

brain metastases (BMs) with only modest improvement of overall survival.

Materials and Methods: To evaluate the impact of PCI on survival we reviewed 179 LD SCLC patients treated with definitive chemoradiotherapy (CRT) in the concurrent or sequential setting. PCI was applied in the partial and complete responders exclusively provided contrast-enhanced cranial magnetic resonance imaging (cMRI) before and after primary treatment showed no signs of occult BMs. Correlation between PCI and time to progression (TTP) as well as overall survival (OS) was analysed. Kaplan-Meier analysis, uni- and multivariate Cox regression were used to describe survival within subgroups defined by treatment response and application of PCI.

Results: Concurrent and sequential chemoradiotherapy CRT was applied in 71 (40%) and 108 (60%) patients, respectively. In 58 (32%) patients metachronous BMs were detected. PCI was applied in 71 (39%) patients. 15 patients developed BMs after PCI. Median TTP and OS in responders treated with PCI were 812 and 801 compared to 355 (range: 284 - 456) ($p < 0.0001$, log-rank test) and 385 (range: 318 - 452) ($p < 0.0001$, log-rank test) days in the rest of the patient cohort. In multivariate analysis, application of PCI in treatment responders comprehensively staged with cMRI was a variable that significantly correlated with TTP (HR 2.16 CI HR 1.37-3.42, $p < 0.001$) and OS (HR 1.89 CI HR 1.37-2.63, $p < 0.0001$) after adjustment of other patient- and treatment-related factors.

Conclusion: In this LD SCLC patient cohort comprehensively staged with cMRI, achievement of maximum treatment response and application of PCI significantly affects time to progression and overall survival.

OC-0145

Preoperative radiotherapy with an integrated boost compared to chemoradiotherapy for rectal cancer.

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Purpose or Objective: Preoperative chemoradiotherapy (CRT) has been established as the standard treatment for T3-4 rectal cancers. In a phase II trial, we reported limited toxicity and excellent local control using image-guided and intensity-modulated RT (IG-IMRT) with a simultaneous integrated boost (RTSIB) instead of concomitant chemotherapy. The present multicentric randomized trial compares this strategy to CRT. In addition, the neutrophil-to-lymphocyte ratio (NLR) and C-reactive protein (CRP) were examined as a prognostic immunoscore in a subset of patients.

Materials and Methods: cT3-4 rectal cancer patients were randomly assigned to receive either preoperative IG-IMRT 46Gy/23 fractions plus capecitabine 825 mg/m² twice daily (CRT-arm) or IG-IMRT 46Gy/23 fractions with a SIB to the rectal tumor up to a total dose of 55.2 Gy (RTSIB-arm). Metabolic tumor activity reduction, by measuring the percentage of SUVmax difference (Response Index = RI) on sequential 18-fluorodeoxyglucose positron emission tomography (FDG-PET), was the primary endpoint. We

assessed whether RTSIB was non-inferior to CRT with a non-inferiority margin of -10% for RI.

Results: A total of 174 patients were randomly assigned to the CRT-arm (n=89) or RTSIB-arm (n=85). A consort flow diagram is presented in Figure 1. The RI difference between RTSIB and CRT was -2.9% (95% CI, -10.1% to 4.3%). The ypCR rate was 24% with CRT compared to 14% with RTSIB ($p=0.13$). There was no significant difference in sphincter preservation (75% vs 68%, $p=0.29$). The R0 resection rate was 98% in the CRT-arm and 97% in the RTSIB-arm. Acute grade 3 toxicity was 6% and 4% in the CRT- and RTSIB-arm, respectively. A detailed analyses of early adverse events is shown in Table 1. The highest quartiles of NLR and CRP identified high-risk patients in terms of disease free and overall survival.

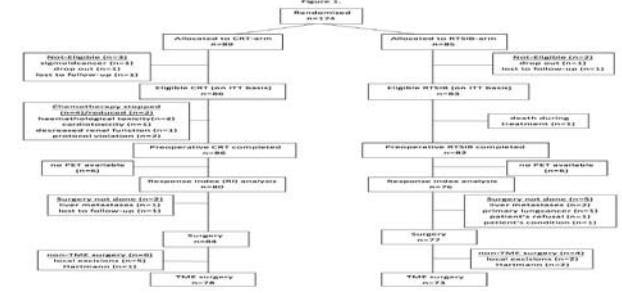


Table 1. Early Adverse Events

Grade	CRT (n=86)		RTSIB (n=82)		p-value
	No. of Patients (%)	No. of Patients (%)	No. of Patients (%)	No. of Patients (%)	
Gastrointestinal					
Diarrhea	36 (42)	1 (1)	35 (43)	2 (2)	.91 (.53)
Dysuria	17 (20)	0	17 (21)	1 (1)	.88 (.30)
Enteritis (abdominal pain)	18 (21)	0	10 (12)	0	.32
Proctitis	13 (15)	1 (1)	18 (22)	1 (1)	.25 (.97)
Urinary					
Dysuria	7 (8)	0	11 (13)	0	.27
Urinary frequency	4 (5)	0	10 (12)	0	.08
	5 (6)	0	4 (5)	0	.79
Haematology					
Anemia	3 (3)	1 (1)	2 (2)	0	.69 (.33)
Leucopenia	0	1 (1)	1 (1)	0	.30 (.33)
Thrombopenia	3 (3)	1 (1)	0	0	.09 (.33)
Other	0	0	1 (1)	0	(.30)
Hand-foot syndrome*	0	0	0	0	
Radiation dermatitis	14 (16)	2 (2)	10 (12)	1 (1)	.45 (.59)
Vaginal mucositis	2 (2)	2 (2)	1 (1)	0	.59 (.16)
Overall toxicity score	43 (50)	5 (6)	46 (56)	3 (4)	.43 (.51)

* 5 patients (6%) in the CRT-arm experienced grade 1 hand-foot syndrome
 p-value from test grade 2 (grade 3)

Conclusion: Preoperative CRT is well tolerated when IG-IMRT is used. RTSIB represents an attractive alternative to CRT for patients with a contra-indication for chemotherapy. The immunological landscape of colorectal cancer shapes novel possibilities for risk assessment.

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The PROS-IT CNR study: comorbidities and medications at the time of diagnosis of prostate cancer

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