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Is Eat, Sleep, Console the New Standard of Care?

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ABBREVIATIONS ESC, Eat, Sleep, Console; FNASS, Finnegan Neonatal Abstinence Scoring System; MRI, magnetic resonance imaging; NOWS, neonatal opioid withdrawal syndrome

KEYWORDS Finnegan Score; neonatal abstinence; neonatal opioids; newborns; withdrawal syndrome

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Over the last 20 years, there has been a significant increase in neonatal opioid withdrawal syndrome (NOWS) and it is currently estimated to affect 7.3 infants per 1000 hospital births.[1]

A clinical diagnosis of NOWS is established when an infant experiences withdrawal symptoms after birth because of *in utero* opioid exposure. The Finnegan Neonatal Abstinence Scoring System (FNASS), originally created as a research tool, has been used for many years to assess these patients and to determine the need for medical intervention. It involves subjectively assessing 21 nonspecific clinical signs, with a score of ≥8 indicating the presence of withdrawal and the need for institution of non-pharmacologic and pharmacologic therapies.[2] A modified version was developed to overcome some of the perceived limitations of the original scoring system. However, the FNASS has significant limitations because the lengthy observations are heavily influenced by the level of training of the observer, a high degree of subjectivity, a lack of internal consistency and rigorous validation of the scores that indicate the need for medical therapy.[3–5] If pharmacologic treatment is initiated, it may commonly involve the use of an opioid including morphine, methadone, buprenorphine, and occasionally an adjunct agent such as clonidine or phenobarbital.[6] More recently, there has been a shift in this approach to management to focus more on non-pharmacologic strategies, as well as encouraging parental bonding.[7] The Eat, Sleep, Console approach (ESC) was developed in 2014, and it uses non-pharmacologic strategies for treatment of NOWS.[8] ESC involves assessing whether the patient takes an age-appropriate amount per feed, sleeps undisturbed for at least 1 hour, and consoles within 10 minutes. ESC focuses more on functionality of the infant, rather than multiple nonspecific clinical signs. A study by Ryan et al[9] evaluated the FNASS and ESC in an in-patient practice and demonstrated a good correlation for identification of NOWS. Furthermore, ESC showed higher sensitivity than FNASS; therefore, it would be very unlikely to miss a NOWS patient.[9,10] Various studies have now shown that the ESC approach decreases use of pharmacologic treatment, shortens length of stay, and decreases hospital costs.[11,12]

In the April 30, 2023, issue of *The New England Journal of Medicine*, Young et al[13] reported the results of the "Eat, Sleep, Console Approach or Usual Care for Neonatal Opioid Withdrawal" trial. This was a multicenter, stepped-wedge, cluster-randomized, controlled trial, carried out in 26 US hospitals, involving patients born at 36 weeks' gestation or more who had evidence of NOWS. For all sites involved, there was a period where they continued their current practice for treatment of NOWS. Then, during a 3-month transition period, staff members were trained on the ESC approach for management of NOWS prior to implementation in their institutions. The primary outcome was time from birth until medical readiness to discharge. Secondary outcomes included length of stay and need for pharmacologic therapy. The trial also incorporated a composite safety secondary outcome that included in-hospital safety, unscheduled health care visits, readmission to the hospital and non-accidental trauma or death. The investigators enrolled 1305 infants (702 during the usual-care periods and 603 during the ESC periods), and 837 met the trial definition and were included in an intention-to-treat analysis. The primary outcome chosen is consistent with current recommendations by the American Academy of Pediatrics. ESC treatment approach resulted in a statistically significant difference in the primary outcome, readiness for discharge (ESC group 8.2 days vs 14. 9 in the usual-care group), with an adjusted mean difference of 6.7 days (95% CI, 4.7–8.8) decreased length of stay. Furthermore, the proportion of infants who received opioid treatment was 52.0% in the usual-care group and 19.5% in the ESC group (absolute difference, 32.5%; RR, 0.38; 95% CI, 0.30–0.47). Despite a significant number of patients discharged prior to meeting the specified criteria, further analysis did not change the results. There was no difference between groups in the specified adverse outcomes.

This was a very well-designed study that adds to the growing body of evidence supporting the use of a more limited and functionally based tool for the assessment

of newborns at risk for NOWS. However, the switch from usual care to ESC-based management in all centers in addition to a very strict training process during the transition period may potentially introduce the bias that ESC is inherently superior. One could argue that usual care can be fraught with problems related to lack of adequate ongoing training of providers or new personnel with a lower level of experience and lack of internal and external consistency. On the other hand, providers received intensive training on ESC prior to the implementation of the program at the participating centers. However, that was precisely the intention of the trial, to compare ESC with "usual care."

In terms of generalizability of the results, the trial was carried out at 26 US hospitals with neonatal units of different configurations and that, in itself, is a strength of the study. The successful statewide implementation of ESC by the Colorado and Massachusetts Collaboratives supports that statement.[14,15] The ESC approach for the treatment of NOWS is a treatment strategy that has the potential to decrease length of stay and need of administration of opioids in neonates. It involves a low stimulation environment, hands-on care for the neonate including skin-to-skin contact, breastfeeding, and active family participation. However, how social determinants of health may affect the successful implementation of ESC in all settings for all patients is not fully answered by this trial.

Prenatal exposure to opioids has been clearly associated with neuronal apoptosis and brain injury in animal models, while in human newborns a decrease in brain connectivity and lower brain volumes were demonstrated by magnetic resonance imaging (MRI). Interestingly, these MRI findings correlated with modifiable maternal comorbidities including mental health disorders.[16]

Therefore, long-term developmental assessment of this cohort will be very important and may provide further evidence of the additional benefits of decreased postnatal exposure associated with ESC.

Finally, we need to realize that the successful implementation of ESC is based on a high degree of planning, education of providers, parental engagement, outpatient follow-up resources, and very importantly administrative support. Whether ESC becomes standard of care for NOWS babies will depend on how the neonatal community interprets and embraces the available evidence.

Article Information

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