Eur Spine J (2005) 14: 854–861
DOI 10.1007/s00586-004-0853-7

ORIGINAL ARTICLE

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Minimum 20-year follow-up results of Harrington rod fusion for idiopathic scoliosis

Received: 20 May 2004
Revised: 29 July 2004
Accepted: 20 November 2004
Published online: 29 April 2005

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Abstract We evaluated the outcome of spinal fusion with a single Harrington distraction rod in patients with idiopathic scoliosis. At follow-up visits a minimum of 20 years post-surgery, we studied 24 patients who had been operated on by the same surgeon. The Scoliosis Research Society (SRS) Instrument and an additional questionnaire of our own, along with an invitation for a follow-up visit, were originally mailed to 28 consecutive patients of the surgeon. The SRS Instrument has seven domains dealing with back pain, general self-image, self-image after surgery, general function, function in terms of level of activity, function after surgery, and degree of satisfaction with the surgery. The length of time between surgery and the follow-up visit averaged 22.9 years (20.2–27.3). The mean age at surgery and follow-up were 15.8 (13–22) and 38.8 (35–48) years, respectively. Twenty-four patients sent back the completed questionnaires and 16 of them participated in the clinic and radiographic follow-up. To assess the meaning of the questionnaires' results, a control group of the same sex, age and geographic provenance was selected from our outpatients without scoliosis. The average follow-up score on the SRS Instrument for the patients was 100.8 (78–110). When we compared the study and control groups, no significant differences in the single SRS domain scores were observed. The mean Cobb angle and rib cage deformity before surgery were 70.46° (40–120) and 36.4 mm (20–60 mm), respectively, whereas on follow-up they were 41.23° (16–75) and 22.3 mm (5–50 mm), respectively. These long-term results lead us to consider Harrington fusion a procedure that produces a long-lasting high degree of self-reported post-operative satisfaction.

Keywords Scoliosis · Quality of life · Spinal fusion · Treatment outcome

Introduction

Harrington rod fusion [13] is a technique for the surgical correction of scoliosis that was used worldwide during the 1970s and 1980s. To date, studies dealing with the long-term outcome of patients operated on with this technique have focused mainly on the clinical and radiographic results [5, 6, 10]. The importance of evaluating patient self-reported satisfaction after surgical treatment for idiopathic scoliosis has been noted [16] and the Scoliosis Research Society (SRS) Instrument was developed and validated for this purpose [12]. To our knowledge, only one study [14] has reported the long-term results of Harrington rod fusion, as assessed by this instrument. The present retrospective study evaluates the clinical, functional, and radiographic outcomes of

patients who underwent Harrington rod fusion for scoliosis at a follow-up visit that occurred 22.9 years post-surgery, on average. The controls were out-patients from the same clinic who did not present with scoliosis.

Materials and methods

This study was conducted between September 2002 and July 2003, to evaluate patients operated on with Harrington instrumentation at our institution from 1976 to 1981. Sixty-two patients with scoliosis were operated on at our Department in the index period. Out of them, 28 consecutive patients were identified and contacted by mail and/or telephone. They fulfilled the following inclusion criteria: idiopathic scoliosis, a minimum 40° Cobb angle [4], and ages equal to or less than 22 years at the time of surgery. All the operations were performed by the senior author (CM) using a single Harrington distraction rod. The patients were always placed in a prone position. The hooks were implanted according to Harrington's recommendations [13]. Autologous bone grafts from the iliac crest were always used. The post-distraction neurological status was evaluated with intra-operative awakening. After the procedure, all the patients were transfused with a minimum of three units of allogenic blood and all wore a post-operative plaster cast for a minimum period of six months. When the plaster cast was removed, a plastic brace was prescribed for an additional six months. Four patients could not be included in the follow-up: two died of causes unrelated to their scoliosis surgery (i.e. one from a road accident, one from lung cancer) and two could not be traced. The remaining 24 patients (19 females and 5 males) sent back completed questionnaires, and 16 volunteered to undergo clinic and radiographic follow-up examinations. The reasons for refusing to participate in the follow-up included business or familial commitments (four patients), excessively long travel distance (three patients), and lack of interest (one patient). The average follow-up date was 22.9 years post-surgery (range 20.2–27.3). The mean age at the time of surgery was 15.8 years (range 13–22), whereas on follow-up it was 38.8 years (range 35–48). Preoperative clinical and radiological data were retrospectively collected from a special form for spinal surgery that had been filled out at the time of the patient's first admission to the hospital. The SRS Instrument [12], along with a questionnaire constructed by the authors, were the instruments chosen to evaluate the patients' follow-up status. The SRS Instrument consists of 24 items designed to measure specific aspects of the patient's state or quality of life. The maximum global score is 120 points, indicating the best outcome. The single responses are aggregated to obtain seven separate scores dealing with the patient's experience of back pain (questions 1, 2, 3, 6, 8, 11 and 18), general self-image (questions 5, 14 and 15), self-image after surgery (questions 19, 20 and 21), general function (questions 7, 12, and 13), function in terms of level of activity (questions 4, 9 and 10), function after surgery (questions 16 and 17), and degree of satisfaction with the surgery (questions 22, 23 and 24). The authors' questionnaire was designed to collect more descriptive data and add explanatory variables to be correlated with the outcomes. It consists of three sections. The first section includes anthropometric, personal, and medical data, such as weight and height, marital status, number of children, and possible comorbidities at the time of the surgery or in the follow-up period. The second section evaluates social and daily living activities with questions regarding employment, practice of sport, distance walked every day, car and bike driving and smoking habits. Particular attention was paid to self-image, with questions regarding the respondent's appearance in clothes or in a bathing suit. In the third section, familial history of scoliosis was investigated: the patients were asked if any of their first or second degree relatives were also affected by the deformity. A control group of the same sex and age distribution was selected from our orthopaedic outpatients without scoliosis. The exclusion criteria for the control group were previous back surgery or any clinical evidence of scoliosis. The control group consisted of 20 females and 4 males, with a mean age of 39.1 years (32–50). The controls completed the same questionnaires as the patients in the study group, except for the last nine items of the SRS Instrument that deal with the results of surgery. All the domains but those assessing post-operative condition were used to compare the study group with the control group. For this purpose, the pain domain was collapsed to six items, since item 18, postoperative variation in the pain state, was dropped from the analysis. The follow-up visit included clinical and radiological examinations. The physical evaluation was carried out by a trained spine surgeon not involved in the primary care of the patients (PB), who was unaware of the results of the questionnaires. The rib hump was measured with a gibbometer and calculated in millimetres. Full-length standing postero-anterior and lateral radiographs of the spine were obtained and measured by an unbiased author (OG). Long-term postoperative Cobb angle of the primary curve and correction rate with respect to the pre-operative angle were calculated. Caudad level and extension of the fusion were recorded. Thoracic kyphosis and lumbar lordosis were measured by the Cobb method on lateral films, selecting segments T3–T12 and L1–L5 as limits, respectively [3]. The status of the instrumentation was evaluated as follows: in place and stable, loose, broken, or removed. Pseudoarthrosis was defined as a radiolucent line in the fusion mass on the radiograph, with or without broken Harrington rod [6]. Degenerative changes in the spine were considered to be present

when there was disc narrowing of more than 50% with respect to the adjacent normal disc space, sclerosis of facet joints, and/or vertebral subluxation in the sagittal or coronal plane [6, 23]. The spinal frontal balance was defined as the horizontal distance of the spinous process of C7 from the center of the sacral line. When this distance exceeded 20 mm, radiological spinal imbalance was judged to be present [14]. Pelvic tilt was calculated by measuring the distance between two horizontal lines passing the two iliac crests. A distance of 10 mm was regarded as acceptable.

Statistical analysis

Continuous variables were expressed as means, standard deviations (SD) and ranges. The SRS Instrument's single domains and global scores were treated as discrete and continuous variables, respectively. Comparisons between the study group and controls were checked with the Mann-Whitney *U* test. To compare proportions between the two groups, we used the Chi-square and Fisher's Exact tests. Spearman rank correlation coefficients were used in the correlation analysis. The explanatory variables included in the correlation analysis with the global SRS score and single domains were: age at operation (continuous), gender (categorical), body mass index (BMI)(continuous), distance walked per day (categorical: 0 = ≤ 1 km, 1 = 1 to 2 km., 2 = ≥2 km), car driving (continuous), aesthetic discomfort (categorical), actual cigarette smoking (categorical), marital status (categorical: 0 = never married, 1 = married/ divorced/ widowed), deliveries (categorical), number of children per woman (continuous), comorbidities involving all organ systems and having required previous hospitalization or any specific medications (categorical), preoperative gibbosity in millimetre (continuous), actual gibbosity in millimetre (continuous), preoperative angle of the primary curve (continuous), actual angle of the primary curve (continuous), correction rate of the primary curve (continuous), preoperative angle of thoracic kyphosis (continuous), actual angle of thoracic kyphosis (continuous), preoperative angle of lumbar lordosis (continuous), actual angle of lumbar lordosis (continuous), preoperative trunk shift imbalance >20 mm (categorical: 0 = none, 1 = yes), postoperative trunk shift imbalance >20 mm (categorical: 0 = none, 1 = yes), preoperative pelvic tilt >10 mm (categorical: 0 = none, 1 = yes), postoperative pelvic tilt >10 mm (categorical: 0 = none, 1 = yes), distal level of the fusion (discrete), length of the fusion area (continuous), and evidence of disc degeneration adjacent to the fused area (categorical: 0 = none, 1 = yes). We also looked for clinically relevant relationships among the domains of the SRS Instrument. SPSS Version 8 software for Windows (SPSS, Chicago, Illinois) was used for the statistical analysis, and *P* values of ≤ 0.05 were considered significant.

Results

Questionnaires

The patients' and controls' responses to the authors' questionnaire, along with their main characteristics, can be seen in Table 1. The only significant difference between the two groups was in aesthetic discomfort, particularly in a bathing suit, reported by ten patients (42%) and two controls (8%) ($P = 0.017$), and a higher rate of Hepatitis C Virus (HCV) infection in the study group. Global and single domain scores from the SRS Instrument in comparison with the control group are shown in Table 2. The average patient follow-up score on the SRS Instrument was 100.8 (78–110). As for the back pain domain, only one patient had never experienced back pain. Pain was reported to be mild and rare by 18 patients (75%), whereas five subjects (21%) in the study group complained of moderate and continuous pain. Sixteen patients (67%) reported no current use of drugs for the back pain. In contrast, five controls (21%) were totally painless and 21 (88%) of them did not reported current consumption of analgesics. In terms of general function and function-activity, although no significant difference between the groups was detected, better scores for the single items constituting these domains were recorded for the patients than the controls. Indeed, only three patients (12.5%) said they had taken sick days because of their backs. In the general self-image domain, the scores for the study group and controls were similar although, as stated above, the patients experienced more aesthetic discomfort. All the patients stated they did very well when asked about postoperative function, but less critical improvements were reported in the postoperative pain and self-image domains. Finally, 23 patients (96%) were extremely or somewhat satisfied with the treatment received and would have had the same treatment again. The only dissatisfied patient was a 35-year-old obese woman who underwent removal of the Harrington rod after early breakage.

Clinical and radiographic results

The clinical and radiographic results in one 35-year old woman are shown in Figs. 1, 2, and 3. The mean preoperative gibbosity of the study group was 36.4 ± 14.7 mm (20–60), whereas on follow-up it was 22.3 ± 17.3 mm (5–50), with a 39% correction rate. Table 3 shows the radiographic results. In the immediate postoperative period the primary scoliotic curve was reduced by 49% with respect to the preoperative angle, with an average

Table 1 Characteristics of the study and control groups

	Surgically treated patients (n = 24)	Controls (n = 24)	P value
Sex			
Female	19 (79%)	20 (83%)	0.712
Male	5 (21%)	4 (17%)	
Mean age ± SD (range)	38.80 ± 3.5 (35–48)	39.08 ± 5.3 (32–50)	0.723
Body mass index ± SD (range)	24.1 ± 3.9 (19.7–32.8)	24.1 ± 4.6 (17.6–33.8)	0.980
Married	14 (58%)	18 (75%)	0.221
Mean no. of children per female (19) ± SD (range)	1.7 ± 0.5	1.9 ± 0.5	0.401
Familial scoliosis	8 (33%)	5 (21%)	0.517
Employment			
Employed	18 (75%)	20 (83%)	0.544
Unemployed	1 (4%)	0 (0%)	
Housewife	5 (21%)	4 (17%)	
Sport practice	5 (21%)	7 (29%)	0.505
Walking distance/day			
< 1 km	7 (29%)	9 (37%)	0.812
1 km	4 (17%)	4 (17%)	
> 1 km	13 (54%)	11 (46%)	
Aesthetic discomfort	10 (42%)	2 (8%)	0.017
Car driving	16 (67%)	20 (83%)	0.182
Bike driving	10 (42%)	6 (25%)	0.221
Actual cigarette smoking	10 (42%)	9 (37%)	0.768
Number of cigarettes/day			
< 10	2 (20%)	4 (45%)	0.490
10–20	4 (40%)	3 (33%)	
> 20	4 (40%)	2 (22%)	
Comorbidities	8 (33%)	6 (25%)	0.525
Post-operation hepatitis C virus (HCV) infection	4 (17%)	0 (0%)	0.037

36° (12–60) Cobb angle. The average loss of correction over the period until follow-up was 5° (7%). No evidence of pseudoarthrosis was noted, even in patients with hardware failure or removal. The primary thoracic and double primary scoliotic curves have been classified according to King et al. [18] as follows: one curve = type 1, two curves = type two, seven curves = type 3, two curves = type 4, two curves = type 5. The remaining patients did not fit the aforementioned classification.

Correlations

There was a significant negative correlation between smoking habits and SRS total score (r = −0.607, P = 0.008), the pain domain score (r = −0.63; P = 0.002), and the satisfaction with surgery domain score (r = −0.58, P = 0.009). A trend toward an inverse correlation between postoperative gibbosity and SRS score was noted, whereas a bigger preoperative gibbosity predicted worse general function on follow-up (r = −0.89, P = 0.041). As expected, the use of analgesics was associated with more severe back pain (r = −0.66, P = 0.002), poorer general function (r = −0.761; P < 0.001), and worse function-activity (r = −0.73, P = 0.004). Surprisingly, more distal extension (r = −0.83; P = 0.002) and length (r = −0.52; P = 0.048) of the fused area negatively affected the general self-image, whereas they were not associated with more pain or degeneration in the adjacent intervertebral discs. Interestingly, a better general

Table 2 SRS questionnaire results

		Surgical group (n = 24)	Control group (n = 24)	P value
Global score		100.8 ± 7.9		
	Pain[a]	4.39 ± 0.57	4.34 ± 0.52	0.567
	General self-image	3.46 ± 0.59	3.53 ± 0.79	0.860
	Self-image after surgery	3.74 ± 0.48		
Domains	General function	4.19 ± 0.31	4.08 ± 0.62	0.585
	Function-activity	4.66 ± 0.61	4.47 ± 0.90	0.651
	Function after surgery	4.96 ± 0.20		
	Satisfaction with surgery	4.42 ± 0.45		

[a]Item 18 was excluded.

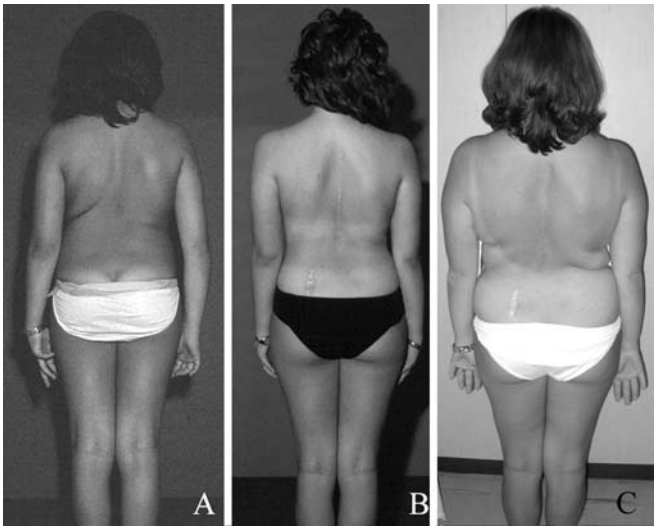

Fig. 1 35-Year-old woman. Clinical picture. **a** preoperative, **b** postoperative, **c** 21-year-follow-up

self-image predicted a higher degree of satisfaction with surgery ($r = 0.55$; $P = 0.015$). With the numbers available, no other significant correlations could be detected and we failed to find any association between pre and postoperative severity of the primary scoliotic curve or pre and postoperative degree of thoracic kyphosis and lumbar lordosis, and both SRS and single domain scores. No correlation analysis of trunk shift and pelvic tilt with outcomes could be performed due to data distribution.

Discussion

This study was carried out to evaluate the long-term results of Harrington rod fusion for scoliosis using the SRS Instrument [12]. Since its first description, several modifications of this questionnaire have been introduced [2] and the most recent 22-item version [1] has overcome previous limitations [17]. The data collection of the present study began when this last version of the Questionnaire was not yet available and therefore our patients completed the first version in order to maintain consistency with the earlier questionnaire data. In spite of the aforementioned limitations, the validity of the original SRS Instrument was recently confirmed [21]. Furthermore, we obtained additional data on the study group using our own questionnaire. To evaluate the meaning of the scores obtained on the SRS Instrument by our study group, we compared the results for the study group with those of a control group that included subjects with characteristics similar to our patients but without scoliosis. At the minimum 20-year follow-up, we found an average self-reported SRS score of 100.8 points, similar to the results obtained by others with the same instrument [14]. The answers of the study group resulted in the same score on the pain domain as the controls' score, and in most patients the pain was mild and not bothersome. However, a smaller proportion of scoliosis patients reported they were pain free and they more frequently reported the use of analgesics. Indeed, an increase in back pain severity and frequency in subjects treated surgically for scoliosis compared to control groups has been reported in several long-term follow-up studies [6, 9, 10]. Most of our patients did very well with regard to function and activity levels. Conversely, although their scores in the general self-image domain were similar to the controls, there was a higher rate of reported aesthetic discomfort, particularly in a bathing suit, in our patients. Other studies have reported similar results [8, 9]. The self-perception of a poor cosmetic appearance could have been one of the reasons for the high rate of subjects who never married in our study group, greater than the rate for the control group and greater than other studies have

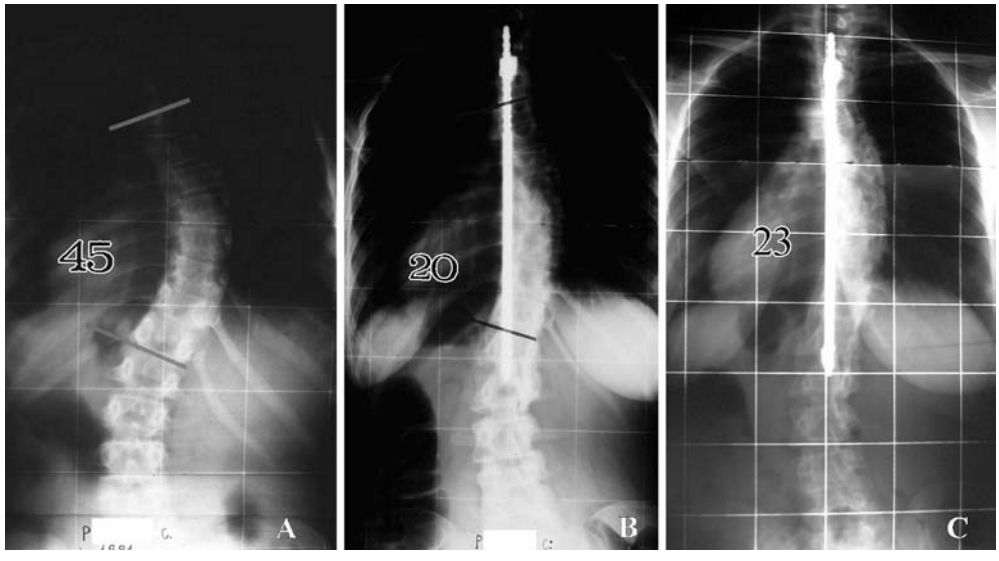

Fig. 2 Standing coronal view radiographs. **a** preoperative, **b** postoperative, **c** 21-year-follow-up. No loss of correction occurred

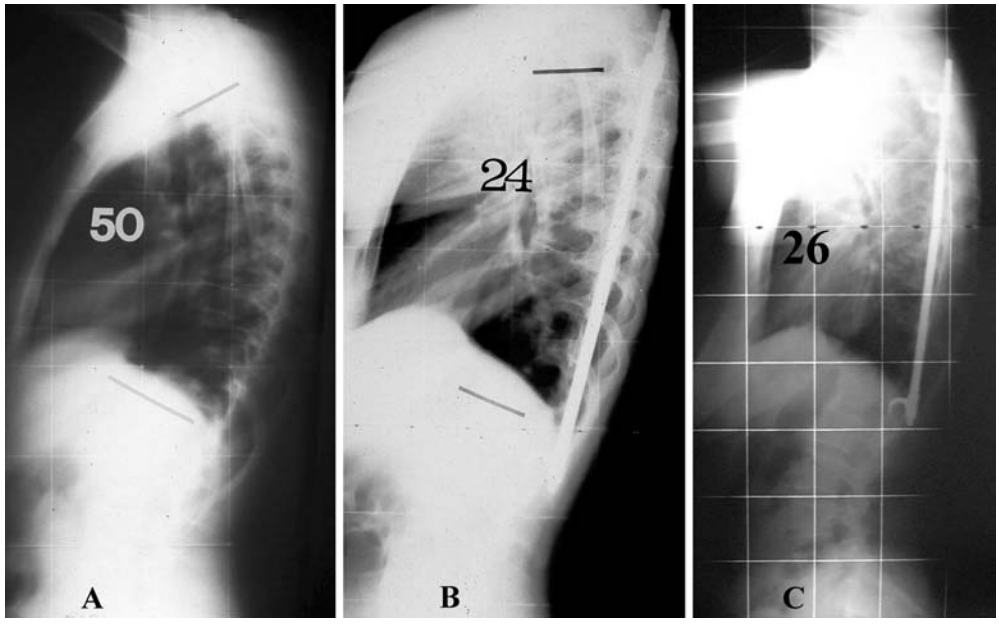

Fig. 3 Standing sagittal view radiographs. **a** preoperative, **b** postoperative and **c** 21-year-follow-up

Table 3 Radiographic results

Curve type, *n* (%)	Double primary	3/16 (19%)
	Thoracic	11/16 (69%)
	Thoracolumbar	2/16 (12%)
	Lumbar	0/16 (0%)
Pre-operative Cobb angle ± SD (range)	70.46 ± 26.4 (40–120)	
Post-operative Cobb angle ± SD (range)	41.23 ± 18.2 (16–75)	
Post-operative correction rate (%)	41	
Pre-operative kyphosis ± SD (range)	35.3 ± 15.9 (9–55)	
Post-operative kyphosis ± SD (range)	31.6 ± 15.3 (9–53)	
Pre-operative lordosis ± SD (range)	48.4 ± 18.1 (25–70)	
Post-operative lordosis ± SD (range)	45.5 ± 16.4 (21–65)	
Distal level of fusion	T12	3/16 (19%)
	L1	6/16 (38%)
	L2	3/16 (19%)
	L3	2/16 (12%)
	L4	2/16 (12%)
Mean number of fused vertebrae ± SD (range)	10 ± 1.6 (6–12)	
Pre-operative spinal imbalance (> 20 mm)	2/16	
Post-operative spinal imbalance (> 20 mm)	0/16	
Pre-operative pelvic tilt > 10 mm	2/16	
Post-operative pelvic tilt > 10 mm	1/16	
Degenerative lumbar changes	7/16 (44%)	
Status of the instrumentation	In place and stable	12/16 (75%)
	Loose	1/16 (6%)
	Broken	1/16 (6%)
	Removed	2/16 (13%)

found [8] or that demographic surveys from Southern Italy report [15]. Moreover, in some subjects the feeling of aesthetic discomfort could have been theoretically responsible for compulsory habits, such as cigarette smoking, that in our study were found to be associated with worst outcomes on the SRS Instrument and a low level of satisfaction with the surgery. We obtained good radiographic results, with a 41% correction rate of the primary scoliotic curve at follow-up, similar to the results of some studies [6, 9] and superior to others [14, 20]. Although the latter studies also noted Cobb angle deterioration over time, the patients' self-reported outcomes were good, i.e., there was a lack of correlation between radiographic and functional results [14, 20]. Like other authors [7, 10], we failed to find any significant correlation between patients' self-reported outcome and curve magnitude or postoperative rate of correction. We detected a 44% rate of lumbar disc degeneration below the fusion mass but no relationship could be detected between this finding and frequency of back pain or SRS score. Conversely, Connolly et al. (1995) [6] using their own questionnaire, reported finding a significant correlation between low spine score and facet joint sclerosis. In our patients, longer and more distally extended fusions negatively affected the general self-image, but were not associated with more pain or greater degeneration in the lumbar spine. While this lack of an association has previously been reported by others [20], the detrimental effect on self-image of a lumbar extended instrumentation could have been secondary to the marked flattening of the lumbar lordosis in these subjects.

A striking finding of our study was the higher percentage of patients with HCV antibodies on follow-up compared to controls. Another recent study from Southern Italy [19] has reported a lower prevalence of HCV antibodies in healthy blood donors and a decrease over time in this infection rate, from 8.5% in 1995 to 5.45% in the 1996–2000 period. The authors noted there are now better blood donation diagnostic/screening procedures than in the earlier period. In the late 1970s and early 1980s, the period in which our patients' surgeries were performed, no pre-donation screening tests for HCV were available and wide diffusion of this infection was observed due to post-operative allogenic transfusions in our geographic area. Moreover, surgery has been proven to be an independent predictor of the likelihood of HCV infection [11, 19].

Several weaknesses intrinsic in the present study design might limit the conclusions that can be drawn from this data. First, our small sample size decreased the power of statistical tests, obscuring possible weaker correlations. Larger long-term follow-up studies using validated questionnaires have been previously published, but with a high percentage of patients lost at follow-up [14, 20]. Moreover, while we collected the baseline physical and radiographic data retrospectively using hospital records, we could not obtain self-reported preoperative data to compare with the follow-up SRS results, since valid patient-oriented instruments were not available 25 years ago. The major strengths of our study are the homogeneous characteristics of the sample, with one surgeon performing all the operations according to the same operative and postoperative protocol, use of a validated self-administered questionnaire, length of the period before follow-up, and the low rate of patients lost to follow-up. Indeed, in our study the response rate was much higher than usually occurs after such a long postoperative period [22].

Conclusion

Despite the unexpected finding of a high rate of postoperative HCV infection, we confirmed a favourable long-term outcome after Harrington fusion, with a high degree of long term postoperative satisfaction in our series of adolescent scoliotic patients. This result is strengthened by the comparison of the patients with a control group with similar characteristics.

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