



No fluoroscopy EP lab, no compromises

“RX exposure reduction in EP procedures guided by 3D advanced mapping: rationale, implications and outcomes”

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“RX exposure reduction in EP procedures guided by 3D advanced mapping: rationale, implications and outcomes”



The 28 December 1895 by the official announcement of Roentgen's discovery of x-rays to the president of the Physical Medical Society of Wurzburg;

The 12 April 1898 Marie Sklodowska Curie announced to the Académie des Sciences in Paris the discovery of Polonium - Radium.

Two dates that mark a turning point in the history of medicine.

“RX exposure reduction in EP procedures guided by 3D advanced mapping: rationale, **implications** and outcomes”

In recent years the capability and complexity of invasive cardiovascular procedures have increased substantially. Originally, fluoroscopically guided procedures were principally **diagnostic**. Currently, many procedures are **therapeutic** as well. As procedures have become increasingly complex, they may employ greater fluoroscopic durations leading to the potential for greater patient radiation exposure

Ionizing radiation, although a **very beneficial aid** to invasive procedures, **can be harmful**. Radiation effects fall into two classes: deterministic effects and stochastic effects.

Adverse Effects of Radiation

Deterministic Effects

- Skin injury and hair loss

- Thresholds

- Dose-response relationships

- Progression of injury

- Eyes

- Other organs

Stochastic Effects

- Neoplasm

- Incidence and mortality risks

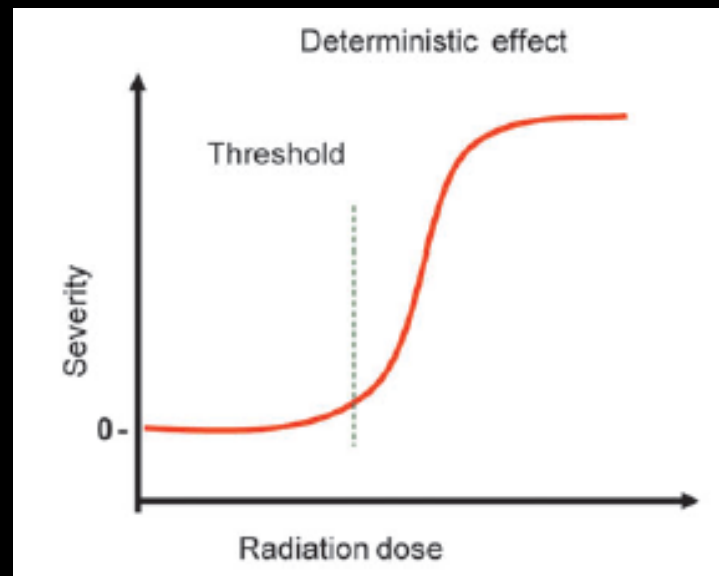
- Risk models for low-dose effects

- Latent periods

- Heritable genetic effects

Deterministic effects

They are **predictable** dose-related phenomena. They have a **threshold** dose below which the effect does not occur. The **threshold is variable**, depending on the nature and condition of the exposed tissue. For doses in excess of the threshold, both the **probability and the severity** of deterministic effects increase with dose. Examples of deterministic effects include radiation-induced epilation, erythema, and necrosis of the skin.



Picano et al. European Heart Journal 2014;35:665-672

TABLE II. Chronology and Severity of Tissue Reactions From Single-Delivery Radiation Dose

Single site (Gy) acute skin dose	Prompt (<2 weeks)	Early (2–8 weeks)	Mid term (6–52 weeks)	Long term (<40 weeks)
0–2	No observable effects expected			
2–5	Transient erythema	Epilation	Recovery from hair loss	None expected
5–10	Transient erythema	Erythema, epilation	Recovery; high doses cause prolonged erythema and permanent partial epilation	Recovery; higher dose cause dermal atrophy/induration
10–15	Transient erythema	Erythema, epilation; dry/moist desquamation	Prolonged erythema permanent epilation	Telangiectasia; dermal atrophy/induration
>15	Transient erythema; Very high dose causes moist desquamation edema/ulceration	Erythema, epilation	Dermal atrophy with secondary ulceration; atrophy/induration; High dose dermal necrosis surgical repair likely	Telangiectasia; dermal Late skin breakdown

Chambers et al. Catheterization and Cardiovascular Interventions 2011;77:546–556

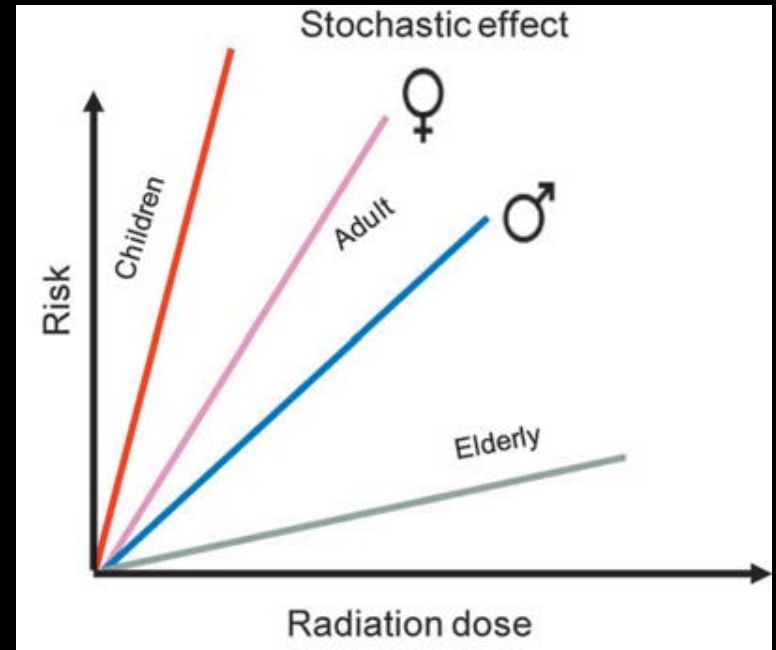
Fluoroscopically Guided Interventional Procedures:

A Review of Radiation Effects on
Patients' Skin and Hair¹



Stochastic effects

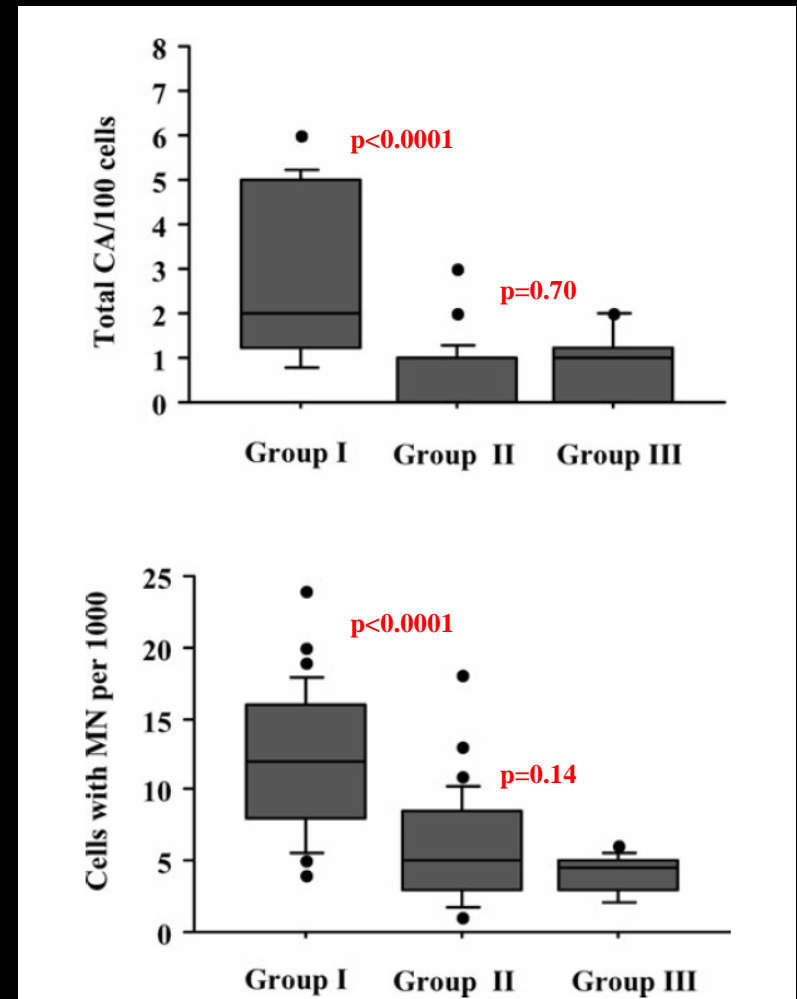
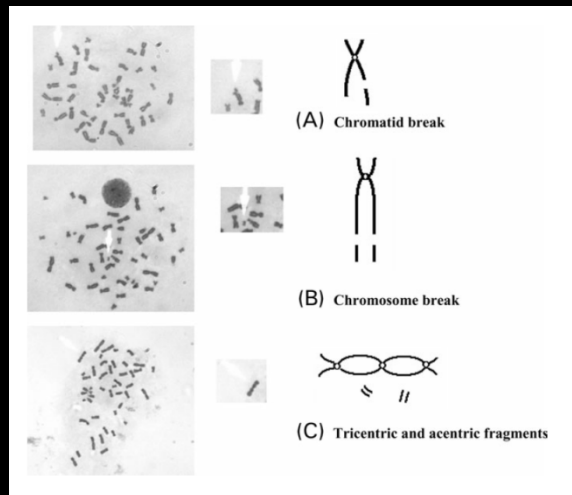
They are **probabilistic** in nature, and their severity has no relationship to dose. The likelihood of inducing a stochastic effect increases with dose, but there is **no identifiable threshold for the effect**. The exact functional relationship with dose is **unknown**. Guidelines exist regarding the risk potential. Examples of stochastic effects include radiation-induced **neoplasm and heritable genetic defects**. This risk is cumulative and lifelong. Cancer may occur after a latency period of many years.



Cardiac catheterization and long-term chromosomal damage in children with congenital heart disease

Risk of chromosomal damage of RX exposed children with repaired CHD.

- GROUP I children who underwent cardiac catheterization for CHD (RX exposed)
- GROUP II healthy age- and sex-matched subjects
- GROUP III newborn non-exposed pts with CHD

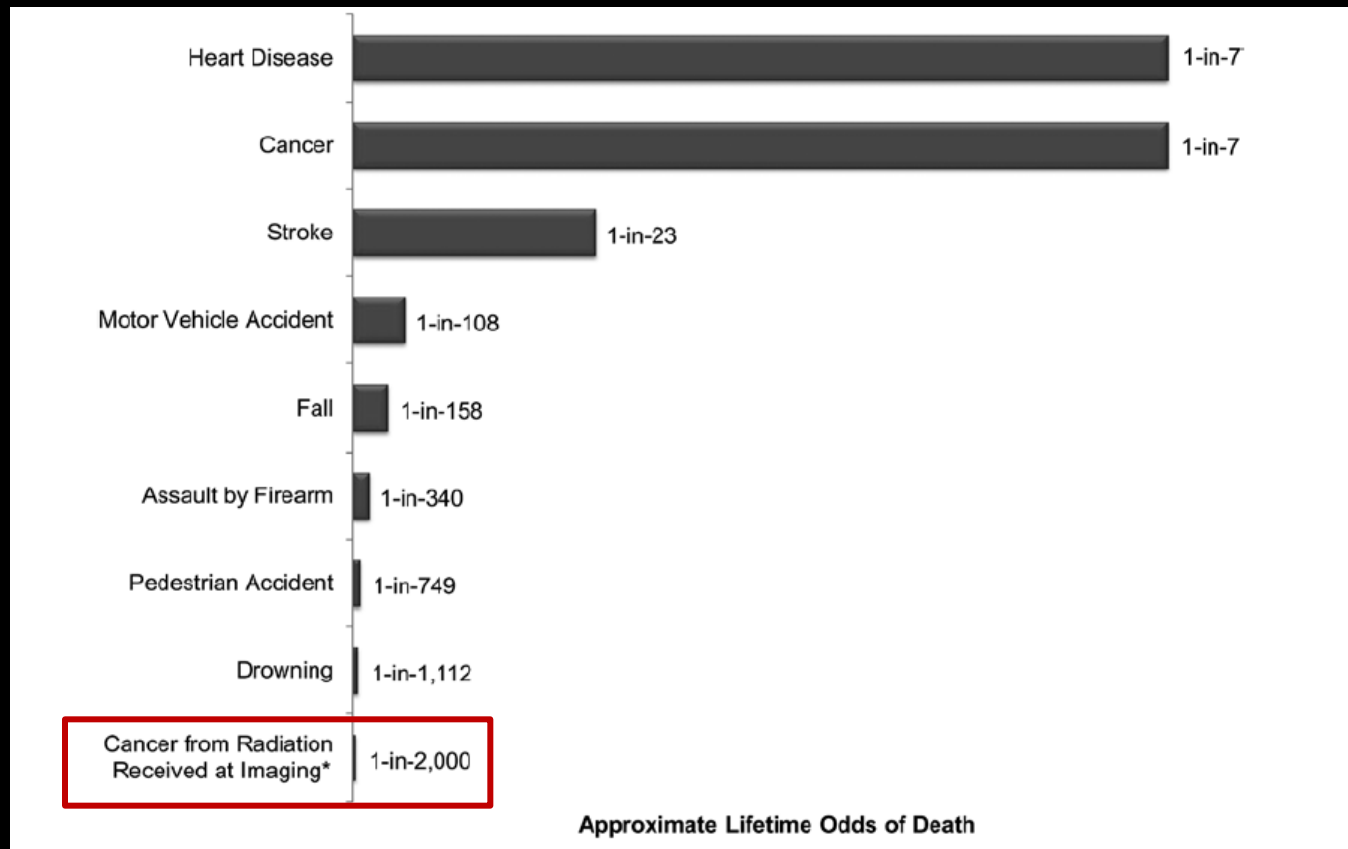


CA:chromosomal aberrations test MN: micronucleus assay in peripheral blood lymphocytes

Radiation Risks From Cardiovascular Imaging Tests

Felix G. Meinel, John W. Nance, Jr, Brett S. Harris, Carlo N. De Cecco, Philip Costello and U. Joseph Schoepf

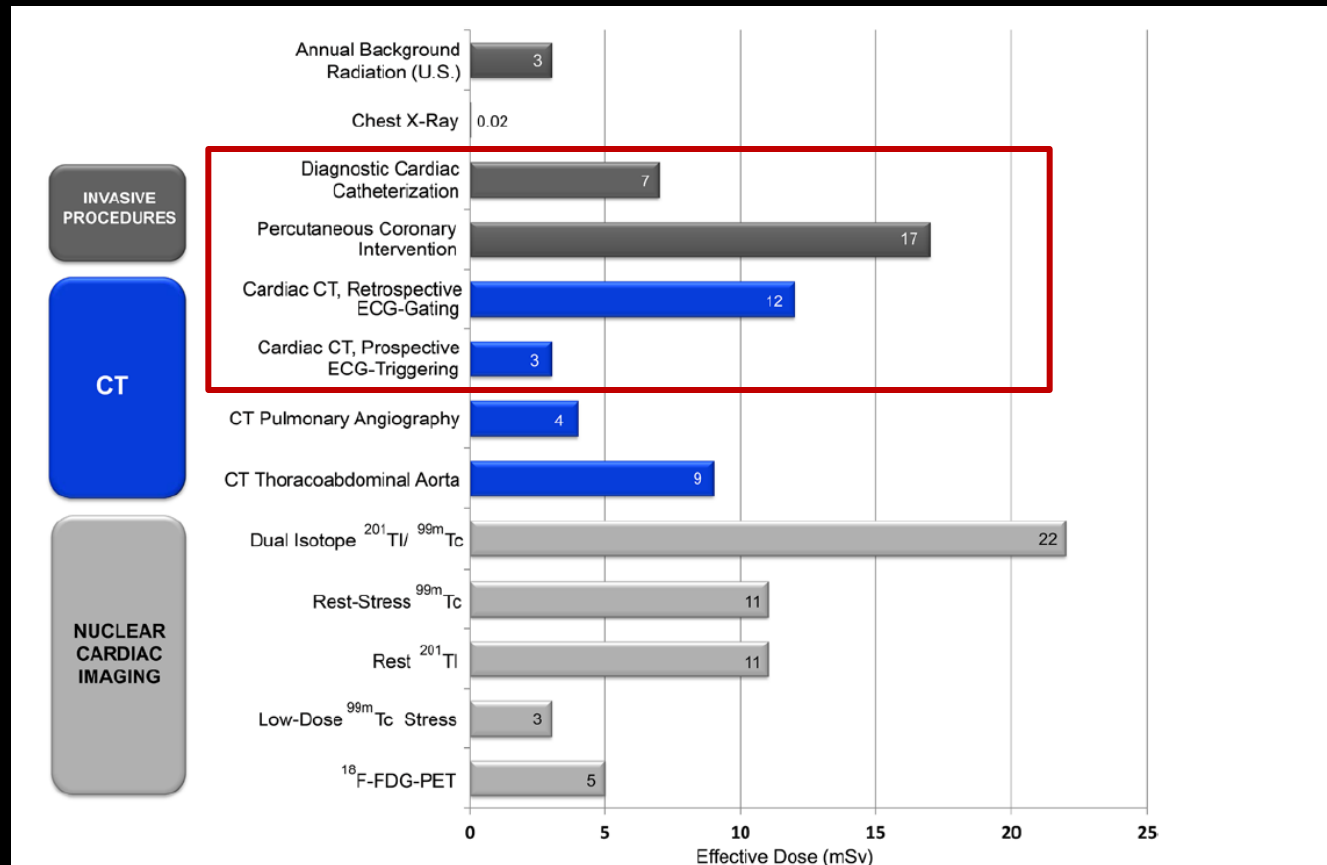
CLINICIAN UPDATE



Radiation Risks From Cardiovascular Imaging Tests

Felix G. Meinel, John W. Nance, Jr, Brett S. Harris, Carlo N. De Cecco, Philip Costello and U. Joseph Schoepf

CLINICIAN UPDATE



The appropriate and justified use of medical radiation in cardiovascular imaging: a position document of the ESC Associations of Cardiovascular Imaging, Percutaneous Cardiovascular Interventions and Electrophysiology

Cardiologists are responsible for about 40% of the entire cumulative effective dose to the US population from all medical sources excluding radiotherapy.

The majority of doctors—including cardiologists—grossly underestimate the radiation doses for most commonly requested tests. **At least one-third of all cardiac examinations are partially or totally inappropriate.**

In addition, the occupational radiation exposure of interventional cardiologists and cardiac electrophysiologists can be two to three times higher than that of diagnostic radiologists, and their exposure has increased steadily in the past few decades.

ACC/AHA Clinical Competence Statement

ACCF/AHA/HRS/SCAI Clinical Competence Statement on Physician Knowledge to Optimize Patient Safety and Image Quality in Fluoroscopically Guided Invasive Cardiovascular Procedures

A Report of the American College of Cardiology Foundation/American
Heart Association/American College of Physicians Task Force on Clinical
Competence and Training

The core principle governing the use of ionizing radiation is **ALARA (As Low As Reasonably Achievable)**. The ALARA principle recognizes that there is no magnitude of radiation exposure that is known to be **completely safe**. This principle confers a responsibility on all physicians to minimize the radiation injury hazard to their patients, to their professional staff, and to themselves.

“RX exposure reduction in EP procedures guided by 3D advanced mapping: rationale, implications and outcomes”

In the past decade, there has been **increasing interest in methods to minimize fluoroscopy during interventional procedures**. Various authors have published methods to lower the total dose. In addition, the use of newer technologies such as nonfluoroscopic three-dimensional navigation systems allow for minimal radiation exposure during catheter ablation. Several authors have already reported their experience with ‘near-zero fluoroscopy’, whereas ablations without radiation exposure are limited in the current literature.

A new electrophysiology era: zero fluoroscopy

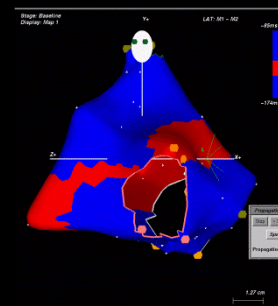
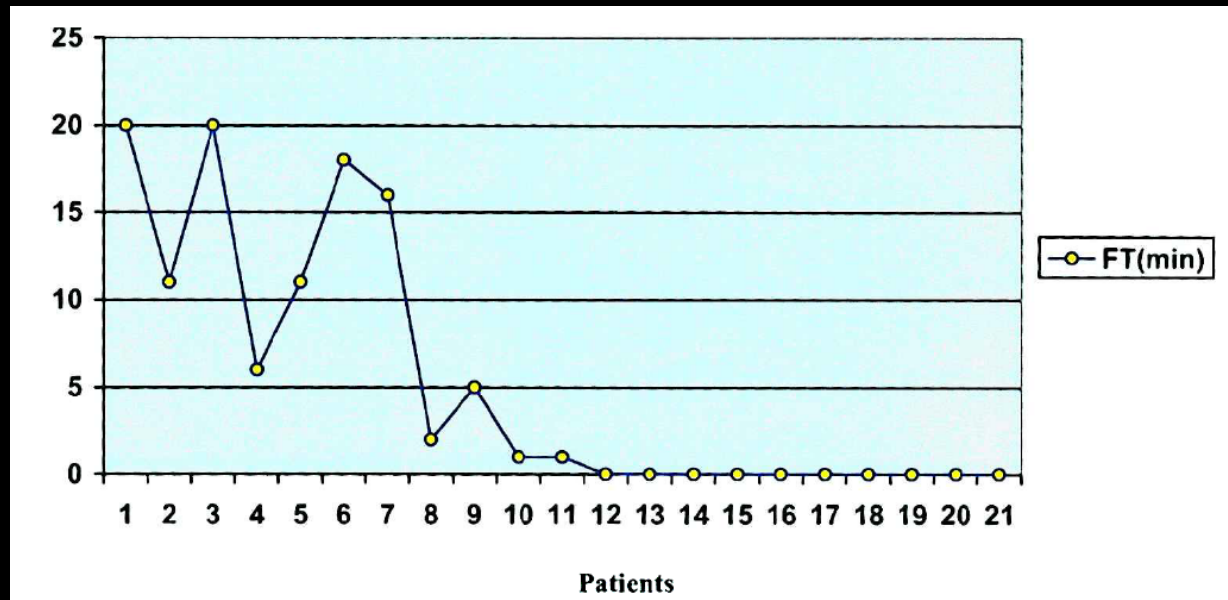
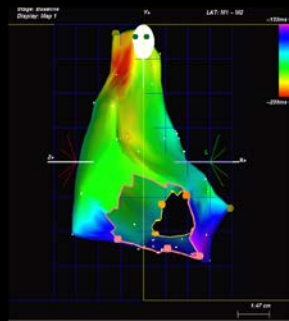
Matteo Anselmino, Dario Sillano, Dario Casolati, Federico Ferraris, Marco Scaglione and Fiorenzo Gaita

Exclusion of Fluoroscopy During Ablation Treatment of Right Accessory Pathway in Children

FABRIZIO DRAGO, M.D., MASSIMO STEFANO SILVETTI, M.D.,
ALFREDO DI PINO, M.D., GIORGIA GRUTTER, M.D., MAURIZIO BEVILACQUA, M.D.,
and SHOSHANA LEIBOVICH, M.D.

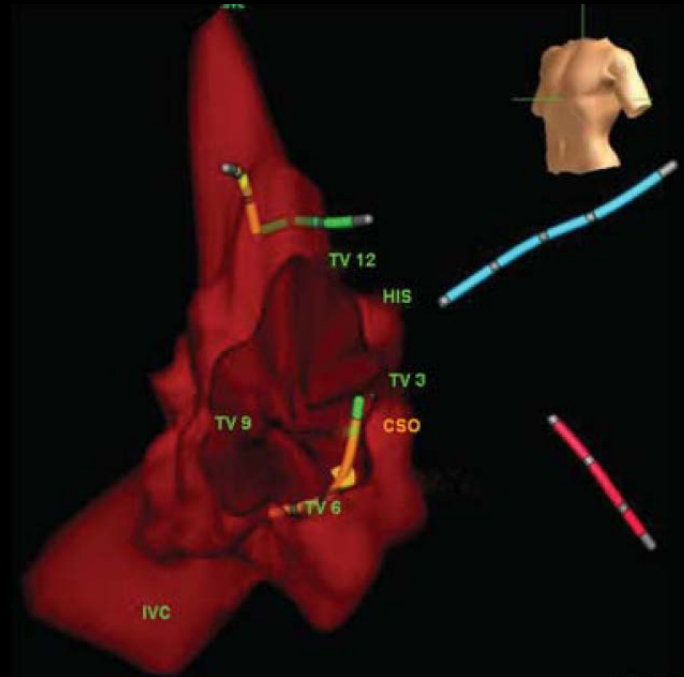
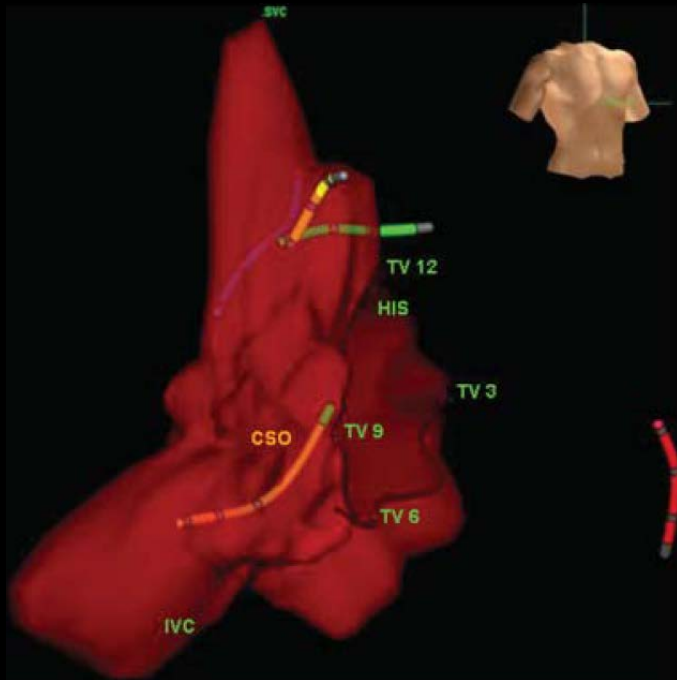
From the Pediatric Cardiology Department, Bambino Gesù' Hospital, Rome, Italy

21 consecutive WPW (due to a right AP) pediatric patients were submitted to radiofrequency ablation guided by CARTO system



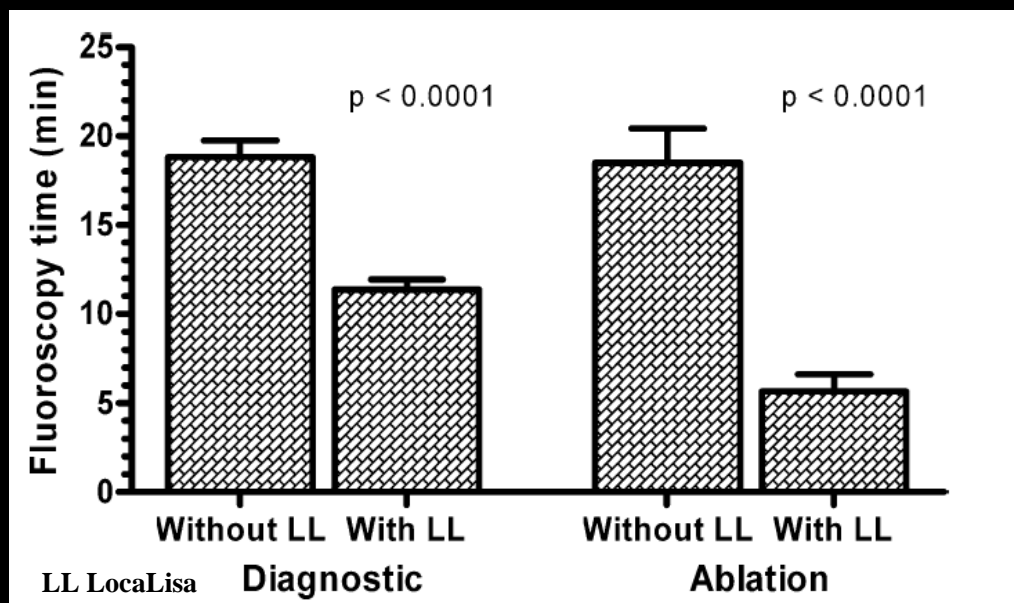
Reduction of fluoroscopy time during the study. Considerable reduction is seen after procedure 8, with definitive elimination of fluoroscopy after procedure 13.

Nonfluoroscopic Catheter Navigation for Radiofrequency Catheter Ablation of Supraventricular Tachycardia in Children



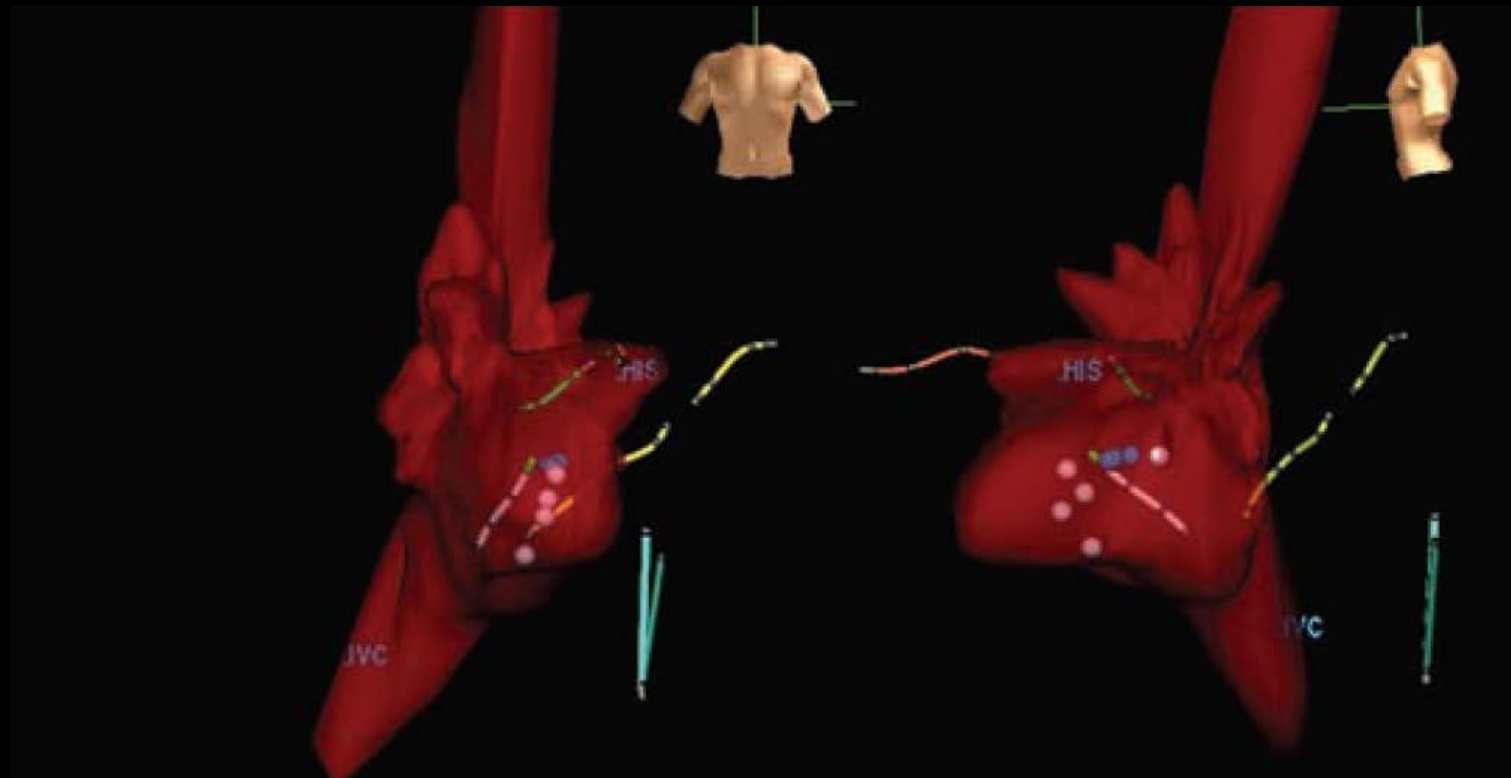
40 consecutive pediatric pts with AP and AVNRT who underwent RFCA with use of a nonfluoroscopic navigation system (Ensité NavX™) were compared retrospectively to 40 consecutive pts with similar diagnosis who underwent RFCA with fluoroscopic guidance only. The use of a nonfluoroscopic system for catheter navigation significantly reduced fluoroscopy exposure and total procedure duration of RCA of common SVT substrates in children. **Reduction of fluoroscopy time for catheter ablation by 42%.**

Impact of a computer assisted navigation system on radiation exposure during pediatric ablation procedures



The use of a computer assisted navigation system can significantly decrease the diagnostic, ablation, and total fluoroscopy times for catheter ablation procedures in children.

A Nonfluoroscopic Approach for Electrophysiology and Catheter Ablation Procedures Using a Three-Dimensional Navigation System



Nonfluoroscopic catheter ablations were performed in 24 of 28 (86%) consecutive pediatric patients and right-sided catheter ablations for supraventricular tachycardia can be safely and effectively performed in the majority of patients **with normal cardiac anatomy** using NavX™.

Elimination of Fluoroscopy Use in a Pediatric Electrophysiology Laboratory Utilizing Three-Dimensional Mapping

Results of Study Group versus Control

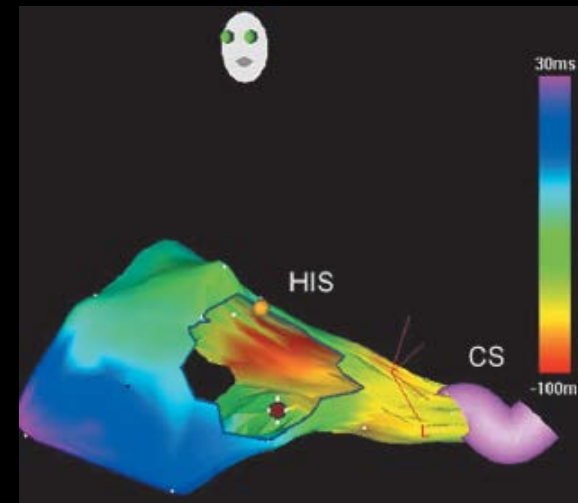
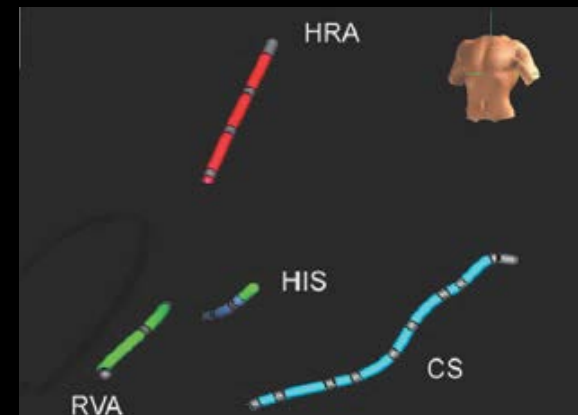
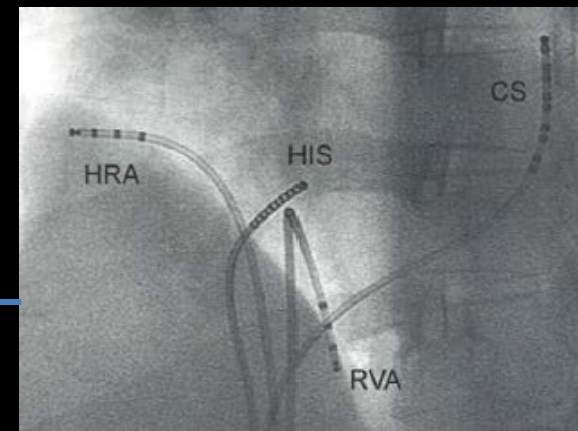
	NavX Group, Mean, (SD)	Control Group, Mean (SD)	P Value
N	30	30	NS
Age (years)	12.9 (4.9)	12.3 (3.8)	NS
Weight (kg)	54.1 (21.4)	52 (18.4)	NS
Procedure time (hours)	3.27 (1.18)	3.17 (1.13)	NS
Fluoroscopy time (minutes)	1.05 (2.96)	21.37 (18.35)	<0.001
Acute success	30/30	29/30	NS
Recurrence	4/30	3/29	NS

NavX was used to effectively guide catheters during ablation procedures resulting in a significant decrease in fluoroscopy use. **In 80% of the procedures**, no fluoroscopy was used. Further advances in the technology may permit additional decreases in x-ray exposure for the 20% of patients who required it.

Radiofrequency ablation of arrhythmias guided by non-fluoroscopic catheter location: a prospective randomized trial

The principal findings of this randomized study are that Ensite NavX exposes patients to the least amount of radiation. Carto also reduces fluoroscopy time when compared with conventional mapping, however the effect is smaller. These reductions are achieved without compromising the duration, effectiveness, or safety of the procedure.

The only study comparing the costs of non-fluoroscopic approach (both with CARTO and NavX system) with those of the standard fluoroscopic approach.



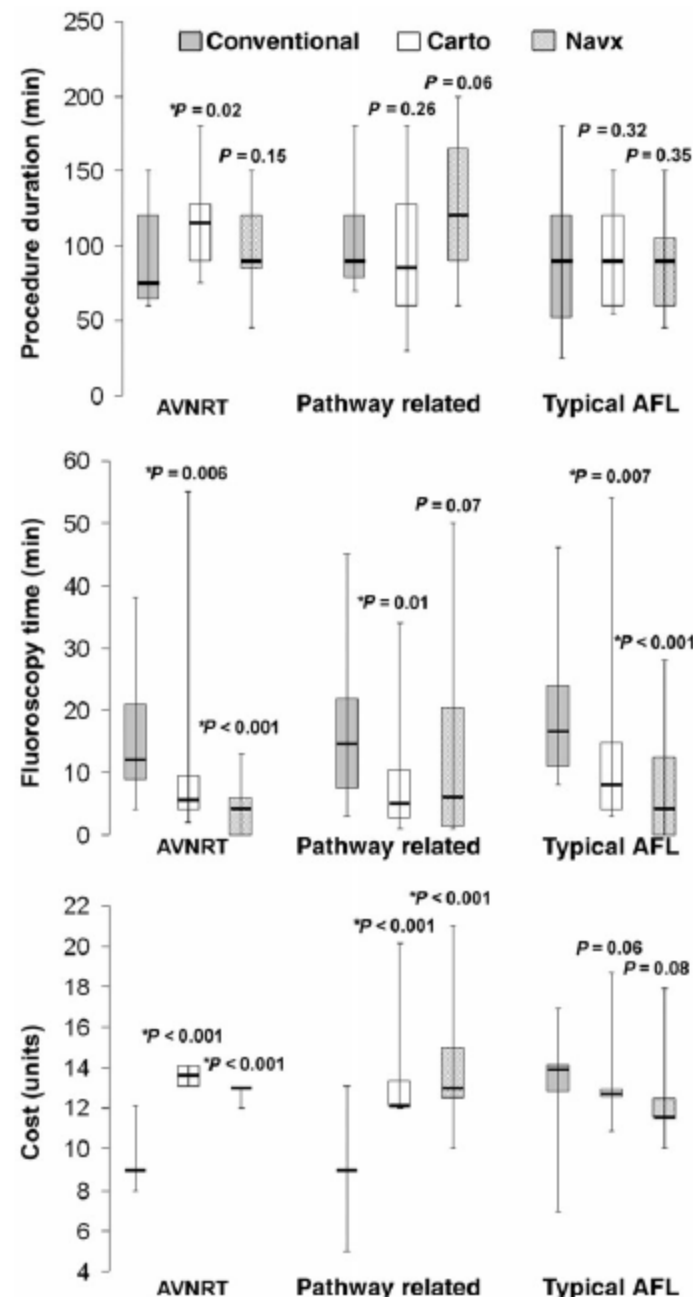
Radiofrequency ablation of arrhythmias guided by non-fluoroscopic catheter location: a prospective randomized trial

Costs increased by **50%** over conventional mapping.....

Only for the ablation of typical atrial flutter, Carto and NavX were cost neutral because their excess cost is balanced by not using a duodecapolar catheter.

But cost analyses are usually invalidated by the difficulty in weighing the cost of 3D mapping system against the benefits of its use... the near-total absence of radiation exposure for the patient, operator, and auxiliary staff, elimination of all radiation protection equipment and possibly of the vertebral strain they impose on operators, and so on.

These benefits can only be assessed meaningfully in a **long-term, "lifetime" perspective**, and although they do carry additional costs they may be significant enough for the community and laboratory staff.



“RX exposure reduction in EP procedures guided by 3D advanced mapping: rationale, implications and outcomes”

Nine brain-cancer cases reported in interventionalists

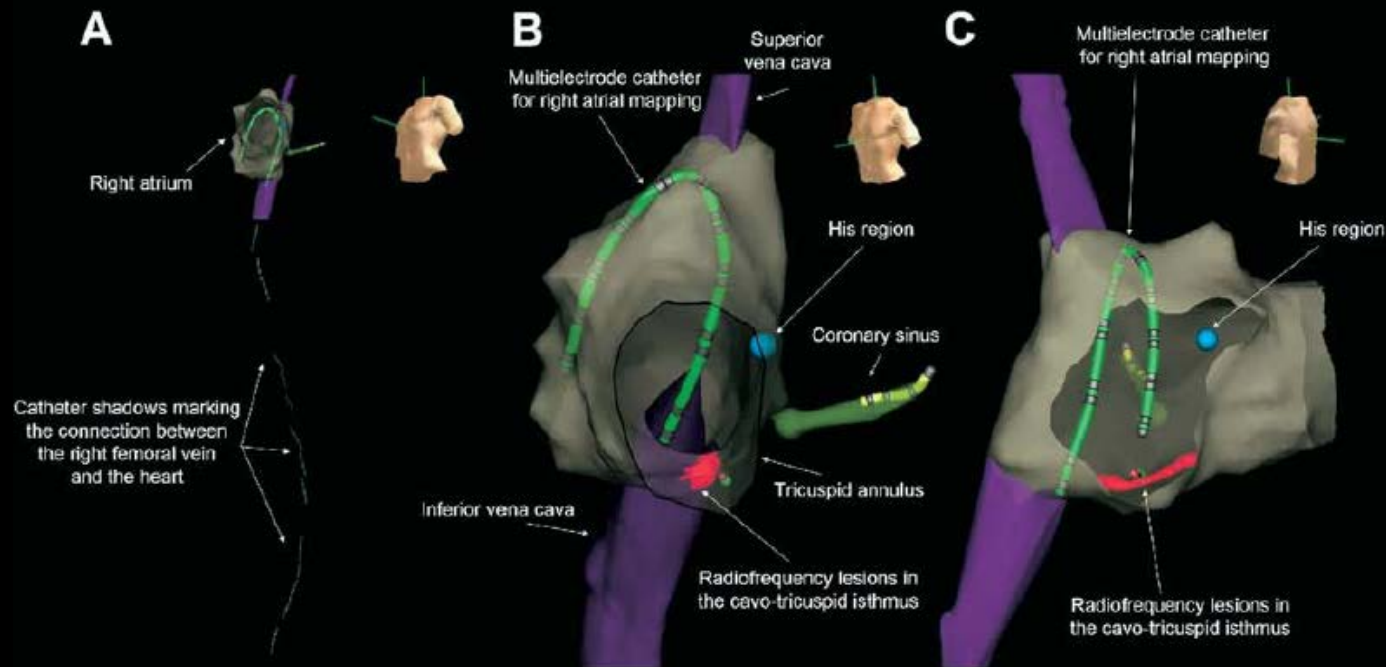
FEBRUARY 23, 2012 [Reed Miller](#)

Haifa, Israel - Researchers in Israel and France have found a few cases that suggest interventional cardiologists and radiologists may be at risk for left-side brain tumors [1].

In the January 2012 issue of *Eurointervention*, **Dr Ariel Roguin** (Technion-Israel Institute of Technology, Haifa, Israel) and colleagues publish the summary of nine reports of brain tumors in people working in catheterization laboratories for 14 to 32 years, including four cases not previously reported in the literature.

The types of tumor reported include glioblastomas, meningiomas, acoustic neurinomas, and oligodendromas.

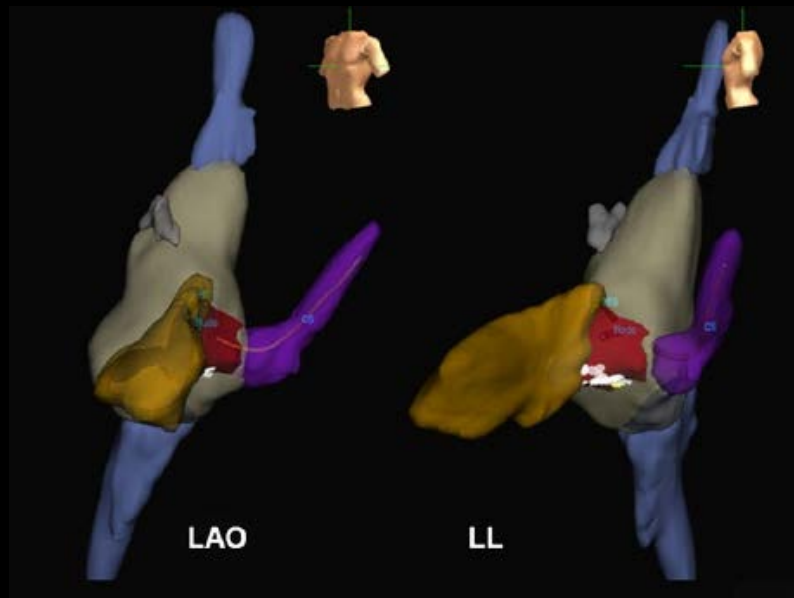
No fluoroscopy for cavotricuspid isthmus-dependent right atrial flutter ablation



The present case demonstrates that use of a nonfluoroscopic navigation system during catheter ablation of isthmus-dependent common-type atrial flutter can be performed without fluoroscopy.

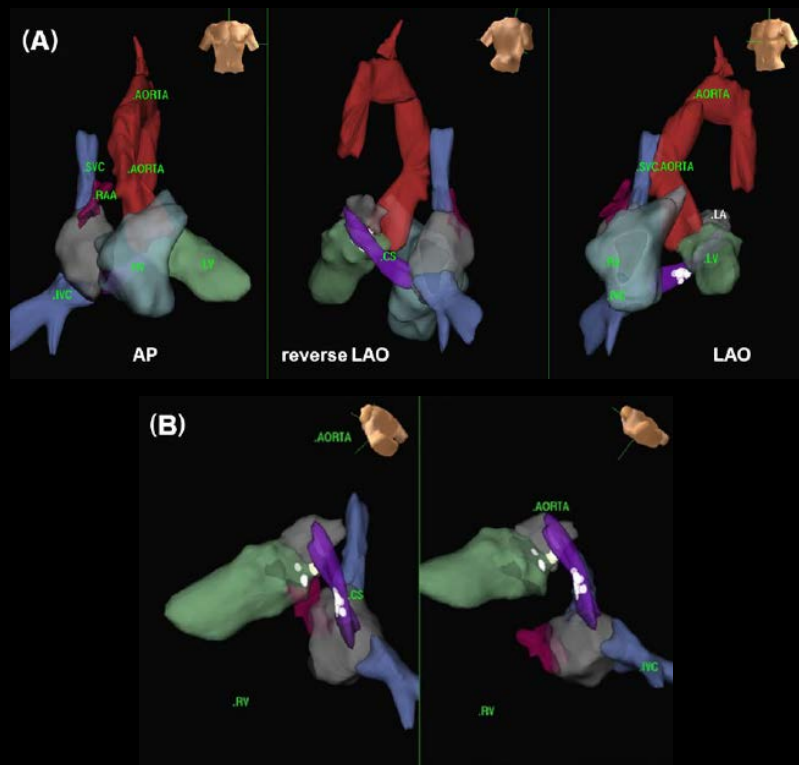
“RX exposure reduction in EP procedures guided by 3D advanced mapping: rationale, implications and outcomes”

“Near-zero” fluoroscopic exposure in supraventricular arrhythmia ablation using the EnSite NavX™ mapping system: personal experience and review of the literature



EnSite NavX™ system is feasible, safe, and effective in a population of relatively young adults.

Casella et al. J Interv Card Electrophysiol 2011;31:109-18.



First report of non-fluoroscopic use for both left- and right-sided ablation in a non-pediatric population

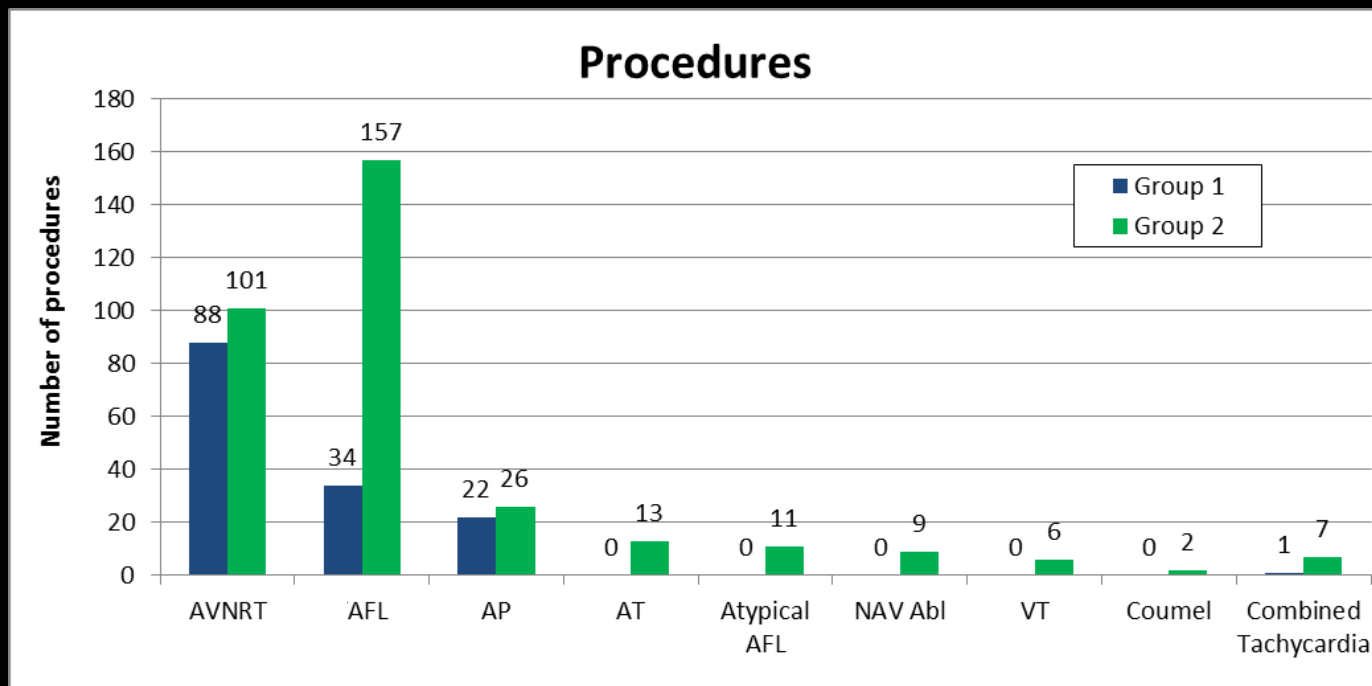
“RX exposure reduction in EP procedures guided by 3D advanced mapping: rationale, implications and outcomes”

“Near-zero” fluoroscopic exposure in supraventricular arrhythmia ablation using the EnSite NavX™ mapping system: personal experience and review of the literature

Our study demonstrates the feasibility, efficacy, and safety of using the non-fluoroscopic EnSite NavX™ mapping system as the sole or prevailing imaging modality to guide ablation of a wide range of supraventricular tachyarrhythmias in young adults.....in a non-pediatric population.

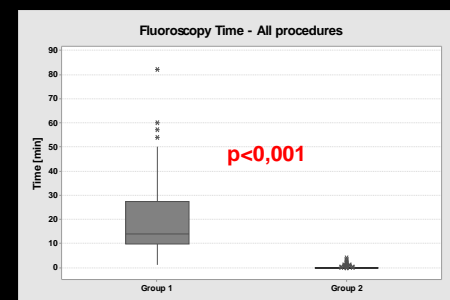
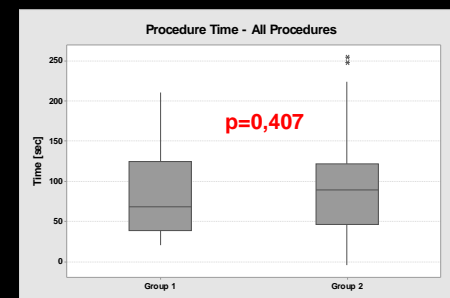
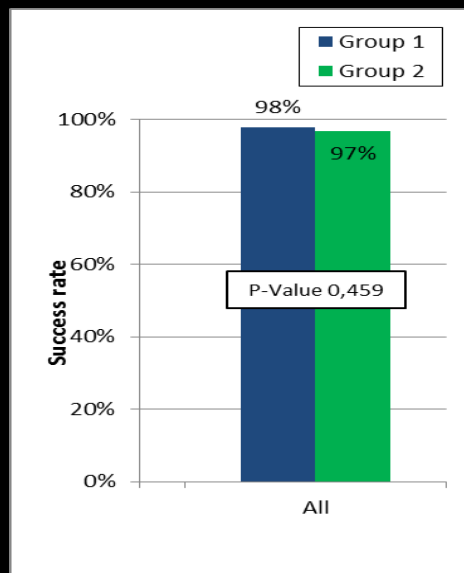
Near Zero X-ray in arrhythmias ablation using EnSite NavX system: a multicenter experience.

RFCA was performed in 477 consecutive patients (58 ± 20 years). The first 145 patients (group 1) were treated only with fluoroscopic guidance, the following 332 cases (group 2) were performed using Ensite Velocity system.



Near Zero X-ray in arrhythmias ablation using EnSite NavX system: a multicenter experience.

The nonfluoroscopic system Ensite Velocity for catheter navigation significantly reduces or eliminates fluoroscopy exposure in RFCA. These procedures can be safely and effectively performed without radiation exposure in the majority of patients.



Near Zero X-ray in arrhythmias ablation using EnSite NavX system: a multicenter experience.



Fluoroscopy was necessary in a total of 35 pts (11%) in group 2

28,6% difficult venous access

28.6% check catheter stability during RFCA

14.2 % confirm catheter location

11.4 % CS frequent dislocation

8.6% technical issues of the Ensite NavX

8.6% check guidewires

In 297 patients (89%) the RFCA was completely performed **without fluoroscopy**

Near Zero X-ray in arrhythmias ablation using EnSite NavX system: a multicenter experience.

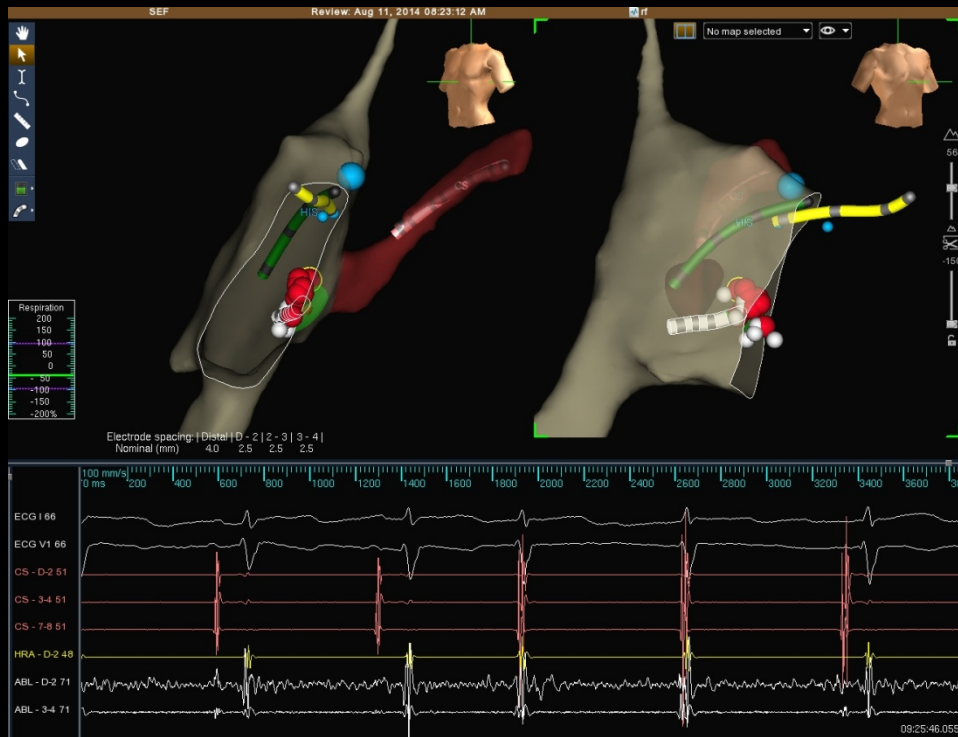
	n° of cases	adverse events	adverse event rate rate	
Conventional Technique	145	3	2,1%	1,062 χ^2
Ensite NavX	332	13	3,9%	0,303 p



5 vascular access complications (only one required surgical correction for arteriovenous fistula);
 4 atrioventricular block, all regressed spontaneously;
 2 transient ischemic accident with transient dysphonia;
 1 pulmonary microembolization;
 1 deep-vein thrombosis;



Follow-up 132 pts 0 RX



EARLY RELAPSES (1 months):

15/132 (11,36%)

8 cases without recurrences after redo

3 cases with recurrences after redo

3 cases with new arrhythmias after redo

1 case without recurrence

LATE RELAPSES (18,3±12.7 months):

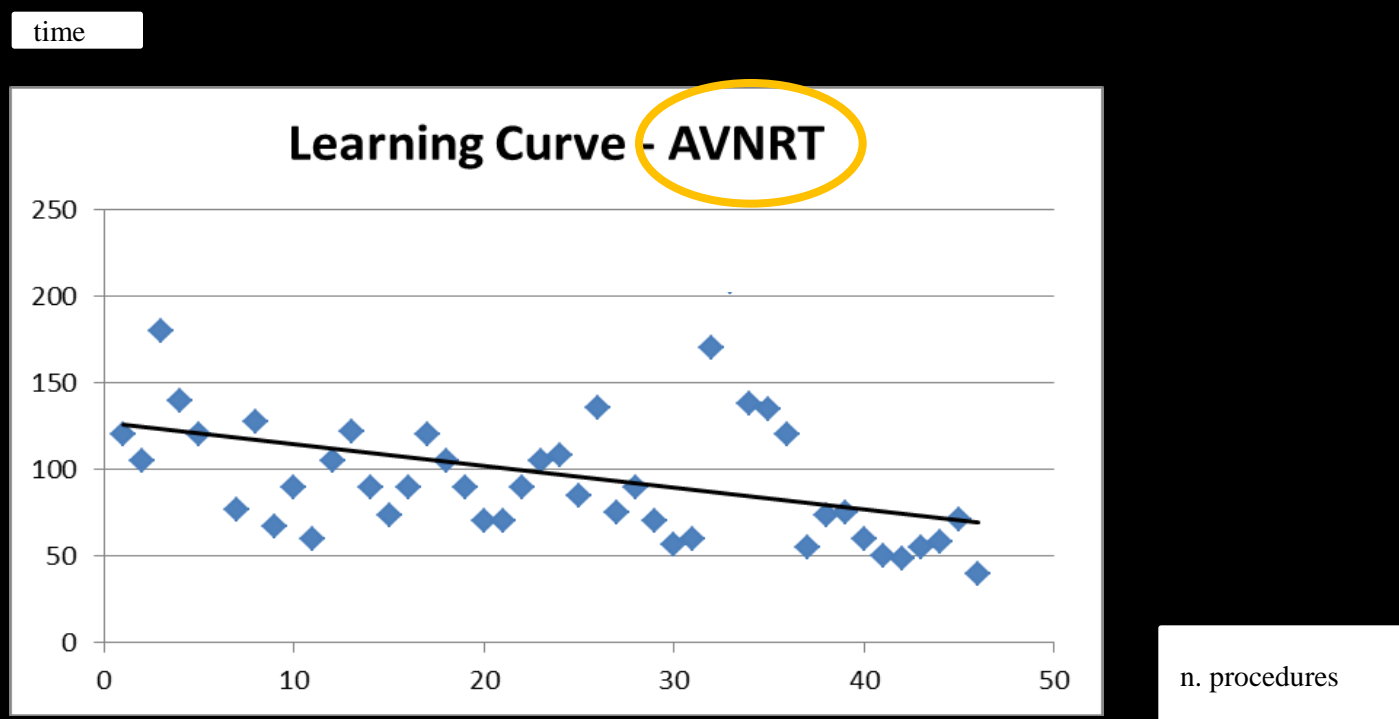
6/132 (4.55%)

3 cases recurred after early

3 new recurrences

5 of which were treated with
effectively redo.

Near Zero X-ray in arrhythmias ablation using EnSite NavX system: a multicenter experience.



Procedure time shortens as a function of experience. After an adequate learning curve, the procedure can be performed in a very acceptable amount of time

'Zero' fluoroscopic exposure for ventricular tachycardia ablation in a patient with situs viscerum inversus totalis

Marzia Giaccardi^{1*}, Leandro Chiodi¹, Attilio Del Rosso², and Andrea Colella³



EUROPEAN
SOCIETY OF
CARDIOLOGY®

Volume 14 Number 3 March 2012
ISSN 1099-5129 (Print) ISSN 1532-2092 (Online)



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Europace

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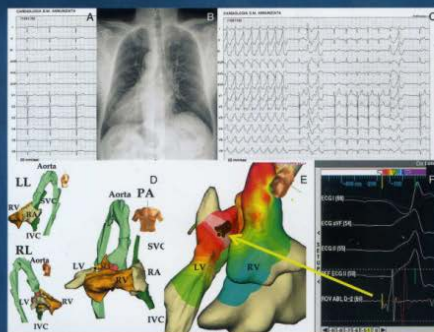
Cost-effectiveness of ILRs in syncope

EUTrigTreat study design: a prospective
observational study for arrhythmia risk stratification

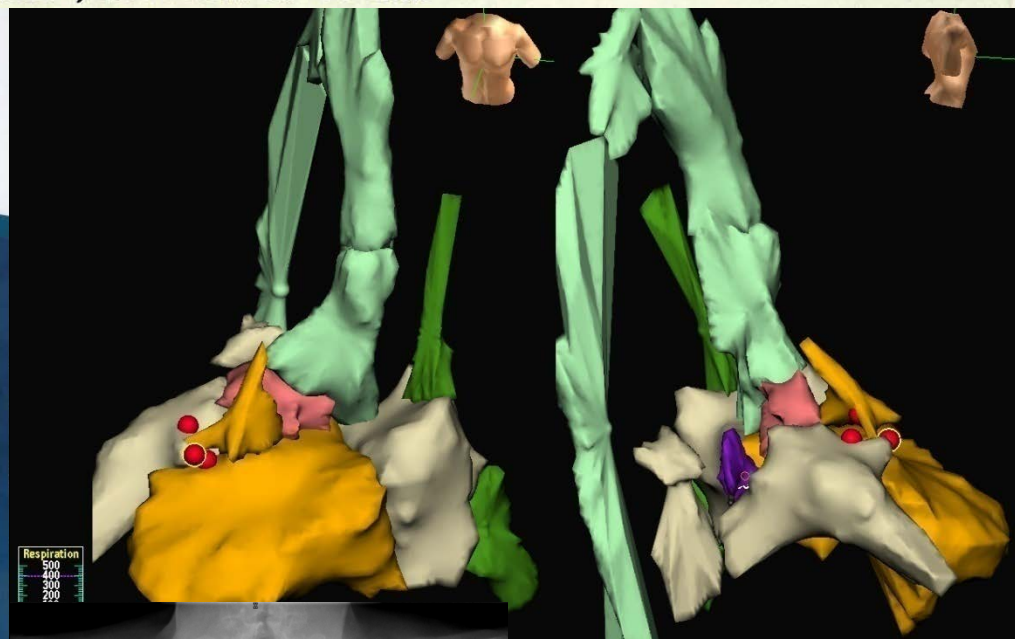
EP Wire: EHRA survey of CIED follow-up in
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*'Zero' fluoroscopic exposure during VT ablation in a patient with situs viscerum inversus totalis. See figure legend on page 449.

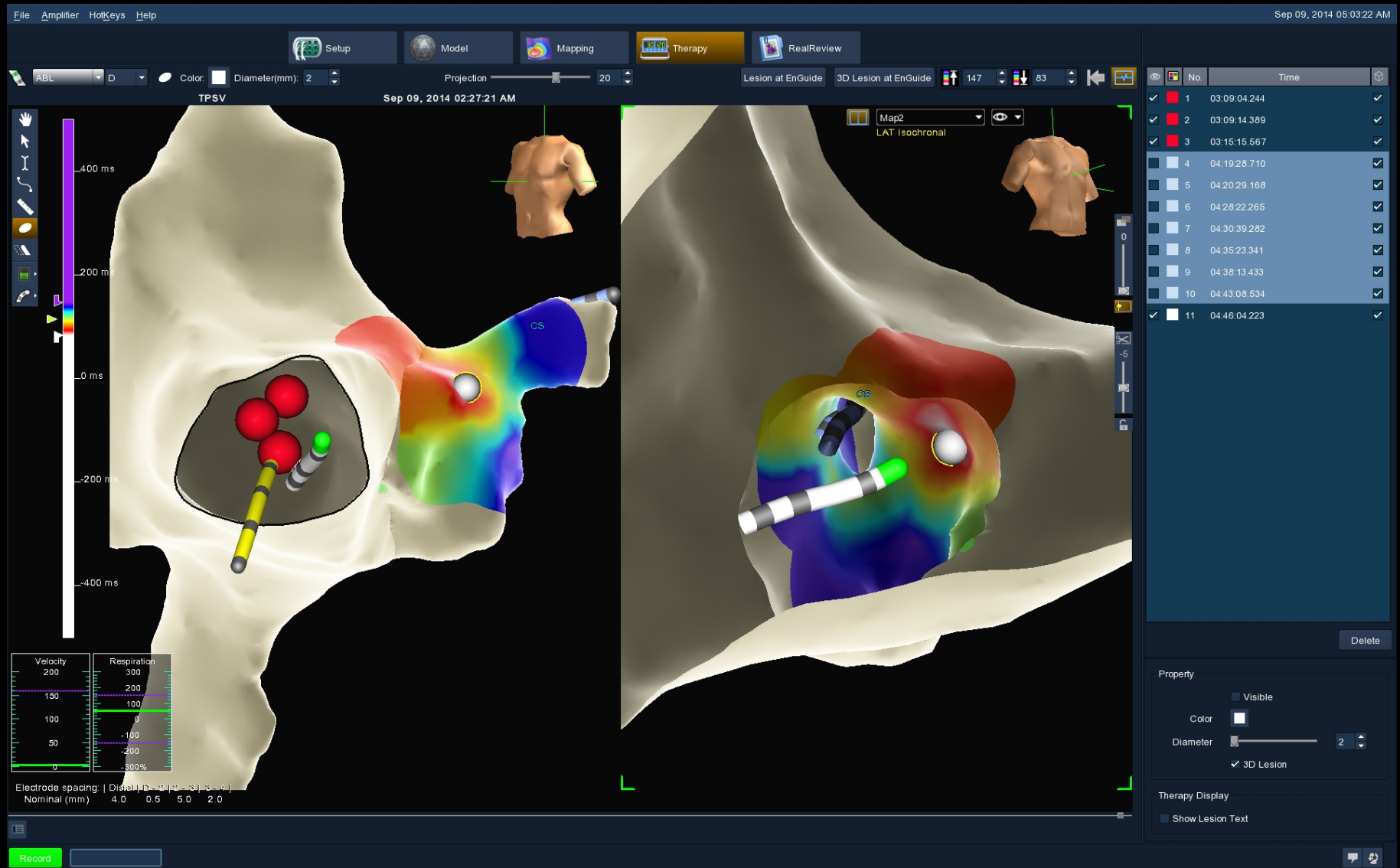


“Congenital diverticulum of the right atrium and concealed WPW”

ZERO RX approach – anatomical mapping



“Congenital diverticulum of the right atrium and concealed WPW” ZERO RX approach – ablation



EDITORIAL

The Risk of Ionizing Radiation in Electrophysiology Studies and Ablations

DOUGLAS MAH, M.D. and JOHN K. TRIEDMAN, M.D.

From the Department of Cardiology, Children's Hospital Boston; and the Department of Pediatrics Harvard Medical School

Although fluoroscopy-free procedures cannot yet be routinely performed by most practitioners, **the hope of it one day becoming the standard of care** brings with it the promise of decreased occupational health risks, chromosomal abnormalities, and malignancy.



Wisdom is a point of view on things

The real voyage of discovery consists not in seeking new landscapes,
but in having new eyes.

Marcel Proust

