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Stereotactic Radiosurgery for Non-brain Cancer

Draft for public comment

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Table 1. Abbreviations and Glossary

Abbreviation	Description
2D-CRT	Conventional radiation therapy
3D-CRT	Three dimensional conformal radiation therapy
ACR	The American College of Radiology
AHA	The American Hospital Association
AHRQ	The Agency for Healthcare Research and Quality
ASTRO	The American Society of Therapeutic Radiology and Oncology
BED	Biologically effective dose
CDRH	Center's for Devices and Radiological Health
CT	Computed tomography
CTC	Common Toxicity Criteria
EBRT	External beam radiation therapy
ECOG	Eastern Cooperative Oncology Group
FDA	United States Food and Drug Administration
IMRT	Intensity modulated radiation therapy
KPS	Karnofsky Performance Status
kVp	KiloVolts peak
linac	Linear accelerator
LQ	Linear quadratic model
MLC	Multi-leaf collimator
mMLC	micro Multi-leaf collimator
MRI	Magnetic resonance imaging
PET	Positron emission tomography
RT	Radiation Therapy
SBRT	Stereotactic Body Radiation Therapy
SRS	Stereotactic radiosurgery
WHO	World Health Organization
Glossary Term	**Description**
Biologically Equivalent Dose (BED)	The amount of absorbed or deposited radiation into the targeted tumor
Bragg Peak	The energy released by protons when they reach the targeted tumor
Collimator	Defines the dimensions and direction of a beam of x-ray radiation, usually by eliminating the peripheral, more divergent part of the x-ray beam.
Fiducial	Markers that help to precisely identify the targeted tumor location. They may be located on a headframe, or surgically implanted for tumor locations throughout the body.
Fractionation	Dividing a prescribed treatment dose into smaller amounts to reduce the surrounding healthy tissues' exposure to the radiation.
Gray (Gy)	A measure of the absorbed radiation dose and equal to the absorption of one joule of energy by one kilogram of matter.
Multi-leaf Collimator (MLC)	A device with individual tungsten leaves that are programmed to moved independently in order to shape the prescribed radiation dose to the targeted tumor.

Introduction

Cancer is a diverse group of diseases characterized by an uncontrollable growth of abnormal cells. These abnormal cells may remain in the originating place of disease or metastasize through blood and lymph systems. According to the American Cancer Society, 1,415,370 new extracranial cancer cases are expected to be diagnosed in the United States (US) in 2008 (This estimate does not include carcinoma in situ of any site except urinary bladder and basal and squamous cell cancers).[5] Approximately 552,580 of these newly diagnosed patients are expected to die from their extracranial tumor.[5] Treatments available for cancer include surgery, various forms of radiation therapy, and chemotherapy.

Stereotactic radiosurgery

Stereotactic radiosurgery (SRS) is a form of external beam radiation that combines multiple finely collimated radiation beams and stereotaxy (3D target localization). The multiple radiation beams intersect to deliver a single, precise, high dose of radiation to a precisely defined location, while minimizing radiation exposure to surrounding tissues. Radiosurgery ionizes the targeted tissue, producing ions and free radicals from either the water in the cells or other biological materials. The free radicals and ions damage the DNA, proteins, and lipids, causing the cells to die and preventing them from reproducing. The targeted tumor may shrink and eventually disappear over time.

In 1951, Dr. Lars Leskell and Borje Larsson introduced the concept of radiosurgery for use in intracranial conditions considered inoperable. Leskell initially used 200 kVp x-rays to deliver, in a single session, a high radiation dose (of the order of 100 Grays) to an intracranial target.[6] In the 1950's orthovoltage x-ray radiosurgery was discontinued. However, the idea of focal brain irradiation was conveyed to other types of radiation beams. These first included cyclotrons, then protons, followed by focused cobalt 60 gamma rays and more recently to megavoltage x-rays from linear accelerators (linacs).[6]

SRS has been used to treat functional disorders of the brain such as trigeminal neuralgia or arteriovenous malformations, vascular malformations, and intracranial and extracranial benign and malignant tumors. Extracranial areas that have been treated with SRS include the abdomen, liver, lung, neck, pancreas, prostate, and spine. This technical brief will focus on the use of stereotactic radiosurgery for solid tumors located outside of the brain.

Stereotactic radiosurgery technology

The components of SRS are: patient immobilization, imaging equipment, target localization software, a treatment planning system, and an appropriate radiation source and radiosurgical treatment technique.[6] The radiation source for current SRS systems is one of three different technologies: the proton-based particle beam accelerator, the photon-based cobalt-60 system, and the photon-based linear accelerator (linac).The goal of each of these technologies is to converge several radiation beams onto one location, sharply focused on the targeted tumor. The differences between these technologies include the source of radiation, the system operation, and the applicability and effectiveness of the technology for the targeted tumor.

Particle beam accelerator

Particle beam therapy devices speed up charged particles such as protons to high energies. Once released from the accelerator, the particle slows down and stops and the energy loss per unit of distance rises sharply to a peak (i.e., the Bragg peak) before dropping off rapidly. Tissue sparing in front and behind the tumor is accomplished by matching the depth of the Bragg peak (dependent upon the energy of the charged particle) with the tumor position. The path of the radiation beam is linear with very little lateral energy scatter. This allows tissue in a direction upstream from the tumor to receive only a small radiation dose, while tissue around and behind the tumor receives virtually no radiation. The purported advantages of protons over photons in radiation therapy include: accurate dosing of targets, reduction of the acute side effects of radiation therapy, lower radiation dose to non-targeted tissue, and safer treatment for pediatric patients vulnerable to radiation side effects. Facilities for delivering proton beam therapy are expensive to construct and operate because of the required large cyclotron and related equipment, and can cost more than $100 million.[7]

Cobalt-60 system

The cobalt-60 system emits gamma irradiation. The gamma rays are photon beams produced by radioactive decay of fixed sources of radioactive cobalt-60.[8] To date, only one SRS system that uses gamma rays exists: Elekta's Gamma Knife. This device was invented by Leskell and Larsson in 1967.[8] The Gamma Knife has been used extensively for intracranial radiosurgery, and is considered the gold standard for this application. The main gantry of the Gamma Knife contains 201 cobalt-60 gamma ray sources arrayed in a hemisphere. Elekta's Gamma Knife is in its fourth generation, and newer versions contain fewer gamma ray sources (e.g., the Perfexion has 196 cobalt sources). Circular beams of radiation are produced that can measure 4 to 18 mm in diameter.[9] The collimator helmet has spaces for 201 collimator inserts, each lined up with one source. Collimators of various sizes can be inserted in each space to regulate the radiation from the corresponding source, or a plug can be inserted to block the radiation completely.

In a typical Gamma Knife radiosurgery procedure, a rigid frame is surgically affixed to the patient's head. The patient is then imaged by CT or MRI, and markers on the headframe appear in the images and provide a fixed point of reference for precisely locating the lesion to be treated. With computer assistance, the physician supervising the treatment develops a plan specifying the location, size, and shape of the tumor, the length of treatment and placement of the collimator(s) within the helmet. The helmet is placed over the patient's head, secured to the headframe, and the patient is placed in the gantry. The use of a headframe limits treatment to a single fraction.

Linear accelerator

A medical linear accelerator (linac) emits a well-defined beam of uniformly intense x-ray photon radiation with energies ranging from 4 to 25 MeV redirected in many arcs. A linac has four major components: a modulator, an electron gun, a radiofrequency power source, and an accelerator guide. The gantry (emission head) on the linac moves in space to change the angle of radiation delivery. The treatment couch (patient table) can also be moved at times in small linear and angular positions. A well-designed, well-aligned and properly maintained isocentric linac must have a stable and small enough isocentre sphere (on the order of 1 mm diameter) to make it suitable for use in radiosurgery.[6] The

measured uncertainty in radiosurgical dose delivery for a linac in excellent mechanical condition is on the order of ±0.5 mm, while for a gamma unit it is somewhat smaller, at ±0.3 mm.[6] Table 2 details the differences between these three technologies.

This technical brief will focus on the linac and cobalt-60 technologies of SRS. The Agency for Healthcare Research and Quality (AHRQ) has recently commissioned a technical brief discussing particle beam radiation for cancer (this report is currently in a draft format).[10]

Table 2. Comparison of SRS technologies

	Particle beam accelerator	**Cobalt-60 system**	**Linear accelerator (Linac)**
Energy source	Protons, Helium and Carbon ions	Gamma-ray Photons	X-ray Photons
Number of radiation sources	Single	Multiple (201)	Single
Treatment sites	Intracranial, Extracranial	Intracranial, head, neck	Intracranial, Extracranial
Radiation distribution	Bragg Peak	Circular beams; target placed in center of simultaneously converging beams	Multiple non-coplanar beams are delivered at the target by rotating treatment head
Dose fractionation	Single or fractionated	Single or fractionated	Single or fractionated
Advantages[11]	✓ Precise dose distribution ✓ High absorbed energy delivered to target	✓ Accurate beam delivery system ✓ Appropriate for small tumors <3.5 cm ✓ Single dose treatment	✓ Low cost of modification ✓ Treatment planning flexibility ✓ No limitation of field size ✓ Precise fractionated treatments possible ✓ Also supports routine external RT ✓ Body radiosurgery applications
Disadvantages[11]	✓ Limited field size ✓ High acquisition costs	✓ Source replacement required every 5-10 years ✓ Progressively longer treatment times because of 5 year half life of cobalt-60	✓ Extensive quality assurance procedures ✓ Longer treatment times per isocenter Time-consuming and labor intensive set up
Year of development	Investigated since the 1940s[1]	1967[8]	Linac radiosurgery first described in 1984 by Betti and Derechinsky[12]

Frame-based and frameless stereotactic radiosurgery

In order to deliver a precisely targeted radiation dose, patient movement must be prevented or automatically accounted for. According to the American Association of Neurological Surgeons, SRS can be performed using a rigidly attached stereotactic guiding device, other immobilization technology (i.e., face molds, repositionable body molds/frames), and/or a stereotactic image-guidance system.[13] Stereotactic frame-based immobilization and localization have long been the hallmark of the radiosurgery method.[14] Practitioners typically use frame-based SRS systems, which immobilize patients with a surgically affixed metal head frame, to treat intracranial conditions (e.g., brain cancers, arteriovenous malformations [AVMs]). Frameless SRS (FSRS) systems, on the other hand, intermittently monitor and compensate for patient movement to allow practitioners to treat intracranial and extracranial tumors without using a head frame or body frames.

Applying SRS to extracranial tumors can be difficult because of organ movement as a result of breathing or patient movement. The desire to treat lesions outside of the head using the highest precision dose delivery in the setting of fractionated stereotactic radiotherapy has led to the development of image-guided radiosurgery/radiotherapy.[14] Some SRS systems use repositionable body molds or frames when performing SRS for extracranial tumors, but like intracranial procedures, positioning the body frame in the exact previous position is difficult. Frameless SRS systems use image guidance (x-ray imaging, on-board CT scanning) to intermittently monitor the targeted tumor by tracking bone structures or implanted fiducials. By monitoring the defined tracking points, the system can compensate for patient movement. These systems allow the elimination of breath-holding during treatment, use little or no sedation during treatment, perform the majority of procedures as outpatient procedures, and allow fractionation of the radiation dose. There is also a reduction in the amount of time the treatment team needs to spend on patient pretreatment, patient preparation, post-treatment manipulation, and patient recovery.

Stereotactic radiosurgery treatment planning and treatment delivery

SRS allows physicians to plan the treatment in advance, and it provides orientation and guidance during the procedures.[15] Factors used to determine if SRS is an appropriate procedure for extracranial tumors include tumor shape, volume (1-35 cm^3),[16] location, histology, invasiveness, and the clinical status of the patient. The exact treatment for each patient is individualized. The key components of a SRS procedure are treatment planning and treatment delivery. The treatment team includes a radiation oncologist, medical physicist, radiation therapist, and depending on the body site and indication, a diagnostic radiologist, nurse, anesthetist, and dosimetrist may also be needed.[17]

Treatment planning includes preplanning imaging, plan development, and patient positioning. An image is taken of the patient and targeted tumor by computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), and/or angiography prior to the day of treatment. These images are uploaded to the treatment planning computer and the treatment team develops a plan for the procedure using software to modify the shape, size, and entry point of the radiation beam to treat the targeted tumor. Before treatment begins the patient is positioned on the treatment couch with or without a body frame or fixation device and reoriented to the SRS system. Some SRS devices can track bone structures or implanted fiducials in real-time during treatment by x-ray imaging cameras located on supports around the patient, eliminating the need for frames or fixation devices. For extracranial

applications, new images are required on the day of treatment to account for any change in shape or size of the target from initial diagnostic scans.[15]

Precision of the radiation beam (positional and numerical accuracy in dose delivery are ±1 mm and ±5 percent)[16] is imperative and determined by the image of the lesion, the imaging technique used to capture the lesion, and how this image is incorporated into the treatment procedure.[18] Imaging software compares the images taken after the patient is positioned on the treatment couch with the preplanning images to confirm the location of the targeted tumor. The system updates the treatment plan with the new information (tumor size, position, etc.), recenters the patient in the x-ray field of view, and begins treatment. This action corrects the dosing orientation to match the treatment plan. The dosage range for SRS/SBRT treatment delivery is approximately 10 to 50 Grays (Gy).[16] Treatment times typically last from 20 to 50 minutes, however, depending on the nature of the tumor, treatment may take up to 90 minutes. Like other forms of radiation therapy, the effects of radiosurgery may take weeks or months to be seen.[19]

Stereotactic radiosurgery terms

The first uses of SRS were intracranial applications given in a single dose to patients wearing a surgically affixed head frame. Therefore, the traditional definition of SRS references a single radiation dose given in a single session.[1] The expansion of SRS to sites within the body (stereotactic body radiation therapy) offers opportunities for patients to receive single session treatment or treatment delivered in relatively few fractions, with or without body frames. Fractionated treatment is an option available to patients not suitable for a single SRS treatment based on factors determined by the treatment team such as tumor location and size, tumor motion, and tumor radiosensitivity.

When a radiosurgery procedure is fractionated it may be referred to as “stereotactic body radiation therapy,” “stereotactic radiotherapy,” “fractionated stereotactic radiosurgery,” “hypofractionated stereotactic radiosurgery,” or “staged radiosurgery”. Within actual practice the differentiation between these various terms is blurred, with terms commonly used interchangeably. Consensus does not exist for the definition of stereotactic body radiation therapy (SBRT) with respect to a maximum number of radiation fractions, the minimum radiation dose per fraction, or the maximum number and diameter of lesions to be treated.[2] However, most define SBRT as the treatment of an extracranial lesion with a single or very few (≤5) high-dose fractions.[3] This technical brief will use stereotactic radiosurgery (SRS) as the general term for a single dose of treatment; and will use stereotactic body radiation therapy (SBRT) when treatment is delivered in a fractionated manner.

Scope of Technical Brief

The Agency for Healthcare Research and Quality (AHRQ) requested a Technical Brief on the application of Stereotactic Radiosurgery for the treatment of extracranial cancers. The following key questions were defined by AHRQ:

Key questions

Key question 1:

1.a. For which cancers (other than brain) has stereotactic radiosurgery been used?

1.b. What are the theoretical advantages and disadvantages of stereotactic radiosurgery compared to other radiation and surgical therapies that are currently used for cancer treatment?

1.c. What are the potential safety issues and harms of the use of stereotactic radiosurgery?

Key question 2:

2.a. What specialized instrumentation is needed for stereotactic radiosurgery at sites other than in the brain and what is the FDA status of this instrumentation?

2.b. What is an estimate of the number of hospitals that currently have the capability for stereotactic radiosurgery at sites other than the brain in the USA?

2.c. What instrumentation technologies are in development?

Key question 3:

Systematic literatures scan on studies on the use and safety of these therapies in cancers other than in the brain, with a synthesis of the following variables:

3.a. Type of cancer and patient inclusion criteria

3.b. Type of radiation and instrumentation and algorithms used

3.c. Study design and study size

3.d. Comparator used in comparative studies (depending on number of studies, may want to limit to comparative studies)

3.e. Concurrent and/or prior treatments used

3.f. Length of follow-up

3.g. Outcomes measured

3.h. Adverse events, harms, safety issues reported

Methods

Literature searches

Narrative review articles and gray literature searches were used to address key question 1 and 2. A systematic scan of the published medical literature was performed to address key question 3.

We searched the internet for gray literature applicable to the background section, key question one and key question two. We performed the internet searches in the Google search engine, and visited relevant links within the first ten pages of search results. Gray literature was also searched within "Windhover", "Current HC News", "Grey Sheet", "The Wall Street Journal", and "Clinica". We also visited association and organization Web sites (e.g., International RadioSurgery Association), and Web sites posted within the organization's site. Our search strategy for published studies involved Ovid MEDLINE, EMBASE, the Cochrane Database, and the Health Technology Assessment Database. Our biomedical engineers and medical physicists suggested confining our searches to the past five to eight years given the technology changes. There are reports in the literature as far back as 1993 for the use of stereotactic radiosurgery for ocular melanoma. Given that this is a technical brief, our search range was limited to 2000 to 2008. The full search strategy can be found in **Appendix A**. Literature search methods. Information for instrumentation was captured by a search of the manufacturers' Web sites and a search of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) (http://www.fda.gov/cdrh/). Instrumentation information can be found in **Appendix F**. Currently marketed devices for SRS/SBRT.

Study eligibility

The titles of the citations identified through the literature searches were screened for relevance to the topic. Articles with titles that seemed potentially relevant were then passed to the abstract screening level. Abstracts were initially screened in duplicate (first 50 abstracts) by two reviewers to determine relevance for stereotactic radiosurgery applied outside of the brain. Duplicate review was used as a quality control measure, making sure the reviewers understood the questions asked in regards to the abstracts retrieved. After screening the first 50 abstracts in duplicate, both reviewers understood the questions and proceeded to screen subsequent abstracts individually. All relevant abstracts were ordered as full-text articles for further review. Again, the first 50 full-text articles were screened in duplicate to determine eligibility for data extraction, and subsequent articles were screened individually. Eligible studies were clinical studies of any design, studies in English, patient population of at least three patients, the use of SRS for solid tumors located outside of the brain, and with treatments delivered in 10 or fewer fractions. Studies not eligible for data extraction included treatment planning (e.g., dosing), treatment delivery (e.g., accuracy), non-malignant tumors, the use of more than ten treatment fractions, and fewer than three patients.

Data extraction

TrialStat SRS 4.0 was used for the data extraction process. If reported, the information extracted included: country of study, year of study, authors, study design, type of cancer, patient inclusion/exclusion criteria, comparators, size of patient population, sex and age of patients, prior or concurrent treatment, instrumentation and type of radiation used (x-ray photons or cobalt-60), algorithms, quality assurance

and/or training procedures, tumor quantity and tumor size, total radiation dosage, number of fractions and dose of each fraction, length of follow-up, outcomes measured and how they were measured, and adverse events/harms.

Summary of items of interest

For key question three, we organized the relevant literature by study design into three tables. Each table is arranged by year of publication (most recent year first) and then alphabetically by author. These tables included the following information: author, year, cancer type, instrumentation/algorithms, study design/study size, prior/concurrent treatment, length of follow-up, outcomes measured, and adverse events. The tables can be found in **Appendix L**. Results for key question 3. The cancer types found within the literature include lung/thorax, colon, liver, pancreas, head and neck, kidney, eye/orbit, pelvic, sacrum, uterus, prostate, and spine.

Software

To calculate overall means and medians for patient ages and lengths of follow-up, we used Microsoft Office Excel 2007.[20]

Results

Key question 1

1.a. For which cancers (other than brain) has stereotactic radiosurgery been used?

Based on our literature search SRS/SBRT has been used for tumors located in the lung/ thorax, spine, pancreas, liver, colon, uterus, pelvis, sacrum, eye, head and neck, kidney, and prostate. The bulk of the studies identified in our searches were for tumors of the lung/thorax (k = 37),[21-55] head and neck (k = 22),[56-77] eye/orbit (k = 18),[78-95] and spine (k = 12).[96-105] Details for these studies can be found in **Appendix L**. Results for key question 3

1.b. What are the theoretical advantages and disadvantages of stereotactic radiosurgery compared to other radiation and surgical therapies that are currently used for cancer treatment?

Photon (x-ray and gamma ray) radiation therapy can be used as a therapeutic or palliative treatment. Treatment can be delivered externally or internally, and depending on the patient's diagnosis, can be used in conjunction with surgery, and/or chemotherapy.

Conventional radiation therapy

Conventional radiation therapy (2D-CRT) defines the targeted tumor in two dimensions and can use x-ray films or electronic portal imaging devices when determining the beam positions for treatment. Treatment planning is performed by using a simulator, and anatomical landmarks or fiducials to help determine the location of the tumor. The positioning of the radiation beams are planned around the patient with the goal of treating the tumor and avoiding the healthy organs and tissues. Conventional radiation therapy is a well established form of treatment, and is adequate for treating multiple tumors. Typical treatment fractions range between 25 and 40 treatments delivered five days a week for approximately five to ten weeks.

Three dimensional conformal radiation therapy

Three dimensional conformal radiation therapy (3D-CRT) allows the targeted tumor and the surrounding healthy tissue or organs to be defined in three dimensions. 3D-CRT uses computer software and special imaging techniques (e.g., CT) to display the size, shape, and location of the tumor.[106] The treatment planning team can determine the size and shape of the radiation beam to fit the targeted tumor by using a MLC or custom fabricated field-shaping blocks.[106] By using tailored radiation beams set to deliver the most effective dose of radiation to the targeted tumor, the healthy tissue that may be affected will receive less radiation and have time to heal between treatments. Typical treatment fractions range between 25 and 40 treatments delivered five days a week for approximately five to ten weeks.

Intensity modulated radiation therapy (IMRT)

Intensity modulated radiation therapy (IMRT) is an advanced form of 3D-CRT delivered by a linear accelerator that allows clinicians to shape radiation doses to more closely follow the contours of a tumor. IMRT systems feature MLCs that shape the photon (x-ray) beams delivered by a linear accelerator. In IMRT, the intensity of the radiation exposure in one portion of the field is modified depending on whether tumor or normal tissue is present in the beam pathway. IMRT involves inverse treatment planning systems which allow the physician to input the desired radiation treatment dose into a computer. The computer then develops a detailed treatment plan of the beams required to deliver the prescribed radiation dose to the shape of the target tumor, and the physician reviews this plan before the procedure begins. During treatment, IMRT divides the beam into multiple beamlets. When the beamlet hits normal tissues, the intensity is lowered, and when the beamlet hits the tumor, the intensity is increased. The changing of beam intensity is computer controlled. Typical treatment fractions range between 25 and 40 treatments delivered five days a week for approximately five to ten weeks.

Arc therapy

Arc therapy extends IMRT treatment by increasing the number of radiation delivery angles. Arc therapy combines image guidance and IMRT by using binary MLCs, and rotates continuously around the patient during treatment. Tomotherapy, Inc. is the manufacturer of the *HI-ART* tomotherapy system. The helical machine combines a dedicated IMRT delivery methodology with CT imaging capability.[107] Treatment is delivered in a spiral fashion, removing the need to manually move the patient between arcs.[107] The machine scans the patient before treatment begins to make sure the patient is in the proper position. A thin beam, modulated by a 64-multileaf collimator, rotates around the body while the patient is moved through the machine allowing treatment from different angles and entry points. Arc therapy is capable of treating small or large, and single or multiple targeted tumors throughout the body. The machine is capable of treating very large volumes in only one single session.[108]

Tomotherapy is not the only manufacturer of systems delivering continuous treatment. Rapid Arc is a technique used for conformal radiotherapy and is similar to Tomotherapy's *HI-ART* and Elekta's VMAT. However, according to Tomotherapy, Inc.'s Web site, clinicians have also used the *HI-ART* system for stereotactic radiosurgery (SRS) and stereotactic radiation therapy (SRT).[109] If used for IMRT treatment, typical treatment fractions range between 25 and 40 treatments delivered five days a week for approximately five to ten weeks. If used for SRS or SRT treatment fewer fractions and sessions are prescribed.

Brachytherapy

Brachytherapy is the placement of temporary or permanent radioactive sources (e.g., ribbons, seeds, capsules, catheters, or wires) inside the body using intracavity or interstitial access. Intracavity treatment involves the placement of radioactive sources in an area near the tumor location. When interstitial treatment is necessary the radioactive sources are inserted into the tissues at or near the tumor site.[110] The dose of radiation delivered by brachytherapy is higher near the targeted lesion, and rapidly decreases outside of this area.

Surgery

Surgery is a treatment option used when the tumor location is not close to critical structures, and as a way to debulk tumors, making them smaller for treating with adjuvant therapy such as radiation therapy and/or chemotherapy. When surgical removal is an appropriate therapy, the treatment team is able to assess the nature of the tumor, the distance the tumor has spread, and how much of the tumor can be removed.

Advantages and disadvantages of SRS/SBRT vs. 2D/3D CRT, IMRT, Arc therapy

SRS/SBRT is a noninvasive procedure that provides a treatment option for tumors considered inoperable. Patients are allowed to return to daily activities after the completion of the procedure, and most patients do not require sedation. However, the results of a SRS/SBRT treatment may not be apparent for weeks or months. Therefore, patients usually attend scheduled follow-up imaging appointments to determine the response of the targeted tumor (s). SRS/SBRT can be used in combination with open surgery for especially difficult or aggressive tumors and conditions, and also after other radiation therapy (RT) interventions.[15]

With stereotactic treatment delivery, high doses are given over a few days.[3] Normal tissue is purposely excluded from the target volume as much as possible.[1] As with other radiation treatments, geographic misses of the targeted tumor can cause damage to surrounding healthy tissues. But, with SRS/SBRT, the destructive high doses of radiation have the potential to cause severe and potentially irreversible damage to accidentally targeted healthy tissues.

Dedicated SRS/SBRT systems can cost more than $3 million, while additional expenses of constructing a vault to shield radiation, treatment planning space, patient care and holding areas can add from $500,000 to $1.5 million to the project costs.[15] According to a search of ECRI's Institute PricePaid database, list pricing for radiotherapy (e.g., IMRT) systems (equipment and accessories) within the past year ranged from $93,000 to $6.5 million. Keep in mind, manufacturers typically offer customized discounts based on a facility's needs or current equipment, in turn decreasing these prices.

External radiation treatment is a continuous progression of technology. With advances in technology, dose planning improvement allows smaller tumors and hard to reach tumors to be treated, and narrows the involvement of the adjacent normal tissues. 2D-CRT and 3D-CRT are the most basic radiation treatments and tend to include larger margins of surrounding normal tissue because it is difficult to clearly define the targeted tumor. IMRT is an advanced form of 3D-CRT and uses more conformal treatment plans. The important component of IMRT is the ability to vary intensities across the treatment field, thereby reducing damage to tissue upstream and downstream from the tumor. Arc Therapy improves the IMRT treatment by delivering continuous (circular) IMRT through the dynamic control of MLCs, and in turn decreasing treatment times. SRS/SBRT's most important features are the use of high dose radiation and the delivery of a single or very few fractions. Table 3 below lists the advantages and disadvantages of SRS/SBRT, 2D/3D-CRT, IMRT, and Arc Therapy.

Table 3. Advantages and disadvantages of 2D-CRT, 3D-CRT, IMRT, Arc therapy, and SRS/SBRT

	Advantages	**Disadvantages**
2D-CRT	✓ Routine planning and treatment process ✓ Useful in treating multiple or diffuse tumors	✓ Typically only 2-3 delivery angles ✓ Long treatment process (25-40 fractions over 5-10 weeks) ✓ Tumor defined in only 2 dimensions ✓ Surrounding normal tissue irradiated
3D-CRT	✓ Uses MLCs ✓ Less radiation delivered to adjacent normal tissues than 2D-CRT	✓ Typically only 5 delivery angles ✓ Long treatment process (25-40 fractions over 5-10 weeks) ✓ Uses custom blocks
IMRT	✓ Beam considered as multiple beamlets ✓ Beam intensity can be varied across field ✓ Inverse treatment planning	✓ Typically only 5 delivery angles ✓ Long treatment process (25-40 fractions over 5-10 weeks)
ARC therapy	✓ Dose delivered in 360 degrees ✓ Improved beam shaping and tissue sparing	✓ Long IMRT treatment process (25-40 fractions over 5-10 weeks) ✓ Complex equipment and planning ✓ May require longer treatment sessions
SRS/SBRT	✓ High dose delivered in few treatments ✓ Used for small and large tumors (approx. 1-35cm^3) ✓ Can treat tumors otherwise considered inoperable ✓ Multiple delivery angles ✓ Shorter overall treatment times ✓ Typically 1-5 fractions ✓ Improved beam shaping	✓ Geographic misses likely to be detrimental ✓ High equipment cost (>$3 million for dedicated systems) ✓ Need thoroughly trained treatment team and stringent quality assurance/quality control procedures ✓ Some systems require stereotactic frames for immobilization ✓ Near or real-time IGRT is necessary to maintain geographic accuracy of treatment

1.c. What are the potential safety issues and harms of the use of stereotactic radiosurgery?

Quality assurance and quality control of SBRT treatment

SRS/SBRT is a high-dose radiation treatment. For high-dose radiation treatments, errors in energy output and spatial positioning must be minimized.[14] If the high-dose treatment beam accidently hits surrounding healthy tissue, severe damage and side effects may occur. The tumor tissue that remains after the radiation treatment will typically shrink. On rare occasions this necrotic or dead tissue can cause further problems such as pain or discomfort and may require removal.[111]

SRS/SBRT treatments can be difficult to plan because tumors located within the body may move periodically (e.g., respiratory movement), irregularly (e.g., peristalsis), or permanently (e.g., shrinkage of tumor) between fractionated treatments. The quality assurance (QA) for SRS/SBRT must go beyond physical measurements and include a proper review of individual patient data.[112] An essential part of SRS/SBRT is the strict quality control of the tumor images and the regular verification of the image sets to maintain the delivery of the prescribed dose. SRS/SBRT requires tight conformity of the prescription dose to the tumor volume, with rapid dose fall off.[113] The targeted tumor can be tracked by methods such as respiratory gating or target tracking. Before a patient is treated, phantoms can be used as part of the QA process to make sure these tracking techniques are measuring the tumor location and movement correctly.[112]

ACR/ASTRO SBRT guideline

In 2004, the American College of Radiology (ACR) and the American Society of Therapeutic Radiology and Oncology (ASTRO) developed a practice guideline for the performance of SBRT. This guideline was amended in 2006. The purpose of the guideline is to provide guidance to practitioners considering using SBRT and to define quality criteria for the delivery of SBRT.[114] The advanced training of personnel and the careful management of patients are the key aspects for performing SBRT safely. **Appendix D** lists the qualifications and responsibilities of the personnel, and **Appendix E** provides a snapshot of the suggestions within the guideline for procedure specifications, quality control of accessories, quality control of images, quality control for the treatment planning system, simulation and treatment, and follow-up.

Key question 2

2.a. What specialized instrumentation is needed for stereotactic radiosurgery at sites other than in the brain and what is the FDA status of this instrumentation?

SRS/SBRT can be delivered by three different technologies: the proton-based particle beam accelerator, the gamma ray photon-based cobalt-60 system, and the x-ray photon-based linear accelerator (linac). A discussion of the proton-based particle beam accelerator is outside the scope of this technical brief, as AHRQ has recently commissioned a technical brief on that topic.[10]

Cobalt 60

There is currently only one United States Food and Drug Administration (FDA) approved photon based cobalt-60 system; Elekta's Gamma Knife (different versions of the Gamma Knife System are listed in **Appendix H**). The main gantry of the Gamma Knife contains 201 cobalt-60 gamma ray sources (newer versions contain fewer gamma ray sources) arrayed in a hemisphere. Circular beams of radiation are produced that can measure 4 to 18 mm in diameter.[9] The collimator helmet contains the spaces for 201 collimator inserts, each lined up with one source. Collimators of various sizes can be inserted in each space to regulate the radiation from the corresponding source, or a plug can be inserted to block the radiation completely.

Linacs

For radiosurgery applications outside of the brain there are SRS/SBRT dedicated systems such as the linac-based CyberKnife; and non-dedicated systems (linacs that have the capability of performing SRS/SBRT with the addition of accessories). Non-dedicated linacs can be just as accurate as dedicated systems, but will require patient immobilization and may not have real-time stereotactic imaging. Non-dedicated systems are capable of performing conventional radiation therapy, IMRT, and Arc Therapy, along with SRS/SBRT. Dedicated SRS/SBRT devices provide improvements in patient positioning and reduce the need to immobilize patients with body frames and fixation devices. On average, one to two stereotactic irradiations can be performed on a non-dedicated linac per day and ten to 15 on dedicated linac.[11] A listing of nine commercially available systems with identifiable features can be found in **Appendix F**. Currently marketed devices for SRS/SBRT.

Linac accessories

Non-dedicated linacs require significant time and physical resources to change from conventional RT to SRS/SBRT.[15] Accessories needed to modify non-dedicated linacs to adjust the size and subsequent intensity of the radiation beam include various sized cones, circular collimators, MLCs or micromulti-leaf collimators (mMLC). MLCs consist of individual leaves generally made of tungsten alloy which may be mounted to or integrated in the linac. MLC leaf widths typically range from 5 mm to 10 mm. More recently marketed mMLCs are designed for the treatment of lesions smaller than 80 mm with leaf widths ranging in size from 1 mm to 4 mm.[115] Treatment planning software, QA hardware, and fixation capability are other requirements for linac modification. A listing of available linac-based stereotactic radiosurgery accessories may be found in **Appendix G**. Linac-based SRS/SBRT accessories.

FDA status of SRS/SBRT equipment

SRS/SBRT devices are regulated by the FDA under the 510(k) process. Most of these devices are generally cleared for marketing for treatment of lesions, tumors, and conditions anywhere in the body. Indications currently approved by the FDA's Center for Devices and Radiological Health (CDRH) as well as marketing clearance information including 510(k) applicant/number, product code, and approval dates are provided in **Appendix H**. Applicant's FDA 510K information. Devices and accessories used for the administration of SRS/SBRT can be accessed by searching the following CDRH codes: IWB, IXI, IYE, and MUJ. Information was captured by a search of the manufacture's web sites (**Appendix I**. Manufacturer web sites) and a search of the FDA's CDRH (http://www.fda.gov/cdrh/).

2.b. What is an estimate of the number of hospitals that currently have the capability for stereotactic radiosurgery at sites other than the brain in the USA?

According to the *2009 Edition of the American Hospital Association (AHA) Guide*[116], approximately 700 facilities claim to administer SRS in the United States (U.S). Of these 700, we identified 305 facilities capable of performing SBRT, and we have identified 15 stand-alone CyberKnife facilities in the U.S. performing SBRT. This information was accessed by visiting the Web sites provided in the AHA guide and by accessing the CyberKnife Web site (http://www.accuray.com). An overall listing of these 320 facilities, including specific extracranial sites treated and devices employed can be found in **Appendix J**. Facilities performing SRS/SBRT for extracranial solid tumors. We have also searched clincaltrials.gov to determine if any trials are currently in progress for SRS/SBRT. **Appendix K** lists the condition being studied, the intervention, study design, primary and secondary outcomes to be measured, estimated enrollment, planned duration, and location of ongoing trials.

2.c. What instrumentation technologies are in development?

The Gyro Knife, manufactured by GammaStar Medical Group Ltd., is commercially available in the European Union having recently received the CE certification for European Union medical devices.[117] This device uses both gamma rays and photons for the treatment of extracranial lesion and is awaiting approval by the FDA.

Key question 3

Evidence base

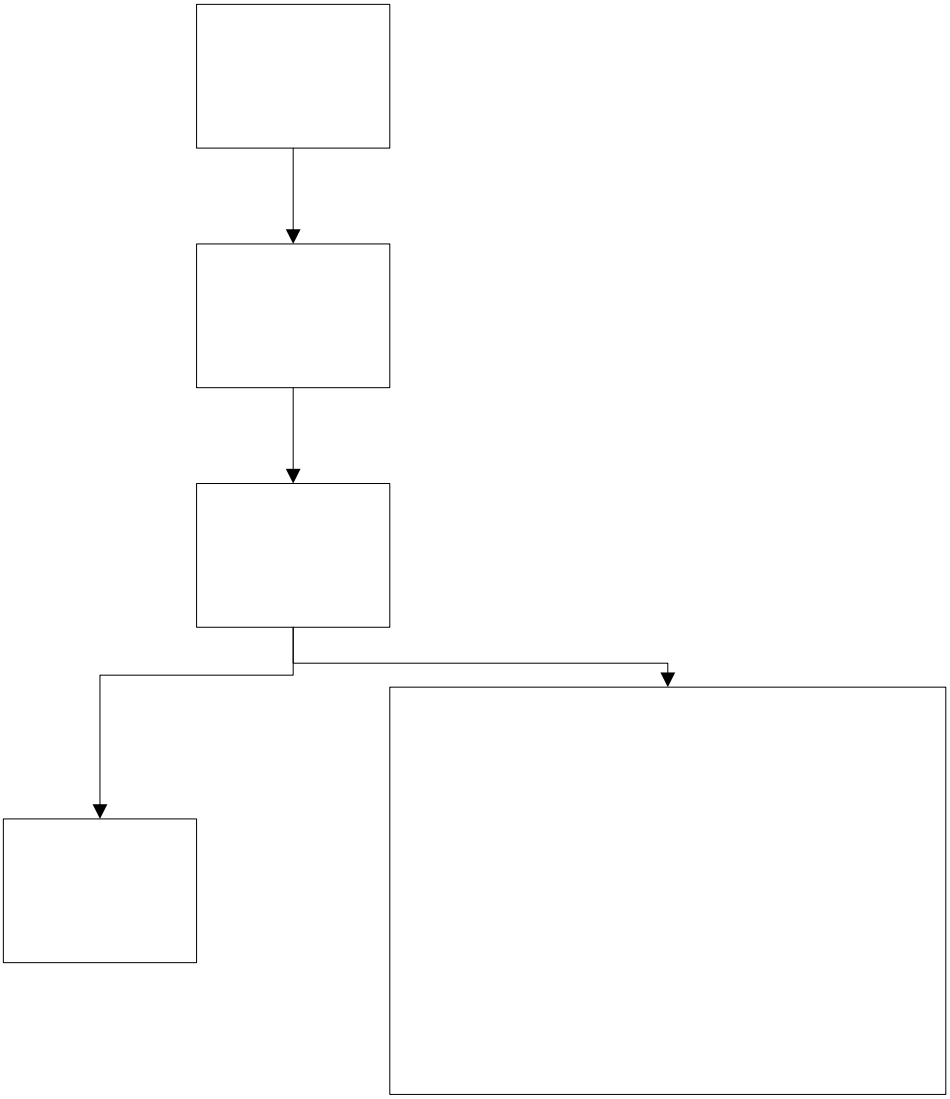
The goal of this systematic literature scan is to provide an overview of the studies performing SRS/SBRT for the treatment of solid tumors outside of the brain. This literature scan will not analyze the quality of the studies nor try to perform any analysis of the data reported by the studies. We have included solid tumors located within the head, but outside of the skull (e.g., eye/orbit, nasopharyngeal).

We have screened the titles of 4,151 citations to determine if the abstract should be reviewed. A total of 1,293 abstracts were screened, and 514 full text articles were ordered for further review. In total, 118 studies were relevant to the topic and data extraction was performed (see Figure 1). The included

studies can be found in **Appendix B**. Included studies, and the excluded studies along with reason for exclusion can be found in **Appendix C**. Excluded studies.

The included studies have been organized into three tables by study design (see **Appendix L**. Results for key question 3). Table 23 lists the non-randomized comparison studies; Table 24 includes the prospective single group studies; and Table 25 consists of retrospective studies. These tables are organized by year of publication (most recent year first), and then alphabetically by author. The study details covered within the tables include: author and year; cancer type; instrumentation/algorithms; study design/study size (n); prior or concurrent treatment; length of follow-up (months), outcomes measured; and adverse events. Patient inclusion criteria have not been included in these tables, but have been addressed in Table 4 in section 3.a.

Figure 1. Study selection process



3.a. Type of cancer and patient inclusion criteria

SRS/SBRT has been proposed as a treatment for several cancers. Our search results identified studies of the use of SRS/SBRT for tumors located in the lung/thorax, spine, pancreas, liver, colon, uterus, pelvis, sacrum, eye/orbit, head and neck, kidney, and prostate. The bulk of the studies were for tumors of the lung/thorax (k = 37),[21-55,118,119] head and neck (k = 22),[56-77] eye/orbit (k = 18),[78-95,120,121] and spine (k = 12).[96-105] We found fewer than ten studies each for tumors located in the pancreas, liver, colon,[122-132] uterus, pelvis, sacrum,[133-136] kidney,[137-140] and prostate.[141-143] There were eight studies that included multiple treatment sites within the study.[144-150]

Patient inclusion criteria for SRS/SBRT treatment varied based on cancer types and individual studies. Criteria commonly used in multiple studies across the different cancer types include: inoperable tumors or patients refusing surgery, biopsy proven disease, a particular patient's life expectancy, no prior RT or prior RT received in an adequate time frame before SRS/SBRT, and a required level of performance on the Karnofsky or World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) scales. The Karnofsky Performance Status (KPS) scoring system measures the cancer patient's abilities to perform ordinary tasks. The scoring system ranges from 0 to 100, and a higher score means a better ability to perform tasks.[151] The retrieved studies often reported KPS scores of at least 40. The WHO/ECOG performance status assesses a patient's functional and/or physical performance. There are six codes used to evaluate a patient, and the codes seen within the retrieved studies were between 0 (fully active) and 2 (ambulatory, capable of self-care but unable to carry out work activities).[152] Since the level of detail of patient inclusion criteria varied with each study, we have provided an overview of the criteria frequently reported within the studies for each cancer type. Table 4 below also lists the cancer type, the number of studies retrieved, and total number of patients.

Table 4. Patient inclusion criteria summary

Cancer type	Number of studies	Total number of patients (n)	Summary of patient inclusion criteria
Gastrointestinal (Colon, Liver, and Pancreas)	11	170	Histologically proven disease, inoperable, tumor size, no prior radiation therapy, life expectancy, WHO/ECOG performance <2, Karnofsky performance >60
Head and Neck	22	799	Histologically proven disease, persistent or recurrent disease, inoperable, tumor size, brachytherapy not an option, Karnofsky performance at least 50
Kidney	4	90	Recurrent disease, inoperable, tumor size, life expectancy, Karnofsky performance >60
Lung/Thorax	37	1,603	Histologically proven disease, inoperable, tumor size, no prior RT or RT received in an adequate time before SBRT, life expectancy, involvement of surrounding tissue, WHO/ECOG performance 0-2, Karnofsky performance <60
Multiple sites (e.g., lung, thyroid, renal, colon, etc. all in one study)	8	308	Inoperable, WHO/ECOG performance <2, Karnofsky ≥70
Ocular	18	1,274	Tumor size, WHO/ECOG 0-1, Karnofsky 70-100
Pelvis, Sacrum, and Uterus	4	60	Inoperable, tumor size, WHO/ECOG performance 1 or 2
Prostate	3	91	Low risk, favorable prognosis, intermediate prognosis
Spine	12	1,189	Histologically proven disease, diagnosed by MRI or CT, Karnofsky performance at least 40

We have put together a table that details the country where the studies took place (see Table 5). Based on our search results, the majority of studies (k = 48) performed since 2000 were in the U.S. Most of the U.S. studies were for tumors located in the lung/thorax, spine, and head and neck. Germany and Japan have also performed several lung studies in the past eight years.

Table 5. Country and number of cancer types

Country	Number of cancer types	Total number of studies
Austria	2 Head & Neck, 5 Ocular	7[63,73,79,83,84,86,95]
Canada	2 GI, 1 Ocular	3[80,122,131]
China	4 Head & Neck	4[59,60,75,76]
Czech Republic	2 Ocular	2[87,93]
Denmark	2 GI, 1 Lung,	3[43,124,125]
Germany	1 GI, 6 Lung, 2 Multiple Sites, 2 Ocular	11[27,32,33,40,53,55,90,91,132,145,150]
Hong Kong	1 Head & Neck	1[77]
Italy	3 Lung, 1 Multiple Sites, 1 Ocular	5[24,45,46,89,146]
Japan	2 Head & Neck, 8 Lung, 1 Multiple Sites	11[21,30,35,37,42,49,51,68,70,118,148]
Singapore	1 Head & Neck	1[67]
Slovakia	1 Ocular	1[82]
South Korea	1 Pelvis, Sacrum, and Uterus, 1 Head & Neck, 2 Lung, 1 Spine	5[39,56,119,121,134]
Spain	1Pelvis, Sacrum, and Uterus, 1 Ocular	2[88,136]
Sweden	1 GI, 1 Kidney, 1 Lung	3[22,123,140]
Switzerland	1 Lung	1[29]
Taiwan	3 Head & Neck	3[57,58,71]
The Netherlands	1 GI, 1 Lung, 1 Multiple Sites, 1 Ocular	4[41,92,130,147]
United Kingdom	1 Ocular	1[78]
USA	4 GI, 2 Pelvis, Sacrum, and Uterus, 7 Head & Neck, 3 Kidney, 13 Lung, 2 Multiple Sites, 3 Ocular, 3 Prostate, 11 Spine	48[23,25,26,28,31,34,36,38,44,47,48,50,52,61,62,64-66,72,74,81,85,94,96-105,120,126-129,133,135,137-139,141-144,149]
USA & China	1 Lung	1[54]
USA & The Netherlands	1 Head & Neck	1[69]

3.b. Type of radiation and instrumentation and algorithms used

Photon radiation was used in all included studies for SRS/SBRT treatment. The instrumentation reported included modified linacs, CyberKnife, Gamma Knife, Novalis Shaped Beam, and Synergy systems. Algorithms are used to plan and deliver treatment, but were not frequently reported in the studies. Of the limited number of studies that reported algorithms, an inverse treatment planning algorithm was specified. An inverse treatment plan allows the physician to input the desired radiation dose into a computer, and the computer develops a detailed plan of the beams required to deliver the prescribed dose. Most of the studies described the treatment plan, imaging procedures, patient set-ups, position verifications, and software used.

SRS/SBRT doses and fractions varied based on factors such as the type of cancer and location of tumor. Typically, doses were delivered between one and five fractions. Eleven studies delivered treatment over five to ten fractions, and still considered this to also be SRS/SBRT. Table 6 lists the eleven studies (also located in **Appendix L**. Results for key question 3) alphabetically by author, and details the cancer type, study design, study size (n), instrumentation/algorithms, and total dose (Gy)/number of fractions.

Table 6. Studies performing more than five fractions

Study	Country	Cancer type	Study design	Study size (n)	Instrumentation/ Algorithms	Total dose (Gy)	Number of fractions
Aoki et al., (2007)[21]	Japan	Primary lung and mets	Case series	n = 19	Mitsubishi EXL-20TP 10-MV standard linac/NR	54	9
Dawson et al., (2006)[122]	Canada	Hepatocellular carcinoma, intrahepatic cholangiocarcinoma, liver metastases	Case series	n = 79	Elekta Synergy/NR	24-57 (Median: 36.6)	6
Guckenberger et al., (2007)[29]	Switzerland	NSCLC and pulmonary metastatic lesions	Non-randomized comparative study (Hypofractionated SBRT (3-8 fractions) vs. 1 fraction SRS)	n = 70	NR/NR	26-56	1-8
Katoh et al., (2008)[65]	USA	Adrenal tumors	Retrospective chart review	n = 9	Linac/NR	48 or 30	8
Katz et al., (2007)[126]	USA	Limited hepatic metastases	Retrospective chart review	n = 69	NR/NR	50	10
Miralbell et al., (2007)[88]	Spain	ocular melanoma	Case series	n = 5	Novalis/NR	50	5 or 10
Ryu et al., (2004)[72]	USA	Squamous cell carcinoma; mucoepidermoid carcinoma, adenoid cystic carcinoma, adenoma, basal cell carcinoma all in the head and neck	Case series	n = 13	Novalis/NR	30-36	5-6

Study	Country	Cancer type	Study design	Study size (n)	Instrumentation/ Algorithms	Total dose (Gy)	Number of fractions
Tse et al., (2008)[131]	Canada	Unresectable hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (IHC)	Case series	n = 41	NR/NR	24-54 (Median: 36)	6
Uematsu et al., (2001)[51]	Japan	Stage 1 NSCLC	Case series	n = 50	FOCAL unit (combination of linac, CT scanner, X-ray simulator, carbon table)/NR	30-60	5-10
Xia et al., (2006)[54]	USA & China	Stage 1 and 2 NSCLC	Case series	n = 43	Gamma-knife (30 rotary conical surface Cobalt 60)/ NR	50-70	10
Yau et al., (2004)[77]	Hong Kong	Persistent nasopharyngeal carcinoma	Retrospective cohort (Brachytherapy boost vs. SRT boost)	n = 45 24 received brachytherapy, 21 received SRT boost	Brachytherapy (MicroSelectron: Nucletron) with iridium 192 SRT (Siemens Mevatron MX-2, a 6 MV linac)/ NR	SRT 20	8

3.c. Study design and study size

Study designs for SRS/SBRT treatment of solid tumors located outside of the brain include non-randomized comparison studies, prospective single group studies, and retrospective studies. Patient populations were heterogeneous across the cancer types, but were as small as three patients for a prospective single group study and as large as 486 for a retrospective study. Table 7, below, lists the smallest and largest patient populations for the studies within each cancer type, and the type of studies conducted for each cancer type. We have also calculated an overall mean and median age for patients within each cancer type (see Table 8). The youngest median and mean age was for the head and neck category (48.4 and 50.6 years respectively), and the oldest median and mean age was 67.5 years for the prostate category.

Table 7. Study designs and sizes

Cancer type	Smallest (n)	Largest (n)	Non-randomized comparison	Prospective single group	Retrospective
GI (Colon, Liver, Pancreas)	n = 4	n = 79	0	9	2
Head and Neck	n = 8	n = 112	4	2	16
Kidney	n = 3	n = 48	0	3	1
Lung/Thorax	n = 9	n = 141	1	24	11
Multiple Sites	n = 14	n = 108	0	4	3
Eye/Orbit	n = 5	n = 211	4	6	8
Pelvis, Sacrum, and Uterus	n = 3	n = 23	0	2	2
Prostate	n = 10	n = 41	0	3	0
Spine	n = 3	n = 486	1	6	6
Total number of studies			**10**	**59**	**49**

Table 8. Overall median and mean ages

Cancer type	Median age (years)	Mean age (years)	Age range (years)
GI (Colon, Liver, Pancreas)	63.4	62.7	27-91
Head and Neck	48.4	50.6	13-85
Kidney	63	61.8	43-85
Lung/Thorax	70.5	69.5	22-96
Multiple Sites	59.5	61.4	2-92
Ocular	61	61.4	21-93
Pelvis, Sacrum, and Uterus	56	63.2	33-92
Prostate	67.5	67.5	48-83
Spine	59	59.8	14-90

3.d. Comparator used in comparative studies

There were 10 studies that compared SRS/SBRT to external body radiation therapy (EBRT), IMRT, brachytherapy, boost SRS, or high dose versus low dose radiation. Most of these studies compared treatments for sites outside of the brain, but located within the head (e.g., uveal melanoma). Table 9, below, lists the comparative studies, the cancer type, and the specific comparator used.

Table 9. Comparative Studies

Study	Country	Study type	Cancer type	Comparison
Douglas et al., (2008)[62]	USA	Non-randomized comparison	Salivary gland	Gamma Knife boost vs. Neutron RT alone
Chua et al., (2007)[60]	China	Non-randomized comparison	Nasopharyngeal Carcinoma	SRS vs. Gold grain implantation (GGI)
Gagnon et al., (2007)[120]	USA	Non-randomized comparison	Breast cancer spinal metastases	SBRT vs. conventional EBRT
Guckenberger et al., (2007)[29]	Switzerland	Non-randomized comparison	NSCLC or pulmonary metastatic lesions	Hypofractionated SBRT (3-8 fractions) vs. 1 fraction SRS
Nijdam et al., (2007)[69]	USA & The Netherlands	Non-randomized comparison	Tonsillar fossa (TF) and soft palate (SP) tumors	IMRT plus CyberKnife SRS vs. IMRT plus Brachytherapy (BT) boost
Furdova et al., (2005)[82]	Slovakia	Non-randomized comparison	Uveal melanoma	SRS or Brachytherapy vs. Enucleation
Yau et al., (2004)[77]	Hong Kong	Non-randomized comparison	Persistent nasopharyngeal carcinoma	SRS boost vs. Brachytherapy boost
Cohen et al., (2003)[78]	United Kingdom	Non-randomized comparison	Uveal melanoma	SRS vs. Enucleation
Georgopoulos et al., (2003)[83]	Austria	Non-randomized comparison	Uveal melanoma	Fractionated high-dose gamma knife stereotactic teletherapy (GK) vs. Fractionated linear accelerator-based stereotactic teletherapy vs. Ruthenium-106 radioactive plaque brachytherapy (RU)
Langmann et al., (2002)[86]	Austria	Non-randomized comparison	Uveal melanoma	High dose SRS vs. Low dose SRS

3.e. Concurrent and/or prior treatments used

The prior and concurrent treatments used varied with each study based on the population evaluated, and on inclusion and exclusion criteria (see the tables in **Appendix L**. Results for key question 3). Some studies included patients with prior and/or concurrent treatment, while other studies excluded patients with prior or concurrent treatment. Prior treatments reported include surgery, radiation therapy (e.g., IMRT, brachytherapy), pharmaceuticals (e.g., tamoxifen), and/or chemotherapy. Some studies specified that prior radiation therapy or chemotherapy had to be completed within a certain timeframe before SRS/SBRT (e.g., 12 weeks). Chemotherapy was the concurrent treatment most often reported within the studies.

3.f. Length of follow-up

The individual study length of follow-up was reported as a mean, median, and/or range. We have calculated an overall mean and median for the length of follow-up for each cancer type. The shortest median and mean follow-up was within the multiple site category (7 and 9.3 months respectively), and the longest median and mean follow-up was within the prostate category (37 months). Table 10 lists the cancer types and the calculated overall median, mean, and range of follow-up within each cancer type.

Table 10. Overall median and mean follow-up

Cancer type	Median follow-up (months)	Mean follow-up (months)	Follow-up range (months)
GI (Colon, Liver, Pancreas)	15.1	17.7	2-101
Pelvis, Sacrum, Uterus	12.6	16.53	2-65
Head and Neck	21.8	29.1	1.2-144
Kidney	31.9	32.1	11-66
Lung/Thorax	14	16.5	1-107
Multiple Sites	7	9.3	1-50
Ocular	31.3	28.1	1-120
Prostate	37	37	2 weeks - 60 months
Spine	9	10.7	0-49.6

3.g. Outcomes measured

The outcomes measured typically included tumor control or tumor response, toxicity, and overall survival. Some studies focused on pain improvement (e.g., relief from spinal compression due to tumor). Overall cause-specific survival rates (chances of death due to cancer at a defined time point), overall survival rates (chances of death due to cancer and/or other complications at a defined time point), and disease-free survival rates were typically calculated using the Kaplan-Meier method. Most studies used four criteria to measure tumor control or tumor response: complete response (disappearance of tumor),

partial response (percentage of decrease in tumor size), stable disease (smaller percentage than partial response of tumor shrinkage), and progression of disease (increase in tumor size). The percentages of tumor response varied with each study. Table 11 lists a summary of the types of outcomes measured within each cancer type.

Table 11. Summary of outcomes measured

Cancer type	Summary of outcomes measured
GI (Colon, Liver, Pancreas)	Toxicity, tumor response, overall survival, progression-free survival, regional failure
Head and Neck	Tumor response, overall survival, local failure, disease-free survival, symptom improvement, toxicity, QoL
Kidney	Survival, pain assessment, tumor response, toxicity
Lung/Thorax	Tumor response, overall survival, cause-specific survival, toxicity
Multiple Sites	Morbidity, tumor response, quality of treatment, survival, local failure, local progression, disease-free survival, toxicity, pain relief
Ocular	Metastasis-free survival, disease-free survival, tumor response, visual acuity, overall survival, eye retention rate, toxicity
Pelvis, Sacrum, Uterus	Pain relief, tumor response, toxicity, local failure
Prostate	PSA response, QoL
Spine	Toxicity, pain relief, neurological improvement, tumor response, overall survival, activity

PSA – Prostate specific antigen
QoL – Quality of Life

Evaluating the extent of cell destruction caused by SRS/SBRT can be a difficult task, as older calculation methods (e.g., linear quadratic model (LQ)) were developed for use with conventional radiation therapy. The LQ model assumes there are two components of radiation cell destruction: one component proportional to dose and one component proportional to the square of the dose.[113] The application of the LQ model for low dose conventional fractions may not have the same consequences as the use of the model with SRS/SBRT. The LQ model possibly overestimates cell destruction, and it may not describe the cell survival curve for the high doses of SRS/SBRT properly.[113] Making comparisons between studies for SRS/SBRT can also be challenging. Studies may report equivalent prescription doses; however, differences in fractionation schedules can result in a substantial difference in the biologically effective dose (BED).[113] The BED is an index that can serve as a useful parameter for comparing the potency of two different fractionation schedules.[153]

3.h. Adverse events, harms, safety issues reported

Radiation Therapy Oncology Group criteria and Common Toxicity Criteria version 2.0 (RTOG/CTC) were typically used to grade acute and late toxicity at each follow-up. In general, Grade 1 toxicities require no treatment, Grade 2 toxicities require medication or a simple intervention, Grade 3 toxicities have more severe symptoms and require more complex interventions, and Grade 4 toxicities can be life threatening.[143] Some studies reported acute versus late complications; however, they did not always specify complications related to individual patients. Some of the most frequently reported adverse events include pain, fatigue, nausea, bleeding, and diarrhea. There were a total of 11 studies that did not report any adverse events for tumors located at the following sites: two head and neck[68,70], one kidney[138], three lung,[28,34,43] one multiple sites,[149] two eye/orbit,[78,88] and two spine.[99,105] Also, some studies did not report adverse events using the RTOG/CTC scale, or stated that investigators and/or patients observed or reported no adverse events. Table 12 summarizes the reported adverse events for the studies within each cancer type.

Table 12. Summary of adverse events

Cancer type	Summary of adverse events
GI (Colon, Liver, Pancreas)	Severe mucositis, epigastric pain, fatigue, deterioration hepatic, abdominal pain, bleeding esophageal varices
Head and Neck	Necrosis, hemorrhage, grade 2/3 mucositis, pain, difficulty swallowing, nosebleed, carotid aneurysm, moderate to severe headaches
Kidney	Fatigue, cough, nausea, vomiting
Lung/Thorax	grade1-4 toxicities, skin rash, pneumonitis, cough, coastal fracture, pneumothorax (fiducial placements), chest wall pain, fatigue, nausea, interstitial local lung tissue changes
Multiple Sites	Grade1-4 toxicities, pain, nausea, diarrhea, rectal bleeding
Ocular	Radiation retinopathy, post-treatment cataracts, neovascular glaucoma, decline visual acuity, vitreous, hemorrhage, retinal detachment, herpes Zoster, subretinal bleeding
Pelvis, Sacrum, Uterus	Abdominal pain, rectal bleeding, nausea
Prostate	Mild rectal toxicity, urinary toxicity, rectal discomfort, diarrhea, occasional blood, constipation
Spine	Necrosis, transient radiculitis, mild transient laryngitis, neurological deterioration, nausea, vomiting, chest pain, diarrhea, vertebral body collapse, motor weakness

Discussion

External radiation treatment has long been a mainstay of cancer treatment. Advances in this technology, have allowed smaller and hard to target tumors to be treated; reducing the amount of radiation received by adjacent healthy tissue. SRS/SBRT is a noninvasive procedure that provides a treatment option for tumors located outside of the brain that are considered inoperable.

This Technical Brief provides a broad overview of the current state of SRS/SBRT for the treatment of extracranial solid malignant tumors. Aspects of the brief include current technologies available to deliver SRS/SBRT; types and locations of tumors that have been treated with SRS/SBRT; the possible advantages and disadvantages of the technology; the extent of diffusion of the technology; and information about advances in the technology that are currently in development. We searched the internet for gray literature to identify information for cancer sites outside of the brain, theoretical advantages and disadvantages of SRS/SBRT, and potential safety issues and harms. Specialized instrumentation for SRS/SBRT, the FDA status, technologies in development, and an estimate of the number of hospitals performing SRS/SBRT in the U.S were also explored using the internet. We feel that this was the best approach to obtain information addressing key questions one and two. If the literature searches for key question three returned relevant information, we also included it in the first two key questions. The information collected for key questions 1 and 2 may not be inclusive of all resources.

The study designs identified in our literature search for SRS/SBRT treatment of solid tumors located outside of the brain included non-randomized comparison studies, prospective single group studies, and retrospective studies. The majority of studies were prospective single group studies and retrospective studies. There were several studies that included duplicate populations. In these instances, we only included the most recent study.

The bulk of the studies were for tumors located in the lung/thorax (k = 37), head and neck (k = 22), eye/orbit (k = 18), and spine (k = 12). We found fewer than ten studies each for tumors of the pancreas, liver, colon, uterus, pelvis, sacrum, kidney, and prostate. These tumor sites can cause treatment difficulties, as there may be periodic (e.g., respiratory movement), irregular (e.g., peristalsis), or permanent (e.g., shrinkage of tumor) movement between fractionated treatments.

Each study's length of follow-up was reported as a mean, median, and/or range. However, loss to followup was not consistently reported. We calculated overall mean and median follow-up, and the shortest median and mean follow-up was within the multiple cancer site category (7 and 9.3 months respectively), and the longest median and mean follow-up was within the prostate category (37 months). The outcomes measured typically included tumor control or tumor response, toxicity, and overall survival, and were often reported in a similar way (e.g., Kaplan-Meier method).

There were a total of ten studies that compared either high dose SRS/SBRT to low dose SRS/SBRT, or SRS/SBRT to another form of radiation (external or internal), or SRS/SBRT with a surgical procedure. Non-randomized comparisons between these options are helpful to guide the design of more stringent studies (e.g., randomized control trial (RCTs)). However, random assignment of patients to high dose delivery with lower doses of external beam radiation may not provide clinically relevant information because some tumors/patients may be more appropriately treated with one modality rather than the other.

The available literature addressing SRS/SBRT is considerably large. This literature base includes many theoretical treatment planning studies and treatment technique studies. This information is important for the development of the technology and its expansion in the future for use to treat cancers in many locations throughout the body. One of the most important aspects of SRS/SBRT is the quality control and quality assurance of the treatment planning and treatment delivery. Locations within the body tend to move (e.g., liver, prostate), and therefore tumor tracking techniques will continue to play an integral role in the procedure. Randomized controlled trials may help determine maximum number of radiation fractions, the minimum radiation dose per fraction, or the maximum number and diameter of lesions for a SRS/SBRT treatment. A systematic review and potentially a meta-analysis may provide useful information for future study development, adverse events, fractionation schedules, follow-up lengths, patient inclusion criteria, and measured outcomes for a specific cancer type and site of disease. However, with only a limited number of comparison studies available to date, providing a definitive answer for efficacy and safety may not be achievable at this time.

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