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NASS Board of Directors Position Statement

Spine Patient Outcome Research Trial (SPORT): Multi-center randomized clinical trial of surgical and non-surgical approaches to the treatment of low back pain

The North American Spine Society (NASS) is a multidisciplinary organization that advances spine care through education, research and advocacy. The NASS membership consists of more than 20 medical specialties that encompass both surgical and nonsurgical approaches to the diagnosis and treatment of spinal disorders, including intervertebral disc herniation, spinal stenosis and degenerative spondylolisthesis.

Intervertebral disc herniation (IDH), spinal stenosis (SpS) and degenerative spondylolisthesis (DS) are the subject of the Spine Patient Outcome Research Trial—A Multi-center Randomized Clinical Trial of Surgical and Non-Surgical Approaches to the Treatment of Low Back Pain (SPORT). The North American Spine Society applauds the SPORT researchers in their undertaking of this study. The use of treatment outcomes of operative and nonoperative care are obviously areas that merit review and have a significant impact on spine patients everywhere. As an organization of spine care providers, NASS is in favor of any effort that is intended to further help our patients. It is an ambitious undertaking and, like all ambitious works, will be prone to critique. In view of the fact that the results of this comparative study could have a significant impact on spine patients and their care, and in the spirit of scientific discourse, NASS would like to provide the following comments for consideration. It is our hope that our comments will strengthen the study and those that follow it, and help spine care providers in interpreting the final study results. NASS does not favor one approach over the other but, like the SPORT authors, is in search of best scientifically proven approaches for patients.

At the request of the Board of Directors, three NASS Committees (Nonoperative Care, Surgical Care, and the Task Force on Clinical Guidelines Work Group) reviewed the study objectives and protocols to identify any areas of potential concern that may impact the study's outcome. NASS felt it was important to comment prior to the conclusion of the study to avoid any perception of bias based on the study results. The NASS Board of Directors then reviewed the committees' comments and a position statement was drafted.

Review Comments

Study introduction

There was some apprehension to find the following statement in the Introduction of the SPORT study "...there is little evidence to prove the effectiveness/efficacy of these therapies (spine surgeries) over non-surgical management." Moreover, the formal evidence analysis process used in the development of the NASS Clinical Guidelines demonstrated that evidence for both surgical and nonoperative treatment was equivalent. However, there is still some debate about this statement. Although perhaps unintentional, the SPORT study seems to announce a preconceived bias against operative care.

Patient selection

The patient selection process presents concerns. One of the cardinal requirements for recommending spine surgery for any of the three conditions being investigated is that patients have first exhausted all means of recovery using nonsurgical interventions. Indeed, the first exclusion criteria is listed as: "Patient has not yet undergone a sufficient trial of non-surgical treatment (six weeks for IDH and twelve weeks for spinal stenosis or degenerative spondylolisthesis)."

"Sufficient" appears to be defined by the passage of a designated number of weeks, independent of—or even regardless of—program content. "Sufficiency" of nonoperative care is the first criteria for determining a patient's candidacy for surgery and, therefore, inclusion in this study. How can randomization be justified to even more nonsurgical care? If the patient is randomized to more nonoperative care, and there is resulting benefit from it, then that patient should not have been eligible for the study in the first place as all nonoperative care options had not yet been exhausted. If the patient is randomized to more nonoperative care and there are no resulting benefits, there can be no expectation of meaningful findings using treatments that have already proven to be unsatisfactory for the patient. At the point of randomization, patients are already failures to nonoperative care. Meaningful findings regarding nonoperative

or operative care will be difficult to determine (i.e., nonoperative care cannot find anything meaningful from repeating an already failed regimen; or surgical care-inherent bias against surgery if initial nonoperative failure is not analyzed with that intent).

In the Protocol for Surgical Intervention for DS (sent to NASS, and dated 9/30/99) is the statement: “Additionally, for those patients who are randomized or who have a preference for fusion...” The notion of a patient having a “preference” for a fusion introduces uncertainties. It would appear that if a patient had a preference for a fusion in this group, it would compromise the randomization process. This may simply be a confusing statement. Such a statement was not included in the summary of the study published in *Spine* (2002;27:1361–1372). This created further confusion.

Concerns about patient selection for the study include the exclusion criteria. In the symptomatic group, patients who require surgical intervention before the full 6–12 weeks of nonsurgical treatment should not be automatically excluded. Those patients choosing a surgical option before this time should be included if they are patients who have clear, compelling indications for surgery, with or without progressive neurological deficit. Debilitating pain is an appropriate surgical indication if the clinical diagnosis is clear. If the intent is to eliminate this group of patients in the study, it must be emphasized; otherwise, the study would be biased toward nonsurgical treatment as many patients without cauda equina syndrome cannot or will not wait the mandatory 6–12 weeks for conservative treatment if there is no progress with nonsurgical care. Eliminating the group who need surgery immediately will bias the results against surgery. The generalized conclusions made from this study will not point out that patients who really needed surgery were not included in the study.

Treatment protocols

Each of the three surgical protocols is very clearly and appropriately stated, making their subsequent analysis valid. The nonsurgical care protocol is lacking by not being equally standardized. While a minimum treatment standard is mandated, the maximal treatment is open-ended and states: “It is highly recommended that sites aggressively utilize all appropriate, non-surgical therapies in those non-surgical patients who do not respond to minimum intervention.” Following this statement is a list of Non-Surgical Treatment Options that include 42 options, ranging from Psychological Assessment/Counseling to Epidural Steroid Injections (a technique some would consider at least invasive, if not operative) and Reiki. Also listed are in excess of 50 possible medications including NSAIDs, steroids, time-released narcotics, and herbal remedies. Such an open-ended protocol, both with respect to duration as well as types of treatment, represents a serious flaw in this design and could seriously bias the outcomes.

Invariably, interpretations of these guidelines will differ in each of the 12 centers. In addition, how does one determine how procedures such as IDET are categorized? It is an intervention, but is it surgical or nonsurgical? A more structured protocol, based on a best-evidence analysis of nonoperative treatments (such as the NASS Clinical Guidelines) should be utilized in a study of this size and importance.

Token efforts are made in the written proposal to suggest that nonoperative care will indeed be standardized, but with only three very general recommended criteria: (1) active physical therapy; (2) education/counseling in home exercise instruction; and (3) the use of NSAIDs if tolerated. The variation in the first two of these criteria across the multiple centers is wide. The lack of such structure seriously compromises the conclusions of the study. The SPORT study introduction states that: “All patients...will receive standardized interventions.” This is clearly not true.

Patient follow-up

NASS has concerns about the study’s ability to adequately follow-up with patients. The follow-up can be very difficult to collect. The NASS Guidelines Study in Houston provides a recent example of the difficulties in follow-up, even with dedicated researchers assigned to the task.

Cross over and analysis

The cross over guidelines for the patient populations is troubling. There is concern about how cross over will be handled and analyzed, as it could seriously impact the outcome of the study. Because intent-to-treat analysis is being used, the initial intervention selected by patients prior to enrollment or by randomization will be used as their designation. Patients who are deemed nonoperative but then cross over to the surgical arm will be designated nonoperative cases even though they received surgery. Patients who select surgery and then decide not to have it will be considered surgical cases, even without the procedure. How cross over is handled and analyzed can alter the conclusion based on the methodology used. Intent-to-treat analyses are usually used in cases where subjects start a specific treatment, but then prematurely drop out. Their gains attributed to that treatment are evaluated using methods such as time-weighted mean changes. It is a methodological “stretch” to handle cross over in an intent-to-treat analysis, especially in two such disparate interventions such as surgical and nonsurgical, when subjects never even began the treatment.

Resource utilization and costs analysis

One of the critical outcome measures in this study is the Resource Utilization and Cost. Looking at direct costs (possibly the most relevant outcome measure in this study to those who will use it to potentially determine health care policy and reimbursement decisions), there is a bias against operative care. This results in large part from the open-ended

protocol selected for nonoperative care patients discussed previously. In calculating operative costs, the data are almost completely and externally verifiable in that these costs will be calculated from CPT and DRG codes recorded at each hospital admission and from external laboratory records. Thus, the costs for surgery, hospitalization and medications can be obtained and verified through coding. National fee schedules can readily be made for these data, leading to reliable cost-estimates. The majority of the nonoperative data will be obtained from “self-report” and, thus, will not be externally verifiable in many cases. Given the fallibility of human memory, this could lead to serious under-reporting of services and, therefore, costs associated with nonoperative treatments. Also, serious assumptions have to be made to develop a national fee schedule for techniques such as acupuncture, therapeutic touch, Feldenkrais, Reiki, energy work, etc. Thus, comparison of the nonoperative care data, that will not be easily verifiable, to that of operative care, most of which will be externally verifiable, will be of questionable validity. Furthermore, how is the evaluation of the treatment going to be defined? Are they using outcomes instruments that are patient-centered, and are reliability and sensitivity tested? If one measures cost, one should measure benefit too.

Summary

NASS applauds this and any effort to continue to further knowledge about the best possible treatments for spine care patients. We do, however, wish to express a few reservations. It should also be noted that representatives of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Spine Section have expressed similar methodological concerns with the SPORT study (Dunsker SB, Awad IA, McCormick PC. *Journal of Neurosurgery* 2003;98:1150–1152). The study may provide a large amount of data, but NASS is concerned that the results may not assist individual doctors help individual patients decide if surgery or nonoperative treatment is appropriate. This should be the fundamental goal of a study that compares treatment outcomes. The interests of NASS lie in seeing results that are accurately reflected through good study design, and that ultimately will benefit all spine care patients. NASS looks forward to the opportunity to further review the results of this study.

North American Spine Society Board of Directors
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