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STUDYING THE SUTURE PATCH DEVICE VIA TONGUE FOR SLEEP APNEA WITH FLUID STRUCTURE INTERACTION MODELING

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ABSTRACT

Background: Sleep-related breathing disorders are highly prevalent globally including in India which has led to the development of various devices to manage sleep apnea. These devices are widely used and are extensively studied by various authors. However, the data is scarce in the literature with no definitive conclusion.

Aim: The present study aimed to assess the accuracy of suture patch devices used via tongue to adjustable oral devices for managing obstructive sleep apnea.

Methods: The retrospective study assessed subjects with sleep apnea using either oral appliances or suture patch devices via the tongue. Before and during the therapy, polysomnography was conducted. The treatment was considered effective when AHI (apnea-hypopnea index) <5 events/hour or <10 events/hour with a resolution of sleepiness (Epworth <10). The efficacy rates were compared for removable oral appliances and suture devices via tongue to identify factors responsible for success.

Results: The study assessed 402 subjects managed with removable oral appliances and 101 subjects using suture devices via the tongue. The mean AHI was 30.5±25.4. Mild, moderate, and severe OSA was seen in 34%, 29%, and 37% of study subjects respectively. OSA was reduced to <10 and <5/h in 47% of subjects with a suture patch device via tongue and 57% of subjects with adjustable oral appliances which was significantly higher with adjustable oral appliances with p=0.02. A similar statistically significant improvement in sleepiness with <10 was seen in 66% of subjects with adjustable appliances (p<0.01). Higher success was seen in subjects with less severe disease, low BMI, and young subjects.

Conclusion: A suture patch device used via tongue for sleep apnea results in a lesser decrease in obstructive sleep apnea events compared to adjustable oral devices. However, a higher success is seen with suture patch devices in mild disease with less success in moderate to severe OSA and high AHI. Hence, appliance type should be selected based on AHI at baseline.

Keywords: AHI, OSA, adjustable oral appliances, sleep apnea, suture patch device

INTRODUCTION

Obstructive Sleep apnea (OSA) is a significant public health problem affecting a large population globally including India. It is associated with impaired cognitive functions and sleepiness leading to various negative consequences including impaired work efficacy, increased morbidity rates, and accidents. OSA is managed with both fixed and removable oral appliances that are custom-made and fabricated individually from the impression of the dentition.[1]

Adjustable oral appliances are titrated using a screw or similar mechanism for optimization of therapeutic efficacy. On insertion, subjects are advised for incremental advancement to find optimal position improving obstructive events and sleep continuity along with a reduction in snoring. Polysomnogram is repeated to assure the adequate ablation of obstructive respiratory events. Adjustable oral devices need adjustments with skilled care providers and are expensive. They also require longer fabrication time and incremental titration for facilitation of tolerance delaying effective management.[2]

Another fixed device used for OSA management is a suture patch device that aims to exert force on the tongue base via suture and patch. The suture goes to fat under the tongue from the epidermis via digastric muscle and from the middle of the tongue causing less discomfort while pulling. The patch can be pasted on the tongue surface or is suction worn to hold the tongue. The patch facilitates even force application on the tongue reducing the penetration. Patch diameter is usually 1-1.5 cm depending on tongue shape and upper airway size. It has a mechanically operated spring screwed to the mandible to control the pulling force. The suture used is non-dissolvable. The patch is soft and light to allow talking and swallowing and should move with the tongue. The material of the plate is vital where titanium is being used owing to being biocompatible.[3]

Despite the effective use of suture patch devices via tongue, literature data are scarce in the literature on the comparison of suture patch devices to the adjustable oral appliances used for the management of OSA. The data available either had a smaller sample size or did not consider polysomnography. Fixed appliances have shown decreased events. However, their role in decreasing AHI is not validated.[4] Hence, the present study aimed to assess the accuracy of suture patch devices used via tongue to adjustable oral devices for managing obstructive sleep apnea.

MATERIALS AND METHODS

The present retrospective clinical study aimed to assess the accuracy of suture patch devices used via tongue to adjustable oral devices for managing obstructive sleep apnea. The study was done Department of ENT, after the clearance was taken from the concerned institutional Ethical committee. The study considered subjects that reported to the Outpatient department of the Institute with sleep apnea confirmed by polysomnogram.

The records for the present study were extracted from the sleep disorder center of the institute. The diagnosis for OSA was made based on the clinical symptomatology and polysomnogram (level I) following the criteria by AASM.[5] All the subjects advised for the oral appliances were educated thoroughly about the devices and ill-effects of OSA, proper use of the device, device

care, and need of the device. Multiple clinical evaluations were done after therapy initiation to get an optimized response. On therapy, a level I polysomnography was repeated to ensure proper OSA management.

The subjects were given treatment options including a suture patch device, adjustable appliances, CPAP, and surgery. The subjects were allowed to select the appropriate therapy with oral appliances being primarily used unless contraindicated.

All the oral appliances were individually fabricated and were custom-made using semi-rigid thermoplastic material and no prefabricated device was used. All subjects were assessed for eligibility by a dentist with expertise in the field. The exclusion criteria were subjects with TMJ (temporomandibular joint) disease, mandibular injuries, active dental diseases, edentulous subjects, intolerant subjects, and craniofacial abnormalities. Any active sinus disease was treated and subjects were checked for mandibular extension without discomfort or pain.

In 101 study subjects, a suture device was used where the suture was placed to fat under the tongue from the epidermis via digastric muscle and from the middle of the tongue causing less discomfort while pulling where a hollow tissue is encountered. The patch was either pasted in the tongue surface or was suction worn to hold the tongue. The patch diameter used was 1-1.5 cm depending on tongue shape and upper airway size. It had a mechanically operated spring screwed to the mandible to control the pulling force. The suture used was a non-dissolvable suture. The patch used was soft and light to allow talking and swallowing and should move with the tongue. A titanium plate was used.

In 402 study subjects with OSA adjustable oral devices were given which were fabricated using maxillary and mandibular impressions using TAP II devices (Thornton Adjustable Positioner). After fabrication and modification, the at-home protocol was applied. The device was set at the normal bite of the subjects with no mandibular advancement. 1 turn or 0.5 mm advancement was advised for each night as tolerated after a comfortable sleep-keeping device at the place. In case of discomfort, 2 turn regression was done and the pace is slowed.

All the subjects were asked to maintain a sleep diary recording apneas, snoring, and sleep continuity along with daytime somnolence. During titration, the device was advanced incrementally to minimize obstructive respiratory events and snoring. Titration polysomnograms were done. During polysomnograms, in the supine position, in response to hypopneas or apneas, the subject was awakened and the device was advanced by a turn with a maximum of 3 turns. No advancement was done in cases of discomfort.

The data gathered for each study subject was anthropometric and demographic data including Mallampati scores, micrognathia, retrognathia, BMI (body mass index), gender, and age. ESS (Epworth Sleepiness Scale) was used to assess the subject's somnolence before and after treatment.[6] Polysomnographic data were assessed at baseline AHI and AHI at prescribed mandibular advancement. The severity of OSA was assessed during polysomnography to mild, moderate, and severe disease considered at 5-14.9, 15-29.9, and ≥30 events per hour respectively. The study assessed the degree of successful OSA treatment. Successful treatment was considered for <5 events/h of AHI. Oral appliance failure was considered with incomplete

obstructive event resolution or device intolerance. The secondary study endpoint was reduced AHI to <10 events/hour or sleepiness resolution with ESS (<10).

The data gathered were analyzed statistically using SPSS software version 17.0 (SPSS Inc, Chicago, IL) with t-test and Fisher exact test. The data were expressed as mean and standard deviations. The level of significance was taken at $p<0.05$.

RESULTS

The present retrospective clinical study aimed to assess the accuracy of suture patch devices used via tongue to adjustable oral devices for managing obstructive sleep apnea. In 101 study subjects, a suture device was used via tongue, whereas, in 402 subjects adjustable oral appliances were used. The mean age of the study subjects with an adjustable oral appliance and suture patch device was 41.1±8.8 years and 42.7±9.4 years respectively which showed a non-significant difference with p=0.07. All other demographic parameters also showed a non-significant difference in the adjustable oral appliance and suture patch device group with respective p-values of 0.87, 0.08, 0.18, 0.16, 0.57, 0.13, 0.26, 0.84, and 0.26 for male gender, ESS, BMI, mild OSA, moderate OSA, severe OSA, Sleep time % at spO2 <90%, AHI (events/hour), and Mallampati scores as shown in Table 1.

On assessing the efficacy of the adjustable device and suture patch device in treating OSA, it was seen that AHI and ESS <10 were seen in 66.2% (n=266) study subjects with an adjustable oral appliance and in 44.5% (n=45) subjects. The difference was statistically significant with $p<0.01$. A similar higher percentage was seen for AHI <10 events per hour and AHI <5 events per hour in subjects with adjustable oral appliances with p=0.01 and 0.03 respectively. The mean AHI in subjects on therapy was significantly higher in subjects with suture patch devices with 10.2±12.2 and $p<0.01$. However, a non-significant difference was seen in oral appliance intolerance, ESS on therapy, Sleep time % at spO2 <90%, and AHI reduction percentage among subjects using an adjustable oral appliance or suture patch device with respective p-values of 0.44, 0.13, 0.24, and 0.07 as depicted in Table 2.

Concerning the successful therapy rates with an adjustable device and suture patch device in treating OSA, higher success rates were seen for all AHI, baseline AHI <45 events/hour, and baseline AHI <30 events/hour with respective p-values of 0.02, 0.04, and 0.01 respectively. However, non-significantly higher success rates were seen for adjustable oral appliances with p=0.15 (Table 3).

The success of therapy in various severity of OSA using adjustable oral appliances or suture patch devices, in mild OSA, AHI, and ESS <10 was seen in subjects on adjustable oral appliances in 81.4% subjects compared to 61.5% of subjects using suture patch devices with $p<0.01$. A non-significant difference was seen for Mean AHI reduction, AHI on adjustable appliance <10, AHI on adjustable appliance <5, AHI on the adjustable appliance, ESS on therapy, baseline ESS, and baseline AHI with respective p-values of 0.13, 0.66, 0.15, 0.63, 0.06, 0.66, 0.08. In moderate OSA, a significantly higher proportion of subjects on adjustable oral appliances had AHI and ESS <10 with 63.9% of subjects compared to 41.7% of subjects on suture patch devices with 41.7% subjects (p=0.02). AHI and ESS <10 was seen in 53.7% and

33.7% using adjustable oral appliances and suture patch device respectively with p=<0.01. Mean AHI was higher with suture patch devices than with adjustable appliances (p=0.01). A nonsignificant difference was seen for Mean AHI reduction, AHI on adjustable appliance <10, AHI on adjustable appliance <5, ESS on therapy, baseline ESS, and baseline AHI with respective p-values of 0.09, 0.12, 0.05, 0.16, 0.42, and 0.14 (Table 4).

In subjects having severe OSA, AHI, and ESS <10 were seen in 53.7% of subjects on adjustable oral appliances and 33.7% of subjects using suture patch devices with p<0.01. However, a non-significant difference among the adjustable device and suture patch device was seen concerning Mean AHI reduction, AHI on the adjustable appliance <10, AHI on the adjustable appliance <5, AHI on the adjustable appliance, ESS on therapy, baseline ESS, and baseline AHI with p=0.08, 0.05, 0.33, 0.24, 0.17, 0.22, and 0.52 respectively (Table 4).

DISCUSSION

In 101 study subjects, a suture patch device was used via tongue, whereas, in 402 subjects adjustable oral appliances were used. The mean age of the study subjects with an adjustable oral appliance and suture patch device was 41.1±8.8 years and 42.7±9.4 years respectively which showed a non-significant difference with p=0.07. All other demographic parameters also showed a non-significant difference in the adjustable oral appliance and suture patch device group with respective p-values of 0.87, 0.08, 0.18, 0.16, 0.57, 0.13, 0.26, 0.84, and 0.26 for male gender, ESS, BMI, mild OSA, moderate OSA, severe OSA, Sleep time % at spO2 <90%, AHI (events/hour), and Mallampati scores. These data aligned with the studies of Lam B et al[7] in 2007 and Lim J et al[8] in 2006 where authors assessed subjects with demographics comparable to the present study.

It was seen that the efficacy of the adjustable device and suture patch device in treating OSA, it was seen that AHI, and ESS <10 were seen in 66.2% (n=266) study subjects with an adjustable oral appliance and 44.5% (n=45) subjects. The difference was statistically significant with p<0.01. A similar higher percentage was seen for AHI <10 events per hour and AHI <5 events per hour in subjects with adjustable oral appliances with p=0.01 and 0.03 respectively. The mean AHI in subjects on therapy was significantly higher in subjects with suture patch devices with 10.2±12.2 and p<0.01. However, a non-significant difference was seen in oral appliance intolerance, ESS on therapy, Sleep time % at spO2 <90%, and AHI reduction percentage among subjects using an adjustable oral appliance or suture patch device with respective p-values of 0.44, 0.13, 0.24, and 0.07. These results were consistent with the previous studies of Deana SA et al[9] in 2009 and Venderveken OM et al[10] in 2007 where authors reported lower AHI and ESS in subjects using oral adjustable appliances for OSA management.

The study results showed that concerning the successful therapy rates with an adjustable device and suture patch device in treating OSA, higher success rates were seen for all AHI, baseline AHI <45 events/hour, and baseline AHI <30 events/hour with respective p-values of 0.02, 0.04, and 0.01 respectively. However, non-significantly higher success rates were seen for adjustable oral appliances with p=0.15. These findings were in agreement with the findings of Maurer JT et

al[11] in 2007 and Barthlen GM et al[12] in 2000 where authors suggested favorable results for AHI and related events in OSA subjects on removable oral appliance therapy.

On assessing the success of therapy in various severity of OSA using adjustable oral appliances or suture patch devices, in mild OSA, AHI, and ESS <10 was seen in subjects on adjustable oral appliances in 81.4% of subjects compared to 61.5% of subjects using suture patch device with p<0.01. A non-significant difference was seen for Mean AHI reduction, AHI on adjustable appliance <10, AHI on adjustable appliance <5, AHI on the adjustable appliance, ESS on therapy, baseline ESS, and baseline AHI with respective p-values of 0.13, 0.66, 0.15, 0.63, 0.06, 0.66, 0.08. In moderate OSA, a significantly higher proportion of subjects on adjustable oral appliances had AHI and ESS <10 with 63.9% of subjects compared to 41.7% of subjects on suture patch devices with 41.7% subjects (p=0.02). AHI and ESS <10 was seen in 53.7% and 33.7% using adjustable oral appliances and suture patch device respectively with p=<0.01. Mean AHI was higher with suture patch devices than with adjustable appliances (p=0.01). A non-significant difference was seen for Mean AHI reduction, AHI on adjustable appliance <10, AHI on adjustable appliance <5, ESS on therapy, baseline ESS, and baseline AHI with respective p-values of 0.09, 0.12, 0.05, 0.16, 0.42, and 0.14. These results were comparable to the results of Almeida FR et al[13] in 2009 and Krishnan V et al[14] in 2008 where authors reported successful management of OSA using the removal of oral appliances as seen in the present study.

It was seen that in subjects having severe OSA, AHI, and, ESS <10 were seen in 53.7% of subjects on adjustable oral appliances and 33.7% of subjects using suture patch device p<0.01. However, a non-significant difference among the adjusted stable device and suture patch device was seen concerning Mean AHI reduction, AHI on the adjustable appliance <10, AHI on the adjustable appliance <5, AHI on the adjustable appliance, ESS on therapy, baseline ESS, and baseline AHI with p=0.08, 0.05, 0.33, 0.24, 0.17, 0.22, and 0.52 respectively. These findings were consistent with the findings of Kato J et al[15] in 2000 and Sadatsafavi M et al[16] in 2009 where authors reported similar results on oral appliances in subjects with severe OSA as in the present study.

CONCLUSION

Within its limitations, the present study concludes that a Suture-patch device used via tongue for sleep apnea results in a lesser decrease in obstructive sleep apnea events compared to adjustable oral devices. However, a higher success is seen with suture patch devices in mild disease with less success in moderate to severe OSA and high AHI. Hence, appliance type should be selected based on AHI at baseline.

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TABLES

Characteristics	**Adjustable device**	**Suture patch device**	**p-value**
Age (years)	41.1±8.8	42.7±9.4	0.07
Male gender (%)	86.2	85.8	0.87
ESS	13.1±5.0	14.1±4.3	0.08

BMI (kg/m2)	28.5±4.2	29.1±4.5	0.18
Mild OSA	30.7	35.3	0.16
Moderate OSA	28.0	30.0	0.57
Severe OSA	40.7	34.5	0.13
Sleep time % at spO2 <90%	5.2±10.2	5.7±12.1	0.26
AHI (events/h)	29.5±24.3	28.9±24.6	0.84
Mallampati	2.7±0.7	2.9±0.7	0.26

Table 1: Demographic data of study subjects with adjustable and suture patch devices at baseline

Parameters	**Adjustable device (n=402)**	**Suture patch device (n=101)**	**p-value**
AHI and ESS <10 (%)	66.2	44.5	**<0.01**
AHI <10 events /h (%)	74.1	63.6	**0.01**
AHI <5 events/h (%)	57.7	46.7	**0.03**
Oral appliance intolerance (%)	15.2	13.1	0.44
ESS on therapy	9.5±4.3	10.4±4.1	0.13
Sleep time % at spO2 <90%	2.6±6.5	4.0±8.7	0.24
AHI reduction (%)	74.2	64.7	0.07
AHI on therapy (events/h)	7.4±9.5	10.2±12.2	**<0.01**

Table 2: Efficacy of adjustable device and suture patch device in treating OSA

Parameter	**Adjustable device**	**Suture patch device**	**p-value**
All AHI	57.7	46.7	**0.02**
Baseline AHI <45 events/h	64.7	53.5	**0.04**
Baseline AHI <30 events/h	63.7	52.1	**0.01**
Baseline AHI <15 events/h	73.2	63.6	0.15

Table 3: Successful therapy rates with adjustable device and suture patch device in treating OSA

Parameters	**Adjustable device**	**Suture patch device**	**p-value**
Mild			
Mean AHI reduction	5.1±5.4	3.6±7.1	0.13
AHI and ESS <10	81.4	61.5	**<0.01**
AHI on adjustable appliance <10	86.3	82.9	066
AHI on adjustable appliance <5	73.2	63.6	0.15
AHI on the adjustable appliance	4.2±5.0	4.7±6.6	0.63
ESS on therapy	9.6±3.7	10.6±4.2	0.06
Baseline ESS	14.2±4.2	14.0±5.4	0.66
Baseline AHI	9.4±2.6	8.6±3.0	0.08
Moderate			
Mean AHI reduction	13.7±8.4	11.2±9.1	0.09
AHI and ESS <10 (%)	63.9	41.7	**0.02**
AHI on adjustable appliance <10 (%)	74.1	61.3	0.12
AHI on adjustable appliance <5 (%)	52	34.8	0.05
AHI on the adjustable appliance	7.3±7.9	10.8±10.1	**0.01**
ESS on therapy	8.2±3.8	8.6±5.2	0.16
Baseline ESS	12.9±3.4	13.1±6.0	0.42
Baseline AHI	20.9±4.1	22.1±4.7	0.14
Severe			
Mean AHI reduction	44.2±15.9	39.7±12.4	0.08

AHI and ESS <10	53.7	33.7	**<0.01**
AHI on adjustable appliance <10	59.9	46.7	0.05
AHI on adjustable appliance <5	44.4	37.6	0.33
AHI on the adjustable appliance	12±15.2	14±14.7	0.24
ESS on therapy	9.6±1.6	10±5.2	0.17
Baseline ESS	15.2±6.4	14.7±6.4	0.22
Baseline AHI	56.1±21.3	54.1±22.4	0.52

Table 4: Therapy success comparison in various OSA severity using suture patch device and adjustable oral appliances