



XXXII CONGRESSO NAZIONALE AIRO
XXXIII CONGRESSO NAZIONALE AIRB
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AIRO2022

Radioterapia di precisione per un'oncologia innovativa e sostenibile

BOLOGNA, 25-27 NOVEMBRE
PALAZZO DEI CONGRESSI



Associazione Italiana
Radioterapia e Oncologia clinica

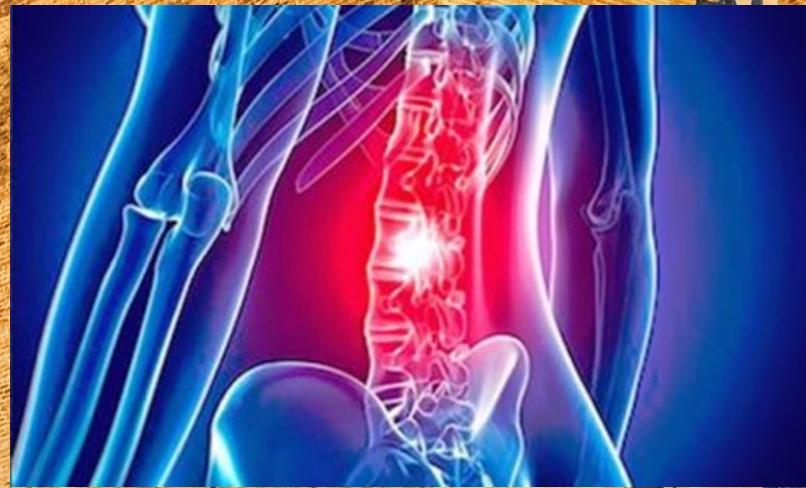


Società Italiana di Radiobiologia



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SHARON BONE: FINAL RESULTS OF A PHASE III RANDOMIZED MULTICENTER TRIAL ON HYPOFRACTIONATED ACCELERATED PALLIATIVE RADIOTHERAPY IN BONE METASTASES

A. Zamagni, S. Bisello, E. Scirocco, F. Candoli, F. Deodato, G. Macchia, F. Fiorica, E. Farina, S. Cilla, I. Ammendolia, L. Caravatta, S. Cammelli, F. Cellini, A.G. Morganti, G. Siepe.



DICHIARAZIONE

Relatore: Alessio Giuseppe MORGANTI

Come da nuova regolamentazione della Commissione Nazionale per la Formazione Continua del Ministero della Salute, è richiesta la trasparenza delle fonti di finanziamento e dei rapporti con soggetti portatori di interessi commerciali in campo sanitario.

- Consulenza ad aziende con interessi commerciali in campo sanitario (**Alfasigma**)
- Fondi per la ricerca da aziende con interessi commerciali in campo sanitario (**Elekta, IGEA, Bayer, Thema Sinergie, Janssen**)
- Partecipazione ad Advisory Board (**Janssen**)



the SHARON project

- Bone metastases
- Brain metastases
- H&N
- Thorax
- Esophagus
- Abdomen
- Pelvis



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Guidelines

ESTRO ACROP guidelines for external beam radiotherapy of patients with complicated bone metastases



Eva Oldenburger^{a,1}, Stephanie Brown^{b,1}, Jonas Willmann^c, Joanne M. van der Velden^{d,e}, Mateusz Spałek^f, Yvette M. van der Linden^{d,e}, Joanna Kazmierska^{g,h}, Johan Menten^{a,i}, Nicolaus Andratschke^{c,2}, Peter Hoskin^{b,j,*}

Complicated bone metastases:

- Metastatic spinal cord compression
- Neuropathic pain
- Fracture and threatened fracture
- Extra-osseous tumoural extension

- In the absence of comparative data a single dose of 8 Gy or palliative fractionation schedule such as 20 Gy in 5 fractions or 30 Gy in 10 fractions may be used to prevent pathological fracture
- Where recalcification is the aim of treatment a single dose of 8 Gy, 20 Gy in 5 fractions or 30 Gy in 10 fractions may be given
- Bone metastases with extra-osseous extension may be treated with palliative radiotherapy encompassing the entire tumour mass using for example a single dose of 8 Gy, 20 Gy in 5 fractions or 30 Gy in 10 fractions



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AIMS

- SHARON BONE
 - phase III randomized controlled multicenter trial to demonstrate
 - non-inferior symptoms relief
 - in painfully complicated bone metastases,
 - of hypofractionated accelerated palliative RT (20 Gy in 4 fr. b.i.d.)
vs
 - standard RT regimen (30 Gy in 10 daily fractions).



METHODS

- 5 Italian RT units (BO, CB, RM-UCSC, CH, Legnago)
- Inclusion criteria:
 - at least 18 years
 - ECOG PS ≤ 3
 - candidates for palliative RT
 - painfully complicated bone metastases
- Allocation not masked because of the nature of the intervention
- Primary endpoint: pain relief 1 month after treatment
- Pain relief, toxicity, and QoL also assessed at 2, 3, 6, and 12 months
- *clinicaltrials.gov*: NCT03503682



RESULTS

- Between February 2018 and December 2021, 83 pts were enrolled
- 30 Gy: 41; 20 Gy: 42

		Number of patients (%)
Median age (range)	64 (23-88)	
Gender	Male	52 (62.7%)
	Female	31 (37.3%)
Primary tumor	Lung	19 (22.9%)
	Breast	14 (16.9%)
	Liver	9 (10.8%)
	Kidney	7 (4.8%)
	Prostate	6 (7.2%)
	Biliary tract	5 (6.0%)
	Other	23 (27.7%)
Metastases site	Spine	38 (45.8%)
	Pelvis	23 (27.7%)
	Rib and sternum	10 (12.0%)
	Scapula	4 (4.8%)
	Other	8 (9.6%)
Type of complication	Extraosseous extension	44 (53.0%)
	Nerve compression	18 (21.7%)
	Pathological fracture	11 (13.3%)
	Spinal compression	8 (9.6%)
	Not available	2 (2.4%)



RESULTS

**30, 3 Gy
2 weeks**

**20, 5 Gy
2 days**

P:



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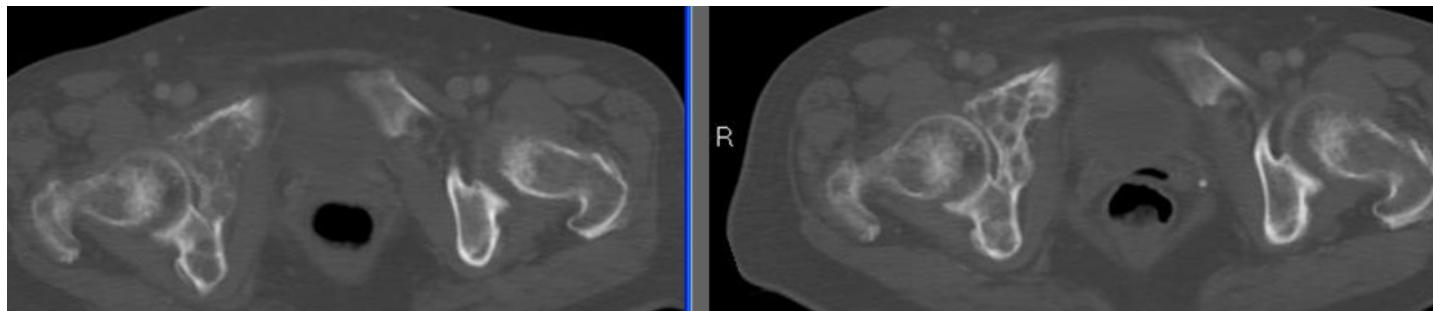
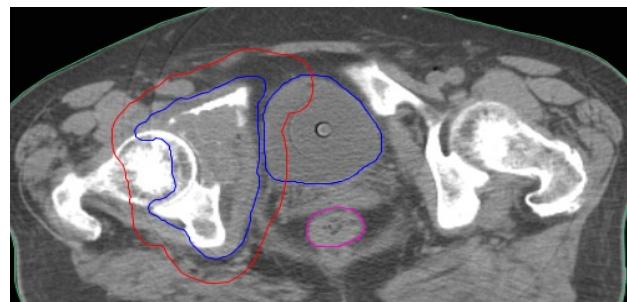


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By the courtesy of Dr. M. Ferro



LIMITATIONS

- Allocation/evaluation not masked
- Primary endpoint: pain relief 1 month after RT
- Pain score: IAEA



CONCLUSIONS

- 20 Gy in 4 fr. b.i.d. is non-inferior to 30 Gy/10 fr.
- at least as safe in terms of acute toxicity,
- with lower rate of RT definitive interruptions.



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SHARON trials

- Whole brain
- H&N
- Thorax
- Esophagus
- Abdomen
- Pelvis

please join us!

Clinical Investigation

Short-Course 2-Dimensional Radiation Therapy
for Early Stage Non-Small Cell Lung Cancer
Study

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