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Less is more - Retrospective analysis of the two-incision implantation technique for hypoglossal nerve stimulation and comparison of respiratory sensing lead curves against the three-incision technique

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ABSTRACT

Introduction: Breathing-synchronized hypoglossal-nerve stimulation is a treatment option for suitable patients with severe obstructive-sleep-apnoea. The classical implantation technique requires three incisions: submental to place the stimulating-electrode on terminal branches of the hypoglossal-nerve, sub-clavicular to place the impulse generator, and on the lateral chest-wall to place a breathing-sensor lead. A two-incision-technique has been propagated and widely adopted whereby the respiratory-sensing-lead is placed deeper to the IPG-pocket.
Research question: Our department switched to the 2-incision-technique in May 2021 and we set out to compare the two methods concerning the generated respiratory-sensing-curves.
Material and method: Cases operated between October 2020 and September 2022 were included. Parameters included age, gender, BMI, OR time, positioning of the detection-lead, and preoperative Apnoea-Hypopnoea Index (AHI). The generated respiratory-sensing curves were categorized by an independent expert blinded to the surgical-technique regarding conduciveness to optimal stimulation.
Result: 21 patients were included. 5 were operated with the 3-incision-technique. Women were underrepresented. There were no further significant differences in patient characteristics. The expert-opinion on the respiratory-sensing-curves did not vary between groups. Mean OR-time was marginally less in the 2-incision group without being statistically significant.
Conclusion: The 2-incision-technique generates respiratory-sensing curves at par with those generated with 3-incision-implants. The limited patient data collected in this analysis suggests that OR-time can be reduced using the 2-incision-technique. There were no cases of postoperative complications in our cohort. It can be postulated that a 2-incision-implant has a lower risk of infection due to the reduced wound-surface.

1. Introduction

Selective hypoglossal nerve stimulation (HNS) has been shown to be a safe and effective therapeutic option for obstructive sleep apnoea (OSA) patients who are unable to adhere to or do not tolerate positive airway pressure therapy (Gillespie et al., 2017; Heiser et al., 2017; Schwartz et al., 2001; Soose et al., 2016; Strollo et al., 2014; Van De Heyning et al., 2012; Woodson et al., 2016). Excellent responder rates of up to 75% at the five-year post-implantation mark have been reported with this technique (Woodson et al., 2018). Undiagnosed and untreated OSA has immense medical and societal costs (Knauert et al., 2015).

The classical implantation method for HNS, a 3-incision technique (3-it), requires three skin incisions to deploy the implant components and two subcutaneous tunnels to connect these components. An anterior submental incision to place the stimulating electrode on selected terminal branches of the hypoglossal nerve, a sub-clavicular one to place the impulse generator, and one on the lateral chest wall to place a respiratory sensing lead in the fifth intercostal space. A two-incision technique (2-it) was propagated and has been adopted by multiple departments (Kent et al., 2020, 2021). Comparative analyses involving operation time and complication rates are available in the published literature (Sagalow et al., 2022).

The stimulation partially relies on the sensing lead to coordinate the applied impulse to time the electrically induced forward motion of the

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Table 1
Patient characteristics in the two groups.

Variable	2-incision technique n = 16	3-incision technique n = 5
	Mean ± SD	Mean ± SD
BMI (kg/m^2)	29.2 ± 2.3	29.1 ± 2.2
Untreated AHI (events/hr)	41.9 ± 11.9	39 ± 13.4
Age (years)	59.3 ± 13.9	55.2 ± 7.4
Male:Female (in numbers and in Percentage)	11:5 69%:31%	5:0 100%:0%

Table 2
Comparison of operative time, BMI and untreated AHI in the two groups.

Variable	2-incision technique *mean (95% CI)*	3-incision technique *mean (95% CI)*	P-value
Operative time (minutes)	134 (112–155)	144 (112–176)	0.276
BMI (kg/m^2)	29 (28–30)	29 (29–31)	0.468
Untreated AHI (events/hr)	42 (39–47)	39 (34–42)	0.355

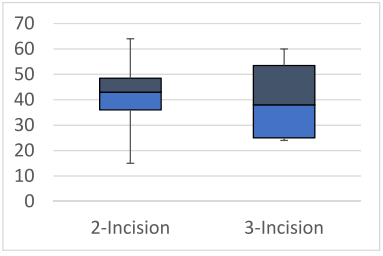

Fig. 1. Box plot for preoperative AHI in the two groups.

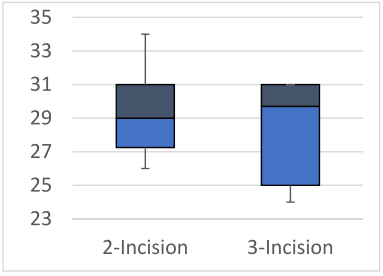

Fig. 2. Box plot for BMI in the two groups.

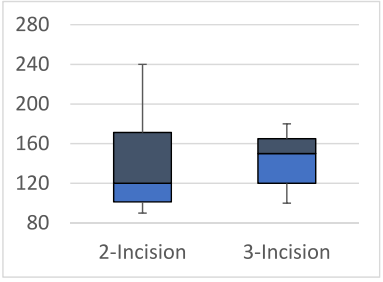

Fig. 3. Box plot for OR Time depicted as median, interquartile range, and minimum/maximum of the total distribution.

tongue and subsequent opening up of the upper respiratory tract. The curves generated from the sensing lead are thus essential in the effective use of the implanted neurostimulation device for optimal therapeutic

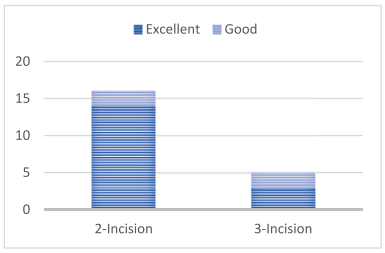

Fig. 4. Respiratory sensor performance blindly graded by an independent field-expert.

results. Our department switched to the 2-it in spring of 2021. We set out on a retrospective comparison of the two techniques, particularly concerning the respiratory sensing lead curves (RSC).

2. Method

All HNS implantations carried out between October 2020 and September 2022 were included. The procedures were all carried out by the same surgeon. All patients underwent a stringent preoperative selection process which included an ENT consultation including polysomnographic sleep assessments and clinical evaluation to rule out other apnoea-causing pathologies, a verification, that multiple positive airway pressure devices had been unsuccessful at alleviating the ailment, and a drug-induced sleep endoscopy (DISE) (Vanderveken et al., 2013) carried out by the implanting surgeon accompanied by a trained academic speech therapist due to hospital regulations. Patients with palatal complete concentric collapse (pCCC) at DISE were excluded and referred back to the respective ENT colleague for re-evaluation of surgical corrective measures like tonsillectomy and uvulopalatopharyngoplasty (TE-UPP). The reimbursement guidelines additionally restricted the procedure to patients with a BMI under 35 kg/m2, AHI between 15 and 65/h, central apnoea <25% of total AHI and those without additional sleeping disorders like restless leg syndrome and periodic limb movement disorder.

The surgical technique for 3-it has been extensively described by various authors. For the relatively novel 2-it, our department closely follows the surgical methodology described by Kent et al. (2020). The implantation of the stimulation cuff electrode is guided intraoperatively using direct nerve stimulation and the more traditional use of transparent surgical drapes around the open mouth. Here a verification of tongue extension is obtained before placing the cuff electrode. Additionally, motor evoked potentials (MEP) recording in response to stimulation are obtained using electrodes placed in the tongue to reduce mixed activation as described by Sturm et al. (2020). Secondly, at the device interrogation and validation stage after all components of the neurostimulator have been placed, the respiratory waveform is reviewed by the implanting surgeon including a comparison of the same with the respiratory curve on the ventilator. This preliminary analysis is recorded in the surgical note. The respiratory lead signals at implantation are recorded on the physician's programming tablet. The system is activated 4 weeks after implantation at first follow-up in an outpatient setting.

The RSCs at follow-up were retrospectively graded by a seasoned surgeon who proctors for the device manufacturer on a regular basis and is blinded to our implantation technique and not involved in the care of our patients. This evaluation service is routinely provided by the device manufacturer as feedback to the implanting surgeon. It must be mentioned that this feedback service does not follow the more stringent objectification criteria that have been proposed to stratify sensor lead function in a recent publication (Saltagi et al., 2023). That being said, the expert takes into account the distinctive curve components as exemplified by the respiratory lead curve of one of the patients from our cohort (Image 1), in this case implanted with 2-it. The vertical blue marker indicates interpretation of inhalation with stimulation-begin,

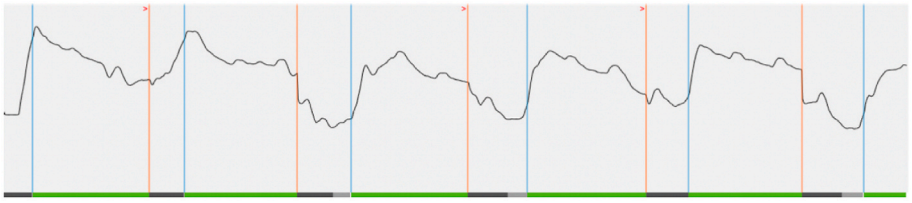

Image 1. Components of the respiratory curve in relation to stimulation. Blue vertical bar – Inhalation and beginning of stimulation, Green horizontal bar- stimulation on, Red vertical bar – Exhalation and end of stimulation, Black horizontal bar - stimulation off (hard), Grey horizontal bar - stimulation off (soft).

denoted by the horizontal green bar on the x-axis. This continues till the vertical red marker indicating exhalation and end-pf stimulation. At this point, the x-axis turns into a black bar, which depicts a "hard" stimulation-off phase. Should there be a longer pause between the exhalation and consequent inhalation, the x-axis turns into a grey coloured bar, depicting a "soft" stimulation-off phase (that can be interrupted as soon as the initiation of inhalation is detected).

Clearly discernible distinctive curve components that would lead to a "coordinated" stimulation were marked by the independent expert as "excellent". Minimal mismatches in this regard were marked as "good". A "poor" performance grading would be allotted for a nearly complete or a complete mismatch.

The patients were divided into 2-it and 3-it groups. Collected patient variables included BMI, untreated AHI, age and gender. Additionally surgical time (incision to postoperative application of sterile dressing) was also tabularised. The evaluation of the pseudonymised RSCs from the blinded independent field expert was then re-assigned to the patients. Patient records were also scanned for complications related to surgery (wound infections, bleeding, pneumothorax and movement-associated pain). T-tests were employed to look for statistically significant differences between the two groups. Additionally, box plots were generated from the thus obtained data.

3. Results

A total of 21 HNS implantations were carried out in the above-mentioned period. The switch from 3-it to 2-it based on the surgeon's preference was strictly chronological. No 3-it procedures were carried out after the technique switch to 2-it. A bias of implantation technique based on patient characteristics can therefore be ruled out. 5 patients had been implanted using the 3-it before adoption of the 2-it which was then used in a further 16 patients. Our patient cohort had an expected statistical outlier regarding gender distribution. Three-fourths of our patients (both groups combined) were masculine. In addition, the 3-it group was comprised exclusively of male patients. The 2-it group had an askew proportion of 3:1 (Tables 1 and 2). Other authors have reported similarly marked gender-related difference in observed prevalence of OSA and thus patients referred for HNS (Gabbay and Lavie, 2012; Suurna et al., 2021; Thaler et al., 2020).

A significant difference regarding patient variables of preoperative AHI or BMI could not be found (Figs. 1 and 2). The operative time was tendentially somewhat lower in the 2-it group but failed to reach statistical significance. The Boxplot (Fig. 3) depicts OR Time as median, interquartile range, and minimum/maximum of the total distribution. The blinded evaluation of RSCs resulted in 2 RSCs from each group being marked "good" while the rest (17 cases) was marked with an "excellent". A statistically significant difference could not be found in the small cohort but it can at least be inferred that the 2-it does not provide subpar RSCs compared to 3-it (Fig. 4). None of the curves in our cohort were graded in the "poor" category There were no infections, no bleeding complications and no pneumothorax in our patient cohort. No upper limb movement related discomfort was reported.

4. Discussion and conclusion

The RSCs delivered using 2-it are non-inferior to 3-it. OR Time may be reduced at least marginally using 2-it. It should be noted that the tendency towards reduction in surgical time with 2-it might partially be attributed to the learning curve and acquired routine with increasing experience. Our cohort fortunately did not present any postoperative infection but it can be assumed that rate of infection in 2-it would be lower in a larger cohort due to reduced wound surface as has been seen in the literature. Similar rationale applies to bleeding complications. Literature reporting a stark under-recognition and lower rates of referral of female patients is abundant. (Larsson et al., 2003; Ye et al., 2009; Young et al., 1997). Our data again underlines the underreporting of OSA in females. Patient and physician awareness needs to be addressed in this regard. None of the RSCs in our cohort were graded as "poor" - most likely owing to the fact that the implanting surgeon did an initial analysis of the intraoperative waveform. It can be postulated that a "poor" performing sensing lead would have triggered a placement alteration during the procedure. Based on our experience, we recommend an initial analysis of the sensing lead curve at implantation and revision of the respiratory sensing component if necessary. Standardized reporting for HNS outcomes as proposed by some colleagues (Dedhia and Tucker Woodson, 2018; Pevernagie et al., 2020) is planned on our side for future endeavours including clinical follow-up parameters.

It would be remiss not to mention that the choice of implant and implantation method used by the authors isn't the only available option. In addition to unilateral HNS with a respiratory-sensing lead, bilateral stimulation of the hypoglossal nerve with implanted leads and an induction-based chip (Eastwood et al., 2020), transcutaneous stimulation using submental patches without any implanted leads whatsoever (Ratneswaran et al., 2023) and bilateral temporal interference (Missey et al., 2023), to name a few, are all OSA-treatment techniques established in their own right with varying degrees of adherence. Additional implant-technique differences lie in the selection and the intraoperative verification of actual nerve implantation site. Whether respiratory sensing and synchronized stimulation lead to a better patient outcome remains to be seen and would require, in an ideal scenario, an RCT comparing various approved and available stimulation devices especially in regard to reduction of OSA-related morbidities like the risk of arrhythmias (Selim et al., 2016). This manuscript pertains mainly to the RSCs generated by two different implantation techniques for HNS. We can recommend a reflected approach to the placement and verification of functionality of individual components that are invasively placed and accompany the patient for his or her entire life.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Johanna Quick-Weller reports a relationship with Inspire that includes: consulting or advisory. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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