XXXIII CONGRESSO NAZIONALE AIRO

AIRO2023

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27-29 OTTOBRE 2023
PALAZZO DEI CONGRESSI

Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

LINAC-Based STereotactic Arrhythmia Radioablation (STAR) for Paroxysmal Atrial Fibrillation in Elderly: results of the first worldwide prospective phase II trial

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Radioterapia Oncologica:
l'evoluzione al servizio dei pazienti

1. Fibrillazione Atriale

2. STUDIO STAR: obiettivi

3. STUDIO STAR: metodi

4. STUDIO STAR: risultati

5. STUDIO STAR: conclusioni

Fibrillazione Atriale

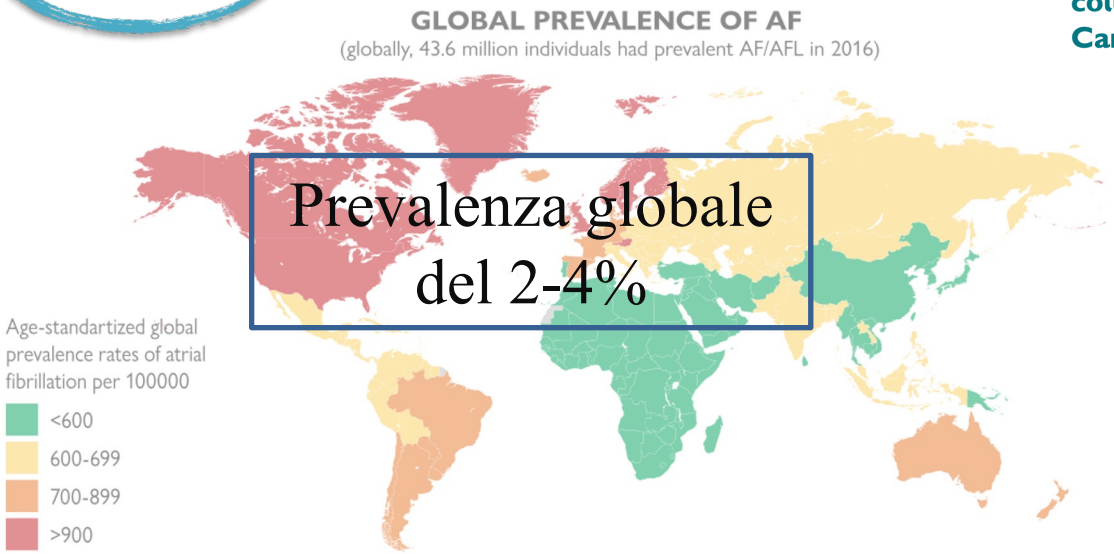
1.

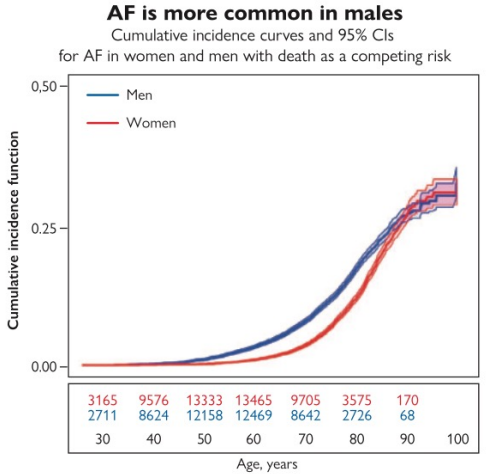
ESC European Society of Cardiology

European Heart Journal (2020) **42**, 373–498
doi:10.1093/eurheartj/ehaa612

ESC GUIDELINES

2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)



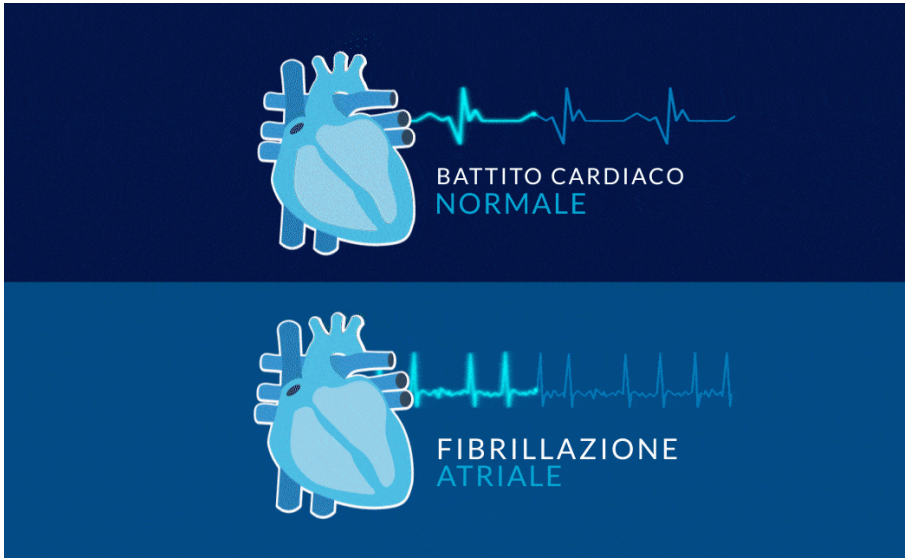


- ATTIVITÀ ELETTRICA INCOORDINATA

- CONTRAZIONE ATRIALE INEFFICACE

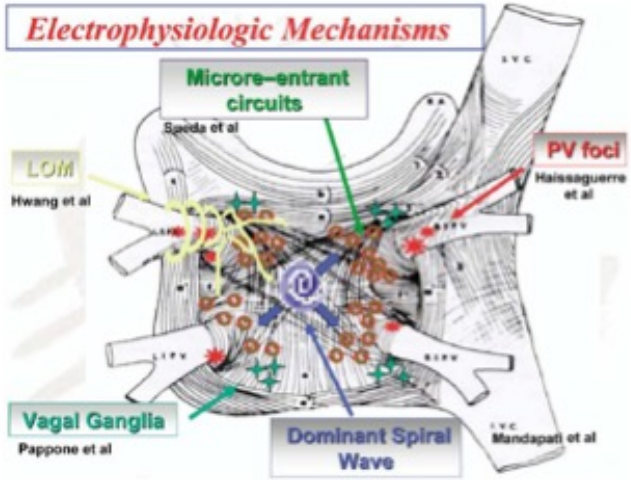
Conseguenze emodinamiche

-Scarso riempimento diastolico
- riduzione della gittata cardiaca
-Aumento delle pressioni nel circolo polmonare



Management della fibrillazione atriale

- terapia farmacologica antiaritmica
- cardioablazione trans-catetere (CA)



Foci ectopici nel 94% dei casi

2. STUDIO STAR: obiettivi

Linac-based STereotactic Arrhytmia Radioablation (STAR)

Studio prospettico Di fase II

(ClinicaTtrials.gov: NCT04575662)

nei pazienti anziani affetti da fibrillazione parossistica atriale

Farmaci antiaritmici nei paziente anziani sindrome tachi-brachi

effetti collaterali gravi della CA

Spesso pazienti anziani non sono candidabili ad altri trattamenti

SBRT nella FA solo case report

Linac-based STereotactic Arrhytmia Radioablation (STAR)

2. STUDIO STAR: obiettivi

Studio prospettico Di fase II
(ClinicaTtrials.gov: NCT04575662)
nei pazienti anziani affetti da fibrillazione parossistica atriale

- Endpoint primario → Sicurezza: effetti avversi di grado G3* ad un mese
- Endpoint secondari → *Recidive, AAT, tossicità tardive*

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Radioterapia Oncologica:
l'evoluzione al servizio dei pazienti

3 STUDIO STAR: metodi

Paroxysmal Atrial Fibrillation in Elderly: Worldwide Preliminary Data of LINAC-Based Stereotactic Arrhythmia Radioablation Prospective Phase II Trial

Antonio Di Monaco [1,2†], Fabiana Gregucci [3†], Ilaria Bonaparte [3], Federica Troisi [1], Alessia Surgo [3], Domenico Di Molfetta [4], Nicola Vitulano [1], Federico Quadrini [1], Roberta Carbonara [3], Gaetano Martinelli [4], Pietro Guida [1], Maria Paola Ciliberti [3], Alba Fiorentino [3] and Massimo Grimaldi [1]*

frontiers in Cardiovascular Medicine

BRIEF RESEARCH REPORT
published: 02 March 2022
doi: 10.3389/fcvm.2022.832446

J. Pers. Med. **2023**, *13*, 596. https://doi.org/10.3390/jpm13040596

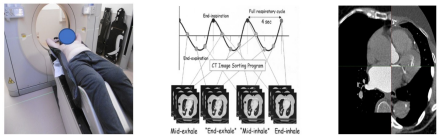
Brief Report

Phase II Trial of LINAC-Based STereotactic Arrhythmia Radioablation (STAR) for Paroxysmal Atrial Fibrillation in Elderly: Planning and Dosimetric Point of View

Ilaria Bonaparte [1], Fabiana Gregucci [1], Antonio Di Monaco [2,3], Federica Troisi [2], Alessia Surgo [1,*], Elena Ludovico [4], Roberta Carbonara [1], Eleonora Paulicelli [1], Giuseppe Sanfrancesco [1], Christian De Pascali [1], Nicola Vitulano [2], Federico Quadrini [2], Maria Paola Ciliberti [1], Imma Romanazzi [5], Fiorella Cristina Di Guglielmo [1], Davide Cusumano [6], Roberto Calbi [4], Massimo Grimaldi [2] and Alba Fiorentino [1,7]

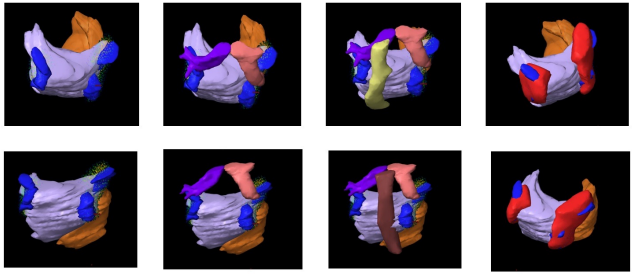
SimulationComputed Tomography

- A vac-lock bag was used for patients' immobilization in the supine position.
- Three Computed Tomography (CT, 1mm slice-thickness) were performed: 1) free-breathing CT for dose calculation; 2) 4-Dimension CT (4D-CT) for moving evaluation; 3) CT with contrast for anatomical accuracy.



(1) Basic free-breathing CT → (2) 4-Dimension CT → (3) CT with contrast

Contouring



(Blu) Pulmonary Veins; (Purple) Left Atrium; (Orange) Right Atrium; (Violet & Pink) Main Bronchus; (Yellow & Brown) Esophagus [taking into account latero-lateral dislocation]; (Red) Target Volume

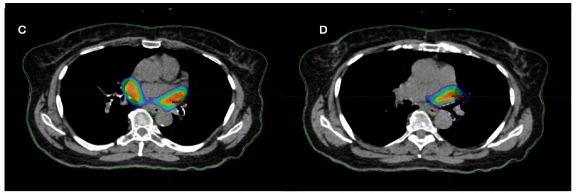


Figure 2. (**A**,**B**) PTV and ITV cropped from OaRs (esophagus and bronchus); (**C**,**D**) STAR Planning with simultaneous integrated protection dose.

Treatment planning

4. STUDIO STAR: risultati

Da Maggio 2021 Luglio 2022

58 elderly patients with sympromatic paroxysmal atrial fibrillation

38 exluded
- 25 met exclusion criteria
- 13 refused the treatment

20 patients enrolled

2 exluded
- 1 withdrew informed consent
- 1 for an anatomical reason

18 patients treated

2 refused to perform ECG-Holter monitoring at 12 months Follow up

16 completed Follow up visits as protocol

4. STUDIO STAR: risultati

Europace. 2023, in press

Follow-up medio di 16 mesi (3-24)
Età MEDIA 77,6 anni (71-90)
60% femmine

STUDY POPULATION (N=18)	
Age (years)	77±6
Gender	56% F
Smoking history	6 (33%)
Body Mass Index (Kg/m²)	26±3
Hypertension	16 (89%)
Dyslipidemia	11 (61%)
Diabetes mellitus	1 (5%)
Chronic renal failure	7 (39%)
Familiarity for cardiovascular disease	15 (83%)
Chronic obstructive pulmonary disease	4 (22%)
Dysthyroidism	7 (39%)
Coronary artery disease	1 (5%)
Valve surgery	0
Stroke	1 (5%)
EHRA Classification	III (14 PT) IV (4 PT)
Echocardiography	LA 44±6 mm; FE 55±5; no significant valvulopathies

Endpoint primario

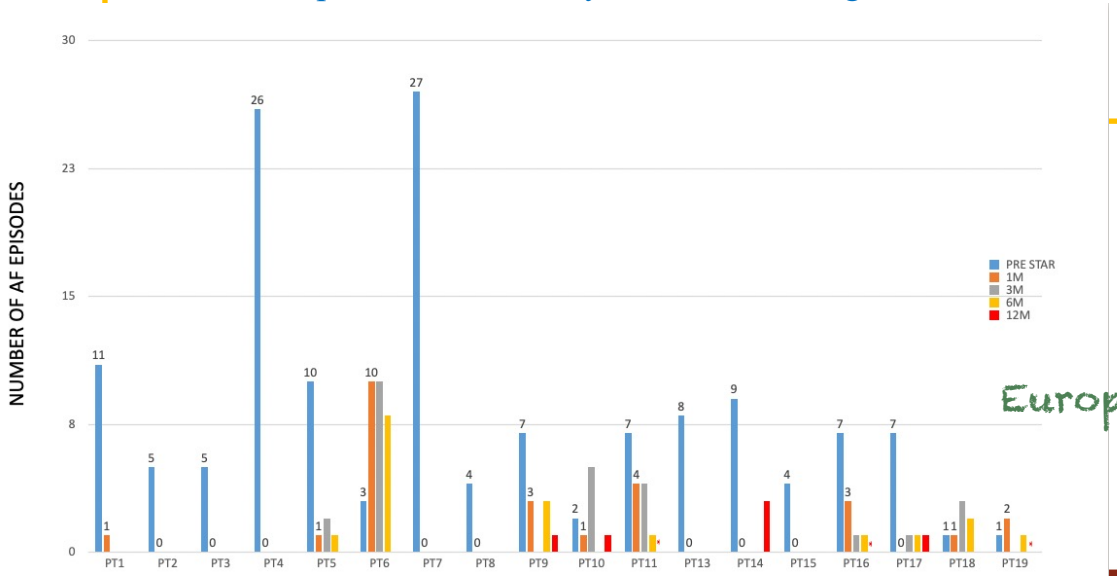
Sicurezza:
Nessun effetto avverso ≥ G2* ad un mese

- 5 patients (27.7%) had a mild esophagitis (grade 1) 24 hours after STAR, the symptoms resolved after 1 week using proton pump inhibitors and sucralfate.
- 8 patients (44.5%) experienced an asymptomatic mild (grade 1) pericardial effusion (max 2 mm): 2 patients after 1 month from STAR and their pericardial effusion completely resolved in 3 months; 6 patients after 6 months from STAR and 1 out 6 had a complete resolution while the other 5 patients had a stable asymptomatic mild pericardial effusion at 1-year FU
- Only 1 patient (5.5%) had a symptomatic (grade 3) pericardial effusion (about 5 mm) documented after 6 months from STAR; the pericardial effusion completely resolved in 2 months using pharmacological treatment with corticosteroids
- One patient had a clinically significant acute event after STAR: after 1 hour from treatment patient n. 13 had a torsade de pointes

Common Terminology Criteria for Adverse Events V. 5.0

Endpoint secondari

- Most patients had a significant reduction in AF episodes during FU,
- Seven patients were arrhythmia free during FU



Patient 12 and 20 did not perform STAR treatment. Patients 11, 16 and 19 had persistent atrial fibrillation after 6 months from STAR treatment (*). Patients 5,18,19 did not performed ECG Holter monitoring at 12 months FU

Figure 1

Europace. 2023, in press

- Compared to pre-treatment number of AF episodes (8 per patient over 15 days), the risk was significantly lower at each post-baseline time point with IRRs indicating a reduction greater than 80% (1-, 3-, 6-, 12-months)

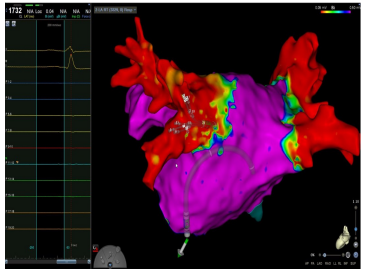
- A significant improvement of quality of life was documented after STAR (48±15 at enrollment vs 75±15 at 12 months FU; p<0.001).

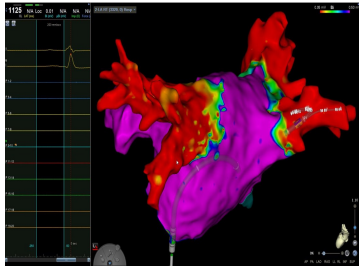
Table 4. Incidence rate of atrial fibrillation episodes by time since STAR treatment and risk of atrial fibrillation for time at risk after thereafter.

	Events per 15 days	Incidence Rate Ratios	p
Pre-treatment	8.00 (6.80-9.42)	1.00	
1-month	1.44 (0.98-2.12)	0.18 (0.12-0.27)	<0.001
3-month	1.44 (0.98-2.12)	0.18 (0.12-0.27)	<0.001
6-month	1.00 (0.63-1.59)	0.13 (0.08-0.20)	<0.001
12-month	0.56 (0.29-1.08)	0.07 (0.04-0.14)	<0.001

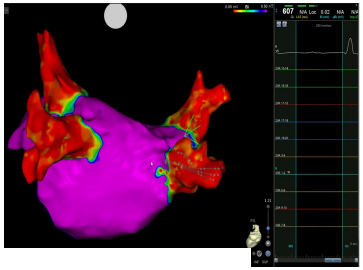
Europace. 2023, in press

Endpoint secondari





Circulation: Arrhythmia and Electrophysiology. 2022;15



RESEARCH LETTER

First Pulmonary Vein Isolation Using LINAC-Based STAR

Antonio Di Monaco, MD*; Fabiana Gregucci, MD*; Ilaria Bonaparte, MD; Federica Troisi, MD, PhD; Alessia Surgo, MD; Domenico Di Molfetta, MD; Nicola Vitulano, MD; Federico Quadrini, MD; Roberta Carbonara, MD; Elena Ludovico, MD; Maria Paola Ciliberti, MD; Alba Fiorentino, MD; Massimo Grimaldi, MD, PhD

Il primo paziente è stato sottoposto a mapping dell'atrio destro attraverso sistema CARTO e catetere Pentaray (Biosense Webster, Ca, USA) documentando isolamento delle vene polmonari, in assenza di stenosi.

Il secondo paziente ha eseguito una mappatura elettroanatomica documentando isolamento delle vene polmonari, in assenza di stenosi e aree a basso voltaggio in entrambi gli atri.

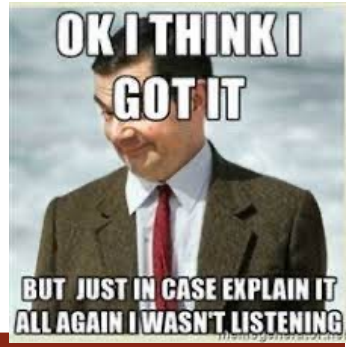
Non induzioni aritmiche dopo stimolazione atriale

Assenza di danni al nervo frenico

STUDIO STAR: conclusioni

- I risultati preliminari dello studio STAR sono promettenti
- Il trattamento è risultato sicuro in termini di tossicità
- Riduzione del burden aritmico significativo
- Migliore QoL dopo il trattamento
- valida alternativa per i pazienti fragili
- Necessari studi prospettici randomizzati

5.



Thanks for your attention