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robust optimization with dose prescribed as per RTOG 0529 (50.4-54 Gy). All patients received two cycles of 5-fluorouracil and Mitomycin concurrently with radiation. Toxicity was assessed at baseline, weekly during chemoradiation and in follow-up using physician graded CTCAE v 4.0 and PRO-CTCAE for relevant domains (17 items). The primary endpoint was to define point estimates and 95% CI for \geq grade 2/3 GI, GU, Dermatologic, and Hematologic toxicity within 90 days from treatment. The proportion of PRO-CTCAE questions scored \geq 3 for each domain was compared to baseline. Survival outcomes were assessed using the Kaplan-Meier method. The proportion of \geq grade 2 and \geq grade 3 toxicities were compared to historic IMRT patients treated on RTOG 0529 using Fisher’s exact test.

Results: Fourteen patients were enrolled from 2017-2020. The median age was 56 (range 31-85) with 50% female participants. Eleven patients (79%) had Stage III disease. The respective T/N stages are T2 (n=5, 36%), T3 (n=7, 50%), T4 (n=1,7%), N0 (n=2,14%), N1 (n=9,64%), and N2 (n=3,21%). All patients completed prescribed treatment with 1 patient requiring a treatment break. **Table 1** shows rates of \geq grade 2/3 CTCAE events for IMPT. Rates of patient reported Derm and GU toxicity were low at baseline with a peak at week 6 (91% and 58% PRO-CTCAE items \geq grade 3, respectively) and normalization to baseline 3 months after IMPT. In contrast, the proportion of high grade PRO-CTCAE GI scores was 40% at baseline which persisted through 1 year post treatment. A complete clinical response at 6 months was observed in 11 patients (79%). The median overall survival was not reached with a median follow-up is 32.5 months. The 2 years overall, progression-free, and colostomy free survival was 92%, 64%, and 85%, respectively. Median time to progression was 9 months with local only (n=2,14%), local and distant (n=2,14%) and distant (n=1,7%) recurrence patterns.

Conclusion: In this single arm trial, rates of clinician reported toxicity with IMPT were similar to IMRT. High grade PRO-CTCAE events were common during IMPT. GU and Derm events normalized at 3 months from treatment but high-grade GI symptoms persisted to 12 months and were similar to baseline. Additional measures are needed to minimize acute and chronic toxicity related chemoradiation.

Abstract 2324 – Table 1: Rates of \geq grade 2/3 CTCAE events for IMPT

Adverse Events	RTOG 0529	UCCC GI-16-01	p value
Grade 2+	39 (75%) 38	10 (71% [42-92])	0.74 0.52 0.
Derm GI GU	(73%) 8 (15%)	9 (64% [35-87])	06 1.0 1.0
Heme Overall	38 (73%) 49 (94%)	6 (43% [18-71]) 11	
		(79% [49-95])	
		13 (93% [66-99])	
Grade 3+	12 (23%) 11 (21%)	3 (21% [5 – 51])	1.0 0.44 0.11
Derm GI GU	1 (2%) 30 (58%)	1 (7%, [0.2-34])	0.54 0.71
Heme Overall	43 (83%)	2 (14% [2-43])	
		10 (71% [42-92])	
		11 (79% [49-95])	

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Predictors of Lymph Node Involvement in Rectal Cancer Patients Treated with Neoadjuvant Chemoradiotherapy

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Purpose/Objective(s): Following neoadjuvant chemoradiotherapy (NART), some rectal cancer patients may have pathologic lymph node involvement (ypN+) despite complete response in the primary tumor, and should not be candidates for non-operative management. The aim of this

study was to determine risk factors for ypN+ in rectal cancer patients treated with NART.

Materials/Methods: Data of rectal cancer patients treated with NART followed by surgery were evaluated. Patients with synchronous colon cancer, radiotherapy to surgery interval longer than 13 weeks, and those without lymph node (LN) dissection were excluded from the analysis. 92 patients were included. Median age was 59 (30-83). Female/male ratio was 35/57. Tumor location was proximal, mid- and distal rectum in 3, 45 and 44 patients, respectively. Tumor histology was adenocarcinoma in 79 patients, signet ring cell in 6 and mucinous carcinoma in 7. Clinical T stage was T2, T3 and T4 in 3, 81 and 8 patients, respectively. 90 patients had clinical LNs larger than 4 mm (10-34 mm: n=46). Median tumor and LNs SUV_{max} were 15 (3.9-46) and 2 (0.5-17.6), respectively. Median tumor GTV was 73 (28.9-370) ml. Median tumor length and thickness were 6 (3-14) cm and 16.5 (7-30) mm, respectively. All patients received 56 Gy to the primary tumor and 50.4 Gy to the lymph node regions, simultaneously in 28 fractions, and concurrent capecitabine. 27 patients had ypN+. Clinical and radiological features at initial presentation were analyzed to predict ypN+ using Chi-square or Mann-Whitney U tests. Logistic regression analysis was performed to determine the factors affecting ypN+. ROC analysis was performed to determine the cutoff values.

Results: Age (p=0.027), tumor SUV_{max} (p=0.001), largest clinical LN size (p=0.007) and number of LNs \geq 10 mm in diameter (p=0.033) were significantly different between ypN0 and ypN+ patients in univariate analysis (Table). Only tumor SUV_{max} (HR (%95 CI): 0.828 (0.731-0.937), p=0.003) and largest clinical LN size (HR (%95 CI): 1.338 (1.023-1.750), p=0.033) were significant in multivariate analysis. Area under the ROC analysis curve (AUC) to determine ypN+ was 68.8% for LN size and 79.3% for tumor SUV_{max}. Cutoff values of LN size and tumor SUV_{max} for ypN+ were 10.5 mm (p=0.005) and 12.57 (p<0.001), respectively. Although ypN+ rates were higher in patients with signet ring cell (83%) and mucinous (43%) histology compared to adeno carcinoma (24%), it was not statistically significant.

Conclusion: Rectal cancer patients with lower tumor SUV_{max} and larger clinical lymph nodes at initial presentation are more likely to have pathologic lymph node involvement following neoadjuvant chemoradiotherapy.

Abstract 2325 – Table 1

Characteristics	HR (%95 CI)	p
Age	0.952 (0.911-0.994)	0.027
Thickness	0.936 (0.855-1.025)	0.154
Length	1.116 (0.914-1.362)	0.282
Tumor GTV	1.004 (0.997-1.011)	0.297
Tumor SUV_{max}	0.837 (0.751-0.934)	0.001
LN SUV_{max}	1.115 (0.947-1.312)	0.19
cLN diameter	1.196 (1.051-1.361)	0.007
#LNs <10 mm	0.956 (0.687-1.328)	0.787
#LNs \geq10 mm	1.608 (1.039-2.489)	0.033

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Pretreatment PET Metrics and Clinical Outcomes of Anal Cancer in Patients Living with and without HIV

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Purpose/Objective(s): This study investigates the association between pre-treatment positron emission tomography (PET) metrics and clinical outcomes in anal squamous cell carcinoma (ASCC) patients treated with