Kulak Burun Bogaz Ihtis Derg 2016;26(5):258-264 doi: 10.5606/kbbihtisas.2016.28924

Original Article / Çalışma - Araştırma

Long-term results of pillar implant procedure

Pillar implant işleminin uzun dönem sonuçları

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ABSTRACT

Objectives: This study aims to investigate the long-term efficiency and reliability of the Pillar Implant (PI) procedure.

Patients and Methods: Between January 2008 and January 2010, a total of 27 patients (16 males, 11 females; mean age 45.8±7.2 years; range 31 to 58 years) who were diagnosed with low obstructive sleep apnea syndrome and simple snoring underwent the PI procedure in this retrospective, nonrandomized study. The patients were evaluated preoperatively with visual analog scale (VAS) scores in terms of snoring, dysphagia, mouth dryness, foreign body sensation, and pain at the first month, third month, and sixth year intervals.

Results: Based on the snoring scale, VAS scores were statistically significantly lower in the first month, third month and sixth year compared to preoperative scores (p=0.001, p=0.008, p=0.017, respectively). There was no pain in any patients beyond the third day. The VAS score averages in all evaluations were higher by statistical significance relative to the preoperative averages (p=0.018, p=0.027, p=0.025, respectively). Mouth dryness was encountered in seven patients. It persisted in seven patients at the third month and in five patients at the sixth year interval. The VAS score averages were statistically significantly higher in all evaluations compared to the preoperative scores (p=0.017, p=0.018, p=0.042, respectively).

Conclusion: Pillar implant is an efficient, reliable method in the long-term; however, it should be considered that it could cause complaints such as dysphagia, foreign body sensation, and mouth dryness.

Keywords: Obstructive sleep apnea syndrome; pillar implant; snoring.

ÖZ

Amaç: Bu çalışmada pillar implant (Pİ) işleminin uzun dönem etkinlik ve güvenilirliği araştırıldı.

Hastalar ve Yöntemler: Bu nonrandomize retrospektif çalışmada Ocak 2008 - Ocak 2010 tarihleri arasında düşük obstrüktif uyku apne sendromu ve basit horlama tanısı konan toplam 27 hastaya (16 erkek, 11 kadın; ort. yaş 45.8±7.2 yıl; dağılım 31-58 yıl) Pİ işlemi uygulandı. Ameliyat öncesi hastaların görsel analog ölçeği (GAÖ) değerleri horlama, yutma güçlüğü, ağız kuruluğu, yabancı cisim hissi ve ağrı açısından, ilk ay, üçüncü ay ve altıncı yılda değerlendirildi.

Bulgular: Horlama skalasına göre GAÖ değerleri, ameliyat öncesi değerler ile karşılaştırıldığında ilk ay, üçüncü ay ve altıncı yılda istatistiksel olarak anlamlı derecede düşük bulundu (sırasıyla, p=0.001, p=0.008, p=0.017). Üçüncü gün sonrasında hiçbir hastada ağrı yoktu. Tüm değerlendirmelerde GAÖ değer ortalamaları ameliyat öncesi ortalamalara göre istatistiksel anlamlı olarak yüksekti (sırasıyla, p=0.018, p=0.027, p=0.025). Ağız kuruluğu ile yedi hastada karşılaşıldı. Bu durum yedi hastada üçüncü ayda ve beş hastada altıncı yıl aralığında devam etti. Tüm değerlendirmelerde GAÖ değer ortalamaları ameliyat öncesi değerleri ile karşılaştırıldığında istatistiksel anlamlı olarak yüksek bulundu (sırasıyla p=0.017, p=0.018, p=0.042).

Sonuç: Pillar implant uzun dönemde etkin, güvenilir bir yöntemdir; ancak disfaji, yabancı cisim hissi ve ağız kuruluğu gibi yakınmalara neden olabileceği dikkate alınmalıdır.

Anahtar Sözcükler: Obstrüktif uyku apne sendromu; pillar implant; horlama.

Available online at
www.kbbihtisas.org
doi: 10.5606/kbbihtisas.2016.28924
QR (Quick Response) Code

Received / *Geliş tarihi:* April 10, 2016 Accepted / *Kabul tarihi:* July 30, 2016

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Snoring and obstructive sleep apnea syndrome (OSAS) include pathologies ranging from partial to complete airway obstruction. Airway collapse can be at the level of the uvula, tonsils, tonsillar pillars, tongue base, pharyngeal muscles, and pharyngeal mucosa. Vibration, however, most frequently occurs at the level of the soft palate.[1] For that reason, the key strategy for preventing snoring is to prevent vibration of the soft palate. Surgeries at the soft palate level can include those that decrease tissue volume, harden the tissue through fibrosis, or both.

The palatal pillar implant (PI) system (Medtronic, Jacksonville, Florida, USA) was introduced as a treatment for snoring in 2003. It is designed to work by stiffening the soft palate. The system is easy to implant under local anesthesia in an office environment. Submucosal thickening is achieved by creating fibrotic capsules around the implants in the soft palate. Its aim is to decrease snoring and vibration of the soft palate. This procedure is irreversible.[2-4]

In recent years, through the popularization of minimally invasive attempts that do not require hospitalization, the popularity of soft palate surgeries for hardening the tissue have increased. Pillar implant, as well, is a new method that has been used since 2003, but the number of studies proving its long-term effects and revealing its side-effect profile are limited. Therefore, in this study, we aimed to investigate the reliability and six-year follow-up results of the PI procedure.

PATIENTS AND METHODS

This nonrandomize clinical study was approved by Istanbul Education and Research Hospital Ethics Committee. Twenty-seven patients (16 males, 11 females; mean age 45.8±7.2 years; range 31 to 58 years) were enrolled in this study. All patients underwent otorhinolaryngology examination, including flexible endoscopy, and Muller's maneuver was also performed. The criteria for inclusion in the study are presented in Table 1. The patients who had complaints of mouth dryness, foreign body sensation, and throat pain and who underwent additional procedures during this period were excluded from the study.

Informed consent was obtained from all patients. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Nocturnal polysomnography was performed before the treatment and 90 days after the operation in order to determine the postoperative apnea-hypopnea index (AHI).

Pillar implant system procedure

All procedures were performed by the same surgeon. After application of topical lidocaine spray, a local anesthetic mixture (1% lidocaine and 1:100,000 adrenaline) was administered. After achieving an adequate view using a tongue depressor, the mucosa was perforated at three different points: 5 mm distal from the edge of the hard palate at the mid-line, and 1 cm from two lateral positions. The cannula was pushed towards the uvula root. After reaching the appropriate position, the implant was placed. After keeping the patients under care for two hours, they were discharged from the hospital, provided they had no complications. They were given permission to begin oral intake, including liquid food, three hours later. After six hours, a normal diet could be started. In case of pain, it was suggested to take 500 mg acetaminophen orally.

Patient follow-up

Gender, age, body masss index (BMI), and AHI of all patients included in the study were recorded. The patients were followed up at the first and third months postoperatively. In order to provide them with long-term follow-up, the patients determined to be appropriate for the study criteria were called in the sixth year, and they and their bed-partners were invited in order to evaluate their progress. Otorhinolaryngology examination was performed on them, and findings and complications in the treated location were noted. A visual analog scale (VAS) (0: absent, 10: very severe) and the Epwort sleepiness scale (EES) were evaluated for snoring, dysphagia, mouth dryness, and foreign body sensation in the throat. Their BMI values were also noted. Moreover, snoring answers given by

Table 1. Criteria to be included into the study

Being over 18 years old
BMI <30
AHI <15
Tonsil length's closing less than 50% of airway
Nasal passage's being open
Implant's staying for more than one year
Being together with the same bed-partner for six years

the bed-partners (0: absent, 10: severe snoring at a level requiring the partner to leave the room) were evaluated.

Statistical analysis

Statistical analysis was performed using SPSS for Windows version 15.0 (SPSS Inc., Chicago, IL, USA). The descriptive statistics were presented as number and percentage for the categorical variables, and average and standard deviation for the numerical variables. The paired t-test was performed when the variables satisfied the condition of normal distribution in two dependent group comparisons, and the Wilcoxon

Table 2. Findings

	n	%	Mean±SD	Median	*p*
Gender					
Male	16	59.3			
Female	11	40.7			
Age (year)			45.78±7.22	47	
Snoring					
Preoperative			7.33±2.34	7	
1st month			5.48±3.36	6*	
3rd month			5.81±3.29	6*	
6th year			6.00±2.96	6*	
Epworth sleepiness scale					
Preoperative			5.52±4.07	6	
1st month			4.93±3.92	5	
3rd month			4.89±4.00	4	
6th year			3.67±3.89	3*	
Apnea-hypopnea index					
Preoperative			6.17±4.20	5.9	
3rd month			5.59±4.14	5.4	
p					0.548
Body mass index					
Preoperative			26.21±2.62	25.4	
3rd month			26.35±2.56	25.8*	
6th year			27.62±3.12	26.6*	
Pain					
Preoperative			0.00±0.00	0	
1st month			0.00±0.00	0	
3rd month			0.00±0.00	0	
6th year			0.00±0.00	0	
Dysphagia					
Preoperative			0.00±0.00	0	
1st month			0.67±1.90	0	
3rd month			0.26±1.35	0	
6th year			0.08±0.39	0	
Foreign body sensation					
Preoperative			0.00±0.00	0	
1st month			0.78±1.55	0	
3rd month			0.67±1.49	0	
6th year			0.37±0.79	0	
Mouth dryness					
Preoperative			0.00±0.00	0	
1st month			1.41±2.66	0*	
3rd month			1.26±2.40	0*	
6th year			0.78±1.74	0*	

SD: Standard deviation; * Different from pre-operation.

test was performed when the condition was not met. Dependent rate comparisons of categorical variables were interpreted with the McNemar test. The statistical alpha significance rate was accepted as $p<0.05$.

RESULTS

All data are summarized in Table 2. The snoring VAS score average of the patients before the PI procedure was 7.33±2.34. All evaluations as of the first month postoperative were low and statistically significant (p=0.001, p=0.008, p=0.017, respectively) (Figure 1).

The ESS preoperative average was 5.52±4.07. There were no statistically significant differences between the preoperative averages and the postoperative averages at the first month, third month, and sixth year intervals (p=0.073, p=0.159, p=0.062, respectively).

The preoperative AHI average was 6.17±4.20. By the third month of evaluation, there was no statistically significant difference (p=0.548).

The preoperative BMI average of the patients was 26.21±2.62. Body mass index averages at the third month and sixth year intervals were higher, at a statistically significant level, compared to the preoperative averages BMI (p=0.019, p=0.001, respectively).

The patients had no preoperative dysphagia, foreign body sensation, mouth dryness, or pain.

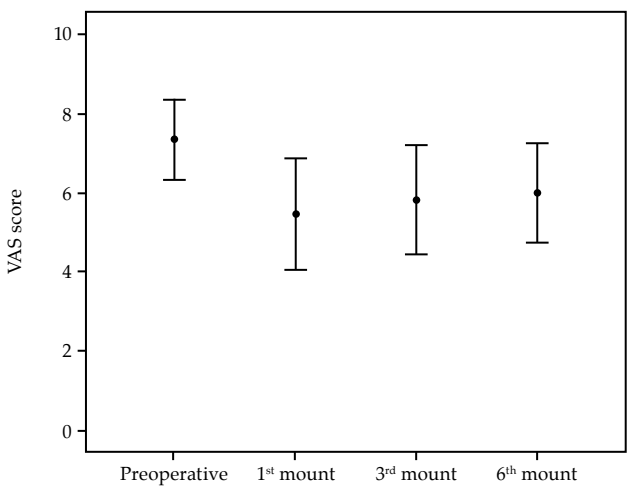

Figure 1. *Snoring scoring can cause minor side effects such as mouth dryness, dysphagia, and foreign body sensation.* *VAS: Visual analog scale.*

The average of the VAS performed postoperatively for pain was 4.9, 3.1, and 1.8, respectively, for the first, second, and third days. No patient described pain after the third day. On the first day, 27 patients, and on the second day, five patients, felt the need for analgesia. In all cases, pain was relieved with 500 mg acetaminophen. By the third day, no patients required analgesia. Dysphagia was encountered postoperatively in four patients (14.8%). It continued in one patient at the third month and sixth year intervals. The rate for postoperative dysphagia was not statistically significantly different (p=0.125). In the postoperative dysphagia VAS averages, no statistically significant change was found (p=0.063).

Postoperative foreign body sensation was encountered in seven patients (25.9%). It persisted in seven patients (25.9%) in the third month and in five patients (18.5%) at the sixth year interval. The rate for postoperative foreign body sensation was higher and statistically significant (p=0.016). The level in the sixth year was not statistically significant (p=0.063). The VAS score averages in all evaluations were higher and statistically significant postoperatively compared to the preoperative averages (p=0.018, p=0.027, p=0.025, respectively).

Mouth dryness was encountered postoperatively in seven patients (25.9%). It persisted in seven patients (25.9%) at the third month and in five patients (18.5%) at the sixth year interval. The rate for postoperative mouth dryness was higher and statistically significant (p=0.016). The level in the sixth year was not statistically significant (p=0.063). The VAS score averages in all evaluations were higher and statistically significant postoperatively compared to the preoperative averages (p=0.017, p=0.018, p=0.042, respectively) (Figure 2).

DISCUSSION

Snoring, vibration in the soft palate, and collapse of the upper airways have been determined to be the most common pathologies. Surgical treatment methods have been developed to decrease the vibration in this region.[1] Although uvulopalatopharyngoplasty (UPPP) has been the most frequently used surgical method, tissue stiffening surgeries have become more popular because they cause less morbidity and provide more patient comfort. Radiofrequency ablation

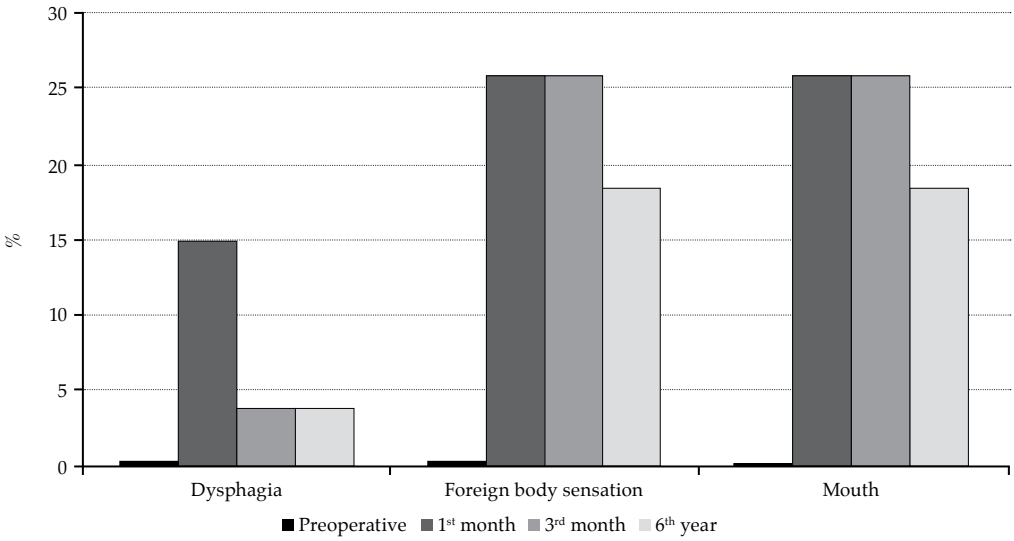

Figure 2. *Scoring of dysphagia, feeling of foreign body, mouth dryness.*

and the PI procedure developed for snoring in 2003 are the foremost of these methods. Because radiofrequency is a frequently preferred older method, many studies have been carried out upon it and its side effects and long-term results are well-established. The efficiency of PI has been described in studies reporting short-term follow-ups.[5-9] However, the number of studies investigating the reliability and long-term results is limited. Neruntarat[10] followed-up their patients for 26 and 32 months. Three-year follow-up was carried out by Skj Stad and Nordg[11] and four-year follow-up was carried out by Rotenberg and Luu[12] these are the studies that include the longest term follow-ups. In both studies, they encountered no patients with major complications, and they did not report any complaints that would qualify as minor complications. In the present study, no major complications were encountered in the patients in the sixth year follow-up; however, we noticed some minor complications such as dysphagia, mouth dryness, and foreign body sensation in some of the patients. The rate for foreign body sensation and mouth dryness in the first three months was statistically significant. In the sixth year, it continued in some of our patients although the prevalence was not statistically significant.

Pillar implant is a system placed on the soft palate from three different areas that creates fibrosis due to a foreign body reaction. Rotenberg et al.[13] followed-up patients for 52 weeks, and reported a decrease in the snoring score later when compared with the first three weeks. In another study, Rotenberg and Luu[12] proved that there was alleviation in snoring in 23 patients compared to the reoperation subjects in 52-week and four-year follow-up period; there was also, however, deterioration when 52-week and four-year follow-ups were compared. They found the average snoring VAS scores to be 9.5 preoperatively, 5.0 in the 52-week follow-up, and 7.0 in the four-year follow-up. They found no change in BMI. In this study, whereas there was a significant decrease in snoring scores when compared with the preoperative scores, there was no statistically significant difference between the first month, third month and sixth year intervals. The preoperative VAS score average was 7.33±2.34, the VAS score in the first month was 5.48±3.36, the VAS score in the third month was 5.81±3.29, and the VAS score in the sixth year was 6.00±2.96. Whereas there was no change in BMI at the third month interval, it significantly increased at the sixth year point (26.21±2.62 preoperatively, 26.35±2.56 in the third month, and 27.62±3.12 in the sixth year). There is no specific information or studies related to the emergence of the implant's efficiency and occurrence of fibrosis. In our study, no progress in snoring scores was noticed after the first month. We did not observe any decrease in long-term efficiency. The increase in

BMI was associated with not suggesting diet or exercise to the patients and long-term follow-up.

Nordgård et al.[4] followed up 35 patients to whom they administered PI for one year. Their patients had pain complaints that required using 50 mg diclofenac for an average of 1.3 days, while 24% of their patients had no need for the use of painkillers. In this study, patients were advised to take 500 mg acetaminophen if needed; all patients took one dose for the first day, and five patients took them for the second day. There were no patients who needed painkillers after the third day.

In another study, Neruntarat[10] followed up his 92 patients for 36 months. This study was undertaken on OSA patients. BMI, AHI, and MMP level was significantly lower preoperative than postoperative. In this study there was no side effect in long-term follow-up.

Rombaux et al.[14] compared UPP, laser-assisted uvulopalatoplasty (LAUP) and radiofrequency implementation in terms of side effect profile. In the study, they reported that two out of 17 patients who underwent UPP experienced mouth dryness, four had globus sensation, and two had a change in voice. Fifteen patients who underwent LAUP experienced no mouth dryness, two had globus sensation, and two had a change in voice; none of the 17 radiofrequency patients had mouth dryness, one had globus sensation, and one had a change in voice. Because PI implementation is a treatment to the soft palate, like other surgical techniques, it is possible to have dysphagia, foreign body sensation, and mouth dryness, depending upon the fibrosis on the soft palate following this procedure. Nordgård et al.,[3] reported a metallic taste complaint in two patients, but they had no patients with dysphagia or speech disorder. Akpinar et al.[15] performed acoustic voice analysis preoperatively on 23 patients who underwent PI and on the eighth day postoperative. They reported changes in some parameters and disorders in articulation. In the present study, dysphagia was encountered in four patients (14.8%) postoperatively. It persisted in one patient at the third month and sixth year. Postoperative foreign body sensation was encountered in seven patients (25.9%). It persisted in seven patients (25.9%) at the third month and in five patients (18.5%) at the sixth year interval. Mouth dryness was encountered postoperatively in seven patients (25.9%). It persisted in seven patients (25.9%) at the third month and in five patients (18.5%) at the sixth year interval. Although the prevalence for foreign body sensation and mouth dryness was statistically significant until the third month in the study, it was not statistically significant at the sixth year; there were, however, patients with ongoing complaints. We proved that although there was no increase in long-term efficiency, there were additional concerns in the side effect profile. Because these side effects were subjective complaints, not using a placebo-controlled group is the weakness of this study.

In their placebo-controlled, randomized study, Maurer et al.[16] revealed that PI was more efficient than placebo on 90-day follow-up. Friedman et al.[17] performed PI on 31 patients and placebo on 31 patients, noticing more significant recovery in the study group compared to the placebo group. In both studies, no minor side effects were mentioned. The outcomes in our study could be a result of the effect of placebo. Without a controlled study, however, the placebo effect cannot be excluded.

In another study, Skjostad and Nordg[11] defined success in their study as needing no additional procedures and bed-partners being satisfied with the procedure. Our two patients had no change in their snoring scores, and they were not satisfied with the procedure. They also did not accept implementing another procedure. In our study, because the patients with extrusion within a year and the ones administered with additional procedures were excluded, it is not appropriate to present the success rate for PI. Nevertheless, we conclude that it is an efficient and effective method for long-term snoring in patients having the PI for more than a year.

In conclusion, PI is an effective and efficient treatment modality for snoring over long-term follow-up, and is easy to implement without causing major complications.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The authors received no financial support for the research and/or authorship of this article.

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