I Sessione

L'irradiazione convenzionale nella pratica clinica: frazionamento obsoleto o ancora attuale?

Moderatori: A. Di Grazia, A. Ciabattoni

Rapporteur: M.C. De Santis

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IV ZOOM Journal Club 2014

Bologna, 20 Febbraio 2015

Associazione Italiana Radioterapia Oncologica

Hypofractionated Radiotherapy: the randomized trial

Trial	Canadian		RMH/GOC			START A			START B	
No. patients	1234		1410			2236			2215	
Med. follow-up	12 years		9.7 years			9.3 years			9.9 years	
Patient/tumor characteristics	pT1-2 N0, breast width ≤25 cm		T1-3 N0-1, age <75 years			pT1-3a N0-1, age >18 years			pT1-3a N0-1, age >18 years	
Surgery	BCS + ALND		BCS ± ALND			BCS ± ALND (85%), mastectomy (15%)			BCS ± ALND (92%), mastectomy (8%)	
Margin status	No tumor on ink		Macroscopically clear margins			≥1 mm			≥1 mm	
Systemic therapy	HT 42%, CT 11%		HT 65%, CT 3%, HT + CT 11%			HT 54%, CT 11%, HT + CT 25%			HT 72%, CT 7%, HT + CT 15%	
Comments	No boost or RNI		14 Gy boost 75%, RNI 21%			10 Gy boost 61%, RNI 14%			10 Gy boost 43%, RNI 7%	
Total dose/no. fractions/weeks	50/25/5	42.5/16/3.2	50/25/5	42.9/13/5	39/13/5	50/25/5	41.6/13/5	39/13/5	50/25/5	40/15/3
IBTR	6.7%	6.2%	12.1%	9.6%	14.8%	7.4%	6.3%	8.8%	5.5%	4.3%
OS[a]	84.4%	84.6%	68% (pooled)			88.9%	88.7%	89.3%	89%	92%
Cosmesis										
Good–excellent	71.3%	69.8%								
Grade 2–3 skin/subcut tissue toxicity	7.7%/10.4%	8.9%/11.9%								
Any photographic change			35%	42%	27%					
			$p < 0.001$ (comparing all 3)							
Overall fair/poor			61%	66%	51%					

No difference in LR and Toxicity

Irradiazione convenzionale frazionamento obsoleto o ancora attuale?

1. TOX → cardiotossicità; ChT

1. Caratteristiche T e pazienti (mastectomia e N; classificazione biologiche e G; età e volume mammario)

2. DCIS → HFRT +/- boost

Is it necessary to avoid hypofractionated radiotherapy in patients with some risk factors such as hypertension and diabetes that can be correlated with higher cardiotoxicity?

Is it necessary to consider more restrictive constraints in hypofractionated radiotherapy?

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Original article

Long-term mortality from cardiac causes after adjuvant hypofractionated vs. conventional radiotherapy for localized left-sided breast cancer

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5334 pts;median FUP 14.2 years

Left-sided cases					Right-sided cases				
Variable	Statistic	CF-WBI ($N = 485$)	HF-WBI ($N = 2221$)	p-Value*	Variable	Statistic	CF-WBI ($N = 455$)	HF-WBI ($N = 2173$)	p-Value*
Age at diagnosis	Median [IQR]	58 [50–66]	58 [48–68]	0.82	Age at diagnosis	Median [IQR]	57 [49–66]	58 [47–68]	0.54
Summary stage	Stage 1	319 (66%)	1460 (66%)	0.99	Summary stage	Stage 1	296 (65%)	1473 (68%)	0.26
	Stage 2	166 (34%)	761 (34%)			Stage 2	159 (35%)	700 (32%)	
Grade	Grade 1	73 (15%)	403 (18%)	0.36	Grade	Grade 1	85 (19%)	390 (18%)	0.61
	Grade 2	233 (48%)	1044 (47%)			Grade 2	217 (48%)	1042 (48%)	
	Grade 3	148 (31%)	704 (32%)			Grade 3	127 (28%)	671 (31%)	
	Unknown	31 (6%)	70 (3%)			Unknown	26 (6%)	70 (3%)	
ER status	ER −ve	103 (21%)	421 (19%)	0.12	ER Status	ER −ve	90 (20%)	452 (21%)	0.58
	ER +ve	298 (61%)	1482 (67%)			ER +ve	307 (67%)	1433 (66%)	
	Unknown	84 (17%)	318 (14%)			Unknown	58 (13%)	288 (13%)	
Hypertension	No	434 (89%)	2042 (92%)	0.08	Hypertension	No	413 (91%)	2021 (93%)	0.10
	Yes	51 (11%)	179 (8%)			Yes	42 (9%)	152 (7%)	
Diabetes	No	461 (95%)	2161 (97%)	0.01	Diabetes	No	429 (94%)	2126 (98%)	<0.0001
	Yes	24 (5%)	60 (3%)			Yes	26 (6%)	47 (2%)	
Other cardiac risks	No	467 (96%)	2168 (98%)	0.10	Other cardiac risks	No	445 (98%)	2134 (98%)	0.56
	Yes	18 (4%)	53 (2%)			Yes	10 (2%)	39 (2%)	
Non-cardiac comorbidities	No	470 (97%)	2151 (97%)	0.94	Non-cardiac comorbidities	No	447 (98%)	2109 (97%)	0.16
	Yes	15 (3%)	70 (3%)			Yes	8 (2%)	64 (3%)	
Surgery type	Lumpectomy	478 (99%)	2127 (96%)	0.003	Surgery type	Lumpectomy	450 (99%)	2102 (97%)	0.01
	Mastectomy	7 (1%)	94 (4%)			Mastectomy	5 (1%)	71 (3%)	
Boost	No	311 (64%)	1598 (72%)	0.001	Boost	No	266 (58%)	1633 (75%)	<0.0001
	Yes	174 (36%)	623 (28%)			Yes	189 (42%)	540 (25%)	
Hormones	No	315 (65%)	1437 (65%)	0.79	Hormones	No	287 (63%)	1476 (68%)	0.04
	Yes	166 (34%)	779 (35%)			Yes	167 (37%)	688 (32%)	
	Unknown	<5 (<1%)	5 (0.2%)			Unknown	<5 (<1%)	9 (0.4%)	
Chemotherapy	No	375 (77%)	1688 (76%)	0.54	Chemotherapy	No	363 (80%)	1645 (76%)	0.06
	Yes	110 (23%)	533 (24%)			Yes	92 (20%)	528 (24%)	
T stage	⩽2 cm	366 (75%)	1689 (76%)	0.79	T stage	⩽2 cm	352 (77%)	1698 (78%)	0.72
	>2 cm	119 (25%)	532 (24%)			>2 cm	103 (23%)	475 (22%)	
N stage	0 nodes +ve	398 (82%)	1739 (78%)	0.51	N stage	0 nodes +ve	350 (77%)	1709 (79%)	0.09
	⩾1 nodes +ve	75 (15%)	359 (16%)			⩾1 nodes +ve	87 (19%)	339 (16%)	
	Unknown	12 (2%)	123 (6%)			Unknown	18 (4%)	125 (6%)	
Year of diagnosis	1990–1992	137 (28%)	562 (25%)	0.11	Year of diagnosis	1990–1992	133 (29%)	551 (25%)	0.11
	1993–1995	173 (36%)	746 (34%)			1993–1995	160 (35%)	745 (34%)	
	1996–1998	175 (36%)	913 (41%)			1996–1998	162 (36%)	877 (40%)	

Note: Unknowns removed before computing statistical test p-values

* Differences between fractionation groups were compared using the chi-squared test and Wilcoxon Rank-Sum test separately for left and ride sided cases.

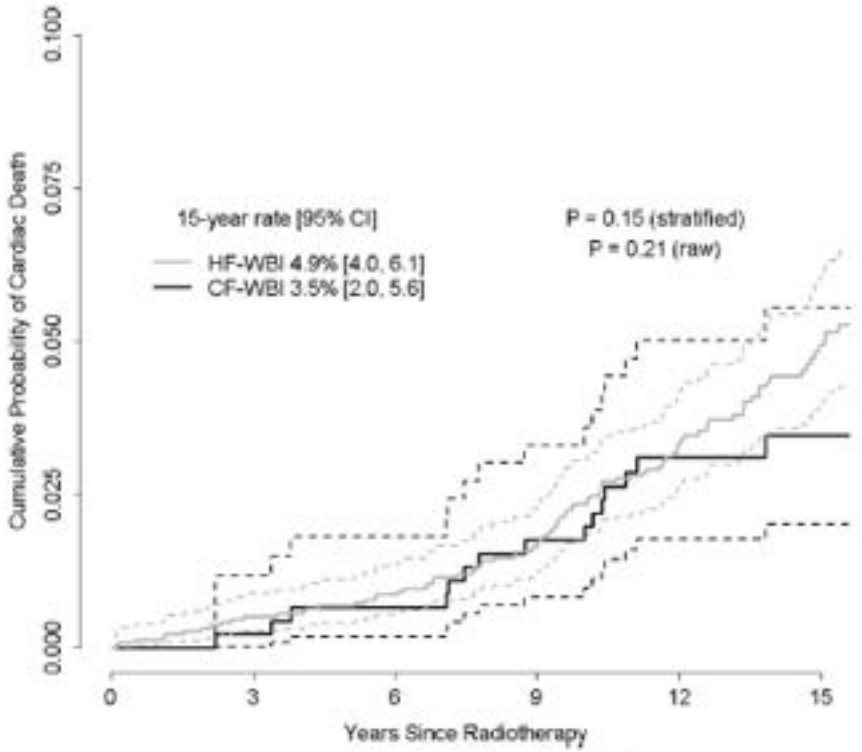


Fig. 2. Cumulative mortality due to cardiac cause for right-sided cases. Gray solid line indicates HF-WBI (hypofractionated whole breast radiotherapy) group; black solid line, CF-WBI (conventional fractionated whole breast radiotherapy) group; dotted gray and black lines indicate 95% confidence interval for HF-WBI and CF-WBI groups respectively. *p* Values are calculated using Gray's test using unadjusted or the propensity score model.

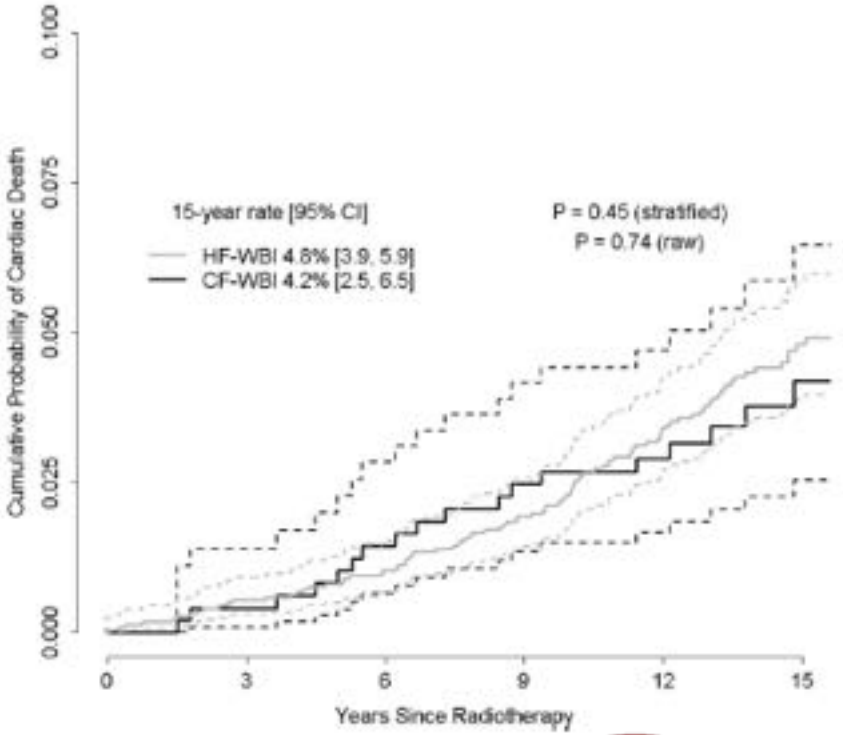


Fig. 1. Cumulative mortality due to cardiac cause for left-sided cases. Gray solid line indicates HF-WBI (hypofractionated whole breast radiotherapy) group; black solid line, CF-WBI (conventional fractionated whole breast radiotherapy) group; dotted gray and black lines indicate 95% confidence interval for HF-WBI and CF-WBI groups respectively. *p* Values are calculated using Gray's test using unadjusted or the propensity score model.

NO DIFFERENCE:
NO CONSTRAINTS USED

Hypofractionation in chemotherapy setting

World Journal

Table 2 Incidence of acute skin toxicity in terms of previous chemotherapy or not

		EORTC/RTOG radiation induced acute skin toxicity grade				Total
		0	1	2	3	
Chemotherapy	No	56/83 (67.5%)	18/83 (21.7%)	7/83 (8.4%)	2/83 (2.4%)	83
	Yes	16/33 (48.5%)	14/33 (42.4%)	2/33 (6.0%)	1/33 (3.0%)	33
Total		72/116 (62.1%)	32/116 (27.6%)	9/116 (7.8%)	3/116 (2.6%)	116

No significant correlation was noted (Pearson χ^2 $P = 0.15$). EORTC/RTOG: Organization for Research and Treatment of Cancer/Radiation Therapy.

NO TOXICITY

...rapy and acute toxicity in ...ted radiotherapy for early breast cancer

...ssilis Kouloulias, Anna Zygogianni, Efrosini Kypraiou, John Georgakopoulos, Zoi Thrapsanioti, Ivelina Beli, Eftychia Mosa, Amanta Psyrri, Christos Antypas, Christina Armbilia, Maria Tolia, Kalliopi Platoni, Christos Papadimitriou, Nikolaos Arkadopoulos, Costas Gennatas, George Zografos, George Kyrgias, Maria Dilvoi, George Patatoucas, Nikolaos Kelekis, John Kouvaris

Table 3 Logistic regression analysis performed for analyzing the contribution of age, chemotherapy and radiotherapy fractions (19 *vs* 20) to the development of acute radiation induced skin toxicity

	Univariate analysis			Multivariate analysis		
	P	RR	95%CI	*P*	RR	95%CI
Age	0.31	-	-	0.41	-	-
Chemotherapy	0.05	2.35	1.01-5.52	0.057	-	-
19 *vs* 20 fractions	0.55	-	-	0.66	-	-

The univariate model chi-square with 3 degrees of freedom was 4.97 ($P = 0.17$). None of the variables entered to the multivariate model. RR: Risk ratio.

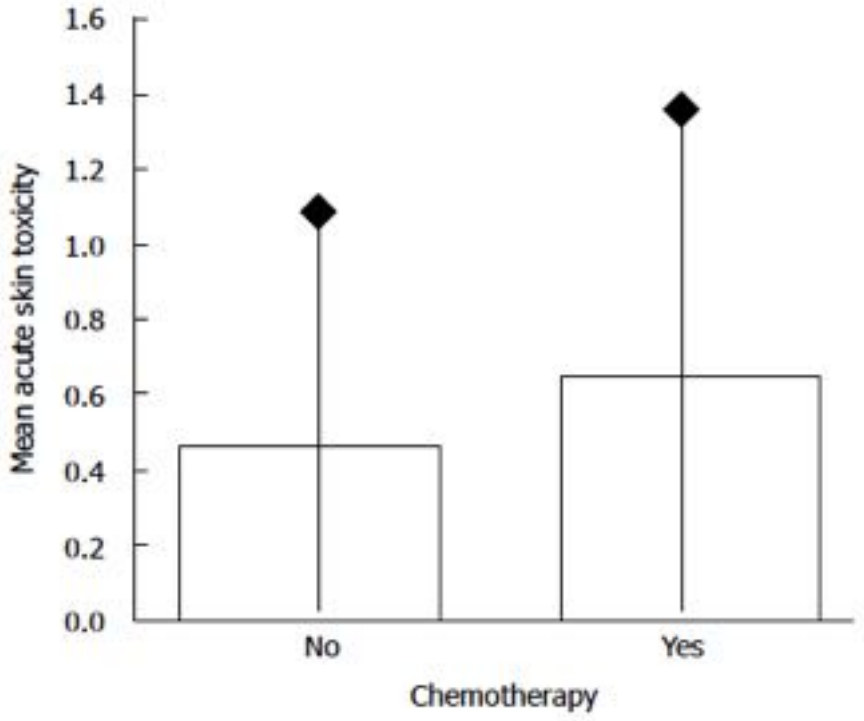
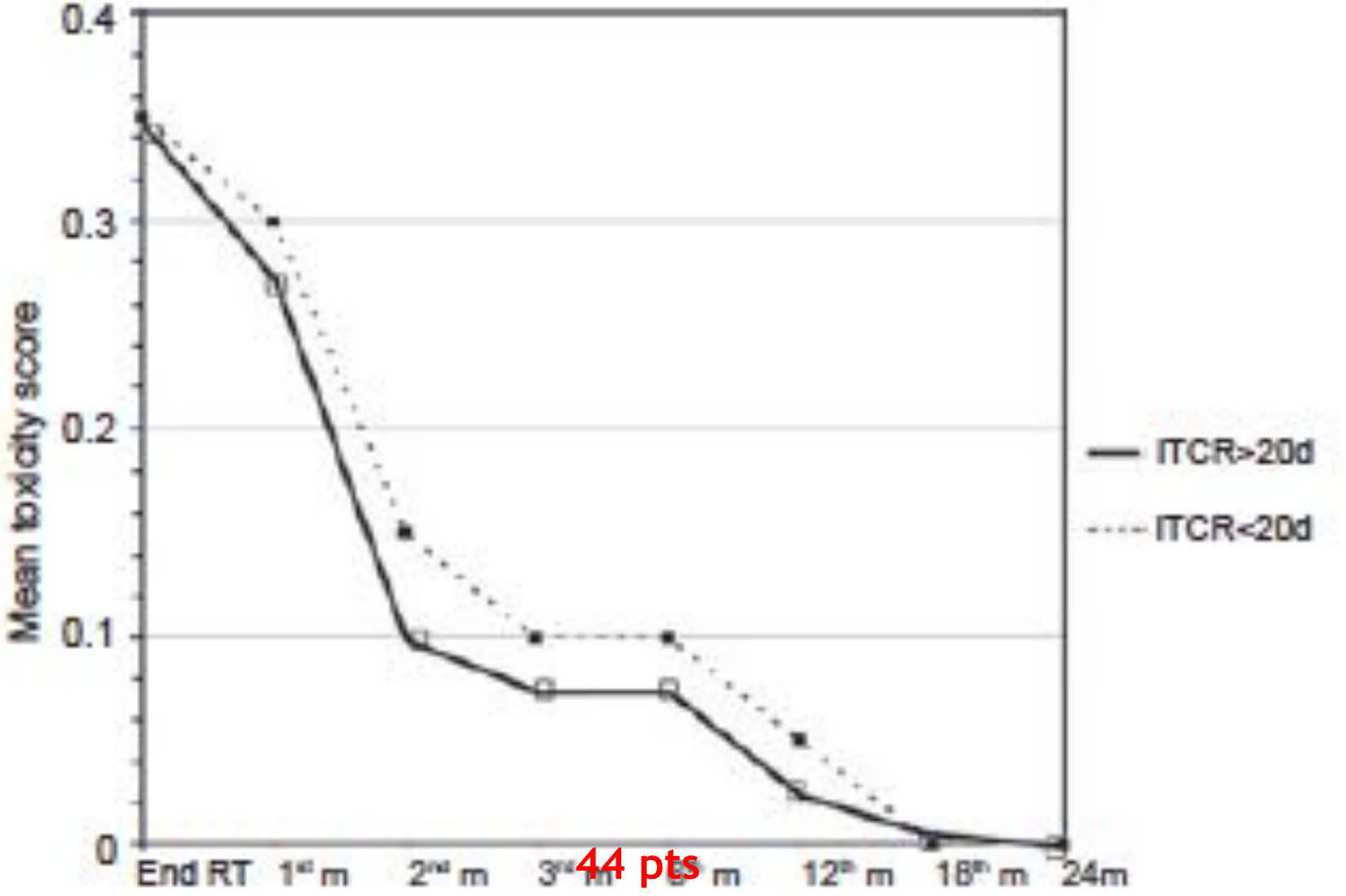


Figure 1 Mean acute skin toxicity score for patients undergone chemotherapy or not ($P = 0.109$, Mann Whitney test).



44 pts
mean FU 7 years
53 Gy/20 fr (2.65Gy/fr)
CT WITH CMF

Figure 2. The toxicity according to the intermediate time between radiotherapy and chemotherapy.

Irradiazione convenzionale frazionamento obsoleto o ancora attuale?

1. TOX → cardiotossicità; ChT

1. Caratteristiche T e pazienti (mastectomia e N; classificazione biologiche e G; età e volume mammario)

2. DCIS → HFRT +/- boost

Hypofractionation in Grade 3 tumor

CANADIAN TRIAL → *the 10-year risk of local recurrence was 15.6% compared to 4.7% in the conventional fractionation arm*

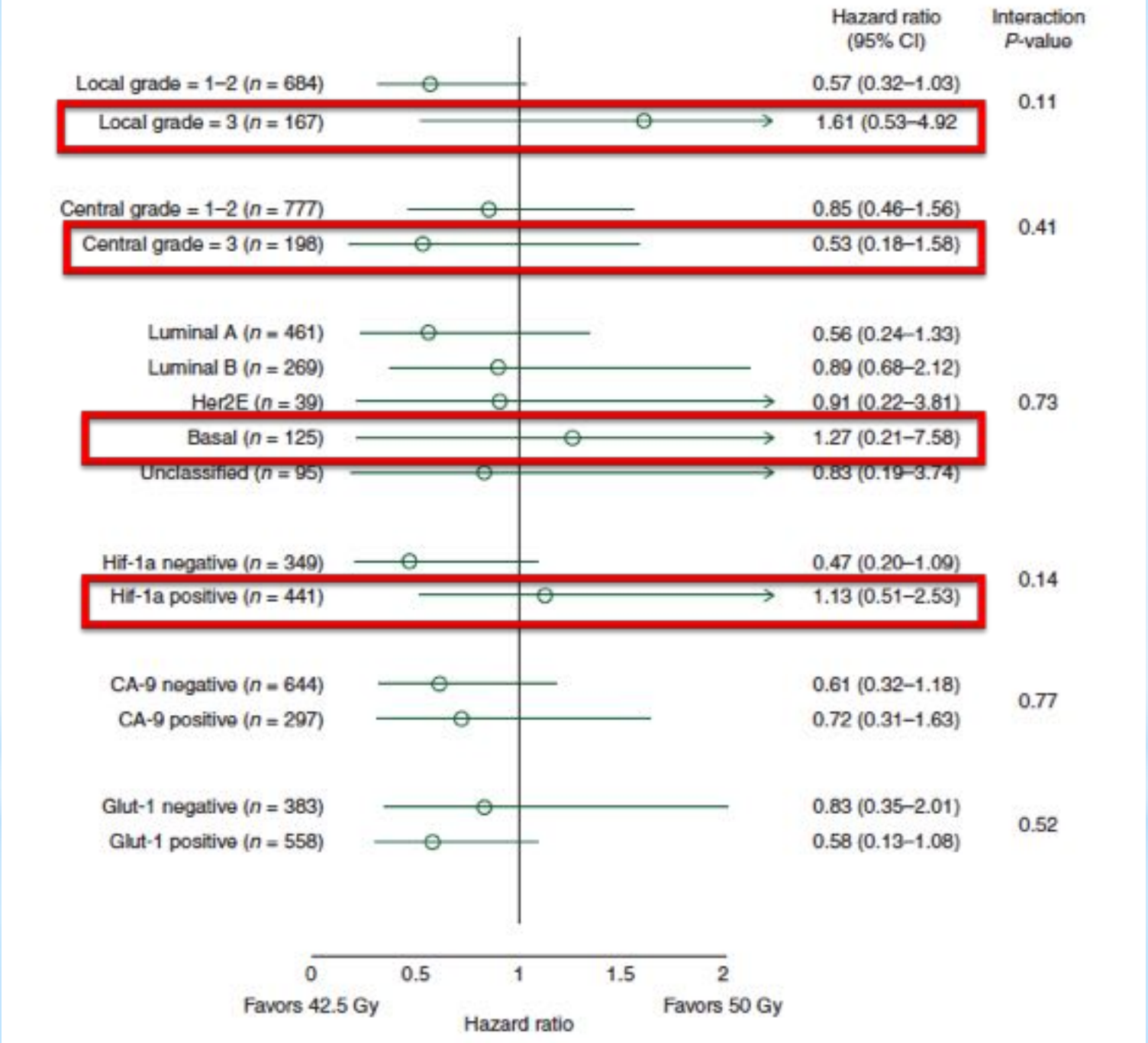
METANALYSIS OF START A/B and RMH/GOCTRIAL
Haviland et al NEJM 2010
Herbert et al IJROBP 2012
→ *No difference*

Bane et al. Annals of Oncology 2014

Tumor factors predictive of response to hypofractionated radiotherapy in a randomized trial following breast conserving therapy

Table 2. Baseline tumor characteristics and outcomes

		Luminal A ($N = 461$)	Luminal B ($N = 269$)	HER2E[b] ($N = 39$)	Basal ($N = 125$)	Unclassified ($N = 95$)	*P*-value
Age	≥50 years	377 (81.8)	182 (67.7)	28 (71.8)	71 (56.8)	79 (83.2)	<0.001[c]
Size	>2 cm	62 (13.5)	68 (25.3)	13 (33.3)	42 (33.6)	14 (14.7)	<0.001[c]
Prior adjuvant	Tamoxifen	238 (51.6)	124 (46.1)	6 (15.4)	16 (12.8)	33 (34.7)	<0.001[c]
systemic therapy	Chemotherapy	12 (2.6)	22 (8.2)	12 (30.8)	64 (51.2)	11 (11.6)	
	None	211 (45.8)	123 (45.7)	21 (53.9)	45 (36.0)	51 (53.7)	
Grade (Nottingham)	I	125 (30.4)	29 (12.6)	1 (3.2)	3 (2.9)	20 (26.3)	<0.001[c]
	II	273 (66.4)	155 (67.4)	17 (54.8)	18 (17.5)	43 (56.6)	
	III	13 (3.2)	46 (20.0)	13 (41.9)	82 (79.6)	13 (17.1)	
Local Recurrence-free	*n* (%) Censored	439 (95.2)	248 (92.2)	31 (79.5)	120 (96.0)	88 (92.6)	<0.001[d]
survival	10-year (95% CI)	95.5 (93.0–97.2)	92.1 (87.8–95.0)	83.1 (66.2–92.1)	95.5 (89.5–98.1)	93.0 (85.0–96.8)	
Radiation treatment received	50 Gy	230 (49.9)	125 (46.5)	22 (56.4)	57 (45.6)	47 (49.5)	
HIF-1α	Positive[a]	170/373 (45.6)	145/238 (60.9)	22/32 (68.8)	93/110 (84.6)	11/37 (29.7)	<0.001[c]
CA-IX	Positive[a]	98/446 (22.0)	94/257 (36.6)	18/34 (52.9)	79/121 (65.3)	8/83 (9.6)	<0.001[c]
GLUT-1	Positive[a]	222/446 (49.8)	195/258 (75.6)	24/34 (70.6)	99/121 (81.8)	18/82 (22.0)	<0.001[c]
Disease-free survival		*n* (%) Censored	709 (71.7)	180 (73.5)	0.72[c]	889 (72.0)	
		10-year (95% CI)	76.6 (73.8–79.2)	78.3 (72.4–83.1)		77.0 (74.5–79.3)	
Overall survival		*n* (%) Censored	780 (78.9)	206 (84.1)	0.13[c]	986 (79.9)	
		10-year (95% CI)	84.2 (81.7–86.4)	86.3 (81.1–90.2)		84.6 (82.4–86.5)	
Radiation treatment received		50 Gy	481 (48.6)	131 (53.5)	0.18[a]	612 (49.6)	
		42.5 Gy	508 (51.4)	114 (46.5)		622 (50.4)	


Hazard ratio (95% CI)
Interaction P-value
Local grade = 1–2 (n = 684)
0.57 (0.32–1.03)
0.11
Local grade = 3 (n = 167)
1.61 (0.53–4.92)
Central grade = 1–2 (n = 777)
0.85 (0.46–1.56)
0.41
Central grade = 3 (n = 198)
0.53 (0.18–1.58)
Luminal A (n = 461)
0.56 (0.24–1.33)
Luminal B (n = 269)
0.89 (0.68–2.12)
Her2E (n = 39)
0.91 (0.22–3.81)
0.73
Basal (n = 125)
1.27 (0.21–7.58)
Unclassified (n = 95)
0.83 (0.19–3.74)
Hif-1a negative (n = 349)
0.47 (0.20–1.09)
0.14
Hif-1a positive (n = 441)
1.13 (0.51–2.53)
CA-9 negative (n = 644)
0.61 (0.32–1.18)
0.77
CA-9 positive (n = 297)
0.72 (0.31–1.63)
Glut-1 negative (n = 383)
0.83 (0.35–2.01)
0.52
Glut-1 positive (n = 558)
0.58 (0.13–1.08)
0
0.5
1
1.5
2
Favors 42.5 Gy
Favors 50 Gy
Hazard ratio

A randomized phase III trial ongoing(NCT00793963)

A. Montero et al. The Breast 2014

Table 1. Key patient characteristics

Chest wall, supraclavicular region and axilla	29 (21.8)
Chemotherapy	
Yes	89 (66.9)
No	44 (33.0)
Hormone therapy	
Yes	84 (63.2)
No	49 (36.8)

Table 3. Acute toxicities from hypofractionated radiotherapy

	Number of patients (%)		
	Skin	Lethargy	Chest wall pain
Grade[8]			
No toxicity	17 (14.0)	52 (48.1)	74 (81.3)
Grade 1	91 (75.2)	52 (48.1)	13 (14.3
Grade 2	13 (10.7)	4 (3.7)	3 (3.3)
Grade 3	0 (0.0)	0 (0.0)	1 (1.1)
Total graded	121	108	91

LRFS 97.6%

133 pts (2003-2008)
median FU 5 years
40Gy/16 fr

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Phase III randomised trial

Hypofractionated whole breast irradiation for patients with large breasts: A randomized trial comparing prone and supine positions

Thomas Mulliez [a,*], Liv Veldeman [a], Annick van Greveling [a], Bruno Speleers [a], Simin Sadeghi [a], Dieter Berwouts [a], Frederik Decoster [a], Tom Vercauteren [a], Werner De Gersem [a], Rudy Van den Broecke [b], Wilfried De Neve [a]

[a] Department of Radiotherapy; [b]Department of Gynaecology, Ghent University Hospital, Belgium

homogeinity in the PTV

advances (prone position; IMRT)

A. Montero et al. The Breast 2014

Table 2
Dose-volume statistics.

Organ	Dose-volume	Treatment group		*p*-value
		Supine	Prone	
PTV_{optim}	Coverage (%)	92.7 ± 4.9	96.2 ± 2.2	**<0.001**
	Homogeneity	0.87 ± 0.04	0.90 ± 0.04	**<0.001**
	V_{105} (cc)	30.9 ± 40.4	8.9 ± 17.7	**<0.001**
	V_{107} (cc)	7.6 ± 12.6	0.9 ± 2.7	**<0.001**
Heart	D_{mean} (Gy)	2.0 ± 1.1	1.5 ± 0.6	0.08
	D_{max} (Gy)	12.1 ± 9.5	9.7 ± 6.5	0.25
	V_5 (%)	5.9 ± 5.5	3.8 ± 3.9	0.09
	V_{20} (%)	1.4 ± 2.3	0.7 ± 0.9	0.12
LAD	D_{mean} (Gy)	9.3 ± 6.5	5.4 ± 3.7	**0.007**
	D_{max} (Gy)	23.0 ± 11.7	19.5 ± 11.1	0.25
Ipsilateral lung	D_{mean} (Gy)	3.8 ± 1.1	1.1 ± 0.9	**<0.001**
	D_{max} (Gy)	26.6 ± 6.5	8.6 ± 8.9	**<0.001**
	V_5 (%)	16.9 ± 5.7	2.9 ± 3.7	**<0.001**
	V_{20} (%)	5.5 ± 3.3	0.9 ± 2.1	**<0.001**

The role of the boost in Hypofractionated Radiotherapy

NO CONSENSUS

Table 8 Univariate and multivariate analysis predictive factors for late radiation induced subcutaneous toxicity

Variables	Univariate analysis	Multivariate analysis
	p value	*p* value [OR]
Chemotherapy	0.118	= 0.0184 [OR 2.5923 (1.1745 – 5.7217)]
Hypertension	0.705	0.731
Age	0.956	0.223
Breast volume	0.694	0.483
Diabetes	= 0.0283	0.055
Surgical deficits	0.854	0.499
Boost administration	0.5157	0.298
V > 100%	-	0.745
V > 104%	-	= 0.00864 [OR 0.07605 (0.01122 – 0.51517)]
V > 107%	-	= 0.02045 [OR 6.26889 (1.33829 – 29.36504)]
Boost V > 100%	-	0.728
Boost V > 104%	-	0.099
Boost V > 107%	-	0.585

Table 7 Univariate and multivariate analysis predictive factors for late radiation induced skin toxicity

Variables	Univariate analysis	Multivariate analysis
	p value	*p* value [OR]
Chemotherapy	0.118	0.232
Hypertension	0.949	0.898
Age	0.603	0.087
Breast volume	0.620	0.692
Diabetes	0.196	0.139
Surgical deficits	0.323	0.890
Boost administration	= 0.007174	= 0.0119 [OR 3.056 (1.280 - 7.297)]
V > 100%	-	0.642
V > 104%	-	0.466
V > 107%	-	0.908
Boost V > 100%	-	0.981
Boost V > 104%	-	0.684
Boost V > 107%	-	0.615

212 pts
median FU 34 months
40.05 Gy/15 fr +/- 9 Gy/3 fr boost

The boost administration was resulted to be a significant adverse prognostic factor for acute and late toxicity

Irradiazione convenzionale frazionamento obsoleto o ancora attuale?

1. TOX → cardiotossicità; ChT

1. Caratteristiche T e pazienti (mastectomia e N; classificazione biologiche e G; età e volume mammario)

2. DCIS → HFRT +/- boost

Table 1
Characteristics of eligible studies.

Author, year	Country	No of patients	Median follow-up	Total dose/fraction (standard)	Total dose/fraction (hypofractionated)	Dose/fraction (boost)	Thresholds for margin status analysis	NOS
Hathout L, 2013	Canada	440	4.4 yrs	–	42.5 Gy/16 fr	10* Gy/4 fr	Positive Close < 3 mm Wide ⩾ 3 mm	7
Julian TB, 2011	USA	1569	14.2 yrs	50 Gy/25 fr	–	NR	Positive Negative	NA
Kim JH, 2014	Korea	728	82 mo	50.4*/28 fr	–	10* Gy/5 fr	Close < 2 mm Negative ⩾ 2 mm	7
Lalani N, 2014	Canada	1609	9.2 yrs	50 Gy/25 fr	40–44 Gy/16 fr	NR	Positive Negative	8
Meattini I, 2013	Italy	389	7.7 yrs	50 Gy/25 fr	–	10–20 Gy/5–10 fr	Positive Negative	7
Omlin A, 2006	USA	373	72 mo	50* Gy/25 fr	–	10* Gy/5 fr	Positive Clear	6
Rakovitch E, 2013	Canada	1895	10 yrs	50 Gy/25 fr	40–44 Gy/16 fr	12* Gy/6 fr	Positive Negative	8
Tunon-de-Lara C, 2010	France	66	160 mo	50 Gy/25 fr	–	10 Gy/5 fr	Positive or close < 3 mm Negative ⩾ 3 mm	7
Vidali C, 2012	Italy	586	136 mo	50* Gy/25 fr	–	10* Gy/5 fr	Positive Close < 2 mm Negative ⩾ 2 mm	7
Wai ES, 2011	Canada	482	9.3 yrs	50 Gy/25 fr	44 Gy/16 fr	7.5 Gy/3 fr	Positive Close < 2 mm Negative ⩾ 2 mm	7
Williamson D, 2010	Canada	266	3.76 yrs	50 Gy/25 fr	42.4 Gy/16 fr or 40 Gy/16 fr	12.5 Gy/5 fr	Close < 1 mm 1–9 mm ⩾ 10 mm	7
Wong P, 2012	Canada	220	46 mo	50 Gy/25 fr	45 Gy/20 fr or 42.5 Gy/16 fr	7.5 Gy/3 fr to 16 Gy/8 fr	Positive or < 1 mm ⩾1 mm	6
Yerushalmi R, 2006	Israel	75	81.5 mo	50 Gy/25 fr	–	10 Gy/5 fr	Positive or < 1 mm ⩾1 mm	6

Abbreviations: NOS, Newcastle–Ottawa scale; yrs, years; Gy, Gray; fr, fraction; NR, not-reported; NA, not-applicable.
* Median dose.

Local recurrence boost vs no boost

Local recurrence boost vs no boost according to age

Local recurrence: Hypofractionated vs. standard radiotherapy

No difference

Local recurrence boost vs no boost according to margin status

BOOST is useful in patients with positive margin

Conclusioni

- *E' indicato nelle pazienti che fanno chemioterapia adiuvante*
- *Non esiste differenza tra HFRT e SRT in termini di mortalità per eventi cardiotossici*
- *E' indicato in tutte le classi prognostiche di carcinoma mammario*
- *Offre un buon LC e non peggiora la tossicità cutanea nelle pazienti mastectomizzate*
- *Permette un LC sovrapponibile al SRT nel DCIS*

Grazie per l’attenzione