children enrolled, 180 children and their caregivers were approached during the study period. Among them Parent did not give consent: (n=5); Not meeting inclusive criteria: (n=12).

Protocol violation: (n=3) were excluded as they displayed a significantly altered emotional state when the operative procedures could compromise a valid expression of the actual perceived pain.

Enrolled children were subdivided into two groups of 90 children in the Intervention Group and 90 in the control group.

Procedural pain scores among study groups were presented in table 1-5. The pain level was evaluated based on observer report and parent report and. The pain levels of children showed statistically significant.

Table-1 illustrated that the age of children ranged from 6 years to 14 years, the major ranged from 4 < 8 were 36%(n=33) of the experimental group and 51.1% (n=46) control group.

As regards gender, for both the experimental and control groups, it was found that45% (n=41) and 56.6% (n=51) were females, compared to 54.4% (n=49) and 43.3% (n=39) being males, respectively.

Less than half, 47.7% (n=43), 52.2% (n=47) of children were second order for both the experimental and control groups, respectively.

Regarding the reason for venipuncture 46.1% (n=83) and 53.8% (n=97) of children for Dental procedure.

Table-2 illustrated that parents' mean age was 34.1 ± 8.45 years in the experimental group compared to 37.3 ± 8.82 years in the control group.

Concerning Caregiver attending the procedure, for both groups, it was found that 45% (n=41) and 46.6% (n=42) were mothers with a non-significance difference (P>0.05) between the two groups.

Regarding parents' educational level 45.5% (n=41) and 34.4% (n=31) of parents in experimental and control groups had secondary education, respectively. More than half, 53% (n=96) of parents live in a rural area while (n=84) 46.6%of parents live in an urban area with a significant difference (p< 0.0001) between the two groups regions.

Table-3 illustrated the Caregivers' Satisfaction Questionnaire for the Buzzy System. 20% (n=18) of parents said they would reuse the Buzzy System in the future for tests done. 1% (n=1) negative opinions were expressed for any of the questions regarding the Buzzy System.

Numerical rating pain scale

Table-4 illustrated the study population's distribution according to projective scales (FAPS and MFAS) during the invasive procedure.

With FAPS, the distribution was uniform for “fearful” and “not fearful” in both phases were Statistics significant. (Wilcoxon signed ranks test, Z = 8.43, p< 0.0001 (HS)

However, with MFAS, the percentage of children with "anxiety scales" during the procedure phase was statistically significant. {Wilcoxon signed ranks test, Z = 9.18, p< 0.0001 (HS)}.

Table-5 and Graph-1 illustrated the Numerical rating pain scale.

In the intervention group, most of the children, 13.8% (n=25), described the pain score '0', which refers to 'no pain'. Only 15 children expressed a pain score of '10', which refers to 'very much pain' in the intervention group.

In the control group, only 2.2% (n=4) children (small group) described pain score '0', which refers to 'no pain'. The second majority of the group, 17.2% (n=31), responded pain score of '10', which refers to 'very much pain'.

As shown in Table-5, there were significantly lower pain scores in the intervention group than in the control group. Table-5 showed that there was an enormously significant (p< 0.0001 HS).

Table-1: Social-demographic Variables of Respondents.

Individual scenario.								
Variables		**Treatment group**				**ANOVA**		
		Intervention Group n=90 (50%)		**Control Group n=90 (50%)**	**Frequency n=180 (100%)**	**Mean ± SD Comparisons**	**Z-score Comparisons**	**Inferential Statistics**
		BDG n=45 (25%)	**DG n=45 (25%)**					
Total no of respondents		180 (100%)						
Age (years).	**6-8 yrs.**	16 (35.5%)	17 (37.7%)	46 (51.1%)	79 (43.8%)	20 ± 10.12	15.81	**p< 0.0001 HS***
	9-11 yrs.	14 (31.1%)	16 (35.5%)	28 (31.1%)	58 (32.2%)			
	12-14 yrs.	15 (33.3%)	12 (26.6%)	16 (17.7%)	43 (23.8%)			
Gender.	**Male.**	26 (57.7%)	23 (51.1%)	39 (43.3%)	88 (48.8%)	30 ± 11.34	13.22	**p< 0.0001 HS***
	Female.	19 (42.2%)	22 (48.8%)	51 (56.6%)	92 (51%)			
Birth order.	**First.**	18 (40%)	19 (42.2%)	43 (47.7%)	80 (44.4%)	30 ± 11.16	13.20	**p< 0.0001 HS***
	Second.	27 (60%)	26 (57.7%)	47 (52.2%)	100 (55.5%)			
Operative procedures.	**Venipuncture.**	19 (42.2%)	20 (44.4%)	44 (48.8%)	83 (46.1%)	30 ± 10.90	13.76	**p< 0.0001 HS***
	Dental procedure.	26 (57.7%)	25 (55.5%)	46 (51.1%)	97 (53.8%)			

Citation:

Volkan Susam, Marie Friedel, Patrizia Basile, Paola Ferri, Loris Bonetti. Efficacy of the Buzzy System for pain relief during venipuncture in children: a randomized controlled trial. Acta Biomed for Health Professions 2018;89(S.6):6-16.

Significance level p< 0.0001, *Significant; HS: Highly significant.

BDG: Buzzy more Distraction cards group.
DG: Distraction cards group.
CG: Control Group.

Table-2: Social-demographic Variables of Parents of Studied groups of buzzy intervention Respondents

Individual scenario.								
Variables		**Treatment group**				**ANOVA**		
		Intervention Group n=90 (50%)		**Control Group n=90 (50%)**	**Frequency n=180 (100%)**	**Mean ± SD Comparisons**	**Z-score Comparisons**	**Inferential Statistics**
		BDG n=45 (25%)	**DG n=45 (25%)**					
Total no of respondents		**180 (100%)**						
Age (years).	**20-30 yrs.**	14 (31.1%)	13 (28.8%)	28 (31.1%)	55 (30.5%)	20 ± 8.35	19.16	p< 0.0001 HS*
	30-40 yrs.	21 (46.6%)	20 (44.4%)	37 (41.1%)	78 (43.3%)			
	40-50 yrs.	10	12	25	47			

		(22.2%)	(26.6%)	(27.7%)	(26.1%)			
Caregiver attending the procedure.	**Mother.**	23 (51.1%)	18 (40%)	42 (46.6%)	83 (46.1%)	20 ± 9.87	16.21	**p< 0.0001 HS***
	Father.	8 (17.7%)	11 (24.4%)	18 (20%)	37 (20.5%)			
	Grandparents.	14 (31.1%)	16 (35.5%)	30 (33.3%)	60 (33.3%)			
Parents' educational level.	**Illiterate.**	4 (8.8%)	5 (11.1%)	19 (21.1%)	28 (15.5%)	15 ± 7.86	20.99	**p< 0.0001 HS***
	Primary.	10 (22.2%)	8 (17.7%)	16 (17.7%)	34 (18.8%)			
	Secondary.	20 (44.4%)	21 (46.6%)	31 (34.4%)	72 (40%)			
	University.	11 (24.4%)	11 (24.4%)	24 (26.6%)	46 (25.5%)			
Residence.	**Urban.**	24 (53.3%)	22 (48.8%)	38 (42.2%)	84 (46.6%)	30 ± 11.38	13.18	**p< 0.0001 HS***
	Rural.	21 (46.6%)	23 (51.1%)	52 (57.7%)	96 (53.3%)			

Citation:

Sahar Sedky Faheem. Efficacy of Buzzy with Distraction Cards Versus the Traditional Method for Reducing Pain and Parent's Satisfaction during Venipuncture in healthy Children. IOSR Journal of Nursing and Health Science. 2019;8(03):78-89.

Significance level p< 0.0001, *Significant; HS: Highly significant.

BDG: Buzzy more Distraction cards group.
DG: Distraction cards group.
CG: Control Group.

Table-3: Description of the Results of Caregivers' Satisfaction Questionnaire for the Buzzy System

Individual scenario.					
Total no of respondents	**90 (100%)**				
Variables	**Frequency- Scores n (%)**				
Parents' satisfaction	**No n (%)**	**Probably not n (%)**	**Do not know. n (%)**	**Yes n (%)**	**Definitely n (%)**
Total no of respondents	**90 (100%)**				
My child was comforted using the Buzzy System during the procedure.	0	2	5 (5.5%)	7 (7.7%)	6 (6.6%)
It was a positive experience.	1 (1.1%)	2 (2.2%)	4 (4.4%)	8 (8.8%)	9 (10%)
I think the Buzzy System is easy.	0	0	3 (3.3%)	5 (5.5%)	9 (10%)
I want to use the Buzzy System for tests done on my son/daughter's future.	0	0	5 (5.5%)	6 (6.6%)	18 (20%)
ANOVA					
Mean ± SD Comparisons	4.5 ± 4.33				
z-score Comparisons	19.74				
Inferential Statistics	**p< 0.0001 HS***				

Citation:

- Friedel M, Whitman J, Magnani L. Boosting pain awareness through Buzzy Bee. Poster presentation at the 2nd European Congress on Pediatric Palliative Care, Fondazione Maruzza, Rome, 19-21st November 2014.
- Hanan Mohamed Mohamed Tork. Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During Venipuncture in a Pediatric Emergency Department. American Journal of Nursing Science. 2017;6(1):26-32.

Significance level p< 0.0001, *Significant; HS: Highly significant.

Table-4: Distribution of study population according to Frankl's behaviour rating scale versus projective scales (FAPS and MFAS)- Numerical Rating Pain Scale

Individual scenario.					
Total no of respondents	**180 (100%)**				
Frankl's behaviour rating scale.	**MFAS n=180 (100%)**			**FAPS n=180 (100%)**	
	No anxiety	**Some anxiety**	**Very high anxiety**	**Fearful**	**Not fearful**
Definitely positive (+ +) n=29	29 (16.1%)	0	0	0	29 (16.1%)
Positive (+) n=60	10 (5.5%)	47 (26.1%)	3 (1.6%)	11 (6.1%)	49 (27.2%)
Negative (−) n=45	6 (3.3%)	29 (16.1%)	10 (5.5%)	23 (12.7%)	22 (12.2%)
Definitely negative (− −) n=46	0	46 (25.5%)	0	46 (25.5%)	0
ANOVA					
Mean ± SD Comparisons	15 ± 17.96			22.5 ± 18.67	
z-score Comparisons	9.18			8.43	
Inferential Statistics	**p< 0.0001 HS***			**p< 0.0001 HS***	

Citation:

Tiwari, Nishidha; Tiwari, Shilpi; Thakur, Ruchi; Agrawal, Nikita; Shashikiran, N D; Singla, Shilpy. Evaluation of treatment-related fear using a newly developed fear scale for children: "Fear assessment picture scale" and its association with physiological response. Contemp Clin Dent 2015;6(3):327-31.

FAPS: Fear assessment picture scale.
MFAS: Modified facial affective scale.
Significance level p< 0.0001, *Significant; HS: Highly significant.

Table-5: Numerical Rating Pain Scale

Individual scenario.							
Total no of respondents					**180 (100%)**		
					**ANOVA (Inference)**		
Variables	**Scores**				**Mean ± SD Comparisons**	**Student's t-test Comparisons**	**Inferential Statistics**
	None **n (%)**	Mild **n (%)**	Moderate **n (%)**	Severe **n (%)**			
BDG n=45 (25 %)	20 (11.1%)	15 (8.3%)	7 (3.8%)	3 (1.6%)	8.3 ± 6.11	t = 4.2042 df = 88	**p< 0.0001 HS***
DG n=45 (25 %)	5 (2.7%)	9 (5%)	19 (10.5%)	12 (6.6%)	13.3 ± 5.13		
CG n=90 (50 %)	4 (2.2%)	36 (20%)	19 (10.5%)	31 (17.2%)	28.6 ± 8.73		
	BDG + DG + CG				21.6 ± 5.85	t = 6.3192 df = 178	**p< 0.0001 HS***

Citation:

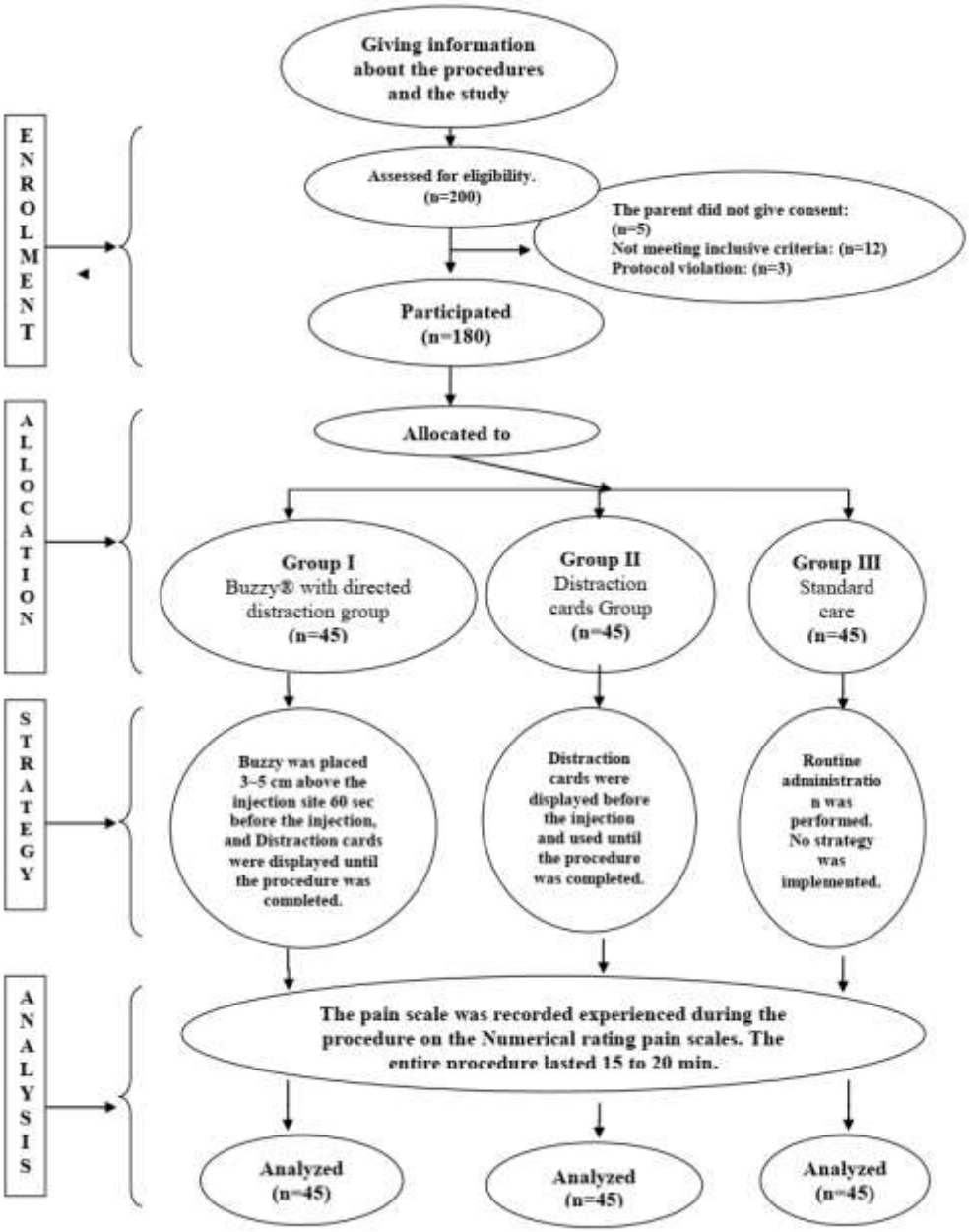
Mc Caffery, M., Beebe, A et al., (1989). Pain: Clinical manual for nursing practice, Mosby St. Louis, MO.

Significance level p< 0.0001, *Significant; HS: Highly significant.

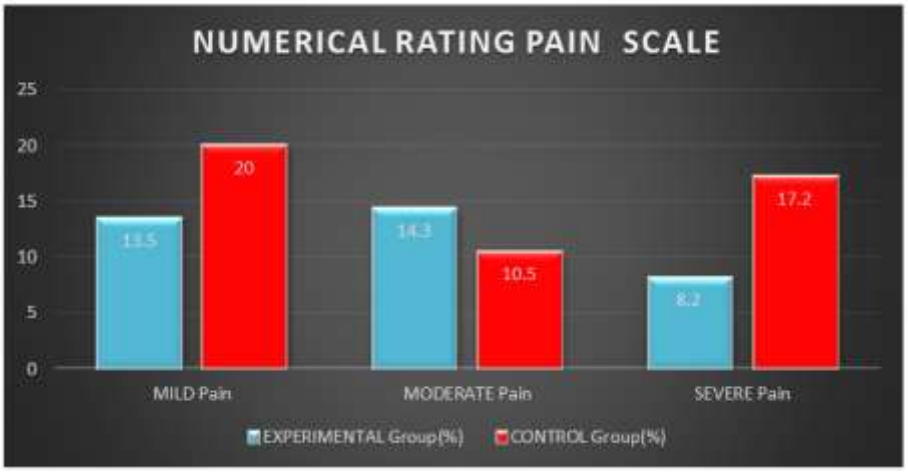
Interpretation of scores of Wong baker faces pain scale:
Score 0 = no pain.

Score 1-3= mild pain.
Score 4-6 = moderate pain.
Score 7-10 = severe pain.

BDG: Buzzy more Distraction cards group.
DG: Distraction cards group.
CG: Control Group.



Flowchart-1: Schematic Representation and Protocol



Graph-1

DISCUSSION

Our results show that pain decreases both with directed distraction and with the combination of directed distraction with the Buzzy®.

A study done by Maria et al., in 2011 had tried to find the validity of four different pain scales using hand immersed in the cold-pressor apparatus, which showed that slight variations in water temperature result in significant differences in pain intensity ratings, with numerical rating scale being the most responsive, followed by visual analogue scale, verbal rating scale and faces pain scale revised [22].

The numerical Pain Rating Scale (NPRS) is an ordinal and subjective scale that can be used for older or less literate or for the one having sustained trauma. NPRS is quicker to score and therefore used in a more excellent range of patients [23].

The present study is per the findings of Goldsmith et al., they have shown that a substantial change is more significant for an individual in the construct validation process. This study found a correlation in context with the individual. On this basis, it was seen that the pain measured by the standard gold method, i.e., pressure pain threshold and by numerical pain rating scale and P4, had a mild and moderate correlation, respectively, which was statistically significant at ($p<0.001$) [24].

A study done by Maria et al., evaluated four different pain scales using hand immersed in the cold-pressor apparatus, which showed that slight variations in water temperature result in significant differences in pain intensity ratings, with numerical rating scale being the most responsive, followed by visual analogue scale, verbal rating scale and faces pain scale revised. Which was per the present study [25].

Pain management during invasive and noninvasive dental procedures is of utmost importance as pain could result in non-compliance and avoidance of treatment [26].

Several methods are suggested to lower the discomfort of LA injection for dental procedures, among which desensitizing the injection site is a recommended strategy [27].

Buzzy® is an economical, versatile, quickly vibrating plastic device designed like a bee with cooled wings. It is hypothesized to work based on the gate control theory, which proposes that pain is conducted from the peripheral nervous system to the central nervous system via modulation through a gating system in the dorsal horn of the spinal cord [28].

This device's vibration component will excite the A-beta fibres (fast nonnoxious motion nerves), which eventually block the A-delta (afferent pain sensory nerves) [29].

The cold component, on the contrary, will excite the C fibres; and, if applied before the pain stimulus, will block the A-delta pain signal as well. Buzzy® has been shown in some studies to be superior to placebo and vapocoolants and analgesic creams [30].

Bartley EJ presented an extreme gender difference in the female to male ratio of 3:1 for orofacial pain, which was attributed to the lower pain threshold and better health motivation of females, resulting in a higher prevalence of females who 'actively' seek treatment for health complaints generally [31].

Only two published studies have investigated the Buzzy method's application in pediatric populations during venipuncture (Baxter et al., 2011; Inal & Kelleci, 2012) [32].

Impact of combined cryotherapy, vibration, and distraction

The effect of cold in pain reduction was demonstrated in several studies [33]. In our study, the impact of combining the cold effect (frozen wings of the Buzzy) with the vibration (produced by the Buzzy) seems to be more efficacious than the magic gloves techniques alone. The lowered pain scores founded in our study confirmed those founds in other studies related to many invasive procedures [34].

A multifaceted approach combining several techniques adapted to children's age and psychology to prevent or reduce the perception of pain is underlined by Landier et al., [35].

One of these multimodal approaches is, in fact, the combination of cryotherapy, vibration and distraction, on which the Buzzy System relies.

Distraction is strongly correlated to hypnosis. Some characteristics are similar, namely the specific involvement of adult (nurses or parents), the possibility for the child to make a choice, and finally, the child's interactivity with an adult. Compared to the complete absence of any form of treatment, the Buzzy System has shown itself to be efficacious in various invasive procedures, helping to reduce the pain felt by the child. In our study, Buzzy System was efficacious in pain reduction compared to other distractive techniques [36].

Nasehi et al., compared the pain level between the conventional method and the DentalVibe-assisted method in 99 patients. A total of 256 injections, which consisted of infraorbital nerve blocks, inferior alveolar nerve blocks, palatal injections, and buccal injections, were conducted. The authors demonstrated a significant reduction in pain level using DentalVibe, which contrasted with the present study using buzzy [37].

Shilpapriya et al., studied the effectiveness of DentalVibe on 30 patients between the ages of 6- and 12-years using Frankel's behaviour scale. The study showed a significant reduction in pain level using Dental Vibe, which contrasted with the present study using buzzy [38].

Impact of Distraction

Vetri Buratti C et al., studies have shown that distraction can diminish the perception of procedural pain in children and adolescents, which was similar to the present study [39].

Sahiner NC et al., stated that distraction cards were found particularly powerful in reducing pain and anxiety levels during venipunctures compared to other distraction techniques such as listening to music or balloon inflation [40].

Triggering children's interactivity during distraction techniques is different from distracting children passively with a doll or a puppet [41].

The role given to caregivers/parents during painful procedures

Acceptability of the Buzzy System by parents was largely confirmed. Five had a negative experience during its use. Five parents would reuse the system in the future. In this aspect, our results confirmed those of Friedel et al., [42].

Goffaux et al., [43] stated that allowing parents to have an active role using distraction cards might empower parents to comfort their child's pain and anxiety instead of feeling helpless and anxious. For children having their parents secured might lower their anxiety. Nevertheless, the Buzzy System's impact may be less efficacious among children who experienced a high level of pain in the past and developed needle phobia, which was not on par with the present study.

In paediatrics, a family-centred approach is a standard of quality care. It underpins the importance of considering the child's experience and his relationship with his parents. Reducing the child's anxiety goes in parallel with comforting parental anxiety.

LIMITATIONS

1. A single researcher stayed with the children during the intramuscular injections and later assessed the self-reported pain in children after the procedure. Having one person administer the intervention and evaluate the results may have induced bias in the children's answers.
2. The degree of anxiety related to needle phobia was not measured in our study.
3. It would be helpful to compare children's perception of pain with parental satisfaction towards the Buzzy System and look after possible correlation.
4. More extensive studies with larger sample sizes should be conducted to obtain more statistically significant results and make them commercially available.

CONCLUSION

Our study's relevance is that the Buzzy System with distraction cards has proved to be efficacious in reducing pain even compared to other distractive techniques, which underlines the relevance of all three components (vibration, cryotherapy and distraction).

Clinical Implication

a) Health care professionals should be aware of the harmful effects of procedural pain and anxiety in children.
b) One of the most common painful procedures in paediatrics.
c) The WHO and several Pediatric Societies advocates improving the approach to pain and anxiety in children in a medical environment.
d) Use distraction methods and know different nonpharmacological methods that may reduce their impact.

Conflict of interest & source of funding:

The author declares no exceptional financial support for this research work from the funding agency, and there is no conflict of interest nor bias among the authors.

Ethical Disclosures:

- **Protection of human and animal subjects:** The authors declare that no experiments were performed on humans or animals for this study.
- **Confidentiality of data:** The authors declare that no patient data appear in this article.
- **Right to privacy and informed consent:** The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author owns this document.

ACKNOWLEDGEMENT

All the authors express sincere gratitude to all respondents whose honest attention, help, support, and study participants lead the Research project to a worthful outcome.

REFERENCES

1. Morone, N. E., & Weiner, D. K. (2013). Pain as the fifth vital sign: exposing the vital need for pain education. Clinical therapeutics, 35(11), 1728-1732.
2. Stedman, T. L. (2000). Stedman's medical dictionary. 27th ed. Lippincott Williams & Wilkins, Baltimore, p.1297.
3. Ramandeep, K., & Vandna, H. V. G. (2019). A study to assess the effectiveness of cough trick method in reducing pain among (6-12yrs) old children undergoing intravenous cannulation, International Journal of Medical and Health Research. 5(11):127-129.
4. Schechter, N. L., Zempsky, W. T., Cohen, L. L., McGrath, P. J., McMurtry, C. M., & Bright, N. S. (2007). Pain reduction during pediatric immunizations: evidence-based review and recommendations. Pediatrics, 119(5), e1184-e1198.
5. Davis, M. J., & Vogel, L. D. (1996). Local anaesthetic safety in pediatric patients. NY. State Dental Journal, 62(2):32-35.
6. Feck, A. S., & Goodchild, J. H. (2005). The use of anxiolytic medications to supplement local anesthesia in the anxious patient. Compendium, 26(3), 183-90.
7. Çelik, N. (2012). Investigation of the effect of "ShotBlocker" on reducing pain and anxiety associated with intramuscular injection. İzmir: Ege University Institute of Health Sciences. p. 1-185.
8. Redfern, R. E., Chen, J. T., & Sibrel, S. (2018). Effects of thermomechanical stimulation during vaccination on anxiety, pain, and satisfaction in pediatric patients: A randomized controlled trial, 38:1-7.
9. Melzack, R., & Wall, P. D. (1965). Pain mechanisms: a new theory. Science, 150: 971-979.
10. Christopher, N. C., Sinha, M., Fenn, R., & Reeves, L. (2015). Evaluation of non-pharmacologic methods anxiety laceration repair management in the pediatric emergency department. Paediatrics, 117(4):1162-1168.
11. Stinson, J. N., Kavanagh, T., Yamada, J., Gill, N., & Stevens, B. (2006). Systematic review of the psychometric properties, interpretability and feasibility of self-report pain intensity measures for use in clinical trials in children and adolescents. Pain, 125(1-2), 143-157.
12. Canakci, C. F., & Canakci, V. (2007). Pain experienced by patients undergoing different periodontal therapies. The Journal of the American Dental Association, 138(12), 1563-1573.
13. Piaggio, G., Elbourne, D. R., Pocock, S. J., Evans, S. J., Altman, D. G., & CONSORT Group, F. T. (2012). Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement. Jama, 308(24), 2594-2604.
14. Kearl, Y. L., Yanger, S., Montero, S., Morelos-Howard, E., & Claudius, I. (2015). Does combined use of the J-tip® and Buzzy® device decrease the pain of venipuncture in a pediatric population?. Journal of pediatric nursing, 30(6), 829-833.
15. Bijttebier, P., & Vertommen, H. (1998). The impact of previous experience on children's reactions to venepunctures. Journal of Health Psychology, 3(1), 39-46.

16. Hockenberry, M. J., & Wilson, D. eds. (2015). "Chapter 5: Pain Assessment and Management". Wong's nursing care of infants and children (10th ed.)
17. Song, C. Y., Lin, S. F., Huang, C. Y., Wu, H. C., Chen, C. H., & Hsieh, C. L. (2016). Validation of the brief pain inventory in patients with low back pain. Spine, 41(15), E937-E942.
18. Friedel, M., Whitman, J., & Magnani, L. (2014 November). Boosting pain awareness through Buzzy Bee. Poster presentation at the 2nd European Congress on Pediatric Palliative Care, Fondazione Maruzza, Rome, 19-21st.
19. Tork, H. M. M. (2017). Comparison of the effectiveness of Buzzy, distracting cards and balloon inflating on mitigating pain and anxiety during venipuncture in a pediatric emergency department. Am J Nurs Sci, 6(1), 26-32.
20. Wai, H. P., Myo, M. A., & Hinn, E. P. (2020). Effect of cold application combined with distraction on venipuncture pain among children. International Journal of Research in Paediatric Nursing, 2(2):1-5.
21. Birnie, K. A., Noel, M., Parker, J. A., Chambers, C. T., Uman, L. S., Kisely, S. R., & McGrath, P. J. (2014). Systematic review and meta-analysis of distraction and hypnosis for needle-related pain and distress in children and adolescents. Journal of pediatric psychology, 39(8), 783-808.
22. Ferreira-Valente, M. A., Pais-Ribeiro, J. L., & Jensen, M. P. (2011). Validity of four pain intensity rating scales. Pain®, 152(10), 2399-2404.
23. Jensen, M. P., & Karoly, P. (2001). Self-report scales and procedures for assessing pain in adults. Handbook of Pain Assessment. New York, NY: Guilford Press. p. 15-34.
24. Goldsmith, C. H., Boers, M., Bombardier, C., & Tugwell, P. (1993). Criteria for clinically important changes in outcomes: development, scoring and evaluation of rheumatoid arthritis patient and trial profiles. OMERACT Committee. The Journal of rheumatology, 20(3), 561-565.
25. Ferreira-Valente, M. A., Pais-Ribeiro, J. L., & Jensen, M. P. (2011). Validity of four pain intensity rating scales. Pain®, 152(10), 2399-2404.
26. Brennan, F., Carr, D. B., & Cousins, M. (2007). Pain management: a fundamental human right. Anesthesia & Analgesia, 105(1), 205-221.
27. Aminah, M., Nagar, P., Singh, P., & Bharti, M. (2017). Comparison of topical anesthetic gel, pre-cooling, vibration and buffered local anesthesia on the pain perception of pediatric patients during the administration of local anesthesia in routine dental procedures. Int J Contemp Med Res, 4(2), 400-403.
28. Melzack, R., & Wall, P. D. (1965). Pain mechanisms: a new theory. Science, 150(3699), 971-979.
29. Kakigi, R., & Shibasaki, H. (1992). Mechanisms of pain relief by vibration and movement. Journal of Neurology, Neurosurgery & Psychiatry, 55(4), 282-286.
30. Inal, S., & Kelleci, M. (2012). Distracting children during blood draw: Looking through distraction cards is effective in pain relief of children during blood draw. International journal of nursing practice, 18(2), 210-219.
31. Bartley, E. J., & Fillingim, R. B. (2013). Sex differences in pain: a brief review of clinical and experimental findings. British journal of anaesthesia, 111(1), 52-58.
32. Inal, S., & Kelleci, M. (2012). Relief of pain during blood specimen collection in pediatric patients. MCN: The American Journal of Maternal/Child Nursing, 37(5), 339-345.
33. Sahiner, N. C., & Bal, M. D. (2016). The effects of three different distraction methods on pain and anxiety in children. Journal of Child Health Care, 20(3), 277-285.
34. Moadad, N., Kozman, K., Shahine, R., Ohanian, S., & Badr, L. K. (2016). Distraction using the BUZZY for children during an IV insertion. Journal of pediatric nursing, 31(1), 64-72.
35. Landier, W., & Alice, M. T. (2010). Use of complementary and alternative medical interventions for the management of procedure-related pain, anxiety, and distress in pediatric oncology: an integrative review. Journal of pediatric nursing, 25(6), 566-579.
36. Jensen, M. P., Jamieson, G. A., Lutz, A., Mazzoni, G., McGeown, W. J., Santarcangelo, E. L., ... & Terhune, D. B. (2017). New directions in hypnosis research: strategies for advancing the cognitive and clinical neuroscience of hypnosis. Neuroscience of consciousness, 2017(1), nix004.
37. Nasehi, A., Bhardwaj, S., Kamath, A. T., Gadicherla, S., & Pentapati, K. C. (2015). Clinical pain evaluation with intraoral vibration device during local anesthetic injections. Journal of clinical and experimental dentistry, 7(1), e23-e27
38. Shilpapriya, M., Jayanthi, M., Reddy, V. N., Sakthivel, R., Selvaraju, G., & Vijayakumar, P. (2015). Effectiveness of new vibration delivery system on pain associated with injection of local anesthesia in children. Journal of Indian Society of Pedodontics and Preventive Dentistry, 33(3), 173-176.
39. Buratti, C. V., Angelino, F., Sansoni, J., Fabriani, L., Mauro, L., & Latina, R. (2015). Distraction as a technique to control pain in pediatric patients during venipuncture. A narrative review of

literature. Professioni infermieristiche, 68(1);52-62.
40. Sahiner, N. C., & Bal, M. D. (2016). The effects of three different distraction methods on pain and anxiety in children. Journal of Child Health Care, 20(3), 277-285.
41. Ebrahimpour, F., Sadeghi, N., Najafi, M., Iraj, B., & Shahrokhi, A. (2015). Effect of playing interactive computer game on distress of insulin injection among type 1 diabetic children. Iranian journal of pediatrics, 25(3):e427.
42. Palermo, T. M., Valrie, C. R., & Karlson, C. W. (2014). Family and parent influences on pediatric chronic pain: a developmental perspective. American Psychologist, 69(2), 142.
43. Goffaux, P., Redmond, W. J., Rainville, P., & Marchand, S. (2007). Descending analgesia–when the spine echoes what the brain expects. Pain, 130(1-2), 137-143.