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Research Article

Efficacy of Helfer Skin Tap (HST) Technique on Pain during Intramuscular Injection among Children Attending Immunisation Clinic - A Randomised Controlled Trial in South India

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A B S T R A C T

Background: Injections for vaccinations are found to be the most common cause of iatrogenic pain in childhood and the association of pain with such types of vaccinations may result in anxiety and discomfort for children as well as for their family members and the healthcare providers who administer them.

Aim: This RCT has been conducted to evaluate the efficacy of the Helfer Skin Tap (HST) technique on pain among children receiving intramuscular immunisation.

Materials and Methods: Quantitative research was carried out with the true experimental post-test only control group design among 40 attending the immunisation clinics selected by convenience sampling technique with random assignment. The intervention was administered by tapping at the injection site for 3 minutes before, during, and after vaccination in the experimental group. The pain was assessed with a standardised FLACC pain scale in both groups.

Results: We analysed the data with chi-square test for homogeneity of sample characteristics and association with pain, and an independent t-test for the effectiveness of HST. There was a statistically significant reduction in pain among the experimental group after HST in comparison with the control group, and none of the variables had any association with pain in children.

Conclusion: The study concluded that the HST technique was significantly effective in pain reduction among children undergoing intramuscular injections at an immunisation clinic.

Keywords: Helfer Skin Tap Technique, Immunisation, Pain, FLACC, Children

Introduction

Pain is the most common symptom reported in healthcare settings and it is a highly prevalent symptom not only in medical and special settings but also in mental health settings. Thus it is defined as an "unpleasant sensory and emotional experience associated with actual or potential damage, or described in terms of that damage".[1]

Injections for vaccinations are found to be the most common cause of iatrogenic pain in childhood and the association of pain with such types of vaccinations may result in anxiety and discomfort for children as well as for their family members and the healthcare providers who administer them. It can even lead to non-adherence to vaccines.[2-4] Routine immunisations are the most frequent painful medical procedure during childhood. The World Health Organization (WHO) estimated that annually, out of 12 billion injections, 5% are childhood vaccinations.[5]

Pain and distress due to medical procedures are quite common among children especially if there are needles associated with the procedures. Needles are introduced very early in children's lives, particularly for the administration of vaccines. The current schedule even suggests that almost 20-30 vaccines are administered before the age of 18 years. Unfortunately, the pain associated with the administration of vaccines is poorly managed on most occasions which could negatively impact the child, family and healthcare providers.[6] Further, a scarcity of pain management strategies while administering immunisation could lead the children to face unwanted suffering and might even develop and end up in fear of needles.[4]

Managing pain among children is a challenging task and requires utmost care and concern especially non-pharmacological measures from the nursing management point of view. The development of various pain assessment tools specific to paediatric patients helped in paediatric pain management in the last decade whereas, in the beginning, paediatric pain assessment and trials lagged due to a lack of clinical knowledge, paediatric research, and the fear of opioid addiction in children. The guidelines issued by major organisations led to numerous paediatric analgesics trials in the development of evidence-based pain management guidelines for children that resulted in the existence of dedicated paediatric pain management services in major children's hospitals.[7]

There are several intramuscular injection techniques used for the management of injection-associated pain including but not limited to applying pressure on the site of injection like manual pressure, Helfer tapping, and applying pressure with plastic devices. Acupressure technique, cold needle technique, and Z-track technique were the other identified techniques to reduce pain. In addition, changing the needle after injecting and warming the injectate was also found to be useful on a few occasions to reduce the pain associated with intramuscular injections.[8]

There are studies which had suggested a combination of interventions to reduce pain among children receiving vaccinations such as combining pharmacologic, physical, and psychological approaches together to relieve pain.[2] Distraction techniques also were reported as a significant strategy to reduce pain among children but the distraction strategies are affected by the age of children, and their traits and interests, but their efficacy is still well supported in the literature.[3]

Managing pain is an important segment of child care and nurses play a significant role in carrying out pain assessment and management. Further, it is suggested that the use of non-pharmacological pain relief techniques may be effective since they have fewer side effects and complications.[9] Though there are numerous studies conducted on the management of pain among children receiving vaccines, the Helfer Skin Tap technique used alone as an intervention is still lacking in the field of paediatrics. Hence, this present RCT was conducted to strengthen the existing evidence to reduce intramuscular injection-associated pain among children receiving immunisation by administering Helfer Skin Tap (HST) technique.

Materials and Methods

A randomised controlled trial on the efficacy of Helfer Skin Tap (HST) technique on pain among children receiving immunisations was carried out during the period from May 2018 to August 2018 in the state of Karnataka, India. The study primarily aimed at evaluating the efficacy of HST technique on pain and its association with selected sample characteristics in both groups. After obtaining ethical approval from the Institutional Ethics Committee of Sri Devaraj Urs College of Nursing, Karnataka (SDUCON/IEC/27/2018-19 dt 04.04.2018), permission was obtained from the concerned authorities of RL Jalappa Hospital and Research Centre, Tamaka, Kolar, Karnataka for conducting a study at their immunisation clinics. The setting chosen for the study was a multi-speciality hospital with 1200 bed strength where an immunisation clinic runs every day and a minimum of 50 children attend it per week. The present study was prepared and reported as per the guidelines/ checklist of Consolidated Standards Of Reporting Trials (CONSORT).

Procedure

A quantitative study was carried out with the true experimental post-test only control group design among 40 children (Experimental = 20, Control = 20) attending the immunisation clinics selected by convenience sampling technique who were then randomised into experimental and control groups through computed generated random

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number assignment. As per the inclusion criteria, the children attending immunisation clinics aged less than 3 years, receiving only intramuscular injections, and whose parents were willing to participate in the study were included. The study excluded those who received any painkillers or analgesics in the past 6 hours. The study did not follow any blinding during the allocation. The sample size was ensured from the difference between the two means calculation n = $2\left[\frac{(Z1-\frac{\alpha}{2}+Z1-\beta)S}{d}\right]^2$ based on the reported mean and standard deviation of experimental and control groups from the previous studies on the efficacy of HST on pain among infants ($\overline{X}_1 = 1.73 \pm 2.04$, $\overline{X}_2 = 5.56 \pm 0.92$)[10] and ($\overline{X}_1 = 2.55 \pm 1.43$, $\overline{X}_2 = 6.59 \pm 1.72$)[11] yielded (G*power) a minimum sample size of 6 per group; and by considering the attrition, a total of 20 subjects per group (N = 40) was recruited in the present study. Children were recruited in the study after written consent was obtained from the mothers of children visiting the immunisation clinic. The participant information sheet was provided with detailed information, and confidentiality was assured. The study was carried out by the guidelines laid by the Indian Council of Medical Research. The Sample characteristics pro form a was used to collect the data regarding sample characteristics with an interview technique and record analysis. Pain was assessed in both groups by standardised FLACC pain scale with the observation technique. Tools were validated by research experts and the inter-rater reliability was ensured before the data collection. After taking consent from mothers of children in Experimental group, they were prepared for vaccination. The child was positioned, site was identified, and injection site was tapped for 3 minutes before, during and after vaccination. The intervention was administered by researcher alone. Pain scores were assessed by video recording from the time of initiating the intervention till completion. Then the video was analysed by using FLACC pain measuring scale. For the babies of control group, routine steps of vaccination were followed and pain scores were assessed. The sample allocation of the subjects has been shown in Consort (Figure 1).

Description of Tool

Sample Characteristics Pro Forma: It included baseline information such as age in months of children, number of vaccines, and type of vaccine administered.

FLACC Pain Scale: It is a standardised observation tool for quantifying pain behaviours in the areas of Facial expression, Leg movement, Activity, Cry and Consolability, each scored on a rating scale of 0-2, to make a total FLACC score of 0-10. The pain is evaluated by the total score and is categorised as no pain (0), mild discomfort (1-3), moderate pain (4-6), and severe pain/ discomfort (7-10). The pain scale in the study had shown acceptable reliability with an inter-rater reliability value of 0.90.

Data Analysis

The data were checked for normal distribution with the Shapiro-Wilk test and it was found that pain scores were normally distributed. The data were analysed with SPSS version 21.0. Descriptive statistics for frequency, percentage, mean, and standard deviation were used to describe the sample characteristics and pain. Inferential statistics such as chi-square were used to check the homogeneity between the groups with regard to sample characteristics and for the association of pain with them. Unpaired t-test was used to test the efficacy of HST technique by comparing the severity of pain between both groups.

Results

Description and Comparison of Sample Characteristics between the Experimental and Control Group Participants

Most of the children who participated in the study were in the age group of 1-9 months in both experimental (80%) and control (70%) groups. The number of vaccinations for most of the participants was between 1-3 times in both experimental (70%) and control (65%) groups, and all of them (100%) received a live vaccine in the experimental group whereas about 80% of children received a live vaccine in the control group. The groups were compared for their homogeneity with regard to sample characteristics. The calculated chi-square test value concluded that all the variables were homogenous and comparable as they were found to be non-significant at a 0.05 level of significance (Table 1).

Description of Pain and Efficacy of Helfer Skin Tap (HST) Technique on Pain among Children

The level of pain in experimental and control group participants revealed that about 13 (65%) participants had moderate pain and 7 (35%) had severe pain in the experimental group, whereas in the control group, 1 (5%) participant had no pain but rest of them (19, 95%) expressed severe pain (Figure 2). Independent t-test was used to analyse the efficacy of HST by comparing the mean pain scores of the experimental and control group participants. The calculated t-test value revealed that the mean pain score of the experimental group (6.30 ± 0.571) was significantly less than the mean pain score of the control group (7.30 ± 1.809) at a 0.05 level of significance with the medium effect size (t = -2.357, p = 0.024, d = 0.74), which infers that the HST technique had significantly reduced the level of pain among the participants (Table 2).

Association of Pain with Sample Characteristics in Experimental and Control Group Participants

The association of pain with sample characteristics was calculated by chi-square. The calculated chi-square value

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revealed that none of the variables had a significant association with pain in both the groups at a 0.05 level of significance which showed that all the variables were found to be independent of pain in both groups (Table 3).

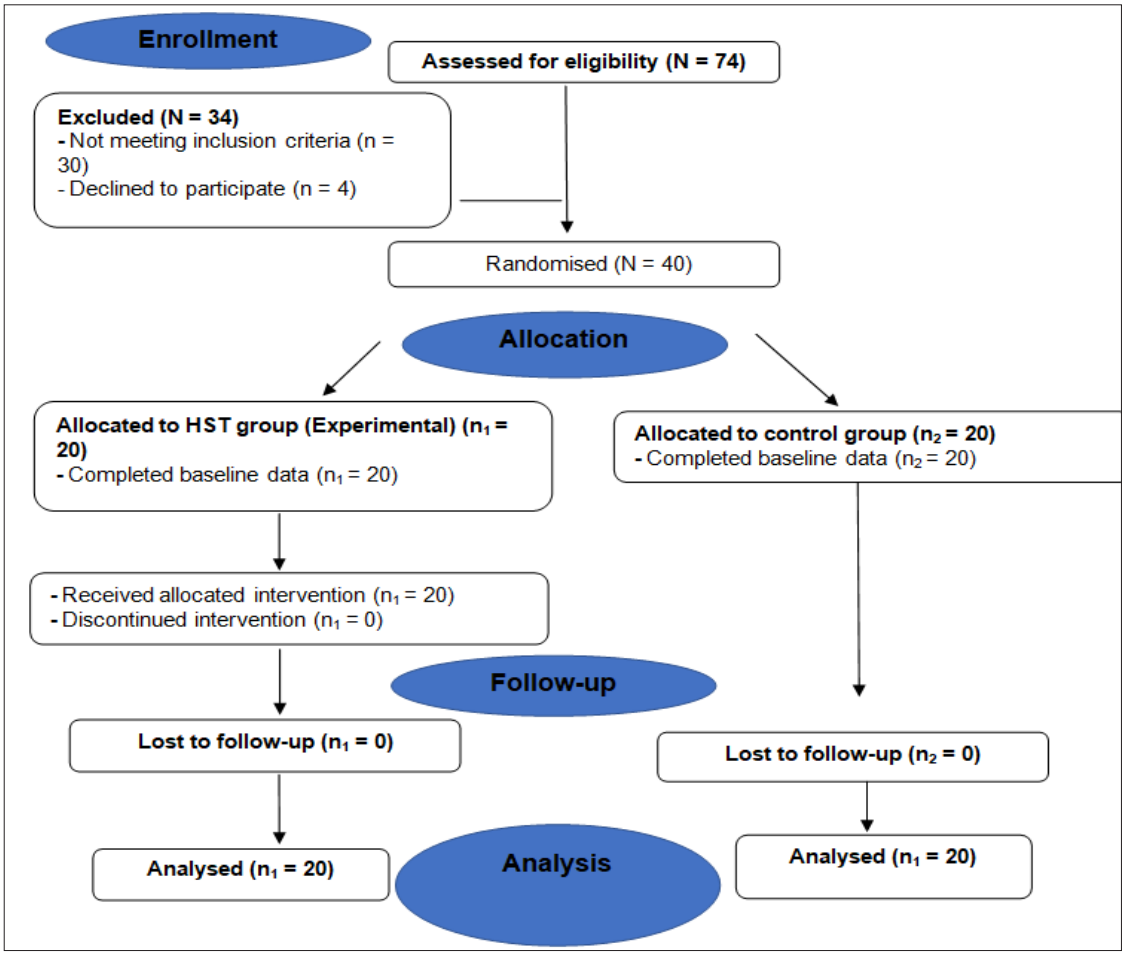

Figure 1.Consort Flow Diagram

Table 1.Comparison of Sample Characteristics between the Experimental and Control Group Participants (N = 40)

Sample Characteristics	Experimental (n = 20)	Control (n = 20)	χ^2	p Value
	n (%)	n (%)		
Age in months				
0-9	16 (80)	14 (70)	0.533	0.465^{NS}
10-18	04 (20)	06 (30)		
No. of vaccines				
1-3	14 (70)	13 (65)	0.114	0.735^{NS}
> 3	06 (30)	07 (35)		
Type of vaccine				
Live	20 (100)	16 (80)	2.500	0.113^{NS}
Killed	0 (0)	04 (20)		

NS: Non-significant, χ^2: Chi-square, χ^2 (1): 3.84

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Table 2.Effectiveness of Helfer Skin Tap (HST) Technique on Pain during Intramuscular Injection among Children (N = 40)

Group	Pain Score Mean ± SD	t	df	p Value	Effect Size (Cohen's d)†
Experimental (n = 20)	6.30 ± 0.571	-2.357	38	0.024*	0.74
Control (n = 20)	7.30 ± 1.809				

*: p-Sig at 0.05 level, t(38) = 2.023, †: 0.20 - Small, 0.50 - Medium, 0.80 - Large effect[12]

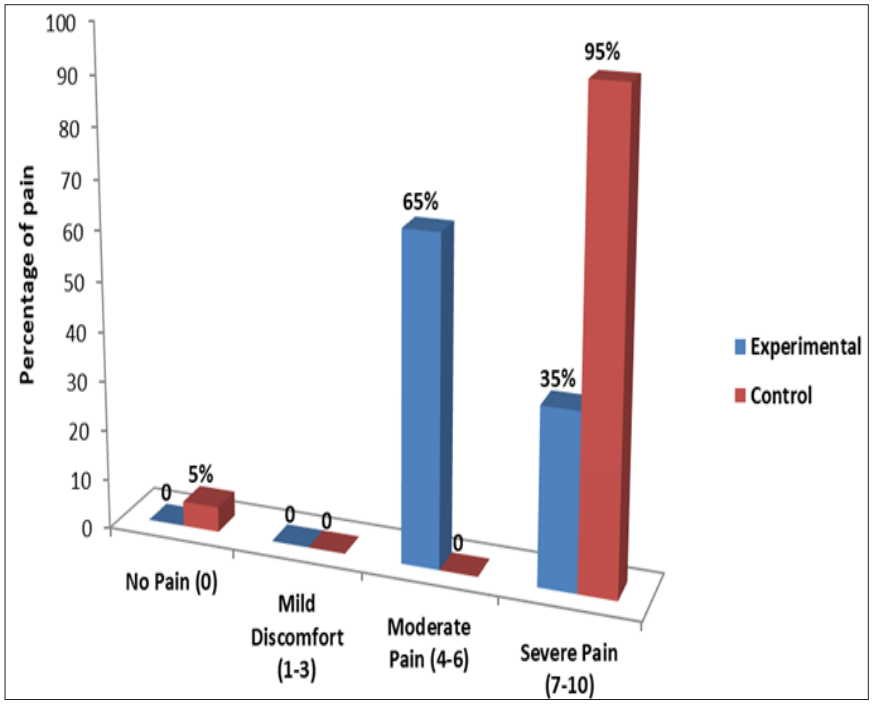

Figure 2.Level of Pain among Children in Experimental and Control Groups

Table 3.Association of Pain with Sample Characteristics among Children in the Experimental and Control Groups (N = 40)

Sample Characteristics	Pain Score							
	Experimental (n = 20)				Control (n = 20)			
	≤ Med†	> Med†	χ^2	p value	≤ Med†	> Med†	χ^2	p value
Age in months								
0-9	9	7	1.113	0.293^{NS}	13	1	0.200	0.654^{NS}
10-18	4	0			6	0		
No. of vaccines								
1-3	8	6	0.376	0.539^{NS}	12	1	0.104	0.747^{NS}
> 3	5	1			7	0		
Type of vaccine								
Live	13	7	NA	NA	15	1	0.592	0.441^{NS}
Killed	0	0			4	0		

Med: Median, †Median: 6, NS: Non-significant, χ^2: Chi-square, $\chi^2(1)$: 3.84

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Discussion

The present randomised controlled trial was conducted to evaluate the efficacy of the Helfer Skin Tap (HST) technique on pain during intramuscular injection among children attending immunisation clinics.

A majority of the children in the present study were in the age group of 1-9 months, the number of vaccinations for most of the participants was between 1-3 times, and maximum received live vaccines in both groups. Similarly, in other studies also, participating infants were mostly less than 9 months of age and almost received only live vaccine.[11,13]

The present study revealed that about 13 (65%) participants had moderate pain and 7 (35%) had severe pain in the experimental group, whereas in the control group, 1 (5%) participant had no pain but the rest (95%) of them expressed severe pain. These findings were almost supported by various other studies. A study revealed that 66.7% of infants had mild pain after HST compared to their counterparts who reported severe pain and about 97% of the participating infants reported no pain to moderate pain,[11] and only 3% experienced severe pain after HST.[13]

Further, in the present study, the calculated t-test value revealed that HST had significantly reduced pain in the experimental group with medium effect size in comparison to the control group ($t = -2.357$, $p = 0.024$, $d = 0.74$). These findings were quite steadily supported by various similar kinds of interventional studies which showed a significant reduction in pain in the HST group in comparison to the control group: ($t = -9.895$, $p < 0.001$),[11] ($t = 5.48$, $p < 0.01$),[14] and ($MD = 3.83$, $p < 0.05$)[10].

Further, there are various other studies which had used HST as an intervention for the reduction of pain among different subjects. They also showed that HST technique had significantly reduced pain in comparison to all other traditional techniques.[8,15,16] In contrast, one study reported breastfeeding, topical anaesthetics, sweet-taste solutions, and a combination of more than one strategy significantly reduced vaccine injection pain in infants and children.[17]

In the current study, none of the variables (such as the age of children, number and type of vaccines) had any association with pain in both groups at 0.05 level of significance. Similarly, other studies conducted on HST among infants revealed no association of pain with various demographic and clinical variables such as age, dose of vaccines, and type of vaccines thus concluding pain is independent of all the demographic and other variables.[11,13]

Conclusion

The present study concluded that the Helfer Skin Tap technique was effective in the reduction of pain among children undergoing intramuscular injections at immunisation clinics. Injections are a common experience for children, hence, it is important for the healthcare professionals, who administer immunisation, to take care of relieving the pain by distracting the infants.

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Conflict of Interest: None

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