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Assessment of the newborn prenatally exposed to drugs: The history

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ABSTRACT

This paper reviews the history of the development of scoring tools used to assess the occurrence and severity of the Neonatal Abstinence Syndrome. Beginning with the first tools published in 1975, this review describes tools published through 2010; identifies each tool's strengths and weaknesses; and discusses their representation in the literature.

1. Introduction

Documentation of the effects of prenatal drug exposure, specifically exposure to opioids such as morphine and heroin, can be found as early as the nineteenth century and included a diagnosis of congenital morphinism [1]. By the late 1950's as cases of prenatal heroin exposure became more common, the term congenital morphinism was replaced with narcotic addiction syndrome (NAS) [2]. Alcohol would normally be included in the category of drug exposure, however because it is a teratogen that causes a constellation of specific deficits, it is usually referenced independently from the category of prenatal drug exposure and is not included in this discussion. However it is interesting to note how the known effects of prenatal alcohol closely follows the same pattern of opioids, i.e. anecdotal information emerged from the English gin epidemic of 1690–1752, the first study of such effects occurred in the nineteenth century, and the identification of specific fetal alcohol effects (FAS) occurred in 1973 [3].

Although cases of NAS began to emerge in the literature in the 1950's [2,4], the number remained small, i.e. < 100. The major turning point was the emergence of a heroin epidemic in the 1960's and the concurrent initiation in 1964 of the use of methadone for the treatment heroin dependence, now defined as opioid use disorder (OUD) [5]. Relative to these events, the National Institute on Drug Abuse (NIDA) was created in 1974. At the same time physicians and scientist voiced concerns about the effects of drug use during pregnancy and Public Law 94–371 mandated the drug abuse and dependence among women be given special consideration for treatment and prevention [6,7]. As a result, some of NIDA's initial funding was to support treatment research grants for programs providing services to pregnant women with OUD. This funding led to efforts to develop NAS scoring tools to quantify the signs and symptoms of withdrawal that provides a threshold score indicating the need for treatment [8,9]. During this time frame the terminology changed from narcotic addiction syndrome to neonatal abstinence syndrome but it is unclear when and why the term was changed. Publications in 1971 still used the term neonatal narcotic addiction, whereas by 1975 use of neonatal abstinence syndrome was the norm. It should be noted that recently the FDA has used the term neonatal opioid withdrawal syndrome (NOWS) on warning labels when referring to maternal use of opioids during pregnancy. While some have recommended that NOWS be used in place of NAS, concern has been raised it is misplaced for use in a clinical setting. When NAS occurs as a result of prenatal exposure to an opioid, it occurs in a number of different contexts and the presentation and severity is related to a number of different factors in addition to the opioid(s). As such NAS is still the recommended clinical term [9].

2. Neonatal abstinence syndrome (NAS)

In 1975 Desmond and Wilson published the first definition of NAS stating, “the abstinence syndrome may be defined as a generalized disorder characterized by signs and symptoms of central nervous system excitation together with respiratory and gastrointestinal dysfunction” [10]. A contemporary publication from 2018 reflects the original definition only with more detail, i.e. “Signs of NAS can be classified in (a) neurologic manifestations due to increased excitability, including tremors, excessive and/or high pitch cry, hyperactive Moro, increased muscle tone, seizures; (b) gastrointestinal manifestations include diarrhea, vomiting, uncoordinated sucking and swallowing; and (c) autonomic manifestation include fever, sweating, nasal stuffiness and increased respiratory rate [11]. A number of studies were published in the early 1970's that reflected general agreement regarding the signs and symptoms of NAS, but there was little uniformity in how symptoms were classified and which symptoms should be used to determine therapeutic decisions [12].

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3. Initial assessment tools for NAS

The first scoring tools for the assessment of NAS were both published in 1975. Both were initiated by clinical staff in hospitals that provided methadone treatment to pregnant women with opioid use disorders and who were motivated by the need to utilize a systematic objective measure to assess the signs symptoms of NAS and to provide a guideline for treatment.

3.1. The Lipsitz score

In 1975 Lipsitz published the Narcotic Withdrawal Score that quantified clinical symptoms of the abstinence syndrome in the newborn [13]. Eleven symptoms were identified; tremors and irritability scored from 1 to 3, hyper-reflexia, increased muscle tone, explosive stools, skin abrasions and tachypnea scored from 1-2, and repetitive sneezing, yawning, vomiting, and fever scored 1. Two pediatric residents scored infants twice daily 90 min before the next feeding. For comparison, infants were grouped accordingly A) 11 term newborns with Apgar's ≥ 7, B) 10 term newborns with Apgar's < 7, C) 7 AGA low birth-weight newborns D) 5 SGA low birth-weight newborns, and E) 8 newborns prenatally exposed to opioids. All infants in groups A-D had scores of 0–4 while only some of the infants in group E had some scores ≤ 4. Thus, the author suggests that 4 is a logical cutoff point in classifying the infant as being prenatally exposed and reports the probability of a successful classification is 77%. The need for additional maternal history and neonatal blood and urine analyses is suggested for confirming a diagnosis. Based on data from 100 patients, a score of 10 is identified as the threshold for initiating treatment [14].

However, the 1975 publication provides no information on the tool's use regarding treatment initiation, dose, or weaning recommendations nor are there any subsequent publications regarding continued development of the tool. It was cited in 1998 by the AAP as having an advantage over other scoring tools due to its simple numeric system and a high sensitivity value [15]. In survey data published in 2006, only 3 of 75 respondents reported using the Lipsitz tool [16] and it is not represented in contemporary literature [17].

3.2. The Finnegan score

The Neonatal Abstinence Scoring Tool by Finnegan, Kron, Connaughton, and Emich was also published in 1975 [18]. This scoring tool was developed specifically to provide a precise method for observing and scoring the clinical manifestations of neonatal opioid withdrawal and in so doing to provide a basis for therapeutic decisions in the care of the newborn (There are three 1975 publications by Finnegan et al., that describe the scoring tool and they are often used interchangeably as references for the tool. This citation is the one that Dr. Finnegan has identified to be used as the primary reference for the tool.).

The three 1975 publications [12,18,19] are similar, with some minor variations in the information provided. The scoring tool consists of 32 scoring options for 20 items; crying, sleep, hyperactive Moro, tremors disturbed, tremors undisturbed, tremors undisturbed, increased muscle tone, generalized convulsion, frantic sucking of fists, poor feeding, vomiting, diarrhea, dehydration, frequent yawning, sneezing, nasal stuffiness, sweating, mottling, fever, tachypnea, and excoriation. These 20 items were chosen based on the authors' clinical experience and reports in the literature [18]. Possible scores were arbitrarily assigned based on clinical significance and ranged from 1 to 5. During the first 24 h the newborn is scored at birth and every hour. In the second 24 h the infant is scored every 2 h. After 48 h the infant is scored every four hours during the first 5 days of life. If therapy is initiated, the infant is scored every four hours until 2 days after drug therapy has been discontinued. Treatment is initiated when the score is 8 or greater. During the first 24 h, scores were averaged and treatment was initiated if the average was > 8. During the second day, 2 successive scores of ≥ 8 would initiate treatment.

Scoring was conducted by nurses trained in the use of the system, with 4 pairs of nurses randomly selected to independently rate the same group of infants. All infants were known to be prenatally exposed to opioids. Inter-rater reliability coefficients in the 4 pairs ranged between 0.75 and 0.96 with a mean of 0.82. The use of the score vs. clinical judgment reduced the percentage of infants who were managed with medication, the mean number of treatment days and the mean length of hospital stay [12].

In 1979 NIDA published a monograph on drug dependency in pregnancy [20]. Included in the Appendix is the scoring tool with some minor changes. It contains 31 scoring options for 21 items. Dehydration and 3 separate scores for excoriation, i.e. nose, knees and toes were eliminated. Added to the score were myoclonic jerks, and nasal flaring. Excoriation was changed to one score. Frantic sucking of fists was changed to excessive sucking. Indications for the initiation of treatment also were modified. No acknowledgement or discussion was included in the monograph or any other publication regarding why items were eliminated and/or added nor has this revised scale been analyzed relative to the original publication.

Subsequent publications of the scoring tool in pediatric textbooks in 1985, 1986, 1990, and 1992 all include the 1979 revised score and recommendations for treatment initiation [21–24]. The 1986 publication identifies the score sheet as adapted from the 1975 publication [18]. The 1980's publications all reflect a change in the scoring time frame. Scoring recommendations are for infants to be assessed initially 2 h after birth and then every 4 h. Treatment is initiated if scores are 8 or greater on 3 consecutive scorings or 12 or greater for 2 consecutive scoring or the average of 2 consecutive scorings is 12 or greater [24].

The number of publications of the tool has led to some misunderstandings and misinterpretations. The first of which is whether the scoring tool has been modified. The citation in the 1986 publication that the score sheet was adapted from the 1975 publication led many to refer to use of the "modified Finnegan tool". This interpretation was further supported by the 2006 Sakar and Donn survey [16] that included questions as to whether the respondents use the "Finnegan-original version" or the "Finnegan-modified version".

However, the author states that minor changes were made to the format but that the score has never been modified (personal communication). This is also reflected in a current publication by the author that includes a scoring form that is the same as the 1986 publication but uses the 1975 citation [25]. It is important to differentiate between "the modified Finnegan" as that does not exist and "a modified Finnegan" of which there are many local unpublished versions as well as some published versions, which will be discussed later.

The second is the actual name of the score. As described above, in the original publication(s) and all subsequent publications up to 1992, the tool was titled the Neonatal Abstinence Score and referred to as the Neonatal Abstinence Scoring tool [12,18,19,21–24]. However, as it became widely used it became commonly known as the Finnegan score. The tool is represented in the current literature as the Finnegan Neonatal Abstinence Scoring Tool (FNAST) [25], the Neonatal Abstinence Scoring system (NASS) [5], or the Finnegan Neonatal Abstinence Scoring System (FNASS) [11].

The tool is the most commonly used NAS assessment tool in the United States and throughout the world. A 2006 survey of neonatal intensive care units found that 65% of respondents used the Finnegan scoring tool [16]. A similar survey in 2009 in Britain and Ireland found 52% of neonatal units used the Finnegan scoring tool [26], despite its widespread use it has a number of limitations.

These include: 1) The number of items is lengthy, some items occur infrequently, and others are hard to rate with a degree of accuracy [5]. The authors originally recognized these problems, as they stated that they intended to conduct multifactorial analyses to identify ambiguous and redundant items [19] but this has never been addressed.

[2) While reliability > 90% can be attained, it requires extensive training, the use of operational definitions for all items, and continuous inter-rater reliability checks not common in most hospital settings [27].

3) The tool was designed for use in newborns and becomes less appropriate as the infants matures [8].

4) The tool was designed specifically to assess neonatal withdrawal from heroin and/or methadone. Data indicates that withdrawal from prenatal buprenorphine exposure differs from prenatal methadone exposure [28] and there are no data to date on if and how withdrawal may differ from prenatal exposure to other opioids such as oxycodone.
5) The validity of the differential weighting among items has not been examined and no studies have reported on the sensitivity and specificity of the NASS [5].

4. Other early assessment tools

4.1. The Ostrea tool

The Ostrea tool was used in research published by Ostrea et al. [29]. The tool scores vomiting, diarrhea, weight loss, irritability, tremors or twitching, and tachypnea and ranks the items as mild, moderate, or severe. It provides no direction for the initiation of pharmacotherapy and was basically limited to use at Ostrea's institution, Hutzell Hospital in Detroit Michigan. While included in the methods section of studies published in the 1970's, the score itself was not actually published until 1993 [30].

4.2. The neonatal narcotic withdrawal index

The Neonatal Narcotic Withdrawal Index published by Green and Suffet [31] includes 7 scoring items, i.e. crying, tremors, muscle tone, respiratory rate, temperature, vomiting and other signs (the other signs category is a potpourri of additional signs included in the NASS. A score of 2 is given if 5 or more of the signs in this category are present). Scores are equally weighted with point values between 0 and 2. A list of operational definitions for the items is included and a high level of inter-rater reliability was reported. This tool was used sparingly after publication and is not represented in the current literature [17].

4.3. Neonatal withdrawal inventory

The Neonatal Withdrawal Inventory was published in 1998 [32]. It was an attempt to address some of the limitations of the NASS, specifically the length of the assessment and the lack of empirical validation. The scoring system consists of 7 withdrawal signs, hyper-tonicity, tremor, hyperactive Moro, sweating/mottling, repeated sneezing/yawning, regurgitation and diarrhea, and a behavior distress scale based on crying and frantic sucking. Each of the signs is assigned a predetermined weight between one and four with the greatest possible score of 19. Evaluation of the score was based on comparing validity, reliability and efficiency to the NASS. The authors report high sensitivity and specificity as well as inter-rater reliability of 0.93. It is unclear why this tool received so little attention or acceptance but its use is not represented in the literature [17].

5. Modifications of the NASS

5.1. The MOTHER NAS scale

The Mother NAS Scale (MNS) is a modification of the NASS that was utilized in the Maternal Opioid Treatment Human Experimental Research (MOTHER) randomized controlled trial [27]. Nine items were eliminated from the NASS score due to an overlap with other items, i.e., projectile vomiting, watery stools, fever > 38.4 C, retractions, convulsions, excessive sucking; or because they are unresponsive to opioid treatment, i.e. myoclonic jerking, mottling, and nasal flaring (These items were retained in the score sheet for data purposes (see following paragraph) but are not scored as part of the MNS). Two items were added, irritability (to assess infants who are irritable but who do not cry) and failure to thrive (in order to assess neonates who experience excessive weight loss) [5]. Operational definitions are included for all items included in the assessment. As with the NASS, the MNS includes a protocol for initiation of pharmacotherapy but unlike the NASS, the treatment regimen is symptom based rather than weight based. The scale, including the operational definitions, is available in the Supplementary Appendix of Jones et al. [27]. The general use of the MNS is unknown but it has been used in a number of clinical trials [33].

A recent study examined the psychometric characteristics of the NASS and the MNS from the MOTHER study and found that both assessments demonstrate poor psychometric properties [34], with internal consistency failing to exceed 0.62 at first administration, peak NAS score, and NAS treatment initiation. While the authors acknowledge this study is limited by the use of secondary analysis of data that was not part of a study designed to examine psychometric properties, they report both measures assess signs that do not necessarily relate to the clinical course or severity of NAS while minimizing more relevant symptoms such as weight loss, feeding difficulty, difficulty sleeping and inability to be consoled.

The NASS and the MNS are the only two scoring tools represented in the literature that examine the developmental outcome of children prenatally exposed to opioids who require treatment for NAS compared to children prenatally exposed who do not required treatment. An early study examining the outcome of children assessed at birth with the NASS found no difference in developmental outcome as measure by the Bayley Scale of Infant Development at 6 months of age between infants who required treatment and those who did not [35]. A recent publication of data from the MOTHER study using the MNS to assess NAS found no effect of treatment for NAS severity relative to not-treated for NAS on growth, cognitive development, language abilities, sensory processing and temperament through 3 years of age [36].

5.2. Shorts forms of the NASS and MNS

Jones et al. [37] developed a brief screening tool to provide early identification of NAS. Opioid and non-opioid exposed neonates were assessed with the MNS by an examiner blinded to group allocation twice daily for the first 2 days postpartum. A 3-item index (hyperactive Moro reflex, mild tremors when undisturbed and increased muscle tone) yielded a useful discriminative index. No non-exposed infants scored on any of these items on any assessment.

A subsequent study of the MOTHER participants found a five item index proved superior to previous indices and discriminated between the treated vs. untreated NAS groups as well as the total MNS score [38].

5.3. Finnegan neonatal abstinence scale-short form

Maguire and colleagues sought to develop a shorten form of the FNAS to reduce the length of the assessment and improve inter-rater reliability [39]. They conducted a factor analysis on 33,856 NASS scores from 171 infants with a diagnosis of NAS. Less than 1% of infants had scores ≥17. The results yielded 2 factors composed of seven items that highly correlate with the 21 item NASS. The first factor, labeled mild/early signs, consists of crying, sleeping and increased muscle tone. The second factor, labeled moderate/progressing signs, consists of tremors, respiratory rate, sweating, and excessive sucking. The scores on the short form were shown to be adequate for 98% of infants within the study. The authors caution that the short form is inadequate to assess escalating withdrawal symptoms of increasing severity and that in such instances the original form of the FNAS should be used. There is no indication that the use of this shorten form has gained any widespread acceptance.

5.4. Simplified version of the Finnegan scoring system (sFNAS)

Gomez Pomar et al. [40], report on the creation of a shortened and simplified version of the FNAS. Using retrospective data from two institutions, they utilized a linear regression model on FNAS data (n = 187) from one institution to determine optimal values for each item in the sFNAS. A backward elimination approach was used to remove items that contributed the least to the correlation. The sFNAS was then cross -validated with data from the second institution (n = 182). The sFNAS items consist of 10 items; cry, tremors, increased muscle tone, sleep, nasal stuffiness, respiratory rate, excessive sucking, poor feeding, feed tolerance, and stools. The correlation between the sFNAS and the FNAS was 0.914 and 0.86 with the MOTHER NAS scale. There are a number of limitations to this study. The psychometrics properties of the FNAS were not addressed, a prospective evaluation of inter-rater reliability was not included, hospital training on reliability was only done annually, and the utility of the sFNAS in pharmacological management was not examined. The authors acknowledge that additional work is required to establish clinical utility, validity and reliability prior to any widespread use of this assessment.

6. Summary

This paper has provided a historical review of scoring tools designed to assess NAS. There are several noteworthy consistencies that emerge. First, all of the assessment tools draw from the list of items identified in the 1970's that characterize NAS and none have been revisited over the course of 50 years. All of the assessment tools draw from the same pool of items but vary in the number of items used in the tool, ranging from 6 to 20. No rationale, with the exception of the MOTHER scale, is provided for the selection of items. None of the tools have acceptable psychometric properties. The most widely used tool is viewed as the most cumbersome, the most labor intensive, and the most difficult to maintain inter-rater reliability.

A heroin crisis provided the impetus for addressing the NAS of the 1960's and 1970's. The current opioid epidemic has placed an unprecedented focus NAS. Hopefully, we can improve the assessment and treatment of NAS by developing valid and highly reliable assessment measure(s); determining if measures need to be drug specific; and systematically identifying effective non-pharmacological and pharmacological treatments.

7. Research directions

- Determine if signs and symptoms of withdrawal differ as a function of specific opioids
- Develop an easy to use highly reliable and valid measure of opioid withdrawal
- Systematically evaluate both pharmacological and non-pharmacological treatment protocols

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