

## **An investigation of the effects of massage therapy on pain caused by umbilical vein catheter insertion in premature neonates: a clinical trial**

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### **ABSTRACT**

**Background:** Infants are more vulnerable to the negative effects of pain than adults and older children. Non-drug pain management includes non-invasive, safe, and low-cost strategies which can be easily conducted by nurses. Massage therapy, as a non-drug method, can be effective in pain relief in infants.

**Aim:** To find out how effective the massage therapy is in reducing the pain caused by umbilical vein catheter insertion in preterm infants.

**Methods:** This present clinical trial study has been conducted in the Neonate Intensive Care Unit (NICU) ward of the Qaem hospital in Mashhad. Sixty-four preterm infants were divided into two groups randomly; control group and experimental one. The experimental group infants were given massage before the umbilical vein catheter insertion. Data collection was performed using questionnaires, checklists, and Premature Infant Pain Profile (PIPP).

**Results:** The findings showed that the mean and standard deviation of pain scores were significantly lower in the experimental group ( $2.66 \pm 2.82$ ) compared to the control group ( $9.78 \pm 3.63$ ) ( $p < 0.0001$ ). Moreover, the mean changes of heart rate during the umbilical vein catheter insertion in the experimental and control groups were  $6.84 \pm 7.19$  and  $18.50 \pm 7.95$ , respectively ( $p < 0.0001$ ).

**Conclusion:** Although various results may be obtained using different pain assessment tools, the result which is presented here show that massage therapy can be effective in management and pain relief. Moreover, applying massage can improve some cardiovascular parameters in infants as a valuable finding.

**Keywords:** Pain, Massage therapy, preterm infants; Umbilical vein catheter

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### **INTRODUCTION**

Newborns in the NICU ward go through many painful but necessary stages during hospitalization. Both consequences of pain caused by these methods and types of pain relief have significant results on the physical and mental development of infants<sup>1</sup>. There are drug-free analgesic techniques especially on long-term neonatal when combined with drug-based analgesia which needs more study to show the safety and effectiveness of them<sup>2</sup>.

Drug-free techniques provide pain relief potentially for both term and preterm infants. Most studies show an improvement in behavioral pain responses including duration of crying or latency to first cry, facial expressions, and physiological parameters (such as SPO<sub>2</sub>, heart and respiratory rate)<sup>3</sup>. Umbilical catheterization offers a particular vascular access that is only possible in the preterm neonatal setting due to unimpeded umbilical vessels from fetal circulation<sup>4</sup>.

Catheters imported to central veins are a basic standard technique of NICU ward and is quick and painful method of gaining access to a deep vein<sup>5,6</sup>. Although, there are a lot of clinical guidelines for controlling acute pain such as surgical pain, but it seems that no enough attention is paid to slight pains<sup>7</sup>. According to Hall and Anand, less than 5% of the infants in the NICU are given painkillers during painful procedures such as tracheal suctioning<sup>6,7</sup>. However, the number of those who receive analgesics during umbilical vein catheter insertion might be less. Preterm infants are especially vulnerable to the effects of pain and stress because of rapidly growing of their nervous system<sup>8</sup>.

Contrary to term infants and older age children, the density of pain receptors in the skin of preterm infants is greater<sup>7</sup>. So, they experience severe pain more than adults. There are many reports of delayed neurobehavioral development in preterm infants that may be due to many stressors present in the NICU ward. Also, repeated stress and pain may result in behavioral and emotional problems at school age for preterm infants<sup>9</sup>; Their Parents usually complain of their children's physical problems at the school age, and the state of hypersensitivity towards pain. This reveals that the painful experiences in the NICU have affected their pain feelings<sup>7-10</sup>. As a result, to reduce stress and pain experienced by infants, it is necessary to minimize the number of painful procedures and utilize drug-based or drug-free techniques<sup>8-10</sup>.

In the past two decades, several interventions have been researched include: positioning, unlimited parental visitation, decreasing environmental stimuli such as noise and light, kangaroo and cluster care, massage therapy, non-nutritive sucking, and bathing in order to promote the developmental outcomes and decrease the stress of the infants who hospitalized in the NICU ward. Two important objective in the NICU which are necessary for developmental outcome of infants especially preterm ones are decreasing stress and promoting growth and one technique that might be helpful is Massage therapy<sup>11</sup>.

Massage therapy with its undeniable clinical effectiveness evidence is defined by the American Massage Therapy Association (AMTF) as "The manipulation of the body soft tissue to boost wellness and health beside to impede and reduce pain, muscle spasm, inconvenience, and stress"<sup>11</sup>. Although we defined

Therapeutic massage as the “manual technique to the superficial skin soft tissue, ligaments, tendons, muscles, and fascia using the hand, arm, foot, elbow, knee, and forearm. But, this technique includes the systematic application such as touch, vibration, stroking, kneading, friction, percussion, stretching, compression or joint movements (both passive and active) within the normal physiologic range of motion”<sup>12,13</sup>.

The relationship between pain responses and massage were assessed in two studies in preterm infants. Diego et al (2009) showed that infants who received massage therapy about 15 minute before the removal of surgical tape in comparison to who didn't receive massage therapy, had less increase in heart rate and experienced lower HR after the removal of surgical tapes<sup>14</sup>. In the Study by Abdallah et al (2013), showed that during a heel stick, lower pain scores on the Premature Infant Pain Profile (PIPP) were assign to the infants who were massaged contrary to who were not massaged; moreover, the first group had lower PIPP scores at discharge time<sup>11,15</sup>.

Massage therapy can be effective in controlling pain pathways and increasing the secretion of endorphins. According to the evidence, the effect of this technique and clinical observations of researchers on the inadequacy of pain control techniques in preterm infants for whom an umbilical vein catheter is implanted, as well as the need to take measures to control, this study was conducted to determine the effect of massage method on decreasing pain in premature infants during intravenous catheter insertion to use the results to improve the compatibility of infants with catheterization. Therefore, the aim of the present study was to find out how effective the massage therapy is in reducing the pain caused by umbilical vein catheter insertion in preterm infants.

## METHODS

**Trial Design:** The present randomized clinical trial (RCT) has been conducted with the aim of evaluating the effects of massage therapy on management of the pain caused by umbilical vein catheter insertion in preterm infants. Data collection was performed in the NICU ward of Qaem Medical Center after obtaining permission of the university ethics committee with IRCTs code IRCT20180116038385N1 and providing permission of the authorities of School Nursing and Midwifery, Mashhad University of Medical Sciences. The samples were randomly (using simple randomization method) selected from the patients admitted to the aforementioned institution's hospitals and care was taken not to lead to allocation concealment when assigning the participants to the groups. All of the subjects of the study without any drop-out finished the trial. Because of this kind of intervention, blinding was not possible.

**The Participants:** Samples were selected from preterm infants who needed insertion of umbilical vein catheter. They were randomly assigned into the experimental and control groups. Inclusion criteria included: being in 30-37<sup>th</sup> week of gestational age, needing umbilical vein catheter insertion, not having hypothermia or hyperthermia (newborn temperature of 36.2-37.2°C), weighing more than 1000 gr, and having a Premature Infant Pain Profile (PIPP)

score lower than 7 before umbilical vein catheterization. In addition, the exclusion criteria included: occurrence of apnea during the insertion of catheter, having addicted mother, 1-minute Apgar less than 5 and 5-minute Apgar less than 7, having obvious congenital anomaly, symptoms of hypoxic ischemic encephalopathy (HIE), signs of kernicterus, Necrotizing enterocolitis (NEC), central nervous system disorders, persistent tachycardia or bradycardia, and taking painkillers during the last 48 hours.

**The intervention:** Research objectives and methods were completely explained to the infant's family and parental consent was obtained. In the experimental group, the intervention was conducted by placing stable infants in reanimators (with identical environmental conditions such as light, temperature, and noise) and connecting them to Nellcor™ pulse oximeter. The sensing probe was placed on the right side, and between the thumb and the second finger, and the vital signs including heart rate, body temperature, and the oxygen saturation level were recorded after 5 minutes. The PIPP was used to measure the pain responses of the infants. In the experimental group, the infants were given 15 min massage (Field technique) consisted of three 5-min phases. In the first and last phases, the baby was put in a prone position and then received massage with gentle strokes. Before starting massage, the researcher applied olive oil (Varamin™, standard and approved, 3-5 drops) and warmed her hands by rubbing them together. Then, using her hands, she stroked for the period of five 1-minute (approximately five second for stroking movement with totally twelve motion) in each area in the following sequence: (A) starting from the head of baby down to the sides of the neck and back again, (B) from the neck down to the shoulders and back again, (C) from the upper back down to the waist and back again, (D) from the hip down to the ankles and back again, (E) from shoulders to the wrist and back again. In the middle phase, supine position was selected for the infants. This phase continued with five 1-minute parts include six passive motion (flexion/extension) which were lasting about 10 second for right and left arms, legs, and finally both legs together [10-14]. The vital signs and PIPP scores were recorded after finishing the massage. Then, the umbilical vein catheter was inserted in sterile condition by a resident in pediatrics (completed at least 6 months of the residency training).

All of the inserted catheters were identical in terms of type and size. The PIPP score and vital signs were measured during the catheter insertion as well as 2 and 5 minutes after it. All of the treatment steps were identical for the infants in the control group except who were not given massage. The PIPP and vital signs were recorded 20 min after connecting to the pulse oximeter and then the catheter was placed. In order to carefully inspect the infant's behavioral status, his/her face was video recorded during the whole session.

In preterm infants, a behavioral scale of pain is the PIPP. The scoring instructions and indicators in PIPP have been provided in Table 1.

In the table, the 0-9% of the observation time defined by the word “absent”; 10% -39%, 40% -69% and ≥70% of the observation time are defined by minimal, moderate and maximal respectively. scores are varying from 0 - 21 in this

scale so in the case of having pain or minimal pain, the score is  $\leq 6$ , and in the case of having moderate to severe pain, the score is  $>12$ .

**Statistical methods:** All data were entered using SPSS version 16 and analyzed using Chi-square, independent t-test was used for categorical and numeral variables. In case of lack of normal distribution of numeral data, Mann-Whitney test was used. Statistically, P-value less than 0.05 was considered significant.

## RESULTS

In this randomized controlled clinical trial, the samples were not significantly different in terms of sex, average age, Apgar score, respiratory score and nutritional status ( $p > 0.05$ ). It was found that before the catheter insertion, the mean arterial oxygen saturation and heart rate were not significantly different in the experimental and control groups. However, after insertion of the umbilical vein catheter, the heart rate was increased in both groups especially in the control one. The difference between two groups after the insertion of the umbilical vein catheter was found to be significant based on independent t-test results ( $p < 0.001$ , Table 2).

During catheter insertion, the arterial oxygen saturation was decreased in both groups. However, more decrement was observed in the control group and the difference was found to be significant based on non-parametric Mann-Whitney test (Table 3).

Due to understand the effects of using massage on pain severity, the changes in mean PIPP scores of the two groups were compared before and during the catheter insertion. Based on the obtained results, changes in the mean PIPP score in the control group was three and a half times greater than experimental group. The statistical Mann-Whitney test indicated that two groups are significantly different ( $p < 0.0001$ , Table 4).

There were nineteen infants (59.4%) in the experimental group with the pain scores ranging from 5 to 10. Moreover, the number of the infants in the control group who had pain scores in the range of 11-15 was fifteen (46.9%). The pain severity scores of nine infants (28.1%) in the control group were in the range of 16-20, while none of the infants in the experimental group had pain scores in this range (Table 4). Also, it took less than 30 s for the majority of the infants in the experimental group (22 infants, 68.8%) to recover the initial heart rate, while it lasted more than 120 s for most of the infants in the control group (19 infants, 59.4%). It was also found that the time required to recover initial oxygen saturation level was less than 30 s for most of the members in experimental group (24 infants, 75%). This was while it took more than 120 s for the majority of the infants in the control group (21 infants, 65.6%). Accordingly, the obtained results from Mann-Whitney test indicated that two groups are significantly different ( $p < 0.0001$ ).

Table 1: Indicators and scoring instructions of PIPP

Indicators	0	1	2	3
Gestational age(weeks)	$\geq 36$	32 -35 weeks & 6 days	28 - 31 weeks & 6 days	$< 28$
Observe the newborn for fifteen second				
Consciousness	C	NC	C	NC
	Awake	Awake	Asleep	Asleep
	OE	OE	CE	CE
	With Facial motions	without facial motions	With Facial motions	without facial motions
Record Heart Rate and SpO <sub>2</sub>				
Maximal Heart Rate	$\uparrow 0 - 4$ beat per minute	$\uparrow 5 - 14$ beat per minute	$\uparrow 15 - 24$ beat per minute	$\uparrow \geq 25$ beat per minute
Minimal saturation	$\downarrow 0 - 2.4\%$	$\downarrow 2.5 - 4.9\%$	$\downarrow 5 - 7.4\%$	$\uparrow \geq 7.5\%$
Observe the Newborn for 30 second				
Frowned forehead	Absent	Minimal	Moderate	Maximal
Eyes squeezed	Absent	Minimal	Moderate	Maximal
Nasolabial furrow	Absent	Minimal	Moderate	Maximal

GA: gestational age; NB: newborn; C: conscious; NC: none conscious; OE: opened eyes; CE: closed eyes

Table 2: Comparing changes in heart rate before and during umbilical vein catheterization

A comparison of changes in heart rate in two steps			
Group	Number of members	Mean $\pm$ SD	Independent t-test result
Experimental	32	6.84 $\pm$ 7.19	t = 6.153
Control	32	18.50 $\pm$ 7.95	P* < 0.001

\* Statistically, P-value less than 0.05 was considered significant

Table 3: Comparing changes in oxygen saturation before and during umbilical vein catheterization

A comparison of changes in oxygen saturation in two steps			
Group	Number of members	Mean $\pm$ SD	Mann-Whitney test result
Experimental	32	-1.40 $\pm$ 2.27	z = 5.20
Control	32	-8.19 $\pm$ 6.00	P* < 0.0001

\* Statistically, P-value less than 0.05 was considered significant

Table 4: Comparing changes in PIPP score before and during umbilical vein catheterization

A comparison of changes in PIPP score in two steps			
Group	Number of members	Mean $\pm$ SD	Mann-Whitney test result
Experimental	32	2.66 $\pm$ 2.82	z = 5.94
Control	32	9.78 $\pm$ 3.63	P* < 0.001

\* Statistically, P-value less than 0.05 was considered significant.

## DISCUSSION

The present study showed that applying massage before insertion of the umbilical vein catheter is associated with significant pain reduction in preterm infants. The effect of massage therapy on pain relief has been previously investigated in a few studies. However, none of the pain management techniques have been investigated for the pain caused by umbilical vein catheter insertion so far. A point to be taken into account is that the present study is the first one which shows the importance of the issue. It has been found that the mean increase in heart rate (before and during insertion of umbilical vein catheter) in the experimental group in comparison to control group was significantly lower ( $p < 0.0001$ ) and the mean of heart rate in the control group was more than another one by 11.66 beats. Diego et al have investigated the effect of massage on the heart rate before removing skin patches. They found that the mean increase in heart rate was 10.03 beats per minute for those who were given moderate massage, while it was 12.33 and 13.23 beats per minute for those who were given mild massage and those in control group, respectively<sup>14</sup>. Rafati et al have investigated the relationship between physiological pain and the effect of massage in infants when getting blood sample. They found that the mean increase in heart rate in the control group ( $152.15 \pm 14.419$ ) has been reported significantly higher than the experimental group ( $138.74 \pm 17.965$ )<sup>16</sup>.

In another study by Jain et al. the mean increase in heart rate in the control group ( $159.2 \pm 13.4$ ) has been reported significantly higher than the experimental group ( $149.2 \pm 13.6$ , and  $p < 0.03$ ). Similar to the obtained results in the present study, they have shown that the heart rate does not change significantly before and after applying massage<sup>17</sup>. It should be mentioned that the intervention type (massage) and the ages of the infants (preterm) in their study were similar to the present one, while it was different in terms of pain assessment tool as well as the kind of painful procedure.

Contrary to the control group, it was found that employing massage before insertion of the umbilical vein catheter resulted in significant decreased pain in the experimental one ( $p < 0.0001$ ). Mathai et al. have measured the pain of heel pricks in stable term infants using DAN scores. They reported the mean pain score of 9.9, 9.4, 7.6, 9.5, 8.8, and 9.2 for massage, expressed breast milk, sucrose, distilled water, NNS, and rocking groups, respectively. Therefore, the pain was significantly reduced in sucrose group after intervention. In their study, the pain severity in the massage group was lower than the others (except the NNS and rocking groups) just in the fourth minute of the intervention<sup>18</sup>. In Jain's research, the mean pain score in the massage group ( $1.5 \pm 0.9$ ) was significantly lower than the control group ( $3.5 \pm 1.5$ ,  $p < 0.001$ ), based on the neonatal infant pain scale (NIPS)<sup>17</sup>.

## CONCLUSION

Accordingly, the present finding suggested that massage therapy can be effective in pain reduction in preterm infants. Anyway, as there are a few reports on the effectiveness of this technique as a pain management method so it still needs to be further investigated. Nevertheless, our finding

may be valuable for future studies since this is the first study which shows the importance of the issue.

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**Conflict of interest:** No conflict of interest to be declared.

**Ethical Approval:** This RCT was assessed in committee for ethics in research of Mashhad University of Medical Sciences and its sampling method and interventions were approved. This RCT was approved by Regional Authority for Registration of Clinical Trials with 89972ID and IRCTs code IRCT20180116038385N1

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