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Evaluation of nasopharyngeal oxygen, nasal prongs and facemask oxygen therapy devices in adult patients: a randomised crossover trial

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SUMMARY

Nasopharyngeal oxygen (NPO) therapy may overcome some of the difficulties associated with nasal prongs and facemask oxygen delivery devices. In response to a lack of published studies of NPO therapy in adults, we conducted a prospective randomised crossover trial to compare the effectiveness of NPO, nasal prongs (NP) and facemasks (FM) when used in an adult population (n=37) from the intensive care unit and general hospital wards. We measured oxygen saturation (SpO_2) using pulse oximetry, oxygen flow (litres per minute), respiration rate (per minute) and comfort using a horizontal visual analogue scale. All three devices were effective in maintaining a SpO_2 of ≥95% (NP 97.0±1.9, NPO 97.7±1.7, FM 98.8±1.3%). NPO therapy consumed less oxygen than NP and FM therapy (NP 2.6±1.0, NPO 2.2±0.9, FM 6.1±0.4 l/min, P <0.001). There was no significant difference in patients' respiratory rates (NP 19.9±3.2, NPO 19.9±3.0, FM 19.8±3.1 per minute, P=0.491). In terms of comfort, patients rated NP higher than NPO and FM using a horizontal visual analogue scale (100 mm=most comfortable) (NP 65.5±14.3, NPO 62.8±19.4, FM 49.4±21.4 mm, P <0.001). We conclude that for adult patients, nasal prongs and nasopharyngeal oxygen therapy consume less oxygen and provide greater comfort than facemasks while still maintaining SpO_2 ≥95%.

Key Words: nasopharyngeal oxygen, nasal prongs, facemask oxygen

Low-flow oxygen therapy devices such as nasal prongs (NP) and simple facemasks (FM) are commonly used in clinical practice. Nasopharyngeal oxygen (NPO) therapy, the delivery of supplemental oxygen directly into the nasopharynx via an oxygen catheter, may overcome some of the difficulties associated with NP and FM oxygen delivery devices. There are few published studies on the use of NPO therapy in adult patients[1]. To understand whether increased use of NPO therapy in adult patients is a feasible alternative to NP and FM, we conducted a prospective randomised crossover trial. The primary outcome measures were: 1) oxygen saturation (SpO_2) using pulse oximetry, 2) oxygen flow (litres per minute), 3) respiration rate (per minute) and 4) comfort using a horizontal visual analogue scale (HVAS).

MATERIALS AND METHODS

Following institutional ethics committee approval, adult patients from the intensive care unit and general hospital wards of two metropolitan hospitals in Melbourne, Australia, were recruited. Data were collected between February and September 2007. Eligible patients were: 1) ≥18 years of age, 2) spontaneously breathing, 3) receiving supplemental oxygen and 4) able to provide informed consent. Patients were excluded if they required high-flow, non-invasive or mechanical ventilation, had a contraindication to the insertion of an oxygen catheter or were particularly susceptible to alterations in oxygen delivery. In order to have a representative sample of typical intensive care unit and general ward patients, no attempt was made to recruit any homogeneous group.

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The oxygen therapy devices used were the 10 FG oxygen catheter (Unomedical, Australia), adult nasal cannula straight prong with 1.8 m tube (Intersurgical, UK) and the adult medium concentration Aerflo Oxygen Mask (Unomedical, Australia). In addition, the pulse oximeters used were the 8500 Digital Handheld Pulse Oximeter (Nonin, USA) and the M1911A Reusable SpO_2 Sensor via the IntelliVue MP90 clinical monitoring system (Philips Healthcare, Australia). Patients from the intensive care unit had fixed pulse oximeters at their bed space, while general ward patients were tested using a portable handheld pulse oximeter. All pulse oximeters are regularly calibrated by the organisation's biomedical engineering department: no attempt was made to cross calibrate the pulse oximeters.

Permuted block randomisation was performed and patients received oxygen by all three devices[2]. The three trial arms for this study were: Arm 1 – NP, NPO, FM; Arm 2 – NPO, FM, NP and Arm 3 – FM, NPO, NP. Each arm of the trial was conducted by GME who had previous experience in administering oxygen by each device. Although the sequentially numbered opaque sealed envelope[3] method of allocation concealment was used, it was impossible to blind GME to the trial arm once randomisation was completed, as the oxygen therapy devices are clearly different.

During each treatment period the oxygen device was correctly fitted. To achieve NPO therapy an oxygen catheter was inserted through a nostril and advanced to the depth of the nasopharynx (equal to the distance from the base of the nose to the beginning of the ear)[4]. The oxygen catheter was secured in position by placing a 3M™ Tegaderm™ (6×7 cm) transparent film dressing (3M Health Care, USA) on the patient's cheek. For NP therapy, the NP tubing was looped over the patient's ears and secured under the chin using the device toggle. For FM therapy, the mask was placed over the patient's nose and mouth and the strapping tightened to achieve a secure and firm fit.

As stated previously, all patients in this study were already receiving oxygen by low-flow devices. Low-flow oxygen therapy devices are generally used in patients with minimal respiratory distress and who require low-level oxygen supplementation. All patients enrolled in the study had normal SpO_2 at the commencement of data collection. For each treatment period, non-humidified oxygen flow was used and the oxygen flow rate was increased to achieve a target SpO_2 of ≥95%. After a period of 10 minutes and achievement of stable SpO_2 waveform, the patient's SpO_2, respiration rate and oxygen flow rate were recorded. Previous studies have demonstrated that 10 minutes is an adequate interval for measuring changes in FiO_2[1,5]. To minimise the interruption to oxygen delivery, the low-flow oxygen therapy device was immediately changed between treatment periods. Following each change of device, the oxygen flow rate was increased to achieve a target SpO_2 of ≥95%. After the third treatment period, each patient rated his or her level of comfort for each device using 100 mm HVAS (0 mm=most uncomfortable to 100 mm=most comfortable). The 10-minute duration of each treatment period served as the washout period for the trial.

Sample size was calculated using the ANOVA module in a software package (PASS, 2004, Utah, USA). Estimated effect size from pilot data was 0.5. Based on this effect size, a sample size of 39 patients would achieve 0.8 power at the 0.05 significance level. The comfort rating for each device was calculated as the distance from the left side (0 mm=most uncomfortable) of the HVAS to the mark placed by the patient. Descriptive statistics and one-way repeated measures ANOVA were performed using SPSS statistical package V.14 for Windows (2005) for data analysis.

RESULTS

Of 73 eligible patients, 37 patients agreed to participate in the study (51%). Reasons for declining were: did not wish to participate (21), did not like the thought of the catheter being inserted through the nose (7), the patient not feeling well enough to participate (5) and nurse refusal on behalf of the patient (3). Of the 37 patients who completed the study, 24 were male and 13 were female. Their mean age was 68 years (SD 10). Seventeen were cardiothoracic patients and 20 were medical/surgical patients.

All devices were effective at maintaining SpO_2 above 97% and patients' respiration rates were unaffected by changes in device. Although there was a statistically significant difference between SpO_2 for the devices, the difference was not clinically significant. NPO required a significantly lower oxygen flow rate compared to NP and FM to achieve an equivalent SpO_2. As expected, FM required more oxygen flow than the nasal devices. There were significant differences in comfort ratings for the three devices with FM rated as the least comfortable by patients. The results of the randomised crossover trial are shown in Table 1.

TABLE 1
Comparison of three low-flow oxygen delivery devices

	Mean (SD)				Multiple comparison
Variable	(1) NP	(2) NPO	(3) FM	*P*	
Oxygenation (SpO_2*)%	97.0 (1.9)	97.7 (1.7)	98.8 (1.3)	<0.001	(1)≠(2)≠(3)
Oxygen flow l/min	2.6 (1.0)	2.2 (0.9)	6.1 (0.4)	<0.001	(1)≠(2)≠(3)
Respiration rate/min	19.9 (3.2)	19.9 (3.0)	19.8 (3.1)	0.491	
Comfort (HVAS mm†)	65.5 (14.3)	62.8 (19.4)	49.4 (21.4)	<0.001	[(1)=(2)]≠(3)

NP=nasal prongs, NPO=nasopharyngeal oxygen, FM=facemask.
*SpO_2 oxygen saturation measured by pulse oximetry. † HVAS=Horizontal visual analogue scale, measured in millimeters (0 mm=most uncomfortable to 100 mm=most comfortable).

DISCUSSION

The findings of the study indicated that all three devices maintained SpO_2 above 97%, therefore meeting the study target of a SpO_2 ≥95%. This finding is important as it suggests that all devices are effective in preventing hypoxaemia and maintaining a normal SpO_2 (>95%). There were no significant differences in respiratory rate between the three devices tested, suggesting that patients did not alter their respiration rate to compensate for a change in oxygen supply.

The absence of indicators of respiratory dysfunction (hypoxaemia, tachypnoea and bradypnoea) for each device tested suggests that the devices were safe and effective at providing low-flow oxygen supplementation for the assessment period. Other studies comparing NP, FM and binasal catheters have shown equivalence in maintaining SpO_2 when the device was correctly positioned[6,7].

In terms of comfort, patients preferred the nasal devices to the FM. Comfort is an important consideration, as comfort is a key factor in compliance with oxygen therapy: interruptions to oxygen therapy place patients at significant risk of hypoxaemia/hypoxia. It is acknowledged that the patient comfort findings may be skewed because of the number (n=28) of patients who declined to participate. Nevertheless, other studies have also shown that patients rate nasal devices (NP and binasal catheters) as more comfortable than FM[6,7]. Further, NP are more likely to remain in situ than FM and are therefore are more likely to maintain and adequate saturation in most patients[6].

FM used significantly higher oxygen flow rates than nasal devices (NPO and NP) to achieve equivalent SpO_2 concentrations. This finding is not surprising given that the minimum flow rate for use with a simple facemask is generally accepted to be six litres per minute to avoid re-breathing of exhaled carbon dioxide[8]. Cost and access to oxygen supply are important (especially in remote locations or developing countries), however the focus of this study was the physiological efficacy of the three devices tested.

Limitations of this and other randomised crossover trials include the possibility of order and carry-over related effects[9]. Typically a 'washout' period lessens the impact of any carry-over effect, yet in this instance, interrupting the delivery of oxygen to patients may have been a threat to patient safety. In lieu of a washout period, a 10-minute period between oxygen administration and outcome measurement for each device was included in the study protocol. To minimise order-related effects, three trial arms were used. While the potential of order and carry-over related effects was recognised a priori, a parallel trial would have doubled the number of patient participants, prolonged the duration of the study and prevented patients from trialling all three devices.

In conclusion, the findings of this study have shown that for adult patients with low level oxygen supplementation requirements, nasal devices allow for less oxygen consumption and greater comfort than facemasks while still maintaining SpO_2 ≥95%. Nasal prongs are used in current practice, however, nasopharyngeal oxygen therapy may be an alternative nasal oxygen delivery device. Future research in the use of nasal prongs and nasopharyngeal oxygen in patients with higher oxygen requirements would be helpful.

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