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Efficacy and Toxicity of CCRT Versus RT Alone in Advanced Esophageal Cancer: A Quasi-Experimental Study

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Abstract

Background: This study compared treatment responses and symptomatic improvement between concurrent chemoradiotherapy (CCRT) and radiotherapy (RT) alone in patients with unresectable locally advanced esophageal cancer.

Methods: In this quasi-experimental study, 60 patients (30 per arm) with comparable sociodemographic characteristics were allocated to Arm A (RT alone: 54 Gy/30 fractions) or Arm B (CCRT: RT+cisplatin/capecitabine). Outcomes included tumor response and symptomatic relief.

Results: The mean age was similar between arms (Arm A: 55.1 ± 9.08 years; Arm B: 55.1 ± 10.32 years), with most patients aged 50–69 years. Male predominance was observed (Arm A: 76.7%; Arm B: 63.3%), though not statistically significant ($P = 0.404$). Pretreatment dysphagia improved substantially in both arms (>80% response), with no significant difference between groups ($P > 0.05$). Tumor response rates showed higher complete (20% vs. 10%) and partial responses (66.7% vs. 60%) in Arm B versus Arm A, though differences were not statistically significant ($P > 0.05$). Stage-stratified analysis revealed similar trends, with no significant differences in partial or stable disease rates across stages ($P > 0.05$).

Conclusion: CCRT demonstrated numerically superior but statistically comparable tumor response and symptom relief compared to RT alone. Both regimens were effective in palliating dysphagia and other cancer-related symptoms, supporting their use in unresectable locally advanced esophageal cancer.

Keywords: Esophageal cancer, CCRT, RT, treatment response, symptom relief, locally advanced esophageal cancer

Introduction

Esophageal cancer remains one of the most aggressive malignancies worldwide, ranking as the eighth most common cancer and the sixth leading cause of cancer-related mortality.[1] The disease demonstrates striking geographic variations in both incidence and histopathological characteristics, with squamous cell carcinoma predominating in Eastern Asia and sub-Saharan Africa, while adenocarcinoma is more prevalent in Western countries.[2] Despite advances in multimodal treatment approaches, the prognosis for patients with locally advanced disease remains poor, with

5-year survival rates historically ranging between 5–10%.[3]

The management of unresectable locally advanced esophageal cancer presents a significant therapeutic challenge. Current treatment paradigms emphasize concurrent chemoradiotherapy (CCRT) as the standard of care based on landmark studies demonstrating superior outcomes compared to radiotherapy (RT) alone.[4,5] The RTOG 85-01 trial established CCRT as the definitive non-surgical approach, reporting a 5-year survival advantage over RT alone.[5] However, this aggressive approach is frequently associated with substantial toxicity, particularly in elderly patients or those with comorbidities.[6]

In clinical practice, many patients are deemed unsuitable for intensive CCRT due to poor performance status, advanced age, or significant comorbidities.[7] Furthermore, in resource-limited settings, the implementation of CCRT faces additional barriers, including limited access to chemotherapy agents and supportive care infrastructure.[8] These realities have prompted ongoing evaluation of RT alone as a potentially viable alternative for selected patient populations, particularly given recent technological advances in radiation delivery.[9]

The comparative effectiveness of CCRT versus RT alone continues to be debated, particularly in specific subgroups such as elderly patients or those with squamous cell histology.[10] While several Western studies have demonstrated clear benefits for CCRT, some Asian trials have reported more modest differences, possibly reflecting variations in tumor biology, staging practices, or treatment protocols.[11,12] Additionally, the optimal radiation dose and fractionation schedule remain controversial, with some evidence suggesting that higher radiation doses may improve outcomes with RT alone.[13]

Esophageal cancer is the leading malignant condition in Bangladesh, with a high mortality rate.[14] This study was designed to compare treatment outcomes between CCRT and RT alone in a cohort of patients with unresectable locally advanced esophageal cancer, with particular focus on tumor response rates and symptomatic improvement. Our investigation provides valuable data from a resource-constrained setting, where treatment decisions must balance efficacy, toxicity, and practical considerations.

In Bangladesh, oesophageal cancer is a growing public health concern, with a higher prevalence in men. According to the National Institute of Cancer Research and Hospital's 2014 report, oesophageal cancer accounted for 4.1% of all newly diagnosed cancers, ranking as the fifth most common malignancy in women. Many patients present at an advanced stage, and radiotherapy—commonly 54 Gy in 30 fractions—is used either alone or with chemotherapy to relieve symptoms and improve survival. While concurrent chemo-radiotherapy shows promise, balancing treatment effectiveness with toxicity remains a key consideration in optimizing patient outcomes.

Methods

Study Population and Sampling

This quasi-experimental study was conducted at the Department of Radiation Oncology, National Institute of Cancer Research and Hospital, Dhaka from January to December 2020.The study enrolled 72 patients (36 per arm) selected through purposive sampling from histologically confirmed cases of unresectable locally advanced oesophageal cancer (Stage IIb to III), those ineligible for surgical resection due to advanced disease (T4 tumors or extensive nodal involvement), comorbidities, or patient refusal. Sample size was calculated based on expected response rate differences (33% vs 10%) with $\alpha = 0.05$ and 80% power. Inclusion required histological confirmation of squamous cell carcinoma or adenocarcinoma with adequate hematologic (WBC $> 4 \times 10^9$/L, platelets $> 100 \times 10^9$/L) and renal function (creatinine <1.3 µmol/L). Exclusion criteria included

age <18 or >75 years, surgical candidates, metastatic disease, pregnancy, or synchronous malignancies.

Treatment Protocols and Procedures

After obtaining informed consent, all participants underwent comprehensive baseline evaluation including medical history, physical examination, laboratory tests, diagnostic imaging, and endoscopic biopsy confirmation. Arm A received radiotherapy alone (54 Gy in 30 fractions over 6 weeks via 3D-CRT using 6-10 MV photons), while Arm B received the same RT regimen plus concurrent chemotherapy (cisplatin 30 mg/m² IV weekly + capecitabine 800 mg/m² BID days 1–5 weekly). Treatment planning included CT simulation with intravenous contrast, thermoplastic immobilization, and strict dose-volume constraints.

Data Collection and Outcome Assessment

A validated, pretested semi-structured questionnaire captured demographic, clinical, treatment, and outcome data. Primary outcomes (tumor response by RECIST v1.1) were assessed via CT and endoscopy at 12 weeks post-treatment. Secondary outcomes included symptom improvement (dysphagia, pain scales), evaluated weekly during treatment and at scheduled follow-ups. Supportive care included nutritional support via nasogastric tube for moderate-severe dysphagia and management of treatment-related toxicities.

Statistical Analysis

Data analysis employed SPSS v22.0, with continuous variables reported as mean ± SD (compared via Student's *t*-test) and categorical variables analyzed using chi-square or Fisher's exact tests. All tests were two-tailed with $\alpha = 0.05$, using complete-case analysis after verifying randomness of missing data patterns. The statistical approach was designed to detect clinically meaningful differences between treatment arms.

Results

This study enrolled 72 patients with unresectable locally advanced esophageal cancer from the National Institute of Cancer Research and Hospital, with 60 patients included in the final analysis after excluding 12 due to treatment discontinuation (6), loss to follow-up (5), or death (1).

The study included 60 patients (30 per arm) with comparable sociodemographic characteristics. The mean age was similar between Arm A (RT alone: 55.1 ± 9.08 years) and Arm B (CCRT: 55.17 ± 10.32 years; $P = 0.027$*), with both groups predominantly aged 50–69 years (70% in Arm A, 53.4% in Arm B). A male predominance was observed in both arms, though more pronounced in Arm A (male-to-female ratio: 3.2:1 vs. 1.7:1 in Arm B; $P = 0.404$) [Table 1].

Table 2 presents the distribution of patients according to the Karnofsky Performance Status (KPS) scale, indicating that, at baseline, the majority of patients in both groups had a KPS score of 70.

Table 3 describes the pretreatment clinical stages of patients in both study arms. In this cohort, 56.6% of patients in Arm A and 56.7% in Arm B were classified as Stage II or III before treatment, with no statistically significant difference between the groups ($P > 0.05$) [Table 3].

Upon assessing the response rates of symptomatic relief and treatment-related side effects among patients in both arms, it was found that most patients in both treatment arms presented with dysphagia before therapy, which improved substantially post-treatment, with response rates above 80% in each arm and no significant difference between groups. Local pain, respiratory symptoms, loss of appetite, and anemia

Table 1: Sociodemographic characteristics of the patients (n = 60)

Variables	Arm A (n = 30), n (%)	Arm B (n = 30), n (%)	P-value
Age (years)			
30–39	1 (3.3)		
40–49	7 (23.3)	10 (33.3)	
50–59	10 (33.3)	8 (26.7)	
60–69	11 (36.7)	8 (26.7)	0.027*
70–75	1 (3.3)	4 (13.3)	
Range (years)	35–75	35–75	
Mean ± SD	55.1 ± 9.08 years	55.17 ± 10.316 years	
Gender			
Male	23 (76.7)	19 (63.3)	0.404
Female	7 (23.3)	11 (36.7)	

Table 2: Distribution of the patients by Karnofsky performance score (KPS) status (N = 60)

Karnofsky performance score	Arm A (n = 30)		Arm B (n = 30)		P-value
	n	%	n	%	
KPS 90	0	0	1	3.33	
KPS 80	10	33.3	15	50	
KPS 70	14	46.7	12	40	0.751
KPS 60	6	20	1	3.33	
KPS 50	0	0	1	3.33	

Table 3: Pretreatment clinical stage of the patients in both arms (N = 60)

Variables	Arm A (n = 30)		Arm B (n = 30)		P-value
T stage	n	%	n	%	
T_{1-2}	4	13.3	6	20	0.576
T_3	23	76.7	19	63.3	
Unknown	3	10	5	16.7	
N stage					
N0	7	23.3	5	16.7	0.240
N1	16	53.3	24	80	
Unknown	7	23.3	1	3.3	
TNM stage					
Stage II	7	23.3	5	16.7	
Stage IIIA	10	33.3	12	40	0.509
Stage IIIB	9	30	11	36.7	
Unknown	4	13.3	2	6.7	

also showed notable improvement following treatment in both arms, though variations in response rates between arms were not statistically significant. Overall, symptom relief was comparable across the two groups, as reflected by *P*-values greater than 0.05 for all parameters [Table 4].

Figure 1 illustrates the response of dysphagia before, during, and after treatment, with only moderate dysphagia considered. There was a significant decrease in symptoms in both arms. During the course of treatment, dysphagia was slightly higher in Arm B due to esophagitis caused by the combined effect of radiotherapy and chemotherapy.

Table 5 summarizes the responses after completion of treatment, post-treatment responses based on required investigations. Tumor response of the patients was evaluated by CT scans and upper GI endoscopy at 12 weeks. While the CCRT group (Arm B) exhibited a numerically superior response compared to the RT-alone group (Arm A), the difference did not reach statistical significance.

Table 6 demonstrates that among stage II and IIIA patients, complete response rates were 10% in Arm A and 20% in Arm B, while partial response rates were 30% and 33.4%, respectively. Stable disease was observed in 16.7% of Arm A and 6.7% of Arm B patients. In stage IIIB disease, partial response was achieved in 20% of Arm A and 30% of Arm B, with stable disease reported in 6.7% and 3.3%, respectively. No statistically significant differences in partial response or stable disease were observed between the two arms across stages ($P > 0.05$).

Table 7 shows final follow up was done at 12 weeks after completion of treatment and it was observed that 60% of patients had partial response in Arm A. In Arm B 66.7% had partial response.

Table 4: Response of patients according to signs and symptoms (at final week of RT) ($N = 60$)

Total patients $n = 30$ (each arm)	Pre-treatment *n* (%)	Post treatment *n* (%)	Response *n* (%)	Chi square value	*P*-value
Dysphagia**					
Arm-A	29 (96.7)	5 (16.7)	24 (82.7)	0.0063	0.982*
Arm-B	27 (90)	4 (26.7)	23 (85.2)		
Local pain					
Arm-A	26 (83.33)	10 (23.33)	16 (61.5)	0.775	0.678*
Arm-B	28 (93.3)	9 (16.66)	23 (82.1)		
Respiratory symptoms					
Arm-A	14 (46.66)	2(6.66)	12 (85.7)		0.722*
Arm-B	11 (36.66)	3(10)	8(72.7)	0.649	
Loss of appetite					
Arm-A	19 (63.3)	12 (40.0)	7 (36.8)		0.939
Arm-B	18 (60.0)	10 (33.3)	8 (44.4)	0.0057	
Anemia					
Arm-A	21 (70.0)	9 (30.0)	12 (57.14)	2.603	0.106*
Arm-B	23 (76.6)	3 (10.0)	20 (86.9)		

*Fisher's exact test. **Pre-treatment-moderate to severe dysphagia considered; Post treatment-Mild dysphagia considered.

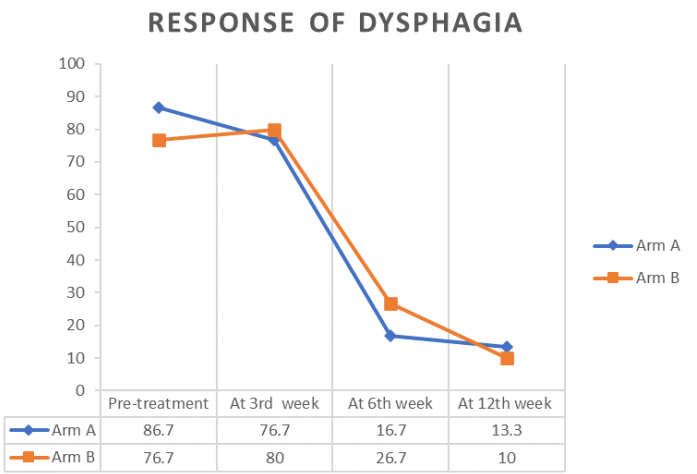

Figure 1: Distribution of patients showing response of dysphagia throughout the course of treatment ($N = 60$).

Table 5: Response of patients according to radiologic findings (after final week of RT) ($N = 60$)

Imaging findings	Complete response *n* (%)	Partial response *n* (%)	Stable disease *n* (%)	Chi square value	*P*-value
Arm-A	3 (10)	18 (60)	9 (30)	0.370	0.579
Arm-B	6 (20)	20 (66.7)	4 (13.3)		

Table 6: Distribution of the patients on the basis of staging and response after completion of treatment at 12th week ($N = 60$)

Total patients *n* = 30 (each arm)	No. of patients *n* (%)	Complete response *n* (%)	Partial response *n* (%)	Stable disease *n* (%)	Progressive disease *n* (%)	Chi square value	*P*-value
Stage II							
Arm-A	7 (23.3)	1 (3.3)	4 (13.3)	2 (6.7)	0 (0.0)	0.394	0.610*
Arm-B	5 (16.7)	3 (10.0)	2 (6.7)	0 (0.0)	0 (0.0)		
Stage IIIA							
Arm-A	10 (33.3)	2 (6.7)	5 (16.7)	3 (10.0)	0 (0.0)	0.293	0.531*
Arm-B	13 (43.3)	3 (10.0)	8 (26.7)	2 (6.7)	0 (0.0)		
Stage IIIB							
Arm-A	8 (26.7)	0 (0.0)	6 (20.0)	2 (6.7)	0 (0.0)	0.291	0.521*
Arm-B	10 (33.3)	0 (0.0)	9 (30.0)	1 (3.3)	0 (0.0)		
Unknown							
Arm-A	5 (16.7)	0 (0.0)	3 (10.0)	2 (6.7)	0 (0.0)	0.401	0.632*
Arm-B	2 (6.7)	0 (0.0)	1 (3.3)	1 (3.3)	0 (0.0)		

*Fisher's exact test.

Table 7: Distribution of the patients according to overall treatment response ($N = 60$)

Response	Arm A (Total = 30) *n* (%)	Arm B (Total = 30) *n* (%)	Total	*P*-value
Complete response	3 (10)	6 (20)	9 (15)	0.530*
Partial response	18 (60)	20 (66.7)	38 (63.3)	
Stable disease	9 (30)	4 (13.3)	13 (21.7)	
Progressive disease	0	0	0	

*Fisher's exact test.

There was no statistically significant difference in partial response and stable disease between two arms on the basis of staging ($P > 0.05$).

Discussion

Our study compared treatment outcomes between CCRT and RT alone in 60 patients with unresectable locally advanced esophageal cancer, demonstrating comparable efficacy between both approaches. The demographic characteristics of our cohort align with global epidemiological patterns of esophageal cancer, showing a male predominance (3.2:1 in RT alone vs 1.7:1 in CCRT) and peak incidence in the sixth to seventh decades of life.[2,3] This consistency with established literature supports the generalizability of our findings.

The baseline comparability between treatment arms was particularly noteworthy, with similar age distributions (mean 55.1 vs 55.2 years) and Karnofsky Performance Status scores (majority KPS 70 in both groups). This balanced distribution is crucial for interpreting subsequent treatment outcomes, as performance status significantly influences therapeutic response in esophageal cancer.[15] Our patient population's characteristics mirror those reported in landmark trials such as RTOG 85-01, which established CCRT as standard care.[16]

Regarding symptomatic improvement, both modalities demonstrated remarkable efficacy in alleviating dysphagia, with response rates exceeding 80% in each arm. This finding corroborates previous studies showing that radiation therapy provides effective palliation for obstructive symptoms.[17] The transient worsening of dysphagia during CCRT, attributable to treatment-induced esophagitis, has been well-documented and typically resolves with supportive care.[18] Our results suggest that while CCRT may cause more acute mucosal toxicity, the ultimate symptom relief equals that achieved with RT alone.

The tumor response patterns observed in our study merit careful consideration. While CCRT showed numerically higher complete (20% vs 10%) and partial response rates (66.7% vs 60%) compared to RT alone, these differences did not reach statistical significance. This finding contrasts with some Western studies reporting superior outcomes with combined modality therapy,[5] but aligns with Asian trials where radiation alone demonstrated considerable efficacy, particularly for squamous cell carcinoma.[11] The 26.7% stable disease rate in the RT alone arm suggests that even without chemotherapy, substantial disease control can be achieved in selected patients.

Stage-specific analysis revealed interesting patterns. For stage II-IIIA disease, CCRT showed a trend toward better outcomes (20% CR vs 10%), while for stage IIIB patients, both modalities yielded similar results. This observation supports the concept of therapeutic stratification based on disease extent, as proposed in recent guidelines.[19] The absence of progressive disease in either arm at 12-week follow-up underscores the value of both approaches for disease stabilization.

Several factors may explain the comparable outcomes between treatment arms. First, our RT dose (54 Gy) was higher than some conventional regimens, potentially enhancing its standalone efficacy.[9] Second, the predominance of squamous cell histology (86.5% overall) may have influenced results, as this subtype is generally more radiosensitive than adenocarcinoma.[2] Third, the relatively small sample size may have limited our ability to detect modest but clinically meaningful differences between treatments.

These findings have important implications for clinical practice, particularly in resource-limited settings. While CCRT remains the evidence-based standard for fit patients, our results suggest that RT alone can provide comparable symptom relief and disease control for selected cases. This is particularly relevant for elderly patients or those with comorbidities who may not tolerate combined modality therapy.[8] The decision between CCRT and RT alone should therefore consider not only efficacy data but also individual patient factors and treatment goals.

Limitations

The study's quasi-experimental design and modest sample size may limit the generalizability of the findings. Additionally, the short follow-up duration (12 weeks) precludes assessment of long-term survival or late toxicities, which are critical for evaluating the full therapeutic impact of CCRT. Future studies with larger cohorts and extended follow-up are warranted to validate these observations.

Conclusion

In this study, CCRT demonstrated a trend toward better tumor response compared to RT alone, though statistical significance was not achieved. Both regimens provided comparable and meaningful symptomatic relief, supporting their roles in managing unresectable locally advanced esophageal cancer. The choice between CCRT and RT alone should be individualized, balancing potential survival benefits against toxicity risks. Our findings reinforce CCRT as the standard for fit patients while affirming RT alone as an effective palliative option.

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