A MAUDE Analysis of Complications Associated with Spinal Cord Stimulation

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Introduction

Spinal cord stimulation is an increasingly common neurosurgical intervention for the management of intractable pain. Though the procedure is effective, device associated complications remain relatively common. The incidence of complications has been estimated in both independent studies and with data directly from the manufacturers. MAUDE, a federally run adverse events reporting database, is a publically available tool which could be valuable for adverse events monitoring of spinal cord stimulators when used correctly.

Objectives

1. To explore the utility of the MAUDE database in examining SCS complications.
2. To provide a gross estimate for the number of on-label SCS complications for the past 10 years.
3. To categorize the different complications within the MAUDE database and provide a proportional prevalence based on the total number of reported SCS complications.

Methods

From the FDA website, we accessed adverse events reports from the MAUDE database for devices used in spinal cord stimulation between June 30, 2007 and June 30, 2017. Duplicate reports were eliminated and those remaining were classified using key word analysis. Reports were classified as “Ineffective” “Lead Migration”, “CSF Leak”, “Infection”, “Inappropriate Shock”, “Paralysis” and “Death”. Reports were further classified as requiring hospitalization or surgical revision.

Results

A total of 126536 adverse event records were obtained. There were 7976 (6.5%) events classified as ineffective, 8467 (7.0%) as lead migration, 357 (0.29%) as CSF leak, 11529 (9.4%) as infection, 25925 (21%) as inappropriate shock, 473 (0.38%) as paralysis, and 1100 (0.89%) as death (Figure 1). Of the 1100 deaths, 261 (24%) were considered unrelated by the reporter, and only 595 (54%) were given the “Death” classification in the MAUDE database. The most adverse events, totaling 20528, were reported in 2013 (Figure 2).

Discussion

Though useful, the MAUDE database presents investigators with a significant number of challenges before the data within can become useful. Multiple reporting, inaccuracies, improper classification, and inconsistent formatting make navigating large data sets extremely difficult (figure 2). Despite this, the database is a trove of valuable information collected from the larger population, and with increased standardization it may become increasingly valuable in post-market device monitoring.

Conclusion

The MAUDE database is a useful tool to investigate device related complications, providing a potential resource for the real-time tracking of adverse events. Reviewing the frequency and nature of complications over the years allows less familiar to make informed treatment decisions. Despite this, further improvements in the database are essential for it to have any true long-term surveillance utility.

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