AF ablasyonunda beklenen çalışmalar, Beklentiler

5. AF Zirvesi , Antalya

Dr. Özcan Özeke

Türkiye Yüksek İhtisas Hastanesi

CABANA

Trial Milestones

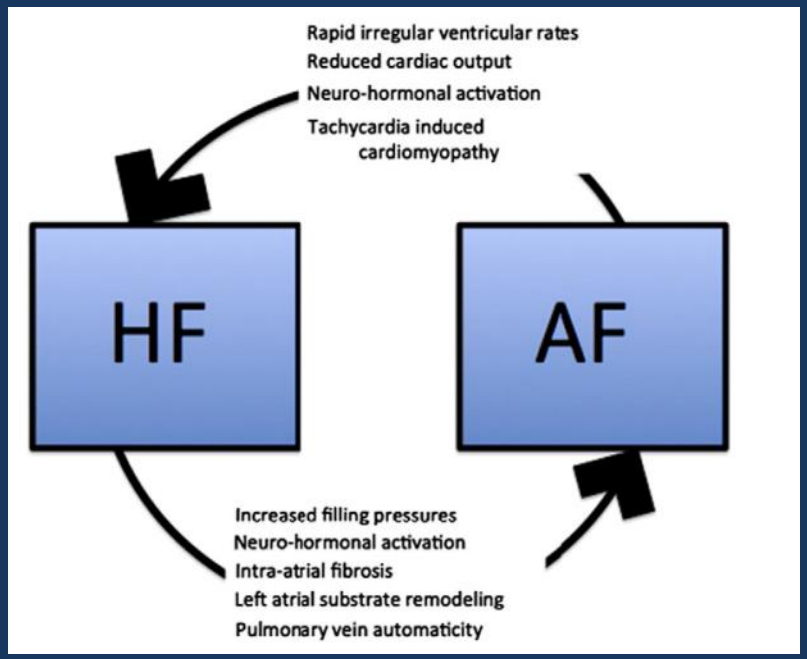
The following dates are available for this trial. Trial information last updated on 14 September 2015.

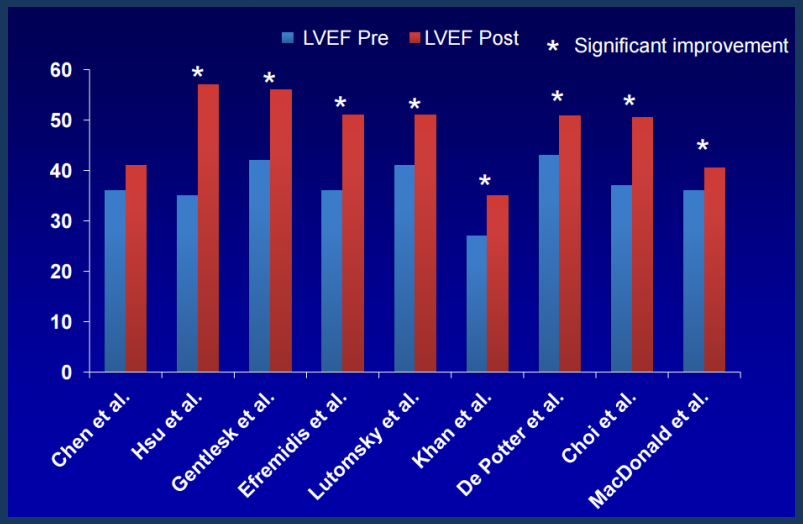
1 AUG 2009	28 MAY 2009	1 DEC 2017	1 JUN 2018	1 SEP 2015	UNAVAILABLE
Start Date	First Received	1st Completion	Completion	Verification	Results

EAST

1 FEB 2011	1 FEB 2011	1 JUN 2019	1 NOV 2019	1 JUL 2015	UNAVAILABLE
Start Date	First Received	1st Completion	Completion	Verification	Results

KALP YETMEZLIĞI- AF





The CAMTAF[3] survey showed that ablation was also superior to medical treatment in patients with heart failure, depressed ejection fraction (EF), and persistent AF. Ablation not only improved EF (from 32 [8%] to 40 [12%]), but also quality of life, oxygen consumption, and B type natriuretic peptide levels. However, this study showed that a single procedure had only moderate efficacy (38%), as 11 of 26 patients (42%) required at least a second procedure.

CASS class 1 ajanlarla mortalite artışı

AF-HF trial sadece amiadorone ya da dofetilid kullanımına rağmen mortalite artışı

Catheter Ablation vs. Standard Conventional Treatment in Patients With LV Dysfunction and AF (CASTLE-AF)

Atrial fibrillation (AF) is the most common arrhythmia encountered in clinical practice. The incidence and prevalence of AF increase exponentially with increasing age and AF is associated with higher mortality, more frequent hospitalization, and lower quality of life. Furthermore, AF is often associated with heart failure. The majority of AF is initiated by ectopic foci found primarily in the pulmonary veins. It was shown that catheter ablation of those veins could eliminate episodes of AF. In patients with heart failure, catheter ablation could improve cardiac function, symptoms and quality of life. It remains still unknown whether AF ablation is more effective than conventional treatment in terms of mortality and morbidity.

Atrial Fibrillation Management in Congestive Heart Failure With Ablation (AMICA)

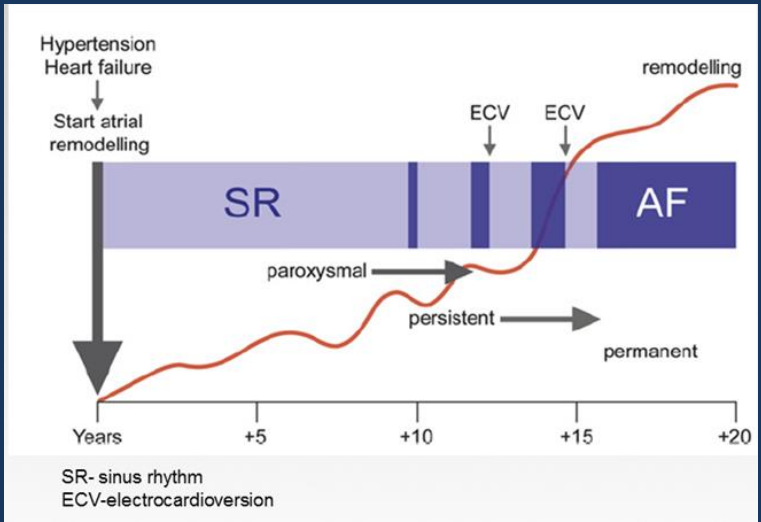
It is the purpose of the study to show the benefit of the endocardial catheter ablation by pulmonary vein isolation in patients with persistent or longstanding persistent atrial fibrillation, low LVEF and requiring ICD or CRT-D therapy compared to the best medical treatment with antiarrhythmic drugs.

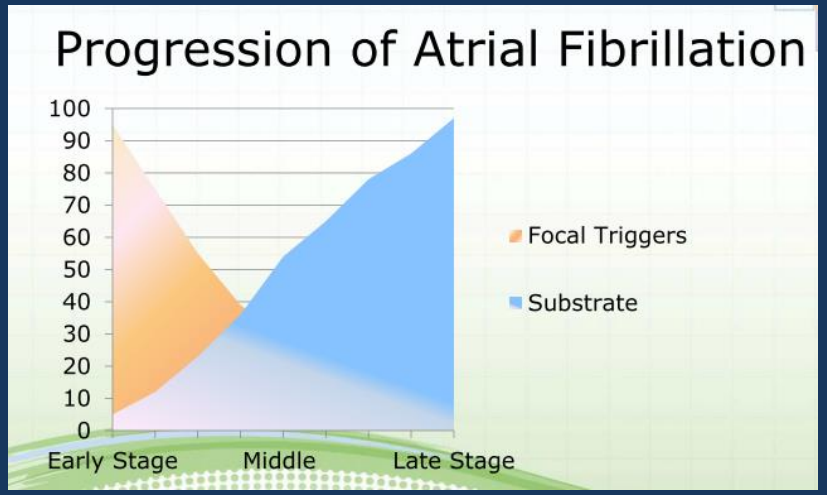
Atrial Fibrillation Ablation Compared to Rate Control Strategy in Patients With Impaired Left Ventricular Function (AFARC-LVF)

Available literature focusing on a direct comparison between two specific management strategies in patients with CHF and AF is limited to a small randomized study comparing pulmonary veins isolation to AV node ablation and biventricular PM implantation (PABA-CHF study). Additional indirect evidences may derive from meta-analyses of observational studies.

The investigators therefore designed this multicenter, randomized controlled trial aiming to assess if, in recently diagnosed (less than 6 months) and optimally treated CHF patients with impaired LV function, AF catheter ablation is effective in improving LV function and clinical functional class, potentially driving to a reduction of device implantations (ICD/CRTs).

İLK SEÇENEK ABLASYON - geç mi tedavi ediyoruz ?
&
YENİ ENDPOINT : PROGRESYONUN DURDURULMASI ?





ATTEST

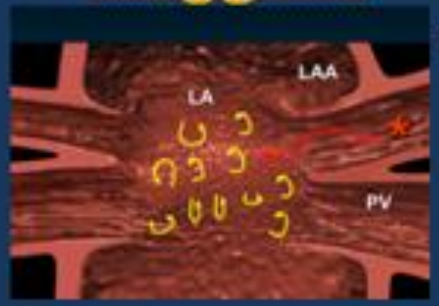
Atrial Fibrillation Progression Trial (ATTEST)

The objective of this study is to determine whether early radiofrequency (RF) ablation treatment, using the CARTO® 3 or CARTO® XP System, and THERMOCOOL® Catheter Family (including THERMOCOOL® SF or THERMOCOOL® SMARTTOUCH™) in subjects with paroxysmal atrial fibrillation (PAF), delays progression of atrial fibrillation (AF) compared with drug therapy (either rate or rhythm control) using current AF management guidelines.

Triggers

PV sleeve, 1988, Haissaguerre M

IVC/SVC/LAA



Modulating Factors

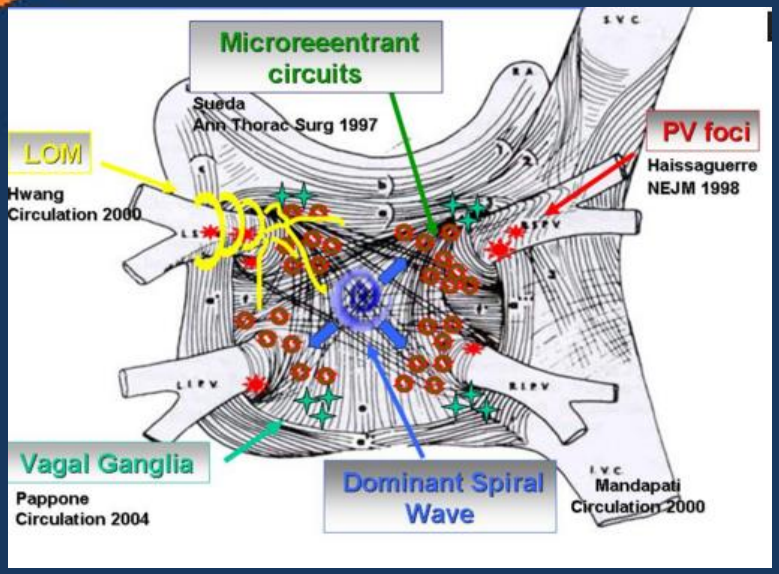
Substrate

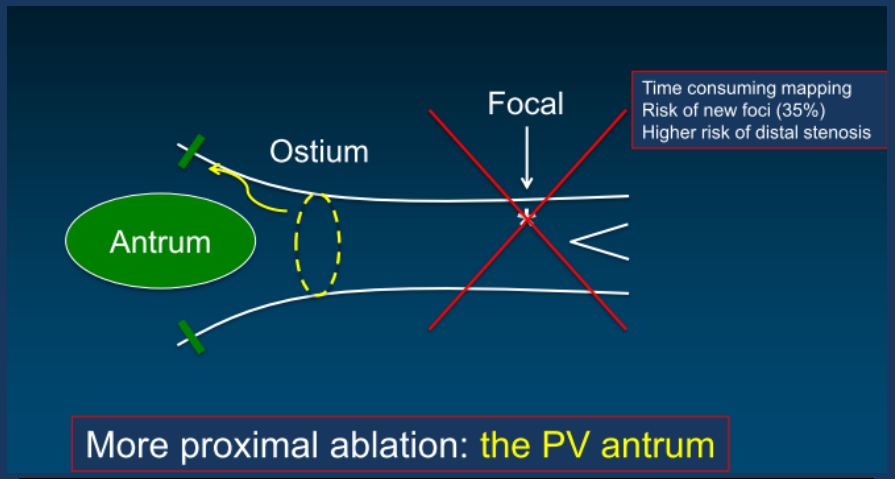
Drivers-substrate

Çoklu reentri

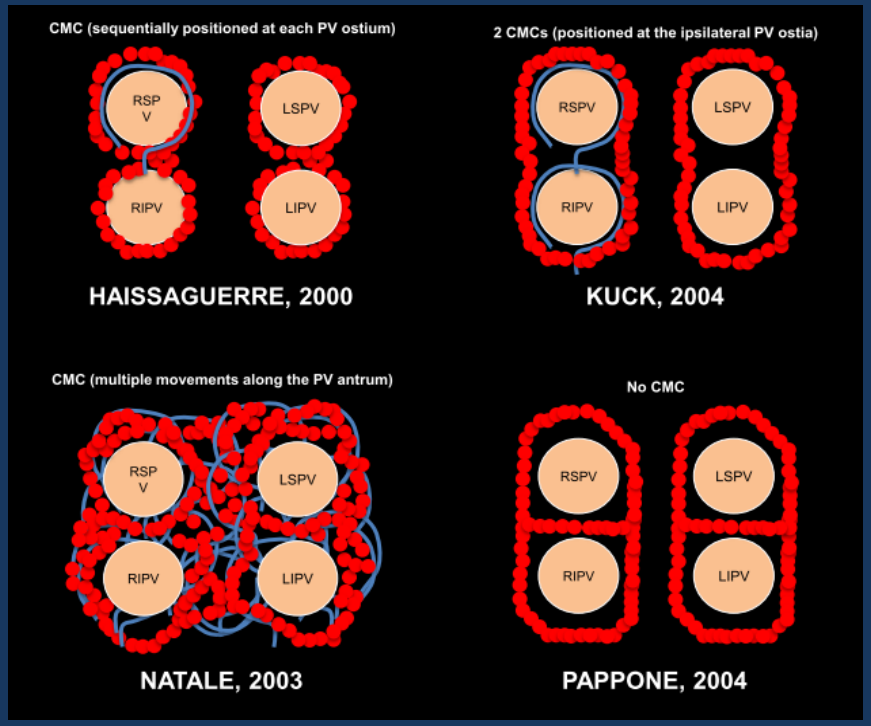
CAFE

rotors





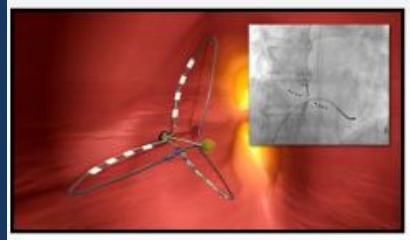
More proximal ablation: the PV antrum

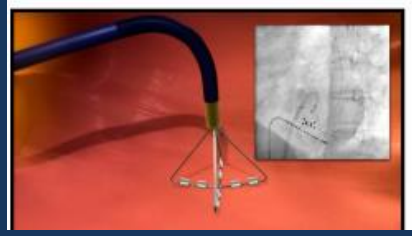


Effectiveness Study of Circumferential vs. Segmental Ablation in Paroxysmal Atrial Fibrillation

This is a PI-initiated study that aims to evaluate the efficacy of two different methods of paroxysmal atrial fibrillation (PAF) ablation. There are currently two strategies for PAF ablation that are routinely performed by electrophysiology clinicians: (1) circumferential pulmonary vein ablation (CPVA) and (2) segmental pulmonary vein isolation (SPVI). However, it is not known if one approach is better than the other. This randomized study will evaluate and compare the efficacy of CPVA versus SPVI in subjects undergoing ablation for paroxysmal atrial fibrillation only. Subjects will have a 50/50 chance of receiving either the CPVA or SPVI ablation method.

Multi Electrode Ablation Catheters





PVI

Pulmonary Vein Ablation Catheter (PVAC)

- **Maps, ablates and confirms isolation of the pulmonary veins**
- **Over-the-wire design facilitates navigation and stability**

CFAE

Multi-Array Septal Catheter (MASC)

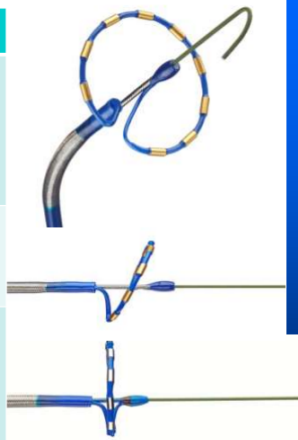
- Maps, paces and ablates arrhythmogenic tissue along the left atrial septum
- Unique electrode placement simplifies septal ablation

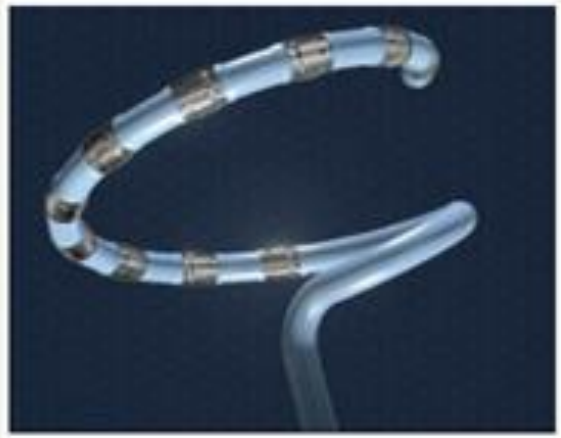
Multi-Array Ablation Catheter (MAAC)

- Maps, paces and ablates arrhythmogenic tissue in the left atrial body
- Bidirectional reach to allow access to the roof and mitral isthmus

Platform for PVAC® GOLD*

Feature	Benefit
Gold electrodes	Gold thermal conductivity allows it to heat more uniformly and cool faster than platinum which provides precise temperature control across the electrode and tighter temperature control throughout the ablation.
Forward tilted array (20˚)	Improved uniformity of electrode contact force which provides more uniform, durable effective ablations
9 electrode array design	Eliminate E1 and E10 Interaction Generates equivalent lesions to Platinum (3mm) by accommodating gold's ability to deliver energy more efficiently.





Ten-pole circular, open irrigated mapping and ablation catheter (nMARQ™, Biosense Webster).

PVAC GOLD Versus Irrigated RF Single Tip Catheter With Contact FORCE Ablation of the Pulmonary Veins for Treatment of Drug Refractory Symptomatic Paroxysmal and Persistent Atrial Fibrillation (GOLD-FORCE)

This study is currently recruiting participants

Verified June 2015 by R&D Cardiologie

Sponsor:
I.V.A. Boersma

ClinicalTrials.gov Identifier:
NCT02463851

First received: June 2, 2015
Last updated: June 4, 2015

Efficiency Study Evaluating the Use of the PVAC Catheter Technology for Performing Ablation in Patients With Atrial Fibrillation (CAPCOST)

This study is currently recruiting participants. (see Contacts and Locations)

Verified January 2016 by Newmarket Electrophysiology Research Group Inc

ClinicalTrials.gov Identifier:
NCT01562912

First received: February 20, 2012

Evaluation of the Phased Radio Frequency Ablation System (VICTORY-AF)

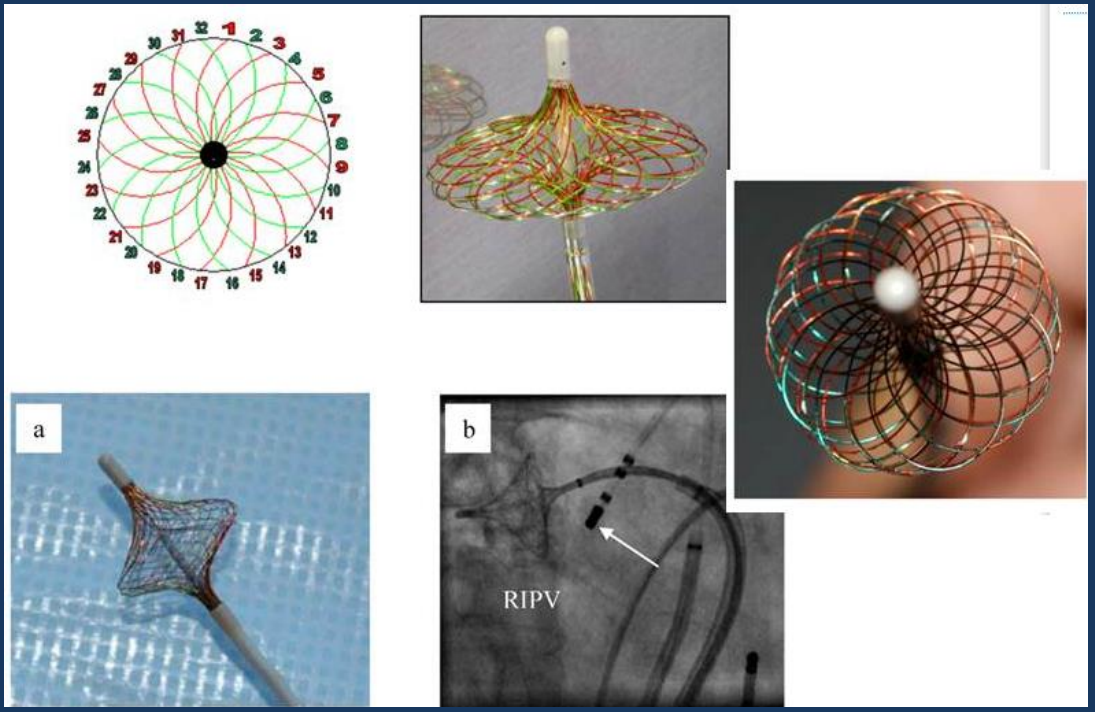
This study is currently recruiting participants. (see Contacts and Locations)

Verified December 2015 by Medtronic Atrial Fibrillation Solutions

Sponsor:
Medtronic Atrial Fibrillation Solutions

ClinicalTrials.gov Identifier:
NCT01693120

First received: September 19, 2012
Last updated: December 3, 2015
Last verified: December 2015

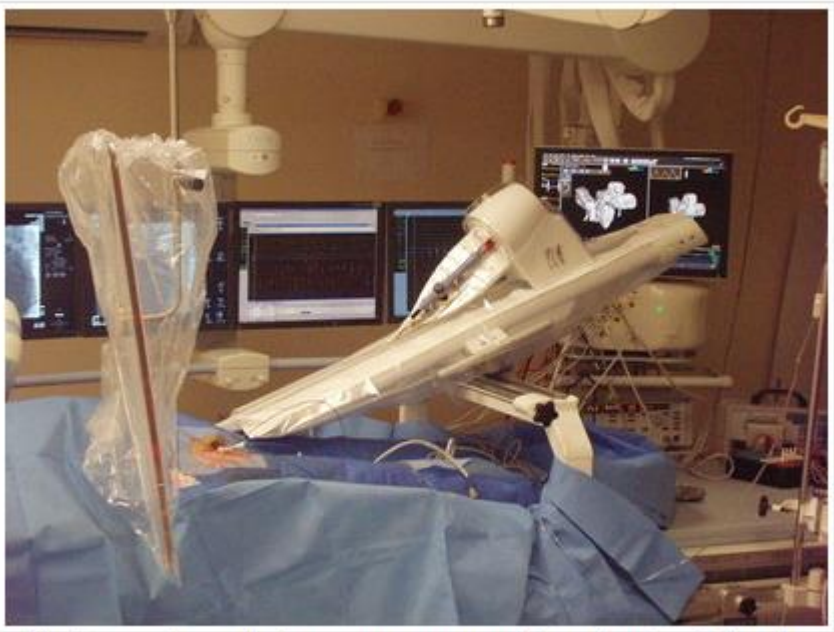


GENESIS Feasibility Study of the BARD Over-the-Wire Mesh Ablation System for the Treatment of Paroxysmal Atrial Fibrillation (GENESIS)

The Genesis Feasibility Study will collect clinical information on the use of the Bard Over-the-Wire Mesh Ablation System to access and perform electrophysiological mapping, cardiac stimulation and radiofrequency ablation in the region of the pulmonary vein (PV) ostia for the treatment of patients with Paroxysmal Atrial Fibrillation. Patients will be followed up for 12 months to assess the primary safety endpoint of Major Complications (a composite safety endpoint)and effectiveness, defined as Long-Term Success (freedom from recurrent atrial arrhythmia.

Manual vs Amigo SmartTouch Atrial Fibrillation Study (MAST-AF)

Atrial fibrillation is a common form of heart rhythm disturbance that for some patients is treated by catheter ablation (making an ablation lesion or burn inside the heart using a fine wire (catheter)). A new system for manipulating the catheters has recently been introduced into clinical practice (the Amigo Remote Catheter System (RCS)). This trial is designed to answer two primary questions: a) is the contact force (the force with which the catheter comes into contact with the heart) any different using the RCS to manual techniques,and b)are the resulting ablation lesions within the heart any different in terms of the volume and contiguity of the lesions produced. Additionally the investigators aim to determine how the two techniques compare in success (the proportion of patients whose heart rhythm disturbance is corrected by the procedure).



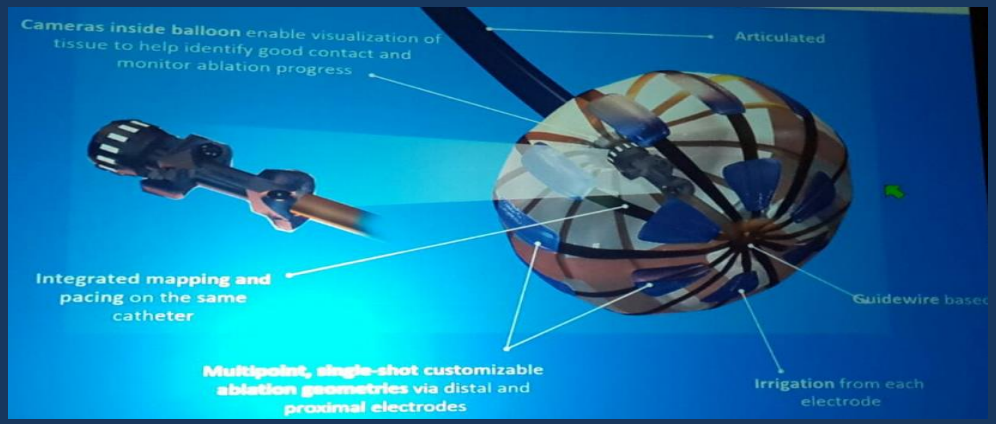
The Amigo robot with the navigation map and force displayed behind it

Use of the Hansen Medical Svstem in Patients With Paroxvsmal Atrial Fibrillation

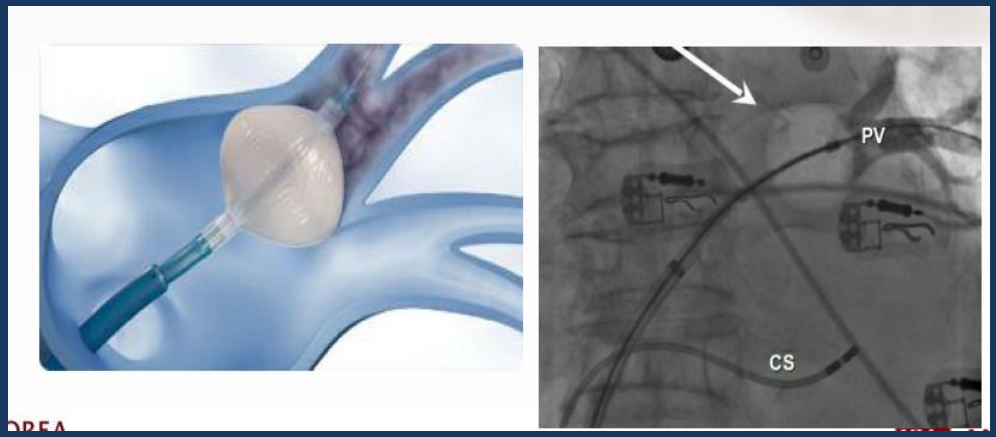
The purpose of this study is to assess the safety and performance of the Hansen Medical Sensei Robotic System and Artisan Catheter when used to robotically manipulate RF ablation catheters for the treatment of paroxysmal atrial fibrillation (irregular heartbeats originating in the upper chambers of the heart)

Balon Teknolojileri

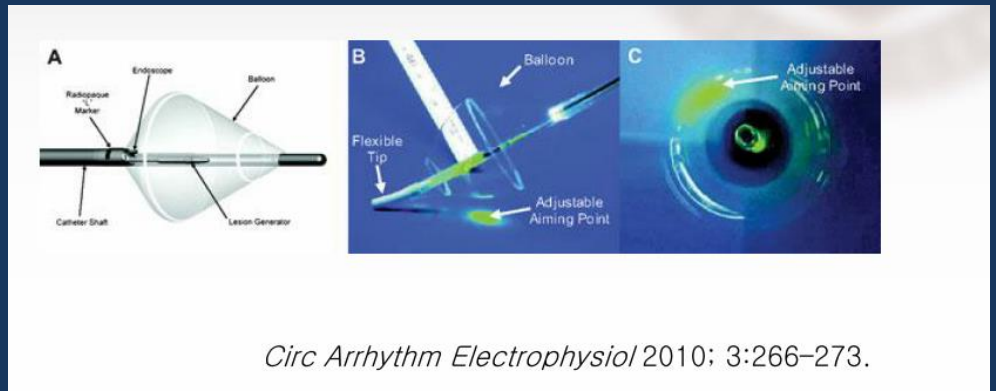
RF/Termal Balon



Laser Balon

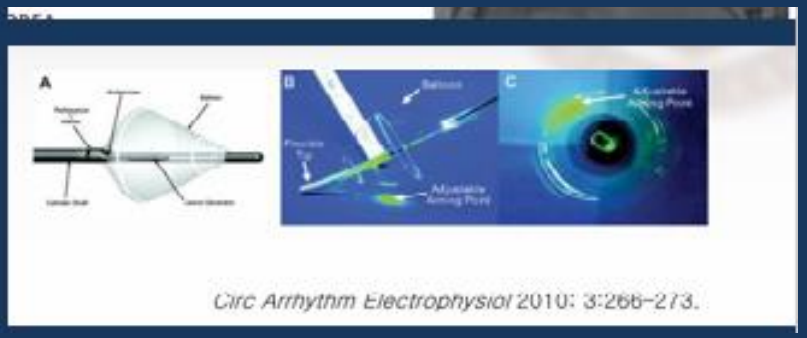


CryoBalon



Circ Arrhythm Electrophysiol 2010; 3:266–273.

Laser Balon



Pulmonary Vein Isolation Using the Visually Guided Laser Balloon: A Prospective, Multicenter, and Randomized Comparison to Standard Radiofrequency Ablation.

Dukkipati SR[1], Cuoco F[2], Kutinsky I[3], Aryana A[4], Bahnson TD[5], Lakkireddy D[6], Woollett I[7], Issa ZF[8], Natale A[9], Reddy VY[10], HeartLight Study Investigators.

⊕ **Author information**

RESULTS: A total of 353 patients (178 VGLB, 175 control) were randomized at 19 clinical sites. The mean procedure, ablation, and fluoroscopy times were longer with VGLB compared with controls. The primary efficacy endpoint was met in 61.1% in the VGLB group versus 61.7% in control (absolute difference -0.6%; lower limit of 95% confidence interval [CI]: -9.3%; p = 0.003 for noninferiority). The primary adverse event rate was 11.8% in the VGLB group versus 14.5% in controls (absolute difference -2.8%; upper limit of 95% CI: 3.5; p = 0.002 for noninferiority), and was mainly driven by cardioversions. Diaphragmatic paralysis was higher (3.5% vs. 0.6%; p = 0.05), but PV stenosis was lower (0.0% vs. 2.9%; p = 0.03) with VGLB.

Eagle AF (Atrial Fibrillation) - Endoscopically Guided Laser Ablation of Persistent Atrial Fibrillation

This study is currently recruiting participants. (see Contacts and Locations)

Verified August 2015 by Märkische Kliniken GmbH

Sponsor:
Prof. Dr. med. Bernd Lemke

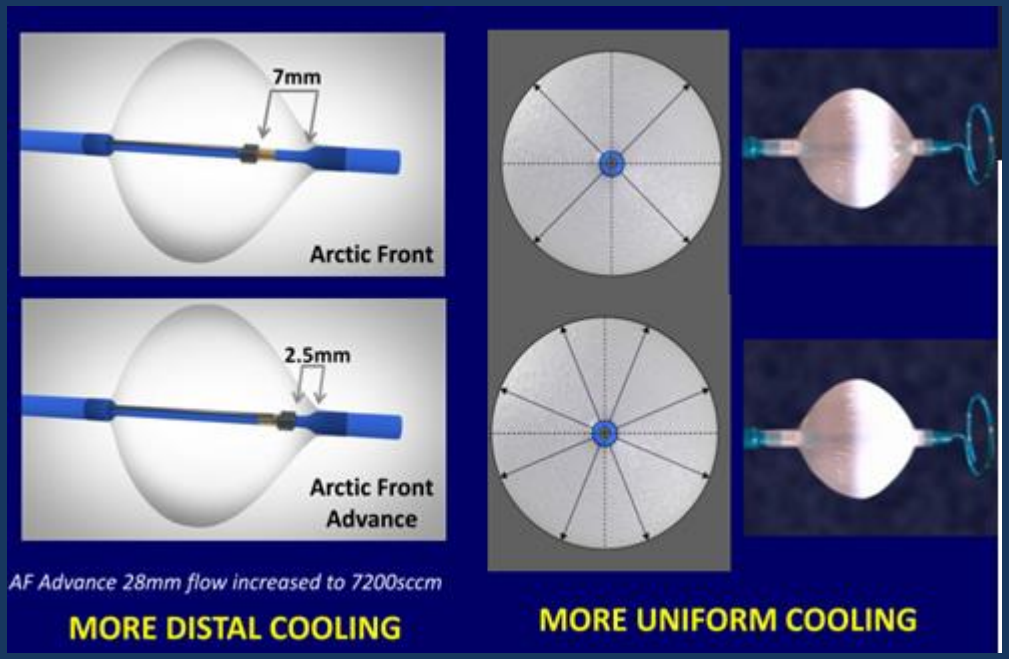
ClinicalTrials.gov Identifier:
NCT02234102

First received: September 4, 2014
Last updated: August 20, 2015
Last verified: August 2015

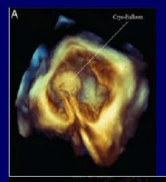
First -Generation

Second-Generation

Third-Generation



3-D TEE-guided Cryoballoon PVI

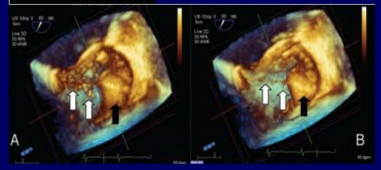


190 PV's in 45 patients

3-D TEE guided complete occlusion in 100% PV's

TEE identified leak in 25 (13%) PV's and guided CB repositioning with abolition of leak

In 4 (2%) PV's, TEE guided successful pull-down manoeuvre

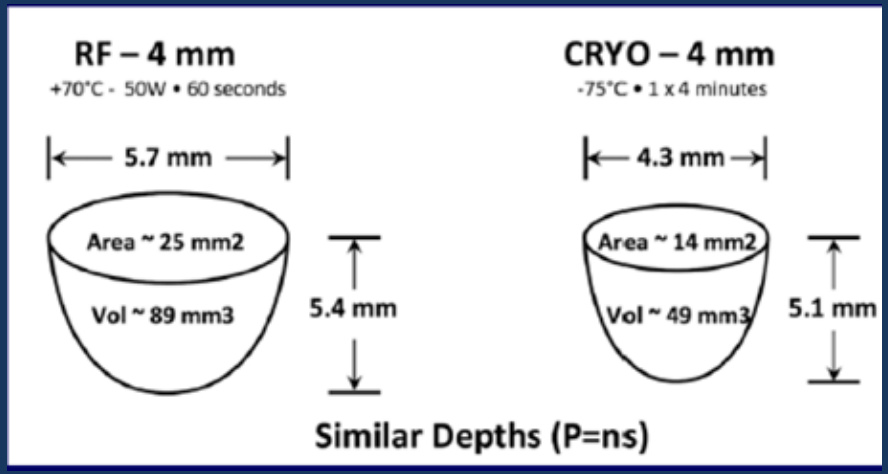


Ottaviano L et al. Cryoballoon ablation for AF guided by real-time 3-D TEE: a feasibility study. Europace 2013;15:944-50.

CoolLoop Paroxysmal Atrial Fibrillation (CoolLoop PAF)

RFA ? Cryo

FREEZE-AF – 2015 NI 5% PNP



FIRE AND ICE: Comparative Study of Two Ablation Procedures in Patients With Atrial Fibrillation

Comparing efficacy and safety of isolation of the pulmonary veins (PV) using a Cryoballoon catheter versus a radiofrequency ablation with a ThermoCool catheter in patients with paroxysmal atrial fibrillation.

SÜRE 300-240-180------120--60 ? SIKLUS SAYISI 1-2

Cryoballoon vs. Irrigated Radiofrequency Catheter Ablation: Double Short vs. Standard Exposure Duration (CIRCA-DOSE)

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and is associated with reductions in quality of life, functional status, cardiac performance, and overall survival.1 Catheter ablation, which is centered on electrical isolation of triggering foci within the pulmonary veins (PVI) through circumferential lesions around PV ostia, has been shown to result in sustained improvements in quality of life, decreased hospitalizations and, potentially, improved survival.2-4 PVI can be accomplished by percutaneous catheter-based thermo-coagulation (burning) with radiofrequency (RF) energy delivery or alternatively by thermo-cooling (freezing) with a cryoballoon catheter.5 Cryothermal ablation with a cryoballoon catheter offers an efficacious means to achieve PVI that is safer than the established technique. Although cryoballoon ablation has been used in clinical practice for sometime, the optimal duration of cryoballoon ablation has not been determined. Moreover, the biophysics of cryo-lesion formation suggests that repeated short freezes ("freeze-thaw-freeze" cycles) may be more efficacious in achieving deep homogenous lesion when compared to prolonged freezing durations. This grant proposal is to verify if repeated short freezing cycles are more efficacious (i.e., fewer recurrence of AF), and safer, than the established standard of long, single freeze cycles.

Arms
Experimental: Standard cryoablation Patients randomized to the standard group will undergo cryoablation with target duration of 240 seconds. Once PVI is achieved a single "bonus" application of 240 seconds will be delivered after the rewarming phase (to +20oC).
Active Comparator: Irrigated RF Ablation Patients randomized to irrigated RF group will undergo standard wide circumferential PVI with an irrigated radiofrequency catheter
Experimental: Short Cryoablation Patients randomized to the multiple-freeze group will undergo cryoablation with target duration of 120 seconds. Once PVI is achieved a single "bonus" application of 120 seconds will be delivered after the rewarming phase (to +20oC).

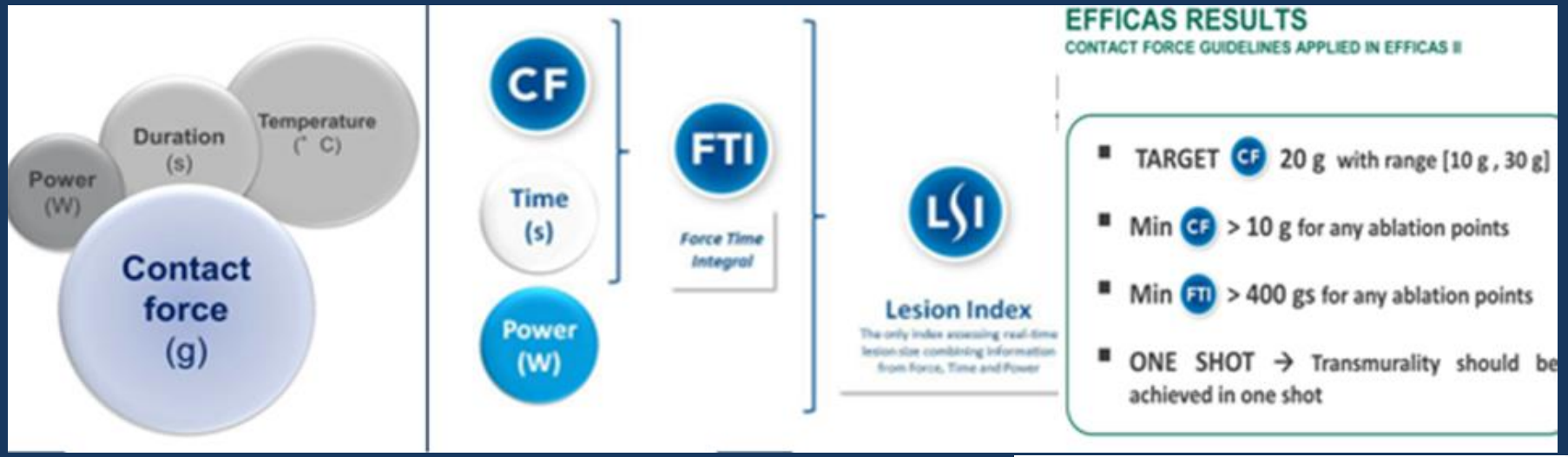
The OneFreeze Study (OneFreeze)

It is an unproven assumption that at least 2 cryoablations is necessary in each pulmonary vein for successful ablation of atrial fibrillation. The investigators hypothesize that a single cryoablation in each pulmonary vein that achieves isolation may leads to equivalent efficacy with decreased risk. The One Freeze Study evaluates this hypothesis.

This study compares one 3-minute cryoablation per pulmonary vein versus two 3-minute cryoablations per pulmonary vein during atrial fibrillation ablation procedures.

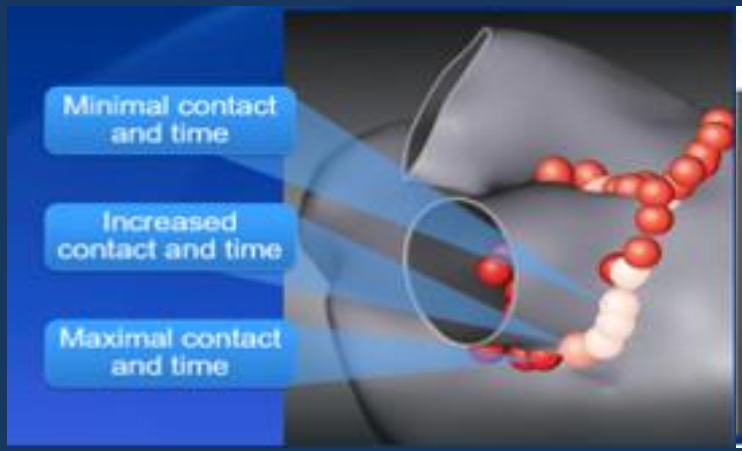
Defining the Optimal Cryoballoon Duration Therapy for Treatment of Atrial Fibrillation: Defining the Optimal Cryoballoon Duration Therapy for Treatment of Atrial Fibrillation: The 1-2-3 Study

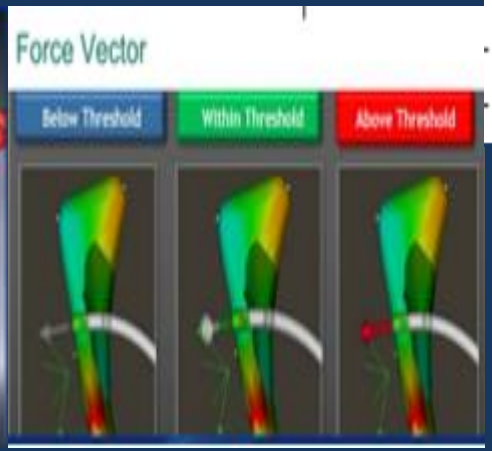
Arms
2 times 1 PVI will be performed using a cryoballoon ablation application time of 2 times 1 minute
2 times 2 PVI will be performed using a cryoballoon ablation application time of 2 times 2 minutes
2 times 3 PVI will be performed using a cryoballoon ablation application time of 2 times 3 minutes



The LSI was clinically validated on EFFICAS I data.

- In a HRS 2012 abstract[1], LSI was validated on a subset of EFFICAS I data.
- LSI demonstrated 10 times greater significance than FTI
- Minimum LSI should be (well) above 4.0





Impedance vs. Contact Force Guided Atrial Fibrillation Ablation Using Automated Annotation System

This study is currently recruiting participants. (see Contacts and Locations)

Verified August 2015 by Keimyung University Dongsan Medical Center

Sponsor:
Keimyung University Dongsan Medical Center

ClinicalTrials.gov Identifier:
NCT02364401

First received: January 30, 2015
Last updated: August 31, 2015
Last verified: August 2015

Comparison of Operator-guided and Automatic Algorithm-guided Atrial Fibrillation Ablation

This study is currently recruiting participants

Verified June 2015 by Military Institute of Medicine, Poland

Sponsor:
Military Institute of Medicine, Poland

Collaborators:
Medical University of Warsaw
Institute of Cardiology, Warsaw, Poland

ClinicalTrials.gov Identifier:
NCT02476227

First received: June 5, 2015
Last updated: June 16, 2015
Last verified: June 2015
History of Changes

Background hypothesis is that automatic algorithm collecting ablation points during pulmonary vein isolation (with certain catheter stability time, range of motion, and catheter-tissue contact force) prevents forming the gaps in the ablation line, thus preventing pulmonary vein reconnection and AF recurrence. The aim of the trial will be 1:1 comparison of the two methods of pulmonary vein isolation: with manual vs. automatic collection of ablation points using CARTO system and contact force catheter.

PV Reconnection After PVAI at Different Power Settings and Adenosine Provocation (ZODIAC)

This study is currently recruiting participants. (see Contacts and Locations)

Verified May 2015 by Texas Cardiac Arrhythmia Research Foundation

Sponsor:
Texas Cardiac Arrhythmia Research Foundation

Collaborator:
California Pacific Medical Center

Information provided by (Responsible Party):
Andrea Natale, Texas Cardiac Arrhythmia Research Foundation

ClinicalTrials.gov Identifier:
NCT01672346

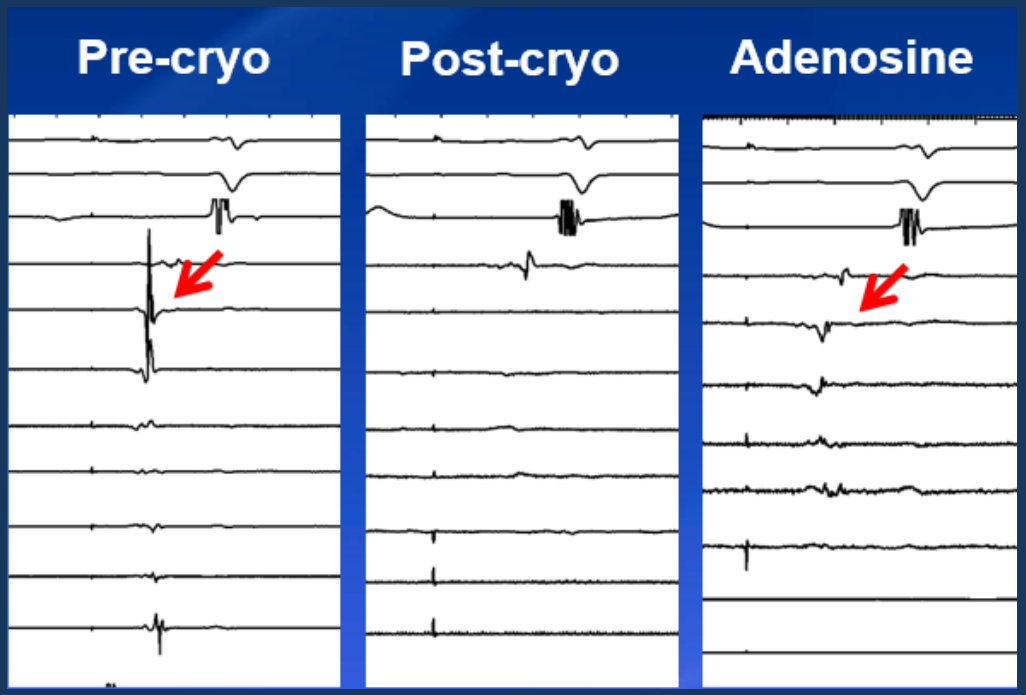
First received: August 21, 2012
Last updated: May 19, 2015
Last verified: May 2015
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

In this prospective randomized study, we aim to compare the rate of PV reconnection following PVAI performed at different energy settings (30 Watts vs 40 Watts) where dormant PV conduction will be unmasked by adenosine-provocation.

ADENOZİNE ?



ADVICE (+) 2015 UNDER-ATP (-)

ödemi/transmural lezyonu daha iyi anlamaya yönelik teknolojiler

REAL TiME MRI

ANATOMIK VARYASYON

GAP- LINEERITE YETERLI MI ?
FıBROSıS YÜKÜ
ABLASYON HEDEF NOKTALARı ?
HıZLı KOMPLIKASYON TANıMA
DÜŞÜK RADYASYON

Efficacy of Delayed Enhancement MRI-Guided Ablation vs Conventional Catheter Ablation of Atrial Fibrillation (DECAAFII)

This study is not yet open for participant recruitment.

Verified September 2015 by University of Utah

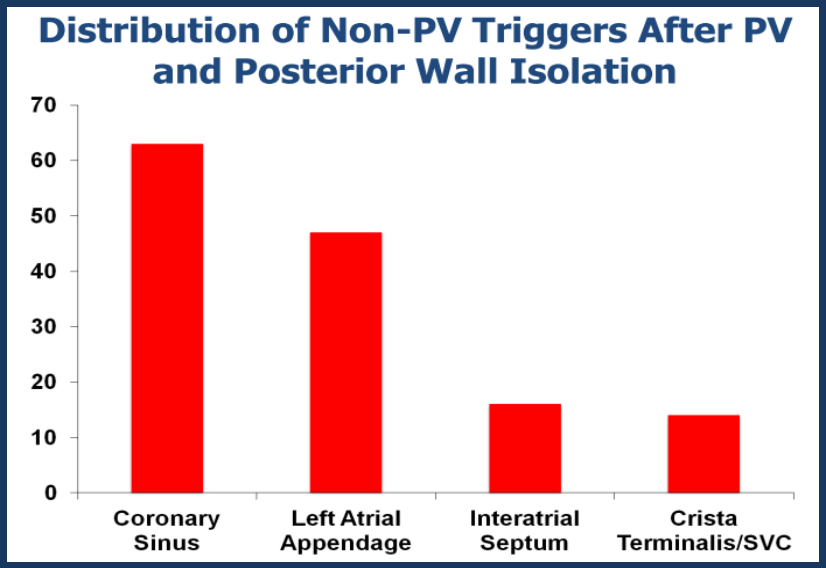
Sponsor:
University of Utah

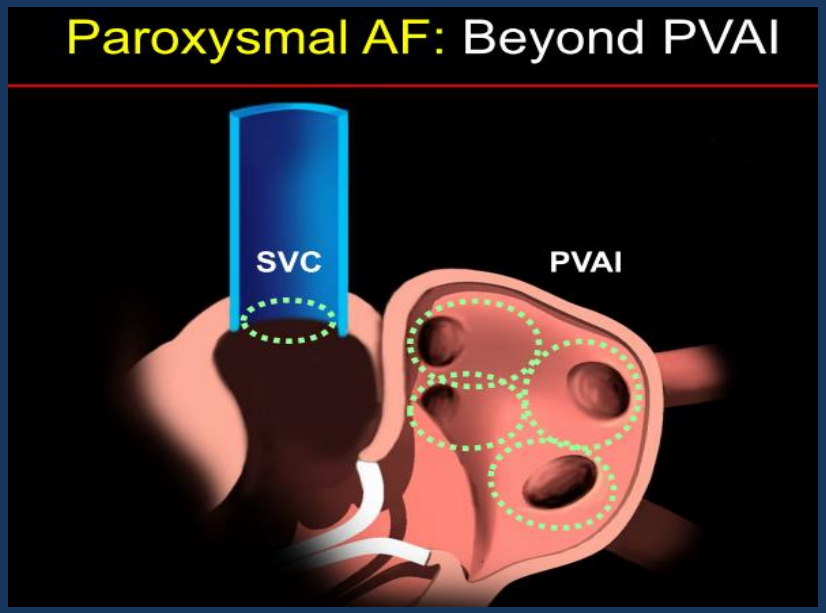
Information provided by (Responsible Party):
Nassir F. Marrouche, MD, University of Utah

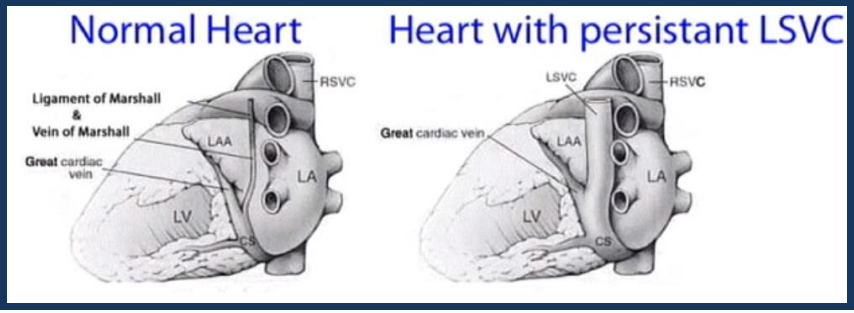
ClinicalTrials.gov Identifier:
NCT02529319

First received: August 11, 2015
Last updated: September 17, 2015
Last verified: September 2015
History of Changes

Triggers : % 90 PV, non-PV ?







Vein of Marshall Ethanol Infusion for Persistent Atrial Fibrillation FIBRILLATION

This study is currently recruiting participants. (see Contacts and Locations)

Verified April 2015 by The Methodist Hospital System

Sponsor:
The Methodist Hospital System

ClinicalTrials.gov Identifier:
NCT01898221

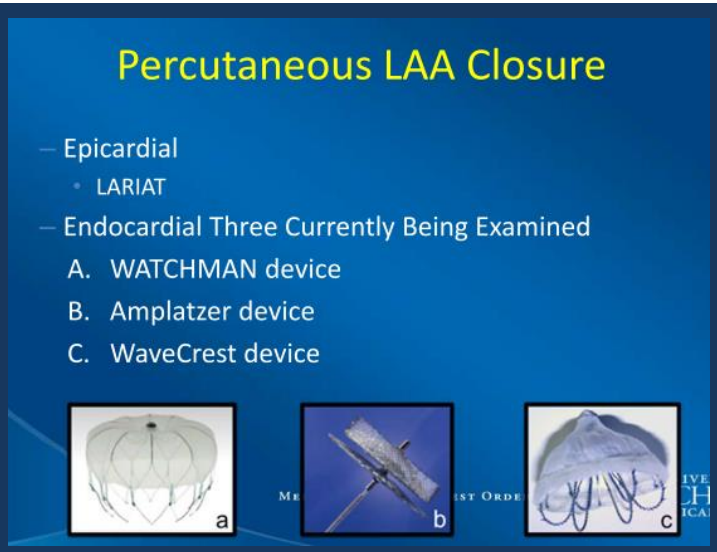
First received: May 28, 2013
Last updated: April 23, 2015
Last verified: April 2015

BELIEF: Isolating Left Atrial Appendage May Halt Persistent AF

COMMENTARY

Doubting the BELIEF Trial on LAA Isolation

In the hot-line discussion, Dr Hindricks presented data from the group of Dr Karl Heinz Kuck (Hamburg, Germany), in which they looked at 50 patients who had LAA isolation. Kuck's group found LAA thrombus in 21%, and three patients had a stroke.



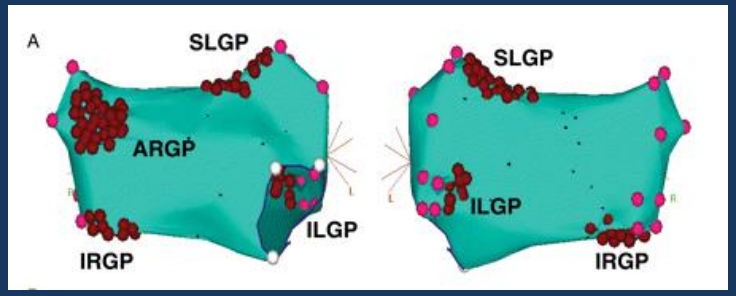
Left Atrial Appendage Electrical Isolation and Occlusion to Treat Persistent Atrial Fibrillation: A Safety and Feasibility Study (LEIO-AF)

We aim to investigate whether it is safe and feasible to ablate the LAA and to implant a Watchman® device during the same procedure in patients who are in atrial fibrillation all of the time.

aMAZE Study: LAA Ligation Adjunctive to PVI for Persistent or Longstanding Persistent Atrial Fibrillation (aMAZE)

This study is a prospective, multicenter, randomized (2:1) controlled study to evaluate the safety and effectiveness of the LARIAT System to percutaneously isolate and ligate the Left Atrial Appendage from the left atrium as an adjunct to planned pulmonary vein isolation (PVI) catheter ablation in the treatment of subjects with symptomatic persistent or longstanding persistent atrial fibrillation.

Modulating Factors



Ganglionated Plexus Ablation For Treatment of Atrial Fibrillation

This study evaluates the effect of catheter ablation of ganglionated plexi (GP) for the treatment of adult patients with atrial fibrillation heart arrhythmias. The location of GP will be demonstrated by a novel nuclear imaging cardiac camera. 3D images from the cardiac camera will guide the GP ablation procedure.

Atrial Ganglionated Plexi Ablation Guided by the SUMO Technology With and Without Conventional Pulmonary Vein Isolation in Patients With Persistent AF

Although circumferential pulmonary vein isolation (PVI) has been considered as the cornerstone for atrial fibrillation ablation, there has been a substantial recurrence rate. The investigators designed a prospectively randomized study to evaluate whether additional atrial ganglionated plexi ablation guided by the SUMO technology improves the clinical outcome in patients with persistent AF.

Atrial Fibrillation Prevention in Post Coronary Artery Bypass Graft Surgery With Cryoablation for Ganglionic Plexi

PVI + RENAL DENERVASYON ?

Renal Nerve Denervation in Patients With Hypertension and Paroxysmal and Persistent Atrial Fibrillation (Symplicity AF)

The purpose of this clinical study is to evaluate the feasibility of performing both renal nerve denervation and pulmonary vein isolation on the same patient with the intent of characterizing both safety and effectiveness in a paroxysmal and persistent atrial fibrillation population with hypertension. To assess safety, the study will measure the occurrence of a composite safety endpoint and, to assess effectiveness, the study will measure freedom of chronic treatment failure through a minimum of six months of follow-up.

Treatment of Atrial Fibrillation in Patients by Pulmonary Vein Isolation, Renal Artery Denervation or Both (ASAF)

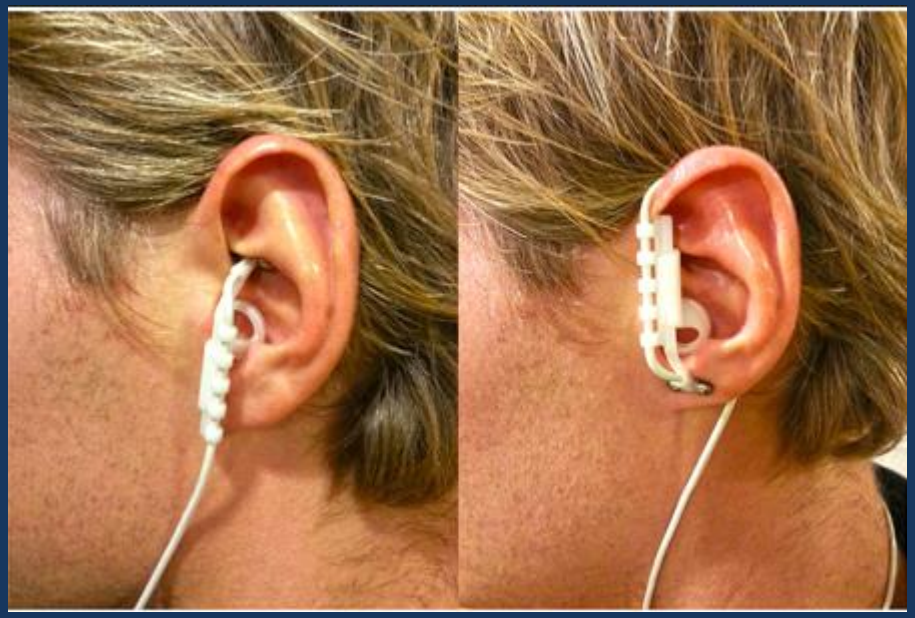
Prospective, randomized, controlled, multicenter, international clinical trial. The study population consist of patients with paroxysmal or persistent atrial fibrillation with out range hypertension or signs of sympathetic overdrive. Patient will be randomized into one of the following three groups.

group 1 : patients will undergo renal artery denervation/ group 2 : Patients will undergo pulmonary vein isolation/ group 3: Patients will undergo pulmonary vein isolation and renal artery denervation.

Comparison of Redo PVI With vs. Without Renal Denervation for Recurrent AF After Initial PVI

The objective of this study is to compare the elimination of atrial fibrillation in patients with recurrent atrial fibrillation despite prior pulmonary vein isolation (PVI) when undergoing repeat PVI (control) vs repeat PVI plus renal denervation.

modulating



Transcutaneous Electrical Vagus Nerve Stimulation to Suppress Atrial Fibrillation (TREAT-AF)

Atrial fibrillation (AF) is the most common cardiac arrhythmia. In previous experimental studies, the investigators found that low-level vagus nerve (VN) stimulation (LLVNS), at voltages substantially below that which slowed the sinus rate, significantly suppressed AF inducibility and decreased AF duration. The investigators subsequently developed a non-invasive neuromodulatory therapy, in which LLVNS was delivered to the auricular branch of the VN located at the tragus, the anterior protuberance of the outer canine ear (low level tragus stimulation; LLTS). The anti-arrhythmic effects of LLTS were similar to those of LLVNS delivered to the cervical VN trunk. More recently, in a proof-of-concept study in humans, the investigators showed that in patients with drug-refractory AF undergoing AF ablation, LLTS for just one hour significantly shortened the AF duration and decreased inflammatory cytokines.

The overall objective of this proposal is to translate in ambulatory patients with paroxysmal AF the results of previous studies showing acute suppression of AF and inflammation in anesthetized canines as well as humans, in order to examine the long-term therapeutic effects of this approach. The investigators hypothesize that intermittent (1 hour daily) LLTS for 6 months may result in long-term decrease of AF burden and suppression inflammatory cytokines in patients with paroxysmal AF. Patients will be randomized to either active or sham LLTS. LLTS will be delivered through a transcutaneous electrical nerve stimulation (TENS) device for 1 hour daily over a 6-month period. AF burden will be defined as the percent of time spent in AF over a 2-week period, assessed by noninvasive continuous ECG monitoring at baseline and at 6 months. In addition, blood samples will be collected from patients at baseline, and at 3 and 6 months, for cytokine measurement. These investigations will establish the first evidence of the long-term effects of LLTS on AF suppression in patients with paroxysmal AF and may provide the basis for a potential expansion of the therapeutic targets of this treatment modality beyond AF.

Persistent AF Ablation

Substrate Modification

Drivers

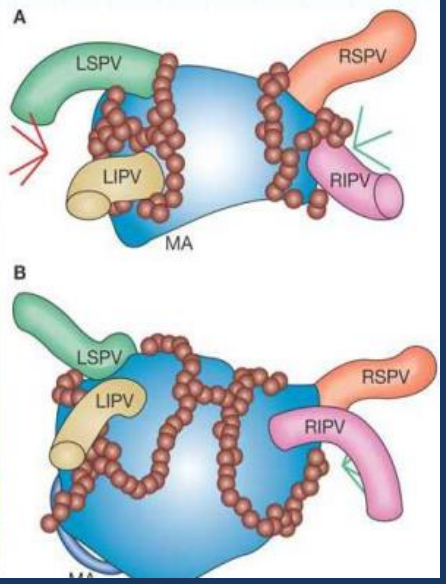
Çoklu reentri

CAFE

rotors

Linear Lesions

- Segment atrium so that reentry no longer possible
- Roof, mitral isthmus, posterior LA
- Modest efficacy
- Pro-arrhythmia



Ablation strategy for per-AF

-- Bordeaux

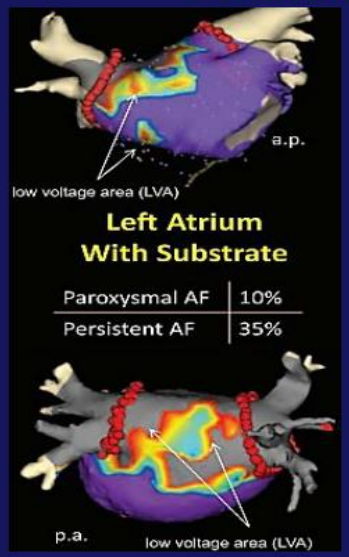
STEP 1: PVI
↓ AF
STEP 2: Roof line ablation
↓ AF
STEP 3: CS/LA CFAE ablation
↓ AF
STEP 4: Mitral isthmus ablation
↓ AF
OPTIONAL：RA/SVC ablation
↓
Ongoing AF: Cardiversion

→ SR

Haïssaguerre M, et al. JCE 2005;16(11):1125-37

Ablation strategy for per-AF

-- CPVI + Substrate （Leipzig）

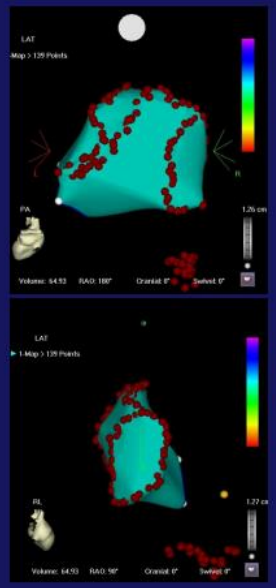


- PVI→Cardiovertion→Voltage map
- LVA: sites of ≥3 adjacent low-voltage points <0.5 mV
- LVA ablation: Significant reduction in local electrograms, defractionation, loss of capture
- Induction: burst pacing
- Procedural End Point: noninducibility of AF/AT

Rolf, et al. Circ AE 2014;7:825-833

Ablation strategy for per-AF

-- 2C3L



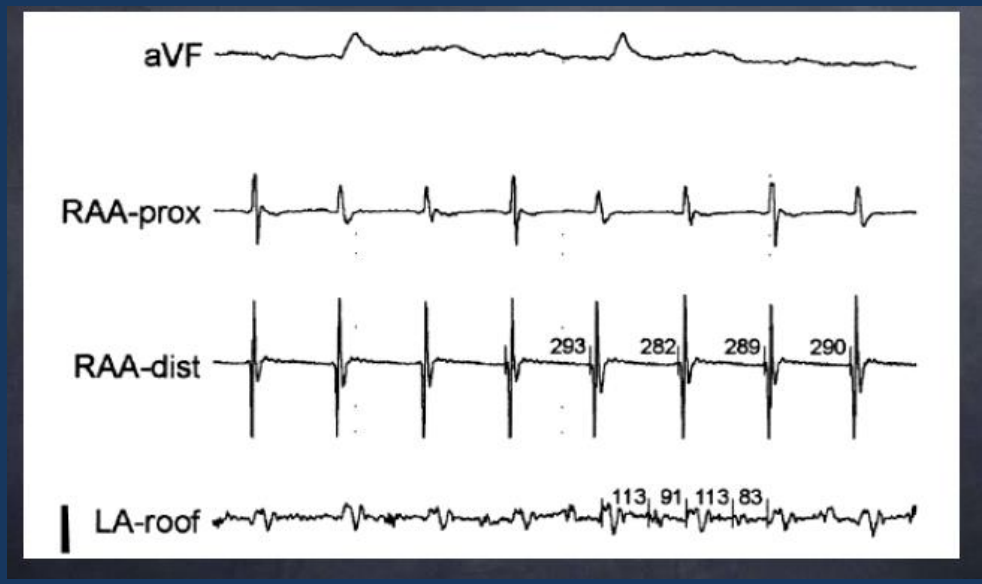
- CPVIs ---------- “2C”
- Roof、MI、CTI ---------- “3L”
- Cardioversion
- Verify CPVI and Bidirectional linear block in sinus rhythm

Heart Rhythm 2010, 7: S332

Nademanee 2004

- Complex Fractionated Atrial Electrograms - CFAE's
- Areas of slow conduction
- Pivot points of wavelets
- CARTO to identify sites in the left and right atrium

Nadamanee K et al. JACC 2004;43:2044-53



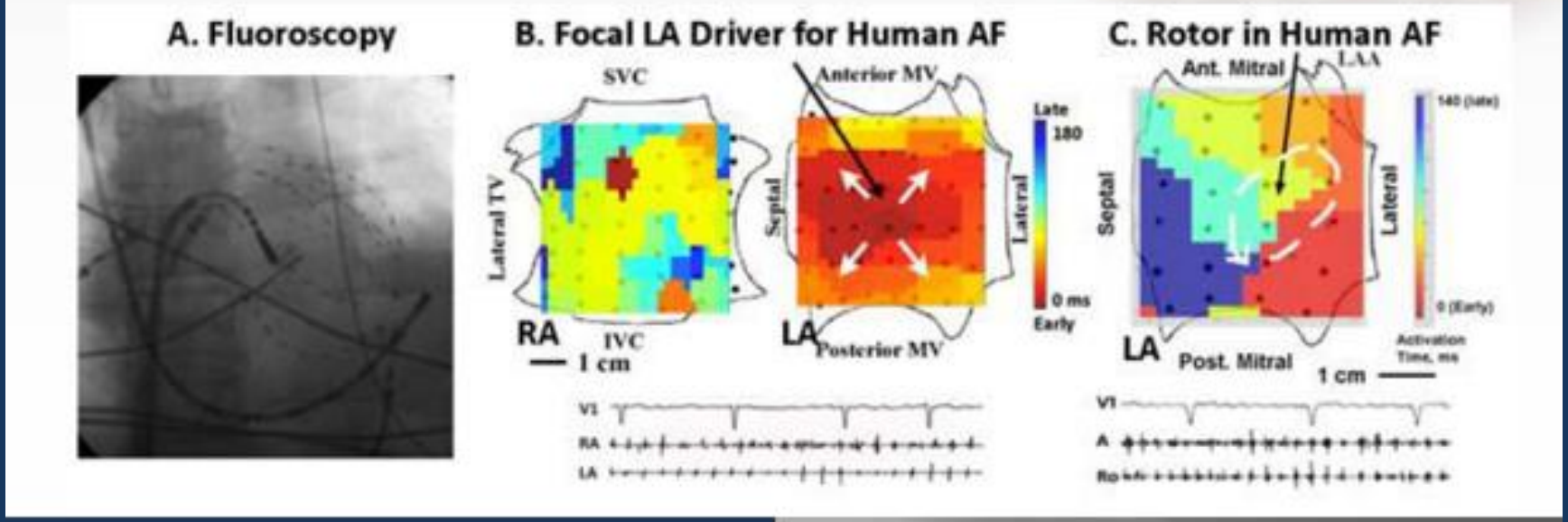
STAR AF 2 ---- ?

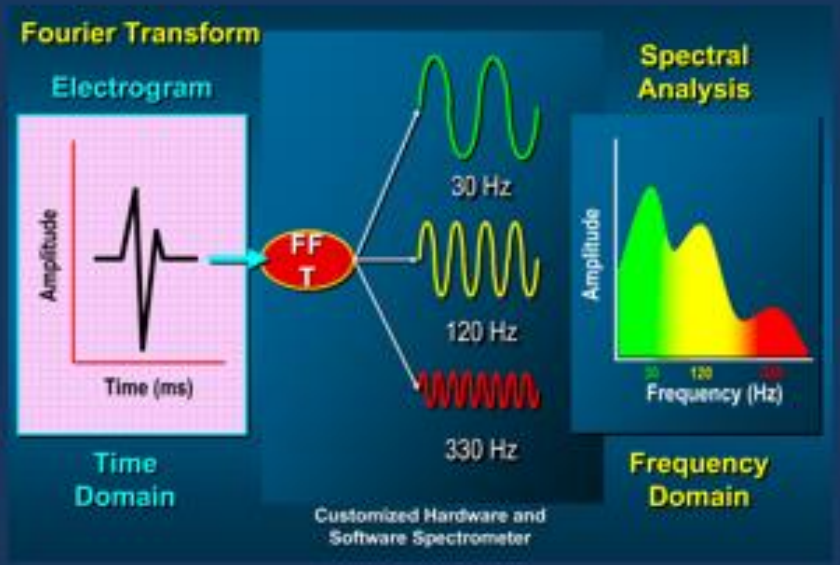
Benefit of Complex Fractionated Atrial Electrograms Elimination in Atrial Fibrillation Ablation

The aim of this study is to evaluate whether performing complex fractionated atrial electrograms ablation improves outcomes in persistent or atrial fibrillation ablation.

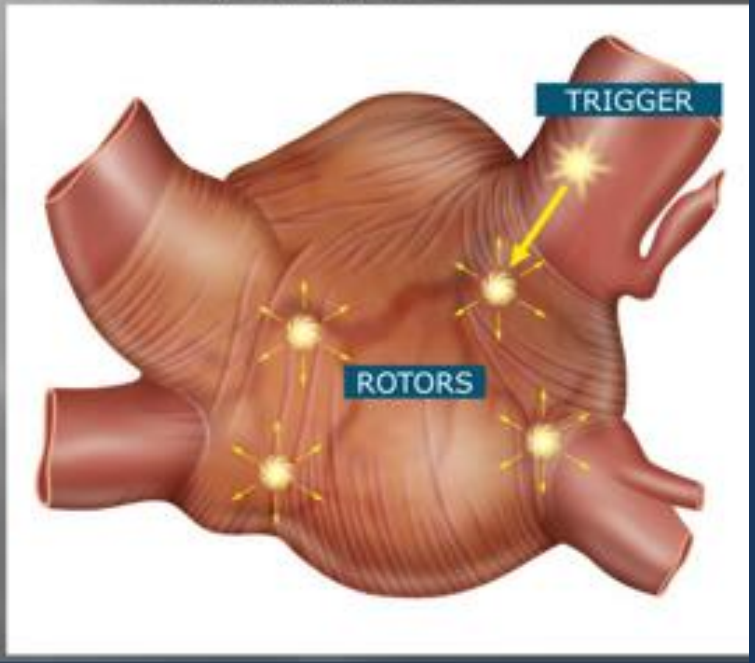
Substrate Ablation Guided by High Density Mapping in Atrial Fibrillation (SUBSTRATE DH)

To evaluate a new AF Substrate mapping method based on automatic high density CFAE detection with a multipolar catheter (Pentaray) and the " SCI 30-40 " setting of CARTO CFAE algorithm.





Jalife J. Cardiovasc Res (2002) 54 (2): 204-216



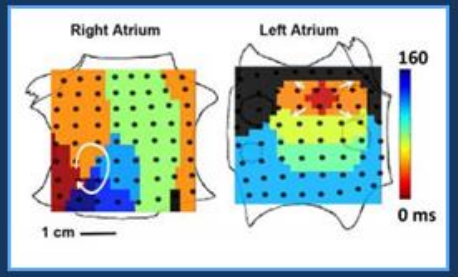
Topera's RhythmView™

3D Electrophysiological Mapping System

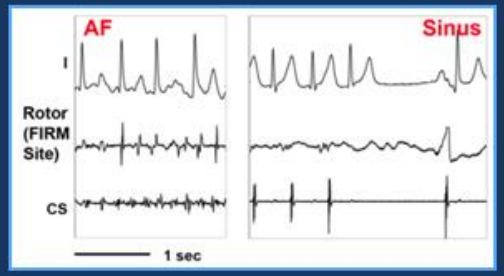
- Multi-polar FIRMap™ catheter
- Single beat mapping of the whole heart chamber all at once
- Advanced signal processing algorithms
- Self referenced map
- Rapidly analyze of the arrhythmia

Narayan et al: JACC 60:628, 2012

Right Atrial Rotor,
Left Atrial Focal Beat in AF



FIRM: Sinus Rhythm in 5.5 minutes



FIRM as a Stand-alone Procedure in the Treatment of Atrial Fibrillation

The FIRM Study Oslo will in two sequential within-patient trials investigate the efficacy of focal impulse and rotor modulation (FIRM) as a stand-alone procedure in the treatment of paroxysmal and persistent atrial fibrillation, evaluated by continuous pre- and post-procedural heart rhythm monitoring.

Evaluation of Conventional Ablation With or Without Focal Impulse and Rotor Modulation to Eliminate Human AF (RECONFIRM)

This prospective randomized study will assess the safety and efficacy of FIRM-guided ablation (FIRM+PVI) compared to pulmonary vein isolation (PVI) alone, for the treatment of symptomatic atrial fibrillation.

Non-invasive Characterization of the Mechanisms of Atrial Fibrillation Maintenance (PERSONALIZE)

Currently available antiarrhythmic drugs for the treatment of atrial fibrillation (AF) have a limited efficacy and often cause long-term side effects. Pulmonary vein isolation is the therapy of choice in drug-refractory patients. Recent studies have shown that ablation have a greater efficacy in patients in whom AF is maintained hierarchically and after ablation of rotors. The non-invasive identification of specific mechanism of AF maintenance in each patient could allow the selection of the most appropriate treatment.

- Patients with paroxysmal AF. Patients with AF episodes that terminates spontaneously or with intervention in less than seven days with clinical indication of pulmonary vein ablation.	Procedure: Pulmonary vein ablation Simultaneous biatrial endocardial electroanatomical mapping by high-density basket catheter (64 pin) and customized body surface mapping (57 electrodes) followed by circumferential pulmonary vein ablation. Other Name: Mitral Valvuloplasty in patients with severe mitral stenosis
- Patients with persistent AF. Patients with AF episodes that fails to self-terminate within seven days or require pharmacologic or electrical cardioversion to restore sinus rhythm with clinical indication of pulmonary vein ablation..	Procedure: Pulmonary vein ablation Simultaneous biatrial endocardial electroanatomical mapping by high-density basket catheter (64 pin) and customized body surface mapping (57 electrodes) followed by circumferential pulmonary vein ablation. Other Name: Mitral Valvuloplasty in patients with severe mitral stenosis
- Patients with mitral stenosis. - Patients with mitral stenosis and clinical indication for AF ablation undergoing percutaneous balloon mitral valvuloplasty (PBMV) with clinical indication of pulmonary vein ablation..	Procedure: Pulmonary vein ablation Simultaneous biatrial endocardial electroanatomical mapping by high-density basket catheter (64 pin) and customized body surface mapping (57 electrodes) followed by circumferential pulmonary vein ablation. Other Name: Mitral Valvuloplasty in patients with severe mitral stenosis

Multimodal Image Processing Software to Guide Cardiac Ablation Therapy (MIGAT)

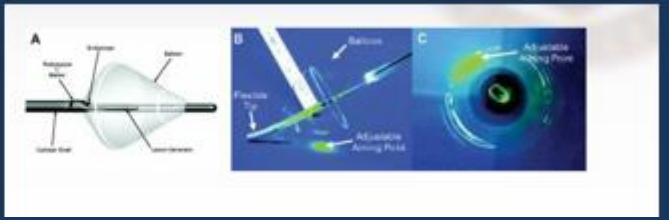
MIGAT will develop and transfer software tools to assist ablation therapy of cardiac arrhythmias. The scientific background and objectives of MIGAT differ between atrial and ventricular arrhythmias, because the knowledge on structure-function relationships and the definition of ablation targets are different.

Hypothesis: The combination of body surface mapping and imaging will enable a comprehensive non-invasive assessment of cardiac arrhythmia mechanisms and localization, myocardial structural substrate, and cardiac anatomy, all of which should be of value to better define targets for ablation therapy. No software solution is currently available for multimodal data processing, fusion, and integration in 3-dimensional mapping systems to assist ablation. Because such a development requires a trans-disciplinary approach (cardiac electrophysiology, imaging, computer sciences), it is likely to emerge from an academic initiative.

Information provided by (Responsible Party):
University Hospital, Bordeaux

History of Changes

CryoBalon



Persistent Atrial Fibrillation Cryoballoon Ablation (PAFCA)

Patients with persistent irregular heartbeats also called persistent atrial fibrillation usually have a lower probability of curing their arrhythmia with ablation with heat called radiofrequency then those with paroxysmal atrial fibrillation, as previous studies have shown.

The emerging ablation with freeze(cryoablation) has not been studied for persistent atrial fibrillation but has been proven to be efficient in the paroxysmal type.

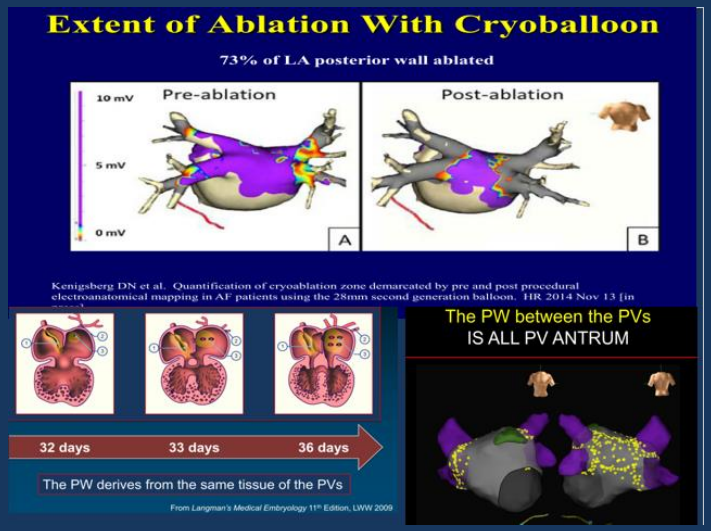
We hypothesized that persistent atrial fibrillation will have a freedom of recurrence rate of 70% after use of cryoablation at one year of follow up.

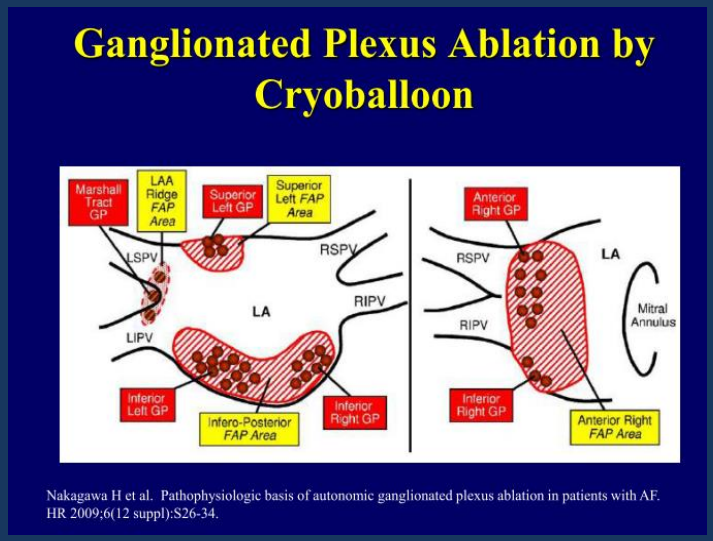
Cryoballoon Ablation for Early Persistent Atrial Fibrillation (Cryo4 Persistent AF)

The purpose of this clinical study is to assess the single procedure outcomes of using cryoballoon ablation without additional empirical lesions and/or complex fractionated electrogram (CFE) ablations for patients with early persistent atrial fibrillation (<1 year from first diagnosis of persistent AF).

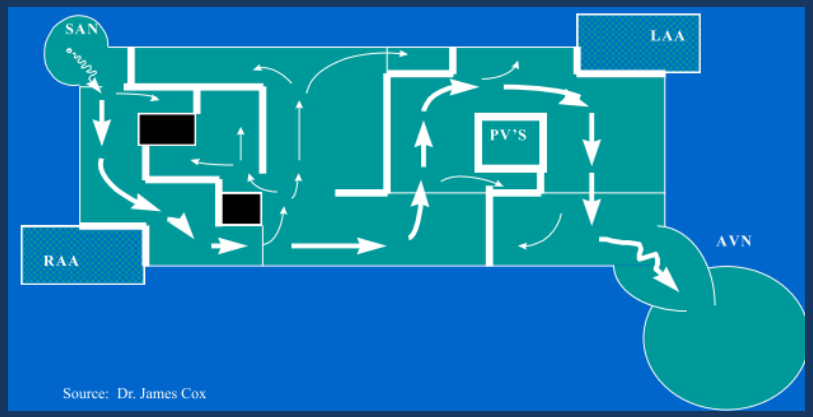
Cryoballoon Ablation in Patients With Longstanding Persistent Atrial Fibrillation (CRYO-LPAF)

Prospective and explorative clinical study. The objective is to assess the clinical efficacy of pulmonary vein isolation using the Arctic Front Advance cryoballoon in patients with longstanding persistent atrial fibrillation (AF) at one year follow up.

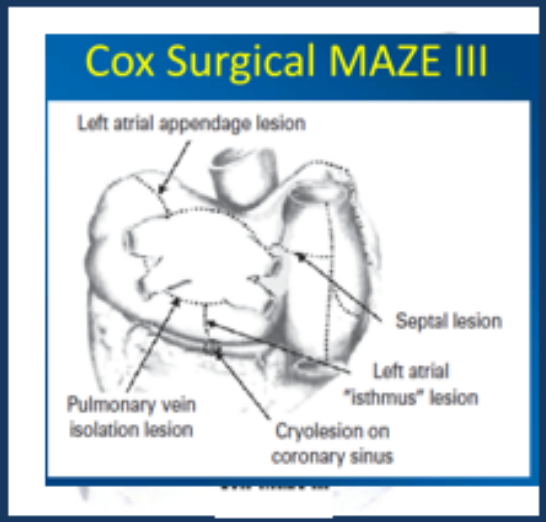




CERRAHI ABLASYON



Corridor---->Cox-Maze----> Cox-Maze III



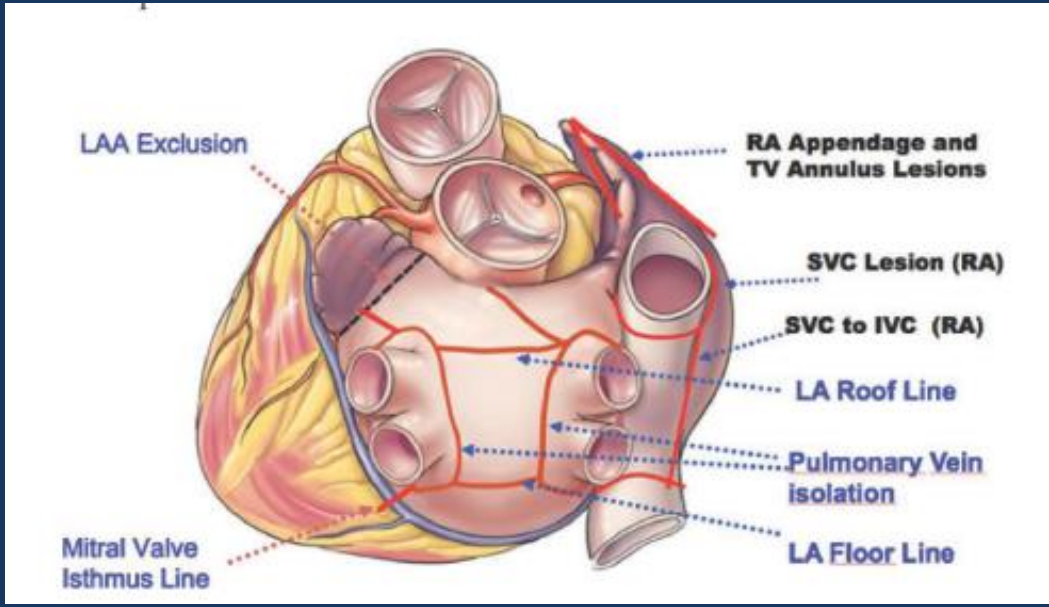
Maze Results: Free of AF	
Mayo Clinic	75%
Wash Univ	97%
Toronto	75%
Cox	98%

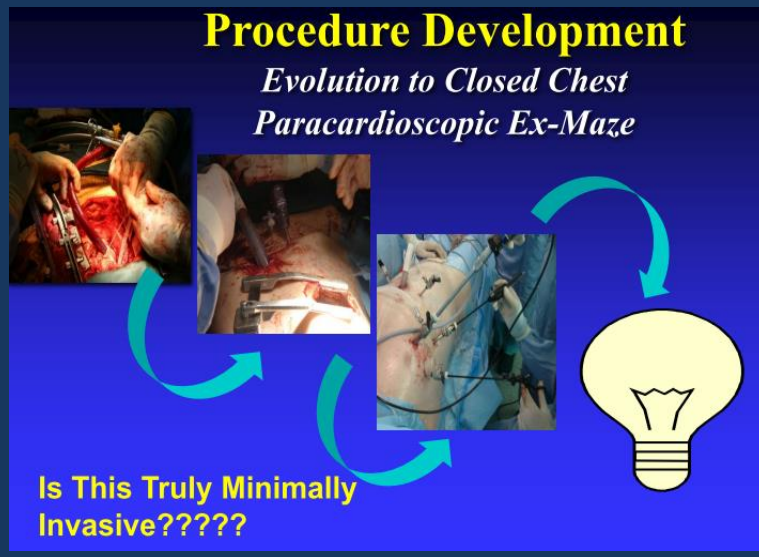
Cut-and-sew Maze, Cox Maze III

sütur-skar-blok transmuralite ve irreversibilite
tüm la duvar kalınlığınca Kalıcı elektriksel blok

Hibrid ablasyon

Cox-Maze IV





Atrial Fibrillation: Ablation or Surgical Treatment II: FAST II

This study has been terminated.

(Too few participants)

Persistent Atrial Fibrillation Ablation Trial (PAAT)

This study has suspended participant recruitment.

(Internal protocol review)

Dual Epicardial Endocardial Persistent Atrial Fibrillation(AF) Study (Staged DEEP)

The purpose of this study is to assess the safety and technical feasibility of treating subjects with Persistent Atrial Fibrillation or Longstanding Persistent Atrial Fibrillation in a minimally invasive thoracoscopic ablation procedure utilizing the AtriCure Bipolar System, with mapping and additional lesion creation/ gap closure (as needed) provided by currently approved catheter technology, when the epicardial and endocardial phases are performed in a staged manner within 1-10 days apart, during the same hospitalization.

Advantages and Disadvantages of Different Substrate Modification Approaches		
	Advantages	**Disadvantages**
Linear ablation	· Recommended by 2012 HRS Consensus Document · Connecting 2 anatomical obstacles empirically · Time-saving without advance mapping procedure	· Difficulty in achieving durable complete conduction block across the line · Gap-related sustained proarrhythmias · Empirical and anatomically defined lines do not address individual localization of the fibrotic substrate
CFAE ablation	· Recommended by 2012 HRS Consensus Document · Some evidence showing favorable outcomes · Eliminating parts of non-PV triggers · Modification of GP activities	· Mapping procedure is required · Unclear specificity of different types of electrograms · Variable definitions of CFAE · Extensive targets, difficult to differentiate culprit from bystander CFAEs
Voltage map-guided ablation	· Homogenization of heterogeneously scarred atrial tissue · Block pathway for left atrial macroreentry tachycardia	· Limited reports and lack of long-term outcome studies · Difficulty in application in advanced fibrotic left atrium (strawberry left atrium) · Small channels or gaps cause proarrhythmias
Rotor ablation	· Identify fibrillatory activation maintaining AF source · Some evidence showing favorable outcomes	· Mechanism and definition of rotor are unclear in clinical AF · Limited reports with variable results

Persistent AF Ablation

Substrate Modification **?**

CHASE-AF RADAR -AF
STAR AF 2

Outcome of Different Ablation Strategies In Persistent and Long-Standing Persistent Atrial Fibrillation (OASIS)

This study is currently recruiting participants. (see Contacts and Locations)

Verified August 2015 by Texas Cardiac Arrhythmia Research Foundation

Sponsor:
Texas Cardiac Arrhythmia Research Foundation

ClinicalTrials.gov Identifier:
NCT02533843

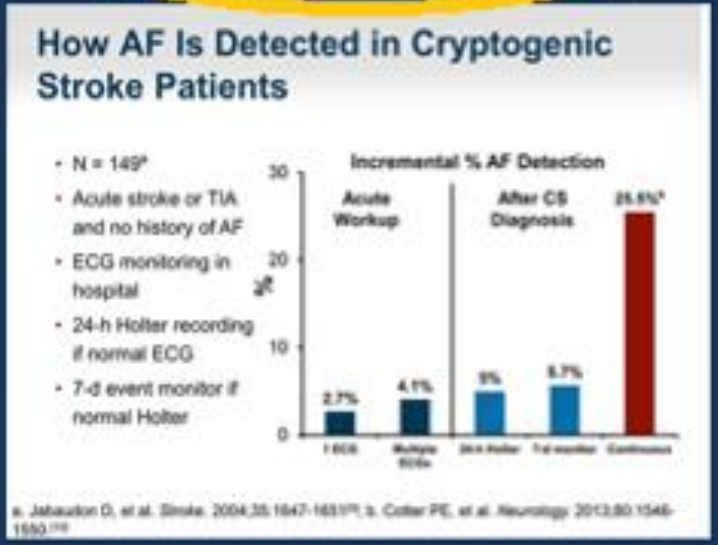
First received: December 5, 2014
Last updated: November 18, 2015
Last verified: August 2015

Specific Aim: This prospective randomized study aims to compare the impact of three different catheter ablation approaches on long-term procedure outcome in terms of arrhythmia recurrence in persistent (PeAF) and long-standing persistent atrial fibrillation (LSPAF) patients. The three strategies to be evaluated are 1) ablation at sources guided by FIRMap (using RhythmView™ Workstation from TOPERA), 2) ablation at sources guided by FIRMap + conventional pulmonary vein antrum isolation (PVAI) and 3) Extended PVAI plus ablation of non-PV triggers and complex fractionated atrial electrograms (CFAE).

- Tek merkez ↑ Çok merkez RKÇ ↓

The ESC co-ordinated Atrial Fibrillation Ablation Pilot Study reported on the 1-year follow-up of 1300 patients who underwent atrial fibrillation ablation in 72 centres in 10 European countries.[13] Registry data are important to observe deviation from best-practice recommendations and indicate opportunities for improvement. Success without antiarrhythmic drugs was achieved in 40.7% of patients (43.7% in paroxysmal AF; 30.2% in persistent AF; 36.7% in long-standing persistent AF) (*Figure 2*). The explanation for the deviation of these results from randomized trials (usually showing a ≥70% success rate in paroxysmal AF patients after a single procedure) needs further research. Interestingly, only 57.4% of the population underwent repeated long-duration (≥24 h) electrocardiographic monitoring, in contrast to HRS/EHRA/ECAS consensus recommendations. Knowing that 26% of recurrences were asymptomatic, this may hint to an even higher recurrence rate. A second ablation was required in 18%. There was a 1.7% major perioperative complication rate that must be weighed against the potential benefits when considering AF ablation in patients with mild symptoms.

KLİNİK TAKİP KRİTERİ ?



ÖSAFAGEAL HASAR TAKİP ?

SESSİZ SEREBRAL İNFARKT ?

VPS-2 SIMPLICITY 3

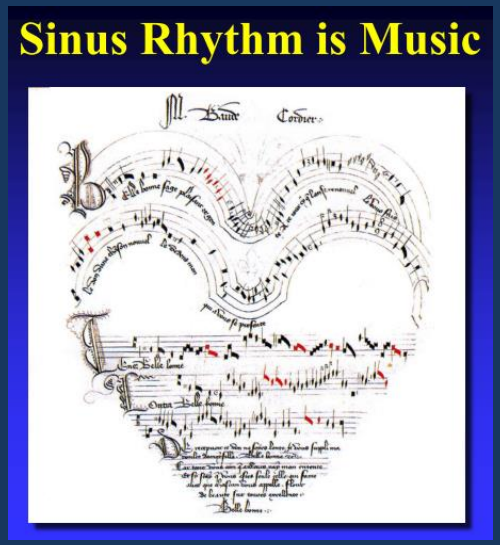
DECAAF LEGACY ?
SORT-AF

Beklentiler

* Tek işlem başarısı % 100 e yakın ve daha az işlem süresi

(PALYATİF İŞLEM den ----------→KÜRATİF İŞLEM)

* Sıfır/ Sıfıra yakın floroskopi (CartoSOUND, eş zamanlı MRI)



*Hasta spesifik tedavi stratejileri

- doğru ablasyon hedefleri (non-PV trigger/driver) bulma
- **KALICI-TRANSMURAL-SÜREKLİLİK GÖSTEREN GAPSİZ** lezyon oluşturma
- ödem gelişimini önceden anlayabilme (adenozin , eşzamanlı MRI)
- işlem esnasında (realtime) lezyon başarısını doğrulama

*CABANA /EAST