

Clinical Study

The impact of obesity on the effectiveness of spinal cord stimulation in chronic spine-related pain patients

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Abstract

BACKGROUND CONTEXT: Chronic pain and obesity are both on the rise. Spinal cord stimulation has gained increasing popularity in the pain management field for the treatment of spine-related chronic pain, however to-date, the correlation between the spinal cord stimulator effectiveness and increasing body mass index (BMI) has not been fully established.

PURPOSE: We aimed to investigate the correlation between patients' BMI and the percentage of pain relief as well as opioid utilization in chronic spine-related pain patients treated with spinal cord stimulation.

STUDY DESIGN: Retrospective cohort study.

PATIENT SAMPLE: Patients with chronic spine-related pain who were treated with a spinal cord stimulator.

OUTCOME MEASURES: Eleven-point numeric rating scale for pain and opioid utilization.

METHODS: Following Institutional Review Board approval, data from all eligible subjects who had undergone successful spinal cord stimulation (SCS)-trial defined as $\geq 50\%$ decrease in pain followed by SCS implant were collected and statistically analyzed. Patients were divided into four groups according to BMI. Self-reported pain scores on the 11-point numerical rating scale were collected at baseline, 6 months and 12 months post SCS-implant visits. Opioid utilization, if any, was collected at baseline and 12 months post-SCS implant.

RESULTS: In all, 181 patients were included. Thirty-three were under and/or normal weight (≤ 24.9 kg/m²), 72 overweight (25.0–29.9 kg/m²), 63 obese (30.0–39.9 kg/m²), and 13 morbidly obese (≥ 40.0 kg/m²). The estimated coefficients from multivariable linear regression analysis were -1.91% (95% CI: -2.82% to -0.991%) and -1.48% (95% CI: -2.30% to -0.660%) reduction in pain improvement per unit increase of BMI for 6 months and 12 months scores, respectively. The estimated coefficient of disability status was -15.3% (95% CI: -22.1% to -8.48%). The estimated coefficient for 12 month opioid equivalence was -0.08% (95% CI: -0.14 to -0.021), per 1 mg unit increase of morphine opioid equivalency. The data showed a statistically significant negative association between increasing BMI and SCS effectiveness at 6 and 12 months post-SCS therapy with a 2% reduction in efficacy for every unit increase of BMI after adjusting for confounding factors and a 20% better response in underweight and/or normal patients over the morbidly obese individuals which was not related to baseline pain score level. The significant difference in pain scores at 6 months ($p = .0003$) and 12 months ($p = .04$) post-SCS implant between obese and nonobese patients was not attributable to differences in baseline pain scores. There was no significant change in opioid utilization between baseline and 12 months post-SCS therapy.

FDA device/drug status: The device, SCS was first FDA approved in 1989. New advances are constantly being submitted for FDA approval.

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CONCLUSION: A negative association between SCS effectiveness and increasing BMI was found, whereas, no significant difference was noted amongst the various BMI cohorts and the daily opioid consumption. © 2018 Elsevier Inc. All rights reserved.

Keywords:

Back pain; BMI; Chronic spine-related pain; Neuromodulation; Obesity; SCS; Spinal cord stimulation

Introduction

Chronic spine or back pain is the most common cause of chronic pain in the general population [1,2]. Neuromodulation using spinal cord stimulation (SCS) implants have gained increasing popularity in the past two decades, reaching 100,000 worldwide implants performed in 2017 [3,4] on a select group of chronic pain patients. The SCS was first approved by the U.S. Food and Drug Administration in 1989 [5]. To date, SCS has been approved for chronic pain of the trunk and limbs as well intractable low back pain whereas in Europe, SCS has additional approval for refractory angina pectoris and peripheral limb ischemia [6].

In general, the literature supports the safety and efficacy of SCS [7–12]. However, the degree of its efficacy has been shown to vary from one patient to another. Causes of variation are still being reviewed. They include nonmodifiable patient factors such as age [12–14], sex [12,14] and the underlying cause of pain [15], as well as, modifiable factors such as depression [13,16,14], smoking [17,18], and obesity [19,20,14].

Obesity is a highly modifiable factor. As chronic pain and obesity commonly occur together [21,22] and about two out of every three US citizens are considered overweight or obese [23], information regarding the influence of obesity on the effectiveness of SCS would be useful. Unfortunately, the effect of obesity as measured by the body mass index (BMI) on the effectiveness of SCS implanted for spine-related chronic pain has been incompletely studied. Only one previous study found BMI as a predictor for the success and/or failure of SCS [19].

The aim of the current study was to investigate, using a large sample size, the impact of obesity on the long-term effectiveness of SCS therapy for chronic spine-related pain with an emphasis on the changes on opioid utilization. We hypothesized that there will be an inversely proportional relationship between SCS effectiveness and BMI, whereas a directly proportional relationship would exist for opioid intake and BMI, for the subset of the patients who were on opioids preoperatively.

Methods

Following Institutional Review Board approval, records were reviewed to identify patients with chronic spine-related pain who were managed with SCS at the Cleveland Clinic Pain Management department between the years 1997 and 2013. Chronic spine-related pain conditions

included postlaminectomy syndrome, degenerative disc disease, chronic radiculopathy, spinal spondylosis, and spinal stenosis. Subjects were excluded if they had incomplete records, were no longer being followed at Cleveland Clinic, or they no longer had the SCS implanted at the 12 months postimplant benchmark.

Patient's demographic data, primary diagnosis, smoking status, BMI, duration of pain, and history of diabetes, disability and depression were extracted from the electronic medical records as shown in the Table. Additionally, self-reported pain scores on the 11-point numerical rating scale (NRS) were collected at baseline, 6 months and 12 months post-SCS implant visits. Opioid utilization, if any, was collected at baseline and 12 months post-SCS implant.

As indexed by the National Heart, Lung and Blood Institute (NHLBI) [24], we subcategorized our sample into four BMI cohorts: under and/or normal weight ($\leq 24.9 \text{ kg/m}^2$), overweight ($25.0\text{--}29.9 \text{ kg/m}^2$), obese ($30.0\text{--}39.9 \text{ kg/m}^2$), and morbidly obese ($\geq 40.0 \text{ kg/m}^2$); with the exception of grouping the underweight and normal weight together caused by having only one subject being considered underweight. For further analysis purposes binary classification was also used using two groups of nonobese ($<30.0 \text{ kg/m}^2$) versus obese ($\geq 30.0 \text{ kg/m}^2$).

Statistical analysis

Multivariable linear regression was used to test for association between BMI and pain relief, measured as the percentage difference between NRS score at 6 and 12 months following SCS therapy from baseline score. Comparative *t* tests were used to examine the potential differences of NRS score at baseline between nonobese ($\text{BMI} < 30.0 \text{ kg/m}^2$) and obese ($\text{BMI} \geq 30.0 \text{ kg/m}^2$) patients and pain score at baseline before SCS treatment, as well as 6 and 12 months after treatment. Analysis of variance (ANOVA) between BMI groups, as defined by NHLBI, was used to test the mean change in pain relief from baseline and at 6 months and 12 months following SCS therapy in order to determine clinical significance. Similarly, ANOVA testing amongst the BMI cohorts was used to test for differences in means of opioids between baseline and 12 months. Additionally, a linear mixed model analysis was performed in order to test for an association across time periods between BMI and baseline confounders against pain score reduction. Additional linear regression analysis and Tukey's test opioid analysis were performed with interest of understanding the relationship of opioids (in mg morphine equivalency) to

Table
Summary statistics of baseline characteristics

Variable	Total N=181	Under/Normal weight (BMI < 25) N=33	Overweight (25 ≤ BMI < 30) N=72	Obese (30 ≤ BMI < 40) N=63	Morbidly obese (BMI ≥ 40) N=13	p value
BMI						
BMI*, kg/m ²	29.8 ± 5.6	22.8 ± 1.9	27.5 ± 1.5	33.6 ± 2.5	42.8 ± 2.3	<.001 ^a
Pain						
Baseline pain score before SCS implant*	7.8 ± 1.3	7.9 ± 1.4	7.8 ± 1.3	7.7 ± 1.4	8 ± 1.4	.91 ^a
Pain score at 6 months*	5.1 ± 1.8	4.3 ± 2.3	4.8 ± 1.7	5.1 ± 2.1	5.7 ± 1.2	.21 ^a
Pain score at 12 months*	5.5 ± 1.9	5.7 ± 2.5	5.5 ± 1.7	5.7 ± 1.7	6.4 ± 1.1	.87 ^a
Opioid use (in mgs)						
Baseline opioids [†]	30.3 [20.0,60.0]	30.0 [20.0,67.0]	30.0 [10.0,60.0]	35 [21.0,61.0]	45 [22.5,92.5]	.73 ^b
Opioid equivalent at 12 months [†]	30.0 [0.00,55.0]	30.0 [17.5,94.8]	30.0 [0.00,64.5]	22.5 [0.00,45.0]	22.5 [0.00,73.0]	.47 ^b
Mean difference (12months-baseline)	-9.5	-13.8	-6.8	+0.06	-17.5	.75 ^a
Baseline confounding variables						
Age at implant*, years	55 ± 12	61 ± 13.7	55 ± 12.7	52.5 ± 10.2	55.8 ± 10.1	.016 ^a
Sex, female	101 (60)	26 (83)	34 (50)	36 (59)	7 (60)	.011 ^c
History of depression	108 (64)	20 (64)	41 (60)	38 (62)	10 (90)	.19 ^c
History of substance abuse	3 (1.7)	1 (3.2)	2 (2.9)	0 (0.0)	0 (0.0)	.19 ^d
Disabled	14 (8.3)	2 (6.4)	5 (7.3)	6 (9.8)	2 (18.2)	.69 ^c
Diabetes	24 (14)	1 (3.2)	6 (8.8)	12 (19.7)	5 (45.5)	.003 ^c
Duration of pain [†] , years	5.0 [2.0,9.0]	4 [2.0, 7.0]	5.0 [3.0, 10.0]	5.0 [2.0, 10.0]	4 [2.0, 9.0]	.21 ^b
Primary pain diagnosis						
Postlaminectomy	154, 85.1	30, 16.6	59, 32.6	52, 28.7	13, 7.2	.51 ^c
Degenerative disc disease	3, 1.7	1, 0.55	1, 0.55	1, 0.55	0, 0	
Radiculopathy	14, 7.7	0, 0	9, 5.0	5, 2.8	0, 0	
Spinal spondylosis	6, 3.3	2, 1.1	2, 1.1	2, 1.1	0, 0	
Spinal stenosis	4, 2.2	0, 0	1, 0.6	3, 1.7	0, 0	
Smoking status						
Active smoker	55, 30.4	13, 7.2	22, 12.2	18, 9.9	2, 1.1	.83 ^c
Nonsmoker	66, 36.5	10, 5.5	26, 14.4	24, 13.3	6, 3.3	
Former smoker	60, 33.2	10, 5.5	24, 13.3	21, 11.6	5, 2.8	

p values: a=ANOVA, b=Kruskal-Wallis test, c=Pearson's chi-square test, d=Fisher's Exact test.

Data are given as N (percentage of each group) unless otherwise indicated.

* Data are given as mean ± SD.

† Data are given as median [Q1, Q3].

BMI. All statistical analysis was performed using R Statistical software Version R3.4.1 (The R Foundation for Statistical Computing, Vienna, Austria).

Results

Between 1997 and 2013, 330 patients had received an SCS implant at Cleveland Clinic Pain Management department and those identified as having chronic spine-related condition were included of which 149 patients were excluded because of either incomplete records or no longer had the SCS implanted. Being a tertiary referral center, a large portion of the excluded patients were those who chose to get the SCS implant performed at Cleveland Clinic, however, for convenience purpose, preferred to have their follow-up visits at their local pain physician closer to home. Therefore, the final analysis included 181 patients who were further classified according to their BMI into the four groups: 33 under and/or normal weight patients (≤ 24.9 kg/m²), 72 overweight patients (25.0–29.9 kg/m²), 63 obese

(30.0–39.9 kg/m²) patients, and 13 morbidly obese (≥ 40.0 kg/m²) patients as illustrated in Fig. 1.

The Table summarizes the various factors and their statistical significance, all of which were used in the primary and secondary analysis for adjustment purposes. Age, BMI, diabetes, and sex were the only significantly different factors amongst the four groups for baseline ($p < .05$).

Multivariable linear regression plotting BMI against percentage pain relief revealed a significant correlation at both, 6 months (adjusted $R^2 = 0.116$, $p < .0001$) and at 12 months (adjusted $R^2 = 0.202$, $p < .0006$) after controlling for baseline confounders listed in the Table (Fig. 2). At 12 months, the only other significant variables for pain improvement were disability status ($p < .035$) and opiates utilization as measured in mg morphine equivalency at 12 months ($p < .01$).

The estimated coefficient from the multivariable linear regression models was approximately -1.91% (95% CI: -2.82% to -0.991%) and -1.48% (95% CI: -2.30% to -0.660%) reduction in pain improvement per unit increase of BMI for 6 months and 12 months scores, respectively. The estimated coefficient of disability status was -15.3%

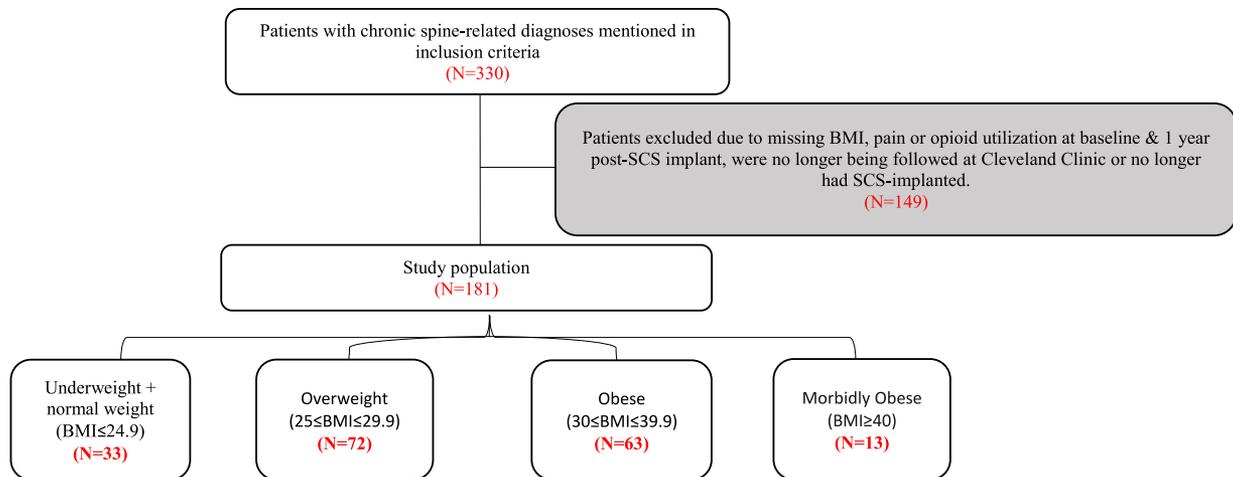


Fig. 1. Flow chart of patient selection.

(95% CI: -22.1% to -8.48%). The estimated coefficient for 12 month opioid equivalence was -0.08% (95% CI: -0.14 to -0.021), per 1 mg unit increase of morphine opioid equivalency. Residuals in both multivariate linear regression models were examined and verified that no significant deviation exists from the model assumptions.

The reduction in pain score caused by BMI was not related to baseline pain score level. Welch's two-sample *t* test of NRS pain scores between obese and nonobese groups revealed that there was no significant difference between baseline pain scores ($p = .70$). However, there was a significant difference in pain scores at 6 months ($p = .0003$) and 12 months ($p = .04$). This provides confirmation that the difference of pain score improvement, post-SCS implant, between obese and nonobese patients is not attributable to differences in baseline pain scores between the two groups (Fig. 3).

In order to examine the relationship of opioid utilization to BMI, ANOVA testing was performed for the mean difference in opioids (mgs) between 12 months and baseline which yielded a nonsignificant correlation ($p = .75$). Further opioid analysis at 12 months was performed using linear regression analysis, which also revealed a nonsignificant interaction ($R^2=0.0003$, $p = .836$), (Fig. 4). To test if there was a difference between any of the four treatment groups, a posthoc Tukey's test was performed, and revealed no significant difference between any two groups (Fig. 5).

There was a significant difference between percentage pain improvement at 6 ($p = .0001$) and 12 months ($p = .001$) when stratified by BMI groups, indicating a significant clinically relevant differential efficacy of SCS treatment with respect to BMI, using ANOVA. The percentage of pain improvements at 6 months stratified by BMI group were: underweight and/or normal, 48.7 ± 28 ; overweight, 38.4 ± 24 ; obese, 23.2 ± 26 ; morbidly obese, 21.9 ± 12 . The percent pain improvements at 12 months stratified by BMI group were: underweight and/or normal, 44.5 ± 28 ;

overweight, 36.1 ± 24 ; obese, 31.6 ± 24 ; morbidly obese, 9.52 ± 18 .

In order to determine specific interaction significance, a Tukey's test was used to compare each of the groups. For the 6-month comparison, there was a significant difference found between underweight and/or normal and obese ($p < .0001$) as well as between the overweight and obese ($p < .05$). For the 12-month comparison, there was a significant difference found between underweight and/or normal and morbidly obese ($p < .001$) as well as between BMI overweight and morbidly obese ($p < .05$) (Fig. 6). These results indicate that a significant portion of pain reduction is associated with BMI and can be understood in terms of clinically relevant groups.

In order to test for potential confounding variables between time periods, a linear mixed model analysis was performed between BMI and baseline confounding variables against pain improvement. Here, we considered that the two individual time points, 6 and 12 months, contained a different population of pain scores (our random-effects). This was compared with our baseline confounders, which we considered, all of which were drawn from the same population (fixed effects). We wanted to test the hypothesis that the four BMI groups (underweight and/or normal, overweight, obese, and morbidly obese) were drawn from different populations of pain score improvement. In order to test this, a likelihood ratio test was constructed which compared linear mixed models with and without BMI. Using a likelihood ratio test to compare between linear mixed models with and without BMI, yielded statistically significant ($p < .01$) evidence that the four BMI groups had different degrees of pain score improvement (Fig. 7). These results indicate that, even after controlling for other confounders and differences between time periods of pain score measurement and inter-subject differences, there was a significant effect of BMI on pain reduction following SCS treatment, with y-intercepts of 9.48% , 4.88% , -4.51% , and

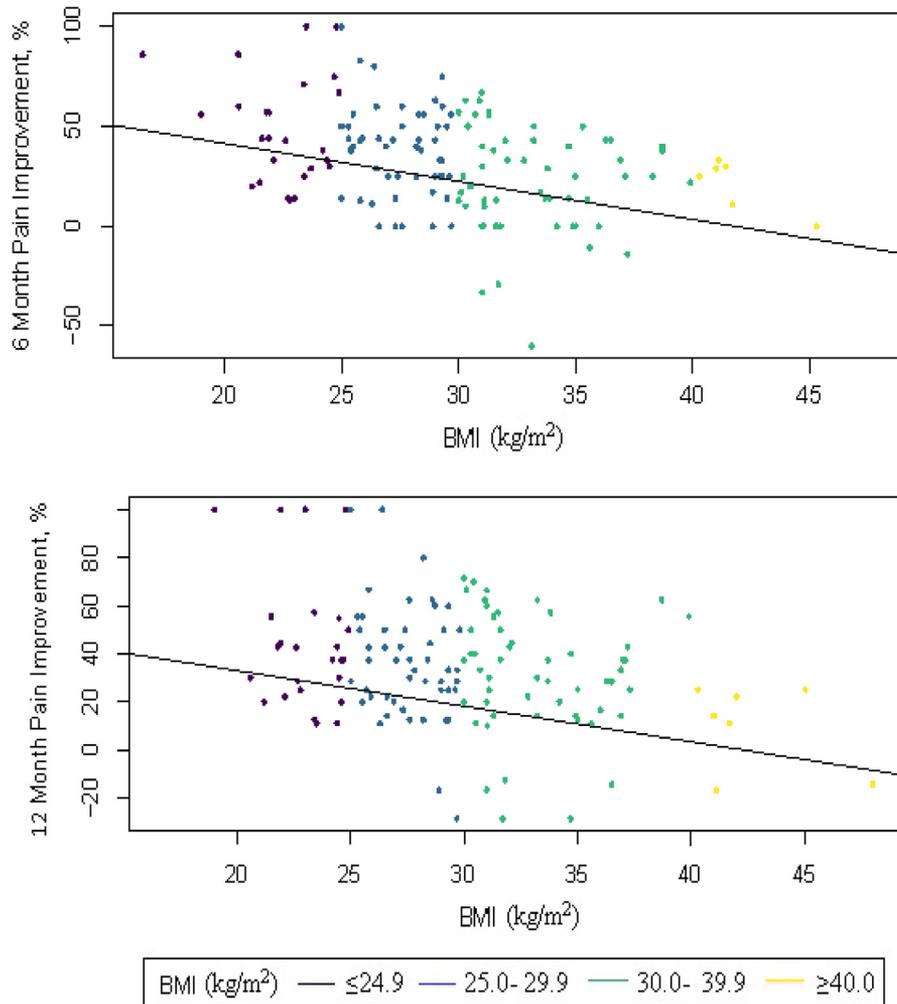


Fig. 2. Plots of BMI and pain improvement at 6 and 12 months following SCS and predicted model of relationship from confounder controlled multivariate linear regression. (Top) Predicted relationship of BMI and pain improvement at 6 months. A significant ($p = .0001$) relationship was found between BMI and pain reduction. Adjusted $R^2 = 0.144$. (Bottom) Predicted relationship of BMI and pain improvement at 12 months. A significant ($p = .006$) relationship was found between BMI and pain reduction. Adjusted $R^2 = 0.202$.

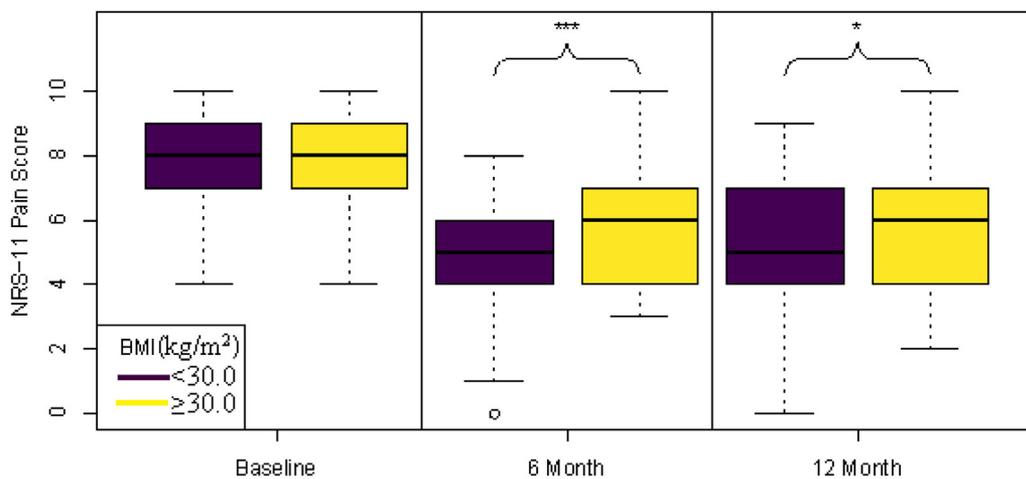


Fig. 3. Boxplot of NRS-11 pain score at baseline, 6 months and 12 months post-SCS implant, categorized by obese and nonobese BMI classification. There was no significant difference for baseline pain scores between obese and nonobese patients. There was significant difference between pain scores at both 6 months ($p = .0003^{***}$) and 12 months ($p = .04^*$), Welch two-sample t test.

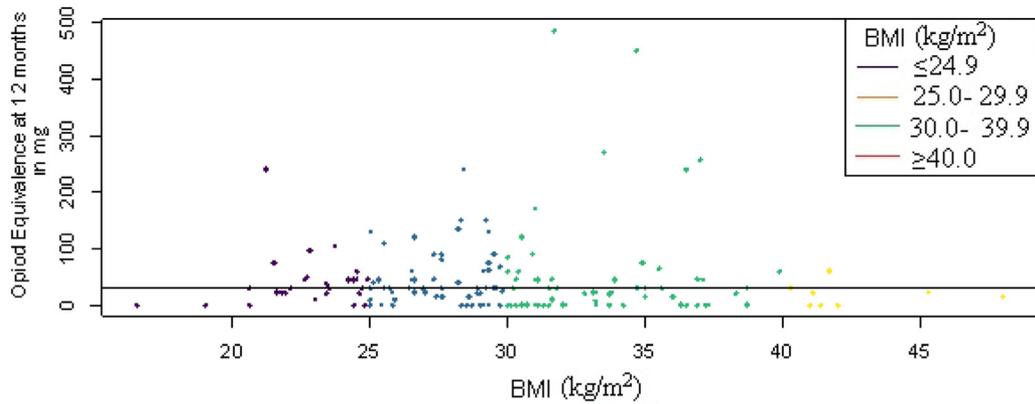


Fig. 4. Plot of BMI and opioid morphine equivalence in mgs, at 12 months following SCS implant, with linear regression fit. No significant relationship found ($p = .836$), $R^2 = 0.0003$.

−9.83% for underweight and/or normal, overweight, obese, and morbidly obese respectively.

Last but not least, a supplemental analysis showing pain improvement percentages for BMI groups, subtracted by intercept values found in linear mixed model analysis was performed as illustrated in Fig. 8. When compared with Fig. 5 we see that the 6 and 12 months pain improvement percentages, subtracted by intercept found in linear mixed model analysis, accurately explain the deviation in the original data with respect to the BMI groups.

Discussion

Our primary objective was to determine if increasing BMI has an adverse effect on patients’ response to SCS therapy, specifically in chronic spine-related pain

etiologies, with emphasis on long-term opioid utilization. With both chronic pain and obesity being on the rise [25,26], the importance of understanding the effect of obesity on SCS effectiveness is momentous, especially with a modifiable risk factor that, if controlled, could ultimately lead to improved long-term SCS outcomes. This is increasingly true in light of existing evidence showing that weight loss can alleviate pain and diminish pain-related functional impairment [22,27–29].

On a molecular level, theories supporting obesity-induced pain presume that obese individuals have an increased inflammatory state [30,31]. The increased adipose tissue in obese patients has endocrine properties by producing cytokines such as interleukin 6 (IL-6), tumor necrosis factor (TNF- α), and Leptin. Furthermore, IL-6 causes the liver to produce C-reactive protein, another

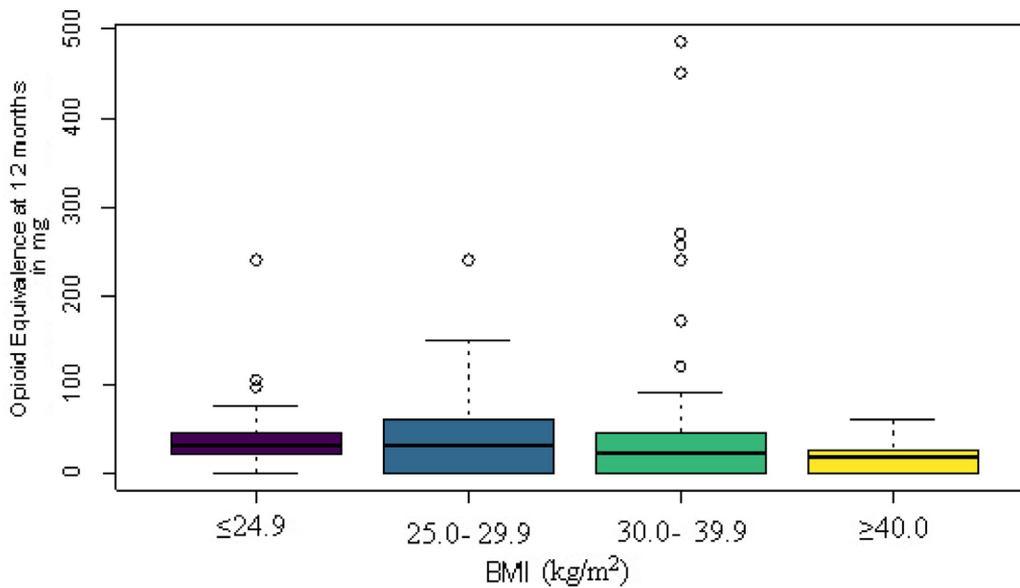


Fig. 5. Opioid morphine equivalence in mgs at 12 months post-SCS implant, stratified by BMI categories as defined by the NIH. No significant relationship was found for any pairs as determined using Tukey’s test (all pairs $p > .60$).

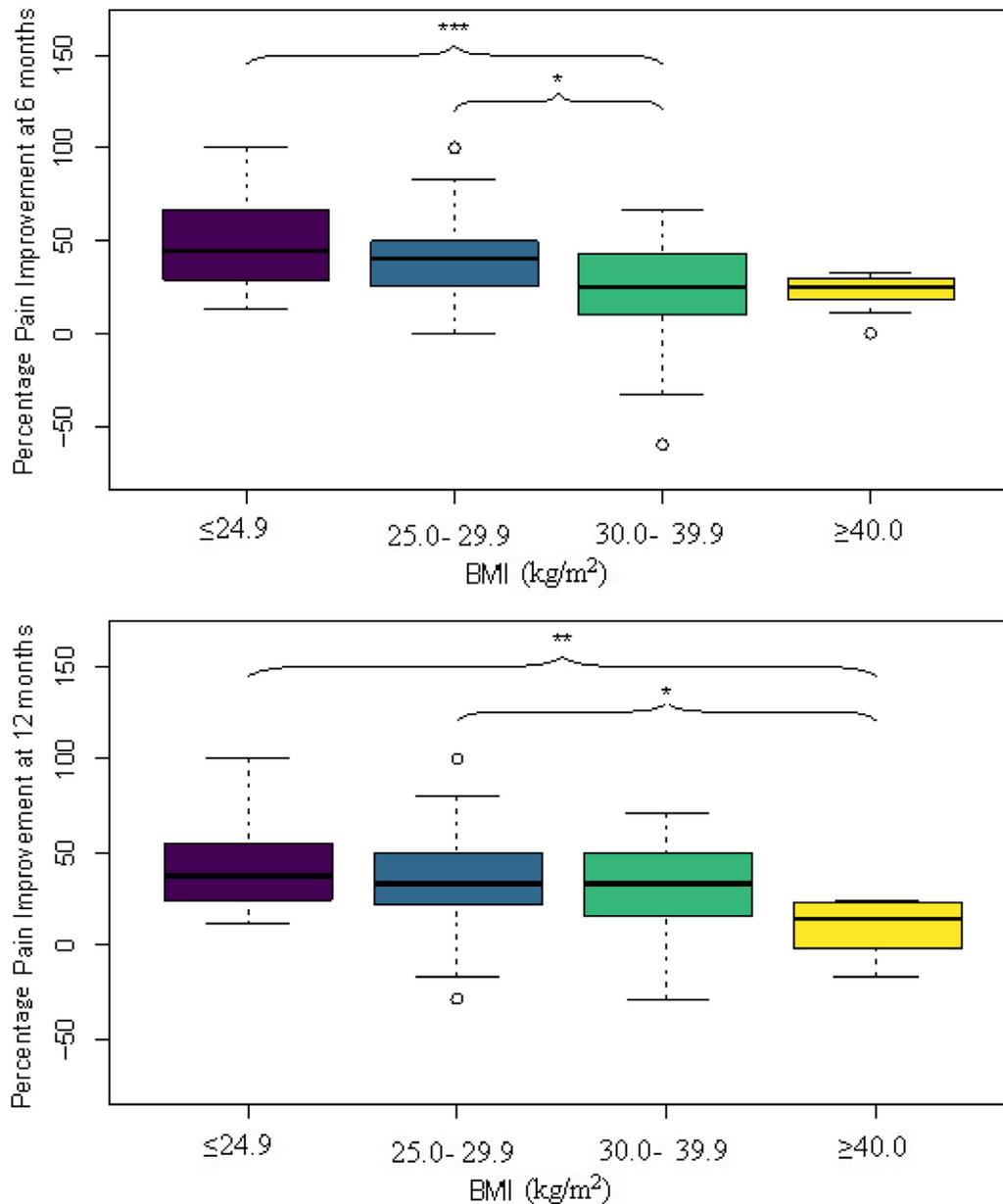


Fig. 6. Pain improvement percentages for NIH defined BMI groups. (Top) Six month percentage improvement in pain. A significant difference in means measured by Tukey's test was discovered between the normal and/or underweight group relative to obese group ($p < .0001^{***}$); and between the overweight group and obese group ($p < .05^*$). (Bottom) Twelve month percentage improvement in pain. A significant difference in means measured by Tukey's test was discovered between the normal and/or underweight group relative to morbidly obese group ($p < .001^{**}$); and between the overweight group and morbidly obese group ($p < .05^*$).

inflammatory mediator. Moreover, the adipose tissue produces a monocyte chemoattractant factor, which attracts and stimulates monocytes to produce additional IL-6. The resulting increased level of inflammatory mediators play a role in modulating neuronal activity and are involved in the production of low-grade chronic inflammatory pain as well as neuropathic pain [30,31].

More specifically, from a SCS standpoint, obese patients pose a higher risk of developing two of the most common complications observed during SCS therapy, lead migration, and hardware malfunction [32], with a prevalence of 13%–22% for the former [33]. This is primarily attributed to the

increased difficulty of lead placement because of harder patient positioning and increased tissue depth [19,34].

Our results demonstrated a significant and clinically relevant association between BMI and degree of pain improvement post-SCS therapy that was maintained throughout the duration of our 12 months follow-up period. The multivariate linear regression controlling for other confounding factors, revealed a significant impact of BMI on pain improvement, measured by percentage change in NRS pain score from baseline to both 6 and 12 months following SCS therapy. The study was also able to quantitate the effect of BMI on the percentage pain reduction score

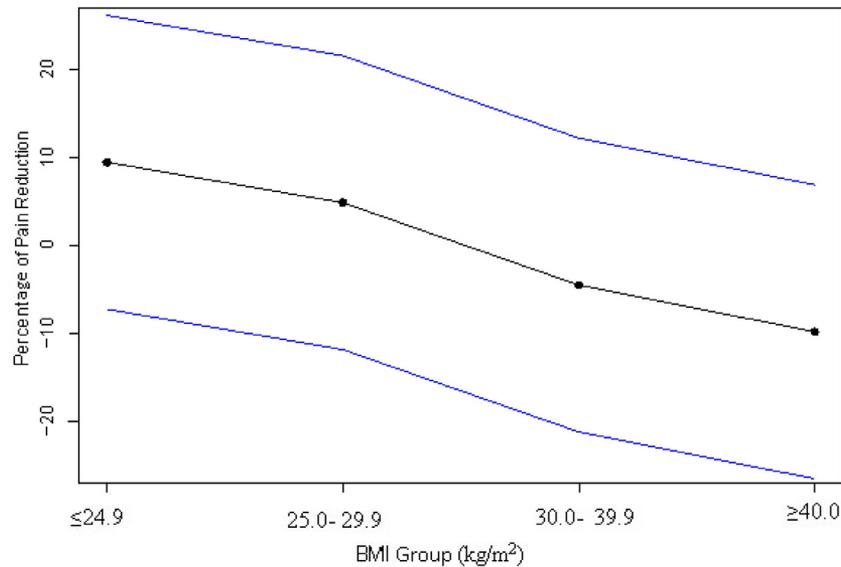


Fig. 7. Intercept values of linear mixed model for each BMI group. A significant association ($p < .01$) between BMI and pain response was found after accounting for differences in time of measurements. Blue lines represent 95% confidence intervals.

following SCS treatment as being around 2% reduction in efficacy of SCS for every unit increase of BMI. The likelihood ratio revealed that underweight and/or normal individuals demonstrated a 20% better response to SCS therapy than morbidly obese individuals, which is consistent with the before-mentioned approximation of 2% reduction in pain score per unit BMI increase.

There was no significant difference detected between differences in baseline pain status between obese and nonobese individuals, indicating that the baseline pain score levels before treatment did not significantly impact the outcome. There was a significant difference in the 6-month and 12-month pain score between obese and nonobese individuals. The ANOVA indicated a difference across NHLBI-indexed BMI groups, establishing evidence for change across a clinically relevant scale. The linear mixed model analysis showed that BMI group was significantly associated with pain score reduction; despite within subject variation and variation between 6-month and 12-month period measurements, and that this trended monotonically. Even after accounting for opioid use at 12 months, the relationship between BMI and pain reduction was not significantly affected. Collectively, we conclude that these results confirm our initial hypothesis that SCS therapy effectiveness is inversely proportionate to increasing BMI and that this negative correlation is only as a result of obesity, as the opioid utilization was not changed.

To our knowledge, Marola et al. [19] are the only authors that published results that specifically included analysis of the effect of BMI on pain in patients treated with SCS implant. The authors performed a prospective study comprised of 77 patients in which high BMI patients were found to experience a statistically significant decreased improvement on the Beck's depression inventory at both 6 and 12 months. Furthermore, there was reduced improvement on

the pain catastrophizing scale at the 1-year benchmark [19]. Of interest, no statistical significance was found between the BMI cohorts for the other questionnaires completed including visual analog scale, McGill pain questionnaire, Oswestry disability index, or insomnia severity index.

Major differences exist between the above-mentioned study and ours making comparability unfitting. Given the prospective nature of Marola et al.'s study, the authors were able to capture more than one outcome measure. However, this was at the expense of a smaller sample size. We sought to divide our sample size into groups based on NHLBI-indexed BMI cohorts providing a more detailed analysis, whereas, Marola et al. divided their sample into two groups based on the 75th BMI percentile, which resulted in comparison of outcomes of patients with BMI greater than or equal to 36.5 kg/m² and patients with BMI less than 36.5 kg/m².

Additionally, a crucial element that may affect results is opioid utilization, which we incorporated in the present retrospective study to ensure that the pain relief experienced is not attributable to an increased opioid dosage. Although we anticipated seeing an inversely proportionate relationship between opioid and BMI, the linear regression analysis and Tukey's test at 12 months showed little to no changes in the morphine equivalent doses between the groups. This confirms that the reduction in pain is not a result of increased opioid dosing.

In our opinion, the lack of significant opioid reduction amongst the BMI cohorts could possibly be explained by patients experiencing decreased pain levels with the SCS implants, consequently resulting in increased physical activity and overall functionality. Another factor to consider is patients suffering from chronic pain are generally resistant to decreasing their medication doses and normally

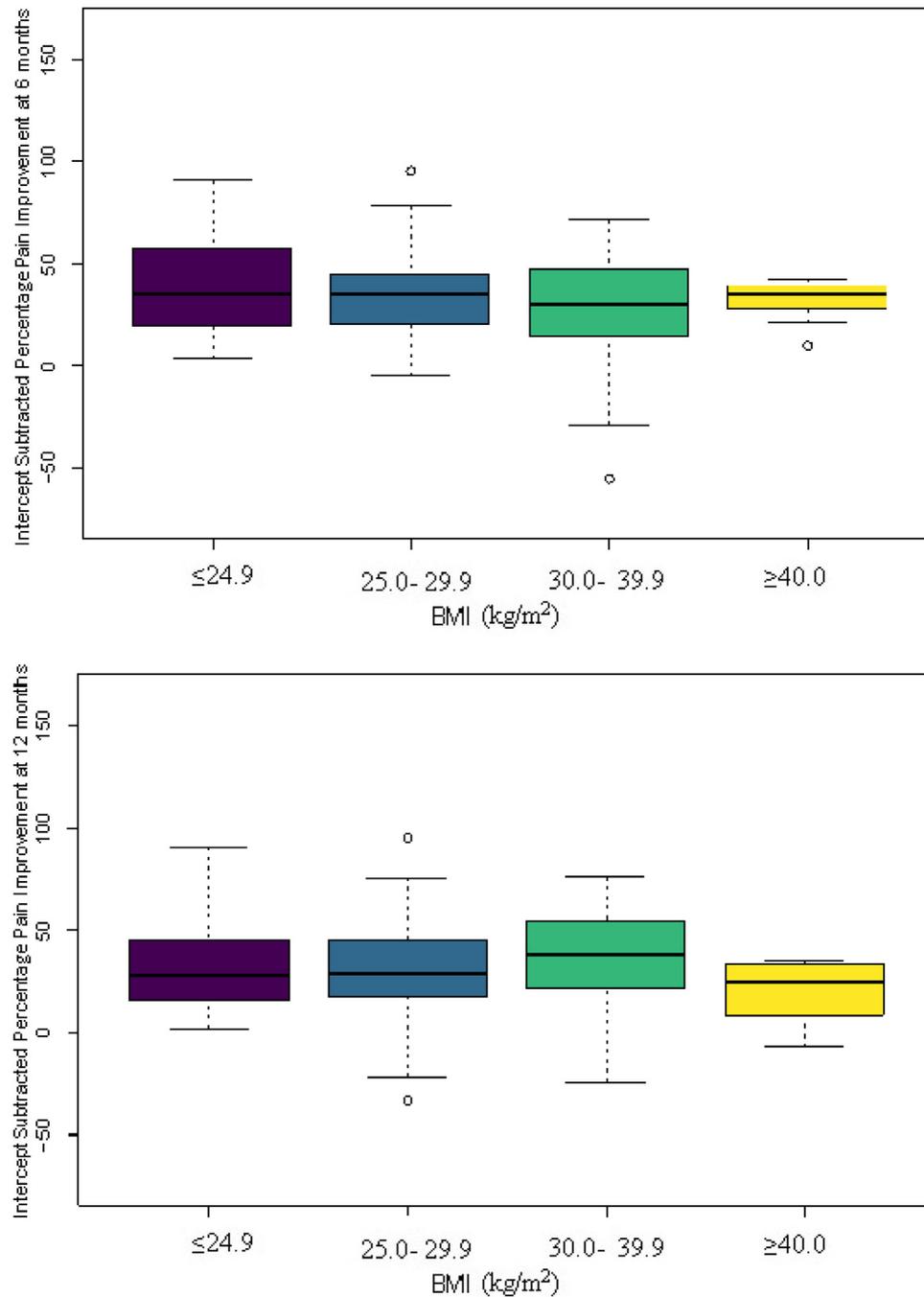


Fig. 8. Pain improvement percentages for NIH defined BMI groups, subtracted by intercept values found in linear mixed model analysis. Compare with Fig. 5. (Top) Six-month pain improvement percentage, subtracted by intercept found in linear mixed model analysis. (Bottom) Twelve-month pain improvement percentage, subtracted by intercept found in linear mixed model analysis. The intercepts found accurately explain the deviation in the original data with respect to the BMI groups.

do not volunteer to wean down unless guided or instructed to do so by their treating physician.

Study limitations

As with all retrospective studies, we cannot be certain that the independent association we found was causal in

nature. Although we studied a large sample size and accounted for the majority of potentially confounding baseline factors, residual bias may still exist, caused by the uncontrolled nature of the retrospective analysis. Additionally, in some instances, for example athletes, BMI may not be the most accurate indication of body fat because it does not take into consideration lean mass, bone weight, and

distribution of fat in the body such as visceral adipose tissue which are equally as important [35]. More accurate results are achieved with waist circumference, a measurement of abdominal fat and waist-to-hip ratio [36], however, this was not feasible given the retrospective nature of the study.

Conclusion

In conclusion, our study illustrated statistically significant results demonstrating a negative association between SCS effectiveness and increasing BMI at 6 and 12 months post-SCS therapy with a 2% reduction in efficacy for every unit of BMI increase, after adjusting for confounding factors, and a 20% better response in underweight and/or normal patients over the morbidly obese individuals. However, we found no significant difference amongst the BMI cohorts and the daily opioid consumption. We believe these results may ultimately aid physicians in determining the optimal course of treatment for their patients, take the necessary precautions, and provide necessary education to patients regarding the utmost importance of weight loss before and after successful neuro-modulator implant. In face of limited research and the high prevalence of obesity and chronic pain, we urge further assessment of the effect of BMI on SCS efficacy and explore possible underlying causes of such an effect in future studies to maximize outcomes and reduce the burden of providing less than optimal pain relief.

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