Potential of predictive computer models for preoperative patient selection to enhance overall quality-adjusted life years gained at 2-year follow-up: a simulation in 234 patients with adult spinal deformity

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OBJECTIVE Patients with adult spinal deformity (ASD) experience significant quality of life improvements after surgery. Treatment, however, is expensive and complication rates are high. Predictive analytics has the potential to use many variables to make accurate predictions in large data sets. A validated minimum clinically important difference (MCID) model has the potential to assist in patient selection, thereby improving outcomes and, potentially, cost-effectiveness.

METHODS The present study was a retrospective analysis of a multiinstitutional database of patients with ASD. Inclusion criteria were as follows: age ≥ 18 years, radiographic evidence of ASD, 2-year follow-up, and preoperative Oswestry Disability Index (ODI) > 15. Forty-six variables were used for model training: demographic data, radiographic parameters, surgical variables, and results on the health-related quality of life questionnaire. Patients were grouped as reaching a 2-year ODI MCID (+MCID) or not (–MCID). An ensemble of 5 different bootstrapped decision trees was constructed using the C5.0 algorithm. Internal validation was performed via 70:30 data split for training/testing. Model accuracy and area under the curve (AUC) were calculated. The mean quality-adjusted life years (QALYs) and QALYs gained at 2 years were calculated and discounted at 3.5% per year. The QALYs were compared between patients in the +MCID and –MCID groups.

RESULTS A total of 234 patients met inclusion criteria (+MCID 129, –MCID 105). Sixty-nine patients (29.5%) were included for model testing. Predicted versus actual results were 50 versus 40 for +MCID and 19 versus 29 for –MCID (i.e., 10 patients were misclassified). Model accuracy was 85.5%, with 0.96 AUC. Predicted results showed that patients in the +MCID group had significantly greater 2-year mean QALYs (p = 0.0057) and QALYs gained at 2 years were calculated and discounted at 3.5% per year. The QALYs were compared between patients in the +MCID and –MCID groups.

CONCLUSIONS A successful model with 85.5% accuracy and 0.96 AUC was constructed to predict which patients would reach ODI MCID. The patients in the +MCID group had significantly greater 2-year mean QALYs (p = 0.0057) and QALYs gained (p = 0.0002).

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KEY WORDS Oswestry Disability Index; minimum clinically important difference; predictive modeling; quality-adjusted life year

ABBREVIATIONS ASD = adult spinal deformity; AUC = area under the curve; BMI = body mass index; HRQOL = health-related QOL; IBF = interbody fusion; LIV = lowermost instrumented vertebra; MCID = minimum clinically important difference; NRS = numerical rating scale; ODI = Oswestry Disability Index; QALY = quality-adjusted life year; QOL = quality of life; SF-36 = 36-Item Short-Form Health Survey; SPO = Smith-Petersen osteotomy; SRS = Scoliosis Research Society; UIV = uppermost instrumented vertebra.

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A DULT spinal deformity (ASD) is a debilitating disease affecting up to one-third of the general population, and its prevalence markedly increases with age.5 As the population of the US ages, ASD is becoming increasingly recognized as a disease that could reach epidemic proportions.6,41 Importantly, the substantial burden of symptomatic ASD on patient health and well-being has been well established, which underscores the need for treating ASD safely and efficiently.5,13,22,24

Although there is still some debate regarding optimum management paradigms, surgical intervention remains one of the cornerstones of therapy. Recent research led by our group and others has shown that, compared with nonoperative treatment, surgery is associated with significantly greater improvement in pain, functionality, and quality of life (QOL), as well as increasing the likelihood of reaching a minimum clinically important difference (MCID) for these improvements.2,3,12,19,27,29,33,35 However, this observation is not universal, because in select patients the associated postoperative complications may impact the benefits. For example, Bourghli et al. found that patients who fail to improve in QOL measures 6 months after surgery are more likely to undergo further revision surgeries for deformity correction.14 Liu et al. also showed that among 239 patients treated surgically for ASD, 44% did not reach an MCID and 5% of patients actually deteriorated.19 For such patients, reoperations can contribute further to personal and financial costs, as well as putting them at additional risk for morbidity or mortality.

Optimizing patient selection has always been a critical ingredient toward maximizing chances for surgical success, but consistently predicting which patients will perform well postoperatively remains a challenging task. Multiple studies have shown that 1) on average, surgical treatment for symptomatic ASD leads to greater qualitative improvements in QOL compared with nonoperative treatment, as measured by patient responses to health-related QOL (HRQOL) questionnaires,2,19,33 and 2) on average, surgical treatment for symptomatic ASD leads to greater quantitative improvements in QOL, as measured by quality-adjusted life years (QALYs).20,27,40 However, no study to date has successfully combined these 2 findings to show that patients who are likely to demonstrate improvements in HRQOL measures also have greater improvements in QALYs.

Thus, the primary goal of this study was to develop and internally validate a preoperative, predictive model to identify which patients will reach a 2-year MCID for the Oswestry Disability Index (ODI), and to subsequently apply this model to demonstrate that these patients achieve greater QALY improvements at 2-year follow-up from surgery. By establishing such a predictive model, we aim to provide a preoperative tool that surgeons can use to help identify which patients are most likely to be successful surgical candidates. In health systems with limited economic resources, the adoption of models as decision tools may assist physicians in guiding cost-effective care. Such a model could potentially find great value when used on a mobile or internet app at point-of-care clinic visits, to facilitate discussions with patients prior to surgery.

Methods

Study Population

In this study, a retrospective review was performed on a prospective, multicenter (11 sites) database of consecutively treated patients with ASD. Inclusion criteria for this database were as follows: 1) age ≥ 18 years and 2) radiographic diagnosis of ASD, defined by at least 1 of the following variables—scoliosis, Cobb angle ≥ 20°, C7–S1 sagittal vertical axis ≥ 5 cm, pelvic tilt ≥ 25°, or thoracic kyphosis ≥ 60°. Patients with active infections, malignancy, and neuromuscular spinal deformities were excluded from the database. For the present study, additional inclusion criteria were applied post hoc and included 1) complete 2-year follow-up and 2) preoperative ODI score > 15. This preoperative ODI cutoff was set based on previously established MCID thresholds for the ODI (−15).20,17

Data Collection—Demographics, Surgical Variables, HRQOL, Radiographic Parameters

In total, 46 variables were collected and included in the initial training of the predictive model. Demographic variables included patient age, sex, race, body mass index (BMI), Charlson Comorbidity Index, and American Society of Anesthesiologists grade, as well as the presence and number of preoperative comorbidities, including arthritis, osteoporosis, depression, and smoking history. Planned surgical variables were either binary (e.g., whether a decompression, osteotomy, Smith-Petersen osteotomy [SPO], 3-column osteotomy, or interbody fusion [IBF] were performed) or continuous (e.g., number of levels fused or decompressed, number of IBFs or SPOs, uppermost instrumented vertebra [UIV], and lowermost instrumented vertebra [LIV]). The HRQOL scores were extracted from patient responses to established questionnaires, including the ODI, 36-Item Short-Form Health Survey (SF-36), Scoliosis Research Society Outcomes Questionnaire (SRS-22r), back and/or leg pain numerical rating scale (NRS) scores, frailty index, and work status. The frailty index is a novel score for preoperative risk stratification (unpublished data), and patients were categorized as being not frail, frail, or severely frail.18 Work status was categorized with a score from 1 to 5, as follows: 1, disabled; 2, employed; 3, retired; 4, retired due to back pain; and 5, unemployed.

In accordance with existing protocols for radiographic evaluation, full-length, free-standing 36-inch cassette lateral spine radiographs were obtained preoperatively.6 These radiographs were analyzed using validated software (Spineview, ENSAM; Laboratory of Biomechanics)45,46 and techniques previously reported in the literature.21,31,36 Model creation was limited to the following preoperative radiographic parameters: maximum thoracic/lumbar Cobb angle groups (< 30°, 30–60°, > 60°); coronal C-7 plumb line; thoracic kyphosis (T4–12 Cobb angle); pelvic tilt; pelvic incidence and lumbar lordosis mismatch; C7–S1 sagittal vertical axis; and T1 pelvic angle.8,24,30 Patients were additionally classified according to the SRS-Schwab coronal curve classification system.32

Patients were stratified based on whether they at least reached an MCID for ODI (+MCID) or not (−MCID) at the 2-year follow-up. The MCID is a variable derived from...
established HRQOL surveys, such as the ODI, and serves as a quantitative measure for whether an intervention resulted in a clinically meaningful difference to patient outcome. Threshold MCID values have been previously established.10,14,16,17

Quality-Adjusted Life Years

A QALY is both a quantitative and qualitative measure, and is calculated as a product of “health state” (ranging from 0 [death] to 1 [completely healthy]) and time spent in that specific health state.39,42 To calculate QALYs, health utility values were derived from Short-Form 6-Dimension (SF-6D) utility index scores at the preoperative time point and at 2 years after surgery, based on established formulas.27,42 The mean QALYs were subsequently discounted at the recommended rate of 3.5% per year.43

Statistical Analysis

Continuous variables were reported as mean ± SD. Baseline parameters between the 2 subgroups (+MCID vs −MCID) were analyzed using the Student t-test or Pearson’s chi-square test for continuous and categorical variables, respectively. For nonparametric variables (tested using the Shapiro-Wilk test), the Mann-Whitney test was used instead. All statistical analyses were performed using SPSS v22 (IBM, Inc.). The threshold for statistical significance was p < 0.05.

During creation of the predictive model, missing data were imputed using standard techniques, and variables were tested for collinearity.1 The target variable was made binary as follows: 1 for patients who achieved at least an MCID for ODI at 2-year follow-up (+MCID) or 0 for patients who did not achieve at least an MCID for ODI at 2-year follow-up (−MCID). Subsequently, an ensemble of decision trees was generated with 5 different bootstrapped models, each of which used a unique random sample of the data, using the C5.0 algorithm. The final model represents a combination of all 5 models. Internal validation was performed using a 70:30 data split for training versus testing of each model.1 Overall accuracy as well as the area under the curve (AUC) were calculated. Predictive modeling was performed using SPSS Modeler version 16 (IBM, Inc.).

Results

Patient Population

A total of 234 patients with ASD met inclusion criteria, of whom 129 were +MCID and 105 were −MCID at 2-year follow-up. There was an overall preponderance of women (195 women, 39 men; 83.3% women), with a mean age of 59.3 ± 13.2 years and a mean BMI of 27.7 ± 5.8. Most patients presented with at least 1 comorbidity (178 patients, 76.1%), and the mean number of comorbidities was 2.3 ± 1.8. No significant differences in demographic variables were observed in the +MCID versus −MCID groups (Table 1).

Radiographic Features

All reported preoperative radiographic parameters were similar in the +MCID versus −MCID groups (Table 2), and no significant differences were appreciated (p > 0.05 for all).

Surgical Parameters

Most surgeries were primary (65.8%) versus revision (34.2%). Both the +MCID and −MCID cohorts under-
Mean QALYs and QALYs gained at 2-year follow-up were calculated. As shown in Fig. 1, when using the predicted results derived from the model, patients in the +MCID group demonstrated higher mean 2-year QALYs (1.2 ± 0.2 vs 1.1 ± 0.2; p = 0.0057). As shown in Fig. 2, the number of QALYs gained at 2 years was also greater in the +MCID group (0.2 ± 0.2 vs −0.02 ± 0.2; p = 0.0002). This effect was observed despite 10 patients being misclassified during model training.

**Discussion**

The overall objective for the present study was to construct an accurate, internally validated, predictive model for identifying patients with ASD who are more likely to be better surgical candidates and thus more likely to derive quantitative improvements in QOL. The results of our investigation provide a proof-of-concept predictive model that 1) predicts with 86% accuracy which patients will achieve at least an MCID for ODI at 2-year follow-up, and 2) demonstrates that patients who do so are more likely to have higher mean and cumulative QALYs gained. Our model demonstrated an AUC of 0.96, which suggests an excellent model fit, and was successfully applied to detect significant differences in QALYs despite 10/165 patients being misclassified on initial training.

**Optimal preoperative patient selection is important to help maximize the chances of achieving surgical success, not only for the surgeon but also, more importantly, for the patient. Although evidence-based care drives much clinical decision making, from the surgeon’s perspective there is a lack of tools currently available that can predict with robust accuracy and consistency which patients are likely to perform better. Even when it pertains to surgical planning, evidence shows that surgeons cannot accurately predict postoperative spinal alignment in 33% of cases, which suggests that there is a need to improve our arsenal...
Predictive model for ODI minimum clinically important difference

From the patient’s perspective, knowledge of their preoperative risk factors and how these impact their chances for a successful outcome can add invaluable information for their decision making as well. Ideally, surgeons and patients both would have access to a preoperative algorithm that can fulfill this function. In that regard, the model built in this current study lays the foundation for predictive analytics upon which such an algorithm can be built and used in the clinical setting prior to considering surgical intervention.

Predictive modeling has been increasingly used by our group over the past several years. The benefits and pitfalls of predictive modeling have been previously described.\textsuperscript{23} Predictive modeling is a statistical technique that represents a departure from the more traditional regression analyses; however, it affords greater flexibility by allowing patterns within the available data to create accurate, patient-specific predictions without the need to establish hypotheses or control groups a priori.\textsuperscript{1} Through this established methodology, we have successfully developed models for accurate prediction of postoperative complications,\textsuperscript{30} proximal junction failure and proximal junction kyphosis,\textsuperscript{28} and length of hospital stay.\textsuperscript{25} In the present study, the same modeling techniques were used in a large cohort of surgically treated patients with ASD to predict which patients will likely to have better outcomes, as defined by meeting MCID thresholds for ODI and QALY improvements.

Our model uses preoperative demographics, surgical variables, HRQOL responses, and radiographic variables to predict which patients will achieve clinically significant improvements in QOL (≥ 1 ODI MCID). Patient demographics (preoperative depression/arthritis/osteoarthritis, presence of comorbidity), surgical variables (decompression, number of levels fused, 3-column osteotomies, UIV), and HRQOL measures (ODI, back and/or leg pain NRS

TABLE 3. Summary of surgical parameters (12 variables) in 234 patients with ASD

<table>
<thead>
<tr>
<th>Variable</th>
<th>All Patients, ( n = 234 )</th>
<th>+MCID, ( n = 129 )</th>
<th>-MCID, ( n = 105 )</th>
<th>( p ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision surgeries</td>
<td>80 (34.2%)</td>
<td>40 (31.0%)</td>
<td>40 (38.1%)</td>
<td>0.256</td>
</tr>
<tr>
<td>Mean no. of posterior levels fused</td>
<td>11.3 ± 4.4</td>
<td>11.7 ± 4.3</td>
<td>10.7 ± 4.6</td>
<td>0.437</td>
</tr>
<tr>
<td>Decompression</td>
<td>162 (69.2%)</td>
<td>94 (72.9%)</td>
<td>68 (64.8%)</td>
<td>0.181</td>
</tr>
<tr>
<td>Mean no. of decompression levels</td>
<td>1.1 ± 0.3</td>
<td>1.1 ± 0.3</td>
<td>1.1 ± 0.3</td>
<td>0.208</td>
</tr>
<tr>
<td>Osteotomy</td>
<td>169 (72.2%)</td>
<td>89 (69.0%)</td>
<td>80 (76.2%)</td>
<td>0.221</td>
</tr>
<tr>
<td>SPO</td>
<td>150 (55.6%)</td>
<td>71 (55.0%)</td>
<td>59 (56.2%)</td>
<td>0.860</td>
</tr>
<tr>
<td>Mean no. of SPO levels</td>
<td>2.9 ± 3.1</td>
<td>3.0 ± 3.2</td>
<td>2.9 ± 3.0</td>
<td>0.542</td>
</tr>
<tr>
<td>3-column osteotomy</td>
<td>55 (23.5%)</td>
<td>25 (19.4%)</td>
<td>30 (28.6%)</td>
<td>0.099</td>
</tr>
<tr>
<td>IBF</td>
<td>165 (70.5%)</td>
<td>92 (71.3%)</td>
<td>73 (69.5%)</td>
<td>0.765</td>
</tr>
<tr>
<td>Mean no. of IBF levels</td>
<td>1.9 ± 1.9</td>
<td>1.9 ± 1.8</td>
<td>1.8 ± 1.9</td>
<td>0.908</td>
</tr>
<tr>
<td>Postop LIV</td>
<td>2 (0.9%)</td>
<td>1 (0.8%)</td>
<td>1 (1.0%)</td>
<td>0.557</td>
</tr>
<tr>
<td>Postop UIV</td>
<td>165 (70.5%)</td>
<td>92 (71.3%)</td>
<td>73 (69.5%)</td>
<td>0.765</td>
</tr>
</tbody>
</table>

Comparison of surgical parameters between patients meeting ODI MCID at 2 years (+MCID) or not (-MCID). Values are expressed as the number of patients (%) or as the mean ± SD.

TABLE 4. Summary of HRQOL parameters (15 variables) in 234 patients with ASD

<table>
<thead>
<tr>
<th>Variable</th>
<th>All Patients, ( n = 234 )</th>
<th>+MCID, ( n = 129 )</th>
<th>-MCID, ( n = 105 )</th>
<th>( p ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ODI</td>
<td>46.5 ± 14.8</td>
<td>48.3 ± 14.2</td>
<td>44.3 ± 15.3</td>
<td>0.038*</td>
</tr>
<tr>
<td>PCS</td>
<td>30.0 ± 8.0</td>
<td>30.0 ± 7.5</td>
<td>30.4 ± 8.7</td>
<td>0.517</td>
</tr>
<tr>
<td>MCS</td>
<td>44.5 ± 14.1</td>
<td>44.0 ± 14.7</td>
<td>45.2 ± 13.2</td>
<td>0.581</td>
</tr>
<tr>
<td>SRS-22r</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>2.8 ± 0.8</td>
<td>2.8 ± 0.8</td>
<td>2.8 ± 0.7</td>
<td>0.572</td>
</tr>
<tr>
<td>Pain</td>
<td>2.3 ± 0.7</td>
<td>2.3 ± 0.7</td>
<td>2.3 ± 0.8</td>
<td>0.993</td>
</tr>
<tr>
<td>Appearance</td>
<td>2.3 ± 0.7</td>
<td>2.3 ± 0.7</td>
<td>2.3 ± 0.7</td>
<td>0.795</td>
</tr>
<tr>
<td>Mental</td>
<td>3.4 ± 0.9</td>
<td>3.4 ± 0.9</td>
<td>3.4 ± 1.0</td>
<td>0.617</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>2.8 ± 1.1</td>
<td>2.7 ± 1.1</td>
<td>2.9 ± 1.1</td>
<td>0.224</td>
</tr>
<tr>
<td>Total</td>
<td>2.7 ± 0.6</td>
<td>2.7 ± 0.6</td>
<td>2.7 ± 0.6</td>
<td>0.799</td>
</tr>
<tr>
<td>Frailty index</td>
<td>3.7 ± 0.9</td>
<td>3.6 ± 0.9</td>
<td>3.7 ± 0.8</td>
<td>0.419</td>
</tr>
<tr>
<td>Frailty index category</td>
<td>1.4 ± 0.5</td>
<td>1.3 ± 0.5</td>
<td>1.4 ± 0.5</td>
<td>0.646</td>
</tr>
<tr>
<td>Work status</td>
<td>2.6 ± 1.1</td>
<td>2.6 ± 1.2</td>
<td>2.6 ± 1.1</td>
<td>0.841</td>
</tr>
<tr>
<td>NRS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain</td>
<td>7.5 ± 2.0</td>
<td>7.3 ± 2.0</td>
<td>7.7 ± 1.9</td>
<td>0.185</td>
</tr>
<tr>
<td>Leg pain</td>
<td>5.0 ± 3.2</td>
<td>5.3 ± 3.3</td>
<td>4.7 ± 3.2</td>
<td>0.120</td>
</tr>
</tbody>
</table>

MCS = mental component summary of the SF-36; PCS = physical component summary of the SF-36.

Comparison of HRQOL parameters between patients meeting ODI MCID at 2 years (+MCID) or not (-MCID). Values are expressed as the mean ± SD.

* Statistically significant at \( p < 0.05 \).
scores) were all well represented among the 11 most important predictors. Preoperative depression was the most highly ranked predictor. This is not an unexpected finding, because Smith and colleagues have already demonstrated that patients with baseline depression have significantly worse SRS-22r and ODI scores.37,38

Interestingly, radiographic parameters did not rank among the most important predictors. However, it should be emphasized that this does not necessarily discount their importance; the final predictive model was built using all 46 variables, and this model is intended to be generalizable. In select patient populations, radiographic parameters may serve a more critical role, especially with longer-term follow-up.

Our model also demonstrates that patients who are predicted to meet the +MCID threshold at 2-year follow-up have significantly higher mean QALYs and QALYs gained. This finding lends greater value to our predictive model, because QALYs represent QOL per unit of time and can thus be used as a proxy to measure quantitative improvements in QOL. Much of the national rhetoric surrounding health care has emphasized the delivery of cost-effective health care, and this model provides evidence that patients predicted to derive qualitative benefits postoperatively are more likely to experience quantitative benefits as well. An argument could be made for possible selection bias, because our analysis excluded patients with a baseline ODI score of < 15. This cohort of patients not only has an excellent baseline QOL, but is also likely to retain an excellent QOL postoperatively,7 potentially translating to greater mean QALYs. By excluding them in the current analysis, we could potentially be underestimating the delivery of cost-effective health care, and this model provides evidence that patients predicted to derive qualitative benefits postoperatively are more likely to experience quantitative benefits as well. An argument could be made for possible selection bias, because our analysis excluded patients with a baseline ODI score of < 15. This cohort of patients not only has an excellent baseline QOL, but is also likely to retain an excellent QOL postoperatively,7 potentially translating to greater mean QALYs. By excluding them in the current analysis, we could potentially be underestimating the delivery of cost-effective health care, and this model provides evidence that patients predicted to derive qualitative benefits postoperatively are more likely to experience quantitative benefits as well. 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not always be captured using HRQOL surveys, and may incorporate elements not covered by our model (e.g., financial burden of surgery impacting QOL). With that being said, this model can serve as a launching point to facilitate point-of-care discussions between surgeons and patients prior to considering surgical intervention for ASD.

Conclusions

A predictive model with 86% accuracy and 0.96 AUC was built to predict which patients are likely to reach MCID thresholds for ODI postoperatively, and the model was used to demonstrate that patients who are better surgical candidates are also more likely to have higher QALYs, as well as to gain more QALYs. Such a model may find use in the clinical setting in the form of a mobile or internet app to quantify each individual patient’s outcome risk, and can assist in the surgical decision-making process.

References


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