

Air Leakage and Adherence to Continuous Positive Airway Pressure Therapy in Patients with Moderate to Severe Obstruction Sleep Apnoea: A Cross Sectional Study

(Kebocoran Udara dan Pematuhan kepada Terapi Berterusan Tekanan Saluran Udara Positif Pesakit dengan Apnea Tidur Halangan Sederhana hingga Teruk: Kajian Keratan Rentas)

NADIA SYAFEERA NASERRUDIN¹, ABDULLAH SANI MOHAMED¹, MAWADDAH AZMAN¹, MAZLINDA MAHADZIR², NORAZMI MOHAMAD³ & MARINA MAT BAKI^{1*}

¹*Department of Otorhinolaryngology, Head and Neck Surgery, Faculty of Medicine, Universiti Kebangsaan Malaysia Medical Centre, 6000 Kuala Lumpur, Federal Territory, Malaysia*

²*Department of Otorhinolaryngology, Head and Neck Surgery, 50586 Hospital Kuala Lumpur, Kuala Lumpur, Federal Territory, Malaysia*

³*Department of Otorhinolaryngology, Head and Neck Surgery, 40000 Hospital Shah Alam, Selangor Darul Ehsan, Malaysia*

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ABSTRACT

This multicentre study aimed to evaluate the air leakage following a palatal surgery and its effect on CPAP adherence in OSA patients. The data on air leakage and adherence were objectively obtained and evaluated from the recorded CPAP therapy data. Forty patients were divided into two groups: surgery (18 patients) and non-surgery (22 patients). The mean air leakage level was $7.62 \pm 8.14\%$ and $12.62 \pm 13.81\%$ and mean adherence was $51.44 \pm 35.27\%$ and $60.03 \pm 27.04\%$ for surgery and non-surgery, respectively. There was no significant difference in CPAP adherence ($p=0.389$) but for mean air leakage it was significantly higher in non-surgery ($p<0.01$). The occurrence of significant air leakage during CPAP therapy was not associated with surgery ($p=0.436$). There was no association between poor CPAP adherence and surgery ($p=0.622$). In terms of impact of palatal surgery, it did not cause significant leakage with no significant association to poor adherence.

Keywords: Adherence; anterior palatoplasty; continuous positive airway pressure therapy; leakage; obstructive sleep apnoea

ABSTRAK

Penyelidikan ini yang melibatkan beberapa institusi bertujuan untuk menilai kebocoran udara selepas pembedahan langit dan kesan ke atas kepatuhan pemakaian CPAP dalam kalangan pesakit OSA. Data kebocoran udara dan kepatuhan didapati dan dinilai secara objektif melalui rekod daripada terapi CPAP. Empat puluh pesakit dibahagikan kepada 2 kumpulan: operasi (18 pesakit) dan non operasi (22 pesakit). Tahap min kebocoran udara adalah $7.62 \pm 8.14\%$ dan $12.62 \pm 13.81\%$ dan min kepatuhan adalah $51.44 \pm 35.27\%$ dan $60.03 \pm 27.04\%$ untuk operasi dan non operasi. Tiada perubahan signifikan di dalam kepatuhan CPAP ($p=0.389$) tetapi untuk min kebocoran udara menunjukkan nilai signifikan yang lebih tinggi untuk non operasi ($p<0.01$). Kejadian untuk signifikan kebocoran udara ketika penggunaan terapi CPAP adalah tiada kaitan dengan operasi ($p=0.436$). Didapati tiada juga kaitan antara kepatuhan pemakaian CPAP yang teruk dan operasi ($p=0.622$). Berkaitan dengan impak pembedahan langit, ia tidak menyebabkan kebocoran signifikan dan juga tiada kaitan signifikan terhadap keterukan kepatuhan.

Kata kunci: Apnea tidur halangan; kebocoran; kepatuhan; palatoplasti anterior; terapi berterusan tekanan saluran udara positif

INTRODUCTION

Obstructive sleep apnoea (OSA) is a type of sleep disorder characterised by recurrent partial or complete

pharyngeal obstruction during sleep (Strollo & Rogers 1997). This results in neurocognitive, cardiovascular, and metabolic disorders (Aurora & Punjabi 2013; Rosenzweig

et al. 2015; Sánchez-de-la-Torre et al. 2013). Therefore, it is crucial to treat OSA patients. CPAP therapy has been the gold standard treatment (Sullivan et al. 1981). However, adherence to CPAP therapy remains an issue due to problems related to mask fit, such as eye irritation, silicone allergies, pressure sores and air leaks (Neuzeret & Morin 2017). Air leakage is experienced by up to 50% of nasal CPAP users (Pépin et al. 1995).

Air leakage can be divided into intentional and unintentional leaks. Intentional leaks are important to allow the exhalation of carbon dioxide. Unintentional air leaks can be caused by leakage from weak mask seal, holes along the tubing and palatal surgery for OSA.

Surgical modality is a treatment option for patients who fail CPAP therapy. Common surgery performed at palatal level include uvulopalatopharyngoplasty (UPPP), cautery assisted palatal stiffening operation (CAPSO), anterior palatoplasty, and their modification. Their aim is to induce fibrosis at soft palate to prevent collapse of the velopharynx during sleep. However, it is common that these patients would still need CPAP when the surgery failed to alleviate the symptoms and cure the OSA. Some studies showed that palatal fibrosis following the surgery may compromise CPAP therapy by increased mouth air leak, leading to poor compliance (Mortimore et al. 1996; Richards et al. 1996), but other studies documented otherwise with improved outcomes (Chandrashekariah et al. 2008; Friedman et al. 2009). Thus, the results in the literature have been contradicting. The present study was performed to compare air leakage between surgery group (those who has underwent anterior palatoplasty with lateral wall release) and non-surgery group and to investigate the association of significant air leakage with the surgery. The study also investigated the effect of the surgery on adherence to CPAP therapy among OSA patients. The hypothesis of this study is anterior palatoplasty would not cause significant air leakage and do not affect the adherence to CPAP therapy.

MATERIALS AND METHODS

ETHICAL CONSIDERATION

Multicentre ethics approval was obtained from the Universiti Kebangsaan Malaysia Medical Centre Ethics Committee (FF-2017-411) and Medical Research and Ethics Committee (MREC) (NMRR-19-612-46902).

STUDY DESIGN AND PARTICIPANTS

We conducted a cross sectional study from 1st September 2017 to 30th July 2019 (23 months) at three tertiary centres

in Malaysia. Based on convenience sampling, the study sample included patients with OSA on CPAP therapy who had or had not undergone anterior palatoplasty with lateral wall release during the period of 1st January 2010 until 31st January 2019. The inclusion criteria were patients designated as moderate to severe OSA, over 18 years old and having been on CPAP therapy for minimum usage of at least 6 months. The recordings of data from both groups were only calculated after the first 3 months of usage of CPAP therapy. This is to avoid any bias due to surgical effect in the surgery group and other issues related to mask fitting and adjustment to CPAP machine. The exclusion criteria were sleep disorders other than OSA and underwent concomitant upper airway surgery other than anterior palatoplasty. They were then divided into surgery and non-surgery groups.

STUDY INSTRUMENTS

The patients' medical records and data were obtained from their SD card in their own auto CPAP therapy machine (37 patients on Lowenstein SOMNObalance e, Germany and 3 patients on Lowenstein Prisma 20a, Germany). All patients were using nasal mask and has no issue with mask fitting. The pressure of autoCPAP mode were set between 4hPa and 16hPa. Parameters that were extracted include percentage of leakage, adherence and AHI. Adherence is defined by Centre of Medicaid and Medicare Services (CMS) rules as use of the CPAP device for at least 4 hours per night for at least 70% of nights during any given consecutive 30-day period (American Medical Association 2010). Unintentional leak of more than 10% is considered as significant leak based on the product information sheet. The AHI levels were grouped as normal (<5), mild (>5-15), moderate (>15-30) or severe (>30) (The Report of an American Academy of Sleep Medicine Task Force 1999). All data recordings were obtained from the therapy data from their CPAP therapy machine, and we do not assess feedback subjectively from patients in terms of their experience with air leakage and adherence to avoid recall bias.

SURGICAL TECHNIQUE OF ANTERIOR PALATOPLASTY WITH LATERAL WALL RELEASE

The anterior palatoplasty that was performed used similar technique in all three centres. It is a modification from Pang and Terries's technique. They described a form of palatoplasty in 2007 consisting of uvulectomy and removal of horizontal strip of mucosa at the soft palate (Pang & Terris 2007).

In the same year, further modification to the surgical technique was done which consisted of tonsillectomy,

expansion sphincter pharyngoplasty, rotation of palatopharyngeus muscle, a partial uvulectomy and closure of the anterior and posterior tonsillar pillars (Pang & Woodson 2007).

Our anterior palatoplasty consisted of tonsillectomy, partial uvulectomy, resection of horizontal strip of soft palate mucosa and lateral pharyngoplasty. For the lateral wall release, horizontal incision was made at the middle part of both anterior and posterior pillars until the pillars blended with the lateral pharyngeal wall (Figure 1(a) to 1(c)). We do not perform the additional procedure in anterior palatoplasty by Pang and Terris's which is the expansion sphincter pharyngoplasty, rotation of palatopharyngeus muscle and closure of anterior and posterior tonsillar pillars. In this study results, patients who had undergone anterior palatoplasty with lateral wall release were labelled as surgery and those without surgery were labelled as non-surgery. None of the patients develop surgical related complications such as velopharyngeal insufficiency.

STATISTICAL ANALYSIS

The data were analysed using the Statistical Package for the Social Science (SPSS) software version 23. Kolmogorov-Smirnov test was applied to test for normality of data of surgery and non-surgery group. Independent t-test was used to compare the mean of air leakage as well as adherence between surgery and non-surgery group. Chi-square test was used to assess the association of significant leakage as well as adherence between surgery and non-surgery group. A p-value of less than 0.05 was considered as statistically significant.

RESULTS AND DISCUSSION

RESULTS DEMOGRAPHY

A total of 40 of 54 patients fulfilled the study criteria with a male to female ratio of 4.7:1. The mean age for surgery group was younger than non-surgery group; in which it was of 42.17 ± 9.68 years versus 58.73 ± 15.12 years. Majority of the patients were obese (67.5%). The mean body mass index (BMI) and pre-CPAP AHI between the 2 groups were similar ($p > 0.05$) (Table 1).

COMPARISON OF MEAN OF AIR LEAKAGE AND ADHERENCE OF CPAP THERAPY

The mean air leakage between surgery and non-surgery groups were of $7.62 \pm 8.14\%$ and $12.62 \pm 13.81\%$, respectively. The mean adherence levels of the surgery

and non-surgery groups were of $51.44 \pm 35.27\%$ and $60.03 \pm 27.04\%$, respectively. There was a significant difference for mean air leakage; which was higher in non-surgery group ($p < 0.01$). Comparison of mean adherence to CPAP therapy between the two groups showed no significant difference ($p = 0.389$).

ASSOCIATION OF SIGNIFICANT AIR LEAKAGE IN SURGERY AND NON-SURGERY GROUP

Majority of patients in this study did not have a significant air leakage (60.0%) during usage of CPAP therapy. For surgery group, 6 patients (33.3%) experienced significant air leakage and 10 patients (45.5%) of the non-surgery had significant air leakage. This data showed that there was no association between significant air leakage and surgery ($p = 0.436$) (Table 2).

ASSOCIATION OF ADHERENCE OF CPAP THERAPY IN SURGERY AND NON-SURGERY GROUP

CPAP adherence data from the report showed that majority of the patients from both groups were not adherent to CPAP therapy (62.5%). The data also showed that 6 patients from the surgery group and 9 patients from the non-surgery group were compliant with CPAP therapy. 66.7% and 59.0% of the surgery and non-surgery groups showed poor adherence, respectively. There was no association found between poor CPAP adherence and surgery ($p = 0.622$) (Table 3).

DISCUSSION

OSA causes many metabolic and neurocognitive morbidities that may be reversed by good adherence to CPAP therapy. One of the factors that contribute to non-adherence is air leakage. Since 1996, palatal surgeries have shown heterogeneity in results towards air leakage. Initial studies demonstrated increased air leakage following palatal surgeries (Mortimore et al. 1996; Richards et al. 1996). Subsequent studies showed that palatal surgery was more effective in the mild to moderate OSA with less encouraging results in moderate to severe group (Friedman et al. 2017, 2009; Han et al. 2006; Pang & Terris 2007; Pang & Woodson 2007).

The present study's main aim was to investigate whether a standardised palatal surgery for OSA (anterior palatoplasty) would cause significant air leakage in CPAP therapy, thus affecting adherence to the treatment. The results showed that surgery did not cause significant air leakage during CPAP therapy as there was no significant association found between

significant air leakage and surgery. Majority (62.5%) of OSA patients in this study were not adherent to CPAP therapy. Comparison of mean CPAP adherence between the two groups (surgery and non-surgery) was not statistically significant ($p>0.05$). The result also showed that there was no significant association between poor adherence and surgery.

Previous studies showed conflicting results on the impact of the upper airway surgery towards air leakage on CPAP therapy. The initial study on the effects of palatal surgery (uvulopalatopharyngoplasty, UPPP) to CPAP therapy was conducted by Mortimore IL and demonstrated significant air leakage following the palatal surgery (Mortimore et al. 1996). They also concluded that a significant reduction in adherence to CPAP therapy following surgery was attributed by the significant air leakage. However, in this study, the air leakage tests were conducted in awake patients. Therefore, the study's conclusions were arguable, as the findings may not be representative of the condition during natural sleep.

On the other hand, another study which included a one arm, small case series showed significant improvements in mean adherence following an upper airway surgery by 49 minutes per night ($p=0.03$) (Chandrashekariah et al. 2008). However, the surgical

intervention performed in this study population was not standardised. Friedman et al. (2009) studied the adherence to CPAP therapy in 52 patients undergoing multilevel surgery that comprised U3P, tongue base reduction and nasal procedures. They demonstrated that the adherence improved significantly comparing before and after the multilevel surgery that includes anterior palatal surgery. The study concluded that the overall surgical intervention to the upper airway may be the contributing factor to the significant improvement in CPAP therapy adherence. 96.2% of the study population were able to maintain optimal pressure without mouth leak.

Han et al. (2006) studied 62 patients with OSA. Among the 31 who had UPPP, 24 patients had classical UPPP which had removal of all of uvula and soft palate and the remaining 7 patients had modified UPPP which kept part of the uvula. They demonstrated that all in modified UPPP group could tolerate CPAP therapy but only 5 patients (16%) who underwent classical UPPP could not tolerate CPAP therapy. The authors concluded that UPPP with greater resection of soft palate may compromise CPAP therapy, and this may be attributed by presence of significant air leakage (Han et al. 2006). However, none of these studies included quantitative air leak as the objective parameter.

TABLE 1. The table depicts the demographic data that were recruited in the study

Demographic	Surgery (n=18)	Non surgery (n=22)	Total (n=40) (%)	p-value
Gender				
Male	15 (37.5%)	18 (45.0%)	33 (82.5%)	0.900
Female	3 (7.5%)	4 (10.0%)	7 (17.5%)	
Age				
18-30	1 (2.5%)	1 (2.5%)	2 (5.0%)	0.061
31-60	15 (37.5%)	11 (27.5%)	26 (65.0%)	
>60	2 (5.0%)	10 (25.0%)	12 (30.0%)	
Mean \pm SD	42.17 \pm 9.68	58.73 \pm 15.12		<0.001
BMI (kg/m²)				
Normal	1 (2.5%)	3 (7.5%)	4 (10.0%)	0.437
Overweight (25-29.9)	3 (7.5%)	6 (15.0%)	9 (22.5%)	
Obese (\geq 30)	14 (35.0%)	13 (32.5%)	27 (67.5%)	
Mean \pm SD	34.92 \pm 6.43	31.71 \pm 6.25		0.119
AHI pre CPAP (per hour)				
Moderate (15-29.9)	5 (12.5%)	8 (20.0%)	13 (32.5%)	0.564
Severe (\geq 30)	13 (32.5%)	14 (35.0%)	27 (67.5%)	

To the best of authors' knowledge, to date, the present study is the only study with a single type, standardised palatal surgery which is the anterior palatoplasty that were compared to non-surgery group that look into the aspect of air leakage during CPAP therapy and adherence to CPAP therapy. We have tried to minimize the other contributory factors towards air leakage by sampling only after ample period of 3 months of adjustment to CPAP therapy as well as in patients with no issue with mask fitting. Our study supports the findings of previous studies showing that palatal surgeries did not affect the subsequent CPAP treatment.

Therefore, the authors believed that anterior palatoplasty can be remained as an option to facilitate CPAP therapy in patients who failed or refuse initial CPAP therapy.

The main limitation of this study was the small number of patients. The data on air leakage before and after surgery were not available for comparison purpose. This is because most of the patients in surgery group had refused CPAP therapy as the primary treatment. A larger prospective study in future that include patients who had anterior palatoplasty and sequentially requiring CPAP therapy due to surgical failure is recommended to confirm the present study's findings.

TABLE 2. The air mask leakage in surgery and non-surgery group

Leakage	Surgery	Non-surgery	Total	p-value
Significant leakage	6 (15.0%)	10 (25.0%)	16 (40.0%)	0.436
Non significant leakage	12 (30.0%)	12 (30.0%)	24 (60.0%)	

TABLE 3. The adherence to CPAP therapy in surgery and non-surgery group

Adherence	Surgery	Non-surgery	Total	p-value
Good adherence ($\geq 70\%$)	6 (15.0%)	9 (22.5%)	15 (37.5%)	0.622
Poor adherence ($< 70\%$)	12 (30.0%)	13 (32.5%)	25 (62.5%)	

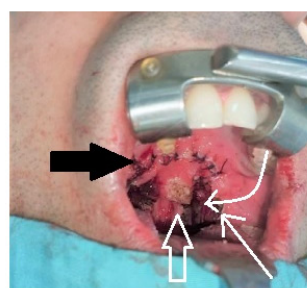
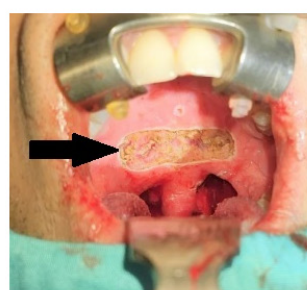
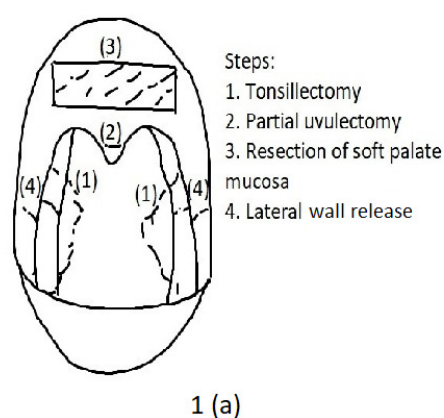


FIGURE 1. (a) Illustration of steps of anterior palatoplasty, which includes tonsillectomy, partial uvulectomy, resection of soft palate mucosa and lateral wall release (b) and (c) Intraoperative view of anterior palatoplasty with lateral wall release in which: (a) mucosa of the soft palate was resected (black arrow); and (b) resected mucosa of the soft palate was sutured (black arrow). Partial uvulectomy (white arrow), tonsillectomy (curved thin arrow) and lateral wall release (straight thin arrow) were performed

CONCLUSION

This study demonstrated that anterior palatoplasty with lateral wall release did not cause negative impact to the subsequent CPAP therapy in OSA patient. The mean air leakage during CPAP therapy was higher in non-surgery group and the presence of significant air leakage was not associated with surgery. Poor adherence to CPAP therapy has no significant association with surgery.

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*Corresponding author; email: marinamatbaki@ppukm.ukm.edu.my