Original Study

Three-year follow-up of a randomized controlled trial comparing preoperative neuroscience education for patients undergoing surgery for lumbar radiculopathy

Adriaan Louw[1], Ina Diener[2], Merrill R. Landers[3], Kory Zimney[4], Emilio J. Puentedura[3]

[1]International Spine Pain Institute, Story City, IA, USA; [2]Department of Physiotherapy, Stellenbosch University, Stellenbosch, South Africa; [3]Department of Physical Therapy, School of Allied Health Sciences, University of Nevada Las Vegas, Las Vegas, NV, USA; [4]Department of Physical Therapy, South Dakota University, SD, USA

Correspondence to: Dr. Emilio J. Puentedura, Associate Professor. Department of Physical Therapy, School of Allied Health Sciences, University of Nevada Las Vegas, 4505 Maryland Parkway, Box 453029, Las Vegas, NV 89154-3029, USA. Email: louie.puentedura@unlv.edu.

Background: Results from a previous multicenter randomized controlled trial (RCT) on preoperative pain neuroscience education (PNE) for lumbar radiculopathy found no significant difference in patient reported outcomes between groups. However, patients who received PNE viewed their surgical experience more favorably and utilized significantly less healthcare compared to those that did not. The purpose is to determine if the reduction in healthcare costs from 1-year would be continued at 3-year following surgery, and to explore differences (if any) in patient reported outcomes. Study design—analysis of 3-year follow-up data from RCT on preoperative PNE for lumbar radiculopathy.

Methods: Participating patients from the previous RCT were contacted for 3-year follow-up. Of the 67 patients who commenced in the study, there were 61 who completed 1-year follow-up. Data packets were sent to these 61 patients to examine post-operative utilization of healthcare (Utilization of Healthcare Questionnaire); LBP [numeric rating scale (NRS)]; leg pain (NRS); function (Oswestry disability index); and beliefs and experiences related to LS (10 item survey with Likert responses).

Results: At 3-year follow-up, 50 patients (29 females) responded, with 22 patients in the experimental group (EG) and 28 in the control group (CG). Cumulative medical expenses were 37% lower for the EG, with those patients spending less on X-rays and visits to their family physician, physical therapist, and massage therapist. There were no differences in patient reported outcomes between groups. Patients who received PNE continued to view their surgical experience more favorably compared to those that did not.

Conclusions: Adding a single PNE session prior to surgery for lumbar radiculopathy results in significant healthcare savings over 3 years. Educating such patients about normal responses to lumbar surgery (LS) in a neuroscience framework may result in lasting behavior changes following surgery.

Keywords: Preoperative; postoperative; neuroscience; lumbar surgery (LS); radiculopathy; education; outcomes; health care costs

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Introduction

Pain, especially acute pain, is a normal human experience and an inability to experience pain poses a significant threat (1,2). Persistent pain and the resultant disability associated with it are not normal and pose a significant challenge for healthcare (3,4). Globally, persistent pain has reached epidemic proportions with the United States (US) alone reporting that more than 100 million people suffer from persistent pain (5-7). Persistent pain is also a concern when it comes to lumbar surgery (LS), where various long-term

studies on decompressive LS suggests that 20–25% of post-surgical patients experience persistent pain and disability at 1-year follow-up (8-12).

While pain after LS is to be expected, findings suggest that patients may in fact expect to be "pain free" which questions the current educational models used to prepare patients for such surgery (12-15). Experiencing persistent pain after LS, when little to no pain is expected, may lead to fears that the surgery was not successful and further exacerbate the pain experience (16,17). Louw *et al.* interviewed patients 4 weeks post-LS and 50% of the patients expressed high levels of fear, given the fact that they were still experiencing pain after their surgery (18).

Recent research has evaluated the use of pain neuroscience education (PNE) in decreasing pain and disability among patients undergoing LS (12,13,19,20). PNE, in direct contrast to traditional anatomical- and Cartesian-based models of pain (1,21), aims to educate patients more about the neurobiological and neurophysiological processes associated with persistent pain, including peripheral and central sensitization, inhibition, facilitation, neuroplasticity, etc. (22-24). Various randomized controlled trials (RCT) and a systematic review have shown that PNE has a positive effect on pain, disability, pain catastrophization, and physical movement for patients with chronic low back pain (CLBP), extending to 1-year outcomes (22-26).

In regard to LS, a preoperative PNE program for LS has been developed (13), tested (19,20) and used in a multi-center RCT with 1-year follow-up (12). The preoperative PNE program for LS has been shown to help patients develop a more realistic expectation regarding pain after LS (14), improved satisfaction after LS, and a 45% reduction in healthcare cost in the one year following surgery (12). These results are quite remarkable, considering a single, 30-minute PNE session resulted in healthcare savings of over $2,000/patient compared to the control group (CG). The purpose of this paper is to report on the outcomes at 3-years postoperatively (12).

Methods

Approval for the original study was obtained from the Health Research Ethics Committee at Stellenbosch University, Cape Town South Africa. Patients with lumbar radiculopathy were recruited from seven clinical sites in the US, based on availability of physical therapists and spine surgeons willing to participate in the study. Once participating surgeons determined that their patient would require LS, their assistants set the surgery date and provided administrative and procedural information to the patients. At the same time, patients were informed about the study examining the effects of a preoperative education program and invited to participate.

If they consented, patients were randomized into one of two groups via computer-generated numbers. They were assigned to a CG which would receive the standard preoperative education and an experimental group (EG) which would receive the same standard preoperative education plus PNE delivered in a one-time 30-minute session with a physical therapist. Patients in the EG were advised that this was their surgeon's usual practice. Surgeons and their assistants were blinded to group assignments.

All intake forms were completed by the patients without input from medical staff or researchers and placed in pre-paid sealed envelopes, to be mailed to an independent research assistant for data entry. Final data for this part of the study was collected 3 years after each patient's surgery, via data packets sent out by and returned to the same research assistant.

Study population

Patients diagnosed with operable lumbar radiculopathy, who were scheduled for LS, were invited to participate. Symptoms had to be predominantly leg pain with or without neurological deficit, and participating surgeons concluded that surgical decompression was warranted. Inclusion criteria were: (I) scheduled for LS for radiculopathy; (II) willingness to comply with the predetermined follow-ups; and (III) willingness to complete postoperative questionnaires at designated time intervals. Exclusion criteria were: (I) younger than 18 or older than 65 years; (II) not being proficient in reading or comprehending the English language; (III) scheduled for LS involving instrumentation (e.g., spinal fusion, arthroplasty); (IV) participation in a formal back school or multi-disciplinary pain management program; (V) undergoing LS for a condition other than lumbar radiculopathy; (VI) presence of chronic pain-related conditions (e.g., fibromyalgia, chronic fatigue syndrome); or (VII) symptoms of cord compression. Ninety-two patients were screened for eligibility and after exclusions, 67 agreed to participate and were enrolled in the study. As noted in the CONSORT (27) study diagram (*Figure 1*), 65 patients underwent surgery, and of those, 61 completed the initial study with 1-year follow-up. Of these,

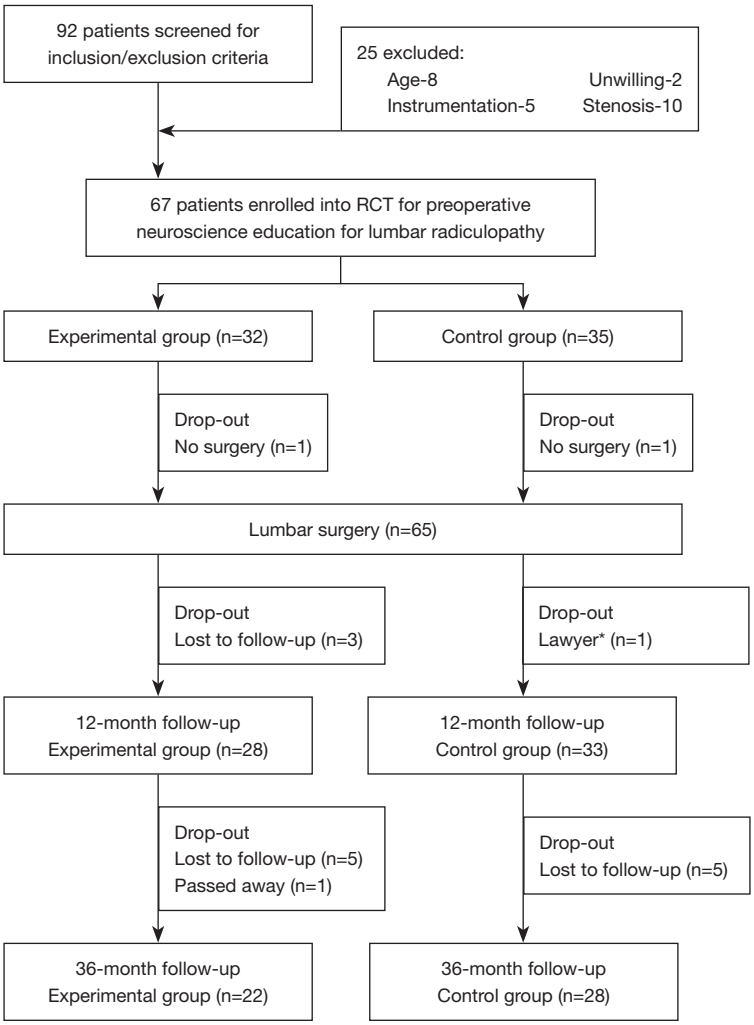

Figure 1 CONSORT diagram of the study. *, patient undergoing litigation and lawyer directed patient withdrawal from study.

11 were lost to follow-up at 3 years, leaving a total of 50 patients.

Trial interventions

Patients in the CG received what constitutes standard preoperative preparation and education from their respective surgeons and staff. To ensure standardization of this education, each participating surgeon (n=7) was asked to complete the Spine Surgery Education Questionnaire (SSEQ) (14). Two investigators independently reviewed the surgeons' responses to ensure their preoperative education was consistent with the findings of the SSEQ. All participating surgeons provided 'standard of care' per the SSEQ.

The development and content of the preoperative PNE has been published elsewhere (13,19,22). Briefly, PNE deemphasizes the traditional anatomical tissue- and Cartesian-based models of pain (1,21), and aims to reduce the fear associated with LBP by providing more information about pain and the neurophysiology of a pain experience. Patients in the EG received the same preoperative preparation and education as the CG with the addition of a preoperative PNE program. The PNE program was provided by participating physical therapists in a one-on-one verbal format, in a conversational and personal approach rather than lecture format and included the use of pictures, examples, metaphors and drawings as needed. Standardization of this PNE program by each therapist was achieved through use of a systematic checklist.

Outcome measures

The primary outcome of interest 3 years after LS was healthcare utilization. Secondary outcome measures were back and leg pain, function and satisfaction ratings regarding the LS.

Healthcare utilization 3-years post LS

Patients were provided with copies of their responses to the 1-year information packets regarding their healthcare utilization in the first year after LS. Patients were then asked to indicate if they had any, and how many, additional of the following medical tests specifically related to their postoperative care: radiographs (X-ray); magnetic resonance imaging (MRI); computerized tomography (CT); bone scan; nerve conduction test (NCT); myelogram; and/or, other medical tests. Additionally, patients were asked to report if they had received any post-surgical treatment or attended for consultations with their spine surgeon; family doctor; physical therapist; other specialist physicians; chiropractor; massage therapist; acupuncturist; psychologist; psychiatrist; and/or, other healthcare professionals. In both cases (medical tests and healthcare providers), patients were asked to indicate how many times they had the tests or treatments. Examples were provided to aid the patients. Data were gathered to determine the total number of visits for each medical test and visits per healthcare provider. For each test and healthcare provider visit, a financial cost was calculated based on the average cost for such tests and visits in the US (www.cms.gov).

Secondary outcome measures

Low back and leg pain were measured using the numeric pain rating scale (NPRS). The NPRS is considered a reliable scaled measure of pain which has a minimal detectable change (MDC) of 2.1 (28), and it has been used in various RCTs for PNE and spinal pain (24,26,29). Level of function at 3-years post-surgery was measured via the Oswestry disability index (ODI) which has very good evidence for its reliability and validity related to low back pain (LBP) (30-32). A change of 5 points (10%) is reported to be the MDC for LBP populations (33). Finally, patients were asked to indicate by means of a numeric scale [1-10] their level of agreement (1 indicating minimal and 10 indicating maximal agreement) with 5 statements about their LS and preoperative educational experience (18,34,35):

(I) "I am glad I underwent surgery for my leg pain";
(II) "I was fully prepared (physically, emotionally, psychologically) for the surgery";
(III) "The preoperative education I received prepared me well for the surgery";
(IV) "Knowing what I know now, I would do this again given the same choices";
(V) "The surgery met my expectations".

Statistical analysis

All analyses were conducted using SPSS version 22.0 (Armonk, NY, USA: IBM Corp) using the significance threshold of α=0.05. As the initial results of this trial (pre, 1 month post, 3 months post, 6 months post, and 1 year post) have already been reported in a previous publication (12), this analysis will focus on the 3-year data. Total medical expenses at 1 year and 3 years after LS were compared for the experimental and CGs using non-parametric Mann-Whitney tests, which was done because of non-normal distribution of the expense data. Medical subgroup expenses (i.e., radiographs, magnetic resonance imaging, computed axial tomography scans, blood work, nerve conduction velocity testing, myelogram, spine surgeon, family doctor, other physician, physical therapy, massage, chiropractic care, acupuncture, psychological services, psychiatry, other) were also analyzed using Mann-Whitney tests.

Mann-Whitney analyses were also used to compare the differences of back surgery-related treatment at the 1- and 3-year points for the following: under current medical care, taking narcotic analgesics, non-steroidal anti-inflammatory medications (NSAIDs), nerve-related medications, antidepressants, and muscle relaxants. The following candidates were analyzed as potential covariates (none met the threshold of correlational coefficients >0.70): age, gender, education, income, and duration of symptoms.

To determine differences in secondary outcome measures between the groups at 3 years, 2 (group: experimental and control) ×2 (time: 1-year post and 3-years post) mixed factorial ANOVAs on three different outcome measures (LBP, leg pain, Oswestry) were conducted. Violations of sphericity were corrected using the Greenhouse-Geisser or Huynh-Feldt methods. Five additional 2 (group: experimental and control) ×2 (time: 1-year post and 3-years post) mixed factorial ANOVAs were conducted for levels of agreement with the 5 statements about LS and preoperative educational experiences (i.e., glad, feeling prepared, prep went well, would do again, met expectations).

Table 1 Descriptive data comparing the original 65 patients who underwent lumbar surgery (LS) to the 50 patients who completed the 3-year follow-up

Variables	Had LS surgery (n=65)	3-year follow-up (n=50)	P value
Age in years (SD)	49.6 (12.99)	50.5 (13.26)	0.352†
Gender (F)	55.2%	59.2%	0.282*
Symptom duration (d)	91.9 (130.16)	74.3 (95.67)	0.068†

†, *t*-test; *, Chi-squared test.

Results

Patients

At 3-year follow-up after LS, 50 patients (female: 29; 58%) completed the necessary outcome measures (*Figure 1*). There were 22 patients in the EG and 28 in the CG, and *Table 1* provides descriptive data comparing the initial 65 who underwent surgery to the 50 who completed the 3-year follow-up.

Healthcare utilization post LS

Sixteen of the 50 patients (10 from the EG and 6 from the CG) had no further healthcare utilization (medical expenses related to their LS) from 1- to 3-year follow-up. Additionally, 4 patients (1 from the EG and 3 from the CG) underwent a second surgical procedure between years 3 and 1. As previously reported, overall medical expenses (estimated in U.S. dollars) were 45% lower at postoperative 1 year for the EG (mean =$2,678.57, SD =3,135.30) than they were for the CG (mean =$4,833.48, SD =$3,256.00), Mann-Whitney U=345.00, Z=–2.700, P=0.007. Cumulative medical expenses remained 37% lower at postoperative 3 years for the EG (mean =$5,982.27, SD =12,975.16) than they were for the CG (mean =$9,451.79, SD =$10,005.22), Mann-Whitney U=168.00, Z=–2.736, P=0.006 (*Figure 2*). Medical expenses between years 1 and 3 were not statistically significant between the two groups, EG (mean =$3,245.45, 95% CI: $–1,453.64 to $7,944.55) compared to the CG (mean =$5,113.21, 95% CI: $1,668.06 to $8,558.37), Mann-Whitney U=223.00, *Z*=–1.689, P=0.091 (*Figure 3*).

Over the 3 years after LS, the CG subgroup expenses were significantly higher for family doctor treatment (P=0.019); physical therapy (P=0.002); and massage (P=0.031). None of the other subgroup expenses (i.e., X-ray, MRI, CT, blood work, NCT, myelogram, spine surgeon, other physician, chiropractic care, acupuncture, psychological services, psychiatry, other) were significantly different, ps ≥0.117.

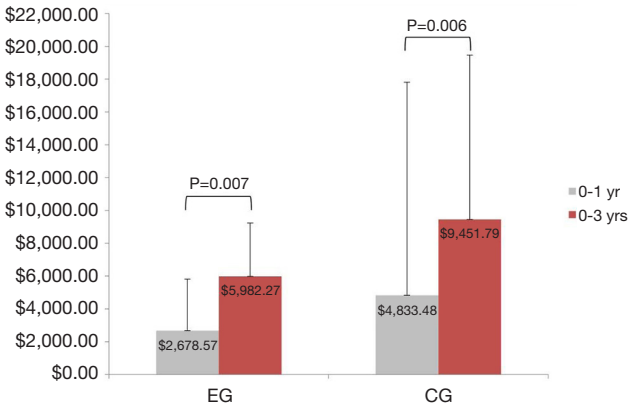

Figure 2 Estimated medical expenses in U.S. dollars (means and standard deviations) related to the LS after 1 and 3years. LS, lumbar surgery.

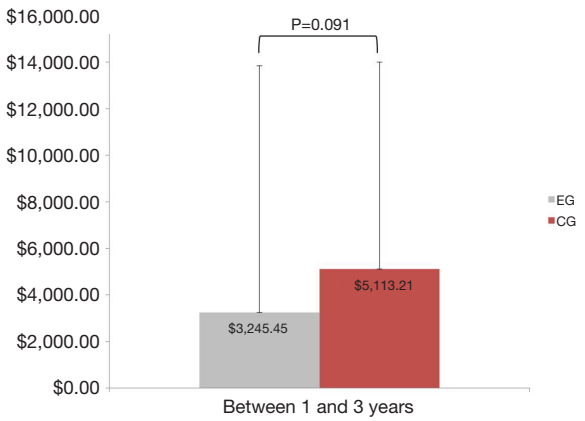

Figure 3 Estimated medical expenses in U.S. dollars (means and standard deviations) for experimental (EG) and control (CG) groups between years 1 and 3 after LS. LS, lumbar surgery.

At 3 years after LS, there were no differences between the two groups in those under current care for their back pain (P=0.913) and taking narcotic analgesics (P=0.482); NSAIDs (P=0.642); nerve-related medications (P=0.084); antidepressants (P=0.393); and muscle relaxants (P=0.822).

LBP

There was no interaction between the EG group and the CG over time on LBP (P=0.405) (*Table 2*). The group

Table 2 P values for the factorial ANOVAs for each outcomes variable

Variable	Interaction	Time main effect	Group main effect
LBP	0.405	<0.001*	0.082
Leg pain	0.665	<0.001*	0.028*
Oswestry	0.520	<0.001*	0.317
Glad about surgery	0.169	0.035*	0.134
Felt fully prepared	0.113	0.121	0.017*
Prep went well	0.203	0.168	<0.001*
Would do again	0.207	0.025*	0.270
Met expectations	0.710	0.221	0.029*

*, statistically significant P<0.05.

main effect was not significant (P=0.082); however, the main effect of time was, suggesting that both groups improved over time. The bulk of improvement occurred from the pre to the 1 year post-test (P<0.001). No significant differences were found between years 1 and 3 (P=0.068) (*Table 2*; *Figure 4*).

Leg pain

There was no interaction between the EG and the CG on leg pain (P=0.665) (*Table 2*). The group main effect was significant (P=0.028) with the CG having more leg pain averaged over the duration of the trial. The time main effect was significant suggesting that leg pain decreased over time regardless of group assignment with the only significant improvement occurring between the pre and the 1 year post-test (P<0.001) (*Table 2; Figure 5*). No significant differences were found between years 1 and 3 (P=0.230).

Low back disability

There was no interaction between the EG and the CG on the Oswestry (P=0.520) (*Table 2*). The group main effect was not significant (P=0.317) but the time main effect was suggesting that low back disability decreased over time regardless of group. Oswestry scores decreased significantly from baseline to 1 year (P<0.001) (*Table 2; Figure 6*). No significant differences were found between years 1 and 3 (P=0.761).

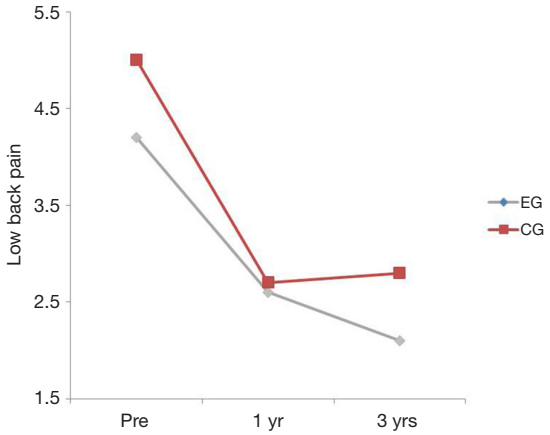

Figure 4 Low back pain over the 3 years for both groups.

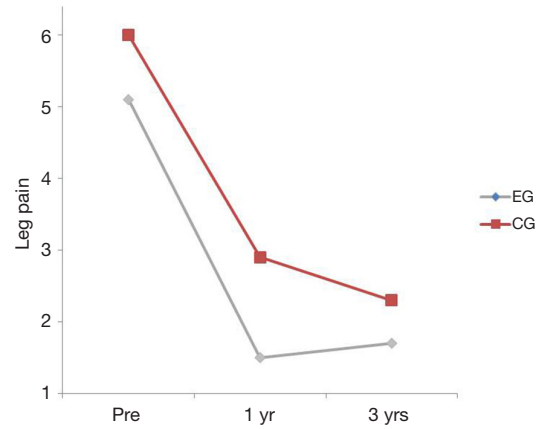

Figure 5 Leg pain over the 3 years for both groups.

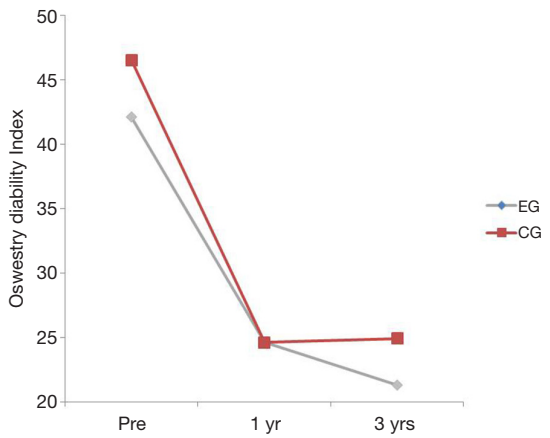

Figure 6 Low back pain disability (Oswestry disability index) over the 3 years for both groups.

Table 3 Means and standard deviations for perceptions related to the LS

Variable	Group	1 year	3 years
Glad about surgery	Experimental	8.9±2.92	8.8±2.89
	Control	7.9±3.24	6.6±4.08
Felt fully prepared	Experimental	9.3±1.25	8.8±2.65
	Control	6.7±2.88	7.4±3.27
Prep went well	Experimental	9.1±1.38	8.8±2.38
	Control	6.8±2.70	7.1±3.19
Would do again	Experimental	8.5±3.42	8.6±2.87
	Control	7.7±3.43	6.4±4.31
Met expectations	Experimental	8.5±3.02	8.3±2.92
	Control	7.3±3.26	6.1±3.93

LS, lumbar surgery.

Post-LS satisfaction

There was no significant interaction between the two groups on post-treatment perceptions of LS (*Tables 2,3*). The group main effects were significantly different for "*felt fully prepared*", "*preoperative prepared me well*", and "*met expectations*" with those in the EG having more agreement with the statements compared to the CG averaged over the 3 years. The time main effect was significantly different for all except "*felt fully prepared*", "*preoperative prepared me well*", and "*met expectations*". Of the two that had a significant main effect for time, the pairwise comparisons did not reveal any change over time for either "*glad I underwent surgery*" (ps ≥0.058) or "*I would do again*" (ps ≥0.117).

Discussion

Despite reporting similar LBP, leg pain and disability 3-year after LS, patients who were taught about the neuroscience of pain, continued to spend less on healthcare compared to patients not receiving such education prior to surgery. The results from this 3-year follow-up RCT on preoperative PNE for LS show that favorable behavior changes 1 year after LS persisted 2 years later. Furthermore, this study highlights the relative success of LS for radiculopathy after 3-year regardless of preoperative education, as both groups reported improved LBP, leg pain and disability compared to pre-surgery.

Pain following LS is to be expected and some level of continued pain and disability appears to be the common experience. The results from this study along with various other studies have shown that a percentage of patients who undergo LS for radiculopathy should expect to continue to experience low level LBP averaging of 2.5–3 out of 10 on the NPRS for 6–12 months post-surgery (16,36-39). Similarly, patients following LS also report persistent disability (16,36-39). In this study, three years after LS, patients in both arms of this study reported moderate disability in excess of 20%. Modern pain science, which therapeutically culminates in teaching people about the neurobiological processes of pain, aims to normalize these experiences (22,40). Reconceptualization of pain is a main focus of PNE, along with aiming directly at pain catastrophization and fear-avoidance (22,41-43). This study demonstrates that the introduction of PNE prior to LS led to behavior change in regards to utilization of health care expenditures after surgery. It has been argued that behavior change needs to last 6 months to 5 years to indicate true change (44,45). At 3 years out, this study shows the behavior change found at 1 year continues through the 3 year follow-up.

Traditional models used to educate patients are biomedically driven with information on anatomy, pathoanatomy and biomechanics (40,46,47). It is argued that these models fall short by virtue of their focus on anatomy and pathoanatomy, which cannot readily explain persistent pain beyond the normal expected phases on healing (46). These traditional models can often infer that persistent pain is due to ongoing tissue damage (48,49). In contrast, modern pain science, by embracing neuroplasticity, peripheral and central sensitization as well as facilitation and inhibition provides a plausible understanding of a persistent pain experience (21,40). Evidence of traditional biomedical educational models failing is demonstrated by the study by Morris *et al.* (50) utilizing a similar multi-center RCT evaluating the outcomes following rehabilitation only, an educational booklet, rehabilitation plus booklet, or usual care only for patients undergoing LS. They found no significant differences in costs or outcomes associated with either intervention (50), while the current preoperative PNE study shows a significant healthcare savings 3-year after LS. The booklet and educational models used by Morris *et al.* (50) had a primary focus on anatomy, biomechanics and pathoanatomy whereas, the education provided in our trial focused more on pain neurobiology and pain neurophysiology. The biomedical (tissue-based) explanation of persistent pain might well foster a belief

that "something is still wrong" (51,52), whereas the PNE approach would explain such pain as a nervous system that has remained 'sensitive to protect' (13).

Limitations

This study contains some limitations, which have been highlighted in the published 1-year outcome study (12). For some of the outcomes, the 3-year results were underpowered which was due, in part, to the loss of patients to follow-up.

Conclusions

Adding a single PNE session to patients prior to LS results in significant reduction in healthcare costs 3-year after LS, despite persistent pain and disability. Educating patients about the normal responses to LS in a neuroscience framework may result in significant behavior changes following surgery, and decrease the ongoing healthcare utilization of a large percentage of LS patients.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by Stellenbosch University Board of Institutional Review/Ethics and written informed consent was obtained from all patients.

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