Public Comment for Implantable Cardiac Defibrillators
Request for Additional Information
CAG-00157R2
June 23-July 23, 2004

Comment #1:
Submitter: Sergio L. Pinski, MD
Organization: Cardiac Pacing and Electrophysiology, Cleveland Clinic Florida
Date: July 7, 2004
Comment:

My name is Sergio L. Pinski, MD. I am a practicing electrophysiologist. I am currently Section Head, Cardiac Pacing and Electrophysiology, Cleveland Clinic Florida. I have been involved in implantable defibrillator therapy for the last 15 years. This area has been the focus of most of my research and clinical activities.

So far, I have refrained to submit my considerations regarding coverage issues, although I have been distraught by your previous decisions and by the unconventional process that you have applied to this therapy in comparison to many others (e.g., coronary artery stenting). I interpreted this as a political process, triggered by fiscal concerns, and fostered by the lack of data on so-called "cost-effectiveness". I did not think that lobbying from my part was appropriate -or even worthwhile. The clinical science (i.e., the results of the randomized clinical trials) spoke by itself.

You are now requesting more specific comments regarding technical issues of ICD therapy. I feel that my expertise in these areas could be helpful to you. It is possible that you are leaning towards expanding coverage of ICDs, while still looking for ways to reduce the associated costs. Cost reduction may be indeed an attainable goal. However, I resist your veiled attempts at "micromanagement" of ICD therapy, mainly by mandating what type of device should be implanted. We have now available several types of ICDs (single-chamber, dual-chamber, CRT-D, with atrial tachyarrhythmia prevention and treatment capabilities, etc.). The decision regarding the best device for each patient should be individualized, based not on a "generic" indication but on the patient's many clinical characteristics and comorbidities. As such, I strongly believe that the selection of the type of ICD should remain the province of the electrophysiologist.

I oppose recommendations regarding the creation of special DRGs based on the indication or the type of device implanted. I believe that the current DRG structure based on the presence of comorbidities (mainly congestive heart failure) adequately reflects the resources consumed in hospital care. Furthermore, I strongly believe that DRG 515 should also be separated in 2 according to the presence of congestive heart failure. Most patients who receive cardiac resynchronization defibrillators today do not undergo invasive EP study or cardiac catheterization during the same admission. The lower reimbursement does not cover the hospital cost of the more expensive device.

Regarding the need for defibrillation threshold testing, there is no randomized clinical data to provide a meaningful response. However, it has been standard clinical practice since the mid-1980s to test the defibrillation capabilities of the device, often times measuring the "defibrillation threshold" (DFT). The origins of this practice go back to the era of epicardial systems with monophasic wavefroms, implanted by surgeons in the OR (see for example Pinski SL, et al. Patients with high defibrillation thresholds: clinical characteristics, management, and outcome. Am Heart J 1991; 122:89?95). Over the years, the performance of these devices improved significantly. With current transvenous, active-can, biphasic waveforms devices implanted by electrophysiologists, failure to defibrillate is uncommon (Shukla HH, et al. High defibrillation thresholds in transvenous biphasic implantable defibrillators : clinical predictors and prognostic implications. PACE 2003; 26:44-8; Hodgson DM, et al. Clinical predictors of defibrillation thresholds with an active pectoral pulse generator lead system. PACE 2002;25:408-13.) Thus, in daily practice (outside clinical trials) measurement of the DFT is no longer necessary. Most of us are satisfied with establishing a "safety margin for defibrillation". In my own practice, this generally entails at most 2 (and often times only one) induction of ventricular fibrillation. This testing carries an additional value: that of assessing the capability of the device to detect ventricular fibrillation. Most of us program a "worst-case" scenario with minimal sensitivity. This is especially useful if the sensitivity needs to be reduced down the road due to oversensing of T waves, myopotentials, or electromagnetic interference. (See for examples: Niehaus M, et al. Adjustment of maximum automatic sensitivity (automatic gain control) reduces inappropriate therapies in patients with implantable cardioverter-defibrillators. PACE 2002;25:151-5; Pinski SL. Evaluation of the pacing function of dual- and triple-chamber implantable defibrillators. In: Barold SS and Mugica J, eds. The Fifth Decade of Cardiac Pacing. New Developments. Futura Publishing, Armonk, NY, 2003). In summary, until definitive randomized data becomes available, I recommend you continue to cover for this service during all ICD implants. (Perhaps the work RVUs assigned to this CPT code could be reduced in the future, to reflect the current practice.) You must be aware that it has been difficult to bill for intraoperative ICD testing (CPT code 93641) in MADIT II patients, as the diagnoses that support medical necessity (ventricular tachycardia, ventricular fibrillation) are not present.

A related question is the need for "pre-discharge" (i.e., next day) retesting of the DFTs. Again, this practice originated in the days of epicardial patches, when the electrophysiologist had little control over what transpired in the OR. Current literature suggests that there is little or no value to routine pre-discharge EP evaluation of the ICD when appropriate function was documented during the implant (see Lurie KG, et al. Prehospital discharge defibrillation testing in ICD recipients: a prospective study based on cost analysis. PACE 1999; 22: 192-6; Glikson M, et al. Are routine arrhythmia inductions necessary in patients with pectoral implantable cardioverter defibrillators? J Cardiovasc Electrophysiol 2000; 11: 127-35.) Most early system malfunctions (lead dislodgement, loose set screw, etc) should be detected by bedside device check, predischarge chest x-ray, and evaluation of the ECG and telemetry strips. Thus, there is no evidence supporting the need for intraoperative plus routine predischarge electrophysiologic testing of the ICD during the same admission.

The evidence that antitachycardia pacing capabilities are valuable in ICD patients is overwhelming. Please note that -contrary to what you state in your question- antitachycardia pacing does not require an extra lead. Antitachycardia pacing is standard in current single-chamber ventricular ICDs. Antitachycardia pacing reduces defibrillation shocks, and defibrillation shocks are the main source of morbidity in ICD patients. The value of antitachycardia pacing was best demonstrated in the PainFree Trial (Wathen MS, et al. Shock reduction using antitachycardia pacing for spontaneous rapid ventricular tachycardia in patients with coronary artery disease. Circulation 2001;104:796-801) and elegantly in a randomized fashion in the still unpublished PainFree II trial. I understand that in SCD-HeFT defibrillators were conservatively programmed as "shock-only". Before endorsing defeatured ICDs on that basis, you should consider 2 facts: a) how many patients in SCD-HeFT could have been spared defibrillation shocks if antitachycardia pacing had been programmed?; and b) in how many SCD-HeFT patients was antitachycardia pacing enabled after an appropriate shock for ventricular tachycardia? Programming an ICD as "shock-only" is not equivalent to implanting a "shock-only" device. In the first case, enabling antitachycardia pacing requires simple reprogramming; in the second case, surgical, costly device replacement. Although you do not want to hear about practice patterns, I would like to let you know that I would never implant an ICD without antitachycardia pacing capabilities. This is really shortchanging the patient.

You are also interested in single- vs. dual-chamber ICD selection. Again, I stress that this decision should be left at the discretion of the electrophysiologist. It must not escape you that the implanting physician has currently no financial incentive to implant a dual-chamber ICD. Contrary to pacemaker implantation, in which there are different CPT codes for single vs. dual-chamber systems, all ICDs insertions are assigned to the same CPT code (33249). Thus, we are not being reimbursed for the extra time, effort, and small risk for additional complications associated with the atrial lead. Thus, if we are rational economic actors (I think we are), when we implant a dual-chamber device we must believe in potential clinical benefit. Again drawing from my clinical practice, I have never regretted implanting a dual-chamber ICD; on the other hand, I have regretted on many occasions implanting a single-chamber system and at times have to come back to revise the system (generally because of the development of unforeseen bradycardias or supraventricular arrhythmias).

You finally ask our opinion regarding the creation of a registry of ICD patients to identify predictors of an appropriate ICD shock. Do you insinuate that such a registry could generate data that overrides the results of multiple randomized clinical trials, the gold-standard for assessing therapies? Are we going backwards? Besides my personal opinion regarding the quality of the data in such registries (i.e., "garbage in-garbage out"), I think that your whole approach to the question is flawed. It appears that you are blind-sided by your perception that this therapy needs to be rationed. What would be the threshold of risk below which one could deny an ICD? The morbidity of ICD therapy is currently so low, that I seriously doubt we would be ever able to reliably and reproducibly identify a

subpopulation of patients with severe left ventricular dysfunction with enough negative predictive value to justify withholding ICD therapy.

Please do not hesitate to contact me if I can be of further assistance.

Comment #2:
Submitter: Juan J Vazquez-Bauza MD FACC RVT
Organization: MidAmerica Cardiovascular Institute
Date: Tues, Jul 13, 2004
Comment:

My name is Juan J Vazquez-Bauza MD FACC, I have been practicing Cardiology since 1990. Currently I am the president of MidAmerica Cardiovascular Institute in Omaha Nebraska. We do not perform ICD' s implants, but deal with all aspect of cardiovascular medicine. We have at our care over 4,000 active patients with about 10% with diagnosis of Cardiomyopathy and CHF. We are the cardiovascular consultant of over 15 Primary care physicians with a combine patient population of over 23,000 lives.

I am writing this letter to you from my concerns in the current guidelines for payment of ICD's. The current criteria have very powerful economic basis to control the use of this devices, and has no valid clinical data. It excludes a significant portion of patients that will benefit from this type of therapy. This patients are been discriminated by economic criteria. This is a contradiction to the Medicare mandate.

It is true that not all patient that meet the MADIT II and SCD-HeFT criteria require the use of this devices. So the question arises on how can we best predict which patients will not benefit of this technology; thus not clinically indicated or been a class III indication for the device.

The technology to predict the patients that do not need the device exist. Microvolt T-wave Alternans (MTWA) is by far the best proven means of risk stratifying the MADIT-II and SCD-HeFT populations. It has the best negative predictive value for any available test (98.8%), by far more than that of the QRS criteria for an equal level of clinical benefit. It also has a high positive predictive value (92%). Certainly, the amount of clinical data evaluating the MTWA is more than that that is currently been used by the CMS.

The current criteria used to pay for the ICD implants is not only limiting the scope of the best practice of medicine, but also opening the door to increase the legal litigations and thus the costs of

malpractice insurance. At the end this will be reflected back in the computation of the RV's.

I urge for a change in position, making MTWA the test for risk stratification and not the QRS determination for the implant of ICD's.

Comment #3:
Submitter: C. David Akin, M.D., F.A.C.C.
Organization: Independence Cardiology Associates, PC
Date: July 13, 2004
Comment:

I am a cardiologist in private practice. We have a group of four cardiologists, none of whom are electrophysiologists. A very common problem in our practice is the appropriate referral for implantation of implantable defibrillators.

This concern is not small, as you know, with risk both ways; i.e., if we refer people who are not candidates, they may end up with a defibrillator they don't need, thus facing the risk and the expense of the procedure. On the other hand, if we don't refer patients who are in need of the defibrillator, sudden death may be the next outcome.

Clearly, in this setting a noninvasive, easily done, reliable risk stratifier to tell us which group of patients does not need implantable defibrillators would be of great value.

I believe that the multiple studies supporting microvolt T-wave alternans (MTWA) as performed by the Cambridge Heart technology supplies this need. Nearly all studies of MTWA have shown extremely low event rates in MTWA negative patients.

Although I know that financial considerations cannot be first in line in these decisions, they are still nonetheless important because of the huge financial impact of putting defibrillators in everybody with an ejection fraction below 35%.

In our practice, we find only one out of three people who meet current criteria as established by the MADIT II trial actually are positive when tested with MTWA. We test approximately six patients per week. Assuming a cost of $400 per MTWA and a cost of $50,000 per implantable defibrillator, a rough estimate is something in the range of $5 million saved per year in avoiding implantable defibrillators that are not indicated in our practice alone. This obviously does not take into consideration the added trauma and risk to patients of getting implantable defibrillators that are not indicated.

At this point in time, MTWA is the only risk stratifier that has this proven track record and I strongly encourage you to consider including the use of this technology in risk stratification of patients with left ventricular dysfunction for consideration of implantable defibrillators.

Comment #4:
Submitter: Bruce G. Hook, MD FACC
Organization: Catholic Medical Center
Date: July 15, 2004
Comment:

I am writing in response to CMS's re-evaluation of indications for reimbursement for ICDs. I am one of 3 electrophysiologists in a 19-person practice based in Manchester, NH, where I have been since 1993. Our site implants approximately 250 ICDs annually. We have been active in clinical trials, having participated in MUSTT, SCD-HeFT and DEFINITE, all of which have provided significant findings now under review. I have several comments which I hope you will take into consideration in formulating CMS policy regarding the prophylactic use of ICDs in high risk patients:

1). Regarding DFT testing, all of the clinical trials demonstrating a survival benefit of the ICD have required successful DFT testing at implant. The entire history of ICD therapy is based on successful defibrillation at implant and to deviate from this practice could jeopardize the beneficial effects of this therapy. In fact, this issue came up early on at an investigators meeting for SCD-HeFT. Several investigators wanted to implant the device without testing, but a forceful argument was made as stated above that the therapy has only been shown to reduce mortality if proven successful defibrillation is demonstrated prior to hospital discharge. To change this policy would require new clinical studies to document that untested device implants achieve the same mortality benefits. Indeed, in the July 7, 2004 issue of JACC Drs. Strickberger and Klein discuss the rationale for DFT testing at the time of implant and provide several references to support this standard of care. I simply cannot imagine abandoning this important aspect of ICD therapy.

2) The current decision to cover the MADIT II population only with a QRS duration greater than 120 ms is based on flawed statistical analysis and does not provide the best discriminator of those patients at lowest risk who may not require ICDs. In fact, data regarding the use of T wave alternans have consistently shown an excellent negative predictive value, with sudden death rates in T wave alternans negative patients less than in MADIT II patients treated with ICDs.

3) The role of antitachycardia pacing in this population is significant. Studies such as the PainFree trial sponsored by Medtronic (in which our center participated) have demonstrated that approximately 80% of VT episodes even at very rapid rates can be terminated with antitachycardia pacing. This can eliminate the discomfort of a shock and offers a significant quality of life benefit. While the SCD-HeFT trial programmed devices to

shock only, I believe strongly that antitachycardia pacing is the best initial therapy for most ventricular tachycardias. Mandating implantation of "shock only" devices would represent an unprecedented intrusion upon physicians' choice in delivering the best care. I don't see CMS dictating which stents the interventional cardiologist implants or which heart valve the cardiac surgeon implants. These clinical decisions are best left to physicians and not payors.

4) Finally, in regard to an ICD patient registry, I can see the benefit of collecting more information of possible clinical predictors of appropriate ICD firing. However, we need to insure that such a registry would not be a substitute for expanded coverage for ICD use. The data from multiple trials showing a survival benefit with prophylactic
ICD use is overwhelming. Our patients need access to this important therapy now. The creation of a registry can certainly provide important additional information, but the evidence is overwhelming in favor of ICD benefit in the populations outlined above.

I hope that you will consider these comments in formulating CMS policy and allow our patients access to this important life-saving therapy.

Comment #5:
Submitter: Anthony R. Magnano, MD
Organization: Columbia University
Date: July 14, 2004
Comment:

I am an electrophysiologist at Columbia University College of Physicians and Surgeons and the New York Presbyterian Hospital. I see a large number of patients with arrhythmias and those who are at risk for sudden cardiac death. I am concerned about the arbitrary way that we are forced as clinicians to triage patients for ICD therapy vs. medical therapy. The current guidelines do not encompass all individuals at significant risk. It is difficult to advise my patients that they fit into multiple consistent clinical trial proving ICD benefit for them (particularly Madit II with narrow QRS complex and SCD-Heft), yet they cannot have the life-saving therapy due to CMS rulings and insurance issues. T wave alternans testing is promising because of its strong negative predictive value and its applicability to a wide range of patient populations (in contrast to EP study). I strongly urge that you consider adopting T wave alternans as a risk stratifying tool. This would provide great benefit to me as a physician and, most importantly to my patients and their families. I am not alone among electrophysiologists in heavily relying on T wave alternans for predicting sudden cardiac death risk in my patients. In fact, T wave alternans positive patients at many

institutions are getting unnecessary EP studies with overly aggressive protocols in hopes of inducing ventricular fibrillation. This finding is scientifically meaningless and the additional testing is potentially dangerous for patients, however it does give a physician an "accepted" reason to give an ICD to a patient who everyone agrees is at high risk. I do not use this approach. Instead I write a lengthy letter to insurance companies explaining why I want to place an ICD, the data and studies that support my decision and ask for their blessing and coverage. I am hoping that there will soon be a day when I can use ICDs in patients who I think are at risk, rather than those who insurance companies think are at risk.

I have developed elaborate algorithms for data driven approach to sudden death risk stratification that relies on clinical trials. Where trials have been "overly inclusive" in their populations studied, I advocate a T wave alternans based approach, relying on its strong negative predictive value to safely defer ICDs in selected populations.

I would like to add that, while I have been involved in research activity, I have no direct or personal financial interests in T wave alternans technology.

While these are difficult times in terms of determining the best way to apply expensive life-saving technology in our population, I envy your position because of your potential to help so many patients.

Comment #6:
Submitter: James Hochrein, MD
Organization:
Date: July 16, 2004
Comment:

I am a community physician in Greensboro, NC. I have a special interest in heart failure and, as such, I have tried to become very familiar with the ICD studies. I read with a critical eye as am an not a paid consultant for any medical device company. It appears to me that we cannot determine high risk individuals based on the length of their QRS on EKG. It is my strong feeling that if one of my loved ones or I had an EF of <35%, from any cause, I would want a defibrillator. It is unfortunate that we cannot yet further risk stratify this group because I do realize what a huge financial impact this will be. However, we continue to participate in studies trying to find tools that will give accurate risk stratification. Until such tools are identified, we need not exclude patients based on sub study information.

Thank you for your time.

Comment #7:
Submitter: Peter Chang-Sing, MD FACC
Organization: American College of Cardiology
Date: July 18, 2004
Comment:

This E-mail is in response to the request for public input into new guidelines for ICD implantation based on the SCD-Heft data.
There seems to be a big push, possible from device manufacturers, to reduce the need for threshold testing at device implant. While the devices have become more sophisticated, as an active implanting board-certified electrophysiologist, I feel comfortable in stating that there are at least a few instances every year when the original implant site of the ICD lead is not associated with effective defibrillation and this failure is only detected with testing, not with fluoroscopic position or other parameters. As you may know, the Heart Rhythm Society, under pressure from the device industry as well as burdened with the need to develop guidelines to avoid completely non-trained cardiologists from implanting ICD's (in many specific areas where EP specialists were less available) , is in the process of establishing such guidelines.

While these are all positive developments to help identify patients in need of these devices and to facilitate providing these beneficial implants, I fear that there will be great room for abuse in terms of selection criteria of patients (how to really quantify an ejection fraction, NYHA Heart Failure Class), implantation by unqualified cardiologists and implantation in hospitals motivated more by providing an extra revenue-generating proceedure but without the necessary personnel to make this service safe.
Removal of the need for threshold testing, removal of the need for American Board of Internal Medicine Board Certification in Clinical Cardiac Electrophysiology and less stringent application of guidelines for patient selection have the potential to create widespread abuse with poor care of patients by physicians who have not met the stringent training requirements of the ABIM and runaway costs since these are not inexpensive devices and should be reserved only for those patients in whom cost-effective benefit has been shown. These are extremely sophisticated devices and many hospitals without active EP programs simply do not have the trained personnel to provide the necessary support for proper implantation and troubleshooting of these devices. Hospitals with only active Cardiac Catheterization Labs and Heart Surgery programs but without active EP labs would still not qualify to provide these highly skilled nursing services.

Based on the current distribution of pacemaker implants geographically and the proposed volume requirements, if your guidelines are not carefully matched to stringent indications and implanter training and board-certification, I estimate that the volume of ICD implants would increase by 50 to 100% within 12 months and this is a conservative estimate.

I thank you for your kind attention to this serious matter.

Comment #8:
Submitter: Arthur J. Moss, MD
Organization: University of Rochester Medical Center
Date: July 18, 2004
Comment:

I understand that you are requesting comments and feedback on three specific questions regarding the appropriate use of the implantable defibrillator.

First, by way of potential conflict of interest, let me say that I am the principal investigator of MADIT-II ICD device trial with support of the research by a grant from Guidant Corp. to the University of Rochester of which I am a senior faculty member. As part of full disclosure, I hold no stock or stock options in any device company and I am not a member of any corporate advisory group or speakers' bureau.

Question 1: What is the evidence surrounding the necessity of threshold testing at the time of implantation? I have no published data on this issue, but it seems to me that it is appropriate to carry out ICD threshold testing at the time of implantation to be sure the defibrillating ICD lead is properly positioned for electrical defibrillation. No one would ever put in a pacemaker without testing the pacing threshold to be sure a pacemaker is working properly. The same rationale should apply to the implantation of a defibrillator. In the absence of defibrillator threshold testing, one cannot be sure that the implanted unit will effectively defibrillate a ventricular fibrillation rhythm. If the defibrillating threshold is inappropriately high, the lead is usually repositioned to obtain a lower defibrillator threshold. To eliminate defibrillator threshold testing would be a life-threatening disservice to some patients.

Question 2: What is the evidence of benefits and risks of adding anti-tachycardia pacing to the function of an implantable defibrillator, including the risk of an additional lead? From MADIT-II, we have the following data that are part of a manuscript that has been accepted for publication in Circulation. First, it should be appreciated that many patients in the ICD trials receive more than one appropriate ICD therapy, although the typical Kaplan-Meir and Cox analysis presentations deal exclusively with only the first therapy. In MADIT-II, 720 patients received an ICD, and 169 of these patients received 701 appropriate ICD therapies for VT or VF. The breakdown of these therapies is as follows: 281 episodes of VT were terminated by anti-tachycardia pacing (ATP); 305 episodes of VT were terminated by shock; and 115 episodes of VF were terminated by shock. Thus, 40% of all VT/VF episodes were terminated by ATP (281/701 = 40%). We simply do not know how many of the 281 VT episodes terminated by ATP would have spontaneously terminated, and how many VT episodes would have progressed to VF. However, the reduction in mortality with the ICD was greater than could be accounted for by the number of fist successful ICD therapies for VF -- strongly suggesting that ATP played an important role in achieving a beneficial hazard ratio of 0.69 for MADIT-II, a value meaningfully lower than the hazard ratio of 0.77 achieved in SCD-HeFT that did not incorporate ATP in the implantable defibrillator. I would be glad to provide a pre-print of the forthcoming MADIT-II publication that

contains this data if you so desire.

In MADIT-II, the overall risk of lead implantation was very small (NEJM 2002;346:877-883) and all patients had ICD units with ATP.

Question 3: Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?" MADIT-II involved an extensive collection of baseline data, and we were not able to identify any baseline characteristic that identified patients who would go on to require ICD therapy for VF. An ICD patient registry would be of some interest and might provide limited new data on predictors of ICD firing for VF. The problem with such registries is that data are often incomplete, cannot include new and sophisticated electrophysiologic data, and are rarely considered scientifically sound. In this regard, we have recently submitted an NIH grant to investigate sophisticated non-invasive predictors for VF firing (heart rate turbulence, T-wave alternans, heart rate variability, etc.) in a large population of patients who are receiving an ICD for an approved indication. I would encourage prospective scientific studies rather than a registry to obtain a valid answer to the question you are raising.

I hope these comments are of help to you in your deliberations.

Comment #9:
Submitter: William C. Lindsay, MD FACC
Organization:
Date: July 17, 2004
Comment:

HRS has asked us to provide you with input on 3 specific questions regarding ICDs.

1 What is the evidence for necessity of threshold testing at the time of implant?

I'm not sure a large scale clinical trial addressing this has ever been performed, nor do I think it would be ethical. Although most of the patients do have acceptable defibrillation thresholds at implant with the first configuration, some don't requiring either repositioning of the lead, replacement of the device with a higher output unit, or reconfiguring the shock vector. Certainly if a test shock under ideal conditions in the OR/lab doesn't get someone out of VF, why would you expect it to work in the field?

2. What evidence of benefits and risks of adding anit tachycardia pacing (ATP) to the function of an implantable defibrillator, including the risk of an additional lead?

As ATP utilizes the sensing portion of the shocking lead, there is no additional hardware required for this feature. If the pace/sense portion of the shocking lead develops a problem, then you have to replace the lead anyway, as

the device otherwise does not function appropriately to detect the patient's rhythm. As far as ATP, I recently had one patient who was pace terminated out of ventricular tachycardia 36 times in a 6 month period and he never knew it. If he had gotten shocked that many times, not only would it have incurred a great deal of cost for him presenting to Emergency Rooms, but it would have depleted the ICDs battery that much faster requiring replacement at a much earlier time incurring yet more unnecessary cost. Cost factors aside, this is a humanitarian issue. ATP is painless. Shocking hurts like hell, and can cause accidents because of either the startle factor, or because of the additional time it takes to charge and deliver a shock could result in impairment of consciousness Thus a study to measure this would likely not be ethical.

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictions of ICD firing for VF (as a proxy for SCD).

The literature does show that a substantial amount of VF is the result of deterioration of VT. If VT is terminated (painlessly) by the ICD via ATP, a VF shock registry would undercount the number of lives saved. I doubt the ethical justification of deactivating ATP to see how many people would get shocked, which could increase the risk of alterations of consciousness and accidents (especially if they were driving at the time), nor could I see a lot of patients volunteering for this experiment.

Comment #10:
Submitter: Daniel L Lustgarten, MD, PhD
Organization: The University of Vermont College of Medicine
Date: July 16, 2004
Comment:

I am writing regarding the upcoming CMS reassessment of indications for ICD implantation.

I am ABIM certified in Cardiovascular Electrophysiology, Cardiology, and Internal Medicine.

I am part of a University-based practice and I am on Faculty at the University of Vermont. My partners and I implant approximately 200 devices per year, and serve an encatchment area of 750,000.

I trained at Massachusetts General Hospital, and my first Faculty appointment was at the University of Oklahoma where I worked with Drs. Warren Jackman and Dwight Reynolds.

I am writing to urge CMS to dispense with QRS duration as a reimbursement criterion. QRS duration is known not to be predictive of

ICD benefit, and patients with QRS < or > 120 msec both benefit from ICD implantation, as demonstrated in SCD-HeFT. Therefore patients who have been determined on the basis of a well designed prospective trial to benefit from ICD implantation are not receiving this life-saving intervention. The disparity between prospective clinical trial data and CMS recommendations places my colleagues and me in an untenable and unethical position of having to ask patients to accept financial responsibility for a life saving therapy which typically they cannot afford.

It is equally clear that we need a better test to define those patients who will actually need the device. While we remain at a loss for a study with adequate positive predictive value, there are excellent clinical data to support the use of annual Microvolt T-Wave Alternans testing as a negative predictor in patients with EF less than or equal to 30% and a narrow QRS complex. Furthermore on the basis of SCD-HeFT findings, I believe this should pertain to patients with EF's up to and including 35%.

Thank you very much for taking this point of view into consideration.

Comment #11:
Submitter: George H. Crossley, MD
Organization:
Date: July 16, 2004
Comment:

1. What is the evidence surrounding the necessity of threshold testing at the time of implantation?

The answer to this question is purely a statistical function. If one were to accept a certain level of failure (deaths), then not testing would be acceptable. In our practice, of the last 450 patients, there were 26 that required that we either move the defibrillation lead or implant additional hardware. These patients would have died with their first shocks if we had not done defibrillation testing at implantation. The risk factors for failure have been reviewed and most people consider that it is not generable predictable. This subject is best reviewed in the chapter written by Mark Kroll and Pat Tchou in Clinical Cardiac Pacing and Electrophysiology (edited by Ellenbogen, Kay and Wilkoff). If you need a photocopy of that chapter, I will gladly provide it.

It is my opinion that the drive to suggest that we should not do defibrillation threshold testing at implantation is purely an economic one. It is an attempt by some of the manufacturers to create a new market of

non-expert implanters. This would be a significant decrease in the level of care that we now provide.

2. What is the evidence of benefits and risks of adding anti-tachycardia pacing to the function of an implantable defibrillator, including the risk of an additional lead?

There are 2 important answers to this question.

FIRST: The strongest benefit of anti-tachycardia pacing is on the quality of life. Shocks hurt and ATP doesn't. If one poorly programs that ATP then one could increase the risk of syncope and or injury. However, the recently completed PainFree study demonstrated that 75% of episodes that ICD patient had could be terminated by ATP. I have attached a copy of that manuscript in PDF format.

SECOND: The question seems to suggest that ATP would require "an additional lead". This is categorically untrue. Single chamber, dual chamber and BiV devices all allow for ATP. The only device that doesn't have ATP is the German made "airbag" device, and based on the above referenced study, the used of that device would be outside the standard of care.

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?"

While I would certainly support such an effort, I suspect that the end result will be similar to the SCDHeFT study.

Shock Reduction Using Antitachycardia Pacing for Spontaneous Rapid Ventricular Tachycardia in Patients With Coronary Artery Disease

Mark S. Wathen, MD; Michael O. Sweeney, MD; Paul J. DeGroot, MS; Alice J. Stark, RN, PhD; Jodi L. Koehler, MS; Michael B. Chisner, MD; Christian Machado, MD; Wayne O. Adkisson, MD; for the PainFREE Rx Investigators

Background—Implantable cardioverter-defibrillators (ICDs) can terminate some ventricular tachycardias (VTs) painlessly with antitachycardia pacing (ATP). ATP has not routinely been applied for VT >188 bpm because of concerns about efficacy, risk of acceleration, and delay of definitive shock therapy. This prospective, multicenter study evaluated the efficacy of empirical ATP to terminate fast VT (FVT; >188 bpm).

Methods and Results—Two hundred twenty coronary artery disease patients received ICDs for standard indications. Empirical, standardized therapy was programmed so that all FVT episodes (average cycle length [CL] 240 to 320 ms, 250 to 188 bpm) were treated with 2 ATP sequences (8-pulse burst pacing train at 88% of the FVT CL) before shock delivery. A total of 1100 episodes of spontaneous ventricular tachyarrhythmias occurred during a mean of 6.9±3.6 months of follow-up. Fifty-seven percent were classified as slow VT (CL≥320 ms), 40% as FVT (240 ms≤CL<320 ms), and 3% as ventricular fibrillation (CL<240 ms). A total of 446 FVT episodes, mean CL=301±24 ms, occurred in 52 patients (median 2 episodes per patient). ATP terminated 396 FVT episodes (89%), with an adjusted efficacy of 77% (95% CI 68% to 83%). VT acceleration caused by ATP occurred in 10 FVT episodes (4%). FVT arrhythmic syncope occurred on 9 occasions (2%) in 4 patients.

Conclusions—FVT (CL<320 ms) is common in ICD patients. ATP can terminate 3 of 4 of these episodes with a low incidence of acceleration and syncope. ATP for FVT may safely reduce the morbidity of painful shocks. **(*Circulation*. 2001;104:796-801.)**

Key Words: tachycardia ■ cardioversion ■ defibrillation ■ pacing

Implantable cardioverter-defibrillators (ICDs) can be programmed to deliver tiered therapy for spontaneous ventricular tachyarrhythmias. Conventionally, slower, hemodynamically stable ventricular tachycardias (VT) are treated with antitachycardia pacing (ATP) and low-energy cardioversion, whereas faster, hemodynamically unstable VT and ventricular fibrillation (VF) are treated with immediate high-energy shock.[1] Cardioversion shocks are very effective in terminating slow and fast VT (FVT) but are painful and impose considerable battery drain, whereas ATP is painless and has negligible battery drain. ATP has been shown to be effective in terminating 90% to 96% of episodes of spontaneous VT with cycle length (CL) >300 ms.[2–8] Many episodes labeled as VF by ICDs actually are rapid monomorphic VT.[9,10] Although evidence exists that ATP can effectively terminate some of these faster VTs,[2,3,5,8] these arrhythmias are usually treated with shocks because of concerns about efficacy, risk of acceleration, and syncope due to delay of definitive shock therapy. The objective of this study was to determine whether spontaneous FVT (CL 240 to 320 ms, 188 to 250 bpm) in patients with coronary artery disease (CAD) can be reliably and safely terminated by ATP, thus reducing painful shocks.

Methods

Patient Selection

Two hundred twenty patients with CAD and standard indications for ICD therapy were enrolled at 25 centers from April 1998 through November 1999. All patients underwent implantation of pectoral ICD systems with a transvenous endocardial lead positioned at the right ventricular apex.

On hospital discharge, patients were given a diary in which they were instructed to list the time and date of symptoms possibly related to spontaneous ventricular arrhythmia, such as near-syncope or syncope. Each patient was followed up for 6 to 12 months, with clinic visits, diary submission, and ICD interrogation every 3

Received February 8, 2001; revision received May 29, 2001; accepted May 31, 2001.

From Vanderbilt University Medical Center, Nashville, Tenn (M.S.W.); Brigham and Women's Hospital, Boston, Mass (M.O.S.); Medtronic, Inc, Minneapolis, Minn (P.J.D., A.J.S., J.L.K.); St Joseph's Hospital, Savannah, Ga (M.B.C.); Providence Hospital, Southfield, Mich (C.M.); and Park Nicollet Heart Center, St Louis Park, Minn (W.O.A.).

P.J. DeGroot, A.J. Stark, and J.L. Koehler are employees of Medtronic, Inc, the manufacturer of the study devices.

Correspondence to Mark Wathen, MD, Vanderbilt Page-Campbell Heart Institute, Vanderbilt University Medical Center, 2220 Pierce, Nashville, TN 37232. E-mail mark.wathen@mcmail.vanderbilt.edu

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months. Stored device data regarding spontaneous detections and therapies were retrieved and transferred to a central database for evaluation. Syncope was defined as complete loss of consciousness with loss of postural tone, and near-syncope was defined as dizziness or lightheadedness.

An independent data and safety monitoring board composed of nonparticipating physicians regularly reviewed all adverse events, including deaths.

Device Description and Programming

All patients had Medtronic ICD systems capable of delivering ATP for FVT within the VF detection zone (MicroJewel model 7221, MicroJewel II model 7223, Gem VR model 7227, Gem DR model 7271, Gem II VR model 7229, and Gem II DR model 7273).

FVT detection and initial therapy programming were standardized. Detection in the VF zone required 12 of the last 16 R-R intervals with CL<320 ms. An FVT detection zone was defined within the VF zone (FVT via VF) for CL 240 to 320 ms. VF zone detections in which ≥1 of the previous 8 R-R intervals were <240 ms were classified as VF and treated with immediate high-voltage shock. The first therapy in the FVT zone was 2 ATP sequences (8-pulse burst pacing train at 88% of the FVT CL). If the first ATP sequence was unsuccessful, the second sequence was delivered at 88% of the FVT CL minus 10 ms. ATP therapies were delivered at maximum voltage and pulse duration (8 V/1.6 ms). Programming of subsequent FVT therapies was left to the investigators' discretion and usually involved shocks. All devices were programmed to store far-field electrograms before the onset of detected episodes to aid in rhythm classification. Investigators were allowed to modify FVT therapy programming after 1 recorded episode of spontaneous FVT. A slow VT zone was not requisite for study participation. If the investigator elected to program a slow VT zone, however, the first therapy was programmed identically to that of the FVT zone.

Rhythm Classification and Definitions

All stored far-field electrograms from spontaneous episodes were classified by predetermined criteria based on visual inspection and comparison with sinus rhythm far-field electrograms. Two additional blinded reviewers evaluated spontaneous episodes classified as supraventricular tachycardia. When the 3 reviewers did not agree, the implanting investigator was consulted for additional clinical data. The majority rule was applied to eliminate supraventricular tachycardias from further analysis. Ventricular tachyarrhythmias were then analyzed by their device classification (VF, FVT, or VT). When the number of episodes exceeded the electrogram storage capability of the device, episodes without an accompanying electrogram were analyzed on the basis of device classification without further screening.

Acceleration was defined as >10% decrease in CL, with the device reporting CL as the mean of the last 4 intervals preceding detection. Episode duration was also defined according to the device and included time after therapy until the episode termination criterion was met. Therapy was deemed successful when the posttherapy rhythm was not a ventricular tachyarrhythmia.

Data Analysis

Data were analyzed on an intention-to-treat basis. ATP therapy was deemed successful if confirmed FVT was terminated by the first- or second-burst ATP sequence. CIs were calculated by use of the exact binomial distribution for percentages applied to the patients' first episodes. To adjust for multiple episodes per patient, the generalized estimating equation was used.[11,12] Mortality rate was determined by Kaplan-Meier estimation. Statistical analyses were performed by use of SAS version 6.12.

Results

Patient Characteristics

Baseline clinical and demographic characteristics of the study population are shown in Table 1.

TABLE 1. Patient Characteristics (N=220 Patients)

Patient demographics	
Age, y	67±10 (36–87)
Male sex	172 (78)
LVEF	33±13 (8–72)
Cardiovascular medical history	
CAD (required)	220 (100)
With MI	176 (80)
Without MI	44 (20)
Hypertension	112 (51)
NYHA functional class	
I	58 (26)
II	105 (48)
III	49 (22)
IV	6 (3)
Unknown	2 (1)
Spontaneous ventricular arrhythmia history	
Sustained monomorphic VT	95 (43)
Sustained polymorphic VT	9 (4)
NSVT	94 (43)
Ventricular flutter	1 (0.5)
Ventricular fibrillation	35 (16)

Values are n (range) or n (%).

Programming compliance was 98% for the 7 variables necessary to achieve uniform detection and initial therapy for FVT (upper and lower detection CL limits, burst therapy, number of sequences, pulses per sequence, percent FVT CL, and minimum pacing interval).

Spontaneous Episodes Detected

During a mean follow-up of 6.9±3.6 months, 1100 episodes of ventricular tachyarrhythmia were detected in 65 patients. An additional 148 episodes of supraventricular tachyarrhythmias were detected but excluded from further analysis. Four hundred forty-six episodes (40%) were de-

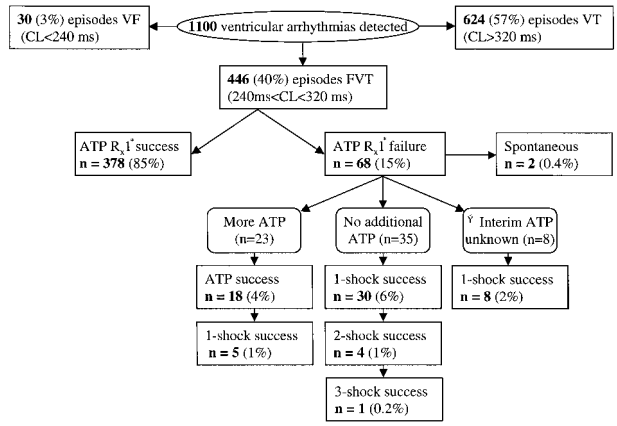

Figure 1. Summary of ventricular arrhythmias detected and therapy sequence for FVT. *By protocol, R_x1 included 2 sequences of burst ATP. YTherapy sequence between ATP failure and 1-shock success unknown because of numerous episodes exceeding device memory capability.

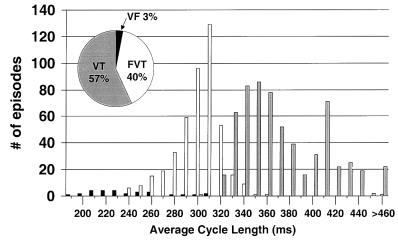

Figure 2. Distribution of ventricular arrhythmias by detection zone and average CL (derived from last 4 CLs before detection, allowing for irregular or undersensed FVT rhythms to have CL>320 ms.)

tected as FVT (mean CL 301±24 ms) in 52 patients (24%) (Figure 1) and were the subject of analysis. Slow VT (mean CL 374±39 ms) occurred for 624 episodes (57%) in 30 patients. Only 30 episodes (3%) in 16 patients were detected in the VF zone (mean CL 236±36 ms). Among the 52 patients with FVT, the median number of FVT episodes per patient was 2 (range 1 to 158). Seventeen patients (7%) had 1 FVT episode, 12 patients (5%) had 2 episodes, and 23 patients (10%) had ≥3 episodes.

Figure 2 shows a CL histogram for spontaneous ventricular tachyarrhythmia episodes. Three fourths of detected FVT episodes had CL 290 to 320 ms. Only 19% had CL≤280 ms, and 6% had CL>320 ms (possible given that CL is the mean of only the last 4 beats before detection). Seventy-four percent of VT episodes fell between 320 and 400 ms, and 26% had CL>400 ms. CL for VF episodes was evenly distributed from 170 to 310 ms.

ATP Efficacy

Of 446 FVT episodes, 378 (85%) were terminated by the first or second ATP sequence (Table 2). Ninety percent of ATP successes came after the first ATP sequence. Outside of the standard study protocol, an additional 18 episodes (4%) were terminated by a third ATP attempt, yielding a total of 89% ATP efficacy. Efficacy adjusted for the occurrence of multiple episodes per patient was 77% (95% CI 68% to 83%).

In 1 episode, the rhythm converted to a slower VT outside the FVT zone, and 1 episode terminated spontaneously before shock delivery. Forty-eight FVT episodes (11%) occurred in

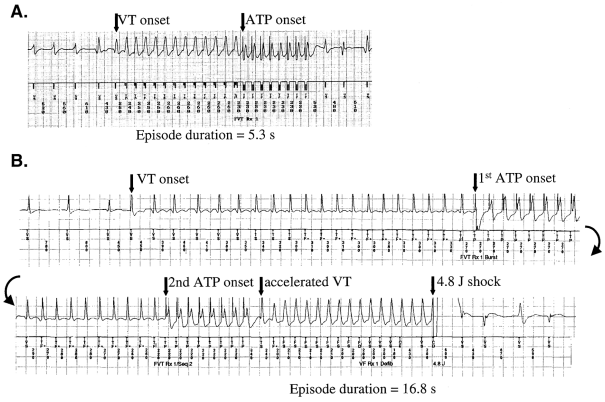

Figure 3. Example of successful termination of FVT by ATP (A). Example of failed ATP accelerating FVT followed by shock termination (B).

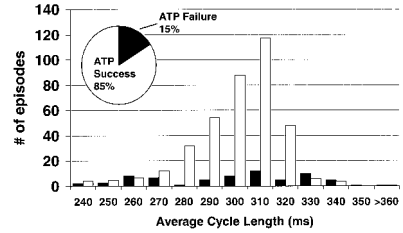

Figure 4. Distribution of ATP success and failure by detected CL.

14 patients who required a shock for episode termination, with no single episode requiring >3 shocks. Examples of ATP success and failure are shown in Figure 3.

Effect of CL on ATP Efficacy

Efficacy of ATP for detected CL is displayed in Figure 4. The mean FVT CL at which ATP was successful versus unsuccessful was not significantly different (301±22 and 299±30 ms, respectively, $P=0.72$). When FVT CLs were dichotomized into two 40-ms groups, initial ATP therapy was successful in 84% of episodes with mean CL 280 to 320 ms versus 69% of episodes with mean CL 240 to 280 ms ($P=0.05$).

Polymorphic VT

Among the 250 episodes with electrograms available for analysis, polymorphic VT was detected in the FVT zone in 6 (2%). ATP was delivered to all and was effective once, whereas a single shock terminated the remainder.

Nonsustained VT

Ninety-four of the 220 patients in this study had a history of nonsustained VT (NSVT). They had higher ATP efficacy than patients without a history of NSVT (90% versus 64%, respectively, $P<0.001$). Patients with NSVT in their arrhythmia history had a median of 2 episodes, whereas those with a history of sustained VT or VF had a median of 1 episode.

Efficacy Within Individuals

The first ATP therapy was effective in terminating 37 of 52 patients' first FVT episode (71%, 95% CI 53% to 83%) (Table 2). In 2 patients (4%), VT was not terminated by the first ATP sequence but ceased spontaneously before the delivery of the second sequence. Thirteen patients (25%) required a shock to terminate their first episode of FVT. Individual success rates were 0% in 6 patients, 100% in 38 patients, and 14% to 75% in 8 patients.

Shocks for FVT Episodes

Fourteen patients (6%) received shocks for FVT. Thirteen required a shock on their first episode of FVT. In patients with ATP success on their first episode, estimated probability of ATP efficacy in subsequent episodes was 99% (95% CI 96% to 100%), and the predicted efficacy after initial ATP failure was 38% (95% CI 15% to 69%, $P<0.001$).

Antiarrhythmic Drugs

One hundred nineteen patients (54%) were on antiarrhythmic drug therapy at the time of ICD implantation (85 on

TABLE 2. Outcome of ATP Therapy for FVT (n=446 Episodes)

Terminating Therapy	Efficacy	Acceleration*	Syncope
ATP therapy (1st or 2nd sequence)			
Raw, n (%)	378 (85)	10 (4)	3 (0.6)
Adjusted†, % (95% CI)	77 (68–83)	7 (3–14)	...
Shock, n (%)	48 (11)	...	6 (1.3)

*Acceleration evaluated in 244 episodes of monomorphic FVT with electrogram stored by the ICD.

†Results adjusted for the occurrence of multiple episodes in the same patient.

β-blockers, 34 on amiodarone, 10 on sotalol, 6 other). In 3 of the 14 patients who received shocks after failed ATP for FVT, the antiarrhythmic drugs were changed after a shock. Limited duration of follow-up prevents us from drawing conclusions as to the effect of the change in drug regimen.

Acceleration

Acceleration was defined as >10% decrease in CL of monomorphic FVT after delivery of therapy. In 244 episodes of monomorphic FVT treated by ATP for which stored electrograms were available for analysis, acceleration occurred in 10 cases (4%, generalized estimating equation adjusted 7%) in 7 patients. All accelerated episodes were redetected in the VF zone (CL<240 ms); 1 self-terminated during capacitor charging, 8 were successfully terminated by a single shock, and 1 required 3 shocks to terminate. Acceleration was associated with syncope in 1 episode terminated by a single shock after 22 seconds.

Episode Duration

The durations of VF and FVT episodes are shown in Figure 5. Episodes initially detected in the VF zone and immediately shocked had a median duration of 10 seconds (range 5 to 16 seconds). Episodes of successful ATP had a median duration of 6 seconds (range 3 to 282 seconds). Episodes in which ATP was unsuccessful and high-voltage shocks were necessary had a median duration of 21 seconds (range 18 to 24 seconds). Each of these durations is statistically different from the others ($P<0.001$). The median duration of all FVT episodes (ATP successful or failed) was 6 seconds (range 3 to 282 seconds).

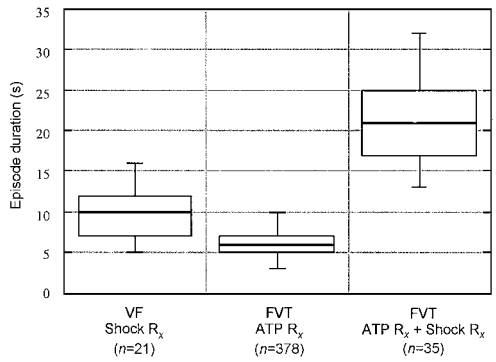

Figure 5. Episode duration associated with episodes of initial VF with shock as first therapy, FVT with successful ATP as first therapy, and FVT with unsuccessful ATP followed by successful shock therapy. Boxes show median and 25th and 75th percentile. Whiskers display SD.

Syncope

Remarkably, most FVT episodes were found incidentally on device interrogation at follow-up because they were asymptomatic. Lightheadedness or dizziness was experienced during 29 of 446 FVT episodes (7%) in 9 patients. The median duration of these episodes was 6 seconds (range 5 to 32 seconds). Syncope occurred in 4 patients during 9 FVT episodes (9 of 446, 2%) (Table 2). In 2 patients with a single syncopal episode and in 1 patient with 2 syncopal episodes, syncope occurred after ATP failure resulted in shock. Each of these patients also had additional episodes of FVT that were successfully pace-terminated without syncope. One patient experienced syncope with each of 5 FVT episodes independently of ATP success or failure. The median duration of syncopal FVT episodes was 17 seconds (range 5 to 33 seconds).

Syncope occurred twice in 1 patient during slow VT and once in each of 2 patients during VF. In addition to the 13 syncopal episodes associated with tachyarrhythmia, there were 6 episodes of syncope not associated with tachycardia.

Death

Thirteen patients died during the study. The cumulative 6-month survival probability for all-cause mortality was 95% (95% CI 90% to 97%). The cause of death was classified by an independent committee as sudden cardiac in 2 patients, nonsudden cardiac in 8 patients, noncardiac in 2 patients, and unknown in 1 patient for whom adequate documentation could not be obtained. One sudden cardiac death occurred in a hospitalized patient whose ICD had been intentionally deactivated. A second patient was unexpectedly found dead at home and classified as sudden cardiac; no postmortem, ICD interrogation, or autopsy data were available.

Discussion

Sustained monomorphic VT in CAD occurs via a macroreentrant mechanism.[13] Pace termination success is therefore limited by ventricular refractoriness, excitable gap, conduction time to the circuit, and circuit abolition or reinitiation.[14] Pace termination becomes more difficult as arrhythmia CL shortens.[3,5,8] The assumption that empirical ATP therapy is ineffective for FVT has resulted in the standard practice of applying shocks as first therapy for FVT. This study demonstrated, however, that empirical ATP therapy terminated 396 of 446 episodes of FVT (89%) and did so with shorter median time to effective therapy. Syncope occurred in 2% of FVT episodes (4 patients), and acceleration occurred in only 4% of episodes. One death had the possibility of being causally related to ATP. The large reduction in number of shocks reduced morbidity caused by shock pain and increased the longevity of ICDs.

This study also demonstrates that rapid monomorphic VT is common, representing 40% of all ventricular tachyarrhythmia episodes. Because previous studies have shown 90% to 96% ATP success rates for VT with CL>320 ms,[2–8] and these data demonstrated an ATP success rate of

89% for VT<320 ms, the combined outcome suggests an opportunity to markedly reduce shocks in ICD patients by optimizing ATP therapy. Furthermore, only 30 episodes (3%) were diagnosed as VF with CL<240 ms. These were the only episodes in this trial that used shock as initial therapy. Given that 13 VF episodes terminated spontaneously, only 17 of 1100 episodes (1.5%) received shock as initial therapy. The ICDs in this trial were used principally as ATP devices with occasional, yet critical defibrillation capabilities.

Quality-of-life scores in the ICD population are poor and are significantly affected by the occurrence of shocks.[15] Shock pain, anticipation of the next shock, antiarrhythmic drugs, and hospitalizations due to shocks are all contributors. A recent trial demonstrated that the principle cause (26%) of all hospitalizations for ICD patients in a 12-month span was due to appropriately detected VT/VF and consequent shocks from their ICD.[16] The results of this trial indicate the possibility of significant hospitalization reduction by empirical ATP for FVT.

The incidence of acceleration of monomorphic VT increases with decreasing VT CL.[3,5,8] To successfully reset VT within the limit of ventricular refractory period, the pacing algorithm in this trial was set at a relatively nonaggressive 8 pulses at 88% VT CL, which yielded an acceleration rate of 4%. Although not desirable, this rate of acceleration compares favorably to previous studies that have shown acceleration rates between 7% and 18% for treatment of spontaneous rapid VT.[2,3] Given the greater success for FVT between 280 and 320 ms, it is possible that both success and acceleration could be improved by different CL cutoffs. The greatest danger may be that acceleration will lead to a rhythm refractory even to shocks. It is possible that 1 patient who died suddenly did so by this mechanism, because no data exist regarding the circumstances of that patient's death. Defibrillation thresholds have been shown to increase with episode duration.[17] In this trial, however, every episode reviewed was terminated successfully by shock when ATP failed, although 4 episodes required 2 shocks and 1 required 3 shocks. Given the probabilistic nature of defibrillation, this is not a disproportionate number of episodes requiring >1 shock to terminate.

Another risk associated with ATP therapy for FVT is the potential for syncope due to delay of shock therapy. In the 6.9 months of follow-up, syncope occurred in 4 patients and 9 episodes. This 2% incidence of syncope is not significantly different from that reported in other ICD patient groups. Bansch et al[18] reported 4% syncopal rate at 6 months and 10% at 12 months. Although failed ATP causes delay, every shock delivered for a rhythm that could have been pace-terminated also represents delay because it required charging a capacitor, whereas ATP is delivered immediately on detection. It has been assumed that on a population scale, effective therapy could be delivered more quickly as shock rather than ATP because of the higher failure rate of the latter. In this trial, the median duration of VF episode was 10 seconds, compared with an FVT episode duration of 6 seconds. Thus, the strategy of using ATP as first therapy and shock as backup did not lead to longer episodes. An empirical ATP approach seems to present less shock risk without increased syncope or acceleration (although in this study, all devices were in their first year of use and thus had minimal charge times). Despite these efforts, tachycardic syncope is not likely to be eradicated in these patients, as exemplified by 1 patient who experienced syncope with episodes lasting 5 and 6 seconds. Delivery of ATP therapy during capacitor charging may be 1 method to prevent episode duration from increasing. Shocks can be aborted when ATP is successful, or a shock can be delivered without delay when ATP fails.

Study Limitations

The trial was not randomized. Even assuming 100% success rate of shock therapy, however, ATP compares favorably, because efficacy was high and risks of syncope, acceleration, and sudden death were low. One possible confounding factor in estimating ATP success is the possibility for nonsustained FVT rhythms to appear as ATP success. It was recognized that older ICDs with committed therapies were shocking after NSVT had terminated.[19] Although shocks require time for capacitor charge before delivery, ATP is delivered immediately on detection. Therefore, ATP may appear to successfully treat VT that would have otherwise self-terminated. It is interesting that the subgroup of patients with a history of NSVT had a higher ATP efficacy than the patients with no history of NSVT (90% versus 64%, $P<0.001$). This result may suggest that some of the successfully treated FVT rhythms were actually episodes of NSVT. If true, then one would expect an unusually high occurrence of FVT episodes. Patients in this study, however, exhibited 0.7 episodes of VT/FVT/VF per patient per month, similar to the 0.5 episodes per patient per month reported by Schaumann et al[2] for patients with empirical ATP programming. Regardless, even if NSVT was in fact detected as FVT and treated by ATP, the value of programming ATP for FVT remains, because the energy cost is trivial, there was minimal acceleration and syncope, and there is significant benefit in terminating the sustained rhythms.

The ATP parameters were specifically designed for rapid reentrant arrhythmias. Thus, only patients with CAD were enrolled. The application of ATP for FVT in the non-CAD patient population needs to be tested.

Clinical and ICD Design Implications

ICD patients may be spared the majority of painful shocks if ATP is programmed as the first therapy for FVT. The longevity of ICDs may be improved by fewer capacitor charges. Future development of ICDs may benefit from algorithms that distinguish polymorphic from monomorphic FVT, more sophisticated ATP with closed loop capability to evaluate the effect of each ATP pacing pulse, and by ATP during capacitor charging. Further trials are needed for VT with even shorter CL. Reduced incidence of shock may improve acceptance of ICDs, currently a major barrier to application of ICD therapy to those at risk for sudden death.

Acknowledgments

This study was supported by a research grant from Medtronic, Inc. The authors wish to acknowledge the help of Mark Anderson, MD, PhD; Linda Johnson, PhD; Kristen McKercher; Dan Roden, MD;

Vinod Sharma, PhD; and Kathy Walter in preparation of the manuscript.

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Comment #12:
Submitter: Steven Higgins, MD
Organization:
Date: July 20, 2004
Comment:

Although it is no longer listed on your "NCAs Open for Public Comment" page, I am under the impression that commentary opportunities are still open regarding the third comment period about the appropriate use of implantable defibrillators.

Question 1. What is the evidence surrounding the necessity of threshold testing (DFT) at the time of implantation?
I have an extensive clinical experience and have published numerous articles on this subject, some of which I will reference below.
Defibrillation threshold (DFT) testing has been the standard of care for ICD implantation since its inception.(1-6) There are no studies comparing the safety of eliminating this testing. There are studies showing that minimizing testing is safe. (4,6) DFT testing is safe, simple and a standard of care. Implantable defibrillators (ICDs) need to reliably detectg and terminate ventricular arrhythmias. Therefore, DFT testing should be considered essential in ICD implantation.

2. What is the evidence of benefits and risks of adding anti-tachycardia pacing (ATP) to the function of an implantable defibrillator, including the risk of an additional lead?

Let me answer the first portion of this question. ATP has been available in ICDs for about 12 years now. It is the standard of care to program an ATP scheme for termination of ventricular tachycardia, regardless of whether ventricular tachycardia termination by ATP has been proven. In both MADIT and MADIT II, ATP was programmed on and utilized frequently for arrhythmia termination. (7,8) This painless therapy was utilized to terminate almost half of the arrhythmias seen in MADIT II. If a device was manufactured or programmed to not use ATP, these patients would be subjected to a painful and much more dangerous therapy to terminate

their arrhythmia. Imagine the patient driving on the freeway who develops non-syncopal VT. ATP can silently terminate that arrhythmia without the risk of a shock and the drivers reaction to it. Regardless of the indication (MADIT, SCD-HeFT, etc.), patients need to have the availability of ATP to best benefit from ICD theray.

The "additional lead" addition is confusing to me. ATP is delivered by a single lead (ventricular) ICD. If you are referring to the "leadless ICD", it is still too early to determine if these devices are effective and of value without ATP. If you are referring to an additonal lead such as an atrial or left ventricular lead, ventricular ATP is not an issue as it is already available via the first ventricular lead. Regarding additional leads, physicians can and should be able to determine the need for such ICD configurations.

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?

While there appears little problem with charging industry to police the efficacy of their devices with a post-approval registry, I have some concerns.
The reliability of such data is always in question. The expense for such registries will add to the already high cost of these devices. The temptation for industry to "reward" physicians for obtaining registry data is a negative impact on the field. I believe this could better be handled in the current fashion of requiring industry to submit detailed documentation of device function before approval and then allowing the medical scientific community to perform peer-reviewed research utilizing these devices. Under this more rigorous model, we are more likely to obtain reliable data regarding device utilization and safety.

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Comment #13:
Submitter: Brian Olshansky, MD
Organization: University of Iowa Hospitals
Date: July 20, 2004
Comment:

I want to provide my opinions concerning issues regarding ICD implants in patients similar to those enrolled in the SCD-HeFT Trial. This involves three specific issues:

1. What is the evidence surrounding the necessity of threshold testing at the time of implantation?

There is substantial evidence that threshold testing is necessary and if it is not performed properly a substantial percent of patients may have ineffective implants increasing the danger to patient. Device testing is presently standard of care and for good reason: if it is not performed a patient may have a device and a lead placed with no evidence of effectiveness. Some patient will suffer and some will die from a device that is not effective. Restricting device choice in policy is not workable and will not likely be followed based on current medical practice by the large majority of electrophysiologists. A device choice found "incorrect" by audit, after the fact, could lead to charge of fraud.

Threshold testing at implant is used to create a safety margin to ensure adequate energy for ambulatory defibrillation. Two primary techniques are in use. A threshold test showing an inadequate margin typically results in lead integrity checks, lead repositioning or an additional lead being added to the system. Threshold testing at implant has been an FDA requirement for over 10 years. Threshold testing is expected to remain an FDA requirement until a clinical trial demonstrates that it is not necessary. The first paper establishing the importance of a 10 joule safety margin was Marchlinski et. al., Am J Cardiol, 1988;62.

SCD-HeFT, a "new indications" trial, was not designed to shed information on device type and features. Patient indications (coverage) is the purview of CMS, not device features. No controlled randomized data support elimination of threshold testing at time of implant.

2. What is the evidence of benefits and risks of adding anti-tachycardia pacing to the function of an implantable defibrillator, including the risk of an additional lead?

Adding anti-tachycardia pacing (ATP) to an ICD is not new. In a 1998 article (Schaumann et. al., Circ., 1998;97) the success rate of ATP in terminating 1,346 spontaneous ventricular tachycardia was 90 %. Five percent of episodes accelerated to ventricular fibrillation . Failure to avoid unnecessary shocks can result in poor quality of life, injury, or refusal to accept an implant, leaving the patient at risk of sudden cardiac death.

ATP is available on single lead and dual lead devices. The device used in the SCD-HeFT trial had ATP capability. While a "shock box"can improve outcomes in a SCD-HeFT type patient, it is not clear that this is the best and only the best ICD intervention in all circumstances. The advantage of ATP for ventricular tachycardia might be great. The decision of the use of ATP should lie in the hands of the implanter. The idea of restricting a proven feature such as ATP should not be given serious consideration.

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?"

The most frequent justification given for patient registries is that once a product is covered by CMS, all research into its use ceases. For ICDs this has not been the case. Since their initial Medicare coverage in the late 80's ICDs have been studied in numerous large trials. In its own documentation CMS has described registries as being far lower in the hierarchy of evidence than clinical trials. Given that trials continue to be done, there is no scientific justification for development of an ICD patient registry at this time.

Comment #14:
Submitter: Michael Springer MD FACC
Organization: Medical Center Cardiologists PSC
Date: July 20, 2004
Comment:

This is in response to the request for information on Implantable Defibrillator procedures.

1. Defibrillation threshold testing is essential. Multiple factors intrinsic to the individual patient and to lead placement may impact on the DFT. I have had numerous experiences with implanting devices where repositioning of the lead was required to obtain an acceptable DFT. On occasion, a different device capable of higher energy output was required due to higher DFT. There is simply no question that testing the leads for their ability to sense, pace and defibrillate is required.

2. Anti tachycardia pacing is also of benefit to patients. Atrial arrhythmias which occur in more that 1/3 of ICD patients can result in ICD discharges. Anti tachycardia pacing in the atrium can convert many of these arrhythmias and an atrial lead helps with the discrimination algorithms used to diagnose arrhythmias both acutely by the device, and later in the clinic.

3. A registry may be helpful but we need to first define what parameters we are looking at.

Comment #15:
Submitter: John M. Miller, MD, FACC
Organization: Indiana University School of Medicine
Date: July 15, 2004
Comment:

As an electrophysiologist with 20 years' experience in the field, I would like to offer my perspectives on the current status of implantable cardioverter-defibrillator (ICD) indications in the light of currently available evidence, as CMS continues its involved and

necessary deliberations on weighty payment issues. The specific points on which comment has been invited include the evidence for threshold testing at the time of ICD implantation; the relevance of antitachycardia pacing in an ICD; and whether an ICD patient registry has merit. I believe there are both scientific evidence as well as logical bases for addressing each of these.

1) *Is threshold testing necessary for ICD implantation?* This question has been debated for a decade. It would certainly simplify the implant procedure somewhat to avoid initiation and termination of ventricular fibrillation (VF). However, there is evidence that a 10J "safety margin" is optimal for assuring efficacy of shocks to terminate spontaneously-occurring episodes of VF (Marchlinski FE, et al, *Am J Cardiol*, 1988). While one can argue that this is old data, using epicardial patches and monophasic shock waveforms, there is no large body of current data to use in preference. The 10-J rule is relevant both because of the unpredictable patient whose defibrillation requirements exceed the capacity of current devices (approximately 2-3% still from ours and others' databases) as well as the well-known change in defibrillation energy requirement with time that some patients experience based on progression of disease, drug therapy, electrolyte imbalance, etc. One can also quibble with the term "defibrillation threshold;" I do not believe its exact determination is necessary, but one should at least abide by the 10-J criterion. Finally, from a logical perspective, placing an ICD and not testing its defibrillation capacity assumes that all connections are good and the [life-saving] device will work first time, every time (no loose set screws, lead damage during implant, connection of leads to incorrect ports). Doing so would be analogous to implanting a pacemaker, simply connecting the leads to the device and not bothering to check to see if sensing and capture were occurring appropriately. No one would think of doing that, any more than one would write a check for a new car before taking a test drive.
2) *Should antitachycardia pacing (ATP) be incorporated in all ICDs?* If an episode of ventricular tachycardia (VT) can be terminated nearly without symptoms using pacing techniques as opposed to shock therapy, why would one not do so? There is ample evidence as the efficacy of ATP, from its inception in the 1980s (but most particularly in a paper by Walthen, *Circulation*, 2001), with up to 89% of episodes successfully terminated with pacing that would have been given shocks with standard programming. Only 4% of pacing attempts resulted in a faster arrhythmia that then required shock therapy. The morbidity of shocks as opposed to pacing termination bears no comparison. ATP is a well-established therapy with good literature support and should be considered an integral feature of modern ICDs.
3) *Is there good reason to establish a registry of patients for ICD therapy?* I believe the rationale for a registry in this application is lacking. In most cases, registries are a low-level means of monitoring outcomes once a therapy has been approved for general use, with the assumption that further well-controlled, long-term, and expensive randomized trials will not be undertaken. This has certainly not been the case with ICDs, there having been about 15 large randomized trials since the initial FDA approval of the ICD. These trials have been driven not by manufacturers touting improvements in device technology, but by clinical

investigators in response to learning more about pathogenesis of and risk factors for ventricular tachyarrhythmias. With additional trials in the planning or pilot stage (AVID II, MADIT III, etc.), it is reasonable to anticipate that further research into not only expansion of indications for ICDs, but finding means of "filtering" their use in only the highest-risk subsets in which they would have the greatest benefit. Thus, there seems little role for a simple registry in this realm.

Although the economic impact of more widespread use of ICDs, especially in relatively "healthy" Class II heart failure patients such as were shown to have improved survival in SCD-HeFT, cannot be brushed aside, neither can the economic impact of loss of one of these very Class II patients to sudden death. A typical demographic of such a patient is a productive member of the workforce who pays taxes and supports a family, both of which would be adversely impacted by sudden death (thereafter costing the government as opposed to supporting it).

I apologize for the length of this letter, but I believe the decision makers should have all the reasonable input they can obtain in deliberating these important issues.

Comment #16:
Submitter: Eric Prystowsky
Organization: Editor-in-Chief, Journal of Cardiovascular Electrophysiology
Date: July 21, 2004
Comment:

This is in response to the queries posted for comment regarding ICDS (CAG-00157R2). Thank you for allowing me to express my views on the following three issues you raised.

1. What is the evidence surrounding the necessity of threshold testing (DFT) at the time of implant?

The improvement in leads and defibrillators, especially biphasic shocks, has substantially enhanced the safety margin for successful defibrillation. Regardless, about 5-8% of patients need adjustments at the time of implant to ensure an adequate DFT safety margin. Trouble shooting may involve changes in the defibrillating lead position in the ventricle, the addition of more leads, and alterations in shock polarity and path of delivery. Further, there are times when the electrical signal during ventricular fibrillation is too small to be detected and this allows for either no defribillator shock on one given

very late, both of which can lead to patient death. Finally, the randomized trials that demonstrated superiority of the ICD to save lives all included DFT testing, and it is not known whether the survival statistics for the ICD would have been as robust without identifiying the DFT.

2. What is the evidence of benefits and risks of adding anti-tachycardia pacing (ATP) to the function of an implantable defibrillator, including the risk of an additional lead?

Multiple trials have demonstated that ATP can minimize inappropriate therapy when used correctly, and it certainly can successfully terminate even some fast ventricular tachycardias and prevent painful shocks. ATP progamming requires expertise in electrophysiology and should be done by an electrophysiologist. Since the ventricular pacing is through the routine ICD lead, one need not implant an additional lead for this purpose. Backup bradycardia pacing is also done through this one lead.

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden death).

I can see benefit in this enterprise. However, care must be taken to ensure "good" data are entered, which can be a very time-consuming process. The data could provide direction for future ICD therapy, but only if the data base were very rigorous in design and implementation. I feel you should not use an ICD shock as a substitute for death, which would overestimate SCD. ATP and ICD therapy should both be included when appropriate treatment is given for a potentially life-threatening arrhythmia.

Comment #17:
Submitter: John M. Fedor, MD
Organization: The Sanger Clinic, PA and Carolinas Medical Center
Date: July 21, 2004
Comment:

I am writing to comment with regard to considerations for future antiarrhythmic therapies. Thank you in advance for inviting my viewpoints. I have been a practicing electrophysiologist for over twenty years. I work with five other electrophysiologist in a large cardiology group in the Carolinas. We will follow over 1000 patients who have ICDs from our clinic.

First and foremost, as you know, the Sudden Death Congestive Heart Failure Primary Prevention Trial (SCD HeFT) has been completed and its results have been presented. The results indicate a significant improvement in survival of patients with congestive heart failure with reduced left ventricular ejection fractions, both ischemic and non-ischemic disease. I think we as a medical community and as a society we should try an offer our patients the benefit of protection from cardiac sudden death.

There are three additional points that I feel deserve comment:

1. A question has been raised as to the necessity for defibrillation testing at the time of AICD implantation. In our practice we have had a population of over a 1000 defibrillator patients. Approximately 12% of these patients require a high output device or a more complicated lead system to ensure an adequate safety margin for protection from fatal cardiac arrhythmias. Without defibrillation threshold testing these patients would not have an adequate safety margin to protect them from ventricular arrhythmias which could potentially cause cardiac sudden death.

2. A second question has been raised as to evidence for the addition of atrial leads for anti-tachycardia therapy or ventricular tachycardia discrimination. As you know the SCD HeFT trial did have a high prevalence of AICD discharge for apparent atrial arrhythmias. We have found in our clinical practice that the majority of patients with atrial leads discrimination algorithms allow us to significantly reduce the amount of inappropriate shocks for otherwise benign atrial arrhythmias and probably is the best method at present to minimize this unpleasant consequence. In addition about 20% of our patients actively use anti-tachycardia pacing to terminate rapidly ventricular or atrial arrhythmias. We have often found this very helpful to minimize the necessity for electrical shock. Furthermore, we have found electrophysiological studies preoperatively are not always the best predictor in selecting patients who would benefit the most from anti-tachycardia pacing therapy. Certainly, however, patients who most predictably benefit the most from an atrial lead or those who have

significant underlying bradycardia and would need the benefits from cardiac pacing in general.

3. A question has also been raised as to whether or not a patient registry to collect information to help us predict which patients may be at the highest risk for appropriate and inappropriate AICD firing may be beneficial. I think, in general, these days studies that verify a clinical practice, the outcomes of well designed clinical studies are certainly worthwhile if the costs can be contained. Often we learn in observational registries things that we have not found apparent in clinical studies and whether or not clinical practice has changed as time evolves through the availability of doing additional therapies. I think if costs can be contained this may be a beneficial modality to help us understand our arrhythmia patients and provide better care for the future.

Comment #18:
Submitter: Ralph Lazzara, M.D.
Organization: Cardiac Arrhythmia Research Institute
Date: July 21, 2004
Comment:

I served on the Data Safety and Monitoring Board of the SCD-HeFT study. I have been made aware of the request by CMS to address three questions; 1) What is the evidence surrounding the necessity of threshold testing at the time of implantation?; 2) What is the evidence of benefits and risks of adding anti-tachycardia pacing to the function of the implantable defibrillator, including the risk of an additional lead?; 3) Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?.

There is considerable observational data supporting both threshold testing and anti-tachcyardia pacing. This data is readily available in the literature to individuals at CMS. In the absence of data from randomized trials, negating the value of threshold testing and anti-tachycardia pacing, I favor their use. Data from randomized clinical trials would be required to invalidate the consensus acceptance of threshold testing and anti-tachycardia pacing. I am not persuaded of any useful purpose or any scientific justification for a registry as addressed in question 3. The difficult question of identification of accurate predictors of sudden death is best approached, as it has in the past in many studies, by planned clinical investigation including clinical trials.

Comment #19:
Submitter: Jim Coman
Organization:
Date: July 21, 2004
Comment:

I have a comment for the open period regarding the questions posed by CMS for ICDs. Your traditional site does not currently accept comments and I have therefore used this "backdoor".

Your first question pertains to the necessity of DFT testing for ICDs at the time of implantation. Performance of system testing to determine the minimum energy needed to restore sinus rhythm has long been the standard of care. There is no evidence for significantly increased risk in performance of this testing and there is no reasonable replacement test to measure the safe margins for conversion of ventricular fibrillation.

Question 2 . What is the evidence of benefits and risks of adding anti-tachycardia pacing (ATP) to the function of an implantable defibrillator, including the risk of an additional lead?

There is clear evidence that the vast majority (nearly 80%) of inappropriate shocks can be avoided with use of ATP. Additionally, 75% of VT episodes can be termintated with ATP, which avoids the increased morbidity of a painful shock (the only other option for VT if ATP is disabled). The final portion of this question regarding the adiditonal lead is unclear. No additional lead is needed to perform ATP as this is both recognized and delivered through the single ventricular lead. If the question is an attempt to understand the nuances of single versus dual chamber models then I would suggest that choice is best made by the physician of record at the time of implantation as this choice has nothing to do with ATP but rather the health of the AV node and use of the additional atrial channel in tachycardia discrimination.

Question 3: Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation

(as a proxy for sudden cardiac death)?

Registries are frequently useful for determining post-market use information and almost always result in both a demonstration of underutilization as well as provide the impetus for correction of that pattern and therfopre increase the use of the item under study. Would the costs of managing such a large and variable database be covered by CMS. Since the majority of the current CMS decisions are overtly driven by cost containment motives, I am unclear how such a registry would serve your interests since the upfront costs would be high and the universal result from these endeavors is higher utilization.

Comment # 20:
Submitter: David L. Hayes, M.D.
Organization:
Date: July 22, 2004
Comment:

> I would like to comment on the issues regarding the evidence for implantable defibrillators. Please note that this is for the Implantable Defibrillators (CAG-00157R2) public comments.
>
> 1. "What is the evidence surrounding the necessity of threshold testing (DFT) at the time of implantation?"
>
> DFT efficacy assessed at the time of implant has been the standard of care since defibrillators were initiated. It makes sense that we need to determine that the defibrillators are going to work and at what threshold. It is in many ways similar to doing a pacemaker implant and saying "do we need to do pacing thresholds or not?" If we do not have reliable sensing and defibrillation and then do not have effective therapy, we have negated any value of putting the device in in the first place. Granted, there are times, perhaps many times, when you could do without a DFT and set the device to standard parameters and the patient can do quite well. However, there may also be several outliers. Not doing DFT could also lead to the more consistent use of "high-output" defibrillators, which would add to the cost of the defibrillators.
>
>
> 2. What is the evidence of benefits and risks of adding anti-tachycardia pacing (ATP) to the function of an implantable defibrillator, including the risk of an additional lead?
>
> We know from many studies that if you have ATP, you may avoid up to three quarters of inappropriate shocks. Shocks are painful, and if they can be avoided, i.e. either appropriate shocks that have been avoided because of ATP or inappropriate shocks, then it is certainly to the patient's advantage. It is generally thought that because ATP is safe

and highly effective, that it should be used in all patients regardless of whether or not they were induced at a formal EP study. This is backed up by the MADIT-II study. Also, because we do not need an additional lead for ATP therapy, there is no additional risk. It is unclear why this part of the question is added. If there is some question as to single versus dual chamber ICDs, I think that is a completely separate question. It does not have any direct relationship to ATP itself.
>
> 3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?
>
> There is not question that a registry can come up with some extraordinarily important data. The real question is how can it be accomplished. Having worked with potential registries both locally and within the potential of a Heart Rhythm Society registry, the logistics of trying to create such a registry became unmanageable. There are questions about who would own it, who could see the results, who manages the day-to-day, and makes sure it is kept up to date, who is going to organize it, how would you get local physicians from around the country who are already extraordinarily busy to take the time and the cost to enter data, who is going to pay for this? I think there are many more questions than answers, and even though I am not opposed, I think that all of these logistics would have to be worked out prior to mandating such a registry.
>
> Thank you for consideration of these comments.
>

Comment # 21:
Submitter: Stephen Hammill, MD and Bruce Lindsay, MD
Organization: Heart Rhythm Society
Date: July 18, 2004
Comment:

During our recent meeting at CMS Headquarters in Baltimore, MD, you requested information regarding placing implantable cardioverter defibrillators (ICDs) in patients suffering from heart failure with NYHA Class IV symptoms. Thank you for providing us another opportunity to submit comments to the SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) coverage decision. We appreciate CMS's willingness to accept information and comments from the Heart Rhythm Society and from the public at large. After our meeting, as President of the Heart Rhythm Society, I contacted the Heart Failure Society of America (HFSA) and provided HFSA leadership an update of our meeting and forwarded the question and request for information pertaining to Class IV heart failure patients and the appropriateness of ICD placement. HRS encouraged HFSA to respond to you directly and it is our understanding HFSA has done so.

The Heart Rhythm Society is supportive of the comments submitted by the HFSA recommending Medicare coverage for ICD placement in Class IV patients who are candidates for cardiac resynchronization therapy (CRT). This recommendation is based on the COMPANION study results which showed a survival benefit in Class IV patients receiving a CRT-ICD. To further clarify this issue, CRT is indicated for Class IV patients who are then expected to move to a lower heart failure class following successful CRT treatment. The lower heart failure class then would make these patients an appropriate candidate for an ICD based on SCD-HeFT and MADIT II trial criteria. Using a CRT-pacemaker as initial therapy and then upgrading to a CRT-ICD at a later time would not be good patient care or appropriate resource utilization.

If you have any questions related to this issue or any other related to ICD or pacemaker coverage, please contact Amy Melnick, Vice President, Health Policy at 202-327-5430 or amelnick@HRSonline.org.

Sincerely,

Stephen Hammill

Stephen Hammill, MD
President,
Heart Rhythm Society

Bruce Lindsay, MD
Chair, Health Policy Committee
Heart Rhythm Society

Comment #22:
Submitter: Seymour Furman, MD
Organization: Montefiore Medical Center
Date: July 23, 2004
Comment:

I've considered the three inquiries and have the following responses:
1-Threshold testing: Threshold testing is a very important effort required to establish the margin of safety of shock delivery in the event of ventricular tachycardia which cannot be terminated by rapid ventricular pacing or ventricular fibrillation which, of course, cannot be treated by rapid pacing. In the presence of an ineffective shock or with a margin too small other measures are indicated.

2-Antitachycardia pacing: This is a very effective and relatively benign mode of termination of ventricular tachycardia. The patient impact is less than a shock and it is well tolerated. It should continue to be the first line of therapy before resorting to a shock which is commonly intrusive and uncomfortable for the patient.

3-A patient registry may be useful for a variety of observations which are less available from a randomized trial. For example, the incidence of surgical complications, the longevity of different devices and leads in actual use can be determined from such a registry. Some indications which are infrequent may be brought to investigators' attention and be deemed to warrant more careful study, can be found in a large registry.

Comment #23:
Submitter: Barbara J. Calvert
Organization: Guidant Corporation
Date: July 23, 2004
Comment:

Guidant Corporation welcomes the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' (CMS) third public comment period for the national coverage reconsideration of implantable cardioverter defibrillators, posted on the CMS website June 23, 2004.

Headquartered in Indianapolis, Indiana, with manufacturing and/or research and development facilities in the states of Minnesota, California and Washington, as well as in Puerto Rico and Ireland, Guidant Corporation is a leading designer and manufacturer of medical technologies used primarily to treat cardiovascular and vascular illnesses. Guidant's products save and enhance lives.

CMS asked that comments submitted be based on the published literature, not practice patterns. Please note that the answers below summarize the clinical evidence available, and refer to the published documents for further details.

1. What is the evidence surrounding the necessity of threshold testing at the time of implantation?

- *The assessment of defibrillation testing (DFT) efficacy at the time of implant has long been the standard of care. Publications by experts routinely assert that it is intuitively reasonable to ensure that the system has an acceptable DFT safety margin at the time of implant.*[1] [2]
- *The reliable sensing of VF and safe and effective defibrillation are crucial for effective ICD therapy, but assurance of both of these functions appears to require implant testing, and while the exact type of implant testing may need to be reappraised* [3]*, there is yet no consensus regarding suitable surrogates for DFT testing.*

[1] Strickberger, SA, Klein, GJ; Is Defibrillation Testing Required for Defibrillator Implantation? JACC 2004; 44:88-91.
[2] Charles D. Swerdlow, MD, FACC, Reappraisal of Implant; Testing of Implantable Cardioverter Defibrillators; JACC 2004; 44:92-94
[3] Charles D. Swerdlow, MD, FACC, Reappraisal of Implant; Testing of Implantable

2. What is the evidence of benefits and risks of adding anti-tachycardia pacing to the function of an implantable defibrillator, including the risk of an additional lead?

- *Clinical evidence shows that 78% of inappropriate shocks may be avoided when the anti-tachycardia pacing (ATP) feature is used appropriately in an ICD.*[4]
- *ATP can terminate 3 of 4 of ventricular tachycardias and may safely reduce the morbidity of painful shocks.* [5]
- *ATP is safe and very effective and should be programmed "on" in all patients regardless of the predischarge EP inducibility.*[6]
- *In MADIT-II, 720 patients received an ICD, and 169 of these patients received 701 appropriate ICD therapies for VT or VF; 40% of all VT/VF episodes were terminated painlessly by ATP (281/701 = 40%). In the absence of ATP, the only alternative therapy would have been DC shocks, resulting in unnecessary discomfort and alarm.* [7]
- *There is no additional lead necessary for ATP, thus the relevance of this part of the question remains unclear. If the question is meant to explore the need for dual chamber ICDs as opposed to single chamber ICDs, this decision is best left to the treating physician. While it has become apparent that unnecessary and/or inadvertent RV apical pacing may be potentially detrimental, this is more a function of device programming than of the presence or absence of an atrial lead. Previous studies have demonstrated the potential value of atrial based pacing for hemodynamic benefit, symptom improvement, atrial arrhythmia detection and other co morbidities.* [8] [9] [10] [11] [12] [13] [14]

Cardioverter Defibrillators; JACC 2004; 44:92-94

[4] Kopelman, H.; Calkins, H.; Zhang, Y.; Breiter, D.; Hahn, S.; for the LESS Investigators (2002), Use of One ATP Attempt Does Not Compromise Overall Conversion Success. PACE 2002; 24:665 (part II, no. 570).

[5] Wathen MS, Sweeney MO, DeGroot PJ, Stark AJ, Koehler JL, Chisner MB, Machado C, Adkisson WO; PainFREE Investigators. Shock Reduction using antitachycardia pacing for spontaneous rapid ventricular tachycardia in patients with coronary artery disease. Circulation 2001; 104:796-801.

[6] Schaumann A, von zur Muhlen F, Herse B, Gonska BD, Kreuzer H. Empirical versus tested antitachycardia pacing in implantable cardioverter defibrillators: a prospective study including 200 patients. Circulation 1998; 97:66-74.

[7] NEJM 2002;346:877-883

[8] Garrigue, S., Bordier, P., Jais, P., Shah, DC, Hocini, M., Raherison, C., Tunon, Lara M., Haissaguerre, M., Clementy, J; Benefit of atrial pacing in sleep apena syndrome, NEJM 2002 Feb 7:346(6):404-12.

[9] Montanez A, Hennekens CH, Zebede J, Lamas GA; Pacemaker mode selection the evidence from randomized trials. Pacing Clin Electrophysiol. 2003 May;26(5):1270-82.

[10] Kerr CR, Connolly SJ, Abdollah H, Roberts RS, Gent M, Yusuf S, Gillis AM, Tang AS, Talajic M, Klein GJ, Newman DM; Circulation. 2004 Jan 27;109(3):357-62. Epub 2004 Jan 05.

[11] Gillis AM. Card Electrophysiol Rev. 2003 Dec;7(4):345-7.

[12] Kristensen L, Nielsen JC, Mortensen PT, Pedersen OL, Pedersen AK, Andersen HR; Incidence of atrial fibrillation and thromboembolism in a randomized trial of atrial versus dual chamber pacing in 177 patients with sick sinus syndrome. Heart 2004 Jun:90(6):593-4.

[13] Mitchell AR, Sulke N, How do atrial pacing algorithms prevent atrial arrhythmias? Europace 2004 Jul;6(4):351-62

[14] Ricci R, Pignalbert C, Santini M, Efficacy of atrial antitachycardia functions for treating atrial fibrillation: observations in patients with a dual-chamber defibrillator. Card Electrophysiol Rev. 2003 Dec;7(4)348-51

- *This issue is perhaps best summarized in a recent publication by Drs. Kopelman, Calkins, et al. Dr. Calkins comments that "About 250,000 ICDs are in use today, and virtually all of them have the ability to use low energy electrical impulses to painlessly pace the heart in an attempt to terminate an abnormal rhythm, or arrhythmia. This recent study appears to put to rest a debate regarding whether pacing should be attempted before shock: not only does pacing correct the most common dangerous arrhythmia nearly 80 percent of the time, even when it does not work, the short delay before a shock is attempted does not decrease the survival rate"…"There appears to be no downside to trying pacing first, yet there are two major upsides - no pain for the patient and less drain on the ICD battery when pacing alone is used."* [15]

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?

The scientific justification for ICD and/or CRT-D therapy derives from a series of well-designed, randomized controlled trials, which have repeatedly demonstrated the life-saving benefits of ICD therapy in the prevention of Sudden Cardiac Death (SCD) in patients with diminished heart function (e.g. AVID, MADIT, MADIT II, MUSTT, SCD-HeFT, DEFINITE, COMPANION). Such trials are recognized to be the highest form of clinical evidence. Post market registries are typically viewed as providing data of significantly less scientific rigor, but potentially greater insight into actual results in broader patient populations than would normally be included in narrowly developed study populations. However, recent ICD trials, most notably MADIT II and SCD-HeFT, were designed with broad entry criteria so that the results would be generalizable to the overall population. As a result, the additive value of registry data with regard to ICD utilization and benefit is much less clear, while the logistical challenges (including provider compliance, ownership, development of standards and processes, compliance with HIPAA regulations and general accuracy) of such a registry would appear daunting.

[15] Kopelman, H.; Calkins, H.; Zhang, Y.; Breiter, D.; Hahn, S.; for the LESS Investigators (2002), Use of One ATP Attempt Does Not Compromise Overall Conversion Success. PACE 2002; 24:665 (part II, no. 570).

Comment #24:
Submitter: Hugh Calkins, M.D., FACC, FAHA
Organization: Johns Hopkins Hospital
Date: July 23, 2004
Comment:

I understand you are requesting comments on three questions regarding ICD usage. I am the Director of the Clinical Electrophysiology at Johns Hopkins Hospital. I would like to take the opportunity to provide feedback on the questions CMS has raised.

1. What is the evidence surrounding the necessity of threshold testing (DFT) at the time of implantation?

VF testing is a standard part of ICD implantation since the inception ot this therapy. Should it be abandoned, it is likely that the efficacy of this therapy would decrease. Some patients require higher energy devices and revised lead systems.

2. What is the evidence of benefits and risks of adding anti-tachycardia pacing (ATP) to the function of an implantable defibrillator, including the risk of an additional lead?

ATP does not require that an additional lead be placed. ATP terminated > 75% of VTs. Even if VT cannot be induced by EPS, ATP frequently prevents painful shocks.

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?

I think such as registry would be nearly impossible to create and maintain. It is also unclear to me how it would be funded.

References:

1. Strickberger, SA, Klein, GJ; Is Defibrillation Testing Required for Defibrillator Implantation? JACC 2004; 44:88-91.

2. Charles D. Swerdlow, MD, FACC, Reappraisal of Implant; Testing of Implantable
Cardioverter Defibrillators; JACC 2004; 44:92-94.

3. Kopelman, H.; Calkins, H.; Zhang, Y.; Breiter, D.; Hahn, S.; for the LESS Investigators (2002), "Use of One ATP Attempt Does Not Compromise Overall Conversion Success." PACE 2002; 24:665 (part II, no. 570).

4. Wathen MS, Sweeney MO, DeGroot PJ, Stark AJ, Koehler JL, Chisner MB, Machado C, Adkisson WO; PainFREE Investigators. Shock Reduction using antitachycardia pacing for spontaneous rapid ventricular tachycardia in patients with coronary artery disease. Circulation 2001; 104:796-801.

Comment #25:
Submitter: Ronald D. Berger, MD, PhD
Organization: Johns Hopkins University and Hospital
Date: July 23, 2004
Comment:

I understand you are requesting comments on three questions regarding ICD usage. I am the Director of the Clinical Electrophysiology Graduate program at Johns Hopkins University and Hospital, and thus implant ICDs and teach ICD implantation technique in a busy academic medical center. I would therefore like to take the opportunity to provide feedback on the questions CMS has raised.

1. What is the evidence surrounding the necessity of threshold testing (DFT) at the time of implantation?

The assessment of defibrillation efficacy requires DFT testing at the time of implant [1]. When DFT testing is precluded due to medical contraindication (such as difficulty in adequately anesthetizing the patient), then the implanting physician is left to perform an "empirical" implant. In this situation, adequacy of lead placement and of deliverable shock energy cannot be assessed. To compensate for this, such a patient typically receives a higher-energy ICD, which is larger, causes more discomfort, and costs more than a standard device. If DFT testing were widely abandoned, then smaller, less expensive, lower-energy devices would likely be abandoned as well.

Furthermore, induction of VF is the only known way to test for appropriate sensing of this arrhythmia. Avoiding VF induction (and therefore DFT testing) will likely increase the burden of inappropriate shocks that the patients subsequently experience. While the exact nature of implant testing will likely evolve [2], there are as yet no suitable surrogates for DFT testing.

2. What is the evidence of benefits and risks of adding

anti-tachycardia pacing (ATP) to the function of an implantable defibrillator, including the risk of an additional lead?

ATP does not require any additional lead, so this part of the question is unclear. Clinical studies have shown that 78% of inappropriate shocks may be avoided when the ATP feature is used appropriately in an ICD [3], ATP terminates 89% of fast ventricular tachycardias while accelerating only 4% [4], and ATP safely terminates >90% of clinical VT episodes even in patients without inducible VT at time of ICD implant [5]. It should therefore be utilized in virtually all ICD patients, regardless of inducibility of VT at EP study.

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?

The value of such a registry is unclear. For risk stratifiers to be adequately evaluated such that their clinical utility can be critically assessed in a statistical sense, there is no substitute for prospective, randomized, controlled clinical trials. Two years ago, CMS questioned the validity of data from one such large randomized trial (MADIT-2). Data from a non-randomized registry will only be of lesser value.

References:

1. Strickberger, SA, Klein, GJ; Is Defibrillation Testing Required for Defibrillator Implantation? JACC 2004; 44:88-91.

2. Charles D. Swerdlow, MD, FACC, Reappraisal of Implant; Testing of Implantable
Cardioverter Defibrillators; JACC 2004; 44:92-94.

3. Kopelman, H.; Calkins, H.; Zhang, Y.; Breiter, D.; Hahn, S.; for the LESS Investigators (2002), "Use of One ATP Attempt Does Not Compromise Overall Conversion Success." PACE 2002; 24:665 (part II, no. 570).

4. Wathen MS, Sweeney MO, DeGroot PJ, Stark AJ, Koehler JL, Chisner MB, Machado C, Adkisson WO; PainFREE Investigators. Shock Reduction using antitachycardia pacing for spontaneous rapid ventricular tachycardia in patients with coronary artery disease. Circulation 2001; 104:796-801.

5. Schaumann A, von zur Muhlen F, Herse B, Gonska BD, Kreuzer H. Empirical versus tested antitachycardia pacing in implantable

cardioverter defibrillators: a prospective study including 200 patients.
Circulation 1998; 97:66-74.

Comment #26:
Submitter: Marye J. Gleva M.D. F.A.C.C.
Organization: Washington University School of Medicine
Date: July 20, 2004
Comment:

Question #1: "What is the evidence surrounding the necessity of threshold testing at the time of implantation?"

As noted in the current viewpoint published by the American College of Cardiology [1], defibrillation testing is the standard of care. Specifically, there is no prospective randomized trial that addresses the safety and efficacy of ICD implantation without DFT testing. The individual DFT is not predictable; there is no mathematical model available that has been validated in the prediction of an individual patient's energy requirement for transvenous defibrillation. Defibrillation thresholds are known to change over time in monophasic systems, and are also influenced by medications and electrolyte abnormalities.

More importantly, the Heart Rhythm Society's Clinical Competency Statement: Training Pathways for Implantation of Cardioverter defibrillators and Cardiac Resynchronization Devices [2] specifically address prophylactic defibrillator implant and testing. Competency includes proctoring by an experienced implanter especially for the "unique issues...such as the need to test defibrillation thresholds (DFTs) and evaluation of sensing problems…"

There is no data on safety or efficacy of ICDs in patients who have not undergone DFT testing. Indeed, testing of the defibrillation threshold is not absolute assurance that all episodes of ventricular fibrillation will be successfully terminated by the ICD. The Low Energy Safety Study [3,4] a randomized prospective multicenter trial employing a dual coil transvenous defibrillation lead and a biphasic shock waveform, had 4 objectives. The first was to quantify energy safety margins required to ensure high defibrillation success, the second was to compare defibrillation thresholds over time, the third was to compare efficacy of shocks in induced ventricular fibrillation to spontaneous episodes, and the last was to compare efficacy of ICD shocks in patients randomized to full-output shocks to the efficacy of lower energy shocks. Data addressing this last objective was published in PACE [4]. In this report, patients randomized to full output shocks were compared to a subset of the same patients who had successful termination of ventricular fibrillation at 14 J. Conversion rates during spontaneous events were the same between the two groups, 92% for the full output group and 89% for the 14J success group. Thus, ten percent of patients in each group, despite a rigorous determination of the defibrillation threshold, failed to convert from a spontaneous episode of VF with the first ICD shock. One,

however, cannot conclude that DFT testing is unnecessary despite the efficacy rates being the same because the tested intervention involved determination of the DFT.

The same analysis from the Low Energy Safety Study reported efficacies of 97% for VF termination after the first two shocks. The results were similar in both groups. This information supports the continued use of a standard ICD and challenges the safety of a device designed with a limited number of therapies.

Question #2: "What is the evidence of benefits and risks of adding anti-tachycardia pacing to the function of an implantable defibrillator, including the risk of an additional lead?"

Antitachycardia pacing is available in single chamber ICD systems, and does not require the addition of another lead. The SCD HeFT trial was not designed to address the risks and benefits of anti-tachycardia pacing. The proven usefulness of anti-tachycardia pacing arises from other studies. In a population of CAD patients with primarily sustained and non-sustained VT, empiric ATP was successful in terminating the arrhythmia 85% of the time. No deaths were related to device pro-arrhythmia [5]. Similarly, empiric and EP-tested ATP schemes were compared in a group of patients comprised of both ventricular fibrillation survivors and those with monomorphic ventricular tachycardia. The termination success rates were 90% or greater. Acceleration of VT by ATP occurred in up to 5% of the total population. No death was related to device pro-arrhythmia. Thus, ATP has efficacy, is safe, and is a useful feature even in patients who presented with ventricular fibrillation.

Question #3: "Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?"

No. The SCD Heft Trial has prospectively collected clinical, electrocardiographic, and other non-invasive information to address this exact question of predictors. This information, since derived from the largest prospective randomized trial involving ICDs, will be more robust than any trend seen in an uncontrolled non-randomized, registry. The role of a registry in clinical trials is to generate further hypotheses to be tested prospectively. Total mortality is the strongest endpoint in arrhythmia trials. The use of ICD discharges as a primary endpoint for arrhythmic death or mortality has been a methodological criticism criticized in prior trials.

References

1. Strickberger SA, Klein GA. Is Defibrillation Testing Required for Defibrillator Implantation? J Am Coll Card. 2004; 44:88-91.

2. Curtis AB, Ellenbogen KA, Hammill SC, Hayes DL, Reynolds DW, Wilbur DJ, Cain ME. Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices. HRS website
3. Gold MR, Higgins S, Klein S, Gilliam FR, Kopelman H, Hessen S, Payne J, Strickberger SA, Breiter D, Hahn S. Efficacy and Temporal Stability of Reduced Safety Margins for Ventricular Defibrillation: Primary Results from the Low Energy Safety Study(LESS). Circulation 2002;105:2043-2048.
4. Gold MR, Breiter D, Leman R, Rashba EJ, Shorofsky SR, Hahn SJ. Safety of a Single Successful Conversion of Ventricular Fibrillation Before Implantation of Cardioverter Defibrillators. PACE 2003;26[Pt. ii}:483-486.
5. Walthen MS, Sweeney MO, DeGroot PJ, Stark AJ, Koehler JL, Chisner MB, Machado C, Adkisson WO for the PainFREE Rx Investigators. Circulation 2001;104:796-801.
6.

Comment #27:
Submitter: James Coromilas, M.D.
Organization:
Date: July 23, 2004
Comment:

I am writing in response to the 3 questions posed by CMS. I was the Columbia University Medical Center principal investigator for SCDHeft and have also been the Columbia Principal Investigator for MUSTT, AFFIRM, and AVID.
I am associate professor of clinical medicine at Columbia and the director of the cardiology fellowship training program. Before responding directly to the 3 questions posed, I would like to express my opinion on coverage of SCDHeft type patients. Clearly, scientifically the best decision would be to cover all patients meeting SCDHeft inclusion criteria and without any of the exclusion criteria. However, based on the results of SCDHeft in theprespecified subgroups of Class II and Class III heart failure, one can make a strong argument for approving the device only for patients with Class II heart failure. Furthermore, I would strongly urge that the 6 minute walk be used as an objective measure of heart failure class with coverage limited to patients able to walk > 900 feet on the 6 minute walk since the results were so striking (marked benefit in patients able to walk 900 feet on teh 6 minute walk and no benefit in patients unable to walk that far).

1. What is the evidence surrounding the necessity of threshold testing at the time of implant? SInce threshold testing was utilized in SCDHeft, AVID, MADIT and is current standard of care it should be maintained. The patients with CHF and LVEF <35% are exactly the subgroup of patients who may have high DFTs (dilated, massive ventricles). It would be incorrect to expose the patient to the risk of the ICD and not do DFT testing and then have the patient succumb to a ventricular tachyarrhythmia that the ICD could not terminate.

2. What is the evidence of benefits and risks of adding anti-thachycardia pacing to the function of an implantable defibrillator, inclusing the risk of an additional lead? Again, in SCDHeft, only 27.7% of patients received shocks and the positive results of the study were achieved with a simple "shock-box" type of defibrillator. While as an electrophysiologist, I find the use of ATP and an atrial lead extremely helpful in the management of complex VT patients, that is not what we are trying to achive in using the defibrillator for primary prophylaxis. It would be far preferable to cover all Class II and III heart failure patients witha simple shock box than to cover only a subgroup with more complex, expensive devices.

3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventriicular fibrillation? ABSOLUTELY. This must be done. Of course we must be careful to distinguish VF from VT which happens to be in the VF zone. Additionally, we may be able to determine characteristics of patients who did not benefit from the ICD.

Comment #28:
Submitter: Adam Strickberger, MD
Organization: Washington Hospital Center and Georgetown University School of Medicine
Date: July 23, 2004
Comment:

I just spoke withJoseph Chin who asked me to email you. I wanted to comment on the need for DFT testing at ICD implant and on ATP, but couldn't do it online. He suggested I email you.

Regarding DFTs, there are no data that demonstrate that ICDs save lives when DFTs are NOT performed at implant. This was recently addressed in a peer review Viewpoint that I coauthored in JACC (2004;vol 44:88-91).

Secondly, all ICDs should have ATP since it is effective and painless therapy for VT; even very rapid VT which is common in the patients who are treated with an ICD for primary prevention of sudden cardiac death. Dr. Wathen of Vanderbilt has studied and published on the topic.

Comment #29:
Submitter: Kevin Wheelan, MD
Organization: Baylor Heart and Vascular Hospital
Date: July 23, 2004
Comment:

On behalf of the electrophysiology staff at Baylor University Medical Center Dallas Tx and out patients, I am writing you to support a decision for expanded coverage to non-ischemic heart disease patients who are at high risk of sudden death as defined by the large Scd-Heft trial. We believe that the decision on which device is used should be individualized for the specific patient and choosen by their physician.

DFT testing is especially important to ensure proper device and lead function and pain free antitachycardia pacing offers many patients a significant benefit.

We do not believe that a mandated registry will be effective or valid unless rigorously designed as a prospective trial which has already been done defining benefit for almost all subgroups of patients.

Our professional organization HRS, has sent you a very eloquent statement concerning these issues and I appreciate the agency's concern to formulate a policy in the best interest of our patients.

Comment #30:
Submitter: Stephen Hammill, MD, FACC and Michael J. Wolk, MD, FACC
Organization: Heart Rhythm Society and American College of Cardiology
Date: July 22, 2004
Comment:

The Heart Rhythm Society is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. The Heart Rhythm Society mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. The Heart Rhythm Society's 3,800 members are physicians, scientists and their support personnel who implant pacemakers and implantable cardioverter defibrillators (ICDs) in patients who require these life-saving devices.

The American College of Cardiology (ACC) is a 30,000 member non-profit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and formulation of health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The Heart Rhythm Society and the ACC appreciate the opportunity to submit additional comments related to SCD-HeFT coverage in response to the most recent CMS posting requesting public input (NCA Tracking Sheet for Implantable Defibrillators CAG-00157R2). CMS raises three questions relating to threshold testing, anti-tachycardia pacing, and the need for a patient ICD registry.

Additionally, based on our June 8, 2004 meeting held at CMS headquarters, the Heart Rhythm Society is also submitting the recently released *Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices* based on the identified need to ensure quality patient care. The Heart Rhythm Society believes it is imperative for the nations' hospitals to adhere to these guidelines to not only ensure appropriate patient care but also to ensure appropriate ICD utilization.

Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices

On July 15, the Heart Rhythm Society issued new guidelines on training requirements for a subgroup of non-electrophysiologists who wish to implant implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy (CRT) devices. Recently published and presented trials, such as MADIT II , COMPANION and SCD-HeFT demonstrate the efficacy of primary prevention of ICDs and CRT devices and have increased physician and public awareness of the importance of these life-saving therapies. The Heart Rhythm Society believes this will naturally create a greater demand for implanting physicians. To ensure appropriate patient care, appropriate training is required to implant these complex devices. The Society is addressing these training needs for non-electrophysiologists through the publication of these Guidelines.

This action and these guidelines were created to safeguard the growing number of patients who will benefit from these devices, and prevent non-electrophysiologists with minimal pacemaker experience and inadequate training in ICD and CRT device therapies from gaining local hospital approval to implant ICD and CRT devices. An electrophysiologist, or heart rhythm specialist, is a cardiologist who has devoted an additional year of training to ICD and CRT device implants and to the diagnosis and treatment of abnormal heart rhythms.

The Heart Rhythm Society expects that non-electrophysiologists meeting the definition of high-volume implanters of standard pacemakers who wish to implant ICD and CRT devices must acquire the additional training mandated by the guidelines. Fulfillment of the guidelines must be demonstrated prior to starting unsupervised ICD and/or CRT implantations. Demonstration of compliance with the new guidelines will require submission of the requirements outlined in the document to the hospital credentialing body.

The Heart Rhythm Society requests that CMS cite the attached document; Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices in the upcoming SCD-HeFT coverage decision as a means to ensure appropriate patient selection, device choice and patient care for individuals requiring ICD therapy.

In summary, the Guidelines state that non-electrophysiologists meeting the definition of high-volume implanters (see definition below) of standard pacemakers who wish to implant ICD and CRT devices must acquire the additional training mandated by the guidelines. Fulfillment of the guidelines must be demonstrated prior to starting unsupervised ICD and/or CRT implantations. Demonstration of compliance with the new guidelines will require submission of the following to the hospital credentialing body:

- Letter and documentation of current experience and privileges, which would include 35 pacemaker implantations per year and 100 implantations over the prior three years.
- Certification of an endorsed CME program that the individual has completed and associated testing and/or successful passing of NASPExAM.
- Letter from an appropriate proctor documenting successful completion of 10 ICD implantations, 5 ICD revisions, and 5 CRT implantations.
- Letter documenting the follow-up plan and a corresponding or co-signed letter from the electrophysiologist with whom the individual will be collaborating.

The guidelines will be sent to all US hospitals where ICD implants occur, are available on the Heart Rhythm Society web site, **www.HRSonline.org**, and will be published in *Heart Rhythm*, the Society's official journal, this Fall.

In response to the three questions as posted on the CMS website our responses are below:

1) What is the evidence surrounding the necessity of threshold testing at the time of implantation:

After the ICD lead and generator have been implanted, ventricular fibrillation is induced to determine the amount of energy required by the ICD to defibrillate the heart (defibrillation threshold, DFT). Over the past several years advances in the design of defibrillators and shock waveforms have provided an average DFT of 8 to 10 joules. Since most available ICDs deliver at least 30 joules of stored energy, some have questioned whether DFT testing is still necessary. We strongly feel that DFT testing remains an important and necessary step in ICD implantation for a variety of reasons:

1. *All of the available clinical trials for primary and secondary prevention of sudden cardiac death with ICDs used a protocol that included DFT testing.* ***Over the past several years multiple trials including AVID, MADIT, MUSTT, MADIT II, AND SCD-HeFT have demonstrated a clear survival advantage of ICD therapy. These trials all included DFT testing, usually with a target 10-joule safety margin between the DFT and the first programmed shock energy. It is not known if similar results would have been achieved with a different implant protocol. It is our understanding that threshold testing at implant has been an FDA requirement for many years and is expected to be a requirement until a clinical trial is completed demonstrating that it is no longer necessary.***

2. *In approximately 5-10% of all ICD implants, the initial DFT will be greater than 20 joules.* ***There are then several options to improve the DFT and provide an increased safety margin. These include repositioning of the defibrillating lead, upgrading to a higher energy ICD system, reversing the shock polarity, and adding a subcutaneous electrode array to increase the surface area of the defibrillating electrode. With appropriate testing and modification of the ICD system, an adequate safety margin can usually be obtained. It seems counter intuitive to place a prophylactic device without knowing if the device will work, especially when DFT testing is relatively simple and safe (see below).***

3. *DFT testing allows an assessment of the sensing characteristics of the ICD.* ***The success of ICD therapy depends on the device appropriately detecting ventricular fibrillation. When detection is not adequate the ICD lead system requires revision. During patient follow-up, external electrical fields, or noise, may at times be interpreted by the ICD as ventricular fibrillation and patients receive inappropriate shocks. The initial testing of various ICD sensitivities at implant can allow for the subsequent non-invasive reprogramming of the ICD to different sensitivity levels to avoid mistaking extrinsic or physiologic "noise" as a shockable arrhythmia.***

4. *Multiple antiarrhythmic agents, most notably amiodarone, increase the DFT.* ***Many patients with ICDs ultimately require pharmacologic therapy during follow-up to suppress ventricular and supraventricular arrhythmias. Since these drugs can increase DFTs, it is important to know the safety margin and defibrillation threshold before these pharmaceutical agents are initiated.***

5. *An accurate assessment of the DFT may allow programming of the first ICD shock to a lower energy.* ***This may more rapidly terminate ventricular tachycardia and ventricular fibrillation preventing patient loss of consciousness, and potentially improve post shock hemodynamics.***

Several arguments have been offered to justify abandoning DFT testing during ICD
implantation that we find without merit. First, it has been suggested that DFT testing is dangerous and results in unnecessary risk and discomfort to the patient. When performed by an experienced electrophysiologist, the intraoperative mortality of ICD implant and testing is approximately 0.1%. Additionally, the use of modern conscious sedation minimizes any discomfort to the patient. Recent articles in the literature provide a discussion of DFT including:

Strickberger SA, Klein GJ. Is defibrillation testing required for defibrillator implantation?
JACC 2004;44:88-91.
Swerdlow CD. Reappraisal of implant testing of implantable cardioverter defibrillators.
JACC 2004;44:92-94.

It has been hypothesized that there is a shortage of implanting electrophysiologists leading to an inability to provide appropriate ICD treatment to all who need it. Actually,

the data available argue the opposite. A recent work-time study sponsored by Heart Rhythm Society determined that most electrophysiologists have excess implant capacity and spend only 12% of their time on implant related activities. Further data presented at the 2004 Heart Rhythm Society national meeting in San Francisco validated this observation. The Heart Rhythm Society believes that the apparent underutilization of ICDs is more likely the result of inadequate patient and referring physician education and disparities in insurance coverage.

In summary, the Heart Rhythm Society and the ACC take the position that DFT testing is an essential step in ICD implantation. Unless further evidence is offered that abandoning DFT testing is safe and results in equivalent clinical outcomes, an assessment of the DFT during ICD implantation should remain the standard for the foreseeable future.

2. What is the evidence of benefits and risks of adding anti-tachycardia pacing to the function of an implantable defibrillator, including the risk of an additional lead?

At our meeting last month, the Heart Rhythm Society submitted lengthy comments related to SCD-HeFT and ICDs in general. At your request, we included comments related to anti-tachycardia pacing. Below are excerpts from the Heart Rhythm Society letter regarding ATP with some additional observations.

ATP is accomplished using standard ventricular ICD leads and is available in most current single and dual chamber ICD systems. Specifically, an atrial lead is not necessary. The multicenter PainFREE study (Circulation 2001;104:796-801) evaluated the benefit of empiric antitachycardia pacing algorithms in patients with standard indications for ICD therapy. The objective was to determine whether ATP would effectively terminate fast VT (CL 240-320 ms). During follow-up, 1,100 spontaneous ventricular arrhythmias occurred in 220 patients. Fifty-seven percent were classified as slow VT (CL $\geq$ 320 ms, 185 bpm or slower), 40% as fast VT (CL 240-320 ms, 185-250 bpm), and 3% as ventricular fibrillation (CL < 240 ms, 250 bpm or faster). ATP terminated 89% of fast VT episodes with a low incidence of acceleration and syncope. The investigators concluded that ICD patients are spared the majority of painful shocks if ATP is programmed for the 1st therapy for VT, and they suggested the longevity of ICDs might be improved by fewer capacitor charges. As it is unlikely that ATP algorithms would add to the cost of an ICD that had back-up pacing, one should anticipate that this option would be incorporated into the fundamental attributes of ICDs that are used for primary prevention of sudden death.

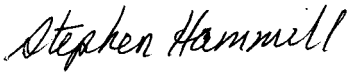
3. Is there sufficient scientific justification for development of an ICD patient registry to collect information to better identify predictors of ICD firing for ventricular fibrillation (as a proxy for sudden cardiac death)?

The Heart Rhythm Society and the ACC believe that although a patient ICD registry may be useful to collect information related to ICDs (firing for ventricular fibrillation being only one data set of many), that there are concerns related to the feasibility and viability

of such an endeavor. An ICD registry will unlikely be able to identify a highly useful predictor of VF shocks, when many clinical trials have so far been unsuccessful at doing so. The design and implementation of such a registry would require considerable resources for data coordinators and equipment of which the hospital and physician community would be unable to provide. Collection of this data at the physician or hospital level would be overly burdensome in the current regulatory and reimbursement environment in which ICD implants are currently performed. We caution CMS about pursuing such a complex project without performing considerable research into the feasibility and funding of such a registry.

The Heart Rhythm Society and the ACC would be pleased to discuss these issues with CMS in further detail and appreciate the opportunity to continue working with CMS towards revising Medicare ICD coverage policies. Please contact Amy Melnick, Vice President, Health Policy at 202-327-5430 or amelnick@HRSonline.org, or Anne Bicha, Associate Director, Regulatory and Legal Affairs, ACC, at 301-493-2384 or abicha@acc.org, if you have any questions or would like to meet and discuss these issues in greater detail.

Sincerely,



Stephen Hammill, MD, FACC
President, Heart Rhythm Society

Michael J. Wolk, MD, FACC
President, American College of Cardiology

Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices

Anne B. Curtis, Kenneth A. Ellenbogen, Stephen C. Hammill, David L. Hayes, Dwight W. Reynolds, David J. Wilber, Michael E. Cain

Implantable cardioverter defibrillators (ICDs) are widely used for the management of patients with life-threatening ventricular arrhythmias (1). The indications for ICD therapy are expanding as the results of clinical trials for primary prevention of sudden cardiac death have shown that survival is improved in patients with serious

heart disease when ICDs are implanted prophylactically, i.e. before a patient has had a potentially lethal arrhythmia (2-4). The results of these clinical trials will continue to be incorporated into the current and upcoming American College of Cardiology/American Heart Association/North American Society of Pacing and Electrophysiology Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices (5).

Another important recent development in cardiac pacing has been resynchronization therapy. It has been found that ventricular dyssynchrony, a common finding in patients with heart failure, can be corrected by pacing the left ventricle via a branch of the coronary sinus simultaneously or near-simultaneously with standard right ventricular pacing. Clinical trials of cardiac resynchronization therapy (CRT) have demonstrated improvements in quality of life, New York Heart Association class, and exercise capacity when compared to standard medical therapy in patients with heart failure and intra- and interventricular conduction delays (6,7).

As increasing numbers of patients receive these devices, it is necessary that physicians involved in the care of these patients have knowledge and expertise in the indications, techniques for implantation, complications, programming and follow-up of these devices. Completion of a fellowship in clinical cardiac electrophysiology is clear evidence of such training. However, there has been increasing interest in training pathways for ICD implantation and CRT by non-electrophysiologists in order to accommodate the large number of patients who could potentially benefit from these devices based on recent clinical trial results.

If physicians other than electrophysiologists are to engage in ICD and CRT device implantation, there is a need to develop a clinical competency statement relating to these modalities to help guide the training of such individuals. With this in mind, the Heart Rhythm Society (HRS) Board of Trustees commissioned a task force that included HRS members, representatives from the Heart Failure Society of America and industry. The purpose of the task force was to develop a training pathway for ICD implantation for prophylactic indications and CRT for cardiologists who are already experienced in pacemaker implantation.

The task force developed initial recommendations that were presented to the HRS Board of Trustees. A subgroup of the Board of Trustees then developed the final document that was presented to the Board of Trustees for approval. The HRS Board of Trustees approved the document on May 18, 2004.

Physicians Currently in Cardiovascular Training Programs

Guidelines already exist for physicians in training who want to be credentialed to implant pacemakers, ICDs, and cardiac resynchronization devices at the end of fellowship training. Nothing in this document is intended to replace the requirements that have already been published for physicians in training. The COCATS guidelines for training in adult cardiology have recently been revised (10). As described in that document, training in device implantation that is applicable to level 2 or level 3 training includes, in addition to didactic training, 50 primary pacemaker implantations, 20 pacemaker system revisions or replacements, 100 pacemaker follow-up visits, 25 primary ICD implantations, 10 ICD revisions or replacements, and a minimum of 50 ICD follow-

up visits. These recommendations are concordant with those in the NASPE Policy Statement: Training Requirements for Cardiac Implantable Electronic Devices: Selection, Implantation, and Follow-up (11) and the NASPE Clinical Competency Statement for ICD Implantation and Follow-up (12). For CRT, the recommended number of supervised implants during training is 15 (11).

Alternate Training Track for ICD and CRT Implantation for Non-Electrophysiologists

It is acknowledged that there are physicians in practice who are already experienced pacemaker implanters yet who have not completed formal training in clinical cardiac electrophysiology. There can be a variety of reasons why such physicians would want to implant ICDs or cardiac resynchronization devices, such as the increasing demand for implantation of ICDs based on recent clinical trial data or the lack of availability of a formally trained electrophysiologist in the area. For such physicians, adding the technical skills required to implant ICDs or coronary sinus leads may not be exceptionally difficult, yet technical skill for implantation alone is clearly insufficient to be credentialed to implant ICD or CRT devices. In particular, implantation of ICDs with no formal didactic education or technical training is not optimal for patient safety or optimal outcomes, no matter how many pacemakers a physician implants.

It should be emphasized that the guidelines outlined below do not pertain to physicians in practice with no device implant experience, but rather only to "experienced implanters," as defined below. A specific example would be the heart failure specialist in practice without any prior training or experience in device implantation. This individual

would still need to fulfill the basic requirements for device implantation as outlined in the section above entitled, "Physicians Currently in Cardiovascular Training Programs."

Definition of Experienced Implanter

For any invasive or surgical procedure, larger volumes performed by an individual physician are usually associated with a lower complication rate and may be correlated with a better outcome for the patient. In limited studies, there is clear cut evidence that pacemaker complications become much more common among physicians who implant <12 pacemakers/year (13-18). While implantation rates over 12/year may be associated with acceptable complication rates, it has also been shown that more experienced implanters (≥30 pacemakers/year) are more likely to use advanced programming features in devices and require less support from industry (17). ICD and CRT systems are clearly more sophisticated devices than standard pacemakers and the consequences of inadvisable programming or device malfunction are potentially dire for the patient, e.g., lethal arrhythmias that are inadequately treated by the ICD, or inappropriate patient shocks that lead to substantial morbidity. Based on the data, the Board of Trustees of the Heart Rhythm Society defines an experienced pacemaker implanter as one who implants a minimum of 35 pacemakers a year, with a minimum of 100 implants over the preceding three years.

In addition to having current privileges to implant permanent pacemakers and having the minimum volume of procedures stated above, the physician must have a documented systematic approach to follow-up of pacemaker patients, either by following

them personally or by making arrangements for each patient to have follow-up in some other appropriate manner.

Training Pathway for ICD Implantation by Experienced Pacemaker Implanters

This training pathway should be considered for pacemaker implanters who wish to implant ICDs for prophylactic indications exclusively, i.e. for patients who are at high risk for a life-threatening ventricular arrhythmia but who have not yet experienced an event. For patients who have had sustained ventricular tachycardia or fibrillation, management can be quite challenging, and such patients should be cared for by an experienced clinical cardiac electrophysiologist.

There are a number of important considerations involved in designing these recommended requirements for training for ICD implantation to maximize patient safety and optimize outcome. There is proper patient selection and device selection, surgical aspects of device implantation, management of problems and emergencies during implantation, and follow-up, including programming and troubleshooting. Some of these items can be dealt with in didactic courses, but others require hands-on experience with implantation. In addition, it is important not only that the physician be competent in ICD implantation, but also that all the technical and nursing staff be competent to handle ICD implantations. Required skills include, among others, conscious sedation and management of emergencies such as inability to defibrillate a patient using the ICD.

Current ACLS certification is strongly recommended but not required. Didactic course work, including CME certification, is required. Such course work cannot be provided directly by industry. Some of the content required as part of a didactic course on

ICD implantation is outlined in Table 1. The course must have a formal assessment as part of the course, either during the course or to be submitted after the course that tests the individual on the course content. A CME certificate should not be provided until the assessment is passed successfully. The didactic course as well as the assessment examination should be sponsored or endorsed by the Heart Rhythm Society. Alternatively, successful passing of the NASPExAM, which tests knowledge in pacemakers and defibrillators, would provide evidence that the physician has the knowledge base for ICD implantation and follow-up.

While satisfactory completion of didactic course work is necessary in order to have the knowledge to properly select, implant, and follow ICDs, course work alone is not sufficient to be credentialed to implant ICDs. The experienced pacemaker implanter who wants to implant ICDs must be proctored for a minimum number of implants prior to proceeding independently. While physicians in cardiovascular training programs are required to participate in a minimum of 25 new ICD implantations and 10 revisions, these requirements were set in the context of physicians who have no prior device implantation experience. The Board of Trustees of the Heart Rhythm Society believes that physicians who meet the definition of an experienced pacemaker implanter as defined in this document already have extensive experience in most relevant surgical aspects of ICD implantation, such as venous access, formation of a pocket, placement of standard pacing leads, and interpretation of electrical measurements. Therefore, the additional skills required for placement of an ICD lead and defibrillation threshold testing do not require performance of a full 25 implantations to perform the procedure safely. Thus, experienced pacemaker implanters should be proctored by a physician experienced in

ICD/CRT implantation for a minimum of 10 ICD implants, with at least 2 of those implantations being performed at the hospital where the physician will be performing the ICD implantations, in order to assure that the technical staff has the requisite skills as well. Since there are unique issues in ICD revisions compared to pacemaker revisions, such as the need to test defibrillation thresholds (DFTs) and evaluation of sensing problems, it is recommended that a minimum of 5 ICD revisions be done in a proctored setting as well. Monitoring of patient outcomes, operator complications, and the ability to complete the procedure in a safe and timely fashion is essential as well. These requirements for documentation of training and competence are summarized in Table 2. A physician experienced in ICD/CRT implantation who qualifies as a proctor should have graduated from an ACGME certified training program that meets the COCATS guidelines in electrophysiology and/or device implantation, be at least two years out of training, currently implanting a minimum of 25 ICDs a year and following a minimum of 50 ICD patients a year personally.

Requirements for CRT Implantation

With respect to CRT, the majority of patients eligible for such devices will also be candidates for prophylactic ICDs, and the requirements above hold for physicians desiring to implant resynchronization ICDs. For experienced pacemaker implanters who want to implant left ventricular leads for resynchronization therapy, it is recommended in addition that at least 2 procedures be observed and that the physician perform at least 5 coronary sinus lead placements in a proctored setting, as recommended previously (11). If an experienced pacemaker implanter is proctored for a resynchronization ICD, that

proctored implant may count toward both the numbers needed for ICD implants as well as for CRT devices. Monitoring of patient outcomes and success rates for adequate coronary sinus lead implantation is essential. A didactic course in CRT that meets CME criteria must also be completed.

ICD Programming and Follow-up

ICD programming prior to discharge of a post-procedure patient from the hospital should be limited to bradycardia parameters and defibrillation therapy only. It is recognized that antitachycardia pacing (ATP) therapy, when programmed empirically, can result in better patient acceptance of therapy through avoidance of shocks (19). However, ATP can also result in acceleration of ventricular tachycardia with syncope and hemodynamic compromise. Therefore, ATP should be prescribed only in consultation with the electrophysiologist who will be involved in the follow-up care of the patient.

Requirements for Follow-up of Patients after Hospital Discharge

ICD follow-up for each patient must be established prior to leaving the hospital. Routine follow-up for patients who have had no serious events can be accomplished by an experienced pacemaker implanter with proper education. Such follow-up includes device interrogation and reprogramming, including evaluation of pacing thresholds, lead impedances, sensing, and rate cut-offs for defibrillation therapy. Establishment of a relationship with an electrophysiologist in the area willing to assume follow-up care of these individuals is also essential for any patient problems that may develop. Once defibrillator discharge has occurred, the patient should be referred for follow-up to a fully

trained electrophysiologist. In addition, patients with CRT devices whose heart failure symptoms do not improve or appear to worsen at follow-up should be referred to a fully trained electrophysiologist and consultation with a heart failure specialist should be considered as well.

Documentation of Successful Completion of Training Requirements

Fulfillment of the guidelines will be demonstrated prior to commencement of unsupervised ICD and/or CRT implants and will require submission of the following to the hospital credentialing body:

- Letter and documentation of current experience and privileges
- Certificate from endorsed CME program that the individual has completed the course and associated testing and/or successful passing of NASPExAM
- Letter from an appropriate proctor documenting successful completion of the required number of proctored implants
- Letter documenting the follow-up plan and a corresponding or co-signed letter from the electrophysiologist with whom the individual will be collaborating

Maintenance of Competence

A minimum of 10 ICD procedures and 10 CRT devices per year is necessary in order to maintain competency in these procedures. Physicians who fall below the numbers of implants required to maintain competence should retrain with an appropriate

proctor for a minimum of five implants. Physicians should follow a minimum of 20 patients per year each with ICDs and CRT devices in order to maintain proficiency in device programming and follow-up. Continuing medical education is also essential in order to keep abreast of new devices, technologies, and programming features to maximize patient benefit. A minimum of two hours of CME per year should be obtained in ICD and CRT devices in order to maintain the knowledge base necessary for optimal patient outcomes.

Summary

ICDs are complicated devices that provide life-saving therapy for patients with a documented history of ventricular arrhythmias or for prophylaxis against sudden cardiac death in patients with serious structural heart disease. CRT devices improve symptoms and quality of life in patients with heart failure. Both modalities require special expertise not only in the techniques of implantation, but also a core of knowledge in the indications for the devices as well as programming and proper follow-up. These guidelines are intended to provide a pathway for non-electrophysiologists already experienced in pacemaker implantations to obtain the skills and knowledge to implant ICD and CRT devices safely and to provide effective therapy to patients in follow-up.

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Table 1. Curriculum Content for Training in ICD and CRT Implantation

- Review basic knowledge required for previous NASPE definition of a Level I and Level II trained physician
- Indications for ICD therapy
- Indications for CRT
- Review of implant techniques, including coronary sinus lead placement
- Defibrillation threshold testing (DFT)
- Review of external defibrillation techniques
- ICD sensing
- Basics of programming
- ICD emergencies
- Hands-on programmer workshop
- Assessment of biventricular and univentricular pacing thresholds
- Programming CRT devices
- ICD troubleshooting

Table 2. Summary of Requirements for Alternate Training Pathway for ICD and CRT Implantations

- Document current experience implanting pacemakers

  35 pacemaker implantations per year and 100 implantations over the prior three years

- Proctored ICD implantation experience

  10 Implantations

  5 Revisions

- Proctored CRT implantation experience: 5 implantations
- Completion of didactic course and/or NASPExAM
- Monitoring of patient outcomes and complication rates
- Established patient follow-up
- Maintenance of competence

  10 ICD and CRT procedures per year

  20 patients per year in follow-up

Comment #31:
Submitter: Marvin A. Konstam, MD and John E. Strobeck, MD, Ph.D.
Organization: Heart Failure Society of America
Date: July 7, 2004
Comment:

Heart Failure Society of America

Court International, Suite 240 South
2550 University Avenue West
St. Paul, MN 55114

Tel: 651-642-1633
Fax: 651-642-1502

www.hfsa.org

July 7, 2004

Steve Phurrough, M.D.
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Dr. Phurrough:

On behalf of the Officers and Executive Council of the Heart Failure Society of America, we are writing to express our consensus opinion regarding implantable Cardioverter Defibrillator (ICD) implantation in our patients suffering from heart failure with NYHA Class IV symptoms.

The Heart Failure Society of America Executive Council and its Guideline Committee have reviewed the results of recent clinical trials that have evaluated the effects of ICD implantation in patients with heart failure associated with reduced left ventricular ejection fraction. In most cases, we have not been able to review the actual data from these studies and have relied instead on public presentations of preliminary results that, in some cases, have not yet undergone peer review. We recognize that the final analyses, when complete, may differ from the results that have been presented to date, and we reserve the right to modify our recommendations to be consistent with the final data. We also appreciate the need to reach coverage decisions that are not only commensurate with the available evidence, but also with the need for cost-effective policies.

In that regard, we present below our official guideline statement regarding:

Recommendations for ICD Placement in Candidates for Cardiac Resynchronization Therapy (CRT) and NYHA Class IV Heart Failure:

Recommendation: In heart failure patients, regardless of etiology, with NYHA Class IV symptoms **and** indications for CRT (biventricular pacing), concomitant ICD placement may be performed at the time of biventricular pacing (Strength of Evidence B).

Few studies have carefully evaluated the potential benefits of ICE placement alone in patients with NYHA Class IV symptoms. In general, NYHA Class IV patients with heart failure and reduced LVEF have been not considered suitable candidates for ICD implantation. However, recent evidence suggests that selected NYHA Class IV patients, without life-threatening co-morbidities, who **ALSO** meet criteria for cardiac resynchronization therapy, derive benefit from concomitant ICD placement. In the COMPANION trial, there was no discernible difference in the point estimates of the hazard ratios for either the primary end point (all cause hospitalization or death) or a mortality end point alone in NYHA Class III versus Class IV patients.

(Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. New England J Med 2004;350:2140-50.)

We therefore urge CMS to offer coverage accordingly for ICD placement in patients and circumstances covered by the above recommendation.

Thank you for affording the Heart Failure Society of America the opportunity to present these recommendations for coverage of ICD placement in heart failure patients with NYHA Class IV symptoms to CMS. If you have any questions, please contact Cheryl Yano, Executive Director, HFSA at cyano@hfsa.org or by calling 651-642-1633. She will be able to put you in touch with the HFSA leadership if you would like to discuss these issues in further detail. Alternatively, please feel free to contact either of us directly.

Sincerely,

Marvin A. Konstam, M.D.
President
Heart Failure Society of America

John E. Strobeck, M.D., Ph.D.
Chair, Advocacy Committee
Heart Failure Society of America

JES/MAK/cjy

CMS-ICD letter

Comment #32:
Submitter: Andrew J. Borin, D.O.
Organization: Osteophathic Clinical Cardiology
Date: July 13, 2004
Comment:

OSTEOPATHIC CLINICAL CARDIOLOGY

BOARD CERTIFIED INTERNAL MEDICINE AND CARDIOLOGY

ANDREW J. BORIN, D.O.
(734) 464-4260

July 13, 2004

JoAnna Baldwin
Centers for Medicare and Medicaid Services
Mail Stop: C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Baldwin:

I am informed that CMS/Medicare has drafted a decision for implantation of cardioverter defibrillators in the MADIT II patient group with a history of ischemic cardiomyopathy, and an ejection fraction of less than 30%, to withhold recommendation for implantation of a defibrillator unless the QRS duration on the 12-lead electrocardiogram is greater than 0.120 milliseconds.

EKG/QRS duration > 0.12 has been the standard recommendation for resynchronized pacing. To use the QRS duration as a qualifier for an internal defibrillator device severely curtails the treatment of this high risk patient population. Experience with the microvolt T-wave alternans diagnostic testing for risk stratification identifies the patient at risk for sudden death with nonischemic dilated cardiomyopathies, as well as ischemic cardiomyopathies. I feel that this is a much better stratifier for the recommendation of an internal cardiac defibrillator, with a highly specific negative microvolt T-wave alternans report, suggesting a true low incidence of sudden cardiac death in these high-risk patients.

I wish you would consider the diagnostic ability of the microvolt T-wave alternans stress procedure, with the highly specific true negative diagnostic result in ruling out risk for sudden cardiac death. The overall incidence of combined studies in MADIT II and SCD-HeFT results in 1.2 percent for annualized spontaneous ventricular tachyarrhythmias and a mortality of 1.9 percent, with a negative microvolt T-wave diagnostic study.

I practice as a private cardiac specialty practice, and am looking forward to identifying a high risk group of patients with the use of the microvolt T-wave alternans stress procedure for prevention of sudden cardiac death. I feel that the use of an electrocardiographic QRS duration of 0.12 has never been discussed in the literature as a risk factor for sudden death.

Sincerely,

AJB:erh

Andrew J. Borin, D.O.

Laurel Park Office Center • 37799 Professional Center Drive • Suite 105 • Livonia, Michigan 48154

Comment #33:
Submitter: Ralph G. Nader, M.D., F.A.C.C., F.S.C.A.I., F.A.C.P.
Organization: Mt. Sinai Medical Center and Miami Heart Institute
Date: July 15, 2004
Comment:

RALPH G. NADER, M.D., F.A.C.C., F.S.C.A.I., F.A.C.P.
Co-Director, Cardiovascular Laboratories
Mt. Sinai Medical Center & Miami Heart Institute
4302 Alton Road, Suite #220
Miami Beach, Florida 33140
Telephone 305-532-6006 & Fax 305-532-5991

July 15, 2004

Ms. Joanna Baldwin
Center for Medicare and Medicaid Services
Mail Stop C1-0906
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Ms. Baldwin,

I'm writing this letter to ask for Medicare to support the use of the micro T wave alternans and TWA as a risk stratifier for sudden cardiac death in MADIT II and SCD-HeFT patients with a QRS duration less than 120 msec.

As you know, the mortality rate of MTWA negative patients in population similar to MADIT II and SCD-HeFT is less than the mortality rate of ICD treated patients in MADIT II and SCF-HeFT. I've been very impressed with the new technology to risk stratify patients for sudden cardiac death.

I am currently practicing in Miami Beach, Fl. I am an interventional cardiologist in a large office based private group in Aventura and Miami Beach. Our practice covers about 20,000 patients.

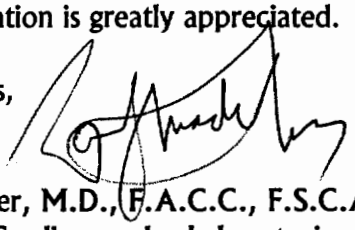
I have done several micro T wave alternans studies and I've read the literature carefully. I have been extremely impressed with the clinical result and reproducibility of the test. I'm most impressed by the fact that several prospective studies have shown patients with negative micro T wave alternans to have an extraordinarily low rate of ventricular tachy arrhythmic events and sudden death, about 1% across many studies. Patients with a negative micro T wave alternans are unlikely to benefit from ICD therapy. Patients with positive micro T wave alternans can be further risk stratified with electrophysiological testing in order to determine the necessity for AICD devices. I believe that the micro T wave alternans technology has changed the way that I practice cardiology in the year 2004. I am making a difference and in my humble opinion, I believe that I have saved a few lives.

I'm concerned about the impact of the pending CMS decision to use only the QRS duration as marker for the approval for AICD implantation. As you well know, the QRS duration has not stood up well as a risk stratifier for sudden cardiac death. The micro T wave alternans is the most scientifically valid and proven tool to rely on for MADIT II and SCD-HeFT populations. Therefore, I beg you to consider approving the micro T wave alternans as the standard for risk stratification for sudden cardiac death.

Continued...

Your consideration is greatly appreciated.

Sincerely yours,



Ralph G. Nader, M.D., F.A.C.C., F.S.C.A.I.
Co-Director, Cardiovascular Laboratories
Mt. Sinai Medical Center & Miami Heart Institute
RGN/jh

E-mail joannabaldwin@cms.hss.cov

Comment #34:
Submitter: Roland Werres, M.D.
Organization: The Heart Specialists, P.A.
Date: July 20, 2004
Comment:

THE HEART SPECIALISTS, P.A.
Roland Werres, M.D., F.A.C.P., F.A.C.C.

July 20, 2004

JoAnna Baldwin
Centers for Medicare and Medicaid Services
Mail Stop: C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Baldwin,

I am a private practice interventional cardiologist based in Maplewood New Jersey.

As you might expect, I care for many post-MI patients who remain at risk for sudden cardiac death after their infarction. I find it difficult to decide which patients would be served best by being referred on to the electrophysiologist and which can be best managed with optimal medical therapy.

While you wrestle with the question about for which you will pay for an ICD, I suggest that you work to resolve the problem of identifying the highest risk patients before paying for an ICD. Having lost patients to SCD in the past, I sought out a solution to this problem and found Microvolt T-wave Alternans testing very helpful.

MTWA testing has been clinically proven to have a very high negative predictive value with applicability to a wide range of patient populations (including MADIT II and SCD-Heft type populations).

I recommend that you require MTWA testing as the primary risk stratifier prior to agreeing to pay for any ICDs. It seems to me that the economic impact of paying for ICDs in these huge patient populations is not prudent when there is a method for culling out those likely to benefit from those not likely to benefit from expensive ICD therapy.

In my practice, I have found that using MTWA testing allows me to conservatively manage those patients that test negative for TWA and refer on to our local EP with confidence those patients testing positive. It is very important that as the gatekeeper of cardiac patients, we have screening tools like MTWA testing on which to rely.

In closing, as a physician that wants the best possible care for his patients and as a taxpayer who wants the most prudent use of our healthcare dollars, the use of Microvolt T-wave Alternans testing represents the best compromise position that serves all stakeholders.

Sincerely,

Roland Werres, M.D.

2130 MILLBURN AVENUE
SUITE A4
MAPLEWOOD, NJ 07040
(973) 275-9300
(973) 275-9220 fax

Comment #35:
Submitter: Barry L. Zaret, M.D.
Organization: Yale University
Date: July 23, 2004
Comment:

Yale University

SCHOOL OF MEDICINE
333 CEDAR STREET, 316 FMP
P.O. BOX 208017
NEW HAVEN, CONNECTICUT 06520-8017

Telephone: (203) 785-4127
Fax: (203) 785-7144
Email: barry.zaret@yale.edu

BARRY L. ZARET, M.D.
Robert W. Berliner Professor of Medicine
Professor of Diagnostic Radiology
Chief, Section of Cardiovascular Medicine
Department of Internal Medicine
Medical Director, YNH Heart Center

(35)

July 23, 2004

Dr. T. Sanders
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
Attn: Public Comments, S3-02-01
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Watch-PAT

Dear Dr. Sanders:

I am writing to voice my strong support for the Watch-PAT technology which I believe is currently being reviewed by the Centers for Medicare & Medicaid Services Office of Clinical Standards and Quality. The issue of ambulatory sleep devices to detect alterations in breathing patterns is extremely important in cardiac disease. The ability to monitor patients at home and detect significant abnormalities is of fundamental importance, particularly in congestive heart failure and hypertension. The prevalence of apneic disorders in such patients is quite high and, when present, is associated with altered outcomes.

I have had personal experience with the Watch-PAT device and I have been extremely impressed with this technology with respect to its accuracy and ease of use. I urge you to act favorably upon this technology with respect to its implementation.

Sincerely,

Barry L. Zaret, M.D.

BLZ:ahs

Comment #36:
Submitter: David R. Nielsen, MD, FACS
Organization: American Academy of Otolaryngology- Head and Neck Surgery
Date: July 22, 2004
Comment:

American Academy of Otolaryngology — Head and Neck Surgery

WORKING FOR THE BEST EAR, NOSE, AND THROAT CARE

HEADQUARTERS
One Prince Street
Alexandria, VA 22314-3357 U.S.A.
1-703-836-4444 FAX: 1-703-683-5100
TTY: 1-703-519-1585 www.entnet.org

WASHINGTON OFFICE
316 Pennsylvania Avenue SE
Suite 403
Washington, DC 20003-1172
1-703-836-4444 FAX: 1-202-544-8454

July 22, 2004

Tiffany Sanders, MD
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality Coverage and Analysis Group
Attn: Public Comments, S3-02-01
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Sanders:

I am writing in response to CMS's second call for comments relating to the national coverage determination (NCD) for diagnosis and treatment of obstructive sleep apnea (OSA) to include multi-channel home sleep testing as an alternative to facility-based polysomnography (PSG). The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS/F) continues to support this proposal as a potential cost-effective alternative to PSG and as means of improving access to care for the large adult population at risk for sleep apnea. We believe that providing beneficiaries with coverage for home sleep studies will improve access to care for beneficiaries, and will provide a cost effective alternative to facility-based polysomnography for diagnosing and treating obstructive sleep apnea.

As CMS had specific questions posed in this second call for comments, please find our responses to these questions below:

How does the diagnostic test performance of unattended portable multi-channel home sleep testing compare to facility-based polysomnography in the diagnosis of obstructive sleep apnea?

Available evidence suggests that the diagnostic test performance of unattended portable home sleet testing is comparable to facility-based polysomnography for some patients. As with most diagnostic tests, there is variability in the quality of the equipment used, just as there is with facility-based equipment.

Dr. Edward Weaver cited in his May 7, 2004 letter to CMS regarding this issue a study conducted by the Group Health Cooperative in western Washington State that had excellent outcomes by implementing a home sleep testing program. Out of 698 home sleep studies performed in a two year period, only 56 (8%) required re-testing due to a lack of diagnosis or technical problem. Dr. David Lewis, the director of Group Health Cooperative Sleep Program, further described the benefits of their home sleep testing program in his May 6, 2004 comment letter to CMS.

If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea which parameters of sleep and cardiorespiratory function (i.e. sleep staging, body position, limb movements, respiratory effort, airflow, oxygen saturation, ECG) are required?

We believe that the following parameters are essential in the diagnosis of sleep apnea: 1) measure of ventilatory signal (e.g. airflow), 2) oxygen saturation, and 3) measure of central vs. obstructive apnea (e.g. respiratory effort by strain gauges). Body position, although helpful, should not be considered mandatory. The key features of a home sleep study are that there is no EEG and it is unattended. If the home sleep study is conducted properly, neither an EEG (sleep staging) nor attendance by health care personnel is required to diagnose and treat most routine cases of sleep apnea. Please note that split-night polysomnography, currently covered under CMS policy for the diagnosis and treatment of sleep apnea, does not accurately measure the relationship between sleep stages and sleep apnea. The diagnostic phase includes only the first part of the sleep period when most people spend little time in the stages of sleep most vulnerable to sleep apnea.

If unattended portable multi-channel home sleep testing is as effective as polysomnography in the diagnosis of obstructive sleep apnea what conditions (i.e. patient education, technician support) are required so that it is done correctly in the home?

Dr. Davidson's proposal would allow home sleep studies as a first line option for diagnosing and treating sleep apnea. We do not believe that home sleep studies should be limited to use as a screening service. Facility-based polysomnography is likely to be required for any technical failures that may occur in a home sleep study, diagnosis ambiguities, or severe/complicated sleep apnea. As mentioned earlier, the choices made for covered equipment will affect the consistency of measures. Covered home sleep study equipment should measure the parameters listed above using validated technologies.

Only a physician experienced in treating patients with sleep apnea and trained in the use of home sleep studies should prescribe a home sleep study and interpret the results. The physician or the physician's support personnel (also trained in the use of home sleep study equipment) should educate the patient on the use of the equipment, and advise the patient of the benefits and limitations of a home sleep study.

AAO-HNS/F thanks CMS for the opportunity to comment again on this potential policy change. If I can be of any further assistance, please call me directly at 703-519-1559.

Sincerely,

David R. Nielsen MD

David R. Nielsen, MD, FACS
Executive Vice President and CEO, AAO-HNS/F

cc: Terence Davidson, MD
Physician Payment Policy Committee (3P)
Edward Weaver, MD, Chairman, Sleep Disorders Committee
Francina Spencer, CMS

Comment #37:
Submitter: Janet Domeier
Organization: BryanLGH
Date: July 16, 2004
Comment:

(37)

BryanLGH MEDICAL CENTER

Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
Attn: EPO Public Comments, S3-02-01
7500 Security Boulevard
Baltimore, MD 21244-1850

July 16, 2004

Subject: EPO & Aranesp Coverage Comments

Dear Jackie Sheridan-Moore;

This letter is in response to your request for comments on coverage of EPO and Aranesp. Coverage and billing requirements for EPO and Aranesp in an outpatient hospital setting has become conflicting and unclear with the recent deluge of transmittals. Some of our questions as a hospital provider are:

1. What are the specific criteria for an "ESRD-related anemia association related to a medical emergency"? (CR 3186 – Transmittal 197 is not clear.)
2. If the patient is receiving an outpatient surgical procedure on the day of scheduled dialysis treatment and/or EPO injection, is the EPO/Aranesp injection covered in a hospital that doesn't have a dialysis center?
3. Are these ESRD patients required to receive all their injections at a dialysis center and will this not cause them extra trips/transportation/inconvenience, especially if they are in a rural area?
4. In CR 3184 – Transmittal 197, it appears that the edit requirements for an emergent situation in a hospital requires a Revenue Code 450, but that doesn't allow medical emergency situations in outpatient surgical areas with Revenue Coe 761, etc.
5. The Dialysis Centers and the Nephrologists need further education on these changes. The hospital providers also will need their assistance to identify outpatients on scheduled dialysis treatment plans, so hospitals know whether EPO/Aranesp injections will be a covered/billable service.

Please take these comments into consideration as you review and update the coverage guidelines.

Sincerely,

Janet Domeier

Janet Domeier
Manager Patient Financial Services

Comment #38:
Submitter: David A. Strouse, M.D., F.A.C.C.
Organization: Arrhythmia Associates, L.L.P.
Date: July 14, 2004
Comment:

ARRHYTHMIA ASSOCIATES, L.L.P.

Adult & Pediatric Cardiac Electrophysiology

TED D. FRIEHLING, M.D., FACC, FACP
ALBERT A. DEL NEGRO, M.D., FACC
MARC H. WISH, M.D., FACC
MARGARET H. BELL, MD., FAAP, FACC

DAVID A. STROUSE, M.D., FACC
KAREN CRAWFORD, P.A.-C
ELIZABETH ROBINSON, P.A.-C

July 14, 2004

Dr. Joanna Baldwin
Medicare/Medicaid Services
Mail Stop: C1-09-06
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: DEFIBRILLATOR IMPLANTATION DECISIONS

To Whom It May Concern:

This is a letter in reference to upcoming planned decisions regarding defibrillator implantations in light of the MADIT II and SCD-HeFT populations. I am currently a cardiac electrophysiologist practicing in Northern Virginia with a practice limited exclusively to arrhythmia patients. Our practice is a large one and we are one of the largest implanters of pacemakers and defibrillators in the country.

I am writing to describe to you my concern about the impact of the impending decisions I know are underway regarding indications for ICD implantations. The clear clinical evidence suggests that patients with severely decreased ejection fraction and cardiomyopathy have a mortality benefit from defibrillator implantation without regard to QRS duration. As we all know, retrospective analysis of some populations of large clinical trials is valuable only in terms of generating new hypotheses for future testing and should not be used as a basis for making clinical decisions.

I am certainly in favor of adopting parameters for implantation of defibrillators that correlate with the well performed clinical trials, which have been repeatedly positive for defibrillator implantation in the population groups.

Understanding the significant financial limitations related to maintenance of this paramount decision, if risk stratifiers must be applied for purely financial reasons, microvolt T-wave alternans testing is important in our office as another modality of assessing risk for future ventricular events. If we are going to use risk stratifiers for determination of defibrillator implantation, then I think microvolt T-wave alternans is certainly an extremely valid and appropriate tool to further evaluation for patients with vulnerability for future ventricular events.

I hope that the physicians of the Department of Medicare and Medicaid services will make every effort in order to allow all appropriate patients to have access to this above therapy, which is clearly of life-threatening importance.

Warm regards,

David A. Strouse, M.D., F.A.C.C.

DAS:rc