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# Ability of diagnostic injection to predict surgical outcomes in patients with chronic low back pain and lumbar radiculopathy

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## Abstract

**Background** Arising from different anatomical structures of the spine, chronic low back pain is one of the leading causes of disability, and its management is still controversial. Thus, appropriate and effective management of chronic low back pain requires a precise diagnostic tool in order to target pain generators. Therefore, the role of diagnostic injection in predicting the outcome of surgical treatment of chronic low back pain and lower limb radicular pain need to be evaluated in order to guide the surgeon, especially in case of unclear pathoanatomical features. Thus, the aim of this study was to assess the predictive value of lumbar spine diagnostic injections in surgical outcome in patients with chronic low back pain and lumbar radiculopathy.

**Patients and methods** This study included 30 patients complaining of chronic low back pain and/or lumbar radiculopathy who underwent lumbar spine surgery following positive diagnostic injections. The pre- and postoperative assessments consisted of a general neurological examination, evaluation of the Oswestry disability index, and a visual analog scale.

**Results** This prospective non-controlled study was conducted on 30 patients complaining of chronic low back pain and/or lumbar radiculopathy. The mean age was  $42.60 \pm 8.27$  years with a range of 24.0–62.0 years. The visual analog scale decreased significantly from preoperative mean value of  $8.26 \pm 0.79$  to postoperative mean value of  $1.97 \pm 0.92$ ; with almost two-thirds of the patients experienced more than 75% pain reduction. The Oswestry disability index decreased significantly from preoperative mean value of  $34.13 \pm 4.88$  to  $11.47 \pm 3.36$  after surgery in the whole sample. The post-selective nerve root block visual analog scale was significantly correlated to the postoperative visual analog scale, while the postoperative Oswestry disability index was not significantly associated with the post-selective nerve root block visual analog scale.

**Conclusion** The use of lumbar selective nerve root block and lumbar provocative discography for patients with chronic low back pain and radiculopathy and equivocal radiological findings can improve surgical outcomes regarding pain intensity and spine functional outcomes. Diagnostic selective nerve root block can predict the postoperative pain relief.

**Keywords** Low back pain, Radiculopathy, Selective nerve root block, Discography, Diagnostic injection

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## Background

Affecting all age groups, chronic low back pain (LBP) is one of the leading causes of disability and one of the most frequently reported symptoms; it is therefore costly for the individual and for society [1, 2]. Low back pain is classified as acute, subacute, and chronic depending on whether symptoms last less than 6 weeks, 6–12 weeks, or persist beyond 12 weeks, respectively [3]. According to the etiological mechanism, it can be classified as specific with a known cause such as fracture, tumors, infections, degenerative spinal disease, arthritis, or as non-specific with no identifiable cause [4, 5]. The latter accounts for about 80–90% of chronic LBP, and its management is often difficult [6].

Reducing pain, improving function, and preventing recurrence are the primary goals in treating patients who complain of chronic low back pain. Although medical treatment is the first line of treatment in most cases, interventional therapy is considered once conservative management and medications have failed. Appropriate and effective management of chronic LBP requires a precise diagnostic tool in order to target pain generators. Based on the clinical examination and radiological findings, as well as the response to directed treatment, the goal of diagnostic procedures is to identify the pain generators [7–10].

A multicenter retrospective study evaluating the results after lumbar discography revealed that the data obtained from lumbar discography can predict the conservative management or surgical outcomes, thereby greatly facilitating clinical decision-making [11]. A study by Sasso et al. showed the predicted value of selective nerve root block (SNRB) in surgical outcomes of patients with radiculopathy. Indeed, SNRB becomes useful for diagnosing the main pain generator in the presence of multiple disk degeneration or equivocal magnetic resonance imaging (MRI) findings uncorrelated with the patient's complaint [12].

According to various study, controversy still exists regarding the treatment of chronic LBP and lumbar radiculopathy. Therefore, the role of diagnostic injection in predicting the outcome of surgical treatment of chronic LBP and lower limb radicular pain need to be evaluated in order to guide the surgeon, especially in case of unclear pathoanatomical features. The aim of this prospective non-controlled study was to determine the predictive value of lumbar spine diagnostic injections in surgical outcome in patients with chronic low back pain and lumbar radiculopathy.

## Methods

This study included 30 patients complaining of chronic low back pain and/or lumbar radiculopathy, with no significant reduction in pain after at least three months of

adequate medical treatment, physiotherapy and physical rest, admitted to the Spine Unit/Neurosurgery Department of Alexandria Main University Hospital and who underwent lumbar spine surgery following positive lumbar selective nerve root block and/or positive lumbar provocative discography.

This study included patients with mild radiological degenerative changes associated with severe and persistent low back or lower limb pain and impairment, lumbosacral radicular symptoms in more than one distribution with multiple structure impingement, or radicular pain without localizing signs to indicate the lumbosacral involved level.

Exclusion criteria were obvious pathoanatomic cause determined radiologically, traumatic spine injury, spinal tumors, spine deformity, significant osteoporosis, associated major comorbidities, pregnancy, presence of infection in the surgical site, allergic reaction to the local anesthetic used in the procedure and patients with negative lumbar diagnostic injections.

During this prospective non-controlled study, patients were assessed as follow: general neurological examination, Oswestry disability index (ODI), visual analog scale (VAS), imaging studies as MRI lumbosacral spine (LSS) and lumbosacral plain X-ray (anteroposterior (AP), lateral and dynamic standing views). Depending on the clinical and radiological characteristics, the diagnostic injections, provocative discography and/or selective nerve root block, were performed for each patient.

Preprocedural evaluation and postprocedural evaluation, at 30 min, 1 h, 3th and 6th hour, were done as follows by neurological examination, repeated and sustained flexion–extension and rotation movements, and visual analog scale.

All patients were followed for a short period with immediate, one-month and at least six months post-surgery assessments as follows: complete general and neurological examination, Oswestry disability index (ODI), and visual analog scale (VAS).

## Technique for lumbar discography

Lumbar discography was performed under local anesthesia and mild sedation with the patient in prone position and a pillow under the anterior superior iliac spines to flatten the normal lumbar lordosis. The lumbar midline and an area 20 cm × 15 cm laterally was cleaned with antiseptic solution, and a fenestrated drape is placed over the sterile area. The skin entry point was located laterally 5–7 cm from the midline. The insertion of the spinal needle into the disk was performed under fluoroscopic guidance in the anteroposterior, lateral and oblique projections, and the position of the needle in the central part

of the disk was confirmed by fluoroscopy before injection of contrast (Ultravist® 300/Bayer) using a long and thin spinal needle (22 gauge) passing posterior to the exiting root and anterolateral to the traversing root. The diffusion of the contrast in the disk was appreciated by a lumbar X-ray, anteroposterior and lateral views, to ensure the filling of the nucleus pulposus as shown in the Fig. 1. The patient was asked whether or not the procedure is painful, similar to or different from usual low back pain and/or radicular pain.

#### Technique for lumbar selective nerve root block

Lumbar selective nerve root block was performed under local anesthesia and mild sedation. The patient was in

prone position with a pillow under the anterior superior iliac spine to flatten the normal lumbar lordosis. The lumbar midline and an area 20 cm×15 cm laterally was cleaned with antiseptic solution, and a fenestrated drape is placed over the sterile area. The target level was identified by counting the spinous processes and confirmed by fluoroscopy. The skin entry point of the needle lies 5–7 cm lateral to the cephalic end of the spinous process of the vertebra. The nerve corresponding to each vertebra emerges just below the transverse process of that vertebra at this site. The spinal needle was introduced in an oblique direction targeting the intervertebral foramen under fluoroscopic guidance with anteroposterior, lateral and oblique projections (Fig. 2).



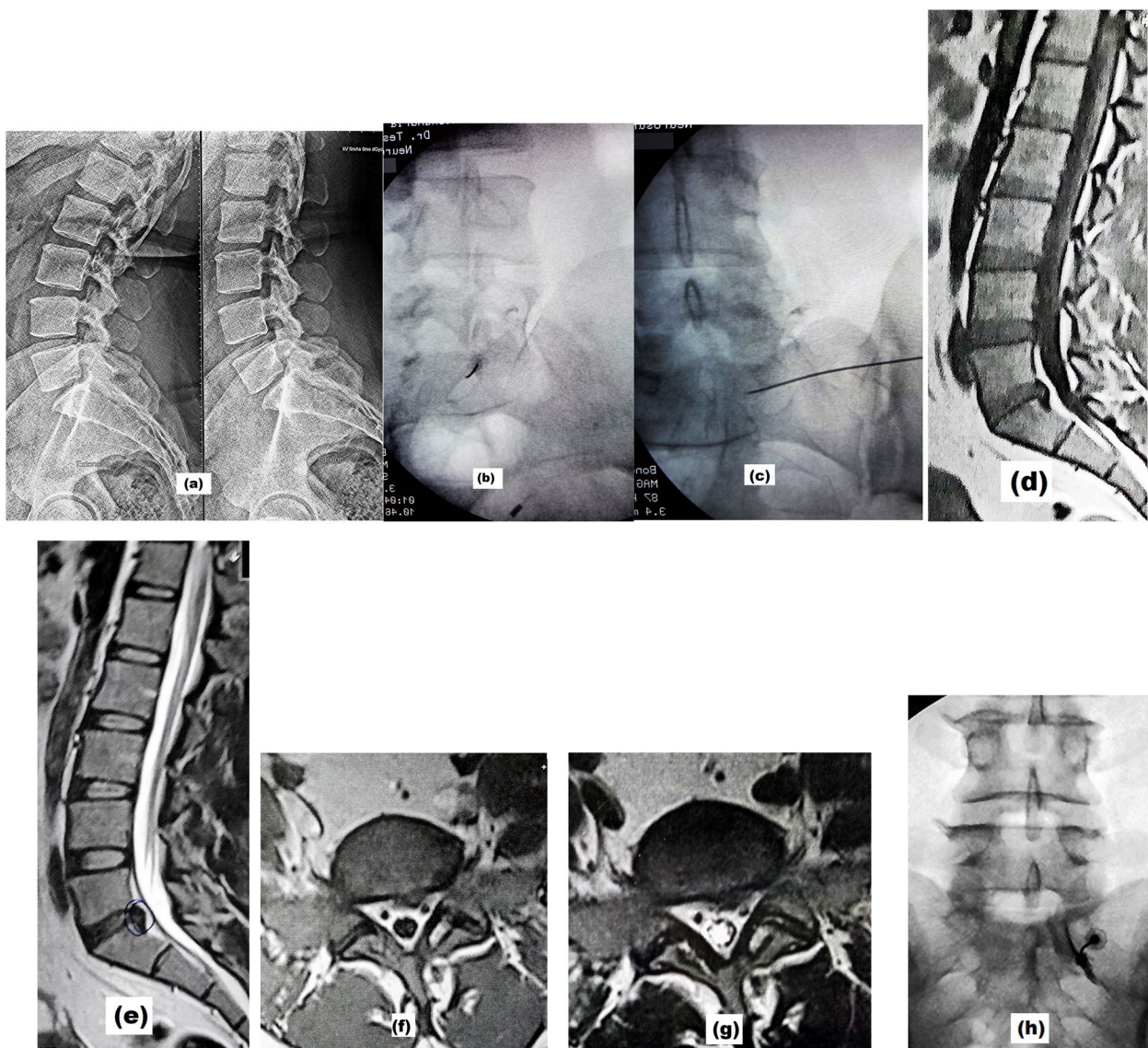
**Fig. 1** Lumbo-sacral spine imaging studies and diagnostic injections of 44-year-old female patient complaining of severe left sciatica since 5 months with chronic low back pain. LSS X-ray [Dynamic standing flexion and extension (a) and (b)] showing normal alignment of the lumbar spine with no signs of instability. Diagnostic injections [lateral (c) and AP (d) views]: Positive L4-5 provocative discography showing type 3 discogram by Adams classification and positive selective left L5 nerve root block. MRI LSS [Sagittal T1 (e), sagittal T2 (f), L4-5 axial T1 (g), L4-5 axial T2 (h)] showing L4-L5 moderate diffuse disk bulge with broad-based central disk herniation indenting the ventral aspect of thecal sac, encroaching upon the neural foramina bilaterally. Intraoperative lateral LSS X-ray showing L4-5 PLIF (i)

The position of the needle tip was confirmed with fluoroscopy before injection of non-irritating dye (Fig. 2). The correct placement was indicated by outlining the nerve root with non-ionic radio-opaque contrast (Ultravist® 300/Bayer), visible on anteroposterior and lateral fluoroscopic views (Fig. 2). After further aspiration, 2.5 ml of bupivacaine was diluted with 7.5 ml of saline solution and injected into the intervertebral foramen and along the path of the spinal needle. A significant relief of pain (more than 60% pain improvement) in distribution of the

blocked nerve root within the first six hours following the selective nerve root block procedure was considered successful blockade.

**Statistical analysis of the data**

Data were fed to the computer and analyzed using the International Business Machines Corporation (IBM) Statistical Package for the Social Sciences (SPSS) software package version 20.0. Qualitative data were described using number and percent. The Shapiro–Wilk test was



**Fig. 2** Lumbo-sacral spine imaging studies and selective nerve root block of 38-year-old female patient complaining of severe left sciatica since 4 months with mild chronic low back pain operated for L5-S1 discectomy following positive left S1 nerve root block. LSS X-ray dynamic standing flexion and extension (a) showing normal alignment of the lumbar spine with no signs of instability, normal spinal canal dimensions. Left S1 selective nerve root block: (b) oblique and AP (c) views showing the position of the tip of spinal needle in the S1 intervertebral foramen. MRI LSS [Sagittal T1 (d), sagittal T2 (e), L5-S1 axial T1 (f), L5-S1 axial T2 (g)] showing L5-S1 posterior disk prolapse with caudal migration with mild compression of ventral thecal sac. Left S1 selective nerve root block AP view (h) after injection of contrast showing the trajectory of S1 nerve root

used to verify the normality of distribution quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range. Significance of the obtained results was judged at the 5% level. Spearman coefficient: to correlate between two distributed abnormally quantitative variables.

**Results**

This prospective non-controlled study was conducted on 30 patients complaining of chronic low back pain and/or lumbar radiculopathy who underwent lumbar spine surgery following positive lumbar spine diagnostic injection. There were 14 (46.7%) female patients and 16 (53.3%) male patients with a mean age of  $42.60 \pm 8.27$  years and a range of 24.0–62.0 years (Table 1). The mean duration of symptoms was  $22.33 \pm 20.78$  months ranged from 4.0 to 60.0 months, while the pain lasted three to six months for six (20.0%) patients, between six and twelve months for eight (26.7%) patients and more than twelve months for 16 (53.3%) patients (Table 1).

Indeed, two types of diagnostic injections, provocative discography and selective nerve root block, were performed either alone for 10 (33.3%) patients or combined for 20 (66.7%) patients (Table 2). Regarding patients with multiple degenerated disk, the provocative discography were performed at different levels and the selective nerve root block were performed at the most suspected

**Table 2** Types of diagnostic injections and surgery

Variables	Total (n = 30)	
	No	%
<i>Types of diagnostic injection</i>		
Provocative discography	4	13.3
Selective nerve root block	6	20.0
SNRB and discography	20	66.7
<i>Types of surgery</i>		
Discectomy	18	60.0
PLIF	12	40.0

*PLIF* Posterior lumbar interbody fusion

level. Patients with positive discography were operated for posterior lumbar interbody fusion. Due to technical limitations to reach the disk for patients with high iliac crest and for patient safety, selective nerve root block was performed alone, especially at lumbosacral junction (L5–S1), for 6 (20.0%) patients. Furthermore, for patients presenting with bilateral radicular pain, selective nerve root block was performed at the most symptomatic side. For the four (13.3%) patients with chronic low back pain and atypical radicular pain, provocative discography was performed alone.

All patients with a positive diagnostic injection underwent lumbar spine surgery, either discectomy for 18 (60.0%) patients or posterior lumbar interbody fusion for 12 (40.0%) patients (Table 2). In all cases, the diagnostic injections were positive only at one level so all of them were operated for single level, either discectomy or PLIF. There were no complications after the diagnostic injection procedures, and no post-surgical complications.

**Table 1** Patient’s general characteristics

Variables	Total (n = 30)	
	No	%
<i>Gender</i>		
Female	14	46.7%
Male	16	53.3%
<i>Age (year)</i>		
Mean	$42.60 \pm 8.27$	
Min–Max	24.0–62.0	
<i>Age range</i>		
20–39 years	10	33.3%
40–59 years	18	60.0%
≥ 60 years	2	6.7%
<i>Duration of symptoms (month)</i>		
Mean ± SD	$22.33 \pm 20.78$	
Min–Max	4.0–60.0	
<i>Duration of symptoms range</i>		
3–6 months	6	20.0
6–12 months	8	26.7
> 12 months	16	53.3

*SD* Standard deviation

**Pain intensity and functional assessments**

Regarding pain intensity, the visual analog scale ranged from 7.0 to 9.90 preoperatively with a mean value of  $8.26 \pm 0.79$ , while the pain decreased significantly postoperatively ranging from 1.0 to 4.0 with a mean value of  $1.97 \pm 0.92$  as shown Table 3. According to pain improvement, the mean reduction in pain intensity was 75.76% with a range of 52.90–89.90. Almost two-thirds of the patients (18/ 60%) experienced more than 75% pain reduction, while pain improvement was less than 75% for the remaining patients (12/ 40%) with a minimum value of 52.9% (Table 3).

Table 4 presents the preoperative ODI ranging from 27.0 to 42.0 with a mean value of  $34.13 \pm 4.88$  and the mean postoperative ODI which was  $11.47 \pm 3.36$  ranging from 8.0 to 21.0. The difference between the preoperative and postoperative ODI was statistically significant. As

**Table 3** General pain assessment

Variables	Total (n = 30)	
	No	%
<i>Visual analog scale</i>		
Preoperative		
Mean	8.26 ± 0.79	
Min–Max	7.0–9.90	
Postoperative		
Mean	1.97 ± 0.92	
Min–Max	1.0–4.0	
<i>p</i>	<b>&lt; 0.001*</b>	
Pain improvement range		
< 75%	12	40.0
≥ 75%	18	60.0
Pain improvement (%)		
Mean ± SD	75.76 ± 11.69	
Min–Max	52.90–89.90	

SD: Standard deviation

\*: Statistically significant at  $p \leq 0.05$ **Table 4** General functional assessment

Variables	Total (n = 30)	
	No	%
<i>Oswestry disability index</i>		
Preoperative		
Mean	34.13 ± 4.88	
Median	34.0	
Min–Max	27.0–42.0	
Postoperative		
Mean	11.47 ± 3.36	
Median	10.0	
Min–Max	8.0–21.0	
<i>p</i>	<b>&lt; 0.001*</b>	
Functional improvement range		
< 50%	2	6.7
≥ 50%	28	93.3
Functional improvement (%)		
Mean ± SD	65.61 ± 11.01	
Median	69.0	
Min–Max	43.20–78.60	

SD: Standard deviation

\*: Statistically significant at  $p \leq 0.05$ 

given in Table 4, the majority of patients (28/93.3%) had a reduction in ODI greater than or equal to 50%, while it was less than 50% for the remaining patients (2/6.7%). The mean percentage of functional improvement after surgery was  $65.61 \pm 11.01\%$  ranging from 43.20 to 78.60%.

**Table 5** Surgical outcomes regarding VAS and ODI

Variables	Total (n = 30)	
	No	%
<i>VAS outcome</i>		
Favorable (VAS < 3)	24	80.0
Non-favorable (VAS ≥ 3)	6	20.0
<i>ODI outcome</i>		
Favorable (ODI ≤ 10)	18	60.0
Non-favorable (ODI > 10)	12	40.0

VAS Visual analog scale, ODI Oswestry disability index

### Surgical outcomes

Most of the patients (24/ 80%) had a favorable outcome regarding the improvement of pain intensity with a postoperative visual analog scale of less than three (Table 5), while one-fifth of patients (6/20%) had a postoperative visual analog scale greater than or equal to three, with the maximum value of VAS equal to 4, considered as a non-favorable outcome as shown in Table 5. The functional outcome was favorable for 18 patients (60%) with a postoperative ODI less than or equal to 10 and non-favorable for 12 patients (40%) with an ODI greater than 10 as shown in Table 5.

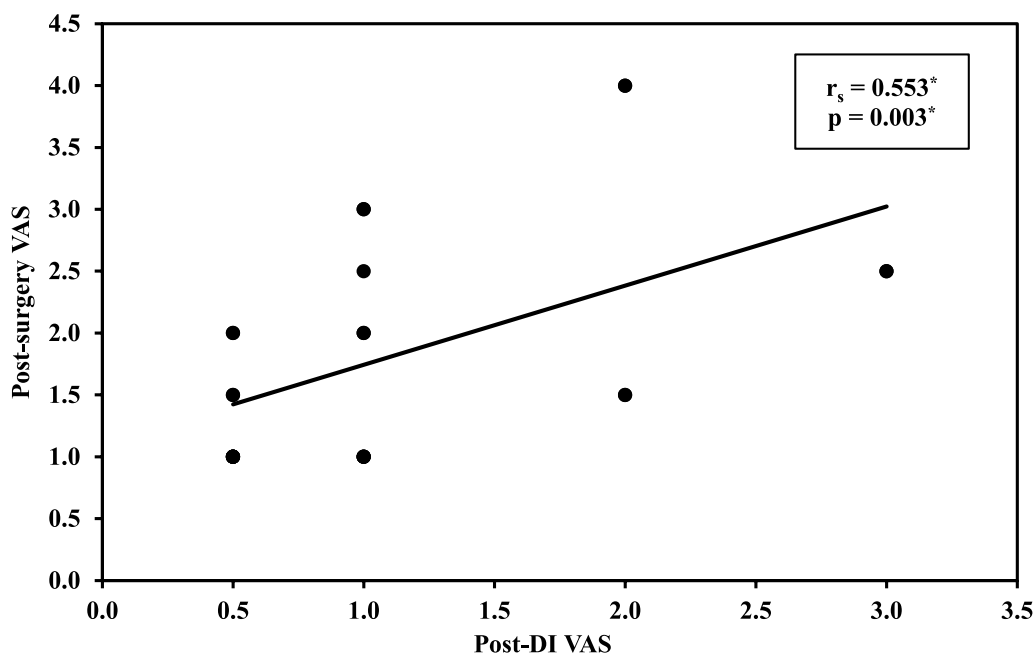
### Correlation and linear regression analysis

The mean visual analog score decreased significantly from  $8.26 \pm 0.79$  with a range of 7.0 to 9.90 before diagnostic injection to  $1.12 \pm 0.75$  ranging from 0.50 to 3.0 in the first six hours following selective nerve root block. The correlation analysis showed the predictive value of post-selective nerve root block regarding the surgical outcomes. The lower the VAS is in the first six hours after selective nerve root block, the greater the decrease in postoperative VAS will be.

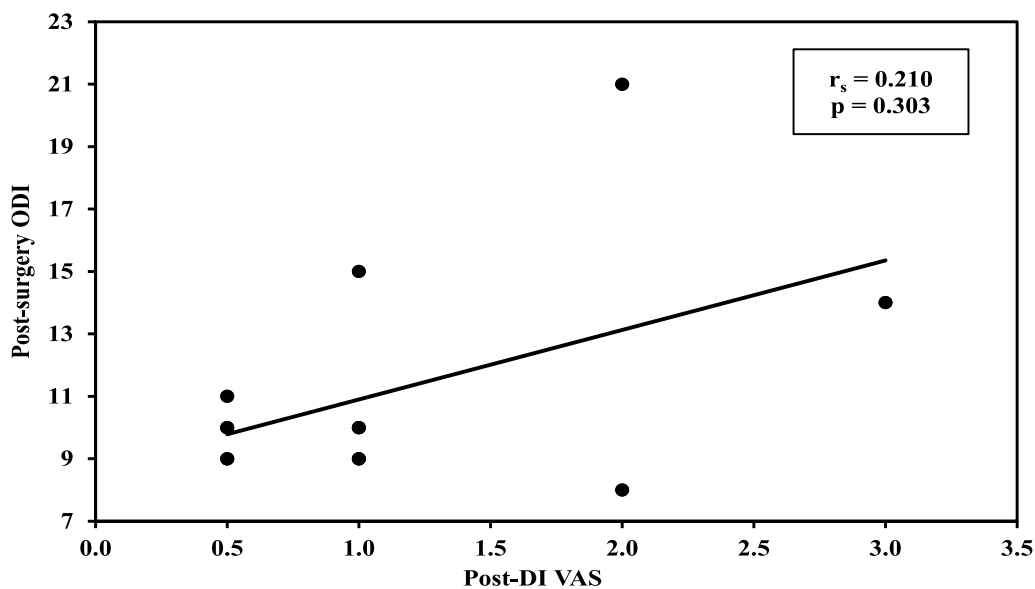
The postoperative visual analog scale was significantly moderately associated with the immediate visual analog scale following the selective nerve root block ( $r_s = 0.553$ ,  $p = 0.003$ ). Figure 3 shows the regression line between the two variables. However, the postoperative ODI was not significantly associated with the post-selective nerve root block as shown in Fig. 4 ( $r_s = 0.210$ ,  $p = 0.303$ ).

### Discussion

Lumbar provocative discography and selective root block are often used for diagnostic reasons to determine a specific source of pain in patients with equivocal radiological findings. Since the advent of MRI and CT (computed tomography) scan, controversies still exist about the role of provocative discography in the diagnosis of degenerative disk disease and the prediction of surgical outcomes. Despite the ability of



**Fig. 3** Correlation between post-diagnostic injection visual analog scale and postoperative VAS.  $r_s$ : Spearman coefficient \*: Statistically significant at  $p \leq 0.05$  VAS: Visual Analog Scale



**Fig. 4** Correlation between post-diagnostic injection visual analog scale and postoperative ODI.  $r_s$ : Spearman coefficient \*: Statistically significant at  $p \leq 0.05$  ODI: Oswestry disability index

advanced imaging techniques to produce better anatomical evaluations surgical lesions, provocative discography remains the only technique to determine if a degenerated disk is the source of pain. Due to its subjective nature depending totally on the description of pain by the patient, there is ongoing debate about the

diagnostic accuracy and validity of provocative discography [13–15].

A systematic review by Ricardo et al. assessing the diagnostic accuracy of discography found strong evidence supporting the value of provocative discography as a diagnostic test for patients with longstanding

discogenic low back pain, moderate evidence, and limited evidence for chronic cervical discogenic pain and dorsal discogenic pain, respectively [14]. Manchikanti et al. [15] also carried out a study evaluating the diagnostic value of provocative discography for chronic low back pain. Their study illustrated the utility of provocative discography in the evaluation of chronic discogenic low back pain and showed it to be level II evidence for diagnostic accuracy when performed according to the criteria of the LBP of the International Association for the Study of Pain. On the other hand, according to Cohen and Hurley systematic review, the evidence for discography for diagnostic accuracy and for predicting surgery was very limited, and there was a lack of randomized studies [16].

Conducted on patients complaining of chronic low back pain and lumbar radiculopathy who showed significant pain relief within the first six hours after selective root block and/or positive provocative discography followed by lumbar discectomy or posterior lumbar interbody fusion, our study showed a significant improvement visual analog scale in the short term postoperative period (from 3-month one-year follow-up). The majority of patients had a favorable pain outcome, and two-thirds experienced a pain reduction of more than 75%. Furthermore, there was a significant improvement in the Oswestry disability index, with most patients having good postoperative functional outcome. These results corroborate with various studies conducted either on provocative discography or on selective nerve root block.

Kim and Cha conducted a cohort study on 52 patients to assess the prognostic role of SNRB. They found good surgical outcome for 40 patients out of 41 patients with positive selective nerve root block and only six patients with good postoperative results out of 11 patients with negative selective nerve root block [17]. All patients were operated on at the level of the positive selective nerve root block and the most suspicious lesion. A similar study by Sasso et al. [12] on 101 patients compared the postoperative outcome among patients with positive results on SNRB and those with negative results. The surgical outcome was significantly better in the positive selective root block group than in the negative selective root block group. They compared the MRI findings with the results of selective nerve root blockade. They concluded that for excluding the presence of a suspected lesion, negative selective root block becomes superior to equivocal or multilevel MRI findings, and/or when the patient's symptoms do not correlate with MRI. Moreover, a retrospective study by Kwon and Chun on 52 patients with radiculopathy who underwent surgery for degenerated lumbar spine disease with or without preoperative selective root block [18] was studied. They evaluated the effectiveness of selective nerve root block in predicting

surgical outcomes. Patients in the SNRB group had better postoperative outcomes regarding VAS than those in the non-SNRB group, although the difference was not statistically significant.

Regarding discography, a randomized controlled trial by Margetic et al. [7] on 310 patients showed that discography was very useful in the detection of the main pain generator and in the surgical selection of patients with degenerated disk disease. The difference between preoperative and postoperative ODI was 17.5 points in the trial group where the patient underwent discography before surgery. While in the control group without discography prior surgery, the difference was 11 points, which is less than the recommended 15 points, and did not achieve significant clinical improvement.

Furthermore, according to correlation and linear regression analysis, this study found a significant positive moderate correlation between post-selective root block visual analog scale and postoperative visual analog scale. There was a strong negative correlation between post-selective root block VAS and postoperative percent of reduction in pain and moderate negative postoperative reduction in ODI, as both correlations were statistically significant. Post-selective nerve root block VAS was also correlated with postoperative ODI, but it was not statistically significant. These findings showed the diagnostic accuracy of selective nerve root block and its ability to predict surgical outcomes in patients complaining of chronic LBP as well as lumbar radiculopathy.

Indeed, few studies have been conducted in order to establish or show a correlation and a linear regression between post-SNRB and surgical outcomes. These results corroborate the study conducted by Ko et al. on 60 patients who underwent selected root block followed by decompressive surgery [19]. Post-selective root block VAS was significantly associated with postoperative improvement of lumbar radiculopathy at one-year follow-up ( $r=0.261$ ,  $p=0.044$ ). However, like the results of our study, there was no correlation between post-selective root block VAS and spinal functional outcomes and quality of life. The authors concluded that the degree of improvement in lumbar radiculopathy within six hours of selective nerve root blockade can predict the degree of improvement seen twelve months after surgery, but cannot estimate functional outcome at any time point.

To assess the prognostic value of SNRB before surgery, Kim and Cha conducted a study on 52 patients, where selective root block was positive for 41 patients and negative for 11 of them [17]. All patients were operated after selective root block regardless of the results. The post-selective nerve root block VAS had a significant strong correlation with the postoperative VAS ( $r=0.65$ ,  $p<0.01$ ), confirmed by logistic regression



analysis where both variables were also correlated significantly (odds ratio = 0.31,  $p = 0.01$ ); thus, the lower the post-SNRB, the better the expected surgical outcome. The specificity and sensitivity of a positive SNRB to predict a good surgical outcome were 75% and 92.5%, respectively. Thus, the authors came to the same conclusion as our study and the Ko et al. study that post-selective nerve root block VAS correlates with postoperative VAS and can predict surgical outcome.

However, this study has certain limitations due to the small number of cases, the absence of a control group and the short follow-up. Further advanced studies are needed in order to assess the ability of diagnostic injection to predict surgical outcomes in patients with chronic LBP and lumbar radiculopathy.

## Conclusion

This study showed that the use of lumbar diagnostic selective nerve root block and lumbar provocative discography for patients with chronic low back pain and radiculopathy and equivocal radiological findings can improve surgical outcomes regarding pain intensity using VAS and functional assessment of the spine using ODI. Selective nerve root block can predict the postoperative pain improvement although it was not correlated with the postoperative functional outcome. Thereby, provocative discography and/or selective nerve root block are important diagnostic tools in decision-making for patients with equivocal radiological findings.

## Abbreviations

AP	Anteroposterior
CT	Computed tomography
IBM	International Business Machines Corporation
LBP	Low back pain
LSS	Lumbosacral spine
MRI	Magnetic resonance imaging
ODI	Oswestry disability index
PLIF	Posterior lumbar interbody fusion
SD	Standard deviation
SNRB	Selective nerve root block
SPSS	Statistical Package for the Social Sciences
VAS	Visual analog scale

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## Author contributions

All authors equally participate in operating patients, data collection, data analysis, and scientific writing. MB performed the diagnostic injection procedures. All authors read and approved the final manuscript.

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## Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Declarations

### Ethical approval and consent to participate

The local Ethical Committee of the Faculty of Medicine, Alexandria University, provided ethics approval. Reference number IRB 00012098 was obtained on May 25, 2021. Consent for participation was obtained from each patient prior to the study.

### Consent to publication

Not applicable. We confirm that all data incorporated into this study are anonymized.

### Competing interests

The authors declare that they have no competing interests.

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