RESEARCH ARTICLE

A Novel Approach to Assessing Infants With Neonatal Abstinence Syndrome

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ABSTRACT

OBJECTIVES: Neonatal abstinence syndrome (NAS) is a growing problem and poses a significant burden on the health care system. The traditional Finnegan Neonatal Abstinence Scoring System (FNASS) assessment approach may lead to unnecessary opioid treatment of infants with NAS. We developed a novel assessment approach and describe its effect on the management of infants with NAS.

METHODS: We retrospectively compared treatment decisions of 50 consecutive opioid-exposed infants managed on the inpatient unit at the Yale New Haven Children's Hospital. All infants had FNASS scores recorded every 2 to 6 hours but were managed by using the Eat, Sleep, Console (ESC) assessment approach. Actual treatment decisions made by using the ESC approach were compared with predicted treatment decisions based on recorded FNASS scores. The primary outcome was postnatal treatment with morphine.

RESULTS: By using the ESC approach, 6 infants (12%) were treated with morphine compared with 31 infants (62%) predicted to be treated with morphine by using the FNASS approach ($P < .001$). The ESC approach started or increased morphine on 8 days (2.7%) compared with 76 days (25.7%) predicted by using the FNASS approach ($P < .001$). There were no readmissions or adverse events reported.

CONCLUSIONS: Infants managed by using the ESC approach were treated with morphine significantly less frequently than they would have been by using the FNASS approach. The ESC approach is an effective method for the management of infants with NAS that limits pharmacologic treatment and may lead to substantial reductions in length of stay.

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Infants born to mothers who used opioids during pregnancy may develop neonatal abstinence syndrome (NAS), a constellation of neurologic, gastrointestinal, and musculoskeletal disturbances associated with opioid withdrawal.[1] The incidence of NAS in the United States has increased almost fivefold from 1.2 per 1000 births in 2000 to 5.8 per 1000 births in 2012.[2,3] In a study using a large national database, researchers found that the average length of stay (ALOS) for infants treated for NAS from 2009 to 2012 was 23 days.[3] This increased incidence of NAS combined with the prolonged ALOS has placed an estimated $1.5 billion annual burden on the health care system.[3,4]

In the American Academy of Pediatrics' (AAP) Report on NAS, researchers recommend a 2-tiered approach to treatment, with first-line therapy focusing on nonpharmacologic interventions such as swaddling, on-demand feeding, and low-stimulation environments.[5] The AAP recommends starting opioids and other adjuvant medications only when nonpharmacologic measures fail.[5,6] In addition, in the report, researchers recommend using a scoring tool to assess signs of withdrawal, and in a 2013 survey, researchers reported that 95% of institutions used the Finnegan Neonatal Abstinence Scoring System (FNASS) to guide pharmacologic treatment.[5,7] The FNASS assigns a score based on 21 clinical signs of withdrawal and, under most hospital protocols, scores ≥8 indicate the need for pharmacologic treatment[8] (see Supplemental Table 3).

The FNASS has been used to guide the management of infants with NAS since its development in the mid-1970s, but despite its wide acceptance, it has never been validated nor have its widely used score cutoffs been tested.[5] The score of 8 appears to be derived from the following quote from Finnegan's original 1975 article: "The infant with a score of 7 or less was not treated with drugs for the abstinence syndrome because, in our experience, he would recover rapidly with swaddling and demand feedings. Infants whose score was 8 or above were treated pharmacologically."[8] The score of 8 was chosen from 1 institution's experience and has been adopted by the vast majority of institutions nationwide.[7]

Although the FNASS provides an exhaustive catalog of the symptoms of opioid withdrawal, it does not focus on how those symptoms affect the infant's ability to function. It also requires the scorer to unswaddle and disturb the infant, which runs counter to the aforementioned AAP recommendation of optimizing first-line, nonpharmacologic interventions. We developed a novel, nonintrusive approach to assessing infants with NAS focused entirely on the infant's ability to function, regardless of the number of withdrawal symptoms. Our aim with this study was to describe this novel approach and compare it to a more traditional FNASS-driven approach.

METHODS

Study Design

We retrospectively compared treatment decisions for opioid-exposed infants, guided by our novel assessment approach to the predicted treatment decisions for the same infants dictated by a traditional FNASS approach. Infants admitted from March 2014 through August 2015 with prenatal exposure to opioids and managed on our inpatient unit were included in the study. During this period, infants with prenatal opioid exposure were initially managed in the well-newborn nursery and then transferred to the general inpatient unit for continued management of NAS. All opioid-exposed infants were managed by using our general NAS inpatient unit guidelines, including routine first-line, nonpharmacologic interventions such as providing a low stimulation environment, rooming-in, swaddling, and on-demand feedings. Opioid-exposed infants were preferentially managed on the general inpatient unit unless they had other medical conditions requiring management in the NICU or there were no available beds on the general inpatient unit.

During the study period, management decisions for all opioid-exposed infants regarding the initiation of pharmacologic treatment were made by using our new approach, which relied on 3 factors: eating, sleeping, and consolability. FNASS scores were obtained for the same infants at least every 4 hours during their entire hospitalization by nursing staff but were not used to guide medical decision-making regarding the initiation of pharmacologic treatment. Management decisions predicted by these recorded FNASS scores were subsequently compared with actual decisions made by using our novel Eat, Sleep, Console (ESC) approach.

ESC Approach

An infant was considered to be well managed by using the ESC approach if the infant was able to eat ≥1 oz per feed or breastfeed well, to sleep undisturbed ≥1 hour, and to be consoled, if crying, within 10 minutes. If the infant was eating <1 oz per feed or not breastfeeding well, sleeping <1 hour undisturbed, and/or was not consolable within 10 minutes, the medical team was alerted, and the treatment was increased either by augmenting nonpharmacologic interventions, if possible, or starting morphine at 0.05 mg/kg every 3 hours. Morphine was decreased by 0.04 mg per dose daily if the infant was considered well managed by the ESC standards (Fig 1). Patients were cleared for discharge 4 to 7 days after birth if they were eating well, sleeping well, and easily consolable for 24 hours.

The ESC approach was developed based on years of observations of patients with NAS. Our multidisciplinary team considered eating and sleeping to be the essential functions of a newborn, and if these functions were not interrupted by withdrawal symptoms, then we could consider the infant's withdrawal to be well managed. Although the FNASS provided a list of the symptoms of withdrawal, we decided that our institutional approach would focus more on a nonintrusive, functional assessment of infants with NAS. In addition, if the infant was difficult to console, that was likely an indication that the infant was in some discomfort and may require further intervention.

FNASS Approach

Treatment decisions made with the ESC approach were compared with the

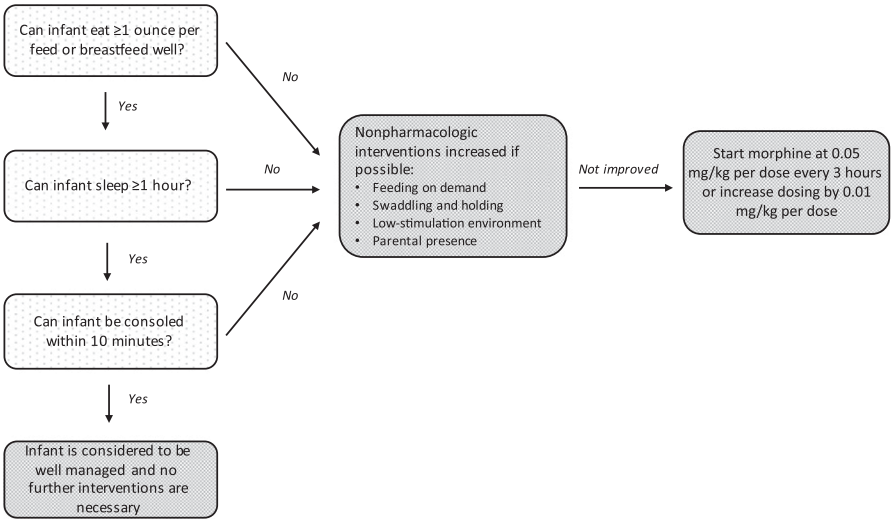

FIGURE 1 ESC approach.

predicted treatment decisions recommended by the FNASS scores. Predicted treatments were based on traditional scoring criteria and referred to as the FNASS approach (Fig 2). FNASS scores were obtained every 4 hours, and 3 consecutive scores ≥8 or 2 consecutive scores ≥12 would lead to the initiation or increase of morphine. Morphine would be weaned when FNASS scores were all <8 for a 24-hour period, and the dose would be kept constant if some but not more than 2 consecutive FNASS scores were ≥8 in a 24-hour period.[9–11] Before the implementation of the ESC approach in our institution, we relied on this FNASS approach, and the nursing staff were experienced in collecting FNASS scores.

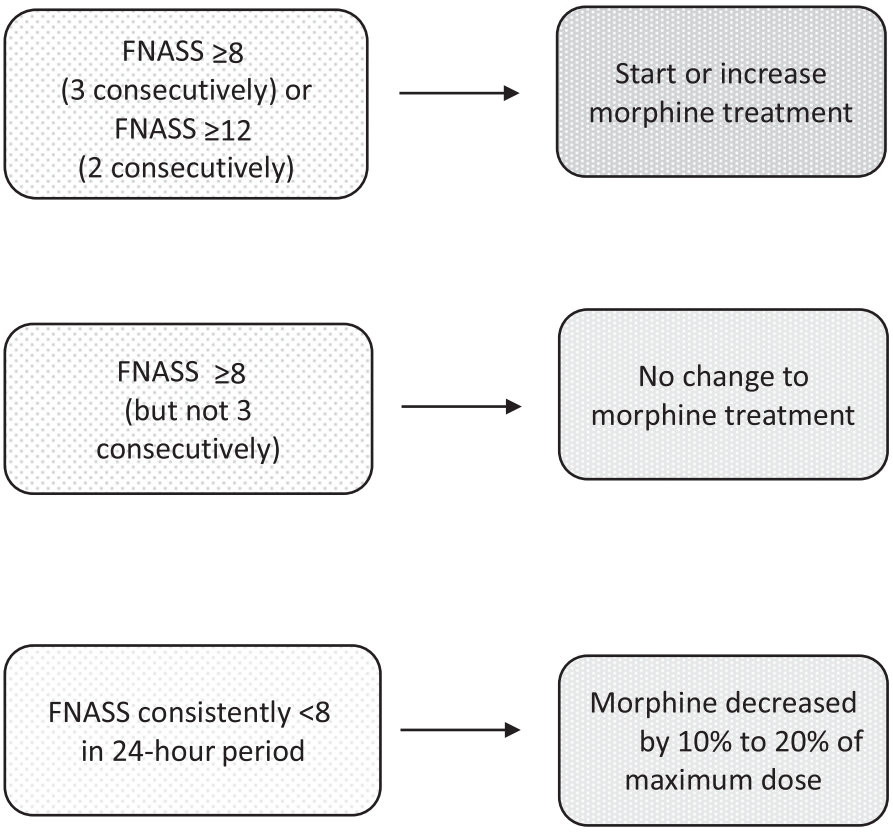

FIGURE 2 FNASS approach.

Study Population

The study population included all infants born at ≥35 weeks' gestation at Yale New Haven Children's Hospital (YNHCH) with prenatal exposure to opioids from March 2014 to August 2015 who were managed on our general inpatient unit. YNHCH is a tertiary care center within an academic medical center with ~4500 births annually. Subjects were identified by using the administrative codes for NAS and prenatal opioid exposure *(International Classification of Diseases, Ninth Revision* codes 779.5 and 760.72) and all electronic medical records were reviewed to confirm inclusion criteria. All data, including FNASS scores, gestational age, birth hospital, and mothers' doses of methadone, were obtained by a review of electronic medical records. We excluded infants with prenatal exposure to opioids of <30 days and/or those who were transferred to the NICU at any point of their initial hospital stay. The Yale University Human Investigation Committee approved this study.

Outcome Measures and Analysis

The primary outcome assessed was the proportion of patients started on morphine therapy by using the ESC approach compared with the predicted proportion of patients who would have been started on morphine by using the FNASS approach. A secondary outcome was the proportion of days that each approach recommended a specific pharmacologic management (no morphine, increased morphine, decreased morphine, or the same dose of morphine).

We also assessed the number of incidences when the ESC approach and the FNASS approach differed in their recommendations for morphine therapy. The approaches could differ in 2 general ways: (1) the ESC approach could direct more morphine therapy than the FNASS

approach (ie, the ESC approach led to an increase in the dose of morphine whereas the FNASS approach recommended either a decrease in morphine or no change in the dose); or (2) the ESC approach could direct less morphine therapy than the FNASS approach (ie, the ESC approach led to not starting morphine therapy or decreasing the dose whereas the FNASS recommended either not changing or increasing the dose of morphine). The day after there was a disagreement between approaches, the average FNASS scores for the day were analyzed to gauge the effect of treatment decisions. Finally, we tracked weight loss and adverse events for these patients including seizures, transfers to an ICU, and 30-day hospital readmissions for withdrawal (identified by review of electronic medical records).

We used Microsoft Excel version 14.4.5 for statistical analysis. Categorical variables were analyzed by using χ^2 or Fisher's exact test as appropriate. Continuous variables were analyzed by using *t* tests.

RESULTS

We reviewed 50 consecutive patients with prenatal exposure to opioids managed on our general inpatient unit with a total of 296 hospital days for an ALOS of 5.9 days. of these patients, 80% were exposed to methadone prenatally, 14% were exposed to buprenorphine, and 6% were exposed to short-acting opioids (Table 1). The ESC approach resulted in morphine initiation for 6 infants (12%) compared with 31 infants (62%) who would have had morphine initiated using the FNASS approach ($P < .001$). Morphine was initiated or increased on 8 patient days using the ESC approach (2.7%) compared with 76 patient days (25.7%) that morphine would have been initiated or increased using the FNASS approach ($P < .001$) (Table 2).

There were 30 patients (60%) in which the approaches disagreed such that using the ESC approach led to no change or a decrease in morphine dose whereas the FNASS approach would have increased morphine therapy. These disagreements occurred on 78 total days (26.4%). On the day after this type of disagreement, the average FNASS score was lower on 69.3% of days and the average FNASS score decreased 0.9 points (95% CI 0.40–1.39) ($P = .01$). There were 2 patients (4%) in whom the dose of morphine was kept stable by using the ESC approach whereas the FNASS approach recommended a decrease in the morphine dose. This type of disagreement occurred on 2 days (0.7%). On the day after these disagreements, the FNASS scores increased both times by an average of 1.7 points (Fig 3).

There were no adverse events reported. No patients had seizures or were transferred to an ICU. The average maximum weight loss for these infants was 8.7% (SD, 2.6) with an average weight loss of 7.2% (SD, 3.3) at discharge. No patients were readmitted within 30 days for management of withdrawal. The 30-day readmission rate for all patients admitted to YNHCH during this time period was 9.9%.

DISCUSSION

With our results, we suggest that using the ESC approach exposed significantly fewer infants to pharmacologic treatment than if we had used the FNASS approach. By using the FNASS to guide treatment, we would have exposed 25 additional infants to opioid therapy, an increase of 516%. Additionally, these infants had a substantially shorter

TABLE 1 Characteristics of the Infant and Their Mothers

	Baseline ($N = 50$)
Characteristics of the Infants	
Girls, *n* (%)	28 (56)
Race, *n* (%)[a]	
White	45 (92)
African American	3 (6)
Hispanic	1 (2)
Birth weight, kg[b]	3.1 ± 0.5
Apgar score at 5 min[b]	8.9 ± 0.3
Head circumference, cm[b]	32.9 ± 1.6
Breastfed, *n* (%)[c]	18 (36)
Maximum weight loss from birth weight, %[b]	8.7 ± 2.6
Weight loss from birth weight at discharge, %[b]	7.2 ± 3.3
Length of stay, d[b]	5.9 ± 2.1
Characteristics of the mothers	
Mother's age, y[b]	28.4 ± 5.0
Gestational age, wk[b]	38.8 ± 1.5
Gravida[b]	3.1 ± 2.2
Cesarean delivery, *n* (%)	11 (22)
Cigarette smoking, *n* (%)	22 (44)
Alcohol, *n* (%)	3 (6)
Public insurance, *n* (%)	44 (88)
Opioid used, *n* (%)	
Methadone	40 (80)
Buprenorphine	7 (14)
Other[d]	3 (6)
Methadone dose, mg/d[b]	87.8 ± 37.2
Polypharmacy, *n* (%)[e]	21 (42)

[a] Data were unavailable for 2 patients.
[b] Mean ± SD.
[c] Breast milk >50% of intake at discharge.
[d] Oxycodone, Oxycontin, and/or Percocet.
[e] Opioid use in addition to mother's use of cocaine, selective serotonin reuptake inhibitors, or benzodiazepines (determined either via history and/or urine testing of mother).

TABLE 2 Outcomes

	Outcome Using ESC Approach	Predicted Outcome Using FNASS Approach	*P*
Infants with NAS receiving morphine, *n* (%)	6 (12)	31 (62)	<.001
Hospital days, *n* (%)[a]			
No morphine	258 (87.2)	156 (52.7)	<.001
Increased morphine dose	8 (2.7)	76 (25.7)	<.001
Decreased morphine dose	21 (7.1)	35 (11.8)	<.001
Same morphine dose	9 (3.0)	29 (9.8)	<.001

[a] $N = 296$.

ALOS than infants in most previous reports without any significant adverse events or readmissions. The ALOS in our study was 5.9 days. Assuming a morphine weaning protocol of 10% of the original dose each day and assuming, in a best-case scenario, that each infant weaned every day, the ALOS using the FNASS protocol would have been at least 10 days longer for these 25 patients for a total of 250 additional patient days.

Use of the FNASS in the management of NAS is the standard approach in the United States.[5,9] However, researchers of 2 quality improvement projects that either simplified the FNASS score or abandoned it entirely have demonstrated an ALOS less than the national average without adverse outcomes. Holmes et al[12] continued to use the FNASS but no longer used the strict scoring parameters and instead prioritized feeding difficulties, weight gain, difficulty sleeping, and inconsolability. This project demonstrated a decrease in opioid exposed infants treated with morphine from 46% to 27% and reduction in ALOS from 16.9 to 12.3 days in infants treated with morphine.[12] At YNHCH, the ESC approach was used as part of a 5-year quality improvement project that led to a decrease in pharmacologically treated infants from 98% to 12% and a decrease in ALOS from 22.5 to 5.9 days.[13]

The FNASS thoroughly catalogs the signs of withdrawal in infants but may lead to overtreatment because our data indicate that many infants will improve even when the FNASS approach recommendations are not followed. This approach may also lead to delays in appropriate escalation of treatment because it may require at least 8 to 12 hours before 3 scores ≥8 have been recorded. In addition, the act of properly scoring an infant using the FNASS requires the scorer to unswaddle and purposely disturb the infant in an attempt to elicit withdrawal signs. These actions directly undermine the recommended first-line treatment of nonpharmacologic interventions. We developed a novel assessment approach because we thought it was more clinically appropriate to determine if the withdrawal signs were interfering with normal neonatal functioning (specifically feeding, comfort, and sleep). The ESC approach focuses on the ability of the infant to function, does not require the infant to be disturbed, and directs clinicians to evaluate and adjust treatment quickly if an infant experiences withdrawal severe enough to interfere with his or her ability to function well and/or be consoled.

The ESC approach is intuitive, easily understood by parents, and is really no different from what most parents and clinicians look for in evaluating any young infant. Infants with NAS have been managed by using scoring tools to quantify withdrawal signs for decades.[14] The ESC approach helps to shift the goal from reducing withdrawal signs at the expense of exposure to additional opioids and other medications to a focused approach aimed at the overall well-being of the infant. Some clinicians may worry that using such an approach will allow the infant to suffer, but the consideration of the infant's ability to be consoled should mollify this concern. Infants who experience pain or suffering are likely to cry and be difficult to console.[15] Infants who are not consolable within 10 minutes would have treatment escalated using the ESC approach. Conversely, infants who remain calm while being held probably do not need opioid therapy and should not

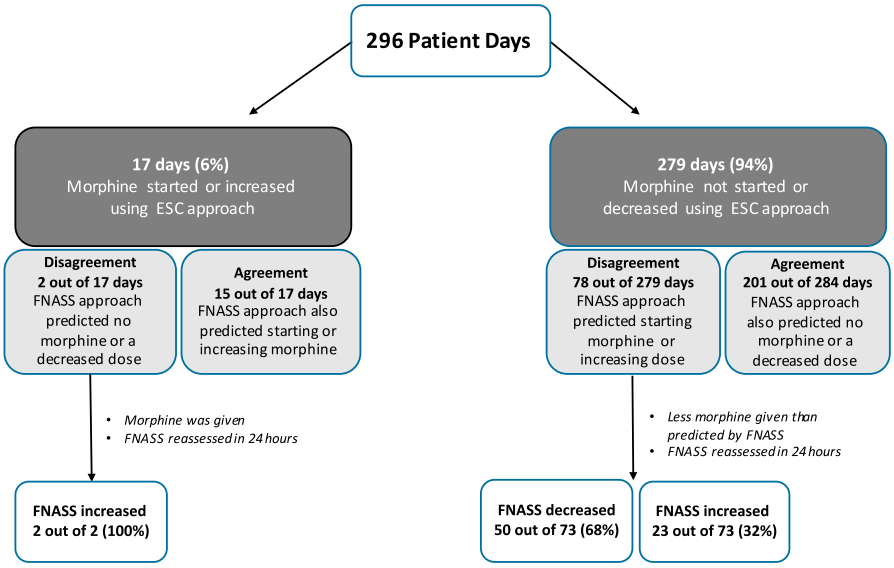

FIGURE 3 Disagreements between the ESC and FNASS approaches.

be disturbed to illicit signs of withdrawal to obtain on accurate FNASS score. It might also be reasonable to expect that an infant's withdrawal symptoms would worsen the following day if we did not initiate or increase morphine according to FNASS approach recommendations. We found, however, that the average FNASS scores actually improved in 69.3% of patients when we followed the ESC approach and did not give morphine to these infants.

Our study has several limitations. First, we did not randomly assign our patients into an FNASS group and an ESC group and therefore could not directly compare the effect of the approaches on length of stay. However, by applying both the ESC and the FNASS approaches to each patient, the patients essentially served as their own controls. The implementation of the ESC approach was part of a larger quality improvement project that led to a dramatic change in the culture and approach to the management of NAS patients. Although the culture surrounding management of NAS had changed, the nursing protocols on our general inpatient unit continued to include documentation of routine FNASS scores. Because these scores were no longer being used to drive management, this environment proved useful in creating the ability to retrospectively compare these 2 approaches. Although we have no direct measurement of the influence of these FNASS scores on various providers' decision-making, we suggest the high rate of disagreement between the 2 approaches reveals a limited effect. These infants were all managed by a small hospitalist group with only 4 physicians, allowing relatively minimal variation in the treatment approach. However, the ESC approach did not use a scoring tool or standardized algorithm, so there may have been some variability in assessment between providers. The FNASS scores were also recorded by a large number of nurses, and we have no documentation of interrater reliability among our staff. Finally, infants could have been readmitted to other community hospitals; however, most hospitals in our region transfer infants with NAS to our institution.

CONCLUSIONS

Infants managed with the ESC approach were treated with morphine significantly less frequently than they would have been using the FNASS approach. The ESC approach is an effective treatment method for the management of infants with NAS that limits pharmacologic treatment and may lead to reductions in length of stay. Further work is needed to assess the long-term neurodevelopmental outcomes associated with various evaluation and treatment approaches.

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