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The Effect of the Helfer Technique in the Facilitated Position on Pain Caused by Hepatitis B Vaccine Injection in Term Infants: A Randomized Clinical Trial

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Abstract

Background: Vaccine-induced pain is a common concern in infancy. Non-pharmacological methods, such as the Helfer technique and facilitated positioning are safe, simple, and cost-effective alternatives for pain management. This study aimed to evaluate the individual and combined effects of these methods on vaccination-induced pain in term infants.

Methods: This four-arm randomized clinical trial was conducted between January and April 2025 at Imam Reza Hospital in Iran. A total of 192 term infants were randomly assigned to one of four groups: Helfer technique, facilitated positioning, combined Helfer technique and facilitated positioning, or a control group (n=48 per group). Pain was assessed during and one minute after vaccination using the Neonatal Infant Pain Scale (NIPS).

Results: The mean NIPS scores during vaccination were 4.65 ± 0.89 (Helfer), 4.88 ± 1.09 (facilitated positioning), 3.71 ± 0.98 (combined), and 5.54 ± 1.08 (control). Analysis of variance revealed significant differences among the groups (P = 0.03). Bonferroni post hoc tests indicated that the Helfer technique significantly reduced pain compared to the control group (P = 0.01), while facilitated positioning alone did not show a statistically significant difference (P = 0.07). The combined approach of the Helfer technique and facilitated positioning resulted in the lowest pain scores, demonstrating a significant reduction compared to the control group (P = 0.03) and suggesting a potential synergistic effect.

Conclusion: The combined use of the Helfer technique and facilitated positioning was more effective in reducing vaccination-induced pain in term infants than either intervention alone. These simple, safe, and low-cost nonpharmacological methods may be recommended for pain management during infant vaccination.

Key Words: Facilitated Position, Helfer Technique, Infants, Pain, Vaccination.

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1- INTRODUCTION

Pain perception development in infants is a complex process that reflects both the sensory and emotional dimensions of pain. In term infants, even within the first week of life, many brain regions associated with pain in adults become active, suggesting that they are capable of experiencing pain both physically and emotionally. This means that infants perceive pain not only as a physical sensation but also as an unpleasant and distressing experience (1).

Pain in infants can arise from various factors; among these, vaccination injections are the most common source of pain during infancy. Vaccination is a major health care procedure worldwide, with approximately sixteen billion injections administered annually in developing countries alone, of which 5 to 10 percent are for disease prevention (2).

Pain from such injections is a source of distress for both infants and their parents, as well as for the personnel performing the injections. If this pain is overlooked, it can lead to anxiety and fear of needles and avoidance of healthcare and vaccination (3). Studies indicate that the infant nervous system is immature and highly plastic, meaning that frequent painful experiences can significantly affect neural connectivity, potentially lowering pain thresholds and influencing long-term psychological outcomes (4, 5). Early painful experiences can markedly affect neural development; for example, research shows that painful procedures in infants are associated with changes in brain development, particularly in limbic system-related regions such as the hippocampus and amygdala. These changes can impact sustained attention and learning capacity in children (6) and may lead to long-term cognitive deficits (e.g., lower IQ) and adverse behavioral, emotional, and sensory outcomes.

Despite substantial advances in understanding and managing pain associated with vaccination, there remains inequity in the implementation of effective pain management strategies across healthcare facilities. Accordingly, the World Health Organization regards pain relief as a core component of immunization programs (7). Pain management is an indispensable part of neonatal care and should be regarded as a routine component of medical and nursing care throughout the neonatal period (3). Pain management comprises assessment, pharmacological and non-pharmacological interventions, and reassessment, with nurses playing a pivotal role in performing non-pharmacological methods to alleviate pain in patients (8). Nevertheless, the discussion regarding the efficacy and selection of an effective method to prevent pain in infants during painful procedures continues. In this context, two other non-pharmacological pain control methods are the Helfer technique and facilitated positioning (9).

The Helfer technique involves rhythmically tapping the injection site on the skin before and during the injection to calm the muscle. This method was first performed in 1998 by J.K. Helfer on 74 adult patients in the emergency department and the results indicated its effectiveness. In this method, tapping the skin during the injection distracts attention and promotes muscular relaxation, thereby reducing resistance to needle entry (10). Some studies have also shown that manual actions, such as applying pressure and tapping the painful area up and down, can release beta-endorphins into the bloodstream, which may contribute to pain relief (11).

Placing the infant in the fetal position is also beneficial for calming the infant through tactile stimuli and allows the infant to assume a physiological position that offers the best protection (12). In a systematic review, Francisco and colleagues concluded that proper positioning during injections is beneficial for pain relief and for stabilizing physiological, hormonal, and behavioral responses (13). Kucukoglu and colleagues examined the effect of the fetal position on reducing pain from vaccination in infants, with results indicating an effect on lowering pain scores and no impact on arterial oxygen saturation (14).

Multimodal analgesia, which combines different pain-management strategies, is increasingly recognized as an effective approach for treating acute pain in infants (15). For example, a study conducted in a neonatal intensive care unit in Taiwan showed that combining non-nutritive sucking with breast milk reduces pain from heel-stick blood sampling, and adding the facilitated position to the aforementioned measures led to faster relief of pain in infants (16). Although nurses are aware that infants experience pain, in the context of pain management during painful procedures such as vaccination, non-pharmacological interventions are rarely utilized in neonatal wards. The primary barrier identified is a lack of sufficient knowledge regarding neonatal pain assessment scales and the absence of standardized protocols, compounded by a culture that prioritizes procedural speed over pain management quality. Moreover, a lack of emphasis on safety culture in professional training means that non-pharmacological methods are often viewed as discretionary rather than essential clinical requirements (17,18). Intramuscular injections with an appropriate pain-control method can reduce infant pain. Therefore, nurses are responsible for employing the optimal approach to pain management. Non-pharmacological interventions such as the Helfer skin tap Technique and Facilitated position are preferred to pharmacological methods due to their lower incidence of side effects and superior cost-effectiveness (19). Although prior research has examined the effects of the Helfer technique and the facilitated position on pain, the combined effect of these two methods, their synergistic impact on pain reduction, and a direct comparison between the two techniques have not yet been studied. Therefore, this study investigates the effect of the Helfer technique in the facilitated position on pain caused by hepatitis B vaccination injections in term infants.

2- MATERIALS AND METHODS

This study utilized a four-arm randomized clinical trial design, consisting of three intervention groups and one control group, conducted from January 1st to April11th, 2025 in the Obstetrics and Gynecology Department of Imam Reza Hospital . The sample size was determined a priori using GPower 5 software. Based on the mean scores of the Oral Assessment Guide before and after the intervention (2.02 ± 1.91 and 1.32 ± 1.813) and an effect size of 0.22, the calculated sample size was 44 infants per group. Allowing for an anticipated 10% attrition, 48 infants meeting the inclusion criteria were invited to participate in each group.

Randomization was performed with Random Allocation Software, generating a list of random blocks with a block size of 4. Each block was assigned a unique identifier. The contents of each block were arranged to ensure balanced allocation across study arms. At enrollment, a block was randomly selected; participants were assigned to one of the study groups according to the pre-specified order within that block.

Inclusion criteria reflected several factors known to influence infant pain perception and response. Eligible participants were term infants (gestational age 37–42 weeks) with normal APGAR scores (7–10), birth weight >2500 g, and no congenital anomalies, respiratory distress, or cardiovascular problems at birth. Additional eligibility criteria included breastfeeding for at least 30 minutes and up to 60 minutes, and cleanliness of the infant's diaper prior to the intervention.

Exclusion criteria included the development of medical complications during the study, parental non-cooperation or withdrawal, and infants whose mothers had a history of substance abuse during pregnancy.

Allocation concealment was maintained using sealed, opaque envelopes. The envelopes, prepared in advance, were sealed and arranged in a stacked sequence. The allocation sequence within each envelope was concealed from those enrolling participants. Envelopes were numbered and opened sequentially for each eligible infant, with the assignment to one of the four groups (three intervention groups and one control group) made according to the contents of the opened envelope.

The data collection tools included a Demographic Information form and the Neonatal Infant Pain Scale (NIPS), which assesses facial expression, crying state, breathing pattern, hand movements, leg movements, and level of alertness. This instrument was used to evaluate behavioral responses to pain in neonates during and immediately after vaccination. A Nellcor pulse oximeter suitable for infants was employed to measure physiological pain indicators (heart rate and oxygen saturation) before, during, and one minute after the intervention. Neonatal pain responses were recorded using the NIPS before, during, and immediately after intramuscular vaccination. The NIPS is applicable for assessing pain in both preterm and term neonates up to six weeks after birth, and encompasses crying, facial expression, breathing pattern, hand movements, leg movements, and level of alertness. Scoring details are as follows:

Crying: 0 = quiet, 1 = moaning, 2 = crying strongly

Facial expression: 0 = calm, 1 = frowning

Breathing pattern: 0 = normal, 1 = alteration in normal pattern

Hand and leg movements: 0 = normal, 1 = flexion/extension

Level of alertness: 0 = sleeping or awake, 1 = irritable

The total score ranges from 0 to 7. A score greater than 2 indicates moderate to severe pain, warranting pharmacological and non-pharmacological interventions.

The reliability and validity of the NIPS have been established; Suraseranivongse and colleagues demonstrated its properties in a study comparing the reliability and validity of three pain scales (NIPS, CRIES, CHIPPS: Children's and Infants' Postoperative Pain Scale) in neonates (20). To assess device reliability, the pulse oximeter accuracy was evaluated against another device prior to the study. The reliability of the NIPS in data classification was quantified using Cohen's kappa, which yielded $\kappa = 0.89$, reflecting very good inter-rater agreement.

Since two vaccines (HBV and BCG) are administered at birth, the hepatitis B vaccine was given first to minimize potential interference with the study.

2-1. Intervention procedures

Group 1 (Helfer Technique): Vaccination was performed with the infant lying on their back, targeting the right lateral deltoid muscle. After identifying and disinfecting the injection site, the skin was tapped 16 times at approximately 5-second intervals with the pad of the finger to loosen the muscle. While the mother held the infant's leg straight, the vaccinator tapped the skin three times. On the third tap, the needle was inserted into the muscle, and tapping continued gently during the injection (taps continued until the needle was withdrawn). Finally, three taps were applied to the skin, and the needle was withdrawn on the third tap. A key aspect of the Helfer technique is that needle insertion and withdrawal are synchronized with the skin taps (21).

Group 2 (Facilitated Position): Vaccination was performed with the infant placed on their side, with arms and legs drawn toward the midline and body flexed.

Group 3 (Facilitated Position + Helfer): The infant was in the facilitated position while the Helfer technique was applied by the vaccinator, combining the facilitated position with the Helfer technique.

Group 4 (Control): The infant was placed in the standard flat position following routine procedures. After selecting the injection site and aseptically preparing the area, the needle was inserted into the muscle at a 90-degree angle, the drug injected, and the needle withdrawn. Following vaccination, as per hospital routine, the infant was held by the mother and breastfeeding was initiated. In all four groups, vaccination was performed by a single vaccinator using a syringe fitted with a 23-gauge needle. The pain level at needle entry, during, and one minute after intramuscular vaccination was assessed via full video recording by a nurse blinded to the study.

Table-1. Intervention procedures.

Group	Technique Name	Infant Position	Procedure Details
Group1	Helfer Technique	Supine	Skin is tapped 16 times (5s intervals) to loosen muscle. Needle insertion and withdrawal are synchronized with rhythmic skin taps. |
Group2	Facilitated position	Side-lying (Flexed)	Infant is placed on their side with arms and legs drawn toward the midline (fetal-like position)
Group3	Combined Method	Facilitated position	Integrates the rhythmic skin tapping of the **Helfer technique** while the infant is held in the **facilitated position.**
Group4	Control	Standard Flat position	Aseptic preparation followed by a 90-degree intramuscular injection and immediate breastfeeding post-procedure

2-2. Data Analysis

Data were analyzed using SPSS version 26 with appropriate statistical tests. Baseline demographic characteristics of the sample were compared across the four groups, and the homogeneity of these variables was assessed. For normally distributed continuous variables, a one-way analysis of variance (ANOVA) was used. For non-normally distributed continuous variables and ordinal variables, the Kruskal-Wallis test was employed. Nominal variables were compared across the four groups using the chi-square test, with Fisher’s exact test used when appropriate. Normality of the distributions of the quantitative variables was assessed a priori to determine the appropriate statistical test, with the Kolmogorov-Smirnov test applied at a 5% significance level. For variables deemed normal, main analyses were performed separately for the four groups and across intervention phases. The selection of the appropriate test for comparing the main variables among the four groups was guided by the normality assessment described above, with Kolmogorov-Smirnov tests and a significance threshold of $p < 0.05$ when normality was confirmed in at least one group. Greenhouse-Geisser correction was used for within-group pain analyses, and Bonferroni post hoc tests were employed for between-group pain comparisons.

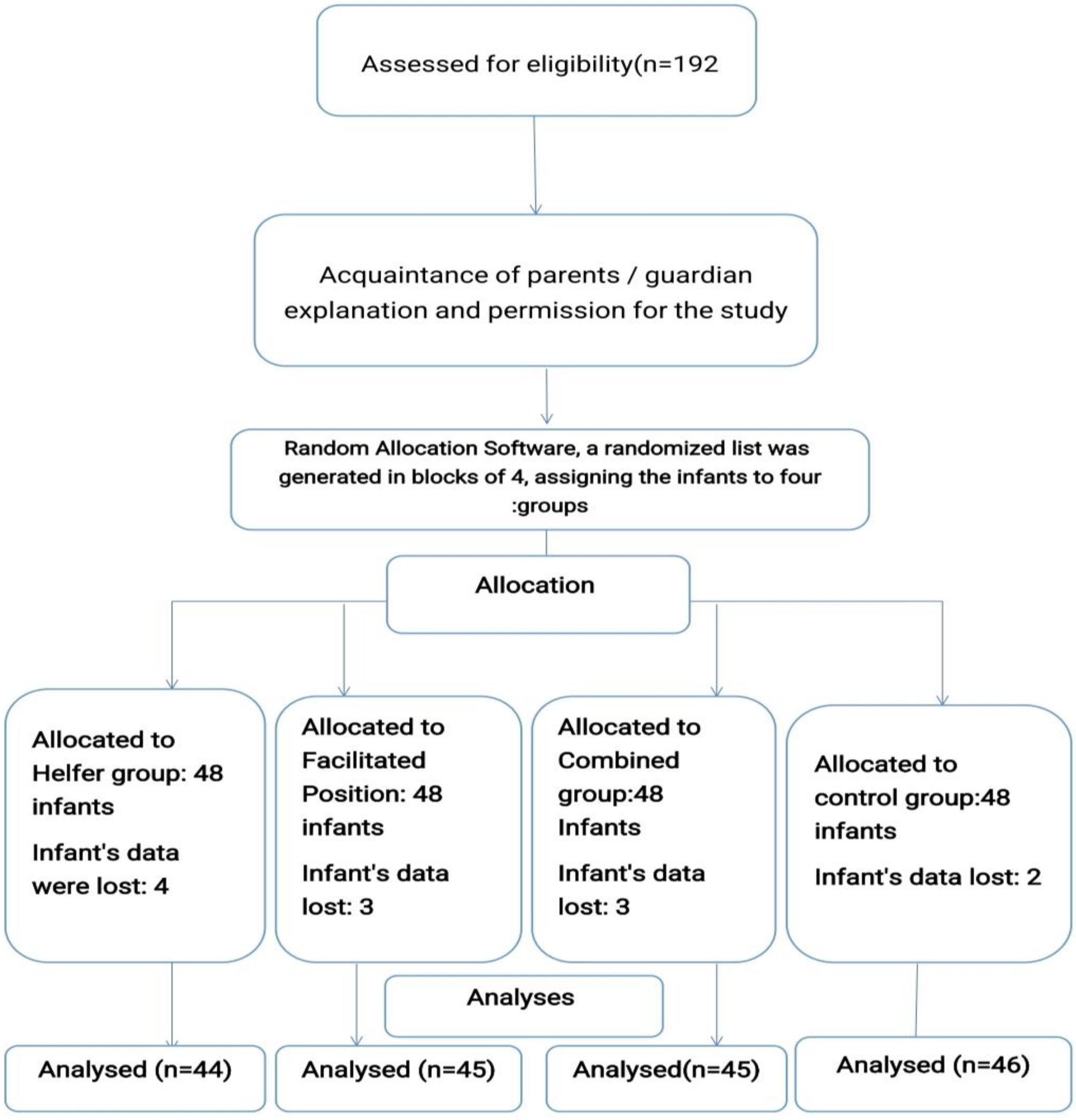

Figure-1: Consort flow chart of the study.

2-3. Ethical Considerations

All ethical considerations were observed, including obtaining ethical approval from the Mashhad University of Medical Sciences Ethics Committee and registration in the Iranian Clinical Trials database (ethical code IR.MUMS.NURSE.REC.1403.030 and clinical trial code IRCT20241030063551N1). After providing a thorough explanation of the study objectives, written informed consent was obtained from the parents. Parents were informed that participation was voluntary, with the right to withdraw at any time, and were assured of confidentiality for all information.

3-RESULT

According to Table 1, which compares demographic variables of the infants across the four groups, there was no evidence of non-homogeneity among the groups. The four study groups were largely comparable and homogeneous with respect to maternal age, birth weight, birth length, head circumference, Apgar scores at 1 and 5 minutes, mode of delivery, and gender. The majority of neonates were delivered by cesarean section, and most were female. Furthermore, the majority of neonates had no congenital disease. Regarding parental characteristics, most mothers and fathers possessed education below a high school diploma; most mothers were homemakers, most fathers were employed, and the cohort overall had adequate socioeconomic status. The four groups were homogeneous with respect to these variables.

In evaluating the effects of the Helfer technique, the facilitated position, and their combination on pain caused by Hepatitis B vaccine injections in infants, the mean pain scores during vaccination were 4.65 ± 0.89 in the Helfer group, 4.88 ± 1.09 in the facilitated-position group, 3.71 ± 0.98 in the combination group, and 5.54 ± 1.08 in the control group. ANOVA indicated statistically significant between-group differences (P = 0.000). Post-injection mean pain scores were 1.26 ± 0.38 in the Helfer group, 1.16 ± 0.46 in the facilitated-position group, 0.98 ± 0.84 in the combination group, and 1.54 ± 1.42 in the control group. The ANOVA showed a statistically significant difference (P = 0.030) (Table 2).

Table-1. Characteristics of the infants among the study groups.

Variable		Group				Test results
		Helfer	Facilitated position	Combined	Control	
Maternal age	*Mean ± SD*	30.23 ± 5.57	27.90 ± 6.78	28.95 ± 7.69	28.31 ± 6.09	F = 1.010 P = 0.390 ANOVA
	Minimum	18	15	17	16	
	Maximum	41	40	44	39	
Apgar score — first minute	*Mean ± SD*	8.0 ± 95.51	8.0 ± 95.30	8.0 ± 82.86	8.0 ± 65-91	P = 0.25 Kruskal-Wallis Test
	Median (25-75 percentile)	9.0 (9.9-0.0)	9.0 (9.9-0.0)	9.0 (9.9-0.0)	9.0 (9.9-0.0)	
Apgar score — fifth minute	*Mean ± SD*	9.0 ± 93.24	9.0 ± 93.29	9.0 ± 91.35	9.0 ± 79.40	P = 0.117 Kruskal-Wallis Test
	Median (25-75 percentile)	10.0 (10.10-10.0)	10.0 (10.10-10.0)	10.0 (10.10-10.0)	10.0 (10.10-10.0)	
Birth weight (g)	*Mean ± SD*	3167.50 ± 392.65	3147 ± 333.25	3260.11 ± 344.09	3056.95 ± 387.36	P = 0.077 ANOVA
	Median	3225	3105	3250	2910	
Length (cm)	*Mean ± SD*	51.00 ± 1.82	51.43 ± 2.04	51.69 ± 2.48	51.02 ± 2.30	P = 0.355 ANOVA
	Median	51	51	51	51	
Head circumference	*Mean ± SD*	34.47 ± 1.13	34.59 ± 1.44	34.63 ± 1.17	34.55 ± 1.11	P = 0.942 ANOVA
	Min-max	32-27	31-17	31-37	32-37	
Mode of delivery	Normal delivery	22 (12.3%)	18 (10.1%)	22 (12.3%)	19 (10.6%)	P = 0.593 Exact Chi-square
	Cesarean	24 (13.4%)	25 (14.0%)	22 (12.3%)	22 (12.3%)	
	Multiple pregnancy	1 (2.1%)	0 (0.0)	1 (0.6%)	3 (1.7%)	
Gender (female)	Female	25 (53.2%)	22 (51.2%)	22 (47.8%)	24 (53.2%)	P = 0.926 Chi-square
	Male	22 (46.8%)	21 (48.8%)	24 (52.2%)	20 (45.5%)	

Table 3 presents a repeated-measures analysis of pain across the four groups (Helfer, facilitated position, combination, control). Given that Mauchly's test indicated a violation of sphericity for the within-subject factor; the Greenhouse-Geisser correction was applied, revealing a statistically significant within-group difference in pain over time (P=0.00). Between-group differences in the trajectory of pain during and after the intervention were significant (P=0.04). Bonferroni post hoc comparisons indicated no significant difference between the Helfer and facilitated-position groups (P = 0.45). However, there was a significant difference between Helfer and the combined group (P= 0.01) and between Helfer and the control group (P = 0.010). In contrast, there was no significant difference between the facilitated-position and control groups (P=0.07). A statistically significant difference was observed between the combined and control groups (P = 0.00). According to the findings presented in Table 3, the 'combined' intervention was the most effective approach in reducing patients' pain scores, demonstrating a mean difference of -1.03 compared to the control group (P < 0.001). Furthermore, the 'combined' method showed a statistically significant superiority over the 'positioning' (mean difference = 0.66; P= 0.001) and 'Helfer' (mean difference= 0.51; P= 0.011) interventions.

The 'Helfer' method ranked second, yielding a significant reduction in pain scores relative to the control group (mean difference = -0.52; P = 0.010). In contrast, the 'positioning' method did not exhibit a statistically significant difference compared to the control group (P=0.073) nor the 'Helfer' group (P=0.451), indicating that facilitated positioning lacks a distinct therapeutic advantage over the other studied interventions.

Comparing the Helfer technique, the facilitated position, and the combined approach, there were no statistically significant differences among the groups with respect to pain, heart rate, oxygen saturation, or infant crying duration (all p > 0.05; Tables 4 and 5).

Table-2. Comparing the level of pain during and after the injection among the groups.

Variable	Groups				Test results
	Helfer	Facilitated Position	Combined	Control	
Pain during injection	4.65 ± 0.89	4.88 ± 1.09	3.71 ± 0.98	5.54 ± 1.08	Between Groups= 0.000
Pain after injection	1.38 ± 1.26	1.46 ± 1.16	0.84 ± 0.98	1.54 ± 1.42	Between Groups= 0.030
Statistical analysis	Tests of Within-Subjects Contrasts= 0.045 Tests of Between-Subjects Effects=0.000				

Table-3. Comparing mean differences of pain score during and after the injection among the groups.

Groups		Mean difference	p-value	95% CI	
				Lower bound	Upper bound
Helfer	Position	-0.15	0.451	-0.55	0.24
	Combined	0.51*	0.011	0.11	0.90
	Control	-0.52*	0.010	-0.92	-0.12
Facilitated Position	Combined	0.66	0.001	0.26	1.06
	Control	-0.37	0.073	-0.77	0.03
Combined	Control	-1.03	0.000	-1.43	-0.63

4- DISCUSSION

This study evaluated the effects of three non-pharmacological strategies -the Helfer technique, the facilitated (fetal) position, and their combination- on pain during and after intramuscular vaccination in term infants, with comparisons to standard care.

Consistent with our hypothesis, regarding the comparison of pain intensity during and after intramuscular vaccination between the Helfer technique and a control condition, the mean pain scores during the vaccination and at one-minute post-injection were significantly lower in the Helfer group than in the control group. We conducted a randomized clinical trial in term newborns delivered vaginally at a Turkish hospital, assigning 60 infants undergoing vaccination to Helfer or control. They reported significantly lower pain levels during injection and afterward in the Helfer group compared with controls, corroborating the present results (22). This consistency across studies confirms that the analgesic effect of the Helfer technique during intramuscular procedures is a robust and well-replicated finding in the literature, applicable to both term infants and older children. An evaluation of the Helfer technique in children aged 4–10 years during intramuscular penicillin administration found reductions in pain, as well as decreases in anxiety and fear, in the Helfer group compared to controls (23). Although differences in participant age and injection type limit direct comparability, these studies collectively support the conclusion that the Helfer technique can attenuate procedural pain across different ages and contexts.

Table-4. Comparison of the heart rate, oxygen saturation, and crying duration before, during and after the injection among the study groups.

Variable		Group: Helfer	Group: Facilitated position	Group: Combined	Group: Control	Test results	
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD		
Heart rate	Before injection	130.63 ± 13.64	128.35 ± 13.82	130.91 ± 10.65	132.12 ± 10.86	Between Groups = 0.544	Greenhous Geisser P = 0.029 Tests of Between-Subjects Effects P = 0.840
	During injection	137.76 ± 22.19	142.14 ± 22.83	144.64 ± 17.10	136.34 ± 22.50	Between Groups = 0.261	
	After injection	132.00 ± 2.85	130.04 ± 13.42	131.06 ± 9.58	133.24 ± 8.96	Between Groups = 0.456	
Oxygen saturation	Before injection	95.85 ± 2.37	96.30 ± 2.89	95.47 ± 2.67	95.77 ± 2.36	Between Groups = 0.511	Greenhous Geisser P = 0.047 Tests of Between-Subjects Effects P = 0.404
	During injection	93.63 ± 4.76	95.16 ± 3.06	94.73 ± 4.14	92.90 ± 5.13	Between Groups = 0.261	
	After injection	95.19 ± 2.81	94.88 ± 2.88	95.58 ± 3.02	95.20 ± 3.31	Between Groups = 0.748	
Crying duration		25.19 ± 19.60	25.37 ± 13.88	19.32 ± 11.93	24.84 ± 18.12	Between Groups = 0.224	

Table-5. Comparison of pain, oxygen saturation, and crying duration during and after the injection among the study groups.

Variable	Group 1	Group 2	Mean difference	P-value	95% CI	
					Lower bound	upper bound
Pain	Helfer	Facilitated position	12.1936	0.406	-7.3867	2.9995
		Combined	1.8913	0.463	-6.9650	3.1824
		Control	1.3386	0.607	-6.4696	3.7924
	Facilitated position	Combined	0.3023	0.909	4.8908	5.4954
		Control	0.8550	0.748	4.3941	6.1041
	Combined	Control	0.5527	0.832	4.5783	5.6837
Oxygen saturation	Helfer	Facilitated position	0.4757	0.289	-1.5786	-0.5560
		Combined	-0.3745	0.467	-1.3884	0.6394
		Control	0.2648	0.611	-0.7607	1.2903
	Facilitated position	Combined	0.1815	0.730	-0.8555	1.2185
		Control	0.8280	0.124	-0.2275	1.8691
	Combined	Control	0.6393	0.223	-0.3916	1.6702
Crying duration	Helfer		Mean difference	Standard Deviation	P-value	
		Facilitated position	-0.1806	3.4236	1.000	
		Combined	5.8654	3.3648	0.498	
		Control	-0.3505	3.4032	1.000	
	Facilitated position	Combined	6.0460	3.4414	0.484	
		Control	0.5311	3.4789	1.000	
	Combined	Control	-5.5148	3.4211	0.6530	

Contrary to our hypothesis, our study also compared pain levels during and one minute after intramuscular vaccination using the facilitated position versus the control group. This finding suggests that the facilitated position alone is not effective in reducing pain for term infants undergoing vaccination.

The literature presents mixed findings. Sundaram et al. conducted a randomized, cross-over trial involving 20 preterm infants aged 28–36 weeks, examining pain from heel-prick blood sampling using the PIPP scale. They discovered a significant decrease in pain among the facilitated-position group (24). The discrepancies between these findings and our results may arise from variations in sample characteristics, such as gestational age and maturity, as well as the type of painful stimulus. Preterm infants, due to their proximal physiological and neurodevelopmental status, might be more responsive to positioning-based analgesia or multimodal cues than term infants receiving vaccinations. A recent systematic review examining nonpharmacological interventions, including the facilitated position, for pain management during painful procedures like heel-stick, in both preterm and term infants, found that the facilitated position significantly reduces observed pain responses in preterm infants. In term infants, however, the results were less consistent and often associated with comfort rather than a clear reduction in pain intensity (25). Similarly, narrative syntheses indicate that although fetal positioning seems beneficial in preterm populations, the evidence in term or older infants is less solid (26).

Possible explanations for the limited effectiveness of fetal positioning in vaccination include: (i) timing constraints, as fetal positioning requires time to induce calm (≥1 minute) whereas vaccination pain can be instantaneous (27); (ii) practical challenges in implementing the repositioning immediately prior to injection, which may increase infant distress (28); and (iii) the purported mechanism of Helfer—distraction via tactile stimulation and motor restraint—which may attenuate pain signaling in a manner not shared by fetal positioning alone. Taken together, fetal positioning may reduce general stress but appears insufficient to address the rapid pain associated with vaccination, and thus is not recommended as a primary intervention for vaccination pain based on current evidence (29). This finding represents new knowledge, as previous evidence of effectiveness was primarily derived from preterm infants undergoing heel-stick procedures (24,25). The present study is among the first to demonstrate that the facilitated position lacks efficacy specifically for vaccination pain in term infants, highlighting the procedure- and population-specific nature of this intervention.

Regarding our hypothesis on the comparative efficacy, when comparing pain intensity in infants during and one minute after intramuscular vaccination using the Helfer technique with the facilitated position, our analysis showed no significant difference between the Helfer and facilitated-position groups. This finding suggests that, as standalone interventions, Helfer and the facilitated position have similar efficacy in reducing vaccination-related pain, given their comparable pain scores during and after the procedure.

Recent studies indicate that touch-based interventions (e.g., Helfer) and the facilitated position may operate via shared physiological and psychological pathways. Both approaches activate cutaneous touch receptors that transmit signals to central pain-modulating circuits and may enhance the release of endogenous opioids, contributing to analgesia. This alignment supports the observed similarity in their analgesic effects (30).

In line with our hypothesis, the combined intervention yielded the lowest mean pain scores, supporting a potential synergistic effect of the two non-pharmacological strategies in mitigating pain during and after infant vaccination. In a study, Lia et al. demonstrated that combining non-nutritive sucking with the facilitated position during heel-stick in preterm infants significantly reduced pain scores (PIPP) and crying duration (29). Other studies assessing multi-modal non pharmacological strategies — such as the combination of the facilitated position, non-nutritive sucking, and skin-to-skin care— have reported greater reductions in PIPP scores compared with single or dual interventions (31). In contrast, Sahoo et al. reported that, during intramuscular vaccination in 62 infants, the Helfer technique reduced pain relative to controls (32); however, in our current study, the combination of the facilitated position and Helfer achieved very low pain scores during and after vaccination, with infants experiencing mild to moderate pain during vaccination. While synergy of multimodal interventions is reported in preterm infants (29,31), this is novel evidence for term infants during vaccination, though the non-significant between-group differences suggest modest synergy requiring confirmation.

With respect to our hypothesis on physiological responses, regarding changes in physiological signs across the four study groups, the control group exhibited the greatest decrease (approximately 2 units), by contrast, the Helfer, and combined intervention groups showed a smaller decline (about 1 unit) and returned to baseline more rapidly, which could imply a protective effect of the interventions. The Position and Control groups remained slightly below baseline. Despite these patterns, results revealed no statistically significant differences in the mean percentage of oxygen saturation before, during, and after the intervention among the four groups.

Heart rate trajectories over time (before, during, and after the injection) varied within groups but did not differ significantly between groups. Ramesh et al. reported that in newborns receiving intramuscular injections, the Helfer technique reduced pain intensity but did not affect physiological signs (heart rate or oxygen saturation) (28). Systematic reviews indicate that the facilitated position does not significantly influence physiological responses in preterm infants during procedures such as suctioning (27).

There was no statistically significant difference in crying duration among the four groups. A study by Bhattacharya in an Indian obstetrics department reported that, although the Helfer technique can reduce pain intensity in term infants during intramuscular injections, it does not produce a significant reduction in crying duration (33). The absence of significant between-group differences in physiological measures suggests that non-pharmacological strategies may influence subjective or behavioral pain responses more consistently than objective physiologic indices in this context.

This study has several limitations that need to be mentioned. Although an independent filmmaker and evaluator were employed, the intervention's identifiable nature in the films rendered full blinding of the evaluators infeasible. Individual and environmental factors, including temperament and baseline pain reactivity of the newborn, as well as the sleep–wake state at the time of administration, could have influenced the observed pain response. Ethical considerations precluded a comparison with a group receiving no analgesia. Furthermore, the single-center design and the inclusion of only term, healthy neonates limit the generalizability of the findings to other populations and settings.

In summary, the following findings from this study are consistent with the broader literature and can be considered confirmed: (1) the analgesic effect of the Helfer technique compared to control; (2) the lack of significant differences in physiological signs across groups. The following findings represent new knowledge or extension of prior evidence: (1) the ineffectiveness of the facilitated position alone in term infants during vaccination; (2) the comparable efficacy of Helfer and facilitated position as standalone interventions; (3) the potential (though not statistically significant) synergistic effect of combining both interventions in term infants. These novel contributions warrant replication in adequately powered multicenter trials.

4-1. Practical and Research Implications

Healthcare policymakers should transition neonatal vaccination guidelines from a focus solely on sterility to one that includes comprehensive pain management. This transition should incorporate the Helfer technique as a safe and cost-effective standard. Standardizing Combined Interventions: The combination of the Helfer technique and facilitated tucking (Group 3) is recommended as the "gold standard" for achieving maximum synergistic pain reduction. Accreditation Incentives: Future accreditation standards should reward hospitals that implement non-pharmacological pain relief methods in neonatal units.

5- CONCLUSION

The Helfer technique reduces pain during and within one minute after intramuscular vaccination in term infants, as opposed to the facilitated position. The combination of Helfer and the facilitated position seemed to result in greater pain reduction, indicating a potential synergistic effect; however, our analyses did not show statistically significant differences between any two groups.

Further adequately powered studies are warranted to clarify whether true synergy exists between these non-pharmacological strategies and to delineate the magnitude of benefit offered by non-pharmacological multi-modal approaches. Given the heterogeneous findings across populations (term vs preterm) and procedures, there is a need for procedure- and age-specific investigations to refine recommendations.

The present findings, together with the broader literature, support the potential of combining non-pharmacological analgesia techniques in infant vaccination. Considering that care teams—especially nurses—are acutely aware of the pain associated with neonatal procedures, it is hoped that these techniques will be implemented effectively. Such adoption could contribute to expanding a culture of pain prevention in infants and young children within the healthcare workforce.

6- CONFLICT OF INTERESTS

The authors report no actual or potential conflicts of interest.

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