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ORIGINAL ARTICLE • SPINE - MEDICAL STATISTICS

Comparative responsiveness of four visual analogue scales in microdiscectomy for lumbar disc herniation

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Abstract

Introduction There is a paucity of studies reporting responsiveness of visual analogue scale (VAS) measures in patients treated by discectomy for symptomatic lumbar disc herniation. The aim of this study was to evaluate the responsiveness of different types of VAS.

Methods VAS score was measured separately for constant leg pain (VAS-LP-constant), severe episode of leg pain (VAS-LP-severe), constant backache (VAS-BP-constant) and severe episode of backache (VAS-BP-severe) in a cohort of patients undergoing discectomy surgery for sciatica. VAS was evaluated preoperatively and postoperatively at final follow-up. Responsiveness was determined using standardised response mean (SRM), effect size (ES) and the area under the curve (AUC) analysis using receiver operating characteristic curves. For AUC analysis, the success of discectomy from the patient's perspective was chosen as the external anchor.

Results Ninety-eight patients were included in this prospective study. Outcome was assessed at a mean follow-up of 12 weeks postoperatively. The SRM of VAS-LP-severe, VAS-LP-constant, VAS-BP-severe and VAS-BP-constant was 2.16, 2.16, 0.87 and 0.53, respectively. The ES of VAS-LP-severe, VAS-LP-constant, VAS-BP-severe and VAS-BP-constant was 3.53, 2.70, 0.89 and 0.53, respectively. The AUC of VAS-LP-severe, VAS-LP-constant, VAS-BP-severe and VAS-BP-constant was 0.88, 0.75, 0.74 and 0.59, respectively.

Conclusion We recommend the use of VAS-LP-Severe as the most responsive VAS measure when evaluating the results of discectomy surgery for sciatica.

Keywords Responsiveness · Lumbar disc herniation · Discectomy · Visual analogue scale (VAS)

Introduction

Responsiveness is the ability of the instrument to detect clinically relevant changes over time [1]. Responsiveness is a context-specific term, and evidence of responsiveness is applicable only to the population of study and the intervention being studied [2, 3]. The responsiveness of an outcome measure depends on a number of factors, such as demographic characteristics of subjects, type of intervention, time of evaluation of outcome and the construct of change being studied [4]. Knowing which outcome measure is most responsive in operatively treated lumbar spinal conditions would have bearing on choice of an outcome measure to be used, and on sample size calculation for randomised controlled trials in surgical interventions. An adequate sample would ensure statistical power is not compromised. A less responsive instrument would need a larger sample size incurring an additional financial burden while a highly responsive instrument would need a smaller sample size [5]. Using an outcome instrument that fails to demonstrate adequate responsiveness might lead to an erroneous interpretation regarding effectiveness of a surgical procedure.

The visual analogue scale (VAS) is used commonly to assess severity of pain after treatment of low lumbar backache. Validity, reliability and responsiveness of VAS for pain assessment have been established but these have been

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in studies evaluating non-surgical treatment of non-specific backache [6–9]. The VAS is commonly assessed separately for backache and leg pain. To the best of our knowledge, there are no studies comparing responsiveness of VAS in patients undergoing microdiscectomy for lumbar disc herniation. The objective of this study was to compare responsiveness of VAS of backache and leg pain using different statistical methods.

Methods

This quantitative, single-site, prospective, observational, cohort study was undertaken after obtaining approval from the hospital research and clinical audit department. A prospective survey linked to service evaluation was undertaken.

No formal estimation of sample size or power calculation was performed before undertaking the study. There is no universally accepted method to estimate sample size for studies on responsiveness. We aimed to have a sample of more than 50 subjects as a sample size of more than 50 subjects is considered optimal [10].

Consecutive patients who underwent discectomy from January 2009 to October 2010 were included in the study. All cases were either performed or supervised by one spinal surgeon. Patients who underwent non-instrumented surgical intervention in the form of discectomy for lumbar disc prolapse were included in the study. All patients had primarily leg pain that was unresponsive to non-operative methods of treatment such as analgesics and physiotherapy. Patients undergoing instrumented spinal surgery, decompression for tumour, trauma and infection were excluded from the study. Written consent was obtained before patients underwent the surgical procedures.

Outcome instruments

The VAS ranges from 0 (no pain) to 10 (most severe pain). The VAS was measured separately for backache and leg pain. As most patients have constant background pain with intermittent severe painful episodes, VAS was measured separately for constant leg pain (VAS-LP-constant), severe episode of leg pain (VAS-LP-severe), constant backache (VAS-BP-constant) and severe episode of backache (VAS-BP-severe). Patients made a mark along a 10 cm long line between 0 (no pain) and 10 cm (worst imaginable pain), and the score is measured from the line to one decimal place.

Data collection

Preoperative data were collected in the hospital ward on the day of operation. Data relating to age, gender, type of surgical intervention (primary or revision discectomy) and the level of pathology were collected. The patients were invited to complete self-assessment of VAS-BP-constant, VAS-BP-severe, VAS-LP-constant and VAS-LP-severe preoperatively on the day of the surgery. All patients were seen postoperatively in clinic 6–12 weeks after the operative intervention and were invited to repeat evaluation of self-assessment of severity of pain using the same VAS measures. As the value of VAS could change during the day or time due to fluctuation in symptoms, the patients were asked to mark their pain level during their worst condition during exacerbation and this represented 'severe pain' and the continuous background pain represented 'constant pain'. Patients were also asked to rate the success of the operative intervention. The questionnaires were completed in paper and pen format.

Based on the question, 'Has the operation been a success?' the patients rated their assessment as 'yes', 'partially' and 'no'. In order to categorise the above external criteria, the ordinal data were converted into binary data. For patient assessment of success of operation, the response 'yes' was grouped as 'responder' while the responses 'partially' and 'no' were categorised as 'non-responder'.

Data analysis

The mean change in the VAS score was the averaged difference between the preoperative VAS score and the postoperative VAS score of individual cases. On the VAS, a positive change score indicated improvement in clinical condition. The data were analysed using IBM SPSS for Windows version 19. Paired *t* test was used to evaluate the statistical significance of the change in the score, and the level of significance was set at 5%.

Distribution-based methods to calculate responsiveness

Standardised response mean (SRM) is the mean change in the value of the outcome instrument divided by the standard deviation of the change in the value of the outcome instrument [11, 12]. Effect size (ES) is the mean change in the value of outcome instrument divided by the standard deviation of the value of the outcome instrument at baseline (pre-intervention) [11, 12]. Both ES and SRM were interpreted as per Cohen's criteria wherein values of 0.2, 0.5 and 0.8 are considered as small, moderate and large effects, respectively [13]. ES and SRM values more than 0.80 are considered optimal evidence of responsiveness of an outcome instrument [14]. The outcome instrument having the highest values of SRM and ES is considered to be the most responsive [15, 16].

Anchor-based methods to calculate responsiveness

Receiver operating curves (ROC) are graphical plots that are used to visually depict diagnostic capabilities of various tests mainly in the specialities of radiology, pathology and biochemistry and also to determine the best cut-off point of a diagnostic test. The ROC is an indicator of how capable the pain severity instrument is at distinguishing patients who felt that the operation was successful (responders) from patients who felt that the operation was not successful (non-responders). ROC is plotted with sensitivity on the *Y*-axis and 1-specificity on the *X*-axis. Sensitivity is the proportion of patients who actually felt that their operation was successful and the pain severity instrument successfully identified them to be 'responders'. Sensitivity can also be construed as an indicator of the true positive rate. 1-specificity is the proportion of patients who actually felt that their operation was unsuccessful but the pain severity instrument incorrectly identified them to be 'responders'. 1-specificity is an indicator of false positive rate or Type I error. An ideal pain severity assessment instrument will have 100% sensitivity and zero value of 1-specificity (100% specificity); however; this is seldom the case. The area under the curve (AUC) is calculated from the ROC curve. AUC value of 0.5 (no discriminatory accuracy) indicates that the ability of the instrument to differentiate patients who improved from those who did not improve is no better than chance. AUC value of 1.0 (perfect discriminatory accuracy) indicates perfect discriminatory ability of the instrument. AUC value of ≥ 0.70 is considered as optimal evidence of responsiveness, and AUC value < 0.70 is considered as evidence of inadequate responsiveness of an outcome instrument [2, 14]. The higher the AUC, the better the pain severity instrument is at discriminating between patients who were classified as 'responders' and felt that the operation was successful and patients who were classified as 'non-responders' and felt that the operation was not successful. An instrument with the highest AUC is considered to be the most responsive [2, 14].

Results

Demographic characteristics

There were 98 participants in the study. The mean age of the study population was 44 years. There were 51 (52%) male and 47 (48%) female participants. Eighty patients (82.5%) had both backache and sciatica, whereas 17 patients (17.5%) had only sciatica preoperatively. Ninety-six (98%) patients had single-level disc prolapse, and two (2%) patients had disc prolapse at two levels. Forty-nine patients (50%) had disc prolapse at L5–S1 level, 45 patients (45.9%) had disc prolapse at L4–L5 level, two patients had disc prolapse at L3–L4 level and two patients (2.2%) had disc prolapse at both L4–L5 and L5–S1 levels. Eighty-five patients (86.7%) underwent primary microdiscectomy, and 13 patients (13.3%) underwent revision microdiscectomy.

The mean postoperative assessment was at 3 months (range 4–25 weeks).

Table 1 Patient response and assessment of success after operative intervention in discectomy group

Outcome response	Frequency (%)
External anchor	
Success of operation ($N=93$ [94.9%])	
Patient response	
Yes	75 (80.6%)
Partially	13 (14%)
No	5 (5.4%)
Created sub-groups	
Responders	75 (80.6%)
Non-responders	18 (19.4%)

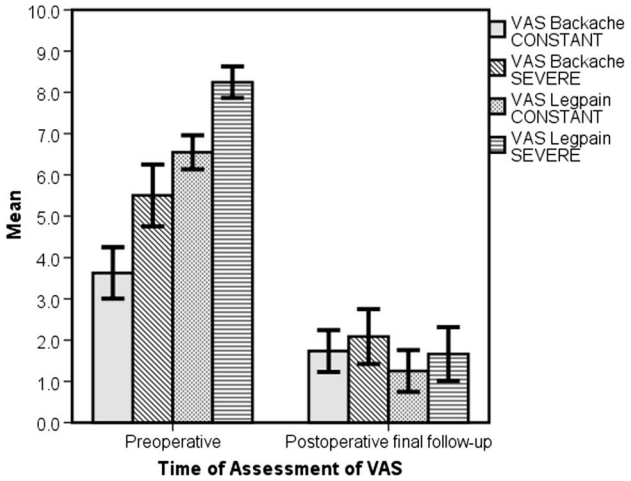

Fig. 1 Significant improvement in values of all severity of pain measurement instruments postoperatively at final follow-up compared to preoperative values

Patient response to operative intervention

Table 1 shows the response of patients to discectomy and their perception regarding the effectiveness of the operative intervention. Figure 1 and Table 2 describe preoperative values, postoperative values and change in values of severity of pain instruments and show significant improvement in scores of all pain measurement instruments.

Table 2 Overall preoperative, postoperative values, difference between preoperative and postoperative values and statistical significance of the change in the value of outcome instruments in lumbar discectomy group

Outcome instrument	Preoperative mean (SD)	Postoperative mean (SD)	Mean (SD) of change in score	95% confidence interval of change in score	*p* value
VAS leg pain severe	8.2 (1.9)	1.6 (2.9)	6.7 (3.1)	6.0–7.3	< 0.0001
VAS leg pain constant	6.6 (2.0)	1.3 (2.4)	5.4 (2.5)	4.8–5.9	< 0.0001
VAS backache severe	5.5 (3.7)	2.2 (3.0)	3.3 (3.8)	2.5–4.1	< 0.0001
VAS backache constant	3.6 (3.0)	1.8 (2.4)	1.6 (3.0)	1.0–2.3	< 0.0001

SD standard deviation

Table 3 Results of analysis of both distribution-based methods (SRM and ES) and anchor-based analysis (ROC using AUC)

	VAS leg pain severe	VAS leg pain constant	VAS backache severe	VAS backache constant
Standardised response mean (SRM)	2.16	2.16	0.87	0.53
Effect size (ES)	3.53	2.70	0.89	0.53
Receiver operating curve (external anchor = success of operation from patient's perspective)				
Area under the curve (AUC)	0.88	0.75	0.74	0.59
95% Confidence interval of AUC	0.77–0.99	0.61–0.89	0.60–0.88	0.41–0.77
p value	< 0.0001*	0.003*	0.004*	0.27

*Suggests that *p* value was significant

Distribution-based method

Table 3 shows that all instruments except VAS-BP-constant showed large effect as per Cohen's criteria for both standardised response mean (SRM) and effect size (ES). All instruments except VAS-BP-constant demonstrated adequate responsiveness using distribution-based methods. VAS-LP-severe showed the highest SRM and ES values, thereby demonstrating highest responsiveness amongst all pain measurement instruments. VAS-BP-constant showed the least responsiveness.

Anchor-based method

Table 3 depicts that area under the curve (AUC) analysis showed that all pain measurement instruments except VAS-BP-constant demonstrated adequate external responsiveness. Figure 2 shows the AUC of different pain measurement instruments. AUC analysis showed that VAS-LP-severe has the highest responsiveness and VAS-BP-constant has the lowest responsiveness. The discriminatory ability of VAS-BP-constant was not statistically significant.

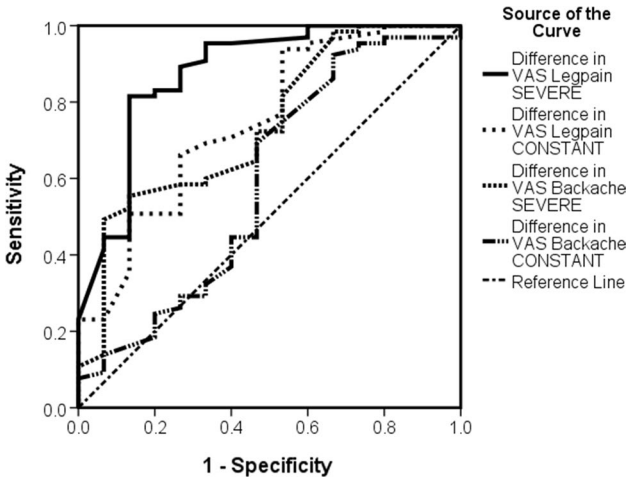

Fig. 2 Area under the curve of various patient-reported pain severity instruments using the success of discectomy from patient's perspective as an external anchor. VAS-LP-severe has the highest AUC, and VAS-BP-constant has the lowest AUC

Discussion

No previously published study on surgical treatment of lumbar spine pathologies has formally reported responsiveness of VAS for back pain (VAS-BP) or VAS for leg pain (VAS-LP). However, in those studies, preoperative values of VAS, postoperative values of VAS and change in values of VAS were given, and from those data, it was possible for us to calculate the SRM and ES. Also in a few studies, the objective was to calculate the minimal clinically important difference of outcome instruments, and in those studies, the values of area under the curve for VAS-BP and VAS-LP were given, and it was possible to extract relevant data from

that information [17–20]. The study by Mannion et al. was on a heterogeneous population of patients with diverse spinal procedures such as decompression, spinal fusion, metalwork removal or combination of the above procedures [21]. The other studies involved a homogenous cohort of patients with specific procedures for specific indications such as transverse lumbar interbody fusion for grade 1 and grade 2 spondylolisthesis, revision posterior lumbar instrumented fusion for backache due to pseudoarthrosis, posterior fusion with extension of previous fusion construct for adjacent segment disease and revision decompression with posterior instrumented fusion for same-level recurrent lumbar canal stenosis [17–20].

The SRM value of VAS-BP in our study ranged from 0.53 to 0.87. In previous studies, the SRM of VAS-BP has been in the range 0.88 to 1.48 [17–21]. The low SRM value observed in the present study could be due to distinction between VAS-BP-constant and VAS-BP-severe. The SRM value of VAS-LP in our study was 2.16 which was higher than previously reported SRM values of VAS-LP which ranged from 1.0 to 1.85 [17, 19–21].

The ES of VAS-BP in the present study ranged from 0.53 to 0.89 which was much lower than previously reported values of ES of VAS-BP which ranged from 2.53 to 4.30 [17–20]. The ES of VAS-LP in the present study ranged from 2.70 to 3.53. The ES of VAS-LP in the literature has been reported in the range of 0.85 to 6.78 [17, 19–21].

The AUC of VAS-BP in our study ranged from 0.59 to 0.80. The AUC value of VAS-BP in previous studies has ranged from 0.69 to 0.93 [17–20]. The AUC of VAS-LP in our study ranged from 0.75 to 0.90. The AUC value of VAS-LP in previous studies has ranged from 0.65 to 0.83 [17, 19, 20].

In our study, both distribution-based and anchor-based methods demonstrate that VAS-LP was more responsive than VAS-BP. This is likely to be because the main indication for microdiscectomy for lumbar disc herniation is unrelenting sciatica and hence postoperatively after successful discectomy, most patients felt significant relief in leg pain. Our findings bear comparison to the findings observed in two studies that evaluated results of surgical treatment for lumbar backache in which the responsiveness of VAS-BP was higher than VAS-LP [17, 19]. The likely explanation is that both the studies involved patients for whom the predominant symptom was backache due to spondylolisthesis or adjacent disc disease.

Being an observational, cohort study, this study was prone to selection bias, information bias, confounding bias and lost-to-follow-up bias [22, 23]. Consecutive operated cases were selected in order to lessen selection bias. Information bias was reduced by using well-defined, validated outcome instruments, and all questionnaires were self-administered only by the patients. The patients decided whether the operative procedures were successful or not. Confounding bias was reduced by a single surgeon being involved in patient selection and operation. Lost-to-follow-up bias was reduced by actively tracing case notes of patients. The present study is the first study to compare responsiveness of VAS-BP-constant, VAS-BP-severe, VAS-LP-constant and VAS-LP-severe in a homogenous group of patients that underwent discectomy for lumbar disc herniation. The study was methodologically robust as we used both distribution-based and anchor-based methods to evaluate responsiveness. Our sample size of 98 patients could be considered as having good number of patients as per COSMIN checklist [24]. Moreover, our sample size was much larger than the sample size of previous studies in surgical cohort wherein the sample size varied from 47 to 57 participants [17–21].

The present study could be criticised for not comparing patient-reported outcome instruments for severity of pain such as VAS for back pain and leg pain with other functional outcome instruments such as Oswestry disability index, Roland Morris disability questionnaire or quality of life instruments such as SF-36 and SF-12. Pain and functional outcomes are different paradigms measuring different aspects of success, and hence, comparing dissimilar instruments might not be justified. External validity could be affected as this was a single-centre study, operated by or supervised by a single surgeon performing a single surgical procedure for a specific condition. The results of this study are applicable only to patients with lumbar disc herniation and treated with lumbar discectomy. Hence, it cannot be applied to group of patients having backache and sciatica due to other causes such as spondylolisthesis and spinal canal stenosis.

The study was undertaken as part of service evaluation audit of spinal surgery services at our district general hospital. Patients were discharged to the care of the GP at either 6 weeks or 3 months depending on the clinical progress of the patient. Hence, long-term follow-up was not undertaken in the study. However, we do not think of this as a limitation because after lumbar discectomy, significant improvement is observed in VAS for backache and VAS for leg pain by as early as 6 weeks [25, 26].

Though pain intensity assessment instruments and functional outcome assessment instruments evaluate different domains, future studies could probably assess correlation between pain and functional outcome instruments with reference to lumbar discectomy.

Conclusion

We recommend evaluation of VAS separately for constant pain and intermittent severe episodes of pain because the responsiveness is different for both the measurements. Also

we recommend that VAS be evaluated separately for back pain and leg pain. VAS-LP-severe, VAS-LP-constant and VAS-BP-severe demonstrated adequate responsiveness. We found that VAS-LP-severe has the highest responsiveness amongst all pain measurement outcome instruments in patients after lumbar discectomy and is the VAS measure of choice for evaluating interventions for patients with sciatic leg pain.

Author contributions All authors were involved in conception and design and collected and assembled the data. Ian Braithwaite was involved in provision of patients. Ian Braithwaite provided administrative support. All authors analysed and interpreted the data. Karthik Vishwanathan was involved in manuscript drafting. Ian Braithwaite contributed to critical revision of the manuscript and supervision.

Compliance with ethical standards

Conflict of interest Dr. Karthik Vishwanathan and Mr. Ian Braithwaite declare that they have no conflict of interest pertaining to the present manuscript.

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