



MHI™ QUARTERLY

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COMPREHENSIVE VALVE TREATMENT FOR AN AGING POPULATION

Traditional thinking for treating valve disorders in the elderly has frequently led to palliative medical therapy rather than surgery and other forms of treatment. Especially with the elderly, certain treatments are deemed effective while others are quickly ruled out. But Wes Pedersen, MD, FACC, interventional valve program director for the Complex Valve Disorder Program at the Minneapolis Heart Institute®, believes it is time to challenge traditional thinking. The two most common valve lesions [aortic stenosis (“sticking” of the aortic valve) and mitral insufficiency (a “leaky” mitral valve)] become more common as the population ages.

The issue of how to treat older patients with valve disorders is magnified when one considers the expanding population of the elderly. “The over-80 population will grow more than any other population base in the country. In fact it will grow by 50 percent in the next 10 years,” said Pedersen.



Wes R. Pedersen, MD, FACC, FSCAI and
Vib R. Kshetry, MD, FACC, FACS, FRCS

What is “Frail”?

With the growth of that age group comes an increasing prevalence of heart-related diseases, including valve disorders. But there’s good news for this aging population: those who were once thought too frail for the standard treatments may be able to undergo procedures which were previously thought to carry too much risk.

Many 80-year-olds, and even appropriately-selected 90-year-olds, may be better served with surgery. Best of all, surgery and other less invasive treatments are significantly improving their quality of life.

“Patients often come in with a preconceived notion regarding whether or not they can tolerate surgery,” said Pedersen. “Perhaps their primary care physician has cautioned them against it. But with our growing experience, new treatment techniques and improved perioperative mortality rates in this population, more of the elderly become good candidates for effective treatments of valve disorders (surgery or “percutaneous treatments”). No one should be denied treatment based on age alone. The elderly want and certainly deserve the better quality of life which accompanies the more aggressive management of degenerative valve disorders.”

Questioning what constitutes a “frail” patient is one part of seeing valve disorders in a new light. Refocusing on older interventions and ways to make them more effective is also making a difference.

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Refocused Therapies

“The incidence of aortic stenosis in people aged 80-90 is roughly five to seven percent,” said Pedersen. “In those over 90 years old, the incidence grows to 10-15 percent.”

For patients between 80 and 90 years old, open-heart surgical mortality is usually less than 8 percent. But for people over 90 years old, mortality is generally greater than 12 percent. Although aortic stenosis is more common in these elderly age groups, mitral insufficiency is not far behind.

A quick survey of complex valvular disease treatments helps set the stage for today’s refocused therapies. Valve treatment usually takes one or more of the following treatment strategies:

- medical therapy
- surgical valve repair or replacement
- percutaneous (by catheter through a vessel) valve repair or implantation.

Medical treatment remains an option for many of the elderly who present with valve disease and an impaired quality of life. These patients are often undertreated and relegated to spending their remaining time limited by congestive heart failure. Medical therapy, as a treatment for valve disorders, has a mortality rate as high as 50 percent within one to two years. It’s a choice some patients have been forced into, but options today are richer and hold more promise for many with valve disease.

Open heart surgery is the most prescribed and effective treatment for valvular disease. The surgical option usually involves valve replacement or repair. With valve replacement, durability of tissue valves is less of a concern in older patients and the risk of bleeding from chronic anticoagulation for those patients receiving mechanical valves is a large concern – therefore, in this population, tissue valves are usually preferred. In patients with mitral regurgitation, mitral valve repair is increasingly emphasized as the preferred treatment, but requires a subspecialty skill only a limited group of cardiac surgeons possess.ⁱⁱ

Percutaneous Valve Therapy Remixed

A European studyⁱⁱⁱ showed one third of patients over age 75 referred for aortic valve replacement (AVR) were denied surgery. “If one includes the even bigger universe of patients who were never even referred for open heart surgery, a remarkable number of elderly patients are abandoned for consideration of any meaningful treatment,” said Pedersen. “In this country, there are probably 40,000 patients annually with aortic stenosis who don’t get operated on because they are considered ‘too old or high risk.’” The situation is similar for those with mitral insufficiency. “There are conservatively 100,000 to 150,000 patients in the U.S. who are not operated on every year because the risk is felt to be too high.”

Consequently, the opportunity for effective and lower risk treatments for patients is huge. In some respects, old thoughts about treatment effectiveness linger. For example, percutaneous therapy using balloon dilatation for aortic stenosis fell into disfavor during the 1980s. At that point, balloon aortic valvuloplasty (BAV) was not offered to the very elderly – poor surgical candidates who, it was later discovered, had the most to benefit. Patients in their 70s (the predominate group initially treated with BAV 20 years ago) are generally good surgical candidates and are best treated with aortic valve replacement (AVR). “We have found no increased risk associated with BAV in patients even in their 90s when compared to younger patients.^{iv} Outcomes are limited somewhat by restenosis over one year’s time. But another lesson learned since early balloon dilatation was just how much symptomatic benefit was gained from the BAV in elderly, nonsurgical patients.

“*Calcific aortic stenosis is the most frequent expression of valvular heart disease in the Western world, with increasing prevalence expected as the population ages. Three percent of all adults >75 years of age have moderate or severe AS, and it is the leading indication for valve replacement in Europe and the United States.*”ⁱ

“An increase in aortic valve area (AVA) by 30-50 percent or greater is symptomatically beneficial,” said Pedersen. Again, the primary limitation of aortic valvuloplasty has been the restenosis rates: 70-80 percent at one year and at a year and a half, even higher: 80-100 percent.

In spite of these high restenosis rates, patients in their late 80s and 90s still benefit from a dramatically improved quality of life, especially when using a strategy of serial dilations for restenosis, much like the treatment of esophageal stricture in gastroenterology. These findings, along with an improved understanding of valvular pathophysiology, led Pedersen to conclude: “Aortic valvuloplasty strategies should be reevaluated, given the enhanced knowledge of vascular and valvular biology that permits targeted therapy to prevent restenosis and to delay or reverse valve mineralization (the major cause of restenosis (calcification)). The increasing numbers of poor surgical candidates in the expanding very elderly population mandate less invasive methods such as BAV to improve quality of life.”ⁱ

Pedersen and his colleagues are evaluating a treatment approach coupling BAV with external beam radiation through a very small window to reduce restenosis rates. Early results from the RADAR (**R**adiation Following Percutaneous Balloon **A**ortic Valvuloplasty to Prevent **R**estenosis) pilot trial show restenosis rates were significantly improved when aortic valvuloplasty patients were treated with radiation immediately after their procedure.^v “Our FDA-approved, double-blinded RADAR, trial comparing radiation versus nonradiation following valvuloplasty, will help us understand the real impact of this therapy on restenosis,” said Pedersen.

“We also hope to begin evaluating percutaneous valve implants [tissue valves delivered through catheters] in the very near future at the Minneapolis Heart Institute® as another potential treatment option for these aortic stenosis patients,” said Pedersen.

Percutaneous Mitral Valve Therapy

“For mitral valve insufficiency, there are a number of novel percutaneous technologies we are currently evaluating,” said Pedersen. “The Minneapolis Heart Institute® participates in two trials we are quite excited about, the MitraClip and iCoapsys mitral valve repair system.”

- MitraClip (Evalve, Inc.) percutaneous mitral valve repair in which a clip is deployed via catheter on the mitral leaflets to create a double orifice mitral valve and reduce mitral regurgitation (leakage).
- iCoapsys (Myocor, Inc.) transcatheter mitral valve repair system, which uses two epicardial pads (on the outside of the heart – one anterior, one posterior) placed on the heart and connected by a flexible transventricular chord. When pulled together, the distance between the pads is reduced, decreasing the A-P dimension of the mitral valve annulus and diameter of the dilated left ventricle, resulting in decreased mitral regurgitation. This system is delivered percutaneously using a specially designed set of catheters from a subxiphoid approach.

“This is an exciting time in the development of novel therapies for the treatment of aortic stenosis and mitral insufficiency in the elderly. The Minneapolis Heart Institute® will continue to pursue these therapies to better serve our patient population. Many patients are already experiencing improved longevity and quality of life – and we are just getting started with these groundbreaking therapies,” concluded Pedersen.

Better Patient Care and Advancing Science

The Complex Valve Disorder Program at the Minneapolis Heart Institute® includes these physicians and auxiliary staff:

Program directors:

Kevin M. Harris, MD, FACC, FASE
Vib R. Kshetry, MD, FACC, FACS, FRCS
Wes R. Pedersen, MD, FACC, FSCAI

Specializing cardiologists:

Wes R. Pedersen, MD, FACC, FSCAI
Kevin M. Harris, MD, FACC, FASE
Richard Bae, MD, FACC, FASE
Terrence F. Longe, MD, FACC
Michael R. Mooney, MD, FACC
Maria-Teresa P. Olivari, MD, FACC
Quirino G. Orlandi, MD, FACC, FASE
Anil K. Poulose, MD, FACC, FSCAI

Specializing cardiothoracic surgeons:

Vib R. Kshetry, MD, FACS, FRCS
Frazier Eales, MD, FACS
Timothy J. Kroshus, MD, PhD, FACS
Thomas F. Flavin, MD, FACS

Research nurse clinicians:

Sara Olson, RN, BSN
Peg Demmer, RN, BSN, CCRC

Nurse practitioner:

Paula Thornton, CNP

- i Hara H, Pedersen WR, Ladich E, et al. Percutaneous balloon aortic valvuloplasty revisited: time for a renaissance? *Circulation*: 115(12):27 March 2007 pp. e334-e338.
- ii Pedersen WE, Block P, Leon M, et al. iCoapsys Transcatheter mitral valve repair system: percutaneous implantation in an animal model. *Catheter Cardiovasc Interv*, in press.
- iii lung, B, Messica-Zeitoun D, Baron G, et al. What patient characteristics lead to contra-indication of surgery in elderly patients with severe, symptomatic aortic stenosis? Poster presentation 1159-47, ACC Scientific Sessions, JACC Supplement abstract, Feb. 1, 2005.
- iv Pedersen WR, Klaassen PJ, Boisjolie CR, et al. Feasibility of transcatheter intervention for severe aortic stenosis in patients ≥90 years of age: aortic valvuloplasty revisited. *Catheterization and Cardiovascular Interventions* 70: 149-154. *Catheter Cardiovasc Interv*. 2007 Jul 1;70(1):149-54.
- v Pedersen WR, Van Tassel RA, Pierce TA, Radiation following percutaneous balloon aortic valvuloplasty to prevent restenosis (RADAR pilot trial). *Catheter Cardiovasc Interv*. 2006 Aug;68(2):183-92.

VASCULAR SURGERY INTEGRATION STRENGTHENS COMMITMENT TO WORLD CLASS VASCULAR CARE

World-class cardiovascular care cannot exist without a substantive commitment to an integrated approach to treating vascular diseases. Early in 2008, four vascular surgeons joined the staff of Abbott Northwestern's Vascular Center at the Minneapolis Heart Institute®, further strengthening an already strong multi-disciplinary approach to vascular care. Three of these surgeons have been practicing with the Vascular Center for many years and have established a vibrant clinical program. A fourth vascular surgeon, while new to the Vascular Center, is nationally recognized for his work in endovascular care. Together, these surgeons offer the clinical talent and vision that will provide the best vascular care to the increasing number of individuals with vascular diseases.

Integrated Vascular Clinical Team

“For the last four years we have had a highly integrated, interdisciplinary clinical Vascular Center that was established by using the best skills of vascular medicine, cardiology, vascular surgery, interventional radiology and vascular nursing,” said Alan T. Hirsch, MD, FACC, director of Abbott Northwestern's Vascular Center. “By better integrating these four skilled and highly experienced vascular surgeons into our team, we have heightened the capabilities for treating carotid, aortic, renal and mesenteric, lower extremity PAD and venous disease. The patient and our community as a whole will be the sure winners.”

Abbott Northwestern's Vascular Center builds deliberate bridges between interventional radiology, cardiology and vascular surgery. “In 2004, when the Vascular Center was started, it was immediately a very positive thing,” said Peter Alden, MD, associate director of the Vascular Center, who joined the Center from Surgical Specialists of Minnesota, where he was a founding partner.

Many were eager to see the program serve more patients, so for Drs. Alden, Alex Tretinyak and Jack Graber, their joining the Vascular Center as full partners will position the entire team to streamline and improve patient care. The ability of Abbott Northwestern's Vascular Center to more fully link to the clinicians and programs of the Minneapolis Heart Institute® will further broaden the multi-disciplinary care team and scope of care for individuals with vascular disorders.

A Care Vision Continuously Refreshed

“It's exciting to join a vascular program that is already so strong,” said Timothy Sullivan, MD, FACS, FACC, who will serve as surgical director of Abbott Northwestern's Vascular Center. Sullivan practiced most recently at North Central Heart Institute, Sioux Falls, S.D., and had also established a national reputation as director of Endovascular Practice with-

in the Division of Vascular Surgery at the Mayo Clinic. Sullivan also served as chief medical officer for the innovative medical device corporation Sage Medical Technologies, Inc.

“The Minneapolis Heart Institute® is clearly committed to being world-class – in everything they do. The strong belief in interdisciplinary care is evidenced in how colleagues interact. And there is tremendous strength created with the existing infrastructure for clinical research. ‘Translational research’ is not a mere phrase here but a core principle of daily practice.”

For Sullivan, vascular clinical research is a natural outgrowth of the day-to-day work of surgery. He has authored more than 100 major peer-reviewed manuscripts and book chapters. His papers regarding vascular surgery care principles and training standards have been presented around the world. Contributing to vascular care knowledge and communicating to colleagues about these advances – always central to the Vascular Center team vision – will be further enhanced and will help the Center grow.

Patient Care at the Core

Sullivan's vision of multi-disciplinary care is straightforward and corresponds precisely to the mission of the larger Vascular Center: “Let experts promptly evaluate patients and make the best care decisions as a team.” He sees the practice as involving six disciplines – vascular medicine, non-invasive and interventional cardiology, diagnostic and interventional radiology, interventional neuroradiology, vascular surgery and vascular nursing – so that the clinical strength of each discipline quickly reaches individual patients in need.

“Physician-to-physician communication is incredibly important,” said Sullivan. Beyond informal communication, Sullivan and his colleagues will help lead weekly vascular case conferences, and monthly morbidity and mortality multi-disciplinary conferences, at which Center clinicians discuss their most challenging cases. Vascular care and science are both advanced when teammates openly share such information, bringing rapid improvements in patient care.

Vascular Center Team Propels Knowledge Growth

“We remain committed to playing a national role in vascular clinical research, including three current National Heart, Lung and Blood Institute (NHLBI)-sponsored clinical trials that test fundamental assumptions about best-care practices for arterial disease. These include the CORAL, CLEVER and stem cell studies for critical limb ischemia,” said Hirsch, principle investigator for such studies.

The CORAL study (Cardiovascular Outcomes for Renal Atherosclerotic Lesions) is a randomized, multi-center

trial that is evaluating best care strategies for patients with high blood pressure and renal artery stenosis. Which treatment is more effective and safer: Endovascular renal artery stenting or antihypertensive medical therapy? The CLEVER study (Claudication: Exercise Versus Endoluminal Revascularization) is a randomized, multi-center trial that similarly evaluates whether supervised exercise, pharmacologic claudication medication or endovascular stenting provide the most effective and safest approach for patients with aortoiliac PAD and claudication. Similarly, Timothy Henry, MD, director of Research at the Minneapolis Heart Institute® Foundation, is actively studying the potential for

stem cells and angiogenic factors to save legs and lives for individuals with critical limb ischemia.

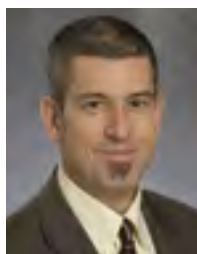
There are few Vascular Centers in the country in which patients and clinicians have access to the best current vascular care standards and the best current vascular clinical research. Individuals in Minnesota and the region have access to exactly this at the Vascular Center at the Minneapolis Heart Institute®. "With our community physician, nurse practitioner and physician assistant partners, we are eager and fortunate to be able to provide such advanced vascular care to our community," Hirsch said.

VASCULAR SURGEONS JOIN MINNEAPOLIS HEART INSTITUTE®

Four vascular surgeons have joined the Minneapolis Heart Institute® at Abbott Northwestern Hospital. They include Peter Alden, MD; John Graber, MD; and Alexander Tretinyak, MD, who have long affiliations with Abbott Northwestern Hospital and have worked closely with the Minneapolis Heart Institute®. Joining them is Timothy M. Sullivan, MD, a leading expert on endovascular care.



Peter B. Alden, MD, FACS, has practiced vascular surgery in the Twin Cities since 1990, first at Park Nicollet Clinic and then in private practice as a founding partner of Surgical Specialists of Minnesota at Abbott Northwestern Hospital starting in 1996. His clinical interests include carotid surgery, aortic aneurysm, vascular problems in diabetics and venous disease. Alden is an associate director of Abbott Northwestern's Vascular Center and is the medical director of the Wound Clinic at Abbott Northwestern. He earned his medical degree from the University of Wisconsin in 1981. His general surgery residency was at the University of Minnesota followed by vascular fellowship training at Washington University in St. Louis, Mo. He is a diplomate of the American Board of Surgery and holds the Certificate of Special Added Qualifications in Vascular Surgery from the American Board of Surgery.



Timothy M. Sullivan, MD, has practiced vascular surgery since 1990. He has served as director of Endovascular Practice in the Vascular Surgery Division at the Mayo Clinic and co-director of the Mayo Clinic Vascular Center's Endovascular Program. Sullivan's clinical interests include both open and endovascular surgical procedures, including aortic dissection, thoracoabdominal aortic aneurysm repair, visceral reconstruction and cerebrovascular disease. He earned his medical degree at the Northeastern Ohio University in Rootstown, Ohio, and completed his general surgery residency at Wright State University in Dayton, Ohio in 1988. He obtained fellowship training in peripheral vascular surgery at St. Vincent Medical Center in Toledo, Ohio and the Cleveland Clinic. Sullivan is a diplomate of the American Board of Surgery and holds the Certificate of Special Added Qualifications in Vascular Surgery from the American Board of Surgery. He will serve as co-director of Abbott Northwestern's Vascular Center and as chairman of Vascular and Endovascular Surgery.



John N. Graber, MD, has practiced vascular surgery in the Twin Cities since 1983. He is a founding partner of Surgical Specialists of Minnesota and served as chief executive officer for more than a decade. Graber is also a clinical instructor in surgery at the University of Minnesota. His clinical interests include management of abdominal aortic aneurysms and carotid artery surgery. He earned his medical degree at St. Louis University School of Medicine and completed his general surgery residency at the Medical College of Wisconsin in 1982. Graber completed fellowship training in vascular surgery at Oxford University in Oxford, England, and Tufts University in Boston, Mass. He is a diplomate of the American Board of Surgery.



Alex Tretinyak, MD, has practiced vascular surgery at Abbott Northwestern Hospital since 2004 as a partner with Surgical Specialists of Minnesota. His clinical interests include endovascular aortic aneurysm repair and peripheral interventions, carotid occlusive disease and treatment of venous insufficiency. Tretinyak received his medical degree at the University of Minnesota where he also completed his residency in general surgery. He obtained vascular surgery fellowship training at the University of Chicago. Tretinyak is a diplomate of the American Board of Surgery and holds the Certificate of Special Added Qualifications in Vascular Surgery.

CAN WE IGNORE PAD AND REMAIN COMMITTED TO CARDIOVASCULAR DISEASE PREVENTION?

In the face of unambiguous data that demonstrate that peripheral arterial disease (PAD) is the most prevalent, morbid and fatal cardiovascular disease – and with these data encompassed in national treatment guidelines – I am amazed that public awareness of this disease remains critically low,” said Alan T. Hirsch, MD, director of Abbott Northwestern’s Vascular Center at the Minneapolis Heart Institute®, professor of Epidemiology and Community Health at the University of Minnesota School of Public Health, and chairman of the national nonprofit Peripheral Arterial Disease Coalition. “I am equally stunned at the challenges that we face. As cardiovascular and primary care clinicians, we’re still anchored in 1965 practice patterns that ignore leg pain as a potentially central cardiovascular ischemic symptom.”

Hirsch, lead author of the national ACC/AHA Guidelines for the Management of Patients with Peripheral Arterial Disease, cited new research that evaluated a representative sample of more than 2,500 adults in the U.S. to evaluate their relative knowledge of PAD and other cardiovascular diseases (Circulation. 2007 Oct 30;116(18):2086-94). Three out of four Americans had no awareness of the existence of PAD. These data also showed:

- PAD awareness was markedly lower than for any other CV disease or risk factor, despite the higher risk associated with PAD
- PAD awareness was much lower than other relatively rare diseases such as cystic fibrosis, Lou Gehrig’s disease and multiple sclerosis
- even among the one in four Americans who had heard of PAD, fewer than one in four knew that people with PAD suffer a five-fold increased relative risk of heart attack and stroke
- among the PAD-aware Americans, fewer than one in seven knew PAD was associated with a two- to three-fold increase risk of death – a risk that is as high or higher than the death rate associated with a recent heart attack.

“We have known for over a decade that leg muscle discomfort from PAD [claudication] is equally or more predictive of death than anginal symptoms or a TIA, but somehow clinicians seem unwilling to ask about leg pain,” said Hirsch. “There’s probably not a member of the public on this planet who does not know that chest pain in an adult is a

potentially important symptom mandating clinical evaluation and often prompting treatment. Shall we simply ignore leg angina for another decade? That’s just not right.

“If all clinicians could confer equal attention to individuals with PAD, and used this concern to actively help our family, friends and patients understand the basics of PAD science – and if we used this attention to extend our practice standards to those at highest cardiovascular risk – we’ll immediately save lives,” said Hirsch. “It’s that simple. And that gratifying.”

These new national PAD public awareness data, along with free public PAD awareness tools, are now available from the PAD Coalition at www.padcoalition.org.

When to Refer and What Tests to Order

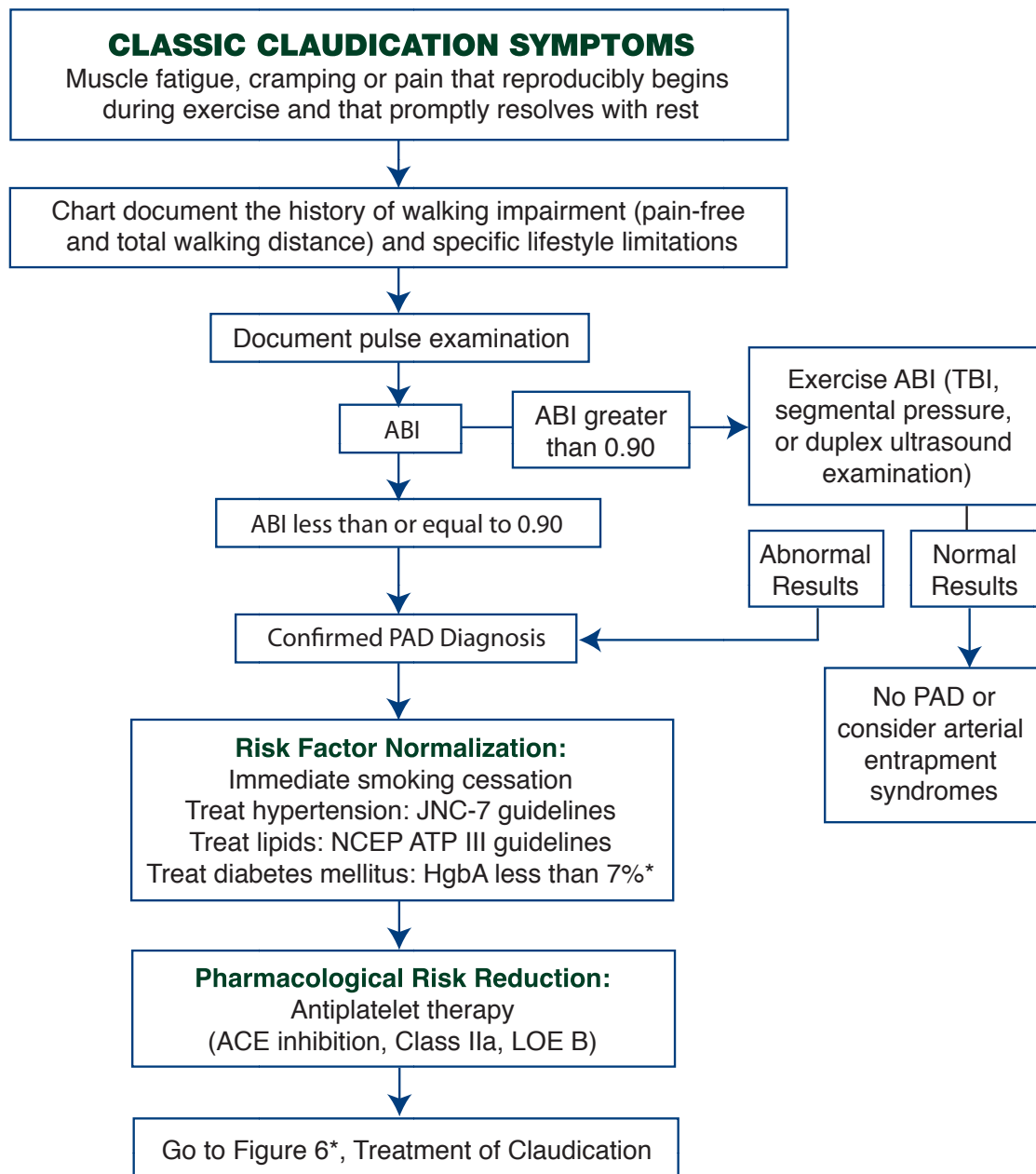
The ACC/AHA Guidelines for the Management of Patients with PAD are concise and accessible, providing the fullest range of options to cost-effectively diagnose and treat peripheral arterial disease. The guidelines recognize that the fundamental starting place for care is identifying individuals who are at high risk for lower extremity PAD (a >25 percent chance of having PAD). This includes individuals who:

- are less than 50 with diabetes and one other atherosclerosis risk factor
- are 50 to 69 with a history of smoking or diabetes
- are older than 70 years
- have leg symptoms with exertion (suggestive of claudication) or ischemic rest pain
- have an abnormal lower extremity pulse examination
- have known atherosclerotic coronary, carotid or renal arterial disease.

Individuals in these categories should undergo:

- a simple history to document any walking impairment and/or limb ischemic symptoms
- a resting ankle-brachial index measurement.

For those patients who have leg symptoms suggestive of claudication, the guidelines¹ provide straightforward algorithms to facilitate a step-by-step approach to diagnosis and treatment.



¹ Reprinted from JACC, Vol. 47, Issue 6, Hirsch AT, Haskal ZJ., Hertzler NR., et al., ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic): Executive Summary, p.33, Copyright 2006, with permission from Elsevier.

* Please refer to the complete guidelines.

Additional PAD Resources

For additional information that may help change practice patterns:

ACC/AHA Guidelines for the Management of Patients with PAD:

(http://www.americanheart.org/downloadable/heart/1137607531918PAD_ES_MASTER.pdf)

PAD Coalition: www.padcoalition.org

Slide set: “Gaps in Public Awareness of PAD” (<http://www.padcoalition.org/wp/gaps-in-public-awareness-of-pad/>)

Minneapolis Heart Institute®: www.mplsheart.com



Staff News

NEW PHYSICIANS AT THE MINNEAPOLIS HEART INSTITUTE®



Desmond Jay, MD, joined the Minneapolis Heart Institute® in August and is practicing at Abbott Northwestern Hospital.

Jay's clinical interests include echocardiography and nuclear cardiology. He completed a cardiology fellowship at Emory University in Atlanta, Ga. Prior to that, Jay completed a chief residency and internal medicine residency at the University of Minnesota. He received his doctor of medicine degree from the University of Colorado in Denver.



Shalini Bobra, MD, joined the Minneapolis Heart Institute® in January and is practicing at Abbott Northwestern Hospital.

Her clinical interests include echocardiography, nuclear cardiology and women's heart health. Bobra completed her cardiology fellowship at the Albert Einstein College of Medicine in New York and an internal medicine residency at Westchester Medical Center, also in New York. She received her doctor of medicine degree from Memorial University Faculty of Medicine in Newfoundland, Canada.

PERSPECTIVE HELPS FRAME THE DRUG ELUTING STENT CONVERSATION

An Update on Stents

Drug-eluting stents (DES) were introduced in 2002 and immediately reduced the need for the additional revascularization procedures required by bare-metal stents (BMS). The DES was designed to include a drug that dissolved over time and blocked the growth of tissue which re-narrowed the artery. The result was a stent with a safety profile (death and MI) similar to bare metal stents but without the additional risks of further coronary artery restenosis (scarring).

"It's easy to see why the drug-eluting stent was something of a star to the media," said Michael Mooney, MD, an interventional cardiologist and researcher with the Minneapolis Heart Institute®. "It's also easy to see why the media jumped on the

recent slight bump in late-stent thrombosis (clotting) with DES – it sounded like a good story. But without understanding the context for the statistics, it's hard to know how to evaluate the numbers.

"We need a bit of perspective and humility when it comes to understanding the statistical validity of low-frequency events like this." The increase in clotting of 0.5 percent per year over a period of two years amounts to roughly six patients in 1,200 in over two years, a small number by most standards – especially when compared with the standard mortality rate cited for heart attacks in the U.S. of 9 percent per year. "Without minimizing the numbers," said Mooney, "a bit of

~ continued on page 9

perspective says the slight increase in thrombosis rates is something to watch but not to worry over.” This slight increase, however, has led to a new recommendation of at least 12 months of dual anti-platelet therapy (aspirin and plavix) following placement of a DES.

“Numbers like those would not have even registered on the radar a few years ago. We’re much better at tracking clinical events today.” Naturally all of these studies have taken place within the boundaries of FDA and ACC treatment guidelines. When bare-metal stents were introduced, studies were less intensive and not powered to answer the kinds of questions we ask today. “Today’s mandates for completeness are much more stringent than past standards,” said Mooney.

Ongoing Studies

“It’s important to realize that the major advances in cardiology over the past three to five years have been less obvious because of these low-frequency issues,” said Mooney. “But advances have kept pace. Physicians at the Minneapolis Heart Institute® are currently working with manufacturers on new stent designs that have faster drug elution. These new technologies make use

of sophisticated, high-powered clinical studies that provide the information we’ll use to make decisions going forward. We are performing studies such as ENDEAVOR which compares Medtronic’s new DES with an already approved DES, Taxus (Boston Scientific Corporation), and COSTAR which will help us evaluate the effectiveness of next generation stents. There’s never been a time when interventional cardiology and overall treatment were as good as they are now,” said Mooney.

Prescribing with Perspective

“These low-frequency events are more than offset by the other proven clinical benefits of the DES, most notably, a 50 percent reduction in the need for further revascularization procedures when compared with BMS,” said Mooney. In addition, the incidence of death and MI remain equal between DES and BMS. “Our advice remains the same – even as we carefully monitor the news and filter it through the larger clinical perspective: we’re convinced that for the great majority of patients, stenting with DES is superior to stenting with BMS which in turn is better than medical management alone.”

MINNEAPOLIS HEART INSTITUTE® AND RIDGEVIEW MEDICAL CENTER PARTNER TO BRING SPECIALIZED CARDIOVASCULAR CARE TO THE WEST METRO AREA

The Minneapolis Heart Institute® at Abbott Northwestern Hospital and Ridgeview Medical Center in Waconia, Minn., signed a long-term agreement to provide enhanced cardiovascular care in the west metro.

The formal partnership – Minneapolis Heart Institute® at Ridgeview Heart Center – strengthens an existing relationship between the two health care providers. Over the last 25 years, cardiologists from the Minneapolis Heart Institute® have seen patients at Ridgeview Medical Center and its associated clinics.

Cardiologists from the Minneapolis Heart Institute® now will have a full-time, in-hospital presence at Ridgeview, providing inpatient cardiology consultations, outpatient consultations and cardiac imaging. Services also include diagnostic coronary angiograms and interventional therapies.

With this partnership, patients will have access to specialty care that is typically not available at a hospital of Ridgeview’s size. The new 11,000-square foot Ridgeview Heart Center will include diagnostic technology, stress test areas and a catheterization lab built to mimic those found at Minneapolis Heart Institute®.

“The Minneapolis Heart Institute® at Ridgeview Heart Center is uniquely positioned to meet the growing cardiovascular care needs of patients in Waconia and the surrounding west-metro communities,” said Kevin Graham, MD, president of the Minneapolis Heart Institute®. “Patients recognize Ridgeview for medical excellence and extraordinary customer service, and the Minneapolis Heart Institute® is one of the top cardiovascular care centers in the country. Together, we will bring the highest quality of care in several specialty areas to patients in the west metro.”

According to Robert Stevens, president and CEO of Ridgeview Medical Center, the goal of expanding services in the west metro is to make it easier for the area’s increasing population to access world-class cardiovascular care. “As a health care organization, we have a duty to respond to the growing health care needs of residents in the west metro. The Heart Center and catheterization lab will allow patients to be treated closer to their homes, families and primary care physicians.”

Luis Pagan-Carlo, MD, a Minneapolis Heart Institute® cardiologist, will serve as the Heart Center medical director and oversee a medical team that will include Ridgeview and Minneapolis Heart Institute® staff, physicians, nurses and technicians.

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2008

**MINNEAPOLIS HEART INSTITUTE®'S
LANDMARKS IN CARDIOLOGY PROGRAM**
Thursday, June 12, evening, and Friday, June 13
Thursday, Oct. 2, evening, and Friday, Oct. 3

For more information: 612-863-6986

SPECIALTY CARE CONFERENCE FOR PRIMARY CARE PROVIDERS
Friday, Oct. 10, 6 to 8:30 p.m. and Saturday, Oct. 11, 8 a.m. – 12 noon
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For more information: vonda.dulas@allina.com

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