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Complete Pathologic Response Rate after FLOT Neoadjuvant Therapy in Gastric Cancer Patients in Iran

Mahya Amini
Shiraz University of Medical Sciences
Nasrin Namdari
namdari_n@sums.ac.ir

Shiraz University of Medical Sciences
Khadijeh Hayati
Shiraz University of Medical Sciences
Maral Mokhtari
Shiraz University of Medical Sciences

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Abstract

Introduction

Pathologic complete response (pCR) to neoadjuvant chemotherapy in gastric cancer increases overall survival. Various factors such as tumor location, grade, presence or absence of H. pylori infection, and histology may affect the response rate.

Method

Seventy-five non–metastatic gastric cancer patients were evaluated in this retrospective study. The patients received 4 cycles of the FLOT regimen as a neoadjuvant, followed by surgery. pCR was reported according to the TRG system by two expert pathologists.

Result

The majority of patients had a partial pathologic response (42.7%), even though 28% reached complete and near-complete pathologic responses and 29.3% showed no or trivial response. Only 6.7% of patients reached the pCR. There was no statistically significant association between age (P-value: 0.38), gender (P-value: 0.94), tumor location (P-value: 0.95) and H. pylori infection (P-value: 0.27) with pCR rate. In addition, pCR was higher in patients with well-differentiated adenocarcinoma (60%) compared to those with moderately or poorly differentiated cancer (20% and 24%, respectively) (the P-value were 0.045 and 0.024 respectively), although we did not find any significant relation between the tumor differentiation and the response to the treatment (P-Value: 0.15).

Conclusion

The pathological complete response rate to neoadjuvant chemotherapy in gastric cancer is low and is not affected by factors such as age, sex, tumor location, and H.pylori infection. The only predictive factor may be tumor differentiation. Further future research studies might be conclusive.

Introduction

Even though gastric cancer incidence and mortality have declined recently, it is still considered to be the fifth most common cancer and also the fourth leading cause of death (1). The highest incidence has been observed in East Asia, Eastern Europe, and Central and South America, with an incidence rate of 1 million per year. (2) Out of this, over 60% is seen in Eastern Asia, approximately 15 million by 2020. It seems that the major culprits are aging and an unhealthy lifestyle, such as smoking, lack of physical activity, obesity, and so forth. (3, 4) In Iran, as in other parts of the world, gastric cancer is claimed to be the fourth leading cause of cancer; it is the first cause of cancer-related death, which might be due to delayed diagnosis. From a geographic aspect, it is more prevalent in northern regions. (5) When it comes to gender and risk factors, it's common among men compared to women. (6) Gastric cancer can affect different parts of the stomach with distinct causes; for instance, H. pylori infection accounts for 90% of

non-cardia cancers, while gastroesophageal reflux is more prevalent in patients with cardia cancer. Various studies conducted in Iran also claim that cigarette smoking, salt or smoked diets, economic status, and heavy alcohol usage might affect the prevalence and incidence of gastric cancer. (7–9)

On the other hand, the Pathologic Complete Response (pCR) is defined as the absence of any residual tumor microscopically after neoadjuvant chemotherapy (NACT) in the resected specimen. Several factors, such as tumor location, grade, chemotherapy regimens, age, and the number of chemotherapy cycles, are claimed to impact pCR and so enhance OS. A complete pathologic response not only means better Event-Free Survival (EFS) and Overall Survival (OS) but also reduces mortality by 50%. NACT affects the pCR by tumor downstaging and micro-metastasis reduction. For evaluation of pathologic response after NACT, various systems have been proposed. Out of them, TNM (Tumor, Node, and Metastasis) and TRG (Tumor Regression Grade) are the most common methods, even though the TRG system, because it is a quantitative method, is considered to be more practical in predicting cancer prognosis. (10–13) The Mandard TRG system is as follows:

TRG1: no residual cancer cells, total fibrosis; TRG2: rare residual cancer cells scattered through the fibrosis; TRG3: more residual cancer cells but outgrown by fibrosis; TRG4: residual cancer cells outgrowing the fibrosis; TRG5: absence of regressive changes.

The combination of neoadjuvant chemotherapy and surgery results in better survival than surgery alone, with a 5-year survival of 36% compared to 23%. Various chemotherapy regimens have been established for NACT, including ECF/ECX (epirubicin, cisplatin, and fluorouracil or capecitabine), FLOT (docetaxel, oxaliplatin, leucovorin, and fluorouracil), and DCF (docetaxel, cisplatin, and fluorouracil). Even though the FLOT regimen is a preferred option for NACT because of higher survival benefits, leading to 1- and 3-year survival of 79.3%, and 58.7%, respectively (15, 16). Also, various studies have shown the efficacy and survival benefits of FLOT over other regimens such as MAGIC (epirubicin, cisplatin plus fluorouracil with capecitabin), and ECF/ECX.

The FLOT regimen not only results in better pCR compared to ECF/ECX but also increases overall survival from 35 months to 50 months (17–19). The FLOT is a combination chemotherapy regimen that includes fluorouracil, leucovorin, oxaliplatin, and docetaxel, which is administered as adjuvant and neoadjuvant every two weeks.

The predictive factors of pCR are not exactly known. Our study aimed to investigate the pCR rate and predictive factors of pCR in gastric cancer patients who underwent neoadjuvant chemotherapy. (20)

Method

This retrospective analysis included patients diagnosed with non-metastatic gastric cancer who received neoadjuvant FLOT therapy between March 20, 2019, and March 20, 2024. Eligible participants were adults (aged 18+) with non-metastatic gastric cancer, confirmed via contrast-enhanced CT scans of the chest, abdomen, or pelvis, who received 4 course of FLOT regimen as neoadjuvant then followed by

surgical resection. Patients with metastatic disease, alternative chemotherapy protocols, or insufficient clinical and pathological documentation were excluded. Collected variables encompassed age, sex, tumor location, histologic grade, H. pylori status, and pathological response to neoadjuvant treatment. This study strictly evaluates the clinical outcomes of patients undergoing the specified FLOT regimen within a defined institutional timeframe for non-metastatic gastric cancer.

Patients received the FLOT regimen, administered in four biweekly neoadjuvant cycles, with the final dose scheduled four weeks prior to surgery, followed by four postoperative cycles. Each cycle comprised docetaxel (50 mg/m²), oxaliplatin (85 mg/m²), and leucovorin (200 mg/m²) on day one, alongside a twenty-four-hour 5-fluorouracil infusion (2600 mg/m²). Gastric specimens were independently reviewed by two pathologists, with the pathological complete response (pCR) formally assessed utilizing the AJCC/CAP Tumor Regression Grade (TRG) system to ensure accurate therapeutic evaluation and clinical outcome reporting.

TRG1 is classified in the complete pathological response group, TRG2 in the near complete response group, TRG3 in the partial pathological response group, and TRG4/5 in the non-response group.

Ethics approval and consent to participate:

The project has been reviewed by the Research Ethics Committee of the School of Medicine, Shiraz University of Medical Sciences, on 2024-05-01.

The study was conducted in accordance with the Declaration of Helsinki and with approval from the Research Ethics Committee of the School of Medicine, Shiraz University of Medical Sciences. Human dignity and patient confidentiality were maintained throughout the study. Based on the retrospective nature of our study, written informed consent was waived by the Ethics committee of Shiraz University of Medical Sciences, and their information was obtained from their hospital records. Permission to carry out the study and access patient records was sought from the Shiraz University of Medical Science administrators, and the study was conducted in compliance following the relevant guidelines and regulations and the Declaration of Helsinki and was also approved by the ethics committee of the university.

The approval ID is **IR.SUMS.MED.REC.1403.073.

Statistical analysis:

Data was analyzed by IBM SPSS version 24. Quantitative data were described by mean and standard deviation, and qualitative data were described by number and percentage. A chi-Square test was utilized for the evaluation of the relation between tumor location, clinical variables, and pCR. In addition, the Pearson correlation coefficient and one-way ANOVA, if data follow the normality test, were used. Kolmogorov-Smirnov was utilized for checking normality. A P-value less than 0.05 was considered to be statistically significant.

Results

In our study, 876 patient files were reviewed, but 801 patients were excluded because of missing data (124 cases), metastasis (373 cases), receiving FLOT less than 4 cycles (20 patients) or more than 4 cycles (19 patients) or modified FLOT (23), surgery in the other center (59 cases), receiving only adjuvant therapy (127), or other chemotherapy regimens (56 cases); and finally, 75 patients were studied (Figure 1). 56 patients (74.7%) were male, and 19 (25.3%) were female. The mean age was 58.32 ± 10.54. The majority of patients had proximal gastric cancer, involving the gastroesophageal junction and cardia, which was 34.7%. Middle (fundus and body) and distal (pylorus and antrum) involvement also had a prevalence of 29.3 and 28%, respectively. Only 8 % of patients had diffuse gastric cancer.

Figure 1. Consort flowchart diagram of participants.

When it comes to tumor differentiation, 66.7% of tumors were poorly differentiated, even though moderately differentiated and well-differentiated cancer was observed in 20% and 13.3% of patients, respectively. The prevalence of H. pylori was 34.7% in the statistical population. Pathological response to treatment was divided into 3 categories: complete or near-complete response (TRG = 0, 1), partial (TRG = 2), and poor or no response (TRG = 3). The most common response to treatment was partial response (42.7%). The prevalence of complete or near-complete response was 28%, and 29.3% of patients had no response or poor response to treatment. A complete response was seen in 5 patients (6.7%) (Table 1).

Table 1: Demographic data in gastric cancer patients receiving FLOT

In our study, there was no statistically significant association between age (P-value: 0.38), gender (P-value: 0.94), tumor location (P-value: 0.95), H. pylori infection (0.27), and tumor differentiation (P-value: 0.15) with the pCR.

The frequency of complete or near-complete response to treatment was higher in patients aged 60 years and younger (35.1%) than in patients aged over 60 years (21.1%). However, the difference was not statistically significant. (P-value: 0.377). Gender and tumor location were not significantly associated with response status.

34.7% of patients with a negative H. pylori test and 19.2% of patients with a positive H. pylori test had a poor or no response to treatment, although the difference was not statistically significant (Table 2).

Table 2: The association between age, gender, H. pylori, tumor differentiation, and tumor location with the pCR.

Patients with well-differentiated gastric cancer exhibited higher rates of complete or near-complete pathologic responses (60%) compared to moderately (20%) and poorly differentiated cases (24%), with respective P-values of 0.045 and 0.024. Nevertheless, the overall correlation between gastric cancer differentiation and therapeutic response remained statistically insignificant, as evidenced by a P-value of 0.15.

Discussion

Staging remains a critical prognostic determinant in gastric cancer, with neoadjuvant chemotherapy (NACT) purported to reduce tumor burden and micrometastatic risk, thereby enhancing the feasibility of radical resection and improving overall survival. As previously discussed, tumor regression grade (TRG) serves as an effective metric for evaluating pathological complete response (pCR) following NACT. Clinical evidence indicates that achieving pCR correlates with favorable long-term outcomes, with reported three- and five-year overall survival rates reaching approximately 90.2% and 83.3%, respectively. Furthermore, corresponding disease-free survival rates remain robust, documented at 86.6% and 82% across various longitudinal investigations into this complex clinical approach.

In the study by Airoldi et al., the pCR rate was reported to be 13%. The risk of death and recurrence was reduced by 71% in patients with pCR. The 5-year survival rate in patients with pCR was 79% compared to 39% in patients without pCR. In fact, the 5-year OS and PFS in patients who achieved pCR were twice as good as in patients who did not. Of course, this study used chemoradiation and different chemotherapy regimens for neoadjuvant treatment. Airoldi et al. believe that, in patients with pCR following neoadjuvant chemotherapy, the administration of adjuvant chemotherapy does not appear to alter prognosis.

We assessed the impact of the FLOT regimen on the pCR in non-metastatic gastric cancer patients, and it was 6.7% even though 28% of patients had a complete or near-complete pathologic response. 29.3% of patients had poor or no response to NACT.

Reported rates of pathological complete response (pCR) demonstrate significant variability across existing literature. For instance, Takei, Arefpour, and Schirren documented pCR rates of 9.5%, 35%, and 37.5%, respectively (26–28). Furthermore, research evaluating FLOT as a neoadjuvant chemotherapy (NACT) regimen indicated a pCR rate of 13% alongside a 56.5% partial pathological response (29), whereas Kaltenmeier reported a markedly lower pCR rate of 2.2%, identifying neoadjuvant chemoradiation, non-signet ring cell histology, and tumor grade as key predictive factors (30). Additionally, a 2018 meta-analysis estimated a mean pCR rate of 6.74% (ranging from 3% to 15%) for gastric and esophageal malignancies, albeit without stratifying by specific NACT protocols (13). Such discrepancies likely stem from inherent patient population heterogeneity and inconsistent methodology across studies. Potential confounding variables include variations in patient age, tumor anatomical location, and undisclosed H. pylori status, alongside the utilization of diverse treatment regimens. Finally, the application of disparate tumor regression grading (TRG) systems across these investigations further complicates direct comparisons, potentially contributing to the observed variance in documented pCR outcomes within the broader body of clinical oncology research (31).

We also did not find any statistically significant association between the pCR and age, location, and tumor differentiation, whereas the pCR was higher in the patients with well-differentiated tumors compared to those with moderate and poorly differentiated gastric cancer. In the study conducted by Sajjadi et al., no correlation was found between the pathological response rate and other variables, including age, gender, tumor histology, and tumor location. (32)

Meanwhile, in another study in Iran, no relation between age, sex, and tumor size with pCR was found. This study had superiority in comparison with other studies, because it was conducted in Iran, which would mitigate the effects of geographic variations to some extent. Even though the sample size was the same as our study, the mean age was about 10 years higher, and the pCR rate was also higher. (26) In contrast, Wang's study showed the effectiveness of the tumor differentiation on the pCR in patients receiving NACT (33); however, Xu mentioned that although TRG was useful in predicting DFS and OS, tumor differentiation was not an independent prognostic factor for TRG. (34)

Eventually, there was no statistically remarkable association between H. pylori infection and the pCR rate, even though we found that the rate of "no response" to NACT was lower in patients with positive H. pylori than those without H. pylori. On the other hand, the effect of H. pylori infection on the pCR, OS, and DFS in patients with gastric cancer was different or even contradictory in various studies. For instance, in a study conducted by Zhong, H. pylori infection decreased major pathologic response (35); however, Nishizuka concluded that H. pylori infection modulates the immune system and enhances chemotherapy efficacy. (36) In the first study, the effect of H. pylori on the various NACTs was not evaluated specifically, and in the second, the patients did not receive NACT.

Pathologic complete response following neoadjuvant therapy in gastric cancer is prognostic and increases overall survival. It is necessary to identify clinical, pathological, and molecular predictors of pCR.

Conclusion

The pathological complete response rate to neoadjuvant chemotherapy in gastric cancer is low and is not affected by factors such as age, sex, tumor location, and H.pylori infection. The only predictive factor may be tumor differentiation. Future studies might be helpful in consolidating our results.

Declarations

- Ethics approval and consent to participate: Ethic code: *IR.SUMS.MED.REC.1403.073.*
- Consent for publication: *Not applicable.*
- Availability of data and materials: *The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.*
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- Authors' contributions: *Study concept and design:* N. N.; Acquisition of data: N. N., M. M., Kh. H. and M. A.; *Analysis and interpretation of data*: N. N. and S. H.; *Drafting of the manuscript:* N. N., M. A., and S. H.; *Critical revision of the manuscript for important intellectual content:* M. M. and N. N.; *Statistical*

analysis: N. N., S. H. and Kh. H.; *Administrative, technical, and material support:* N. N., Kh. H., M. A. and M. M.; *Study supervision:* N. N. and M.M.

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Tables

Table 1
Demographic data in gastric cancer patients receiving FLOT.

Parameters	Value
Age (year) median ±	58.32 ± 10.54
Sex m/f (%)	56/19 (74.7/25.3%)
Pathologic response (%) Complete and near complete Partial response No response)	 21 (28%) 32 (42.7%) 22 (29.3%)
Tumor differentiation (%) Well differentiated Intermediate differentiated Poor differentiated	 10 (13.3%) 15 (20%) 50 (66.7%)
Tumor location (%) Proximal Middle Distal Diffuse	 26 (34.7%) 22 (29.3%) 21 (28%) 6 (8%)
H. pylori (%) Positive Negative	 26 (34.7%) 49 (65.3%)

Table 2
The association between age, gender, H. pylori, tumor differentiation, and tumor location with the pCR.

		COMPLETE RESPONSE		OR	CI95%	P-value
		Yes No. (%)	No No. (%)			
H. Pylori	Negative	14 (28.6)	35 (71.4)	1	-	0.88
	Positive	7 (26.9)	19 (73.1)	0.921	0.317–2.673	
Sex	Male	15 (26.8)	41 (73.2)	1	-	0.69
	Female	6 (31.6)	13 (68.4)	0.793	0.255– 2.46	
Age	≤ 60 yr	13 (35.1)	24 (64.9)	2.031	0.724–5.698	0.178
	> 60 yr	8 (21.1)	30 (78.9)	1	-	
Differentiation	Well	6 (60)	4 (40)	4.75	1.146–19.69	0.032
	Moderate	3 (20)	12 (80)	0.792	0.191–3.28	0.747
	Poor	12 (24)	38 (76)	1	-	-
Location	Proximal	7 (26.9)	19 (73.1)	1.84	0.18– 18.657	0.605
	Middle	6 (27.3)	16 (72.7)	1.875	0.180–19.525	0.599
	Distal	7(33.3)	14 (66.7)	2.50	0.243– 25.717	0.441
	Diffuse	1 (16.7)	5 (83.3)	1	-	-

Figures

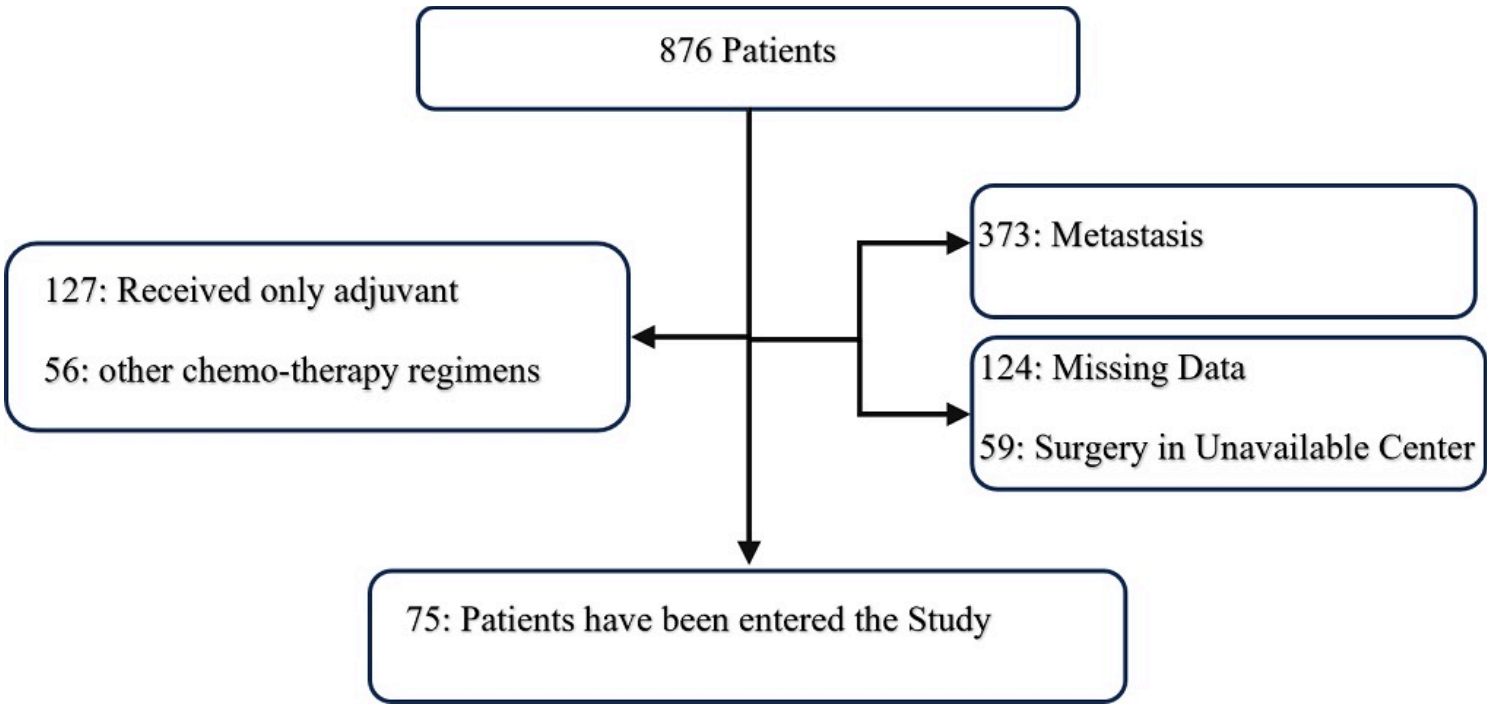


Figure 1

Consort flowchart diagram of participants.

Supplementary Files

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