Original Article

Trifluridine/tipiracil (FTD/TPI) in advanced gastric cancer—a retrospective cohort study providing real-world survival and safety data from the United Kingdom

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Background: In advanced gastric adenocarcinoma (aGC), the TAGS study demonstrated a survival advantage of trifluridine/tipiracil (FTD/TPI) over placebo in ≥3rd line setting. This led to approval in the United Kingdom (UK). Clinical trial and real-world patients often differ in age, fitness and comorbidity, which has implications for safety and survival. Real-world data can inform clinical practice. This study sought to define the UK patient population who have received FTD/TPI and compare outcomes to TAGS.

Methods: This was a retrospective study. Patients with aGC commenced on FTD/TPI prior to 1st February 2024 were eligible. Patients were identified from electronic health records. Data on baseline demographics and cancer outcome, including survival and toxicity, were collected.

Results: Data was collected for 58 patients from 12 centres in England, Scotland and Northern Ireland. Median age was 68.5 (range, 40–85) years, 44 (75.9%) were male and 10 (17.2%), 35 (60.3%) and 13 (22.4%) were Eastern Cooperative Oncology Group performance status (ECOG PS) 0, 1, and ≥2, respectively. Most primary tumours were gastroesophageal junctional (70.7%) and 24.1% were human epidermal growth factor receptor 2 (HER2) positive. FTD/TPI was given in 3rd line for 44 (75.9%) patients, 48 (82.8%) were commenced on full dose and on progression 6 (10.3%) received subsequent therapy. Median number of cycles received was 3 (range, 1–11). Median overall survival (mOS) in the whole population was 4.0 months [95% confidence interval (CI): 3.5–5.4], with mOS 5.9 *vs.* 4.0 *vs.* 2.5 months for ECOG PS 0, 1, and ≥2 respectively. On cox-regression analysis, with age, sex, ECOG PS, HER2 status, primary site and albumin as variables, ECOG PS ≥2 [hazard ratio (HR) =3.00; 95% CI: 1.07–8.35; P=0.04] and albumin ≥35 g/L (HR =0.47; 95% CI: 0.25–0.89; P=0.02) were prognostic; 29 (50%) and 16 (27.6%) patients required dose delay

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and reduction respectively, most commonly due to neutropenia. Grade ≥3 toxicity, attributed to FTD/TPI, was observed in 17 (29.3%) patients; 14 (82.4%) due to neutropenia and 3 (17.6%) anaemia. One (1.7%) patient stopped due to toxicity.

Conclusions: We present UK real-world data regarding use of FTD/TPI for aGC. Compared to TAGS, the patient population differed and mOS was lower than the reported 5.7 months, but long-term survivors are observed. Pre-treatment ECOG PS and albumin appear prognostic. Toxicity is in line with that reported previously. Our data support the use of FTD/TPI in selected populations with aGC.

Keywords: Trifluridine/tipiracil (FTD/TPI); gastric cancer; real-world data; survival; toxicity

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Introduction

Background

Gastric cancer is the fifth most common cancer globally with almost 1 million cases per year (1). In the United Kingdom (UK), there are approximately 6,600 new cases diagnosed each year, and the incidence rate has increased over the last decade (2). Median age at diagnosis in the UK is 73 years and the majority of patients present at an advanced stage.

Despite recent advances in the first-line management of advanced disease, with the emergence of immune checkpoint inhibitors and other targeted therapies (3-6), prognosis remains poor for the majority of patients. Upon progression on first-line treatment, fewer than half of patients are fit for subsequent systemic therapy and prognosis is typically 4–6 months in non-biomarker selected patients (7,8). In the third-line setting, outside of clinical trials, options are limited to trifluridine/tipiracil (FTD/TPI), a taxane or irinotecan (9).

FTD/TPI is an oral chemotherapy. It has established use in colorectal cancer, either alone or in combination with bevacizumab (10,11). The TAGS study established FTD/TPI as third-line option for patients with advanced gastric cancer by demonstrating improved overall survival (OS) compared to placebo (12). This led to the approval of FTD/TPI for use in the UK (Scottish Medicines Consortium in 2021 and National Institute of Clinical Excellence in 2022) (13-15).

Highlight box

Key findings
- Real-world patients with advanced gastric cancer receiving trifluridine/tipiracil (FTD/TPI) differ from the TAGS trial.
- Median overall survival in the whole cohort was lower than reported in TAGS.
- Pre-treatment Eastern Cooperative Oncology Group performance status and albumin appear prognostic.

What is known and what is new?
- In advanced gastric adenocarcinoma, the TAGS study demonstrated a survival advantage of FTD/TPI over placebo in ≥3rd line setting.
- This study provides real-world data relating to patient demographics and outcomes (survival and toxicity) with FTD/TPI.

What is the implication, and what should change now?
- This study supports the use of FTP/TPI in selected real-world patients with advanced gastric cancer.

Rationale and knowledge gap

It is well established that clinical trial populations can differ from real-world patients in both demographics, clinical phenotype and cancer outcomes including survival and treatment toxicity (16). In general, trial population have improved survival and lower treatment related toxicity than is observed in the real-world. This is relevant in gastric cancer where poorer functional status and co-morbidities are common, particularly in the later line setting. As such, patient selection and personalised cancer management is a challenge. In addition, the TAGS trial had a number of limitations relevant for real-world application including a relatively young population (median age 64 years), no patients with an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of ≥2 were included and not all human epidermal growth factor receptor 2 (HER2)-positive patients had received prior anti-HER2 therapy.

Objective

In this study, we sought to describe the clinical phenotype of patients in the UK with advanced gastric cancer who received FTD/TPI as at least third-line therapy in the year following its approval. We also sought to describe survival and toxicity in the population and compare it to the TAGS trial. We present this article in accordance with the STROBE reporting checklist (available at https://jgo.amegroups.com/article/view/10.21037/jgo-2025-119/rc).

Methods

This was a retrospective cohort study. Patients with advanced gastric cancer (defined as non-resectable) commenced on FTD/TPI prior to 1st February 2024 were eligible for inclusion. Patients were identified from electronic chemotherapy systems in 12 cancer centres in the UK (Table S1) and were treated as per local protocol at each centre. Clinical data were then obtained from paper and electronic medical records. Data on baseline demographics [including age, sex, site of primary, body mass index (BMI), ECOG PS], baseline bloods (including albumin, neutrophil leucocyte ratio, haemoglobin, creatinine and bilirubin), cancer site, staging and HER2 status, prior cancer treatment and subsequent cancer outcome, including survival and toxicity [using Common Terminology Criteria for Adverse Events (CTCAE)v5] while on treatment, were collected.

The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. The study was approved by institutional ethics board of NHS Tayside (No. IGTCAL10664). Local ethics approval for the study was then obtained at each cancer centre. All participating hospitals were informed and agreed on the study. Informed consent was not required as this was a retrospective study.

Statistical analysis

A descriptive analysis of patient characteristics was performed. Kaplan-Meier survival analysis was performed—OS was calculated from the start date of cycle one of FTD/TPI to the date of death with a censor date of 14th February 2024. Survival was reported in the cohort as a whole. Multivariate subgroup analysis was then performed using Cox regression to study the effect of common trial stratification (age, sex, ECOG PS) physiological (albumin) and tumour variables (primary site and HER2 status) on prognosis with treatment. A P value <0.05 was considered significant. R statistical software version 4.0.2 was used for data analysis.

Results

Demographics

During the time period, 58 patients who had received FTD/TPI were identified. The demographic characteristics of the population are shown in *Table 1*. Median age was 68.5 (range, 40–85) years, 75.9% of patients were male and ECOG PS was 0, 1 and ≥2 or more in 10 (17.2%), 35 (60.3%) and 13 (22.4%) of cases respectively. The majority (70.7%) had primary tumours located at the gastroesophageal junctional (GOJ) and 14 (24.1%) were documented as HER2 positive. The median number of metastatic sites was two with 14 (24.1%) having peritoneal metastasis.

In this pre-treated cohort, 12 (20.7%) patients had received a resection in the curative setting and 9 (15.5%) had received a prior immune checkpoint inhibitor. FTD/TPI was given as third-line therapy in 44 (75.9%) cases. Most (n=48, 82.8%) started the regimen at full dose with the median number of cycles completed being 3 (range, 0–14); 10.3% of patients were given subsequent therapy following disease progression.

Survival

Survival was analysed at a population-level and according to ECOG PS. Median overall survival (mOS) in the whole population was 4.0 months (95% CI: 3.5–5.4), with an estimated 1-year survival of 7.4% (*Figure 1A*). Improved pre-treatment fitness was associated with improved survival; for those meeting TAGS trials inclusion (i.e., ECOG PS 0 or 1), mOS was 4.1 months (95% CI: 3.7–6.6) (*Figure 1B*). When ECOG groups were analysed individually, ECOG PS 0 mOS was 5.9 *vs.* 4.0 months for PS 1 *vs.* 2.7 months for PS ≥2 (*Figure 1B*).

On Cox-regression analysis a pre-treatment serum albumin level of ≥35 g/dL was associated with an improved survival [hazard ratio (HR) =0.47; 95% confidence interval (CI): 0.25–0.89; P=0.02], while an ECOG PS ≥2 was associated with poorer survival (HR =3.00; 95% CI: 1.07–8.35; P=0.04) (*Figure 2*).

Dosing modification and toxicity

Dosing modification (dose delay or reduction) was

Table 1 Demographics of included population (n=58)

Demographics	Values
Age (years)	
Mean ± SD	66.3±11.5
Median [min, max]	68.5 [40.0, 85.0]
Sex, n (%)	
Female	14 (24.1)
Male	44 (75.9)
ECOG PS, n (%)	
0	10 (17.2)
1	35 (60.3)
≥2	13 (22.4)
HER2 status, n (%)	
Negative/unknown	44 (75.9)
Positive	14 (24.1)
Primary site, n (%)	
Gastric	17 (29.3)
GOJ	41 (70.7)
Baseline albumin (g/dL), n (%)	
<35	24 (41.4)
≥35	34 (58.6)
Number of sites of metastasis, n (%)	
1	15 (25.8)
2	23 (39.7)
3 or more	20 (34.5)
Previous lines of systemic therapy, n (%)	
2	44 (75.9)
3	10 (17.2)
4 or more	4 (6.9)

ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; GOJ, gastroesophageal junction; PS, performance status; SD, standard deviation.

observed in 77.6% of patients throughout the course of treatment. Half of patients (50%) required at least one dose delay and 27.6% required a dose reduction at some stage during treatment, most often due to neutropenia. On commencement of treatment, 29.3% of patients developed one or more CTCAE ≥ grade 3 toxicity secondary to FTD/TPI (*Table 2*). Haematological toxicities were the most frequently observed ≥ grade 3 toxicity, with 24.1% of patients having ≥ grade 3 neutropenia and 8.6%≥ grade 3 anaemia. One patient discontinued treatment due to non-haematological toxicity.

Discussion

Key findings and comparison with similar research

Despite recent advances in systemic management, advanced gastric cancer has a poor prognosis. Following progression on first-line therapy, treatment options are limited. An added challenge is that physical deconditioning driven primarily by systemic disease and reduced nutrition limits the number of patients who are fit to receive subsequent therapy.

One option, recently approved for use in the third-line and beyond setting is FTD/TPI following the publication of the TAGS trial (12). The primary aims of this study were to characterise the UK population with advanced gastric cancer who receive subsequent line treatment and compare their real-world outcomes, relating to the safety and efficacy profile of FTD/TPI with the phase 3 TAGS trial.

This analysis is important as there is often a discordance between trial and real-world outcomes (16). In a poor prognosis cancer where the balance of quality and quantity of life takes on added importance (17), it is therefore vital we ascertain whether or not the patients we encounter in clinic are likely to benefit and what factors may limit the tolerability of the drug and/or require dosing modification compared to the original highly-selected study population.

In our analysis, the patients included were older (median 68.5 *vs.* 64 years) and less fit (ECOG 0 or 1 77.5% *vs.* 100%) than the TAGS study. The most common primary site of disease in our study was GOJ (70.7%) which is much higher than TAGS in which 71% of study participants had gastric cancer and only 29% had GOJ malignancy. Despite this, HER2 positivity was similar between the two (24.1% *vs.* 20%). These clinical features are representative of the UK gastric cancer population (18) and the higher rates of GOJ tumours may reflect the greater incidence of cancers driven by gastroesophageal reflux disease in Western populations.

The TAGS population appeared to have a higher burden of disease with 54% having three or more sites of metastatic disease compared to 34.5% in our study, however, rates of peritoneal metastases were similar 26% compared to 24.1%. In addition, patients in TAGS had greater rates of prior

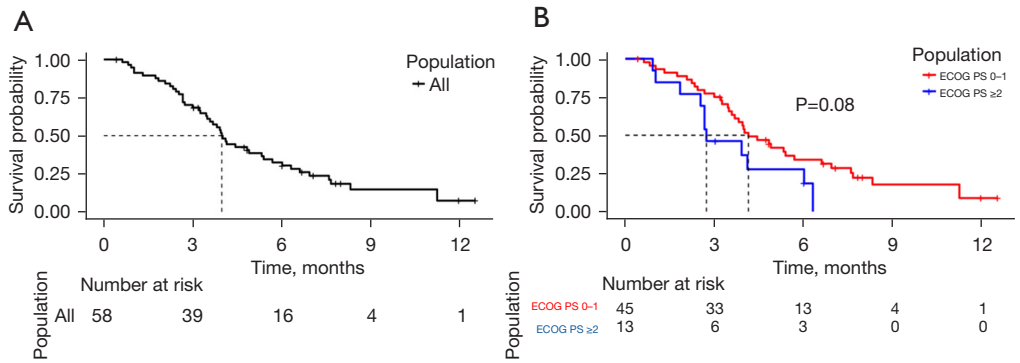

Figure 1 Kaplan-Meier curves for overall survival. (A) Overall survival in the cohort as a whole. (B) Overall survival according to ECOG PS. ECOG PS 0–1 (trial eligibility) compared to ECOG PS ≥2. ECOG, Eastern Cooperative Oncology Group; PS, performance status.

Variable		N	Hazard ratio (95% CI)	P
Age (years)	<70	31	Reference	
	≥70	27	0.61 (0.32, 1.16)	0.13
Sex	Female	14	Reference	
	Male	44	1.33 (0.60, 2.96)	0.48
ECOG	ECOG PS 0	10	Reference	
	ECOG PS 1	35	1.55 (0.67, 3.61)	0.31
	ECOG PS ≥2	13	3.00 (1.07, 8.35)	0.04
Albumin	<35 g/dL	24	Reference	
	≥35 g/dL	34	0.47 (0.25, 0.89)	0.02
HER2	Negative/Unknown	44	Reference	
	Positive	14	1.66 (0.75, 3.66)	0.21
Site	Gastric	17	Reference	
	GOJ	41	1.02 (0.50, 2.08)	0.96

Figure 2 Cox-regression analysis of overall survival. CI, confidence interval; ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; GOJ, gastroesophageal junction; PS, performance status.

resection (44% *vs.* 20.7%) and were more heavily pretreated with 63% having three or more prior lines of therapy compared to 24.1% in our population. This may reflect a population with a different disease biology or a cohort who are physiologically fitter and therefore able to tolerate more lines of therapy.

Despite this, outcomes in our cohort were comparable. Median survival in the UK population with an ECOG PS of 0 was 5.9 months, in line with the 5.7 months reported in TAGS. However, in the patients with ECOG PS ≥2 who would have been excluded from TAGS, survival was in line with supportive care alone (8). This data therefore does not support the use of FTD/TPI in patients with poorer fitness. Our data also highlight the importance of baseline albumin which can be a surrogate for nutrition or systemic inflammation (19) and has been shown to be prognostic across tumour groups (20). Those patients with a normal serum albumin had significantly improved survival compared to those who did not (HR =0.47).

Interestingly the rates of toxicity observed were lower than that reported in TAGS; 29.3% had a treatment related grade 3 or more toxicity compared to 80%. Similar

Table 2 Selected toxicities reported as associated with FTD/TPI treatment

Toxicity	Number of patients (%)		
	Grade 1	Grade 2	Grade 3 or more
Haematological			
Anaemia	4 (6.9)	5 (8.6)	5 (8.6)
Thrombocytopenia	2 (3.4)	2 (3.4)	–
Neutropenia	2 (3.4)	9 (15.1)	14 (24.1)
Non-haematological			
Nausea	6 (10.3)	2 (3.4)	–
Vomiting	1 (1.7)	–	1 (1.7)
Diarrhoea	4 (6.9)	2 (3.4)	–
Fatigue	8 (13.8)	5 (8.6)	–
Anorexia	2 (3.4)	2 (3.4)	1 (1.7)
Constipation	4 (6.9)	–	1 (1.7)

FTD, trifluridine; TPI, tipiracil.

to TAGS, the most frequent toxicities observed in our population were neutropaenia and anaemia. The differences in rates of severe toxicity may reflect clinicians practice, with 17.2% of patients commencing on a dose reduction or a less heavily pretreated population. In addition, a higher proportion of patients in our study also required a subsequent dosing modification compared to TAGS (27.6% *vs.* 11%), which may again reflect clinicians practice—these modifications were most common in those with ECOG PS 0 and therefore may also reflect the need to modify as treatment continues in order to maintain treatment.

Strengths and limitations

The strengths of our study are that the data represents a real-world UK population and thus provides insights into outcomes. In addition, the data was collected by practising Oncologists and the patients were recruited from centres across the UK. As such the cohort is representative and provide valuable insight into the clinical phenotype of patients treated in the third line and beyond setting. However, we must acknowledge the limitations. Our retrospective analysis is limited as it lacks a control group and thus it is not possible to directly compare efficacy or adverse event rates. The data was recorded retrospectively and as such was reliant on accurate recording of information at the time of any toxicity. There may therefore be limitations in the quality of data. We also were not able to assess quality of life or time to physical deterioration.

Conclusions

In conclusion, we present the first data from the UK regarding the use of FTD/TPI in advanced gastric cancer. We demonstrate that the real-world population is older and less fit than those recruited to the TAGS clinical trial. In our population, survival outcomes in the fittest patients were comparable to the trial data. In addition, our data provide reassuring information regarding the toxicity of treatment.

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None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jgo.amegroups.com/article/view/10.21037/jgo-2025-119/rc

Data Sharing Statement: Available at https://jgo.amegroups.com/article/view/10.21037/jgo-2025-119/dss

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. The study was approved by institutional ethics board of NHS Tayside (No. IGTCAL10664). Local ethics approval for the study was then obtained at each cancer centre. All participating hospitals were informed and agreed on the study. Informed consent was not required as this was a retrospective study.

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