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IN THIS ISSUE

PDA Closure in a Very Low-Weight Premature Infant with ADO II Device

By Jesús María Damsky Barbosa, MD; J. Alonso, MD; A. de Dios, MD
Page 1

Pulmonary Arterial Hypertension with Atrial Septal Defect in a Newborn Baby with Goldenhar Syndrome

By Preeti Srivastava, DNB; Asit Kumar Mishra, MD; Md Waseem Uddin, MD; Mrigendra Nath Tudu, MD
Page 6

NT COLUMNS

National Perinatal Association, 2015

By Raylene M. Phillips, MD
Page 9

DEPARTMENTS

Advancing Hope Act 2015

Page &

Medical News, Products & Information

By Tony Carlson, Senior Editor
Page 11

Upcoming Meetings

9th International Conference on Brain Monitoring and Neuroprotection in the Newborn 2015 Symposium

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PDA Closure in a Very Low-Weight Premature Infant with ADO II Device

By Jesús María Damsky Barbosa, MD;
J. Alonso, MD; A. de Dios, MD

Introduction

Endovascular closure of Patent Duct Arteriosus (PDA) is a procedure of choice.¹ More and more centers have started closing PDA in patients under 8 kg; PDA with substantial diameters are capable of producing severe heart failure and high morbidity in these patients. This situation is worse in premature infants where PDA is of a considerable diameter, large and tubular.²

Gregory Moore et al³ suggest that PDA ligation is associated with an extended duration of mechanical ventilation and longer hospital stays in survivors, although mortality has decreased over time.

The United Kingdom Surgical Central Cardiac Audit Database for children weighing <2.5 kg and undergoing surgery demonstrates that ligation of the arterial conduits has an 8% mortality at 30 days for this group of patients, claiming that mortality would be associated with comorbidities rather than with the surgical technique⁴ and proposes to avoid thoracotomy as a co-morbidity factor.

Since April 2011, our group has been developing a PDA closure protocol⁵ with the aim of reducing morbidity, which could be used in patients weighing <3 kg. PDA closure is achieved only by venous puncture, without arterial puncture and under strict echocardiography control.

Thus, both the use of contrast and the fluoroscopy time are reduced and potential arterial lesions, resulting from arterial puncture, are avoided.

After experience with 16 cases using this protocol in different ages and weights, we decided to start closing PDA in patients weighing <3 kg.

Case Report

A 26-week gestation preterm male patient with 15 days of chronological age, weighing 1,040 gr., required mechanical ventilation (MRA) due to congestive heart failure and pulmonary edema. The patient was transferred from another institution by a PDA complicated with an intraventricular hemorrhage.

Transthoracic echocardiography showed a PDA with left chambers dilation and moderate mitral valve regurgitation. Medical treatment with Indomethacin was soon started: two series were performed without favorable response, with persisting mitral valve regurgitation and significant left chambers dilation.

We decided to carry out an endovascular PDA closure.

The patient was transported to the cath lab in a neonatal transport incubator. When we arrived, the patient had to be conditioned because the transportation had increased the heart insufficiency due to the low temperature of the incubator (it was impossible to maintain a stable temperature), and the vibrations produced by

“Since April 2011, our group has been developing a PDA closure protocol⁵ with the aim of reducing morbidity, which could be used in patients weighing <3 kg. PDA closure is achieved only by venous puncture, without arterial puncture and under strict echocardiography control”

PLEASE READ THIS LETTER ON AN IMPORTANT BILL (ADVANCING HOPE ACT 2015) THAT IS NOW BEFORE CONGRESS

Extending this act, is a win-win for pediatric patients, physicians and the companies that provide the products and services. After reading this letter, if you agree, download the form letter and send to your Senator.

For additional information, please contact:

Saira Sultan, JD, President of Connect 4 Strategies, LLC at: saira.sultan@connect4strategies.com

SUGGESTED LETTER (See Links Below to Find your Senator and Download this letter)

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[Date]

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RE: The Advancing Hope Act of 2015

Dear [Your Senator],

As a physician who treats and serves hundreds of premature babies suffering from respiratory distress syndrome, I write to you today with great interest and concern regarding proposed legislation which will affect about 65,000 premature infants each year in the U.S. The Advancing Hope Act is a bill intended to reauthorize and make permanent a priority review program at the Food and Drug Administration (FDA), which will encourage development of new treatments for rare pediatric diseases such as RSD.

As a neonatologist at [insert name of your institution] treating these infants, I wanted to write to let you know how much institutions like ours in [insert your state] stand to benefit from additional research in rare pediatric diseases. Historically, our youngest and most vulnerable patients have been underserved and ignored in the drug development arena due to the high-risk nature and small size of pediatric patient populations. This is why many drugs used in infants and children have never been tested in these age groups, and therefore, must be used off-label.

As you are surely aware, drug development is expensive and requires many years of effort. The positive impact of an incentive program such as the Pediatric Review Voucher Program is significantly diminished if it is too short-lived or requires frequent reauthorizations. This is because the value of the incentive is not actually realized until many years after the development process has begun. Small companies like mine, our clinical researcher partners, and our investors, need confidence that approval-related incentives like the voucher will still exist when the early-stage discoveries we are developing in the clinic finally make it through the approval process and to the patients' bedsides.

I hope you will consider supporting efforts to make permanent this voucher program described in the Advancing Hope Act of 2015. This bill will significantly benefit the large, under-served population of infants and children who need new innovative therapies to ensure their best healthcare outcomes. There is a tremendous need for new therapies for these patients, many of which bear a terrible lifelong burden not only for these young patients and their families, but also costs the U.S. healthcare system billions per year to support the infants and children who may continue to require medical support throughout their lives. It is incumbent upon us to work together on behalf of those suffering these enormous challenges to create and promote programs that can benefit their health and potentially reduce overall healthcare costs.

Thank you your sincere consideration. Please contact me at [Your phone number or email] if I can be of any assistance on this important issue of making the rare pediatric priority review voucher program permanent.

Sincere regards,

[Your Name]

[Your Title]

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the movements. The whole process took around one hour.

When the patient was compensated, the procedure started.

A right femoral vein puncture was performed. The PDA was catheterized using a right coronary 4 Fr catheter, with the help of a Terumo 0.035" guide. Lateral view (see Figure 1) and right anterior oblique angiographies were performed.

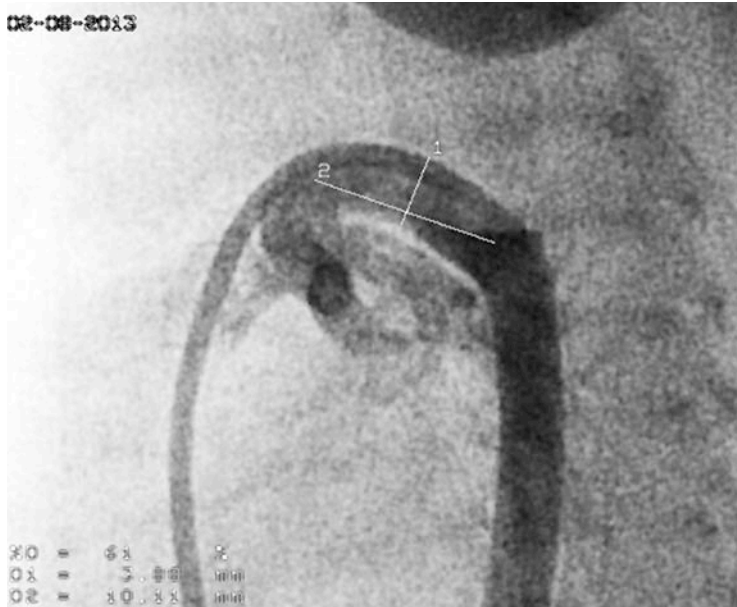


Figure 1. Lateral view: shows PDA and its measurements.

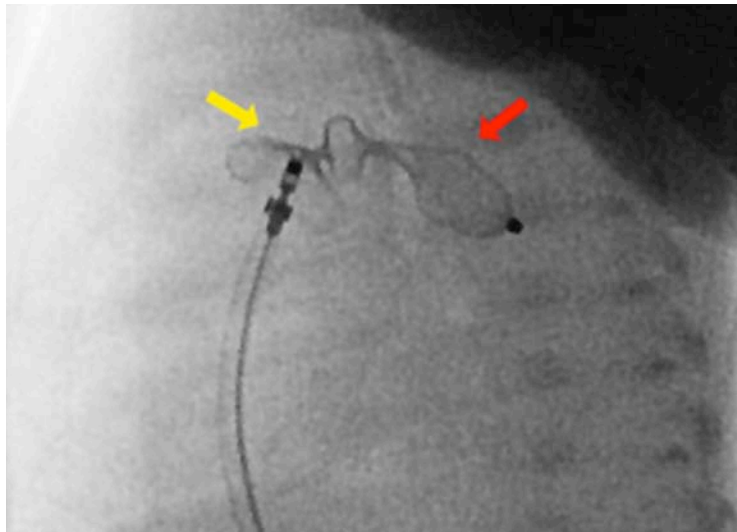


Figure 2. Lateral view: half-open left disk (red arrow) within the PDA and the right one (yellow arrow) absolutely unfolded in pulmonary artery.

The measurements of echocardiography showed that PDA had a diameter of 3.9 mm throughout its extension and a length of 10 mm.

We proceeded to occlude the PDA with an II 4-5 Amplatzer device (see Figure 2).

Transthoracic echocardiography control was then performed which ruled out left pulmonary artery stenosis or residual aortic coarctation (see Figure 3).

The total amount of nonionic contrast agent used was 6 cc, and the overall fluoroscopy time was 7 minutes.

Follow-up

At the immediate period, the pressures of the MRA were reduced because oxygenation was easier to control. The systolic hypotension and necessity for inotropics were not observed. As the pulmonary flow normalized, it reduced the size of the heart on the chest x-ray one hour after procedure.

It was impossible to wean the patient because he did not have spontaneous breathing. Therefore, this sustained situation caused a sepsis and the p ultimately died.

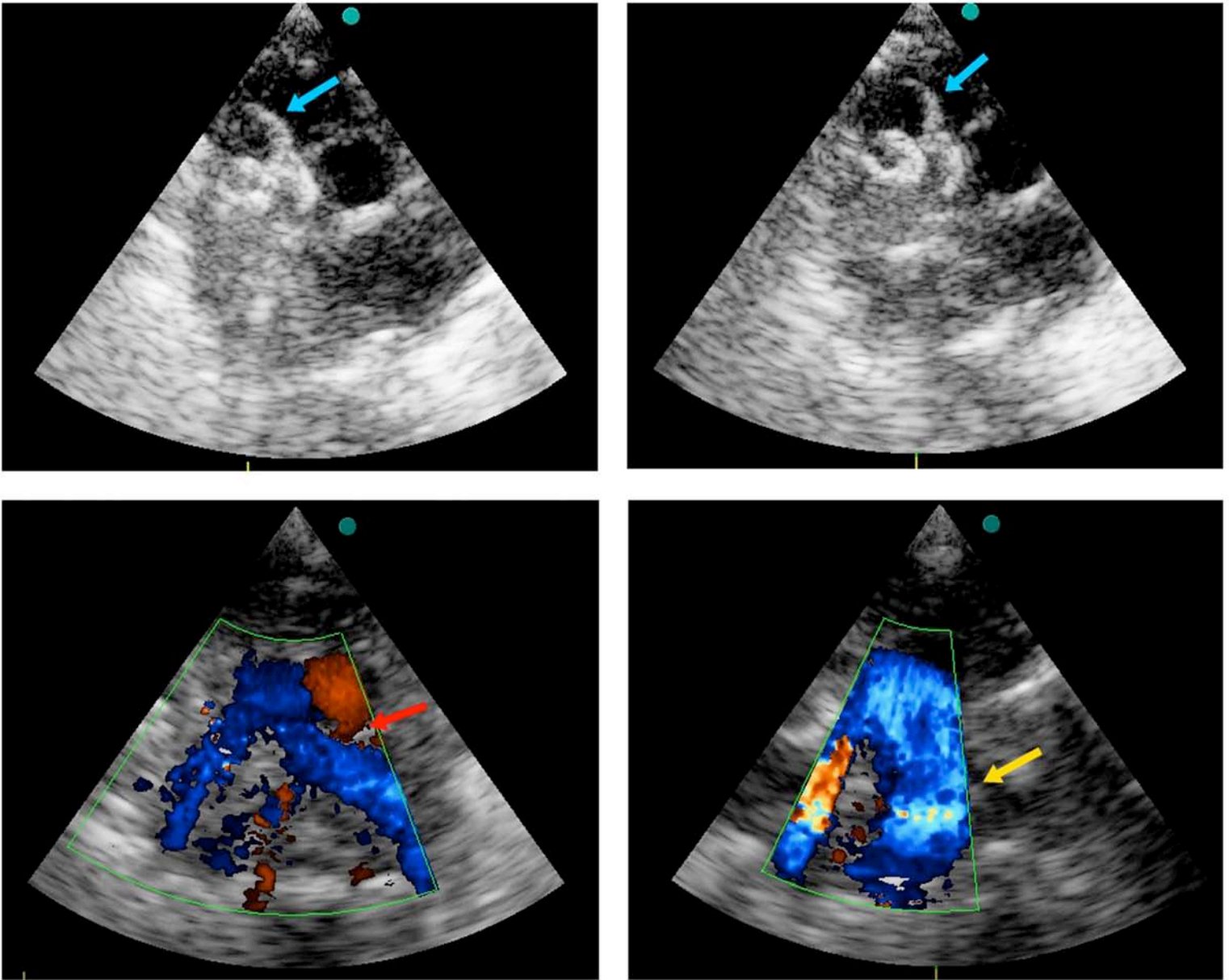
Discussion

Endovascular PDA closure in very low-weight premature patients is a developing procedure. All these patients are usually critical, under mechanical ventilation, have hemodynamic decompensation and, in general, have had a previous medical treatment without favorable response. An endovascular procedure is recommended to reduce postoperative morbidity.

“Endovascular PDA closure in very low-weight premature patients is a developing procedure. All of these patients are usually critical, under mechanical ventilation, have hemodynamic decompensation and, in general, have had a previous medical treatment without favorable response. An endovascular procedure is recommended to reduce postoperative morbidity.”

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Picture 3: Shows the device correctly positioned in the right PDA (blue arrow) and absence of residual gradient in the left pulmonary artery (red arrow) and descending aorta (yellow arrow) from suprasternal view.

To carry out this procedure,⁵ it is required to know the PDA's anatomy by transthoracic echocardiography, which allows us to decide which is the correct prosthesis for each case, and to reduce the doses of contrast and fluoroscopy time.⁶ Arterial puncture should be avoided. Accessing only by venous puncture reduces the possibility of damaging the artery.

As the procedure was carried out in the cath lab, the transportation had an impact on the results and the clinical condition of the patient had worsened.

Different prostheses have been used to close PDA in premature infants: from coils⁷ to Amplatzer devices.⁸ In this case, we decided to use ADO II instead of ADO II AS, as recommended by Neil Wilson,⁶ due to the disparate relation between the 3.9 mm diameter PDA and the 5 mm diameter Amplatzer, which caused concern for the possibility of embolization. As this was a large PDA, we decided to place an ADO II 5-4 (5 mm central body and 4 mm length with an 11 mm disk). The left disk was half-open in the PDA and the right one

entirely open in the pulmonary artery without generating gradient either on the left branch or descending aorta. The immediate result was excellent.

In the future, we hope to see the procedure carried out in the incubator, as Neil Wilson proposes.

This was the "first experience in Argentina."

Conclusion

1. PDA closure was successfully achieved in a very low-weight premature infant.

2. The procedure was done by venous vascular access.
3. TTE helped in assessing the correct position of the device and ruled out residual aortic coarctation and left pulmonary stenosis.
4. The transportation had an impact on the result that would be desirable to avoid.
5. In spite of the correct performance of the procedure, the previous clinical condition determined the success of the overall process.

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Corresponding Author



*Jesús María Damsky Barbosa, MD
Chief of Hemodynamic Laboratory
"Pedro de Elilzade" Children Hospital
Buenos Aires, Argentina
Mobile: +54 9 11 5803-8203*

jdamskyb@gmail.com

*J. Alonso, MD
Hemodynamic Laboratory,
"Dr. Juan P. Garrahan" Hospital
Buenos Aires, Argentina*

*A. de Dios, MD
Chief Unit of Cardiology
"Pedro de Elilzade" Children Hospital
Buenos Aires, Argentina*

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- The main text of the article should be written in informal style using correct English. The final manuscript may be between 400-4,000 words, and contain pictures, graphs, charts and tables. Accepted manuscripts will be published within 1-3 months of receipt. Abbreviations which are commonplace in pediatric cardiology or in the lay literature may be used.
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Pulmonary Arterial Hypertension with Atrial Septal Defect in a Newborn Baby with Goldenhar Syndrome

Preeti Srivastava, DNB; Asit Kumar Mishra, MD; Md Waseem Uddin, MD; Mrigendra Nath Tudu, MD

Introduction

Goldenhar Syndrome (oculoauriculo-vertebral dysplasia - OAVS) with hemifacial microsomia is a rare congenital anomaly involving the first and second branchial arches.

It is a disorder where the patient's facial features are incompletely developed on one side, resulting in eye, ear, and jaw abnormalities. In 85% of patients with Goldenhar Syndrome, only one side of the face is affected. Cervical spine vertebral deformities are part of the collection of symptoms.¹

The syndrome was first described in 1952 by the French ophthalmologist Maurice Goldenhar.² The incidence of Goldenhar Syndrome has been reported to be between 1:3500 and 1:5600, with a male:female ratio of 3:2(3). The exact etiology is not known. However, it is possible that abnormal embryonic vascular supply, disrupted mesodermal migration or some other factor leads to defective formation of the branchial and vertebral systems.^{3,4} Most of the cases

“It [Goldenhar Syndrome] is a disorder where the patient's facial features are incompletely developed on one side, resulting in eye, ear, and jaw abnormalities. In 85% of patients with Goldenhar Syndrome, only one side of the face is affected. Cervical spine vertebral deformities are part of the collection of symptoms.”

have been sporadic. Autosomal dominant, autosomal recessive and multifactorial modes of inheritance have also been suggested.³

Ingestion of drugs such as thalidomide, retinoic acid, tamoxifen, and cocaine by the pregnant mother may be related to the development of this syndrome. Maternal diabetes, rubella, and influenza have also been suggested as etiologic factors.⁵

The classic features of this syndrome include: ocular changes such as microphthalmia, epibulbar dermoids, lipodermoids, and coloboma; aural features such as pre-auricular tragi, hearing loss, and microtia; and vertebral anomalies such as scoliosis, hemivertebrae, and cervical fusion.^{2,5}

Systemic features are cardiac and renal malformations.^{6,7} Congenital heart defects have been reported in 5–58 % of patients with OAVS. Tetralogy of Fallot and Ventricular Septal Defects are the most common cardiovascular anomalies associated with OAVS.⁵

Here we report a rare association of Atrial Septal Defect with Pulmonary Arterial Hypertension in a newborn with Goldenhar Syndrome presenting with congestive cardiac failure.

Case Report

A 5-day-old, male baby, weighing 2.4 kg was admitted with complaints of breathing difficulty and refusal to feed for 3 days. The baby was born at 38 weeks gestational age to a 32 year old, gravida 3, para 2, abortion 1, mother by normal delivery. The baby had cried immediately after birth, and was started on breastfeeds soon after birth. Antenatal history was insignificant.

On examination, baby was sick having respiratory distress, mild icterus, head-to-foot examination revealed several anomalies in form of abnormal pinna of right ear (Figure 1), right mandibular hypoplasia, right-sided facial paralysis (Figure 2), bilateral coloboma of iris (Figure 3) and retinochoroidal coloboma. Systemic examination showed

normal lungs, hyperdynamic precordium with normal heart sounds, abdomen was soft with palpable liver 4 cm below the subcostal line. A detailed work-up was done to rule out other anomalies. CECT brain scan showed posterior falx, tentorial and bitemporal minimal cortical hemorrhage (Figure 4).



Figure 1.



Figure 2.

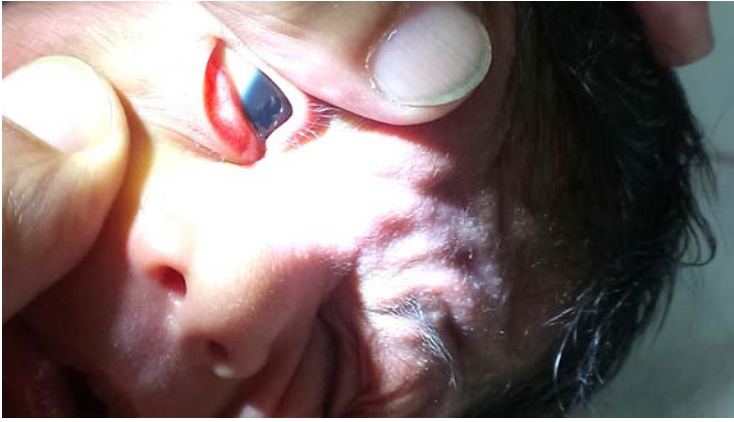


Figure 3.

Echocardiography revealed 12 mm ASD, L-R shunt, 3 mm PDA with moderate PAH (Figure 5). USG abdomen was normal. Chest X-ray and OAE were normal. X-rays of thoracic and lumbar spine were normal.

Baby was managed with antibiotics, fluid, and oxygen. Cardiac decongestive measures were added after ECHO findings. Baby gradually stabilized, and was put on feeds. He was discharged after 7 days on decongestive measures, and advised to attend a cardiac centre.

Discussion

Review of literature reveals that patients with Goldenhar Syndrome usually present in childhood, adolescence or adulthood with audiovisual or skeletal problems. They might present in infancy due to facial dysmorphism or complications arising due to Congenital Heart Disease. Frequency of cardiovascular malformations in this syndrome varies between 5-58%.^{8, 9} Cardiovascular developmental anomalies in Goldenhar Syndrome are usually severe, such as Tetralogy of Fallot, Ventricular Septal Defect, Wolf-Parkinson-White Syndrome and other vascular anomalies.^{8, 9} In our case, the baby presented in early neonatal period (on day 5) with signs of congestive heart failure. Echocardiography revealed a large ASD with small PDA and moderate PAH. The occurrence of features of CCF with the identified cardiac lesions could not be explained and hence baby was referred to higher cardiac centre for further evaluation.

This case is being reported due to the rare presentation of Goldenhar Syndrome with ASD, PAH and CCF in the early neonatal period.

Profile of Principal Author

Preeti Srivastava, DNB (Paediatrics)

Currently working as Registrar in Dept. of Paediatrics, Tata Main Hospital, Jamshedpur. The first author has had four and half years of post PG experience and is currently working in the neonatal unit for two and a half years. The author firmly believes in serving the paediatric community with competence and compassion and has a special interest in Pediatric Neurology subspecialty.

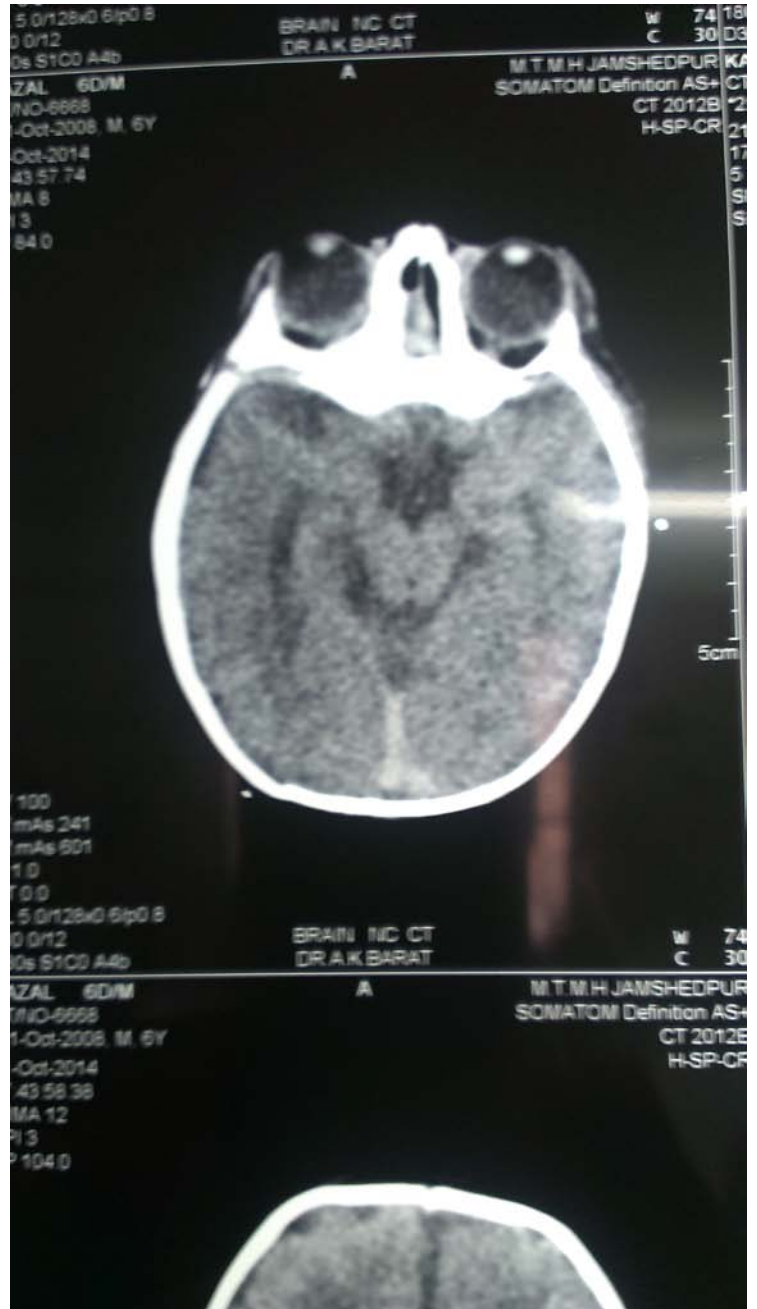


Figure 4.

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Name: **B/O KAJAL**

Age:

Id: 4889/14

Ref. By:

Sex:

Date: 22/10/2014

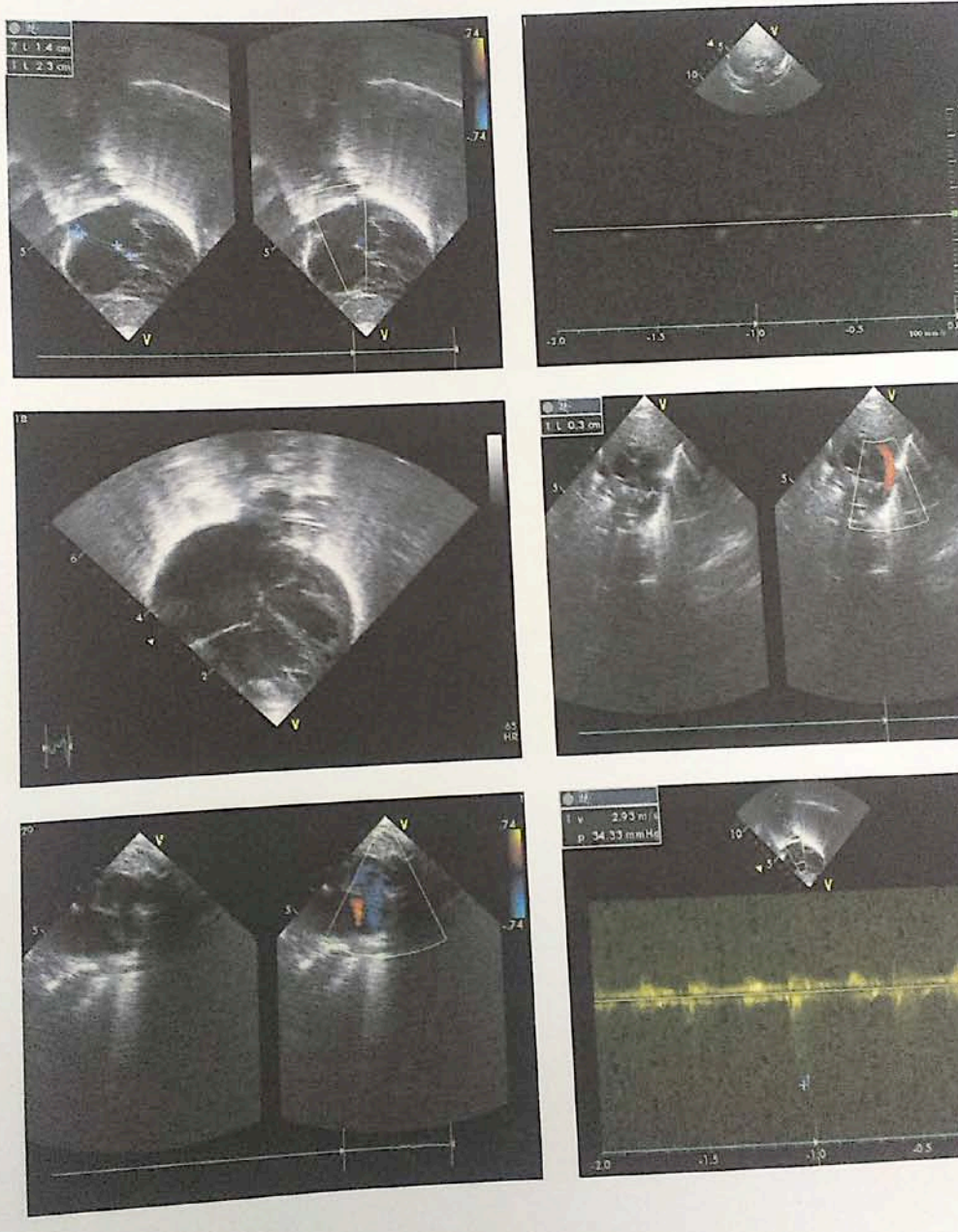


Figure 5.

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Principal Author



Preeti Srivastava, DNB (Paediatrics)
 2-A, Circuit House Area (East)
 Jamshedpur- 831001
 Jharkhand, India
 Mobile- +91 8092084743
dr.preetisri@gmail.com

Asit Kumar Mishra, MD
 Specialist-in-Charge, Neonatal Unit
 Dept. of Paediatrics
 Tata Main Hospital
 Jamshedpur

Md Waseem Uddin, MD
 Dept. of Paediatrics
 Tata Main Hospital
 Jamshedpur

Mrigendra Nath Tudu, MD
 Dept. of Paediatrics
 Tata Main Hospital
 Jamshedpur

Mrigendra Nath Tudu, MD
 Dept. of Paediatrics
 Tata Main Hospital
 Jamshedpur

NT Column: National Perinatal Association, 2015

By Raylene M. Phillips, MD

The NPA will be writing a regular column in *Neonatology Today*. Dr. Phillips and others from the association will share important news about and from the organization.



The National Perinatal Association's (NPA) unique mission is to provide a forum for all healthcare providers and caregivers involved in the care of babies, mothers and families. The goal is to communicate and work together as we search for more effective ways to provide support during the perinatal period. Our primary methods to accomplish this mission are to Convene, Educate, Advocate, and Integrate.

Last month we shared information about two upcoming events that illustrate opportunities to "Convene" including:

NPA's symposium in October 2015 (Nashville, TN) focused on substance use in pregnancy and the issues that arise for mothers, babies, families, healthcare providers and mental health professionals.

www.nationalperinatal.org/Nashville

NPA's annual conference in April 2016 (Houston, TX), which will explore the multifaceted process of modern decision making in perinatal care and the wide range of choices involving conception, prenatal care, labor management, birth sites, delivery methods, immediate postpartum care, infant feeding and more.

www.nationalperinatal.org/annualconference

This month, we will focus on how NPA fulfills its mission to "Educate." Conferences and symposiums are natural vehicles for education. In addition to our annual conference, which will now occur each spring, NPA convenes webinars,

"Because the NPA is a relatively small organization, we are extremely flexible. This gives us the ability to quickly respond to our community's needs. NPA can facilitate events in weeks to months that larger organizations take months to years to plan and execute."

summits, and symposiums on timely topics throughout the year. Because the NPA is a relatively small organization, we are extremely flexible. This gives us the ability to quickly respond to our community's needs. NPA can facilitate events in weeks to months that larger organizations take months to years to plan and execute. Whenever an individual or group within the organization identifies a need and expresses a desire to share new, evidenced-based information that will inform and update those involved in some aspect of perinatal care, NPA responds.

If someone has a passion for some aspect of perinatal care, a proposal for a position statement, a guideline, a practice update, or an event, it can be submitted to the **Board of Directors** for evaluation at info@nationalperinatal.org. If accepted, NPA will facilitate the development and execution of the proposal. For example, evidenced-based Position Statements developed by teams of experts with a passion for particular topics can be found on the NPA website and include Each bullet links directly to the topic):

- Egg Freezing
- Breastfeeding
- Choice of Birth Setting
- Depression Screening for New Fathers
- Medical Liability Reform
- Domestic Violence
- Midwifery
- Palliative Care
- NICU Developmental Care
- Substance Abuse Among Pregnant Women
- Supporting the Legal Autonomy of Pregnant Women
- Transcultural Perinatal Care



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Multidisciplinary Guidelines for the Care of Late Preterm Infants was an educational project facilitated by the NPA involving experts from 20 organizations involved in the care of late preterm infants. The Guidelines were published as a Supplement to the *Journal of Pediatrics* (2013) 33, S3-S22 (and can be found on the NPA website) with the goal of providing education for healthcare providers and parents to encourage more uniform care and decrease the high rates of preventable morbidities common in this vulnerable population. www.nationalperinatal.org/Resources/LatePretermGuidelinesNPA.pdf.

Family Advocacy Network is an NPA forum to educate and support family advocates from every arena of maternal-infant care. Webinars and phone conferences are used to share ideas and cultivate talents as participants address the medical, educational, and psychosocial needs of families. Archived webinars and phone calls and schedules for upcoming calls and events can be found on the NPA website. www.nationalperinatal.org/fan.

Psychologists in the NICU is a group that is focused on providing information relevant to the growing role of psychologists working in NICU. NICU psychologists from across the country share activities, tools and assessments used by and articles written by NICU psychologists during discussions on phone conference calls. Archived phone calls and schedules for upcoming calls can be found on the NPA website. www.nationalperinatal.org/psychologists

NPA's 2015 Respiratory Syncytial Virus (RSV) Prevention Guidelines are an educational resource to provide information about RSV, a virus that causes the common cold and can lead to significant morbidity or mortality in high risk infants. The 2015 NPA RSV Prevention Guidelines can be found in the **November 2014 issue of Neonatology Today (Volume 9/Issue 11)** and also at www.nationalperinatal.org/rsv. In this issue of *Neonatology Today*, Dr. Mitchell Goldstein, past president of NPA, gives a fresh perspective on priorities to consider when developing strategies for prevention of disease in at-risk populations.

“No matter how you are involved across the spectrum of care for mothers, babies and families, the NPA provides programs, services and opportunities to learn and engage.”

There are many opportunities in the NPA to contribute to educating professionals, care providers, and the public about issues in perinatal care. We invite you to join us in an interdisciplinary dialogue and to participate in the creation and delivery of new and innovative ways to educate. No matter how you are involved across the spectrum of care for mothers, babies and families, the NPA provides programs, services and opportunities to learn and engage. We invite you to join NPA in this exciting venture! If you would like to be involved, you can find more information on our website at www.nationalperinatal.org or contact our Director of Operations at 888-971-3295.

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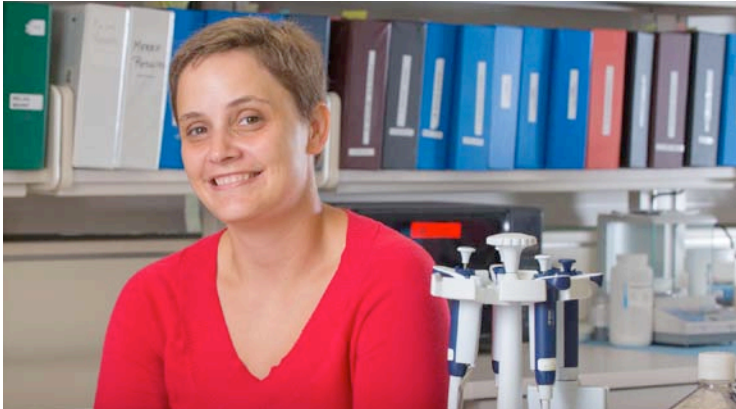
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Compiled and Reviewed by Tony Carlson, Senior Editor

Study Demonstrates Potential of Rapid Whole-Genome Sequencing in Critically Ill Infants



Laurel Willig, MD - Childrens Mercy Kansas City.

A study published recently in *The Lancet Respiratory Medicine* and presented at the annual Pediatric Academic Societies Meeting revealed the early results of the clinical usefulness of rapid whole-genome sequencing in neonatal and pediatric intensive care units (NICUs and PICUs). Children's Mercy Kansas City's STAT-Seq test helped diagnose a genetic disease in more than one half of 35 critically ill infants tested, compared to just nine percent with standard genetic tests.

As a result of receiving a specific disease diagnosis, clinical care was refined in 62% of infants, including 19% who had a markedly favorable change in treatment, and palliative care was initiated in 33%. Lead authors of the study were Laurel Willig, MD, Josh Petrikin, MD, and Stephen Kingsmore, MB, ChB, BAO, DSc, FRCPath, of Children's Mercy Kansas City.

"Genomic diseases are the leading cause of death in NICUs and PICUs, but a timely and accurate diagnosis can significantly improve the precision of the care we provide. We've shown that rapid diagnosis using whole-genome sequencing is feasible and changed management for a majority of infants that were diagnosed," said Dr. Willig, a pediatric nephrologist. "We hope STAT-Seq will be instrumental in introducing precision medicine into the NICU and PICU."

Still a research protocol, STAT-Seq is the fastest whole-genome test in the world, taking less than 50 hours from test order to delivery of an initial report. STAT-Seq can identify mu-

tations across the genome associated with approximately 5,300 known genetic diseases, and in some cases even identify previously unknown genetic diseases. In contrast, standard clinical practice calls for an array of genetic tests to be performed (94 standard genetic tests were ordered on patients in this study), which are time-consuming and can only test for a limited set of disorders.

The symptoms and signs of genetic diseases in neonates are often overlapping, making identification of a specific diagnosis difficult. Further, infants frequently show only a fraction of the full set of symptoms and signs of genetic diseases, further complicating timely diagnosis and specific treatment. STAT-Seq bypasses these difficulties by casting the widest net in defining the underlying etiology.

"STAT-Seq dramatically improves our ability to rapidly detect thousands of genetic diseases, including those we wouldn't have anticipated or that have never been seen before," said Dr. Petrikin, a neonatologist. "Armed with a precise diagnosis, we may be able to try potentially effective treatments, stop ineffective treatments, or ease discomfort by instituting palliative care."

These retrospective results underscore the importance of a larger, prospective, randomized study now under way: In September 2013, Children's Mercy became one of four pilot projects to explore newborn genomics through funding by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the National Human Genome Research Institute (NHGRI), both parts of the National Institutes of Health. Other projects include teams at Brigham & Women's Hospital at Boston Children's Hospital; University of California San Francisco and University of North Carolina Chapel Hill. Comprised of these four programs, the Newborn Sequencing In Genomic medicine and public Health (NSIGHT) program aims to explore, in a limited but deliberate manner, the implications, challenges and opportunities associated with the possible use of genomic sequence information in the newborn period. The four programs convened in April at the 6th Annual Pediatric Genomics Conference at Children's Mercy Kansas City.

Honored as one of TIME magazine's Top 10 Medical Breakthroughs of 2012, STAT-Seq is being developed in collaboration with Illumina, Inc.

For more information about Children's Mercy and its research, visit childrensmercy.org. For breaking news and videos, follow on Twitter, YouTube and Facebook.

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Loyola Study Provides Further Evidence That Premature Girls Thrive More Than Premature Boys - Findings Also Help Predict When Premies Will Go Home from Hospital

Newswise — A new study from Loyola University Medical Center provides further evidence that female infants tend to do better than males when born prematurely.

The study found that female infants independently orally fed one day earlier than males. The ability to suck, swallow and breathe simultaneously are reflexes that many premature infants are unable to do. Learning to master these skills and eat independently without feeding tubes is necessary before an infant can safely go home from the hospital.

Researchers set out to determine the mean age when premature infants are able to eat orally from a bottle or the breast and whether gender, gestational age, delivery route or birth year affects this reflex.

They conducted a retrospective review of 2,700 preterm infants born before 37 weeks of pregnancy who were admitted to a level III neonatal intensive care unit between 1978 – 2013. They found that premature infants achieved independent oral feeding at 36 weeks and four days on average. In addition to their gender findings, researchers revealed that being born before 29 weeks of pregnancy negatively influenced the infants' ability to eat independently (37 weeks and three days versus 36 weeks and one day for babies born between 29 – 33 weeks of pregnancy and 36 weeks and three days for babies born late preterm between 34 – 36 weeks and six days of pregnancy). Preterm infants born with severe complications also experienced a delay in independent oral feeding.

Babies born vaginally transitioned to independent oral feeding three days earlier than babies born via C-section. Preterm infants born before 2000 also achieved independent oral feeding two days later than babies born more recently. These findings were published in the latest issue of the *Journal of Neonatal-Perinatal Medicine*.

Since 1981, the preterm birth rate in the United States has increased by more than 33%, and in 2012, 11.5% of all births were preterm (<37 weeks of pregnancy), with 29% of preterm births occurring before 34 weeks of pregnancy. Many advances in medical care have led to improved survival of extremely preterm infants. However, despite increased survival, those born at less than 28 weeks continue to have a high incidence of medical complications. The average length of stay in the NICU has risen due to the increasing survival of extremely preterm infants.

This study confirms that the majority of preterm newborns can be safely discharged three to four weeks before their due date. At this time, newborns are mature enough to maintain their temperature, consistently gain weight and coordinate sucking, swallowing, eating and breathing without gagging or choking.

“This study gives us insight into the factors that influence when an infant is likely to eat independently without complications,” said Jonathan Muraskas, MD, senior author, and

Co-Medical Director, Neonatal Intensive Care Unit, Loyola University Health System, and professor, Loyola University Chicago Stritch School of Medicine. “This information will allow parents and the healthcare team to better plan for when the infant will go home from the hospital.”

Other study authors included: Sarah Van Nostrand, DO, Larry Bennett, MD, medical student Victoria Coraglio and biostatistician Rong Guo from Loyola University Health System.

Premature Birth Alters Brain Connections

Premature birth can alter the connectivity between key areas of the brain, according to a new study led by King's College London. The findings should help researchers to better understand why premature birth is linked to a greater risk of neurodevelopmental problems, including autistic spectrum disorders and attention deficit disorders.

The NIHR-funded study, published in the journal *PNAS*, used functional magnetic resonance imaging (fMRI) to look at specific connections in the brains of 66 infants, 47 of whom were born before 33 weeks and were therefore at high risk of neurological impairment, and 19 born at term. The brain connections investigated were between the thalamus and the cortex, connections which develop rapidly during the period a preterm infant is cared for in a neonatal unit.

Researchers found that those born in the normal window of birth (37-42 weeks) showed a remarkably similar structure to adults in these brain regions, strengthening existing evidence that the brain's network of connections is quite mature at the time of birth.

However, infants born prematurely (before 33 weeks gestation) were found to have less connectivity between areas of the thalamus and particular areas of the brain's cortex known to support higher cognitive functions, but greater connectivity between the thalamus and an area of primary sensory cortex which is involved in processing signals from the face, lips, jaw, tongue, and throat.

The greater the extent of prematurity, the more marked were the differences in the pattern of brain connectivity.

The authors suggest that the stronger connections involving face and lips in babies born preterm may reflect their early exposure to breastfeeding and bottlefeeding, while the reduced connectivity in other brain regions may be linked to the higher incidence of difficulties seen in later childhood. Dr Hilary Toulmin, first author from the Centre for the Developing Brain at King's College London, said: 'The next stage of our work will be to understand how these findings relate to the learning, concentration and social difficulties which many of these children experience as they grow older.'

Professor David Edwards, senior author from the Centre for the Developing Brain at King's College London, said: 'The ability of modern science to image the connections in the brain would have been inconceivable just a few years ago, but we are now able to observe brain development in

babies as they grow, and this is likely to produce remarkable benefits for medicine.'

Survey Finds Miscarriage Widely Misunderstood: Guilt, Shame and Lack of Emotional Support Are Common after Miscarriage

Newswise — A survey of more than 1,000 U.S. adults has found that misperceptions about miscarriage and its causes are widespread. Results of the survey, conducted by researchers at Albert Einstein College of Medicine of Yeshiva University and Montefiore Health System, show that feelings of guilt and shame are common after a miscarriage and that most people erroneously believe that miscarriages are rare. The findings were published online May 11th in the journal *Obstetrics & Gynecology*.

Nearly one million miscarriages occur in the U.S. each year. Miscarriages end one in every four pregnancies and are by far the most common of all pregnancy complications. Yet 55% of respondents to the Einstein/Montefiore survey believed that miscarriages are “uncommon” (defined in the survey as less than 6% of all pregnancies).

“Miscarriage is a traditionally taboo subject that is rarely discussed publicly,” said Zev Williams, MD, PhD, Director of the Program for Early and Recurrent Pregnancy Loss (PEARL) at Einstein and Montefiore. “We initiated this survey to assess what the general public knew about miscarriage and its causes and how miscarriage affects them emotionally.” Dr. Williams is also Assistant Professor of Obstetrics & Gynecology and women’s health, and of genetics, at Einstein.

Dr. Williams and colleagues devised a 33-item survey to assess perceptions of miscarriage; 10 items were specifically directed to men or women reporting a history of miscarriage. The survey was posted online using Amazon.com’s MTurk, a crowdsourcing web service. The anonymous participants—adults 18 or over from 49 states—received 25 cents as compensation. Of the 1,084 valid survey responses collected over a 3-day period in 2013, 45% were from men and 55% from women. Fifteen percent reported that they or their partner had suffered a miscarriage. Participants generally mirrored 2010 national census statistics with respect to gender, age, religion, geographic location and household income.

Among other significant survey findings:

- Twenty-two percent of participants incorrectly believed that lifestyle choices during pregnancy (such as smoking or using drugs or alcohol) are the single most common cause of miscarriage, more common than genetic or medical causes. Actually, 60% of miscarriages are caused by a genetic problem – abnormal chromosomes. Other established causes include structural abnormalities of the uterus, endocrine disorders such as hypothyroidism, and autoimmune disorders such as anti-thyroid antibodies. Less-educated respondents – defined as not having completed college – were twice as likely as higher-educated respondents to believe lifestyle choices are the most common cause; men were 2.6 times likelier than women to have this misperception.

- Twenty-eight percent of those suffering a miscarriage reported that celebrities’ disclosure of miscarriage had eased their feelings of isolation, and 46% said they felt less alone when friends disclosed their own miscarriages.
- Participants incorrectly believed that a stressful event (76%) or longstanding stress (74%) can cause miscarriage. Other incorrectly perceived causes of miscarriage included lifting heavy objects (64%), having had a sexually transmitted disease (41%), past use of an intrauterine device (IUD) (28%), past use of oral contraceptives (22%) and getting into an argument (21%).
- Of men and women reporting that they or their partner had experienced a miscarriage, 47% reported feeling guilty, 41% felt they had done something wrong, 41% reported feeling alone and 28% reported feeling ashamed. Only 45% felt they had received adequate emotional support from the medical community.
- Thirty-six percent of participants—including those who had never experienced pregnancy loss—reported that suffering a miscarriage would be extremely upsetting, equivalent to losing a child.
- An overwhelming majority (88%) of participants would want to know the cause of a miscarriage if something could be done to prevent a future miscarriage, and 78% would want to know the cause even if nothing could be done to prevent a miscarriage in the future.

“The results of our survey indicate widespread misconceptions about the prevalence and causes of miscarriage. Because miscarriage is very common but rarely discussed, many women and couples feel very isolated and alone after suffering a miscarriage. We need to better educate people about miscarriage, which could help reduce the shame and stigma associated with it,” said Dr. Williams. “We want people who experience miscarriage to know that they’re not alone—that miscarriages are all too common and that tests are available to help them learn what caused their miscarriage and hopefully to help them in subsequent pregnancies.”

The article is titled “Public Perceptions of Miscarriage: A National Survey.” Other PEARL-affiliated authors were former Einstein medical students, lead author Jonah Bardos, MD, MBE, now a resident at Mount Sinai Medical Center, New York, NY; and Jenna Friedenthal, MD, now at New York University-Langone Medical Center, New York, NY. Additional authors were: Daniel Hercz, MSc, at University of Sydney Medical School, Sydney, Australia; Stacy Missmer, ScD, at Harvard School of Public Health, Boston, MA.

The research was supported by the department of obstetrics & gynecology and women’s health at Einstein and Montefiore and the National Institutes of Health (HD068546). The authors report no conflicts of interest.

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tion health perspective that focuses on the comprehensive needs of the communities it serves. For more information please visit www.montefiore.org.

Hospital to Create Emergency Experiences Using Virtual Reality: Walk Around Inside Crisis Situations

Next Galaxy Corp. in May announced the signing of an agreement with Miami Children's Hospital. Next Galaxy will develop immersive Virtual Reality medical instructional content for patient and medical professional education using the Company's VR Model. Per the multi-year agreement, Next Galaxy and Miami Children's Hospital are jointly creating VR Instructionals on cardiopulmonary resuscitation (CPR) and other lifesaving procedures, which will be released as an application for smartphones.

Incorporating eye gaze control, gestures, and voice commands while "walking around" inside an emergency medical experience or crisis, Next Galaxy's Virtual Reality Model engages participants far beyond today's methodology of passively watching video and taking written tests.

"Assessments are incorporated directly into the medical VR models. We will design situations where participants are required to make the appropriate decisions about proper techniques. The Virtual CPR instructional will measure metrics and provide real-time feedback ensuring participants accurately perform CPR techniques. Further, the instructional will explain any mistake and prompt users to try again when errors are made. Supportive messages are delivered upon success," states Mary Spio CEO, Next Galaxy Corp.

The medical VR models will be viewable through smartphones and desktops as 3D, and via VR devices such as Google Cardboard, VRONE and Oculus Rift.

Next Galaxy Corporation is a leading developer of innovative content solutions and fully Immersive Consumer Vir-

tual Reality technology. For further information, www.nextgalaxycorp.com.

Wellington Regional Medical Center Selects Digisonics Cardiovascular Information System

Wellington Regional Medical Center in Wellington, Fla. has selected the Digisonics Cardiovascular Information System (CVIS) for their echo and cardiac catheterization studies. The hospital's clinicians will utilize the Digisonics CVIS to quickly review images and create structured reports for their cardiology studies. Users will also benefit from fully-functional web-based access to the entire cardiovascular information system from anywhere at anytime.

Wellington Regional Medical Center's cardiac catheterization structured reporting workflow will be streamlined by a HemoLink interface to connect the hospital's GE MacLab hemodynamics system and the Digisonics CVIS. Patient demographics, hemodynamic measurements, medications and other data will be auto-populated directly into the study, reducing entry time and eliminating potential entry errors. The facility will also benefit from integration with Cedaron for seamless registry reporting to Cath PCI.

Digisonics Search Package, a comprehensive, user-configurable search engine, will be implemented at Wellington Regional Medical Center for their echo and cath patient study database. This powerful tool allows the facility to quickly set up search criteria to extract clinical information for use in research, compile statistics required for accreditation and generate management reports for improved productivity.

The hospital will benefit from seamless integration with their incumbent vendor systems for steamlined workflow. HL7 interfaces for Orders In and Results Out will connect their Cerner EMR with the Digisonics CVIS. A DigiLink add-on to the HL7 Results Out interface provides their clinicians with access to PDFs of the finalized cardiology reports within

their EMR. Integration with the facility's Philips ultrasound machines will auto-populate the patient demographics and measurements directly into the Digisonics structured report. DICOM Modality Worklist will automate transfer of patient demographics to the facility's imaging modalities, creating a list of scheduled patient studies, and significantly reducing manual data entry time.

As a result of implementing the Digisonics Cardiovascular Information System, Wellington Regional Medical Center will create a seamless digital workflow for improved efficiency, greater reporting accuracy and faster report turnaround times.

For further information, www.digisonics.com.

How Does Human Behavior Lead to Surgical Errors? Mayo Clinic Researchers Count the Ways

Newswise — Why are major surgical errors called "never events?" Because they shouldn't happen — but do. Mayo Clinic researchers identified 69 "never events" among 1.5 million invasive procedures performed over five years and detailed why each occurred. Using a system created to investigate military plane crashes, they coded the human behaviors involved to identify any environmental, organizational, job and individual characteristics that led to the never events. Their discovery: 628 human factors contributed to the errors overall, roughly four to nine per event. The study results were published in the journal *Surgery*.

The "never events" included performing the wrong procedure (24), performing surgery on the wrong site or wrong side of the body (22), putting in the wrong implant (5), or leaving an object in the patient (18). All of the errors analyzed occurred at Mayo; none were fatal.

The Mayo Rochester campus rate of never events over the period studied was roughly 1 in every 22,000 proce-

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dures. Because of inconsistencies in definitions and reporting requirements, it is hard to find accurate comparison data, but a recent study based upon information in the National Practitioner Data Bank estimated that the rate of such “never events” in the United States is almost twice that in this report, approximately 1 in 12,000 procedures.

Nearly two-thirds of the Mayo never events occurred during relatively minor procedures such as anesthetic blocks, line placements, interventional radiology procedures, endoscopy and other skin and soft tissue procedures.

Medical teams are highly motivated and skilled, yet preventing “never events” entirely remains elusive, says senior author Juliane Bingener, MD, a gastroenterologic surgeon at Mayo Clinic. The finding that factors beyond “cowboy-type” behavior were to blame points to the complexity of preventing never events, she says.

“What it tells you is that multiple things have to happen for an error to happen,” Dr. Bingener says. “We need to make sure that the team is vigilant and knows that it is not only OK, but is critical that team members alert each other to potential problems. Speaking up and taking advantage of all the team’s capacity to prevent errors is very important, and adding systems approaches as well.”

For example, to help prevent surgical sponges from being left in patients, Mayo Clinic installed a sponge-counting system and uses that bar code-scanning system and vigilance by the surgical team to track sponges. Other preventive systems include use of The Joint Commission health care quality organization’s Universal Protocol, team briefings and huddles before a surgery starts, a pause before the first incision is made, and debriefings using a World Health Organization-recommended safety checklist.

To investigate the “never events,” the researchers used human factors analysis, a system first developed to investigate military aviation accidents. They grouped errors into four levels that included dozens of factors:

- “Preconditions for action,” such as poor hand-offs, distractions, overconfidence, stress, mental fatigue and inadequate communication. This category also includes channeled attention on a single issue: In layman’s terms, focusing so much on a tree that one cannot see the forest.
- Unsafe actions, such as bending or breaking rules or failing to understand. This category includes perceptual errors such as confirmation bias, in which surgeons or others convinced themselves they were seeing what they thought they should be seeing.
- Oversight and supervisory factors: Inadequate supervision, staffing deficiencies and planning problems, etc.
- Organizational influences: Problems with organizational culture or operational processes.

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In addition to systems approaches and efforts to improve communication, attention should be paid to cognitive capacity, such as team composition, technology interfaces, time pressures and individual fatigue, the researchers say.

The stakes are high for patients, physicians and hospitals, Dr. Bingener says.

“The most important piece is the patient perspective. You don’t want a patient to have to experience a ‘never event.’ The breach in trust that happens with that is the most important part,” she says.

The study was funded in part by National Institute of Diabetes and Digestive and Kidney Diseases grant K23DK93553. The research team included members of the Mayo Clinic Department of Surgery, the Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Quality Management Services and Pulmonary and Critical Care Medicine.

Disclosures: Dr. Bingener is supported through an NIDDK research grant, specified research through Nestle and Stryker Endoscopy, has received travel support from Intuitive Surgical, and serves on Titan Medical’s Surgeon Advisory Board. Co-author Su-

san Hallbeck, PhD, receives grant funding from Stryker Endoscopy.

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Publication Headquarters

8100 Leaward Way
PO Box 444
Manzanita, OR 97130 USA
www.NeonatologyToday.net

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