

Comparison of nose and face mask CPAP therapy for sleep apnoea

I L Mortimore, A T Whittle, N J Douglas

Abstract

Background—Many patients with sleep apnoea/hypopnoea syndrome (SAHS) find nasal continuous positive airway pressure (CPAP) treatment unsatisfactory due to side effects related to mouth air leakage. A study was performed to compare side effects with face mask and nose mask CPAP therapy in patients with SAHS, with and without uvulopalatopharyngoplasty (U3P).

Methods—Twenty newly diagnosed patients with SAHS took part in a randomised double limb trial of face or nose mask CPAP therapy (four weeks per limb) in which CPAP compliance in terms of machine run time was measured and patients answered a symptom questionnaire on side effects resulting from the mask. Ten patients with SAHS with U3P (SAHS/U3P) who were already regular users of nasal CPAP were also given a four week trial of face mask CPAP to compare compliance and symptoms. Ten patients with SAHS were matched with the 10 SAHS/U3P patients for body mass index, age, apnoea/hypopnoea index, and CPAP pressure. Long term compliance was estimated one year after the mask comparison studies.

Results—For patients with SAHS nightly compliance was higher with a nose mask (mean (SE) 5.3 (0.4) hours/night CPAP) than with a face mask (4.3 (0.5) hours/night CPAP), $p = 0.01$ (mean difference 1.0 hour/night, 95% CI 1.8 to 0.3). Nose masks were rated more comfortable by 19 of 20 patients ($p < 0.001$) despite more mouth leak related symptoms. For SAHS/U3P patients compliance was marginally higher with nose masks (5.1 (0.7) hours/night CPAP) than with face masks (4.0 (0.8) hours/night CPAP), $p = 0.07$ (mean difference 1.1 hour/night, 95% CI 2.1 to 0.1). Nose masks were rated more comfortable by seven of 10 patients. There were no significant differences in side effect scores with face and nose masks. At one year nine of 10 SAHS patients and nine of 10 SAHS/U3P patients were still using CPAP. Compliance was 5.4 (0.6) hours/night for the SAHS patients and 3.5 (0.4) hours/night for the SAHS/U3P pa-

tients, $p = 0.02$ (mean difference 1.9 hour/night, 95% CI 3.6 to 0.3).

Conclusions—Compliance is greater with nose mask CPAP than with face mask CPAP because the overall comfort is better and compensates for increased symptoms associated with mouth leakage. Improved face mask design is needed.

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Keywords: continuous positive airway pressure; sleep apnoea/hypopnoea syndrome; face masks

Continuous positive airway pressure (CPAP) therapy for sleep apnoea/hypopnoea syndrome (SAHS) is traditionally given via a nose mask. However, many patients with SAHS find this method of treatment unsatisfactory, often due to symptoms related to mouth air leakage.¹ Patients who have had unsuccessful uvulopalatopharyngoplasties (U3P) for treatment of SAHS are particularly likely to experience increased mouth leakage on nasal CPAP which is associated with reduced nightly compliance.² The CPAP pressure required is essentially the same for nose masks and face masks,³ so face masks which cover both nose and mouth may be advantageous if they reduce the symptoms associated with mouth leakage.

We have compared nose and face mask CPAP therapy with respect to side effects from the mask and compliance in newly diagnosed patients with SAHS in a randomised double limb trial. We also compared nose and face mask CPAP in patients with unsuccessful uvulopalatopharyngoplasties for treatment of SAHS (SAHS/U3P patients).

Methods

All subjects gave informed consent to take part in the study.

RANDOMISED TRIAL

Twenty consecutive newly diagnosed patients with SAHS (mean (SE) apnoea/hypopnoea index 34 (5.2)/hour, age 52 (3) years, body mass index 32 (1) kg/m², CPAP pressure 9 (1) cm H₂O) were enrolled into the study after their CPAP titration night. Initial CPAP titration was performed using a nose mask. Patients were randomised to face mask or nose mask CPAP for four weeks each. At the end of

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Table 1 Median symptom scores for face mask (FM) and nose mask (NM) CPAP therapy in patients with sleep apnoea/hypopnoea syndrome (SAHS) with and without uvulopalatopharyngoplasty (U3P)

	SAHS patients (n=20)			U3P/SAHS patients (n=10)		
	FM	NM	p value	FM	NM	p value
Daytime sleepiness	2.0	1.5	0.07	3.9	3.5	0.1
Mask comfort	1.1	6.5	0.001	2.1	6.7	0.06
Sore nasal bridge	1.0	2.0	0.06	2.0	2.0	0.9
Nasal stuffiness	1.5	1.0	0.7	1.5	3.5	0.1
Dry throat/mouth	1.0	2.0	0.03	2.5	4.6	0.4
Dry nose	0	1.5	0.05	2.7	3.6	0.3
Mask leak	6.0	1.0	0.003	6.3	2.6	0.3
Red/sore eyes	1.4	0	0.02	2.0	2.0	0.2
Snoring	0	0.5	0.4	1.1	2.1	0.3
Claustrophobia	4.0	0	0.0004	2.5	0.5	0.6
Difficulty exhaling	1.0	0	0.04	0.5	2.0	0.6

each limb subjects were asked to complete a questionnaire on side effects relating to the mask (10 cm visual analogue scale) and the Epworth sleepiness score.⁴ CPAP compliance was also assessed covertly as CPAP machine (Sullivan III, Resmed, Sydney, Australia) run time (hours/night).

NON-RANDOMISED TRIAL

Ten SAHS patients with U3P (mean (SE) apnoea/hypopnoea index 46 (10)/hour, age 50 (3) years, body mass index 31 (4) kg/m², CPAP pressure 10.5 (1) cm H₂O) who had recently started nose mask CPAP therapy were offered face mask treatment for four weeks. Prior to starting face mask CPAP patients completed the symptom questionnaire and compliance with nose mask CPAP was measured. At the end of the face mask trial period they completed the symptom questionnaire and CPAP compliance was calculated.

COMPARISON OF LONG TERM COMPLIANCE

Ten patients with SAHS from the randomised trial were matched with the 10 SAHS/U3P patients for age (p = 0.3), body mass index (p = 0.6), apnoea/hypopnoea index (p = 0.2), and CPAP pressure (p = 0.3). These patients were followed up for one year after the randomised and non-randomised trials so that long term compliance could be assessed.

MASKS

Patients were offered either Resmed (Sydney, Australia) or Respironics (Pennsylvania, USA) nose masks. Face masks were Respironics. Masks were fitted/sized in the laboratory and patients were given a day time trial of CPAP for approximately 40 minutes in order to facilitate mask choice.

FOLLOW UP

All patients were followed up in the sleep clinic/laboratory after CPAP titration using the same protocol by staff who were unaware of the trials. Additional supportive measures including changing mask sizes were taken if appropriate during follow up in an effort to maximise compliance.

ANALYSIS OF RESULTS

Comparisons were made using *t* tests or Wilcoxon matched pairs signed rank tests as appropriate.

Results

RANDOMISED TRIAL

Median nose and face mask questionnaire symptom scores are shown in table 1. Nightly compliance by patients with SAHS was higher with a nose mask (5.3 (0.4) hours/night) than with a face mask (4.3 (0.5) hours/night), p = 0.01 (mean difference 1 hour/night, 95% CI 1.8 to 0.3) and the Epworth score was lower with nose mask CPAP (nose mask 8.2 (0.9) and face mask 9.8 (0.9), p<0.01). Face masks were rated more comfortable by only one of the 20 subjects.

NON-RANDOMISED TRIAL

Questionnaire symptom scores with nose and face masks for SAHS/U3P patients are shown in table 1. Nightly compliance was higher with nose masks (5.1 (0.7) hours/night) than with full face masks (4.0 (0.8) hours/night), but the difference was not statistically significant, p = 0.07 (mean difference 1.1 hour/night, 95% CI 2.1 to 0.1). The Epworth score was no different between nose and face masks (face mask 10 (2), nose mask 9 (1), p = 0.9). Full face masks were rated more comfortable by three of the 10 subjects.

COMPARISON OF LONG TERM COMPLIANCE

At one year one patient from each group had stopped using CPAP. All nine patients with SAHS on CPAP therapy were using a nose mask and only one of the SAHS/U3P patients was using a full face mask. Compliance was 5.4 (0.6) hours/night for the SAHS patients and 3.5 (0.4) hours/night for the SAHS/U3P patients, p = 0.02 (mean difference 1.9 hours/night, 95% CI 3.6 to 0.3).

There were no significant weight changes in any of the groups during the trial periods.

Discussion

Overall, for the 20 SAHS patients face mask use significantly reduced complaints of dry mouth/nose but at the expense of more problems associated with air leaks from around the edge of the mask and increased feelings of claustrophobia. Nose masks were rated significantly more comfortable than face masks with 19 patients with SAHS preferring nose mask CPAP therapy. The lone patient preferring face mask CPAP had significant problems with mouth leakage using nose masks.

Three of 10 SAHS/U3P patients preferred face mask CPAP therapy. Symptoms of mouth leakage were marginally reduced by face masks compared with nose masks (table 1) but symptoms associated with mask comfort were worse and presumably contributed to the overall mask preference. In addition, most of the patients had been on nose mask CPAP therapy for longer than the four weeks of the face mask trial which probably served to enhance the rating of the nose masks.

After one year of follow up all the SAHS patients had used nose masks exclusively and demonstrated significantly better compliance than matched SAHS/U3P patients which is consistent with our previous findings.⁴ Eight of

nine SAHS/U3P patients used nose masks exclusively during this period.

There were no incentives to enter the trials and SAHS/U3P patients were not aware of CPAP therapy at the time of operation and therefore were not initially biased against CPAP therapy.

We conclude that, despite the potential advantages of face masks in terms of reduction in mouth leak associated symptoms, nose masks are more comfortable than currently available face masks and overall symptom scores are therefore better with nose masks. Face mask CPAP therapy is, however, a useful alternative in a few patients. Face mask use

does not seem to resolve completely the problem of decreased CPAP compliance in SAHS/U3P patients. Improved face mask design in future may overcome this limitation.

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Reduced mortality in association with the acute respiratory distress syndrome (ARDS)

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Abstract

Background—A study was undertaken to investigate possible reductions in mortality and/or changes in outcome predictive factors in patients with the acute respiratory distress syndrome (ARDS) managed in a single centre.

Methods—The study was a prospective observational cohort study of two patient populations with ARDS. Group 1 comprised 41 patients enrolled between May 1990 and April 1993, and group 2 consisted of 78 patients enrolled between June 1993 and March 1997. The end points of the study were mortality and various factors predictive of death.

Results—There was a marked reduction in mortality between groups 1 and 2 (66% versus 34%; relative risk 1.77; CI 1.23 to 2.55). There were no significant differences between the groups in terms of age (40.6 (3.3) versus 45.5 (2.2) years), APACHE score (14.5 (0.72) versus 13.6 (0.1)), lung injury score (2.95 (0.07) versus 2.8 (0.1)), incidence of multi-organ failure (29% versus 32%), incidence of sepsis (31% versus 39%), or P_{aO_2}/F_{iO_2} (kPa) ratio (11.8 (0.67) versus 12.0 (0.6)). There was a significantly lower proportion of men in group 1 (51% versus 74%). The case mix of the two groups was closely matched: following elective surgery 48% versus 48%, trauma 17% versus 16%, primary lung injury 12% versus 24%. Patients in group 1 were supported using several ventilatory and other modes (volume preset, non-inverse ratio ventilation, $n = 15$; pressure controlled inverse ratio ventilation (PC-IRV), $n = 11$; ultra high frequency jet ventilation (UHFJV), $n = 13$; an intravascular

oxygenation device (IVOX) and extracorporeal gas exchange (ECGE), $n = 2$). Within group 1 no significant difference in mortality was observed between the patients on volume controlled ventilation and the remainder. In group 2 all patients received PC-IRV ($n = 78$) but, in addition, some received other support techniques (UHFJV $n = 4$, ECGE $n = 2$). In group 1 only sepsis on admission (21% (survivors) versus 56% (non-survivors)) predicted death. In group 2 age of survivors and non-survivors (41.2 (2.6) versus 52.6 (3.5)), APACHE score (12.2 (0.6) versus 15.8 (0.9)), and P_{aO_2}/F_{iO_2} (12.8 (0.86) versus 10.5 (0.72)) predicted survival, but not the incidence of sepsis or multi-organ failure.

Conclusions—In recent years a highly significant reduction in mortality associated with ARDS has been observed between two groups of patients well matched for disease severity and case mix. Changes in ICU organisation rather than specific interventions may account for this reduction, although different ventilatory and other management strategies used in the two groups may also be relevant.

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Keywords: acute respiratory distress syndrome (ARDS); prognosis; outcome

The acute respiratory distress syndrome (ARDS) in adults is characterised by refractory hypoxaemia in the presence of radiographic evidence of bilateral pulmonary infiltration. ARDS may be precipitated by a number of direct and indirect pulmonary insults. A survey of the relevant literature suggests that little

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Table 1 Mean (SE) demographic and clinical characteristics of patient populations

	Group 1 (1990–93) (n = 41)	Group 2 (1993–97) (n = 78)	p value
Mortality	27 (66%)	29 (34%)	0.003
M/F	21/20	58/20	0.01
Age	40.6 (3.3)	45.5 (2.2)	0.2
APACHE II	14.5 (0.72)	13.6 (0.1)	0.2
Lung injury score	2.95 (0.07)	2.8 (0.1)	0.22
Pao ₂ /Fio ₂	11.8 (0.67)	12.0 (0.6)	0.13
Sepsis on admission	13/41 (31%)	31/78 (39%)	0.4
MOF on admission	12/41 (29%)	25/78 (32%)	0.5

MOF = multi-system organ failure.

change occurred in the high associated mortality (40–80%) from 1967 when the syndrome was first formally described¹ until approximately 1994.² Moreover, certain precipitating conditions such as generalised sepsis and primary pulmonary disease are associated with a higher mortality than others such as trauma and fat emboli. Nevertheless, other recent studies suggest that the mortality associated with ARDS has fallen in certain centres³ and that improved modes of ventilatory support may be a major contributing factor to improved outcome.⁴

Our previously published data⁵ concerning outcome in ARDS represent the only sizable UK series from a tertiary referral centre and indicated a mortality of 66% from 1990 to April 1993. In view of the suggestion that modern approaches to the clinical management of this condition have made an impact on the mortality associated with ARDS, we have reassessed our outcome data in patients admitted to our unit from June 1993. Direct comparisons were made with our previously published data to assess whether there has been a change in mortality or factors predictive of outcome.

Methods

PATIENT POPULATION

Patients were enrolled prospectively from 1990 to 1997. They were divided into two groups: group 1 (n = 41) enrolled between May 1990 and April 1993⁵ and group 2 (n = 78) enrolled from June 1993 to March 1997. The referral basis of the two groups was identical with 21 of 41 patients (51%) in group 1 and 40 of 78 (51%) in group 2 being referred from other centres.

The enrolment criteria were as follows. Briefly, a clinical condition associated with ARDS was identified in the presence of bilateral pulmonary infiltrates on chest radiography. In group 1 refractory hypoxaemia was defined as a ratio of arterial oxygen tension to fractional inspired oxygen concentration (Pao₂/Fio₂ (kPa)) of <20. Following the publication of the Consensus Guidelines criteria for the definition of ARDS in 1994⁶ a Pao₂/Fio₂ ratio of <26.7 was used for patients in group 2. In both groups the pulmonary artery occlusion pressure (PAOP) was required to be less than 18 mm Hg. In all cases lung injury (LIS, according to the criteria of Murray⁷) and acute physiology and chronic health evaluation (APACHE II) scores were recorded on the day of admission or on the day on which ARDS was diagnosed and were calculated from the worst

values obtained within the first 24 hours. Organ system failures were defined according to the criteria of Montgomery *et al.*⁸ and sepsis was defined according to the consensus criteria published in 1992.⁹

CLINICAL MANAGEMENT

All patients were managed with mechanical ventilation (Drager Evita I or II, Drager UK Ltd, Luton, Bedfordshire, UK) using a balloon tipped pulmonary artery catheter of the thermodilution type. The mode of ventilation employed at the time of most severe lung injury was noted. The presence or absence of sepsis (defined according to the criteria of the ACCP/SCCM⁷) and organ dysfunction were noted. Mortality was defined as death in hospital.

STATISTICAL ANALYSIS

Data are presented as mean (SE) throughout. Statistical analysis was performed using Fisher's exact test or the unpaired *t* test with *p* values equal to or less than 0.05 being considered significant.

Results

There were no significant differences between the two groups in terms of age (40.6 (3.3) versus 45.5 (2.2) years, *p* = 0.22), APACHE score (14.5 (0.72) versus 13.6 (0.1), *p* = 0.2), Lung Injury Score (2.95 (0.07) versus 2.8 (0.1), *p* = 0.22), Pao₂/Fio₂ ratio (11.8 (0.67) versus 12.0 (0.6), *p* = 0.13), incidence of multi-system organ failure on admission (29% (12/41) versus 32% (25/78), *p* = 0.5), or incidence of sepsis on admission (31% versus 39%, *p* = 0.40). There was a significantly lower proportion of men in group 1 (51% versus 74%, *p* = 0.01; table 1)

The case mix of the two groups was closely matched (postoperative 48% versus 48%, trauma 17% versus 16%, primary lung injury 12% versus 24% for groups 1 and 2, respectively, *p* = 0.23). Patients in group 1 were ventilated using several different modes (volume preset, non-inverse ratio, n = 15; pressure controlled, PC-IRV, n = 11; ultra high frequency jet ventilation (UHFJV), n = 13; extracorporeal or intracorporeal gas exchange (ECGE), n = 2). All the patients in group 2 received PC-IRV but, in addition, some received other support techniques (UHFJV, n = 4; ECGE, n = 2).

There was a highly significant reduction in mortality between patients in group 1 (66%) and group 2 (34%; *p* = 0.0037; relative risk, 1.77; CI 1.23 to 2.55).

In group 1 the presence of sepsis on admission, seen in 21% of survivors and 56% of non-survivors, was the sole predictor of death (*p* = 0.05). No significant difference in mortality was observed between patients receiving volume-controlled ventilation and the remainder. In group 2 age (41.2 (2.6) versus 52.6 (3.5), *p* = 0.01), APACHE II score (12.2 (0.6) versus 15.8 (0.9), *p* = 0.001), and Pao₂/Fio₂ (12.8 (0.86) versus 10.5 (0.72), *p* = 0.04) for survivors and non-survivors, respectively, were significant predictors of survival. Sepsis (survivors 47% versus non-survivors

31%, $p = 0.2$) and multi-organ failure (survivors 36% versus non-survivors 41%, $p = 0.2$) at the time of admission were not predictive of survival.

Discussion

Recent publications³ have suggested that a dramatic reduction in the mortality associated with ARDS may have occurred in recent years and the results of this study seem to confirm this impression. The authors acknowledge that there was a slight loosening of the oxygenation entry criteria in 1994 following publication of the consensus guidelines. However, the two cohorts were not significantly different with regard to lung injury score, APACHE II score, and incidence of multi-organ failure or sepsis on admission, and the case mix was almost identical in terms of precipitating condition which is known to influence outcome in ARDS. In particular, the mean P_{aO_2}/F_{iO_2} ratio of the two groups was almost identical. Thus, the change in entry P_{aO_2}/F_{iO_2} ratio cannot explain the reduction in mortality.

Examination of possible predictive factors for mortality was revealing. Age, APACHE II scores, and P_{aO_2}/F_{iO_2} ratios which predicted survival in group 2 were not significant in group 1. Moreover, the presence of sepsis at admission was a significant predictor of death in group 1, yet was not in group 2. Increased awareness of the dangers of sepsis in recent years has led to advances in the prevention and diagnosis of nosocomial infection¹⁰ which suggests that strategies to prevent this common complication of critical illness have improved in recent years. However, within group 2 47% of survivors displayed evidence of sepsis at the time of admission compared with 31% of non-survivors ($p > 0.05$), which suggests that better management of sepsis may also have been an important factor in improving outcome.

The predictive power of indices of the severity of illness (APACHE II) and respiratory failure (LIS, P_{aO_2}/F_{iO_2}) was surprising in that neither have had clear prognostic significance in other published series.² Moreover, the majority of patients with ARDS do not die of respiratory insufficiency but rather of multiple organ failure,¹¹ the incidence of which was not predictive of mortality in this study.

The optimal mode of ventilatory support for patients with ARDS has been the subject of considerable debate in recent years. Specifically, a recently published randomised controlled study has shown improved outcome in patients with ARDS using a low volume, pressure-limited strategy aimed at alveolar recruitment compared with a traditional preset volume-controlled ventilatory approach.⁴ Our ventilatory strategy has certainly changed in recent years. All patients in group 2 were supported using PC-IRV with only six receiving

other support techniques. In contrast, patients in group 1 received a variety of ventilatory and other support techniques. However, within group 1 there were no differences in survival between those who received a traditional volume controlled strategy and those who received other support techniques. Unfortunately, as the various modes of support were not allocated as part of a structured protocol over the eight year period, it is not possible to draw reliable conclusions about the efficacy of any particular mode in this study. Other therapeutic support systems such as inhaled nitric oxide, turning patients prone, and (late) administration of corticosteroids have also been widely used on an individual patient basis. Their potential contribution to the improved overall mortality figures in patients in group 2 cannot therefore be meaningfully assessed.

This study has clearly shown that, within our unit, there has been an improvement in outcome associated with ARDS over an eight year period in patients well matched for disease severity and case mix. Unfortunately no clear answers as to why this should be so have emerged from our data or, indeed, that published by others. We suggest that the improvement is most likely to be multifactorial in origin, attributable both to better general patient management strategies—particularly those of ventilation and sepsis—and to the use of newer therapeutic strategies such as inhaled nitric oxide, prone positioning, and late administration of corticosteroids.

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