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Original Research Article

Effect of skin tap technique on pain during hepatitis B vaccination among newborns: a randomized controlled trial

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ABSTRACT

Background: Pain is all about an unpleasant sensation created by stimuli. Every child has his or her own perception of pain. It is unpleasant sensory and emotional experience associated with actual or potential tissue damage. Mechanical stimulation given by taping can diminish the influence of tiny, pain-carrying fibers. This study aimed to assess the effect of skin tap technique on pain during hepatitis-B vaccination.
Methods: A randomized controlled trial was carried out among 60 newborns in postnatal ward. Consecutive sampling technique was used to enroll the newborn who met the inclusion criteria. Data pertaining to newborn and a clinical characteristics birth order, gestation age, birth weight and mode of delivery were collected from medical record. Data regarding assess the level of pain during hepatitis-B vaccination by using the neonatal pain scale were collected from skin tap technique. Data were analyzed using Chi-square test, t-test.
Results: The data collected was analyzed by using mean and standard deviation. The study findings high light that among 30 newborns vaccinated with the skin tap technique in the experimental group, the majority of newborns, 20 (66.7%), had mild to moderate pain, and 10 (33.3%) had severe pain. Among 30 newborns vaccinated as a routine manner in the control group, the majority of newborns, 22 (73.3%), had severe pain, and 8 (26.7%) had mild to moderate pain, respectively. The skin tap technique was effective compared to the control group. The pain score was 3.83±1.147 and 5±1.174. Respectively with a statistically significant p=0.000.
Conclusions: The skin tap technique was effective in reducing pain during hepatitis-B vaccination among the newborns.

Keywords: Pain, Skin tap technique, Hepatitis-B vaccination

INTRODUCTION

Routine assessment and management of newborn pain has progressed to become an important therapeutic goal in the 21st century. During the 20th century, however, most procedures and clinical practices established in Neonatal intensive care units (NICUs) consistently denied or unseen the occurrence of newborn pain. One unfortunate consequence was that newborn pain was conducted routinely with minimal or no anesthesia until the late 1980s.[1] Every newborn experience painful and the invasive procedure because of the need for diagnostic therapeutic and sometimes preventive measures.[2] Immunization is a stressful experience for children and parents. During the clinical experience, the investigator found that vaccine administration causes iatrogenic pain in children.[3] This newborn period is a time of rapid brain development and potential vulnerability. Thus, there has been long standing concern regarding potential effects of neonatal pain on the immature brain in neonates. Nociception stimuli reach the cortex, induce pain-specific activation and alter peripheral and the central

pain processing in neonates.[4] Children fear injections, and because of that fear, they cry. All parents continually strive to find the best way to respond to those cries. Pain is an unpleasant sensation caused by stable stimuli which create severe pain. It is a triggered in the nervous system. Pain may be sharp or dull. It may be come and go; it may be constant.[5] Pain management is an essential portion of nursing. Nurses are responsible for managing patients' pain and have a more significant role in minimizing pain and discomfort during invasive procedures. The nurse can reduce the hurt and pain during intra-muscular injection by using the skin tap technique and implementing different physical inteventions.[6]

A number of evidence based non pharmacological method have been reported to reduce pain, some of which include kangaroo care, non-nutritive sucking, oral sucrose, massage, skin tap, and acupuncture therapy. They are used for procedures causing transient or mild pain and adjunctive treatment for moderate to severe pain.[7]

Inadequate pain management in infants may lead to permanent changes in the process of organizing the brain and appearing maladaptive behavior. Pharmacological and non-pharmacological methods control pain in neonates. Non pharmacological pain treatment is a safe, non-invasive, in expensive method that nurses could perform independently. Reducing non pharmacological pain does not cost much and does not cause side effects for patients, therefore could be very useful pain management reduces suffering and improve patients' quality of life.[8]

For many years it was it believe that the infants and children would not feel pain due to the under development of their nervous system. However, research has shown that infants are more prone to pain than adults. The expression of pain is difference from old children to adults.[9]

From the birth babies are experience pain such as vitamin K injection, vaccinations, circumcisions and heel sampling. They respond to the pain through facial expression and the behaviors.[10]

Immunization associated with pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage.[11]

The skin tap technique is tapping the skin. The method uses basic concepts of the theory of pain, including the gate control theory. Mechanical stimulation given by tapping can diminish the influence of tiny, pain-carrying fibers. It consists of two essential points: muscle relaxation, which physically decreases the resistance to needle entry into the skin. Divert by simultaneous tapping over the skin before the needle is inserted and removed.[12] Every person is born with the responsibility to protect the health and that of others. Routine immunizations are the most frequent painful medical procedure during childhood. The world health organization estimates that 12 billion injections are given annually and that approximately 5% are childhood vaccinations. In India, was survey found that 96% of all injections given by private doctors were of antibiotics, vitamins, and analgesics. A conservative estimate of the usual number of injections ranged from 0.9 to 8.5 per person per year, with a median of 1.5 per person per year. According to the World Health Organization, intramuscular injection is an administration of medication through a skin puncture by a syringe and a needle more profound into a large muscle of the body for prophylactic or curative purposes.[13]

Pain is an unpleasant sensation and an emotional experience that is associated with actual or potential tissue damage.[14] There are twelve billion intramuscular injections administered annually throughout the world. Intramuscular injection may be an unpleasant experience. Pain management throughout any invasive procedure may challenge the health care delivery system. Injections are the most using the medical procedure. With an estimated 12 billion administered all over the world on an annual basis.[15]

Infants are unable to express pain, but in response to painful stimuli, a range of behavioral and physiological reactions such as facial changes, crying, increase heart rate and respiration and decrease oxygen saturation could be observed in them. This is conclusive evidence of their pain.[16]

Vaccination is the most practiced procedure. Each child stays compulsorily exposed to this in their early childhood. The most common side-effect of vaccination is pain. Kids do not like them, and parents do not like seeing their children suffer. Fear of needles is a common phobia for children.[17]

Among these skins tap techniques was a newborn. The Newborn was allowed to lie on the bed, and the investigator tapped the injection site. Non-pharmacological pain control methods are suitable for relieving pain during painful procedures since they have a short-term impact and are well-tolerated. One of the non-pharmacological methods is the skin tap technique, in which the investigator will tap over the IM injection site with a palmer aspect of the finger, providing mechanical stimulation and distraction during IM injection. It helps to decrease pain as described by gate control theory which keeps the muscles relaxed and thus reduces pain.

Studies have shown that uncontrolled pain experiences negatively affect the development of the central nervous system. Therefore, the number of painful stimuli is kept to a minimum, and these stimuli are rendered less painful during this period Therefore they study was conducted to assist the level of pain during hepatitis B vaccination during immunization.

So far only few study have been conducted on effect of skin tap technique on pain during vaccination and that to compare the pain level of newborns during intramuscular injection with and without the use of skin tap technique was done in experimental group and control group. Only sivapriya studies neonatal infant pain scale (NIPS) is a behavioural assessment tool measurement of pain can be used to monitor to preterm and full-term neonates before, during and after a painful procedure in experimental and control. In this study NIPS Score measure the pain during the vaccination and randomized controlled trial was carried out and among sampling population only newborn was enrolled. In previous studies only NIPS score was assessed but in this study in addition to score different categories of NIPS status and correlation of NIPS score with clinical characteristics of newborn were also assessed.

METHODS

A randomized controlled trial was adopted to identify the effect skin tap technique on pain among newborns. The study was conducted in postnatal ward of a tertiary care hospital, JIPMER, Puducherry, during December 2021 to January 2022. Based on pain score among newborns consider the minimum expected mean difference between the two groups. The sample size was estimated to be 30 in each group at a 5% level of confidence and 90% power 60 newborns were enrolled in the study. Newborns admitted in postnatal ward and who are receiving hepatitis-B vaccination was included in the study. Newborns with congenital anomalies, sick infants and birth asphyxia were excluded from the study. Everyday newborns who met the inclusion criteria were selected through consecutive sampling method. Informed consent was obtained from parents.

Data regarding clinical characteristics of newborns were collected from case sheet. Neonates were assigned to the experimental and control group by block randomization with varying block sizes generated through the computer. In the experimental group, the newborns were allowed to lie on the bed, and the investigator tapped the injection site (vastus lateralis) with the palmer aspect of fingers for 16 times before insertion of the needle and continued three times during the injection and pain score was assessed by NIPS.

For the control group, hepatitis-B vaccination was given routinely, and pain score was evaluated using the NIPS. Data collection instruments had three section, first section included data regarding clinical characteristics of newborn. It comprised of birth order, gestation age, birth weight and mode of delivery. Second section had data on pain score was evaluated by using the NIPS. It comprised of pain (no pain to mild pain 0-2, moderate pain 3-4, severe pain >4) cry, breathing pattern, arms, legs, state of arousal. Third section dealt with data regarding assess the level of pain to the newborn data was collected by skin tap technique during hepatitis B vaccination. The study was approved by the Nursing Research Monitoring Committee (Regn No: JIP/CON/NRMC/M.Sc./2020/PN/1) and the Institutional ethics Committee for Human studies (Regn No: JIP/CON/IEC/M.SC/2020/PN/1).

The trial was filed with the clinical trial registry of India, and the registration number is CTRI/2022/02/040328. Data were analyzed using SPSS version 25 (SPSS Inc., Chicago, 111. USA) were used to describe the clinical variables to identify the level of pain. Chi-square was used to identify the association between the level of pain with clinical variables.

RESULTS

Among 60 study participants in the experimental group, the majority, 18 (60%), were male. Whereas in the control group, half of them, 15 (50%), were male. Regarding the birth order, in the experimental group, the majority were first child 16 (53.3%). In the control group18 (60%) were in 1st birth order. Regarding gestational age in the experimental group, the majority, 23 (76.7%), was born at the age >38 weeks. In the control group, 26 (86.7%) were born at the gestational age >38 weeks. The experimental and control group's mean gestational age is 38.17+0.986 and 38.60+1.037. Regarding the birth weight, in the experimental group, the majority of 21 (70%). Whereas in the control group, 25 (83.3%) were categorized into the birth weight of low birth weight and normal birth weight. The mean birth weight is 2.746+0.408 and 2.993+0.409 in the experimental and control group. Regarding the mode of delivery in the experimental group, the majority were 29 (96.7%).

Whereas in the control group, 27 (90%) were spontaneous vaginal delivery respectively (Table 1). The frequency and percentage-wise distribution of pain levels during hepatitis B vaccination among newborns in experimental and control groups. In the experimental group, the majority of newborns, 20 (66.7%), had mild to moderate pain and 10 (33.3%) had severe pain. In the control group, the majority of newborns, 22 (73.3%), had severe pain, and 8 (26.7%) had mild to moderate pain, respectively (Table 2). The mean and standard deviation of the pain score between the experimental and control group during vaccination. Mean pain scores were 3.83±1.147 and 5±1.174. Respectively with the statistically significant p=0.000 (Table 3). Using Chi-square, it was evidenced that the clinical variables have not demonstrated a statistically significant association between level of pain during hepatitis B vaccination among newborns in experimental group (Table 4). Using Chi-square, it was evidenced that the clinical variables have not demonstrated a statistically significant association between the levels of pain during hepatitis B vaccination among newborns with the clinical variables in the control group (Table 5). There was statistically significant between experimental and control group.

Table 1: Frequency and percentage wise distribution of clinical variables among newborns in experimental and control groups.

S. no.	Clinical variables	Experimental group		Control group	
		N	%	N	%
1	Gender				
	Male	18	60	15	50
	Female	12	40	15	50
2	Birth order				
	1	16	53.3	18	60
	2	10	33.4	10	33.4
	3	3	10	1	3.3
	4	1	3.3	1	3.3
3	Gestational age (weeks)				
	<37	7	23.3	4	13.3
	>38	23	76.7	26	86.7
	Mean gestational age	38.17+ 0.986		38.60+1.037	
4	Birth weight				
	Low birth weight	9	30	5	16.7
	Normal birth weight	21	70	25	83.3
	Mean birth weight	2.746+0.408		2.993+0.409	
5	Mode of delivery				
	Spontaneous vaginal delivery	29	96.7	27	90
	Vacuum delivery	1	3.3	1	3.3
	LSCS	0	0	2	6.7

Table 2: Frequency and percentage wise distribution of the level of pain during hepatitis B vaccination among newborns in experimental and control group (n=60).

Level of pains	Experimental group		Control group	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
No pain to mild pain (0-2)	0	0	0	0
Mild to moderate pain (3-4)	20	66.7	8	26.7
Severe pain (>4)	10	33.3	22	73.3
Total	30	100	30	100

Table 3: Comparison between the effect of skin tap technique on pain during hepatitis B vaccination among newborns in experimental and control group (n=60).

Effectiveness	Groups	Mean	Standard deviation	Mean difference	T value	DF	P value
Pain	Experimental	3.83	1.147	-1.167	-3.892	58	0.000** HS
	Control	5	1.174				
Facial expression	Experimental	0.70	0.466	0.033	0.273	58	0.786 NS
	Control	0.67	0.479				
Cry	Experimental	0.93	0.365	-0.400	-3.635	58	0.001** HS
	Control	1.33	0.479				
Breathing pattern	Experimental	0.40	0.498	-0.233	-1.829	58	0.073 NS
	Control	0.63	0.490				
Arms	Experimental	0.53	0.507	-0.233	-1.921	58	0.060 NS
	Control	0.77	0.430				
Legs	Experimental	0.60	0.498	-0.200	-1.703	58	0.094 NS
	Control	0.80	0.407				
State of arousal	Experimental	0.67	0.479	-0.133	-1.161	58	0.250 NS
	Control	0.80	0.407				

**p<0.001 HS-Highly significant, NS-Non significant.

Table 4: Association between level of pain during hepatitis B vaccination among newborns with selected baseline and clinical variables in experimental group (n=60).

S. no.	Baseline and clinical variables	Level of pain				Chi square X^2	DF	P value
		Mild to moderate		Severe pain				
		N	%	N	%			
1	Gender							
	Male	12	60	6	60	0.000	1	1.000 NS
	Female	8	40	4	40			
2	Birth order							
	1	10	50	6	60	0.675	3	0.897 NS
	2	7	35	3	30			
	3	2	10	1	10			
	4	1	5	0	0			
3	Gestational age (weeks)							
	<37	5	25	2	20	0.093	1	0.760 NS
	>38	15	75	8	80			
4	Birth weight							
	Low birth weight	5	25	4	40	0.714	1	0.398 NS
	Normal birth weight	15	75	6	60			
5	Mode of delivery							
	Spontaneous vaginal delivery	20	100	9	90	2.069	1	0.150 NS
	Vacuum delivery	0	0	1	10			
	LSCS	0	0	0	0			

NS-Non-significant.

Table 5: Association between level of pain during hepatitis B vaccination among newborns in clinical variables in control group (n=60).

S. no.	Baseline and clinical variables	Level of pain				Chi square X^2	DF	P value
		Mild to moderate		Severe pain				
		N	%	N	%			
1	Gender							
	Male	5	62.5	10	45.5	0.682	1	0.409 NS
	Female	3	37.5	12	54.5			
2	Birth order							
	1	3	37.5	15	68.2	4.432	3	0.218 NS
	2	5	62.5	5	22.8			
	3	0	0	1	4.5			
	4	0	0	1	4.5			
3	Gestational age (weeks)							
	<37	1	12.5	3	13.6	0.007	1	0.935 NS
	>38	7	87.5	19	86.4			
4	Birth weight							
	Low birth weight	1	12.5	4	18.2	0.136	1	0.712 NS
	Normal birth weight	7	87.5	18	81.8			
5	Mode of delivery							
	Spontaneous vaginal delivery	7	87.5	20	91	0.928	2	0.629 NS
	Vacuum delivery	0	0	1	4.5			
	LSCS	1	12.5	1	4.5			

NS-Non significant.

Data from table 1 shows the clinical variables among newborns in the experimental and control group. Among 60 study participants in the experimental group, the majority, 18 (60%), were male. Whereas in the control group, half of them, 15 (50%), were male. Regarding the birth order, in the experimental group, the majority was

16 (53.3%). In the control group 18 (60%) were in 1st birth order. Regarding gestational age in the experimental group, the majority, 23 (76.7%), was born at the age >38 weeks. In the control group, 26 (86.7%) were born at the gestational age >38 weeks. The experimental and control group's mean gestational age is 38.17+0.986 and 38.60+1.037.

Regarding the birth weight, in the experimental group, the majority 21 (70%). Whereas in the control group, 25 (83.3%) were categorized into the birth weight of low birth weight and normal birth weight. The mean birth weight is 2.746+0.408 and 2.993+0.409 in the experimental and control group. Regarding the mode of delivery in the experimental group, the majority were 29 (96.7%). Whereas in the control group, 27 (90%) were Spontaneous vaginal delivery respectively. Table 2 depicts the frequency and percentage-wise distribution of pain levels during hepatitis B vaccination among newborns in experimental and control groups. In the experimental group, the majority of newborns, 20 (66.7%), had mild to moderate pain and 10 (33.3%) had severe pain.

In the control group, the majority of newborns, 22 (73.3%), had severe pain, and 8 (26.7%) had mild to moderate pain, respectively. Table 3 represents the mean and standard deviation of the pain score between the experimental and control group during vaccination. Mean pain scores were 3.83±1.147 and 5±1.174. Respectively with the statistically significant p=0.000 Table 4 shows that using chi-square, it was evidenced that the clinical variables have not demonstrated a statistically significant association between levels of pain during hepatitis B vaccination among newborns in experimental group.

Table 5 shows that using chi-square, it was evidenced that the clinical variables have not demonstrated a statistically significant association between the level of pain during hepatitis B vaccination among newborns with the clinical variables in the control group.

DISCUSSION

This randomized controlled trial study included 60 newborns. Assess The pain level during hepatitis-B vaccination among newborns in experimental and control groups. The mean and standard deviation of the pain of the score in between groups was 3.83±1.147 and 5±1.174. The study revealed that reduced pain with statistically significant at p=0.000. Similarly, an experimental basis study conducted by Meera et al in M.M.I.M.S.R and Hospital, Mullana, city of hospital Ambala. Among 100 infants to evaluate the effectiveness of helfer skin tap technique on pain during immunization. The mean score of control (6.7±1.35) is higher than the experimental group (5.4±1.030). The study revealed that pain level was significantly reduced in treatment group ($p<0.05$).[18] In consistent with this a quasi-experimental timeseries design study was conducted by Menaka et al among 60 infants in tertiary hospital, Coimbatore. To assess the vaccination pain for before giving vaccination, and at 10 minutes after vaccination.[5,10] The study revealed that there was a significant decrease in the pain score between administration of IM injection with Helfer skin tap technique at $p<0.001$.[19] The experimental design study was conducted by Bhuvaneswari et al among 6 infants in primary health center, Nemam.

The pain level compared between experimental and control groups. The study revealed that decrease the level of pain with significant at $p<0.05$.[20] Furthermore a true experimental post-test control design was conducted by Sivapriya et al among 100 newborns in tertiary level hospital, UP. Compare the pain level of newborns during intramuscular injection with and without the use of skin tap technique. The study revealed that there is a significant difference in the pain score between the administration of IM injection with skin tap technique with $p<0.05$.[21] quasi-experimental design study conducted by Negi Parvadi among 60 infants in IGMC and Hospital. Skin tap technique used in experimental and control groups. The study revealed that highly significant at the pain level of $p<0.001$.22 Similarly quantitative approach and research design study was conducted by Blessy Peter among 70 children between 0 to 12 month in Jhunjunu, Rajasthan.

This study one group post-test only. The result revealed that majority 57% of infants had mild pain and association of pain level with variables was calculated using chi square with significant at 0.05.[23] Similarly prospective randomized controlled trial study conducted by Bhattcharya et al among 60 neonates in SRK University, Bhopal, Madya Pradesh, India. Enrolled the neonates in 3 groups 1 control and two interventions. The study revealed that the mean pain score of the three groups had Group 1-4.5, Group 2-3.55, and Group 3-3.[19] Skin tap technique before injection can quickly reduce the pain. Inconsistent with this, Sr. Serena, conducted a study among 60 patients. The mean score of the control (6.7=-1.35) is higher than the experimental group (5.5 +1.030). The pain level was significantly reduced in the treatment group ($p<0.05$).[24] Quasi experimental research design study conducted by Joanne helfer in 1998 among sixty infants. The study revealed that statistically significant difference was found between the groups and the level of pain at 0.001.[25]

Current study revealed that level of pain score to the newborns in the experimental group in compare with the control group indicated that 20 (66.7%) had mild to moderate pain and 10 (33.3%) had severe in experimental group. 22(73.3%) had severe pain and 8(26.7%) had mild to moderate pain.[26] Similarly the study was level of pain found by Negi Parvati among 60 infants, it was revealed that in experimental group 66.7% had mild and 23% had moderate in control group 40% had severe pain, 47% had moderate pain and 13% had mild pain.[27]

Similarly, the study level of pain perception found by Bhuvaneswari et al among 60 infants. The result reveal that in experimental 26.66% had discomfort and 56.66% had pain and 10% had worst pain. In control group (13.33%) had comfort and 60% pain and 26.66% had worst pain.[28]

Similar study found by Maj Sivapriya among 100 newborns during intramuscular injection. in the experimental group 86% of the neonates had mild pain only 14% perceived severe pain during IM injection by using the skin tap technique, and in the control group 86% of the neonates had severe pain, only 14% perceived moderate pain during IM injection by using the conventional routine method.[29]

CONCLUSION

The present randomized controlled trial was conducted among 60 newborns. The pain was measured using the NIPS during hepatitis B vaccination. The result showed that the mean pain score is lower in the skin tap technique group compared to routine manner group during vaccination, also the level of pain reduced and it was statistical significance p=0.000 level.

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