



Cardiological safety of 5-fraction whole breast irradiation: SAFE-FORWARD trial

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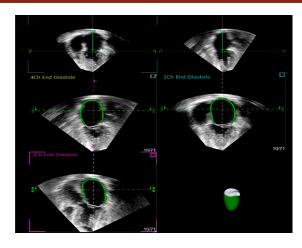
Disclosure

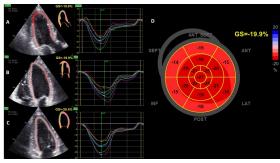
I have no conflicts of interest to disclose

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Purpose

- Our study aims to assess heart toxic effect in patients receiving a **5-fraction (total dose 26Gy)** postoperative radiation therapy (RT) for breast cancer (BC) using a reliable cardiac assessment:
 - standard and 3-dimensional (3D) echocardiography
 - left ventricular (LV) global longitudinal strain (GLS)





Material/Methods

- **SAFE-FORWARD** is an **observational prospective cohort study** (NCT04842409)
- Inclusion criteria were:
 - patients with invasive BC receiving ultra-hypofractionated whole breast irradiation (WBI) (26Gy in 5 fractions)¹ after breast conserving surgery (BCS)
 - 2. NO cardiovascular comorbidity
 - 3. NO previous thoracic irradiation/chemotherapy
- Prospective cardiac assessment for 12 months (baseline, at 2-, 6-, and 12-month after RT)
- Acute safety profile is evaluated according to CTCAE (v.5) scales
- Primary endpoint → detection of any subclinical impairment in myocardial function and deformation (decrease ≥10%) measured with standard and 3D echocardiography and LV GLS

WBI 26Gy in 5F - Constraints

		Objective	Costraint
PTV	24.7 Gy	≥ 95%	≥ 90%
	27.3 Gy	≤ 5%	≤ 7%
	27.8 Gy	-	≤ 2%
	Max Dose (D0.5cc)	-	≤ 28.6 Gy
Ipsilateral Lung	7.8 Gy	≤ 15%	≤ 17%
Heart	-	as low as possible	-
	6.5 Gy	-	≤ 5%
	1.3 Gy		≤ 30%

1. Brunt et al., Lancet 2020

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Results

- 50 women were enrolled in the study
- We analyzed 40 patients who had completed the cardiological assessment at 12 months

Table 1. Population's main characteristics.

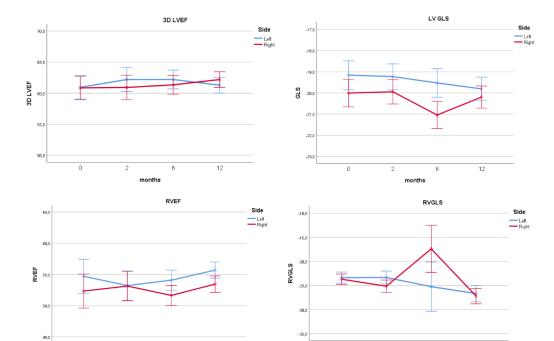
Variables	Patients (%)	
Age		
median	67 years	
range	48-84 years	
BMI		
median	23.88	
range	15.78 - 30.22	
Menopausal Status		
Premenopausal	3 (6%)	
Postmenopausal	47 (96%)	
Breas <mark>t side</mark>		
Left	27 (54%)	
Right	21 (42%)	
Bilateral	2 (4%)	
Pathological T Stage		
pT1	46 (92%)	
pT2	4 (8%)	
Pathological N Stage		
pN0-N1mi	43 (86%)	
pN1a	2 (4%)	
pNx	5 (10%)	
range	1-5	
DIBH		
у́вс	11 (22%)	
no:	39 (78%)	
-poor compliance	18 (46%)	
-right breast	21 (54%)	
Adjuvant Endocrine Therapy		
yes:	33 (66%)	
-Tamoxifen	3 (%)	
-AI	30 (91%)	
no	17 (34%)	

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Parameters	Left Breast (median; range)	Right Breast (median; range)
PTV cc	689 (326-1552)	840 (22-1689)
Ipsilateral Lung		
Volume (cc)	1911 (954-2954)	1636 (1222-2459)
MIN Value (cGy)	5.3 (0.4-78)	7.8 (1-20)
MAX Value (cGy)	2623 (2471-2780)	2626 (2516-2892)
Mean Value (cGy)	306 (145-412)	353 (77-420)
Heart		
Volume (cc)	554 (357-833)	609 (453-848)
MIN Value (cGy)	17.5 (2.7-130)	6.2 (3.8-46)
MAX Value (cGy)	2321 (397-2698)	143 (42-248)
Mean Value (cGy)	87.7 (48-275)	40 (25-139)

Fast Forward trial constraints were respected for all patients

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months

3D-LVEF remains stable during observation, both for the left- and right-side treated breast

GLS worsened 4% or less, both for the left- and right-side treated breast, and remained in normal range for all the time points

The **only exception was for RVGLS** at 6 months for right-sided treatment where it reached a borderline value (-17.4±4.9 SE)

months

12

AIRO2023 Conclusion



THE 5-FRACTION SCHEDULE AFTER BCS IS WELL TOLERATED



THE INTENSIVE 1-YEAR CARDIOLOGICAL MONITORING SHOWED NO SIGNIFICANT DIFFERENCES OVERTIME IN CARDIAC FUNCTIONING

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GRAZIE A TUTTI PER L'ATTENZIONE

