Identifying Subsets of Patients With Adult Spinal Deformity Who Maintained a Positive Response to Nonoperative Management

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BACKGROUND: Adult spinal deformity (ASD) represents a major cause of disability in the elderly population in the United States. Surgical intervention has been shown to reduce disability and pain in properly indicated patients. However, there is a small subset of patients in whom nonoperative treatment is also able to durably maintain or improve symptoms. **OBJECTIVE:** To examine the factors associated with successful nonoperative management in patients with ASD. **METHODS:** We retrospectively evaluated a cohort of 207 patients with nonoperative ASD, stratified into 3 groups: (1) success, (2) no change, and (3) failure. Success was defined as a gain in minimal clinically importance difference in both Oswestry Disability Index and Scoliosis Research Society-Pain. Logistic regression model and conditional inference

decision trees established cutoffs for success according to baseline (BL) frailty and sagittal vertical axis. **RESULTS:** In our cohort, 44.9% of patients experienced successful nonoperative treatment, 22.7% exhibited no change, and 32.4% failed. Successful nonoperative patients at BL were significantly younger, had a lower body mass index, decreased Charlson Comorbidity Index, lower frailty scores, lower rates of hypertension, obesity, depression, and neurological dysfunction (all P < .05) and significantly higher rates of grade 0 deformity for all Schwab modifiers (all P < .05). Conditional inference decision tree analysis determined that patients with a BL ASD-frailty index \leq 1.579 (odds ratio: 8.3 [4.0-17.5], P < .001) were significantly more likely to achieve nonoperative success.

CONCLUSION: Success of nonoperative treatment was more frequent among younger patients and those with less severe deformity and frailty at BL, with BL frailty the most important determinant factor. The factors presented here may be useful in informing preoperative discussion and clinical decision-making regarding treatment strategies.

KEY WORDS: Adult spinal deformity, Spine surgery, Nonoperative management, Nonoperative, Spine, Thoracolumbar spine

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ABBREVIATIONS: ASD, adult spinal deformity; BL, baseline; GAP, Global Alignment and Proportion; MCID, minimal clinically importance difference; LIV, lower instrumented vertebra; MCS, mental component score; ODI, Oswestry Disability Index; PCS, pain catastrophizing scale; SRS, Scoliosis Research Society; SVA, sagittal vertical axis; UIV, upper instrumented vertebra. dult spinal deformity (ASD) is a complex and increasingly prevalent spinal condition that may lead to substantial pain and disability.¹ Despite providing meaningful clinical improvement, corrective deformity surgery is associated with a high risk of complications ranging from 10% to 40% in the literature.²⁻⁴ Furthermore, ASD often presents in patients who are physiologically frail and have other medical comorbidities.^{5,6}

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Surgeons must balance the potential for complications and other adverse events in an otherwise already high-risk population against the potential for meaningful recovery from what is often a high-intensity surgical intervention.⁷⁻⁹ When medical or surgical complications, as well as mechanical failure, occur after surgery, the ultimate trajectory and ceiling for clinical recovery could be compromised.¹⁰⁻¹²

As a result, without the presence of neurological symptoms or deficits at presentation, a nonoperative approach is generally considered the initial treatment strategy including spinal injections, physical therapy, exercise, bracing, and medication management.¹³⁻¹⁵ Among patients who undergo nonoperative treatment and fail to respond, a delay in spine surgery can cause protracted disability, discomfort, pain, and economic burden with increased resource utilization.¹⁵⁻¹⁷ Therefore, it becomes imperative to properly differentiate and recognize patients who would respond successfully to nonoperative management vs those for whom continued nonoperative care may prove futile.^{18,19} However, the factors at baseline (BL) which might inform such determinations are presently unknown.

In this context, we sought to determine patient characteristics at BL that would be informative of successful nonoperative management in the setting of ASD. To investigate this question, we used the multicenter clinical registry of the International Spine Study Group. This data set has previously been successfully used to study different aspects in the surgical management of ASD, including prognostic factors linked to outcomes.²⁰⁻²² We hypothesized that patients with lower levels of frailty at BL, as well as those with less severe spinal deformity, would be more likely to achieve success with nonoperative management.

METHODS

Study Design, Setting, and Participants

This study was a retrospective analysis of a prospectively collected, multicenter database containing patients with ASD enrolled at 13 participating centers from 2009 to 2018. Institutional Review Board approval was obtained at each participating site, and all patients provided informed consent before enrollment. Patients enrolled in the database were older than 18 years, had a preliminary plan to undergo surgical correction within 6 months of enrollment dependent on success of nonoperative treatment consisting of patientspecific combinations of physical therapy, medication or injection pain management, and/or dietary counseling, and met at least one of the following radiographic criteria for ASD: coronal Cobb angle ≥ 20°, sagittal vertical axis ≥ 50 mm, pelvic tilt $\ge 25^\circ$, and thoracic kyphosis >60°. Patients with spinal deformity of neuromuscular etiology and those with active infections or malignancy were excluded from the database. All data collection at the participating sites was subject to rigorous quality control. Quarterly query reports were compiled and sent to designated research coordinators at participating sites to reconcile any missing or potentially erroneous data points.

Variables, Data Collection, and Radiographic Parameters

Demographic and surgical characteristics were obtained with standardized data collection forms. Patient-reported outcome measures administered at BL and follow-up intervals included The Oswestry Disability Index (ODI), Scoliosis Research Society Outcomes Questionnaire (SRS-22), and Short Form-36 questionnaire. Minimal clinically importance difference (MCID) thresholds were applied to evaluate improvement in outcomes using previously published values for ODI (12.8), Short Form-36 (4.9), SRS-Pain (0.587), SRS-Appearance (0.8), SRS-Activity (0.375), and SRS-Mental (0.42).

Whole-body free-standing lateral radiographs (36-inch cassette) were collected of the spine and assessed at BL and follow-up. Radiographics were analyzed by SpineView (ENSAM, Laboratory of Biomechanics) software according to standardized validated techniques as previously published in the literature. Spinopelvic radiographic parameters measured were pelvic tilt, pelvic incidence, sagittal vertical axis, and mismatch between pelvic incidence and lumbar lordosis.

Quantitative and Statistical Analysis

All statistical testing was performed using SPSS software (v21.0). Patients were stratified into 3 cohorts on the basis of outcome of nonoperative treatment: (1) success, (2) no change, and (3) failure. Success was defined as a gain in MCID in both ODI and SRS-Pain. Patients with a BL ODI less than or equal to 20 and those who also maintained an ODI less than or equal to 20 by 2-year follow-up were also considered nonoperative successes. Failure was defined as a loss in MCID in both ODI and SRS-Pain for those who continued nonoperative treatment or conversion to operative management at any time. Patients who did not meet the criteria for success or failure were characterized as having no change. Comparisons were made using the cohort experiencing failure as the referent. BL comparisons across demographic, clinical and radiographic characteristics were made using the χ^2 and independent samples t tests for categorical and continuous outcome variables, respectively. Multivariable logistic regression analysis was used to identify factors independently associated with success after nonoperative management adjusting for confounders. Conditional inference decision trees established cutoffs for success according to frailty and sagittal vertical axis (SVA). Subanalysis was performed to assess the impact of frailty on successful vs unsuccessful nonoperative treatment based on findings of previous studies (Ref. D). Statistical significance was set to P < .05 with odds ratio (OR) and 95% CIs exclusive of 1.0 after regression testing.

RESULTS

Cohort Overview

We included 207 patients who received nonoperative treatment for ASD and who also had complete BL and 2-year followup clinical and radiographic data. The mean patient age was 52.6 ± 15.8 years, body mass index (BMI) of 25.4 ± 5.4 kg/m², mean Adult Spinal Deformity Frailty Index (ASD-FI), was $1.9 \pm$ 1.5, with 86% of patients being female. Of the included patients, 83.1% were older than 35 years.

BL Radiographic and Clinical Background

BL radiographic parameters for the nonoperative cohort were as follows: pelvic incidence minus lumbar lordosis of 4.4 ± 16.4 , pelvic tilt of 19.6 ± 10.3 , and SVA of 18.9 ± 51.4 . Schwab-SRS classification deformity for pelvic tilt was $0\ 114$, +54, ++34; SVA: $0\ 143$, +45, ++13; and pelvic incidence minus lumbar lordosis:

Nonoperative success vs			
failure group	Mean	SD	Significance
Failure	46.61	19.49	P = .964
Success	46.73	16.38	
Failure	30.17	10.96	P = .000
Success	36.18	10.27	
Failure	23.92	11.26	<i>P</i> = .002
Success	18.73	10.35	
Failure	54.09	12.96	P = .667
Success	54.91	11.95	
Failure	16.09	18.71	<i>P</i> = .000
Success	2.87	16.66	
Failure	38.00	18.33	<i>P</i> = .000
Success	52.03	15.16	
Failure	47.98	63.21	P = .000
Success	11.60	47.67	
	Success Failure Success Failure Success Failure Success Failure Success Failure Success Failure Success Failure	Success46.73Failure30.17Success36.18Failure23.92Success18.73Failure54.09Success54.91Failure16.09Success2.87Failure38.00Success52.03Failure47.98	Success 46.73 16.38 Failure 30.17 10.96 Success 36.18 10.27 Failure 23.92 11.26 Success 18.73 10.35 Failure 54.09 12.96 Success 54.91 11.95 Failure 16.09 18.71 Success 2.87 16.66 Failure 38.00 18.33 Success 52.03 15.16 Failure 47.98 63.21

TABLE 1. BL Radiographic Descriptors of Successful vs Failed

0 132, +31, ++39. By Global Alignment and Proportion (GAP) score, 27.7% of patients were proportioned (GAP-proportioned), 29.7% were moderately disproportioned (GAP-moderately disproportioned), and 42.6% were severely disproportioned (GAP-severely disproportioned). By Ames cervical deformity cervical SVA classification, 70.5% of patients were classified as low deformity, 8.7% were classified as moderately deformed, and 20.8% were classified as highly deformed. BL radiographic parameters of successful vs failed nonoperative patients are presented in Table 1. Ames et al defined T1 Slope minus cervical lordosis criteria further stratified patients as 36.6% as low deformity, 20.7% as moderately deformed, and 42.7% as highly deformed. By Roussouly classification, 13.1% of patients were classified as Grade 1, 40.3% as Grade 2, 31.1% as Grade 3, and 15.5% as Grade 4. The most common comorbidities were arthritis (23%), hypertension (19%), depression (15%), osteoporosis (11%), and stomach ulcers (8%). Prior surgical history is presented in Table 2.

Successful vs Failed Nonoperative Treatment

Overall at 2 years, 44.9% of patients met the parameters for our definition of successful nonoperative treatment, 22.7% exhibited no change, and 32.4% were classified as having failed nonoperative management (Figure 1).

TABLE 2. Prior History of Surgical Management in Successful vs
Failed Nonoperative Patients

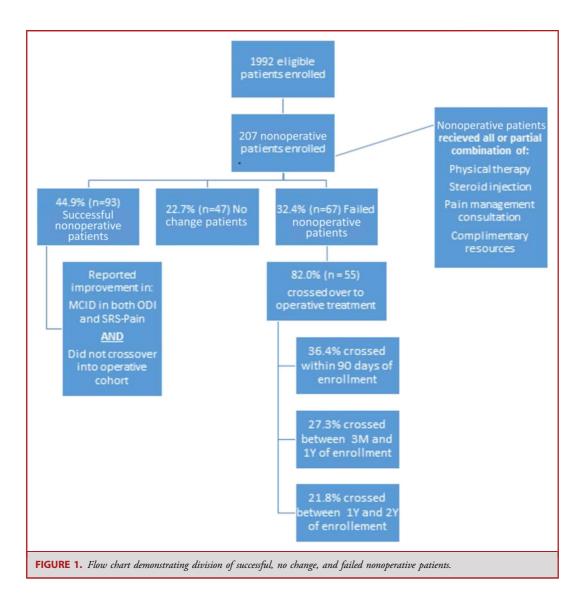
Parameter	Nonoperative success vs failure group	Mean	SD	Significance
Prior spine surgery (unspecified) (%)	Failure	0.35	0.48	<i>P</i> = .035
	Success	0.2	0.404	
Prior decompression (%)	Failure	0.65	0.493	<i>P</i> = .048
	Success	0.34	0.484	
Prior fusion (%)	Failure	0.67	0.482	<i>P</i> = .610
	Success	0.6	0.497	
Prior UIV	Failure	12.93	7.043	P = .328
	Success	15.12	5.195	
Prior LIV	Failure	20.64	7.034	<i>P</i> = .163
	Success	23.47	1.7	
History of revision (unspecified) (%)	Failure	0.3	0.483	P = .398
	Success	0.14	0.363	

BL, baseline; LIV, lower instrumented vertebra; SVA, sagittal vertical axis; UIV, upper instrumented vertebra.

BL comparisons demonstrated that patients who achieved success after nonoperative management were significantly younger, had a lower BMI, decreased Charlson Comorbidity Index, less frail, and had lower rates of hypertension, obesity, depression, and neurological dysfunction at BL (all P < .05). With respect to the severity of deformity, successful nonoperative patients presented with significantly greater rates of grade 0 deformity for all SRS-Schwab Modifiers (all P < .05). Among patients who failed nonoperative treatment, 82% crossed over to operative treatment at an average of 377 days after initial enrollment. Patients who crossed over were significantly more likely to have lower Health-Related Quality of Life measures at BL, higher rates of lung disease, and higher frailty scores (all P < .05) (Table 3).

Stratifying patients by BL disability because of observed diminishment in nonoperative success in severely frail patients, those with an ODI less than 40 had significantly higher rates of successful nonoperative treatment compared with patients with an ODI greater than 40 (P < .001). Comprehensive 2-year HRQL values are presented in Table 4. After multivariate regression analysis that accounted for confounders, increased frailty was the strongest predictor of failed nonoperative treatment (OR: 2.2 [1.6-3.0], P < .001). Even when excluding patients younger than 35 years and those with a prior history of

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revision surgery, and controlling for BL Charlson Comorbidity Index, C7-S1 SVA, T1PA, and Roussouly mismatch via backstep regression, only frailty remained a significant predictor of achieving nonoperative success in the studied cohort (P < .001). However, neither age nor a history of spine surgery was significant individual predictors in the model including all patients older than 18 years with the aforementioned controls in place (both P > .05). In addition, successful nonoperative patients were significantly more likely to present as GAP-proportioned at BL than their nonoperative failure counterparts (OR: 2.7 [1.1-6.3], P < .05).

After conditional inference decision tree analysis, we determined that patients presenting with a BL ASD-FI \leq 1.6 (OR: 8.3 [4.0-17.5], *P* < .001) were significantly more likely to achieve success after nonoperative treatment.

Case Example—Nonoperative Success

We present a 71-year-old man with a BMI of 23.0 kg/m², with no history of prior fusion, and an ODI score of 18 (Figure 2). The patient was matched in SRS-Schwab pelvic tilt, SVA, and lumbar lordosis criteria and remained as Roussouly Grade 1 from BL to 2 years. At 2 years, the patient did not demonstrate evidence of radiographic deterioration nor significant complications, although no improvements in GAP or SRS-Schwab criteria were noted.

Case Example—Non-Operative Failure

We present a 73-year-old woman with a BMI of 22.6 kg/m², with a history of arthritis, neurological dysfunction, gastric ulcers, and no prior fusion, and an ODI score of 48 (Figure 3). The patient was matched in SRS-Schwab SVA criteria and remained as

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TABLE 3. Successful vs Failed Nonoperative BL Patient-Reported Outcomes Summary				
Nonoperative success vs failure group	Mean	SD	Significance	
Failure	20.315	16.752	P = .817	
Success	19.219	15.570		
Failure	43.835	9.735	P = .706	
Success	44.999	10.276		
Failure	47.236	7.299	P = .122	
Success	51.848	10.022		
Failure	3.800	0.644	P = .275	
Success	4.044	0.744		
Failure	3.367	0.771	P = .495	
Success	3.544	0.870		
Failure	3.233	0.665	P = .495	
Success	3.391	0.772		
Failure	3.683	0.618	P = .347	
Success	3.890	0.734		
Failure	3.583	1.104	<i>P</i> = .542	
Success	3.399	0.989		
Failure	3.527	0.521	P = .392	
3.687	0.626			
	Nonoperative success vs failure group Failure Success Failure Success Failure Success Failure Success Failure Success Failure Success Failure Success Failure Success	Nonoperative success vs failure groupMeanFailure20.315Success19.219Failure43.835Success44.999Failure47.236Success51.848Success51.848Failure3.800Success4.044Failure3.631Success3.544Failure3.233Success3.391Failure3.683Success3.890Success3.890Success3.392Success3.392Failure3.583Success3.392Failure3.527	Nonoperative success vs failure group Mean SD Failure group Mean SD Failure group 16.752 Success 19.219 15.570 Failure 43.835 9.735 Success 44.999 10.276 Failure 47.236 7.299 Success 51.848 10.022 Failure 3.800 0.644 Success 4.044 0.744 Failure 3.367 0.711 Success 3.544 0.870 Failure 3.363 0.618 Success 3.391 0.772 Failure 3.683 0.618 Success 3.391 0.772 Failure 3.683 0.618 Success 3.890 0.734 Failure 3.683 0.618 Success 3.890 0.734 Failure 3.583 1.104 Success 3.391 0.527	

BL, baseline; ODI, Oswestry Disability Index; MCS, mental component score; PCS, pain catastrophizing scale; SRS, Scoliosis Research Society.

Roussouly Grade 4 from BL to 1 year. At 225 days after study enrollment, the patient was deemed a failed nonoperative patient because of worsening pain and neuromotor function and required 10-level thoracolumbar fusion. At 2 years, the patient did not demonstrate evidence of PJK, PJF, or significant complications, although overall HRQLs decreased over time.

DISCUSSION

Key Findings

Our study demonstrated that nonoperative treatment had higher prevalence of success in patients who were younger, with less severe deformity, a lower BMI, and lower rates of depression and neurological dysfunction at BL. Furthermore, patients who presented with a BL ODI below 40 were significantly
 TABLE 4.
 Successful vs Failed Nonoperative Y2 Patient-Reported

 Outcomes Summary
 Patient Summary

	Nonoperative success vs failure			
Parameter	group	Mean	SD	Significance
Y2 ODI	Failure	46.667	19.341	P < .001
	Success	17.394	15.292	
Y2 PCS	Failure	33.705	9.088	P < .002
	Success	45.679	10.705	
Y2 MCS	Failure	42.533	12.865	<i>P</i> = .001
	Success	52.707	9.863	
Y2 SRS-Activity	Failure	3.217	0.863	P < .001
	Success	4.084	0.714	
Y2 SRS-Pain	Failure	2.225	0.594	P < .001
	Success	3.666	0.861	
Y2 SRS- Appearance	Failure	2.933	0.668	<i>P</i> = 49
	Success	3.423	0.828	
Y2 SRS-Mental	Failure	3.650	0.939	<i>P</i> = .184
	Success	3.954	0.738	
Y2 SRS- Satisfaction	Failure	2.792	0.865	P < .001
	Success	3.784	0.913	
Y2 SRS-Total	Failure	2.991	0.659	P < .001
	Success	3.782	0.622	
Y2 ODI MCID	Failure	-1.000	0.000	P < .001
	Success	0.070	0.252	
Y2 MCS MCID	Failure	-0.830	0.389	P < .001
	Success	0.020	0.606	
Y2 SRS-Activity MCID	Failure	-0.750	0.622	P < .001
	Success	0.050	0.666	
Y2 SRS-Pain MCID	Failure	-1.000	0.000	P < .001
	Success	0.130	0.514	
Y2 SRS- Appearance MCID	Failure	-0.250	0.622	<i>P</i> = .173
	Success	0.020	0.389	
Y2 SRS-Mental MCID	Failure	0.000	0.603	P = .823
	Success	0.040	0.558	

MCID, minimal clinically importance difference; MCS, mental component score; ODI, Oswestry Disability Index; PCS, pain catastrophizing scale; SRS, Scoliosis Research Society; Y2, 2-year.

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FIGURE 2. A 71-one-year-old man with no history of prior thoracolumbar fusion exemplifying successful nonoperative treatment. No major complications or deterioration from baseline to 2 years postoperatively noted.

more likely to experience success after nonoperative care. In our multivariable analysis, we determined that the most influential independent predictor of nonoperative success or failure appears to be frailty, with a cutoff threshold of 1.579 on the ASD-FI.

Limitations

There are some important limitations to this study. Many of these are inherent to retrospective work conducted using multicenter registries, including the potential for errors in data entry and misclassification. Furthermore, limited long-term follow-up, particularly 10 years or greater, precludes analysis of patients who demonstrate durable improvement without operative treatment, and future studies with longer follow-up are necessary. There is also the prospect of selection and indication bias and restricted clinical variation that cannot be fully addressed. Pursuant to this, although there are more than 200 patients in the cohort overall, smaller numbers are present in our subgroups and outcomes of interest, including treatment success and failure. This limits the capacity to effectively control for interactions and some of the prognostic factors identified here, such as age, severity of deformity and frailty, which may be colinear. Our statistical models should be viewed as hypothesis generating as opposed to prescriptive as a result. The factors identified here, as well as the frailty cutoffs generated, could be parochial to our cohort, and further testing in larger samples from other centers is likely necessary before these determinations can be considered definitively translatable. Furthermore, we recognize that the findings of this patient cohort may not be applicable to patients with complex deformity, as such individuals see greater risk by delaying operative treatment. Finally, we do recognize that our definitions of success and failure are study-specific to some degree, although we do believe that they have acceptable clinical and face validity. Surgeons or patients who would use different definitions of success from those applied here should adjust the application of our findings to those specific clinical contexts.

Interpretation and Generalizability

ASD has been shown to be increasingly prevalent within the aging populations of developed nations. Although advancements in surgical techniques and perioperative management have

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nonoperative failure.

resulted in dramatic improvements in outcomes and reduced complications for surgical interventions used to correct ASD over the past 20 years, the fact remains that these are still highly intense surgical procedures.²³ At the same time, given the nature of ASD, some patient complaints may be resistant to conventional non-operative measures. In previous work, *Passias et al*¹⁴ suggested that there may be threshold of disability and malalignment where patients are at increased risk of crossing over from nonoperative to operative care. Surgeons must account for the risks of surgical intervention and balance these against a patient's capacity to benefit from surgery as opposed to nonoperative treatment.^{24,25} However, this paradigm is impaired to some degree at present, as current literature does not provide adequate information

regarding the factors that may influence success after nonoperative treatment. $^{26}\,$

As far as we are aware, this work is the first to consider clinical and radiographic characteristics that may be predictive of the success of nonoperative treatment in patients with ASD. Our work is advantaged by a relatively large sample, collected at multiple institutions over a narrow time frame that represents the modern period of spinal instrumentation and techniques used to treat ASD. We believe that the results are important for patients, surgeons, and health care systems. Specifically, our findings indicate that young patients, with lower levels of frailty and less severe spinal deformity likely should be considered for less invasive and less expensive nonoperative interventions, as a first-line treatment. Those who do not possess these characteristics might better be considered for a surgical intervention, if indicated, as a means to minimize health care expenditures and procedural exposure that may not be likely to result in meaningful improvements regarding care.

CONCLUSION

Success of nonoperative treatment was more frequent among younger patients and those with less severe deformity and frailty at BL. When controlling for all other confounders, BL frailty was the most important determinant of successful nonoperative management. The prognostic factors identified here may be useful in informing preoperative discussions and clinical decision-making regarding treatment strategies in patients presenting with ASD. Specifically, relatively young patients, with lower levels of frailty and less severe spinal deformity could be considered for less invasive and less expensive nonoperative interventions, before exploring surgical solutions. At the same time, those who do not possess any of the favorable characteristics informing success of nonoperative treatment might benefit from more direct consideration for surgery at the time of initial presentation. Additional study is also needed to better assess the threshold at which surgical benefit outweighs complication risk, especially for frail patients who are both at higher inherent risk of complications and may not tolerate their deformity and their less frail counterparts.

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