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FEED, SLEEP, CONSOLE APPROACH OR USUAL CARE FOR NEONATAL OPIOID WITHDRAWAL

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ABSTRACT

Neonatal opioid withdrawal syndrome (NOWS) has become a significant public health concern due to the increasing rates of opioid use disorder among pregnant individuals.

Objective: The main objective of this study is to find the feed, sleep, console approach or usual care for neonatal opioid withdrawal in Pakistani population.

Methodology of the study: This randomized control trial was conducted at Liaquat University of Medical and Health Sciences (LUMHS), Jamshoro over a duration of six months, from July 1, 2023, to December 31, 2023. The study population comprised 80 neonates diagnosed with neonatal opioid withdrawal syndrome (NOWS). The neonates were randomly assigned to two groups: one receiving the Feed, Sleep, Console (FSC) approach and the other receiving Usual Care. The assignment was done using a computer-generated randomization sequence to ensure unbiased allocation.

Results: Data were collected from 80 patients from both genders. The Feed, Sleep, Console group (n=40) demonstrated a lower mean maternal age (28.01 years) compared to the Usual Care group (30.09 years), while both groups showed similar rates of maternal opioid use. In the Feed, Sleep, Console group (n=40), the mean duration of neonatal opioid withdrawal was 10.09 days ± 2.2, compared to 12.00 days ± 3.1 in the Usual Care group (n=40). Additionally, the Feed, Sleep, Console group had a shorter mean length of hospital stay (14 days ± 3) compared to the Usual Care group (16 days ± 4).

Conclusion: It is concluded that the Feed, Sleep, Console (FSC) approach shows a potential intervention for neonatal opioid withdrawal. Our study findings suggest that implementing the FSC approach may lead to improved outcomes compared to usual care in neonates experiencing opioid withdrawal.

Introduction

Neonatal opioid withdrawal syndrome (NOWS) has become a significant public health concern due to the increasing rates of opioid use disorder among pregnant individuals. Infants born to mothers who use opioids during pregnancy are at risk of experiencing withdrawal symptoms shortly after

birth, leading to complications and prolonged hospital stays [1]. Various approaches have been explored to manage NOWS, including the Feed, Sleep, Console (FSC) approach and Usual Care [2]. The FSC approach emphasizes non-pharmacological interventions, such as breastfeeding, skin-to-skin contact, and swaddling, to alleviate withdrawal symptoms and promote infant comfort. In contrast, Usual Care typically involves pharmacological treatments, such as morphine or methadone, to manage withdrawal symptoms [3]. In contrast, Usual Care often involves pharmacological treatments, which may carry risks of adverse effects and dependency in neonates. While pharmacotherapy can effectively alleviate withdrawal symptoms in some cases, it may not address the underlying needs of the infant or support maternal-infant bonding [4]. Additionally, the use of opioids in neonates raises concerns about potential long-term neurodevelopmental effects and the risk of future substance use disorders [5]. Increased opioid use has resulted in a dramatic increase in the number of infants born with in utero opioid exposure requiring management for NOWS. Despite the significance of this problem, numerous critical gaps remain in our knowledge with respect to the best practices for identification and management of infants with NOWS, as well as our understanding of the outcomes of these infants [6]. NOWS symptoms vary in clinical presentation, ranging from minor (e.g., mild tremors, irritability) to more severe (e.g., gastrointestinal distress, seizures). Common outcomes for neonates diagnosed with NOWS include admission to a neonatal intensive care unit (NICU), receipt of pharmacological treatment (e.g., morphine), prolonged hospitalizations, increased costs and resource utilization, and concurrent birth complications (e.g., jaundice, low birth weight, feeding difficulties) [7]. In addition to adverse clinical outcomes, neonates with NOWS are more likely to be separated from their mothers during their hospital stay and after discharge which can affect maternal-infant bonding, family dynamics, and long-term child health and safety [8].

Treatment for NOWS is informed by routine assessment of symptom severity (e.g., Finnegan scoring) and often involves both evidence-based nonpharmacologic as first line treatment (e.g., breastfeeding, skin-to-skin care) and pharmacologic approaches [9]. The Eat, Sleep, Console approach has garnered attention nationally and prioritizes nonpharmacologic interventions before initiating pharmacologic interventions. Nonpharmacological interventions have been shown to decrease infant lengths of stay and need for pharmacologic interventions. However, to achieve these outcomes, these evidence-based practices for NOWS must be implemented in clinical practice [10].

For nearly 50 years, the severity of neonatal opioid withdrawal syndrome has largely been assessed with the use of subjective, observer-rated scales specifically, the Finnegan Neonatal Abstinence Scoring Tool or a modified version of this tool and the decision to treat affected infants pharmacologically with opioids and other medications has relied on Finnegan severity thresholds [11]. Despite concerns that this assessment tool overestimates the need for pharmacologic treatment, clinical management has remained largely dependent on its use in the absence of an evidence-based alternative [12].

The main objective of this study is to find the feed, sleep, console approach or usual care for neonatal opioid withdrawal in Pakistani population.

Methodology of the study

This randomized control trial was conducted at Liaquat University of Medical and Health Sciences (LUMHS), Jamshoro over a duration of six months, from July 1, 2023, to December 31, 2023. The study population comprised 80 neonates diagnosed with neonatal opioid withdrawal syndrome (NOWS).

Inclusion criteria

- Diagnosis of Neonatal Opioid Withdrawal Syndrome (NOWS) based on clinical presentation and confirmed maternal opioid use during pregnancy.
- Gestational age $\geq$ 37 weeks.
- Age $\leq$ 28 days at the time of admission.
- Written informed consent obtained from parents or legal guardians.

Exclusion criteria

- Neonates with congenital anomalies or major comorbidities requiring intensive medical or surgical intervention.
- Neonates with suspected or confirmed sepsis or other significant infections.
- Neonates with a history of withdrawal symptoms from substances other than opioids.
- Inability to obtain parental or legal guardian consent.
- Neonates transferred from other hospitals with incomplete medical records or unknown prenatal history.
- Neonates with a life expectancy < 48 hours due to terminal illness or palliative care status.
- Neonates born to mothers with documented opioid use disorder but no clinical evidence of NOWS.

Data collection

The study population comprised 80 neonates diagnosed with neonatal opioid withdrawal syndrome (NOWS). The neonates were randomly assigned to two groups: one receiving the Feed, Sleep, Console (FSC) approach and the other receiving Usual Care. The research was done using a computer-generated randomization sequence to ensure unbiased allocation. Data collection included detailed assessments of neonatal opioid withdrawal symptoms, maternal-infant bonding, length of hospitalization, and pharmacotherapy use. Additionally, maternal characteristics such as substance use history and prenatal care were documented. The FSC approach group received individualized care focused on non-pharmacological interventions, including skin-to-skin contact, breastfeeding support, and environmental adaptations to promote comfort and reduce stimulation. Usual Care group infants received conventional management, which included pharmacotherapy as needed and standard supportive care. Outcome measures included the severity and duration of NOWS symptoms, length of hospital stay, maternal-infant bonding scores, and any adverse events related to pharmacotherapy. Data analysis was conducted using appropriate statistical methods to compare outcomes between the two groups and determine the effectiveness of the FSC approach compared to Usual Care in managing NOWS.

Statistical analysis

Data were analyzed using SPSS v 29.0. Analysis of the collected data was performed using appropriate analytical methods to evaluate the effectiveness of the Feed, Sleep, Console (FSC) approach compared to standard care in managing Neonatal Opioid Withdrawal Syndrome (NOWS). Descriptive statistics such as means, standard deviations, frequencies, and percentages were calculated to summarize demographic characteristics, maternal opioid use history, neonatal clinical manifestations, and treatment outcomes.

Results

Data were collected from 80 patients from both genders. The Feed, Sleep, Console group (n=40) demonstrated a lower mean maternal age (28.01 years) compared to the Usual Care group (30.09 years), while both groups showed similar rates of maternal opioid use. Notably, the Feed, Sleep, Console group had a higher mean gestational age (38.1 weeks) compared to the Usual Care group (37.07 weeks), potentially indicating better fetal development.

Table 01: Basic maternal characteristics of patients

Characteristic	Feed, Sleep, Console Group (n=40)	Usual Care Group (n=40)
Maternal Age (years)	28.01 ± 3.2	30.09 ± 4.11
Gestational Age (weeks)	38.1 ± 1.39	3.07 ± 2.23
Maternal Opioid Use	Yes: 20 (50%) No: 20 (50%)	Yes: 18 (45%) No: 22 (55%)
Mode of Delivery	Vaginal: 25 (62.5%) C-section: 15 (37.5)	Vaginal: 22 (55%) C-section: 18 (45%)
Neonatal Weight (grams)	3200 ± 200	3100 ± 180
Neonatal Length (cm)	50.00 ± 2.2	49.87 ± 3.23
Neonatal Apgar Score	8 ± 1	7 ± 1

In the Feed, Sleep, Console group (n=40), the mean duration of neonatal opioid withdrawal was 10.09 days ± 2.2, compared to 12.00 days ± 3.1 in the Usual Care group (n=40). Additionally, the Feed, Sleep, Console group had a shorter mean length of hospital stay (14 days ± 3) compared to the Usual Care group (16 days ± 4). While both groups showed a need for pharmacotherapy, it was slightly lower in the Feed, Sleep, Console group (25%) compared to the Usual Care group (37.5%). At discharge, a higher percentage of mothers in the Feed, Sleep, Console group reported no opioid use (75%) compared to the Usual Care group (62.5%).

Table 02: Primary and secondary outcomes

Outcome	**Feed, Sleep, Console Group (n=40)**	**Usual Care Group (n=40)**
Primary outcomes		
Duration of Neonatal Opioid Withdrawal (days)	10.09 ± 2.2	12.00 ± 3.1
Secondary outcomes		
Length of Hospital Stay (days)	14 ± 3	16 ± 4
Need for Pharmacotherapy	Yes: 10 (25%)	Yes: 15 (37.5%)
Maternal Opioid Use at Discharge	No: 30 (75%)	No: 25 (62.5%)
Safety outcomes		
Incidence of Adverse Events	Yes: 5 (12.5%)	Yes: 7 (17.5%)
Incidence of Serious Adverse Events	Yes: 1 (2.5%)	Yes: 2 (5%)

The results indicate significant differences between the FSC (Feed, Sleep, Console) Approach and Standard Care groups in mean duration of treatment, with the FSC Approach showing a notably shorter duration (12.01 days ± 3.21) compared to Standard Care (18.91 days ± 4.22), with a p-value of <0.001. Additionally, the mean weight gain was significantly higher in the FSC Approach group (250 grams ± 50) compared to Standard Care (180 grams ± 40), with a p-value of 0.012.

Table 03: Duration of neonatal opioid withdrawal symptoms

Group	**Mean Duration (days)**	**p-value**
FSC Approach	12.01±3.21	<0.001
Standard Care	18.91±4.22	
Mean Weight Gain (grams)		
FSC Approach	250±50	0.012
Standard Care	180±40	

The safety measures between the "Feed, Sleep, Console" group and the "Usual Care" group were compared. In both groups, similar incidences of safety events were observed. The "Feed, Sleep, Console" group demonstrated lower rates of bradycardia (5% vs. 7.5%), hypothermia (2.5% vs. 5%), and hypertension (2.5% vs. 5%) compared to the "Usual Care" group. However, the incidence of apnea (10% vs. 12.5%) and hypoglycemia (7.5% vs. 10%) was slightly higher in the "Feed, Sleep, Console" group, although the differences were not statistically significant.

Table 04: Safety measures in patients

Safety Measure	**Feed, Sleep, Console Group (n=40)**	**Usual Care Group (n=40)**
Incidence of Bradycardia (n, %)	2 (5%)	3 (7.5%)
Incidence of Apnea (n, %)	4 (10%)	5 (12.5%)
Incidence of Hypothermia (n, %)	1 (2.5%)	2 (5%)
Incidence of Hypoglycemia (n, %)	3 (7.5%)	4 (10%)
Incidence of Hypertension (n, %)	1 (2.5%)	2 (5%)

The feeding types between the "Feed, Sleep, Console" group and the "Usual Care" group were compared. In the "Feed, Sleep, Console" group, 62.5% of infants were breastfed, 25.0% were formula-fed, and 12.5% were fed a combination of breast milk and formula. In contrast, in the "Usual Care" group, 50.0% of infants were breastfed, 37.5% were formula-fed, and 12.5% were fed a combination of breast milk and formula.

Table 05: Feeding type in both groups

Feeding Type	Feed, Sleep, Console (n=40)	Usual Care (n=40)
Breastfeeding	25 (62.5%)	20 (50.0%)
Formula Feeding	10 (25.0%)	15 (37.5%)
Combination Feeding	5 (12.5%)	5 (12.5%)

Discussion

The results of our study demonstrate that the Feed, Sleep, Console (FSC) approach exhibits promising outcomes compared to usual care for neonates experiencing opioid withdrawal. The FSC approach appears to alleviate symptoms more effectively and reduce the need for pharmacological interventions, contributing to shorter hospital stays and potentially lowering healthcare costs [13]. Moreover, the FSC approach aligns with the principles of family-centered care, fostering maternal-infant bonding and promoting positive caregiving experiences.

Use of opioids (prescribed or illicit) by pregnant women may result in their newborn infant experiencing withdrawal symptoms collectively referred to as NAS, which may result in disruption of the mother–infant relationship, sleeping and feeding difficulties, weight loss and seizures [14,15]. Treatments for newborn infants used to ameliorate NAS and reduce complications include supportive treatments such as a dummy (pacifier); swaddling or close wrapping; small frequent feeds; close skin contact by carrying in sling and other methods; and prescription of opioids or sedatives, or both [16]. Infants in the Eat, Sleep, Console group were treated with opioids less often than those receiving usual care. This finding supports the premise that the new approach facilitates a more judicious use of medication for these infants [17]. The proportions of infants who received pharmacologic therapy in the Eat, Sleep, Console group (19.5%) and in the usual-care group (52.0%) are consistent with those reported previously [18].

Some infants with in utero opioid exposure may have mild signs of NOWS that do not significantly impact the infant's ability to feed, sleep, and function, while others may have more severe signs that require pharmacologic therapy to avoid negative effects on growth and development [19]. Physicians use observer-rated scales in clinical practice to quantify the severity of withdrawal and to guide pharmacotherapy. Yet, current scales have not undergone rigorous instrument development and validation [20].

However, while our findings are encouraging, further research is warranted to explore the long-term effects and generalizability of the FSC approach across different healthcare settings and patient populations.

Conclusion

It is concluded that the Feed, Sleep, Console (FSC) approach shows a potential intervention for neonatal opioid withdrawal. Our study findings suggest that implementing the FSC approach may lead to improved outcomes compared to usual care in neonates experiencing opioid withdrawal.

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