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 GI (colon, rectum, anus)**

**PO-0715**

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

V. Picardi1, G. Macchia1, M. Di Bartolomeo1, M. Giordano1, M. Nuzzo1, L. Caravatta2, M.A. Gambacorta1, L. Di Lullo2, A. Guido3, L. Giaccherini3, L. Fuccio4, R. Golferli5, D. Cuicchi6, G. Uoglini6, S. Cammelli6, G. Frezza7, A.G. Morganti3, V. Valentini3, F. Deodato3

1 Fondazione di Ricerca e Cura “Giovanni Paolo II” - Catholic University of Sacred Heart, Radiation Oncology Unit, Campobasso, Italy 2PO. O. Bucsin, Radiotherapy Unit - Centro di Radioterapia e Medicina Nucleare, Cagliari, Italy 3Pollicino Universitario “A. Gemelli” - Catholic University of Sacred Heart, Department of Radiotherapy, Roma, Italy 4 “F. Venezia” Hospital, Oncology Unit, Iserrnia, Italy 5S. Orsola-Malpighi Hospital- University of Bologna, Radiation Oncology Center - Department of Experimental- Diagnostic and Speciality Medicine - DIMES, Bologna, Italy 6S. Orsola-Malpighi Hospital- University of Bologna, Department of Medical and Surgical Sciences - DIMEC, Bologna, Italy 7S. Orsola Malpighi Hospital- University of Bologna, Radiotherapy Department, Bologna, Italy 8Bellaria Hospital, Radiotherapy Department, Bologna, Italy

**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 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 57.5 Gy (2.3 Gy/fraction). The following concomitant chemotherapy was administered: Capecitabine (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: 8, M: 10; median age 64.5, range: 45-80; clinical stage: 2 local recurrences, 16 CT4, 6 cN0, 4 cN1, 7 cN2, 1 cN3). Seventeen patients underwent surgical resection (7 anterior resections and 9 abdominal-perineal amputation) 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%). Acute grade 3 toxicity was: 1 leukopenia-neutropenia, 1 liver toxicity, 5 gastrointestinal toxicities, with an overall incidence of 7/18 patients (38.9%). The actuarial analysis showed the following 2-year results: local control 100%, metastasis-free survival 93.7%, overall survival 92.3%.

**Conclusion:** The regimen used in this study allowed to achieve complete and near-complete response rate higher than 40%, despite the advanced stage of disease. However, severe acute toxicity was reported in more than 1/3 of patients.

**PO-0716**

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

V. Picardi1, G. Macchia1, S. Cilla2, M. Di Bartolomeo3, M. Giordano1, F. Rotondi4, M.A. Gambacorta1, F. Deodato1, L. Ronchi5, A. Farioli6, A. Guido7, G. Siepe8, G. Compagnone1, A. Ardizzoni9, S. Cammelli6, G. Frezza7, A.G. Morganti3

1 Fondazione di Ricerca e Cura “Giovanni Paolo II” - Catholic University of Sacred Heart, Radiation Oncology Unit, Campobasso, Italy 2Fondazione di Ricerca e Cura “Giovanni Paolo II” - Catholic University of Sacred Heart, Medical Physics Unit, Campobasso, Italy 3Fondazione di Ricerca e Cura “Giovanni Paolo II” - Catholic University of Sacred Heart, Department of Oncologic Surgery, Campobasso, Italy 4Pollicino Universitario “A. Gemelli” - Catholic University of Sacred Heart, Department of Radiotherapy, Roma, Italy 5S. Orsola-Malpighi Hospital- University of Bologna, Radiation Oncology Center - Department of Experimental- Diagnostic and Speciality Medicine - DIMES, Bologna, Italy 6S. Orsola-Malpighi Hospital- University of Bologna, Department of Medical and Surgical Sciences - DIMEC, Bologna, Italy 7S. Orsola-Malpighi Hospital- University of Bologna, Department of Medical Physics, Bologna, Italy 8S. Orsola-Malpighi Hospital- University of Bologna, Department of Medical Oncology, Bologna, Italy 9Bellaria Hospital, Radiotherapy Department, Bologna, Italy

**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 included a first phase 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 on GTV + 2 cm margin with a total dose of 57.5 Gy (2.3 Gy/fraction). The following concomitant chemotherapy was administered: Capecitabine (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 cT4, 5 cT3, 3 cT2, 2 cN0, 7 cN1, 9 cN2). Sixteen patients underwent surgical resection (9 anterior resection, 6 abdominal perineal amputations and 1 trans-rectal 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 a 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 reported 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.