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Retrospective Clinical Studies: Surgical Treatment and Quality of Life in Patients Undergoing in Lumbar Arthrodesis Surgery

Antonio Molina Ros^{1*}, Alejandro del Arco Churruca¹, G Saló BruFull Name¹, Gema Vila¹ and G Musumeci²

¹Mar Health Park Pompeu Fabra University (Barcelona) ²Pompeu Fabra University

* Corresponding Author

Antonio Molina Ros, Department of Orthopedic Surgery and Traumatology Hospital del Mar, Parc de Salud MAR, Passeig Maritim 25-27.08003, Barcelona, Spain, Tel: +34617703881, E-mail: molinarosantonio@gmail.com

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Abstract

Objective

Measure, compare and psychometrically analyse the evolutionary results of instrumented arthrodesis surgical technique, performed in patients with low back pain from degenerative disease by quality of life questionnaire.

Material and Methods

Retrospective study of ninety-eight patients undergoing lumbar fusion technique surgery for degenerative lumbar pathology. 30-77 age years (39 men and 57 women). The study period pre-surgery, post-surgery: two to eight years, used SF36, DEYO and ODI questionnaires.

Results

Increased quality of life of patients being two to eight years, presenting a general improvement, pain and disability reduction. SF36 increases the dimensional score up to seven at two years (p <0.05). Oswestry Disability Index from 44.6 \pm 16.8 disabilities passes 35.7 \pm 23.1 (two years -9.2% disability) and 38.3 \pm 21.5 (eight years -5.8% disability). Outcomes Core Measures Index improvement is obtained in all items 76.29 \pm 1.11 to 57.4 \pm 1.41 (2 years; -22.6% disability) and 57.4 \pm 1.29 (eight years; -18.9% disability).

Keywords: Low back pain; Quality of Life; Functional Capacity; Lumbar Arthrodesis; SF36; DEYO; ODI

Chronic low back pain is the leading cause of activity limitation and is the most prevalent in over 65 musculoskeletal pathology [4-13].

The classic surgical treatment of chronic low back pain by disc degeneration has been arthrodesis. The benefit is based on the lumbar pathology originates abnormal mobility between vertebral segments and adjacent segments suffer greater mobility fixing [10].

The clinical measurement of muscle strength and range of motion not many correlated with actual patient's symptoms. Commonly used medical assessments are highly subjective and do not distinguish capabilities that can improve.

A direct measure of patient status is needed then. In this paper the improvement of health and functional capacity (CF) using instruments that provide a standardized measure, the completeness, reproducibility and validity are discussed [18, 14].

The quality of life (QOL) is related to health and health conditions of persons referred from the subjective experiences of them on their overall health [11, 14].

Theaim of this study is to measure, compare and psychometrically analyze the evolutionary results of instrumented arthrodesis technique, performed in patients with low back pain from degenerative disease through questionnaires quality of life and functional capacity; measurements on different aspects of health: physical, psychological and social.

Hypothesis

Null hypothesis

Changing postoperative results (two to eight years) after surgery for degenerative lumbar pathology, in terms of CV and disability, do not change over time.

Primary Hypothesis

The change of postoperative result (two to eight years) following surgery for degenerative lumbar pathology, in terms of CV and disability are influenced by the course of time.

Material and Method

Of deciento sixty-three patients undergoing surgery for degenerative lumbar pathology at Hospital del Mar (Department of Orthopedic Surgery and Traumatology) between 2005 and 2013, a retrospective study of ninety-eight patients undergoing surgery is performed using technique of lumbar arthrodesis using data available in the database of data.

The aged 30-77 years (39 men and 57 women) with a mean age of 56.6 years and a variable number of segments (Table 1).

	Mean	Total mean	Patient total						
Age-Yr	<65* 49,73±9,68	56,60±12,68	66(67%)						
	>65 69,73±5,12		32(33%)						
Sex	Male	Female							
	39(40%)	57(60%)							
	I 63 (64%) Patient								
Vertebral fixation **	II 22 (23%)								
	III 11(12%)								

Table 1: Demographic Characteristics

*Only seventeen patients in total have lower age is forty-five years.

** Lumbar vertebral fixation between 1and 3.

The study period was: pre surgery, post-surgery at two and eight. Questionnaires CV and functional capacity (FC) were used.

The inclusion criteria used: adult, lumbar arthrodesis intervention at any level, not having similar intervention previous and had not improved with conservative treatment.

Excluded: patients with barrier, osteoporosis, metabolic bone disease, active infection, rheumatic diseases, primary tumor or metastasis and contraindication for anesthesiological criteria.

The pathology diagnosis was carried out by clinical examination and MRI.

The study was approved by the research committee of the center. All were adequately informed of the benefits and risks of intervention and signed the corresponding informed consent specific.

The operations were performed under general anesthesia and prone.

Questionnaire used in the study

Patients were assessed by self-questionnaires administered versions validated in Spain, with Medical Outcomes Study Short Form 36 versione 2 (SF36 v2), Oswestry Disability Index (ODI) and Core Outcomes Measures Index DEYO (COMI), preoperatively, two and eight years after surgery.

The SF36 evaluates different aspects of health [9]; adapted in Spain by J. Alonso et al. The score can range from a minimum of 0 to a maximum of 100. The normal values would be within a range between 50-100% related to each dimension, age and sex [14]. less than fifty scores indicate poorer level of health.

The ODI, equivalent to Roland-Morris. The total score, expressed as a percentage (0 to 100) [6]. (Total Points/50-(unanswered questions)) X100 =% disability [5]

COMI is characterized by seven questions to assess the fiveitem disorder of the lumbar spine. The seven survey questions provide results from 1 to 5; 1 is the best possible outcome.

This set of questionnaires related to some excellent psychometric characteristics in patients with low back pain that surgical treatment [8] was performed.

Statistical analysis

The statistical methods used for assessing the scale were the mean, standard deviation.

Statistical analysis was performed using SPSS 18.0 (SPSS Inc., Chicago, IL) and Microsoft EXEL 2013. The results of quantitative variables were compared using the Student t test double tail. All 98 patients enrolled in the study completed the three questionnaires.

Results with a value of p <0.05 was considered statistically significant. differences between the curves of major and minor subset of patients sixty-five years applying the T Student (table 2) was found. The difference between the means was not significant [1]. By this age as a variable that could introduce bias was discarded.

Results

The average age of the operated patients was 56.6 years (between 30 and 77 years). The ninety-eight patients selected, 66% are under sixty-five and 66% of the total are women. Seventeen patients have less than forty-five years (Table 2) age.

The three questionnaires give us consistent results related to the quality of life of patients over two to eight years, presenting a general improvement, pain and autonomy (greater sensitivity the COMI). It calculates the difference between the result of the items and dimensions of the third phase of the questionnaires (difference in percentage) No significant difference was seen between surgery two and eight years (p> 0.05).

In the middle of the body curves patients with lower and higher age sixty-five years applying Student T with 95% not significant (Table 2). It then checks that there is no difference by age.

Comparing SF36 have an overall improvement between one and seven points at two years (Table 3). The "physical function" improvement of 7 points: from 28.8 to 35.1; physical pain from 30.1 to 37.7 (p < 0.05); "vitality" and "social function" increases almost five points (p < 0.05). It remains stable "mental health" (results are significant) and the "general health", remaining to the pre-surgery values. Eight years did not observe an improvement over the two years; It highlights a worse score of "physical function" (31.8) and a slight improvement of the "mental health" (40.2) for two years. The "physical performance" improvement 5,13 points (two years) and 3.7

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(eight years), p <0.05. The "pain" improved 7.09 points to two years and down 3 points to eight years, p <0.05. The "general health" is worse after surgery for eight years with p> 0.05.

The ODI (Table 4) from an initial 44.6 \pm 16.8 disability is reduced to 35.7 \pm 23.1 at two years (9.2 points) and 38.3 \pm 21.5 to eight years (5.8 points).

Table 2. IC 95% estimate between lower and higher than sixty-five yea	rs
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	Pre-surgery	2 Age	8 Age
SF-36	0,46	0,25	0,07
ODI	0,86	0,43	0,50
COMI	0,40	0,90	0,33

T student in patients with age younger and older than sixty-five years shows no significance at P <0.05

	Pre-surgery		2 Age				2-8 Δσe*		
	Mean		1ean Mean Difference**		P value	Mean	Difference**	P value	P
Physical functioning	28,88±9,25		35,14±12,23	6,26	,00,	31,87±11,72	2,99	,04	,00,
Physical role	30,59±8,09		35,72±12,23	5,13	,00,	34,33±11,31	3,74	,01	,16
Bodily pain	30,12±7,21		37,21±10,31	7,09	,00,	33,12±9,27	3	,00,	,00,
General health	41,48±9,12		40,82±10,36	-0,66	,70	37,45±10,28	-4,03	,64	,00,
Vitality	34,68±9,83		39,68±9,40	5	,00,	35,60±10,23	0,92	,63	,00,
Social role	31,84±13,6		35,36±15,69	3,52	,37	32,58±16,30	0,74	,00,	,05
Emotional role	37,12±15,1		39,98±15,42	2,86	,16	41,11±15,36	3,99	,78	,65
Mental health	39,70±11,1		39,34±7,48	-0,36	,81	40,25±12,49	0,55	,17	,89

 Table 3: SF-36. Results of pre-surgery questionnaire 2 and 8 years

 \ast 2-8 years t test column represents the average between two to eight years.

** Difference between Pre- surgery and two to eight years.

Student t test for comparison of means between groups (IC 95%). It has been found that in some dimensions there are recommendations for small changes or differences are clinically relevant; according to some studies a difference of seven points is quite clinical relevance. (17)

	Pre-si	urgerv	2 Age					8 Age						
ITEM										Age*				
	M	an	Mean		Difference		Mean		Difference		Р	P value		
	2.07		2.45		% **	value	value		% **		value			
Pain intensity	2,97:	±1,16	2,45	±1,45	10,40	,00	2,45	5±1,39	10,40		,00	1,00		
Standing	3,02:	±1,23	2,44	±1,39	11,60	,00,	2,59	9±1,50	8,6	8,60		,30		
Personal care	1,79	±1,25	1,53	8±1,32	5,20	,06	1,47	47±1,38 6,40 ,0		,04	,67			
Sleeping	1,46	±1,43	1,05	±1,15	6,20	,01	1,14	4±1,19	6,4	6,40		6,40 ,07		,24
Lifting	2,95:	±1,17	3,29)±1,22	-6,80	,01	3,15	5±1,22	-4,00		,14	,44		
Sex life	2,44	±1,58	2,05	5±1,84	7,80	,04	2,15	2,15±1,88		5,80		,54		
Walking	1,86	±1,35	1,51±1,44		7,00	,12	1,53	1,53±1,64 6,		6,60		,53		
Social life	2,88	±1,34	2,04	±1,61	16,80	,00,	2,43	3±1,60	9,0	9,00 ,0		,00		
Sitting	1,96	±1,47	1,65	5±1,27	6,20	,02	1,60)±1,04	7,2	7,20 ,00		,54		
Travelling	1,15:	±1,05	1,84	1,84±1,57 -13,80 ,05 2,00±1,60 -17,00		,00	,53							
Total mean item ***	2,24:	±1,30	1,98±1,43				2,05	5±1,44						
total disability %	44,9	±16,8	35,9)±23,1			39,1	1±21,5						
			2 Age	9			8 Age	е				2-8 Age		
reduced total disability %			9,2				5,8					-2,6		

Table 4: Oswestry D	Disability Index (ODI).	Results of pre-surgery	y questionnaire 2 and 8	year
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* 2-8 years t test column represents the average between two to eight years. ** Difference between Pre- surgery and two to eight years.

*** valores de cada ítem: entre 0-5 (0 ningún problema, 5 máximo);

Disability is estimated between 0-20%: minimum functional limitation; 20% -40%: moderate; 40% -60%: intense; 60% -80%, and above 80%: maximum functional limitation. The authors estimated the minimum detectable change (with a reliability of 90%) for a clinically significant improvement is serious about 4 and 16 points according to some and 10 according to other authors (7) (17). The recovery of disability throughout the year was 2.6% of the lost.

All items are significant except for the "walk" personal care two years, and neither are "sexual activity" and "sleep", "lift weights" at eight years (p <0.05). Yet the "sleep" and walk have good differential score is to eight years two 6.2 and 6.4; and 7 and 7.6). "Social Life", "stand" and "pain intensity" have the best score of all items 16.8 and 9; 11.6 and 8.6; 10.4 and 10.4 (two to eight years with p <0.05). The "pain" improved 10.4 points to two to eight years (p <0.05). The "travel" and "lifting" have a negative difference, you do not experience an improvement after treatment (-13.8 and -17, -6.8 and -4). Although the "heavy lifting" is not significant at eight years (p> 0.05).

No item is significant between two and eight years. At eight years of disability obtained difference, it is reduced to 2.6%.

The COMI an improvement is obtained in all seven item in two to eight years with p <0.05. Total disability passes from 76.29 \pm 1.11 to 57.4 \pm 1.41 to two years (22.6% less disability) and 57.4 \pm 1.29 to eight years (18.9% less disability). It has exception seventh item where disability increased 1.4 but with p> 0.05 appears only eight years. The results have been particularly demonstrative fourth item with a value of 55.8 and 28.2 sex with eight years. The lowest was the seventh item related to treatment satisfaction. Comparing the results, total disability decreases between two and eight years is -3.7% with p <0.05 in all the meaning of the fifth item to item.

Calculation of the differential rating

To calculate the differential rating has used the following rule:

initial ratings in percentage of each item / dimension - Final score percentage of each item / dimension. The results are the rating earned after surgery.

ITEM	Pre-su	urgery		2 Age		8 Age				2-8 *	
				Difference	Р	Mean	Diffe	rence	Р	Age	
	Me	ean	Mean	% **	value		0/ **		value	value	
1) DURING THE LAST WEEK					- Tanac					Tarac	
HAS MUCH DISTURBED BACK	4,21	L±,87	3,15±1,38	21,20	,00	3,54±1,17	13,4		,00,	,01	
PAIN?											
2) During the last week how											
much it bothered leg pain	3,72±1,27		2,55±1,40	23,40	,00	3,12±1,42	12,0		,03	,00	
(sciatica)?											
3) During the past 4 weeks											
until PAIN LE POINT she has											
hindered their regular work?	4,05:	±1,09	3,03±1,50	20,40	,00	3,38±1,47	13,4		,00	,05	
(INCLUDING THE WORK OUT											
OF HOUSE AND Chores?											
4) How would you feel VD.											
IF YOU HAD TO SPEND THE											
REST OF YOUR LIFE WITH	4,82	2±,54	4 3,36±1,42	29,20	,00,	2,03±1,16	55,8	;	,00	,00	
DISCOMFORT THAT HAS AT											
THIS TIME?											
5) During the past 4 weeks			61 2,54±1,68	17,60		2,60±1,45	16.4		,01	,86	
how many days had to											
stop doing any of the daily	3,42:	±1,61			,03						
activities that occupy him							10,-	10,4			
USUALLY OVER HALF DAY											
FOR BACK PAIN / PIE?											
bow many days had to stop											
	2 21.	⊥1 0 7	1 00+1 51	20.20	00	2,17±1,46	22.0	,	00	05	
OF HIS CLASS DACK DAIN /	3,31	1,07	1,9011,91	20,20	,00		22,8		,00	,05	
UF THE CLASS BACK FAIN /											
7) AS OF SATISFIED WITH											
STATE HAS APPLIED FOR											
TREATMENTS BACK PAIN or	2,94±1,13		2,24±1,21	14,00	,00	3,01±1,17	-1,4		,90	,00	
leg?											
Total mean item	3,78	± 1.20	$2,69\pm1,14$			2,87±1,33					
iotal uisdullity 70	70,29	<u>, , , , , , , , , , , , , , , , , , , </u>	<u>33,/±1,41</u>			9 Age			-		
			z Age			o Age		1	2-	o Age	
reduced total disability %			22,6			18,9		- 3,7		,7	

 Table 5: Core Outcomes Measures Index DEYO (COMI).
 Resultado del cuestionario pre-cirugía, 2 y 8 años

* 2-8 years t test column represents the average between two to eight years. ** Difference between Presurgery and two to eight years.

*** valores de cada ítem: entre 1-5 (1 ningún problema, 5 máximo); The recovery of disability throughout the year was 3.7%

Discussion

The health-related CV is used to evaluate health-related variables from the perspective of the individual. This study has determined how clinical outcomes evolve as time elapses after surgery and describing the mean values of quantitative fundamental variables that define the clinical status of the patient in pre and post-surgical different years [1].

The SF36, ODI and COMI showed an overall improvement in CV and CF with a reduced degree of disability (Figure 1,2,3).



The curves represent the results of the questionnaire: pre, post-surgery two years and eight years. "Vitality" worst score.



Figure 1: Comparison of each dimension of Sf 36 and the three phases of the questionnaire

The curves represent the results of the questionnaire: pre, post-surgery two years and eight years. "Lifting" and "social life" worst score.

Figure 2: Compare each item in the ODI and the three phases of the questionnaire



The curves represent the results of the questionnaire: pre, post-surgery two years and eight years.

Figure 3: Comparison of each item of COMI and the three phases of the questionnaire

On average and dispersions of each item that makes up the scale SF36 ordered by sub-dimensions it is observed that these patients have limited the development of their daily physical activities. For the improvement in clinically meaningful treatment opinions vary between four and sixteen points according to ten according to other aut hors [8, 15] in ODI-COMI and SF36 point seven [17].

In the SF36 note that the patient has a slight decrease in health status in relation to the fifth question in the questionnaire, while COMI health status and disability is assessed in the fourth question which seems an improvement in these parameters at two and eight years.

Regarding the evolution of pain, in relation to the patient's perception of their frequency and intensity, is valued at SF36 in the fourth question, in ODI first question, and the first specific and second question COMI, all parameters different questionnaires improved significantly.

Improving the "physical function" of the SF36 (the impact of physical limitations on daily activities and the fulfillment of their productive tasks), related to this area the can be found in ODI item two, three, seven, with important than improvement the seven points, COMI the three fifth and sixth

The degree to which the disease interferes with the "social life" and "emotional" patient has a significant social impact on SF36. Mild improvement after treatment but with p>0.05, may mean that the questionnaire responses have been very varied; Item eighth ODI positive (16.8 points) and sexual activity (7.8 points) at two years; respectively in the fourth item COMI is similar with significant reduction (over 20 points).

Mental health includes the recognition of the effect it can have the disease on anxiety, depression and mood of the patient, also it remains low after treatment with p> 0.05. Probably caused by high expectation of improvement that had patients.

"Vitality" in SF36 has a positive value particularly at two years (worth five). Analogous COMI the fifth item. The dimension "general health" remains almost the same, probably related to chronic diseases. COMI something related in the 6 item with good results.

In the seventh item COMI is no good treatment received satisfaction at two years.

Overall improvement in CV and decreased pain remain for long: in SF36, ODI item first item COMI first and seconded. Those who are not improved in ODI: "lifting" and "travel"; The "sleep" and "walk with" good score two to eight years (consistent with item "pain"), but they are probably not significant relating to N.

These results are similar to findings in other studies of similar populations who have used the SF36 [17].

Conclusions

The result after surgery for degenerative lumbar pathology regarding disability CV and more short-term improvement.

The result of the surgery is indicated if it meets patient expectations

The age of patients is not a contraindication to surgical (2).

Study limitations

One limitation of the study was a small number of case (N), higher N would have given more precise information and more narrow curves.

It considers that the questionnaires did not include some health concepts: cognitive, family function.

The number of patients at levels set was not sufficiently broad to determine the influence they can have this variable.

Strength

The strength of the study is related to the use of standard psychometric questionnaires and proven friability, sensitivity, accuracy.

Clinical study in patients

Long period study

Cross different tests

As a point of reference literature confirms the results obtained.

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