PLACE

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

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30 Settembre
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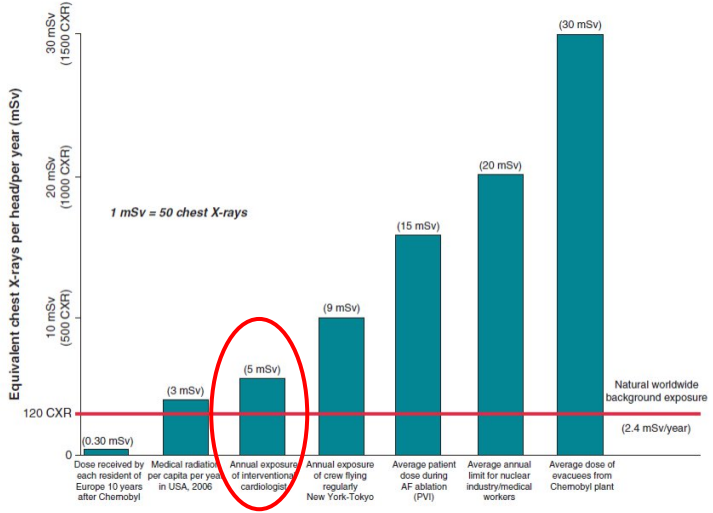
# IL RUOLO DEL MAPPAGGIO E DELL'IMAGING NELL'ABLAZIONE: DALLA RIDUZIONE DELLA FLUOROSCOPIA AD UN'ABLAZIONE 4D

## Come l'integrazione di Mappaggio 3D ad alta definizione, eco intracardiaco e introduttore visualizzabile riducono l'esposizione fluoroscopica nell'ablazione?

**Francesco Notaristefano**
**Perugia**

# No disclosures

# Radiation exposure during interventional EP procedures




| | Effective dose (mSv) | Equivalent CXRs | Background radiation (years) |
|---|---|---|---|
| **Cardiac electrophysiology** | | | |
| Diagnostic EP studies | 3.2 (1.3–23.9) | 160 | 1.2 |
| Ablation procedure: | 15.2 (1.6–59.6) | 760 | 5.7 |
| AF | 16.6 (6.6–59.2) | 830 | 6.9 |
| AT-AVNRT-AVRT | 4.4 (1.6–25) | 220 | 1.8 |
| VT | 12.5 (3 to ≥45) | 625 | 5.2 |
| Regular PM or ICD implant | 4 (1.4–17) | 200 | 1.6 |
| CRT implant | 22 (2.2–95) | 1100 | 9.1 |
| **CT** | | | |
| 64-slice coronary CTA | 15 (3–32) | 750 (150–1600) | 6.25 |
| Calcium score | 3 (1–12) | 150 | 1.25 |

Heidbuchel et al. Europace 2014

# Radiation exposure during interventional procedures induces chromosomal abnormalities

1. Monozygotic twins
2. 37 years old healthy males
3. Same lifestyle (including smoking, alchol and infancy infectious disease)
4. 1-lawyer
5. 2-interventional cardiologist with 10 years of professional exposure
6. Cytogenetic biodosimetry should be added to physical dosimetry

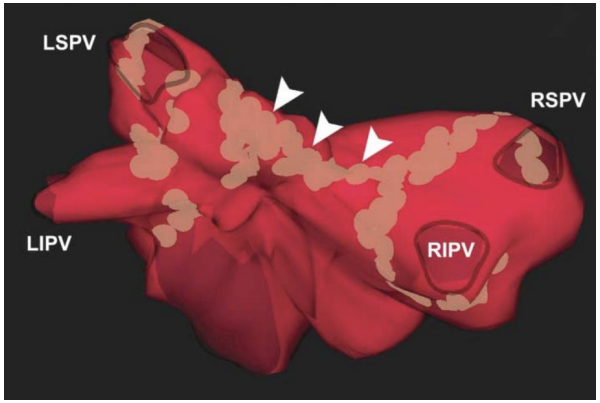
A)

B)

| Chromosomal alterations | Twin 1 (unexposed) | Twin 2 (exposed) |
|---|---|---|
| Chromatid breaks | 5 | 3 |
| Chromosome breaks | 1 | 7 |
| Acentric Fragments | / | 2 |
| Exchanges (quadriradial) | / | 1 |
| Dicentric chomosome | / | 3 |
| Total aberrant cells/500 | 6 | 16 |
| Frequency (%) | 1.2 | 3.2 |

Andreassi MG et al Int J Cardiol 2007

# Radiation exposure reduction with non-fluoroscopic mapping systems



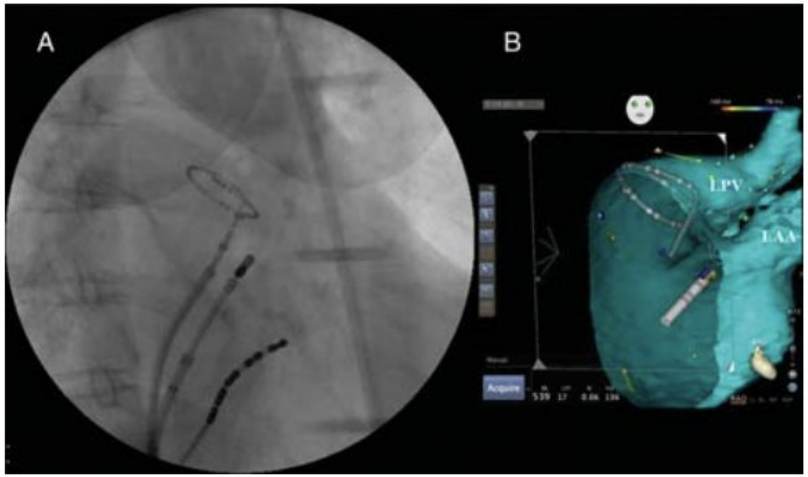

- Randomized controlled trial
- 72 patients
- NAVx mapping system
- PVI (roof line in persistent or AF inducible after PVI)

| | | Study group ($n = 35$) | Control group ($n = 37$) | *P*-value |
|---|---|---|---|---|
| Geometry | Fluoroscopy | 3.9 ± 1.2 | – | |
| | Procedure duration | 8.2 ± 2.1 | – | |
| PV isolation including time for geometry | Fluoroscopy | 15.4 ± 3.4 | 21.3 ± 6.4 | <0.001 |
| | Procedure time | 52 ± 12 | 61 ± 17 | 0.02 |
| | RF time | 33 ± 8 | 35 ± 11 | 0.3 |
| | | ($n = 18$) | ($n = 21$) | |
| Roofline | Fluoroscopy | 5.6 ± 2.2 | 9.9 ± 4.8 | 0.003 |
| | Procedure time | 14.7 ± 5.5 | 26.6 ± 16.9 | 0.007 |
| | RF time | 10.2 ± 4.5 | 12.8 ± 5.9 | 0.2 |

Non fluoroscopic 3-D mapping system reduced fluoroscopy and procedure time compared to fluoroscpy alone.

Rotter M et al Eur Heart J 2005

# Radiation exposure reduction with non-fluoroscopic mapping systems

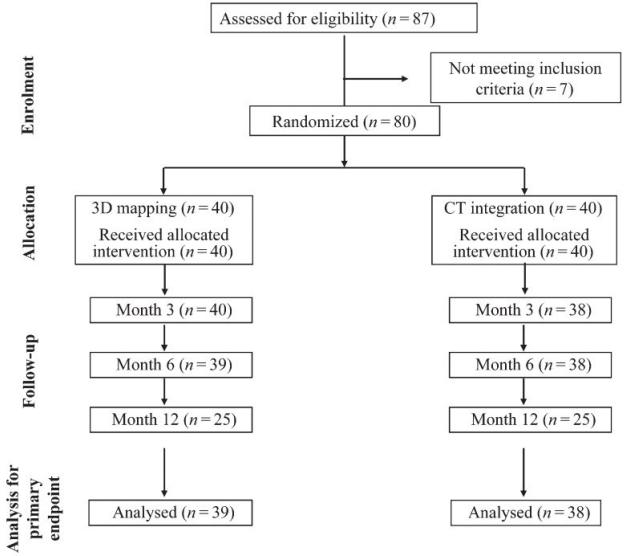



| Centre (patients enrolled) | Group A (CARTO® 3 system) (min) | Group B (CARTO® XP system) (min) | *P* | Δ (%) |
|---|---|---|---|---|
| 1 (36) | 15.06 ± 5 | 34 ± 7.68 | <0.001 | −56 |
| 2 (60) | 2.48 ± 1.17 | 10.12 ± 3.74 | <0.001 | −75 |
| 3 (30) | 12.47 ± 8.76 | 20.51 ± 10.69 | 0.03 | −39 |
| 4 (31) | 27.13 ± 10.11 | 39.88 ± 9.11 | <0.001 | −32 |
| 5 (33) | 30.98 ± 10.48 | 41.06 ± 13.96 | 0.03 | −25 |
| 6 (50) | 17.08 ± 9.54 | 24.56 ± 12.44 | 0.02 | −30 |
| Overall | 15.9 ± 12.3 | 26 ± 15.1 | <0.001 | −39 |

Real-time visualization of both mapping and ablation catheter
Significantly reduced the fluoroscopy time

Stabile G. et al Europace 2012

# Image integration, radiation exposure and AF ablation success



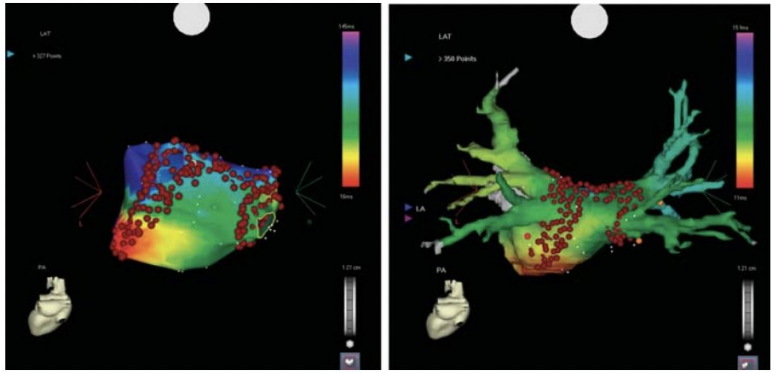

| | EAM (n = 40) | CT integration (n = 39) | P-value |
|---|---|---|---|
| PV electrical isolation | | | |
| RPVs | 92% | 97% | 0.6 |
| LPVs | 100% | 100% | >0.99 |
| Procedure duration (min) | 225 ± 56 | 232 ± 65 | 0.6 |
| Skin to double LA access (min) | 26 ± 12 | 26 ± 11 | >0.99 |
| Registration (min) | 28 ± 14 | 24 ± 13 | 0.2 |
| RPV electrical isolation (min) | 57 ± 24 | 66 ± 35 | 0.2 |
| LPV electrical isolation (min) | 46 ± 25 | 49 ± 18 | 0.5 |
| Fluoroscopy time | | | |
| Total (min) | 57 ± 23 | 53 ± 18 | 0.4 |
| For PVI | 52 ± 21 | 43 ± 22 | 0.1 |
| PV reconnection (% patients) | 14 (35%) | 10 (26%) | 0.5 |

| | EAM (n = 39) | CT integration (n = 38) | P-value |
|---|---|---|---|
| Single procedure success at 6 month Holter (total) | 22/39 (56%) | 19/38 (50%) | 0.65 |
| Recurrent AT/AF during 12 month follow-up | 20/39 (51%) | 22/38 (58%) | 0.65 |
| Second procedure | 14/39 (36%) | 16/38 (42%) | 0.64 |
| Rhythm at second procedure | | | |
| Atrial tachycardia | 2 | 6 | 0.23 |
| Atrial fibrillation | 12 | 10 | 0.23 |
| PV reconnection | 100% | 100% | >0.99 |
| 1–2 PVs | 6 (43%) | 11 (69%) | 0.27 |
| 3–4 PVs | 8 (57%) | 5 (31%) | 0.27 |
| Long-term success | 30/39 (77%) | 27/38 (71%) | 0.61 |
| Follow-up (weeks) | 59 ± 11 | 59 ± 13 | >0.99 |

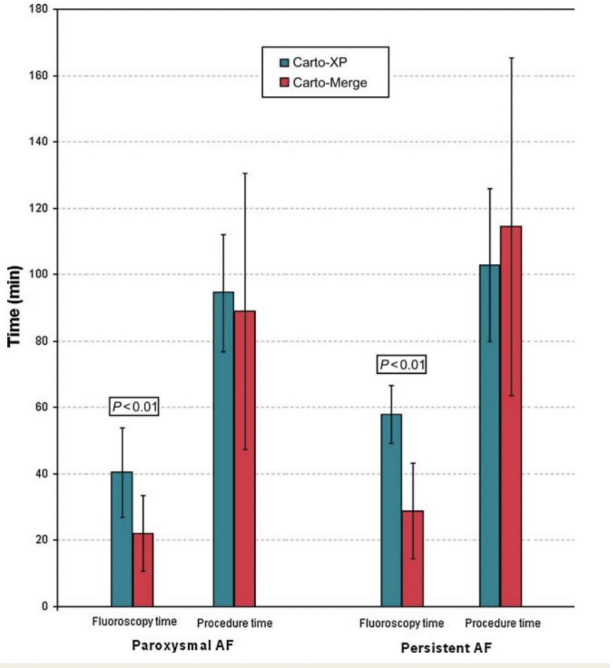
CT integration did not reduce procedure time, fluoroscopy time and long term success

Kistler PM et al Eur Heart J 2008

# Image integration, radiation exposure and AF ablation success



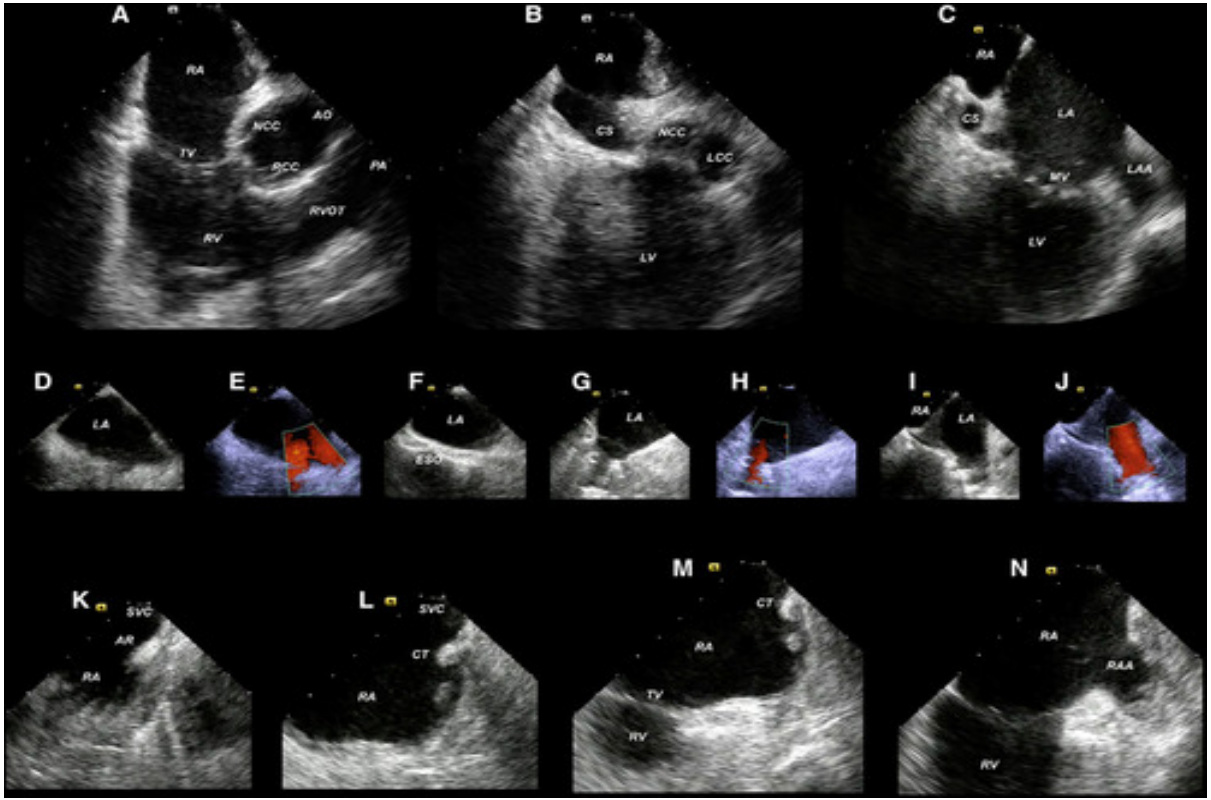
| | | | Carto-XP | Carto-Merge | P-value |
|---|---|---|---|---|---|
| Skin to catheter positioning | | Time | 13′30″ ± 2′ | 14′30″ ± 1′30″ | n.s. |
| | | Fluoroscopy | 2′40″ ± 35″ | 2′30″ ± 35″ | n.s. |
| LA electroanatomic mapping | | Time | 26′30″ ± 3′ | 19′ ± 7′ | <0.01 |
| | | Fluoroscopy | 11′ ± 2′ | 2′ ± 35″ | <0.01 |
| Ablation | | Time | 60′ ± 16′ | 65′ ± 29′ | n.s. |
| | | Fluoroscopy | 28′ ± 5′ | 15′30″ ± 10′ | <0.01 |
| Fluoroscopy time | Paroxysmal AF | CVT isthmus | 6′ ± 1′ | 6′20″ ± 30″ | n.s. |
| | | LA ablation | 34′ ± 40″ | 15′10″ ± 10″ | <0.01 |
| | Persistent AF | CVT isthmus | 7′30″ ± 2′ | 7′ ± 1′30″ | n.s. |
| | | LA ablation | 50′ ± 1′30″ | 21′ ± 3′ | <0.01 |




Neither procedure time nor AF recurrences were affected by MR integration but MR merge significantly shortened fluoroscopy time

Caponi D et al Europace 2010

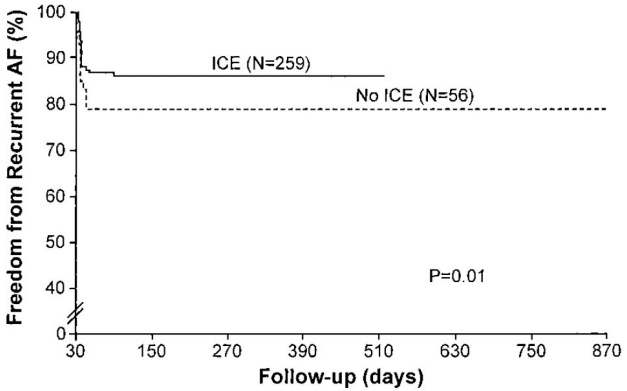
# Intra-cardiac echo (ICE)



# Early days of AF ablation: ICE

315 patients

1. PV angiography and circular mapping catheter
2. ICE
3. ICE + power titration according to micro-bubbles




| | No ICE, Group 1 (n=56) | ICE Without Bubbles, Group 2 (n=107) | ICE With Bubbles, Group 3 (n=152) |
|---|---|---|---|
| No. isolated PVs, RUPV/RLPV/LUPV/LLPV | 56/50/56/49 | 107/97/107/94 | 152/142/152/140 |
| AAD | 3±0.7 | 3.6±1.1 | 2.6±1.3 |
| Fluoroscopy time, min | 81±29 | 60±20* | 59±21* |
| Procedure time, min | 250±66 | 190±48* | 185±65* |
| Mean No. RF lesions/PV (min) | 14±2 (10.5±4) | 10±3 (7.5±2.2) | 8.5±2 (6.2±1.5)* |
| Follow-up, days | 639±79 | 437±46 | 288±67 |
| Recurrence of AF | 19.6% (11 of 56) | 16.8% (18 of 107) | 9.8% (15 of 152)† |
| Moderate PV stenosis/PV | 5% (11 of 211) | 4.5% (18 of 405) | 2.5% (12 of 586) |
| Moderate PV stenosis/patient | 9% (5 of 56) | 6.5% (7 of 107) | 4% (5 of 152)‡ |
| Severe PV stenosis/PV | 3% (6 of 211) | 1% (4 of 405) | None‡ |
| Severe PV stenosis/patient | 3.5% (3 of 56) | 1.8% (2 of 107) | None‡ |
| Embolic events including TIA§ | 3.5% (2 of 56) | 3% (3 of 107) | None‡ |

ICE icreased AF ablationsafety and efficacy

NO mapping system, contact force and lesion formation indexes!

Marrouche N et al Circ 2003

# ICE and 3D mapping system

60 AF patients randomized

1. 3D mapping + MRI
2. 3D mapping + ICE
3. 3D mapping + ICE + MRI

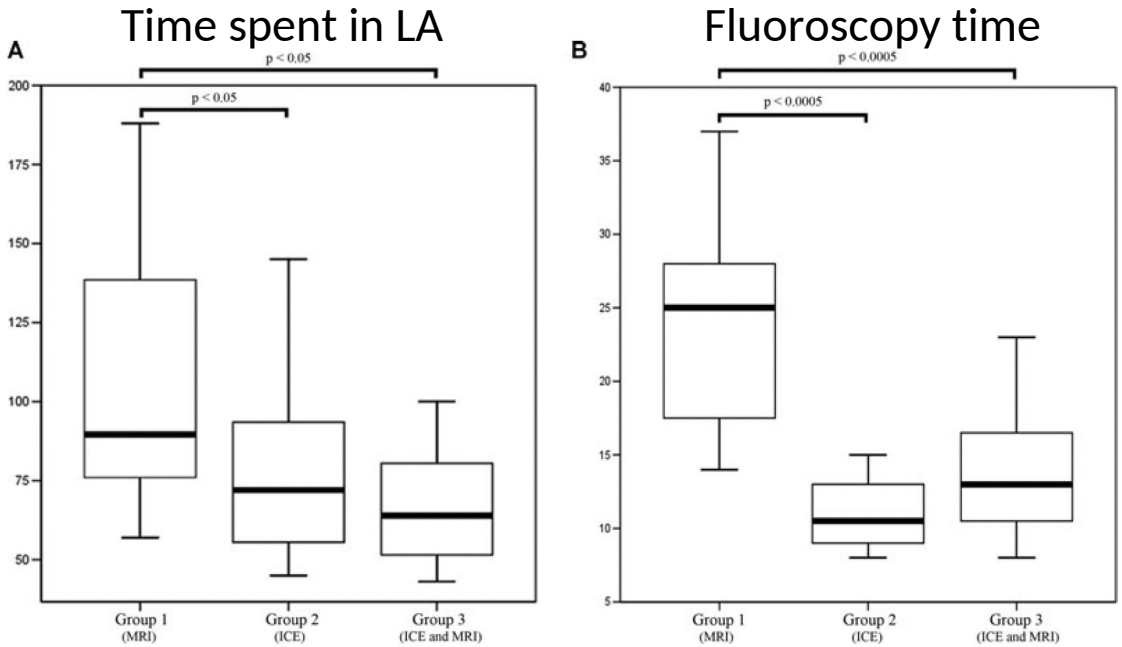



Image integration with ICE significantly shortened the LA dwelling time and significantly reduced fluoroscpy time.

MR integration with or without ICE did not seem to add significant benefit

Pratola C et al PACE 2011

# ICE for arrhythmia ablation: effectiveness and safety: Meta-Analysis

| Outcome of interest | Main analysis (all arrhythmia types) | | Sensitivity analysis (AF only) | |
|---|---|---|---|---|
| | Estimate[a] | *P*-value | Estimate[a] | *P*-value |
| Fluoroscopy time (Hedges' *g*) | −1.06 | <.01 | −1.25 | <.01 |
| Fluoroscopy time (MD, min) | −6.95 | <.01 | −8.12 | <.01 |
| Fluoroscopy dose (Hedges' *g*) | −1.27 | <.01 | −1.32 | <.01 |
| Procedure time (Hedges' *g*) | −0.35 | .02 | −0.43 | <.01 |
| Procedure time (MD, min) | −15.2 | <.01 | −17.96 | <.01 |
| Acute success (RR)[b] | 1.01 | .43 | 1.00 | .86 |
| Peri-procedural complications, excluding venous access (RR)[b] | 0.66 | .08 | 0.71 | .24 |
| Venous access complications (RR)[b] | 1.93 | .14 | 3.26 | .21 |
| Freedom from arrhythmia (RR) | 1.04 | .24 | *Same – all studies in AF* | |

ICE during endocardial ablation shortened procedure and fluoroscopy time without affecting the effectiveness

Goya M et al J Cardiov Electr 2020

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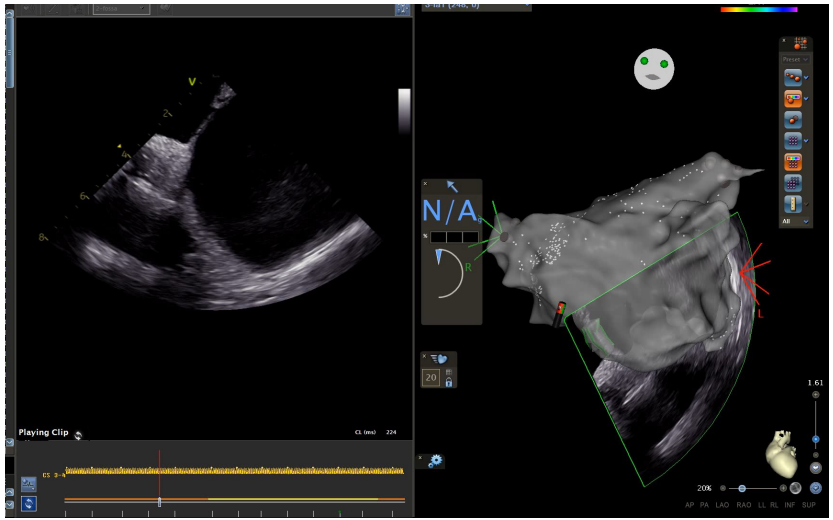
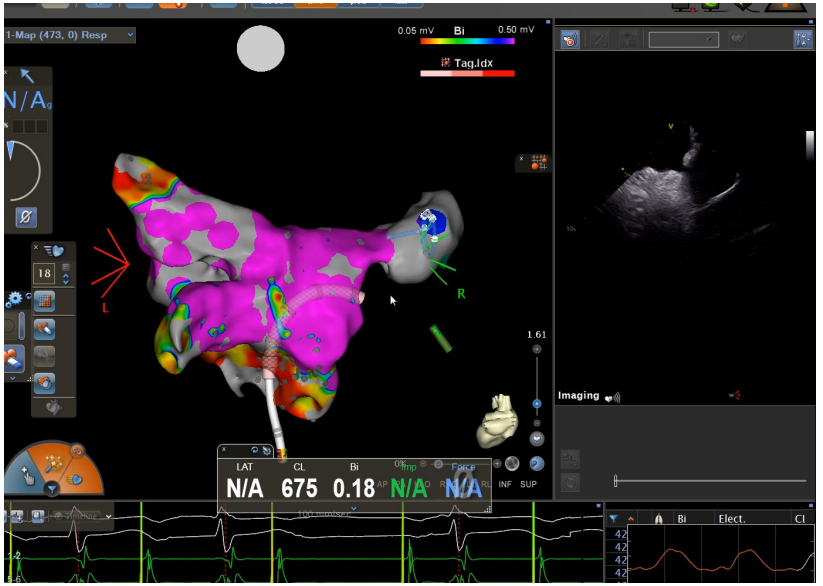
# Transeptal Puncture





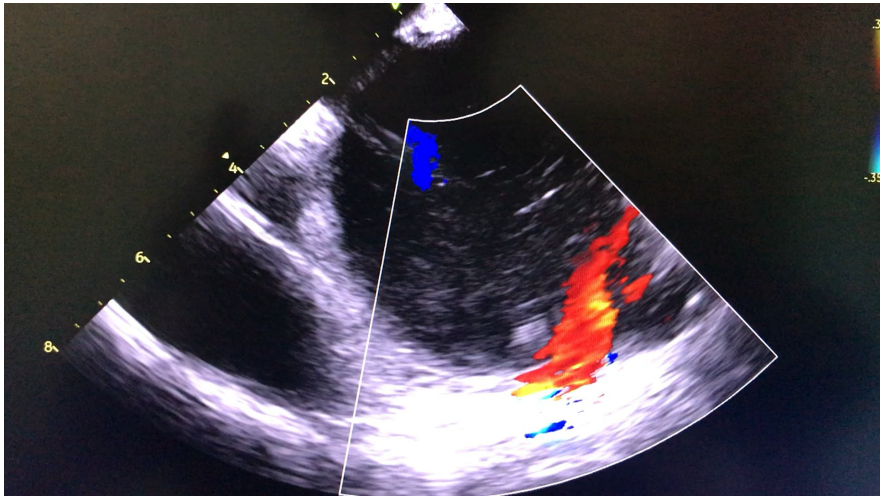
# LA mapping


Non fluoroscopic steerable sheath

# Anatomical landmarks: esophagus and aorta

# Left PV mapping



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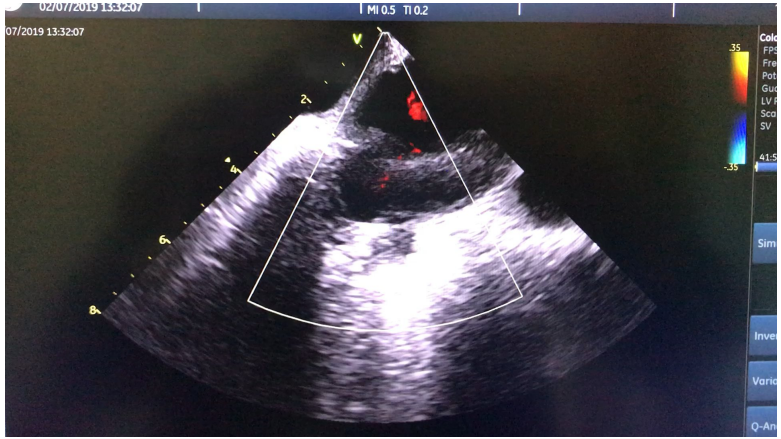
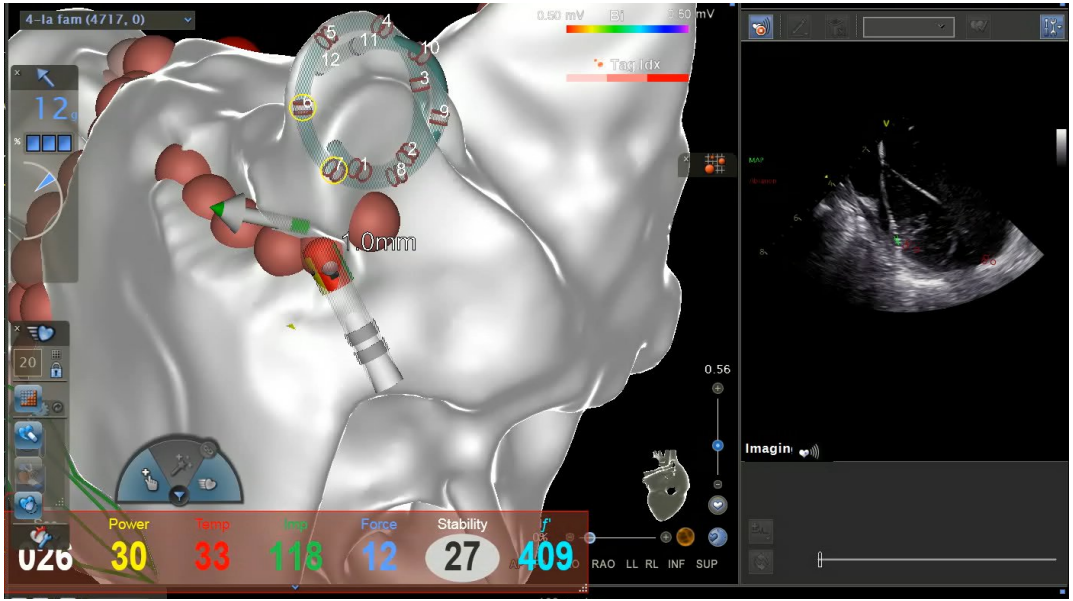
# Right inferior PV mapping and ablation



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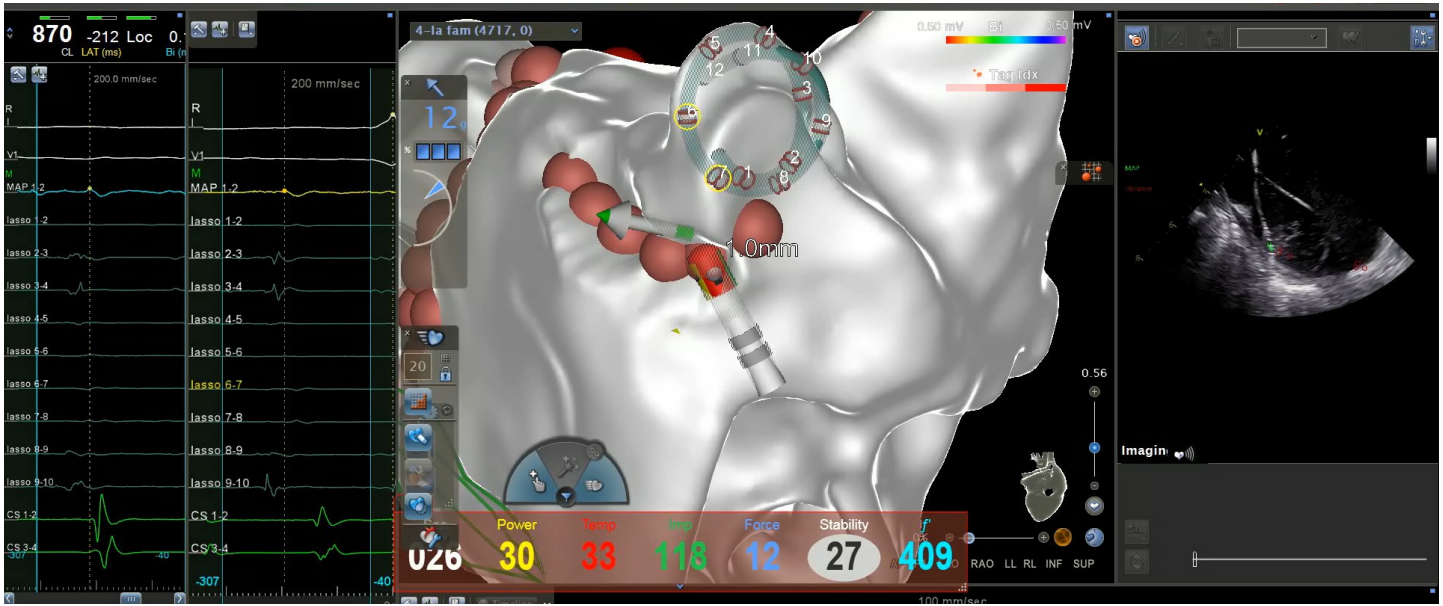
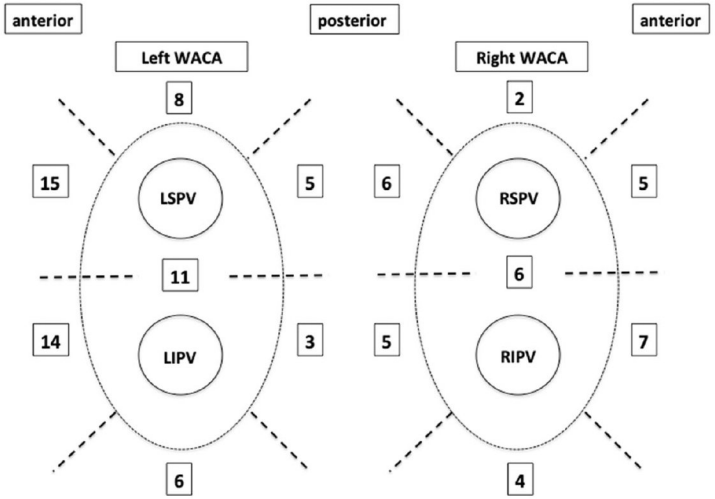
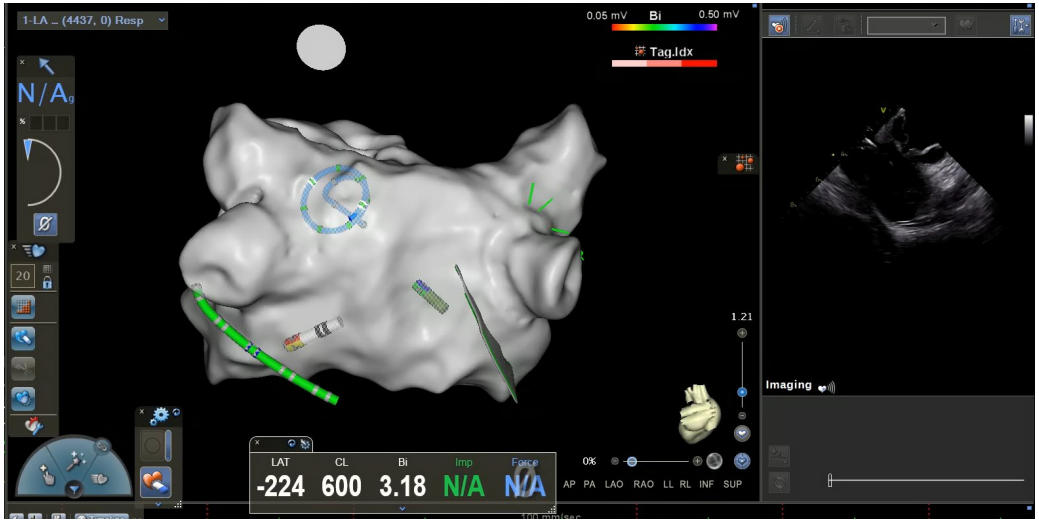
# Right inferior PV mapping and ablation



# ICE to improve anatomical definition during mapping
## Common re-connection sites




Reinsch N J Int Card Electr 2020

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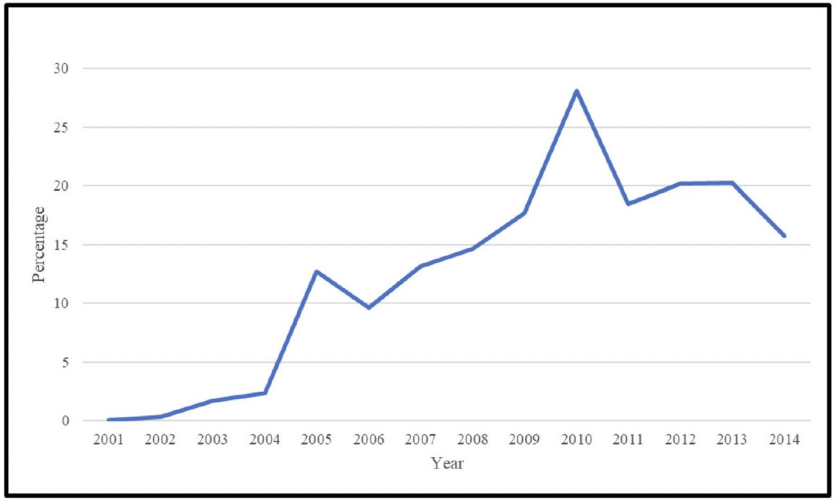
# ICE: outcomes and cost for AF ablation

US data set 2001-2014
299.152 ablations (15.6% with ICE)

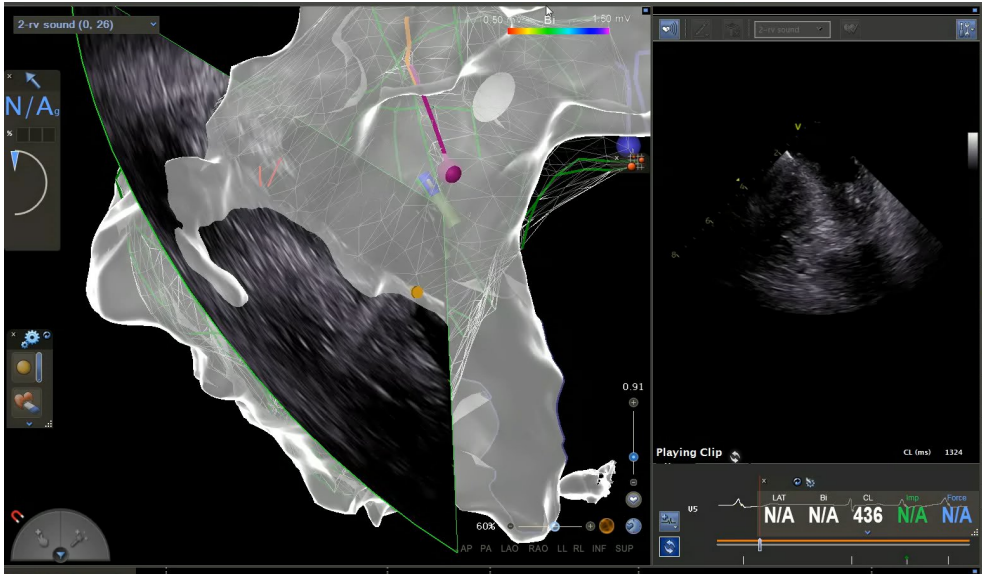



| Clinical outcomes | ICE | | *p* value[1] | HR (95% CI) | *p* value[2] |
|---|---|---|---|---|---|
| | Yes | No | | | |
| In-patient death | 0.11% | 0.54% | < 0.0001 | 0.72(0.71–0.73) | < 0.0001 |
| Any procedural complications | 9.35% | 10.41% | 0.2015 | 0.48(0.44–0.51) | < 0.0001 |
| Vascular complications | 5.64% | 5.03% | 0.3287 | 0.79(0.78–1.4) | 0.2531 |
| • Postop hemorrhage | 4.81% | 4.33% | 0.4019 | 0.38(0.34–1.1) | 0.5934 |
| • Postop hemorrhage requiring transfusion | 0.87% | 1.14% | 0.0772 | 0.36(0.28–0.47) | < 0.0001 |
| • Vascular complications requiring surgery | 0.24% | 0.29% | 0.4348 | 0.32(0.20–0.52) | < 0.0001 |
| • Other vascular complications | 0.73% | 1.01% | 0.015 | 0.32(0.25–0.41) | < 0.0001 |
| Cardiac complications | 3.67% | 4.51% | 0.025 | 0.51(0.45–0.58) | < 0.0001 |
| • Iatrogenic cardiac complications | 1.92% | 1.66% | 0.2186 | 0.42(0.35–0.49) | < 0.0001 |
| • Pericardial complications | 1.41% | 2.45% | < 0.0001 | 0.32(0.27–0.37) | < 0.0001 |
| • Requiring open heart surgery | 0.21% | 2.02% | < 0.0001 | 0.40(0.26–0.63) | < 0.0001 |
| Respiratory complications | 0.47% | 1.0% | < 0.0001 | 0.65(0.47–0.91) | 0.0105 |
| • Pneumothorax | 0.08% | 0.22% | 0.0075 | 0.82(0.39–1.7) | 0.6004 |
| • Hemothorax | 0.07% | 0.19% | 0.0084 | 0.61(0.27–1.4) | 0.2395 |
| • Other iatrogenic respiratory complications | 0.25% | 0.41% | 0.0223 | 0.63(0.39–0.99) | 0.0477 |
| • Chest tube insertion | 0.16% | 0.34% | 0.0059 | 0.49(0.29–0.86) | 0.0128 |
| Neurological complications (stroke/TIA) | 0.90% | 1.84% | < 0.0001 | 0.78(0.62–0.98) | 0.0311 |

ICE reduced mortality and in hospital complications
The higher cost was offset by the shorter lenght of hospitalization

Isath A et al J interv card electr 2020

# ICE: complications

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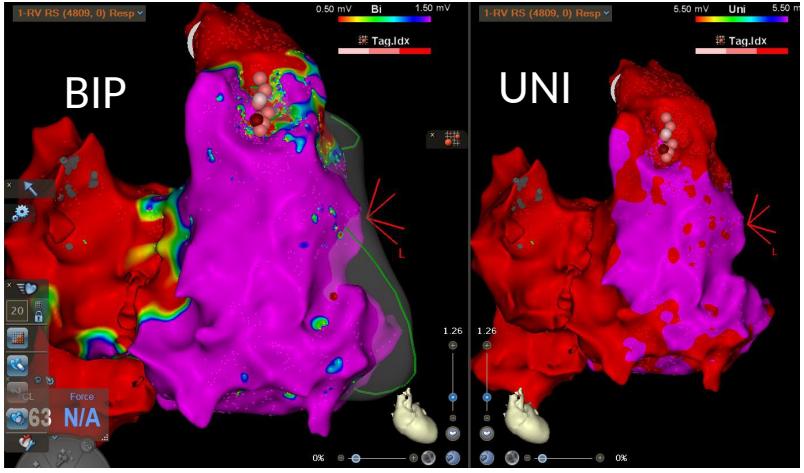
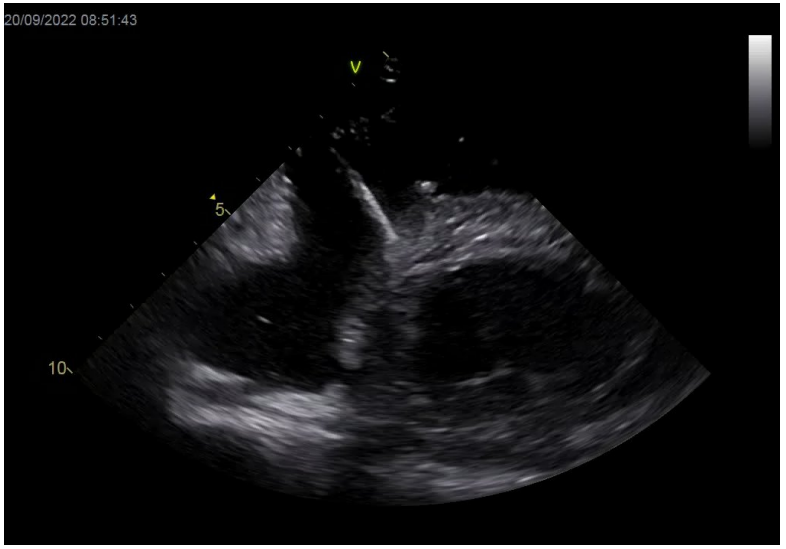
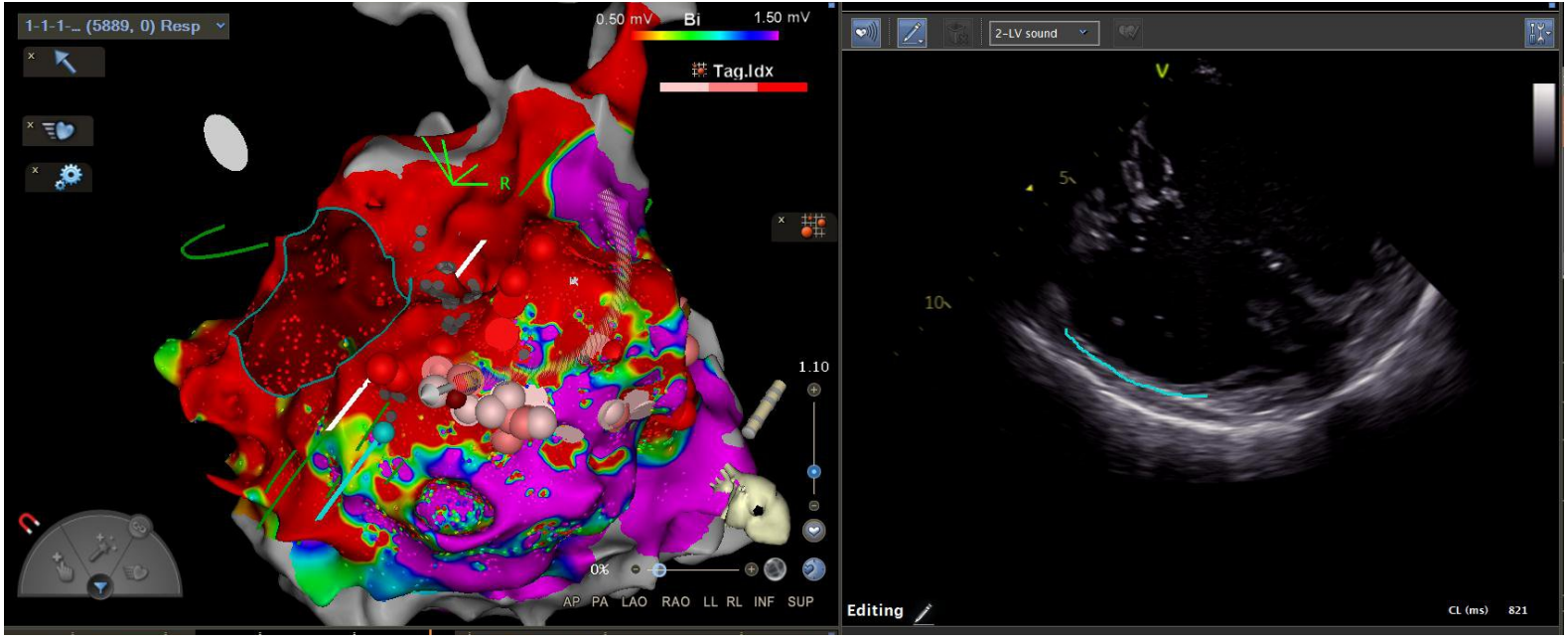
# ICE: one tool for many procedures



# ICE: one tool for many procedures



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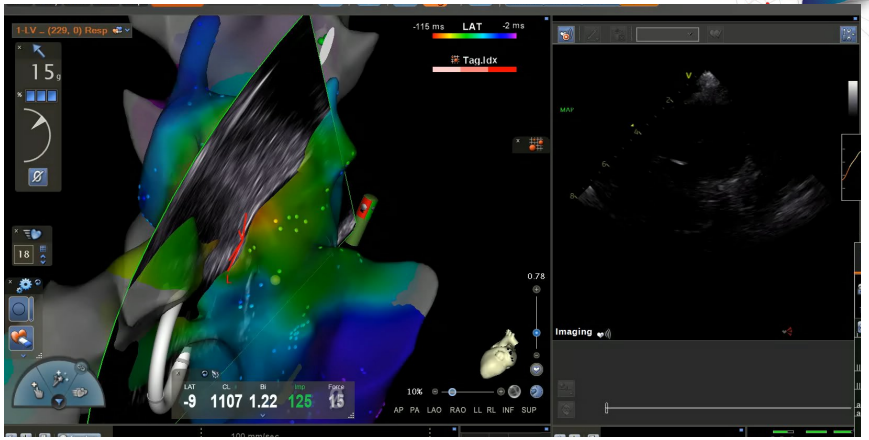
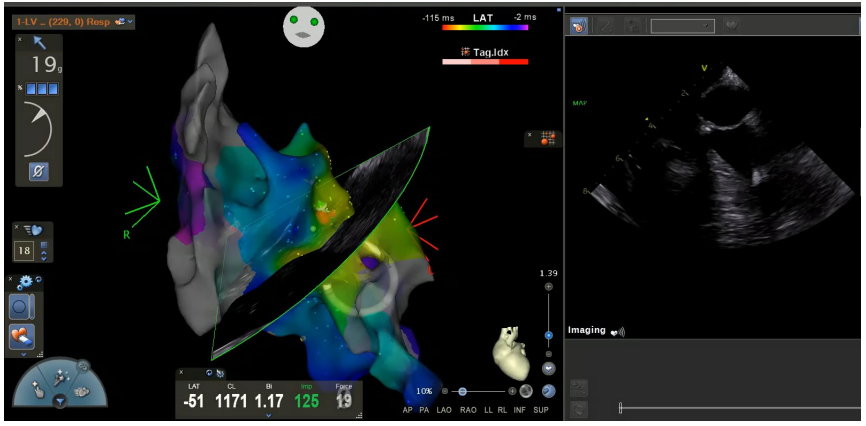
# ICE: one tool for many procedures

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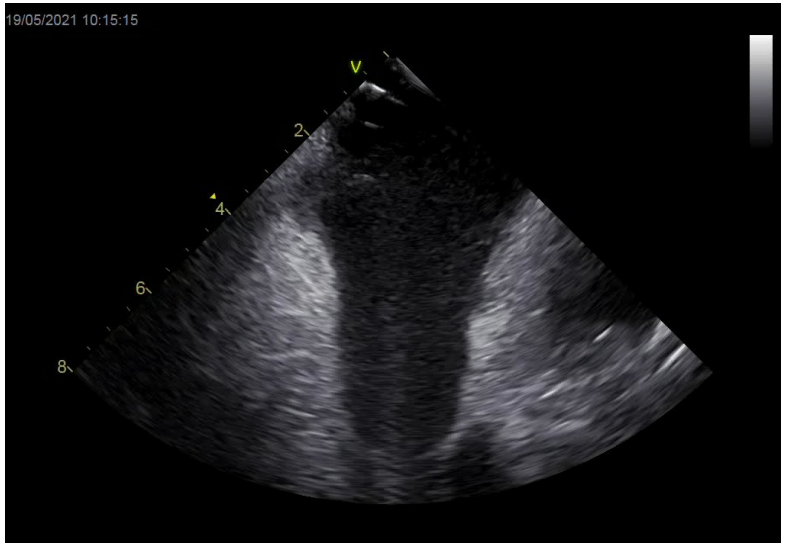
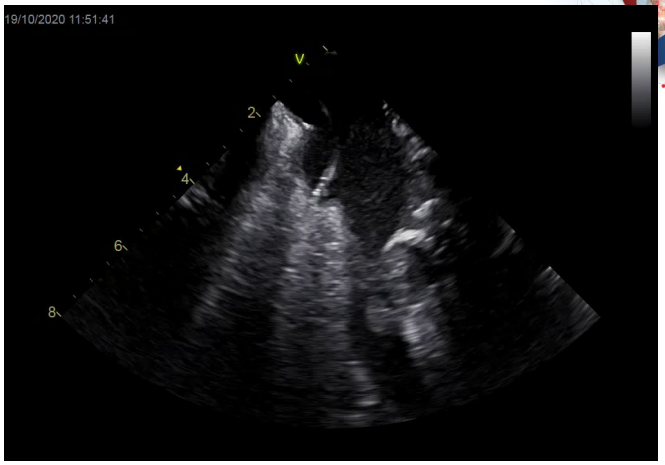
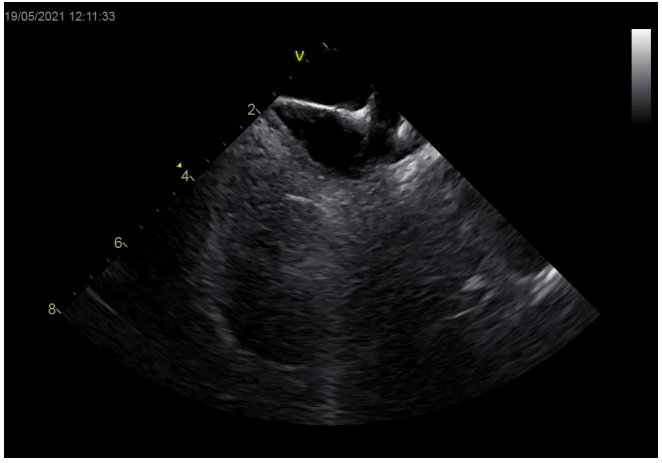
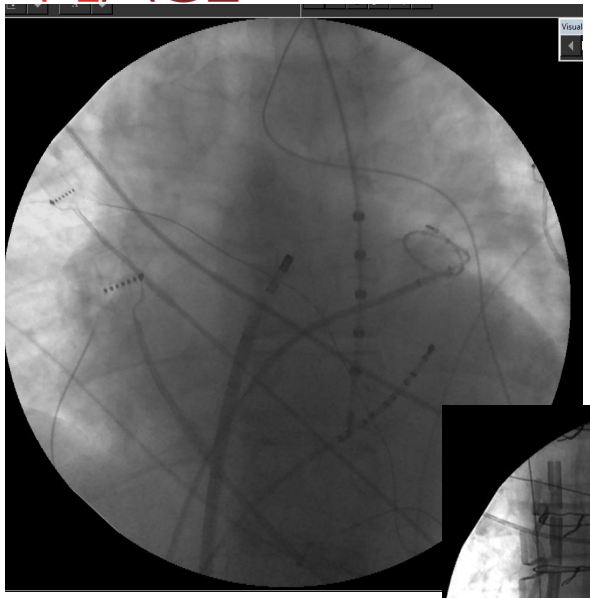
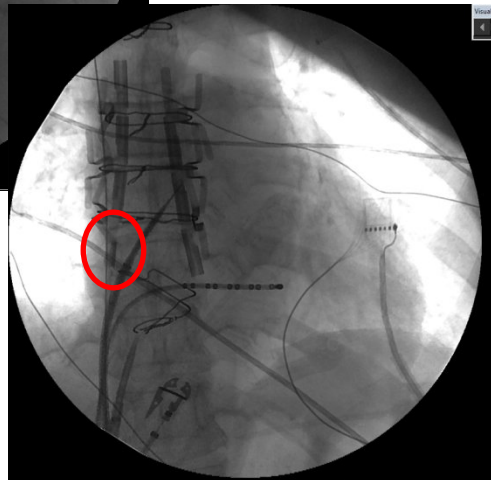


# AF ablation





- General Anesthesia
- 3-4 echo-guided venous accesses (2 R – 1 L)
- 1 transeptal
- Lasso or multipolar catheter through SL0 sheath
- Ablation catheter through Agilis steerable sheath
- Decapolar catheter in CS
- Esophageal Temperature probe (39°C)
- ICE only for complex procedures
- 45 W (AI 400) posterior – 50 W (AI 550) anterior
- with interlesion distance < 6 mm

# AF ablation
# Hospital Perugia (2019-2021)

| | No ICE 220 (87%) | ICE 34 (13%) | p |
|---|---|---|---|
| Procedure Time | 134±21 | 152±36 | 0,03 |
| Fluoro Time | 12±5 | 6±3 | 0,001 |
| Cardiac Tamponade | 2 (0,9%) | 0 (0%) | ns |

# Conclusion

- 3D mapping system reduces fluoroscopy and procedure time
- ICE merged with 3D MS further reduces radiation exposure and may improve short and long-term outcomes
- ICE is useful mainly in specific subsets of patients to guide the ablation and avoid or timely detect complications
- ICE can be used in many different procedures (AFL, VT, Biopsy, lead extraction)
- Cost and single-use devices are the main (only!) limitations
- No powered RCTs

PLACE
PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

# Parachute use to prevent death and major trauma when jumping from aircraft: randomized controlled trial

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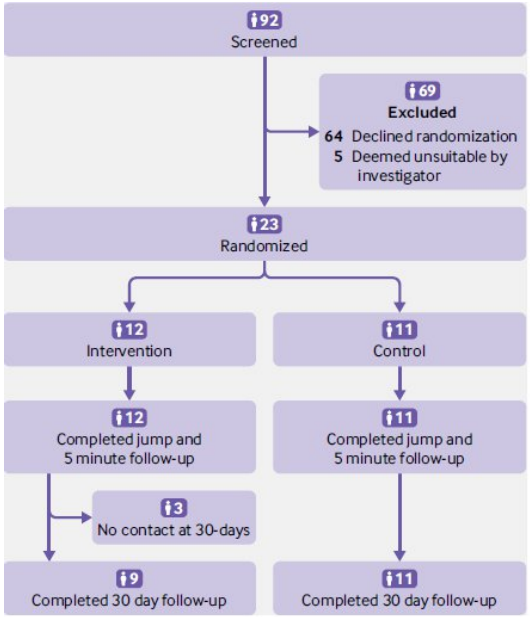


| Endpoint | Parachute | Control | Mean difference (95% CI) | P value |
|---|---|---|---|---|
| On impact | | | | |
| Death or major traumatic injury | 0 (0) | 0 (0) | 0 | >0.9 |
| Mean (SD) Injury Severity Score | 0 (0) | 0 (0) | 0 | >0.9 |
| 30 days after impact | | | | |
| Death or major traumatic injury | 0 (0) | 0 (0) | 0 | >0.9 |
| Mean (SD) Injury Severity Score | 0 (0) | 0 (0) | 0 | >0.9 |
| Health status | | | | |
| Mean (SD) Short Form Health Survey score | 43.9 (1.8) | 44.0 (2.4) | 0.1 (−2.0 to 2.2) | 0.9 |
| Mean (SD) physical health subscore | 19.6 (0.7) | 19.7 (0.5) | 0.04 (−0.5 to 0.6) | 0.9 |
| Mean (SD) mental health subscore | 24.3 (1.3) | 24.3 (2.1) | 0.08 (−1.6 to 1.8) | 0.9 |

Yeh R et al BMJ 2018

# Thank You!