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Rates of initial acceptance of PAP masks and outcomes of mask switching

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Abstract
Purpose Recently, we noticed a considerable development in alleviating problems related to positive airway pressure (PAP) masks. In this study, we report on the initial PAP mask acceptance rates and the effects of mask switching on mask-related symptoms.
Methods We prospectively collected all cases of mask switching in our sleep unit for a period of 14 months. At the time of the study, we used ResMed™ CPAP devices and masks. Mask switching was defined as replacing a mask used for at least 1 day with another type of mask. Changing to a different size but keeping the same type of mask did not count as mask switching. Switching outcomes were considered failed if the initial problem persisted or reappeared during the year that followed switching.
Results Our patient pool was 2768. We recorded 343 cases of mask switching among 267 patients. Of the 566 patients who began new PAP therapy, 108 (39 women) had switched masks, yielding an initial mask acceptance rate of 81 %.

The reason for switching was poor-fit/uncomfortable mask in 39 %, leak-related in 30 %, outdated model in 25 %, and nasal stuffiness in 6 % of cases; mask switching resolved these problems in 61 %.

Mask switching occurred significantly (p = 0.037) more often in women and in new PAP users. The odds ratio for abandoning PAP therapy within 1 year after mask switching was 7.2 times higher (interval 4.7–11.1) than not switching masks.

Conclusion The initial PAP mask acceptance rate was high. Patients who switched their masks are at greater risk for abandoning PAP therapy.

Keywords CPAP interface · Mask switching · Sleep apnea · Side effects · Outcomes

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Introduction

Positive airway pressure (PAP) therapy, the standard treatment for obstructive sleep apnea (OSA) [1], lowers the apnea-hypopnea index, reduces nocturnal hypoxemia [2], and improves sleep regulation [3].

PAP consists of a pump which blows air into the patient's nose, mouth, or both during sleep to hold the airways open and to avoid obstructions. A connecting hose and "mask," which rests on the patient's face, connects the pump to the patient. Types of interface available for PAP use include masks which fit into the nostrils (nasal pillows) or which cover the nose (nasal mask), the mouth, both the nose and mouth (oronasal), or even the entire face (helmet) [4, 5]. Local side effects, such as pressure sores, skin ulcerations, air leaks, mask dislodgement, claustrophobia, or local allergic reactions, occur in up to 50 % of patients [6, 7]. The intrusive nature of PAP therapy into the sanctity of the bedroom and the natural aversion to wearing unattractive headgear to bed are often reasons for non-adherence to PAP [8]. Because the PAP mask must be tailored to the individual, proper mask fitting and patient education are important and may lead to fewer air leaks, better adjustment of the mask, and improved adherence to treatment [6].

Despite numerous improvements in the technology of PAP masks and devices, the major challenge for physicians is to increase patient acceptance of and adherence to PAP treatment

[9]. Meanwhile, an orientation session led by a technician can improve objective sleep quality and mask acceptance during the night of PAP titration and may improve PAP adherence [10].

Mask switching, or replacing a mask with another type or brand in order to reduce or resolve a mask-related problem, has recently become more common in our sleep unit. Effectively, the greater availability of mask types to satisfy PAP patients may make an individual's mask choice more challenging, thus leading more easily to mask switching. Nowadays, mask companies target patients more directly in their product advertising.

Theoretically, mask switching leads to more visits and therefore requires more medical resources, but it may also resolve mask-related problems, thereby reducing the need for frequent interventions.

The incidence of mask switching, the rates of initial mask acceptance, and the causes and outcomes of mask switching have seen little study.

In this prospective study, we report the different reasons for mask switching and their outcomes in PAP patients.

Methods

For 14 months beginning in November 2012, we collected data on all cases of mask switching among the patients we followed in our sleep unit for PAP therapy. Because we follow our patients yearly, we chose a 14-month study period to ensure the turnover of all our PAP patients. After this 14-month period, we followed patients who switched masks for 1 year to evaluate the outcomes after switching. The ethics committee of the Helsinki University Hospital, Department of Internal Medicine, approved the study (code M101080009, permit number 159/2012).

Definition

Mask switching was defined as replacing a mask that was used for at least 1 day with another mask type. Switching is considered when, for example, a nasal mask is switched to pillows or to a full face mask, or when a nasal mask is replaced by another nasal mask but from a different type (model) or from a different brand. Changing to a different size but keeping the same type and brand was not considered mask switching.

Patients

All new PAP patients underwent a 1-h familiarization session at the hospital with the PAP device and masks, as described previously [4, 11]. Patients tried several mask types and sizes to find the most appropriate interface for each patient. The patients received training in PAP management and in solving potential problems that might arise with the PAP device. The next visit to the sleep unit took place within 2 to 5 days of PAP initiation, followed by subsequent visits every 2 to 3 months and thereafter yearly. Patients were given the telephone number of a nurse to contact in the event any problems would arise, such as a malfunctioning PAP device, deterioration of consumables, or other unsolved problems. During each visit, we checked the PAP mask and switched it for another one when necessary. Switching masks was not subject to strict rules, as the medical team always aimed to resolve any mask-related problems and ultimately to achieve better PAP adherence. In the event of leak-related problems, we switched masks if patients reported a disturbing leak or if the medical team noticed a substantial leak. No leak threshold was set for mask switching.

We collected data on the type of mask, the reason for switching, and the patient's request to switch masks.

The brand and type of PAP interfaces are chosen in our sleep units every 2 years, according to local legislation. We used masks mainly from ResMed (ResMed Corp. San Diego, CA, USA) at the time of the study. National public health insurance fully covers the cost of PAP devices and interfaces delivered to our patients.

Switching outcomes

The sleep nurse was asked to predict the usefulness of mask switching on a visual analogue scale (0 = useless, 100 = useful).

A mask switch was considered a failure (failure group) if the mask-related problem persisted and led to another switch or to the patient abandoning PAP therapy within 1 year after switching.

A mask switch was considered successful if the switch resolved the mask-related problem and the patient continued using the PAP device for at least 1 year after switching.

Statistics

A software statistical package (IBM SPSS® Statistics 22.0, Armonk, NY, USA) served to analyze the results. We used the Student's *t* test for continuous variables with normal distribution and the chi-square tests for categorical variables. When the assumption, in the chi-square test, is violated, we used the Fisher's exact test.

To evaluate the ability of our medical team to predict the outcomes of mask switching or to evaluate the possibility of abandoning CPAP therapy, we used the receiver operating curve (ROC) and also calculated the area under the curve. The usefulness score served as the test variable, and the successful outcome or the situation of abandoning CPAP therapy served as the state variable. We also used the crosstabs calculation of the SPSS program to evaluate the odds of switching

in women compared to men, in patients over 60 versus patients under 60 years old and in new versus old CPAP users. The odds of abandoning CPAP was calculated in the switching group compared to the non-switching group. The 95 % confidence interval and the statistical significance of the odds ratio were also reported. All p values were two-sided, and the level of significance was set at 0.05.

Results

The study began in November 2012. During the following 14 months, we recorded 343 cases of mask switching among 267 patients and 2501 patients did not switch at all. We found no significant difference in mean age between the switching and the non-switching groups TS = t (2766) = −0.052; (p = 0.959). However, we did find significantly more women in the switching group than in the non-switching group χ^2 (1, N = 2768) = 4.54, p = 0.033. Moreover, the mean duration of PAP therapy was significantly shorter in the switching group (40 months) than in the non-switching group (59 months) [TS = t (583) = −4.222; (p = 0.001)] (Table 1).

Switching occurred only once in 209 patients, twice in 40 patients, and three or more times in 18 patients. The group that made one switch showed no significant difference in gender from the group that made more than one switch [χ^2 (1, N = 267) = 0.275, p = 0.600]. Meanwhile, it was slightly younger than the "more than one switch group" 58 ± 12 years vs 62 ± 11 [TS = t (267) = −2.493; (p = 0.013)], respectively.

Initial mask acceptance rate

During the study period, 566 patients began a new PAP therapy. Of them, 108 patients (39 women) switched masks and 458 continued to use their initial mask for at least 1 year, yielding an initial mask acceptance rate of 81 %.

Timing of mask switching

In the new PAP user group, the mean first mask switch occurred at 16 ± 45 days from PAP initiation, the second at 101 ± 124 days, and the third at 143 ± 117 days from PAP initiation. Meanwhile, in patients whose PAP therapy began before this study did, the first observed mask switch occurred at a mean of 66 ± 30 months of PAP therapy.

Reasons for mask switching

The major reason for mask switching was poor-fit/uncomfortable mask (problems related to pressuring of the skin or to skin wounds were also included in this category) in 133 cases (38.8 %), followed by leak-related problems (air blowing into the eyes, mouth drying related to leaks, and noisy device because of abnormal leak were also included in this category) in 102 cases (29.7 %), an outdated model (i.e., the masks were no long available in Finland) in 85 cases (24.8 %), and problems related to nasal stuffiness in 23 cases (6.7 %).

Of the 102 cases involving leak-related problems, patients in 55 cases asked to switch masks because they found the leak disturbing. Meanwhile, in 47 cases, the medical team switched the mask due to a substantial leak.

Outcomes of mask switching

Of the 343 cases involving mask switching, the initial problem persisted in 134 cases (failure group) and was resolved in 209 cases (success group), yielding a successful outcome rate of 61 %. The patient's age or gender did not predict the outcomes of switching. Nevertheless, the outcomes differed significantly [χ^2 (3, N = 343) = 23.97, p = 0.001] in the reasons for switching, which showed the highest success rate (80 %, standard residual 2.7) in cases related to outdated masks, followed by cases related to poor-fit masks (62 %). Meanwhile, the

Table 1 Characteristics of mask switching and non-switching patients and values of the odds ratio for

	Switching	Non-switching	p	Odds ratio	95 % confidence interval	
Patients	267	2501				
Women	89 (33 %)	680 (27 %)	*0.033*	1.226	1.023	1.470
Age, year, mean (SD)	59 (12)	59 (13)	*0.959*			
PAP duration, months, mean (SD)	40 (54)	59 (59)	*0.001*			
New PAP patients	108	458	*0.001*	2.209	1.868	2.611
Age over 60	130 (49 %)	1150 (46 %)	*0.402*	0.950	0.841	1.073
Abandoned PAP	34 (12.7 %)	44 (1.8 %)	*0.001*	7.238	4.711	11.120

Mask switching occurred in women significantly [χ^2 (1, N = 2768) = 4.539, p = 0.033] more often than in men and more often in new PAP patients than in old PAP users

Patients who switched their mask had a seven times more tendency to abandon their PAP therapy during the year that followed the switch

success rate was 50 % for leak-related cases and 35 % for cases related to nasal stuffiness. Cases of leak-related switching showed no differences in outcomes between leaks that patients found disturbing and a switch decided by the medical team due to a substantial leak [χ^2 (1, N = 102) =0.641, p = 0.423]. Meanwhile, the outcomes differed significantly ($p < 0.001$) according to the type of mask, whether baseline or new. Table 2 shows the success rates for the old and new masks. No differences in the mask outcomes were noticed between the types of the baseline masks (old masks), [χ^2 (2, N = 343) = 0.930, p = 0.624]. Meanwhile, we found a significant difference in the outcomes of switching according to the type of the new mask, [χ^2 (2, N = 343) = 14.689, p = 0.001] with the best outcomes obtained in nasal masks.

Requesting mask switching and the usefulness score

In 46 % (158 cases) of switching cases, the medical team recommended switching, and in 54 % (185 cases), the patients requested it. An outdated mask was the main reason why the medical team switched masks (54 %). We found no significant differences in the outcomes of switching between cases where patients requested the switch and those where the medical team recommended switching [χ^2 (1, N = 343) = 3.667, p = 0.056]. The contingency coefficient for this association was low at 0.103 indicating no association.

The medical team evaluated the usefulness of each case of mask switching (except those involving outdated masks) on a scale from 0 = useless to 100 = useful. Effectively, the usefulness scores were significantly [TS = t (256) = −2.932; (p = 0.004)] higher in the successful group than in the failure group (mean 75 ± 23 vs. 65 ± 29, respectively). Meanwhile, our medical team was unable to predict the outcomes of mask switching with reasonable sensitivity and specificity, as the calculated area under the ROC curve was only 0.585.

The switching outcomes were significantly [χ^2 (1, N = 343) = 55.296, p = 0.001] higher in patients with one switch than in those with two or more switches (76 vs. 36 % of successful outcomes, respectively) (Table 3).

Mask switching, patients' characteristics

Mask switching occurred in women significantly [χ^2 (1, N = 2768) = 4.539, p = 0.033] more often than in men [odds ratio (OR), 1.226; 95 % confidence interval (CI) 1.023–1.470; p = 0.033] and significantly [χ^2 (1, N = 2768) = 72.675, p = 0.001] more often in new PAP patients than in old PAP users [OR, 2.209; 95 % CI, 1.868–2.611; p = 0.001] (Table 1).

Risk of abandoning PAP after mask switching

A total of 34 patients (12.7 %) stopped their PAP therapy within 1 year after switching masks, whereas the corresponding number in the non-switching group was significantly [χ^2 (1, N = 2768) = 106.105, p = 0.001] lower (44 patients, 1.8 %) (Table 1). The odds ratio for abandoning CPAP within 1 year after a mask switch is 7.2 times higher [OR, 7.238; 95 % CI, 4.711–11.120; p = 0.001] in patients who switched masks than in patients who did not switch masks. A usefulness score below 10 showed high sensitivity (90 %) in predicting PAP

Table 2 Outcomes of switching according to the baseline or to the new mask

			Mask baseline			
			Nasal	Pillow	Full face	Total
Outcomes	Problem resolved	Count	139	30	38	207
		Std. residual	−0.3	0.3	0.4	
	Problem unresolved	Count	98	17	21	136
		Std. residual	0.4	−0.4	−0.5	
Total		Count	237	47	59	343

No differences in the mask outcomes were noticed between the types of the baseline masks [χ^2 (2, N = 343) = 0.930, p = 0.624].

			New mask			
			Nasal	Pillow	Full face	Total
Outcomes	Problem resolved	Count	126	32	49	207
		Std. Residual	1.6	−1.6	−0.9	
	Problem unresolved	Count	55	38	43	136
		Std. Residual	−2.0	1.9	1.1	
Total		Count	181	70	92	343

We found a significant difference in the outcomes of switching according to the type of the new mask [χ^2 (2, N = 343) = 14.689, p = 0.001]

Switching to nasal masks resulted in better outcomes; the standard residual was significant at 2.0

Table 3 Differences in switching outcomes according to the frequency of switching

		Succeeded	Failed		Success %	*P*
Switching	Once	159	50	209	76	
	Twice or more	48	86	134	36	
Total		207	136	343	60	0.001

Switching masks more than once reduces the succeeded outcomes

abandonment within 1 year of switching masks, whereas its specificity was exceptionally low (2 %) and the area under the ROC curve was only 0.671.

Among the switching group, 21 new PAP patients out of 108 (19.4 %) had abandoned PAP therapy within 1 year, which is significantly [χ^2 (1, N = 267) = 7.349, p = 0.007] higher than in the group of old PAP patients [13 patients out of 159, (8.2 %)]. Meanwhile, among the non-switching group, the percentage of patients who abandoned PAP therapy during the 1-year follow-up did not differ significantly [χ^2 (1, N = 2501) = 0.001, p = 0.982] between the new and the old PAP users [8 patients out of 458, (1.7 %)] vs. [36 patients out of 2043 (1.8)], respectively.

In the outdated mask group, one patient in the successful group and two patients in the failed group had abandoned CPAP therapy. The difference between the failed and the successful group was not statistically significant [Fisher's exact test, χ^2 (1, N = 85), p = 0.112].

Discussion

The main finding of this study is the initial mask acceptance rate of 81 % that we report here. This means that 81 in 100 patients found the first delivered mask suitable for at least 1 year from PAP initiation. This is an important point in planning resources for PAP follow-up.

A first-line mask policy means that all patients start PAP therapy with one mask model (called the first-line mask) and later adjust or switch masks when needed. In theory, this policy has the advantage of simplifying patient preparation, reducing costs, and facilitating logistical needs, though under a first-line policy, not every patient's specific needs are satisfied in the earliest stage of PAP therapy. In this study, however, we *did not* apply a first-line mask policy. Our medical team tried different mask types and models to ensure the patient's initial satisfaction; the results of these attempts determined which mask type would be the first used. Our initial mask acceptance rate seems relatively high, but because this study is the first to report on the rate of mask acceptance among newly initiated PAP therapy patients, we could not evaluate this rate in relation to those of other patient groups in similar circumstances.

The second major finding is that a patient who switched masks was at a sevenfold higher risk for stopping PAP therapy during the year after the switch than was one who did not switch. Interestingly, patients who did not switch abandoned PAP with the same low rate of 1.7 %, whether they were new or old PAP users. Mask switching therefore seems to indicate a problem with PAP therapy that, if it persists, may lead to therapy interruption. In short, we found that mask switching resolved 62 % of mask-related poor-fit problems and only half of leak-related problems.

The major reason for mask switching was poor-fit or discomfort mask in more than one third of cases. A mask which may initially fit comfortably may later begin to pressure the skin and fit poorly and uncomfortably. In two studies exploring the acceptance and side effects of nasal pillows [5, 12], the authors followed up their patients up to a period of 4 weeks and concluded no superiority in regard of CPAP adherence, though they concluded that the pillows were more comfortable than the standard nasal masks. We have previously found that about 9 % of our patients were nasal pillows users and reported no differences in the patient's satisfaction rates between interfaces [4]. Moreover, in this study, we noticed that patients with nasal pillows had switched as much as patients with other masks did. Effectively, our follow-up period was 1 year. We showed that switching a poorly fitting mask resolved the problem in about two thirds of cases. Meanwhile, when the need to switch masks more than once in a year arises, the number of successful outcomes dropped significantly.

The second major reason for switching masks was that they were outdated. At our institution, we choose PAP interface brands every 2 years according to national legislation. But because the speed of product development is increasing, every year sees new masks on offer. This trend compels us to hypothesize that the life cycle of a mask (period during which a product continues to be produced and commercialized) is shrinking. Currently, we took the estimated life cycle of a PAP mask to be 5 years (i.e., all our PAP patients must switch masks at least once in 5 years). This study showed that the success rate of outdated masks was 80 %, which means that 20 % of patients were unhappy with their new masks. This may result in more medical visits, increased medical costs, and a decrease in patient satisfaction. In light of these factors, the influence of outdated masks on medical resources could be substantial. We showed above that switching per se is a risk factor for abandoning CPAP therapy; therefore, we recommend expanding the mask lifecycle. This prolongation may be obtained if medical institutions request that the mask producers make their mask products available longer on the market.

A leak poses a major problem in PAP therapy. Masks should seal well and, at the same time, fit comfortably. Previously, we reported that 65 % of PAP patients found leaks frequently disturbing, yet we also found no correlation between disturbing leaks and the objective measurements of

such leaks [4]. A disturbing leak may stem from the amount of air blowing toward the eyes or from a large amount of air, causing abnormal noise. Although 65 % of our patients experienced a disturbing leak [4], in this study, only 0.1 % (55 of 2768 patients) requested a mask switch. Switching resolved half of leak-related switches. Some leaks may occur only when PAP pressures are high, and still other cases may occur at night, when the temperature of the strap changes, thereby reducing the mask's sealing capacity, or when the position of the patient's head asymmetrically pushes the mask from one side, thus leading to imperfect sealing.

Nasal stuffiness is a common symptom among PAP patients even before beginning PAP therapy [13]. To manage nasal stuffiness, we must treat its causes and also provide an alternative way to breathe, such as the use of an oronasal mask. Unfortunately, but as expected, switching due to nasal stuffiness resolved the problem in only one third of cases.

Women switched 1.2 times more often than men did, probably because masks were initially designed for men. New PAP users switched their masks significantly more often than old users did. Mask switching among old PAP users may stem from chronic skin irritation at the point of contact with the mask, or from changes in the patient's weight that may compromise the mask's fit, or from changes in pressure requirements that lead to more leaks. Unfortunately, our medical team was unable to predict the usefulness of mask switching with acceptable precision, possibly because some patients sought new masks in search of *perfect* comfort and were thereafter satisfied with the switch (classified as success), whereas the medical team considered the patient's claim unnecessary and classified the usefulness score of the mask switch as useless. This is an important issue in controlling costs in public health care services, where restrictions are usually severe to limit abuse.

Our study has some limitations. Our results apply to public institutions that provide PAP devices and masks free of charge. Private institutions may have different billing systems based on the amount of service provided to each patient. Moreover, we did not collect data on the severity of sleep apnea and its relation to mask switching. Oral masks were reported as efficacious interfaces for long-term CPAP therapy in patients with sleep apnea [14]. None of our patients, in this study, used oral masks. Effectively, our limited experience with the oral masks failed to fulfill our expectations.

Future studies ought to investigate the first-line mask policy and study the influence of mask advertising on the frequency of mask switching and its outcomes, as we recently noticed an increase in patient requests to switch to new mask models that are not yet available at our institutions.

In conclusion, four in five patients accepted their initial PAP mask and most patients switched masks due to poor fit. Patients who switched masks were at a seven times higher risk for stopping their PAP therapy within 1 year than were patients who did not switch their PAP mask.

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Compliance with ethical standards

Conflict of interest statement The authors declare that they have no competing interests.

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