Title

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A Retrospective Comparison of the Modified Shealy Technique versus the Australian

Technique for The Treatment of Lumbar Facet Arthropathy

A thesis submitted in partial satisfaction

of the requirements for the degree Master of Science

in Clinical Research

by

Jeffrey T. Loh

2013

ABSTRACT OF THE THESIS

A Retrospective Comparison of the Modified Shealy Technique versus the Australian

Technique for The Treatment of Lumbar Facet Arthropathy

by

Jeffrey T. Loh

Masters of Science in Clinical Research

University of California, Los Angeles, 2013

Professor Robert M. Elashoff, Chair

Multiple techniques exist to target nerves that transmit pain due to facet arthropathy,

however no study has demonstrated a superior technique. This retrospective cohort study

identified patients who underwent lumbar facet denervation, analyzing each patient's

treatment technique, Modified Shealy versus Australian, as well as benefit. Pre-and post-

procedural visual numeric scale (VNS) scores, and VNS score changes between the two

groups showed no differences ($p = 0.72, 0.06, 0.08$). Patient reported benefit and

duration of relief was greater in the Australian group ($p = 0.012, 0.022$). Male gender

and no pain medication use at baseline was associated with decreased post-ablation VNS

scores, while increasing age and higher pre-ablation VNS scores was associated with

increased post-ablation VNS scores. Increasing age and the Australian technique

conferred greater treatment benefit. The results of this study indicate superiority of the

Australian over the Modified Shealy technique for the treatment of lumbar facet pain.

The thesis of Jeffrey T. Loh is approved.

Janet Sinsheimer

Katrina Dipple

Aman Mahajan

David Elashoff

Robert M. Elashoff, Committee Chair

University of California, Los Angeles

2013

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Introduction

Chronic pain is a widespread disorder with a prevalence of 2 to 40% in the United States.

Within this population of individuals suffering from chronic pain, 28% complain of low

back pain (1). Low back pain has been shown to affect both individuals suffering from

the pain as well as the greater society. The medical, social and economical burden to

Western societies costs $215.5 billion with lost productivity costs of $45 to 54 billion

(1,2,3).

While back pain presents a significant challenge to society, the possible etiologies of

back pain remains varied and unclear. Excluding non-structural causes of pain, low back

pain can arise from multiple areas, including the intervertebral discs of the spine, the

zygapophysial (facet) joints of the spine, as well as the paravertebral muscles, ligaments,

and fascia (4,5). Post-mortem studies have revealed that intervertebral discs and

zygapophysial joints exhibit the greatest degree of degeneration within the spine, thus

indicating the potential role of these structures in causing low back pain (6). However,

multiple studies utilizing MRI analysis have shown that degenerative findings do not

always correlate with an individual's back pain (7,8,9).

In patients where back pain is attributable to a structural cause, 15% of cases have low

back pain arising from the lumbar facet joints (10,11). The etiology of lumbar facet joint

pain is thought to result from repetitive stress and trauma to the joint, leading to

inflammation and stretching of the joint capsule (11). Given the underlying cause of

facet pain, treatment options range from conservative management with the use of

medications and manipulation, to interventional management with the use of intra-articular facet joint injections and radiofrequency ablation of the nervous innervation to the facet joints (11,12,13,14).

Multiple studies have been performed assessing the efficacy of radiofrequency ablation to denervate the facet joint as a means of treating low back pain. While the efficacy of facet joint denervation remains inconclusive, recent studies support the efficacy of this treatment modality (15,16,17). Within the trials examining the efficacy of radiofrequency ablation in the treatment of facet joint pain, different procedural techniques were utilized to ablate the nerves that innervate the facet joints. Multiple papers have detailed the anatomic course of the nerves innervating the facet joints of the spine (18,19,20), however few studies have compared the efficacy of the different procedural techniques in treating lumbar facet arthropathy (21). No clinical trials, retrospective or prospective, have been performed directly comparing the efficacy of the Australian versus the Modified Shealy facet joint denervation technique.

Nikolai Bogduk first described the Modified Shealy in 1980, with the target points being the dorsal surface of the transverse process just caudal to the most medial end of the superior edge of the transverse process (19). Bogduk more recently described the Australian technique in 2004, where a steep caudocephalad axial tilt of the fluoroscopy beam, along with a 20 degree lateral tilt, allows the radiofrequency ablation needle to hug the anterolateral aspect of the base of the superior articular process (21).

In this study, we sought to examine the efficacy of the Modified Shealy technique against the Australian technique in terms of patient pain relief, both quantitative and subjective, as well as duration of relief. The rate of complications, the need for follow-up procedures, and whether patient factors affected outcomes was also assessed to determine whether one technique provided better patient safety and treatment.

Methods

This retrospective chart review was approved by our institutional IRB committee. Based off CPT coding, patients who underwent a lumbar facet radiofrequency denervation procedure from the years of 2008 to 2012 at the UCLA pain management center and presented for at least one follow-up encounter were included in this study. For each patient that underwent a lumbar facet radiofrequency denervation procedure, the patient's age, gender, ethnicity, pre- and post-procedure visual numerical scores (VNS) were collected, with the VNS scale consisting of a score between 0 and 10. Each patient's chart was also assessed to see whether that patient underwent a Modified Shealy versus Australian facet radiofrequency denervation technique, as well as which facets levels were treated. Patient charts were also assessed for whether patients reported subjective improvement in pain following their radiofrequency denervation, and whether they had any adverse reactions to their procedure.

To further evaluate the efficacy of each patient's procedure, the time to recurrence of a patient's facet pain following radiofrequency denervation was also analyzed. Patients that reported resolution of their pain at their post-procedural clinic visit, but were subsequently lost to follow-up, were classified as having resolution of their pain. In these patients, the time frame between their radiofrequency denervation procedure and their last clinic visit was reported as the period of pain relief obtained. For all other patients, the duration of pain relief was able to be determined from follow-up visits reporting recurrence of the patient's lumbar facet pain.

Pain medication consumption was assessed, with recording of whether patients required pain medications prior to their procedure and whether patients required increased, decreased, or no change in pain medication amounts post-procedurally. Each patient's chart was also analyzed to determine whether that patient underwent a subsequent, non-facet denervation, pain-related intervention for the treatment of their low back pain.

Because this study spans a four-year duration, many individuals received repeated facet radiofrequency denervation procedures. To allow for a more appropriate comparison between the Modified Shealy and the Australian facet radiofrequency denervation techniques, and to better assess the baseline efficacy of radiofrequency denervation in the treatment of facet pain, only the initial facet radiofrequency denervation technique of each patient was used for analysis.

To analyze the efficacy of the Modified Shealy technique against the Australian technique, Student's *t*-tests were used to compare pre- and post-ablation VNS test scores as well as change in VNS test scores. An assessment of the distribution of the VNS scores for the Modified Shealy and Australian technique was performed to ensure a Gaussian distribution. To compare the subjective benefit rates reported between patients of the two groups, a Chi Square test was performed. As the duration of relief between the two groups did not follow a normal distribution, a Wilcoxon Rank Sum test was performed to determine whether a difference existed between the two groups. Time to failure was plotted using the Kaplan Meier method and the resulting curves were compared between groups using the log rank test. Cox proportional hazard analysis was

utilized to construct a regression model for the failure time and to assess the contribution of technique as well as adjust for patient demographics factors. Logistic and linear regression analyses were performed to model patient reported benefit and VNS outcome scores respectively, to adjust for the effect of demographic variables in addition to treatment technique. To ensure model validity, interaction effects were tested in the regression models and an examination of outliers was performed. Post-procedural complications and the need for non-ablative follow-up procedures were summarized for each group, and a Chi Square analysis was performed to compare rates of these events between groups.

Results

A total of 373 patients underwent lumbar facet denervation between the years of 2008 and 2012. Ninety-four patients were treated with the Australian technique, while 279 patients were treated with the Modified Shealy technique. However, 12 patients in the Australian group and 38 patients in the Modified Shealy group were excluded from the inclusion cohort due to lack of data or follow-up. Demographic data for the two groups can be seen in Table 1. The average age was 57.8 and 60.5 years for the Australian and Modified Shealy groups, respectively. The gender breakdown for these two groups was 41.5% male in the Australian group and 36.1% in the Modified Shealy group. For all the demographic data, no significant differences were noted except the Australian group had a noticeably greater portion of Asian patients compared to the Modified Shealy group (p = 0.001) (Figure 1a &1b).

Both the Australian and Modified Shealy group showed comparable baseline VNS scores, 6.45 and 6.55 respectively, with no statistical difference between the two groups. The post-ablative VNS scores for the Australian group were roughly 0.6 points better than the scores for the Modified Shealy group, however both the post-ablative scores and the VNS differences for the two groups did not reach a statistically significant level based on a *t*-test analysis (Table 2). To ensure validity of the *t*-test employed for statistical analysis, the distribution of the Australian and Modified Shealy VNS scores was plotted, with a near normal distribution noted for the scores reported in both groups. The minor outlier noted in both the Australian and Modified Shealy groups was the increased number of events reported as 0 for the VNS change in both groups.

To further assess the efficacy of Modified Shealy and Australian technique on pain relief, a qualitative assessment on patients' reported pain relief was performed. Overall, a larger percentage of patients in the Australian group reported subjective pain relief (85.4% versus 70.5%). A Chi square analysis of this data showed a statistically significant difference, with a p-value of 0.012 (Table 2). Because non-ablative follow-up procedures can provide an indication on the effectiveness of the facet denervation performed, the need for non-ablative procedures (epidural steroid injections, sacroiliac joint injections, piriformis injections) to further treat the patient's original pain was also assessed. The Australian group had a slightly higher follow-up procedure rate of 32.9% versus the 27.8% of the Modified Shealy group. However, a Chi Square analysis showed this difference to be non-significant with a p-value of 0.38 (Table 2).

An assessment of the risk of complications between the Australian and Modified Shealy technique showed that complications including bruising, infection, parasthesias, neuritis, and muscle spasms occurred in roughly 9.8% and 6.6% of patients in the Australian and Modified Shealy groups respectively. A Chi Square analysis showed no significant difference, with a p-value of 0.37. To better assess the risk of neuritis, a Chi Square analysis of this single complication was performed, with both groups showing similar occurrence rates of 3.7% and 2.5%, and a p-value of 0.58 (Table 2, Figures 5 & 6).

In addition to analyzing initial pain relief obtained from undergoing a lumbar facet denervation for the treatment of lumbar facet pain, the duration of relief was also

measured. In the Australian technique population, 20 out of 82 (24.3%) patients reported

resolution of their pain, while 33 out of 241 (13.7%) of patients in the Modified Shealy

group reported resolution of their pain. For those patients who had a recurrence of their

pain, a Kaplan Meier curve was plotted to assess for a statistical difference between the

two groups (Figure 4). Immediate procedural treatment failure was higher in the

Modified Shealy group, with 50% of all patients in the Modified Shealy group showing

recurrence of pain by 1.5 months time. In contrast, the Australian group showed that

50% of patients continued to remain pain free by 4 months time.   This difference in

treatment effect was statistically significant based off a log rank analysis, with a p-value

of 0.022. However, by 11 months post-procedural time, the pain relief between the

Australian and Modified Shealy groups became negligible, with nearly 90% of all

patients in both groups reporting recurrence of their pain.

An assessment on the effects of demographic variables influencing the duration of pain

relief was also assessed using a Cox proportional hazards model (Table 3). Out of the

demographic factors analyzed, only the treatment group showed a significant difference

(p = 0.01). The effect of treatment group showed that the Australian technique conferred

a beneficial effect on the failure rate for patients undergoing a lumbar facet denervation

procedure, with a Hazard rate of 0.83. The effects of age, gender, ethnicity, pre-ablation

VNS, and pain medication consumption were all statistically non-significant.

A linear regression analysis evaluating variables' effect on post-ablation VNS scores was

performed, with age, gender, pre-ablation VNS, and pain medication use showing

importance. Gender, pre-ablation VNS, and pain medication use showed statistical significance, while age demonstrated near statistical significance (Table 4). Age and pre-ablation VNS demonstrated a positive correlation with post-ablation VNS scores, with increases in age and pre-ablation VNS scores resulting in increased post-ablation scores. Gender and pain medication use had a negative correlation with post-ablation VNS scores, with Male gender and no pain medication use being associated with a decreased post-ablation VNS Score.

A logistic regression analysis revealed that age and treatment group was significantly associated with patient reported procedural benefit (Table 5). Age demonstrated a positive correlation with patient reported benefit, with an odds ratio of 1.02, indicating a greater chance of benefit as patients became older. The effect of treatment group on outcome demonstrated that the Australian technique produced better outcomes, with the Australian group having a beneficial outcome 1.46 times more than the Modified Shealy group. To assess the model fit of the logistic regression, an ROC curve was plotted, with a calculated of 0.6138 (Figure 7).

Discussion

Within the current literature, no studies exist comparing the efficacy of different lumbar facet joint denervation techniques. In those studies assessing the efficacy of radiofrequency ablation to denervate the facet joint, outcomes remain inconclusive (22). Recent studies potentially show benefit (16), however further validation studies are lacking. A study published by Lau, et al. effectively demonstrated the anatomic pathway of the nervous innervation for the lumbar facet joints, arguing that parallel placement (Australian technique) of the radiofrequency probes against the medial branch nerves is key to successful treatment of facet arthropathy (20). Based on the anatomic finding in this study, Lau, et al. argue that many lumbar facet denervation techniques, including the Modified Shealy, fail to appropriately ablate the nervous innervation to the lumbar facet joints. While the authors provide a thorough anatomic analysis, they did not evaluate the clinical efficacy and duration of a parallel ablative technique in reducing a patient's low back pain resulting from a facet arthropathy. Thus, this study sought to address whether significant differences exist between radiofrequency ablative techniques that place the lesioning probe parallel to the nervous innervation of the facet joint (Australian technique) versus perpendicular to the nervous innervation (Modified Shealy).

Based on the results from this retrospective review, the benefit and the duration of pain relief reported by patients was found to be significantly greater in patients treated with the Australian technique versus the Modified Shealy technique. This outcome is consistent with findings detailed in recent studies (16,17,20). However, a study by Dreyfuss, et al. demonstrated prolonged benefit with the use of the Australian technique

in appropriately selected patients. This study fails to replicate the lasting beneficial effects seen within the Dreyfuss study. Patients demonstrated median recurrence of pain by 1.5 month and 4 months within the Modified Shealy and Australian groups respectively. By 12 months time, 90% of patients in both groups demonstrated recurrence of their pain (Figure 4), which is noticeably different than the 60-80% of patients that continued to experience pain relief seen within the Dreyfuss study (17).

A possible explanation for the lack of prolonged benefit experienced by patients in this study is the multi-factorial cause of back pain. The different causes for back pain range from facet arthropathy, spinal stenosis, radiculopathies, to muscular and fascial etiologies. In many patients, facet arthropathy, spinal stenosis and lumbar radiculopathy often co-exist. Thus, a degree of confounding as to the cause of patient's back pain results in the patient receiving only partial treatment of his low back pain. This reduction in pain relief that a patient may experience helps provide a potential explanation for the immediate failure rates of 12.8% and 25.4% in the Australian and Modified Shealy groups respectively.

To ensure that only patients with confirmed lumbar facet pain underwent a radiofrequency ablation of their lumbar facet joint, patients initially underwent a screening process that involved a diagnostic injection of 0.25% bupivacaine to the lumbar medial branch nerves. The utility of diagnostic medial branch nerve injections to determine the candidacy of a patient for denervation of the facet joints remains unclear (23,24,25,26), with studies showing that 2 rounds of diagnostic injections may be

necessary to improve the efficacy of identifying ideal candidates for facet denervation treatments (17,26). The results seen within this study support these prior findings, potentially helping to further explain the poor duration of benefit experienced by patients in both groups. Overall, the outcomes seen in both groups stresses the need for better screening methods that will help determine which patients are candidates for undergoing a lumbar facet denervation procedure.

While the duration of pain relief of the two groups was shorter compared to prior studies, the pain relief obtained for both groups was clinically beneficial. Both groups experienced a decrease in VNS pain scores of greater than 2 points, which is a clinically relevant result. Though the change in VNS scores between the two groups did not reach a statistically significant difference, based on a *t*-test analysis, the Australian group demonstrated roughly 0.6 point greater pain relief in VNS scores compared to the Modified Shealy group, again providing further evidence that the Australian technique provides improved treatment of lumbar facet arthropathy (Table 2).

One detail observable within distribution plots of both the Australian and Modified Shealy VNS differences is the elevated number of events at a VNS difference level of 0 (Figure 2c & 3c). Excluding this elevation, both plots demonstrate a nearly perfect normal distribution of data. As data collection for this study was performed retrospectively, with VNS scores based off patient report, patients occasionally stated that the procedure provided no benefit and their pain level remained the same as prior. This lack of a VNS number resulted in imputed data, causing more events to occur at a VNS

difference of zero, which would have been otherwise more normally distributed within the data plot.

When examining the differences between the Australian and Modified Shealy groups, no significant differences existed, except between the ethnic groups represented. Within the Australian group, roughly 19% of the population was Asian in ethnicity, while only 1.1% of the Modified Shealy group was Asian (p = 0.001). However, the outcomes observed were not influenced by ethnicity. Results of the Cox proportional hazard model shows that only the treatment group significantly affected the recurrence rate for a patient's pain (p = 0.01), with ethnicity having a p-value of 0.55. To determine which factors affected a patient's post-ablation VNS pain score, a linear regression analysis was performed. Age, gender, pre-ablation VNS, and pain medication were significant factors, but ethnicity did not influence the change in VNS scores reported by the patient. Similarly, the logistic regression analysis found age and treatment group to be significantly correlated with patient pain relief. Thus, while the ethnic breakdown between groups was statistically different, this difference between the two treatment groups did not affect the outcomes observed.

Another interesting observation in this study is that the treatment group was not a significant variable in the linear regression analysis, but had a significant effect in the Cox proportional hazards model and the logistic regression model. The lack of the treatment group being a significant variable in the multiple regression analysis is not concerning, as the outcome in the linear regression analysis is the post-ablation VNS

score. The level of benefit a patient receives from his procedure is more likely related to the change in an individual's VNS score. Thus, while the treatment group is a significant factor in determining whether a patient derives benefit from a lumbar facet denervation procedure, the treatment group does not play a significant role in influencing a patient's post-procedural VNS score.

Within the linear regression analysis, the factors that did prove significant appear clinically sound. Age and pre-ablation VNS had a positive correlation with post-procedural VNS scores, which one expects. As an individual grows older, the lumbar spine of that individual is subject to increased degenerative processes, which increases the likelihood for the development of low back pain, either from a single or varied etiology. Thus, clinically, one anticipates that the treatment of facet arthropathy would be more difficult in elderly patients as they have more potential sources for pain, resulting in higher post-ablation VNS scores. Similarly, if an individual starts with a higher pre-ablation VNS score than another subject, that individual should have a higher post-ablation VNS score compared to the other subject, even if the ablative procedure confers the same degree of benefit. As Male gender based on the Cox hazard analysis, confers a better outcome, with Male gender having a 0.99 hazard ratio compared to woman, the decrease in post-ablation VNS score of 0.312 for being Male appears clinically appropriate. Similar to gender, patients not using a pain medication had a hazard ratio of 0.91 compared to patients that did require use of pain medications. Thus, one would expect a better pain relief/lower VNS scores in patients that did not take pain medications at baseline. This outcome is confirmed in the linear regression analysis, with

patients who did not take pain medications at baseline having a post-ablation VNS score 0.408 points lower than in patients who used pain medications at baseline.

In contrast to the linear regression analysis, only age and the treatment group significantly impacted whether patients felt their lumbar facet denervation procedure was beneficial. Increasing age was associated with an increased likelihood of patient reported benefit. While this outcome may seem contradictory, these two outcomes are independent of one another. Thus, while older patients may have higher post-ablation VNS scores, they are also more likely to find benefit from denervation of their lumbar facet joints. As expected of the treatment group, patients who received a parallel ablative technique were 1.46 times more likely to receive benefit than those who received a Modified Shealy technique. This outcome corresponds with the prior outcomes seen with the Cox proportional hazard model, the Chi square analysis of benefit, and the *t*-test analysis of VNS scores, further validating the benefit of the Australian technique over Modified Shealy technique. While the results of the logistic regression appear clinically sound, the AUC of 0.6138 for this analysis highlights the weakness of model fit. Thus, future studies that examine other potential variables, including patient co-morbidities may more accurately determine factors that influence the benefit experienced by patients.

Though patients in the Australian group had significantly better outcomes than in the Modified Shealy group, this patient population also received a higher percentage of post-procedural non-ablative pain treatments. Roughly 32.9% of patients in the Australian treatment group received a follow-up procedure while 27.8% of patients in the Modified

Shealy group received a follow-up procedure. The difference between these two values was non-significant. The majority of post-ablation procedures consisted of an epidural steroid injection, a sacroiliac joint injection or a piriformis injection, with 89% and 73% of follow-up procedures consisting of one of these three injections in the Australian and Modified Shealy groups respectively. The need for such varied follow-up procedures again highlights the diverse etiologic causes of low back pain.

In addition to evaluating the benefits of the Australian and Modified Shealy techniques in the treatment of lumbar facet pain, the safety of these two techniques was also assessed. The risk of complications was clinically significant, with both groups having a complication rate of between 1 in 10 to 1 in 20 patients. The two groups did not have a statistically different rate of complications based off a Chi square analysis. Because the Australian technique is associated with potentially closer placement of the radiofrequency ablative probe near the exiting nerve roots of the spine, increasing the risk for the development of neuritis, the prevalence of this complication was compared between treatment groups. No statistically significant difference in the development of neuritis was seen between the two groups, which demonstrates the ability of the Australian technique to provide a better treatment to patients without an increased risk of adverse events.

The main limitation of this study is its retrospective design. While most demographics, excluding ethnicity, were not significantly different between the two treatment groups, the retrospective nature of this trial is susceptible to potential issues of confounding and

bias. Future studies designed as a prospective, randomized, double-blind trial will allow for more equitable distribution of patients and better identification of patients with only lumbar facet pain. By removing patients with confounding causes of low back pain, a more accurate assessment of the benefit, both in pain reduction and duration of pain relief, for the Australian and Modified Shealy techniques can be performed.

The etiologic causes of low back pain remains varied and unclear, often proving difficult to treat. While this study has limitations due to its retrospective nature, this study does examine previously unreported factors. No studies have compared the efficacy of the different lumbar facet denervation techniques to determine whether one proves superior. All prior prospective studies have been limited in sample size and duration of effect, with a study by Nath, et al., being one of the few studies examining the efficacy of lumbar facet denervation for the treatment of facet pain in a large patient population (15,16,17,27,28). Thus, this study provides further insight into the benefits of the Australian technique for the treatment of lumbar facet arthropathy, as well as the efficacy and durability of a lumbar facet denervation treatment in patients with pain due to lumbar facet arthropathy.
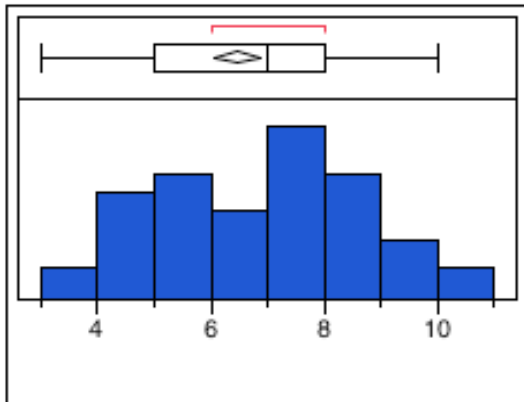
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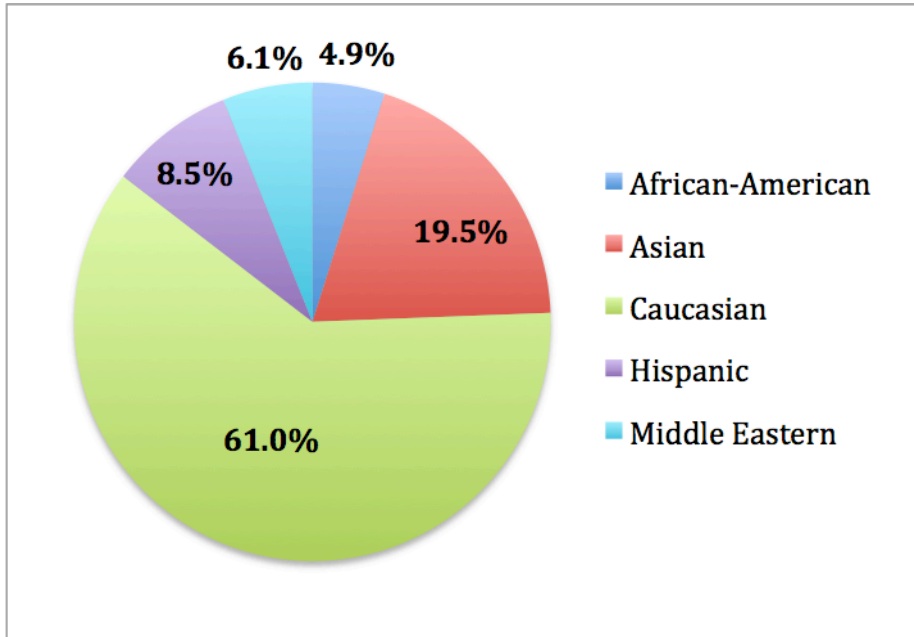
Australian Technique Ethnicity Demographics
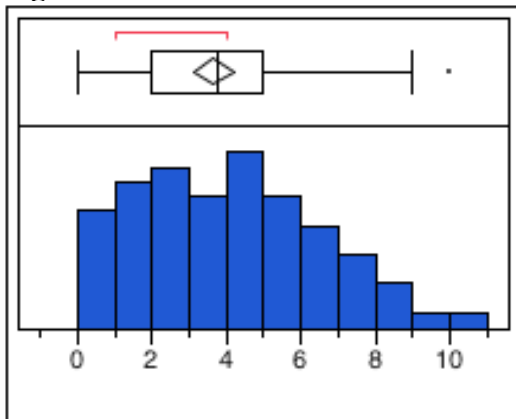
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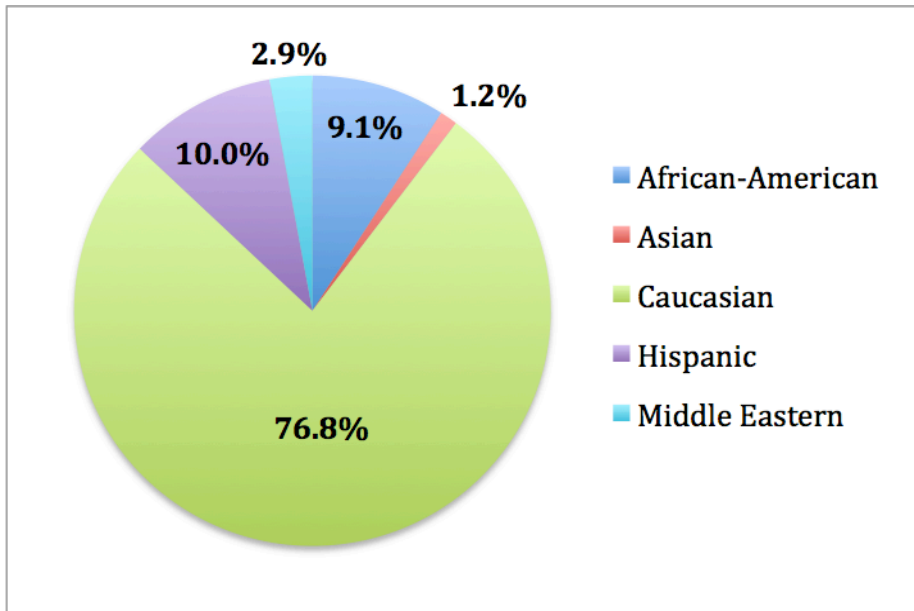
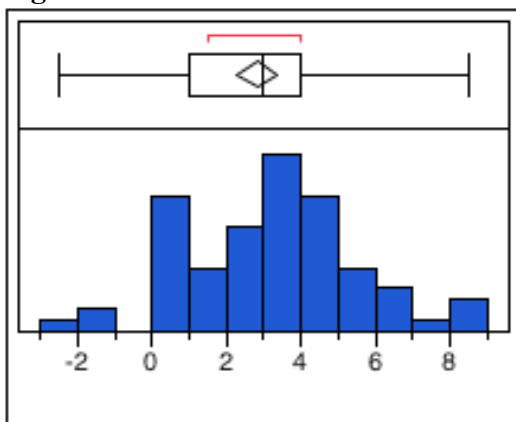Modified Shealy Technique Ethnicity Demographics

Figure 2a.

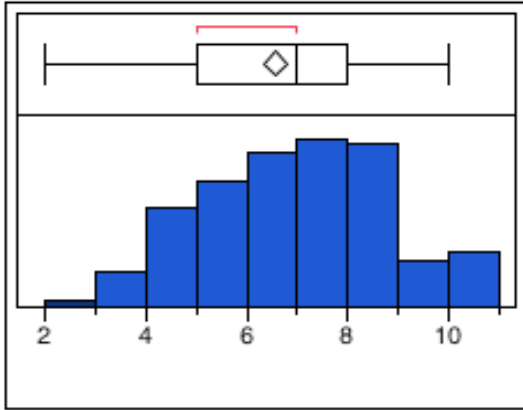Australian Technique Pre-Ablation VNS Distribution

Figure 2b.

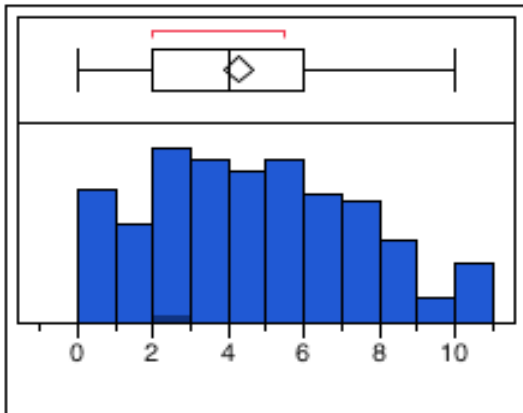Australian Technique Post-Ablation VNS Distribution

Figure 2c.

Australian Technique VNS Difference Distribution
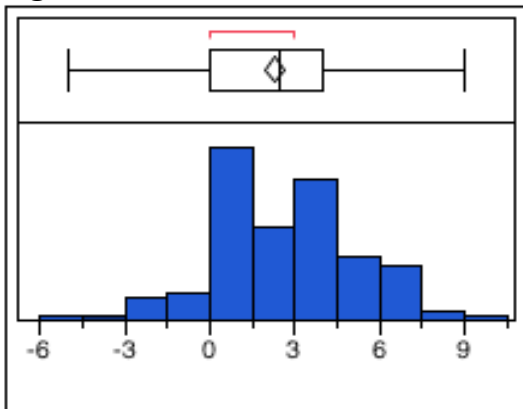
20

Figure 3a.

Modified Shealy Technique Pre-Ablation VNS Distribution
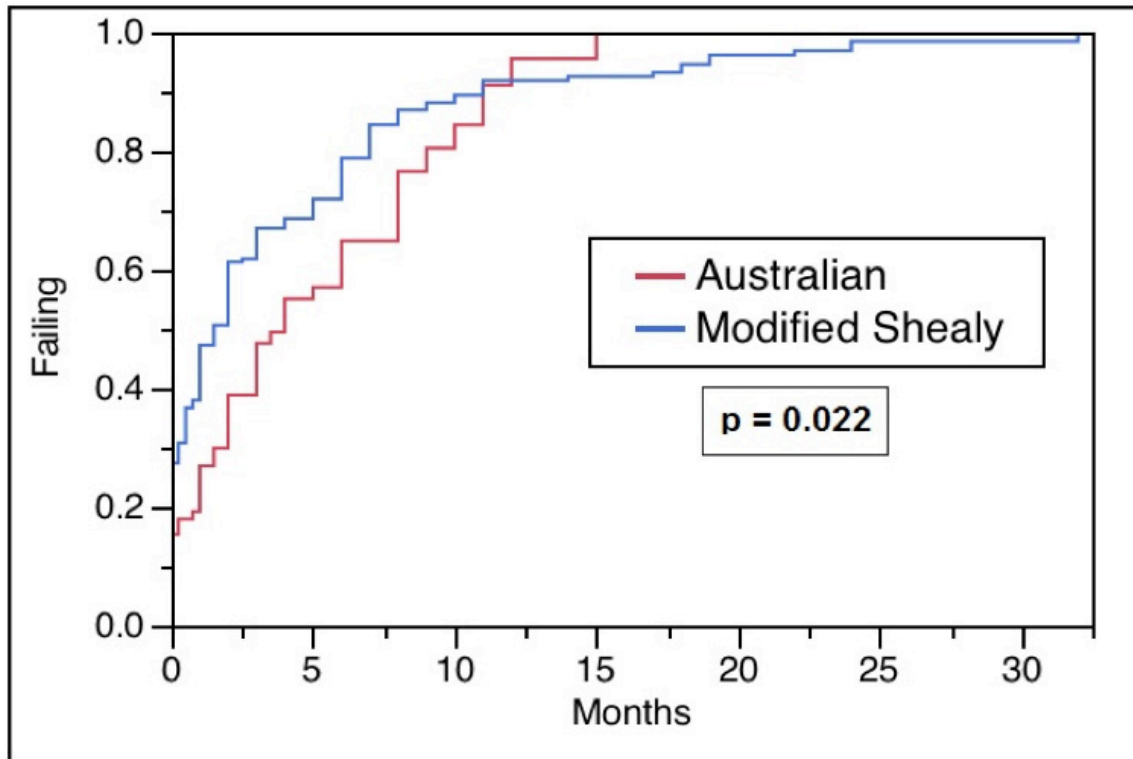

Figure 3b.

Modified Shealy Technique Post-Ablation VNS Distribution
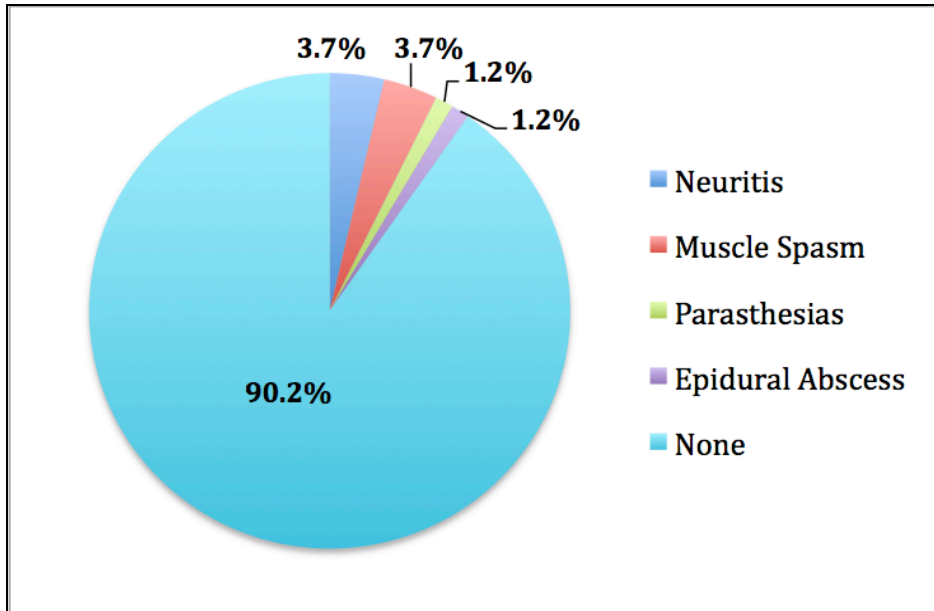

Figure 3c.

Modified Shealy Technique VNS Difference Distribution

Figure 4.

Kaplan Meier curve showing failure rate over time in months between the Australian and Modified Shealy groups. A statistically significant difference between the two groups was determined based off the p-value of 0.022 calculated using a Log Rank test.
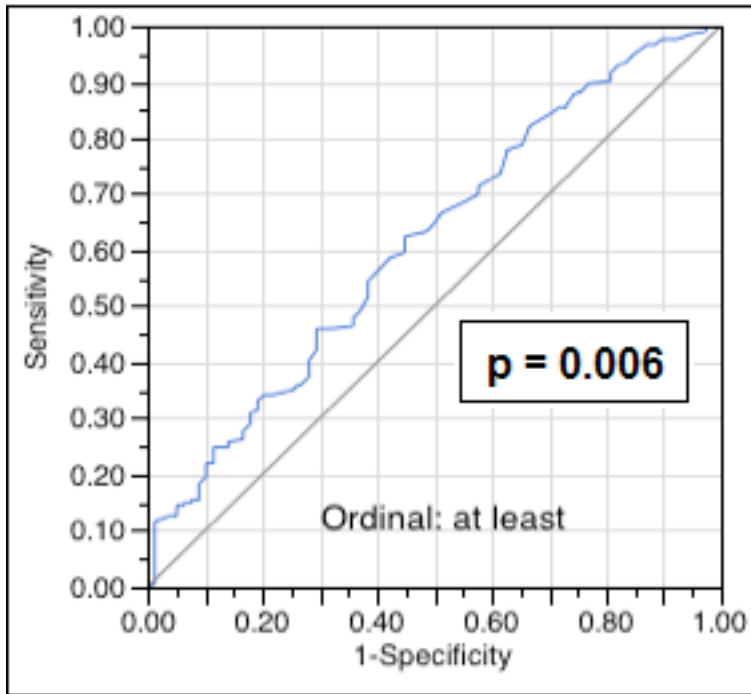
Figure 5.

Distribution of complications encountered with the Australian technique.

Figure 6.
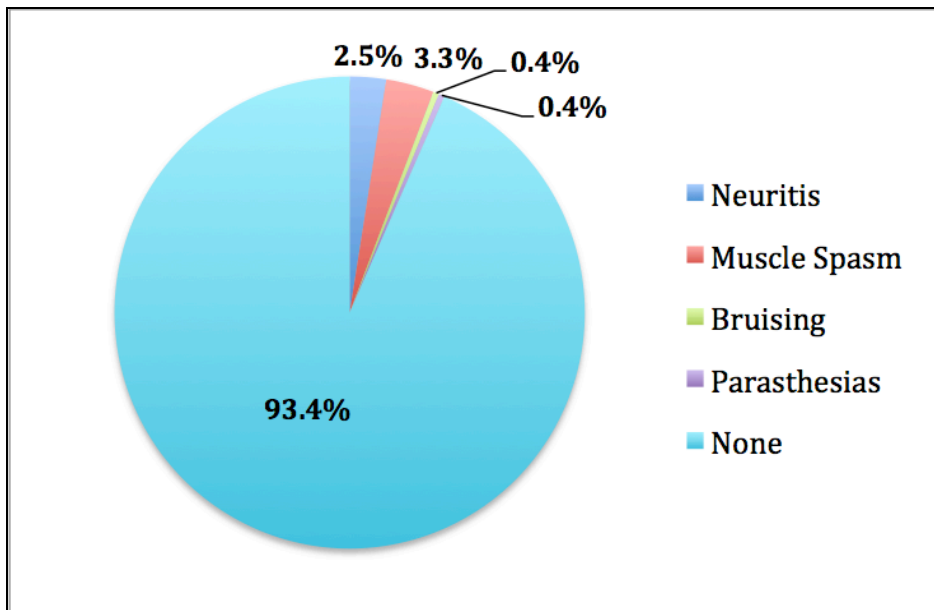
Distribution of complications encountered with the Modified Shealy technique.

Figure 7.

Logistic Regression ROC curve: AUC calculated to be 0.6138.

Table 1.

		Australian Technique (82)	**Modified Shealy Technique (241)**	**p-value**
Ethnicity [n (%)]	Caucasian	50 (61.0%)	185 (76.8%)	0.01
	African-American	4 (4.9%)	22 (9.1%)	
	Asian	16 (19.5%)	3 (1.2%)	
	Hispanic	7 (8.5%)	24 (10.0%)	
	Middle Eastern	5 (6.1%)	7 (2.9%)	
Gender [n (%)]	Male	34 (41.5%)	87 (36.1%)	0.39
	Female	48 (58.5%)	154 (63.9%)	
Mean Age	Years (Std Dev)	57.8 (15.9)	60.5 (15.0)	0.17

Demographic data comparing the Australian Technique and the Modified Shealy Technique.

Table 2.

		Australian Technique	**Modified Shealy Technique**	**p-value**
VNS Data	Pre-Ablation Mean VNS	6.45 (1.77)	6.55 (1.78)	0.72
	Pre-Ablation Median VNS	7 [5-8]	7 [5-8]	
	Post-Ablation Mean VNS	3.64 (2.41)	4.27 (2.71)	0.06
	Post-Ablation Median VNS	3.75 [1.75-5]	4 [2-6]	
	Mean VNS Difference	2.82 (2.30)	2.28 (2.54)	0.08
	Median VNS Difference	3 [1-6]	2.5 [0-6]	
Benefit [n (%)]	Yes	70 (85.4%)	170 (70.5%)	0.012
Relief	Median Duration (months)	4.0 (2,6)	1.5 (1,2)	0.022
Complications [n (%)]	All complications (events)	8 (9.8%)	16 (6.6%)	0.37
	Neuritis (events)	3 (3.7%)	6 (2.5%)	0.58
Follow-up Procedure [n (%)]	Yes	27 (32.9%)	67 (27.8%)	0.38

Mean, Median, VNS Difference and Standard Deviation for reported VNS scores between the Australian and Modified Shealy Technique. The standard deviation is reported with each VNS mean and the interquartile range is reported with each VNS median. The benefit reported between the Australian and Modified Shealy groups was assessed using a Chi Square analysis. The median duration of relief is listed, with the 95% confidence interval reported. Duration of relief between the two treatment groups was assessed using a Log Rank analysis. A comparison of complications and need for follow-up procedures was assessed using a Chi Square analysis.

Table 3.

Factors	Category	Hazard Ratio (95% Confidence Interval)	p-value
Age (Years)		1.00 (0.99 to 1.01)	0.77
Gender (Male)	Male	0.99 (0.87 to 1.13)	0.91
Ethnicity (Caucasian)	Caucasian	0.96 (0.84 to 1.11)	0.55
Treatment Group (Australian)	Australian	0.83 (0.71 to 0.96)	0.01
Pre-Ablation VNS		1.04 (0.97 to 1.12)	0.25
Pain Medication (No)	No	0.91 (0.78 to 1.06)	0.23

Cox Proportional Hazards outcomes for individual variables and their effect on the recurrence of a patient's pain.

Table 4.

Factors	Coefficient (Standard Error)	p-value
Age (Years)	0.02 (0.01)	0.08
Gender (Male)	-0.31 (0.15)	0.03
Pre-Ablation VNS	0.58 (0.08)	< 0.01
Pain Medication Use (No)	-0.41 (0.17)	0.02
Treatment Group (Australian)	-0.20 (0.17)	0.22

Linear Regression Model with Post-Ablation VNS as the outcome measure. Age, Gender, Pre-Ablation VNS and Pain Medication Use are the four variables found to significantly affect an individual's Post-Ablation VNS score.

Table 5.

Factors	Odds Ratio (95% Confidence Interval)	p-value
Age (Years)	1.02 (1.00,1.04)	0.04
Group (Australian)	1.46 (1.04,2.06)	0.03

Logistic Regression Model with benefit as the outcome response. Age and Treatment Group are the two variables that impacted whether a patient had a beneficial response to their treatment.

Statistical Addendum

To ensure model validity of the linear regression performed, an examination of potential outliers was assessed (Figure 8 & 9). An examination of the residual versus predicted plot for post-ablation VNS scores showed a distribution of data points with no observable outliers that could potentially affect the interpretation of the linear regression analysis. When analyzing for potential outliers using a Cook's D distribution, three points were noted to have a value greater than 0.025 (Figure 9). In two of the three points, the main reason for these points appearing as outliers stems from the fact that the patients reported a worsening of their pain. One patient reported a worsening in a pre-ablation VNS score of 5 to a post-ablation VNS score of 10, while the other patient had change in VNS scores from 6 to 7. The resulting negative value of the VNS difference was uncommon within this study analysis, likely causing these patients to appear as outliers. In the third outlier point, the VNS scores decreased from 9 to 0, which is not an abnormal finding. However, this patient was one of only 3 Asian patients who underwent the Modified Shealy technique, and had substantial benefit. The other two Asian patients demonstrated minimal to no benefit. This large decrease in VNS score in combination with the patients ethnicity and treatment group resulted in the patient being an outlier.

To assess model accuracy, a comparison of the actual versus predicted points for the linear regression analysis was performed (Figure 10). The results of this analysis show a heterogeneous distribution of points, with few data points falling on the straight line indicative of when actual and predicted plots are equivalent. The diffuse distribution of points highlights the inaccuracy of this model, which is also confirmed by the correlation

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coefficient of this model. The R-Square value of 0.21 provides an R-value of 0.46. While the correlation coefficient value of 0.46 shows a moderately strong correlation between model variables and outcome, this value highlights the need to further determine additional variables that affect the post-ablation VNS outcome.

Further model validation analyses performed included assessing the interaction effects in both regression models. Within the logistic regression model, age and treatment group were the two statistically significant variables. Performing the analysis with an age and treatment group interaction effect showed no statistical benefit, with a p-value of 0.50 for this interactive effect. Within the linear regression analysis, age, gender, pre-ablation VNS, and baseline pain medication use were the four variables of relevance in the reported analysis. When examining the interaction effect between these four variables, none of the 6 possible interaction combinations demonstrated a statistically significant p-value. The age and gender interaction effect had a p-value of 0.95, while the interaction variables for age and pre-ablation VNS and age and pain medication use had p-values of 0.22 and 0.35. Interaction effects for gender and pre-ablation VNS, gender and pain medication use, and pre-ablation VNS and pain medication use had p-values of 0.41, 0.12, and 0.43 respectively. With all six interactions, inclusion of these variables into the multiple regression analysis did not affect the p-values of the four significant and independent variables.

To further evaluate the effects of the demographic variables on a patient's quantitative pain relief, a linear regression analysis on the VNS score change was also performed. In

this analysis, age, gender, treatment group, and baseline pain medication use did not show any statistical significance. Pre-ablation VNS was excluded from the analysis, as this variable is utilized to determine the measured outcome. While none of the demographic variables demonstrated significance, the four variables still demonstrate the same clinical outcome as the original linear regression analysis, where post-ablation VNS is the outcome (Table 6). Increasing age was associated with a smaller VNS score change. This result mirrors the outcome seen in the original linear regression analysis where advancing age results in higher post-ablation VNS scores. Male gender, the Australian technique, and the lack of baseline pain medication use were all associated with greater changes in VNS scores, which again mirrors the original linear regression outcome, where male gender, the Australian technique, and no baseline pain medication use resulted in lower post-ablation VNS scores.
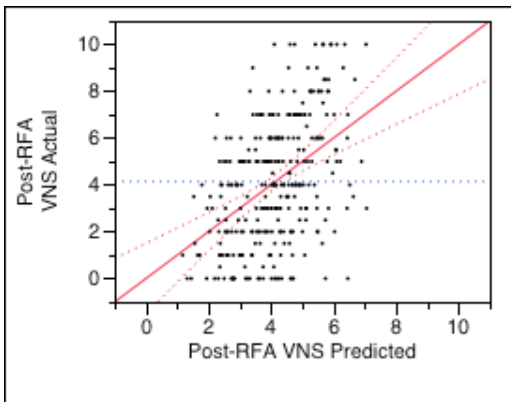
Figure 8.
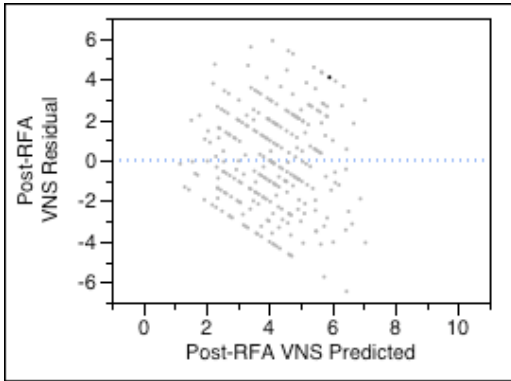
Residuals versus Predicted Plot for the Linear Regression Analysis

Figure 9.
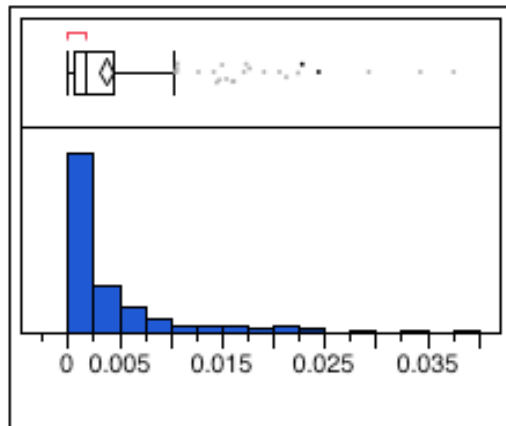
Cook's D Distribution of the Linear Regression Analysis

Figure 10.

Actual versus Predicted Plot for the Linear Regression Analysis. R-Square value of 0.2.

Table 6.

Factors	Coefficient (Standard Error)	p-value
Age (Years)	-0.01 (0.62)	0.17
Gender (Male)	0.21 (0.01)	0.16
Pain Medication Use (No)	0.27 (0.18)	0.13
Treatment Group (Australian)	0.21 (0.17)	0.22

Linear Regression Model with VNS change as the outcome measure.

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