



Analysis of Complications Associated with Restorative Neuromodulation in the FDA MAUDE Database

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INTRODUCTION

- Chronic low back pain (CLBP) is a common pain condition, associated with decreased quality of life, disability, and a high cost. (1,2)
- It is multifactorial and may involve the loss of neuromuscular control of spine stabilizing muscles, particularly lumbar multifidi, which may contribute to recurrence and chronicity of CLBP.
- Restorative neurostimulation is an emerging technique that activates dysfunctional multifidi with the goal of restoring functional stability and reducing pain. (2)
- The aim of this study is to evaluate complications associated with restorative neurostimulation in a real-world setting as its use becomes more prevalent.

METHODS



DATA EXTRACTION
- The Manufacturer and User Facility Device Experience (MAUDE) database
-Description: "Stimulator, Neuromuscular, Lower Back Muscles, Totally Implanted For Pain Relief"
-Product Code: QLK
-Time frame: 6/2021-6/2025
-Total medical device reports (MDRs): n=249

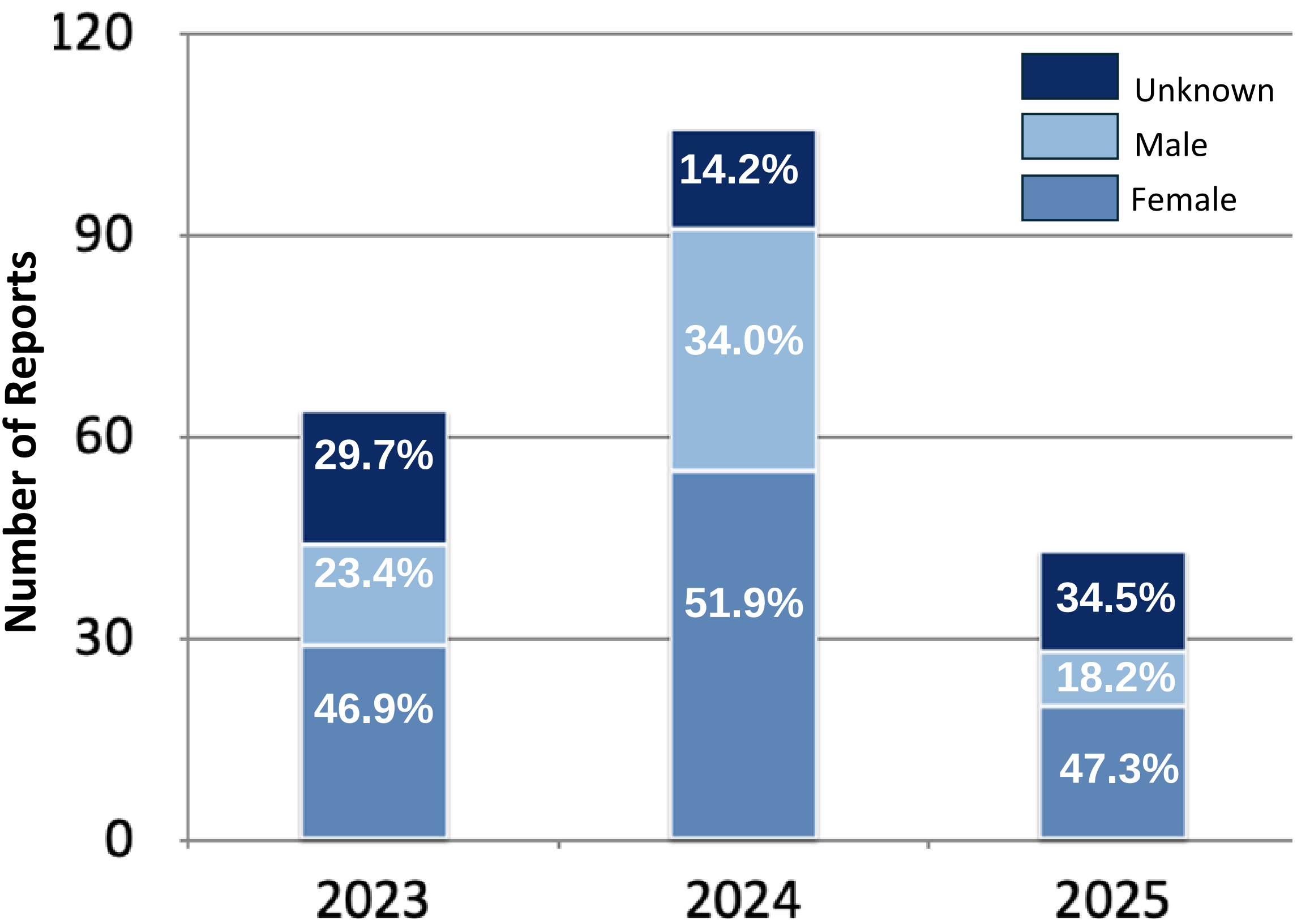


CLASSIFICATION OF ADVERSE EVENTS

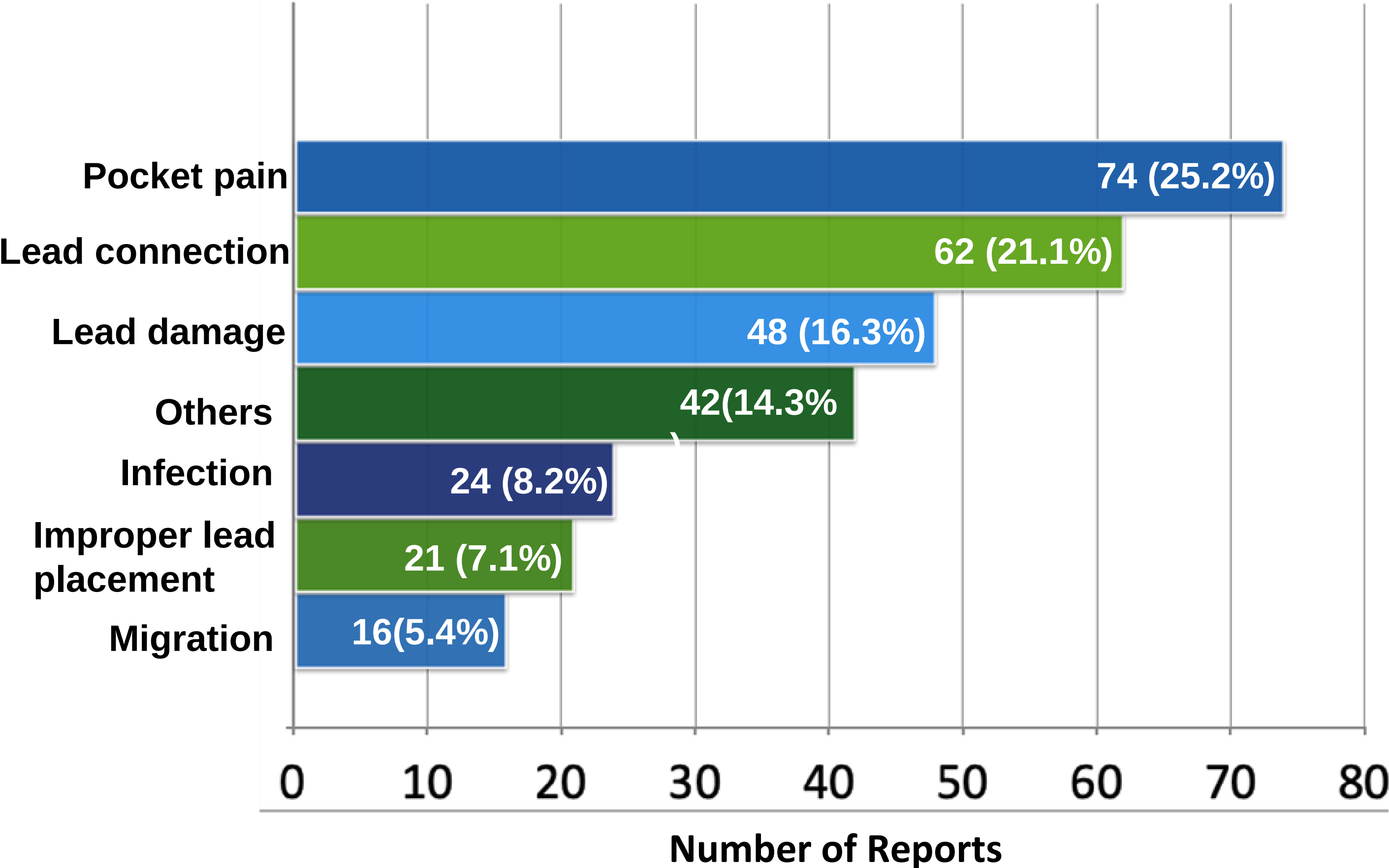
DEVICE-RELATED	Migration, erosion, lead damage, damage to sheath, lead connection failure, hardware malfunction, difficult insertion or removal
PATIENT-RELATED	Pocket pain, unwanted stimulation
SURGERY-RELATED	Neurologic symptoms, dural puncture, infection, hematoma/seroma)

RESULTS

Procedures by Year and Gender (2023-2025)

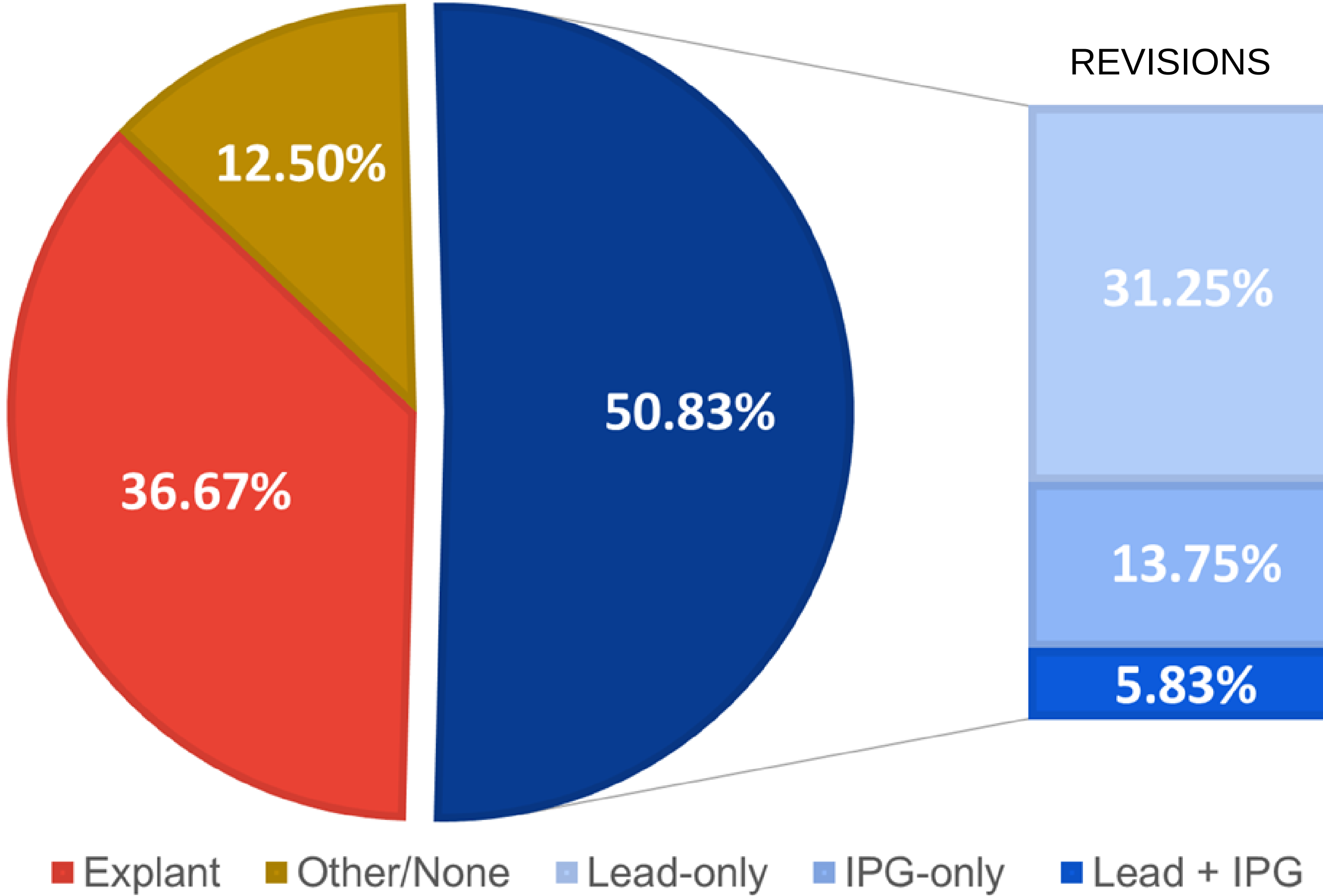


Reported Complication Types by Category (n=294)



- There were 240 total unique MDRs with a total of 294 complications, with the most MDRs in 2024 (n=105), followed by 2023 (n=62), and 2025 (n=42).
- Reported data the cohort was predominantly female (116 vs 59 males), with an average age 52±14.75.
- There were 162 (55.1%) device-related complications, the most common of which were lead connection (n=62, 38.3%), followed by lead damage (n=48, 29.6%) and migration (n=16, 9.9%).
- There were 76 (25.9%) patient-related complications with pocket pain (n=74, 56%) being the most common.
- Finally, there were 56 (19%) procedure-related complications with infection (n=24, 42.9%) being the most common followed by improper lead placement (n=21, 15.9%).

MANAGEMENT APPROACHES FOR REPORTED COMPLICATIONS (%)



DISCUSSION & CONCLUSION

This analysis provides real world data regarding complications with restorative neuromodulation. The data suggests that most adverse events were mechanical or tolerable rather than causing severe or lasting harm, being consistent with published clinical studies demonstrating low rates of serious complications and sustained therapeutic benefit. (2,3)
Data such as these can provide valuable information to guide clinical decisions, mitigate risks and lead to device optimization.

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