NEONATOLOGY TODAY

News and Information for BC/BE Neonatologists and Perinatologists

Volume 2 / Issue 9
September 2007

IN THIS ISSUE

NEONATOLOGY TODAY

Editorial and Subscription Offices
16 Cove Rd, Ste. 200
Westerly, RI 02891 USA

www.NeonatologyToday.net

Neonatology Today (NT) is a monthly newsletter for BC/BE neonatologists and perinatologists that provides timely news and information regarding the care of newborns and the diagnosis and treatment of premature and/or sick infants.

ISSN: 1932-7129 (print); 1932-7137 (online). Published monthly.

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The Electronic Medical Record and the Data Warehouse in Neonatal Practice - Improving Patient Care Through Modern Technology

By Alan R. Spitzer, MD

As healthcare has continued to evolve, the demands upon the practicing neonatologist and the neonatal nurse practitioner with respect to chart documentation have become increasingly onerous. The daily progress note, once a brief reminder of the aspects of care that needed to be followed, now must meet an extensive series of requirements for a variety of reasons. Few practicing physicians have not had payments denied, for example, because of supposedly insufficient documentation, often during periods when the demands of the patient have been the greatest. In a busy NICU full of critically ill patients, getting to the chart is often highly problematic, even when one has the best intentions. Furthermore, the constant scrutiny given to charts by malpractice attorneys further enhances the need to be accurate and precise in note writing. In many instances, however, the demands of the patient often conflict with the demands of charting. With so few hours in the day, one is commonly faced with the decision to either take care of a critically ill neonate or take care of the chart. For all of us, that choice is a non-decision, and we often must forego the hand-written note in the chart to be sure that an infant receives whatever is necessary to insure his or her well-being. Needless to say, our concern for the patient may leave us with potential liability if we fail to document adequately.

In addition to the demands that many of us now experience in charting, new requirements have appeared on the horizon which will also impact neonatal practice. The American Board of Pediatrics (ABP), to insure the general public of the value in Board Recertification, has determined that participation in meaningful continuous quality improvement (CQI) will be a component of recertification beginning in 2010. In order to meet this obligation, a physician (not a collective practice) will need to demonstrate his or her active participation in CQI. The individual will need to identify an issue, measure a particular outcome, define an intervention to be made, and then re-assess the outcome that follows the intervention. Quality improvement, which has great inherent value for neonatal patients and represents an important initiative, will require not only demonstration of active participation, but also demand active data tracking of patient outcomes on an ongoing basis.

Lastly, the ABP, the American Academy of Pediatrics (AAP), the National Association of Children's Hospitals and Related Institutions (NACHRI), and the Children's Health Corporation of America (CHCA) have joined together in an Alliance for Pediatric Quality. This Alliance intends to evaluate processes that can improve outcomes and deliver higher levels of quality of care to all pediatric patients. In part, the response of this group of leaders in Pediatrics has been stimulated by Pay-for-Performance (P4P) projects that are emerging throughout medical practice. The concept of

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P4P is a novel one. For the first time, providers are being asked not just whether something has been done for a patient, but how well it has been done. "Transparency of outcomes" has become the medical phrase of the day. By establishing certain criteria, the goal of P4P is that these additional quality measures will produce better results and improved outcomes for patients. For practitioners who meet the P4P standards, improved reimbursement (or some other incentive) will be forthcoming. Without question, this era in medicine is going to be a challenging one, and one which will create significant additional requirements with respect to charting and outcomes for all neonatal care providers.

A Two-Fold Approach to Improving Neonatal Outcomes

Nearly a decade ago, Pediatrix Medical Group anticipated that the demands outlined above were likely to emerge as medical realities in the not-too-distant future. In addition, there was a growing awareness that one of the greatest strengths of a large, multicenter group practice was the ability to merge and examine patient outcomes to both better understand and improve the quality of care being delivered. With these concepts in mind, a two-phased project was devised to meet these goals, which appears to now have broad applicability for many of the initiatives outlined above: the development of an electronic medical record (EMR) for the use of physicians in their daily practice and an electronic data warehouse (DW) that would serve as a repository of information generated by the EMR. The DW would be dual in nature. It would have graphic output that would allow the practicing physician to track an extensive array of clinical information such as unit census data, length of stay, survival rates, and morbidities such as ROP, IVH, BPD, etc. Moreover, it would permit comparisons between NICUs so that one could see if patient outcomes in one NICU were comparable to, or better than, those observed in other NICUs. Because there is a tendency to explain away outcome variation by stating that "my patients are different (or sicker or inner city, etc.)," the data ideally would also permit realistic comparisons between similarly sized and configured NICUs to eliminate this rationalization. Lastly, the DW patient population would have identifying information removed to make it HIPAA compliant, be submitted to a national IRB for approval, and be available for novel research investigations involving large numbers of patients, which could not be obtained in any other manner.

Because the detail of the information entered each day into the EMR is so extensive, the level of granularity of data in the Pediatrix Data Warehouse (DW) for research is remarkable. It does not appear that there is a comparable project in medicine in the country at the present time, and the Data Warehouse has already served as the source of a significant number of publications in major pediatric journals. The DW has been annually certified by the Western IRB (Olympia, WA), a national IRB, as being HIPAA compliant. It is, therefore, the purpose of this article to review the use of the EMR and the DW to show how these tools are being used to meet the growing demands of modern neonatal practice, while insuring optimal patient outcomes. It is our belief that the concepts of the EMR and the DW can be applied to all neonatal practices to improve the care of critically ill neonates.

The Electronic Medical Record (EMR)

Historically, physician notes in the medical record have been hand-written, a tedious and time-consuming process. For much of the past, notes were a random musing of the physician's primary concerns about the patient, the progress being made in an individual's care, and the plan of therapy. In the 1970's, the introduction of the Weed system of charting brought a more formal and organized nature to the somewhat random record, and resulted in improvement in the organization of the medical chart. Yet the note remained hand-written, and any attempt to gather information from a series of patients required a chart review that was often tedious to do (assuming records could be located in hospital Medical Records departments) and necessitated a painstaking investment of many hours of one's time.

With the introduction of the desktop and laptop computer, however, the electronic medical record not only became feasible, but very attractive as a time-saving measure. The time required to generate a detailed note was drastically reduced, and the ability to collect and summarize information from groups of patients was readily apparent. The first EMRs began to appear during the 1980's, but were somewhat cumbersome in nature, and the slow speed of available computer processors made it difficult to enter little more than basic patient information. As processor speed improved, however, so did the EMR, and the physician could go through multiple screens quickly to enter large volumes of data. The EMR note could be printed and placed in the patient's hospital record, while the information could be simultaneously gathered for investigational purposes.

Development of the EMR at Pediatrix went through two different stages and two separate EMRs, which later proved challenging to merge into a single data set. The current EMR, known as BabySteps©, has been developed within the company and progressively introduced into the 260 NICUs run by the company across the country. The initial screen for a NICU hospitalization appears as follows:

- **Figure 1: The Admission Note Screen**: One can anticipate how the note progressively emerges from the various categories listed along the left side menu. Clicking through the menu items brings up individual screens to which appropriate information can be added. Similarly, the daily progress note can also provide inclusive amounts of information. Here is one screen of the Daily EMR note of BabySteps©.
- **Figure 2: The Daily Medical Record Note Home Screen.**

It should be noted, however, that one of the emerging issues that has been observed in the EMR is the fact that great amounts of information can be entered and brought along on an ongoing basis, potentially leading to voluminous notes that are difficult to read and follow. Furthermore, the cloning of notes may raise issues relative to compliance, in that it is difficult to insure the presence of the care-provider if the note does not change much each day (Report on Medicare Compliance, May 28, 2007).

The greatest value of an EMR note, therefore, as with any note in the medical record, occurs when it contains all the essential information, but is concise and focused. There appears to be a fine line between precise, thoughtful documentation and excessive documentation. As can be seen, the daily progress note defaults to certain observations for ease of documentation that can be readily changed by the clinician as necessary. In general then, we have observed that the following issues must be carefully monitored during the use of the EMR:

- There is a tendency to enter far too much unnecessary data and to "clone" it along for too long a period of time. A good note is complete, yet concise.
- The greater the amount of note copying, or "cloning" that occurs from day to day, the more likely that there will be inconsistencies within the record, a major source of concern during medico-legal review. Noting that an infant needs to be placed on ECMO, while the physical exam section documents clear and equal breath sounds in room air, will make a malpractice attorney joyous. Carryover of information from day to day is to be discouraged (with rare exceptions).
- The more detail that is added to the daily note, the more difficult it is to understand what has occurred on a specific day. The daily progress note should be exactly that – a record of the events that transpire in a patient during a specific day. It should not be an ongoing recitation each time of everything that has happened to an infant since the day of birth.

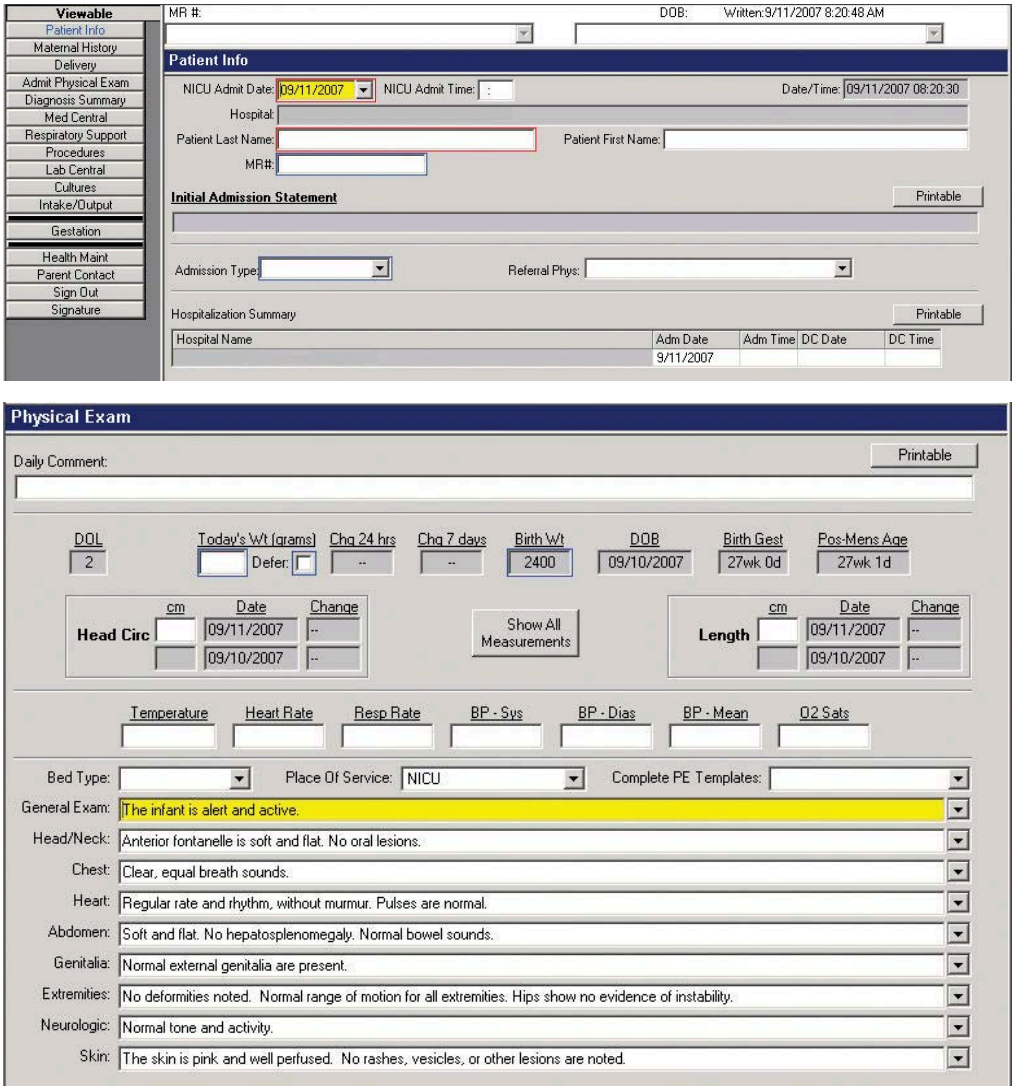

Figure 1. The Admission Note Screen (top).
Figure 2. The Daily Medical Record Note Home Screen (bottom).

As with any computer system, data entry must be performed in a succinct, orderly way. The old adage "garbage in, garbage out" most definitely applies to the EMR if one anticipates extracting data subsequently. Furthermore, it is simply not possible to identify all the ways in which physicians refer to certain events, so that consistency in the approach to documentation is critical. In our explorations of the medical record, for example, we have observed that physicians can refer to an intraventricular hemorrhage in literally dozens of slightly different ways (IVH, head bleed, Grade II, intracranial bleed, intracranial hemorrhage, intraventricular bleed, full choroid, subependymal bleed, etc.). To provide a program with sufficient instructions to wander throughout the

entire medical record in search of all those permutations is not possible. We have therefore devised a documentation education program for the medical record, which enables the NICU team to produce focused, concise, internally consistent notes. Drop-down boxes are used wherever possible to insure accuracy of data entry, both in an individual institution, as well as among NICUs that hope to examine comparative outcomes. While there must be chart areas that allow for appropriate discussions about patient progress, these areas have limited value for data collection, since they can be so different from physician to physician. Also, the development of clear, accurate definitions for events is an essential part of establishing criteria for subsequent comparisons. Educationally guiding physicians and nurses through the charting process is a critical component of successful electronic records.

The EMR should also provide summary information that can be shared for sign-out at night and on weekends, as well as a discharge note for the physician(s) who will assume care for the child after the hospital stay. But perhaps the greatest value of the EMR lies in the ability to extract information on substantial numbers of patients in order to make observations that might not otherwise be apparent and to learn how we might enhance patient care. This concept then leads to the discussion of the "warehousing" of data for evaluation and improvement of patient outcomes.

The Clinical and Research Data Warehouse (DW)

Without question, the most exciting and valuable aspects of the EMR emerge when one examines collected data in order to see the trends that emerge from one or more NICUs over some period of time. For this to happen and permit comparison to other NICUs, a series of steps must take place that require programming sophistication. Validation of data must occur at several steps along the way to insure that what is initially placed in the daily EMR entry ultimately emerges unchanged (except for de-identification) in the final collection of reported data. At Pediatrix, this process was further complicated by the use of two separate EMRs during the past decade, each of which collected information differently, yet had to be merged into a single data set. It is a tribute to our IT programming team that they have been able to successfully accomplish this feat. To our knowledge, there is no other comparable data set in neonatal medicine like this one, in which the daily medical record is imported into a multi-center data set for both examination of clinical outcomes and research investigations on an ongoing basis. There is therefore no cleansing of data entry, no discarding of possible outliers, and the entire patient population data collection is configured prospectively with as high a degree of accuracy as possible.

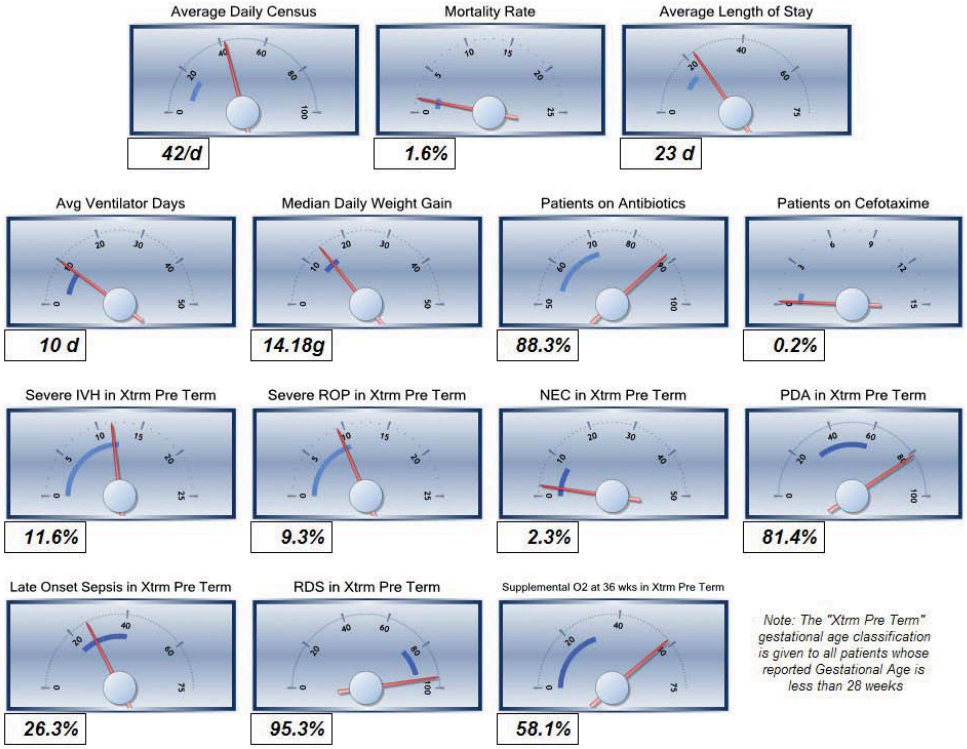

Figure 3. Data Warehouse Dashboard Summary.

It is our belief that a DW should provide reports that are readily understandable, even to non-medically trained individuals, first in a summary format that can quickly define some of the essential outcomes for any NICU. For the Pediatrix Data Warehouse, we have employed a dashboard concept to provide our NICU Medical Directors with an overall picture of the quality of their outcomes. The current dashboard can be seen in Figure 3.

The categories selected are fairly self-explanatory, and reflect both decision-making process measures (median daily weight gain, average ventilator days for neonates treated with mechanical ventilation, antibiotic use, etc.) as well as outcome measures (mortality rates, IVH, ROP, NEC, etc., in the extreme low birth weight infant). The use of cefotaxime was included because of a DW outcome observation that we published last year in

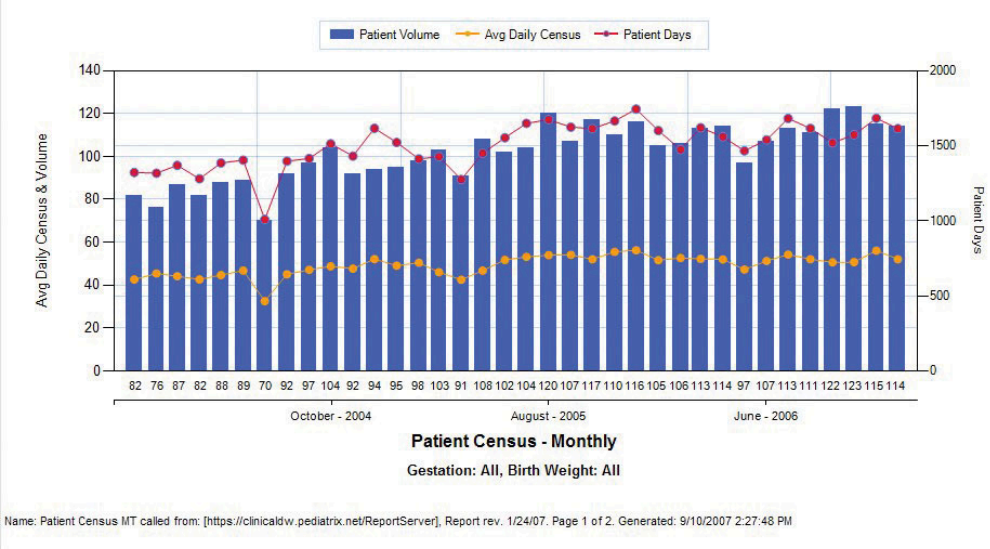

Figure 4. Patient Census Activity

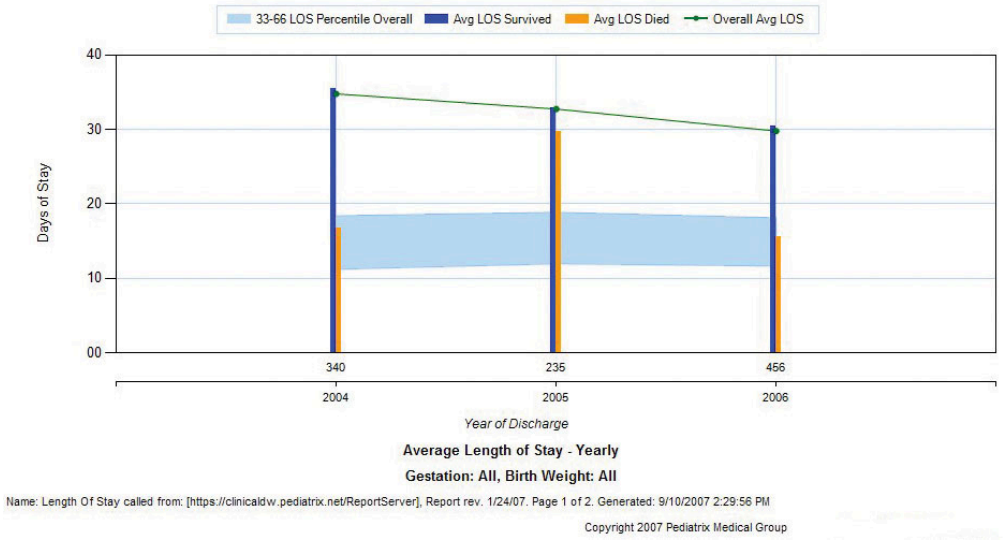

Figure 5. Length of Stay. Bars indicate the median LOS for survivors and non-survivors. Dots indicate overall LOS. Background gray reflects middle third percentile for all Pediatrix Medical Group NICUs.

Pediatrics that indicated a higher mortality rate in the neonate with the use of this antibiotic. We anticipate this summary measure soon being replaced with an analysis of dexamethasone use in the NICU, since the use of cefotaxime has fallen significantly in our NICUs. The bar seen in each gauge just below the numbers reflects the middle third (33-66% median value) of all Pediatrix Medical Group hospitals, enabling a quick visual comparison of the outcome data of an individual NICU to all Pediatrix NICUs. The newest version of the DW (in development) will allow hospitals to select other Pediatrix institutions of similar size for their comparison standard, in order to make observations even more meaningful. It is hardly appropriate for a large tertiary center with highly complicated patients to be compared to a small Level II NICU that transports out most of their complicated patients. Once the summary data have been evaluated, the DW allows the individual physician to hone in on other select information with a series of more detailed clinical reports.

Census measures, for example, that reflect clinical activity are important to follow and share with hospital administration. Here is a hospital that is demonstrating progressive monthly growth in overall numbers. See Figure 4—Patient Census Activity.

One can see that there is, in general, an upward increase in the number of patient days (dark circles), though the average daily census increases only slightly during this three-year period (light circles). What is interesting, however, is the growth in patient volume (bars) during this time. Patient volume refers to the number of individual patients in the unit that have a unique medical record during the time period selected (in the DW, one can select for annual, quarterly, or monthly report formats). In the highlighted NICU, this number grows from the low 80's to approximately 115-120 during the three years shown. The daily census, however, only increases from the low 40's to the mid 40's during this interval. One would consequently suspect that the efficiency in this NICU has improved, which should be reflected in decreased length of stay (LOS). This expected change in LOS for this NICU can be seen in Figure 5-Length of Stay.

The DW, therefore, can demonstrate that a nursery can have a substantial increase in overall activity and a sense of "busyness," which may not be entirely reflected in the average daily census, a number used by many hospital administrators to make staffing decisions. For example, although the census rises by only 2-3 patients per day in this case, more than 30 additional NICU patients are being cared for each month, placing a substantial strain on the staff. Having access to data like these can be of great value in supporting requests for additional NICU staff.

One of the key outcome measures of interest in any DW is the mortality rates (Figure 6). In this hospital, mortality rates are shown by the dark circle, with 95% confidence intervals marked by the bars. The median third (33-66%) of all Pediatrix hospitals is represented by the grey background. The survival data for all our hospitals defined by birth weight and gestational age is currently available on our web site and can be found at: http://www.pediatrix.com/body_university.cfm?id=596

A data warehouse should also provide information on a variety of other measures, especially major NICU morbidities. If one intends to establish a CQI program

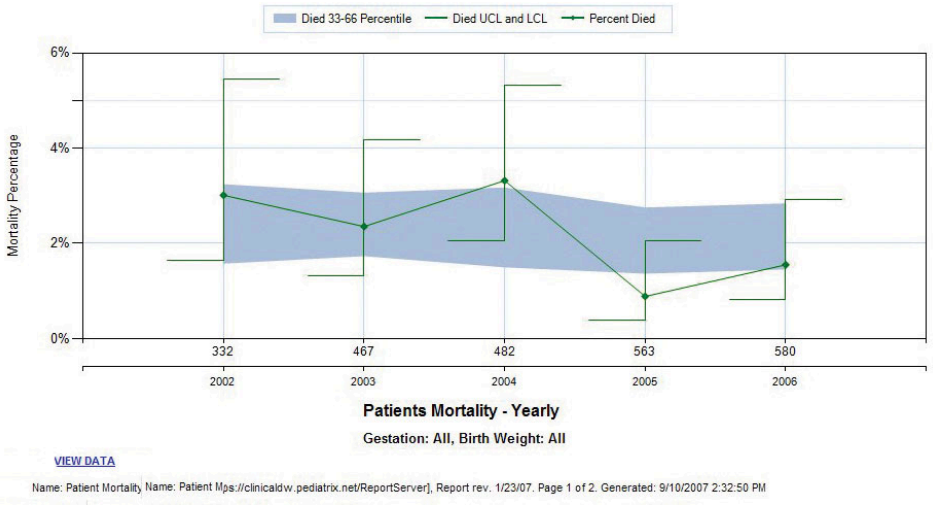

Figure 6. Yearly Mortality.

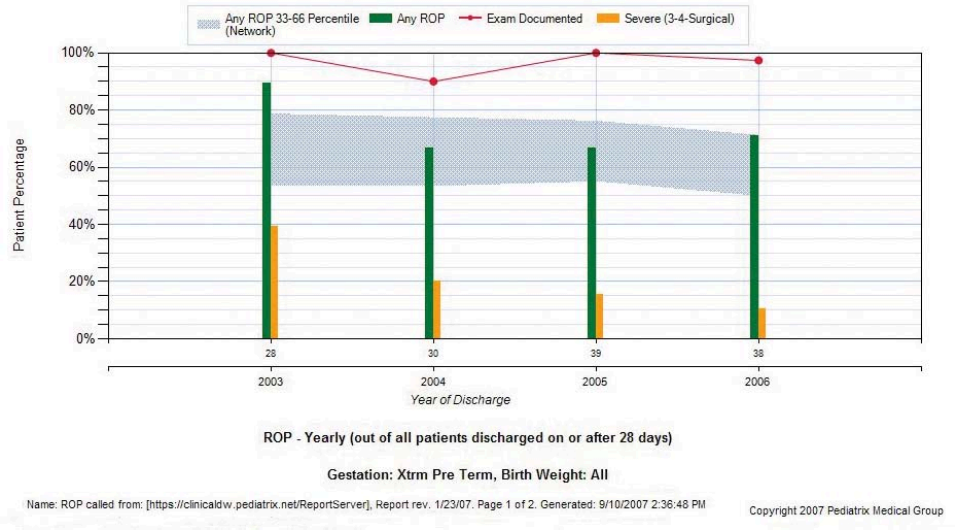

Figure 7. Changing Rates of ROP over a four-year period in an individual NICU as well as Pediatrix Medical Group overall.

that is intended to alter the rates of a specific morbidity, having the ability to track that outcome before and after intervention is essential. Here, for example, are the results seen in one of our NICUs that initiated a large-scale multi-center project to reduce the rate of severe retinopathy of prematurity (Figure 7).

This report examines the rate of eye examinations (the closed circles) in extreme pre-term infants (<28 weeks gestation), the rate of any detectable ROP, the rate of severe ROP (Grades 3, 4 and surgically treated ROP), and the background rate for Pediatrix Medical Group in this patient population. Of note in this report are: 1) the decline in this individual NICU's severe ROP rate (light color bars) from 40% to 10% in extreme pre-term infants since the institution of targeted oxygen saturation monitoring; and 2) the decline in median overall rates of ROP for Pediatrix Medical Group as demonstrated by the declining margins of the 33-66% group, especially in 2006. The availability of reports like this one can serve as ideal data sets for examining the results of interventions. One can define a CQI program and follow the data along as often as desired. Repeated examination of the information can also provoke new ideas for strategic approaches intended to reduce rates of any serious complication of care.

The Clinical Data Warehouse should have a wide variety of reports. The Pediatrix DW presently has the following available clinical reports, with more in development:

- **Activity Reports**: Types of discharges (home, transfer, in-hospital, etc.); Admissions by GA; Admissions by BW: Length of stay, Average daily census; Mortality; Survival.
- **Best Demonstrated Process Reports**: Median daily weight gain during the first 28 days; Hepatitis B immunization rates; Per cent of Infants breast feeding at Discharge.
- **Morbidity Reports**: BPD at 28 days of life; BPD at 36 weeks' gestational age; IVH; Late-onset Sepsis; NEC; PDA; PVL; RDS and surfactant use; ROP; Severe IVH; Severe ROP.
- **Antibiotic Reports**: Percent of NICU admissions treated with antibiotics; Median days of antibiotic therapy with negative cultures; Use of cefotaxime; Percent of patients treated without cultures.
- **Acuity Reports**: Median Ventilator Days.
- **Summary Dashboard Report**.

Infants can be examined in the following categories by gestation: Extreme Pre-term (<28 weeks' gestation); Pre-term (28 weeks to 33 6/7 weeks' gestation); Late pre-term (34 weeks to 36 6/7 weeks' gestation); Term (37 to 42 weeks' gestation); and Post-term (> 42 weeks/ gestation. Subdivision by weight categories is also possible, as is combination of groups of premature infants. Each of the reports noted can then be viewed by either gestational age or birth weight.

Finally, it is our strong belief that the value of the DW is enhanced the more it is utilized. We have had the privilege of working in collaboration with many institutions in both the clinical and research arms of the IRB approved Data Warehouse, and the results of many of these investigations are listed in the references below. We strongly encourage anyone with ideas that might be answered by a query of the DW to contact us about the possibility of collaboration.

Summary

The availability of Electronic Medical Records and Data Warehouses now provide neonatology practices with a capability that has not previously existed. In an era in which transparency of outcomes is becoming paramount in the minds of the federal government, payors, hospital administra-

" With the introduction of the desktop and laptop computer, however, the electronic medical record not only became feasible, but very attractive as a time-saving measure."

tors, and the public, the DW is ideally situated to move neonatal practices into the future of medical care. Furthermore, the tracking of outcomes following interventions establishes an optimal process for quality improvement projects and should enable newborn medicine to emerge as one of the leaders in all of medical care.

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Role of Interventional Cardiology in Neonates – Part I - Non-Surgical Atrial Septostomy

By P. Syamasundar Rao, MD

"Role of Interventional Cardiology in Neonates – Part I" is the first in a series of three articles by P. Syamasundar Rao, MD, Professor of Pediatrics and Medicine Director, Division of Pediatric Cardiology University of Texas-Houston Medical School. The second and third articles will appear in the October and November issues respectively.

INTRODUCTION

Whereas the seeds of interventional pediatric cardiology were planted in the 1950s by Rubio-Alvarez and Limon-Lason by their work on transcatheter pulmonary and tricuspid valvotomy[1,2], by Dotter and Jedkins in the early 1960s by their gradational vascular dilatation techniques [3], by Rashkind in the mid-1960s by introduction of balloon atrial septostomy[4], by Porstmann in late 1960s by percutaneous closure of patent ductus arteriosus[5,6], and by King and Mills in mid-1970s by non-operative closure of atrial septal defects[7,8], it was not until Kan and her associates[9] adapted Gruntzig's technique[10] of balloon angioplasty with double-lumen balloon catheter for pediatric use in early the 1980s did transcatheter therapy in children become a reality[11-15]. These techniques were extended slowly, but surely to treat neonates with congenital heart defects[16-20]. In this review, various catheter interventional techniques (Table I) that are currently being used in neonates will be discussed; in Part I, Non-surgical atrial septostomy will be reviewed, and the remaining items listed in Table I will be dealt with in subsequent issues of this publication.

In 1966, Rashkind and Miller [4] described a technique, now called Rashkind balloon atrial septostomy, which was extensively used to improve atrial mixing in neonates with transposition of the great arteries. It was subsequently applied to many other disease entities in which enlarging the atrial defect is beneficial[21]. In mid to late 1970s, Park and his associates extended the utility of balloon septostomy by introducing blade atrial septostomy to enlarge defects with thick atrial septae[22]. A built-in retractable blade (knife) cuts the lower margin of the patent foramen ovale (PFO) which is followed by balloon atrial septostomy. More recently, balloon angioplasty[21,23,24], stents[25,26], Ross transseptal puncture[27], radiofrequency ablation[28-30] and cutting balloons [30] were applied to create and/or enlarge the atrial defects.

Table I. Catheter Interventional Techniques Used in the Neonate

- Non-surgical atrial septostomy
- Balloon angioplasty/valvuloplasty
- Radiofrequency perforation of atretic pulmonary valve
- Transcatheter occlusion of shunts
- Stents

Cardiac defects in which atrial septostomy is likely to be useful will be reviewed followed by a description of septostomy procedures.

Table II. Septostomy Procedures

- Rashkind balloon atrial septostomy
- Blade atrial septostomy
- Balloon angioplasty
- Atrial septal perforation
- Stent implantation

SEPTOSTOMY PROCEDURES

Various septostomy procedures that are currently used will be discussed hereunder.

TRANSPOSITION OF THE GREAT ARTERIES

In transposition of the great arteries (TGA), the aorta arises from the right ventricle and the pulmonary artery from the left ventricle. Consequently, the systemic venous return is pumped back into the body and the pulmonary venous return is ejected back into the lungs. Instead of having a normal in-series circulation, the TGA patients have parallel circulation. Without either an intracardiac or extra-cardiac shunt, the infants with TGA will not survive. The fetal circulatory pathways {PFO and patent ductus arteriosus (PDA)} will initially provide some mixing. In most neonates with TGA, the PFO and PDA tend to undergo spontaneous closure, resulting in a severely cyanotic infant. Rashkind balloon atrial septostomy has been extensively used in the palliation of the neonate with complete TGA. The improved mixing at the atrial level allows the neonate with transposition to grow up to an age (usually 3 to 6 months) at which time a venous switch (Mustard or Senning) procedure could safely be performed. With the introduction of arterial switch (Jatene) procedure which is usually performed at approximately one week of age, balloon atrial septostomy is not necessary in all babies. If naturally present PFO and/or Prostaglandin E1 (PGE1) infusion do not result in reasonably good oxygen saturations (60 to 70% without metabolic acidosis), balloon atrial septostomy should be performed, preparatory to arterial switch procedure.

TRICUSPID ATRESIA

Tricuspid atresia may be defined as congenital absence or agenesis of the morphologic tricuspid valve[31,32]. In tricuspid atresia an obligatory right-to-left shunt occurs at the atrial level. Usually, this shunting is through a PFO. Because of the obligatory nature of the shunt, this fetal pathway persists in the postnatal period; this is in part related to low left atrial pressure. But, the entire systemic venous return must pass through the patent foramen ovale. Therefore, interatrial obstruction is anticipated, but very few patients with tricuspid atresia have clinically significant obstruction[33]. The right-to-left shunt occurs in late atrial diastole with augmentation during atrial systole ('a' wave [34,35]. A mean interatrial pressure difference greater than 5 mm Hg with very prominent 'a' waves (15 to 20 mmHg) in the right atrium is generally considered to represent obstructed interatrial septum [33,36]. Balloon atrial septostomy[37], if unsuccessful, blade atrial septostomy [22,38], and rarely surgical atrial septostomy, may be necessary to relieve the obstruction. Significant interatrial obstruction requiring atrial septostomy in the neonate is rare and unusual although this can be a significant problem later in infancy[36,39].

PULMONARY ATRESIA WITH INTACT VENTRICULAR SEPTUM

Pulmonary atresia with intact ventricular septum is a complex cyanotic congenital heart defect characterized by complete obstruction of the pulmonary valve, two distinct ventricles, a patent tricuspid valve and no ventricular septal defect. The right ventricle is usually, but not invariably, small and hypoplastic. Because of atretic pulmonary valve, there is no forward flow from the right ventricle and the blood regurgitates back into the right atrium. Therefore, an

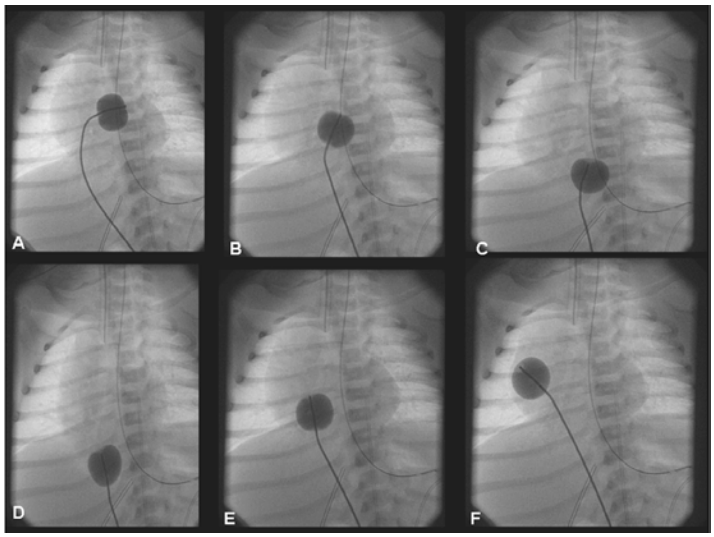

Figure 1. Selected cinfluroscopic frames of the Rashkind's balloon septostomy procedure. Note the position of the inflated balloon in the left atrium (A) and in right atrium and inferior vena cava in successive frames, as it is rapidly and forcefully withdrawn across the atrial septum (B,C, & D). After it reaches the inferior vena cava (D), it is rapidly advanced into the right atrium (E & F) in order not to inadvertently occlude the inferior vena cava in case of failure to deflate the balloon (which is quite rare).

obligatory right-to-left shunt occurs across the atrial septum. The objectives of any treatment plan are to achieve a four-chamber, bi-ventricular, completely separated circulation[40-43]. This aim may be achieved only in the absence of a) right ventricular dependent coronary circulation b) severe right ventricular hypoplasia, and c) infundibular atresia. In the subgroup of neonates with unipartite or extremely small right ventricle with infundibular atresia and/or right ventricular dependent coronary circulation, a modified Blalock-Taussig shunt to provide pulmonary blood flow and atrial septostomy to decompress the right atrium should be performed. The usefulness of atrial septostomy in improving outcomes of systemic-to-pulmonary artery shunts in pulmonary atresia patients is demonstrated in early studies [44]. Balloon atrial septostomy, if unsuccessful blade atrial septostomy, and rarely surgical atrial septostomy, as described in tricuspid atresia section, may be necessary to promote egress of right atrial blood. However, it should be noted that no atrial septostomy should be undertaken in patients in whom transcatheter or surgical opening of the atretic pulmonary valve is contemplated; the objective in this scenario is to encourage anterograde pulmonary flow across the opened pulmonary valve.

HYPOPLASTIC LEFT HEART SYNDROME

In hypoplastic left heart syndrome (HLHS), there is hypoplasia of the left heart structures. Similar to other congenital heart defects, HLHS also shows a spectrum of severity. In the most severe form, aortic and mitral valves are atretic with a diminutive ascending aorta and markedly hypoplastic left ventricle[45,46]. The left atrium is usually smaller than normal. Because of obstruction at the mitral valve, pulmonary venous blood must cross the atrial septum via a PFO and mix with desaturated systemic venous blood in the right atrium. In some patients the PFO may be restrictive and occasionally the atrial septum may be intact. In the neonate, obstruction at the level of the PFO may be treated with conventional Rashkind balloon atrial septostomy[4]. However, since the left atrium is small, Rashkind septostomy may not be feasible. In addition, the septum may be too thick to be torn by balloon septostomy; therefore, Park blade septostomy[22] has been considered. But again, because of left atrial hypoplasia, blade septostomy may not be feasible. Static dilatation of the atrial septum[21,23,24] with a balloon angioplasty catheter may be used which may not only relieve the obstruction, but also keep some restriction such that there is no rapid fall in the pulmonary vascular resistance. Static balloon dilatation is preferred by the author. In some patients the atrial septum may be intact or have a tight patent foramen ovale which may not even allow passage of a catheter. In such situations, puncture of the atrial septum by Ross technique [27] or radiofrequency perforation of the atrial septum[28-30] followed by static balloon atrial septal dilatation[21,23,24] or stent implantation [25,26] may become necessary.

MITRAL ATRESIA

The considerations for mitral atresia are similar to those described for HLHS and the utility of balloon septostomy in this group of patients has been well documented[47,48].

TOTAL ANOMALOUS PULMONARY VENOUS CONNECTION

In this entity, all the pulmonary veins drain into systemic veins, most commonly they drain into a common pulmonary vein which is then connected to left innominate vein, superior vena cava, coronary sinus, portal vein or other rare sites. Occasionally individual veins drain directly into the right atrium. Irrespective of the type, all pulmonary venous blood eventually gets back into right atrium, mixes with systemic venous return and gets redistributed to the systemic and pulmonary circulations. The systemic flow is through the PFO. Consequently, restrictive PFO will cause decreased systemic perfusion and may indirectly result in pulmonary venous obstruction. In the neonate, the most common form is obstructive infradiaphragmatic type causing severe pulmonary venous obstruction because the pulmonary venous return has to go through hepatic circulation. Occasionally, however, cardiac and supracardiac types may have restrictive PFO and in such patients balloon atrial septostomy is beneficial [49].

Rashkind Balloon Atrial Septostomy

In TGA patients who are stable, the usual hemodynamic data including cine-angiography, as needed, are performed. If the infant is unstable or has extremely low oxygen saturations, one may proceed directly with balloon septostomy. In such situations, aortic saturation and pressure pullback across the atria and echocardiographic size of atrial defect are recorded. The balloon septostomy procedure involves inserting a balloon septostomy catheter, usually via a sheath percutaneously placed in the femoral vein, into the left atrium via the PFO. The balloon is inflated with diluted contrast material to a sub-maximal amount (usually 3 ml) and rapidly pulled back across the atrial septum (Figure 1) after ensuring that the catheter tip is located in the left atrium either by lateral fluoroscopy or by echocardiography. Once the catheter is pulled back to the inferior vena cava, the catheter should be rapidly advanced into the right atrium; all this is done as a single motion. The balloon should be deflated as the catheter is repositioned into the right atrium. This jerking motion of the contrast filled balloon catheter produces a tear in the lower margin of the PFO (septum primum) which is very thin and frail in the newborn. We usually perform one additional septostomy following what may be considered good septostomy.

Increase in systemic arterial oxygen saturation, disappearance of pressure gradient across the atrial septum and echographic increase in the size of the atrial defect (Figure 2) with non-restrictive Doppler

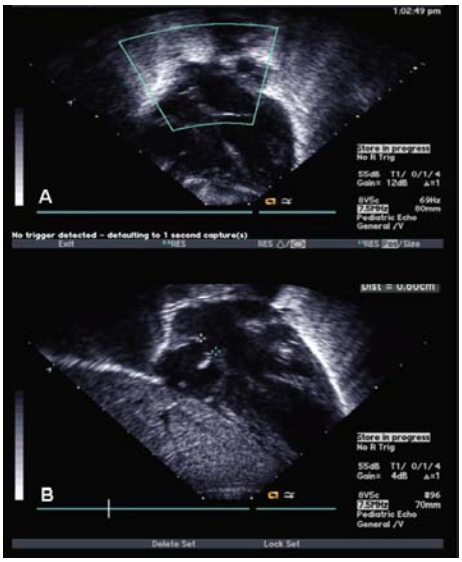

Figure 2. Selected video frames showing a very small inter-atrial opening (A) which became larger (B) following balloon atrial septostomy.

flow across the atrial septum (Figure 3) are demonstrated in successful procedures. In patients in whom atrial septostomy is performed to relieve interatrial obstruction, trans-atrial pressure gradient is reduced or abolished. Some cardiologists balloon-size the atrial defect both prior to and following balloon septostomy and this is another method of assessment of result of the septostomy.

In the initial description of balloon septostomy by Rashkind[4], the catheter was introduced into the femoral vein by cut-down.

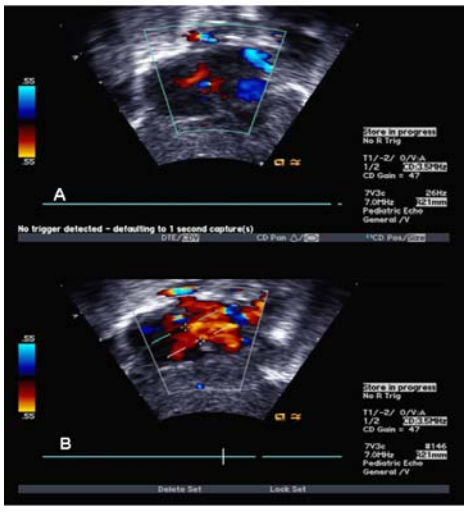

Figure 3. Selected video frames showing a very small color flow jet across the inter-atrial opening (A) which became larger (B) following balloon atrial septostomy.

To avoid femoral venous cut-down, insertion of the catheter and performance of balloon septostomy via the umbilical vein [50] has been advocated. When percutaneous technology became available, the balloon catheter was introduced via an appropriate sized percutaneously inserted femoral venous sheaths[51,52].

Our first choice is to perform balloon septostomy via the umbilical venous route. Therefore, we encourage our neonatology colleagues to place an umbilical venous line early on, with its tip well into the right atrium, before the ductus venosus constricts. At the time of septostomy, this line is exchanged over a wire with an appropriate-sized sheath.

The feasibility of performing balloon septostomy bedside, under echo guidance, has been demonstrated[53,54]. But, most cardiologists perform the procedure in the catheterization laboratory which is preferred.

Initially, Rashkind balloon septostomy catheters (USCI, Boston, MA) were used. Because the catheters were straight, sometimes making it difficult to advance the catheter into the left atrium, and because of the limited volume of fluid that these balloons would take, most cardiologists have switched to Edwards septostomy catheters (American Edwards Baxter, McGow Park, IL). These catheters have a gentle curve at the tip, facilitating easy access into the left atrium and larger volume of fluid could be injected into these balloons. More recently, atrioseptostomy catheters (B/Braun, Bethlehem, PA) have become available. There are no studies comparing the relative effectiveness of the available catheters and therefore, the selection of the type of catheter used is at the discretion of the operator.

Blade Atrial Septostomy

In older patients and in some conditions such as hypoplastic left heart syndrome, the lower margin of the PFO is thick and can't be ruptured by conventional balloon septostomy. The septostomy may simply stretch and not tear the lower margin of the PFO. Park and his associates[22] developed catheters with build-in blade (knife) (Cook Inc., Bloomington,, IN) to address such thick atrial septae. Three blade sizes are commercially available. The selected catheter (smallest size for the newborn) is positioned across the PFO, the position of the tip of the catheter is confirmed and the blade opened. While pointing the blade anteriorly and to the left (Figure 4), the catheter is slowly withdrawn (not a jerky motion as in balloon septostomy), thus cutting the lower margin of the PFO. This is repeated one or two more times, varying the angle slightly. This is followed by balloon septostomy. Evaluation of the results is similar to that described in the balloon septostomy section. Success rate ranged between 70 and 90% [55,56]

Balloon Angioplasty

Mitchell et al[57] and Sideris et al[58] performed static dilatation of the atrial septum

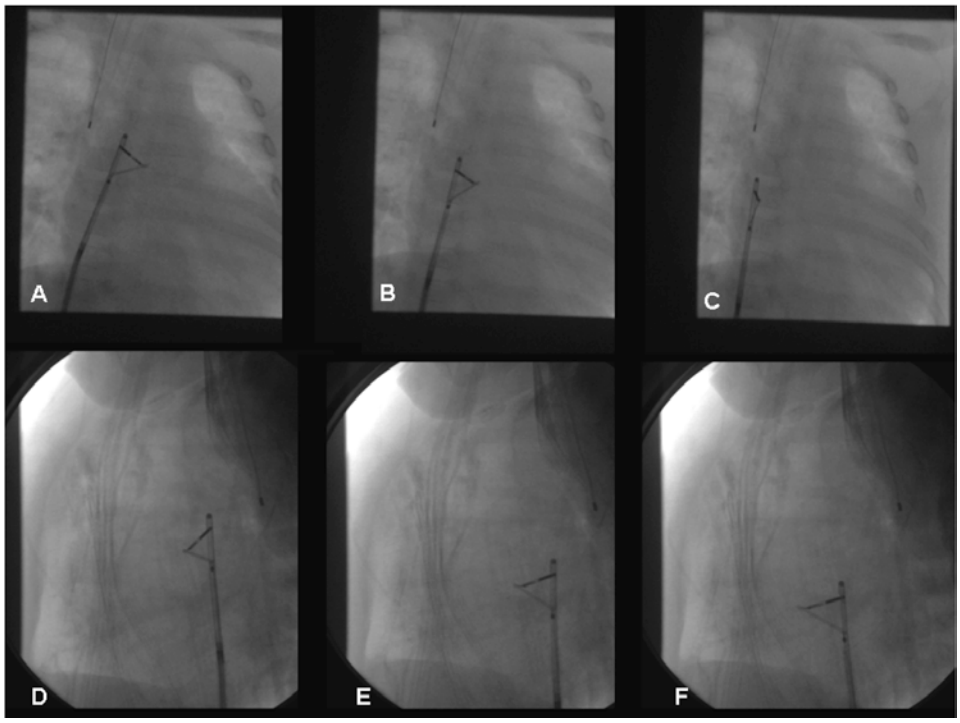

Figure 4. Selected cinfluroscopic frames of the blade septostomy procedure. The top three figures (A,B & C) show the position of the catheter with the blade open in the posterior-anterior projection while bottom three (D,E & F) show the lateral view. Note the position of the blade pointing to left and anteriorly. This procedure is performed by slow withdrawal of the blade catheter in contradistinction to very rapid pullback in the Rashkind's balloon septostomy procedure.

successfully in animal models. The first clinical application was reported by Shrivastava and her colleagues.[23]. The procedure involves advancing either an end-hole or a multipurpose catheter from the right atrium to the left atrium across the PFO and from there into a left pulmonary vein (we prefer left lower). An exchange length, extra-stiff Amplatz guide wire is positioned in the pulmonary vein via the catheter and the catheter removed, leaving the guide wire in place. Selected balloon angioplasty catheter is advanced over the wire, positioned across the atrial septum and the balloon inflated to 3 to 5 atmospheres of pressure (Figure 5), taking care not to inadvertently dilate the pulmonary vein. The balloon inflation is repeated once or twice. The recommended duration of inflation is 5 seconds with a 5-minute interval in between each dilatation. Waisting of the balloon during the initial phases of balloon inflation and the disappearance of the waist indicates that the PFO is stretched beyond its initial size. Lack of waist in subsequent balloon inflations indicates that there is enlargement of the PFO. There are no data to indicate the most appropriate size of the balloon that should be used; 8 to 20 mm balloons have been used[21]. Based on theoretical considerations, the final diameter of the balloon should be three to four times the echographic size of the PFO is a good choice[21]. The balloon size should not exceed the size of the atrial septum. We usually end up with a balloon diameter of 14 to 15 mm. Evaluation of the results, again, is similar to that described in the balloon septostomy section. Increase in the size of the defect (similar to Figure 2) and in color Doppler flow width (Figure 6) demonstrates success of the procedure. There are only anecdotal reports of success, but no systematic studies to evaluate the results are published.

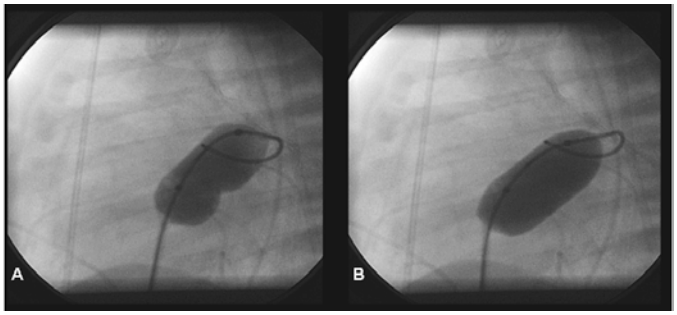

Figure 5. Selected cinfluroscopic frames of balloon angioplasty procedure (to enlarge the patent foramen ovale) demonstrating an inflated balloon in the lateral view showing waisting of the balloon (A) which was completely abolished following further inflation of the balloon (B).

Atrial Septal Perforation

In a small percentage of patients, the atrial septum is intact (no PFO), particularly in HLHS. In such situations the septum can't be crossed with conventional catheters. Traversing the septum either by Ross/Brockenbrough's transseptal technique or radiofrequency perforation may be required.

Transseptal catheterization was initially described by Ross, Brockenbrough and their colleagues [59,60]. This was subsequently adapted to pediatric patients [61,62]. More recently, the technique was extended to neonates [27]. In the Ross technique, initially an end-hole or multipurpose catheter is advanced from the femoral vein into the superior vena cava through which a guide wire is introduced and the catheter removed. The transseptal sheath assembly (Cook, Bloomington, IN) is advanced over the wire and the wire removed. The tip of the transseptal catheter should be pointing posteriorly and to the left (medial) and slowly withdrawn under fluoroscopy in the lateral view. As the tip of the catheter enters the right atrium, it flips suddenly; at this point the position of the

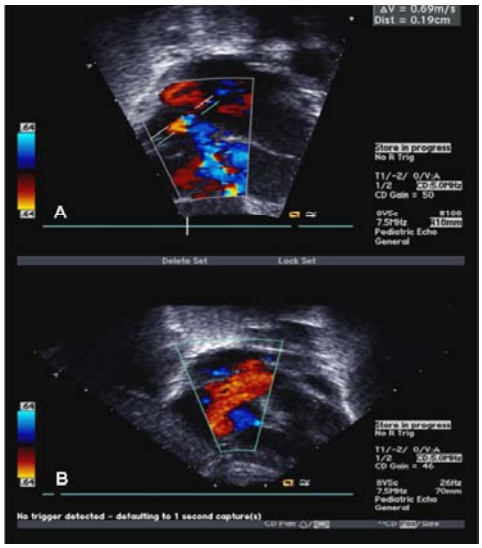

Figure 6. Selected video frames showing a very small color flow jet across the inter-atrial opening (A) which became larger (B) following balloon angioplasty of the atrial septum.

tip of the catheter against the atrial septum is confirmed by echocardiography, indenting the atrial septum. The needle of the transseptal assembly is gently advanced across the atrial septum; a slight "give" indicates entry into the left atrium. The cannula is advanced slightly and the needle removed and the pressure recorded, confirming the left atrial position. Once confirmed to be in the left atrium, the dilator and the sheath assembly is advanced into the left atrium and the dilator removed leaving the sheath in place.

In the radiofrequency (RF) perforation procedure, the technique is similar except that the RF wire is used instead of the needle. Once in the left atrium, static dilatation of the atrial septum as described in the preceding section or stent implantation (to be described in the next section) is performed.

Stent Implantation

Because of tendency for closure of dilated atrial septal openings, stents to keep the defects open may have to be used[25,26]. Stents should be implanted only across the highly restrictive PFO or after septal perforation by one the above described techniques. Initially the guide wire is positioned into the left lower pulmonary vein and an appropriately sized delivery sheath is positioned across the atrial septum. The stent-mounted balloon catheter (large coronary or small peripheral stent of approximately 10 to 15 mm length) is advanced over the wire, but within the sheath. Based on boney land marks the stent is positioned in such way that it is centered across the atrial septum. The delivery sheath is withdrawn into the right atrium while keeping the stent catheter in place. A combination of test injection via the side arm of the sheath and echocardiogram (trans-thoracic or transesophageal) is used to ensure correct position of the stent. The balloon is inflated at the manufacturer's stated pressure, thus expanding the stent. The balloon is deflated and removed, taking care not to dislodge the stent. This is followed by the removal of the guide wire. Recording of pressures across the atrial septum, via the stent, is not recommended to reduce the probability of stent dislodgement. Echo is used to record Doppler flow velocity across the stent. Low velocity flow indicates good result.

CONCLUSIONS

There are a number of cardiac defects in which an atrial septal defect is beneficial. But, the naturally occurring PFO undergoes spontaneous closure, causing poor mixing and/or obstruction to systemic or pulmonary venous flow. In such situations, the PFO may be enlarged or an atrial septal defect created by transcatheter methods. The selection of the method used is largely based on the atrial septal anatomy and left atrial size. In the vast majority of the patients, the septostomy procedures are successful in creating an appropriate sized opening. In the rare cases, surgical septostomy may be required.

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NEONATOLOGY TODAY

ISSN: 1932-7129 (print); 1932-7137 (online).
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