

XXXII CONGRESSO NAZIONALE AIRO
XXXIII CONGRESSO NAZIONALE AIRB
XII CONGRESSO NAZIONALE AIRO GIOVANI

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

 Associazione
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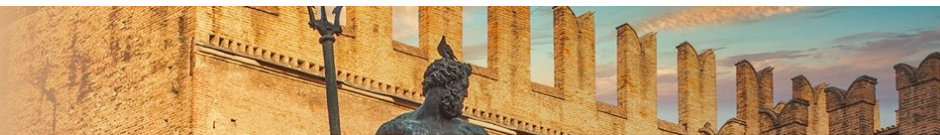
Radioterapia di precisione per un'oncologia innovativa e sostenibile

BOLOGNA, 25-27 NOVEMBRE
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NON-METASTATIC MALIGNANT PLEURAL MESOTHELIOMA PATIENTS TREATED WITH LUNG-SPARING SURGERY, CHEMOTHERAPY AND RADICAL HEMITHORACIC RADIOTHERAPY: LONG TERM RESULTS FROM A PHASE III RANDOMIZED CLINICAL TRIAL

Dr. Alberto Revelant





DICHIARAZIONE

Relatore: Dr. Alberto Revelant

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.

- Posizione di dipendente in aziende con interessi commerciali in campo sanitario (NIENTE DA DICHIARARE)
- Consulenza ad aziende con interessi commerciali in campo sanitario (NIENTE DA DICHIARARE)
- Fondi per la ricerca da aziende con interessi commerciali in campo sanitario (NIENTE DA DICHIARARE)
- Partecipazione ad Advisory Board (NIENTE DA DICHIARARE)
- Titolarità di brevetti in compartecipazione ad aziende con interessi commerciali in campo sanitario (NIENTE DA DICHIARARE)
- Partecipazioni azionarie in aziende con interessi commerciali in campo sanitario (NIENTE DA DICHIARARE)



Phase III Randomized Controlled Trial

Clinical Trial > Int J Radiat Oncol Biol Phys. 2021 Apr 1;109(5):1368-1376.
doi: 10.1016/j.ijrobp.2020.11.057. Epub 2020 Nov 28.

Radical Hemithoracic Radiotherapy Versus Palliative Radiotherapy in Non-metastatic Malignant Pleural Mesothelioma: Results from a Phase 3 Randomized Clinical Trial

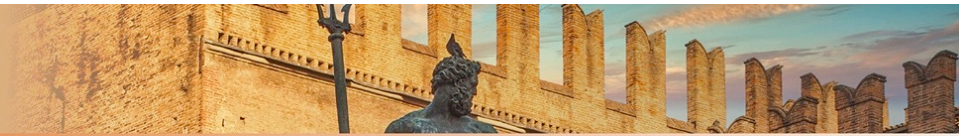


108 patients **NOT** treated with ***not-radical*** surgery

- ARM A: 54 treated with palliative RT (20-30 Gy in 3-10 fractions)
- ARM B: 54 treated with RHR “Radical Hemithoracic Radiotherapy” (50Gy in 25 fractions + 60Gy boost)

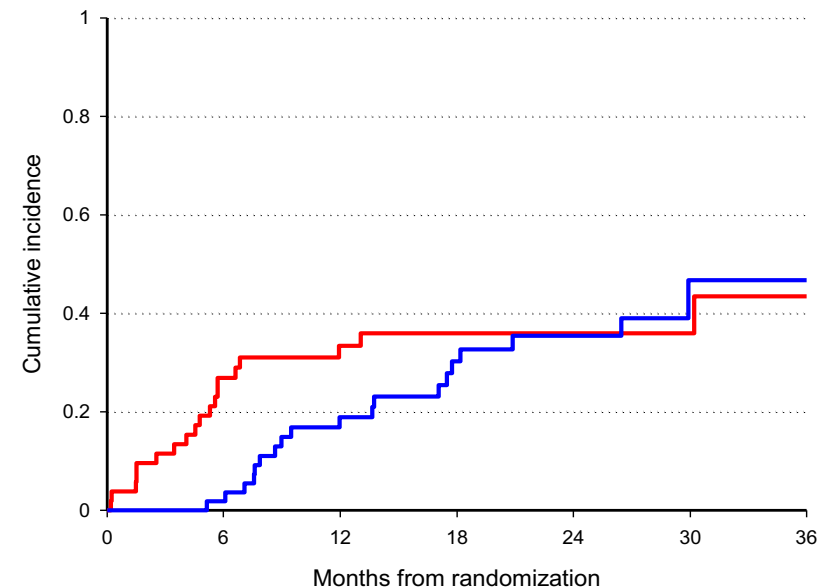
Criteria of inclusion:

- Biopsy or not-radical surgery only
- Stage I-IVa (TNM 7° edition)
- 4 (median) cycles of neoadjuvant of double-agents CHT (Platin \ Pemetrexed)



Background

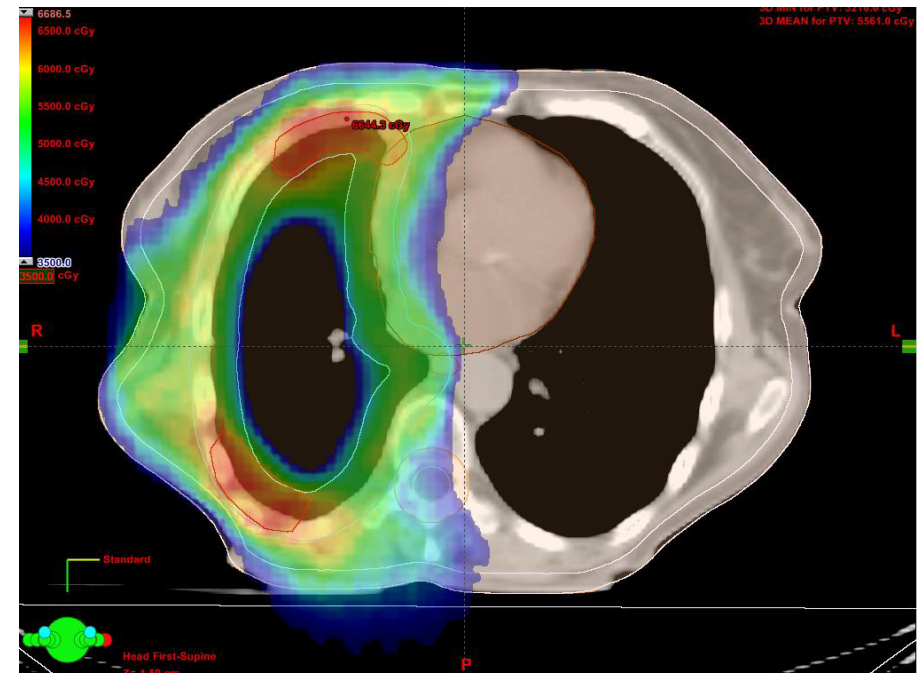
- Statistically significant increase in OS (58% in ARM B vs 28% ARM A)
- Good Local Control rate with RHR
- Same risk of distant failure in both ARMS
- Moderated toxicity in ARM B (16% of pneumonitis Grade ≥ 2)

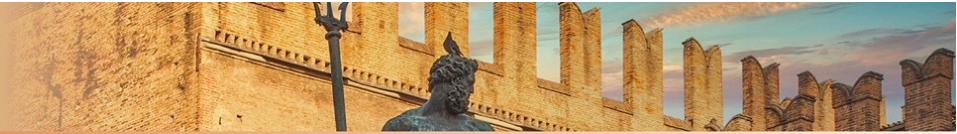




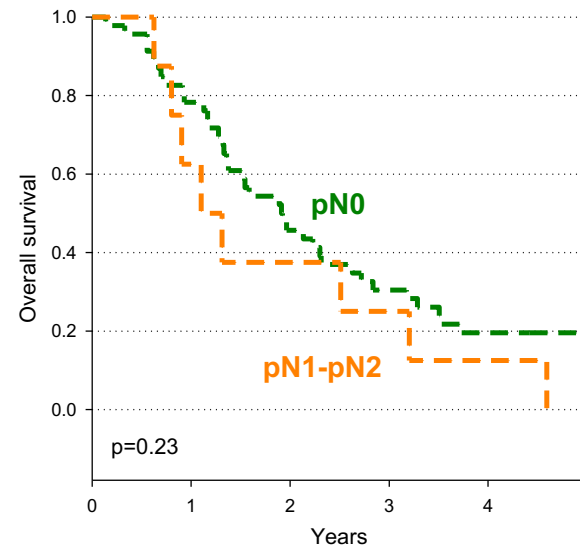
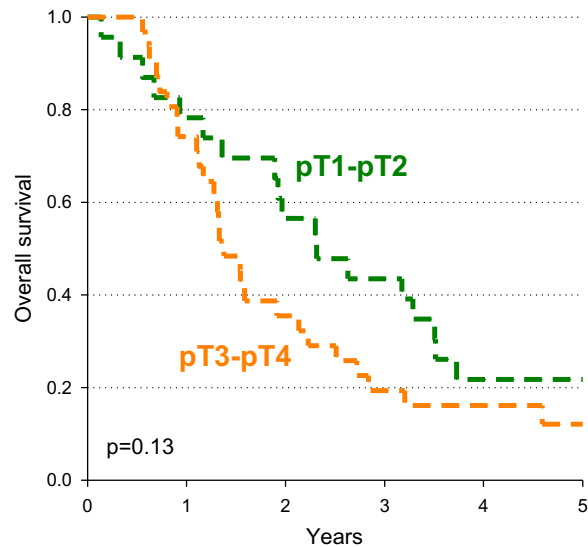
Aim

Aim of this paper is report the long-term survival and toxicity outcomes for malignant pleural mesothelioma (MPM) patients treated with lung-sparing surgery (LSS), chemotherapy (CT) and Radical Hemithoracic Radiotherapy (RHR). Previously published phase III randomized clinical trial demonstrated significant advantages of RHR compared to palliative radiotherapy (PR) in terms of overall survival.



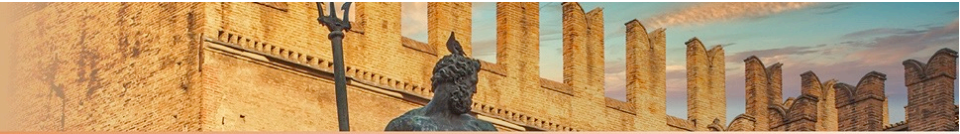


Results – OS

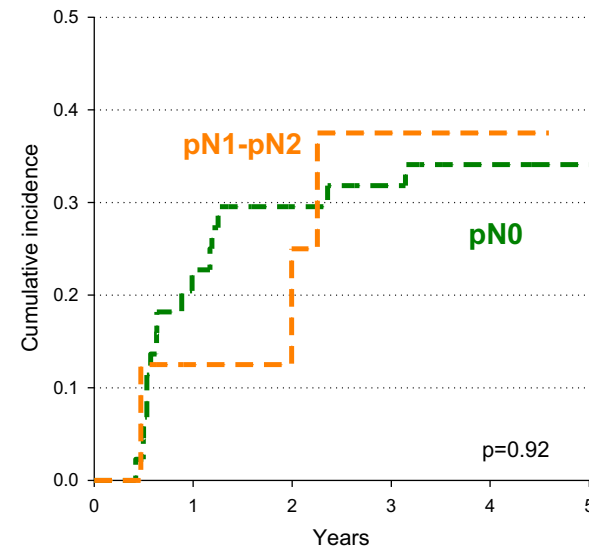
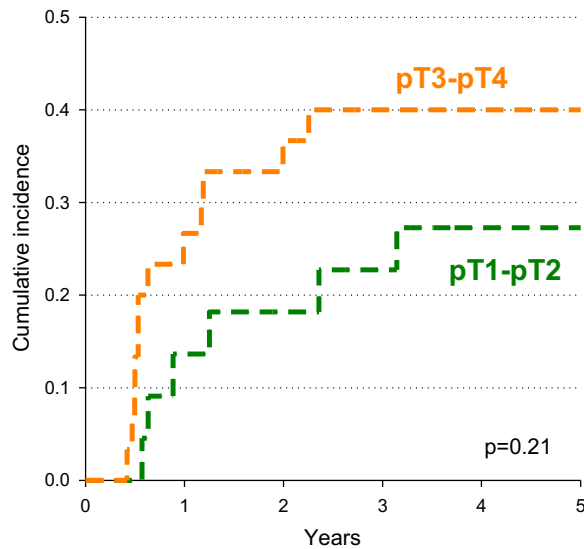


After a median Follow-up period of 35 months, the median **OS** was 22,8 months, the 1, 2 and 3-years OS rates were 76%, 45% and **30%** respectively. The median OS for patients with pN1-2 disease was 13 months vs. 23 months for the group pN0 (p 0,23).

Patients with pT1-2 disease had the better prognosis with a median survival of 27.8 months.



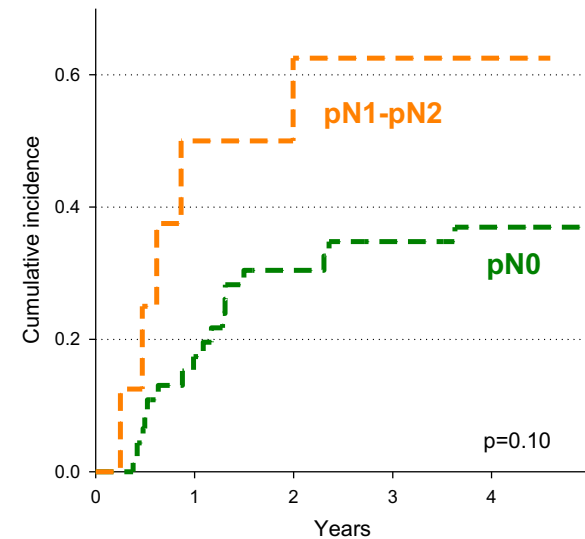
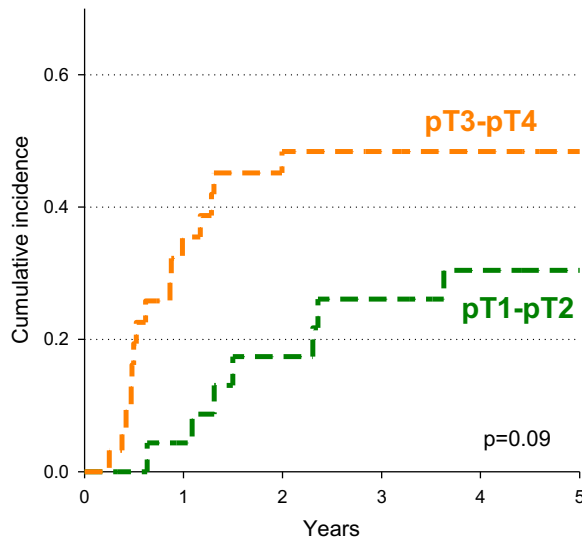
Results - LRR



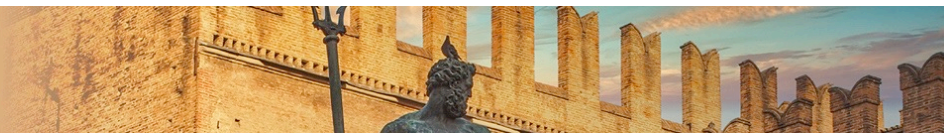
The 3-years rate of **LRR** was 33%. Lower, but not statistically significant ($p=0.21$), LRR rate for pT1-2 vs. pT3-4. No difference in the 3-years **LRR** rates (38% vs. 32%) for pN1-2 vs. pN0.



Results - DRR

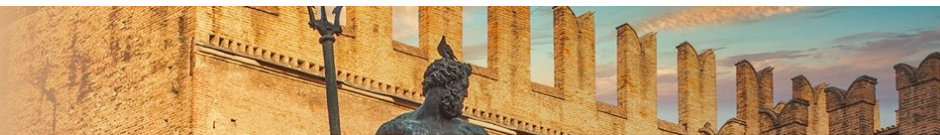


The 3-years rate of **DRR** was 55%. **DRR** is confirmed to not be affected by **RHR**. Not statistical differences in subgroup analyses but there is an advantage in patients with limited disease (pT1-2) or without nodal involvement (pN0).



Toxicities

Late adverse events					
Alanine amino-transferase increased	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)
Anorexia	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)
Cough	4 (12)	7 (21)	2 (6)	0 (0)	0 (0)
Dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphagia, esophagitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dyspnea	5 (15)	3 (9)	5 (15)	0 (0)	0 (0)
Fatigue	1 (3)	3 (9)	1 (3)	0 (0)	0 (0)
Fever	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fracture	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Gamma glutamyl transferase increased	4 (12)	4 (12)	0 (0)	0 (0)	0 (0)
Hemoglobin decreased	1 (3)	2(6)	0 (0)	0 (0)	0 (0)
Lymphocyte count decreased	0 (0)	1 (3)	3 (9)	0 (0)	0 (0)
Nausea, vomiting	1 (3)	1 (3)	0 (0)	0 (0)	0 (0)
Neutrophil count decreased	0 (0)	2 (6)	0 (0)	0 (0)	0 (0)
Pain	5 (15)	0 (0)	0 (0)	0 (0)	0 (0)
Pericardial effusion	0 (0)	4 (12)	1 (3)	1 (3)	0 (0)
Platelet count decrease	2 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Pleural effusion	1 (3)	1 (3)	2 (6)	0 (0)	0 (0)
Pneumonitis	0 (0)	2 (6)	1 (3)	0 (0)	0 (0)
Thromboembolic event	0 (0)	0 (0)	4 (12)	0 (0)	0 (0)
Weight loss	6 (18)	0 (0)	0 (0)	0 (0)	0 (0)



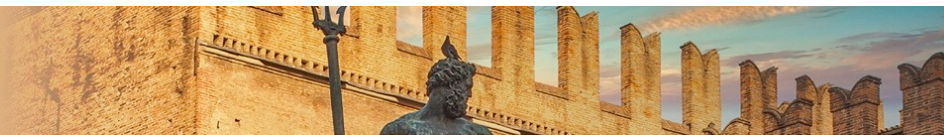
Conclusions

- MPM is a rare disease with poor prognosis.
- According to this study, patients underwent RHR had significant better prognosis compared to historical data with a **3 year OS of 30%**.
- In subgroup analyses, **local control and distant relapse seems to be affected by extension of disease** (better prognosis of pT1-2 and pN0).
- Rate of **toxicity is acceptable and steady** in long-term survivors.
- Due to limited number of patients enrolled, more studies are needed to confirm our results.

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Thanks for your attention!

