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RESEARCH ARTICLE

Neoadjuvant pembrolizumab with paclitaxel and carboplatin in locally advanced esophageal and esophagogastric junction carcinoma: short-term outcomes of a single-center retrospective cohort

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ABSTRACT

Background: The addition of anti–PD-1 therapy to chemotherapy has become standard in advanced esophageal cancer and, as adjuvant nivolumab, after chemoradiotherapy and R0 resection. Its role in the neoadjuvant setting is still being defined, and real-world data from routine practice, particularly where chemoradiotherapy capacity is limited, remain sparse. We describe short-term outcomes of neoadjuvant pembrolizumab combined with paclitaxel and carboplatin in patients treated at a single center.

Methods: We retrospectively identified 14 consecutive patients with locally advanced esophageal or esophagogastric junction (EGJ) carcinoma who received neoadjuvant pembrolizumab 200 mg every 3 weeks with paclitaxel and carboplatin, with planned esophagectomy. The primary endpoint was pathological complete response (pCR, ypT0 ypN0). Secondary endpoints were the radiographic objective response, R0 resection, treatment completion, adverse events (CTCAE v5.0), postoperative morbidity, and short-term disease status. Continuous variables are summarized as median (range) and categorical variables as counts (percentages); no inferential testing was performed given the sample size.

Results: Twelve of 14 patients (85.7%) had squamous cell carcinoma; 9 (64.3%) had clinical stage III disease. All cycles were delivered as pembrolizumab plus paclitaxel–carboplatin; 6 patients (42.9%) completed all three planned cycles and 9 (64.3%) had at least one dose delay. A radiographic objective response was recorded in 9 patients (64.3%). Ten patients (71.4%) underwent esophagectomy, all with R0 resection; the four remaining patients did not proceed to surgery because of progressive disease (1), medical unfitness (2), or patient refusal (1). pCR occurred in 3 of 14 patients on an intention-to-treat basis (21.4%) and in 3 of 10 resected patients (30.0%); all three had had a complete clinical response and the highest PD-L1 combined positive scores in the cohort. Grade 3–4 adverse events occurred in 6 patients (42.9%) and immune-related adverse events in 5 (35.7%), including one grade 3 immune hepatitis and one grade 2 pneumonitis. After a median follow-up of 7.8 months (range 3.0–11.2), no deaths had occurred and two patients had developed recurrence.

Conclusions: In this small cohort, neoadjuvant pembrolizumab with paclitaxel and carboplatin was deliverable and permitted R0 resection in all operated patients, with a pCR rate consistent with early-phase neoadjuvant chemoimmunotherapy experience. Toxicity was not negligible and limited full-course delivery in more than half of patients. The sample size, absence of a comparator, and immature follow-up preclude conclusions about efficacy or survival; the findings are hypothesis-generating.

Keywords: esophageal cancer; squamous cell carcinoma; neoadjuvant therapy; pembrolizumab; immune checkpoint inhibitor; pathological complete response

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Introduction

Esophageal cancer remains among the more lethal solid tumors[1], and locally advanced disease is rarely cured by surgery alone. Neoadjuvant chemoradiotherapy following the CROSS regimen[2,3] and, in Asian squamous cell disease in particular, neoadjuvant chemotherapy[4] have each improved outcomes relative to surgery alone, yet a substantial proportion of patients relapse. Pathological complete response after multimodal therapy is achieved in a minority and is closely linked to subsequent survival[3], which has motivated efforts to intensify preoperative treatment.

Immune checkpoint inhibition has reshaped systemic therapy for this disease. Pembrolizumab added to chemotherapy prolonged survival in previously untreated advanced esophageal and EGJ cancer[5], nivolumab-based combinations showed comparable benefit in squamous histology[17], and adjuvant nivolumab improved disease-free survival in patients with residual disease after chemoradiotherapy and R0 resection.[6] These results provide a rationale for moving anti–PD-1 therapy earlier, into the neoadjuvant window, where a larger tumor burden and an intact draining lymphatic bed might favor priming

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of antitumor immunity. Several early-phase studies of neoadjuvant chemoimmunotherapy in esophageal squamous cell carcinoma have reported encouraging pathological response rates[7,8], but most were conducted in specialized centers, used varied chemotherapy backbones, and enrolled selected patients.

How this approach performs in routine practice—especially where neoadjuvant chemoradiotherapy is not readily available and where patients frequently present with weight loss and reduced performance status—is less well characterized. Data describing feasibility, resection rates, and toxicity outside of trial conditions are needed to inform local practice. We therefore reviewed our initial experience with neoadjuvant pembrolizumab combined with paclitaxel and carboplatin, without radiotherapy, in patients with locally advanced esophageal and EGJ carcinoma, with the objective of describing treatment delivery, pathological response, resection outcomes, and early toxicity.

Methods

Study design and setting

This was a retrospective cohort study conducted at a single tertiary center. Consecutive patients who received neoadjuvant pembrolizumab with paclitaxel and carboplatin for locally advanced esophageal or EGJ carcinoma were identified from institutional records and included when treatment was given with curative intent and planned esophagectomy. The study period and exact accrual dates were not available in the dataset provided and should be specified by the authors before submission.

Eligibility criteria

Eligible patients had histologically confirmed esophageal or EGJ carcinoma, clinically resectable locally advanced disease, and received at least one cycle of pembrolizumab-based neoadjuvant therapy. Patients treated with definitive chemoradiotherapy or with palliative intent were not included. Staging followed the AJCC eighth edition[9] using endoscopy, cross-sectional imaging, and endoscopic ultrasound where performed; the dataset did not record staging modality per patient.

Treatment

Neoadjuvant therapy consisted of pembrolizumab 200 mg intravenously every 3 weeks with paclitaxel and carboplatin, for three planned cycles. Dose reductions, delays, and their reasons were recorded as documented by the treating team. Decisions on proceeding to surgery, operative approach, and perioperative care followed institutional practice and were made at multidisciplinary review.

Variables and endpoints

Collected variables comprised demographics, performance status, tobacco and alcohol history, comorbidity, body mass index, nutritional indices (hemoglobin, serum albumin, three-month weight loss, and a categorical nutritional risk assessment), tumor histology and location, clinical T and N category and stage, PD-L1 combined positive score (CPS), treatment delivered, adverse events, radiographic best response, surgical details, pathological stage, tumor regression grade, postoperative complications, length of stay, 30-day readmission, follow-up duration, and disease status at last contact.

The primary endpoint was pathological complete response, defined as ypT0 ypN0 in the resection specimen, reported both on an intention-to-treat basis (denominator of all 14 patients) and among resected patients. Secondary endpoints were the radiographic objective response (complete or partial response by the treating team's assessment, consistent with RECIST v1.1[10] categories), R0 resection, resection rate, treatment completion, major pathological response defined as College of American Pathologists tumor regression grade 0 or 1[12], adverse

events graded by CTCAE v5.0[11], immune-related adverse events, postoperative morbidity, and disease status at last follow-up. Overall and disease-free survival were prespecified as descriptive only in view of the anticipated event numbers.

Statistical analysis

Analyses were descriptive. Continuous variables are reported as median (range) and categorical variables as counts and percentages. Because of the small sample and the single-arm design, no hypothesis testing, regression modeling, or formal time-to-event estimation was undertaken; associations between PD-L1 CPS and response are described qualitatively. Missing data were not imputed, and denominators are stated where they differ from the full cohort. Analyses were performed in Python 3 (pandas).

Ethics

As a retrospective analysis of routinely collected, de-identified clinical data, the study required institutional review board approval or a formal waiver; the applicable approval reference and consent arrangements were not contained in the dataset and must be inserted by the authors. The work should be reported in accordance with the STROBE statement.[13]

Results

Patient characteristics

Fourteen patients were included (Table 1). The median age was 59 years (range 43–74), and 10 patients (71.4%) were male. Baseline ECOG performance status was 0 in 3 patients, 1 in 8, and 2 in 3. Twelve patients (85.7%) had squamous cell carcinoma and 2 (14.3%) had adenocarcinoma, both at the EGJ. Tumors were located in the middle (5), lower (4), and upper (3) thoracic esophagus and at the EGJ (2). Clinical stage was II in 3 patients, III in 9, and IVA in 2; nodal involvement was present in 13 of 14 (cN1 in 6, cN2 in 7). PD-L1 CPS was 1 or higher in all patients, with a median of 26 (range 6–66) and a value of 10 or higher in 12 patients. Markers of nutritional compromise were common: the median serum albumin was 3.2 g/dL (range 2.6–4.5), median three-month weight loss was 9.7% (range 4.7–20.3), and 7 patients (50.0%) were categorized as high nutritional risk.

Treatment delivered

All patients received pembrolizumab 200 mg every 3 weeks with paclitaxel and carboplatin (Table 2). Six patients (42.9%) completed all three planned cycles and the remaining eight received two cycles; the median number of cycles delivered was two. A dose delay occurred in 9 patients (64.3%), attributed to poor tolerance and infection, immune hepatitis, sepsis after cycle 2, cytopenia, patient preference after toxicity, and poor nutritional status. The chemotherapy dose was adjusted in two patients.

Primary endpoint: pathological complete response

pCR was recorded in 3 of 14 patients on an intention-to-treat basis (21.4%) and in 3 of 10 resected patients (30.0%). All three patients with pCR had had a complete clinical response before surgery and a tumor regression grade of 0, and they had the three highest PD-L1 CPS values in the cohort (53, 53, and 66).

Secondary endpoints

A radiographic objective response was observed in 9 patients (64.3%): complete clinical response in 3 and partial response in 6. Four patients had stable disease and one had progressive disease. Ten patients (71.4%) proceeded to esophagectomy—five McKeown, three Ivor Lewis, and two transhiatal procedures—and all achieved R0 resection, giving an R0 rate of 100% among operated patients and 71.4% on an intention-to-treat basis. Four patients did not undergo surgery: one because of progressive disease, two because of medical unfitness after neoadjuvant therapy, and one who declined operation. A major pathological response (tumor regression grade 0 or 1) was present in 5 of 10 resected patients; the distribution of tumor regression grade among resected patients was grade 0 in 3, grade 1 in 2, grade 2 in 4, and grade 3 in 1. Residual nodal disease (ypN1–N2) was found in 3 resected patients.

Toxicity

Grade 3–4 adverse events occurred in 6 patients (42.9%). The severe events recorded were grade 3 neutropenia, febrile neutropenia, grade 3 infection with sepsis, grade 3 fatigue, and grade 3 immune-related hepatitis. Immune-related adverse events of any grade occurred in 5 patients (35.7%): hypothyroidism, hyperthyroidism, and rash (each grade 1), pneumonitis (grade 2), and hepatitis (grade 3); one grade 3 immune-related event was therefore observed (7.1%). Adverse events contributed to dose delay in several patients and, together with clinical deterioration, to the decision against surgery in two (Table 3).

Postoperative outcomes

Among the 10 resected patients, a postoperative complication was documented in 5: anastomotic leak (grade B) in 1, pneumonia in 2, and chylothorax in 2. The median length

of stay was 10 days (range 4–17), and two patients were readmitted within 30 days. No perioperative deaths were recorded.

Disease status and survival

After a median follow-up of 7.8 months (range 3.0–11.2), no deaths had occurred, so overall survival could not be estimated. Nine patients (64.3%) were alive without evidence of disease and five (35.7%) were alive with disease; the latter group comprised the four unresected patients and one resected patient with the poorest tumor regression (grade 3) who subsequently relapsed. Recurrence was recorded in 2 patients (14.3%). Given the absence of death events and the short, variable follow-up, formal Kaplan–Meier estimation was not performed; the individual clinical course of each patient is shown in Figure 2 (Table 4 summarizes outcomes).

Subgroup observations

Formal subgroup analysis was not appropriate at this sample size. Descriptively, the three patients with pCR clustered at the upper end of the PD-L1 CPS distribution, whereas the single patient with progressive disease and the two judged medically unfit had among the lowest albumin values and the greatest weight loss. These observations are exploratory and should not be interpreted as evidence of predictive value.

Discussion

In this single-center cohort of 14 patients, neoadjuvant pembrolizumab with paclitaxel and carboplatin was administered without radiotherapy, permitted esophagectomy in 71% of patients, and produced R0 resection in every operated patient. pCR occurred in 21% of the intention-to-treat population and 30% of resected patients, and the three responders had complete radiographic responses and the highest PD-L1 scores. These outcomes were obtained in a population with a high burden of nutritional compromise and node-positive disease.

The pCR rate sits within the range reported by early-phase neoadjuvant chemoimmunotherapy studies in esophageal squamous cell carcinoma[7,8], most of which combined anti–PD-1 therapy with a taxane–platinum backbone. Direct numerical comparison is limited by differences in histology mix, chemotherapy, PD-L1 selection, and the inconsistent use of an intention-to-treat denominator; we have therefore avoided cross-trial percentage comparisons. The R0 rate among operated patients is consistent with the high resection quality expected after effective induction therapy and with the CROSS experience for chemoradiotherapy[2], although the two approaches are not interchangeable and radiotherapy contributes to local downstaging in ways

Table 1: Baseline characteristics (N = 14)

Characteristic	Value
Age, years, median (range)	59 (43–74)
Male sex, n (%)	10 (71.4)
ECOG PS 0 / 1 / 2, n	3 / 8 / 3
BMI, kg/m², median (range)	20.7 (18.4–25.7)
Tobacco current / former / never, n	5 / 5 / 4
Alcohol use, n (%)	8 (57.1)
Any comorbidity, n (%)	10 (71.4)
Squamous cell carcinoma, n (%)	12 (85.7)
Adenocarcinoma (EGJ), n (%)	2 (14.3)
Tumor location upper / middle / lower / EGJ, n	3 / 5 / 4 / 2
Clinical stage II / III / IVA, n	3 / 9 / 2
cN1 / cN2, n	6 / 7
PD-L1 CPS, median (range)	26 (6–66)
PD-L1 CPS ≥10, n (%)	12 (85.7)
Hemoglobin, g/dL, median (range)	10.8 (9.5–14.0)
Albumin, g/dL, median (range)	3.2 (2.6–4.5)
Weight loss over 3 months, %, median (range)	9.7 (4.7–20.3)
High nutritional risk, n (%)	7 (50.0)

Table 2: Treatment delivery (N = 14)

Parameter	Value
Regimen	Pembrolizumab 200 mg q3w + paclitaxel–carboplatin
Planned cycles	3
Cycles delivered, median	2
Completed all 3 cycles, n (%)	6 (42.9)
Received 2 cycles, n (%)	8 (57.1)
Any dose delay, n (%)	9 (64.3)
Chemotherapy dose adjustment, n (%)	2 (14.3)
Proceeded to esophagectomy, n (%)	10 (71.4)
Procedure: McKeown / Ivor Lewis / transhiatal, n	5 / 3 / 2

Table 3: Adverse events

Event	*n (%), N = 14*
Any grade 3–4 adverse event	6 (42.9)
Any immune-related adverse event	5 (35.7)
Grade ≥3 immune-related adverse event	1 (7.1)
Hepatitis (grade 3)	1 (7.1)
Pneumonitis (grade 2)	1 (7.1)
Hypothyroidism (grade 1)	1 (7.1)
Hyperthyroidism (grade 1)	1 (7.1)
Rash (grade 1)	1 (7.1)
Selected chemotherapy-related events	
Neutropenia / febrile neutropenia (grade 3)	2 (14.3)
Infection / sepsis (grade 3)	1 (7.1)
Fatigue (grade 3)	1 (7.1)

chemotherapy may not. The improvement in disease-free survival seen with adjuvant nivolumab in patients with residual disease after chemoradiotherapy[6] and the survival benefit of pembrolizumab–chemotherapy in advanced disease[5] frame the biological plausibility of neoadjuvant checkpoint blockade, but neither establishes benefit in the preoperative setting, which remains under investigation in randomized trials. In squamous histology, neoadjuvant chemoradiotherapy improved survival in the NEOCRTEC5010 trial[18], and anti–PD-1 monotherapy is active after progression on chemotherapy[19]; combination immunotherapy has since been extended to adenocarcinoma of the stomach and junction[20] and to the perioperative treatment of gastric and junctional adenocarcinoma.[21]

The concentration of pathological response among patients with high PD-L1 CPS is compatible with the predictive signal seen in advanced disease, where benefit

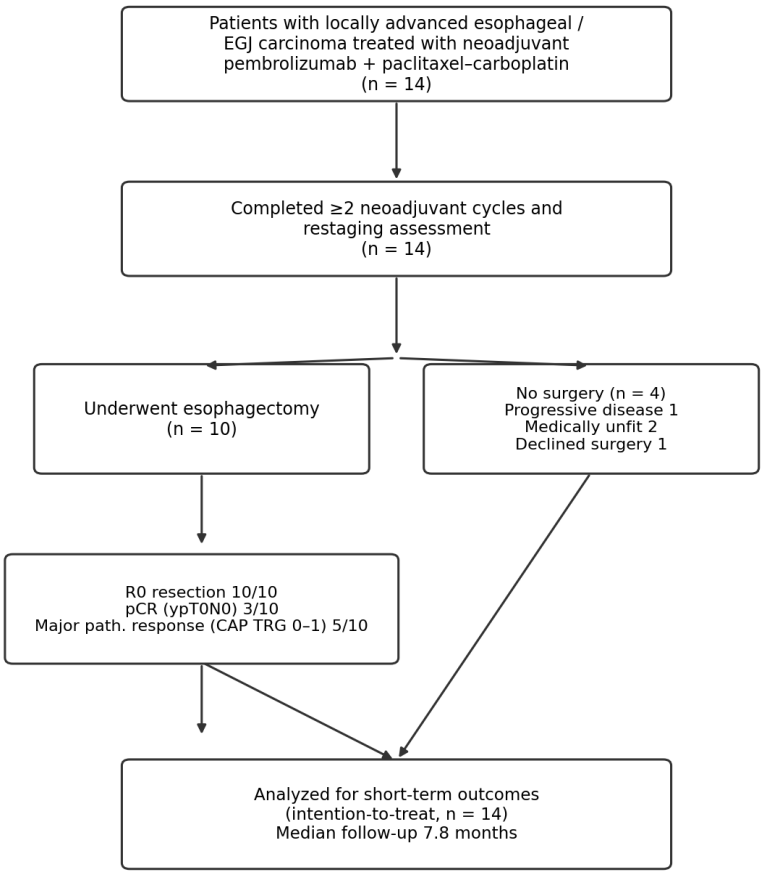

Figure 1: Patient flow according to the STROBE statement, showing treatment delivery, surgical disposition with reasons for non-operation, resection and pathological outcomes among operated patients, and the intention-to-treat analysis population.

Table 4: Response, resection, and short-term outcomes

Outcome	*Value*
Radiographic objective response (CR+PR), n (%)	9 (64.3)
Complete clinical response, n	3
Partial response / stable / progressive, n	6 / 4 / 1
pCR, intention-to-treat, n/N (%)	3/14 (21.4)
pCR among resected, n/N (%)	3/10 (30.0)
Major pathological response (CAP TRG 0–1), resected	5/10 (50.0)
R0 resection, resected / intention-to-treat	10/10 (100) / 10/14 (71.4)
Postoperative complication, resected, n (%)	5 (50.0)
Length of stay, days, median (range)	10 (4–17)
30-day readmission, resected, n (%)	2 (20.0)
Median follow-up, months (range)	7.8 (3.0–11.2)
Deaths, n	0
Recurrence, n (%)	2 (14.3)
Alive without disease / with disease, n	9 / 5

from pembrolizumab is greater at higher CPS[5,15]. With only three responders, this cohort cannot test that relationship, and CPS should not be used here to select or exclude patients for neoadjuvant therapy. The association we observed between low albumin, marked weight loss, and both progression and inoperability is unsurprising and likely reflects tumor burden and frailty rather than a specific interaction with immunotherapy.

Toxicity merits emphasis. More than half of patients did not complete the three planned cycles, dose delays were frequent, and grade 3–4 events affected 43%. The immune-related events—most low grade, but including grade 3 hepatitis and grade 2 pneumonitis—are consistent with the known profile of anti–PD-1 therapy and are relevant when this regimen is used in nutritionally depleted patients with limited physiological reserve. Two patients became unfit for surgery after neoadjuvant treatment, a reminder that induction therapy carries a cost that can remove the opportunity for curative resection. Careful baseline assessment, nutritional support, and vigilance for immune toxicity are practical priorities, particularly in settings where supportive-care resources are constrained.

For centers without ready access to neoadjuvant chemoradiotherapy, a chemoimmunotherapy backbone that does not require a radiotherapy facility is attractive,

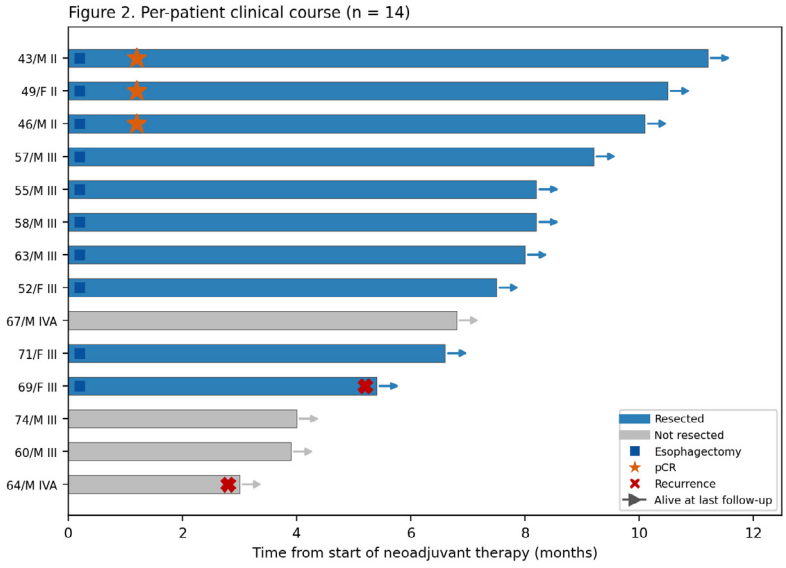

Figure 2: Per-patient clinical course. Each bar represents one patient (labeled by age/sex and clinical stage), with length equal to follow-up duration; the arrow indicates that the patient was alive at last contact. Squares mark esophagectomy, stars mark pathological complete response, and crosses mark recurrence. The exact timing of surgery and of recurrence within follow-up was not recorded, so event markers are placed schematically. A Kaplan–Meier survival figure (originally planned as Figure 2) was not generated because no deaths occurred and follow-up was short; overall survival is not estimable from these data. A forest plot (Figure 3) was not applicable, as the sample size did not support subgroup effect estimation.

and our experience suggests it can be delivered with acceptable surgical outcomes. That practical advantage does not by itself justify substituting chemoimmunotherapy for an evidence-based chemoradiotherapy or perioperative chemotherapy pathway[3,14,16] where the latter is available, and the choice should remain individualized and, wherever possible, made within a clinical trial.

The limitations are substantial and constrain interpretation. The cohort is small, retrospective, and single-center, without a comparator arm; selection and documentation biases are unavoidable, and adverse-event capture depended on chart records. Follow-up was short and no deaths had occurred, so survival endpoints are uninformative and were not modeled. The dataset lacked treatment dates, the interval to surgery, and per-patient staging modality, and included two adenocarcinomas within a predominantly squamous cohort, limiting histology-specific inference. Response assessment was investigator-reported rather than centrally reviewed. These features place the study at the level of a descriptive case series, and its estimates are imprecise.

Within these constraints, neoadjuvant pembrolizumab with paclitaxel and carboplatin was feasible and allowed margin-negative resection in all operated patients, with pathological responses concentrated among PD-L1–high tumors and a toxicity burden that limited full-course delivery in a substantial minority. Whether this translates into a survival advantage over established neoadjuvant strategies can be answered only by randomized trials with mature follow-up; the present data support continued, carefully monitored use in appropriately selected patients and contribute real-world observations from a resource-aware practice setting.

Table 1. ECOG PS, Eastern Cooperative Oncology Group performance status; BMI, body mass index; EGJ, esophagogastric junction; CPS, combined positive score. Percentages are of the full cohort.

Table 2. q3w, every 3 weeks. Reasons for dose delay included poor tolerance with infection, immune hepatitis, post-cycle sepsis, cytopenia, patient preference after toxicity, and poor nutritional status.

Table 3. Graded by CTCAE v5.0. Events are worst grade per patient as recorded; a single patient may appear under more than one category. The grade 3 immune hepatitis is counted within both the immune-related and grade ≥3 rows.

Table 4. CR, complete response; PR, partial response; pCR, pathological complete response (ypT0 ypN0); CAP TRG, College of American Pathologists tumor regression grade; R0, microscopically margin-negative resection.

Declarations

Ethics approval

Institutional review board approval or waiver reference to be inserted by the authors; the dataset did not contain this information.

Funding

To be completed by the authors.

Conflicts of interest

To be completed by the authors.

Data availability

De-identified data are held at the study institution and may be available on reasonable request, subject to institutional policy.

Author note on this manuscript

All numerical results were derived directly from the supplied dataset of 14 patients. Variables absent from that dataset—including accrual dates, interval to surgery, ethics reference, funding, and per-patient staging modality—are marked as to be completed and were not inferred.

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