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Attrition After Neoadjuvant Therapy in Patients Planned for Curative Esophagectomy: A Single-Institution Retrospective Cohort Study

Sanket Desai [1]

1. Surgical Oncology, GCS Medical College, Hospital and Research Centre, Ahmedabad, IND

Corresponding author: Sanket Desai, sanketdesai2124@gmail.com

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Abstract

Background: Neoadjuvant therapy, followed by esophagectomy, is a standard treatment for locally advanced, resectable cancer of the esophagus and gastroesophageal junction (GEJ). Not every patient who starts neoadjuvant therapy reaches surgery. In trials reporting outcomes on an intention-to-treat basis, patients who do not reach surgery after neoadjuvant therapy remain included in survival estimates but are often absent from surgical series; attrition therefore reflects the gap between the intended multimodal treatment strategy and the treatment actually received. We examined how often this occurred in a tertiary surgical oncology unit in India, why it occurred, and which patient characteristics were associated with it.

Methods: We retrospectively reviewed a departmental database for consecutive patients planned for curative esophagectomy after either neoadjuvant chemoradiotherapy (nCRT) with the Chemoradiotherapy for Oesophageal Cancer Followed by Surgery Study (CROSS) regimen (weekly carboplatin and paclitaxel with 41.4 Gy of radiotherapy) or perioperative chemotherapy with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT). Baseline characteristics, treatment received, toxicity, and radiological response were compared between resected and non-resected patients using the Mann-Whitney U test, the Fisher exact test, and the chi-square test, as appropriate. The comparisons were unadjusted.

Results: The cohort included 21 (100.0%) patients; the median age was 60 years. There were 16 (76.2%) men, 11 (52.4%) patients with squamous cell carcinoma (SCC), and 18 (85.7%) with clinical stage III disease. Esophagectomy was performed in 14 (66.7%) patients; seven (33.3%) did not undergo surgery (95% confidence interval for attrition: 15-57%). Among non-resected patients, the reasons were disease progression in three (42.9%), decline in performance status in one (14.3%), acute treatment-related toxicity in one (14.3%), medical decompensation in one (14.3%), and patient refusal in one (14.3%). Compared with resected patients, non-resected patients were older (median = 67 vs. 57.5 years; $p = 0.003$) and more often had baseline Eastern Cooperative Oncology Group (ECOG) performance status 2 (3 (42.9%) vs. 0 (0.0%); $p = 0.026$). SCC (7 (100.0%) vs. 4 (28.6%); $p = 0.004$) and nCRT (7 (100.0%) vs. 5 (35.7%); $p = 0.007$) were more common, whereas radiological response was less common (1 (14.3%) vs. 14 (100.0%); $p < 0.001$). Among resected patients, 13 (92.9%) had an R0 resection, two (14.3%) had a pathological complete response, and six (42.9%) had a major pathological response. All resected patients, 14 (100.0%), were alive at a median follow-up of 16.5 months; four (57.1%) non-resected patients had died at a median follow-up of nine months ($p = 0.006$).

Conclusions: In this small cohort, attrition after neoadjuvant therapy was substantial, and short-term outcomes in non-resected patients were poor. Older age, poor baseline performance status, thoracic SCC treated with nCRT, and absence of a radiological response were associated with attrition; the effects of histology and regimen could not be separated. Early prehabilitation and the reporting of outcomes on an intention-to-treat basis deserve more attention.

Categories: Oncology
Keywords: esophageal cancer, esophagectomy, intention-to-treat, neoadjuvant chemoradiotherapy, perioperative chemotherapy, treatment attrition

Introduction

Esophageal cancer invades local structures and spreads to distant sites early in its course. In India, squamous cell carcinoma (SCC) of the thoracic esophagus accounts for most cases, although adenocarcinoma of the distal esophagus and gastroesophageal junction (GEJ) is being seen more often. For locally advanced tumors, surgery is combined with neoadjuvant treatment. In the Chemoradiotherapy for Oesophageal Cancer Followed by Surgery Study (CROSS), preoperative chemoradiotherapy increased the rate of microscopically complete (R0) resection and prolonged overall survival compared with surgery alone [1]. In the FLOT4 trial in gastric and GEJ adenocarcinoma, perioperative fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) improved overall survival compared with an epirubicin-based perioperative regimen [2].

In the CROSS trial, 161 (90.4%) patients assigned to chemoradiotherapy and surgery went on to resection [1]. Outside of trials, the picture can be different. In a single-center series, 114 (16.8%) patients scheduled for neoadjuvant therapy, followed by esophagectomy, never underwent resection because of disease progression, poor general condition, irresectability, the patient's own decision, or death during neoadjuvant treatment [3]. In trials reporting outcomes on an intention-to-treat basis, patients who do not reach surgery after neoadjuvant therapy remain included in survival estimates but are often absent from surgical series; attrition therefore reflects the gap between the intended multimodal treatment strategy and the treatment actually received. The problem might be expected to be greater where patients present late, are older, or are already malnourished from dysphagia.

We set out to measure the proportion of our patients who did not reach resection after starting neoadjuvant treatment, to document the reasons, to explore unadjusted associations between baseline and on-treatment features and attrition, and to report outcomes for the whole cohort on an intention-to-treat basis. Given the small sample size, these associations were considered exploratory and hypothesis-generating, rather than evidence of independent predictors of attrition.

Materials And Methods

Study design and patient population

This was a retrospective, single-institution cohort study conducted at GCS Medical College, Hospital and Research Centre, Ahmedabad, India. The patient inclusion period was from January 2022 to January 2026. We reviewed the departmental database for consecutive patients in whom the plan at the outset was neoadjuvant treatment, followed by esophagectomy, with curative intent. Patients with distant metastases at presentation, patients selected for definitive chemoradiotherapy from the outset, and patients taken for upfront surgery were not included. The final cohort comprised 21 patients. The study was approved by the Institutional Ethics Committee of GCS Medical College, Hospital and Research Centre, Ahmedabad, India. The requirement for individual informed consent was waived because the design was retrospective and observational.

Work-up consisted of upper gastrointestinal endoscopy with biopsy, contrast-enhanced computed tomography (CT) of the neck, chest, and abdomen, and 18F-fluorodeoxyglucose positron emission tomography/CT in selected cases. Tumors were staged according to the eighth edition of the American Joint Committee on Cancer/Union for International Cancer Control TNM (tumor, node, and metastasis) classification [4]. Functional status was recorded using the Eastern Cooperative Oncology Group (ECOG) Performance Status Scale described by Oken et al. [5]. Nutritional status, weight loss, dysphagia severity, and comorbidities were not included in the comparative analyses.

Neoadjuvant protocols and re-evaluation

The choice of regimen was made at the multidisciplinary tumor board. Neoadjuvant chemoradiotherapy (nCRT) followed the CROSS regimen: weekly carboplatin (area under the curve of 2) and paclitaxel (50 mg/m^2) for five cycles, with concurrent external beam radiotherapy to 41.4 Gy in 23 fractions [1]. This regimen was used for all patients with SCC and for some patients with adenocarcinoma. Perioperative chemotherapy followed the FLOT regimen: four preoperative cycles, given every two weeks, of docetaxel 50 mg/m^2, oxaliplatin 85 mg/m^2, leucovorin 200 mg/m^2, and fluorouracil 2,600 mg/m^2 as a 24-hour infusion, with a further four cycles planned after surgery [2]. This regimen was used for adenocarcinoma of the lower esophagus and GEJ. Regimen selection was therefore closely linked to histology and was not randomized.

Toxicity was graded using the U.S. National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 5.0 (published November 27, 2017) [6]. Cross-sectional imaging was repeated four to six weeks after the end of neoadjuvant treatment, and response was assessed using the Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1, described by Eisenhauer et al. [7]. Radiological response comprised complete or partial response; stable disease and progressive disease were classified as nonresponse. Surgery, consisting of open or minimally invasive Ivor Lewis or McKeown esophagectomy with two-field lymphadenectomy, was planned for six to eight weeks after completion of neoadjuvant treatment.

Outcomes and statistical analysis

The primary outcome was attrition, defined as failure to undergo the planned curative esophagectomy. Reasons for attrition were obtained from the clinical records, with one documented reason reported for each non-resected patient. Secondary outcomes were R0 resection, pathological response (complete response, ypT0N0; major response, 10% or less residual viable tumor; or partial response), postoperative complications of Clavien-Dindo grade IIIa or above, and overall survival measured from the start of treatment.

Continuous data are presented as median and range and were compared with the Mann-Whitney U test. Categorical data are presented as N (%), using the corresponding cohort or subgroup denominator, and were compared using Fisher's exact test or the chi-square test, as appropriate. For ECOG performance status, a single exploratory comparison of ECOG 2 versus ECOG 0-1 was performed using a two-sided Fisher's exact

test.

The ECOG p-value represents the two-sided Fisher's exact comparison of ECOG 2 versus ECOG 0-1. Other heading-row p-values compare the corresponding category distributions.

A two-sided p-value below 0.05 was used as an exploratory threshold. All comparisons were unadjusted for confounding, and no multivariable analysis was performed. Associations were interpreted as hypothesis-generating and did not establish independent predictors or causal effects. Follow-up duration and vital status at last follow-up were summarized descriptively. Comparisons of deaths represented crude comparisons of proportions, did not account for unequal follow-up duration, and were not time-to-event analyses. The original analyses were performed in SPSS version 21.0 (IBM Corp., Armonk, NY).

Results

Baseline characteristics

The cohort comprised 21 (100.0%) patients. The median age was 60 years (range = 47-72); 16 (76.2%) patients were men, 11 (52.4%) had SCC, and 18 (85.7%) had clinical stage III disease. nCRT was administered to 12 (57.1%) patients and FLOT to nine (42.9%) patients. Baseline and treatment characteristics and the comparison between resected and non-resected patients are shown in Table *1*.

Parameter	Total cohort	Resected	Non-resected	p-value
Group size, N (%)	21 (100.0%)	14 (66.7%)	7 (33.3%)	—
Age (years), median (range)	60 (47–72)	57.5 (47–65)	67 (56–72)	0.003
Male sex, N (%)	16 (76.2%)	9 (64.3%)	7 (100.0%)	0.123
ECOG performance status, N (%)	—	—	—	0.014
ECOG 0	5 (23.8%)	5 (35.7%)	0 (0.0%)	—
ECOG 1	13 (61.9%)	9 (64.3%)	4 (57.1%)	—
ECOG 2	3 (14.3%)	0 (0.0%)	3 (42.9%)	0.026
Tumor location, N (%)	—	—	—	0.035
Upper thoracic	1 (4.8%)	0 (0.0%)	1 (14.3%)	—
Mid thoracic	8 (38.1%)	3 (21.4%)	5 (71.4%)	—
Distal thoracic	8 (38.1%)	7 (50.0%)	1 (14.3%)	—
GEJ	4 (19.0%)	4 (28.6%)	0 (0.0%)	—
Histology, N (%)	—	—	—	0.004
Squamous cell carcinoma	11 (52.4%)	4 (28.6%)	7 (100.0%)	—
Adenocarcinoma	10 (47.6%)	10 (71.4%)	0 (0.0%)	—
Clinical stage III, N (%)	18 (85.7%)	11 (78.6%)	7 (100.0%)	0.521
Neoadjuvant regimen, N (%)	—	—	—	0.007
CROSS nCRT	12 (57.1%)	5 (35.7%)	7 (100.0%)	—
FLOT	9 (42.9%)	9 (64.3%)	0 (0.0%)	—
Completed neoadjuvant therapy, N (%)	20 (95.2%)	14 (100.0%)	6 (85.7%)	0.333
Grade 3–4 toxicity, N (%)	5 (23.8%)	2 (14.3%)	3 (42.9%)	0.28
Radiological response (CR + PR), N (%)	15 (71.4%)	14 (100.0%)	1 (14.3%)	<0.001

TABLE 1: Baseline and treatment characteristics by resection status.

Values are N (%) or median (range). Group-size percentages use the whole cohort; other percentages use column totals. Heading-row p-values compare category distributions; the ECOG 2 p-value compares ECOG 2 with 0–1. Percentages are rounded to one decimal place.

ECOG: Eastern Cooperative Oncology Group; GEJ: gastroesophageal junction; CROSS: Chemoradiotherapy for Oesophageal Cancer Followed by Surgery Study; nCRT: neoadjuvant chemoradiotherapy; FLOT: fluorouracil, leucovorin, oxaliplatin and docetaxel; CR: complete response; PR: partial response.

Patterns and correlates of attrition

Esophagectomy was performed in 14 (66.7%) patients, whereas seven (33.3%) patients did not undergo surgery (95% confidence interval for attrition: 15-57%). The documented reasons for attrition are presented in Table *2* as N (%) of non-resected patients and of the whole cohort.

Reason	Non-resected patients, N (%)	Whole cohort, N (%)
Disease progression	3 (42.9%)	3 (14.3%)
Decline in performance status	1 (14.3%)	1 (4.8%)
Acute treatment-related toxicity	1 (14.3%)	1 (4.8%)
Medical decompensation (unfit for surgery)	1 (14.3%)	1 (4.8%)
Patient refusal	1 (14.3%)	1 (4.8%)
Total	7 (100.0%)	7 (33.3%)

TABLE 2: Documented reasons for not proceeding to surgery.

Each patient had one recorded reason for attrition. Data are N (%); percentages in the non-resected column use the non-resected subgroup as the denominator, and percentages in the whole-cohort column use all included patients as the denominator. Percentages are rounded to one decimal place and may not sum exactly because of rounding.

Non-resected patients were older than resected patients (median = 67 vs. 57.5 years; p = 0.003) and more often had an ECOG performance status of 2 before treatment (3 (42.9%) vs. 0 (0.0%); p = 0.026). SCC was present in seven (100.0%) non-resected patients versus four (28.6%) resected patients (p = 0.004), and nCRT had been administered to seven (100.0%) versus five (35.7%), respectively (p = 0.007). These variables were not independent: all patients with SCC, 11 (100.0%), received nCRT, while nine (90.0%) patients with adenocarcinoma received FLOT. The distribution of tumor location also differed (p = 0.035): tumors were in the upper or mid thoracic esophagus in six (85.7%) non-resected patients and three (21.4%) resected patients. Sex, clinical stage, completion of neoadjuvant therapy, and grade 3-4 toxicity did not differ significantly between the groups (Table *1*). Radiological response was observed in 14 (100.0%) resected patients compared with one (14.3%) non-resected patient (p < 0.001).

Operative, pathological, and survival outcomes

Pathological, postoperative, and follow-up outcomes, according to resection status, are summarized in Table *3*.

Endpoint	Resected	Non-resected
Group size, N (%)	14 (66.7%)	7 (33.3%)
Time to surgery (days), median (range)	46.5 (38–61)	NA
R0 resection, N (%)	13 (92.9%)	NA
Pathological complete response (ypT0N0), N (%)	2 (14.3%)	NA
Major pathological response (≤10% viable tumor), N (%)	6 (42.9%)	NA
Partial pathological response, N (%)	6 (42.9%)	NA
ypN0, N (%)	9 (64.3%)	NA
Postoperative morbidity, Clavien-Dindo grade ≥IIIa, N (%)	4 (28.6%)	NA
In-hospital or 90-day mortality, N (%)	0 (0.0%)	NA
Follow-up (months), median (range)	16.5 (10–22)	9 (6–11)
Progression or recurrence, N (%)	3 (21.4%)	4 (57.1%)
Dead at last follow-up, N (%)	0 (0.0%)	4 (57.1%)

TABLE 3: Pathological, postoperative, and follow-up outcomes.

Data are N (%) unless otherwise indicated. Percentages in the group-size row use the whole cohort as the denominator; all other categorical percentages use the respective resection group as the denominator. Percentages are rounded to one decimal place. The proportion of patients who had died at last follow-up differed between the groups (p = 0.006).

NA: not applicable; R0: resection with microscopically negative margins; ypT0N0: no residual tumor in the primary site or lymph nodes after neoadjuvant therapy; ypN0: no residual nodal disease after neoadjuvant therapy.

Secondary outcomes were R0 resection, pathological response, postoperative complications of Clavien–Dindo grade IIIa or above, and overall survival measured from the start of treatment. Pathological complete response (pCR) was defined as ypT0N0, indicating no residual viable carcinoma in the primary tumor or regional lymph nodes. Major pathological response (MPR) was defined as ≤10% residual viable tumor and was reported excluding patients with pCR. Complete, major, and partial pathological responses were reported as mutually exclusive categories.

The pathological response categories are mutually exclusive, and MPR excludes pCR. Percentages for pathological response are calculated among the 14 patients who underwent resection.

Recurrence occurred in three (21.4%) resected patients, all of whom had ypN1 disease and a partial pathological response. No recurrence was documented among patients with ypN0 status or a major or complete pathological response at the time of analysis. In the non-resected group, four (57.1%) patients had died, all between six and nine months after the start of treatment; 0 (0.0%) resected patients had died (p = 0.006). On an intention-to-treat basis, 13 (61.9%) patients had an R0 resection, two (9.5%) had a pathological complete response, seven (33.3%) had disease progression or recurrence, and four (19.0%) had died at last follow-up.

Discussion

Attrition affected seven (33.3%) patients who started neoadjuvant treatment with the intention of proceeding to esophagectomy. Their outcome was poor: four (57.1%) non-resected patients had died within nine months of starting treatment.

The observed attrition rate was numerically higher than those reported in randomized trials, although differences in patient selection and the small sample limit direct comparisons. In the CROSS trial, 17 (9.6%) patients assigned to chemoradiotherapy and surgery did not undergo resection [1]. In Neo-AEGIS, 11 (6.2%) patients in the chemoradiotherapy arm and 22 (12.0%) in the perioperative chemotherapy arm did not undergo surgery [8]. In a single-center series from routine practice, attrition affected 114 (16.8%) patients overall and 62 (24.9%) patients with SCC; non-resected patients were older than resected patients [3]. Trials enroll selected patients; Neo-AEGIS, for example, required minimum cardiac and pulmonary function for entry [8]. In everyday practice, patients may arrive frail, with borderline performance status and considerable weight loss from dysphagia. In our non-resected subgroup, progression accounted for three (42.9%) cases of attrition; decline in performance status, acute toxicity, medical decompensation, and refusal of surgery each accounted for one (14.3%). These frequencies describe seven patients and do not establish the relative importance of individual causes in a broader population.

Histology and regimen overlapped almost completely. All patients with SCC, 11 (100.0%), received nCRT, while nine (90.0%) patients with adenocarcinoma received FLOT, reflecting conventional treatment selection. In Neo-AEGIS, 166 (90.2%) patients assigned to perioperative chemotherapy completed their preoperative cycles, and 162 (88.0%) underwent surgery; 167 (93.8%) patients assigned to CROSS-type chemoradiotherapy also underwent surgery [8]. These trial findings do not establish comparative regimen effects in our cohort. Chemoradiotherapy can cause hematological toxicity, anorexia, and fatigue [1], but our data do not demonstrate that these effects explain the observed attrition. The higher representation of SCC and nCRT among non-resected patients is an exploratory, unadjusted finding. Our data cannot distinguish the contributions of regimen, histology, and other patient characteristics, and neither SCC nor nCRT can be regarded as an independent predictor of attrition.

Radiological response was closely associated with reaching surgery. All resected patients, 14 (100.0%), had responded on imaging, whereas six (85.7%) non-resected patients had not responded. This association partly reflects the treatment pathway because progression on restaging was itself the reason for not operating in three (42.9%) non-resected patients. Radiological response therefore cannot be interpreted as an independent predictor of attrition in this analysis. Functional decline and lack of tumor shrinkage may coexist; the available aggregate data do not establish their separate contributions to attrition.

The recorded cases of functional decline and medical decompensation suggest that measures directed at patient fitness deserve further study. In a randomized trial in patients awaiting resection for esophagogastric cancer, a program of preoperative exercise and nutritional optimization improved functional capacity before and after surgery [9]. Whether such a program, started at diagnosis, would reduce attrition during neoadjuvant therapy cannot be determined from the present study.

Limitations

The main limitation is the small size of the cohort, comprising 21 patients and seven attrition events. The confidence intervals are wide, statistical power is limited, and the comparisons were unadjusted for confounding. The findings should therefore be interpreted as exploratory and hypothesis-generating. Because histology and regimen were almost perfectly collinear, their independent contributions to attrition could not be established. Nutritional status, weight loss, dysphagia severity, and comorbidities were not included in the comparative analyses, leaving potentially important confounding unaddressed. The association between radiological response and resection was also influenced by progression being a reason for not proceeding to surgery.

Follow-up was short and differed between the groups. The comparison of deaths represents a crude comparison of proportions rather than a time-to-event analysis. Patients had to survive and remain fit long enough to be classified as resected, introducing potential selection and immortal-time biases; the observed difference in deaths cannot establish a causal survival benefit from surgery. The classification of reasons for attrition depended on documentation in the case notes, and reporting one reason per patient may not capture overlapping contributors. Finally, the retrospective, single-institution design limits generalizability.

Conclusions

In this small retrospective, single-institution cohort, about one in three patients who began neoadjuvant treatment for resectable esophageal cancer did not reach surgery, and their short-term outcome was poor. Associations with older age, impaired baseline performance status, and absence of a radiological response were exploratory and unadjusted. Independent predictors were not established, and the contributions of histology and treatment regimen could not be separated.

Prospective studies should assess whether early nutritional support, physical conditioning, and close reassessment during treatment can reduce attrition. Reporting outcomes for all patients who start neoadjuvant treatment provides a fuller assessment of the planned multimodal strategy.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Sanket Desai

Acquisition, analysis, or interpretation of data: Sanket Desai

Drafting of the manuscript: Sanket Desai

Critical review of the manuscript for important intellectual content: Sanket Desai

Supervision: Sanket Desai

Disclosures

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