Complete Summary

GUIDELINE TITLE

Stereotactic radiosurgery for patients with vestibular schwannomas.

BIBLIOGRAPHIC SOURCE(S)

International RadioSurgery Association (IRSA). Stereotactic radiosurgery for patients with vestibular schwannomas. Harrisburg (PA): International RadioSurgery Association (IRSA); 2006 May. 16 p. (Radiosurgery practice guideline report; no. 4-06). [110 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Vestibular schwannoma (acoustic neuroma)

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Internal Medicine
Neurological Surgery

Neurology
Radiation Oncology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Hospitals
Managed Care Organizations
Nurses
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To develop an evidence and consensus-based stereotactic radiosurgery practice guideline for radiosurgery treatment recommendations to be used by medical and public health professionals following the diagnosis of vestibular schwannoma

TARGET POPULATION

Patients diagnosed with vestibular schwannoma (acoustic neuroma)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Pre-radiosurgery evaluation including
    - High resolution magnetic resonance imaging (MRI) (or computed tomography [CT] in patients who cannot undergo MRI)
    - Audiological tests (pure tone average [PTA] and speech discrimination score [SDS]
2. Radiosurgery using Gamma Knife, modified linear accelerators (LINACs), or proton beam
3. Pre-radiosurgery corticosteroids (a single stress dose or several doses at regular intervals on day of procedure)
4. Follow up including MRI scans at specific intervals, hearing level assessment, and assessment for hydrocephalus if indicated
5. Surgical decompression for patients with large tumors causing brainstem compression
6. Shunt insertion prior to radiosurgery for patients with hydrocephalus but without symptoms of brainstem compression

MAJOR OUTCOMES CONSIDERED

- Tumor growth control
- Hearing and speech preservation rate
- Facial nerve and trigeminal nerve function
- Complication rates
- Hospital length of stay and total management charges
- Mean time away from work
- Overall patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE and PUBMED searches were completed for the years 1966 to March 2006. Search terms included vestibular schwannoma, schwannoma, neuroma, neurinoma, stereotactic radiosurgery, stereotactic radiation therapy, Gamma Knife®, CyberKnife®, linear accelerator, irradiation, proton beam, clinical trial, research design, practice guidelines, and meta-analysis. Bibliographies from recent published reviews were reviewed and relevant articles were retrieved.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review
Review of Published Meta-Analyses

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The working group included physicians from the staff of major medical centers that provide radiosurgery. Two members of the working group reviewed the identified literature; opinions were sought from experts in the diagnosis and management of vestibular schwannoma, including members of the working group.

The initial draft of the consensus statement was a synthesis of research information obtained in the evidence gathering process.

Members of the working group provided formal written comments that were incorporated into the preliminary draft of the statement. No significant disagreements existed.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The final statement incorporates all relevant evidence obtained by the literature search in conjunction with the final consensus recommendations supported by all working group members listed in the original guideline document.

This practice guideline, together with a report on "Vestibular Schwannoma Management" is an original guideline approved by the IRSA® (International RadioSurgery Association) Board of Directors and issued in May 2006.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Patients with vestibular schwannomas defined by modern neurodiagnostic imaging (computed tomography [CT], magnetic resonance imaging [MRI]) constitute the study group. Such patients typically present with symptoms of hearing loss, tinnitus, and/or imbalance. Vestibular schwannomas are considered suitable for various management strategies such as observation with serial imaging, stereotactic radiosurgery, and surgical excision. Stereotactic radiosurgery is typically employed as the first management option in patients with small to medium size tumors (without symptomatic brainstem compression). It is also used to control growth of recurrent or residual tumor after surgical resection. Stereotactic radiosurgery, a minimally invasive, single high-dose, closed skull management strategy, may be especially suitable for patients who desire preservation of neurological function (cochlear, facial nerve) and a high rate of tumor growth control.
- Stereotactic volumetric MR imaging (high resolution) is usually necessary for precisely conformal dose planning. Contrast-enhanced gradient recalled MR images are ideal for radiosurgery dose planning. T2 weighted MR images (3-D volume) are helpful in defining the cranial nerves and the inner ear structures

(cochlea and semicircular canals). Sharp fall-off of the radiation dose outside of the target volume is required.

- Current radiation delivery technologies for volumetric conformal stereotactic radiosurgery include Gamma Knife®, proton beam using the Bragg peak effect, and specially modified linear accelerators (LINACs).
- The optimal single session dose range for volumetric conformal stereotactic vestibular schwannoma radiosurgery has been largely established based on tumor anatomy (proximity of brainstem), hearing status, tumor volume, and estimated adverse radiation risks. Minimum doses to the margin of vestibular schwannoma typically range from 12–13 Gy in a single session.
- Depending upon treating physicians' preferences, patients may or may not receive a single stress dose of corticosteroids at the beginning or conclusion of the radiosurgery procedure. Alternatively several doses of steroids at regular intervals (3–4 hourly) can be given on the day of the procedure. Patients can continue to take other medications as recommended by their physicians.
- Post-radiosurgical clinical examinations and MR studies are typically performed at predetermined intervals such as at six months, one year, two years, and four years. For patients with preserved serviceable hearing, audiograms are recommended at intervals coinciding with clinical and neuroimaging re-evaluations. Tumors proven to be stable over 4–5 years can subsequently be reassessed at 2–4 year intervals.
- Patients with large tumors causing symptomatic brainstem compression should be managed with surgical decompression of the tumor. Residual tumor can be treated by radiosurgery.
- Patients with hydrocephalus but without symptoms of brainstem compression can have a shunt inserted prior to radiosurgery, especially if the patient is aged or medically infirm and consequently not a good candidate for resection.
- Causes for failure of stereotactic radiosurgery include inadequate visualization of the tumor, lack of intraoperative stereotactic 3-D (volumetric) imaging, and insufficient dose (due to large tumor volume and proximity to the brainstem) to achieve a growth control response.

Stereotactic Radiosurgery for Vestibular Schwannomas

Stereotactic radiosurgery is defined as a single session, high-dose delivery of focused radiation precisely to the vestibular schwannoma, as identified by stereotactic imaging. In systems requiring head fixation of the stereotactic frame (e.g., Gamma Knife®), radiation delivery occurs under the direct supervision of a medical team consisting of a neurosurgeon, radiation oncologist, registered nurse, and medical physicist, at a minimum. At some centers a neurotologist is also part of the radiosurgery team. The neurosurgeon and/or neurotologist are an integral part of the critical decision making steps and the target planning and dose approval within the brain for both LINAC and proton beam based systems (whether single session or stereotactically hypofractionated radiation therapy) regardless of head fixation system. The radiation delivery of the approved targeting and dosing plan (as designed and approved by the neurosurgeon/neurotologist and radiation oncologist together) may occur on subsequent days for LINAC or proton beam based single session or hypofractionated sessions under the direct supervision of a radiation oncologist without the neurosurgeon or neurotologist present. In this case, the minimum delivery team should consist of a certified radiation therapist and medical

physicist. Should the original targeting plan require modification during the radiation delivery of the subsequent sessions, the neurosurgeon and/or neurotologist should review/design and approve the new targeting and dosing plan before the continuation of the radiation delivery by the radiation oncologist.

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for Management of Acoustic Tumors.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Improved management of patients with vestibular schwannoma

Specific Benefits

- Benefits of *radiosurgery* include minimally invasive approach, high rates of tumor growth control (95–98%), serviceable hearing preservation (60–70%), facial nerve preservation (>95%), and trigeminal nerve preservation (>95%).
- The medical literature has documented the cost savings benefit of stereotactic radiosurgery versus open surgical procedures and the lower risk potential of bleeding, anesthesia problems, infections and side effects which may result in transient or permanent disabilities from open surgery.

POTENTIAL HARMS

Adverse Effects of Radiosurgery

Major adverse effects of radiosurgery are based on location, volume, and dose. These risks can be estimated based on published data and experience. Individual risks are related to the anatomic proximity of vestibular schwannoma to the cochlea, semicircular canals, cochlear nerve, facial nerve, trigeminal nerve, and the brainstem. For linear accelerator (LINAC) and proton beam based fractionated radiation treatments with a frameless system, the total radiation dose is usually higher than with single session radiosurgery. The higher dose is an issue as the risk of complications is directly related to the dose and treatment volume. Complications after radiosurgery are rare, but may include hearing loss, facial numbness, facial pain, facial weakness, and temporary unsteadiness.

CONTRAINDICATIONS

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Vestibular schwannoma diameter greater than 3 cm is a relative contraindication for stereotactic radiosurgery, depending upon individual circumstance.

QUALIFYING STATEMENTS

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- This guideline is intended to provide the scientific foundation and initial framework for the person who has been diagnosed with a vestibular schwannoma. The assessment and recommendations provided in this guideline represent the best professional judgment of the working group at this time, based on research data and expertise currently available. The conclusions and recommendations will be regularly reassessed as new information becomes available.
- This guideline is not intended as a substitute for professional medical advice and does not address specific procedures or conditions for any patient. Those consulting this guideline are to seek qualified consultation utilizing information specific to their medical situation. Further, International RadioSurgery Association (IRSA) does not warrant any instrument or equipment nor make any representations concerning its fitness for use in any particular instance nor any other warranties whatsoever.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

International RadioSurgery Association (IRSA). Stereotactic radiosurgery for patients with vestibular schwannomas. Harrisburg (PA): International RadioSurgery Association (IRSA); 2006 May. 16 p. (Radiosurgery practice guideline report; no. 4-06). [110 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 May

GUIDELINE DEVELOPER(S)

IRSA - Professional Association

SOURCE(S) OF FUNDING

IRSA (International RadioSurgery Association)

GUIDELINE COMMITTEE

The IRSA Medical Advisory Board Guidelines Committee and physician representatives in the industry.

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

This radiosurgery guidelines group is comprised of neurosurgeons, neurotologists, and radiation oncologists.

Group Members: L. Dade Lunsford, MD, Neurosurgeon, *Chair*; Ajay Niranjan, MBBS, MCh, Neurosurgeon; Georg Norén, MD, Neurosurgeon; Jay Loeffler, MD, Radiation Oncologist; Alain de Lotbinière, MD, Neurosurgeon; Jordan Grabel, MD, Neurosurgeon; Douglas Kondziolka, MD, Neurosurgeon; Jean Régis, MD, Neurosurgeon; Pierre-Hughes Roche, MD, Neurosurgeon; Robert Smee, MD, Radiation Oncologist; Burton Speiser, MD, Radiation Oncologist; Mark Alden, MD, Radiation Oncologist; Sandra Vermeulen, MD, Radiation Oncologist; William F. Regine, MD, Radiation Oncologist; Barry Hirsch, MD, Neurotologist; Tonya K. Ledbetter, MS, MFS, Editor; Rebecca L. Emerick, MS, MBA, CPA, *ex officio*

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

IRSA makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of a personal, professional, or business interest of a member of the radiosurgery guidelines group.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the IRSA Web site.

Print copies: Available from the IRSA, P. O. Box 5186, Harrisburg, PA 17110

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Acoustic tumor management algorithm. Brain Talk 2004; 9(2):7.

Electronic copies: Available in Portable Document Format (PDF) from the IRSA Web site.

PATIENT RESOURCES

The following are available:

- Vestibular schwannoma (acoustic neuroma) & stereotactic radiosurgery. Harrisburg (PA): International RadioSurgery Association (IRSA); 2005. 6 p.
- Acoustic neuroma. Another Perspective 1997;2(1):1-16.

Print copies: Available from IRSA, 3002 N. Second Street, PO Box 5186, Harrisburg, PA 17110

The following are also available:

- Acoustic neuroma. Another Perspective 2000;5(3):1-12. Electronic copies: Available in Portable Document Format (PDF) from the IRSA Web site.
- Acoustic neuroma & patient choice. Brain Talk 2004;9(2):1-2. Electronic copies: Available in Portable Document Format (PDF) from the IRSA Web site.

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NGC STATUS

This NGC summary was completed by ECRI on July 26, 2006. The information was verified by the guideline developer on September 27, 2006.

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