P040

Early results from a phase II randomized trial testing stereotactic body radiation therapy in patients with oligometastatic castration resistant prostate cancer undergoing I line treatment with abiraterone acetate (ARTO trial-NCT03449719)

European Urology Open Science 2020;21(Suppl 3):S150

Francolini G.[1], Garlatti P.[1], Detti B.[1], Bruni A.[2], Mantini G.[3], Pergolizzi S.[4], Borghetti P.[5], D'Angelillo R.M.[6], Alongi F.[7], Jereczek-Fossa B.A.[8], Franzese C.[9], Tagliagambe A.[10], Di Cataldo V.[1], Aquilano M.[1], Mariotti M.[1], Salvestrini V.[1], Ciccone L.[1], Stocchi G.[1], Livi L.[1]

[1]AOU Careggi - University of Florence, Dept. of Radiation Oncology, Florence, Italy, [2]University Hospital of Modena, Radiotherapy Unit, Modena, Italy, [3]A. Gemelli Hospital, Sacred Heart Catholic University, Dept. of Radiotherapy, Rome, Italy, [4]University of Messina, Dept. of Radiation Oncology, Messina, Italy, [5]University and Spedali Civili Hospital of Brescia, Dept. of Radiotherapy, Brescia, Italy, [6]Policlinico Tor Vergata University, Radiotherapy Unit, Dept. of Oncology and Hematology, Rome, Italy, [7]IRCCS Sacro Cuore Don Calabria Cancer Care Center, Dept. of Advanced Radiation Oncology, Verona, Italy, [8]University of Milan, IEO European Institute of Oncology IRCCS, Division of Radiotherapy, Dept. of Radiation Oncology, Milan, Italy, [9]Humanitas University, IRCCS, Dept. of Radiotherapy and Radiosurgery, Milan, Italy, [10]Hospital of Carrara, Dept. of Radiation Oncology, Carrara, Italy

Introduction & Objectives: In January 2019 a multicenter, randomized trial (ARTO-NCT03449719) was started in nine italian centers. Thirty-seven per cent of the accrual target population have been currently enrolled. The present analysis is a preliminary report about clinical outcomes and adverse events registered within patients with a follow-up ≥ 3 months.

Materials & Methods: Available data from patients with follow up ≥ 3 months were collected and reported. All patients were affected by oligometastatic Castrate Resistant Prostate Cancer (CRPC), defined as ≤ 3 non-visceral metastatic lesions. Patients were randomized 1:1 to receive either Abiraterone Acetate alone (control arm) or associated with stereotactic body radiation therapy (SBRT) on all sites of disease (treatment arm). Toxicity was assessed by the Common Terminology Criteria for Adverse Events toxicity scale (CTCAE v.4.03). Assessments comprehensive of clinical examination, PSA and quality of life evaluation by EORTC QLQ-C30 and BPI-SF were performed every three months.

Results: Overall, complete data at 3 months after treatment start were available for 28 patients, 14 for each arm. Twenty-two metastatic lesions were treated in the SBRT arm (6, 6 and 2 patients were treated with LINAC based intensity modulated RT, Cyberknife(R) robotic technique and helical Tomotherapy(R), respectively). No adverse events occurred in both arms of treatment. SBRT had no significant impact on Global Health Status of patients included in treatment arm. Median PSA drop after 3 months was 1.51 (-13.5 to 13.2) and 4.2 (-0.8 to 29.4) ng/ml in the control and treatment arm, respectively. No significant difference in terms of PSA drop at three months were detected (p=0.63). Biochemical response (PSA reduction ≥ 50%) was detected in 57.1 vs 64.3 % of patients in control vs SBRT arm, respectively (p=0.69). All patients are alive, 1 vs 0 progression free survival event occurred in the control vs SBRT arm.

Conclusions: Early results from ARTO trial showed that SBRT+ Abiraterone treatment was safe and well tolerated in the experimental cohort, without any increase in terms of adverse events or quality of life impairment if compared to Abiraterone treatment. Non-significant trend in terms of PSA drop and biochemical response at 3 months was detected in SBRT arm. Mature data are needed to explore benefit yielded by SBRT addition to Abiraterone therapy in I line oligo-metastatic CRPC patients.