Jefferson Health

VICKIE AND JACK FARBER INSTITUTE FOR NEUROSCIENCE
OUTCOMES & RESEARCH: VOLUME 6

PITUITARY TUMOR, MENINGIOMA AND GLIOBLASTOMA

CURRENT RESEARCH AND INNOVATIVE TREATMENTS

A MESSAGE FROM THE PRESIDENT/CEO, VICKIE AND JACK FARBER INSTITUTE FOR NEUROSCIENCE

Dear Colleagues,

Thomas Jefferson University Hospital's Departments of Neurology and Neurosurgery and the Vickie and Jack Farber Institute for Neuroscience – Jefferson Health are constantly engaged in research that will help discover innovative treatments for various neurologic conditions, thus improving patient care.

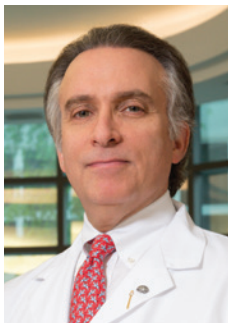
I am pleased to be sending you another volume of our series that describes research and superior patient care in which our physicians and departments engage. In previous brochures, we have described our research in spinal cord injury; cognitive functioning in temporal lobe epilepsy; ALS; ongoing clinical trials and treatment for both aneurysm and stroke; and Jefferson's advancements in the treatment of Parkinson's disease.

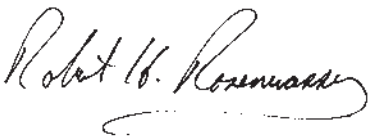
In this current volume, we highlight the work Jefferson Health is doing in the area of brain tumor research and patient care, under the direction of Division Chief James J. Evans, MD, FACS, FAANS in collaboration with David W. Andrews, MD; Nina Martinez, MD; Iyad Alnahhas, MD, MSc; and others who are involved in various innovative projects, including but not limited to, glioblastoma immunotherapy.

At Jefferson Health, we value our clinicians and researchers who contribute to the well-being of patients with neurological impairment. We continue to improve treatments for patients with various neurological conditions. Substantive research guides all of our treatment modalities.

Now, I invite you to explore current research and treatment options for patients with brain tumors. I hope you will find it informative to read about the ways we are working to enhance the quality of life for our patients and those at other hospitals.

Sincerely,





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RESEARCH AND TREATMENT IN PATIENTS WITH BRAIN TUMORS

Brain Tumor Statistics

A diagnosis of brain tumor is a life-altering event. Over 780,000 people in the United States are currently living with a brain tumor, and nearly 84,000 will be diagnosed with a primary brain tumor in 2021. Overall, the chance that a person will develop a malignant tumor of the brain or spinal cord in his or her lifetime is less than 2%, but brain tumors account for the fourth-highest cancer for numbers of years lost, averaging 20 years lost per patient. Despite advances in research and clinical treatment, survival for malignant brain tumors remains poor overall. Up to 30% of patients with metastatic cancer will have disease to the brain, which is even a more common finding in the era of improved lifespan with cancer due to targeted molecular therapy and immunotherapy.

Brain Tumor Care at Jefferson Health

Jefferson Health performs a high volume of surgical and stereotactic radiation treatments annually, in addition to clinical trial enrollment and non-operative management, making it one of the top-ranked neuroscience and cancer care centers for brain tumors. Jefferson Health is one of the National Cancer Institute's 70 designated cancer centers in the nation and continues to have the highest volume of treated brain tumors in the Greater Philadelphia region.

At Jefferson Health, our neurosurgeons and neuro-oncologists provide innovative treatment options for tumors that are both complex and require a combination of treatments for the best outcomes. Strong interdisciplinary patient management between neurosurgery, neuro-oncology, radiation oncology, otolaryngology, neuro-ophthalmology, and critical care offer patients the best possible treatment options. Clinicians also engage with community providers to allow patients the choice of treatment closer to home if they desire. Jefferson Health serves as a major teaching facility with professors and fellows visiting from around the world to learn leading-edge surgical techniques as well as neuro-oncology and radiation oncology treatments.

The following pages describe some of the work currently taking place within the Vickie and Jack Farber Institute of Neuroscience and Sidney Kimmel Cancer Center including Jefferson Health's treatment modalities and research activities in the area of brain tumor care. Our team of neurosurgeons, neuro-oncologists, medical and radiation oncologists, dedicated nurses, and other allied healthcare specialists combine their expertise to provide an aggressive treatment plan for brain tumor patients and provide support for patients' loved ones.

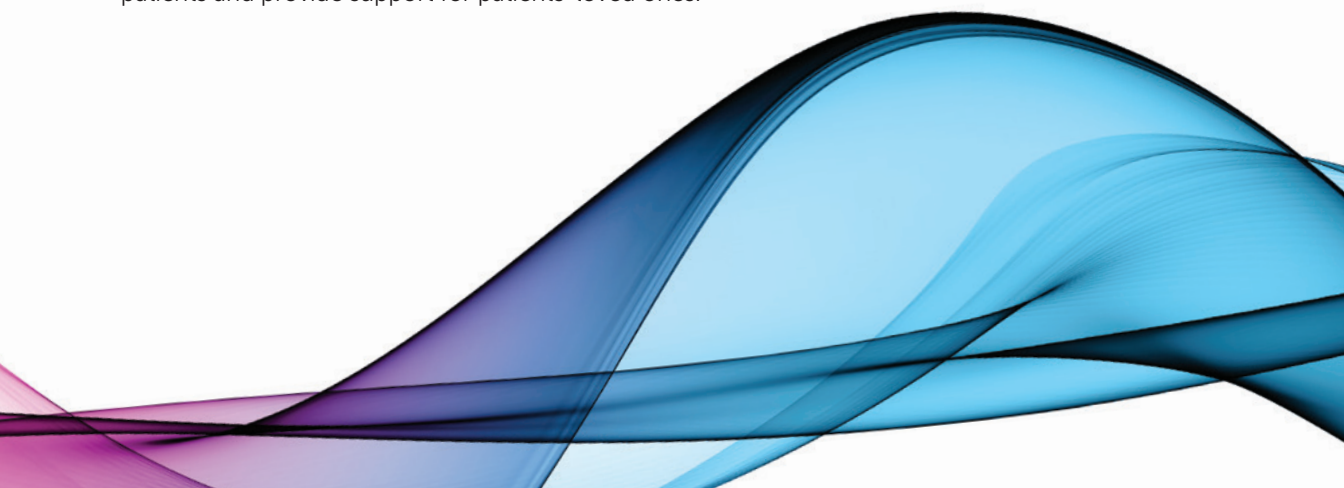


Figure 1: Multidisciplinary patient care Source: Jefferson Health.

RESEARCH AT JEFFERSON ON BRAIN TUMORS

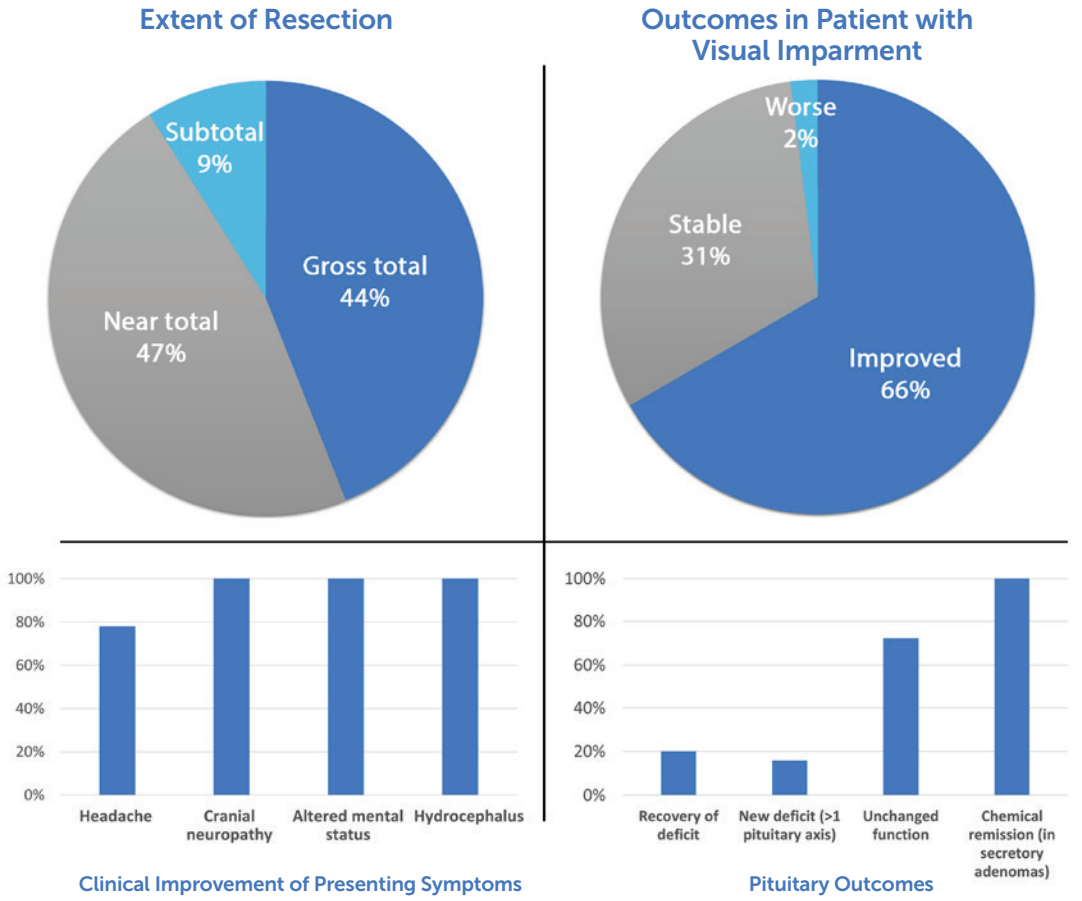
Dr. James J. Evans, Chief of the Brain Tumor Division, and Past President of the North American Skull Base Society, along with his team of neurosurgeons, performs complex cranial, skull base, and endoscopic minimally invasive neurosurgery to treat a wide range of disorders and tumors of the brain and skull base. Below are several of his team's studies.

Pituitary Adenoma

Giant pituitary adenomas, defined as >4 cm in maximal tumor diameter, compose ≈5% to 14% of adenomas and present a particular surgical challenge given their size and frequent involvement of critical neurovascular structures. Dr. Evans and colleagues reviewed the cases of 55 patients (mean age 55.2 years) with giant pituitary adenomas who underwent surgery with an endoscopic endonasal approach (EEA) between 2008 and 2016. Factors affecting the extent of tumor removal were evaluated.

Gross total resection was achieved in 24 patients (44%), and near-total resection (>90%) in 26 patients (47%) (Table 1). A multilobular configuration (P=0.002) and cavernous sinus invasion (P=0.044)

Figure 2. Outcomes after endonasal resection of giant pituitary adenomas. Source: Jefferson Health.



negatively affected the extent of resection, whereas tumor size, intraventricular, and anterior or posterior fossa extension did not. Ten patients underwent adjuvant radiotherapy.

With regard to patient outcomes, 66% of patients showed visual improvements or even normalization, whereas 31% exhibited stable vision. Visual deterioration occurred in only 1 patient. A new hormonal deficit occurred in 8 patients (17%), whereas recovery of an existing hormonal deficit occurred in 6 patients (20%). Functional tumors were only seen in 4 patients and all patients with hormone-secreting adenomas required adjuvant medical and/or radiotherapy to achieve biochemical remission. After a mean follow-up of 41 months, tumor recurrence/progression occurred in 6 patients (11%). Complications included apoplexy of residual tumor resulting in ischemic stroke in 1 patient, postoperative cerebrospinal fluid leak in 1 patient, permanent diabetes insipidus in 4 patients (7%), and medical complications in 3 patients (5%).

Table 1. Clinical Outcomes after Endonasal Resection Giant Pituitary Adenomas

OUTCOME	VALUE (%)
Extent of resection (n=55)	
• Gross total resection	• 24 (44)
• Near total resection (>90%)	• 26 (47)
• Subtotal resection (<90%)	• 5 (9)
Outcome in patients with visual impairment before surgery (n=48)	
• Improved	• 32 (66)
• Stable	• 15 (31)
• Worse	• 1 (2)
Outcome in patients with normal vision before surgery (n = 6)	
• Stable	• 6 (100)
• Worse	• 0
Pituitary function	
• Recovery	• 6/29 (20)
• New deficit (>1 pituitary axis)	• 8/45 (17)
• Unchanged function	• 40 (73)
• Chemical remission (in secretory adenomas)	• 4/4 (100)
Clinical improvement of presenting symptoms	
• Headache	• 7/9 (78)
• Cranial neuropathy	• 3/3 (100)
• Altered mental status	• 3/3 (100)
• Hydrocephalus	• 22/22 (100)

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Source: Jefferson Health

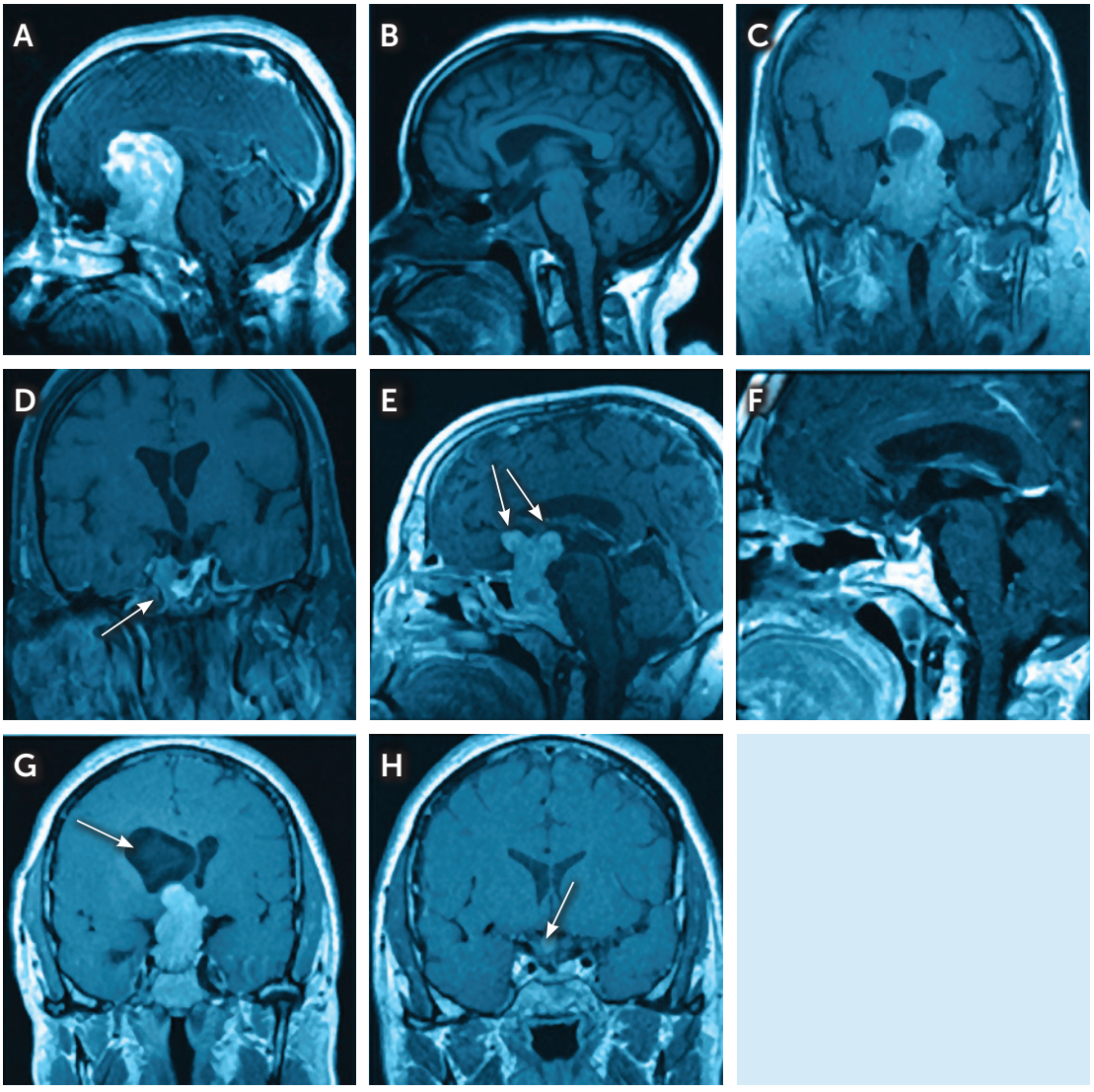

Figure 3: Examples of tumor resection in our series.

(A and B) Case 1. (A) Preoperative contrast-enhanced sagittal T1-weighted magnetic resonance imaging (MRI) showing a giant adenoma with invasion of the sphenoid sinus, clivus, and anterior skull base and extension into the anterior cranial fossa and the third ventricle. (B) Postoperative MRI showing gross total resection (GTR) after 2 staged endonasal surgeries. (C and D) Case 2. (C) Preoperative contrast-enhanced coronal MRI demonstrating a giant adenoma with extension into the third ventricle and invasion of the right cavernous sinus. (D) Postoperative MRI showing near- total resection (NTR) with small residual inside the cavernous sinus (arrow). (E and F) Case 3. (E) Preoperative contrast-enhanced sagittal MRI showing a giant adenoma with suprasellar extension and bilobular superior pole of the tumor, with 1 lobe extending into the anterior cranial fossa and the other lobe extending into the third ventricle (arrows). (F) Postoperative MRI showing GTR of the tumor after an expanded endonasal approach. (G and H) Case 4. (G) Preoperative contrast-enhanced coronal MRI showing extension of the tumor into the third ventricle causing localized hydrocephalus within the right lateral ventricle (white arrow). (H) Postoperative MRI showing NTR of the lesion after a standard transsellar approach with resolution of the hydrocephalus and very small residual attached to the anterior cerebral artery (arrow). Republished with permission from Elshazly et al. Clinical Outcomes after Endoscopic Endonasal Resection of Giant Pituitary Adenomas. *World Neurosurg.* (2018) 114:e447-e456.

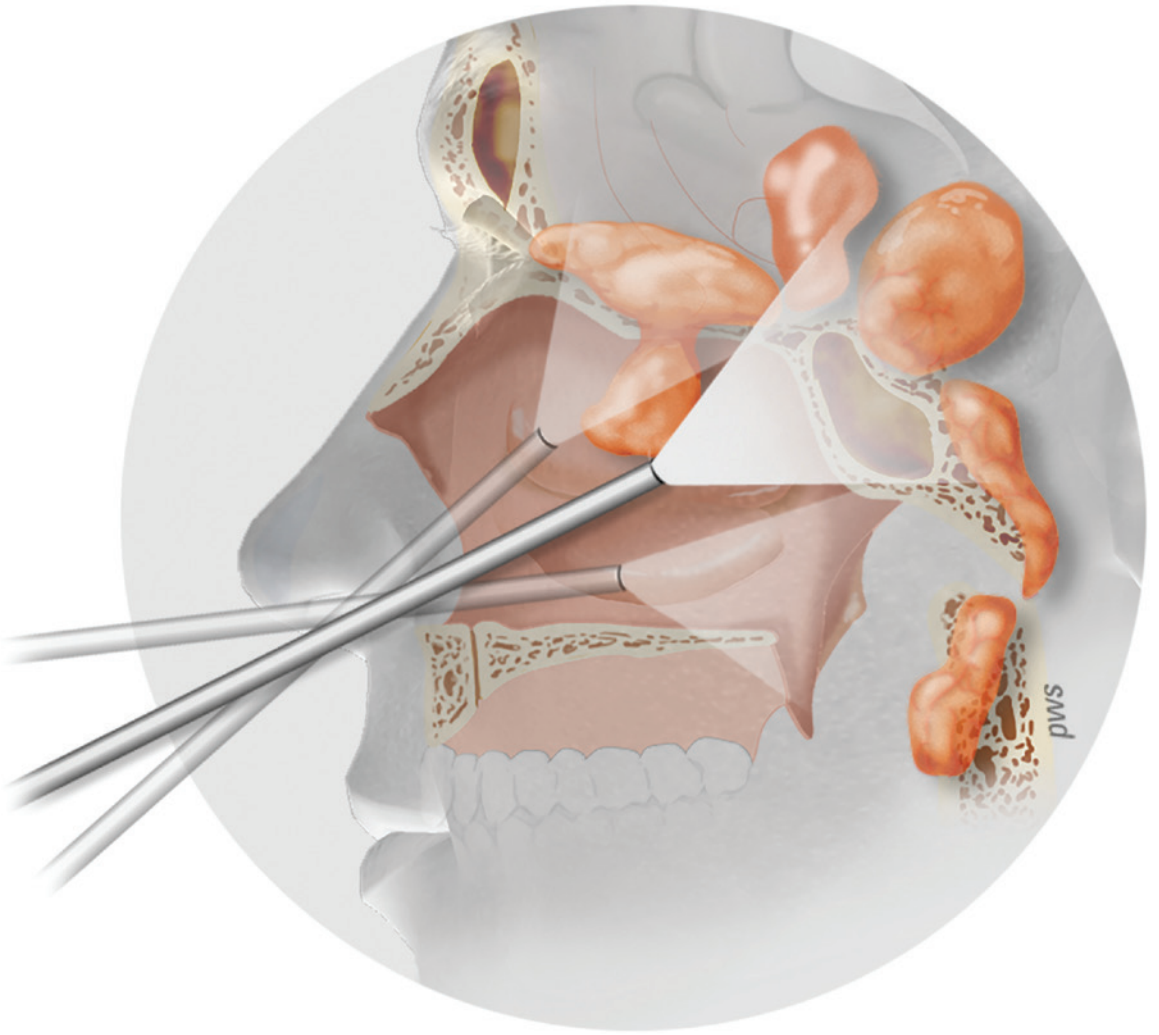

Figure 4: Potential treatment sites accessible with endonasal approaches. Source: Jefferson Health

This study supported the use of EEA as an excellent option for managing giant pituitary adenomas and demonstrated at least comparable efficacy to traditional microscopic transsphenoidal and transcranial approaches. The EEA for giant pituitary adenomas achieved high rates of near or complete resection, and visual improvement as well as low rates of complications. Adjuvant radiation treatment was useful for unresectable tumors and functional adenomas. Some tumors may require staged approaches with either staged endonasal or staged craniotomy/endonasal surgeries, but one must be aware of the risk of postoperative ischemia and apoplexy within giant pituitary adenomas that have undergone subtotal resection.

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Tuberculum Sella Meningiomas

Minimally invasive treatment of anterior skull base meningiomas is another area of focus for Jefferson Health physicians. Led by Dr. Evans, Jefferson Health's team is among the most experienced in the world at treating these common benign brain tumors, using the most current endoscopic, microsurgical, and stereotactic radiosurgery techniques.

Transcranial microsurgical resection via various approaches (e.g., pterional, orbitozygomatic) has historically been the standard treatment for symptomatic tuberculum sella meningiomas (TSM). The development of endoscopic endonasal approaches (EEA) has generated interest in treating these tumors by less invasive procedures. Surgical goals are the same regardless of approach: preservation or restoration of visual and neurological function with maximal safe tumor removal, including any areas of dural and bony involvement.

In a recent study, Dr. Evans and his colleagues reviewed an institutional database of over 1000 EEA cranial base cases for histologically confirmed meningiomas originating from the tuberculum sella treated by an endonasal approach, with 25 consecutive cases identified from the time period of March 2008 to January 2016.

Figure 5. Outcomes after endonasal resection of tuberculum sella meningiomas. Source: Jefferson Health.

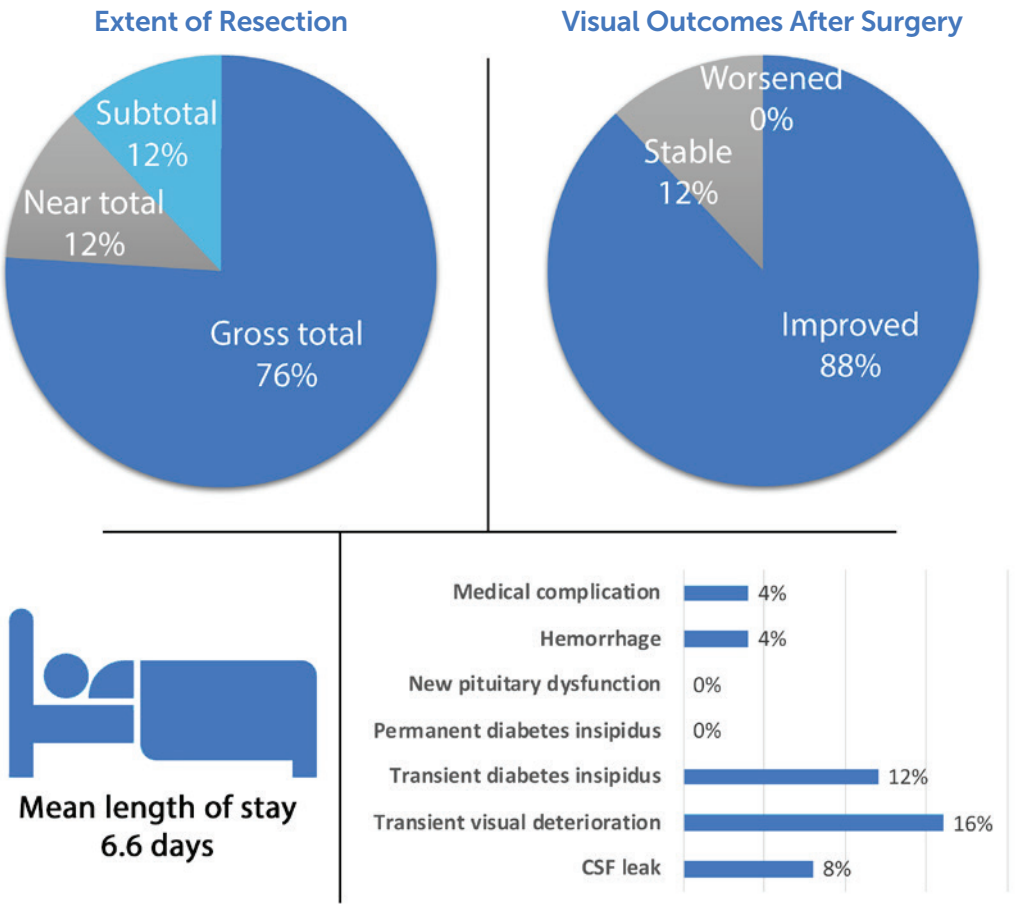

Table 2: Clinical Outcomes after Endonasal Resection of Tuberculum Sellae Meningiomas

OUTCOME	VALUE (%)
Extent of resection after surgery	
• GTR overall	• 19 (76)
• GTR for patients with planned GTR	• 19 (95)
• NTR	• 3 (12)
• STR	• 3 (12)
Length of stay, days	• 6.6
Visual impaired before surgery	
• Improved	• 15/17 (88)
• Stable	• 2/17 (12)
• Worsened	• 0 (0)
Headache improvement	• 4/4 (100)
Complications	
• CSF leak	• 2 (8)
• Transient visual deterioration	• 4 (16)
• Transient diabetes insipidus	• 3 (12)
• Permanent diabetes insipidus	• 0 (0)
• New pituitary dysfunction	• 0 (0)
• Hemorrhage	• 1 (4)
• Medical complications	• 1 (4)

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Source: Jefferson Health

The mean patient age was 53.9 years, with female predominance (84%). Preoperatively, 84% of patients had vision impairment and 68% had optic canal tumor invasion. Tumor was abutting or partially encasing the anterior cerebral artery in 14 (56%) and 3 (12%) patients, respectively. The supraclinoid internal carotid artery (ICA) was partially or completely encased in 4 (16%) and 4 (16%) patients, respectively. Gross total resection (GTR) was achieved in 19/25 (76%) cases. Among patients without complete ICA encasement, GTR was achieved in 19/20 (95%) patients. Optic canal invasion, tumor volume, intratumoral calcifications, and partial vascular encasement were not limiting factors for GTR. A total of 88% of patients with preoperative visual impairment had improvement or normalization of vision. No patient experienced permanent visual deterioration or new permanent pituitary dysfunction. Complete ICA encasement was the most common reason for subtotal resection. Complications included cerebrospinal fluid leak in 2 (8%) cases, transient diabetes insipidus in 3 (12%) cases, hemorrhage in 1 (4%) case, and medical complications in 1 (4%) case.

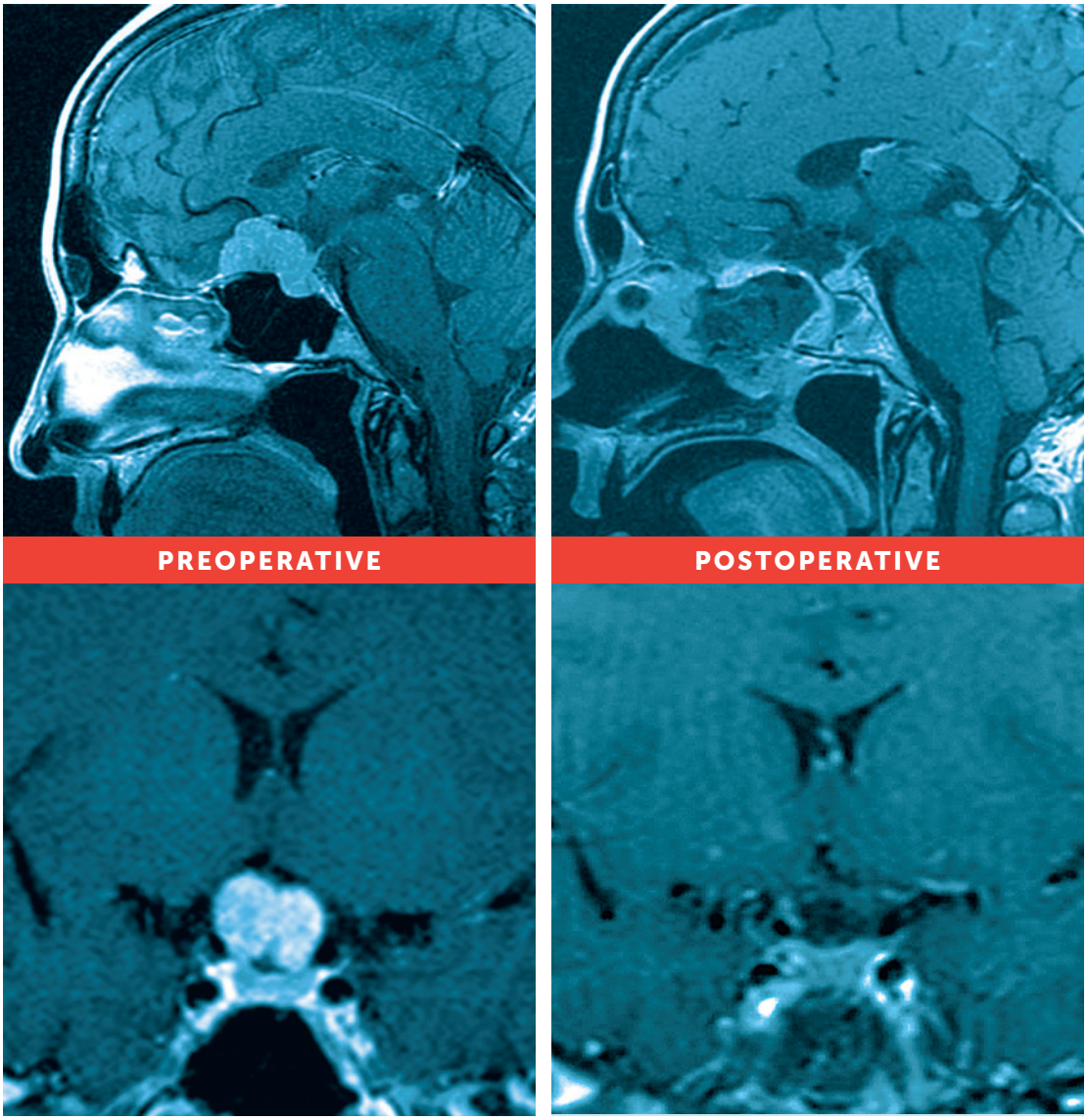

Figure 6: EPreoperative and postoperative images demonstrate the endonasal resection of a tuberculum sellae meningioma. Source: Jefferson Health.

These results strengthen the growing body of literature suggesting that EEA can provide high rates of complete resection and visual improvement with low rates of complications for TSM. Nonetheless, successful removal of these tumors requires significant experience in endoscopic endonasal cranial base surgery and an understanding of the indications and limitations of the EEA. In our experience, the primary limitation precluding GTR was complete ICA encasement. Conversely, optic canal invasion, tumor volume, partial ACA or ICA encasement, and significant tumor calcification were not found to be limiting factors.

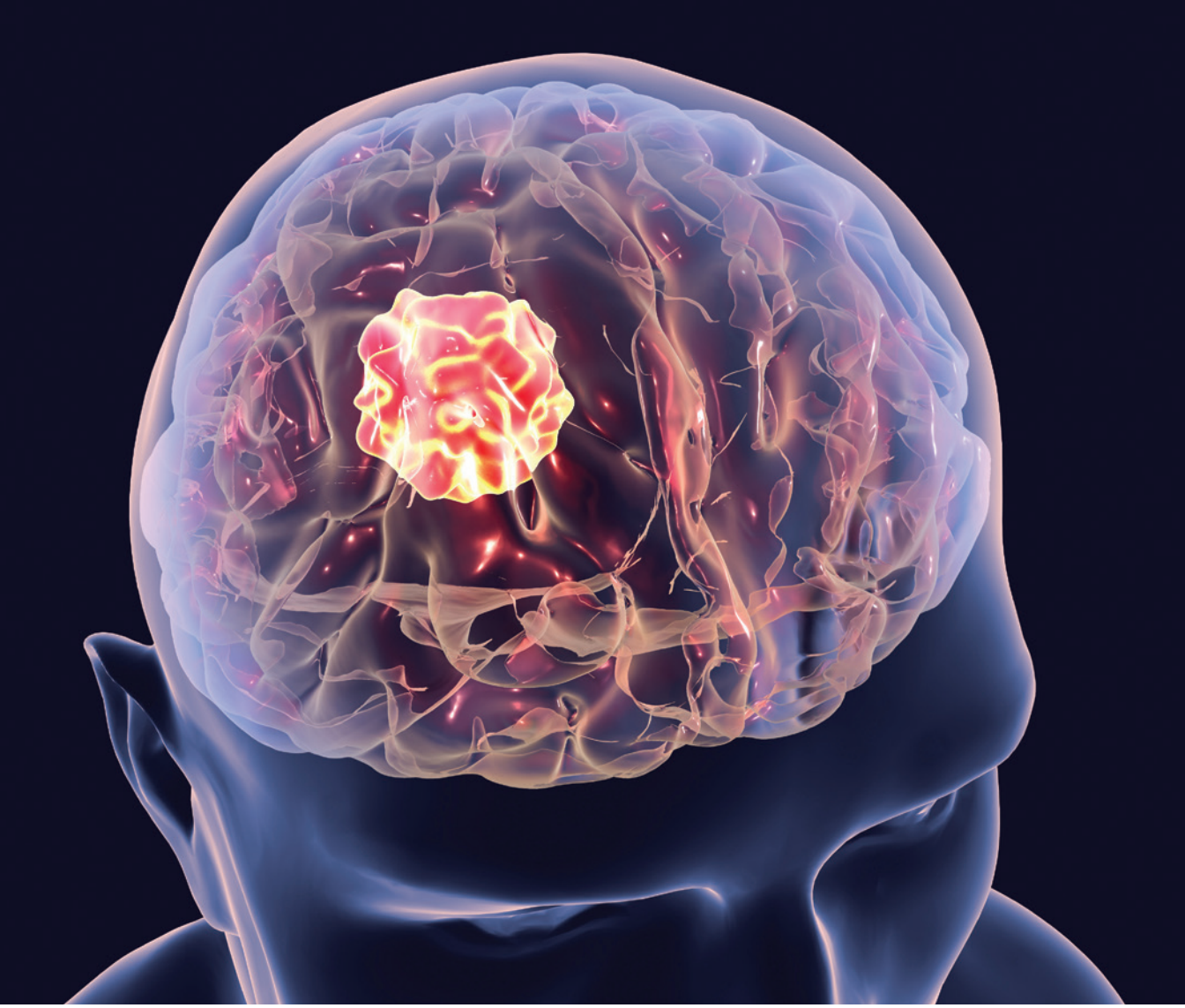

Table 3: Anatomical and Pathological Factors Determining Optimal Surgical Approaches for Tuberculum Sellae Meningiomas

TRANSCRANIAL	TRANSNASAL
Absolute indication • Extension lateral to optic nerve • Anterior cerebral artery encasement • "Kissing" carotids	Absolute indication • Sellar extension with prefixed optic chiasm
Relative indication • Abuts anterior cerebral artery with history of radiation • Ventral extension to cribiform	Relative indication • Tumor inferior to ipsilateral optic nerve

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Khaled Elshazly, Varun R. Kshettry, Christopher J. Farrell, Gurston Nyquist, Marc Rosen, James J. Evans. Clinical Outcome after Endoscopic Endonasal Resection of tuberculum Sella Meningiomas. *Oper Neurosurg.* 2018 14(5):494-502.

Jefferson Health Researchers Challenge "Straw" Dogma

Evans and colleagues recently published results challenging the dogma of banning straws after endonasal surgery, often an important tool in allowing patients to stay hydrated after surgery. The intent was to study the common belief that the use of straws postoperatively in this patient population is contraindicated due to the negative pressure created and the risk of exacerbating bleeding or CSF leakage. This dogma has led to the restriction of straw use after endonasal procedures, such as pituitary surgery, at most medical centers.

Pressure catheters were placed in the nasal cavity of healthy volunteers (N=20), and pressure measurements were recorded while participants drank liquids of different viscosities from a cup versus through a straw. Measurements were recorded with and without subjects occluding their nose to simulate postoperative nasal obstruction. (See Figure 5). There were no statistically significant differences in pressure when comparing drinking from a cup, using a straw, or occluding the nose and using a straw (P>0.05).

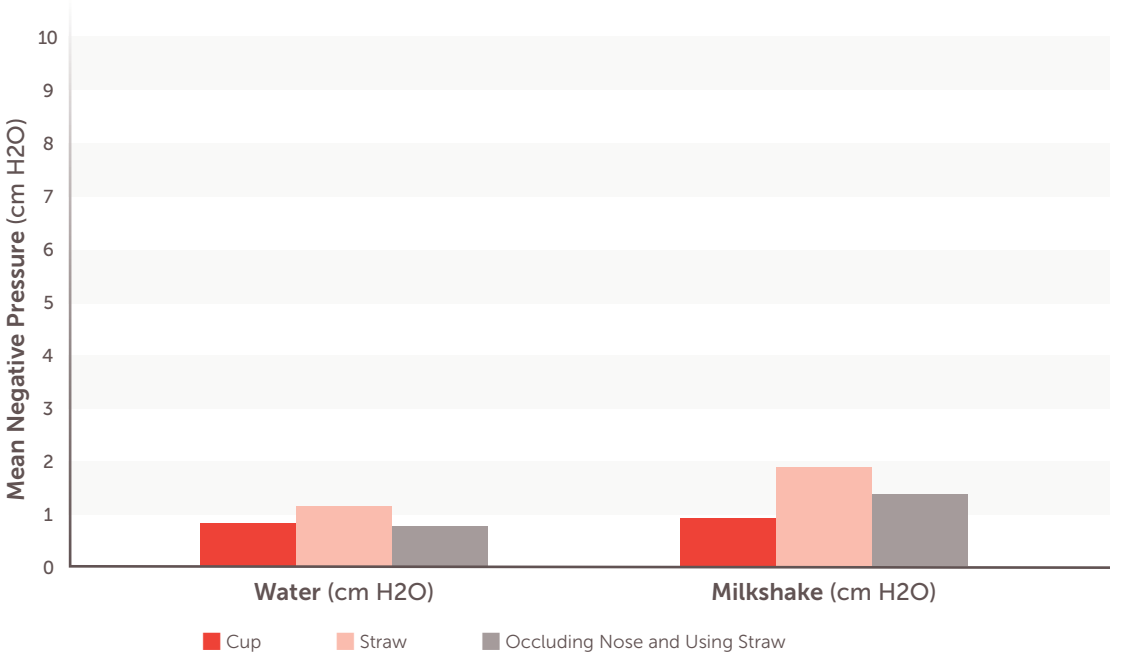

Figure 7. Pressure during Drinking Water vs Milkshake. Source: Jefferson Health

Conclusion: Straw use is not associated with the generation of significant negative pressure in the nasal cavity. The pressure generated when drinking from a straw is not significantly different from that of drinking from a cup. This supports that straw use may be safe for patients following endoscopic skull base surgery.

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Erin K Reilly, et al. **Straws Don't Suck: Are Straws Dangerous after Endoscopic Skull Base Surgery?** *Journal of Neurological Surgery*, Part B: Skull Bas; August 2020, DOI: 10.1055/s-0040-1714095

David W. Andrews, MD: Imvax and a Glioblastoma Immunotherapy Trial

The Search for a Cure for Glioblastomas

David W. Andrews, MD, is the Anthony Alfred Chiurco, MD Professor of Neurological Surgery, Vice Chair of Clinical Services in the Department of Neurological Surgery at Thomas Jefferson University Hospital. Dr. Andrews has spent the past two decades leading a team of researchers and clinicians at Jefferson Health working on immunotherapy treatments for rare and deadly types of brain cancers, such as glioblastoma multiforme. It was Dr. Andrews who established the Brain Tumor Division at Jefferson in 1995.

In addition to his many duties and responsibilities at Jefferson Health, Dr. Andrews is also the Chief Medical Officer and Founder of Imvax, Inc. His work, at Jefferson Health and Imvax, is also dedicated to finding a vaccine to alleviate or eradicate glioblastoma, the most aggressive type of primary brain tumor with a prognosis of little more than a year with standard treatment. He is joined in this endeavor by immunologist, D. Craig Hooper, PhD, a professor of cancer biology at the Sidney Kimmel Cancer Center—Jefferson Health.

Glioblastomas are deadly tumors – the same that killed Senators John McCain and Edward Kennedy, as well as Beau Biden. Imvax, an immunotherapy startup, is advancing a new treatment option for glioblastomas, using autologous tumor cell vaccine. Recently, interim results from a phase 1b clinical trial were released. This new experimental glioblastoma vaccine – developed by Jefferson Health and Imvax – showed the treatment was tolerated well by patients, slowed tumor recurrence, and prolonged patient survival.

Recently, interim results from a phase 1b clinical trial were released and presented at the American Association for Cancer Research's annual meeting in early 2019 and published in the journal, Clinical Cancer Research. Despite standard of care (SOC) established by Stupp (2005), glioblastoma remains a uniformly poor prognosis. The study evaluated IGV-001, which combines autologous glioblastoma tumor cells and an antisense oligonucleotide against insulin-like growth factor type 1 receptor (IMV-001), in newly diagnosed glioblastoma. Results were published by Dr. Andrews, Dr. Hooper and their team at Jefferson Health.

This open-label protocol, approved by the IRB at Jefferson, collected tumor cells during resection. They were treated ex vivo with IMV-001, encapsulated in biodiffusion chambers with additional IMV-001, irradiated, then implanted in abdominal acceptor sites. Patients were randomized to 4 exposure levels and SOC was initiated 4-6 weeks later. Based on clinical improvements, randomization was halted after patient 23 and subsequent patients received only the highest exposure. Safety and tumor progression were primary and secondary objectives, respectively. Time-to-event outcomes were compared to the SOC arms of published studies.

The trial enrolled 33 patients with newly diagnosed glioblastoma who were treated with the novel cancer vaccine (IGV-001) in the prospective phase 1b study. Median follow-up was 3.1 years. Six patients had adverse events (grade =3), possibly related to IGV-001. Median progression-free survival (PFS) was 9.8 months in the intent-to-treat population (vs. SOC, 6.5 months; P=.0003). In IGV-001-treated patients who met Stupp-eligible criteria, PFS was 11.6 months overall (n=22; P=.001) and 17.1 months at the highest exposure (n=10; P=.0025). The greatest overall survival was observed in Stupp-eligible patients receiving the highest exposure (median, 38.2 months; P=.044). Stupp-eligible patients with methylated O6-methylguanine–DNA methyltransferase promoter (n=10) demonstrated median PFS of 38.4 months (P=.0008). Evidence of immune activation was noted. IGV-001 was well-tolerated, PFS compared favorably to SOC, and evidence suggested an immune-mediated mechanism. (Clinicaltrials.gov NCT02507583). Imvax now plans a phase 2b trial for newly diagnosed glioblastoma patients. In addition to Jefferson Health, several other medical centers on the East Coast (Boston, Cleveland, and Washington, DC), will be involved in this trial.

Imvax has been named by Fierce Biotech as one of 2020's Fierce 15 biotechnology companies, designating the company as one of the most promising private biotechnology companies in the industry. For patients diagnosed with the type of cancer that the Imvax vaccine work is focused on there is great enthusiasm that the development of novel patient-specific vaccines and immunotherapy strategies will provide the possibility of hope and someday, a cure.

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NEURO-ONCOLOGY RESEARCH

Iyad Alnahhas, MD, MSc, is a board-certified neuro-oncologist actively involved in translational and clinical research projects in the Brain Tumor Division at Jefferson. His primary focus of research is in cancer genomics for gliomas and CNS lymphoma. One notable current translational research project addresses the role of 5-Methylthioadenosine phosphorylase (MTAP) in isocitrate dehydrogenase (IDH) mutant gliomas, and the interaction between the epidermal growth factor receptor (EGFR) and platelet-derived growth factor receptor (PDGFR) in IDH-wild-type glioblastoma. These projects are in the process of being translated to investigator-initiated clinical trials. Other projects include evaluating serum markers for radiation necrosis as well as advanced radiomics research.

INVESTIGATOR-INITIATED CLINICAL TRIALS

SPARE Scalp Preservation and Radiation Plus Alternating Electric Tumor Treatment Field (novoTTF, Optune) for Patients with Glioblastoma: A Pilot Study

Glioblastoma (GBM) is the most common malignant brain cancer. Unfortunately, few advancements have been made in the management of GBM despite extensive research efforts. Tumor-treating fields (TTF) or Optune is an FDA-approved treatment for patients with glioblastoma in the adjuvant phase of treatment after completion of radiation therapy. It delivers low intensity alternating electric fields, which interfere with cell division, using transducer arrays, and has shown positive results in a phase III clinical trial (EF-14). In this investigator-initiated pilot trial, we are combining TTF upfront with radiation aiming to increase the efficacy of this treatment against the deadly disease. In addition, this effort is now being expanded to a large national phase III trial (the TRIDENT trial).

Scalp-Sparing Intensity-Modulated Stereotactic Radiation Therapy in Treating Patients with Grade II-IV Glioma

Radiation Therapy (RT) is one of the mainstay treatments for patients with gliomas. The goal of this phase II clinical trial is to make RT better tolerated for patients. The main objective is to determine the effect of scalp-sparing intensity-modulated (IM)-stereotactic radiotherapy (SRT) on the incidence of wound infection and/or wound dehiscence as well as scalp thickness for patients with grade II-IV gliomas. The study also looks at the incidence of hair loss and recovery rate as well as quality of life of patients living with this disease.

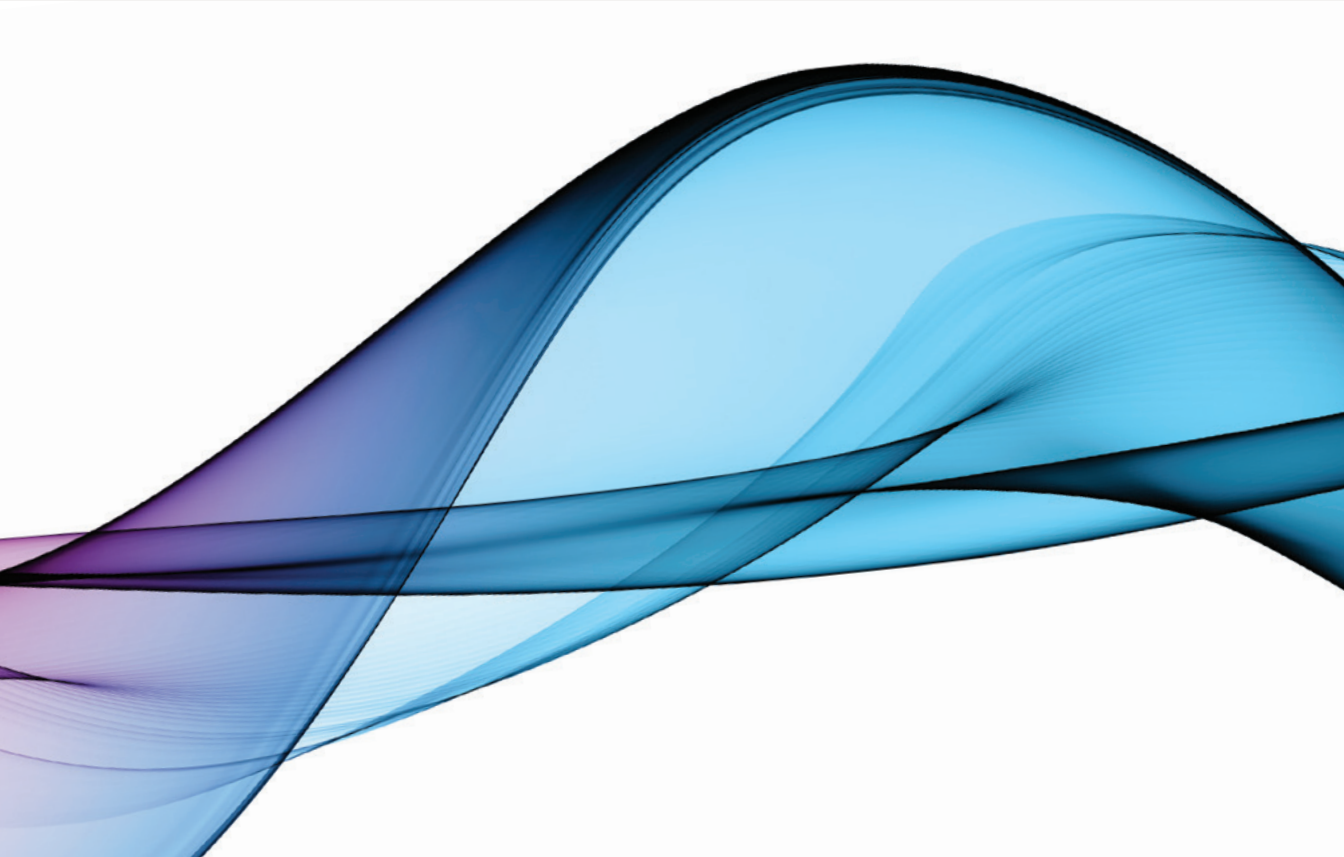

Table 4. Current Open Central Nervous System Trials

Disease	Title	Note
Newly Diagnosed GBM	SPARE Scalp Preservation and Radiation Plus Alternating Electric Tumor Treatment Field (novoTTF, Optune) for Patients with Glioblastoma: A Pilot Study	Optune Spare
Various Tumors	A Single Institution Pilot Study using head and neck Maskless Immobilization Device (MID) for patients with intracranial tumors	MID PI- Bar-Ad
	Laser Ablation of Abnormal Neurological Tissue using Robotic NeuroBlate System (LAANTERN) Prospective Registry	LAANTERN
	Phase II Randomized Trial Of Stereotactic Radiotherapy (SRT) Followed by intravitreal Aflibercept Injection for patients with ocular melanoma.	Aflibercept
	Intensity-modulated Stereotactic Radiotherapy as an Upfront Scalp-sparing Intervention for the Treatment of Newly Diagnosed Grade II-IV Gliomas	Scalp-Sparing
Anaplastic or Low Grade Glioma	Alliance Codel N0577 Phase III Intergroup Study of Radiotherapy with concomitant and adjuvant Temozolomide vs Radiotherapy Adjuvant PCV chemotherapy in Patients with 1p/19q deleted Anaplastic Glioma	N0577
Recurrent Glioma	STELLAR Phase 3 Randomized, Open Label Study to evaluate the efficacy and safety of Eflornithine with Lomustine compared to Lomustine alone in patients with AA that progress/recur after irradiation and adjuvant TMZ chemotherapy	Stellar
	A Phase 1, Open-Label, Multicenter, Dose Escalation and Expansion Study of PRT811 in Subjects with Relapsed/Refractory Myelofibrosis, Advanced Solid Tumors and Recurrent High-Grade Gliomas	PRT-811
	Standard Chemotherapy versus Chemotherapy Chosen by Cancer Stem Cell Chemosensitivity Testing in the Management of Patients with Recurrent Glioblastoma Multiforme (GBM)	Chemo ID
Brain Metastasis	Neurocognition in Patients with Multiple Brain Metastases treated with Neurosurgery: A Phase II Study	Neurocog
	Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery (SRS) Compared with Fractionated SRS (FSRS) for Resected Metastatic Brain Disease	SRS PI Dr. Wenyin Shi
	Genomically-Guided Treatment Trial in Brain Metastases	Genom
Surgery	Ethicon: EVICEL Dual Sealing Clinical Trial	EVICEL

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