Conclusion: Neoadjuvant radiation dose to the gastric fundus has a significant influence on the risk of postoperative anastomotic leakage in patients with esophageal cancer treated with nCRT followed by transthoracic esophagectomy and cervical anastomosis. This finding is important for clinical practice because it suggests that efforts should be made to minimize the radiation dose to the gastric fundus when planning neoadjuvant radiation treatment for esophageal cancer.

PV-0121
Falcon based Clinical Target Volume Delineation to support Inter-Society Rectal Cancer Guidelines.

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Purpose or Objective: The delineation of clinical target volume (CTV) is a crucial step) in radiation therapy procedure. Uncertainties are related to the availability of several contouring guidelines suggesting different subvolumes and anatomical limits in rectal cancer. Furthermore, individual training creates large inter-operator variability in delineation. An international consensus among expert radiation oncologists might significantly reduce this variability. The definition of the procedures needed to produce consensus guidelines for rectal cancer through Falcon, the educational web-based multifunctional platform for delineation endorsed by ESTRO, was the primary aim of this study

Material and Methods: Seven skilled radiation oncologists, delegated from ESTRO, ASTRO, TROG, EORTC, defined the steps to produce consensus rectal cancer guidelines on elective nodal level delineation during a preliminary meeting held in August 2014. Step 1: six rectal cancer cases with different clinical stage were chosen and the related CT scans were shared and unanimously approved. Step 2: the experts firstly delineated online the selected CT scan slices following each his own approved guidelines. Step 3: Meeting on person to discuss the first delineation outcome, with also surgeon and radiologist ad hoc invited. Step 4: all the experts had to delineate online the same CT scan slices, based on the new table of boundaries. Step 5: Peer review meeting to evaluate the final outcome and to define the publication plan. The degree of agreement was evaluated through the EduCause STAPLE algorithm (ECSa). Step 6: preparation of the cases in Falcon to allow a free consultation after the publication of the guidelines

Conclusion: The ESTRO’s Falcon platform of delineation showed to be a valuable tool in the definition of consensus guidelines for rectal cancer. These procedures might be reproduced to support the reproduction, discussion and comparison of delineations among skilled radiation oncologists to converge to consensus guidelines also for other scenarios.

PV-0122
Clinical factors as a selection tool for organ-preserving treatment strategies in rectal cancer

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Purpose or Objective: The standard treatment for locally advanced rectal cancer is radio(chemo)therapy (RCT) followed by total mesorectal excision (TME) surgery. Patients who achieve a good response to RCT may be offered less invasive surgery such as local excision or even no surgery at all. Before such a policy could be safely implemented, precise selection of the eligible patients is mandatory. This study identifies the pretreatment clinical factors that are associated with pathological complete response (pCR) and ypT0-1N0 and evaluates their performance as a tool to select patient for organ-preserving treatment strategies.

Results: Falcon platform allowed to succeed in any steps: selection and upload of the proper CT scans proposed among the experts leaving different countries; optimal compliant of all expert their delineation exercise; the possibility to review and share the online delineation, to support the discussion by telephone conference. Some Falcon’s features were considered significant to compare concurrently all the experts’ delineations, allowing to identify critical nodal boundaries as areas of disagreement. Furthermore the ECSAs, has allowed to evaluate during the validation step the degree of agreement where the shared voxels between experts’ delineations are graphically represented through an area with different levels of confidence (from 85% to 100%) for each structure set.

Table 5: Univariable logistic regression analysis of gastric fundus dose characteristics among patients with recurrent without anastomotic leakage

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (n = 26)</th>
<th>mean dose (Gy)</th>
<th>mean dose (Gy)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor or no leakage</td>
<td>17 (1.6)</td>
<td>17.4 (13.5)</td>
<td>17.4 (13.5)</td>
<td>0.002 (0.081)</td>
<td>0.67</td>
</tr>
<tr>
<td>Mean dose (Gy)</td>
<td>20 (1.9)</td>
<td>24.9 (11.3)</td>
<td>24.9 (11.3)</td>
<td>0.003 (0.031)</td>
<td>0.67</td>
</tr>
<tr>
<td>Minor or no leakage</td>
<td>15 (1.5)</td>
<td>9.1 (3.4)</td>
<td>9.1 (3.4)</td>
<td>0.004 (0.031)</td>
<td>0.67</td>
</tr>
<tr>
<td>CTV (Gy)</td>
<td>20 (1.9)</td>
<td>24.9 (11.3)</td>
<td>24.9 (11.3)</td>
<td>0.003 (0.031)</td>
<td>0.67</td>
</tr>
<tr>
<td>Maximum dose (Gy)</td>
<td>17 (1.6)</td>
<td>24.9 (11.3)</td>
<td>24.9 (11.3)</td>
<td>0.002 (0.081)</td>
<td>0.67</td>
</tr>
<tr>
<td>V2 (Gy)</td>
<td>17 (1.6)</td>
<td>84.5 (27.1)</td>
<td>84.5 (27.1)</td>
<td>0.004 (0.031)</td>
<td>0.67</td>
</tr>
<tr>
<td>V50 (Gy)</td>
<td>17 (1.6)</td>
<td>50.7 (26.3)</td>
<td>50.7 (26.3)</td>
<td>0.004 (0.031)</td>
<td>0.67</td>
</tr>
<tr>
<td>V70 (Gy)</td>
<td>17 (1.6)</td>
<td>26.1 (9.9)</td>
<td>26.1 (9.9)</td>
<td>0.004 (0.031)</td>
<td>0.67</td>
</tr>
<tr>
<td>V90 (Gy)</td>
<td>17 (1.6)</td>
<td>17.4 (6.5)</td>
<td>17.4 (6.5)</td>
<td>0.004 (0.031)</td>
<td>0.67</td>
</tr>
</tbody>
</table>

*p value < 0.05 was considered significant. (CI) Confidence interval.
Material and Methods: Patients with histologically confirmed rectal adenocarcinoma who were treated with preoperative RCT and TME between January 2000 and December 2014 were retrospectively included. Patients who received no preoperative RCT, patients treated with postoperative RCT and those treated for a local recurrence were excluded. Following pretreatment clinical characteristics were extracted from the medical files: age, gender, body mass index, CA 125 score, cT-stage, cN-stage, tumor distance from the anal verge, pretreatment CEA, pretreatment hemoglobin and distance from the mesorectal fascia. Univariable and multivariable binary logistic regression models were used to predict pCR and ypT0-1N0. A multivariable prediction model was obtained by combining all predictors and by applying a backward selection procedure with 0.157 as critical level for the p-value. The discriminative ability of the prediction models was evaluated by receiver operating characteristic analysis. To avoid that the same data were used to develop and to validate the model, the area under the curve (AUC) was based on a leave-one-out cross-validation.

Results: A total of 620 patients were included of whom 120 patients experienced a pCR (19%) and 170 patients achieved a ypT0-1N0 response (27%). A low pretreatment CEA, a high pretreatment hemoglobin and a high cN-stage were associated with pCR in multivariable analysis (Table). A low pretreatment CEA, a low cT-stage and a high cN-stage were associated with ypT0-1N0. After cross-validation, the AUC of the pCR and ypT0-1N0 prediction model equaled 0.609 and 0.632, respectively.

Conclusion: The present analysis provides compelling evidence regarding gender-specific differences in the occurrence of secondary malignancies after pelvic radiation. Indeed, radiation for rectal cancer is associated with a significantly decreased risk of prostate cancer, however, an increased risk of endometrial, lung, and bladder cancer as well as lymphoma. Patients undergoing radiation for rectal cancer must be informed regarding the potentially increased risk of secondary malignancies.

PV-0124
Does daily intake of resistant starch reduce the acute bowel symptoms in pelvic radiotherapy? R. Warschkow1, U. Güller2, T. Cerny2, B.M. Schmied1, L. Plasswilm1, P.M. Putura4
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5Christian Medical College Hospital, Gastroenterology, Vellore, India

Purpose or Objective: The purpose of the study is to look at the benefit of administering of an oral resistant starch in reducing the incidence of acute radiation proctitis, a distressing symptom in patients receiving radiation therapy for cancer of the cervix.

Material and Methods: The study was conducted between 2011 and 2014 in 104 patients receiving radical chemo-radiotherapy for carcinoma cervix. Patients were randomized to two arms receiving 30 gm of resistant starch or digestible starch on a daily basis through out the course of the external radiotherapy. All patients received standard 4-field box radiation portals, 50 Gy in 25 fractions with 4 cycles of weekly concurrent Cisplatin. All of them underwent LDR brachytherapy of 30 Gy at completion of external beam radiotherapy. The study was double blinded and allocation was concealed from the investigators. The investigator recorded the radiotherapy related toxicity of the patients according to CTC V 3.0. The incidence and severity of grade 2-4 diarrhoea and proctitis were documented on a weekly basis and compared across the two randomized groups and analysed. Stool short chain fatty acid concentrations were measured at baseline at 2nd and 4th week and after 6 weeks analysis using conventional multivariable analyses as well as propensity score matching to assess this relationship.

Results: Of 77,484 patients, 34,114 underwent radiation and 43,370 did not. Overall, radiation therapy was not associated with secondary malignancies (hazard ratio [HR] = 0.97 (95%CI: 0.92−1.02, P=0.269). In female patients (HR = 1.11, 95%CI:1.02−1.21, P=0.021) the risk for secondary malignancies was increased after radiation therapy, while a decrease of secondary malignancies was found in male patients (HR = 0.90, 95%CI:0.85−0.96, P=0.002). The risk for prostate cancer was significantly decreased (HR=0.44, 95%CI:0.38−0.51, P<0.001) whereas the risk for endometrial cancer was increased (HR=2.07, 95%CI:1.56−2.75, P<0.001). The cancer for lung cancer (HR=1.20, 95%CI:0.84−1.75, P=0.001), bladder cancer (HR=1.50, 95%CI:1.26−1.82, P=0.001), and lymphoma (HR=1.29, 95%CI:1.02−1.25, P=0.032) were increased after radiation in the overall population.

Conclusion: Despite their statistical significance, the value of pretreatment clinical variables in the prediction of pCR and ypT0-1N0 is very limited. To safely select rectal cancer patients for organ-preservation, other strategies using functional imaging or molecular markers need to be explored.

PV-0123
Gender and secondary malignancies in rectal cancer patients with and without radiation therapy R. Warschkow1, U. Güller2, T. Cerny2, B.M. Schmied1, L. Plasswilm1, P.M. Putura4
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Purpose or Objective: The relationship between radiation therapy for rectal cancer and secondary malignancies is debated. The present study is the first population-based