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Impact of Complications on the Quality of Life of Patients Who Underwent Surgery for Adult Spinal Deformity

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ABSTRACT

Study Design: A multicenter, retrospective review of surgical patients with adult spine deformity.

Objective: Analyze the impact on the quality of life of patients who suffer complications in adult spine deformity surgery.

Summary of Background Data: Adult spine deformity surgery is classically associated with a high rate of complications, in particular it is estimated around 40%. The knowledge of the impact these complications could be a useful to improve the outcome in quality of life of patients.

Methods: Retrospective analysis of a prospective database of a cohort of patients who underwent spinal deformity surgery. Patients with 4 or more instrumented vertebrae and 2 years follow-up of were included. We created two groups based on the development or not of complications. VAS, ODI and SRS22, as a quality of life questionnaires, were used. Statistical analysis was performed using: T Student and U Mann-Whitney tests depending if variables were adjusted or not to normality; independent and related samples were analyzed with Wilcoxon test.

Results: 65 patients from primary surgery completed all the protocols (75.4% female), mean age of the cohort was 68 ± 6.21 years, the average number of levels fused was 7 ± 3.37 , with an operative time of 305.47 ± 116.90 minutes with 406.50 ± 92.7 mL of estimated blood loss. 24 patients suffered complications including PJK, instrumentation rupture, malposition material and infection. The results of the quality of life of patients with complications showing a significant statistical improvement in all parameters except the function subdomain (Pre-Complication: 2.55 ± 0.66 ; Post-Complication 2.93 ± 0.85 , $p = 0.082$) and satisfaction subdomain (Pre-Complication 3.25 ± 1.25 ; Post-Complication 3.84 ± 0.91 , $p = 0.095$) of the SRS-22 regarding the preoperative. The disability, that the ODI shows, is better and statistically significant than the preoperative one although it remains at high levels (Pre-Complication 57.58 ± 16.01 ; Post-Complication 43.47 ± 17.1 , $p < 0.05$). Considering the pain in the VAS back [(Pre-Complication 8 (5.50-9); Post-Complication 4 (1.50-7.50), $p < 0.05$] and VAS leg [(Pre-Complication: 8 (5-8); Post 2 (0.50-5), $p < 0.05$] this significant improvement after complication. Quality of life parameters in patients with complications were affected, although with no statistically significant differences in comparison to the group of patients without re-surgery for some complication.

Conclusions: The impact on quality of life of subjects who suffer complications in comparison to those that do not is reflected in greater functional limitations and worse results in subdomains of the SRS-22 questionnaire, despite improving after the surgery and without significant differences in comparison to the group of patients free from complications.

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Level of Evidence: 2

Key points

- We investigated adult spinal deformity surgeries that were performed in terms of complications and health related quality of life.
- Rate of complications occur is highly variable and have been evaluated thoroughly, but our results are according to the literature.
- Patients with complications, higher functional limitation and

worst improvement in quality of life.

Mini Abstract

Adult spinal deformity surgery is a complex procedure that imply different risks. The impact of complications in patients with this medical condition is reflected in a greater functional limitation that affects quality of life. Therefore, it is necessary a successful surgery approach to reduce possible future complications.

Introduction

Spinal deformity is defined as a curvature in the spine where the alignment is outside of defined normal limits and as a consequence with a significant and measurable impact on health-related quality of life (HRQoL). Considering that adult spinal deformity (ASD) surgery is a complex procedure that involve many risks, a benefit of the surgery must be achieved [1-3]. The prevalence of adult scoliosis in the general population has been reported to be up to 32% and as high as 68% in the older population [4-8].

The complications in deformity surgery are diverse, there are a variety of authors who talk about them and the rate at which they occur is highly variable [9, 10]. Glassman et al reported that 108 of 434 (24.9%) of ASD patients developed a complication, a combined medical and surgical complications [11]. Schwab et al found that 80 of 953 (8.4%) ASD patients had a major complication in their study the series was retrospective and also combined surgical and medical complications [12].

The evaluation of the impact that ASD has on health has been facilitated by the development of validated HRQoL questionnaires [13, 14]. General health questionnaires are designed to assess the overall physical and mental health status of the individual for example the Medical Outcomes Short Form 36 (SF-36) and EuroQol Five Dimension questionnaire (EQ5D). Disease-specific questionnaires are designed to assess the impact that a specific disease process has upon quality of life, two examples of this are the Oswestry Disability Index (ODI) which measure disability percent that people suffer in their daily life and the Scoliosis Research Society (SRS) questionnaire, which is designed to evaluate functional limitations secondary to spinal deformities and which provide 5 subdomains: function, pain, self-image, mental health and satisfaction[15,13 & 16-18]. According to HRQoL and complications found that the incidence of implant-related complications was 31.7% and 52.6% of these patients were re-operated, rod breakage accounted for 47% of implant-related complications, and proximal junction kyphosis (PJK) accounted for 54.5% of radiographic complications, all these complications negatively affected HRQoL measurement. Apart of this, early revision surgery for unforeseen complications has a negative impact on health, 41.3% of complications were implant related, 19.6% due to deep surgical site infections, 19.6% due to PJK [19-20].

The purpose of this study was to further examine the impact of postoperative complications on clinical outcome. In particular, we analyze the impact on the quality of life of patients suffering complications in ASD surgery.

Material and Methods

Database

This study is a retrospective analysis of a multicenter prospective database of consecutively enrolled patients with ASD.

Inclusion Criteria

Inclusion criteria for the whole database were age more than 18

years and presence of spinal deformity, as defined by at least 1 of the following: scoliosis Cobb angle of 20° or greater, sagittal vertical axis (SVA) of 5 cm or greater, pelvic tilt (PT) of 25° or greater, and/or thoracic kyphosis of 60° or more. The minimum of instrumented vertebra were 4. The present study included patients only with completed and 2 years follow-up. Exclusion criteria were spinal deformity of a neuromuscular etiology, presence of malignancy and patients who were not able to complete the questionnaires.

Data Collection

Demographic and Surgical Data

The demographic and clinical data were obtained for each patient: age, sex, body mass index (BMI), instrumented levels, time of surgery and bleeding.

Health-Related Quality of Life (HRQoL)

Standardized HRQoL measures included Visual Analogue Scale (VAS) spine and leg, Oswestry Disability Index (ODI), Refined Scoliosis Research Society-22 (SRS-22), and were collected at baseline and post-complication and at the end of follow-up.

Complications

Complications included were instrumentation rupture, material malposition and PJK (Fig 1). Medical complication registered was infection with revision surgery.

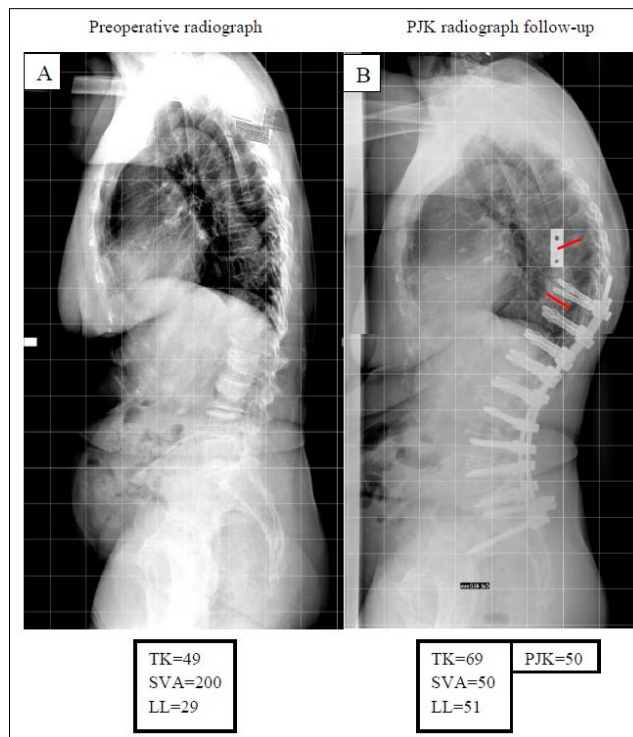


Figure 1: (A) Preoperative lateral radiograph showing global sagittal malalignment with 49° thoracic kyphosis (TK), 29° lumbar lordosis and 200 mm of sagittal vertical axis (SVA) in a patient with a history without previous instrumentation surgery. (B) A radiograph obtained 1 year postoperatively showing a 50 degrees of proximal junctional kyphosis (PJK).

Statistical Analysis

Statistical analysis was performed using SPSS v21 (IBM). Statistical analysis was performed using T Student test and U Mann-Whitney test depending on whether the variables adjusted to normality or not for independent samples and for related samples W-Wilcoxon test.

Results

Of 83 cases enrolled, 65 (79%) with 2 years follow-up were therefore included in the study. Within this population, 75.4% (n = 49) were female, mean age of the cohort was 68 ± 6.21 years, the average number of levels fused was 7 ± 3.37, with an operative time of 305.47 ± 116.90 minutes with 406.50 ± 92.7 mL of estimated blood loss. Implant-related complications were seen in 18 (27.69 %) and medical complications were observed in 6 patients (9.23%).

In patients who had complications, there were no significant statistical differences in SRS22 function subdomain pre-surgery before complication (2.55 ± 0.66) compared to one year postoperative (2.93 ± 0.85, p = 0.082) and neither between SRS22 satisfaction subdomain pre- surgery (3.25 ± 1.25) and one year postoperative (3.84 ± 0.91, p = 0.095). There were no significant differences in remain domains of SRS-22 scores, VAS back, VAS leg and ODI questionnaires among pre-surgery before complication and at one year postoperation (Table 1). Patients with HRQoL at 2 years follow-up were divided in two groups, with and without complications. 24 patients (36.95%) had some type of complication (Table 2).

Table 1: Health-Related Quality of Life Scores in patients pre-surgery before complication and at one year postoperation

	Pre	Post	p-value
VAS back*	8 (5.50-9)	4 (1.50-7.50)	<0.05
VAS leg*	8 (5-8)	2 (0.50-5)	<0.05
ODI	57.58 (16.01)	43.47 (17.1)	<0.05
SRS22 Function	2.55 (0.66)	2.93 (0.85)	0.082
SRS22 Pain *	1.80 (1.40-2.90)	3.00 (2.20-4.00)	<0.05
SRS22 Self-image	2.23 (0.86)	3.04(0.70)	<0.05
SRS22 Mental health	2.30 (0.81)	3.65 (0.77)	<0.05
SRS22 Satisfaction	3.25 (1.25)	3.84 (0.91)	0.095
SRS22 Total	2.33 (0.69)	3.19 (0.76)	<0.05

Values expressed in means and standard deviations. P-values calculated with the Student’s T test for related samples.

* No-normal values: data expressed in medians and interquartile ranges. P-value calculated with the Wilcoxon W test

Table 2: Complications in study population

Complication Type	Prevalence
Proximal Junctional Kyphosis (PJK)	16.92 %
Instrumentation rupture	6,15 %
Malposition material	34.62 %
Infection	9.23 %

There was no significant statistics differences in all questionnaires SRS-22, VAS back, VAS leg and ODI between groups, biggest limitation was observed in patients who suffered complications (46.00 ± 15.99) compared to no complications (39.22 ± 19.47, p = 0.175) (Table 3).

Table 3: Health-Related Quality of Life Scores in two groups (yes o no complication) 2 years follow-up

	No complication	Yes complication	P-value
VAS Back*	2.50 (0-6)	5 (2.50-8)	0.086
VAS Leg*	2 (0-5.25)	4 (1-7.75)	0.204
ODI	39.22 (19.47)	46 (15.99)	0.175
SRS22 Function	3.01 (0.81)	2.86 (0.79)	0.543
SRS22 Pain	2.96 (0.93)	2.88 (1.02)	0.781
SRS22 Self-image*	3 (2.45-3.80)	3 (2.20-3.40)	0.285
SRS22 Mental health	4 (2.65-4.509)	3.80 (3-4)	0.190
SRS22 Satisfaction*	4.25 (3.50-4.88)	4 (3-4.50)	0.389
SRS22 Total	3.25 (0.80)	3.11 (0.72)	0.520

Values expressed in means and standard deviations. P-values calculated with the Student’s T test for related samples.

* No-normal values: data expressed in medians and interquartile ranges. P-value calculated with test U de Mann-Whitney

Discussion

The diversity of complications are a reflect that the complexity of spinal surgery. These complications may occur months and years later because this procedures are a complex and high-risk. Surgical treatment for ASD is increasing due to high number of elderly patients in the general population. The initial decision from these patients would likely to be based avoiding unnecessary risk and adopt conservative measures, but when this decision failed the surgery could be the only option. Under this premise, every effort should be undertaken to avoid as much as possible to appear a lot of future complications in ASD surgery [10, 21, 22].

Complications associated with ASD surgery have been evaluated thoroughly. The complications in deformity surgery are diverse, there are a variety of authors who talk about them and the rate at which they occur is highly variable [9, 10]. The ISSG group conducted a systematic review that concluded the total number of complications was 3.615 in relation of 11.692 people population of study. The overall rate complication rate was 55%. And long-term complications occurred at an average rate of 20.5% [23]. In our study, we found that 18 of 65 (36.92%) of patients developed a complication, the complication rate in our series is according to the literature.

One of the most relevant complication in ASD is PJK but at the moment authors have no agreement on its definition, Bridwell and colleagues were first defined PJK in the literature as a “the caudal endplate of the UIV to the cephalad endplate two vertebrae proximal. Abnormal PJK was defined by 2 criteria: (1) proximal junction sagittal Cobb angle ≥ 10° and (2) proximal junction sagittal Cobb angle at least 10° greater than the preoperative measurement” [24]. Other researcher defined as Bridwell but the angle was 20 degrees [25]. Different studies reported that angulation varied from 5 to 20 degrees [24-28]. To date, more accepted angulation for PJK in the literature is 10 degrees greater than preoperative measurement [24, 29-31]. For that reason our PJK angle was defined as at least 10 degrees regarding preoperative. The prevalence of PJK is not defined completely

because depends on variety of factors [32-34]. Therefore, PJK prevalence rates fluctuate widely, it is possible to find that PJK occurs in 5% to 46% of patients who go through spinal deformity surgery [35]. Our PJK prevalence (16.92%) is not much elevated according to this information.

Infections from surgery can manifest months or years later even 8 years after surgery. 5-10% of patients developing deep infections its produced the next 11-45 months after surgery [36-38]. Infections reportedly are becoming more common, perhaps due to larger instrumentation used or maybe due to the increasing prevalence of multi-drug resistant bacteria in hospital settings [10, 39]. We analyzed a combined complications but we know our infection percentage was 9.23% its higher than studies reported about medical complications for example this author Charosky et al showed in a retrospective series that 3.7% ASD patients experienced a medical complication [40]. Additionally, Blamoutier et al in their retrospective review of ASD patients demonstrated that 5.5% had a medical complication. Plitter et al had a 11.8% infection rate that was higher than our outcome that involve infection incidence is highly variable [41-42].

The impact of complications on HRQoL after ASD surgery is controversial in the literature but is associated with a significant negative impact on HRQoL in affected individuals [4, 19]. Some studies suggest that complications significantly affect HRQoL scores, with patients who experience late complications having a lesser improvement in ODI this occur in our patients who suffer complications in comparison with 1 year and 2 years follow-up [11, 43, 44].

When the SRS questionnaire scores of ASD patients are compared to scores reported by age- matched individuals without spinal deformity, patients with ASD have greater pain like our patients in VAS outcomes greater limitations in function, as well as poorer selfimage and mental health however we don't found significant differences in both groups in this terms [4, 45]. Complications also demonstrated no significant effect on satisfaction agree on Hamilton et al [46]. Our patients obtain an improvement in HRQoL after surgery despite suffer complications.

One of the limitations of the study might be the inherent limitations to all multicentre studies and this study is a retrospective study. This introduces susceptibility to unidentified confounders and both selection and information bias. These prejudice were mitigated, however, by the fact that the data was collected in a prospective manner. Other limitation very important is the small sample size and the lack of statistical power to detect differences between groups. With a bigger sample, possible differences might be better delimited and/or patients could be stratified according to complication characteristics.

Conclusion

The impact on the quality of life of patients who have complications is reflected in a greater functional limitation and worse results in the SRS-22 subdomains, but despite these patients have an improvement in their HRQoL. Knowing the complication rate of ASD surgery can allow us to establish and to improve as much the surgery planing as the quality of life to potential patients.

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