An Alternative Method to Evaluating the Value of Adult Spinal Deformity Interventions

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INTRODUCTION:

The economic evaluation of adult spinal deformity (ASD) interventions has traditionally relied on the Quality Adjusted Life Years (QALYs) metric. However, the recent passage of H.R. 485 by the U.S. House of Representatives challenges the use of QALYs in federally-funded healthcare programs due to concerns about potential discrimination against individuals with chronic disabilities and the elderly, including ASD patients. In response, the Centers for Medicare & Medicaid Services (CMS) announced plans to consider Equal Value Life Years Gained (evLYG) for pricing and reimbursement decisions. To date, no studies have examined the long-term benefits of ASD interventions using the evLYG metric. METHODS:

We analyzed 820 operative ASD patients with complete baseline and two-year follow-up data, including radiographic, health-related quality of life, and cost metrics, as part of a retrospective cohort study from a prospectively enrolled database. The analysis began by mapping the Oswestry Disability Index (ODI) to the SF-6D using validated regression models, followed by transformation according to the QALY modeling techniques of Sheer et al. 2018. We then derived the expected value of Life Years Gained (evLYG) from total costs and established QALY values for operative versus nonoperative management of ASD, utilizing a Markov cohort simulation model.

RESULTS: In this study, 448 patients met the inclusion criteria, with an average age of 60.1 ± 14.3 years and 80.3% being female. The mean BMI was 27.1 ± 5.6 kg/m², and the mean Charlson Comorbidity Index (CCI) was 1.7 ± 1.7 . Surgically, the average operative time was 413.7 ± 177.8 minutes, mean estimated blood loss (EBL) was 1581.8 ± 1389.4 mL, and an average of 13.2 ± 2.8 levels were fused. Of these, 20.1% (90 patients) experienced a major complication and 16.5% (74 patients) specifically endured a mechanical complication. By the two-year mark, 20.3% (91 patients) required reoperation. Proximal junctional kyphosis (PJK) occurred in 16.1% by 6 months, 32.6% by one year, and 37.1% by two years. Proximal junctional failure (PJF), as defined by Lafage, was experienced by 1.8% of patients at 6 months, increasing to 5.6% by one year and 8.0% by two years, with 7.8% requiring reoperation. Financially, the mean cost of the index operation over two years was $$69,002.34\pm$18,260.67$, while the reoperation cost averaged $$21,396.23\pm$39,202.47$. The overall cost, including complications and reoperations, reached $$90,285.85\pm$42,231.24$. The utility gained over two years was 0.16 ± 0.20 , with a 2-year Quality-Adjusted Life Year (QALY) of 1.14 ± 1.15 . The expected value of Life Years (evLY) for operative treatment, adapted from validated 3-year QALY values, was 0.85 compared to 0.52 for nonoperative management, indicating an expected Life Years Gained (evLYG) of 0.33 ± 0.33 for surgical interventions. The evLYG-based incremental net monetary difference at 3 years for patients with complications or reoperations was approximately \$57,285, while it was about \$36,002 for those without complications.

DISCUSSION AND CONCLUSION:

Discussion: The findings of this study provide a comprehensive evaluation of adult spinal deformity (ASD) interventions using both the traditional Quality Adjusted Life Years (QALYs) and the emerging Equal Value Life Years Gained (evLYG) metrics. The demographic and clinical characteristics of the cohort, including a predominance of females, an average age of 60.1 years, and significant comorbidities, highlight the complexity of ASD patient management. The high rates of major and mechanical complications, proximal junctional kyphosis (PJK), and proximal junctional failure (PJF) underscore the challenging nature of surgical interventions for ASD. Our analysis revealed that the average cost of ASD surgery, including complications and reoperations, is substantial, reaching over \$90,000 within two years. Despite these costs, the utility gained (0.16) and the resulting QALY (1.14) suggest a positive impact on patients' quality of life. Importantly, the evLYG metric, which adjusts for life years gained irrespective of quality, indicates a clear advantage for surgical intervention in ASD can lead to significant life years gained, even when factoring in the high complication rates and costs. The economic implications are profound. The evLYG-based incremental net monetary difference for patients with complications or reoperations was approximately \$57,285, compared to \$36,002 for those without complications. This data suggests that while the upfront costs and risks of surgery are high, the long-term benefits in terms of life years gained can justify these investments, particularly when using the evLYG metric.

Conclusion: This study underscores the potential value of utilizing the Equal Value Life Years Gained (evLYG) metric in evaluating the economic and clinical outcomes of adult spinal deformity (ASD) interventions. The evLYG metric addresses some of the limitations associated with QALYs, particularly in populations with chronic disabilities and the elderly. Our findings indicate that despite significant costs and complications, surgical intervention for ASD results in meaningful life years gained. This supports the CMS's consideration of evLYG for healthcare pricing and reimbursement decisions,

promoting a more equitable assessment of treatment benefits. Further research is warranted to validate these findings and explore the broader applicability of evLYG in different patient populations and healthcare settings.