Helical intensity-modulated radiotherapy of the pelvic lymph nodes with a simultaneous integrated boost to the prostate - first results of the PLATIN 1 trial.

Definitive, percutaneous irradiation of the prostate and the pelvic lymph nodes in high-risk prostate cancer is the alternative to prostatectomy plus lymphadenectomy. To date, the role of whole pelvis radiotherapy (WPRT) has not been clarified especially taking into consideration the benefits of high conformal IMRT (intensity modulated radiotherapy) of complex-shaped target volumes. From 2009 to 2012, 40 patients of high-risk prostate cancer with an increased risk of microscopic lymph node involvement were enrolled into this prospective phase II trial. Patients received at least two months of antihormonal treatment (AT) before radiotherapy continuing for at least 2 years. Helical IMRT (tomotherapy) of the pelvic lymph nodes (51.0 Gy) with a simultaneous integrated, moderate hypofractionated boost (single dose of 2.25 Gy) to the prostate (76.5 Gy) was performed in 34 fractions. PSA levels, prostate-related symptoms and quality of life were assessed at regular intervals for 24 months. Of the 40 patients enrolled, 38 finished the treatment as planned. Overall acute toxicity rates were low and no acute grade 3 or 4 gastrointestinal (GI) and genitourinary (GU) toxicity occurred. 21.6 % of patients experienced acute grade 2 but no late grade $\geq 2$ GI toxicity. Regarding GU side effects, results showed 48.6 % acute grade 2
and 6.4% late grade 2 toxicity. After a median observation time of 23.4 months the PLATIN 1 trial can be considered as sufficiently safe meeting the prospectively defined aims of the trial. With 34/37 patients free of a PSA recurrence it shows promising efficacy. Tomotherapy of the pelvic lymph nodes with a simultaneous integrated boost to the prostate can be performed safely and without excessive toxicity. The combined irradiation of both prostate and pelvic lymph nodes seems to be as well tolerated as the irradiation of the prostate alone. Trial Numbers: ARO 2009-05, ClinicalTrials.gov: NCT01903408.