

# Safety, Acceptability, and Feasibility of Auricular Acupuncture in Neonatal Abstinence Syndrome: A Pilot Study

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## ABSTRACT

**Background:** Auricular acupuncture (AA) has not been studied in neonatal abstinence syndrome (NAS).

**Objective:** The aim of this research was to evaluate AA safety, feasibility, and acceptability as a non-pharmacologic adjunct in NAS.

**Materials and Methods:** *Design/Setting:* A pilot study was conducted on 20 infants with NAS requiring pharmacologic treatment and neonatal intensive care unit admission. *Intervention:* SEIRIN<sup>®</sup> Pyonex **press needles** were used to access 3–4 of the following AA sites: *Shen Men*; Sympathetic; Lung; Kidney; Liver; Frustration; R-point; and Psychovegetative rim. Needles remained in one ear for  $3 \pm 1$  days before removal and placement in the opposite ear. Treatments continued until methadone was discontinued or a discharge dose was established. *Outcome Measures:* Safety was determined by the incidence of cellulitis; acceptability by a parent and provider survey; and feasibility by rate of needle dislodgements, adverse events, study retention, rate of consent, completed documentation, and time to first AA treatment and to address needle displacements.

**Results:** There was a 58% consent rate. AA was administered at an average of 21.5 hours after obtaining consent. Two percent of the needles became dislodged. All were replaced within 3 days. No infants were withdrawn from the study, and none had cellulitis. Both parents and providers increased their acceptability of AA.

**Conclusion:** AA as a nonpharmacologic adjunct in NAS is safe, feasible, and acceptable to parents and providers.

**Trial Registration:** ClinicalTrials.gov (trial #: NCT02062151).

**Key Words:** Neonatal Abstinence Syndrome, Auricular Acupuncture, Drug Withdrawal, Infant, Drug Abuse

## INTRODUCTION

NEONATAL ABSTINENCE SYNDROME (NAS) is a constellation of signs and symptoms presenting after birth in infants exposed to illicit drugs *in utero*.<sup>1</sup> The incidence of NAS is increasing in the United States, and more infants are requiring pharmacologic treatment.<sup>2</sup> While treatment often

includes pharmacologic and nonpharmacologic approaches,<sup>3</sup> nonconventional modalities such as acupuncture have not been evaluated for use with neonates.

Acupuncture is a component of Traditional Chinese Medicine and is based upon a theory of vital energy (or Qi) that circulates through the body in channels (or meridians). Disease occurs when these meridians are blocked, disrupting the flow

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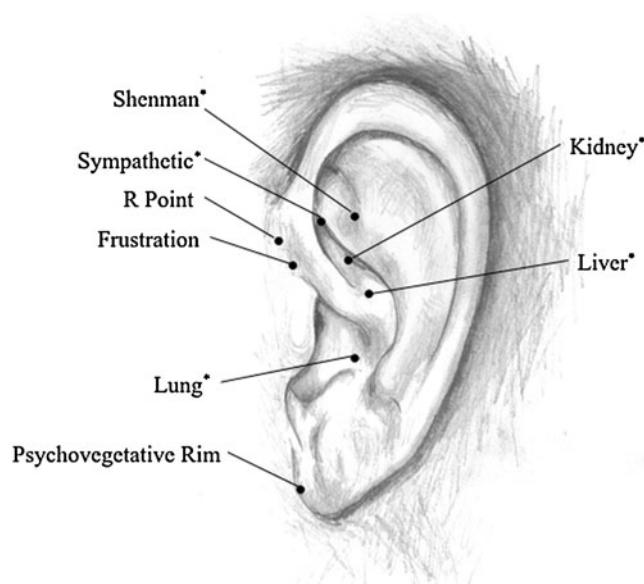
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*This trial was registered at ClinicalTrials.gov (trial #: NCT02062151).*

of energy.<sup>4</sup> Acupuncture has been shown to be safe in pediatric patients, with minimal adverse effects,<sup>5</sup> having particular benefit for patients who have asthma, allergies, or nocturnal enuresis, as well as for pain management.<sup>6-8</sup> Auricular acupuncture (AA) has been used to treat adult withdrawal symptoms using six auricular sites known as the National Acupuncture Detoxification Association (NADA) points.<sup>9</sup> These NADA points, developed by Michael Smith, MD (Lincoln Hospital, Bronx, NY) in 1985, include *Shen Men*, Sympathetic, Kidney, Liver, and Lung (Fig. 1).<sup>10</sup> Three additional AA sites in infants with NAS were identified by using a neuronal pen, which integrates optical and sound signals into an ear map.<sup>11</sup> These psychotropic points are active and easily detected in infants with NAS, and include the Frustration point, R-point, and Psychovegetative rim (Fig. 1).<sup>12</sup> Acupuncture efficacy in drug withdrawal using NADA points may result from the competitive uptake of endorphins by opioid receptors or from its anxiolytic effects.<sup>9</sup>

Noninsertive acupuncture is a technique that involves applying a finger or metal probe to body parts. A retrospective study evaluating noninsertive acupuncture in NAS reported reductions of restlessness, and improvements in sleeping and feeding, after treatment.<sup>13</sup> Schwartz et al. studied acupressure use in NAS by taping herbal seeds to NADA points with periodic massage of the seeds.<sup>14</sup> While these researchers concluded that acupressure was safe in neonates, the researchers found no difference in length of stay (LOS) or hospital course when acupressure was applied.<sup>14</sup> To the current authors' knowledge there are no published data evaluating the use of press needle AA in infants who have NAS. The objective of the current study



**FIG. 1.** Auricular acupuncture sites used. \*National acupuncture detoxification association points include: *Shen Men*, Sympathetic, Kidney, Liver, and Lung. Drawing by Velukutty Balakrishnan, PhD; used with permission.

was to determine the safety, feasibility, and acceptability of using AA to treat NAS in the current authors' neonatal intensive care unit (NICU), which uses both pharmacologic and nonpharmacologic management.

## MATERIALS AND METHODS

### Design

This was a prospective study conducted over a 2-year period. The University of South Florida and Tampa General Hospital (TGH) institutional review boards (IRBs) approved this pilot study, and it was registered at ClinicalTrials.gov (trial #: NCT02062151).

### Objectives

The primary objectives of this pilot study were to assess the safety, feasibility, and parental and provider acceptance of AA as a nonpharmacologic adjunct to treat infants with NAS. The secondary objective was to measure the number of days for infants in the study to regain birth weight. It was hypothesized that using AA in addition to pharmacologic treatment in infants who have NAS is safe, feasible, and acceptable for parents and providers.

### Participants

Inclusion criteria for infants were gestational ages  $\geq 37$  weeks 0/7 days (by last menstrual period, ultrasound dating, or best obstetric estimate), a diagnosis of NAS, and admission to the NICU. Exclusion criteria were ear helix or antihelix deformations that prevented needle placement, suspected or confirmed genetic or metabolic syndrome, or custody retained by the Department of Children and Families. From March 14, 2014, to April 9, 2015, the research team approached parents of all eligible infants and enrolled participants into the study.

### Setting

The study was conducted in the Jennifer Leigh Muma NICU, which is a level III unit in TGH. It is a University of South Florida (USF)-affiliated urban hospital with  $\sim 5500$  deliveries per year. The NICU admits an estimated 70 infants per year who are  $\geq 37$  weeks 0/7 days with a NAS diagnosis, and  $\sim 75\%$  of these infants require pharmacologic treatment. NICU providers responsible for making NAS medication decisions include pediatric residents, neonatology fellows, nurse practitioners, and neonatologists.

### Care of Infants with NAS

The Modified Finnegan Neonatal Abstinence Severity scoring tool was used to evaluate infants for neonatal opioid abstinence; this tool is commonly extrapolated for use in assessment of other *in utero* substance exposures resulting

in withdrawal. The tool contains 21 items that are used to evaluate a number of central nervous system, metabolic, respiratory, vasomotor, and gastrointestinal signs and symptoms of withdrawal.<sup>15</sup> Neonatal nurses in the TGH's NICU are trained in Finnegan scoring. Annual in-services for nurses ensure interobserver reliability in Finnegan scoring.

USF pediatricians manage infants at TGH born to mothers with substance abuse. Infants are initially monitored in the newborn nursery, and if NAS symptoms develop, the infants are transferred to the transitional NICU for Finnegan scoring. Criteria for NICU admission include two consecutive scores  $\geq 8$ , any one score  $\geq 12$ , or feeding difficulty. The NICU uses a guideline that includes both nonpharmacologic and pharmacologic measures to manage infants with NAS. Nonpharmacologic treatment is the standard of care for all infants with NAS. This includes the following: standardized guidelines for evaluation and treatment; facilitated communications between infants, parents, and providers; promotion of parent–infant bonding; minimization of NAS symptoms; and the involvement of consultants (in lactation, occupational therapy, social work).

Methadone is the primary pharmacologic agent used, with clonidine used as an adjunct if NAS severity is not well-controlled with methadone. Outpatient methadone treatment by USF pediatric clinics is an option for parents who prefer outpatient NAS management, and is used if the infant is cleared socially and medically to be discharged to go home on methadone. The TGH inpatient NAS guidelines were implemented from October 2012 to October 2014. During this AA study, 47 infants with a gestational age  $\geq 37$  weeks 0/7 days were admitted to the NICU for NAS and required pharmacotherapy. The average inpatient LOS for these NAS infants was  $23 \pm 15$  days.<sup>16</sup>

## Interventions

The principal investigator (PI), a pediatrician, who is board-certified in medical acupuncture and has more than 10 years of experience, placed all the AA needles using SEIRIN<sup>®</sup> Pyonex 0.2 mm  $\times$  0.6–mm single-use needles. The PI (L.W.) has extensive experience using these Pyonex **press needles** with good skin adherence and patient compliance. The first AA needles were placed at an average of 21.5 hours (0–26 hours) after obtaining informed consent. A hand-held acupuncture point locator (Point Plus, TENS Plus Industrials, Hong Kong, China) was used to detect points of lower skin resistance where the needle would be inserted.

AA sites used included: *Shen Men*, Sympathetic, Lung, Kidney, Liver, Frustration, R-point, and Psychovegetative rim (Fig. 1). An infant's active AA points and ear size determined the number of AA needles inserted. After cleaning the ear points with alcohol, the needles were inserted into 3–4 active AA points of one ear, as found by maximum pointer plus activity. Active points varied in individual infants and sometimes between AA treatments in the same patient.

The most commonly used AA sites were *Shen Men*, Liver, Lung, R-point, and Psychovegetative rim. Needles were attached to a sterile micropore tape that is made of breathable, waterproof material that adheres easily to the skin. No manual needle stimulation was done after needle insertion. Needles remained in place for  $3 \pm 1$  days before removal and placement of new AA needles in the opposite ear.

This procedure of acupuncture treatments was repeated until either methadone was discontinued or an established discharge dose of methadone was reached (single, daily dose  $< 0.16$  mg/kg/day), at which time AA would be stopped. To determine if there was recurrence of severe NAS symptoms post-AA, infants were monitored after acupuncture was completed. However, acupuncture was not restarted after being discontinued.

While infants were receiving AA treatments, their NICU nurses examined the acupuncture sites twice daily for needle placement, skin breakdown, and evidence of cellulitis. Findings were recorded on the study's Needle Documentation form. Any dislodged AA needles were removed and discarded by the NICU nurses, and these incidents were reported to the acupuncturist, who replaced the needles within 3 days. Skin breakdown and cellulitis were indications to discontinue acupuncture, with cellulitis treatment initiated at the discretion of the NICU medical team.

## Outcomes

Demographic data collected included: gestational age; gender; birth weight; date of birth; NICU admission and discharge; type of insurance; prenatal care; urine drug screen results for mother and infant; status of maternal enrollment in a drug-treatment facility; inpatient consultations (in social work, lactation, occupational therapy); and discharge care provider. NAS treatment data collected included: pharmacologic treatment (drug used, duration, peak dose [mg/kg], total dose [mg/kg], discharge dose if applicable); and AA details (duration, number of needles placed, and reports of dislodgement). Growth data collected included feeding type and days to regain birth weight.

Safety was determined by the incidence of skin breakdowns and cellulitis. Feasibility of AA in infants was determined by the rate of needle displacements, number and type of adverse events, and study retention rate. The feasibility of providers routinely administering AA was assessed by study recruitment and consent rate, ability to start AA within 2 days of obtaining consent, percentage of completed Needle Documentation forms, and the number of needle displacements unable to be addressed by the acupuncturist within 3 days.

Parental acceptance was gauged by surveys administered before acupuncture was performed (Pre-Acupuncture Survey 1; 100% response rate) and after it was discontinued but prior to hospital discharge (Post-Acupuncture Survey 1; 95% response rate).

NICU provider acceptance was evaluated by a voluntary survey administered 1 month before study initiation (Pre-Acupuncture Survey 2) and 1 month after study completion (Post-Acupuncture Survey 2). These written provider surveys were randomly administered to neonatologists, neonatology fellows, nurse practitioners, and NICU nurses, and collected within 1 hour by study personnel, allowing for a 100% response rate. While the provider surveys were administered to the same number of the above personnel, the same individuals did not complete this survey. Each survey included 5 questions and was used to assess respondent perceptions of AA and infant pain using a 5-point Likert scale.

### Sample Size and Statistical Analysis

This study was designed to test feasibility and not powered to detect a specific treatment difference; therefore, no formal sample size calculations were made. Nominal data were reported as frequency (%). Continuous data were reported as mean  $\pm$  standard deviation (SD) for normally distributed data and as median (range) for data not normally

distributed. While the majority of continuous data in this study was not normally distributed, this article reports both, as future studies may need to know the mean  $\pm$  SD for sample size planning and study development.

The caregiver pre- and post-survey “yes” or “no” responses were dependent and were analyzed using the McNemar test. Given that the provider surveys were from independent groups, “yes” or “no” questionnaire responses were analyzed using the Fisher’s exact test and values were expressed as a mean  $\pm$  SD, with the range of possible scores being 0–1. Likert-scale responses for both surveys were analyzed using the Student’s *t*-test. The analysis was conducted using Stata 13.1 (StataCorp., 2013, Stata Statistical Software: Release 13, College Station, TX: StataCorp LP).

### RESULTS

Approximately 77% ( $n=36$ ) of the infants admitted to the NICU with a diagnosis of NAS were eligible for the study. Parental consent was obtained for 58% ( $n=21$ ) with 20 infants enrolled (Fig. 2). Of these 20 infants, 14 were male

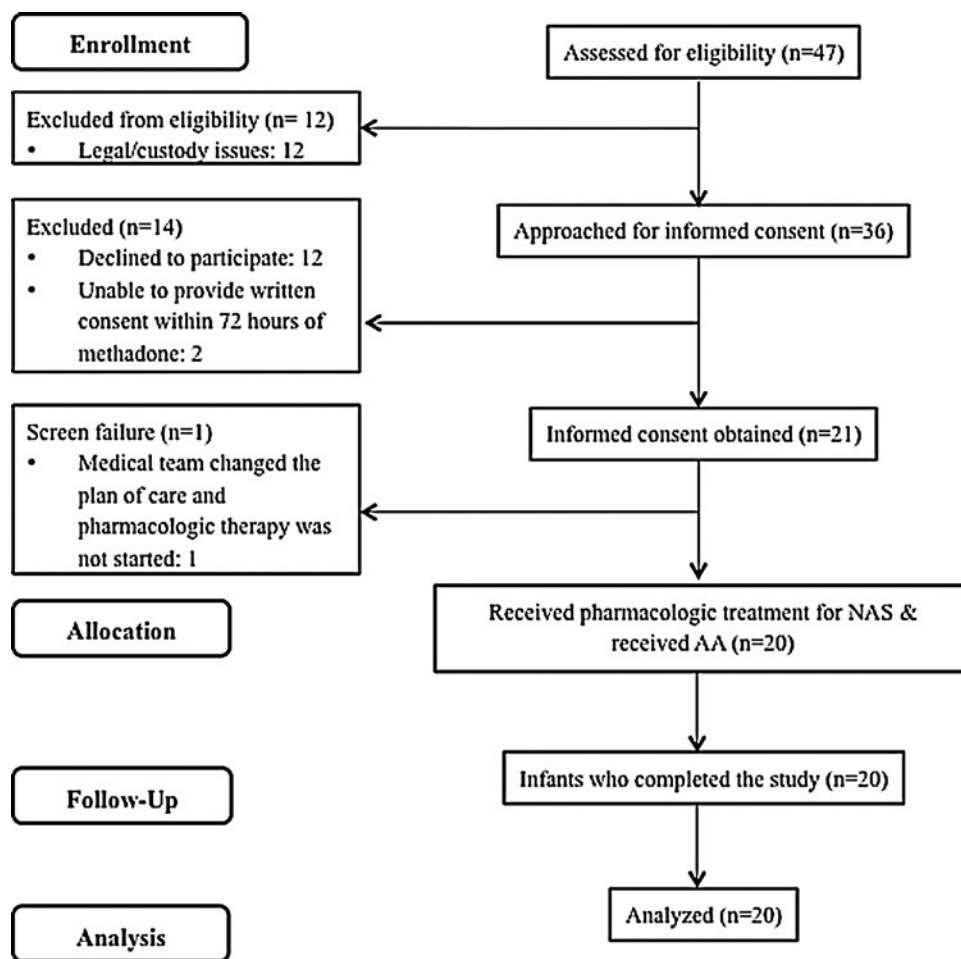


FIG. 2. Study flow diagram. NAS, neonatal abstinence syndrome; AA, auricular acupuncture.

with a median gestational age of 39 weeks (37–41 weeks) and an average birth weight of  $3198 \pm 417$  g. The median time to obtain consent after the infant's first methadone dose was 16 hours (0–69 hours). All infants received their first AA treatment within 2 days of enrollment and completed the study (Table 1).

Of 394 needles placed, only 2% ( $n=7$ ) became dislodged and the PI replaced all of these within 3 days. There was no skin breakdown and cellulitis reported. One event was reported to one of the IRBs, whereby an AA needle was changed on day 6 rather than day 4. Another unanticipated problem occurred when an infant with AA needles underwent a magnetic resonance imaging study. The infant had no apparent adverse effect and this event was reported to one of the IRBs, wherein an amendment was made to the protocol and education implemented to the NICU providers caring for AA study infants. There were no reports of limitations to care (e.g., feeding, holding infants, medical procedures) as a result of AA needle placements.

Nurses completed the Needle Documentation form 78% ( $n=563$ ) of the time. Parents and providers had increased

acceptability regarding AA after completing the study; these results are summarized in Tables 2 and 3, respectively.

All mothers of enrolled infants had documented prenatal care; 80% ( $n=16$ ) had Medicaid insurance, and 60% ( $n=12$ ) were enrolled in a substance-abuse treatment facility. The majority of mothers and infants were exposed to methadone (Table 4). All enrolled infants received pharmacologic management with methadone, and 30% ( $n=6$ ) were discharged with outpatient methadone management (Table 1). No infants required clonidine treatment.

Compliance with inpatient consultations was high, with all infants being evaluated by social work personnel and 90% ( $n=18$ ) by occupational therapy personnel. Lactation consults were done for 75% ( $n=15$ ) of mothers. All infants were discharged in the care of their parents ( $n=18$ ) or relatives ( $n=2$ ). There were 3 hospital readmissions for 2 infants; both were monitored for 26–47 hours after AA was discontinued and were discharged on outpatient methadone treatment. Only 1 readmission was for NAS management, and the readmission occurred 20 days after NICU discharge. The other readmissions were for upper respiratory-tract infection symptoms and poor weight gain. Both infants were weaned off of methadone prior to discharge after hospital readmission. The median percentage of weight loss from birth weight was 7.4% (–1.4; 13.8%) and the average time to regain birth weight was 12 days (0; 27 days). While the majority of infants received a combination of breast milk or formula, 20% ( $n=4$ ) were solely formula-fed.

TABLE 1. TREATMENT CHARACTERISTICS FOR NAS INFANTS RECEIVING ACUPUNCTURE (N=20)

Characteristics	Median (range)	Average (SD)
Duration of NICU admission (in days)	23 (7,69)	26 (15)
Pharmacologic treatment		
Duration of methadone treatment (in days)	17 (6–64)	21 (14)
Peak methadone dose (mg/kg/day)	0.2 (0.08–0.6)	0.23 (0.13)
Total amount of methadone received during admission (mg/kg)	1.8 (0.6–7.9)	2.8 (2.3)
Discharge methadone dose (mg/kg) <sup>a</sup>	0.07 (0.05–0.13)	0.08 (0.03)
Acupuncture treatment		
Time from methadone to informed consent (hours)	16 (0–69)	19 (17)
Time from informed consent obtained to 1st acupuncture treatment (in hours)	22 (0–26)	17 (10)
Duration of acupuncture (in days)	16 (5–56)	18 (14)
Number of AA needles placed per patient <sup>b</sup>	15 (6–19)	20 (14)
Time from acupuncture discontinuation to discharge (in hours)	70 (2–580)	108 (128)

<sup>a</sup>6 infants were discharged with outpatient methadone management.

<sup>b</sup>A total of 394 AA needles were placed for the 20 patients.

NAS, neonatal abstinence syndrome; SD, standard deviation; NICU, neonatal intensive care unit; AA, auricular acupuncture.

## DISCUSSION

AA used as a nonpharmacologic adjunct to treat NAS appeared to be safe, feasible, and acceptable to parents and providers in this study. This article described methadone treatment for NAS at TGH and noted that study infants did not have unexpectedly high postnatal weight losses.

Acupuncture has been shown to be safe in pediatric and adult populations with few adverse effects.<sup>5,8,17–19</sup> Several large studies in adults, including ~30,000 treatments, reported 3%–15% of adverse events that were predominantly transient and mild (e.g., tiredness, minor bleeding, bruising, pain).<sup>18,19</sup> In a systematic review evaluating the safety of acupuncture in children, researchers found that no fatal side-effects were reported<sup>8</sup>; however, adverse events were often ignored or inadequately reported. Other systematic reviews of AA in children estimate that 2%–12% of treatments were associated with adverse events, most of which were classified as mild.<sup>17,20</sup> Severe adverse events with acupuncture are rare, but have included the following: infection; pneumothorax; cardiac tamponade; thumb deformity; and nerve impairment.<sup>20</sup> These events are often ascribed to poor-quality treatments using improper techniques.

When an appropriately trained practitioner gives acupuncture treatments, they are described as safe.<sup>5,20</sup> This

TABLE 2. PARENT ACCEPTABILITY OF AA FROM PRE- AND POST-SURVEY 1

Survey statements	Pre-AA (N=20)	Post-AA (n=19)	Mean difference $\pm$ SE	P-value
"I have received acupuncture." <sup>a</sup>	0.1 (0.66)	1 (0.82)	0.9 $\pm$ 0.17	< 0.001
"I believe acupuncture helps relieve NAS symptoms in babies." <sup>b</sup>	-0.89 (0.94)	-1.42 (0.69)	-0.53 $\pm$ 0.26	0.056
"I believe that using acupuncture with medication to treat NAS will help babies use less medication." <sup>b</sup>	1.32 (0.48)	1.43 (0.51)	0.11 $\pm$ 0.07	0.163
"I believe placement of acupuncture needles is painful." <sup>b</sup>	-0.68 (0.82)	-1.26 (0.73)	-0.58 $\pm$ 0.21	0.012
"I am concerned that acupuncture needles can cause infection." <sup>b</sup>	0.47 (0.84)	1.21 (0.79)	0.74 $\pm$ 0.23	0.005

Note: Survey 1 responses were obtained from mothers of enrolled infants (pre AA  $N=20$ , post-AA  $n=19$ ).

<sup>a</sup>Responses for this question included "yes" or "no." Values are expressed as mean (standard deviation) with the range for possible scores being 0 to 1. A McNemar test was used to analyze responses.

<sup>b</sup>Values are expressed as mean (standard deviation) and mean difference  $\pm$  standard error. Responses for these questions were on a 5-point Likert scale and included "strongly agree" (1), "agree" (2), "neutral" (3), "disagree" (4), and "strongly disagree" (5). A positive mean difference indicates a positive change in perception. A Student's  $t$ -test was used to analyze responses.

AA, auricular acupuncture; NAS, neonatal abstinence syndrome; SE, standard error

article describes the safety of AA in neonates according to evaluations of the local effects of skin breakdown and cellulitis. While measurements were not made of infant pain or local bruising and bleeding at the sites of acupuncture, no skin breakdown or cellulitis was reported.

In adults, AA has been shown to be safe and effective as adjunctive treatment for drug withdrawal, with benefits of reductions in cravings, insomnia, and withdrawal symptoms.<sup>18,21-24</sup> In addition, adults undergoing AA have had a lower risk of relapse.<sup>21-25</sup> The TGH NICU has single-bed rooms where AA treatments were administered. This private setting may improve efficacy of nonpharmacologic management techniques and potentially decrease NAS symptoms. NADA points have been used successfully to treat a variety of conditions in group and disaster-relief settings, homeless shelters, and prisons.<sup>26</sup> This may suggest that AA

with NADA points can be helpful even in settings that are not private (e.g., open-concept NICUs, waiting rooms).

Infants with NAS have lower birth weights and poorer weight gains than unaffected term infants.<sup>27</sup> When mothers received medication-assisted treatment and enrolled in treatment programs, these mothers' infants had higher birth weights and were more likely to be discharged to their mothers' care.<sup>28</sup> A high proportion of mothers in the current study population received these services, which made it unsurprising that the infants had birth weights that were considered average for the gestational ages, and that 90% of mothers retained custody of their infants.

Postnatal weight loss among infants exposed to methadone is reported to be between 8% and 10%<sup>29</sup> versus 3% and 7% in healthy non-drug-exposed term infants.<sup>30</sup> Higher postnatal weight loss is reported in breast milk-fed infants,

TABLE 3. PROVIDER ACCEPTABILITY OF AA FROM PRE- AND POST-SURVEY 2

Survey statements	Pre-AA (n=70)	Post-AA (n=70)	Mean difference $\pm$ SE	P-value
"I believe acupuncture helps relieve NAS symptoms in babies." <sup>a</sup>	0.14 (0.71)	0.6 (0.91)	-0.46 $\pm$ 0.12	< 0.001
"I believe that using acupuncture with medication to treat NAS will help babies use less medication." <sup>a</sup>	0.35 (0.76)	0.59 (0.83)	0.24 $\pm$ 0.13	0.08
"I believe placement of acupuncture needles is painful." <sup>a</sup>	-0.43 (0.95)	-0.9 (0.76)	0.5 $\pm$ 0.14	0.001
"I am concerned that acupuncture needles can cause infection." <sup>a</sup>	-0.37 (0.97)	-0.84 (0.83)	0.47 $\pm$ 0.15	0.003

Note: Pre- and Post- Survey 2 responses were obtained from neonatologists and neonatology fellows ( $n=24$ ), nurse practitioners ( $n=16$ ), and neonatal intensive care unit nurses ( $n=100$ ).

<sup>a</sup>Values are expressed as mean (standard deviation) and mean difference  $\pm$  SE. Responses for these questions were on a 5-point Likert scale and included "strongly agree" (1), "agree" (2), "neutral" (3), "disagree" (4), and "strongly disagree" (5). A positive mean difference indicates a positive change in perception. A Student's  $t$ -test was used to analyze responses.

$n=70$ , 70 respondents to the survey.

AA, auricular acupuncture; NAS, neonatal abstinence syndrome; SE, standard error.

TABLE 4. URINE DRUG SCREEN RESULTS FOR MOTHERS AND INFANTS<sup>a</sup>

<i>Screens</i>	<i>Mother % (n)</i>	<i>Infant % (n)</i>
Unknown	10 (2)	N/A
Methadone		
Single substance positive	55 (11)	75 (11)
+ opiate	5 (1)	5 (1)
+ opiates + benzodiazepines	15 (3)	N/A
Opiates <sup>b</sup>		
Single substance positive	5 (1)	15 (3)
+ Amphetamines + oxycodone	5 (1)	N/A
Amphetamines + oxycodone	N/A	5 (1)
Benzodiazepines	5 (1)	N/A

<sup>a</sup>The Tampa General Hospital urine drug screen reports presence of methadone, opiates, benzodiazepines, amphetamines, oxycodone, cannabinoids, ethanol, barbiturates, cocaine, and phencyclidine. This urine drug screen distinguishes methadone from other opiates. As some mothers were polysubstance users, the percentages do not equal 100.

<sup>b</sup>A total of 2 mothers and 3 infants were positive for opiates. Of these 5 positive urine drug screens, 60% ( $n=3$ ) of the mothers were prescribed opiates by their obstetricians during labor.

N/A, not applicable.

compared to those predominantly receiving formulas.<sup>29</sup> The median weight loss in the current study group was 7.4% (−1.4,13.8%), which is slightly less than that reported for drug-exposed infants. One possible explanation for this may be that all of the study infants received some formula, with none exclusively receiving breast milk.

While median LOS was 23 days (7–69 days), 4 infants were hospitalized for more than 30 days. These atypical stays were likely secondary to both medical factors (e.g., challenging NAS symptoms resulting in difficulty weaning from methadone or polysubstance *in utero* exposure) and social issues (e.g., difficulty in determining discharge-care provider). Despite 60% of mothers being enrolled in drug-treatment facilities, only 30% of study infants were cleared for outpatient methadone management; thus, the majority of infants remained as in-patients. Social factors play a key role in determining discharge-care providers and clearance for outpatient methadone treatment. TGH social work and the Hillsborough County Child Protective Investigations Division make decisions regarding clearance for outpatient methadone treatment.

A limitation of the current study was the small sample size, restricting the ability to generalize results. Social determinants associated with drug use—such as legal, child custody, economic, or transportation issues—affected the ability to obtain informed consent. Despite this, 58% of mothers who were approached chose to allow their infants to receive AA. Unfortunately the reasons for parent refusal were not collected. The TGH NICU has developed a collaborative relationship with the chief medication-assisted treatment center involved in caring for these mothers.

Similar to the TGH infant management, mothers are primarily treated with methadone. Consequently the study population of infants may differ from populations of infants who are largely exposed to illicit drugs.

Other potential advantages at TGH are private patient rooms that may improve efficacy of nonpharmacologic therapies and availability of inpatient consultations (e.g., in social work, occupational therapy, lactation support). There was wide variation in the duration of time that infants were monitored after AA was discontinued. In future studies it may be prudent to provide a minimum observation period after AA completion. A limitation in survey analysis is that responses were anonymous; thus, while the same number of nurse practitioners, fellows, and attendings responded to the pre- and postsurvey 2, they may not have been the same individuals. Although systematic collection of narrative comments from nursing or medical providers was not done, many providers commented on the positive effects of AA, including less infant crying, easier calming of infants, and lower overall Finnegan scores.

The results of the current study have implications for the management of NAS and neonatal pain management. These results may enable researchers to evaluate efficacy better and reveal the mechanism of AA, potentially providing an alternative to pharmacologic treatment and decreasing inpatient LOS further for infants with NAS. The current authors plan to evaluate pharmacologic and AA NAS management, using a randomized controlled trial design.

## CONCLUSIONS

This pilot study demonstrated the safety, feasibility, and acceptability of using AA in an NICU for infants with NAS. AA using NADA points may provide a potentially effective nonpharmacologic adjunct to standard care. Future research is needed to evaluate the effect of AA on specific outcome measures in infants with NAS.

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## AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist for any author of this article.

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