

A cost-effectiveness comparisons of adult spinal deformity surgery in the United States and Japan

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Abstract

Purpose Information about the cost-effectiveness of surgical procedures for adult spinal deformity (ASD) is critical for providing appropriate treatments for these patients. The purposes of this study were to compare the direct cost and cost-effectiveness of surgery for ASD in the United States (US) and Japan (JP).

Methods Retrospective analysis of 76 US and 76 JP patients receiving surgery for ASD with ≥ 2 -year follow-up was identified. Data analysis included preoperative and postoperative demographic, radiographic, health-related quality of life (HRQOL), and direct cost for surgery. An incremental cost-effectiveness ratio (ICER) was determined using cost/quality-adjusted life years (QALY). The

cost/QALY was calculated from the 2-year cost and HRQOL data.

Results JP exhibited worse baseline spinopelvic alignment than the US (pelvic incidence and lumbar lordosis: 35.4° vs 22.7° , $p < 0.01$). The US had more three-column osteotomies (50 vs 16%), and shorter hospital stay (7.9 vs 22.7 days) ($p < 0.05$). The US demonstrated worse post-operative ODI (41.3 vs. 33.9%) and greater revision surgery rate (40 vs 10%) ($p < 0.05$). Due to the high initial cost and revision frequency, the US had greater total cost (\$92,133 vs. \$49,647) and cost/QALY (\$511,840 vs. \$225,668) at 2-year follow-up ($p < 0.05$).

Conclusion Retrospective analysis comparing the direct costs and cost-effectiveness of ASD surgery in the US vs JP demonstrated that the total direct costs and cost/QALY were substantially higher in the US than JP. Variations in patient cohort, healthcare costs, revision frequencies, and HRQOL improvement influenced the cost/QALY differential between these countries.

This study was approved by the institutional review board.

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Introduction

Soaring healthcare costs due to medical care advances and increased life expectancy have become a major economic burden on healthcare systems. Orthopedic surgery is particularly costly, and, for patients with degenerative spine conditions, cost-effectiveness studies are useful for providing appropriate treatment and resource allocation. Due to the aging of the population, the proportion of people suffering from adult spinal deformity (ASD) is increasing [1]. Thus, more patients are expected to present

with painful spinal conditions requiring corrective spinal surgery in the coming years [2]. The decision to perform surgery is based on the type and severity of the patient's symptoms as well as the potential risk of surgical intervention. A recent prospective study showed that surgical treatment of ASD can provide significant improvement in health-related quality of life (HRQOL) at a 2-year minimum follow-up, whereas non-surgical treatment on average has little effect on reducing pain and disability [3]. Although the clinical outcomes of corrective spine surgery for ASD are favorable, the surgeries are often lengthy and require multiple devices, osteotomies, long-segment spinal fusions, blood transfusions, and long hospitalizations [4]. In addition, the un-planned reoperation rate after the initial surgery is relatively high, with 15–20% of the patients requiring reoperation within 2 years of the initial surgery [5–7]. Scheer et al. reported that 17% of 352 ASD patients required un-planned reoperation and 5% of the reoperations occurred within 30 days of the initial surgery [8].

To assess the cost and cost-effectiveness of a medical intervention, it is essential to take into account the country in which the care is being provided, since there are unique features of the healthcare systems in each country. The World Health Organization (WHO) carried out the first ever analysis of the world's health systems in 2000 [9]. Using five performance indicators to measure health systems in 191 member states, the report indicated that France provided the best overall healthcare among major countries. The report found that the US health system spends a markedly higher portion of its gross domestic product on healthcare than any other country assessed while Japan health system spends 24th among 34 organization for economic co-operation development (OECD) member countries [9]. There is a significant difference for healthcare systems between the US and Japan. Healthcare in the US is provided by many distinct organizations and healthcare facilities are largely owned and operated by private sectors [9]. In contrast, healthcare in JP is provided from the government and the National Health Insurance Act established a healthcare system in JP that has covered the entire population since 1961 [10]. Yet there is a variation in performance, even among countries with similar levels of income and health expenditure, therefore it is helpful for decision-makers to understand the underlying factors for the cost and cost-effectiveness of each medical intervention. Thus, comparing the cost and outcomes of ASD surgery, especially across different countries, may provide insights for improving treatments. The goal of the present study was to compare the direct cost and cost-effectiveness of surgically treating ASD patients in the US and JP.

Materials and methods

Patient population

This study used prospective database from one US comprehensive spine center and two JP high-volume centers representing 76 US and 76 JP consecutive patients who had undergone corrective spine surgery between 2010 August and 2014 March. The all three spine centers are representative and state of art center for the treatment of spinal disorders and all surgeries were done by Scoliosis Research Society (SRS) active fellows in each center. All data were corrected prospectively and then analyzed retrospectively.

Inclusion and exclusion criteria

Patients included in our study were adults (age ≥ 50 years) diagnosed with a spinal deformity, defined by a Cobb angle $\geq 20^\circ$, C7SVA ≥ 5 cm, pelvic tilt (PT) $\geq 25^\circ$, and/or thoracic kyphosis (TK) $\geq 60^\circ$. The patients selected for analysis had a minimum of five fused vertebral levels and complete 2-year follow-up data. Patients were excluded if they did not have appropriate radiographs or had syndromic, neuromuscular, or other pathological conditions.

Data collection and radiographic assessment

The demographic and clinical data collected included patient age, gender, and spine surgery history. The surgical data collected included the osteotomy (three-column osteotomy [3CO]), the number of posterior spine levels fused, and the length of hospitalization. Full-length standing spine radiographs at baseline, 6-week, and 2-year follow-ups were analyzed. Radiographic measurements included thoracic kyphosis (TK), lumbar lordosis (LL), C7SVA, PT, and the mismatch between pelvic incidence (PI) and lumbar lordosis (PI–LL).

All costs were recorded on the basis of resource use, derived from institutional records. Hospital discharge and billing records for all study patients were collected in a prospective longitudinal registry. All billable procedures from the index hospitalization and all hospitalization related to the surgery in 2-year post-operation were recorded prospectively. The direct hospital costs incurred for the operation and any readmission-related costs were collected from hospital administrative data. These costs included all direct supply costs incurred by the hospital, but did not include the overhead and non-hospital employee (e.g., surgeon and anesthesiologist) fees in the US. In contrast, in JP the surgeon, anesthesiologist, and all other physicians are paid by the healthcare system and are therefore included in the direct costs. Operating room costs

included all direct costs incurred during the operation, the majority of which were for implants and biologics. Examination costs including radiographs, computed tomography scans, magnetic resonance imaging, and electromyography, were recorded. Hospital costs included pre- and postoperative epidural steroid injections, back-specific medications (non-steroidal anti-inflammatory drugs, Cox-2 inhibitors, oral steroids, narcotics, muscle relaxants, and antidepressants), physical therapy, food, room cost, etc. The average US/JP exchange rate between 2010 and 2015 was used (1 dollar = 95.5 Yen), and the price difference was adjusted based on the 2011 World Bank international price difference report (JP 173.6, US 129.0) [10].

Clinical outcomes

Patient outcomes were evaluated using two measures of HRQOL, the Scoliosis Research Society Patient Questionnaire (SRS-22r) and the Oswestry disability index (ODI). Baseline and 1- and 2-year postoperative ODI and SRS scores were determined.

Cost-effectiveness analysis

Cost-effectiveness was determined using cost/quality-adjusted life years (QALYs) [12, 13]. Cost/QALY was calculated from the 2-year cost and ODI. Based on a previously reported regression model, we calculated QALY by converting ODI scores to short-form health survey (SF-6D) scores [14].

For this study, the baseline and 1- and 2-year follow-up HRQOL data were available.

Statistical analysis

Descriptive statistics were used to summarize collected data. Changes in HRQOL scores were evaluated using a paired *t* test. Differences between groups were measured using Mann–Whitney *U* test and Chi-square analysis. *p*-values < 0.05 were considered statistically significant. Data were analyzed using SPSS Statistics, version 21.0 (IBM Corp., Armonk, NY).

Results

Demographic and radiographic data comparisons

The JP patients had more severe baseline sagittal spinopelvic malalignment, as demonstrated by their larger PI–LL ($35.4 \pm 19.5^\circ$ vs. $22.7 \pm 18.9^\circ$, Table 1, $p < 0.01$). Forty percent of the US patients and 10% of the JP patients

had a history of previous spine surgery ($p < 0.01$). Three-column osteotomies were more common (50 vs. 16%, $p < 0.01$), and hospitalizations were shorter (7.9 ± 4.4 vs. 22.7 ± 7.1 days, $p < 0.01$) in the US.

HRQOL comparisons

The baseline SRS-22r scores, 2-year postoperative SRS-22r scores, and 2-year postoperative ODI were all worse for the US than the JP patients (Tables 2, 3). The cumulative 2-year postoperative QALY gains were 0.19 for the US patients and 0.28 for the JP patients (Table 5).

Cost comparisons

Total direct hospital costs of the initial surgical treatment averaged $\$71,638 \pm 23,246$ in the US and $\$44,479 \pm 10,943$ in JP (Table 4). Thirty US patients (40%) and 7 JP patients (9%) were readmitted for a spine-related procedure over the follow-up period ($p < 0.01$). The total hospital cost per patient, including readmission during the 2-year follow-up period, averaged $\$92,133 \pm 48,268$ in the US and $\$49,647 \pm 9428$ in JP, indicating that both the initial surgery and overall costs were significantly lower in JP ($p < 0.01$). The cost of implants was also significantly higher in the US ($\$31,407 \pm 10,134$ vs. $\$23,217 \pm 6516$, $p < 0.01$, Table 4).

Cost comparison by group

Patients were subcategorized by the presence or absence of 3COs. The total direct cost of the surgical treatment of patients with 3COs was slightly higher than that of patients without 3COs in the US, but this difference was not statistically significant (US patients with 3COs vs. those without 3COs, $\$96,999 \pm 54,311$ vs. $\$87,139 \pm 41,272$, $p = 0.37$).

Cost-effectiveness comparisons

The projected cost/QALY decreased from $\$1,151,665 \pm 1,368,801$ at 1-year to $\$511,840 \pm 530,504$ at 2-year post-surgery in the US and from $\$459,135 \pm 392,101$ at 1-year to $\$225,668 \pm 190,528$ at 2-year post-surgery in JP (Table 5).

Discussion

Due to the escalation of medical costs around the world, the optimization of costs and outcomes for surgical approaches for treating degenerative conditions is critical. Here, we analyzed the cost and cost-effectiveness of surgical treatments for 76 US and 76 JP ASD patients, at

Table 1 Summary of patient cohorts in the US and JP

	JP	US	<i>p</i> value
Number of patients	76	76	
Age (years)	63.7 ± 13.6	62.8 ± 12.0	0.69
Gender (female %)	93	76	<0.01*
Schwab-SRS curve type	T5D16L32N23	T9D21L26N20	0.84
History of previous spine surgery (%)	8/76 (10.5)	30 (39.5)	0.01*
Hospitalization (days)	22.7 ± 7.9	7.9 ± 4.2	<0.01*
Number of fused vertebrae	12.2 ± 2.5	13.2 ± 3.9	0.14
Patients with 3COs (%)	16	50	<0.01*
PI–LL (°)	35.4 ± 19.5	22.7 ± 18.9	<0.01*
C7SVA (cm)	10.8 ± 6.2	9.2 ± 5.7	0.09

Data represent means and standard deviations

PI–LL Mismatch between pelvic incidence and lumbar lordosis, 3COs three-column osteotomies, C7SVA C7 sagittal vertical axis

* Statistically significant

Table 2 Comparison of preoperative clinical outcomes in JP and the US

	JP	US	<i>p</i> value
ODI (%)	56.4 ± 12.3	56.1 ± 14.9	0.90
SRS22 function	2.84 ± 0.69	2.26 ± 0.65	<0.01*
SRS22 pain	2.44 ± 0.77	2.07 ± 0.66	<0.01*
SRS22 self-image	2.34 ± 0.64	2.06 ± 0.66	0.02*
SRS22 mental health	2.37 ± 0.80	2.95 ± 0.92	<0.01*
SRS22 satisfaction	2.44 ± 0.97	2.51 ± 1.08	0.81
SRS22 total	2.51 ± 0.66	2.36 ± 0.54	<0.01*

Data represent means and standard deviations

ODI Oswestry disability index, SRS22 scoliosis research society patient questionnaire

* Statistically significant

Table 3 Comparison of postoperative clinical outcomes in JP and the US

	JP	US	<i>p</i> value
ODI (%)	33.9 ± 11.9	41.3 ± 21.6	<0.01*
SRS22 function	3.39 ± 0.51	2.67 ± 0.90	<0.01*
SRS22 pain	3.47 ± 0.55	2.87 ± 1.01	<0.01*
SRS22 self image	3.67 ± 0.52	3.08 ± 0.91	<0.01*
SRS22 mental health	3.99 ± 0.51	3.56 ± 1.01	0.01*
SRS22 satisfaction	4.12 ± 0.60	3.89 ± 1.09	0.23
SRS22 total	3.62 ± 0.66	3.13 ± 0.81	<0.01*

Data represent means and standard deviations

ODI Oswestry disability index, SRS22 scoliosis research society patient questionnaire

* Statistically significant

2-year time points post-surgery. The mean cost/QALY at 2 years was \$511,840 in the US and \$225,668 in JP, with a mean cumulative QALY improvement of 0.22 in the US and 0.28 in JP. The QALY improvement in the US in the present study was slightly better than the previous report by Fischer et al., whereas the Cost/QALY was worse than the previous report [15]. The higher estimated 2-year cost/QALY in the US may be due to several factors.

1. Variations in healthcare costs in JP and the US

The healthcare systems are quite different in the US and JP. Medical insurance systems in Japan are generally influenced by budgetary planning. In addition, the medical costs of Japan's national healthcare system are tax-supported, and the system covers almost 70% of medical costs [16]. However, in both countries, total medical expenses increase every year [11, 12, 16]. Since JP has the largest aging population in the world, the total medical expenses are regulated by the government to maintain an affordable healthcare system [16]. The surgical reimbursement for the hospital (includes employees fee) has been constrained in the same amount for each surgical procedure by the government by code (the operation code; K-code. scoliosis surgery; \$8,734 [adjusted by exchange rate and price difference]). Thus, each hospital in JP must reduce its costs, which probably reduces the total hospital costs.

2. Reoperation frequencies in JP and the US

The reoperation rate of ASD patients was higher in the US, increasing total costs by ~30% and decreasing Cost/QALY by \$113,861. The greater use of 3COs in the US could contribute to the higher reoperation rate. Previous studies showed that ASD patients receiving PSOs have relatively high reoperation rates due to rod fracture [17].

Table 4 Comparison of 2-year direct costs in the US and JP

	JP	US	<i>p</i> value
Direct costs			
Initial surgery	\$44,479 ± 10,943	\$71,638 ± 23,246	<0.01*
2-year total	\$49,647 ± 9428	\$92,133 ± 48,268	<0.01*
Breakdown of the costs			
Operating room costs	\$15,965 ± 3222	\$13,105 ± 6776	0.34
Implant costs	\$23,217 ± 6516	\$39,407 ± 10,134	<0.01*
Exam costs	\$501 ± 272	\$3,381 ± 1245	<0.01*
Hospital costs	\$7,630 ± 2646	\$28,416 ± 10,657	<0.01*
Data represent means and standard deviations			
* Statistically significant			

Table 5 Comparison of 2- and 5-year postoperative QALY and ICER scores in the US and JP

	JP	US	<i>p</i> value
Modeled SF-6D scores			
Preoperative	0.49 ± 0.06	0.49 ± 0.08	0.90
2-year postoperative	0.60 ± 0.06	0.57 ± 0.11	<0.01*
QALY improvements			
2-year postoperative	0.28 ± 0.06	0.22 ± 0.08	<0.01*
Cost/QALY			
2-year postoperative	\$225,668 ± 190,528	\$511,840 ± 530,504	<0.01*
Data represent means and standard deviations			
SF-6D Short-form health survey, QALY quality-adjusted life years			
* Statistically significant			

Furthermore, Smith et al. reported that rod fractures occurred in 22% of ASD patients who received PSOs with a 1-year minimum follow-up [18]. Thus, the greater use of 3COs in the US appears to increase the incidence of revision surgery, resulting in increased total costs and Cost/QALY over the 2-year follow-up. Although PSO is technically demanding and carries substantial risk for the complications, the long-term clinical outcomes are favorable and is a useful tool for obtaining the restoration of lumbar lordosis in a fixed sagittal malalignment [19].

Additionally, the reoperation frequency for surgical site infection (SSI) was different between the US and JP. Only one JP patient (1.3%) was readmitted to the hospital for the treatment of a SSI, while 4 US patients (5.3%) had surgical site infection and were treated with irrigation and debridement.

Ishii et al. previously described that the incidence of SSI in the instrumented spinal fusion in adult patients was 1.1% among 3,462 instrumented spinal surgeries in JP [20]. On the other hand, Pull ter Gunne et al. described that the incidence of SSI in the same population was 5% among 3,174 instrumented spinal surgeries in the US [21]. Adogwa O et al. have described that in elderly patients undergoing elective spine surgery, SSI was the most common primary reason for un-planned readmission [22].

The higher proportion of patients with a history of spine surgery may at least partially explain the higher incidence of SSI in the US patients. Hence, the early infection would have been treated without the need of readmission thereby given a false-negative readmission rate in Japan.

In the present study, patients in JP stayed in the hospital significantly longer than those in the US. The US patients stayed in the hospital for 7.9 days on average and JP patients for 22.7 days ($p < 0.05$). However, the average total hospitalization charge was 3.5 times higher in the US than in JP. Previous comparisons of hospital stay between the US and JP for myocardial infarction also showed that JP patients stayed 3 times longer in the hospital, whereas the average total charge for hospitalization was 2.3 times higher in the US than in JP [23]. Although the length of hospital stay is determined mainly by physician judgment and by healthcare system factors, patients and their family members often participate in decision-making about discharge dates.

3. Differences in HRQOL scores in JP and the US

The baseline SRS22 scores were all significantly worse in the US cohort, indicating that the US ASDs in this study had more severe disabilities than the JP ASDs. In contrast, the baseline ODI scores of the US and JP patients were not significantly different, suggesting a possible discordance

between the ODI and SRS-22r measurements in either the US or JP group. Bridwell et al. reported that there are differences in the responsiveness of the SRS22, ODI, and SF-12 to change in ASD patients following surgery. They concluded that the SRS total score showed greater change at 2-year post-operation than either the ODI or SF-12, and ODI was least responsive to changes following surgery. They also concluded that patients with double major and lumbar curves were not more likely than those with thoracic curves to experience surgery-induced improvement in SRS function and pain or ODI scores. These findings suggested that ICER analysis using ODI data may not fully capture the HRQOL improvements.

4. Differences in spinal implant costs in JP and the US

Spinal implant costs, which included the cost of biologics used to stimulate spinal fusion, were significantly higher in the US. Since in JP most fusion biologics have not yet been approved for clinical use, they are not used during ASD surgery. The average fusion biologics cost in the US (\$4,588 ± 866 for the initial surgery) increased the total implant cost in the US by ~12% and the ICER by ~6%.

In addition to the factors described above, patients' medical histories might also affect postoperative ODIs. Forty percent of the US patients and 10% of the JP patients in our study had previous spine surgery. Revision spine surgery is technically demanding, especially when treating spinal deformity conditions [24], and the risk of major complications is significantly increased in revision surgery for ASD [17]. Thus, the higher numbers of revision surgeries associated with ASD patients can increase the cost of ASD surgical treatment in the US.

Our study has some limitations. First, the heterogeneity of the study population made it difficult to draw strong conclusions about ASD surgery outcomes based on ICER results. ASD patients are a heterogeneous population that includes patients with idiopathic scoliosis, de novo scoliosis, pure kyphosis, and postoperative deformity [12, 19]. Some ASD patients have severe disability while others have no symptoms. In addition, healthcare system differences in JP and the US may affect the direct cost of ASD surgery in these countries, complicating the cost-effectiveness determination [14, 25].

Although ASD surgery significantly improved clinical outcomes, the treatment costs at the 2-year period in the US and in JP were beyond the upper threshold for cost-effectiveness set by the WHO (3 times per capita GDP, or \$145,000 in the US and \$173,000 in JP [adjusted] [26]). The high initial cost of orthopedic surgery highlights the importance of long follow-up periods and accurate HRQOL estimations for evaluating the cost-effectiveness of ASD surgery.

Low reoperation rates and better clinical outcomes were both indispensable for obtaining better ICERs. Even though the short-term (2-year) Cost/QALY does not much the WHO criteria for cost-effectiveness, previous literatures have described the importance and necessity of surgical treatment for ASD. Paulus et al. have compared the non-surgical versus surgical treatment of ASD and describes that non-surgical treatment does not seem to be cost-effective and has not shown to have a positive impact on quality of life [27]. Moreover, McCarthy et al. have described that the surgical treatment for ASD is cost-effective after a 10-year period based on predicted deterioration in HRQOL without surgery [28]. On the other hand, Bourghli et al. have reported that lack of improvement in HRQoL scores at 6 months after surgery for ASD predicts high revision rate in the second postoperative year [29]. Therefore, physicians should choose appropriate patients for surgery and weigh the surgical risks to avoid major complications requiring additional surgery.

Conclusion

A retrospective analysis of the direct costs and cost-effectiveness of ASD surgery in the US and JP demonstrated that the total direct costs and cost/QALY were substantially higher in the US than in JP at 2-year post-surgery. Variations in healthcare costs, reoperation frequencies, implant costs, and HRQOL improvements influenced the cost difference between these countries. The different types of patients in the US and Japan may also be a factor in the variation of the cost-effectiveness and the cost/QALY outcomes. Further research is needed to identify methods for reducing costs and improving patient-reported outcomes.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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