Associazione Italiana Radioterapia e Oncologia clinica

Società Italiana di Radiobiologia

STereotactic Ablative RadioTherapy in NEWly diagnosed and oligo-metastatic locally advanced non-small cell lung cancER pAtients: safety and treatment compliance analysis of the START-NEW-ERA non-randomised phase II trial

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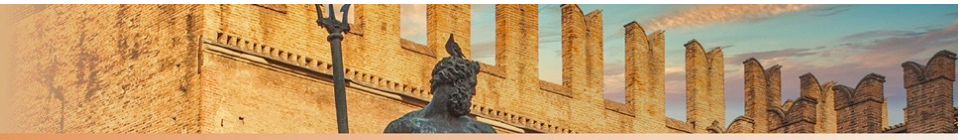

DICHIARAZIONE

Relatore: FABIO ARCIDIACONO

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)**

unresectable LA-NSCLC

Fit for RT-CT

CT-RT 60Gy/30 fx
RTOG 0617
CT-RT 55Gy/20 fx
SOCCAR

Durvalumab
(PD-L1 ≥1%)
PACIFIC

Unfit for RT-CT
Fit for CT

START NEW ERA
Trial

CT → **SAbR** 5fx

Durvalumab
(PD-L1 ≥1%)
PACIFIC

Unfit for CT

SAbR 5fx

Between 12/2015 and 12/2021 **64** LA-NSCLC and **24** oligo-M LA-NSCLC patients were enrolled.
Median age was 73 years (range,39-89), 74 (84%) had ultra-central tumor.

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Clinical trials.gov NCT05291780

FULL LENGTH ARTICLE | ARTICLES IN PRESS

STereotactic Ablative RadioTherapy in NEWly diagnosed and recurrent locally advanced non-small cell lung cancer patients unfit for concurrEnt RAdio-chemotherapy: early analysis of the START-NEW-ERA non-randomised phase II trial

Fabio Arcidiacono, MD • Paola Anselmo, MD • Michelina Casale, PhD • Cristina Zannori, MD • Mark Ragusa, MD • Francesco Mancioli, MD • Giovanni Marchetti, MD • Fabio Loreti, MD • Marco Italiani, PhD • Sergio Bracarda, MD • Ernesto Maranzano, MD • Fabio Trippa, MD • Show less

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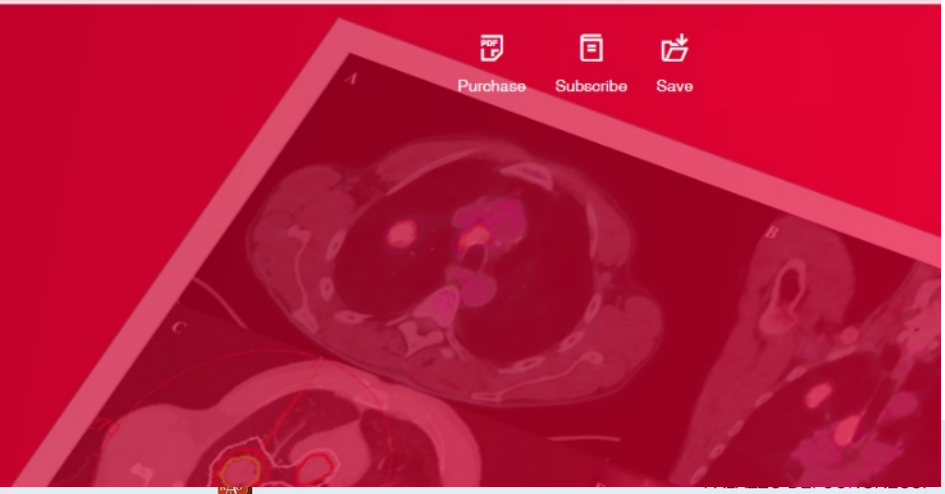


Enrollment

- Patients firstly discussed within the **multidisciplinary lung cancer group** and judged **unfit** for surgery and concurrent CT-RT
- ECOG **PS ≤2**
- De-novo or recurrent or oligo-M LA-NSCLC
- **PET/CT** and brain **MRI** (CT)

- Neoadjuvant CT (**CCDP and Vinorelbine** x3-4) in fit patients
- After PACIFIC trial results patients who had no progression after CT and SAbR received **Durvalumab**

- **Oligo-M (synchronous or metachronous):**

  standard systemic therapy + **SAbR in oligo-M sites and primary tumor (and nodes)**

Radiation Planning

- **GTV-T** and **GTV-N** → residual disease on PET-CT after CT and pre-SAbR
- **GTV-M** (Cox Guidelines spine bone M)
- SAbR delivered by **V-MAT**

- **SIB** was optimized to differentiate the dose for T and N (and M for spine bone M)

Treatment Planning

- Treatment schedule based on target volume and closeness to **OAR**
- Total prescribed dose biologically equivalent to 54-60 Gy in 27-30 fractions (**BED_{10} = 59,5Gy-72Gy**)
- PTV Dmax no more than 107% of the prescription dose

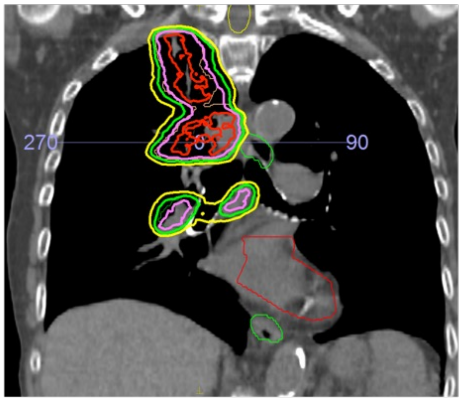
- OAR dose constraints:

❑ **normal lungs - GTV**, V_{20Gy} <10%
❑ **heart**: $D_{0.5cc}$ <27-29 Gy
❑ **esophagus**: $D_{0.5cc}$ <32-34 Gy
❑ **trachea, proximal bronchial tree and ipsilateral bronchus**: $D_{0.5cc}$ <35 Gy
❑ **aorta and others great vessels**: $D_{0.5cc}$ <53 Gy
❑ **spinal cord**: $D_{0.5cc}$ 30 Gy

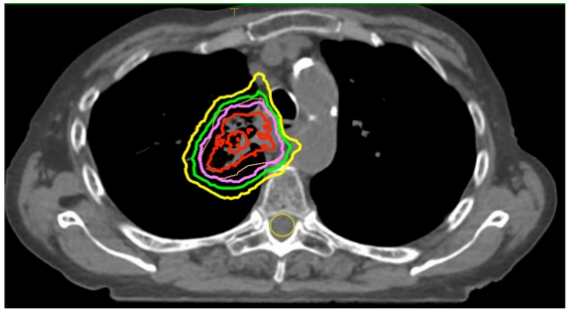
Endpoints

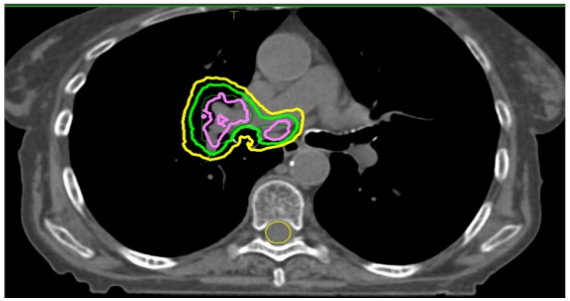
Primary

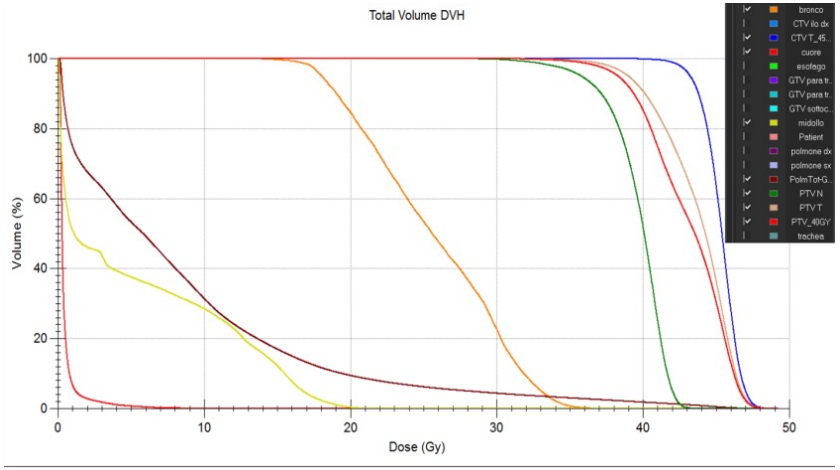
- **LOCAL CONTROL**: lack of progression of the treated volume.
- **SAFETY**: absence of ≥G3 toxicity according CTCAE v4.0



45 Gy | 40 Gy | 35 Gy | 30Gy







DVH

Results

All patients completed SAbR in a median time of **5 days** (range, 5-7) and **treatment compliance was 100%**.

Long-term clinical information about treatment **safety** was **available for all patients**.

After a **median follow-up of 23 months** (range, 4-83) **only one** (1.1%) patient (submitted to ChT-SAbR-Immunotherapy) **developed ≥ grade (G) 3 esophageal toxicity**.

Safety

No patients developed **≥G3** **acute** toxicities

1% patients developed ≥G3 **late** toxicities

Thanks for your attention!!!!

every component is important to complete this difficult and intriguing LA-NSCLC puzzle!!!!