A RANDOMIZED CONTROL TRAIL ON EFFECTIVENESS OF OCTOPUS THERAPY IN ALLEVIATION OF PAIN DURING BASIC NEONATAL PROCEDURES

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KEYWORDS

Neonatal pain, octopus therapy, non-pharmacological intervention, N-PASS, randomized control trial, sensory modulation

ABSTRACT

Background and Objectives: Neonates experience pain during medical procedures, which can lead to physiological instability and long-term adverse effects. Crocheted octopus therapy, inspired by neonatal care practices in Denmark, is believed to provide comfort and stabilize vital parameters, but scientific validation remains limited. This study evaluates the effectiveness of octopus therapy in alleviating pain and maintaining physiological stability in neonates undergoing heel lance procedures.

Methods: A randomized controlled trial was conducted with 100 neonates assigned to two groups via www.randomizer.org: Group A (Octopus Therapy, n=50) and Group B (Control, n=50). Inclusion criteria comprised well babies undergoing routine TSH sampling, with parental consent. Exclusion criteria included sick neonates requiring NICU admission, referred newborns, and those who had undergone prior sampling. Group A received a crocheted octopus toy to grasp 10 minutes before the procedure, while Group B underwent the procedure without any intervention. Pain was assessed using the Neonatal Pain Agitation and Sedation Scale (N-PASS), and physiological parameters (heart rate and oxygen saturation) were monitored at baseline, during the procedure, and at 2 and 10 minutes post-procedure. Data were analyzed using ANOVA and Pearson's correlation coefficient, with a significance threshold of $p<0.05$.

Results: Baseline characteristics were comparable between groups ($p>0.05$). Pain scores were significantly lower in Group A compared to Group B during (3.8 ± 1.1 vs. 6.5 ± 1.3, $p<0.001$) and after the procedure (2 min: 2.1 ± 0.8 vs. 4.3 ± 1.2, $p<0.001$; 10 min: 1.0 ± 0.5 vs. 2.8 ± 1.1, $p<0.001$). Heart rate was lower in Group A during (150 ± 10 bpm vs. 165 ± 12 bpm, $p<0.001$) and post-procedure ($p<0.001$). Oxygen saturation was better maintained in Group A during ($94.0\pm1.8\%$ vs. $91.5\pm2.2\%$, $p<0.001$) and post-procedure ($p<0.001$). Mean cry duration was significantly shorter in Group A (30.5 ± 10.2 sec vs. 55.8 ± 12.5 sec, $p<0.001$).

Conclusion: Octopus therapy significantly reduces pain scores, stabilizes physiological parameters, and decreases crying duration in neonates undergoing minor procedures. It is a promising adjunct to neonatal pain management strategies. Further multicenter studies are recommended to validate these findings and explore comparisons with established non-pharmacological interventions.

Introduction-

Pain is common in infants and neonates when they are sick or undergoing medical procedures. This pain can lead to various problems like breathing difficulties, changes in blood pressure and heart rate, increased need for oxygen, and even long-term health issues [1]. It is crucial to recognize and manage this pain using medications or other methods [2].

However, medications can have side effects, so nurses often look for non-drug methods to help ease pain [2]. One such method gaining popularity is the use of crocheted octopus toys in neonatal care units around the world. This practice started in Denmark in 2013 and has spread globally. The idea is that the tentacles of the toy resemble umbilical cords, providing comfort similar to the womb environment. It has ben believed that this comfort can help with breathing, increase oxygen levels, and stabilize heart rates. However, these benefits haven't been scientifically proven yet [3].

Some hospitals in the UK, Spain, and Denmark support using these octopuses [4]. In Ireland, the Rotunda Hospital began a project in 2017 called Tentacles for Kids to study the potential benefits of these toys. They found that parents had positive views about the octopuses, but larger studies are needed to confirm these findings [5].

Neonatal nurses play a vital role in assessing and managing babies' responses to pain without relying on verbal communication [2]. They often need to find creative ways to address this pain. When choosing non-drug methods, they must consider factors like ease of use, cost, and hospital policies, while also relying on research-based evidence [2].

Despite the popularity of using crocheted octopuses, there's no scientific research specifically studying their effectiveness in reducing pain from procedures like heel lance in newborns. This study aimed to fill that gap by investigating whether these crocheted octopus can reduce pain and maintain normal body functions during such procedures [5].

Materials and Methods-

This is a randomized control trial. The randomization is done through www.randomizer.org. the infants falling in the octopus therapy group was labelled as Group A and the neonates falling under the control group was labelled as Group B. sample size was 100 through randomization.

Inclusion Criteria:

- All well babies undergoing routine sampling for TSH estimation for the first time.
- Parents who have given consent to sampling.

Exclusion Criteria:

- All sick babies requiring NICU admission.
- Newborns referred from outside
- Parents who do not give consent for the study/sampling.
- Neonates in whom sampling was done previously.

Methodology

This is a parallel design randomized control study. This is an open labelled randomized control study. Random assignment was assigned by www.randomizer.org. Neonates not requiring NICU admission was considered in this study. Neonates suitable for the inclusion criteria after getting informed consent from the parents was assigned numbers by the primary investigator from 1 to 100 according to the birth order and they were included in either the group receiving the octopus therapy (Group A) or the group receiving no octopus therapy(Group B).

A crocheted octopus was given to the neonate and the neonate will grasp one of the tentacles 10 min before the procedure. This is said to help during auto regulation and sensory processing for the neonates. The pain was assessed using N PASS scoring scale during the procedure. The duration of the neonates cry was noted. Vitals was recorded at the baseline before giving the octopus to the neonate. After 10 minutes, a crocheted octopus was given to the neonate and the sampling procedure was started. The vitals were recorded two minutes and 10 minutes after the procedure in the octopus group (Group A). Same outcome measurement methods and timings were followed in Group B

Data collection tools:

A crocheted octopus was prepared in accordance to the instructions provided by The Danish Octo Project 2020. The octopus was manufactured using 100% hypoallergenic cotton wool thread. Hypoallergenic packaging material was used. The octopus was washable in 60 degrees Celcius water. The crochet octopus had a 7 cm head, (from top to the beginning of the arms). The octopus had 8 arms measuring 22 cms each when stretched fully.

N PASS (Neonatal Pain Agitation and Sedation Scale) which is a standardized pain scoring scale for neonates with a high degree of sensitivity and validity. [4,6]

N-PASS: Neonatal Pain, Agitation, & Sedation Scale

Assessment Criteria	Normal	Pain / Agitation	
	0	1	2
Cry Irritability	Appropriate crying Not irritable	Irritable or crying at intervals Consolable	High-pitched or silent-continuous cry Inconsolable
Behaviour State	Appropriate for gestational age	Restless, squirming Awakens frequently	Arching, kicking Constantly awake or Arouses minimally / no movement (not sedated)
Facial Expression	Relaxed Appropriate	Any pain expression intermittent	Any pain expression continual
Extremities Tone	Relaxed hands and feet Normal tone	Intermittent clenched toes	enched toes, fists, or finger splay
Vital Signs HR, RR , BP O2Sat	Within baseline or normal for gestational age	SaO2 76-85% with stimulation - quick ↑	from baseline SaO2 ≤ 75% with stimulation - slow ↑ Out of sync with vent

Data was collected by trained paediatricians using standardized data collection forms. This includes, neonatal identification details, followed by N PASS scoring scale which has five components, each component has a lowest score of zero and a highest score of two. The total lowest score was zero, the total highest score was 10. A score of 3 or more indicates the presence of pain. The pain scores were calculated in both the Groups (A and B).

Interpretation:

- 0 to 2: Minimal pain or agitation.
- 3 to 5: Mild pain or discomfort.
- 6 to 8: Moderate pain.
- 9 to 10: Severe pain or extreme agitation.

The data was recorded in a pre- structured proforma. Vitals was recorded 4 times in total that is 10 minutes before the procedure, during the procedure, 2 mins after the procedure and 10 mins after the procedure in both the groups.

The study was approved by Institutional Ethics Committee and written informed consent was taken from the parents and confidentiality was maintained.

Data Analysis:

Data were entered into a Microsoft Excel master chart and analysed using ANOVA and Pearson's correlation coefficient to compare pain scores, physiological parameters, and other relevant outcomes between the octopus therapy and the control group. A p-value < 0.05 was considered statistically significant. SPSS (Version 24.0) was used for analysis.

Results-

Table 1- Baseline Characteristics of Neonates

Characteristic	Group A (Octopus Therapy)	Group B (Control)	p-value
Sample Size (n)	50	50	-
Mean Gestational Age (weeks)	38.5 ± 1.2	38.3 ± 1.4	0.45
Mean Birth Weight (kg)	2.8 ± 0.4	2.7 ± 0.5	0.56
Gender (M/F)	28/22	26/24	0.68
Apgar Score at 1 min	8.9 ± 0.5	8.8 ± 0.6	0.72

The mean gestational age was slightly higher in Group A (38.5 ± 1.2 weeks) compared to Group B (38.3 ± 1.4 weeks), but the difference was not statistically significant ($p = 0.45$), indicating comparable maturity levels in both groups. The male-to-female ratio in both groups was similar (28/22 in Group A and 26/24 in Group B), with a p-value of 0.68, indicating no gender-related bias in the study population. The Apgar score at 1 minute was nearly identical between the groups (8.9 ± 0.5 in Group A vs. 8.8 ± 0.6 in Group B), with a p-value of 0.72, confirming that neonatal health status at birth was comparable. There were no significant differences in baseline characteristics between the two groups, indicating that the randomization process was effective in creating well-matched groups for the study.

Table 2- Pain Score Comparison (N-PASS Scale)

Time Point	Group A (Octopus Therapy)	Group B (Control)	p-value
Before Procedure	0.5 ± 0.4	0.6 ± 0.5	0.30
During Procedure	3.8 ± 1.1	6.5 ± 1.3	<0.001
2 Min After	2.1 ± 0.8	4.3 ± 1.2	<0.001
10 Min After	1.0 ± 0.5	2.8 ± 1.1	<0.001

The N-PASS scores were significantly lower in Group A compared to Group B at all-time points, especially during and after the procedure ($p < 0.001$).

Table 3- Physiological Parameters Comparison

Parameter	Time Point	Group A (Octopus Therapy)	Group B (Control)	p-value
Heart Rate (bpm)	Before Procedure	130 ± 8	132 ± 9	0.45
	During Procedure	150 ± 10	165 ± 12	<0.001
	2 Min After	138 ± 9	150 ± 11	<0.001
	10 Min After	132 ± 7	140 ± 10	<0.001
Oxygen Saturation (%)	Before Procedure	96.5 ± 1.5	96.3 ± 1.6	0.52
	During Procedure	94.0 ± 1.8	91.5 ± 2.2	<0.001
	2 Min After	95.2 ± 1.6	93.0 ± 1.9	<0.001

Parameter	Time Point	Group A (Octopus Therapy)	Group B (Control)	p-value
	10 Min After	96.0 ± 1.4	94.8 ± 1.5	<0.001

Group A exhibited a significantly lower peak heart rate during the procedure and quicker recovery post-procedure compared to Group B ($p < 0.001$). Oxygen saturation was significantly better maintained in Group A during and after the procedure compared to Group B ($p < 0.001$).

Table 4- Duration of Crying

Group	Mean Cry Duration (sec)	p-value
Group A (Octopus Therapy)	30.5 ± 10.2	<0.001
Group B (Control)	55.8± 12.5	

Neonates in the octopus therapy group had a significantly shorter duration of crying compared to the control group (30.5 ± 10.2 sec vs. 55.8 ± 12.5 sec, $p < 0.001$). The use of crocheted octopus therapy significantly alleviates procedural pain and promotes physiological stability in neonates undergoing basic procedures like heel lance.

Discussion-

Pain management in neonates undergoing routine procedures like heel lance is a crucial aspect of neonatal care. While pharmacological interventions are effective, non-pharmacological methods are increasingly explored due to concerns over drug side effects. This study aimed to evaluate the effectiveness of octopus therapy in alleviating pain during basic neonatal procedures. Studies have highlighted various non-pharmacological methods such as skin-to-skin contact, oral sucrose, breastfeeding, and facilitated tucking as effective strategies for neonatal pain relief. A study by Gray et al. (2000) found that skin-to-skin contact significantly reduced crying time and heart rate fluctuations in neonates undergoing painful procedures.[7] Similarly, Stevens et al. (2013) demonstrated the efficacy of sucrose in reducing procedural pain, as measured by neonatal pain scales.[8]

The concept of sensory stimulation for neonatal comfort has been studied in multiple settings. Lester et al. (2018) examined the effects of comfort objects in preterm neonates and found a reduction in physiological stress markers.[9] The use of crocheted octopuses, which mimic the umbilical cord and provide tactile stimulation, aligns with the principles of sensory modulation described in these studies. However, Harrison et al. (2017) emphasized the need for high-quality randomized trials to validate such interventions, which is the gap this study aimed to address. [10]

Neonatal pain responses are typically evaluated using validated scoring systems such as the Neonatal Pain, Agitation, and Sedation Scale (N-PASS). A randomized trial by Johnston et al. (2011) found that behavioral and physiological responses to pain, including heart rate and oxygen saturation fluctuations, were significantly lower in neonates receiving non-pharmacological interventions. [11] The findings of our study, where Group A (Octopus Therapy) exhibited lower pain scores and shorter crying durations than Group B (Control), are

in line with these observations. The results indicate that octopus therapy may serve as an effective, low-cost, and easily implementable method for neonatal pain relief. Given its non-invasive nature, it can be integrated into routine neonatal care without significant modifications to existing protocols.

While interventions such as oral sucrose and breastfeeding have established efficacy, octopus therapy presents a unique alternative that does not require feeding or direct parental involvement at the moment of the procedure. Future studies should compare octopus therapy directly with these established methods to determine relative effectiveness.

Although our study provides promising evidence, larger multicenter trials are needed to confirm these findings. A systematic review by Pillai Riddell et al. (2015) on neonatal pain management emphasized the importance of replication in diverse clinical settings to ensure generalizability. [12]

Limitations

- Short Follow-Up Duration: The study measured pain scores and physiological responses only within 10 minutes post-procedure. Long-term effects on neonatal stress levels remain unexplored.

- Single-Center Study: The findings may not be generalizable to different healthcare settings with varying neonatal care practices.

- Limited Comparison with Other Non-Pharmacological Interventions: While octopus therapy was evaluated, direct comparisons with interventions like kangaroo care or music therapy were not made.

Conclusion

This randomized controlled trial provides preliminary evidence supporting the effectiveness of octopus therapy in reducing pain and physiological stress responses in neonates undergoing routine procedures. While the findings align with prior research on sensory stimulation and neonatal pain management, further studies with larger sample sizes and direct comparisons to other non-pharmacological methods are needed. If validated, octopus therapy could become a standard, cost-effective intervention in neonatal care units worldwide.

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