From Surviving to Thriving: The Impact of Cranial Deformation and Pressure Ulcers in the Hospitalized Infant

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Abstract

Neonatal and pediatric patients often experience significant periods with minimal movement which can be even more pronounced in the NICU and PICU settings due to therapeutic equipment, external monitoring, or an otherwise fragile patient. Over time, this can lead to periods of prolonged pressure especially in the cranial area.

Increased pressure is linked to the development of pressure ulcers and positional plagiocephaly, both of which are drivers for increased healthcare expenditures. In the case of positional plagiocephaly, evidence continues to accumulate that cranial deformations can negatively impact long-term quality of life, including serious implications of alterations in appearance, the inappropriate neuronal mapping secondary to anatomical anomalies, or delayed developmental milestones.

Hospital acquired pressure ulcers, in addition to increasing healthcare costs, can result in litigation, government penalties, and impact hospital metrics. The 2011 Institute for Healthcare Improvement's "How-to Guide: Prevent Pressure Ulcers" states that "Redistribution of pressure, especially over bony prominences, is of primary concern. Patients with limited mobility are especially at risk for the development of pressure ulcers. Every effort should be made to redistribute the pressure on the skin, either by repositioning or by utilizing pressure-redistribution surfaces."

A prevention strategy of providing continuous reduction in the peak pressure applied to the cranium represents a wise investment for a high reliability organization on a journey to eliminate preventable harm. This is true whether the infant has restricted mobility or has sufficient strength to move its head and neck.

Pressure Ulcers

Prolonged exposure to pressure must be managed at all hours, regardless of staffing levels, fatigue, or other emergent and acute conditions. In the PICU and NICU, the current standard of care calls for frequent checks, for instance, to ensure that the infant has not rolled off a positioning aid, and then to reposition the head after a prescribed period of time. In some hospital protocols, this procedure must also be entered in the medical record which is often completed outside of the normal shift as mandatory overtime. Despite best efforts and enhanced protocols, pressure ulcer occurrence in the PICU and NICU continues to be a concern for providers.

Pediatric pressure ulcer prevalence rates vary greatly throughout the hospital with published reports ranging from less than 1% to nearly 30%, with higher rates occurring in intensive care units.[1-3] Pressure ulcers are also more prevalent in younger pediatric patients and patients with limited mobility which places patients in the NICU and the youngest in the PICU at risk.[4-6] In a multi-center prospective cohort study across three PICUs, a total of 199 pressure ulcers developed in 86 of the 322 enrolled patients (27%).[7] A later study of PICUs in nine institutions found the average incidence rate per 100 admissions was 10.2.[8]

The cranium is of particular concern for pressure ulcer development due to its weight relative to the body in young patients and the presence of bony prominences that can be exposed to prolonged pressure.[1,4,9] Patients lacking the strength to move their head or having impaired mobility have a further increased risk.[6,10] In Curley's study of 322 PICU patients, 33% of the pressure ulcers were located on the head with 19% on the occiput and 14% on the ears.[7] Baldwin's questionnaire-based study echoed these difficulties with 17.4% of pressure ulcers occurring on the occiput of hospitalized children.[1] Groeneveld et al found among hospitalized children that over 50% of pressure ulcers occurred on the occiput or ears (19.0% and 33.3%, respectively).[4] Curley et al[7] also report marked increases in the risk of pressure ulcers in the presence of concomitant therapies as follows (odds ratios reported):

- Use of mechanical ventilation = 7.8
- Use of high frequency oscillation vent = 7.3
- Use of chemical paralysis = 4.6
- Total parenteral nutrition = 3.0.

Pressure ulcers in neonatal and pediatric patients have also been linked to complications brought on by medical devices affixed to the patient[7,11] such as extracorporeal membrane oxygenation (ECMO) cannula, nasogastric tubes, and EEG leads. Providing a cushioned boundary between these medical devices and the patient's skin may prevent or reduce the severity of the hospital acquired pressure ulcers.

The impact of pressure ulcers on the hospitalized infant to a healthcare organization is profound. A review of over 500,000 patient discharges in the National Inpatient Sample Dataset

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from 2009 to 2011 identified cases of pressure ulcers in patients between 1 and 4 years of age. These cases were matched to controls via propensity scoring in order to assess differences in treatment costs and length of stay in patients with otherwise comparable medical conditions. In this sample, the authors estimated the average impact associated with the development of pressure ulcers was $86,000 and 14 additional days stay.[5] Aggressively moving on even Stage I or II pressure ulcers is a prudent part of a patient safety program. Brilli et al describe this as a preoccupation with failure in which a small error is a major event waiting to happen.[12]

While less easily quantifiable, an important financial impact of hospital acquired pressure ulcers can be felt through Medicaid reimbursement. The Centers for Medicare & Medicaid Services (CMMS) can withhold a hospital's Medicaid reimbursement based on their quality performance, 30% of which is based on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. The occurrence of a pressure ulcer may negatively impact families' satisfaction with the care of their infant. Finally, providing nurses with tools to help prevent pressure ulcers can improve job satisfaction and employee retention. The cost of replacing a nurse can be twice the annual salary of that nurse.[13]

Pressure ulcers are a significant concern for children in the PICU and NICU due to their stage of development and the likelihood of impaired mobility in an environment that must continually assess myriad competing risks. Evidence suggests there may be substantial impact on the resulting treatment costs and length of stay in this especially vulnerable population. Patients with known risks for pressure ulcers or patients with existing Stage I pressure ulcers may warrant focused preventive measures.

Positional Plagiocephaly

Positional plagiocephaly is another known risk associated with prolonged exposure to extracranial pressure in infants. A 2011 clinical report by the American Academy of Pediatrics indicates that the prevalence of cranial asymmetry has markedly increased since the inception of the "back to sleep" campaign urging parents to have infants sleep on their backs.[14] This increased prevalence is found in healthy and hospitalized infants alike.

In a prospective cohort study of 380 healthy consecutively born neonates, a total of 84 (22%) were found to have "severe skull deformity." Of these, 75 (89%) did not have plagiocephaly at birth which suggests environmental factors result in cranial deformation.[15] These findings mirror earlier data collected by Hutchison et al where the prevalence of plagiocephaly or brachycephaly was found to be 19.7% at four months of age, dropping off with increasing age.[16] Very pre-term infants have been found to have an even greater incidence of plagiocephaly with one study showing an incidence of 38% for very preterm infants as opposed to 23% across all births.[17]

Collett et al provide a review of the impact of plagiocephaly on quality of life concerns and note that "…children's overall attractiveness may be compromised by plagiocephalic head shape. Parents frequently report being afraid that their child will be 'teased, embarrassed, or otherwise stigmatized because of the condition'."[18] Numerous studies highlight the nature and extent of the distinct cranial deformities that can occur, ranging from facial asymmetry, visual field constriction, astigmatism, malocclusion of the jaw, otitis media, and malposition of ears

Figure 1. GELShield on patient

to statistically significant dimensional differences measured by MRI.[19-26] In a study of auditory evoked potentials in infants with and without deformational plagiocephaly, differences were detected in amplitudes of certain components of the evoked potential.[27] The authors opine that this might indicate "an auditory processing dysfunction, as a possible result of the delayed or disturbed maturation of the auditory pathways." The decrease in the evoked potential amplitude was focused in the region of the skull that was deformed. To the extent that visual or auditory acuity is adversely affected, the development of neuronal networks may also be affected during this vulnerable period of brain development.

Purzycki et al (2009) studied the occurrence of otitis media in patients with deformational plagiocephaly and the associated hearing problems. They concluded, "Considering the time that otitis media presents, the loss of hearing causes real concerns for language, speech, and cognitive developments."[24]

The 2011 Clinical Report by the American Academy of Pediatrics[14] indicated that sufficient evidence did not yet exist associating plagiocephaly with developmental issues; however, more recent published studies indicate that there may in fact be such an association:

- A 2016 study of malocclusion in children with and without positional plagiocephaly found that "the prevalence of orthodontic abnormalities is increased in children with former positional plagiocephaly" when compared to a control group of normal children.[23]
- A 2011 longitudinal study indicated increased relative risks for Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) score categorized as "delayed" when compared to children without plagiocephaly in the areas of adaptive behavior, motor, language and cognitive. Language and cognitive differences were still present at 36 months.[28,29] In addition, 37% of children with previously diagnosed plagiocephaly participated in some form of developmental intervention, such as physical or occupational therapy or speech-language therapy vs 6% without a prior diagnosis.
- Published 2012 results of an 80 patient survey indicated parent-reported developmental delay occurred frequently, distributed as 21% having language difficulties, 28% having motor difficulties, and 15% requiring special education. This exceeded the population averages for developmental delay, which occurs in 5-6% of children.[30]

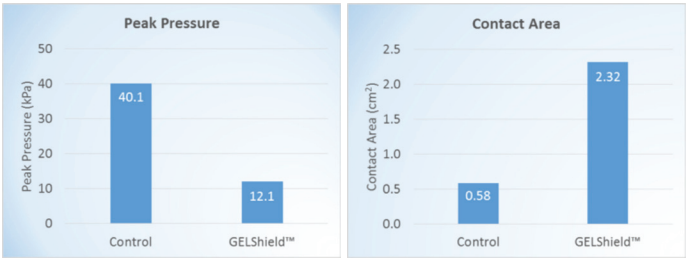

Figure 2. Pressure reduction and increase in contact area

Litigation in cases of plagiocephaly has become a significant threat for providers as well, with one plaintiff's attorney noting that the "expert psychiatrist contended that the child will probably suffer significant emotional turmoil because of the deficits as he goes through elementary school."[31] Multiple seven figure verdicts have been reported.[31-33]

The standard treatment for moderate and severe cases of plagiocephaly is cranial helmet therapy.[19] In general, cranial helmets are prescribed to be worn about 23.5 hours per day and are reported to cost between $2,000 and $4,000 per device with more than one device often needed during the course of treatment as the child grows; this cost is not generally covered by insurance.[34] Despite its routine use, there is a paucity of Class I literature actually supporting the use of cranial helmet therapy in plagiocephalic patients and helmet use has been associated with complications including skin erosions and infections.[35-37]

Prolonged pressure is known to affect cranial shape in the very young and can lead to more serious deformities that are associated with significant treatment costs. Additionally, emerging evidence continues to indicate that the effects may substantially impact quality of life, cognition, and development. Given the acute concerns of pressure ulcers and long term consequences of cranial deformity, there is an emerging need for an easy-to-use device to help reduce cranial pressure in hospitalized infants and children.

The Invictus Medical GELShield with its Pressure Relief System is a device that fits securely to an infant's head and provides a continuous reduction in the peak pressure applied to the cranium of a recumbent infant (Figure 1). This device reduces the peak pressure experienced by the head by dispersing the force of the head over a larger area. In this manner, manually repositioning the infant's head may become less time-critical since the device absorbs much of the pressure that the head experiences.

The Association of Women's Health, Obstetric and Neonatal Nurses (AWOHNN) for pressure ulcer prevention in neonates of less than 32 weeks of gestation recommends gel pads placed behind the ears and occiput.[38] The GELShield addresses this recommendation by placing a foam encapsulated hydrogel pack directly behind the occiput and a padded strap above the ear so that the device is able to move with the patient during normal activity. Figure 2 details the results of bench testing on the pressure reduction and increase in contact area achieved with GELShield.

Cost and potential impact

Review of ICU data shows that the average length of stay for preterm infants is 21 days at an average cost of stay for preterm infants of $121,000 ($5,600/day) with lower gestational ages costing more.[39] The cost of devices to alleviate these enumerated problems need to be evaluated in light of these per-day costs. From another point of view, the costs associated with pressure ulcers are straightforward. The prevalence of pressure ulcers in the PICU is well documented,[1-8] many of these occur on the occiput or around the ears,[1,4,7] and they can result in an increased length of stay and costs.[5] Pressure ulcers would likely have a negative impact on CMMS reimbursement secondary to poor HCAHPS scores.

The costs of deformational plagiocephaly affect the healthcare institution less directly than that of pressure ulcers. The costs to the larger healthcare delivery system are real nonetheless. The cost of orthotic helmets are generally borne by the family directly. And while physical therapy has shown some positive effect on the degree of cranial molding,[40] this can involve many months of physical therapy with return visits to a plagiocephaly clinic. These families are obligated to make return visits to the clinic, in some cases arranging for transportation and obtaining time off work. These can be a significant financial burden on many families.

Clinical approaches that can positively impact risk mitigation, cost control, patient satisfaction, and staff satisfaction, especially those approaches that are easy to implement, should be explored.

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