CLINICAL PRACTICE
GUIDELINES ON
RADIOSURGERY AND
STEREOTACTIC RADIOTHERAPY

Academy of Medicine, Singapore
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I. INTRODUCTION

Stereotactic radiosurgery (SRS) is a minimally invasive technique, which delivers a single, high-dose ionising radiation that conforms to the shape of the intracranial target volume with a steep dose gradient at the target periphery. It was introduced in 1994 using the linear accelerator-based system. The Gamma Knife was acquired in 1995.

The Gamma Knife is constructed for radiosurgery of intracranial lesions. It consists of 201 cobalt sources, arranged in a hemisphere in such a way that all beams converge on the same focal point. An interchangeable secondary collimator system, with four different collimator sizes ranging from 4 to 18 mm, gives the machine a capacity to create spheres of radiation of four different sizes. The mechanical accuracy is within 0.1 mm and is stable over time. Currently, the Gamma Knife is not routinely adapted for multiple fractions of radiosurgical treatments.

The linear accelerator-based radiosurgical system uses a modified linear accelerator (LINAC). The LINAC is a routine device employed to deliver fractionated external beam radiation treatment of tumours in any location of the body. It is modified for radiosurgery by the addition of a secondary collimator to provide small X-ray beams for irradiation of the target lesion.

The LINAC uses either converging arc beams or static fields with different collimator sizes, resulting in a higher degree of homogeneity. The beam shape and dose intensity can be respectively modified by the use of multi-leaf shielding and intensity modulated software to achieve a higher degree of conformity.

A radiosurgical procedure starts with the application of a stereotactic frame on the head of the patient. After stereotactic localisation of the lesion using the appropriate imaging modality [almost exclusively magnetic resonance (MR) imaging currently due to its superior image resolution], dose planning is performed. The aim of dose planning is to have an exact match between the radiation field and the target volume, achieved by using one or more isocentres. During the treatment, the head of the patient is immobilised in order to ensure the required accuracy.
Stereotactic radiotherapy (SRT) uses the accuracy of stereotactic localisation to deliverfractionated radiation treatment. The well-defined treatment isodoses are useful in tumours without widespread extension and are useful in boosting small, residual or recurrent tumours.

Imaging, planning and treatment occur on the same day for single fraction treatments and should be accurate to within 1 mm. This leaves little room for error in the overall process. Hence, quality control is essential, especially in the LINAC radiosurgical system with its heavy moving parts.

This document outlines the standards and describes a minimal set of criteria for a SRS quality-assurance programme adapted from the American College of Radiology Standard for the performance of Stereotactic Radiation Therapy/Radiosurgery(1) and a consensus statement by the American Association of Neurological Surgeons Task Force and American Society of Therapeutic Radiation Oncologists Task Force(2). It also incorporates the consensus guidelines on Patient Selection Criteria from our working group.

II. QUALITY CRITERIA FOR RADIOSURGERY

Radiosurgery can be divided into three equally important steps: patient selection, patient treatment and follow up. It is impossible for any centre to perform state-of-the-art radiosurgery without having expertise in all these steps.

A. PATIENT SELECTION

For some diagnoses, e.g. arteriovenous malformations (AVMs), trigeminal neuralgia and acoustic neuromas, both radiosurgery and microsurgical removal of the lesion should be considered. Only a properly trained neurosurgeon has the knowledge to compare these two treatment options and chose the one best for the patient. For other diagnoses, e.g. benign and malignant primary brain tumours, multiple meningiomas, the expertise of a properly trained radiation oncologist is necessary to decide between radiosurgery and fractionated radiotherapy to treat the disorder. Finally, for some lesions, e.g. multiple brain metastases, the input is necessary both from the neurosurgeon and the radiation oncologist to optimise treatment for the patient. Radiosurgery should only be used when it is considered beneficial for the patient; this treatment should never be indicated due to a lack of other treatment options.

B. PATIENT TREATMENT

The expertise needed when treating the patient varies with the equipment used. For Gamma Knife radiosurgery, the knowledge of a neuroradiologist is necessary, for defining the optimal imaging technique needed to visualise and outline the target as accurately as possible, by defining optimal examination protocols, optimal slice thickness, etc. For MR, a routine QC for distortion is also necessary. The knowledge of a physicist is essential in transporting the images from the scanner to the dose planning computer, and in defining the images in stereotactic space. The knowledge from a neurosurgeon is critical to define the neuroanatomical relation between the target volume and the surrounding critical structures, e.g. the chiasma and the other cranial nerves. This knowledge is also mandatory when the doseplan is made in order to achieve maximal conformity with minimal risk for radiation-induced damage to healthy tissue. Finally, the knowledge of both a neurosurgeon and a radiation oncologist is needed to define the accurate prescription dose in order to have an optimal cost/benefit relation. Naturally, all the specialists mentioned above need to have proper training and knowledge for the task.

C. PATIENT FOLLOW UP

The aim of radiosurgery is to inactivate a lesion or obliterate an AVM. Thus, regular follow up is necessary after the treatment; how often and how long is dependent on the pathology of the disease being treated. Knowledge in image interpretation and in the natural course of the disease is necessary to correctly interpret the clinical and radiological follow-up information. For most cases, a treatment team consisting of the neurosurgeon and radiation oncologist is best qualified to properly interpret the follow up information.

Feedback is also mandatory in the process of optimising the radiosurgical treatment itself as well as the inclusion criteria for patient selection.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

The following are minimal recommendations for staffing levels and their responsibilities while participating in an SRS procedure. Specific duties may be reassigned where appropriate.
A. The Neurosurgeon

An accredited neurosurgeon should have a commitment to and training in radiosurgery, with expertise in tumour and vascular malformation management, including target definition, the principles of computed tomography (CT), MR imaging, angiographic imaging, basic radiation therapy and radiobiology. The responsibilities of the neurosurgeon should be clearly defined and should include the following:

1. Participate in initial treatment management, when necessary, with the therapeutic radiologist.
2. Apply the stereotactic head frame.
3. Oversee radiosurgery management of the patient.
4. When necessary, in concert with a neuroradiologist, locate and specify the target volume and relevant critical normal tissues.
5. Perform the iterative process of plan development.
6. Ensure that patient alignment on the treatment unit is appropriate.
7. Follow the patient for control of abnormalities and for monitoring potential complications.

B. The Therapeutic Radiologist / Radiation Oncologist

An accredited radiation oncologist or therapeutic radiologist, who should have a commitment to and training in radiosurgery, is required to perform this procedure. The responsibilities of the therapeutic radiologist shall be clearly defined and should include the following:

1. Assess the suitability of the tumour for treatment and the possible side effects.
2. Define the tumour volume and where necessary, seek the participation of the neuroradiologist and neurosurgeon.
3. Review the treatment plan and modify it where necessary, taking into consideration the critical organs adjacent to the tumour.
4. Confirm the treatment plan and supervise the treatment.
5. Follow up for response and monitor side effects of the treatment.
6. In the case of Stereotactic Radiotherapy, the radiation oncologist assumes the role of the primary physician in carrying out the treatment as in any case requiring radiotherapy.

C. Radiation Physicist

A qualified radiation physicist must have at least three years working experience in Therapeutic Radiological Physics in a clinical environment with training in Stereotactic Radiosurgery. The responsibilities of the qualified radiation physicist shall be clearly defined and should include the following:

1. Acquire and ensure the accuracy of beam and treatment planning data.
2. Perform QA checks on the treatment unit and its associated equipment for stereotactic radiosurgery.
3. Plan treatment and the handling of CT, MRI and angiography data.
4. Verify treatment time.
5. When necessary, counter-check treatment parameters during patient set-up and treatment.

D. Therapeutic Radiographer

The qualified therapeutic radiographer should have training in Stereotactic Radiosurgery. The responsibilities of the therapeutic radiographer shall be clearly defined and may include the following:

1. Prepare the treatment room for the stereotactic radiosurgery procedure.
2. Assist the treatment team with patient positioning/immobilisation.
3. Operate the treatment unit after the clinical and technical aspects for beam delivery have been approved by the neurosurgeon, therapeutic radiologist and qualified radiation physicist.
E. Other Team Members

A multidisciplinary team should include a neuroradiologist, nursing staff, and for children and young adults, an anaesthetist.

F. Training Guidelines

The multidisciplinary team performing stereotactic radiosurgery should have broad expertise. The neurosurgeon should have expertise in conventional stereotactic surgery, microsurgery, and the selection of target volumes defined by neuroimaging. The neurosurgeon and the therapeutic radiologist should be familiar with the principles of stereotactic imaging and should have experience or training with precise single-fraction irradiation of small-target volumes. Each member of a team initiating a radiosurgical programme should have specific, intensive, and documented training in radiosurgery. Such training includes attendance at specific courses or symposia and a site visit and observation of patient planning and treatment at one or more centres currently performing radiosurgery. Education should include an analysis of previous results, patient selection guidelines, stereotactic head-frame application techniques, stereotactic neurodiagnostic imaging using all pertinent modalities, target selection, dose determination, dose prescription, treatment delivery, and instructions regarding radiation effects, protection, and recognition of complications.

For radiation oncology, it is recommended that there should be a satisfactory supervised performance of the first 10 cases at an accredited centre under the guidance of an accredited radiation oncologist in Radiosurgery.

There should be a minimum of 1 week radiosurgical training in an accredited centre and should include hands-on training in the treatment planning and quality assurance procedures.

IV. QUALITY CONTROL OF THE TREATMENT UNIT

The mechanical precision and electronic complexity of the treatment-delivery unit requires the implementation of and adherence to an ongoing QC programme. The QC programme assures that the SRS treatment unit is in compliance with recommendations of the treatment unit manufacturer, the specified clinical tolerances, and possibly, regulatory requirements. It is recognised that various test procedures, with equal validity, may be used to ascertain that the treatment-delivery unit is functioning properly and safely.

The test results should be documented, archived, and signed by the person doing the testing. Important elements of the treatment-delivery unit QC programme are:

1. Radiation-beam alignment testing to assure the beam is correctly aimed at the targeted tissues.

2. Radiation dose per unit time (or per monitor unit) calculation based on physical measurements for the treatment field size at the location of the target.

V. QUALITY CONTROL OF THE STEREOTACTIC ACCESSORIES

Ancillary instrumentation used to determine the stereotactic coordinates of the target and used to immobilise the patient with accuracy and precision should be routinely monitored to assure that it is functioning properly and within their specified tolerances.

VI. QUALITY CONTROL OF IMAGES

SRS is an image-based treatment. All salient anatomical features of the SRS patient, both normal and abnormal, are defined with CT, MR, or angiography. Both high 3-D spatial accuracy and tissue-contrast definition are very important imaging features if one is to utilise SRS to its fullest positional accuracy.

The medical images used in SRS are critical to the entire process. They are used for localisation of the target boundaries as well as the generation of the target coordinates at which the treatment beams are to be aimed. They are used for creating an anatomical patient model (virtual patient) for treatment planning, and they contain the morphology required for the treatment plan evaluation and dose calculation. Accuracy and precision required by SRS must be assured. This assurance issue is addressed in the QC programme for the treatment-planning system. However, general consideration should be given to the following issues:

1. The targeting of AVMs for SRS planning may include plain film angiography, CT angiography, and MR angiography. Digital angiography must be thoroughly investigated for SRS use to correct for potential spatial distortions that may arise from the imaging chain.

2. MR imaging is the most useful imaging modality for radiosurgery due
to the better visualisation of the target tissue and normal tissue structures. However, there is a problem with magnetic susceptibility artefacts and image distortion inherent with this technique. Routine QA is therefore necessary to ensure that the distortion is at a subclinical level. The MR images must therefore always be checked, and phantom measurements must be performed on a regular basis. CT imaging can also be performed, and the dose distribution from the final dose plan compared between the MR and CT images.

VII. QUALITY CONTROL FOR THE 3-D IMAGE-BASED TREATMENT-PLANNING SYSTEM

In Gamma Knife radiosurgery, the dose planning software is an integrated part of the Gamma Knife system. It is developed by the manufacturer of the hardware, who also guarantees the accuracy of the software and the resulting treatment plan, i.e. that the dose will be delivered exactly as in the dose plan. For LINAC-based radiosurgery system, where the hardware and the software are delivered by different manufacturers, the situation is different. Here, the 3-D image-based radiation therapy treatment-planning (RTP) systems use data input from medical imaging devices in conjunction with a mathematical description of the external radiation beams to produce an anatomically detailed patient model, illustrating the dose distribution with a high degree of accuracy and precision. Because of the system's complexity, the qualified medical physicist may elect to perform the required validation and verification testing that only reflect the features of the system that are in current clinical use at the facility (e.g., testing the system's ability to fuse MR and CT data would not have to be done in a department that only uses CT images).

Documentation must exist to indicate that the qualified medical physicist has authorised the system for clinical use and established the QC programme to monitor the 3-D system's performance as it relates to the 3-D planning process. Consequently, the QC programme involves elements that may be considered to be dosimetric and nondosimetric in nature. Furthermore, it is recognised that various testing methods may be used, with equal validity, to assure that a system feature or component is performing correctly. It is also noted that the commercial manufacturer may recommend specific QC tests to be performed on its planning systems. For these reasons, the important elements of the QC programme for the 3-D image-based (RTP) system are identified, but the method and testing frequency are not specified. Information with more scientific detail may be found in the AAPM TG-53 report.

A. System Maintenance and Fault Reporting Log

An ongoing system log should be maintained, indicating system component failures, error messages, corrective actions, and system hardware/software changes.

B. System Data Input Devices

Image-based planning systems' input devices, such as digitiser tablets, medical imaging data (CT, MR, angiography, etc.) input interface and video digitisers, should be checked for functionality and accuracy, to assure correct anatomical registration (left, right, anterior, posterior, cephalad and caudal).

C. System Output Devices

All printers, plotters, and graphical display units that produce, using digitally reconstructed radiographs (DRR) or the like, a beam's eye view (BEV) rendering of anatomical structures near the treatment beam isocentre, must be checked and assured of functionality and accuracy. Correct information transfer and appropriate dimensional scaling must be ensured.

D. System Software

The continued integrity of the RTP system data and information files used for modelling the external radiation beams must be ensured. There must be confirmed agreement of the beam modelling to currently accepted clinical data derived from physical measurements. Similarly, the integrity of the system to render the anatomical modelling correctly must be ensured.

VIII. VALIDATION OF THE TECHNIQUE AS IMPLEMENTED

In LINAC radiosurgery, once the individual components of the SRS planning and treatment technique are commissioned, it is recommended that the QC programme include an "operational test" of the SRS system. This test should be performed before treating the patient's brain with the single, high radiation dose. The "operational test" should mimic the patient treatment and should utilise the same equipment used for treating the patient. An added benefit to the above approach would be the training of each team member for his/her participation in the procedure.
IX. FOLLOW-UP GUIDELINES

The diligent post-treatment assessment of patients is critical both to the individual patient and to the field of stereotactic radiosurgery in general. Information acquired may prove crucial to the subsequent management of other patients; an incipient radiation-induced neurological deficit might be forestalled by medical therapy, a persistent filling AVM might require retreatment; and a recurrent tumour might need microsurgical resection. Similar findings commonly encountered might warrant modification of the criteria for patient selection or changes in treatment parameters. Follow-up evaluations should be timed so as to optimise the chance of detecting both the complication of and the favourable responses to treatment. Evaluation should be standardised and, whenever possible, be conducted by the treating physician. Results should be compiled, analysed, and shared with others performing radiosurgery.

X. PATIENT SELECTION GUIDELINES

A. Patient Selection

The selection of patients for stereotactic radiosurgery involves a judicious balance of the benefits versus the risks of radiosurgery, relative to the natural history of the disease and to those of alternative therapies. The relative demographic and medical profile of the individual patient, as well as the nature, size, shape, and location of the lesion, must be considered in assessing the relative risks and benefits of stereotactic radiosurgery. This assessment requires a combination of neurodiagnostic, neurosurgical, therapeutic radiological, and radiation physics expertise.

Radiosurgery has often been used to treat relatively small, well-circumscribed tumours or vascular malformations readily identified by current high-resolution neuroimaging techniques. The selection of radiosurgery in lieu of other treatment modalities involves assessments of its risks and likely benefits in the context of patient preference, the neurological hazards of open surgical resection that requires general anaesthesia, the need for precise targeting during irradiation and the radiobiological efficacy of alternative radiation techniques.

B. Patient Selection Criteria

Literature searches did not yield any published clinical practice guidelines on patient selection criteria for radiosurgery.

However, the working group deems it necessary to establish consensus guidelines on patient selection criteria while waiting for the outcome of the development of a more comprehensive clinical practice guideline.

Consensus Patient Selection Criteria

1. Intracranial or base of skull lesions less than 35 mm in diameter.\(^{(2)}\)
2. Lesion(s) must be measurable on CT, MRI or angiography.\(^{(4)}\)
3. Histologic diagnosis where feasible.\(^{(4)}\)
4. Life expectancy of greater than three months.\(^{(4)}\)
5. Karnofsky Performance Status of at least 70.\(^{(4)}\)
6. Medically and psychologically capable of tolerating the procedure.\(^{(4)}\)
7. Controlled primary or metastatic disease.\(^{(4)}\)
8. No lesion within 2 mm of optic apparatus (optic apparatus should receive less than 8 Gy of radiation dose)
9. Specific diagnosis as defined by the following categories:\(^{(3)}\)

Category A

These are generally well-accepted indications for radiosurgery, but not all indications here are proven in a randomised controlled trial, hence it is not exactly equivalent of standard therapy.
- Schwannoma;
- AVM;
- Meningioma;
- Metastases.

Category B

These are indications that are less well accepted but with enough scientific evidence to support the use of radiosurgery.
- Trigeminal neuralgia;
- Pituitary adenoma.
**Category C**

In this category would lie unproven, experimental or controversial indications for radiosurgery (NB: this list is not exhaustive):
- Malignant glial tumours;
- Cavernous angioma;
- Craniopharyngioma;
- Nasopharyngeal carcinoma;
- Haemangioblastoma;
- Ependymoma;
- PNET;
- Pineal tumours including germinoma;
- Chordoma;
- Chondrosarcoma;
- Pallidotomy and thalamotomy for Parkinson's disease;
- Thalamotomy for essential tremor;
- Thalamotomy for pain;
- Cluster headache;
- Cingulotomy/anterior capsulotomy for psychosurgical indications or cingulotomy for pain;
- Amygdalo-hippocampectomy for epilepsy.

Note: The above selection criteria are to be used by physician as a general guide only. Actual eligibility must be determined on a case-by-case basis. The guidelines do not absolve clinicians of responsibility to individual patients.

In the case of stereotactic radiotherapy, the patient selection criterion is similar to patients requiring radiotherapy. However, as the data for its use is only now being gathered worldwide, patients must be told that there is only, at best, well-designed controlled studies without randomisation (Evidence level II) for use.

**Informed consent**

Informed consent describing the risks, benefits and alternatives should be explained to patients prior to commencement of the procedure.

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**XI. SUMMARY**

The quality of a SRS programme is only as good as its weakest link. It is a very involved procedure requiring participants from many disciplines. High spatial accuracies are expected, and time constraints are short. Equipment foreign to conventional radiation therapy is used. The treatment is given only once, so there is little chance for adjustment afterward. All of the above demands a highly organised and efficient SRS team. Checklists are required to ensure that all aspects of the procedure are completed properly by each team member. The procedure must be appropriately staffed. Adhering to these details and those elaborated above provide the basis for a high standard of practice.
REFERENCES


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