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CONGENITAL CARDIOLOGY TODAY

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Intraoperative "Hybrid" Stent Delivery Under Direct Vision Using Endoscopic Guidance

By Ralf J. Holzer, MD MSc; Matt Sisk, RCIS; Alistair Phillips, MD

"...intraoperative 'Hybrid' stent delivery using direct visualization and endoscopic guidance is a fairly simple, quick, and effective procedure to allow accurate stent placement to treat proximal pulmonary arterial lesions in patients who require cardiopulmonary bypass surgery for pulmonary valve or conduit replacement. Close cooperation between surgical and interventional team is essential to facilitate a successful outcome."

Case Report

A 19-year-old female patient was evaluated for surgical pulmonary valve replacement. She was born with Tetralogy of Fallot and underwent complete repair at about one year of age, which included patch closure of a ventricular septal defect (VSD), as well as placement of a transannular right ventricular outflow tract (RVOT) patch. She did not require any further surgical or transcatheter interventions and remained cardiovascularly asymptomatic at NYHA class I. However, on echocardiography and serial MRI assessments she developed increasing right ventricle (RV) size and reduction in RV function because of significant pulmonary insufficiency (PI).

An EKG documented right bundle branch block with a QRS duration of 124ms. MRI revealed RVEDVi of 103ml/m2 and RVESVi of 48ml/m2. The RV ejection fraction (RVEF) was 53% (compared to 57% 2 years prior) and the pulmonary regurgitant fraction was 52%. The MRI also documented a stenosis at the LPA origin, measuring at its narrowest 14mm. A 24-hour Holter recording did not document any evidence of atrial or ventricular arrhythmias. Based on echocardiography, RV pressures were estimated to be normal (TR 2.4m/s). An exercise test revealed VO2 max of 22ml/kg/min. There were no ischemic changes during the exercise test.

She subsequently underwent combined transcatheter and EP evaluation in preparation of pulmonary valve replacement. This demonstrated normal RV pressures (25/9mmHg)

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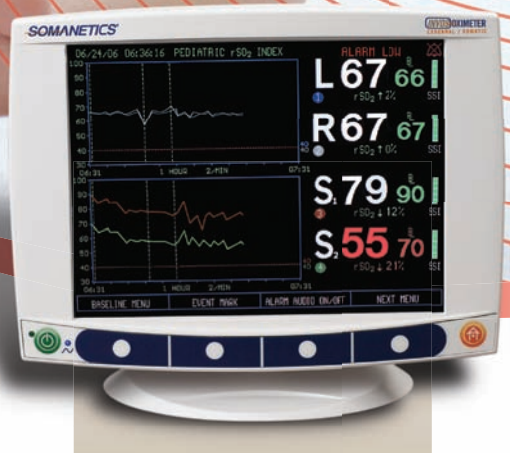

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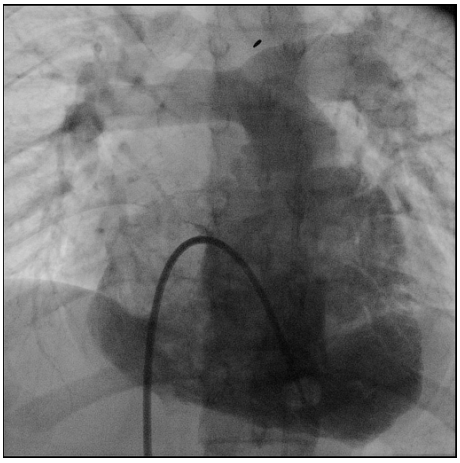

Figure 1. RV angiogram documenting a large dilated right ventricle. The right pulmonary artery appears to be unobstructed while the left pulmonary artery is not adequately profiled on this projection.

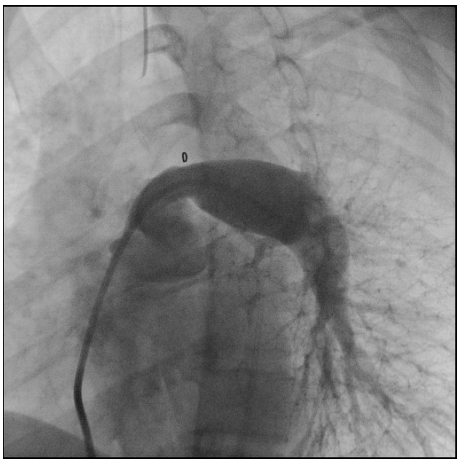

Figure 2. LPA angiography in LAO-cranial projection, documenting a kink of the proximal left pulmonary artery.

with a small 4mmHg peak systolic gradient to the LPA. There was no residual L-R shunt. Angiographic evaluation documented severe pulmonary insufficiency, a large dilated RV (Figure 1), as well as a fold in the proximal LPA (Figure 2). The LPA at its narrowest at the origin measured 11.8mm, with the poststenotic

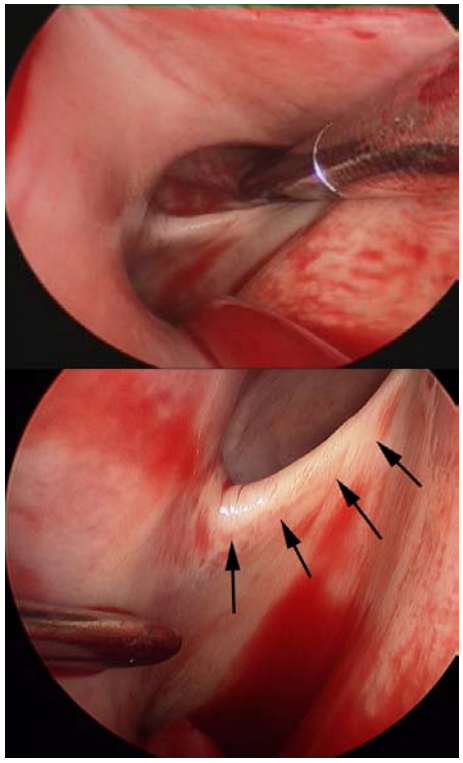

Figure 3. Endoscopic evaluation of the LPA intraoperatively. The top image shows the pulmonary artery bifurcation. Of note is the ridge/fold at the LPA origin which is further depicted in the bottom picture (arrows).

dimension being 24.8mm, and the LPA at the hilum being 19.7mm. The findings were discussed with the cardiac surgical team and it was felt that the lesion would be best treated intraoperatively, possibly through patch augmentation, but more likely through intraoperative stent placement.

The patient was subsequently taken to the operating room and intraoperative inspection confirmed a kink of the proximal LPA (Figure 3). It was decided to proceed with intraoperative stent placement. A Stryker endoscope (Stryker, Kalamazoo, MI) was utilized to inspect the LPA proximal and distal to the kink, as well as to assess the distance to

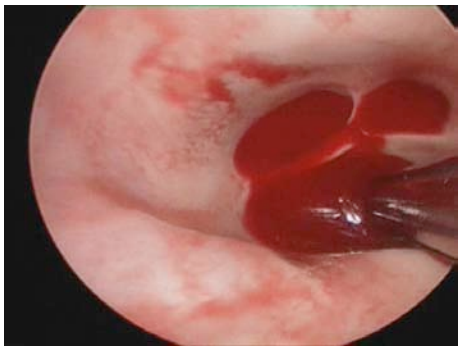

Figure 4. Endoscopic evaluation of the left pulmonary artery, documenting the lobar branching.

the origin of the left upper lobe branch (Figure 4). Under endoscopic guidance, a standard .035" guidewire was placed in the left lower lobe branch pulmonary artery. A 26mm Max LD stent was mounted on a 22mm*3cm BiB balloon catheter (NuMED, Hopkinton, USA), and the assembly advanced over the guidewire across the stenotic lesion. Using continuous visualization with endoscopic guidance, the inner balloon was inflated and the stent position adjusted. This was followed by inflation of the outer balloon. The balloon was deflated and removed and subsequent endoscopic evaluation documented excellent stent position with complete relief of the obstruction, and sufficient distance to any lobar branch pulmonary arteries. Finally, the edges of the stent were 'crimped' manually to allow a 'smooth' entrance into the LPA and avoid any luminal protrusion of stent meshwork (Figure 5).

Following intraoperative stent placement, a 21mm bovine pericardial valve was implanted. The patient was separated from cardiopulmonary bypass without difficulty and extubated in the operating room. She was discharged home five days following the procedure.

Discussion

Intraoperative 'Hybrid' stent delivery is an important treatment alternative to transcatheter stent therapy and surgical

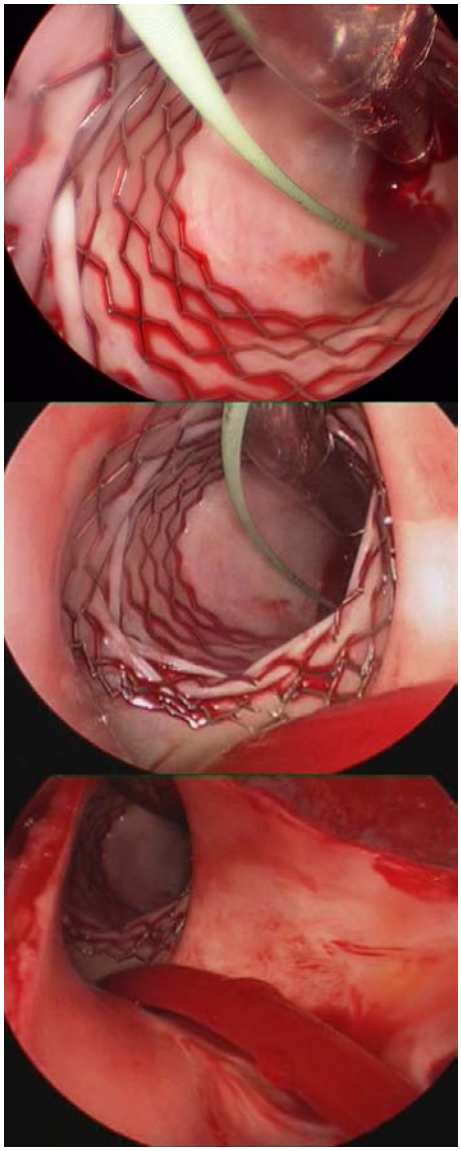

Figure 5. After stent deployment, endoscopic evaluation documents sufficient distance of the stent from lobar branching of the LPA (top image). The LPA appears to be wide open and the middle images shows the stent being 'crimped' over the crest between LPA and RPA. The bottom image shows the LPA origin from a distance, with the vessel being widely patent (note the difference from the pre-procedural images).

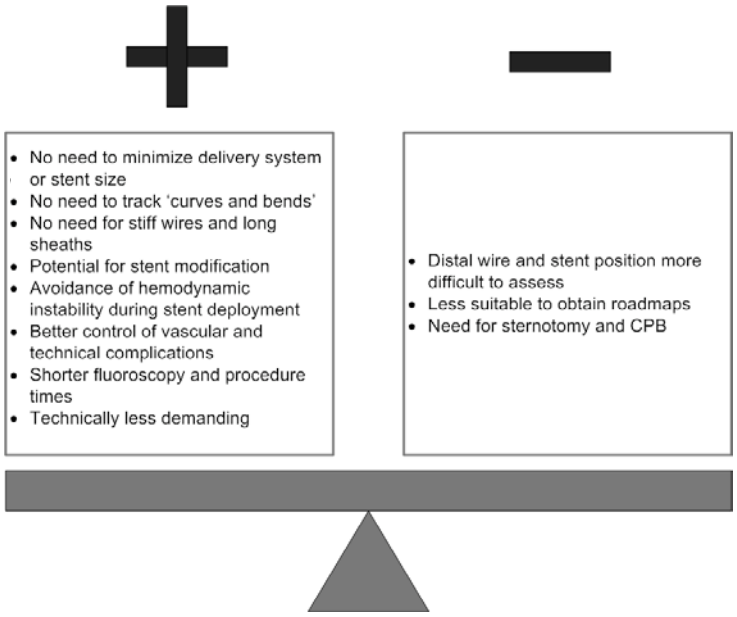

Figure 6. Advantages and disadvantages of intraoperative 'Hybrid' stent delivery under direct visualization and endoscopic guidance, when compared to a transcatheter approach.

patch angioplasty. Techniques and equipment available to perform intraoperative stent placement have expanded considerably [1-4]. While surgical patch augmentation has distinct advantages to treat very calcified proximal stenotic lesions, it is less suited to deal with kinked vessels or external obstructions. The choice between intraoperative and transcatheter stent placement has to be made individually for each specific patient, and is often dependent on operator preference. However, there are very distinct advantages and disadvantages of "Hybrid" stent therapy when compared to transcatheter therapy, which should guide any individualized approach (Figure 6).

Intraoperative stent placement can be performed using either direct visualization with endoscopic guidance, which is the preferred treatment in patients who require cardiopulmonary bypass to address associated lesions, or in the beating heart using intraoperative angiographic guidance and direct stent delivery through a sheath inserted into the main pulmonary artery. We recently published a study of 20 patients who underwent "Hybrid" stent delivery in the pulmonary circulation [5], where direct visualization with endoscopic guidance was used in 75% of patients during stent delivery.

In most patients, the decision to perform intraoperative stent delivery does not eliminate the need for a pre-procedural angiographic evaluation. Cardiac catheterization not only provides important hemodynamic information, but also gives accurately calibrated measurements as well as possible landmarks that can be used for stent delivery.

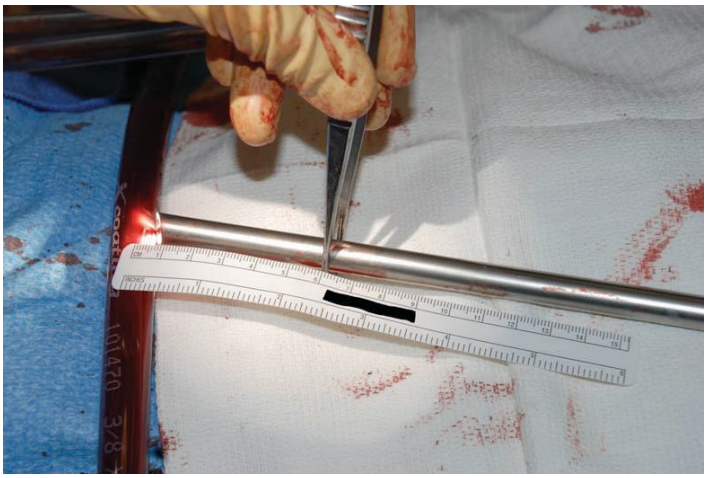

Figure 7. Stryker endoscope used for 'Hybrid' stent delivery under direct vision. The endoscope can be helpful in assessing the distance towards the origin of the pulmonary arterial side branches.

MRI data alone is frequently not sufficient to select the most appropriate stent and balloon size. In a recent evaluation of patients undergoing elective catheterization prior to PVR (unpublished), we found that the angiographically calibrated dimensions of stenotic vascular lesions differed by more than 2mm from MRI data in 75% of patients who required subsequent stent therapy. While some of this information could be obtained through intraoperative angiography, in most cases it is more practical to obtain this data during a separate catheterization procedure prior to the surgical intervention. This facilitates intraprocedural communication between cardiothoracic surgeon and interventional cardiologist, which allows an informed management decision at a time when all three treatment options (surgical patch, "Hybrid" stent, transcatheter stent) are still available.

The largest group of patients undergoing intraoperative stent placement under direct vision using endoscopic guidance are those with repaired Tetralogy of Fallot or PAVSD, who require pulmonary valve replacement and who have an associated isolated proximal pulmonary artery stenosis or kink [5;6]. While stent placement in the catheterization laboratory is certainly feasible, it frequently is a more time-consuming undertaking, when compared to stent implantation under direct vision. Stents are frequently expanded to large diameters, requiring long (frequently non-reinforced) sheaths, stiff wires and accurate stent positioning may be more difficult to attain. While stent implantation under direct vision offers a much simpler approach, a few technical considerations are important for a successful result. One of the biggest advantages of transcatheter stent implantation is accurate visualization of pulmonary arterial side branches in relation to the distal end of the stent. During intraoperative stent placement, the endoscope is a perfect tool to measure the distance to the first side branch (Figure 7), as well as to allow placing a wire into a larger, usually lower lobe pulmonary

arterial branch. It is important to avoid the temptation to deploy the stent without a wire, as the position of the distal end cannot be reliably assessed during balloon inflation. The tip of the balloon can easily slip into a smaller side branch. This may result not only in jailing of other branches, but also potentially lead to vascular injury, if stent and/or balloon are inflated within a small vessel.

Stents deployed under direct vision can even be shortened manually if the stenotic lesion is very short [3], an approach not recommended for transcatheter stent delivery. Furthermore, after stent deployment, the stent edges can be folded/crimped by the surgeon (Figure 5), which avoids any luminal protrusion of stent meshwork. This can be a significant benefit if the stent has to be entered in the future using a transcatheter approach. Stent delivery under direct vision in the operating room is more forgiving vis a vis technical problems such as balloon rupture or stent migration, and a suboptimally deployed or not fully expanded stent can usually be removed without great difficulty. Even though intraoperative stent placement can be readily assessed using endoscopy, a completion angiogram prior to coming off cardiopulmonary bypass, may be helpful to further evaluate the result of intraoperative stent placement.

In conclusion, intraoperative 'Hybrid' stent delivery using direct visualization and endoscopic guidance is a fairly simple, quick, and effective procedure to allow accurate stent placement to treat proximal pulmonary arterial lesions in patients who require cardiopulmonary bypass surgery for pulmonary valve or conduit replacement. Close cooperation between surgical and interventional teams is essential to facilitate a successful outcome.

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Corresponding Author

Ralf J. Holzer, MD, MSc
Assistant Director, Cardiac Catheterization & Interventional Therapy
Assistant Professor of Pediatrics
Cardiology Division
The Ohio State University
The Heart Center
Nationwide Children's Hospital
700 Children's Drive
Columbus, OH 43205, USA
Tel: 614 722-2537; Fax: 614 722-5030
ralf.holzer@nationwidechildrens.org

Matt Sisk, RCIS
The Heart Center
Nationwide Children's Hospital
700 Children's Drive
Columbus, OH, USA

Alistair Phillips, MD
The Heart Center
Nationwide Children's Hospital
Department of Surgery, Ohio State University School of Medicine
Columbus, OH, USA

LIVE CASES AT THE UPCOMING: WorkshopIPC & ISHAC
March 22-25 - Milan, Italy

This Case Report article Illustrates a good example of the type of 'live' case that Drs. Ralf Holzer and Alistair Phillips will be performing at the joint meeting of *Workshop IPC & ISHAC* (International Symposium on the Hybrid Approach to Congenital Heart Disease) in Milan, Italy, this March 22-25, 2009.

There will be a total of 23 live cases performed by well-known physicians from all over the world at the joint meeting this year. For more information about attending *WorkshopIPC & ISHAC* visit: www.WorkshopIPC.com

You may also watch selected live cases, hosted by Congenital Cardiology Today, from the 2007 and 2008 *ISHAC* meetings. These include:

- *NCH Hybrid Catheterization/OR Suites*
- *Pulmonary Artery Flow Restrictors*
- *Transcatheter Valve*
- *Intra-operative PA Stent*
- *Perventricular Muscular VSD Device Closure*
- *Closure of Septal Defect Using Real Time 3D Echo Guidance*
- *High Frequency Ultrasound Creation of ASD*
- And more...

In addition, there are live cases from past *PICS-AICS* and *WorkshopIPC* meetings. To view these lives cases online, visit: www.CHDVideo.com

Medical News, Product and Information

Epocrates Survey Identifies Trends in Online Resource Use Among Physicians

A new survey released this November reveals physicians are accessing online clinical resources more than ever, and 75% prefer to obtain information from professional websites rather than through Internet searches. Epocrates, Inc., developer of mobile and online decision support resources, conducted this nationwide survey to evaluate the impact online resources have on patient communication and care.

More than 500 physician respondents confirmed that online resources help improve patient safety, provide patients up-to-date information and even save patients money, which is crucial in this economic climate. The survey found that through online resources, such as Epocrates Online (www.epocrates.com/online/?CID=PROnline), physicians are:

- Making technology a part of the consultation – Today's doctors are using technology to check drug dosing, side effects, interactions or treatment guidelines during patient visits. Nearly 50% of physicians report they most frequently use the Internet during patient consultations, rather than between patient visits or after hours.
- Enhancing patient visits – Nearly 90% of physicians strongly agreed or agreed that accessing clinical information online improves patient satisfaction and communication. Specifically, physicians reported the use of an online resource helped:
  - increase medication compliance
  - decrease pharmacy callbacks
  - patients appear more at ease
  - some patients disclose information physicians would have not otherwise known
- Saving money with generics – 70% of physicians have prescribed a lower cost or generic medication for a patient in the last month using the drug pricing or coverage features available on Epocrates Online. Furthermore, one-in-five physicians report saving their patients money 10 or more times in the four-week period.

Technology is becoming more prevalent in clinical practices, with 97% of survey respondents reporting computer access at their practice or institution, and more than 50% working at a wireless facility. Approximately 75% of physicians report going online more today than a year ago. More than 70% go online for clinical information at least once a day, of which nearly 20% report using web-based resources five or more times per day.

Quintet of Proteins Forms New, Early-Warning Blood Test Before Heart Attack Strikes

Newswise — A team of Johns Hopkins biochemists has identified a mixed bag of five key proteins out of thousands secreted into blood draining from the heart's blood vessels that may together or in certain quantities form the basis of a far more accurate early warning test than currently in use of impending heart attack in people with severely reduced blood flow, or ischemia.

The work, involving more than a dozen scientists and taking more than a year to perform, is believed to be the largest protein analysis ever done at Hopkins. It was based on 76 arterial blood samples from 19 men and women taken immediately before and after a period of medically induced ischemia lasting as long as 45 minutes.

All had ischemia induced through accelerated pacing of the heart's main chambers. Blood samples were provided by cardiologists at the University of Texas Southwestern.

Key to the researchers' selection criteria of which proteins to analyze from among tens of thousands in the blood was what they call "a pipeline approach."

"From the start, we knew that we were looking for rare, almost unique biomarkers that bore some direct relationship with ischemia," says study senior investigator Jennifer Van Eyk, PhD, whose first step was to remove from the analysis common blood proteins, such as albumin and globulins. That left batches of 400 proteins for in-depth measure of any changes before and after ischemia.

Their analysis, which was presented at the American Heart Association's (AHA) annual Scientific Sessions in New Orleans, found that only the five proteins were present in significantly increased amounts after ischemia occurred, with at least a doubling in the blood concentration, compared with those recorded during healthy blood flow. These were lumican, semenogelin, angiogenin, extracellular matrix protein, and so-called long palate, lung and nasal epithelium carcinoma-associated protein 1.

All of the proteins are believed to originate in the heart, but they can also be found in other tissues varying from the corneas of the eyes (lumican) to semen. Semenogelin, as it is known, has never before been seen in the heart, while others, such as angiogenin, are more predictably found in growing blood vessels and muscle tissue, and are actively involved in tissue repair. Little is known about the remaining two, which, ironically, have the longest names: extracellular matrix protein, secreted in a rare inflammatory disease; and long palate, lung and nasal epithelium carcinoma-associated protein 1, thought to play a role in innate immunity.

The Johns Hopkins biochemists say the presence of all or even a selected set of these proteins in a simple, rapid blood test could aid emergency paramedics and physicians during the critical 12- to 24-hour window before ischemia causes substantial heart tissue damage or death from heart attack.

A positive reading on a blood test incorporating these proteins, they add, could provide first responders with advance warning to take urgent action, such as using blood thinners like aspirin to prevent

clotting, or performing cardiac catheterization to check for any more blockages in the blood vessels feeding the heart, which may in turn prompt more aggressive treatment. Further actions could involve angioplasty, in which a balloon device is threaded into the heart's surrounding blood vessels and then expanded to widen the arteries, or even surgery.

"Our results lay the foundation for a first-of-a-kind, early-warning system that could save tens of thousands of people on the brink of a heart attack," says Van Eyk, a professor at the Johns Hopkins University School of Medicine and its Heart and Vascular Institute. "People experiencing chest pain too often come to the emergency room, with subsequent electrocardiogram, also called EKG, readings not showing any evidence that a heart attack has occurred, but still leaving open the question of whether or not a heart attack is imminent and about to happen or has already happened," adds Van Eyk, Director of the Johns Hopkins NHLBI Proteomics Group and the Proteomics Center at Johns Hopkins Bayview Medical Center, where the protein analysis took place.

Van Eyk says people frequently have symptoms of chest pain, shortness of breath and dizziness, with pale or clammy skin coloring, while arterial blood is constricted, but not yet closed. But this myriad of complaints can just as easily be mistaken for the more everyday, less-serious problems of heartburn, stomach cramps or gas. In 2006, the US Centers for Disease Control and Prevention reported more than 12,000 visits to doctors' offices and emergency rooms by people complaining of chest pain.

A new test based on these five proteins, says Van Eyk, could provide a "more definitive answer" to the question "how serious is it?" much earlier than existing assays for heart attack, such as tests for troponin proteins I and T.

Van Eyk says commercially available tests for cardiac troponin, which is released into the blood in telltale patterns for heart attack, provide results "too late to take preventive action," and "after some damage has already occurred." Troponin lab tests also depend on the heart muscle dying first, which can take hours to detect, "So a negative reading is unreliable and can still mean that an ischemic problem is about to happen or has already happened," she says.

In the study, the protein analysis was conducted by mass spectrometry machines that can measure the presence of proteins in minute amounts. The machines, operated six days a week for six months, consumed more than 3,700 hours of spectrometric analysis.

Researchers next plan to verify the presence of the five proteins in a larger study with at least 150 participants, and more than 1,000 blood samples. Simultaneously, they plan further analysis of the proteins to map their molecular structures, so that an antibody can be identified to bind to one or several of the proteins, laying the basis for a blood test for ischemia. And they will conduct tests to verify that their study findings also apply to ischemia in stroke.

Funding support for this study was provided by Inverness. The technology development in the study and the "pipeline approach" were supported by the Johns Hopkins Bayview Proteomics Center. The Johns Hopkins NHLBI Proteomics Group is one of 10 centers funded as part of the US, seven-year program dedicated to the study of proteomics and understanding the functions of proteins in the development of cells, tissues and organisms, in both normal and disease processes. Van Eyk has a patent pending on the protein analysis. Under an option agreement with The Johns Hopkins University, Inverness Medical Innovations' Unipath Ltd., in Bedford, United Kingdom, has the right to negotiate a license to the patent.

Other Johns Hopkins researchers who took part in this study were Qin Fu, PhD; Simon Sheng, MSc; Steven Elliott, MSc; and Miroslava Stastna, PhD. Additional support was provided by James de Lemos, MD, at the University of Texas Southwestern.

For more information:
www.proteomics.jhu.edu/index.php?id=248

Doctors should disclose off-label prescribing to their patients

Doctors should be required to disclose when they are prescribing drugs off-label, argues an article in the November 11, 2008 edition of PLoS Medicine. Michael Wilkes and Margaret Johns from the University of California Davis argue that the ethics related to informed consent and shared decision- making provide an imperative for doctors to inform patients about the risks of a medical treatment when their use has not been approved by regulators.

Off-label prescriptions are those that do not comply with the use approved by the Food and Drug Administration (FDA) for the drug. While off-label prescribing is legal and accounts for roughly half of all prescriptions currently written in the US, it is often not supported by sound scientific evidence. Worse, say the authors, off-label prescribing can put patients at risk and drive up healthcare costs.

The public often assumes that all common uses of prescription drugs have been approved by the FDA, say the authors. But current law does not prevent doctors from prescribing a drug to any patient for any use whether it was approved for this use or not.

And while off-label prescribing is common and sometimes necessary (as in the area of paediatrics where many drugs have not been tested on children), Wilkes and Johns argue that off-label prescribing can also pose potentially serious risks. By definition no governmental body has conducted a review of the effectiveness or safety of the drug for the off-label use, they say. As a result, an off-label prescription may be ineffective or detrimental, and could be more costly than existing drugs.

Wilkes and Johns argue that the strict requirement that doctors obtain informed consent from patients before enrolling in a research study means they should obtain the same consent when a drug is being prescribed off-label as each such prescription is just like a mini research study. The contemporary expectation for shared decision-making between doctors and patients also supports full disclosure about off-label prescribing, leaving the option open for patients to opt for a drug which has received FDA approval for the condition in question.

"From an ethical perspective," say Wilkes and Johns, "[what is required is] open, honest discussions where doctors tell their patients that the use of the drug will be off-label and thus not approved for this indication, explain the risks, potential benefits, and alternatives, and then ask patients for their permission to proceed."

A recent PLoS Medicine paper (http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050210) described techniques by which drug companies covertly promote off-label use. Adriane Fugh-Berman (Georgetown University Medical Center, Washington, DC) and Douglas Melnick (a preventive medicine physician working in North Hollywood, CA) discussed the use of "decoy indications" and drug representatives to engage in illegal pharmaceutical marketing. Pharmaceutical marketing, they say, has "distorted the discourse on off-label uses and encouraged the unmonitored, potentially dangerous use of drugs by patients for whom risks and benefits are unknown."

"Companies that engage in off-label promotion should be heavily fined and their future marketing practices subject to increased scrutiny by regulatory agencies," say Fugh-Berman and Melnick.

Citation: Wilkes M, Johns M (2008) Informed consent and shared decision-making: A requirement to disclose to patients off-label prescriptions. PLoS Med 5(11):e223.doi: 10.1371/journal.pmed.0050223

http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050223

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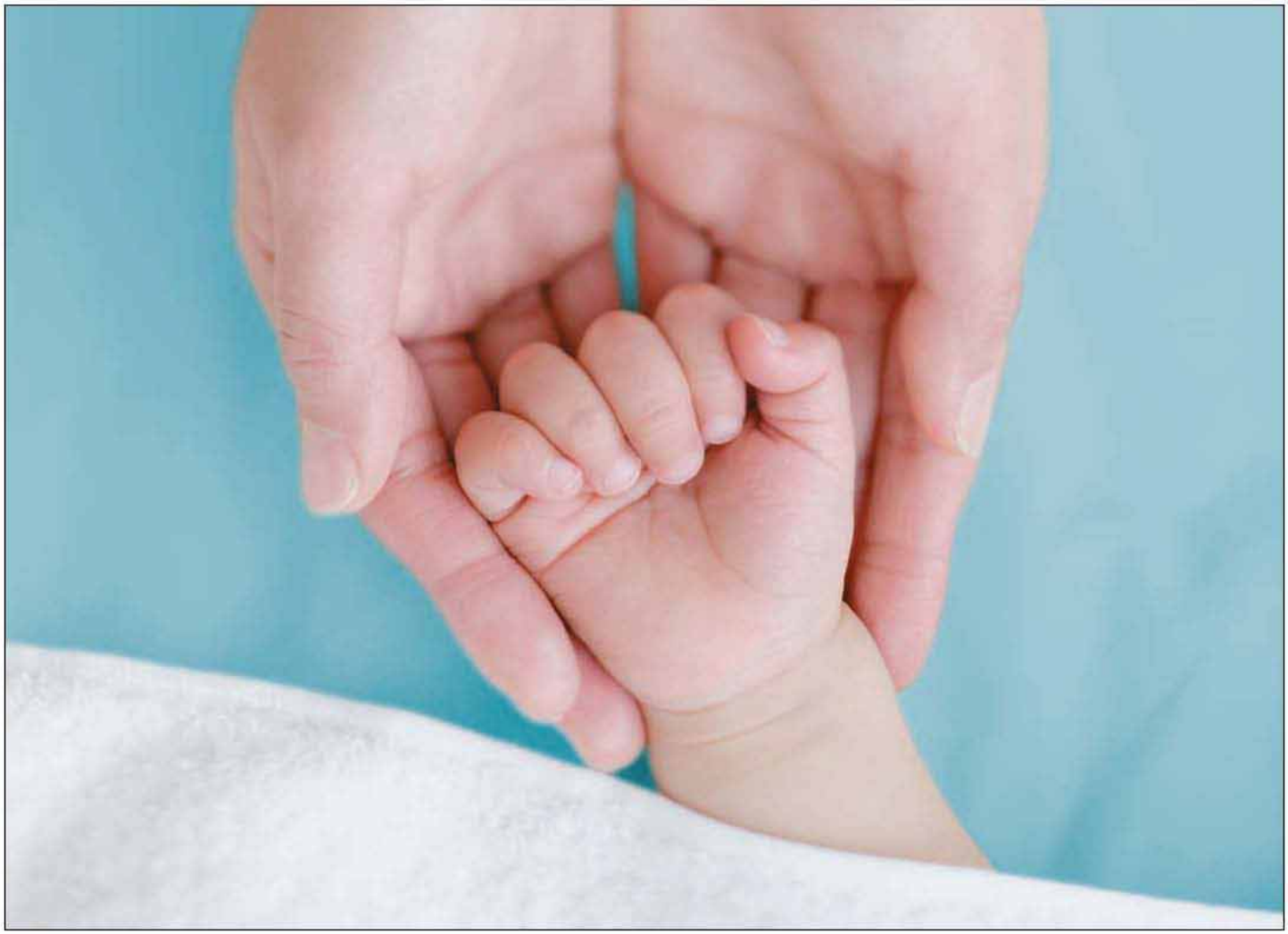

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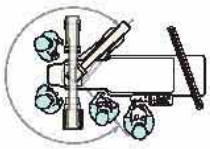

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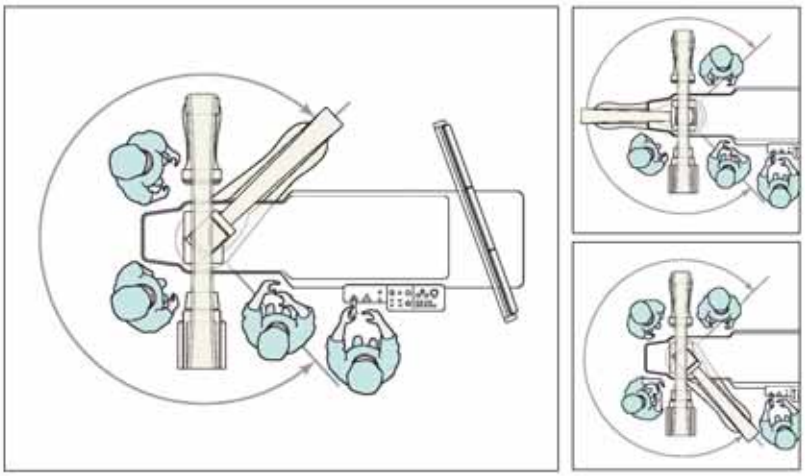
North American Technology Innovation Award

Whether for diagnostic, interventional or hybrid procedures, Toshiba Infinix-i represents the industry's broadest selection of systems, including the Infinix CF-i/BP biplane.



AWARDED FOR INNOVATION

Infinix™ CF-i/BP cardiovascular biplane system has received the Frost & Sullivan 2007 North American Cardiovascular X-ray Technology Innovation Award.

"Currently, Toshiba is the only manufacturer to offer a system that can be manuevered in all angles, supporting the ability to do cardiac and peripheral work...Toshiba's significant contribution to the medical imaging market with its innovative, first-to-market 5-axis Infinix CFi-BP system ensures the ability to meet the needs of the cardiac population while staying abreast of the surging hybrid market."

- 2007 Frost & Sullivan award statement

For more information, please call (800) 421-1968 or visit us at medical.toshiba.com