Cureus

Self-Shielding Gyroscopic Radiosurgery: Prospective Experience and Analysis of the First 100 Patients

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Abstract
Published 03/06/2024

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Categories: Medical Physics, Radiation Oncology
Keywords: gyroscopic radiosurgery

How to cite this abstract
Ehret F, Kohlhase N, Eftimova D, et al. (March 06, 2024) Self-Shielding Gyroscopic Radiosurgery: Prospective Experience and Analysis of the First 100 Patients. Cureus 16(3): a1161

Abstract

Objectives:

Stereotactic radiosurgery is a well-established treatment option for the management of various benign and malignant brain tumors. It can be delivered with several treatment platforms, usually requiring radiation vaults to meet regulatory safety requirements. Recent technical advances have led to the first self-shielding treatment tool enabling the delivery of gyroscopic radiosurgery (GRS). Given the limited number of available GRS platforms, the novelty of its characteristics, and the lack of available data, we report our experience with the first 100 patients treated with GRS in the setting of a prospective clinical study.

Methods:

Patients undergoing GRS with the ZAP-X® system (ZAP Surgical Systems Inc., San Carlos, CA, USA) for the treatment of at least one intracranial tumor between December 2021 and November 2022 were enrolled in this prospective study (clinical trials identifier: anonymized for review). All patients were required to have at least one available follow-up. Patient and treatment characteristics, including patient satisfaction and dosimetric indices, were collected and analyzed. All treatment targets underwent volumetric assessment at their first follow-up with comparison to the initial gross tumor volume (GTV). Volumetric data were analyzed utilizing a Wilcoxon sign-rank test. Assessment for correlation was done using Spearman's rank correlation coefficient ρ. Patient satisfaction with the treatment experience was optionally measured at the first follow-up on a five-level Likert scale (“1” to “5”; “1” stands for “very satisfied” and “5” for “very disappointed”). P-values ⩽0.05 were considered significant. Statistical analysis was performed using STATA MP 17.0 (StataCorp, College Station, TX, USA). All patients provided informed consent prior to study enrollment. This study was approved by the local institutional review board.

Results:

A total of 100 patients with 155 tumors were analyzed. The most frequent tumors treated comprised brain metastases (BM) (49%), vestibular schwannomas (31%), and meningiomas (14%). The median prescription dose for malignant and benign tumors was 20 and 13 Gy, respectively. The median prescription isodose line was 56%. GTVs were small, with a median of 0.37 cc for BM and 0.92 cc for the other entities. Eighty patients were treated for a single target, with the maximum number of targets being 10 in two patients with BM. The median total treatment time was 40 minutes, which increased with the number of beams, monitor units, isocenters, and planning target volume (ρ=0.63, ρ=0.62, ρ=0.59, ρ=0.43, all p< 0.01). Most treatments were delivered in less than 60 minutes (84%). Dosimetric performance indices showed median values of 1.20 (conformity index), 1.24 (new conformity index), 1.74 (homogeneity index), and 3.13 (gradient index). The median coverage was 98.4%. Volumetric assessment of all treated tumors showed an overall decrease in size at the first follow-up. While meningiomas showed a significant reduction in volume at the first follow-up (after six months, p< 0.01), BM (after three months, p=0.07) and vestibular schwannomas (after six months, p=0.21) did not, the latter having a proportion of tumors (45.8%) with swelling, i.e., volume increase. A total of 82 patients agreed to report their overall treatment experience with GRS (response rate 82%). Most patients were “very satisfied” (75 patients, 91.4%), six patients (7.3%) selected “2” on the scale, while only one patient was not satisfied, i.e., ⩾ “3”.

Conclusion(s):

To our knowledge, this is the world’s first prospective analysis of the use of GRS. The user experience of the

treatment platform was favorable. Analyses of the dosimetric performance, treatment times, volumetric changes, and patient satisfaction demonstrate its suitability for stereotactic treatments of intracranial tumors. Consistent and continuous assessment of the use of new treatment platforms in radiation oncology and radiosurgery is crucial to maintain quality standards and refine future treatments.