

Studio di fase II di irradiazione della mammella con schema di ipofrazionamento e impiego di tecnica VMAT-SIB: valutazione della tossicità e primi risultati clinici in 300 pazienti

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Introduzione



The UK Standardisation of Breast Radiotherapy (START) trials of radiotherapy hypofractionation for treatment of early breast cancer: 10-year follow-up results of two randomised controlled trials

Joanne S Hawland, J Roger Owen, John A Dewar, Rajiv K Agrawal, Jane Barrett, Peter J Barrett-Lee, H Jane Dobbins, Penelope Hopwood, Pat A Lawton, Brian J Magee, Judith Mills, Sandra Simmons, Mark A Sydenham, Karen Venables, Judith M Bliss*, John R Yarnold*, on behalf of the START Trialists' Group



- Studi di Fase III randomizzati confermano la non-inferiorità del regime ipofrazionato in termini di IBR a 5-10 anni



An initiative of the ABIM Foundation

2013

ASTRO releases list of five radiation oncology treatments to question as part of national Choosing Wisely® campaign

- Don't initiate whole breast radiotherapy as a part of breast conservation therapy in women age ≥ 50 with early stage invasive breast cancer without considering shorter treatment schedules.

Whole breast radiotherapy decreases local recurrence and improves survival of women with invasive breast cancer treated with breast conservation therapy. Most studies have utilized "conventionally fractionated" schedules that deliver therapy over 5-6 weeks, often followed by 1-2 weeks of boost therapy. Recent studies, however, have demonstrated equivalent tumor control and cosmetic outcome in specific patient populations with shorter courses of therapy (approximately 4 weeks). Patients and their physicians should review these options to determine the most appropriate course of therapy.

Questioni aperte



Review

Accelerated hypofractionated breast radiotherapy: FAQs (Frequently Asked Questions) and facts[☆]

Angel Montero*, Xavier Sanz, Raul Hernanz, Dolores Cabrera, M.
Eloisa Bayo, Ferran Moreno, Manel Algara

Radiation Oncology Department, University Hospital Ramon y Cajal, Madrid, Spain

- DCIS
- Boost sequenziale o concomitante
- Pazienti giovani
- CT adiuvante
- Pazienti con macromastia

Clinical
Hypo
Carc

Lara H
Horia I
Louise

Phase
Hypo
breast
Thom
Dietel
Rudy
^aDepart



for Breast Ductal

D.^{1,2} Bernard Fortin, MD,^{*}
A.¹ Alain Albert, MD,[†] Houda Bahig, MD,^{*}
A.¹ Daniel Yassa, MD^{*}



patients with large
and supine positions

J.¹ Bruno Speleers^a, Simin Sadeghi^a,
J.¹ Werner De Gersem^a,



Obiettivo dello studio



- Valutare tossicità, cosmesi e risultati clinici relativi all'impiego di un trattamento radiante ipofrazionato con tecnica volumetrica a modulazione d'intensità (VMAT) e sovradosaggio concomitante sul letto operatorio

Scorsetti et al. Radiation Oncology 2012, 7:145.
<http://www.ro-journal.com/content/7/1/145>



STUDY PROTOCOL

Open Access

Phase I-II study of hypofractionated simultaneous integrated boost using volumetric modulated arc therapy for adjuvant radiation therapy in breast cancer patients: a report of feasibility and early toxicity results in the first 50 treatments

Marta Scorsetti¹, Filippo Alongi^{1*}, Antonella Fogliata², Sara Pentimalli¹, Pierina Navarrta¹, Francesca Lobefalo³, Carlos Garcia-Etienne³, Alessandro Clivio², Luca Cozzi², Pietro Mancosu¹, Giorgia Nicolini², Eugenio Vanetti², Marco Eboli³, Carlo Rossetti³, Arianna Rubino³, Andrea Sagona³, Stefano Arcangeli¹, Wolfgang Gatzemeier³, Giovanna Masci⁴, Rosalba Torrisi⁴, Alberto Testori⁵, Marco Alloisio⁵, Armando Santoro⁴ and Corrado Tintemi³

Criteri di inclusione



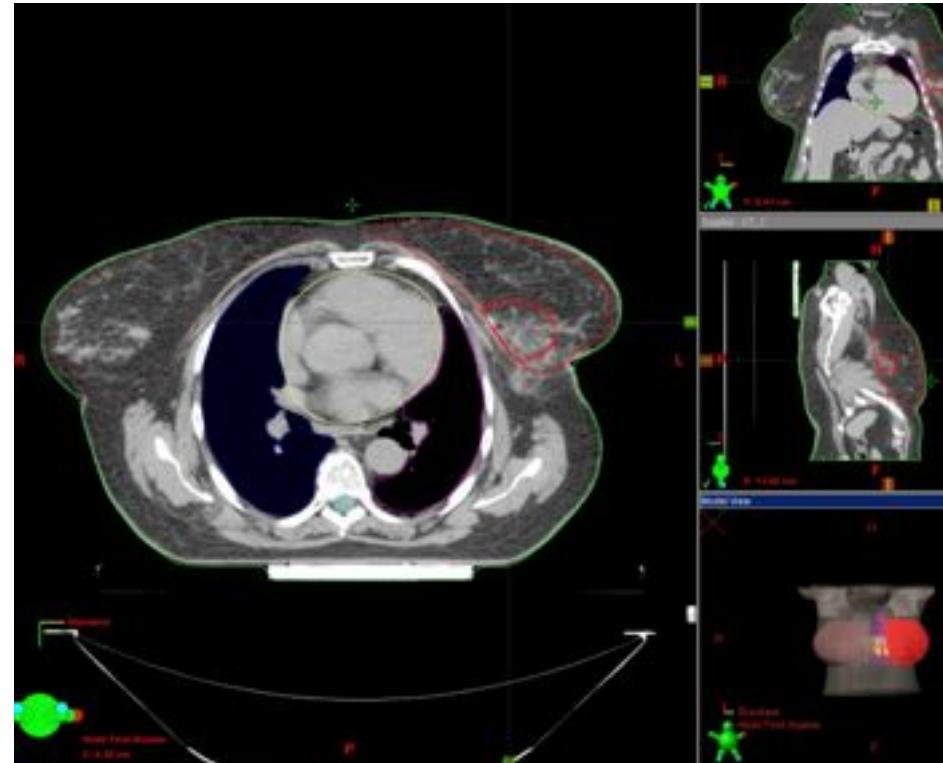
- Età >18 anni
- Conferma istopatologica di Ca. invasivo o in situ
- Stadio I - II ($T < 3$ cm and $N \leq 3$)
- Intervento chirurgico di tipo conservativo
- Non limiti relativi alla esecuzione di CT adiuvante



Materiali e Metodi



Fase di Simulazione e Contouring



Materiali e Metodi

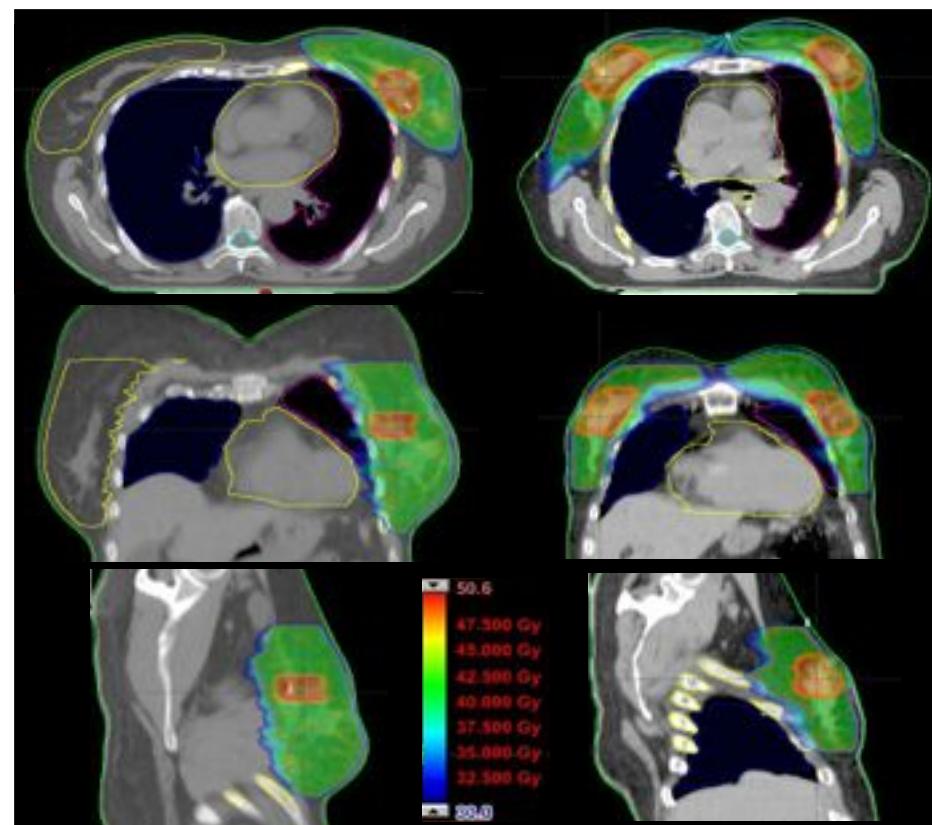
Fase di Planning

- WBI: 40,5 Gy
- SIB: 48 Gy

15 sedute con tecnica VMAT

Dose constraints

- Cuore
D mean < 4 Gy; V18 < 5%
- Polmone omo
V20 < 10%; D mean < 10 Gy
- Mammella contro
D mean ≤ 3 Gy



Risultati

Caratteristiche delle pazienti



Agosto 2010 - Dicembre 2013: **300** pazienti (305 trattamenti)

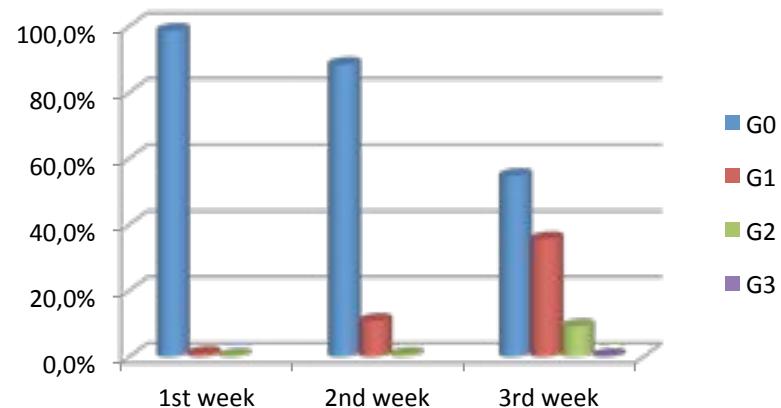
Follow up mediano: **18** mesi (range 10-45)

> 2 anni di follow up: 92 pazienti

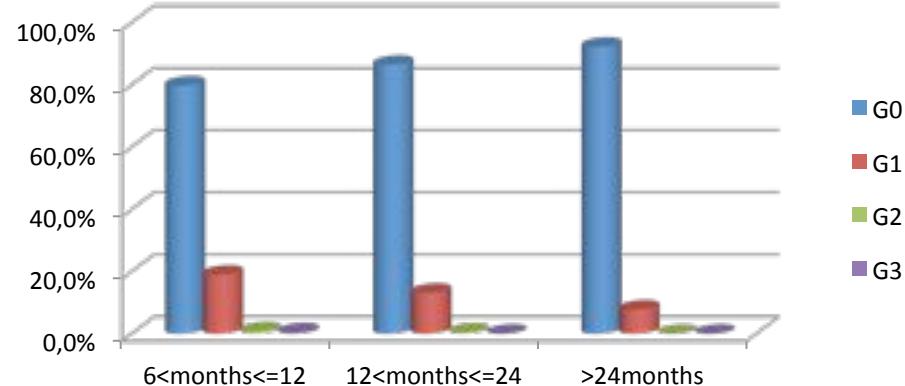
Age (years)	Median Range	61 27 - 88	Grading	I II III	36 (12%) 213 (71%) 51 (17%)
pT	pTis pT1mic pT1a pT1b pT1c pT2	2 (0.7%) 7 (2.2%) 13 (4.4%) 84 (27.9%) 152 (50.7%) 42 (14%)	ER	Positive Negative	279 (93%) 21 (7%)
pN	pN0 pN1	252 (84%) 48 (16%)	PgR	Positive Negative	234 (78%) 66 (22%)
Disease Stage	I II	222 (74%) 78 (26%)	C-erb	Positive Negative	267 (89%) 33 (11%)
Histology	IDC ILC Other Invasive DCIS	246 (82%) 37 (12.4%) 15 (5.25%) 2 (0.75%)	Ki67	≤ 20% > 20%	237 (79%) 63 (21%)

Risultati

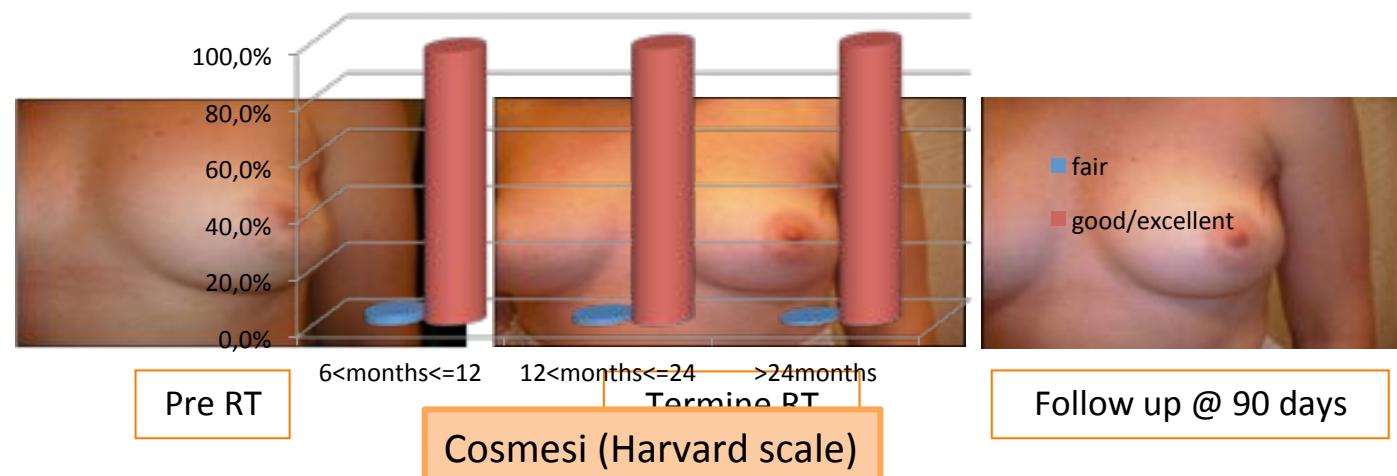
Tossicità cutanea e cosmesi



Tox acuta durante RT (RTOG score)



Tox tardiva (CTCAE v.4.0 score)



Conclusioni



- **Ottima tolleranza** in termini di tossicità cutanea acuta e precoce tardiva
- **Ottimo risultato cosmetico**
- **Risultati clinici** in linea con i dati di letteratura
- **No tossicità cardiologica o polmonare**
- Necessità di **più lungo follow up** per confermare risultati clinici e dati di tossicità tardiva