Published in final edited form as:

Spine Deform. 2018 January ; 6(1): 67–71. doi:10.1016/j.jspd.2017.05.003.

Health Related Quality of Life Scores Underestimate the Impact of Major Complications in Lumbar Degenerative Scoliosis Surgery

Steven D. Glassman, MD, Keith H. Bridwell, MD², Christopher I. Shaffrey, MD³, Charles C. Edwards II, MD⁴, Jon D. Lurie, MD, MS⁵, Christine R. Baldus, MA², and Leah Y. Carreon, MD, MSc¹

¹Norton Leatherman Spine Center, 210 East Gray Street, Suite 900, Louisville, KY 40202

²Department of Orthopaedic Surgery, Washington University School of Medicine, 660 S Euclid Ave, Campus Box 8233, St. Louis, MO 63110

³University of Virginia, Department of Neurosurgery, PO Box 800212, Charlottesville, VA 22908, USA

⁴The Maryland Spine Center at Mercy Medical Center, 301 St. Paul Place, Baltimore MD, 21202

⁵Department of Medicine, Geisel School of Medicine at Dartmouth, One Medical Center Drive, Lebanon, NH 03756

Abstract

Study Design—Retrospective cohort

Objective—To examine Charlson Comorbidity Index (CCMI) as a marker for deterioration in health status not reflected in standard Health Related Quality of Life (HRQOL) measures.

Summary of Background Data—HRQOLs have become a primary metric for assessing outcomes following spinal deformity surgery. However, studies have reported limited impact of complications on postoperative HRQOLs.

Methods—We examined serial CCMI, complications and HRQOLs for 138 adult lumbar deformity patients treated surgically with a minimum two-year follow-up that included 126 females (91%) with a mean age of 59.8 years (range, 40.2–78.5). Patients with No, Minor or Major complications were compared at baseline and at one- and two-years post-op.

Results—Minor complications were observed in 26 patients (19%) and major complications in 15 (11%). Major complications included motor deficit (7), DVT (4) and respiratory failure (3). There was no difference in pre-op SF-36 PCS or SRS scores among the groups at baseline. Pre-op CCMI was lowest in the No complication group (3.52 ± 1.70) followed by the Major (4.00 ± 1.13)

Corresponding Author: Leah Y. Carreon, MD, MSc, Norton Leatherman Spine Center, 210 East Gray Street, Suite 900, Louisville, KY 40202, Tel: 502-992-0488 x 4139, Fax: 502-589-0849.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

and Minor complication groups (4.15 ± 1.71 , $p=0.165$). At one-year, there was a significantly greater CCMI deterioration in the Major complication group (0.80 ± 1.01) compared to both the Minor (0.08 ± 0.27) and No complication groups (0.27 ± 0.47 , $p<0.001$). There was no significant difference in SF-36 PCS or SRS scores among the three groups. Similar findings were observed at two-years.

Conclusions—Despite similar one and two-year HRQOL improvement, patients with major complications had greater deterioration in CCMI. As CCMI is predictive of medical and surgical risk, patients who sustained a major complication now carry a greater likelihood of adverse outcomes with future interventions including any subsequent spinal surgery. While this increased risk may not alter the patient's perception of their current health status, it may be important, and should be recognized as part of the shared decision-making process.

Level of Evidence—II (High Quality Prognostic Study)

Keywords

lumbar scoliosis; adult spinal deformity; complications; patient reported outcomes; prospective cohort

Introduction

Preliminary assessment of lumbar degenerative scoliosis primarily focuses upon the radiographic appearance of the deformity and the extent of associated neural compression. However, surgical decision-making is driven largely by the severity of clinical symptoms [1–6]. The risk of complications is also a key element in surgical decision-making, particularly as the increasing demands and expectations of an aging population have resulted in more frequent surgical treatment in older patients [5, 7]. The challenge of managing complex pathology in high-risk patients has led to strategies designed to better quantify the impact of baseline demographics and co-morbidities on perioperative complication rates and subsequent clinical outcomes. This analytic approach is termed risk stratification.

Historically, the success of an adult scoliosis surgery had been judged based upon the extent of radiographic correction, the presence of a solid fusion and the absence of complications [8–11]. Over the past 10 years, patient reported Health Related Quality of Life (HRQOL) measures have become a primary metric for the assessment of clinical outcome following spinal deformity surgery [12–14]. Although radiographic results and complications are still routinely reported, the argument has been made that these traditional radiographic measures may be less important, particularly for coronal plane deformity; as patient reported outcomes (PROs) more accurately reflect the patient's experience and perceived benefit.

The degree to which perioperative complications impact clinical outcomes, and the relative importance of complications in determining the value of surgical treatment is less clearly defined. Certainly major neurologic complications remain a primary concern for both patients and surgeons [15–17]. In contrast, recent studies have reported only limited impact of complications, including major complications, on postoperative HRQOL scores [18, 19]. While it makes sense that occurrence of a urinary tract infection might not alter one or two-

year postoperative health status, it seems counter-intuitive that major complications would not be more consequential.

The purpose of this study was to further examine the impact of postoperative complications on clinical outcome. As part of an NIH funded randomized controlled trial of adult lumbar degenerative scoliosis surgery, data collection included perioperative complications, HRQOL measures and serial Charlson comorbidity index (CCMI) scores [20]. In particular, we examined CCMI as a marker for deterioration in health status which might not be adequately reflected in patient reported outcomes.

Methods

The Adult Symptomatic Lumbar Scoliosis Study (ASLS) is an NIH-sponsored multicenter prospective study designed to compare the outcomes of surgery and non-operative treatment in patients with adult degenerative scoliosis. Enrollment criteria included patients aged 40 to 80 with adult degenerative scoliosis defined as a lumbar curve with a coronal Cobb measurement of 30° or more, who did not have a prior spine fusion procedure, and either of the following: Oswestry Disability Index version 2.1a (ODI) [21, 22] score of 20 or more; or Scoliosis Research Society -22R Instrument (SRS-22R) [23] instrument score of 4.0 or less, in the domains of pain, function and/or appearance.

The present study included ASLS patients enrolled in both the randomized and observational surgical arms who reached a minimum of two-year follow-up after the index surgery. As part of the data collection schedule, subjects complete SF-36 and SRS-22R surveys and the Charlson Comorbidity Index (CCMI) [20] every three months for the first two years after surgery and every six months at three, four and five years after surgery. In addition, the subject's medical history was reviewed by the clinician at 3 months post-operatively and annually for five years post-operatively.

Peri-operative complications were classified into major and minor complications [19]; and were also categorized based on the physiologic system being affected. Subjects were grouped into those who have no complications, those who have a minor complication and have a major complication. Comparisons of HRQOL outcomes and serial changes in CCMI among these three groups were performed using ANOVA on ranks with post-hoc Bonferroni correction. All statistical analyses were performed using IBM SPSS version 21.0 (Somes, New York).

Institutional Review Board Approval was received for both the primary study and the current secondary analysis.

Results

Of 153 patients eligible for two year follow-up, serial CCMI, complications and HRQOLs were available in 138 (90%) patients. Major complications were seen in 15 (11%) and minor complications were observed in 26 patients (19%). There were no statistically significant difference in age, gender, smoking status, body mass index, number of levels fused and operative time among the three complication groups (Table 1).

Age at surgery and number of levels fused were equivalent among the three complication groups. Patients who had no complication had the lowest estimated blood loss among the three groups (Table 1). Major complications included motor deficit (7), DVT requiring anti-coagulation (4) and respiratory failure (3) (Table 2). There was no difference in pre-op SF-36 PCS or SRS scores among the three complication groups. Pre-op CCMI was lowest in the No complication group (3.52 ± 1.70) but similar in the Major (4.00 ± 1.13) and Minor complication groups (4.15 ± 1.71 , $p=0.165$).

At one-year post-op, there was a significant CCMI deterioration in the Major complication group (0.80 ± 1.01) compared to the Minor (0.08 ± 0.27 , $p<0.001$) and No complication groups (0.27 ± 0.47 , $p<0.001$). This pattern persisted at two-year follow-up with greater deterioration from baseline in the Major complication group (0.93 ± 0.96) versus the Minor complication group (0.15 ± 0.37) and the No complication group (0.46 ± 0.61) ($p=0.001$). There were no significant differences in SF-36 PCS or SRS scores among the three groups at one or two years post-op (Table 3). There was a non-significant decrement in SF-36 improvement from the No complication group (10.0) to the Minor complication group (8.87) to Major complication group (6.32) at two years post-op.

Discussion

Patient reported outcomes (PROs) have become an increasingly important component of clinical decision-making in spinal surgery. This transition has been easier and more intuitive for lumbar degenerative disease, as radiographic outcomes are only loosely tied to clinical success [24]. Reliance upon PROs in spinal deformity surgery is less intuitive as the radiographic characteristics of the deformity and deformity correction are considered integral to surgical treatment [8, 14].

Nonetheless, treatment of adult spinal deformity (ASD) is driven by clinical symptoms more so than radiographic appearance, and thus patient based outcomes have superseded radiographic correction as the key measure of treatment success. This trend has been supported by the validation of the deformity specific SRS-22 instrument [12] and multiple studies correlating HRQOL improvements and radiographic correction, particularly in the sagittal plane [6, 8, 12, 14, 25]. Recent studies have also suggested that the impact of complications on clinical outcome may not be clearly reflected in HRQOL scores [18, 19]. The goal of this study was to explore that proposition.

Prior studies have demonstrated that minor complications do not impact one or two year postoperative HRQOL scores [19], and this makes sense. There is little reason to assume that a peri-operative urinary tract infection or ileus would have any residual effect at one or two years postoperatively. Thus, while minor complications are frequent in adult spinal deformity surgery [17], they may represent an acceptable risk.

In contrast, an important tenet of risk stratification is the need to avoid the potential long-term impact of major complications. That model assumes the ability to quantify the value of risk modification, and HRQOL measures may not meet that need. Glassman et al. reported on 47 major complications in 46 patients, reporting that the rate of change in the SF-12

general health subscore was the only significant difference between major, minor and no complication groups [19]. Cho et al. reported on 166 revision adult deformity cases, observing no negative impact on clinical outcome with peri-operative major complications [18]. Limited impact for major complications is counterintuitive to most spine surgeons.

While there are obvious reasons to value the patient's perception of clinical improvement over traditional measures such as radiographic deformity correction, HRQOL measures don't necessarily convey the whole picture. This study demonstrates that despite equivalent one and two year HRQOL benefit, patients with major complications had greater deterioration in Charlson comorbidity score. CCMI reflects the patient's co-morbidity profile, so that even if patients with higher CCMI report feeling well, they carry a greater likelihood of adverse outcomes with future interventions including any subsequent spinal surgery. The patient who suffers a myocardial infarction at the time of lumbar degenerative scoliosis surgery may not report any associated symptoms at one or two years postoperatively, but they are certainly at increased risk for recurrent cardiac complications or even death with any future intervention as their CCMI score has increased [26]. These risks, although not reflected in HRQOL scores, should be part of the shared decision making process for patients undergoing spinal deformity surgery.

This study is not intended to question the value of HRQOL measures or the importance of the patient's perception of their health status. The fact that CCMI increases somewhat in many patients undergoing major surgery, and more so as the result of major complications, is a self-fulfilling prophecy. CCMI is simply an index of prior medical illness. However, these observations do suggest that a solitary focus on HRQOL scores or patient satisfaction may be misleading. Adult deformity surgery offers significant benefit for appropriately selected patients [1, 4, 6, 25], but at the same time carries significant risk. Fully recognizing the near and long term impact of these risks will help to optimize surgical decision making for both adult scoliosis patients and spinal deformity surgeons.

Acknowledgments

The manuscript submitted does not contain information about medical devices or drugs. This study was reviewed and approved by the University of Louisville Institutional Review Board

References

1. Fu KM, Bess S, Shaffrey CI, Smith JS, Lafage V, Schwab F, Burton DC, Akbarnia BA, Ames CP, Boachie-Adjei O, Deverin V, Hart RA, Hostin R, Klineberg E, Gupta M, Kebaish K, Mundis G, Mummaneni PV. International Spine Study Group. Patients with adult spinal deformity treated operatively report greater baseline pain and disability than patients treated nonoperatively; however, deformities differ between age groups. *Spine (Phila Pa 1976)*. 2014 Aug 1; 39(17):1401–7. [PubMed: 24859590]
2. Glassman SD, Schwab FJ, Bridwell KH, Ondra SL, Berven S, Lenke LG. The selection of operative versus nonoperative treatment in patient with adult scoliosis. *Spine*. 2007; 32(1):93–97. [PubMed: 17202898]
3. Liu S, Schwab F, Smith JS, Klineberg E, Ames CP, Mundis G, Hostin R, Kebaish K, Deviren V, Gupta M, Boachie-Adjei O, Hart RA, Bess S, Lafage V. Likelihood of reaching minimal clinically important difference in adult spinal deformity: a comparison of operative and nonoperative treatment. *Ochsner J*. 2014 Spring;14(1):67–77. [PubMed: 24688336]

4. Scheer JK, Hostin R, Robinson C, Schwab F, Lafage V, Burton DC, Hart RA, Kelly MP, Keefe M, Polly D, Bess S, Shaffrey CI, Smith JS, Ames CP. the International Spine Study Group. Operative Management of Adult Spinal Deformity Results in Significant Increases in QALYs Gained Compared to Non-operative Management: Analysis of 479 patients with Minimum 2-year Follow-up. *Spine (Phila Pa 1976)*. 2016 Apr 11. [Epub ahead of print].
5. Sciubba DM, Scheer JK, Yurter A, Smith JS, Lafage V, Klineberg E, Gupta M, Eastlack R, Mundis GM, Protopsaltis TS, Blaskiewicz D, Kim HJ, Koski T, Kebaish K, Shaffrey CI, Bess S, Hart RA, Schwab F, Ames CP. International Spine Study Group (ISSG). Patients with spinal deformity over the age of 75: a retrospective analysis of operative versus non-operative management. *Eur Spine J*. 2016 Aug; 25(8):2433–41. [PubMed: 25657104]
6. Smith JS, Lafage V, Shaffrey CI, Schwab F, Lafage R, Hostin R, O'Brien M, Boachie-Adjei O, Akbarnia BA, Mundis GM, Errico T, Kim HJ, Protopsaltis TS, Hamilton DK, Scheer JK, Sciubba D, Ailon T, Fu KM, Kelly MP, Zebala L, Line B, Klineberg E, Gupta M, Deviren V, Hart R, Burton D, Bess S, Ames CP. International Spine Study Group. Outcomes of Operative and Nonoperative Treatment for Adult Spinal Deformity: A Prospective, Multicenter, Propensity-Matched Cohort Assessment With Minimum 2-Year Follow-up. *Neurosurgery*. 2016 Jun; 78(6):851–61. [PubMed: 26579966]
7. Acosta FL, Cloyd JM, Aryan HE, Ames CP. Perioperative complications and clinical outcomes of multilevel circumferential lumbar spinal fusion in the elderly. *J Clin Neurosci*. 2009 Jan; 16(1):69–73. [PubMed: 19019682]
8. Daubs MD, Lenke LG, Bridwell KH, Kim YJ, Hung M, Cheh G, Koester LA. Does correction of preoperative coronal imbalance make a difference in outcomes of adult patients with deformity? *Spine*. 2013; 38(6):475–483.
9. Kim YJ, Bridwell KH, Lenke LG, Rinella AS, Edwards C II. Pseudarthrosis in primary fusions for adult idiopathic scoliosis: incidence, risk factors, and outcome analysis. *Spine*. 2005; 30(4):468–474. [PubMed: 15706346]
10. Lapp MA, Bridwell KH, Lenke LG, Riew KD, Linville DA, Eck KR, Ungacta FF. Long-term complications in adult spinal deformity patients having combined surgery: A comparison of primary to revision patients. *Spine*. 2001; 26(8):973–983. [PubMed: 11317124]
11. Scheer JK, Mundis GM, Klineberg E, Hart RA, Deviren V, Burton DC, Protopsaltis TS, Gupta M, Rolston JD, Bess S, Shaffrey CI, Schwab F, Lafage V, Smith JS, Ames CP. International Spine Study Group (ISSG). Recovery following adult spinal deformity surgery: the effect of complications and reoperation in 149 patients with 2-year follow-up. *Eur Spine J*. 2016 Aug; 25(8):2612–21. [PubMed: 25657105]
12. Berven S, Deviren V, Demir-Deviren S, Hu SS, Bradford DS. Studies in the modified Scoliosis Research Society Outcomes Instrument in adults: validation, reliability, and discriminatory capacity. *Spine (Phila Pa 1976)*. 2003 Sep 15; 28(18):2164–9. [PubMed: 14501930]
13. Carreon LY, Glassman SD, Shaffrey CI, Fehlings MG, Dahl B, Ames CP, Matsuyama Y, Qiu Y, Mehdian H, Cheung KM, Schwab FJ, Pellisé F, Kebaish KM, Lenke LG. Predictors of Health-Related Quality-of-Life After Complex Adult Spinal Deformity surgery: A Scolio-RISK-1 Secondary Analysis. *Spine Deform*. 2017 Mar; 5(2):139–144. [PubMed: 28259266]
14. Ploumis A, Liu H, Mehdian AA, Transfeldt EE, Winter RB. A correlation of radiographic and functional measurements in adult degenerative scoliosis. *Spinev(Phila Pa 1976)*. 2009 Jul 1; 34(15):1581–4.
15. Kelly MP, Lenke LG, Shaffrey CI, Ames CP, Carreon LY, Lafage V, Smith JS, Shimer AL. Evaluation of complications and neurological deficits with three-column spine reconstructions for complex spinal deformity: a retrospective Scolio-RISK-1 study. *Neurosurg Focus*. 2014 May. 36(5):E17.
16. Lenke L, Fehlings MG, Shaffrey CI, Cheung KMC, Carreon L, Dekutoski MB, Schwab FJ, Boachie-Adjei O, Kebaish KM, Ames CP, Qiu Y, Matsuyama Y, Dahl BT, Mehdian H, Pellisé-Urquiza F, Lewis SJ, Berven SH. Neurologic outcomes of complex adult spinal deformity surgery: Results of the prospective, multicenter Scolio-Risk-1 study. *Spine*. 2016; 41(3):204–212. [PubMed: 26866736]

17. Sansur CA, Smith JS, Coe JD, Glassman SD, Berven SH, Polly DW, Perra JH, Boachie-Adjei O, Shaffrey C. Scoliosis Research Society morbidity and mortality of adult scoliosis surgery. *Spine*. 2011; 39(9):E593–E597.
18. Cho SK, Bridwell KH, Lenke LG, Yi JS, Pahys JM, Zebala LP, Kang MM, Cho W, Baldus CR. Major complications in revision adult deformity surgery. Risk factors and clinical outcomes with 2 to 7 year follow-up. *Spine*. 2012; 37(6):489–500. [PubMed: 21587110]
19. Glassman SD, Hamill CL, Bridwell KH, Schwab FJ, Dimar JR, Lowe TG. The impact of perioperative complications on clinical outcome in adult deformity surgery. *Spine*. 2007; 32(24): 2764–2770. [PubMed: 18007258]
20. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis*. 1987; 40(5):373–83. [PubMed: 3558716]
21. Fairbank J, Pynsent P. The Oswestry Disability Index. *Spine*. 2000; 25:2940–53. [PubMed: 11074683]
22. Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry Low Back Pain Questionnaire. *Physiotherapy*. 1980; 66:271–273. [PubMed: 6450426]
23. Asher MA, Min Lai S, Burton DC. Further development and validation of the Scoliosis Research Society (SRS) outcomes instrument. *Spine (Phila Pa 1976)*. 2000 Sep 15; 25(18):2381–6. [PubMed: 10984792]
24. Djurasovic M, Glassman SD, Dimar JR II, Howard JM, Bratcher KR, Carreon LY. Does Fusion Status Correlate with Patient Outcomes in Lumbar Fusion? *Spine*. 2011; 36(5):404–409. [PubMed: 21325934]
25. Bridwell KH, Baldus C, Berven S, Edwards C, Glassman S, Hamill C, Horton W, Lenke LG, Ondra S, Schwab F, Shaffrey C, Wooten D. Changes in radiographic and clinical outcomes with primary treatment adult spinal deformity surgeries from two years to three- to five-years follow-up. *Spine*. 2010; 35(20):1849–1854. [PubMed: 20802383]
26. Wang TY, Martin JR, Loriaux DB, Desai R, Shammass RL, Adogwa O, Moreno J, Kuchibhatla M, Bagley CA, Karikari IO, Gottfried ON. Risk assessment and characterization of 30-day perioperative myocardial infarction following spine surgery: A retrospective analysis of 1346 consecutive adult patients. *Spine*. 2016; 41(5):438–444. [PubMed: 26693673]

Table 1

Summary of Demographic and Surgical data

	Complication			p-value
	No	Minor	Major	
N	97	26	15	
Female, N (%)	88 (91%)	26 (100%)	12 (80%)	0.085
Smoking Status, N (%)				
Never smoker, N (%)	64 (66%)	17 (65%)	8 (53%)	0.954
Former Smoker, N (%)	29 (30%)	8 (31%)	6 (40%)	
Recent smoker, N (%)	2 (2%)	1 (4%)	1 (7%)	
Smoker, N (%)	2 (2%)	0	0	
Age at Index Surgery, years, Mean (SD)	59.12 (8.91)	62.37 (8.12)	59.74 (7.29)	0.237
Body Mass Index, kg/m ² , Mean (SD)	27.26 (5.10)	26.29 (4.77)	27.62 (4.60)	0.620
Number of levels fused, Mean (SD)	11.81 (3.82)	11.58 (3.67)	11.93 (3.37)	0.947
Operative time, hours, Mean (SD)	6.57 (1.63)	6.83 (1.74)	7.12 (0.98)	0.400
Estimated Blood Loss, mL, Mean (SD)	1789.54 (1456.39)	3377.81 (2239.50)	2653.33 (1729.85)	<0.000

Table 2

Frequency of complications

Major Complications	Frequency*	Percent
Cauda equina	1	0.7
Cord deficit	1	0.7
Motor deficit	7	5.1
Deep Vein Thrombosis	4	2.9
Heart Failure	1	0.7
Respiratory Failure	3	2.2
Myocardial Infarction	1	0.7
Pulmonary Embolism	1	0.7
Acute Renal Failure	1	0.7
Case aborted due to hypotension	1	0.7
Anaphylaxis	1	0.7
Minor complications		
Sensory deficit	4	2.9
Cerebrospinal Fluid Leak	9	6.5
Radiculopathy	2	1.4
Ileus	4	2.9
Superficial Infection	4	2.9
Poor fixation	1	0.7
Excessive Blood Loss	8	5.8
Other	14	10.1

* Values indicate frequency of event and not cases.

Table 3

Summary of Outcome Measures

Variable	Complication group			p-value
	No	Minor	Major	
N	97	26	15	
Charlson Comorbidity Index, Mean (SD)				
Pre-operative	3.52 (1.70)	4.15 (1.71)	4.00 (1.13)	0.165
One Year Deterioration	0.27 (0.47)	0.08 (0.27)	0.80 (1.01)	<0.000
Two Year Deterioration	0.46 (0.61)	0.15 (0.37)	0.93 (0.96)	0.001
Short Form-36 PCS, Mean (SD)				
Pre-operative	34.30 (9.73)	31.23 (10.02)	30.81 (8.02)	0.199
One Year Improvement	7.24 (10.54)	8.88 (10.88)	4.63 (11.53)	0.497
Two Year Improvement	10.01 (9.76)	8.87 (11.43)	6.32 (11.72)	0.461
SRS Subscore, Mean (SD)				
Pre-operative	3.07 (0.59)	2.96 (0.56)	3.08 (0.50)	0.655
One Year Improvement	0.76 (0.58)	0.68 (0.53)	0.59 (0.51)	0.527
Two Year Improvement	0.83 (0.58)	0.65 (0.65)	0.78 (0.56)	0.373