ClinicalTrials.gov title: Intramural Needle Ablation for Ablation of Recurrent Ventricular Tachycardia

NCT01791543

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Sec. 812.25 Investigational plan.

(a) Purpose

This is an early feasibility study, that is a single-arm, non-randomized study to determine the feasibility of using a *needle ablation catheter* to ablate recurrent ventricular arrhythmia that has failed antiarrhythmic drug therapy and standard radiofrequency (RF) catheter ablation.

Following ablation patients will be monitored for 6 months.

The duration of the study is two years.

Introduction

Catheter ablation has emerged as a first line therapy for many supraventricular tachycardias. Ablation for ventricular tachycardias has remained more challenging. In the largest multicenter observational trial of irrigated RF ablation for VT after myocardial infarction, at least one VT remained inducible in 43% of patients; 47% had recurrent VT meeting the study endpoint during the initial 6 months of follow-up.[1] The one year mortality was 18% and recurrence of VT was associated with a 3 fold increase in mortality. One of the important reasons for failure of ablation is inability to adequately damage the arrhythmia substrate. Standard catheter ablation approaches the ventricles through the vasculature, reaching the endocardial surface. Failure of RF lesions created with present technology to reach some intramural or epicardial circuits contributes to ablation failures. A percutaneous epicardial approach allows epicardial ablation for some patients, but is not possible without surgery in patients who have pericardial adhesions from prior cardiac surgery. Once epicardial access is achieved, ablation is sometimes limited by the presence of epicardial fat, or overlying coronary arteries that protect the ablation target. Options for patients who fail ablation are limited. Transcoronary ethanol ablation is considered at some centers, but limited by coronary anatomy. Intraoperative surgical ablation can be considered for some patients, but has significant morbidity, and technologies for operative mapping have not kept up with percutaneous techniques, and few centers maintain a surgical ablation program. Use of left ventricular support devices is problematic in patients with recurrent VT due to the fall in venous return that occurs with VT in the absence of right heart support. In some cases the only option is cardiac transplantation. Application of radiofrequency ablation current through a needle inserted into the myocardium offers the potential for ablation of VTs that have an origin deep to the endocardium, that are not adequately treated by other means. [2]

(b) Protocol

This is a non-randomized early feasibility study. Patients with recurrent sustained or incessant ventricular arrhythmia who have failed antiarrhythmic drug therapy and prior catheter ablation will be offered participation. Ablation will be performed with the needle ablation catheter. Patients will be monitored in hospital for complications and during 6 months follow-up.

Screening Procedures
Patients referred to Vanderbilt University Medical Center or Brigham and Women's hospital for catheter ablation of sustained or incessant ventricular arrhythmia or symptomatic monomorphic ventricular tachycardia and who have failed attempted radiofrequency catheter ablation will be offered participation in this study.

Informed Consent
The investigator or designated member of the research team will approach the patient to obtain written informed consent. The background of the proposed study and the potential benefits and risks of the procedures and study will be explained to the subject. The patient must sign the consent form prior to enrollment.

Patients who are consented but in whom the needle catheter is not inserted, and consequently are not treated with the needle ablation catheter will be exited from the study and not included in the final analysis.

Patient Selection – Inclusion Criteria
Candidates for the study must meet ALL of the following criteria:

1. Monomorphic ventricular tachycardia or incessant ventricular arrhythmia (defined as > 20% of beats due to ventricular arrhythmia including unifocal PVCs, couplets, Nonsustained VT) that is causing a decline in LV ejection fraction to less than 50% that meets the following criteria:
    a. Ventricular arrhythmia is recurrent and symptomatic
    b. prior antiarrhythmic drug therapy has failed due to recurrent ventricular arrhythmia, toxicity, or intolerance
2. Age 18 or older
3. Left ventricular ejection fraction > 10% as estimated by echocardiography or contrast ventriculography within the previous 90 days.
4. Failed prior VT or PVC ablation due to spontaneous recurrence of sustained VT or frequent clinical PVCs .

5. Able and willing to comply with all pre-, post-, and follow-up testing and requirements.
6. Signed Informed Consent

Exclusion Criteria

1. Patients with idiopathic VT defined as VT that originates from a region without evidence of scar detected by MRI or voltage mapping in a patient without other evidence of heart disease that is not causing significant depression of ventricular function.
2. Definite protruding LV ventricular thrombus on pre-ablation echocardiography when LV ablation is required.
3. Thrombotic myocardial infarction within the preceding two (2) months.
4. Other disease process that is likely to limit survival to less than 12 months.
5. Class IV heart failure, unless heart failure is due to frequent or incessant VT.
6. Contraindication to heparin.
7. Allergy to radiographic contrast dye.
8. Severe aortic stenosis
9. Severe mitral regurgitation with a flail mitral valve leaflet.
10. Significant congenital anomaly or medical problem that in the opinion of the principal investigator would preclude enrollment into the study.
11. Enrolled in another investigational study evaluating a drug or device.
12. Unstable angina that is not due to frequent or incessant VT.
13. Women who are pregnant.
14. Thrombocytopenia (platelet count < 50,000) or coagulopathy.
15. Acute non-cardiovascular illness or systemic infection.
16. Cardiogenic shock unless it is due to incessant VT

Study Endpoints

Primary Endpoints

a. Efficacy endpoint for VT: control of VT as defined by: freedom from hospitalization for recurrent VT during the 6 months following ablation.

b. Safety endpoint: absence of all serious adverse events that are listed below that are potentially device related and occur within 30 days of the ablation procedure (see below)

c. Efficacy endpoint for ventricular arrhythmia causing significant ventricular dysfunction: decrease in ambient ventricular arrhythmia to < 5000 ventricular beats daily

Secondary Endpoints

a. Acute Procedural Success defined as termination of at least one clinical or presumptive clinical monomorphic VT by RF ablation or rendering that VT no longer inducible. It is recognized that this secondary efficacy endpoint will not be assessed in all patients because VT induction will not be attempted in patients in whom, in the judgment of the investigator, attempted VT induction imposes unwarranted risk of hemodynamic deterioration. A clinical or presumptive clinical VT is one that has been documented to occur spontaneously, or is within 20 ms in cycle length of a VT that has been documented to occur spontaneously.

Definition of serious adverse events:

1. stroke
2. pericardial effusion causing cardiac tamponade or requiring drainage.
3. myocardial infarction due to coronary occlusion
4. Peripheral arterial thromboembolism
5. cardiogenic shock not due to ventricular tachycardia
6. vascular bleeding or injury requiring transfusion or surgical intervention for vascular repair or to stop bleeding.
7. valve injury: new moderate or severe aortic regurgitation, new mitral valve disruption with severe mitral regurgitation
8. Heart failure exacerbation not due to uncontrollable ventricular tachycardia, defined as requiring hospitalization for > 24 hours
9. Death
10. Sepsis

Other adverse events (not necessarily device related or serious) that will be collected post procedure:

1. syncope
2. chest pain
3. new hyperthyroidism
4. new hypothyroidism
5. urinary tract infection
6. pneumonia
7. drug allergic reaction

Description of Treatments

Pre-Procedure Assessments

The following pre-procedure assessments will be performed for a subject undergoing treatment prior to the study procedure:

- Baseline medical history (including arrhythmia symptoms and hospitalizations)
- Laboratory values (creatinine, CBC, PT/PTT, electrolytes, and pregnancy test, if applicable)
- ICD interrogation (if applicable)
- Transthoracic echocardiogram within 3 weeks and after the latest non-study catheter ablation procedure.
- If the subject has had an echo within 90 days to evaluate LV ejection fraction and valve function, Intra cardiac echocardiogram (ICE) would be an option to evaluate for left ventricular thrombus prior to deployment of any catheter in the left ventricle.
- 24-48 hour holter monitor since last ablation procedure to quantify arrhythmia burden in subjects with ventricular arrhythmia/PVC induced cardiomyopathy

Electrophysiologic Study

After written informed consent has been obtained eligible patients will be brought to the cardiac electrophysiology laboratory in the post-absorptive state. Hemodynamic monitoring and conscious sedation and general anesthesia will be implemented according to hospital standards. Urinary bladder catheter may be placed to allow for monitoring of urine output and fluid balance, especially for subjects with a history of congestive heart failure, or who are hemodynamically unstable, or have an ejection fraction of <40%. Subjects will have continuous monitoring of arterial pressure during the mapping and ablation procedure. Arterial and venous hemostatic sheaths will be inserted, though which one or more diagnostic electrode catheters will be introduced at the discretion of the investigator, to confirm the diagnosis and facilitate mapping as per usual practice. If VT is not incessant, programmed cardiac stimulation will be performed to confirm the diagnosis of ventricular tachycardia. Atrial pacing and recording may be performed at the discretion of the operator.

Programmed ventricular stimulation for assessing VT inducibility:

Ventricular stimulation will be performed from the right ventricular apex and/or right ventricular outflow tract at > twice threshold stimulus strength. Programmed stimulation at two drive cycle lengths (typically 600 and 400 ms) with up to triple ventricular extrastimuli and burst ventricular pacing will be performed from two right ventricular sites. Burst pacing to a cycle length of 250 ms or loss of 1:1 capture can be performed. Left ventricular pacing may be used if RV pacing is ineffective. The endpoint of stimulation is

the final stimulus reaching the refractory period, or a coupling interval of 180 ms or initiation of sustained ventricular tachycardia or ventricular fibrillation. The endpoint of the procedure is absence of inducible sustained monomorphic VTs that were targeted for ablation or absence of adequate target sites.

Initial Mapping to Identify the Target Region

Once the diagnosis of VT has been confirmed an intracardiac ultrasound catheter will be inserted for monitoring ventricular function, catheter location, and pericardial effusion. Initial ventricular mapping will then be performed with a standard (non-needle) ablation (Biosense Webster, Inc Thermocool, Navistar, EZ Steer, or Surround Flow catheters) catheter for identification of the likely VT origin and to create a voltage map of the region to define potential scar using the CARTO electroanatomic mapping system (Biosense Webster, Inc). The likely origin of VT will be defined based on any of activation: sequence mapping, entrainment mapping, or pace-mapping as per usual laboratory practice.

For left ventricular mapping (and ablation), systemic anticoagulation with heparin should be administered with activated clotting time (ACT) checked throughout the procedure at the investigators discretion or per customary policy to maintain ACTs of 250-350 seconds. For left ventricular access transeptal or retrograde aortic approaches can be used.

If long sheaths are used to access the LV (e.g. for transeptal approach) these will be continuously irrigated with heparinized saline.

Mapping and Ablation with the Needle Catheter

1. The needle length will be set to 7 to 8 mm initially. If this is subsequently ineffective and there has been no evidence of myocardial perforation with that needle length, the length can be increased to 10 mm for septal or LV applications.

2. Set the RF generator to temperature control mode.

3. Start continuous irrigation with room temperature, heparinized saline (1 u heparin/1ml Saline) at a flow rate of 1 ml/min during mapping.

With a second irrigation pump start continuous irrigation with heparinized saline to the central lumen of the catheter that irrigates the gap between the needle at a flow rate of 1/ml/min. throughout the procedure.

4. At the potential target site the needle is inserted into the tissue. The catheter stopcock is set to manual injection, and 1 mL of 50% heparinized saline (1000 u/L) and isovue contrast is injected through the needle. The stopcock is set to the Cool flow pump and the pump irrigation flow rate is set to 2 ml/min. After 30- 60 seconds RF application can be initiated. The 2 ml/min flow rate is continued until 2-5 seconds after the termination of RF energy application.

5. Prior to RF initiation the position of the needle in the tissue is assessed from evidence of capture during pacing on the needle and / or appearance of the contrast in the tissue. If the site is felt to be potentially related to the arrhythmia and there is no evidence that the needle has reached the pericardial space then ablation can be performed. Otherwise, the needle will be retracted back into the catheter and catheter repositioned for additional mapping or better deployment.

The length of the needle is set to be shorter than myocardial thickness as assessed from ICE to reduce the chance that the needle can reach the pericardial space. Evidence that the needle has potentially reached the pericardial space includes staining of the pericardial space by injected contrast, or development of a new pericardial effusion or increase in previous pericardial effusion assessed from ultrasound imaging. If this occurs the needle the needle will be retracted into the catheter. Intracardiac ultrasound monitoring of the pericardial space will be used to detect early formation of an increasing pericardial effusion. If an increasing pericardial effusion is observed, heparin will be reversed and all catheters removed from the left heart. Preparations for pericardiocentesis will be implemented and performed if the effusion continues to increase or there is any evidence of impending pericardial tamponade by intracardiac echocardiography, or hemodynamic deterioration.

If contrast appears in the pericardium, the needle will be withdrawn and close monitoring for pericardial effusion continued with intracardiac ultrasound for the duration of the procedure. An increasing pericardial effusion will be indication to reverse anticoagulation and remove all catheters from the left heart.

6. The initial ablation temperature should be 60C and maximum power 35 Watts. If needed, power can be increased (to maximum 50 W). The duration of each RF application should target is 60 seconds and will not exceed 120 seconds. RF ablation can be interrupted early if there is evidence of inefficacy, such as failure of VT to terminate after 10 to 30 seconds of RF when ablation is done during VT, or if temperature does not increase as expected, indicating possible inadequate needle deployment, or if dislodgement of the needle is suspected by the operator.

7. If, for any ablation, the impedance rises 5- 10 ohms or more during RF application, the RF application should be terminated immediately. The catheter should be removed and any visible coagulum cleaned, if present. The flow of irrigation throughout the catheter should be verified before re-inserting the catheter.

8. Ablation during sinus rhythm - When RF energy is delivered during sinus rhythm, power levels up to 50 Watts will be delivered for each RF application for up to 2 minutes, at the Investigator's discretion.

9. While it is recommended that continuous RF application should not exceed 120 seconds, the Investigator has the option of terminating RF current delivery at any time and at any given power level as dictated by the patient's clinical condition. For every application of RF energy, the maximum power, maximum temperature, maximum impedance and duration of burn will be monitored continuously and recorded either on optical disc or paper.

10. After RF termination electrograms are recorded from the needle and pacing may be performed through the needle after ablation to assess capture if desired. The needle is then retracted back into the catheter and the irrigation rate reduced to 1 ml/minute.

11. Verification of the effects of the ablation procedure on inducible VTs using programmed electrical stimulation may be performed based on the subject's hemodynamic stability, at the Investigator's discretion. Using the same stimulation protocol as prior to ablation (above). If VT remains inducible, the mapping procedure is repeated at adjacent sites. Once an RF lesion terminates or prevents VT, ~~two~~ additional lesions can be applied at closely adjacent sites if desired, provided that intracardiac ultrasound does not show evidence of new pericardial effusion.

If defibrillation is required to terminate VT while the needle is deployed, the needle will be retracted before the defibrillator is discharged.

12. At the end of the procedure ultrasound images will be assessed for the presence of pericardial effusion.

Procedure endpoints:

1. All targeted VTs are no longer inducible or the targeted ventricular arrhythmia is no longer present

2. Ablation has been performed at the target region, and programmed stimulation to assess inducibility is not desired because of concern that it may precipitate hemodynamic deterioration
3. There are no target sites identifiable

Repeat Ablation Procedures
Repeat ablation procedures will be at the discretion of the investigator and will follow the standard of care.

5.6 Post-Procedure Assessments

After the procedure, management of the arterial sheath and heparin usage will be at the discretion of
the investigator. Prior to discharge, the investigator will assess and record the subject's clinical status and any complications, and complete the following assessments:

a. CK-MB and Cardiac Troponin will be measured 4 to 8 hours and approximately 24 hours after the ablation procedure.
b. Post-procedure ICD interrogation
c. Post-procedure echocardiogram will be obtained prior to hospital discharge

Drug Management
Drug management during the follow-up period will be at the discretion of the investigator and treating physicians. Anticoagulation with aspirin, warfarin, or direct acting oral anticoagulation is required for a minimum of three (3) months. Warfarin or direct acting oral anticoagulation is recommended for subjects who receive left ventricular RF ablation lesions over large areas such that the lesions are separated by more than 3 cm.

Patients will be observed in hospital for a minimum of 24 hours after the procedure with continuous ECG telemetry monitoring.

Follow-up Visits
Follow-up visits will be performed at Brigham and Women's Hospital, unless travel imposes a hardship on the patient, in which case the patient's cardiologist/electrophysiologist can perform the follow-up visit and send the required information to the investigator. Each follow-up visit will include assessment of adverse events, antiarrhythmic drug use, and anticoagulant use.

Follow-up visit one will be between 3 and 6 weeks after ablation with:

- ICD interrogation (if the patient has an ICD)

- Medical history since the last visit
- For patients with ventricular arrhythmia that is not VT that was producing depressed ventricular function, a holter will be obtained between 3 and 6 weeks after ablation.

Follow-up visit two will be between 5 and 7 months post ablation.

This visit includes the following:

- Transthoracic echocardiogram
- ICD interrogation
- Medical history since the last visit

(c) **Risk Analysis*:***

As discussed in the introduction, failed ablation is associated with risks of recurrent VT, ICD shocks in patients with ICDs, and mortality associated with recurrent VT.[1]

Possible increased risks of this investigation include the following:
Increased risk of perforation or tamponade
Increased risk of thromboembolism
Increased risk of myocardial dysfunction
Increased risk of injury to cardiovascular structures or pericardiac structures
Increased risk of proarrhythmia
Risk of contrast allergy

The following precautions and procedures are taken to minimize risks:

Increased risk of perforation or tamponade: Catheter mapping and ablation have a risk of cardiac perforation and tamponade that is approximately 1%.[3] Inserting the needle itself into the myocardium is anticipated to increase the risk of perforation. It is expected that the small size of this needle (27 gauge) will be associated with a minimal risk of significant pericardial bleeding, based on animal studies. Larger needles are commonly inserted into the myocardium during cardiac surgery for "de-airing" the ventricle and do not produce significant bleeding. The larger and deeper lesions produced by needle ablation compared to standard ablation, however, are anticipated to have an increased risk of cardiac perforation and tamponade. Precautions include: assessment of needle position in the myocardium based on contrast injection. If the tip of the needle reaches the pericardial space, it is anticipated that this will be recognized by contrast injection (the contrast dispersing in the pericardium), and the needle will be retracted without application of RF

energy. Intracardiac ultrasound will be employed to monitor for pericardial effusion throughout the procedure so that this complication can be promptly detected and treated. The investigators are experienced in recognition and treatment of pericardial effusion and tamponade. The procedures are performed at Brigham and Women's hospital with immediate availability of cardiac surgery if required for persistent or uncontrollable bleeding.

Increased risk of thromboembolism: Catheter mapping and ablation has a known risk of thromboembolism that is less than 1%.[1, 4-6] Thrombus on the needle catheter has not been observed during animal studies. None of the initial 3 patients experienced an embolic event. The needle will be irrigated with heparinized saline. For left heart mapping, systemic anticoagulation with heparin will be employed. RF application will be promptly terminated if impedance increases, which can be an indication of coagulum formation with standard RF ablation.

Increased risk of myocardial dysfunction: Greater ablation lesion size is anticipated to have greater risk of myocardial damage. Ablation targets will be restricted to regions that are felt to cause VT, and which in the majority of patients are areas of scar that do not appear to contribute to ventricular function. Gaining control of the arrhythmia in these patients is felt to out-weigh the risk of myocardial damage. Hemodynamic monitoring will be continuous during the procedure.

Increased risk of damage to cardiovascular structures: valves, blood vessels: This is also a known risk with standard catheter ablation. The needle will be kept retracted within the shaft of the catheter until deployment into the targeted myocardium. If defibrillation is required to terminate VT while the needle is deployed, the needle will be retracted before the defibrillator is discharged. Intracardiac ultrasound and fluoroscopy will be used to monitor catheter position. The investigators are experienced with catheter mapping.

Increased risk of proarrhythmia: Larger ablation lesions could theoretically increase the risk of aggravating arrhythmias. Cardiac rhythm will be continuously monitored during the procedure and until hospital discharge. It is anticipated that the majority of patients with have implanted defibrillators. Pre-clinical studies have demonstrated that needle ablation lesions are homogeneous with sharp border zones; features characteristic of radiofrequency ablation lesions which likely contributes to their very low proarrhythmic potential.[2, 7]

Risk of contrast allergy: Patients with a documented contrast allergy are excluded from participation.

In addition to these risks, there are risks inherent in the electrophysiologic procedure that are not specific to the needle ablation. These include: Other potential complications which may result from catheter insertion and manipulation as part of the prerequisite electrophysiology study and mapping procedure include: Allergic reaction to the local anesthetic, sedatives, heparin, protamine, or other agents administered during the procedure (risk <1%). Arterial or venous injury, including arterial dissection, thrombosis, occlusion or hemorrhage at the catheter insertion sites or at other sites along the vessels. This may produce hemorrhage, hematoma or ischemic injury to an extremity or major organ. Hemorrhage as a result of anticoagulation (risk <0.5%) which may require transfusion. Infection, either at the catheter insertion site or systemically, including endocarditis and septic emboli (risk <0.5%). This risk can be minimized by using standard aseptic technique and, when indicated, by the use of antibiotic agents.

Risks/Discomforts that may be increased with needle ablation	Severity	Expected Frequency: common = 10 – 20 per 100 less common = 2 – 9 per 100; rare = 1 per 100
Damage to other parts of the normal electrical conduction system.	mild to moderate	less common
Trigger an irregular fast heart rhythm	mild	common
Injury to the heart muscle with bleeding into the pericardium (heart sac) surrounding the heart.	severe	less common
Injury to the heart valves which are located between each of the four heart chambers.	mild to severe	rare
Development of blood clots and the movement of blood clots, during or after the procedure. You will be given an anti blood-clotting medication to help stop the blood clots from developing.	moderate to severe	less common
chest pain	mild	common

The following risks exist for all ablation procedures:		
reactions to medication and/or drugs that are given during anesthesia (drugs used to help a person relax and eliminate pain during a procedure),	mild to severe	less common
blood loss	mild to severe	less common
fever	mild	less common
infection	mild to severe	less common
myocardial infarction	severe	less common
stroke	moderate to severe	less common
air embolism	mild to severe	less common
pericarditis (pain from inflammation around the heart)	mild	less common
bleeding into the groin area causing pain and black and blue area	mild to moderate	common
damage to an artery in the groin that may require surgery (known in medical terms as a pseudoaneurysm or AV fistula)	moderate	less common
collapsed lung	severe	rare
bleeding or fluid accumulation into the lung or space around the lung	severe	rare
congestive heart failure	moderate	less common
low blood pressure	mild to severe	less common
fainting	mild to moderate	less common
damage or movement of a defibrillator wire that may require surgery	moderate	less common
shocks from an implanted defibrillator	mild	less common
shortness of breath	mild	less common
injury to the nerve to the diaphragm that can cause shortness of breath	moderate	less common
blood loss causing a low blood count	mild to moderate	less common
skin burns from defibrillator patches or the ablation catheter grounding pad	mild to moderate	less common
blood in the urine and pain from the	mild	less common

urinary catheter insertion		
rarely, death	severe	less common

(d) Device Description

(see Biosense Webster, Inc Master Access File # MAF-1893)
Authorization letter of June 17, 2016 from Biosense Webster is attached.
The Biosense Webster Needle Ablation Diagnostic/Ablation Catheter is an 8 F, steerable, multi-electrode, irrigated, luminal catheter with three distinct electrodes: a needle electrode for RF delivery plus a 4 mm tip electrode and ring electrode which are used for mapping, recording and stimulation purposes. The catheter has a unidirectional deflectable tip designed to facilitate electrophysiological mapping of the ventricles of the heart and to transmit radiofrequency (RF) current to the catheter needle electrode for ablation purposes. For ablation, the catheter is used in conjunction with an RF generator and a dispersive pad (indifferent electrode). The catheter has a usuable length of 115 mm.

The catheter has a high-torque shaft with a unidirectional deflectable tip section containing a single platinum ring electrode. The tip and the ring electrodes are made of platinum-iridium. The needle electrode is made of Nitinol. The needle is used to deliver RF current from the RF generator to the desired ablation site.

The catheter incorporates one thermocouple temperature sensor located within the distal tip of the needle. The RF generator monitors the temperature of the needle thermocouple allowing it to use temperature feedback to limit power delivery.

The needle electrode is controlled at the proximal end of the catheter. Pushing the needle thumbknob into the injector barrel extends the needle electrode. A locking mechanism holds the thumbknob in place once the thumbknob has been pushed down, if the thumbknob is not locked and force is removed a spring automatically retracts the needle. The needle extends a maximum of 10 mm from the distal portion of the tip electrode. This length of the extended needle can be reduced by rotating the thumbknob clockwise.

At the proximal end of the catheter, a fluid input port with a standard Luer fitting terminates from the open lumen. This port serves to permit the injection of heparinized normal saline to irrigate the needle electrode. During ablation, heparinized normal saline is passed through the needle to irrigate and cool the ablation sites as well as the needle electrode. An irrigation pump must be used to control the saline irrigation. The port also allows the injection of Isovue or a similar contrast agent to verify under fluoroscopy the placement of the needle within the myocardium. An additional input port allows irrigation

of the gap surrounding the needle. The gap is irrigated with a second pump to prevent blood retrograde flow inside the catheter shaft.

Tip deflection is controlled at the proximal end by a handpiece in which a piston slides; a deflection thumbknob on the piston controls piston travel. When the deflection thumbknob is pushed forward, the tip is deflected (curved). When the deflection thumbknob is pulled back, the tip straightens. The shape of the curve depends on the deflectable tip length. The high-torque shaft also allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site.

The catheter features single location sensor mounted within the tip of the catheter which transmit location information to the CARTO® 3 EP Navigation System. An appropriate reference device is required for location reference position purposes. The catheter interfaces with an RF Generator via a Catheter Interface Cable.

During mapping the needle is retracted within the catheter and irrigated at a rate of 1 ml/minute using a continuous flow pump (Cool flow , Biosense Webster, Inc). After extension of the needle into the myocardium a hand injection of 1 ml of a 50:50 saline contrast mixture is applied to stain the tissue demonstrating needle deployment in the tissue, followed by continuous irrigation at 2 ml/minute during RF current application. The gap is irrigated continuously with a second irrigation pump at a rate of 1ml/min.

Patient Population and Justification of Risk

Patients will be adults of either gender with symptomatic ventricular tachycardia that is either immediately life-threatening or causing ventricular dysfunction and that have failed antiarrhythmic drug therapy and prior catheter ablation procedure. In this setting, failure to achieve control of the arrhythmia can result in eventual death or need for cardiac replacement therapy (e.g. transplantation).[1, 5, 6] This patient population has a significant mortality.[1, 5] In one multicenter study of post-infarction patients who had failed antiarrhythmic drug therapy and were undergoing catheter ablation the one year mortality was 18%, and recurrent VT, indicating failure of ablation, was associated with a 3 fold greater risk of mortality.[1] Those who are able to survive with recurrent ventricular arrhythmias are often subject to recurrent episodes producing syncope or eliciting ICD shocks have reduced quality of life and significant psychological dysfunction.[4 8] If needle ablation achieves arrhythmia control, these individuals could experience substantial improvement in quality of life and survival.

This is an early feasibility trial in 50 patients. The endpoints focus on identifying device related complications and showing the possibility of efficacy. Because this patient

population has frequent arrhythmias a successful ablation that controls the arrhythmia could be dramatically successful, as has been observed in the small number of patients evaluated at QEII Health Sciences Centre in Halifax, Nova Scotia to date. It is anticipated that the major complications will be procedure related and evident during or shortly after the procedure, prior to hospital discharge.

Data Analysis

The populations baseline characteristics, and procedure characteristics will be described with the use of proportions, medians and inter-quartile ranges as appropriate. The primary endpoint will be assessed with a Kaplan Meier survival curve. The safety endpoint will be reported as the proportion of patients experiencing any adverse event, and each adverse event. The secondary endpoint will be reported as the proportion of patients meeting that endpoint.

(e) Monitoring procedures.

Early Feasibility of Intramural Needle Ablation for Ablation of Recurrent Ventricular Tachycardia that has Failed Conventional Radiofrequency Ablation

Applicability

This monitoring plan addresses study-specific issues for monitoring of "Early Feasibility of Intramural Needle Ablation for Ablation of Recurrent Ventricular Tachycardia that has Failed Conventional Radiofrequency Ablation".

Study Design

A prospective, non-randomized study will be conducted. A total of 130 subjects with recurrent drug/ablation refractory sustained monomorphic ventricular arrhythmia who are > 18 years old will be enrolled in this trial.

Investigator and Clinical Site

This study is a physician sponsored IDE with two approved sites.

William G. Stevenson, M.D. is the Sponsor- Investigator
Vanderbilt University Medical Center
Medical Center East
1215 21st Ave. S.
Nashville, TN 37232-8802

Usha Tedrow, M.D. is the site Primary Investigator
Brigham and Women's Hospital
75 Francis Street
Boston, MA 02115

Study Staff

The study site will have dedicated study coordinators. If the study coordinators are unable to attend EP cases, then the investigator performing the case is responsible for study data.

Device Storage and Accountability

The site is responsible for managing investigational device inventory in accordance with institution policy and federal regulations. Investigational devices will be kept in a designated locked cabinet. Devices will be logged in upon arrival and will be logged out when used during a study procedure or expired. Expired catheters will be sent back to the manufacturer and when applicable a replacement device will be ordered. Following use, investigational devices must be handled according to manufacturer's specifications. Device records will be kept in the regulatory binder under the catheter accountability section.

Study coordinator will review catheter accountability records to verify appropriate documentation of investigational devices.

If a discrepancy is noted during monitoring, immediate corrective action will be taken. The discrepancy and corrective action will be documented in study records and reviewed with the study staff.

Routine Data Monitoring

Monitoring will be performed by Dr. Bruce Koplan, M.D. and Dr. Melanie Maytin, M.D., every 6 months or more often if subject enrollment is high.

During monitoring, the Monitor will ensure:

Regulatory and protocol adherence by investigators and study staff.
Accurate CRF documentation by comparing CRF entries to patient medical records.
Capture of AE data by reviewing patient medical records and follow-up records.
Reporting of AE's to the IRB, manufacturer, and FDA as per study plan and regulations.
Each case of cardiac tamponade or cardiogenic shock will be reviewed to make a determination of whether these events warrant stopping the study.
The study will be suspended for interim analysis in the event of 3 serious adverse events related to the procedure such as need for surgical treatment for tamponade or procedure-related death.

Adverse events will be adjudicated by the study Medical Monitors.

Monitoring Reports

Monitoring reports will be completed after every monitoring visit. Any deficiencies and corrective actions will be documented and discussed with investigators and study staff. Checklist and worksheets will be filed in Monitoring section of regulatory binder.

(f) Labeling. Copies of all labeling for the device. N/A

(g) Consent materials. see attached Consent Form

(h) IRB information.

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Sec. 812.27 Report of prior investigations.

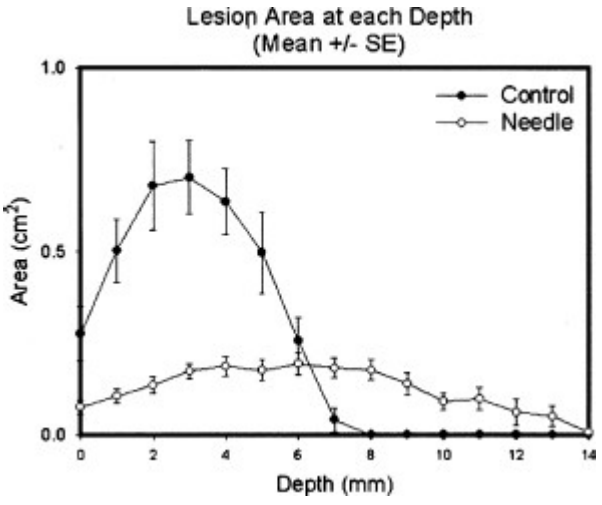
(a)General.

Previous Experience with the Device

Animal Investigations
The investigations below were performed in the cardiac experimental laboratory at Brigham and Women's hospital and were not conducted under GLP regulations, as they were either exploratory or conducted with a limited budget.

Initial in-vivo without Irrigation
The initial pilot study was performed in 3 swine (32 – 58 kg).[2] Ventricular lesions were created by extending the needle to its full depth and applying RF current for two minutes,

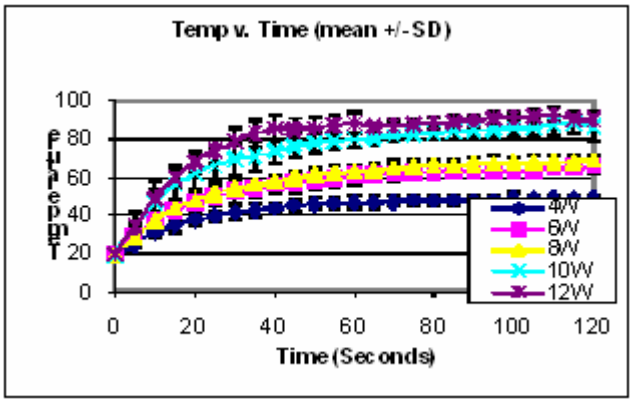
with manual titration of energy to a needle temperature at or slightly below 90 degrees C. These were compared to control lesions created with a 4 mm solid tip electrode. Irrigation was not applied to either catheter. A total of 14 needle ablations were created, one could not be definitely located. Data from the remaining 13 showed lesions that extended the full depth of the needle, but narrow, (only a mean of 4.4±0.1 mm wide), compared to control lesions which had a mean diameter of 8.5±2 mm (figure). Mean power for needle ablation was only 2 Watts to achieve 90 degrees C.(Stevenson WG, Sapp J, Annual and Final Report to CIMIT September 2002). Animals were sacrificed immediately after completion of the lesion creation protocol. One animal had cardiac tamponade after perforation of the thin LV apex with the needle catheter. A second had a hemopericardium without tamponade at examination. Conclusions were that deep lesions could be created, with efficient energy application, but lesion diameter was likely insufficient.

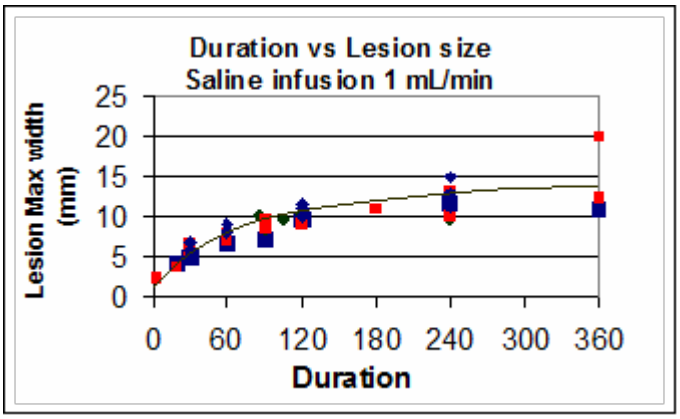


from ref Sapp et al PACE 2004;27:594-599.[2]

In-vitro with Saline Irrigation

The second set of investigations was performed to determine if saline irrigation of the needle during RF application would increase lesions size. In- vitro experiments were performed in bovine myocardium in a saline bath.(Stevenson WG, Sapp J, Annual and Final Report to CIMIT September 2002). Saline irrigation was applied during RF application and a range of powers from 4 to 12 Watts, and duration of applications studied. Tissue temperature was recorded from an intramural sensor 2 mm from the electrode. Tissue temperature increased with power delivery and occasionally exceeded 100 degrees C at 12 Watts (figure). Lesion diameter often exceeded 10 mm (figure) and plateaued after 90 to 120 seconds of the application (figure). Steam pops occurred at 12 Watts, but none were observed at 10 Watts and below, suggesting that the risk of pops can be controlled with limiting power delivery.

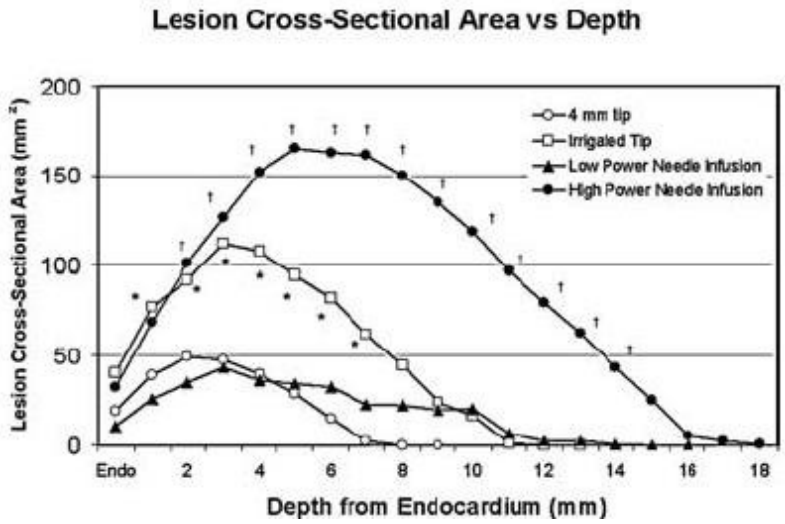




In-Vivo Studies with Irrigated Needle

In-vivo studies were then performed in 6 goats (37 – 43 kg) and 11 swine (32 – 90 kg).[7] The LV was accessed by the retrograde aortic approach. A total of 46 needle ablation lesions were created. The needle was extended 5 – 7 mm. Saline solution (0.9%) was infused at 1 mL/min for 60 seconds and was continued during the RF application of 120 seconds. RF power was 10 – 14 W for 9 lesions (low power group) and titrated to 30 to 40 Watts for 37 lesions (high power group). After needle RF ablation, an endocardial surface lesion was created to facilitate locating the needle from endocardial inspection by applying RF to the dome electrode without irrigation (titrated to a 10 ohm impedance fall for 120 seconds). The needle/endocardial lesions were compared to 18 standard RF lesions created with a 4 mm solid electrode with RF power titrated to a temperature of 65 degrees C for 120 seconds; and a second set of 17 control lesions created with a saline irrigated RF ablation catheter (Thermocool) with power limited to 50 Watts, temperature limited to < 50 degrees C, flow at 30 ml/min and duration 60 to 120 seconds.

High power needle ablation lesions were substantially larger than standard irrigated lesions (figure). Low power irrigated lesions had similar depth to standard irrigated lesions, but depth was limited due to maximal extension of the needle and thickness of the ventricle. On gross examination, the lesions were typical of RF lesions, showing a region of central pallor and a hemorrhagic border (figure). Grossly there was no surface charring or thrombus.



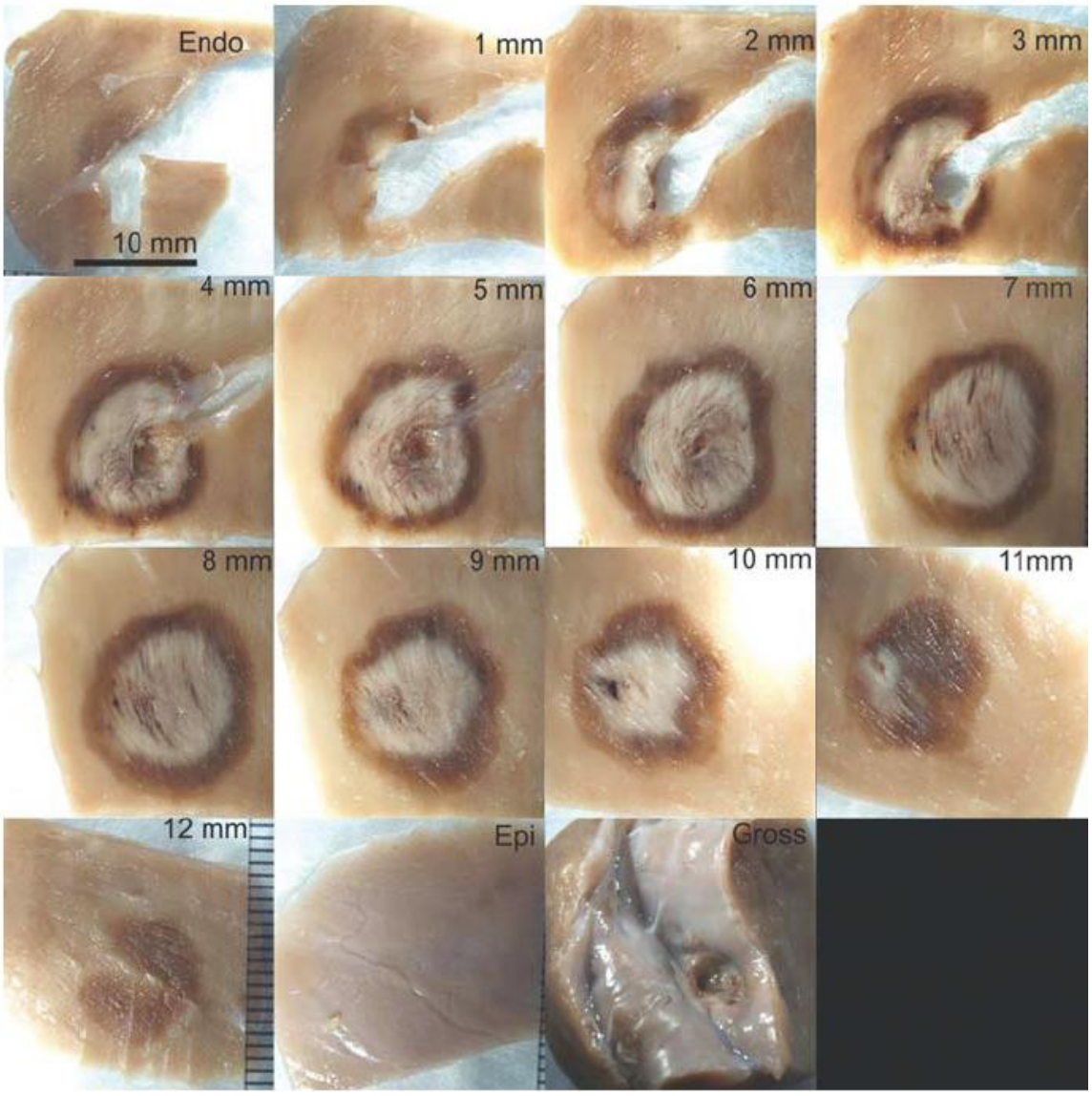


Figure: Serial 1 mm sections Serial 1-mm sections through a high-power infusion-needle ablation lesion are shown. The sections are shown serially from the endocardium ("Endo") to the epicardium ("Epi") with depths from the endocardium marked. The reference bar in the first panel is 10 mm in length. The uncut ("Gross") endocardial surface is seen in the final panel, and is smooth and free of char. The cross-sectional area of the lesion increases over the first four sections, and reaches a stable diameter which persists throughout the depth of the lesion. The lesion has an inner area of pallor and desiccation, surrounded by a narrow
hemorrhagic rim, which is sharply demarcated from surrounding myocardium. The lesion tapers and ends within 1 mm of the epicardium, at a depth of 12 mm from the endocardium. From Sapp et al J Cardiovas Electrophys 2006;17:657 – 661.[7]

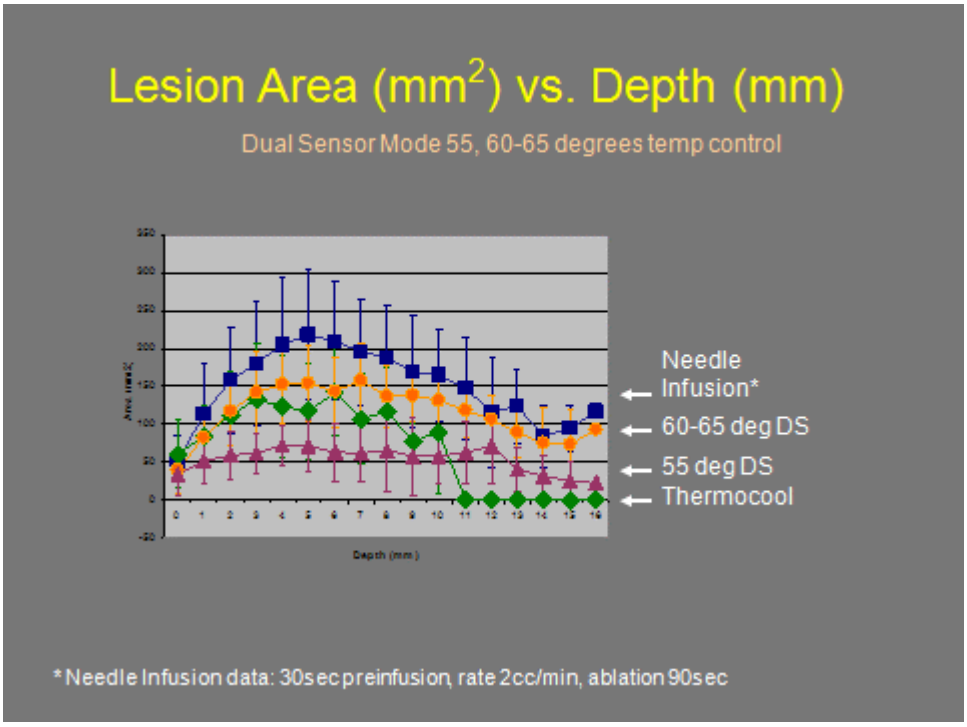
In-vivo Irrigated Needle with temperature monitoring from the dome and needle and thrombus assessment

These studies limited power according to temperature at the needle or dome electrodes. The needle was inserted 5 – 9 mm. RF power was increased manually with temperature limited to 60 – 65 degrees C (dome or needle) or 55 degrees C. Irrigation was initiated at 2 ml/min after needle extension and after 30 sec at that flow rate RF was initiated and continued for 90 seconds.

A protocol to assess for thrombus formation at the needle was also employed. A short sheath was inserted into the carotid artery, though which a long sheath was inserted into the LV. The catheter was inserted into the LV through the long sheath After each needle lesion, the catheter was withdrawn into the long sheath without retracting the needle, and the long sheath and catheter removed and inspected for thrombus char. Animals were systemically anticoagulated with heparin.

Control lesions (10 in 3 animals) were created with a Thermocool irrigated catheter (40 or 50 Watts) for 60 seconds, irrigated at 30ml/min.

In 5 goats 10 needle lesions were created at 60 – 65 degrees C (mean power 19.8 $\pm$ 5.1 Watts) and 11 needle lesions were created at 55 degrees C (mean power 16.8 $\pm$ 4.9 Watts) (figure). Lesion depth was similar to the previous studies. Lesion size was greater with the 60 – 65 degree C lesions. No char or thrombus was observed on the catheter or aspirated from the sheath after removal.



In-vivo Irrigated Needle with 50:50 contrast saline mix to assess needle position and perforation

In 11 goats (35 – 47 Kg) ventricular lesions were created during infusion of saline contrast mixture. The needle was inserted 5 – 9 mm. The contrast : saline mixture was Infused for 5 to 60 seconds then RF was applied for total infusion duration of 2 minutes with fluoroscopic imaging. After the last lesion, animals were sacrificed and the pericardium opened for inspection. Lesions were sectioned. (Zei, PC et al. Contrast-enhanced fluoroscopic real-time localization of intramural infusion and RF ablation with a novel infusion needle catheter. HRS abstract 2007)

50 total needle deployments with extension of the needle outside the catheter in an attempt to drive it into the myocardium were performed.

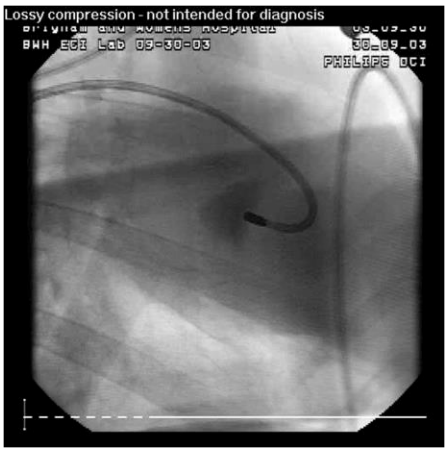
In 3 needle extensions no visible contrast seen intramurally suggesting intracavitary deployment.

In 3 needle extensions pericardial staining suggesting perforation and the needle was withdrawn. In two, the catheter was intentionally wedged in the LV apex and the needle extended for intentional perforation to assess recognition of perforation. No animal

developed hemodynamic compromise. At Post-mortem there was a small amount of blood tinged pericardial fluid in all 3 of these animals

In 44 needle deployments well defined tissue staining was observed (figure). At post mortem 43 lesions identified and had a mean lesion volume 1.45±0.82 cm2. There were no needle dislodgements during infusion or RF application. During continued observation, contrast was observed to gradually dissipate with time, as is observed when tissue contrast staining is used to guide transeptal puncture or pericardial puncture procedures.

In summary, the use of a contrast-saline mixture for initial irrigation through the needle allowed prompt recognition of deployment in the myocardium, penetration into the pericardial space, or failure to enter the myocardium.



Human Experience

Human Experience

The needle ablation catheter has been used with permission of the Queen Elizabeth II Health Sciences Center in 8 patients in Halifax Nova Scotia, Canada. Primary physician operators were John L. Sapp, MD and William G. Stevenson, MD. All patients had failed prior antiarrhythmic drug therapy and catheter ablation attempts. All had recurrent ventricular arrhythmias that had failed antiarrhythmic drug therapy and prior RF ablation attempts. For our 8 patients overall, 4 are free of ventricular tachycardia. Patients 1, 3, 5 and 6 had recurrent arrhythmias. Patient 5 has had one episode of spontaneously terminating slow VT, which is a marked improvement compared to prior to ablation. There was one major procedure related complication, which was cardiac tamponade in patient 3. This patient's course was complicated by renal failure, from which he recovered, but he subsequently died from heart failure (see below). In addition one patient (patient 5) had heart block due to ablation in the basal septum, but this was expected due to the location of the VT at that region. In patient 8, ablation near the epicardial LV pacing lead rendered this lead no longer able to capture, as expected from RF ablation in that area. There has been no procedure related mortality and no embolic events. In the last three patients a small amount of coagulum has been noted at the hole in the dome electrode after catheter removal. We feel this is indicative of heating of the dome electrode as it lies on the tissue. The coagulum has been adherent to the dome electrode, and tiny (figures below); smaller than that often encountered with the use of 8 mm electrodes and occasionally even on irrigated electrodes, in our experience. Use of longer RF applications may be a factor in these patients. Details of all the 8 cases are provided below.

Patient 1:

13 year-old male
Incessant VT; 70% of beats
EF 25%; LVEDD 79 mm
4 prior ablation procedures, including endo/epi last procedure; refractory to flecainide, amiodarone, beta-blockers, sotalol
Broad area of early activation inferoapical region
General anesthetic: suppressed ectopy
Combination of pace mapping and activation mapping
Suppressed with RF
PVC2 recurred upon withdrawal of GA
Suppressed with reintubation/sedation, limiting mapping largely to pace-mapping during the later part of the case.

Further RF delivered
A total of 12 RF applications (3-less than 10 seconds when they had no effect on ectopy)
No adverse effects

Procedure details:
At baseline there was ventricular bigeminy. The PVCs had RB morphology, axis -60 and slight variations in the notching. Activation mapping of the LV revealed early activation surrounding the apical inferolateral papillary muscle as visualized by ICE. The site of earliest activation appeared to be just distal (apical) to the papillary muscle. The earliest site of activation was identified, and the needle was extended. The earliest site was 10 msec preceding the QRS on at least one PVC morphology, and had a QS morphology on the unipolar electrogram. RF was delivered at 3 sites that appeared promising, but PVCs persisted, although the initial morphology changed. Another site just distal to the initial sites with angulation of the tip towards the base had early activation. Extending the needle into the myocardium at this site revealed a site with local activation preceding the QRS by 20 msec. RF was delivered here and abolished all ectopy.

No further ectopics were seen during a further 60 minutes of testing and observation, including with administration of epinephrine 10 and 20 mcg, and later after esmolol to slow the heart rate. Rapid burst pacing failed to induce any ectopy.

After the sheaths were removed and hemostasis achieved, the patient went into bigeminy with a different morphology PVC, more positive in V1. This had not been seen previously.

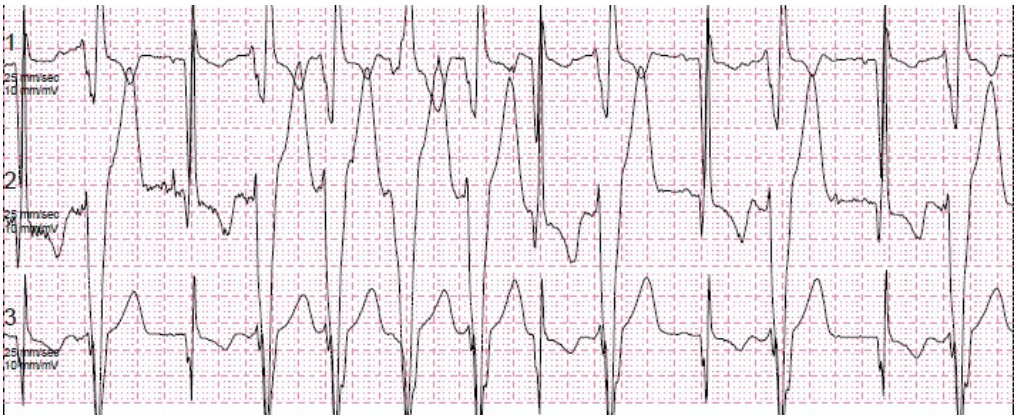
Vascular access was re-obtained, this time with a Mullins sheath rather than the steerable Agilis sheath, and with an 8 Fr arterial sheath.
Retrograde mapping was attempted, but electrograms appeared to have greater noise. Therefore we reverted to a transeptal approach and were able to re-approach the culprit area. Ectopics were extremely rare and so a combination of pace mapping and very limited activation mapping was performed. A slightly more apical portion of the same area was identified as the best target, and 2 needle ablation lesions were delivered. No ectopy was observed at all thereafter. After reversal of heparinization, sheaths were removed and the patient was extubated. He was transported to PICU in stable condition. There were no complications and only very rare ventricular ectopics observed overnight.

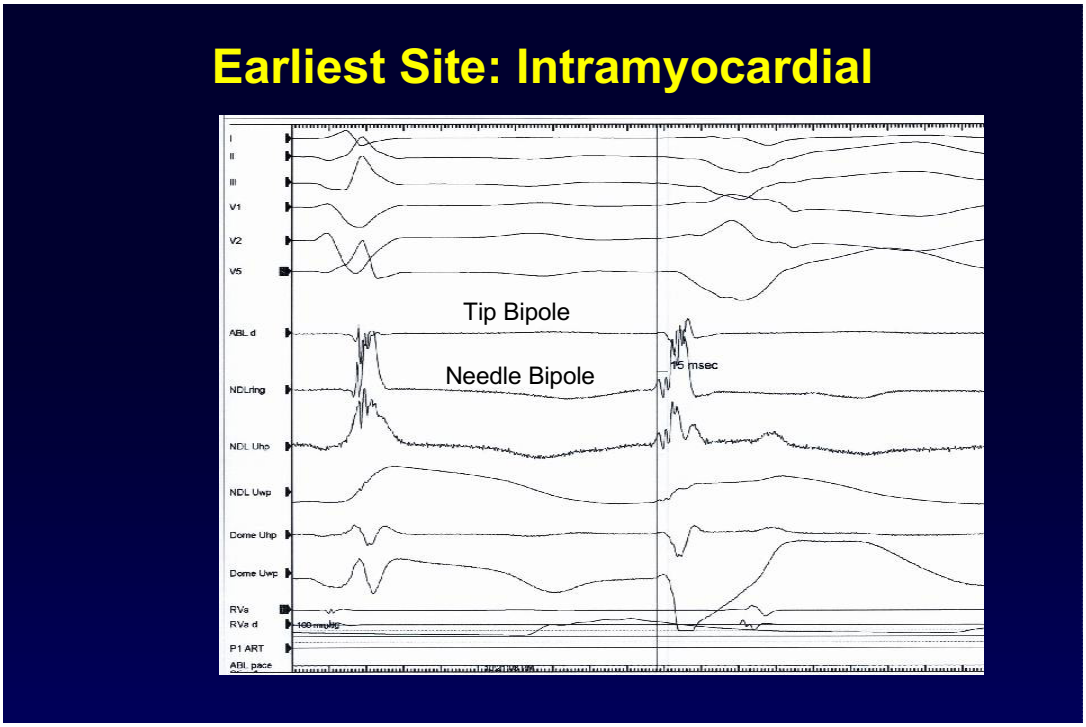
The patient recovered from the procedure normally without evidence of complications.

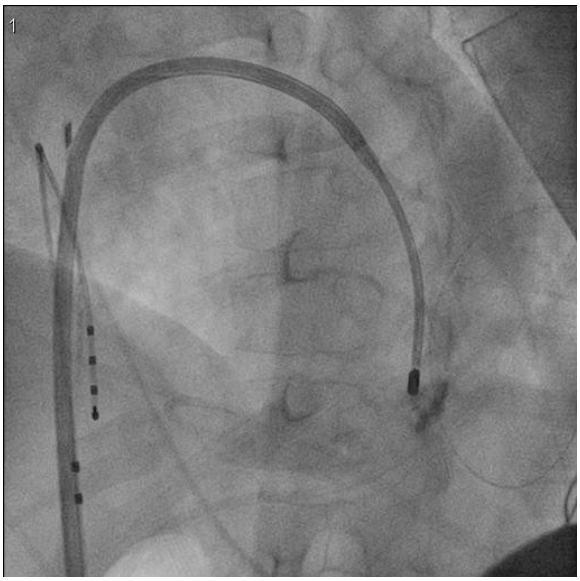
Holter 24 hr recording after procedure showed 3% PVCs. On day 4 after the procedure occasional PVCs emerged. The patient returned home to the Netherlands. By 5 weeks later periods of ventricular bigeminy, and occasional couplets were present.

Needle Catheter Performance

When mapping was reinitiated a new catheter was inserted. With injection of saline, saline was observed to leak from the Redel connector of this second catheter. A third catheter was removed from the packaging and after the cables were plugged in it was found that the Hypertronics connector wasn't securely glued into the handle as the PCB came out. A fourth catheter was then used without difficulty.







Ablation Summary

Target Arrhythmia	Result	Time		Temp	Power	Imp
		60	Avg	58	14	120
# 1			Max	63	24	185
Comments:						
		60	Avg	57	23	106
# 2			Max	61	32	137
Comments:						
		12	Avg	50	19	109
# 3			Max	62	35	122
Comments:						
		7	Avg	51	14	108
# 4			Max	60	22	114
Comments:						
		3	Avg	48	9	111
# 5			Max	53	18	113
Comments:						
		67	Avg	58	7	111
# 6			Max	60	12	125
Comments:						
		15	Avg	53	14	119
# 7			Max	63	27	130
Comments:						
		6	Avg	54	11	122
# 8			Max	62	17	125

Comments:					
	61	Avg	57	16	94
# 9		Max	61	21	116
Comments:					
	60	Avg	57	19	95
# 10		Max	62	26	111
Comments:					
	60	Avg	58	17	92
# 11		Max	60	24	147
Comments:					
	60	Avg	58	13	92
# 12		Max	60	17	123

Patient 2 6/15/2011

This 41 year-old woman had a history of VT and cardiomyopathy diagnosed in 2006, attributed to prior myocarditis, based on previous MR imaging that showed subendocardial scar. An ICD had been placed in 2007. In early June 2011 she presented with incessant VT that could not be interrupted with medications. An endocardial ablation procedure was attempted in Winnipeg, Canada. Earliest endocardial activation was identified at the basal lateral LV, but irrigated RF lesions had no effect on tachycardia. Congestive heart failure developed and LV ejection fraction was 16%. She was transferred to Halifax for attempted needle catheter ablation.

Intracardiac ultrasound showed a minimal pericardial effusion at baseline. The VT had axis -150, RBBB morphology, transition in V6 and Rs in V5. Transeptal puncture was performed and the ablation catheter inserted through a large curve steerable sheath to the left ventricle. Activation mapping revealed earliest endocardial activation at the posterobasal LV where an early far-field signal was also seen. The needle was deployed into the myocardium at 9 sites to determine the earliest intramyocardial site. At the 10th site an early pre-potential was identified within the area that was earliest endocardially. A 1 CC bolus of 50:50 contrast/hepaarinized saline was injected at this site to verify that we were intramyocardial. There was good contrast tissue staining, consistent with intramyocardial deployment. We then pre-injected at 2 mL/min heparinized saline, and delivered temperature-controlled RF for 60 seconds at 60 degrees, limited to 40W. The VT terminated within 5 seconds. RF was then restarted and continued for another 26 seconds. The needle was withdrawn into the catheter. Programmed ventricular stimulation with single and double ventricular extrastimuli were delivered, with no reinduction of VT. We

did not appreciate a change in the tissue and there was no change in the minimal pericardial effusion that had been present at baseline.

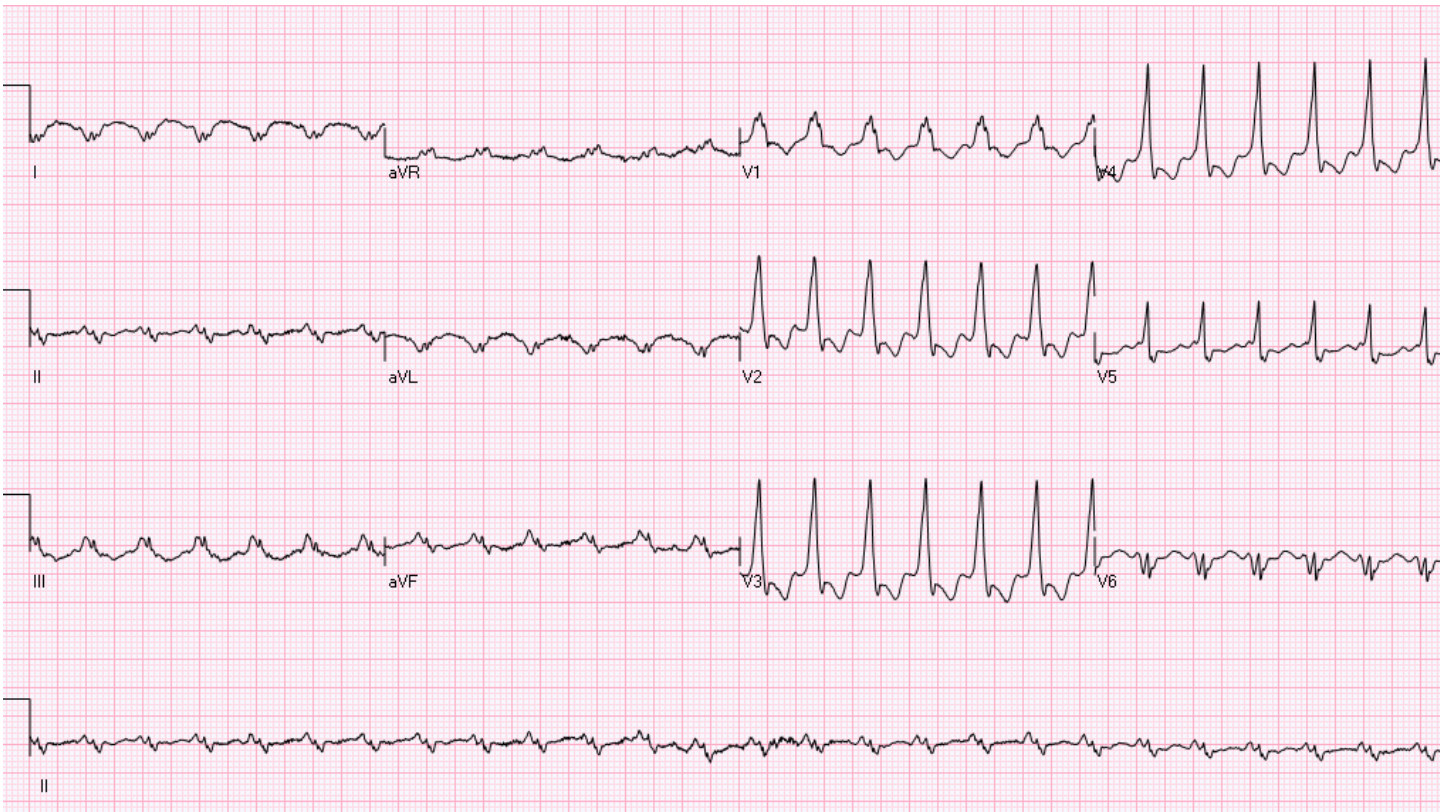
The needle was reinserted to the same area and a second lesion was delivered. Programmed ventricular stimulation was then repeated with 1 to 3 ventricular extra-stimulation from two intracardiac sites at two drive cycle lengths and only brief polymorphic VT was inducible.

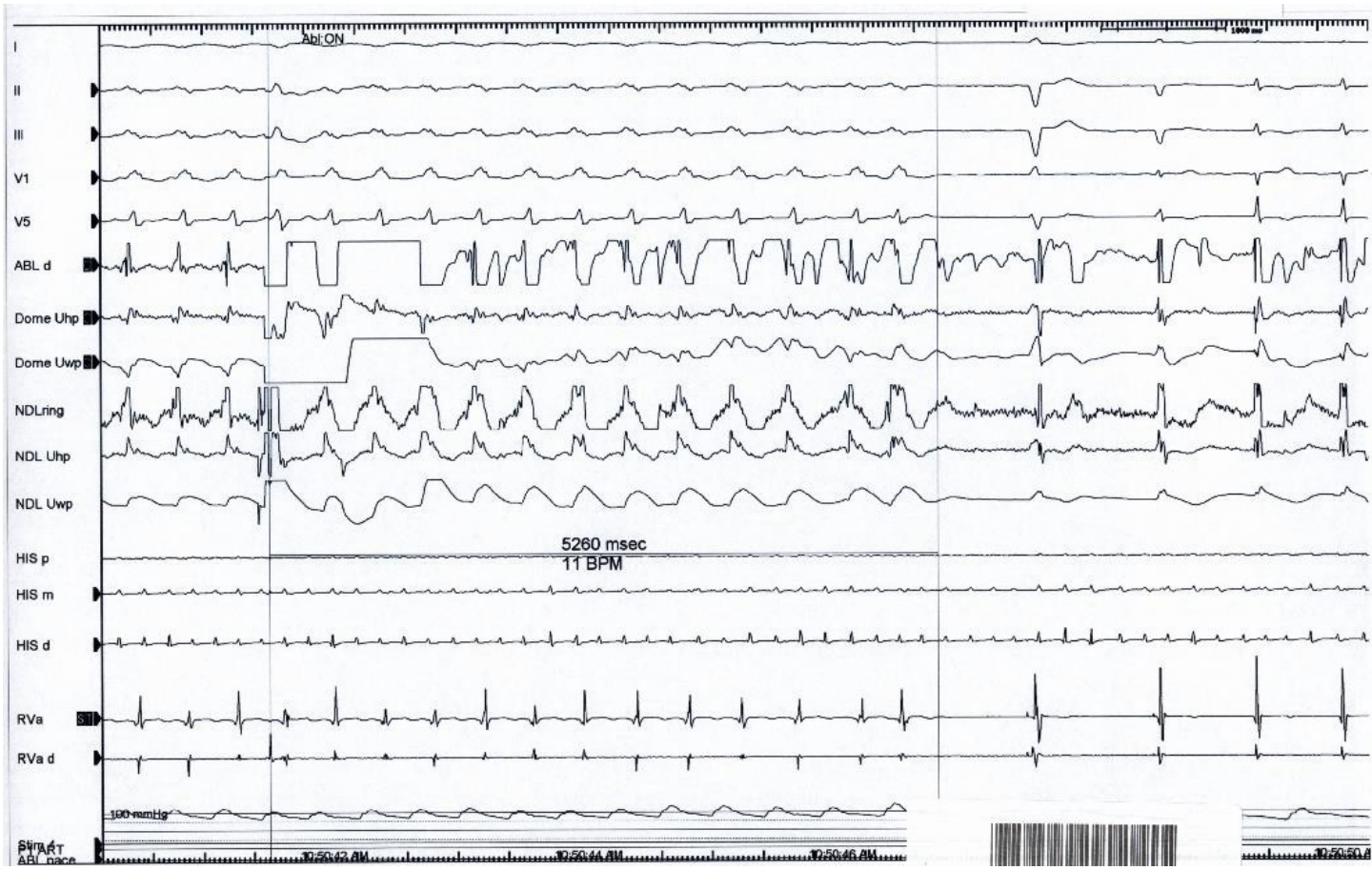
There were no procedure complications and the patient recovered well.

As of July 29, 2011 there was no recurrence of VT as detected by ICD. LV function had improved.

Needle Catheter Performance

There were no problems with needle catheter performance.





Ablation Summary

Target Arrhythmia	Result	Time		Temp	Power	Imp
		60	Avg	58	20	130
# 1			Max	62	29	171
Comments:						
		26	Avg	54	11	125
# 2			Max	60	18	150
Comments:						
		45	Avg	58	11	115
# 3			Max	60	14	125

Patient 3 7/27/2011

68 year-old man with ischemic cardiomyopathy, heart failure, prior myocardial infarction, left anterior descending angioplasty, LV ejection fraction of 30%, and VT with prior ICD placement. Endocardial RF ablation for VT had been performed in 2008. In July 2011 he presented with recurrent episodes of VT, heart failure and ICD therapies despite amiodarone and mexiletine therapy. Another endocardial RF ablation was attempted and failed to control VT and he was transferred for attempted needle ablation.

Procedure
Four morphologies of VT were induced with isoproterenol and programmed stimulation with double extrastimuli. Initial mapping in the RV suggested that the VT was in the LV. Despite the use of intracardiac echocardiography transeptal puncture was performed with difficultly due to atrial enlargement, a large coronary sinus and posteriorly positioned fossa ovalis. A steerable mapping catheter was advanced to the LV through a large curve steerable sheath. Earliest sites for VT1 and VT2 were in the region of the left ventricular outflow tract immediately below the aortic valve on the septal side. Catheter stability at that region was difficult. We then exchanged the mapping catheter for the needle ablation catheter. The needle was deployed into the myocardium in this basal septal superior LV region. Repeated deployments were performed, as insertion into the myocardium was difficult with the sheath coming downward through the mitral valve and then directed the catheter superiorly. However, sites with intramural activation time that preceded the QRS onset were identified and RF ablation lesions applied. Initial lesions rendered VT1 and VT2 no longer inducible. With isoproterenol stimulation and programmed stimulation, VT3 and VT 4 remained inducible, but were less reliably provokable. Additional needle deployments were performed from the LV by both a transeptal and retrograde aortic approach. Additional deployment from the right ventricle was also performed in the basal septal area. A total of 48 RF applications were performed ranging from 14 to 120 seconds in duration. No VT was inducible with programmed stimulation during isoproterenol infusion.

Complete heart block occurred during ablation, as anticipated from ablation in the basal septum in the region of the AV conduction system, but it was felt that heart block with control of VT would be preferable to continued VT.

A small pericardial effusion was noted on intracardiac imaging during the later portion of the procedure, but was stable with repeated imaging. Approximately one hour later the patient developed hypotension and transthoracic echocardiography showed a large pericardial effusion, which was evacuated with a subxiphoid pericardial puncture. Over the

next 5 days he had acute exacerbation of (in addition to his chronic renal insufficiency) renal failure, which subsequently resolved. He was discharged home. Approximately 3 months later he was readmitted to hospital for heart failure. During follow-up he had no further spontaneous episodes of VT, but heart failure continued to be a problem. He wished no further therapy, his ICD was inactivated, he was made "do not resuscitate" and died of heart failure.

Needle Catheter Performance

Deploying the needle into the basal LV septum was difficult, as is often the case for mapping this area with usual ablation catheters. From the transeptal approach it requires the catheter traverse the sheath into the LV, which typically points inferiorly, then flexing superiorly to reach the target area. It was difficult to maintain that position with sufficient force, such that the needle with deploy into the myocardial tissue when extruded and multiple attempts to insert the needle were made with failure of contrast injection to reveal tissue staining. After 1 hr and 35 min the irrigation solution could no longer be injected through the needle, indicating that it had clogged with the mixture of viscous contrast and saline. The catheter was replaced without incident.

Complications:

This was a challenging case due to multiple VTs from the basal septum. Heart block was an anticipated complication due to the location of the VT, requiring ablation in the basal septum, and has been observed in other VT ablation studies.(4,6).

Pericardial tamponade occurs in approximately 1% of VT ablation cases (Tokuda in press). It is possible that it was related to myocardial puncture with the needle, or the diagnostic catheter in the RV during this long procedure. The transeptal puncture was also difficult and tamponade is a known risk. Tamponade presented over one hour after the procedure suggesting that the bleeding was slow and it resolved without requiring surgery. This course is relatively typical for tamponade related to catheter ablation. Acute renal failure was felt to be due to acute tubular necrosis, secondary to transient hypotension and hypoperfusion from cardiac tamponade on top of chronic renal failure. The patient had a history of heart failure and this continued after ablation. Heart failure is a major cause of mortality in this patient population, as has been observed in other VT ablation studies.(6) It is possible that the ablation procedure aggravated his heart failure, either through myocardial injury or disadvantaged myocardial contractility induced by pacing dependence, although if VT had not been controlled, this would likely have had still greater adverse impact.

Ablation Summary

Target Arrhythmia	Result	Time	Temp	Power	Imp

	33	Avg	54	16	108
# 1		Max	66	30	118
Comments:					
	61	Avg	55	20	97
# 2		Max	64	29	118
Comments:					
	19	Avg	54	16	99
# 3		Max	63	28	109
Comments:					
	51	Avg	58	15	93
# 4		Max	63	25	103
Comments:					
	60	Avg	57	23	94
# 5		Max	60	28	150
Comments:					
	60	Avg	57	17	95
# 6		Max	62	28	124
Comments:					
	80	Avg	58	17	99
# 7		Max	61	28	134
Comments:					
	69	Avg	53	23	90
# 8		Max	63	29	121
Comments:					
	60	Avg	53	21	100
# 9		Max	61	30	107
Comments:					
	15	Avg	45	18	108
# 10		Max	57	30	114
Comments:					
	60	Avg	46	23	110
# 11		Max	55	30	116
Comments:					
	15	Avg	57	2	134
# 12		Max	60	4	141
Comments:					
	20	Avg	57	3	130
# 13		Max	60	13	141
Comments:					

	71	Avg	58	5	103
# 14		Max	61	11	128
Comments:					
	19	Avg	51	14	112
# 15		Max	63	30	123
Comments:					
	18	Avg	49	20	108
# 16		Max	60	30	113
Comments:					
	14	Avg	56	3	118
# 17		Max	60	12	124
Comments:					
	27	Avg	55	16	100
# 18		Max	61	21	119
Comments:					
	61	Avg	57	21	84
# 19		Max	62	29	97
Comments:					
	65	Avg	55	26	85
# 20		Max	60	29	103
Comments:					
	70	Avg	58	16	86
# 21		Max	61	21	106
Comments:					
	91	Avg	58	15	92
# 22		Max	63	25	133
Comments:					
	90	Avg	58	13	94
# 23		Max	61	20	133
Comments:					
	24	Avg	55	15	90
# 24		Max	66	23	108
Comments:					
	19	Avg	57	8	89
# 25		Max	63	14	91
Comments:					
	20	Avg	55	8	89
# 26		Max	60	17	93
Comments:					

	61	Avg	58	12	85
# 27		Max	62	19	95
Comments:					
	61	Avg	58	6	95
# 28		Max	60	12	119
Comments:					
	91	Avg	57	19	83
# 29		Max	63	30	108
Comments:					
	30	Avg	42	30	108
# 30		Max	45	37	111
Comments:					
	28	Avg	43	32	108
# 31		Max	45	35	111
Comments:					
	36	Avg	42	33	107

Patient 4 date: 4/17/2012

The patient is a 61 year old male with previous aortic root repair, aortic valve replacement, inferior wall myocardial infarction, now with a left ventricular ejection fraction of 0.45. He had a history of recurrent ventricular tachycardia (VT) for which an ICD had been implanted. VT recurrences had failed to be suppressed by therapy with amiodarone and mexiletine and two prior endocardial catheter ablation procedures.

Procedure:
Patient was in sinus rhythm with a prolonged HV interval at the start of the case. Five different morphologies of monomorphic VT were inducible with programmed ventricular stimulation. A transeptal puncture was performed and the left ventricle accessed via the left atrium and across the mitral valve. Initial mapping during sinus rhythm and VT was performed with a Biosense Webster Surround Flow catheter and was consistent with inferolateral low voltage scar, but a relatively broad endocardial exit for the predominant VT with the endocardium not in the reentry circuit. We initially focused on VT3, which was felt to be the predominant clinical VT. VT3 induced and was mapped to the superior aspect of the inferoposterobasal scar. The initial mapping catheter was then exchanged for the needle catheter. Infusion needle ablation was carried out across the sites of earliest endocardial activation in the band between the endocardial scar margin as determined by bipolar electrogram (< 1.5 mV) and the apparent epicardial scar margin as determined by

unipolar electrogram amplitude (< 8.3 mV). Sites with close pace matches for the induced VTs were sought. At the site of best pace match, access to the subepicardial region was limited by what appeared to be a papillary muscle base and very thick tissue at this region. Sites with intramyocardial late potentials or where intramyocardial capture with delay (needle unipolar pacing) was achieved especially if a near match to an induced VT, were specifically targeted. During RF at a site with an early intramyocardal potential VT terminated, preceded by slight slowing and a PVC. The same VT recurred later additional RF lesions were placed in that are with the needle extended to 9 mm.

Near the end of the procedure the initial VTs were not inducible with right ventricular outflow tract pacing. A fast poorly tolerated VT (VTE) was induced prior to the final lesions delivered; further testing was not performed after final lesion delivery. The patient recovered from the procedure well and remained free of sustained VT. There were no complications. He recovered well.

Needle Catheter Performance:

Needle applications are listed in the table from the EP lab recording system below. A total of 40 RF applications were delivered. As discussed above we had the impression that the thick myocardium over the region added to difficulty in region the reentry circuit. There was no difficulty in catheter maneuverability. After several applications, the resistance to flow through the infusion channel of the needle increased, such that it required substantial force to inject the saline contrast mixture, and subsequently became completely occluded. The catheter was exchanged. The channel of the second catheter later became partially obstructed, limiting infusion and probably limiting lesion creation. Both catheters were returned to Biosense Webster for examination.

Note that in the table, the recording system resets and designates a new lesion when power ramps to 0 in response to reaching temperature maximum. Thus the number continuous applications is fewer than the total number in the table.

Ablation Summary

Target Arrhythmia	Time		Temp	Power	Imp
	60	Avg	58	16	113
# 1		Max	62	27	151
Comments:					
	61	Avg	58	15	117
# 2		Max	60	19	132
Comments:					

	12	Avg	54	7	146
# 3		Max	62	17	158
Comments:					
	11	Avg	56	8	141
# 4		Max	63	19	146
Comments:					
	6	Avg	54	10	136
# 5		Max	63	21	140
Comments:					
	29	Avg	55	15	129
# 6		Max	63	33	137
Comments:					
	15	Avg	58	0	201
# 7		Max	60	1	210
Comments:					
	14	Avg	53	12	131
# 8		Max	62	29	137
Comments:					
	8	Avg	53	12	133
# 9		Max	62	32	137
Comments:					
	5	Avg	53	11	132
# 10		Max	59	28	136
Comments:					
	76	Avg	58	7	110
# 11		Max	60	11	131
Comments:					
	65	Avg	58	6	124
# 12		Max	61	11	132
Comments:					
	91	Avg	59	4	108
# 13		Max	60	11	126
Comments:					
	91	Avg	59	5	103
# 14		Max	60	10	120
Comments:					
	91	Avg	59	5	102
# 15		Max	61	10	115
Comments:					

	23	Avg	58	1	132
# 16		Max	60	10	142
Comments:					
	92	Avg	58	10	111
# 17		Max	60	19	131
Comments:					
	60	Avg	57	24	88
# 18		Max	60	32	97
Comments:					
	71	Avg	58	14	96
# 19		Max	60	20	112
Comments:					
	60	Avg	57	22	93
# 20		Max	60	28	106
Comments:					
	61	Avg	58	10	101
# 21		Max	62	26	122
Comments:					
	61	Avg	58	15	92
# 22		Max	60	19	103
Comments:					
	61	Avg	58	12	97
# 23		Max	61	16	109
Comments:					
	90	Avg	59	8	94
# 24		Max	60	10	111
Comments:					
	16	Avg	58	1	120
# 25		Max	60	10	128
Comments:					
	6	Avg	53	3	122
# 26		Max	58	10	130
Comments:					
	90	Avg	59	8	101
# 27		Max	60	11	126
Comments:					
	91	Avg	59	8	95
# 28		Max	61	14	108
Comments:					

	91	Avg	59	8	94
# 29		Max	61	11	110
Comments:					
	61	Avg	58	11	93
# 30		Max	61	15	107
Comments:					
	45	Avg	57	9	90
# 31		Max	61	14	94
Comments:					
	60	Avg	58	10	91
# 32		Max	61	16	105
Comments:					
	61	Avg	58	8	96
# 33		Max	60	12	109
Comments:					
	68	Avg	58	5	95
# 34		Max	61	10	113
Comments:					
	6	Avg	56	1	174
# 35		Max	59	2	178
Comments:					
	91	Avg	59	4	133
# 36		Max	60	7	179
Comments:					
	97	Avg	59	4	111
# 37		Max	60	12	146
Comments:					
	91	Avg	59	3	111
# 38		Max	60	9	135
Comments:					
	9	Avg	51	10	126
# 39		Max	60	25	134
Comments:					
	5	Avg	53	11	130
# 40		Max	59	31	143
Comments:					
	11	Avg	51	12	139
# 41		Max	62	31	162
Comments:					

	26	Avg	58	2	115
# 42		Max	60	11	128
Comments:					
	54	Avg	58	6	92
# 43		Max	60	9	103
Comments:					
	90	Avg	59	5	90
# 44		Max	60	8	99
Comments:					
	84	Avg	34	44	98
# 45		Max	36	50	120
Comments:					
	80	Avg	33	39	97
# 46		Max	35	50	109
Comments:					
	119	Avg	33	43	92
# 47		Max	34	45	105
Comments:					
	60	Avg	59	4	95
# 48		Max	60	9	104
Comments:					
	60	Avg	62	6	86
# 49		Max	65	9	93
Comments:					

Patient 5 date: 4/18/2012

The patient is a 48 year old woman with nonischemic dilated cardiomyopathy left ventricular ejection fraction of less than 0.40. She had recurrent ventricular tachycardia (VT) for which an ICD had been implanted. VT recurrences had failed to be suppressed by therapy with amiodarone and mexiletine and two prior endocardial catheter ablation procedures. The last ablation procedure in 2009 was complicated by right ventricular perforation requiring emergency cardiac surgery for closure of a laceration in the free wall of the right ventricular outflow tract that was attributed to a steam pop during ablation near that location.

Procedure:
Patient was in sinus rhythm with a prolonged HV interval at the start of the case. A transeptal puncture was performed and the left ventricle accessed via the left atrium and across the mitral valve. Seven different morphologies of monomorphic VT were inducible with programmed ventricular stimulation or catheter induced ectopy. Initial mapping during sinus rhythm and VT was performed with a Biosense Webster Surround Flow catheter.

VT1 was mapped to the superior basal mitral annulus. Frequently the VT morphologies would change between VT1 and VT2. The needle was inserted into that area and midmyocardial signal preceded the QRS during VT and was earlier than the endocardial signal. Coronary angiography confirmed adequate distance to the left coronary system. Infusion needle ablation rendered this VT no longer inducible. VT2 was initiated by ventricular pacing and appeared to originate from the same general area near the basal aortic-mitral region. Further infusion needle RF lesions were delivered at site of delayed midmyocardial potentials, or at sites where unipolar needle pacing matched the VT morphology.

VT4 was mapped to the inferobasal septal mitral annulus and ablated in this region.

VT5 and VT6 were mapped to the septal aspect of the right ventricular outflow tractregion and needle ablation was applied in this region both from the RV and LV sides of the sepum. The area of the his bundle was tagged and carefully avoided.

During a relatively prolonged episode of ventricular tachycardia with borderline BP requiring DC cardioversion VT was mapped to the inferior basal septum and Rf was applied. After cardioversion heart block was observed. This site was well below the site of the His bundle recording.

Programmed stimulation for induction testing was not repeated at the end of the procedure, but multiple attempts at induction prior to the last RF delivery had failed to induce the initial VTs, inducing only the VT targeted with the last ablation.

The patient recovered from the procedure well and was discharged from hospital 2 days after ablation. Other than AV block, there were no complications. AV block is a recognized complication of ablation in the region of the basal septum which was required for these VTs. It was surprising that it emerged following an ablation lesion that was well below the His bundle region, but this could have been due to expansion of a prior lesion or block of a portion of the left posterior fascicle in that ablation region.

At 2 months interrogation of her ICD showed one slow (105/min) episode of VT that terminated spontaneously, which is a marked improvement compared to prior to ablation.

Needle Catheter Performance:

There were 21 needle RF ablation lesions delivered (table below). There was no difficulty in catheter maneuverability. There was no increase in resistance to flow through the infusion channel of the needle.

Note that in the table, the recording system resets and designates a new lesion when power ramps to 0 in response to reaching temperature maximum. Thus the number continuous applications (24) is fewer than noted in the table.

Target Arrhythmia	Time		Temp	Power	Imp
	60	Avg	57	24	118
# 1		Max	62	32	157
Comments:					
	60	Avg	58	15	111
# 2		Max	61	20	130
Comments:					
	61	Avg	58	9	121
# 3		Max	62	16	143
Comments:					
	60	Avg	57	16	106
# 4		Max	61	25	125
Comments:					
	61	Avg	58	14	111
# 5		Max	63	23	129

Comments:					
	60	Avg	58	8	112
# 6		Max	61	12	133
Comments:					
	61	Avg	57	20	97
# 7		Max	63	30	119
Comments:					
	76	Avg	58	13	103
# 8		Max	61	18	120
Comments:					
	90	Avg	58	13	105
# 9		Max	61	17	124
Comments:					
	90	Avg	59	8	104
# 10		Max	60	13	117
Comments:					
	60	Avg	57	22	105
# 11		Max	61	28	191
Comments:					
	15	Avg	58	2	148
# 12		Max	64	7	154
Comments:					
	90	Avg	58	16	98
# 13		Max	60	21	136
Comments:					
	91	Avg	58	16	92
# 14		Max	61	21	110
Comments:					
	17	Avg	54	12	121
# 15		Max	66	22	129
Comments:					
	37	Avg	54	22	100
# 16		Max	60	33	123
Comments:					
	61	Avg	57	20	98
# 17		Max	61	33	120
Comments:					
	61	Avg	57	14	93
# 18		Max	60	20	105

Comments:					
	61	Avg	57	17	98
# 19		Max	63	31	111
Comments:					
	90	Avg	58	17	90
# 20		Max	63	28	108
Comments:					
	5	Avg	56	1	210
# 21		Max	60	3	223
Comments:					
	5	Avg	58	1	227
# 22		Max	61	3	244
Comments:					
	93	Avg	58	15	107
# 23		Max	64	29	250
Comments:					
	41	Avg	57	8	96
# 24		Max	61	13	112
Comments:					

Patient 6: date 6/14/2012

This 63 year old man had nonischemic dilated cardiomyopathy, an ICD and recurrent VT. He had failed prior endocardial and epicardial attempts at catheter ablation. Access to the LV was obtained by a transeptal approach. The bipolar voltage map did not suggest endocardial scar, however, the unipolar voltage map indicated a large posterobasal region of low voltage, consistent with intramural or epicardial scar. The clinical VT was repeatedly induced with catheter manipulation, but could not be induced with programmed stimulation and the limited activation mapping that could be performed suggested that the VT exit was lateral to the aortic valve. Needle ablation lesions were delivered as closely as possible to the site of early activation. Needle deployment was very difficult here, because of difficulty achieving catheter contact. Further needle was delivered throughout the region of low unipolar signal amplitude from the mitral end toward the apical end of the low voltage area. At each site contrast was injected to verify intramyocardial location. Verification of loss of capture was performed after RF delivery in most cases. On multiple occasions very fast VT was induced with catheter manipulation or double extrastimuli. These failed to respond to burst pacing and required shocks on each

occasion. This severely limited induction testing and mapping. Induction testing was performed with pacing from the LV and RV. Single extrastimuli and burst pacing and catheter manipulation failed to induce VT at the end of the procedure. We could not be sure VT was abolished since it was not inducible at the beginning of the procedure. There were no complications and specifically no clinically evident embolic events. The patient recovered well but had recurrent ventricular tachycardia of a different morphology than observed during ablation. Amiodarone was increased. At two months of follow-up he has had further VT.

Needle catheter performance

Power was limited to 35W and temp to 60W. Each site had 1CC 50:50 contrast/saline, then 2CC of saline before RF application for up to 90 sec. There were 24 RF needle applications. We paid attention to avoiding repeated torquing of the catheter and had no problems. It was difficult to deploy the needle into myocardium adjacent to the aortic valve from the transeptal approach as it is difficult to exert force in the cranial direction when the catheter must come through the mitral valve in the inferior direction. On removal of the catheter a tiny amount of coagulum was noted along the perimeter of the dome needle hole (figure 1 below left panel).

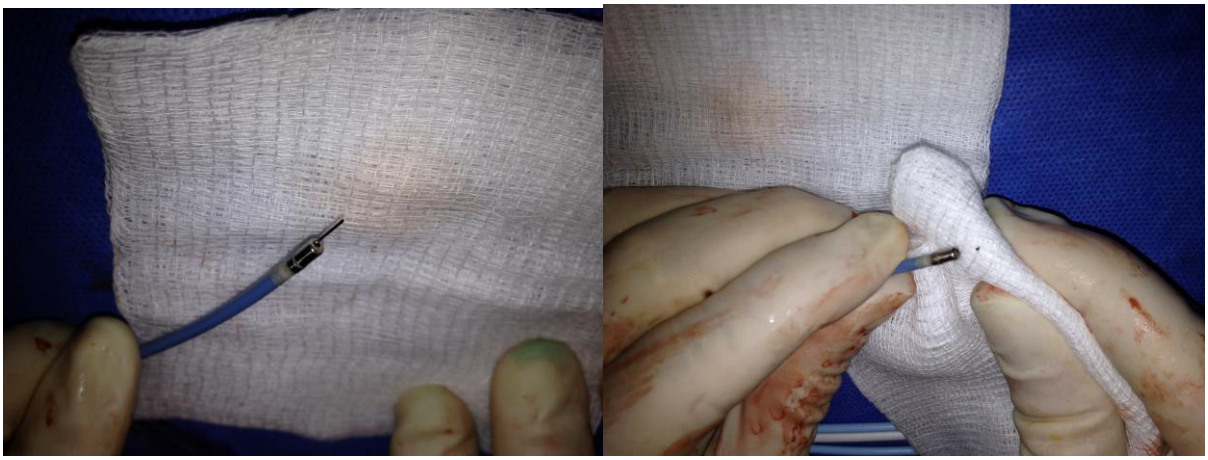


Figure 1. Coagulum around hole in dome electrode (left) and shown after removal on gauze (right).

Note that in the table, the recording system resets and designates a new lesion when power ramps to 0 in response to reaching temperature maximum. Thus the number continuous applications (24) is fewer than noted in the table.

Target Arrhythmia	Time		Temp	Power	Imp
	16	Avg	53	19	132
# 1		Max	65	28	146
Comments:					
	73	Avg	58	20	123
# 2		Max	62	30	130
Comments:					
	90	Avg	58	16	119
# 3		Max	63	26	142
Comments:					
	85	Avg	56	23	106
# 4		Max	63	34	123
Comments:					
	90	Avg	57	25	108
# 5		Max	61	33	143
Comments:					
	43	Avg	55	20	146
# 6		Max	60	35	181
Comments:					
	4	Avg	46	12	140
# 7		Max	59	15	150
Comments:					
	10	Avg	53	16	123
# 8		Max	62	24	132
Comments:					
	73	Avg	58	22	115
# 9		Max	63	31	129
Comments:					
	6	Avg	49	11	131
# 10		Max	60	20	139
Comments:					
	56	Avg	58	18	111
# 11		Max	63	30	129
Comments:					
	90	Avg	58	20	107
# 12		Max	64	32	146
Comments:					
	90	Avg	58	22	105

# 13		Max	61	32	147
Comments:					
	90	Avg	58	20	103
# 14		Max	62	29	121
Comments:					
	90	Avg	58	19	112
# 15		Max	65	33	158
Comments:					
	7	Avg	54	11	138
# 16		Max	61	18	154
Comments:					
	79	Avg	57	15	113
# 17		Max	64	32	134
Comments:					
	17	Avg	54	15	122
# 18		Max	63	25	142
Comments:					
	71	Avg	58	18	110
# 19		Max	62	30	121
Comments:					
	90	Avg	58	21	105
# 20		Max	63	34	135
Comments:					
	90	Avg	58	19	105
# 21		Max	62	34	138
Comments:					
	36	Avg	57	15	109
# 22		Max	60	21	132
Comments:					
	90	Avg	58	17	99
# 23		Max	61	24	118

*nc post = no capture at 10 ma pacing from the needle after ablation.

Patient 7

66 year-old man with recurrent VT and nonischemic cardiomyopathy, left ventricular ejection fraction approximately 40%. Has an ICD, history of amiodarone pulmonary toxicity, and failed therapy with sotalol and mexiletine. Previous catheter ablation attempt performed ablation in the septum in the para-Hisian region which was acutely successful although caused heart block. He had biventricular ICD upgrade and unfortunately developed recurrent VT and ICD shocks progressing to incessant VT despite antiarrhythmic therapy including trials of dofetilide and flecainide. A second catheter ablation procedure one week ago terminated the incessant VT. Unfortunately faster VTs recurred requiring ICD shocks.

Procedure

Programmed ventricular stimulation induced sustained monomorphic VT3 that was moderately well tolerated hemodynamically but did not usually sustain sufficiently to allow extensive mapping. Pace-mapping was consistent with origin from the basal inferior LV septum. Infusion needle ablation lesions were delivered from the LV side. VT remained inducible and limited mapping in VT showed a site of early activation at the basal inferior LV septum. The needle was deployed and the recording from the needle was even earlier. RF terminated VT after which it was no longer inducible. Additional RF lesions were applied to that area. RV was then explored and further RF delivered with the needle inserted into the septum at the RV side across from the inferior basal LV from the lesion that terminated VT. Programmed stimulation was performed and no VT was inducible. During recovery occasional runs of AIVR likely arising from just inferior to the site of ablation were observed transiently.

There were no complications and he recovered well. Following the procedure he remained free of recurrent VT at two months of follow-up.

Needle Catheter Performance

The catheter handled well. Power was limited to 35W and temp to 60W. Each site had 1CC 50:50 contrast/saline, then 2CC of saline before RF application for up to 90 sec. A total of 16 RF applications through the needle were applied. During RF application 6 spontaneous bubbles were noted on intracardiac ultrasound, similar to those that are observed during standard RF ablation and that have been thought to indicate heating at the electrode tissue interface with increasing temperature. The catheter was removed and and inspected. A small ring of coagulum was noted around the dome needle hole

(figure 2), which was cleaned. The catheter was inspected again after lesions 12 and 16 and no coagulum was identified. There were no thromboembolic complications.

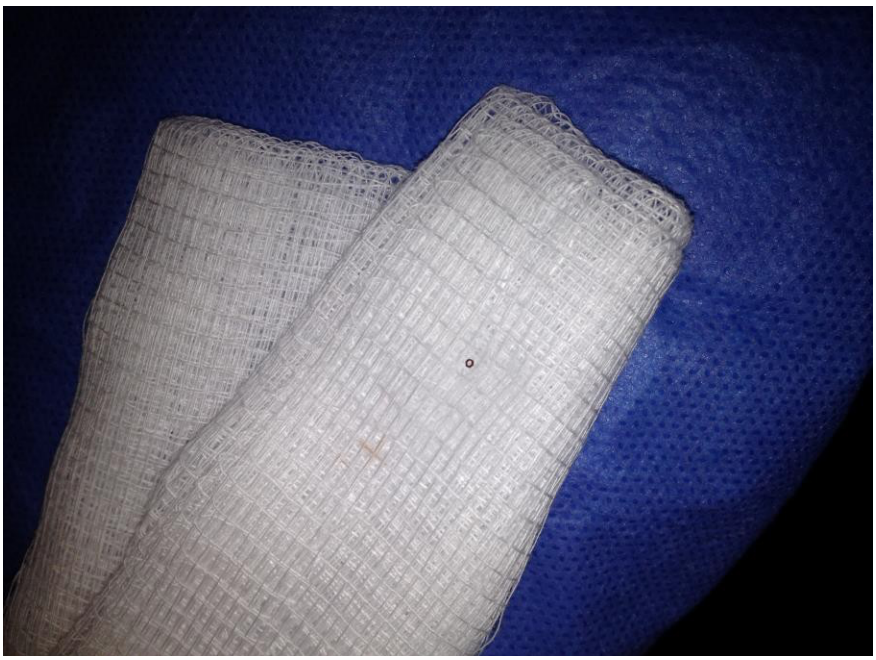


Figure 2. Circular coagulum removed from dome electrode.

Note that in the table, the recording system resets and designates a new lesion when power ramps to 0 in response to reaching temperature maximum. Thus the number continuous applications (24) is fewer than noted in the table.

Target Arrhythmia	Time		Temp	Power	Imp
	90	Avg	57	26	77
# 1		Max	63	33	99
Comments:					
	25	Avg	48	26	84
# 2		Max	56	33	117
Comments:					
	90	Avg	57	26	69
# 3		Max	63	34	98
Comments:					
	10	Avg	57	1	163
# 4		Max	60	3	182
Comments:					
	43	Avg	54	22	81
# 5		Max	63	34	98
Comments:					

	7	Avg	53	9	78
# 6		Max	58	23	85
Comments:					
	38	Avg	54	15	77
# 7		Max	63	34	85
Comments:					
	10	Avg	48	18	85
# 8		Max	61	29	93
Comments:					
	8	Avg	51	12	85
# 9		Max	60	20	88
Comments:					
	5	Avg	50	12	85
# 10		Max	62	22	90
Comments:					
	6	Avg	50	17	83
# 11		Max	60	26	88
Comments:					
	8	Avg	52	13	84
# 12		Max	60	24	88
Comments:					
	8	Avg	52	15	83
# 13		Max	65	32	88
Comments:					
	32	Avg	56	21	80
# 14		Max	63	33	86
Comments:					
	85	Avg	59	10	84
# 15		Max	64	14	102
Comments:					
	90	Avg	57	26	70
# 16		Max	62	33	127
Comments:					
	90	Avg	56	15	71
# 17		Max	62	27	85
Comments:					
	90	Avg	56	27	64
# 18		Max	60	33	105
Comments:					

	13	Avg	53	10	94
# 19		Max	66	28	103
Comments:					
	72	Avg	53	25	64
# 20		Max	67	33	98
Comments:					
	90	Avg	58	15	69
# 21		Max	60	22	87
Comments:					
	36	Avg	47	24	65
# 22		Max	56	33	84
Comments:					
	10	Avg	52	12	64
# 23		Max	61	24	66
Comments:					
	17	Avg	53	18	63
# 24		Max	59	33	66
Comments:					
	24	Avg	54	17	62
# 25		Max	59	30	65
Comments:					
	90	Avg	57	19	66
# 26		Max	61	33	83
Comments:					
	90	Avg	58	17	66
# 27		Max	62	28	87
Comments:					
	56	Avg	55	18	66
# 28		Max	63	32	80
Comments:					
	9	Avg	53	10	65
# 29		Max	60	23	68
Comments:					
	5	Avg	51	8	65
# 30		Max	58	17	68

This 70 year-old man with prior right coronary artery stent and nonischemic cardiomyopathy recurrent VT despite antiarrhythmic drug therapy with sotalol and mexiletine and had a history of amiodarone lung toxicity. Prior endocardial and then endocardial and epicardial RF catehter ablation ablation in May 2011 failed. Recurrent VT episodes continued despite therapy with sotalol and mexiletine.

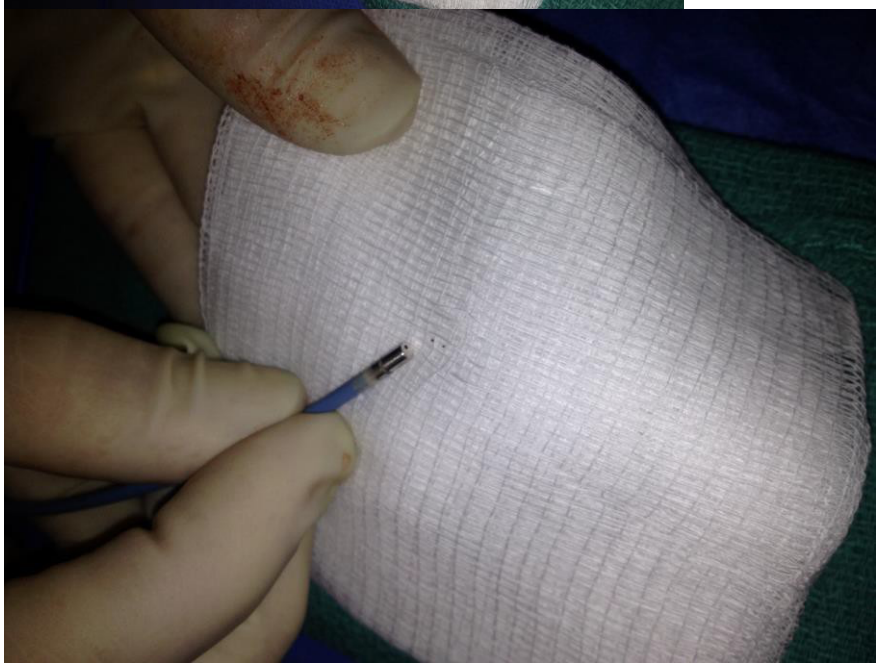
Procedure

Programmed ventricular triple extrastimuli from the left ventricle induced two VTs: VT1 had a cycle length of 280 ms, right bundle branch block configuration in V1 and cycle length of 280 ms. VT2 had a cycle length of 270 ms, right bundle branch block configuration in V1. A transseptal approach was taken to access the left ventricle. The endocardial bipolar voltage was largely normal. At the basal septum there was a reduced unipolar signal amplitude, as well as a small patch at the superobasal-lateral area consistent with intramural or epicardial scar. Frequent PVCs arose from the high basal lateral LV, and appeared to be epicardial (slurred QRS upstroke, and no early endocardial activation, with radial spread from the high basal lateral LV). Earliest endocardial activation for VT1 was at the high basal lateral LV. Infusion needle ablation lesions were delivered at the earliest area. VT1 was no longer inducible. A new VT, VT2 was induced with had a more superior/medial endocardial exit. Further needle RF applications into that area rendered this noninducible. The ICD was programmed back on at the end of the procedure. The LV lead was immediately above the site of best match, and indeed pacing from the LV lead had the best match for VT1. Aggressive needle ablation was performed immediately below the LV lead. As expected the LV lead no longer captured after ablation. Of note, it had been programmed off previously, because of concerns of possible proarrhythmia, and because his QRS was narrow.

There were no complications. The patient recovered well and was discharged home.

Needle Catheter Performance

Ten needle ablation lesions were applied. On removal of the catheter a small amount of coagulum was noted at the needle hole in the dome (figure 3).



Target Arrhythmia	Time		Temp	Power	Imp
	90	Avg	58	20	133
# 1		Max	62	31	159
Comments:					
	90	Avg	58	21	122
# 2		Max	62	29	146
Comments:					
	90	Avg	58	20	130

# 3		Max	62	31	159
Comments:					
	90	Avg	58	20	121
# 4		Max	63	32	147
Comments:					
	90	Avg	58	16	116
# 5		Max	61	24	142
Comments:					
	90	Avg	58	21	119
# 6		Max	61	27	140
Comments:					
	90	Avg	55	18	118
# 7		Max	63	33	132
Comments:					
	36	Avg	53	26	149
# 8		Max	60	35	171
Comments:					
	90	Avg	54	26	129
# 9		Max	62	35	191
Comments:					
	90	Avg	58	18	117
# 10		Max	62	31	137

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