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Stereotactic Radiosurgery for Spine Metastases: A Multidisciplinary Approach

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With an estimated 125,000 new cases annually in the United States, spine metastases represent the most common site of bone metastases in cancer patients.¹ Due to proximity to a critical neurologic organ (the spinal cord) and involvement of load-bearing bones integral to ambulation, spine metastases represent a complex neurologic threat to cancer patients' quality of life beyond the most common bone metastasis symptom of pain. While traditionally palliated with conventionally fractionated external beam radiotherapy ± surgical decompression/stabilization, with conventional therapy less than two-thirds of patients will experience partial or complete pain relief, and the duration of palliation is often short-lived.²

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Disclosures

Doctors Gebhardt, Ferris, Heron, Amankolor, Horne, Engh, Ohr, and Ms. Quinn report no relationships with proprietary entities producing health care goods and services.

Dr. Vargo reports CE Speakers' Bureau for BrainLab Spine SRS Circle ASTRO 2016, Boston, Mass.

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Stereotactic Radiosurgery for Spine Metastases *(Continued from Page 1)*

Historically, patients who fail conventional treatment were left with few treatment options and suffered the consequences of uncontrolled cancer of the spine, including: poor pain control, loss of ambulation, impairment of bowel/bladder continence, and neurologic deficits. Improvements in systemic therapy that increase the duration of survival and control of systemic disease have placed increasing onus on more durable treatment options for patients with spine metastases. Stereotactic radiosurgery has emerged as an important treatment modality in three main clinical scenarios:³

- Salvage radiosurgery for recurrent or progressive spine metastases that have failed prior conventional radiotherapy (Figure 1)
- Primary radiosurgery for select patients with oligometastatic, previously unirradiated spine metastases
- Postoperative radiosurgery after surgical intervention with or without spinal stabilization or separation surgery (See Figure 2 on Page 7)

Within these scenarios, radiosurgery has been shown to provide rapid and durable pain relief with a median time to pain relief of 14 days; 1-year pain control rates > 85% to 90%; high rates of local control > 70% to 90%, which transcends primary histology; and low rates of toxicity < 1% to 5% even in the re-treatment setting.^{4,5}

Management of patients with spine metastases, especially patients with recurrent tumors that have failed prior radiation therapy, often represent challenging clinical scenarios for which comprehensive multidisciplinary care that includes both radiation oncology and neurosurgery is critical, as the best treatment course may include stereotactic radiosurgery, surgery, or a combination of both.

Additionally, the high dose-per-fraction treatment essential to overcoming radioresistance of spine metastases, especially in the re-irradiation setting, and of melanoma, sarcoma, or renal cell histology, hinges on submillimeter tumor and critical organ delineation best performed with the collaborative input of both an expert radiation oncologist and

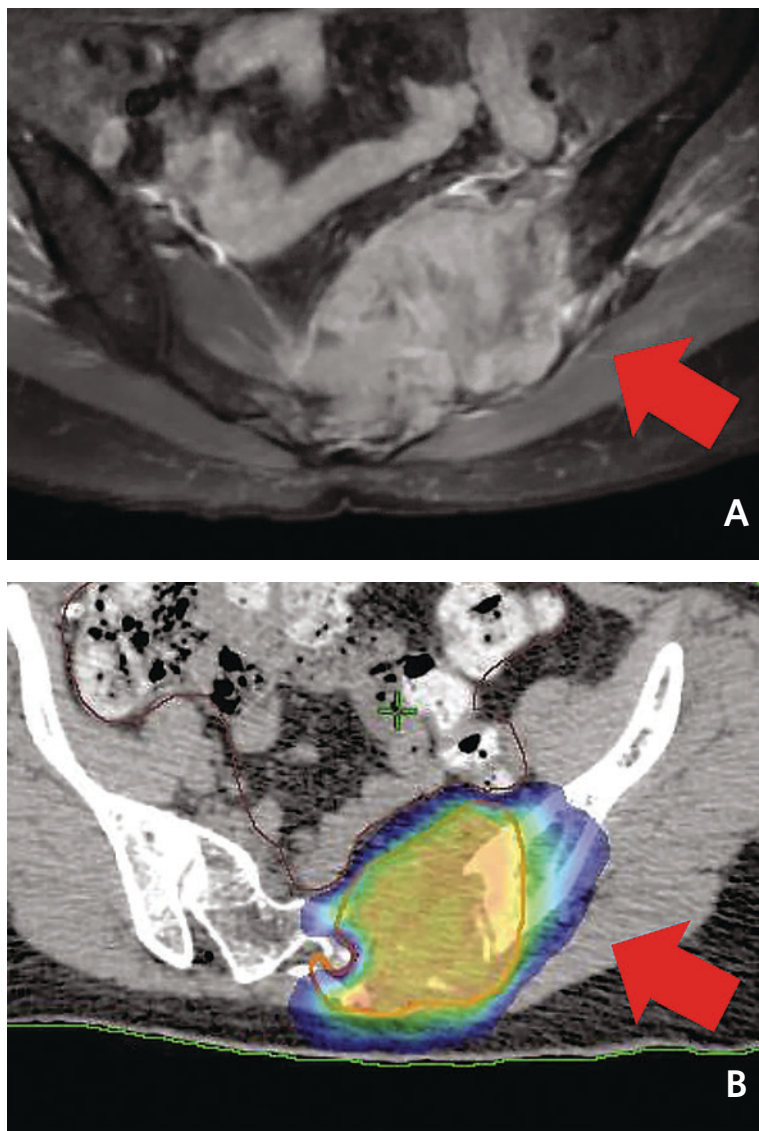


Figure 1. Salvage Spine Radiosurgery for Previously-Irradiated Spine Metastases. A 65-year-old woman with a history of stage IV ovarian clear cell carcinoma, treated with surgical debulking and IV/IP chemotherapy, developed progression of disease including bone and liver metastases and is treated with 30 Gy/12 fractions for a large, painful sacral metastasis (A, top). She gets initial pain relief after palliative radiotherapy and is set to start second line chemotherapy when she is admitted with 10/10 pain and a new S1 radiculopathy. Despite Dilaudid PCA, methadone, and selective sacral nerve block, she still has 10/10 pain and remains hospitalized. She is transferred to UPMC Shadyside and receives radiosurgery to 14 Gy in a single fraction (B, bottom) with rapid pain relief within post-procedure day 1-2, allowing her to be discharged home on oral pain medication and to regain ambulation without assistance 1-week post-procedure.

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Stereotactic Body Radiation Therapy in Head and Neck Cancers

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Despite advances in multimodality management, locoregional recurrence remains the primary mode of failure in both Human Papilloma Virus (HPV) and non-HPV-mediated head and neck cancers. Surgical salvage remains the preferred method of local salvage; however, given the complexity of recurrent head-and-neck cancers in extent of disease, distortion of anatomy from prior therapies, and medical comorbidities many patients are not candidates for surgical salvage and historically were left with limited, primarily palliative treatment options. More recently, with improvements in radiation delivery and treatment planning widening the therapeutic ratio, re-irradiation therapy has emerged as an important salvage option for patients with locally-recurrent, previously irradiated head and neck cancers (Figure 1). Investigators at the University of Pittsburgh have pioneered the use of Stereotactic Body Radiation Therapy (SBRT), first with a phase I dose escalation study, and more recently with a phase II study combining SBRT and concurrent epidermal growth factor inhibition via cetuximab.^{1,2} Expanding this paradigm, the efficacy and safety of SBRT + cetuximab and has been validated by a number of international phase II studies, as well as by a large-scale cooperative group study being developed through NRG Oncology that integrates SBRT with recently approved second-line therapy in head and neck cancer, programmed cell death inhibitor pembrolizumab.

At the University of Pittsburgh Cancer Institute, there remains a strong commitment to advancing treatment options for patients with locally-recurrent, previously irradiated head and neck cancers. With the increasing role of systemic therapies, an ongoing phase II study is examining the addition of concurrent docetaxel to SBRT + cetuximab, then further randomizing patients to additional adjuvant cetuximab + docetaxel. Additionally, for patients with resectable recurrences, and with high-risk features following surgical salvage, an ongoing prospective phase II study is examining the potential role of re-irradiation with SBRT. There remains a continuing need to improve treatment options and outcomes for patients with locally-recurrent, previously irradiated head and neck cancer, and the multidisciplinary Head and Neck Cancer Program at the University of Pittsburgh Cancer Institute provides an important avenue for this challenging subset of patients to be seen comprehensively across disciplines, evaluated for surgical salvage by world-renowned experts in head and neck surgery, and offered aggressive non-surgical salvage with modern re-irradiation strategies, such as SBRT, at an internationally recognized leading institution.

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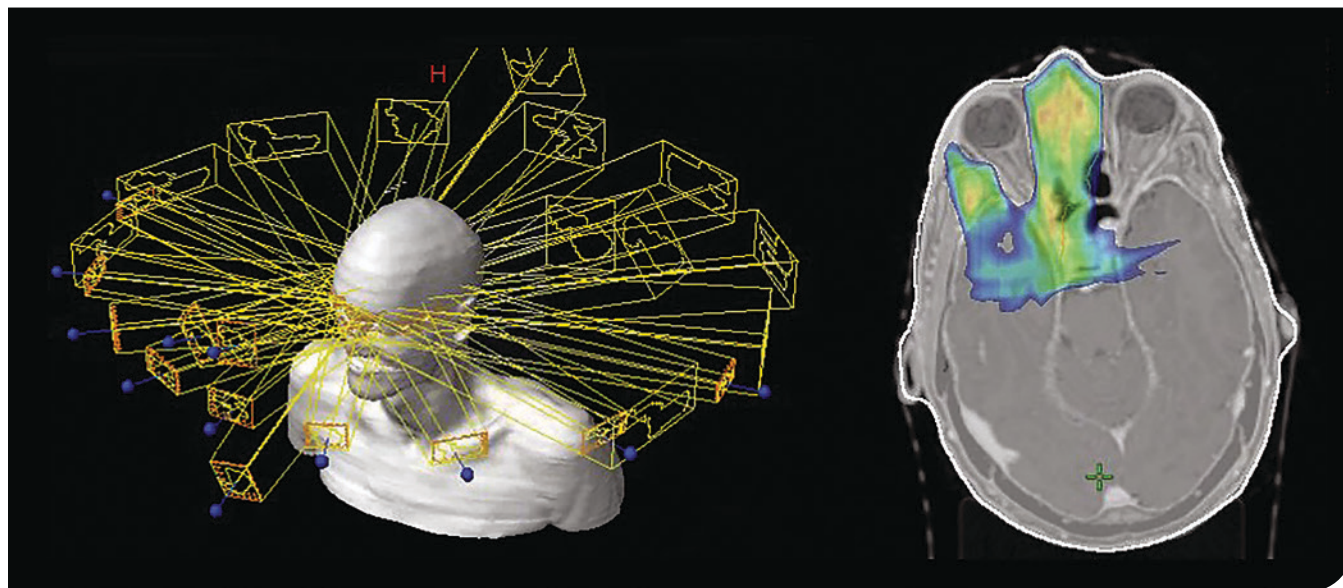


Figure 1. Stereotactic Body Radiation Therapy in Head and Neck Cancer. Notice the complex non-coplanar multi-beam delivery that affords millimeter dose delivery to complex targets such as this base of skull recurrence. Highlighted is the 50% radiation dose that completely spares the optics despite a complex target shape in close proximity to a number of critical neural structures.

CLINICAL TRIALS

Stereotactic Body Radiotherapy for Oligometastatic Disease

Zachary D. Horne, MD

The oligometastatic state is one that has been relatively recently described and represents a transitional zone between localized and widespread systemic disease. The discovery of this intermediary state has prompted a paradigm shift in which patients with a limited number of oligometastases (typically five or fewer sites) undergo potentially curative therapy with either surgery or focal radiotherapy.¹ The therapeutic approach depends on a number of factors, including: location of metastasis, potential morbidity of selected intervention, age, and performance status.

Because surgical resection is not always feasible, stereotactic body radiotherapy (SBRT) has emerged as a viable alternative and has been utilized extensively in multiple disease sites, including lung, prostate, and colon cancer.²⁻⁴

UPMC has been at the forefront of stereotactic body radiotherapy, and has opened two phase II trials to prospectively evaluate the use of stereotactic body radiotherapy in the treatment of five or fewer sites of oligometastatic disease

in three or fewer organ systems, for those who are diagnosed with synchronous oligometastases and also those who develop metachronous oligometastatic disease following definitive treatment of their primary tumors. Treatment consists of one to five fractions of radiotherapy administered every other day. An initial report revealed a median disease-free survival of 5.9 months, and 1-year survival of 77% without any impact on PR-QOL.⁵

In patients diagnosed with hepatic oligometastases, a third phase I protocol has been launched to determine the maximum tolerated dose and safety of the treatment, as liver SBRT has been less comprehensively studied than in other disease sites. Patients are eligible if they have less than 100cc of cumulative tumor burden in three or fewer discrete nodules, and no lesion greater than 6 cm in size. They must have adequate baseline liver function, as there is potential for the therapy to impact hepatic processing capabilities. Patients undergo the implantation of gold fiducial markers in and around the lesions in interventional radiology for the purposes of targeting, and begin their treatment approximately two weeks thereafter. The course of SBRT consists of five fractions of treatment delivered over the course of a week and a half.



Stereotactic Body Radiotherapy for Locoregionally Recurrent Head and Neck Cancer

Zachary D. Horne, MD

Locoregional recurrence is a major cause of morbidity and mortality in patients with head and neck cancers. In patients with HPV-negative disease, the field cancerization effect also leaves patients at risk of a second malignancy following definitive therapy. Because locoregional relapse remains a significant mode of failure even in the HPV era, optimal salvage therapy techniques are now being

questioned. Previously, salvage surgery was the standard of care, but was frequently precluded because of tumor location and extent, or medical comorbidities. Historically, re-irradiation of the head and neck has been difficult because of a poor therapeutic ratio between acute and late toxicities and poor expected survival. For these reasons, stereotactic body radiotherapy has emerged as a successful alternative in the salvage setting of head and neck cancers.

UPMC is currently enrolling patients into two clinical trials: a phase II trial of SBRT with concurrent and adjuvant cetuximab \pm the addition of docetaxel, and a phase II trial of surgical resection with or without adjuvant SBRT in patients with previously irradiated, recurrent head and neck cancers. We previously performed a phase II trial of SBRT with concurrent and adjuvant cetuximab and demonstrated a 1-year local control rate of 60% and a median survival of 10 months.⁶ 10% of patients were alive and without progression. SBRT for recurrent head and neck cancers is not without toxicity; most patients have acute swallowing, speech, and salivary dysfunction, though late effects appear to be minimal.^{6,7}

In patients who are able to undergo surgical resection of their recurrent disease, the role of adjuvant SBRT is unclear, though there is a suggestion that for high-risk features, such as nodal extracapsular extension or a positive margin, SBRT may offer an opportunity to increase local control. Therefore, our second institutional protocol is randomizing patients who undergo surgical salvage to observation or adjuvant SBRT. A small series of patients treated with SBRT who had high-risk postoperative features showed a 1-year locoregional control of 51% and survival of 64% with no grade 3 acute toxicity and 8% late grade 3 toxicity.⁸ Our current trial is designed to better define patient selection and expected outcomes from this treatment regimen. Treatment in both trials consists of five fractions of radiotherapy over the course of a week and a half.

CLINICAL TRIALS

Multidisciplinary Treatment of Postoperative Pancreatic Cancer With Close or Positive Margins

Zachary D. Horne, MD

Pancreatic cancer is the fourth leading cause of cancer death for both men and women, with more than 37,000 new cases and 34,000 deaths per year in the United States. Surgical resection offers the only viable option for cure, and the choice of adjuvant therapy remains controversial. The standard of care after definitive resection was adjuvant chemoradiation, based off of a small Gastrointestinal Tumor Study Group trial.⁹ Other clinical trials evaluating the impact of radiotherapy have failed to prove its utility. ESPAC-1 showed a benefit for adjuvant chemotherapy alone and a detriment to chemoradiotherapy, and CONKO-001 showed a benefit to adjuvant gemcitabine,^{10,11} which have led to the current standard of adjuvant chemotherapy following R0 resection.

The feasibility of using SBRT for locally-advanced pancreatic cancer was established at Stanford University in a phase I dose-escalation study, which reported 100% local control rate with single-fraction SBRT. A follow-up study combining single-fraction SBRT with gemcitabine showed 100% 1-year local control and 81% local control overall with 47% grade 2+ late toxicity, mainly duodenal ulcers.^{12,13} We have previously reported our institutional outcomes for patients treated with adjuvant SBRT in the setting of close or positive margins and found freedom from local progression in 73% of patients with close margins and 48% of patients with positive margins. Grade 1-2 gastrointestinal toxicity was 12.9% and there was no grade 3+ toxicity.¹⁴ Currently, we are enrolling patients into a phase II study of adjuvant SBRT for resected pancreatic cancer with close or positive margins. Our treatment regimen differs from the previously published Stanford regimen in that treatment is delivered in three fractions over the course of one to two weeks.

Stereotactic Body Radiation Therapy for Low and Intermediate Risk Prostate Cancer

Brian J. Gebhardt, MD

Prostate cancer is the most common malignancy in men, and an estimated 219,000 cases will be diagnosed in the United States in 2007.¹⁵ PSA screening has led to earlier-stage diagnoses, with 92% of prostate cancers diagnosed with clinically organ-confined disease.¹⁶ Multiple options exist for low- and intermediate-risk prostate cancers, including active surveillance, surgery, external beam radiation therapy, and radioactive seed implants.¹⁷ While associated with excellent cancer control outcomes, conventional

external beam radiation therapy treatment courses typically last for up to eight to nine weeks, which imposes a substantial burden on patients' time and resources.

Protracted radiation treatment courses have traditionally been employed due to concerns with toxicity to surrounding organs, including the rectum and bladder. In recent years, advanced radiation planning techniques known as stereotactic body radiation therapy (SBRT) have allowed physicians to deliver higher doses of focused radiation in much shorter courses. These techniques utilize a large number of beam angles to deliver a highly precise dose of radiation to the target while minimizing the dose to surrounding organs, and have been shown to result in excellent rates of tumor control and low toxicity.¹⁸⁻²⁰ UPMC is currently enrolling patients with low- and intermediate-risk prostate cancer to UPCI 09-031, a phase II study of SBRT delivered in five treatments in order to determine cancer outcomes and treatment side effects.

Stereotactic Radiosurgery Protocols for the Treatment of Brain Metastases

Brian J. Gebhardt, MD

Brain metastases affect approximately 30% of cancer patients, with an annual incidence of up to 40,000 patients in the United States.^{21,22} Treatment options are dependent upon the number and size of brain metastases and whether or not they are causing significant neurologic symptoms. Because of the limited efficacy of most systemic agents due to the blood-brain-barrier, treatment has typically involved some combination of surgery and/or radiation therapy. Traditional radiation therapy methods have involved treating the entire brain in 10 to 14 treatments, though this is associated with late neurocognitive impairment.²³ Stereotactic radiosurgery (SRS), by contrast, delivers a high dose of radiation to brain metastases in a single treatment and is associated with excellent rates of local control while avoiding many of the long-term side effects of whole brain radiation therapy (WBRT).²⁴

Surgical resection is often required for large tumors that are causing significant mass effect and neurological symptoms. While surgery is effective for alleviating symptoms, postoperative radiation therapy in the form of either WBRT or SRS is indicated to reduce the risk of local failure.²⁵ While SRS generally offers a more favorable side effect profile than WBRT, targeting the surgical resection bed can be a challenge due to the difficulty of distinguishing postsurgical changes from residual tumor. An alternative approach that has been investigated is to give preoperative radiosurgery to patients pending resection of a brain metastasis. This approach has been shown to potentially reduce leptomeningeal spread of disease, as well the

(Continued on Page 6)

CLINICAL TRIALS (continued)

development of late radiation effects.²⁶ UPCI 14-150 is currently accruing patients with one to four brain metastases to determine the efficacy of preoperative SRS followed by surgical resection.

An alternative situation that often arises is when a patient presents with an asymptomatic brain metastasis that does not require surgical resection, but the dose of radiation that can be delivered in a single SRS treatment is limited by the size of the lesion and the

corresponding risk of late radiation effects.²⁷ In these situations, SRS is often delivered in a course of three treatments, though the appropriate dose of this regimen is not fully known. UPCI is currently enrolling patients with large brain metastases on protocol 11-091. This is a phase I trial seeking to identify an efficacious dose of fractionated SRS that is associated with safe delivery and high control rates.

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Stereotactic Radiosurgery for Spine Metastases *(Continued from Page 2)*

neurosurgeon with special interest and training in stereotactic radiosurgery and spine disease management. UPMC has been at the forefront of stereotactic radiosurgery for spine metastases⁶, and has recently developed a comprehensive, multidisciplinary clinic that allows patients with cancer of the spine to be seen collaboratively by an expert neurosurgeon and radiation oncologist in a coordinated, same-day visit, thereby increasing the number of patients with access to specialized care, decreasing the time to intervention for symptomatic patients, and improving integration across specialties.

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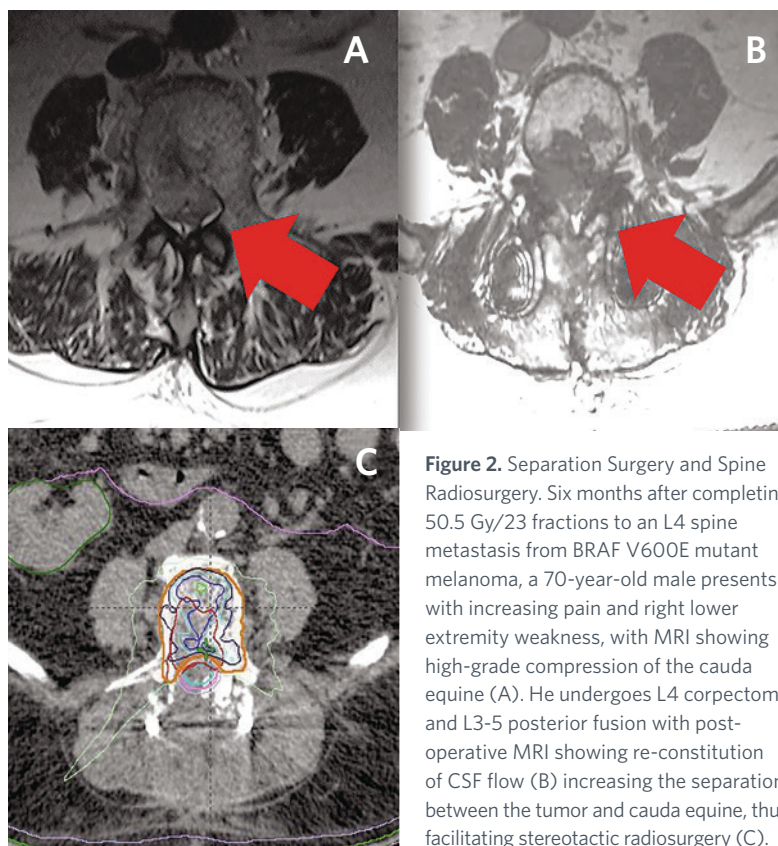


Figure 2. Separation Surgery and Spine Radiosurgery. Six months after completing 50.5 Gy/23 fractions to an L4 spine metastasis from BRAF V600E mutant melanoma, a 70-year-old male presents with increasing pain and right lower extremity weakness, with MRI showing high-grade compression of the cauda equine (A). He undergoes L4 corpectomy and L3-5 posterior fusion with post-operative MRI showing re-constitution of CSF flow (B) increasing the separation between the tumor and cauda equine, thus facilitating stereotactic radiosurgery (C).

Patient Referrals and Program Information

To learn more about the Stereotactic Radiosurgery Program at UPMC CancerCenter, or to refer a patient for consultation please call 855-SRS-FACT (777-3228), or email RadioSurgeryTeam@upmc.edu.

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Dwight Heron, MD, provides an overview of some of the new options and challenges in head and neck cancers.

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Constance Jennings, MD, shares some information and thoughts on respiratory insufficiency in cancer survivors. The focus of this presentation is on the management of dyspnea in lung cancer survivors.

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