

Posterior Cerebral Artery Compression and Subsequent Infarction after Implantation of a GliaSite™ Balloon

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Citation

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Abstract

Objective and Importance: Brachytherapy with the GliaSite® balloon system, is a recently-developed treatment option for recurrent malignant glioma. We report a complication with the intent of supplementing the limited published clinical experience with this device.

Clinical Presentation: Following resection of recurrent glioblastoma in the right temporal lobe of a 66 year-old man, a GliaSite™ balloon was implanted. Ninety minutes postoperatively, the patient developed left hemiparesis. Imaging revealed an acute infarct within the distribution of the right posterior cerebral artery.

Technique: Prior reported clinical experiences were explored to elucidate the potential frequency of neurological deficits associated with balloon inflation, with emphasis on the relative geometries of the balloon and resection cavity.

Conclusion: Risk of acute neurological deficits and possible stroke may be underappreciated with the GliaSite™ system. Additional investigations into the pressure-volume relationships as a function of resection cavity deviation from spherical shape may be helpful in patient selection and device utilization.

OBJECTIVE AND IMPORTANCE

Despite advances in surgery, radiation, and chemotherapy, long-term survival of patients with glioblastoma multiforme (GBM) remains poor, with the vast majority of patients suffering recurrent tumor. Options for treating recurrent GBM include surgery, chemotherapy (systemic or implanted), and/or radiation. Retreatment with radiation requires focal therapy to minimize the volume of normal brain tissue receiving high cumulative doses. Consequently, various forms of brachytherapy have been used to administer radiation in the setting of recurrent GBM. Recently, brachytherapy using the GliaSite™ (Proxima Therapeutics Inc., Alpharetta, Georgia, USA) intra-cavitary radiation system has been reported for recurrent malignant glioma.^{1,2} The GliaSite™ device consists of a silicone balloon that comes in a variety of sizes which can be intraoperatively fitted to relatively spherical resection cavities. The device is then after-loaded by filling with an aqueous iodine-125 solution. Consistent spatial localization of the radiation dose is achievable with this relatively rigid spherical balloon system.³ We present a complication associated with use of

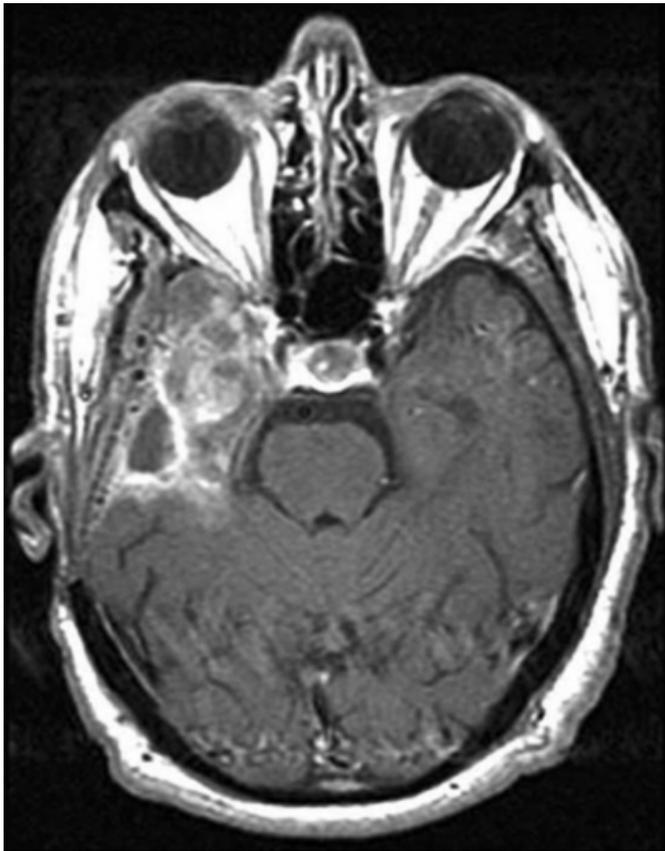
this system that may be more common than previously recognized.

CLINICAL PRESENTATION

A 66 year-old man presented for resection of a recurrent right temporal GBM (Figure 1).

Figure 1

Figure 1: Initial MRI, T1 sequence with gadolinium.



He had previously undergone two gross total resections of this mass, and had received fractionated external beam radiation and systemic chemotherapy. His most recent operation was complicated by an infected bone flap which was removed seven months prior to this procedure. Pre-operative neurological examination showed no motor deficits. The patient was taken to the operating room, and the procedure was performed under general anesthesia. The dura was opened along the inferior aspect of the right temporal lobe, and the tumor was immediately encountered. Using an ultrasonic aspirator and bipolar electrocautery, a sub-pial dissection of the tumor and mesial temporal lobe structures was performed (the lateral temporal lobe had been previously resected), taking care to preserve the pia overlying the anterior choroidal artery and the posterior cerebral artery. The vessels were visualized through the pia at this time with no evidence of injury or spasm. Once hemostasis was achieved, the resection cavity was lined with Surgicel™ (Johnson & Johnson Gateway, Piscataway, New Jersey, USA).

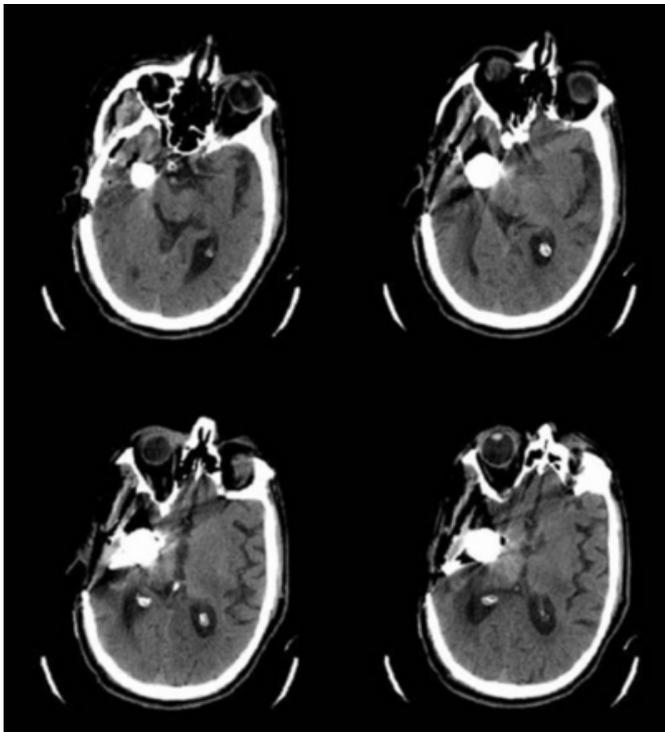
The volume of the resection cavity was estimated to be at

least 5 ml, but clearly deviated from spherical shape. A GliaSite™ balloon (2 cm maximum diameter) was placed within the resection cavity and inflated to its nominal volume. The balloon was too small to satisfactorily seat within the resection cavity. The next larger GliaSite™ balloon (3 cm maximum diameter) was then placed within the resection cavity and inflated to a volume of 6 ml (43% of nominal volume). This balloon lodged against the residual temporal lobe, tentorium, and lateral dura. The dura was then closed, allowing the GliaSite™ catheter to exit the subdural space. The subgaleal access port for the balloon was then secured above the superior margin of the cranial defect with the provided titanium screws. The soft tissue flap was then closed in standard layered fashion.

The patient was extubated in the operating room and taken to the recovery room. On initial assessment, he was moving all four extremities to command and verbalizing normally. A mild left hemiparesis was noted. He was subsequently transferred to the intensive care unit (ICU) for overnight observation and recovery. En route to the ICU, a non-contrast CT scan was obtained. The GliaSite™ balloon was noted to be in the correct position and no abnormalities were appreciated (Figure 2).

Figure 2

Figure 2: Immediate post-operative CT showing the contrast filled GliaSite™ balloon in the right temporal tumor resection cavity.



Approximately ninety minutes after the patient had left the operating room, the ICU nurse caring for the patient reported to the neurosurgical team that he was no longer moving his left side and had developed a left facial droop. Based on the CT scan which had been obtained 30 minutes before, it was felt that the balloon might be contributing to his weakness, as no intraparenchymal, subdural, or epidural hematoma had been seen. The balloon was immediately deflated at the bedside using sterile technique via aspiration of the GliaSite™ system's subgaleal access port. An MRI was obtained which demonstrated deflation of the balloon and an incomplete right posterior cerebral artery (PCA) infarct (Figures 3 & 4).

Figure 3

Figure 3: T1 (A) and FLAIR (B) sequence MRI showing the deflated balloon.

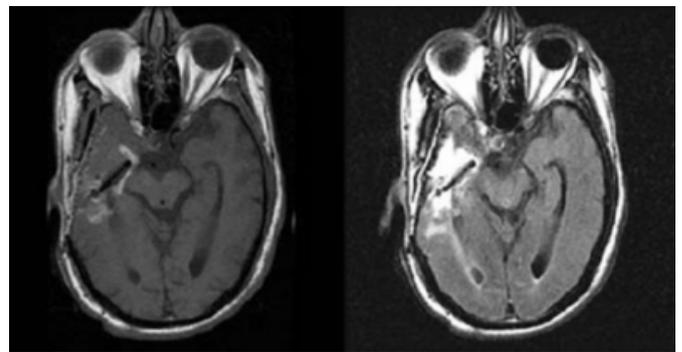
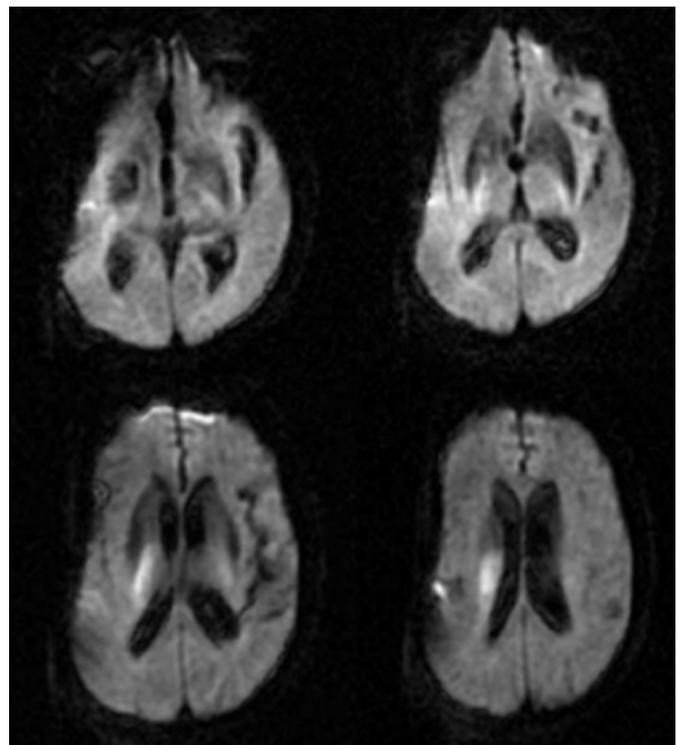


Figure 4

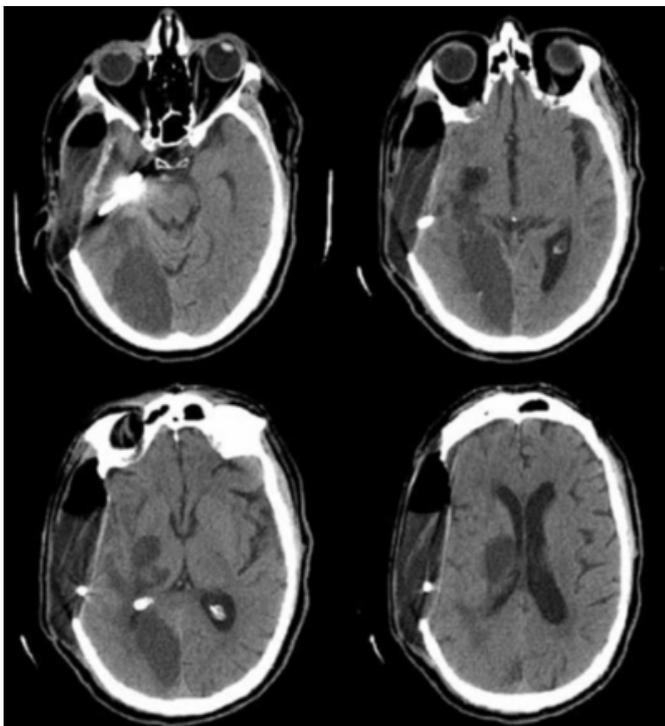
Figure 4: Diffusion weighted MRI with early indications of ischemic changes in the right posterior cerebral artery distribution.



The infarct included the posterior limb of the internal capsule and corona radiata, explaining the hemiparesis. Four days postoperatively, a CT scan showed a complete right PCA distribution infarct (Figure 5).

Figure 5

Figure 5: CT scan on post-operative day 4 with a clearly defined right posterior cerebral artery distribution infarct.



Given this significant vascular injury, it was felt that re-inflation of the balloon to administer the iodine-125 solution was contra-indicated. The patient was taken back to the operating room one week later for removal of the GliSite™ system and cranioplasty. He tolerated the procedure without difficulty and was eventually transferred to the rehabilitation service with hemiparesis.

TECHNIQUE

Published clinical trials utilizing the GliSite™ balloon system were examined with respect to patient numbers and frequency of complications that may relate to balloon inflation. Technical aspects of the balloon structure and pressure-volume effects related to deviation of resection cavities from spherical shape were considered.

CONCLUSION

The reported clinical experience with GliSite™ is limited to two studies, one of which was multi-institutional₂ in patients with a variety of recurrent malignant gliomas, and the other of which was from a single institution₁ in patients specifically with recurrent GBM. The single institution was included within the multi-institutional consortium. There were only 45 patients combined between those two studies, which overlapped by 6 months in their accrual period. The

number of patients in common to both reports was not stated. Consequently, 45 should be viewed as the maximum number of patients that may have been reported in combining these studies. In fact, it is likely that the number of patients reported in the clinical trials for GliSite™ is less due to patients common to both studies.

Both clinical trials reported good tolerance of treatment with GliSite™._{1,2} However, two cases of adverse neurological events (one in each report) occurred that may have related to pressure effects of the inflated balloon on surrounding brain tissue. In the multi-institutional trial, one patient was described as developing focal neurological symptoms during postoperative catheter inflation, which required the balloon to be deflated to 66% of its nominal volume.₂ This event was not included among the authors' summary of the ““only significant adverse events possibly or probably related”” to the treatment or the procedure.₄ In the single institutional trial, one patient was described as developing transient global aphasia shortly after treatment in a lesion close to Broca's area.₁ The precise timing of the event in relation to balloon inflation, and whether the deficit occurred with inflation using contrast agent or radioactive material was not described. Considering the two events reported in the relatively small clinical trials along with the case reported here, the risk of pressure-induced neurological deficit from this balloon system may be underappreciated.

The double-balloon design of the GliSite™ radiation therapy system provides reliable containment of the iodine-125 solution and a predictive spherical volume that enables distribution of a uniform radiation dose to adjacent tissue.₃ The balloon is made of relatively rigid silicone, and is ideally used in a spherical resection cavity. Reported selection criteria have included maximum tumor enhancing diameter of 2 to 5 cm, and ““a ratio of major axes of enhancing tumor that is 1.5 cm or less.””₂ It is not clear if the intent of the latter criterion was to limit the ratio of major axes (which should be expressed as a unit-less value) or to limit the difference in dimension of major axes (which would include a unit of distance, but not be referred to as a ““ratio””). A cavity that deviates from spherical shape will have less surface area in contact with the inflated balloon. Upon inflation, the short axis of a non-spherical cavity will be the location of first contact between balloon and cavity wall. The balloon will be constricted between the cavity walls of narrowest dimension before reaching its nominal volume. Continued infusion of liquid to the nominal balloon

volume would increase tension along the balloon surfaces not in contact with the surrounding cavity. Consequently, the pressure required to fill the balloon to its nominal volume, which equals the pressure applied to the tissue in contact with the balloon, will be greater in a non-spherical cavity than in a spherical one that allows symmetric expansion. Instructions for filling the GliSite™ balloon are based on volume without guidelines for utilizing pressure as an endpoint. No data have been published on the local pressure applied by this balloon to adjacent tissue. Intracranial pressure was found to transiently increase in dogs with GliSite™ balloon inflation, but was not associated with neurological or behavioral deficits.⁴ However, acute neurological injury associated with local compression of tissue upon balloon inflation is unlikely related to global intracranial pressure changes. Additional study into the pressure-volume relationships of the GliSite™ balloon as a function of asymmetric wall constriction may be useful in

elucidating conditions under which filling pressure exceeds safe levels for major arteries adjacent to the short axis of resection cavities.

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