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Ear drainage and the role of sepsis evaluations in the neonatal intensive care unit

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Abstract

Aim—To design and implement an intervention to reduce ear drainage and subsequent sepsis evaluation and treatment in the neonatal intensive care unit.

Methods—From 2008 to 2011, we observed an increase in the rates of ear drainage warranting investigation. Data collection was performed from 1991 to 2013 on 50 cases. Preliminary analysis revealed an association between timing of endotracheal tube tape changes and onset of drainage. We speculated that pooling of anti-adhesive solution into the external auditory canal was precipitating an inflammatory process. Unit-wide education was conducted to protect the ears during tape removal. Post-initiative rates of drainage were collected and compared with pre-initiative rates.

Results—Median gestational age and birth weight were 26 weeks and 754 grams. In 64% of cases, an anti-adhesive solution was used on the face within 48 hours of the onset of drainage. Sepsis evaluation was performed in 68% of cases. Rates of ear drainage peaked from 2008–2011 at 9.18 per 1,000 admissions when a new anti-adhesive product was used, declining to 0.66 post-initiative (rate difference: –8.52; 95% CI: –12.00, –5.03).

Conclusion—Protecting the ear from anti-adhesive solutions during tape removal may reduce rates of non-infectious ear drainage and limit unnecessary interventions.

Keywords

Neonate; ear drainage; sepsis evaluation

Introduction

Ear drainage is a relatively uncommon finding in neonatal intensive care unit (NICU) populations. It is most often described in premature infants requiring endotracheal intubation and typically believed to represent otitis externa or otitis media with perforation (1,2). These diagnoses require confirmation by otoscopy (2,3), which is particularly difficult, if not

impossible, to perform in the extremely low birth weight infant. As a result of this difficulty, and the high risk and consequences of infection in the NICU population (4), standard practice in our NICU for infants with ear drainage is to assume it to be of an infectious aetiology and to initiate evaluation, including culture of ear drainage, and empiric treatment for local and systemic infection.

Between 2008 and 2011, we observed a marked increase in cases of ear drainage in our NICU despite no apparent change in admission rates, demographics, or practices. Most of the affected infants had no other associated signs or symptoms of infection, yet were subjected to venipunctures, lumbar punctures, and broad-spectrum antibiotics. We therefore sought to investigate this dramatic change from baseline and hypothesised that not all episodes were of an infectious aetiology. Our main objective was to determine risk factors for ear drainage in premature infants in an effort to uncover non-infectious causes. If this proved to be the case, we aimed to design and implement an intervention to reduce cases of non-infectious ear drainage in our NICU and their associated and potentially unnecessary interventions.

Patients and Methods

The NICU at Yale-New Haven Children's Hospital is a 54-bed level IV NICU, with approximately 800 to 900 NICU admissions per year. Data were collected retrospectively on all infants who had an ear drainage culture performed from 1 January 1991 to 30 June 2011 and then prospectively from documented cases from 1 July 2011 to 31 October 2013. Retrospective cases were identified through our microbiology laboratory database. Additional data were obtained from the medical record and electronic databases maintained by the NICU.

Data collection included gestational age (GA), birth weight (BW), sex, method of delivery, presence of maternal chorioamnionitis, a description of amniotic fluid, mode of respiratory support at the onset of ear drainage, the presence of a nasogastric or orogastric tube at the onset of ear drainage, clinical and laboratory data and assessment at the onset of drainage including complete blood count, urinalysis, urine culture, blood culture, cerebrospinal fluid (CSF) culture and analysis, and description, gram stain and culture of ear drainage.

In addition to collecting these predetermined variables, we convened a multidisciplinary focus group to discuss other potential factors related to the onset of ear drainage. Discussions with our bedside nursing staff raised concerns about a possible link to an anti-adhesive solution used to remove tape securing endotracheal tubes. The edges of this tape typically terminated at the tragus (Figure 1a). Prior to 2004, we exclusively utilised anti-adhesive "solution A" for tape removal. A small amount of solution was expressed from a bottle onto a gauze pad that was gently rubbed against the junction of the tape and skin to facilitate removal. In 2004, anti-adhesive "solution B" was introduced and by 2008 became the only anti-adhesive product available in our NICU. The solution is expressed from a saturated pad onto the skin and the pad used to assist with tape removal. Any residual solution is removed from the face with a normal saline wash. This process was performed with the vast majority of infants remaining in the supine position both during and after tape

removal, thereby facilitating entry, pooling, and stasis of solution in the external auditory canal.

A phonecall was made to the manufacturer of solution B which confirmed that the product contained certain chemicals, including dipropylene glycol, methyl ether, and benzyl alcohol, which, after prolonged contact with the skin, could result in significant inflammation and irritation. A preliminary analysis of our data was then conducted, which revealed an association between the timing of endotracheal tube tape change/ removal and the onset of ear drainage.

A multidisciplinary group was then assembled to review this practice and to investigate similar practices in other area NICUs. Alternate anti-adhesive solutions were researched, all of which carried similar risks. We also entertained the use of normal saline to assist with tape removal, but had concerns regarding injury to premature skin without the use of an anti-adhesive. We decided to continue to use the same anti-adhesive, but designed and implemented a strategy for ear protection during its use. We accomplished this by placing gauze over the external auditory canal and covering the gauze and the external ear with a clear, adhesive dressing. We also altered the method of securing the endotracheal tube by insuring that the edges of the tape terminated in the mid-maxillary area to decrease proximity to the external auditory canal (Figure 1b). Education was conducted for our nursing staff over several months and the practice change initiated in November of 2011. Data were then collected post-initiative to compare rates of ear discharge before and after this change. The Yale University Human Investigation Committee approved this investigation.

Statistical analyses

Continuous data were presented as medians and 25th and 75th percentile ranges and dichotomous data as absolute numbers and percentages. Continuous data were compared using Mann-Whitney U test and dichotomous data using Chi-square or Fisher's Exact test for any cell with a count of less than or equal to five. A p-value less than 0.05 was considered statistically significant.

The rate of ear drainage was reported as the number of cases per 1,000 NICU admissions. Crude, unadjusted rates and 95% confidence intervals (CI) were calculated and compared between the pre- and post-initiative periods using rate differences. Data were analysed using SPSS v. 19.0 (SPSS Inc., Chicago, IL.).

RESULTS

We identified 50 episodes of ear drainage in 50 infants from 1 January 1991 to 31 October 2013. The median GA of the study population was 26 weeks with a median BW of 754 grams. The majority was male and delivered via caesarian section. The median day of life at presentation of ear drainage was 17 days, 58% were intubated, all orally, and 82% of infants had an orogastric or nasogastric tube in place at the time the ear drainage was documented (Table 1).

In 64% of the study population, an anti-adhesive solution was used on the face within the 48 hours before the onset of ear drainage, with a median duration from exposure to onset of 30.5 hours (23 to 48 hours). The majority (78%) of drainage was unilateral and described as purulent in 95%, with the remaining 5% described as serosanguinous (Table 1). A pediatric otolaryngology consult was obtained in only three cases with inability to visualise the tympanic membrane reported in all.

A sepsis evaluation was performed in 68% of cases and antibiotics initiated in 70% (94% systemic, 6% local). In 32 cases (64%), blood culture(s) were obtained yielding three positive results. Two blood cultures in separate infants were positive for *Candida albicans* and one for *Klebsiella spp.* All three infants with positive blood cultures were <750 grams BW and in all cases the central line was documented as the source of infection. CSF cultures were obtained in 27 cases (54%). No CSF cultures or fluid evaluation confirmed or was suspicious for meningitis. Cultures of ear drainage were positive in 34 cases (68%), of which 41% yielded polymicrobial flora, 21% Coagulase-negative *staphylococci*, and 9% *Staphylococcus aureus*. In the three infants with blood stream infections, the ear cultures all revealed mixed flora, none of which matched the organism retrieved from the blood.

The overall rate of ear drainage for the entire study period was 2.64 cases per 1,000 NICU admissions. From 1 January 1991 to 31 December 2007, the rate was 1.13 per 1,000 admissions representing less than one case per year. This rate increased significantly to 9.18 cases per 1,000 NICU admissions from 1 January 2008 to 31 December 2011, representing approximately eight cases per year. During this four year period, affected infants were noted to be of significantly lower BW than in years prior and a significantly higher percentage were intubated (Table 2). In addition, 93% of infants had a tape change within 48 hours of the onset of ear drainage as compared with 55% of those from 1991 to 2007 (Table 2). No significant differences with respect to GA, male sex, timing of ear drainage, or the presence of a nasogastric or orogastric tube at presentation of drainage were noted (Table 2).

After instituting a program for ear protection during tape change (1 January 2012 to 31 October 2013), the rate of ear drainage decreased from 9.18 (2008 to 2011) to 0.66 cases per 1,000 NICU admissions (rate difference: -8.52; 95% CI: -12.00, -5.03) (Figure 2). The post-initiative rate represented one case over a 22-month period.

Discussion

The neonate has underlying abnormal structure and function of the eustachian tube (2,5) which is responsible for regulating middle-ear air pressure, removing normal ear secretions, and protecting otic tissues from nasopharyngeal secretions (6). In neonates, the eustachian tube is shorter, wider, and more horizontal than in adults (2). Without normal venting and clearance of secretions by the eustachian tube, mucosal secretions may accumulate leading to inflammation of the tympanic cavity with development of effusion and subsequent infection. Aspiration of meconium or infected amniotic fluid through the eustachian tube has been reported as a risk factor for otitis media (6,7). Irritation and obstruction caused by support apparatus such as nasogastric and nasotracheal and orotracheal tubes can precipitate middle ear effusions.

For these reasons, in our NICU, ear drainage was traditionally believed to be of an infectious aetiology, resulting in sepsis evaluation and initiation of broad-spectrum antimicrobials. This response is not without potential consequences related to the inherent risks of performing invasive procedures as well as the risks of potentially unnecessary antibiotic exposure, including development of antimicrobial resistant organisms, and an increased risk for necrotising enterocolitis in exposed infants (8). Given this, when we observed a substantial increase in cases of ear drainage in our NICU, we chose to investigate.

We identified a probable, non-infectious aetiology for ear drainage in premature infants precipitated by exposure of the external auditory canal to chemicals in an anti-adhesive solution. When this association was first observed, we sought alternatives to the use of anti-adhesive products in our NICU, including the use of saline wipes. In the NICU, adhesives are frequently utilised to secure support and monitoring devices to under keratinised and extremely sensitive skin (9). Removal of adhesives results in more than 1.5 million injuries each year in the United States (9,10) with the skin of the preterm neonate being particularly at risk for injury (11). In addition to pain, damage to the epithelium may serve as an entry port for infectious pathogens. We therefore believed that if used properly and promptly removed from the skin, an anti-adhesive agent could play an important role in facilitating tape removal while maintaining skin integrity. Our nursing education initiative focused on ear protection during anti-adhesive administration. After implementation of this practice change, we were able to almost eradicate ear drainage and its associated interventions from our NICU.

Despite these findings, the role of evaluation for systemic infection and empiric treatment with broad-spectrum antibiotics in the setting of ear drainage in the NICU remains uncertain. In our cohort, the majority of infants with drainage had ear, blood, and CSF cultures obtained. In three separate cases, the blood culture(s) were positive. In two infants with fungemia, the only clinical indication for sepsis evaluation was ear drainage. In no cases was the CSF culture or fluid analysis suggestive of meningitis nor did the ear cultures match the organisms retrieved from the blood stream. Ear cultures typically yielded polymicrobial results and/or skin flora. While we believe that we have eradicated the majority of ear drainage in our NICU returning to a baseline rate of approximately one case per year, we believe that infectious otitis externa and otitis media is a real entity with potential risks to our population that should not be overlooked. Therefore, even in the absence of other clinical signs, we continue to evaluate and treat the infant with ear drainage in our NICU. However, we believe that our data has shown no utility in obtaining an ear drainage culture and have therefore eliminated this practice.

Our investigation and its results have limitations, some of which are related to the retrospective nature of our pre-initiative data collection. Given the uncertainty of the aetiology of ear drainage in this population, it is quite possible that other contributing variables were overlooked. Furthermore, we could only retrospectively identify cases through a laboratory database of ear drainage cultures. It is possible that while culturing ear drainage was standard practice during the study period, there may have been some cases where the clinical team opted not to perform a culture. This may have resulted in an underestimation of the baseline rate. Alternatively, although culture of ear drainage was still

recommended in the post-initiative period, it is possible that staff knowledge of our initiative may have caused some to assume the drainage non-infectious and to not opt for further evaluation. This may have then resulted in an underestimate of rates in the post-initiative period as well. Lastly, the exact timing of complete removal of solution A from our NICU is uncertain, but by 2008 only solution B was available.

We conclude that premature infants in the NICU are at significant risk for local and systemic infections including otitis media and externa that may present as ear drainage. However, not all ear drainage may be of an infectious aetiology and may be precipitated by exposure of sensitive skin to chemical irritants. We recommend that, if an anti-adhesive solution is utilised during tape removal, the ear canal be protected. This may in turn reduce the risk of ear discharge and limit unnecessary interventions and exposures. However, given the high-risk nature of the patient population, the inability to properly evaluate the ear and the risk of local infection to quickly become systemic, we believe sepsis evaluation and treatment in the setting of ear drainage remains warranted. Cultures of ear drainage, however, do not appear to yield any useful results and should not be included as part of the evaluation.

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Abbreviations

NICU	neonatal intensive care unit
GA	gestational age
BW	birth weight
CSF	cerebrospinal fluid
CI	confidence interval

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Key notes

- Ear drainage in the neonatal intensive care unit (NICU) is primarily believed to be of an infectious aetiology, often resulting in sepsis evaluation and systemic antimicrobial treatment.
- We determined that an increase in rates of ear drainage in our NICU was related to use of an anti-adhesive solution on the face.
- After an educational initiative, we were able to significantly reduce rates of drainage and limit unnecessary treatments and interventions.

Figure 1a.

Figure 1b.

Figure 1.

Figure 1a depicts our post-initiative method of securing endotracheal tubes. Note the tape terminates at the tragus.

Figure 1b depicts our post-initiative method for covering the external auditory canal prior to endotracheal tube tape change. A piece of gauze is placed over the canal and then covered with a clear dressing. Also note that edge of the tape terminates in the mid-maxillary area.

Figure 2. depicts the rates of ear drainage per 1,000 NICU admissions over three time periods: 1 January 1991 to 31 December 2007, 1 January 2008 to 31 December 2011, and 1 January 2012 to 31 October 2013.

Table 1

Description of 50 infants with ear drainage, January 1, 1991 through October 31, 2013

Variable	Median (range)	N (%)
Gestational age (weeks)	26 (24.75 to 28)	
Birth weight (grams)	754 (637.5 to 987.5)	
Male		30 (60)
Vaginal delivery		16 (32)
Chorioamnionitis		9 (18)
Onset of ear drainage (day of life)	17 (7.74 to 34.5)	
Drainage within 48 hours of tape change		32 (64)
Nasogastric tube at onset of drainage		41 (82)
Respiratory support at onset of drainage		
HFOV		3 (6)
SIMV		26 (52)
NIPPV		6 (12)
NCPAP		5 (10)
Nasal cannula		5 (10)
Room air		3 (6)
Site of drainage		
Unilateral-right		24 (48)
Unilateral-left		13 (26)
Unilateral-unspecified		2 (4)
Bilateral		5 (10)
Not recorded		5 (10)

HFOV: high frequency oscillatory ventilation; SIMV: synchronized intermittent mandatory ventilation; NIPPV: nasal intermittent positive pressure ventilation; NCPAP: nasal continuous positive airway pressure

Table 2

A comparison of cases of ear drainage between two time periods

Variable	Period 1 ^a (N=19)	Period 2 ^b (N=30)	p-value
Gestational age (weeks) ^c	26 (26 to 29)	26 (24 to 27.25)	0.145
Birth weight (grams) ^c	915 (721 to 1418)	698 (571.25 to 907.5)	0.023
Male ^d	11 (58)	11 (37)	0.238
Onset of ear drainage (day of life) ^c	16 (6 to 40.5)	19 (12.25 to 33)	0.669
Drainage within 48 hours of tape change ^d	6 (55) *	26 (93) **	0.012
NGT or OGT at onset of drainage ^d	15 (79)	25 (83)	0.720
Intubated at onset of drainage ^d	7 (37)	21 (70)	0.037

^a January 1, 1991 through December 31, 2007^b January 1, 2008 through December 31, 2011^c Median (interquartile range)^d N (%)

* N=11

** N=28

NGT=nasogastric tube; OGT=orogastric tube