to CT-CAE criteria v3.0. Biochemical failure was calculated according to the Phoenix definition.

Results: Between December 2011 and March 2015, 90 patients were enrolled (53 low risk, 37 intermediate risk). The median age was 71 years (range 48 – 82 y). The median Gleason Score was 6 (range 6-7) and the median initial PSA was 6.9 ng/ml (range 2.7 – 17.0). Acute toxicity was mild, with 32.2 patients presenting a G1 urinary toxicity and 31.1% of patients presenting a G2 urinary toxicity, mainly represented by urgency, dysuria and stranguria. A rectal G1 toxicity was found in a 15.5% of patients, while a rectal G2-toxicity was recorded in 6.6% of patients. Regarding late toxicity, a G1 proctitis was recorded in 11.1% of patients and a G1 urinary (urgency, cystitis) in 38.8%; only 2 events of G2 urinary toxicity were observed (transient urethral stenosis, resolved by a 24-hour catheterization). At a median follow up of 27 months (range 6 - 62 months) only two intermediate risk patients experienced a biochemical failure (22 and 24 months after radiotherapy, respectively). PET Choline revealed a nodal recurrence in one patient who underwent a further stereotactic radiotherapy and is now free of disease. In the other patient a local recurrence was diagnosed, associated to bone progression (rib), therefore the patient started ADT. Compliance to treatment was good, as reported by the EPIC questionnaires, which revealed a slight worsening in the urinary domains during treatment, with a return to baseline three months after treatment.

Conclusion: Stereotactic Body Radiotherapy seems to be a valid therapeutic option in low and intermediate risk prostate cancer patients, warranting an adequate control of disease, with mild toxicity profiles and good patient-reported quality of life perception.

EP-1346

Intraoperative radioterapy (IORT) in the multimodality treatment of locally advanced prostate cancer

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Purpose or Objective: The treatment for locally advanced prostate cancer is still a controversial issue and multimodality treatment can lead to treatment optimization. The aim of this study is to describe technical and clinical aspects of intra-operative radiotherapy (IORT) in patients with locally advanced prostate cancer.

Material and Methods: Between September 2005 and September 2015, a total of 110 patients were enrolled. The statistical analysis was performed in 95 patients with follow up > 12 months. Inclusion criteria were: patients age < 76 years, KPS > 90, initial PSA (iPSA) > 10 ng/ml, clinical staging > cT2c according with TNM, probability of organ-confined disease < 25% according to MSKCC nomogram. Median age was 66.9 years (range 51-83), median iPSA was 14.6 ng/ml (range 2.0-80) and median Gleason Score (GS) was 8 (range 4-10). After surgical exposure of the prostate, IORT was delivered by a dedicated linear accelerator (Mobetron, Intraop, Sunnyvale, CA) with 30° beveled collimator, using an electron beam of 9 or 12 MeV to a total dose of 12 Gy. IORT was followed by radical prostatectomy and regional lymph node dissection. Rectal dose was measured "in vivo" by radio-chromic films placed on a rectal probe. All cases with pathological staging pT3a, positive margins (R1) or metastatic lymph nodes (N1) received postoperative external beam radiotherapy (EBRT), delivered to surgical bed with 3D conformal technique or intensity modulated radiation therapy to a total dose of 46-50 Gy (2Gy/fraction). Patients with pT3 or pT4 disease and/or N1 received adjuvant hormonal therapy.

Results: IORT procedure lasted in average 30 minutes (range 15-50). No major intra- or post-operative complication occurred. Median dose to the anterior rectal wall was 4.32 Gy (range 0.06-11.3). Pathological stage was: 30 pT2, 60 pT3, 5 pT4. 55/95 (57.9%) patients were R1 and 27/95 (28.4%) patients were N1. Median post operative PSA was 0.06 ng/ml (range 0-4). Post-operative radiotherapy was delivered to 73/95 patients (76.8%) with pathological staging pT3a or R1. Hormone therapy was prescribed to 61/95 patients (64.2%). Acute toxicity was: 16 G2 (9 GU; 7 GI), 2 G3 (1 GU; 1 GI). Late toxicity was: 11 G2 (5 GU, 6 GI), 4 G3 (2 GU; 2 GI). No G4 acute or late toxicity was observed. Four patients died of prostate cancer. With a median follow-up of 61.5 months (range 12-108), 26/95 patients experienced biochemical failure. Overall biochemical free survival (BFS) was 50% at 5 years. 5 years BFS was 78% and 42 % in high and very high risk classes according to NCCN classification. No evidence of failure in the prostate surgical bed was observed.

Conclusion: IORT during radical prostatectomy is a feasible procedure and allows to deliver safely post-operative EBRT to surgical bed without a significant increase of toxicity. With a median follow-up of 61.5 months, biochemical control seems to be optimal in particular for high risk patients.

EP-1347

Could "radical" RT be a reasonable choice in bone oligometastatic prostate cancer patients?

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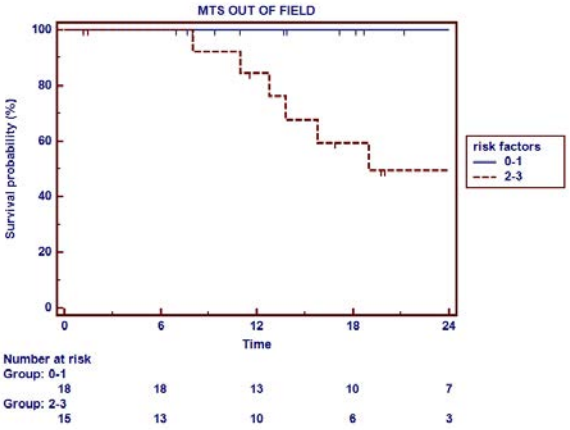
Purpose or Objective: To evaluate toxicity, clinical outcome and predictive response factors in patients with prostate cancer (PCa) oligometastatic (<2 lesions) to the bone at diagnosis, simultaneously treated with curative radiotherapy (RT) to primary tumor/prostatic bed (PB) and bone metastases.

Material and Methods: From February 2009, 33 patients with oligometastatic PCa (OPC), 18 of whom previously treated with radical prostatectomy and pelvic lymphadenectomy, underwent RT at "radical" dose to bone metastases (median 2-Gy equivalent dose, EQD2, >40 Gy, for α/ß=2,2), to the pelvic ± lomboaortic nodes (51,8 Gy for α/ß=1,5), and to the PB (median EQD2 72,4 Gy) or the prostate (median EQD2 88 Gy) within the same RT course in association with androgen deprivation therapy (ADT). To evaluate the possible role of adding a local treatment (radical dose RT to all sites of disease) to ADT, the biochemical relapse-free survival (bRFS), clinical failure-free survival (CFFS) and freedom from distant progression (FFDP, when the disease occurred in a different site from that treated) were considered, starting from the first day of RT.

Results: After a median follow-up of 20.2 months, 3 patients died, 1 were lost to follow-up, 2 showed in-field and 7 out-of-field progression, 3 have ended ADT and are still free from any progression. Acute toxicity was very mild with no Grade >2 events, and only 2 serious late events, 1 G3 and 1 G4 late urinary toxicity, only in the hypofractionated postoperative cohort. With respect to bone irradiation, no Grade toxicity were reported. Median bRFS, CFFS and FFDP were 15,8 months, 16,9 months and 17,2 months, respectively. When considering FFDP, the most significant clinical end-point to evaluate the role of RT in this subset of patients, the most predictive factors were: PSA at diagnosis (iPSA>24,2 ng/ml, most-informative cut-off, AUC 77%, p=0,008) (HR=4.2, p=0,05), 2 vs 1 metastasis (HR=2.87, p=0,1), and no previous prostatectomy (HR=3,19, p=0,08), while no role emerged for the site of metastases (pelvic or not). When stratifying

patients by the presence of 0-1 or 2-3 risk factor, the 2-year actuarial FFDP was 100% and 49% respectively (p=0,01, Fig 1).



Conclusion: Although with a small cohort and a limited follow-up, these results seem to suggest that radical dose RT to all localization of disease is a valid approach in osseous OPC patients in association with ADT, also considering the low toxicity profile. Our predictive model aiming at identifying which patients may benefit of this kind of treatment seems to show that the ideal candidate could be a previously operated patient, with a iPSA≤24,2 ng/ml and with only one bone metastasis.

EP-1348

Endoscopic evaluation of late rectal toxicity after radiotherapy in 597 prostate cancer patients

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Purpose or Objective: Late rectal toxicity (LRT) is one of the main limitations of external radiotherapy (RT) for prostate cancer (PC). Purpose of this study was to evaluate the impact of various parameters on LRT, in a large cohort of patients undergoing radical or adjuvant RT in a series of clinical trials.

Material and Methods: 597 patients were selected (median age: 70 years; range: 43-88; NCCN risk class: 59 low, 199 intermediate, 339 high). Impact on grade ≥2 (RTOG) LRT of a series of parameters was analysed: previous radical prostatectomy, RT technique, type and duration of any adjuvant hormone therapy, RT dose and fractionation, acute rectal toxicity. LRT free survival curves were estimated according to the Kaplan Meier method. Univariate analysis was performed using log-rank test. Multivariate analysis was performed using "Cox's proportional hazard models".

Results: Table 1 shows the results of the analysis. Overall, grade > 2 LRT free survivals was respectively 89.5% and 84.9% at 2 and 5 years. At univariate analysis only acute rectal toxicity was significantly related to LRT (p <0.001) while there was a negative trend in patients receiving adjuvant hormone therapy, especially with LH-RH analogues. Multivariate analysis confirmed only the correlation between acute rectal toxicity and LRT (p: 0.006).

Table 1: Grade ≥ 2 late rectal toxicity free survival (%)

		Patients	2-year	5-year	Univariate analysis (log-rank), p:	Multivariate analysis (Cox), p:
Previous R.P.	no	403	88.6	81.1	0.175	
	yes	194	91.6	91.6		
Technique	3D	155	91.1	87.3		
	IMRT	418	88.4	80.1	0.878	
	VMAT	23	95.0	n.v.		
A.O.T. type	no	49	100.0	87.5		
	LH-RH analogue	287	86.8	83.7	0.065	0.991
	Bicalutamide	239	90.8	86.5		
A.O.T. duration	no	49	100.0	87.5		
	6 months	250	86.6	85.3	0.539	
	24 months	298	90.5	85.5		
Dose	≤ 70 Gy	378	90.0	90.0	0.303	
	> 70 Gy	219	88.7	83.1		
ENI	no	75	85.7	70.6	0.268	
	yes	522	90.5	89.9		
Fractionation	≤ 2 Gy/fr.	227	89.0	83.6	0.413	
	> 2 Gy/fr.	370	89.7	89.7		
Acute toxicity	G 0-2	571	90.3	85.6	<0.001	0.006
	G > 2	10	50.6	50.6		

R.P: radical prostatectomy; A.O.T.: adjuvant hormone therapy; ENI: elective nodal irradiation.

Conclusion: The results of this analysis showed no correlation between treatment parameters and LRT. This unexpected result is likely to be related to the use of modulated RT techniques in the majority of patients and to the distribution of the analysed parameters. For example, patients who have previously undergone radical prostatectomy, or treated with a hypofractionated regimen, generally received a lower total dose. The close correlation between acute and late toxicity seems to confirm the existence of a "consequential late toxicity" in radiation-induced damage to the rectum. This seems to suggest the utility of close endoscopic monitoring in the follow-up of patients with severe acute rectal toxicity.

EP-1349

Long term results of a phase I-II study of moderate hypofractionated IGRT in prostate cancer

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Purpose or Objective: To report long term clinical outcomes in prostate cancer patients (pts) treated with IGRT Moderate Hypofractionated Simultaneous integrated boost (SIB) by Tomotherapy in a phase I-II study.

Material and Methods: Between 2005 and 2011, 211pts were treated with IGRT Moderate Hypofractionated SIB in a phase I-II study . A subgroup of 128 pts (55 low- risk[LR], 33 intermediate- risk [IR] and 40high-risk[HR]) with 5 years minimum follow up were considered for this analysis. IR and HR pts received 51,8 Gy on pelvic lymph-nodes (LN) and concomitant SIB to prostate up to 74,2Gy in 28 fr; LR pts were treated to the prostate to 71,4Gy in 28fr. Androgen deprivation (AD) was delivered to 27% LR/57% IR/87% HR pts for a median time of 12.5, 13.7 and 15,5 months (m) respectively. Biochemical relapse free (bRFS) survival (Phoenix definition), cancer-specific (CCS) and overall survival (OS) actuarial curves were assessed. Selected clinical/dosimetry variables were tested as potential predictors of GI /GU toxicity and of BCR/CCS/OS (Cox test) .