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Loma Linda Publishing Company Acquires Neonatology Today

By Mitchell Goldstein, MD

I would like to start off by thanking Tony Carlson, Dr. John Moore and Richard Koulibanis for starting *Neonatology Today* and creating what I believe is the most provocative format for publication in Neonatology. Over the many years that I received the publication, I have seen it develop into a very contemporary source of new information, all while literally embracing the field of Neonatology.

At the *Pediatric Academic Society Meeting* this past spring, Tony Carlson and I had lunch. We discussed the future of *Neonatology Today*. As President of the National Perinatal Association, I and the organization as a whole had contributed significantly to the volume of published manuscripts. Tony wondered whether I might be interested in running the publication. We both left the meeting motivated to see if we could make this work. After exploring several options for a new home for *Neonatology Today*, and much thought and careful consideration, I determined the best course for *Neonatology Today* would be to bring it to a respected academic institution with experience in fact-based writing, editing and publishing. This led me to discussions with the academic division at Loma Linda University.

After significant vetting, it was decided that the Division of Neonatology in the Department of Pediatrics at Loma Linda University School of Medicine would fund the creation of a not-for-profit publishing company that would acquire *Neonatology Today*. As such, it gives me great pleasure to announce the formation of Loma Linda Publishing Company (A 501-C3 Delaware Corporation). From March 2018, we will assume publication control of *Neonatology Today* from Tony, John and Richard.

What does this mean for you, our readers?

We plan on continuing the current look and feel of the publication and will continue to publish monthly. But there will be some changes “under the hood.”

1. All manuscripts submitted will be peer-reviewed. I will be contacting our editorial board and plan to add additional reviewers as needed to

“After significant vetting, it was decided that the Division of Neonatology in the Department of Pediatrics at Loma Linda University School of Medicine would fund the creation of a not-for-profit publishing company that would acquire Neonatology Today.”

accommodate the demand. My commitment will be to provide feedback on any submission in fewer than 14 business days.

2. We will actively solicit and publish case reports that provide insights into management of complex conditions confronting practicing neonatologists. Although many journals have discouraged case report submission, it is our feeling that these provide a way of disseminating meaningful academic information that may not otherwise see the light of day.
3. We will be making *Neonatology Today* a multidisciplinary publication, open to all professionals who engage in academic pursuits in the fields of Neonatology, Perinatology, and Pediatrics.
4. We hope to increase our readership by striving to be first to report on innovative new concepts in all of the associated specialties.
5. We will expand our readership by adding an international component to our board.
6. We will continue to commit to not charge authors for publication of their manuscripts.
7. Highlighting the work of The patient and provider advocacy community including organizations like the National Coalition for Infant Health (NCfIH), (infanthealth.org).
8. We will start having monthly open conference calls for our readers to

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In 2004, the American Academy of Pediatrics published guidelines for the management of hyperbilirubinemia.³ Since then, there have been only modest treatment advancements in jaundice. The current standard of care requires periods of isolation that can compromise the potential of the mother-infant bond.⁵

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“... it gives me great pleasure to announce the formation of Loma Linda Publishing Company (A 501-C3 Delaware Corporation). From March 2018, we will assume publication control of Neonatology Today from Tony, John and Richard.”

comment on and make suggestions on how to make NT a better publication.

9. We will have a dedicated message line for questions, concerns, and comments.
10. We will continue to provide the journal for free to our readers.

I look forward to serving you.

Sincerely,

Mitchell Goldstein, MD
Editor-In-Chief
Neonatology Today

NT

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Neonatology Today 2006-2018: A Brief History

by Tony Carlson, Founder

In the early 1990's, my neighbor was Dr. John Moore, a well-known Pediatric Cardiologist and currently Director, Division of Cardiology at Rady Children's Hospital. Our kids were close in age and played the same sports. John and I spent many years watching our kids grow up and play sports together. One day I asked John what he did. He said he was a Pediatric Cardiologist and I asked what is that. He said it is like being a "plumber" for children with heart problems. I told him that I created and published custom publications for technology companies like Microsoft, HP, and others focused on solving problems for their customers. John felt there was no publication focused on Pediatric Cardiology because the Cardiology market was 90% adult and 10% children. After 10 years of talking about it, we finally launched *Congenital Cardiology Today* (CCT) in September 2003, and it was very well-received! We are now in our 16th year as a worldwide monthly publication.

When I met Dr. Alan Spitzer in 2004, he was a Neonatologist and a Pediatric Cardiologist at PEDIATRIX. We met at various cardiology and neonatology meetings including *Tiny Baby* (now *NEO, The Conference for Neonatology*). We talked about the possibility of a medical publication focused editorially on Neonatology, Perinatology and the NICUs with a similar format as CCT. Alan agreed that the benefits of a similar publication for Neonatologists, Perinatologists and their NICU teams would be a needed resource. In May 2006, we launched the first monthly issue of *Neonatology Today*. We now have 4,000 readers (Neonatologists, Perinatologists, and their NICU teams of Fellows, and NNPs) at 1,045 NICUs throughout the USA and Canada.

I met Dr. Mitchell Goldstein, Director of Neonatal ECMO at Loma Linda University Children's Hospital, and have known each other for many years. With Mitchell's NICU experience and being a prolific writer, it was a good match from the start. He was added to the *Neonatology Today* Editorial Board, and since then he has authored many quality articles that we published. As I "matured" and wanted more time to spend with my grandkids, I asked Mitchell if he would be interested in running the publication. I wanted to make sure *Neonatology Today* would be in the best hands. And the rest is history.

On behalf of myself and my two business partners, Dr. John Moore, and Richard Koulbanis, I want to thank our readers and the companies that have supported us for making our dream become a reality for the past 12 years.

“On behalf of my two business partners, Dr. John Moore, and Richard Koulbanis, I want to thank our readers and the companies that have supported us for making my dream become a reality for the past 12 years.”

Tony Carlson
Founder
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Effect of Type of Feeding on Infants with Neonatal Abstinence Syndrome

By Ahmad Aboaziza, MD; Darshan Shah, MD; Jennifer Gibson MD; Des Bharti, MD

Introduction

The incidence of Neonatal Abstinence Syndrome (NAS) continues to rise in the United States as the number of pregnant mother using opioids continues to grow.¹ As reported in recent literature, the incidence of NAS had nearly tripled from year 2000 to 2009.^{2,3} With the increase incidence of infants diagnosed with Neonatal Abstinence Syndrome, heavy hospitalization costs continue to escalate.^{1,4}

This study aims to explore the effect of feeding type (breast milk, formula, or both) on the length of stay (LOS), requirement of replacement therapy, and relapse rates in infants diagnosed with Neonatal Abstinence Syndrome.

Methods

We conducted a retrospective chart review of 200 neonates admitted to a Level III Neonatal Intensive Care Unit with a diagnosis of NAS without comorbidity between August 2012 and August 2014. Approval for this study was obtained from the Institutional Review Board (IRB). During each infant's hospitalization, an institutionally-developed objective scoring tool was used to assess signs of NAS every 4 hours, and neonates were treated

“As reported in recent literature, the incidence of NAS had nearly tripled from year 2000 to 2009.^{2,3} With the increase incidence of infants diagnosed with Neonatal Abstinence Syndrome, heavily hospitalization costs continue to escalate.^{1,4.}”

with opiate replacement therapy for two consecutive scores >10. Patients were discharged when they had no increased scores for 48 hours after the morphine was discontinued. The information collected included gestational age, feeding type, LOS (measured in days), and requirement of opiate replacement therapy, as well as information about recurrence of NAS signs after weaning of replacement therapy or treatment discontinuation. T-test, F-test, chi-square test, and fisher test were used to compare the outcomes of the subgroups.

Results

In the study population, 22 babies (11%) were fed exclusively breast milk (BMB), 122 (61%) were fed exclusively formula (FFB), and 56 (28%) were fed both breast milk and formula (BFB) (Figure 1).

The LOS was significantly longer ($p < 0.0001$) in FFB (mean 20.4 days) than

in either BMB (10.6 days) or BFB (13.8 days) regardless of gestational age (Figure 2).

Formula fed babies were significantly more likely ($p = 0.0004$) to require opiate replacement (90.2%) than BMB (59.1%) and BFB (75.0%). FFB were also significantly more likely ($p = 0.0153$) to experience relapse of NAS signs after discontinuation of opiate replacement and during the weaning process (30.3%) than BMB (9.1%) and BFB (14.3%) (Figure 3).

Conclusion

In this study, infants diagnosed with NAS who were fed exclusively formula had significantly increased length of hospital stay, and increased requirement for opiate replacement therapy. The exclusively formula fed infants also had increased episodes of failed weaning of opiate replacement with relapses of NAS

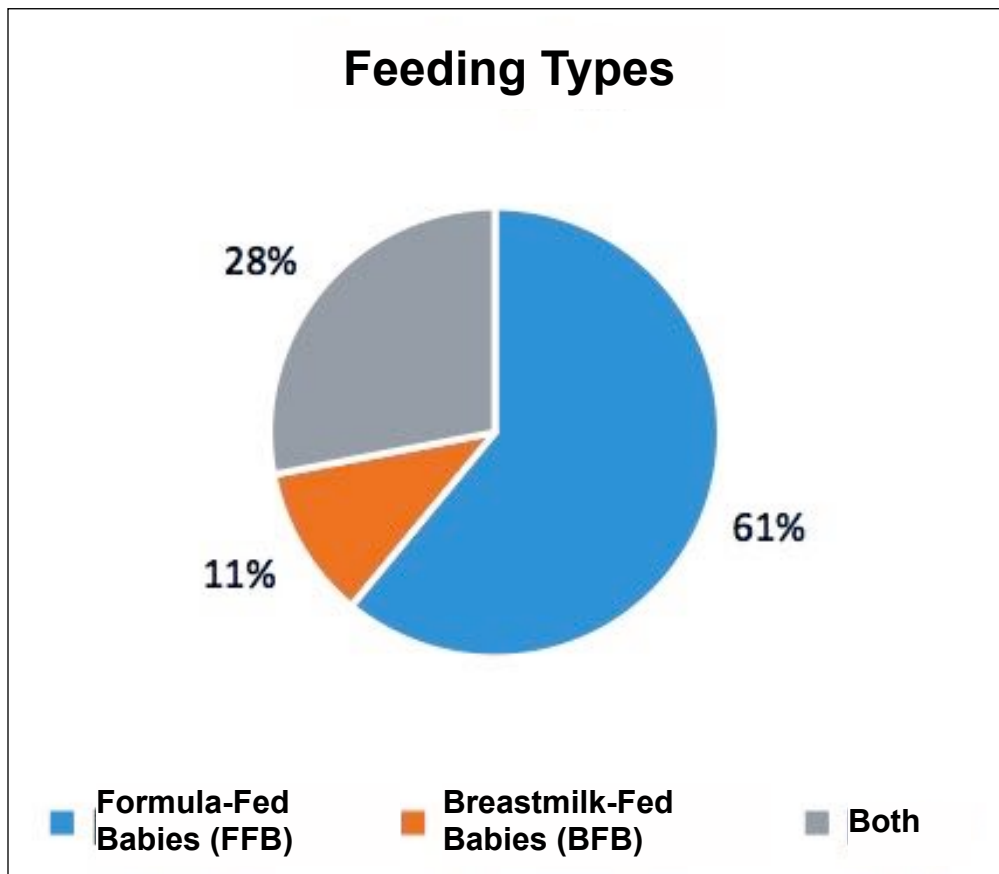


Figure 1. Pie chart shows the number of infants (in percentage) per feeding type received.



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Dr. Ahmad Aboaziza is currently a PGY-5 NiCU Fellow working at East Carolina University/Vidant Medical Center in Greenville, NC. His hometown is San Diego, CA. Dr. Aboaziza attended medical school at University of Benghazi, Libya, and completed his pediatric residency training at East Tennessee State University, Johnson City, TN. He enjoys soccer, traveling, and swimming.

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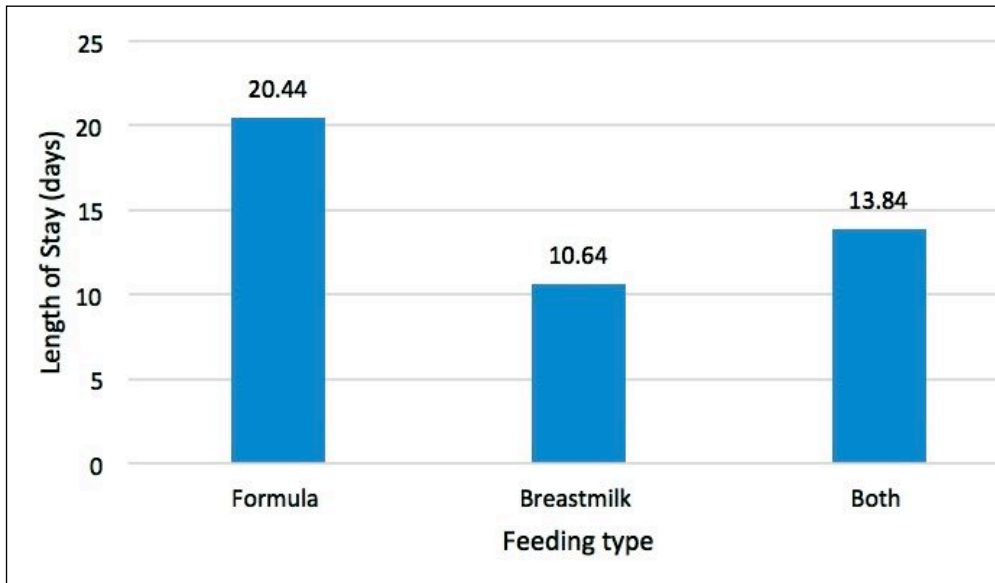


Figure 2: Bar graph comparing length of hospital stay (in days) to type of feeding among NAS babies.

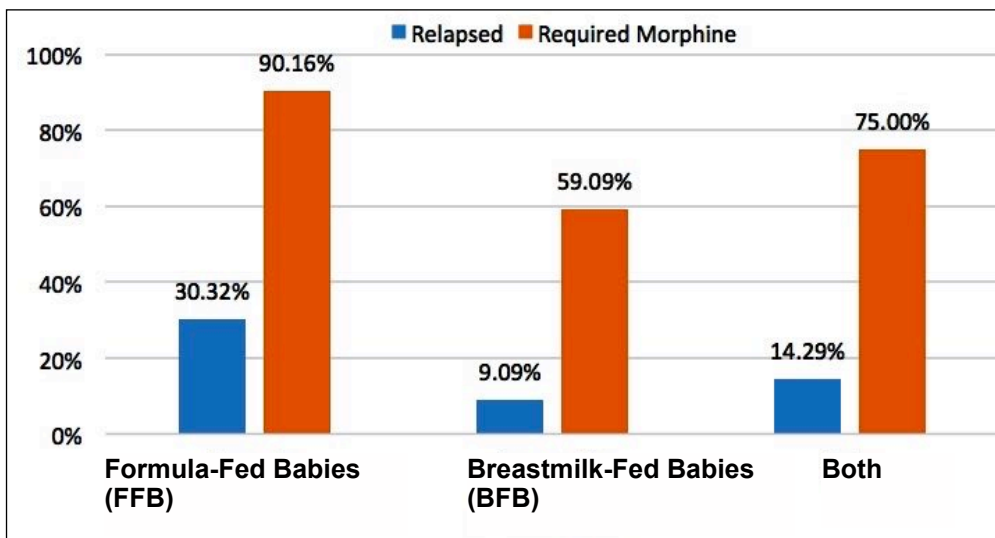


Figure 3: Bar graph showing per feeding type the number of NAS babies (in percentage) that received morphine treatment and percentage of NAS babies having relapsed after initial treatment.

symptoms when compared with infants fed exclusively breast milk or a combination of breast milk and formula.

This study brings awareness to the importance of breast milk for infants

diagnosed with NAS. Feeding with breast milk should be recommended to all mothers of infants diagnosed with Neonatal Abstinence Syndrome to decrease the infants' duration of stay, symptom severity, and risk for relapse.

“This study brings awareness to the importance of breast milk for infants diagnosed with NAS. Feeding with breast milk should be recommended to all mothers of infants diagnosed with Neonatal Abstinence Syndrome to decrease the infants’ duration of stay, symptom severity, and risk for relapse.”

Disclosure

The authors of this article have no conflict of interest to disclose.

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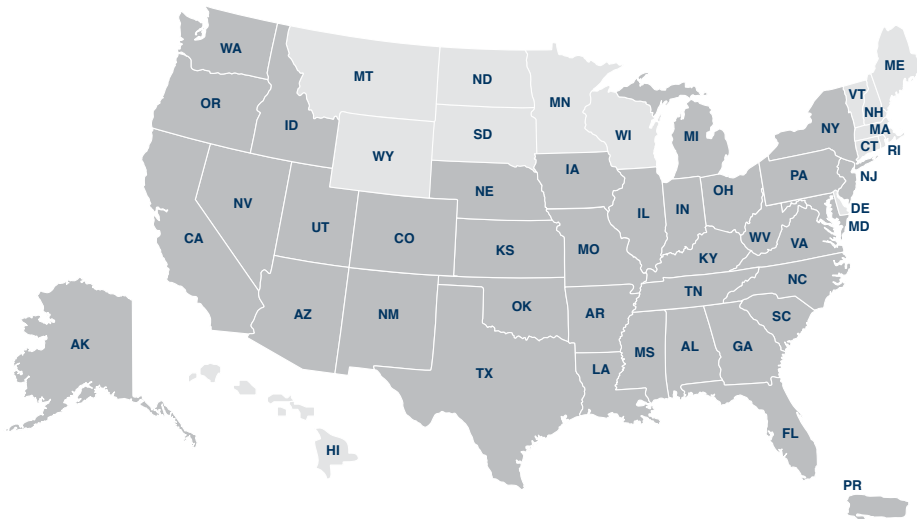


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Effective FiO₂ While Using Vapotherm: Weaning Flow Is as Important as Weaning Oxygen

By Shabih Manzar, MD

Effective FiO₂ is the actual oxygen concentration delivered to the alveoli. When oxygen is given through the nasal cannula (NC), it gets mixed with room air (RA) at the nostrils, thus affecting the delivered O₂ concentration. The flow rate when using Vapotherm (high flow humidified air) also affects the O₂ delivery to alveoli and work of breathing in infant.¹ Therefore, weaning strategy should be based on these principles.

In premature infants, the weaning process on Vapotherm therapy depends upon the respiratory status of the infant viz. work of breathing and oxygen saturations. Flow is weaned by monitoring the work of breathing, while O₂ is weaned following the target saturations. In our unit, we follow high oxygen saturation targets of 91%-95% as per Support Study.² Some follow low targets per Schmidt et al.³ When the flow is high, oxygen delivered is equal to the effective FiO₂. However, when the flow reaches about or below the body weight of premature infants, a change in flow affects FiO₂. By keeping the O₂ percent constant, changing

“Effective FiO₂ is the actual oxygen concentration delivered to the alveoli. When oxygen is given through the nasal cannula (NC), it gets mixed with room air (RA) at the nostrils, thus affecting the delivered O₂ concentration. The flow rate when using Vapotherm (high flow humidified air) also affects the O₂ delivery to alveoli and work of breathing in infant.¹ Therefore, weaning strategy should be based on these principles.”

Flow (L/min)	Oxygen (%)	Factor*	Effective FiO ₂
0.5	40	25	0.25
1	40	50	0.30
1.5	40	75	0.35
2	40	100	0.40

**Based on Benaron and Benitz 4*

Calculated for an infant weighing 2 Kg

If flow exceeds the current body weight (weight 2 kg, flow 2 L/min) then effective FiO₂ = Nasal cannula O₂

the flow rate changes the effective FiO₂ delivered to alveoli (see Table 1). Once the target saturations are met, the flow rate should be weaned.

For example, an infant who is at 2 L flow and 40% O₂ essentially gets 0.40 FiO₂. But if flow is weaned, the FiO₂ is brought down (see Table 1). Once an infant reaches the flow equal to the body weight, the oxygen given is equal to the effective FiO₂ (40% O₂ = 0.40 FiO₂). The table helps estimating the FiO₂ when the flow rates go down below the body weight. The calculations were based on the mathematical formulae generated by Benaron and Benitz.⁴ Point to note is that in a 2 kg infant, 2 L flow with 50% O₂ and 1 L flow with 100% O₂ will not deliver equal FiO₂. The former combination will deliver 0.50, while the later 0.60, as depicted in Table 1 and 2 in an earlier study by Walsh et al.⁵ Once a low flow is achieved, the combination of saturation and effective FiO₂ can be used to predict successful weaning to room air. Walsh et al⁵ reported a positive predictive value of 66.3% with saturation of >96% and effective FiO₂ of ≤0.23.

In conclusion, when a preterm infant is weaned to a flow of less than his/her body weight, a tabulated approach could be followed to know the effective FiO₂ helping in further weaning and room air challenges sooner than later.

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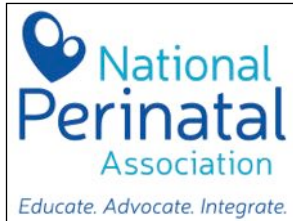


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Can People Heal as They Grieve?

By Andrea Werner Insoft, LICSW, ACSWD

Members of the NPA write a regular column in *Neonatology Today*.



Sometimes babies die. That is a sad truth of our work in perinatal healthcare. No one likes to talk about babies dying, but silence does not

make it go away. As a perinatal social worker who specializes in grief, I see, hear about, and feel the impact of these short lives every day. Try as we might to keep every baby alive, there are often circumstances beyond our control that make it impossible to reach that goal. When a baby dies, how can we help families – and each other – heal as we grieve?

In *Companioning the Bereaved*, Alan Wolfelt talks about just that – companioning. If you look up the word “companioning,” you will see that it’s meaning comes from the Latin words *com-with*, and *pane-bread*. It literally means “breaking bread with another soul.” Companioning the bereaved is all about taking a journey with someone else, being beside him or her as they begin to make sense of what life has handed them.

The death of a child either during pregnancy or after birth defies the natural order of our world, which we have come to accept. We are not supposed to bury our children. These deaths rock our very sense of who we are in this world. In fact, there is no word in the English language for a parent whose child has died. There are words to identify others who have lost a loved one, such as widows, widowers, and orphans, but how do parents, whose children have died, identify themselves? I have come across a phrase in Hebrew – “horeh shechol.” “av shechol” or “am shechol” which translates to father or mother of loss. Sanskrit uses the word “vilomah,” which means, “against a natural order.” And while labels often feel like a way of pigeon-holing an individual, they also provide a sense of who we are and what behavior is expected of us. Grieving parents have to make it up as they go along.

To provide grieving parents with a tool to guide their recovery, I use an acronym: LEVER, which stands for Language, Express, Validate, Educate, Rituals. A lever is a device that allows one to lift something that one could not lift on their own.

Language is so important. The words we use can hurt or heal. After a stillbirth, it’s important to talk about the baby, not the pregnancy. Refer to the parents as “parents” – moms and dads. Acknowledge their identity. They are parents, even though their child may never have taken a breath. They have loved that child – often even before conception. They did not “lose” their child. They didn’t leave their child in the checkout line at the grocery store. Their child died. I will often explain to my clients that I use these words deliberately. It is true that some people may object to these words, so it’s important to recognize this response, if it occurs, and act in whatever way is most comforting to the people with whom you work.

We need to express how we feel and encourage the families with whom we work to express themselves. These expressions of grief can appear so different from person to person: stony silence, howling rage, a torrent of tears, intensely working, incessantly exercising, or simply withdrawal. In my experience, parents often need to hibernate for a while after a death. Their loved ones may encourage them to get out, take a walk, come over for coffee, get busy to “take your mind off of it.” And while these all may be good coping mechanisms, they may not work for that individual. We are part of the animal kingdom. When an animal – perhaps a dog – is hurt, it will go somewhere to hide, perhaps under the porch, for a while to lick its wounds. I believe humans need time to do that as well. They may need to stay “under the porch” for a while until they are ready to emerge.

This is where validation and education are so important. Many grieving parents – and the professionals who grieve right along with them – need to know that whatever they are feeling is all right. It may be necessary to remind them that no two people grieve in the same way. This fact can often create conflict in couples and maybe among staff. One person needs quiet alone time, and the other person may feel best among people. Educate your clients and colleagues about the grief process. It is not linear. It is not necessarily how Kubler-Ross identified it. One does not go from stage to stage in an orderly fashion. Grief can be seen as a spiral, laid on its side. The grieving person has a reaction or feeling and then may begin to feel more like him or herself for a bit. Something inevitably happens which forces a step or slide back. Each slide is an opportunity to process and reprocess the events and fallout of the death. The hope is that these backslides will get shorter and shorter, and when one emerges from this slide, it is often with the realization that a little more healing has taken place. There is no real end. Closure is an artificial construct. Many people feel that healing means moving

on and is the end of pain. As we know, as long as we love, we will grieve. And that, I believe is the good news. Parents feel a great burden lift when they learn that what they are experiencing is normal, that they are not necessarily depressed, and that healing is possible.

Ritual is one of the most healing tools parents can use. How does a religion or certain culture observe death and allow grief? What are the steps grieving parents can make to acknowledge that this terrible thing has happened – that it was real? Some religions don’t allow for ritual around certain types of death – early pregnancy loss or termination for fetal anomaly. These deaths are real and need acknowledgment. It can be as simple as a few words said in the cemetery or a more formal funeral with flowers and prayer. Lighting a candle and putting up a Christmas stocking for the baby who died are all ways of recognizing that this short life had meaning. In the NICU, many staff struggle with the decision about whether or not to attend a funeral. Rituals are important for both parents and caregivers, and grieving parents benefit from the continued connection with and validation from the professionals who cared for their baby – regardless of the length of that child’s life. NICU and perinatal caregivers, who are also grieving, benefit from supporting parents, ensuring that the parents know their baby’s life matters, and reassuring themselves that they did all they could to help this family.

Making meaning out of an event that was so unexpected or arbitrary is at the heart of healing. Love and grief go hand in hand. The goal is not to let go, but to integrate this experience into who we are, to create a new identity that allows joy to co-exist with sadness.

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Establishing a Robust Transcatheter PDA Closure Program for Extremely Low Birth Weight Infants

By Shyam Sathanandam, MD; Leah Apalodimas, MSN, APN, CCRN, CPNP; Mark Weems, MD; B. Rush Waller, MD; Ranjit Philip, MD

Introduction

Extremely Low Birth Weight (ELBW) infants (weight <1kg at birth) frequently present with a large, hemodynamically significant Patent Ductus Arteriosus (PDA).¹ The PDA in ELBW infants can contribute to worse outcomes.²⁻⁴ However, there are no management algorithms that exist for ELBW infants with a hemodynamically significant PDA. Established treatment options include the administration of cyclooxygenase (COX) inhibitors and surgical ligation of the PDA (SLP) via a thoracotomy. COX-inhibitors are not always effective.⁵⁻⁷ SLP has not been shown to positively impact survival.^{5,7-9} Procedural complications and long-term sequelae⁷⁻⁹ have made this option less attractive. There is also a general belief that treatment of the PDA beyond the first few weeks of life in the ELBW infants may not significantly alter outcomes.^{1,3,5-6} This has led to a practice of a trial of medical therapy in the first 2-3 weeks of life, and if unsuccessful, no further intervention is sought.^{2-3, 6-7} Many neonates continue to languish with a large, hemodynamically significant PDA on a ventilator with evolving Chronic Lung Disease (CLD) and Pulmonary Hypertension (PHT).

Transcatheter PDA closure (TCPC) is the established mode of treatment for PDAs in children >5 kg.¹⁰ TCPC in ELBW infants is slowly being implemented by many centers.¹¹⁻¹³ Advantages of TCPC in ELBW newborns include immediate PDA closure compared to several days to weeks until closure with medications,¹¹⁻¹² and that TCPC is less invasive than SLP.¹¹⁻¹² Despite these perceived advantages, TCPC does not feature in the current treatment algorithm for PDA in the ELBW newborn. The challenges that prevent this therapy from becoming readily available to this population of patients include: a general concern for any procedural adverse events in extremely small babies, need for miniaturizing catheters and devices required for TCPC, concern of transporting the patient to a different environment for the procedure, use of radiation and contrast to perform TCPC, and lack of awareness of the availability of TCPC as a treatment option for ELBW newborns, among others. The aim of this report is to describe how we established a robust TCPC program for ELBW infants.

The TCPC Program for ELBW Infant

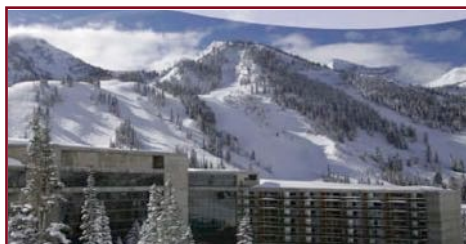
Currently, we have a one-of-a-kind infants comprehensive PDA program unlike anything in the United States which has enabled us to provide exceptional care for these infants both during their hospitalization and throughout their childhood. This has been accomplished through several years of extremely collegial and collaborative work between the neonatologists, cardiologists, congenital cardiac surgeons, and pulmonologists, among others, along with support from hospital administration. Generally, any ELBW newborn with a large, hemodynamically-significant PDA would have a course of medical therapy to close the PDA. If the therapy fails (the

PDA is still large and hemodynamically significant based on echocardiographic and clinical assessment), then the patient is referred for TCPC after a multi-disciplinary discussion between the primary neonatologist, consulting cardiologist and cardiac surgeon. To date, we have performed TCPC on 80 ELBW infants that weighed <2 kg at the time of the procedure, 37 of whom were <1 kg with the smallest weighing 640 grams at the time of TCPC. The median gestation age for these patients is 25 weeks (range 22-27 weeks). The patient is managed by the neonatologists in the Neonatal Intensive Care Unit (NICU) with the cardiologist assessing the child once a week till hospital discharge. Recently, we have started an out-patient PDA clinic for follow-up of these patients. The PDA clinic encompasses a multi-specialty team that is invested in discovering the long-term outcomes ELBW infants who continue to have PDAs and those who have undergone PDA closures. Cardiology, pulmonology, developmental pediatrics, nutrition, and nursing are all integral members of this multi-specialty team. Infants that are seen by pulmonology for bronchopulmonary dysplasia and also have a PDA (open or closed) are seen in this clinic by both pulmonology and cardiology teams with expertise in pulmonary hypertension. Growth and development are vital areas of tracking, most especially in our formerly, ELBW, premature patients. Nutrition and feeding abilities are regularly assessed at these visits as well.

TCPC Technique

All cases are performed in the cardiac catheterization lab (Figure 1). The interventional cardiologist rounds with the NICU staff for at least two days prior to the procedure in order to understand how to best manage the patient during the procedure. Our specialized technique included making modifications to how we transport the patient and how the staff cares for them in the catheterization laboratory. Prior to transport, the entire team including the cath lab staff, the interventional cardiologist, and anesthesia team receive bedside hand-off in the NICU.

We utilize a Giraffe Shuttle which is a mobile isolate that provides electrical power for ventilator support and thermoregulation. Intubated patients remain ventilated with the Neopuff (versus manual bag ventilation) in order to decrease risk of extubation, maintain lung volumes, and decrease risk of causing oxygenation-ventilation problems in these fragile infants. Our patients are returned to the NICU post-procedure in the same fashion with another bedside hand-off with the NICU team. In the catheterization lab, the temperature is increased to 75 degrees Fahrenheit and a heat lamp is placed over the patient to support thermoregulation. A temperature probe is placed in the esophagus to monitor core temperature throughout the procedure. The patient is kept warm using heat lamps and a heating blanket with continuous temperature monitoring via an esophageal probe. The blood pressure (BP) cuff is placed around the left lower extremity and is cycled every 5-minutes. A Trans-Thoracic Echo (TTE) is performed initially by the non-invasive cardiologist standing at the head end of the table to determine ideal windows for scanning during the procedure. Measurement of the PDA length, and diameters at the



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Figure 1. Photograph of the procedure performed in the cath lab using echocardiographic and fluoroscopic guidance.

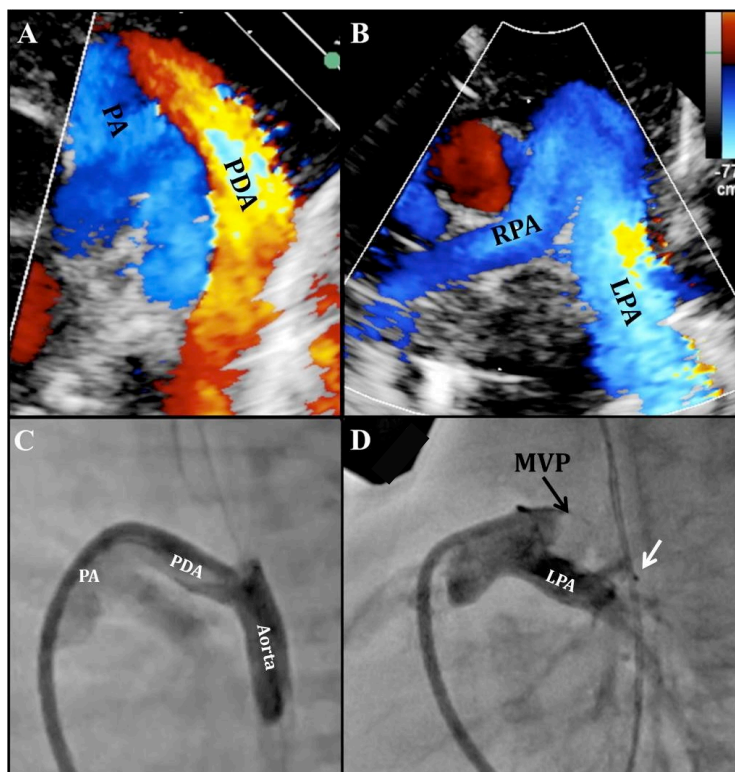


Figure 2. PDA occlusion using the Microvascular plug (MVP) using transthoracic echocardiography (TTE) and fluoroscopic guidance. A. Color Doppler TTE image showing a large PDA. B. Color Doppler image post PDA closure using the MVP demonstrating no PDA and stenosis of the left pulmonary artery (LPA). C. Angiogram performed in straight lateral projection demonstrating a large tubular PDA. D. Angiogram post-occlusion of PDA with MVP shows no LPA stenosis. The white arrow demonstrates the relationship of the distal end of the device to the esophageal temperature probe.

Pulmonary Artery (PA) end, and aortic end are obtained from various windows. The patient is prepped and draped in the standard sterile fashion. The patient is draped with a clear drape so that the entire body can be visualized at all times during the procedure. A 4-French, 7cm, introducer sheath is placed in the right femoral vein using ultrasound-guidance. Intravenous heparin bolus is not administered. Procedural heparinized saline flushes are sufficient to maintain the

activated clotting times between 200-250 seconds. Prophylactic antibiotic is administered.

Under fluoroscopy, a 4-French Glide catheter (Terumo, Japan) and a 0.035", Wholey wire (Medtronic, Minneapolis, MN) are used to access the PDA antegrade and to cross into the aorta. Hand injection of contrast through this catheter is used to obtain an aortogram in straight lateral projection for measurement of the PDA (Figure 2). An appropriate size Microvascular plug (MVP; Medtronic, Minneapolis, MN) is advanced through the same catheter and deployed in position across the PDA (Figures 2). If an Amplatzer device (Abbott Structural Heart, Abbott Park, IL) is chosen for occlusion, the femoral venous sheath is exchanged for a longer delivery sheath/catheter over a wire placed in the descending aorta through the PDA. The device is delivered through this sheath using standard technique. Presence of residual shunting and obstruction to the aorta or the left pulmonary artery (LPA) by the device are checked using TTE with the device repositioned as necessary (Figure 2). The esophageal temperature probe on fluoroscopy usually corresponds to the aortic end of the PDA and is helpful in device positioning.

A hand injection of contrast is performed through a Y-adapter connected to the end of the catheter in a straight lateral projection to assess device positioning and stenosis of the proximal LPA (Figure 2). TTE, in conjunction with palpation of the femoral arterial pulsations and non-invasive BP measurement in the left lower extremity prior to and post-device occlusion, helps rule out stenosis of the descending aorta. Once the position of the device is found to be acceptable, it is detached from the delivery wire, the catheter and sheath are removed, and patient is transported back to the NICU. Follow-up TTE and chest radiographs are obtained 6-hours post-procedure and as clinically indicated thereafter. An earlier practice of obtaining a lower extremity venous and arterial Doppler following the procedure is not followed anymore as there have been no access vessel complications.

Lessons Learned

As with any procedure, TCPC in ELBW infants has a learning curve. We have achieved a level of comfort that the median procedure time (physician scrub in to scrub out time) is less than 30 minutes; the fluoroscopy time is less than 5 minutes (median radiation exposure < 4 mGy), the median contrast volume used is <2mL/kg among the most recent 50 ELBW patients referred for TCPC. Figure 3 illustrates the gradual decline in the procedure age and weight of the patients in whom TCPC was performed. More recently, with referrals coming from other centers, we have seen a slight increase in the procedure weight of the ELBW infants undergoing TCPC. Similarly, there is a gradual decline in the procedure time and fluoroscopy time with experience.

The learning curve started nearly 6 years ago, when we noticed that formerly premature infants who were now much older were being referred for pulmonary hypertension studies to the catheterization laboratory. These older infants had severe bronchopulmonary dysplasia, sometimes with ventilator dependency, and large PDAs with some already developing irreversible pulmonary hypertension. Most of these children had undergone medical therapy to attempt PDA closure earlier in life. We began to wonder, if there was an intention to close the PDA with medical therapy that failed, then why were they not referred sooner for another form of PDA closure? We, therefore, decided to embark on altering the traditional TCPC technique to be suitable for ELBW infants.

The first step was to understand the morphology of the PDA in ELBW infants. What we discovered was that the morphology of these PDAs resemble their fetal counterpart and are large and long with a slightly tortuous connection to the PA giving a "hockey stick" appearance (Figure 4).¹⁴ We defined this morphology as Type F PDAs, as they are "fetal type" PDAs and do not fit the conventional classification system proposed by Krichenko.¹⁵ Having an understanding of the distinctive morphology of the PDAs in premature infants was an important step in

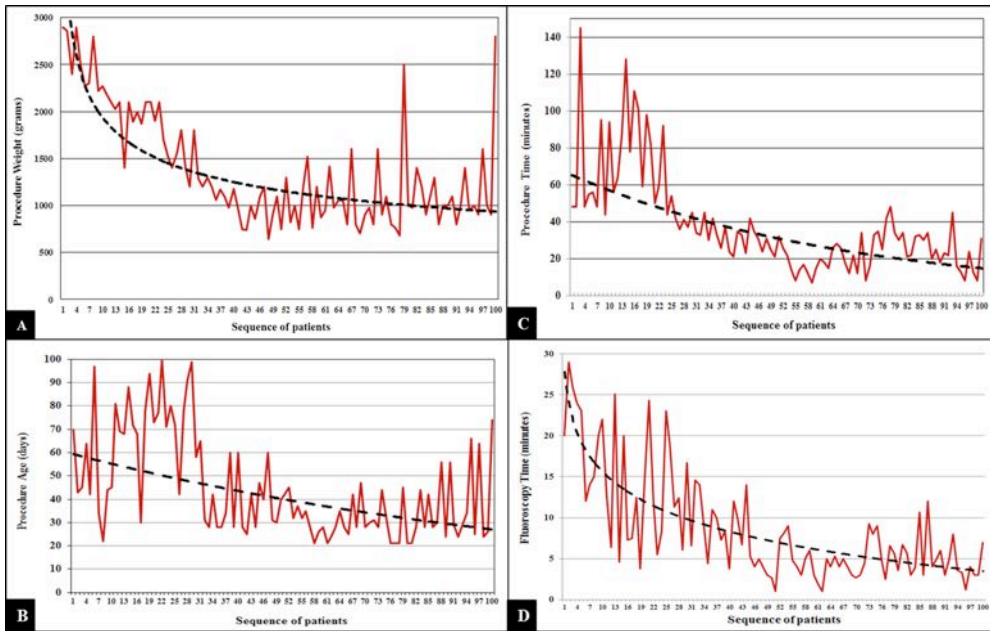


Figure 3. Graphical illustrations of the learning curve associated with TCPC performed in 100 consecutive ELBW infants weighing <3kg represented in sequence. **A.** Gradual decline in the procedure weight of patients undergoing TCPC. We were consistently performing procedures in children <1 kg after 40 cases. There is a gradual rise in the procedure weights afterwards as other centers started referring slightly older and bigger patients for TCPC. **B.** There is a similar trend towards performing TCPC at a younger age after the first 40 cases and a slight increase in patient age more recently with new referring centers. **C.** Downward trend in procedure times despite TCPC being performed in smaller and younger patients. This coincided with the exclusive use of the MVP as there is no sheath exchange, and almost one size device used for all, making the procedure simpler. **CI.D.** Downward trend in fluoroscopy times for similar reasons.

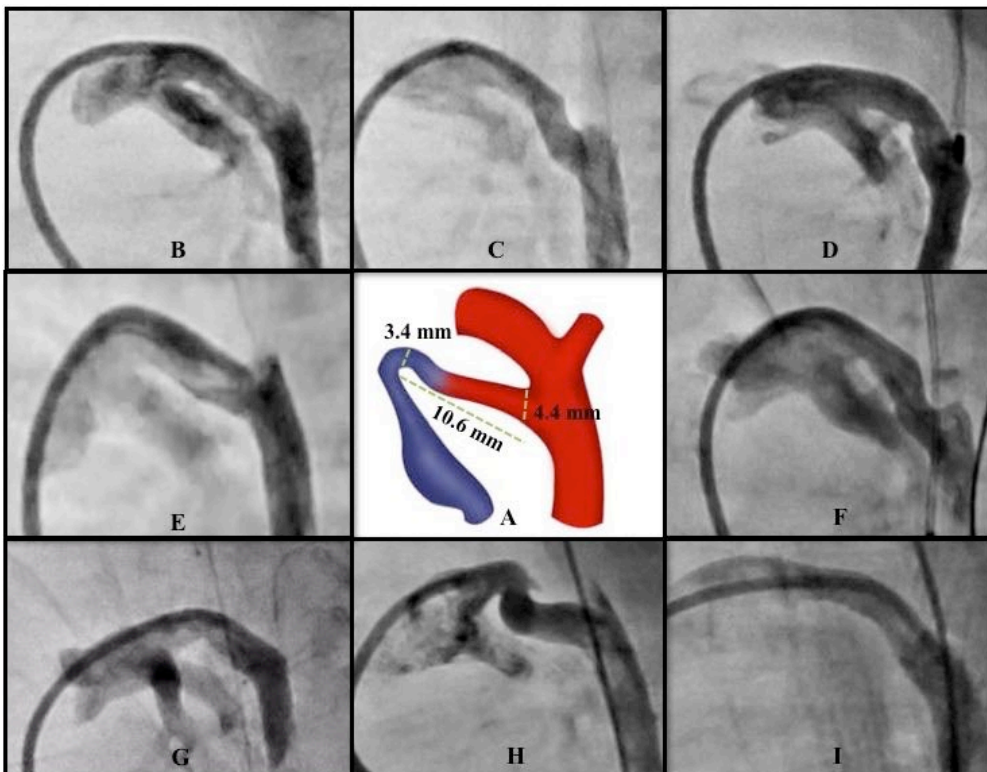


Figure 4. A collage of angiograms performed in children <1kg, demonstrating similar PDA morphology. The median PDA diameter at the pulmonary artery (PA) end was 3.4 mm and the median length of the PDA was 10.6 mm. These “fetal type”, or Type-F PDAs have a “hockey-stick” appearance - Tubular and long with a slight angulation as it connects to the PA from the aorta.

the process of improving our technique and appropriate device selection.

Traditionally, TCPC involves femoral arterial access to perform an aortogram. However, the prevalence of arterial access complications in children <2 kg is very high, with a real risk of limb loss.¹⁶ Therefore, similar to what was described by other operators,^{11,13,17} we only use femoral venous access for these interventions. TTE guidance eliminates the need for arterial access and aortograms. Ultrasound is used to guide needle access into the common femoral vein and to prevent inadvertent femoral arterial puncture. Additionally, ultrasound provides visualization of the needle entering the vein and care is taken not to puncture the back wall of the vein. All operators at our site routinely use ultrasound-guided vascular access for patients of all ages. Therefore, the expertise in this technique is very high. In fact, it only takes one needle puncture to access the right femoral vein, and we have seldom needed to access the vein more than once. The left femoral vein has only been used twice, secondary to the presence of a right lower extremity PICC line. The idea of TCPC performed at the patient’s bedside in the NICU without fluoroscopy relying entirely on TTE is attractive.¹⁷⁻¹⁸ However, the complete avoidance of fluoroscopy would limit the ability to manage device complications such as malposition or embolization.

Our goal is to perform TCPC limiting the occurrence of any adverse event. Every catheter maneuver that is made within the patient must be intentional and precise with care taken to not impose any superfluous movements. Precision of movements will help decrease procedure time and prevent complications. We prefer the use of an angled glide catheter, which is one of the most flexible catheters, along with the 0.035” Wholey wire with an atraumatic tip. This combination prevents catheter-wire size mismatch and is less likely to cause any vessel injury.

Initially, like many other operators, we used the Amplatzer Vascular Plug-II (AVP-II) device for TCPC.^{11-12,17,19} However, there are several pitfalls of using this device. As stated earlier, the PDA size is very consistent at least in the smaller (<1.5 kg) neonates. In our series, the median PDA diameter at the PA end was 3.4 mm and the median length of the PDA was 10.6 mm (Figure 4). It was frustrating to us that the 4mm AVP-II was a bit too small for the PDA and the 6mm AVP-II was a bit too large, and a 5mm AVP-II was not manufactured. Therefore, the MVP-5Q device is practically a one-size-fits-all for PDAs of patients <1.5 kg.²⁰ This was the most commonly used device in our series with its use in 58 of the 80 children <2 Kg that underwent TCPC. Secondly, the disks of the AVP-II have the potential to cause stenosis of either the LPA or the aorta.^{17,19} We had one LPA stenosis

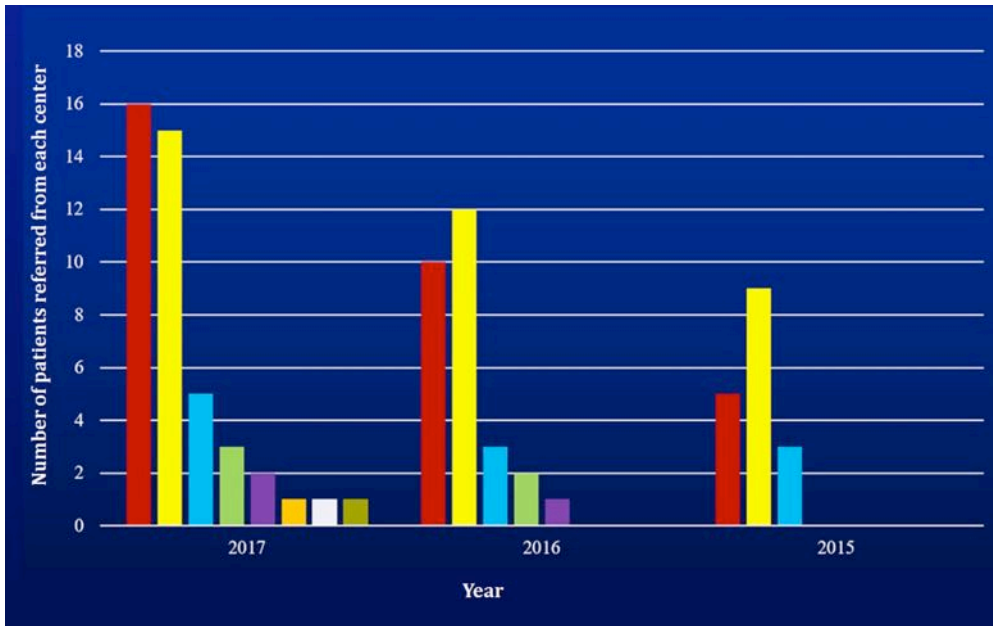


Figure 5. Graph showing the increase in the number of patients referred and the number of referring centers for TCPC for ELBW infants over the past 3 years. Each color bar represents a different center.

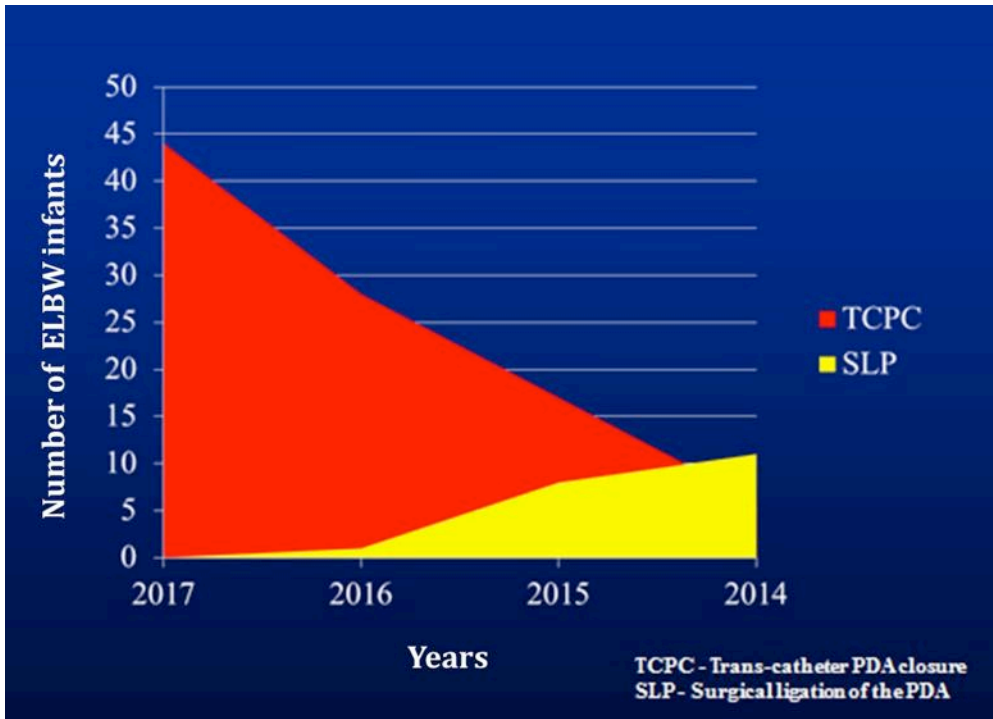


Figure 6. Graph showing the increase in the number of ELBW infants undergoing TCPC along with a decline in the number of surgical PDA ligations from 2014-2017.

caused by the use of a 6 mm AVP-II in a 1 kg neonate. This complication was identified during the procedure itself and the device was retrieved easily. The PDA in that particular patient went into spasm and did not reopen leading to a “deviceless” closure of the PDA. The MVP device being a “diskless” device is less likely to cause vessel stenosis.²⁰ Third, extremely small patients do not tolerate stiff wires and delivery cables to cross the tricuspid and pulmonary valves that are required for device

deployment. The delivery cable of the MVP is less stiff compared to other devices and, consequentially, easier to maneuver through the heart in neonates weighing as small as 600 grams.²⁰ In the past two years, we have almost exclusively used the MVP, especially in neonates ≤ 1.2 kg because of the less stiff delivery cable. The MVP has the advantage of being delivered through the same catheter that is used to cross the PDA,²⁰ avoiding the need for a sheath exchange unlike the AVP-II.^{11-12,17,19}

We had one mortality relatively early in our experience during the sheath exchange needed to implant an AVP-II in an 840-grams neonate. The sheath exchange led to an inadvertent laceration of the inferior vena cava that was recognized only at the end of the procedure, and the infant could not be resuscitated. Besides this one mortality and the LPA stenosis that was immediately “cured” by removing the device, there was one other procedure-related complication. The third complication was in a 900-grams child that had a small pericardial effusion before the procedure that increased in size 24-hours post-procedure. Though there were no signs of tamponade in this patient, it was decided to electively drain the effusion percutaneously. The effusion was hemorrhagic in nature and therefore attributed as a procedural complication. In fact, all three adverse events happened relatively early in our experience when the AVP-II was exclusively utilized. There have been no TCPC procedure related adverse events in the most recent 60 patients and none with the use of the MVP. We, therefore, believe that if TCPC is performed carefully, it is a safe procedure for most ELBW infants and the MVP may be the most appropriate device to use in the smallest of patients. With the ADO-II AS US IDE trial (Amplatzer Duct Occluder II Additional Sizes, United States Investigation Device Exemption Clinical Trial, IDE#G160190, Identifier #NCT03055858 on clinicaltrials.gov) recently completing patient enrollments, we could soon have an FDA-approved device available for TCPC in ELBW infants.²¹

As we progressed to performing TCPC earlier in life, we found a distinct benefit in early TCPC vs. delayed TCPC. Early TCPC (within the first 4 weeks of life) seems to afford faster weaning off ventilator and oxygen support and lower incidence in development of Pulmonary Hypertension (PHT). In fact, ELBW neonates undergoing TCPC early in life seem to have no PHT compared to their older counterparts, who almost invariably seem to have PHT associated with their large PDA. It becomes challenging to treat the PHT in these patients with pulmonary vasodilators in the presence of large left-to-right shunt across the PDA. We have not encountered the dreaded “Post-PDA Ligation Syndrome” that sometimes occurs after surgical PDA ligation.²² Anecdotally, when we have performed TCPC early, we have observed that these patients have not gone on to develop IVH or NEC post-TCPC. It is hard to prove if PDA closure early in life prevents the development of IVH and NEC. A randomized control trial comparing outcomes following early TCPC for large, hemodynamically-significant PDA vs. no PDA closure may be necessary to answer the question of whether early TCPC is beneficial with improved patient outcomes. In our fairly large experience with TCPC in ELBW infants, there seems to be a trend

towards possible benefit to closing the PDA earlier in life.

Expansion of the TCPC Program

This experience has sincerely convinced us that TCPC is the “correct” treatment for ELBW infants with a large, hemodynamically significant PDA. This conviction has genuinely made us resolve that TCPC should be in the management algorithm for ELBW infants with a large PDA. We are absolutely dedicated to the care and welfare of these ELBW infants, and are determined to expand the availability of this procedure to all at-risk ELBW infants. Our series of 80 TCPC in children <2 kg, with 37 being performed in children <1 kg to date, represents the largest series in ELBW infants. The neonate that underwent TCPC at 640 grams is the smallest patient on record to undergo this procedure. This has led to a spike in the referrals for this procedure. Figure 5 demonstrates the increasing number of centers referring ELBW infants for TCPC and Figure 6 demonstrates the change in practice at our site from SLP to TCPC for failure of pharmacotherapy. Our greatest success is reflected by the increasing referrals from our neonatology colleagues in the smaller outlying communities of rural Arkansas, Mississippi, and Tennessee after receiving informative brochures detailing our experience. As we continue to successfully perform this procedure on infants <1 kg, we anticipate that the number of TCPCs performed at our site will increase exponentially. We even had one patient referred for TCPC from a center that is 6 hours away from us. This 700-gram neonate was transferred to our facility and back after the procedure via air transportation. This patient has subsequently been discharged home and is without any major sequelae. This is a huge accomplishment and represents the true success of our program.

Conclusions

In summary, TCPC is feasible and is safe in most ELBW infants. TCPC is less invasive than surgical PDA ligation and will definitively close the PDA, unlike medical therapy. The MVP and the ADO-II AS may be the devices ideally suited for these patients. We established a robust TCPC program which is all inclusive from management of ELBW newborns that failed medical therapy to close the PDA to long-term follow-up in a dedicated, multi-specialty PDA clinic. The success of the program at our center should be easy to replicate throughout the country. With the increasing use of this procedure, TCPC is likely to find its way into the management algorithm of ELBW infants with a large, hemodynamically-significant PDA.

If you want to learn more about TCPC in ELBW infants, you can consider attending

the *2018 International PDA Symposium*. This inaugural symposium will be held on May 18th-19th, 2018 at The Westin in downtown Memphis, Tennessee. This is an exciting and creative approach to foster multi-specialty dialogue among neonatologists, pediatric cardiologists, and pediatric cardiovascular surgeons, as well as other sub-specialists. The symposium will feature informative talks, debates, hands-on sessions, and a live TCPC case. Experts from around the world in each of these specialties will be in Memphis to promote lively discourse. A panel discussion at the end of the meeting will attempt to come up with a consensus statement.

If you are interested in learning more about the symposium, or would like to register to attend, please visit www.methodistmd.org/cme. You can also contact Ms. Margaret Long for more information at margaret.long@lebonheur.org or call 901-516-8933.

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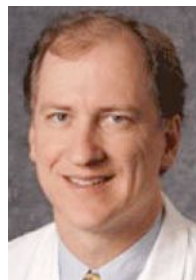
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Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

What Happens to Hospitalized Patients when Substitute Doctors Fill in?

Newswise — When you are hospitalized and the regular doctor is out sick, on vacation or at a scientific conference, you are increasingly likely to receive treatment not from the doctor's colleague or another hospital staff physician, but by an outsider hired to fill in, like a substitute school teacher.

The growing trend—a multi-billion-dollar industry—is fueled by physician staffing shortages and shifting employment patterns.

But do these temps—so-called “locum tenens” physicians—provide the same level of care as the doctors they are filling in for? The answer appears to be “yes,” at least when it comes to death rates in the month following treatment, according to research led by Harvard Medical School published Dec. 5 in *JAMA*.

The findings, based on a review of millions of Medicare hospitalization records, provide the first insight into this booming business. The results show that patients treated by substitute doctors and regular hospital staffers had similar death rates in the 30 days following hospitalization.

Yet, the researchers caution, there were some small but statistically significant differences in other measures. Patients treated by substitute physicians had somewhat higher spending and slightly longer hospitalizations.

“Our findings so far are reassuring, but some of the trends we found demand that we look more closely at how the system works in a more granular way,” said study senior author Anupam Jena, the Ruth L. Newhouse Associate Professor of Health Care Policy at Harvard Medical School.

Temporary docs might pick up shifts at a number of different hospitals around a single metropolitan area or they might travel across the country to work in a rural hospital far from their home, Jena explained.

These doctors generally do not have any relationship with their patients, are not familiar with the local community, and may never have worked with the hospital's electronic health records system, hospital staff or local network of facilities where patients may be discharged to after hospitalization, the researchers said.

The researchers analyzed 1.8 million Medicare hospital admissions that took place between 2009 and 2014, using algorithms that allowed them to compare the results for doctors working with similar patients at similar hospitals. Nearly 40,000 of the 1.8 million admissions received care by substitute doctors. In that time frame, one of 10 physicians was replaced by a substitute doctor.

Patients who received care by substitute physicians were no more likely to die within a month of hospital admission—8.8% of those patients died—than those who received care by regular staff physicians—8.7% died in that group.

However, when the researchers analyzed various sub-groups within the overall sample, they noticed some concerning trends: Hospitals that used substitute physicians less often had somewhat worse patient mortality outcomes. Daniel Blumenthal, Harvard Medical School Instructor in Medicine at Massachusetts General Hospital and the study's first author, said the finding might be due to the geographic remoteness of these hospitals, to limited financial resources or to a lack of robust support systems to help temporary doctors plug in to the hospitals' systems.

“As the market place shifts and employment patterns fluctuate, we owe it to our patients to make sure that the way we cover for doctors who are out of the office is safe and effective,” Blumenthal said.

Co-authors included: Andrew Olenski, of Columbia University and Yusuke Tsugawa, of the University of California, Los Angeles. This study was supported by funding from the Office of the Director, National Institutes of Health (Dr. Jena, NIH Early Independence Award, Grant 1DP5OD017897).

Additional disclosures: Jena reports receiving consulting fees unrelated to this work from Pfizer, Hill Rom Services, Bristol-Myers Squibb, Novartis Pharmaceuticals, Vertex Pharmaceuticals and Precision Health Economics. Blumenthal reports receiving consulting fees unrelated to this work from Precision Health Economics and Novartis Pharmaceuticals.

Blood Flow Altered in Brains of Preterm Newborns vs. Full-Term Infants - Blood, Oxygen and Nutrients Follow Function, with More Flowing to Rapidly Developing Cerebral Regions

Cerebral blood flow (CBF) of key regions of newborns' brains is altered in very premature infants and may provide an early warning sign of disturbed brain maturation well before such injury is visible on conventional imaging, according to a prospective, observational study published Dec. 4, 2017 in *The Journal of Pediatrics*.

“During the third trimester of pregnancy, the fetal brain undergoes an unprecedented growth spurt. To power that growth, cerebral blood flow increases and delivers the extra oxygen and nutrients needed to nurture normal brain development,” says Catherine Limperopoulos, PhD, Director of the Developing Brain Research Laboratory at Children's National Health System and senior author of the study. “In full-term pregnancies, these critical brain structures mature inside the protective womb where the fetus can hear the mother and her heartbeat, which stimulates additional brain maturation. For infants born preterm, however, this essential maturation process happens in settings often stripped of such stimuli.”

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The challenge: How to capture what goes right or wrong in the developing brains of these very fragile newborns? The researchers relied on Arterial Spin Labeling (ASL) Magnetic Resonance Imaging (MRI), a noninvasive technique that labels the water portion of blood to map how blood flows through infants' brains in order to describe which regions do or do not receive adequate blood supply. The imaging work can be done without a contrast agent since water from arterial blood itself illuminates the path traveled by cerebral blood.

"In our study, very preterm infants had greater absolute cortical cerebral blood flow compared with full-term infants. Within regions, however, the insula (a region critical to experiencing emotion), anterior cingulate cortex (a region involved in cognitive processes) and auditory cortex (a region involved in processing sound) for preterm infants received a significantly decreased volume of blood, compared with full-term infants. For preterm infants, parenchymal brain injury and the need for cardiac vasopressor support both were correlated with decreased regional CBF," Limperopoulos adds.

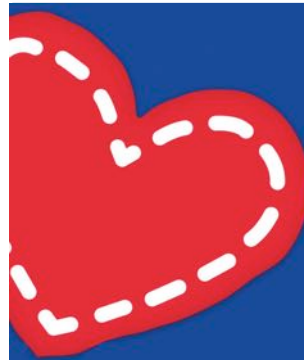
The team studied 98 preterm infants in the study who were born June 2012 to December 2015, were younger than 32 gestational weeks at birth and who weighed less than 1,500 grams. They matched those preemies by gestational age with 104 infants who had been carried to term. The brain MRIs were performed as the infants slept.

Blood flows where it is needed most with areas of the brain that are used more heavily commandeering more oxygen and nutrients. Thus, during brain development, CBF is a good indicator of functional brain maturation since brain areas that are the most metabolically active need more blood.

"The ongoing maturation of the newborn's brain can be seen in the distribution pattern of cerebral blood flow, with the greatest volume of blood traveling to the brainstem and deep grey matter," says Marine Bouyssi-Kobar, MS, the study's lead author. "Because of the sharp resolution provided by ASL-MR images, our study finds that in addition to the brainstem and deep grey matter, the insula and the areas of the brain responsible for sensory and motor functions are also among the most oxygenated regions. This underscores the critical importance of these brain regions in early brain development. In preterm infants, the insula may be particularly vulnerable to the added stresses of life outside the womb."

Of note, compromised regional brain structures in adults are implicated in multiple neurodevelopmental disorders. "Altered development of the insula and anterior cingulate cortex in newborns may represent early warning signs of preterm infants at greater risk for long-term neurodevelopmental impairments," Limperopoulos says.

Research reported in this news release was supported by the Canadian Institutes of Health Research, MOP-81116; the SickKids Foundation, XG 06-069; and the National Institutes of Health under award number R01 HL116585-01.



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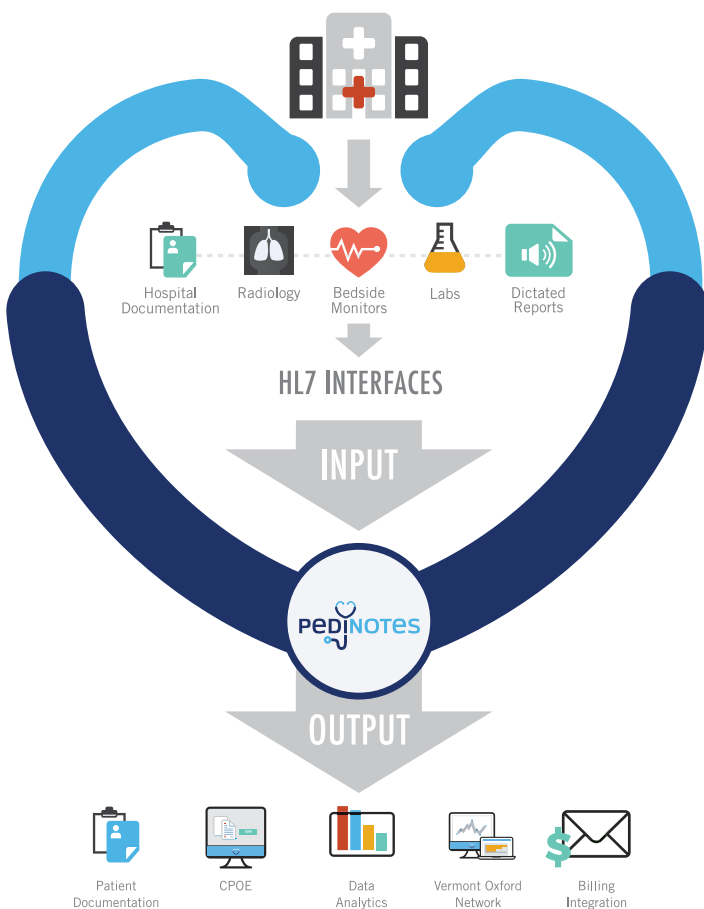
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International PDA Symposium

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7th International Conference on Clinical Neonatology

May 26-26, 2018; Turin, Italy
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