Recently there have been articles in the New York Times questioning the value of fusions and possible overuse of spine surgery. The Center for Medicare/Medicaid Services (CMS) has contacted SRS and other spine societies to ask for comment.

CMS query into the efficacy of spinal surgery - by Dr. David Polly:

CMS has initiated a query into the efficacy of spinal surgery. This query appears to be the result of the New York Times articles published at the end of December 2003, and the opinion piece (Sounding Board) in the New England Journal of Medicine by Nachemson, Deyo and Mirza. As a result, Sean Tunis, MD, MSc, Director, Coverage and Analysis Group, Office of Clinical Standards and Quality, Health Care Financing Administration has contacted organized Neurosurgery (CNS and AANS) as well as AAOS, along with direct contact of Dr. Nachemson and initiated a discussion about this topic. Unfortunately the AAOS did NOT contact the SRS and ask for our participation. NASS and the CSRS were contacted and invited to send representatives.

At issue is is there evidence-based support for the efficacy of spine surgery for back pain. Obviously this is a controversial topic since neither diagnosis nor treatment is well agreed upon. When there is wide practice variation there are opportunities for application of scientific rigor to identify best practices. Pragmatically, the greatest increases in surgical expenditures for payors has been in bariatic surgery and spinal fusion surgery. With the dwindling health care pie (due to the significant increase in cost of the prescription drug benefit as well as the changed-increased- reimbursement for cancer chemotherapy) in the dollar neutral CMS budget, offsets have to be achieved somewhere. This is the reality of the political environment.

Why does this matter for our patients? CMS sets a national policy for coverage or non-coverage of procedures. While most of the fusion for back pain is not in the Medicare beneficiary population, their coverage decisions are nearly universally adopted by other third party payors. If CMS chooses not to cover this procedure, then it is very likely the others will follow suit.

So then at issue is what is the scientific basis for our treatment decisions and are they cost effective? Optimal information from the CMS viewpoint is derived from multiple, high quality prospective randomized trials. Here there is much debate. The first question is what data exists. The Swedish Lumbar Spine Study Group has done and published a prospective, randomized trial between non-operative treatment and fusion for low back pain. The fusion group had two subsets- instrumented and uninstrumented fusion. The study showed the benefit of fusion compared to non-operative treatment. It did not show significant incremental benefit to the use of instrumentation (pedicle screws). There are other studies that have been presented but not yet published in peer-reviewed literature. This leads to methodologists arguing against this form of treatment as being unproven. There are a number of important caveats. There are no prospective, randomized trials comparing non-operative treatment of degenerative joint disease of the hip or knee, to total joint arthroplasty. Yet total joint replacement has been touted as one of the most cost-effective musculoskeletal interventions based upon SF-36 benefit per dollar expended. So it is not at risk for a decision not to be a covered benefit from CMS.

So what compelling data exists to support fusion for back pain? There have been a number of high quality clinical trials comparing different forms of surgical treatment. Herkowitz has compared decompression alone to decompression and fusion for degenerative spondylolisthesis. This demonstrated the superiority of fusion to decompression alone. Next he looked at fusion with and without instrumentation. At 2 years the data showed a higher fusion rate in the instrumented group but no difference in clinical outcomes. However at 5 years, the patients who had solid fusions had better outcomes than those who had pseudarthroses. What about fusion for pure, discogenic back pain? The rhBMP-2 clinical trials have provided a wealth of data showing significant outcomes improvement for the experimental and control patients. The magnitude of the Oswestry Disability Index improvement as well as the SF-36 PCS benefit is profound and commensurate with the improvement seen in the best orthopaedic interventions (similar to total hips and better than total knees). However the methodologists argue against this being compelling data. But they are surprisingly not arguing against total joint replacement!). Interestingly the SF 36 data sets available show that chronic low back pain is very debilitating and that it tends to continue to deteriorate over time rather than spontaneously improving. The changes in the clinical trials are profound improvements rather than slow continued deterioration.

So the big question facing us as spine surgeons is will CMS mandate prospective, randomized US data comparing non-operative to operative treatment. As surgeons do we consider it ethical to randomize our patients when they have usually already failed non-operative treatment? Are there other ways to demonstrate the efficacy of our interventions? Will CMS have any interests in trials that do not include patients that are in their beneficiary population or will this battle have to be fought with each and every insurer?

Sincerely,
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SRS Advocacy Committee Member