Laser Interstitial Thermal Therapy for Brain Tumors: A Prospective Multicenter Analysis of Patients From the LAANTERN Study

Eric C. Leuthardt, MD, MBA[1]; Veronica Chiang, MD[2]; Constantinos G. Hadjipanayis, MD, PhD[3]; Patrick Landazuri, MD[4]; Dimitris G. Placantonakis, MD, PhD[5]; Steven R. Abram, MD[6]; David A. Sun, MD, PhD[7]; Kris A. Smith, MD[8]; Alireza M. Mohammadi, MD[9]; Clark C. Chen, MD, PhD[10]; Brian J. Williams, MD[11]; David E. Piccioni, MD, PhD[12]; Tiffany R. Hodges, MD[13]; Andrew E. Sloan, MD[14]; Bradley Lega, MD[15]; Analiz Rodriguez, MD, PhD[16]; Michel Lacroix, MD[17]; Fedor Panov, MD[18]; Hamid Borghei Razavi, MD[19]; James Baumgartner, MD[20]; Taylor J. Abel, MD[3]; Kathleen Bandt, MD[21]; Matthew D. Smyth, MD[22]; Ganesh Rao, MD[23]; Peter E. Fecci, MD, PhD[24]; Adrian W. Laxton, MD[25]; Stephen B. Tatter, MD, PhD[25]; Albert H. Kim, MD, PhD[1]; and Sujit S. Prabhu, MD[26]

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ABSTRACT

PURPOSE Laser interstitial thermal therapy is a surgical tool used to ablate brain tumors, radiation necrosis, and epileptic foci. Data from the LAANTERN prospective multicenter registry (ClinicalTrials.gov identifier: NCT02392078), containing patients with tumor from 25 US centers between 2015 and 2023, were analyzed to determine clinical outcomes.

METHODS All patients with primary or metastatic brain tumors treated with LITT using the Monteris NeuroBlate System were included in this analysis. Demographics, intraprocedural data, adverse events, survival data, and data pertaining to functional status over time were prospectively collected and then analyzed. Both univariable and multivariable analyses were performed.

RESULTS A total of 787, primary (445) and metastatic brain tumor (342), patients were included. The median age was 59.6 years and the median pediatric age 15 years (n = 18). The median length of hospital stay was 32.4 hours, and 62.6% avoided intensive care unit admission. The adverse event rate was 12.8%, with 65.5% of events considered transient. Mortality rate was 0.25%. Anticonvulsants were stopped in 30%-40% of patients, and 80% of patients stopped steroids after LITT. Quality of life remained stable up to 3 years post-LITT. Greater extent of ablation (EOA) and smaller lesion size were associated with significant improvements in survival outcomes in patients with high-grade glioma and recurrent metastases.

CONCLUSION The data from this largest, prospective LITT cohort support the consideration of LITT as a cytoreductive tool for patients with primary and metastatic tumor with short hospital stays, low complication rates, and preserved functional status. The EOA in glioblastoma and lesion volume in metastatic disease emerge as factors that may guide patient selection.

ACCOMPANYING CONTENT

Data Sharing Statement

Data Supplement

Protocol

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INTRODUCTION

Magnetic resonance imaging–guided laser interstitial thermal therapy (LITT) is a minimally invasive neurosurgical approach for ablating or cytoreducing intracranial tumors using hyperthermia.[1] LITT has been used across a myriad of oncologic diagnoses, including newly diagnosed and recurrent gliomas, metastatic tumors, and radiation necrosis (RN; Fig 1).[1-6]

The Laser Ablation of Abnormal Neurological Tissue Registry using NeuroBlate System (LAANTERN, ClinicalTrials.gov identifier: NCT02392078) began in 2015 to collect postmarket, real-world data on the use of the NeuroBlate System (NBS). LAANTERN closed in 2023 and represents the largest prospective, multicentered cohort of LITT patients to date, consisting of 1,057 patients across 25 US institutions, including 787 patients with tumor. Subsets of oncology data from LAANTERN have previously been published.[2-5]

METHODS

Study Design

Each site had Institutional Review Board approval. Patients provided written consent for enrollment and underwent

CONTEXT

Key Objective
For patients with brain tumors undergoing cytoreductive laser interstitial thermal therapy (LITT), what procedural factors predict survival outcomes?

Knowledge Generated
Extent of ablation ≥91% in newly diagnosed glioblastoma and 100% in recurrent metastases was associated with improved survival. Smaller tumor volume (<14.1cc in glioblastoma, <7.9cc in recurrent metastases) also predicted better survival outcomes.

Relevance *(C. Chung)*
When considering local therapies such as LITT, common patient prognostic factors persist including the volume of the disease and the achieved delivery coverage of the present disease by the local therapy.*

*Relevance section written by *JCO* Associate Editor Caroline Chung, MD, MSc, FRCPC.

LITT using NBS between 2015 and 2023. Study details were previously described.[2,6] Patients were followed up to 5 years post-LITT.

Participants

Patients enrolled in LAANTERN receiving LITT for a primary or metastatic brain tumor, or RN, were included for analysis. Patients were stratified into cohorts based on LITT biopsy data (Data Supplement, Fig S1, online only). The WHO classification of CNS tumors was updated during enrollment. Grade-4 astrocytoma patients with *IDH* wild-type status were reclassified into the glioblastoma (GBM) WHO grade-4 cohort, whereas patients previously considered *IDH*-mutant glioblastoma WHO grade 4 were reclassified as astrocytoma WHO grade-4, per updated 2021 criteria.[3,7] In the recurrent metastasis cohort, the procedure-day biopsy or a biopsy performed within 4 weeks of the LITT procedure was used to categorize tumor recurrence versus RN. Patients without biopsy determination of tumor versus RN were excluded from survival analysis.

Procedures

All centers used the US Food and Drug Administration (FDA)–cleared NBS as previously described.[8] Extent of ablation (EOA) was neurosurgeon-determined based on postprocedural imaging and thermal-dose threshold (TDT-line) coverage, per NBS software. This coverage was categorized by superimposition of final LITT treatment volume over initial tumor volume and reported as <10%, 10%-50%, 51%-90%, 91%-99%, and 100%.

Outcomes

LAANTERN collected demographics, health history information, and disease-specific details in addition to survival and quality-of-life data (QOL). Overall survival (OS) was defined as time from initial disease diagnosis to death for patients with newly diagnosed primary tumor or time from LITT-to-death (post-LITT OS) for recurrent disease. For metastatic patients, survival was time from LITT to death (post-LITT OS). For both primary and metastatic patients, progression-free survival (PFS) was defined as the time from LITT to treated-lesion progression or death, whichever came first.

Disease progression was determined at each institution using standard-of-care criteria based on multidisciplinary clinical and imaging review. For patients with multiple lesions ablated, disease progression analysis was performed on the largest ablated lesion. Adverse events were independently adjudicated by an external physician safety committee to determine relationship to the LITT procedure.

Statistical Analysis

Survival was determined using Kaplan-Meier analyses[9] and compared across cohorts using log-rank tests. PFS estimated by using the Kaplan-Meier method considered patients at risk until they had disease progression or until their last follow-up/death date and were otherwise censored from the analysis. Rates of adverse events were compared using the Clopper-Pearson exact binomial method. Wilcoxon signed-rank test was used to compare Karnofsky Performance Status (KPS) from independent follow-up time points to baseline scores. P values were two-sided; $P < .05$ was considered significant. Hazard ratios (HRs) were estimated using Cox proportional hazards modeling. All hypothesis tests, including the reduction from full model to additive model, used Generalized Likelihood Ratio tests. Ties were handled using the Efron method. All confidence intervals were done at the 95% level unless stated

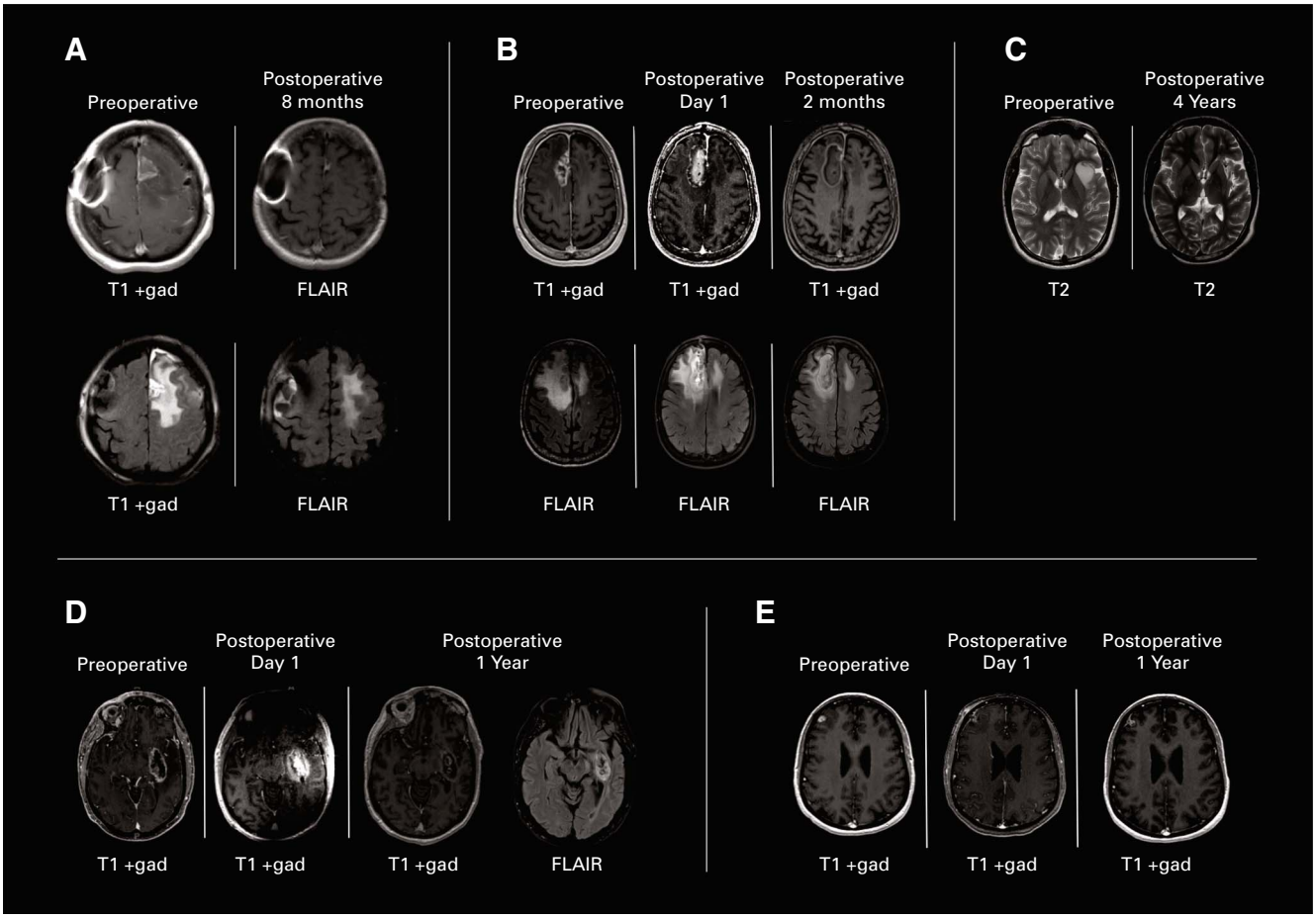


FIG 1. Radiographic changes over time from laser ablation cases of varying pathology. (A) Recurrent GBM; (B) glioma radiation necrosis; (C) newly diagnosed low-grade glioma; (D) newly diagnosed GBM; (E) recurrent brain metastasis.

otherwise. All statistical analyses were performed using R version 4.4.0.

RESULTS

A total of 787 patients were analyzed. Of them, 445 (56.5%) had primary brain tumors (291 recurrent, 120 newly diagnosed, and 34 RN) and 342 (43.5%) had metastatic lesions (164 recurrent, 163 RN, and 15 newly diagnosed). Biopsy-proven RN (163/342) was the most common brain metastasis pathology, followed by non–small cell lung cancer (57/342) and breast cancer (35/342). For primary tumors, GBM was the most frequent lesion pathology (190/445), followed by grade-4 astrocytoma (79/445; Data Supplement, Table S1). The median follow-up duration was 12 months (Table 1). Rate of study completion at 6 months, 1 year, 3 years, and 5 years was 60%, 41%, 6%, and 1% for patients with primary tumor and 64%, 46%, 7%, and 2% for patients with metastatic tumor. Rate of completion reflects participant data entered at an in-person visit and does not necessarily equate to survival time.

Demographic and Procedure Characteristics

The average age was 57.3 years, and 18 patients were <22 years (adolescent age per FDA) at enrollment.[10] Ninety-five percent of procedures involved a single lesion, with a median procedure time of 163.0 minutes and a median 5 mL of blood loss. The median hospital stay was 32.4 hours (min-max 5.1-846.1), and most (62.6%) did not require intensive care unit (ICU) stay (Table 1). The frontal lobe was the most common site for both primary (45.6%) and metastatic (42.1%) tumors. Just over half (51.7%) of primary tumors were designated as deep-seated versus 38.3% of metastatic lesions (Table 1). The Data Supplement (Fig S2) displays the locations of the patients with newly diagnosed glioblastoma (nGBM).

Temporal Trends

Comparison of LITT procedures performed between 2014 and 2019 versus 2020 and 2023 revealed improvements in efficiency. The mean procedure time decreased from 191.8 minutes (standard deviation [SD], 88.5) to 164.2 minutes (SD,

TABLE 1. Demographics and Procedural Information

Measure	N = 787
Metastatic brain tumors	342
New metastatic brain tumor	15
Metastatic radiation necrosis	163
Recurrent metastatic brain tumor	164
Primary brain tumor	445
New primary brain tumor	120
Primary radiation necrosis	34
Recurrent primary brain tumor	291
Female , No. (%)	396 (50.3)
Age at time of LITT in years	
Mean ± SD	57.3 ± 14.5
Median [IQR] (min-max)	59.6 [18.0] (6.6-95.8)
Pediatric patients (<age 22 years at time of consent), n/N	18/787
Age, years, median [IQR] (min-max)	15.0 [6.5] (6.6-21.6)
Race, No. (%)	
White/Caucasian	694 (88.2)
Asian	13 (1.6)
American Indian or Eskimo/Aleutian	2 (0.3)
Black/African American	58 (7.4)
Native Hawaiian/Pacific Islander	0 (0.0)
Multiracial	3 (0.4)
No. of lesions ablated	N = 838
Mean ± SD (min-max)	1.06 ± 0.25 (1-2)
Average blood loss during procedure, mL	N = 751
Mean ± SD	16.4 ± 35.3
Median [IQR] (min-max)	5 [8] (0-400)
Median laser fire in minutes, range	18.9, 1-173.6
Total estimated procedure time (skin-to-skin), min	N = 781
Mean ± SD	177.1 ± 85.0
Median [IQR] (min-max)	163.0 [87] (19-709)
Length of hospital stay, hours	N = 778
Mean ± SD	60.5 ± 85.0
Median [IQR] (min-max)	32.4 [25.3] (5.1-846.1)
Length of hospital stay median hours, [IQR]: Primary tumor, metastatic tumor	33.1 [25.95], 31.6 [24.7]
Primary length of stay in ICU, hours	N = 178
Mean ± SD	52.0 ± 104.2
Median [IQR] (min-max)	23.8 [22.9] (0.8-726.2)
Metastatic length of stay in ICU, hours	107
Mean ± SD	42.5 ± 66.9
Median [IQR] (min-max)	23.5 [10.1] (3.7-454.5)
Unit transferred to postprocedure, No. (%)	N = 773
ICU	289 (37.4)
Step down	150 (19.4)
Standard floor	334 (43.2)
Discharged to, No. (%)	N = 785
Home	89 (699)
Rehab facility	5.7 (45)
Skilled nursing facility	3.2 (25)
Another acute care hospital	0.8 (6)
In-patient rehab at current hospital	0.9 (7)
Other	0.4 (3)
Median follow-up duration, months	12
Median lesion size cc, min-max	
Primary tumor	11.5 (0.03-344.8)
Metastatic tumor	7.2 (0.07-179.6)
Ablation ≥91%, % (n/N)	
Primary tumors, metastatic tumors	75.5 (308/408), 85.9 (275/320)
Biopsy acquired preceding LITT, % (n/N)	79.3 (624/787)
Ablation location recorded: Primary, metastatic, %	N = 445, N = 342
Frontal lobe	45.6, 42.1
Parietal lobe	16.6, 22.5
Temporal lobe	22.7, 15.5
Occipital lobe	7.6, 12.6
Cerebellum	1.1, 9.6
Brain stem	0.7, 0.3
Thalamus	7.2, 1.5
Hypothalamus	0.7, 0.0
Insula	2.9, 1.2
Amygdala	0.0, 0.0
Hippocampus	0.7, 0.0
Pineal body	0.4, 0.0
Other deep nuclei	0.9, 0.6
Corpus callosum	6.5, 0.9
Other	7.4, 2.6
Lesion recorded as deep-seated: Primary % (n/N), metastatic % (n/N)	51.7 (230/445), 38.3 (129/337)
Prior LITT recorded	30
Which recurrence LITT treated, No. (%)[a]	N = 128
1st	84 (66)
2nd	28 (22)
3rd	7 (5.5)
4th	9 (7)

Abbreviations: ICU, intensive care unit; LITT, laser interstitial thermal therapy.
[a]This question added late in the course of the registry.

79.6; $P < .0001$). ICU utilization declined substantially from 46.7% to 27.9% ($P < .0001$), and length of stay decreased from median 33.4 hours (27.1 IQR) to 31.6 hours (22.5 IQR; $P < .0001$; Data Supplement, Table S2).

Survival Outcomes

Patients with newly diagnosed GBM (n = 69) achieved a median OS of 1.2 years (95% CI, 0.6 to 2.1) and PFS of 0.5 years (95% CI, 0.3 to 1.1). Post-LITT OS for patients with recurrent GBM (n = 121) was 0.9 years (95% CI, 0.8 to 1.1) and

PFS was 0.4 years (95% CI, 0.4 to 0.6; Data Supplement, Table S3). In the recurrent metastatic cohort (n = 164), the median survival was 2.02 years from the LITT procedure (95% CI, 1.33 to 2.68), and the median PFS was 0.70 years (95% CI, 0.49 to 1.05). RN cases (n = 163) showed an OS of 4.18 years (95% CI, 1.98 to value not available/reached [NA]) with a median PFS of 1.89 years (95% CI, 1.38 to 2.94; Data Supplement, Table S3).

Extent of Ablation

Near-total ablation (≥91%) was achieved in 75.5% of primary and 85.9% of metastatic lesions (Table 1). Patients with newly diagnosed grade 4 GBM with ≥91% ablation (n = 37) showed significantly longer median PFS (1.32 *v* 0.24 years, P = <.0001) and OS (2.1 *v* 0.36 years, P = <.0001) compared with those with ≤90% ablation (n = 26; Figs 2A and 2B). Similarly, patients with newly diagnosed grade 4 astrocytoma with ≥91% ablation demonstrated significantly longer PFS (0.84 *v* 0.25 years, P = .0065) and OS (0.31 years *v* NA, P = .0004). In recurrent GBM, patients with ≥91% ablation did not show significantly longer survival outcomes in PFS 0.46 versus 0.42 years (P = .75) or in post-LITT OS (0.95 *v* 0.91, P = .26; Table 2).

For patients with brain metastasis with recurrent tumor, post-LITT OS was significantly improved if EOA of 100% was achieved compared with ablation of ≤99% (2.8 years *v* 1.3 years, P = .03) with a trend toward improved PFS across the categories <90% versus 91%-99% versus 100% (P = .06; Table 2; Figs 2E and 2F). For patients with metastatic disease with RN, EOA did not affect post-LITT OS or PFS across the categories of <90% versus 91%-99% versus 100% (P = .37 and P = .10).

Effect of Lesion Volume

The median lesion size for primary tumors was 11.5cc compared with 7.2cc for metastatic lesions (Table 1). Analysis showed no significant relationship between lesion size and PFS for grade-1 gliomas, grade 2 to 3 gliomas (P = .441) or for grade-4 astrocytomas (P = .3272). There was a statistically significant difference in PFS for GBMs measuring less than the median 14.1cc (P = .035) and meningioma <17.4cc (P = .0402). Only grade 4 GBM showed a significant relationship between lesion volume and OS, where lesions <14.1cc showed an OS of 2.2 years versus 1.6 years (>14.1cc; P = .0053), with the relationship remaining when stratified by new and recurrent disease (Data Supplement, Table S4). Figures 3A-3D show GBM survival by lesion volume, by newly diagnosed and recurrent disease.

Decreased recurrent metastatic tumor volume significantly influenced survival outcomes with lesion volume <7.9cc (diameter 2.47 cm) showing substantially longer median PFS (1.2 *v* 0.5 years, P = .001; Data Supplement, Table S4, Figs 3E and 3F). No significant difference in PFS was seen for metastatic RN when assessed by lesion size (P = .22).

Impacts on EOA

Select subcohorts with greater EOA, particularly nGBM, showed longer survival. Analysis was performed to determine whether EOA was affected by other patient characteristics. Patients with nGBM with KPS ≥80 were more likely to achieve ≥91% EOA (P = .041). Neither age nor lesion volume predicted the ability to achieve ≥91% EOA (P = .80, P = .19, respectively). For recurrent glioblastoma (rGBM), smaller lesion volume was predictive of ≥91% EOA achievement (P = .0061), but age and KPS had no association (P = 1.0, P = .65, respectively). The only significant impact on EOA in the metastatic cohort was lesion size (P = .047 in recurrent metastases; Data Supplement, Table S5).

Multivariable Analysis

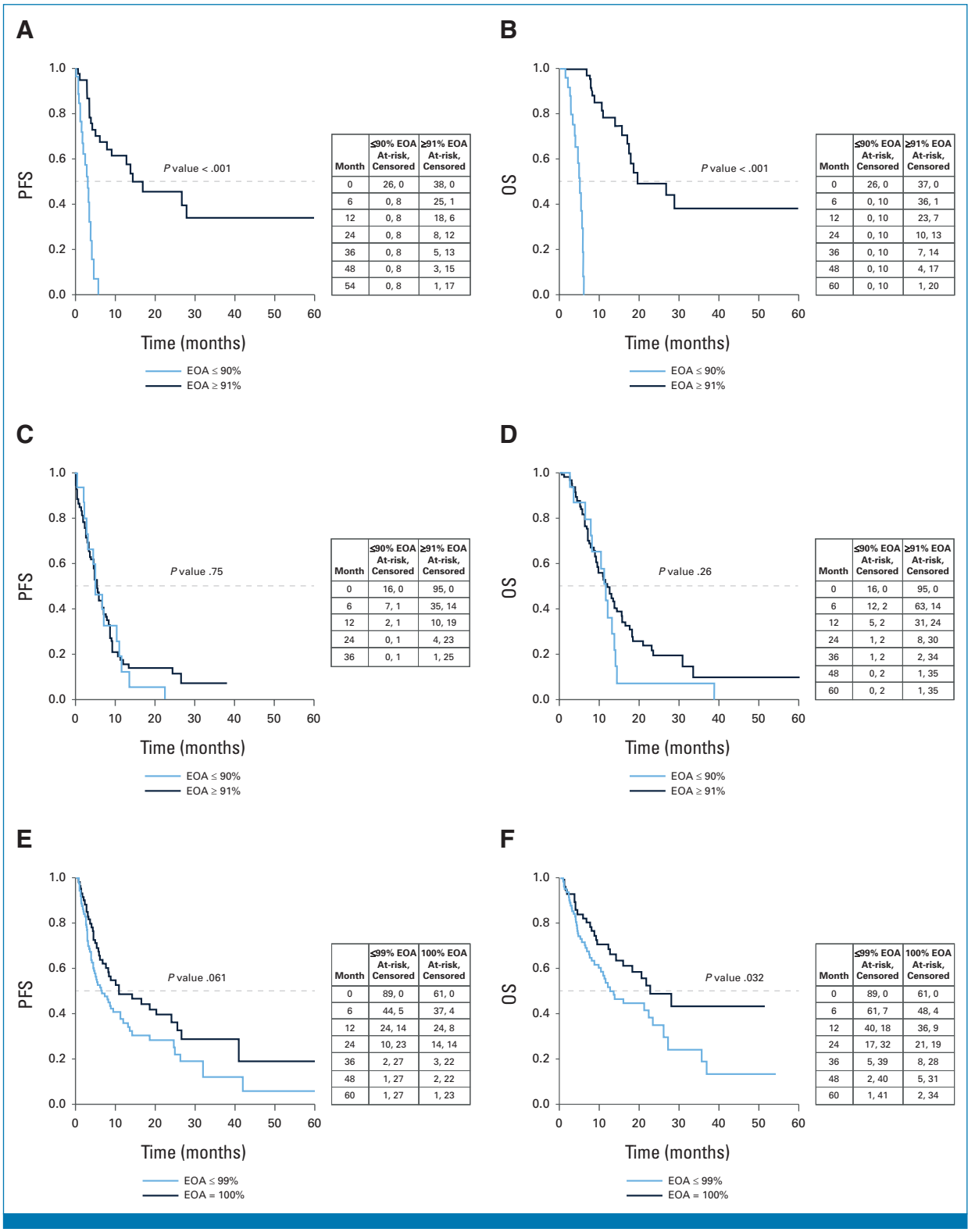
The relationship between lesion size and EOA on survival outcomes was examined for GBM (new and recurrent) and recurrent metastatic lesions. For patients with nGBM, post-LITT OS was mildly benefited by smaller lesion size only in the higher EOA group (≥91%; HR, 0.51 [95% CI, 0.20 to 1.33]). Smaller lesion size also interacted with EOA and contributed a small benefit to PFS but was not significant (HR, 0.86 [95% CI, 0.36 to 2.03]).

In rGBM, smaller lesions had better survival outcomes and lesion size mattered more in post-LITT OS than EOA in both ablation groups (HR, 0.50 [95% CI, 0.23 to 1.06]).

In metastatic patients with tumor recurrence, post-LITT OS was affected by both EOA and lesion size. Lesions <7.9cc (diameter of 2.5 cm) ablated to 100% had a HR of 0.90 (95% CI, 0.45 to 1.81) compared with 91%-99% ablation (HR, 1.75 [95% CI, 0.88 to 3.50]) and <90% (HR, 4.61 [95% CI, 1.22 to 17.42]) suggesting that EOA had increasing benefit in smaller lesions. For patients with metastatic RN, both EOA and lesion size equally influenced post-LITT OS, although to a less variable degree than for tumor recurrence (HR, 0.99, 0.37 and 0.70 for 100% EOA, 91%-99% and <90%, respectively; Data Supplement, Table S6).

Seizure Reduction

Patients with primary tumor experienced a significant reduction in reported seizures, from 54.1% at baseline to 11.0% at 6 months (absolute reduction 43.1%, P < .0001) and 19.9% at 12 months (absolute reduction 34.2%, P < .0001). Data differentiating a single seizure event from refractory epilepsy were unavailable. Metastatic patients similarly demonstrated reduction from 35.3% at baseline to 7.7% at 6 months (absolute reduction 27.6%, P < .0001) and 7.9% at 12 months (absolute reduction 27.4%, P < .0001) (Data Supplement, Table S7). Following LITT, 19.5% of patients with primary tumor discontinued anticonvulsants within 24 months, whereas 29.8% of patients with metastatic tumor and 46.7% of patients with metastatic RN discontinued anticonvulsants by 24 months (Data Supplement, Table S8).



Month	≤90% EOA At-risk, Censored	≥91% EOA At-risk, Censored
0	26, 0	38, 0
6	0, 8	25, 1
12	0, 8	18, 6
24	0, 8	8, 12
36	0, 8	5, 13
48	0, 8	3, 15
54	0, 8	1, 17

Month	≤90% EOA At-risk, Censored	≥91% EOA At-risk, Censored
0	26, 0	37, 0
6	0, 10	36, 1
12	0, 10	23, 7
24	0, 10	10, 13
36	0, 10	7, 14
48	0, 10	4, 17
60	0, 10	1, 20

Month	≤90% EOA At-risk, Censored	≥91% EOA At-risk, Censored
0	16, 0	95, 0
6	7, 1	35, 14
12	2, 1	10, 19
24	0, 1	4, 23
36	0, 1	1, 25

Month	≤90% EOA At-risk, Censored	≥91% EOA At-risk, Censored
0	16, 0	95, 0
6	12, 2	63, 14
12	5, 2	31, 24
24	1, 2	8, 30
36	1, 2	2, 34
48	0, 2	1, 35
60	0, 2	1, 35

Month	≤99% EOA At-risk, Censored	100% EOA At-risk, Censored
0	89, 0	61, 0
6	44, 5	37, 4
12	24, 14	24, 8
24	10, 23	14, 14
36	2, 27	3, 22
48	1, 27	2, 22
60	1, 27	1, 23

Month	≤99% EOA At-risk, Censored	100% EOA At-risk, Censored
0	89, 0	61, 0
6	61, 7	48, 4
12	40, 18	36, 9
24	17, 32	21, 19
36	5, 39	8, 28
48	2, 40	5, 31
60	1, 41	2, 34

FIG 2. Kaplan-Meier curves detailing survival analysis by extent of ablation. (A) Newly diagnosed grade 4 GBM, procedure to progression or death (PFS) by extent of ablation. (B) Newly diagnosed grade 4 GBM, diagnosis to death (OS) by extent of ablation. (C) Recurrent grade 4 GBM, procedure to progression or death (PFS) by extent of ablation. (D) Recurrent grade 4 GBM, procedure to death (OS) by extent of ablation. (E) Recurrent metastases tumor, procedure to progression or death (PFS) by extent of ablation. (F) Recurrent metastases tumor, procedure to death (OS) by extent of ablation. EOA, extent of ablation; GBM, glioblastoma multiforme; OS, overall survival; PFS, progression-free survival.

TABLE 2. Median Survival by EOA

Lesion Type EOA	Median PFS, years (IQR)	*P*	Median Post-LITT OS (IQR)	*P*	Median Diagnosis to Death (OS), Years (IQR)	*P*
Newly diagnosed GBM						
≤90%, n = 26	0.24 (0.14-NA)	<.0001	0.27 (0.22-NA)	<.0001	0.36 (0.27-NA)	<.0001
≥91%, n = 37	1.32 (0.72-NA)		2.1 (1.32-NA)		2.1 (1.35-NA)	
Recurrent GBM						
≤90%, n = 16	0.42 (0.28-0.95)	.75	0.91 (0.65-1.12)	.26	—	
≥91%, n = 93	0.46 (0.40-0.64)		0.95 (0.73-1.24)		—	
New grade 4 astrocytoma						
≤90%, n = 4	0.25 (0.15-NA)	.0065	0.25 (0.16-NA)	.0004	0.31 (0.22-NA)	.0004
≥91%, n = 8	0.84 (0.70-NA)		NA (1.26-NA)		NA (1.04-NA)	
Recurrent grade 4 astrocytoma						
≤90%, n = 10	0.31 (0.13-NA)	.59	NA (0.41-NA)	.86	—	
≥91%, n = 50	0.51 (0.30-1.61)		1.20 (0.86-NA)		—	
Metastasis recurrent tumor						
≤90%, n = 19	0.8 (0.24-NA)	.65	2.1 (0.54-NA)	.21	—	
≥91%, n = 124	0.73 (0.56-1.2)		2.2 (1.3-NA)		—	
Metastasis recurrent tumor						
≤99%, n = 89	0.6 (0.4-1.0)	.06	1.3 (1.0-2.7)	.032	—	
100%, n = 61	0.9 (0.6-2.2)		2.8 (1.8-NA)		—	
Metastasis radiation necrosis						
≤90%, n = 22	1.6 (0.4-NA)	.34	1.9 (1.0-NA)	.10	—	
≥91%, n = 126	2.0 (1.4-NA)		4.2 (2.1-NA)		—	
Metastasis radiation necrosis						
≤99%, n = 98	1.6 (0.8-NA)	.087	4.2 (1.9-NA)	.37	—	
100%, n = 58	2.1 (1.7-NA)		2.6 (1.9-NA)		—	

Abbreviations: EOA, extent of ablation; GBM, glioblastoma multiforme; LITT, laser interstitial thermal therapy; NA, value not available/reached; OS, overall survival; PFS, progression-free survival.

Steroids/Bevacizumab

Steroid cessation, defined as discontinuation for ≥28 consecutive days, was achieved in 82% of patients with primary tumor, 90% primary tumor RN, 96% metastatic tumors, and 98% of metastatic RN. Steroid cessation occurred at a median of 14.0 days (IQR, 41.0) post-LITT for primary tumors, 34.0 days (IQR, 44.0) for primary RN, 24.5 days (IQR, 73.0) for metastatic tumors, and 16.0 days (IQR, 60.0) for metastatic RN (Data Supplement, Table S9).

Bevacizumab initiation within 30 days of LITT was minimal across all cohorts (2.9% nGBM, 4.1% rGBM, 0% rMets and Mets RN) suggesting that LITT-associated edema is typically manageable without anti-vascular endothelial growth factor therapy (Data Supplement, Table S10).

Functional Outcomes

KPS showed stability from baseline (median 90.0 [Q1, Q3 80.0, 90.0]) to 1 month (90.0 [Q1, Q3 70.0, 90.0]) with modest decline at 3 months (80.0 [Q1, Q3 70.0, 90.0]). The median KPS reverted to baseline score (90.0 [Q1, Q3 70.0, 90.0]) at 12 months, although responses decreased to n = 246 (Data Supplement, Table S11). QOL, measured by FACT-Br, showed minimal changes in overall scores from baseline (mean 144.8, SD 28.4) to 12 months (mean 145.0, SD 34.9; mean difference −3.38, $P = .0611$) and remained stable through 3 years (mean 154.3, SD 34.9; mean difference 0.19, $P = .9646$; Data Supplement, Fig S3).

Adverse Events

The overall per-person AE rate was 12.8% (110 AEs in 101/787 patients). Of the 110 AEs, 90 (82%) were neurologic, 72 (65.5%) resolved completely, and 17 (15.5%) were classified as serious per the external safety committee. Overall, per-person AE risk of severe/irreversible AEs was 2.3% (18/787). The most frequent complications were bleeding (18/110 events), cerebral edema (16/110), seizures (new-onset or worsened existing) (13/110), and motor weakness (10/110; Data Supplement, Fig S4). Of those with a reported bleeding complication, 6/18 events required additional surgical intervention (6/787, 0.76%). Two deaths were adjudicated as related to surgery—one case of edema and one of hemorrhage—surgical mortality rate 0.25% (2/787).

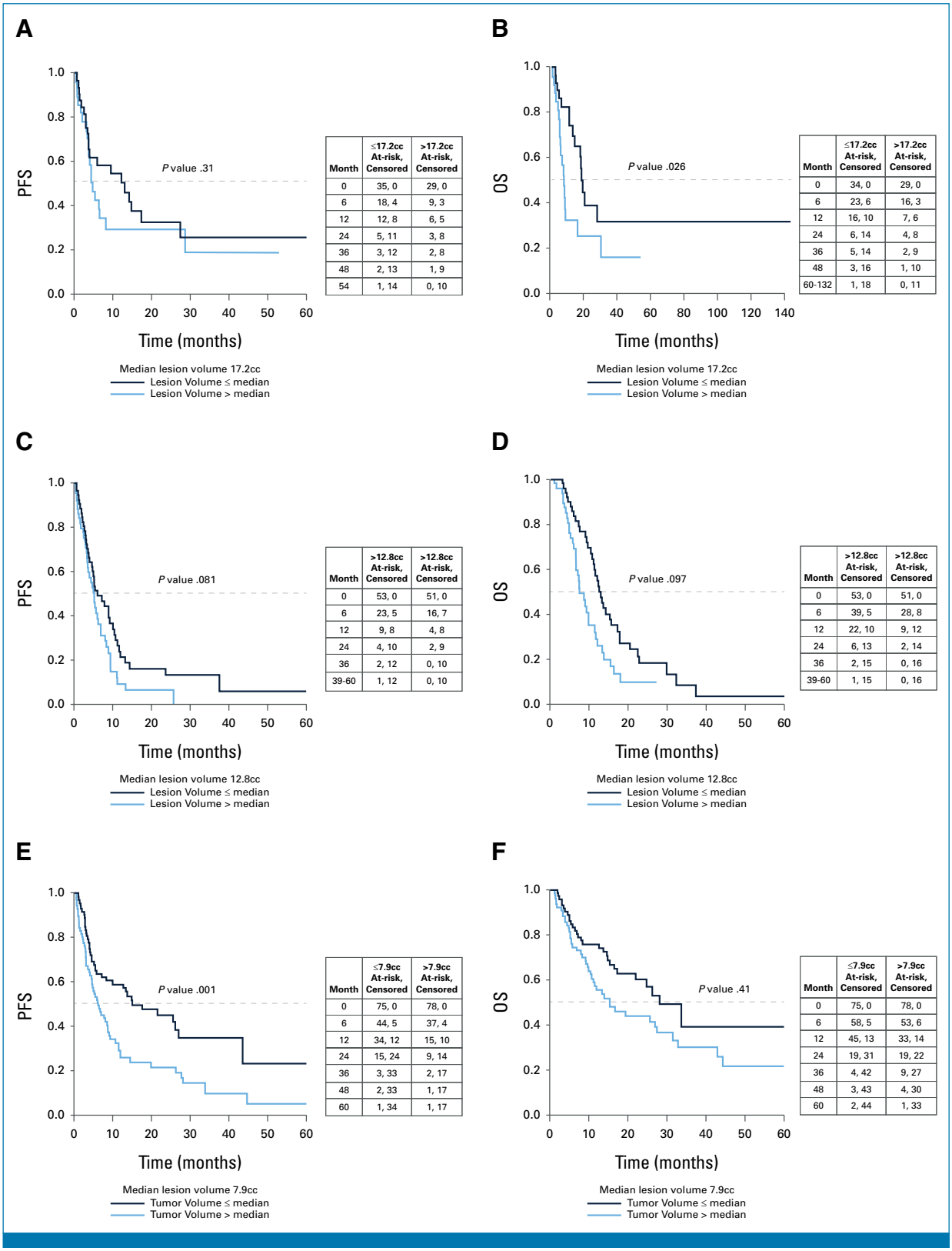


FIG 3. Kaplan-Meier curves detailing survival analysis by tumor volume. (A) Newly diagnosed grade 4 GBM, procedure to progression or death (PFS) by lesion volume. (B) Newly diagnosed grade 4 GBM, diagnosis to death (OS) by lesion volume. (C) Recurrent grade 4 GBM, procedure to progression or death (PFS) by lesion volume. (D) Recurrent grade 4 GBM, procedure to death (OS) by lesion volume. (E) Recurrent metastases tumor, procedure to progression or death (PFS) by lesion volume. (F) Recurrent metastases tumor, procedure to death (OS) by lesion volume. EOA, extent of ablation; GBM, glioblastoma multiforme; OS, overall survival; PFS, progression-free survival.

Surgical infection rate (cellulitis-1, pneumonia-1, wound dehiscence-2) was 0.5%. Readmission rates within 30 days were 2.7% for primary and 3.5% for metastatic cases. Longer procedure duration trended toward more complications: 15% AE rate for procedures exceeding 190 minutes compared with 10%-11% in shorter procedures (P = .091). Increasing lesion volume was a predictor of complications in the primary cohort (<11.5cc 16.4% AE rate v ≥ 11.5cc 30% P = .0237) but not in the metastatic cohort (Data Supplement, Table S12). No AEs were reported in the pediatric subgroup (n = 18).

DISCUSSION

To our knowledge, this analysis of 787 patients represents the largest, prospective evaluation of LITT for intracranial tumors to date.

When EOA was maximized, survival improved, particularly in nGBM (Figs 2A and 2B) and recurrent brain metastases (Fig 2F). For GBM, reported median OS is 15-18 months with current standard-of-care therapy[11,12] and 2.3 years if complete resection is achieved.[13] In patients with nGBM, achieving ≥91% ablation resulted in significant lengthening of median OS, 2.1 years, versus 0.27 years for those with ≤90% ablation (P = <.0001). EOA mattered most in this group versus rGBM, where lesion size played a larger role. These findings are consistent with prior studies on extent of open-resection[14,15] and reinforce the importance of maximal/aggressive cytoreduction regardless of surgical technique in nGBM management.[16,17]

For recurrent metastatic disease, there was a significant effect of both lesion volume and EOA on outcomes. Tumors <7.9cc had a median PFS gain of 8-months, and the beneficial impact of EOA was greater in smaller lesions. These results may suggest favorable outcomes in utilizing LITT early, while the lesion remains small.

Consistent with other reports, patients with biopsy-proven RN demonstrated favorable outcomes following LITT.[18,19] The median OS approached 4 years, and patients with RN stopped steroids by 2 weeks postprocedure. Simultaneous biopsy + LITT for RN can enable diagnosis confirmation, durable lesional control, and avoidance of prolonged steroid use, consistent with other reports.[20] These results add to the literature that supports LITT as a valuable management option for RN.

LITT offers several advantages for brain tumor management with a low surgical mortality rate of 0.25% (2/787 patients) and an infection rate of 0.5%. The median hospital stay of 32.4 hours and the minimally invasive nature of the procedure can enable fast patient recovery and early return to adjuvant therapies. LITT was used to treat deep-seated lesions, constituting 51.7% of primary tumors. These locations, including basal ganglia, thalamus, insula, and corpus callosum, typically present with a high surgical risk with open approaches,[21,22] and survival outcomes are reduced when no cytoreduction is offered.[23,24] The ability to safely access these regions with minimal disruption of intervening tissue is an important consideration in surgical strategy.[25,26]

As a prospective registry study without a control arm, direct comparisons to craniotomy outcomes must be made cautiously. Selection bias may affect our cohort, as larger tumors may have been directed to open surgery, while patients considered to be poor surgical candidates were potentially directed to LITT. Variations in LITT practice introduce heterogeneity into the data set. Furthermore, recurrence was determined clinically/radiographically per the treating physician and could be subject to institutional variance. To conform to updated 2021 WHO guidelines, patients with GBM and high-grade astrocytoma were recategorized by presence of *IDH* status. Not all recategorized patients had data available regarding *TERT* promoter mutation or *EGFR* gene amplification, and some may have been erroneously recategorized, skewing survival analysis. *MGMT* status was not available on all patients but would also have been important for survival analysis. Understanding neurologic versus non-neurologic death would have also been additive to survival analysis in the metastasis cohort. Rate of study completion declined over time. Less than 50% completed 1-year follow-up, and 1%-2% of patients completed visits at 5 years. Patient drop-out may reflect high mortality, clinical deterioration, local follow-up after traveling to LITT institutions, and COVID-19 pandemic impact. LAANTERN did not incentivize participation and had no active post-procedure intervention, likely affecting follow-up. Analyses were performed per the registry's Data Analysis Plan (DAP), set forth before data-lock. We acknowledge, however, that the DAP was designed to accommodate a real-world evidence registry rather than a hypothesis-driven trial, with multiple ad hoc exploratory analyses developed later. Finally, although correlations were identified between EOA and survival, interpretation of these findings requires nuance. The ≤90% EOA group is not monolithic: For grade-4 GBM, 89% of patients with ≤90% ablation achieved 51%-90% EOA rather than representing true ablation failures. Importantly, median lesion volumes differed substantially across EOA categories (51%-90%: 21.5 cc; 91%-99%: 12.8 cc; 100%: 8.2 cc), suggesting that baseline tumor characteristics may influence survival differences (Data Supplement, Table S13). Poor outcomes in the lower EOA group may reflect tumor biology (larger, more aggressive tumors), technical limitations of current LITT approaches for tumors >15-20 cc, or unmeasured confounders rather than lack of treatment benefit. Collecting data on reasons for incomplete ablation would have been additive to the study. Additional studies will help establish how LITT can further optimize survival.[27,28] Understanding the benefits of LITT versus craniotomy, particularly in locations such as the insula, where there may be more equipoise between the two procedures,[25,26] represents a possibility for future exploration.

In conclusion, this largest-to-date prospectively collected cohort of 787 patients supports the consideration of LITT as a minimally invasive and safe cytoreductive tool for select patients with primary and metastatic brain tumors, including RN. Associated outcomes are optimized by ablating when lesions are smaller and by maximizing the EOA.

AFFILIATIONS

[1]Department of Neurosurgery, Washington University, St Louis, MO
[2]Department of Neurosurgery, Yale University, New Haven, CT
[3]Department of Neurological Surgery, University of Pittsburgh, Pittsburgh, PA
[4]Department of Neurology, University of Kansas Medical Center, Kansas City, KS
[5]Department of Neurosurgery, NYU Grossman School of Medicine, New York, NY
[6]Ascension St Thomas Brain and Spine Tumor Center, Howell Allen Clinic, Nashville, TN
[7]Norton Neuroscience Institute, Norton Health Care, Louisville, KY
[8]Barrow Neurological Institute, Phoenix, AZ
[9]Brain Tumor and Neuro-Oncology Center, Cleveland Clinic, Cleveland, OH
[10]Department of Neurosurgery, Brown University, Providence, RI
[11]Brain & Spine Institute, University of Louisville Health, Louisville, KY
[12]Department of Neurosciences, University of California San Diego School of Medicine, San Diego, CA
[13]Brain Tumor and Neuro-Oncology Center, University Hospitals Cleveland Medical Center, Cleveland, OH
[14]Division of Neurosurgery, Neuroscience Institute, Premier Health & Wright State University School of Medicine, Dayton, OH
[15]Department of Neurosurgery, Peter O'Donnell Brain Institute, University of Texas Southwestern Medical Center, Dallas, TX
[16]Department of Neurosurgery, University of Arkansas for Medical Sciences, Little Rock, AR
[17]Department of Neurosurgery, Geisinger Neuroscience Institute, Danville, PA
[18]Department of Neurosurgery, Mount Sinai, New York, NY
[19]Department of Neurosurgery, Cleveland Clinic, Weston, FL
[20]Department of Neurosurgery, Florida Hospital Advent Health, Orlando, FL
[21]Department of Neurological Surgery, Northwestern University, Chicago, IL
[22]Department of Neurological Surgery, Johns Hopkins All Children's Hospital, St Petersburg, FL
[23]Department of Neurosurgery, Baylor College of Medicine, Houston, TX
[24]Department of Neurosurgery, University of Colorado School of Medicine, Aurora, CO
[25]Department of Neurosurgery, Wake Forest University School of Medicine, Winston-Salem, NC
[26]Department of Neurosurgery, The University of Texas MD Anderson Cancer Center, Houston, TX

CORRESPONDING AUTHOR

Eric C. Leuthardt, MD, MBA; e-mail: leuthardte@wustl.edu.

DISCLAIMER

LAANTERN registry is sponsored by Monteris Medical Corp. Study investigators had full autonomy for the procedure, data entry, follow-up, and final analysis. Monteris was responsible for monitoring study compliance. Authors had access to the final data but were not granted access at the patient-level, except at their own institution. The funder, Monteris Medical, was responsible for study-monitoring activities and data preparation. The investigators had full autonomy for the procedure, data entry, and clinical follow-up. Investigators were responsible for interpretation of the data, review, approval of the manuscript; and decision to submit the manuscript for publication.

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CLINICAL TRIAL INFORMATION

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DATA SHARING STATEMENT

A data sharing statement provided by the authors is available with this article at DOI https://doi.org/10.1200/JCO-25-02604.
All data, including deidentified individual participant data, collected in the LAANTERN registry is made available to all primary and sub-investigators, including those listed as authors here, but is not in the public domain. Additional information about the LAANTERN study is found under NCT02392078

AUTHOR CONTRIBUTIONS

Conception and design: Eric C. Leuthardt, Alireza M. Mohammadi, Clark C. Chen, Andrew E. Sloan, Hamid Borghei Razavi, Adrian W. Laxton, Stephen B. Tatter, Albert H. Kim, Veronica Chiang
Administrative support: Andrew E. Sloan, Stephen B. Tatter
Provision of study materials or patients: All authors
Collection and assembly of data: Eric C. Leuthardt, Veronica Chiang, Patrick Landazuri, Dimitris G. Placantonakis, Steven R. Abram, David A. Sun, Kris A. Smith, Alireza M. Mohammadi, Clark C. Chen, Brian J. Williams, David E. Piccioni, Tiffany R. Hodges, Andrew E. Sloan, Bradley Lega, Michel Lacroix, Fedor Panov, Hamid Borghei Razavi, James Baumgartner, Taylor J. Abel, Kathleen Bandt, Matthew D. Smyth, Ganesh Rao, Peter E. Fecci, Adrian W. Laxton, Stephen B. Tatter
Data analysis and interpretation: Eric C. Leuthardt, Veronica Chiang, Constantinos G. Hadjipanayis, Patrick Landazuri, Clark C. Chen, Brian J. Williams, Andrew E. Sloan, Analiz Rodriguez, Fedor Panov, Matthew D. Smyth, Adrian W. Laxton, Stephen B. Tatter, Albert H. Kim, Sujit S. Prabhu
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

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Laser Interstitial Thermal Therapy for Brain Tumors: A Prospective Multicenter Analysis of Patients From the LAANTERN Study

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Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians (Open Payments).

Eric C. Leuthardt
Employment: Kandu
Leadership: Kandu
Stock and Other Ownership Interests: Kandu, Cordance Medical, Aurenar, Silent Surgical, Sora Neuroscience
Consulting or Advisory Role: Monteris Medical
Research Funding: Kandu
Patents, Royalties, Other Intellectual Property: I have over 600 patents. Licensing includes Sora Neuroscience, Neurolutions, Inner Cosmos, Cordance Medical

Veronica Chiang
Consulting or Advisory Role: Monteris Medical, MRI Interventions
Expert Testimony: Monteris Medical

Constantinos G. Hadjipanayis
Consulting or Advisory Role: Hemerion Therapeutics, Stryker Corp, Synaptive Medical, FluoGuide, Reveal Surgical, Integra LifeSciences
Research Funding: Hemerion Therapeutics

Patrick Landazuri
Consulting or Advisory Role: NeuroPace, Inc
Travel, Accommodations, Expenses: UniQure

Dimitris G. Placantonakis
Consulting or Advisory Role: Nxera
Patents, Royalties, Other Intellectual Property: Nonprovisional Patent Application No. 18/790,680

Steven R. Abram
Consulting or Advisory Role: Monteris Medical

Kris A. Smith
Stock and Other Ownership Interests: GammaTile
Speakers' Bureau: Aesculap

Clark C. Chen
Consulting or Advisory Role: Medtronic, GT Medical Technologies, Everfront
Travel, Accommodations, Expenses: GT Medical Technologies

Brian J. Williams
Stock and Other Ownership Interests: Von Vascular
Consulting or Advisory Role: Monteris Medical, Areva Pharmaceuticals
Research Funding: GT Medical Technologies (Inst)

David E. Piccioni
Consulting or Advisory Role: Novartis, GlaxoSmithKline

Andrew E. Sloan
Stock and Other Ownership Interests: Surgical Theater
Consulting or Advisory Role: Medtronic

Bradley Lega
Stock and Other Ownership Interests: Nia Therapeutics
Patents, Royalties, Other Intellectual Property: Patented brain stimulation method (Inst), Patented Brain Stimulation Method (Inst)

Analiz Rodriguez
Consulting or Advisory Role: Medexus Pharmaceuticals, Nico Corporation, Monteris Medical
Research Funding: Nico Corporation
Patents, Royalties, Other Intellectual Property: Patent application—Detection of Malignancy in Brain Cancer (WO2015070197 A1) Recipient: Wake Forest University Health Sciences Amount: None Start Date: 2015 End Date: Present Comments: Co-inventor, no royalties received, Patent application, Simultaneous *MGMT* and *IDH* Biomarker Detection in Diffuse Glioma (WO2021/072374A1) Recipient: University of Arkansas for Medical Sciences Amount: None Start Date: 2021 End Date: Present Comments: Co inventor, no royalties received

Fedor Panov
Speakers' Bureau: NeuroPace, Inc

Hamid Borghei Razavi
Consulting or Advisory Role: Johnson & Johnson/MedTech

James Baumgartner
Employment: Advent Health
Consulting or Advisory Role: PMT Corporation
Patents, Royalties, Other Intellectual Property: I hold a patent for a surgical device currently under review by the FDA. The device will be marketed by PMT Corporation if/when FDA approval is granted

Kathleen Bandt
Employment: Indiana University Health
Patents, Royalties, Other Intellectual Property: patent held for work completed during prior employment with Northwestern University

Matthew D. Smyth
Consulting or Advisory Role: Monteris Medical, Zimmer BioMet, Cranial Technologies, BrainLAB

Ganesh Rao
Employment: AstraZeneca (I)
Consulting or Advisory Role: CarThera, Monteris Medical

Peter E. Fecci
Stock and Other Ownership Interests: Nexsis Biosciences
Honoraria: BrainLAB
Consulting or Advisory Role: Monteris Medical, Black Forest Medical
Research Funding: Monteris Medical, ARCE Therapeutics
Patents, Royalties, Other Intellectual Property: Numerous pending patents for cancer immune-based platforms
Travel, Accommodations, Expenses: Monteris Medical

Adrian W. Laxton
Consulting or Advisory Role: Monteris Medical

Stephen B. Tatter
Research Funding: Monteris Medical, Inc (Inst)

Albert H. Kim
Consulting or Advisory Role: Monteris Medical
Research Funding: Stryker (Inst)
Patents, Royalties, Other Intellectual Property: Grace Medical. I am a Patent holder for a bone wax applier, and we are licensing this Grace Medical

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