Retrospective Clinical Research Report

Journal of INTERNATIONAL MEDICAL RESEARCH

Journal of International Medical Research
50(1) 1–13

DOI: 10.1177/03000605211073302
journals.sagepub.com/home/imr
SAGE

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 (Naśtent; Corinium Medical Equipment Ltd., Cirencester, UK). The Naśtent 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 Naśtent 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 Naśtent 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 Naśtent did not influence retrolingual or multilevel obstructions. Using a 40% reduction of the apnea–hypopnea index by the Naśtent as a cut-off value, 85.7% of soft palate obstructions were detected compared with DISE.

Conclusions: The Naśtent 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, Naśtent, drug-induced sleep endoscopy, split-night examination, peripheral arterial tonometry

Date received: 19 June 2021; accepted: 17 December 2021

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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 (Naśtent; 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 topodiagnostics 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 Naśtent, 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 Naśtent 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 Naśtent, which was removed for the second half of the night. The following morning, DISE was performed with and without the Naśtent.

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 Naśtent insertion. Because the Naśtent 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 2019-001 49). All patients provided written informed consent. The reporting of this study conforms to the STROBE guidelines.[12]

The Naśtent is a registered medical product with Conformitè Europëenne 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 Naśtent 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 Naśtent 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 Naśtent in place. The Naśtent was then removed by a nurse, and the time of the removal was noted. The patients slept the rest of the night without the Naśtent. 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 Naśtent (AHI_{withNS}) and without the Naśtent ($AHI_{withoutNS}$) was used to evaluate the percentage of palatal obstruction. Palatal obstruction was defined as a ≥40% reduction in the AHI with the Naśtent compared with the AHI without stenting. An AHI reduction of <40% was considered non-palatal obstruction, either multilevel or predominantly retrolingual. The Naśtent treatment responder rate was

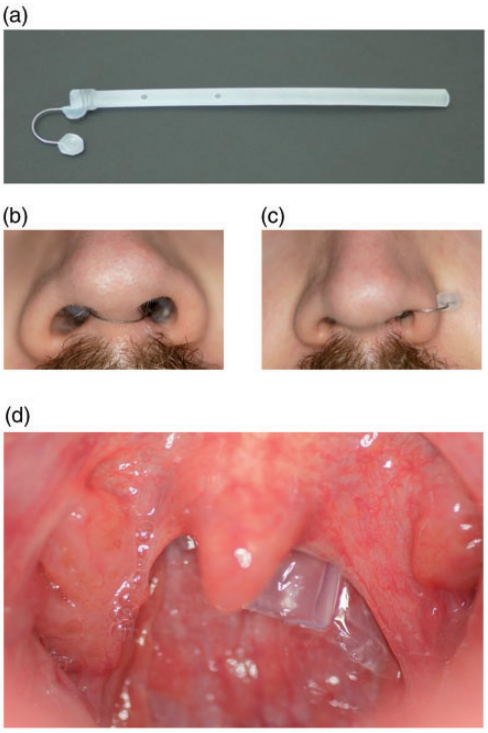

Figure 1. Naśtent. (a) The Naśtent is a soft silicone tube with a diameter of 4.4 mm. It is available in eight lengths (between 130 and 155 mm). The perforations along the side allow for easier breathing and should always be facing upward. Different stents are available for the left and right side. (b) The Naśtent can be anchored on the columella. (c) Alternatively, the Naśtent can be anchored on the nostril for more comfort because the columella is sometimes sensitive. (d) Enoral view of the Naśtent after transnasal insertion and adaption. About 3 to 5 mm of the silicone tube should be visible below the inferior margin of the soft palate.

defined according to the Sher criteria: an AHI reduction of >50% from baseline and an AHI of <20 events/hour with the Naśtent.[13]

Comparison of the absolute AHI reduction would not have provided complete insight into the therapeutic value of the Naśtent according to OSA severity. Therefore, the percent reduction in the AHI by the Naśtent ($\%AHI_{reduction}$) was used in this study. The $\%AHI_{reduction}$ was defined as the ratio of $AHI_{withoutNS}$ and AHI_{withNS} divided by $AHI_{withoutNS}$, 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,[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). Naśtent 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.[15,16]

The Naśtent is designed to treat only the velopalatal area.[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 Naśtent 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 Naśtent. 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 Naśtent 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 Naśtent 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/m^2 (range, 17.3–40.0 kg/m^2).

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

The overall responder rate according to the Sher criteria[13] 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 Naśtent, 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 Naśtent during the second half of the night was 28.4 ± 17.8 events/hour, and the mean RDI with Naśtent 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 Naśtent during the second half of the night was 13.3 ± 14.9 events/hour, and the mean ODI with the Naśtent 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 Naśtent 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 Naśtent had

Table 1. Severity of sleep-related breathing disorder and AHI responder rates (Sher criteria) with Naśtent.

	Habitual snoring	Mild OSAS	Moderate OSAS	Severe OSAS	Total
Patients, n	3	37	30	31	101
Sher responders, n (%)		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 Naśtent).

AHI, apnea–hypopnea index; OSAS, obstructive sleep apnea syndrome.

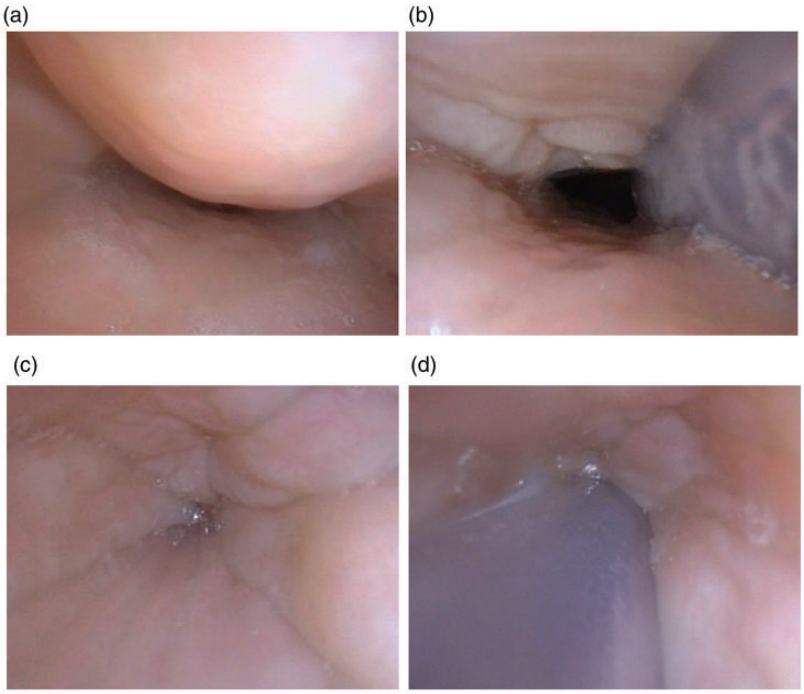

Figure 2. Anteroposterior and concentric palatal collapse as seen during drug-induced sleep endoscopy. (a, b) The same palatal anteroposterior collapse is shown with and without the Naśtent. A significant stenting effect of the collapse can be observed. (c, d) The same concentric palatal collapse is shown with and without the Naśtent. The only therapeutic effect is created by the Naśtent lumen itself because the Naśtent is encased by soft tissue.

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 Naśtent and collapse of its lumen.

The distribution of collapse patterns and the corresponding $AHI_{withoutNS}$ and $\%AHI_{reduction}$ 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 Naśtent, as expected. It was compared to mainly retrolingual 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, $\%AHI_{reduction}$ 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[18] (Table 3). The AHI was only significantly reduced by the Naśtent 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

Table 2. AHI without and with Naśtent with respect to main obstruction site in DISE.

Main obstruction site in DISE	AHI (events/hour) with Naśtent	AHI (events/hour) without Naśtent	$\%AHI_{reduction}$	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.

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 Naśtent and 41.8% with the Naśtent. The mean percent of sleep time with snoring at >50 dB was 12.5% without the Naśtent and 15.7% with the Naśtent. The Naśtent 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 Naśtent.

WatchPAT measures REM sleep as the percent of total sleep time. The mean REM sleep time with the Naśtent was 14.7% ± 9.0%, and that without the Naśtent was 29.9% ± 12.2%. The difference was statistically significant ($p < 0.0001$) according to the paired t-test. The mean REM AHI with the Naśtent was 23.2 ± 19.2 events/hour, and that without the Naśtent 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 Naśtent 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.

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 AlaxoStent[3,9,11] or the Naśtent.[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]

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		AHI (events/hour) AP collapse		AHI (events/hour) Conc. collapse		%$AHI_{reduction}$		
Size of tonsils (Brodsky grade)	AP collapse	Conc. collapse	With Naśtent	Without Naśtent	With Naśtent	Without Naśtent	AP collapse	Conc. collapse	p value
Grade 0 (n = 14)	9	5	10.2 ± 13.3	20.3 ± 19.6	20.7 ± 20.9	24.2 ± 18.7	50.2 ± 9.5	19.4 ± 42.0	0.05
Grade 1 (n = 26)	15	11	13.0 ± 9.7	24.5 ± 13.8	14.8 ± 7.5	19.9 ± 10.3	39.4 ± 48.4	13.8 ± 49.5	0.12
Grade 2 (n = 9)	4	5	10.8 ± 7.1	20.0 ± 4.2	12.3 ± 8.2	22.3 ± 12.8	49.9 ± 25.0	42.8 ± 22.8	0.73

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 $AHI_{withoutNS}$ and AHI_{withNS} with respect to the Brodsky tonsil grade. The %$AHI_{reduction}$ was defined as the difference between $AHI_{withoutNS}$ and AHI_{withNS} divided by $AHI_{withoutNS}$. 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.

In our study, the Naśtent was mainly used for diagnostic purposes both in a split-night examination with the WatchPAT and during DISE. Overall, the Naśtent was poorly tolerated, and 30% of patients complained of significant adverse effects. Only 2 of 101 patients decided to try the Naśtent 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,[21] especially when assessing therapeutic measures such as CPAP.[22,23] A split-night examination is an easy and rather cost-effective way to evaluate treatment effects in only one night.[24] A treatment response is defined as a >50% reduction in the AHI from baseline and an AHI of <20 events/hour with the Naśtent.[13]

Nasopharyngeal stents are devised exclusively for stenting palatal collapses.[4–6,8] 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 Naśtent 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 Naśtent 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 4. Percent sleep time with snoring loudness of >40 dB and >50 dB with respect to collapse pattern as recorded by WatchPAT.

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

Data are presented as mean ± 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 Naśtent did not significantly reduce snoring in any main or subgroup analysis.
AP, anteroposterior.

Table 5. Incidence and severity of discomfort caused by Naśtent during first half of split-night examination.

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 = no discomfort, 1 = mild discomfort, 2 = moderate discomfort, 4 = severe discomfort, and 5 = intolerable discomfort). The Naśtent 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.

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 Naśtent was disappointingly small. Our results are in accordance with the findings in the literature, where the Naśtent 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 Naśtent 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

as a nasopharyngeal stent in an exclusively male study population. The difference in these results using the Naśtent might been because rescue tubes are much stiffer and therefore less compressible. Compression of the Naśtent 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 Naśtent. However, the sleep time with snoring of >40 dB was increased in all groups with the Naśtent 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 Naśtent. Louder breathing noises and noises of air rushing through the Naśtent 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 Naśtent.

Despite its design for increased comfort, the Naśtent was not readily tolerated by most patients. In addition, our findings suggest that if the Naśtent 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 Naśtent may be useful for identifying the main obstruction site. Using an AHI reduction of 40% by the Naśtent 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 Naśtent 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.[8] 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 Naśtent 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.[32,33] Therefore, the treatment effect of the Naśtent 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 Naśtent in place; this would again result in overestimation of its treatment effect.

In conclusion, the Naśtent 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 Naśtent 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 Naśtent 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 Naśtent is an inexpensive and easily performed topodiagnostic method for soft palate collapses when DISE is not available. The Naśtent 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.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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