# *Robotic Ablation for Ischemic VT*

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Intermountain Heart Institute
Salt Lake City, UT

5/9/17

SCRN

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# Disclosures

- Stereotaxis Inc.
- Biosense Webster Inc.
- St. Jude Medical Inc.

# Mr. C

- 69 yo man, Anterior MI and 5 Vessel CABG 2004
- Documented sustained VT 10/2009
  - Dual Chamber ICD, Sotalol 80mg BID
- 6/2012 with recurrent VT: initial ablation
- Referred to us 7/2015 with recurrent VT
  - On amiodarone and mexilitine
  - Slow VT: HR 135-10
  - Averaging 6 episodes per month over past 3 months

# The Plan

- General anesthesia
  - Femoral A access for BP monitoring and “what if”
- Transseptal approach
  - “Mullins” type or other large curve sheath placed at Mitral Annulus
- Diagnostic catheters
  - RV, CS
- ICE

# Why Magnetic Navigation?

- Ease of navigation
- Effective lesion formation
- Growing evidence of clinical effectiveness
- Less stress on me = doing my best work for my patients

# Getting Places in Tough Cases

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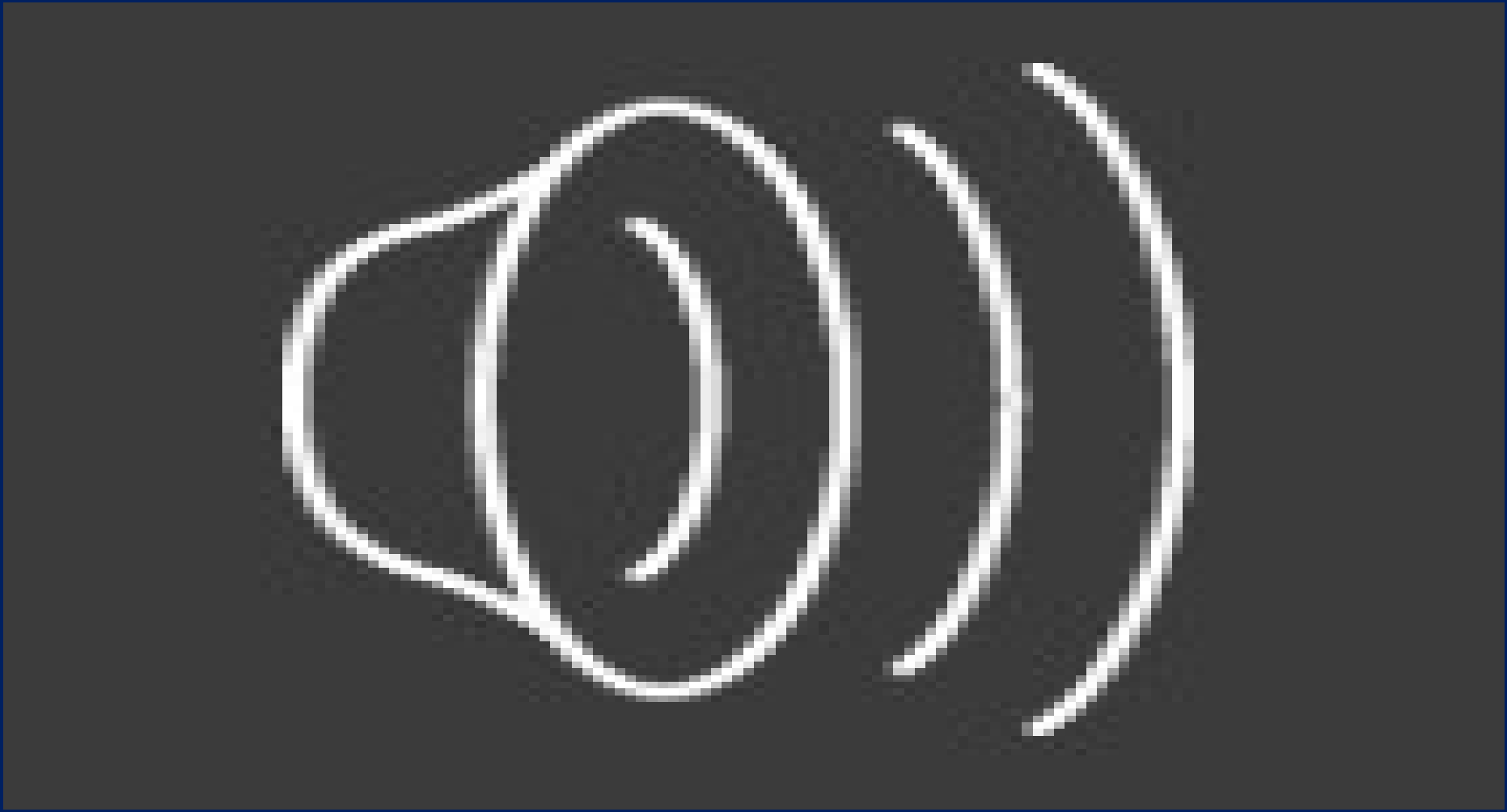
# Easy Access and Catheter Stability



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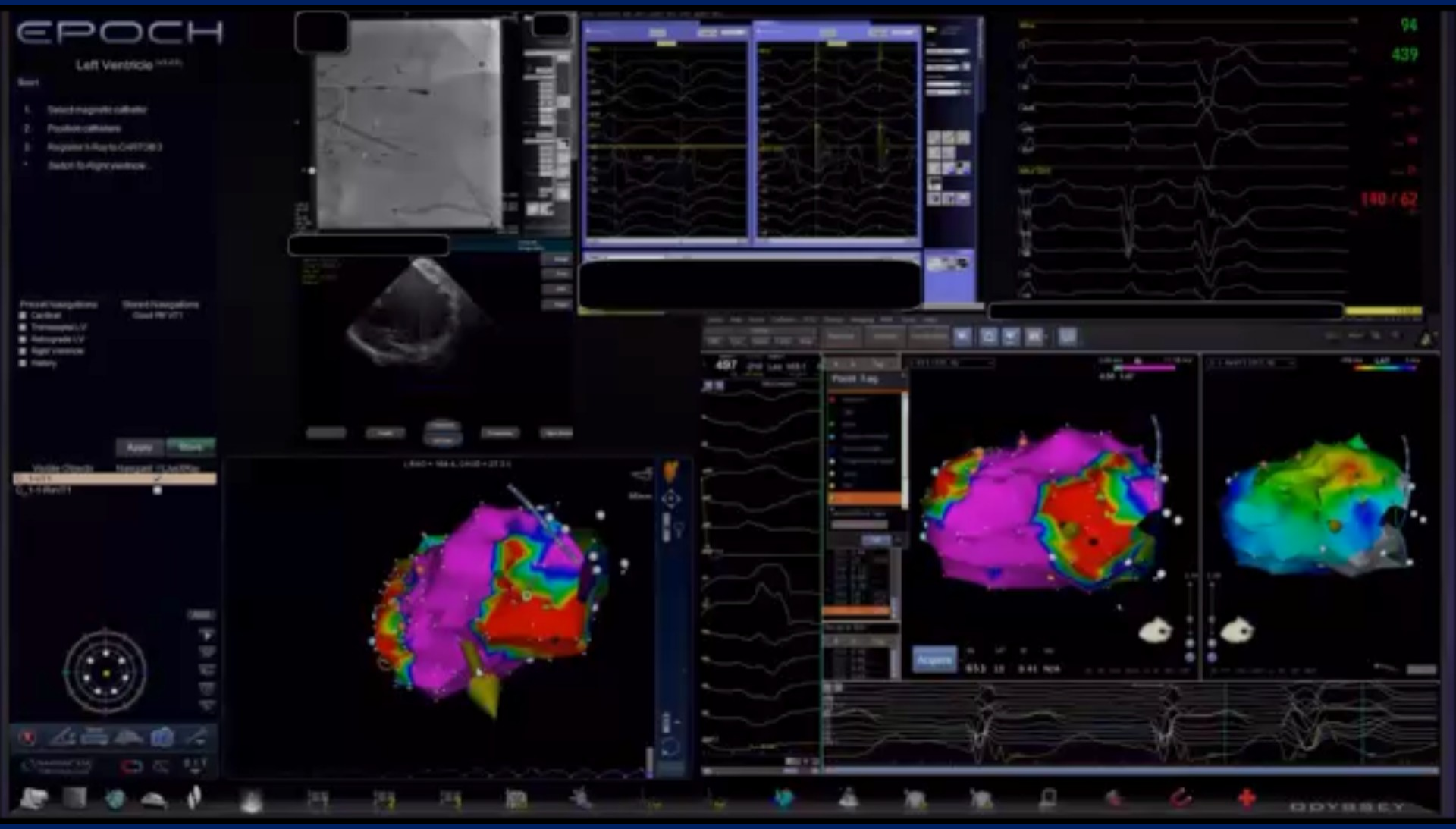
# Workspace for VT

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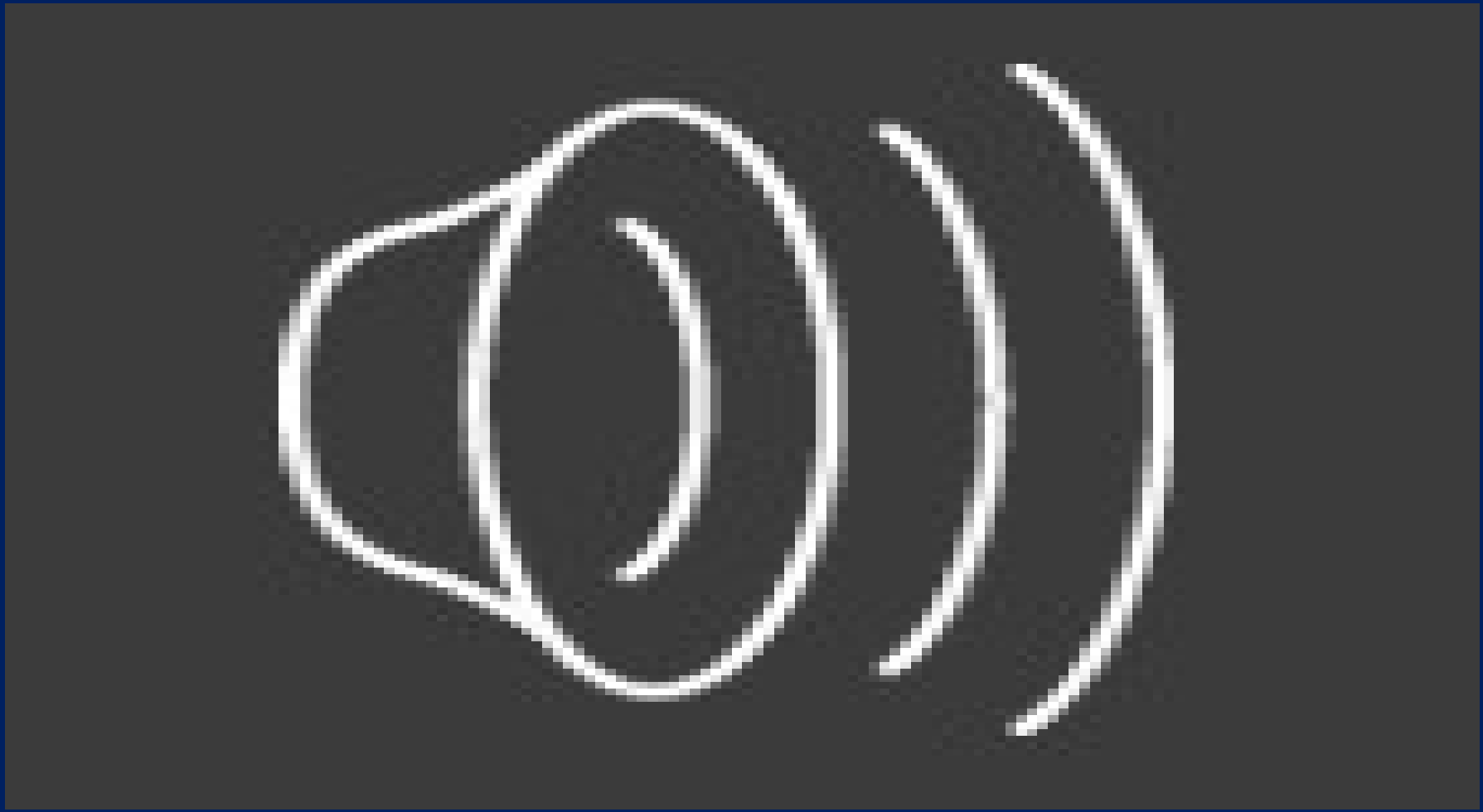
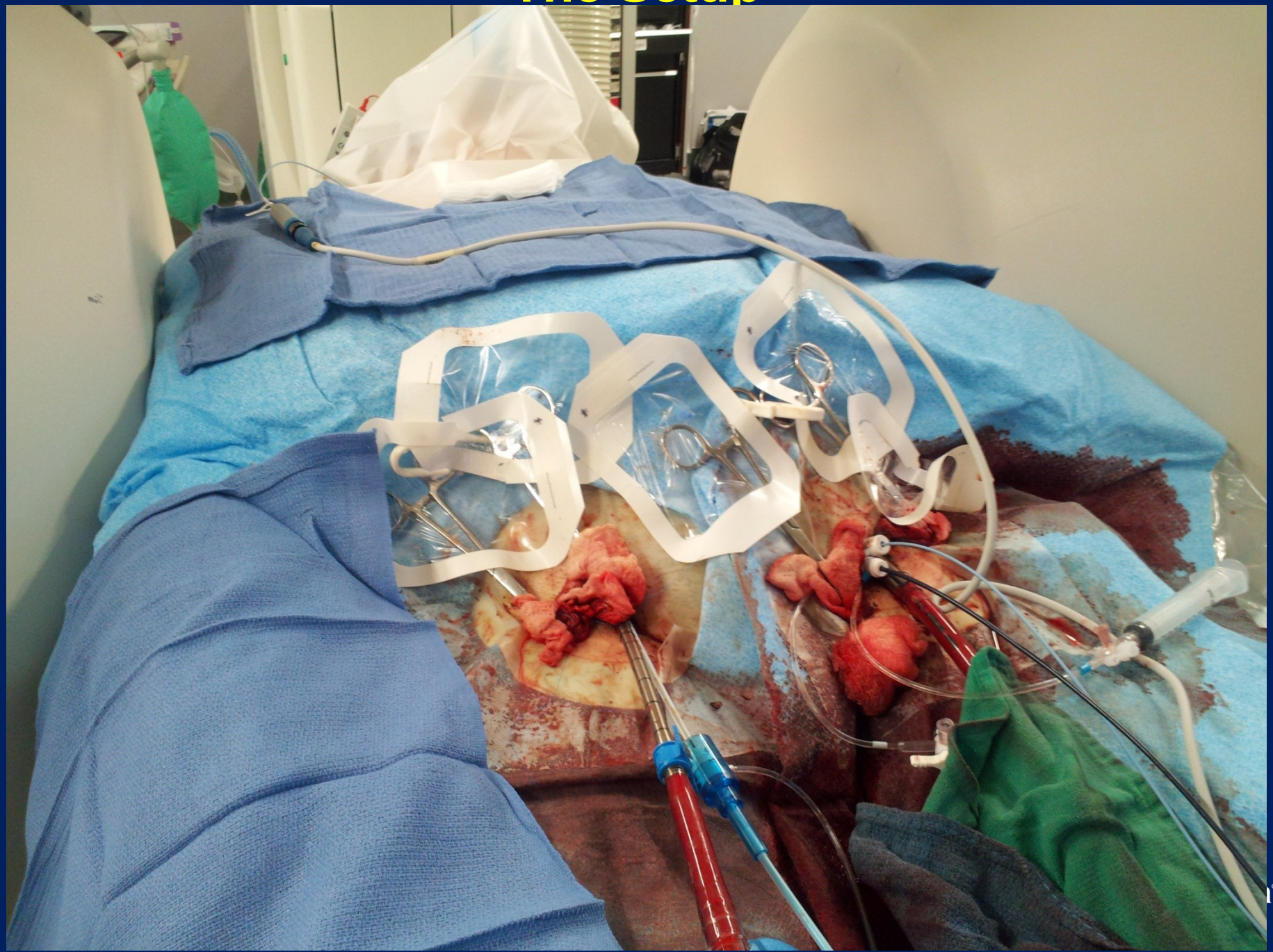


# Case Summary

- Large inferior scar
- Inducible clinical VT 145ish BPM
  - Targeted Ablation
  - Substrate modification of LAVA and Late Potentials
- At end only V Flutter 250 BPM with aggressive PES.
- Procedure time 4:25:00
- Fluorosopy time 00:06:18

# The Setup



**Remote Magnetic Navigation:** A Focus on Catheter Ablation of Ventricular Arrhythmias

PHILIP AAGAARD, M.D., Ph.D.,* ANDREA NATALE, M.D., F.A.C.C., F.H.R.S., F.E.S.C.,†,§,¶,#,,**,†† DAVID BRICENO, M.D.,* HIROSHI NAKAGAWA, M.D., Ph.D.,‡‡ SANGHAMITRA MOHANTY, M.D.,† CAROLA GIANNI, M.D.,† J. DAVID BURKHARDT, M.D.,† and LUIGI DI BIASE, M.D., Ph.D., F.A.C.C., F.H.R.S.*,†,‡,§

**TABLE 1**

Comparison of Manual versus Remote Navigation for VT Ablation

| Parameter | Manual versus RMN |
|---|---|
| Efficacy | Similar |
| Safety | Favors RMN |
| Radiation exposure | Favors RMN |
| Fluoroscopy times | Favors RMN |
| Procedure time | Favors RMN |
| Access to difficult anatomy | Favors RMN |

*J Cardiovasc Electrophysiol, Vol. 27, pp. S38-S44, March 2016)*

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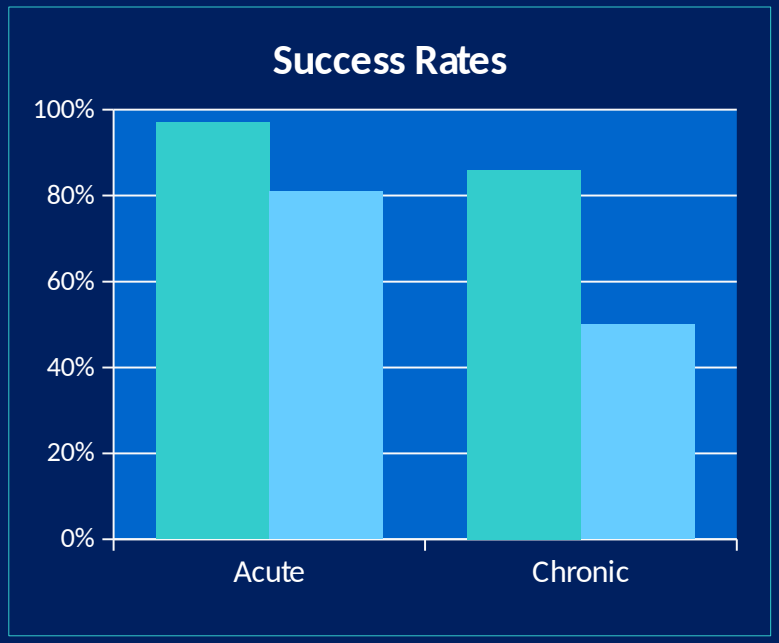
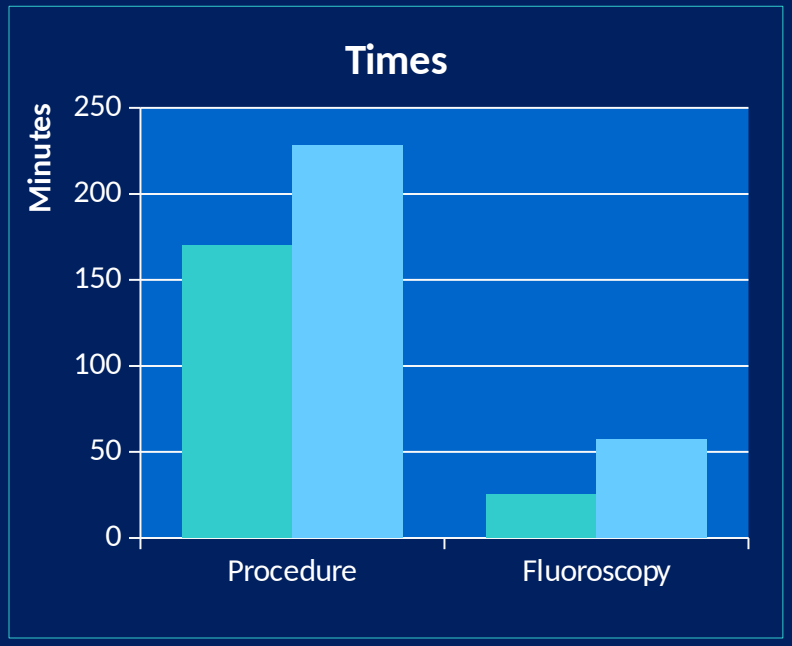
# *Usefulness of the Magnetic Navigation System in Ablation of VT*

*Schwagten et al, European Heart Journal, 2010:31(Abstract Supplement):932*




Magnetic Manual

Compared 37 procedures with magnetic navigation (12 month follow-up) to 27 procedures performed with pull-wire catheters (8 month follow-up).

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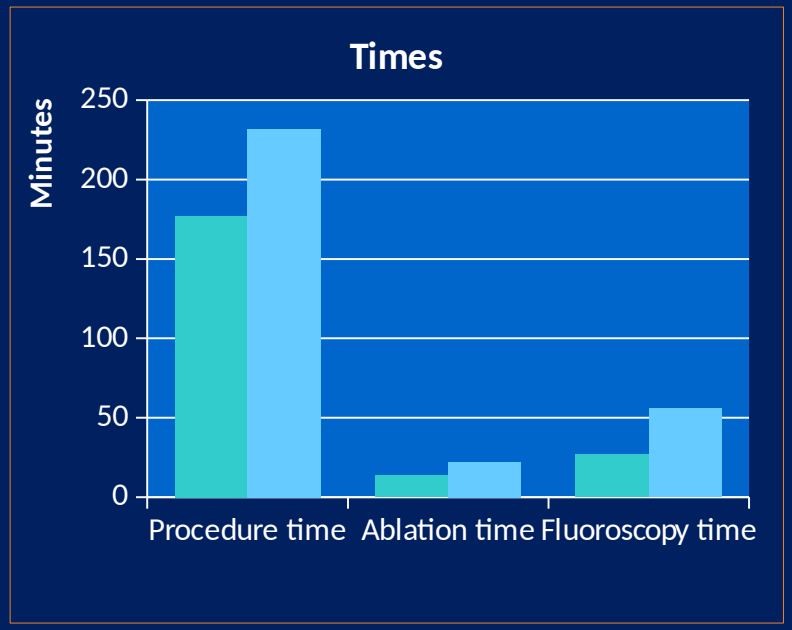
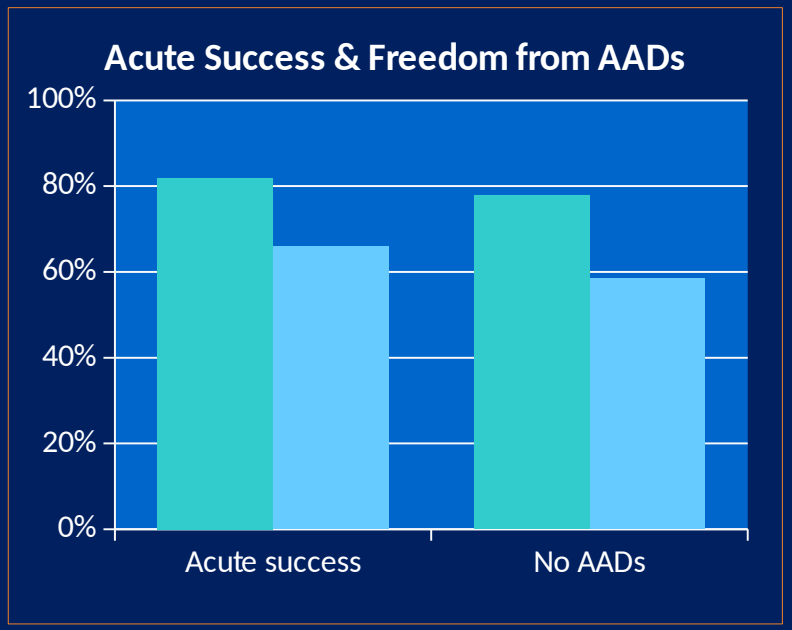
# *Catheter Ablation of VT Using Remote Magnetic Navigation*

*Szili-Torok et al, J Cardiovasc Electrophysiol, 2012 Sep, 23(9):948-54*




Magnetic Manual

A consecutive case-control study involving 113 patients.

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# Safety and Clinical Outcome of Catheter Ablation of Ventricular Arrhythmias Using Contact Force Sensing: Consecutive Case Series

HENDRIKS, A. A., AKCA, F., DABIRI ABKENARI, L., KHAN, M., BHAGWANDIEN, R., YAP, S.-C., WIJCHERS, S. and SZILI-TOROK, T. (2015), J Cardiovasc Electrophysiol, 26: 1224–1229. doi:10.1111/jce.12762

**Purpose**

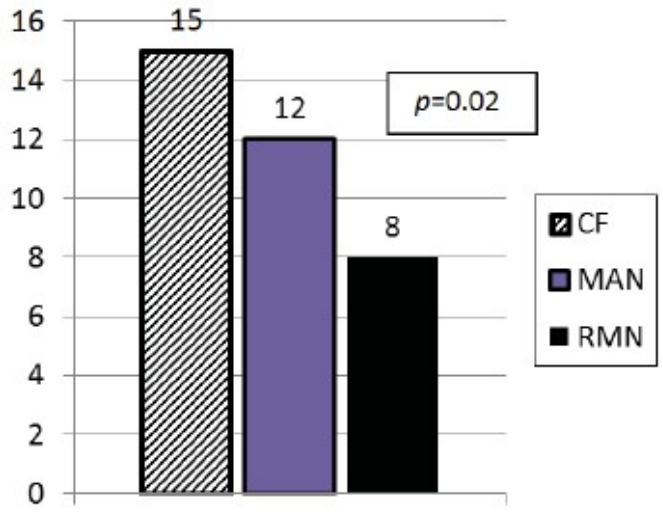
The aim of this study was to compare CF ablation to manual ablation (MAN) and remote magnetic navigation (RMN) ablation for safety and efficacy in acute and long-term outcome.

**Methods**

A total of 239 consecutive patients who underwent VT ablation with the use of MAN, CF, or RMN catheters were included in this single-center cohort study from January 2007 until March 2014. The primary endpoints were procedural success, acute major complications, and VT recurrences at follow-up. The median follow-up period was 25 months.

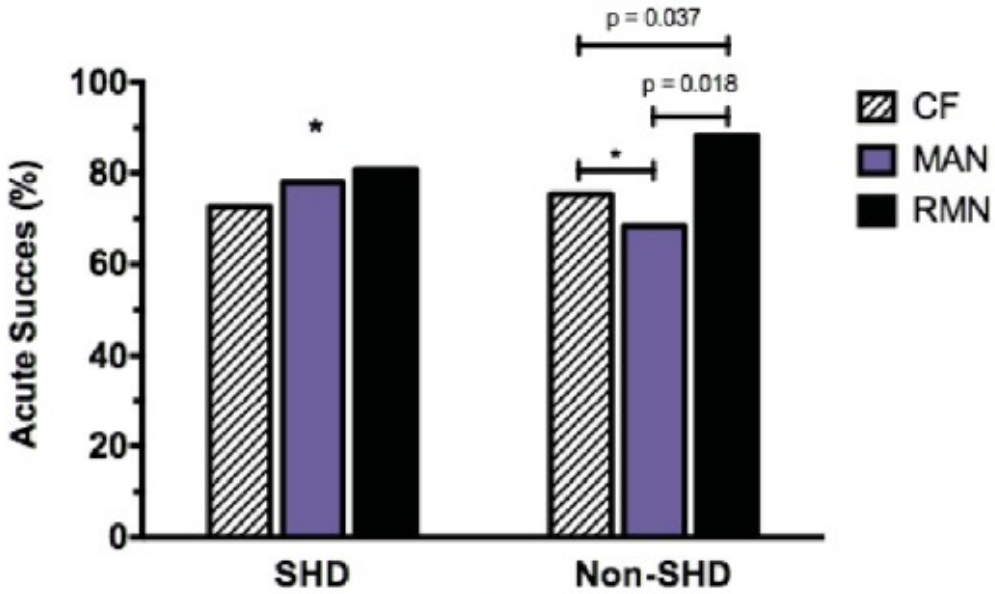
# Results

## SECTION 1: MAIN FINDINGS




Procedure Outcomes

The RMN group had fewer RF applications (p=0.02).

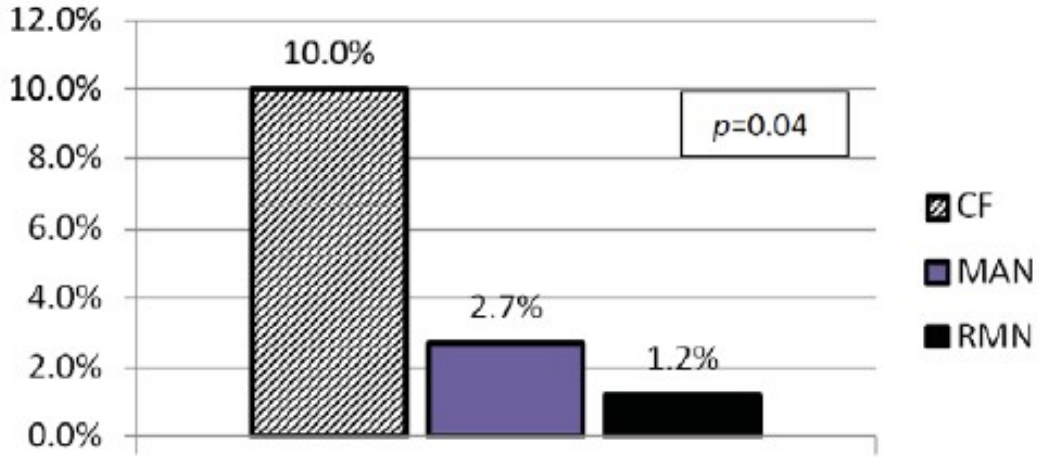



Acute Success

For structural heart disease (SHD), there were no statistically significant differences between acute success outcomes: CF (73%), MAN (78%), RMN (81%). For Non-SHD, acute success for RMN was statistically higher compared to both of the other groups: CF (68%), MAN (62%), RMN (88%). Note that the p–values above are both below $p<0.05$ indicating statistical significance (RMN vs. CF (20% difference) and RMN vs. MAN (26% difference)).

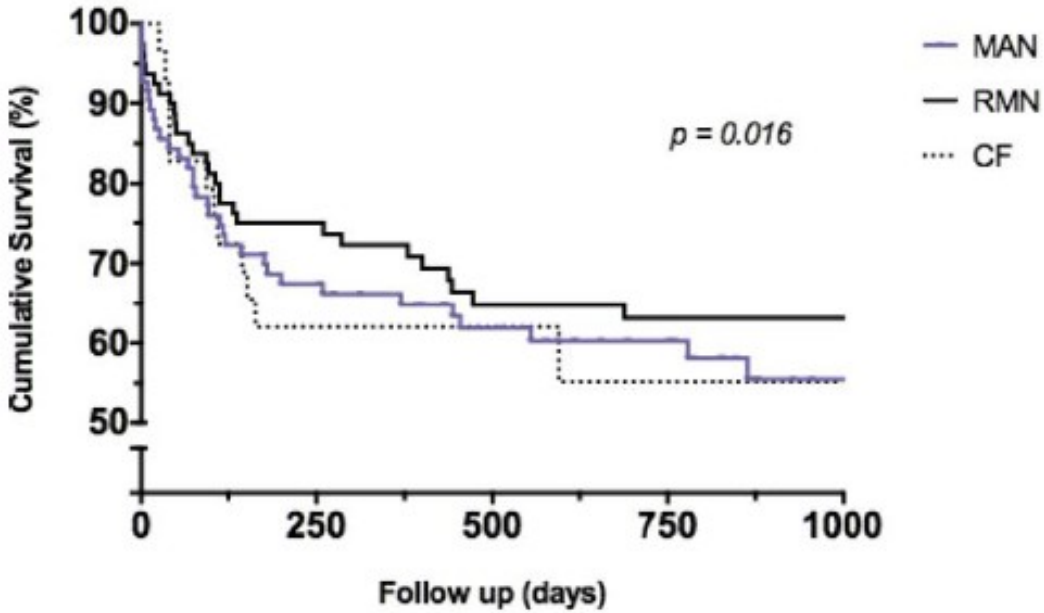
## Major Complications

The RMN group (1.2%) had significantly fewer complications than the CF group (10%).




## Survival Analysis

The Kaplan-Meier analysis demonstrated that the RMN group had the highest recurrence-free survivorship rate.



## SECTION 2: ADDITIONAL RESULTS

| | CF | MAN | RMN | p-value | Comment |
|---|---|---|---|---|---|
| **Patients** | | | | | |
| -Overall Acute Success | 71% | 71% | 86% | 0.03 | Favors RMN<br>Combines SHD and Non-SHD patients |
| -Long-term Success (All pts) | 41% | 43% | 58% | 0.07 | Strong trend toward statistical significance favoring RMN |
| **Safety** | | | | | |
| -All Complications | 19% | 12% | 6% | 0.06 | Strong trend toward statistical significance favoring RMN |
| -Death | 1 | 0 | 0 | n/a | Death from refractory heart failure after failed VT ablation |

# Conclusion

*Direct quote from article:*
"The use of CF sensing catheters did not improve procedural outcome or safety profile in comparison to non-CF sensing ablation in this observational study of ventricular arrhythmia ablations. RMN was superior with regard to acute success, reduction of major complications and recurrence rate using an intention-to-treat analysis."

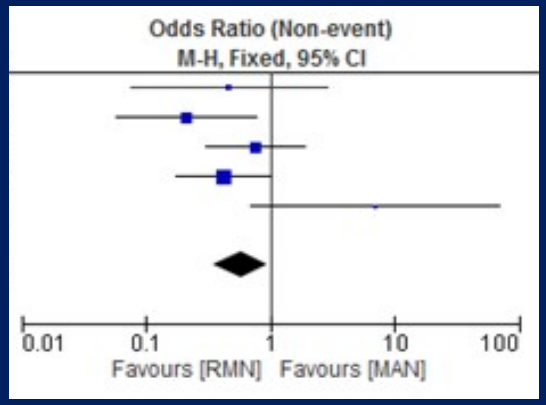
# *Manual Navigation vs Remote Magnetic System for VT Ablation*

***Gunda et al, literature review presented at HRS 2015***

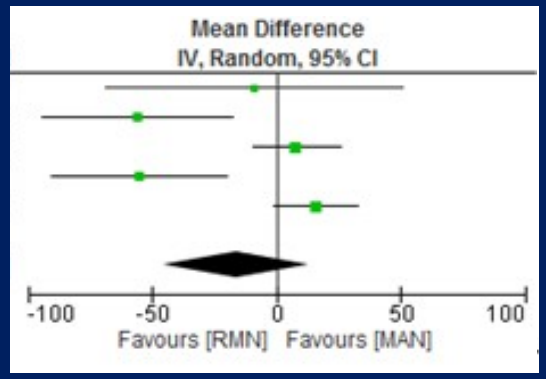
**Overview**

A meta-analysis of five studies including 356 patients.

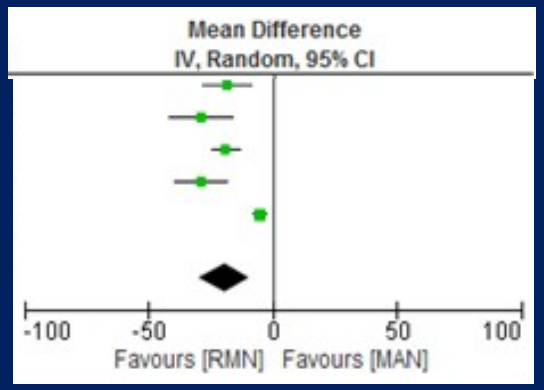
## Acute Success



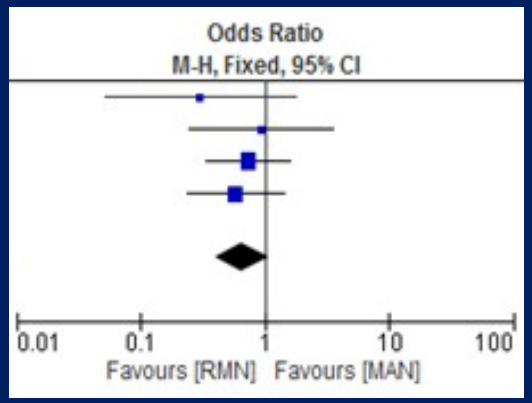

## Procedure Time



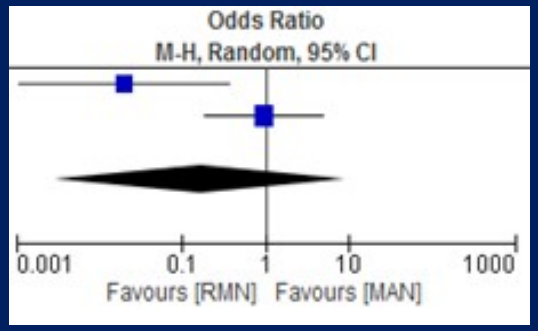

## Fluoroscopy Time




## Recurrence




## Pericardial Effusion Incidence

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# *Scar Homogenization Ablation in Ischemic Cardiomyopathy*

*Di Biase et al, Circulation.2015; 132: A14384*

**Study Aim**

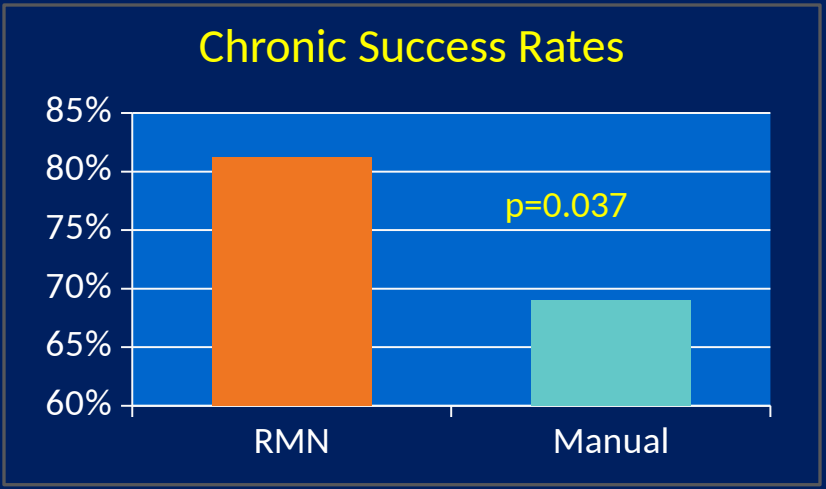
Compare procedural benefit and outcomes of patients with ischemic cardiomyopathy (IC) undergoing ventricular arrhythmias (VA) ablation with remote magnetic navigation (RMN) versus a manual approach.

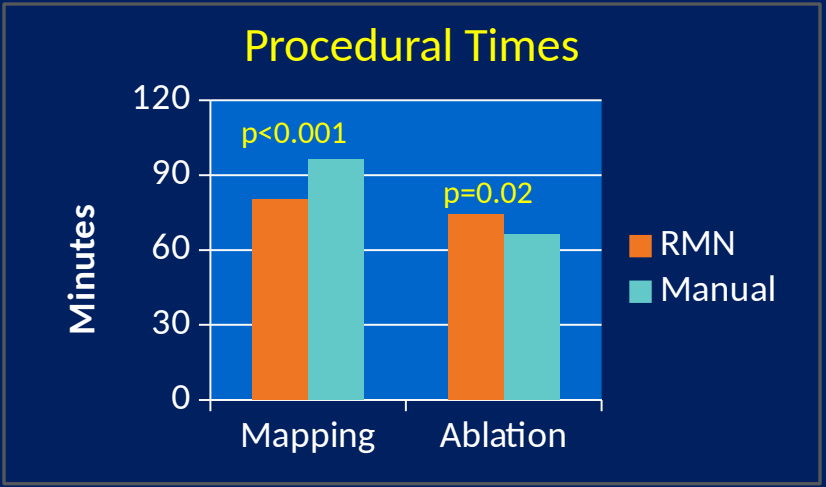
**Methods & Results**

Multi-center study of 218 consecutive patients with scar size > 60 $cm^2$ undergoing scar homogenization with either RMN (138 pts) or manual (80 pts) ablation. Density of the substrate map was higher in RMN group than manual (553±118 vs 347±97, p<0.001). Mean follow-up was 15.4±6.8 months.

**Conclusion**

Using RMN in pts with IC and a scar size greater than 60 $cm^2$ increases success rate at follow up when

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# Catheter Ablation of Ischemic Ventricular Tachycardia With Remote Magnetic Navigation: STOP-VT Multicenter Trial

SKODA, J., ARYA, A., GARCIA, F., GERSTENFELD, E., MARCHLINSKI, F., HINDRICKS, G., MILLER, J., PETRU, J., SEDIVA, L., SHA, Q., JANOTKA, M., CHOVANEC, M., WALDAUF, P., NEUZIL, P. and REDDY, V. Y. (2016), J Cardiovasc Electrophysiol, 27: S29–S37.
doi:10.1111/jce.12910

- Prospective, single-procedure, multicenter study
- 53 consecutive patients with ischemic CM (median age 67 years, 49 men, median LVEF 31%)
- The primary endpoints:
  - (i) non-inducibility of the target VT or any other sustained VT;
  - (ii) elimination of sustained VT/VF during ICD follow-up of up to 12 months.

# Catheter Ablation of Ischemic Ventricular TachycardiaWith

**Remote** Multicenter

**TABLE 3**

Procedure Parameters

| Variable | Median or % (IQR) | Frequency (N) |
|---|---|---|
| Number of VT morphologies per subject (%) | | |
| 1 | 45.3% | 24 |
| 2 | 18.9% | 10 |
| 3 | 20.8% | 11 |
| 4 | 9.4% | 5 |
| 5 | 3.8% | 2 |
| 8 | 1.9% | 1 |
| All VT cycle length, seconds | 360 (307–410) | 116 |
| Unstable VT cycle Length, seconds | 298 (280–326) | 53 |
| Unstable VT proportion, pts | 58% | 30 |
| Unstable VT proportion, N of VTs | 47% | 53 |
| Procedure and fluoroscopy times | | |
| *Elapsed time of procedure (minutes, N = 52)* | 220 (176–292) | |
| *Fluoro exposuretime* | | |
| *- Before mapping (minutes)* | 6.7 (4.2–9.6) | |
| *- Mapping (minutes)* | 0.48 (0.2–2.5) | |
| *- Ablation (minutes)* | 0.46 (0.1–2.8) | |
| *- Total (minutes)* | 8.65 (5.3–16.5) | |

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# Catheter Ablation of Ischemic Ventricular TachycardiaWith Remote Magnetic Navigation: STOP-VT Multicenter Trial

**TABLE 4**

Acute Ablation Success

| Acute Success | N | % |
|---|---|---|
| Target VT non-inducible | 49/52 | 94.2% |
| Any VT non-inducible | 38/52 | 73.6% |
| Procedure failure | 3/52 | 5.8% |

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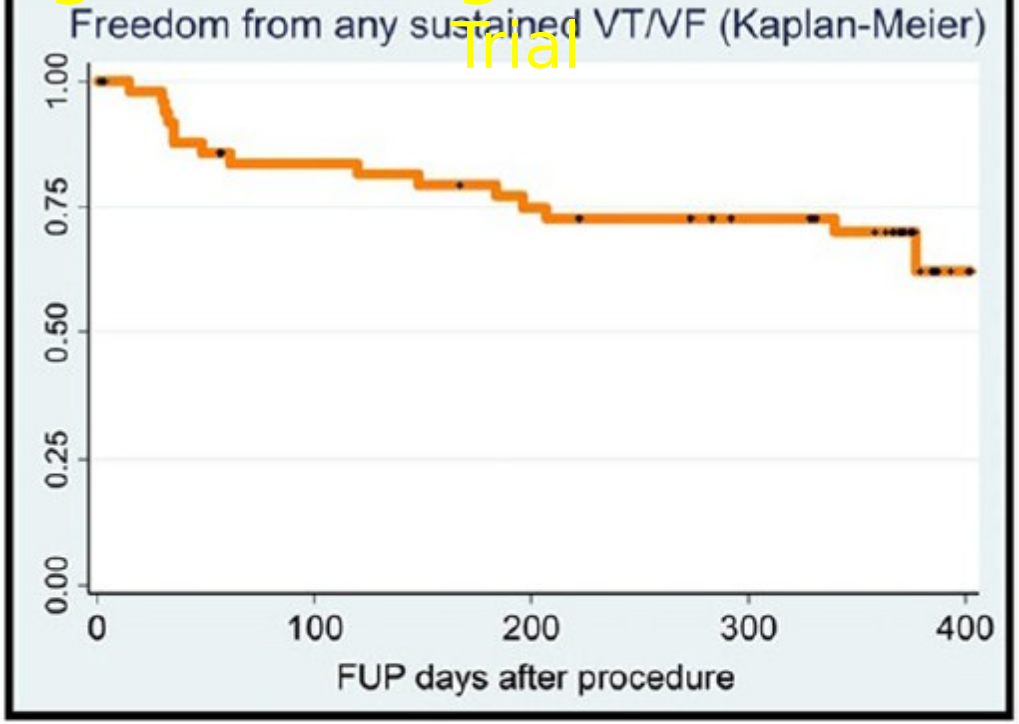
# Catheter Ablation of Ischemic Ventricular TachycardiaWith Remote Magnetic Navigation: STOP-VT Multicenter Trial




To be included in a long-term success table the patient must be an acute success

| ICD Follow-up (months) | At-Risk (n) | Recurrent VTs (n) | Censored (n) | Cumulative freedom from any sustained VT (%) |
|---|---|---|---|---|
| 1 month | 49 | 8 | 2 | 84% |
| 6 months | 39 | 5 | 2 | 73% |
| 12 months | 32 | 2 | 30 | 62% |

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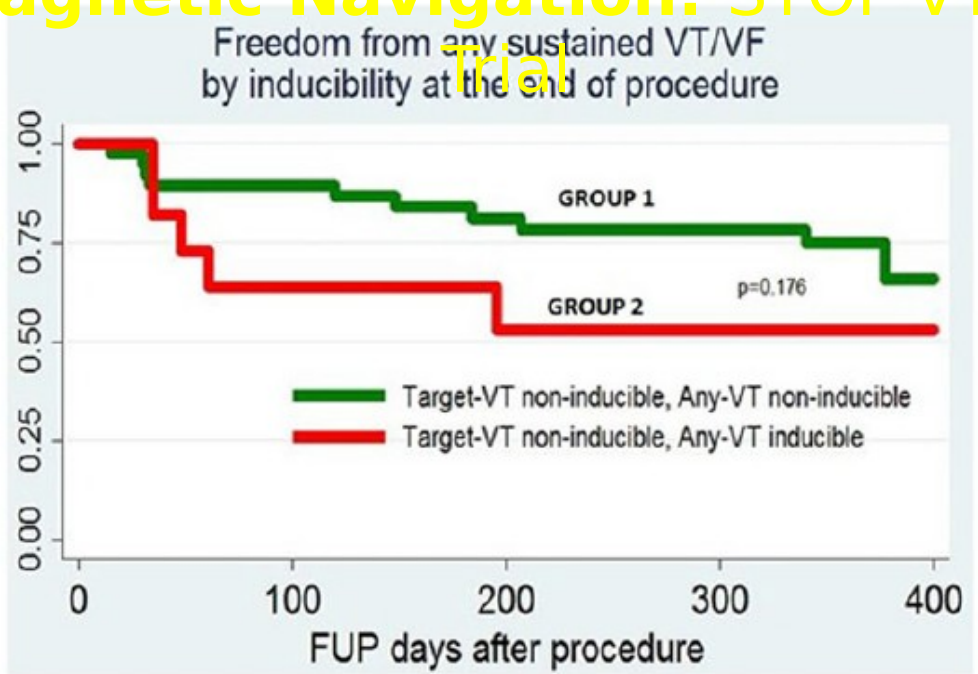
# Catheter Ablation of Ischemic Ventricular TachycardiaWith Remote Magnetic Navigation: STOP-VT Multicenter Trial




| Follow-up (months) | At-Risk (n) | Recurrent VTs (n) | Censored (n) | Cumulative freedom from any sustained VT/VF (%) |
|---|---|---|---|---|
| Ablation | 38/14 | 0/0 | 0/0 | 100/100% |
| 1 month | 38/11 | 4/4 | 2/0 | 89/64% |
| 6 months | 32/7 | 4/1 | 1/1 | 78/53% |
| 12 months | 27/5 | 2/0 | 25/5 | 65/53% |

Numbers depicted as group 1/ group 2

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# Catheter Ablation of Ischemic Ventricular TachycardiaWith Remote Magnetic Navigation: STOP-VT Multicenter Trial

## Discussion

This prospective, multicenter, single arm, single procedure trial indicates that remote magnetic navigation is safe and effective for endocardial catheter ablation of post-MI scar-related VT. The main findings are as follows:

(1) A combined ablation approach reflecting daily clinical practice, including entrainment mapping, pace-mapping, pathological potentials elimination and substrate modification was accompanied with a positive procedural outcome and a 62% freedom from VT/VF or appropriate ICD therapy at one year.
(2) Low flouroscopy times were recorded, including both mapping and ablation;
(3) No complications occurred.

# MAGNETIC VT study: a prospective, multicenter, post-market randomized controlled trial comparing VT ablation outcomes using remote magnetic navigation-guided substrate mapping and ablation versus manual approach in a low LVEF population

Luigi Di Biase[1,2,3,4] · Roderick Tung[5] · Tamás Szili-Torok[6] · J. David Burkhardt[1] · Peter Weiss[7] · Rene Tavernier[8] · Adam E. Berman[9] · Erik Wissner[10] · William Spear[10] · Xu Chen[11] · Petr Neužil[12] · Jan Skoda[12] · Dhanunjaya Lakkireddy[13] · Bruno Schwagten[14] · Ken Lock[15] · Andrea Natale[1,3,16,17,18,19,20] · on behalf of MAGNETIC VT investigators

"The MAGNETIC VT trial will assess if VT ablation using the Niobe™ ES magnetic navigation system results in superior outcomes compared to a manual approach in subjects with ischemic scar VT and low ejection fraction."

https://clinicaltrials.gov/ct2/show/study/NCT02637947

J Interv Card Electrophysiol
DOI 10.1007/s10840-016-0217-3

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# MAGNETIC VT

- Randomized, single-blind, prospective, multicenter post-market study
- 386 subjects (193 per group) will be enrolled and randomized 1:1
- Ischemic cardiomyopathy, LVEF of ≤35%, ICD in place, sustained monomorphic VT

# MAGNETIC VT

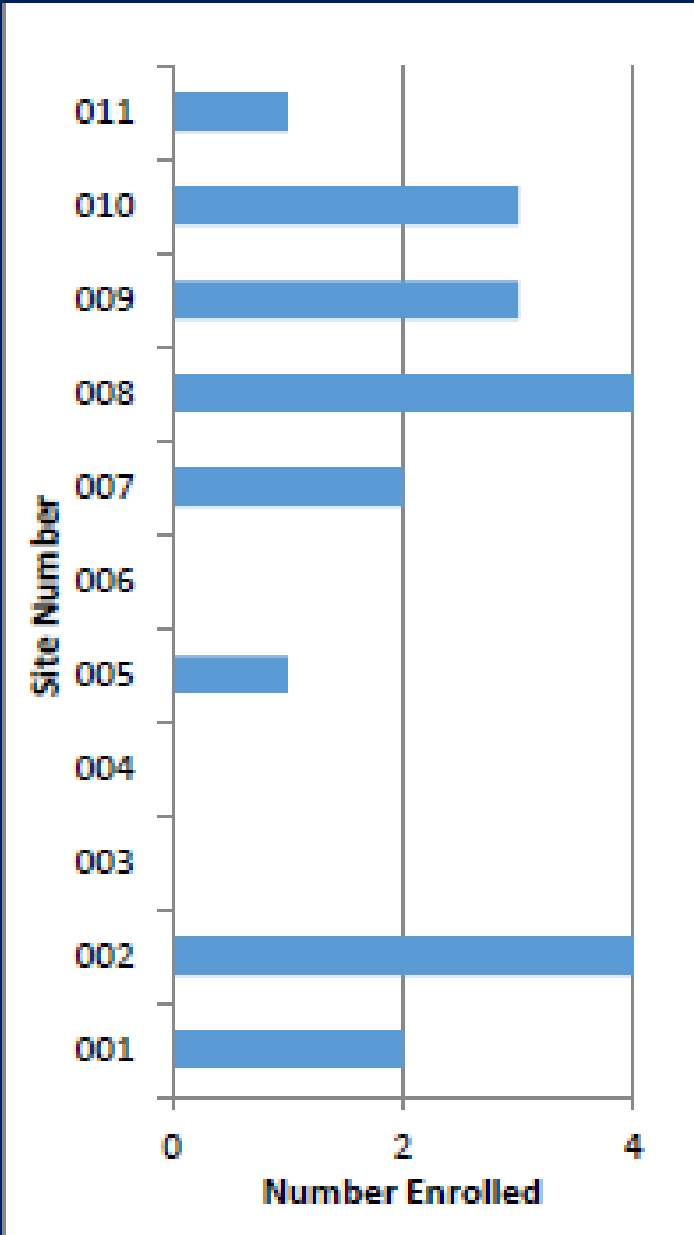
- Primary endpoint: freedom from any recurrence of VT through 12 months
- Secondary endpoints:
  - Acute success
  - Freedom from any VT at 1 year
  - Procedure-related major adverse events
  - Mortality rate through 12-month follow-up
- Follow-up will consist of visits at 3, 6, 9, and 12 months, all of which will include ICD interrogation

# MAGNETIC VT

## Site Activation

### Activated Sites:

Rene Tavernier, MD, PhD
Algemeen Ziekenhuis, Belgium
Andrea Natale, MD
Texas Cardiac Arrhythmia
J. Peter Weiss, MD
Intermountain Medical Center, USA
Adam Berman, MD
Augusta University, USA
William Spear, MD
Advocate Christ Medical Center, USA
Dhanunjaya Lakkireddy, MD
The University of Kansas Hospital, USA
Roderick Tung, MD
The University of Chicago Medicine, USA
Tamas Szili-Torok, MD, PhD
Erasmus MC, Netherlands
Xu Chen, MD
Rigshospitalet, Denmark
Petr Neuzil, MD, PhD
Nemocnice Na Homolce, Czech Republic
Bruno Schwagten MD
ZNA Middelheim, Belgium

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# Thank You!

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