

CardiovascularUpdate

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New Subcutaneous ICD Offers Less Invasive Alternative to Select Patients



Yong-Mei Cha, MD, Paul A. Friedman, MD

In 2012, the US Food and Drug Administration approved the first subcutaneous implantable cardioverter-defibrillator (S-ICD) system for use in the United States. The approval was granted after extensive review of data obtained from pilot studies and the European EFFORTLESS registry.

Traditional ICD systems comprise the generator and 1 or more transvenous leads and have sensing, antibradycardia and antitachycardia pacing, and shocking capabilities. The need in some patients for a system that avoids the use of transvenous leads has been long recognized. Patients with underlying congenital or structural cardiac abnormalities or with limited or difficult vascular access that precludes placement of transvenous leads require epicardial leads and patches. Individuals with channelopathies that confer a risk of sudden cardiac death often have no need for routine pacing, and transvenous leads rarely last the life of the (usually) young individuals receiving a device for this indication. Since intravascular leads become fibrosed in place over time, lead revision and extraction procedures are challenging and not without risk. A system that does not require intracardiac leads may be appealing in other primary prevention settings. The S-ICD is a system without transvenous leads that provides defibrillation for patients at risk for sudden cardiac death due to ventricular tachyarrhythmias.

Clinical trials involving S-ICDs have demonstrated the efficacy and optimal configuration of the device. The pilot study (*New England Journal of Medicine* 2010; 363:36-44) established concept viability and identified the ideal device configuration: the pulse generator along the left lateral chest wall and the subcutaneous electrode in a left parasternal position (Figure). The device was as effective as standard transvenous devices in



Figure. Optimal S-ICD placement of pulse generator and subcutaneous lead.

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Luis R. Scott, MD, Director Win-Kuang Shen, MD Komandoor Srivathsan, MD terminating induced ventricular fibrillation, although with higher energy requirements (36.6 J \pm 19.8 J [S-ICD] vs 11.1 \pm 8.5 J [transvenous ICD]); the higher impedance and greater distance from the heart inherent in subcutaneous systems increases the energy requirements approximately 3-fold for successful defibrillation. Induced ventricular fibrillation was detected by the device in all 137 episodes.

A subsequent investigational device exemption trial (330 patients) and the ongoing European EFFORTLESS registry have confirmed these initial positive results. The incidence of inappropriate shocks in EFFORTLESS is about 7%, and most occurred in individuals who received early implants and who did not have recommended preprocedural ECG screening to ensure proper QRS and T-wave sensing. Current devices have both a "shock zone," which commits to shock therapy based strictly on heart rate, and a "conditional shock zone," which employs additional discriminators to determine whether shock therapy is warranted.

The system has some limitations. S-ICD is not indicated in patients who require antibradycardia pacing or in those with heart failure for whom cardiac resynchronization is indicated. The device can deliver postshock pacing therapy, but in doing so, it also paces the muscle wall, which can be uncomfortable in conscious patients. It cannot provide antitachycardia pacing, which can painlessly terminate ventricular tachycardia, and is not designed to treat ventricular arrhythmias at rates lower than 170 bpm. The incidence of device infection was 2.5% in the EFFORTLESS registry. The use of lead anchoring sleeves mitigated the risk of subcutaneous lead migration.

Mayo Clinic in Rochester, Arizona, and Florida offers S-ICD to patients for whom standard ICD placement is precluded or not preferred. Candidates include patients with structural heart disease, patients who lack venous access for transvenous lead placement, patients with channelopathies that confer risk of SCD and who do not need antibradycardia pacing, some patients awaiting cardiac transplantation, and those primary prevention patients who are best treated without a transvenous lead due to tricuspid valve concerns or a previously infected transvenous system.

RECOGNITION



Bernard J. Gersh, MD, PhD, a cardiologist at Mayo Clinic in Rochester, received the James B. Herrick Award from the Council on Clinical Cardiology of the American Heart Association at the 2012 annual meeting in Los Angeles, California. Pictured with Dr Gersh at the award presentation is Mrs Gersh (left) and council president L. Christine Newby, MD.

Evolving Management of Type A Aortic Dissection



Alberto Pochettino, MD

Acute type A aortic dissection continues to be a catastrophic event that requires emergent surgical intervention (Figure). The process typically starts with an intimal tear in the mid ascending aorta, which allows blood to split the "at risk" media proximally toward the aortic root as well as distally into the remaining ascending aorta, into the arch, and, in the majority of patients, down the descending thoracic aorta to the abdominal aorta. If untreated, the early mortality is due to proximal acute aortic valve insufficiency leading to acute pulmonary edema; compromised perfusion of the coronary arteries leading

to ischemia, myocardial infarction, and lethal arrhythmias; malperfusion of the arch vessels leading to large strokes; and finally, leakage and rupture of the ascending aorta leading to pericardial tamponade or exsanguination.

The surgical treatment of acute type A dissection must address the structural abnormalities that lead to death if uncorrected, most commonly within 48 hours of the onset of ascending intimal tear development. The aortic valve is resuspended, if feasible, and the aortic root can be stabilized by various techniques. Typically, with use of Teflon stent buttressing to prevent coronary dissections and malperfusion, the ascending aorta is replaced in its entirety as it is the at-risk aortic segment for rupture. The aortic arch is also stabilized to minimize the risk of cerebral malperfusion, with techniques ranging from open distal anastomosis buttressed by Teflon felt to total arch replacement. "In large centers, the surgical outcome of acute repair has improved, with reports of acute mortality as low as 10% to 15%, although Medicare data suggest that, in the United States, the overall average mortality from acute type A dissection remains higher than 25%," according to Alberto Pochettino, MD, a cardiovascular surgeon at Mayo Clinic in Rochester.

Despite progress in the outcome of the proximal repair, the majority of patients who present with acute type A dissection are left with residual dissection beyond the end of the initial repair, typically at the distal arch, with dissection that extends down to the iliac bifurcation. Essentially, in these patients, the dissection is converted from a type A to a type B anatomically, which is then managed medically. The early morbidity and mortality of a native type B dissection or a residual type B after repair of a type A are low, but up to 80% of these patients will experience aneurysmal degeneration of their remaining dissected aorta. Aneurysmal degeneration can be particularly accelerated in the proximal descending thoracic aorta, where expansion of the false lumen has been documented to be as much as 4 mm per year. As the descending aorta reaches a maximal diameter of more than 6 cm, the risk of rupture is significant and surgical intervention is indicated."These late interventions can carry a

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Figure. Standard classification of aortic dissection. Both types may extend below the diaphragm.

high risk, especially if undertaken in an urgent/ emergent setting," says Dr Pochettino.

While significant advances have been implemented over the past decade to better treat such catastrophic disease, there remains much room for improvement. The first questions relate to the techniques used during the acute repair. As the patients are often unstable at presentation, it is important to recognize that survival is the first priority. Sound repair of the aortic root and complete replacement of the ascending aorta are imperative. Inadequate repair and replacement can account for some of the early mortality and lead to progression of root aneurysm and worsening aortic valve insufficiency, eventually requiring reintervention. Next, many surgeons underestimate the importance of stabilization of the aortic arch at the time of acute presentation. The variations in procedures used for arch stabilization are in part related to the lack of familiarity of many cardiac surgeons with surgical intervention on the aortic arch. While it is rarely necessary to perform a total arch replacement in the setting of acute dissection, prevention of devastating cerebral malperfusion by appropriate arch repair likely reduces acute mortality. Thus, the most commonly performed procedure is a buttress extended hemiarch technique.

The optimal treatment approach to acute presentation of an individual to a local emergency department remains controversial. It may be difficult to decide whether a potentially unstable patient is best served by being operated on expeditiously at an institution unfamiliar with aortic surgical interventions and a mortality of over 25% or whether rapid transport to an experienced tertiary center with a mortality of less than 15% is worth the risk potentially incurred during the transport period. Data about timing between diagnosis and surgery suggest that, in most instances, several hours elapse before surgical intervention is carried out, and often delays are magnified in small communities where the cardiac surgical team is not readily available 24/7. The additional risk incurred during transport may be offset by the survival advantage of having the procedure performed in a large-volume aortic center.

But aside from the controversy of upfront mortality related to volume and expertise of the surgeons involved, the standard surgical technique leaves the patient with a type B dissection. Even if repair is carried out successfully with a good early outcome, all these patients need to be followed closely, and the majority require additional intervention. One potential advance has been to address the residual type B dissection at the time of the acute repair. Certainly, this only makes sense when applied at a center where the acute early mortality is low, as adding more upfront surgical interventions may increase the morbidity and mortality of the primary operation. A technique designed to stabilize the dissected descending thoracic aorta involves placement of a stent graft in an antegrade fashion across the open arch at the time of primary proximal repair. Such techniques have been championed over the past 5 years by Dr Pochettino. This technique is sometimes termed "a frozen elephant trunk," reflecting the fact that the stent graft is inserted in an antegrade fashion at the time of hypothermic circulatory arrest.

The idea of adding this technique to the acute treatment of type A dissection occurred following increased familiarity and success in treating complicated type B dissection with endovascular techniques. The main obstacle to generalized use of stent grafts in uncomplicated type B dissection is the low but significant risk of retrograde type A dissections. It would stand to reason that if the overall operative risk is not affected by stenting of the residual thoracic dissection up front, the benefits of acute stenting of type B dissection should be realized without the possibility of retrograde type A dissection. Indeed, no significant differences in the acute mortality or morbidity were demonstrated in 55 acute DeBakey I dissections treated with additional antegrade stent grafting between June 2005 and June 2012, compared with 355 acute DeBakey I dissections treated with standard repair between June 1993 and June 2012. Overall, the acute mortality was 11%. During follow-up, no patients treated with antegrade stenting developed distal thoracic or thoracoabdominal dissecting aneurysms compared with the group operated on with the standard optimal proximal repair, in which almost 30% required open reoperation.

Mayo Clinic in Rochester is a large-volume tertiary center where expertise is available to manage all aspects of aortic dissection, from the acute setting where the standard technique can be complemented with a frozen elephant trunk, to the chronic setting, regardless of where the primary operation may have been performed. Cardiologists, geneticists, internists, cardiothoracic surgeons, and vascular surgeons at the Thoracic Aortic Clinic work as a team to optimize diagnostic, medical, and surgical options to care for patients with aortic aneurysms and dissections, who are recognized to have often challenging multisystem anatomic and physiologic problems.

Results of Trial to Assess Chelation Therapy (TACT) Study Presented



Stephen L. Kopecky, MD

The Trial to Assess Chelation Therapy (TACT) was the first large-scale, multicenter study designed to determine the safety and efficacy of EDTA chelation therapy for individuals with coronary artery disease (CAD) and prior myocardial infarction (MI). The National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI) and National Center for Complementary and Alternative Medicine (NCCAM) cosponsored the study, and the results were presented at the American Heart Association Scientific Sessions in November 2012. Principal investigator at Mayo Clinic in Rochester was Gerald T. Gau, MD.

Rationale

"Chelation is a process in which a substance is used to bind molecules, such as minerals, and remove them from the body. Its use grew by nearly 68% between 2002 and 2007 in the United States, to 111,000 people, despite there being no evidence of its safety, efficacy, or mechanism of action," according to Stephen L. Kopecky, MD, a cardiologist at Mayo Clinic in Rochester. It was this rise in use nationwide that led the NHLBI and NCCAM to evaluate the efficacy of disodium EDTA chelation in the treatment CAD.

Methods

For the TACT study, the protocol specified 40 infusions of at least 3 hours each—30 weekly infusions followed by 10 maintenance infusions 2 to 8 weeks apart. For the active chelation arm, a 10-component chelation solution was selected to match most closely the standard solution used by chelation practitioners. The solution contained up to 3 g of disodium EDTA, 7 g of ascorbic acid, 2 g of magnesium chloride, 100 mg of procaine hydrochloride, 2500 U of unfractionated heparin, 2 mEq of potassium chloride, 840 mg of sodium bicarbonate, 250 mg of pantothenic acid, 100 mg of thiamine, 100 mg of pyridoxine, 100 mg of procaine, and sterile water to make up 500 mL of solution. The placebo solution consisted of 500 mL of normal saline and 1.2% dextrose.

The study was conducted at 134 research sites in the United States and Canada. The research sites represented a mix of clinical settings—university or teaching hospitals, clinical practices or cardiology research centers, and chelation practices. A total of 1,708 patients were randomized—839 patients to chelation and 869 patients to placebo. Participants were at least 50 years old, had an MI at least 6 weeks prior to enrollment, and had not had coronary or carotid revascularization procedures within the past 6 months or smoked cigarettes within the past 3 months.

On average, TACT participants were 65 years old, 8% were women, and 9% were minorities. Participant MI had, on average, occurred 4.6 years before enrollment. The study population had a high rate of diabetes (31%), prior coronary revascularizations (83%), and use of medications, such as aspirin (84%), β -blockers (72%), and statins (73%). A total of 55,222 infusions were completed in the study, with 65% of patients completing all 40 infusions and 76% completing at least 30 infusions. Thirty percent of those enrolled discontinued infusions due to subject refusal (53%), adverse event (12%), open-label chelation (11%), IV access problems (10%), and other reasons (10%). Seventeen percent of patients withdrew consent, therefore precluding any follow-up for events.

Results

Over the 4-year follow-up, the difference in the primary endpoint, 26.5% in the EDTA group vs 30.0% in the placebo group, just reached statistical significance at P=.035, with a hazard ratio (HR) of 0.82 (95% confidence interval [CI], 0.69-0.99). Subjects randomly assigned to active chelation infusions showed an 18% drop in the trial's primary endpoint—a composite of all-cause

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Carmen M. Terzic, MD, PhD Martha A. Mangan, CNP mortality (10.4% vs 10.7%), MI (6.2% vs 7.7%), stroke (1.2% vs 1.5%), coronary revascularization (15.5% vs 18.1%), and hospitalization for angina (1.5% vs 2.1%). There were no significant differences in the individual components of the primary endpoint in chelation patients vs controls although there seemed to be a trend toward benefit for coronary revascularization (P=.076).

In a prespecified subgroup analysis, the 31% of the study population with diabetes showed greater benefit for the primary endpoint compared with nondiabetic patients with an HR of 0.61 (95% CI, 0.45-0.83; P=.002); in nondiabetic patients, the HR was 0.96 (95% CI, 0.77-1.20; P=.725). Also, anterior MI patients showed benefit vs other MI locations (P=.03). Possibly due to the fact that 83% of patients had previously undergone revascularization and 80% had no anginal symptoms at baseline, chelation therapy had minimal effect on standard measures of quality of life at 6, 12, and 24 months, with the exception of slight improvement in self-reported anginal symptoms at 1 year (P=.016). Adverse effects were similar in both groups.

More Questions

"The trial results were the focus of much discussion at the recent 2012 AHA annual meeting in Los Angeles where the TACT results were presented, with multiple reasons being offered," says Dr Kopecky. The usual answer in randomized placebo-controlled clinical trials—that the active treatment (chelation) is better than placebo—was not believed by most in attendance to be the cause. Other possible reasons were offered, including the following:

1. Difference in low-density lipoprotein cholesterol levels at baseline. Subjects randomly assigned to active chelation therapy had a lower baseline LDL than the placebo group (87 mg/dL vs 90 mg/dL). This level of difference would be expected to result in 3% less major cardiovascular events after 5 years, very close to the 3.5% actually seen in the study.

2. Placebo glucose infusion in the diabetic group. Since most of the benefit of chelation was seen in diabetic patients, some postulated that the placebo glucose infusion may have led to increased adverse outcomes in this subset.

3. Incomplete data due to dropout. Seventeen percent of patients withdrew consent (3%-5% is common in large trials), which prohibited investigators from ascertaining any endpoint data, thereby potentially missing some major cardiovascular events.

While being provocative, due to its borderline significance and the above-mentioned reasons, the TACT study is not conclusive and should not change clinical practice. The results do warrant further study, especially in patients with diabetes or prior anterior MI, due to a signal of benefit in these subgroups. "For now, we should await complete review and vetting of the data via the publication process before making final decisions on the role of chelation therapy in the treatment of CAD," says Dr Kopecky.



The Department of Medicine at Mayo Clinic in Rochester has announced the 2012 Faculty Recognition Awards. Honorees from the Division of Cardiovascular Diseases include John A. Heit, MD, who received the Research Career Achievement Award; Patricia A. Pellikka, MD, who received the Outstanding Mentorship Award; Titus C. Evans, MD, who received the Henry S. Plummer Distinguished Physician Award; and Kyle W. Klarich, MD, who was honored for Distinguished Contributions to Medical Education.

RECOGNITION

RECOGNITION



Stephen C. Hammill, MD, a cardiologist at Mayo Clinic in Rochester, is recognized as the William S. and Ann Atherton Professor of Cardiology Honoring Robert Frye, MD.



David R. Holmes Jr, MD, a cardiologist at Mayo Clinic in Rochester, was named the 2012 Medical School Alumnus of the Year by the Medical College of Wisconsin/Marquette Medical Alumni Association.



Win-Kuang Shen, MD, chair of the Division of Cardiovascular Diseases at Mayo Clinic in Arizona, has been named to a 3-year term on the ACC/AHA Task Force on Practice Guidelines.





Mayo Clinic in Arizona celebrated 25 years of providing patient care in Arizona this past summer. The outpatient sites in Scottsdale, Phoenix, and Glendale and the Mayo Clinic Hospital in Phoenix employ almost 500 physicians and scientists and more than 5,000 allied health care staff members. In 2015, Mayo Medical School–Arizona Campus will open in collaboration with Arizona State University.







Malini Madhaven, MD, Selma Mohammed, MD, and Marysia Tweet, MD, trainees in the cardiovascular disease program at Mayo Clinic in Rochester, received Women in Cardiology Trainee of Excellence Awards at the American Heart Association meeting in November.

ANNOUNCEMENTS





The Latest From Mayo Clinic on The Heart.org

Advances in Interventional Cardiology: Treating Diabetics and Chronic Stable Angina

Recent research has made important contributions to the treatment of heart disease in patients with diabetes as well as those with chronic stable angina. Drs David R. Holmes Jr, John F. Bresnahan, Bernard J. Gersh, and Rajiv Gulati recently gathered to discuss the FREEDOM and FAME II trials and review why they are the most important recent interventional studies and how they help improve patient care. Visit http://www.theheart.org/article /1482499.do to view the video.

Check out additional videos and podcasts by Mayo Clinic physicians at www.theheart.org/mayoclinic.

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Heart Failure Management for Nurse Practitioners, Physician Assistants,

and Primary Care Providers Mar 17-19, 2013, San Antonio, TX

Echo Fiesta: An In-Depth Review of Adult Echocardiography for Sonographers and Physicians

Mar 21-24, San Antonio, TX

Echocardiography for the Nation's Capital: Practical Review of Adult Echocardiography for Physicians and Sonographers Apr 13-15, 2013, Washington, DC

Cardiology in the Capital Apr 25-27, 2013, Washington, DC

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May 3, 2013, Rochester, MN

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New Frontiers in Endovascular Therapy May 17-18, 2013, Jacksonville, FL

Clinical Autonomic Quantitation Workshop May 17-19, 2013, Rochester, MN

Internal Medicine Board Review: Certification and Maintenance of Certification Jul 15-19, 2013, Rochester, MN

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Oct 11-12, 2013, Rochester, MN

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Southwest Arrhythmia: Bridging the Gap Between Internists and Subspecialists Dec 4-7, 2013, Scottsdale, AZ

Echo on Marco Island: A Case-Based Approach Dec 5-8, 2013, Marco Island, FL

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Mayo Clinic International Vascular Symposium Mar 27-29, 2014, Buenos Aires, Argentina

OTHER EDUCATION OPPORTUNITIES

ACC.13: 61st Annual Scientific Session Mar 9-11, 2013, San Francisco, CA Website: www.accscientificsession.org

International Society for Heart and Lung Transplantation 33rd Annual Meeting and Scientific Sessions

Apr 24-27, 2013, Montréal, Québec Website: www.ishlt.org

Heart Rhythm Society 34th Annual Scientific Sessions

May 8-11, 2013, Denver, CO Website: www.hrsonline.org

Society for Cardiovascular Surgery and Interventions Scientific Sessions

May 8-11, 2013, Orlando, FL Website: www.scai.org

Heart Failure Congress 2013

May 25-28, 2013, Lisbon, Portugal Website: www.escardio.org

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