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# A CROSS-SECTIONAL ANALYSIS OF CONFLICTS OF INTEREST IN RANDOMIZED CLINICAL TRIALS RELATED TO SPINAL CORD STIMULATION

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## Introduction

Spinal cord stimulation (SCS) has revolutionized pain management by providing opioid-sparing and targeted pain relief, which is supported by overwhelmingly positive results published in the literature. However, conflicts of interest (COI) may introduce substantial bias into the outcomes of clinical trials, which serve as a foundation for evidence-based medicine. Industry funding is particularly prevalent in interventional chronic pain medicine, which carries the highest number of monetary transactions in the pain medicine field. (1) This interplay with industry facilitates medical innovations but also raises concerns about the potential underreporting of unfavorable results. SCS manufacturing industries provide notable funding for research, medical advice, and other consultancy fees, which may make interventional pain physicians susceptible to COI. Prior publications have underscored the impact of minor gifts on physicians' perceptions of the company's product and demonstrated an association between investigators' financial ties and positive trial outcomes. (2,3) These findings raise concerns about study design, publication bias, and potentially reporting negative results in a favorable light to meet the industry's expectations. (4) Despite this current environment, there are no studies exploring COI in the context of neuromodulation for chronic pain. This cross-sectional study aims to address this gap and investigate the prevalence of COI among randomized controlled trials (RCTs) related to SCS and analyze the association between the presence of COI and trial outcomes.

## Materials and Methods

The present study is deemed exempt from Mayo Clinic Institutional Review Board. To identify relevant RCTs, we conducted comprehensive searches in electronic databases (Medline, Embase, Cochrane, Scopus) from January 1st, 2013, to July 28th, 2023. The time period is chosen based on the Open Payment database release date. Exclusion criteria included non-English studies, pediatric population, and non-RCT studies. The publication year, author names, SCS manufacturer, RCT study design, primary outcomes, favorability of results (met primary endpoint), disclosed financial COIs, and funding were extracted from included articles. COI for each author was identified in the disclosure section of each manuscript, the online Centers for Medicare and Medicaid Services Open Payments database, and through online searches. Reported COIs were limited to companies manufacturing SCS.

The primary outcomes were (1) prevalence of COI among RCTs and (2) if the presence of COI correlated with favorability of results. The secondary outcome included the association between the total industry funding amount per RCT and the favorability of results. Continuous and categorical variables were displayed as mean (standard deviation) and frequency (percentage), respectively. Regression models were constructed to determine the association between COI and favorability of results, as well as funding amount and favorability of results. Regression models were adjusted for covariates, including study size, design, country of origin, and blinding. Statistical significance was set at a p-value < 0.05.

## Results/Case Report

This study identified a high prevalence of COI among RCTs related to SCS therapy. Further, we report associations between the presence of COI and favorability of results.

## Discussion

While the majority of studies in interventional pain approaches currently rely on industry support, this observation is particularly prominent in the literature related to SCS therapy. To maintain research integrity in neuromodulation, it is essential to explore and prioritize transparency, independent funding mechanisms, and rigorous justification of any deviation from trial protocols.

## References

1. Goel, Vasudha, et al. "Industry Payments to Pain Medicine Physicians: An Analysis of the Centers and Medicaid Services Open Payments Program." *Pain Medicine* 22.6 (2021): 1376-1386.
2. Katz, Dana, Arthur L. Caplan, and Jon F. Merz. "All gifts large and small: toward an understanding of the ethics of pharmaceutical industry gift-giving." *The American Journal of Bioethics* 10.10 (2010): 11-17.
3. Ahn, Rosa, et al. "Financial ties of principal investigators and randomized controlled trial outcomes: cross sectional study." *bmj* 356 (2017).
4. Friedman, Lee S., and Elihu D. Richter. "Relationship between conflicts of interest and research results." *Journal of general internal medicine* 19 (2004): 51-56.

## Disclosures

No

## Tables / Images