Lumbar degenerative scoliosis is a relatively common problem, and is being treated more frequently due to the confluence of an aging population and an increased capacity and willingness to manage difficult problems in older patients. Lumbar degenerative scoliosis is a complex pathology as it often involves the intersection of degenerative spinal stenosis and spinal deformity. While previous studies provide an indication that these patients may benefit from surgical treatment, the substantial variability in treatment underscores the opportunity for improvement. Optimizing treatment for lumbar degenerative scoliosis is critical as surgical intervention, while potentially providing substantial clinical benefit also entails measurable risk and significant expense. In light of these issues, evidence-based guidance generated through Appropriate Use Criteria (AUC) development offers the potential to improve both the quality and cost effectiveness of care.

The lumbar degenerative scoliosis AUC represents a significant step toward evidence-based treatment in spinal surgery. This is the first time that spine societies and industry partners have collaborated to support evidence development. The willingness of all involved to support a completely independent process underlines a commitment to trust the evidence. Subsequent studies may validate and/or refine the AUC recommendations, but the most important result is that the standard for evidence quality has been raised.

KEY WORDS: Lumbar degenerative scoliosis, Appropriate use criteria

Evidence-based treatment is an important tenet of optimal medical and surgical management and of cost-effective care. The application of evidence-based treatment in clinical practice requires sufficient high-quality evidence to drive consensus and guide decision making, but spine surgeons have been slow to build an adequate evidence base for many commonly performed lumbar spine procedures. With the exception of decompression for spinal stenosis or disk herniation, and decompression and fusion for spondylolisthesis, there are few well-supported, noncontroversial evidence-based treatment algorithms.\textsuperscript{1,2,3} Thus, spine surgeons routinely make treatment recommendations and decisions based on limited information, or low-quality data, particularly for complex pathologies. The presence of variability in the management of complex disorders of the spine is a reflection of the absence of an evidence-based approach to care.\textsuperscript{4,5}

Adult lumbar degenerative scoliosis is a common spinal disorder that is characterized by significant variability in clinical presentation and management. Patients with adult lumbar scoliosis have a wide spectrum of clinical symptoms, spinal deformity patterns, neurological involvement, and associated comorbidities. The heterogeneity of clinical presentation and structural pathology in patients with adult lumbar degenerative scoliosis has complicated rigorous clinical investigation, and contributed to the absence of clear guidelines for care. Despite this level of complexity, lumbar degenerative scoliosis is a diagnostic entity for which there seems to be some underlying consensus regarding treatment.

Although adult lumbar degenerative scoliosis presents with a wide range of clinical scenarios, patients may be divided into 2 fairly distinct
populations. The first is a population with symptoms stemming from the deformity itself. These tend to be larger curves, and may have associated spinal stenosis, but treatment is often driven by symptoms of sagittal imbalance. These patients typically require significant deformity correction as part of any surgical treatment strategy. The second populations, much more common in standard clinical practice, are patients with primary complaints of spinal stenosis in whom treatment is complicated by a concomitant scoliosis. These are often smaller curves without sagittal imbalance that might not require surgical treatment in isolation, but must be addressed in order to facilitate appropriate management of the associated spinal stenosis.

The assumption that these smaller curves would require stabilization to allow adequate decompression has been challenged by a series of payer-generated treatment guidelines that sought to delineate the role and scope of surgical intervention for lumbar degenerative scoliosis. A representative example is a draft medical policy issued in 2011 by a regional southeast Blue Cross Blue Shield provider. The proposed policy authorized lumbar degenerative scoliosis fusion based on standard adolescent idiopathic scoliosis surgical indications (curve progression and Cobb Angle > 50°), but did not really address the common application of lumbar fusion to facilitate adequate decompression in the setting of spinal stenosis and lumbar scoliosis. While discussions between the Blue Cross Blue Shield provider and several national orthopedic, neurosurgical, and spine societies led to a change in the proposed medical policy, this interaction was one of many which emphasized the need for evidence-based guidance for the treatment of lumbar degenerative scoliosis.

Over the next year, the Scoliosis Research Society investigated potential pathways to support improved evidence development. While a formal evidence-based guideline process might be ideal, the body of literature seemed insufficient to generate meaningful recommendations. Support for randomized trials presented challenges both in terms of cost and time course. Also, efforts at randomization in the adult deformity population had proven difficult. Therefore, potential avenues that were considered included society-generated treatment recommendations, a systematic review, a cost-effectiveness modeling study, and Appropriate Use Criteria (AUC) development. At that time, AUC methodology had been widely used in cardiology, but had not yet been widely adopted by the American Academy of Orthopedic Surgery or other Spine Societies.

AUC is a methodology developed by the RAND Corporation and the University of California Los Angeles (RAND/UCLA) that combines best available evidence and multispecialty expert opinion in an iterative process designed to optimize medical decision making. The methodology is most applicable where there is agreement that an intervention may be efficacious, but uncertainty as to the specific clinical indication best suited for that intervention. This approach seemed ideal for lumbar degenerative scoliosis, as there was a reasonable evidence base supporting surgical treatment, but substantial patient heterogeneity and therefore less clarity as to which specific patient was best treated by decompression alone, decompression and fusion, deformity correction, or with no surgery.

The Scoliosis Research Society collaborated with the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, and industry partners Medtronic, DePuy Synthes, and K2M to fund an AUC through a foundation mechanism. RAND/UCLA designed and executed the lumbar degenerative scoliosis AUC independently, under the direction of Teryl Nuckols, MD. The decision to invest in an independent process, rather than to perform an AUC internally, reflected the anticipated level of scrutiny surrounding evidence development for spine surgery. The purpose of this paper is to review the process of AUC development for adult lumbar degenerative scoliosis, and to summarize the findings regarding appropriate and inappropriate care for specific clinical scenarios.

### AUC METHODOLOGY

The RAND–UCLA Appropriateness Method was developed to guide decision making based on the combination of expert opinion and best available information. The method is based on the definition that an appropriate procedure is one for which “the expected health benefit (eg, increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeds the expected negative consequences (eg, mortality, morbidity, anxiety, pain, time lost from work) by a sufficiently wide margin that the procedure is worth doing, exclusive of cost. The appropriateness of an intervention is considered for a specific clinical scenario, with consideration of risks and benefits in the setting of granular information regarding the specific case.

RAND solicited and selected an 11-member expert panel consisting of orthopedic surgeons, neurosurgeons, physiatrists, pain management physicians, and primary care providers,

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### TABLE. Lumbar degenerative scoliosis treatment pathway

<table>
<thead>
<tr>
<th>Degenerative scoliosis surgical evaluations</th>
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<tr>
<td><strong>Prerequisite assumptions</strong></td>
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<tr>
<td>1. Substantial pain/disability</td>
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<td>2. Failed non-op treatment</td>
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<tr>
<td>3. Weight bearing x-ray (36 films preferred)</td>
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<tr>
<td>4. Advanced imaging (MRI/Myelo/CT scan)</td>
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<tr>
<td><strong>Key questions</strong></td>
</tr>
<tr>
<td>1. Does the patient have neurogenic symptoms; radiculopathy, neurogenic claudication, or weakness?</td>
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<tr>
<td>2. Severity of stenosis on imaging (mild, moderate, severe).</td>
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<tr>
<td>3. Does the patient have standing imbalance (sagittal or coronal)?</td>
</tr>
<tr>
<td>4. Radiographic curve parameters (Cobb angle, sagittal imbalance)</td>
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<tr>
<td>5. Medical risk for surgical treatment (comorbidities)</td>
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</tbody>
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reflecting the diverse clinicians who care for patients with lumbar degenerative scoliosis. An important tenet of AUC methodology is that the panel ratings reflect the views of all relevant care providers, with less than half the panel consisting of practicing surgeons. The RAND team also performed a systematic review of the existing literature as a resource for the expert panel. Based on the existing evidence, the RAND team developed hypothetical clinical scenarios, and a draft set of questions regarding treatment selection. The draft questions were subsequently modified and refined as part of the panel process.10

The lumbar degenerative scoliosis AUC was somewhat unique in that the panel addressed not only patient selection but also the spectrum of surgical procedures that could theoretically be used for each clinical scenario. For those patients identified as appropriate surgical candidates, the surgical treatment options considered were decompression alone, decompression and fusion in Situ, decompression with fusion and deformity correction, fusion in Situ alone, and fusion with deformity correction. Panel members reviewed multiple case scenarios, first independently and subsequently as a group. Treatment options were ultimately graded as inappropriate, indeterminate, or appropriate depending upon the level of consensus among the panel regarding optimal treatment.

As the panel assessed multiple procedural options for each clinical scenario, it was possible that more than 1 treatment option might be considered appropriate. This is consistent with both clinical practice and the fact that AUC methodology is designed to identify areas of panel agreement, disagreement, or equipoise for each surgical treatment option. The process of precisely defining which procedures are appropriate or inappropriate for each clinical scenario, “based on the best available evidence combined with expert opinion,” distinguishes the AUC from more common general treatment guidelines.11 While strong support is reached for certain scenarios, there are also many
clinical scenarios for which appropriateness or inappropriateness of a surgical procedure is found to be indeterminate. Finally, panel agreement that a certain surgical procedure is inappropriate for a specific clinical scenario should be viewed as a strong recommendation against its use.

In a later follow-up discussion, the panel also rated the “necessity” of those procedures deemed appropriate in the initial evaluation. This secondary analysis sought to determine which procedures “should” be offered as a part of optimal shared decision making, as compared to procedures that were seen as a viable treatment alternative that the surgeon might consider. A finding of “necessity” indicates that the panel felt that the potential benefits of the procedure highly outweighed the risks of the procedure and that not discussing the option as part of the shared decision-making process would be less than optimal care.

**AUC FINDINGS**

Initially, the panel established a set of prerequisite assumptions upon which analysis of the clinical scenarios would be based (Table). While the effectiveness of nonsurgical treatment for lumbar degenerative scoliosis is controversial, all of the clinical scenarios assumed a patient that failed a reasonable trial of nonsurgical care. The analysis also assumed adequate quality neuroimaging with MRI scan, and/or myelogram and postmyelographic CT scan where necessary. Importantly, the panelists concluded that weight-bearing radiographs, preferably full-length (36") standing radiographs, were a necessary component of the evaluation. Therefore, the first recommendation of the panel was that standing radiographs and adequate advanced imaging should precede surgical decision making for lumbar degenerative scoliosis patients.

Based on the assumptions noted, the panel generated treatment recommendations for 260 clinical scenarios. AUC methodology does not regiment treatment decisions, which are obviously patient specific. However, the flow diagram in Figure 1 outlines a simplified summary of the panel recommendations. Application of this guidance for clinical decision making, best practice guidelines, or payer authorization will obviously require formatting appropriate to the intended utilization.

Clinical scenarios with mild symptoms or limited stenosis and small deformities (<20°) were generally deemed inappropriate for surgery. Although representing a minority of the hypothetical scenarios evaluated by the panel, it is important to remember that limited symptoms, mild stenosis, and limited deformity are by far the most common presentation seen in clinical practice. Other clinical scenarios that led to a recommendation against surgical treatment included the patient with moderate or severe leg pain or neurogenic claudication but only mild stenosis, or moderate stenosis but unacceptable medical comorbidities. Similarly, surgery was not recommended in patients with moderate or severe back pain but a small deformity and acceptable standing balance. In these scenarios, additional work-up to identify an alternative source of the symptoms may be warranted.

Although the majority of clinical scenarios that the panel deemed appropriate for surgical treatment included significant neurogenic symptoms and spinal stenosis, there were also scenarios with back pain only identified as appropriate for surgery. Clinical scenarios in which the primary complaint was moderate to severe back pain suggested an initial focus on the spinal deformity. The panel recognized a subset of cases in which substantial back pain might be associated with a curve <40° and acceptable coronal and sagittal balance. Although an infrequent scenario, these patients might be appropriately treated with fusion in Situ or with limited deformity correction. The more common primary deformity scenario was the patient with scoliosis >40° or with substantial coronal or sagittal imbalance (Figure 2). In these cases, the panel indicated, with a high level of agreement, that appropriate treatment required deformity correction and fusion.

The most common clinical scenarios found appropriate for surgical treatment involved patients with moderate to severe leg pain or neurogenic claudication. In these cases, surgical decision making requires an assessment of the severity of the stenosis, as well as the characteristics of the lumbar degenerative scoliosis and the patient’s associated comorbidities. In patients with mild stenosis or moderate stenosis but significant comorbidities, the panel typically recommended against surgery. In patients with severe stenosis or moderate stenosis and acceptable comorbidities,
the panel recommended a combination of decompression with the addition of fusion and/or deformity correction dependent upon the specific characteristics of the lumbar scoliosis (Figure 3). In general, small curves (10°–20°) with limited rotation and normal standing balance were identified as candidates for decompression alone (Figure 4). Moderate curves (15°–40°) with evidence of mechanical instability or significant rotation, or with severe or concave side compression, suggest the need for decompression and fusion, but without correction or with only limited correction of the deformity (Figure 5). Larger curves (>40°) or associated coronal or sagittal imbalance indicate the need for decompression with both fusion and deformity correction.

There was strong agreement among the panel that limited procedures in the setting of substantial deformity, and particularly in patients with sagittal imbalance, were unlikely to be successful. While these cases represent a minority of patients presenting to most surgeons in standard clinical practice, they may be overlooked without appropriate work-up including standing radiographs and clinical assessment of standing balance and gait. The panel summarized the appropriate surgical treatment in this subset of patients as “go big, or go home.” This recommendation is consistent with the majority of the adult spinal deformity literature.13,14

For many patients undergoing surgical treatment for lumbar degenerative scoliosis, the curves are not large or out of balance, and the need for surgery is driven by symptoms of spinal stenosis. The potential role of fusion is to facilitate adequate decompression and to avoid recurrent stenosis or curve progression. The AUC panel did identify a subset of patients with limited

DISCUSSION

Lumbar degenerative scoliosis is a complex pathology as it often involves an intersection of degenerative spinal stenosis and spinal deformity. Despite this, lumbar degenerative scoliosis is being treated much more frequently due to the confluence of an aging population and an increased capacity and willingness to manage complex problems in older patients. While previous studies provide an indication that these patients may benefit from surgical treatment, the substantial variability in treatment paradigm underscores the opportunity for improvement. Optimizing treatment for lumbar degenerative scoliosis is critical as surgical intervention, while potentially providing substantial clinical benefit also entails measurable risk and significant expense. In light of these issues, evidence-based guidance generated through the lumbar degenerative scoliosis AUC process offers the potential to improve both the quality and cost effectiveness of care.

It is important to recognize that AUC-generated guidance is a starting point, not an end point. An AUC is designed to identify appropriate care, not to dictate a monolithic care pathway. Informed choice includes both evidence-based clinical recommendations and patient preferences. Variability in approach to a specific case is appropriate and reasonable based on the individual patient’s values and preferences. Further, AUC-based treatment guidance needs to be validated, both in terms of clinical benefit and cost effectiveness. This will involve significant time and effort on the part of surgeons and other spine care providers, as well as new partnerships with healthcare systems and payers.

This effort also represents a potential roadmap for other societies and subspecialties. While the need for high-quality evidence is clear, it is equally clear that a reliance on randomized controlled trials alone is unrealistic. This may be particularly true for complex pathologies and diverse patient populations. Alternative approaches including registries and AUC development may not always provide granular treatment recommendations, but they are likely to narrow the variability in care and to inform more specific future studies.

The lumbar degenerative scoliosis AUC represents a significant step toward evidence-based treatment in spinal surgery. This is the first time that spine societies and industry partners have collaborated to support evidence development. The willingness of all involved to support a completely independent process underlines a commitment to trust the evidence. Subsequent studies may validate and/or refine the AUC recommendations, but the most important result is that the standard for evidence quality has been raised.

Disclosures

Dr Glassman is an employee and receives research funding from Norton Healthcare as well as royalties and consulting fees from Medtronic Sofamor Danek. NuVasive provides funds directly to database company; however, no funds were paid to Dr Glassman or his institution. Dr Glassman is Past President of the Scoliosis Research Society. Dr Berven receives personal fees from Medtronic.
and Stryker. He has received grants and personal fees from Globus. Dr Berven has received personal fees from RTI and grants from NSF and AO Spine. Other disclosures are with Simpirda and Providence Medical outside the submitted work. Dr Shaffrey is a consultant for Zimmer-Biomet, Medtronic, NuVasive, K2M, and Stryker. He receives royalties from Zimmer-Biomet, Medtronic, and NuVasive. Dr Shaffrey holds patents with Zimmer-Biomet, Medtronic, and NuVasive. He has received grants from NIH, Department of Defense, NACTN, AO, NREF, Depuy-Synthes, and ISSG. Dr Mummaneni is a consultant and receives royalties from Depuy Spine. He has received an honoraria and grant from AO Spine. Dr Mummaneni has received royalties from Thieme Publishing, Springer Publishing, as well as Taylor Francis Publishing. He has received honoraria from Globus and holds stock in Spincity.

Dr Polly has no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

REFERENCES