

Paroxysmal Atrial Fibrillation in Elderly: Clinical and Dosimetric Data of LINAC-Based Stereotactic Arrhythmia Radioablation Prospective Phase II Trial

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Abstract

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Abstract

Objectives:

In elderly, paroxysmal atrial fibrillation (AF) is difficult to treat with drugs and catheter ablation due to the higher complication rate. Thus, non-invasive approaches should be favorite. STereotactic Arrhythmia Radioablation (STAR) was used for ventricular tachycardia, but no data are available for LINear ACcelerator (LINAC)-based STAR in AF patients. Based on this background, the primary and secondary endpoints of present prospective phase II trial are to evaluate, respectively, safety and efficacy of LINAC-based STAR for AF elderly patients. Here, clinical, dosimetric and planning data were reported.

Methods:

The study was designed as a prospective phase-II trial started in May 2021, conducted in a single, referral center (ClinicalTrials.gov: NCT04575662). The inclusion criteria were: patients aged over 70 years, with symptomatic paroxysmal AF; intolerance or non-response to anti-arrhythmic (ATT) drugs. The primary study endpoint was the 1-month post-STAR safety, as complete STAR delivery and no acute treatment-related adverse events more than G3, assessed according to the Common Terminology Criteria for Adverse Events (version 5.0). Secondary endpoints were: reductions in AF episodes and in AAT, overall survival. The sample size planning is 20 cases based on 95% success for the primary endpoint, with a significant level of 5% and a power of 90%. The date of the last follow-up was August 2022.

All patients underwent to the following simulation and treatment procedures. A vac-lock bag was used for patients' immobilization in the supine position and a Computed Tomography (CT, 1mm slice-thickness) was performed. The clinical target volume (CTV) was identified by radiation oncologist and cardiologist and was defined as the area around pulmonary veins. An internal target volume (ITV) was added to CTV to compensate heart and respiratory movement. The planning target volume (PTV) was defined adding 1-3 mm to the ITV. STAR was performed in free breathing with a PTV prescription total dose (Dp) of 25Gy in 1 fraction. A "simultaneous integrated protection" dose distribution was created at the interface between PTV and organs at risk in order to ensure the tolerability of critical structures. Flattening Filter Free Volumetric Modulated Arc Therapy (VMAT) plans were generated, optimized, and delivered by TrueBeam™ (Varian Medical System). Image-guided radiotherapy with Cone Beam CT and Surface-Guided RadioTherapy with Align-RT (Vision RT) were employed.

Results:

Patient enrollment was closed in July 2022 with an accrual of 20/20 (100%), of these 18 patients were treated, 1 withdrew consent for treatment and 1 was excluded due to unfavorable anatomy. All patients completed STAR. No acute treatment-related adverse events (\geq G2) at 1-month from procedure were registered. At a median follow up time of 6 months (range 11-1), 4 patients (25%) developed acute G1 esophagitis, resolved with local lenitive oral treatment and 2 patients (12%) reported a mild asymptomatic pericarditis to the 6-months control chest CT. In 1 patient, cardiac arrest occurred 15 minutes after the procedure, requiring cardiopulmonary resuscitation, without subsequent sequelae. No late side effects were

reported. After the treatment, in 16 patients no episode of AF was recorded anymore and no AAT were used, while 2 patients experienced a relapse of AF approximately 6 months after the procedure. Mean CTVs, ITVs and PTVs were 23.6 cc, 44.32 cc, 62.9 cc respectively; while the mean prescription isodose level and D2% were 76.5% and 31.2 Gy, respectively. Regarding organ at risk, average heart and left anterior descending artery (LAD) Dmean were 3.9 and 6.3 Gy, respectively; while mean Dmax for LAD, spinal cord, left and right bronchus and esophagus were 11.2, 7.5, 14.3, 12.4 and 13.6 Gy respectively. The Overall Treatment Time (OTT) was 3 minutes.

Conclusion(s):

Clinical data suggest that LINAC-based STAR in AF patients would appear to be a safe and effective treatment, although longer follow-up and a prospective phase III study will be needed to validate this evidence. Dosimetric and planning data showed an optimal target coverage, sparing surrounding tissue, in a 3 minute of OTT. Considering the large diffusion of LINAC in the world and the large incidence of AF in elderly population, the present results are interesting and promising. LINAC-based STAR for AF could represent a valid non-invasive alternative therapy for elderly who were excluded from catheter ablation.