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Surgery versus conservative management for lumbar disc herniation with radiculopathy: A systematic review and meta-analysis

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ABSTRACT

Introduction: Lumbar disk herniation with radiculopathy (LDHR) appears to be a large and costly problem. The standard procedure regarding the best treatment for LDHR has being between surgery and conservative management. The aim of this study was to compare and summarize evidence regarding the effectiveness of surgery and conservative treatment for individuals with sciatica due to LDH.

Methods: This study reviewed all literatures published on individuals with LDHR, who were managed either through surgery or conservative method. Pain and functional disability were the main outcome measures analyzed. A comprehensive search of PubMed, translating research into practice, physiotherapy evidence database (PEDro), and CINAHL was conducted from October 2011 to June 2017. Two independent researchers selected the studies and extracted the data. Methodological quality was assessed using the PEDro scale. Meta-analysis was carried out where suitable.

Results: Eight studies involving (n = 1507) participants were included in the review Meta-analysis was conducted for only four studies (n = 784). The meta-analysis showed significant benefit for early surgery than conservative care (-8.01, 95% CI, -9.27-6.72) in the short-term effect (-0.49, 95% CI, -0.7--0.28). However, the result for long-term effect did not show any significant difference between surgery and conservative care (1.60, 95% CI, -6.85-10.05).

Conclusion: This current evidence suggests that early surgery for individuals with LDH with radiculopathy is better than conservative care in the short-term without any long-term difference. The results of this review should be interpreted with caution as the populations of the included studies were largely heterogeneous.

Key words: Systematic review; meta-analysis; surgery; conservative care

INTRODUCTION

Low back pain (LBP) appears to be a major problem globally, with the highest prevalence during the middle age life span (1). It leads to physical impairment and poor quality of life for individuals, as well as increased absenteeism and early retirement (2).



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Lumbar disc herniation (LDH), defined as localized displacement of disc material beyond the limits of the intervertebral disc, is believed to be a major contributor to the estimated 60–80% of lifetime incidence of LBP in general population (3) and is among the most common causes for sciatica (4).

Sciatica goes together with almost 10% of cases of LBP (5) with a lifetime incidence ranging from 13% to 40% (6). Symptoms of sciatica may be very difficult to deal with because over 50% of people reporting sciatica or radiculopathy indicate a pattern of intermittent presentation, with relapsing being very common (4,6). This pattern has been estimated to increase the prevalence of long-term disability by 10% (7) and to triple the likelihood that people will seek additional medical care (8,9). Thus, the importance of identifying effective treatment strategies for sciatica has been emphasized as it is said to be associated with delayed recovery from LBP, persistent disability, and increased health-care system utilization and costs (4,8,9).

Microdiscectomy and endoscopic surgeries that are minimally invasive are the most common type of surgery used in the management of individuals with LDH with radiculopathy (LDHR). (10). However, an absolute indication for lumbar disc surgery is a progressive neurological deficit commonly associated with the cauda equina syndrome (11). In addition, Cakir et al. (12) stated that the only clear and objective indication for early surgery is the cauda equina syndrome. Furthermore, the same authors also emphasized that there is no any outstanding evidence with regard to the necessity for immediate surgery even in individuals with severe complication. Therefore, the relative indications for discectomy vary between surgeons and patients (13).

According to Ogink et al. (14), it is incumbent on clinicians to discuss the advantages, disadvantages, risks, alternatives, and estimated expected outcomes with patients before any disc surgery. Most often, the primary aim of lumbar disc surgery is to relieve the patient from pain in the leg. Other symptoms, such as back pain and possible muscle weakness in the leg, appear to be more difficult to reduce with surgery. In this regards, the general recommendation, when patients report symptoms from LDH, is to start with non-surgical treatment. A previous research (4) has mentioned that a period of 3 months was enough to show if a conservative management would be successful in the management of LDHR or not. However, they did not mention if it requires any standardization in terms of frequency and expertise as well as specificity of the type of conservative management that is administered. Thus, they mentioned that, if no or little improvement occurred during this period, then the patient would be a good candidate for surgical intervention (4).

The effectiveness of many conservative treatments for LDHR in comparison with surgery is still unclear. This has been in part due to the heterogeneity of the conservative interventions (15,16) and lack of validated outcome measures in early studies (17). A systematic review by Jacobs et al. (18) has collated the published evidence on conservative treatments for LDHR compared with surgery up to October 2009, However, the study was not able to pool results of the findings due to participants' heterogeneity. Shojania et al. (19) recommended that the average survival time of any systematic review is 5.5 years, with 23% of the reviews becoming outdated within 2 years of publication (19). There appears to be increasing and new literatures since 2009 when the last systematic review on LDHR was published. The objective of this present systematic review was to compare and summarize evidence regarding the effectiveness of surgery compared with conservative treatment for patients with LDHR and also identify who benefits more from surgery and who from conservative care. This systematic review was registered with the Prospero database with an ID number (CRD42017071624).

METHODOLOGY

Evidence acquisition

The databases of PubMed, translating research into practice database, physiotherapy evidence database (PEDro), and the cochrane library were searched from June 2011 to June 2017. The MeSH criteria for PubMed search strategy was used (Table 1). In PEDro, simple search was conducted, combining search terms separately. Manual searches of the reference list was also conducted.

Inclusion criteria

Studies were included if they met the following criteria:

- 1. Participants included were between the ages of 18 and above with LDHR.
- 2. The study compared surgery to conservative interventions.
- 3. The outcome(s) evaluated included at least one of the main clinically relevant outcome measures for LDHR (i.e., pain, functional ability, return to work, absenteeism, or recovery) using a valid instrument.
- 4. Studies were randomized controlled trials (RCTs) and published in English.
- 5. The follow-up of the studies was at least 4 weeks.

Study selection

Covidence trial version was used by the two independent reviewers (MSD and BB) to carry out the electronic database searches and screened the title and abstracts. Full copies of potential eligible papers were also retrieved and screened by the two independent reviewers (BB and MSD).

TABLE 1. PubMed	search strategy
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Search terms
(1) LDH or discogenic disk
(2) Surgery or microdiscectomy
(3) Non-surgical or non-operative treatment or conservative
treatment
(4) Randomized controlled trials or clinical trials
(5) 1 and 2 and 3 and 4
LDH: Lumbar disk herniation

TABLE 2. Rating of trials on the PEDro methodological quality scale

Exclusion criteria

This review excluded any study which participants had LDHR with known cause of the problem. These include the following: Individuals with systemic inflammatory diseases, spinal stenosis, spondylolisthesis, spine fractures, tumors, infections, or osteoporosis.

Data extraction

Data extracted from the included studies were study design, sample size, sex, age, participants, interventions, outcomes, and follow-up. Information was also retrieved directly from the study of Jacobs et al. (18).

Quality assessment

The methodological quality score of the reviewed studies is reported in Table 2. Rating of trials and risk of bias was carried out using the PEDro Methodological Quality Scale due to its high validity and reliability (20) (Appendix 1). Previous authors have shown that studies scoring ≥ 6 of 10 were often considered to be of high quality (20,21) (Table 2).

Data analysis

The following headings were used to extract data for the table of evidence: Author, year of publication, study population, type of interventions, design, outcome measures, results, and conclusion. Comparison was done on the same reported outcomes and all the data were pooled using RevMan 5 software.

 I^2 statistic was used to assess for any statistical difference between-study heterogeneity, and any value \geq 75% was considered high while \leq 25% are said to be low while 50% was considered moderate heterogeneity. Funnel plots were assessed to identify the publication bias (Figures 1-3).

Studies	1	2	3	4	5	6	7	8	9	10	11	Total
Lurie et al. (22)	Y	Y	Y	Y	Ν	N	Ν	Y	Y	Y	Y	7
McMorland et al. (26)	Y	Y	Y	Y	Ν	Ν	Ν	Y	Y	Y	Y	7
Österman et al. (24)	Y	Y	Y	Y	Ν	Ν	Ν	Y	Y	Y	Y	7
Peul et al. (23,25)	Y	Y	Y	Y	Ν	Ν	Ν	Y	Y	Y	Y	7
Weinstein et al. (15,16)	Y	Y	Y	Y	Ν	Ν	Ν	Y	Y	Y	Y	7
Weber (17)	Y	Y	Y	Ν	Ν	Ν	Ν	Y	Ν	Y	Y	5
Total	8	8	8	7	0	0	0	8	7	8	8	

Key: Y=Yes, N=No. PEDro: Physiotherapy evidence database



FIGURE 1. Flow chart of study selection process.

RESULTS

The overall search resulted in eight studies that met the inclusion criteria. Initial database search produced 257 citations, of which 10 were appropriate for full-text review. Figure 4 shows the complete study selection process. Four studies met the inclusion criteria of the present study which were not part of the 2011 review, while another four studies were drawn from the 2011 study, making a total of eight studies in the present review.

Characteristics of included studies

Table 3 a shows summary of the characteristics of the included studies with their findings. Two

	Early	Surge	ery	Prolonged (conservat	. Care		Mean Difference		Me	an Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, I	Random, 95%	CI	
3.1.1 Disability													
Peul et al. 2007	6.1	0.5	125	9.2	0.5	87	12.6%	-3.10 [-3.24, -2.96]			•		
Peul et al. 2008	6.1	0.5	125	9.2	0.5	80	12.6%	-3.10 [-3.24, -2.96]			<u>.</u>		
Subtotal (95% CI)			250			167	25.3%	-3.10 [-3.20, -3.00]					
Heterogeneity: Tau ² =	0.00; Chi	² = 0.0	10, df =	1 (P = 1.00); I	² = 0%								
Test for overall effect:	Z = 62.02	2 (P < (0.00001)									
3.1.2 Leg Pain													
Peul et al. 2008	10.2	1.9	125	27.9	1.9	80	12.4%	-17.70 [-18.23, -17.17]					
Peul et al. 2007	10.2	1.9	125	27.9	1.9	87	12.4%	-17.70 [-18.22, -17.18]					
Subtotal (95% CI)			250			167	24.8%	-17.70 [-18.07, -17.33]	•				
Heterogeneity: Tau ² =	0.00; Chi	² = 0.0	00, df =	1 (P = 1.00); I	² = 0%								
Test for overall effect:	Z = 93.19	9 (P < 0	0.00001)									
3.1.3 Back Pain													
Peul et al. 2008	14.4	2.1	125	25.7	2.1	80	12.3%	-11.30 [-11.89, -10.71]					
Peul et al. 2007	14.4	2.1	125	25.7	2.1	87	12.3%	-11.30 [-11.87, -10.73]		-			
Subtotal (95% CI)			250			167	24.6%	-11.30 [-11.71, -10.89]		•			
Heterogeneity: Tau ² =	0.00; Chi	² = 0.0	10, df =	1 (P = 1.00); I	² = 0%								
Test for overall effect:	Z = 53.83	8 (P < 0	0.00001)									
3.1.4 Perception of R	ecovery												
Peul et al. 2007	2.2	0.1	125	3.1	0.1	87	12.7%	-0.90 [-0.93, -0.87]			- 1		
Peul et al. 2008	0.8	0.1	125	0.4	0.1	80	12.7%	0.40 [0.37, 0.43]			ŀ		
Subtotal (95% CI)			250			167	25.3%	-0.25 [-1.52, 1.02]			•		
Heterogeneity: Tau ² =	0.84; Chi	² = 42	25.61, c	if = 1 (P < 0.0	0001); I ² =	100%							
Test for overall effect:	Z = 0.38	(P = 0.	.70)										
Total (95% CI)			1000			668	100.0%	-8.01 [-9.27, -6.76]		•			
Heterogeneity: Tau ² =	3.23; Chi	² = 182	294.72,	df = 7 (P < 0.0	00001); I² :	= 100%			+		-		
Test for overall effect:	Z = 12.53	B (P < 0	0.00001)					-20	-10 Favours Early Su	0	10	20

FIGURE 2. Surgery versus prolonged conservative care for short-term effect.



FIGURE 3. Funnel plot for surgery versus prolonged conservative care for short-term effect.

Author(s)	Sample	%	Average	Participants	Interventions	Outcomes	Follow-up
Lurie et al. (22)	501	43	aye (years) 42.3	Symptoms and confirmatory	Surgical group: open	Pain, Functional disability,	6 weeks, 3 months, 6
				signs of lumbar radiculopathy on imaging, symptom lasting for 6 weeks	discectomy. Non-operative group: usual care	Physical function and quality of life.	months, and annually for up to 8 years.
McMorland et al. (26)	40	40	40	Leg dominant symptom with objective sign of nerve root tethering±neurologic deficit correlated with MRI lasting for 3 months and more.	Surgical group: Microdiscectomy. Non-operative group: Spinal Manipulation	McGill pain, functional disability (RMDQ), and QOL (SF-36).	3 months and 1 year
Österman et al. (24)	20	6 E	37.5	Below knee radicular pain of 6–12 weeks intervertebral disc extrusion or sequester (CT) positive SLR <70° Muscle weakness, altered Deep tendon reflex or dermatomal sensory change	Experimental: Microdiscectomy (2 weeks). Control: Conservative management	Leg pain (VAS), LBP and workability (VAS), ODI, QOL, risk of depression, satisfaction with treatment, perceived recovery and clinical status	6 weeks, 3 months, 1 and 2 years.
Peul et al. (23,27)	283	44	42.3	Lumbosacral radicular syndrome. Radiologically confirmed disc herniation dermatomal pattern of pain distribution with concomitant neurological disturbances that correlated to the same nerve root being affected	Experimental: Early surgery Control: Prolong conservative management	Leg pain (VAS), Functional disability (RMDQ), QOL, Neurological status, Self- perceived recovery, and PROLO scale	2, 4, 8, 12, 26, 38, and 52 weeks for 2007 study and additional 78 and 104 weeks for 2008 study.
Weber (17)	126	42	41.6	Clinical signs/symptoms Of 5th lumbar and/or 1st sacral nerve root lesion corresponding with radiculopathy	Microdiscectomy (2 weeks). Control: Conservative management	Clinicians perception of recovery (working capacity, deficits, pain, and mobility of the spine: relaose)	1, 4, and 10 years

(Contd...)

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TABLE 3. Characteristics of included study

		•					
Author(s)	Sample	%	Average	Participants	Interventions	Outcomes	Follow-up
	size	Female	age (years)				
Weinstein (15,16)	501	42	42	Radicular pain knee for	Control: Non-operative	Sciatica Bothersome- ness	6 months annually, 1-2
				lower lumbar knee for lower	treatment, consisting of	Index	years for Weinstein,
				lumbar herniations, into the	conservative care		2006, and Up to 4
				anterior thigh for upper lumbar			years for 2008 Stu-
				herniations) at least 6 weeks			
				Evidence of nerve root irritation			
				with a positive nerve root tension			
				sign (SLR positive between			
				30° and 70° or positive femoral			
				tension sign) or a corresponding			
				neurologic deficit advanced			
				vertebral imaging			
RMDQ: Roland Morris	Disability	, Questionn	iaire, QOL: Qi	MDQ: Roland Morris Disability Questionnaire, QOL: Quality of life, VAS: Visual analog scale, ODI: Oswestry Dsability Index, LBP: Low back pain, CT: Computed tomography,	scale, ODI: Oswestry Dsability Ir	ndex, LBP: Low back pain, CT:	Computed tomography,
SLR: Straight leg raise							

Musa Sani Dan-Azumi et al. Journal of Health Sciences 2018;8(1)42-53

studies compared early surgery with prolonged conservative care for 6 months followed by surgery if needed (22,23). Five studies contrasted surgery with usual conservative care (15,17,18,24,25) and one study contrasted surgery with manipulation (26).

Study quality and bias

The PEDro scores of the included studies ranged from 5 to 7, with a mean score of 6.8 (Table 2). All participants were randomly allocated, and all studies provided adequate results and analysis. All studies concealed allocation and seven studies assessed baseline comparability. No study blinded participants, therapists, and outcome assessors. With all studies, the greatest possible source of bias was related to blinding. Four publications scored >6 (16,22,25,26) along with three (15,23,24) from the 2011 review totaling 7 studies of high quality.

Data synthesis

Due to inherent heterogeneity among the included studies, only four studies were pooled for inclusion into meta-analysis. Two studies (15,23) from the 2011 review and the other two studies (18,27) from the remaining included studies. However, meta-analysis for this review was conducted in two phases. The first phase involved the pooling of two studies (22,27) that compared early surgery with prolonged conservative care followed by surgery if needed. These studies are homogenous in participants' characteristics, interventions, and outcomes. Data for these studies were pooled for short-term (8 weeks) and long-term (52 weeks) effects on disability (Roland-Morris Disability Questionnaire), pain (visual analog scale), and global perceived recovery (7-point Likert scale).

Similarly, the second phase involved pooling the remaining two studies (15,16) that contrasted surgery with usual conservative care. These studies, however, like those in the first phase were homogenous in participants' characteristics, interventions, as well as outcomes. Data for these studies were equally pooled into meta-analysis for only long-term (2 years) effects on BP (SF-36 BP), PF (SF-36 PF), and functional disability (Oswestry Disability Index).



FIGURE 4. Surgery versus prolonged conservative care for long-term effect.

Surgery with prolonged conservative care followed by surgery if needed

Short-term effect

Meta-analysis showed significant benefit for early surgery versus conservative care followed by surgery if needed for short-term disability (-3.10, 95% CI, -3.20--3.00), leg pain (-17.7, 95% CI, -18.07--17.33), and back pain (-11.30, 95% CI, -11.71--10.89) with no significant benefit for either surgery or prolonged conservative care for global perception of recovery (-0.25, 95% CI, -1.52--1.02) (Figure 5). There was no any significant difference between groups for disability, leg pain, back pain, and global perception of recovery with a between-study heterogeneity ranging from high to negligible ($I^2 = 0\%$, 0%, 0%, and 100%), respectively. However, the overall short-term effect favored early surgery (-8.01, 95% CI, -9.27--6.72), but the result has no clinical significance $(I^2 = 100\%)$ due to the high rate of heterogeneity of participants.

Long-term effect

The meta-analysis result for early surgery versus conservative care followed by surgery if needed for long-term effect showed significant improvement for disability (-0.40, 95% CI, -0.50--0.30) and back pain (-2.30, 95% CI, -2.72--1.88) with no significant benefit for either surgery or prolonged conservative care for leg pain (-0.00, 95% CI, -0.37-0.37) and global perception of recovery (-0.05, 95% CI, -0.34-0.24) (Figure 6). There was no significant difference between groups for disability, leg pain, back pain, and global perception of recovery with between-study heterogeneity ranging from high to negligible ($I^2 = 0\%$, 0%, 0%, and 100%), respectively. The study did not favor or preferred any intervention in terms of clinical benefit on a long-term basis.

Surgery versus usual conservative care for long-term

The result for surgery versus usual conservative care for long-term effect showed no statistical significant



FIGURE 5. Funnel plot for surgery versus prolonged conservative care for Long-term effect.

difference for bodily pain (6.60, 95% CI, -0.45-13.66), physical function (6.25, 95% CI, -5.02-17.52), and disability (-8.05, 95% CI, -18.53-2.44) with a high between-study heterogeneity ($I^2 = 100\%$, 100%, and 100%), respectively (Figure 7). In addition, the overall effect is equally statistically and clinically not significant (1.60, 95% CI, -6.85-10.05) with a high between-study heterogeneity ($I^2 = 100\%$).

DISCUSSION

This current study identified and reviewed eight studies that compared surgery with conservative care in the management of individuals with LDHR. Due to high heterogeneity of the included studies, only four studies were pooled into meta-analysis. Two studies (23,25) contrasted early surgery with prolonged conservative care followed by surgery if needed. The outcome of this review revealed that early surgery is better than prolonged conservative care for short-term but not different in the longterm effects. This outcome may be possible as some of the patients (39% for Peul et al. (23) and 44% for Peul et al. (25)) in the prolonged conservative care group had to cross-over to surgery due to persistent sciatica or increasing leg pain. Moreover, another reason for the above result could have been that the patients in the early surgery group had more severe symptoms that they could not cop up with the prolonged hospital visits of the prolonged conservative management.

The meta-analysis result of the other two pooled studies (15,16) that contrasted surgery with conservative management did not favor either surgery or non-operative management. However, in addition to more cross-over from conservative treatment to surgery than cross-over from surgery to conservative treatment, patients in the surgical group had more severe symptoms than patients in the conservative treatment group. Furthermore, the conservative treatment protocol was not standardized in all the studies which are in contrast to surgery in which standard open discectomy with examination of the involved nerve root was used. This lack of conservative treatment standardization coupled with

	Su	irgery		Non-Op	erative	Care		Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
1.1.1 SF-36 for Bodily	Pain								
Weinstein et al. 2008	40.5	1.9	187	37.5	1.9	191	16.7%	3.00 [2.62, 3.38]	
Weinstein et al. 2006	42.6	1.1	456	32.4	1.9	165	16.7%	10.20 [9.89, 10.51]	
Subtotal (95% CI)			643			356	33.3%	6.60 [-0.45, 13.66]	
Heterogeneity: Tau ² =	25.89; Cl	hi² = 8	26.30, d	if = 1 (P <	0.00001	1); l² = 1	00%		
Test for overall effect:	Z = 1.83	(P = 0	.07)						
1.1.2 SF-36 for Physic	cal Func	tion							
Weinstein et al. 2008	36.2	2	187	35.7	2	191	16.7%	0.50 [0.10, 0.90]	
Weinstein et al. 2006	43.9	0.99	456	31.9	1.9	165	16.7%	12.00 [11.70, 12.30]	
Subtotal (95% CI)			643			356	33.3%	6.25 [-5.02, 17.52]	
Heterogeneity: Tau ² =	66.09; Cl	hi² = 1	992.89,	df = 1 (P ·	< 0.0000	01); l² =	100%		
Test for overall effect:	Z = 1.09	(P = 0	.28)						
1.1.3 Oswestry Disab	ility Inde	x							
Weinstein et al. 2006	-37.6	0.85	456	-24.2	1.7	165	16.7%	-13.40 [-13.67, -13.13]	•
Weinstein et al. 2008	-31.5	1.7	187	-28.8	1.7	191	16.7%	-2.70 [-3.04, -2.36]	
Subtotal (95% CI)			643			356	33.3%	-8.05 [-18.54, 2.44]	
Heterogeneity: Tau ² =	57.22; Cl	hi² = 2	304.32,	df = 1 (P ·	< 0.0000	01); l² =	100%		
Test for overall effect:	Z = 1.50	(P = 0	.13)						
Total (95% CI)			1929			1068	100.0%	1.60 [-6.85, 10.05]	
Heterogeneity: Tau ² =	111.56; 0	Chi² =	19900.8	38, df = 5 (P < 0.00	0001); l²	= 100%		
Test for overall effect:	Z = 0.37	(P = 0	.71)						-20 -10 0 10 20 Favours Surgery Favours NonOperative Care
Test for subgroup diffe	roncos: (hi2 -	5 50 df	- 2 (P - 0	06) 12 -	- 64 20/			avours ourgery ravours non-operative care

FIGURE 6. Surgery versus usual conservative care for long-term effect.



FIGURE 7. Funnel Plot for surgery versus usual conservative care for long-term effect.

heterogeneous patient populations may be responsible for the non-beneficial effect of conservative treatment.

Comparison with other reviews

This current review differed from the previous review (18) that compared surgery with conservative management for LDHR. However, differences in inclusion criteria and search strategies between our review and 2011 review seemed to result in a considerably different collection of trials. For example, only four of the eight trials in our review were included in the 2011 review. This seemed to be attributable to the different databases used as well as increase in new trials published. In addition, the different collection trials in the previous review led to some differences in evidence summaries. Although our review was able to do meta-analysis for four studies, 2011 review could not do it due to heterogeneity of the included trials.

The most common methodological flaws of the trials included in this review were failure to blind participants, therapists, and outcome assessors. Future trials should aim at having a single or double RCT. Another limitation common in the included trials is failure to standardize the conservative treatment protocols. Only one study (26) compared microdiscectomy with manipulative therapy, and all other studies did not standardize the conservative care. It is pertinent, therefore, that subsequent trials should focus on the standardization of the non-operative management.

CONCLUSION

The current evidence suggests that early surgery is better than prolonged conservative care in the shortterm for individuals with LDH with radiculopathy. However, results for the long-term effect showed no significant difference between the interventions.

RECOMMENDATION

There is the need for further trials to include homogenous patient populations as well as to standardize the conservative protocols in the treatment of individuals with LDH with radiculopathy.

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APPENDIX

APPENDIX 1. PEDro scale.

Items/Description

- (1) Was eligibility criteria specified?
- (2) Were all subjects randomly allocated?
- (3) Were allocations concealed?
- (4) Were the groups similar at baseline?
- (5) Was there blinding of all subjects?
- (6) Was there blinding of all therapists?
- (7) Was there blinding of all assessors?

(8) Was there a measure of at least one key outcome for more than 85% of the subjects initially allocated to groups?

(9) Did all subjects for whom outcome measures were available receive the treatment or control condition as allocated or, where this was not the case data for at least one key outcome was analyzed by "intention to treat"?

(10) Were the results of between group statistical comparisons reported for at least one key outcome?

(11) Did the study have both point measures and measures of variability for at least one key outcome?

Items 2–9 refer to the internal validity of a paper, and items 10 and 11 refer to the statistical analysis, ensuring sufficient data to enable appropriate interpretation of the results. Item 1 is related to the external validity and therefore not included in the total PEDro scores (Maher et al., 2003).