QUALITY OF REPORTING IN EVALUATIONS OF SURGICAL TREATMENT OF TRIGEMINAL NEURALGIA: RECOMMENDATIONS FOR FUTURE REPORTS

Joanna M. Zakrzewska, M.D.

Barts and the London Hospital Oral Medicine, Dental Institute, Queen Mary's School of Medicine and Dentistry, London, England

Benjamin C. Lopez, F.R.C.S.

Department of Neurosurgery, The Royal London Hospital, Barts and the London National Health Service Trust, London, England

Reprint requests:
Joanna M. Zakrzewska, M.D., Barts and the London Hospital Oral Medicine, Dental Institute, Queen Mary's School of Medicine and Dentistry, Turner Street, London E1 2AD, England.
Email: J.M.Zakrzewska@qmul.ac.uk

Received, August 28, 2002.
Accepted, March 11, 2003.

OBJECTIVE: There are numerous reports on the surgical treatment of trigeminal neuralgia, but the studies do not use uniform outcome measures, which makes it difficult for patients and clinicians to determine which treatment may be most appropriate. The objectives of this study were to set quality criteria and standards for outcome reporting for the surgical treatment of trigeminal neuralgia (on the basis of international expert opinion), to identify and assess all studies of the surgical treatment of trigeminal neuralgia and evaluate the studies against those criteria, and to provide recommendations for submitting reports on the outcomes of surgical treatment of trigeminal neuralgia.

METHODS: The types of data that 11 neurosurgeons and 2 neurologists considered essential for articles reporting the outcomes of surgical treatment of trigeminal neuralgia were the quality criteria used by the two authors. Standards were established in terms of the minimal number and type of criteria that studies should meet to allow their use in a potential systematic review of pain outcomes of surgical treatment of trigeminal neuralgia. Studies were identified in MEDLINE searches and from other sources and were independently scored against those criteria by the two authors. The reproducibility of the method was checked with assessments of inter- and intra-rater reliability. A checklist for the reporting of studies was formulated.

RESULTS: A total of 281 studies were identified, of which 222 were scored. Seventy-one (32%) of the studies reached the minimal set standards, but only 28 (13%) could be used for assessment of pain outcomes, because they included actuarial analyses. There was good agreement between the two authors in the scoring of the studies, although some criteria required stricter definitions. A checklist for the reporting of future studies on the surgical treatment of trigeminal neuralgia was proposed.

CONCLUSION: When assessed against the proposed criteria and standards, the quality of reporting was generally poor. The methods for reporting surgical outcomes for trigeminal neuralgia were not uniform; therefore, the comparability of results and techniques was low. Data should be collected and reported in a standardized way. A protocol for data collection and reporting on the surgical treatment of trigeminal neuralgia has been proposed. Further research is needed to evaluate this tool.

KEY WORDS: Balloon microcompression, Gamma knife surgery, Microvascular decompression, Percutaneous glycerol rhizotomy, Radiofrequency thermorhizotomy, Systematic review, Trigeminal neuralgia

Neurosurgery 53:110-122, 2003 DOI: 10.1227/01.NEU.0000068862.78930.EE www.neurosurgery-online.com

Decisions regarding the treatment of trigeminal neuralgia should be made on the basis of the best evidence available. These data are needed by both clinicians treating patients and the patients themselves. The data must be presented in a standardized way, so that treatments can be compared using the same criteria.

The best evidence comes from well-designed, well-conducted, randomized, controlled trials. The ideal summary of the evidence is a systematic review with a meta-analysis of all randomized controlled trials. Systematic reviews provide important data needed for policy formulation, because they establish generalizability, increase power and precision (if a

meta-analysis has been possible), and limit bias. At the opposite end of the evidence spectrum are descriptive studies by experts. Such studies are the most likely to be heavily biased. In some areas of clinical practice, there are no randomized controlled trials and observational studies must be used to provide the evidence. Within such areas, the hierarchy adopted is as follows: 1) well-designed, well-conducted, prospective, cohort studies and 2) well-designed, well-conducted, retrospective, case-control studies (1). When data are collected prospectively, the study is more likely to have been planned and to be more reliable and complete, because the selection of participants is not based on outcomes.

There have been four randomized controlled trials of the surgical treatment of trigeminal neuralgia, two assessing the use of peripherally injected streptomycin (2, 19), one assessing the use of a laser (21), and one assessing radiosurgery (4). An attempt to find a systematic review of the surgical treatment of trigeminal neuralgia yielded no data. There have been no case-control studies, and the only data sources are observational data reports by experts. Within this group, many are retrospective studies (23). Hamlyn (5) attempted a review and found 1400 articles on the entire subject of trigeminal neuralgia. He selected 86 articles on microvascular decompression that he considered useful for his study, but he did not validate his selection criteria. The aims of this study were thus 1) to set criteria and quality standards that should be met by studies reporting outcomes of the surgical treatment of trigeminal neuralgia, 2) to identify all of the studies, published since the development of electronic databases, on the surgical treatment of trigeminal neuralgia and to evaluate them by using the set criteria, and 3) to propose a protocol for data collection and outcome reporting for the surgical treatment of trigeminal neuralgia.

MATERIALS AND METHODS

This review attempted to use the principles used by the Cochrane Collaboration to conduct systematic reviews, but with application to observational data.

Search Strategy

Publications were retrieved with a computerized search of the following databases: MEDLINE (1966–2001), EMBASE (1980–2001), and Cochrane Library 2001 (Issue 3). The editorial team of the journal *Clinical Evidence* screened the search as part of the preparation of an article on the treatment of trigeminal neuralgia for their journal (22). The methods they use are described in their publication and on the Internet (www.clinicalevidence.com). Medical subject headings (the National Library of Medicine controlled-vocabulary thesaurus) and free-text terms were used. The diagnostic terms used were *trigeminal neuralgia, tic douloureux, facial neuralgia,* and *trigeminus*. Those terms were combined with the following surgical terms: *cryotherapy, alcohol, neurectomy, laser, acupuncture, phenol, streptomycin, cavitational radionecrosis, gasserian ganglion, radiofrequency thermocoagulation, rhizotomy, rhizolysis, electrocoagulation, coagulation, retrogasserian, thermal rhizotomy, ganglionolysis, percutaneous glycerol rhizotomy, microcompression, compression, balloon compression, microvascular decompression, posterior fossa surgery, partial rhizotomy, radiosurgery,* and *stereotactic surgery*. To the resulting reference list were added personal references, which have been regularly updated since 1995 with monthly alerts. The bibliographies of retrieved articles were searched; this procedure was especially useful for identifying non-English language studies. Four books on trigeminal neuralgia were also searched for references. The search strategies are available from us.

Identification of Studies on the Surgical Treatment of Trigeminal Neuralgia

Every study was assessed for relevance by using the data in the abstract. If the abstract was not available or provided insufficient data for assessment of its relevance, then the reprint of the full article was obtained.

The studies included in the review were restricted to full reports (i.e., those including methods, results, and discussion sections), published up to December 2001. All studies describing surgical treatments that provided outcome data on either pain or complications were included. The non-English language literature was included. Studies reporting only on the treatment of recurrences after surgery were also included.

Distinguishing between case studies and cohort studies was sometimes difficult, because most studies were cross sectional. The studies needed to clearly state in the introduction or methods section that the patients had trigeminal neuralgia. Studies that included other diseases, such as hemifacial spasm or secondary trigeminal neuralgia (as defined by the International Association for the Study of Pain [9]), were included only if the data could be separated.

Duplicate articles and those that reported on the same cohorts of patients (with increasing numbers and longer follow-up periods) were excluded. If it could not be determined with certainty that no overlap existed among the patients, all of the studies except for the report with the largest number of patients were excluded. In many instances, authors were contacted to confirm this fact and to provide additional data. This method was previously described (18).

Establishment of the Quality Criteria and the Minimal Standards

Although criteria have been established for the appraisal of cohort studies, they were not considered specific enough for this study and would not sufficiently discriminate between low- and high-quality articles (3). It was considered appropriate to ask those who publish studies on the surgical treatment of trigeminal neuralgia and those who read them to set the criteria. This was performed as follows. 1) Criteria (data that should be present) for evaluation of the articles were selected on the basis of international guidelines established for the assessment of cohort studies (1, 13). These criteria were put into the format of a questionnaire. 2) The questionnaire was

pilot-tested with three neurosurgeons and was altered accordingly. 3) The questionnaire was then given to 15 neurosurgeons and 3 neurologists (different from those who had participated in the pilot testing). Replies were obtained from 11 neurosurgeons and 2 neurologists (listed in the Acknowledgments). All are members of the Medical Advisory Board of the United States or United Kingdom Trigeminal Neuralgia Support Group (both of which are charities supporting patients). They were asked whether they regarded as essential, highly desirable, desirable, or nonessential the presence of each type of data (criterion) in studies evaluating outcomes of surgical treatments of trigeminal neuralgia (e.g., the presence of Kaplan-Meier survival charts or explicit definitions of what the authors considered a recurrence, atypical trigeminal neuralgia, anesthesia dolorosa, or severe paresthesiae) (*Table 1*). 4) The 13 types of data (criteria) that were considered essential by at least 7 of the 13 evaluators were transferred to a data extraction form (containing additional types of data), which was then used to evaluate each article.

TABLE 1. Results of survey among 11 neurosurgeons and 2 neurologists to determine data that should be used to report outcomes of surgical treatment of trigeminal neuralgia

Criterion	No. of clinicians who assessed relevance			
	Essential	Highly desirable	Desirable	Nonessential
1. Define diagnostic criteria used[a]	8	2		
2. Types of cases included (e.g., multiple sclerosis or tumors)[a]	9	1	1	
3. Inclusion/exclusion criteria[a]	7	2	1	1
4. Age at disease onset	2	6	2	1
5. Age at surgery	2	6	2	1
6. Duration of disease	3	6	2	
7. Location of pain[a]	7	3	1	
8. Details of previous surgery	4	6	1	
9. Daily drug dosage before surgery	3	5	1	2
10. Preoperative measure of pain	2	6	3	
11. Preoperative sensory testing		7	3	1
12. Preoperative investigations (e.g., magnetic resonance imaging)	3	6	1	1
13. Describe surgical technique[a]	7	2	2	
14. Describe operative findings	6	3	2	
15. Report perioperative complications[a]	7	1	3	
16. Length of follow-up period[a]	9	1	1	
17. Account for all patients included[a]	7	3	1	
18. Define recurrence[a]	7	3		1
19. Define outcome measures (e.g., 50% reduction in pain severity is good outcome)[a]	8	2	1	
20. Measure postoperative pain	5	2	4	
21. Measure patient satisfaction	4	6	1	
22. State who collected outcome data	2	4	4	1
23. State how outcome data were collected	4	4	3	
24. State time at which data were collected	3	7	1	
25. Recurrence rates analyzed using actuarial analysis (i.e., Kaplan-Meier method)	4	6	1	
26. Analysis by intention to treat	6	4	1	
27. Mortality rate reported[a]	8	3		
28. Report absence/presence of standard complications[a]	8	3		
29. Define complications (e.g., sensory loss or dysesthesia)[a]	9	2		

[a] Essential criteria.

Evaluation of the Quality of the Studies and the Reproducibility of the Method

Extraction forms (on which the data were collected) were prepared, and the relevant studies were graded. The 15 categories deemed essential, as indicated in *Table 2*, were scored with 1 point if present (in the form, "yes"), 0 points if absent (in the form, "no" or "unable to ascertain"), and occasionally 0.5 point if present but incomplete.

The minimal standard (score) required depended on the type of surgery to which the article referred. The minimal quality score was set at 7 points for peripheral branch surgery, 10 for percutaneous procedures, and 11 for micro-

vascular decompression. In addition to the scores, for inclusion of studies in a potential systematic review of pain outcomes, studies on gasserian ganglion surgery required actuarial analysis for at least 3 years and less than 20% of patients lost to follow-up monitoring. Articles on posterior fossa surgery required scores of 11 or higher, inclusion of at least 40 patients, actuarial analysis for at least 5 years, and not more than 20% of patients lost to follow-up monitoring. Radiosurgery studies required scores of 11 or higher, inclusion of at least 20 patients, and a minimal median follow-up period of 12 months. These criteria were determined on the basis of the estimated median time to recurrence for each procedure and discussions among the two authors and patients attending support group meetings. *Clinical Evidence* (www.clinicalevidence.com) uses the criterion that studies should be used only if more than 80% of patients have undergone follow-up monitoring.

TABLE 2. Number of studies complying with each set criterion

Criterion	No. of studies		
	Data present	Data absent	Unable to ascertain
1. No. of patients	50 (100%)	0	
2. Prospective study	17 (34%)	33	
3. Independent observer	13 (26%)	29	7
4. Diagnostic criteria stated[a]	36 (72%)	14	
5. Mixed cases but can differentiate in analysis (e.g., tumor, multiple sclerosis, atypical)[a]	30 (60%)	11	8
6. Age at operation or at disease onset	49 (98%)	1	
7. Sex	48 (96%)	2	
8. Side/division[a]	41 (82%)	9	
9. Duration of disease before operation	37 (74%)	12	
10. No. with previous surgery	40 (80%)	7	3
11. Results reported in relation to previous surgery	32 (64%)	15	3
12. Preoperative measure of pain or assessment	1 (2%)	48	
13. Preoperative sensory assessment	17 (34%)	33	
14. Definition of recurrence/success[a]	42 (84%)	8	
15. Length of follow-up			
Range[a]	49 (98%)	1	
Mean[a]	44 (88%)	5	1
16. Withdrawals accounted for[a]	35 (70%)	13	2
17. Description of operative findings[a]	47 (94%)	3	
18. How was outcome reported[a]	50 (100%)		
19. Kaplan-Meier analysis/yearly outcome[a]	32 (64%)	18	
20. Mortality rate[a]	47 (94%)		3
21. Report of complications outside cranial nerve V area[a]	44 (88%)	6	
22. Report of complications within Cranial Nerve V area[a]	50 (100%)		
23. Report of perioperative complications[a]	38 (76%)	13	
24. Definition of terms (e.g., sensory loss)[a]	19 (38%)	31	
25. Psychological morbidity	2 (4%)	48	
26. Quality of life assessment	3 (6%)	49	
27. Economic costs	2 (4%)	48	
28. Questionnaire/interview	32 (64%)	18	

[a] Criteria used for scoring.

For assessment of inter-rater variability, κ statistical analyses were performed for 38 studies, i.e., a randomly selected 10% of the high- and low-scoring studies for each surgical technique plus all borderline-scoring studies. The scores of the two authors for each criterion were compared and their overall assessments of whether the study had attained the required standard were also compared by using κ statistical analyses. For estimation of same-rater reliability, 13 articles were rescored by the same author 2 months later and κ analysis was performed.

For determination of which studies could be used for the final evaluation of outcomes, all studies that were just at or below the required standard were rescored by both assessors. Differences were resolved with discussion and review of each study, and an agreement was reached regarding the final score and whether the study could be used for outcome analysis. The checklist for the reporting of surgical studies of trigeminal neuralgia was written after completion of the analysis.

Data Extraction

Information was extracted from the selected studies as indicated in *Table 2*.

RESULTS

Results of Searches

The editorial team of *Clinical Evidence* provided 85 references, 14 of which did not have abstracts; other sources identified an additional 196 references, 8 of which predated electronic databases. Of these, 32 were non-English language reports (8 French, 4 Spanish, 2 Italian, 4 German, 6 Japanese, 2 Czech, 2 Polish, 1 Chinese, 1 Danish, 1 Portuguese, and 1 Russian). Five reports identified in other reference lists could not be found. Studies were found not only in the neurosurgical and neurological literature but also in journals relating to pain, anesthetics, and oral and maxillofacial surgery, as well as in general medical journals.

In total, 281 studies were identified and read in full or abstract form, and 222 were scored. The rest were excluded because they were repeat studies, addressed only complications, and/or described treatments or recurrences among specific groups. There were 4 randomized controlled trials, no case-control studies, and 17 prospective studies. The rest of the studies were all presumed to be retrospective. For 13 studies, it was possible to ascertain that an independent observer had analyzed the data. Thirty-two studies stated that some form of questionnaire or telephone interview was used to obtain data from the patients, but only one study published its questionnaire in full.

Two assessors, who were not blinded to each other, read the majority of the studies written in a non-English language. Translators were not found for eight non-English language studies, but the lack of tables and figures indicated that the data were incomplete. Some of those studies not only had English abstracts but also provided translations of their tables and figures.

Results of Standards Setting

The criteria with which the 50 best studies (except for those on peripheral branch surgery) were scored are presented in *Table 2*. The indicated criteria were used to make up the maximal total score of 15. *Table 3* demonstrates how the relevant studies were finally identified, as well as the range of scores obtained. With application of the aforementioned criteria, 71 studies (32%) attained scores at or above the set standard, but pain outcome results with actuarial analysis were identified in only 28 studies (13%); the variation of this factor among the different procedures is presented in *Table 3*. If a standard of 10 instead of 7 had been set for peripheral surgery reports, then only seven studies would have achieved the standard. The scores ranged from 2 to 15.

Only one of the studies written in a non-English language reached the required standard, but three others were also published in English and two of them did then reach the required standard. Studies involving the largest numbers of patients were published in Japanese, but the reports concentrated more on techniques than on outcomes. *Table 4* highlights the lack of global data on this topic. None of the non-English language studies used actuarial methodology.

Almost two-thirds of the studies provided some indication of the diagnostic criteria they used, and two-thirds provided details of the type of trigeminal neuralgia of the patients. Definitions of recurrence or failure were provided in or could be inferred from 84% of the studies, but few studies provided clear definitions.

There were some details that most studies included, such as age, follow-up times (range and mean), and complications within the trigeminal nerve area. Only 34% of studies reported preoperative sensory changes, but all reported postoperative changes. One study measured pain preoperatively (24).

Although outcomes were noted as being present, these were generally inferred from the results and not clearly defined. For

TABLE 3. Selection of studies describing pain outcomes and complications in the surgical management of trigeminal neuralgia, using the criteria in *Table 1*[a]

Procedure	Total no. of studies	No. of studies scored	No. of studies reaching standard	No. of studies used for pain outcomes	Range of scores
Peripheral	46	34	19 (56%)	3 (9%)	2–12
Radiofrequency thermorhizotomy	77	71	19 (27%)	8 (11%)	3–14
Percutaneous glycerol rhizotomy	38	31	13 (41%)	6 (19%)	4–14
Balloon microcompression	23	19	3 (16%)	1 (5%)	3–11
Microvascular decompression	72	55	13 (24%)	8 (15%)	4–15
Radiosurgery	25	11	4 (36%)	2 (18%)	6–15
Total	281	222	71 (32%)	28 (13%)	2–15

[a] More studies were used for assessment of complications than for assessment of pain outcomes. Studies reaching standard, studies that scored at or above the standard set; studies used for pain outcomes, only studies with actuarial data, studies that were repeated or addressed only complications were excluded.

TABLE 4. Country or continent of origin of all studies identified and of those that reached the required standard[a]

Procedure	No. of studies						Origin of 52 studies reaching the standard
	Total	North America	South America	Europe	Asia	Australia	
RFT	71	18	1	43	7	2	7 US, 9 Europe, 2 Asia, 1 South America
PRG	31	13		13	5		6 US, 6 Europe, 1 Asia
Balloon	19	5	2	9	2	1	2 US, 1 Europe
MVD	55	15	1	21	13	5	7 US, 5 Europe, 1 Asia
GKS	11	9		1	1		4 US
Total	187	60	4	87	28	8	26 (50%) US, 21 (40%) Europe, 4 (8%) Asia, 1 (2%) South America

[a] RFT, radiofrequency thermorhizotomy; PRG, percutaneous glycerol rhizotomy; balloon, balloon microcompression; MVD, microvascular decompression; GKS, gamma knife radiosurgery; US, United States.

determination of pain outcomes, only studies using actuarial (Kaplan-Meier) methodology were selected, because these were the most reliable, accounting for patients who were lost to follow-up monitoring, those who had not experienced a recurrence, and those who had died (14, 23). This approach enables yearly data to be assessed, and studies can then be compared within the same time frame.

One study that used actuarial methodology for patients who had undergone microvascular decompression scored 10 (just below the standard) but was included in the pain outcome analysis. It failed to reach the standard because it did not report whether patients had undergone prior surgical procedures, had secondary trigeminal neuralgia, or developed immediate postoperative complications. However, one study on gasserian ganglion surgery that scored 10 (the set standard) was excluded because it reported two different types of surgery but did not separate the results. One study that used actuarial methodology was excluded because of the exclusion of 40% of the patients from the Kaplan-Meier analysis. Some of the other high-scoring studies that could not be used for the pain outcome analysis were used to provide data on complications.

Not all articles reported on non-neurological perioperative complications, which were rarely mentioned in the poorer-quality studies. Deaths and significant morbidity that affected the overall quality of life (e.g., permanent cerebrovascular accident-related morbidity) were reported in all published studies. The rates of major complications were compared between high- and low-scoring studies and did not exhibit major differences.

Results of κ Statistical Analyses and Reproducibility of the Method

The κ values measure agreement between assessors. The maximal level of agreement is indicated by a κ value of 1. The κ values for individual criteria between the two authors ranged from -0.05 to 1, as indicated in *Table 5*.

The highest level of agreement was observed with respect to the presence of Kaplan-Meier analyses. Because of the low κ values for some of the criteria, it was important to ascertain whether these differences resulted in significantly different numbers of studies being classified as having attained the necessary standard. Of the 38 studies analyzed, the two authors agreed that 14 studies had reached the required standard and 16 were below the standard. The two authors disagreed with respect to 8 of 38 studies; of these studies, BCL accepted 5 that JMZ rejected, and JMZ accepted 3 that BCL rejected. The κ value for this comparison was 0.6. After discussion of these 38 studies, 17 were considered to have attained the required standard and 21 were excluded. For the 13 studies reexamined by the same assessor, the κ score was more than 0.6 for all criteria.

Although we made the assumption that, if Kaplan-Meier analyses had been performed, all patients would have been accounted for, it was evident that the standards used for the construction of Kaplan-Meier curves were not uniform. JMZ made this assumption, whereas BCL carefully checked the numbers to determine whether all treated patients were accounted for. Exact details regarding all withdrawals and patients lost to follow-up monitoring are essential, because there was poor agreement for this criterion. The results for good-quality studies were remarkably consistent, however, and this assumption was considered to be safe.

The lowest level of agreement in the scores was on the criterion of how outcomes were reported. JMZ inferred the outcome definitions from the results, whereas BCL scored this criterion only if outcome measures were explicitly defined. This criterion required a better definition.

On the basis of these findings and our analysis of the results, we propose that a checklist (essential and desirable criteria) be

TABLE 5. Agreement between the two assessors in appraisals of the criteria used to set standards, with 38 studies[a]

Criterion	κ
4. Diagnostic criteria stated	0.57
5. Mixed cases but can differentiate in analysis (e.g., tumor, multiple sclerosis, atypical)	0.32
8. Side/division	0.82
14. Definition of recurrence/success	0.74
15. Length of follow-up period	
Range	0.48
Mean	0.8
16. Withdrawals accounted for	0.37
17. Description of operative findings	0.79
18. How was outcome reported	−0.05
19. Kaplan-Meier analysis/yearly outcome	0.94
20. Mortality rate	0.35
21. Report of complications outside Cranial Nerve V area	0.64
22. Report of complications within Cranial Nerve V area	0.66
23. Report of perioperative complications	0.57
24. Definition of terms (e.g., sensory loss)	0.37

[a] Criteria numbered as in *Table 2*.

used for reporting trigeminal neuralgia surgical results. This checklist is presented in *Table 6*. The methods and results sections must contain clear statements regarding definitions, outcome measures, patients lost to follow-up monitoring, and complications. Quality of life and pain outcome measures should be used to provide a more balanced account of outcomes. Some estimates of costs, which would be based on the costs of preoperative assessments, treatment of complications, and follow-up appointments, would also be useful.

DISCUSSION

Patients' autonomy is paramount, which means that patients must be able to give informed consent to any surgical treatment. Patients and clinicians must therefore have access to data on pain outcomes and complications, in a form that is useful to them. These data must be international, and each unit performing these procedures must be able to inform patients how its results compare with the international data. All new treatments should be evaluated in this way.

This study reports the methods we used to select the best studies with which to perform a systematic review of the outcomes of surgical treatment of trigeminal neuralgia. The specific quality criteria established by 13 clinicians are described above. This review identified 222 studies that described outcomes after a variety of surgical procedures for the treatment of trigeminal neuralgia, but only 71 studies (32%) met the standards and only 28 (13%) could be used to reliably estimate the probability of being pain-free for a 3- to 10-year period. The majority of published reports evaluating outcomes after surgical treatment of trigeminal neuralgia are descriptive studies by experts, which represent the weakest type of evidence.

Weaknesses of the Study

The Cochrane Collaboration set standards for systematic reviews. One of the requirements for Cochrane systematic reviews is independent data extraction by at least two reviewers. Limited resources precluded the use of that method for this study. JMZ (a Cochrane reviewer) scored all 222 articles and BCL scored the 71 high-quality articles plus 10% of the low-scoring reports and all of the borderline articles. To ensure that data were being extracted uniformly, the two authors calculated κ statistics for 10% of the high- and low-scoring studies for each technique and all of the borderline studies independently. This proved to be a very useful procedure, because it indicated that certain criteria needed to be more carefully defined and assessed.

The differences in scoring between the two authors were based on how they interpreted the criteria and how prepared they were to infer data from the study (e.g., inferring that all patients were accounted for if actuarial analyses were performed, compared with counting all patients described in different sections of the article). We therefore suggest that studies should state the exact numbers of patients treated and the exact numbers of patients included in follow-up monitoring with the use of a flow chart, as indicated in the Consolidated Standards of Reporting Trials guidelines (10). The criteria related to diagnostic parameters and definitions of sensory loss were open to interpretation, and we suggest that, in the future, these factors should be assessed as being present only if they are clearly defined in the methods section.

The largest disagreement between the two authors was in defining outcome measures. BCL scored this criterion as being present only if the outcome measures used were clearly defined, whereas JMZ inferred the definitions from the results. Future studies using this method must ensure that criteria are scored as present only if explicitly defined.

After the criteria were defined, it was important to determine how many criteria needed to be fulfilled for the study to be classified as acceptable. The rationale used was that, for more-invasive techniques, longer pain-free periods were needed for the procedure to be worthwhile for the patient. Patients surveyed by JMZ at trigeminal neuralgia support group meetings in the United States and the United Kingdom expressed their views that this would be 3 years for percutaneous procedures and 5 years for microvascular decompression. Therefore, the more-invasive techniques required longer

TABLE 6. Recommendations for future reports on surgical management of trigeminal neuralgia

A. Essential data

1. *Abstract in structured format.*
2. *State type of study (prospective, retrospective, case-controlled, use of independent observers to assess outcomes).*
3. *Use International Headache Society definitions for diagnostic criteria used to classify cases into primary or secondary and typical or atypical trigeminal neuralgia, and report outcomes separately for these groups.*
4. *Provide basic demographic data, such as age at onset, side and division affected, sex, duration of disease, and age at operation.*
5. *Detailed pre- and postoperative sensory assessments.*
6. *Details of previous treatments and data to be analyzed in relation to this factor (number and types of previous procedures, resulting sensory deficits or constant background pain).*
7. *Brief description of operative technique and findings, including report of technical failures and number of surgeons performing the procedures.*
8. *Details of follow-up periods, including median and range.*
9. *Details of how follow-up monitoring was performed, by whom, and how complete. Follow-up data must be available for ≥80% of the patients. If by questionnaire, state details of whether by mail or direct interview and provide copy of the questionnaire.*
10. *Explicit definitions of outcome measures used: (complete relief with no medication needed, partial relief but patient considers pain adequately controlled, or treatment failure). Report outcomes separately for complete and partial relief.*
11. *Definition of recurrence (minor and major). Report separately.*
12. *Detailed complications (hypesthesia in response to cotton wool and pin, corneal reflex loss, paresthesiae and severity, dysesthetic phenomena, anesthesia dolorosa, masseteric weakness, neurological complications outside the trigeminal nerve territory, systemic complications, or death). Specify if absent.*
13. *Detailed Kaplan-Meier survival charts for at least 3 years. Report exact numbers of patients available at each follow-up interval. Provide raw data so re-calculations are possible.*
14. *Report complete and partial relief and all recurrences separately. Typical and atypical cases and primary and secondary cases should be reported separately. Do not include final outcomes for patients treated more than once because of recurrence or technical failure.*
15. *Details of drug-related side effects if reporting on partial relief, and latency to maximal pain relief in radiosurgery.*

B. Desirable data

1. *Analysis of data in relation to preoperative pain intensity and quality of life (pre- and postoperative Brief Pain Inventory and Hospital Anxiety and Depression scale results); essential if reporting partial relief outcomes, patients with complications, or atypical trigeminal neuralgia.*
2. *Provide results of magnetic resonance imaging or other investigations.*
3. *Details of patients lost to follow-up monitoring, including how they may differ from the reported patients and why they may be lost to follow-up monitoring.*
4. *Report complications in relation to time and severity, showing which are transient and which are permanent.*
5. *Cost analysis.*

follow-up periods and thorough descriptions of deaths and neurological, local, and systemic complications; the assumption that complications were not present if not mentioned was considered unsafe. For the less-invasive techniques, however, this assumption was considered safe (e.g., mortality rates of 0% not mentioned in radiosurgery articles) and follow-up periods could be shortened, thus lowering the score required for a study to achieve high-quality standards.

The criteria used for this study were not initially weighted, which might have given an advantage to studies with only a few but important flaws (e.g., patients lost to follow-up monitoring), because they might still be ranked among the best studies. However, weighting took place at the time of selection of studies for the evaluation of outcomes; we rejected two-thirds of the studies that had achieved the minimal score or standard, because they lacked actuarial analyses or had lost to follow-up monitoring more than 20% of the patients.

Published data may represent the best of the data, as Sweet and Poletti (20) demonstrated in their survey of approximately 200 fellow neurosurgeons. Of those, 140 (in 91 units in the United States and elsewhere) replied to the survey. The report highlighted how major morbidities and deaths occur and remain unreported. More deaths were noted in the authors' report than in all of the published studies they had identified. This method may need to be refined and a degree of flexibility, to adjust it to individual techniques, may be justified.

Proposals for Future Reports

Demographic and General Data

These data, including age, sex, division, laterality, number and type of previous surgical procedures, and previous complications resulting from surgery or medical treatment, should be collected and reported in detail (*Table 6*). These data are not

difficult to collect and may become relevant in future epidemiological studies. Basic details of all operations (e.g., radiosurgical dose, degree and timing of balloon compression or temperature and timing of radiofrequency thermorhizolysis, presence of a groove in the trigeminal nerve, or simply arterial or venous contact) should be provided (5, 23).

Diagnostic Criteria and Definitions

There was a marked lack of consistency in the reports, beginning with the diagnostic criteria, which were noted in only two-thirds of studies and often were not explicitly defined. Definition of the diagnostic criteria is essential for comparisons of data. Typical and atypical trigeminal neuralgia should always be clearly defined. The International Association for the Study of Pain definition of trigeminal neuralgia applies to typical trigeminal neuralgia (9). Atypical trigeminal neuralgia involves, in addition to the paroxysms of lancinating pain, constant background pain. The outcomes for patients with typical and atypical trigeminal neuralgia may be, and usually are, reported in conjunction, but data suggest that outcomes (in terms of pain relief, recurrence rates, and local complication rates after further lesional procedures) may be quite different (12, 17, 24). We suggest that the two types be defined clearly and reported on separately. Patients with primary ("idiopathic") or secondary (to multiple sclerosis or tumors) trigeminal neuralgia are reported on separately in most studies, which is entirely necessary because outcomes for multiple sclerosis-related trigeminal neuralgia may be different.

Systematic Measurements of Pain

Measurements of pain are desirable. It is difficult to understand how pain can be said to have been relieved or partially relieved unless it is systematically measured preoperatively and postoperatively. Pain is entirely subjective and is impossible to measure directly, but there are now many well-validated measurement methods. We propose that all patients undergo pain assessments preoperatively and at each follow-up examination, with visual analog scales such as that in the Brief Pain Inventory, which also assesses quality of life (11). This is particularly relevant for radiosurgery; some patients with partial pain relief still consider the procedure beneficial and would have it repeated (16).

The McGill Pain Questionnaire can help clinicians differentiate between atypical facial pain and trigeminal neuralgia (8). It should be used routinely, at least at the first visit. When patients report pain after surgery, it is essential to ascertain whether the pain is truly that of trigeminal neuralgia and not of another type and how it compares with the preoperative pain. We recommend the use of the Brief Pain Inventory preoperatively and at each follow-up visit.

Definition and Reporting of Pain Outcomes

For data to be comparable, universal definitions must be adopted. Definitions of what is meant by a failure, a recurrence, and complete and partial pain relief are essential. The use of and the need for trigeminal neuralgia drugs have been used as outcome measures. Although this approach is probably useful, it must be remembered that some patients continue to take drugs not because they have pain and need the drugs but because they fear the return of their pain.

In the context of trigeminal neuralgia, the realistic goal of any surgeon is to completely relieve the patient's symptoms. Anything other than complete relief is, in principle, a failure to achieve the initial goal of treatment.

The designation of "excellent outcome" for complete pain relief in a disease with such high recurrence rates seems enthusiastic. In our opinion, a good outcome for any surgical technique for trigeminal neuralgia treatment is complete pain relief without the need for medications and with no complications. Some patients, however, experience only partial pain relief but consider their pain adequately controlled (16).

An outcome of "50% pain relief," as used in most studies reporting outcomes of radiosurgery, is a good measure of relative treatment success in chronic pain states but, in our opinion, is unsatisfactory for trigeminal neuralgia. Trigeminal neuralgia tends to be an all-or-none phenomenon and, unless the severity of pain has been measured preoperatively, 50% relief may mean two mild attacks per week for one patient and one severe attack every 2 months for another. If partial pain relief is to be regarded as a measure of relative treatment success, then it must be measured or qualified with patient satisfaction.

Complete pain relief and partial pain relief are very different outcomes for trigeminal neuralgia surgery, and they must be reported separately. We propose that three treatment outcomes be reported, namely, complete pain relief without the need for medication (complete relief, good outcome), partial pain relief but the patient considers the pain adequately controlled (partial relief, fair outcome), and treatment failure.

A patient's pain may be totally controlled with drugs after surgical treatment but, if the drugs are at all needed for symptom control, then the pain cannot be said to have been completely relieved with surgery. All patients should undergo gradual discontinuation of their drugs after treatment, except for the few who genuinely feel psychologically dependent on them. If drugs are at all needed for symptom control after treatment, then patients should be considered to be partially relieved of their pain, even if their symptoms are totally controlled with small doses of medication. Data suggest that recurrence rates after radiosurgery may be different for such patients (6, 15).

North et al. (12) demonstrated how recurrence rates varied depending on whether a recurrence was defined as any return of pain, even if controlled by medication, or a recurrence was recorded only if repeat surgery was needed. Pain recurrence is, in principle, any occurrence of pain for a patient who was previously pain-free; however, patients with partial relief who consider their pain adequately controlled can and do experience recurrences. We propose that recurrences be defined and reported as "minor" and "major."

"Minor recurrence" indicates recurring symptoms that the patient considers adequately controlled, with or without medication, for a patient who was previously completely pain-free. It follows that patients who are partially relieved of their symptoms but regard them as adequately controlled after surgery cannot experience minor recurrences. "Major recurrence" indicates that the symptoms are not adequately controlled, irrespective of whether the pain was previously completely or partially relieved, whether the patients wish to repeat their perioperative experiences or not, and whether they wish to take medications or not. Minor and major recurrences should be reported separately. If this is impractical because of small patient numbers, then all recurrences should be accounted for in the construction of the Kaplan-Meier charts for actuarial analysis.

Kaplan-Meier actuarial methodology must be adopted as the standard method of reporting pain outcomes, because it allows all patients to be included in the analysis, whether they have been lost to follow-up monitoring, have died, or have not experienced a recurrence of pain. It also allows data to be compared at the same regular intervals and allows statistical analyses to be performed. If follow-up periods vary among patients, then it is impossible to determine an accurate recurrence rate unless actuarial methodology is used. However, problems in the interpretation of Kaplan-Meier graphs can occur. For example, a study reporting results for 300 treated patients may indicate that 70% of those available for evaluation at 5 years are still pain-free, but this finding may refer to seven patients available at that follow-up time. Unless such data are known, the interpretation of the results could be misleading. It is therefore essential that the numbers of patients available at each follow-up time be clearly stated in the chart, unless all patients were monitored until the end of the observation period. If the patient numbers are missing, then the results should not be extrapolated beyond the median follow-up time for the whole series (14). Studies evaluating the outcomes of surgical treatment of trigeminal neuralgia must at least provide detailed actuarial data on complete pain relief and major recurrence rates.

Quality of Life Assessments

Quality of life measures are rarely used, although it may be the patients' quality of life that drives them to surgery and quality of life may be the only factor that differentiates one type of operation from another. Pain relief at all costs may not be what all patients want. All patients want to know how complications could affect their quality of life. A significant number of complications, some of which are serious, are transient; however, very few studies report changes with time, and most of those studies note changes in sensation and hearing. It is thus difficult to advise patients how long the transient complications are likely to last. Some of the low-scoring studies, for example, did not record the number of patients with sensory losses after radiofrequency thermorhizotomy, possibly because the authors assumed that sensory loss is normal. However, the higher-quality studies demonstrated that not all patients experience sensory losses. One study of a small group of patients who underwent radiofrequency thermorhizotomy demonstrated how complications (e.g., eye problems and the inability to eat) changed with time (24).

Pain relief alone is not enough to achieve a high quality of life; therefore, it is desirable that all outcome reports include detailed descriptions of complications and basic quality of life assessments. The two scales that should be used, as a minimum, to report quality of life are the Hospital Anxiety and Depression scale for the assessment of depression and anxiety and the Brief Pain Inventory, both of which are currently being used nationally by the United Kingdom Pain Society (23).

Unanswered Questions

The results of this study might seem to leave clinicians and patients in a state of uncertainty regarding the outcomes of the different treatments for trigeminal neuralgia and how different surgical techniques compare with each other. Despite its methodological limitations, this study has confirmed the flaws of medical literature in general. However, it has identified good-quality data in well-constructed studies. It has also demonstrated that many well-gathered data could not be used for evaluation of pain outcomes because of methodological errors in reporting.

Until data are universally reported in a uniform robust manner, we can only attempt to identify the best studies and "gather" their data to apply those results to our clinical practices. The methods for identifying high-quality studies must be rigorous, transparent, and reproducible, so that biases are minimized. This may be the best evidence presently available. We need generally accepted criteria for the reporting of future studies, such as those proposed for the reporting of randomized controlled trials (the Consolidated Standards of Reporting Trials statement) (10). It may also become easier for non-English-speaking authors to report their data, so that a more global perspective is obtained.

McCulloch et al. (7) analyzed the difficulties of performing randomized controlled trials in surgery and proposed a strategy that involves integrating modified randomized controlled trials with prospective audit and quality-control studies. They proposed that, for surgical research, "detailed prospective audit data collection is essential" and "continuous quality control techniques should be used to determine whether randomized controlled trials are appropriate" (7, p 1451). Those authors stressed the importance of improved cooperation and the need for larger randomized studies. They also highlighted the difficulties of performing randomized controlled trials when learning periods and alterations in techniques must be taken into account, and they argued that data from studies other than randomized controlled trials can and should be used. The proposed definitions, data collection checklist, and methods for evaluating and reporting outcomes attempt to address these issues in the field of surgical treatment of trigeminal neuralgia. The proposed methods must be validated with further research.

CONCLUSION

Studies evaluating the outcomes of surgical treatment of trigeminal neuralgia are generally not reported in a robust manner. This study, which was performed by a pain physician and a neurosurgeon, aims to be a starting point for establishing internationally accepted guidelines for future trials, which can benefit from criticism by clinicians.

The proposed definitions and outcome measures (or others, if universally adopted) and the proper use of actuarial methodology to report results should facilitate outcome evaluation and enhance comparability among different centers and surgical techniques. Clinicians should then be able to better tailor surgical procedures to individual patients, and patients should be able to make informed decisions on the basis of good-quality evidence.

REFERENCES

1. Anonymous: NHS Centre for Reviews and Dissemination Report 4, 2001. Available at: http://www.york.ac.uk/inst/crd/report4-ph5, section 2.5.5.2.
2. Bittar GT, Graff-Radford SB: The effects of streptomycin/lidocaine block on trigeminal neuralgia: A double blind crossover placebo controlled study. **Headache** 33:155–160, 1993.
3. Crombie IK: *The Pocket Guide to Critical Appraisal*. London, BMJ Publishing Group, 1996.
4. Flickinger JC, Pollock BE, Kondziolka D, Phuong LK, Foote RL, Stafford SL, Lunsford LD: Does increased nerve length within the treatment volume improve trigeminal neuralgia radiosurgery? A prospective double-blind, randomized study. **Int J Radiat Oncol Biol Phys** 51:449–454, 2001.
5. Hamlyn PJ: *Neurovascular Compression of the Cranial Nerves in Neurological and Systematic Disease*. Amsterdam, Elsevier Sciences BV, 1999.
6. Maesawa S, Salame C, Flickinger JC, Pirris S, Kondziolka D, Lunsford LD: Clinical outcomes after stereotactic radiosurgery for idiopathic trigeminal neuralgia. **J Neurosurg** 94:14–20, 2001.
7. McCulloch P, Taylor I, Sasako M, Lovett B, Griffin D: Randomised trials in surgery: Problems and possible solutions. **BMJ** 324:1448–1451, 2002.
8. Melzack R, Terrence C, Fromm G, Amsel R: Trigeminal neuralgia and atypical facial pain: Use of the McGill Pain Questionnaire for discrimination and diagnosis. **Pain** 27:297–302, 1986.
9. Merskey H, Bogduk N: *Classification of Chronic Pain: Descriptors of Chronic Pain Syndromes and Definitions of Pain Terms*. Seattle, IASP Press, 1994.
10. Moher D, Schulz KF, Altman D: The CONSORT statement: Revised recommendations for improving the quality of reports of parallel-group randomized trials. **JAMA** 285:1987–1991, 2001.
11. Newton-John J: Measurement of pain in adults, in Zakrzewska JM, Harrison SD (eds): *Assessment and Management of Orofacial Pain*. Amsterdam, Elsevier Science, 2002, ed 1, pp 87–104.
12. North RB, Kidd DH, Piantadosi S, Carson BS: Percutaneous retrogasserian glycerol rhizotomy: Predictors of success and failure in treatment of trigeminal neuralgia. **J Neurosurg** 72:851–856, 1990.
13. Peto R, Pike MC, Armitage P, Breslow NE, Cox DR, Howard SV, Mantel N, McPherson K, Peto J, Smith PG: Design and analysis of randomized clinical trials requiring prolonged observation of each patient: Part II—Analysis and examples. **Br J Cancer** 35:1–39, 1977.
14. Pocock SJ, Clayton TC, Altman DG: Survival plots of time-to-event outcomes in clinical trials: Good practice and pitfalls. **Lancet** 359:1686–1689, 2002.
15. Pollock BE, Phuong LK, Gorman DA, Foote RL, Stafford SL: Stereotactic radiosurgery for idiopathic trigeminal neuralgia. **J Neurosurg** 97:347–353, 2002.
16. Rogers CL, Shetter AG, Fiedler JA, Smith KA, Han PP, Speiser BL: Gamma knife radiosurgery for trigeminal neuralgia: The initial experience of the Barrow Neurological Institute. **Int J Radiat Oncol Biol Phys** 47:1013–1019, 2000.
17. Saini SS: Reterogasserian anhydrous glycerol injection therapy in trigeminal neuralgia: Observations in 552 patients. **J Neurol Neurosurg Psychiatry** 50:1536–1538, 1987.
18. Smetana GW, Shmerling RH: Does this patient have temporal arteritis? **JAMA** 287:92–101, 2002.
19. Stajcic Z, Juniper RP, Todorovic L: Peripheral streptomycin/lidocaine injections versus lidocaine alone in the treatment of idiopathic trigeminal neuralgia: A double blind controlled trial. **J Craniomaxillofac Surg** 18:243–246, 1990.
20. Sweet RL, Poletti CE: Complications of percutaneous rhizotomy and microvascular decompression operations for facial pain, in Schmidek HH, Sweet WH (eds): *Operative Neurosurgical Techniques*. New York, Grune & Stratton, 1988, pp 1139–1143.
21. Walker JB, Akhanjee LK, Cooney MM, Goldstein J, Tamayoshi S, Segal-Gidan F: Laser therapy for pain of trigeminal neuralgia. **Clin J Pain** 3:183–187, 1988.
22. Zakrzewska JM: Trigeminal neuralgia. **Clin Evid** 7:1221–1231, 2002.
23. Zakrzewska JM: Trigeminal neuralgia, in Zakrzewska JM, Harrison SD (eds): *Assessment and Management of Orofacial Pain*. Amsterdam, Elsevier Science, 2002, ed 1, pp 263–366.
24. Zakrzewska JM, Jassim S, Bulman JS: A prospective, longitudinal study on patients with trigeminal neuralgia who underwent radiofrequency thermocoagulation of the gasserian ganglion. **Pain** 79:51–58, 1999.

Acknowledgments

We are grateful to the following clinicians who participated in establishing the criteria or appraising articles: P. Atkin, P. Bullock, R. Brisman, K. Burchiel, K. Casey, H. Coakham, S. Chong, K. Campbell, M. Escudier, S. Haines, J. Miles, O. Sparrow, and J. Tew. We are grateful to the editorial team of *Clinical Evidence* for their expertise in searching databases and for providing reprints when necessary; various friends assisted in the translation of articles. Helen Worthington and Wagner Marcenes provided statistical support, for which we are grateful. Neither author had any personal or institutional financial interest.

COMMENTS

Reports that evaluate management outcomes in patients with trigeminal neuralgia vary widely. Reports focus mainly on aspects such as technical issues, pain relief and the need to use medication, the degree or the quality of pain relief that patients experience, or management morbidity. The authors of this article have used a team of physicians experienced in the management of trigeminal neuralgia patients. They have reviewed the available articles on this topic and critiqued them with regard to the type of data presented. Overall, the authors have tried to create a rating scale for quality and to set a standard for data reporting. Interestingly, 56% of peripheral nerve procedure reports reached that standard, but the range of scores is wide. Glycerol rhizotomy reports were the best among the rhizotomy procedures, with 41% of studies reaching the authors' standard. Microvascular decompression reports faired less well, at 24%. Thirty-six percent of radiosurgical reports met the standard, and the range of scores for all articles was slightly higher. These findings may simply reflect the more recent use of radiosurgery in patients with trigeminal neuralgia. Particularly in an era of evidence-based medicine,

most such experts report data that deal not only with technique, morbidity, and outcomes but also with the patient's degree of pain relief.

At surgical seminars in which different management options for trigeminal neuralgia (or any other pain syndrome, for that matter) are discussed, it is clear that investigators evaluate and report their data differently. I hope that the recommendations contained in this report create a minimum standard for data reporting, which may allow patients to choose more intelligently among their available treatment options.

Douglas Kondziolka
Pittsburgh, Pennsylvania

I was among the neurosurgeons surveyed during the preparation of this article and am greatly sympathetic to the authors' goals, yet herein I attempt to comment on their article with as much objectivity as possible. The authors clearly point out the incompleteness, inconsistency, and lack of comparability of reports in the neurosurgical literature of the treatment of patients with trigeminal neuralgia. Although individual reports of a surgeon's or institution's experience are undoubtedly of value, particularly in the process of improving local practice and in providing suggestions regarding how neurosurgeons might improve their practice, their deficiencies become glaringly obvious when an attempt is made to compare and combine results to arrive at a generalizable conclusion.

For all of the reasons that the authors clearly point out, a meta-analysis of the reports of surgical therapy for trigeminal neuralgia cannot reasonably be accomplished at this time. There is not sufficient consistency in diagnosis, treatment, or outcome evaluation to even consider combining or comparing results statistically, and subjective comparison simply makes the risk of biased assessment even worse. The authors' message, simply stated, is that after decades of surgical treatment of trigeminal neuralgia, although a good deal is known about the prognosis for patients treated by some neurosurgeons in various ways, a comprehensive, scientifically supportable judgment cannot be made about the relative safety and efficacy of these procedures that is generalizable to most neurosurgeons or most patients with trigeminal neuralgia.

This analysis is not ideal, either. I take particular issue with the authors' use of different outcome standards for different surgical procedures. For example, requiring different lengths of follow-up and different numbers of patients in studies of treatment of the same disease is difficult to justify. The patient seeks one outcome: a life free of pain and without treatment complications. That standard should be applied to the evaluation of all treatments.

I hope that the authors continue to monitor the quality of reporting in neurosurgery journals and that neurosurgeons who report the results of their own process improvement projects heed these authors' suggestions so that all neurosurgeons may learn how to improve the treatment of patients with trigeminal neuralgia.

Stephen J. Haines
Charleston, South Carolina

This important, informative study should be read by anyone who is planning or conducting a study of the surgical treatment of patients with trigeminal neuralgia. In neurosurgical practice, this diagnosis is relatively common, and, considering that it is a relatively homogenous and "easy" diagnostic entity, I am surprised that the great majority of published studies apparently are of such poor quality and represent the weakest type of evidence. I was amazed that not more than 28 of 222 studies could be used to reliably estimate the probability of providing complete long-term pain relief after surgery. Few prospective studies are available. It also should be noted that an independent observer assessed the outcome in only 13 of the 222 studies. One can only fantasize about the generalizability of meta-analyses such the present one of trigeminal neuralgia applied to the treatment of other diseases in neurosurgery, in particular surgery performed to treat other forms of pain. It should be realized, however, that the inherent nature of surgery precludes blinded treatments, because sham surgery is unacceptable; therefore, most studies of the efficacy of surgery rely on observational data, which inevitably leads to the production of relatively low-level evidence.

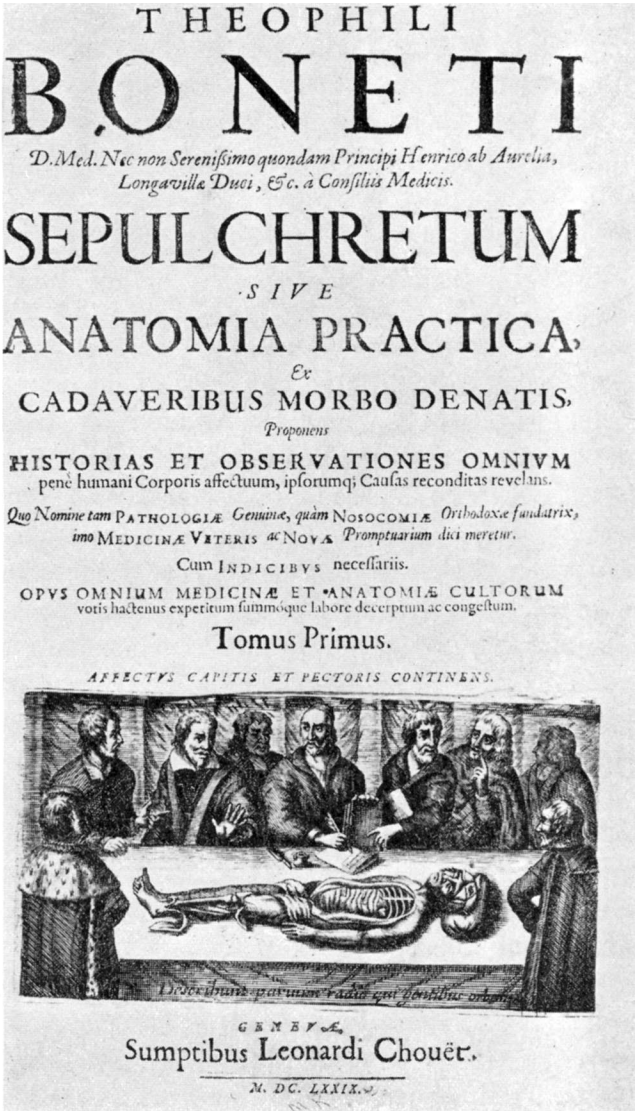
Perhaps the most valuable contribution of this study is its recommendations regarding the design of future investigations of surgical treatment in patients with trigeminal neuralgia. In the assessment of pain and its relief as a result of treatment, the visual analog score (VAS) is used extensively. VAS undoubtedly has proved to be clinically useful, but there are considerable problems involved in its practical application and interpretation. The outcome of VAS assessment is generally expressed as a number on a 10-step scale but without specifying whether the score refers to pain intensity and at best representing, for example, the transitory effect of a treatment (e.g., analgesia, stimulation) or the average pain intensity during the patient's awake hours.

The nature of typical trigeminal neuralgia—paroxysmal pain attacks and no continuous pain components—makes the VAS unsuitable as the sole and universal pain assessment measurement tool. Thus, VAS cannot be used for global assessment of pain with regard to suffering and discomfort. In contrast to other forms of chronic pain, however, quantitative assessment is suitable for patients with trigeminal neuralgia to measure alteration in the number of daily or weekly attacks. "Partial pain relief" often implies not only a reduced number of attacks but also decreased intensity of paroxysmal pain. This latter dimension, of course, is suitable for VAS evaluation. Such a composite evaluation supplements the recording of the improved effect of medication as a criterion for partial pain relief. As the authors emphasize, all outcome evaluations should include an assessment of the patient's quality of life.

Over the years, I have reviewed numerous articles on the surgical treatment of patients with trigeminal neuralgia. I have been astounded by the unprofessional way of reporting changes in trigeminal cutaneous sensation that may be a side effect of surgery. Generally, these changes are described as merely "sensory deficits," without specification of the extent or the degree of the severity or modality of the deficits, which implies that the possible presence of dysesthesia, hyperalgesia, or allodynia has not been taken into account. This issue is of considerable importance because such abnormalities of sensation are often associated with the occurrence of new spontaneous as well as evoked pain. Therefore, the present authors' recommendations regarding this aspect of the side effects of surgery are welcome.

The stringent specification of data that should be included in future studies of surgical treatment for patients with trigeminal neuralgia applies also to surgery performed for other forms of pain. The present study is indeed makes a major contribution toward the ultimate goal of obtaining evidence of the best possible quality in clinical studies.

Björn Meyerson
Stockholm, Sweden



Théophile Bonet (1620–1689), compiler and editor of the Sepulchretum, *published in 1679, a 1700-page work that preserved the work of others. It stands as the single greatest collection of work in the history of pathology.*