ORIGINAL ARTICLE

Effect of Proximal Oxygen Adding to a Bag Valve Mask with a Mechanical Filter in Healthy Volunteers: A Randomized Crossover Trial

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Background: Preoxygenation using a bag valve mask (BVM) with a filter is recommended to reduce the risk of viral transmission. Preoxygenation in hypoxaemic patients may require a positive end-expiratory pressure (PEEP) valve. Applying a filter to a BVM with or without a PEEP valve can increase resistance and work of breathing.

Objective: To evaluate the efficacy of proximal oxygen added to BVM with mechanical filter in healthy volunteers.

Materials and Methods: The present study was a crossover trial that randomized 48 volunteers to receive four preoxygenation techniques: BVM with a filter as group F, BVM with a filter and proximal oxygen as group FO, BVM with a filter and PEEP valve as group FP, and BVM with a filter, PEEP valve, and proximal oxygen as group FPO. Fraction of expired oxygen (FEO_2) and continuous positive airway pressure (CPAP) were measured. Comfort was assessed using a numerical rating scale (NRS). The primary outcome was FEO_2 at five minutes.

Results: Data from 46 volunteers were analyzed. Adding oxygen proximal to the filter in the FO group increased FEO_2 at five minutes by 7.07% (95% CI 4.87 to 9.26) and decreased the time to reach FEO_2 90% by 301.74 seconds (95% CI 282.82 to 320.66) compared with the times in group F. Similarly, supplemental proximal oxygen including a PEEP valve increased FEO_2 at five minutes by 6.07% (95% CI 3.87 to 8.26) and decreased the time to reach FEO_2 90% by 242.13 seconds (95% CI 223.21 to 261.05). CPAP was 2.27, 3.61, 11.65, and 13.14 mmHg in group F, FO, FP, and FPO, respectively. The NRS score was 6.51 and 6.07 in groups F and FO, and 3.15 and 3.70 in groups FP and FPO, respectively.

Conclusion: Adding proximal oxygen to a BVM with a filter improved the efficacy of preoxygenation.

Keywords: Bag valve mask; Efficacy of preoxygenation; Healthy volunteers; Mechanical filter; Positive end-expiratory pressure; Positive end-expiratory pressure valve

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An outbreak of a novel coronavirus began in mid-December 2019. Most infected patients had mild or no symptoms; however, 5% of cases developed respiratory failure and required endotracheal intubation[1]. Endotracheal intubation and positive pressure ventilation are aerosol-generating procedures that increase the risk of viral transmission among health care workers. Guidelines have recommended rapid sequence induction for endotracheal intubation to avoid positive pressure ventilation before intubation[2-5]. Preoxygenation with 100% oxygen should be performed for three to five minutes or until end-tidal oxygen reaches 90% before intubation to minimize the risk of hypoxaemia during the apnoeic period[3,6]. A high-efficiency hydrophobic filter should be interposed between the face mask and the breathing circuit or between the face mask and a bag valve mask (BVM)[3,4,6,7]. In patients with hypoxaemia, a positive end-expiratory pressure (PEEP) valve may be applied to improve oxygenation[8].

Applying a high-efficiency hydrophobic filter or mechanical filter increases resistance of air flow during preoxygenation. The resistance is reported as pressure across the filter, and values vary from 0.8 to 3.5 cmH_2O, depending on the flow rate and type of filter[9]. This extra pressure is required to drive the oxygen from the distal part of the system to flow across the filter to the patient end of the system. This

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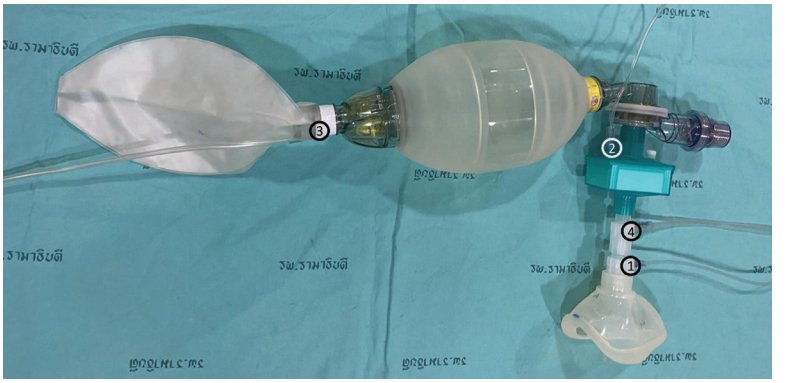

Figure 1. Assembly of BVM in FPO group. The BVM was connected to a reservoir bag, mechanical filter, facemask, and PEEP valve. Two extra straight connectors with sampling port were located between facemask and mechanical filter. Pressure monitoring tubing (1) was attached to an adapter near the facemask. Gas sampling tubing (2) was attached to the gas sampling port at mechanical filter opposite to the patient side. There were two oxygen connection points, the distal one (3) was located at the normal oxygen port of the BVM. The proximal one (4) was at an adapter near the mechanical filter. Oxygen flow were 15 liters per minute. PEEP valve was set at 10 mmHg.

pressure can be generated either by negative pressure from the patient or by positive pressure from distal high oxygen flow. Adding a PEEP valve to a BVM results in increased resistance at the BVM expiratory port. Therefore, distal oxygen is more likely to be released at the distal relief valve rather than moving to the proximal part near the patient. As a result, the combination of a filter and a PEEP valve with a BVM may dramatically increase the work of breathing and reduce oxygen flow to the patient leading to a longer time required for adequate preoxygenation.

Adding oxygen proximal to the filter is one method to supply oxygen directly to the patient. Studies added proximal oxygen through a nasal cannula during preoxygenation and found that the efficacy of preoxygenation improved in some conditions[10,11]. The authors hypothesized that adding oxygen proximal to the filter would provide oxygen directly to the patient regardless of the resistance created by the filter and PEEP valve. Therefore, proximal oxygen should improve the efficacy of preoxygenation and decrease the work of breathing in a BVM system with a filter and a PEEP valve. The aim of the present study was to evaluate the efficacy of proximal oxygen adding to BVM with mechanical filter with or without PEEP valve during preoxygenation.

Materials and Methods

The present trial was reviewed and approved by the Human Research Ethics Committee, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Thailand, on March 23, 2021 (COA No. MURA2021/220), and registered at thaiclinicaltrials.org (Study ID TCTR20210720001 on July 18, 2021). The present study was conducted between July 20 and September 13, 2021. The trial was conducted in accordance with the principles stated in the Declaration of Helsinki and Good Clinical Practice guidelines. Written informed consent was obtained from all volunteers prior to participating in the present study.

Study design and participants

The present study was a randomized crossover trial. All volunteers received four preoxygenation techniques in different sequences. The preoxygenation techniques were BVM with a filter as group F, BVM with a filter and proximal oxygen as group FO, BVM with a filter and a PEEP valve as group FP, and BVM with a filter, PEEP valve, and proximal oxygen as group FPO. Figure 1 shows the components of the equipment in the FPO group. The filter was a Covidien DAR™ mechanical filter (compact size; Covidien, Mansfield, MA, USA). The Laerdal silicone resuscitator BVM (Laerdal Global Health, Stavanger, Norway), adult size, 1,600 mL, with an oxygen reservoir bag was used in the present study. There were two oxygen connection points in the preoxygenation system. One was the distal oxygen port that was integrated in the BVM. Fifteen liters per minute of oxygen was added to this port in all settings. Another one was the proximal oxygen connection point, which was an extra adapter located between the facemask and the mechanical filter. Fifteen liters per minute of oxygen was added to this port in FO

and FPO groups. In the FP and FPO groups, the PEEP valve was set at 10 mmHg using an adjustable PEEP valve.

Healthy volunteers aged between 20 and 65 years were included in the present study. Participants with a history of recent or current respiratory symptoms, asthma, chronic obstructive respiratory disease or pregnancy or with body mass index greater than 30 kg/m² were excluded.

Randomization and masking

There were 24 different patterns of assigning subjects to the four preoxygenation techniques. Forty-eight volunteers were included in the present study. Therefore, all possible sequences were randomized, twice in a sequence, in a complete counterbalancing design. A simple randomization was generated using the online software (www.sealedenvelope.org) by the research assistant. Allocation sequences were concealed using a closed envelope method. The envelope was opened after a blindfold was applied to the participants. GT and KS enrolled and assigned the participants to the interventions.

Procedures

Baseline fraction of expired oxygen (FEO_2) was measured before performing the first preoxygenation technique. Each technique was conducted while the subject was in the supine position, and the volunteers received preoxygenation for at least five minutes for each technique. FEO_2 and continuous positive airway pressure (CPAP) were measured each minute until five minutes after preoxygenation, and the time to reach FEO_2 90% was recorded. If FEO_2 90% was not achieved within five minutes, the preoxygenation was continued until 90% was achieved or ten minutes of preoxygenation was reached.

The CPAP level was measured by a pressure transducer connected to a Nihon Kohden monitor (model MU-651 RK; Nihon Kohden Corporation, Tokyo, Japan). FEO_2 was measured by a gas analyzer attached to a GE Healthcare anesthetic machine (model: Avance CS²; GE Healthcare, Chicago, IL, USA). The mean pressure was recorded for CPAP, and the end-tidal concentration was recorded for FEO_2.

Each participant's level of comfort during preoxygenation was assessed at the end of each technique using a numerical rating scale (NRS). The NRS score ranged from 0 to 10, where 0 was the least comfortable and 10 was the most comfortable. Preoxygenation was terminated if the volunteer was uncomfortable and unable to tolerate the procedure. After each preoxygenation technique, volunteers rested by breathing room air for 10 minutes, after which, FEO_2 was remeasured. The next preoxygenation technique was started after FEO_2 returned to baseline.

Outcomes

The primary outcome was FEO_2 five minutes after preoxygenation. The secondary outcomes were the time to reach FEO_2 90%, the CPAP level, and NRS score.

Statistical analysis

The sample size was calculated in accordance with the formula for a multiple-sample Williams crossover trial design (4 by 4 crossover). A sample size of 48 participants was estimated to ensure 80% power for detecting an expected 10% difference in FEO_2.

Data were described using mean and standard deviation (SD) or median and range, as appropriate, for continuous variables, and as percentage for categorical variables. Outcomes were compared between the F and FO groups and between the FP and FPO groups with repeated measures using multilevel mixed-effects linear regression. Outcomes were presented as mean and standard error (SE), and mean difference and 95% confident intervals. Statistical analyses were performed using Stata Statistical Software, version 17 (StataCorp LLC, College Station, TX, USA), with a significance threshold p-value of less than 0.05 (two-sided).

Results

Forty-eight healthy volunteers were enrolled. The consort flow diagram of the study population is shown in Figure 2. Two volunteers could not tolerate the preoxygenation process and were excluded from the final analysis. The first excluded volunteer experienced nasal pain during the first preoxygenation method, which was FO technique. The other excluded volunteer could not tolerate the fourth method, which was FPO technique in the fourth minute. The participants' characteristics data are shown in Table 1. Most volunteers were female at 78.3%, and the volunteers' average age was 28.3 years. Baseline FEO_2 before participating in the study was 15.3%.

The FEO_2 at five minutes, time to reach FEO_2 90%, CPAP level, and NRS score for each preoxygenation technique are presented in Table 2. The effect of adding oxygen proximal to the filter

Table 1. The participants' characteristics data

Characteristic	n=46
Age (year); mean [SD]	28.3 [3.9]
Sex; n (%)	
Female	36 (78.3)
Male	10 (21.7)
Weight (kg); mean [SD]	55.3 [10.9]
Height (m); mean [SD]	1.6 [0.1]
BMI (kg/m^2); mean [SD]	20.6 [3.1]
Baseline FEO_2 (%); mean [SD]	15.3 [1.0]

SD=standard deviation; BMI=body mass index; FEO_2=fraction of expired oxygen

in systems with or without a PEEP valve is shown in Table 3. Adding oxygen proximal to the filter in the FO group increased FEO_2 at five minutes by 7.07% and decreased the time to reach FEO_2 90% by 301.74 seconds compared with the times in the F group. Likewise, supplemental oxygen proximal to the filter when a PEEP valve was added to the FPO group, increased FEO_2 at five minutes by 6.07% and decreased the time to reach FEO_2 90% by 242.13

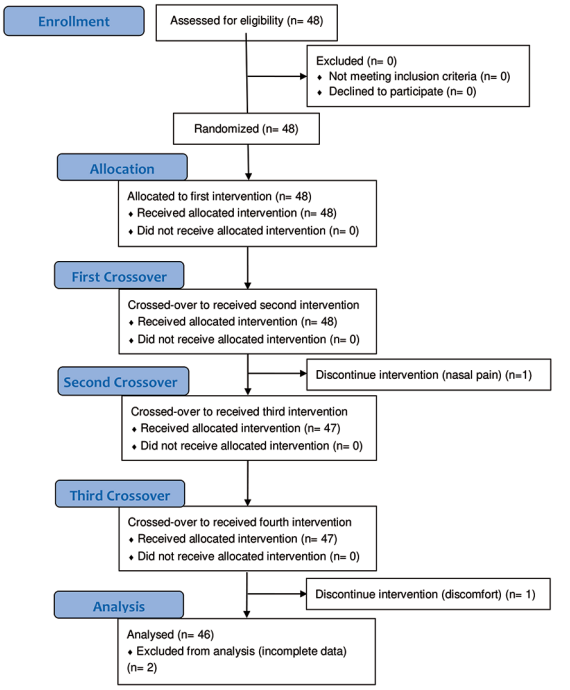

Figure 2. Consort flow diagram of the study population.

Table 2. Primary and secondary outcomes of each preoxygenation technique

Outcome	F; mean (SE)	FO; mean (SE)	FP; mean (SE)	FPO; mean (SE)
FEO_2 at 5 minutes (%)	88.85 (0.84)	95.91 (0.84)	89.24 (0.84)	95.30 (0.84)
Time to reach FEO_2 90% (second)	370.43 (14.49)	68.70 (14.49)	336.11 (14.49)	93.98 (14.49)
CPAP (mmHg)	2.27 (0.14)	3.61 (0.14)	11.65 (0.14)	13.14 (0.14)
NRS	6.51 (0.24)	6.07 (0.24)	3.15 (0.24)	3.70 (0.24)

F=bag valve mask with a filter; FO=bag valve mask with a filter and proximal oxygen; FP=bag valve mask with a filter and a positive end-expiratory pressure valve; FPO=bag valve mask with a filter, positive end-expiratory pressure valve and proximal oxygen; FEO_2=fraction of expired oxygen; SE=standard error; CPAP=continuous positive airway pressure; NRS=numerical rating scale

Table 3. Comparison of outcomes between preoxygenation techniques with and without oxygen added proximal to the filter

Outcome	Mean difference	95% CI	p-value
FEO_2 at 5 minutes (%)			
FO vs. F	7.07	4.87 to 9.26	<0.001
FPO vs. FP	6.07	3.87 to 8.26	<0.001
Time to reach FEO_2 90% (second)			
FO vs. F	−301.74	−320.66 to −282.82	<0.001
FPO vs. FP	−242.13	−261.05 to −223.21	<0.001
CPAP (mmHg)			
FO vs. F	1.34	1.11 to 1.58	<0.001
FPO vs. FP	1.49	1.26 to 1.72	<0.001
NRS			
FO vs. F	−0.43	−0.67 to −0.20	0.001
FPO vs. FP	0.54	0.31 to 0.78	<0.001

CI=confidence interval; FEO_2=fraction of expired oxygen; F=bag valve mask with a filter; FO=bag valve mask with a filter and proximal oxygen; FP=bag valve mask with a filter and a positive end-expiratory pressure valve; FPO=bag valve mask with a filter, positive end-expiratory pressure valve and proximal oxygen; CPAP=continuous positive airway pressure; NRS=numerical rating scale

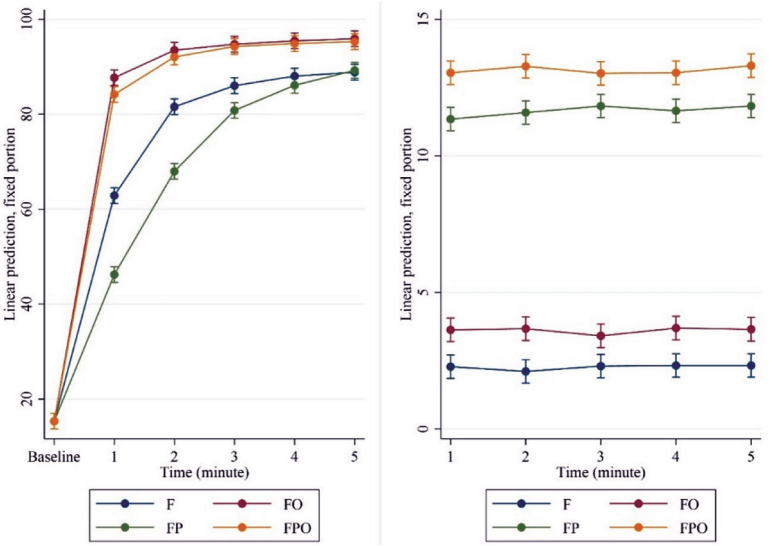

Figure 3. FEO_2 and CPAP during preoxygenation with each preoxygenation technique. The graph on the left indicates the FEO_2 values, and the graph on the right indicates the CPAP values.

seconds compared with the respective values in the FP group. Moreover, adding proximal oxygen increased the CPAP level by 1.34 mmHg in the FO group and by 1.49 mmHg in the FPO group.

Figure 3 shows the FEO_2 and CPAP values during preoxygenation with each technique. Multilevel mixed-effects linear regression showed that supplemental oxygen proximal to the filter in the FO group significantly increased FEO_2 by 10.00% (95% CI 5.28 to 14.71; $p<0.001$) compared with the FEO_2 value in the F group. Similarly, FEO_2 was 15.07% higher in the FPO group than the value in the FP group (95% CI 10.35 to 19.78; $p<0.001$).

Discomfort during preoxygenation with proximal oxygen added occurred when no PEEP valve was used. The NRS score in the FO group was less than that in the F group by 0.43. However, adding proximal oxygen improved the participants' comfort when a PEEP valve was used. The NRS score in the FPO group was higher than that in the FP group by 0.54.

Discussion

The present study found that adding oxygen to the proximal part of the system improved the efficacy of preoxygenation using a BVM with a mechanical filter. The FEO_2 value at five minutes was higher, and the time to reach an FEO_2 of 90% was faster, in the FO and FPO groups compared with the values in the F and FP groups. These results were inconsistent with those of another study that showed adding an oxygen nasal cannula and providing oxygen at 10 liters per minute during preoxygenation did not improve preoxygenation efficacy when using a well-sealed BVM[11]. Furthermore, other researchers reported that FEO_2 was lower when an oxygen nasal cannula and oxygen at a 15 liters per minute were added during preoxygenation using a BVM with or without a PEEP valve[12]. The difference between these two studies and the present study was that a mechanical filter was added to the BVM in the present study. In the Laerdal BVM system, oxygen administered at the oxygen port flows past two relief ports before reaching the patient, a positive pressure relief valve near the reservoir bag and another at the expiratory port near the patient. Adding a filter increases resistance by 0.8 to 3.5 cmH_2O[9]. In the present study, the Covidien DAR™ mechanical filter (compact size) was used, and the resistance reported by the manufacturer was 0.8 to 1.9 cmH_2O with an oxygen flow rate of 30 to 60 liters per minute[13]. With this resistance, oxygen is more likely to leave the circuit rather than running through the filter to reach the patient. Therefore, adding proximal oxygen should be more beneficial in a BVM with a filter than that in a BVM without a filter.

In a study using a BVM with a filter, the authors found that adding oxygen via a nasal cannula at a flow rate of 15 liters per minute during preoxygenation improved FEO_2 at 1 minute; however, FEO_2 plateaued at 85% to 86% at two to three minutes[10]. In contrast, in the present study, FEO_2 in the FO group was significantly higher than that in the F group until five

minutes. FEO_2 in the FO group increased from 87.6% at one minute to 93% to 94% at two to three minutes. The possible explanation for this difference was the method of adding proximal oxygen. In the present study, oxygen was added directly into the system, which led to better mask sealing and less room air contamination compared with adding proximal oxygen via a nasal cannula.

The participants' comfort level appeared to be associated with the addition of a PEEP valve rather than with oxygen added to the system. In the F and FO groups, the NRS score was 6.51 and 6.07, respectively. In comparison, the NRS scores were 3.15 and 3.70 in the FP and FPO groups, respectively. Adding oxygen appears to decrease a person's comfort level during preoxygenation in systems without a PEEP valve. This might be because of the effects of a CPAP value of 3.61 mmHg in healthy lungs. However, adding proximal oxygen appears to improve comfort during preoxygenation using a BVM with a filter with a PEEP valve. The potential reason might be that the work of breathing decreases by adding proximal oxygen. In a BVM system with a filter and a PEEP valve, during the inspiratory phase, negative pressure must be created to overcome resistance from the intake disk membrane, lip valve, and mechanical filter. During the expiratory phase, positive pressure is needed to overcome resistance from the mechanical filter, proximal disk membrane, and PEEP valve. Oxygen given directly to the patient at the proximal end of the system reduces the work to overcome these resistances. However, in the present study, the differences in the NRS scores after adding oxygen proximal to the filter were 0.55 and 0.44 in systems with and without a PEEP valve, respectively. However, the values were too small to claim any clinical significance.

The present study has limitations. First, the participants in the study were young healthy volunteers in whom the effectiveness of preoxygenation might differ from that in patients who require intubation owing to respiratory failure. Increased work of breathing usually does not cause problems in the healthy population. Therefore, the decrease in the work of breathing by adding proximal oxygen might be overpowered by discomfort owing to CPAP, in healthy lungs. Another limitation was the method of measuring FEO_2. The sampling line was connected to the mechanical filter; thus, proximal oxygen might have diluted the expiratory oxygen. However, this FEO_2 measurement method allowed continuous measurement of expired oxygen, and the method proved reliable in a previous study[10]. The authors recorded the end-tidal oxygen as described in the previous study to minimize the effect of sample line contamination[10]. Future studies are required to prove that adding proximal oxygen is beneficial in terms of effectiveness of preoxygenation and comfortableness in patients with acute respiratory failure.

Conclusion

The present study demonstrated that adding oxygen proximal to the mechanical filter in the BVM system improved the efficacy of preoxygenation, with 1.34 to 1.49 mmHg increase in CPAP. In case a PEEP valve was added to the system, participants would experience less comfort which was slightly improved by adding proximal oxygen. The authors conclude that adding proximal oxygen 15 liters per minute to the BVM system with a mechanical filter is a highly effective method of preoxygenation with low discomfort level.

What is already known on this topic?

Adding oxygen via nasal cannula 10 to 15 liters per minute did not improve the efficacy of preoxygenation by BVM system without a filter either with or without PEEP valve. However, it improved preoxygenation efficacy when BVM with a filter without PEEP valve alone was used.

What this study adds?

In this study, the authors added proximal oxygen to the BVM system with a filter, either with or without PEEP valve. The method of adding oxygen also differed from other studies. This technique would improve sealing between mask and the patient's face, hence, improved the efficacy of preoxygenation. Moreover, the authors also recorded the time to reach FEO_2 90% of each technique while other studies only recorded the FEO_2 at specific time points.

Funding disclosure

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Conflicts of interest

The authors declare that they have no competing interests.

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