To: Medtronic, Inc. (trademark@medtronic.com)

Subject: TRADEMARK APPLICATION NO. 77278969 - CLOSURE - T1093US

Sent: 2/19/2009 5:39:41 PM

Sent As: ECOM114@USPTO.GOV

Attachments:
Attachment - 1
Attachment - 2
Attachment - 3
Attachment - 4
Attachment - 5
Attachment - 6
Attachment - 7
Attachment - 8
Attachment - 9
Attachment - 10
Attachment - 11
Attachment - 12
Attachment - 13
Attachment - 14
Attachment - 15
Attachment - 16
Attachment - 17
Attachment - 18
Attachment - 19
Attachment - 20
Attachment - 21
Attachment - 22
Attachment - 23
Attachment - 24
Attachment - 25
Attachment - 26
Attachment - 27
Attachment - 28
Attachment - 29
Attachment - 30
Attachment - 31
Attachment - 32
Attachment - 33
Attachment - 34
Attachment - 35
Attachment - 36
Attachment - 37
Attachment - 38

Attachment - 39
Attachment - 40
Attachment - 41
Attachment - 42
Attachment - 43
Attachment - 44
Attachment - 45
Attachment - 46
Attachment - 47
Attachment - 48
Attachment - 49
Attachment - 50
Attachment - 51
Attachment - 52
Attachment - 53
Attachment - 54
Attachment - 55
Attachment - 56
Attachment - 57
Attachment - 58
Attachment - 59
Attachment - 60
Attachment - 61
Attachment - 62
Attachment - 63
Attachment - 64
Attachment - 65
Attachment - 66
Attachment - 67
Attachment - 68
Attachment - 69
Attachment - 70
Attachment - 71
Attachment - 72
Attachment - 73
Attachment - 74
Attachment - 75
Attachment - 76
Attachment - 77
Attachment - 78
Attachment - 79
Attachment - 80
Attachment - 81
Attachment - 82

Attachment - 83
Attachment - 84
Attachment - 85
Attachment - 86
Attachment - 87
Attachment - 88
Attachment - 89

UNITED STATES PATENT AND TRADEMARK OFFICE

SERIAL NO: 77/278969

MARK: CLOSURE

CORRESPONDENT ADDRESS:
TRADEMARK DEPT.
MEDTRONIC, INC.
710 MEDTRONIC PARKWAY
LC 340
MINNEAPOLIS, MN 55432-5604

GENERAL TRADEMARK INFORMATION:
http://www.uspto.gov/main/trademarks.htm

APPLICANT: Medtronic, Inc.

CORRESPONDENT'S REFERENCE/DOCKET NO:
T1093US
CORRESPONDENT E-MAIL ADDRESS:
trademark@medtronic.com

REQUEST FOR RECONSIDERATION DENIED

ISSUE/MAILING DATE: 2/19/2009

Applicant is requesting reconsideration of a final refusal issued/mailed January 14, 2009.

After careful consideration of the law and facts of the case, the examining attorney must deny the request for reconsideration and adhere to the final action as written since no new facts or reasons have been presented that are significant and compelling with regard to the point at issue.

Applicant argues that the refusal based on a likelihood of confusion with the mark in U.S. Registration No. 2236135, CLOSURE, for intravascular catheters, should be withdrawn because the registrant "promotes its intravascular catheters for use in treating varicose veins." Applicant's mark is also CLOSURE and applicant's goods consist of surgical implants and instrument sets for use in atrial occlusion procedures.

A determination of whether there is a likelihood of confusion is made solely on the basis of the goods

and/or services identified in the application and registration, without limitations or restrictions that are not reflected therein. *In re Dakin's Miniatures, Inc.*, 59 USPQ2d 1593, 1595 (TTAB 1999); TMEP §1207.01(a)(iii). If the cited registration describes the goods and/or services broadly and there are no limitations as to their nature, type, channels of trade or classes of purchasers, then it is presumed that the registration encompasses all goods and/or services of the type described, that they move in all normal channels of trade, and that they are available to all potential customers. *In re Linkvest S.A.*, 24 USPQ2d 1716, 1716 (TTAB 1992); *In re Elbaum*, 211 USPQ 639, 640 (TTAB 1981); TMEP §1207.01(a)(iii).

Here, no such limitations exist in the registration, which describes registrant's goods broadly as, "intravascular catheters." Thus, the registrant's goods include goods that may be used for procedures similar to those for which the applicant's goods are used. This is true even though the registrant's goods may not yet be used for such procedures.

Applicant further argues that the word "closure" is not descriptive of applicant's goods. However, as the attached Internet and article evidence suggests, the word "closure" is used in the medical field to refer to the occlusion of "atrial appendages" or areas within the heart during open heart surgery. *See* the attached definition found in Exhibit "Closure0-1" and the attached Internet evidence, including Exhibit "Closure G1-01." The word "closure" in this context thus describes the purpose, function or use of applicant's surgical implants and instrument sets for use in atrial occlusion procedures.

Accordingly, applicant's request for reconsideration is *denied*. The time for appeal runs from the date the final action was issued/mailed. 37 C.F.R. Section 2.64(b); TMEP Section 715.03(c). If applicant has already filed a timely notice of appeal, the application will be forwarded to the Trademark Trial and Appeal Board (TTAB).

/Edward Fennessy/
Trademark Examining Attorney
Law Office 114
1.571.272.8804

STATUS CHECK: Check the status of the application at least once every six months from the initial filing date using the USPTO Trademark Applications and Registrations Retrieval (TARR) online system at http://tarr.uspto.gov. When conducting an online status check, print and maintain a copy of the complete TARR screen. If the status of your application has not changed for more than six months, please contact the assigned examining attorney.

http://www.biology-online.org/dictionary/Atrial 02/19/2009 11:34:38 AM

Atrial

Atrial

(Science: anatomy) Pertaining to an atrium.

Please contribute to this project. If you have more information about this term feel free to edit this page

http://www.biology-online.org/dictionary/Atrium 02/19/2009 11:35:07 AM

Atrium

Atrium

(Science: anatomy) a chamber used in anatomical nomenclature to designate a chamber affording entrance to another structure or organ. Usually used alone to designate an **atrium** of the heart.

Origin: L., gr. Atrion = hall Any chamber that is connected to other chambers or passageways (especially one of the two upper chambers of the heart) The central area in a building open to the sky A chamber found in the heart that receives deoxygenated blood from the body

Please contribute to this project, if you have more information about this term feel free to edit this page

Atrium

Atrium

(Science: anatomy) a chamber, used in anatomical nomenclature to designate a chamber affording entrance to another structure or organ. Usually used alone to designate an **atrium** of the heart.

Origin: L., gr. Atrion = hall Any chamber that is connected to other chambers or passageways (especially one of the two upper chambers of the heart) The central area in a building, open to the sky A chamber found in the heart that receives deoxygenated blood from the body.

Please contribute to this project, if you have more information about this term feel free to edit this page

This page was last modified 21:16, 3 October 2005. This page has been accessed 2,173 times.
What links here | Related changes | Permanent link

Source: **Combined Source Set 106 - Cardiovascular Week; Surgery Litigation & Law Weekly; Health & Medicine Wee...**
Terms: **atrial and implant and catheter** (Edit Search | Suggest Terms for My Search)

Select for FOCUS™ or Delivery

ATRIAL FIBRILLATION; VCU Pauley Heart Center First to use Technologically Enhanced Intracardiac Ultrasound for the Treatment of Atrial Fibrillation Surgery Litigation & Law Weekly January 9, 2009

Surgery Litigation & Law Weekly

January 9, 2009

SECTION: EXPANDED REPORTING; Pg. 120

LENGTH: 903 words

HEADLINE: **ATRIAL** FIBRILLATION;
VCU Pauley Heart Center First to use Technologically Enhanced Intracardiac Ultrasound for the Treatment of **Atrial** Fibrillation

BODY:

The Virginia Commonwealth University Pauley Heart Center is the first in the United States to use a new type of intracardiac

BODY:

The Virginia Commonwealth University Pauley Heart Center is the first in the United States to use a new type of intracardiac ultrasound machine that produces enhanced imaging of the heart, allowing cardiac electrophysiologists to better diagnose and treat **atrial** fibrillation (see also **Atrial** Fibrillation).

Atrial fibrillation, or a-fib, is caused by abnormal electrical impulses that begin at the top of the heart and travel down the upper chambers, or atria, causing erratic contractions. The irregular rhythm, which affects more than 2 million Americans, interferes with the heart's ability to efficiently pump blood. As a result, blood can pool in the atria, which can lead to the formation of clots and the possibility of a stroke.

Intracardiac ultrasound (ICU) is a technique that allows doctors to better visualize structures in the heart using a special **catheter** that is laced through a blood vessel in the leg and advanced into the heart. Traditionally, ultrasound imaging of the heart is done outside the chest with a probe and requires a large, heavy machine that cannot be moved easily.

"Using the ICU **catheter** allows us to better visualize important structures in the heart, it allows us to better move our **catheters** around more safely inside the heart and finally, it allows us to move **catheters** to certain areas in the heart where we feel we need to deliver radio frequency energy so we can ablate the right tissues," said Kenneth Ellenbogen, M.D., professor of cardiology and director of the cardiac electrophysiology lab at the VCU Medical Center, who performed the imaging technique using the new technology.

GE Healthcare developed the small and compact, Vivid i system that delivers imaging performance equal to that of today's leading high-end console ultrasound systems without crowding the lab. The Vivid i ultrasound system displays high quality images of the anatomical structures of the heart and delicate valvular structures, helping to improve efficacy of the **catheter**

leading high-end console ultrasound systems without crowding the lab. The Vivid i ultrasound system displays high quality images of the anatomical structures of the heart and delicate valvular structures, helping to improve efficacy of the **catheter** ablation and patient safety.

"We're going from a machine that is quite big and takes up a lot of space to one the size of a laptop computer that is positioned at the bedside. It gives us spectacular images of the heart, our **catheters** in the heart and the structures in the heart and helps us do an even better job of ablating **atrial** fibrillation more safely and more effectively," Ellenbogen said.

Using ICU, cardiac electrophysiologists can to some extent avoid or decrease the use of X-ray or radiation to image the heart because the **catheter** uses sound waves to help detect what's going on in the heart.

About 10 years ago, VCU cardiac electrophysiologists, together with experts from several other centers, pioneered the use of this **catheter** to treat a-fib.

Catheter ablation is used to burn sites inside the atria and ventricles the heart's lower pumping chambers that cause arrhythmias. In the procedure, one or more **catheters** is placed inside the heart to locate the origin of the electrical short circuits. Once the area is located, the surgeon delivers heat energy to destroy the abnormal electrical circuit.

"Through **catheter** ablation of a-fib, our main goal is not just to improve efficacy but to make it safer for patients. The way we do that is to make it so we're better able to visualize what we're doing inside the heart, by avoiding delicate structures that we don't want to treat and using our imaging tools and technology to get the best and safest results," Ellenbogen said.

###

About the VCU Pauley Heart Center: The VCU Pauley Heart Center is recognized nationally for its heart failure and heart

###

About the VCU Pauley Heart Center: The VCU Pauley Heart Center is recognized nationally for its heart failure and heart transplantation programs, and was among the first in the United States to **implant** the CardioWest temporary Total Artificial Heart, or TAH-t the only total artificial heart approved by the U.S. Food and Drug Administration. The heart center is comprised of the Divisions of Cardiology, Cardiothoracic Surgery and Pediatric Cardiology. There is close collaboration between the divisions to provide advanced, patient-centered care to patients of all ages, with every type of heart disease, with the best possible outcomes. Pauley Heart Center's superior performance resulted in VCU Medical Center being recognized as one of the top 100 U.S. hospitals for cardiovascular care, according to a Thomson Reuters study.

About VCU and the VCU Medical Center: Virginia Commonwealth University is the largest university in Virginia and ranks among the top 100 universities in the country in sponsored research. Located on two downtown campuses in Richmond, VCU enrolls 32,000 students in 205 certificate and degree programs in the arts, sciences and humanities. Sixty-five of the programs are unique in Virginia, many of them crossing the disciplines of VCU's 15 schools and one college. MCV Hospitals and the health sciences schools of Virginia Commonwealth University compose the VCU Medical Center, one of the nation's leading academic medical centers. For more, see www.vcu.edu.

-30-

CONTACT: Joe Kuttenkuler

VCU Communications and Public Relations

Phone: 804.827.6607

Source: **Combined Source Set 106 - Cardiovascular Week; Surgery Litigation & Law Weekly; Health & Medicine Wee...**
Terms: **atrial and implant and catheter** (Edit Search | Suggest Terms for My Search)

Select for FOCUS™ or Delivery

ST. JUDE MEDICAL, INC.; St. Jude Medical Announces the Release of EnSite System Version 8.0 Software Cardiovascular Week
May 26, 2008

Cardiovascular Week

May 26, 2008

SECTION: EXPANDED REPORTING; Pg. 566

LENGTH: 594 words

HEADLINE: ST. JUDE MEDICAL, INC.;
St. Jude Medical Announces the Release of EnSite System Version 8.0 Software

BODY:

St. Jude Medical, Inc. (NYSE:STJ) announced the release of its EnSite(TM) System Version 8.0 software. The new software will

St. Jude Medical, Inc. (NYSE:STJ) announced the release of its EnSite(TM) System Version 8.0 software. The new software will help physicians more intuitively visualize the anatomy of the heart to diagnose and treat abnormal heart rhythms. St. Jude Medical will feature the EnSite v.8.0 at Heart Rhythm 2008 on May 14 - 17 (see also St. Jude Medical, Inc.).

The EnSite System is used in minimally invasive electrophysiology (EP) procedures. **Catheters** with electrodes are inserted into the cardiac chamber and then are located and visualized by the EnSite System, which records electrical information and creates a rendering of the chamber anatomy. The resulting images help physicians create detailed heart models to facilitate the diagnosis and delivery of therapy for abnormal **atrial** heart rhythms, including **Atrial** Fibrillation (AF). The EnSite System allows **catheter** navigation to occur without fluoroscopy and reduces the risk associated with too much exposure to X-rays.

The new EnSite v.8.0 software expands the capability of the EnSite System to help physicians better visualize reentrant arrhythmia circuits, a common abnormal heart rhythm. The EnSite v.8.0 also gives physicians the ability to view how these reentrant circuits propagate or move about the cardiac chamber. This feature improves physicians' ability to identify the location of the arrhythmia so they have more control over the procedure.

Additional features include map visualization enhancements, which provide a more realistic perspective on the location of **catheters,** lesions, and anatomical points of interest. EnSite v.8.0 also includes enhancements to the electrical "noise" filters to improve cardiac signal detection and help physicians better analyze low amplitude signals such as complex fractionated electrograms, a growing area of interest for EP physicians.

"This new version of our EnSite System will help physicians better diagnose their patients with arrhythmias," said Jane J. Song, president of the St. Jude Medical **Atrial** Fibrillation Division. "It also underscores our leadership in the industry and our continued dedication to improving the lives of patients."

Heart Rhythm 2008 takes place May 14-17 at the Moscone Convention Center in San Francisco. The meeting is the most

Heart Rhythm 2008 takes place May 14-17 at the Moscone Convention Center in San Francisco. The meeting is the most comprehensive educational event on heart rhythm disorders, offering 250 educational opportunities in multiple formats. The world's most renowned scientists and physicians will present a wide range of heart rhythm topics including advances in statins, cardiac resynchronization therapy, **catheter** ablation, cardiac pacing and heart failure and the latest technology, including state-of-the-art pacemakers and defibrillators. www.HRSonline.org

St. Jude Medical -Highlights at Heart Rhythm 2008

On Thursday, May 15 at 1:30 p.m., during the oral abstract session, Andrew Epstein, M.D., will present the results of multiple St. Jude Medical -lead registries. The studies analyzed the experience of more than 7,000 patients who were implanted with Riata high voltage leads. In addition, St. Jude Medical -will showcase new cardiac leads and cardiac lead **implant** tools, new electronic health record connectivity features and the company's cardiac rhythm management device programmer (which is now available in eight languages).

Keywords: Anatomy, Arrhythmia, **Atrial** Fibrillation, Cardiology, Electrophysiology, Physiology, Therapy, Treatment, St. Jude Medical Inc. -

LOAD-DATE: May 21, 2008

Source: **Combined Source Set 106 - Cardiovascular Week; Surgery Litigation & Law Weekly; Health & Medicine Wee...**
Terms: **atrial and implant and catheter** (Edit Search | Suggest Terms for My Search)

BIOMEDICINE; Aporo Biomedical Announces Global Licensing Agreement for Proprietary Polymers Used to Treat Structural Heart Disease Cardiovascular Week February 11, 2008

Cardiovascular Week

February 11, 2008

SECTION: EXPANDED REPORTING; Pg. 407

LENGTH: 550 words

HEADLINE: BIOMEDICINE;
Aporo Biomedical Announces Global Licensing Agreement for Proprietary Polymers Used to Treat Structural Heart Disease

BODY:

Aporo Biomedical, a San Francisco/Bay Area-based medical device company, reported an exclusive global licensing agreement

Aporo Biomedical, a San Francisco/Bay Area-based medical device company, reported an exclusive global licensing agreement with mNEMOSCIENCE GmbH for its proprietary biodegradable shape memory polymers (BIO-SMP(TM)). Aporo's goal is to provide significant clinical value by delivering novel transcatheter devices that close defects and then biodegrade over time, leaving behind no permanent **implant.** Initially, Aporo will use these materials to treat Patent Foramen Ovale (PFO), a type of structural heart disease that involves closing an open tunnel between the upper left and right chambers of the heart. In the future, the company will use the polymers in devices to treat **Atrial** Septal Defect (ASD), another structural heart disease, and for vascular closure after **catheter**-based interventional procedures (see also Biomedicine).

While a PFO typically closes within the first few days after birth, approximately 25% of the population has a passageway or hole that remains open. In fact, PFO's may cause an estimated 200,000 strokes per year. PFO's are also believed to be a factor in migraine headaches, which affect 12% of the population. Studies indicate that PFO closure may bring migraine relief. Currently, several transcatheter closure devices are in clinical trials to evaluate PFO closure and the impact on stroke and migraine.

Although minimally invasive **catheter**-based procedures are relatively short and can provide significant benefits to the patient, there is a growing desire among clinicians to avoid the potential complications and disadvantages from permanently implanting a large device in an otherwise healthy heart. Aporo Biomedical will address this concern by delivering a biodegradable device that closes the PFO without leaving a permanent **implant.**

"The next significant advance in medical technology will be biodegradable devices that disappear once they've done their job," commented Carolyn Patrick, President and CEO of Aporo Biomedical. "As patients are treated younger and live longer, it's even more important for physicians to have options that consider not only the patients' immediate outcomes and quality of life, but their future medical needs as well. Aporo Biomedical is well-positioned to advance the field of PFO closure with a fully biodegradable device. We look forward to working with mNEMOSCIENCE(R) and utilizing the novel BIO-SMP(TM) technology to bring these transformative devices to market."

bring these transformative devices to market."

"We are delighted to partner with such a skilled and innovative medical device manufacturer for our BIO-SMP(TM) technology," said Christian Palme, CEO, mNEMOSCIENCE. "Securing high-quality, progressive partners like Aporo Biomedical has been a key focus of our strategic development plan and represents an important milestone in advancing our BIO-SMP(TM) commercialization program."

Terms of the agreement were not disclosed.

Keywords: **Atrial** Septal Defect, Bioengineering, Biomedical Engineering, Biomedicine, Business, Cardiology, Clinical Trial Research, Headache, Heart Disease, Marketing and Licensing Agreements, Medical Device, Migraine, Migraine Disorder, Neurology, Patent Actions, Patents, Aporo Biomedical.

LOAD-DATE: February 8, 2008

Source: **Combined Source Set 106 - Cardiovascular Week; Surgery Litigation & Law Weekly; Health & Medicine Wee...**
Terms: **atrial and implant and catheter** (Edit Search | Suggest Terms for My Search)

Select for FOCUS™ or Delivery

BIOMEDICINE; Reports from University of Minnesota, Department of Biomedical Engineering add new data to research in biomedicine Health & Medicine Week October 29, 2007

Health & Medicine Week

October 29, 2007

SECTION: EXPANDED REPORTING; Pg. 3462

LENGTH: 440 words

HEADLINE: BIOMEDICINE;
Reports from University of Minnesota, Department of Biomedical Engineering add new data to research in biomedicine

BODY:

Research findings, 'Variation in pacing impedance: impact of **implant** site and measurement method,' are discussed in a new

Research findings, 'Variation in pacing impedance: impact of **implant** site and measurement method,' are discussed in a new report (see also Biomedicine). According to recent research from the United States, "' Variations in pacing impedance may be observed during implantation of various active fixation pacing leads. However, these variations can be influenced by the nature of the fixation, the **implant** site, or the measurement method."

"Here we describe **implant** dynamics for a 4.1F, **catheter**-delivered pacemaker lead. Endocardial active fixation leads were implanted under direct intracardiac visualization in two right **atrial** sites and three right ventricular sites in isolated swine (n=6) and human (n=4) hearts. Impedance measurements were recorded at each site employing three different measurement techniques-Pacing System Analyzer (PSA) 5311, PSA 2090, and the Impedance Tone Box (Medtronic, Inc., Minneapolis, MN, USA)-with four different degrees of lead fixation: helix touching, one turn fixed (1 TF), two turns fixed (2 TF), and overtorqued. Pacing impedances increased from touching to 1 TF to 2 TF at all **implant** sites in both swine and human hearts. Overtorquing applied to leads was associated with visible distortion at the endocardial tissue-lead interface in at least 60% of swine (18 of 30 **implants)** and human hearts (nine of 14 **implants)**. Impedance values in the right **atrial** high septum were significantly larger than in any other **implant** site ($p < 0.05$). The three measurement methods did not yield significantly different impedance measurements," wrote S.E. Anderson and colleagues, University of Minnesota, Department of Biomedical Engineering.

The researchers concluded: "Variations in measured impedances were associated with the nature of **implant** fixation at all sites in both swine and human hearts."

Anderson and colleagues published their study in *PACE - Pacing and Clinical Electrophysiology* (Variation in pacing impedance: impact of **implant** site and measurement method. *PACE - Pacing and Clinical Electrophysiology*, 2007;30(9):1076-82).

For additional information, contact S.E. Anderson, University of Minnesota, Dept. of Biomedical Engineering, Minneapolis, MN 55455 USA..

PEDIATRICS; FDA Approves GORE HELEX Septal Occluder for Treatment of Atrial Septal Defect Surgery Litigation & Law Weekly October 19, 2007

Surgery Litigation & Law Weekly

October 19, 2007

SECTION: EXPANDED REPORTING; Pg. 744

LENGTH: 599 words

HEADLINE: PEDIATRICS;
FDA Approves GORE HELEX Septal Occluder for Treatment of **Atrial** Septal Defect

BODY:

W. L. Gore & Associates (Gore) announced that the U.S. Food & Drug Administration (FDA) granted approval for the GORE HELEX

W. L. Gore & Associates (Gore) announced that the U.S. Food & Drug Administration (FDA) granted approval for the GORE HELEX Septal Occluder with modified **catheter** delivery system indicated for the transcatheter closure of **atrial** septal defect (ASD). An ASD is a congenital heart defect that affects thousands of patients every year. The GORE HELEX Septal Occluder is a permanently implanted prosthesis and the first device of its kind to use ePTFE, a biocompatible material that allows tissue ingrowth, to seal the defect. The recently approved **catheter**-based delivery system allows for easier device deployment via standard femoral venous access, bringing the GORE HELEX Septal Occluder to the forefront of non-surgical ASD repair (see also Pediatrics).

An ASD is an abnormal hole in the wall between the upper chambers of the heart, which allows blood to improperly flow from the left side of the heart to the right, forcing the right side of the heart and lungs to overexert to compensate for the problem. Left untreated, an ASD can cause the heart to enlarge, or weaken, leaving the patient at risk for serious conditions like **atrial** fibrillation, pulmonary hypertension, heart failure or stroke. The defect is most often treated in pediatric patients.

"In treating such a delicate area of the heart, particularly in small children, interventional cardiologists need to be confident that treatment will be effective for the long term," said Dr. Alexander Javois, The Heart Institute for Children, Advocate Hope Children's Hospital, Oak Lawn, Illinois. "Percutaneous ASD closure is successful in the very young patient using the GORE HELEX Septal Occluder. Its design and conformity allows tissue to incorporate the device easily so that it becomes part of the heart's anatomy, sealing the ASD successfully and improving, even normalizing, the patient's heart function without open heart surgery."

The GORE HELEX Septal Occluder is composed of ePTFE patch material supported by a single nitinol wire frame that bridges and eventually occludes the septal defect to stop the shunting of blood between the atria. Over the course of several weeks to months, cells begin to infiltrate and grow over the ePTFE membrane, resulting in successful closure of the defect.

"Open heart surgery is no longer the only available option to correct an ASD in young children and in patients with complicating health factors. Interventional cardiologists can close the defect permanently through a minimally invasive procedure with a

CARDIOLOGY; Coherex Medical to Begin its COHEREX-EU Study to Pursue CE Mark Clearance for its Coherex FlatStent PFO Closure System Health & Medicine Week October 15, 2007

Health & Medicine Week

October 15, 2007

SECTION: EXPANDED REPORTING; Pg. 519

LENGTH: 623 words

HEADLINE: CARDIOLOGY;
Coherex Medical to Begin its COHEREX-EU Study to Pursue CE Mark Clearance for its Coherex FlatStent PFO Closure System

BODY:

Coherex Medical, Inc., a privately held medical device company, announced it will soon begin its COHEREX-EU Study to pursue

Coherex Medical to Begin its COHEREX-EU Study to Pursue CE Mark Clearance for its Coherex FlatStent PFO Closure System

BODY:

Coherex Medical, Inc., a privately held medical device company, announced it will soon begin its COHEREX-EU Study to pursue CE Mark clearance for the Coherex FlatStent(TM) PFO Closure System. Additionally, Professor Horst Sievert, M.D. (an internationally renowned interventional cardiologist) has been selected by the company as its Principal Investigator for its COHEREX-EU Study (see also Cardiology).

Coherex(TM) will soon begin enrolling patients for its COHEREX-EU Study and anticipates completing the first human **implants** of its Coherex FlatStent PFO Closure System in the near future.

"We are extremely pleased to have received all of the clearances and approvals necessary from the governing regulatory agencies and committees to begin our COHEREX-EU Study," said Richard J. Linder, president and CEO of Coherex Medical. "In addition, we are quite honored to have Professor Sievert lead this study as our Principal Investigator and look forward to tracking his progress as we pursue CE Mark clearance for the Coherex FlatStent PFO Closure System."

"Coherex has developed a unique approach to treating the common heart defect we know as PFO (Patent Foramen Ovale)," Prof. Sievert said. "The Coherex FlatStent has potential significant benefits over existing PFO closure technologies because it promises to be safer, easier to use and may improve closure rates. Given that approximately 25 percent of adults have a PFO, there is a significant need for the Coherex FlatStent. I look forward to evaluating this novel new technology in the coming days."

Professor Horst Sievert, M.D. Background Information

Professor Horst Sievert, M.D. Background Information

Dr. Sievert is the Director of the CardioVascular Center Frankfurt, Sankt Katharinen, and the Department of Internal Medicine, Cardiology and Vascular Medicine of the Sankt Katharinen Hospital in Frankfurt, Germany. He is also an Associate Professor of Internal Medicine/Cardiology at the University of Frankfurt.

Dr. Sievert received his medical degree at the University of Frankfurt, Germany. After training in internal medicine, nephrology and intensive care medicine, he completed a fellowship in cardiology and vascular medicine under the direction of Dr. Martin Kaltenbach. Dr. Sievert became director of the Department of Interventional Cardiology and Angiology of the Heart Center Rotenburg in 1990, senior consultant at the Bethanien Hospital in Frankfurt in 1993 and director of the CardioVascular Center Frankfurt, Sankt Katharinen in 2003. Additionally, earlier this year Dr. Sievert was appointed Director of Structural Heart Interventions and the Peripheral Cath Lab at the Washington Hospital Center in Washington, D.C.

He has been the Principal Investigator of numerous clinical trials and has authored more than 130 manuscripts and 600 abstracts in peer-reviewed journals, as well as 70 books and book contributions. Dr. Sievert has also delivered more than 600 invited lectures around the world.

He has personally performed more than 16,000 PCIs (percutaneous coronary interventions) and 6,000 peripheral angioplasties. However, his activity in the cath lab is focused on highly specialized non-coronary interventions for patients with congenital heart disease, carotid disease or a high risk of stroke, among other conditions. Dr. Sievert was the first physician to close a left **atrial** appendage percutaneously. He has the most experience in the world in **catheter** closure of heart defects in adults and regularly receives referrals from around the world.

Keywords: Business, Cardio Device, Cardiology, Internal Medicine, Medical Device, Patents, Coherex Medical.

Source: **Combined Source Set 106 - Cardiovascular Week; Surgery Litigation & Law Weekly; Health & Medicine Wee...**
Terms: **atrial and implant and catheter** (Edit Search | Suggest Terms for My Search)

Select for FOCUS™ or Delivery

CARDIOLOGY; Data from Stanford University, U.S., provide new insights into cardiology Surgery Litigation & Law Weekly October 5, 2007

Surgery Litigation & Law Weekly

October 5, 2007

SECTION: EXPANDED REPORTING; Pg. 889

LENGTH: 1116 words

HEADLINE: CARDIOLOGY;
Data from Stanford University, U.S., provide new insights into cardiology

BODY:

Researchers from Stanford University, U.S., have published new cardiology data.

Study 1: A new study, "Aortic root dynamics and surgery: from craft to science," is now available. "Since the fifteenth century beginning with Leonardo da Vinci's studies, the precise structure and functional dynamics of the aortic root throughout the cardiac cycle continues to elude investigators. The last five decades of experimental work have contributed substantially to our current understanding of aortic root dynamics," researchers in the United States report.

"In this article, we review and summarize the relevant structural analyses, using radiopaque markers and sonomicrometric crystals, concerning aortic root three-dimensional deformations and describe aortic root dynamics in detail throughout the cardiac cycle. We then compare data between different studies and discuss the mechanisms responsible for the modes of aortic root deformation, including the haemodynamics, anatomical and temporal determinants of those deformations. These modes of aortic root deformation are closely coupled to maximize ejection, optimize transvalvular ejection haemodynamics and-perhaps most importantly-reduce stress on the aortic valve cusps by optimal diastolic load sharing and minimizing transvalvular turbulence throughout the cardiac cycle. This more comprehensive understanding of aortic root mechanics and physiology will contribute to improved medical and surgical treatment methods, enhanced therapeutic decision making and better post-intervention care of patients," wrote A. Cheng and colleagues, Stanford University.

The researchers concluded: "With a better understanding of aortic root physiology, future research on aortic valve repair and replacement should take into account the integrated structural and functional asymmetry of aortic root dynamics to minimize stress on the aortic cusps in order to prevent premature structural valve deterioration."

Cheng and colleagues published their study in *Philosophical Transactions* (Aortic root dynamics and surgery: from craft to science. *Philosophical Transactions*, 2007;362(1484):1407-19).

For additional information, contact A. Cheng, Stanford University School of Medicine, Dept. of Cardiovascular and Thoracic Surgery, Stanford, CA 94305-5247 USA..

For additional information, contact A. Cheng, Stanford University School of Medicine, Dept. of Cardiovascular and Thoracic Surgery, Stanford, CA 94305-5247 USA..

Study 2: Fiberoptic imaging of intracardiac structures during cardiac resynchronization therapy (CRT) implantation can be performed rapidly in a wide range of patients with an endocardial visualization **catheter** (EVC).

"Despite improvements in CRT implantation techniques, a significant minority of CRT attempts are unsuccessful. Inability to cannulate the coronary sinus (CS) because of difficult anatomy is a major reason for unsuccessful CRT implantation. Direct visualization of intracardiac structures during the **implant** may facilitate access into the CS. The present study describes CRT implantation with the aid of an EVC," scientists writing in the journal *Heart Rhythm* report.

"Fifty-eight consecutive patients (mean age 72±12 years; ejection fraction 26.2%±7.0%; New York Heart Association [NYHA] class 2.9) underwent CRT implantation using a steerable fiberoptic EVC (Acumen Medical, Inc., Sunnyvale, CA). The EVC was able to visualize the CS ostium in all cases. The CS was successfully cannulated in 57 (98.3%) of 58 patients. The time from vascular access to CS visualization was 6±5 minutes, and the total time to CS access was 8±6 minutes," wrote D.J. Anh and colleagues, Stanford University.

They continued, "Successful left ventricle (LV) lead implantation was accomplished in 55 (94.8%) of 58 patients. Three patients who had a previous history of failed LV lead implantation were successfully implanted using the EVC. Fiberoptic imaging of intracardiac structures during CRT implantation may be performed rapidly in a wide range of patients with an EVC."

The researchers concluded, "The ability to visualize right **atrial** anatomy may aid CS access and LV lead implantation."

Anh and colleagues published their study in *Heart Rhythm* (Early human experience with use of a deflectable fiberoptic endocardial visualization **catheter** to facilitate coronary sinus cannulation. HEART RHYTHM, 2006;3(8):875-878).

Source: **Combined Source Set 106** - **Cardiovascular Week; Surgery Litigation & Law Weekly; Health & Medicine Wee...**
Terms: **atrial and implant and catheter** (Edit Search | Suggest Terms for My Search)

Select for FOCUS™ or Delivery

CARDIOLOGY; Data from Stanford University, U.S., provide new insights into cardiology Cardiovascular Week October 1, 2007

Cardiovascular Week

October 1, 2007

SECTION: EXPANDED REPORTING; Pg. 268

LENGTH: 1112 words

HEADLINE: CARDIOLOGY;
Data from Stanford University, U.S., provide new insights into cardiology

BODY:

Researchers from Stanford University, U.S., have published new cardiology data.

Surgery, Stanford, CA 94305-5247 USA..

Study 2: Fiberoptic imaging of intracardiac structures during cardiac resynchronization therapy (CRT) implantation can be performed rapidly in a wide range of patients with an endocardial visualization **catheter** (EVC).

"Despite improvements in CRT implantation techniques, a significant minority of CRT attempts are unsuccessful. Inability to cannulate the coronary sinus (CS) because of difficult anatomy is a major reason for unsuccessful CRT implantation. Direct visualization of intracardiac structures during the **implant** may facilitate access into the CS. The present study describes CRT implantation with the aid of an EVC," scientists writing in the journal *Heart Rhythm* report.

"Fifty-eight consecutive patients (mean age 72±12 years; ejection fraction 26.2%±7.0%; New York Heart Association [NYHA] class 2.9) underwent CRT implantation using a steerable fiberoptic EVC (Acumen Medical, Inc., Sunnyvale, CA). The EVC was able to visualize the CS ostium in all cases. The CS was successfully cannulated in 57 (98.3%) of 58 patients. The time from vascular access to CS visualization was 6±5 minutes, and the total time to CS access was 8±6 minutes," wrote D.J. Anh and colleagues, Stanford University.

They continued, "Successful left ventricle (LV) lead implantation was accomplished in 55 (94.8%) of 58 patients. Three patients who had a previous history of failed LV lead implantation were successfully implanted using the EVC. Fiberoptic imaging of intracardiac structures during CRT implantation may be performed rapidly in a wide range of patients with an EVC."

The researchers concluded, "The ability to visualize right **atrial** anatomy may aid CS access and LV lead implantation."

Anh and colleagues published their study in *Heart Rhythm* (Early human experience with use of a deflectable fiberoptic endocardial visualization **catheter** to facilitate coronary sinus cannulation. HEART RHYTHM, 2006;3(8):875-878).

Additional information can be obtained by contacting D.J. Anh, 300 Pasteur Dr., H2146, Stanford, CA 94305, USA.

40 migraine headache specialists and interventional cardiologists have committed to participate in MIST II.

The bioabsorbable BioSTAR **implant** will be used in the MIST II study. As reported in NMT's recently completed BEST study, BioSTAR achieved a post **implant** complete closure rate of 92% at 30 days and 96% at 6 months. Over time, 90% to 95% of the BioSTAR **implant** is absorbed and replaced with the patient's native tissue providing a more natural, biological closure of the PFO.

Report 3: NMT Medical, Inc. (NMTI) announced recently that the company and the Children's Medical Center Corporation (CMCC) have filed a notice of appeal of a decision from the U.S. District Court for the District of Minnesota regarding a patent infringement lawsuit.

The lawsuit was originally filed in September 2004 against Cardia, Inc. of Burnsville, Minnesota alleging that Cardia's Intrasept device infringes upon CMCC's U.S. Patent No. 5,451,235 (the '235 Patent), which NMT licenses exclusively. The recent district court order held that Cardia's device does not infringe the patent.

The order has no effect on the validity and enforceability of the '235 Patent. NMT stands by its initial allegations against Cardia and intends to pursue an appeal to overturn the ruling. Cardia has not asserted any claims against NMT's products, and the district court's decision will have no impact on NMT's ability to sell its products.

The company also serves the pediatric interventional cardiologist with a broad range of cardiac septal repair **implants** delivered with nonsurgical **catheter** techniques.

Source: **Combined Source Set 106** - **Cardiovascular Week; Surgery Litigation & Law Weekly; Health & Medicine Wee...**
Terms: **atrial and implant and catheter** (Edit Search | Suggest Terms for My Search)

Select for FOCUS™ or Delivery

NMT MEDICAL; NMT Medical provides an activity update Surgery Litigation & Law Weekly September 28, 2007

Surgery Litigation & Law Weekly

September 28, 2007

SECTION: EXPANDED REPORTING; Pg. 1616

LENGTH: 924 words

HEADLINE: NMT MEDICAL ;
NMT Medical provides an activity update

BODY:

NMT Medical provides an activity update.

Source: **Combined Source Set 106** - **Cardiovascular Week; Surgery Litigation & Law Weekly; Health & Medicine Wee...**
Terms: **atrial and implant and catheter** (Edit Search | Suggest Terms for My Search)

Select for FOCUS™ or Delivery

HANNOVER MEDICAL SCHOOL, GERMANY; Journal papers present study findings from Hannover Medical School, Germany
Surgery Litigation & Law Weekly August 31, 2007

Surgery Litigation & Law Weekly

August 31, 2007

SECTION: EXPANDED REPORTING; Pg. 1696

LENGTH: 1271 words

HEADLINE: HANNOVER MEDICAL SCHOOL, GERMANY;
Journal papers present study findings from Hannover Medical School, Germany

BODY:

Journal papers present study findings from Hannover Medical School, Germany,.

compare RF ablation and cryoablation for their impact on markers for myocardial injury and inflammation," scientists in Hannover, Germany report.

"Nineteen patients received **catheter** ablation for **atrial** flutter by either cryoablation (10 patients) or open-irrigated RF ablation (nine patients). Venous blood samples for troponin T (TnT), creatinkinase (CK), and the cardiac isoenzyme MB (CKMB) were obtained before, at six hours after the end of ablation, and the following day. C-reactive protein (CRP) levels were measured before ablation and the following day. Bidirectional isthmus block was achieved in all patients. Cryoablation showed significantly higher TnT following ablation (0.85 microg/l ±0.39 microg/l) compared to RF ablation (0.36 microg/l ±0.24 microg/l; p=0.01) with declining levels the following day (cryoablation: 0.58 microg/l ±0.20 microg/l; RF ablation 0.34 microg/l ±0.21 microg/l; p=0.03). We observed equal findings for CK and CKMB, both significantly higher in cryoablation. RF ablation led to a nonsignificant rise in CK and CKMB. CRP was elevated significantly higher following RF ablation (12.3 mg/dl ±4.1 mg/dl) compared to cryoablation (6.9 mg/dl ±4.0 mg/dl; p=0.01). We show reduced inflammation despite higher markers for myocardial injury in cryoablation. The difference in biomarkers reflects different lesion formation in cryoablation and RF ablation. Cryoablation shows less systemic inflammatory reaction," wrote H. Oswald and colleagues, Hannover Medical School, Department of Cardiovascular Medicine.

The researchers concluded: "This might be due to less endothelial damage and surface thrombosis in cryoablation."

Oswald and colleagues published their study in *PACE - Pacing and Clinical Electrophysiology* (Difference in humoral biomarkers for myocardial injury and inflammation in radiofrequency ablation versus cryoablation. *PACE - Pacing and Clinical Electrophysiology*, 2007;30(7):885-90).

For additional information, contact H. Oswald, Hannover Medical School, Dept. of Cardiovascular Medicine, Hannover, Germany.

Study 2: The first human prototype auditory midbrain **implant** (AMI) is developed.

Source: **Combined Source Set 106 - Cardiovascular Week; Surgery Litigation & Law Weekly; Health & Medicine Wee...**
Terms: **atrial and implant and catheter** (Edit Search | Suggest Terms for My Search)

Select for FOCUS™ or Delivery

ST. JUDE MEDICAL, INC.; Recent developments announced by St. Jude Medical, Inc. Surgery Litigation & Law Weekly July 20, 2007

Surgery Litigation & Law Weekly

July 20, 2007

SECTION: EXPANDED REPORTING; Pg. 1554

LENGTH: 1662 words

HEADLINE: ST. JUDE MEDICAL, INC.;
Recent developments announced by St. Jude Medical, Inc.

BODY:

Recent developments announced by St. Jude Medical, Inc.

This trend article is an immediate alert from NewsRx to identify the most recent news developments at St. Jude Medical, Inc.

Report 1: St. Jude Medical, Inc. (NYSE:STJ) announced expanded European CE Mark approval to include the Therapy(TM) Cool Path(TM) irrigated ablation **catheter** with bi-directional steering for use in ablation procedures to treat abnormal heart rhythms.

This **catheter** is the first open-irrigated ablation **catheter** to provide bi-directional steering, a feature designed to help physicians maneuver the **catheter** in difficult areas of the heart and perform complex ablations more efficiently.

"The main advantage of the bi-directional **catheter** is its ease of use in reaching difficult anatomical locations," said Carlo Pappone, M.D., Ph.D., F.A.C.C., director of the Arrhythmology Department at San Raffaele University Hospital in Milan. "Because the **catheter** requires less manipulation and provides for greater simplicity of navigation, my procedural time was improved by about 20 percent."

"We are excited to offer physicians the first bi-directional, open-irrigated **catheter** in the European market," said Peter Chen, president of Irvine Biomedical, Inc., a St. Jude Medical Company. "As the population ages, the demand for more effective treatment of cardiac arrhythmias will only increase."

St. Jude Medical also announced U.S. Food and Drug Administration (FDA) approval and release of the uni-directional Therapy (TM) Cool Path(TM) open-irrigated ablation **catheter** for use in patients with type 1 **atrial** flutter. With **atrial** flutter, the heart's upper chambers beat steadily faster than normal, often resulting in a feeling of lightheadedness.

Catheter ablation therapy is used by physicians to restore a normal heart rhythm in patients with cardiac arrhythmias. During the procedure, an electrophysiologist uses a **catheter** (a long narrow tube) to deliver radiofrequency energy to create lesions in specific areas of cardiac tissue. The lesions, or tiny scars, interrupt the abnormal electrical signals that contribute to erratic heart

... Dimpi Patel, MD=, Dhanunjaya Lakkireddy, MD=, Jennifer E. Cummings, MD=, Robert A. Schweikert, MD=, J. David Burkhardt, MD=, Claude S. Elayi, MD=, Mohamed Kanj, MD=, Lucie Popova, MD=, Subramanya Prasad, MD=, David O. Martin, MD=, Lourdes Prieto, MD=, Walid Saliba, MD=, Patrick Tchou, MD=, Mauricio Arruda, MD=, Andrea Natale, MD=

Volume 48, Issue 12, Pages 2493-2499 (19 December 2006)

Received 28 June 2006; received in revised form 1 August 2006; accepted 8 August 2006; published online 29 November 2006.

Pulmonary Vein Total **Occlusion** Following **Catheter** Ablation for **Atrial** Fibrillation: Clinical Implications After Long-Term Follow-Up

Luigi Di Biase, Tamer S. Fahmy, Oussama M. Wazni, Rong Bai, Dimpi Patel, Dhanunjaya Lakkireddy, Jennifer E. Cummings, Robert A. Schweikert, J. David Burkhardt, Claude S. Elayi, Mohamed Kanj, Lucie Popova, Subramanya Prasad, David O. Martin, Lourdes Prieto, Walid Saliba, Patrick Tchou, Mauricio Arruda, Andrea Natale

We present the clinical course and management outcomes of 18 patients with total pulmonary vein **occlusion** after **atrial** fibrillation ablation. In our series, the cumulative stenosis index (i.e., sum of percent stenosis of the unilateral veins divided by the total number of ipsilateral veins) correlated with symptoms, lung perfusion, and time to interventions. Patients with a single pulmonary vein **occlusion** were mostly asymptomatic and should undergo routine imaging. Patients with a cumulative stenosis index ≥75% had <25% lung perfusion and appeared to improve mostly when early and repeated dilation/stenting were performed.

Objectives

We present the clinical course and management outcomes of patients with total pulmonary vein **occlusion** (PVO).

Background

Pulmonary vein **occlusion** is a rare complication that can develop after radiofrequency **catheter** ablation (RFA) of **atrial** fibrillation (AF). The long term follow-up data of patients diagnosed with PVO are minimal.

Methods

Data from 18 patients with complete **occlusion** of at least one pulmonary vein (PV) were prospectively collected. All patients underwent RFA for AF using different strategies between September 1999 and May 2004. Pulmonary vein **occlusion** was diagnosed using computed tomography (CT) and later confirmed by angiography when intervention was warranted. Lung perfusion scans were performed on all patients before and after intervention. The percent stenoses of the veins draining each independent lung were added together to yield an average cumulative stenosis of the vascular cross-sectional area draining the affected lung (cumulative stenosis index [CSI]).

stenosis of the vascular cross-sectional area draining the affected lung (cumulative stenosis index [CSI]).

Results

The patients' symptoms had a positive correlation with the CSI ($r = 0.843$, $p < 0.05$) and a negative one with the lung perfusion ($r = -0.667$, $p < 0.05$). A CSI ≥75% correlated well with low lung perfusion (<25%; $r = -0.854$, $p < 0.01$). Patients with a CSI ≥75% appeared to improve mostly when early ($r = -0.497$) and repeat dilation/stenting ($r = 0.0765$) were performed.

Conclusions

Patients with single PVO are mostly asymptomatic and should undergo routine imaging. On the other hand, patients with concomitant ipsilateral PV stenosis/PVO and a CSI ≥75% require early and, when necessary, repeated pulmonary interventions for restoration of pulmonary flow and prevention of associated lung disease.

Abbreviations and Acronyms: AF, **atrial** fibrillation, CSI, cumulative stenosis index, CT, computed tomography, NYHA, New York Heart Association, PPi, percutaneous pulmonary intervention, PV, pulmonary vein, PVO, pulmonary vein **occlusion**, PVS, pulmonary vein stenosis, RFA, radiofrequency **catheter** ablation

* Department of Cardiovascular Medicine, Section of Cardiac Electrophysiology and Pacing, Cleveland Clinic, Cleveland, Ohio
† Department of Cardiovascular Science, University of Insubria, Varese, Italy.

[1] Drs. Di Biase and Bai are trainees from the program "Second Level Master of Cardiac Electrophysiology and Pacing," organized by University of Insubria, Varese, Italy.

[2] Dr. Peichl was supported by a grant from the Department of Cardiology, Institute for Clinical and Experimental Medicine, Prague, Czech Republic.

Reprint requests and correspondence: Dr. Andrea Natale, Department of Cardiovascular Medicine, Head, Section of Cardiac Electrophysiology and Pacing, Cleveland Clinic, 9500 Euclid Avenue, Cleveland, Ohio 44195.

PII: S0735-1097(06)02446-6

doi:10.1016/j.jacc.2006.08.038

Acute Fatal Pulmonary Vein Occlusion after Catheter Ablation of Atrial Fibrillation

Journal	Journal of Interventional Cardiac Electrophysiology
Publisher	Springer Netherlands
ISSN	1383-875X (Print) 1572-8595 (Online)
Issue	Volume 11, Number 2 / October, 2004
DOI	10.1023/B:JICE.0000042350.16930.cb
Pages	127-130
Subject Collection	Medicine
SpringerLink Date	Monday, January 03, 2005

PDF (163.7 KB)

Brian Nilsson[1], Xu Chen[1], Steen Pehrson[1], Helle Lone Jensen[2], Lars Søndergaard[1], Morten Helvind[1], Lars Willy Andersen[1] and Jesper Hastrup Svendsen[1]

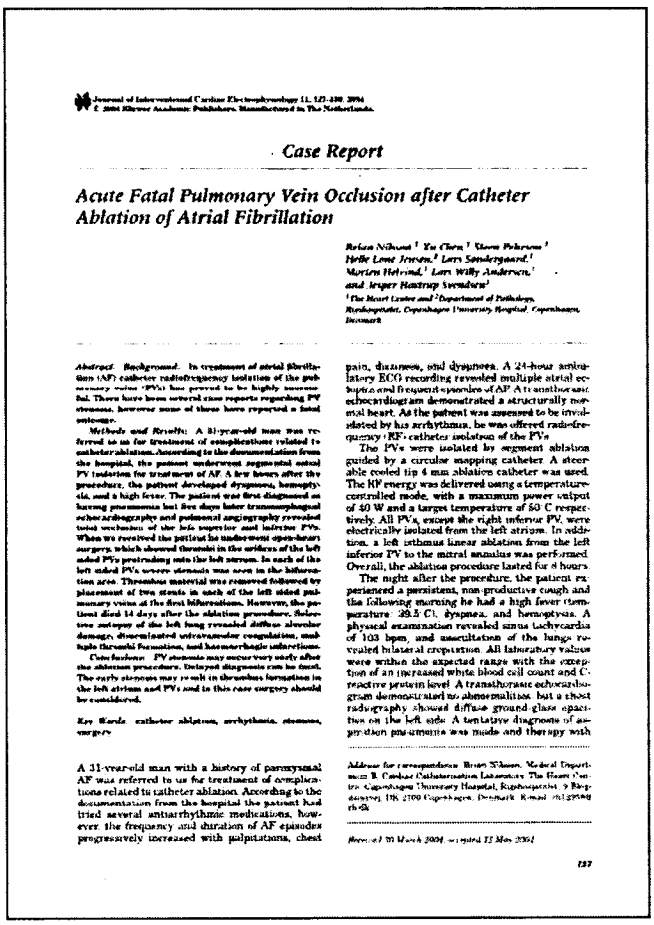
(1) The Heart Centre, Copenhagen University Hospital, Copenhagen, Denmark
(2) Department of Pathology, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark

Abstract *Background*: In treatment of atrial fibrillation (AF) catheter radiofrequency isolation of the pulmonary veins (PVs) has proved to be highly successful. There have been several case reports regarding PV stenosis, however none of these have reported a fatal outcome.
Methods and Results: A 31-year-old man was referred to us for treatment of complications related to catheter ablation. According to the documentation from the hospital, the patient underwent segmental ostial PV isolation for treatment of AF. A few hours after the procedure, the patient developed dyspnoea, hemoptysis, and a high fever. The patient was first diagnosed as having pneumonia but five days later transesophageal echocardiography and pulmonal angiography revealed total occlusion of the left superior and inferior PVs. When we received the patient he underwent open-heart surgery, which showed thrombi in the orifices of the left sided PVs protruding into the left atrium. In each of the left sided PVs severe stenosis was seen in the bifurcation area. Thrombus material was removed followed by placement of two stents in each of the left sided pulmonary veins at the first bifurcations. However, the patient died 14 days after the ablation procedure. Selective autopsy of the left lung revealed diffuse alveolar damage, disseminated intravascular coagulation, multiple thrombi formation, and haemorrhagic infarctions.
Conclusions: PV stenosis may occur very early after the ablation

Conclusions: PV stenosis may occur very early after the ablation procedure. Delayed diagnosis can be fatal. The early stenosis may result in thrombus formation in the left atrium and PVs and in this case surgery should be considered.

catheter ablation - arrhythmia - stenosis - surgery

Fulltext Preview (Small, Large)



Journal of Interventional Cardiac Electrophysiology 11, 127–130, 2004
© 2004 Kluwer Academic Publishers. Manufactured in The Netherlands.

Case Report

Acute Fatal Pulmonary Vein Occlusion after Catheter Ablation of Atrial Fibrillation

Brian Nielsen[1], Yu Chen[1], Claus Pedersen[1], Helle Lene Iversen,[2] Lars Sondergaard,[1] Morten Helvind,[1] Lars Willy Andersen,[1] and Jesper Hastrup Svendsen[1]

[1]The Heart Center and [2]Department of Pathology, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark

Abstract. Background. In treatment of atrial fibrillation (AF) catheter radiofrequency isolation of the pulmonary veins (PVs) has proved to be highly successful. There have been several case reports regarding PV stenosis, however none of these have reported a fatal outcome.

Methods and Results: A 31-year-old man was referred to us for treatment of complications related to catheter ablation. According to the documentation from the hospital, the patient underwent segmental ostial PV isolation for treatment of AF. A few hours after the procedure, the patient developed dyspnoea, hemoptysis, and a high fever. The patient was first diagnosed as having pneumonia but five days later transesophageal echocardiography and pulmonal angiography revealed total occlusion of the left superior and inferior PVs. When we received the patient he underwent open-heart surgery, which showed thrombi in the orifices of the left sided PVs protruding into the left atrium. In each of the left sided PVs severe stenosis was seen in the bifurcation area. Thrombus material was removed followed by placement of two stents in each of the left sided pulmonary veins at the first bifurcations. However, the patient died 14 days after the ablation procedure. Subsequent autopsy of the left lung revealed diffuse alveolar damage, disseminated intravascular coagulation, multiple thrombi formation, and haemorrhagic infarctions.

Conclusion: PV stenosis may occur very early after the ablation procedure. Delayed diagnosis can be fatal. The early stenosis may result in thrombus formation in the left atrium and PVs and in this case surgery should be considered.

Key Words: catheter ablation, arrhythmia, stenosis, surgery

A 31-year-old man with a history of paroxysmal AF was referred to us for treatment of complications related to catheter ablation. According to the documentation from the hospital the patient had tried several antiarrhythmic medications, however the frequency and duration of AF episodes progressively increased with palpitations, chest pain, dizziness, and dyspnoea. A 24-hour ambulatory ECG recording revealed multiple atrial ectopics and frequent episodes of AF. A transthoracic echocardiogram demonstrated a structurally normal heart. As the patient was assessed to be invalidated by his arrhythmia, he was offered radiofrequency (RF) catheter isolation of the PVs.

The PVs were isolated by segment ablation guided by a circular mapping catheter. A steerable cooled tip 4 mm ablative catheter was used. The RF energy was delivered using a temperature-controlled mode, with a maximum power output of 40 W and a target temperature of 50 C respectively. All PVs, except the right inferior PV, were electrically isolated from the left atrium. In addition, a left isthmus linear ablation from the left inferior PV to the mitral annulus was performed. Overall, the ablation procedure lasted for 8 hours.

The night after the procedure, the patient experienced a persistent, non-productive cough and the following morning he had a high fever (temperature 39.5 C), dyspnea, and hemoptysis. A physical examination revealed sinus tachycardia of 103 bpm, and auscultation of the lungs revealed bilateral crepitation. All laboratory values were within the expected range with the exception of an increased white blood cell count and C-reactive protein level. A transthoracic echocardiogram demonstrated no abnormalities, but a chest radiography showed diffuse ground-glass opacities on the left side. A tentative diagnosis of aspiration pneumonia was made and therapy with

Address for correspondence: Brian Nielsen, Medical Department B, Cardiac Catheterization Laboratory, The Heart Center, Copenhagen University Hospital, Rigshospitalet, 9 Blegdamsvej, DK-2100 Copenhagen, Denmark. E-mail: nielsen@rh.dk

Received 30 March 2004; accepted 12 May 2004

127

References

1. Arentz T, Jander N, von Rosenthal J, Blum T, Furmaier R, Gornandt L, Josef Neumann F, Kalusche D. Incidence of pulmonary vein stenosis 2 years after radiofrequency catheter ablation of refractory atrial fibrillation. *Eur Heart J* 2003;24:963-969.

2. Ernst S, Ouyang F, Goya M, Lober F, Schneider C, Hoffmann-Riem M, Schwarz S, Hornig K, Muller KM, Antz M, Kaukel E, Kugler C, Kuck KH. Total pulmonary vein occlusion as a consequence of catheter ablation for atrial fibrillation mimicking primary lung disease. *J Cardiovasc Electrophysiol* 2003;14:366-370.

3. Fink C, Schmaehl A, Bock M, Tuengerthal S, Delorme S. Images in cardiovascular medicine. Pulmonary vein stenosis after radiofrequency ablation for atrial fibrillation: Image findings with multiphasic pulmonary magnetic resonance angiography. *Circulation* 2003;107:e129-e130.

4. Qureshi AM, Prieto LR, Latson LA, Lane GK, Mesia CI, Radvansky P, White RD, Marrouche NF, Saad EB, Bash DL, Natale A, Rhodes JF. Transcatheter angioplasty for acquired pulmonary vein stenosis after radiofrequency ablation. *Circulation* 2003;108:1336-1342.

5. Seshadri N, Novaro GM, Prieto L, White RD, Natale A, Grimm RA, Stewart WJ. Images in cardiovascular medicine. Pulmonary vein stenosis after catheter ablation of atrial arrhythmias. *Circulation* 2002;105:2571-2572.

6. Saad EB, Rossillo A, Saad CP, Martin DO, Bhargava M, Erciyes D, Bash D, Williams-Andrews M, Beheiry S, Marrouche NF, Adams J, Pisano E, Fanelli R, Potenza D, Raviele A, Bonso A, Themistoclakis S, Brachmann J, Saliba WI, Schweikert RA, Natale A. Pulmonary vein stenosis after radiofrequency ablation of atrial fibrillation: Functional characterization, evolution, and influence of the ablation strategy. *Circulation* 2003;108:3102-3107.

7. Tsao HM, Chen SA. Evaluation of pulmonary vein stenosis after catheter ablation of atrial fibrillation. *Card Electrophysiol Rev* 2002;6:397-400.

8. Scanavacca MI, Kajita LJ, Vieira M, Sosa EA. Pulmonary vein stenosis complicating catheter ablation of focal atrial fibrillation. *J Cardiovasc Electrophysiol* 2000;11:677-681.

9. Yu WC, Hsu TL, Tai CT, Tsai CF, Hsieh MH, Lin WS, Lin YK, Tsao HM, Ding YA, Chang MS, Chen SA. Acquired pulmonary vein stenosis after radiofrequency catheter ablation of paroxysmal atrial fibrillation. *J Cardiovasc Electrophysiol* 2001;12:887-892.

10. Robbins IM, Colvin EV, Doyle TP, Kemp WE, Loyd JE, McMahon WS, Kay GN. Pulmonary vein stenosis after catheter ablation of atrial fibrillation. *Circulation* 1998;98:1769-1775.

11. Marrouche NF, Martin DO, Wazni O, Gillinov AM, Klein A, Bhargava M, Saad E, Bash D, Yamada H, Jaber W, Schweikert R, Tchou P, Abdul-Karim A, Saliba W, Natale A. Phased-array intracardiac echocardiography monitoring during pulmonary vein isolation in patients with atrial fibrillation: Impact on outcome and complications. *Circulation* 2003;107:2710-2716.

Pulmonary vein total occlusion following catheter ablation for atrial fibrillation: clinical implications after long-term follow-up. - Di Biase L - *J Am Coll Cardiol* - 19-DEC-2006; 48(12): 2493-9 (MEDLINE is the source for the citation and abstract of this record.)

Abstract:

OBJECTIVES: We present the clinical course and management outcomes of patients with total pulmonary vein occlusion (PVO). BACKGROUND: Pulmonary vein occlusion is a rare complication that can develop after radiofrequency catheter ablation (RFA) of atrial fibrillation (AF). The long term follow-up data of patients diagnosed with PVO are minimal. METHODS: Data from 18 patients with complete occlusion of at least one pulmonary vein (PV) were prospectively collected. All patients underwent RFA for AF using different strategies between September 1999 and May 2004. Pulmonary vein occlusion was diagnosed using computed tomography (CT) and later confirmed by angiography when intervention was warranted. Lung perfusion scans were performed on all patients before and after intervention. The percent stenoses of the veins draining each independent lung were added together to yield an average cumulative stenosis of the vascular cross-sectional area draining the affected lung (cumulative stenosis index [CSI]). RESULTS: The patients' symptoms had a positive correlation with the CSI ($r = 0.843$, $p < 0.05$) and a negative one with the lung perfusion ($r = -0.667$, $p < 0.05$). A CSI > or =75% correlated well with low lung perfusion (<25%; $r = -0.854$, $p < 0.01$). Patients with a CSI > or =75% appeared to improve mostly when early ($r = -0.497$) and repeat dilation/stenting ($r = 0.0765$) were performed. CONCLUSIONS: Patients with single PVO are mostly asymptomatic and should undergo routine imaging. On the other hand, patients with concomitant ipsilateral PV stenosis/PVO and a CSI > or =75% require early and, when necessary, repeated pulmonary interventions for restoration of pulmonary flow and prevention of associated lung disease.

Note: Performing your original search, ***atrial occlusion and catheter***, in PubMed will retrieve ***811*** records.

Display Abstract Show 20 Sort By Send to
All: 1 Review: 0

1: J Interv Card Electrophysiol. 2004 Oct;11(2):127-30. Related Articles, Links

SpringerLink

Acute fatal pulmonary vein occlusion after catheter ablation of atrial fibrillation.

Nilsson B, Chen X, Pehrson S, Jensen HL, Søndergaard L, Helvind M, Andersen LW, Svendsen JH.

The Heart Centre, Copenhagen University Hospital, Copenhagen, Denmark. rh12958@rh.dk

BACKGROUND: In treatment of atrial fibrillation (AF) catheter radiofrequency isolation of the pulmonary veins (PVs) has proved to be highly successful. There have been several case reports regarding PV stenosis, however none of these have reported a fatal outcome. METHODS AND RESULTS: A 31-year-old man was referred to us for treatment of

Related Resources
Order Documents
NLM Mobile
NLM Catalog
NLM Gateway
TOXNET
Consumer Health
Clinical Alerts
ClinicalTrials.gov
PubMed Central

complications related to catheter ablation. According to the documentation from the hospital, the patient underwent segmental ostial PV isolation for treatment of AF. A few hours after the procedure, the patient developed dyspnoea, hemoptysis, and a high fever. The patient was first diagnosed as having pneumonia but five days later transesophageal echocardiography and pulmonal angiography revealed total occlusion of the left superior and inferior PVs. When we received the patient he underwent open-heart surgery, which showed thrombi in the orifices of the left sided PVs protruding into the left atrium. In each of the left sided PVs severe stenosis was seen in the bifurcation area. Thrombus material was removed followed by placement of two stents in each of the left sided pulmonary veins at the first bifurcations. However, the patient died 14 days after the ablation procedure. Selective autopsy of the left lung revealed diffuse alveolar damage, disseminated intravascular coagulation, multiple thrombi formation, and haemorrhagic infarctions. CONCLUSIONS: PV stenosis may occur very early after the ablation procedure. Delayed diagnosis can be fatal. The early stenosis may result in thrombus formation in the left atrium and PVs and in this case surgery should be considered.

Publication Types:
- Case Reports

PMID: 15383775 [PubMed - indexed for MEDLINE]

Display Abstract Show 20 Sort By Send to

Write to the Help Desk
NCBI | NLM | NIH
Department of Health & Human Services
Privacy Statement | Freedom of Information Act | Disclaimer

Heart
Full text from 1997 at Heart Online

Journal List > Heart > v.75(1); Jan 1996

Heart. 1996 January; 75(1): 83–88. PMCID: PMC484230

Transcatheter closure of secundum atrial septal defects with the atrial septal defect occlusion system (ASDOS): initial experience in children.

G. Hausdorf, M. Schneider, B. Franzbach, C. Kampmann, K. Kargus, and B. Goeldner

Department of Paediatric Cardiology, Humboldt-University, Berlin, Germany.

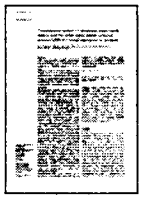
Abstract

OBJECTIVE--To report initial experiences with transcatheter occlusion of atrial septal defects using a new occlusion device. SUBJECTS--10 children aged 1.1 to 14.9 years. INCLUSION CRITERIA--Patients with a body weight above 10 kg, normal pulmonary resistance and an indication for surgical closure of a secundum atrial septal defect, a residual tissue rim of interatrial septum surrounding the defect of more than 5 mm, and a maximum defect diameter of 20 mm. METHODS--The defects were closed by a transcatheter device (ASDOS) consisting of two umbrellas which are introduced over a guidewire loop. Both umbrellas consist of a central body and five arms formed from preshaped nitinol wire covered with a thin polyurethane patch. The central body of the distal umbrella contains a thread, the proximal umbrella contains a bolt. The two umbrellas are connected by screwing the bolt on the thread using a screwdriver catheter. RESULTS--The implantation was performed under echocardiographic guidance; in six of 10 patients, transoesophageal echocardiography was necessary. The "stretched" diameter of the defect evaluated during balloon sizing ranged from 10 to 20 mm, and the pulmonary to systemic blood flow ratio from 1.5:1 to 2.8:1. Transcatheter closure was successfully performed in 9/10 patients using devices with a diameter of 25 mm to 40 mm. No severe complications occurred. However, in one patient with a pre-existing prolonged PR interval brief periods of second and third degree

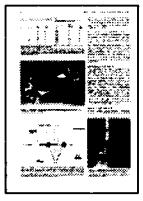
atrioventricular block occurred after the implantation but normalised within 3 d. During a follow up period of 21 to 29 weeks no device embolisation, thromboembolic complications, fractures of the implanted device, atrial perforations, pericardial effusions, obstructions of systemic or pulmonary veins, atrioventricular valve dysfunction, or other complications occurred. CONCLUSIONS--The new device is a promising transcatheter approach for the occlusion of secundum atrial septal defects in children. However, further evaluation and long term data are needed before this transcatheter technique can be recommended.

Full text

Full text is available as a scanned copy of the original print version. Get a printable copy (PDF file) of the **complete article** (2.3M), or click on a page image below to browse page by page. Links to PubMed are also available for **Selected References**.



83



84

85

86

87

88

Images in this article




Image on p.84

Image on p.84

Image on p.85

Image on p.85

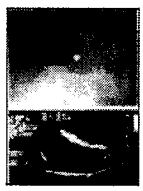


Image on p.86

Click on the image to see a larger version.

Selected References

These references are in PubMed. This may not be the complete list of references from this article.

- King, TD; Thompson, SL; Steiner, C; Mills, NL. Secundum atrial septal defect. Nonoperative closure during cardiac catheterization. *JAMA.* 1976 Jun 7;235(23):2506–2509. [PubMed]
- Rashkind, WJ. Transcatheter treatment of congenital heart disease. *Circulation.* 1983 Apr;67 (4):711–716. [PubMed]
- Rao, PS; Sideris, EB; Hausdorf, G; Rey, C; Lloyd, TR; Beekman, RH; Worms, AM; Bourlon, F; Onorato, E; Khalilullah, M, et al. International experience with secundum atrial septal defect occlusion by the buttoned device. *Am Heart J.* 1994 Nov;128(5):1022–1035. [PubMed]
- Rome, JJ; Keane, JF; Perry, SB; Spevak, PJ; Lock, JE. Double-umbrella closure of atrial defects. Initial clinical applications. *Circulation.* 1990 Sep;82(3):751–758. [PubMed]
- Das, GS; Voss, G; Jarvis, G; Wyche, K; Gunther, R; Wilson, RF. Experimental atrial septal defect closure with a new, transcatheter, self-centering device. *Circulation.* 1993 Oct;88(4 Pt 1):1754–1764. [PubMed]
- Babic, UU; Grujicic, S; Popovic, Z; Djurisic, Z; Vucinic, M; Pejcic, P. Double-umbrella device for transvenous closure of patent ductus arteriosus and atrial septal defect: first experience. *J Interv Cardiol.* 1991;4(4):283–294. [PubMed]

- Rao, PS; Langhough, R; Beekman, RH; Lloyd, TR; Sideris, EB. Echocardiographic estimation of balloon-stretched diameter of secundum atrial septal defect for transcatheter occlusion. *Am Heart J.* 1992 Jul;124(1):172–175. [PubMed]

- King, TD; Thompson, SL; Mills, NL. Measurement of atrial septal defect during cardiac catheterization. Experimental and clinical results. *Am J Cardiol.* 1978 Mar;41(3):537–542. [PubMed]

- Hellenbrand, WE; Fahey, JT; McGowan, FX; Weltin, GG; Kleinman, CS. Transesophageal echocardiographic guidance of transcatheter closure of atrial septal defect. *Am J Cardiol.* 1990 Jul 15;66(2):207–213. [PubMed]

- Boutin, C; Musewe, NN; Smallhorn, JF; Dyck, JD; Kobayashi, T; Benson, LN. Echocardiographic follow-up of atrial septal defect after catheter closure by double-umbrella device. *Circulation.* 1993 Aug;88(2):621–627. [PubMed]

- Lock, JE; Rome, JJ; Davis, R; Van Praagh, S; Perry, SB; Van Praagh, R; Keane, JF. Transcatheter closure of atrial septal defects. Experimental studies. *Circulation.* 1989 May;79 (5):1091–1099. [PubMed]

- Sideris, EB; Sideris, SE; Fowlkes, JP; Ehly, RL; Smith, JE; Gulde, RE. Transvenous atrial septal defect occlusion in piglets with a "buttoned" double-disk device. *Circulation.* 1990 Jan;81(1):312–318. [PubMed]

- Ishii, M; Kato, H; Inoue, O; Takagi, J; Maeno, Y; Sugimura, T; Miyake, T; Kumate, M; Kosuga, K; Ohishi, K. Biplane transesophageal echo-Doppler studies of atrial septal defects: quantitative evaluation and monitoring for transcatheter closure. *Am Heart J.* 1993 May;125(5 Pt 1):1363–1368. [PubMed]

- Ferreira, SM; Ho, SY; Anderson, RH. Morphological study of defects of the atrial septum within the oval fossa: implications for transcatheter closure of left-to-right shunt. *Br Heart J.* 1992 Apr;67 (4):316–320. [PubMed]

- Ishii, M; Kato, H; Inoue, O; Takagi, J; Maeno, Y; Sugimura, T; Miyake, T; Kumate, M; Kosuga, K; Ohishi, K. Biplane transesophageal echo-Doppler studies of atrial septal defects: quantitative evaluation and monitoring for transcatheter closure. *Am Heart J.* 1993 May;125(5 Pt 1):1363–1368. [PubMed]

http://74.125.47.132/search?q=cache:V-VrhFJQjm0J:www.thewellingtoncardiacservices.com/our-treatments-cardiology.asp+atrial+occlusion+and+closure&hl=en&ct=clnk&cd=6&gl=us 02/19/2009 12:38:18 PM

NON INVASIVE CARDIOLOGY
INVASIVE CARDIOLOGY
CARDIAC SURGERY
RHYTHM MANAGEMENT
IMAGING

OUR PROCEDURES

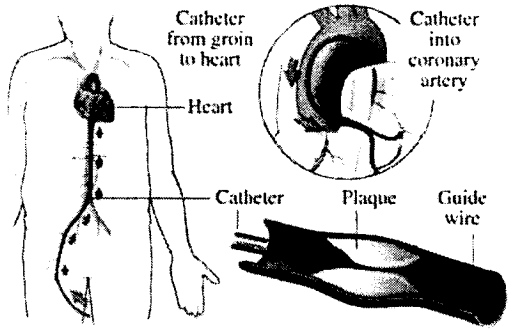
Invasive Cardiology

- Cardiac catheterisation / Coronary angiography
- Percutaneous Transluminal Coronary Angioplasty (PTCA -balloon treatment) and stenting
- Flow Reserve studies
- Rotational atherectomy (Rot ablation)
- Patent Foramen Ovale **occlusion** (PFO **closure**)
- Single and dual chamber pacemaker implantation
- Electro Physiological studies (EPS)
- Ablation for cardiac arrhythmias
- **Atrial** fibrillation (AF) ablation
- Cardiac Resynchronization Therapy (CRT heart failure devices) pacemaker implantation
- Implantable cardioverter defibrillator (ICD) implantation

Cardiac catheterisation / Coronary angiography

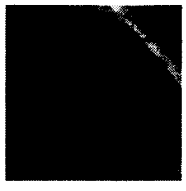
Cardiac catheterisation is an invasive procedure which involves having a fine hollow tube (catheter) placed into an artery or vein under local anaesthetic. The tube is then passed along the blood vessels and guided to the heart under X-ray imaging. The test is carried out most commonly for coronary angiography., although is sometimes performed to measure blood pressures and oxygen readings in different parts of the heart. The procedure can be carried out as a day case or as an inpatient procedure. Coronary angiography is of the tests used to diagnose the degree and severity of coronary artery heart disease. The tip of the catheter is positioned at the opening of the coronary artery, contrast medium is then injected into the artery which produces a clear X-ray image of the very fine network of arteries which make up the blood supply in the heart muscle, any narrowing's or blockages are normally very easily detected. Contrast medium is also injected into the main pumping chamber of the heart (left ventricle). This can sometimes cause a hot or flushing sensation which is transient and passes very quickly. The whole test can take between 10 minutes to one hour.

Coronary angiography is a relatively safe procedure, though complications such as stroke and heart attack can occur during and are estimated at approximately 1:1000. A detailed discussion of the risks versus benefits with the cardiologist will provide an individual guide.

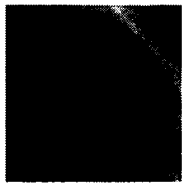


: Back to Top :

Percutaneous Transluminal Coronary Angioplasty (PTCA -balloon treatment) and stenting



Angiogram of a tight narrowing in the main coronary artery to the front of the heart (Left Anterior Descending artery)



Angioplasty balloon inflated in the narrowing

Opened up artery after PTCA

A PTCA is often carried out if narrowing's or blockages are found in the coronary arteries, it may be possible to open the narrowing using a tiny fluid filled balloon which is guided into the narrowed artery using an extremely fine catheter. The catheter is placed in an artery, commonly the femoral artery, this catheter has a small deflated balloon at the tip. Under X-ray guidance, the cardiologist advances this catheter into the narrowed or blocked artery of the heart. When it is in position, the cardiologist inflates the balloon, thereby opening up the blocked artery and blood can then flow through the artery again. Sometimes the Cardiologist may decide to implant a small reinforced metal spring called a stent to help to keep the artery open after the procedure. The stent is mounted on a PTCA balloon catheter which is then inflated inside the artery. The stent expands and is left in place as the balloon is deflated and the catheter is withdrawn. Occasionally the artery can block again over time to cause a condition called restenosis. If this happens, the cardiologist may have to repeat the procedure. Stents used to be made from bare metal. Unfortunately, these had a high probability of restenosis. Recent advances in stent technology are having an impact on restenosis. These new stents are called drug eluting stents. As the name

technology are having an impact on restenosis. These new stents are called drug eluting stents. As the name suggests, they have a drug impregnated into them that helps stop the restenosing process.

Patients come in for the procedure and go home the next day. During the procedure the ECG and blood pressure are very carefully monitored. Patients usually have some sedative medication to help them relax during the procedure as it may take up to 1 to 2 hours. They may also experience some angina type symptoms as the balloon is inflated but this soon passes. For any coronary invasive intervention, there are associated risks. The artery may become completely blocked and depending on the importance of this artery, it may be necessary to undergo an immediate bypass graft operation. This is a rare event, with approximately one out of every two hundred people undergoing PTCA converting to coronary artery bypass graft surgery (CABG). A detailed discussion of the risks versus benefits with the cardiologist will provide an individual guide prior to the procedure

: Back to Top :

Flow Reserve studies

This is a quick procedure which is carried out in the cath lab to assess the severity of any narrowing's which cannot otherwise be assessed radiographically. A very fine catheter with a sensitive blood pressure detector mounted at its tip is guided through the narrowed vessel. A drug which dramatically increases the workload of the heart is then administered to the patient. The effects of the drug are very short lasting but last long enough to let us know whether enough blood flow is getting passed the narrowing under stressful conditions and therefore whether it is necessary to carry out a PTCA to the narrowing.

: Back to Top :

Rotational atherectomy (Rotablation)

Chronic narrowing's or blockages may become calcified or have a lot of atheroma in them making them very difficult to treat with just a balloon. Rotablation is a procedure where, once again, a very fine wire is guided through the narrowing and then a catheter with a small device called a burr, similar to drill, mounted at its tip is guided to the beginning of the narrowing. The burr is connected to an external device which when activated by the cardiologist causes the burr to spin at very high speeds inside the narrowing, thereby creating a channel wide enough for a balloon or stent to then be used.

: Back to Top :

Patent Foramen Ovale occlusion (PFO closure)

Atrial Septal Defect (ASD) is a hole in the heart, specifically in the wall separating the left and right atria. There are 3 main types of ASD, the most commonly seen is called a Patent Foramen Ovale and can exist in adults with no symptoms. ASDs are the 4th most common congenital defect. A more serious defect (Ostium secundumcum) where the septum has failed to grow properly in the foetus, leads to blood shunting from the left side of the heart (high pressure) to the right side (low pressure). This can lead to volume overload, high blood pressure in the lungs and arrhythmias. There is a known link between ASDs and strokes. In recent years there have also been a number of studies carried out which show that there may also be a link to migraine. Clinical findings normally show up in the 2nd, 3rd decade of life. Closures of ASDs are more commonly carried out in childhood or at the time of the diagnosis later in life. Patients need to have a full echo study to assess their cardiac status and to measure the ASD in multiple views.

Surgical **closure** is very effective but carries higher risks of morbidity and other complications related to surgery as well as increased hospital stays. **Closure** can also be performed trans luminally using a catheter device called a Septal Occluder. The device is a self expanding double disc made of a nickel and titanium wire mesh and looks a bit like an umbrella. The device is delivered into the heart through a long introducer sheath which is positioned across the ASD. The septal occluder(or umbrella) is positioned on one side of the septum and one of the discs is opened out, the catheter is then pulled back across the ASD to stent the defect. The 2nd disc is then opened out and deployed on the other side of the septum. During the procedure a Trans Oesophageal Echo probe is positioned in the Oesophagus just behind the heart providing the cardiologist with a good view of the septum and the device as it is deployed. If a good position is confirmed then the device is released from the delivery system and the delivery system and sheath are removed. A whole range of sizes are required for the procedure as sizing the defect occurs at the time of the cardiac cath using a low pressure dilation balloon.

: Back to Top :

Single and dual chamber pacemaker implantation

Despite the different types of pacemaker, essentially they all have the same function - to detect and act as the hearts pacemaker if an abnormality in rhythm is detected. There are specific abnormal heart rhythms that will require a pacemaker to be inserted - if the heart beat is too slow (bradycardia) or too fast (tachycardia), if there is a irregular heart rate, heart failure, or when the heart does not receive the normal signals sent out by the sinoatrial (SA) node. This is termed heart block. Sometimes electrical impulses generated by the heart's normal pacemaker are not transmitted to the ventricles quickly enough. This is often referred to as a conduction abnormality. Heart failure can cause this, as well as some drugs and cardiac surgery. Heart block has various well defined stages with the last stage resulting in complete heart block. In this stage, no information from the heart's normal pacemaker reaches the ventricles. Luckily, the ventricles have their own built in pacemaker, though this is insufficient in providing the amount of blood the body needs to function adequately. As a result, fainting is a common problem with this form of heart disease. Pacemakers therefore provide an adequate pulse rate when the heart's rate is abnormal.

There are 3 different types of pacemaker - single chamber, dual chamber and biventricular chamber. The implantation procedure is normally carried out under local anaesthetic in the cardiac cath lab. The ECG, blood pressure and Oxygen level in the blood are all very closely monitored throughout. For the single chamber pacemaker, an electrode wire is inserted into a large vein, normally a vein near the shoulder. This wire is the guided under X-ray by a cardiologist into the right atria or ventricle of the heart. Once positioned in the heart the wire is tested by the cardiac physiologist through an external device called a pacing system analyzer. This measures the amount of energy the heart muscle needs to cause it to contract, the size, in millivolts, of the hearts own electrical impulses and whether the electrode is in a satisfactory position for it to be connected to the implantable pacemaker. During the testing of the wire/s, the patient may be aware of their heart beating slightly faster than usual or palpitations. The wire at the skin is then "tunneled" away from the insertion point, and a small pocket is made under the skin where it is attached to the actual pacemaker box. For a dual chamber pacemaker, the same technique is used but there are 2 leads. One lead is guided to the right atria and the other to the right ventricle. A biventricular pacemaker has 3 leads or electrodes that are guided into the right atria and right and left ventricle. Depending on the type of rhythm or severity of heart disease, the cardiologist will choose the most appropriate one.

: Back to Top :

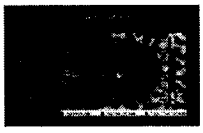
Electro Physiological studies (EPS)

In the normal heart, electrical impulses flow through the specialized conductive cells in an ordered fashion causing the heart to beat in a regular way and at appropriate rates. Any disturbance or interruption of the normal electrical system can give rise to heart rhythm disturbances or ARRYTHMIAS. An ECG is the first test on the path to diagnosing an arrhythmia, however, if the arrhythmia happens only occasionally, a normal ECG may not be enough to diagnose and therefore treat the arrhythmia properly. An Electrophysiological study (EPS) is an invasive procedure carried out in our specially designed cardiac cath labs kitted out with the most advanced EP technology and equipment. The procedure is performed by a highly specialized rhythm management cardiologist. The procedure involves passing catheter electrodes in to the vein in the groin under local anesthetic and guiding them into position around the heart under X Ray imaging. The electrode catheters are then connected to a large external EP device and electrical data is gathered from the small complex signals generated from various locations inside the heart. During the procedure, the cardiologist may be able to provoke arrhythmias and therefore analyze the 'map' of electrical signals during the event. This provides the cardiologists with diagnostic information and will help her decide on the appropriate treatment for the specific arrhythmia. Depending on the type of arrhythmia, some patients may be referred for an ablation procedure.

: Back to Top :

Ablation for cardiac arrhythmias

The ablation procedure is similar in set up to an EPS. Long flexible wires or "catheter electrodes" are introduced from a peripheral blood vessel into the heart and navigated to critical areas responsible for causing cardiac rhythm disorders.

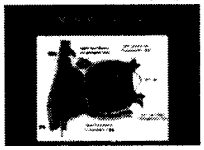


Delivery of a focal energy source from the tip of the catheter, either high frequency radio waves causing heating of tissue or freezing cryo ablation can be delivered at the tip of these catheters causing small discrete (4-5mm) irreversible areas of tissue destruction which render these abnormal areas of electrical activity non functional.

The rest of the heart function is unaffected and the lesions created are usually permanent. A curative catheter ablation approach is preferred by many patients who have recurrent symptoms which cannot be controlled by drugs or who do not wish to take drugs long term. This is an extremely effective form of treatment for arrhythmia, with long term studies showing successful ablation treatment is persistent over time, and that late recurrence of aberrant conduction is a rare event.

: Back to Top :

Atrial fibrillation (AF) ablation

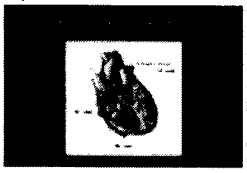


Atrial fibrillation (AF) is the commonest arrhythmia in man, with an estimated prevalence of 1% under 60 years and increases rapidly with age to more than 10% in those over 80 years AF is the commonest arrhythmic cause for hospitalizations, and is associated with increased morbidity (adverse events) and mortality (risk of death). Despite the prevalence of this condition, it was not until 1998 that the primary cause of AF was discovered. There are some areas of the heart muscle, usually located around the pulmonary veins which deliver oxygen rich blood back to the heart from the lungs, which, for some reason have retained autonomous and inappropriate rapid firing electrical activity and is capable of sending the whole of the atrium into a completely chaotic rhythm resulting in clinical symptoms. During ablation for AF, in order to record the electrical signals and apply the ablation treatment to the appropriate area, the catheter electrodes have to be passed through a thin section of the heart which separates the right from the left side of the heart. This is called a Trans septal puncture. The electrodes are then placed around the openings of the 4 pulmonary veins and ablation treatment applied to the muscle. This has the effect of electrically isolating each pulmonary vein from the left

treatment applied to the muscle. This has the effect of electrically isolating each pulmonary vein from the left atrium. Consequently, any abnormal electrical signals arising from the pulmonary veins cannot be conducted to the atrium and cause **Atrial** fibrillation. The duration of the procedure may be slightly longer than for other types of ablation and a CT scan of may be required before coming to have the ablation as we have a particularly advance piece of equipment which allows extremely precise electrical mapping of a 3D image of the left atrium and pulmonary veins.

Back to Top

Cardiac Resynchronization Therapy (CRT heart failure devices) pacemaker implantation



This is a new type of pacemaker which attempts to resynchronize the right and the left ventricles if they are found to be beating in co-ordinately (dysynchrony). The procedure is similar to that of a normal pacemaker implantation; however, as well as an electrode being positioned within the right ventricle, an extra pacemaker electrode is introduced into a large blood vessel running around the heart which allows the electrode to be in close proximity to the left ventricle. The biventricular pacemaker, or CRT device, can sense signals from both ventricles' and decide to pace both ventricles if the signals are found to be too far apart to produce an adequately coordinated contraction of the heart and thereby a forceful enough ejection of blood around the body. These devices have been shown to improve cardiac function, patient quality of life, improve exercise distance and reduce heart failure events. Not all patients with heart failure are suitable for this treatment, but it is thought that up to 30% of this population may benefit from CRT.

Patients will often undergo an echocardiogram for assessment or confirmation of dysynchrony before the implant procedure and often afterwards to optimise the settings of the device to produce the greatest amount of improvement in cardiac function.

Back to Top

Implantable cardioverter defibrillator (ICD) implantation

There are many types of heart rhythm, some can be tolerated by the body reasonably and others cannot. 2 types of rhythm which are not well tolerated are Ventricular tachycardia (VT) and Ventricular fibrillation (VF).

VT is a rhythm whose origin is initiated somewhere in the ventricles, instead of the atria. This causes the heart to beat very rapidly. The heart cannot fill adequately in this rhythm, making the patient feel light headed and weak. This can lead to fainting if not corrected promptly. It can also lead to death if not treated at all.

VF is more serious than VT. In VF, the heart has no coordinated activity. There are a multitude of signals sent out in all directions across the heart. Due to the chaotic activity, the pumping mechanism is totally ineffective. This is a medical emergency, and if not treated promptly, results in death.

The ICD is a device, similar to a pacemaker, which can be fully implanted within the body under local anesthetic taking approximately an hour. The procedure is similar to that of a pacemaker implantation but the patient will have some additional ECG electrodes connected before the procedure and they may receive slightly more sedative medication. A wire electrode is inserted in a vein near the shoulder, in a similar way to a pacemaker wire. This is introduced into the correct position in the heart by a cardiologist. A small pocket is then made underneath the muscle high up on the chest, commonly the pectoral muscle. The ICD is placed here and the electrode tunneled from its insertion point and attached.

The ICDs can be programmed specifically to suit the patients individual needs and are used in some patients who are at risk of developing the life threatening arrhythmias VT or VF. The ICD can terminate some rapid heart rhythms by use of the pacemaker function of the device, which is painless and is successful in 80% of cases. But when the heart is so rapid or irregular that it has stopped pumping, (VF) the device will deliver a shock to reset the heart and restore a normal rhythm.

Patients undergoing ICD implantation should have consulted a Cardiac Rhythm Specialist who will fully assess the suitability and benefit of such a device.

Back to Top

Resource Library

Powered by Dorland's Medical Dictionary for Healthcare Consumers

Return to Main Index >> How to Use

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z

occlusion (ə-kloo´zhən) obstruction.
the trapping of a liquid or gas within cavities in a solid or on its surface.
the relation of the teeth of the upper and lower jaws when in functional contact during activity of the mandible.
momentary complete closure of some area in the vocal tract, causing breathing to stop and pressure to accumulate.

http://www.mercksource.com/pp/us/cns/cns_search_results.jsp?ip_text=closure&queryterm=closure&hitsPerPage=15&searchType=B 02/19/2009 12:42:52 PM

MERCK SOURCE *A world of health information at your fingertips.*

Home | Condition Guides | Health Centers | Resource Library | Health Tools | You and Your Doctor

Search RESULTS

Search Help | Advanced Search

MERCKSOURCE SEARCH: ☐ within current results

SEARCH

You asked for: **closure**

Showing results 1-15 of 117

<< Previous 15 Results Next 15 Results >>

angle-closure glaucoma

angle-closure glaucoma glaucoma in which the angle of...root of the iris against the cornea. The **closure** obstructs the flow of aqueous humor from...outflow of aqueous humor is caused by **closure** of the anterior angle, with apposition...

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

velopharyngeal closure

velopharyngeal **closure** closure of nasal air escape by the elevation of the soft palate and contraction of the posterior pharyngeal wall; see also velopharyngeal insufficiency. Elsevier Logo

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

closure

closure (klo'zhar) occlusion. obstruction. delayed primary **closure** the surgical closing of a wound several days after...also healing by third intention. Vacuum Assisted **Closure**(VAC) trademark for a system that uses the controlled...

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

eyelid closure reflex

eyelid **closure** reflex corneal r. (def. 1). conjunctival reflex. Elsevier Logo

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

delayed primary closure

delayed primary **closure** the surgical closing of a wound several days after the injury because the wound was initially too contaminated to close; called also healing by third intention. Elsevier Logo

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

Vacuum Assisted Closure

Vacuum Assisted **Closure**(VAC) trademark for a system that uses the controlled negative pressure of a vacuum to promote healing of certain types of wound...

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

heart sounds

...contraction; a louder sound of higher frequency caused by **closure** of the mitral and tricuspid valves; a vibration caused by opening...than the first, is heard as a "dupp" and is produced by **closure** of the aortic and pulmonary valves. The third heart sound...

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

orbicularis pupillary reflex

orbicularis pupillary reflex unilateral contraction of the pupil, followed by dilatation after **closure** or attempted **closure** of eyelids that are forcibly held apart. Elsevier Logo

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

Related Terms

- elsevier logo
- wound
- assisted closure
- vacuum assisted
- delayed primary
- promote healing

Refine Your Search

- ⊟ Merck Source (117)
  - Health News (3)
  - ⊞ Health References (109)
  - ⊞ Images and Animations (5)

Doctor's Bag Search Tool

Download this desktop search tool to your computer and be one click away from health information on MerckSource.
Learn More

Download

MedlinePlus®

closure

SEARCH MEDLINEPLUS®

A service of the National Library of Medicine.

neural tube defect

neural tube defect a congenital defect in closure of the bony encasement of the spinal cord or of the skull...mass with no bony covering. Spina bifida refers to abnormal closure of the vertebral canal with or without visible protrusion...

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

strictureplasty

...See illustration. Strictureplasty. (A), Stricture; (B), longitudinal incision; (C), transverse closure. Strictureplasty. (A), Stricture; (B), longitudinal incision; (C), transverse closure. Elsevier Logo

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

laryngospasm

laryngospasm (lə-ring'go-spaz"əm) spasmodic closure of the larynx; called also laryngismus, glottic spasm, and laryngeal spasm. Elsevier Logo

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

dicrotic wave

dicrotic wave the second portion of the tracing of a sphygmograph of the arterial pulse or arterial pressure after the dicrotic notch, attributed to the reflected impulse of closure of the aortic valves. Called also recoil wave Elsevier Logo

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

obstruction

...struk'shən) the act of blocking or clogging. the state or condition of being clogged; see also atresia. Called also blockade, closure, and occlusion. chronic airflow obstruction , chronic airway obstruction name given to a group of disorders in which the...

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

epiphyseal plate

epiphyseal plate the thin plate of cartilage between the epiphysis and the shaft of a long bone; it is the site of growth in length and is obliterated by epiphyseal closure. Elsevier Logo

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

aortic insufficiency

aortic insufficiency inadequate closure of the aortic valve, permitting aortic regurgitation. Elsevier Logo

Resource Found in: Health References > Medical Dictionary > Dorland's Medical Dictionary for Health Consumers

« Previous 15 Results 1 2 3 4 5 6 7 8 Next 15 Results >>
Page 1 of 8

Display Results in Groups of 15

Animations Images PDF Document Tools Audio Photography

MERCKSOURCE SEARCH. within current results

SEARCH

http://74.125.47.132/search?q=cache:kKW71FEI1e4J:www.csmc.edu/2363.html+catheter+closure&hl=en&ct=clnk&cd=2&gl=us 02/19/2009 12:54:53 PM

Programs and Services

Cedars-Sinai Heart Institute
About Us
Anatomy of the Heart
Cardiothoracic Surgery Services
Cardiovascular Intervention Center
Clinical Trials
Conditions of the Heart
Contact Us
Diagnostic Procedures
Drug Therapy
For Patients
For Physicians
Frequently Asked Questions
Glossary
In the News
Managing Risk Factors

Trans-Catheter Closure of Holes in the Heart

Printer Friendly
Email to a Friend
Have Questions?

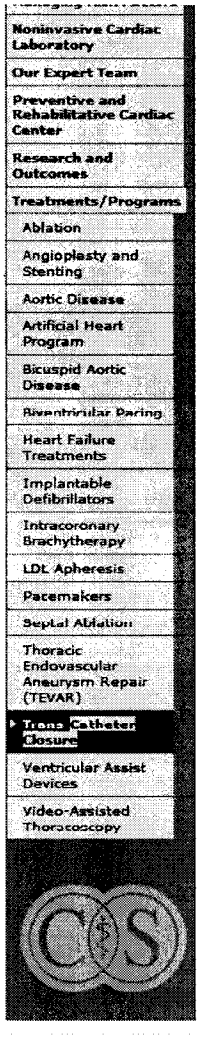
When a person has abnormal holes in his or her heart - a condition known as atrial septal defect and patent foramen ovale - a transcatheter **closure** device can help close them up. The device is often used on babies and adults and avoids open-heart surgery.

The transcatheter **closure** device - typically a single or double wire frame covered by fabric - is placed in the heart through a **catheter** (tube) that is inserted through a vein in the groin.

Half of the device is connected to one side of the atrial septum (wall between the two upper chambers of the heart), and the other half of the device is attached to the other side of the atrial septum, forming a sort of "sandwich" of the hole in the heart.

Within six to eight weeks, the device acts as a skeleton, stimulating normal tissue to grow in and over the hole. These devices can be safely used in growing children because while the device does not grow, the tissue that covers the device does, and will continue to grow with the child.

http://74.125.47.132/search?q=cache:kKW71FEI1e4J:www.csmc.edu/2363.html+catheter+closure&hl=en&ct=clnk&cd=2&gl=us 02/19/2009 12:54:53 PM



http://74.125.47.132/search?q=cache:E75FkLg7DE8J:www.amplatzer.com/USProducts/ASDDevices/tabid/179/Default.aspx+catheter+closure&hl=en&ct=clnk&cd=3&gl=us 02/19/2009 12:55:56 PM

AMPLATZER® Septal Occluder for Atrial Septal Defect **Closure**

Availability: USA and International

AGA Medical introduced the AMPLATZER® Septal Occluder, the first **catheter** delivered atrial septal **closure** device. Introduced in most countries beginning in 1996, over 90,000 Septal Occluders have been manufactured and delivered worldwide to cardiac physicians to date.

Indications, contraindications, warnings, precautions and instructions for use can be found in the Instructions For Use available by request or online at www.amplatzer.com/products.

AMPLATZER® Septal Occluder

AMPLATZER® Septal Occluder for heart defect repair utilizes the shape memory of Nitinol, a wire made from an alloy of nickel and titanium. Each Occluder is made of a Nitinol wire mesh that is shaped into two flat discs and a middle, or "waist" to fit the defect size, with polyester fabric inserts designed to help close the hole and provide a foundation for growth of tissue over the occluder after placement.

The placement procedure typically takes place in a special room called a catheterization laboratory (cath lab) where many minimally invasive, non-surgical procedures are performed. The Septal Occluder is delivered to the correct place in the heart through a **catheter**, a small plastic tube used by an interventional cardiologist to access the heart and place the occluder using x-ray and echocardiography. The physician deploys the occluder to expand each disc on either side of the

For Medical Professionals

- AMPLATZER Septal Occluder Instructions for Use
- AMPLATZER Cribriform Occluder Instructions For Use
- Product Numbers and Accessories
- Implanting the Septal Occluder
- AMPLATZER® ASD Simulation Training
- Case Studies
- Related Articles

For Product Reimbursement Information:

Email: agareimbursements@amplatzer.com
Phone: 1-888-548-4407 ext. 3177

Guidelines & Downloads

- MRI Compatibility
- Latex Free Statement

Contact Us

AGA Medical Corporation
5050 Nathan Lane North
Plymouth, MN 55442
USA

defect, closing off the hole.

Toll Free: 1-888-546-4407
Phone: 1-763-513-9227
Fax: 1-763-513-9226

To Find a Physician:
Use our Facility Locator

AMPLATZER® Multi-Fenestrated Septal Occluder – "Cribriform"

The AMPLATZER® Multi-Fenestrated Septal Occluder - "Cribriform" is designed for use in multiple hole Atrial Septal Defects. It is placed exactly like the AMPLATZER® Septal Occluder, but has a narrow waist to place it through one of the central holes in the septal wall, with the discs covering the surrounding holes.

Video Demonstrations

- The AMPLATZER Septal Occluder
- Septal Occluder Placement
- AMPLATZER® Multi-Fenestrated Septal Occluder – "Cribriform"

How Your Doctor Will Implant the AMPLATZER Septal Occluder

What to expect during and after the procedure will vary. Discuss any questions or concerns you have with your doctor.

Read More

Patient Informational Guide on ASD **Closure**

ASD Patient Guide - English and Espanol

The PDFs provided are useful informational booklets about ASD and **closure** using the AMPLATZER® Septal Occluder and Multi-fenestrated ASD and **closure** using the AMPLATZER® Cribriform Occluder, in English and Spanish. For additional information contact AGA Medical.

- AMPLATZER Septal Occluder Patient Guide – English
- AMPLATZER Septal Occluder Patient Guide – Espanol
- AMPLATZER Cribriform Occluder Patient Guide – English
- AMPLATZER Cribriform Occluder Patient Guide – Espanol

The Journal of Invasive Cardiology
The Official Journal of the International Andreas Gruentzig Society

Journal of Invasive Cardiology
- Home
- Current Issue
- Archived Content
- Archived Digital Issues
- Print Subscriptions
- Author Instructions
- View Online Media Kit
- Reprints, Rights, Permission and
- Translation

Hot Cardiology Topics
- Angioplasty
- Atherectomy
- Brachytherapy
- Cardiac Imaging
- Chronic Occlusion
- Coronary Anomalies
- Flow Dynamics
- Restenosis
- Stroke
- Valvuloplasty

Community

Catheter Closure of Atrial Septal Defects

VOLUME: 15 PUBLICATION DATE: Jul 05 2003

Issue Number:
7 (July 2003)

author:

P. Syamasundar Rao, MD

Since the initial description in the mid 1970s by King and Mills et al.[1–3] of an **atrial** septal defect occluding device, a number of other devices have been studied, including: Rashkind's devices (hooked and double umbrella), Clamshell occluder, buttoned device, Pavcnik's mono-disk device, modified Rashkind's patent ductus arteriosus umbrella device, ASDOS (**atrial** septal defect occluding system), Das Angel Wing device, Amplatzer septal occluder, CardioSeal and StarFlex devices, Centering-on-demand buttoned device, Helex device, transcatheter patch and others, as reviewed elsewhere.[4,5] Transcatheter **closure** of **atrial** septal defects using various devices[6–18] is now an established practice in most cardiac centers. These techniques have proven to be safe, cost-effective and favorably compare with surgical **closure**.[19,20]

In this issue of the Journal, Staniloae and colleagues[21] present the results of implantation of the Amplatzer Septal Occluder (ASO) in adults with ostium secundum **atrial** septal defects. Successful deployment of the ASO device was accomplished in 109 (91%) of 117 patients taken to the catheterization laboratory with intent to occlude. Patients in whom the device implantation was not feasible had larger defects with larger shunts than those in whom the device was successfully implanted. At the conclusion of the procedure, complete occlusion of the defect was demonstrated in 75% patients. Small (< 5 mm) residual shunts were present in 23% patients and 2% patients had large (> 5 mm) residual shunts. At a mean follow-up of 19 months, remarkable improvement in symptomatology was observed. Residual shunts were present in 10% patients at 1-month follow-up, and in 1% of patients at 1-year follow-up. Only one patient, with fenestrated defect, required surgical intervention two years following initial device placement. The authors conclude that percutaneous **closure** of the **atrial** septal defects with ASO is safe, and mid-term results compare favorably with those reported following surgical **closure**. They recommend device **closure** as the first-line therapeutic option in adult patients with **atrial** septal defects.

This is a well-written paper reporting a single-institution experience in closing **atrial** septal defects with ASO. They also mention the use of the 60° angulated delivery sheath (Hausdorf's **catheter**, Cook Corporation) in patients in whom the device could not be positioned parallel to the interatrial septum. The candid reporting of air embolism brings the point home that we should continue to be diligent to prevent vacuum creation in the sheath and take all precautions to avoid air embolism. Whereas the authors used transesophageal echocardiography for monitoring device placement, intracardiac echocardiography[22] appears to be gaining acceptance and may have advantages in that no general anesthesia is required.

As reviewed in the introductory paragraph, many devices are available to the interventional cardiologist, but selection of a particular device becomes difficult because of lack of randomized clinical trials. A few studies[23–26] attempted to compare the results of multiple devices, as and when they became available, but these studies are neither randomized nor blinded and are unlikely to shed any more light than the single device studies. With existing economical, ethical and medical considerations, it is not possible to conduct a prospective randomized clinical trial utilizing all the eligible devices. Because of this reason, selection of the device may have to be based on results of

Community

Andreas Greuntzig

- Society
- Editorial Board
- Submit Manuscripts
- Review Manuscripts

CLINICAL EVENTS CALENDAR

Start
Jan 18,2009
End
Jan 22,2009
International Symposium on Endovascular Therapy

Start
Feb 08,2009
End
Feb 12,2009
International Congress XXII Endovascular Interventions

Start
Feb 12,2009
End
Feb 14,2009
JIM 2009

Start
Feb 19,2009
End
Feb 21,2009
Scottsdale Interventional Forum

more

The Journal of Invasive Cardiology
Stemi Interventions»

Non-Accredited Education

CLINICAL EXPERIENC

eligible devices. Because of this reason, selection of the device may have to be based on results of clinical trials conducted separately by the inventor or manufacturer of the device. A careful comparison[27–30] of implantation feasibility (ratio of implantations VS patients taken to the catheterization laboratory with the intent to occlude), percent device dislodgements, misplacements, and embolizations, and percent of patients with effective occlusion and reintervention-free rates during follow-up, tabulated elsewhere,[29,30] reveal that these are similar and comparable for most if not all devices. In addition to feasibility, safety and effectiveness data, the availability, cost, and size of the delivery sheath, as well as other factors, may have to be considered in the selection of the device.

Of the devices listed above, some devices were discontinued because of the identified problems during the study of the respective devices. At the present time, ASO is the only device approved by the FDA for general clinical use for **closure** of the **atrial** septal defects. To my knowledge, CardioSeal/StarFlex, Centering-on-demand buttoned and Helex devices, and the transcatheter patch are undergoing FDA-approved clinical trials; they appear to be at varying stages in the clinical trials. These devices will be briefly reviewed:

Amplatzer Septal Occluder. The ASO consists of two self-expandable round discs connected to each other with a 4 mm waist, made up of 0.004 0.005" nitinol wire mesh filled with Dacron fabric. This is a relatively new, double-disc, self-centering device with rapid accumulation of implantation data, recently approved by the FDA. Short- and mid-term follow-up data have been published. Implantation of the device is relatively easy and requires a small delivery sheath. The device can be retrieved with ease into the sheath prior to release. It can also be repositioned. The prevalence of residual shunts is low. The disadvantages are a thick profile of the device and concern related to a large amount of nitinol (a nickel-titanium compound) in the device and consequent potential for nickel toxicity.

CardioSeal/StarFlex devices. Following withdrawal of the clamshell device because of fracture of the arms of the device, the device was redesigned. An additional bend was introduced and the wire material was changed to non-ferromagnetic alloy. At the same time, the fabric covering the device was changed to Dacron. It received HDE (Humanitarian Device Exemption) from the FDA for use in some cardiac defects, but does not include ostium secundum **atrial** defects. The preliminary experience with implantation of the device is reasonably good, but requires a large delivery sheath and is difficult to retrieve. The CardioSeal is not a self-centering device, but the further modified version by StarFlex system made it more self-centering than CardioSeal. Arm fractures seen with the clamshell device have also been reported with this device, thus raising concerns about long-term safety.

Centering-on-demand (COD) buttoned device. This is a modified fourth-generation buttoned device with two spring buttons and a centering mechanism sutured on the right **atrial** aspect of the left **atrial** occluder. Also, the device was made round. The technique of implantation of the COD device implantation is more complex than the fourth-generation buttoned device, but it can easily be learned. The device delivery **catheter** is small (10 French [Fr]) for most devices, although larger devices (>= 50 mm) require 11 or 12 Fr sheaths. The COD buttoned device has been approved by FDA for clinical trials in the U.S., and the clinical trials continue. However, the clinical experience thus far[10,31] is encouraging.

Helex device. This is the newest of the devices. It is a double-disc device built on single strand nitinol wire draped with ultrathin ePTEE. It may be delivered via a 9 Fr delivery **catheter** without a sheath. The implantation of the device is simple, and the device can be withdrawn into the **catheter** before detachment and redeployed as desired. However, the human experience with this device is limited. FDA-approved clinical trials with an IDE are currently in progress.

Transcatheter Patch. The currently available devices are double-disc devices and have similar limitations in that they require septal rims to hold the device. Furthermore, wire-related problems such as **atrial** perforation, aortic perforation, mitral valve injury, wire fractures and embolization potentially exist in all devices. In response to resolving these problems, wireless devices have been conceived by Sideris and his associates;[18,32] detachable balloon and transcatheter deliverable patches have been developed. Polyurethane patches, supported by modified balloon catheters, are implanted across **atrial** septal defects, left in situ for 48 hours, and balloon withdrawn, leaving the patch in place. Following the feasibility and safety studies in piglets,[32] human trials began outside the US.[33] FDA approval with IDE for human trials in the U.S. has been recently granted for a pilot study.

Summary and conclusions. Following the pioneering works of King, Rashkind and their associates in mid 1970s, a number of devices have been designed and tested in animal models and human subjects. Some devices have been discontinued and others were modified followed by further clinical trials. At the time of this writing, only one device, ASO, was approved by the FDA for general clinical use to occlude **atrial** defects. There are a number of other devices which are in clinical trials, including the CardioSeal/StarFlex, COD buttoned, Helex and transcatheter patch devices. The preceding paper reports on the utility of ASO in occluding **atrial** defects in adult patients; the results appear good with extremely rare major complication and little need re-intervention during follow-up. It is envisioned that several other devices will be approved by the regulatory authorities in the foreseeable future so that an appropriate device for a given type of **atrial** septal defect may be selected by the practicing interventional cardiologist.

References:

1. King TD, Mills NL. Nonoperative **closure** of **atrial** septal defects. Surgery 1974;75:383–388.
2. Mills NL, King TD. Nonoperative **closure** of left-to-right shunts. J Thorac Cardiovasc Surg 1976;72:371–378.
3. King TD, Thompson SL, Steiner C, et al. Secundum **atrial** septal defect: Nonoperative **closure**

3. King TD, Thompson SL, Steiner C, et al. Secundum **atrial** septal defect. Nonoperative **closure** during cardiac catheterization. J Am Med Assoc 1976;235:2506–2509.
4. Chopra PS, Rao PS. History of the development of **atrial** septal occlusion devices. Curr Intervent Cardiol Reports 2000;2:63–69.
5. Rao PS. History of **atrial** septal occlusion devices. In: Rao PS, Kern MJ (Eds). **Catheter** Based Devices in the Treatment of Non-Coronary Cardiovascular Disease in Adults and Children. Lippincott, William & Wilkins, Philadelphia, 2003: pp. 1–9.
6. Rashkind WJ, Cuaso CE. Transcatheter **closure** of **atrial** septal defects in children. Eur J Cardiol 1977;8:119–120.
7. Rome JJ, Keane JF, Perry SB, et al. Double-umbrella **closure** of **atrial** defects: Initial clinical applications. Circulation 1990;82:751–758.
8. Rao PS, Sideris EB, Hausdorf G, et al. International experience with secundum **atrial** septal defect occlusion by the buttoned device. Am Heart J 1994;128:1022–1035.
9. Rao PS, Berger F, Rey C, et al. Transvenous occlusion of secundum **atrial** septal defects with 4th generation buttoned device: Comparison with 1st, 2nd and 3rd generation devices. J Am Coll Cardiol 2000;36:583–592.
10. Pavcnik D, Wright KC, Wallace S. Monodisk device for percutaneous transcatheter **closure** of cardiac septal defects. Cardiovasc Intervent Radiol 1993;16:308–312.
11. Redington AN, Rigby ML. Transcatheter **closure** of interatrial communication with a modified umbrella device. Br Heart J 1994;72:372–377.
12. Babic UU, Grujicic S, Popvic Z, et al. Double-umbrella device for transvenous **closure** of patent ductus arteriosus and **atrial** septal defect: First clinical experience. J Intervent Cardiol 1991;4:283–294.
13. Das GS, Harrison JK, O'Laughlin MP. The Angel Wings Das device for **atrial** septal defect **closure**. Curr Intervent Cardiol Reports 2000;2:78–85.
14. Waight DJ, Koenig PR, Cao Q, et al. Transcatheter **closure** of secundum **atrial** septal defects using Amplatzer Septal Occluder; clinical experience and technical considerations. Curr Intervent Cardiol Reports 2000;2:70–77.
15. Hausdorf G, Kaulitz R, Paul T. Transcatheter **closure** of **atrial** septal defect with a new flexible, self-centering device (The Starflex Occluder). Am Heart J 1999;84;1113–1116.
16. Rao PS, Sideris EB. Centering-on-demand buttoned device: It's role in transcatheter occlusion of **atrial** septal defects. J Intervent Cardiol 2001;14:81–89.
17. Latson LA, Zahn EW, Wilson N. Helex septal occluder for **closure** of **atrial** septal defects. Curr Intervent Cardiol Reports 2000;2:268–273.
18. Zamora R, Rao PS, Sideris EB. Buttoned device for **atrial** septal defect occlusion. Curr Intervent Cardiol Reports 2000;2:167–176.
19. Berger F, Vogel M, Alexi-Meskishvili V, Lange PE. Comparison of results and complications of surgical and Amplatzer device **closure** of **atrial** septal defects. J Thorac Cardiovasc Surg 1999;118:674–678.
20. Du ZD, Hijazi ZM, Kleinman CS, et al. Comparison between transcatheter and surgical **closure** of secundum **atrial** septal defect in children and adults: Results of multicenter nonrandomized trial. J Am Coll Cardiol 2002;39:1836–1844.
21. Staniloae CS, El-Khally Z, Ibrahim R, et al. Percutaneous **closure** of secundum **atrial** septal defect in adults — A single center experience with Amplatzer septal occluder. J Invas Cardiol 2003;15:393–397.
22. Hijazi ZM, Wang Z, Cao QL, et al. Transcatheter **closure** of **atrial** septal defects and patent foramen ovale under intracardiac echocardiographic guidance: Feasibility and comparison with transesophageal echocardiography. Cathet Cardiovasc Intervent 2001;52:194–199.
23. Walsh KP, Tofeig M, Kitchiner DJ, et al. Comparison of the Sideris and Amplatzer septal occlusion devices. Am J Cardiol 1999;83:933–936.
24. Formigari R, Santoro G, Rosetti L, et al. Comparison of three different **atrial** septal defect occluding devices. Am J Cardiol 1998;82:690–692.
25. Sievert H, Koppeler P, Rux S, et al. Percutaneous **closure** of 176 interatrial defects in adults with different occlusion devices — Six years experience (Abstr). J Am Coll Cardiol 1999;33:519A.
26. Keppeir P, Rux S, Dirko J, et al. Transcatheter **closure** of 100 patent foramina ovalia in patients with unexplained stroke and suspected paradoxic embolism: A comparison of five different devices (Abstr). Eur Heart J 1999;20:196.
27. Rao PS. **Closure** devices for **atrial** septal defect: Which one to chose? (editorial). Indian Heart J 1998;50:379–383.
28. Rao PS. Transcatheter **closure** of **atrial** septal defects: Are we there yet? (editorial). J Am Coll Cardiol 1998;31:1117–1119.
29. Rao PS. Summary and comparison of **atrial** septal defect **closure** devices. Curr Intervent Cardiol Reports 2000;2:367–376.
30. Rao PS. Comparative summary of **atrial** septal defect occlusion devices. In: Rao PS, Kern MJ (Eds). **Catheter** Based Devices in the Treatment of Non-Coronary Cardiovascular Disease in Adults and Children. Lippincott, William & Wilkins, Philadelphia, 2003: pp. 91–101.
31. Rao PS, Sideris EB. Buttoned device modifications: Influence on feasibility, safety and effectiveness (Abstr). Cathet Cardiovasc Intervent 2003;59:153.
32. Sideris EB, Sideris SE, Kaneva A, et al. Transcatheter occlusion of experimental **atrial** septal defects by wireless occluders and patches (Abstr). Cardiol Young 1999;9:92.
33. Sideris EB. Wireless devices for the occlusion of **atrial** septal defects. In: Rao PS, Kern MJ (Eds). **Catheter** Bases Devices in the Treatment of Non-coronary Cardiovascular Disease in Adults and Children. Lippincott, William & Wilkins, Philadelphia, 2003: pp. 79–84.

Average:

Average:
☆☆☆☆☆
No votes yet

Login or register to post comments Email this page

Press Release

Miami Poised to Challenge America's Number One Killer

LUMEN 2009 hosts top docs in cardiac medicine focused on increasing survival rates of heart attack victims

Miami, FL (January 28, 2009) – On February 26th through the 28th, at the Loews Miami Beach Hotel in Miami Beach, FL, many of the nation's most respected and innovative practitioners of cardiac medicine will come together at *LUMEN 2009. The Symposium on Optimal Treatments for Acute MI*, for the purpose of affecting America's number one killer – heart disease. Present will be the President of the American College of Cardiology, Dr. W. Douglas Weaver, who has been an outspoken advocate for healthcare reform in the U.S.

READ MORE

Protection
Complimentary CME Accredited Webcast
Dates: November 18, 2008 Time: 6:00 pm ET November 19, 2008 Time: 3:00 pm ET
This activity is sponsored by the **North American Center for Continuing Medical Education.**

LUMEN 2009 - THE SYMPOSIUM ON OPTIMAL TREATMENTS FOR ACUTE MI
Live Symposium
Date: February 26-28
Location: Loews Miami Beach Hotel Miami Beach, Florida 33139
This activity is sponsored by the **North American Center for Continuing Medical Education.**

http://74.125.47.132/search?q=cache:A48tAmXiGsIJ:www.ist-world.org/ResultPublicationDetails.aspx%3FResultPublicationId%3Da50827373b0b42368a50a33fa15dff83+catheter+closure+atrial&hl=en&ct=clnk&cd=9&gl=us
02/19/2009 12:57:46 PM

istworld

Language: English

Find: Go!

BOOKMARK

HELP | ABOUT

• BECOME PART OF EUROPEAN RESEARCH IN IST WORLD :

PUBLICATIONS

Query Definition:

» IST World » All data sets » Publications » 1 Result » **Details Vi**

Publication:

Use of Intracardiac Echocardiography to Guide **Catheter Closure** of **Atrial** Communications

Selected Dataset:

Search Method:

» Basic Search

» Categorical Search

Use of Intracardiac Echocardiography to C **Catheter Closure** of **Atrial** Communica

Publication Year: 2003

Type

Unknown Type

Authors

Analytic Tools:

» Result List

» **Details View**

Advanced Tools:

» Collaboration Diagram

» Competence Diagram

Experimental Tools:

» Collaboration Trends

» Competence Trends

» Consortia Prediction

Adv » Semantic Search

Results Collaboration Competence Consortium Com. Trends Coll. Trends

Abdulla R

Cao QL

Hijazi ZM

Koenig PR

1

http://74.125.47.132/search?q=cache:A48tAmXiGsIJ:www.ist-world.org/ResultPublicationDetails.aspx%3FResultPublicationId%3Da50827373b0b42368a50a33fa15dff83+catheter+closure+atrial&hl=en&ct=clnk&cd=9&gl=us
02/19/2009 12:57:46 PM

Related Publications (similar authors)

Advanced Analysis ...

Results Collaboration Competence Com. Trends

0.750 Transcatheter **Closure** of Secundum **Atrial** Septal Defects Using the Amplatzer Septal Occluder:

0.500 Pediatric Interventions Transcatheter **Closure** of **Atrial** Septal Defects and Patent Foramen Ovale

0.500 Intracardiac echocardiographic guidance of transcatheter **closure** of **atrial** septal defects and patent

0.500 Hybrid Pediatric Cardiac Surgery

0.500 Speed of normalization of right ventricular volume overload after transcatheter **closure** of **atrial**

0.500 Transcatheter **closure** of **atrial** septal defects and patent foramen ovale under intracardiac

0.250 Coronary artery fistula complicating the evaluation of Kawasaki disease

0.250 Multiplane transthoracic echocardiography: Image orientation, anatomic correlation, and clinical

0.250 Transcatheter **closure** of **atrial** septal defects and patent foramen ovale under intracardiac

0.250 Physiologic significance of chronic coronary aneurysms in patients with Kawasaki disease

1 2 3 4

Datasets

GoogleScholar Parts

Please send corrections and pointers to missing information to feedback@ist-world.org.

Information Society

The Journal of Invasive Cardiology
The Official Journal of the International Andreas Gruentzig Society

Journal of Invasive Cardiology
- Home
- Current Issue
- Archived Content
- Archived Digital Issues
- Print Subscriptions
- Author Instructions
- View Online Media Kit
- Reprints, Rights, Permission and
- Translation

Hot Cardiology Topics
- Angioplasty
- Atherectomy
- Brachytherapy
- Cardiac Imaging
- Chronic Occlusion
- Coronary Anomalies
- Flow Dynamics
- Restenosis
- Stroke
- Valvuloplasty

Community

Catheter Closure of Atrial Septal Defects

VOLUME: 15 PUBLICATION DATE: Jul 05 2003

Issue Number:
7 (July 2003)

author:

P. Syamasundar Rao, MD

Since the initial description in the mid 1970s by King and Mills et al.[1–3] of an **atrial** septal defect occluding device, a number of other devices have been studied, including: Rashkind's devices (hooked and double umbrella), Clamshell occluder, buttoned device, Pavcnik's mono-disk device, modified Rashkind's patent ductus arteriosus umbrella device, ASDOS (**atrial** septal defect occluding system), Das Angel Wing device, Amplatzer septal occluder, CardioSeal and StarFlex devices, Centering-on-demand buttoned device, Helex device, transcatheter patch and others, as reviewed elsewhere.[4,5] Transcatheter **closure** of **atrial** septal defects using various devices[6–18] is now an established practice in most cardiac centers. These techniques have proven to be safe, cost-effective and favorably compare with surgical **closure**.[19,20]

In this issue of the Journal, Staniloae and colleagues[21] present the results of implantation of the Amplatzer Septal Occluder (ASO) in adults with ostium secundum **atrial** septal defects. Successful deployment of the ASO device was accomplished in 109 (91%) of 117 patients taken to the catheterization laboratory with intent to occlude. Patients in whom the device implantation was not feasible had larger defects with larger shunts than those in whom the device was successfully implanted. At the conclusion of the procedure, complete occlusion of the defect was demonstrated in 75% patients. Small (< 5 mm) residual shunts were present in 23% patients and 2% patients had large (> 5 mm) residual shunts. At a mean follow-up of 19 months, remarkable improvement in symptomatology was observed. Residual shunts were present in 10% patients at 1-month follow-up, and in 1% of patients at 1-year follow-up. Only one patient, with fenestrated defect, required surgical intervention two years following initial device placement. The authors conclude that percutaneous **closure** of the **atrial** septal defects with ASO is safe, and mid-term results compare favorably with those reported following surgical **closure**. They recommend device **closure** as the first-line therapeutic option in adult patients with **atrial** septal defects.

This is a well-written paper reporting a single-institution experience in closing **atrial** septal defects with ASO. They also mention the use of the 60° angulated delivery sheath (Hausdorf's **catheter**, Cook Corporation) in patients in whom the device could not be positioned parallel to the interatrial septum. The candid reporting of air embolism brings the point home that we should continue to be diligent to prevent vacuum creation in the sheath and take all precautions to avoid air embolism. Whereas the authors used transesophageal echocardiography for monitoring device placement, intracardiac echocardiography[22] appears to be gaining acceptance and may have advantages in that no general anesthesia is required.

As reviewed in the introductory paragraph, many devices are available to the interventional cardiologist, but selection of a particular device becomes difficult because of lack of randomized clinical trials. A few studies[23–26] attempted to compare the results of multiple devices, as and when they became available, but these studies are neither randomized nor blinded and are unlikely to shed any more light than the single device studies. With existing economical, ethical and medical considerations, it is not possible to conduct a prospective randomized clinical trial utilizing all the eligible devices. Because of this reason, selection of the device may have to be based on results of

Community

Andreas Greuntzig

- Society
- Editorial Board
- Submit Manuscripts
- Review Manuscripts

CLINICAL EVENTS CALENDAR

Start
Jan 18,2009
End
Jan 22,2009
International Symposium on Endovascular Therapy

Start
Feb 08,2009
End
Feb 12,2009
International Congress XXII Endovascular Interventions

Start
Feb 12,2009
End
Feb 14,2009
JIM 2009

Start
Feb 19,2009
End
Feb 21,2009
Scottsdale Interventional Forum

more

The Journal of Invasive Cardiology
Stemi Interventions»

Non-Accredited Education

CLINICAL EXPERIENC

eligible devices. Because of this reason, selection of the device may have to be based on results of clinical trials conducted separately by the inventor or manufacturer of the device. A careful comparison[27–30] of implantation feasibility (ratio of implantations VS patients taken to the catheterization laboratory with the intent to occlude), percent device dislodgements, misplacements, and embolizations, and percent of patients with effective occlusion and reintervention-free rates during follow-up, tabulated elsewhere,[29,30] reveal that these are similar and comparable for most if not all devices. In addition to feasibility, safety and effectiveness data, the availability, cost, and size of the delivery sheath, as well as other factors, may have to be considered in the selection of the device.

Of the devices listed above, some devices were discontinued because of the identified problems during the study of the respective devices. At the present time, ASO is the only device approved by the FDA for general clinical use for **closure** of the **atrial** septal defects. To my knowledge, CardioSeal/StarFlex, Centering-on-demand buttoned and Helex devices, and the transcatheter patch are undergoing FDA-approved clinical trials; they appear to be at varying stages in the clinical trials. These devices will be briefly reviewed.

Amplatzer Septal Occluder. The ASO consists of two self-expandable round discs connected to each other with a 4 mm waist, made up of 0.004 0.005" nitinol wire mesh filled with Dacron fabric. This is a relatively new, double-disc, self-centering device with rapid accumulation of implantation data, recently approved by the FDA. Short- and mid-term follow-up data have been published. Implantation of the device is relatively easy and requires a small delivery sheath. The device can be retrieved with ease into the sheath prior to release. It can also be repositioned. The prevalence of residual shunts is low. The disadvantages are a thick profile of the device and concern related to a large amount of nitinol (a nickel-titanium compound) in the device and consequent potential for nickel toxicity.

CardioSeal/StarFlex devices. Following withdrawal of the clamshell device because of fracture of the arms of the device, the device was redesigned. An additional bend was introduced and the wire material was changed to non-ferromagnetic alloy. At the same time, the fabric covering the device was changed to Dacron. It received HDE (Humanitarian Device Exemption) from the FDA for use in some cardiac defects, but does not include ostium secundum **atrial** defects. The preliminary experience with implantation of the device is reasonably good, but requires a large delivery sheath and is difficult to retrieve. The CardioSeal is not a self-centering device, but the further modified version by StarFlex system made it more self-centering than CardioSeal. Arm fractures seen with the clamshell device have also been reported with this device, thus raising concerns about long-term safety.

Centering-on-demand (COD) buttoned device. This is a modified fourth-generation buttoned device with two spring buttons and a centering mechanism sutured on the right **atrial** aspect of the left **atrial** occluder. Also, the device was made round. The technique of implantation of the COD device implantation is more complex than the fourth-generation buttoned device, but it can easily be learned. The device delivery **catheter** is small (10 French [Fr]) for most devices, although larger devices (>= 50 mm) require 11 or 12 Fr sheaths. The COD buttoned device has been approved by FDA for clinical trials in the U.S., and the clinical trials continue. However, the clinical experience thus far[19,31] is encouraging.

Helex device. This is the newest of the devices. It is a double-disc device built on single strand nitinol wire draped with ultrathin ePTEE. It may be delivered via a 9 Fr delivery **catheter** without a sheath. The implantation of the device is simple, and the device can be withdrawn into the **catheter** before detachment and redeployed as desired. However, the human experience with this device is limited. FDA-approved clinical trials with an IDE are currently in progress.

Transcatheter Patch. The currently available devices are double-disc devices and have similar limitations in that they require septal rims to hold the device. Furthermore, wire-related problems such as **atrial** perforation, aortic perforation, mitral valve injury, wire fractures and embolization potentially exist in all devices. In response to resolving these problems, wireless devices have been conceived by Sideris and his associates;[18,32] detachable balloon and transcatheter deliverable patches have been developed. Polyurethane patches, supported by modified balloon catheters, are implanted across **atrial** septal defects, left in situ for 48 hours, and balloon withdrawn, leaving the patch in place. Following the feasibility and safety studies in piglets,[32] human trials began outside the US.[33] FDA approval with IDE for human trials in the U.S. has been recently granted for a pilot study.

Summary and conclusions. Following the pioneering works of King, Rashkind and their associates in mid 1970s, a number of devices have been designed and tested in animal models and human subjects. Some devices have been discontinued and others were modified followed by further clinical trials. At the time of this writing, only one device, ASO, was approved by the FDA for general clinical use to occlude **atrial** defects. There are in number of other devices which are in clinical trials, including the CardioSeal/StarFlex, COD buttoned, Helex and transcatheter patch devices. The preceding paper reports on the utility of ASO in occluding **atrial** defects in adult patients; the results appear good with extremely rare major complication and little need re-intervention during follow-up. It is envisioned that several other devices will be approved by the regulatory authorities in the foreseeable future so that an appropriate device for a given type of **atrial** septal defect may be selected by the practicing interventional cardiologist.

References:

1. King TD, Mills NL. Nonoperative **closure** of **atrial** septal defects. Surgery 1974;75:383–388.
2. Mills NL, King TD. Nonoperative **closure** of left-to-right shunts. J Thorac Cardiovasc Surg 1976;72:371–378.
3. King TD, Thompson SL, Steiner C, et al. Secundum **atrial** septal defect: Nonoperative **closure**

3. King TD, Thompson SL, Steiner C, et al. Secundum atrial septal defect. Nonoperative closure during cardiac catheterization. J Am Med Assoc 1976;235:2506–2509.
4. Chopra PS, Rao PS. History of the development of atrial septal occlusion devices. Curr Intervent Cardiol Reports 2000;2:63–69.
5. Rao PS. History of atrial septal occlusion devices. In: Rao PS, Kern MJ (Eds). Catheter Based Devices in the Treatment of Non-Coronary Cardiovascular Disease in Adults and Children. Lippincott, William & Wilkins, Philadelphia, 2003: pp. 1–9.
6. Rashkind WJ, Cuaso CE. Transcatheter closure of atrial septal defects in children. Eur J Cardiol 1977;8:119–120.
7. Rome JJ, Keane JF, Perry SB, et al. Double-umbrella closure of atrial defects: Initial clinical applications. Circulation 1990;82:751–758.
8. Rao PS, Sideris EB, Hausdorf G, et al. International experience with secundum atrial septal defect occlusion by the buttoned device. Am Heart J 1994;128:1022–1035.
9. Rao PS, Berger F, Rey C, et al. Transvenous occlusion of secundum atrial septal defects with 4th generation buttoned device: Comparison with 1st, 2nd and 3rd generation devices. J Am Coll Cardiol 2000;36:583–592.
10. Pavcnik D, Wright KC, Wallace S. Monodisk device for percutaneous transcatheter closure of cardiac septal defects. Cardiovasc Intervent Radiol 1993;16:308–312.
11. Redington AN, Rigby ML. Transcatheter closure of interatrial communication with a modified umbrella device. Br Heart J 1994;72:372–377.
12. Babic UU, Grujicic S, Popvic Z, et al. Double-umbrella device for transvenous closure of patent ductus arteriosus and atrial septal defect: First clinical experience. J Intervent Cardiol 1991;4:283–294.
13. Das GS, Harrison JK, O'Laughlin MP. The Angel Wings Das device for atrial septal defect closure. Curr Intervent Cardiol Reports 2000;2:78–85.
14. Waight DJ, Koenig PR, Cao Q, et al. Transcatheter closure of secundum atrial septal defects using Amplatzer Septal Occluder; clinical experience and technical considerations. Curr Intervent Cardiol Reports 2000;2:70–77.
15. Hausdorf G, Kaulitz R, Paul T. Transcatheter closure of atrial septal defect with a new flexible, self-centering device (The Starflex Occluder). Am Heart J 1999;84;1113–1116.
16. Rao PS, Sideris EB. Centering-on-demand buttoned device: It's role in transcatheter occlusion of atrial septal defects. J Intervent Cardiol 2001;14:81–89.
17. Latson LA, Zahn EW, Wilson N. Helex septal occluder for closure of atrial septal defects. Curr Intervent Cardiol Reports 2000;2:268–273.
18. Zamora R, Rao PS, Sideris EB. Buttoned device for atrial septal defect occlusion. Curr Intervent Cardiol Reports 2000;2:167–176.
19. Berger F, Vogel M, Alexi-Meskishvili V, Lange PE. Comparison of results and complications of surgical and Amplatzer device closure of atrial septal defects. J Thorac Cardiovasc Surg 1999;118:674–678.
20. Du ZD, Hijazi ZM, Kleinman CS, et al. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults. Results of multicenter nonrandomized trial. J Am Coll Cardiol 2002;39:1836–1844.
21. Staniloae CS, El-Khally Z, Ibrahim R, et al. Percutaneous closure of secundum atrial septal defect in adults — A single center experience with Amplatzer septal occluder. J Invas Cardiol 2003;15:393–397.
22. Hijazi ZM, Wang Z, Cao QL, et al. Transcatheter closure of atrial septal defects and patent foramen ovale under intracardiac echocardiographic guidance: Feasibility and comparison with transesophageal echocardiography. Cathet Cardiovasc Intervent 2001;52:194–199.
23. Walsh KP, Tofeig M, Kitchiner DJ, et al. Comparison of the Sideris and Amplatzer septal occlusion devices. Am J Cardiol 1999;83:933–936.
24. Formigari R, Santoro G, Rosetti L, et al. Comparison of three different atrial septal defect occluding devices. Am J Cardiol 1998;82:690–692.
25. Sievert H, Koppeler P, Rux S, et al. Percutaneous closure of 176 interatrial defects in adults with different occlusion devices — Six years experience (Abstr). J Am Coll Cardiol 1999;33:519A.
26. Keppeir P, Rux S, Dirko J, et al. Transcatheter closure of 100 patent foramina ovalia in patients with unexplained stroke and suspected paradoxic embolism: A comparison of five different devices (Abstr). Eur Heart J 1999;20:196.
27. Rao PS. Closure devices for atrial septal defect: Which one to chose? (editorial). Indian Heart J 1998;50:379–383.
28. Rao PS. Transcatheter closure of atrial septal defects: Are we there yet? (editorial). J Am Coll Cardiol 1998;31:1117–1119.
29. Rao PS. Summary and comparison of atrial septal defect closure devices. Curr Intervent Cardiol Reports 2000;2:367–376.
30. Rao PS. Comparative summary of atrial septal defect occlusion devices. In: Rao PS, Kern MJ (Eds). Catheter Based Devices in the Treatment of Non-Coronary Cardiovascular Disease in Adults and Children. Lippincott, William & Wilkins, Philadelphia, 2003: pp. 91–101.
31. Rao PS, Sideris EB. Buttoned device modifications: Influence on feasibility, safety and effectiveness (Abstr). Cathet Cardiovasc Intervent 2003;59:153.
32. Sideris EB, Sideris SE, Kaneva A, et al. Transcatheter occlusion of experimental atrial septal defects by wireless occluders and patches (Abstr). Cardiol Young 1999;9:92.
33. Sideris EB. Wireless devices for the occlusion of atrial septal defects. In: Rao PS, Kern MJ (Eds). Catheter Bases Devices in the Treatment of Non-coronary Cardiovascular Disease in Adults and Children. Lippincott, William & Wilkins, Philadelphia, 2003: pp. 79–84.

Average:

Average:
☆☆☆☆☆
No votes yet

Login or register to post comments Email this page

Press Release

Miami Poised to Challenge America's Number One Killer

LUMEN 2009 hosts top docs in cardiac medicine focused on increasing survival rates of heart attack victims

Miami, FL (January 28, 2009) – On February 26th through the 28th, at the Loews Miami Beach Hotel in Miami Beach, FL, many of the nation's most respected and innovative practitioners of cardiac medicine will come together at *LUMEN 2009: The Symposium on Optimal Treatments for Acute MI*, for the purpose of affecting America's number one killer – heart disease. Present will be the President of the American College of Cardiology, Dr. W. Douglas Weaver, who has been an outspoken advocate for healthcare reform in the U.S.

READ MORE

Protection
Complimentary CME Accredited Webcast
Dates: November 18, 2008 Time: 6:00 pm ET November 19, 2008 Time: 3:00 pm ET
This activity is sponsored by the **North American Center for Continuing Medical Education.**

LUMEN 2009 - THE SYMPOSIUM ON OPTIMAL TREATMENTS FOR ACUTE MI
Live Symposium
Date: February 26-28
Location: Loews Miami Beach Hotel Miami Beach, Florida 33139
This activity is sponsored by the **North American Center for Continuing Medical Education.**

Method and device for left atrial appendage occlusion

Valved self-perfusing catheter guide
According to the present invention, apparatus and methods are provided for directionally inserting ...

Method and apparatus for providing external perfusion lumens on balloon catheters
According to the present invention, methods and apparatus are provided for establishing perfusion ...

Intravascular catheter with infusion array
The present invention provides an intravascular **catheter** for administering a therapeutic agent to a ...

High pressure perfusion device
The structure and function of the preferred embodiments can best be understood by reference to the ...

Drain cannula
When appropriately indicated, modern medical treatment frequently includes the procedure of

Details

Inventors: Lesh, Michael D.; van der Burg, Erik J.;
Assignee: Appriva Medical, Inc. (Sunnyvale, CA)
Primary Examiner: Dawson; Glenn K.
Assistant Examiner:
Attorney, Agent or Firm: Knobbe, Martens, Olson & Bear, LLP

A device and method for obliterating or occluding a body cavity or passageway, in particular, the left **atrial** appendage of a patient's heart. The procedure can be carried out intraoperatively, but is preferably carried out percutaneously by use of a delivery **catheter** to position an occluding device adjacent a patient's left **atrial** appendage. The occluding device may prevent the passage of embolic or other material to or from the left **atrial** appendage by volumetrically filling the appendage, closing the opening of the appendage with an occluding member, or pulling the tissue around the opening of the appendage together and fixing it in a closed state.

DETAILED DESCRIPTION FIGS.

1-3 show an embodiment of an occluding device 10 having features of the invention where an occluding member 11 is secured to a retention member 12 that is arranged to fix the occluding member in a desired position within a body passageway or cavity.

The occluding member 11 generally has disc shape with an outer rim 13 around the perimeter of a frame structure 14 which supports a barrier 15.

The outer rim 13 can be circular or polygonal, or any other shape that is suitable for conforming to the inside surface of a body cavity.

A hub 16 can be located near the center of the occluding member 11 which serves to connect the retention member 12 to the occluding member, in addition to other functions.

The outer rim 13 is typically made from a soft polymer material 17 which permits flexibility of the outer rim and facilitates sealing of the outer rim against the inside surface of a body cavity or passageway.

The barrier 15 can be a thin mesh or film of material which serves to block the passage of material within an area surrounded by the outer rim 13.

The barrier 15 can be secured to the outer rim 13 along its entire perimeter 18 in order to achieve a complete seal therebetween and can be molded into the outer rim 13 or bonded thereto by a suitable method such as gluing, welding, sewing or other suitable method.

The outer rim 13 is at least partially supported by the frame structure 14 which connects the outer rim and the hub.

The frame structure 14 can be made from one or more elements of high strength material such as stainless steel or MP35N, or may preferably be made from shape memory or pseudoelastic alloys such as NiTi.

Preferably, the frame structure 14 is made from a material which can be self expanding from a

includes the procedure of moving ...

constrained configuration so that the occluding device 10 can be delivered to the deployment site in a low profile an flexible configuration which facilitates percutaneous delivery.
Preferably a radial hoop 21 is contained within the soft polymer material 17 of the outer rim 13 and serves to maintain the annular shape of the outer rim and facilitate radial expansion of the outer rim from a constrained position or configuration

System and method for endoluminal grafting of bifurcated or branched vessels
The present invention provides a system and method for edoluminal grafting of a blood vessel or ...

Delivery of a composition to the lung
In general, the invention features a method and apparatus for facilitating delivery of a ...

Method and apparatus for treatment of congestive heart failure by improving perfusion of the kidney by infusion of a vasodilator
OF A PREFERRED EMBODIMENT OF THE INVENTION FIG. 1 shows one embodiment of the proposed therapy ...

Linkage steering mechanism for deflectable catheters
What is claimed is: 1. A rotationally-actuated mechanism for deflectable catheters, comprising: a ...

Epoxide resin-modified polyester coat with alkyd topcoat
We claim: 1. A coating composition applied to a substrate comprising an alkyd resin based topcoat ...

Related patents

Method and apparatus for patching a tissue opening
The present invention provides a **closure catheter** and methods for closing an opening in tissue, a body lumen, hollow organ or other body cavity. The **catheter** and methods ...

Filter apparatus for ostium of left **atrial** appendage
The invention provides a filtering membrane that allows blood to pass therethrough while substantially preventing blood clots formed in the **atrial** appendages from ...

Patches and collars for medical applications and methods of use
Referring to FIGS. 1-3, a vascular **closure** system 100 generally includes two components: a arterial **closure** device ("ACD") 105 and a deployment instrument 110. The ACD 1...

Device for containing embolic material in the LAA having a plurality of tissue retention structures
There is provided in accordance with one aspect of the present invention, a method of occluding an **atrial** appendage. The method comprises the steps of inhibiting changes ...

Control of tissue growth in textured blood-contacting surfaces
What is claimed is: 1. A blood pump comprising: a blood flow channel having a textured surface and a smooth surface adjacent to the textured surface; and a rotor ...

Pulp washing shower
The present invention provides a shower pipe with a single, substantially straight line of racetrack-shaped slots and a set of distributors, all of a single type. ...

Narrow profile transformer having interleaved windings and cooling passage
The present invention is defined by the appended claims with specific embodiments being shown in the attached drawings. For the purpose of summarizing the invention, the ...

Brachytherapy seed deployment system
A preferred embodiment of the present brachytherapy seed deployment system comprises at least two seeds and a filament joining the at least two seeds. The seeds may be ...

Apparatus and method for multiple organ procurement
The present invention includes a method and device for the removal of visceral organs from an animal for purposes of transplantation, such organs having branch ...

Bidirectional check valve **catheter**
The present invention provides an improved bidirectional check valve **catheter** which is easy to manufacture, installs easily and permits long term placement in the ...

An official publication of
WORLD HEART FEDERATION

CASE STUDY

CME *Nature Clinical Practice Cardiovascular Medicine* (2006) **3**, 456-459
doi:10.1038/ncpcardio0610
Received 28 December 2005 | Accepted 5 May 2006

Percutaneous left atrial appendage closure in a patient with atrial fibrillation

Peter C Block About the author

Correspondence Emory University Hospital, 1364 Clifton Road F606, Atlanta, GA 30322, USA

Email peter_block@emoryhealthcare.org

SUMMARY

Background A 73-year-old woman presented with a history of persistent atrial fibrillation, which had lasted more than five years. She also had a remote history of transient ischemic attack and had received warfarin therapy. The international normalized ratio had been carefully maintained at slightly subtherapeutic levels because of recurrent gastrointestinal bleeding, which was severe enough to require frequent blood transfusions. With colonoscopy, the source of bleeding was localized to multiple arterial-venous malformations. The patient underwent catheter ablation of the atrioventricular junction and received a single chamber pacemaker. Two years later, she received a dual chamber pacemaker followed by cardioversion to restore a sinus rhythm. Following brief cardioversion, her symptoms of atrial fibrillation returned after two days.

Investigations Transesophageal echocardiography, pacemaker interrogation.

Diagnosis Persistent atrial fibrillation, gastrointestinal bleeding requiring transfusion.

Management Percutaneous left atrial appendage occlusion, antiplatelet therapy.

Keywords: atrial fibrillation, left atrial appendage occlusion, warfarin

THE CASE

Top

A 73-year-old woman presented with persistent atrial fibrillation (AF), which had lasted more than 5 years. In an effort to control the ventricular response to AF, she had previously undergone catheter ablation of the atrioventricular junction and received a single chamber pacemaker. Anticoagulation therapy with warfarin was initiated at this time, but unfortunately the patient developed recurrent gastrointestinal bleeding complications requiring multiple blood transfusions. By using colonoscopy, the source of the bleeding was eventually localized to multiple arterial-venous malformations. To minimize gastrointestinal blood loss, warfarin anticoagulation was carefully controlled at slightly subtherapeutic levels of the international normalized ratio. Six months before admission to hospital, the patient had received a dual chamber pacemaker and dofetilide therapy for cardioversion. Although her sinus rhythm briefly returned to normal, the AF had returned. Cardioversion was attempted again using dofetilide and although the patient had a normal sinus rhythm for 2 days, she had persistent AF for the subsequent 4 months.

The patient had NYHA Class II symptoms of heart failure, mainly due to fatigue caused by AF and anemia. Her medical history was notable for a transient ischemic attack 10 years previously—possibly due to a thromboembolic event—that manifested as weakness and clumsiness in the right hand. No abnormalities were found on physical examination except for a grade 2/6 systolic murmur radiating from the apex to the axilla. Echocardiography confirmed that this murmur was caused by mild mitral regurgitation. No signs of atherosclerotic disease were found using carotid ultrasonography. Transesophageal echocardiography was performed to exclude other possible sources of thromboemboli. There was no evidence of patent foramen ovale, the left ventricle was normal in size and function, the transverse and descending aorta were free of significant atherosclerotic disease and no thrombus was detected in the left atrial appendage (LAA; Figure 1A). Furthermore, no spontaneous echo contrast was observed in the left atrium.

Figure 1 Transesophageal echocardiography of the left atrial appendage.

(A) A transesophageal echocardiogram of the left atrial appendage before placement of the PLAATO device **(B)** A transesophageal echocardiogram of the left atrial appendage after percutaneous occlusion.

An arrow shows deployment of a PLAATO device in the left atrial appendage. Abbreviations: LA, left atrial body; LAA, left atrial appendage.

Full figure and legend (9K)
Figures & Tables index
Download PowerPoint slide (216K)

The patient was considered a poor candidate for long-term anticoagulation therapy with warfarin, because of recurrent gastrointestinal bleeding. Pulmonary vein ablation was considered, but this strategy was not advised because aggressive anticoagulation therapy is necessary after the procedure. Instead the patient was referred for percutaneous LAA occlusion as a participant in the Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO) trial. After informed consent, she was taken to the cardiac catheterization laboratory and sedated with fentanyl and midazolam. Baseline transesophageal echocardiography was repeated to rule out intercurrent development of LAA thrombus and was also used to monitor placement of an LAA occlusion device.

By using echocardiography, the neck of the LAA was estimated to have a diameter of 25 mm. The right femoral vein was cannulated using the Seldinger technique and a trans-septal puncture was performed with a Mullins sheath and Brockenbrough needle. Following intravenous administration of weight-based heparin, a Cook wire guide was advanced into the left atrium through the sheath; the Mullins sheath was then replaced with a preformed delivery sheath that accompanied the PLAATO device. A 32 mm occlusion device (ev3 Inc., Plymouth, MN, USA) was advanced through the delivery catheter and deployed under echocardiographic and fluoroscopic guidance (Figure 1B, Figure 2). Doppler echocardiography and contrast injections through the delivery catheter confirmed that the device was positioned so that the neck of the LAA was completely occluded, and the PLAATO device was then released. A final angiogram of the left atrium showed that the LAA had not filled with contrast agent (Figure 3). A 300 mg loading dose of clopidogrel and 325 mg of aspirin were administered. The patient tolerated the procedure well and was released from hospital the following day. Clopidogrel and aspirin therapy was continued for 6 months, and changed to aspirin only thereafter. Endocarditic prophylaxis was prescribed indefinitely, as judged by the treating physician.

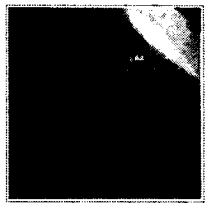
Figure 2 A cineangiographic frame of the PLAATO occlusion device.

An arrow shows the PLAATO device immediately after deployment and before its release from the delivery catheter. Abbreviation: DC, delivery catheter.

Full figure and legend (6K)
Figures & Tables index
Download PowerPoint slide (212K)

Download PowerPoint slide (212K)

Figure 3 A cineangiographic frame of the final left atrial angiogram.



No contrast agent leak can be seen around the device or in the left atrial appendage. An arrow indicates the PLAATO device after release. Abbreviation: LAA, left atrial appendage.

Full figure and legend (6K)

Figures & Tables index

Download PowerPoint slide (212K)

Clopidogrel therapy was stopped 1 month after the patient had undergone the PLAATO procedure, because of recurrent gastrointestinal bleeding. She continued to take 180 mg aspirin daily, but clopidogrel therapy was resumed 8 months later after an episode of blurred vision. A head CT scan carried out as part of the diagnostic work-up did not reveal any acute changes. Only small areas of encephalomalacia were noted, which were probably related to remote ischemia. Chest X-ray showed the device in the left atrial appendage. Carotid ultrasonography revealed only minimal atherosclerotic changes, without evidence of significant stenosis. One year later, the patient underwent endoscopic cauterization of colonic arterial-venous malformations, which successfully controlled the gastrointestinal bleeding. With iron supplementation alone, she now maintains a hematocrit of 35%. Two years after percutaneous LAA closure, the patient continues to do well clinically.

DISCUSSION OF DIAGNOSIS

Top

Patients with AF have a five-fold increased risk of stroke compared with patients in normal rhythm.[1] When atrial thrombus is seen by transesophageal echocardiography in patients with non-rheumatic AF, 90% of the time it resides in the LAA. Anticoagulation with warfarin is an effective management strategy for patients with paroxysmal or fixed AF. This treatment reduces the risk of stroke by almost 70% and is more effective than aspirin or aspirin plus low-dose warfarin therapy.[2, 3, 4] Patients with the highest risk of stroke gain the most benefit from anticoagulation therapy, yet these same patients are more likely to have contraindications, or might not receive such therapy.[3, 4, 5] Of particular concern are patients with AF who have bleeding episodes while taking anticoagulant therapy, those with a high risk of injury that might be complicated by bleeding, (e.g. after a fall) and patients who are difficult to monitor adequately.

TREATMENT AND MANAGEMENT

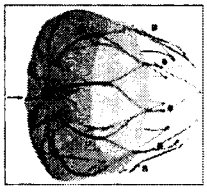
Top

Closure of the LAA seems to be a reasonable prophylactic treatment to help prevent thromboembolism. Although surgical closure of the LAA can be performed, it is invasive and associated with poor patient outcomes.[6, 7, 8] Transvenous closure of the LAA is a new approach, and recent trials have tested its safety and efficacy.[9, 10] A recent study by Ostermeyer *et al.* comprised two registries of 111 patients (aged 71 ± 9 years).[11] Patients recruited to the trial had contraindications for anticoagulation with warfarin and one or more of these additional risk factors for stroke: presence of congestive heart failure; a left ventricular ejection fraction less than 40%; systolic hypertension greater than 160 mmHg; diabetes; age >65 years; previous myocardial infarction or known coronary stenosis of more than 50%; spontaneous echo density in the LAA or a blood flow velocity in the LAA of less than 20 cm/sec. Their data show that this investigational strategy is promising; one neurological death was reported within 30 days of the PLAATO procedure and three patients required in-hospital pericardiocentesis for hemopericardium during or following the procedure. After a follow-up of almost 10 months, only 2 out of 111 patients had experienced a stroke (2%). This was equivalent to a 60% reduction in stroke rate, as the anticipated incidence of stroke had been 6.3%, based on the patients' CHADS2 (i.e. congestive heart failure; hypertension; age >75 years; diabetes; stroke or transient ischemic attack) risk stratification scores.[12] Transesophageal echocardiography at follow-up showed that the device had not migrated and no mobile thrombi were seen in any patients. Five patients had major adverse events (new major or minor stroke, cardiac or neurological death, myocardial infarction or requirement for cardiovascular surgery) related to the PLAATO procedure. Although the risk of stroke was not abolished by LAA occlusion in this study, it does seem to have been reduced. A non-cardiac thromboembolism, a thrombus in the left atrial body, or other causes could account for continued stroke occurrence.

Only a randomized trial, however, can establish the actual reduction in stroke rate following LAA occlusion. A new trial called the WATCHMAN Left Atrial Appendage System for Embolic PROTECTion in Patients with AF (PROTECT AF) trial is underway to evaluate the stroke rate following LAA occlusion using the Watchman® device (Atritech Inc. Plymouth, MN; Figure 4). The Watchman® device is not immediately occlusive, but acts as a filter until endocardialization of its atrial surface occurs. Patients who enter the trial must be able to take warfarin for at least 45 days and aspirin thereafter. One in three patients receives warfarin therapy alone, while the remaining patients receive a Watchman® device. This trial should give further insight into the efficacy of this strategy. If it yields positive results in terms of patient outcome, LAA percutaneous occlusion could be an attractive management option for many patients with AF. Such patients might not be ideal candidates for

with AF. Such patients might not be ideal candidates for warfarin therapy or choose to take warfarin for only a short period of time after percutaneous LAA occlusion, before switching to aspirin therapy alone.

Figure 4 The Watchman® occlusion device.



Barbs on the outer edge of the wires help to fix this device to the musculature of the left atrial appendage. An arrow shows which side faces the left atrium when the device is deployed. Abbreviation: B, barbs.

Full figure and legend (17K)
Figures & Tables index
Download PowerPoint slide (222K)

CONCLUSION

Top

AF is associated with a significantly increased risk of stroke and necessitates treatment with warfarin anticoagulation. Few alternative options exist, however, for patients who cannot tolerate this treatment or who develop bleeding complications, as in the present case. Surgical left atrial ablation is one alternative and another option is antiplatelet therapy with aspirin, clopidogrel or a combination of these. Early results of a Phase I trial of percutaneous LAA occlusion are promising, and an ongoing prospective randomized trial will help to determine its usefulness as an alternative therapeutic strategy.

Top

REFERENCES

1. Wolf PA *et al.* (1991) Atrial fibrillation as an independent risk factor for stroke: The Framingham Study. *Stroke* **22**: 983–988 | PubMed | ISI | ChemPort |
2. Atrial Fibrillation Investigators (1994) Risk factors for stroke and efficacy of antithrombotic therapy in atrial fibrillation. Analysis of pooled data from five randomized controlled trials. *Arch Intern Med* **154**: 1449–1457 | PubMed | ISI |
3. van Walraven C *et al.* (2002) Oral anticoagulants vs aspirin in nonvalvular atrial fibrillation: an individual patient meta-analysis. *JAMA* **288**: 2441–2448 | Article | PubMed | ChemPort |
4. Hart RG *et al.* (2003) Lessons from the stroke prevention in atrial fibrillation trials. *Ann Intern Med* **138**: 831–838 | PubMed |
5. Bungard TJ *et al.* (2000) Why do patients with atrial fibrillation not receive warfarin? *Arch Intern Med* **160**: 41–46 | Article | PubMed | ISI | ChemPort |
6. Blackshear JL and Odell JA (1996) Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg* **61**: 755–759 | Article | PubMed | ISI | ChemPort |
7. Madden J (1948) Resection of the left auricular appendix. *JAMA* **140**: 769–772
8. Johnson WD *et al.* (2000) The left atrial appendage: our most

8. Johnson WD *et al.* (2000) The left atrial appendage: our most lethal human attachment! Surgical implications. *Eur J Cardiothorac Surg* **17**: 718–722 | Article | PubMed | ChemPort |
9. Sievert H *et al.* (2002) Percutaneous left atrial appendage transcatheter occlusion to prevent stroke in high-risk patients with atrial fibrillation—early clinical experience. *Circulation* **105**: 1887–1889 | Article | PubMed | ISI |
10. Hanna IR *et al.* (2004) Left atrial structure and function after percutaneous left atrial appendage transcatheter occlusion (PLAATO): six-month echocardiographic follow-up. *J Am Coll Cardiol* **43**: 1868–1872 | Article | PubMed | ISI |
11. Ostermayer SH *et al.* (2005) Percutaneous left atrial appendage transcatheter occlusion (PLAATO System) to prevent stroke in high-risk patients with non-rheumatic atrial fibrillation. *J Am Coll Cardiol* **46**: 9–14 | Article | PubMed | ISI |
12. Gage BF *et al.* (2004) Selecting patients with atrial fibrillation for anticoagulation: stroke risk stratification in patients taking aspirin. *Circulation* **110**: 2287–2292 | Article | PubMed | ISI | ChemPort |

▲Top

Competing interests

The author declared no competing interests.

▲Top

▸ Contact the journal about this article

Nature Clinical Practice Cardiovascular Medicine ISSN 1743-4297 EISSN 1743-4300

Arquivos Brasileiros de Cardiologia
Print ISSN 0066-782X

Arq. Bras. Cardiol. vol.72 n.1 São Paulo Jan. 1999

doi: 10.1590/S0066-782X1999000100005

Original Article

Percutaneous Closure of Atrial Septal Defects. The Role of Transesophageal Echocardiography

Simone R. F. Fontes Pedra, Carlos Augusto Cardoso Pedra, Jorge Eduardo Assef, Renata de Sá Cassar, César Augusto Esteves, Sérgio N. Braga, Sérgio Pontes Jr, Valmir Fernandes Fontes

São Paulo, SP - Brazil

PURPOSE *– Evaluation of the role of transesophageal echocardiography in percutaneous* ***closure*** *of* ***atrial*** *septal defects (ASD) with the Amplatzer septal occluder.*

METHODS *– Patients were selected for percutaneous* ***closure*** *of ASD by transesophageal echocardiography (TEE), which was also used to monitor the procedure, helping to select the appropriate size of the Amplatzer device, to verify its*

procedure, helping to select the appropriate size of the Amplatzer device, to verify its position, and to access the immediate results of the procedure. During the follow-up, TEE was used to evaluate the presence and magnitude of residual shunt (RS), device position, and right cardiac chamber diameters.

***RESULTS** – Twenty-two (40%) of a total of 55 studied patients were selected. Thirteen underwent Amplatzer device implantation, eight are still waiting for it, and one preferred the conventional surgical treatment. All procedures were successful, which was mainly due to proper patient selection. Six (23%) patients acutely developed RS, which spontaneously disapeared at the three-month follow-up examination in three patients. There was a significant reduction in the right ventricle diastolic diameter, from 27mm (average) to 24mm and 20mm, one and three months after the procedure, respectively ($p<0.0076$).*

***CONCLUSION** – With the aid of TEE, percutaneous **closure** of ASD can be successfully, safely, and effectively performed.*

Key words: atrial septal defects, interventional cardiology, echocardiography

In recent years, several congenital cardiac defects have been successfully treated with therapeutic catheterization [1-10]. In 1974, King and Mills [11] made the first attempts at percutaneous **closure** of **atrial** septal defects (ASD). Since then, several prostheses have been examined for possible use in this procedure. Currently, five are under investigation with varying results [12-19]. Our experience was developed with the Amplatzer septal occluder [20], which was experimentally introduced in September 1995 [21].

The success of percutaneous **closure** of ASD is directly related to the proper selection of the patients for implantation. Defects of the *ostium secundum* type, located in the central portion of the **atrial** septum, with thick borders and dimensions large enough to sustain the device, are ideal for percutaneous **closure**. The detailed study of the defect with measurement of its dimensions, in at least two planes, can be performed in a precise way through transesophageal echocardiography (TEE). In addition to patient selection, echocardiography has been used in the hemodynamic room for the continuous monitoring of the procedure, providing additional safety and significantly reducing radiation-exposure. Using TEE clinicians not only can verify the position of the Amplatzer septal occluder in relation to the ASD but can also evaluate residual shunt (RS) immediately after can implantation and during the late follow-up. TEE is therefore important in conjunction with this procedure.

In this study our initial experience with percutaneous **closure** of ASD by means of the Amplatzer septal occluder is presented, stressing the role of TEE.

Methods

Since August 1997, patients with clinical signs of ASD, diagnosed with transthoracic echocardiography (TTE) as the *ostium secundum* type, underwent TEE to evaluate the possibility of using percutaneous treatment. Ages of patients ranged from three years and two months to 65 years. TEE was performed after consent of the patient or the patient's guardian. Because only adult esophageal probes were available, for the

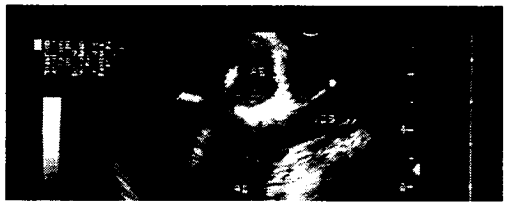
examination to be safely performed it was required that the patient's minimum weight was 16kg. Patients under 15 years of age underwent TEE with general anesthesia; therefore, an anesthesiologist and a nurse were required to be present in the echocardiography laboratory. Under continuous electrocardiographic monitoring and pulse oximetry, patients were anesthetized with propofol and halothane after receiving midazolam as a pre-anesthetic. Then, the esophagus was easily lubricated with lidocaine gel and a probe was inserted. At the end of the procedure, the anesthetic effect of midazolam was reversed with flumazenil. Some adults also needed sedation with propofol because they could not tolerate the examination with local anesthesia alone. Ultramark 9 equipment (Advanced Technologies Laboratories Inc., Bothell, Washington, US) was used with an adult biplanar esophageal probe (11mm) and color pulsed Doppler. The defect site, position, and number were analyzed, as were the connections of pulmonary veins and cardiac chamber sizes. Hemodynamic impact of the lesion and shunt direction were also noted. Other defects and signs of pulmonary hypertension were also described. The selected patients had defects with borders that had a minimum diameter of 4 to 5mm that allowed the satisfactory placement of the occluder's discs in the **atrial** septum without invading or harming the adjacent cardiac structures. These borders were classified according to their positions as: if in the transversal plane, the one close to the tricuspid valve is the anteroinferior, and the one close to aorta is the anterosuperior; if in the longitudinal plane, the one related to the superior vena cava is the posterosuperior, and the one related to the inferior vena cava is the posteroinferior.

Right ventricle (RV) size prior to implantation was also objectively analyzed, through the measurement of its final diastolic diameter in the M mode and this was compared to other measurements during follow-up.

The criteria required for implantation were: 1) *ostium secundum* type of ASD; 2) maximum defect diameter = 21mm; 3) RV dilatation due to volumetric overload; 4) left-right shunt; 5) minimum distance of 4 to 5mm between the defect borders and the coronary sinus, the atrioventricular valves, the right superior pulmonary vein, and the superior and inferior vena cava.

For the selected patients, the percutaneous treatment was offered and performed after they or their guardians had read all the information about the procedure and had signed the consent form.

In the catheterization laboratory, the use of TEE was characterized by: Demonstration of the defect to the interventional team; monitoring and measuring the stretched diameter, monitoring the opening and placement of the discs and waist of the device in the **atrial** septum; checking the position of the implanted prosthesis prior to the withdrawal of the delivery **catheter**; and finally, evaluation of RS (location and classification), whenever present.



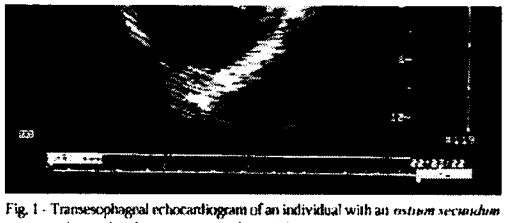


Fig. 1 - Transesophageal echocardiogram of an individual with an *ostium secundum* type atrial septal defect, presenting favorable characteristics to percutaneous closure with the Amplatzer prosthesis (longitudinal plane).

The stretched diameter was measured with a balloon **catheter** inflated inside the left atrium and moved towards the **atrial** septum. After color Doppler showed total **occlusion** of the defect, the balloon was slowly deflated. At the exact moment it passed through the **atrial** septum plane, its diameter was obtained by echocardiography. This diameter was compared to that obtained with balloon inflation outside the body, with the same amount of contrast medium used at the moment of passage to the right atrium and estimated using a grid.

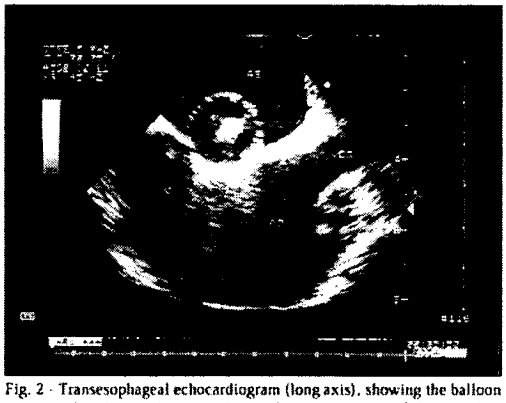


Fig. 2 - Transesophageal echocardiogram (long axis), showing the balloon positioned in the atrial septum during the measurement of the stretched diameter.

RS was characterized by a left-right flow between the defect's borders and the prosthesis, and classified according to the proposal of Boutin and co-workers [22]: trivial <1mm; mild = 1 <2mm; moderate = 2 <4mm; and severe = 4mm.

After implantation, the patients stayed in the Intensive Care Unit for observation until the following morning, being discharged after chest radiography, electrocardiography (ECG), and TEE were performed. Salicylic acid was prescribed at a dose of 5 to 10mg/kg/day for six months, and prophylaxis for infectious endocarditis was indicated for six months or in the presence of RS for life. The proposed protocol for late follow-up consisted of clinical evaluation, chest radiography, ECG, and echocardiography

consisted of clinical evaluation, chest radiography, ECG, and echocardiography scheduled for one month, three months (also included a new TEE), and 12 months after implantation.

The non-parametrical test of Friedman was used to compare the average of the final RV diastolic diameters before, one day after, one month after, and three months after implantation. The correlation between the diameter of the ASD and the stretched diameter was evaluated by linear regression.

Results

Twenty-two of 55 patients studied with TEE were selected for implantation according to the criteria of inclusion. The reasons for excluding the others were: absence of **atrial** shunt, defects with no hemodynamic impact, defects of the sinus venosus type, with or without partial anomalous pulmonary drainage, multiple defects or defects with dimensions above 21mm, eccentric ASD, or ASD with very thin borders.

There were no complications during selection, and tracheal intubation was not necessary. The patients were discharged on the same day after a short period of post-anesthetic observation.

Thirteen of the 22 selected patients were referred to the catheterization laboratory. One preferred the conventional surgical treatment but eight are still waiting for the procedure. The clinical feature as well as the anatomical and hemodynamic findings of the thirteen patients are listed in table I. Implantation was successfully performed in all patients.

Table I - Clinical, anatomical and hemodynamic characteristics of patients who underwent percutaneous closure of atrial septal defects

Number	Age (years)	Weight (kg)	ASDD (mm)	QP/QS	Str. D (mm)	Prost. N	Obs.
1	5	24	13.5	3.4	17	19	-
2	13	58	9.4	1.6	14	16	
3	10	27	8.7	1.5	12.3	13	
4	7	20	10.3	2.4	12.4	13	
5	50	69	20	2.6	23	24	
6	9	21	13 and 5	5.7	21 and 9	22 and 8	PCA
7	12	27	16	1.6	27	24	
8	11	31	14.8	2.8	21	22	
9	29	58	21	2.1	26	26	
10	6	22	16.3	2.3	20	20	
11	21	68	21	2.4	25.3	26	
12	7	21.5	15.5	2.1	18.7	19	
13	3	20	13.5	1.6	20.6	20	

Where: ASDD - atrial septal defect diameter; Str.D - stretched diameter; Prost.N - prosthesis number; PDA - persistence of ductus arteriosus; Obs. - Observation.

The stretched diameter calculated by TEE was 15% to 68% (average of 34%) larger than the largest diameter of the ASD determined prior to implantation, also by TEE (Table I). There was a strong linear correlation between them ($r=0.8646$ – $p<0.0001$). The choice of prosthesis was based on the diameter of its central point (waist), which was equal to or 1mm larger than the stretched diameter obtained.

Patient number 2 presented a very thin posteroinferior border, which impaired its visualization between the two discs of the prosthesis, making it difficult to determine if the occluder's position was correct. Patient number 7 also had very thin borders, with a stretched diameter almost twice the real diameter of the ASD. In this case, the size 24 prosthesis was arbitrarily chosen after confirming that the total extension of the septum would bear the device. This prosthesis fit the septum perfectly and, by the following day the defect was totally occluded. Patient number 6 had two ASD with a border of 8mm between the orifices and a short ductus arteriosus. In this case, two prostheses were used. They were arranged like a sandwich (the superior embracing the inferior) in the **atrial** septum and a Gianturco coil was implanted through the aorta for the [redacted] of the ductus arteriosus [23]. During the first prosthesis implantation, the patient experienced a supraventricular tachycardia, immediately reversed with adenosine. At the end of the procedure, the ductus arteriosus was totally occluded and the two prostheses seemed well positioned with no RS. The other procedures were uneventfully performed.

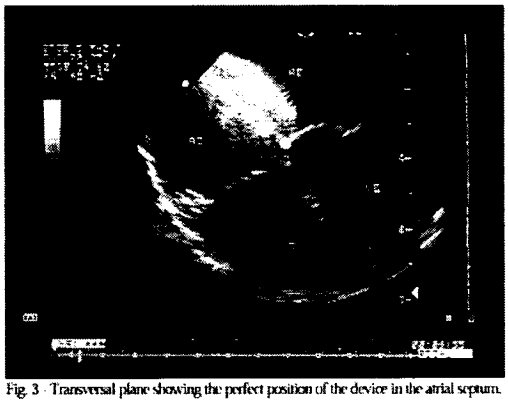
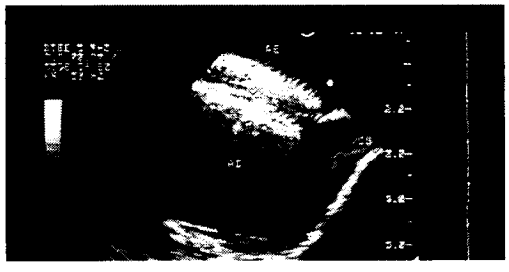


Fig. 3 - Transversal plane showing the perfect position of the device in the atrial septum.



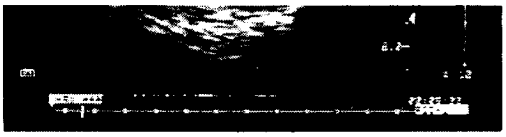


Fig. 4 - Longitudinal axis showing the prosthesis adequately positioned in the atrial septum.

Immediately after the implantation, five patients experienced mild RS. In one of them, RS was only observed by TEE on the following day, probably due to the different incidence of the ultrasound beam of the transthoracic via in relation to the transesophageal one. Similarly, a patient had acute RS that seemed to close on the following day, but the TEE performed three months later again revealed a shunt. In the patient receiving two prostheses, TEE also showed a mild RS (1.9mm) three months after implantation. In this case, the left-right flow was at a high speed, and was not noticed immediately after the procedure. Due to these variations, the prevalence of RS was calculated at the third month after implantation. It was 23% (3 patients out of 13). There were three spontaneous closures, one occurring 24 hours after the procedure, and the other two by the third month follow-up. In regard to the evaluation of RV dimensions, there was a reduction of some millimeters in the final diastolic diameter in all cases. The statistical analysis showed a very significant difference ($p<0.0076$) between the averages of the diameters before the implantation, after one and three months. It is necessary, however, to evaluate this result critically, due to the presence of three adults in the sample, which makes the group very heterogeneous.

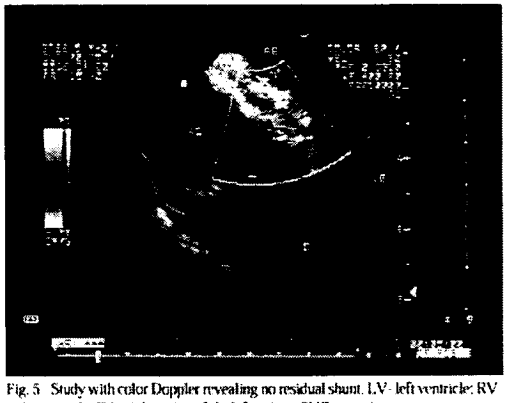


Fig. 5 - Study with color Doppler revealing no residual shunt. LV - left ventricle; RV - right ventricle; RA - right atrium; LA - left atrium; SVC - superior vena cava.

In our experience, there was neither embolization of the prostheses nor thromboembolic phenomena.

Discussion

The treatment of ASD by means of therapeutic catheterization can be considered very attractive. The possibility of therapy with no surgical scar, no pain - common in the postoperative period - no transfusion, short hospital stay, and significant reduction in the costs are unequivocal advantages. The devices available for percutaneous **closure** of ASD have become more technologically refined with time. They are safer, more efficient, have less risk of embolization and of pole fracture, and present a lower incidence of RS. It has also been possible to reduce the profile of the sheaths necessary to deliver the prosthesis (6 Fr for the smallest Amplatzer prostheses), increasing the therapeutic possibility for symptomatic infants.

The Amplatzer occluder's basic principle of approaching the ASD is the insertion of its central point in the defect, providing stability to the device and eliminating the need for metal arms or frameworks. This waist centralizes the prosthesis automatically in relation to the septum, independent of the implantation angle, facilitating its positioning. As the discs do not need large dimensions for the device's stabilization, their implantation can be potentially extended to defects not having extensive borders that would keep them apart from other intracardiac structures. These discs as well as the whole metallic structure of nitinol are extremely flexible and do not contain any sharp elements or hooks, which minimizes the risk of perforation during and after the procedure.

As previously reported, the success of implantation is directly related to the proper selection of patients, which was very well demonstrated in our series – all patients referred to percutaneous **closure** of ASD had a successful outcome. TEE allows perfect visualization posterior structures of the heart , particularly the detailed study of the **atrial** septum and its defects [22]. For this reason, a transthoracic evaluation suggesting ASD susceptible to percutaneous treatment should be complemented with a TEE. The fact that only 40% of the 55 patients studied by TEE presented favorable characteristics for this treatment stresses even more the need for selection of patients using this technique. Despite the necessity of general anesthesia for pediatric patients, the procedure can be safely performed on an outpatient basis, as long as equipment for cardiorespiratory monitoring and appropriate anesthetic drugs are readily available. In our experience, patient selection was uneventful.

The possibility of monitoring the implantation with TEE makes the procedure easier because ASD cannot be as well analyzed by angiography. Besides, the technique allows patient and staff to be spared from exposure to radiation [24]. Fifteen minutes of fluoroscopy are necessary for the implantation. With TEE, the use of contrast medium is limited to the initial diagnostic angiography. The Amplatzer septal occluder causes no reverberation of the ultrasound beam; therefore it can be very well evaluated by echocardiography. The verification of the borders between the two discs of the device in the longitudinal and transversal planes provides accurate confirmation that the device is properly positioned. This is a key role of TEE because the prosthesis can only be released when its appropriate position is confirmed.

RS is best evaluated by color Doppler. Angiography immediately after the implantation can reveal a left-right shunt through the prosthesis mesh, since the epithelization process has not yet begun. Through the use of TEE it is possible to evaluate the real presence of RS and to determine the shunt's magnitude by measuring its width [22]. RS rates vary according to the different techniques and prostheses used for evaluation. In a multicenter study of the Sideris prosthesis, RS prevalence in one month was 80.5%,

dropping to 45% in six months, and to 19% in one year [13]. In another study carried out in Toronto with the Clamshell prosthesis (Bard USCI Division, C.R. Bard, Billerica, MA, USA), an incidence of acute RS of 91% was reported, with regression to 71% 24 hours later. In an average follow-up of 10 months, the rate dropped to 47% [22]. In the initial global experience with 230 cases of Amplatzer prosthesis implantation, the occlusion rate was higher than 95% after the first month of follow-up [21]. In our initial experience, there were three patients out of 13 (23%) with mild RS three months after implantation confirmed by TEE. Maybe our results, in regard to RS, are not so good due to the fact that ours is a small series, and also to the unusual case where two prostheses were simultaneously implanted in the same patient. Sometimes, RS could not be seen by TTE, which is not surprising considering the greater sensitivity of TEE for the visualization of the **atrial** septum. However, it surprised us to observe RS by TTE, on the following morning, because it had not been visualized by TEE immediately after the implantation in the catheterization laboratory. Maybe the difference in the direction of the ultrasound beam in the two procedures could explain this phenomenon, allowing us to suggest that, after the end of the implantation, RS investigation should also be carried out using TTE.

Trivial and discrete RSs do not cause any volume overload to the right chambers and, many times, do not have murmurs. The disappearance of the fixed splitting of the second cardiac sound can also be observed. Therefore, the ASD can be considered treated from the clinical-functional point of view, even in the presence of these small shunts. It is worth stressing that the real incidence of RS in the postoperative period of ASD correction is not completely known, because there are no consistent studies in this area. The major problem of RS rests in the unknown incidence of infectious endocarditis, especially after the introduction of a foreign body into the septum. This is the reason why prophylaxis is recommended. In our protocol, those patients with a persistent RS after the third month follow-up should have TEE repeated one year after the implantation to determine the necessity of continued prophylaxis.

In conclusion, percutaneous **closure** of ASD today is a reality. The Amplatzer septal occluder has produced very favorable results with low risks. TEE is fundamental in the selection of candidates for implantation, procedure monitoring, and follow-up of these patients.

Acknowledgments

We wish to express our gratitude to Mrs. Angela Paes for her help with the statistical analysis, and to the staff of the echocardiography and catheterization laboratories of Instituto Dante Pazzanese de Cardiologia, for the collaboration .

References

1. Kan JS, White RI, Mitchell SE, Anderson JH, Gardner TJ – Percutaneous transluminal balloon valvuloplasty for pulmonary valve stenosis. Circulation 1984; 69: 554-60.
[Links]

2. Mrantz PM, Huhta JC, Mullins CE, Murphy DJ, Nihill MR, Ludomirsky A – Results of

2. Mirantz PH, Hunter JC, Mullins CE, Murphy DJ, Ninth MK, Ludomirsky A - Results of balloon valvuloplasty in typical and dysplastic pulmonary valve stenosis: Doppler echocardiographic follow-up. J Am Coll Cardiol 1988; 12: 476-91. [Links]

3. Rao OS - Balloon pulmonary valvuloplasty: a review. Clinical Cardiology 1989; 12: 55-74. [Links]

4. Choy M, Beekman RH, Rocchini AP, et al - Percutaneous balloon valvuloplasty for valvar aortic stenosis in infants and children. Am J Cardiol 1987; 59: 1010-13. [Links]

5. Lababidi Z, Wu J, Walls JT - Percutaneous balloon aortic valvuloplasty: results in 23 patients. Am J Cardiol 1984; 53: 194-7. [Links]

6. Beekman RH, Rocchini AP, Dick M, et al - Percutaneous balloon angioplasty for native coarctation of the aorta. J Am Coll Cardiol 1987; 10: 1078-84. [Links]

7. Delezo JS, Sancho M, Pan M, Romero M, Oliveira C, Luque M - Angiographic follow-up after balloon angioplasty for coarctation of the aorta. J Am Coll Cardiol 1989; 13: 689-95. [Links]

8. Kan JS, White RI, Mitchell SE, Farmalett EJ, Donahoo JS, Gardner TJ - Treatment of restenosis of coarctation by transluminal angioplasty. Circulation 1983; 68: 1087-94. [Links]

9. Rashkind WJ, Mullins CE, Hellenbrand WE, Tait MA - Nonsurgical **closure** of patent ductus arteriosus: clinical application of the Rashkind PDA occluder system. Circulation 1987; 75: 583-92. [Links]

10. Hellenbrand WE, Mullins CE - **Catheter closure** of congenital cardiac defects. Cardiol Clinics 1989; 7: 351-68. [Links]

11. King DT, Mills NL - Secundum **atrial** septal defects: non-operative **closure** during cardiac catheterization. JAMA 1976; 235: 2506-9. [Links]

12. Rao PS, Sideris EB, Hausdorf G, et al - International experience with secundum **atrial** septal defect **occlusion** by the buttoned device. Am Heart J 1994; 128: 1022-35. [Links]

13. Haddad J, Seches A, Finzi L, et al - Oclusão percutânea transvenosa da comunicação interatrial mediante a utilização do *buttoned device*. Arq Bras Cardiol 1996; 67: 17-22. [Links]

14. Das GS, Voss G, Jarvis G, Wyche K, Gunther R, Wilson RF - Experimental **atrial** septal defect **closure** with a new transcatheter self-centering device. Circulation 1993; 88 (part I): 1754-64. [Links]

15. Sievert H, Babic UU, Ensslen R, et al - Verschluss des vorhofseptumdefektes mit einem neuen Okklisionssystem. Z Kardiol 1996; 85: 97-103. [Links]

16. CardioSeal Septal **Occlusion** System - Nitinol Medical Technologies, Inc. USA Brochure, 1997. [Links]

17. Oberfundin MJA, Gu X, Titus J, et al - Transvenous closure of secundum septal

17. Sharafundin MJA, Gu X, Titus J, et al – Transvenous **closure** of secundum septal defects: preliminary results with a new self-expanding nitinol prosthesis in a swine model. Circulation 1997; 95: 2162-8. [Links]

18. Bjornstad PG, Smevik P, Fiane AE, et al – **Catheter**-based **closure** of **atrial** septal defects with a newly developed nitinol double disc: an experimental study. Cardiol Young 1997; 7: 220-4. [Links]

19. Bjornstad PG, Masura J, Thaulow E, et al – Interventional **closure** of **atrial** septal defects with the Amplatzer device: first clinical experience. Cardiol Young 1997; 7: 277-83. [Links]

20. Fontes VF, Pedra CAC, Pedra SRFF, et al – Experiência inicial no fechamento percutâneo da comunicação interatrial com prótese de Amplatzer. Arq Bras Cardiol 1998; 70: 147-53. [Links]

21. Masura J, Gavora P, Formanek A et al – Transcatheter **closure** of secundum **atrial** septal defects using the new self-centering Amplatzer Septal Occluder. Initial Human Experience. Cath Cardiovas Diagn 1997; 42: 388-93. [Links]

22. Boutin C, Musewe NN, Smalhorn JF, Dyck JD, Kobayashi T, Benson LN – Echocardiographic follow-up of **atrial** septal defect after **catheter closure** by double-umbrella device. Circulation 1993; 88: 621-7. [Links]

23. Pedra CAC, Pedra SRFF, Esteves CA, Assef JE, Fontes VF, Hijazi ZM – Multiple **atrial** septal defects and patent ductus arteriosus: successful outcome using two Amplatzer septal occluders and Gianturco coils. Cath Cardiovas Diagn 1998; 45: 257-9. [Links]

24. Velde VME, Perry ST, Sanders SP – Transesophageal echocardiography with color Doppler during interventional catheterization. Echocardiography 1991; 8: 721-30. [Links]

Instituto Dante Pazzanese de Cardiologia - São Paulo
Mailing address: Simone R. F. Fontes Pedra - Instituto Dante Pazzanese de Cardiologia - Av. Dr. Dante Pazzanese, 500 - 04012-180 - São Paulo, SP - Brazil

Av. Marechal Câmara, 160 - 3º Andar - Sala 330
20020-907, Centro, Rio de Janeiro, RJ - Brazil
Tel.: +55 21 3478-2700
Fax: +55 21 3478-2770

eMail
arquivos@cardiol.br

To:	Medtronic, Inc. (**trademark@medtronic.com**)
Subject:	TRADEMARK APPLICATION NO. 77278969 - CLOSURE - T1093US
Sent:	2/19/2009 5:39:44 PM
Sent As:	ECOM114@USPTO.GOV
Attachments:	

IMPORTANT NOTICE
USPTO OFFICE ACTION HAS ISSUED ON 2/19/2009 FOR APPLICATION SERIAL NO. 77278969

Please follow the instructions below to continue the prosecution of your application:

VIEW OFFICE ACTION: Click on this link **http://tmportal.uspto.gov/external/portal/tow?DDA=Y&serial_number=77278969&doc_type=REC&mail_date=20090219** (or copy and paste this URL into the address field of your browser), or visit **http://tmportal.uspto.gov/external/portal/tow** and enter the application serial number to **access** the Office action.

PLEASE NOTE: The Office action may not be immediately available but will be viewable within 24 hours of this notification.

RESPONSE MAY BE REQUIRED: You should carefully review the Office action to determine (1) if a response is required; (2) how to respond; and (3) the applicable **response time period**. Your response deadline will be calculated from **2/19/2009**.

Do NOT hit "Reply" to this e-mail notification, or otherwise attempt to e-mail your response, as the USPTO does NOT accept e-mailed responses. Instead, the USPTO recommends that you respond online using the Trademark Electronic Application System response form at http://www.uspto.gov/teas/eTEASpageD.htm.

HELP: For *technical* assistance in accessing the Office action, please e-mail **TDR@uspto.gov**. Please contact the assigned examining attorney with questions about the Office action.

WARNING

1. The USPTO will NOT send a separate e-mail with the Office action attached.

2. Failure to file any required response by the applicable deadline will result in the ABANDONMENT of your application.