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Lead Detachment and Chest Wall Hematoma Following Minor Physical Exertion in a Patient with an Implanted Hypoglossal Nerve Stimulator for Obstructive Sleep Apnea: A Case Report

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Abstract

Hypoglossal nerve stimulation (HNS) using the Inspire device (Inspire Medical Systems) has emerged as an effective treatment for obstructive sleep apnea (OSA) in patients who are intolerant of or non-adherent to continuous positive airway pressure (CPAP) therapy. While the overall safety profile of HNS is favorable, device-related complications including lead fracture, lead migration, and hematoma formation have been reported. This case describes a 62-year-old woman with moderate-to-severe OSA (pre-implant AHI 34 events/h, Epworth Sleepiness Scale 14, BMI 29.8 kg/m^2) and an implanted Inspire device who developed acute chest wall hematoma after the respiratory sensing lead detached from the implantable pulse generator (IPG) during the act of lifting her dog, approximately two years after implantation. The hematoma was managed conservatively, and the patient subsequently underwent successful outpatient surgical revision with lead reconnection. This case highlights the potential for late lead detachment following seemingly minor physical exertion and adds to the growing body of literature on device-related complications of upper airway stimulation therapy.

Keywords

Obstructive Sleep Apnea, Hypoglossal Nerve Stimulator, Chest Wall Hematoma

1. Introduction

Obstructive sleep apnea is a prevalent sleep-disordered breathing condition with important cardiovascular, metabolic, and neurocognitive consequences. Population-based estimates vary according to the diagnostic threshold and population studied, but clinically relevant OSA is common among adults [1]. Continuous positive airway pressure (CPAP) remains first-line therapy; however, long-term adherence is suboptimal, and discontinuation rates as high as approximately 50% have been reported [2]. Hypoglossal nerve stimulation was developed as an alternative for appropriately selected patients with moderate-to-severe OSA who cannot tolerate or do not benefit adequately from positive airway pressure therapy. The Inspire system consists of a stimulation electrode placed on the hypoglossal nerve, a respiratory sensing lead positioned in the intercostal musculature, and an implantable pulse generator (IPG) placed in the infraclavicular region. Current US Food and Drug Administration labeling permits use in selected adults with an apnea-hypopnea index of 15 - 100 events/h who fail or cannot tolerate positive airway pressure and who do not have complete concentric palatal collapse; a BMI up to 40 kg/m^2 is included in the expanded labeling warning range [3].

The landmark STAR trial demonstrated substantial reductions in the apnea-hypopnea index and improvements in patient-reported outcomes after upper-airway stimulation, with relatively few serious device-related adverse events [4]. Subsequent clinical and postmarket studies have generally supported the effectiveness and safety of hypoglossal nerve stimulation, while identifying complications including infection, pneumothorax, hematoma or seroma, pain, lead migration, and device malfunction [5] [6]. Respiratory sensing lead damage and malfunction are increasingly recognized causes of device failure and revision surgery [7] [8].

2. Case Presentation

A 62-year-old woman with a history of moderate-to-severe obstructive sleep apnea (pre-implant AHI 34 events/h, Epworth Sleepiness Scale [ESS] score 14, BMI 29.8 kg/m^2), previously treated with CPAP but intolerant due to claustrophobia and mask discomfort, had undergone successful implantation of the Inspire hypoglossal nerve stimulator system approximately two years prior. Pre-implant drug-induced sleep endoscopy had demonstrated anteroposterior palatal collapse without complete concentric collapse, confirming candidacy. Her postoperative course had been uncomplicated, and she had been using the device nightly with significant improvement in her AHI (post-titration AHI 8 events/h) and daytime sleepiness (ESS improved from 14 to 6). Her medical history was otherwise notable for hypertension and hypothyroidism. She was not on anticoagulation therapy.

The patient presented to the clinic with acute onset of right-sided chest wall swelling, ecchymosis, and pain that developed shortly after she bent down and lifted her medium-sized dog (approximately 15 kg). She reported feeling a sudden "pop" or "snap" sensation in the right infraclavicular region during the lifting motion, followed by progressive swelling over the ensuing hours. She denied dyspnea,

fever, or any change in device function. She had not experienced any prior trauma to the device site.

On examination, there was a visible, tender, fluctuant swelling overlying the right infraclavicular region consistent with a chest wall hematoma. The overlying skin was ecchymotic but intact without signs of infection. No crepitus was palpated. Vital signs were stable.

Chest radiography revealed the IPG in its expected position in the right infraclavicular region; however, the respiratory sensing lead appeared to have retracted from its connection to the IPG, with the distal tip displaced from its expected intercostal position. There was no pneumothorax or pleural effusion. Device interrogation confirmed loss of respiratory sensing waveform and high system impedance on the sensing lead channel, consistent with lead disconnection from the IPG.

A computed tomography (CT) scan of the chest was subsequently obtained to further characterize the hematoma extent, evaluate for active extravasation that would necessitate surgical intervention, and precisely localize the retracted sensing lead tip relative to surrounding structures in preparation for potential surgical revision. CT confirmed the hematoma in the subcutaneous tissue overlying the IPG pocket and demonstrated the retracted sensing lead. No active extravasation was identified. The stimulation lead on the hypoglossal nerve appeared intact and in appropriate position.

A brief clinical timeline is summarized below:

1) Month 0: Inspire HNS system implantation (pre-implant AHI 34, ESS 14, BMI 29.8).

2) Months 0 - 24: Uncomplicated postoperative course; nightly device use with therapeutic benefit (post-titration AHI 8, ESS 6).

3) Month 24 (Day 0): Acute lead detachment during lifting; chest wall hematoma develops.

4) Day 0: Clinic evaluation; chest radiograph and device interrogation confirm lead disconnection; CT chest obtained to characterize hematoma and localize retracted lead.

5) Days 1 - 14: Conservative hematoma management with serial clinical assessments.

6) Week 4 (Day 28): Outpatient surgical revision with lead reconnection.

7) Week 8 (Day 56): Follow-up confirms normal device function; nightly use resumed with continued therapeutic benefit.

3. Management

Given the patient's hemodynamic stability, the absence of expanding hematoma, and no evidence of active bleeding on CT, a conservative management approach was adopted. The patient was instructed to discontinue use of the Inspire device, apply local ice compresses, avoid strenuous upper extremity activity, and monitor for signs of hematoma expansion or infection. Serial clinical assessments were

performed over the following two weeks, during which the hematoma gradually resolved.

Once the hematoma had sufficiently resolved (approximately four weeks after the initial event), the patient was scheduled for outpatient surgical revision. Lead reconnection rather than full lead replacement was chosen because the lead body was confirmed to be intact on preoperative imaging and device interrogation showed normal impedance on the lead itself (with high impedance only at the IPG-header interface), indicating that the failure was at the connector rather than within the lead. Intraoperatively, the IPG pocket was explored, and the respiratory sensing lead was found to have completely detached from the IPG header. The lead body was intact without evidence of fracture or insulation breach. The connector pin and IPG header receptacle were inspected and showed no visible damage or corrosion. The lead was retrieved from its retracted position, reconnected to the IPG header, and secured with reinforced anchoring at the connector site. System testing confirmed restoration of appropriate respiratory sensing waveforms and normal impedance values. The patient tolerated the procedure well and was discharged the same day.

At follow-up one month postrevision, the device was functioning normally with appropriate sensing and stimulation parameters. The patient resumed nightly use of the device with continued therapeutic benefit.

4. Discussion

This case illustrates a relatively uncommon but clinically significant complication of the Inspire HNS system: detachment of the respiratory sensing lead from the IPG following minor physical exertion, resulting in a chest wall hematoma. The mechanism most likely involved sudden traction on the lead during the combined bending and lifting motion, generating sufficient force to dislodge the lead from the IPG header connection. However, a single case cannot establish causation; late connector loosening, gradual anchoring failure, or chronic mechanical stress over the two-year implant period may have predisposed the lead-header interface to failure, with the lifting event serving as the final precipitant. Comparable mechanical mechanisms have been described in other implanted pulse-generator systems, in which generator movement and repetitive shoulder-girdle motion can transmit traction to connected leads [9] [10]. Lead migration, fracture, and disconnection are also well-recognized hardware complications across neuromodulation systems [11].

Lead-related complications are increasingly recognized as an important source of device failure in HNS. Alapati *et al.* reported that 16 of 348 patients (4.6%) required revision for device failure over seven years, with respiratory sensing lead damage accounting for 11 of 16 failures (68.8%) [7]. Islam *et al.* found sensing lead malfunction in 4 of 190 patients (2.1%) at a high-volume center; in their accompanying MAUDE database review, sensing lead tip separation from the lead body was the most frequently reported sensing-lead event [8]. Lead dislodgement

was also among the serious device-related events reported in the pivotal STAR trial [4].

The Inspire system's respiratory sensing lead is positioned within the intercostal musculature and tunneled subcutaneously to the infraclavicular IPG [3] [4]. This anatomical course may expose the lead to mechanical stresses from respiratory excursion, trunk rotation, and upper-extremity movement. Tabatabai *et al.* described generator migration requiring reoperation and identified obesity and abundant breast tissue as potential contributors to device displacement [9]. In the cardiac implantable electronic device literature, Morales *et al.* described idiopathic lead migration variants and noted that mechanical forces associated with body and upper-extremity movement may contribute even when deliberate generator manipulation is absent [10].

Hematoma and seroma are among the more commonly reported adverse events after HNS implantation. Bestourous *et al.* identified hematoma or seroma in 17 of 146 patient adverse events (11.6%) in their MAUDE database review [5]. Bentan and Nord identified hematoma or seroma in 10.2% of 1312 adverse events reported from 2014 through 2023 [6]. In the present case, the hematoma likely resulted from disruption of small vessels in the IPG pocket or along the lead tunnel during acute lead detachment.

The decision to manage the hematoma conservatively was based on the patient's hemodynamic stability, the contained nature of the collection, and the absence of infection or active bleeding. Pocket hematomas associated with implanted devices require close follow-up because clinically significant hematomas can increase the risk of subsequent infection; intervention is generally reserved for enlarging, infected, compressive, or otherwise clinically significant collections [12]. Once the hematoma resolved, outpatient lead revision and reconnection restored normal device function.

This case underscores the importance of counseling patients with implanted HNS devices about the possibility of late mechanical complications. Although no evidence supports broad long-term activity restrictions after uncomplicated HNS implantation, patients should be advised to seek evaluation after sudden pain, swelling, a palpable change at the generator pocket, or loss of therapeutic effect. A recent systematic review found that most reported adverse events occur around implantation and treatment acclimatization, but emphasized heterogeneous safety reporting and the need for standardized adverse-event definitions [13].

5. Limitations

This report has several limitations inherent to a single case. The causal relationship between the lifting event and lead detachment cannot be definitively established; chronic mechanical fatigue or subclinical connector loosening may have contributed. The absence of routine surveillance imaging prior to the event means that early signs of lead migration or connector loosening, if present, were not captured. Additionally, the generalizability of this case to other patients is limited, as

individual anatomic factors, surgical technique, and anchoring methods may influence the risk of lead detachment.

6. Conclusion

This case adds to the growing literature on device-related complications of hypoglossal nerve stimulation for obstructive sleep apnea. Lead detachment from the IPG following minor physical exertion is an uncommon but important complication that can cause chest wall hematoma and loss of device function. Conservative management of the stable hematoma followed by outpatient surgical revision with lead reconnection resulted in a favorable outcome. As utilization of hypoglossal nerve stimulation expands, clinicians should remain alert to delayed mechanical complications and report them using standardized definitions [13].

Patient Consent and Ethics

Written informed consent was obtained from the patient for publication of this case report. Artificial intelligence was used only for grammar, spelling, and overall language polishing.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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