Preface

Summary
The IRSA® (International RadioSurgery Association) Radiosurgery Practice Guideline Initiative aims to improve outcomes for trigeminal neuralgia patients (classified ‘typical’) by assisting physicians and clinicians in applying research evidence to clinical decisions while promoting the responsible use of health care resources.

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KEY WORDS • trigeminal neuralgia • tic douloureux • stereotactic radiosurgery • Gamma Knife® • linear accelerator • irradiation

Consensus Statement

Objective
To develop a consensus-based radiosurgery practice guideline for trigeminal neuralgia treatment recommendations to be used by medical and public health professionals following the diagnosis of trigeminal neuralgia.

Participants
The working group included physicians from the staff of major medical centers that provide radiosurgery treatment.

Evidence
The first author(s) (LDL/AN) conducted a literature search in conjunction with the preparation of this document and development of other clinical guidelines. The literature identified was reviewed and opinions were sought from experts in the diagnosis and management of trigeminal neuralgia, including members of the working group.

Consensus Process
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. The final statement incorporates all relevant evidence obtained by the literature search in conjunction with final consensus recommendations supported by all working group members.

Group Composition
The radiosurgery guidelines group is comprised of neurosurgeons, radiation oncologists and physicists. Community representatives did not participate in the development of this guideline.

Names of Group Members: L. Dade Lunsford, M.D., Neurosurgeon, Chair; Ajay Niranjan, M.B.B.S., M.Ch., Neurosurgeon; Ron Young, M.D., Neurosurgeon; Ronald Brisman, M.D., Neurosurgeon; David Cunningham, M.D., Neurosurgeon; Christer Lindquist, M.D., Neurosurgeon; David Newell, M.D., Neurosurgeon; John C. Flickinger, M.D., Radiation Oncologist; Ann Maitz, M.S., Medical Physicist; Tonya K. Ledbetter, M.S., M.F.S., Editor; Rebecca L. Émerick, M.S., M.B.A., C.P.A., ex officio.
Conclusions
Specific recommendations are made regarding target population, treatment alternatives, interventions and practices and additional research needs. Appropriate use of radiosurgery to those with intractable trigeminal neuralgia following medical management may be beneficial.

This guideline is intended to provide the scientific foundation and initial framework for the person who has been diagnosed with Intractable Typical Trigeminal Neuralgia. The assessment and recommendations provided herein 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.

Stereotactic Radiosurgery
Brain Stereotactic Radiosurgery involves the use of precisely directed closed skull single fraction (one session) of radiation to create a desired radiobiologic response within the brain with minimal effects to surrounding structures or tissues. In the case of trigeminal neuralgia a relatively high dose of focused radiation is delivered precisely to the trigeminal nerve under the direct supervision of a radiosurgery team. In Centers of Excellence, the radiosurgery team is composed of a neurosurgeon, radiation oncologist, physicist and registered nurse.

Trigeminal Neuralgia: Overview and Surgical Management

Background
Trigeminal neuralgia (TN), also known as tic douloureux, is a pain syndrome recognizable by patient history alone. The condition is characterized by intermittent unilateral facial pain. The pain follows the unilateral (>95%) sensory distribution of trigeminal nerve (V), typically radiating to the maxillary (V2) or mandibular (V3) area.

Ophthalmic division (V1) pain alone occurs in <5% patients. Physical examination findings are typically normal, although mild light touch or pin perception loss has been described in the central area of the face. Significant sensory loss suggests that the pain syndrome is secondary to another process, and requires high-resolution neuroimaging to exclude other causes of facial pain.

Pathophysiology
The mechanism of pain production remains controversial. One theory suggests that peripheral injury or disease of the trigeminal nerve increases afferent firing in the nerve, perhaps by ephaptic transmission between afferent unmyelinated axons and partially damaged myelinated axons; failure of central inhibitory mechanisms may also be involved. Pain is perceived when nociceptive neurons in a trigeminal nucleus involve thalamic relay neurons. Blood vessel-nerve cross compression, aneurysms, chronic meningeal inflammation, tumors or other lesions may irritate trigeminal nerve roots along the pons.

Uncommonly, an area of demyelination, such as may occur with multiple sclerosis, may be the precipitant. In some cases no vascular or other lesion is identified, rendering the etiology uncertain. Development of trigeminal neuralgia in a young person (<45 years) raises the possibility of multiple sclerosis, which should be investigated. Lesions of the entry zone of the trigeminal roots within the pons may cause a similar pain syndrome. Thus, although TN typically is caused by a dysfunction in the peripheral nervous system (the roots or trigeminal nerve itself) [1-3], a lesion within the central nervous system (1-8%) may also cause similar problems [4].

Sex
Male-to-female ratio is 2:3.

Age
The average age of pain onset in idiopathic TN typically is the sixth decade of life, but it may occur at any age. Symptomatic or secondary TN tends to occur in younger patients. Trigeminal neuralgia caused by arterial compression is more likely in older patients.

Nature of pain
Pain is stabbing or an electric shock-like sensation and is typically quite severe. Pain is brief (few seconds to 1-2 minutes) and paroxysmal, but it may occur in volleys of multiple attacks. Pain may occur several times a day; patients typically experience no pain between episodes.

Distribution of pain
Pain is unilateral (rarely bilateral) [5]. One or more branches of the trigeminal nerve (usually maxillary or mandibular) are involved. It is rare that pain is simultaneously bilateral, but pain on the contralateral side is seen in about 5% of patients with TN and about 20% of patients with trigeminal neuralgia and multiple sclerosis.

Trigger points
Various triggers may commonly precipitate a pain attack. Light touch or vibration is the most evocative. Activities such as shaving, face washing or chewing often trigger an episode. Over years periods of remission are less and less and severity of pain increases.

Disease Course
The disease course is usually one of clusters of attacks that wax and wane in frequency. Over the years recurrences become sharper and exacerbations longer. Some patients report that their exacerbations commonly occur in the fall and spring.

Causes
Some patients' conditions are idiopathic, but compression of the trigeminal root entry zone by blood vessels (especially branches of the superior cerebellar arteries or venous channels) or tumors may cause pain.

Imaging Studies
Patients with characteristic history and normal neurologic examination may be treated without further workup. An MRI scan with and without contrast is essential to rule out the presence of a tumor, arteriovenous malformation, or multiple sclerosis, all of which can cause trigeminal neuralgia in a small number
of patients. In addition, skull base conditions such as maxillary sinusitis may mimic symptoms of TN.

Medical Management

The goal of pharmacologic therapy is to reduce pain. Carbamazepine is regarded as the most effective medical treatment. Oxcarbazepine (Trileptal) is often effective like carbamazepine, but has fewer side effects. Additional agents that may benefit selected patients include baclofen, gabapentin (Neurontin), and Klonazepin. The combination of carbamazepine and baclofen may provide relief from episodic pain. Other anticonvulsants, including phenytoin, reportedly are beneficial in some patients. Topiramate may be beneficial in refractory cases; however, controlled studies have not been performed. Some patients are not helped by these medications, experience breakthrough pain, or suffer with undesirable side effects. In such cases a referral to a neurosurgeon is indicated [6].

Surgical Management

Prior to considering surgery, all eligible patients should have an MRI, with close attention being paid to the posterior fossa. Imaging is performed to rule out other causes of compression of the trigeminal nerve such as mass lesions, large ectatic vessels, or other vascular malformations. Thin section MRI (with contrast) may be helpful (although not with 100% accuracy) in identifying blood vessel contact and/or compression of the trigeminal nerve. The surgical options for TN include peripheral nerve blocks or ablation, gasserian ganglion and retrogasserian ablative procedures, microvascular decompression (MVD) and stereotactic radiosurgery [7]. Percutaneous transovale techniques include radiofrequency trigeminal electrocoagulation, glycerol rhizotomy and balloon microcompression [8].

Microvascular decompression is often preferred for younger patients with typical trigeminal neuralgia. High initial success rates (>90%) have led to the widespread use of this procedure. Pain control rate after single MVD at 10 years is 64% with good results in an additional 4% [9]. This procedure provides treatment of the cause of TN in many patients. Percutaneous techniques are advocated for elderly patients, patients with multiple sclerosis, patients with recurrent pain after MVD, and patients with impaired contralateral hearing [10]; however, some authors recommend percutaneous techniques as the first surgical treatment for most patients [11-12]. In a comparative study of three techniques, Lee et. al. noted initial success rates of 96.5%, 92% and 83% for MVD, radiofrequency trigeminal electrocoagulation and glycerol rhizolysis, respectively [13].

Facial dysesthesias were reported for 6.3%, 5% and 3% of patients, respectively. In a review of different techniques, Lovely and Jannetta reported excellent or good pain control for 78%, 74% and 56% of patients using MVD, radiofrequency trigeminal electrocoagulation, and glycerol rhizolysis, respectively [14]. MVD was associated with a 0.5% mortality rate and 3-29% facial numbness rates. In a study of balloon microcompression treatment of trigeminal neuralgia, 62.5% of patients achieved excellent pain control, whereas 32.5% developed recurrences (after a median interval of 51 months). Sensory dysesthesia was noted for 3% and hearing impairment was observed for 11% of patients.

It is generally agreed that MVD provides the longest duration of pain relief while preserving facial sensation. In experienced hands, MVD can be performed with low morbidity and mortality. Most authors offer MVD to young patients with TN [15-16].

Radiosurgery

Several reports have documented the efficacy of Gamma Knife® radiosurgery for TN [7, 17-34]. Because radiosurgery is the least invasive procedure for TN, it is a good treatment option for patients with co-morbidities, high-risk medical illness or pain refractory to prior surgical procedures.

Radiosurgery is a good alternative for most patients with medically refractory trigeminal neuralgia, especially those who do not want to accept the greater risk of an MVD for a greater chance of pain relief.

Between December 1992 and January 2003, a total of 507 radiosurgical procedures for TN were performed at the University of Pittsburgh Medical Center (Presbyterian). This report summarizes the long-term outcome in 220 patients who had undergone Gamma Knife® radiosurgery for idiopathic, longstanding pain refractory to medical therapy [35]. One hundred and thirty-five patients (61.4%) had prior surgeries including microvascular decompression, glycerol rhizotomy, radiofrequency rhizotomy, balloon compression, peripheral neurectomy or ethanol injections. Eighty-six patients (39.1%) had one, 39 (17.7%) had two, and 10 (4.5%) had three or more prior operations. For the other 85 patients, radiosurgery was the first surgical procedure. A maximum dose of 70-80 Gy was used.

Follow-up and Medications

After radiosurgery, patients were followed to assess pain relief at three months, six months and yearly intervals. Their pre-radiosurgery pain medications are continued at the same doses until pain relief is obtained. Medications then can be gradually tapered off if the patient remains pain free.

Pain Relief After Radiosurgery

The outcome of pain relief was categorized into four results (excellent, good, fair, and poor). Complete pain relief without the use of any analgesic medication was defined as an excellent outcome. Complete pain relief while still requiring some medication was defined as a good outcome. Partial pain relief (>50% relief) was defined as a fair outcome. No or less than 50% pain relief was defined as a poor outcome. Most patients responded to radiosurgery within six months (median, two months).

At the initial follow-up within six months after radiosurgery, complete pain relief without medication (excellent) was obtained in 105 patients (47.7%), and excellent and good outcomes were obtained in 139 patients (63.2%). Greater than 50% pain relief (excellent, good, and fair) was obtained in 181 patients (82.3%). At the last follow-up (median 22 months after radiosurgery), 88 patients (40%) maintained an excellent outcome, 121 (55%) maintained excellent or good outcomes, and 152 (69.1%) maintained fair or better outcomes.
The most important factor causing a poor response was the presence of atypical pain features (constant dull or burning pain, or a tingling sensation) in addition to the typical trigeminal neuralgia. Only 43.8% of the patients with atypical pain features responded at six months, whereas 84.4% of patients with typical pain experienced pain relief. Regis et al. reported that 87% of patients were initially free of pain in their series of 57 patients treated with a maximum dose of 75-90 Gy [25, 26]. In many patients, they used the higher maximum dose of 90 Gy, and their target was placed in a more anterior site (closer to retrogasserian portion).

In a series of 441 patients presented at the 2001 meeting of the International Stereotactic Radiosurgery Society, Young et al. noted that 87% of patients were free of pain after radiosurgery, with or without medication (median follow-up period, 4.8 years, including repeat procedures). Brisman et al. noted vascular contact with trigeminal nerve on thin section MRI in 59% of patients with TN. These authors reported a particularly good response to Gamma Knife® radiosurgery (no pain, no medicines in 56%, 90-100% pain relief with small doses of medicine in 16%, and 50-80% pain relief in 8% of patients at two years post radiosurgery) in patients with no previous surgery and vascular contact on MRI [36].

Recurrence After Radiosurgery
Some patients have recurrent pain despite the initial response after radiosurgery as well as other surgical procedures. Thirty patients (13.6%) experienced recurrence of pain after the initial pain relief with a mean duration of 15.4 months. The duration of pain relief after the initial response was analyzed in all patients using the Kaplan-Meier product-limit method. Complete pain relief (excellent or good) was maintained in 63.6 ± 3.3% of patients at one year and in 56.6 ± 3.8% at three years. Greater than 50% pain relief was maintained in 75.8 ± 2.9% of patients at one year and in 67.2 ± 3.9% at three years.

A history of no prior surgery was significantly associated with achieving and maintaining complete pain relief (p=0.01). The absence of preradiosurgical paresthesia, which is strongly correlated with no prior surgery, was significantly associated with achieving and maintaining greater than 50% pain relief (p=0.02). According to the other literatures, recurrence rates at the last follow-up after radiosurgery varied from 3.3-21% [37, 38].

Complications After Radiosurgery
The main complication after radiosurgery was new facial sensory symptoms caused by partial trigeminal nerve injury. Seventeen patients (7.7%) in one series developed increased facial paresthesia and/or facial numbness that lasted longer than six months [35]. One patient (0.4%) developed deafferentation pain. No patient developed other neurological morbidities. Other reported risks include new facial sensory symptoms (2.7-10%). Increased risk of trigeminal nerve dysfunction has been reported with the use of high-dose (90 Gy) radiosurgery for TN [39, 40].

Repeat Radiosurgery
Patients who experience recurrent pain during the long-term follow-up despite initial pain relief after radiosurgery can be treated with a second radiosurgery procedure [38]. At the second procedure, the radiosurgical target and dose slightly differ from the first procedure. The target is placed anterior to the first target so that the radiosurgical volumes at the second procedure overlap with the first one by 50%. Dose selection is still controversial. We advocate less radiation dose (50-70 Gy) for the second procedure, because we believe that a higher combined dose would lead to a higher risk of new facial sensory symptoms. On the other hand Pollock et al. [37] suggest a greater radiation dose to the same target at the second procedure than at the first. They reported results of repeat radiosurgery in 10 patients with a median follow-up of 15 months after the second procedure. Initially, nine patients were pain free and could taper off their medications. Of these, eight patients continue to be pain free without medication, and only one patient had recurrence three months after the repeat radiosurgery. However, all patients with persistent pain relief developed minor neurological dysfunction after repeat radiosurgery.

Indications for Radiosurgery
Many surgical treatments exist for trigeminal neuralgia, and long-term results have been reported. We have identified a high rate of imaging-defined pontine or cerebellar infarction (24%) in patients who had prior microvascular decompressions [41]. Gamma Knife® radiosurgery is usually recommended first for older or infirm patients because it is the least invasive option. The lack of mortality and the low risk of facial sensory disturbance, even after a repeat procedure, argue for the use of primary or secondary radiosurgery in this setting.

Repeat radiosurgery remains an acceptable treatment option for patients who have failed other therapeutic alternatives.
A number of factors are considered in making a recommendation. These factors include:

1. Patient's age
2. Response to medication
3. Patient's medical condition
4. Presence or absence of multiple sclerosis
5. Presence or absence of vascular contact and/or compression on thin section MRI
6. Presence or absence of prior procedures
7. The type of prior procedure and its response
8. Severity of pain and how long the patient can reasonably wait for pain relief
9. Patient's concern and risk tolerance for dysesthesias, recurrence, or complications from surgery

A broad outline of management algorithm is shown; however, the final recommendation is usually influenced by the recommending neurosurgeon's experience along with patient preference.

**Trigeminal Neuralgia Management Algorithm**

![Diagram of Trigeminal Neuralgia Management Algorithm]

- **RMC** = Retro-Mastoid Cranietomy
- **MVD** = Microvascular decompression
- **PRR** = Percutaneous Retrogasserian Rhizotomy (Glycerol / Radiofrequency / Balloon compression)
- **SR** = Stereotactic Radiosurgery

**References**

Complete Summary

TITLE:
Stereotactic Radiosurgery for Patients with Intractable Typical Trigeminal Neuralgia Who Have Failed Medical Management.

DEVELOPER AND FUNDING SOURCE:
IRSA (International RadioSurgery Association)

DEVELOPER COMMENT:
IRSA (International RadioSurgery Association) is a non-profit entity dedicated to promoting the development of scientifically relevant practice guidelines for stereotactic radiosurgery. IRSA is a professional organization that works to educate and provide support for physicians, hospitals, insurers, and patients.

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

GROUP COMPOSITION:
The radiosurgery guidelines group is comprised of neurosurgeons, radiation oncologists and physicists.

Names of Group Members:
L. Dade Lunsford, M.D., Neurosurgeon, Chair; Ajay Niranjan, M.B.B.S., M.Ch., Neurosurgeon; Ron Young, M.D., Neurosurgeon; Ronald Brisman, M.D., Neurosurgeon; David Cunningham, M.D., Neurosurgeon; Christer Lindquist, M.D., Neurosurgeon; David Newell, M.D., Neurosurgeon; John C. Flickinger, M.D., Radiation Oncologist; Ann Maitz, M.S., Medical Physicist; Tonya K. Ledbetter, M.S., M.F.S., Editor; Rebecca L. Emerick, M.S., M.B.A., C.P.A., ex officio.

DISEASE/CONDITION:
Trigeminal neuralgia, typical (tic douloureux)

NUMBER OF REFERENCES:
43

CATEGORY:
Treatment, proposed surgical management

CLINICAL SPECIALTY:
Neurological surgery
Neurology
Radiation oncology

INTENDED USERS:
Physicians
Health Care Providers
Hospitals
Managed Care Organizations
Nurses
Utilization Management

OBJECTIVES:
To develop a evidenced and consensus-based stereotactic radiosurgery practice guideline for trigeminal neuralgia treatment recommendations to be used by medical and public health professionals following the diagnosis of trigeminal neuralgia.

TARGET POPULATION:
Men and women with intractable (medically refractory) typical trigeminal neuralgia, often those with concomitant medical co-morbidity or advanced age.

INTERVENTIONS AND PRACTICES:
Stereotactic radiosurgery of the trigeminal nerve is performed using the following dose schedules:
- 75 Gy in a single fraction to the trigeminal nerve
- 80 Gy in a single fraction to the trigeminal nerve
- 90 Gy in a single fraction to the trigeminal nerve
- 60-70 Gy in a single fraction for repeat radiosurgery for recurrent trigeminal neuralgia

Follow-up
- Assess pain relief (3, 6, 12, months)
- Taper off medications if patient remains pain free

Recurrent trigeminal neuralgia
- Assess repeat radiosurgery (50-60 Gy)

OUTCOMES CONSIDERED:
Pain control is the primary endpoint of interest. Use of pain medications, quality of life (addressed through the adverse effects of radiosurgery) and neurological outcome are also considered.

METHODS TO COLLECT EVIDENCE:
Hand Searches of Published Literature (Primary Sources); Hand Searches of Published Literature (Secondary Sources); Searches of Electronic Databases

DESCRIPTION OF METHODS TO COLLECT EVIDENCE:
MEDLINE and PUBMED searches were completed for the years 1966 to September 2003. Search terms included: tic douloureux, trigeminal neuralgia, stereotactic radiosurgery, Gamma Knife®, linear accelerator, irradiation, clinical trials, research design, practice guidelines and meta-analysis. Bibliographies from recent published reviews were reviewed and relevant articles were retrieved.

METHODS TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE:
Expert consensus (committee)

METHODS TO ANALYZE EVIDENCE:
Review of published meta-analysis

REVIEW METHODS:
External peer review; internal peer review

DESCRIPTION OF REVIEW METHODS:
The recommendations were a synthesis of research obtained in the evidence gathering process by a core group of two members (AN and LDL). These recommendations were mailed to all committee members. Feedback was obtained through this mailed survey consisting of proposed guidelines asking for comments on the guidelines and whether the recommendation should serve as a practice guideline. No significant disagreements existed. 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.
MAJOR RECOMMENDATIONS:

- Patients with typical trigeminal neuralgia who have had an adequate trial of medications can be offered stereotactic radiosurgery. Typically used in patients with medical co-morbidities, patients at risk for side effects from percutaneous ablative procedures, and those in more advanced age groups. Patients (any age) may choose radiosurgery for personal reasons after having adequate trial of medications with failure as an alternative to other more invasive procedures.

- The optimal dose range for trigeminal neuralgia has been established. A commonly used dose range of 75-90 Gy in a single fraction to the trigeminal nerve is suggested, using a 4 mm collimator radiation field. Most centers prefer 80 Gy as a central dose targeted to the trigeminal nerve a few millimeters proximal to its entry into the brain stem; however, 90 Gy as a central dose to the trigeminal nerve near the trigeminal ganglion has also been used routinely in some centers.

- Patients who have failed other surgical procedures for trigeminal neuralgia should also receive 75-90 Gy to the trigeminal nerve. A safe interval between the initial surgery and stereotactic radiosurgery is unknown, but it is reasonable to perform radiosurgery if there is no improvement or pain recurs following the initial surgical procedures.

- After radiosurgery, patients are followed to assess pain relief at three month, six month and yearly intervals. Their pre-radiosurgery pain medications are continued at the same doses until pain relief is obtained. Medications can then be gradually tapered off if the patient remains pain free.

- Patients who have recurrence of pain following trigeminal neuralgia radiosurgery or who had a partial initial response can undergo a second stereotactic radiosurgery using 50-70 Gy to the trigeminal nerve (depending on the elapsed time between treatments). A generally safe interval between first and second radiosurgeries is six months.

- At present, technology to deliver focal small-volume fields is limited to Gamma Knife® by the strength of published data. (Gamma Knife® is a registered trademark of Elekta Instruments, Inc.) Early data from dedicated modified linear accelerator centers with documented ability to deliver beams < 5 mm are under evaluations.

- Stereotactic radiosurgery is defined as a relatively high dose of focused radiation delivered precisely to the trigeminal root nerve, under the direct supervision of a medical team (neurosurgeon, radiation oncologist, registered nurse, and medical physicist), in one surgical treatment session.

POTENTIAL BENEFITS:

All of the published studies have shown a significant decrease in pain (decreased severity and reduced need to take medications).

Literature has documented the cost savings benefit of stereotactic radiosurgery versus invasive surgical procedures and the lower risk potential of bleeding, anesthesia problems, infections and side effects which may include transient or permanent disabilities from open surgery.

SUBGROUP(S) MOST LIKELY TO BENEFIT:

Typical trigeminal neuralgia (intermittent lancinating pain typically relieved by carbamazepine) without prior surgical procedure.

POTENTIAL HARMs:

Major adverse effects of trigeminal neuralgia radiosurgery occur very infrequently.

Facial numbness <10%
Neuropathic pain <1%
Motor weakness <1%

SUBGROUP(S) MOST LIKELY TO BE HARMED:

Patients with atypical facial pain (non-paroxysmal pain), deafferentation facial pain, TMJ related facial pain or orofacial pain

GUIDELINE STATUS:

This is the full current release of the guideline

GUIDELINE AVAILABILITY:

Electronic copies: Available in Portable Document Format (PDF) from www.IRSA.org

Print copies: Available from IRSA, 3005 Hoffman Street, Harrisburg, PA 17110

PATIENT RESOURCES:

Patient resources are available on line at www.IRSA.org, by email at intouch@IRSA.org, or by calling +717-260-9808.

See "publications" for patient resources for trigeminal neuralgia: www.IRSA.org/publications.html/

Brain Talk® Volume 8, No. 2; Volume 6, No. 1;
Another Perspective® Volume 3, No. 1; Volume 4, No. 2
Brochure on trigeminal neuralgia available by mail.

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