

Decision analysis to identify the ideal treatment for adult spinal deformity: What is the impact of complications on treatment outcomes?



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ABSTRACT

Objective: The aim of this study was to analyze the impact of treatment complications on outcomes in adult spinal deformity (ASD) using a decision analysis (DA) model.

Methods: The study included 535 ASD patients (371 with non-surgical (NS) and 164 with surgical (S) treatment) from an international multicentre database of ASD patients. DA was structured in two main steps; 1) Baseline analysis (Assessing the probabilities of outcomes, Assessing the values of preference -utilities-, Combining information on probability and utility and assigning the quality adjusted life expectancy (QALE) for each treatment) and 2) Sensitivity analysis. Complications were analyzed as life threatening (LT) and nonlife threatening (NLT) and their probabilities were calculated from the database as well as a thorough literature review. Outcomes were analyzed as improvement, no change and deterioration. Death/complete paralysis was considered as a separate category.

Results: All 535 patients were analyzed in regard to complications. Overall, there were 78 NLT and 12 LT complications and 3 death/paralysis. Surgical treatment offered significantly higher chances of clinical improvement but also was significantly more prone to complications (31.7% vs. 11.1%, $p < 0.001$).

Conclusion: Surgical treatment of ASD is more likely to cause complications compared to NS treatment. On the other hand, surgery has been shown to provide a higher likelihood of improvement in HRQoL scores. So, the decision on the type of treatment in ASD needs to take both chances of improvement and burden associated with S or NS treatments and better be arrived by the active participation of patients and physicians equipped with the present information.

Level of evidence: Level II, Decision analysis.

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Introduction

Adult spinal deformity (ASD) is a very complex and diverse disorder. Surgical treatment may be associated with dire complications whereas conservative treatment may be ineffective in improving the patients' health related quality of life (HRQoL). Our

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previous work has demonstrated that the adult deformity population is very inhomogeneous in terms of perceived problems as well as expectations, based on patient age, gender, diagnosis and several radiological parameters.¹ Especially the sagittal balance as a single parameter may as well be responsible of the decreased HRQoL in this population.²

In this context, the decision between operative and nonoperative treatment for ASD may be difficult for surgeons and patients. It needs to be based on multiple factors including the severity of the patient's symptoms as well as the magnitude and risk of potential interventions. These are weighed against the potential risks and complications related to the proposed nonsurgical and/or surgical treatment.^{3,4}

A recent systematic review of clinical studies evaluating conservative treatment suggests that caregivers more frequently prescribe non-surgical treatment in adult scoliosis patients based on a perception of high complication rates with surgery.³ On the other hand, a) there is no consensus on the indications for conservative treatment for adult spinal deformity, and b) the current evidence is indeterminate with level 4 evidence on the role of physical therapy, chiropractic treatment, and bracing and level 3 evidence on the use of injections for treatment.^{3,5} We have recently investigated the effect of treatment decision (i.e., surgical vs. non-surgical) on clinical outcomes using the same decision analysis model as in the present study and concluded that surgery, as hypothesized, provided a higher likelihood of clinical improvement.⁶

Another problem in decision-making in ASD though, is the difficulties in estimating the effects of complications on the outcomes of treatment, especially for surgery. Surgery related factors like blood loss, surgical time, length of hospital stay, and length of overall recovery as well as complication rates may be fairly high in these patients. Analyzing the results of surgery even in the larger ASD population (from 18 years of age on) reveals that the complication rates are indeed higher compared to alternative treatment modalities.^{7,8} In addition, even these rate may be considered as underestimations, as younger patients should be expected have a significantly lower number of comorbidities or other associated health problems and therefore be less prone to complications, thereby diluting the overall rate and impact of complications.

Several recent papers have specifically reported on the effects of complications on treatment outcomes. Daubs and coworkers have investigated the complications and outcomes 46 patients over the age of 60 who underwent thoracic or lumbar arthrodesis of five or more levels with a mean follow-up of 4.2 years. They concluded that the overall complication rate in this patient population was 37% (with a major complication rate of 20%), and patients over the age of 69 years had yet higher complication rates. In spite of this, clinical outcomes at final follow-up were significantly improved in ODI scores.⁷ Likewise, a study by Ayhan and coworkers focusing on spinal osteotomies in ASD patients have demonstrated that complications do not necessarily affect the clinical outcomes in this sub-population of patients.⁹ On the other hand, Glassman and coworkers, reporting on the effect of treatment complication on 46 adult deformity patients undergoing surgery, demonstrated that major complications have adversely affected the outcome as evidenced by the SF-12 general health scores at 1 year follow-up.¹⁰ In another study, Scheer et al have investigated the effect of complication on the recovery of patients using an integrated health score (IHS) and concluded that there was a significantly protracted mental recovery phase associated with patients that had at least one complication, as well as either a minor and major complication. The addition of a reoperation also adversely affected the mental recovery as well as overall satisfaction.⁸ It needs to be noted that none of these studies have compared the treatment modalities for complications.

Furthermore, it is fairly common for the physicians involved in the care of patients with adult spinal deformity to assume that only surgical treatment is associated with dire complications and their non-surgical alternatives are immune to any adverse effects. It is correct that these complications have not been specifically investigated for this patient population but it also would be reasonable to assume that non-surgical treatments such as NSAID use or epidural and/or facet injections should be as prone to complications as when they are performed under other more common indications. Based on this defect in our general knowledge on ASD, the purpose of this study was to investigate the effect of complications on the overall outcome and quality adjusted life expectancy (QALE) using a decision analysis model.

Our hypotheses for this study were:

- Surgical treatment of ASD is associated with a higher rate of treatment complications compared to non-surgical treatment.
- Surgery may provide better outcomes even for patients with complications.

Material and methods

Patients

Patient material for the analysis was extracted from a multi-center international database on adult spinal deformity. This registry includes all patients over 18 years of age with spinal deformity defined as any one of:

- Coronal plane deformity >20°
- Spinal vertical axis >50 mm
- Pelvic tilt >25°
- Thoracic kyphosis >60°.

At the time of this analysis, database consisted of a total of 968 patients 338 of who had been treated surgically. Of this cohort, only patients with complete 1-year follow-up (535 patients, 371 treated conservatively and 164 treated surgically) were evaluated for complications and constituted the patient population of the present study. A more detailed description of this patient population may be found in a report by us focusing on the clinical outcomes.⁶ In this study, surgical treatment consisted of any combination of anterior and posterior surgery, fusion, instrumentation and decompression whereas non-surgical treatment refers to follow-up under observation and/or analgesic or NSAID prescriptions in the majority of patients, 12 out of 371 patients having been referred to a structured physical therapy program and only 6 to injections or other forms of invasive treatment. All these patients had complete radiological data in addition to records of all complications and unplanned hospitalizations as well as HRQoL measures (SRS22, ODI and SF-36) taken at baseline (entry to the registry) and at 6 and 12 months.

Extraction of data and quality checks

The data for baseline measurements and 1-year follow-up measurements were combined into a single data set using the subject IDs. Quality control checks were performed for checking any errors during data preparation.

Definition of outcomes

Outcomes (as favorable or unfavorable) were based on the HRQoL measures of the patients from ESSG registry, favorable outcome described as at least 8 points of improvement in ODI

(accepted as the Minimum Clinically Important Difference for ODI at the time of the start of the study) and unfavorable outcome as less than 8 points improvement or deterioration in ODI from enrollment or surgery.^{11,12}

Structuring the decision tree

Making a decision on which treatment is the best for adult spinal deformity is difficult as each treatment carries trade-offs between potential beneficial and harmful effects. Furthermore, the probability of these effects is uncertain (expressed as average and 95% CI or Range).

The first thing that was done is referred as structuring the decision tree. Different options for treatment and possible benefits and potential risks of each treatment were identified as in the balance sheet seen on Table 1.

Constructing the decision tree

A decision tree represents both the decision options (a square node between branches) and the uncertainty corresponding to each decision option (a circular node). During the construction of a decision tree, we need to consider that the model;

- Needs to be complex enough to cover all important events that might happen to a patient.
- Should be simple enough to be understandable.
- Should be simplified for actual decision making but incorporate all the risks and benefits associated with that decision.

In the decision model used, patients were assumed to undergo only one of the possible treatments (i.e., crossovers from conservative to surgery were analyzed as surgical cases whereas patients with previous back surgery who were decided to be candidates for non-operative treatment at this referral were analyzed as non-surgical patients). Adverse events (complications) were analyzed as life threatening and non-life threatening based on the real threat to the patients life due to the decision of treatment taken.

Table 1
Balance sheet for adult spinal deformity treatment decision.

Intervention	Benefit	Risk (major complications)
Non-surgical	Decrease in pain scores and HRQL measures in clinically relevant level	<ul style="list-style-type: none"> • Non-surgical (NSAIDs): <ul style="list-style-type: none"> ◦ Myocardial infarction ◦ Stroke ◦ UGIB ◦ Heart failure • Non-surgical (PT, chiropractor, manipulation etc.): <ul style="list-style-type: none"> ◦ Neurological loss • Non-surgical (invasive treatments such as injection): <ul style="list-style-type: none"> ◦ Infection ◦ Neurological loss
Surgical	Decrease in pain scores and HRQL measures in clinically relevant level	<ul style="list-style-type: none"> • General health: <ul style="list-style-type: none"> ◦ Death ◦ MI ◦ ARDS ◦ DVT/PT • Surgical: <ul style="list-style-type: none"> ◦ Infection ◦ CSF leak, fistula ◦ Pseudoarthrosis/implant failure • Neurology: <ul style="list-style-type: none"> ◦ Cord/caudaequina ◦ Nerve root

Classification of complications into these categories can be seen on Table 2. For the sake of simplicity in the decision tree, death and total paralysis was considered as life-threatening complications.

The last structural elements were the outcomes that are the endpoints to be considered in the analysis (i.e., favorable outcome and unfavorable outcome). Outcomes (as favorable or unfavorable) were based on the HRQoL measures of the patients from the registry, as described above.

Based on these the simplest initial decision tree was constructed as in Fig. 1. Therefore, all risks for either the conservative or the surgical branches were compiled into corresponding “Life-threatening complications present” or “Non-life-threatening complications present” branches using probabilities and utilities as described below.

Assessing the probabilities

After constructing the preliminary decision tree with identified potential benefits and risks corresponding to each option, the probabilities of each node were investigated in detail. The likelihood of the occurrences is gathered from literature as well as the data from the registry.

Using research evidence

For the systematic review the following steps as described in Khan et al 2003, “Five steps to conducting a systematic review” were followed.¹³

- Step 1: Framing questions for a review

The problems to be addressed by the review should be specified in the form of clear, unambiguous and structured questions before beginning the review work. Once the review questions have been set, modifications to the protocol should be allowed only if alternative ways of defining the populations, interventions, outcomes or study designs become apparent.

Table 2
Classification of probable complications associated with the treatment of ASD into life threatening (LT) and non-life threatening complications.

LT (life threatening) complications	NLT (non-life threatening) complications
Death	Epidural hematoma
Myocardial infarction	CSF leak, fistula/Dural tear
Heart failure	Cardiac (other)/Arrhythmias
Neurological loss (Permanent, Motor Deficit)	Pseudoarthrosis/Implant failure
Deep wound infection	Superficial wound infection, Wound drainage
ARDS (Acute respiratory distress syndrome)	Respiratory (Effusion/Pneumothorax/others)
Pulmonary thrombus, embolus	DVT (Deep vein thrombus)
Cord/CaudaEquina injury	Nerve root injury (sensory or reversible)
Systemic infection/Sepsis	CSF leak, fistula, dural tear
Stroke	Vascular injury
GI Bleeding	Urinary tract infection (UTI)
	Renal (other)/Urinary retention
	Gastrointestinal (Constipation/ileus/others)
	Altered mental status
	Intractable pain
	Pseudoarthrosis/Instrumentation related failure
	Junctional kyphosis/Vertebral body fracture
	Disc herniation
	Coronal or sagittal imbalance

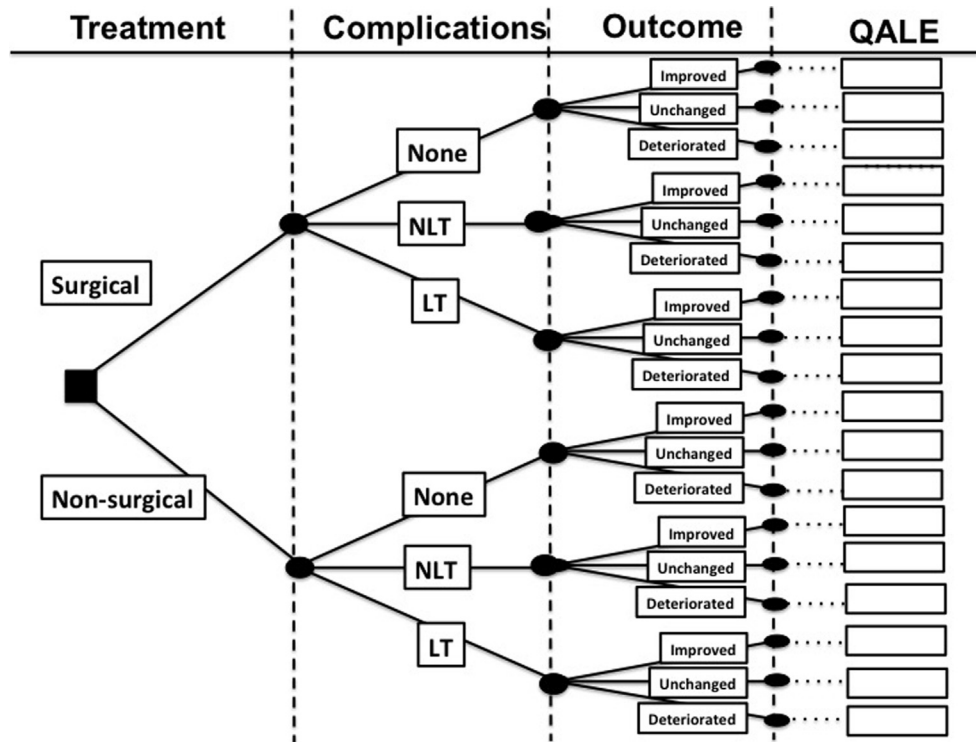


Fig. 1. Constructed decision tree incorporating all of the probable outcomes.

- Step 2: Identifying relevant work

The search for studies should be extensive. Multiple resources (both computerized and printed) should be searched without language restrictions. The study selection criteria should flow directly from the review questions and be specified *a priori*. Reasons for inclusion and exclusion should be recorded.

- Step 3: Assessing the quality of studies

Study quality assessment is relevant to every step of a review. Question formulation (Step 1) and study selection criteria (Step 2) should describe the minimum acceptable level of design. Selected studies should be subjected to a more refined quality assessment by use of general critical appraisal guides and design-based quality checklists (Step 3). These detailed quality assessments will be used for exploring heterogeneity and informing decisions regarding suitability of meta-analysis (Step 4). In addition they help in assessing the strength of inferences and making recommendations for future research (Step 5).

- Step 4: Summarizing the evidence

Data synthesis consists of tabulation of study characteristics, quality and effects as well as use of statistical methods for exploring differences between studies and combining their effects (structured literature review). Exploration of heterogeneity and its sources should be planned in advance (Step 3). If an overall meta-analysis cannot be done, subgroup meta-analysis may be feasible.

- Step 5: Interpreting the findings

The issues highlighted in each of the four steps above should be met. The risk of publication bias and related biases should be

explored. Exploration for heterogeneity should help determine whether the overall summary can be trusted, and, if not, the effects observed in high-quality studies should be used for generating inferences. Any recommendations should be graded by reference to the strengths and weaknesses of the evidence.

In accordance with these guidelines, a computerized query of the PubMed and Scopus databases was performed to identify any articles that were pertinent to the aforementioned clinical questions and published between 1950 and 2014. An initial search using the key words “adult spine deformity”, “adult spine deformity surgery”, “adult spine surgery complications”, “adult scoliosis”, “adult scoliosis surgery”, “adult scoliosis surgery complications” was performed. This query provided 8441 potentially applicable studies. We restricted our work by using only English language articles and clinical studies that offer. Based on this, after all abstracts were reviewed, 149 articles were selected for detailed review. In the full text assessment, we excluded the studies which include case reports, small series (<20 patients reported), single anatomical region deformity studies (only cervical or other), revision case series, series in which complication incidences and results were not clearly documented and studies which did not meet the inclusion criteria. Additionally, review articles were excluded if they did not add significantly over an “expert opinion” level of evidence. Using these criteria, 98 studies were excluded and 52 studies were identified so as to be evaluated for a detailed review of methodology and results.^{10,14–63} For each article, the study design (retrospective or prospective), year of publication, number of patients, mean patient age, mean follow-up, complication types (pre-operative, intra-operative and post-operative) and incidences were analyzed and noted. In addition, clinical outcome data, based on complications that can be classified as life threatening/non-life threatening or major/minor, were also recorded when available. Of the 52 studies that met inclusion criteria, none were randomized controlled trials, the majority

were retrospective database case series and only five included prospective databases. Further, as these studies represented results from a wide range of patients and pathologies, 4 studies in which the studied populations were considered to be similar to our population and reported results of 1 year follow-up was selected and analyzed separately (Table 3).

Our database was also analyzed to assess the probabilities that can be used for the baseline analysis. These probabilities were then combined with those from the literature using the same methodology described above for combining the individual probabilities obtained from the literature (Table 4).

Patient and physician values or preference: utilities

Incorporating patients' preferences for different decision options is a challenging task during evidence-based decision-making process.⁶⁴ Decision analysis explicitly incorporates patient perceptions or preferences as utilities. Utility is a quantitative measure that might be referred as “health state preference” and reflects the patients' (or health care providers') perceived values for a given health state. In the utility scale, perfect health (or complete satisfaction with the outcome corresponds to a scale of 1.0 whereas death or complete paralysis (for the purposes of the present study)

to 0.0. In this study Mapping SF-36 patients' perspective was performed for utility calculation.⁶

Combining information on probability and utility in the decision tree

In medical decision-making process it is of interest to calculate the quality adjusted life expectancy (QALE) of the patient population. For this reason, all the probabilities in Table 4 and utilities were incorporated into the decision tree. Once the decision model was populated with probabilities and utilities for all outcome states, the model calculated the values of each intervention by multiplying proportion of cohort by their perspective utilities and adding them within a particular branch. Then, the utility of health states and the life expectancy of population with adult spinal deformity was used to calculate the QALE.

Life expectancy values for this table had not been taken from the European Union Life Expectancy Tables⁶⁵ based on the average age of patients in the database as average ages in different branches of the decision tree could potentially be significantly different (thereby carrying the potential for a strong bias against the branches with relatively older population). Therefore, a fixed life expectancy of 100 years (arbitrarily) was used.

Table 3
Probabilities for complications in studies reporting on similar populations and follow-up.

Reference#	60	32	10	55
Paper ID	Charosky S, et al.	Pull ter Gunne AF, et al.	Glassman SD, et al.	Blamoutier A, et al.
Type	Multicentric retrospective	Retrospective cohort	Retrospective case control	Retrospective
N	306	830	434	180
Treatment	Lumbar adult & degenerative scoliosis	Deformity	Deformity	Deformity
Age group	>50 years	>30	>17	>50
Mean age	63 (50–83)	55.4 (±16.1)	50.2 (17–81)	63
Males (%)	17	26,50	17	12
Complication type	Post-op	Post-op	Peri-op	Post-op
Follow-up time	>1 year	>1 year	>1 year	>1 year
Overall complication rate	39%			44%
Overall major complication rate			13.80%	32%
Overall minor complication rate			22.10%	
Death	0%			0.00%
Myocardial infarction(MI)				0.55%
Deep Vein Thrombus (DVT)	2%		0.92%	
ARDS				
Superficial wound infection	3.70%	2.00%	1.38%	
Deep wound infection		3.50%	2.07%	5.50%
CSF leak, Fistula, Dural tear	0.98%		1.38%	3.30%
Nerve root injury (sensory)	2.28%		1.15%	3.30%
GI bleeding, Upper				
Neurological complications	4.57%		1.61%	1.66%
Vascular injury			0.92%	
Stroke				
Urinary tract infection (UTI)				6%
Pulmonary Thrombus(PT) Pulmonary Embolus(PE)	0.70%		0.69%	1.00%
Pneumonia				1.00%
Renal (other)/Failure/Urinary retention				
Cardiac(other)/arrhythmias	1%		0.69%	1.00%
Altered mental status	1.70%			4.50%
Respiratory(other)/pleural effusion/pneumothorax	2%			1.00%
Intractable pain				
Pseudoarthrosis/Instrumentation related failure	12.40%		2.99%	24.40%
Junctional kyphosis/vertebral body fracture	8.70%			
Sepsis				
Gastrointestinal (other)/Constipation/ileus				
Wound drainage			2.76%	
Disc herniation				
Epidural Hematoma				
Wound dehiscence			3.22%	
Coronal or sagittal imbalance	2%			

Table 4
The incidence table for major complications obtained via the systematic review of the literature for surgical intervention.

Complication	Type	All studies	Similar studies
		Median (Min–Max)	Median
Death	–	0.25% (0.0%–2.2%)	0
Myocardial infarction	LT	1.20% (0.0%–9.5%)	0.6%
Neurological loss	LT	1.78% (0.1%–12.5%)	1.7%
Deep infection	LT	4.19% (0.3%–19.0%)	3.5%
Upper GI bleeding	LT	3.44% (2.1%–4.8%)	Not reported
Stroke	LT	5.00% (0.0%–10.0%)	Not reported
ARDS	LT	4.24% (1.3%–7.8%)	Not reported
PE	LT	1.22% (0.1%–9.5%)	0.7%
Systemic infection/ Sepsis	LT	1.66% (0.0%–11.4%)	Not reported
Combined probability LT		2.61 (0.0%–19.0%)	1.64%
DVT	NLT	2.00% (0.0%–7.3%)	2%
Pseudoarthrosis/ Implant failure	NLT	3.15% (0.5%–54.0%)	12.40%
CSF leak, Fistula	NLT	4.67% (0.3%–15.0%)	1.38%
Nerve root	NLT	1.66% (0.1%–6.7%)	2.28%
Combined probability NLT		2.58 (0.3%–54.0%)	2.28% (0.9%–24.4%)

Sensitivity analysis

Sensitivity analysis is a way of assessing the robustness of the decision analysis to the utility and the probability values used. While performing the sensitivity analysis, probabilities and/or the utilities in the decision model were altered (in accordance with the ranges) in order to investigate the impact of these alterations on the expected value of the different branches and any change on the optimal decision as a result.

Results

Structuring the decision tree

A decision tree incorporating all of the probable outcomes was constructed as demonstrated in Fig. 1. As described above, each branch of the tree corresponds to one treatment option (i.e., conservative or surgical) and one of the probable outcomes for this treatment option (death or complete paralysis, favorable outcome and unfavorable outcome). Fig. 1 depicts the decision tree for the primary setting, i.e., complications stratified as none (patients with no complications), NLT (patients with non-life threatening complications) and LT (patients with at least one life threatening complication regardless of the presence of other associated LT and NLT complications).

Table 5
Overall treatment results of the entire study population grouped by complications but regardless of diagnosis, patient age and pre-treatment level of disability (for the definitions of improvement, no change and deterioration, please see text).

	Surgical				Non-surgical			
	N	Deteriorate	No change	Improve	N	Deteriorate	No change	Improve
None	112	8 (9.4%)	27 (31.8%)	50 (58.8%)	330	47 (17.5%)	184 (68.7%)	37 (13.8%)
NLT	39	2 (7.4%)	13 (48.1%)	12 (44.4%)	39	6 (15.4%)	26 (66.7%)	2 (17.9%)
LT	10	1 (12.5%)	4 (50%)	3 (37.5%)	2	1 (50%)	1 (50%)	0
Death								
Total	164				371			

Probabilities

As described above, probabilities pertaining to specific branches of the decision tree were obtained through a detailed literature review. The probabilities obtained via the systematic review were combined into probabilities of LT complication or NLT complication as in Table 4. In the third column (titled all studies) data from all studies regardless of the patient population characteristics were analyzed and compiled whereas in the fourth column, only probabilities from papers identified as reporting similar patient populations were analyzed and compiled in a similar manner. Median of the probability values from different studies for each complication has been presented together with the minimum and maximum probability values as the range. Median values of similar studies were used to populate the relevant branches of the decision tree for the primary setting, whereas both values were used for the sensitivity analyses.

Overall, patients treated non-surgically demonstrated a low likelihood of having a favorable outcome (6.7%) compared to those treated surgically (42%) (Table 5). There were 78 NLT and 12 LT complications and 3 death/paralysis. For the purposes of the present study, only 12-month data of patients having at least one year follow up was used so as to construct the decision analysis model. As hypothesized, surgical treatment was significantly more prone to complications (31.7% vs. 11.1%, $p < 0.001$; Table 5, Fisher's exact test). Presence of complications did affect the outcomes, thereby those patients treated surgically and did not encounter any complications had the highest probability of having a favorable outcome (Table 5).

Utilities

Table 6 summarizes the results of the primary sensitivity analysis based on the probability variation (i.e., what would be the probability if we had taken similar studies only and if we had included the probabilities from all studies). As can be seen, utility variations can be very high especially in patients with no complications. On the other hand, the averages of these variations are below the calculable significance thresholds in all categories and fairly close to the utility calculation of the baseline analysis.

QALE values

Results of QALE assessments are summarized in Table 7 as well as Fig. 2. As can be seen, in most of the settings, conservative treatment appears to yield better QALE values compared to surgery. However, overall, the calculated QALE values are compiled within a very narrow range (56–69) and the difference between the two treatment types do not exceed 5 years (%) in any setting.

Table 6

Sensitivity analysis for utilities with binary outcome presentation. a) Analysis based on the SF-36 mapping range, and b) Analysis based on the probability variation (similar studies vs. all available studies).

Outcomes	Surgical	Non-surgical	Threshold
Baseline analysis	0.61	0.65	–
Utility sensitivity analysis (a)			
Unfavorable outcomes			
Surgical/No complication	0.53–0.69	0.65	0.74
Surgical/NLT complication	0.58–0.65	0.65	0.87
Surgical/LT complication	0.60–0.61	0.65	–
Non-surgical/No complication	0.61	0.39–0.90	0.60
Non-surgical/NLT complication	0.61	0.62–0.67	–
Non-surgical/LT complication	0.61	0.65	–
Favorable outcomes			
Surgical/No complication	0.52–0.69	0.65	0.75
Surgical/NLT complication	0.59–0.63	0.65	–
Surgical/LT complication	0.61	0.65	–
Non-surgical/No complication	0.61	0.63–0.67	–
Non-surgical/NLT complication	0.61	0.64–0.65	–
Non-surgical/LT complication	0.61	0.65	–
Probability sensitivity analysis (b)			
Surgical/LT – similar	0.61	0.65	–
Surgical/NLT – similar	0.61	0.65	–
Surgical/LT – all studies	(0.59–0.61) ^a	0.65	–
Surgical/NLT – all studies	0.61	0.65	–

^a 0.59 is calculated assuming 19% LT complication rate, while 0.61 is calculated assuming no LT complication.

Table 7

Final table with clinical outcomes in 3 categories and probabilities and utilities associated with these outcomes.

Outcomes	N	Bayesian Parametric Utilities (range)
Unfavorable outcomes		
Surgical/No complication	8	0.57 (0.41–0.66)
Surgical/NLT complication	2	0.58 (0.56–0.59)
Surgical/LT complication	1	0.38 (–)
Non-surgical/No complication	47	0.54 (0.33–0.79)
Non-surgical/NLT complication	6	0.40 (0.30–0.54)
Non-surgical/LT complication	1	0.75 (–)
Intermediate outcomes		
Surgical/No complication	27	0.65 (0.41–0.85)
Surgical/NLT complication	13	0.62 (0.45–0.87)
Surgical/LT complication	4	0.49 (0.38–0.58)
Non-surgical/No complication	184	0.68 (0.36–0.97)
Non-surgical/NLT complication	26	0.70 (0.37–0.97)
Non-surgical/LT complication	1	0.69 (–)
Favorable outcomes		
Surgical/No complication	50	0.62 (0.36–0.88)
Surgical/NLT complication	12	0.63 (0.40–0.89)
Surgical/LT complication	3	0.61 (0.59–0.64)
Non-surgical/No complication	37	0.62 (0.40–0.89)
Non-surgical/NLT complication	7	0.61 (0.40–0.85)
Non-surgical/LT complication	–	–

Discussion

This study aimed to find the best treatment modality in Adult Spine Deformity using a decision analysis approach. From an existing international multicentre database of ASD patients, 535 who had completed 1-year follow-up (371 conservative, 164 surgical) and have complete complications data constituted the population of this study. Decision analysis was structured in two main steps of baseline analysis and sensitivity analysis. Overall, of 432 patients with complete ODI documentation, 73 (16.8%) were found to have favorable outcomes (defined as an improvement in ODI over 8 points) whereas 359 had unfavorable outcomes. Overall, patients treated non-surgically demonstrated a low likelihood of having a favorable outcome (6.7%) compared to those treated

surgically (42%). Presence of complications was found to affect the outcomes especially in the surgical treatment group, patients treated surgically with no complications having the highest likelihood of having a favorable result. Although non-surgical treatment was also demonstrated to be prone to complications, the same trend did not appear in this group, that is, QALE in the non-surgical group was not necessarily affected by complications. The overall QALE calculations ranged from 56 to 69 (out of 100 years) and demonstrated better outcomes in the conservative group.

Adult spinal deformity remains to be one of the most difficult fields in the subspecialty of spine. On the one hand there is the young patient with little or no disability seeking treatment (presumably because of problems with self image) whereas on the other, there is the elderly patient who is severely disabled because of the deformity or problems associated with the deformity. Given this diversity, the quest for an ideal treatment that would encompass both extremes of spectrum may seem to be futile. One can argue that the younger “adults” seeking treatment for reasons of cosmesis should not be considered as being candidates for surgery just for this, while on the other extreme, the argument may be that these elderly patients presenting with severe pain and disability (usually associated with problems with spinal balance and alignment) are usually to be considered for surgery. One solution to this problem may be to accept that this indeed is a situation of apples and oranges and to stratify the ASD population by age and/or diagnosis (the two most important diagnoses being idiopathic and degenerative) and perform prospective/retrospective studies comparing treatment modalities. We do agree that this approach is valid and probably much better than simple comparisons of treatment modalities. On the other hand, another possible solution for the problem of diversity may be the decision analysis approach as has been used in this study. Decision analysis, by virtue of the decision tree that is constructed enables comparisons between treatment modalities not only based on the end results but also on the burden of these modalities to the patients (and eventually to the society). This burden (envisioned in the concept of “utility”) is very difficult to quantify and incorporate into the decision processes with statistical methods for simple comparisons (and is usually overlooked because of this) but as has been demonstrated in this study, may actually be the decisive factor.

Overall, this decision analysis study has demonstrated that complications of treatment do affect the outcomes, although to a lesser extent than the treatment decision itself. The first part of this phrase, i.e., that complications affect the outcomes may seem to be overly obvious. But interestingly, as summarized above, several recent studies in literature suggest diverse opinions in this regard. One reason for this quasi-controversy may indeed be the type of HRQoL measurement instrument being used. Although there is no evidence in the literature on this so far, some tests may be more prone to be affected by complications. Or phrased in another way, some HRQoL measures may be more sensitive to the effects of complications. It may be necessary to underline that utilities in this studies were calculated from SF-36 (not necessarily from any specific domain or score, by mapping of the entire data set) while the outcomes are reported based on the ODI scores. Therefore, our findings probably not necessarily contradict any previous studies but just demonstrate the differences between different HRQoL measures. In fact, although demonstrating a visible deleterious effect of complications on outcomes, our results are more in line with the studies claiming negligible effects, as even with the adverse effect of complications, surgical patients still had a higher likelihood of improvement.

In respect to decision making in ASD, we have demonstrated that the two facets of treatment outcomes; improvement vs. no change/deterioration and the burden of the disease (utilities) may

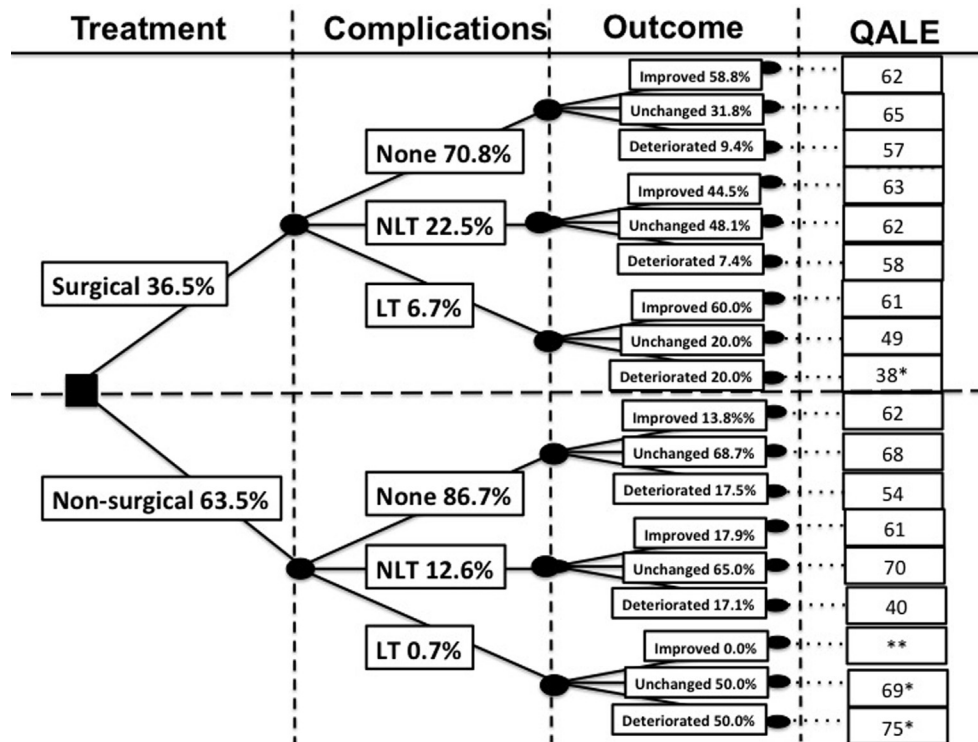


Fig. 2. Results of quality adjusted life expectancy assessments.

affect the eventual decision making in different directions. When we look at the probability of getting better by treatment, surgery appears to be obvious treatment of choice. On the other hand, surgery is more prone to complications (which affect the outcome to a minor extent) and associated with a heavier treatment burden as well. As stated in discussions above, this is the main advantage of performing decision analysis as this and only this type of analysis gives the health care professionals the ability to see all sides of the problem at the same time and base their treatment decisions on a wider range of factors. In summary, unless we can develop mechanisms that would identify patients who would have complications in their treatment accurately, the treatment decision should be arrived in with active and equal participation of the patients as well as the physicians, both sides equipped with the information provided by the present study.

Shortcomings of this study include these intrinsically associated with the decision analysis method used and may be listed as:

1. Underreporting of complications: This is a well-known problem associated with any patient series including large multi-center databases. It has to be noted that as the structure of larger databases eventually ensures the anonymity of the individual contributing centers/surgeons, this effect may be lower in these. It would be appropriate to emphasize that our complication rate is within the range of other similar series reported in the literature and therefore any underreporting should be minor if present at all.
2. Failure in identification of complications in patients treated non-surgically: This has not been reported before but we may suppose that some complications in the non-surgical treatment group may not have been identified as complications. An example may be a patient experiencing an acute myocardial infarction while being treated by NSAIDs for a long period of time. Although we have exercised utmost attention to identify these patients as well, some may still have gone undetected.

Conclusions

In conclusion, this study has demonstrated that surgical treatment of ASD is more likely to cause complications compared to non-surgical treatment. On the other hand, surgical treatment has been shown to provide a higher likelihood of improvement in HRQoL scores and this applies to patients with complications as well. These findings may be very important in clinical decision making as well as communicating with the patients. Although the heavier burden and complications of surgical treatment are readily acknowledged by all parties involved (caregivers and patients), the higher likelihood of having clinical improvement is not necessarily as readily recognized and may merit more profound emphasis.

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