Delivery of TTFields with head-flexible arrays: post-market analysis

Matthew Williams[1], Erika Cataldo[2], Franziska Oldenburg[3], Dina Daitchman[4], Gordon Chavez[5], Yair Horesh[6], Nick Avgeropoulos[7], Patrick Conlon[7], Santiago Cabezas-Camarero[8]

1. Department of Oncology, Charing Cross Hospital - Imperial College Healthcare NHS Trust, London, UK; 2. Medical Safety Systems, Novocure Inc, Portsmouth, NH, USA; 3. Post-market Safety Medical Review, Novocure GmbH, Baar, Switzerland; 4. Data Analysis, Novocure Ltd, Haifa, Israel; 5. Research Initiatives & Real-World Evidence, Novocure Inc, Portsmouth, NH, USA; 6. Real World Evidence, Novocure Ltd, Haifa, Israel; 7. Medical Affairs, Novocure Inc., Portsmouth, NH, USA; 8. Department of Medical Oncology, Hospital Clinico Universitario San Carlos (IdISSC), Madrid, Spain

SCAN FOR MORE INFORMATION ABOUT TUMOR TREATING FIELDS

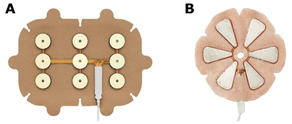
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BACKGROUND

- The TTFields device delivers electric fields via a portable medical device to disrupt cellular processes critical for cancer cell viability[1]
- TTFields therapy concomitant with maintenance temozolomide (TMZ) for newly diagnosed GBM has demonstrated statistically significant survival benefits vs TMZ alone[2,3]
- Approved in the USA and/or Europe for recurrent and newly diagnosed glioblastoma (WHO grade 4 glioma in Europe), malignant pleural mesothelioma (mesothelioma in Europe), metastatic non-small cell lung cancer (NSCLC), and locally advanced pancreatic adenocarcinoma[4-7]
- Recommended by guidelines, including those from the German DGHO and DGN,[8,9] and the US NCCN,[10] for maintenance treatment of newly diagnosed grade 4 glioma
- Most device-related adverse events are mild-to-moderate skin reactions beneath the arrays[11]
- A new-generation polymer-based array technology (HFE, head flexible electrode; **Figure 1**) that is lighter and more flexible with the aim of improving comfort compared with previous-generation arrays (insulated field-inducing electrode, INE), is available. This study reports first post-marketing experience with HFE arrays

Figure 1. A) INE and B) HFE arrays



OBJECTIVES

- To report first post-marketing experience with HFE arrays
- To evaluate patient tolerability and usability metrics of HFE and INE

METHODS

Post-marketing surveillance and matched-cohort analysis

- Unsolicited safety data were collected from routine post-marketing surveillance of patients with CNS tumors treated with TTFields using HFE arrays globally between November 2022 until December 2025
- For patients with newly diagnosed GBM, time- and region- matched cohorts of patients initiating TTFields in 2024 (INE matched cohort) and in 2025 (HFE matched cohort) were also analyzed
- Adverse event data were coded using MedDRA version 28.0. Administrative device status records were used to track device discontinuation

Study endpoints

Safety

- Adverse event incidence, all new start HFE patients
- Comparative cohort analysis: INE vs HFE, newly diagnosed GBM
  - All-cause adverse events
  - TTFields-related adverse events
  - TTFields-related adverse events, >5% in INE cohort
    - Skin-related, electrical sensation, warming

Treatment break patterns

- Frequency, duration of skin-related treatment breaks: INE vs HFE
- Frequency of temperature alarms

Device utilization

- Median duration, average device usage, usage dynamic
- Average current and resistance

RESULTS

HFE cohort patient demographics

- Data were collected for patients treated using HFE transducer arrays in Austria, Belgium, Croatia, Czech Republic, Denmark, France, Germany, Israel, Italy, Japan, Luxembourg, Norway, Poland, Spain, Sweden, Switzerland, UK and USA between November 2022 and December 2025
- Of the 8,284 patients included in the HFE cohort, 91% were treated for newly diagnosed GBM and 4% for recurrent GBM (**Table 1**)
- Median patient age was 58 (26–83) years and 63% of patients were male, reflecting real-world practice with TTFields (**Table 1**)

Table 1. Demographic and clinical characteristics of the HFE cohort

Characteristic	HFE cohort n=8,284
Age, years	
Median (range)	58 (26–83)
Gender, %	
Male	63
Female	36
Unknown	0.5
Diagnosis, n (%)	
Newly diagnosed GBM	7,521 (91)
Recurrent GBM	325 (4)
Other	438 (5)
Geography, n (%)	
North America	3,709 (44.8)
Europe & Israel	4,028 (48.6)
Japan	547 (6.6)

HFE, head flexible electrode; GBM, glioblastoma

Safety profile: HFE cohort

- The most commonly reported device-related adverse events in the HFE cohort were skin reactions (36%), heat sensation (6%), and electric sensation (6%) (**Table 2**)

Table 2. Adverse events reported in >5% of the HFE cohort

SOC and Preferred Term (n=8,284)	All adverse events, n (%)	Related adverse events, n (%)	Serious adverse events, n (%)
Patients with ≥1 adverse event reported	5,093 (61.5)	3,659 (44.2)	2,179 (26.3)
General disorders and administration site conditions	2,213 (26.7)	1,195 (14.4)	781 (9.4)
Death	536 (6.5)	–	536 (6.5)
Electric sensation	495 (6.0)	495 (6.0)	2 (0.02)
Heat sensation	535 (6.5)	535 (6.5)	–
Nervous system disorders	1,946 (23.5)	367 (4.4)	1,086 (13.1)
Headache	436 (5.3)	323 (3.9)	63 (0.8)
Seizure	641 (7.7)	–	526 (6.4)
Skin and subcutaneous tissue disorders	3,056 (36.9)	2999 (36.2)	90 (1.1)
Skin reaction	2,943 (35.5)	2,940 (35.5)	65 (0.8)

HFE, head flexible electrode; SOC, system organ class

Safety profile: HFE vs INE overall cohorts

- Rates of reported all-cause and device-related adverse events, skin reactions, electric sensation, and heat sensation were all lower with HFE compared with data for INE reported previously[12] (**Table 3**)

Table 3. Adverse event rates in the HFE and INE cohorts

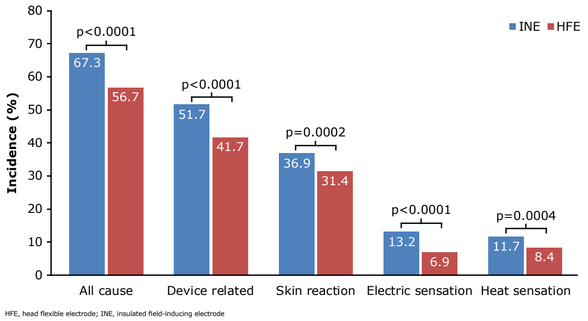
Adverse event	HFE (%)	INE (%)
All cause	61.5	73.0
Device related	44.2	56.0
Skin reaction	35.5	43.0
Electric sensation	6.0	14.0
Heat sensation	6.5	12.0

Unmatched descriptive comparison with a historical INE cohort; HFE, head flexible electrode; INE, insulated field-inducing electrode

Safety profile: HFE vs INE matched US cohorts

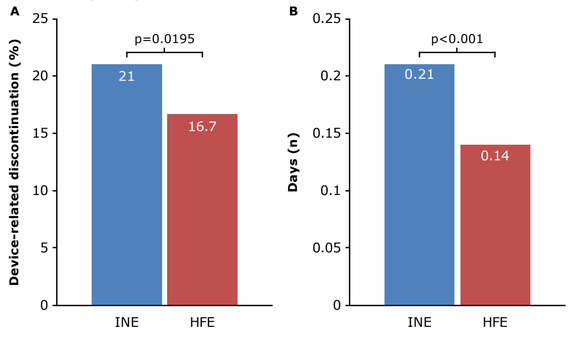
- Time and regional matching resulted in matched US cohorts with 12 months maximum follow-up for INE (2024; n=1,972) and HFE (US 2025; n=2,123)
- Rates of reported all-cause and device-related adverse events, skin reactions, electric sensation, and heat sensation were all significantly lower in the HFE overall cohort than the INE cohort (**Figure 2**)
- The reported incidence of non-device-related adverse events was comparable between cohorts (INE: 16.5%; HFE: 17.0%; p=0.5122)
- Device-related discontinuation rates were 21.0% in the INE cohort and 16.7% in the HFE cohort (p=0.0195) (**Figure 3**)
- With 12-month maximum follow-up, median duration of TTFields was prolonged by 9% in the HFE cohort

Figure 2. Adverse event rates in matched US HFE and INE cohorts



HFE, head flexible electrode; INE, insulated field-inducing electrode

Figure 3. A) Discontinuation rates and B) frequency of ≥1 overheating alarm during a day



HFE, head flexible electrode; INE, insulated field-inducing electrode

CONCLUSIONS

- **Assessment of post-marketing adverse events demonstrated that TTFields delivered using HFE arrays has a tolerable safety profile**
- **In global post-marketing surveillance of 8,284 patients with GBM treated with TTFields delivered using HFE arrays, 44.2% of patients had at least one reported device-related adverse event; skin reactions were the most commonly reported adverse event (35.5%)**
- **From time and region-matched cohort analysis, device-related adverse events were reduced for patients starting treatment with the HFE vs INE arrays**
- **In addition, the rate of device-related discontinuation and frequency of device alarms were significantly lower for patients treated using the HFE arrays**
- **Overall, results suggest improved tolerability with the HFE arrays. Extended follow-up is warranted**

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DISCLOSURES

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CONTACT INFORMATION Santiago Cabezas-Camarero at santicc81@gmail.com