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**Efficacy of Radiofrequency Ablation or Spinal Cord Stimulation for Management of
Chronic Mechanical Low Back Pain**

By

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Capstone Project

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Background

With over 191 million prescriptions for opioid medications being written annually, 11.5 million Americans abusing opioid prescription medications each year and on average 130 Americans dying from opioid overdoses every day¹, finding alternatives to opioids for the management of chronic pain is more important now than ever. Since the early 1990s opioids have been the primary method for managing chronic pain. While the number of opioid prescriptions has decreased since its peak in 2010, the morphine milligram equivalents of the prescriptions written today are generally three times greater than they were in 1999. Non-pharmacological methods for chronic pain management such as radiofrequency ablation, spinal cord stimulation, acupuncture, massage, chiropractic, and meditation are available and are being offered to patients more often now than during peak opioid prescription writing. Many patients may be hesitant to try these different methods for pain management for a number of reasons: radiofrequency ablation and spinal cord stimulation are more invasive than pain medications, research confirming their efficacy compared with opioid medications is limited, and many patients whose pain is controlled on opioids fear that changing therapy might increase their pain. Of the non-medicinal therapies, radiofrequency ablation and spinal cord stimulation will be examined as pain relief tools for patients with chronic mechanical low back pain. If they are found to be effective, then they could be confidently recommended to these patients, either as a replacement or an adjunctive analgesic therapy, thus diminishing the reliance on opioids.

Discussion

Research from the last five years on these non-pharmacologic therapies has included randomized clinical trials (RCTs), meta-analyses, and retrospective observational studies. Six

studies examined radiofrequency ablation, whereas seven investigated spinal cord stimulation. Although strengths included RCT designs, these trials were not double-blinded. The meta-analyses were stronger if the individual RCTs were of good design. In contrast, observational studies, especially retrospective approaches, were inherently weaker than RCT designs. Limitations also included small sample sizes, the subjectivity of outcome determinations, variability due to procedures being performed by different clinics and doctors, and other weaknesses.

Radiofrequency Ablation

The six articles on radiofrequency (RF) ablation were either retrospective analyses or randomized clinical trials (RCTs) and examined the efficacy of this method for relief of chronic mechanical low back pain, chiefly in patients who were not controlled on pain medications or other therapies. The results were mixed, neither substantiating nor disproving the effectiveness of this therapy. Of significance, none of the RCTs were double-blinded. Furthermore, only subjective tools were used to assess the degree of pain relief. Most of these studies used the Visual Analog Scale (VAS) for pain measurements and the patient's perceived quality of life scores to determine the efficacy of this treatment. The VAS pain measurement system is a validated, subjective scale scoring pain on a one to ten spectrum with one being "no pain" and ten being "worst pain", while the perceived quality of life scale is a psychological assessment which measures multi-faceted areas of health-related and non-health-related aspects of a patient's well-being. Despite these limitations, preliminary results from one retrospective analysis by Jeong et al., examining 52 patients post procedure revealed that endoscopic radiofrequency denervation of the medial branch nerve could be an effective alternative

treatment modality for chronic back pain originating from facet joints². These patients were carefully evaluated for the origination of their pain, confirming that the origin was from the facet joints and not from other areas in the spinal column. Three additional studies investigated the long-term efficacy of radiofrequency ablation. One prospective observational study by McCormick et al., examining 62 patients treated with RF ablation, found statistically significant findings: 58% of the patients retained long-term improvement in function, and greater than 50% of patients experienced continued pain relief along with an increased quality of life score, averaging 3.4 points above the baseline for up to 39 months.³ The second long-term follow-up retrospective study by Ramirez et al., evaluating 73 patients, showed that RF ablations of the medial branch and nerves in the joint capsule lead to sustained pain relief results in a high percentage of the patients at the one-year mark after the ablation.⁴ The third long-term follow-up prospective observational study by Pevsner et al., following 122 patients revealed that the majority (75%) of the patients who had RF ablation had a reduction in their pain one month post procedure, 71% at 3 months, 66% at 6 months, and 63% at 12 months still had significant relief of their pain⁵. Findings from another RCT of 58 patients by Shabat et al., focused on the use of RF ablation in the treatment of elderly patients who were not considered candidates for surgery or opioid therapies (also a long-term study). This trial confirmed that RF ablation was a safe and effective method for pain relief in this population and that 74% of the patients who had RF ablation had clinically significant reductions in their pain post-procedure. Pain relief in this study was: 66% of patients still found adequate relief at three months, 57% of patients still had relief at six months, and 52% continued to report relief from their pain at one year.⁶ Nonetheless, the population is narrowly focused and hence, the findings are not applicable to many other patients with mechanical low back pain. While these studies all showed promising

results, another study of 681 patients followed for 3 months post procedure by Juch et al., done as part of a three multicenter, nonblinded randomized clinical trial, found that RF ablation combined with a standardized exercise program resulted in either no improvement or no clinically important improvement in chronic low back pain when compared with a standardized exercise program alone⁷. Despite mixed results on whether or not radiofrequency ablation provides adequate pain relief, the available research suggests that it could be considered for specific patient populations who may not qualify for other methods of pain control and/or when the origin of a patient's pain is carefully evaluated and found to be from facet joints or median nerves.

Spinal Cord Stimulation

Seven studies, including retrospective observational analyses and meta-analyses, evaluated the effectiveness of spinal cord stimulation for chronic mechanical low back pain. The patients in these studies were asked about perceived pain using the VAS pain scale and perceived changes in their quality of life after implantation of the stimulators, both subjective assessments. While most of these studies consisted of large patient samples with well-matched treatment and placebo groups, none of them were double-blinded for either treatment modality or pain relief outcomes. The evidence from this research showed trends that the implantation of spinal cord stimulators was associated with both increased odds of reducing pain medication consumption⁸ and improved scores in patients' perceived quality of life.^{9,10,11} Among these studies, a comprehensive systematic review by Grider et al., consisting of six studies, totaling 460 patients with chronic spinal pain (pain originating from cervical, thoracic, or lumbar spinal regions) showed statistically significant evidence that spinal cord stimulation provided pain relief and

improved function in patients with failed lumbar back surgery syndrome.⁹ Although this review found favorable results for spinal cord stimulator implantation, the population was restricted and thus, limited the generalizability of this evidence. Another prospective, multicenter clinical trial by Deckers et al, examined 53 patients with chronic mechanical low back pain who had failed conventional therapy and were not candidates for traditional back surgery. Spinal cord stimulator implantation improved patients' overall satisfaction, which included reduced back pain, decreased perceived disability, and increased quality of life. No one outcome measure was significantly better clinically in the treatment group compared with the control group (no stimulators implantation) but when compared with their baselines in these areas patients had statistically significant improvements.¹⁰ Another study DiBenedetto, et al. examined the retrospective data from medical records of patients with at least 24 months of active treatment in an interdisciplinary community pain center. The 32 patients who had spinal cord stimulators implanted were compared with 64 patients who received only conventional pain control therapy. The patients who had spinal cord stimulators implanted experienced diminished opioid utilization, decreased interventional pain procedures, and reduced perceptions of disability.¹¹ Another study by Faber et al. consisting of 122,827 patients, of which 5,328 underwent SCS and 117,499 were managed with conventional pain management, focused on initial costs of spinal cord implantation versus cost reduction over time from reduced opioid medication use and traditional pain management methods. The total annual costs for pain management strategies were decreased following implantation of the spinal cord stimulator systems in these patients at 1,3, 6, and 9 years¹². Lastly, in another prospective multi-center RTC by Rigoard et al., spinal cord stimulators were added to optimal medical management in 218 patients with failed back surgery syndrome and continued mechanical low back pain. When compared with optimal

medical management alone, the addition of spinal cord stimulation resulted in superior back and referred leg pain reductions and increases in overall life satisfaction.¹³ All these studies showed that properly implanted spinal cord stimulators were effective for reducing chronic low back pain, decreasing the overall cost of pain management, and diminishing patients' perceptions of their disability.

Conclusion

In conclusion, while the research on radiofrequency ablation had mixed results with some studies showing good pain relief and others showing insignificant pain improvement, the evidence from research on spinal cord stimulator implantation was consistently favorable with good responses overall, primarily improved pain relief after implantation. Based on the available research, patients who have chronic low back pain due to mechanical mechanisms should be offered either RF ablation or spinal cord stimulator implantation according to their needs. After thorough informed consent about the pros and cons, these treatments can augment and optimize their pain control. Nevertheless, many aspects of this research could be improved. For example, comparing-pain relief with these methods compared with opioids alone should be investigated in head-to-head trials. Also, a more objective method of determining pain relief should be established for a more accurate evaluation of pain. Additionally, standardization of procedures for radiofrequency ablation and spinal cord stimulator placement would permit research studies to be more readily compared with one another. Careful patient selection with more rigorous inclusion/exclusion criteria would allow providers to determine which patient populations would benefit the most from these treatment modalities. Altogether, radiofrequency ablation and spinal cord stimulators have value as methods of achieving pain relief. Patients should be screened

carefully for characteristics favorable for beneficial outcomes. These options should be offered either as an alternative to or in addition to opioids, in order to reduce the amounts of opioids being prescribed. Patients who do not qualify for other means of pain control should also be offered these methods because the evidence points to some degree of pain relief for some patients.

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