Turkish Archives of Otolaryngology
Türk Otolarengoloji Arşivi

Turk Arch Otolaryngol 2014; 52: 93-7

Which Patients Can Benefit from Pillar Palatal Implant Procedure?

Hangi Hastalar Pillar İmplanttan Fayda Görebilir?

Original Investigation
Özgün Araştırmalar

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Abstract

Objective: The aim of this prospective study is to determine which patients may benefit from pillar procedure as a treatment for snoring.

Methods: A total of 37 patients (25 males and 12 females) with a history of snoring were implanted with 3 pillar palatal implants. Flexible fiberoptic examination was used to evaluate the upper airway, especially the retropalatal and retrolingual areas. Visual analog scale (VAS) and polysomnography were performed on before and 3rd months after the pillar procedure. The implantation was performed under local anesthesia.

Results: The mean VAS score was reduced from 9.3±0.6 to 6.2±1.1 at the 3rd month. VAS scores of snoring intensity were reduced >50% in 24 of the patients (64.8%). The mean apnea-hypopnea index (AHI) was 11.7±2.3 before the implantation and was reduced to 8.4±1.6 at the 3rd month. VAS and AHI had a close relation with gender, body weight, and oropharynx class. There were no major complications, such as infection, extrusion, and major bleeding.

Conclusion: Pillar procedure has a high success rate if it is done with appropriate patient selection, but overall effectiveness remains limited. Initial AHI and VAS values, oropharynx and tonsil position scores, and gender are important determinants of pillar procedure.

Key Words: Pillar implants, snoring, obstructive sleep apnea, polysomnography

Özet

Amaç: Horlama hastalarında pillar palatal implanttan hangi hastaların fayda görebileceğini saptamak için yapılmış prospektif bir çalışmadır.

Yöntemler: Horlama şikayeti ile başvuran 25'i erkek, 12'si kadın 37 hastaya yumuşak damağa 3 adet pillar palatal implant tatbik edilmiştir. Fizik muayene özellikle üst havayolunun retropalatal ve retrolingual alanları değerlendiren fleksible fiberoptik ile yapılmıştır. Hastaların operasyon öncesi ve pillar uygulaması sonrası 3. ayda vizüel analog skala (VAS) skoru ve polisomnografi testleri yapılmıştır. İmplantasyon işlemi lokal anestezi altında gerçekleştirilmiştir.

Bulgular: Üçüncü ayın sonunda VAS skorunda 9.3±0.6'dan 6.2±1.1'e düşme gözlenmiştir. Yine 24 hastada (%64.8) VAS skorunda %50'den fazla bir azalma saptanmıştır. 3. ayın sonunda ortalama apne hipopne indeksi (AHI) 11.7±2.3'den 8.4±1.6'a düşmüştür. VAS ve AHI cinsiyet, vucut ağırlığı ve orofarinks klas'ı ile yakın ilişki göstermektedir. Enfeksiyon, atılım ve major kanama gibi büyük komplikasyonlar hiç bir hastada gözlenmemiştir.

Sonuç: Pillar prosedürü uygun hasta seçimi sonrasında uygulandığı takdirde yüksek başarı oranına sahiptir. Ancak genel effektivitesi limitli olan bir yöntemdir. Başlangıç AHI ve VAS değerleri, orofarinks, tonsillerinin durumu ve cinsiyetin pillar prosedürünün başarı oranında etkisi belirgindir.

Anahtar Kelimeler: Pillar implant, horlama, tıkayıcı uyku apnesi, polisomnografi

Introduction

Many surgical procedures for obstructive sleep apnea (OSA) and snoring can be applied for treatments, such as tissue resection. This technique can cause postoperative pain, and it has a low success rate. For patients with snoring or obstructive sleep apnea, various treatment modalities have been introduced, and their efficacies have been evaluated (1). A few systematic reviews about surgical treatment for OSA and snoring have been published. Most of them have dealt with laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty (UPPP), and maxillomandibular advancement (2). Surgeons have increasingly understood multilevel obstruction. So, the majority of publications includes multiple additive surgical procedures with uncertainty as to the effectiveness of any particular component (3).

The ideal surgical procedure should be minimally invasive, single-staged, and minimally morbid. Recent studies of isolated palate implants for snoring and OSA have demonstrated some benefit clinically, but there was no placebo control (4). Pillar procedure has been a treatment of snoring and mild-moderate sleep apnea since early 2000. The pillar implant was designed to reduce vibration or

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Received Date/Geliş Tarihi: 11.02.2014
Accepted Date/Kabul Tarihi: 26.06.2014
Available Online Date/Çevrimiçi Yayın Tarihi: 25.08.2014

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DOI:10.5152/tao.2014.470

narrowing of the soft palate by increasing its stiffness (5). The implants consist of 18-mm polyethylene terephthalate implants permanently inserted within the muscular layer of the soft palate. The implants induce a chronic inflammatory response that creates a fibrous capsule around the implants and are designed to reduce the soft palate flutter and collapsibility that contribute to sleep-disordered breathing at the velopharyngeal level (6). The most important handicap of pillar procedure is to be performed on which patients; so, proper patient selection is the most important factor to achieve success. Simple snorers, female patients, and patients with normal weight are more likely to achieve high success rate from pillar procedure (7).

The aims of the study are to determine which criteria are associated with treatment success of snoring and mild/moderate OSA patients, as judged by the bed partner, as well as certain factors that may be associated with pillar-related complications.

Methods

This prospective study included 37 patients (25 males, 12 females) who were admitted with complaints of snoring to Hacettepe University Hospitals Department of ENT between 2009-2012. All patients were married, up to 18 years old, and without nasal obstruction. ENT examination, polysomnogram (PSG), and visual analog scale (VAS) were evaluated in all patients. This prospective study was accepted by the Hacettepe University Faculty of Medicine Ethics Committee, and consent forms were obtained from each patient at Hacettepe University Hospital Department of ENT and Head and Neck Surgery VAS was taken from the bed partners of patients. VAS values of all patients were considered to be 10 before the implantation. Patients with snoring due to palatal flutter, soft palate length 3 cm or longer, and who had apnea-hypopnea index (AHI) <15 were included (6). Being <18 years of age, pregnancy, breastfeeding, neurologic disorders, significant nasal obstruction, BMI >35, unstable psychiatric disorder, and the absence of a bed partner were the exclusion criteria.

Three pillar implants were implanted under local anesthesia with no complication. The patients were given an oral antibiotic 20 minutes prior to the procedure, which was continued for an additional 24 hours. Three months after pillar procedure, VAS and PSG were performed again.

Physical examination included BMI, and flexible nasopharyngoscopy was used to evaluate the upper airway, especially the retropalatal and retrolingual areas. Hypopharynx grade was detected by flexible nasopharyngoscopy.

The one-night polysomnographic study was performed according to the Guidelines of the American Electroencephalographic Society (1994) and included the following parameters according to standard methods: electroencephalography (EEG), electroculographic activity, submental electromyographic activity, intercostal electromyographic activity, chest and abdominal movements, snoring, airflow (oronasal flussimetry), oxygen saturation and plethysmography, lower limb movement, and electrocardiographic activity (8). The eight hour polysomnogram was attended by a trained technologist, manually scored, and interpreted by a trained clinical polysomnographer according to standardized criteria. OSA diagnosis was based on the Criteria of the International Classification of Sleep Disorders (American Sleep Disorders Association). Obstructive apnea was defined as a cessation of air flow for at least 10 s in the presence of a respiratory effort despite cessation of airflow. Hypopnea occurred when there was a reduction of airflow by 50% or more for at least 10 s. The number of apnea or hypopnea events per hour was obtained by dividing the total number of such events by total sleep time, as defined by the apnea-hypopnea index (AHI) (American Sleep Disorders Association). The mean percentage of time at SaO_2 below 90% (sO_2<90%) and the average time spent in the supine position (TSP) during total sleep were also calculated.

Statistical Analysis

All data were analyzed using the Statistical Package for the Social Sciences (SPSS) 15.0. The following statistics were used: t-test, homogeneity of variance (Levene) test, Mann-Whitney U-test, Fisher's chi-square test, simple correlation, and regression analysis method.

Results

There were 25 males and 12 females with a mean age of 38.3±9.7 (males 41.4±11.2, females 35.8±7.3). The patients had a history of snoring for 2 to 25 years. Mean BMI was found to be 25.6±5.3. Mean VAS scores were reduced from 9.3±0.6 to 6.2±1.1, and mean AHI was 11.7±2.3 before the implantation. Twenty-nine patients had tonsil grade 0. None of the implants was extruded, and there were no postprocedure major complications or infections. The most common complication was minor bleeding on the soft palate, and it was seen in 11 patients. Seven patients complained of swallowing dysfunction for 1 to 3 days (Table 1). At 3 months, the patients were reevaluated for VAS and polysomnography.

At 3 months, it was detected that snoring severity significantly improved according to VAS scores obtained from the partners. The mean VAS score was reduced from 9.3±0.6 to 6.2±1.1 at the 3rd month. VAS scores were reduced by more than 50% in 24 patients (64.8%). The snoring intensity did not change in 7 patients (18.9%) and decreased to some extent in 6 patients. The mean AHI was reduced from 11.7±2.3 to 8.4±1.6 at the 3rd month. AHI was reduced by more than 50% in 17 patients (45.9%). It was reduced nearly 30% in 8 patients (21.6%). AHI did not change significantly in 12 patients (32.5%) (Figure 1).

The average time spent in the supine position (TSP) during sleep was increased from 67±13 to 148±21 minutes at the 3rd month. TSP was increased by more than double in 27 patients (72.9%).

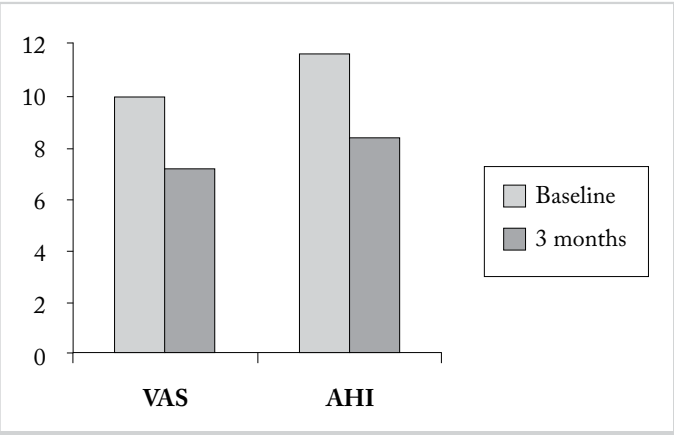


Figure 1. VAS and AHI baseline and 3-month values
VAS: visual analog scale; AHI: apnea-hypopnea index

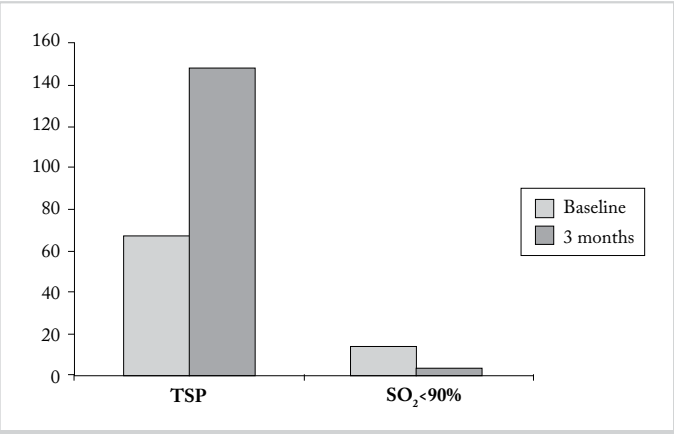


Figure 2. TSP and sO_2<90% for 1 minute
TSP: the supine position

The mean percentage of time at SO below 90% (sO_2<90%) was decreased from 13.2 to 4.6 minutes at 3rd month (p<.05) (Figure 2). There were differences in VAS scores and other polysomnographic parameters with respect to gender, tonsil position, and BMI variables. VAS score had improved in 83.3% of female patients and 56% of male patients. AHI was decreased by more than 50% in 66.6% of female patients and 36% of male patients. Similarly, VAS score had in improved 72.4% of the patients with no tonsil hypertrophies. AHI was decreased by more than 50% in 56.5% of the patients with no tonsil hypertrophies. VAS score had improved in 82.3% of patients with normal weight (BMI<24) and 17.7% of patients with overweight. AHI was decreased by more than 50% in 74.6% of patients with normal weight and 5.9% of patients with overweight. The body weight significantly influenced VAS and AHI but tonsil position and gender did not (Table 2).

The success of VAS score did not correlate with any clinical-endoscopic examination and polysomnographic finding except TSP. There was a strong correlation between TSP and VAS (coefficient 0.659; p<.005). There was slight correlation between AHI and VAS score. Thirteen patients had AHI under 5, and 87% of these patients were treated successfully.

Table 1. Demographic characteristics of patients

Patients	Number
Gender	
Female	12
Male	25
Mean Age	38.3 (26-54)
Mean BMI	25.6±5.3
Mean VAS	9.3±0.6
Mean AHI	11.7±2.3
Tonsil	
0	29
1	6
2	2
Minor Bleeding	11
Swallowing disfunction	7

VAS: visual analog scale; AHI: apnea-hypopnea index; BMI: body mass index

Table 2. Gender, weight, and examination characteristics of patients

	Number	Baseline	VAS 3rd month	Baseline	AHI 3rd month
Female	12	7.9	4.1	7.5	4.3
Male	25	9.6	7.7	12.6	10.3
Tonsil					
Grade 0	29	7.1	3.4	9.3	6.2
Grade 1	6	9.0	8.8	11.2	9.8
Grade 2	2	9.8	9.6	13.6	11.9
BMI					
<24	17	6.9	3.1	6.2	1.9
>24	20	8.9	8.7	13.1	9.2

VAS: visual analog scale; AHI: apnea-hypopnea index

Discussion

Snoring may arise from any anatomical region of the upper respiratory tract (soft palate, tongue, lateral pharyngeal wall, etc). Many surgical procedures can be applied for treatment, such as tissue resection. However, it may cause postoperative pain and nasal regurgitation. Commonly it requires general anesthesia (8). Radiofrequency and laser are alternative techniques to make up scar tissue, but these techniques may be irreversible (9-12). In general, isolated palate surgery, including UPPP, is not curative for OSA in the absence of tonsil hypertrophy (13).

VAS of snoring intensity is a frequently used instrument in snoring practice and research; these scales are sensitive to improvements in snoring intensity (14). Other studies of palate implants for mild to moderate OSA have demonstrated significant AHI reduction, persisting at 1 year posttreatment but with modest

reductions (15). This study agrees with earlier studies that the pillar system reduces snoring; also, VAS decreased among bed partners, and AHI decreased at the 3-month follow-up. Most studies about OSA (16-19) found no relation between VAS and AHI. In this study, we observed a slight correlation between AHI and VAS. VAS score was reduced from 10 to 7.2, and AHI was reduced from 11.7 to 8.4 at the end of 3 months. We also found a high success rate in selected patients, unlike the other studies. It is established that some factors of subjects possibly affected success rate in this study. These factors are gender, patient's weight, and tonsil position score. The noticeable changes were seen in these groups. We found that patients whose BMI was under 24 showed the maximum benefit from the procedure. VAS score had improved in 82.3% of patients with normal weight (BMI<24) and 17.7% of patients with overweight. AHI was decreased by more than 50% in 74.6% of patients with normal weight and 5.9% of patients with overweight. Female patients benefited remarkably, too. VAS score had improved in 83.3% of female patients and 56% of male patients. AHI was decreased by more than 50% in 66.6% of female patients and 36% of male patients. The factors apnea existence and tonsil position score also had an effect on the success rate. Pillar procedure is more effective in simple snorers than mild/moderate patients with OSA (20). In our study, we found that 13 patients were classified as a simple snorers, and 87% of these patients were treated successfully. Similarly, patients with small tonsils benefited more than others. Polysomnographic parameters, such as mean percentage of duration at SaO_2 below 90% and average time spent in the supine position, were related to snoring, too. When these parameters were analyzed, both of them showed significant improvement compared with before and after pillar procedure. TSP during sleep was increased from 67±13 to 148±21 minutes at the 3rd month. TSP was increased by more than double in 72.9% of patients. This may be interpreted as prolonged supine position causes higher patient satisfaction.

The main advantages of the pillar system are the minimal pain and morbidity of the procedure, the ability to resume a regular diet immediately, and the relatively low complication rate (18). The clinical relevance of the results of this study may be that palate implants may significantly improve simple snoring and mild OSA in a small proportion of subjects with minimal morbidity and may represent an attractive first step alternative to traditional UPPP for isolated patients (19). This study suggests that proper patient selection is the most important factor to achieve high success rates from the pillar procedure.

The principal limitation of this study is the shorter average follow-up times for patients with satisfied bed partners. This shorter follow-up time prevents us from knowing whether the initial snoring satisfaction is stable over time. The second limitation is that there is currently no universal objective standard by which to judge snoring improvement, and current methods that rely on bed partner reports can not account for individual differences (eg, bed partner sleep problems) that are likely to impact VAS score. Finally, this study focused on simple snorers and mild/moderate OSA. There was no knowledge of other outcomes of interest, such as daytime sleepiness, and health outcomes, which may be of interest in the snoring population.

Conclusion

Palatal implants are a quick and simple office-based procedure that can be performed with minimal morbidity. The overall effectiveness of isolated palate implants for OSA is limited, but selected patients may benefit from pillar procedure with a high success rate. However, there is a need for more studies including a large series of patients. It is our current practice to require a sleep study to rule out severe OSA prior to pillar implantation.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Hacettepe University Faculty of Medicine (2009/LUT 09-218).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - O.K., Ö.G; Design - O.K., T.S.; Supervision - O.Ö., M.D.B.; Funding - Ö.G., T.S.; Materials - O.K., M.D.B.; Data Collection and/or Processing - Ö.Ö., O.K.; Analysis and/or Interpretation - T.S., Ö.G.; Literature Review - O.K., Ö.G.; Writing - O.K., T.S.; Critical Review - O.Ö., M.D.B.; Other - O.K., Ö.G.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study has received no financial support.

Etik Komite Onayı: Bu çalışma için etik komite onayı Hacettepe Üniversitesi Tıp Fakültesi'nden alınmıştır (2009/LUT 09-218).

Hasta Onamı: Yazılı hasta onamı bu çalışmaya katılan hastalardan alınmıştır.

Hakem Değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Fikir - O.K., Ö.G.; Tasarım - O.K., T.S.; Denetleme - O.Ö., M.D.B.; Kaynaklar - Ö.G., T.S.; Malzemeler - O.K., M.D.B.; Veri Toplanması ve/veya İşlemesi - O.Ö., O.K.; Analiz ve/veya Yorum - T.S., Ö.G.X.; Literatür Taraması - O.K., Ö.G.; Yazıyı Yazan - O.K., T.S.; Eleştirel İnceleme - O.Ö., M.D.B.; Diğer - O.K., Ö.G.

Çıkar Çatışması: Yazarlar çıkar çatışması bildirmemişlerdir.

Finansal Destek: Yazarlar bu çalışma için finansal destek almadıklarını beyan etmişlerdir.

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