Adversarial Events in Hypoglossal Nerve Stimulator Implantation: 5-Year Analysis of the FDA MAUDE Database

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Background

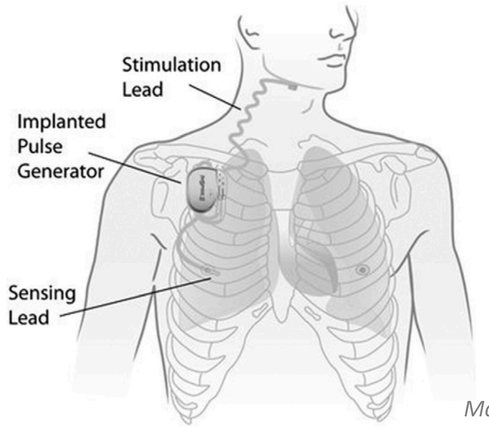
Use of hypoglossal nerve stimulator implantation has dramatically improved the surgical treatment of multilevel airway collapse during obstructive sleep apnea (OSA). The Inspire System (Inspire Medical Systems, Inc) was approved by the FDA for clinical use in 2014, based on its safety and efficacy in the STAR trial.

Objectives

1. To report post-market surveillance of an FDA approved HNS.
2. To identify technical steps associated with novel complications.

Methods

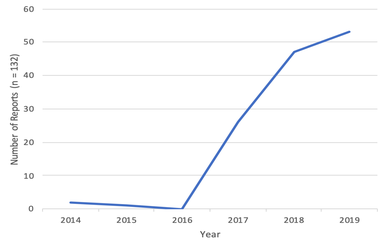
- Queried the FDA Manufacturer and User Facility Device Experience (MAUDE) database for reports associated with hypoglossal nerve stimulator implantation
- Searched for reports filed under the manufacturer Inspire between May 2014 and September 2019
- Examined reports for intra- and postoperative complications, need for revision surgery, and need for device explant
- Reports detailed the specific component of the device. This included the first- and second-generation implantable pulse generators (models 3024 and 3028), stimulation lead (model 4063), and sensing lead (model 4323).



Maurer 2012

Results

- 132 Reports, 134 Adverse Events
- Revision Surgery – 32
- Explant - 17
- Increased in number over each progressive year.



Device	No. of Reports	No. of Revisions	No. of Device Explants
Implantable Pulse Generator – Model 3024	28	7	4
Implantable Pulse Generator – Model 3028	45	5	8
Stimulation Lead	35	10	3
Sensing Lead	26	10	2

Device	Notable Complications - # of reports
Implantable Pulse Generator – Model 3024	Device Migration – 3 Infection - 4
Implantable Pulse Generator – Model 3028	Device Migration – 4 Infection - 16
Stimulation Lead	Infection – 8 Lead too superficially place – 3 Lead wire protrusion from wound - 5
Sensing Lead	Lead migration to pleural space – 2 Pleural effusion, atelectasis – 1 Pneumothorax – 5

Discussion

- Previous data have demonstrated hypoglossal nerve stimulator implantation results in reliable OSA improvement.
- The Inspire being utilized in an increasing number of centers each year.
- Our study finds rare safety issues, not seen in prior major studies
- Prevention of these uncommon complications depends on reduction of technical error
- Eliminating pneumothorax risk centers on careful retraction of the intercostal muscles and cautious positioning when the sensor lead is placed
- Device and lead migration avoidance requires adequate anchoring and limited fascial pocket dissection during device placement
- Limitations of the MAUDE database: Incomplete, unverified or inaccurate data can skew conclusion. There is a high risk of underreporting since reporting is voluntary. Also, there is restricted patient demographic and follow-up data, and no information on surgeon experience and case volume.

References

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