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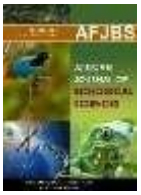

Effectiveness of Buzzy in pain during administration of intramuscular injection among children: Open randomized trial

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Abstract:

Background:
Evidence suggests that considerable number of children receive suboptimal care for injection-related pain, which may have long-term deleterious impacts on development and future pain tolerance. Hence this study was directed to study the effectiveness of Buzzy in pain reduction following intramuscular injection.

Methodology:
An open randomised trial was conducted in the pediatric OPD of a tertiary care hospital in Chengalpattu. 70 participants were enrolled based on inclusion and exclusion criteria into the study group and control group respectively. Following injection, the pain perceived was observed using the FLACC scale.

Results:
The mean age of buzzy bee group was 10.15 ± 6.5 months whereas it is 9.85 ± 6.1 in control group. Female participants were predominant in both the groups.When compared to control group, buzzy bee group had reduced mean pain score at 0 and 5thminute following vaccination. Also, buzzy bee was found effective in pain reduction at 0-minute ($p < 0.001$).

Conclusion:
Buzzy bee was found to be effective in pain reduction and can be used by paediatrics healthcare team as it is cost-effective and relatively easy to use.

Keywords:
pain, injection, buzzy bee, non-pharmacological, children

Introduction:

McCaffery (1999) defined pain as "whatever the experiencing person says it is, and existing whenever the person says it does".[1]Pain serves as a warning signal to alert the body to potential harm or injury, prompting protective behaviour to prevent further damage.[2]The commonest use of injection in healthcare sector is during vaccination, administration of medicine diagnostic procedures, fluid replacement, pain management and treatment of allergic reactions.[3]Around 16 billion intramuscular injections (IMI) are performed worldwide every year in a range of healthcare settings, making IMI a widely used therapeutic treatment.[4]Healthcare providers often employ strategies to help minimize injection pain and improve the overall experience for children.

Several pharmacological, non-pharmacological, behavioural therapies, and injection technique have been proposed to lessen injection-associated pain during vaccine administration as they have an advantage over other methods and they can be quickly and easily implemented into clinical practice without incurring additional costs or time. Physical techniques have attracted a lot of interest when compared to pharmaceutical and behavioural therapies. Cold application, manual pressure, accupressure, vibration, Z track technique, air-lock technique, Buzzy, and Shot Blocker are some of the physical methods which are used to alleviate injection-induced pain.[5]

In search of a quick, reusable, and pain-relieving solution for kids having needle-related operations, a paediatrician and a nurse developed Buzzy.[6]The descending inhibitory controls and gate control theories serve as the foundation for the Buzzy device.[7]This device is designed like a bee and is made up of two parts: the detachable ice wings (ice) and the bee's body (which vibrates). The Buzzy gadget is then positioned as close to the needle insertion site as feasible (about 5 cm above the insertion site), either by strapping it to the arm or keeping it there manually, and the vibration is turned on.[8]

The primary objective of this study was to figure out the effectiveness of Buzzy device in reducing injection related pain among the study participants. The aim of this study was to determine the pain levels among study participants during intramuscular injections, the effectiveness of Buzzy in relieving pain caused by intramuscular injections and factors that affect the effectiveness of Buzzy.

Materials and Methods:

A randomized control trial was conducted between February 2024 and April 2024 in the Outpatient Department of paediatrics department in a private medical college situated at Chengalpattu district, South India. **Inclusion criteria**: Children less than 2 years of age who are received vaccines through intramuscular route and those parents willing to give consent to participate in the study. **Exclusion criteria**: Children with neurodevelopmental disorder, fever, skin diseases,children receiving vaccines via subcutaneous or intradermal route,who had infections at the injection site and those whose parents were not willing to participate were excluded from the study.

A sample size of 70 per group was calculated using standard deviation of 2.94 and 2.28 with mean difference of 1.7 and 0.65 as effect size.[9]After obtaining IHEC approval from the institution, through simple random sampling technique, a total of 70 participants were recruited in both buzzy bee group and in the control group. The buzzy group had application of buzzy 15 to 30 seconds before the vaccination process. However, the control group received vaccination without any interventions. The children were observed for half an hour after administration of vaccine for adverse effects also.

Data collection was done using a semi-structured proforma. The proforma comprised of questions pertaining to baseline demographic characteristics of the child, immunization details, vitals and FLACC score following vaccination at 0, 5 and 15th minute.[10]**Statistical analysis:** The data collected were entered in Microsoft Excel spreadsheet and analyzed using IBM SPSS v 21. The descriptive statistics of categorical variables were expressed in terms of frequency and percentages, for continuous variables it was expressed as mean and standard deviation. Chi-square test and Independent t testwas applied to find the association between the variables and p value < 0.05 was considered statistically significant.

Results:

Table 1: Distribution of Age among the study participants

Characteristics	**Age (in months)**		**p-value**	**95%CI**
	Mean	**Standard Deviation**		
Buzzy Bee group	10.15	6.5	0.775	-1.81,2.42
Control group	9.85	6.1		

*Independent T- test, p < 0.05 is significant

The mean age of buzzy bee group was 10.15 ± 6.5 months whereas it is 9.85 ± 6.1 in control group. Age was not found to be determining factor for pain reduction in both the groups (Table 1).

Table 2: Distribution of gender among the study participants

Characteristics	Gender		p-value	95%CI
	Male	Female		
Buzzy Bee group	27	43	0.607	0.40,1.55
Control group	31	39		

*Chi-square test, $p < 0.05$ is significant

Female participants were predominant in both the groups. However, gender was not found to be a determining factor for pain reduction in both the groups (Table 2)

Table 3: Frequency distribution showing allergic reactions following injection among the study participants

Characteristics	Allergic reactions	
	Yes	No
Buzzy Bee group	0	70
Control group	0	70

Table 4: Frequency distribution depicting adverse events among the study participants

Characteristics	Adverse events following current immunization	
	Yes	No
Buzzy Bee group	0	70
Control group	0	70

None of the participants had reported vaccine allergy, adverse events following immunization in both the groups (Table 3,4).

Table 5: Frequency distribution showing type of vaccine administered to the study participants

Characteristics	Type of vaccine taken	
	Live	Killed
Buzzy Bee group	0	70
Control group	0	70

Table 6: Frequency distribution depicting immunization scheduled followed among the study participants

Characteristics	Immunization schedule followed	
	NIS	IAP
Buzzy Bee group	46	24
Control group	45	25

Almost all the participants in this study took killed vaccine, however, majority followed NIS immunization schedule in both the groups (Table 5,6).

Table 7: Distribution of heart rate following immunization among the study participants

Characteristics	Heart rate following immunization	
	Mean	Standard Deviation
Buzzy Bee group	111.89	8.9
Control group	115.80	6.3

The mean heart rate following vaccination in buzzy bee group was found to be low when compared to the control group (Table 7)

Table 8: Distribution of SpO2 following immunization among the study participants

Characteristics	SpO2 following immunization	
	Mean	Standard Deviation
Buzzy Bee group	98.27	0.87
Control group	98.47	1.05

Table 9: Distribution of temperature before immunization among the study participants

Characteristics	Temperature recorded before immunization	
	Mean	Standard Deviation
Buzzy Bee group	97.94	0.49
Control group	97.97	0.44

Table 10: Distribution of FLACC score at 0 minute among the study participants

Characteristics	FLACC – 0 min		p-value	95%CI
	Mean	Standard Deviation		
Buzzy Bee group	4.13	0.7	**0.001**	-1.65, -1.14
Control group	5.53	0.8		

*Independent T- test, $p < 0.05$ is significant

When compared to control group, buzzy bee group reduced mean pain score at 0-minute following vaccination. Also,buzzy bee was found effective in pain reduction at 0-minute ($p < 0.001$) (Table 10).

Table 11: Distribution of FLACC score at 5th minute among the study participants

Characteristics	FLACC – 5 min		p-value	95%CI
	Mean	Standard Deviation		
Buzzy Bee group	0.16	0.4	0.253	-0.27,0.72
Control group	0.26	0.5		

*Independent T- test, $p < 0.05$ is significant

When compared to control group, buzzy bee group had reduced mean pain score at 5th minute following vaccination. However, buzzy bee was not found effective statistically in pain reduction at 5thminute (Table 11).

Table 12: Distribution of FLACC score at 15th minute among the study participants

Characteristics	FLACC – 15 min	
	Mean	Standard Deviation
Buzzy Bee group	0	0
Control group	0	0

Pain score at 15 minute was found to be zero in both the groups (Table 12).

Discussion:

A major quantity of available literature has compared buzzy bee with either a non-pharmacological device or a pharmacological technique but the present study has compared

buzzy with a control group alone. The mean age of buzzy bee group was 10.15 ± 6.5 months whereas it is 9.85 ± 6.1 in control group. Majority of the participants were female and almost all the participants took killed vaccine.Inthis study FLACC scale was used to assess the pain which coincides with Cho et al,[11]however different assessment scales like Wong-baker FACES pain rating scale, Children Fear scale, Ontario pain scale, Revised face pain scale and visual analogue scale were also used in other studies.[12,13,14,15,16]

The mean score at 0min and 5th min was lower in the buzzy bee group when compared to the control group in this study. Similar findings were observed in several studies done by Moeini MS et al,[12]Moaded et al,[17]Canbulat et al,[18]Tork et al,[13] Ahmed et al,[19]Susam et al[16] and Cho et al.[11] Factors like age and gender were not found to be associating factors in the current study which adds another feature to the findings by Tork et al,[13] Ahmed et al,[19]Susam et al[16] and Bergomi et al[20] in their studies.

It is hard to comment on the pain variation at 0, 5 and 15th minute following injection because the literature that are currently accessible used various study tools that did not measure pain variation at 0,5 and 15thminute. However, a significant association was derived only for pain reduction at 0-minute in this study.

Conclusion:

The study's findings conclude that, in comparison to the control group, children's pain levels were effectively reduced by the Buzzy technique.The present study suggests that paediatric healthcare units and paediatric nurses should acquire training on the benefits of buzzy as non-pharmacological pain control techniques during IMI. To confirm the advantages of this technique, additional research through randomized controlled trials using a placebo should also be encouraged. Also, more research is required to assess the effects of buzzy in relation to other non-pharmacological pain management strategies in children undergoing IMI, like distraction and relaxation.

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