

Understanding Air Leak in Positive Airway Pressure Ventilation in Management of Obstructive Sleep Apnea

Deepak Shrivastava

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Abstract

Air leak is common in patients using positive pressure airway therapy. Intentional leak is deliberately allowed to eliminate carbon di oxide. Unintentional leak generally occurs at the mask interface and causes a wide spectrum of complications and leads to poor CPAP adherence. This article reviews the interpretation of the leak profile. Many positive pressure systems have different algorithms to respond and quantitatively record the air leak. Once the high air leak is confirmed then variety of interventions are discussed to resolve the air leak and improve its efficacy. Two case examples are provided to fully understand the complex interplay amongst airflow; positive pressure ventilation to open the airway, volume of air leak and its impact on arousals and sleep is discussed.

Introduction

Continuous positive airway pressure ventilation (CPAP) is the recommended mode of therapy for obstructive sleep apnea (OSA). Ambient air is generally circulated through the CPAP machine in to the patient's airways under a predetermined pressure; enough to keep the airway open and prevent its collapse during inspiration. Since the system in CPAP is a closed circuit until mouth opens and air escapes, there has to be a mandatory passage of the expired air needed to entrain fresh air with ambient oxygen and to washout the carbon-di-oxide. This predetermined volume of air is variable at different pressures and is called *intentional* "leak". This leak serves an important function of ventilation process. The manufacturers provide the leak volume information. Clearly, certain amount of air leak is acceptable at a given pressure.

Address for correspondence

Dr. Deepak Shrivastava, MD, FAASM, FCCP, FACP
Department of Internal Medicine Division of Sleep,
Pulmonary and Critical Care San Joaquin General
Hospital and University of California, Davis,
Stockton, California 95231, USA
Email: drshrivastava@comcast.net

Air may escape from the mask making noises sometimes loud enough to wake the sleep partner up. Mask leak could be the result of the incorrectly adjusted head gear, either too loose or too tight, frequent positional changes displacing the mask and sometimes lost mask elasticity due to ageing. Mask leak could also occur if pressure continues to increase in a system that responds to the increasing resistance like Auto-PAP devices. Such leak is unacceptable and is considered *unintentional*.

Mouth breathing is a common problem in patients using positive pressure therapy. In general, it occurs intermittently and is exacerbated during the periods of common cold, allergy related congestion and possibly alcohol related vasodilation; conditions that increase the downstream resistance. A person using a nasal mask may breathe throughout the respiratory cycle via mouth and inhale unpressurised air that does not open the airway. Alternatively, the pressurized air flows through the nasal mask during inspiration but flows out of the open mouth to partially or completely lose its pressure and become ineffective in keeping the airway open. In other setting the open mouth may allow exhaled air to escape. Mouth

leak is another form of *unintentional* leak.

Rare causes of leak include intra-cranial leak producing pneumocephalus in patients with previous sinus or skull surgery or trauma¹ and retrograde lacrimal duct leak with eye irritation (Waller EA, Sleep disorders and the eye². Aerophagia can contribute to leak as the swallowed air is not expired and most algorithms involve detection of inspiratory versus expiratory flow discrepancies³. Aerophagia may potentially create a spurious situation when part of the inspiratory volume goes in to gastroesophageal tract and is not detected during the measurement of the expired volume causing perceived discrepancy between the two volumes that may be misread as a leak.

An understanding of the normal tidal volume and minute ventilation is important to fully comprehend the concepts of leak volume and its effects. A normal tidal breath is about 500 ml and at a normal respiratory rate of 10 breaths per minute it yields a minute ventilation of 5 liters per minute or 0.08 liters per second. In general, a leak rate of 0.4 liter per second (24 liters per minute) is acceptable. Any higher volume of leak is associated with patient discomfort, interrupted sleep and suboptimal efficacy of the CPAP in the treatment of OSA. As the pressure in the CPAP system increases the leak volume increases as well. However, if pressure does not increase but leak occurs then effective pressure will drop. Many systems are designed to activate an alert alarm at a leak rate of 0.7 liters per second (42 liters per minute) or higher. Some machines report the mean or median leak for 95% of the night while others report average leak over 7 and 30 days.

Importance of air leak

A small leak at the side or the bottom of the nasal mask may be acceptable but air leak from the top of the mask may cause irritation, soreness or dryness of the eyes. Large leaks can compromise CPAP effectiveness in treating OSA.

Approximately 40% CPAP users experience air leak⁴. Many of the inconsequential leaks (of around 0.4 L/s) may cause discomfort, treatment intolerance and adverse effects like eye irritation, mouth dryness, and nasal symptoms. In addition, it may lead to failure in the reliability of calculation of optimal pressure of automatic CPAP titration systems, poor functioning of automatic CPAP titration systems and decrease in ventilation

effectiveness in volume ventilation mode.

On the other hand, significant leaks make it impossible to maintain optimal pressure in treatment with CPAP that may be associated with sleep fragmentation and decrease in ventilation effectiveness in pressure-support ventilation mode. In patients who require mechanical ventilatory support, for example, patient with neuromuscular diseases, it may cause of inspiratory trigger failure, prolongation of inspiratory time as the end of inspiration is not detected and greater requirement of oxygen in the circuit⁵.

Richards et al. reported large increase in nasal resistance due to mouth leak in patients with nasal CPAP. During the mouth leak challenge, the resistance was continuously measured over 20 minutes. Resistance increased from a baseline mean of 2.21 cm H₂O/L/s to a maximum mean of 7.52 cm H₂O/L/s within 1 minute of the challenge. It was attributed to high unidirectional nasal airflow caused by the mouth leak⁶. Another study showed that nasal CPAP with a mouth leak and subsequent unidirectional airflow across the nasal mucosa caused a 65% increase in nasal mucosal blood flux as measured by laser Doppler flow meter. Acoustic rhinometry however, did not show any change in nasal volume or minimal cross sectional area⁷.

Mouth leak leads to mucosal drying, nasal congestion, unresolved tiredness, odynophagia and poor therapy quality causing increase in airway resistance. Such increase in resistance can worsen obstructive sleep apnea, cause loss of comfort and resultant poor compliance.

Unintentional leaks tend to occur more frequently in patients with mouth breathing during sleep⁸.

Physiologic effect and clinical impact of excessive air leak

The treatment of OSA with auto-titration positive airway pressure (auto-PAP) is common due to its many advantages. Clinical trials indicate that auto-PAP titration is as good as in-laboratory polysomnography based titration^{9, 10, 11}.

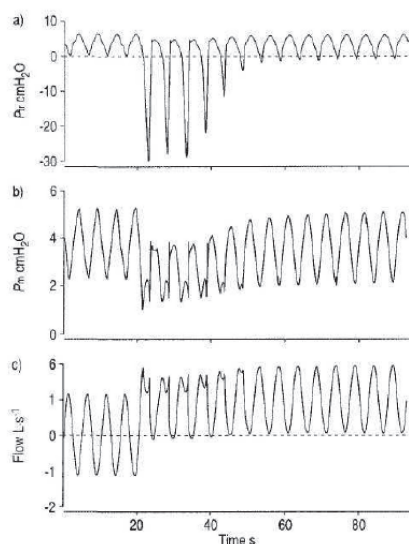
Episodes of mouth leaks often follow with arousals. Arousals are more frequent during light sleep (stages N1 and N2) and reduce the quality of sleep by causing fragmentation^{12, 13, 14}. On the other hand, it has been clearly shown that sleep disruption has, in turn, negative effects on ventilatory control because the response to hypoxia

and hypercapnia is reduced, and thus a vicious circle develops.

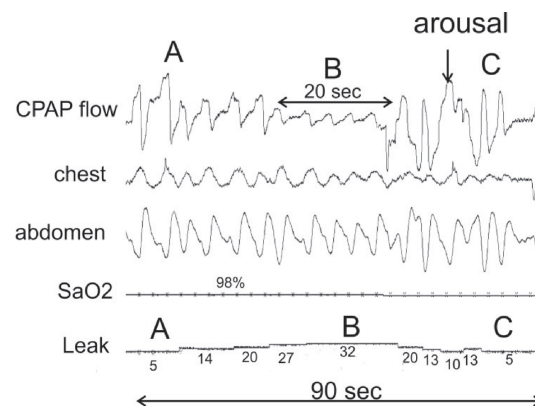
Severe mask leak can prevent successful titration with an auto-PAP device. Number of studies has tested the effectiveness of the AutoSet self-titrating nasal CPAP system in treating OSA, and choosing a suitable pressure for subsequent conventional fixed-pressure CPAP therapy. In one study severe mask leak prevented automated titration in the subject and caused transient unnecessary increases in pressure in three subjects indicating that auto-PAP is a reasonable treatment option for most of the OSA subjects¹⁵. Auto-PAP devices may perform suboptimal in the presence of air leak. Specifically, in the presence of air leak, the auto-PAP device may fail to detect the events of OSA, and thereby either fail to respond or respond in a sub-optimally leading to lower levels of delivered pressures. The pressure response of an auto-PAP device was reduced by 56% in the presence of air leak of 30 L/minute^{16, 17}.

In a retrospective cohort systematic study of the effect of air leak on adherence to auto-PAP therapy, the authors found a direct correlation between high residual respiratory events, volume of the air leak and the non-adherence to the CPAP therapy¹⁸.

Leak profile and its interpretation



An example of a mask leak at 20 second mark causing swings in the tracheal pressure (top panel), a drop in mask pressure (middle panel), and an upward shift and flattening of air flow. At 50 second mark the device compensated for the leak and increased the mask pressure to baseline levels, normalized the tracheal pressure swings and improved the airflow to round curve. (Adopted from Eur Respir J 2004; 24:649-658)



A 90 second tracing during a PAP titration. A period of increased leak (B) is associated with a drop in CPAP flow signal. With arousal (C), the leak suddenly dropped. Video monitoring showed mouth opening during (B). (Adopted from Berry RB, Sleep medicine pearls, second edition, Philadelphia, PA: Hanley and Belfus, 2003; 130)

Leak profiles can be objectively identified and reliably correlated to the leak rates and clinical outcomes. Baltzan et al. prospectively studies leak profiles of 35 subjects. Adverse effects increased according to the patient surveys with increasing leak.¹⁹

Mask leak can be quantified for its significance. Respiration positive airway pressure device in current clinical practice would identify a large leak for over one hour. Respiration protocol reports 30 second average leak of up to 7 liter/minute. The leak may be averaged over one hour, single night or 7 and 30 days to give an approximation of the average leak volume. The Resmed would record leak rates over 24 liters/minute (95th percentile); and over 36 L/minute for a full face mask (95th percentile), DeVilbiss unit a mask leak of over 95 liters/minute and Fisher & Paykel a mask leak over 60 liters/minute. There may be no leak threshold that is "clinically meaningful", as even a small leak directed into patients eyes can be a problem. Averaged data over weeks or months may be reported.

CPAP manufacturers provide information for how to measure the mask leaks. Manufacturers have different interface, materials and manufacturing processes. Given the patient side of the interface, facial fitting, muscle tone and skin conditions due to oil and sweat etc. leak could only be estimated. Considering the variable proprietary algorithms for the detection of leak available it is important to keep an anticipated leak threshold for the reporting purposes. Any higher threshold will cause higher incidence of complications and thus poor adherence.

Respironics algorithm subtracts intentional leak from the total flow. It takes in to account the average leak through all mask exhalation ports at various pressures. Resmed takes device flow intentional leak and add mouth leak and reports as 95th percentile leak at two levels of leak more than 24 liters/ minute and more than 36 liters per minute that includes mask and exhaust flow from the mask. Fisher & Paykel reports total leak over 60 liters per minute. DeVilbiss records high leak flow time as a percentage of the time the leak was above 95 liters per minute. (Schwab, University of Pennsylvania Medical Center)

Suspecting air leak as a potential problem in CPAP management

The answers to some basic questions can raise degree of suspicion that an unintentional leak is present. For example, whether patient often wakes up with a dry mouth and/or throat, tends to breathe through the mouth, suffers from allergies or hay fever, has a blocked nose/congestion, has a deviated nasal septum, currently uses nasal spray therapy or medication, continues to snore even when using therapy, uses a chin strap and if leak is indicated by flow generator data?

The problems of how to handle mask/mouth leak and central apnea have provided a challenge for the designers of Auto-PAP. Mask/mouth leaks tend to increase the baseline flow delivered by the machine and reduces the variations in flow during inspiration and expiration. The resulting airflow signal may be interpreted as an apnea or hypopnea and prompt an increase in pressure that may further increase leak. In impedance-based systems, a mask leak results in a spurious low impedance that does not reflect the actual state of the airway.²⁰

To handle the leak problem many units have algorithms that limit pressure increases when leak exceeds certain values or when increases in blower speed no longer result in increases in mask pressure. Other units have leak alarms that could prompt the patient/staff to readjust the mask. Mouth leaks could be approached by treating nasal congestion, using heated humidification, chin straps, or using a mask covering the nose and mouth.

Potential solutions and troubleshooting

There are no data to constitute a clinically significant mask leak. Mask leak data are averaged measurements and may not reflect recent changes in the CPAP interface. Intermediate residual AHI data can be difficult to interpret and should be examined within the clinical context. A reduction in CPAP mask leak can improve adherence and improved adherence can improve OSA outcomes, mask leaks depend on both the mask (nasal pillows, or full face) and the pressure being delivered.

If the patient's mask leak is significantly greater than the leak threshold specified by the specific CPAP manufacturer, the interface could be changed. The new CPAP adherence tracking devices measure many other respiratory signals data, including periodic breathing (Cheyne-Stokes pattern), vibratory snoring, flow limitation and clear airway apnea (central sleep apnea). Unfortunately there are essentially no methods to examine the validity, reliability, reproducibility, or utility of these signals.

AASM Current guidelines suggest that unintentional leaks should be minimized with proper mask selection and fitting prior to the titration. PAP mask refit or readjustment should be performed whenever any significant unintentional leak is observed. In the case of "mouth leak", addition of a chinstrap to reduce mouth opening or switching to a full-face/oro-nasal mask may be beneficial. A study examining the effects of mask leak on the efficacy of BPAP therapy reported that the patients showed improved oxygenation, decreased arousal index, and increased REM sleep when this leak was minimized²¹.

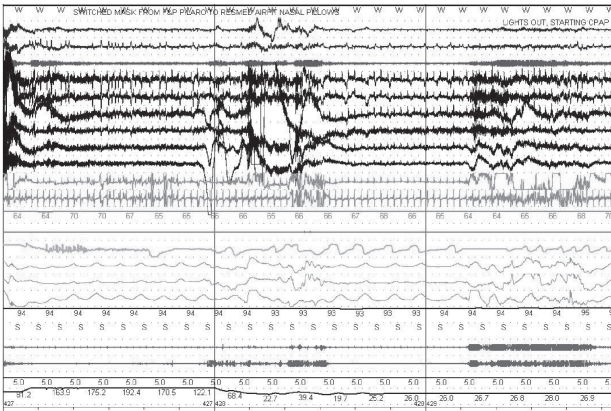
Since the exact amount of leak varies with the type of interface, it makes identification of an unacceptable leak value difficult. Clinical judgment based on laboratory-specific criteria or the leak vs. pressure relationship supplied by the manufacturer for a given interface is recommended. A sudden increase in leak without a pressure change should alert for a possible increase in mask/mouth leak^{11, 22}.

Many CPAP machine provide a leak alarm system. This system should be enabled. Change to a full face mask may provide a better seal and less chance of a leak. Patients intolerant to the full face mask may benefit from a chin strap. Nasal pillows and inflatable cushion that contours the face may be a reasonable option to

consider. Use of heated humidification or nasal steroid sprays has been clinically proven to improve the congestion and lower the airway resistance²³. Cleaning mask daily with soap and water is highly recommended as skin oils make the leak worse. Washing the mask improves the maximum seal and efficiency. Excessive mask leak and poor seal may be an indication that the mask needs to be replaced.

Leak compensating devices are new and these compensate for unintentional leaks by automatic compensation that ensures the delivery of desired pressure to keep the airway open. Addition of expiratory pressure reduction or use of auto-adjusting CPAP which lowers mean pressure may improve leak. Although relatively expensive the Auto-PAP may improve the outcomes.

Illustrative case one



Polysomnogram tracings obtained from Respiration Alice 6 recording showing from top to bottom: electro-oculogram (2 channels), chin electromyogram (1 channel), electroencephalogram (6 channels), electrocardiogram (2 channels), heart rate (1 channel), disabled (1 channel), flow (1 channel), effort (3 channels), oxygen saturation (1 channel), body position (1 channel), leg electromyogram (2 channels), baseline CPAP (1 channel) and leak (1 channel). In this 1 and 1/2 minute view an air leak of up to 192.4 liters per minute noted (Epoch 427). The leak improved to normal value after the nasal interface was changed (Epoch 428 and 429). Courtesy of Derrell Whisenton, RPSGT, San Andreas Sleep Center, San Andreas, California (with permission)

Acquisition # 45399: Epochs 427-429

Description: Split Night Study

Patient started with an F&P Pilaro Q nasal pillows mask. The nasal pillows did not seem to seal on the inside of patients nostrils due to large nasal openings. The air leak went up to 192.4 liters per minute. Since F&P Pilaro Q only comes in one size, mask was switched to ResMed AirFit P10 Large Nasal Pillows. Excessive leak was resolved.

Additional Options:

Switch to nasal mask or full face mask

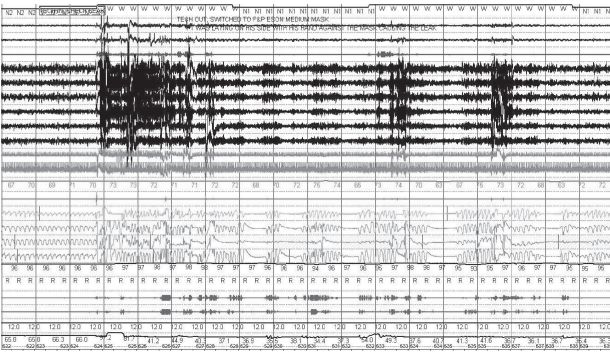
Attempt to adjust nasal pillows for better seal

Acceptable Pressure to Leak Ratios: (ResMed AirFit P10 Nasal Pillows)

Therapy Pressure: 4 to 20 cm H2O

Pressure (cm H2O)	Leak (L/min)
4	20
8	29
12	37
16	43
20	49

Illustrative case two



Polysomnogram tracings obtained from Respiration Alice 6 recording showing from top to bottom: electro-oculogram (2 channels), chin electromyogram (1 channel), electroencephalogram (6 channels), electrocardiogram (2 channels), heart rate (1 channel), disabled (1 channel), flow (1 channel), effort (3 channels), oxygen saturation (1 channel), body position (1 channel), leg electromyogram (2 channels), baseline CPAP (1 channel) and leak (1 channel). In this 10 minute view an air leak of up to 176 liters per minute noted (Epoch 625) causing arousal. The leak improved to normal value after the nasal interface was changed (Epoch 626 to 632) restoring sleep. A second leak increase to 78 liters per minute (Epoch 632) caused arousal. Courtesy of Derrell Whisenton, RPSGT, San Andreas Sleep Center, San Andreas, California (with permission)

Acquisition # 272: Epochs 620 - 640

Description: CPAP Titration

Patient started with a ResMed AirFit P10 Nasal Pillows Mask. When the patient turned onto his side he also placed his hand against his mask causing an excessive leak. Mask was switched to F&P Eson Medium Mask. Excessive leak was resolved

Additional Options:

Ask patient to move his hand and/or ask patient to lay supine

Attempt to adjust head gear to help secure mask position

Acceptable Pressure to Leak Ratios: (F&P Eson Nasal Mask)

Therapy Pressure: 4 to 25cm H₂O

	Leak (L/min) With	Leak (L/min) Without
Pressure (cm H ₂ O)	Diffuser System	Diffuser System
4	17	20
7	23	26
11	30	33
15	35	39
19	40	43
23	43	47
25	44	48

Conclusion

Excessive leak during CPAP may compromise treatment efficacy by increasing respiratory events, sleep fragmentation and poor adherence. Leak compromises the automatic response of the auto-PAP system. Excessively worn-out or broken masks and headgear perpetuate air leak and tubing or loose connector problems may further confound the problem. There is little information available regarding aerophagia. However its incidence may be as high as 50%. Most patients do not report aerophagia related symptoms like burping and belching. However, patients who are intolerant to CPAP should be asked about the aerophagia. Aerophagia contributes to leak as the swallowed air is not expired and most leak algorithms involve detection of inspiratory vs expiratory flow discrepancies. Management of leak includes optimization of mask and headgear fit, comfort and seal and comfort, verification of the integrity of the circuit, and use of heated humidification, with in some

instances nasal lubricant or inhaled steroid, to minimize nasal symptoms^{24, 25}.

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