Purpose or Objective: Although intensity modulated radiotherapy (IMRT) permits the delivery of a highly conformal dose to target volumes while sparing dose to identified organs at risk, it results in a higher whole body integral dose due to irradiation of a larger volume of tissue at lower doses. A randomized clinical trial in head and neck cancer comparing IMRT with 3-D conformal radiotherapy, demonstrated higher acute fatigue in the IMRT cohort, raising the possibility of an association with higher integral dose. We hypothesized that a higher integral whole body dose is associated with worsening fatigue and an adverse functional outcome in patients with localized prostate cancer treated with intensity modulated external beam radiotherapy.

Material and Methods: 26 patients with localized adenocarcinoma of prostate treated with intensity modulated external beam radiotherapy were included in this analysis. The integral dose was calculated as the product of mean body dose and body volume and the study cohort was dichotomized using the median integral dose as the cut-off value. The fatigue, physical functioning and role functioning domains of the EORTC QLQ-C30 questionnaire prior to radiotherapy and upon completion of radiotherapy were assessed. The outcome measure was defined as worsening in any of these three domains.

Results: The median integral dose was 119.7 litre-Gy (range 90.5 - 168.1). In the whole population 17/26 (65%) had worsening of fatigue, physical or role functioning. A significantly higher proportion of patients with an integral dose above median had worsening fatigue, physical and role functioning compared with patients with an integral dose below median. (6/13 versus 11/13; z test for proportions p=0.04).

Conclusion: To our knowledge, this is the first study linking acute worsening of fatigue and functional outcome with whole body integral dose. Further validation in a larger cohort and in different tumour sites is necessary and the relationship between integral dose and toxicity merits further investigation.

PO-0755
Intestinal toxicity from WPRT delivered with IMRT is negligible. A multicentric observational trial.

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Purpose or Objective: To prospectively evaluate acute intestinal toxicity (AIT) from RT including whole-pelvis irradiation (WPRT) for prostate cancer by means of a validated questionnaire (IBDQ, Intestinal Bowel Disease Questionnaire), and to investigate the intestinal symptoms that most affect patient quality of life (QoL).

Material and Methods: In 2014 a multicentric, observational trial aimed at assessing IT from RT including WPRT was activated. Prior to study activation, a pilot feasibility study was started in the coordinating Institute. For the study’s purpose, the IBDQ is to be filled in by pts at baseline, RT mid-point and end, and thereafter every 6 months up to 5 years. The questionnaire comprises 32 items investigating bowel symptoms (10 items), emotional health (12), systemic symptoms (5) and social function (5). The responses are scored on a seven-point scale in which 7 corresponds to the best function and 1 to the worst. Average per item scores can be calculated for each of the 4 domains. This analysis pertains to the first 144 pts (8 Institutes) with complete data available at baseline, RT mid-point and end. Initially, only pts treated with post-prostatectomy RT with either adjuvant (ADV, n=71) or salvage (SALV, n=73) intent were enrolled. Pts were treated with static-field IMRT (n=31), Tomotherapy (n=42) and VMAT (n=71), with conventional (1.8-2 Gy/fr, n=78) or moderate hypofractionation (2.15-2.65 Gy/fr, median 2.35, n=66). The median EQD2 dose to the prostatic bed and pelvic lymph nodal area was 71.2 and 50 Gy, respectively. 58 pts received concomitant androgen deprivation.

Results: Overall, self-perceived intestinal toxicity from WPRT was mild: mean scores for bowel symptoms at baseline, RT mid-point and end were in fact 6.58, 6.09, 5.90 (repeated measures Anova, p<0.0001), for emotional health 5.94, 5.79, 5.69 (0.0003), for social function 6.20, 5.83, 5.65 (p<0.0001) and for systemic symptoms 5.95, 5.55, 5.40 (p<0.0001), respectively. For the evaluation of acute toxicity, the worst variation (delta) between baseline and RT mid-point or end was considered. With respect to the bowel symptoms, the median score decrease (worsening) was 2 points for only one item (frequent bowel movements), 1 point for loose bowel movements, gas passage, abdominal bloating and urge to defecate, and 0 for abdominal pains and cramps, rectal bleeding, accidental soiling and nausea. Nevertheless, abdominal pain and urge to defecate were the two items with higher predictive power (AUC 72-79% at ROC curve analysis) with respect to a worsening of ≥1 point (25th percentile) of either emotional or systemic or social domains, as well as gas passage, urge to defecate and nausea (AUC 72-73%) for emotional.

Conclusion: The self assessed AIT from WPRT delivered by means of modern IMRT technique is negligible. Abdominal pain and urge to defecate are the 2 symptoms mostly correlated with a worsening of patient’s QoL.

PO-0756
Choline PET/CT and Stereotactic Body Radiotherapy in oligometastatic prostate cancer patients

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Purpose or Objective: To prospectively evaluate acute intestinal toxicity (AIT) from RT including whole-pelvis irradiation (WPRT) for prostate cancer by means of a validated questionnaire (IBDQ, Intestinal Bowel Disease Questionnaire), and to investigate the intestinal symptoms that most affect patient quality of life (QoL).

Material and Methods: In 2014 a multicentric, observational trial aimed at assessing IT from RT including WPRT was activated. Prior to study activation, a pilot feasibility study was started in the coordinating Institute. For the study’s purpose, the IBDQ is to be filled in by pts at baseline, RT mid-point and end. Initially, only pts treated with post-prostatectomy RT with either adjuvant (ADV, n=71) or salvage (SALV, n=73) intent were enrolled. Pts were treated with static-field IMRT (n=31), Tomotherapy (n=42) and VMAT (n=71), with conventional (1.8-2 Gy/fr, n=78) or moderate hypofractionation (2.15-2.65 Gy/fr, median 2.35, n=66). The median EQD2 dose to the prostatic bed and pelvic lymph nodal area was 71.2 and 50 Gy, respectively. 58 pts received concomitant androgen deprivation.

Results: Overall, self-perceived intestinal toxicity from WPRT was mild: mean scores for bowel symptoms at baseline, RT mid-point and end were in fact 6.58, 6.09, 5.90 (repeated measures Anova, p<0.0001), for emotional health 5.94, 5.79, 5.69 (0.0003), for social function 6.20, 5.83, 5.65 (p<0.0001) and for systemic symptoms 5.95, 5.55, 5.40 (p<0.0001), respectively. For the evaluation of acute toxicity, the worst variation (delta) between baseline and RT mid-point or end was considered. With respect to the bowel symptoms, the median score decrease (worsening) was 2 points for only one item (frequent bowel movements), 1 point for loose bowel movements, gas passage, abdominal bloating and urge to defecate, and 0 for abdominal pains and cramps, rectal bleeding, accidental soiling and nausea. Nevertheless, abdominal pain and urge to defecate were the two items with higher predictive power (AUC 72-79% at ROC curve analysis) with respect to a worsening of ≥1 point (25th percentile) of either emotional or systemic or social domains, as well as gas passage, urge to defecate and nausea (AUC 72-73%) for emotional.

Conclusion: The self assessed AIT from WPRT delivered by means of modern IMRT technique is negligible. Abdominal pain and urge to defecate are the 2 symptoms mostly correlated with a worsening of patient’s QoL.
Purpose or Objective: A new entity of patients with recurrent prostate cancer limited to a small number of active metastatic lesions is having growing interest: the oligometastatic patients. Patients with oligometastatic disease could eventually be managed by treating all the active lesions with local therapy, i.e. either surgery or ablative stereotactic body radiotherapy. This study aims to assess the impact of [18F]Choline ([18F]FMCH) PET/CT and the use stereotactic body radiotherapy (SBRT) in patients (pts) with oligometastatic prostate cancer (PCa).

Material and Methods: Twenty-nine pts with oligometastatic PCa ≤3 synchronous active lesions developed > three active synchronous metastases. Primary endpoint was systemic therapy-free survival measured from the baseline [18F]FMCHPET/CT.

Results: A total of 45 lesions were treated with SBRT. After a median follow-up of 11.5 months (range 3-40 months), 20 pts were still in the study and did not receive any systemic therapy. Nine pts started systemic therapy, and the median time of the primary endpoint was 39.7 months (CI 12.20-62.14 months). No grade 3 or 4 toxicity was recorded.

Conclusion: Repeated salvage [18F]FMCHPET/CT-guided SBRT is well tolerated and could delay the beginning of systemic therapy in selected patients with oligometastatic PCa.

PO-0757
SBRT for prostate cancer using tomotherapy: interim analysis of a prospective trial in 82 patients
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Purpose or Objective: 5-fraction SBRT using CyberKnife is a well-established safe alternative treatment for selected low-risk (LR) and intermediate-risk (IR) prostate cancer. The aim of this study is to determine prospectively the morbidity (CTCAE) and QOL (auto-administered IPSS) of an 8-fraction scheme for high-risk (HR), IR and LR using tomotherapy.

Material and Methods: Exclusion criteria were T3b-4, GS 9-10, PSA ≥50, IPSS ≥20. Since 2012 eighty-two patients were treated: 41 HR (23/41 with GS8 or PSA ≥50 or T3a, and 18/41 with 2 intermediate risk factors), 17 IR (GS 7 or PSA 10-20 or T2b-c), and 24 LR. 57/82 patients received 6-month hormonal therapy (HT).

8 fractions of 5.65 Gy for HR-IR, and 5.48 Gy for LR patients were delivered every other day over about 2.5 weeks. EQD2 is 92.3 Gy (HR, IR) or 87.4 Gy (LR) for prostate cancer (a/b 1.5), and 78.2 or 74.3 Gy for late-responding tissues (a/b 3), respectively.

Results: Median follow-up was 13.7 months (0.3-40.1). No acute/late grade ≥3 events were observed. Late GU or GI grade 2 toxicities were far below 10% (see Table). We observed a slight urinary flare at 18 months.

IPSS scores (Q1-7) and patient satisfaction (Q8) returned to baseline at 6 months (p=0.21), after they significantly worsened at the last fraction (p=0.00), especially the IPSS-obstructive component (see Figure).

Without HT, PSA nadir has not been reached yet. Mean value at 24 months was 0.66 ng/mL. With HT, PSA nadir was reached between 1-6 months and then raised up to 0.37 ng/mL average at 18 months (mean testosterone 291 ng/dL), to remain steady afterwards. No biochemical (nadir-2) /clinical failure was found. One unrelated cancer/treatment death occurred during SBRT.

Conclusion: To our knowledge this is the first communication of SBRT using helical tomotherapy for localized prostate cancer. The 8-fraction scheme is being well tolerated, with no moderate-severe toxicity, suggesting that this approach is safe. Longer follow-up is needed to find out whether the delivery of equivalent doses near the plateau of the dose-response curve (>90 Gy) results in better tumour control in this cohort of patients (mostly HR and IR tumours).

PO-0758
Adjuvant or Salvage? 10-y results of the AIRO Group on Prostate cancer multicentre prospective trial