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Subpectoral Implantation of the Hypoglossal Nerve Stimulator: An Effective Technical Modification

Nicholas L. Deep, MD; John Peyton Hines, MD; James M. Parish, MD; Michael L. Hinni, MD; Stephen F. Bansberg, MD

Upper airway stimulation is now a well-established treatment option for selected patients with obstructive sleep apnea. The implanted pulse generator of this system activates the hypoglossal nerve and is routinely placed in a subcutaneous pocket overlying the pectoralis muscle. This case report describes a patient with a history of bilateral mastectomy and radiation for breast cancer who required explantation due to device exposure and infection. The patient was successfully reimplanted by placing the implantable pulse generator deep to the pectoralis major muscle. Clinical circumstances involving the chest wall may warrant subpectoral placement of the implanted pulse generator.

Key Words: Upper airway stimulation, obstructive sleep apnea, sleep-disordered breathing, hypoglossal nerve.

CASE REPORT

A 67-year-old female with severe OSA (Apnea/Hypopnea Index [AHI] 45) was scheduled for implantation of the Inspire II UAS system (Inspire Medical Systems, Inc., Maple Grove, MN) after meeting U.S. Food and Drug Administration-approved selection criteria. The patient’s history was significant for bilateral total mastectomy and postoperative chemoradiation 6 years prior. Physical examination revealed thinning of the skin/subcutaneous tissue layer bilaterally, with scarring of the thinned cutaneous covering to the rib cage on the right side. The left side was chosen for implantation because there appeared to be adequate tissue coverage for the IPG. Implantation with device model 3024 (Inspire Medical Systems, Inc.) was performed in April 2016. The three components of the Inspire system (activation lead/wire, IPG, sensing lead/wire) were implanted without difficulty or complication. The skin and subcutaneous tissue layer overlying the IPG was noted to be thin and atrophic. Both chest incisions were covered with a light dressing, which was removed the following day. Dusky skin changes were noted at the inferior margin of the IPG on postoperative day 10. This skin area progressed to full-thickness necrosis, implant exposure, and purulent discharge on postoperative day 29 (Fig. 1). Surgical debridement, antibiotic irrigation, and coverage of the IPG with a pectoralis muscle flap was performed the following day. Culture-directed intravenous antibiotics were administered for 3 days, followed by oral antibiotic therapy for 5 months. During this report describes successful implantation of the IPG deep to the pectoralis muscle following subcutaneous implantation complicated by skin necrosis and infection.
time, the patient underwent device activation and titration. The patient adapted to UAS therapy quickly and endorsed substantial symptom improvement with excellent device tolerance. Twenty days following discontinuation of the antibiotics, the patient noted redness, swelling, and fluid weepage at the sensing lead incision. The patient was returned to the operating room and, although the pectoralis muscle had protected the device from extruding through the atrophic skin, persistent infection was evident secondary to a biofilm involving the IPG and sensing lead wire (Fig. 2). Therefore, all device components were removed.

The patient was motivated for reimplantation, which was performed in August 2017. In order to prevent similar complications of device extrusion, the implant was placed on the contralateral (right) side in a subpectoral pocket using IPG model 3028 (Inspire Medical Systems, Inc.). The patient’s shoulder was abducted to expose the axillary area and the lateral border of the pectoralis major muscle. A 5-cm incision was made laterally in the axillary area, and dissection through the subcutaneous plane allowed for identification of the lateral border of the pectoralis major muscle (Fig. 3A). Blunt dissection in the submuscular plane deep to the pectoralis major muscle and overlying the pectoralis

![Fig. 1. Implant exposure noted on postoperative day 29. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]](image1)

![Fig. 2. Purulence seen at the site of the sensing lead. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]](image2)

![Fig. 3. Reimplantation via the subpectoral technique is shown. The contralateral (right) side was chosen for reimplantation. (A) A lateral 5-cm incision is made, and dissection is carried down to identify the lateral border of the pectoralis major muscle (white asterisk). (B) A subpectoral pocket is created to accommodate the IPG, as well as to extend inferiorly to place the sensor lead via the same incision. (C) The IPG is placed and sutured to the periosteum of the rib bone, outermost fascia of the intercostal muscle, and surrounding tissues. IPG = implanted pulse generator. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]](image3)
minor and serratus muscle created a generous pocket for the IPG (Fig. 3B). The IPG was placed inside the subpectoral pocket along the midclavicular level, then fixed with sutures onto the rib peristomeum and outermost fascia of the intercostal muscle (Fig. 3C). The respiratory sensing lead was placed in the fifth intercostal space within this dissection field, thereby eliminating the need for a separate incision. The activation wire transitioned from a subcutaneous tunnel in the neck through the pectoralis major muscle into the chest pocket. Drains were not placed, and the incisions were closed in a standard fashion. Postoperatively, the patient did well without evidence of complication, including no evidence of hematoma or seroma formation. Device activation and titration were performed at 30 and 60 days postoperatively. The titration polysomnogram demonstrated resolution of OSA (AHI 0.1) at 2.3 volts (voltage range 1.9–2.3), with substantial sleep quality improvement and excellent tolerance. The patient continues to do well 12 months postoperatively and uses the device nightly, 48 hours per week.

DISCUSSION

Direct stimulation of the hypoglossal nerve has emerged as an effective treatment option for patients with moderate to severe OSA. Early experience with HNS has demonstrated a low incidence of adverse effects related to device placement with a safety profile comparing favorably to other implantable device procedures. The recommendation is made to patients to avoid movements and activities for 3 weeks postoperatively that result in overactivity of the pectoralis muscle. Seroma detection necessitates immediate and careful drainage through percutaneous needle puncture and aspiration, followed by the application of a pressure dressing. We have managed two seromas involving the IPG in other patients without adverse consequences.

Our patient presented with bilateral chest deformity resulting from breast cancer treatment. Special considerations for IPG implantation in women have been discussed. The addition of the sensing lead and required subcutaneous tunneling of the sensing wire can pose a challenge to the patient with prior mastectomy, breast reconstruction, or breast augmentation. Our patient demonstrated minimal increase in subcutaneous tissue thickness on the left side compared to the right. A thin subcutaneous/skin layer was noted after development of the implant pocket. Despite avoidance of a pressure dressing, skin changes overlying the IPG representing impending necrosis were noted on postoperative day 10. We speculate whether skin necrosis and implant exposure/infection would have occurred if the next generation, thinner Inspire IPG model 3028 (Inspire Medical Systems, Inc.) would have been available for our patient’s initial procedure.

The decision to attempt right-sided subpectoral implantation was driven by the patient’s desire for UAS therapy. Head and neck surgeons will find this technique to be straightforward because the approach is similar to the initial steps in developing a pectoralis major flap. Advantages of this technique include a more favorable scar position, need for two incisions instead of three, and improved camouflage of the device. Additionally, the subpectoral procedure did not substantially extend operative time. Specifically, when comparing the operative time for the current case with the historical average for cases using the traditional subcutaneous placement, total time difference was less than 15 minutes.

There were no complications following subpectoral placement of the IPG in our patient. However, subpectoral surgical dissection and implant placement is not without potential complications. The thoracocromial artery, cephalic vein, and lateral pectoral nerve are at risk with this approach. Increased dissection and retraction are required for exposure to place both the IPG and sensing lead via the same incision. Theoretically, the risk for hematoma or seroma is increased. However, in our patient no drains were placed, and these complications were not observed.

Early clinical experience with the Inspire UAS system has confirmed the safety and efficacy of IPG implantation into a subcutaneous pocket. A main advantage of the manufacturer-recommended subcutaneous location for the IPG is the relative ease of access for both primary implantation and subsequent device replacement. Presumably, future IPGs will be smaller and carry less risk of cosmetic deformity or implant exposure. Contralateral subcutaneous IPG placement is possible and is recommended in patients with unilateral chest wall pathology (e.g., deformity, prior surgery, external beam radiation, skin thinning or scarring, and presence of another neuromodulator or pacemaker).

This case report has demonstrated that the IPG can be successfully implanted into the subpectoral position. Consideration for subpectoral placement must be done on an individualized basis, taking into account patient history and clinical evaluation, surgeon experience, and patient preference. Subpectoral placement should be considered in patients with a history of bilateral chest pathology due to mastectomy; breast reconstruction; chest wall deformity; and skin thinning/scarring resulting from radiation treatment used for chest skin, breast, or thoracic cancers.

CONCLUSION

Upper airway stimulation has emerged as an important treatment option for select patients with moderate to severe OSA. Conventional IPG placement into a subcutaneous pocket overlying the pectoralis major muscle and positioning of the sensing lead and wire can be challenged by a thin chest aesthetic, prior breast cancer treatment, or with breast reconstruction/augmentation. Further surgical experience may identify clinical circumstances in which subpectoral placement of the IPG would be recommended as the initial surgical approach. This case report presents a proof of concept for subpectoral IPG placement in patients with OSA undergoing UAS treatment.

BIBLIOGRAPHY


