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Plasma Radiofrequency Preceded by Pressure Recording Enhances Success for Treating Sleep-Related Breathing Disorders

Magne Tvinnereim, MD, PhD; Svetislav Mitic, MD; Rolf K. Hansen, PhD

Objectives: Sleep-related breathing disorders (SRBD) that cannot be treated conservatively are commonly treated using uvulopalatopharyngoplasty, although success rates are generally less than 70%. The purpose of this study was to assess a plasma-mediated radiofrequency (RF)-based coblation assisted upper airway procedure (CAUP) to treat SRBD patients determined to have obstruction localized to the upper (mid)-pharyngeal region. _Study Design:_ Prospective case series (n = 40). _Methods:_ Six patients had socially bothersome snoring, and 34 patients had mild to moderate sleep apnea (apnea/hypopnea index [AHI] <20), with the primary level of obstruction (>50%) within the upper pharyngeal region as determined using whole night recordings, including airway pressure fluctuation monitoring (ApneaGraph, MRA-Medical Ltd, Gloucestershire, UK). CAUP consisted of making a lateral palatal incision, ablating three upward channels on each side of the midline (fan-shaped) into the soft palate using a plasma mediated RF-based device (ArthroCare Corporation, Austin, TX), and performing a partial uvulectomy. Clinical outcomes included the Epworth Sleepiness Scale (ESS), partner rating of snoring using a visual analogue scale (VAS), and night-time apnea and hypopnea events (AHI, hypopnea index [HI], apnea index [AI]). _Results:_ Patients were 28 to 68 (46 ± 12) years old; 28 (70%) were male. Preoperatively, clinical assessment scores (median ± interquartile range) were as follows: ESS (11.0 ± 3.0), VAS (8.15 ± 1.00), AHI (9.58 ± 5.58), HI (9.00 ± 5.29), AI (0.333 ± 0.625). After CAUP, no postoperative scarring, fibrosis, or any other clinically significant side effects were observed. Postoperatively (9.1 ± 1.5; 7–15 mo), ESS (4.0 ± 1.0), VAS (2.70 ± 1.38), AHI (3.75 ± 2.92), HI (3.58 ± 2.50), and AI (0.167 ± 0.167) were significantly improved ($P < .001$). _Conclusion:_ CAUP preceded by site-specific obstruction diagnosis using pressure recording is a well-tolerated outpatient treatment that is well suited for treating SRBD.

Key Words: Snoring, obstructive sleep apnea syndrome, sleep-related breathing disorder, surgery, site of obstruction, pressure recording, ApneaGraph, bipolar radiofrequency, plasma mediated, coblation, long-term outcome, coblation assisted upper airway procedure, site specific obstruction diagnosis.

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INTRODUCTION

Obstructive sleep apnea syndrome (OSAS) is a common clinical problem,[1] with prevalence in middle-aged people (30–60 yr) of approximately 3% to 5%, although this condition is likely to be under-reported.[2] Sleep-related breathing disorders (SRBD) resulting from partial or total obstruction of airflow through the upper airways is a result of decreased muscle tone and anatomic narrowing that occurs while a person is fully relaxed during sleep. The most frequent symptoms are snoring, sleep deprivation, daytime hypersomnolence, personality changes, and physical and mental impairment. With the well-documented increased risk of stroke, hypertension, and cardiac arrhythmias associated with SRBD,[3,4] developing an effective strategy for treating this condition is important.

Conservative therapies to treat SRBD most commonly consist of recommending weight loss and avoidance of alcohol and relaxing medication. Mandibular repositioning devices are also used to a limited degree,[5] whereas a continuous positive airway pressure (CPAP) procedure is considered to be the gold standard, although patient compliance is poor.[6] As a result, a variety of pharyngeal widening procedures, including different approaches for performing uvulopalatopharyngoplasty (UPPP), have been developed. Unfortunately, the success rates are poor (40–80%), which diminish even further as time passes after surgery.

Enhancing surgical outcomes within the SRBD population requires properly identifying the site of partial or total pharyngeal obstruction during sleep as well as using a surgical tool allowing for site-specific surgery.[7] To target the optimal surgical site in SRBD patients, we have used a system consisting of micropressure transducers mounted in

From EuroSleep (M.T.), Bergen, Norway; the ENT Department (S.M.), Akershus University Hospital, Norway; and Kahrs Hansen AS (R.K.H), Bergen, Norway.

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Send correspondence to Dr. M. Tvinnereim, EuroSleep, Nattlandsveien 8, NO-5093 Bergen, Norway. E-mail: mt@eursleep.no

a thin, soft, and flexible polyurethane catheter (ApneaGraph, MRA-Medical Ltd, Gloucestershire, UK) for several years to measure pressure gradients in the upper airway and esophagus and to collect polygraphy information during sleep. We recently began using bipolar plasma-mediated radiofrequency-based (coblation) instruments to perform UPPP procedures, allowing for treatment under local anesthesia on an outpatient basis. Furthermore, these devices allow tissue excision as well as volumetric reduction while affecting adjacent nontargeted tissue less than cautery type electrosurgery.[8] The purpose of this study was to assess the use of a coblation assisted upper airway procedure (CAUP) for treating patients with snoring and mild to moderate sleep apnea who were determined to have obstruction localized to the upper pharyngeal region using the ApneaGraph device. Postoperative follow-up ranged from 7 to 15 months.

MATERIALS AND METHODS

Patients

Forty otherwise healthy adult patients with socially disruptive snoring (n = 6) and concomitant mild to moderate sleep apnea (n = 34) referred by their general practitioners went through a complete ear, nose, and throat examination, including endoscopy of the upper airway. They were informed about all possible treatment modalities; all were initially offered CPAP treatment if appropriate. All patients had body mass index (BMI) less than 30, apnea/hypopnea index (AHI) less than 20, and more than 50% of the airway obstruction was determined to be localized to the upper pharyngeal region. No patient in the study had received prior surgery for airway obstruction, nasal blockage, adenotonsillar hypertrophy, or other manifest upper airway diseases. All patients provided informed consent before undergoing the procedure, and patient care and data collection was performed following the guidelines provided by our institution.

Preoperative Determination of Pharyngeal Obstruction

Patients underwent night cardiorespiratory monitoring (ApneaGraph, MRA-Medical Ltd, Gloucestershire, UK) to determine candidacy for undergoing CAUP. The ApneaGraph tool is designed to combine a polygraphy sleep study while recording nasal-pharyngeal pressures and temperature (flow) fluctuations from sensors in a thin, soft catheter. With this information, it is possible to identify the site of airway obstruction. The AG200 consisted of a battery-operated data logger and a pressure/temperature sensor catheter. Data were collected over 6 hours. The ApneaGraph recorded arterial oxygen saturation (SaO2%), pulse variation, body position, snoring, breathing activity, and mid-esophageal and pharyngeal pressure fluctuations (Fig. 1). The AHI, apnea index (AI), and hypopnea index (HI) were automatically calculated by the software.

Surgical Procedure

All cases were performed under local anesthesia, with the patient seated opposite the surgeon, upright in an ENT examination chair. Immediately before the procedure, the patient was made comfortable (seated, listening to music, reading a magazine or newspaper) and was given 5 to 10 mL 2% xylocain gel. After 15 to 20 minutes, 5 to 10 mL xylocain/adrenalin 1% was injected into the soft palate, uvula, and pillars. Because OSAS patients are reported to have a narrow transversal pharyngeal diameter,[9] widening of the pharyngeal opening was mandatory and was conducted by making a transverse incision, typically 45 degrees, between the rim of the soft palate and the adjoining pillars (Fig. 2). If the clinical examination showed a thick, floppy palate, a more upwardly angled incline was made (e.g., 60 degrees). If less tissue retraction was desired, the incision was made more horizontally to avoid excessive shrinkage and potential corresponding incompetence in nasal closing. Sufficient infusion of the treated area with local anesthetic was mandatory to avoid discomfort during tissue cutting. Despite this, occasionally, patients experienced pain stemming from the lateral region, which may indicate localized larger vessels. To prevent excessive bleeding, we suggest not ablating too far laterally; however, we did not encounter any problematic bleeding.

Three channels were ablated on each side of the midline in a fan-shaped, upward direction into the soft palate to retract the tissue and diminish the thickness of the soft palate (Fig. 3). All procedures were performed using a bipolar radiofrequency-based wand (Reflex 55, ArthroCare Corporation, Austin, TX). The partial uvulectomy was initiated by passing the activated tip of the device through the planned incision area to coagulate the vessels before excising the distal portion (1/3) of the uvula. On average, the entire procedure took approximately 15 minutes.

Outcome Measures

The patients were followed up as is routine practice in our clinic through 6 months before the postoperative ApneaGraph readings were collected between 7 and 15 (9.1 ± 1.5) months. Before surgery and at the 9 month postoperative examination, patients were asked to complete the Epworth Sleepiness Scale (ESS). In addition, the spouse, partner, or other close family member was asked to subjectively rate snoring loudness by marking a 100 mm visual analogue scale (VAS) with reference anchors of “no snoring” on the left side and “devastating noise” on the right side.

Statistical Methods

Statistical comparisons were made using nonparametric tests (e.g., median values instead of mean values). With non-normally skewed distributions of this type, the median is more stable because the mean is very much influenced by the presence of isolated high values. In some instances, parametric statistics were evaluated. The differences between medians were computed using the Hodges-Lehman method, which uses the median of all the pair-wise differences. The Wilcoxon signed rank test was used to evaluate statistical significance.[10] The Analyze-it software (Analyze-it Software, Ltd., Leeds, UK) was used to perform the statistical analyses.

RESULTS

Forty patients with socially disruptive snoring (n = 6) and additional mild to moderate sleep apnea (n = 34) ranging in age from 28 to 68 (46 ± 12) years underwent treatment; 28 (70%) patients were male. BMI ranged from 20 to 38 (25.5 ± 7.2) kg/m^2.

In no case did we observe any evidence of postoperative scarring, fibrosis, or any other clinically significant side effects. Two patients complained of a mild degree of mouth dryness, and one reported a globulus sensation. Postoperatively, ESS, VAS, AHI, HI, AI, and oxygen desaturation index were significantly reduced from preoperative scores (Table I). Notably, along with significant reduction of the number of postoperative obstructive apnea (AI) and hypopnea (HI) events, the variability of these parameters was reduced as well. Despite this, no improvement was observed in arterial oxygen saturation (SaO_2)

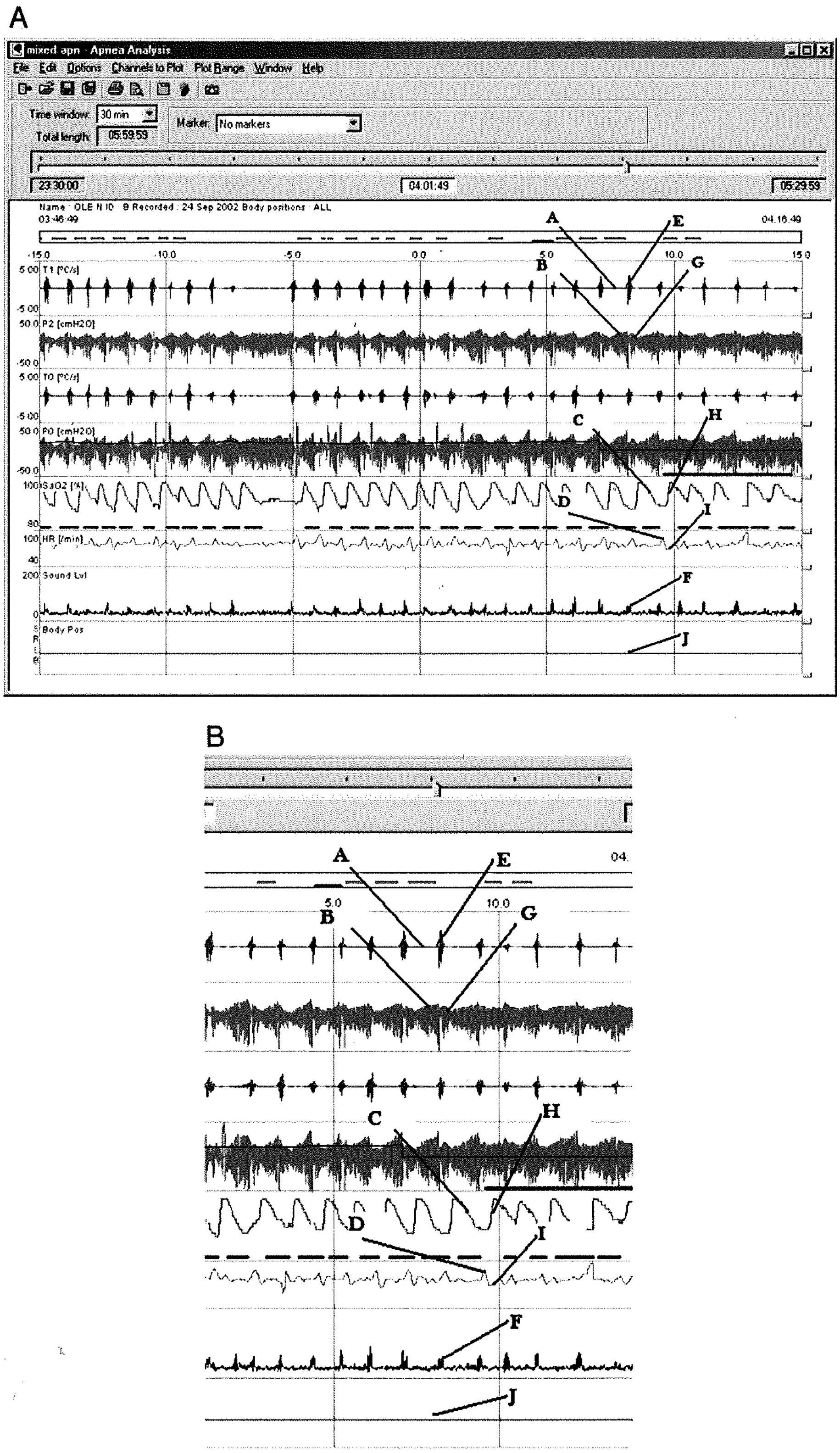

Fig. 1. (A) A typical ApneaGraph data plot showing data collected over a 30-minute window. Starting at the top, each temporal line shows: Proximal temperature; proximal pressure; distal temperature; distal pressure (mid-oesophageal); oxygen saturation in percent (%); pulse rate; sound level; and body position. (B) A series of obstructive apneic events were detected: Apneic episode is shown by the zero temperature variation (arrow A) and increased breathing effort (arrow B) by the patient; followed by a drop in oxygen saturation (arrow C) and increased pulse rate (arrow D). Opening of the breathing channel leads to immediate airflow (arrow E), snoring (arrow F), and reduction of the pressure fluctuations (arrow G) followed by an increase in oxygen saturation (arrow H) and reduced pulse rate (arrow I). The patient was sleeping on his left side (arrow J).

values, which may be because of the fact that SaO_2 was nearly normal preoperatively in all patients.

All patients reported improvement in VAS score ($\geq$3 points) for snoring, and all showed improvement in AHI score (Fig. 4); 21 (62%) patients had postoperative AHI less than 5. Thirty-two (80%) patients had a change ratio ([preoperative AHI - postoperative AHI]/preoperative AHI) greater than or equal to 50%, indicating that their

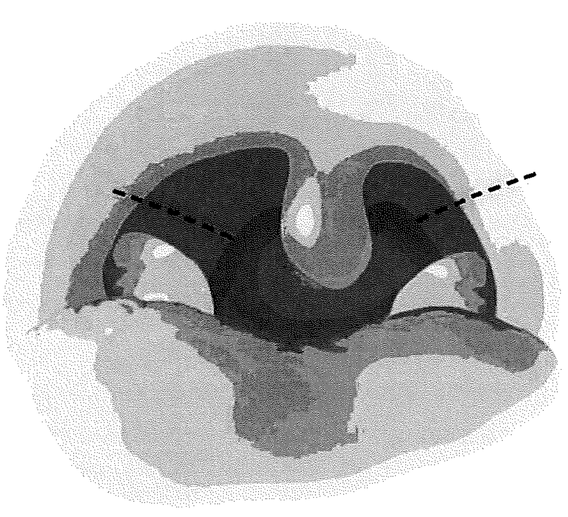

Fig. 2. Bilaterally ascending incisions between the rim of the soft palate and caudal part of the adjoining pillars.

postoperative AHI score was less than or equal to half of their preoperative AHI score (Fig. 5). All 40 patients had a change ratio greater than 25%, indicating that their postoperative AHI score was less than 75% of their preoperative AHI score. The average reduction in AHI (ratio between postoperative AHI score and preoperative AHI score, in percent) was 38.8 ± 17.0% (95% confidence bounds = 33.4, 44.3%).

DISCUSSION

The aim of this study was to evaluate the effectiveness of using CAUP to treat patients with symptomatic obstruction localized to the upper pharyngeal region. With CAUP, we were hoping to achieve a greater than 50%

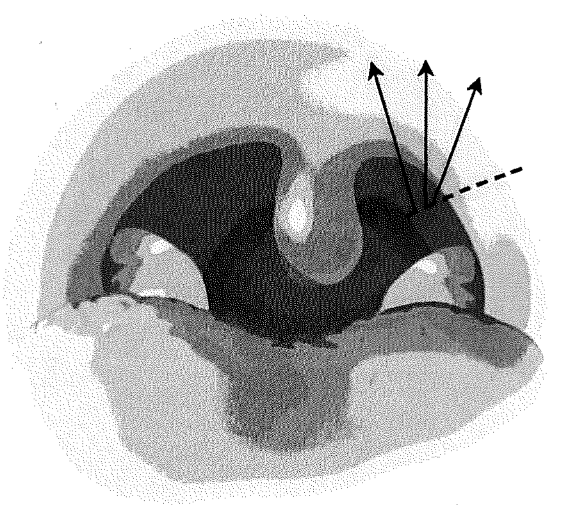

Fig. 3. Three ablating channels on each side of the midline, in a fan-shaped, upward direction into the soft palate.

reduction in AHI in individual patients, with the secondary aim of having patients end up with AHI less than 5 postoperatively; these expectations are consistent with the standard international criteria accepted for defining successful surgery. The first criterion was achieved in 80% of the patients. The second criterion was observed in 21 of 34 (62%) of the OSAS patients, and in all 6 (100%) patients who had AHI score less than 5 preoperatively.

It appears that approximately 20% of patients may require a second procedure, which corresponds with our expectations given these guidelines. Despite it being a common disease with serious, well-documented complications and side effects, no general agreement regarding standard treatment modalities exists for SRBD. Anatomic narrowing of the upper airways is considered one of the reasons for patients developing SRBD. Still, surgical treatment for opening up the obstructed area has not gained popularity, mainly because of the poor outcomes[7] and undesirable side effects, including postoperative pain, scarring, fibrosis, and mouth dryness.[11] With the CAUP procedure, no such negative effects were observed.

The bipolar coblation tool appears to provide several advantages over other traditional SRBD surgical approaches. By avoiding removal of the mucosal lining, the moistening effect of the mucosal glands is kept intact. This avoids mouth dryness, thus facilitating the physiologic functioning during speaking, singing, chewing, and swallowing.[12] In contrast with what is found when using different types of higher-temperature electrosurgical devices, channeling using a coblation device leaves the mucosal lining undamaged, preserving the mucociliary apparatus (personal communication, A. Helmy, Zagazig University, Sharkia, Egypt, November 11, 2005). Furthermore, shrinking and stiffening of the tissue retracts and straightens the soft palate and pushes it forward, resulting in a longer anteroposterior diameter. Consequently, a three-dimensional treatment effect is achieved in which the tissue is moved upward, the palate is thinned, and the transversal diameter is diminished. Because we have only observed this using CAUP, we attribute it to the ability of the device to both cut and shrink tissue.

The varying results from different types of treatment, such as UPPP, tongue base reduction, and maxillomandibular surgery, along with the consensus agreement that the likelihood of collapse at several additional pharyngeal is high,[13] has made multilevel upper airway surgery a more attractive option.[14] For SRBD surgery to be successful, both site-specific diagnosis as well as site-specific surgical methods may be the most appropriate approach. The coblation devices are well suited for performing multilevel surgery, in which the same bipolar device (Reflex 55) can be used for all procedures, making multilevel surgery cost effective.

Patients were treated using site-specific CAUP, localized to the soft palate, including lateral palatal incision with upward channeling, as well as partial uvulectomy and channeling. If necessary, palatal arch-channeling and anterior as well as posterior pillar-channeling can also be performed. All of our procedures were carried out under local anesthesia, with the alert patient seated in front of the surgeon, holding the tongue depressor. Allowing the

TABLE I.
Pre- and Postoperative Subjective Snoring Score and Objective ApneaGraph Scores.

	Mean	Standard Deviation	Median	Interquartile Range	Range	One-Tailed *P* Value
ESS, preop	10.5	2.7	11.0	3.0	4–16	—
ESS, postop	4.58	1.60	4.00	1.00	0–9	<.0001
VAS, preop	8.08	0.86	8.15	1.00	5.8–9.5	—
VAS, postop	2.81	0.97	2.70	1.38	1.1–5.2	<.0001
AHI, preop	9.86	4.81	9.58	5.58	0.7–18.7	—
AHI, postop	4.18	3.02	3.75	2.92	0.0–12.2	<.0001
HI, preop	9.12	4.37	9.00	5.29	0.3–17.2	—
HI, postop	3.92	2.77	3.58	2.50	0.0–12.2	<.0001
AI, preop	0.742	1.016	0.333	0.625	0.0–4.83	—
AI, postop	0.254	0.560	0.167	0.167	0.0–3.17	<.0001
SaO_2, preop	94.7	1.4	95.0	2.0	91–97	—
SaO_2, postop	94.6	1.6	95.0	2.3	90–97	.70
ODI, preop	29.7	25.2	23.0	24.8	0–130	—
ODI, postop	22.5	27.5	15.5	16.3	1–159	<.0017
Pulse rate, preop	63.0	7.3	64.0	10.0	49–85	—
Pulse rate, postop	63.1	7.1	62.0	8.0	48–78	.84

Wilcoxon one-sided signed rank tests were used to evaluate statistical difference between preoperative and postoperative values.

preop = preoperative (n = 40); postop = postoperative (n = 37); ESS = Epworth Sleepiness Scale; VAS = visual analogue scale score for snoring loudness; AHI = apnea/hypopnea index; HI = hypopnea index; AI = apnea index; ODI = oxygen desaturation index; SaO_2 = oxygen saturation.

patients to take part helps them control any vomiting and cuffing reflexes and greatly diminishes issues with cooperation. Moreover, this intervention works well as an outpatient procedure, which again makes it relatively cost effective. After these types of coblation procedures, postoperative pain was found to be acceptable when compared with other interventions used to treat SRBD.[15]

Channeling of the soft palate is best carried out by performing upward, fan-like ablations, beginning the ablation through the initial transverse incision. When a patient with a thick voluminous palate required treatment, results were more favorable if the tunnels were placed relatively more anteriorly compared with when a patient with a less voluminous palate is treated. The tissue retraction that follows will be more likely to result in the desired forward tilting of the soft palate. In performing a multilevel procedure, channeling of the pillars

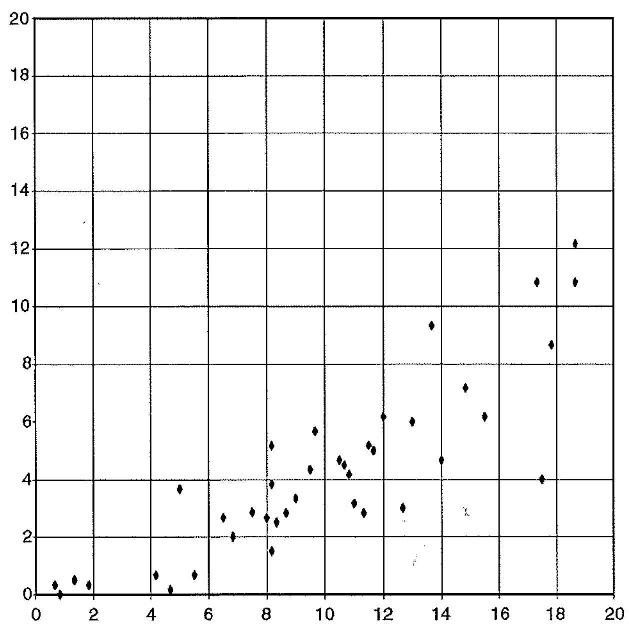

Fig. 4. All 40 patients demonstrated improved apnea/hypopnea index (AHI) postoperatively. The postoperative AHI is along the ordinate while the preoperative AHI is along the abscissa. One point is defined by its preoperative AHI vs. postoperative AHI, and all points are lower than the line preoperative=postoperative, hence there is improvement in all cases.

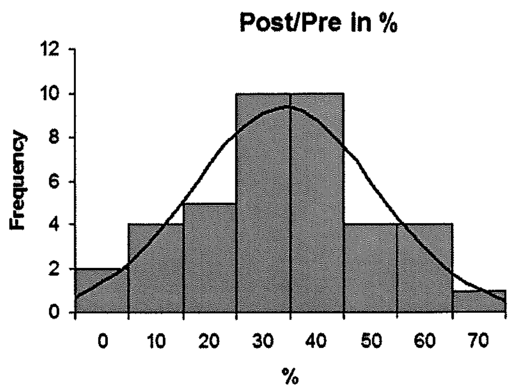

Fig. 5. The mean apnea/hypopnea index (AHI) improvement (postoperative AHI/preoperative AHI) is 38.8% with a standard deviation of 17.0%. The 95% confidence interval of the mean is between 33.4% and 44.3%.

may be added, which provides even better lateralization of the soft tissue.

Polysomnography is still considered to be the gold standard for diagnosing SRBD because it is sufficiently reliable in defining the type and numbers of hypopneas and apneas and provides information about the stages of sleep and sleep disturbances.[1] However, this assessment tool lacks the ability to give precise information about the site(s) of pharyngeal obstruction. Thus, it is of little use for enabling the surgeon to design a clear surgical plan to enhance surgical outcomes. Other investigational tools, such as sleep endoscopy, radio cephalometry, and acoustic reflectometry, have also been reported to provide relatively poor information. For several years, we have used the ApneaGraph, which is designed to provide polygraphy readings as well as pressure recordings to allow a site-specific diagnosis, thus permitting the clinician to develop a more effective fine-tuned surgical procedure.

CONCLUSION

CAUP is a new procedure that shows promise for improving long-term success rates. In our series, we achieved satisfactory clinical results in 80% of the treated patients, although only one single treatment was performed. No untoward undesirable side effects were observed. Determination of the level of obstruction using the ApneGraph accompanied by stepwise treatment using the CAUP procedure provided good results at a mean follow-up time of 9 months. Overall, this strategy offers a complete, logical, and cost-effective line for step-by-step treatment of snoring and mild to moderate obstructive sleep apnea. Our findings in regard to AHI and daytime hypersomnolence were excellent, corresponding to better sleeping conditions for the patients' partners. We conclude that CAUP preceded by site-specific obstruction diagnosis is a well-tolerated and highly recommendable treatment that is well suited for treatment of snoring and mild to moderate sleep apnea using local anesthesia in an outpatient setting.

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