Evaluation of a nasopharyngeal stent in patients with obstructive sleep-related breathing disorders

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Abstract
Objective: This study was performed to evaluate the therapeutic effect and diagnostic value of a novel nasopharyngeal stent (Naštent; Corinium Medical Equipment Ltd., Cirencester, UK). The Naštent is designed to stent palatal collapse in patients with sleep-related breathing disorders.

Methods: The study was conducted from 2018 to 2019. Patients who did not qualify for continuous positive airway pressure therapy underwent split-night examination with an inserted Naštent for the first half of the night. The next morning, drug-induced sleep endoscopy (DISE) was performed.

Results: Of the 122 enrolled patients, 21 were excluded because of Naštent intolerance (n = 14) or technically invalid examinations (n = 7). Among the remaining 101 patients, in correlation with DISE, the apnea–hypopnea index was significantly reduced in patients with palatal obstructions, mainly in those with anteroposterior collapse patterns. The Naštent did not influence retrolingual or multilevel obstructions. Using a 40% reduction of the apnea–hypopnea index by the Naštent as a cut-off value, 85.7% of soft palate obstructions were detected compared with DISE.

Conclusions: The Naštent is a viable tool to reduce palatal obstructions, although it is not readily tolerated. It may also be helpful for diagnosis of sleep-related breathing disorders when DISE is unavailable.

Keywords
Obstructive sleep apnea syndrome, nasopharyngeal tube, Naštent, drug-induced sleep endoscopy, split-night examination, peripheral arterial tonometry

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Introduction

Nasopharyngeal stents have been proposed for the treatment of obstructive sleep-related breathing disorders for several decades. In the 1970s, reductions in obstructive events were demonstrated by Walsh et al.\(^1\) and Guilleminault et al.\(^2\).

The therapeutic use of a nitinol-based nasopharyngeal stent (AlaxoStent; Alaxo GmbH, Krün, Germany) was described by Traxdorf et al.\(^3\) in 2016, who proposed this device as a treatment option for continuous positive airway pressure (CPAP) non-compliant patients with obstructive sleep apnea (OSA). Okuno et al.\(^4\) demonstrated a significant reduction in snoring and the respiratory disturbance index (RDI) using a nasopharyngeal stent (Na\(^/C\)19 stent; Corinium Medical Equipment Ltd., Cirencester, UK). They also demonstrated an association between responders and a narrow velopharynx in cephalography.\(^4\)

Nasopharyngeal stents have also been used as devices for topodiagnostic in patients with OSA during polysomnography and drug-induced sleep endoscopy (DISE).\(^5\)–\(^7\) One study showed that a significant reduction in the apnea–hypopnea index (AHI) with nasopharyngeal stenting was associated with a positive outcome of uvulopalatopharyngoplasty (UPPP).\(^8\)

Nasopharyngeal stents have also been applied during DISE. In addition to reduced velopharyngeal collapse in such cases, reduction of downstream obstruction was demonstrated in patients with multilevel collapse.\(^7\) Hence, nasopharyngeal stents can be used for both therapeutic and diagnostic purposes in sleep medicine.

In most studies, standard stents from rescue medicine were used.\(^8\) Conventional stents, as well as the AlaxoStent, seem to be less readily tolerated by patients.\(^9\)–\(^10\) Yenigun et al.\(^11\) reported the successful use of a similar nitinol-based, self-expanding nasopharyngeal stent in five patients. The novel nasopharyngeal stent Naštent, which was specially designed for increased patient comfort, was introduced in Europe in 2017.

The goal of the present study was to evaluate the clinical value of the Naštent nasopharyngeal stent in the treatment and diagnostic work-up of patients with obstructive sleep-related breathing disorders using a split-night examination with peripheral arterial tonometry (PAT) followed by DISE.

Methods

We reviewed the clinical charts of patients who underwent topodiagnostic evaluation for sleep-related breathing disorders from January 2018 to December 2019. All patients underwent a split-night examination using PAT (WatchPAT 200; Itamar Medical, Caesarea, Israel) and insertion of the Naštent, which was removed for the second half of the night. The following morning, DISE was performed with and without the Naštent.

The inclusion criteria for the study were snoring or a diagnosis of OSA, age of \(>18\) years, disqualification for CPAP therapy, and provision of written informed consent. The exclusion criteria were central sleep apnea, age of \(<18\) years, and bilateral total obstruction of the nasal cavity.

All patients underwent a nasal examination before Naštent insertion. Because the Naštent is made of rather soft and flexible material, only bilateral total obstruction of the nasal cavity was selected as an exclusion criterion. No patient presented such findings. The less severely obstructed nasal cavity was chosen for insertion of the stent.

All procedures performed in this study were in accordance with the ethical standards of the Swiss Association of Research Ethics Committees and with the 1964 Helsinki Declaration and its later amendments. This study was approved by
the Swiss Ethics Committees on research involving humans (EKNZ No 2019-00149). All patients provided written informed consent. The reporting of this study conforms to the STROBE guidelines.12

The Naštent is a registered medical product with Conformité Européenne certification of conformity, and it is designed for the treatment of snoring and mild to moderate OSA (Figure 1(a)). It is a tube made of soft silicone and is available in eight different sizes. The tube is inserted transnasally with the intention of stenting the palatal velum (Figure 1(b)–(d)) to reduce snoring, hypopneas, or apneas.4

The Naštent was inserted by medical staff, and the appropriate insertion depth was ensured (Figure 1(b)–(d)). The correct insertion depth was checked by oral inspection. The distal end of the stent was ideally 2 to 3 mm below the inferior margin of the soft palate. If the Naštent was found to be too long, it was removed and cut to the desired length. The patients slept for the first half of the night (at least 3 hours) with the Naštent in place. The Naštent was then removed by a nurse, and the time of the removal was noted. The patients slept the rest of the night without the Naštent. During the whole night, the patients were monitored using PAT (WatchPAT 200). The recordings were analyzed separately for the times with and without the stent in place. The PAT-derived AHI (pAHI), PAT-derived RDI (pRDI), PAT-derived oxygen desaturation index (pODI), rapid eye movement (REM) sleep time, and percent time snoring at >40 dB (light snoring) and >50 dB (heavy snoring) were recorded.

Patients with an AHI of <5 events/hour were considered habitual snorers. The severity of OSA was classified as mild (AHI of 5 to <15 events/hour), moderate (AHI of ≥15 to <30 events/hour), or severe (AHI of ≥30 events/hour).

Comparison between the values obtained with the Naštent (AHI withNS) and without the Naštent (AHI withoutNS) was used to evaluate the percentage of palatal obstruction. Palatal obstruction was defined as a ≥40% reduction in the AHI with the Naštent compared with the AHI without stenting. An AHI reduction of <40% was considered non-palatal obstruction, either multilevel or predominantly retrolingual. The Naštent treatment responder rate was
defined according to the Sher criteria: an AHI reduction of >50% from baseline and an AHI of <20 events/hour with the Naštent.\textsuperscript{13}

Comparison of the absolute AHI reduction would not have provided complete insight into the therapeutic value of the Naštent according to OSA severity. Therefore, the percent reduction in the AHI by the Naštent ($\%$AHI\textsubscript{reduction}) was used in this study. The $\%$AHI\textsubscript{reduction} was defined as the ratio of AHI\textsubscript{withoutNS} and AHI\textsubscript{withNS} divided by AHI\textsubscript{withoutNS}, presented as a percentage.

The morning following the split-night examination, DISE was performed. The patients were sedated with a combination of midazolam and propofol. Target-controlled infusion of propofol was used to reach the desired bispectral index of 50 to 60. The obstruction was assessed using the VOTE classification,\textsuperscript{14} which is used to report DISE findings according to the characteristics of obstruction at the velum, oropharynx, tongue base, and epiglottis. The main obstruction was defined as palatal, retrolingual (lateral oropharynx (including tonsils), tongue base, or epiglottis), or multilevel (in patients with both palatal and retrolingual obstruction). Naštent insertion was performed as a third maneuver after the standard Esmarch maneuver and head-rotation test.

The DISE findings were compared with the results from the split-night analysis. Because the split-night data were analyzed later that morning, the examiner had no knowledge of these findings during the execution of DISE. All DISE recordings were reviewed by the first author of this study to reduce inter-rater variability.\textsuperscript{15,16}

The Naštent is designed to treat only the velopalatal area.\textsuperscript{17} Mainly palatal obstructions were divided into two subsites depending on the collapse pattern: anteroposterior (AP) collapse or concentric collapse.

The primary endpoint of the study was the AHI reduction by insertion of the Naštent and the correlation of the topographic information obtained from the split-night examination with the findings of DISE. The secondary endpoints were the reduction of the RDI and ODI as well as the adverse effects and patient discomfort associated with the Naštent. Discomfort was analyzed using a 1- to 5-point visual analog scale (0 = no discomfort, 1 = mild discomfort, 2 = moderate discomfort, 4 = severe discomfort, and 5 = intolerable discomfort). All patients were asked if they would possibly use the Naštent as a treatment option for their sleep-disordered breathing disorder.

The statistical analysis was performed with IBM SPSS Statistics for Windows, Version 26 (IBM Corp., Armonk, NY, USA) using the Spearman rho correlation coefficient (two-tailed), Kruskal–Wallis test, paired t-test, Wilcoxon matched-pairs signed rank test, and Wilcoxon–Mann–Whitney test. The level of significance was defined as $p = 0.05$.

**Results**

From January 2018 to December 2019, 122 patients underwent a split-night examination followed by DISE. All patients had either a diagnosis of OSA or severe snoring that caused impairments in their daily lives. The patients did not qualify for CPAP therapy because of exclusive snoring or mild OSA (n = 48), CPAP intolerance (n = 20), or CPAP refusal (n = 54).

We excluded 21 patients because of technically flawed WatchPAT recordings caused by either an insufficient duration of split-night examinations or patients who forgot to initiate the measurement before bedtime (n = 7) and lack of tolerance of the Naštent or the need to remove it prematurely (n = 14).
Therefore, 101 patients were included in the final analysis. Only patients with complete datasets were included. The patients’ average age was 51.4 years (range, 21–84 years). The male:female ratio was 85:16. The average body mass index was 28.3 kg/m² (range, 17.3–40.0 kg/m²).

The mean AHI without the Naštent during the second half of the night was 24.6 ± 18.3 events/hour, and the mean AHI with the Naštent was 18.5 ± 15.5 events/hour. The average absolute AHI reduction under Naštent therapy was 6.1 events/hour (−24.8%). The reduction was statistically significant (Wilcoxon–Mann–Whitney test: p = 0.01). The mean individual AHI reduction with the Naštent was 16.8% ± 75.5%.

The overall responder rate according to the Sher criteria was 25.7%. The distribution of the severity of sleep-related breathing disorders among all patients and the respective responder rates are shown in Table 1. The AHI responder rates according to the Sher criteria, defined as a > 50% reduction in the baseline AHI and an AHI of < 20 events/hour with the Naštent, were significantly worse in patients with severe OSA than in those with mild and moderate OSA (Kruskal–Wallis test: p = 0.01). However, no statistically significant difference was found between patients with mild and moderate OSA.

The mean RDI without the Naštent during the second half of the night was 28.4 ± 17.8 events/hour, and the mean RDI with Naštent was 23.1 ± 14.9 events/hour. The reduction was statistically significant (Wilcoxon matched-pairs signed-rank test: p < 0.0001).

The mean ODI without the Naštent during the second half of the night was 13.3 ± 14.9 events/hour, and the mean ODI with the Naštent was 10.8 ± 13.2 events/hour. The reduction was statistically significant (Wilcoxon matched-pairs signed-rank test: p < 0.0001).

The main obstruction site in DISE was an isolated collapse of the velopharynx (palatal collapse) in 49.5% (50/101) of patients, an isolated collapse in the retrolingual area (base of tongue, lateral oropharynx (including tonsils), and/or epiglottis) in 28.7% (29/101), and a multilevel collapse in 21.8% (22/101). A subgroup of retrolingual obstruction due to isolated tonsillar hyperplasia was found in 15.8% (16/101) of patients. During the third maneuver, insertion of the Naštent led to no improvement in either snoring or observed obstructions in patients with retrolingual collapse and multilevel collapse. Palatal collapse was partially improved depending on the pattern of collapse. The best results with respect to reduction of snoring and obstructions were observed in patients with isolated palatal AP collapse (Figure 2(a) and (b)), and less marked results were observed in patients with isolated palatal concentric collapse (Figure 2(c) and (d)). The Naštent had

| Table 1. Severity of sleep-related breathing disorder and AHI responder rates (Sher criteria) with Naštent. |
|---------------------------------------------------------------|
| Patients, n | Habitual snoring | Mild OSAS | Moderate OSAS | Severe OSAS | Total |
| Sher responders, n (%) | 3 | 37 | 30 | 31 | 101 |
| 9 (24.3%) | 13 (43.3%) | 3 (9.7%) | 26 (25.7%) |

The severity of sleep-related breathing disorder was defined as habitual snoring (AHI of < 5 events/hour), mild OSAS (AHI of 5–15 events/hour), moderate OSAS (AHI of 15–30 events/hour), or severe OSAS (AHI of > 30 events/hour). The respective responder rates according the Sher criteria are shown (> 50% reduction in baseline AHI and AHI of < 20 events/hour with Naštent).

AHI, apnea–hypopnea index; OSAS, obstructive sleep apnea syndrome.
no stenting effect in patients with isolated tonsillar collapse or lateral pharyngeal wall collapse. The concentric pressure from the surrounding tissue led to at least partial compression of the Naštent and collapse of its lumen.

The distribution of collapse patterns and the corresponding $\text{AHI}_{\text{without NS}}$ and $\% \text{AHI}_{\text{reduction}}$ are shown in Table 2. Subgroup analysis of data was performed based on the main obstruction site found in DISE. Isolated palatal collapse ($n = 50$) was of predominant interest and was indeed the region most affected by the Naštent, as expected. It was compared to mainly retro-lingual collapse ($n = 13$) and multilevel collapse ($n = 22$). There were no statistically significant differences in sex, snoring, or body mass index among these groups. However, $\% \text{AHI}_{\text{reduction}}$ was the highest in the palatal collapse group with statistical significance ($p < 0.002$).

Data from patients with a main obstruction at the level of the palate were further analyzed with respect to the collapse pattern in DISE and Brodsky tonsil size\textsuperscript{10} (Table 3). The AHI was only significantly reduced by the Naštent in patients without tonsils (Brodsky grade 0) and AP collapse patterns. The overall AHI responder rate for isolated soft palate collapse was 38%. The responder rates for soft palate AP and concentric collapse were 57% and 25%, respectively. The difference was not statistically significant. Although a trend of increasing prevalence of concentric

Figure 2. Anteroposterior and concentric palatal collapse as seen during drug-induced sleep endoscopy. (a, b) The same palatal anteroposterior collapse is shown with and without the Naštent. A significant stenting effect of the collapse can be observed. (c, d) The same concentric palatal collapse is shown with and without the Naštent. The only therapeutic effect is created by the Naštent lumen itself because the Naštent is encased by soft tissue.
collapse with growing tonsil size was seen, the statistical analysis did not show a significant correlation.

The WatchPAT measures snoring loudness of >40 dB and >50 dB as the percent of sleep time. For the whole study population, the mean percent of sleep time with snoring at >40 dB was 31.8% without the Na/C19 stent and 41.8% with the Na/C19 stent. The mean percent of sleep time with snoring at >50 dB was 12.5% without the Na/C19 stent and 15.7% with the Na/C19 stent. The Na/C19 stent did not significantly reduce snoring in the total study group for the percent of sleep time with snoring at either >40 or >50 dB.

When snoring was analyzed according to the collapse pattern (Table 4), the only positive effect on snoring was observed for snoring at >50 dB caused by palatal AP collapse. However, the reduction did not reach the level of statistical significance. In all other cases, and especially in multilevel collapses, an increase in snoring was registered with the Na/C19 stent.

WatchPAT measures REM sleep as the percent of total sleep time. The mean REM sleep time with the Na/C19 stent was 14.7% ± 9.0%, and that without the Na/C19 stent was 29.9% ± 12.2%. The difference was statistically significant (p < 0.0001) according to the paired t-test. The mean REM AHIs with the Na/C19 stent was 23.2 ± 19.2 events/hour, and that without the Na/C19 stent was 30.5 ± 19.9 events/hour. The Wilcoxon matched-pairs signed-rank test showed a significant difference between these two AHIs (p < 0.0001).

The incidence and severity of patient discomfort are shown in Table 5. Of the initial 122 patients who underwent the split-night procedure, 14 patients did not tolerate the stent at all and had to be excluded from this study. Of the 101 patients remaining for the final analysis, 32.7% reported severe adverse effects. The main complaints were nasopharyngeal irritation and a stuffed nose. One patient had mild epistaxis for 2 days. Only two patients considered the Na/C19 stent as a further treatment option. Both patients stopped its use after several weeks because of progressive nasal and pharyngeal irritation. All symptoms ceased 2 to 3 days after discontinuing therapy.

**Table 2.** AHIs without and with Na/C19 stent with respect to main obstruction site in DISE.

| Main obstruction site in DISE | AHI (events/hour) with Na/C19 stent | AHI (events/hour) without Na/C19 stent | %AHI reduction | p value |
|------------------------------|-------------------------------------|----------------------------------------|----------------|---------|
| Soft palate collapse (n = 50) | 13.5 ± 10.5                         | 22.4 ± 13.9                            | 36.1 ± 40.5    | 0.0001  |
| Retrolingual collapse (n = 13)| 20.2 ± 13.3                         | 26.1 ± 15.7                            | 8.9 ± 44.0     | 0.27    |
| Multilevel collapse (n = 22) | 24.0 ± 18.6                         | 28.3 ± 22.9                            | −25.5 ± 130.0  | 0.28    |

Data are presented as mean ± standard deviation. The sex distribution and body mass index were comparable between the groups. The Wilcoxon matched-pairs signed rank test was used for statistics.

AHI, apnea–hypopnea index; DISE, drug-induced sleep endoscopy.

**Discussion**

Different kinds of nasopharyngeal stents can be used for treatment of snoring and OSA, including conventional tubes used in rescue medicine,6,8,10,17 the AlaxoStent3,9,11 or the Na/C19 stent.4 Few studies to date have examined the treatment acceptance of nasopharyngeal tubes over an elongated period of time.19 A rather high difference in treatment acceptance rates is found among these studies, ranging from very good to a 100% dropout rate after 2 weeks.9,10,20
In our study, the Na/C19 stent was mainly used for diagnostic purposes both in a split-night examination with the WatchPAT and during DISE. Overall, the Na/C19 stent was poorly tolerated, and 30% of patients complained of significant adverse effects. Only 2 of 101 patients decided to try the Na/C19 stent for treatment of OSA, and both of these patients discontinued treatment after several weeks because of increasing adverse effects.

According to the American Academy of Sleep Medicine guidelines, split-night examinations are an acceptable alternative to conventional two-night examinations, especially when assessing therapeutic measures such as CPAP. A split-night examination is an easy and rather cost-effective way to evaluate treatment effects in only one night. A treatment response is defined as a >50% reduction in the AHI from baseline and an AHI of <20 events/hour with the Na/C19 stent.

Nasopharyngeal stents are devised exclusively for stenting palatal collapses. Therefore, the low responder rates of 13% and 15% in patients with predominant obstruction in lower areas or multilevel obstructions of the upper airway were well within our expectations. However, the low responder rate of only 38% for mainly palatal collapses was disappointing. These results can be explained by the DISE findings. During DISE with the Na/C19 stent in place, we observed that the velopharyngeal level was well stented and kept open in patients with AP collapse, but not in patients with concentric collapse. In patients with concentric collapse, the Na/C19 stent was compressed and encased from all sides, allowing only a slight reduction in snoring and apnea, if any. These findings were corroborated by a subgroup analysis of the responder rate stratified for the collapse pattern in patients with isolated palatal obstruction with a high responder rate of 57% in AP collapse but of only 25% in concentric collapse. In comparison, the

| Table 3. Subgroup analysis of patients with main obstruction at the level of the soft palate with respect to collapse pattern and tonsil size. |
|---|
| **Number of patients** | **AP collapse** | **Conc. collapse** | **AP** | **Without Na/C19 stent** | **With Na/C19 stent** | **Conc.** | **Without Na/C19 stent** | **With Na/C19 stent** | **%AHI reduction** | **p value** |
| **Size of tonsils (Brodsky grade)** | | | | | | | | | | |
| Grade 0 (n = 14) | 9 | 5 | 10.2 | 13.3 | 20.3 | 13.9 | 20.7 | 20.1 | 10.6 | 13.0 |
| Grade 1 (n = 26) | 15 | 5 | 3.0 | 9.7 | 24.5 | 13.3 | 14.8 | 7.5 | 12.3 | 8.2 |
| Grade 2 (n = 9) | 4 | 5 | 7.1 | 20.0 | 4.2 | 12.3 | 19.4 | 12.8 | 25.0 | 22.8 |
| **AHI (events/hour)** | | | | | | | | | | |
| **With Na/C19 stent** | 20.9 | 24.2 | 18.3 | 19.4 | 42.0 | 13.9 | 39.4 | 48.4 | 13.8 | 49.5 |
| **Without Na/C19 stent** | 20.7 | 24.2 | 18.3 | 19.4 | 42.0 | 13.9 | 39.4 | 48.4 | 13.8 | 49.5 |
| **%AHI reduction** | | | | | | | | | | |
| **AP** | 10.6 | 13.0 | 10.6 | 13.0 | 10.6 | 13.0 | 10.6 | 13.0 | 10.6 | 13.0 |
| **Conc.** | 25.0 | 22.8 | 25.0 | 22.8 | 25.0 | 22.8 | 25.0 | 22.8 | 25.0 | 22.8 |

Data are presented as mean ± standard deviation. The table shows the collapse pattern at the level of the velum during drug-induced sleep endoscopy and the AHI with and without Na/C19 stent with respect to the Brodsky tonsil grade. The %AHI reduction was defined as the difference between AHI with Na/C19 stent and AHI without Na/C19 stent, divided by AHI without Na/C19 stent. The sex distribution and body mass index were comparable between the groups and are therefore not listed. The Wilcoxon matched-pairs signed-rank test was used for statistics.

AHI, apnea–hypopnea index; AP, anteroposterior; Conc., concentric.
responder rates of UPPP range from 50% \(^{25,26}\) to 78\% \(^{27}\) depending on the technique and study. Concentric collapse in DISE is a negative prognostic factor for UPPP and even an exclusion criterion for upper airway stimulation therapy (hypoglossal nerve stimulation) \(^{28,29}\). Conversion of a concentric collapse to an AP collapse pattern is possible using UPPP and tonsillectomy \(^{30}\). Notably, most studies addressing this topic have been small case series of selected patients treated by varied preoperative and surgical approaches, with no standardized methodology \(^{31}\). The prognostic difference between AP collapse and concentric collapse prior to UPPP has not yet been sufficiently investigated. To our knowledge, this is the first study to correlate the findings from a split-night examination using a nasopharyngeal tube with DISE.

The overall AHI reduction of merely 6.1 events/hour \((-24.8\%)\) using the Na\(sents\) was disappointingly small. Our results are in accordance with the findings in the literature, where the Na\(sents\) reduced the RDI from 22.4 to 15.7 events/hour with a similar reduction of \(-29.9\%\). \(^4\) In the same study, the responder rate with the Na\(sents\) was 37\% compared with our overall responder rate of 26\%. Li et al. \(^8\) found a considerably better reduction in the initial AHI from 41 to 22 events/hour \((49\%)\) using a rescue tube.

### Table 4.

| Main collapse site                  | Percent sleep time with snoring at >40 dB with Na\(sent\) | Percent sleep time with snoring at >40 dB without Na\(sent\) | Percent sleep time with snoring at >50 dB with Na\(sent\) | Percent sleep time with snoring at >50 dB without Na\(sent\) |
|-------------------------------------|-------------------------------------------------------------|---------------------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|
| Soft palate collapse \(n = 50\)     | 36.5 \(\pm\) 28.0                                          | 27.6 \(\pm\) 26.0                                            | 11.7 \(\pm\) 20.7                                         | 9.7 \(\pm\) 17.5                                          |
| AP collapse \(n = 29\)              | 33.5 \(\pm\) 25.0                                          | 27.0 \(\pm\) 28.2                                            | 7.1 \(\pm\) 11.2                                          | 8.8 \(\pm\) 17.7                                          |
| Concentric collapse \(n = 21\)      | 40.9 \(\pm\) 32.1                                          | 28.4 \(\pm\) 23.0                                            | 18.6 \(\pm\) 28.9                                         | 11.1 \(\pm\) 17.7                                         |
| Retrolingual collapse \(n = 13\)     | 54.5 \(\pm\) 36.0                                          | 46.1 \(\pm\) 28.9                                            | 24.6 \(\pm\) 23.1                                         | 16.9 \(\pm\) 18.7                                         |
| Multilevel collapse \(n = 22\)       | 41.6 \(\pm\) 31.8                                          | 32.2 \(\pm\) 26.4                                            | 17.3 \(\pm\) 23.4                                         | 14.9 \(\pm\) 20.4                                         |

Data are presented as mean \(\pm\) standard deviation.

Subgroup analysis was performed according to the collapse pattern (AP or concentric) for the main obstruction at the level of the soft palate. The Na\(sents\) did not significantly reduce snoring in any main or subgroup analysis.

AP, anteroposterior.

### Table 5.

| Degree of discomfort | None   | Mild   | Moderate | Severe | Intolerable |
|---------------------|--------|--------|----------|--------|-------------|
| Patients, n (%)     | 17 (14.8) | 19 (16.5) | 32 (27.8) | 33 (28.7) | 14 (12.2)   |

The patients \((n = 115)\) were asked to rate their discomfort on a 0- to 5-point visual analog scale \((0 = \text{no discomfort}, 1 = \text{mild discomfort}, 2 = \text{moderate discomfort}, 4 = \text{severe discomfort}, \text{and 5} = \text{intolerable discomfort})\). The Na\(sents\) had to be removed prematurely in the 14 patients with intolerable discomfort. Seven patients were not included in the discomfort analysis because of technical failure in the WatchPAT study.
as a nasopharyngeal stent in an exclusively male study population. The difference in these results using the Naštent might be because rescue tubes are much stiffer and therefore less compressible. Compression of the Naštent lumen was observed during DISE, especially in patients with tonsillar level obstruction and palatal concentric collapse.

Objective analysis of snoring loudness is of special interest in the field of ear, nose, and throat medicine because snoring is many patients’ main complaint. During DISE in the present study, a decrease in snoring during the third maneuver was only documented in patients with isolated palatal collapse, mainly AP collapse. Correspondingly, only patients with AP collapse showed a relevant decrease (30%) in the mean sleep time with snoring of >50 dB in the WatchPAT analysis compared with the period without the Naštent. However, the sleep time with snoring of >40 dB was increased in all groups with the Naštent in place. In patients with multilevel and retrolingual obstruction, an increase in the sleep time with snoring of >40 dB and >50 dB was observed with the Naštent. Louder breathing noises and noises of air rushing through the Naštent most likely led to this increase in recorded snoring. These findings are supported by the fact that patients with multilevel obstruction had an overall increase in the AHI by 25% with the Naštent.

Despite its design for increased comfort, the Naštent was not readily tolerated by most patients. In addition, our findings suggest that if the Naštent is considered for treatment of OSA and/or snoring, its effect must be monitored because snoring and the AHI can be increased, especially in patients with multilevel or retrolingual obstruction.

The reduction in the AHI with the Naštent may be useful for identifying the main obstruction site. Using an AHI reduction of 40% by the Naštent as the cut-off value, it was possible to identify 85.7% (41/50) of patients with predominant palatal obstruction and 76.5% (39/51) of patients with predominant non-palatal obstruction compared with the gold standard of DISE. Therefore, a split-night examination with and without the Naštent may yield topodiagnostic information of the main obstruction site, especially if correlated with anatomic findings during ear, nose, and throat examination. However, DISE seems to have superior topodiagnostic value because it gives information regarding not only the site of obstruction but also the collapse pattern. Using a nasopharyngeal rescue tube, Li et al. showed better outcomes of UPPP for patients in whom the initial AHI was reduced by >15 events/hour compared with patients who had a reduction of <15 events/hour. However, the possible predictive value of UPPP seems to be limited to isolated palatal collapses with prior tonsillectomy or small tonsils because tonsillar collapses could not be improved.

This study has several limitations. Split-night examinations, although common, have certain drawbacks. Sleep is interrupted by the manipulation associated with Naštent removal after the first half of the night. Additionally, REM sleep is more prevalent during the second half of the night, which was demonstrated in our data and might lead to an increase in the AHI per se because the AHI is often more elevated in REM than non-REM sleep. Therefore, the treatment effect of the Naštent during the first half of the night, which is predominantly characterized by non-REM sleep, might be overestimated. Inter-rater variability in the DISE findings was minimized but not eliminated. In our study, DISE was originally performed by all authors but reviewed only by the first author. However, examiners might only record events during DISE they deem of interest. This leads to a certain preselection
of available information because the DISE findings are not reviewable in their entirety. Finally, a foreign body sensation caused by the stent might disturb some patients during the split-night examination, resulting in more fragmented and lighter sleep and thus leading to underestimation of the AHI in the first half of the night with the Naštent in place; this would again result in overestimation of its treatment effect.

In conclusion, the Naštent can be a viable but not always readily tolerated option for treating snoring and light OSA in patients with mainly palatal collapse. It yields better results in patients with AP than concentric collapse patterns. Because the Naštent is effective exclusively at the soft palate level and has only a limited impact even at that location, its therapeutic effect must be monitored with polygraphy or other techniques. The literature to date contains no data on monitoring the treatment effect of the Naštent using respiratory polygraphy or polysomnography, and its long-term compliance remains unknown. It is not readily tolerated, mostly because of the foreign body sensation in the nose and throat, which might lead to sleep disruptions. A split-night examination with the Naštent is an inexpensive and easily performed topodiagnostic method for soft palate collapses when DISE is not available. The Naštent remains an interesting device for insertion during DISE as a third maneuver. Possible prognostic information that will help in patient selection for UPPP by either a third maneuver or split-night examination seems to be limited to patients with no tonsillar contribution to the palatal obstruction (i.e., patients with previously removed or small tonsils). Further investigation is needed in this regard.

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