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# Stereotactic Arrhythmia Radioablation (STAR) for Paroxysmal Atrial Fibrillation in Elderly: Results of the First Worldwide Prospective Phase II Trial

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## Abstract

Objectives:

to investigate the feasibility of stereotactic arrhythmia radioablation (STAR) for the treatment of paroxysmal atrial fibrillation (AF) in elderly patients (NCT04575662).

Methods:

The inclusion criteria are age > 70 years, symptomatic AF, antiarrhythmic drugs intolerance or non-response. A sample size of 20 patients is planned to complete trial. All patients undergo to 4D CT simulation. The clinical target volume (CTV) is identified in the area around PVs. Internal target volume (ITV) and Organs at Risks (OaRs) planning risk volume (PRV) are created to compensate heart and respiratory movement. The planning target volume (PTV) is defined adding 0-3 mm to the ITV in all directions. STAR is performed with a total dose of 25Gy (single fraction).

Results:

From May 2021 and June 2022, the enrollment goal was achieved (20 enrolled patients). Eighteen patients underwent STAR. One patient withdrew informed consent before treatment and one patient was excluded after the enrollment due to the unfavorable anatomy. With a median follow-up of 16 months (range 12-23), no acute toxicity more than G3 was reported, demonstrating the safety of STAR in this setting of patients. Five patients had a G1 esophagitis 24 hours after STAR; the symptoms resolved after 1 week using proton pump inhibitors and sucralfate. Eight patients had an asymptomatic grade 1 pericardial effusion (max 2 mm) documented after 3-6 months from STAR treatment. Only, one patient had a clinically significant acute event after STAR. In particular, after 1 hour from STAR, patient 13 had a torsade de pointes treated effectively by electrical cardioversion and subsequent cardiac ICD implantation. It is not possible to determine if this event was due to STAR or to a chance.
Frequent atrial ectopies and atrial tachycardias episodes were documented in all patients during the first 2 months after STAR. Most patients had a significant reduction in AF episodes. Five patients performed electrophysiological study after STAR. Patient 1 and 3 performed the study after 6 months while patients 9,10 and 13 after 12 months from STAR. In all patients the electric ablation of PVs was highlighted.
Finally, a significant improvement of quality of life was documented (48±15 at enrollment vs 75±15 at 12 months FU; p< 0.001).

Conclusion(s):

The present phase II trial demonstrated the safety of STAR in AF elderly patients, reporting also promising results in terms of outcome and quality of life. Surely, robust data are needed.