Aim: A risk-adapted strategy for metastatic seminoma may further refine the necessary burden of chemotherapy while sparing futile treatment for early recognized good responders. The objective of this proof-of-principle study was to evaluate the association of an early metabolic response to PEB and the dimensional response at the end of treatment.

Methods: Patients (pts) with newly-diagnosed seminoma and who were candidate to PEB were staged at baseline by computed tomography (CT), PET and serum tumor markers (STM). Then, restaging with PET after 2 cycles of PEB (PET2), and with CT after treatment (3-4 cycles [CT3-4]) were provided. One (greatest) target lesion was chosen to evaluate metabolic/dimensional changes in each case. The primary endpoint was the association between PET2 (EORTC criteria) and CT3-4 response. Secondary endpoints were progression-free survival (PFS) and ability to detect visceral metastases. An analysis after the initial 35 pts was planned.

Results: In the time-frame 06/2010-11/2013, 35 pts have been enrolled in this single-site study. Two pts had CSIIA, 12 CSIIB, 13 CSIIC, and 8 CSIII. 3 had an intermediate prognosis because of liver (1) and bone (2) disease. These two were recognized by PET while having a bone-negative CT scan. 4 had a retroperitoneal and 1 a mediastinal primary. All pts had a PET-positive target disease (retroperitoneal in 33 and mediastinal in 2). After 2 cycles of PEB, 25 pts (71.4%) had a metabolic complete response (CR), 10 a partial response (PR). 10 pts had a CR at CT3-4. PET2-negative pts had a significantly smaller residual disease at CT3-4 scan (median 1.2 cm [IQR: 2.8-6] vs 4 cm [IQR: 1-1.9], p < 0.001 at Mann-Whitney test) as well as a significantly greater shrinkage at CT3-4 compared to baseline (median 6 cm [IQR: 4.4-6.5] vs 2.85 [IQR: 1.5-6], p = 0.026). 6 pts further received RT, 1/10 pt progressed and received II line treatment. After a median follow up of 14.8 months (IQR: 10.9-30.1), all pts are alive.

Conclusions: PET2 early identified pts having the greatest response to chemotherapy and who finally reached the cut off for observation only (<3cm). Also, baseline PET was able to identify bony disease in 2/35 pts otherwise categorized with a good prognosis. These findings warrant further investigation and provide the rationale for an expansion cohort aimed to analyze the association with PFS.

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