World Journal of Otorhinolaryngology-Head and Neck Surgery (2017) 3, 92–96

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journal homepage: www.keaipublishing.com/WJOHNS; www.wjent.org

Research Paper

Application of drug-induced sleep endoscopy in patients treated with upper airway stimulation therapy

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Received 15 April 2017
Available online 9 June 2017

KEYWORDS
Drug-induced sleep endoscopy;
Drug-induced sedation endoscopy;
Upper airway stimulation;
Sleep-disordered breathing;

Abstract *Objective:* To determine the level of agreement among experienced operators of candidacy for upper airway stimulation (UAS) based on evaluation of drug-induced sleep endoscopy (DISE).
Methods: The trial was designed as a single-blinded cross-sectional study. Four otolaryngologists with extensive DISE experience were given 63 video clips from the STAR trial video library. These videos were graded using the VOTE classification. Percentage agreement and Cohen's κ (for inter-rater reliability) were calculated between pairs of reviewers, assessing palatal complete concentric collapse (CCC) and determining UAS eligibility. Subjects were also grouped based on collapse severity for each reviewer.

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Peer review under responsibility of Chinese Medical Association.

Production and Hosting by Elsevier on behalf of KeAi

http://dx.doi.org/10.1016/j.wjorl.2017.05.014

Obstructive sleep apnea;
Inter-rater reliability

Results: The reviewers had excellent (approximately 90%) agreement on findings at the level of the soft palate and tongue base. The inter-rater reliability for palatal CCC ranged from moderate to substantial. The agreement on determining the criteria for UAS implantation ranged from poor to moderate. All 4 upper airway structures as classified by the criteria of the VOTE were graded by all the reviewers as contributing to obstruction in a majority of subjects who were performed via application of DISE.
Conclusion: Application of DISE remains a subjective examination, even among those experienced operators, therefore more studies need to be performed for evaluation of improvement in inter-rater reliability after implantation of training videos.

Introduction

As an implantable hypoglossal nerve stimulation system, upper airway stimulation (UAS), was recently developed to treat patients with moderate-to-severe obstructive sleep apnea (OSA) who do not tolerate continuous positive airway pressure (CPAP). The effectiveness of UAS was demonstrated in the STAR trial, a prospective, multi-institutional clinical trial.[1] The subjects were screened with drug-induced sleep endoscopy (DISE) in order to exclude those patients with complete concentric collapse (CCC) of the velopharynx (soft palate) because previous studies showed that the patients in this group did not have adequate reductions in their apnea hypopnea index (AHI) following implantation of UAS.[2] Thus, identification of palatal CCC was an important exclusion criterion to determine the eligibility for UAS implantation.

DISE was developed to visualize upper airway obstruction in sedated patients during simulated sleep. Since palatal CCC was associated with poor outcomes for UAS implantation, it was performed in all the subjects who potentially qualified for UAS prior to implantation. Assessment of the pattern of obstruction via DISE is inherently subjective and the reliability ranged from poor to substantial in previous studies.[3–5] The aims of this study were to determine the level of agreement among experienced DISE operators via the VOTE criteria,[6] and scoring to determine if the patient is eligible for UAS implantation.

Methods

Study design

The STAR trial (MUSC IRB HR#20673) is a prospective multicenter clinical trial to determine the safety and efficacy of UAS in CPAP-intolerant adults with moderate-to-severe OSA. Subject eligibility criteria and study design have been published previously.[1] The present study is a single-blinded cross-sectional study to utilize video clips collected as a part of the STAR trial in order to determine the inter-rater reliability among the experienced DISE operators and to assess their agreement in determining the eligibility criteria for UAS implantation. The study protocol was approved via an investigational review board.

DISE

The STAR trial investigators randomly chose DISE video clips in a population of 63 patients who were screened as a part of the STAR trial. No subject data (including demographic data and whether the subjects were ultimately implanted with UAS) were included with the videos. The videos were loaded on a secure website that can be accessed for scoring. Each DISE clip lasted approximately 2 min and the analyses were completed within 3 weeks by the reviewers.

Each DISE video clip was graded using the VOTE scoring system.[6] The responses were compared based on the presence of collapse at the velum, or opharynx, tongue, or epiglottis using dichotomous values (yes or no). Less attention was given to the type of collapse in each area with the exception of the presence or absence of palatal CCC. Each reviewer then determined whether the subject would be a suitable candidate for UAS implantation based on the results collected from application of the DISE. The VOTE score was calculated as the sum of the locations with the obstruction present for a maximum score of 4.

Statistical analysis

All the statistical analyses were performed using SPSS (version 23; IBM, Armonk, New York). Both the percentage of agreement and Cohen's kappa (κ) were used to measure the agreement between two raters. The two raters either agreed in their rating (i.e. the category that a subject is assigned to) or they disagreed; there were no degrees of disagreement (i.e. no weightings). The Cohen's kappa cannot be computed when there was no variation between the two raters. The levels of agreement were not aligned based on the Cohen's kappa. Interpretation of Cohen's κ as introduced by Landis and Koch is presented in Table 1.[7]

Results

A total of 63 DISE videos extracted from the STAR trial video library were reviewed by four experienced DISE operators who were participating investigators in the STAR trial. The percentage of agreement between the pairs of reviewers is presented in Table 2. The reviewers consistently agreed on the presence or absence of obstruction at the level of the