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Mapping and Ablation in AF: how can we evaluate the lesion formation?

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MY CONFLICTS OF INTEREST ARE

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THE BEATLES


YOU'LL NEVER WALK ALONE
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Liverpool Heart and Chest Hospital

- 1400 EP cases annually (550 AF cases)
- Predominantly Carto-based PVI since 2009
- BWI External Evaluation Site for
  - Carto version 3.3 (2012)
  - ST SF catheters (June 2014)
  - Carto version 4.0 (Aug 2014)
  - Ablation Index (Nov 2014)

Parameters to evaluate lesion formation

- Contact Force
- Energy delivery Time
- Power
- Impedance decrease
- Electrogram Changes
- Electrode and Tissue temperature

FTI

Limitations of FTI

No allowance for Power

- Lesion size with FTI 300 3 times bigger for 35W than 20W*

No allowance for Parabolic nature of lesion creation

- application duration contributes little to lesion size beyond 20secs **

* Guerra JM et al, J Cardiovasc Electrophysiol 2013; 24:1157-62

** Wittkampf FH et al, Circulation 1989; 80: 962-68

Force Power Time Integral

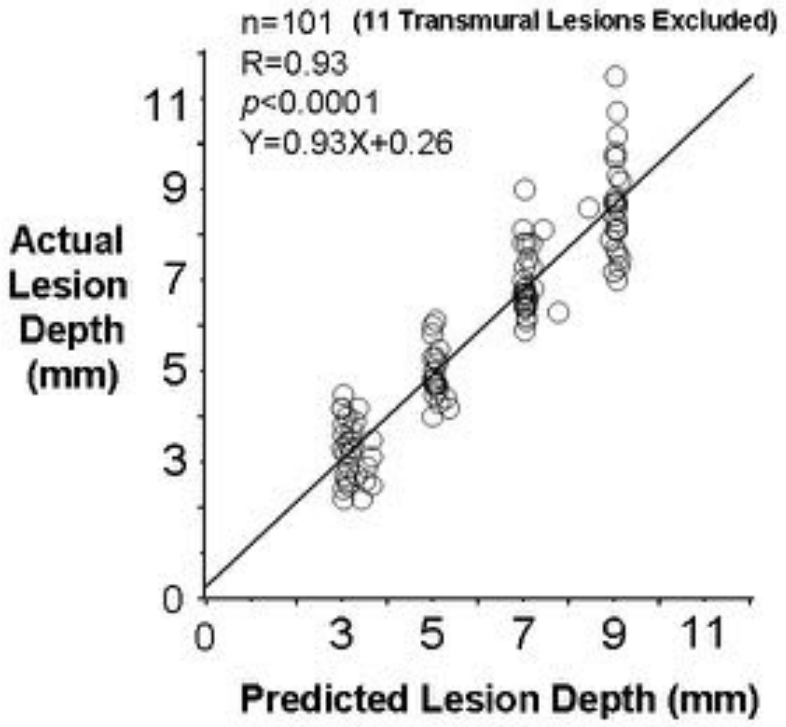
A formula developed by Nakagawa et al based upon biophysics of lesion formation

Based upon retrospective analysis of lesion depth in canine RV and LV

Greater impact of Power over Contact Force

Greater impact of the Initial Phase of Ablation

Predictive Value of FPT Integral



Prospective Study to Test the Ability to Create RF Lesions at Predicted Depths of 3, 5, 7 and 9 mm Using a New Formula Incorporating Contact Force, Radiofrequency Power and Application Time (Force-Power-Time Index) in the Beating Canine Heart. Heart Rhythm 2013;10:S481

FPT Integral to 'Ablation Index'

- FPTI was introduced as ABLATION INDEX in Carto® 3, v4 (external evaluation)
  - Not validated to assess lesion depth in human tissue
- First Phase: AI could be reviewed retrospectively
- Second Phase: AI could be monitored prospectively
  - AI Bars
  - AI color coded tags
  - Force sampled every 50 ms (Carto)
  - Power sampled every 100 ms (Stockert™)

Clinical Evaluation of Ablation Index

Evaluation of Force, Time, Stability (CF catheter and FTI)		
TOCCATA	**EFFICAS I**	**EFFICAS II/TOCCASTAR**
3D and CF guided PVI	3D guided PVI	CF& FTI guided Ablation
Unblinding of FTI	Unblinding of FTI	
Clinical Outcome vs FTI	Late Gap at 3 months vs FTI	Gap at 3 months/ Clinical results
N=32	N=40	N=24/300

Evaluation of Force, Power, Time, Stability (Ablation Index)		
Multicentre Analysis	**PRESSURE**	**PRAISE / CLOSE**
3D and CF guided PVI	3D and CF guided PVI	AI guided Ablation
Unblinding of AI	Unblinding of AI	
Acute Gaps vs AI	Late Gaps at 2 months vs AI	Gap at 3 months/ Clinical results
N=155 (Liverpool, Bruges, Aarhus, Bad Kronizen)	N=40 (Liverpool)	N=50 (Liverpool, Milan) N=130 (Bruges, Tokyo)

Phase 1:Multicentric Study to develop AI

Hiroshi Nakagawa, Oklahoma

- Mattias Duytschaever, Bruges, Belgium
- Dhiraj Gupta, Liverpool, UK
- Amir Jadidi, Freiburg, Germany
- Peter Lukac, Aarhus, Denmark

Ablation Protocols

- Lasso guided PbP-PVI, Adenosine and >20’ waiting
- Thermocool Smatrtouch® and Visitag™ module
  - Catheter Position Stability: 5-8 sec, 2-3 mm
  - Force over Time: 3-5 g, >30-40%
  - Impedance Drop not targeted
- Minimum Target CF 5-10 g
- FTI target of 400 used at Bruges and BK

Ablation Index Predicts Sites of Acute Reconnection after Pulmonary Vein Isolation: a Multi-Center Retrospective Analysis

Moloy Das[1], Mattias Duytschaever[2], Dhiraj Gupta[1], Peter Lukac[3], Jeremie Sorrel[4], Thomas Phlips[2], Amir S. Jadidi[4], Hiroshi Nakagawa[5]

[1]Liverpool Heart and Chest Hospital, UK; [2]St Jan Hospital Bruges, Belgium; [3]Aarhus University Hospital, Denmark; [4]University Heart Center Freiburg–Bad Krozingen, Germany; [5]University of Oklahoma Health Sciences Center Heart Rhythm Institute, OK, USA

Introduction

- Delivery of transmural ablation lesions during pulmonary vein isolation (PVI) for atrial fibrillation (AF) is of critical importance
- In a previous canine study on RF ablation, lesion depth was described accurately by a logarithmic function of contact force (CF), power and application time (Force-Power-Time Index Formula)
- Ablation Index (CARTO® 3 V4) utilises this formula to predict lesion depth at each ablation site
- We hypothesized that the minimum Ablation Index value within a segment of a circumferential PVI ring would predict acute segment reconnection

Aims

We aimed to retrospectively analyse the relationship between the minimum Ablation Index value (AI_{min}) within a circumferential PVI (CPVI) segment and acute reconnection of that segment (spontaneous or adenosine-mediated) in patients with AF undergoing PVI.

Methods

Study population

- 159 AF patients undergoing CPVI in 4 centers were retrospectively studied (age 60±10 years, 70% male, 87% paroxysmal AF, LAd 41±5mm).

PVI procedure

- CPVI was performed using operator-selected CF, time and power settings
- VisiTag™ automated lesion tagging was utilised in all cases, using operator –specified settings:
  - Catheter Position Stability :
    - Minimum time: range 3-10secs (median 8secs)
    - Maximum range: range 2-5mm (median 3mm)
  - Force Over Time:
    - Time: range 30-70% (median 30%)
    - Minimum CF: range 3-10g (median 5g)

Assessment for acute PV reconnection

- PVs were assessed for acute reconnection with a circular catheter after a minimum 20-minute waiting period
- Adenosine was administered to unmask dormant acute reconnection
- Sites of acute reconnection were recorded according to a 9-segment model
- For each subject, the ablation maps was reviewed offline to identify the AI_{min} for each of the 9 CPVI segments (Figures 1 and 2)

Figure 1

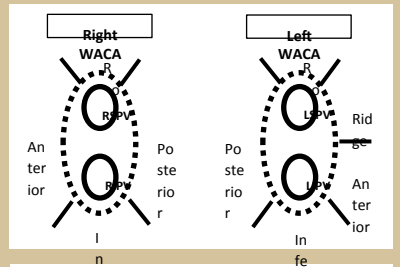


Fig. 1: Diagram showing the 9-segment CPVI model

Results

Prevalence of acute PV reconnection

Acute reconnection was identified in:

- 49 of 159 (31%) patients
- 80 of 1413 (6%) CPVI segments

Predictive value of AI_{min}

The median AI_{min} for acutely reconnected segments was significantly lower than that for non-reconnected segments (median 293 [IQR 255-344] vs. 342 [293-397], *P*<0.0001, Figure 3).

Regional differences

Median AI_{min} values for individual segments by reconnection status are shown in Table 1

Table 1

Segment	No reconnection	Acute reconnection
Roof	350	293
Anterior	362	351
Ridge	364	291
Posterior	315	286
Inferior	328	270

Figure 2

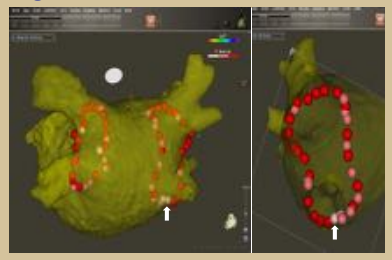


Fig. 2: Snapshots showing VisiTags color-coded by Ablation Index value. The lesion with the AI_{min} value within the inferior segment of the right WACA circle is marked with an arrow

Figure 3

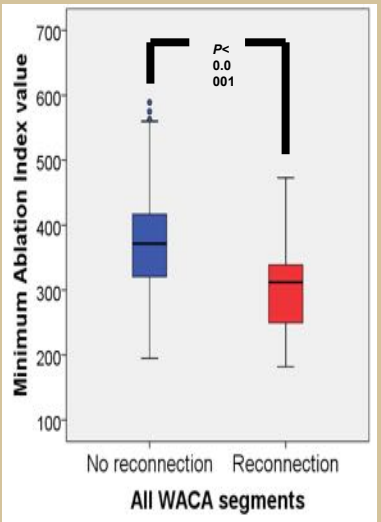


Fig.3: Box plot showing AI_{min} values for acutely reconnected and non-reconnected segments. The thick line indicates the median, the box represents the interquartile range and the whiskers represent the 5th and 95th centiles

Results

Predictive value of AI_{min} by region

As posterior and inferior PV segments were found to have similar values, these were grouped

- The AI_{min} for reconnected posterior/inferior segments was significantly lower than for those without reconnection (286 [243-327] vs. 321 [278-372], *P*=0.0001, Figure 4)

The values for anterior, ridge and roof segments were also similar

- The AI_{min} for reconnected anterior/ridge/roof segments was significantly lower than for those without reconnection (298 [261.5-366.5] vs. 358 [307-421], *P*<0.0001, Figure 4)

The AI_{min} for non-reconnected anterior/ridge/roof segments was significantly higher than that for non-reconnected posterior/inferior segments (*P*<0.0001)

Figure 4

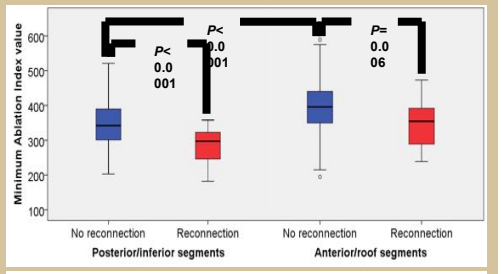


Fig. 4: Box plots showing AI_{min} values for acutely reconnected and non-reconnected segments by left atrial region

Target Ablation Index values to minimise acute PV reconnection

The 100% positive predictive value AI_{min} thresholds associated with no acute reconnection were:

- 380 for posterior/inferior segments
- 550 for anterior/ridge/roof segments

Conclusions

- The AI_{min} within a CPVI segment predicts acute reconnection within that segment
- Higher AImin values are required for anterior/ridge/roof segments than for posterior/inferior segments to prevent acute reconnection, suggesting thicker LA wall in these regions

Phase 1: Multicentric Study to develop AI

Acute reconnection identified in

- 49 of 159 (31%) patients
- 80 of 1413 (6%) segments

Segment	No reconnection	Acute reconnection
Roof	350	293
Anterior	362	351
Posterior	315	286
Inferior	328	270

The 100% PPV AI_{min} thresholds associated with no ARC

- 380 for posterior/inferior segments
- 550 for anterior/ridge segments

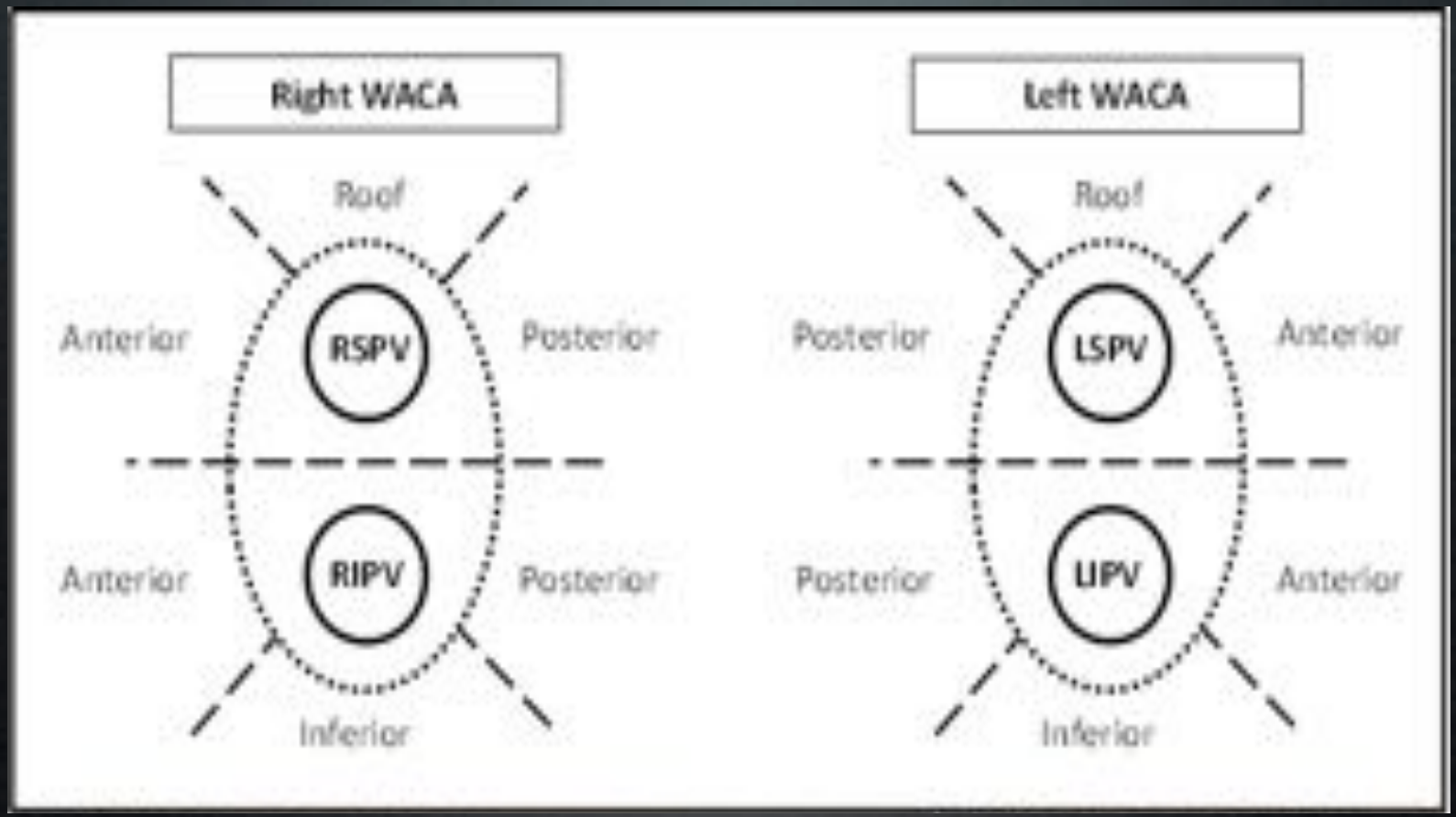
Multicentric analysis of Ablation Index

- Unblinding of the Ablation Index in CF/FTI guided ablation revealed a wide variation in reached AI values
- The marked consistency across the 4 centres allows to prespecify region-specific targets for AI-guided ablation
- This suggested a potential incremental benefit of on top of CF/FTI-guided ablation

Phase 2: Late PV reconnection and AI PRESSURE study

- Prospective Trial: 80 patients with PAF
- Randomised to mandatory repeat EP procedure at 2 months, or routine management
  - All Antiarrhythmic drugs stopped at 4 weeks
  - Daily ECG recordings for 12 months

NCT01942408, Funded by BSW grant, IIS-239

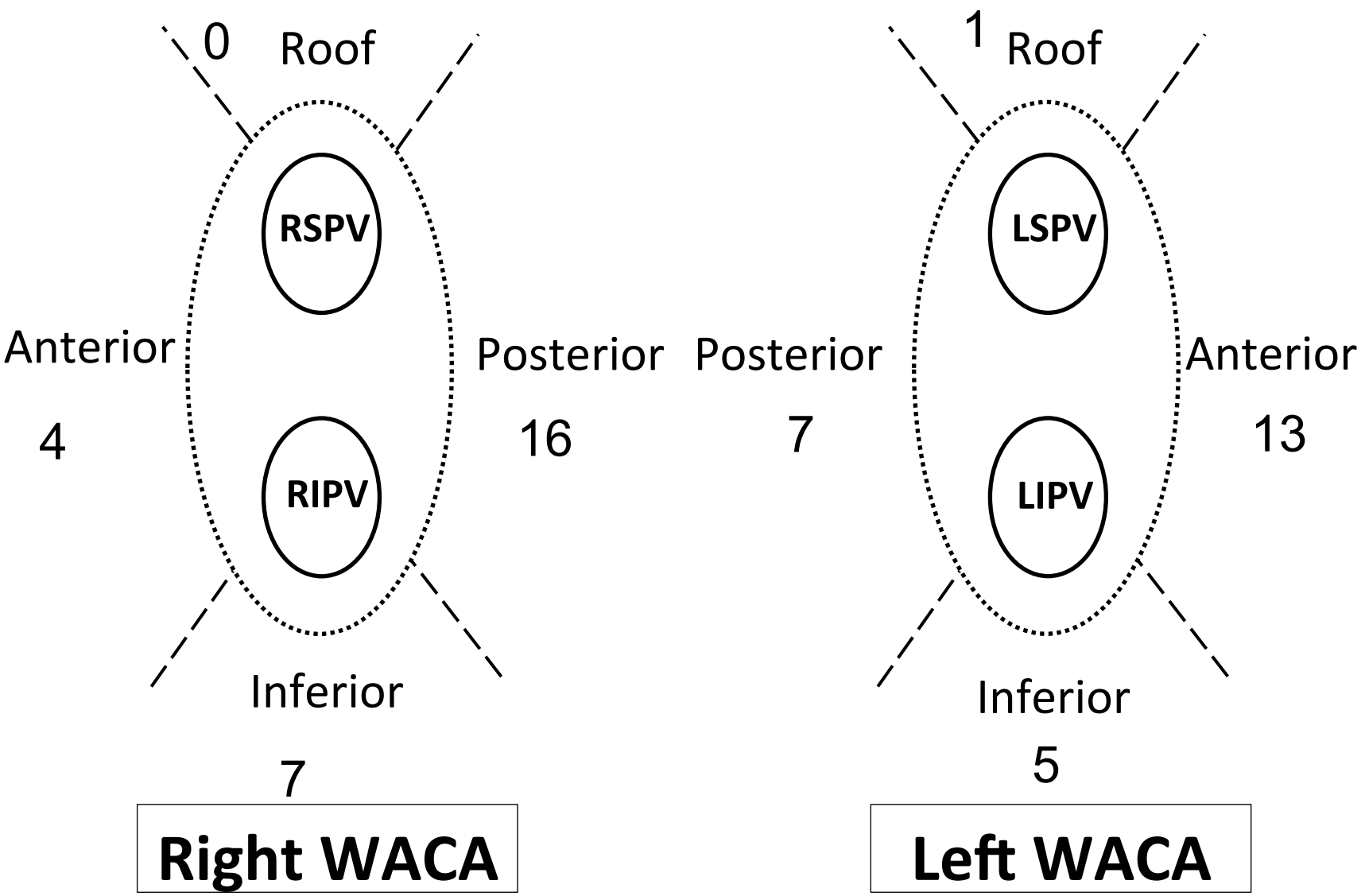

Right WACA
Roof
Anterior
RSPV
Posterior
Anterior
RIPV
Posterior
Inferior
Left WACA
Roof
Posterior
LSPV
Anterior
Posterior
LIPV
Anterior
Inferior

Enduring PV isolation

	EFFICAS I (n=40/46)	EFFICAS II (n=24/26)	PRESSURE (n=40/40)
Ablation Tools	Endosense/ Ensite	Endosense/ Ensite	Smartouch/ Carto
Technique	Blinded to CF	CF & FTI target	CF and Visitag guided
Late RC			
Patients	26/40 (65%)	9/24 (38%)	25/40(62%)
Circles	39/80 (49%)	12/48 (24%)	30/80 (38%)
Veins	44/160(28%)	14/91 (15%)	40/160 (25%)
Segments	52/318 (16%)	14/192 (7.2%)	53/480 (11%)

EFFICAS I: P Neuzil et al. Circ Arrhythm Electrophysiol 2013;6:327–33
EFFICAS II: J Kautzner et al, Europace 2015;17:1229-35
PRESSURE: M Das et al, Circ Arrhythm Electrophysiol 2015 (in press)

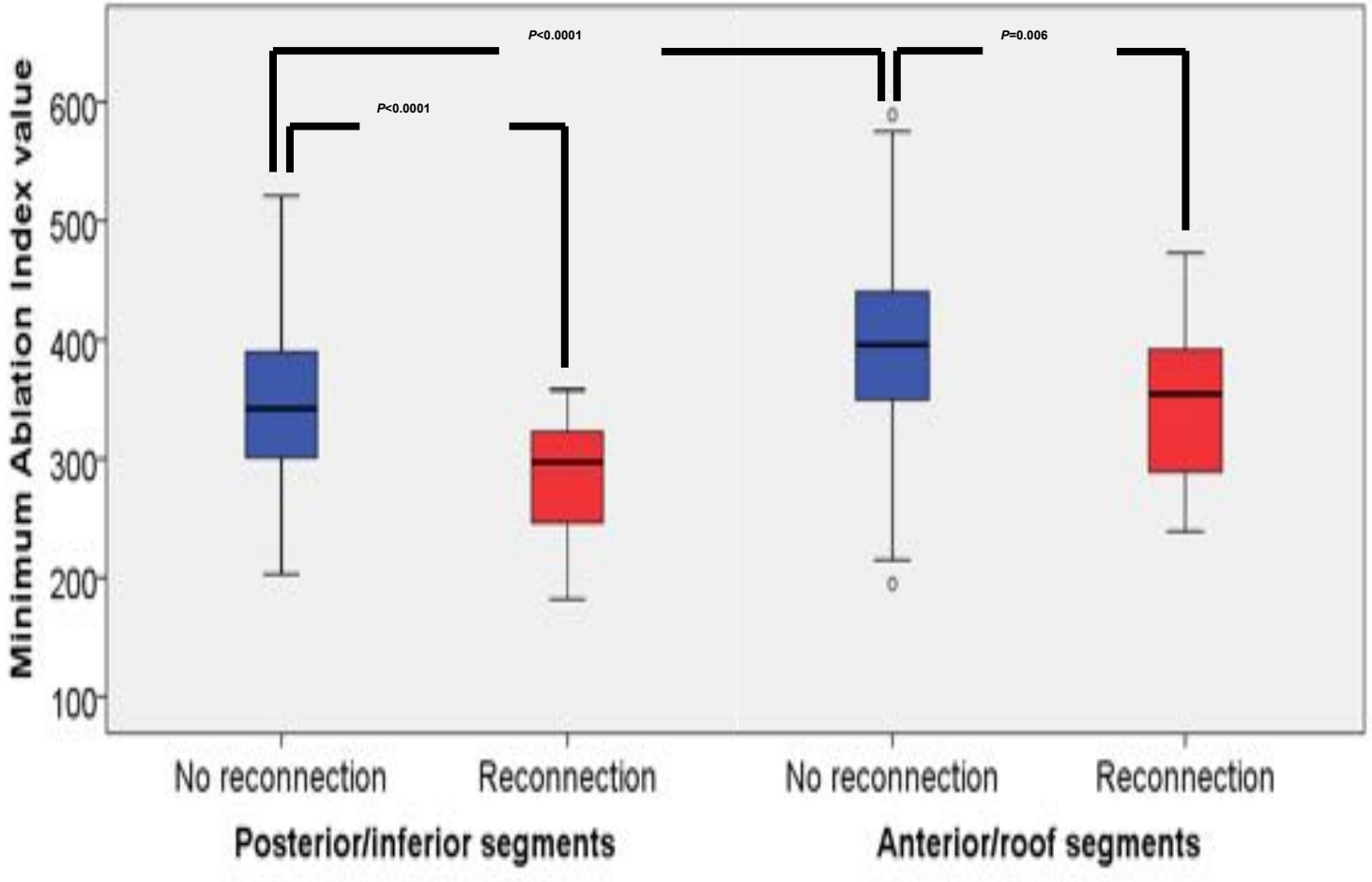
Distribution of reconnected segments



	Ablation Index value		Force Time Integral (gsecs)	
	Non-reconnected	Reconnected	Non-reconnected	Reconnected
Roof	402 (346-441)	294*	298 (197-363)	92*
Anterior	410 (358-452)	342 (290-395)	268 (181-375)	185 (92-271)
Posterior	344 (303-394)	295 (250-330)	203 (140-286)	127 (91-169)
Inferior	349 (296-384)	301 (236-322)	179 (126-263)	126 (80-162)

Univariable regression analysis: both minimum AI and minimum FTI predictive of reconnection ($P<0.0001$)

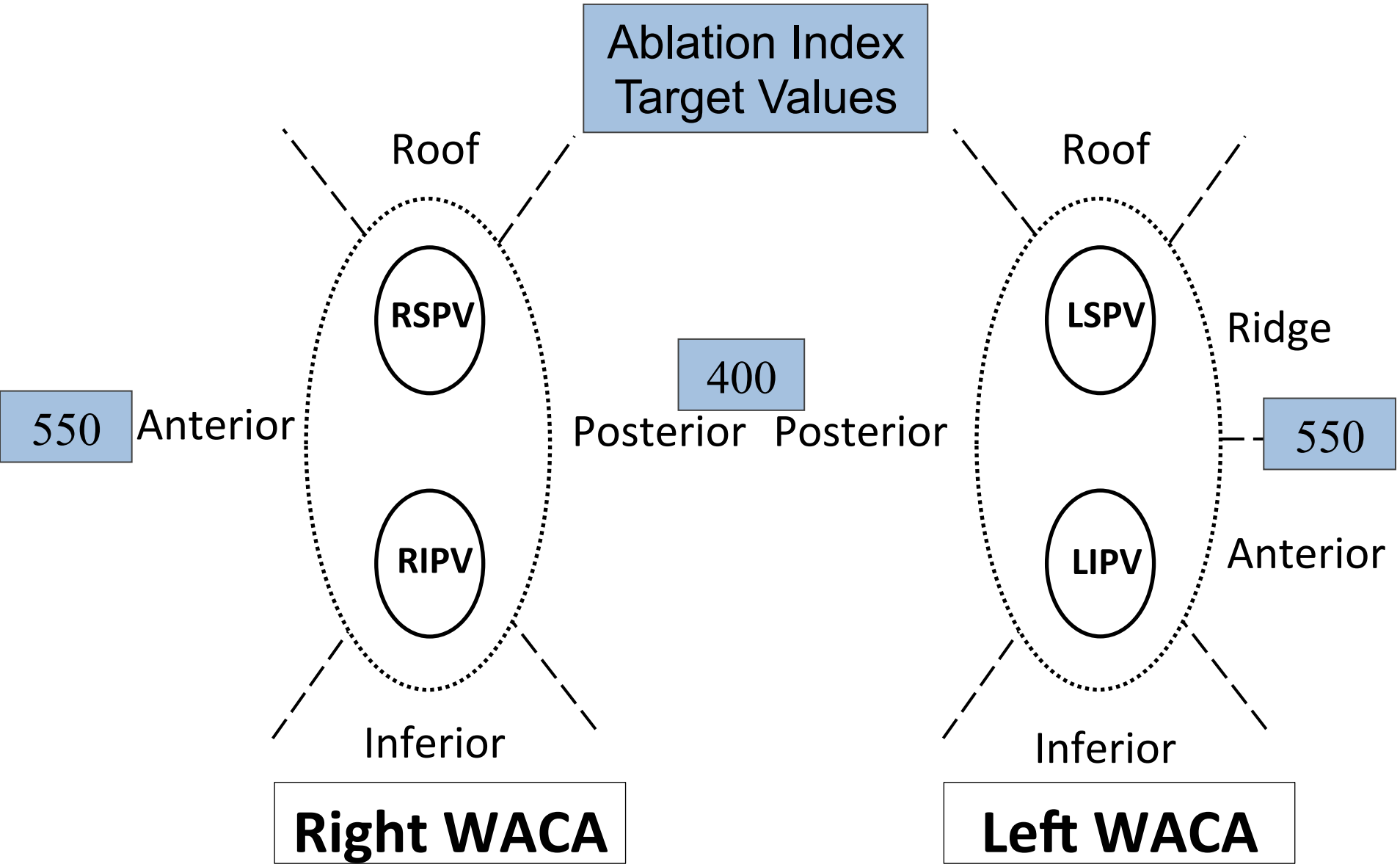
Multivariable model: Only minimum AI independently predictive ($P=0.019$) whereas minimum FTI was not ($P=0.193$)



The 100% PPV AI_{min} thresholds associated with no late RC

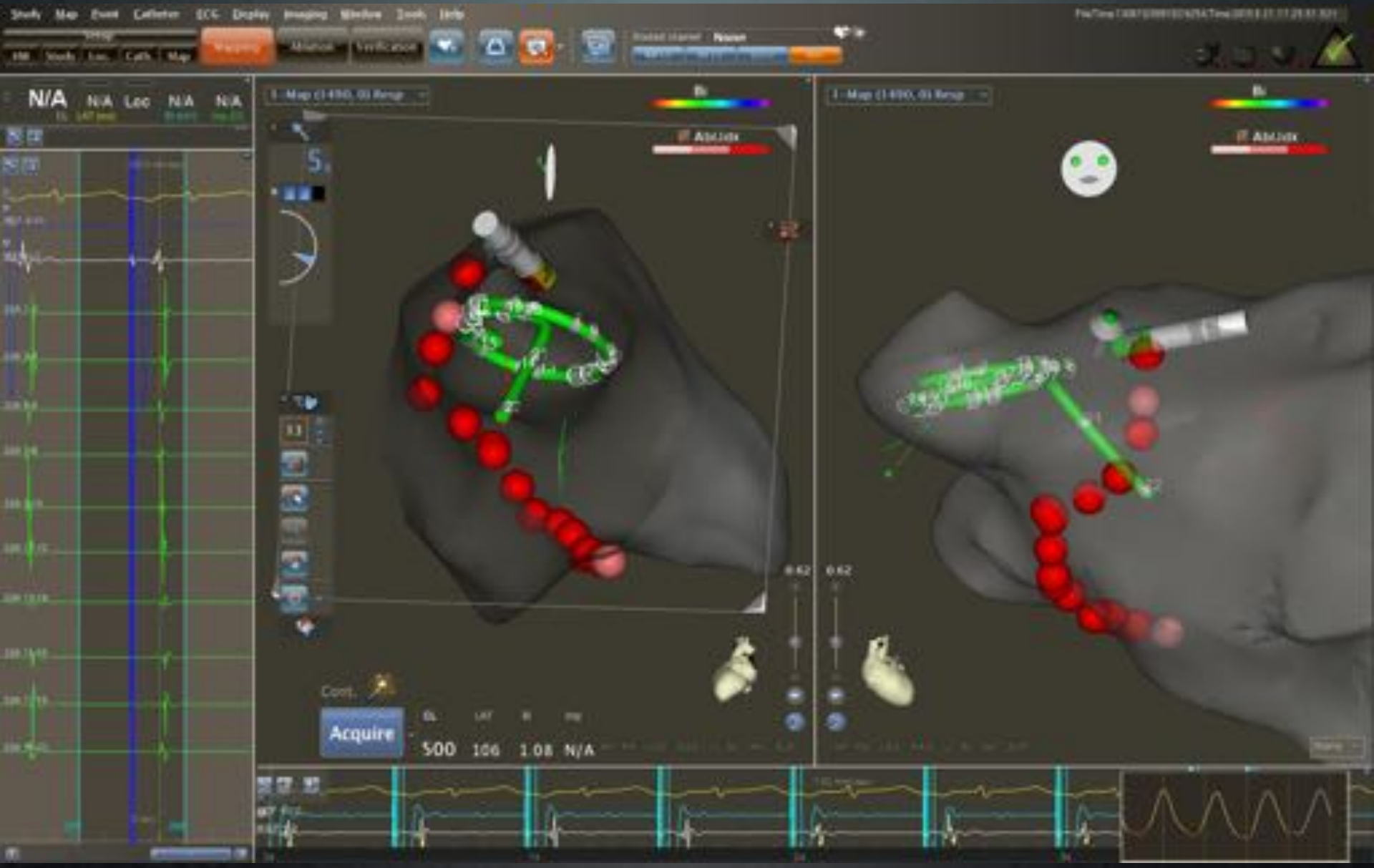
- 370 for posterior/inferior segments
- 480 for anterior/ridge/roof segments

Phase 3: Ablation Index guided ablation



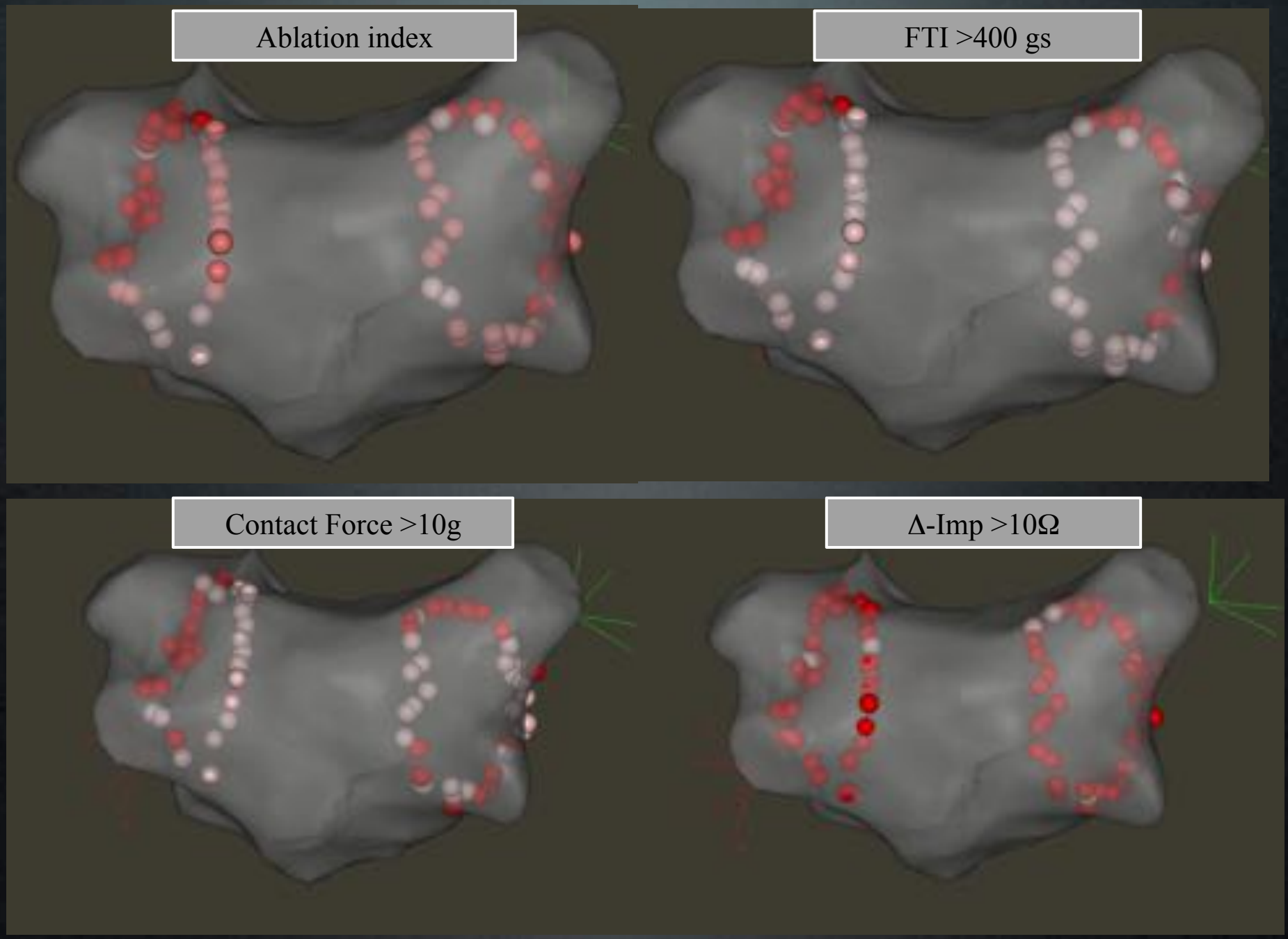
AI guided Ablation Protocol

- Lasso guided PbP-PVI, Adenosine and >20’ waiting
- Smarttouch Thermocool® and Visitag™ with Ablation Index
  - Catheter Position Stability: 8 sec, 3 mm
  - Force over Time: >3g, >30%
- Target CF 10-40g, Target Power 35-40 W
- Contiguous and continuous lesions
- Ablation Index target of 400 on Post Wall, 550 on Ant Wall
- If incomplete lesion (pink tag), cover if due to dislocation


Study Map Event Catheter ECG Display Imaging Window Tools Help
Mapping Ablation Verification
N/A N/A Loc N/A N/A
Acquire
500 106 1.08 N/A

Phase 3: Ablation Index guided ablation

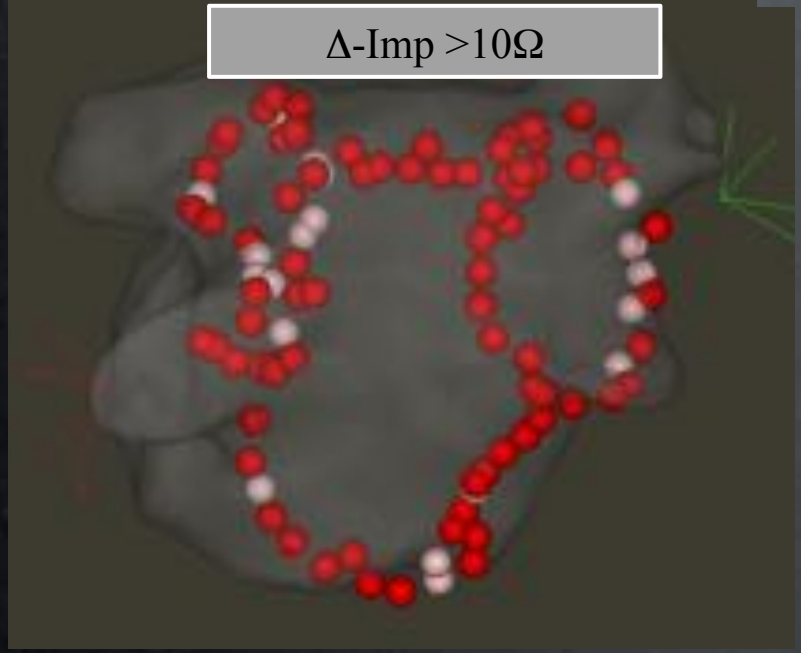
Contiguity along the circles


Ablation index
FTI >400 gs
Contact Force >10g
Δ-Imp >10Ω

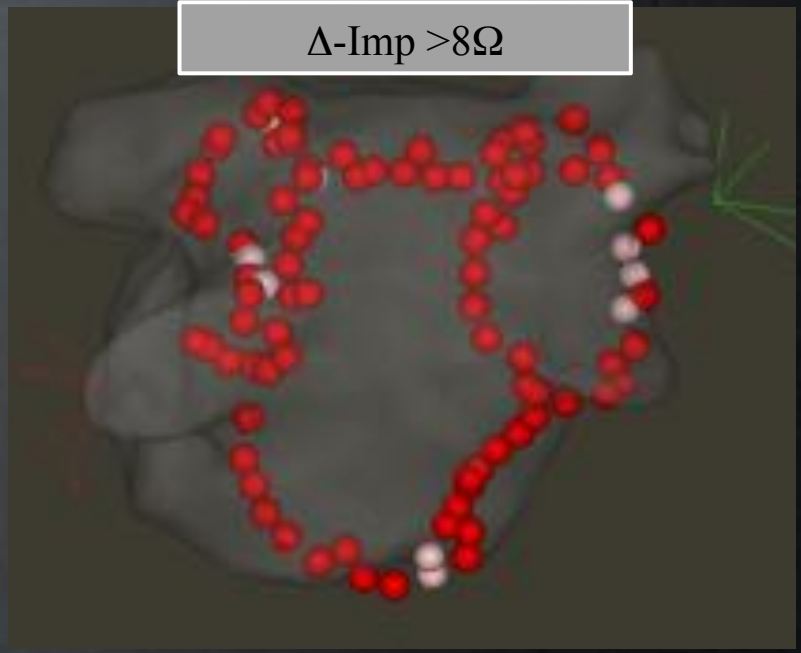
Ablation index

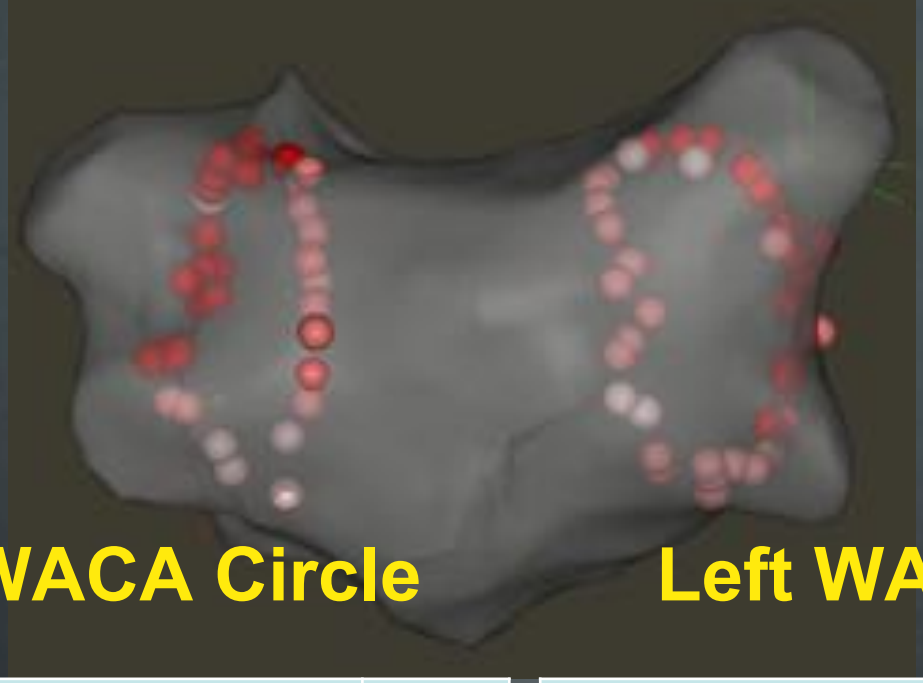
FTI >400 gs

Δ-Imp >10Ω



Δ-Imp >8Ω





Right WACA Circle

RF time, s	966
Applications, n	39
Mean duration of applications, s	24
Isolation after First Pass	Yes
Reconnection with Adenosine and 20’ wait	No

Left WACA Circle

RF time, s	1159
Applications, n	40
Mean duration of applications, s	29
Isolation after First Pass	Yes
Reconnection with Adenosine and 20’ wait	No

Phase 3: Ablation Index guided ablation

Comparative data

Parameters	CF/FTI (n=50)	Abl' Ind (n=50)	
Procedure time, min	194±42	143±17	p<0.0001
Ispilateral encirclement			
RF time, min	27.7±7.4	17.8±3.8	p<0.0001
Isolation after 1st circle, n	55/100 (55%)	98/100 (98%)	p<0.0001
Isolation proof to adeno/waiting, n	76/100 (76%)	97/100 (97%)	p<0.01
Complications			
Stroke/TIA	0/50 (0%)	0/50 (0%)	
Tamponade	1/50 (2%)	0/50 (0%)	
FU at 6 months without blanking			
Free of Afib, n (%)	40/50 (80%)	48/50 (96%)	p<0.0001
N of repeats, n (%)	7 (14%)	2 (4%)	

Slide courtesy of Prof M Duytschaever, Bruges

Phase 3: **P**ulmonary vein **R**econnection following **A**blation **I**ndex-guided ablation: a **S**uccess **E**valuation (**PRAISE**)

- Prospective cohort study in 50 patients with continuous Persistent AF
  - Liverpool Heart and Chest Hospital, Liverpool, UK (n=40)
  - Centro Cardiologico Monzino, Milan, Italy (n=10)
- Initial PVI procedure will be performed guided by AI targets of 550 for the roof and anterior wall, and 400 for the posterior and inferior walls
- All patients (regardless of AF recurrence) will undergo a repeat EP study at 3 months to identify and re-ablate PV reconnection
- Funded by Biosense Webster (IIS-386)

Summary

- Ablation Index guided PVI is feasible and reproducible
- Shortens RF time and procedure time, and virtually eliminates acute PV reconnection
- Makes procedure times more consistent and predictable
- Effect on long-term lesion durability and clinical efficacy needs to be proven