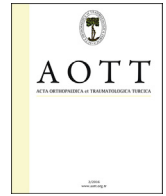


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## Decision analysis to identify the ideal treatment for adult spinal deformity: What is the impact of complications on treatment outcomes?

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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.<sup>1</sup> Especially the sagittal balance as a single parameter may as well be responsible of the decreased HRQoL in this population.<sup>2</sup>

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.<sup>3,4</sup>

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.<sup>3</sup> 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.<sup>3,5</sup> 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.<sup>6</sup>

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.<sup>7,8</sup> 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.<sup>7</sup> 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.<sup>9</sup> 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.<sup>10</sup> 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.<sup>8</sup> 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.<sup>6</sup> 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

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