Outcomes from Novel Hearing Protective Device for Neonates Exposed to Noise during Critical Care Transportation

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Introduction

In normal circumstances, while in utero, fetuses are protected from exposure to high-frequency sounds but experience low frequency sounds that are important for neurosensory development.[1-2] Prematurely born neonates have immature neurosensory development. Excessive auditory stimulation caused by exposure to noise outside the womb may have negative consequences for premature infants, including increased stress, unstable physiologic responses, and may influence auditory and neurological development.[3-4]

The National Vital Statistics report in 2021 indicated that nearly 400,000 newborns in the United States were born prematurely prior to the expected due date—before the 37th week of gestation.[5] Most of those premature neonates are admitted to Neonatal Intensive Care Units (NICUs), with 20% requiring emergency transport via ground or air ambulance to receive specialty care. External noises created by emergency transport vehicles, such as helicopters, airplanes, or ground ambulances are generally loud and noxious and could elicit stress responses in these neonates.[6-7] A study by Karlsson, et al, linked air and ground transport to increases in heart rate that may be attributed to an increase in stress. Their recommendation was to reduce exposure to noise during transport of neonates.[8]

As part of a program to reduce noise exposure during neonatal transport, sounds levels inside transport incubators within emergency transport vehicles were evaluated at various points of travel on simulated transports by the study organization personnel along with the transport team from the NICU. A sound level meter was placed inside the vehicle and a separate sound level meter was also placed inside the transport incubator. Measurements of sound level (decibels) were obtained in the ground ambulance during idle, cruise and end idle time periods, and in the helicopter, from start-up, cruise, and final approach. These periods were deemed those with the highest degree of noise/sound. Figure 1 summarizes typical sound level meter readings recorded during the beginning, middle and end of these of these experiments.

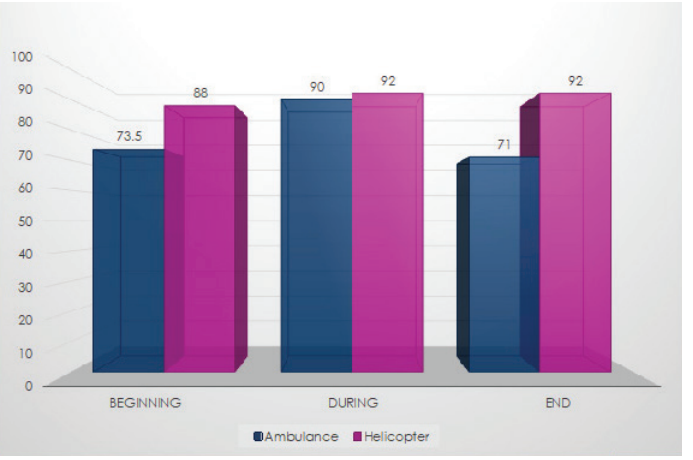

Figure 1. Typical sound level meter readings (dBA) measured in rotor wing and ground ambulance transports.

Some commercially available ear protection devices are appropriately sized for small infants or children, but they do not properly fit smaller, premature neonates. While noise levels in transport vehicles are known, the frequency composition of that noise is not generally known and is an important factor for developing proper hearing protection devices. Additionally, the actual degree of protection provided by commercially available ear protector devices in actual transportation environments has not been published. The study organization partnered with NEATCap Medical, LLC to measure both the sound levels and frequency distribution of noise experienced within transport vehicles. These measurements were a precursor to a real-world test to evaluate a novel ear covering hearing protection device designed for premature neonates exposed to those specific transport noises.

A simulated premature baby manikin fitted with one microphone at each ear location was used to record the sound level and sound frequency distribution within the transport incubator. Continuous recordings were made before, during and after completion of transport runs in both helicopter and ground ambulances. One ear was covered with a hearing protector and the other ear was uncovered, allowing for an assessment of the effectiveness of sound blocking of actual transport sounds. Figure 2 shows the manikin inside the transport incubator.

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Figure 2. Simulated patient setting for recording sounds within the incubator during transport. Manikin in photo is wearing DREAMIES T-M device.

Data obtained with the manikin verified that both air and ground transport sound environments are dominated by very low frequency sounds less than 300 Hz. Such low frequency sounds are often difficult to block.

A hearing protection device (NEATCAP DREAMIES) designed to block high-frequency alarm sounds during routine care in the NICU was studied with 50 babies (clinicaltrials.gov #NCT02744066)[9] at another hospital site with no serious adverse events after 3 days of use with perceived observations of increased patient sleep.[10] The company developed a new product with modified ear cups (DREAMIES T-M) to mitigate transport noise. With the manikin wearing these ear cups, an actual sound reduction of 18-20 dB was measured during helicopter transport at sound levels up to 90 dBA. A sound reduction of 17-18 dB was measured during ground ambulance transport at sound levels up to approximately 80 dBA. Prior to this study, this device had not been studied with actual patients during transport.

Purpose of the Study

The purpose of this study was to evaluate the performance of and outcomes of using DREAMIES T-M in a real-world setting during ground and air transport of actual neonatal patients to the organization's neonatal intensive care unit. The study was a prospective, descriptive, exploratory, and observational pilot design to evaluate the performance of the device and infant stress markers during transportation to the NICU. Inclusion criteria for the study were neonates transported ≤ 96 hours after birth without skin or head trauma during delivery with parental consent.

Methods

After obtaining parental informed consent, transport team members measured the infants' occipital frontal head circumference to determine the appropriate device size, then applied the device over the neonate's ears per the instructions for use. During transport, the transport team monitored and recorded movements and stress signals of the infant, skin condition before and after application and use of the device, maintenance of the device position, and ease-of-use by transporters.

Vital signs and NPASS (Neonatal Pain, Agitation and Sedation Scale) scores were recorded as indicators of neonatal distress. During length of time of the transport, vital signs including heart rate, respiratory rate, oxygen saturation and NPASS scores were measured every 5-30 minutes depending on the stability of the infant. NPASS is a validated tool for neonatal stress with agitation/stress scores of 0, 1 or 2 assigned in five categories (Crying/Irritability, Behavior State, Facial Expression, Extremities Tone, Vital Signs) resulting in a minimum score of 0 (appropriate, normal, relaxed) and a maximum score of 10 (significant pain/agitation).[11]

Results

The study sample included 49 infants; 57% were male. Mean gestational age was 37 ±3.43 weeks (range 23.7-42 weeks) and mean weight was 2910 ±880 grams (range 570-4810 grams). Sizes used with the device were extra small (n=2), small (n=6), medium (n=22), and large (n=18). Data for the size of one infant was missing. Skin condition was assessed before and after application and 41/49 (84%) had no issues, 8 had some redness that quickly resolved after removal (16.3%).

Device use

Transporters reported that the application process for the device was very easy (96%, n=47) or easy (4%, n=2). The device stayed in place during transport 98% of the time and one device ear cup fell off one ear, requiring adjustment. The same number of responses (98%) indicated that the device did not interfere with care, except for the one device that fell off the ear, requiring the device to be adjusted back into place.

The length of time that infants wore the device during transport ranged from 29 to 155 minutes. Thus, comparison of all vital signs (VS) was challenging. Since the number of VS taken were dictated by the length of the transport ride, the first and last VS taken were recorded and evaluated for differences to determine stress signals from VS over the transport period. Table 1 summarizes these results. There were no statistical differences between these values.

Likewise, in measuring the NPASS scores, a similar approach was taken to measure the start (First) and ending (Last) values for differences. One infant had no NPASS scores documented. To note, no infants were sedated during transport, thus sedation scores were not included. There were no statistical differences between the first and last NPASS scores. NPASS results are presented in Figure 3.

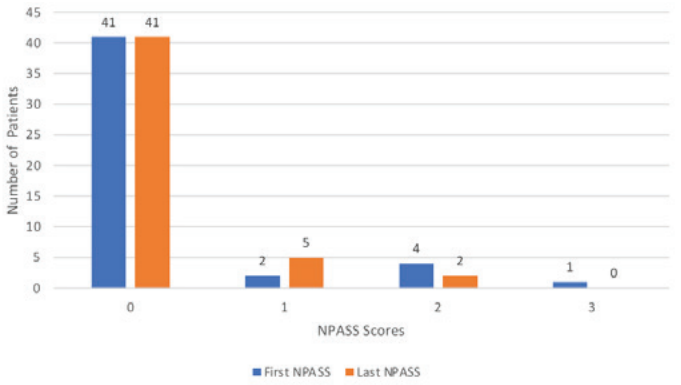

Figure 3. First and Last NPASS scores and comparison

We found that the first and last, and first and mean values of all measures were highly correlated and statistically significant.

Table 1. Vital Signs measurements and comparison.

Measurement	FIRST Measure	LAST Measure	MEAN of all Measures	Significance First vs Last P < .05
Heart Rate/min	135.4 ± 17.69	141.12 ± 19	137.8 ± 13.6	P = .054 NS
Resp. Rate/min n=48	54.73 ± 14.08	50.4 ± 14.62	51.41 ± 11.03	P = .111 NS
SpO2 in %	95.2 ± 6.33	96.27 ± 3.56	95.4 ± 6.34	P = .109 NS

There was no correlation between demographics of weight, gender, or gestational age on any of the vital sign measures.

In conclusion, very few issues were found by transporters using the novel ear protection devices. The devices were generally easy to apply, remained in place, and did not interfere with care. Vital signs and measures of neonatal stress using the NPASS scores were stable across the transport period while neonates wore the device and neonates were generally calm without visible signs of stress.

Manikin measurements revealed that overall sound levels inside an actual transport incubator were reduced by about 20 dB using the novel hearing protection device during simulated ground and air transport runs. This means the noise exposure was reduced from very loud, stress-inducing levels to a volume typical of normal human conversation.

Recommendations for practice are to consider some form of ear protection in premature neonates, particularly during transport in vehicles known to have excessive noise and vibration. Further studies are needed in this area to determine long-term impact of noise-reduction strategies in neonates over time.

Funding

This study was conducted without funding for research activities, however NEATCap Medical, LLC provided the DREAMIES T-M devices for the study.

Institutional Review Board Review

The study was approved by the Orlando Health Institutional Review Board with expedited review. Informed consent was required by parents of neonates involved in the study.

Conflict of Interest

None of the investigators in the study declare any conflict of interest with regards to the study. No payments were made to any investigators for the study.

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