Tumor Treating Fields therapy in patients with newly diagnosed glioblastoma and poor performance status: real-world analysis of patients treated in the US

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2044

BACKGROUND

- Glioblastoma (GBM) is the most common intrinsic brain tumor, accounting for 52.2% of all malignant brain tumors in the USA[1]
- Due to the aggressive nature of the disease, prognosis with available treatments remains poor, with a 5-year survival rate of 6.6% in the USA[2]
- Outcomes for patients with poor performance status (PS) are especially poor (median overall survival [OS]: 4 to 9 months), with limited contemporary datasets available for these patients[3–5]

Tumor Treating Fields (TTFields) Therapy

Delivers electric fields via a portable medical device to disrupt cellular processes critical for cancer cell viability[6–8]

In the EF-14 trial, TTFields therapy concomitant with temozolomide (TMZ) for GBM has demonstrated statistically significant survival benefits vs TMZ alone[9]

Approved for recurrent GBM and for newly diagnosed GBM by the US Food and Drug Administration and CE-marked for grade 4 glioma[10,11]

In the NCCN Clinical Practice Guidelines in Oncology, TTFields therapy is recommended for use concomitantly with adjuvant TMZ for patients with newly diagnosed GBM who are ≤70 years old and have a Karnofsky Performance Status (KPS) ≥60[12]

- In the EF-14 trial survival benefits with concomitant TTFields were found to be independent of KPS[9]
- However, only patients with a KPS ≥70 were eligible for the study, and there remains a high clinical need for effective treatments for patients with poor PS

OBJECTIVE

- To analyze real-world outcomes of patients with newly diagnosed GBM and poor PS who received TTFields therapy

METHODS

Participants and Study Design

- This retrospective cohort study accessed electronic medical records (EMRs) via the xCures real-world data platform and Novocure systems for patients with newly diagnosed GBM who initiated TTFields therapy in the US between January 1, 2019 and December 31, 2021
- Participants had a documented new diagnosis of GBM within 180 days of initiating TTFields and a KPS ≤60 or Eastern Cooperative Oncology Group (ECOG) PS ≥2 within 3 weeks of treatment initiation
  - Tumor isocitrate dehydrogenase (*IDH*) status was determined where data were available
- Patients were divided into high usage (≥50% and treatment duration ≥30 usage days) and low usage groups (<50% or treatment duration <30 days, excluding patients who died within 30 days of initiating TTFields)

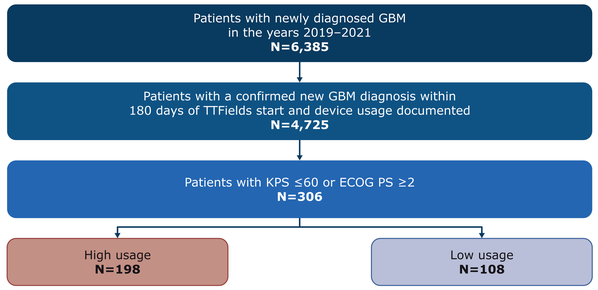
Assessments

- Demographics, disease characteristics, treatment duration, and OS were evaluated
  - OS was calculated from the date of documented GBM diagnosis
- Device usage was defined as the average percentage of time the device was used during the initial 3 months of TTFields therapy, as recorded from device log files
- Data cutoff for analysis was January 7, 2026

RESULTS

Cohort Selection and Usage Groups

Figure 1. Cohort Selection



GBM, glioblastoma; ECOG PS, Eastern Cooperative Oncology Group Performance Status; KPS, Karnofsky Performance Status; TTFields, Tumor Treating Fields

- Usage was further evaluated in the following subgroups:
  - KPS data available: 136 patients
  - ECOG performance status data available: 170 patients
  - Age ≥65 years: 143 patients
  - Age <65 years: 163 patients

Baseline Demographics and Clinical Characteristics

- Characteristics of patients in the total cohort were typical of the newly diagnosed GBM population and balanced between groups (**Table 1**)

Table 1. Baseline Demographics and Clinical Characteristics

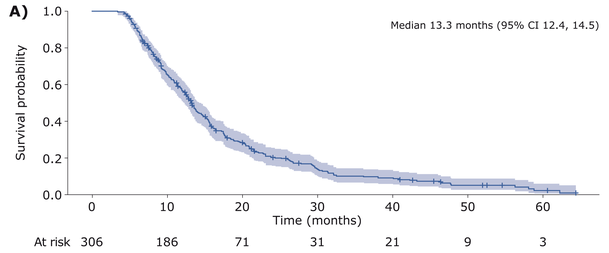
Characteristic	High usage (N=198)	Low usage (N=108)	All (N=306)
Age, years			
Median (range)	63 (25, 82)	64 (19, 85)	64 (25, 85)
Sex, n (%)			
Male	119 (60)	61 (56)	180 (59)
Female	79 (40)	47 (44)	126 (41)
Extend of resection, n (%)			
Biopsy	40 (20)	19 (18)	59 (19)
Partial resection	62 (31)	27 (25)	89 (29)
Gross total resection	63 (32)	45 (42)	108 (35)
Unknown	33 (17)	17 (15)	50 (17)
IDH1 status, n (%)			
Wild-type	173 (87)	99 (92)	272 (89)
Mutated	6 (3)	4 (4)	10 (3)
Unknown	19 (10)	5 (4)	24 (8)
MGMT promotor methylation, n (%)			
Methylated	72 (36)	38 (35)	110 (36)
Unmethylated	88 (44)	53 (49)	141 (46)
Unknown	38 (20)	17 (16)	55 (18)
KPS (n=136)			
Median (range)	60 (30, 60)	60 (40, 60)	60 (30, 60)
KPS 60, n (%)	61 (62)	22 (56)	83 (61)
KPS ≤50, n (%)	36 (38)	17 (44)	53 (39)
ECOG PS (n=170)			
Median (range)	2 (2, 4)	2 (2, 4)	2 (2, 4)
ECOG PS 2	67 (66)	54 (78)	121 (71)
ECOG PS ≥3	34 (34)	15 (22)	49 (29)
TTFields usage			
Median duration, months (range)	5.8 (1, 55)	0.9 (0, 15)	3.0 (0, 55)
Median usage during first 3 months, % (range)	79.6 (51, 96)	44.9 (2, 88)	73.7 (2, 96)

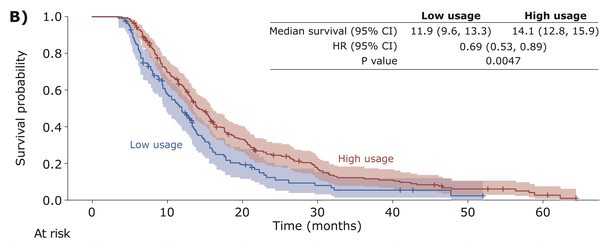
ECOG PS, Eastern Cooperative Oncology Group Performance Status; IDH1, isocitrate dehydrogenase 1; KPS, Karnofsky Perfomance Status; MGMT, O⁶-methylguanine-DNA methyltransferase; TTFields, Tumor Treating Fields

Overall Survival

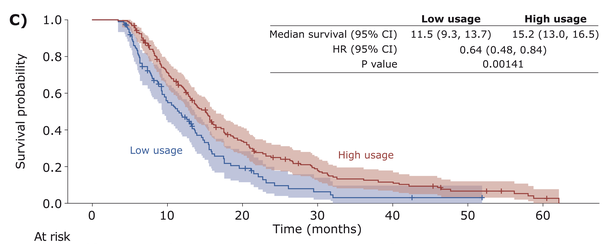
- Median OS from diagnosis for patients with poor PS was 13.3 months (95% CI, 12.4–14.5; **Figure 2A**)
- Median OS was 14.1 months (95% CI, 12.8–15.9) in the high usage group compared with 11.9 months (95% CI, 9.6–13.3) in the low usage group (hazard ratio [HR], 0.69 [95% CI, 0.53–0.89]; P=0.005; **Figure 2B**)
- Among patients with *IDH* wildtype tumors, a similar effect was observed for high vs low usage groups (HR, 0.64 [0.48–0.84], P=0.001; **Figure 2C**)
- Similar results were observed regardless of the performance scale utilized (data not shown). Multivariate analysis confirmed the effect to be significant when adjusting for known prognostic factors and performance scale type (P<0.01)

Figure 2. Overall survival analysis for A) poor PS cohort, B) low vs high usage, and C) low vs high usage among patients with *IDH*-wildtype tumors





	Low usage	High usage
Median survival (95% CI)	11.9 (9.6, 13.3)	14.1 (12.8, 15.9)
HR (95% CI)	0.69 (0.53, 0.89)	
P value	0.0047	

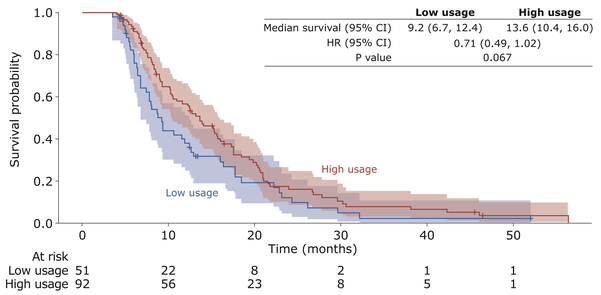


	Low usage	High usage
Median survival (95% CI)	11.5 (9.3, 13.7)	15.2 (13.0, 16.5)
HR (95% CI)	0.64 (0.48, 0.84)	
P value	0.00141	

CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group Performance Status; HR, hazard ratio; IDH, isocitrate dehydrogenase; KPS, Karnofsky Performance Status; TTFields, Tumor Treating Fields

- The observed treatment effect was consistent among patients ≥65 (**Figure 3**) and <65 years of age (HR, 0.71 [0.49–1.02], P=0.067 and HR, 0.69 [0.47–1.00], P=0.049, respectively)

Figure 3. Overall survival analysis by usage group for patients ≥65 years of age



	Low usage	High usage
Median survival (95% CI)	9.2 (6.7, 12.4)	13.6 (10.4, 16.0)
HR (95% CI)	0.71 (0.49, 1.02)	
P value	0.067	

CI, confidence interval; HR, hazard ratio; TTFields, Tumor Treating Fields

CONCLUSIONS

- Patients with newly diagnosed GBM and poor performance status receiving TTFields therapy in the real-world setting appear to have favorable survival when compared with limited historical data[3–5]
- Increased usage is associated with improved survival in this population, including among elderly patients for whom treatment options are limited
- Additional studies examining TTFields in this high-need population with limited trial options are warranted

ACKNOWLEDGMENTS

Medical writing support was provided by Andrew Noble of Bioscript Group, Macclesfield, UK, and was funded by Novocure Inc.

FUNDING

This study was funded by Novocure Inc.

DISCLOSURES

OHB serves on the advisory board for Novocure and as a consultant for Menarini; **DD**, **YH**, and **NA** are employees of Novocure; **OF** and **PC** are employees and stockholders of Novocure; **JMC** has no disclosures to report

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Presented at the 2026 ASCO Annual Meeting, May 29–June 2 2026, Chicago, IL