Background

- Cox-MAZE open chest, cardiac surgery was a very successful invasive procedure for treatment of AF[1], but highly invasive
- Since the landmark trial by Haissaguerre et al.[2], PV isolation by catheter ablation (CA) has become accepted therapy for paroxysmal and persistent AF refractory to AAD (Class IIA/B, LOE-B/C[3])
- However, AF recurrence after ablation often relates to restoration of conduction between the LA and the PV found at redo procedure
- Wolf et al.[4] described a successful minimally invasive surgical approach including PVI, ganglionic plexi ablation, and LAA excision (SA), indicated only if ablation fails (Class IIB, LOE-B)
- FAST is the first randomized clinical trial, directly comparing the efficacy and safety of CA to SA

1. Prasad et al. J Thoracic Cardiovasc Surgery 2003, 2. Haissaguerre et al. NEJM 1998,
3. ESC Guidelines AF therapy 2010, 4. Wolf et al. J Thoracic Cardiovasc Surgery 2005

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Trial design and selection criteria

- Two-Center randomized clinical trial with a 12 mo follow-up
- CA vs. SA, 1:1 randomization, July 2007-July 2011
- Inclusion:

  Drug-refractory AF, documented in the last 12 mo, symptom duration>1 year, high chance of CA failure[1] due to:

  1. LA diameter >40-44 mm with hypertension, or
  2. LA diameter≥45 mm, or
  3. Failed prior catheter ablation
- Exclusion:

  longstanding persistent AF>1 yr, permanent AF, LAD>65 mm, LVEF<45%, prior stroke/embolism, significant valvular disease
- Pre-procedure 7-day Holter, TTE&TEE, and CT/MRI

1. Berruezo et al. Eur Heart J 2007

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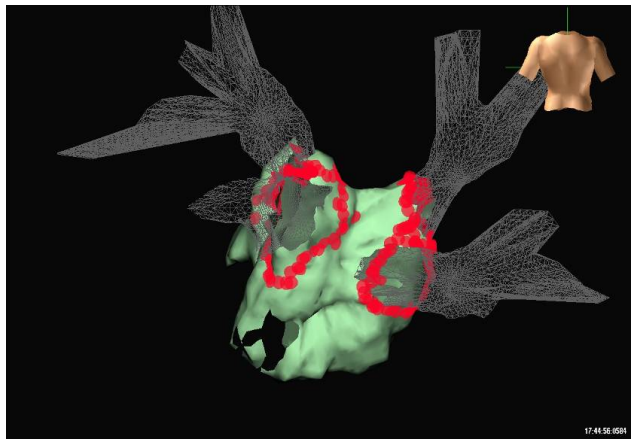
Treatment protocol for CA and SA

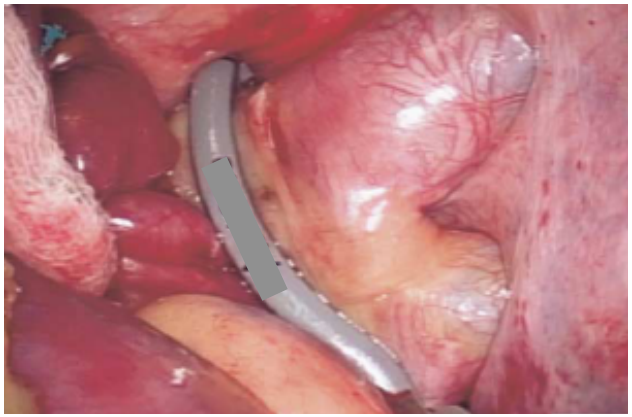
CA group :

- Catheter ablation: single tip RF catheter guided by 3-D mapping[1] (NavX/CARTO) under conscious sedation
- Wide encircling linear antral PV isolation
- Additional LA lines at the discretion of the individual operator



SA group:

- Video-assisted thoracoscopic surgery: Bipolar RF, coolrail, and RF pen (AtriCure)
- PV isolation, LA ganglionic plexi ablation, and LA appendage excision[2]
- Additional lines at the operator discretion



1. Courtesy of St.Jude medical, 2. Wolf et al. J Thor Cardiovas Surgery,

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Follow-up and Endpoints

Follow-up schedule:

- ECG at outpatient clinic 1, 3, 6, 12 mo, or anytime during complaints
- 7-day Holter performed at 6, 12 mo

Primary Efficacy Endpoint after 12-mo:

- Freedom of LA arrhythmia lasting >30 sec in the absence of Class I&III AAD

Primary Safety Endpoint after 12-mo:

- Significant Adverse Event rate both procedural and chronic

Statistical analysis:

- 124 pts were randomized assuming an efficacy of CA 60% and SA 85%, power of 80% (1-sided Fishers Exact test), significance level 0.025
- Outcome measures: 2-sided Pearsons' Chi-square test/Yates continuity correction, Odds ratios with 95% CI, and Fishers Exact test

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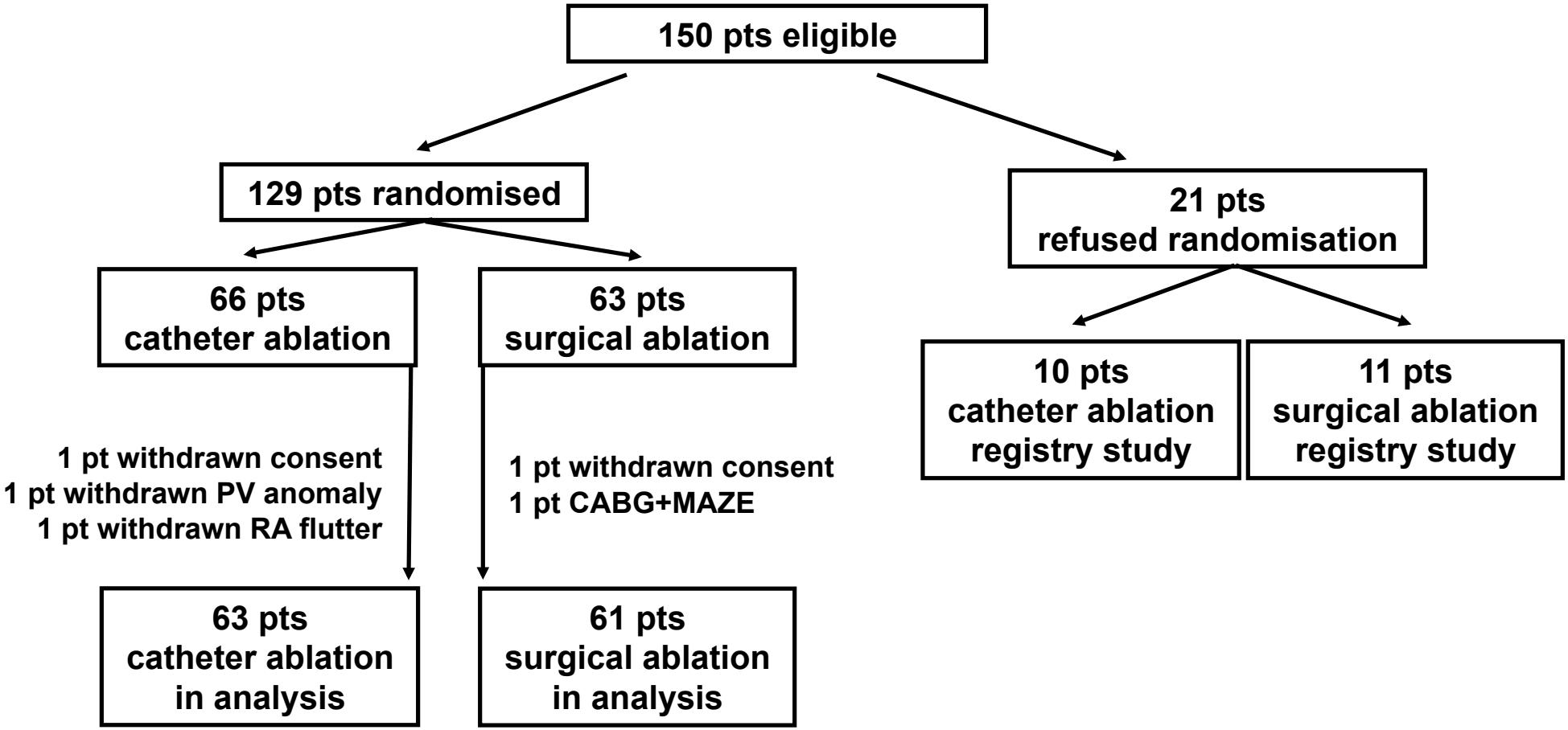
Screening, inclusion, and randomization



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Baseline characteristics CA and SA - 1

		CA N=63	SA N=61
Male		55(87.3%)	45(73.8%)
Age, yr		56.0±7.2	56.1±8.0
BMI, Kg/m^2		28.6±3.5	27.8±4.6
Prior MI		2(3.2%)	-
LVEF		55.5±8.2%	57.7±6.8%
LA diameter, mm		43.2±4.8	42.5±6.5%
Prior failed CA		38(60.3%)	45(73.8%)
LA diameter 40-44 mm & hypertension		15(23.8%)	8(13.1%)
LA diameter ≥45 mm		10(15.9%)	8(13.1%)
AF type:	PAF	37(58.8%)	45(73.8%)
	PersAF	26(41.2%)	16(26.2%)
Years since diagnosis		6.8±5.3	7.4±6.3

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Baseline characteristics CA and SA - 2

		CA N=63	SA N=61
Prior AAD use:	1	28.3%	16.3%
	2	41.5%	35.7%
	3	15.1%	32.7%
	≥4	15.1%	16.3%
	Amiodarone	26(41.3%)	30(49.2%)
$CHADS_2$ score:	0	35(58.3%)	38(63.3%)
	1	17(28.3%)	17(28.3%)
	≥2	8(13.4%)	4(6.7%)
Pre-procedure Holter:	No AF	23(40.4%)	29(55.8%)
	PAF	10(17.5%)	12(23.1%)
	Continuous AF	24(42.1%)	11(21.2%)

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Procedural data CA and SA

		CA N=63	SA N=61
Total procedure time, min		163±55	188±59 (p=0.0177)
Flurorscopy time, min		27±11	-
PVI		62 (98.2%)	60 (98.3%)
LAA excision		-	60 (98.3%)
PV reablated redo:	1	1 (2.6%)	-
	2	9 (23.7%)	-
	3	3 (7.9%)	-
	4	25 (65.8%	45 (100%)
Additional LA lines:	1	17 (27.4%)	9 (14.8%)
	2	14 (22.6%)	2 (3.3%)
	3	-	8 (13.1%)
RF energy PVI		33±20 min	8.9±2.8 applications

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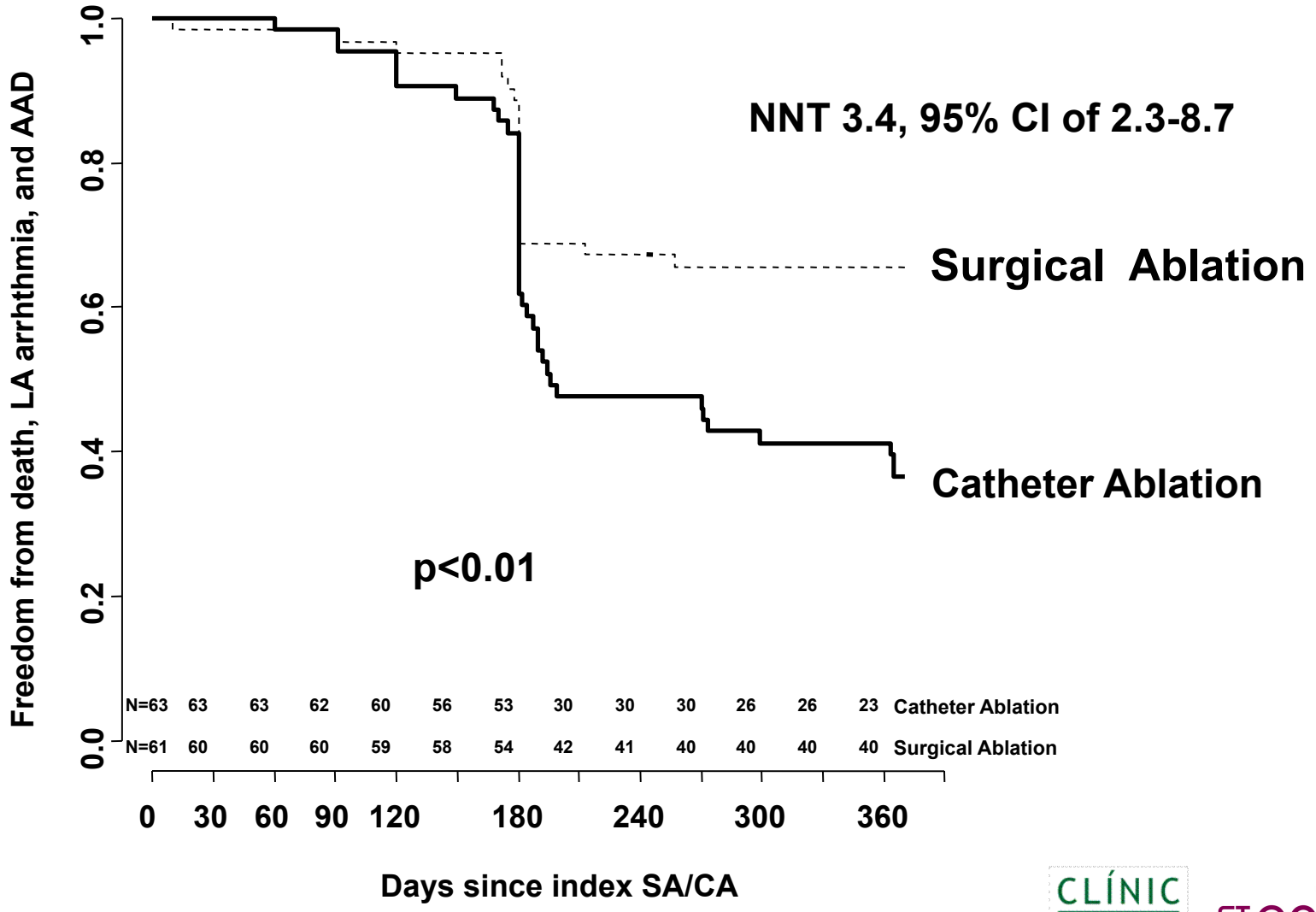
Primary Efficacy Endpoint at 12 mo



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Efficacy CA versus SA during FU

Freedom LA arrhythmia	CA N=63	SA N=61	P-value
Overall, 12 mo	23(36.5%)	40(65.6%)	p=0.0022*
Overall, 12 mo allowing AAD	27(42.9%)	48(78.7%)	p<0.0001*
PAF group	13/37(35.1%)	31/45(68.9%)	p=0.0047
PersAF group	9/25 (36.0%)	9/16(56%)	p=0.3411
Prior failed CA	14/38(36.8%)	30/44(68.2%)	p=0.0089
LA dilation/hypertension	9/25(36.0%)	10/17(58.8%)	p=0.3411
Nieuwegein	10/30(33.3%)	18/29(62.1%)	p=0.0513
Barcelona	13/33(39.4%)	22/31(70.9%)	p=0.0336

Heterogeneity analysis non-significant, p-value>0.2

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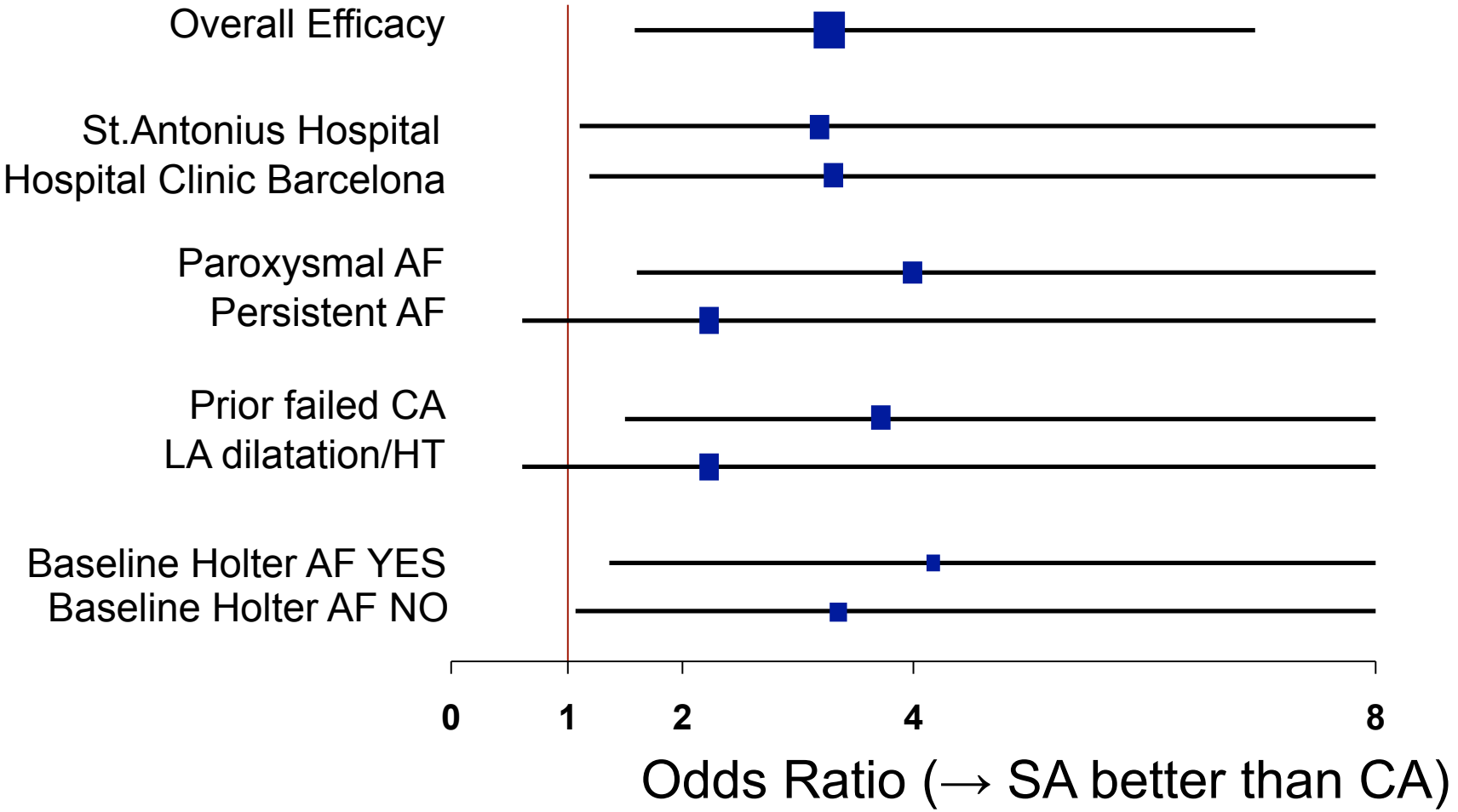
Subgroup analysis for CA and SA



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Procedural Safety CA and SA

Adverse events	CA N=63	SA N=61	P-value
Pericardial effusion/tamponade	1	1	
TIA/Stroke	1	1	
Pneumothorax	-	6	
Hematothorax	-	1	
Rib fracture	-	1	
Sternotomy for bleeding	-	1	
Pneumonia	-	1	
PM implant	-	2	
Death	-	-	
Total	**2 (3.2%)**	**14 (23.0%)**	**p=0.001**
Minor			
Groin hematoma/bleed	4 (6.3%)	-	

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Safety CA and SA after 12 mo FU

Adverse events	CA N=63	SA N=61	P-value
Stroke	1	-	
TIA	1	-	
Pneumonia	2	2	
Hydrothorax	-	2	
Heart failure by AF	2	-	
SAB causing death	1	-	
Pericarditis	-	1	
Fever unknown origin	-	1	
Ileus	1	1	
PV stenosis>70%/symptomatic	-	-	
Total	**8 (12.7%)**	**7 (11.5%)**	**p=1.0**
Minor			
Groin hematoma/bleeding	2 (3.2%)	-	

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Conclusions

- In a population of patients with AF, with a dilated LA and hypertension, or a failed prior AF catheter ablation, minimally invasive Surgical Ablation was superior to Catheter Ablation to achieve freedom of LA arrhythmia without anti-arrhythmic drugs during a follow-up of 12 months

- Surgical ablation was accompanied by a higher adverse event rate than catheter ablation

- These findings may be used by physicians and patients to guide optimal invasive therapy

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Atrial Fibrillation Catheter Ablation Versus Surgical Ablation Treatment (FAST)

A 2-Center Randomized Clinical Trial

Lucas V.A. Boersma, MD, PhD, FESC; Manuel Castella, MD, PhD; WimJan van Boven, MD; Antonio Berruezo, MD; Alaaddin Yilmaz, MD; Mercedes Nadal, MD; Elena Sandoval, MD; Naiara Calvo, MD; Josep Brugada, MD, PhD, FESC; Johannes Kelder, MD; Maurits Wijffels, MD, PhD; Lluís Mont, MD, PhD, FESC

Background—Catheter ablation (CA) and minimally invasive surgical ablation (SA) have become accepted therapy for antiarrhythmic drug–refractory atrial fibrillation. This study describes the first randomized clinical trial comparing their efficacy and safety during a 12-month follow-up.

Methods and Results—One hundred twenty-four patients with antiarrhythmic drug–refractory atrial fibrillation with left atrial dilatation and hypertension (42 patients, 33%) or failed prior CA (82 patients, 67%) were randomized to CA (63 patients) or SA (61 patients). CA consisted of linear antral pulmonary vein isolation and optional additional lines. SA consisted of bipolar radiofrequency isolation of the bilateral pulmonary vein, ganglionated plexi ablation, and left atrial appendage excision with optional additional lines. Follow-up at 6 and 12 months was performed by ECG and 7-day Holter recording. The primary end point, freedom from left atrial arrhythmia >30 seconds without antiarrhythmic drugs after 12 months, was 36.5% for CA and 65.6% for SA (P=0.0022). There was no difference in effect for subgroups, which was consistent at both sites. The primary safety end point of significant adverse events during the 12-month follow-up was significantly higher for SA than for CA (n=21 [34.4%] versus n=10 [15.9%]; P=0.027), driven mainly by procedural complications such as pneumothorax and major bleeding. In the CA group, 1 patient died at 1 month of subarachnoid hemorrhage.

Conclusion—In atrial fibrillation patients with dilated left atrial and hypertension or failed prior atrial fibrillation CA, SA is superior to CA in achieving freedom from left atrial arrhythmias after 12 months of follow-up, although the procedural significant adverse event rate is significantly higher for SA than for CA.

Clinical Trial Registration—URL: http://clinicaltrials.gov. Unique identifier: NCT00662701.

(*Circulation*. 2012;125:00-00.)

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