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Does mother scented simulated hand promote comfort, reduce pain, and distress among mechanically ventilated preterm neonates during invasive procedures?

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ABSTRACT

Introduction: Breakthrough technologies in the neonatal intensive care unit (NICU) revolutionized neonates' quality of care. Mother scented simulated hand (MSSH) is an ergonomically designed supportive hand that uses the power of touch to simulate the feeling of being held and cuddled. This study aimed to determine the effect of MSSH on promoting comfort among mechanically ventilated preterm neonates during invasive procedures.

Methods: A quasi-experimental, pre-posttest two groups study was carried out in NICU in Smouha, Alexandria. A sample of 62 mechanically ventilated neonates was randomly assigned to two equal groups; the study group wrapped with a warm MSSH during the invasive procedures while the control group received standard care of NICU. Two observers independently rated the neonates' level of comfort, distress, and pain during endotracheal suctioning (ETS) and heel prick using COMFORTneo scale.

Results: It is revealed that the mechanically ventilated neonates had a significantly higher comfort level with MSSH than the standard care during and after both ETS and heal break ($p < 0.001$ for each). The neonates had significantly lower distress and pain scores when encircled by MSSH during invasive procedures than standard care ($p < 0.001$ for NRS distress and $p < 0.001$ for NRS distress).

Conclusion: Wrapping the preterm neonates with a warm MSSH promotes comfort and reduces their pain and distress during invasive procedures, especially when their mothers are not physically available.

Keywords: Simulated hand; comfort, pain; distress; invasive procedures; preterm neonates

INTRODUCTION

Preterm neonates face challenges during the process of adaption from fetal to postnatal life (1). They are abruptly shifted from a safe and secure intrauterine environment to a confusing, stressful, and painful extra uterine one (2). Critically ill preterm neonates admitted to neonatal intensive care unit (NICU) are particularly vulnerable to major iatrogenic and environmental threats. Light, cold, sound, odors, inappropriate handling, radiation, medications' ingredients, and chemicals are potential sources of such iatrogenic noxious stimuli (3). Unlike older children, preterm neonates are ill-equipped to deal with life outside the womb as their organ systems are still developing. Being mechanically ventilated adds an extra encumbrance on the preterm neonates undergoing an array of painful and stressful procedures (4).

Conventionally, it was reckoned that preterm neonates are experiencing less pain due to their undeveloped nervous system. However, it is scientifically confirmed that the pain nerve fibers are functionally devolved in the early stage of fetal development, and the afferent nerve fibers to the cerebral cortex are completely formed at the 20–26th weeks of gestation (5). Besides, evidence reported low pain thresholds among infants, particularly preterm neonates who are extremely sensitive to painful stimuli and unable to effectively express and cope with painful experiences (6,7). During the critical period of brain growth, the painful insults may expose the preterm neonates to potentially long-term developmental problems later in childhood (2). Moreover, exposure to invasive procedures may induce many adverse physiological reactions among these fragile neonates (8,9). Painful and stressful stimuli can increase the catecholamine level, blood pressure, heart rate, and intracranial pressure. Deoxygenation, hyperglycemia, and respiratory arrhythmias can also be associated with such stress-inducing experiences (5).

Throughout the mechanical ventilation period, preterm neonates are deprived of their mother's hug, voice, scent,

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empathetic touch, and warm-heartedness (10). Recently, maternal engagement has been acknowledged as an essential aspect of care for hospitalized preterm neonates and positively influences their clinical outcomes (11,12). In that sense, many evidence-based practices had strongly advocated the therapeutic impact of both tactile and olfactory stimulations among preterm neonates (13,14). In fact, touch is a primitive way of communication between the mother and her neonate. It promotes a sense of love and security and maintains the neonates' physiologic and psychologic regulations (15). On the other side, neonates are familiar with and prefer their mothers' related scent and the odor of her amniotic fluid and breast milk in their early life. Neonates respond to olfactory stimulation with both positive and negative behaviors (16). Positive benefits from sniffing these preferred odors include self-regulation, promoting comfort, and reducing pain and distress levels. However, the negative olfactory experiences in the surrounding NICU environment, such as skin preps, alcohol pads, and adhesive removers, may hinder preterm neonates' ability to cope with stressful experiences (15,17). Therefore, adopting innovative pain management approaches that involve the mothers' positive participation in the care of their NICU admitted neonates are crucial (17).

Breakthrough technologies in NICU revolutionized the quality of care offered to neonates. In this regard, one of the recent inventions is the Simulated Human Hand. It is an ergonomically designed supportive pillow that simulates the shape, weight (500 g), heat, and human hands and arms touch. The simulated human hand uses the power of touch to simulate the feeling of being held (like a HUG) and enhances the release of both melatonin and serotonin hormones that induce relaxation and calmness (5).

Preterm neonates undergoing mechanical ventilation are daily exposed to multiple painful, invasive procedures. Exposure to painful stimuli in early life has both short- and long-term negative impacts on the neonate's health (18). Treating procedural pain stands as an existing challenge for NICUs nurses. Recently, utilizing the innovative approaches to promote neonates' comfort and minimize their pain and stress is appreciated rather than performing the standard care. Unfortunately, the standard NICU care did not support the multisensory stimulation and containment, in addition to limiting the mothers' opportunities to participate in their neonates' care (19). Although the standard NICU care for the preterm neonates, such as mother skin-to-skin contact (kangaroo care), is strongly recommended in the literature, the excessive handling of the mechanically ventilated preterm neonates during the invasive procedures may increase the risk of accidental extubation of the non-coughed endotracheal tube (20,21). In this context, nurses could use a multi-modal approach such as a weighted maternally scented simulation device. It simulates the weight, containment, and maternal scent together. These could reduce neonates' stress-related behaviors, promote self-regulation, and enhance optimal brain development (15). In addition, this technique supports the mothers' active participation in caring for their preterm neonates who suffer from serious illnesses.

Since researches addressed the use of this modality in the NICUs during painful procedures are scarce. Hence, this study aimed to determine the effect of mother scented simulated hand (MSSH) on comfort, pain, and distress among mechanically ventilated preterm neonates during invasive procedures. The research outcomes are directed to implement MSSH to promote the preterm neonates' comfort in NICU during the invasive procedures.

Hypothesis of this research was:

- Preterm neonates who receive MSSH exhibit higher levels of comfort during invasive procedures than those who receive standard care.
- Preterm neonates who receive MSSH exhibit lower levels of pain and stress during invasive procedures than those who receive standard care

METHODS

This quasi-experimental, two-group, pre-posttest study was carried out in NICU at University Specialized Hospital in Smouha, Alexandria, for 3 months. The unit is classified into three levels. The study was conducted at level III, where the mechanically ventilated neonates were admitted. The nurse-to-patient ratio at this level was 1:1. An assistant nurse helped the assigned nurse during the performance of the invasive procedure.

A convenience sampling of 62 mechanically ventilated preterm neonates who fulfilled the following inclusion criteria comprised the study subjects; preterm (<37 weeks of gestation) newly admitted and had hemodynamic stability. However, neonates who received sedatives, muscle relaxants, or analgesics; had a low Apgar score lower than 3 at 5 min, hypothermia, hypoglycemia, or hyperglycemia, intraventricular hemorrhage Grades III and IV, and neonatal seizures were excluded from the study.

Epi Info program version 10 was used to estimate the sample size using the following parameters; population size of 151, confidence coefficient of 95%, expected frequency of 50%, and acceptable error of 10%. The minimum sample size required was 59 mechanically ventilated preterm neonates.

During the study period (April–June 2021), 62 out of 84 neonates were eligible for the study. Neonates were randomly assigned to two equal parallel groups using a random number generator program; one neonate was assigned to the study group, and the next neonate was assigned to the control group. The study group was wrapped with a warm MSSH during the invasive procedures while the control group received standard care of NICU, as illustrated in Figure 1.

For this research, two research instruments were used:

Preterm neonates' physiological response assessment sheet

The researcher developed this tool after a review of related literature to assess neonates' characteristics, physiological parameters throughout the invasive procedures, namely, endotracheal suctioning (ETS) and heel prick. It included heart rate and oxygen saturation (SpO_2). Demographic characteristics of neonates as age, gender, gestational age, birth weight, and the medical diagnosis were attached to this tool.

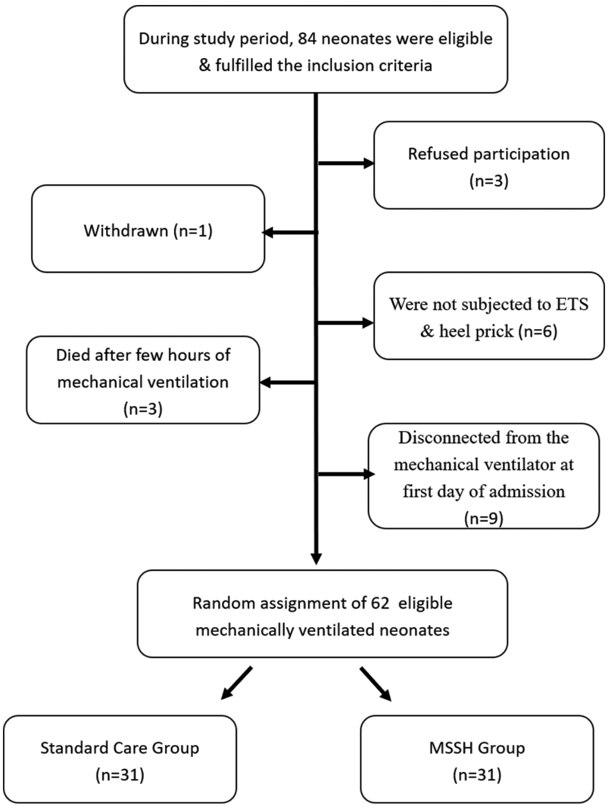

FIGURE 1. Flowchart of participants' recruitment process.

COMFORTneo scale

This scale was developed by Dijk et al. (2009) (22) to assess neonates' comfort, distress, and pain levels. Regarding the assessment of the comfort, the scale has six subcategories; alertness (5 items ranged from quiet sleep to facial tension), calmness/agitation (5 items ranged from calm to panic), respiratory response (5 items ranged from no spontaneous respiration to fights ventilator), body movement (5 items ranged from no or minimal movement to up to three vigorous arms and/or leg movements), facial tension (5 items ranged from fully relaxed to grimacing), and muscle tone (5 items ranged from fully relaxed to extreme muscle tone). The neonates' behavioral response was rated on 5 points numerical rating scale (NRS) (1-5), and the total score of the comfort subscale ranged from 6 to 30. The lower score indicates a higher level of comfort and vice versa. The COMFORTneo scale has additional two NRSs for pain and distress. These scales are scored after the COMFORTneo score. Both range from 0 to 10; the 0 score represents no pain or distress, while the 10 score represents the worst imaginable pain or distress. The levels of pain or distress were categorized into three levels; mild (score 1–3), moderate (score 4–6), and severe (score 7–10). The scale proved to be valid and reliable. The Cronbach alpha coefficient was determined as 0.84 for the primary observer and 0.88 for the assistant observer. Inter-rater reliability was good, and the median linearly weighted Cohen kappa was 0.79 (22).

Initially, the researchers recorded neonates' biodemographic and clinical characteristics in the standard care and MSSH groups. During the invasive procedures, the NICU environment was adjusted to avoid interruption, for example, select suitable time away from other diagnostic procedures (e.g., X-ray) and doctors' rounds.

Patients are divided in two groups:

The standard care groups (control group)

On day 1 of mechanical ventilation, the neonates were provided with standard care, which entailed maintaining a quiet environment with minimal stimulation, uninterrupted periods of sleep, and containment. Neonates were placed in a side-lying position while their extremities were flexed close to the body and wrapped with rolled sheets or towels to simulate the intrauterine posture. This position was maintained during the performance of the invasive procedures, for example, ETS and heel prick. Suction was performed only when indicated. However, the heal prick procedure was performed routinely to obtain the daily blood samples. Neonates' physiological responses were assessed before, during, and after exposure to the invasive procedures. Simultaneously, two observers (two nurses trained by the researchers) rated the neonates' comfort, distress, and pain levels independently before, during, and after the invasive procedure, and inter-rater agreement was ascertained to avoid subjectivity and ensure consistency of the observed behaviors.

The MSSH groups (Study group)

On day 1 of mechanical ventilation, the neonates received the same standard care of the NICU, while they wrapped with a warm MSSH as follows; a simulated hand was scented with mothers' body odor by placing it on the mothers' bare chest or behind the neck for 1 h. Then, the MSSH was placed under a radiant warmer for a couple of minutes to reach the mothers' unique warm touch. Inside the incubator, the mechanically ventilated neonates were placed in a side-lying flexed fetal position, where they encircled with the two warm simulated human hands to contain them. Where the palm of one MSSH cupped the neonates' head, and the palm of the other hand cupped the lower part of the body and extremities. The neonates were kept in such a position throughout the mentioned invasive procedures, as shown in Figure 2. Neonates' physiological response, comfort, distress, and pain levels were assessed the same way as the 1st day.

An approval from the Ethical Research Committee of Faculty of Nursing, Alexandria University, was obtained (14/3/2021). Furthermore, official permissions for conducting the study were obtained from the director of the previously mentioned setting. The researchers approached guardians of the neonates who matched the inclusion criteria. The study's aim was explained to them, and their free decision to voluntary participation in the study was strictly emphasized. The researchers also stressed the guardians' right to refuse to participate or withdraw from the study. After their agreement, written informed consent was obtained from the neonates' guardians. Confidentiality of the obtained data was assured, and participants' anonymity was respected. Neonates' privacy was maintained during the implementation of the study.

For data analysis, Statistical Package for the Social Sciences version 23 was used.

Descriptive statistics included number, percentage, the mean, and standard deviation to describe demographic characteristics and physiological and behavioral responses to endotracheal tube suctioning among mechanically

FIGURE 2. Application mother scented simulated hand among mechanical ventilation neonates.

ventilated preterm neonates. Kolmogorov–Smirnov test was used to check the normality of study variables, and it showed that they were not normally distributed.

Analytical statistics, a comparison between the neonates in the two study groups regarding their mean age, physiological, and behavioral responses before, during, and after 5 min from the invasive procedures were made using Mann–Whitney (Z) tests. Intraclass correlation coefficient (ICC) was used to assess the degree of agreement between the two raters/observers. All of the statistical analyses were considered significant at $p < 0.05$.

RESULTS

Table 1 presents characteristics of mechanically ventilated preterm neonates. It is revealed from the table that 58.06% and 48.39% of the preterm neonates in the MSSH group and standard care group were in the 1st week of life. The mean age of the neonates in the MSSH group was 8.49 ± 7.75 days and 7.29 ± 7.75 days in the standard care group, with no significant statistical difference between the two groups. Moreover, 67.7% and 61.2% of the preterm neonates of both groups were male, respectively. Regarding neonates' gestational age, it is observed that 61.2% of the neonates in the MSSH group and 67.7% of the neonates of the standard care group were moderate preterm. It is clear from the same table that 58.08% of the neonates in the MSSH group and 67.74% of those in the standard care group had low birth weight. Moreover, half of the neonates, 58.06% and 51.61% in both groups, had respiratory distress.

Table 2 displays that the mean SpO2 of neonates in the standard care group was 90.18 ± 27 compared to 94.00 ± 2.99 of the MSSH group during ETS ($p < 0.001$). The mean SpO2 increased after suctioning with applying the MSSH ($p = 0.01$).

The mechanically ventilated preterm neonates had lower scores on the COMFORTneo scale when warped with MSSH than the standard care during and after ETS ($p < 0.001$ for each). Similarly, the COMFORTneo NRS-distress and The COMFORTneo NRS-pain showed lower scores with using MSSH than standard care during and after ETS ($p > 0.001$ for both NRS distress and NRS distress).

Table 3 highlights the physiological and behavioral responses to heel prick among the mechanically ventilated neonates. The mean SpO2 was higher with applying MSSH during the heel prick procedure than applying the standard care (93.04 ± 2.98 and 95.08 ± 1.34, respectively). Unlike standard care, the mean heart rate did not show significant increment during the heel prick when MSSH encircled the preterm neonates as it raised from 129.61 ± 13.56 and 146.78 ± 13.90 compared to130.33 ± 13.68 and 159.31 ± 13.76 with following the NICU standard care ($p = 0.000$).

Concerning COMFORTneo scale assessment, it is revealed that the mean score of the neonates who warped by MSSH had lower scores during and after heel prick (4.63 ± 1.36 and 2.84 ± 1.16, respectively) compared to those who received the standard care of NICU (7.06 ± 1.21 and 3.65 ± 1.54, respectively) and $p < 0.001$ was considered. Likewise, differences were found between the standard care and MSSH regarding the COMFORTneo NRS-pain and distress subscales ($p < 0.001$ for each).

Table 4 portrays the interobserver agreement regarding preterm neonates' behavioral response to invasive procedures. The agreement between the two raters was excellent when observing the neonates' comfort, distress, and pain levels during ETS with NICU standard care (ICC = 0.97, ICC = 0.92, and ICC = 0.97, respectively, and $p < 0.001$ for each). The agreements were also excellent while the observers rated the pain and distress level during the ETS among MSSH (ICC = 0.90 and ICC = 0.92, respectively, and $p < 0.001$for each). The table also reflects moderate agreements between the raters before and after the invasive procedures regarding the comfort, distress, and pain scales.

TABLE 1. Characteristics of mechanically ventilated preterm neonates

Characteristics	Standard care (*n*=31)	MSSH (*n*=31)	Significance
	No. (%)	No. (%)	
Age/days			
1–7	18 (58.06)	15 (48.39)	F^{ET}=11.25 *p*=0.136
8–14	5 (16.13)	4 (12.90)	
15–21	5 (16.13)	7 (22.58)	
21–28	3 (9.68)	5 (16.13)	
Mean±SD	8.49±7.75	7.29±7.75	Z^{MW}=−1.94 *p*=0.352
Gender			
Male	21 (67.74)	19 (61.29)	χ^2=1.63 *p*=0.44
Female	10 (32.26)	12 (38.71)	
Gestational age			
Late preterm	9 (29.03)	7 (22.58)	F^{ET}=3.25 *p*=0.237
Moderate preterm	19 (61.29)	21 (67.74)	
Very preterm	1 (3.23)	3 (9.68)	
Birth weight			
Normal birth weight	0 (0.00)	1 (3.23)	F^{ET}=8.59 *p*=0.145
Low birth weight	18 (58.06)	21 (67.74)	
Very low birth weight	10 (32.26)	8 (25.81)	
Extremely low birth weight	3 (9.68)	1 (3.23)	
Diagnosis			
Respiratory distress	18 (58.06)	16 (51.61)	F^{ET}=−2.12 *p*=0.091
Congenital pneumonia	5 (16.13)	7 (22.58)	
Infant diabetic mother	1 (3.23)	0 (0.00)	
Neonatal sepsis	3 (9.68)	3 (9.68)	
Pneumonia	4 (12.90)	5 (16.13)	

χ^2: Chi-square test, F^{ET}: Fisher's exact test, Z^{MW}: Mann–Whitney U-test, *significant at *p<0.05. MSSH: Mother scented simulated hand

TABLE 2. Physiological and behavioral responses to endotracheal tube suctioning among mechanically ventilated preterm neonates

	Before		Sig.	During		Sig.	After 5 min		Sig.
	Standard care (*n*=31)	MSSH (*n*=31)		Standard care (*n*=31)	MSSH (*n*=31)		Standard care (*n*=31)	MSSH (*n*=31)	
	Mean±SD	Mean±SD		Mean±SD	Mean±SD		Mean±SD	Mean±SD	
Physiological response									
SpO2 (%)	97.43±2.53	97.20±2.60	Z=−0.366 *p*=0.714	90.18±2.70	94.00±2.99	Z=−3.355 *p*=0.001***	95.41±2.52	98.20±2.04	Z=−2.191 *p*=0.01*
Heart rate (bpm)	129.71±13.49	129.18±12.91	Z=−0.154 *p*=0.877	153.12±12.23	145.96±14.32	Z=−2.306 *p*=0.021*	137.31±12.17	132.92±13.03	Z=−1.901 p=0.057
COMFORTneo score									
First observer	11.98±1.89	12.16±1.37	Z=−0.252 *p*=0.801	22.20±2.97	12.39±2.26	Z=−6.038 *p*<0.001**	16.43±3.95	11.41±2.00	Z=−5.525 *p*<0.001***
Second observer	12.02±2.28	12.00±1.50	Z=−0.262 *p*=0.793	22.47±3.05	11.22±1.62	Z=−6.042 *p*<0.001***	17.78±3.40	10.67±2.74	Z=−5.974 *p*<0.001***
COMFORTneo NRS-distress scores									
First observer	2.15±0.95	2.71±0.96	Z=−0.252 *P*=0.801	6.53±1.53	4.63±1.35	Z=−4.951 *p*<0.001***	3.45±1.54	3.01±2.21	Z=−1.282 *p*<0.001***
Second observer	2.04±0.73	3.45±1.70	Z=−0.958 *p*=0.338	6.67±1.52	4.41±1.53	Z=−5.187 *p*<0.001***	3.90±1.12	2.97±1.75	Z=−2.728 *p*=0.006**
COMFORTneo NRS-pain scores									
First observer	2.65±0.95	2.71±0.96	Z=−0.252 *p*=0.801	6.53±1.53	4.63±1.35	Z=−4.951 *p*<0.001***	3.75±2.44	2.84±1.21	Z=−1.282 *p*<0.001***
Second observer	3.04±0.93	3.45±1.70	−0.958 *p*=0.338	6.67±1.52	4.41±1.53	Z=−5.187 *p*<0.001***	3.81±2.32	2.92±0.95	Z=−4.116 *p*<0.001***

Z: Mann–Whitney U-test, *significant at * *P*<0.05, ***p*<0.01, ****p*<0.001. NRS: Numerical rating scale, MSSH: Mother scented simulated hand, SpO2: Oxygen saturation

TABLE 3. Physiological and behavioral responses to heel prick among mechanically ventilated preterm neonates

	Before		Sig.	During		Sig.	After 5 min		Sig.
	Standard care (*n*=31)	MSSH (*n*=31)		Standard care (*n*=31)	MSSH (*n*=31)		Standard care (*n*=31)	MSSH (*n*=31)	
	Mean±SD	Mean±SD		Mean±SD	Mean±SD		Mean±SD	Mean±SD	
SpO2 (%)	97.49±2.53	97.35±1.73	Z=−0.548 *p*=0.584	93.04±2.98	95.08±1.34	Z=−3.690 *p*<0.001***	97.41±2.52	96.20±2.04	Z=−2.191 *p*=0.028*
Heart rate (bpm)	130.33±13.68	129.61±13.56	Z=−0.363 *p*=0.716	159.31±13.76	146.78±13.90	Z=−3.704 *p*<0.001***	139.47±10.46	135.65±11.37	Z=−2.156 *p*=0.031*
COMFORTneo score									
First observer	10.63±1.51	10.57±1.62	Z=−0.294 *p*=0.769	22.18±2.20	13.12±3.28	Z=−5.916 *p*<0.001***	15.94±5.18	9.84±1.68	Z=−5.668 *p*<0.001***
Second observer	10.49±1.62	10.06±1.59	Z=−1.195 *p*=0.232	21.18±2.38	12.96±3.05	Z=−5.735 *p*<0.001***	15.12±4.88	10.06±1.36	Z=−5.776 *p*<0.001***
COMFORTneo NRS-distress scores									
First observer	2.59±0.89	2.47±0.68	Z=−0.719 *p*=0.472	7.06±1.21	4.63±1.36	Z=−5.576 *p*<0.001***	3.65±1.54	2.84±1.16	Z=−1.900 *p*=0.057
Second observer	2.76±0.75	2.73±0.81	Z=−0.024 *p*=0.981	7.14±1.22	4.73±1.38	Z=−5.543 *p*<0.001***	3.90±1.12	2.71±0.91	Z=−4.534 *p*<0.001***
COMFORTneo NRS-pain scores									
First observer	2.31±0.68	2.53±0.84	Z=−1.262 *p*=0.207	6.71±1.43	4.20±1.27	Z=−5.696 *p*<0.001***	3.92±1.55	3.17±1.28	Z=−0.033* *p*=0.158
Second observer	2.82±0.97	2.61±1.04	Z=−1.071 p=0.284	7.08±1.41	4.37±1.44	Z=−5.633 p<0.001***	4.00±1.18	3.31±1.12	Z=−3.924 p<0.001***

Z: Mann–Whitney U-test, significant at significant at **p*≤0.05, ****p*<0.001. NRS: Numerical rating scale, MSSH: Mother scented simulated hand, SpO2: Oxygen saturation

DISCUSSION

Although modern health-care technologies introduced innumerable benefits, they also resulted in painful experiences during the early neonates' life. Mechanically ventilated preterm neonates admitted to NICUs encounter approximately fourteen painful procedures daily (23).

TABLE 4. Interobserver agreement regarding behavioral response to invasive procedures among mechanically ventilated preterm neonates

	Before				During				After 5 min			
	Standard care (*n*=31)		MSSH (*n*=31)		Standard care (*n*=31)		MSSH (*n*=31)		Standard care (*n*=31)		MSSH (*n*=31)	
	ICC	*p* value	ICC	*p* value	ICC	*p* value	ICC	*p* value	ICC	*p* value	ICC	*p* value
COMFORTneo score												
ETS	0.62	0.003**	0.70	0.009 a	0.97	< 0.001***	0.75	< 0.001***	0.51	0.007**	0.61	0.002**
Heel prick	0.85	<0.001***	0.78	<0.001***	0.72	<0.001***	0.69	0.043*	0.89	<0.001***	0.51	0.034
COMFORTneo NRS-distress												
ETS	0.78	<0.001***	0.65	0.021 a	0.92	<0.001***	0.90	< 0.001**	0.61	0.002**	0.60	0.001**
Heel prick	0.81	<0.001***	0.66	<0.001***	0.99	<0.001***	0.95	<0.001***	0.55	0.043	0.78	<0.001***
COMFORTneo NRS-pain scores												
ETS	0.70	<0.001***	0.59	0.021 a	0.97	<0.001***	0.92	<0.001***	0.65	0.003**	0.80	<0.001***
Heel prick	0.37	0.055	0.79	<0.001***	0.87	<0.001***	0.86	<0.001***	0.61	0.002**	0.59	0.001**

ICC: Intraclass correlation coefficient at significant at $*p \leq 0.05$, $**p<0.01$, $***p<0.001$. NRS: Numerical rating scale, EST: Endotracheal suctioning, MSSH: Mother scented simulated hand

These noxious events occur during the critical period of brain growth. Hence, it is reasonable to adopt various nursing strategies that promote the preterm neonates' optimal neurodevelopment (23). Stimulating neonates' senses were approved as an influential nursing maneuver that could enhance the critically ill neonates' comfort. Recently, mothers' scented simulated hand integrates multi-modal approaches that provide adequate support for the mechanically ventilated neonates, especially during painful procedures (13,15).

According to the Sanative model, preterm neonates respond to stimuli with unique stressful or self-regulating cues (24). The COMFORTneo scale assessed these responses in the form of the degree of alertness, calmness/agitation, respiratory response, body movement, facial tension, and muscle tone. The current study revealed that COMFORTneo scores showed a significantly lower score, reflecting a higher comfort level among neonates of MSSH compared to the control group. Placing neonates in a flexed posture enhance an elegant frozen position, limit their response to pain by restricting their body and limbs' abrupt movement (19). Sequentially, the transmission of pain through afferent fibers was blocked, and perception of painful stimuli was modified during fetal positioning. Thus, it provides relaxation and diminishes stress among mechanically ventilated neonates (25).

Furthermore, weighted simulated human hand and containment improves the sense of being held (15). Simply, touch stimulates pressure receptors which, in turn, stimulate the vagal nerve and increase its activity (26). It leads to a relaxed general behavior as a result of tactical stimulation (13). From another perspective, the olfactory stimulation by maternal scent could reduce neonates' stress-related behaviors and promote self-regulation (9). A combination of such approaches could enhance comfort during invasive procedures among mechanically ventilated neonates (27). These findings are congruent with Russell et al. (2015) who applied neuroprotective care using the weighted maternally scented simulation device and concluded that this innovative device significantly reduced stressful behavior among neonates (15).

Unlike other researches exploring the positive impact of single sensory stimulation, our study investigated the combined effect of weight, scenting, and containment on critically ill preterm neonates when their mothers are not physically available during the invasive procedures. One of the present study's exclusive results is that the NRS-distress and NRS-pain showed significantly lower scores with MSSH than standard care during ETS and heel prick. In that sense, Hassankhani et al. (2020) conducted a study in Iran about mothers' role during their neonates' exposure to painful procedures (28). They reported that maternal inclusion and containment had a unique positive influence in calming the neonate during the painful procedures and prevented crying. They also noticed that neonates were aware and calmed by their mothers' presence (28).

From another perspective, the higher level of comfort among neonates of the MSSH group during the invasive procedure in our study could be justified in the light of the fact that neonates had the ability to distinguish their mothers' unique olfactory signature shortly after birth, as evidenced by the newborn's first attempt to locate the mother's nipple (9). This process is possibly made easier by the high norepinephrine release and the arousal of the locus coeruleus at birth (29). Such naturally, mother's odors play an essential role in mediating their neonates' pain behavioral response (30). In this regard, Badiee et al. (2013) studied the calming effect of maternal breast milk odor on premature infants (31). They reported that availability of the maternal scent before and after heel stick among preterm neonates significantly reduced the premature infant pain profile scores compared to the control group (31).

The current study revealed a significant reduction in the distress and pain levels associated with invasive procedures among the MSSH group compared to the control one. This finding could be attributed to supporting the preterm neonates with a hand that looks like their mothers' hand in both weight and size (32). Furthermore, this hand was scented with maternal order and ergonomically placed in a position. These give the neonate a sensation of being cuddled and touched by their mothers during these stressful situations (15). Moreover, the neonates were placed in an utero position that may be analogous to the uterus's internal space. This posture creates a more confining containment that promotes neonates' sense of safety, security, and comfort (20). Furthermore, fetal positioning could increase the serum cortisol and beta-endorphins level and stabilize autonomic and motor systems. These changes led to lower stress levels among the neonates (33).

Repeated exposure to stressful procedures in the neonatal period is associated with increased demands on cardiopulmonary parameters (34). It is inferred from the present study findings that the application of MSSH significantly promotes better stability in the heart rates and SpO2 among mechanically ventilated neonates. The combined maternal tactile and olfactory stimulations assist in increasing the neonates' blood flow to the heart and brain. Furthermore, Dezhdar et al. (2016) added that MSSH could also enhance SpO2, diminishing the neonates' exaggerated reaction to pain (21). It consequently saves oxygen and safeguards it from being utilized in excessive, unnecessary movements. Likewise, Salmani et al. (2017) evaluated the effect of facilitated tucking with simulated hands-on physiological pain indicators during venipuncture in premature infants (32). According to their results, a significantly improved physiological parameter was observed among the intervention group compared to the control one.

On the contrary, Kucukoglu et al. (2015) studied fetal positioning's effectiveness on neonates' pain management during vaccination (35). The authors found no significant difference between the study groups regarding SpO2. This discrepancy between the results might be due to different samples and research interventions. Grunau and Linhares (2014) also studied the analgesic effect of multisensory stimulation on preterm neonates and concluded that these maneuvers produce positive changes in the cardiopulmonary parameters (36). The congruency between this study and the current study's finding could be related to the use of MSSH integrates multisensory stimulation approach as warm touch, mothers' smell, and containment (13).

Limitation of the study

The researchers faced the challenge of maintaining blindness during data collection where the raters were able to distinguish the neonates in the study who were supported by the new device (MSSH) and the control group. Although the current study showed a favorable impact of MSSH on preterm neonates, the study has limitations related to the small sample size. The authors also struggled with some variables, as eligible cases were disconnected from the mechanical ventilation before completing the study. Moreover, some cases did not require ETS or heel prick. This limitation was overcome using a valid and reliable scale (COMFORTneo) that has objective criteria. Two independent raters assessed the neonate's behavioral response and rated pain and distress. The degree of agreement between them was calculated. In the current study, short-term results have been evaluated (comfort, pain, and distress). Further studies with larger sample sizes and long-term assessments are needed to confirm the findings.

CONCLUSION

The simulated mother hand might be applied for preterm neonates to promote their comfort and alleviate their suffering during the stressful NICU experience, especially when their mothers are not physically available. The impact of simulated mother hand on other variables such as sleep pattern, physical growth, and neonates' neurodevelopment is worth exploring.

We can conclude that wrapping the preterm neonates with a warm MSSH promotes comfort and reduces pain and distress during invasive procedures.

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CONFLICTS OF INTEREST

No conflicts of interest have been declared by the authors.

REFERENCES

1. Wu T, Azhibekov T, Seri I. Transitional hemodynamics in preterm neonates: Clinical relevance. Pediatr Neonatol 2016;57(1):7-18.
   https://doi.org/10.1016/j.pedneo.2015.07.002
2. Holsti L, Grunau R, Shany E. Assessing pain in preterm infants in the neonatal intensive care unit: Moving to a 'brain-oriented' approach. Pain Manag 2011;1(2):171-9.
   https://doi.org/10.2217/pmt.10.19
3. Woodward, L, Bora S, Clark CA, Montgomery-Hönger A, Pritchard VE, Spencer C, et al. Very preterm birth: Maternal experiences of the neonatal intensive care environment. J Perinatol 2014;34(7):555-61.
   https://doi.org/10.1038/jp.2014.43
4. Lai T, Bearer C. Iatrogenic environmental hazards in the neonatal intensive care unit. Clin Perinatol 2008;35(1):163-81.
   https://doi.org/10.1016/j.clp.2007.11.003
5. Salmani N, Karjoo Z, Dehghani K, Sadeghnia A. Effect of facilitated tucking with the nurse and a simulated hand on physiological pain index during vein puncture on premature infants. J Babol Univ Med Sci 2018;20(9)14-9. Available from: http://www.jbums.org/article-1-7562-en.html. Accessed At: 1st July 2021.
6. Ibrahim G. Effect of expressed breast milk versus leg massage on preterm neonates' pain during heel prick. IOSR J Nurs Health Sci 2018;7(3):85-94.
   https://doi.org/10.9790/1959-0703038594
7. Sathish Y, Lewis L, Noronha J, George A, Snayak B, Pai S, et al. Clinical outcomes of snuggle up position using positioning aids for preterm (27-32 weeks) infants. Iran J Neonatol 2017;8(1):1-6.
8. Kahraman A, Başbakkal Z, Yalaz M, Sözmen E. The effect of nesting positions on pain, stress and comfort during heel prick in premature infants. Pediatr Neonatol 2018;59(4):352-9.
   https://doi.org/10.1016/j.pedneo.2017.11.010
9. Loos H, Reger, D, Schaal B. The odour of human milk: Its chemical variability and detection by newborns. Physiol Behav 2019;199:88-99.
   https://doi.org/10.1016/j.physbeh.2018.11.008
10. Boorman R, Creedy D, Fenwick J, Muurlink O. Empathy in pregnant women and new mothers: A systematic literature review. J Reprod Infant Psychol 2019;37(1):84-103.
    https://doi.org/10.1080/02646838.2018.1525695
11. Novak J, Vittner D. Parent engagement in the NICU. J Neonatal Nurs 2020, 27(4). 257-262. https://doi.org/10.1016/j.jnn.2020.11.007
12. Pineda R, Bender J, Hall B, Shabosky L, Annecca A, Smith J. Parent participation in the neonatal intensive care unit: Predictors and relationships to neurobehavior and developmental outcomes. Early Hum Dev 2018;117:32-8.
    https://doi.org/10.1016/j.earlhumdev.2017.12.008
13. Zeraati H, Nasimi F, Rezaeian A, Shahinfar J, Ghorban Zade M. Effect of multisensory stimulation on neuromuscular development of premature infants: A randomized clinical trial. Iran J Child Neurol 2018;12(3):32-9.
14. Vittner D, Butler S, Smith K, Makris N, Brownell E, Samra H, et al. Parent engagement correlates with parent and preterm infant oxytocin release during skin-to-skin contact. Adv Neonatal Care 2019;19(1):73-9.
    https://doi.org/10.1097/anc.0000000000000558
15. Maher G, Elarousy W. Effect of nested and swaddled prone positioning on sleep and physiological parameters of low birth weight neonates. Int J Nurs Health Sci 2018;5(3):48-55.
    https://doi.org/10.2147/rrn.s41292
16. Russell K, Weaver B, Vogel R. Neuroprotective core measure 2: Partnering with families-effects of a weighted maternally-scented parental simulation device on premature

infants in neonatal intensive care. Newborn Infant Nurs Rev 2015;15(3):97-103.

https://doi.org/10.1053/j.nainr.2015.06.005

17. Altimier L, Phillips R. The neonatal integrative developmental care model: Advanced clinicalapplications of the seven core measures for neuroprotective family-centered developmental care. Newborn Infant Nurs Rev 2016;16:230-44.

    https://doi.org/10.1053/j.nainr.2016.09.030

18. Walkera SM. Seminars in fetal and neonatal medicine. Semin Fetal Neonatal Med 2019;24:101005.

19. Costa K, Beleza L, Souza L, Ribeiro L. Hammock position and nesting: Comparison of physiological and behavioral effects in preterm infants. Rev Gaucha Enferm 2017;37:e62554.

    https://doi.org/10.1590/1983-1447.2016.esp.62554

20. Mosayebi Z, Javidpour M, Rahmati M, Hagani H, Movahedian AH. The effect of kangaroo mother care on pain from heel prick in preterm newborns admitted to neonatal intensive care unit: A crossover randomized clinical trial. J Compr Pediatr 2014;5(4):e22214.

    https://doi.org/10.17795/compreped-22214

21. Dezhdar S, Jahanpour F, Bakht S, Ostovar A. The effect of kangaroo mother care and swaddling on venipuncture pain in premature neonates: A randomized clinical trial. Iran Red Crescent Med J 2016;18(4):e29649.

    https://doi.org/10.5812/ircmj.29649

22. Dijk M, Roofthooft D, Anand K, Guldemond F, de Graaf J, Simons S, et al. Taking up the challenge of measuring prolonged pain in (premature) neonates: The COMFORTneo scale seems promising. Clin J Pain 2009;25(7):607-16.

    https://doi.org/10.1097/ajp.0b013e3181a5b52a

23. Williams M, Lascelles D. Early neonatal pain-a review of clinical and experimental implications on painful conditions later in life. Front Pediatr 2020;8:30.

    https://doi.org/10.3389/fped.2020.00030

24. Carteaux P, Cohen H, Check J, George J, McKinley P, Lewis W, et al. Evaluation and development of potentially better practices for the prevention of brain hemorrhage and ischemic brain injury in very low birth weight infants. Pediatrics 2003;111:489.

25. Sekulic S, Gebauer-Bukurov K, Cvijanovic M, Kopitovic A, Ilic D, Petrovic D, et al. Appearance of fetal pain could be associated with maturation of the mesodiencephalic structures. J Pain Res 2016;9:1031-8.

    https://doi.org/10.2147/jpr.s117959

26. Kaniusas E, Kampusch S, Tittgemeyer M, Panetsos F, Gines RF, Papa M, et al. Current directions in the auricular vagus nerve stimulation I-a physiological perspective. Front Neurosci 2019;13:854.

    https://doi.org/10.3389/fnins.2019.00854

27. Prestes A, Balda R, Santos G, Rugolo LM, Bentlin MR, Magalhães M, et al. Painful procedures and analgesia in the NICU: What has changed in the medical perception and practice in a ten-year period? J Pediatr (Rio J) 2016;92(1):88-95.

    https://doi.org/10.1016/j.jped.2015.04.009

28. Hassankhani H, Negarandeh R, Abbaszadeh M, Jabraeili M. The role of mothers during painful procedures on neonates: A focused ethnography. J Neonatal Nurs 2020;26:340-3.

    https://doi.org/10.1016/j.jnn.2020.03.002

29. Atzori M, Cuevas-Olguin, R, Esquivel-Rendon, E, Garcia-Oscos F, Salgado-Delgado R, Saderi N, et al. Locus ceruleus norepinephrine release: A central regulator of CNS spatio-temporal activation? Front Synaptic Neurosci 2016;8:25.

    https://doi.org/10.3389/fnsyn.2016.00025

30. Tasci B, Kuzlu Ayyildiz T. The calming effect of maternal breast milk odor on term infant: A randomized controlled trial. Breastfeed Med 2020;15(11):724-30.

    https://doi.org/10.1089/bfm.2020.0116

31. Badiee Z, Asghari M, Mohammadizadeh M. The calming effect of maternal breast milk odor on premature infants. Pediatr Neonatol 2013;54(5):322-5.

    https://doi.org/10.1016/j.pedneo.2013.04.004

32. Salmani N, Karjoo Z, Dehghani K, Sadeghnia A. Effect of facilitated tucking created with simulated hands on physiological pain indicators during venipuncture in premature infants. Iran J Neonatol 2017;8(4):7-12.

    https://doi.org/10.22038/ijn.2017.21562.1247

33. Hill S, Engle S, Jorgensen J, Kralik A, Whitman K. Effects of facilitated tucking during routine care of infants born preterm. Pediatr Phys Ther 2005;17(2):158-63.

    https://doi.org/10.1097/01.pep.0000163097.38957.ec

34. Stevens B, Johnston C, Horton L. Factors that influence the behavioral pain responses of premature infants. Clin J Pain 1994;59(1):101-9.

    https://doi.org/10.1016/0304-3959(94)90053-1

35. Kucukoglu S, Kurt S, Aytekin A. The effect of the facilitated tucking position in reducing vaccination-induced pain in newborns. Ital J Pediatr 2015;41(1):61.

    https://doi.org/10.1186/s13052-015-0168-9

36. Grunau R, Linhares M. Effect of multisensory stimulation on analgesia in preterm neonates. Pediatrics 2014;13(8):460-3.

    https://doi.org/10.1203/00006450-200204000-00010