ORIGINAL RESEARCH

05. Sleep Solutions or Sleepless Nights? Adverse Events in Mandibular Adjustment Devices and Hypoglossal Nerve Stimulator Treatment of Obstructive Sleep Apnea

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https://www.youtube.com/watch?v=4rJ3DHWeKRs&list=PLhqNq3xJClbafO0Y5bvBcgMmXpgzJxd44&index=6&t=1020s

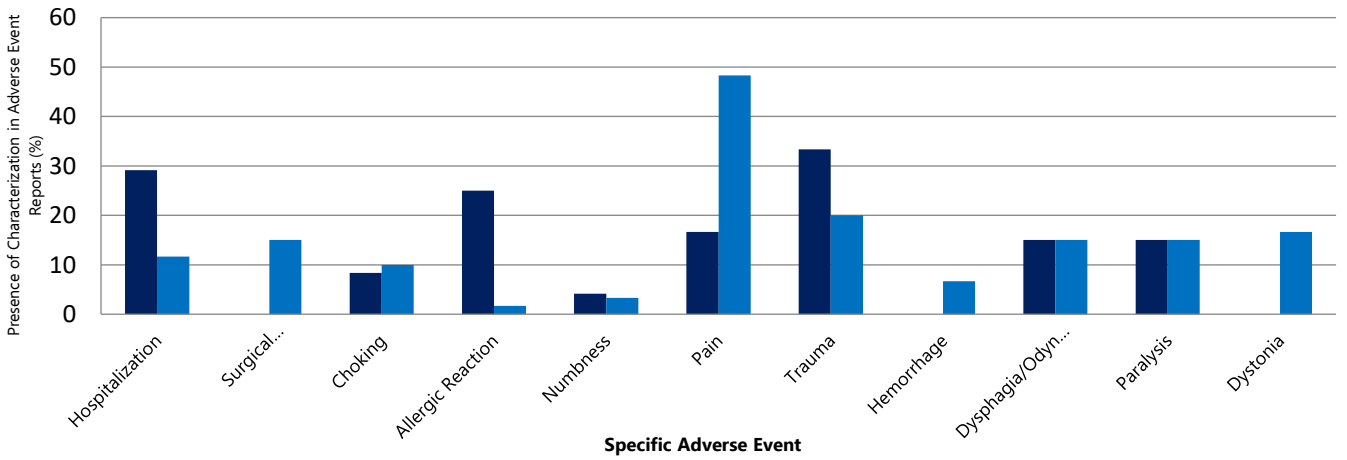
Background: Novel therapies for patients with obstructive sleep apnea (OSA) are gaining popularity as many turn away from traditional continuous positive airway pressure (CPAP) treatment. This study aims to analyze and compare the adverse events (AEs) associated with two alternative therapies to CPAP, mandibular adjustment devices (MADs) and hypoglossal nerve stimulators (HGNs).

Methods: A retrospective database analysis was conducted of the adverse event (AE) reports extracted from The Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database. Devices included MADs (SomnoMed Herbst Advance, Sydney, Australia, product codes DYJ, LRK, ECN, and EJF) and HGNs (Inspire Implant, Golden Valley, Minnesota, USA, product code MNQ) for all years reported. Duplicate entries and reports related to device malfunction were excluded. AEs were analyzed for severity of the adverse event and classified using the Clavien-Dindo scale. AEs were classified based on the severity of harm, type of harm (Allergic Reaction, Choking, Numbness, Pain, Trauma, Paralysis, Dystonia, Hemorrhage, Dysphagia/Odynophagia), and patient outcomes (Hospitalization, Surgical Management).

Results: A total of 24 MADs and 60 HGNs met the inclusion criteria for analysis. Trauma was the most frequently reported AE for MADs (n=8, 33.333%) while pain was most frequently reported for HGNs (n=29, 48.333%). Allergic reactions were significantly more prevalent in MADs compared to HGNs (n=6, 25.000% vs n=1, 1.667%, p=0.002). On the other hand, pain was significantly more prevalent with the use of HGNs compared to MADs (n=4, 16.667% vs n=29, 48.33%, p=0.012). The mean severity of the AE was higher in HGNs compared to MADs (3.000 vs 2.375, p=0.005) indicating a higher level of intervention was required and increased risk of life-threatening outcomes. No statistically significant difference in association was observed between MADs and HGNs for hospitalization, surgical management, choking, numbness, trauma, paralysis, dystonia, hemorrhage, dysphagia/odynophagia. Several outcomes and AE types approached statistical significance but did not meet the threshold for significance ($p<0.05$).

Conclusion: Mandibular adjustment devices and hypoglossal nerve stimulators have distinct differences in their adverse event profile. Hypoglossal nerve stimulators demonstrate higher severity burden and association with pain while mandibular adjustment devices showed higher association with allergic reactions. Given that both mandibular adjustment devices and hypoglossal nerve stimulators have the capacity to pose significant harm to patients, comprehensive investigation is needed to identify the causes and risk factors for complications to advance patient safety. Additionally, novel treatments for obstructive sleep apnea are needed to meet the increasing demand for alternatives to CPAP.

Figure 1. Comparison of Obstructive Sleep Apnea Device-Associated Adverse Event Reports



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