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The Value Assessment of Clinical Trials Based on Electrophysiologically Verified Lumboischialgia

ABSTRACT

Introduction: Lumboischialgia is defined as pain in the distribution of ischemic nerve caused by a pathological change in the nerve itself, whereas lumbago is a localized spondylogenic pain that is not followed by a neurological deficit, and is a consequence of muscular bone dysfunction of the lumbosacral region. Previous studies which investigated the value of clinical trials in the diagnosis of lumboischialgia did not find a high sensitivity and specificity in those tests.

Objective: Our objective was to define clinical tests that indicate the existence of radiculopathy and to determine the value of the overall diagnostic finding in relation to the findings of the EMNG examination.

Methods: The sample consisted of 100 patients of both genders, aged 18-65. The inclusive criteria were: strong lower back pain propagating in one of both legs and lasting for 1-3 months and the medical history suggesting a radicula lesion. Non-inclusion criteria were the following: symptoms of cauda equine, acute febrile condition, existence of tumors, vertebral fractures, lesions of central motoneuron, inability to perform the EMNG examination, acute psychotic conditions, operations of the spine and pregnancy. Immediately before each EMNG examination, medical history was taken with defined questions on the existence of pain stronger in the leg than in the spine, dermatome deficit, pain during labor and weakness in the leg.

Results: Patients usually have a total of two (31%) and three (26%) positive clinical signs of lumboischialgia. By statistical analysis, three clinical trials proved to be discriminatory in terms of verification of radiculopathy: positive Lazarevic test, paresis of a particular muscle group, and absence or reduction of the patellar or Achilles reflex. After processing with logistic regression, the statistically predictive value is retained by a positive Lazarevic test. The analysis of the surface under ROC curve shows that the positivity of four or more clinical tests is statistically the best limit value, with a specificity of 67% and a sensitivity of 56%.

Conclusion: The conducted study indicates the statistical significance of the frequency of positive clinical trials: Lazarevic test, objective muscular weakness and absent reflex, in persons with electrophysiologically verified lumboischialgia.

Key words: clinical signs, radiculopathy, electromyoneurography

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Introduction

Ischialgia is defined as pain in the distribution of ischemic nerve caused by a pathological change in the nerve itself. Lumbago implies localized spondylogenic pain not accompanied by neurological deficits and is the consequence of muscular bone dysfunction of the lumbosacral region.¹

Hippocrates (460-357B.C.) first used the term ischias that comes from the Greek word ischios (hip) in its work "Tractat about Diseases ". Under this name, he implied a pain in the hip joint that spreads from buttocks and neck along the thigh and leg.² Laza Lazarević, was a prominent writer of Serbian realism, a doctor, a lawyer and practically the first Serbian neurologist. In his work "Ishias Cotunnii's post "^{3,4} he was the first to describe the characteristic sign of the sciatica (from which he himself suffered).

The pain of a radicular character that occurs when lifting the leg is still called Lazarevic's sign. Other clinical cardinal signs of radiculopathy include lower back pain and radiance in the root distribution, often associated with loss of sensitivity and cramps of paravertebral musculature. Motor weakness may also be present. The sensory and motor symptoms of radiculopathy depend on the nerve root or the roots that are damaged. Each nerve root provides a sensation of sensitivity to a specific skin region known as dermatom and motor inertia of certain muscles known as myotoma.

Musculoskeletal reflexes can also show abnormalities in radiculopathy, depending on the damaged nerve root. At the lower extremities, the patella and Achilles reflexes are usually examined. Patellar reflex may be lower in damage to the root of L3, L4, rarely L2. The Achilles reflex is absent and decreased in the root lesion S1. There is no routine reflex for estimating root L5, occasionally a reflex m. tibialis post. and medial hamstrings can be induced. And in case of asymmetry, L5 radiculopathy can be suggested. However, both of these reflexes are often absent in healthy individuals.

EMNG of lower extremities is an objective and highly reliable diagnostic test method for suspected lumbosacral radiculopathy^{5,6} and, according to the protocol, it is performed after a clinical examination. The Needle EMG Analysis of electrical activity in the relaxed muscle and during its contraction determines the level of lesion with a specificity of 85%.⁷

Objective

The objective is to examine the degree of compatibility of the clinical finding and objectively electrophysiologically

verified lumbosacral radiculopathy through the individual definition of the sensitivity and specificity of clinical trials in relation to the same.

Methods

Basic cohort consisted of 100 patients of both genders, aged 18-65. The inclusive criteria were: strong lower back pain propagating in one of both legs and lasting for 1-3 months and the patient history suggesting a radicula lesion. Non-inclusion criteria were the following: symptoms of cauda equine, acute febrile condition, existence of tumours, vertebral fractures, lesions of central motoneuron, inability to perform nuclear magnetic resonance examination (due to metal objects in the organism, claustrophobia), acute psychotic conditions, inability to perform the EMNG examination (due to the phobia of needles), operations of the spine and pregnancy.

Clinical examination

The clinical examination, by examining the mobility of the lumbosacral spine and leg, the paralumbar muscular tension, the gross motor power of leg segments, sensitivity and muscular tendon reflexes, was performed just prior to electrophysiological examination, which is a common practice.

Electromyoneurography (EMNG)

Electrophysiological confirmation of the existence of the acute polyradiculopathy included the registration of the acute denervation in the investigated muscles and long polyphasic potential in more than 30% of the motor units. In every investigated muscle, 10 different motor units were electrophysiologically studied by estimating the average amplitude, duration and the percentage of polyphasic potential, as well as the degree of regrutation of the voluntary sample.

Analysis of data

Data obtained through conversation and the electrophysiological examination were imported into the pre-defined data in the software Microsoft Excel 2003. It was ascertained that there were no incorrect data and no missing data. The rest of the analysis was performed by the specialised statistical packages of the SPSS 15.0.¹⁷

Results

Table 1 shows the prevalence in the overall sample of particular clinical signs, such as the Schober sign, Lazarević's sign of the raised leg, the absent reflex, the sensitivity drop, the weakness of the myotoma, and Bell's

sign of the paralumbular musculature.

Table 1. Prevalence of individual clinical signs in the total sample

Sign	N	%
Schober sign	61	61.0
Lazarević sign	57	57.0
Reflex absent	41	41.0
Sensitivity drop	34	34.0
Weakness of myotoma	28	28.0
Bellov sign	26	26.0

The most common clinical signs in the overall sample of patients with a clinical picture of lumbosacral radiculopathy are Schober's sign (61%) and Lazarević's sign (57%). Distribution of the total number of clinical signs in the total sample is shown in Table 2. Patients

in the total sample usually have a total of two (31%) and three (26%) positive clinical signs.

Table 2. Distribution of the summed number of clinical signs in the total sample

No. of signs	N	%
0	6	6.0
1	15	15.0
2	31	31.0
3	26	26.0
4	18	18.0
5	4	4.0
6	0	0.0

Patients in the total sample usually have a total of two (31%) and three (26%) positive clinical signs.

Table 3. The absence or reduction of the patellar or Achilles reflex

Sign	Electromyoneurographic finding				X ²	P*	Φ	OR	95% CI
	Negative		Positive						
	N	%	N	%					
Bellov sign									
Negative	28	(37.8)	46	(62.2)	0.42	0.637	0.06	1.37	(0.53-3.56)
Positive	8	(30.8)	18	(69.2)					
Schober sign									
Negative	11	(28.2)	28	(71.8)	1.69	0.209	-0.13	0.57	(0.24-1.34)
Positive	25	(41.0)	36	(59.0)					
Lazarević sign									
Negative	23	(53.5)	20	(46.5)	10.02	0.003	0.32	3.89	(1.64-9.21)
Positive	13	(22.8)	44	(77.2)					
Sensitivity drop									
Negative	22	(33.3)	44	(66.7)	0.60	0.511	-0.08	0.71	(0.30-1.68)
Positive	14	(41.2)	20	(58.8)					
Reflex absent									
Negative	27	(45.8)	32	(54.2)	5.95	0.020	0.24	3.00	(1.22-7.38)
Positive	9	(22.0)	32	(78.0)					
Weakness of myotoma									
Negative	31	(43.1)	41	(56.9)	5.56	0.021	0.24	3.48	(1.19-10.18)
Positive	5	(17.9)	23	(82.1)					

* Probability calculated on the basis of Fischer's exact test

Clinical signs as individual predictors of positive EMG findings

When taken into consideration individually, three clinical trials have been shown to be discriminatory in terms of verification of radiculopathy: a positive test of Lazarevic, a paresis of a particular muscle group, and the absence or reduction of the patellar or Achilles reflex (Table 3). However, after the processing by logistic regression, the statistical predictive value is retained by a positive Lazarevic test (Table 4).

Although Table 5 indicates that the sum of specific clinical signs shows a statistically significant predictor property, the analysis of the surface under ROC curve shows that it is only in a zone of poor diagnostic significance.

Table 4. Clinical signs as individual predictors of positive EMG findings

Sign	b	SEb	P	OR (95% i.p.)	
Bellov sign	0.48	0.55	0.375	1.62	0.56-4.74
Schober sign	-0.90	0.51	0.076	0.41	0.15-1.10
Lazarević sign	1.44	0.48	0.003	4.20	1.64-10.80
Sensitivity drop	-0.29	0.51	0.572	0.75	0.28-2.03
Reflex absent	0.69	0.54	0.206	1.99	0.69-5.75
Weakness of myotoma	0.92	0.62	0.139	2.51	0.74-8.51

The overall model is statistically significant : $\chi^2(6) = 21,27, P = 0,002$

Table 5. Significance statistics for the sum of clinical trials

	b	SEb	P	OR (95% i.p.)		ROC površina (95% i.p.)	
Sum of clinical signs	0.45	0.18	0.014	1.57	1.10 - 2.26	64.8	(54.6 - 74.1)

Table 6. Classification table based on the number of clinical signs

No. of clinical signs	Electromyoneurographic finding			
	Negative		Pozitive	
	n	%	n	%
0	0	0.0	0	0.0
1	4	66.7	2	33.3
2	8	53.3	7	46.7
3	12	38.7	19	61.3
4	7	26.9	19	73.1
5	5	22.7	17	77.3
6	0	0.0	0	0.0

Table 6 shows the classification based on the number of clinical signs, and Table 7 is the diagnostic classification value based on the number of clinical signs.

Table 7. Diagnostic classification value based on the number of clinical signs

No. of clinical signs	Sensitivity	95% i.p.	Specificity	95% i.p.
1 and more	100	94.3-100.0	0	0.0-9.8
2 and more	96.87	89.1-99.5	11.11	3.2-26.1
3 and more	85.94	75.0-93.3	33.33	18.6-51.0
4 and more	56.25	43.3-68.6	66.67	49.0-81.4
5	26.56	16.3-39.1	86.11	70.5-95.3

*Maximum value of the Iouden index, which, statistically speaking, represents an optimal limit value

The positivity of four or more clinical tests is statistically the best limit value, with a specificity of 67% and a sensitivity of 56% in the diagnosis of LS radiculopathy (EN1).

Discussion

The values of the clinical findings are being increasingly neglected in relation to excessive and almost exclusive use of visualization methods of testing. However, an isolated clinical trial of patients with symptoms of lumbar radiculopathy does not often give satisfactory conclusions. Electrophysiological examination can be very useful in the diagnosis of lumbosacral radiculopathies by determining the degree and level of the lesion, but also by excluding the existence of peripheral nervous lesions due to other causes. The true diagnostic accuracy and the value of clinical trials of lumbar radiculopathies provokes numerous debates. The sensory deficit, the absence of deep tendon reflexes, and motor weakness may be present at a different degree of manifestation and in different diseases. The loss of tendon reflexes is often taken with the utmost certainty to confirm the actual radiculopathy: the patellar reflex for the roots L2 and L3, the variable reflex m. tibialis post. for the root of L5, and Achill's root-root reflex S1. It is generally accepted that these clinical tests record good specificity, but low sensitivity. In our research, the asymmetry of reflex, muscle paresis and Lazarević's sign show a predictive diagnostic value for lumbosacral radiculopathies, but in total with poor diagnostic significance precisely because of low sensitivity.

In any case, the values of the specificity and sensitivity of particular clinical data obtained in this study are slightly lower than previously published. The differences in studies originate primarily from differences in the population sample, and partly in the different designs of studies.¹¹

In our study, the positive finding of the defined clinical trials was not an including factor for entering the study, and therefore potential verification burden was avoided.¹² It is also evident that our examination included a sample of general population without isolating specific population samples, thereby avoiding new restrictions. For example, both sexes are equally represented, while the majority of the previous trials included approximately twice as many men. In order to avoid asymptomatic patients and insignificant problems, only patients with severe pain in the lower part of the back that radiated to the legs and caused significant disability, were involved. These symptoms are generally accepted anamnestic parameters of acute lumbosacral radiculopathies.

According to the research, independent indicators of actual radiculopathy in the clinical finding are:

- Objective muscle weakness,
- Positive Lazarevic test,

- Absent reflex

Such findings are in line with existing clinical practice experience. It is surprising that there is no dermatome sensitivity outbreak as a predictor of radiculopathy, although it was expected that the Schober test would be a predictor of radiculopathy, primarily due to the stretching of the meninge and roots, but also because of the reversal of lumbar lordosis, which has a mechanical protective effect on the present herniation of the disc. This sign did not prove to be predictive in this study. The position of the lumbar spine opens up the space of the last part of the intervertebral space and could aggravate and intensify the present herniation. However, most other causes of pain in the back of non-radicular etiology would limit this movement. For this reason, the anteflexive test is insufficiently specific.¹³ It appears that this test also indicates the irritation and tension of the root, and not just the compression.¹⁴ The clinical sign of lifting the stretched leg, that is, Lazarević's sign, was the only one among the studied clinical trials proved predictive and through statistical method of logistic regression. This finding is expected because this sign proved to be highly sensitive (91%), but low in specificity (up to 45%).^{15, 16}

Conclusion

The performed study indicates the statistical significance of the clinical tests of the raised leg, i.e. the Lazarevic test, the objective weakness of the muscle and the absent reflex, in the diagnosis of lumbosacral radiculopathy. A detailed clinical examination can lead to a quicker and easier diagnosis, as well as to significant savings in the healthcare system, avoiding often unnecessary additional diagnostic procedures.

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Procjena vrijednosti kliničkih testova na osnovu elektrofiziološki verifikovane lumboishijalgije

SAŽETAK

Uvod: Lumboishijalgija se definiše kao bol u distribuciji ishijadičnog nerva uzrokovana patološkom promjenom samog nerva, dok je lumbago lokalizovani spondilogeni bol koji nije praćen neurološkim deficitom i posljedica je mišićno koštane disfunkcije lumbosakralne regije. Dosadašnje studije koje su istraživale vrijednost kliničkih testova u dijagnostici lumboishijalgija nisu našle visoku senzitivnost i specifičnost ispitivanih testova.

Cilj rada: Cilj nam je bio definisati kliničke testove koji ukazuju na postojanje radikulopatije i utvrditi vrijednost cjelokupnog dijagnostičkog nalaza u odnosu na nalaz EMNG pregleda.

Metode: Istraživanje je provedeno na uzorku od 100 pacijenta, oba pola, starosti od 18-65 godina. Inkluzioni kriterijumi su bili jak bol u donjem dijelu leđa sa širenjem u jednu ili obe noge u trajanju od jednog do tri mjeseca i klinička slika koje jasno sugeriše postojanje radikularne lezije. Ekskluzioni kriterijumi su bili: simptomi caudae equinae, akutna febrilna stanja, postojanje tumora, frakture pršljenova, lezije centralnog motornog neurona, akutna psihotična stanja, nemogućnost elektromiografskog pregleda. Svakom EMNG pregledu je prethodio detaljan klinički pregled.

Rezultati: Pacijenti najčešće imaju ukupno dva (31%) i tri (26%) pozitivna klinička znaka lumboishijalgije. Statističkom analizom tri klinička testa su se pokazala diskriminativna u pogledu verifikacije radikulopatije: pozitivan test Lazarevića, pareza određene mišićne grupe, te odsustvo ili redukcija patelnog ili Ahilovog refleksa. Nakon obrade logističkom regresijom, statistički prediktivnu vrijednost zadržava pozitivan test Lazarevića. Analiza površine pod ROC krivom pokazuje da pozitivnost četiri i više kliničkih testova predstavlja statistički gledano najbolju graničnu vrijednost, sa specifičnošću od 67% i senzitivnošću od 56%.

Zaključak: Provedena studija ukazuje na statističku značajnost učestalosti pozitivnih kliničkih testova: Lazarević testa, objektivne slabosti mišića i ispada refleksa, kod osoba sa elektrofiziološki verifikovanom lumboishijalgijom.

Ključne riječi: lumboishijalgija, klinički testovi, EMNG