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Predictors of successful natural sleep MRI for sensorineural hearing loss in infants

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ABSTRACT

Objectives: Cochlear implantation (CI) in children with sensorineural hearing loss (SNHL) before 12 months of age (mo) improves language outcomes. MRI is important to assess CI candidacy. Anesthesia before 3 years old may increase risk of neurocognitive delay. Natural sleep MRI (NS-MRI) is an emerging technique to avoid anesthesia in infants, but relies on successful sleep for adequate imaging. Our multidisciplinary team hypothesized the following predictors of successful NS-MRI for CI evaluation: age, distance travelled, comorbidities, primary language, insurance type, HL characteristics, time and duration of MRI.

Methods: We performed retrospective review of children 0–12mo who attempted NS-MRI. The NS-MRI was successful if imaging was sufficient for definitive clinical management per the managing otolaryngologist.

Results: Among 26 patients (29 scans), the median age was 3.2mo (range: 1.2–6.8mo), distance travelled was 16.3 miles (range: 0.9 to 365 miles), 12 (46%) children had medical comorbidities. 8 (31%) had public insurance. 10 (38%) had bilateral HL. 52% (15/29) of scans were successful. Patients with comorbidities had significantly lower odds of successful NS-MRI (OR 0.09; 95% CI 0.01–0.54). Success was not associated with age, distance travelled, insurance type, primary language, HL characteristics, time or duration of MRI on univariable analysis. All 11 children who failed NS-MRI underwent hearing-aid fitting and/or imaging with sedation and CI as clinically indicated before 12mo.

Conclusion: NS-MRI was successful in 52% of infants, regardless of age, demographics, HL or MRI characteristics. Unsuccessful NS-MRI did not result in delayed intervention. NS-MRI is an effective consideration for a broad range of infants with SNHL.

1. Introduction

Hearing loss (HL) is the most common congenital sensory impairment. The average incidence of neonatal HL is about 0.1% [1]. For children with severe to profound HL, cochlear implantation (CI) can provide access to sound, which is necessary to support spoken language development. Current FDA guidelines allows implantation for as young as 9 months of age [2]. Speech and language outcomes in children undergoing CI are better with younger age of implantation down to 6 months of age [3–7].

MRI of the internal auditory canals (IAC) is an important component of CI candidacy workup as it can evaluate for the presence and size of the cochlear nerves. Traditionally, such workup in infants has required general anesthesia to prevent patient motion to obtain adequate resolution of the 7th and 8th cranial nerve complex within the IAC. However, recent studies have shown that even a single exposure to anesthesia before 3 years of age increases the risk of neurocognitive delay and that multiple exposures increases the risk of developing certain

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neurocognitive disorders, such as attention-deficit hyperactivity disorder [8–10]. As such, alternative methods are being developed to avoid anesthesia in infants while obtaining adequate MRI imaging [11,12]. One emerging technique is natural sleep MRI (NS-MRI), which avoids anesthesia in infants, but relies on successful sleep for adequate imaging [13,14].

In this pilot study, we determined the diagnostic success rate of NS-MRIs at our institution and evaluated factors hypothesized to be associated with successful NS-MRI. Our multidisciplinary team of pediatric otolaryngologists, neuroradiologists, audiologists, child life specialists, and radiology nurses, considered the following predictors of success: age, distance travelled, comorbidities, health literacy (using primary language and insurance type as proxies), laterality and severity of HL, time of day of NS-MRI, and duration of MRI. We also sought to understand whether patients who failed NS-MRI went on to experience subsequent delays in care.

2. Material and methods

2.1. Study population

We performed a retrospective review of a convenience sample of children 0–12 months of age who attempted NS-MRI at one tertiary children's hospital system from January 1, 2015 to March 1, 2022. Patients were included if an NS-MRI was attempted at the University of California, San Francisco (UCSF)-Benioff Children's Hospital. This study was approved by the Institutional Review Board at UCSF. For this exploratory pilot study, we sought to evaluate a broad array of possible factors that could be associated with differences in NS-MRI success. These factors were identified through discussion with our multidisciplinary clinical team, which included pediatric radiologists, child-life specialists, radiology technicians, pediatric otolaryngologists, and audiologists.

2.2. Sociodemographic variables

Patient gender, ethnicity, race, home ZIP code, and insurance type were extracted from the electronic medical record and were based on parent self-report. Patients were classified as an under-represented minority (URM) based on the National Institutes of Health's working definition of underrepresented minorities [15]; i.e. those who self-report as Black, Hispanic, Native American/Alaskan Native, Native Hawaiian/Other Pacific Islander, or two or more races when one or more are from the forementioned categories, were defined as URM. These sociodemographic factors were evaluated as proxies for health literacy and access to care, which may impact comprehension and adherence to instructions given in preparation of NS-MRI [16,17].

2.3. Audiologic and medical variables

The presence of comorbidities was determined by manual review of otolaryngology notes. HL type, laterality, and severity were determined by audiology notes. HL severity was based on pure tone averages of the first available diagnostic audiogram or auditory brainstem response recording (ABR). Pure tone averages were calculated as an average of audiometric or estimated hearing thresholds (dB HL or eHL) at 500Hz, 1000Hz, 2000Hz, and 4000Hz; speech detection or reception thresholds (SDR/SRT) were used if these data were not available; sound fields were used if neither were available.

2.4. Imaging variables

Date of NS-MRI, start time, end time, duration of imaging, location of imaging (either one of two hospitals), whether MRI was solely of the IACs or combined with other additional imaging, if the MRI was terminated early and why, and whether the interpreting neuroradiologist recommended repeating the scan, were collected from radiology reports of the NS-MRI. Distance travelled for imaging was calculated by inputting the location of imaging and patient's self-reported home ZIP code into Google Maps.

2.5. NS-MRI protocol and determination of success

A few days before the NS-MRI, families receive a telephone call and are given instructions on how to prepare their child for NS-MRI. Caregivers are asked to keep the infant awake and to avoid feeding them for several hours prior to the appointment to increase the chance that the infant will fall asleep during the NS-MRI. Additional instructions may be given to help prepare the infant for the NS-MRI based on the infant's sleep environment and sleep patterns. For example, playing videos with NS-MRI sounds while the infant is falling asleep a few days prior to the visit may be recommended for the family, to help the infant acclimate to the sounds in the MRI suite.

Once the caregivers and infant arrive for their NS-MRI appointment, they are brought into a quiet room, where the caregivers can then feed and swaddle their child. After the infant falls asleep, they are brought into the scanner suite. Lights are dimmed if able. Soft earplugs and/or external ear muffs may be used to minimize noise. The infant is then secured to the MRI table and the NS-MRI scan begins. Imaging of the IAC through the cerebellopontine angle is performed on a 3-T scanner using a standardized protocol: axial and bilateral oblique sagittal three-dimensional balanced steady-state free precession, axial non-echo planar imaging-diffusion weighted imaging, three-dimensional T1-

Table 1
Pediatric NS-MRI sequences used to image the internal auditory canal.

Sequence	Field of View	Slice thickness	Notes
Axial 3D b-SSFP (FIESTA on GE, CISS on Siemens, balanced TFE on Philips)	IAC through the cerebellopontine angle	0.6 mm for <12 year old 1 mm for >12 year old	
Oblique sagittal 3D b-SSFP	IAC through the cerebellopontine angle	0.6 mm for <12 year old 1 mm for >12 year old	Separate bilateral acquisitions angled perpendicular to the long axis of the IACs
Axial non-EPI DWI b800	IAC through the cerebellopontine angle	3mm/skip 0 mm	Generate ADC map
Sag 3D T1	IAC through the cerebellopontine angle	1mm/skip 0 mm	Reformat into 3 planes
Axial T2 SE	IAC through the cerebellopontine angle	2mm/skip 0 mm	
Optional: post-contrast 3D T1 FS	IAC through the cerebellopontine angle	1mm/skip 0 mm	Perform if concern for infection or inflammation. Contrast not needed for structural evaluation. Reformat into 3 planes.

3D = three dimensional.
b-SSFP = balanced Steady State Free Procession.
FIESTA = Fast Imaging Employed Steady-state Acquisition.
CISS = Constructive Interference in Steady-State.
bFFP = balanced Turbo Field-Echo.
IAC = internal auditory canal.
EPI = echo planar imaging.
DWI = Diffusion Weighted Imaging.
ADC = Apparent Diffusion Coefficient.
SE = spin echo.
FS = fat saturated.

weighted, and two-dimensional axial T2-weighted spin-echo sequences (Table 1). The study is stopped if the baby wakes up during imaging. Caregivers can help the baby fall back asleep, in which case the NS-MRI scan resumes.

Success of NS-MRI was determined upon manual review of radiology and otolaryngology notes. The NS-MRI was successful if it was sufficient for definitive clinical management by the managing otolaryngologist, without further need for repeat imaging under general anesthesia (Fig. 1).

2.6. Delays in care

Delays in care were determined if the children did not meet the Joint Committee on Infant Hearing 1-3-6 guideline for intervention at 6 mo for hearing aids [18] and/or did not meet FDA guidelines for cochlear implantation at 24 mo or older for severe to profound HL and 12 mo or older for profound HL [2]. Though the FDA approval age for cochlear implantation was lowered to 9 months in 2020, the 12-month threshold was maintained across the full study cohort for consistency.

2.7. Statistical analysis

Descriptive statistics were used to describe the cohort: frequencies and percentages were used for categorical variables; medians and ranges were used for continuous variables, as the variables did not follow a normal distribution. Variables were compared with odds ratios using logistic regression. Power of 0.8 and significance level alpha = 0.05 was used to calculate the minimum number of subjects needed for adequate study power [19].

3. Results

26 children met the inclusion criteria, completing 29 NS-MRIs between them. Among the 29 scans, 15 (52%) scans were successful and 14 (48%) were not. At the individual child level, NS-MRI was ultimately successful in determining the next step in clinical management for 15/26 (58%) children, and not successful for 11/26 (42%) children. The median age at testing was 3.2 months of age (range: 1.2–6.8 months of age). This cohort included 13 (50%) females, 7 (27%) URM, 5 (19%) whose parents did not speak English as their primary language, and 8 (31%) with public insurance. The median distance from the imaging center was 16.3 miles (range 0.9–365 miles). Ten (38%) had bilateral hearing loss, 20 (77%) were diagnosed with SNHL, and 6 (23%) were diagnosed with auditory neuropathy spectrum disorder. See Table 2 for more details on demographics and Table 3 for list of patient information.

Though some factors showed odds ratios associated with increased or decreased odds of successful NS-MRI, only the presence of comorbidities was significantly associated with decreased odds of successful NS-MRI on univariable analysis (OR 0.09; 95% CI 0.01–0.54). All of the other hypothesized predictors of success were not significantly associated with success on univariable analysis: age at testing, gender, URM status,

Table 2
Demographics.

Demographics	Study cohort, n = 26
Age at NS-MRI, median (range), months	3.2 (1.2–6.8)
Female, n (%)	13 (50)
Under-represented minority, n (%)	7 (27)
Primary language is not English, n (%)	5 (19)
Public insurance, n (%)	8 (31)
Presence of other medical comorbidities, n (%)	10 (38)
Distance from imaging, median (range), miles	16.3 (0.9–365)
Audiologic Data	
Age at diagnostic testing, median (range), months	2.4 (0.7–7)
Bilateral HL, n (%)	10 (38)
Type of HL	
- Sensorineural, n (%)	20 (77)
- Auditory Neuropathy Spectrum Disorder, n (%)	6 (23)
Severity of HL	
- PTA better ear, median (range), dB	20 (0–104)
- PTA worse ear, median (range), dB	80 (40–109)

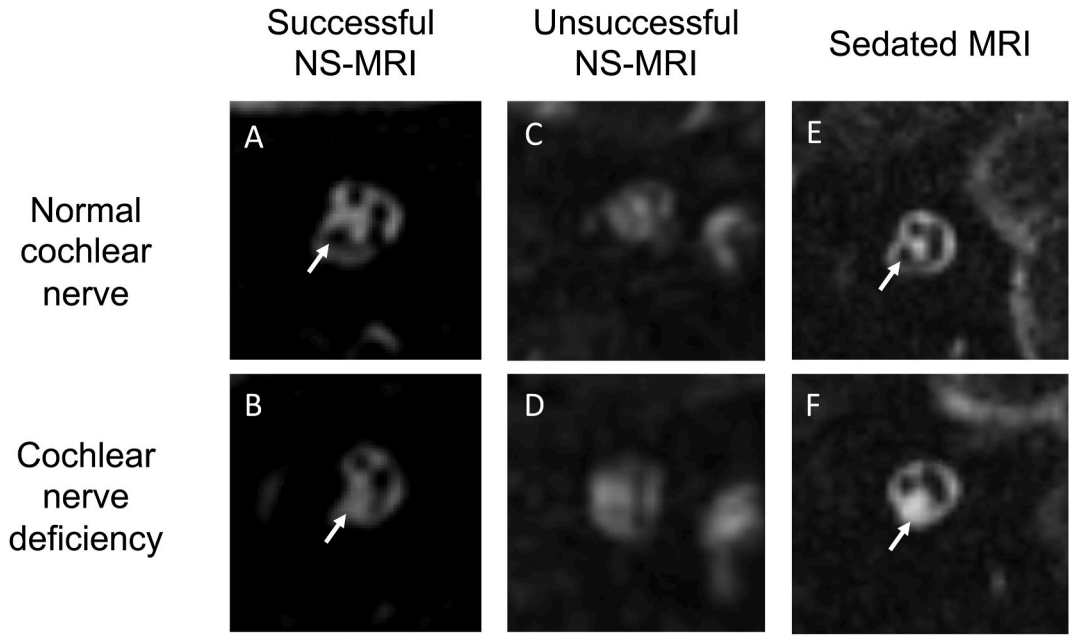

Fig. 1. T2-weighted MR images in the sagittal plane of the IAC, with both NS-MRI and sedated MRI techniques, across 4 patients. **A)** Successful NS-MRI showing normal cochlear nerve (arrow). **B)** Successful NS-MRI showing cochlear nerve deficiency (arrow). **C)** Unsuccessful NS-MRI with patient ultimately found to have a normal cochlear nerve. Patient subsequently received a diagnostic sedated MRI (shown in panel E). **D)** Unsuccessful NS-MRI with patient ultimately found to have a cochlear nerve deficiency. Patient subsequently received a sedated MRI (shown in panel F). **E)** Successful sedated MRI showing normal cochlear nerve (arrow). This patient received sedated MRI due to unsuccessful NS-MRI (shown in panel C). **F)** Successful sedated MRI showing cochlear nerve deficiency. This patient received sedated MRI due to unsuccessful NS-MRI (shown in panel D).

Table 3
Description of patients in study cohort.

	Age at each NS-MRI (mo)[a]	Gender	Race/ Ethnicity	Primary language	Insurance type	Comorbidities	Distance from imaging (miles)	Hearing loss characteristics	PTA Right Ear (dB)	PTA Left Ear (dB)	Number of NS-MRIs attempted	Final NS-MRI was successful?	R Cochlear Nerve Status	L Cochlear Nerve Status	Delayed care if unsuccessful NS-MRI?
1	5.6	F	Non-Hispanic Asian	English	Private	None	16.3	Unilateral SNHL	82.5	15	1	Yes	Deficiency	Normal	
2	3.4	M	Non-Hispanic Asian	English	Private	Pinna abnormalities, infantile hemangioma, small head size	16.3	Unilateral SNHL	55	0	1	No	Unable to determine	Unable to determine	No, unilateral HL not an indication for CI. Hearing aids at 4mo
3	5.9	F	Non-Hispanic Other	English	Private	None	45	Unilateral SNHL	57.5	10	1	No	Unable to determine	Unable to determine	No, unilateral HL not an indication for CI. Hearing aids at 6mo
4	2.7	M	Non-Hispanic Asian, American-Indian	English	Public	None	10.3	Unilateral SNHL	83.75	8.75	1	No	Unable to determine	Unable to determine	No, unilateral HL not an indication for CI. Hearing aids at 6mo
5	2.4	M	Non-Hispanic White	English	Public	Hypotonia, delayed visual maturation	364	Bilateral symmetric SNHL	71.25	61.25	1	Yes	Nerve present. Dysplastic cochlea	Nerve present. Dysplastic cochlea	
6	6.1	F	Hispanic White	English	Public	Growth hormone deficiency, hypotonia, delayed milestones, ectopic posterior pituitary	365	Bilateral symmetric SNHL	53.75	53.75	1	Yes	Nerve present. Dysplastic cochlea	Nerve present. Dysplastic cochlea	
7	1.8, 2.0	M	Non-Hispanic Asian	English	Private	None	0.9	Unilateral ANSD	8.75	83.33	2	Yes	Present	Deficiency	
8	1.8	M	Non-Hispanic Asian	English	Private	None	6.1	Unilateral ANSD	90	12.5	1	Yes	Deficiency	Normal	
9	3.4	F	Non-Hispanic Asian, White	Spanish	Private	Pendred	5.8	Bilateral symmetric SNHL	45	55	1	No	Unable to determine	Unable to determine	No, known Pendred syndrome and progressive HL with confirmatory diagnostic CT at 6mo
10	1.2	F	Non-Hispanic Asian	English	Private	None	16.3	Bilateral symmetric ANSD	80	80	1	Yes	Normal	Normal	
11	3.2, 3.5	M	Non-Hispanic Asian	English	Private	None	6.1	Unilateral SNHL	6.25	70	2	Yes	Normal	Deficiency	
12	2.7	F	Non-Hispanic Asian	Mandarin	Public	None	9.4	Unilateral SNHL	80	15	1	Yes	Deficiency	Normal	
13	3.3	M	Non-Hispanic White	English	Private	None	4.3	Bilateral symmetric SNHL	52.5	50	1	Yes	Normal	Normal	

(*continued on next page*)

Table 3 (*continued*)

	Age at each NS-MRI (mo)[a]	Gender	Race/ Ethnicity	Primary language	Insurance type	Comorbidities	Distance from imaging (miles)	Hearing loss characteristics	PTA Right Ear (dB)	PTA Left Ear (dB)	Number of NS-MRIs attempted	Final NS-MRI was successful?	R Cochlear Nerve Status	L Cochlear Nerve Status	Delayed care if unsuccessful NS-MRI?
14	2.3	F	Non-Hispanic White	English	Private	Infantile hemangioma[b]	4.7	Unilateral SNHL	6.25	80	1	Yes	Normal	Deficiency	
15	6.8	M	Non-Hispanic White	English	Private	None	61.1	Unilateral ANSD	15	95	1	No	Normal	Deficiency	No, unilateral HL not an indication for CI. Diagnostic sedated MRI at 8mo
16	1.3	M	Non-Hispanic Asian, White	English	Private	CHARGE syndrome, Choanal atresia, OSA, congenital cardiovascular differences, rectal prolapse, adrenal insufficiency	53.3	Bilateral symmetric SNHL	90	90	1	No	Deficiency	Normal	No, diagnostic sedated MRI at 3mo
17	3.1	F	Non-Hispanic White	English	Private	None	18.1	Unilateral ANSD	20	65	1	Yes	Normal	Normal	
18	2.6	F	Non-Hispanic White	Spanish	Private	Usher syndrome, infantile hemangioma	95.2	Bilateral symmetric SNHL	78.75	81.25	1	No	Normal	Normal	No, bilateral CI at 8mo
19	4.0, 5.0	M	Non-Hispanic Asian, White	English	Private	Pendred syndrome	31.5	Bilateral symmetric SNHL	40	36.25	2	No	Normal	Normal	No, known Pendred syndrome with confirmatory diagnostic sedated MRI at 11mo
20	5.5	M	Non-Hispanic White	English	Public	L pre-auricular tag, frontal bossing, torticollis	291	Unilateral ANSD	12	90	1	No	Unable to determine	Unable to determine	No, unilateral HL not an indication for CI.
21	5.4	F	Hispanic Other	English	Public	None	10.1	Unilateral SNHL	86.66	20	1	Yes	Deficiency	Normal	
22	4.1	F	Hispanic Other	Spanish	Public	None	62.6	Bilateral symmetric SNHL	108.75	103.75	1	Yes	Normal	Normal	
23	1.8	M	Non-Hispanic Asian	English	Private	Bilateral thumb hypoplasia[b]	2.7	Unilateral ANSD	10	90	1	Yes	Normal	Deficiency	
24	2.4	F	Non-Hispanic White	English	Private	Congenital cardiovascular differences	18.1	Unilateral SNHL	56.25	8.75	1	No	Unable to determine	Unable to determine	No, unilateral HL not an indication for CI.
25	3.2	M	Non-Hispanic Other	English	Private	None	27.8	Bilateral symmetric SNHL	95	95	1	Yes	Normal	Normal	
26	3.3	F	Hispanic Other	Cantonese	Public	Chronic cough, hypotonia, gross motor delay	11.8	Unilateral SNHL	20	93.33	1	No	Normal	Deficiency	No, unilateral HL not an indication for CI. Diagnostic sedated MRI at 4mo

ANSD: auditory neural spectrum disorder. CI: cochlear implantation. F: female. HL: hearing loss. L: left. M: male. Mo: months old. NS-MRI: non-sedated MRI. OSA: obstructive sleep apnea. R: right. SNHL: sensorineural hearing loss.

[a] May have more than one age listed if patient underwent NS-MRI more than one time.

insurance type, primary language, comorbidities, laterality of HL, type of HL, severity of HL, distance travelled, time at start of MRI, or duration of MRI (Table 4). A power analysis revealed that 76 patients were needed to find with 80% certainty a difference of 30% or more in patients who had a successful NS-MRI (compared to failed NS-MRI). For our sample size of 29 scans, we have 80% power to detect a difference of 45% or more. For each factor, we provided an estimate of the sample size that would be needed to be adequately powered to confirm the preliminary odds ratios found in this pilot study.

For the 11 children that did not have a successful scan, we determined that all of them underwent hearing-aid fitting and/or imaging under general anesthesia and subsequent cochlear implantation as clinically indicated prior to 12 months of age: 7 children had unilateral hearing loss, which is not an FDA-approved indication for CI in this age group, 2 had syndromic sensorineural HL, 1 with diagnostic sedated MRI

Table 4
Predictors of successful NS-MRI.

	Success	Failed	Odds ratio	95% Confidence interval	Sample size
N, (%)	15 (52)	14 (48)			
Demographics					
Age at NS-MRI, median (range), months	3.1 (1.2–6.1)	3.3 (1.2–6.8)	0.84	0.52–1.37	466
Female, n (%)	8 (53)	5 (36)	2.05	0.46–9.13	290
Under-represented minority, n (%)	4 (27)	2 (14)	2.18	0.33–14.36	330
Primary language is not English, n (%)	2 (13)	3 (21)	1.77	0.25–12.60	740
Public insurance, n (%)	5 (33)	3 (21)	1.83	0.34–9.72	462
Presence of other medical comorbidities, n (%)	2 (13)	9 (64)	0.09	0.01–0.54	
Audiologic Data					
Bilateral HL, n (%)	6 (40)	6 (43)	0.89	0.20–3.90	458
Type of HL - Sensorineural, n (%)	10 (66)	12 (86)	0.33	0.05–2.10	162
- Neural, n (%)	5 (33)	2 (14)	1.17	0.48–18.93	176
Severity of HL - PTA better ear, median (range), dB	20 (7–104)	14 (0–90)	1.01	0.99–1.04	350
- PTA worse ear, median (range), dB	80 (53–109)	76 (40–95)	1.03	0.98–1.08	100
Day of Imaging Logistics					
Travelled more than 16.3 miles^, n (%)	5 (33)	8 (57)	0.38	0.08–1.69	150
Start time, mode	Between 15:00 to 17:59	Between 6:00 to 8:59	1.24	0.76–2.05	N/A
Duration of MRI, median (range), min	76 (26–195)	80 (24–250)	0.99	0.98–1.01	208
Only IAC sequences used, n (%)	13 (87)	11 (79)	1.77	0.25–12.60	740

^16.3 miles was the median distance travelled for all patients. "Sample size" indicates the number of scans that would be needed to adequately power a study to evaluate that factor.

[b] Two children with minor, isolated congenital comorbidities (infantile hemangioma and bilateral thumb hypoplasia) were analyzed as part of the "no comorbidity" group.

at 3 months of age, and 1 with cochlear implantation before 12 months of age.

4. Discussion

In summary, we performed a retrospective pilot study to analyze factors predictive of successful NS-MRI in a convenience sample of infants undergoing workup for CI candidacy. Our results showed that NS-MRI was successful in 58% of infants in our cohort, who were imaged between 1 and 7 months of age; infants with comorbidities had significantly lower odds of successful NS-MRI. Unsuccessful NS-MRI did not result in delays in intervention. To our knowledge, this is the first study to investigate how sociodemographic, audiologic, and day of testing logistics may influence the success of NS-MRI and ultimately, intervention with hearing devices.

This experience demonstrates that NS-MRI was an effective tool for a broad range of infants with SNHL, including those who are considering CI. This included infants up to 7 months of age, some with unilateral SNHL, and others who lived far from our facility and had limited health literacy. To date, we found two studies that have quantified the diagnostic success rate of NS-MRIs: 61% of 28 NS-MRI scans were diagnostic in children with SNHL in Boston, Massachusetts [14]; 86.8% of 53 NS-MRI scans of the temporal bone and brain were diagnostic in children with SNHL in Perth, Australia [20]. While there has been an accumulation of institutional experience and anecdotes on sociodemographic, audiologic, and imaging characteristics that will make an NS-MRI successful, there have been few studies investigating and quantifying these factors [11,21].

MRIs are one of the most common neonatal imaging modalities and sometimes require sedation or anesthesia due to the longer durations of the studies [22]. Risks of sedation or anesthesia for newborns include developing neurocognitive delays as well as cardiac and respiratory complications [22]. In 2016, the U.S. Food and Drug Administration (FDA) discouraged the use of some anesthetic and sedation agents in children younger than 3 years of age due to concerns for neurotoxicity [23,24]. However, reactions from medical societies been mixed due to limited data in children (the studies are largely animal models) [25]. Regardless, NS-MRI is a promising emerging technique that can not only avoid these risks, but also decrease costs by avoiding risk of neurocognitive delay, decreasing length of MRI appointments, lowering costs, and increasing ease of preparation [11]. These benefits are directly due to avoiding anesthesia. These results suggest that NS-MRI may also be an effective alternative to MRI under general anesthesia for other conditions where such imaging is necessary for infants. One potential drawback, however, to attempting NS-MRI is that with any failed attempt requiring rescheduling for a definitive sedated study can impose additional costs on the medical system and impact access. We did not quantify this impact in this study, and the actual impact would likely be highly site-specific.

Ultimately, our power calculations showed that our study is largely underpowered to detect small associations with clinical and demographic factors associated with success, should they exist. Nonetheless, our preliminary statistical analysis provides some insight into the relationships between sociodemographic variables and successful NS-MRI. From our clinical experience, those who have more difficulty hearing the white noise from the MRI scanner, spend less time in the scanner, and have scans later in the day, have a greater chance at success, which is correlated with our preliminary findings. We hope that reporting the minimum number subjects needed to have statistically significant findings facilitates future studies to plan and analyze these variables effectively.

While our study did not show an association between success and factors such as distance travelled, we recognize that this decision is ultimately shared with the caregivers and that some families may prefer undergoing MRI under general anesthesia due to personal and/or medical preferences, such as decreasing time off work.

This study has limitations. As a retrospective study, there were many variables that could predict success that were not recorded in the electronic medical record. For instance, during the triage phone call, Child Life Specialists assess the baby's sleeping environment and characteristics (eg co-sleeping, deep sleeper, sleeps during the day, etc), and whether the child has been sleeping with white noise that sounds similar to an MRI scanner. Additional factors in the hospital that may affect success include the strength of the MRI, experience of the radiology technologist and radiologist with NS-MRI, otolaryngologist clinical decision-making using MRI results, and types and number of ear plugs used. We were also not able to determine what happened during the scans for the patients that failed. To better understand factors that contributed to a successful NS-MRI, we included any repeated scans that a patient completed. Due to the small cohort, the study was largely underpowered to evaluate for statistically significant associations between successful MRI and the variables that we examined. The one factor that we did find to be highly significantly associated with failure was the presence of medical comorbidities; however, the comorbidities present were highly heterogeneous, so we are not able to identify what specific comorbidities would be more likely to be impactful.

This study may have limited generalizability to hospitals without access to Child Life Specialists. At our institution, there is a dedicated Scan Without Anesthesia Program (SWAP) team led by radiologists and Child Life Specialists. The radiologists have tailored the SWAP imaging protocols to make these as targeted and short as possible, prioritizing the most relevant sequences first. The Child Life Specialists prepare the family extensively before and during the visit to set expectations and create a sense of ease. This team conducts a phone call before the visit to assess and advance readiness and develops individualized coping plans. During imaging, they are present with the patient and their families to help encourage the infant to fall asleep, such as providing ear plugs and showing caregivers different ways to swaddle the infant. After the infant is asleep, they are taken to the MRI suite and placed on the exam table for the MRI scan. The radiologists perform real-time scan checks as necessary to facilitate faster, more targeted imaging. The success of NS-MRI may be directly attributable to the efforts of this multidisciplinary team, and these factors may be further studied in the future to enable broader generalization of the critical components of successful programs.

5. Conclusion

NS-MRI is an effective consideration for evaluation of inner-ear anatomy for a broad range of infants with SNHL, including those who are considering CI. More research is warranted to determine and optimize sociodemographic and day-of-testing logistical factors that may facilitate the successful NS-MRI in infants.

Authorship

ENL designed the study, collected the data, analyzed the data, wrote the paper. YL designed the study, created Table 1, and reviewed the paper. AF, LL, JC, MH, KL, LM, GSN, JV, JW, TT helped design the study and reviewed the manuscript. NIM, ET collected the data. DKC designed the study and provided final review of the manuscript.

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References

[1] S. Mehra, R.D. Eavey, D.G. Keamy Jr., The epidemiology of hearing impairment in the United States: newborns, children, and adolescents, Otolaryngol. Head Neck Surg. 140 (4) (2009 Apr) 461–472, https://doi.org/10.1016/j.otohns.2008.12.022. PMID:19328331.

[2] https://www.asha.org/policy/tr2004-00041/.

[3] T.Y. Ching, H. Dillon, L. Button, et al., Age at intervention for permanent hearing loss and 5-year language outcomes, Pediatrics 140 (2017) 4274.
[4] S.J. Dettman, R.C. Dowell, D. Choo, et al., Long-term communication outcomes for children receiving cochlear implants younger than 12 Months: a multicenter study, Otol. Neurotol. 37 (2) (2016) e82, https://doi.org/10.1097/MAO.0000000000000915.
[5] R.F. Holt, K.I. Kirk, Speech and language development in cognitively delayed children with cochlear implants, Ear Hear. 26 (2) (2005) 132–148.
[6] J.G. Nicholas, A.E. Geers, Will they catch up? The role of age at cochlear implantation in the spoken language development of children with severe to profound hearing loss, J. Speech Lang. Hear. Res. 50 (4) (2007) 1048–1062, https://doi.org/10.1044/1092-4388(2007/073.
[7] J.K. Niparko, E.A. Tobey, D.J. Thal, et al., Spoken Language development in children following cochlear implantation, JAMA 303 (15) (2010) 1498–1506, https://doi.org/10.1001/jama.2010.451.
[8] J. Sprung, R.P. Flick, S.K. Katusic, et al., Attention-deficit/hyperactivity disorder after early exposure to procedures requiring general anesthesia, Mayo Clin. Proc. 87 (2) (2012) 120–129, https://doi.org/10.1016/j.mayocp.2011.11.008.
[9] R.P. Flick, S.K. Katusic, R.C. Colligan, et al., Cognitive and behavioral outcomes after early exposure to anesthesia and surgery [published correction appears in Pediatrics, Pediatrics 128 (5) (2011) e1053–e1061, https://doi.org/10.1542/peds.2011-0351, 2012 Mar;129(3):595.
[10] C. Ing, C. DiMaggio, A. Whitehouse, et al., Long-term differences in language and cognitive function after childhood exposure to anesthesia, Pediatrics 130 (3) (2012) e476–e485, https://doi.org/10.1542/peds.2011-3822.
[11] S.G. Harrington, C. Jaimes, K.M. Weagle, M.C. Greer, M.S. Gee, Strategies to perform magnetic resonance imaging in infants and young children without sedation [published online ahead of print, 2021 Apr 8], Pediatr. Radiol. (2021) 1–8, https://doi.org/10.1007/s00247-021-05062-3.
[12] G. Licameli, M.A. Kenna, Is computed tomography (CT) or magnetic resonance imaging (MRI) more useful in the evaluation of pediatric sensorineural hearing loss, Laryngoscope 120 (2010) 2358–2359.
[13] C. Jaimes, C.D. Robson, F. Machado-Rivas, et al., Success of nonsedated neuroradiologic MRI in children 1-7 Years old, AJR Am. J. Roentgenol. 216 (5) (2021) 1370–1377, https://doi.org/10.2214/AJR.20.23654.
[14] E. Ronner, R. Reid, R.A. Basonbul, et al., Outcomes with non-sedated MRI for infants with sensorineural hearing loss, Int. J. Pediatr. Otorhinolaryngol. 127 (2019), 109662, https://doi.org/10.1016/j.ijporl.2019.109662.
[15] Populations underrepresented in the extramural scientific workforce | SWD at NIH. Accessed February 9, 2022. https://diversity.nih.gov/about-us/population-underrepresented.
[16] S.P. Verney, L.E. Gibbons, N.O. Dmitrieva, et al., Health literacy, sociodemographic factors, and cognitive training in the active study of older adults, Int. J. Geriatr. Psychiatr. 34 (4) (2019) 563–570, https://doi.org/10.1002/gps.5051.
[17] V.G. Villagra, B. Bhuva, E. Coman, D.O. Smith, J. Fifield, Health insurance literacy: disparities by race, ethnicity, and language preference, Am. J. Manag. Care 25 (3) (2019) e71–e75.
[18] American Academy of Pediatrics, Joint Committee on Infant Hearing, Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs, Pediatrics 120 (4) (2007) 898–921, https://doi.org/10.1542/peds.2007-2333.
[19] S.P. Kane, Sample size calculator, ClinCalc (2019). Updated July 24, https://clincalc.com/stats/samplesize.aspx. (Accessed 7 April 2022).
[20] W. Weng, A. Reid, A. Thompson, J. Kuthubutheen, Evaluating the success of a newly introduced Feed and Wrap protocol in magnetic resonance imaging scanning of the temporal bone for the evaluation of congenital sensorineural hearing loss, Int. J. Pediatr. Otorhinolaryngol. 132 (2020), 109910, https://doi.org/10.1016/j.ijporl.2020.109910.
[21] B. Walker, H.M. Conklin, D.L. Anghelescu, et al., Parent perspectives and preferences for strategies regarding nonsedated MRI scans in a pediatric oncology population, Support. Care Cancer 26 (6) (2018) 1815–1824, https://doi.org/10.1007/s00520-017-4009-9.
[22] R.B. Parad, Non-sedation of the neonate for radiologic procedures, Pediatr. Radiol. 48 (4) (2018) 524–530, https://doi.org/10.1007/s00247-017-4002-y.
[23] Commissioner O of the, FDA Statement from Dr. Janet Woodcock, director of FDA's Center for Drug Evaluation and Research, on new safety information on anesthesia use in young children and pregnant women. FDA, Published March 24, https://www.fda.gov/news-events/press-announcements/fda-statement-dr-janet-woodcock-director-fdas-center-drug-evaluation-and-research-new-safety, 2020. (Accessed 24 October 2022).
[24] D.E. Research C for, FDA Drug Safety Communication: FDA review results in new warnings about using general anesthetics and sedation drugs in young children and pregnant women, FDA (2019). Published online June 18, https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-review-results-new-warnings-about-using-general-anesthetics-and. (Accessed 24 October 2022).
[25] E. Raeford, M.D. Brown Jr., M.D. Rita Agarwal, AAP responds to FDA warning on anesthesia use in children, Published online January 10, https://publications.aap.org/aapnews/news/7049/AAP-responds-to-FDA-warning-on-anesthesia-use-in, 2017. (Accessed 24 October 2022).