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INSIDE THIS ISSUE

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SUTURE-MEDIATED CLOSURE OF FEMORAL VENOUS ACCESS SITES AFTER CARDIAC CATHETERIZATION

By Ralf J. Holzer, MD, MSc; James M .Sisk, RCIS; Paul E. Lawrence, RCIS; Sharon L. Hill, ACNP; Joanne L Chisolm, RN; and John P. Cheatham, MD

INTRODUCTION

A variety of devices are available for vascular closure after diagnostic as well as therapeutic catheterizations. Most devices have been developed for use in the context of therapeutic coronary interventions and are, therefore, not specifically geared towards the congenital interventionalist. Transcatheter interventions in patients with congenital heart disease frequently require the use of large venous hemostatic sheaths and manual pressure hemostasis in these patients usually requires immobilization for six hours or longer. Choosing an appropriate closure device for 'off-label' use for venous closure in this group of patients may facilitate earlier mobilization and, when chosen appropriately, may reduce the incidence of adverse vascular events and re-bleeding when compared to pressure hemostasis. We report a single-center experience in applying the Perclose suture mediated closure device (Abbott Vascular, Abbott Park, Illinois, Figure 1) to femoral venous entry sites in patients with congenital heart disease. While the use of this device in patients with congenital heart disease has been evaluated before [1;2], reports have been limited to an adult population and variable techniques have been described for closure of those entry sites with sheath sizes in excess of 8Fr.

METHODS

Study population

The study was conducted as a retrospective case note review. An electronic catheterization database query retrieved 138 catheterization procedures, performed between November 2004 and March 2007, in which a suture-mediated closure device (Perclose) was listed as equipment that had been opened during the procedure. One hundred and eighteen procedures were identified in which the Perclose device was used to (attempt) closure of at least one venous entry site. Ninety-eight out of one hundred eighteen (83.1%) procedures were therapeutic catheter interventions, including occlusion of septal defects (56 procedures), occlusion of vascular structures (11 procedures), balloon angioplasty and/or stenting (25

Figure 1: The Perclose Proglide device (Abbott Vascular, Abbott Park, Illinois).

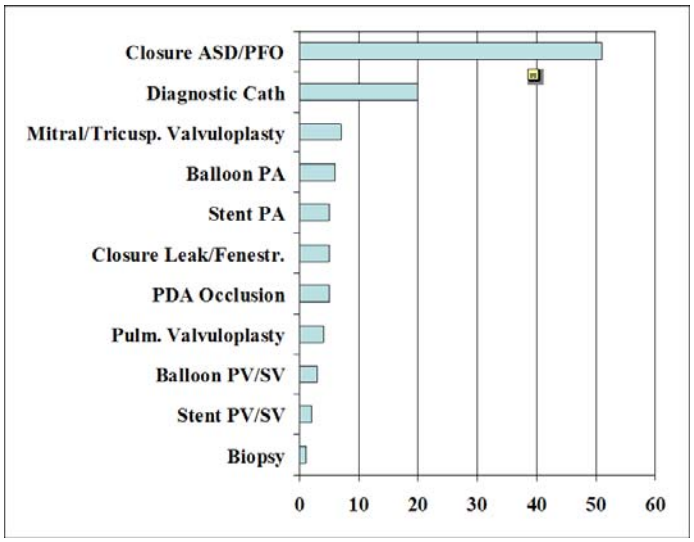

Figure 2: Transcatheter interventions performed using femoral venous access and subsequent placement of suture mediated closure device.

procedures), or balloon valvuloplasty (12 procedures). Figure 2 shows therapeutic interventions performed through femoral venous access. The median age was 34.3yr (7.8-74.5yr) and the median weight was 74.6g (30.3-170kg).

Data Collection

Collected procedural data included the femoral venous and arterial entry sites that were accessed during the procedure, as well as additional details of those vascular sites that had closure devices applied (location, initial sheath size, final sheath size, closure technique). The catheterization report as well as the technician-generated step-by-step catheterization protocol was reviewed for each procedure to identify any difficulties or adverse events that were encountered when applying device closure techniques, as well as the subsequent need for prolonged manual compression after use of a closure device. All electronic inpatient nursing records were reviewed to identify occurrences of rebleeding (or prolonged oozing), hematoma, or the presence of a large bruise at the site of closure. The time of bed rest post procedure was documented for each patient. For all patients, the first follow-up clinical letter was reviewed to identify any occurrence of localized pain, bruising or hematoma, peripheral pulse abnormalities, as well as leg-swelling or congestion.

Device

The Perclose A-T and its successor the Perclose Proglide device (Abbott Vascular, Abbott Park, Illinois) are 6Fr suture-mediated closure systems that were initially developed and evaluated for vascular closure of common femoral arterial entry sites after diagnostic or interventional catheterization procedures. It was designed for use in 5Fr to 8Fr access sites. It consists of a sheath and guide, with the guide housing the main components such as needles, sutures and foot. After vascular access is obtained, the Perclose device is inserted over a 035" wire into the vessel. The wire is then removed and the device advanced further until free backflow of blood is visible from the side port. Once the footplate is deployed the device is pulled back against the vessel wall until some slight resistance is felt, followed by deployment of the sutures. After the sutures are deployed, the vessel can either be closed directly (Perclose), or a wire can be reintroduced to facilitate placement of the appropriately-sized sheath for the catheterization procedure (Pre-Perclose), leaving the suture in place for closure at the end of the procedure. Perclose is generally preferable up to a maximum sheath size of 8Fr because it avoids the risk of suture dislodgement during sheath exchanges. Pre-Perclose has the advantage of facilitating the use of the Perclose device with larger-sized sheaths if sutures are being placed in advance. Angiographic evaluations of the femoral venous dimensions can be performed prior to placing the Perclose device (Figure 3). However, our previous experience has not documented any vessel dimensions that were prohibitive of placing the Perclose suture-mediated closure device if used in patients with a weight in excess of 35kg [3].

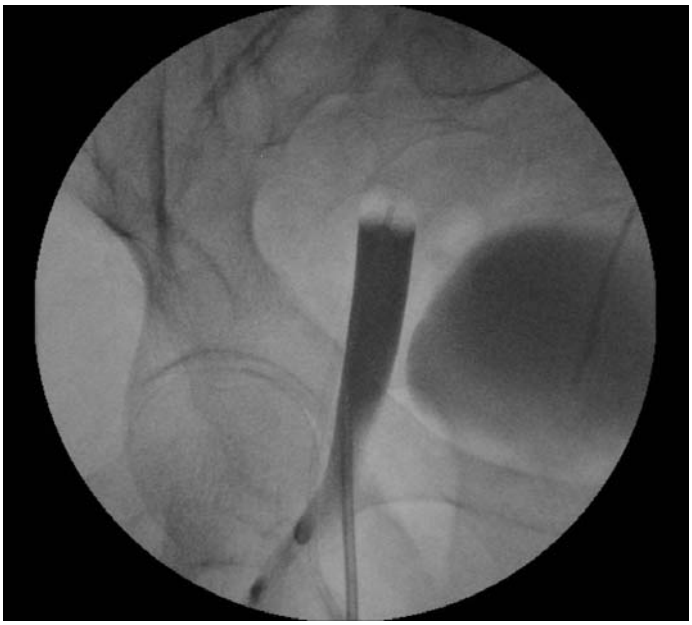

Figure 3: Cine angiographic of the right femoral vein prior to placing a Perclose device, using a Berman angiographic catheter and a balloon occlusion technique.

RESULTS

In addition to femoral venous access, femoral arterial access was obtained in 115/118 (97.4%) procedures and bilateral femoral venous and/or arterial access was required in 37/118 (31.4%) procedures. In 54/118 (45.7%) procedures, all vascular sites that were accessed were successfully closed using available closure techniques. In 63/118 (53.4%) procedures at least one femoral venous access site was successfully perclosed, with additional pressure hemostasis being applied to achieve hemostasis after removal of a femoral arterial monitoring cannula (54 procedures), femoral arterial sidearm sheath (10 procedures), or additional femoral venous sidearm sheath (5 procedures). Of those 64 patients that required additional pressure hemostasis, 36 patients had bilateral venous and/or arterial entry sites with either all right or all left femoral access site(s) being completely closed through available closure techniques. In two procedures, suture-mediated closure of a femoral venous entry site was unsuccessful. In both cases, pre-Perclose technique had been employed and multiple sheath exchanges led to unraveling of the placed suture.

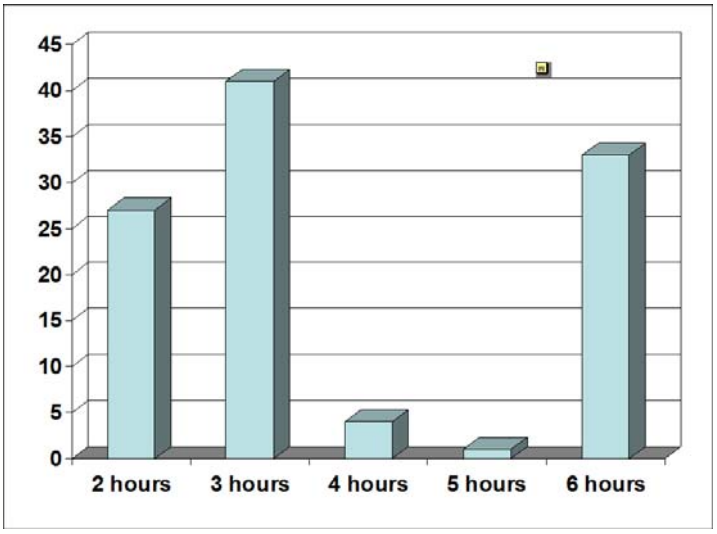

Figure 4. Bed rest applied to patients after suture-mediated closure of femoral venous entry site(s).

Pre-Perclose technique was employed in 51 venous access sites, with the medium sheath sized being placed to accommodate the transcatheter intervention being 11Fr (8-14 Fr). The Perclose suture was placed directly at the end of the procedure (without pre-perclosing the entry site) in 77 procedures with a sheath size of up to 8Fr, and in 19 procedures with a sheath size in excess of 8Fr (9Fr-16Fr). Closure devices were used to close arterial entry sites in 53 procedures, using AngioSeal in 12 procedures (4-6Fr), and (Pre) Perclose in 41 procedures (5-14Fr).

No patient required prolonged pressure hemostasis in the catheterization laboratory. Patients were allowed to mobilize at a median interval of 3hrs (2-6hr) (Figure 4). During the earlier experience, 15 patients were restricted to bed rest of 6 hours, despite all vascular entry sites being successfully closed using closure devices. Adverse events after catheterization were encountered in 6/118 (5.1%) patients. Early adverse events during the initial hospital admission included re-bleeding from the entry site requiring pressure hemostasis in 3 patients, as well as a moderate or large hematoma in 2 patients. Loss of peripheral pulses, clinical evidence of venous thrombosis, or femoral AV fistulas was not observed.

Follow-up data was available for 61/118 (51.7%) patients. The first documented clinical follow-up after catheterization occurred at a median interval of 105d (2d-1.5yr). One patient visited an outside emer-

gency room 2 days after the procedure with unilateral leg swelling and subsequently lost to follow-up. Abnormalities of femoral access sites, peripheral pulses abnormalities, groin pain or clinical evidence of venous thrombosis/DVT were not observed in any other patient. Six patients subsequently underwent repeated catheterization procedures, four of which were of electrophysiological nature, all of whom had a previously perclosed vascular site accessed without difficulty. Two of those patients had a previously perclosed venous entry site closed again using a suture-mediated closure device (Perclose).

DISCUSSION

Closure devices have mainly been evaluated and used to close femoral arterial access sites after coronary transcatheter interventions. There is an abundance of data on femoral arterial closure with the overall rate of vascular complications after arterial closure having been reported to be about 4.2% [4]. However, data on closure of femoral venous entry sites is limited [1;2;5-7], despite the very frequent need to close larger femoral venous entry sites after transcatheter interventions for congenital heart disease.

Shaw and colleagues reported on the use of the Perclose suture-mediated closure device to close femoral venous access sites in 42 patients [2]. Nine patients had sheath sizes in excess of 8Fr closed (9-14Fr). In two patients there was failure of Perclose requiring manual compression, including one of two patients who had 14Fr entry sites closed. In three patients a second suture had to be deployed. It appears as though the authors used a standard Perclose technique, rather than using a pre-Perclose device. Two patients developed complications, one patient acquiring a wound infection and another patient developing deep vein thrombosis and pulmonary embolism. In our series, 19 patients had femoral venous entry sites in excess of 8Fr perclosed directly. With the exception of one patient who developed significant bruising at the entry site and thigh, no adverse events were observed in this group of patients, with the largest venous entry site closed directly being 16Fr without adverse events!

Mylonas and colleagues reported on 45 adult patients that underwent antegrade aortic valvuloplasty [5]. All patients had the venous entry site Pre-Perclosed using the 6Fr Perclose Closer S device (Abbott Vascular, Abbot Park, Illinois), prior to inserting a 14Fr sheath to facilitate transcatheter intervention. Immediate hemostasis was achieved in 95.6% with only 2 failures that were subsequently managed through pressure hemostasis. Adverse events such as rebleeding, clinical venous thrombosis or other vascular complications were not observed in any patient. A group from Toronto reported on the use of the Perclose-AT or Proglide device to close femoral venous entry sites in 146 patients, 65 of which were undergoing ASD closure [1]. Similar to the study by Mylonas and colleagues, Pre-Perclose technique was used in all patients in this series. The maximum femoral venous entry site closed was 14Fr. There were 3 device failures and major suture-related complication occurred in 2 patients (groin hematoma with blood transfusion, re-hospitalization for recurrent bleed requiring manual compression). Forty-three patients had Doppler ultrasound evaluations, documenting patency of all femoral veins without pseudoaneurysm or arteriovenous fistula. Sixty-five patients that underwent ASD device closure had 2 femoral venous entry sites closed within the same femoral vein.

In our series, we employed the Pre-Perclose technique in 51 venous access sites, with adverse events in 5/51 (9.8%) patients. While the rationale behind using the Pre-Perclose technique is to accommodate larger-sized sheaths (>8Fr) through previously placed sutures, our own data has not documented a lower rate of adverse events using this technique (9.8%) when

compared to the direct application of Perclose to vascular entry sites in excess of 8Fr (5.5%) (p=0.6151). In addition, placing the suture at the beginning of a procedure requires extra care by the operator during sheath exchanges. Both incidences of suture failure in our series occurred when using the Pre-Perclose technique due to unraveling of the suture associated with multiple sheath exchanges.

The use of femoral closure devices in smaller patients is usually not recommended due to the risk of creating vascular obstructions. This risk appears to be lesser when using the Perclose device as compared to AngioSeal, where a failure to reabsorb the collagen plug can create significant morbidity to the vasculature and patient [2]. In our study we used Perclose in four patients with a weight below 35kg. All entry sites were successfully closed primarily, but one patient who had a 14Fr venous entry site closed using a Pre-Perclose technique developed a rebleed on the floor requiring manual compression. However, this patient also had arterial access through a 4Fr monitoring cannula which only had manual compression applied. None of the smaller patients developed any clinical signs of deep venous thrombosis.

One of the main benefits of applying closure techniques is the earlier mobilization, especially in elderly patients. In the early transitional period after introducing suture-mediated closure devices at our institution, patients were unnecessarily restricted to bed rest for as much as 6hrs after suture mediated closure. We have not identified a higher incidence of adverse events in patients that were mobilized after 2 or 3 hours. However, all 4 patients that developed rebleeding or moderate-large bruising had hemostasis applied to additional ipsilateral arterial vascular access sites, solely through manual compression instead of application of an additional closure device.

To summarize, vascular closure of venous entry sites can be facilitated safely using the Perclose suture mediated closure system. There is a suggestion that direct Perclose as well as Pre-Perclose technique are both equally safe and effective even for larger venous entry sites of up to 16Fr. However, our data is limited and selection bias may have occurred when identifying patients for direct Perclose technique of femoral venous entry sites in excess of 8Fr.

Patients can be mobilized as early as 2-3 hours after the procedure, but associated arterial entry sites should, whenever possible, have closure devices applied as well, to facilitate this early mobilization. While the use of closure devices in very small patients has associated risks of creating vascular obstructions, our limited data suggests that closure may be safely attempted in patients as low as 30kg. When planning to apply vascular closure devices to multiple venous entry sites within the same vessel, it is essential to achieve an adequate distance between vascular entry sites.

REFERENCES

1. Mahadevan VS, Jimeno SS, Benson LN, McLaughlin PR, Horlick EM. Pre-closure of femoral venous access sites used for Large sized sheath insertion with the Perclose TM device in adults undergoing cardiac intervention. Heart Online 2006;DOI:10.1136/hrt.2006.095935.

2. Shaw JA, Dewire E, Nugent A, Eisenhauer AC. Use of suture-mediated vascular closure devices for the management of femoral vein access after transcatheter procedures. Catheterization & Cardiovascular Interventions 2004;63:439-43.

3. Sisk M, Lawrence P, Hill SL, Daniels C, Cheatham JP. Suture-Mediated Closure Device in Femoral Veins Following Cardiac Catheterization [abstr]. Catheterization and Cardiovascular Intervention 2005;66:125.

4. Resnic FS, Blake GJ, Ohno-Machado L, Selwyn AP, Popma JJ, Rogers C. Vascular closure devices and the risk of vascular complications after percutaneous coronary intervention in patients receiving glycoprotein IIb-IIIa inhibitors. American Journal of Cardiology 2001;88:493-6.

5. Mylonas I, Sakata Y, Salinger M, Sanborn TA, Feldman T. The use of percutaneous suture-mediated closure for the management of 14 French femoral venous access. Journal of Invasive Cardiology 2006;18:299-302.

6. Coto HA. Closure of the femoral vein puncture site after transcatheter procedures using Angio-Seal. Catheterization & Cardiovascular Interventions 2002;55:16-9.

7. Metzger DC, Gupta S, Braden GA. Vascular Access and Complications [abstr]. Am J Cardiol 2004;125E.

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CLINICAL TRIALS

Preventive IVIG Therapy for Congenital Heart Block (PITCH)

This study is currently recruiting patients.

Sponsors and Collaborators: New York University School of Medicine; Alliance for Lupus Research.

Purpose: Neonatal lupus (NL) is the name given to a group of conditions that can affect the babies of mothers who have certain autoantibodies against components of the body's cells that are called SSA/Ro and SSB/La. NL can appear as a temporary rash that usually goes away by the time the baby is 6 months old, or very rarely an abnormal blood or liver condition that also improves with time – or it can cause permanent and often life-threatening damage to the fetal heart, known as congenital heart block (CHB). In women with anti-Ro/La antibodies who are pregnant for the first time, only about 2% of the babies will develop CHB. But for a woman who has already had a child with CHB or NL rash, the risk of CHB in her next pregnancy is nearly 20%. Unfortunately, once complete (third degree) heart block has been unequivocally identified in a fetus, it has never been reversed with any of the therapies that have been tried to date. Our previous studies strongly indicate that scarring of the conduction system (the heart's own natural "pacemaker"), a consequence of inflammation triggered by the mother's antibodies, damages or even destroys the cells that allow the heart to beat at a normal rhythm. Instead, the damaged heart beats extremely slowly, to an extent that is fatal to nearly 20% of affected babies (with most deaths occurring as fetal demises). Nearly all surviving children with CHB require permanent implantation of a pacemaker device. Because it is so difficult to treat or repair the damaged heart, a high-priority strategy is to try to prevent the inflammatory process before irreversible scarring can occur. The aim of this clinical-based proposal is to determine whether treating the pregnant mother with intravenous immune globulin (IVIG) will prevent the development of CHB.

Study Type: Interventional

Condition: Congenital Heart Block; Neonatal Lupus; Autoantibody-Associated Heart Block

Intervention: Drug: intravenous immune globulin (IVIG)

Phase: Phase II; Phase III

Study Design: Prevention, Non-Randomized, Open Label, Historical Control, Single Group Assignment, Efficacy Study

Primary Outcome Measures: 2nd or 3rd degree heart block

Total Enrollment: 54

Eligibility: Female; 18 - 50 years

Inclusion Criteria: (1) Mother must currently have an intrauterine pregnancy of less than 12 weeks. (2) Mother must have antibodies to SSA/Ro and/or SSB/La (will be confirmed in the clinical immunology laboratory at the NYU-Hospital for Joint Diseases). (3) Mother can be asymptomatic or have any rheumatic disease (such as lupus, Sjogren syndrome or other). (4) Mother must have had a previous child with one of the following: (a) congenital heart block (any degree) documented by EKG if live birth and/or echocardiogram if fetal demise; (b) characteristic neonatal lupus rash confirmed by photograph revealing annular lesions (evaluated by the PI), dermatology note, and/or biopsy; (c) congenital heart block and rash. (5) Mother may be taking 20 mg prednisone per day or less.

Exclusion Criteria: (1) Mother does not have antibodies to either SSA/Ro or SSB/La. (2) Mother is taking greater than 20 mg prednisone per day. (3) Mother has any condition that would contraindicate the use of IVIG: (a) prior serious reaction to IVIG infusion; (b) known IgA deficiency; (c) intolerance of volume load, e.g., congestive heart failure; (d) nephrotic syndrome. (4) Identification in the fetus of any of the following structural lesions considered causal for congenital heart block: (a) atrioventricular septal defects; (b) single ventricle; (c) developmental tricuspid valve disease; (d) L-transposition of the great arteries; (e) heterotaxia.

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For Detailed Information:

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Last Updated: April 13, 2007

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ClinicalTrials.gov

Identifier: NCT00460928

Health Authority: United States: Institutional Review Board

ClinicalTrials.gov processed this record on May 29, 2007

For continuing up-to-date information on this clinical trial visit www.ClinicalTrials.gov

HIGHLIGHTS FROM THE SIXTH INTERNATIONAL PEDIATRIC CARDIOVASCULAR SYMPOSIUM: NOVEL MEDICAL INTERVENTIONS AND THEIR ROLES IN CHILDREN WITH HEART DISEASE

By Janet M. Simsic, MD and William T. Mahle, MD

Children's Healthcare of Atlanta hosted the *Sixth International Pediatric Cardiovascular Symposium: Novel Medical Interventions and their Roles in Children with Heart Disease,* June 26 through July 1, 2007 at the Ritz-Carlton on Amelia Island. The three day symposium began with a nursing preconference and continued with a day of new innovations in noninvasive technology, invasive technology and hot topics in outpatient pediatric cardiology. There were over 100 attendees from 25 States. Guest faculty included our keynote speaker, Dr. Philipp Bonhoeffer, Chief of Cardiology at Great Ormond Street Hospital for Children in London; Dr. Anthony Chang, Director of Cardiology at Children's Hospital Orange County, California; Dr. Audrey Marshall, pediatric cardiologist from Children's Hospital Boston; Dr. Jack Rychik, Director of the Fetal Cardiac Program at Children's Hospital of Philadelphia; and Dr. Lloyd Tani, Chief of Cardiology at Primary Children's Medical Center in Salt Lake. The keynote speaker for the nursing preconference was Karen Uzark, PhD, CPNP from Cincinnati Children's Hospital.

The highlight of the symposium was Dr Philipp Bonhoeffer's keynote address on the "The Percutaneous Pulmonary Valve: Oh the Places You'll Go with a Valve Like That." Dr. Bonhoeffer discussed the history and evolution of percutaneous valve implantation. He also provided a vision of the future of transcatheter valve therapy.

The nursing preconference began with the keynote nursing address "Evidence-Based Practice" by Karen Uzark. The examination of practice patterns and outcomes, evidence base, leads to potential changes in practice which results in the best outcomes for our patients. This was followed by "Beyond the Bundles" by Nicole Jarrell addressing the important topic of reducing blood stream infections. Mary Stevens discussed "Pediatric Safety in the Cardiac Catheterization Laboratory" including radiation safety and parent teaching. Lisa Pugsley reviewed "Nursing Attitudes towards their Profession" focusing on the nursing shortage. Lastly, Nicole Jarrell presented "Colorful Communication" a tool to identify different styles of communication to build a stronger team.

The first session, noninvasive technology, focused on the recent advances in echocardiography, magnetic resonance imaging, CT, and near infrared spectroscopy. The noninvasive technology session began with Dr. Jack Rychik's presentation of "Tissue-Doppler and Strain Imaging: Is it Worth the Trouble?" His answer: "I'm a Believer." Dr. Derek Fyfe then discussed "3-D Echocardiography: Finally Ready for Primetime?" "Vascular Ultrasound in Pediatrics" was the next topic presented by Dr. Bill Mahle, encouraging the audience to consider expanding the imaging capabilities of the pediatric echo lab. Additional presentations addressed expanded indications for Cardiac MRI, Coronary Artery Imaging: CT, MRI or Both? and Near Infrared Spectroscopy (NIRs) the 6th Vital Sign. Collectively, the speakers presented a balanced view of these emerging technologies. They expressed optimism about the pace of development in this field, but cautioned against adopting new technologies that do not materially impact patient care.

The second day's session, invasive technology, focused on the recent advances in interventional cardiac catheterization, electrophysiology, ventricular assist devices, and resuscitative extra-corporeal membrane oxygenation. The day began with our keynote address by Dr. Bonhoeffer, followed by "Plugging Holes – Device Update" by Dr. Audrey Marshall. Dr. Marshall reviewed devices for ASD, VSD and PDA closure. Dr Robert Vincent presented a historical perspective of interventional cardiac catheterization from Forssman to Amplatzer; Nadas to Bonhoeffer. "Opening Holes and Vessels– Radio Frequency Catheter Alation – Not Just for EP and Stents" was the next

presentation by Dr. Philipp Bonhoeffer. Dr. Anthony Chang discussed ventricular assist devices and their multifaceted care. The strategy of resuscitative ECMO was reviewed by Dr. Paul Kirshbom. The second day ended with a talk by Dr. Audrey Marshall, "Interventions in the Fetus – Past, Present and Future."

The third day's session, "Hot Topics in Outpatient Pediatric Cardiology," focused on important current issues for the outpatient cardiologist. The session addressed many of recent recommendations and statements dealing with hypertension, dyslipidemias and Kawasaki Disease. Of particular interest was a presentation by Dr. Lloyd Tani on the "Endocarditis: Prevention and Treatment." Not surprisingly a lively debate centered around the recent recommendations regarding endocarditis prophylaxis from the American Heart Association.

Sunday morning began with "Breakfast with the Experts," a time for our conference attendees to meet in small groups with our guest and local faculty to discuss specific topics of interest.

The symposium was an excellent educational (and social) opportunity for pediatric cardiologists, nurses, surgeons, and pediatricians, thanks to the variety of current topics, esteemed guest and local faculty, and wonderful location. The Ritz-Carlton venue provided a family-friendly, upscale beach resort environment. The meeting was set up so that attendees would have an opportunity to enjoy the resort's numerous activities. Many rounds of golf were played at various resort courses by the conference attendees. Several adventuresome nurses, physician assistants and physicians went on a kayaking trip down the St. John River. And, of course, there was a lot of fun in the sand and surf.

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AMERICAN SOCIETY OF ECHOCARDIOGRAPHY—18TH ANNUAL SCIENTIFIC SESSIONS—SEATTLE, WA – JUNE 16-20, 2007 MEETING HIGHLIGHTS

The 2007 Annual Scientific Sessions, held in Seattle, Washington, was another successful conference with programs designed to meet all attendees' needs. Following are the standout new programs, initiatives and announcements that defined the 18th annual meeting:

Noteworthy

Six hundred-seventy-one abstracts were submitted and narrowed down to a final list of 285 for poster sessions.

Congenital Heart Disease was a hot topic of the meeting, driving several symposia.

NEW - IV insertion clinic to train sonographers – for use in stress echo and contrast echo.

NEW - Live scanning and computer sessions – Faculty assistance was available to teach attendees the best ways to quantify cardiac function, assess dyssynchrony and crop 3D echo image sets.

Symposia

Perioperative Echocardiography for Heart Failure, featuring a live surgical transmission from Northwestern Memorial Hospital, Chicago, IL.

"You Are the Surgeon" – Always a hit, this year's symposia offered opportunity for hands-on operation of a porcine heart using heart ultrasound for guidance.

Announcements

Echo ToolBox™ Launch - ASE launched an innovative Web-based product to enhance lab quality and facilitate the Intersocietal Commission for the Accreditation of Echocardiography Laboratories' (ICAEL) accreditation process. This tool came to further ASE's mission of promoting lab quality, and as a result of the announcement from UnitedHealth Group that accreditation is mandatory by March 2008 as a condition for reimbursement for all outpatient heart ultrasound exams. The launch was kicked off with a "Taste of Seattle" reception. Laboratories can learn more by visiting www.echotoolbox.com.

Announcement of New President - The American Society of Echocardiography (ASE) announced the election of Thomas Ryan, MD, director of the Ohio State University Heart Center in Columbus, OH and heart ultrasound expert, as its new president. Dr. Ryan will serve as president of the Society through June 2008. Dr. Ryan holds the John G. and Jeanne McCoy chair in cardiovascular medicine at Ohio State University and is director of the Richard Ross Heart Hospital at the Ohio State University Medical Center.

Release of Appropriateness Guidelines - The American College of Cardiology Foundation (ACCF) and the American Society of Echocardiography (ASE), together with other specialty associations, released Appropriateness Criteria for two of the most commonly used cardiac ultrasound techniques – transthoracic (TTE) and transesophageal (TEE) echocardiography.

Designed to give physicians more confidence when ordering an echo, the TTE/TEE Appropriateness Criteria review common scenarios found in clinical practice and address the appropriateness of ordering echocardiograms for each. The Criteria was published in the July 2007 issue of The Journal of the American Society of Echocardiography (JASE) and can be found online at www.asecho.org.

Special Lectures

2007 Feigenbaum Lecture – Marielle Scherrer-Crosbie, MD, PhD of Massachusetts General Hospital in Boston was named the eighth annual ASE Scientific Sessions Feigenbaum Lecturer. The Feigenbaum Lecture was named in honor of the founder and first president of ASE, Harvey Feigenbaum, MD, FASE. This lectureship is awarded to a young investigator in recognition of his/her significant contribution to research in the field of echocardiography and his/her potential to continue at a high level of achievement. Dr. Scherrer-Crosbie presented her lecture titled, "Echocardiography in Translational Research: Of Mice and Men."

2007 Edler Lecture – Given by outgoing ASE president, Michael H. Picard, MD, FASE of Massachusetts General Hospital in Boston. Created in 1990, the annual Edler Lecture honors the founder of echocardiography, Dr. Inge Edler. Dr. Picard presented his lecture titled "The Future of Echocardiography: What Follows the Tipping Point?"

Awards

ASE Pediatric and Congenital Heart Disease Council's Founders Award – Steven D. Colan, MD, FASE of Children's Hospital in Boston, was named the tenth recipient of the ASE Pediatric and Congenital Heart Disease Council's Founders Award. This award recognizes continued major scholarly contribution to the field of pediatric echocardiography. Dr. Colan presented his lecture titled, "The Changing Face of Pediatric Echocardiography: Implications for Training, Manpower Shortage and Job Satisfaction."

2007 Arthur E. Weyman Young Investigator's Award – This award is given to young investigators under the age of 40 to recognize their contributions to echocardiography. The 2007 winner was Beat A. Kaufmann, MD, of Oregon Health & Science University in Portland, OR for his research on "Molecular imaging of inflammation in atherosclerotic lesions: A potential method for early detection and risk assessment."

ASE Pediatric and Congenital Heart Disease Council Travel Grant Recipients –The following trainees were awarded $1600 toward his/her travel expenses to the ASE 18th annual Scientific Sessions as part of an ongoing effort by the council to encourage fellows to enter the pediatric cardiovascular imaging field, and to create a meaningful mentoring opportunity for trainees and established imaging faculty at the ASE Scientific Sessions:

- Shelby Kutty, MD, Children's Hospital of Wisconsin.
- Timothy Slesnick, MD, and Karen M. Texter, MD, Texas Children's Hospital, Baylor College of Medicine.

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MEDICAL NEWS, PRODUCTS AND INFORMATION

Medtronic Combines Vascular and Cardiac Surgery Businesses

New CardioVascular Business Assembles Full Spectrum of Surgical and Minimally Invasive Products for Cardiovascular Disease.

On April 11, 2007, Medtronic, Inc. (NYSE:MDT) announced the formation of Medtronic CardioVascular, a new, global business combining Medtronic's existing Vascular and Cardiac Surgery businesses.

The new CardioVascular business at Medtronic will bring together people, technology and worldwide operations focused on delivering products, treatments and therapies for coronary artery, vascular and structural heart disease. The new business will have combined revenues of approximately $1.9 billion (FY07) and will consist of four major divisions:

- Coronary and Peripheral – minimally invasive catheter and stent-based technologies for the treatment of atherosclerosis;
- Endovascular Innovations – stent grafts for the treatment of aortic abdominal and thoracic aneurysms;
- Structural Heart Disease – products for the treatment of heart valve disease and atrial fibrillation; and
- Revascularization and Surgical Therapies – open heart and coronary bypass grafting surgical products

The four core divisions will remain in their current locations but will leverage common business processes and specific functional infrastructure while expanding scientific knowledge and engineering capabilities to advance cardiovascular care.

"Medtronic is combining these two world-class organizations to more strategically align our resources and investments aimed at treating and improving the lives of patients with cardiovascular disease," said William Hawkins, president and chief operating officer of Medtronic. "This new business unit also provides Medtronic the opportunity for more growth, as we translate certain efficiencies gained by this combination into new investments in research, clinical studies and technology."

The new CardioVascular business unit will be led by Scott Ward, who currently serves as senior vice president and president of the company's Vascular business. Ward joined Medtronic in 1981 and has been president of the Vascular business since May 2004. Prior to his current position, Ward served as president of the company's Neurological and Diabetes businesses.

"The new CardioVascular business will assemble an exceptional collection of people, technology and global operations that will be focused on collaborating with physicians to improve the quality of care for people with cardiovascular disease," said Ward. "Medtronic will continue to be a powerful innovative force supporting the convergence of cardiovascular specialties focused on applying both surgical and minimally invasive approaches to patient care."

For more information visit: www.medtronic.com

Physicians Take Aim at Children's Cholesterol with CardioChek

National Cholesterol Month is coming up in September. With compelling evidence showing that the atherosclerotic process begins in childhood and progresses slowly into adulthood, Cholesterol Month is a time for parents and doctors to take an interest in children's cholesterol. A device like CardioChek® PA can help physicians quickly and easily provide an assessment of a child's cholesterol level.

CardioChek® PA is a diagnostic analyzer for medical professional testing of cholesterol and is FDA cleared for use on patients of all ages. The easy-to-use device provides medical professionals with a cost-effective, simple way to track important health factors in the convenience of their own office - with one fingerstick. New to CardioChek® PA is the direct determination of LDL, without requiring fasting like other diagnostic systems. Medical professionals can use individual PTS Panels Test Strips, CLIA-waived and CE labeled, to measure the following key health indicators:

- Lipid profile results (Total Cholesterol, HDL Cholesterol, Triglycerides, Direct LDL Cholesterol by calculation) - all from a single fingerstick whole blood sample.

- Also tests for Glucose, Creatinine*, Ketone and Total Cholesterol with individual strips. (All strips are CLIA-Waived except Creatinine).

With the help of CardioChek® PA, physicians can quickly pre-screen the cholesterol levels of at-risk children so they can immediately provide the counseling, education, or the recommended lifestyle changes patients may need. While not a replacement for more intense lab work, CardioChek® PA can certainly provide immediately preliminary information.

For more information: www.CardioChek.com/professional/index.asp

Ten Years After Bristol Inquiry Parents Get Access to Survival Rates at Congenital Heart Disease Centres

Parents of children with congenital heart disease can now, for the first time ever, get detailed information about survival rates at every specialist heart centre in the UK - via a new website launched by The Information Centre for health and social care (The IC) June 1, 2007.

In a world first, the *Congenital Heart Disease W*ebsite has been developed by the leading independent provider of health information in order to help parents and carers make informed decisions about their child's care.

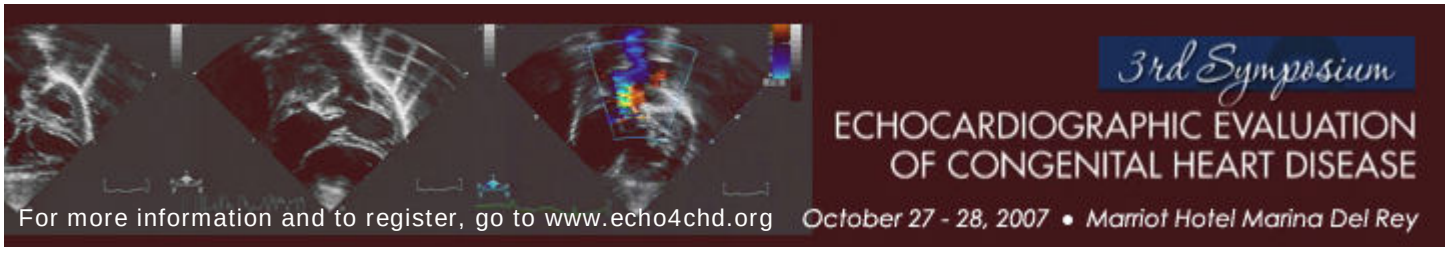
The initiative comes ten years after the Bristol Inquiry and, by presenting the results of interventions for public and professional scrutiny, is designed to reassure parents about the quality of care available to their child.

Specialists from The Society of Cardiothoracic Surgeons of Great Britain and Ireland and The British Congenital Cardiac Association helped develop the website which was funded by independent health watchdog the Healthcare Commission.

The website profiles every congenital heart disease centre in the UK, including the number and range of procedures they carry out and survival rates for the most common types of treatment.

The information presented is from data provided by clinicians and hospitals to The IC's Central Cardiac Audit Database (CCAD) which is used to collect information for the National Heart Disease Audits.

The IC's chief executive, Professor Denise Lievesley, said, "This is the first time any country in the world has made infor-



mation of this type available to parents and carers and we hope it helps and reassures them."

Ten years after the Bristol Inquiry, the site has been developed with considerable input from surgeons and medical teams across the country and draws on data from the national audits that we carry out on heart treatment.

"We hope parents find the website a useful, additional source of information and that it helps them when they are discussing their child's treatment with their doctor or specialist."

Head of clinical audit at the Healthcare Commission Jonathan Boyce remarked, "Cardiac surgery on babies and children is often complicated and always stressful for the families involved. The information being made available publicly for the first time is an important step on the journey to greater partnership between patients and their doctors. It should prove useful to parents and their GPs as well as those responsible for running those services."

President of The Society of Cardiothoracic Surgeons of Great Britain and Ireland and commissioner for the Healthcare Commission Sir Bruce Keogh said, "Just over a decade ago the sad events in Bristol cast a cloud over British cardiac surgery. Now this comprehensive website, which is the first of its kind in the world, shows that those involved in the highly complex area of children's heart surgery have risen to the challenge by presenting the results of their interventions for public and professional scrutiny. Parents can be reassured that the quality of treatment in the UK is as good, if not better, than anywhere else in the world."

Dr. John Gibbs, lead clinician for congenital heart disease for The Information Centre's Central Cardiac Audit Database (CCAD) and president of the British

Congenital Cardiac Association, said, "This information should help families understand the risks of treatment as well as help them make informed decisions about where treatment is carried out. We hope that the public will be reassured that constant and transparent assessment of outcomes is taking place in all UK specialist congenital heart disease centres. Open sharing of data will help to identify best practice and will contribute to the further improvement of results of treatment for our patients."

Professor Roger Boyle, national director for heart disease and strokes at the Department of Health said, "I really welcome this addition to the suite of clinical information that is made available to the public about heart disease and how it is managed. To analyse and make sense of the many complex operations that are performed for children with heart disease requires a huge effort by the clinical community. I am sure that having this information available for parents and families will be welcomed by all concerned."

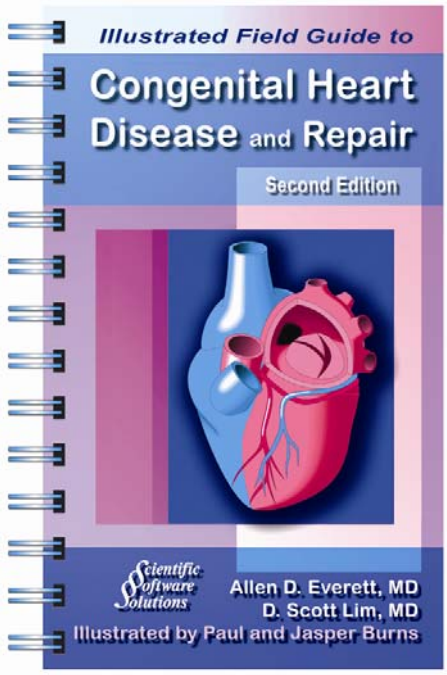
Consultant paediatric cardiac surgeon at The Newcastle upon Tyne Hospital NHS Foundation Trust Leslie Hamilton said:, "Surgery for congenital heart defects is very much a team effort. We hope that this information will provide parents with reassurance that their child is receiving high quality care wherever they live in the UK."

Chief executive of the Children's Heart Federation, Anne Keatley Clarke, said, "The publication of this data is a really important step in giving parents access to the information they need in order to make decisions about their child's treatment. We hope that this information will also help to focus the current debate about the future of the paediatric and congenital cardiac service."

The website is at www.ccad.org.uk/congenital.

BOOK REVIEW: ILLUSTRATED FIELD GUIDE TO CONGENITAL HEART DISEASE AND REPAIR. (SECOND EDITION) PUBLISHED BY SCIENTIFIC SOFTWARE SOLUTIONS, INC.

By John W. Moore, MD, MPH



The Second Edition of the *Illustrated Field Guide to Congenital Heart Disease and Repair* (www.pedheart.com) is, quite clearly, a substantial improvement over the First Edition. Not only have Drs. Allen Everett and D. Scott Lim added important new chapters, they have also revised and expanded the original chapters. The excellent illustrations by Paul and Jasper Burns have been retained. The impact of the new edition will be to better serve as a pocket-sized illustrated reference and teaching tool for care providers and for patients with congenital heart disease, their family members and guardians.

New subject chapters have been added on Echocardiography, Cardiac ICU, Electrophysiology, and Cardiac Pharmaceuticals. These chapters succeed in filling in the gaps which were noticeable in the First Edition.

The chapter on Echocardiography is written by Howard Gutgesell, MD, includes a concise, and complete discussion of Two-Dimensional, M-mode and Doppler Echocardiography. Excellent diagrams and still frames from appropriate studies complement the discussion of the subject matter. In addition, the chapter covers: Normal Values, Frequently Used Formulas, as well as Basic Quantitative Echocardiography.

"Overall, I recommend the Second Edition of the Illustrated Field Guide to all the readers of Congenital Cardiology Today. This Guide is better than ever and is a truly outstanding teaching and learning aid for all of us."

Robert Gajarski, MD and Stacie Peddy, MD contributed an excellent chapter covering Cardiac ICU Topics. Intraoperative events such as Cardiopulmonary Bypass, Cross Clamp Time, Circulatory Arrest and MUF are defined. Assessing the Post-Operative Patient and Intracardiac Monitoring Lines and other "Accessories" are discussed. Common post-operative pathophysiologic problems including low cardiac output syndrome, pulmonary hypertension, arrhythmias, and issues unique to the Single Ventricle patient are discussed. Finally, there are good sections on mechanical support and pharmacology.

The Electrophysiology Chapter is introduced by Jane Crosson, MD, who provides an erudite discussion of the electrocardiogram, conduction disturbances , abnormal rhythms and treatment of arrhythmias. The illustrations in her chapter are particularly well-done and support her text extremely well. Explaining rhythm disturbances is always difficult, and Dr. Crossan's Chapter, in my opinion, is extremely helpful.

The final new Chapter is by Marcia Buck, Pharm D. She has put together a comprehensive table of cardiac medications for infants and children, which is complete and right to the point. This table will be a very useful reference for care provides at all levels including staff pediatric cardiologists.

In addition to the new chapters, all of the original chapters have been substantially expanded and updated where appropriate. Particularly dear to me is the chapter about catheterization laboratory interventions. Scott Lim, MD has added sections on a variety of important topics which are difficult to explain to patients and families, such as transhepatic venous access. There are also some much improved explanations for common procedures such as ASD occlusion with new excellent illustrations of the Amplatzer Septal Occluder and its implantation procedure. Of course, it is difficult to keep up with the very latest interventions, e.g transcatheter valve therapy. Scott left a few topics for the Third Edition.

Overall, I recommend the Second Edition of the *Illustrated Field Guide* to all the readers of Congenital Cardiology Today. This Guide is better than ever, and is a truly outstanding teaching and learning aid for all of us.

~CCT~

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MEDICAL SYMPOSIA

25th International Congress of Pediatrics
August 25-30, 2007; Athens, Greece
www.icp2007.gr

2nd Annual Pediatric Telehealth Colloquium
September 6-8 2007; San Francisco, CA USA
www.ucdmc.ucdavis.edu/children/Telemedicine/Telemedicine_colloquium.html

21st Annual Meeting of the European Association for Cardio-Thoracic Surgery
September 15-19, 2007; Geneva, Switzerland
info@eacts.co.uk

Pedirhythm 3
October 3-6 2007; Istanbul, Turkey
www.pedirhythm.org

Pediatric Cardiology and Cardiac Surgery Meeting
October 4-5 2007; Brussels, Belgium
ccv@chir.ucl.ac.be

Evolving Concepts in Management of Complex Congenital Heart Disease
October 5-6, 2007; San Diego, CA USA
www.rchsd.org

48th Annual Meeting of the European Society for Paediatric Research
October 6-8, 2007; Prague, Czech Republic
www.kenes.com/paediatric-research

5th Annual Symposium on Advances in Perinatal Cardiology (Special Focus: Evolution of Fetal Congenital Heart Disease)
October 11-13, 2007; San Diego, CA USA
www.allkids.org/conferences

2nd Annual European Echocardiography on Congenital Heart Disease
October 10-13, 2007; Prague, Czech Republic
www.hotel-ilf.cz/echocardiography2007/

NPCNA (Northeast Pediatric Cardiology Nurses Association) Annual Fall Conference
October 27, 2007; Boston, MA USA
Julianne.Evangelista@Cardio.chboston.org

Cardiology 2008
February 6-10, 2008; Scottsdale, AZ USA
www.chop.edu/cardiology2008

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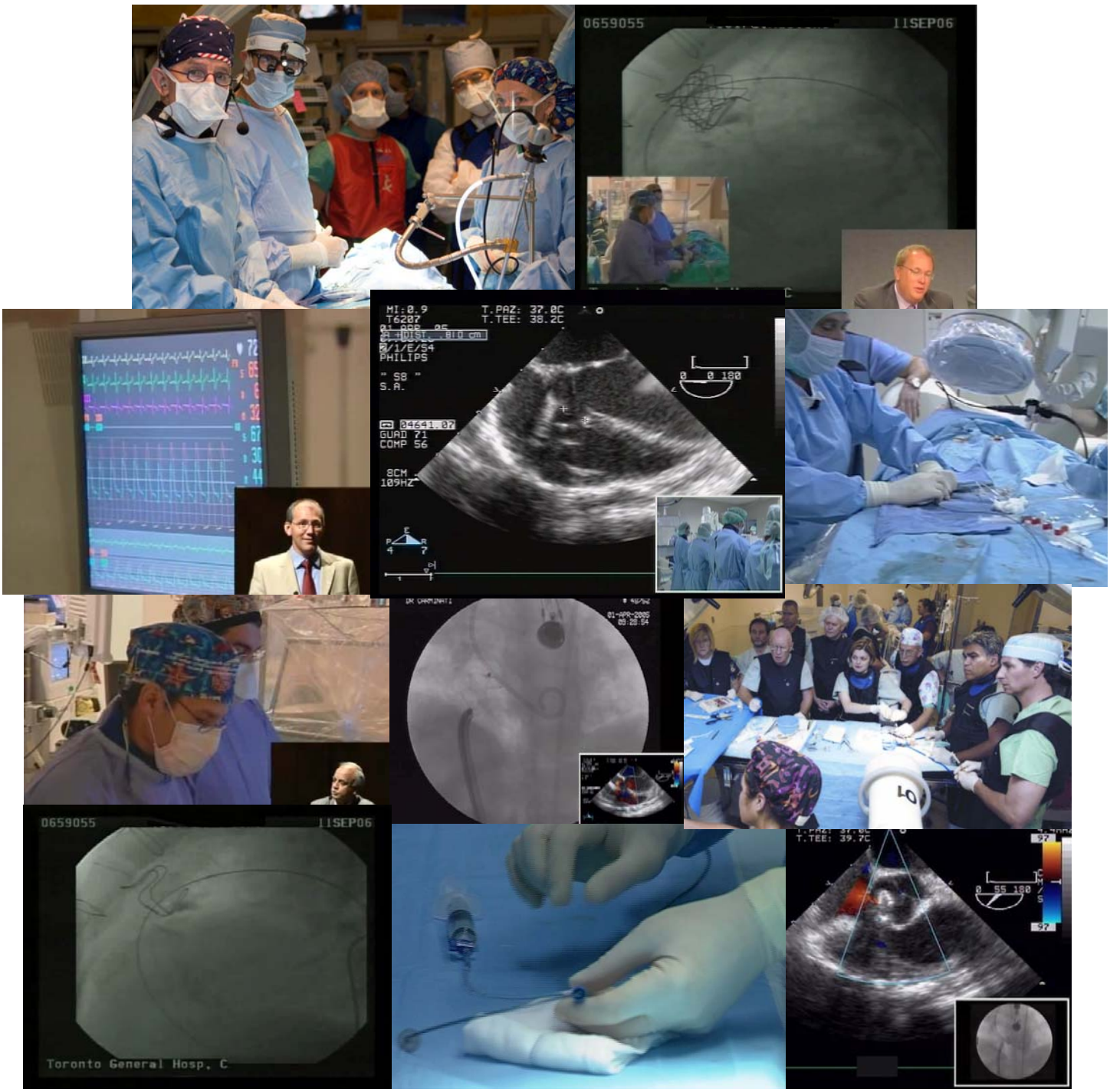

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