with at least 1 cm margin. In view of considerable variability between different authors, there is an obvious need for the international consensus guidelines.

**Poster: Clinical track: Lower Gl (colon, rectum, anus)**

**PO-0715**

Chemoradiation with concomitant boost in rectal cancer (T4&recurrences): a phase II study

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**Purpose or Objective:** Aim of this clinical study was to evaluate resectability and pathological response after preoperative concurrent chemotherapy with 2 different drugs and radiation therapy (RT) intensified with concomitant boost.

**Material and Methods:** A clinical trial based on two-stage Simon’s design was planned. The trial included a first phase with enrolment of 9 patients. If 0/9 patients had complete pathologic response (pCR) the study had to be closed. In the case of 1/9 patients with pCR it was scheduled to enrol other 8 patients. RT was performed with 3D-conformal technique. The dose to mesorectum and pelvic lymph nodes was 45 Gy (1.8 Gy/fraction). A concomitant boost was delivered to GTV + 2 cm margin with a total dose of 55.5 Gy (2.3 Gy/fraction). The following concomitant chemotherapy was administered: Raltitrexed (3 mg/m2) and Oxaiplatin (130 mg/m2) on days 1, 17, 35 of RT. Acute and late toxicities were evaluated according to CTC-AE v.3.0 criteria.

**Results:** All 9 patients enrolled in the 1st phase underwent radical surgical resection, with 4/9 pCR. Then, 9 additional patients were enrolled for a total of 18 patients (F: 7, M: 11; median age 62, range: 39-79); clinical stage: 4 local recurrences, 6 abdominal perineal amputations and 1 trans-anal resection) while 2 patients did not undergo surgery for early metastatic progression (1) or death from acute pulmonary oedema prior to surgery (1). R0 resection was achieved in all patients who underwent surgery. Overall, 5 patients had pCR and 2 patients showed only microscopic residual disease (pT0-Tmic: 7/17 = 41.2%). Sixteen patients underwent surgical resection (9 anterior resection, 6 abdominal perineal amputations and 1 trans-anal resection) while 2 patients did not undergo surgery for early metastatic progression (1) or death from acute pulmonary oedema prior to surgery (1). R0 resection was achieved in all patients who underwent surgery. Overall, 4 patients had pCR and 7 patients only a microscopic residual of disease (pT0-Tmic: 11/18 = 61.1%). Acute grade 3 toxicity was: 1 leukopenia - neutropenia, 1 skin toxicity, 1 genitourinary toxicity and 5 gastrointestinal toxicities, with an overall incidence (considering the patient who died after radio chemotherapy) of 7/18 patients (38.9%). The actuarial analysis showed the following 2-year results: local control 80%, metastasis-free survival 93.7%, overall survival 88.9%.

**Conclusion:** The regimen used in this study showed excellent results in terms of pathologic responses (pT0-Tmic: 61.1%). However, despite the use of VMAT technique, more than 1/3 of patients had severe acute toxicity.

**PO-0716**

Preoperative chemoradiation with VMAT-SIB in rectal cancer: a phase II study (Grace-Rectum-1)

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**Purpose or Objective:** Aim of this analysis was to describe the results of a phase II study based on the use of VMAT in preoperative combined treatment of locally advanced rectal cancer.

**Material and Methods:** A clinical trial based on two-stage Simon’s design was planned. The trial includes a 1st phase of enrolment of 9 patients. If 0/9 patients had complete pathologic response (pCR) the study had to be closed. The trial included a first phase with enrolment of 9 patients. If 0/9 patients had complete pathologic response (pCR) the study had to be closed. In the case of 1/9 patients with pCR it was scheduled to enrol other 8 patients. Radiation therapy was performed using VMAT-SIB technique. The dose to mesorectum and pelvic lymph nodes was 45 Gy (1.8 Gy/fraction). A concomitant boost was delivered to GTV + 2 cm margin with a total dose of 57.5 Gy (2.3 Gy/fraction). The following concomitant chemotherapy was administered: Cefotaxime (825 mg/m2 twice daily, 5 days/week) and Oxaliplatin (130 mg/m2 on days 1, 17, 35). Acute and late toxicities were evaluated according to CTC-AE v. 3.0 criteria.

**Results:** All 9 patients enrolled in the 1st phase underwent radical surgical resection, with 4/9 pCR. Then 9 additional patients were enrolled for a total of 18 patients (F: 7, M: 11; median age 62, range: 39-79); clinical stage: 4 local recurrences, 6 abdominal perineal amputations and 1 trans-ana resection) while 2 patients did not undergo surgery for early metastatic progression (1) or death from acute pulmonary oedema prior to surgery (1). R0 resection was achieved in all patients who underwent surgery. Overall, 4 patients had pCR and 7 patients only a microscopic residual of disease (pT0-Tmic: 11/18 = 61.1%). Acute grade 3 toxicity was: 1 leukopenia - neutropenia, 1 skin toxicity, 1 genitourinary toxicity and 5 gastrointestinal toxicities, with an overall incidence (considering the patient who died after radio chemotherapy) of 7/18 patients (38.9%). The actuarial analysis showed the following 2-year results: local control 80%, metastasis-free survival 93.7%, overall survival 88.9%.

**Conclusion:** The regimen used in this study showed excellent results in terms of pathologic responses (pT0-Tmic: 61.1%). However, despite the use of VMAT technique, more than 1/3 of patients had severe acute toxicity.