Case Report: Multiple Genetic Mutations in an Infant with Refractory Brugada-Like Syndrome

By Katie Kowalek, MD; Ricardo A. Samson, MD; Kevin Engelhardt MD; Yung Lau, MD; Santiago O. Valdes, MD

Abbreviations: Brugada Syndrome (BrS); Right Bundle Branch Block (RBBB); beats per minute (bpm); electrocardiogram (ECG); ventricular tachycardia (VT); atrioventricular (AV); cardiopulmonary resuscitation (CPR); extracorporeal membrane oxygenation (ECMO), implantable cardioverter defibrillator (ICD).

Introduction

Brugada Syndrome (BrS) was first described by Pedro and Josep Brugada in 1992 as Right Bundle Branch Block (RBBB) with ST segment elevation, conveying increased risk of sudden cardiac death.1,2 Over time, BrS has been found to be associated with gene mutations encoding for cardiac sodium, calcium, or potassium ion channels.3 These channelopathies predominate mostly in the epicardium, resulting in a loss of function of sodium or calcium channels, or a gain of function in potassium channels. Consequently, during early depolarization (Phase I of the cardiac action potential), decreases in INa or increases in Ito cause a transmural voltage gradient which leads to the characteristic electrocardiographic changes of BrS.1 While BrS is more commonly diagnosed in adults, it is rare in children.4 Additionally, the typical BrS ECG pattern may not be observed in infants. As described in a case series by Kanter et al,4 out of 5 infants with genetic mutations encoding for BrS did not demonstrate classic RBBB with ST elevation. They used the term Brugada-like Syndrome to describe this group of patients. We present an infant with refractory ventricular tachycardia who was found to have three distinct mutations encoding for cardiac ion channels consistent with Brugada-like Syndrome.

Case Report

A 39 day-old male presented to the hospital for fever and dyspnea associated with perioral cyanosis. Admission examination was significant for tachypnea with upper airway congestion and auscultation revealing coarse breath sounds. Cardiac examination revealed a normal S1/S2 without murmurs, rubs, or gallops, and strong distal pulses. Abdominal exam was benign without hepatomegaly.

Shortly after receiving an albuterol treatment for wheezing and hypoxia, he developed tachycardia with a rate of up to 300 beats per minute (bpm). He was hemodynamically stable. An electrocardiogram (ECG) revealed a wide-complex tachycardia, rate 252 bpm with RBBB morphology and QRS axis of -126° (Figure 1). Administration of adenosine did not convert his tachycardia, but did reveal atrioventricular (AV) dissociation. He was given...
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two IV boluses of amiodarone and placed on a continuous infusion. Within 6 hours, he converted to sinus rhythm, 102 bpm with wide QRS (172 ms) and RBBB morphology in lead V1 (Figure 2). Thereafter, however, sustained Ventricular Tachycardia (VT) recurred and persisted, during which time only rate control could be achieved. He received multiple boluses of IV amiodarone and the continuous infusion was increased to 15 mcg/kg/min. Eventually, the VT terminated, with resulting sinus rhythm with first degree AV block and narrow QRS alternating with wide QRS in a 2:1 to 3:1 fashion. On hospital Day 2, he developed 2:1 AV block with associated bradycardia (Figure 3), hypotenion, and poor perfusion. Vasopressin was started, amiodarone was weaned, and he was placed on IV lidocaine infusion up to 40 mcg/kg/min. Seizures developed secondary to lidocaine toxicity and breakthrough VT occurred as lidocaine was decreased, therefore, an esmolol infusion was added. By hospital Day 3, he continued to have intermittent non-sustained VT with resultant hypotension and worsening metabolic acidosis. When his VT converted he was significantly bradycardic, therefore, a temporary transvenous pacing catheter was placed. On hospital Day 7, he once again developed sustained VT with hypotension and poor perfusion. Despite resuscitative efforts he became bradycardic and pulseless; cardiopulmonary resuscitation (CPR) was initiated and advanced life support given. After one hour of chest compressions, he was emergently placed on venous-arterial Extracorporeal Membrane Oxygenation (ECMO). He remained on ECMO for four days, during which time he returned to sinus rhythm with PR interval 176 ms, and QRS duration of 172, RBBB morphology with ST segment elevation in lead V1.

Figure 2. After receiving two boluses of IV amiodarone, 12-lead ECG shows sinus rhythm 102 bpm, with PR interval 176 ms, and QRS duration of 172, RBBB morphology with ST segment elevation in lead V1.

Figure 3. On hospital day 2, 12-lead ECG shows sinus rhythm with 2:1 AV block, RBBB, and prolonged PR interval and QTc. He had been on an amiodarone drip for approximately 12 hours at this point.

DNA for genetic testing of cardiac ion channel mutations was sent in the first week of hospitalization and results returned after discharge. He was found to have two distinct Class I mutations – SCN5A Arg225Trp, SCN5A Val845fs – and a third Class II mutation, SCN5A Thr630Met.

At 5 months of age, this patient and his family relocated. Based on the results of the DNA testing, amiodarone was discontinued and quinidine was started. He continued on mexiletine and propranolol. Unfortunately, he continued to have incessant non-sustained VT. An Implantable Cardioverter Defibrillator (ICD) with epicardial leads was placed, during which he was noted again to have high pacing thresholds. He had multiple admissions for un-responsive with no documented arrhythmias and had developed seizure activity that was confirmed by electroencephalogram. Levetiracetam was started to control seizure activity.

He had multiple echocardiograms throughout his course. Those in the first 5 months of life showed normal cardiac anatomy with a patent foramen ovale. Beyond 5 months, echocardiograms showed a dilated left ventricle with left ventricular diastolic dimensions greater than the 99 percentile for body surface area, which never recovered on subsequent echocardiograms. Ejection fractions ranged from 30% to 70%.

At 10 months of age, the patient developed a seizure associated with profound bradycardia. He had subsequent loss of pacer capture and required CPR and advanced life support. He was placed on ECMO, from which he could not be weaned and he unfortunately died.

Discussion

Brugada Syndrome has been previously described in infants and children in scattered case reports and one case series. The incidence of BrS is difficult to determine, but is estimated to be 1-5 per 10,000. In adults, BrS is more common in men; however, in children, there seems to be no sex predilection. Whereas the classic ECG
Findings of RBBB with ST segment elevation in lead V1 is often noted in adults with BrS; these ECG features may not be present in infants. Kanter et al. described 5 infants with genetic-proven BrS-causing mutations, but only one patient manifested the typical RBBB and ST elevation. They reasoned that normal developmental changes in cardiac ion channel density and function could contribute to the lack of a classic BrS ECG pattern. They also surmised that the relatively higher balance of right ventricular to left ventricular mass in infants compared to mature patients might also have influence on the surface ECG. As such, they proposed the term Brugada-like Syndrome to apply to these patients who may have a “heterogeneous electrophysiologic milieu.”

The clinical presentation of infants with BrS is variable. Skinner et al. reported a 21-month-old child with recurrent febrile seizures, who was found to have VT during these episodes consistent with BrS. Her seizures were felt to be a result of poor cerebral perfusion during episodes of VT. Other case reports describe aborted sudden cardiac death, recurrent episodes of cyanosis with crying, and febrile upper respiratory infection with signs of low cardiac output on exam. A common presentation, such as in our patient, is VT that occurs with fever.

Our patient also had the characteristic of high pacing thresholds noted on two surgical procedures for pacemaker and ICD implantation. Such a finding was previously reported by Lopez et al. in a patient with homozygous mutation for SCN5A and in Kanter’s series, 3 infants had high ventricular pacing thresholds. Of interest, Lopez demonstrated poor atrial capture thresholds, Kanter demonstrated poor ventricular thresholds, and our patient had both poor atrial and ventricular capture thresholds. To our knowledge, no other reports have described poor atrial and ventricular capture thresholds in patients with SCN5A mutations.

A review of the literature reveals that multiple mutations in the SCN5A gene in the same person are very uncommon. Barajas-Martinez et al. reported a 45-year-old man shown to have lidocaine-induced BrS ECG findings. Genetic analysis revealed a double-mutation in SCN5A (Val232Ile and Leu1308Phe). Nof et al. described a 16-year-old male with bradycardia and RBBB, found to have three mutations in SCN5A (Val1251Met, Val1924Thr, and Lys1492Del). An international multi-center retrospective analysis by Kapplinger et al. revealed a small cohort of patients with two SCN5A mutations. It was noted that these patients were younger at diagnosis than the remainder of the cohort (29.7±16.2 vs. 39.2±14.4). However, the youngest patient in that cohort was 2 years of age. There are no reports of multiple genetic mutations in SCN5A in infants to our knowledge.

Our patient had genetic analysis completed by Transgenomic, Inc. (New Haven, CT). The results are categorized by class. Class I mutations are expected to predispose to disease. Class II mutations may predispose to genetic heart disease. However, it has not been fully shown to be of significance. Neither Class I nor II mutations have been found in healthy controls in the general population. Class III mutations have been found in healthy controls and are not thought to be disease-causing mutations. Our patient’s testing revealed two Class I mutations (SCN5A: Arg225Trp, Val845fs); one Class II mutation (SCN5A: Thr630Met), and three Class III mutations (CACNA1C: Leu1869Pro; SCN1B: Leu210Pro; SCN5A: His558Arg). The SCN5A Arg225Trp mutation is a point mutation, resulting in an amino acid change within the transmembrane region of the SCN5A protein. In vitro analysis of this missense mutation caused a 90% reduction in INa in sodium channels expressed in Xenopus oocytes. While this mutation has been reported in patients suspected of having Long QT Syndrome and cardiac conduction disease, Kapplinger et al. have also observed this mutation in three unrelated probands suspected of having BrS. The SCN5A Thr630Met has not been reported in the literature but has not been observed in healthy controls. The Val845fs mutation is a frameshift mutation which likely results in abnormal termination of the SCN5A protein in Domain II, transmembrane region 5, and would be expected to have deleterious effects on sodium channel function. It too has been reported in one patient suspected of having BrS.
given the complexity of his social situation, obtaining biological samples from family members was not able to be performed.

Conclusions

In summary, we present an interesting case of an infant with Brugada-like Syndrome who presented with fever, refractory ventricular tachycardia, and high pacing thresholds. He did not have the typical ECG pattern of BrS but was ultimately found to have three mutations significant for BrS. To our knowledge, this has yet to be described in an infant. Unlike many previous reports of infants with BrS, our patient had an extremely difficult course with refractory ventricular arrhythmias. The acuity of his course and ultimate demise may have been related to the multiple mutations in the SCN5A gene, resulting in marked aberrations in the function of this ion channel.

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Supporting Families on Their Journey Home: A Comprehensive Approach to NICU Discharge/Transition Planning

By Vincent C. Smith, MD; Trudi N. Murch, PhD, CCC-SLP

Introduction

When going home from the Neonatal Intensive Care Unit (NICU) with their babies, families often have powerful and even conflicting emotions accompanying them during the transition. The family is leaving an environment where they trust their baby is being well cared for and suddenly they are solely responsible for the well-being of their child. That experience can be terrifying. The days, weeks, and months immediately following a baby’s discharge from the NICU constitute a critical period in the life of the family. While trying to balance multifaceted emotions, the family must also deal with their job-related demands, financial responsibilities, the needs of other family members, and numerous other stressors including mental health issues. Families need help and support.

The field of infant mental health helps us understand the primary importance of a positive parent-child attachment relationship in determining a child’s future well-being. This leads to a focus on ways professionals can support parent-child attachment relationships and mitigate some factors that can threaten those relationships. In this regard, NICU and community providers have an opportunity to work together to provide comprehensive and well-integrated support for families during the transition from NICU to home.

With this column, we describe some of the processes, resources, and guiding principles which can lead to positive outcomes for the baby and the family. We also offer ideas and considerations about how keeping a focus on the parent-infant relationship during the discharge/transition process can promote optimal outcomes for both baby and caregiver, and help mitigate some of the potential challenges they face.

It is well-established that NICU babies are at high-risk for hospital re-admission, and that a well-supported discharge/transition can reduce this risk. A comprehensive approach to discharge/transition planning that includes psycho-social support and focuses on the caregiver-child relationship offers families the support they need and deserve at a critical time in their lives.

The transition to home may occur when the infant has achieved physiological maturity and has completed all pre-discharge testing and treatment. A successful transition for the parents involves acquiring technical skills and infant care knowledge, preparation of the home environment where the infant will be joining the family, and management of the complicated emotions that can be associated with the pregnancy, birth, NICU hospitalization/discharge, and beyond.

At home, usually the parents will be the infant’s primary caregivers and, therefore, should be their primary attachment figures. Keeping this concept in mind, the discharge preparation program should be grounded in Family-Centered Care (FCC). FCC is the concept that parents are an integral part of the care team who work in partnership with the medical providers on decision-making and providing care for the infant. The four central tenets of Family-Centered Care are: family participation in care, information sharing, family collaboration and shared decision making, and dignity and respect for the family and their role in the infant’s life. FCC may ameliorate the stressors that families experience due to the separation from their infant, inability to experience a traditional parenting role, and the inclusion of multiple caregivers in daily care.

Structured discharge teaching should begin early and be distributed throughout the NICU hospitalization to prevent the family from being overwhelmed with a large volume of content near the end of the hospitalization. Discharge teaching should be tailored to the family’s specific circumstance, be structured to include the skills and knowledge parents are expected to master, and provide parents with adequate opportunities to practice skills initially under direct supervision then with supervisory support as needed. All of the discharge preparation should be adapted to the family such that it is racially, ethnically and culturally sensitive as well as appropriate for their sociodemographic and health literacy level.

The NICU discharge planning process can be heavily task and skill acquisition focused. Less time is generally spent sitting down with the family to listen to how they are doing and what they are feeling. While technical skills and knowledge are an essential part of NICU discharge planning, it is also important for a successful discharge/transition to find out what the parents are worried about and/or don’t understand.

The need for parental self-care is critical, but not often discussed, planned for, or acknowledged as important during the transition process. That is an oversight of many discharge planning programs. Parents often report feeling guilty about taking any time for themselves, including adequate time for sleep and recovery. This can lead to parental exhaustion and/or depression. Parents may need encouragement to care for themselves, so they can care for their infant.

Similarly, emotions are a common part of the NICU experience and their identification and management can be decisive factors in the transition from the NICU home. In addition to the traditional rollercoaster ride of emotions, some parents have mental health issues such as anxiety or depression, and numerous parents will develop Post-Traumatic Stress Disorder (PTSD) during or after the NICU experience. NICU parents experience a high rate of perinatal mood disorders. These include: post-partum depression, PTSD, anxiety disorder, and obsessive-compulsive disorder.
It is important to provide mental health screening and support to identify and attend to parent’s mental health needs while they are in the NICU, and then help them connect with needed resources as part of the discharge planning process. NICU staff will benefit from training in recognizing signs of caregivers’ social/emotional difficulties so that they can: (a) connect families with appropriate services, and (b) provide care for the family which is informed by an understanding of trauma, depression, and/or anxiety.

When parents transition home, they often encounter a confusing and fragmented service delivery system. Even when there is a wide range of programs and services available, the system can be difficult to understand, navigate, and access. This is made all the more challenging because most families are not familiar with these resources, and they are already managing competing priorities simultaneously.

Ideally, every family will have a medical home which will offer assistance with care coordination and systems navigation. Unfortunately, fragile infants and children with disabilities are less likely than healthy typically developing babies to have a medical home. In these cases, it is especially important for the NICU discharge planning process to offer opportunities for families to actually meet representatives from community programs if at all possible – or for there to be an identified person they can connect with prior to discharge who they can also meet with once they get home. Whenever possible, community service referrals should be made in the form of a “warm hand-off” – one that involves some level of personal connection.

Discharge/transition planning will be greatly enhanced when NICU and community providers work together, develop collaborative relationships, and are knowledgeable about each other’s systems and requirements. Together they can weave a safety net which will keep families from falling through the cracks at a vulnerable time in their lives. An example is the importance of NICU discharge planning staff having a detailed understanding of specific state eligibility requirements for early intervention services (e.g. occupational, physical, and speech therapy). While these services are mandated by the Federal Individuals with Disabilities Education Act (IDEA) – Part C Infants and Toddlers, each state has considerable leeway in how eligibility is determined. When NICU and community Part C providers work together, they can help assure that the referrals they submit contain the information most likely to secure eligibility – up to and including use of specific medical diagnostic terminology.

NICU staff and community providers can also work together to provide families with comprehensive information about available resources and services. As noted above, all states offer some early intervention support through IDEA, but there are a host of other programs such as hospital developmental follow-up clinics, and home-visiting services funded through Federal Maternal Infant Early Childhood Home Visiting programs (e.g. Early Head Start and Healthy Families).

In order for parents to provide a secure base for their infant, they themselves need to feel held and protected. This concept of “parallel process” is central to the field of infant mental health and critical to an understanding of NICU families as they transition home. NICU and

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community providers both have a responsibility to actively pursue collaborative relationships and partnerships with each other. The more they understand about each other’s language, systems, and constraints, the better the potential outcomes for families.

Selected Resources

The Fussy Baby® Program
www.ericson.edu/fussybaby/national-network

Boston Jewish Family and Children’s Services’ Fragile Beginnings®
www.jfcsboston.org

Smooth Way Home Program (SWH)®
www.swhd.org/programs/disabilities-services/smooth-way-home/

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Has the Magic Bullet to Prevent Kernicterus Been (Re)Discovered?

Michael Narvey, MD

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As the saying goes, “What is old is new again,” and that may be applicable here when talking about prevention of kernicterus. In the 1990s there was a great interest in a class of drugs called mesoporphyrins in the management of hyperbilirubinemia. The focus of treatment for many years had been elimination of bilirubin through the use of phototherapy but this shifted with the recognition that one could work on the other side of the equation. That is to prevent the production of bilirubin in the first place.

Tin mesoporphyrins (SnMP) have the characteristic of being able to inhibit the enzyme heme oxygenase quite effectively. By achieving such blockade the breakdown of heme to carbon monoxide and biliverdin (the precursor of bilirubin) is inhibited. In so doing, the production of bilirubin is reduced, making one less dependent on phototherapy to rid the body of elevated levels. So simple and as you might imagine a good reason for there to have been significant interest in the product. One article by Martinez et al entitled Control of severe hyperbilirubinemia in full-term newborns with the inhibitor of bilirubin production Sn-mesoporphyrin was published in 1999, and demonstrated that infants with severe hyperbilirubinemia between 48-96 hours could have their need for phototherapy eliminated by use of the product compared to 27% of the infants in the control group needing treatment. Additionally, total bilirubin samples were reduced from a median of 5 to 3 with the use of one IM injection of SnMP. This small study was hampered though by inability to really look at adverse outcomes despite its effectiveness. What has been seen however, is that SnMP, if given to infants who are then treated with white lights, can create a rash which is not seen however when special blue light is employed.

Two other studies followed exploring the use of SnMP in cases of severe hyperbilirubinemia in term infants and were the subject of a Cochrane review in 2003. The conclusions of the review essentially became the death noll for the therapy as they were as follows: “...may reduce neonatal bilirubin levels and decrease the need for phototherapy and hospitalization. There is no evidence to support or refute the possibility that treatment with a metalloporphyrin decreases the risk of neonatal kernicterus or of long-term neurodevelopmental impairment due to bilirubin encephalopathy... Routine treatment of neonatal unconjugated hyperbilirubinemia with a metalloporphyrin cannot be recommended at present.”

The literature after this basically dries up, that is, until April 2016 when a paper emerged that is best described as a story of mystery and intrigue!

Prophylactic Use of SnMP From 2003 Published in 2016!

This paper as you read it almost seems like a conspiracy story. The paper is by Bhutani et al (as in the nomogram) Clinical trial of tin mesoporphyrin to prevent neonatal hyperbilirubinemia. The study set out to answer a different question than had been previously studied. The question here was, if you provided a single IM dose of SnMP to infants who were at or above the 75th percentile on the risk nomogram, could you prevent the need for phototherapy or exchange transfusion as the primary outcome. Secondly, the authors truly wanted to demonstrate safety of the product and planned on recruiting 800 patients per arm in the study. The study appeared to be well planned and as with many studies had a safety monitoring committee which was to do interim analyses. After the first analysis the FDA became involved and recommended studies to look at a prophylactic versus therapeutic approach. Due to the interim
analysis, the study had been halted, and after the FDA made their suggestion, the study was simply never restarted as future studies were planned to look at the effectiveness and safety of the two approaches. The authors state that they planned on reporting their results in 2006/7, but elected to wait until long-term data emerged. Now, finally 9 years later, they decided to release the results of the partially completed study. The story around this study I find as interesting as the results they obtained!

So What Happened?

Before closing the study, they managed to recruit 87 into the intervention arm and 89 into the placebo group and lost none to follow-up. One dose of SnMP had a significant effect on the trajectory of curves for bilirubin production as can be seen in the first figure.

The graph demonstrates what percentage of patients had a bilirubin level above 220 umol/L (12.9 mg/dl) after the single injection of SnMP (black bars) compared to placebo (white bars).

What Can We Do with These Results?

It would be tough to argue anything other than this being an effective treatment to prevent significant hyperbilirubinemia. Unfortunately, like many studies that were never completed this one remains underpowered to conclusively demonstrate that the use of SnMP is safe in both the short-term and long-term periods. The absence of such data make it very difficult to recommend SnMP as standard of care. One has to add to this that while we have evidence to show it reduces the rate of rise of bilirubin, what we don’t know is whether in a larger study the incidence of bilirubins >425 umol/L or the need for exchange transfusion might be reduced. If this were the case, it would make for a compelling argument to try SnMP.

That is the approach for standard of care though. In the setting of a patient with a known blood group incompatibility who was at high risk for exchange transfusion, if they received IVIG and the bilirubin continued to climb might there be a role here? I would tend to say yes if we could get our hands on some. The authors, by sharing this data, have shown the medication is effective in doing what it is supposed to do. Given that, at least in our centre, all of our lights are of the new variety, the risk of rash would be nonexistent. The risk for kernicterus, or at least an exchange transfusion, though, would not be minimal. So if we have this in our toolbox, I would, after weighing the risks, opt to give it.

“The risk for kernicterus, or at least an exchange transfusion, though, would not be minimal. So if we have this in our toolbox, I would, after weighing the risks, opt to give it.”

I certainly wonder if there are places out there who have used it, and if so, what is your experience?

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Clinical Trials (from ClinicalTrials.gov)

GPS (Giving Parents Support): Parent Navigation After NICU Discharge (GPS)

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Purpose:

BACKGROUND: Annually >400,000 US newborns require Neonatal Intensive Care Unit (NICU) care; 1/3 will require ongoing or specialty care after discharge. Some NICU graduates can be classified as children with special health care needs (CSHCN) who will require health and related services of a type or amount beyond that required by children generally. NICU parents report increased anxiety and stress during their stay and transition home from the NICU. Short-term peer-to-peer programs during hospitalization decrease stress, anxiety and depression for mothers; however, no studies have evaluated the effects of long-term post-discharge peer support. Children’s National (CN) provides medical home services to CSHCN through its Parent Navigator Program (PNP). Parent Navigators (PNs) are CSHCN parents who provide peer emotional support, access to community resources, and assistance with navigating complicated health systems. NICU graduates and their caregivers may benefit from support provided by PNs after discharge. No data regarding the impact of PNs on patient and family outcomes of the NICU graduate are available.

OBJECTIVE: To assess the impact of a PNP on a parent’s self-efficacy, stress, anxiety, depression; infant health care utilization, and immunization status.

METHODS: Three hundred NICU graduates will be randomized to receive either PN for 12 months (intervention group) or usual care (comparison group). Baseline data at 1 week: 1, 3, 6, and 12 months after discharge will be collected from caregivers in both groups including: scales for self-efficacy, stress, anxiety, and depression, infant healthcare utilization, and immunization status. Outcomes will be compared at 12 months.

PATIENT OUTCOMES (PROJECTED): The study outcomes are parental self-efficacy, stress, anxiety, and depression; infant health care utilization and immunization status.

ANTICIPATED IMPACT: Prior studies utilizing small samples have suggested that peer support in the NICU can reduce anxiety and depression in caregivers. It is unclear whether peer support after discharge, when a family is faced with the total care of their child without structured supports, can significantly impact parents’ ability to care for their child. The investigators anticipate that this simple intervention will increase self-efficacy in caregivers, reduce stress, anxiety, and depression, in turn resulting in improved health outcomes for their child.

Condition:
- Premature Birth of Newborn
- Family
- Immature Newborn
- Newborn Morbidity
- Infant Newborn Disease

Intervention:
- Behavioral: Parent Navigator

- Behavioral: Care Notebook

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Supportive Care

Official Title: GPS (Giving Parents Support): Parent Navigation After NICU Discharge

Primary Outcome Measures:

- Parental Self Efficacy [Time Frame: One year] [Designated as safety issue: No] Parenting self efficacy will be measured using the Perceived Maternal Parenting Self-Efficacy (PMP SE). It is derived from multi-item scales, and will be treated as continuous measurements. The mean score will be determined at selected time points and compared between both groups over time to determine change within and between groups.

- Parental Anxiety [Time Frame: One Year] [Designated as safety issue: No] Parental anxiety will be measured using the State Trait Anxiety Inventory (STAI) in primary caregivers from the intervention and control groups at selected time periods.

- Parental Depression [Time Frame: One Year] [Designated as safety issue: No] Parental depression will be measured using the Center for Epidemiological Study Depression (CESD) in primary caregivers from the intervention and control groups at selected time periods.

- Emergency Room visits after discharge [Time Frame: One Year] [Designated as safety issue: No] Number of Emergency Room visits within 12 months after discharge

- Primary Care and Specialty Visits [Time Frame: One Year] [Designated as safety issue: No] Number of visits to the pediatrician or subspecialty provider within 12 months after discharge.

- Immunizations Status during the first year [Time Frame: One Year] [Designated as safety issue: No] Number of neonates with a complete immunization series within 12 months after discharge will be compared between groups. Complete immunization status is defined as receipt of...
A care notebook will be provided to all parents at discharge. The notebook was created to provide resources and serve as an organizer for appointments for parents of NICU graduates. It was based on peer-to-peer feedback from former NICU parents, in addition to community resources developed by current Parent Navigator Program at Children's National Health System.

Eligibility:

Ages Eligible for Study: Child, Adult, Senior

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Inclusion Criteria: parents of neonates receiving care in the Children's National NICU

Exclusion Criteria:

- Infant is not being discharged with a custodial parent (e.g., in custody of Child Protection Services).
- Neither parent can complete an interview in English, the parent who will be providing most of the care is younger than 18-years of age,
- Those with insufficient knowledge of English to participate in the telephone interviews.
- The parent/caregiver has plans to leave the District of Columbia (DC) metropolitan area permanently within the following year.

Recruiting Contacts and Locations:

Principal Investigator: Karen Fratantoni, MD, MPH
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Sponsors and Collaborators:

- Children's Research Institute
- Patient-Centered Outcomes Research Institute

ClinicalTrials.gov Identifier: NCT02643472
Other Study ID Numbers: IHS-1403-1567
Study First Received: December 22, 2015
Last Updated: February 14, 2016

Health Authority: United States: Institutional Review Board Plan to Share IPD: No

For Additional Information and Updated Changes:

https://clinicaltrials.gov/ct2/show/study/NCT02643472?term=nicu&rank=3#desc

Our Mission: To provide financial, logistical and emotional support to families facing a complex Congenital Heart Defect (CHD) who choose to travel for a Fetal Cardiac Intervention and follow up care to treat this defect.

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Very Premature Infants: Towards Better Care

Born too soon, very premature infants are particularly vulnerable and need appropriate care. The European project, EPICE (Effective Perinatal Intensive Care in Europe) - (www.epiceproject.eu), examines how medical practices based on scientific evidence are incorporated into the care of these neonates. The study, coordinated by Inserm (http://english.inserm.fr), and published in The British Medical Journal, highlights the underuse of four effective practices for improving their survival and long-term health, and estimates its impact on mortality and morbidity.

Very premature infants, born before 32 weeks of gestation, (8th month of pregnancy), represent 1-2% of all births. For these neonates, the risks of mortality and long-term neurological disorders are higher than for infants born at full term. It is essential to provide them with appropriate care in order to guarantee them better health.

The EPICE project created a population cohort in 2011, comprising all very premature infants from 19 regions in 11 countries of the European Union (Belgium, Denmark, Estonia, France, Germany, Italy, the Netherlands, Poland, Portugal, Switzerland and the United Kingdom). The goal of the project is to evaluate the "evidence-based medical practices" applied to these infants.

Evidence-based medicine, which takes research data, clinical expertise, and patient needs into consideration, enables health professionals to make care choices based on proven clinical efficacy. In this study, Jennifer Zeitlin, Inserm Research Director, studied four of these medical practices in particular, in order to measure their impact on neonatal mortality:

- Transfer of pregnant women to specialised centres designed to accommodate very premature infants - antenatal administration of corticosteroids (for maturation of the lungs),
- Prevention of hypothermia,
- Administration of surfactant (an essential substance for respiratory function that lines the pulmonary alveoli) within 2 hours after birth, or nasal positive pressure ventilation, for infants born before 28 weeks of gestation

While there was frequent use of each practice individually (75-89%), only 58% of very premature infants received all four recommended practices.

The study simulated two models to measure the impact of this inadequate care. If every infant had received all four recommended practices, mortality would have been reduced by 18%. These results demonstrate the importance of evidence-based medical care in improving the health of very premature infants.

The EPICE project is dedicated to the medical care of very preterm infants born before 32 weeks of gestation, in eleven European countries. The aim of the project is to assess practices in order to improve health care for this population of high risk babies.

The EPICE project was launched in 2011 and has been supported by the European Union (FP7) for five years. It is coordinated by Inserm, just like 27 other European "health" projects. The project involves 12 partners and 6 associate partners, based in 11 European countries.

The 12 partners:
- Inserm (coordinator), France
- SPE, Belgium
- Hvidore Hospital, Denmark
- Universitas Tartuensis, Estonia
- Philippus Universitat Marburg, Germany
- Bambino Gesu Ospedale Pediatrico, Italy
- Laziosanita Agenzia Di Sanita Pubblica, Italy
- Radboud University Nijmegen Medical Centre, the Netherlands
- Poznan University of Medical Sciences, Poland
- U.Porto, Portugal
- University of Leicester, United Kingdom
- Karolinska Institutet, Sweden
- EPICE in France

The EPICE project in France is part of a national study entitled EPIPAGE 2 (an epidemiological study on very preterm babies). It is a cohort study of very preterm infants, launched in 2011 in the 22 regions of mainland France and the French overseas departments. The study will monitor over 6000 premature children up to the age of 11 to 12. Three regions in France: Ile-de-France, Nord-Pas-de-Calais and Bourgogne participate in the EPICE project.

The EPIPAGE 2 project is managed by the Inserm unit 953 ("Epidemiological research into perinatal health and the health of women and infants"), in collaboration with team 2, from UMRS 1027, directed by Dr Catherine Amraud (Perinatal epidemiology, handicap of child and health of adolescents).

For further information on this study: www.epipage2.inserm.fr (Head of studies: Pierre-Yves Ancel, Inserm U953).

Sources

Use of evidence-based practices to improve survival without severe morbidity for very preterm infants: results from the EPICE population-based cohort.


1. Senior researcher, Inserm UMR 1153, Obstetrical, Perinatal and Pediatric Epidemiology Research Team

Mission: To foster hope in families affected by Hypoxic Ischemic Encephalopathy (HIE) through awareness, education and support

www.hopeforhie.org
12. Professor of Epidemiology, EPIUnit-Institute of Public Health Sciences, University of Leicester, Leicester, LE1 6TP, UK.

13. Head of Unit of Neonates and Infants. Tallinn Children's Hospital, Tartu, Estonia.

14. Professor of Pediatrics and Neonatal Medicine, Department of Clinical Science, Intervention and Technology, Division of Pediatrics, Karolinska Institutet; and Department of Neonatal Medicine, Karolinska University Hospital, SE 14186 Stockholm, Sweden.

15. Senior researcher, Inserm UMR 1153, Obstetrical, Perinatal and Pediatric Epidemiology Research Team (Epopé), Center for Epidemiology and Statistics Sorbonne Paris Cité,DUH Risks in pregnancy, Paris Descartes University, Paris, France.

16. Researcher, Inserm UMR 1153, Obstetrical, Perinatal and Pediatric Epidemiology Research Team (Epopé), Center for Epidemiology and Statistics Sorbonne Paris Cité, DUH Risks in pregnancy, Paris Descartes University, Paris, France.

17. Professor of Perinatal and Paediatric Epidemiology, Department of Health Sciences, University of Leicester, Leicester, LE1 6TP, UK.

18. Director of the Children’s Hospital and Chairman for Paediatrics, Children’s Hospital, University Hospital, Philippus University Marburg, Marburg, Germany.


NIH Awards UAB 3 Maternal and Infant Health Grants

The University of Alabama at Birmingham is the only university to be awarded grants in all three perinatal networks from the Eunice Kennedy Shriver National Institute of Child Health and Human Development to improve maternal and infant health.

UAB is a member of the NICHD Maternal-Fetal Medicine Units Network, NICHD Neonatal Research Network, and the NICHD Global Network for Women’s and Children’s Health Research.

Over more than two decades, these networks have brought to UAB more than $20 million to fund research for pregnant women and babies, and the new awards total a $1.1 million base per year for the next five years.

"It has been a great honor and privilege to participate in these perinatal networks for the past 25 years," said Joseph Biggio, MD, Vice Chair for Research in the Department of Obstetrics and Gynecology and Director of the UAB Division of Maternal-Fetal Medicine. "Being a member of these networks has allowed us to advance the care of pregnant women and babies, especially those who are born premature."

NICHD Maternal-Fetal Medicine Units (MFMU) Network

UAB's Division of Maternal-Fetal Medicine was awarded $200,000 per year in base funds for the next five years. UAB has participated in the cooperative agreement for 25 years as one of 14 university-based clinical centers in the MFMU Network (https://mfmu.bsc.gwu.edu).

The MFMU Network focuses on answering clinical questions in Maternal-Fetal Medicine and Obstetrics in regard to the continuing problem of preterm birth through translational research, the use of genetics, and the evaluation of new technologies in the promotion of maternal-child health and prevention of disease. This award also brings UAB an additional $500,000 to $1 million each year as a result of UAB's participation in several ongoing research projects through the Center for Women's Reproductive Health.

UAB's Division of Maternal-Fetal Medicine, in conjunction with other members of the MFMU Network, has published multiple studies identifying new practice procedures and treatments under the leadership of Alan Tita, MD, PhD, Professor in UAB's MFM division and Principal Investigator of the MFMU Network.

In April 2016, a network study was published in the New England Journal of Medicine describing the need for administering betamethasone, a steroid medication, to women at risk for late preterm delivery to reduce the risk of neonatal respiratory and other complications.

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For 25 years, UAB's Division of Neonatology has participated in the NICHD NRN and was recently awarded $200,000 in base funds per year, with an additional $500,000 to $1 million per year to conduct additional research in the network.

The NRN was established in conjunction with the MFM Units Network to do similar research in Pediatric Neonatology. Areas addressed by the NRN include: trials of therapies for sepsis, intraventricular hemorrhage, chronic lung disease and pulmonary hypertension, as well as the impact of drug exposure on child and family outcomes. Principal investigators for the network, Wally Carlo, MD, Edwin M. Dixon Endowed Chair in Neonatology, and Namasivayam Ambalavananan, MD, Co-Director of the Division of Neonatology, have led nationwide studies on ventilator care, antenatal steroids, chronic lung disease and neurodevelopmental outcomes.

A study in the NICHD NRN published in the NEJM reported that neonatal mortality has been decreased over the last 10 years, including decreases in almost all specific causes of neonatal mortality, because of improvements in care implemented in the NRN centers. A second paper showed that improvements in perinatal care, including obstetrical and neonatal interventions, are increasing survival rates substantially in the most premature babies. Survival rates are substantially increasing among those delivered at a gestational age of 20 weeks to 25 weeks and six days.

UAB has participated in the NICHD GN for more than 13 years. The most recent research grant exceeding $700,000 per year renews a partnership to help improve maternal and infant health outcomes and build health research capacity in resource-poor settings for testing cost-effective, sustainable interventions.

The National Perinatal Association (NPA) is an interdisciplinary organization that gives voice to the needs of parents, babies and families and all those interested in their health and wellbeing. Within NPA, parents and professionals work together to create positive change in perinatal care through education, parent programs, professional guidelines and events.

www.nationalperinatal.org
UAB investigators developed and led the testing of innovative interventions that reduced childhood mortality and neurodevelopmental disabilities through grants received from the NICHD GN. The resuscitation program developed and found effective by UAB investigators has been introduced in more than 75 countries to save babies’ lives at birth, with the potential to reduce infant deaths soon after birth by 1 million.

‘Early-Term’ Births Significantly Increase Risk of Preterm Births, Says Study - When First Child Born at 37 to 38 Weeks, Second More Likely to Be Born Even Earlier

A new study led by UC San Francisco researchers found that women whose first child was born at 37 to 38 weeks – so-called “early-term” birth – are two to three times more likely to experience preterm birth, defined as birth at a gestational age less than 37 weeks, when giving birth to a second child. The identification of this new risk factor may be a boon to doctors, who are rarely able to predict preterm birth, which occurs in nearly one in 10 births and is the leading cause of infant mortality.

The heightened risk was present whether a woman spontaneously delivered early, or if the birth was induced due to another medical consideration.

“The magnitude of the increased risk surprised us – it really is a potent factor,” said Laura Jelliffe-Pawlowski, PhD, Associate Professor of Epidemiology and Biostatistics at UCSF, Associate Director of Precision Health with the UCSF California Preterm Birth Initiative (PTBi-CA), and senior author of the new study.

The study, published July 11th, 2016, in Obstetrics & Gynecology, is the first systematic look at how the gestational age in a first pregnancy predicts the second, analyzing data from more than 160,000 California women who gave birth between 2005 and 2011. It comes as the preterm birth rate has inched up for the first time in more than a decade.

As in previous studies, the researchers noted additional risk factors for premature birth, which is more frequent in African-American mothers, when there is an inter-pregnancy interval of less than 6 months, with illicit drug use during pregnancy, or when mothers have been diagnosed with hypertension, preexisting diabetes, or urinary tract infections.

Preterm birth is linked to a myriad of poor health outcomes. According to the Centers for Disease Control and Prevention, preterm birth is the chief cause of infant death, as well as a major predictor of neurological problems with life-long consequences, such as cerebral palsy, developmental delays, and vision and hearing impairment.

“Delaying labor by just two weeks could make a major difference in neurologic outcomes and adult health,” said Larry Rand, MD, Associate Professor of Obstetrics, Gynecology & Reproductive Sciences at UCSF.

The new finding could expand the number of women targeted for interventions to reduce the chance of delivering preterm. The primary treatments for at-risk women are progesterone and careful monitoring of the cervix and for uterine contractions to catch signs of early labor. Progesterone can extend pregnancy, whereas signs of early labor can indicate the need for additional medical interventions to slow or stop the labor.

Jelliffe-Pawlowski suggested that clinical trials could be undertaken to confirm if women with an early-term delivery could similarly benefit from progesterone treatments in subsequent pregnancies. If progesterone proves effective in these patients, many more women at risk for a preterm birth could be treated. For example, of all first pregnancies in the current study, 5.7% of women gave birth preterm and would be considered at high risk in a second pregnancy, but a much larger group – 22% -- delivered early term, and would not be flagged for intervention under the current standard of care, even though they are at higher risk for delivering a preterm baby.

“Delaying labor by just two weeks could make a major difference in neurologic outcomes and adult health,” said Rand. “We are on the edge of a new era in prematurity prevention and improving associated outcomes – there are new blood tests that can help improve identifying who’s at risk for prematurity. When coupled with important risk factors, like maternal conditions and previous pregnancy duration, not only do we get a more precise picture of risk, but also a more informed sense of what interventions could be most powerful to mitigate those risks.”

The other key change Jelliffe-Pawlowski suggests is enhanced doctor-patient communication. She said the risk of early-term birth should be clearly conveyed, so women understand their own risks.

For the new study, researchers in UCSF’s PTBi-CA initiative collaborated with lead author Juan Yang, PhD, a research scientist at the California Department of Public Health, and additional scientists in California, Iowa, Ohio, and Philadelphia.

The study was funded by the PTBi at UCSF’s School of Medicine, the March of Dimes Prematurity Research Center at Stanford University, the March of Dimes Prematurity Research Center Ohio Collaborative, the Bill and Melinda Gates Foundation, and the Eunice Kennedy Shriver National Institute of Child Health and Development.

The PTBi is a multidisciplinary research effort to limit the number of preterm births, particularly in the initiative’s study areas of California (San Francisco, Oakland, Fresno) and East Africa (areas of Kenya, Uganda, and Rwanda). The project is supported by Lynne and Marc Benioff and the Bill and Melinda Gates Foundation. For more information, www.ucsf.edu/news_

Developmental Differences in Late Preterm Babies May Not Emerge Until After Age 2

Newswise - Developmental differences in babies born 4 to 6 weeks early may not show up until after they turn two, a new study suggests.

Researchers from C.S. Mott Children’s Hospital at the University of Michigan tracked children from infancy through kindergarten and compared developmental outcomes between late preterm infants
(born between 34 and 36 weeks); those born early term (37 to 38 weeks) and term (39 to 41 weeks).

At age two, late preterm babies were developmentally on track with peers, performing equally well on tasks such as recognizing faces and objects, understanding directions and naming items. By preschool and kindergarten, however, this group showed less than optimal math and reading scores compared to children born at full term, according to the findings published in Pediatrics.

“We found small but meaningful differences in developmental outcomes between late preterm infants and full-term groups, which if applied to larger populations, may have potentially significant long-term public health implications," says lead author Prachi Shah, MD, a Developmental and Behavioral Pediatrician at U-M’s C.S. Mott Children’s Hospital.

“We found that developmental differences began emerging between 24 months and preschool, which suggests that late preterm infants may benefit from closer developmental monitoring and interventions before starting school.”

Outcomes Among a Representative Population

Researchers analyzed data on 1,000 late preterm, 1,800 early term and 3,200 full-term infants from the Early Childhood Longitudinal Study, Birth Cohort. The study is the first to track and compare developmental outcomes of early term and at term groups in a nationally representative, population-based U.S. sample.

Authors point to potential explanations for the pattern of development in late preterm infants from nine months to kindergarten. Compared with infants born full term, the late preterm brain has lower brain volume and less distinct patterns of neural connectivity. These structural differences, including lower gray matter volume, may have implications for developmental outcomes which emerge in the preschool and early childhood period.

Limitations in tools used to track early development and subtle differences in brain development that become more noticeable with age may also help explain the lack of observable developmental differences before 24 months, researchers say.

“We have come a long way in improving outcomes for babies born early, but more research is needed to understand long-term developmental outcomes,” says senior author Julie Lumeng, MD, a Developmental and Behavioral Pediatrician at C.S. Mott Children’s Hospital.

Takeaways for pediatricians:
- Late preterm infants born slightly preterm are typically not followed in neonatal follow-up clinics and merit close developmental monitoring in the period prior to school entry.
- For the child born late preterm, the preschool and kindergarten health supervision visits are an important opportunity to inquire about skills in early reading and math including: letter and word recognition, letter sounds, number recognition, counting and recognition of colors and shapes, which are some foundational skills for school readiness.
- Promoting early literacy and numeracy in the health supervision visit is indicated for all children, but may be especially helpful for children born late preterm. Parents should be encouraged to provide opportunities to foster skills in early reading and math, including: reading to children, encouraging conversation around book sharing and practicing counting and pattern recognition.
- If a child born in the late preterm period demonstrates suboptimal early reading and math skills in the preschool and kindergarten period, the child should be referred for psychoeducational testing through the school system, with consideration for more in-depth developmental testing.
Neonatal Nurse Practitioner, St. Luke’s Children’s Hospital - Idaho!

Boise, Idaho
St. Luke’s Children’s Hospital in Boise seeks an NNP to assist with coverage in our NICU’s. The Neonatology team is comprised of 10 BC Neonatologists and 10 NNP’s. The Children’s Hospital provides a full complement of Pediatric Subspecialty services with the exception of ECMO & complex congenital heart surgery. The level IV Boise NICU is a modern 61-bed unit with 900 admissions annually providing advanced technology support (HFV, iNO, therapeutic hypothermia, non-invasive ventilation), semi-private rooms and a priority of family-centered care. The program is supported by a skilled Obstetrical department including 5 full-time MFM specialists. At this facility NNP’s provide daily rounding support and in-house night coverage along with a Neonatologist. In addition, the team provides coverage at our 12-bed, Level IIb NICU in Meridian, ID 0 just 10 miles from Boise. NNP’s provide weekend coverage and home call at this facility.

Known as the "City of Trees," Boise is Idaho’s capital city—both a cultural center and a playground for those who love the outdoors. A vibrant downtown area affords fine dining, theatre, music, and college and semi-professional sports. Whole Foods, Trader Joe’s, The Boise Co-op, and seasonal farmers markets are within a mile of the hospital. The Greenbelt follows the beautiful Boise River corridor for more than 30 miles, and the Boise foothills are home to miles of hiking and biking trails.

Twin Falls, Idaho
St. Luke’s Children’s Hospital seeks an experienced NNP to join the team in our Twin Falls location! This position currently covers nights with opportunity for future daytime coverage. The ideal candidate for this position is an experienced NNP with strong teaching skills and a desire to educate front-line staff to the higher skill set that a Level II NICU demands. Built in 2011, this state-of-the art 18-bed Level IIIa NICU with 250 admissions annually, and excellent growth potential. While based in Twin Falls, this position rotates regularly through the NICU at St. Luke’s Children’s in Boise. This provides opportunity to maintain a higher acuity skillset and consistency across the Health System NICUs. Additionally, as part of this larger practice group, coverage for time off and conferences is well-supported.

Twin Falls is located in an area of Idaho referred to as the Magic Valley. It has a population of 44,000 and is the fastest growing city in south central Idaho. It is located in the heart of a rich agricultural area of the state along the mighty Snake River. Housing is affordable, and recreational opportunities abound, with rafting, hiking, skiing, and fishing easily accessible in the immediate area. South central Idaho has a mild, 4-season, high-desert climate. Summers are hot with low humidity, great for outdoor activities. In winter, the valley is largely protected from the cold arctic fronts by the mountains to the north, with occasional snow within the city. Sun Valley, Idaho is just an hour away with excellent skiing in the winter and abundant outdoor recreation in the summer.

To learn more please contact: schechir@slhs.org or 208.493.0354
About Neonatology Today
Neonatology Today (NT) is the leading monthly publication that goes to over 4,000 BC/BE neonatologists, Perinatologists, Fellows, NNPs, and their NICU teams. Neonatology Today provides timely news and information regarding the care of newborns, and the diagnosis and treatment of premature and/or sick infants. In addition, NT publishes special issues, directories, meeting agendas and meeting dailies around key meetings.

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