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Acute toxicity associated with a 3-week versus a standard 5-week regimen for locoregional breast radiotherapy delivered in the UNICANCER HypoG-01 phase III trial

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Background

In most countries, the 5-week normofractionated (NF) locoregional radiotherapy (RT) is still the standard of care for breast cancer with an indication for regional lymph node irradiation. HypoG-01 (NCT03127995) is a randomized phase 3 clinical trial evaluating the safety and efficacy of a 3-week moderate hypofractionated (HF)-RT against NF-RT regimen. Here, we report for the first time the acute toxicity results, a secondary endpoint of the trial.

Methods

Women with pT1-3 pN0-3 M0 breast cancer were randomized 1:1 after surgery to receive either HF-RT: 40 Gy/15 fractions/3 weeks or NF-RT: 50 Gy/25 fractions/5 weeks. Acute toxicities were graded using CTCAE V4.0 at baseline, weekly during RT, and 1 month after the end of RT (end of treatment visit); the maximum grading is reported. Since arm lymphedema is the primary endpoint of the trial, it is not included in the acute toxicities of interest.

Results

From 09/2016 to 03/2020, 29 French sites enrolled 1265 women (HF-RT arm: 633, NF-RT arm: 632). All patients (median age: 58 years) received their allocated RT and completed their scheduled end of treatment visit. Acute grade 3 toxicities were rare in both treatment arms (HF-RT: 5.4%, NF-RT: 5.7%) and no grade 4-5 toxicities were observed (Table). The rate of overall grade 2 or higher acute toxicities was lower with HF-RT (38.4%) than with NF-RT (48.1%). Grade 2 or higher dermatitis were more frequent in patients with BMI ≥30 in both arms: 34/118 (29%) in HF-RT and 59/124 (48%) in NF-RT. In total 18 patients experienced at least 1 acute Serious Adverse Event (HF-RT: 10, NF-RT: 8) of which only 2 were considered treatment-related (HF-RT: 1, NF-RT: 1).Table: 121MO

Acute adverse events of interest

	HF-RT				NF-RT				TOTAL
	G 1 n (%)	G 2 n (%)	G 3 n (%)	HF Total n (%)	G 1 n (%)	G 2 n (%)	G 3 n (%)	NF Total n (%)	n (%)
Dermatitis	418 (66)	82 (13)	9 (1)	509 (80)	365 (58)	183 (29)	13 (2)	561 (89)	1070 (85)
Fatigue	263 (42)	41 (6)	4 (1)	308 (49)	293 (46)	45 (7)	4 (1)	342 (54)	650 (51)
Pain	223 (35)	39 (6)	4 (1)	266 (42)	246 (39)	46 (7)	3 (0)	295 (47)	561 (44)
Dysphagia	109 (17)	16 (3)	-	125 (20)	135 (21)	11 (2)	-	146 (23)	271 (21)
Pruritus	112 (18)	10 (2)	-	122 (19)	155 (25)	10 (2)	3 (0)	168 (27)	290 (23)
Dyspigmentation	74 (12)	4 (1)	-	78 (12)	69 (11)	11 (2)	2 (0)	82 (13)	160 (13)
Respiratory disorders	88 (14)	11 (2)	1 (0)	100 (16)	125 (20)	11 (2)	2 (0)	138 (22)	238 (19)
Cardiac disorders	3 (0)	2 (0)	1 (0)	6 (1)	1 (0)	-	1 (0)	2 (0)	8 (1)

Conclusions

In women receiving locoregional RT, acute toxicities with a 3-week moderately hypofractionated regimen were mild and raised no important acute safety concerns. Further long-term follow-up is ongoing.

Clinical trial identification

NCT03127995, Release date: 23/06/2016

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Legal entity responsible for the study

UNICANCER.

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