Effectiveness of Swaddling on Pain in Neonates during Chest Physiotherapy: A Randomized Control Trial

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ABSTRACT
BACKGROUND: Aim of the present study was to investigate the effectiveness of swaddling on pain during Chest Physiotherapy in Neonates.

MATERIALS AND METHODOLOGY: The research was carried out on neonates at Tertiary care hospital. 30 neonates were included in study based on inclusion criteria. The neonates were randomly allocated into group A who were given chest physiotherapy only and group B were given chest physiotherapy and swaddling by senior physiotherapist. At the first visit the pain level of neonates in both groups was recorded using “Neonatal Infant Pain Scale” by principal investigator

RESULTS: In the study, Statistical analysis was done using Mann Whitney U test and P value was set at less than 0.05. It was detected that there was no significant difference between pain score in group A and group B at pre, during, immediate and 2 minute, however a significant difference in pain score was noted at 4, 6 and 8 minutes.

CONCLUSION: Swaddling is effective in controlling pain in neonates during chest physiotherapy at 4, 6 and 8 minutes.

KEYWORDS: Neonates, Chest Physiotherapy, Swaddling, Pain, Infants.

INTRODUCTION
An infant is very young off spring of human. The word infant is derived from Latin word infans which means speechless or unable to speak.¹ infants in its first 4 week is known as a neonate.² Many critical events takes place like Feeding patterns are established, bonding between parents and infant begin, many birth or congenital defects are first noted and the risk of infection confined to lung may start from birth or after 7 days and might become more serious³,⁴. Respiratory problems occur in 4 to 6% of neonates and account for significant mortality in the neonatal period.⁵ Chest Physiotherapy (CPT) is a practice that improves oxygen saturation, facilitates the removal of secretions and helps in ventilating the lung in newborns with respiratory problems. Techniques commonly used during the neonatal period is active chest physiotherapy (percussion, tapping or vibration delivered on the chest) and non-active technique positioning and suctioning alone.⁴ In the past, health professionals often claimed that neonates and infants do not experience as much pain as adults.⁶ Due to lack of myelination of nerve fibers there was lack of transmission of pain in neonates.⁷ But, this belief was proved false by reviewing several papers.⁶ Pain is an unpleasant sensory and emotional expression associated with actual or potential tissue damage. All neurotra-
Transmitters and receptors related with pain modulation are present and responsive from 24 weeks post-conceptional age. Hence, fetus and newborn can feel pain. Pain is subjective, complex and a multi-factorial phenomena. Hence it falls short in relation to those unable to communicate like neonates.

Managing a child’s pain during first year of life involves assessing the intensity of pain, implementing a treatment plan and evaluating the effectiveness of the treatment given. Several pain assessment tools that combine behavioral and physiological variables are developed. Neonatal infant pain scale (NIPS) is used in neonates and infants. This scale uses body language and physiological parameters to help us to understand the neonate is in pain.

Once a child’s pain has assessed a treatment plan should be devised. This includes the use of drug and non-drug methods. There are several non-drug methods that can be used specifically with neonates. Swaddling a baby is traditional in many countries around the world. It fell out of support in the Western world in prior decades due to its adverse effects. However, swaddling is making a comeback as research confirms what many knew regarding the many benefits of this age-old technique in calming and comforting crying, unsettled newborns. It is also called binding or bundling and was a very common infant care practice before the 18th century. When compared with massage, excessively crying infants cried less when swaddled and swaddling can soothe pain in infants.

METHODS

Study Design
This study was a randomized control trial conducted during first session of chest physiotherapy.

Setting and Samples
The study was conducted during working hours. Study was carried out on neonates who received first session of chest physiotherapy. According to the formula the determined sample size for the study was 30 neonates, who were randomly allocated in each group by lottery method.

Inclusion Criteria
The study included all male and female neonates who were receiving first session of chest physiotherapy, parents who were willing to give assent for participation, stable neonates whose weight was not less than 1000 grams and who did not have any congenital abnormality.

Data Collection Tools
Informed assent was taken from parent or care giver, data collection sheet which included Neonatal Infant Pain Scale, pencil or pen and stop watch was used to score the scale at different time points. A blanket or sheet was used to swaddle neonate in group B.

Neonatal Infant Pain Scale (NIPS)
Neonatal Infant Pain Scale (NIPS) uses behavioural cues and physiological parameter variables. The behavioural clues consist of 6 components Facial expression, Cry, Breathing Pattern, Arms, Legs, State of Arousal. Each behavioural indicator is scored with 0 to 1 except ‘cry’ which has 3 possible descriptors. The 2 physiological variables consist of Heart Rate which is scored as 0, 1 or 2 and O2 saturation scored as 0 or 1. The total score ranges from 0-10. Most of the time a score greater than 3 tells as a child is likely to be experiencing pain or discomfort. A score ranging from 0-3 is considered as mild pain and managed with Non-pharmacological intervention, 4-6 is considered as moderate pain and managed with both Pharmacological and Non-pharmacological intervention, 7-10 is considered as severe pain and managed with pharmacological intervention.

Procedure
Permission was obtained from institutional ethical committee. All participants were screened for inclusion criteria. Inform assent was obtained from parent or primary care giver to carry out the study. 30 neonates were randomly allocated in
group A and group B by lottery method. Regular demographic characteristics regarding age, birth weight, gestational age and head circumference were obtained from medical records.

In both groups NIPS was scored by principal investigator and chest physiotherapy (percussion, vibration, postural drainage and suctioning) was administered by senior physiotherapist. In group A pre NIPS was scored, only chest physiotherapy was given to neonate followed by scoring of NIPS at different time points (during, immediate, at 2 minute, 4 minute, 6 minute and 8 minute).

In group B pre NIPS was scored and active chest physiotherapy (percussion and vibration) was given to neonate and during the procedure NIPS was scored followed by swaddling and non active chest physiotherapy (postural drainage and percussion) was administered to neonate followed by scoring of NIPS immediate, at 2, 4, 6 and 8 minutes.

**Routine Chest Physiotherapy**
The position of neonate during chest physiotherapy was depending on area affected. Active Chest Physiotherapy included 3 sets of percussion at the rate of 3 per second with cupped hand. Followed by 3 sets of vibration using index, middle and ring finger of the therapist. Non active Chest Physiotherapy which included positioning of baby was done depending on area affected.

**Swaddling**
Swaddling was done using a cloth or blanket. The blanket was squared by diagonally folding it. The neonate was placed in supine position centrally on the squared blanket such that the upper edge of blanket was resting behind neonate’s neck. The left arm was crossed gently across the midline and placed comfortably on chest. The corner of the blanket on left side was crossed diagonally across body and was tucked behind the back. Similar method was followed on right side. The leg end of the sheet which was left off was tucked under chin and made sure legs were in relaxed position.

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**RESULT**

**Data Analysis**

Statistical analysis for the present study was done manually as well as using statistical package of social sciences (SPSS) version 21 so as to verify the results obtained. For this purpose data was entered into the Microsoft Excel Sheet, tabulated and subjected to statistical analysis. Percentage of distribution, Mean, standard deviation and test of significance i.e Mann-Whitney U test was used to compare the two groups. P<0.05 was considered significant in all analyses.

Table 1 describes the comparison of 2 groups (Group A and Group B) with demographic characteristics of neonate taken during the initial assessment. It was determined that total number of male neonates were 8 (53.33%) in group A and female neonates were 7 (46.66%) in group B. Total number of male neonates were 11 (73.33%) and female were 4 (26.67) in group B. The mean gestational age of the neonate in Group A and Group B was 37.40 ± 1.99 and 37.00±2.62 with p-value 0.6414. The mean age of neonate in group A and group B was 10.67 and 8.47, the difference of mean age in group A and group B was 10.67±9.42 and8.47±6.02 with p=0.4523. The mean birth weight of the neonate in group A was 2.27kg ±0.59 and group B was 2.29kg ± 0.65 with p=0.9533. The mean head circumference of neonate in Group A and group B was 32.67±2.47 and 32.00±1.65 with p=0.3917. There was no Statistical significant with respect to gender, gestational age, age, birth weight and head circumference when p value was set less than 0.05.

Table 2: Shows Comparison of two groups (Group A and Group B) with respect to NIPS scores at different time points using Mann-Whitney U test. It was found that mean pre intervention score for group A was 0.80±0.86 and group B was 1.20±1.86 with p value of 0.9835. Mean during intervention score for group A was 3.47±2.17 and group B was 3.47±1.55 with p value of 0.5476. Mean immediate intervention score for group A was 4.73±1.91 and group B was 4.53±1.58 with p value of 0.8682. Mean 2 minute intervention for
group A was 4.47±1.81 and group B was 3.27±1.67 with p value of 0.0815. Mean 4 minute intervention for group A was 4.07±2.25 and group B was 1.67±1.29 with p value of 0.0023. Mean 6 minute intervention score for group A was 2.53±1.55 and group B was 1.00±1.00 with p value of 0.0051. Mean 8 minute intervention score for group A was 1.53±1.13 and group B was 0.60±0.74 with p value of 0.0213.

Table 1: Comparison of two Groups with mean demographic characteristics

| Demographic Characteristics | Group A       | Group B       | t-value | p-value |
|-----------------------------|---------------|---------------|---------|---------|
| Gender                      | n  | %   | n  | %   | t-value | p-value |
| Male                        | 08 | 53.33 | 11 | 73.33 |         |         |
| Female                      | 07 | 46.67 | 04 | 26.67 |         |         |
| Gestational age             | 37.40±1.99   | 37.00±2.62   | 0.4708 | 0.6414 |
| Age in days                 | 10.67±9.42   | 8.47±6.02    | 0.7623 | 0.4523 |
| Birth weight                | 2.27±6.59    | 2.29±0.65    | -0.0591| 0.9533 |
| Head circumference          | 32.67±2.47   | 32.00±1.65   | 0.8699 | 0.3917 |

*p<0.05

Table 2: Comparison of two groups (Group A and Group B) with respect to NIPS scores at different time points.

| Time points | Group A         | Group B         | U-value | Z-value | P-value |
|-------------|-----------------|-----------------|---------|---------|---------|
| Pre         | 0.80±0.86       | 1.20±1.86       | 112.00  | -0.0207 | 0.9835  |
| During      | 3.47±2.17       | 3.47±1.55       | 98.00   | -0.6014 | 0.5476  |
| Immediate   | 4.73±1.91       | 4.53±1.85       | 108.50  | -0.1659 | 0.8682  |
| 2 minutes   | 4.47±1.81       | 3.27±1.67       | 70.50   | -1.7421 | 0.0815  |
| 4 minutes   | 4.07±2.25       | 1.67±1.29       | 39.00   | -3.0486 | 0.0023* |
| 6 minutes   | 2.53±1.55       | 1.00±1.00       | 45.00   | -2.7998 | 0.0051* |
| 8 minutes   | 1.53±1.13       | 0.60±0.74       | 57.00   | -2.3020 | 0.0213* |

*p<0.05

GRAPHS Comparison of two groups (A and B) with respect to NIPS score at different time points.
DISCUSSION

Pain is the common adverse stimuli experienced by neonate, occurring as a result of injury, illness and necessary medical procedures. Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. By this definition we get to know pain is complex, subjective and multi-faceted phenomena. Hence, it falls short in relation to those who are unable to communicate like neonates. The two components by which we get to know child is in pain is behavior and physiological response which can be observed and recorded. It is shown that adults and infants behavioral response to pain is same. But time duration taken by adult response is in between one to four seconds and infants is 0.12 to 0.70 seconds. Neonatal response to pain is with leg withdrawal and followed by crying.

Lawrence L. et.al (13) whose one of the objective was to develop a behavioral assessment tool for measurement of pain in preterm and full term neonates. Neonatal Infant Pain Scale (NIPS) was used to score behavior before, during and after each intrusive procedure and found that NIPS has high Interrater reliability and internal consistency. Likewise, the outcome measure used in the present study i.e. NIPS measured pain in terms of facial expression, cry, breathing pattern, arms, legs, state of arousal, heart rate and oxygen saturation. In this study also it was found that neonates perceived pain during Chest physiotherapy.

There are several medical procedures a neonate undergoes like endotracheal intubation, ventilator support, endotracheal suctioning and chest physiotherapy. Even though Chest Physiotherapy (CPT) improves oxygen saturation, facilitates the removal of secretions and helps ventilation of lung in newborns with respiratory problems. chest physiotherapy is considered one of the noxious stimulus in infants. This could be supportive to this study were it showed that pre intervention pain was same in both the groups

Study done by Carmen Giannantonio et.al (4) to understand the role of CPT in neonatology and the role of CPT in neonates with respiratory diseases remains debated and needs further evaluation. But its consideration respiratory physiotherapy as a resource for the treatment of neonate lung disease. Swaddling was used as one of the non pharmacological methods to reduce pain in neonates, supported by a study done by Lai Ping Ho RN et.al (15) showed that swaddling is feasible and efficacious in controlling pain for heel stick procedure among preterm infants.

Similarly a study was conducted by S Ohgi et.al (16) to show the effectiveness of swaddling versus massage therapy in management of excessive crying infants with cerebral insults and showed that swaddling may be more effective than massage intervention in reducing cry in infants.

Morrow et.al (17) also conducted a study to measure the difference in pain score for newborns when held and swaddled and unswaddled while routine heel stick procedure. And concluded that swaddling is effective non pharmacological method to reduce newborn pain for heel lance.

The current study was proposed to investigate the effectiveness of swaddling on pain during chest physiotherapy in neonates.

In current study pain perceived by neonate immediately after intervention was same in both the groups. Where at 4 minutes the swaddled neonate showed significant reduction in pain score. Federal De et.al conducted a study on 70 healthy neonates to find pain perceived during blood sampling procedure at different time points using Neonatal Infant Pain Scale and concluded it is suitable tool for evaluation of pain at different time points.

Fatemen Hashemi et.al. (18) conducted a study on infants to know effects of swaddling and breast feeding and their combined effects in which infants were swaddled 2 minutes before and after as. vaccination and 45 minutes of breast feeding before and after vaccination. And concluded that swaddling is non pharmacological method to relive pain. The findings of the above study can be considered and concluded that swaddling is effective way to soothe neonate when in pain.

In the current study it was shown that after swaddling neonates showed reduced NIPS score
at 4, 6 and 8 minutes. This could be due to the calming effect of swaddling which mimicking the containment feeling that infant experience intrauterine. Swaddling limits neonate’s movements which in turn prohibits muscle stretch, causing muscle relaxation. Hence, improving respiration increasing oxygen saturation and decreasing heart rate by organizing nervous system. S Ho and L Ho (20) which showed the average pain during blood sampling in swaddling had significant reduction compared to control group and also showed that heart rate and oxygen saturation reached baseline in 2 minutes, where as in controlled group 6 to 8 minutes were needed for indexes to return to baseline. The finding of the above study are in line with the present study considering the result of current study, swaddling is an effective way to stabilize the physiological variables of the neonates. In the current study showed that in experimental group physiological variables were less in score than the controlled group. A systemic review was done in 2007 on swaddling behavior and stated that swaddling organizes the nervous behavior of neonate which in line with the findings of this study. There are several studies refer to the effect of swaddling on neonatal sleep. It is possible that improvement in neonatal sleep by swaddling can be a reason which reduces facial changes in response to pain. In the current study it may be proposed that neonates fell asleep when swaddled and this reduces the change in facial expression during chest physiotherapy intervention. As stated by Fernandez the reaction appearing can be more practically observed than body movements and crying can be more specific than physiological variables change which are total response to painful stimuli. Assuming that it is true, physiotherapist can understand the neonatal pain experienced without using specific tool and by only observing face of the neonate. But on the contrary, current study showed significant difference between group A and group B at 4 minute; it was observed that pain score was less when chest physiotherapy was done along with swaddling in group B. A possible explanation may be neonates sleep after swaddling and it mimics the experience of intrauterus, another possibility would be that muscles are relaxed after swaddling. Results indicate that swaddling is effective technique in reducing pain. Although it might not have immediate effect but certainly has significant effect on reducing pain at the minimal time of 4 minutes.

CONCLUSION
Results indicate that swaddling is effective technique in reducing pain. Although it might not have immediate effect but certainly has significant effect on reducing pain at the minimal time of 4 minutes.

ACKNOWLEDGMENTS
We are very gratified to the parents who allowed their neonates to participate in this study. We would like to acknowledge the assistance and guidance provided by

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