Safety, Feasibility, and Effectiveness of Weighted Blankets in the Care of Infants With Neonatal Abstinence Syndrome

A Crossover Randomized Controlled Trial

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ABSTRACT

Background: Nurses are caring for increasing numbers of infants diagnosed with neonatal abstinence syndrome (NAS). The recommended initial line of treatment to alleviate NAS symptoms includes nonpharmacologic interventions; however, there is little rigorous evidence on the effectiveness of nonpharmacologic interventions.

Purpose: The purpose of this study was to assess the safety, feasibility, and effectiveness of weighted blankets in the care of NAS infants.

Methods: This pilot study was a crossover randomized nonblinded controlled trial conducted at a level III neonatal intensive care unit. Infants' care included 30-minute sessions utilizing either a nonweighted or weighted blanket, with infants serving as their own controls.

Results: A total of 16 patients were enrolled for a total of 67 weighted blanket sessions. To address safety, no adverse events were observed, the weighted blankets were never removed due to infant distress, and infants experienced no significant temperature change. To address feasibility, 94% of approached mothers were receptive to the use of weighted blankets and staff reported no obstacles to using the blanket. Finally, to assess effectiveness, there was a significant decrease in the infant's heart rate and Finnegan score when a weighted blanket was used. There was no significant change in respiratory rate with the use of a weighted blanket.

Implications for Practice: Weighted blankets may be safe, feasible, and effective in decreasing NAS symptoms.

Implications for Research: Larger studies are needed to thoroughly study the use of weighted blankets in this population and examine additional outcomes, such as need for pharmacologic intervention, length of hospital stay, and cost of hospital stay.

Key Words: neonatal abstinence syndrome, neonate, nonpharmacologic intervention, weighted blanket

With the increasing prevalence of opioid abuse, hospital staff are treating increasing numbers of infants diagnosed with neonatal abstinence syndrome (NAS). Infants with NAS can display a range of symptoms related to dysfunctional regulation of their central nervous systems and autonomic nervous systems.[1] These symptoms include hyperactivity, irritability, tremors, excessive high-pitched crying, restlessness, increased tone, jitteriness, poor sleep patterns, sweating, frequent sneezing, increased respiratory rate, excessive sucking, poor feeding, vomiting, and watery stools.[2] The recommended initial line of treatment to alleviate these symptoms includes nonpharmacologic interventions, such as keeping the infant in a quiet and dark room, clustering care, swaddling, swaying, rocking, breastfeeding, providing frequent and small volumes of milk, rooming-in, and noninsertive acupuncture.[2,3] If these nonpharmacologic interventions do not relieve symptoms, drug therapy is recommended. Drug therapy has been shown to provide short-term alleviation of symptoms. However, use of pharmacologic intervention is associated with a longer duration of hospitalization and can present a potential barrier to maternal–infant bonding.[2] Because of the limited benefit and potential adverse effects of pharmacologic intervention, it is important that the best nonpharmacologic interventions are used in the first line of treatment to potentially reduce the need to advance treatment to drug therapy. There is little rigorous evidence on the effectiveness of nonpharmacologic interventions in this patient population.[1] One innovative nonpharmacologic intervention that has not been studied for infants with NAS is utilization of weighted blankets.

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LITERATURE REVIEW

Weighted blankets are a noninvasive method to provide deep tissue pressure and tactile sensory integration. It is theorized that tactile sensory integration

helps patients organize their sensory input and adjust better to environmental stimuli, thereby decreasing anxiety and promoting calmness.[4] Weighted blankets, or weighted vests, have been studied in several pediatric patient populations, including children with autism,[5-9] children with attention deficit-hyperactivity disorder (ADHD) or difficulty attending,[10,11] children with developmental disorders.[12,13]

Most research on weighted blankets and vests has evaluated their use with children with autism. Several studies in this patient population have reported no statistically significant benefits with weighted blanket use, including no decrease in stereotyped behaviors, arousal, motoric stereotyped behaviors, or heart rate,[7] no effect on competing behaviors of joint attention,[8] and no increase in sleep time, decrease in time to fall asleep, or decrease in number of times children woke during sleep.[6] However, studies have reported child and parent preference for using weighted blankets.[6,8] In contrast, Gee and colleagues[5] found that the use of weighted blankets resulted in an increase of 1 to 3 hours in the amount of sleep per night and a slight decrease in the time to fall asleep. In a systematic review of studies that examined the use of weighted vests in individuals with autism, Taylor and colleagues[9] concluded that weighted blankets are not an evidence-based practice in this population. They cite the methodological limitations and lack of experimental rigor in the studies examining the use of weighted blankets in this population. While only one study found statistically significant results in children with autism, families and children report that they like using the weighted blankets and no adverse events were reported.

The use of weighted blankets or vests has been studied less frequently in other patient populations but has demonstrated some potential benefits. Using a weighted blanket or vest was associated with decreased time to fall asleep, improved teacher ratings of symptoms of activity level, and improved attention span among 21 children with ADHD.[11] Another study examined the use of weighted vests among 10 elementary school students who had attention difficulties and found no significant impact on time on task.[10] Fertel-Daly et al[12] studied 5 preschool-age children with pervasive developmental disorders and found that use of a weighted vest resulted in an increase in attention to task, decrease in self-stimulatory behaviors, and a decrease in number of distractions.

Overall, there is mixed and contradictory evidence around the use of weighted blankets with a range of patient populations. Many of these studies involved a small sample size and lacked power to detect small effects of the intervention. However, there is some preliminary evidence that the use of weighted blankets could improve sleep patterns[5,11] and decrease self-stimulatory behaviors,[12] which are symptoms also observed in infants with NAS. Anecdotally, nurses noticed that when developmental aides that are typically used for positioning were draped on infants with NAS, the infants appeared to be calmer. Nurses wondered whether weighted blankets designed specifically for this purpose would demonstrate the same clinical changes. However, to date, the use of weighted blankets has not been studied in infants with NAS. This study seeks to fill this gap by assessing the safety, feasibility, and effectiveness of weighted blankets in the care of infants with NAS.

The purposes of this pilot study were (1) to assess the safety of using weighted blankets in the care of hospitalized infants with NAS, (2) to explore the feasibility of using weighted blankets in this patient population, and (3) to obtain preliminary data on effectiveness of weighted blankets in decreasing symptoms of NAS.

What This Study Adds

- Evidence that weighted blankets are a safe, feasible, and inexpensive intervention to use when caring for infants with NAS.
- Preliminary evidence that weighted blankets decrease heart rate and Finnegan scores of infants with NAS without significant changes in temperature.

METHODS

Design

This study was a crossover randomized non-blinded controlled trial. Approval was obtained by the organization's institutional review board. Six neonatal intensive care unit (NICU) staff nurses completed human subjects' protection training and study-specific training. Written informed consent was obtained from the mothers before enrolling infants in the study.

Sample

The study took place in a 60-bed open multipod designed level III NICU that provides care for premature infants and infants with critically ill conditions. Greater than 900 infants are admitted to the unit annually, with provision of care for approximately 2 to 5 infants with NAS each month. Infants with NAS are scattered throughout the unit and are admitted preferentially into quiet corners whenever possible or in sections of the NICU associated with less traffic.

Inclusion criteria for the study included (1) infants admitted to the NICU with a diagnosis of NAS, (2) infants with gestational age 37 weeks or more, and (3) infants whose mothers had a positive maternal drug screen at delivery. Exclusion criteria included

(1) infants with intrauterine growth restriction and (2) infants with any medical diagnosis in addition to an NAS diagnosis.

Since there are no published data on the use of weighted blankets in this population, the effect size is unknown, and a power analysis could not be conducted. Therefore, a pilot study was designed to collect data for 7 months and all eligible infants admitted to the NICU during study recruitment were approached. All patients who met the inclusion/exclusion criteria and whose mother consented to the study were enrolled.

Intervention

Therapeutic weighted blankets are made from a cotton and polyblend and are machine washable. Blankets are 11 inches by 20 inches and are filled with nonmolding polypellets, resulting in a weight of 1 lb. Blankets remained in the infants' room until discharged from the unit or until the study was completed. Then, weighted blankets were cleaned following the procedure used to clean linens on the unit and were available for use with the next infant enrolled. During the intervention, infants were placed supine and swaddled in a muslin or cotton wrap and a weighted blanket was then laid directly on top of swaddled infants. The weighted blanket covered the infant from their shoulders to their feet. Blankets were not wrapped around infants, which allowed the infant to move under the blanket. Weighted blankets remained in place for 30 minutes (see Figure 1). All infants were placed on heart rate and respiratory rate monitors during the blanket application. Study team members remained in the infant's room for direct visual observation of the infant during the entire time a weighted blanket was in use. If any distress was noted, team members removed the blanket immediately and reported the incident to the study team.

FIGURE 1

Image of placing weighted blanket on an infant.

Measures

Infant Characteristics

Demographic and infant clinical data were collected to describe the population including the infant's age, gender, weight, current medications, step of methadone weaning protocol (if applicable), and the nonpharmacologic interventions being used.

Safety

There were 2 measures of safety. One safety measure assessed temperature changes to evaluate the infants' ability to thermoregulate with blanket use. Temperature was measured in degrees Fahrenheit using an axillary temperature probe. Temperature was measured before blanket placement, after the blanket had been in place for 30 minutes, and then 30 minutes after the blanket was removed. Mean change in temperature was calculated. The second measure of safety was analysis of adverse events. Study team members remained in the room directly observing infants during blanket use and were trained to document any adverse events and intervene if events occurred. Data collection forms contained a section for study team members to document any adverse events occurring during blanket use. Study team members were asked to document whether the blanket was removed for safety reasons and to document the reason for blanket removal.

Feasibility

There were 2 measures to assess feasibility. The first measure looked at acceptability of the blanket use among families. This was determined by calculating the percentage of eligible infants approached about study participation whose mother agreed to allow blanket placement. The second measure of feasibility examined the feasibility of using the blanket by staff. During training, study staff were asked to provide feedback and obstacles to blanket use directly to the principal investigator and document these on the data collection form.

Preliminary Effectiveness

Effectiveness was assessed by collecting 3 measures: heart rate, respiratory rate, and NAS symptoms. Heart rate and respiratory rate were measured by

continuous monitors placed on the infants. Heart rate and respiratory rate were obtained from monitor readings and documented on data collection form before blanket placement, 30 minutes after the blanket was in place, and 30 minutes after the blanket was removed. Mean change in heart rate and mean change in respiratory rate were calculated. NAS symptoms were measured using the *Modified Finnegan Neonatal Abstinence Scoring Tool*. This tool is the predominant tool used clinically in the United States to quantify the severity of symptoms of NAS. It provides a summative score, Finnegan score, obtained from the assessment of 21 items related to neonatal withdrawal. The total score ranges from 0 to 43, with a higher score indicating more severe symptoms. Scores above 8 have been described as indicative of NAS.[14,15] The total score of this tool has been found to have excellent interrater reliability, $r = 0.82$,[14] intraclass correlation coefficient = 0.996.[16]

Procedures

Each day of data collection, the study staff reviewed the patients admitted to the NICU to determine potential subjects. When a potentially eligible infant was identified, a study staff team member approached the mother and described the study. If the mother was interested in enrolling their infant in the study, the study staff team member reviewed the informed consent form, answered any questions, and obtained written informed consent. A study staff team member performed a baseline assessment of NAS symptoms using the *Modified Finnegan Neonatal Abstinence Scoring Tool*.

After obtaining baseline NAS symptom data, the subject was randomized into 1 of 2 groups, either the group that used the weighted blanket first or the group that used the nonweighted blanket first. All infants received identical care with both the weighted blanket and the nonweighted blanket, allowing them to serve as their own controls. Data collection was initiated when study nurses were available; typically this occurred within 24 hours of obtaining consent. When possible, study nurses were assigned to care for the infant directly. Other times, nurses not trained in the study provided direct care of the infant while trained study nurses obtained data during blanket use. Approximately 30 minutes before the next scheduled feeding or sleeping time, the study staff began the 24-hour data collection period by obtaining an infant's Finnegan score, heart rate, respiratory rate, and temperature. The infant was placed supine and swaddled. Then the study staff team member placed either the weighted blanket or a nonweighted blanket on the infant depending on their group assignment. The blanket stayed in place for approximately 30 minutes with the infants on heart rate and respiratory monitors and with a study staff team member visualizing the infant. Following 30 minutes of blanket use and before removing the blanket, the study staff team member obtained a Finnegan score, heart rate, respiratory rate, temperature, and noted any observations about the infant's behavior or response to the blanket. Next, the study staff team member removed the blanket and the clinical staff continued provision of nursing care. Approximately 30 minutes after the blanket was removed, the study staff team member obtained a Finnegan score, heart rate, and respiratory rate. This same procedure, alternating between a weighted blanket and nonweighted blanket, was repeated each time a scheduled feeding or sleeping episode occurred, for a maximum of 4 times (2 sessions with a weighted blanket and 2 sessions with a nonweighted blanket) in a 24-hour period. This continued every 24-hour period until the infant was discharged from the NICU.

Statistical Analysis

Statistical analyses were performed using SPSS statistical software. Descriptive statistics were used to describe the sample. Safety of weighted blanket use was assessed by examining reasons that study staff removed blankets prematurely and any adverse events reported by study team members. Additionally, to assess the effect of weighted blankets on infants' ability to thermoregulate, paired *t* tests were used to assess changes in temperature before and after 30 minutes of blanket use. Feasibility of weighted blanket use was assessed by evaluating the percentage of mothers approached for the study who enrolled their infant and the data collected by study team members around use of the blankets and any difficulties or challenges encountered. Finally, to begin to examine effectiveness, the Wilcoxon signed-ranks test was used to compare the change in Finnegan scores following weighted blanket use to the change in Finnegan scores following nonweighted blanket use.

RESULTS

A total of 16 patients were enrolled during the 7-month data collection period. Infants ranged from 1 to 28 days old at enrollment into the study (mean = 5.63, SD = 6.49). Infants' weights ranged from 2390 to 3530 g (mean = 3029.7, SD = 369.7). Fifty percent of the infants had been exposed to just one drug while in utero; the other half were exposed to multiple drugs. During the study, the majority (81.2%) of infants were receiving pharmacologic intervention and all infants were receiving nonpharmacologic interventions (see Table 1). Each infant experienced between 1 and 8 thirty-minute sessions with the weighted blanket over their hospital stay (median = 4 sessions). Variations in the number of weighted

TABLE 1. Demographics of the Sample (N = 16)

Characteristic	Range, Mean (SD) or n (%)
Age at time of enrolling, d	1-28, 5.63 (6.49)
Weight at time of enrolling, g	2390-3530, 3029.7 (369.7)
Gender	
Female	9 (56.2%)
Male	7 (43.8%)
In utero, patient experienced	
Single drug exposure	8 (50%)
Multiple drug exposure	8 (50%)
Medications taken during study	
Methadone	12 (75%)
Phenobarbital and clonidine	1 (6.2%)
None	3 (18.8%)
Nonpharmacologic interventions	
Swaddle	11 (68.8%)
Bendy/z flow	11 (68.8%)
Frog	7 (43.8%)
Cuddler	7 (43.8%)
Swing	4 (25%)
Kangaroo care	1 (6.2%)
Pacifier	1 (6.2%)

blankets sessions resulted from availability of study nurses and timing of patient discharge. A total of 67 weighted blanket sessions occurred during the entire study.

To address safety of the use of weighted blankets in this population, adverse event data and infant temperatures were examined. There were no adverse events observed during the 67 weighted blanket sessions. The weighted blankets were never removed due to infant distress or any safety concerns. To assess whether infants would have difficulty thermoregulating when a weighted blanket was in place, mean temperature change from baseline to 30 minutes after blanket was placed were compared between weighted blanket sessions and nonweighted blanket sessions. During the weighted blanket sessions, infant temperatures changed from a decrease of 1°F to an increase of 1.4°F, with a mean temperature decrease of 0.104°F (SD = 0.586°F). A similar change was found when examining temperatures before and after nonweighted blanket sessions, with temperatures changing from a decrease of 0.9°F to an increase of 1.1°F, with a mean temperature increase of 0.089°F (SD = 0.531°F). The difference between mean temperature change in infants after weighted blanket placement was not significantly different from the mean temperature change in infants after nonweighted blanket placement, $t(47) = -1.209$, $P = .233$.

To address feasibility of the use of weighted blankets in this patient population, 17 infants were identified as eligible to use the intervention. Mothers of 16 (94%) of these infants were receptive to the intervention and were willing to allow staff to use the weighted blanket. One mother decided not to enroll her infant in the study. She stated that because this had not been used in infants with NAS before, she was concerned the weighted blanket may cause increased distress and could increase her infant's length of stay. Study staff reported no obstacles or difficulties using the weighted blanket.

Next, effectiveness in decreasing NAS symptoms was assessed by examining 3 outcome variables: heart rate, respiratory rate, and Finnegan score. A Wilcoxon signed rank test indicated a significantly larger decrease in mean heart rate change from preintervention to 30 minutes after blanket placement when a weighted blanket was used (decrease of 7 beats per minute [BPM]) compared to when a nonweighted blanket was used (increase of 5 BPM), $P = .011$ (effect size $r = .448$). While heart rate decreased significantly when a weighted blanket was used, this decrease in heart rate was only noted while the weighted blanket was in use and was not sustained in the 30 minutes following blanket removal, $P = .10$ (see Figure 2).

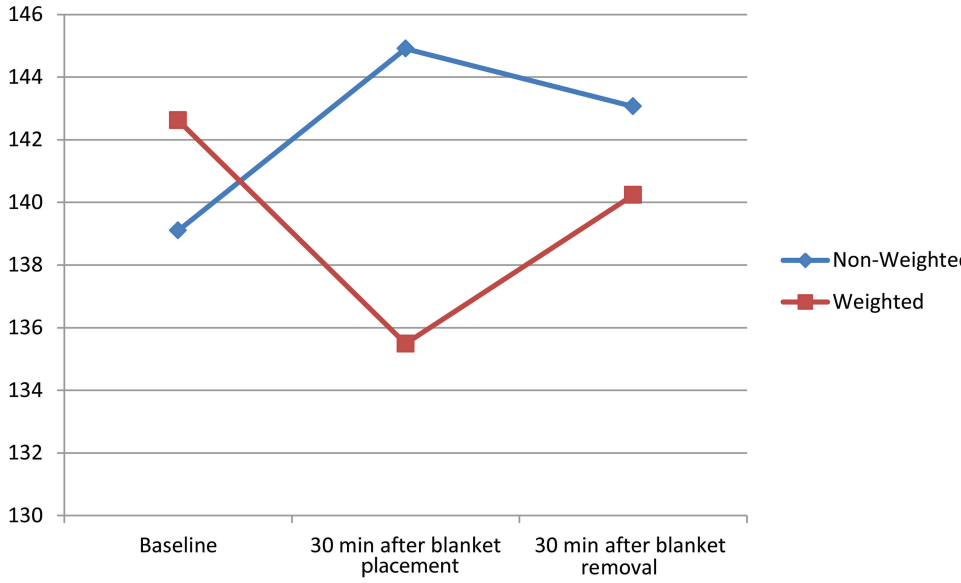
No significant difference was found in respiratory rate change from preintervention to 30 minutes after blanket placement when a weighted blanket was used (decrease of 5 revolutions per minute [RPM]) compared to when a nonweighted blanket was used (decrease of 5 RPM), $P = .307$. A change in respiratory rate remained nonsignificant in the 30 minutes following blanket removal, $P = .589$ (see Figure 3).

Finally, there was a significantly larger decrease in Finnegan score change from preintervention to 30 minutes after blanket placement when a weighted blanket was used (mean decrease of 1.485) compared to when a nonweighted blanket was used (mean decrease of −0.18), $P = .016$ (effect size $r = 0.469$). While Finnegan scores decreased significantly when a weighted blanket was used, this decrease was only noted while the weighted blanket was in use and was not sustained in the 30 minutes following blanket removal, $P = .594$ (see Figure 4).

DISCUSSION

To date, this pilot study is the first study to examine the use of weighted blankets in infants with NAS. Through 67 thirty-minute sessions using the weighted blanket among 16 infants, no adverse events were identified. Additionally, vital signs, including

FIGURE 2

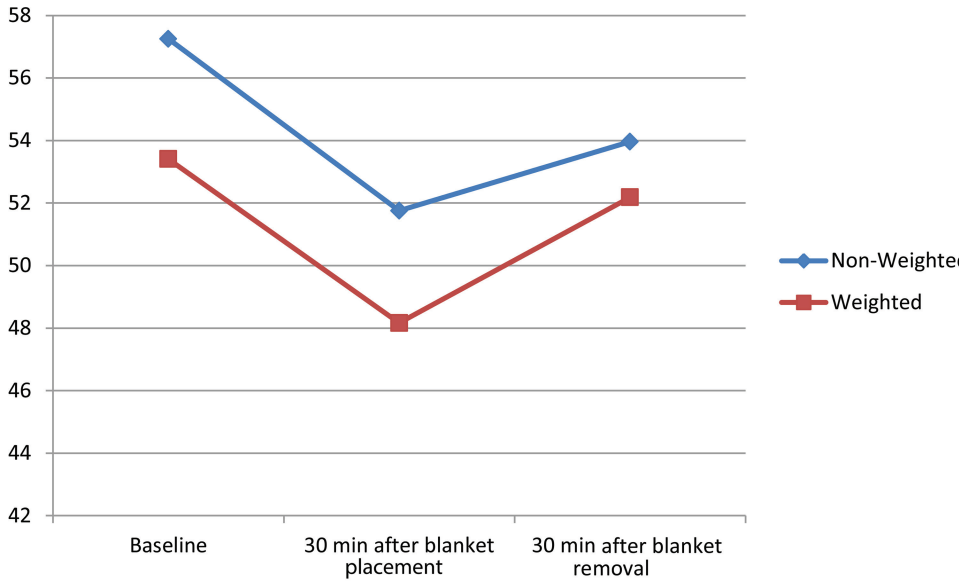


Mean heart rate preintervention, 30 minutes after blanket placement, and 30 minutes after blanket removal.

temperature, were stable throughout weighted blanket use. These findings are consistent with previous research that found no adverse events when weighted blankets or weighted vests were used in other populations[6-8] and found that weighted blankets were well received by parents.[6,8] Study staff reported no difficulties or obstacles were encountered when using the weighted blankets and most mothers approached were receptive to the use of weighted blankets.

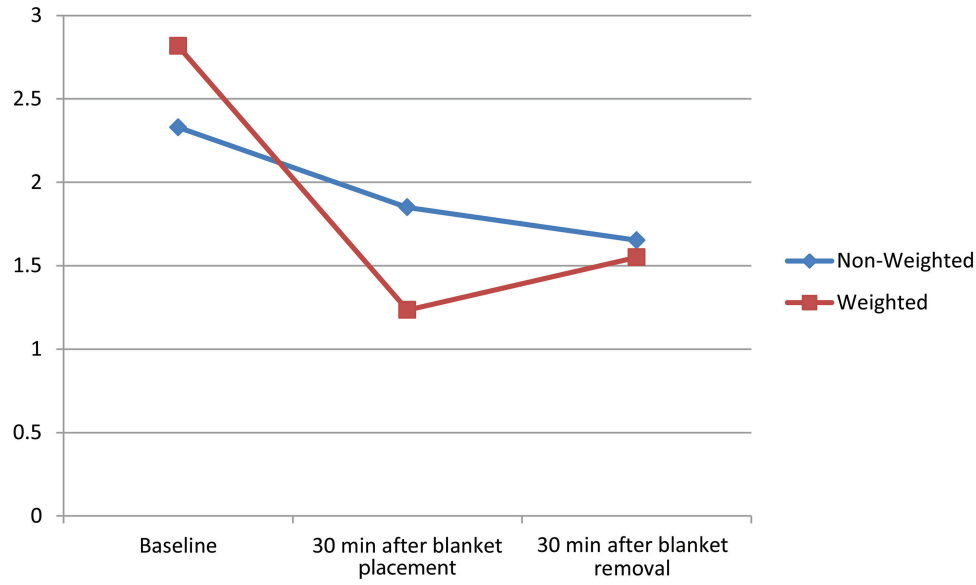
While the study provided initial data that the intervention is safe and feasible to use in this patient population, a surprising finding was that there were statistically significant results even in a small sample size. Compared to when nonweighted blankets were used, when infants had a weighted blanket in place, heart rate and Finnegan scores significantly decreased. The decreases were evident after 30 minutes of weighted blanket placement but were

FIGURE 3



Mean respiratory rate preintervention, 30 minutes after blanket placement, and 30 minutes after blanket removal.

FIGURE 4



Mean Finnegan score preintervention, 30 minutes after blanket placement, and 30 minutes after blanket removal.

not sustained after the weighted blanket was removed.

After the conclusion of the study and sharing of the statistically significant results, the nurses' desire to continue using the weighted blankets, and the families' positive feedback of weighted blanket use, the institution's policy was changed and weighted blankets were added to the available nonpharmacologic interventions for use in the NICU. In this study, weighted blankets were evaluated for use in a NICU setting only where all infants are continually monitored. They were not commercially available for purchase. Parents were aware that the blankets were for hospital use only and did not comply with safe sleep guidelines for use at home. Upon consult with a commercial company, a weighted sleep sack was developed that subscribes to safe sleep guidelines. Our team is in the process of implementing this new product that will provide weighted intervention while role modeling safe sleep practices for families.

Limitations and Future Research

While the current study provides promising initial findings, there are limitations to the study. This study enrolled a small sample size with only 16 infants participating. A larger well-powered study would be important to fully investigate the safety and effectiveness of this intervention. Additionally, the weighted blankets were used by study staff team members who were responsible for performing the study procedures. While these nurses serving as study team members reported no obstacles with use, it would be important to evaluate the use of weighted blankets by the clinical nurses caring for the infants to assess any obstacles encountered in usual clinical use outside the controlled situation of a research study. It would be important to study the use of weighted blankets in routine clinical care to see whether the feasibility findings translate from a controlled research setting to routine clinical care.

Another limitation to the current study was a large amount of missing temperature data. Four of the 16 infants did not have temperature data recorded both before and after the weighted blanket use. Study staff often recorded the infant's baseline temperature but then documented that the infant was sleeping after 30 minutes of weighted blanket use and therefore they did not want to wake the infant and did not obtain a temperature.

Future research should be designed to build upon these findings. To address missing temperature data, future research could replicate this study using a temperature probe for continuous data collection throughout weighted blanket use. With initial findings that weighted blankets may be beneficial in decreasing NAS symptoms, it would be important to compare weighted blanket use among patients receiving pharmacologic intervention and patients not receiving pharmacologic intervention. Additional outcomes to examine could include whether using weighted blankets before initiation of pharmacologic intervention would decrease the need for pharmacologic intervention and whether weighted blanket use could impact the amount and length of pharmacologic support required. It would be interesting to examine whether weighted blanket use impacts infants' sleep duration and quality, neurodevelopmental stability, and mother–infant bonding.

Summary of Recommendations for Practice and Research	
What we know:	• There is little evidence supporting the effectiveness of specific NAS nonpharmacologic interventions. • Evidence that weighted blankets are a safe, feasible, and inexpensive intervention to use when caring for infants with NAS. • Preliminary evidence demonstrated that weighted blankets had a significant decrease in heart rates and Finnegan scores of infants with NAS without significant changes in temperature. • Infants with NAS appeared to be calmer and more comfortable when a weighted blanket is utilized.
What needs to be studied:	• Impact on medication use and length of use. • Impact on length of stay with potential cost savings. • Impact on infant sleep quality and duration utilizing EEG data. • Impact on long-term neurodevelopmental outcome and mother–infant bonding.
What we can do today:	• Continue to utilize blankets in safe controlled environment. • Communicate effectiveness regionally and nationally. • Encourage further multisite weighted blanket studies for the NAS population.

The current study examined a 1-lb traditional blanket design that was placed over a swaddled infant. Future research could examine different blanket characteristics including blankets of variable weights, sizes, and blanket designs that would promote safe sleep practices such as a swaddled blanket or sleep sac.

The weighted blankets used in this study were donated by a commercial source. Future research could evaluate cost savings by determining blanket cost and potential decrease in hospital length of stay with subsequent cost savings. Additionally, the current study examined the use of weighted blankets with monitored infants in a NICU setting. Future research could evaluate the feasibility and safety of weighted blanket use in non-NICU settings where infants are not continuously monitored.

CONCLUSION

This pilot study provides preliminary data that weighted blankets can be used easily and safely in a controlled environment with infants with NAS. Additionally, there is preliminary evidence that weighted blankets temporarily decrease heart rate and Finnegan scores. With a rise in opioid addiction nationwide and subsequent increase in neonatal drug abuse exposure, reliance on inexpensive and easy-to-use nonpharmacologic interventions is imperative.

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