The European Council Directive 97/43/EURATOM introduce specific requirements aimed at the reduction of the probability and the magnitude of accidents in radiotherapy. Within a European Commission (EC) project, the implementation of these requirements in radiotherapy in Europe is reviewed through detailed web-based questionnaires, focusing on the national systems of risk management in external beam radiotherapy and the national systems for classification, recording and reporting of adverse events or near misses concerning patient safety in external beam radiotherapy. The results, together with a review of available international systems related to risk management, are used to prepare European guidelines on a risk analysis of accidental and unintended exposures in external beam radiotherapy.

The results of the questionnaires reveal that more than half of the countries already implemented the legal basis for risk analysis and event’s classification, recording and reporting. However, the lack of this basis in many countries and the lack of practical implementation in most of the countries highlight the need for further European guidelines. The guidelines under preparation will review the available risk assessment methodologies, both general methodologies like Event Tree, Fault Tree and Process analysis including critical point, and methodologies dedicated to radiotherapy such as Failure Mode and Effects Analysis (FMEA) and Risk Matrix. The risk assessment methodologies vary as for their purpose and capabilities in different steps of the risk management: hazard and failure identification, events’ consequence, likelihood and severity evaluation, actions decision process and feedback analysis. The guidelines will discuss the value of the various methodologies and give advice and examples on their application in radiotherapy, aiming to establish a minimum approach dedicated to radiotherapy.

Further, basic terminology for classification and reporting of adverse events and near misses is proposed. Common terminology facilitates the classification and comparison of reported data from different sources and is a key to compare the risk of radiotherapy with other health care areas. Existing general healthcare taxonomies with specific codes for radiotherapy should be used as much as possible in order to integrate the radiotherapy reporting in existing general healthcare reporting systems with an important save of resources. The event reporting systems should preferably be called event learning systems, to emphasize that reporting is only one step in a process aimed at learning from events. Departmental reporting/learning systems should be part of the safety culture and ideally, a module in radiotherapy information systems. Monitoring is fundamental to demonstrate the implementation of remedial actions, to close the cycle of learning and improving safety after an event takes place. The risk management envisaged in the guidelines will significantly contribute to the improvement of patient safety in radiotherapy.

POSTER DISCUSSION: 4: CLINICAL: PROSTATE

PD-0129
GTV and CTV in prostate cancer: distance and size of satellites relative to the Index lesion
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Purpose/Objective: Prostate cancer is predominantly a multifocal disease, which consists of an index lesion and one or more satellites. The success of focal radiation treatment relies primarily on how well prostate tumors can be delineated by using MR imaging. The sensitivity and specificity for tumor detection on multi-parametric MRI is highly reduced for tumors smaller than 5 mm in diameter. Focal therapy for prostate cancer can be delivered in different ways. Focal-only therapy will treat only the visible tumor and not the whole prostate. Focal boost therapy (e.g. FLAME study) will treat the whole prostate and boost visible tumor. The aim of this study was to analyze distances and volumes of satellites relative to the index lesion in order to investigate the potential of a CTV margin for use in focal therapy.

Materials and Methods: A total of 61 patients who underwent a radical prostatectomy were included in this study. On the H&E stained slides retrieved from these specimens, the uro-pathologist contoured the index lesion and satellites. Then the slides were digitized and stacked with a 4 mm distance. The slide-stacks were imported in our in-house developed delineation program (WorldMatch) for further analysis. The distance between the borders of the delineated tumors was measured and volumes of all delineated tumors were calculated.

Results: Of the 61 patients, 51 (84%) had multifocal disease. The median number of satellites in all patients was 3. In 50% of the patients, the distance of the index lesion to the satellites was 1.0 cm or more, with a maximum of 4.4 cm. 32% of the satellites were smaller than 5 mm in diameter. Of the total tumor volume 14% was located in the satellites. However, the contribution of satellites smaller than 5 mm to the total tumor volume only amounted to an average of 0.9%. If all tumors larger than 5 mm were assumed to be GTV, 54% of the patients did not have any tumor volume outside of the GTV.

Conclusions: A CTV margin around the index lesion which contains all satellites will cover in the majority of patients nearly the entire prostate. The limited contribution of satellites smaller than 5 mm to the overall tumor load however raises the question as to their clinical relevance. If the small satellites are of no/little clinical relevance and the GTV for focal therapy includes all tumors ≥ 5 mm in diameter, than focal-only therapy to the GTV may be safe. If however small satellites are clinically relevant, treatment of the entire prostate is necessary with possibly a focal boost to the GTV.

In both cases, careful screening to identify larger satellites is warranted.

PD-0130
Dependence of intra-fraction prostate motion on fraction duration during pelvic radiotherapy with RapidArc vs IMRT
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Purpose/Objective: To compare the 3-dimensional intra-fraction variations of prostate position within the pelvis with whole-pelvic four-field intensity-modulated radiation therapy (IMRT) vs. intensity-modulated arc therapy (IMAT) in high-risk prostate cancer (PCa).

Materials and Methods: Fifteen PCa patients underwent whole pelvic radiotherapy using either dynamic IMRT with a sliding window technique (n= 8) or IMAT (n= 7). All the patients had a kV cone-beam computed tomography (CBCT) before and immediately after each fraction of IMRT or IMAT.

Intra-fraction motions of the prostate were determined using a 2-step procedure performed on each pre- and post-treatment imaging: 1)
planning CT and CBCT were matched on bony structures after automatic semi-rigid fusion alongside the 3 axis: xsoft, ysoft, zsoft. The position of the prostate within the pelvis for each pre- and post-treatment study was defined as xsoft = (xCT - xb) + xsoft, ysoft = (yCT - yb) + ysoft, and zsoft = (zCT - zb). Rectum and bladder were outlined on each CBCT with the aim to assess changes in rectal or vesical repletion during each fraction. Organ distortion was assessed by measuring the average rectal cross- sectional area (rcSA; defined as the rectal volume divided by length), and the area of the bladder when evaluated 2.5cm above the prostate base (A-blad) on pre- and post-treatment CBCT.

Results: Two hundred and ninety four CBCT were reviewed for this analysis. The average fraction duration was shorter with IMAT than with IMRT (4.49 vs. 11.00", p< 0.001). During fractions of IMRT the prostate showed statistically significant shifts in the longitudinal (p=0.049) and lateral (p=0.013) axis while it was not statistically significant during fractions of IMAT. Intra-fraction rcSA increased neither during IMAT nor IMRT whereas A-blad increased only during fractions of IMRT but with no correlation with prostate displacements.

Conclusions: The prostate movement within the pelvis during an IMAT course which could lead to a greater daily geographic miss when compared to the IMAT technique.

PD-0131
To predict nodal status using Artificial Intelligence approaches in prostate cancer: beyond the Roach formula
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Purpose/Objective: To present an innovative approach based on the methods of Artificial Intelligence (AI) to better predict N status in prostate cancer patients (pts), integrating some important clinical and therapeutic parameters (Gleason Score/sum, age, initial PSA, prostate cancer patients (pts), integrating some important clinical and therapeutic features perform better than the Roach formula.

Materials and Methods: A total of 1808 pts from a National Italian multicentric database was analyzed. Following the D’Amico criteria, we found 317 low risk, 577 intermediate risk and 914 high risk pts. With a known N status at diagnosis, N-pts were defined as those with a positive contrast enhanced pelvic MRI and /or CT scan; those showing a nodal only relapse after RT were also classified as N+ (as none of them received pelvic RT). Finally, 3 AI classifications method, based on decision trees (the J48 method, the Forrest Tree method and the Random Tree method) combined with 3 techniques of manipulation of imbalanced samples (oversampling, undersampling and combined under/oversampling) were used to predict the N status. The accuracy of the Roach formula was calculated.

Results: Table 1 resumes the performances of the Roach formula and of the 3 AI methods. All the proposed AI methods taking in account more clinical and therapeutic features perform better than the Roach formula. Looking at the whole population, the classic approach showed an accuracy (i.e. true positives + true negatives/whole population) rate ranging, depending on the cut-off, between 34.6% and 56.5%. In the same population, the 3 AI methods showed an accuracy rates of 100%, 96.9% and 98.2%, respectively.

Conclusions: Roach formula is suboptimal in predicting the nodal status of prostate cancer patients. Non-linear relationships with more than two variables probably exist. New approaches taking into account more variables could possibly better predict the nodal status of the patients.

PD-0132
Weekly bladder dose and clinical factors predict acute GU symptoms assessed by IPSS after RT for prostate cancer
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Purpose/Objective: In April 2010 the prospective observational study started with the aim of developing predictive models of genito-urinary (GU) toxicity and erectile dysfunction for prostate cancer patients (pts) treated with high dose radiotherapy (RT) delivered with conventional (1.8-2Gy/fr, CONV) or moderate hypo-(2-2.7Gy/fr HYPO) fractionation. In this ad-interim analysis the correlation between dosimetry/clinical factors and the modifications between pre-RT/IPSSbasal and final (IPSSend) IPSS values were investigated.

Materials and Methods: For all pts several clinical factors were collected as: T stage, hormonal therapy, smoking, use of drugs, presence of concomitant pathologies, previous surgery, age. Bladder parameters were also recovered: volume, D1%, mean dose, DVH and Dose Surface Histogram (DSH) in absolute and in relative value, referred to both the whole treatment and to the weekly delivered treatment (DVHw/DSHw, expected to be more predictive of acute symptoms). DSH were calculated using a dedicated software (Vodca, IPSend). IPSSend was considered as end-point. Logistic uni- and backward multi- variate (MVA) analyses were performed. Sub-analyses were repeated in two selected subgroups: (1) pts with IPSSbasal<15 (2) pts in the HYPOarm.

Results: At the time of analysis (November 2012), 212 pts were available: full 3D dose-volume data were available for 177/212 (73 CONV and 104 HYPO). IPSSend was 56/212 (26%). The dosimetry factors more predictive were assessed by looking to the most significant differences between DSH/DVH (DVHw/DSHw) of pts with IPSSend or <15. Best predictors were the absolute bladder surface 8.5Gy/week and <12.5 Gy/week; the correlation was also significant, although lower, for absolute DVHw and % DSHw/DVHw. In Fig1 the mean DSHw for pts with IPSSsend ≥15 are shown (HYPO group). The correlation was stronger for the HYPO group. Total DSHw/DVHw were not correlated with IPSSend<15. At MVA (p<0.0001), the main independent predictors of IPSSend<15 were: baseline IPSS (OR:1.99, p<0.001), S12.5w(abs) (OR:1.04, p<0.005); S8.5w(abs) (OR:1.01, p=0.13); use of anti-hypertensive (OR:2.08, p=0.058). The predictive value of the model was relatively high (AUC=78.2%, CI:71-84%). The independent role of S8.5w and S12.5w was confirmed when excluding pts with baseline IPSS≤15 (AUC=76.6%) and in the HYPO sub-group (AUC=76.2%).

Fig1 The average of DSHw for pts with IPSSend ≥15.

Conclusions: Absolute weekly DSH/DVH predicts the risk of IPSSend<15 together with baseline IPSS and the use of anti-hypertensive. The correlation was confirmed if excluding pts with large basal IPSS and in the HYPO subgroup. To our knowledge, this result represents the first evidence of a dose-volume/surface effect for acute GU symptoms prospectively measured in an observational study. The inclusion of HYPO pts likely enhanced the effect, due to the