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Introduction and methodology: guidelines for the surgical management of cervical degenerative disease

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In March 2006, the Joint Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and Congress of Neurological Surgeons compiled an expert group to perform an evidence-based review of the clinical literature on management of cervical degenerative spine disease. This process culminated in the formation of the *Guidelines for the Surgical Management of Cervical Degenerative Disease*. The purpose of the *Guidelines* was to address questions regarding the therapy, diagnosis, and prognosis of cervical degenerative disease using an evidence-based approach. Development of an evidence-based review and recommendations is a multitiered process. Typical guideline development consists of 5 processes: 1) collection and selection of the evidence; 2) assessment of the quality and strength of the evidence; 3) analysis of the evidentiary data; 4) formulation of recommendations; and 5) guideline validation. This manuscript details the methodology in compiling the *Guidelines for the Surgical Management of Cervical Degenerative Disease*. *(DOI: 10.3171/2009.1.SPINE08712)*

Key Words • cervical spine • cervical spondylosis • methodology • practice guidelines

The surgical treatment of degenerative spine disease has increased in frequency and complexity. Using data from the National Hospital Discharge Survey, Davis[2] reported a > 70% increase in age-adjusted cervical fusion rates and a > 45% increase in rates of hospitalization for cervical spine surgery between 1979 and 1990. Angevine et al.[1] examined National Hospital Discharge Survey data between 1990 and 1999 and noted that the age-adjusted rates for cervical surgery remained the same throughout the decade but that the rates of fusion increased 40% in men and 62% in women. Rates of fusion varied regionally, with patients in Western US having the lowest rate of admission for cervical surgery and in the South having the highest. Northeastern US had the lowest rate for fusion.[1] North of the forty-ninth parallel, Pickett and colleagues[6] found differences in practice patterns among Canadian spinal surgeons as well. Various practitioners have used fusion and fixation at differing rates. With improvements in medical imaging of the cervical spine, the diagnosis of cervical degenerative disease has become easier. In concert with this progress have been technological advances in the surgical treatment of cervical spinal disease.

The purpose of this compendium, *Guidelines for the Surgical Management of Cervical Degenerative Disease*, is to address questions regarding the therapy, diagnosis, and prognosis of cervical degenerative disease using an evidence-based approach. The techniques to treat compression of the spinal cord and/or nerve root have evolved from simple anterior or posterior decompression to more elaborate means. Anterior decompression may be supplemented with fusion (allograft, autograft, or bone substitutes) and fixation (rigid or dynamic plates). Posterior decompression may be supplemented with fusion and fixation (off-label use of lateral mass screws) or laminoplasty. As practitioners rapidly mastered these techniques, questions have arisen as to the efficacy and timing of these therapies.

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Abbreviation used in this paper: RCT = randomized controlled trial.

Spine and Peripheral Nerves of the American Association of Neurological Surgeons/Congress of Neurological Surgeons compiled an expert group to perform an evidence-based review of the clinical literature on the management of cervical degenerative spine disease. Comprising the group were spinal neurosurgeons and orthopedic surgeons active in the Joint Section and/or the North American Spine Society. This combination of specialties ensured the comprehensive participation of both surgical specialties. At least half of the group had participated in prior guidelines development, and several had completed the evidence-based course developed by the North American Spine Society. The multiple recommendations that follow represent the product of this group with input from the Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons.

Chapters in this series first examine outcome measures. Thereafter, the compendium focuses recommendations on patient selection using clinical, radiographic, and electrophysiological factors, followed by recommendations for radiographic assessment of fusion status. The next series of recommendations involves surgery for nerve root compression (anterior and posterior decompression for radiculopathy). The final set of recommendations is for surgical treatment of myelopathy using anterior and posterior techniques. Included also are recommendations for management of pseudoarthrosis.

Methodology

Development of an evidence-based review and recommendations is a multitiered process. Guideline development within the realm of spinal surgery has followed a rigorous process delineated in prior specialty-specific guidelines.[7] These methods also conform to standard guideline development.[5] Typical guideline development consists of 5 process: 1) collection and selection of the evidence; 2) assessment of the quality and strength of the evidence; 3) analysis of the evidentiary data; 4) formulation of recommendations; and 5) guideline validation. Because the recommendations stemming from any evidence-based review are only as strong as the studies and analyses supporting them, the reader is strongly encouraged to review the scientific foundation supporting a given recommendation.

To determine topics to be reviewed, the guidelines group used the nominal group technique. The group facilitator solicited nominations for topics from each member. The initial target was to be upward of 20 topics reviewed. If > 20 topics were nominated, group members were to rank privately the priority of each topic. The 20 topics gaining the highest priority score would be reviewed. With redundancies eliminated from all nominations, the total topics numbered 16. Because the total was < 20, priority scores were not necessary.

Once topics were determined, the facilitator assigned topics to 1 of 5 subgroups consisting of 2 people each. Each subgroup undertook electronic literature searches of the National Library of Medicine and the Cochrane Database of Systematic Reviews for the years spanning 1966–2007, reviewed abstracts, and retrieved relevant articles. Each subgroup reviewed the bibliography of each relevant article for secondary sources, which were retrieved if relevant. The methodology was consistently applied across the different chapters. Due to the difference in subject matter, further details of the search process are contained in each chapter.

In the course of reviewing these topics, no series of sizeable, well-controlled RCTs was found. When smaller RCTs were found, a systematic review was undertaken. When a rigorous search finds many RCTs, reviewers may undertake a systematic review. The purpose of the systematic review is to strengthen (or weaken) the conclusion by examining consistencies (or inconsistencies) in the data of several RCTs. In the ideal circumstance, a meta-analysis may be performed by combining the data of several RCTs. When RCTs were lacking, evidence was analyzed primarily using a review process.

Quality of Evidence

The mainstay of any evidence-based review lies in the assessment of the quality of strength of the data. The group assessed the methodology of each manuscript carefully and assessed each study according to its relevant category—diagnosis, therapy, prognosis, or harm. The group applied a weighting scheme according to the methods delineated by Sackett and colleagues.[8] After review of the study methods, the group determined how well each individual study met the validity requirements within its category and assigned a class to the study. In keeping with prior surgical guidelines, a 3-class system (Classes I, II, and III) was used.[5,7,8] Class I evidence evolved from well-designed RCTs. Class II evidence arose from RCTs with design problems or from well-designed cohort studies. Class III evidence arose from case series or poorly designed cohort studies. It was the group's conclusion that expert opinion and case reports did not add significantly to the evidence used for the formulation of recommendations and should not be separately classified.

When disagreement arose as to the strength of evidence (that is, determining how well the methods conformed to the weighting scheme), the group resolved said disagreement by expert consensus within itself. To avoid the undue influence of a single individual, each member had the opportunity to list the reason(s) why a study should be downgraded or upgraded. Group members then prioritized each reason. If a reason had low priority, it was eliminated. Ultimately, there was convergence of opinion within the group.[3] The result was unanimity to support publicly the assessment of the quality of evidence and the strength of the guidelines despite potential individual reservations regarding specific details.

Formulation and Strength of Recommendations

The group formulated recommendations using expert consensus in a consensus development conference. After assessment of the quality and strength of evidence, the assigned subgroup summarized the studies leading to the basis of the Scientific Foundation section of each chap-

ter. In general, if high-quality (Class I or II) data were available on a particular topic, poorer quality evidence was only briefly summarized. If no high-quality evidence existed, Class III data formed the basis of the scientific foundation. Based on the quality and strength of data, each subgroup formulated initial treatment recommendations. Each subgroup presented these to the entire group whose membership included active members of the Congress of Neurological Surgeons, the American Association of Neurological Surgeons, the North American Spine Society, and the American Academy of Orthopedic Surgery. The presentation was a plenary session acting as a consensus development conference from which final recommendations arose.[3,5] Validation of the guidelines was done through external peer review prior to publication.

The group gave each recommendation a grade for strength based on the quality of the underlying studies. Grading was based on the methods of the Scottish Intercollegiate Guidelines Network[4] and also mirrored that used by the Oxford Centre for Evidence-Based Medicine (www.cebm.net). In brief, a recommendation based on consistent Class I studies was graded "A." A recommendation based on a single Class I study or consistent Class II studies was graded "B." A recommendation based on a single Class II study was graded "C." Finally, recommendations based on Class III or weaker data, or based on inconsistent data were graded "D."

Summary

During guideline development, the group commonly encountered unsophisticated or poorly designed comparative methods in clinical trials. The most common flaw was the lack of a control group or the utilization of historical controls. Other common flaws were invalid outcome measures, and the lack either of randomization or blinding of outcome assessors. Specific examples are provided in the text of each topic. At the conclusion of each chapter are suggestions for future areas of study and ideas to improve the quality of clinical research.

With each recommendation comes the risk of conformational bias. The recommendation of a therapeutic option presumes that functional and economic preferences have been determined. Reliable and valid outcome measures help in this respect. It is hoped that such functional and economic outcome measures represent the values important to the patient and society and less the practitioner. By focusing attention on outcome measures in each study, the values of the patient and society are represented in these guidelines.

To minimize any specialty bias, spinal surgeons from both orthopedic and neurosurgery departments participated in the creation of these guidelines. However, although invited, nonsurgical stakeholders did not participate—a circumstance that some might argue would predispose to conformational bias toward strong surgical recommendations. It is hoped in the future that nonsurgical stakeholders will participate. During this process, the entire group made a concerted effort to be unprejudiced. Many authors acknowledged that poor quality or controversial data often formed the basis of their predetermined ideas regarding standard treatment. It is expected that certain practitioners may disagree with the recommendations. However, with careful review of the scientific foundation, the critically thoughtful reader should find the recommendations warranted.

It is anticipated that these guidelines will act as a comprehensive review of the state of the field as it currently exists. Furthermore, it is hoped that their dissemination will stimulate areas for future rigorous clinical research.

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