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10.20960/radiocirugia.2019.00020

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Introduction and objectives: SBRT-SG 05 (ClinicalTrials.gov NCT02192788) is a collaborative (SBRT-SG, GICOR and SEOR) phase II trial testing SBRT and hormonotherapy in oligometastatic prostate cancer patients. The aim of this study is to determine response, and biochemical control rates, progression free survival, chemotherapy free survival and impact of treatment on quality of life. We describe here the protocol and first results. This type of studies are currently on the rise worldwide representing interest for this kind of approach.

Material and methods: Patients with histologically confirmed prostate cancer (hormone-sensitive or castration-resistant) in an oligo-recurrent stage after primary treatment for their disease were assigned to receive SBRT (vertebral metastases: 1 x 16-18 Gy or 3 x

8-9 Gy. Lymph node metastases: 3 x 10-11 Gy or 6 x 7.5 Gy. Non spinal one metastases: 1 x 16 Gy or 3 x 10 Gy). Medical treatment could include LHRH analogues or antiandrogens. *Inclusion criteria:* time to biochemical recurrence more than 1 year; PSA doubling time > 2 months; less than 5 bone or lymph node metastases (including spinal) by Choline PET-CT or/and WB-DWI-MRI. To ensure homogeneity in the sample, all patients should have hormone therapy according to current recommendations planning its withdrawal within two years after treatment if biochemical control has been achieved. The percentage of castration resistance patients will be at most 30% and at least 10% of the sample. Concomitant treatment with chemotherapy, abiraterone or enzalutamide is not allowed.

Results: From December 2015 to February 2017, 54 patients recruited at 12 centers. At the time of the analysis 59 lesions had been treated and evaluated. Median follow-up of the cohort is 6 months (range 1-24 months). To date, 4 patients (8.7%) have presented disease progression. Moderate-severe toxicities (grades 2-4) have not been observed.

Conclusions: This trial presents a favorable pace of recruitment with good initial figures of biochemical control and local control without the appearance of remarkable SBRT related toxicity at this time.

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