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Supraglottic jet oxygenation and ventilation during colonoscopy under monitored anesthesia care: a controlled randomized clinical trial

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Abstract. – OBJECTIVE: Supraglottic jet oxygenation and ventilation may provide active pulse oxygenation and ventilation in patients with respiratory suppression. This randomized controlled clinical study was designed to determine the efficacy and safety of supraglottic jet oxygenation/ventilation during monitored anesthesia care (MAC) by intravenous (IV) infusion of propofol in patients undergoing colonoscopy.

PATIENTS AND METHODS: Forty-nine adult patients receiving colonoscopy were randomly divided into two groups: the control group with passive oxygen supply from regular nasal cannula (N = 24) and the supraglottic jet oxygenation/ventilation (SJV) group with active pulse oxygen supply and ventilation using a manual jet ventilator (N = 25). MAC was induced and maintained by intravenous injection of propofol. HR, ECG, BP, SaO_2 were continuously monitored during and 1 hour after the procedure.

RESULTS: Demographic characteristics were similar in height, weight, age and BMI (Body Mass Index) between the two groups. Compared to the control group, the SJV group had similar averaged lowest SaO_2, but highest SaO_2 in SJV group were significantly lower during operation ($p = 0.01$). The proportion of maximum chest rise movement were increased significantly in SJV group ($p = 0.03$) compared with control group. Demographic characteristics were similar in the times needed to use facial mask ventilation, percentage of time to maintain SaO_2 above 96%, average $PetCO_2$ during the procedure, or complications between the two groups.

CONCLUSIONS: SJV can provide adequate oxygenation/ventilation during monitored anesthesia care and convenient monitoring for patients' breath, without complications.

Key Words:
Supraglottic jet oxygenation, Pulse oxygenation, Ventilation, Respiratory suppression.

Introduction

Millions of patients receive colonoscopy each year worldwide. Colonoscopy is increasingly performed under monitored anesthesia care, primarily with intravenous infusion of propofol. The use of propofol for endoscopic sedation has been increased significantly during the last 10 years[1,2]. Since propofol can cause significant respiratory depression; especially in sick and obese patients, resulting in hypoxia[3-5] oxygen is usually provided to patients via a nasal cannula to minimize the risk of hypoxia[3]. Supraglottic jet oxygenation and ventilation have been successfully used in various types of difficult airway management, without significant complications[6-8]. However, it is not clear if the methods can be used safely for oxygenation and ventilation in patients with respiratory depression due to sedation by intravenous propofol or other anesthetics, without tracheal intubation. Although our recent case report describes effectiveness of SJV to maintain oxygenation in an obese patient[9], the safety and effectiveness of SJV via nasal approach need further clinical trials. In this controlled randomized clinical study, we compared the efficacy and safety of the SJV with the regular oxygen supply by a nasal cannula in patients receiving colonoscopy under monitored anesthesia care with propofol.

Patients and Methods

Patients

This clinical study was reviewed and approved by the Ethics Committee of Qingpu Hospital, Fudan University School of Medicine, Shanghai,

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China in Jan 5, 2012. Fifty patients (ASA I-II grade) were recruited to the study and randomized to the control group or the supraglottic jet ventilation (SJV) group equally from Mar 10, 2012 to Oct 10, 2013. We registered this study at the http://clinicaltrials.gov/ct2/show/NCT02005406 with the registration number of NCT02005406. SAS Programs for Calculating Sample Size, variability analysis for clinical trial between two groups $[p_1(1- p_1) + p_2 (1-p_2)] (Z_{1-\square/2} + Z_{1-\square})^2/\delta^2 p_1$ for rate in WEI Jet group; p_2 for rate for Control group; δ for two groups difference with clinical significance in two-tailed test. The randomization was accomplished by using the allocation sequence numbers generated from the program SPSS17.0. The blinding was performed by two anesthesiologists and one nurse. The nurse had sole access to the randomization tables. One anesthesiologist labeled patients from either SJV or control group, and the second anesthesiologist administers the oxygenation and anesthesia. The inclusion criteria consisted of the following: patients receiving procedures of colonoscopy under sedation who provided written informed consent. Patients with the following conditions were excluded from the study: heart, lung, liver and kidney diseases; increased intracranial pressure (ICP); full stomach; pulse oxygen saturation (SaO_2) < 95% on room air; obesity (BMI > 35); pregnancy.

Anesthesia

Anesthesia was induced by a bolus IV infusion of propofol (0.5 mg/kg) and fentanyl (1 μg/kg). For anesthesia maintenance, a continuous propofol IV infusion (150-200 μg/kg/min) was maintained, together with a fentanyl infusion at a variable rate of 0.01-0.1 μg/kg/min. Oxygen saturation was maintained above 90%, a bolus of phenylephrine (100 μg) or ephedrine (6 mg) was administered as needed to maintain a target mean arterial pressure of 70 mmHg. Bolus infusion of propofol (0.2~0.5 mg/kg) was given as needed to maintain adequate anesthesia level. Immediately after anesthesia induction, a regular nasal airway with a regular nasal oxygen supplying cannula located on anterior nostril was placed into one of nostrils, with constant supply of oxygen (6 L/min) in the control group. In the SJV group, a 11 Fr (ID, 2.3 mm) tube exchanger (Cook Critical Care, Bloomington, IN, USA) was inserted into one of the nostrils of patient to about 15 cm in length (Figure 1A), a pediatric fiberoptic scope was inserted into the another nostril to view the distal end of Cook tube exchanger and adjusted its position to just above the vocal cord. This position was checked again to make sure that distal end of the Cook tube exchanger was not moved at the end of anesthesia. A 22 G IV 15 cm black angiocatheter for 1.5 mm in internal diameter with the needle removed was attached to the distal end of the cook tube exchanger and connected to a $PetCO_2$ monitoring to measure the level of $PetCO_2$. The proximal end of the Cook tube exchanger was connected to a Sandler manual jet ventilator (Anesthesia Associates, Inc., San Marcos CA, USA) and used as jet catheter (Figure 2). Jet connected catheter 80 cm in length, 3 mm in internal diameter, $PetCO_2$ monitoring catheter 100 cm in length, 3 mm in internal diameter. Supraglottic jet oxygenation/ventilation was delivered to the patient continuously with following parameters: Driving pressure: 15 Psi or 1 kg/cm^2; Respiratory frequency, 15/min; Inspiration/Expiration ratio: 1:1.

Intraoperative Monitoring

We monitored following parameters throughout the anesthesia: HR, ECG, systolic arterial blood pressure (SAP), diastolic arterial pressure (DAP), mean aortic pressure (MAP), pressure of end-tidal CO_2 ($PetCO_2$), and pulse oxygen saturation (SaO_2). If SaO_2 decreased below 90%, mask ventilation up to peak inspiratory pressure (PIP) around 20 cmH_2O was performed until the SaO_2 reached acceptable values. We also observed the chest rise at grades from 1 to 3 as described in a previous study[8] (1, mild chest rise; 2, regular or moderate chest rise; and 3, maximum chest rise). In addition, we examined the lowest SaO_2 and recorded the times of mask ventilation performed during the entire procedure. The effectiveness of the SJV in maintaining proper oxygenation and the use of $PetCO_2$ monitoring were compared with that of in the control group. Immediately and 1h after the operation, we observed following complications: sore throat, nausea and vomiting, nose bleeding, barotraumas including gastric extension, pneumothorax, and subcutaneous emphysema.

Statistical Analysis

Continuous variables were shown as mean ± SD and analyzed with the SPSS 17.0 software (SPSS Inc., Chicago, IL, USA). Independent sample *t*-test was used for continuous variables between group comparison about age, height, weight and BMI, etc. Categorical variables such as the frequency of patients include snore history, smoke history, ASA grade, normal ECG,

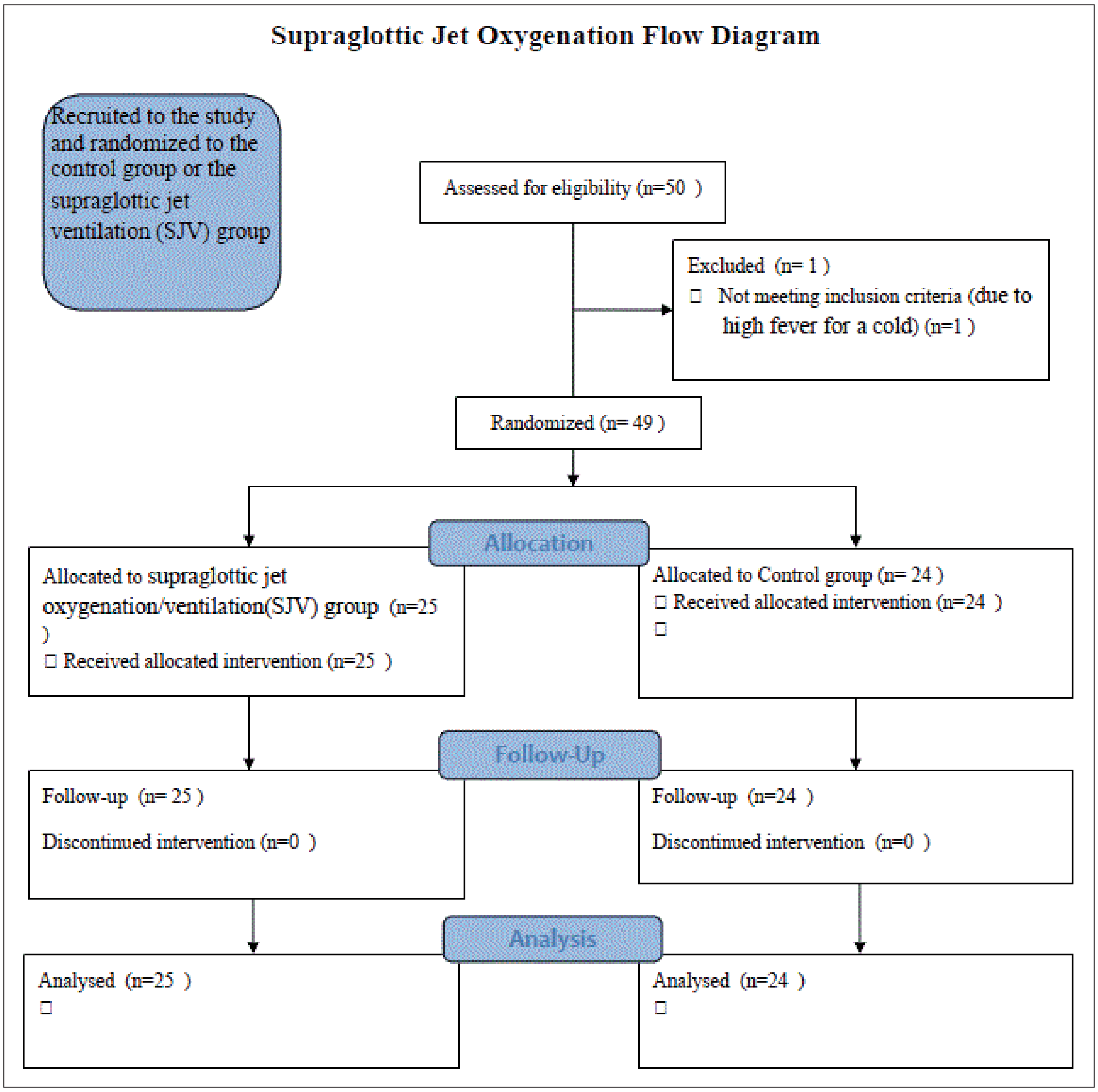

Figure 1. Supraglottic jet oxygenation flow diagram. Forty nine adult patients receiving colonoscopy were randomly divided into two groups: the control group with passive oxygen supply from regular nasal cannula (N = 24) and the supraglottic jet oxygenation/ventilation (SJV) group with active pulse oxygen supply and ventilation using a manual jet ventilator (N = 25). One patient in the control group was excluded due to high fever for a cold.

chest rise grade, nose bleeding and sore throat, etc. These variables were recorded for each group and the chi-square test was used for categorical variables between group comparison. $p < 0.05$ was considered statistically significant.

Results

As shown in Figure 1, forty-nine adult patients receiving colonoscopy were randomly divided into two groups: the control group with passive oxygen supply from regular nasal cannula (N=24) and the supraglottic jet oxygenation/ventilation (SJV) group with active pulse oxygen supply and ventilation using a manual jet ventilator (N=25)[8,9]. One patient in the control group was excluded due to high fever for a cold. As shown in Table I, the demographic characteristics were similar in height, weight, age and BMI between the two groups. Demographic character-

Figure 2. Supraglottic jet oxygenation and ventilation setting during colonoscopy examination. ***A,*** A Sandler manual jet ventilator was connected to the proximal end of the Cook tube exchanger and deliver jet ventilation. ***B,*** A Cook tube exchanger placed into a patient's right nostril under the assistance of pediatric fiberoptic scope in the left nostril.

istics were similar in the lowest SaO_2 between the two groups. As illustrated in Table II, the SJV group had 20% patients for maximum chest rise compared to 4% in control group. The proportion of maximum chest rise movement were increased significantly in SJV group (p = 0.03) compared with control group. SJV group had reduced levels of the averaged highest SaO_2 (97.7 ± 0.6 *vs*. 98.2 ± 0.5, p = 0.01). Demographic characteristics were similar in averaged $PetCO_2$, the times of mask ventilation used and the percentage of time to maintain SaO_2 above 96% during the procedure (Table II).

The comparisons of complications between the two groups are shown in Table III. Two patients had nose bleeding after SJV while one patient had nose bleeding in the control group. No other complications could be detected. Demographic characteristics were similar in sore throat, nausea and vomiting, and barotraumas between the two groups.

Discussion

Our previous case report study demonstrated that the procedure of supraglottic jet oxygenation and ventilation was as effective and safe in an obese patient under propofol sedation[9]. However, randomized control studies are needed to study the efficacy and safety of SJV under monitored anesthesia care with intravenous propofol sedation. This pilot study investigated the usefulness and safety of SJV in patient receiving colonoscopy,

Table I. Baseline of patients incontrol and SJV groups.

Monitored variables	Control (n = 24)	SJV (n = 25)	*p*
Age (yr., mean ± SD)	43 ± 9	41 ± 10	0.39
Sex (M:F, n)	3:21	9:16	0.05
Height (cm, mean ± SD)	165.3 ± 6.9	165.7 ± 7.9	0.52
Weight (kg, mean ± SD)	59.0 ± 11.2	59.3 ± 11.0	0.93
BMI ($kg.m^{-2}$, mean ± SD)	21.6 ± 3.1	21.5 ± 3.3	0.99
Smoke history (n)	8	6	0.40
ECG normal (n, %)	24 (100%)	25 (100%)	–
Snore history (n)	2	2	0.17
ASA grade (n, %)			
I	16 (67%)	18 (72%)	0.64
II	8 (33%)	7 (28%)	

BMI: body mass index; ASA: American Society of Anesthesiologists. Demographic chraracteristics were similar (p > 0.05) for all the variables between the two groups.

Table II. Comparison of monitored oxygenation and ventilation values.

Monitored variables	Control (n = 24)	SJV (n = 25)	p
Mild chest rise (1);	18 (75%)	18 (72%)	0.03
Regular moderate chest rise (2);	5 (21%)	2 (8%)	
Maximum chest rise (3)	1 (4%)	5 (20%)*	
Highest SaO_2 during operation, %	98.2 ± 0.51	97.7 ± 0.61*	0.01
Lowest SaO_2 during operation, %	92.4 ± 4.8	92.5 ± 3.4	0.99
$PetCO_2$	41.5 ± 4.3	41.2 ± 3.7	0.87
The use of mask ventilation (n, %)	6 (25%)	4 (16%)	0.35
Percentage of time (%) to maintain SaO_2 above 96% during the procedure	82.4 ± 19.7	86.3 ± 12.1	0.26

Categorical variables such as the frequency of patients was measured number (%). Continuous values are mean ± SD. *< 0.05 compared to the Control group. Pet CO_2: pressure of end-tidal carbon dioxide.

providing the basis for future clinical studies of using SJV in other kinds of outpatient's procedures under monitored anesthesia care.

With an increasing demand for monitored anesthesia care under intravenous propofol for outpatient procedures, such as colonoscopy, upper gastrointestinal endoscopy, and endoscopic retrograde cholangiopancreatography (ERCP), it is important to maintain patient arterial oxygen and CO_2 levels within a physiological range to minimize the brain damage and other complications. The airway management for monitored anesthesia care during colonoscopy is usually readily handled, because of the easy access to the upper airway and the convenient use of the facial mask, even if colonoscopy examination and treatment under painless general anesthesia had a quite a few advantages such as fewer sufferings of patients, short time, quick recovery, fewer complications[10]. However, the oxygen supplies using a regular nasal cannula and nasal airway may still not be efficient to maintain oxygen/ventilation if the patient is obese or with sleep apnea. A recent study[9] demonstrated the effective oxygenation by SJV in an obese patient underwent upper GI endoscopy under propofol infusion. For the upper gastrointestinal endoscopy and ERCP, it usually needs a deeper level of monitored anesthesia care to facilitate the placement of the endoscope into the stomach, which often significantly depresses patient's respiration and results in hypoxia. Frequently, the oxygen supply via a regular nasal cannula cannot maintain the SaO_2 within a normal range (> 92%). Also, it is inconvenient to use a facial mask to augment the oxygen supply. With the open feature of jet ventilation, the supraglottic jet oxygenation and ventilation procedure is capable of providing active pulse oxygen and improving the oxygenation and ventilation. The SJV used in this study seems working efficiently provide oxygenation/ventilation, with minimal complications. More clinical studies using SJV in upper GI endoscopy and ERCP are needed to prove this concept in the future.

One of the concerns to use jet ventilation is the barotraumas. Based on the position of the jet pulses, jet ventilation can be divided into either supraglottic (jet pulses above the vocal cord) or infraglottic (jet pulses below vocal cord). Barotraumas during jet ventilation are usually caused by the infraglottic but not supraglottic jet ventilation, due to its feasibility to keep the airway open via the mouth and nose and minimization of accumulation of high airway pressure[11-13]. This feature is especially useful in providing supraglottic jet oxygenation/ventilation during the upper gastrointestinal endoscopy or ERCP, without significant risk of barotraumas.

Table III. Complications in control and SJV croups.

	Monitored variables	Control (n = 24)	SJV (n = 25)	p
Intraoperative period	Nose bleeding (n, %)	1 (4%)	2 (8%)	0.54
	Sore throat (n)	0	1	0.32
Postoperative period	Nose bleeding (n, %)	1	0	0.15
	Dry mouth (n)	0	0	–

Categorical variables such as the frequency of patients was measured number (%). $p > 0.05$ compared to the control group.

Although the primary purpose of supraglottic jet oxygenation/ventilation in this study was to assure adequate oxygenation and minimize hypoxia, adequate ventilation via the SJV was also achieved according to the results that the chest rise in SJV group was significantly higher than that of in the control group. We speculate that the good cheat rise gives adequate ventilation, which is helpful to maintain $PaCO_2$ (Partial Pressure of Carbon Dioxide in Artery) within the physiological range. This may be dependent on the position of the distal end of the jet catheter (Figure 2) and the direction of the jet pulse. We believe that, the closer the jet pulse to the vocal cord, the less chest rise and the less jet ventilation due to less Venturi effects[7,14].

Conclusions

The SJV may help to minimize the risk of hypoxia and improve patient safety during monitored anesthesia care without significant risk of barotraumas. Further studies need to develop methods for adequate positioning of the jet catheter, which will not only provide adequate oxygenation, but also adequate ventilation.

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Clinical Trial Registration

This clinical study has been registered at the http://clinicaltrials.gov/ct2/show/NCT02005406 with the registration number of NCT02005406.

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Conflict of Interest

The Authors declare that there are no conflicts of interest.

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