Transforaminal lumbar interbody fusion and posterior lumbar interbody fusion utilizing BMP-2 in treatment of degenerative spondylolisthesis: neither safe nor cost effective

Bradley Moatz, P. Justin Tortolani

Department of Orthopaedic Surgery, MedStar Union Memorial Hospital, Baltimore, Maryland

E-mail: Bradley Moatz - lyn.camire@medstar.net; *P. Justin Tortolani - lyn.camire@medstar.net
*Corresponding author

Received: 20 January 13   Accepted: 25 January 13  Published: 22 March 13

Abstract

Background: With the rise of health care costs, there is increased emphasis on evaluating the cost of a particular surgical procedure for quality adjusted life year (QALY) gained. Recent data have shown that surgical intervention for the treatment of degenerative spondylolisthesis (DS) is as cost-effective as total joint arthroplasty. Despite these excellent outcomes, some argue that the addition of interbody fusion supplemented with bone morphogenetic protein (BMP) enhances the value of this procedure.

Methods: This review examines the current research regarding the cost-effectiveness of the surgical management of lumbar DS utilizing interbody fusion along with BMP.

Results: Posterolateral spinal fusion with instrumentation for focal lumbar spinal stenosis with DS can provide and maintain improvement in self-reported quality of life. Based on the available literature, including nonrandomized comparative studies and case series, the addition of interbody fusion along with BMP does not lead to significantly better clinical outcomes and increases costs when compared with more routine posterolateral fusion techniques.

Conclusions: To enhance the value of the surgical management for DS, costs must decrease or there should be substantial improvement in effectiveness as measured by clinical outcomes. To date, there is insufficient evidence to support the use of interbody fusion devices along with BMP to treat routine cases of focal stenosis accompanied by DS, which are routinely adequately treated utilizing posterolateral fusion techniques.

Key Words: Bone morphogenetic protein, cost-effective, degenerative spondylolisthesis, interbody fusion device, quality adjusted life year

INTRODUCTION

Over the past decade there has been an increased emphasis on examining the utility of one intervention (via quality adjusted life year [QALY]) combined with the cost of that particular intervention (incremental cost: utility ratio [ICUR]). This enables the comparison of ICURs for the treatment of multiple conditions. Our primary objective in this review was to assess the improved health vs. maintained-related quality of life (QALY) for...
those undergoing decompression with interbody fusion accompanied by bone morphogenetic protein (BMP) for spinal stenosis with degenerative spondylolisthesis (DS) vs. more routine posterolateral fusion (PLF) techniques without BMP.

**DEFINITION OF QUALITY ADJUSTED LIFE YEAR**

The concept of health status, indicated by QALY, represents individual responses to the physical, mental, and social effects of illness on daily living, while taking into account both the quantity and quality of life generated by health care interventions. QALY is a product of life expectancy and a measure of the quality of the remaining-life years, and therefore provides a common currency to assess the extent of the benefits gained from a variety of interventions in terms of health-related quality of life and survival for the patient.

This tool becomes particularly valuable for policy makers and clinical personnel given the virtually unlimited health care needs and increasingly expensive treatment methods available. For example, primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) have proven to be among the most cost-effective surgical interventions both musculoskeletal and otherwise at $8031 per QALY for THA and $18,300 per QALY for TKA.

**Summary:** QALY is a tool used to measure the quality of remaining-life years, and therefore provides a common currency to assess the extent of the benefits gained from a variety of interventions.

**DEGENERATIVE SPONDYLOLISTHESIS**

**Better outcomes following decompression with fusion vs. decompression alone**

Over the past decade, management strategies and outcomes of the operative management of spinal disorders with DS have come under increasing scrutiny. Surgical alternatives have included decompression alone vs. decompression with various stabilization procedures. In 1991, Herkowitz and Kurz performed a prospective randomized study in which 50 DS patients were assigned to decompression alone vs. decompression and bilateral posterolateral arthrodesis. At an average of three postoperative years, clinical outcomes were significantly improved in patients undergoing decompression with PLF. They attributed this success to addressing either residual instability or the development of increased olisthesis associated with performing decompressions. Ghogawala, et al. prospectively evaluated the outcomes of patients with DS to determine whether instrumented PLF influenced functional 1-year postoperative outcomes; 20 patients underwent decompressions alone vs. 14 who had decompressions with instrumented PLFs. At one postoperative year, instrumented fusions positively correlated with statistically significant greater functional improvement.

**Summary:** Clinical outcome studies have shown that decompression with fusion leads to improved patient outcomes compared with decompression alone for the surgical management of DS.

**Spine patient outcomes research trial study indicates improved outcomes with fusion for degenerative spondylolisthesis**

The Spine Patient Outcomes Research Trial (SPORT) study examined a randomized cohort of 304 patients who received either nonoperative or operative management for DS. Four years postoperatively, those in the operative cohort reported statistically significant improvements in bodily pain, physical function, and disability vs. those who did not have surgery. Alternatively, the 5% of patients undergoing decompression alone exhibited inferior functional improvement vs. those undergoing decompression with fusion.

**Summary:** The SPORT study, involving a randomized cohort of 304 patients undergoing nonoperative vs. operative management for DS, showed at four postoperative years, statistically significant improvements in bodily pain, physical function, and disability vs. those who did not have surgery.

**SPINAL INSTRUMENTATION: BALANCING CLINICAL OUTCOMES WITH POTENTIAL COMPLICATIONS**

The use of spinal instrumentation has been critically evaluated to balance clinical outcomes with potential complications. In 1997, Fischgrund, et al. published a prospective randomized study comparing the results of decompression/fusion alone vs. decompression/fusion with instrumentation. Sixty-seven patients with DS were randomized to one of the two treatment groups, and were followed up on an average of 2 years. Although the clinical outcome difference was not statistically significant, fusion rates improved from 45% for noninstrumented to 82% for instrumented fusions. Kornblum, et al. published a follow-up study examining the long-term outcomes of the same patients previously studied by Herkowitz and Kurz and Fischgrund, et al. Clinical outcomes were good to excellent in 86% of patients with a solid arthrodesis and in a lesser 56% of patients with pseudoarthrosis; this difference was statistically significant. Patients who solidly fused exhibited better long-term results, while those with pseudoarthrosis did not do as well. Based on these findings, the addition of spinal instrumentation in order to achieve a solid fusion appeared reasonable for treating patients with DS.

**Summary:** In 1997 Fischgrund, et al. documented higher fusion rates performing instrumented fusions for DS (82%) vs. decompression/fusion alone (45%).
SPINAL INSTRUMENTATION HAS DRAMATICALLY INCREASED THE COSTS FOR LUMBAR FUSION

Costs have increased dramatically as a result of the use of spinal instrumentation for lumbar fusion. In 1992, lumbar fusion represented 14% of total spending for back surgery; by 2003, lumbar fusion accounted for 47% of spending. Nevertheless, despite the widespread use of spinal instrumentation for DS, the cost-effectiveness of this intervention remained unknown.

Summary: In 1992, lumbar fusion represented 14% of total spending for back surgery; by 2003, lumbar fusion accounted for 47% of spending. Nevertheless, the cost-effectiveness of instrumented fusion for DS remains unknown.

Cost-effectiveness research for degenerative spondylolisthesis

Work by Rampersaud, et al. has shown that posterolateral spinal fusion with instrumentation for focal lumbar spinal stenosis with DS can obtain and maintain improvement in self-reported quality of life (QALY) comparable to that of total hip and knee arthroplasty. In this study, patients were obtained for prospective outcomes databases including total joint arthroplasty (hip and knee) and spine, and preoperative vs. 2-year postoperative SF-36 scores were compared for the two groups. At 1 year, Mental Health Scales did not significantly increase in either group. However, by the second postoperative year, the Mental Health Scale scores improved significantly in the spinal stenosis and hip osteoarthritis group but not in the knee osteoarthritis group.

Summary: Research has shown that PLF with instrumentation for DS can lead to improvements in QALY comparable to that of TKA and THA.

ICURs for decompression vs. decompression/fusion/instrumentation for DS, THA, and TKA

A more recent study compared the ICURs of decompression alone and decompression with fusion and instrumentation for DS patients vs. ICURs for THA and TKA. Ninety-nine age- (within 2 years) and sex-matched patients were analyzed in each group (spine surgery, TKA, and THA). The lifetime ICURs were per QALY: $5321 for THA, $11275 for TKA, $2307 for spinal decompression, and $7153 for spinal decompression (laminectomy)/posterolateral instrumented (pedicle/screw fixation) fusion (Canadian dollars). Although the results of decompression alone were more favorable, these results represent the perspective of overall end-stage management of patients with focal lumbar spinal stenosis with or without DS.

Summary: The lifetime ICUR per QALY for spinal decompression with instrumented PLF is more expensive than THA but cheaper when compared with TKA.

TRADITIONAL BENCHMARK OF COST-EFFECTIVE TREATMENT: $50,000 PER QALY

The traditional benchmark for a cost-effective treatment is $50,000 per QALY. When taken in the context of the dramatic impact of THA and TKA on the quality of life of our society, these findings provide powerful justification for the use of lumbar laminectomy with or without posterolateral spinal fusion and instrumentation in the treatment of spinal stenosis and DS. Based on the ICUR, in order to enhance the value and cost-effectiveness for any procedure and, in particular, lumbar decompression with PLF with instrumentation for the treatment of DS, it is necessary to either improve patient outcomes (increase QALY) or decrease the cost of the procedure. Despite the positive findings reported by Rampersaud, recent trends would suggest that surgeons are looking to further enhance outcomes by adding posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF) devices to the laminectomy and PLF with instrumentation.

Summary: The traditional benchmark for cost-effectiveness is $50,000 per QALY. In order to enhance value there must be a substantial improvement in QALY or a decrease in the cost of the procedure.

Comparison of fusion rates with and without interbody supplementation for degenerative lumbar disease

Although the costs of interbody devices (TLIF, PLIF, and anterior lumbar interbody fusion (ALIF)) add substantial direct (device-related) and indirect (operative time and blood loss) costs to the procedure, their benefits (e.g., improved outcomes/utility) remain controversial. In a randomized controlled trial from the Swedish Lumbar Spine Study Group, Fritzell, et al. compared three surgical techniques: PLF without instrumentation, PLF with instrumentation, and PLF with instrumentation and ALIF or PLIF (circumferential fusion) for the treatment of chronic low back pain with associated spondylosis. The fusion rates for the PLF with instrumentation and the 360° groups were 87% and 91%, respectively; these differences were not significant (P = 0.529). The fusion rate for the PLF group without instrumentation was 72%. Kim, et al. compared the clinical outcomes of three fusion methods using the posterior approach: PLF, PLIF, and circumferential fusion (PLF and PLIF). All three groups showed high union rates at the last follow-up;
92% for the PLF group, 95% for the PLIF group, and 93% for the circumferential group; there were no statistically significant differences between union rates ($P = 0.667$) or clinical results among the groups ($P = 0.704$).

**Summary:** Research has shown that the supplementation of PLF with an interbody device for the treatment of spondylolysis does not lead to statistically significant improvement in fusion rate or clinical outcomes.

**PLF vs. PLIF for isthmic spondylolisthesis**

Ekman, *et al.*[^8] compared the outcomes of 86 patients who underwent PLIF and a historical control of 77 patients who underwent PLF for the treatment of isthmic spondylolisthesis; the type of fusion, PLF or PLIF, did not affect 2-year outcomes. However, they did not describe the relative costs associated with each procedure.

Inamdar, *et al.*[^16] compared PLF and PLIF in the treatment of spondylolysis in a small study with 11 patients in each group. They reported no cases of pseudoarthrosis in either group, and clinical outcomes were not significantly different between the two groups. Although they did not examine the relative costs of these procedures, the authors recommended PLF over PLIF because of the simplicity of the procedure, lower complication rate, and good clinical and radiological outcomes.

**Summary:** Research has shown that PLIF for the treatment of isthmic spondylolisthesis does not significantly improve outcomes.

**Cost ineffectiveness of TLIF vs. posterolateral instrumented fusion for DS**

In a separate study, Adogwa, *et al.*[^1] examined 45 patients undergoing TLIF for DS and calculated resource use and health-state values to determine cost-effectiveness of the procedure. The authors reported that the total cost for QALY gained with TLIF was $42,854 when evaluated 2 years after surgery for the treatment of Grade I DS. When compared with data from Rampersaud, *et al.*, TLIF is approximately six times less cost-effective for the treatment of DS than PLF and instrumentation.[^25]

**Summary:** When compared with data from Rampersaud, *et al.*, TLIF is approximately six times less cost-effective for the treatment of DS than PLF and instrumentation.[^25]

**COMPLICATIONS OF TLIF AND PLIF**

The most common complications associated with PLIF and TLIF include subsidence, osteolysis, postoperative radiculopathy, heterotopic ossification, dural tear, interbody implant migration, or intraoperative neurologic injury.[^4] The overall complication rate varies from 8% to 80% with an average of 36.4%.[^4]

**Summary:** The most common complications associated with PLIF and TLIF include subsidence, osteolysis, postoperative radiculopathy, heterotopic ossification, dural tear, interbody implant migration, or intraoperative neurologic injury with an average incidence of 36.4%.[^4]

**Battered root syndrome with PLIF and TLIF**

Perhaps the most disabling of all of the potential complications is the so-called “battered root” syndrome leading to postoperative radiculopathy, which has been reported to occur in 7% of cases.[^4] With all other factors being equal, this complication alone subjects the patient to substantially increased risk when comparing TLIF or PLIF with standard PLF with instrumentation.

**Summary:** Postoperative radiculopathy due to nerve injury during interbody instrumentation has been reported to occur in 7% of cases.

**Implant migration or subsidence, dural tears, and increased epidural bleeding with TLIF and PLIF**

Despite the substantial variation in reporting of major and minor additional complications,[^4] the complication profile of PLIF and TLIF sharply reduces the effectiveness of these added techniques in the treatment of DS. Implant migration and/or subsidence has been reported in conjunction with TLIF and PLIF.[^4] Because TLIF and PLIF procedures require mobilization and retraction of the dura, dural tears are also more likely to occur with these procedures. Anesthesia time and epidural bleeding are also increased in cases of TLIF and PLIF.

**Summary:** Despite the substantial variation in reporting of major and minor additional complications,[^4] the complication profile of PLIF and TLIF sharply reduces the effectiveness of these added techniques in the treatment of DS.

**RISKS, COMPLICATIONS WITH PREDOMINANTLY “OFF-LABEL” USE OF BMP WITH PLIF OR TLIF CONSTRUCTS**

BMPs are frequently used in PLIF and TLIF procedures. The US Food and Drug Administration (FDA) has granted approval for use of rhBMP-2 (Infuse, Medtronic, Memphis, TN) for single-level anterior fusions from L4 to S1 within a tapered metallic cage (LT Cage).[^4] Of 340,251 cases in which BMP was used between 2003 and 2007, approximately 30% (102,162 cases) involved off-label use in primary TLIF or PLIF procedures.[^21] Although recombinant BMP in many situations is used in lieu of iliac crest autograft to avoid donor site complications, there is increasing concern for the use of BMP in interbody fusion because of its many complications [Table 1].

**Summary:** Approximately 30% of cases that involved the use of BMP between 2003 and 2007 was “off-label.” There is increasing concern surrounding BMP use because of its many complications.
Table 1: Complications reported utilizing BMP for performing spinal fusions for DS/degenerative disc disease

| Author          | Procedures                          | Complication          |
|-----------------|-------------------------------------|-----------------------|
| Haid, et al.    | PLIF/BMP vs. PLIF/Autograft (Iliac) | Heterotopic Ossification 75% vs. 13% Control |
| Rihn, et al.    | TLIF/BMP vs. TLIF/Autograft (Iliac) | Radiculitis 14% vs. 3% Control |
| Helgeson, et al.| TLIF/BMP                           | Osteolysis 54% 3-6 Months 76% 1 Year |
| Vaidya, et al.  | Allograft/BMP vs. Allograft/DBM ALIF TLIF, ACDF | Graft Subsidence ALIF 27% (13-42%) TLIF 24% (13-40%) ACDF 53% (40-58%) ACDF 4.6% (0-15%) |

PLIF: Posterior Lumbar Interbody Fusion, BMP: Bone Morphogenetic Protein, TLIF: Transforaminal Interbody Fusion, DBM: Demineralized Bone Matrix, ACDF: Anterior Cervical Diskectomy and Fusion, ALIF: Anterior Lumbar Interbody Fusion

BMP-associated complications may range from 10% to 50% vs. <0.5%

When Carragee, et al. reviewed data submitted to the FDA from the industry-sponsored BMP-related trials, they concluded that BMP-associated complications may range from 10% to 50% instead of the <0.5% found in the literature. The authors concluded that BMP was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes in patients undergoing PLIF. The authors further noted that in 1999, when the FDA conducted a study involving 67 patients who underwent PLIF for the treatment of single-level degenerative disc disease the study was suspended after 9 months “out of abundant caution.” The FDA researchers found heterotopic ossification extending outside of the disc space and into the spinal canal or neuroforamina in 75% of patients in the experimental BMP cohort compared with 13% of patients in the cohort who received iliac crest bone graft. Of interest, despite these findings, the investigators could not correlate postoperative leg pain and heterotopic ossification.

Summary: BMP use has been linked to radiculitis, ectopic bone formation, and osteolysis at a rate of 10-50%.

BMP-related radiculitis

Rihn, et al. reported on a series of 119 patients who underwent TLIF of which 14% treated with rhBMP-2 developed postoperative radiculitis as opposed to 3% in patients treated with iliac crest bone graft.

Summary: Nearly 14% of patients who underwent TLIF with rhBMP-2 developed postoperative radiculitis as opposed to 3% without BMP.

BMP-related osteolysis

Osteolysis has also been associated with BMP-linked osteoclastic activation. Helgeson, et al. found BMP-related osteolysis in 54% of patients at 3-6 months postoperatively. In this study, the rate of fusion was not affected by the presence of osteolysis but did persist for 76% of affected patients at 1 year postoperatively. Vaidya et al. reported a revision rate of up to 31% due to implant migration with the use of BMP in PEEK cages for interbody fusion in patients undergoing spinal fusion.

Summary: BMP use has been linked to a relatively high incidence of osteolysis.

HOSPITAL COSTS INVOLVING BMP ARE SIGNIFICANTLY HIGHER

On average, hospital costs involving BMP are also significantly higher compared with procedures without BMP. Deyo, et al. reported that adjusted hospital charges for operations involving BMP were about $15,000 more than hospital charges for fusions without BMP. They did, however, find that the use of BMP led to fewer nursing home discharges, but was not associated with a reduced likelihood of reoperation.

Summary: Hospital adjusted charges for operations involving BMP were about $15,000 more than hospital charges for fusions without BMP.

ICUR studies needed to assess utility of BMP for PLIF and TLIF

To date, the ICUR studies have not been performed for the use of BMP inside PLIF and TLIF interbody devices. Nonetheless, considering (1) how much less cost-effective PLIF and TLIF procedures are compared with PLF with instrumentation alone, (2) how expensive BMP is, and (3) the recently reported complication profile for the use of BMP inside interbody devices, it stands to reason that adding BMP to the surgical management of DS further reduces the cost-effectiveness when compared with PLF with instrumentation.

Summary: Adding BMP to the surgical management of DS further reduces its cost-effectiveness when compared with PLF with instrumentation.

CONCLUSION

In conclusion, lumbar decompressive laminectomy with posterolateral spinal fusion and instrumentation is an effective technique that is both cost-effective and leads to improvements in quality of life similar to those found in THA or TKA [Table 2]. Historically,
Surgical Neurology International

Table 2: Summary of sections

| Definition of QALY | QALY is a tool used to measure the quality of remaining-life years, and therefore provides a common currency to assess the extent of the benefits gained from a variety of interventions. |
|-------------------|---------------------------------------------------------------------------------------------------------------|
| Better Outcomes Following Decompression with Fusion vs. Decompression Alone | Clinical outcome studies have shown that decompression with fusion leads to improved patient outcomes compared with decompression alone for the surgical management of DS. |
| Spine Patient Outcomes Research Trial (SPORT) Study Indicates Improved Outcomes with Fusion for Degenerative Spondylolisthesis | The SPORT study, involving a randomized cohort of 304 patients undergoing nonoperative vs. operative management for DS, showed at 4 postoperative years, statistically significant improvements in bodily pain, physical function, and disability vs. those who did not have surgery. Additionally, there was a higher fusion rate when fusion was performed with instrumentation. |
| Spinal Instrumentation: Balancing Clinical Outcomes with Potential Complications | In 1997 Fischgrund et al. documented higher fusion rates performing instrumented fusions for DS (82%) vs. decompression/fusion alone (45%).

A subsequent study further documented superior (e.g., 86%) good to excellent outcomes for patients with a solid arthrodesis vs. 56% for those with pseudoarthrosis. |
| Spinal Instrumentation Has Dramatically Increased the Costs for Lumbar Fusion | In 1992, lumbar fusion represented 14% of total spending for back surgery; by 2003, lumbar fusion accounted for 47% of spending. Nevertheless, the cost-effectiveness of instrumented fusion for DS remains unknown. |
| Cost-Effectiveness Research for Degenerative Spondylolisthesis | Research has shown that posterolateral fusion with instrumentation for DS can lead to improvements in QALY comparable to that of TKA and THA. |
| ICURs for Decompression vs. Decompression/Fusion/Instrumentation for DS, THA, and TKA | The lifetime ICUR per QALY for spinal decompression with instrumented posterolateral fusion is more expensive than THA but cheaper when compared with TKA. |
| Traditional Benchmark of Cost-effective Treatment: $50,000 per QALY | The traditional benchmark for cost-effectiveness is $50,000 per QALY. In order to enhance value there must be a substantial improvement in QALY or a decrease in the cost of the procedure. |
| Comparison of Fusion rates with and without Interbody Supplementation for Degenerative Lumbar Disease | Research has shown that the supplementation of posterolateral fusion with an interbody device for the treatment of spondylolisthesis does not lead to statistically significant improvement in fusion rate or clinical outcomes. |
| PLF vs. PLIF for Isthmic Spondylolisthesis | Research has shown that PLIF for the treatment of isthmic spondylolisthesis does not significantly improve outcomes. |
| Cost Ineffectiveness of TLIF vs. Posterolateral Instrumented Fusion for DS | When compared to data from Rampersaud et al., TLIF is approximately six times less cost-effective for the treatment of DS than posterolateral fusion and instrumentation. |
| Complications of TLIF and PLIF | The most common complications associated with PLIF and TLIF include subsidence, osteolysis, postoperative radiculopathy, heterotopic ossification, dural tear, interbody implant migration, or intraoperative neurologic injury with an average incidence of 36.4%. |
| Battered Root Syndrome with PLIF and TLIF | Postoperative radiculopathy due to nerve injury during interbody instrumentation has been reported to occur in 7% of cases. |
| Implant Migration or Subsidence, Dural Tears, and Increased Epidural Bleeding with TLIF and PLIF | Despite the substantial variation in reporting of major and minor additional complications, the complication profile of PLIF and TLIF sharply reduces the effectiveness of these added techniques in the treatment of DS. |
| Risks, Complications with Predominantly “Off-Label” Use of BMP with PLIF or TLIF Constructs | Approximately 30% of cases that involved the use of BMP between 2003 and 2007 was “off-label.” There is increasing concern surrounding BMP use because of its many complications. |
| BMP-associated Complications May Range from 10% to 50% vs. <0.5% | BMP use has been linked to radiculitis, ectopic bone formation, and osteolysis at a rate of 10-50%. |
| BMP-Related Radiculitis | 14% of patients who underwent TLIF with rhBMP-2 developed postoperative radiculitis as opposed to 3% without BMP. |
| BMP-Related Osteolysis | BMP use has been linked to a relatively high incidence of osteolysis. |
| Hospital Costs Involving BMP are Significantly Higher | Hospital adjusted charges for operations involving BMP were about $15,000 more than hospital charges for fusions without BMP. |
| ICUR Studies Needed To Assess Utility of BMP for PLIF and TLIF | Adding BMP to the surgical management of degenerative spondylolisthesis further reduces its cost-effectiveness when compared to posterolateral fusion with instrumentation. |

QALY: Quality adjusted life year, TKA: Total knee arthroplasty, TLIF: Transforaminal lumbar interbody fusion, PLIF: Posterior lumbar interbody fusion, THA: Total hip arthroplasty, DS: Degenerative spondylolisthesis, BMP: Bone morphogenetic protein
hip replacement has had an substantial positive impact on our society with a calculated ICUR of $5321. In Canadian dollars, the $7153 ICUR of laminectomy with standard PLF and pedicle screw instrumentation as reported by Rampersaud, et al, approximates THA, and along with other prospective randomized controlled trials, establishes this technique as the gold standard in the treatment of focal spinal stenosis in patients with DS. To enhance the value of this procedure, either costs must decrease or there must be substantial improvement in effectiveness as measured by clinical outcomes. With a paucity of level-I trials examining the cost-utility of PLIF/TLIF with or without BMP, to date there is insufficient evidence to support the use of such devices in routine cases of focal stenosis in the setting of spondylolisthesis.

ACKNOWLEDGMENTS

The authors thank Lyn Canire, MA, ELS, of their department for editorial assistance.

REFERENCES

1. Adogwa O, Parker SL, Davis BJ, Aaronson O, Devin C, Cheng JS, et al. Cost-effectiveness of transforaminal lumbar interbody fusion for Grade I degenerative spondylolisthesis. J Neurosurg Spine 2011;15:138-43.
2. Bowling S. Measuring health: A review of quality of life measurement scales. Buckingham, England: Open University Press; 1992.
3. Carragee EJ, Hurwitz EL, Weiner BK. A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: Emerging safety concerns and lessons learned. Spine J 2011;11:471-91.
4. Chrastil J, Patel AA. Complications associated with posterior and transforaminal lumbar interbody fusion. J Am Acad Orthop Surg 2012;20:283-91.
5. Dall BE, Rowe DE. Degenerative spondylolisthesis. Its surgical management. Spine (Phila Pa 1976) 1985;10:668-72.
6. Deyo RA, Ching A, Matsen L, Martin Bl, Kreuter W, Jarvik JG, et al. Use of bone morphogenetic proteins in spinal fusion surgery for older adults with lumbar stenosis. Trends, complications, repeat surgery, and charges. Spine (Phila Pa 1976) 2012;37:222-30.
7. Dobrow MJ, Goel V, Upshur RE. Evidence-based health policy: Context and utilisation. Soc Sci Med 2004;58:207-17.
8. Ekman P, Moller H, Tullberg T, Neumann P, Hedlund R. Posterior lumbar interbody fusion versus posterolateral fusion in adult ischemic spondylolisthesis. Spine (Phila Pa 1976) 2007;32:2178-83.
9. Fischgrund JS, Mackay M, Herkowitz HN, Brower R, Montgomery DM, Kurz LT. 1997 Volvo Award winner in clinical studies. Degenerative lumbar spondylolisthesis with spinal stenosis: A prospective, randomized study comparing decompressive laminectomy and arthrodesis with and without spinal instrumentation. Spine (Phila Pa 1976) 1997;22:2807-12.
10. Fritzell P, Hagg O, Wessberg P, Nordwall A. Chronic low back pain and fusion: A comparison of three surgical techniques: A prospective multicenter randomized study from the Swedish lumbar spine study group. Spine (Phila Pa 1976) 2002;27:131-41.
11. Ghogawala Z, Benzle EC, Amin-Hanjani S, Barker FG, Harrington JF, Magge SN, et al. Prospective outcomes evaluation after decompression with or without instrumented fusion for lumbar stenosis and degenerative Grade I spondylolisthesis. J Neurosurg Spine 2004;1:267-72.
12. Golish SR, DeHart MM. Principles and practice of statistics. In: Miller MD, editor. Review of Orthopaedics. 5th ed. New York: Elsevier; 2008. p. 674-87.
13. Haid RW Jr., Branch CL Jr., Alexander JT, Burkus JK. Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages. Spine J 2004;4:527-38.
14. Helgeson MD, Lehman RA Jr., Patzkowski JC, Dmitriev AE, Rosner MK, Mack AW. Adjacent vertebral body osteolysis with bone morphogenetic protein use in transforaminal lumbar interbody fusion. Spine J 2011;11:507-10.
15. Herkowitz HN, Kurz LT. Degenerative lumbar spondylolisthesis with spinal stenosis: A prospective study comparing decompression with decompression and intertransverse process arthrodesis. J Bone Joint Surg Am 1991;73:802-8.
16. Inamdar DN, Alagappan M, Shyam L, Devadoss S, Devadoss A. Posterior lumbar interbody fusion versus intertransverse fusion in the treatment of lumbar spondylolisthesis. J Orthop Surg (Hong Kong) 2006;14:21-6.
17. Jones CA, Pohar S. Health-related quality of life after total joint arthroplasty: A scoping review. Clin Geriatr Med 2012;28:395-429.
18. Kim KT, Lee SH, Lee YH, Bae SC, Suk KS. Clinical outcomes of 3 fusion methods through the posterior approach in the lumbar spine. Spine (Phila Pa 1976) 2006;31:1351-7.
19. Kornblum MB, Fischgrund JS, Herkowitz HN, Abraham DA, Berkower DL, Ditkoff JS. Degenerative lumbar spondylolisthesis with spinal stenosis: A prospective long-term study comparing fusion and pseudarthrosis. Spine (Phila Pa 1976) 2004;29:726-33.
20. La Puma J, Lawlor EF. Quality-adjusted life-years. Ethical implications for physicians and policymakers. J Am Med Assoc 1990;263:2917-21.
21. Ong KL, Villarraga ML, Lau E, Carreon LY, Kurz SM, Glassman SD. Off-label use of bone morphogenetic proteins in the United States using administrative data. Spine (Phila Pa 1976) 2010;35:1794-800.
22. Owens DK. Interpretation of cost-effectiveness analyses. J Gen Intern Med 1998;13:716-7.
23. Rampersaud YR, Ravi B, Lewis SJ, Stas V, Barron R, Dawey R, et al. Assessment of health-related quality of life after surgical treatment of focal symptomatic spinal stenosis compared with osteoarthritis of the hip or knee. Spine J 2008;8:296-304.
24. Rihn JA, Patel R, Makda J, Hong J, Anderson DG, Vaccaro AR, et al. Complications associated with single-level transforaminal lumbar interbody fusion. Spine J 2009;9:623-9.
25. Tso P, Walker K, Mahomed N, Coyte PC, Rampersaud YR. Comparison of lumbar interbody fusion versus intertransverse fusion in the treatment of lumbar spondylolisthesis. J Orthop Surg (Hong Kong) 2006;14:21-6.
26. Vaidya R, Sethi A, Bartol S, Jacobson M, Coe C, Craig JG. Complications in degenerative lumbar spondylolisthesis with spinal stenosis. A prospective study comparing decompression with decompression and intertransverse process arthrodesis. J Bone Joint Surg Am 1991;73:802-8.
27. Weinstein JN, Lurie JD, Olson PR, Bronner KK, Fisher ES. United States’ trends and regional variations in lumbar spine surgery: 1992-2003. Spine (Phila Pa 1976) 2006;31:1351-7.
28. Weinstein JN, Lurie JD, Tosteson TD, Zhao W, Blood EA, Tosteson AN, et al. Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis: A scoping review. Spine (Phila Pa 1976) 2006;31:1351-7.
29. Ditkoff JS. Degenerative lumbar spondylolisthesis with spinal stenosis: A prospective long-term study comparing fusion and pseudarthrosis. Spine (Phila Pa 1976) 2004;29:726-33.