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Respiration and the Airway

Supraglottic jet oxygenation and ventilation enhances oxygenation during upper gastrointestinal endoscopy in patients sedated with propofol: a randomized multicentre clinical trial

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Abstract

Background. Hypoventilation is the main reason for hypoxia during upper gastrointestinal endoscopy procedures with sedation. The key to preventing hypoxia is to maintain normal ventilation during the procedure. We introduced supraglottic jet oxygenation and ventilation (SJOV) through a new Wei nasal jet tube (WNJ) to reduce the incidence of hypoxia in patients sedated with propofol during upper gastrointestinal endoscopy procedures.
Methods. In a multicentre, prospective randomized single-blinded study, 1781 outpatients undergoing routine upper gastrointestinal endoscopy who were sedated with propofol by an anaesthetist were randomized into the following three groups: the supplementary oxygen via nasal cannula group [nasal cannula oxygen: O_2 (2 litres min^{-1}) was administered via a nasal cannula]; the supplementary oxygen via WNJ group [WNJ oxygen: O_2 (2 litres min^{-1}) was administered through a WNJ]; and the SJOV via WNJ group (WNJ SJOV: SJOV was administered via WNJ) at three centres from March 2015 to July 2016. The primary outcome of interest was the incidence of hypoxia (peripheral oxygen saturation of 75–89%). Other adverse events were also recorded.
Results. Supraglottic jet oxygenation and ventilation decreased the incidence of hypoxia from 9 to 3% ($P<0.0001$). No severe hypoxia occurred in the WNJ SJOV group, one instance occurred in the WNJ oxygen group, and two instances were observed in the nasal cannula oxygen supply control group. Supraglottic jet oxygenation and ventilation-related minor adverse events increased significantly within 1 min after the procedure but decreased 30 min later.
Conclusions. The use of SJOV during upper gastrointestinal endoscopy for patients who are sedated with propofol reduces the incidence of hypoxia, with minor and tolerable adverse events. Supraglottic jet oxygenation and ventilation has a favourable risk-to-benefit ratio and may improve patient safety.
Clinical trial registration. NCT02436018.

Key words: gastroscopy; hypoxia

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Editor's key points

- Hypoxia is one major complication during upper gastrointestinal endoscopy in patients who are sedated with propofol.
- Compared with administration of oxygen through a nasal cannula, jet oxygenation and ventilation through a nasal tube (which was placed above the glottis) reduced the incidence of hypoxia.

Endoscopy is the standard tool for the diagnosis and treatment of many gastrointestinal (GI) diseases. It is estimated that 8.6 per 1000 adult patients require upper GI endoscopy procedures.[1] Nearly 98% of upper GI endoscopies in the USA are performed under sedation to eliminate pain and improve patient comfort.[2–4] Owing to the short-acting pharmacokinetic properties of propofol,[5] international guidelines have suggested the use of propofol during upper GI endoscopies.[6–8] However, propofol can cause respiratory depression, airway obstruction, and haemodynamic instability.[9]

Hypoxia is a common occurrence during upper GI endoscopy,[10–13] with a reported incidence ranging from <1[14 15] to 85%,[16] which is largely the result of different definitions and practitioners. Prolonged hypoxia is the most common reason for cardiac arrhythmias[10] and coronary ischaemia.[13 17] Supplemental oxygen is helpful for reducing the incidence of hypoxia[10] and has been recommended by the ASA and the American Society for Gastrointestinal Endoscopy.[18 19] However, supplemental oxygen may mask hypoventilation during a procedure.[20] The key to prevention of hypoxia is to ensure the safe oxygenation and ventilation of patients during these procedures. One way to ensure that both oxygenation and ventilation occur during upper GI endoscopy is to use supraglottic jet oxygenation and ventilation (SJOV), which can be accomplished by placing a jet catheter inside the patient's nose with jet pulses above but towards the vocal cords.[21] A new convenient device is the Wei nasal jet tube (WNJ; inner diameter 5.0 mm, outer diameter 7.5 mm, length 180 cm; Well Lead Medical Co. Ltd, Guangzhou, China; Fig. 1).[22 23] Compared with a typical nasal airway, it has two channels built inside the wall of the tube: one for jet oxygenation and ventilation and the other for monitoring the end-tidal partial pressure of CO_2. Previous studies have demonstrated that SJOV can be used effectively in instances of difficult airway management[22–25] and in colonoscopy procedures with propofol infusion.[21 26]

This study was a multicentre, randomized controlled and prospective clinical trial. We hypothesized that SJOV via WNJ would reduce the rate of hypoxia during upper GI endoscopic procedures in patients sedated with propofol.

Methods

Study design

A multicentre, prospective randomized single-blinded clinical trial was conducted in the following three centres: Renji Hospital, School of Medicine, Shanghai Jiaotong University (Shanghai, China); Shanghai Tongji Hospital (Shanghai, China); and Shanghai Pudong New Area People's Hospital (Shanghai, China). This study was conducted in accordance with the Declaration of Helsinki, was approved by the local ethics committees ([2014]139K), and is registered at ClinicalTrials.gov (NCT02436018). Written informed consent was obtained from all patients. All authors had access to the study data and reviewed and approved the final manuscript.

All investigators, including nurses and anaesthetists, participated in standardized training for the use of jet ventilation, including the mechanism of action, indications and contraindications for its use in upper GI endoscopy, and precautions for and management of predicted adverse events.

Patient recruitment and exclusion

Outpatients undergoing routine upper GI endoscopy who were sedated with propofol by an anaesthetist were recruited. Inclusion criteria were as follows: (i) patients undergoing upper GI endoscopy; (ii) age >18 yr; and (iii) signed informed consent form. Exclusion criteria were as follows: (i) coagulopathies or nose bleeding; (ii) clear diagnosis of heart disease (heart failure, angina, myocardial infarction, arrhythmia, etc.); (iii) clear diagnosis of pulmonary disease (asthma, chronic obstructive pulmonary disease, pulmonary embolism, pulmonary oedema, or lung cancer); (iv) pregnancy; (v) hepatic disease; (vi) renal disease; (vii) increases in intracranial pressure; (viii) emergency procedures; (ix) multisystem trauma; (x) ASA Physical Status classification above IV; (xi) infection of the mouth, nose, or throat; and (xii) allergy to propofol, eggs, soybean, or albumin. Sick and complicated patients were excluded to ensure patient safety in this initial clinical trial using a new WNJ device to perform SJOV.

Group design and study procedure

Patients were administered a propofol infusion (1 mg kg^{-1}) followed by additional boluses of propofol (10 or 20 mg) that were titrated to achieve a moderate to deep sedation level [Observer's Assessment of Alertness/Sedation (OAA/S) score of 2 or 3].[27] The OAA/S is based on a combination of observations in the resting patient and the patient's responses to verbal commands of increasing intensity. The scores range from 1 (does not respond) to 5 (alert).[27]

We assessed the depth of sedation using the OAA/S and recorded scores every 2 min. We maintained the sedation levels between moderate (patients were responsive to verbal stimulus) and deep (patients not aroused easily but responded to superficial painful stimulus). Additional boluses of propofol (10 or 20 mg) were titrated to maintain the desired sedation levels based on clinical signs and the OAA/S score.

Patients were randomly assigned to one of the following three groups: the supplementary oxygen administered via nasal cannula group (nasal cannula oxygen); the supplementary oxygen administered via WNJ group (WNJ oxygen); or the SJOV via WNJ group (WNJ SJOV).

In the oxygen via nasal cannula group, oxygen (2 litres min^{-1}) was delivered via a nasal cannula throughout the entire procedure. In the WNJ oxygen group, oxygen (2 litres min^{-1}) was delivered directly through the jet port of the WNJ without using a jet ventilator. In the WNJ SJOV group, SJOV was performed via the WNJ by connecting a manual jet ventilator (Anaesthesia Associate, Inc., San Marcos, CA, USA) to the jet port of the WNJ (Fig. 1) with the following settings: driving pressure 15 psi, respiratory rate 20 bpm, inspiratory-to-expiratory ratio 1:2, and gas supply 100% oxygen. We adjusted the WNJ tube until the chest excursion after every manual jet ventilation was visible. We first measured the distance between the tip of the nose and the earlobe on one side using the metre on the

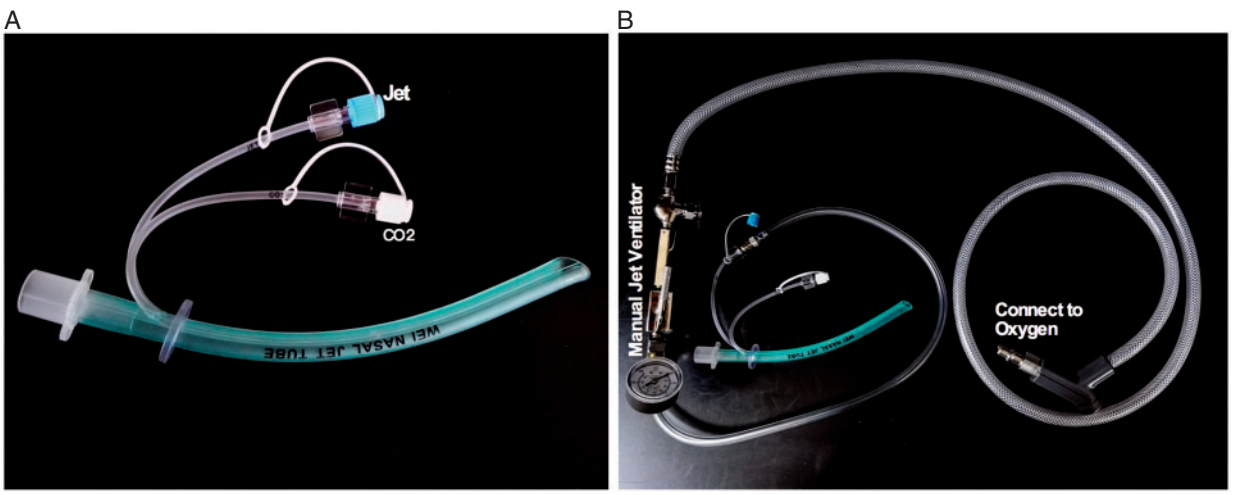

Fig 1 Wei nasal jet tube and the manual jet ventilator. (A) Wei nasal jet tube, with two channels built inside the wall of the tube, one for jet oxygenation and ventilation and the other for the end-tidal partial pressure of CO_2 monitor. (B) A manual jet ventilator is connected to the Wei nasal jet tube.

exterior wall of the WNJ. Then, the WNJ was inserted nasally to the earlier measured depth. If it was difficult to insert WNJ, we would try the other naris. If we were unsuccessful four times, we would not continue, and the patient would be excluded. No patients were excluded because of insertion difficulties in the present study. Thereafter, SJOV was initiated, and the depth of the WNJ was adjusted slightly in or out of the nose until the we achieved maximal visible chest excursion. Occasionally, the head was slightly tilted to the left or the right to maintain the chest excursion effect. In a few circumstances, chest excursion could not be achieved even after attempting all of the above adjustments, and the location of the WNJ was considered acceptable as long as there was strong effluent flow from the WNJ that was without obvious turbulent jet sounds, which usually occur when jet pulses are not delivered towards the vocal cords and the lungs.[22 24]

All patients received standard monitoring, including pulse oximetry and heart rate and blood pressure measurement, every 2 min. Supplemental oxygen (2 litres min^{-1}) was administered immediately after the baseline vital signs were recorded. Patients were then placed into the left lateral recumbent position and propofol was injected at a loading dose of 1 mg kg^{-1}. Propofol was then titrated according to individualized patient response, and the total doses of propofol were recorded. After reaching the desired depth of sedation, the lubricated WNJ was gently inserted into one of the nostrils. The oxygen supply was changed from nasal cannula to jet port in the WNJ oxygen or the WNJ SJOV groups based on the group assignment. The WNJ was removed before the patients were brought out of sedation. Consequently, the patients were blinded to the grouping condition.

When hypoxaemia [peripheral oxygen saturation (SPo_2) <90%] occurred in the oxygen via nasal cannula oxygen and oxygen via WNJ groups, it was corrected using the following sequence: (i) patient stimulation; (ii) withholding medications; (iii) increasing the volume of supplementary oxygen from 2 to 6 litres min^{-1}; (iv) opening the airway with the jaw-thrust manoeuvre; (v) removing the gastroscopy tube and mask ventilation; and (vi) tracheal intubation for mechanical ventilation. When hypoxemia occurred in the WNJ SJOV group, we corrected the hypoxemia by following these sequential steps: (i) patient stimulation; (ii) withholding medications; (iii) adjusting the jet ventilation rate to 30 bpm and increasing the driving pressure to 20 psi; (iv) stopping SJOV and opening the airway with the jaw-thrust manoeuvre; (v) removing both the gastroscopy tube and mask ventilation; and (vi) tracheal intubation for mechanical ventilation.

Randomization and sample size estimations

Computer-generated randomization sequences were used for every study centre. The PROC program in SAS (version 9.0, SAS Institute Inc, Cary, NC, USA) was used to generate the sample randomization sequence with a 1:1:1 allocation with a block=300 and a length=6. The randomization sequence was generated by a research assistant who was independent of the study and who did not have contact with the study participants. Randomization was done using opaque sealed envelopes, before induction of anaesthesia.

Pass (version 11.0, NCSS, LLC, Kaysville, Utah, USA) software was used for the sample size calculation. The χ^2 test for a multiple proportions procedure was used. With an α=0.05, a power of 90%, an effect size=0.09, and degrees of freedom=2, we estimated that 1563 patients would be required for our study. If the attrition rate was set at 15%, a total of 1800 patients (600 in each group) would be required. The effect size was calculated from the assumption that the WNJ SJOV would achieve a reduction from 12 to 6% for the incidence of hypoxia. The incidence of hypoxia during upper GI endoscopy for patients who were sedated with propofol has been reported to be in the range of 7–16%.[28] Therefore, a proportion of 12% of the patients in the oxygen via nasal cannula group were expected to develop hypoxia, which was used to calculate the sample size.

The WNJ manufacturer (Well Lead Medical Ltd, Guangzhou, China) provided the WNJ as an investigational device but had no role in the study design, data collection, data analysis, or manuscript preparation.

Data collection

Adverse events were recorded by a separate investigator using the tools proposed by the world Society of Intravenous Anaesthesia (SIVA) International Sedation Task Force.[29] Step 1 was a subjective judgement of whether an adverse occurred. If an adverse event had occurred, it was described in Step 2. Hypoxia-related adverse events were of minimal risk to the patient and are described as follows: subclinical respiratory depression (SpO_2=90–95%); minor risk, hypoxia (SpO_2=75–89% for <60 s); and sentinel risk, severe hypoxia (SpO_2<75% at any time or <90% for >60 s). Step 3 included a list of the necessary interventions used to treat the adverse events: increased oxygen supply, performance of a jaw-thrust, and performance of bag–valve mask-assisted ventilation. Step 4 was the patient outcome, including no adverse outcome, unplanned hospitalization, permanent neurological deficit, or death. Step 5 involved rating the adverse events according to the four categories of minimal, minor, moderate, and sentinel events. Jet ventilation-related adverse events, including pharyngalgia, xerostomia, nasal bleeding, or any barotrauma (gastric distension, pneumothorax, subcutaneous emphysema, etc.), were recorded at 1 and 30 min after the conclusion of the procedure.

Study end points

The primary outcome was hypoxia, which was defined as an oxygen saturation of 75–89% for <60 s. The secondary outcomes included: (i) other adverse events listed in the report tools; and (ii) adverse events related to the SJOV.

Statistical analysis

Statistical analyses were performed according to the assigned methods. The patient data are presented as the number and percentage or as the mean and SD. A value of $P<0.05$ was considered statistically significant. The Kruskal–Wallis test was used for the gastroscopy intubation time, procedure time, and total propofol dosage because these data were not normally distributed. If $P<0.05$, the Nemenyi test was used to compare the difference among the three groups. A χ^2 test and Fisher's exact test were used to analyse the adverse event incidence rate. As two χ^2 tests were performed, the P-value was adjusted to 0.025.

Results

From March 2015 to July 2016, a total of 1815 patients were enrolled, and 19 were excluded (15 had incomplete consent forms, and four had missing basic data). A total of 1796 patients were randomized and distributed to the three groups. Of the 1796 patients, 10 withdrew their consent after randomization, one patient in the nasal cannula oxygen group received SJOV to correct the hypoxia, two patients received additional fentanyl, and one patient had preexisting tachycardia. Thus, 1781 patients were included in the per-protocol analysis. The results of statistical analyses were maintained on per-protocol analysis (Supplementary material, Fig. S1).

All patients tolerated the procedure well, and there were no instances of serious morbidity or death. No barotrauma (i.e. abnormal gastric distension or pneumothorax) was recorded.

General patient information

General patient information is listed in Table 1. As this study was a randomized clinical trial, we did not perform a statistical analysis of the general information for the three groups. The patients' characteristics for the three groups, including age, sex, BMI, medical history, baseline SpO_2, and ASA classification, were comparable. The airway-related variables, including Mallampati scores, inter-incisal distance, thyromental distance, snoring, and obstructive sleep apnoea–hypopnea syndrome, were also comparable among the three groups.

In the control group, a larger number of patients required more than one attempt to perform the gastric intubation. Two patients in the control group required four attempts for successful gastric intubation. Although $P<0.05$ for the procedure time compared with the control group and the WNJ oxygen group, this difference (4.9 *vs* 4.8 min) lacked clinical significance. The total propofol dosage among the three groups was not significantly different. This finding indicates that SJOV through the

Table 1 General characteristics of patients. Inter-incisal distance (1/2/3): 1=one finger, 2=two fingers, and 3=three fingers. Thyromental distance (I/II/III): I > 6.5 cm, II 6–6.5 cm, and III<6 cm. OSAHS, obstructive sleep apnea–hypopnea syndrome; SJOV, supraglottic jet oxygenation and ventilation; SpO_2, peripheral oxygen saturation; WNJ, Wei nasal jet tube

Characteristic	Nasal cannula oxygen (n=593)	WNJ oxygen (n=596)	WNJ SJOV (n=592)
Age [yr; mean (range)]	46 (18–86)	48 (18–88)	47 (18–90)
Sex (male)(female)	(272)(321)	(271)(325)	(277)(315)
BMI [kg m^{-2}; mean (SD)]	23 (2.98)	23 (3.14)	23 (3.04)
History of hypertension [n (%)]	51 (9)	62 (10)	49 (8)
History of diabetes [n (%)]	13 (2)	21 (4)	10 (2)
Mallampati Class (I)(II)(III)(IV)	(220)(321)(35)(17)	(208)(347)(31) (10)	(209)(333)(31) (19)
Inter-incisal distance (1)(2)(3)	(1)(15)(571)	(0)(7)(589)	(0)(11)(581)
Thyromental distance (I)(II)(III)	(562)(22)(9)	(521)(66)(9)	(566)(19)(7)
Snore [n (%)]	167 (28)	170 (29)	182 (31%)
OSAHS [n (%)]	2 (0.34)	0	0
SpO_2 before sedation [%; mean (SD)]	99 (1.00)	99 (1.21)	99 (1.05)
ASA grade (I)(II)(III)	(527)(66)(0)	(526)(70)(0)	(531)(60)(1)

Table 2 Data about the procedure and propofol dosage. SJOV, supraglottic jet oxygenation and ventilation; WNJ, Wei nasal jet tube

	Nasal cannula oxygen (I) (n=593)	WNJ oxygen (II) (n=596)	WNJ SJOV (III) (n=592)	P-value (Kruskal–Wallis)	P-value (I *vs* II)	P-value (I *vs* III)
Gastroscopy intubating times 1/2/3/4	587/4/0/2	592/4/0/0	590/2/0/0	0.364	—	—
Procedure time [min; mean (SD)]	4.8 (0.83)	4.8 (0.99)	4.9 (0.83)	0.01	0.99	0.03
Total propofol dose [mg; mean (SD)]	107.69 (28.71)	107.22 (29.65)	108.12 (28.35)	0.784	—	—

Table 3 adverse events and intervention related to hypoxia. The χ^2 test (Fisher's exact test) was used to analyse the adverse events incidence rate. Given that two χ^2 tests were done, the P-value was adjusted to 0.05/2=0.025. SJOV, supraglottic jet oxygenation and ventilation; WNJ, Wei nasal jet tube

	Nasal cannula oxygen (I) (n=593)	WNJ oxygen (II) (n=596)	WNJ SJOV (III) (n=592)	P-value (I *vs* II)	P-value (I *vs* II)
Total adverse events [n (%)]	231 (39)	209 (35)	156 (26)	0.165	<0.0001
Subclinical respiratory depression [n (%)]	82 (14)	72 (12)	59 (10)	0.370	0.040
Hypoxia [n (%)]	53 (9)	46 (8)	16 (3)	0.447	<0.0001
Severe hypoxia [n (%)]	2 (0.3)	1 (0.2)	0	0.624	0.5
Jaw lift [n (%)]	105 (18)	56 (9)	20 (3)	<0.0001	<0.0001
Mask ventilation [n (%)]	4 (0.7)	1 (0.2)	0	0.271	0.124

WNJ did not affect the procedure time or the propofol dose (Table 2).

Primary outcome

Supraglottic jet oxygenation and ventilation significantly decreased the incidence of hypoxia

Using the adverse event reporting tool proposed by the world SIVA International Sedation Task Force,[29] we recorded all adverse events.

Adverse events and interventions related to hypoxia are listed in Table 3. Compared with the nasal cannula oxygen or WNJ oxygen groups, the use of SJOV via WNJ during the procedure significantly decreased the total percentage of adverse events from 39 to 26% ($P<0.0001$). For the minor-risk adverse events, the use of SJOV decreased the incidence of hypoxia (SPo_2=75–89%) during upper GI endoscopy in patients who were sedated with propofol from 9 to 3% ($P<0.0001$).

There were no significant differences in the incidence of subclinical respiratory depression (SPo_2=90–95%) between the WNJ SJOV group and nasal cannula oxygen group.

No severe (SPo_2<75% at any time) or prolonged (<90% for >60 s) hypoxia occurred in the WNJ SJOV group, one instance occurred in the WNJ oxygen group, and two occurred in the nasal cannula oxygen supply control group. However, there was no significant difference among the three groups in terms of severe hypoxia.

In the WNJ SJOV group, only 20 patients (3%) required a jaw thrust to correct the hypoxia, which was significantly lower than those required in the nasal cannula oxygen supply control group (105, 18%). In the WNJ SJOV group, it was not necessary to stop the procedure to perform bag–valve mask ventilation to correct the hypoxia. In contrast, four patients (0.7%) required bag–valve mask ventilation in the nasal cannula oxygen supply control group. There was no statistically significant difference among the three groups.

No moderate or sentinel adverse events occurred in the WNJ oxygen or SJOV group, but one moderate and three sentinel adverse events occurred in the nasal cannula oxygen group (Supplementary material, Fig. S2). The three sentinel adverse events occurred because the tip of the upper GI endoscope was unintentionally located in the trachea.

No other differences were found among the three groups for other general adverse events (Table 4).

Secondary outcome

Supraglottic jet oxygenation and ventilation increased minor adverse events

The most common adverse event related to SJOV at 1 min after the procedure was xerostomia. In the WNJ SJOV group, 94 (16%) patients experienced xerostomia; this percentage is significantly higher than that in the WNJ oxygen group (61, 10%). At 30 min after the procedure, the incidence of xerostomia decreased significantly (WNJ oxygen group: 11, 2%; SJOV 51, 9%; Table 5).

Pharyngalgia and nasal bleeding also occurred at 1 min after the procedure in the WNJ oxygen group (pharyngalgia 14, 2%; nasal bleeding four, 0.7%) and in the WNJ SJOV group (pharyngalgia 26, 4%; nasal bleeding 12, 2%). Thirty minutes later, only four (0.7%) patients in the WNJ oxygen group and 15 (3%) in the WNJ SJOV group still complained of pharyngalgia; no nasal bleeding was noted 30 min after the procedure in any group. All pharyngalgia was clinically minor, with no

Table 4 General adverse events except hypoxia. A χ^2 test (Fisher's exact test) was used to analyse the adverse events incidence rate. Given that two χ^2 tests were done, the *P*-value was adjusted to 0.05/2=0.025. NS, not significant; SJOV, supraglottic jet oxygenation and ventilation; WNJ, Wei nasal jet tube

	Nasal cannula oxygen (I) (*n*=593)	WNJ oxygen (II) (*n*=596)	WNJ SJOV (III) (*n*=592)	*P*-value (I *vs* II)	*P*-value (I *vs* III)
Total adverse events [*n* (%)]	231 (39)	209 (35)	156 (26)	0.165	<0.0001
Minimal risk adverse events [*n* (%)]					
Nausea/retching	22 (4)	13 (2)	24 (4)	0.119	0.759
Muscle rigidity, myoclonus	0	1 (0.2)	0	1	NS
Hypersaliavation	56 (9)	67 (11)	73 (12)	0.309	0.111
Paradoxical response	8 (1)	6 (1)	15 (3)	0.584	0.139
Recovery agitation	0	4 (0.7)	1 (0.2)	0.124	1
Recovery delay	2 (0.3)	0	0	0.249	0.5
Minor risk adverse events [*n* (%)]					
Airway obstructed	1 (0.2)	0	0	1	1
Allergic reaction without anaphylaxis	0	0	0	NS	NS
Bradycardia	4 (0. 7)	7 (1.2)	3 (0.5)	0.368	1
Tachycardia	2 (0.3)	0	0	0.249	0.5
Hypertension	1 (0.2)	1 (0.2)	0	1	1
Hypotension	6 (1)	10 (2)	2 (0.3)	0.319	0.157
Seizure	0	0	0	NS	NS
Sentinel risk adverse events [*n* (%)]					
Cardiovascular collapse/shock	0	0	0	NS	NS
Cardiac arrest/absent pulse	0	0	0	NS	NS

Table 5 Adverse events related to the SJOV. NS, not significant; SJOV, supraglottic jet oxygenation and ventilation; WNJ, Wei nasal jet tube

	WNJ Oxygen (*n*=596)	WNJ SJOV (*n*=592)	*P*-value
1 min after procedure [*n* (%)]			
Pharyngalgia	14 (2)	26 (4)	0.058
Xerostomia	61 (10)	94 (16)	0.04
Nasal bleeding	4 (0. 7)	12 (2)	0.043
Barotrauma	0	0	NS
30 min after procedure [*n* (%)]			
Pharyngalgia	4 (0.7)	15 (3)	0.011
Xerostomia	11 (2)	51 (9)	<0.0001
Nasal bleeding	0	0	NS
Barotrauma	0	0	NS
Nausea	0	0	NS
Vomiting	0	0	NS
Impairment of airway	0	0	NS
Other adverse events	0	0	NS

interventions necessary for treatment. All nasal bleeding stopped naturally, without the need for medical or surgical treatment. There was no incidence of nausea, vomiting, or obvious barotrauma in any patient or group (Table 5).

Discussion

This study is the first multicentre, randomized controlled clinical trial to investigate the effectiveness of SJOV via WNJ to improve oxygenation and ventilation during upper GI endoscopy in patients sedated with propofol. Our results suggest that SJOV via the new WNJ airway device significantly decreased hypoxia, with minor and tolerable adverse events.

Jet ventilation was developed in the late 1960s. Low-frequency jet ventilation with hand-triggered devices is a traditional and conventional approach that is frequently used to perform trans-tracheal jet ventilation (TTJV), which is one of the emergency airway management rescue approaches recommended in the ASA guidelines.[30] In the present study, we successfully used the SJOV technique to minimize hypoxia during upper GI endoscopy without the severe complications that have been reported with TTJV.[31] To date, only supplemental oxygen has been proved to be an effective intervention to reduce the incidence of hypoxia during upper GI endoscopy procedures.[10] In the present study, we demonstrated that the incidence of hypoxia (SPo_2=75–89%) was still 9% when only supplemental oxygen was used. When SJOV was used, the incidence decreased to 3%. The prevention of hypoxia during propofol infusion is important to minimize morbidity and mortality during many procedures.

The adverse events related to the SJOV were minor and tolerable. Barotrauma during the use of jet ventilation, especially with TTJV,[31] is a well-known severe complication that limits its common use. Supraglottic jet oxygenation and ventilation assures the features of open ventilation with patency of the nose and mouth, thus minimizing the chance of barotrauma. There were no instances of barotrauma in this relatively large patient cohort, which strengthens the finding suggested by previous studies,[21 22 23 24 26 32] namely, that SJOV is much less likely to cause barotrauma than TTJV. Supraglottic jet oxygenation and ventilation may help to promote the popular use of jet ventilation in the future, pending the results of more clinical

studies. Increases in other minor complications, such as xerostomia, pharyngalgia, and nasal bleeding, attributable to the use of SJOV, appear tolerable and easily manageable. In the present study, no humidified oxygen was used because the duration of the procedure was very short (~5 min). Humidified oxygen could possibly reduce the incidence of the xerostomia after the use of SJOV. Most xerostomia resolved within 30 min of the end of the procedure. Pharyngalgia and nasal bleeding were tolerable, and no patient required any medications for analgesia or to achieve haemostasis. Most pharyngalgia and nasal bleeding stopped within 30 min of the end of the procedure. In the present study, none of the endoscopists complained about the use of SJOV being inconvenient during the procedure. This study highlights the risk-to-benefit ratio of using SJOV during upper GI endoscopy in patients sedated with propofol.

Recent studies have suggested that SJOV may also be a useful technique for emergency and elective difficult airway management. Li and colleagues[33] reported an emergency 'cannot intubate and cannot ventilate' situation, in which the patient survived because of the use of SJOV. Wu and colleagues[34] demonstrated that SJOV via WNJ can be used successfully to assist in fibreoptic bronchoscopic intubation for the elective difficult airway. Compared with the use of SJOV in apnoeic patients after the administration of neuromuscular blocking agents, the use of SJOV in propofol-sedated patients has the following differences: (i) the patient's chest excursion may be less obvious because of lower pulmonary compliance, and vocal cord opening may be minimized in lightly sedated patients, whereas heavily sedated patients may have similar pulmonary compliance and vocal cord opening when neuromuscular blocking agents are used; (ii) the patient's spontaneous breathing may not be synchronized with the jet ventilation, which interferes with the efficiency of oxygenation and ventilation; and (iii) because of the existence of spontaneous breathing in patients, SJOV may augment the oxygenation and prevent hypoxia even if the jet pulses are not directed towards the vocal cord opening in patients who are sedated by propofol.

A recent study by Yang and colleagues[21] suggested that SJOV could maintain oxygenation with minimal side-effects in patients undergoing colonoscopy who were sedated with propofol. As bag–valve mask ventilation is easily used for the correction of hypoxia during colonoscopy, SJOV is less valuable in those situations, but is extremely useful during upper GI endoscopy when bag–valve mask ventilation usually cannot be used because of the location of the existing endoscope. Supraglottic jet oxygenation and ventilation may be especially useful in reducing the risk of hypoxia in obese patients who are sedated with propofol. Obesity is a risk factor for cardiopulmonary complications that might occur during sedation.[35] Wani and colleagues[36] demonstrated that an increased BMI was associated with an increased use of airway manoeuvres during advanced endoscopic procedures. Levitt and Wei[26] reported a morbidly obese patient, in whom SJOV was successfully used to complete an upper GI endoscopy with propofol sedation. In the present study, the average BMI in our patient cohort was ~23 kg m^{-2}, which is in the normal range, and there were not enough higher BMI patients in our study who could be analysed. Further clinical studies are warranted for the effectiveness and safety of SJOV in obese patients. Endoscopic retrograde cholangiopancreatography (ERCP) procedures require more time, deeper levels of sedation, and pronated positioning; therefore, the likelihood for hypoxia is higher in these procedures.[37] Supraglottic jet oxygenation and ventilation might be an effective method to reduce the higher instances of hypoxia encountered during ERCP in patients who are sedated with propofol; however, additional clinical studies are needed in this area. As jet ventilation is featured with an open system, the WNJ is designed to have a small outer diameter to facilitate placement with minimal nose bleeding, and it is easily tolerated by alert patients. Unpublished data have suggested that the use of the WNJ in awake patients who need an urgent tracheostomy because of oropharyngeal cancer was successful. Further studies are needed to investigate the usefulness of SJOV during awake craniotomies, especially in obese patients.

The present study had some limitations. The WNJ tube sometimes led to discomfort and even nasal bleeding in a few patients after the tube was removed, which might have allowed patients to deduce to which group they were allocated. Either a regular nasal cannula or a WNJ tube was nasally inserted after patients lost consciousness, and all tubes were removed before the patients awoke. Although patients might have deduced their group allocation, it would be difficult for them to guess correctly. Therefore, we believe that the present study is a single-blinded protocol. The investigator was not blinded, which might have resulted in bias and could have affected the power of this study. However, the objective parameter of hypoxia was the major parameter in the present study, which might correct the single-blindness. In addition, no capnographic monitoring was used because of a lack of equipment in the GI endoscopy suite. However, Friedrich-Rust and colleagues[38] found that capnographic monitoring cannot reduce severe hypoxia, although it does reduce hypoxia during the procedural sedation associated with gastroscopy.[39] It is very convenient to monitor capnography because of the built-in end-tidal CO_2 monitoring catheter in the exterior wall of the WNJ (Fig. 1). The addition of CO_2 monitoring using the built-in CO_2 monitoring catheter on the WNJ may improve the earlier detection of suppressed or apnoeic breathing. This possibility requires further study in future clinical trials. We did not include the nasal cannula oxygen supply group in the adverse events related to jet oxygenation or ventilation, but they were estimated to be similar to those in the WNJ oxygen group because both groups used a low-pressure and low-flow oxygen supply.

Although it is much more convenient to use WNJ for SJOV and the monitoring of patient breathing, other methods of assembled apparatus to produce SJOV have been reported, including the combination of a regular nasopharyngeal airway, a soft-suction catheter,[26] and a Cook airway exchange catheter.[21] Consistent with a previous report,[26] SJOV seems to be more effective in reducing the incidence of hypoxia during upper GI endoscopy, especially in obese patients. Moreover, it is difficult to perform typical bag–valve mask ventilation during upper GI endoscopy because of the existence of the endoscope in the oral cavity, whereas SJOV can be performed easily using a jet catheter above the vocal cords, using the opening feature of jet ventilation. Owing to the low incidence of hypoxia and the convenience of using bag–valve mask ventilation to correct hypoxia during colonoscopy, SJOV seems to provide fewer advantages during colonoscopy than during upper GI endoscopy.[21 40] Based on our current clinical experience, SJOV appears to be a desirable option for the reduction of hypoxia in ERCP procedures with pronated patients who are sedated with IV infusions of propofol, but this possibility will require further well-designed clinical studies.

In conclusion, SJOV during upper gastroscopy in patients who were sedated with propofol significantly decreased the incidence of hypoxia and produced only minor and tolerable adverse events.

Authors' contributions

Study conception: D.S.S, L.Z.L., X.Q.Z., X.R.W., W.F.Y.
Study design: D.S.S., X.R.W., W.F.Y., H.F.W.
Study conduct: Y.Q., L.Z.L., X.Q.Z., Y.W., Y.L.W.
Data analysis: Y.Q., D.S.S.
Data interpretation: D.S.S, Y.Q., H.F.W.
Drafting of the manuscript: D.S.S, Y.Q., H.F.W.
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Supplementary material

Supplementary material is available at *British Journal of Anaesthesia* online.

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Declaration of interest

H.F.W. is the inventor of the WEI nasal jet tube (WNJ), which was used to generate SJOV in this study. The University of Pennsylvania initiated and granted the patent application for the WNJ in several countries, including the USA, China, Europe, Japan, Canada, Australia, and Brazil. The other authors have no potential conflicts of interest to declare.

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