Results

ECU Health GammateTile™ Experience & Case Example of Placement: No Adverse Event

**Illustrative Case:** The patient’s radiologic images and pathology specimens and ECU Health GammateTile™ Experience & Case Example of Placement: No Adverse Event

**Summary of Adverse Events & Grade 1-3**

- **Adverse Events (AE)**: In 133 Patients with 30-Day Postoperative Evaluation
  - **Grade 1** (4)**
  - **Grade 2** (5)**
  - **Grade 3** (2)**

**References**

- **Nakaji, P. Resection and permanent intracranial brachytherapy using modular, biocompatible cesium 131 implants: results in 20 recurrent brain implants after FDA clearance.** J Ther Nucl Med 11, 1. 2020

**Adverse Events: Compiled Data from GammaTile Registry To 05/27/2023**

- **ECU Health GammateTile™ Experience & Case Example of Placement: No Adverse Event**

**Conclusions**

- **GammaTile brachytherapy is emerging as an important radiation therapy option for primary and metastatic CNS neoplasms with placement of tiles after re-resection of a neoplasm or after initial resection as a surgically-targeted radiation therapy (STaRT).**
- **The 30-day morbidity and readmission rates following tumor resection and GammaTile placement are similar to those previously reported for patients undergoing conventional craniotherapy for resection of a neoplasm.**
- **The low 30-day adverse event rate (6.8%) and low readmission rate (1.4%) to date across 25 enrolling institutions support a highly favorable safety profile for GammaTile therapy.**
- **Study accrual is on-going.**
- **Future reports will help benchmark clinical outcomes of GammaTile therapy, provide comparisons to existing treatments, and facilitate future clinical trial design.**

**Background**

- **Placement of a radiation source within a neoplasm, brachytherapy, has been used effectively to treat a variety of neoplasms.**
- **This localized delivery of radiation therapy has been shown to be effective and avoids external beam radiation and associated morbidities.**
- **Brain tumors include primary neoplasms, metastatic neoplasms, and neoplastic neoplasms.**
- **Traditional and emerging modalities of diagnosis and therapy of brain tumors include:**
  - **Biopsy or resection**
  - **Radiation therapy**
  - **Chemotherapy and immunotherapy**
- **The Food and Drug Administration cleared the use of an implanted device, GammaTiles™ (GT Medical Technologies, Tempe, AZ), consisting of cesium-131 seeds embedded in a collagen carrier, for use after resection of recurrent brain tumors (2016) and subsequently for newly-diagnosed intracranial neoplasms (2018).**
- **GammaTiles provide a potential additional treatment modality for the treatment of brain neoplasm as ‘brachytherapy’ where radioactive material is implanted along the cavity following resection of a neoplasm.**
- **This study:**
  - **Provides a case summary of a patient with recurrent glioblastoma treated with GammaTiles™**
  - **Reports findings from a multi-institutional consortium of centers deploying GammaTiles as part of treatment of CNS neoplasms to evaluate the patterns of clinical application and evaluate the safety profile through characterization of morbidity, mortality, and readmission within 30 days across institutions and tumor types.**

**Methods/Materials**

- **Illustrative Case:** The patient’s radiologic images and pathology specimens and electronic medical records were thoroughly reviewed.
- **Adverse event data from the GammaTile registry are compiled.**

**GammaTile Information**

- **GammaTiles™ consist of a biodegradable collagen carrier:**
  - **Tiles are implanted with circa-131 seeds.**
- **Tiles are structurally offset of the radiation source from the brain tissue to prevent direct seed-to-tissue contact and associated radiation necrosis.**
  - **Tiles are designed to achieve 60 Gy dose of radiation at 5 mm depth when 3+ tiles are placed.**

**GammateTile™ Information**

- **ECSmallest Global Distribution and Intensity**
  - **Soom Park, M.D., Holding Gammate Tile, Non-Radiative Model**
  - **David Brachman, M.D., GT Medical Technologies, Tempe, AZ https://gammatile.com/**

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**References**

- **Nakaji, P. Resection and permanent intracranial brachytherapy using modular, biocompatible cesium 131 implants: results in 20 recurrent brain implants after FDA clearance.** J Ther Nucl Med 11, 1. 2020