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Upper airway stimulation for obstructive sleep apnea

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Upper airway stimulation as treatment of obstructive sleep apnea has gained an enormous worldwide interest, in particular since the publication of exciting 12 months results in early 2014, although results remain constant after 12 months. Earlier, we reported in detail on the implantable system, patient selection criteria, operative technique, device programming, and mechanism of action. After the publication of this paper, surgical modifications have taken place; the present improved technique is quicker and easier. In this article, the authors report their experience in more than 50 patients, including recommended recent surgical modifications.

Introduction

The therapeutic efficacy of upper airway stimulation (UAS) as treatment of obstructive sleep apnea (OSA) has gained an enormous worldwide interest, in particular since the publication of the STAR trial 12 months results in New England Journal of Medicine (NEJM) in early 2014.[1] Results over 18 months remain constant. Earlier, we reported in detail on the implantable system, patient selection criteria, operative technique, device programming, and mechanism of action.[2] After the publication of this paper, some surgical modifications have taken place; the present improved technique is quicker and easier. In this article, the authors report their experience in more than 50 patients.

Implantable pulse generator

The implantable pulse generator (IPG) is implanted subcutaneously under the right clavicle (Figure 1), and connects to the stimulation lead and sensing lead. The IPG has a titanium case and contains an algorithm that synchronizes stimulation of the hypoglossal nerve with respiration signals, which can be programmed for the individual patient. The battery inside the IPG is expected to last approximately 8 years.

Stimulation lead

The cuffed stimulation lead includes 3 electrodes in a guarded-bipolar configuration. The center electrode is connected to a pole of the stimulation (eg, negative pole) and is flanked on each side by 2 electrodes connected to the opposite pole of stimulation (eg, positive pole). The cuff is placed at the hypoglossal nerve, and the connector end of the lead is connected to the IPG. The cuff electrodes apply electrical current that stimulates the nerve, which causes the tongue to move forward.

Sensing lead

The sensing lead has a differential pressure sensor and a connector end that is connected to the IPG. The device

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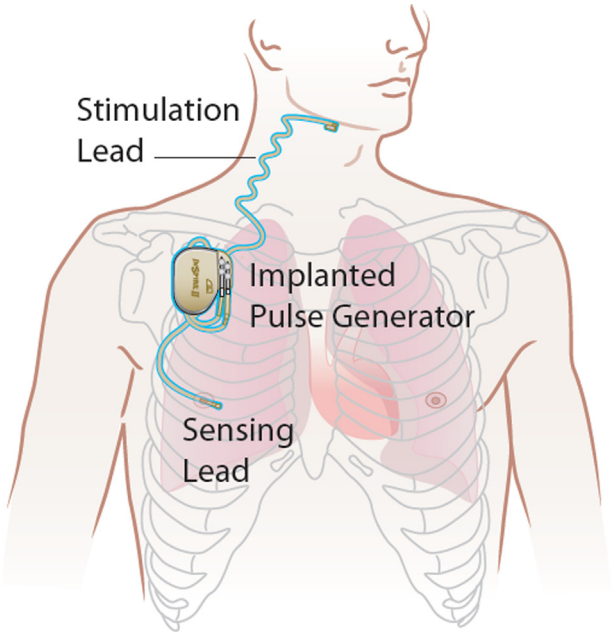

Figure 1 Inspire system components and positioning. The Inspire system senses respiration patterns and stimulates the hypoglossal nerve in synchrony with respiration effort. The respiration-synchronous stimulation contracts a patient's upper airway muscles to keep the airway open during inspiration. (Color version of figure is available online.)

senses pressure variations that relate to respiration. The pressure waveform is monitored by the IPG algorithm and triggers stimulation therapy synchronous with respiration.

Physician and patient programmers

The physician programmer is used by a physician to noninvasively communicate with the IPG (Figure 2). The programmer consists of a tablet computer and a telemetry head. The telemetry head is powered by a wall outlet connection and communicates with the IPG through the skin via radiofrequency telemetry and wirelessly (Bluetooth) with the physician programmer. The physician programmer has the capability to conduct system self-test, monitor respiratory waveforms, program stimulation modes, adjust stimulation parameter values, and store waveforms and programmed patient settings.

The patient programmer (Figure 3) is a remote control, of approximately the size of a cell phone, and is used by the patient to activate the system before going to sleep. It has a start delay. The patient places the programmer over the IPG, and uses buttons to turn the therapy ON or OFF, temporarily suspend therapy, or make adjustments to the stimulation amplitude (within physician-preselected limits).

Figure 2 Inspire physician programmer.

Contraindications

The most important contraindications include hypoglossal nerve palsy, neuromuscular disease, radiotherapy or ablation therapy for the head or neck or both, surgical resection for cancer or congenital malformations in the larynx, tongue, or throat (with the exception of tonsillectomy or adenoidectomy or both), obvious fixed upper airway obstructions (tumors, polyps, and nasal obstruction), anticipated exposure to magnetic resonance imaging, or required diathermy.

Preoperative evaluation

Preoperative evaluation of patients includes a polysomnography. Patients should not have too much central or mixed apneas and should not be to too positional. Patients should have a BMI $\leq$35 (probably $\leq$32 is better) and an apnea-hypopnea index between 15 and 65 (probably $\leq$50 is better).

Figure 3 Inspire patient programmer.