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Scientific Article

Outpatient ocular brachytherapy: The USC Experience

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Abstract

Purpose: Ocular brachytherapy is a standard-of-care surgical procedure for globe salvage in the treatment of uveal melanoma. The procedure involves the placement and subsequent removal of a radioactive plaque several days later. At many locations, patients are admitted on an inpatient basis until plaque removal due to radiation safety concerns. However, patients may be discharged to home after plaque insertion, and subsequently return to the medical facility for plaque removal. This study aimed to evaluate the safety and systematic financial benefit of the outpatient ocular brachytherapy program at the University of Southern California (USC) Roski Eye Institute for 30 years.

Methods and Materials: A single-institution retrospective record review was performed on all 275 patients who underwent brachytherapy for ocular tumors between January 1, 1989 and December 31, 2019 to assess for occurrences of reportable radiation and/or patients safety events. The treatment protocols at our institution are described. Data on hospital-adjusted expenses per inpatient day from the American Hospital Association's 2018 Annual Survey were used as a proxy for costs to patients and the health care system to perform a cost−benefit analysis comparing outpatient versus inpatient brachytherapy.

Results: Of the 275 plaque procedures over a 30-year period that were reviewed, there were no internally or externally reportable patient or radiation safety events. There were no adverse events related to patient transportation to the hospital, the patient not returning for plaque removal, operative issues in removing the plaque on time due to cancelled or delayed cases, or loss of radioactive material. Additionally, our cost−benefit analysis estimates that outpatient brachytherapy reduced costs for USC's patients in 2018 by an average of $24,722 per patient treated with ocular brachytherapy.

Conclusions: With appropriate measures, outpatient ocular brachytherapy allows patients to safely return home with the added benefit of decreased financial burden for both patients and the broader health care system.

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Introduction

Uveal melanoma is the most common, adult, primary, intraocular cancer in the United States at a mean age-adjusted incidence of 5.2 cases per million yearly.[1] Brachytherapy is now the standard of care for globe salvage in the treatment of uveal melanoma without extraocular extension, and the 1998 Collaborative Ocular Melanoma Study demonstrated that there was no survival difference between enucleation and globe sparing Iodine-125 brachytherapy.[2] Ocular brachytherapy is performed in the operating room, often under general anesthesia. During the procedure, a trained ocular oncologist sutures a radioactive plaque onto the scleral wall, followed by surgical removal once the prescribed dose duration has been achieved generally after 3−7 days).[3,4] Although a lead shielding eye patch worn over the eye is effective at decreasing radiation emitted from the patient,[5] patients are often admitted to the hospital for the duration of their brachytherapy treatment due to concerns related to pain control, delays in plaque removal caused by patient-specific issues (eg, failure to return for removal), and other radiation safety considerations.

However, with a comprehensive protocol, radiation safety standards can be maintained while treating patients on an outpatient basis between plaque placement and removal. At the University of Southern California (USC) Roski Eye Institute, outpatient brachytherapy treatment for uveal melanomas and other ocular tumors has been the norm for the past 32 years. Thus, the goal of this retrospective review was to evaluate reportable radiation safety incidents since 1989, perform a cost−benefit analysis of outpatient versus inpatient treatment, and outline the processes and procedures to establish an outpatient brachytherapy service. Herein, we show that outpatient ocular brachytherapy is safe and allows both patients and the health care system to forego both monetary and non-monetary costs associated with an inpatient hospital stay.

Methods and Materials

Plaque design and surgical placement

All elements of our brachytherapy program follow the published recommendations from the American Association of Physicists in Medicine and the American Brachytherapy Society.[5,6] Historically at the USC Roski Eye Institutee, iodine-125, ruthenium-106, and iridium-192 plaques have been used in accordance with a published protocol,[3,4] with iodine-125 becoming the sole radioisotope used since 1994. For the majority of patients, plaques are prescribed to a dose of 85 Gy at a rate of 0.5 Gy per hour over 7 days to the tumor apex with a margin of 2 mm. Eye Physics (Los Alamitos, CA) plaque treatments are designed using the Plaque Simulator software, which has been described previously.[7-9] Briefly, Eye Physics plaques use a slotted design to collimate seed radiation toward the tumor, effectively reducing toxicity to the adjacent sclera and retina while allowing for a decreased plaque thickness compared with Collaborative Ocular Melanoma Study plaques.[9-14] Surgical plaque placement and removal techniques have also been published previously.[9,11] All eye plaques placed during the period of this review, from 1989 to 2019, were managed on an outpatient basis.

Discharge procedures and patient education

Nuclear Regulatory Commission guidelines, found in 10 CFR 35.75 and NUREG-1556U,[15,16] are used in accordance with the California Department of Public Health's Radiologic Health Branch to guide patient release and safety instructions. Additionally, ensuring patient safety in an outpatient brachytherapy service requires significant coordination between ophthalmology, ocular oncology, radiation oncology, radiation physics, surgical scheduling, nursing care, and radiation safety. This is facilitated by a careful plan and policy for outpatient brachytherapy, which includes multiple system checks among the radiation oncologist, ophthalmologist/ocular oncologist, and qualified medical physicist (QMP). This coordination ensures the correct treatment plan for the patient before plaque insertion, radiation surveys during plaque placement and removal (Suppl. Material 1) documenting compliance with regulatory standards, and patient education on radiation safety guidelines at home.

Patient release criteria as defined by the Nuclear Regulatory Commission and the California Department of Public Health's Radiologic Health Branch require that any patients with a radioactive implant that contains reactor byproduct material be provided written instructions upon release if their radiation dose rate surveyed at 1 m is measured to be >0.2 millirems per hour.[17,18] Guidance on these limits is established by 10 CFR 35.75, and further clarified in NRC Regulatory guide 8.39.[17,18] Protocols also follow previously published recommendations from the American Association of Physicists in Medicine and the American Brachytherapy Society.[5,6]

At our institution, the patient is surveyed by a QMP using an ionization chamber at 3 different times: After initial placement of the eye plaque with overlying lead shield in place at the end of surgery, before discharge from the recovery room, and after eye plaque removal. All dose rate survey measurements are taken at a 1 m distance from the patient, and maximum readings are recorded. A lead-lined eye patch is placed on all patients at the end of surgery and with the patch in place, we require the reading at 1 m to be <1 millirems per hour before patient release. However, all our patients are provided with verbal and written instructions regardless of their dose rate survey measurement. For patients released to a residence out of state, the QMP completes a patient release form that the hospital radiation safety officer uses to coordinate with the corresponding state's regulatory agency. The designated radiation safety officer provides further critical support in adhering to state and federal radiation safety guidelines.

Before patient discharge, patient education is provided in the form of a Radiation Safety Interview Checklist (Supplemental Material 2), and the QMP directly reviews this information with the patient and/or guardian. The patient and/or guardian provides a list of all family members or visitors, with their ages, who the patient will be in contact with while at home between plaque placement and removal. A radioactive materials warning label is affixed to the patient's plastic hospital bracelet that reads "Caution. Radioactive Material, Temporary Implant," and written and verbal instructions are provided that include the necessity to remain at 1 location for the duration of the implant, instructions to wear the shielding lead eye patch when near other individuals, avoiding close contact with children, avoiding close contact with anyone who may be pregnant, sleeping in a separate bed from others, instructions on how to handle an extruded or loose radiation source, whom to contact in an emergency, and procedures in case of hospitalization or death.

The patient signs 2 forms indicating that the instructions have been received, and a copy is given to the patient. If the patient will be traveling outside the state of California, the radiation safety officer contacts and coordinates procedures for patient travel and release with the receiving state's regulatory agency.

Safety event review

This study was approved by the institutional review board at USC, and conformed to the requirements of the U.S. Health Insurance Portability and Privacy Act of 1996. The radiation safety records of all patients who underwent outpatient brachytherapy between January 1, 1989 and December 31, 2019 were identified using the current procedural terminology code for brachytherapy (67218) and pulled for review. The total number of patients who received outpatient brachytherapy each year, whether internal or external radiation safety events, and details of any safety event were recorded. Clinical records, including patient demographics, details of care, surgical reports, and clinical outcomes, were not accessed.

Internal safety events were defined as incident at home preventing the patient from returning for scheduled plaque removal, incident during travel to and from the hospital, incident requiring an unplanned admission of the patient for pain control during the brachytherapy period, or delay in plaque removal resulting in a deviation of >3% (higher or lower) in prescribed radiation dose (defined as >5 hour operative delay based on 168 hours of brachytherapy).

External safety events were those reportable to the California Department of Public Health's Radiologic Health Branch by law, which are incidents consisting of >20% deviation (higher or lower) in prescribed radiation dose.[19]

Cost–benefit analysis

The cost difference between outpatient and inpatient brachytherapy was estimated based on the cost of an inpatient hospital stay. Open-access data delineating hospital-adjusted expenses per inpatient day from the American Hospital Association's Annual Survey were downloaded via the Kaiser Family Foundation's website.[20] Hospital-adjusted expenses per inpatient day were defined as all operating and nonoperating expenses incurred by the hospital to provide 1 day of inpatient care. Available data at the time of download were from the years 1999 to 2018, and the averages from the state of California, as well as the United States as a whole, were chosen. Estimated per-year cost reductions based on yearly caseload at the USC Roski Eye Institutee were then calculated.

Results

Between January 1, 1989, and December 31, 2019, a total of 275 plaque treatments were performed at the USC Roski Eye Institute. During this time, zero internal and zero external radiation safety incidents were documented. Eye-related clinical outcomes are outside the scope of this paper, but previously published results have discussed similar cohorts at length.[9,13,21]

At the time of this review, the most current publicly available American Hospital Association Annual Survey was for the year 2018, which reported that the average hospital-adjusted expenses per inpatient day was $3532 in the state of California and between $1594 and $3552 in the United States.[20] Therefore, at our institution in

2018, for every patient allowed to recover and complete a 7-day course of ocular brachytherapy at home versus at the hospital, an average of $24,722 in-hospital operating expenses was averted. For institutions elsewhere in the United States, average hospital expense savings ranged from $9597 to $24,864 for each 7-day outpatient brachytherapy course in 2018.

Both the ocular brachytherapy caseload at the USC Roski Eye Institute and the costs per day of inpatient hospital expenses within California have increased from 1989 to 2018 (Fig 1). Given these trends, our institution's outpatient ocular brachytherapy program has been able to save significant resources for both patients and the health care system as a whole.

Discussion

We describe 30 years of experience with outpatient ocular brachytherapy at the USC Roski Eye Institute between 1989 and 2019, during which our institution performed 275 brachytherapy procedures. In these 30 years, our institution had no radiation or patient safety-related incidents, either externally or internally. External radiation safety events are defined as a deviation in the prescribed radiation dose by >20%, which would be reportable to the California Department of Public Health's Radiologic Health Branch by law. Internal radiation safety events are defined as a deviation in the prescribed dose of radiation by >3% (±5 hour operative delay based on 168 hours of brachytherapy). Additionally, we had zero incidents of safety events related to patient transportation to the hospital, the patient not returning for plaque removal, operative issues in removing the plaque on time due to cancelled or delayed cases, or loss of radioactive material in any way. With the policies and procedures in place as described, our institution has been able to safely perform ocular brachytherapy in the outpatient setting from 1989 to today.

In addition to maintaining standards of safety, our practice of outpatient brachytherapy has averted approximately $25,000 in treatment costs per patient. Thus, with the caveat that costs of inpatient stays vary depending on locale, institutions currently using inpatient brachytherapy programs have the potential to significantly decrease the overall health care costs of providing ocular brachytherapy by establishing outpatient programs. Conclusions about survival or disease outcomes are outside the scope of this study, but our review of safety incidents associated with outpatient brachytherapy looks at tier 2 health outcomes or "complications encountered in the treatment process" as defined in value-based health care delivery.[22] The value-based health care framework centers around controlling systemic health care costs by optimizing health outcomes that matter to patients with the costs to achieve them. In demonstrating a 30-year history of zero safety and radiation incidents at our institution, as well as comparisons of cost between outpatient and inpatient treatment, we demonstrated how outpatient ocular brachytherapy can yield superior value to patient.

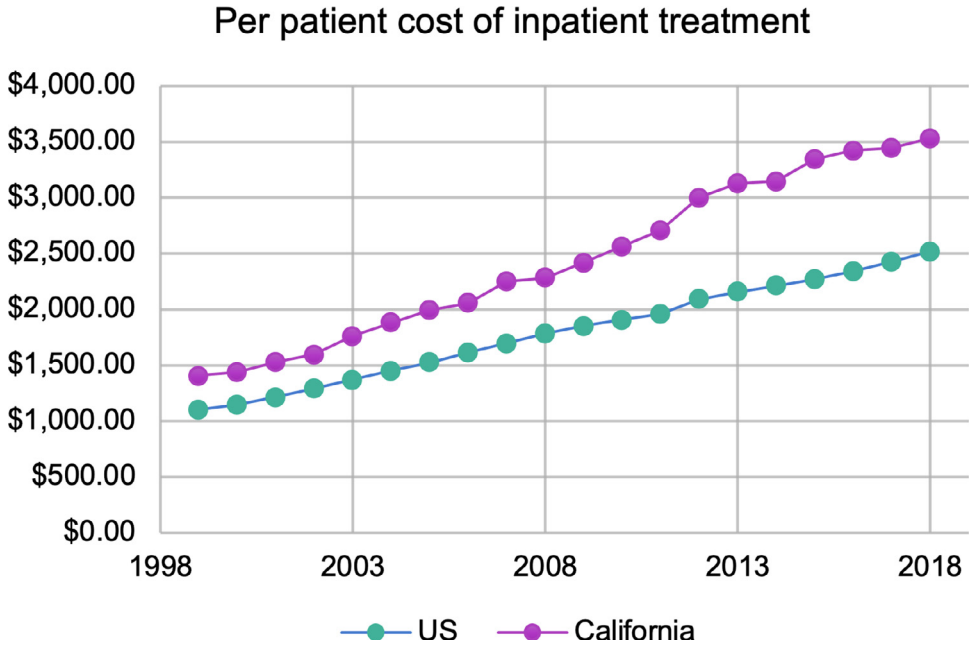

Fig. 1 Comparison of hospital-adjusted expenses per inpatient day of treatment in the state of California and the United States between 1999 and 2018.[18] Based on a treatment length of 7 days, there is a cost reduction of $24,722 per patient in California and $17,622 per patient in the United States in 2018.

A limitation of our study is that we were unable to perform a cost-effectiveness or cost-utility analysis given that our institution only performs outpatient brachytherapy, so we could not officially compare clinical outcomes between inpatient and outpatient brachytherapy cohorts with regard to survival or degree of health or recovery. However, because there were no radiation safety events documented in our 30 years of outpatient brachytherapy experience, we posit that there was no loss of quality adjusted life years in our cohort. Furthermore, this analysis did not include the risks of inpatient hospital stay on patient health (ie, nosocomial illness or transportation safety hazards).

Although clearly not an intended goal of the outpatient brachytherapy service, an added benefit of outpatient treatment made clear during the current COVID-19 pandemic is the sparing of inpatient hospital beds for more critically ill patients. During a time when nonemergent surgeries are placed on hold to conserve medical resources, there were no shutdowns or delays in the care of patients with ocular cancer at our center, because there was no need for admission and utilization of critical inpatient resources. Future studies should expand beyond the cost−benefit analysis performed herein to further clarify the benefits of outpatient brachytherapy programs.

Conclusions

Outpatient ocular brachytherapy offers the potential for programs to reduce operating expenses and costs of care for patients in a safe manner. In the setting of annually increasing costs of inpatient hospital stays, we present our experiences as a model for institutions interested in the development of outpatient ocular brachytherapy programs.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.adro.2021.100737.

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