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RESEARCH ARTICLE

A RANDOMIZED CONTROL TRIAL TO ASSESS THE EFFECT OF DISTRACTION TECHNIQUE ON PAIN DURING IMMUNIZATION AMONG INFANTS

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ABSTRACT

Background: Immunization is an important part of health promotion and disease prevention strategy for all children and it is essential in the provision of primary care to infants, but pain experienced by infants during immunization makes it a distressing experience for the infant, parents and practitioners.

Aim: The aim of study is to assess the effect of distraction techniques (light and sound) on pain during immunization among infants coming for immunization.

Materials and Methods: A Quantitative research approach and Randomized Control Trial design was used to assess the effect of distraction techniques on pain during immunization among infants (0-1 year) coming for immunization in Guru Teg Bahadur Sahib (C) Hospital, Ludhiana. 90 infants were selected by simple random sampling technique and randomized in three groups- control, experimental group I and II. During immunization, standard care was given to control group, light producing toy was shown as distraction to Experimental group I and sound producing toy to Experimental group II. Pain was assessed using Neonatal Infant Pain Scale. Results were analysed using descriptive and inferential statistics.

Results: The findings of the present study revealed that the mean pain score of Control group was higher (6.87) as compared to that of Experimental group I (3.27) and Experimental group II (2.50). The difference between mean pain score of infants in Control, Experimental group I and Experimental group II was found to be statistically significant at $p < 0.01$ level. The difference in mean pain score between Control and Experimental group I and also between Control and Experimental Group II was statistically significant at $p < 0.01$ level and the difference in mean pain score between Experimental group I and Experimental group II was statistically significant at $p < 0.05$ level.

Conclusion: During immunization, in Control group, maximum infants experienced severe pain, in Experimental group I (who were given light producing toy) mild pain and in Experimental group II (who were given sound producing toy) maximum infants had no pain during immunization. Distraction was found to be effective in reducing adverse behavioural response to pain and Sound was found to be better distractor from pain than light.

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INTRODUCTION

Immunization is an important part of health promotion and disease prevention strategy for all children and it is regarded as one of the most significant medical achievements of all times. Immunization is a global health priority. Routine immunization is the most common painful procedure of childhood. Most of these vaccines are administered early in a child's life. With the continuous introduction of new vaccines, children may now receive up to 20 injections by their second birthday (Evelyn Cohen Reis *et al.*, 2003). Immunization is essential in the provision of primary care to infants, but it is a distressing experience for the infant, parents and practitioners. Pain is one of the most common adverse stimuli experienced by children

receiving vaccines Vaccination related pain in infants deserves our attention. Parents often report withholding follow up immunization from their infants on account of the distress seen. This will contribute to failure in community compliance with the recommended immunization schedules (Lewinon *et al.*, 1998). Despite of an increased focus on pain assessment and management, vaccination related pain remains largely untreated. Though the relief of pain is one of the basic principles of fundamental care and medicine, still its alleviation is not much emphasized during vaccination. Relief of pain is a basic need and right of all children. Injection related pain deserves our attention. Untreated pain has immediate and measurable effects, most notably child and parental distress (Evelyn Cohen Reis *et al.*, 2003). To ensure adequate pain relief or to make pain more tolerable and to give the children a sense of control over the situation, non-pharmacological methods are widely accepted as additional strategies that may

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be used independently or in addition to medication (James Jeena *et al.*, 2012).

One of the most frequently used non-pharmacological interventions of acute pain management is distracting the child’s attention away from painful procedures (Kleiber 1999). Distraction is a non- pharmacological intervention that diverts attention from a noxious stimulus through passively redirecting the subject’s attention or by actively involving the subject in the performance of diversion task. Distraction involves capturing child’s attention and focusing away from stressful situation and towards something more pleasant. It takes little training to learn, is easy to administer, and requires very less material that may be familiar to most individuals. There may be difference in the effectiveness of distraction related to the individual being given the intervention (Koller Donna *et al.*, 2012).

OBJECTIVES OF STUDY

1. To assess the level of pain during immunization among infants in control group.
2. To plan and implement distraction technique among infants in Experimental group I and Experimental group II.
3. To assess the level of pain during immunization among infants in Experimental group I and Experimental group II.
4. To compare the level of pain among infants in Control and Experimental groups.
5. To find the association between level of pain among infants in Control and Experimental groups with selected demographic variables like Age, Gender, Type of vaccine, Prior history of vaccination, Number of vaccines received at a time, Site of vaccination and Presence of care giver.

MATERIALS AND METHODS

A quantitative research approach and Randomized Control Trial (Post test only control group design) was used to assess the effect of distraction technique on pain during immunization among infants in the age group of 0-1 year undergoing immunization (DPT, Hib, Hep B, Measles and combination vaccine). Conceptual framework for this study is based on Roy’s Adaptation Model. The hypothesis framed in the study was as follows:-

H₁ - There will be a significant difference in the level of pain during immunization among infants of Control and Experimental groups as measured by Neonatal Infant Pain Scale at p <0.05 level.

H₀. There will be no statistically significant difference in level of pain during immunization among infants of Control and Experimental group as measured by Neonatal Infant Pain Scale at p < 0.05 level.

In order to assess the effect of Distraction Technique on Pain during Immunization among infants, a baseline proforma and a standardized tool namely Neonatal Infant Pain Scale (NIPS) was used. It included the assessment of six parameters i.e.

facial expressions, cry, breathing pattern, arm and leg movement and state of arousal .Permission for using this tool was obtained from Professor Patrick McGrath OC, PhD. The researcher had taken training for the application of NIPS from Dr. Harinder Singh, HOD Pediatric Department of GTBS (C) Hospital, Ludhiana. The tool was having the following parts:-

Part I: Baseline proforma

It was used to collect data regarding socio-demographic variables like Age, Gender, Type of vaccine, Prior history of vaccination, Number of vaccines received at a time, Site of vaccination and Presence of care giver.

Part II: Neonatal Infant Pain Scale (NIPS)

This standardized scale was used to observe level of pain among infants during vaccination. It included the assessment of six parameters i.e. facial expressions, cry, breathing pattern, arm and leg movement and state of arousal. The parameters were categorized according to the behavioral response of the infant. The maximum pain score of tool was 7 and minimum was 0.

Neonatal Infant Pain Scale			
Pain Assessment			Score
Facial expression	<ul style="list-style-type: none"> • Relaxed muscles • Grimace 	Restless face, neutral expression Tight facial muscles, furrowed brow/chin/jaw	0 1
Cry	<ul style="list-style-type: none"> • No cry • Whimper • Vigorous cry 	Quiet, not crying Mild moaning, intermittent crying Loud screaming, rising, shrill, continuous crying	0 1 2
Breathing pattern	<ul style="list-style-type: none"> • Relaxed • Change in breathing 	Normal or usual pattern of breathing Indrawing of chest, irregular breathing faster than normal, gagging and breath holding	0 1
Arms	<ul style="list-style-type: none"> • Relaxed/ Restrained • Flexed/ Extended 	No muscular rigidity, occasional random movements of arms. Tense, straight arms, rigid or rapid extension/ flexion.	0 1
Legs	<ul style="list-style-type: none"> • Relaxed/ Restrained • Flexed/ Extended 	No muscular rigidity, occasional random movements of legs. Tense, straight arms, rigid or rapid extension/ flexion.	0 1
State of arousal	<ul style="list-style-type: none"> • Sleeping/ awake • Fussy 	Quiet, peaceful sleeping. Alert, restless/thrashing.	0 1

Maximum pain score - 7
Minimum pain score – 0

Criterion measure of Neonatal infant pain scale (NIPS)

Score	Interpretation (Level of pain)
0-2	No pain
3-4	Mild pain
5-7	Severe pain

The pilot study was conducted in month of December, on 1/10th of total sample (i.e. nine healthy infants) to assess the feasibility of the study. As Standardized tool – Neonatal Infant Pain Scale (NIPS) was used to assess the level of pain during immunization among infants, reliability was already established. Inter – rater reliability of NIPS was 0.9.

DATA COLLECTION PROCEDURE

The procedure of data collection was carried out in the month of March, 2014. A formal written permission was obtained from Ethical committee of INE, GTBS © Hospital and Medical Superintendent of Guru Teg Bahadur Sahib (C) Hospital, Ludhiana after discussing the purpose and objective of the study with them. Keeping in mind the inclusion and exclusion criteria, sample was identified and details of the study were explained to parents and informed consent was obtained for the participation of their infant in study. Baseline information was collected from parents. This was a single blind trial in which the researcher was not aware about the randomization that whether the infant will be assigned to any of the two experimental groups or control group. Simple random sampling method i.e. lottery method was used to randomize the infants in Control group, Experimental group I and Experimental group II. In this process Chits on which was written Control group, Experimental group I & II were prepared and thereafter for each selected infant one chit was picked and accordingly the infant was placed in Control group, Experimental group I & Experimental group II.

To the Control group standard care was given, to the Experimental group I light producing toy was given and to the Experimental group II sound producing toy was given as intervention by researcher. The distraction technique started 30 seconds before vaccination and it lasted until 15 seconds after vaccination of each infant. Same nurse immunized all the infants under study, using same gauge needle i.e. 26 gauge. During immunization the researcher assessed the parameters of pain by using Neonatal Infant Pain Scale. Then the findings of all groups were recorded and compared to see the effectiveness of distraction technique.

RESULTS

The analysis of data was done in accordance with the objectives of study. The findings have been organized and presented under following sections-

Section I: Socio-demographic variables.

Section II: Findings related to Level of pain during immunization among infants in Control group and Experimental group I & II.

Section III: Findings related to Comparison of level of pain during immunization among infants in Control and Experimental group I & II.

Section IV: Findings related to Relationship of level of pain during immunization among infants in Control and Experimental groups with selected demographic variables.

Table 1. Mean Pain Score of Infants during Immunization in Control group, Experimental group I & Experimental group II

(N=90) (n ₁ =30, n ₂ =30, n ₃ =30)			
Groups	n	Mean	Mean %
Control group	30	6.86	98
Experimental group I	30	3.27	46.71
Experimental group II	30	2.50	35.71

Maximum score – 7

Minimum score – 0

Table 1 shows that mean pain score of infants in Control group was 6.86 and mean percentage was 98% whereas in Experimental group I mean pain score of infants was 3.27 and mean percentage was 46.71 and in Experimental group II mean pain score of infants was 2.50 and mean percentage was 35.71. It was inferred that level of pain among infants during immunization was highest in control group followed by Experimental group I and least in experimental group II.

Table 2. Frequency and Percentage distribution of Infants according to their level of Pain during Immunization

(N=90) (n ₁ =30, n ₂ =30, n ₃ =30)							
		Control Group		Experimental group I		Experimental Group II	
Level of Pain	n ₁	%	n ₂	%	n ₃	%	
No pain	-	-	5	17	15	50	
Mild pain	1	3	24	80	13	43	
Severe pain	29	97	1	3	2	7	

Table 2 shows that in Control group, majority of infants 29 (97%) had severe pain and only 1 (3%) had mild pain during immunization whereas in Experimental group I, majority 24 (80%) infants had mild pain, 5 (17%) had no pain and only 1(3%) had severe pain. In Experimental group II, 15 (50%) infants had no pain, 13 (43%) had mild pain and only 2(7%) had severe pain. Thus it was inferred that maximum infants in Control group experienced severe pain whereas level of pain experienced by infants markedly decreased in both the Experimental groups.

Table 3 depicts that in Control group maximum infants (29) had severe pain with highest mean pain score 6.96 and mean percentage 99.4%, followed by (1) infant having mild pain with mean pain score 4.00 and mean percentage 57.1%. In Experimental group I only 1 infant had severe pain with highest mean pain score 5.00 and mean percentage 71.4%, followed by maximum infants (24) having mild pain with mean pain score 3.58 and mean percentage 51.1% and least infants (5) having no pain with lowest mean pain score 1.44 and mean percentage 20.5 %. In Experimental group II only 2 infants had severe pain with highest mean pain score of 5.00 and mean percentage 71.4% followed by 13 infants having mild pain with mean pain score of 3.46 and mean percentage of 49.4% and maximum number of infants (15) had no pain with least mean pain score of 1.33 and mean percentage of 19%. Thus it was inferred that distraction technique was very effective in reducing the level of pain in infants of both the experimental groups.

Table 3. Level of Pain during Immunization among Infants in Control Group, Experimental Group I and Experimental Group II

		(N=90) (n ₁ =30, n ₂ =30, n ₃ =30)											
		Control Group				Experimental group I				Experimental group II			
Level of Pain	n ₁	Mean	Mean %	S.D	n ₂	Mean	Mean %	S.D	n ₃	Mean	Mean %	S.D	
No pain	-	-	-	-	5	1.44	20.5	0.8	15	1.33	19	0.89	
Mild pain	1	4.00	57.1	-	24	3.58	51.1	9	13	3.46	49.4	0.50	
Severe pain	29	6.96	99.4	0.18	1	5.00	71.4	0.50	2	5.00	71.4	-	

Maximum score - 7

Minimum score - 0

Table 4. Comparison of Mean Pain Scores during Immunization among Infants in Control group, Experimental Group I and Experimental group II

		(N=90) (n ₁ =30, n ₂ =30, n ₃ =30)				
Groups	N	Mean	SD	d	F	
				BG/WG		
Control group	30	a 6.87	0.57			
Experimental group I	30	b 3.27	1.05	2 /87	5.21**	
Experimental group II	30	c 2.50	1.46			
Tukey's HSD		a vs b		14.40**		
		a vs c		11.28**		
		b vs c		2.33*		

Maximum score -7

Minimum score - 0

**Significant at p<0.01 level

* Significant at p<0.05 level

Table 4 depicts the comparison of mean pain score during immunization among infants in Control, Experimental group I & Experimental group II. It reveals that the mean pain score of Control group was higher (6.87) as compared to that of Experimental group I (3.27) and Experimental group II (2.50). Based on one way analysis of variance, the difference between mean pain score of infants in Control, Experimental group I and Experimental group II was found to be statistically significant at p<0.01 level. According to Tukey's HSD, the difference in mean pain score between Control and Experimental group I and also between Control and Experimental Group II was statistically significant at p< 0.01 level and the difference in mean pain score between Experimental group I and Experimental group II was statistically significant at p< 0.05 level. Hence it can be concluded that infants in Experimental group I who were given light producing toy and infants in Experimental group II who were given sound producing toy as distraction technique experienced less pain as compared to those who did not receive any distraction technique. There is significant difference in effectiveness of sound and light producing toy when used as distraction technique and it was found that sound as a distraction technique was more effective as compared to light as distraction from pain during immunization among infants. Hence the Research hypothesis was accepted and Null hypothesis was rejected. Thus the distraction is an effective technique in reducing level of pain among infants during immunization.

Hence it was concluded that infants in Experimental group I who were given light producing toy and infants in Experimental group II who were given sound producing toy as distraction technique experienced less pain as compared to those who did not receive any distraction technique. There is significant difference in effectiveness of sound and light producing toy when used as distraction technique and it was

found that sound as a distraction technique was more effective as compared to light as distraction from pain during immunization among infants. Hence the Research hypothesis was accepted and Null hypothesis was rejected. Thus the distraction is an effective technique in reducing level of pain among infants during immunization.

DISCUSSION

Based upon findings from the analysis of data and review of literature, discussion was done according to the objectives written as below:

In Control group maximum infants (29) had severe pain with highest mean pain score 6.96 and mean percentage 99.4%, followed by (1) infant having mild pain with mean pain score 4.00 and mean percentage 57.1%. Similar findings were reported by Kyoung JH and Cho SC⁶ who found that in the Control group, Neonatal infant pain scale score was 4 whereas in the Experimental group the Neonatal infant pain scale score was 2. There was a significant difference in behavioral changes and pain score of newborn infants to pain between Experimental group and Control group. In Experimental group I only 1 infant had severe pain with highest mean pain score 5.00 and mean percentage 71.4%, followed by maximum infants (24) having mild pain with mean pain score 3.58 and mean percentage 51.1% and least infants (5) having no pain with lowest mean pain score 1.44 and mean percentage 20.5%. In Experimental group II only 2 infants had severe pain with highest mean pain score of 5.00 and mean percentage 71.4% followed by 13 infants having mild pain with mean pain score of 3.46 and mean percentage of 49.4% and maximum number of infants (15) had no pain with least mean pain score of 1.33 and mean percentage of 19%. These findings support previous research findings of Moghadam (2011) who revealed that the mean pain scores were significantly lower in Experimental group as compared to the control group at p<0.01.

The mean pain score of Control group was higher (6.87) as compared to that of Experimental group I and Experimental group II (3.27 & 2.50) respectively. The difference between mean pain score of infants in Control and Experimental group I and also between Control and Experimental group II was found to be statistically significant at $p < 0.01$ level. The difference between mean pain score of infants in Experimental group I and Experimental group II was found to be statistically significant at $p < 0.05$ level. Hence the research hypothesis was accepted that there will be a significant difference in the level of pain during immunization among infants of control and experimental groups as measured by neonatal infant pain scale at $p < 0.05$ level. Similar findings were reported by Sevil Inal, Meral Kelleci (2012) who found that the Experimental group had significantly lower pain and anxiety levels (at $p < 0.01$) as compared to the Control group during the blood specimen collection procedure.

In socio demographic variables, age was found to be significantly related with level of pain experienced by infants during immunization whereas other variables like Gender, Type of vaccine, Prior history of vaccination, Number of vaccine received at a time, Site of vaccination and Presence of primary care giver were not found to be significantly related with level of pain during immunization.

Conclusion

From the findings of the study following conclusions were drawn:

1. The difference in mean pain score between Control and Experimental group I and also between Control and Experimental Group II was statistically significant at $p < 0.01$ level and the difference in mean pain score between Experimental group I and Experimental group II was statistically significant at $p < 0.05$ level. Thus the infants in Experimental group I who were shown light producing toy and infants in Experimental group II who were shown sound producing toy as distraction technique experienced less pain as compared to those who did not receive any distraction technique.
2. There is significant difference in effectiveness of Sound and Light producing toy when used as distraction technique and it was found that Sound as a distraction technique was more effective as compared to Light as a distraction technique from pain during immunization among infants.
3. In socio demographic variables, age was found to be significantly related with level of pain experienced by infants during immunization whereas other variables like Gender, Type of vaccine, Prior history of vaccination, Number of vaccine received at a time, Site of vaccination and Presence of primary care giver were not found to be significantly related with level of pain during immunization.

Recommendation

Based on the result of study following recommendations are made

- Vaccination related pain in infants deserves our attention. Minimizing pain during childhood vaccination will help to prevent distress, development of needle fears and subsequent health care avoidance behaviors, such as non adherence with vaccination schedules. One of the most frequently used non-pharmacological interventions of acute pain management is distracting the child's attention away from painful procedures. Distraction involves capturing child's attention and focusing away from stressful situation and towards something more pleasant. It takes little training to learn, is easy to administer, and requires very less material that may be familiar to most individuals. Some distracters must be used in immunization clinics as well as in all those areas where painful procedures are carried on with children. Distracters that can be used include cartoon movies, party blowers, kaleidoscopes, blowing bubble, short stories, humor and joke telling, music, puppetry, virtual reality glasses, picture books, talking with the child, prop up book, hand held computer games, imaging fun and exciting things or quiet and relaxing scenes.

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