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Review

Effect of supraglottic jet oxygenation and ventilation on hypoxemia in patients undergoing endoscopic surgery with sedation: A meta-analysis of randomized controlled trials

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HIGHLIGHTS

- Compared with COT, there was a significantly reduction of intraoperative hypoxemia during endoscopic surgery with SJOV.
- SJOV can decrease the incidence of hypoxemia, especially in high-risk patients during the endoscopic surgery with sedation.
- There was no increased risk of nose bleeding or sore throat between SJOV and COT group, except for dry mouth.

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ABSTRACT

Background: Nasal cannulas and face masks are common oxygenation tools used in conventional oxygen therapy for patients undergoing endoscopic surgery with sedation. However, as a novel supraglottic ventilation technique, the application of supraglottic jet oxygenation and ventilation (SJOV) in endoscopic surgery has not been well established.

Method: We searched six electronic databases from inception to January 16, 2024, to assess the oxygenation/ventilation efficacy and side effects of the of SJOV in endoscopic surgery. The primary outcome was the incidence of hypoxemia. The secondary outcomes were the incidence of respiratory depression and adverse effects (nasal bleeding, sore throat, and dry mouth).

Results: Nine trials involving 2017 patients were included. The results demonstrated that the incidence of hypoxemia was lower in the SJOV group compared with the conventional oxygen therapy (COT) group [9 trials; 2017 patients; risk ratio (RR) = 0.18; 95% confidence interval (CI), (0.11–0.28)]. Subgroup analyses showed that SJOV reduced the incidence of hypoxemia in the high-risk group but had no effect on the low-risk group. The incidence of respiratory depression is lower in SJOV than in COT, but has increased side effects such as dry mouth. There was no statistically significant difference in nose bleeding or sore throat between the two groups.

Conclusion: Compared with the COT, the SJOV decreased the incidence of hypoxemia in high-risk patients during endoscopic surgery with sedation. There was an increased risk of dry mouth, but not of nose bleeding or sore throat, during endoscopic surgery under sedation.

1. Introduction

Although sedation can improve patient tolerance and satisfaction

during endoscopic surgery, it can cause respiratory depression [1–3]. Conventional oxygen therapy (COT), such as nasal cannulas or face masks, is commonly used in endoscopic surgery, but its effect on

Abbreviations: SJOV, supraglottic jet oxygenation and ventilation; COT, conventional oxygen therapy; RR, risk ratio; CI, confidence interval; RCT, randomized controlled trial.

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Table 1
Characteristics of included studies.

| Author | Population | Risk of hypoxemia | Number of patients (SJOV/COT) | SJOV group | COT group | Definition of hypoxemia |
|-------------------------|----------------------------|-------------------|-------------------------------|---|--|-------------------------|
| Wei 2023 | Bronchoscopy | High | 88(44/44) | FiO ₂ :100%; DP:103 kPa; JF:15 bpm; I:E ratio: 1:2 | Nasopharynx, 4 L/min | SpO ₂ < 90% |
| Jiang 2022 | Gastrointestinal Endoscopy | High | 72(36/36) | FiO ₂ :100%; DP:103 kPa; JF:20 bpm; I:E ratio: 1:2 | Nasal cannula; 2 L/min | SpO ₂ <90% |
| Liang 2019 _a | Hysteroscope (obesity) | High | 67(34/33) | FiO ₂ :100%; DP:100 kPa; JF:15 bpm; I/E ratio: 1:1.5 | Face mask; 6 L/min; FiO ₂ :100% | SpO ₂ <90% |
| Qin 2017 | Gastrointestinal Endoscopy | High | 1185(592/593) | FiO ₂ :100%; DP:103 kPa; JF:20 bpm; I:E ratio: 1:2 | Nasal cannula; 2 L/min | SpO ₂ <90% |
| Yang 2016 | Colonoscopy | Low | 49(25/24) | DP:103 kPa or 100 kPa; JF:15 bpm; I:E ratio: 1:1 | Nasal cannula; 6 L/min | SpO ₂ <90% |
| Zha 2021 | Bronchofiberscope | High | 280(140/140) | FIO ₂ :100%; DP:103 kPa; JF:20 bpm; I:E ratio: 1:2 | Nasal cannula; 4 L/min | SpO ₂ < 90% |
| Liang 2019 _b | Hysteroscope | Low | 120(60/60) | DP:100–300 kPa; JF:15–20 bpm; I:E ratio: 1:1.5 | Face mask, 6 L/min, FiO ₂ :45% | SpO ₂ < 95% |
| Wu 2020 | Gastroscope | High | 100(50/50) | DP:103.4 kPa; JF:15–20 bpm | Nasal cannula, 6 L/min | SpO ₂ < 95% |
| Xiao 2013 | Gastroscope | High | 64(33/31) | DP: 100 kPa; JF: 30–50 bpm | Nasal cannula, 4–5 L/min | SpO ₂ <90% |

DP: Driving pressure;
JF: Jet frequency = Respiratory rate;
Inspiratory/Expiratory (I: E) ratio: I:E ratio;
1 psi = 6.895 kPa, 1 psi = 0.069 bar.
OSAHS: obstructive sleep apnea-hypopnea syndrome;
Liang.2019_a and Liang.2019_b are two studies by the same author.

maintaining satisfactory oxygenation is still limited, especially for patients at a high risk of hypoxemia [4,5]. Consequently, it is crucial to provide a constant oxygen supply during endoscopic surgery under sedation to prevent hypoxemia [6]. Recent studies have focused on the application of - supraglottic jet oxygenation and ventilation (SJOV) in patient airway management, both in acute trauma and endoscopic surgery [7–9], which indicates the potential superiority of SJOV in maintaining oxygenation.

The SJOV is a novel minimally invasive supraglottic oxygenation/ventilation technique [10]. The unique feature of SJOV lies in its delivery of oxygen to the supraglottic region through high or normal frequency jet ventilation, utilizing a driving pressure of 10–30 psi (approximately 0.67–2.07 bar, 68.94–206.84 kPa) [10]. The principle of jet ventilation involves a high-pressure pulsed gas flow creating overpressure at the distal end of the nozzle formed by the conduit, whereas the flowing gas generates negative pressure at the proximal end of the conduit through the “Venturi effect,” thereby entraining the surrounding atmospheric gas to form the total airflow for delivery [11]. This enables the SJOV to have an effective ventilation process. Previous studies have focused on the SJOV in laryngeal or minimally invasive surgeries [12,13], but few studies have applied it to endoscopic surgery. Thus, we aimed to explore the effectiveness of SJOV in decreasing the incidence of hypoxemia during endoscopic surgery compared to COT.

2. Methods

This meta-analysis was in compliance with the PRISMA statement [14]. The protocol was registered on the Internet Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY2022100059).

2.1. Inclusion criteria

Studies meeting the following criteria were included: population: adults (age ≥ 18 years) undergoing endoscopic surgery, including

digestive endoscopy, hysteroscopy, fiberoptic bronchoscopy; intervention: SJOV, using nasopharyngeal cannulas or Wei-tube; control group: COT; study design: randomized controlled trials (RCTs). Studies were excluded if mechanical ventilation was performed.

2.2. Data sources and searches

We performed a thorough search of six databases (PubMed, Embase, Cochrane Library, China Biology Medicine Disc, China National Knowledge Infrastructure, and Wanfang Data) from their establishment to January 10, 2024, without any restrictions. According to the rule of “PICOS,” participants(P) were searched for “endoscopy,” “bronchoscopy,” “gastrointestinal endoscopy,” “hysteroscopy,” “gastrosocopy,” or “colonoscopy.” Intervention (I): “High-Frequency Jet Ventilation” (MeSH Browser) or (“jet ventilation,” “jet oxygenation,” “supraglottic,” “oropharyngeal,” “nasopharyngeal,” “transoral,” or “transnasal”) [Title/Abstract]. When the number of retrieved articles was insufficient, we used the intervention (I) method. Then manual filtering was performed based on RCT(s) and “PICOS.”

2.3. Study selection

Two reviewers screened the relevant literature. Any disputes were settled through discussion or by a third person. EndNote 9× was used to delete duplicate studies from the preliminary acquisition. First, the relevance of the title or abstract was assessed and further screened according to the study type and outcome indicators. Finally, we browsed the full text.

2.4. Data extraction

One researcher extracted the data, while the other two were responsible for inspection. Any differences were resolved through discussion. For each study, the following information was extracted:

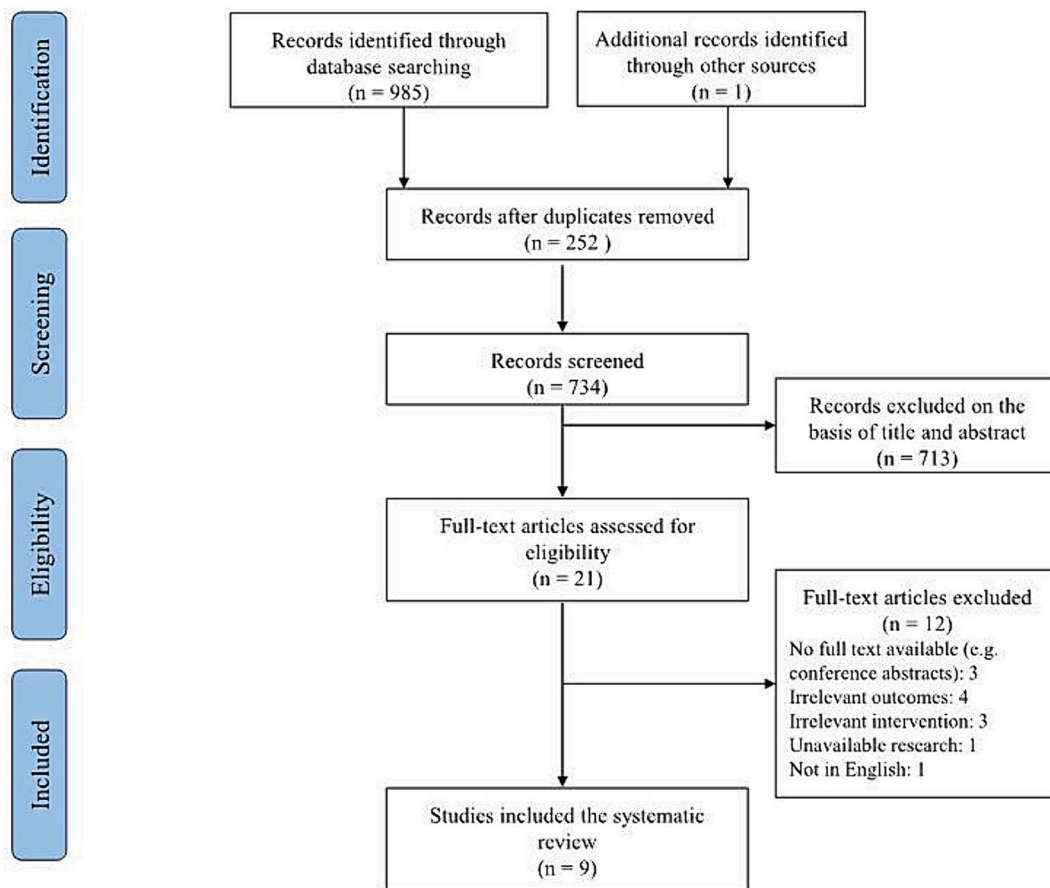


Fig. 1. Flowchart of selection of studies included in meta-analysis.

author, year of publication, population, risk of hypoxemia, equipment parameters, and definition of hypoxemia. The data are summarized in Table 1. The primary outcome was the incidence of hypoxemia (as defined by the individual trials). Secondary outcomes were the incidence of respiratory depression and adverse effects (sore throat, nose-bleeding, and dry mouth).

2.5. Quality assessment

Two researchers evaluated these studies using the Cochrane collaboration's tool [15]. The risk bias tool included the following sections: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcomes, and other biases. Each result was divided into three levels (high, low, and unclear risk) for judgement, and the process was recorded using Review Manager Software (RevMan 5.4) [16]. When the two researchers disagreed with the results of one study, a third researcher participated.

2.6. Statistical analysis

RevMan 5.4 was used for statistical analysis. Dichotomous outcomes were expressed as relative risks (RR) and 95% confidence intervals (CI). The Q statistic (chi-square value of the heterogeneity test), P -value, and I^2 statistic were used to evaluate the heterogeneity among studies [17]. $P \leq 0.1$ or $I^2 > 50\%$ was considered significant heterogeneity [18]. We chose a random-effects model using the DerSimonian and Laird method, which is more suitable for various populations with a wide background [19]. Stata Statistical Software 17 (StataCorp., T.X., USA) was used for sensitivity analysis [20]. Qwing to insufficient literature, we did not

identify publication bias using a funnel plot.

3. Results

3.1. Search results

A total of 985 records were initially retrieved and 260 duplicate articles were deleted. Finally, 713 studies were excluded based on the relevance of the titles or abstracts. After obtaining 21 full-text articles, 9 trials were finally included (Fig. 1).

3.2. Trial characteristics

The study characteristics are presented in Table 1. The sample sizes for the individual trials ranged from 49 to 1185. The primary outcomes included high- and low-risk subgroups based on surgical or patient-related factors affecting the airway during surgery.

Considering the risk of reflux aspiration during the operation and the impact on the respiratory tract when the gastroscope was inserted, we performed upper gastrointestinal endoscopic surgery in the high-risk group. Finally, seven studies [8,21–27] were classified as high-risk subgroups including bronchoscopy, upper gastroscopy, and patients with obesity or obstructive sleep apnea-hypopnea syndrome, whereas the other two [28,29] (colonoscopy and hysteroscopy) were classified as low-risk subgroups. Hypoxemia was defined based on the included studies (Table 1). In addition, four studies mentioned the concept and scope of subclinical respiratory depression (90–95%), which was conducted in a statistical study (Fig. 5a). The COT group provided oxygen flow and delivery device for each group: two studies [21,28] used face

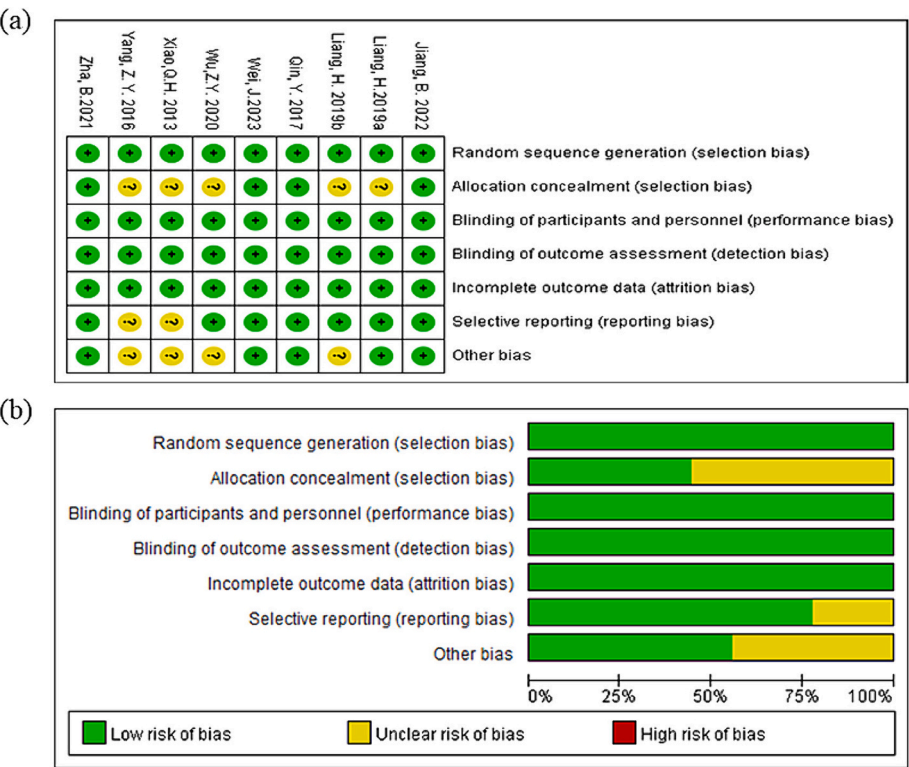


Fig. 2. Risk of bias graph and risk of bias summary. (a) the risk of bias graph: review each risk of bias item presented as percentages across all included studies. (b) the risk of bias summary.

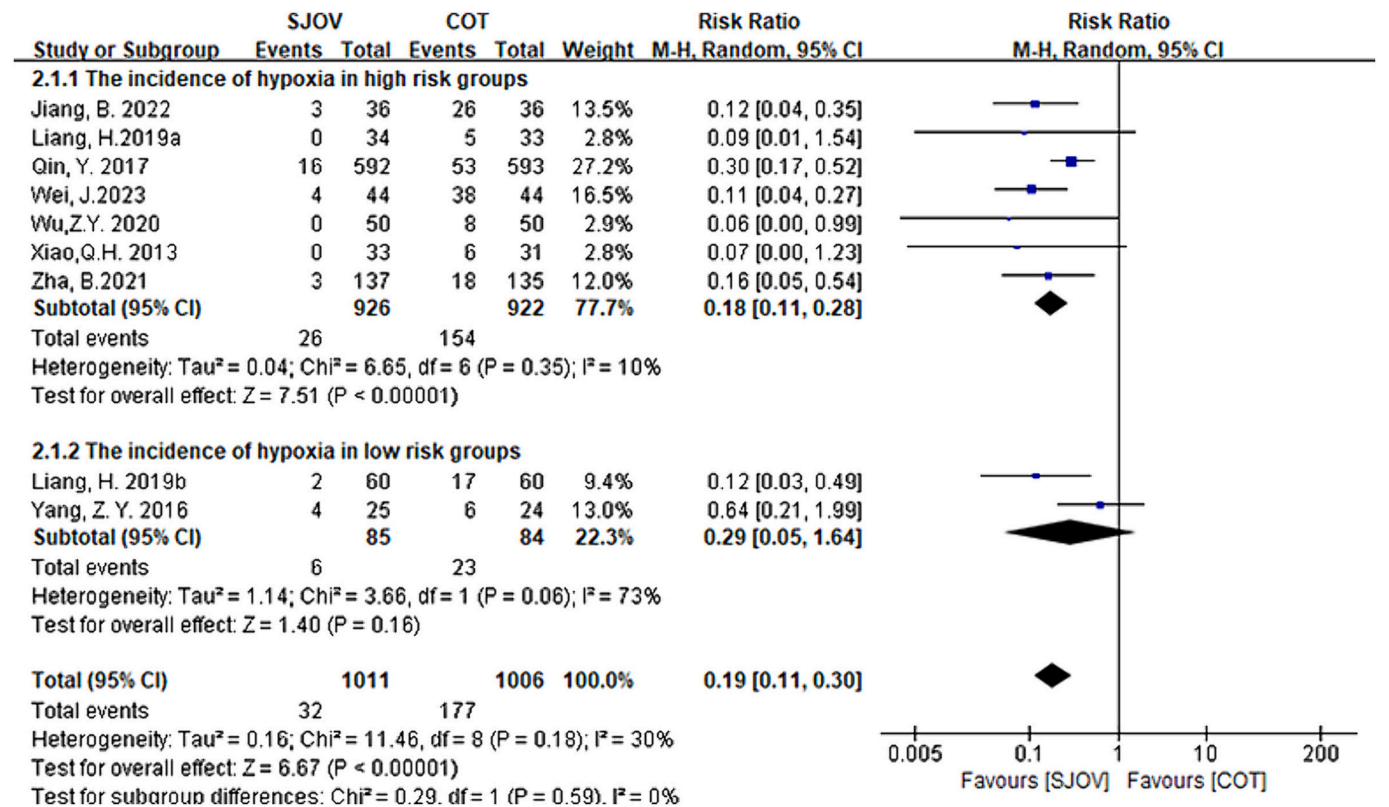


Fig. 3. The forest plot of the incidence of hypoxemia (high and low risk subgroups). SJOV, supraglottic jet oxygenation and ventilation; COT, conventional oxygen therapy; CI, confidence interval; RR, risk ratio.

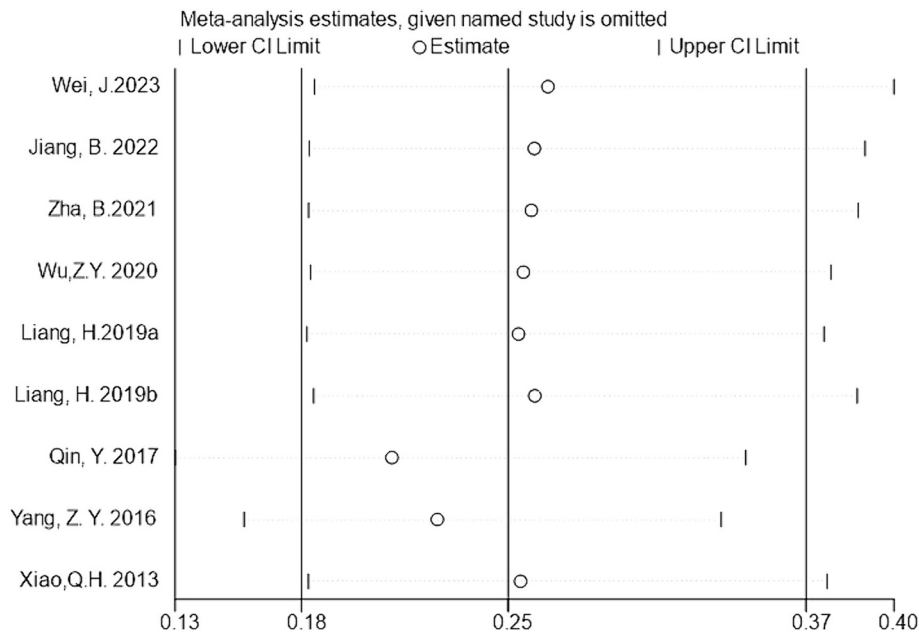


Fig. 4. Sensitivity analysis. CI, confidence interval; RR (95%CI) = 0.19 (0.11, 0.33). After deleting any study, the 95% CI of the combined efficacy of the remaining studies did not include 1.

masks, other eight studies [8,22,24–27,29] used nasal cannulas for oxygenation. The driving pressure, jet frequency, and inspiratory/expiratory ratio were measured in the SJOV group. The results of the risk quality assessment are shown in Fig. 2. Four studies referenced allocation concealment, and all studies were rated as low risk in terms of random sequence generation, incomplete outcome data, and selective outcomes. All studies were considered to have a low risk of blindness in participants, and the personnel for the main outcome was an objective indicator that did not depend on whether the patient knew the experiment. Four studies had low risk of bias, and five studies had an unclear risk of bias.

3.3. Incidence of intraoperative hypoxemia

Nine studies (2017 patients) compared the incidence of hypoxemia between the SJOV and COT groups. There was a low heterogeneity among the studies ($P = 0.18$, $I^2 = 30\%$). The total effect showed that SJOV can decrease the incidence of hypoxemia compared with the COT (RR = 0.19, 95% CI [0.11–0.30], $P < 0.00001$) (Fig. 3).

3.4. Subgroup and sensitivity analyses

There were seven studies (1848 patients) in the high-risk subgroup with low heterogeneity among the studies ($P = 0.35$, $I^2 = 10\%$). The result has showed SJOV was superior to COT in reducing the incidence of hypoxemia (RR = 0.18, 95% CI [0.11, 0.28], $P < 0.00001$) (Fig. 3). In the low-risk subgroup, the results from two studies (169 patients) showed no statistically significant difference in the incidence of hypoxemia between the SJOV and COT groups (RR = 0.29, 95% CI [0.05, 1.64], $P = 0.16$; $I^2 = 73\%$) (Fig. 3). What is more, we carried out the sensitivity analysis via Stata17 by deleting one study at a time, combined 95% CI from (0.13–0.37) to (0.18–0.40), which demonstrated the robustness of result analysis (Fig. 4).

3.5. Incidence of intraoperative respiratory depression

Four studies (1765 patients) clearly proposed the range of respiratory depression (SpO_2 : 90–95%) and compared it between the two groups. The heterogeneity analysis showed $P = 0.01$ and $I^2 = 68\%$. The

results showed that the difference in the incidence of respiratory depression between patients with SJOV and COT was statistically significant (RR = 0.43, 95% CI [0.26, 0.70], $P = 0.0006$) (Fig. 5a).

3.6. Adverse effects

Our findings do not support the use of SJOV for more cases of nasal bleeding and sore throat than COT, except for dry mouth. Six studies (648 patients) compared the incidence of nasal bleeding (RR = 0.97, 95% CI [0.57, 1.63], $P = 0.90$; $I^2 = 0\%$) (Fig. 5b); Six studies (648 patients) compared the incidence of pharyngeal pain between the two groups (RR = 1.39, 95% CI [0.92, 2.11], $P = 0.12$; $I^2 = 0\%$) (Fig. 5b); Four studies (499 patients) compared the incidence of postoperative dry mouth (RR = 5.25, 95% CI [2.29, 12.02], $P < 0.0001$; $I^2 = 0\%$) (Fig. 5b).

4. Discussion

Our findings indicate that high-risk patients receiving SJOV had a lower incidence of hypoxemia than those receiving COT. In patients undergoing digestive endoscopic or fiberoptic surgery with sedation, SJOV was associated with minor complications, but not more than COT, except for dry mouth. The increased incidence of dry mouth may be due to the constant injection of oxygen without humidification.

Physiologically, the SJOV delivers oxygen directly into the trachea through the nasopharynx to the upper glottis via synchronous injection at a high or low frequency for effective pulmonary ventilation [10]. During bronchoscopy, jet pulses of the SJOV provide greater aerodynamic force than the COT, and the injected gas passes through the vocal cords into the trachea even under moderate to severe sedation [9]. Simultaneously, the pulse influx of flowing gas constantly updates lung gas and promotes gas exchange, thus providing adequate oxygenation and ventilation [30]. As a novel ventilation method, the oxygenation effect of SJOV is independent of whether patients open their mouths [10,31]. It also does not restrict the patient's breathing status. Moreover, the SJOV with adequate sedation can decrease the intraoperative body motion reactions caused by surgical stimulation [21]. In contrast to transtracheal jet ventilation, SJOV significantly reduces invasive injury via a Wei-tube [10]. Additionally, unlike subglottic jet ventilation, SJOV is not used in relatively confined spaces. The air pressure created by the

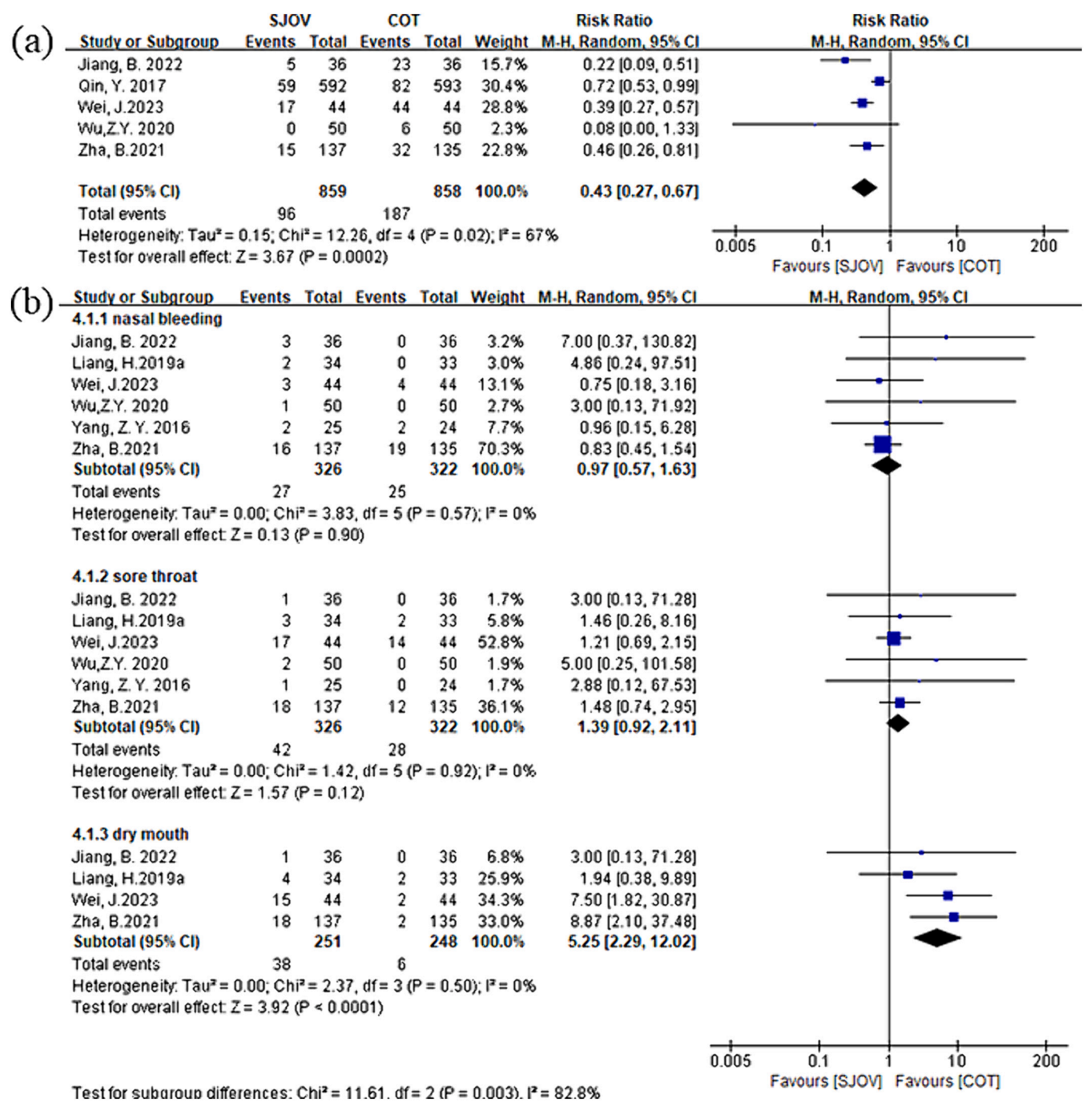


Fig. 5. Secondary outcome. SJOV, supraglottic jet oxygenation and ventilation; COT, conventional oxygen therapy; CI, confidence interval; RR, risk ratio. (a): The forest plot of the incidence of respiratory depression (SpO2: 90%–95%). Four studies all from high-risk group. (b): The forest plot of the incidence of adverse effects.

SJOV can be expelled through the open mouth or nasal cavity, significantly decreasing the risk of subglottic barotrauma significantly [21,22,32].

Currently, studies on the SJOV using endoscopic procedures are limited. A previous review noted the use of the SJOV in various procedures, including in this area, but this was not statistically analyzed [10]. A cohort study of 371 patients investigating the efficacy of the SJOV in laryngotracheal stenosis with endoscopic treatment showed that the incidence of intraoperative complications (such as severe hypoxia, barotrauma) was <1% [33]. Meanwhile, a case report of Levitt et al. reported the successful application of the SJOV in gastrointestinal endoscopic surgery in a 160 kg morbidly obese patient with a BMI of 54

kg/m² [34]. These studies show that the SJOV is a novel and promising ventilation tool that can be used as a substitute for the COT in endoscopic surgery.

This meta-analysis supports the use of SJOV in the 2022 guidelines for difficult airway management and as a supplementary ventilation mode in guidelines for sedation and anesthesia in GI endoscopy [35,36]. Comparison to other ventilation tools, the SJOV offers several advantages. Compared with the COT, the use of the SJOV in endoscopic surgery can provide better oxygenation. Unlike mechanical ventilation, SJOV allows spontaneous breathing during endoscopic procedures without the need for muscle relaxants. This not only enhances patient comfort but also increases the flexibility of surgical procedures,

particularly in upper gastrointestinal or fiberoptic bronchoscopy [22]. Furthermore, SJOV has been successfully applied to patients with difficult airway in previous studies [34,37–39]. Thus, it is recommended to be used more widely in endoscopic surgery with sedation. We look forward to exploring its advantages and applications through more robust research.

To our knowledge, this is the first meta-analysis to compare the SJOV and COT during endoscopic surgery. We conducted a comprehensive literature search, complied with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses declaration [14] and adhered to the registry protocol. We also analyzed the subgroups based on airway risk. Although heterogeneity may have affected the results due to differences in the definition of hypoxemia, intervention methods, different types of procedures, and other aspects, we conducted subgroup analysis, random-effects model, and sensitivity analysis to reduce bias resulting from the heterogeneity of the included studies. Despite our data analysis yielding relatively reliable results, inevitable bias and heterogeneity were observed. Because only two studies were included in the low-risk subgroup, there may have been a type II error in the results. Hence, it is prudent to interpret the effects of SJOV. In addition, while the SJOV with a Wei tube (WNJ) can measure intraoperative CO₂ in patients, another potential advantage of the SJOV is that we cannot conduct a data analysis because few studies included the WNJ. Therefore, there are certain limitations to the function and application scope of the SJOV in our study. However, the potential applications and advantages of SJOV require further reliable research.

5. Conclusion

Compared to COT, SJOV decreased the incidence of hypoxemia in high-risk patients during endoscopic surgery with sedation. There was no increased risk of nose bleeding or sore throat during endoscopic surgery with sedation, except for dry mouth.

Authors' contributions

Conception or design of the work: Xiaoliang Wang, Rukun Xu, Hongwei Shi; Literature search and selection: Rukun Xu, Zixuan Li, Xue Jiang; Methodology: Zixuan Li, Wenwen Zhang; Data extraction and analysis: Yong Zhang, Yajie Xu, Lili Zhu, Rukun Xu; Drafting the manuscript: Rukun Xu, Zixuan Li; Review and editing of the manuscript: Xiaoliang Wang, Hongwei Shi, and Huafeng Wei. The final version of the manuscript has been read and approved by all authors.

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Ethics approval and consent to participate

Not applicable.

Consent for publication

Written informed consent for publication was obtained from all participants.

CRediT authorship contribution statement

Rukun Xu: Writing – original draft, Investigation, Formal analysis, Data curation. **Zixuan Li:** Methodology, Formal analysis, Data curation. **Xue Jiang:** Formal analysis, Data curation. **Wenwen Zhang:** Methodology, Investigation. **Yajie Xu:** Formal analysis, Data curation. **Yong Zhang:** Investigation, Data curation. **Lili Zhu:** Data curation. **Huafeng Wei:** Writing – review & editing. **Hongwei Shi:** Writing – review & editing, Conceptualization. **Xiaoliang Wang:** Writing – review &

editing, Conceptualization.

Declaration of competing interest

All authors declare that there are no conflicts of interest.

Data availability

The datasets used and analyzed in this study are available from the corresponding authors upon reasonable request.

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RESEARCH

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Efficacy and safety of supraglottic jet oxygenation and ventilation to minimize sedation-related hypoxemia: a meta-analysis with GRADE approach

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Abstract

Introduction Hypoxemia is a common complication of sedation. This meta-analysis aimed to evaluate the efficacy and safety of supraglottic jet oxygenation and ventilation (SJOV) in preventing hypoxemia during sedative procedures.

Methods Randomized controlled trials (RCTs) that compared SJOV with conventional oxygen therapy in sedated patients were searched in five databases (MEDLINE, EMBASE, Cochrane Library, China National Knowledge Infrastructure [CNKI], and Google Scholar) from their inception to March 2024. The primary outcome was the proportion of patients who developed hypoxia ($\text{SpO}_2 < 90\%$). The secondary outcomes included subclinical respiratory depression ($90\% \leq \text{SpO}_2 < 95\%$), severe hypoxemia ($\text{SpO}_2 < 75\%$), airway interventions, adverse events, hemodynamics, propofol dosage, and procedure time. The certainty of evidence was determined using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

Results Twelve trials ($n = 3058$) were included in the analysis. The evidence suggests that SJOV results in a large reduction in the risk of hypoxemia (risk ratio [RR], 0.26; 95% confidence interval, 0.19–0.36; low certainty) and subclinical respiratory depression (RR, 0.40; low certainty) compared with the control. SJOV likely resulted in a large reduction in the risk of severe hypoxemia (RR, 0.22; moderate certainty). In addition, it may result in a large reduction in the need for jaw lift (RR, 0.22; low certainty) and mask ventilation (RR, 0.13; low certainty). The risk of sore throat probably increases with SJOV (RR, 1.71; moderate certainty), whereas SJOV may result in little to no difference in nasal bleeding (RR, 1.75; low certainty). Evidence is very uncertain regarding the effect of SJOV on hemodynamics (very low certainty) and procedure time (very low certainty). SJOV probably resulted in little to no difference in sedative doses between the groups (moderate certainty).

Conclusion According to the GRADE approach, SJOV likely results in a large reduction in the risk of severe hypoxemia but probably increases the risk of sore throat. Compared with the control, evidence suggests that SJOV results

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in a large reduction in the risk of hypoxemia, subclinical respiratory depression, and the need for airway manipulation, with little to no difference in nasal bleeding. The integration of SJOV into clinical practice may help minimize hypoxemic events in at-risk patients.

Keywords Supraglottic jet oxygenation and ventilation, Hypoxemia, Sedation, Propofol, Wei nasal jet tube

Introduction

Procedural sedation and analgesia are commonly performed to provide patient comfort and minimize pain, anxiety, and movement during invasive procedures [1–3]. In clinical settings, propofol is the preferred sedative because of its ability to induce sedation quickly and allow rapid recovery [4, 5]. However, the use of propofol with or without opioids can lead to dose-dependent respiratory depression and airway obstruction, thereby increasing the risk of hypoxemic events [6, 7]. Approximately 12–33% of patients experience transient oxygen desaturation during procedural sedation [6, 8–11]. Severe intraprocedural desaturation often requires brief positive-pressure ventilation to restore adequate oxygenation, which may interfere with the procedure. If untreated, these episodes of hypoxemia can progress to cyanosis, arrhythmia, organ dysfunction, and cardiovascular collapse [12–14]. In this regard, hypoxemia is responsible for as many as 25% of anesthesia-related deaths [15]. Minimizing sedation-related hypoventilation and maintaining optimal oxygenation throughout the procedure are critical [16]. Researchers have been interested in exploring alternative options to propofol [17–19] or combining other sedative agents with propofol [20–24] to improve patient safety during sedation. However, substantiating the efficacy and safety of these interventions is time-consuming.

In addition to improvements in pharmacological approaches, advanced oxygen delivery techniques such as high-flow nasal oxygen (HFNO) therapy have been reported to reduce the occurrence of hypoxemia during procedural sedation [25–27]. These advanced high-flow systems are often utilized to avert respiratory failure in critical care settings [28, 29], so their use in sedation settings remains uncommon. Supraglottic jet oxygenation and ventilation (SJOV) is an alternative technique that involves inserting a catheter (e.g., Wei nasal jet tube) into the nose or mouth, positioning its tip just above the vocal cords, and connecting it to a jet ventilator to deliver high-pressure pulses of oxygen [30, 31]. The high-pressure jet of oxygen helps to push oxygen into the lungs and flush out carbon dioxide to oxygenate the patient and provide ventilation [30]. SJOV can reduce the risk of hypoxemia in patients who undergo bronchoscopy or colonoscopy under sedation [32–34]. Although SJOV may be a promising technique for reducing the risk of hypoxemia, its

efficacy and safety have not yet been assessed using a systematic approach. The number of diagnostic and therapeutic procedures requiring sedation has increased substantially [35, 36]. Consequently, ensuring the safety and quality of sedation is necessary to meet this increased demand. This systematic review and meta-analysis aimed to evaluate the existing evidence regarding the efficacy and safety of SJOV compared with standard oxygenation in minimizing sedation-related hypoxemia.

Method

This systematic review and meta-analysis adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The protocol for this meta-analysis was registered with the International Prospective Register of Systematic Reviews (PROSPERO) prior to conducting the literature search and data extraction (registration number: CRD42024519442; registration date: March 2, 2024).

Search strategy and data sources

A literature search was conducted to identify all relevant randomized controlled trials (RCTs) on the efficacy and safety of SJOV in minimizing sedation-related hypoxia. The following databases were searched from inception to March 2024: MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), China National Knowledge Infrastructure (CNKI), and Google Scholar. The search strategy combined controlled vocabulary specific to each database (e.g., Medical Subject Headings terms in MEDLINE) and free-text words relevant to the research topic. Search terms included (“Supraglottic jet oxygenation” or “SJOV” or “Wei nasal jet tube” or “supraglottic jet oxygenation and ventilation” or “Transnasal jet ventilation” or “Wei nasal jet ventilation” or “jet ventilation” or “apneic ventilation” or “high frequency jet ventilation”) AND (“Sedation” or “Sedative procedure” or “Procedural sedation” or “Monitored anesthesia care” or “Colonoscopy” or “Bronchoscopy” or “Endoscopic retrograde cholangiopancreatography” or “gastrointestinal endoscopy” or “gastroscopy” or “propofol” or “intravenous anesthesia”) AND (“Respiratory depression” or “Hypoxaemia” or “Nasal bleeding” or “Hypoxia” or “Adverse events” or “tracheal intubation”). No restrictions were placed on language or publication

year. The reference lists of all eligible studies and relevant systematic reviews were manually examined to identify additional relevant studies. The search strategy for one of the databases is listed in Supplemental Table 1.

Inclusion and exclusion criteria

The following inclusion criteria were used: (1) patients aged ≥ 18 years undergoing procedures under sedation with or without analgesia; (2) intervention involving SJOV administered through an oral or nasal route; (3) control group using conventional oxygenation techniques, such as oxygen supplementation via nasal cannula; (4) reported incidence of hypoxemia and/or adverse events; and (5) RCTs with full text available.

Studies were excluded if (1) they were animal or simulation studies; (2) they focused on patients under general anesthesia with or without muscle relaxants; (3) SJOV was employed either before or during tracheal intubation; (4) they were presented as case reports, observational studies, review articles, case series, or conference abstracts; or (5) a tracheal tube or laryngeal mask airway was used to protect the airway during sedation. Two reviewers independently assessed all studies for eligibility using predefined criteria. We excluded conference abstracts from our analysis because they often lack detailed methodology and results, making it difficult to assess study quality and risk of bias. In addition, data published in conference abstracts are often preliminary and may change significantly after peer review, risking inaccuracies in the meta-analysis.

Selection process for studies

The study selection process was conducted in two phases. In the first phase, two independent reviewers screened the titles and abstracts of the retrieved records to identify potentially eligible studies. In the second phase, the same reviewers assessed the full texts of potentially eligible articles in detail using the same eligibility criteria. Disagreements at both stages were resolved by consensus or consultation with a third reviewer.

Data collection

Two independent reviewers extracted relevant data from the included studies in a standard form. The extracted information included the following:

- (1) Study characteristics: authors, year, study design, setting, and country.
- (2) Patient characteristics: demographics, American Society of Anesthesiologists' (ASA) Physical Status, sex distribution, and body mass index (BMI).

- (3) Details on intervention and control groups: device used and oxygen flow rate.
- (4) Details on the procedure: type of procedure performed, procedural timing, and dosage of propofol.
- (5) Outcomes: incidence of hypoxemia (as defined by the study), need for airway assistance (e.g., mask ventilation), adverse events (e.g., sore throat, nasal bleeding), and hemodynamic instability (e.g., hypertension).

For studies with multiple publications, the most complete and recent reports on outcomes were used. Missing data were requested by the authors via email. The extracted data were cross-checked by two reviewers to resolve any discrepancies.

Outcome and definition

The primary outcome was the incidence of intraoperative hypoxemia, defined as the proportion of patients experiencing $< 90\%$ oxygen desaturation during the procedure in each study group. The secondary outcomes included the incidence of subclinical respiratory depression (i.e., $90\% \leq \text{SpO}_2 < 95\%$), severe hypoxemia (i.e., $\text{SpO}_2 < 75\%$), need for airway assistance (e.g., mask ventilation), hemodynamic instability, adverse events, and differences in propofol dosage and procedure time. Our definitions of hypoxemia and categorizations of hypoxemia severity were based on consistent criteria used across all included studies. Regarding procedural time, we considered a difference of at least 5 min to be clinically relevant based on clinical judgment.

Quality of assessment for studies

The methodological quality of the included RCTs was assessed using the revised Cochrane risk of bias tool for randomized trials (RoB 2) [37]. Two independent reviewers assessed the presence of bias across the following domains: bias arising from the randomization process, bias due to deviations from the intended interventions, bias from missing outcome data, bias in the measurement of the outcome, and bias in the selection of the reported result. For each domain, the risk of bias was categorized as low, "some concerns," or high. An overall risk of bias judgment was made across the domains for each included trial. Disagreements between the two reviewers were resolved by discussion and consensus or by consulting a third reviewer. The results were drawn using the risk of bias visualization tool [38].

Certainty of evidence

The certainty of evidence for each outcome was determined using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach

[39]. Two independent reviewers rated the certainty of each outcome as high, moderate, low, or very low based on the risk of bias, inconsistency, indirectness, imprecision, and publication bias. The level of certainty within the domain of imprecision was adjusted downwards according to newly established criteria [40]. Any discrepancies in the GRADE assessments were discussed between the two reviewers to reach a consensus or resolved by a third author. GRADE certainty ratings were detailed, summarized into a table, and employed to determine the strength of evidence for guiding practice recommendations using the GRADEpro Guideline Development Tool (McMaster University and Evidence Prime, 2022; available at grade.pro.org). In addition, we present the findings of the meta-analysis using a standardized approach to effectively communicate the results [41].

Statistical analysis

All analyses were conducted using the Cochrane Review Manager (RevMan 5.3; Copenhagen: The Nordic Cochrane Center, The Cochrane Collaboration, 2014) or Comprehensive Meta-Analysis version 4 (Biostat, Englewood, NJ, USA). Dichotomous outcomes are expressed as risk ratios (RR) with 95% confidence intervals (CIs). Continuous outcomes were summarized using mean differences with 95% CIs. For studies with more than two control arms, participant data in the intervention group were split to create multiple pairwise comparisons while preventing double counting [42]. The number of events and participants in the shared study arms were evenly divided among the comparison groups. This approach enabled the inclusion of multiple control groups per study while avoiding overlap in participants across comparisons.

As clinical and methodological variability was expected between studies, a random-effects model was used for analysis, regardless of heterogeneity. Sensitivity analyses using the leave-one-out approach were conducted to evaluate the robustness of the findings. If at least 10 studies or datasets were included for any outcome, publication bias was assessed by visual inspection of funnel plots and Egger's regression test for asymmetry. The I^2 statistic was used to evaluate between-study heterogeneity for each outcome, with $I^2 > 75\%$ indicating substantial heterogeneity. Sources of heterogeneity were explored through subgroup and meta-regression analyses, if substantial heterogeneity was present. A two-sided p -value < 0.05 was considered statistically significant for all analyses. Trial sequential analysis (TSA) was performed on the primary outcome to examine the robustness of the evidence. We applied a type I error of 5%, power of 80%, and

relative risk reduction of 20% based on the minimal clinically important difference for intervention efficacy.

Results

Search results and study characteristics

The initial literature search yielded 118 records from various databases, which was reduced to 93 after removing 25 duplicates (Fig. 1). Screening of titles and abstracts excluded 59 records that did not meet the inclusion criteria. Of the 34 full texts assessed, 22 were excluded for the following reasons: lack of control groups ($n=3$), tracheal intubation or laryngeal mask airway involvement ($n=13$), and absence of an intervention group ($n=6$) (Supplemental Table 2). Ultimately, 12 RCTs (two arms: eight trials [32, 34, 43–48], three arms: four trials [31, 33, 49, 50]) with 3058 participants were included in the analysis (Table 1).

The mean age of the participants ranged from 41 to 73 years, with the percentage of males ranging from 0 to 77%. Eleven RCTs included the general population, whereas one trial focused on obese patients [49]. Most studies enrolled patients with ASA physical status I–III who received sedative agents, including propofol, with or without opioids. Sedation levels varied across studies, ranging from monitoring anesthesia care to deep sedation. SJOV was delivered using a Wei nasal jet tube in 11 trials and via an 11 Fr tube exchanger in one trial [34]. In all cases, the devices were inserted through the nostrils. The SJOV settings included an oxygen flow rate of 8–20 L/min and driving pressure of 14.5–45 psi, with a commonly used driving pressure of 15 psi. The control group received oxygen supplementation at 2–6 L/min, using various airway devices. Among the five studies that examined CO_2 levels with SJOV use, three found that the levels were associated with a low risk of CO_2 retention, whereas two did not report similar findings (Supplemental Table 3). Additionally, two studies measured gastric volume using ultrasound before and after SJOV use, and the results showed no significant difference in gastric volume (Supplemental Table 3). No studies reported the occurrence of barotrauma (Supplemental Table 3). All studies were conducted in China. The funding sources for each study are provided in Supplemental Table 4.

Risk of bias

The risk of bias assessment of the included studies for the primary outcome is shown in Fig. 2. The majority of trials were judged to have some concern in the randomization process, with the exception of four studies that had a low risk of bias. All studies were considered to have a low risk of bias for deviations from the intended interventions, missing outcome data, and outcome measurements. Regarding the risk of bias in the selection of

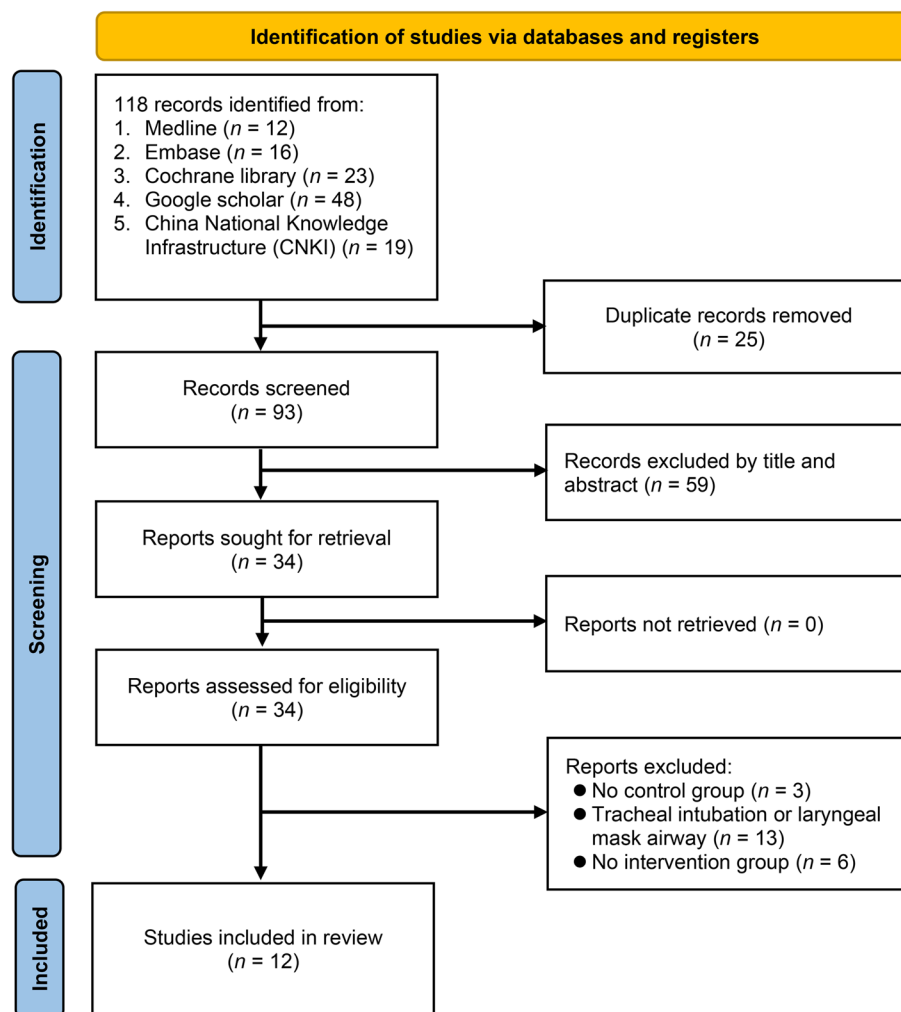


Fig. 1 Flow chart of study selection

reported results, most studies were judged to have a low risk, except for one study that had some concerns. The overall risk of bias was low in four studies [33, 34, 44, 50], while seven studies had some concerns [31, 43, 45–49]. One of the studies had a high risk of bias [32]. The risk of bias assessment for the secondary outcomes is presented in Supplemental Table 5.

Outcomes

Primary outcome: risk of hypoxemia

The evidence suggested that SJOV results in a large reduction in the risk of intraoperative hypoxemia ($\text{SpO}_2 < 90\%$) compared to the conventional oxygenation techniques (3.1% vs. 13.6%; $\text{RR}=0.26$, 95% CI 0.19 to 0.36; $p<0.00001$; $I^2=0\%$, low certainty evidence) (Fig. 3). Subgroup or meta-regression analyses were not performed because of lack of heterogeneity. TSA showed

that the z-curve crossed trial sequential monitoring boundaries, indicating the robustness of the evidence (Fig. 4).

Secondary outcomes

The evidence suggested that SJOV results in a large reduction in the risk of subclinical respiratory depression (SpO_2 90–95%) (9.7% vs. 20.7%, $\text{RR}=0.40$, 95% CI 0.29–0.56, $p<0.00001$; $I^2=51\%$, low certainty evidence) (Fig. 5). SJOV likely results in a large reduction in the risk of severe hypoxemia ($\text{SpO}_2 < 75\%$) (0 vs. 1.7%, $\text{RR}=0.22$, 95% CI 0.08–0.64, $p=0.005$; $I^2=0\%$, moderate certainty evidence) (Fig. 6). In addition, SJOV may result in a large reduction in the need for jaw lift (3.7% vs. 18.7%, $\text{RR}=0.22$, 95% CI 0.16 to 0.31, $p<0.00001$; $I^2=0\%$, low certainty evidence) (Fig. 7) and mask ventilation (0.0% vs. 4.1%, $\text{RR}=0.13$, 95% CI 0.05 to 0.31, $p<0.00001$; $I^2=0\%$, low certainty evidence) (Fig. 8). SJOV may result

Table 1 Characteristics of 12 randomized controlled studies ($n = 3058$)

| Studies | RCT design | Age (years) ^a | BMI (kg/m ²) | Male (%) ^a | N | ASA | Sedation level | Sedation agents | SJOV setting (DP) ^b | Control setting (device/flow) | Procedure | Country |
|----------------|------------|--------------------------|--------------------------|-----------------------|------|-------|----------------|-----------------|--------------------------------|--------------------------------|--------------|---------|
| Fu 2023 | 2-arm | 45/44 | 22/22 | 48/46/ | 100 | I–III | Deep sedation | Pro/re | 18–20 psi | NPA 6 L/min | ERCP | China |
| Jiang 2022 | 2-arm | 49/50 | 24/ 23 | 50/53 | 72 | I–III | OAA/S: 1–2 | Pro | 15 psi | NC 2 L/min | GI endoscopy | China |
| Li 2019 | 2-arm | 73/73 | 19/19 | 63/60 | 60 | I–II | BIS < 60 | Pro/Suf | 35–45 psi | NC 5 L/min | FB | China |
| Liang 2019 (1) | 2-arm | 45/43 | 24/23 | 0 | 120 | I–II | BIS: 45–60 | pro/re | 14.5–43.5 psi | Mask 6 L/min | Hysteroscopy | China |
| Liang 2019 (2) | 3-arm | 44/45/44 | 33/33/33 | 0 | 100 | I–II | BIS: 45–60 | pro/re | 14.5 psi | Mask 6 L/min WNU 6 L/min | Hysteroscopy | China |
| Qin 2017 | 3-arm | 47/46/48 | 23/23/23 | 47/45/46 | 1781 | I–III | OAA/S: 2–3 | pro | 15 psi | NC 2 L/min, WNU 2 L/min | GI endoscopy | China |
| Su 2024 | 3-arm | 56/56/56 | 23/23/22 | 45/48/39 | 167 | I–III | BIS 45–60 | pro/re/dex | 15 psi | NPA 4–6 L/min WNU 4–6 L/min | ERCP | China |
| Wei 2024 | 3-arm | 59/59/62 | 24/23/23 | 57/50/61 | 132 | I–III | MOAA/S: 1–2 | pro/re | 15 psi | NC 4 L/min WNU 4 L/min | FB | China |
| Wu 2020 | 2-arm | 44/44 | na | 48/44 | 100 | I–III | Deep sedation | pro | 15 psi | NC 6 L/min | gastrosocopy | China |
| Yang 2023 | 2-arm | 51/51 | 23/22 | 66/64 | 105 | I–III | RSS score: 4–5 | pro/re | 14.5 psi | Mask | FB | China |
| Yang 2016 | 2-arm | 41/43 | 22/22 | 36/13 | 49 | I–II | MAC | Pro/fe | 15 psi ^c | NC 6 L/min | Colonoscopy | China |
| Zha 2021 | 2-arm | 52/53 | 21/21 | 77/77 | 272 | I–III | MOAA/S 2–3 | pro/re | 15 psi | NC 4 L/min | FB | China |

ASA Anesthesiologists physical status classification system, BIS Bispectral index, BMI Body mass index, dex dexmedetomidine, DP Driving pressure, ERCP Endoscopic retrograde cholangiopancreatography, fe fentanyl, FB Flexible bronchoscopy, GI Gastrointestinal, MAC Monitored anesthesia care, MOAA/S Modified Observer Assessment of Alertness/Sedation Scale, na not available, NC Nasal cannula, NPA nasopharyngeal airway, OAA/S Observer's Assessment of Alertness/Sedation, pro Propofol, RCT Randomized controlled trial, re remifentanyl, RSS Ramsay sedation scale, SJOV Supraglottic jet oxygenation and ventilation, suf sufentanil, WNU Wei nasal jet tube

^a presented as intervention/control groups

^b frequency: 8–20 min, FIO₂ = 1

^c Cook tube exchanger used



Fig. 2 Risk of bias assessment of included studies by using the revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

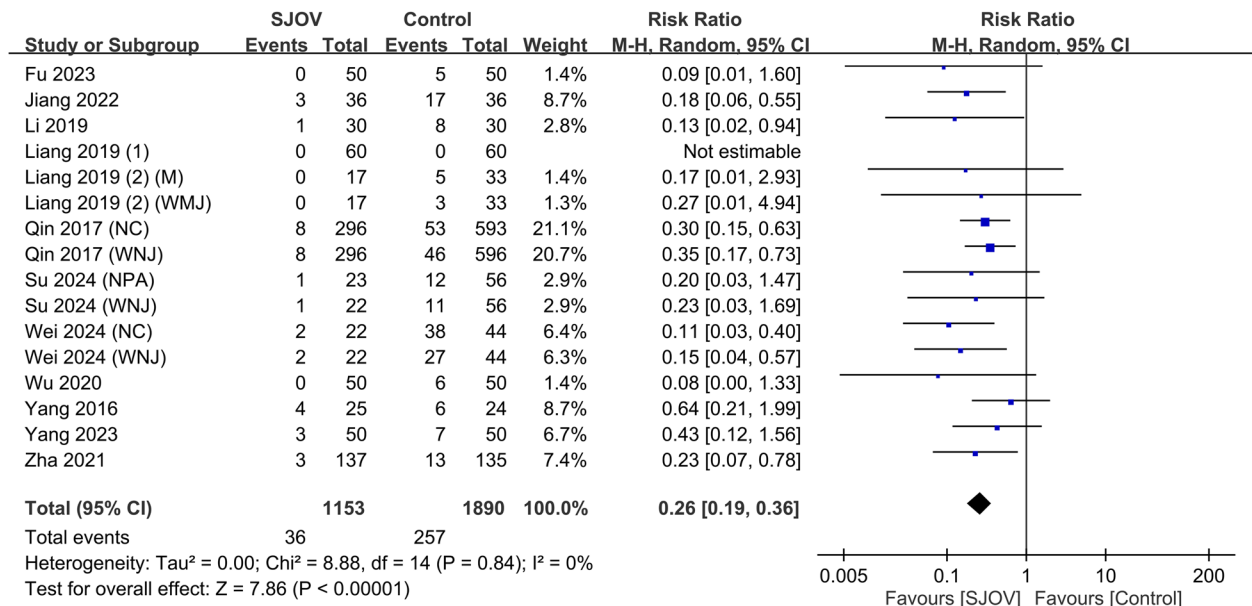


Fig. 3 Forest plot showing the efficacy of supraglottic jet oxygenation and ventilation (SJOV) against intraprocedural hypoxemia defined as SpO₂ < 90%. CI: confidence interval. M-H, Mantel-Haenszel; NPA, nasopharyngeal airway; WNJ, Wei nasal jet tube; NC, nasal cannula; M, mask

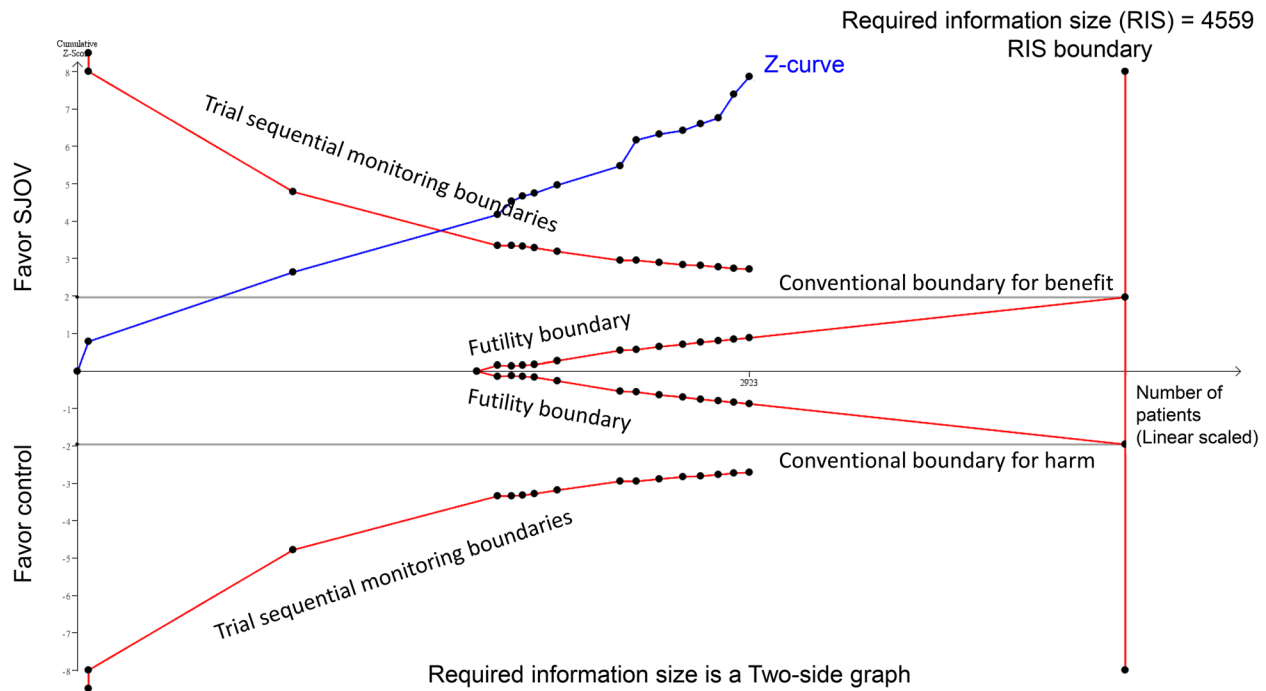


Fig. 4 Trial sequential analysis (TSA) of the primary outcome demonstrated that the z-curve crossed the trial sequential monitoring boundaries, indicating the strong robustness of the evidence

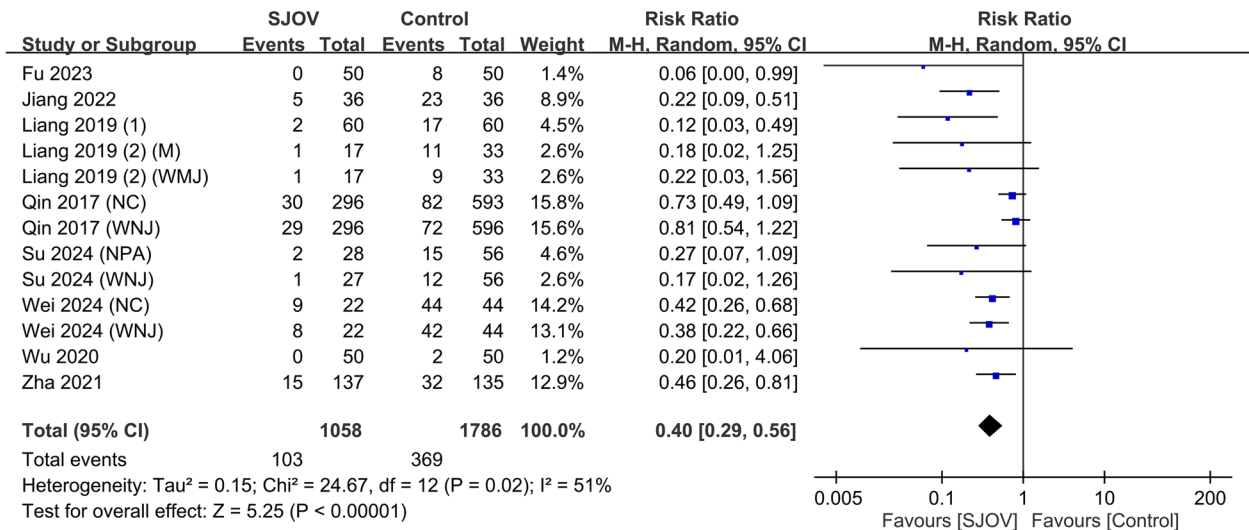


Fig. 5 Forest plot showing the risk of subclinical respiratory depression in the supraglottic jet oxygenation and ventilation (SJOV) versus control group. CI, confidence interval; M-H, Mantel-Haenszel; NPA, nasopharyngeal airway; WNJ, Wei nasal jet tube; NC, nasal cannula; M, mask

in little to no difference in nasal bleeding (2.1% vs. 1.6%, RR=1.75, 95% CI 0.89–3.45, $p=0.11$; $I^2=0\%$, low certainty evidence) (Supplemental Fig. 1). However, the risk of sore throat is probably increased with SJOV (6.7% vs. 4.7%, RR=1.71, 95% CI 1.22–2.39, $p=0.002$; $I^2=0\%$, moderate certainty evidence) (Supplemental Fig. 2).

The evidence is very uncertain regarding the effect of SJOV on the incidence rates of bradycardia (3.5% vs. 3.7%, RR=0.82, 95% CI 0.52–1.28, $p=0.38$; $I^2=0\%$, very low certainty evidence) (Supplemental Fig. 3), tachycardia (0.9% vs. 1.5%, RR=0.74, 95% CI 0.33–1.68, $p=0.92$; $I^2=4\%$, very low certainty evidence) (Supplemental

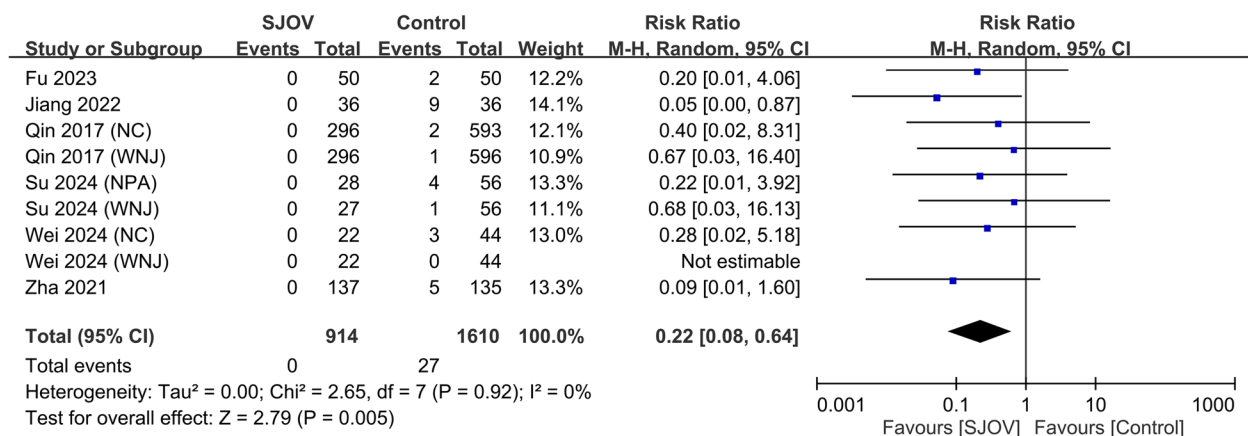


Fig. 6 Forest plot showing the risk of severe hypoxemia in the supraglottic jet oxygenation and ventilation (SJOV) versus control group. CI, confidence interval; M-H, Mantel–Haenszel; NPA, nasopharyngeal airway; WNJ, Wei nasal jet tube; NC, nasal cannula

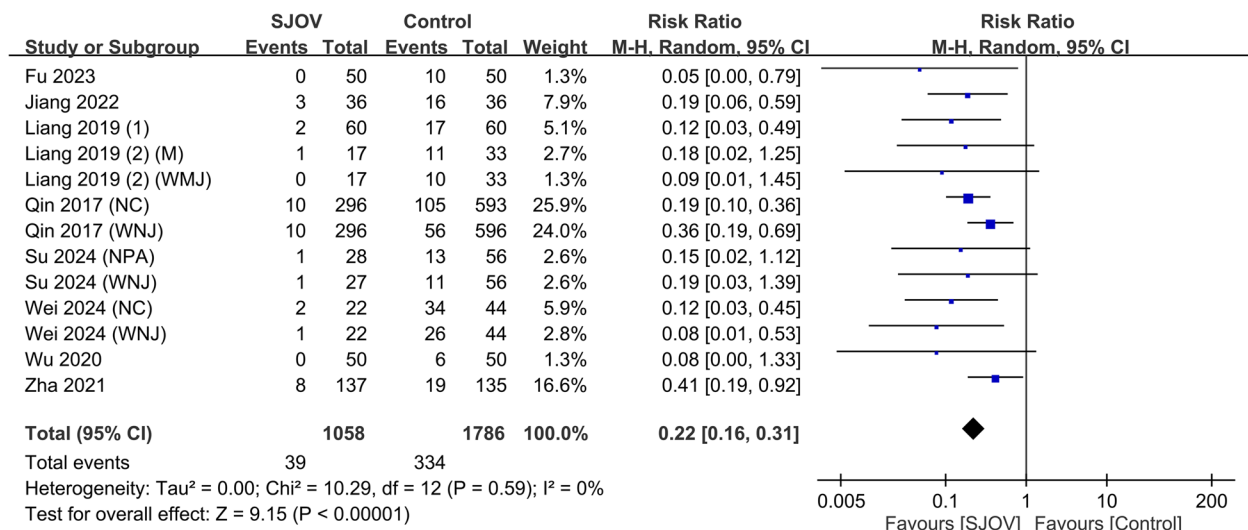


Fig. 7 Forest plot showing the risk of jaw lift in the supraglottic jet oxygenation and ventilation (SJOV) versus the control group. CI, confidence interval; M-H, Mantel–Haenszel; NPA, nasopharyngeal airway; WNJ, Wei nasal jet tube; NC, nasal cannula; M, mask

Fig. 4), hypertension (0.8% vs. 2.0%, $RR=0.48$, 95% CI 0.2–1.14, $p=0.1$; $I^2=0\%$, very low certainty evidence) (Supplemental Fig. 5), and hypotension (2.7% vs. 2.7%, $RR=0.91$, 95% CI 0.52–1.59, $p=0.74$; $I^2=0\%$, very low certainty evidence) (Supplemental Fig. 6). SJOV probably resulted in little to no difference in sedative doses between the groups ($MD = -0.03$ mg, 95% CI -2.39 to 2.33 , $p=0.98$; $I^2=0\%$, moderate certainty evidence) (Supplemental Fig. 7). The evidence is very uncertain regarding the effect of SJOV on procedure time (mean difference -0.6 min, 95% CI -1.04 to -0.16 , $p=0.007$; $I^2=81\%$, very low certainty evidence) (Supplemental Fig. 8). Although this difference was statistically

significant, it is well below the minimal clinically important difference of 5 min and therefore may not be clinically important.

Sensitivity analysis

Sensitivity analyses using the leave-one-out method showed consistent results for most outcomes except for nasal bleeding, hypertension, and procedure time. After excluding one study [33], a higher nasal bleeding risk was found in the SJOV group (the p -value changed from 0.11 to 0.03). Removing one study [44] showed reduced hypertension risk in the SJOV group (p -value changed from 0.1 to 0.03). Excluding another study

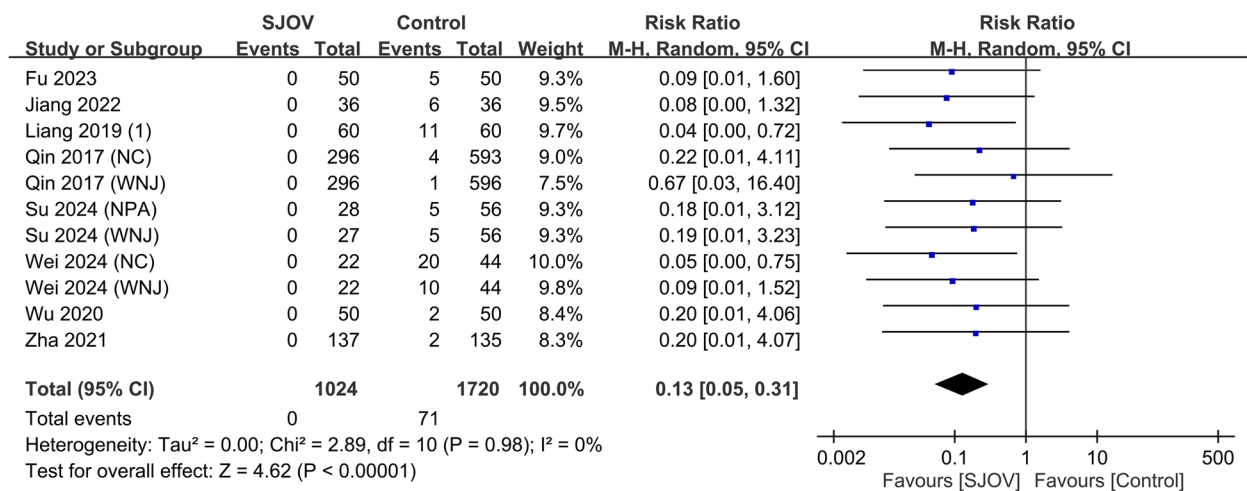


Fig. 8 Forest plot showing the risk of mask ventilation in the supraglottic jet oxygenation and ventilation (SJOV) versus control group. CI, confidence interval; M-H, Mantel–Haenszel; NPA, nasopharyngeal airway; WNJ, Wei nasal jet tube; NC, nasal cannula

[32] indicated similar procedure times between groups (p -value changed from 0.007 to 0.21). These findings suggest inconsistencies in the effects of SJOV on nasal bleeding, hypertension, and procedure time.

Publication bias

An examination of the funnel plot for outcomes with more than 10 datasets was conducted, focusing on the risks of hypoxemia (Supplemental Fig. 9) (Egger's test: $p=0.05$), subclinical respiratory depression (Supplemental Fig. 10) (Egger's test: $p=0.001$), jaw lift (Supplemental Fig. 11) (Egger's test: $p=0.007$), mask ventilation (Supplemental Fig. 12) (Egger's test: $p=0.0006$), nasal bleeding (Supplemental Fig. 13) (Egger's test: $p=0.51$), sore throat (Supplemental Fig. 14) (Egger's test: $p=0.18$), dosage of propofol (Supplemental Fig. 15) (Egger's test: $p=0.4$), and procedure time (Supplemental Fig. 16) (Egger's test: $p=0.01$). The results based on Egger's test indicated that publication bias was present for several outcomes, including subclinical respiratory depression, jaw lift, mask ventilation, and procedure time. The funnel plot also demonstrated asymmetry in these outcomes.

Certainty of evidence

The certainty of evidence for each outcome is summarized in Table 2. Evidence certainty received a very low grading for bradycardia, tachycardia, hypertension, hypotension, and procedure time. It was graded as low for another five outcomes, which included hypoxemia, subclinical respiratory depression, jaw–thrust, mask ventilation, and nasal bleeding, and as moderate for three outcomes: severe hypoxia, sore throat, and propofol dosage.

Discussion

This meta-analysis of 12 RCTs ($n=3058$) demonstrated that SJOV likely results in a large reduction in the risk of severe hypoxemia (RR, 0.22; moderate certainty) and probably results in little to no difference in sedative doses between the groups (moderate certainty). Additionally, the risk of sore throat is probably increased with SJOV (RR, 1.71; moderate certainty). The evidence also suggested that SJOV results in a large reduction in the risk of hypoxemia (RR, 0.26; low certainty), subclinical respiratory depression (RR, 0.40; low certainty), the need for jaw lift (RR, 0.22; low certainty), and mask ventilation (RR, 0.13; low certainty). Furthermore, SJOV may result in little to no difference in nasal bleeding (RR, 1.75; low certainty). Finally, evidence regarding the effect of SJOV on hemodynamics and procedure time is very uncertain (very low certainty).

SJOV is an innovative, minimally invasive technique that optimizes oxygenation by delivering high-flow, high-concentration oxygen through a specialized nasal tube or catheter [30]. The device is strategically positioned to direct a jet of oxygen towards the vocal cords, enabling rapid pulsatile delivery into the trachea [30]. This targeted approach enhances gas exchange and may increase lung functional residual capacity, thereby improving overall oxygenation [30]. SJOV can be used as a continuous oxygen source or integrated into a jet ventilator to provide oxygenation and ventilation support. The precise physiological mechanisms underlying the effect of SJOV on pulmonary shunt fraction and ventilation-perfusion matching remain to be fully elucidated [30]. SJOV offers a promising means of minimizing hypoxemia risk during

Table 2 The certainty of evidence for each outcome based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach

| No. of studies | Outcomes | Certainty assessment | | | | | No. of patients | | Effect | | Absolute (95% CI) | | Certainty |
|----------------|------------------------------------|----------------------|----------------|----|----------------|----------------|-----------------|------------------|---------------------------|--|---|--|------------------|
| | | A | B | C | D | E | SJOV | Control | Relative (95% CI) | | | | |
| 16 | Hypoxemia | VS ^a | NS | NS | NS | None | 36/1153 (3.1%) | 257/1890 (13.6%) | RR 0.26 (0.19 to 0.36) | | 101 fewer per 1000 (from 110 to 87 fewer) | | ⊕⊕⊕⊕ Low |
| 13 | Subclinical respiratory depression | S ^b | NS | NS | NS | Y ^c | 103/1058 (9.7%) | 369/1786 (20.7%) | RR 0.40 (0.29 to 0.56) | | 118 fewer per 1000 (from 140 to 87 fewer) | | ⊕⊕⊕⊕ Low |
| 9 | Severe hypoxemia | S ^b | NS | NS | NS | None | 0/914 (0.0%) | 27/1610 (1.7%) | RR 0.22 (0.08 to 0.64) | | 13 fewer per 1000 (from 15 to 6 fewer) | | ⊕⊕⊕⊕ Moderate |
| 13 | Jaw-thrust | S ^b | NS | NS | NS | Y ^c | 39/1058 (3.7%) | 334/1786 (18.7%) | RR 0.22 (0.16 to 0.31) | | 146 fewer per 1000 (from 157 to 129 fewer) | | ⊕⊕⊕⊕ Low |
| 11 | Mask ventilation | S ^b | NS | NS | NS | Y ^c | 0/1024 (0.0%) | 71/1720 (4.1%) | RR 0.13 (0.05 to 0.31) | | 36 fewer per 1000 (from 39 to 28 fewer) | | ⊕⊕⊕⊕ Low |
| 12 | Nasal bleeding | S ^b | NS | NS | S ^d | None | 21/1023 (2.1%) | 19/1157 (1.6%) | RR 1.75 (0.89 to 3.45) | | 12 more per 1000 (from 2 fewer to 40 more) | | ⊕⊕⊕⊕ Low |
| 11 | Sore throat | S ^b | NS | NS | NS | None | 65/973 (6.7%) | 52/1107 (4.7%) | RR 1.71 (1.22 to 2.39) | | 33 more per 1000 (from 10 to 65 more) | | ⊕⊕⊕⊕ Moderate |
| 8 | Bradycardia | VS ^a | NS | NS | S ^d | None | 26/747 (3.5%) | 53/1433 (3.7%) | RR 0.82 (0.52 to 1.28) | | 7 fewer per 1000 (from 18 fewer to 10 more) | | ⊕⊕⊕⊕ Very low |
| 8 | Tachycardia | VS ^a | NS | NS | S ^d | None | 7/747 (0.9%) | 22/1433 (1.5%) | RR 0.74 (0.33 to 1.68) | | 4 fewer per 1000 (from 10 fewer to 10 more) | | ⊕⊕⊕⊕ Very low |
| 8 | Hypertension | VS ^a | NS | NS | S ^d | None | 6/747 (0.8%) | 29/1433 (2.0%) | RR 0.48 (0.20 to 1.14) | | 11 fewer per 1,000 (from 16 fewer to 3 more) | | ⊕⊕⊕⊕ Very low |
| 8 | Hypotension | VS ^a | NS | NS | S ^d | None | 20/747 (2.7%) | 38/1433 (2.7%) | RR 0.91 (0.52 to 1.59) | | 2 fewer per 1,000 (from 13 fewer to 16 more) | | ⊕⊕⊕⊕ Very low |
| 12 | Propofol dosage | S ^b | NS | NS | NS | None | | | - | | MD 0.03 mg fewer (2.39 fewer to 2.33 more) | | ⊕⊕⊕⊕ Moderate |
| 12 | Procedure time | VS ^a | S ^e | NS | NS | Y ^c | | | - | | MD 0.6 min lower (1.04 lower to 0.16 lower) | | ⊕⊕⊕⊕ Very low |

A risk of bias, B Inconsistency, C Indirectness, D Imprecision, E other consideration, Y publication bias strongly suspected

CI Confidence interval, MD Mean difference, RR Risk ratio, SJOV Supraglottic jet oxygenation and ventilation, VS Very serious, S Serious, NS Not serious

Explanations:

^a More than half of the enrolled studies were evaluated as having an overall risk of bias rated as "some concern," and there was also one enrolled study assessed with a "high" overall risk of bias^b Over one-quarter of the enrolled studies were evaluated as having "some concern" regarding their overall risk of bias^c Egger's test, $p < 0.05$ ^d A wide 95% confidence interval that crosses the minimally important difference threshold, set as 0.8 to 1.2^e I-square more than 60%

procedural sedation by maintaining elevated pharyngeal oxygen concentrations, particularly when the ventilator FiO_2 is set at 100%.

Evidence suggests that SJOV results in a large reduction in the risk of hypoxemia ($\text{SpO}_2 < 90\%$) and likely results in a large reduction in the risk of severe hypoxemia ($\text{SpO}_2 < 75\%$). The robustness of these findings is supported by evidence that SJOV may result in a large reduction in the need for jaw lift and mask ventilation. Consistency in the direction and magnitude of the effects across oxygenation and airway management outcomes provides strong evidence of the efficacy of SJOV in preventing hypoxemic events during procedural sedation. Although concerns about the methodological quality of the included studies resulted in low certainty of evidence for the primary outcome, TSA revealed that the evidence was sufficient to support the efficacy of SJOV in reducing the risk of hypoxemia during procedural sedation. This finding suggests that despite the limitations in the quality of the included trials, the observed treatment effect is likely to be reliable.

Regarding adverse events, the evidence from our meta-analysis indicated that there may be little to no difference in nasal bleeding risk between the SJOV and control groups. For hemodynamic instability (e.g., bradycardia), the evidence is very uncertain about any differences between SJOV and control due to the very low certainty of evidence. However, sensitivity analysis revealed that the removal of one study [33] resulted in a significantly higher risk of nasal bleeding in the SJOV group ($p = 0.03$), suggesting the need for further research to clarify this potential adverse event. Post-procedural sore throat was the only adverse event that probably occurred more frequently with SJOV, based on evidence of moderate certainty. The increased risk of sore throat in the SJOV group ($\text{RR} = 1.71$) may be attributed to the placement of the tube device in the supraglottic region and the high-pressure oxygen flow directed towards the vocal cords.

Notably, the certainty of the evidence varied across the outcomes evaluated in this meta-analysis. Findings related to severe hypoxemia, sore throat, and propofol dosage had moderate certainty of evidence, providing a higher level of confidence in these results. The reduction in severe hypoxemia and the absence of a difference in propofol dosage between the SJOV and control groups highlight that SJOV can effectively prevent severe desaturation events without necessitating a reduction in sedative doses. However, the increased risk of sore throat with SJOV should be considered and communicated to patients. In contrast, the outcomes of hypoxemia, subclinical respiratory depression, jaw thrust, mask ventilation, and nasal bleeding had low certainty of evidence,

indicating that these findings should be interpreted with caution. Clinicians should weigh the potential advantages of SJOV against the uncertainty surrounding these outcomes when making decisions regarding its use in procedural sedation.

The development of barotrauma remains a concern when jet ventilation is used [51, 52]. Although no barotrauma was reported in the current meta-analysis, SJOV should be used judiciously or avoided in patients with bullous lung disease, pulmonary emphysema, or a history of spontaneous pneumothorax. In these patients, the high pressure required for adequate jet ventilation may overwhelm areas with cystic lung architecture and precipitate tension pneumothorax or pneumomediastinum. If SJOV is used as a rescue device in emphysematous or post-pneumothorax patients, the lowest effective jet ventilation pressure should be used, and chest radiography after the procedure should be considered to rule out the development of barotrauma.

Current evidence for the use of SJOV in difficult airway management is limited to observational studies and case reports [53–55]. Case reports observed improvements in oxygen saturation when SJOV was used in emergency “cannot intubate, cannot ventilate” scenarios [53, 54]. Although our meta-analysis demonstrated the efficacy and safety of SJOV in reducing the risk of hypoxemia during procedural sedation, we cannot draw definitive conclusions regarding the efficacy and safety of SJOV in patients with difficult airways. Future research should carefully investigate complications (e.g., sore throat and barotrauma), particularly in high-risk groups, to provide more robust recommendations for clinical practice.

One review article [30] suggests that SJOV can be used without a specific time constraint, but it acknowledges that the longest reported usage duration is 45 min in a patient with “cannot intubate and cannot ventilate” emergency difficult airway [53]. In our meta-analysis, the maximum duration noted in the included studies was 32 min. Therefore, the safety of prolonged SJOV use remains unclear. Based on available evidence, SJOV and HFNO [25, 27, 56] appear to be more effective than conventional oxygen therapy in reducing the risk of hypoxemia during sedative procedures. The current meta-analysis found that SJOV was associated with a 74% relative risk reduction in hypoxemia ($\text{RR} = 0.26$) compared to the control. Previous meta-analyses demonstrated that HFNO significantly reduced the risk of hypoxemia in sedated patients undergoing sedative procedures ($\text{RR}, 0.23–0.37$) [25, 27, 56]. Although direct comparisons between SJOV and HFNO are lacking, both techniques appear to offer substantial benefits in maintaining adequate oxygenation during procedural sedation. Nevertheless, SJOV may provide some degree of ventilatory support in addition

to oxygenation, whereas HFNO primarily focuses on oxygenation optimization. Further head-to-head trials comparing SJOV and HFNO are warranted to determine whether one approach is superior to the other in terms of efficacy, safety, and cost.

This meta-analysis had several limitations. First, only one study enrolled patients with a high body mass index [49]. Given the risk of hypoxemia due to oxygen desaturation and hypoventilation in obese patients, further studies are required to examine the effects of SJOV in this vulnerable population. Second, considering the lack of heterogeneity in the primary outcome across studies, we did not perform subgroup analyses to examine whether the effects differed across different types of procedures. The efficacy and safety of SJOV in different patient subgroups should be examined in future studies. Third, all included RCTs were conducted in China, which may affect the generalizability of the results to other geographic settings and ethnicities. Fourth, the potential for publication bias remains for several secondary outcomes, which may be partially attributable to the fact that we did not contact authors for unpublished data and excluded conference abstracts from our analysis. While these decisions were made to ensure that all included studies could be adequately assessed for methodological quality, they may have inadvertently contributed to publication bias by omitting relevant unpublished or preliminary findings. Finally, the reduction in hypoxemia risk does not equate to improved clinical outcomes. Future studies should determine whether improved intraprocedural oxygenation with SJOV leads to short recovery times, low healthcare costs, and other patient-centered outcomes.

Conclusion

This meta-analysis of 12 RCTs demonstrated that SJOV likely resulted in a large reduction in the risk of severe hypoxemia and probably resulted in little to no difference in sedative doses between the groups. However, SJOV is probably associated with an increased risk of sore throat, while showing little to no difference in nasal bleeding. Moreover, some complications (e.g., barotrauma) have not yet been evaluated, necessitating careful investigation of adverse events in future studies. The safety and efficacy of prolonged SJOV use in patients with difficult airways remain unclear. Clinicians should carefully balance potential benefits and risks for individual patients, use the lowest effective ventilation pressure if SJOV is employed, and vigilantly monitor for adverse events.

Supplementary Information

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Additional file 1: Supplemental Figs. 1–16

Additional file 2: Supplemental Tables 1–5

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Authors' contributions

Kuo-Chuan Hung, I-Wen Chen, and Yen-Ta Huang: conceptualization, methodology, software; Wei-Ting Wang, Pei-Chun Lai, and Yao-Tsung Lin: data curation; Chun-Ning Ho and Chien-Ming Lin: visualization, investigation; Kuo-Chuan Hung: supervision; Yen-Ta Huang: validation; Kuo-Chuan Hung and I-Wen Chen: writing—original draft preparation; Kuo-Chuan Hung and Yen-Ta Huang: writing—reviewing and editing.

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Data availability

The datasets used and/or analyzed in the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Advancement of supraglottic jet oxygenation and ventilation technique

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Since the introduction of the supraglottic jet oxygenation and ventilation (SJOV) technique in 2006,^[1] it has been increasingly used for various aspects of airway management. The technique has been facilitated largely by the introduction of the jet endotracheal tube^[1-3] and the jet nasal tube.^[4-18] A large number of studies, including a multicentre randomised clinical trial,^[16] demonstrated the high efficiency of SJOV to prevent or treat hypoxia during upper gastrointestinal (GI) endoscopy,^[3,8,10,11,14-16,19] colonoscopy,^[20] endoscopic retrograde cholangiopancreatography^[4] and hysteroscopy,^[12] under propofol sedation/anaesthesia, especially in obese patients^[11-13,15,21] or in locations with high altitude (e.g., Tibet, China).^[8] In a previous analysis of closed claimed liability cases that took place in non-operating rooms, a majority (58%) of the claimed cases were under monitored anaesthesia care (MAC), while 50% of cases were in the GI suite with inadequate oxygenation and ventilation, which was the most common cause of severe complications or patient death (30%).^[22] Clearly, prevention of hypoxia and hypoventilation during MAC is critical for patient safety in a GI suite. Compared to high-flow nasal oxygenation (HFNO), SJOV not only promoted oxygenation by increasing the fraction of inspired oxygen (FiO₂) and oropharyngeal pressure like HFNO did but was also capable of ventilating patients to eliminate carbon dioxide, especially in

patients with apnoea.^[3] Furthermore, SJOV is also effective to oxygenate/ventilate patients even when the mouth is open in an open airway system.^[3] SJOV has been used to facilitate bronchoscopy under propofol sedation/anaesthesia and prevent or treat hypoxia during the procedure.^[5,9] SJOV has been used to maintain oxygenation/ventilation during elective difficult airway management and to facilitate tracheal intubation.^[1,2,18,23] The new guideline on difficult airway management by the American Society of Anesthesiologists in 2022 suggested that SJOV could be considered one of the approaches to rescue patients with urgent or emergent difficult airways.^[13,17,24] Hence, the SJOV technique has advanced quickly in operating or non-operating rooms to promote oxygenation/ventilation and prevent or treat hypoxia during airway management. Its potential use in treating respiratory failure in emergency or critical medicine needs to be investigated further.

One of the major concerns of using transtracheal jet ventilation (TTJV) during difficult airway management is its high incidence of complications and high failure rate. It was reported that emergent TTJV resulted in barotrauma complications and device failure rate during the 'cannot intubate and cannot oxygenate' emergent airway management, at rates as high as 32% and 42%, respectively.^[25] In contrast, there has

not been a single reported case of barotrauma to date in all studies using the SJOV technique, which has a high success rate in preventing or treating hypoxia/hypoventilation in elective^[3-5,8,9,16,18,23] or urgent/emergent^[13,17] airway management. This advantage of SJOV in comparison to TTJV is largely due to the placement of the jet pulse above the vocal cord, rather than below the vocal cord, which effectively prevents injection of a high volume of gas into a closed airway system and breakage of alveoli with a rapid increase in abnormal high airway pressure.^[3] Common side effects of SJOV are sore throat and dry mouth, with the risk factors being previous history and procedure duration.^[26] In almost all studies to date, humidified oxygen or air was not used for SJOV. Dry mouth could be minimised if humidified oxygen/air is used as a driving gas, especially during chronic use of SJOV for respiratory failure. A minor increase in nose bleeding has been reported in cases when a jet tube is employed via the nose for SJOV,^[16] although SJOV can be performed by inserting a jet catheter via the mouth beside the hollow bite block used for upper GI endoscopy to minimise the minor complications of nose bleeding.

Overall, the SJOV technique has been advancing rapidly and successfully, especially in MAC cases in a non-operating room, with a high efficiency to promote non-invasive oxygenation/ventilation, causing minimal side effects. The potential use of SJOV in emergency and critical medicine requires further investigation.

Conflicts of Interests

Dr. Huafeng Wei is the inventor of the WEI Jet Endotracheal Tube (WEI JET) and WEI Nasal Jet Tube (WEINASALJET or WNJ), which is proposed to generate SJOV used in most clinical studies. Dr. Huafeng Wei is a consult of Well Lead Medical Company, Guangzhou, China.

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RESEARCH

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Supraglottic jet oxygenation and ventilation improves oxygenation during endoscopic retrograde cholangiopancreatography: a randomized controlled clinical trial

Dan Su^{1†}, Wei Zhang^{1†}, Jingze Li^{2†}, Xi Tan², Huafeng Wei³, Yinglin Wang^{1*} and Zhonghua Ji^{1*}

Abstract

Purpose Hypoxia is one of the most frequent adverse events under deep sedation in the semiprone position. We hypothesized that supraglottic jet oxygenation and ventilation (SJOV) via Wei nasal jet tube (WNJ) can reduce the incidence of hypoxia in patients under deep sedation during endoscopic retrograde cholangiopancreatography (ERCP).

Methods A total of 171 patients were divided into three groups: N group, supplementary oxygen via a nasopharyngeal airway (4–6 L/min); W group, supplementary oxygen via WNJ (4–6 L/min); WS group, SJOV via WNJ. The primary outcome was the incidence of adverse events, including sedation-related adverse events [SRAEs, hypoxemia ($\text{SpO}_2 = 75\text{--}89\%$ lasted less than 60 s); severe hypoxemia ($\text{SpO}_2 < 75\%$ at any time or $\text{SpO}_2 < 90\%$ lasted more than 60 s)] and subclinical respiratory depression ($\text{SpO}_2 = 90\text{--}95\%$). Other intraoperative and post-operative adverse events were also recorded as secondary outcomes.

Results Compared with the N group, the incidence of hypoxemia and subclinical respiratory depression in the WS group was significantly lower (21% vs. 4%, $P = 0.005$; 27% vs. 6%, $P = 0.002$). Compared with Group W, the incidence of hypoxemia and subclinical respiratory depression in Group WS was also significantly less frequent (20% vs. 4%, $P = 0.009$; 21% vs. 6%, $P = 0.014$). No severe hypoxia occurred in the group WS, while four and one instances were observed in the group N and group W respectively. There were no significant differences in other adverse events among the three groups.

Conclusion SJOV can effectively improve oxygenation during ERCP in deeply sedated semiprone patients.

Keywords Endoscopic retrograde cholangiopancreatography, Hypoxia, Deep sedation, Ventilation, Semiprone position

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a technique for evaluating the bile duct, pancreatic duct, and ampulla. With the development of endoscopic sphincterotomy in recent years, ERCP has evolved from a purely diagnostic imaging method into a way to perform both diagnostic and therapeutic procedures [1]. Compared with other endoscopic procedures, ERCP is more invasive; thus, comparatively deep sedation to prevent uncontrolled movements and coughing is often required to meet the procedure requirements [2].

Hypoxia is the most common cardiopulmonary complication during ERCP, with a reported rate of 16.2 to 39.2% [3]. A left-semiprone position, which is often used in ERCP procedures, will lead to hypoventilation for decreased chest wall compliance, reduced functional residual capacity (FRC) and suppressed breathing [4]. Besides, propofol and opioids are likely to result in respiratory depression and airway obstruction, leading to hypoxia [5]. Therefore, it is critically important to prevent hypoxia during sedation for patients' safety and procedural success in ERCP [6].

The key to preventing hypoxia is to ensure the sufficient oxygenation and ventilation of patients during these procedures. The commonly used approaches to treat hypoxia with a non-instrumented airway are increasing the oxygen flow and lifting the jaw, applying with both hands, displacing the jaw upwards and anteriorly, which allowed the upper airway to remain open [7]. The placement of a nasopharyngeal airway may be a good approach to prevent hypoxia, by keeping the airway open, while it is difficult to detect hypoventilation promptly when patients are under suppressed breathing [3, 4]. Tracheal intubation devices could provide mechanical ventilation by connecting to ventilators, but may take up the space of duodenal rectoscope, which would interfere with duodenoscopy procedures [8]. Previous research has confirmed that supraglottic jet oxygenation and ventilation (SJOV) through a new Wei nasal jet tube (WNJ) enhances oxygenation during upper gastrointestinal endoscopy in sedated patients [9–12]. However, as ERCP is more invasive, requiring deeper sedation and longer duration of procedure, which means higher incidence of hypoxia, it is not very clear the efficacy of SJOV through WNJ to prevent hypoxia in deeper sedated patients during the longer procedure.

This study was a prospective, single-blinded and randomized controlled clinical study. We hypothesized that SJOV via WNJ could prevent hypoxia in patients under deep sedation during ERCP.

Methods

Ethics, clinical trial, consent and permissions

This clinical study was approved by the Institutional Review Board and Ethics Committee of Affiliated East Hospital of Tongji University (2021, No.097), Shanghai, China (Chairperson Prof Zengguang Xu) on 5 November 2021, and was registered at chictr.org.cn (ChiCTR2100053532, <https://www.chictr.org.cn/showprojEN.html?proj=139528>, Principal investigator: Zhonghua Ji, Date of registration: 2021.11.24). The clinical trial was registered prior to patient enrollment. The written informed consent was obtained from all subjects participating in the trial. This study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines and was conducted in accordance with the Helsinki Declaration-2013.

Patient inclusion and exclusion

Inclusion criteria were as follows: (1) Ages from 18 to 65 years; (2) American Society of Anesthesiologists (ASA) classification from I to III; (3) The general state was stable, and the respiratory function reserve was good; (4) Procedure time < 2 hours. Exclusion criteria were as follows: (1) Coagulopathy or epistaxis; (2) Body mass index (BMI) over 28 kg/m²; (3) Concomitant severe heart diseases (heart failure, angina pectoris, myocardial infarction, arrhythmia, etc.); (4) Concomitant severe lung diseases (asthma, chronic obstructive pulmonary disease, pulmonary embolism, pulmonary oedema or lung cancer, etc.); (5) Pregnancy; (6) Increased intracranial pressure; (7) Infection of the nasal cavity, oropharynx, or other contraindication to insert the nasopharyngeal airway and WNJ, such as nasal surgery, etc.; (8) Allergy to propofol, egg, soy or albumin. Withdrawal criteria as follows: (1) Procedure time more than 2 hours; (2) Undergoing angiography instead of treatment; (3) Failure to insert the nasopharyngeal airway and WNJ; (4) Failure to follow up; (5) Failure to finish the trial for other reasons.

Randomization, group allocation and blinding

Patients were randomized into three groups based on the approaches of oxygen supplies: the supplementary oxygen via a nasopharyngeal airway group at an oxygen flow of 4–6 L/min (N group), the supplementary oxygen at 4–6 L/min via the WNJ (WNJ; Well Lead Medical Company Ltd., Guangzhou, China) (W group), or the SJOV via the WNJ (SJOV working parameters: the driving pressure is 15 psi, the breathing rate is 20 breath per minute, the inspiratory to expiratory ratio is 1:2, the gas supply was maintained for 5 min after inserting the WNJ successfully, and the concentration of oxygen is 100%. Apart from the SJOV, the supplementary oxygen was at 4–6 L/min via WNJ) (WS group). Internet-based randomization software (<http://www.randomization.com>) was used

for randomization. Patients were allocated blindly after randomization. Other individuals who participated in the research were not blinded to the group assignments. The data were collected by a resident.

Sample size calculation

PASS software (version 15.0, NCSS, LLC, Kaysville, UT, United States) was used to determine the sample size. The contingency table (chi-square test) was performed for multiple comparison of proportion. When α was 0.05, the test power was 80%, the effect size was 0.25, and the degree of freedom was 2, we calculated that 155 patients were needed. The attrition rate was set at 10%, requiring a total of 171 patients (57 of each group). The effect size was calculated based on the assumption derived from our pretest study that the incidence of hypoxemia ($\text{SpO}_2=75\text{--}89\%$ lasted less than 60 s) during ERCP under deep sedation with SJOV via WNJ was 5%. The incidence of hypoxemia during ERCP for patients who were oxygenated with a nasopharyngeal airway was 25% in our preliminary experiments.

Procedure and sedation strategy

Sedation was performed by a team that involved attending anesthesiologists and nurse anesthetists. All patients were fasted for 6 h for food and 2 h for clear liquid prior to the procedure. After entering the endoscopy suite, venous access was established, and the vital signs of the

patients were monitored, including electrocardiograph (ECG), peripheral oxygen saturation (SpO_2), heart rate (HR), noninvasive systolic arterial pressure (SAP), diastolic arterial pressure (DAP), mean arterial pressure (MAP), respiratory rate (RR), bispectral index (BIS), and end-tidal carbon dioxide partial pressure (P_{ETCO_2}). Patients were positioned in the semiprone position with the right side elevated with a chest pillow.

Before placing the nasopharyngeal airway or WNJ, a cotton swab with saline was used to clear the nasal cavity, and ephedrine (0.6%, 2 ml) and lidocaine (2%, 5 ml) were then sprayed to numb the nasal vestibule and passage to reduce nose bleeding [13]. The tip of the nasopharyngeal airway or WNJ [Fig. 1(1)] was lubricated with 1 ml paraffin oil. The depth of placement was roughly equivalent to the distance from the alar of the nose to the earlobe on the same side [9]. Then, we started placing the nasopharyngeal airway or WNJ at the appropriate depth as measured in advance, its position was affirmed again by the duodenal rectoscope [Fig. 1(3, 4)], and appropriate adjustments were performed if necessary. When there were difficulties in inserting the nasopharyngeal airway or WNJ via the selected naris, the other naris was available for further attempts. After three failures, the placement of nasopharyngeal airway or WNJ was considered to be failed.

In group N, nasal cannula was used to supply oxygen through nasopharyngeal airway. In group W and WS,

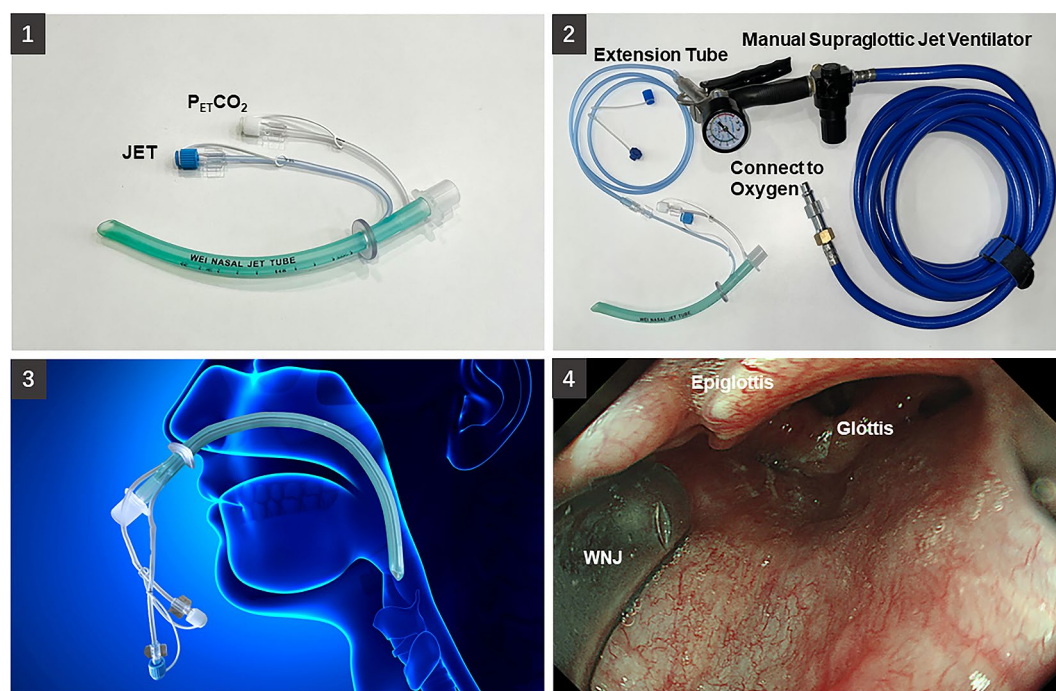


Fig. 1 (1) Wei nasal jet tube (WNJ) with a manual jet ventilator and end-tidal CO_2 pressure (P_{ETCO_2}) monitoring. (2) The supraglottic jet oxygenation and ventilation (SJOV) via a WNJ connected to a manual jet ventilator. (3) The position of WNJ in patients. (4) The best position of the WNJ tip is between the epiglottis and uvula

the connector of the WNJ was connected to the threaded pipe joint of the anesthesia machine (Aespire 7100, Datex-Ohmeda, Inc., Madison, WI, USA) for oxygen supply. The CO₂ catheter of the WNJ was connected to the portable end-tidal carbon dioxide partial pressure monitor (KMI605D, Kingst, Inc., Beijing, China), and the jet catheter of the WNJ in the WS group was connected to a manual jet ventilator (Anesthesia Associate, Inc., San Marcos, CA, USA) [Fig. 1(2)] to conduct supraglottic jet oxygenation and ventilation (SJOV).

Sedation was conducted by intravenous administration of propofol, remifentanyl and dexmedetomidine. Dexmedetomidine was infused with a preloading dose of 1 µg/kg for 10 min, and the target blood concentration of remifentanyl was set at 1 ng/ml [14]. Propofol infusion was given with a target-controlled infusion (TCI) system composed of an ALARIS ASENSA TIVA pump produced by ALARIS and a propofol prefilled syringe produced by Astrazeneca Pharmaceutical Co., Ltd. The initial target blood concentration of propofol was set at 3.0 µg/ml, and adjustments of 1.5–1.7 µg/ml were made to achieve the expected sedation level by monitoring the BIS value from 45 to 60 [15]. The Marsh parameter model [16] was referenced, and the ideal concentrations of propofol and remifentanyl were set at 10 mg/ml and 20 µg/ml, respectively. Intravenous premedication with hyoscine 0.3 mg/kg was given to patients in all 3 groups to relieve spasms of the duodenum.

All procedures were provided by an experienced endoscopist (Jingze Li, who had completed more than 200 ERCPs independently) with the assistance of 1 to 3 endoscopic nurses. The endoscopist started the procedure after BIS reached the target value with a standard duodenoscope (TJF 240 or 260 V; Olympus Optical Co., Ltd., Tokyo, Japan). Under the direct vision of the duodenoscope, when the duodenoscope reached near the glottis, the WNJ was adjusted in and out slightly along the nasal cavity to ensure that the tip of the WNJ was directly opposite the glottis.

When SpO₂<90% occurred in Groups N and W, remedial measures were executed sequentially, including (i) adjusting the position of the nasopharyngeal airway or WNJ, (ii) opening the airway with the jawlift manoeuvre, (iii) mask pressurized ventilation, and (iv) removing the choledochoscope and tracheal intubation. When SpO₂<90% occurred in Group WS, the position of the WNJ was adjusted at first, and then application of SJOV via the WNJ was performed again for another 5 min (increasing the rate of jet ventilation to 30 breath per minute and the driving pressure to 20 psi if necessary) until SpO₂>95%. If it did not work, we followed measures (ii–iv) above.

Outcome measurement

We recorded the clinical indicators of the three groups, including sedation time (time from induction with propofol to opening eyes in response to sound), procedure time (time from endoscope insertion to withdrawal), recovery time [time from drug withdrawal until the patient's Aldrete score=8 (This assigns a score of 0, 1 or 2 to activity, respiration, circulation, consciousness and oxygen saturation, giving a maximal score of 10.) and the Aldrete score was assessed at one, five and ten minutes after the procedure by a nurse anesthetist in the PACU)] [17], total propofol dosage, total remifentanyl dosage, and total dexmedetomidine dosage. Primary intraoperative adverse events were divided into two categories: sedation-related adverse events (SRAEs) and subclinical respiratory depression (SpO₂=90–95%) [9]. SRAEs included hypoxemia (SpO₂=75–89% lasted less than 60 s), severe hypoxemia (SpO₂<75% at any time or SpO₂<90% lasted more than 60 s) and implementation of the above emergency measures [18, 19].

Other intraoperative adverse events included cough, laryngospasm, muscle twitch, tachycardia (heart rate more than 100 bpm), bradycardia (heart rate less than 60 bpm), hypertension (blood pressure increased to more than 20% of baseline), hypotension (blood pressure decreased to more than 20% of baseline) [15], and body movement. Postoperative adverse events involved nose bleeding, nausea or vomiting, recovery delay (delayed recovery time for more than 30 min), dysphoria, xerostomia, pharyngalgia, barotrauma, and airway injury were recorded at 5, 30 min and 24 h after the procedure.

Statistical analysis

Measurement data are presented as the mean (SD), and count data are presented as the number and percentage. One-way ANOVA or the Pearson χ^2 test was used to compare differences in the general data of patients according to the type of data. The differences in sedation time, procedure time, recovery time, and dosage of anaesthetics were tested by the Kruskal–Wallis H test between different groups. Dunn's z test was used to compare the differences among the three groups when $P<0.05$. The χ^2 test and Fisher's exact test were used to analyse the rates of SRAEs and other adverse events. A χ^2 test and Fisher's exact test were used to analyse the adverse event incidence rate. As three χ^2 test were performed, the P -value was adjusted to $0.05/3\approx0.017$ by Bonferroni adjustment.

Results

A total of 253 patients were assessed for eligibility, but 18 patients were classified as ASA more than III, 39 patients were aged over 65 years, 9 patients had a BMI over 28 kg/m², and 16 patients had severe cardiopulmonary diseases. In total, 171 patients were enrolled and

equally randomized to three groups. There were 1 and 2 patients excluded due to receiving only diagnostic cholangiogram but not treatment in Group N and Group WS, respectively, and 1 patient in Group W was excluded due to the procedure lasting more than two hours. In total, 167 patients were included in the final statistics. All of the patients tolerated the procedure well. The insertion of the nasopharyngeal airway and WNJ were both successful. No severe adverse events, such as aspiration, laryngospasm, barotrauma and death, occurred (Fig. 2).

Clinical characteristics of the study population

General patient information is shown in Table 1. Age, sex, BMI, history of hypertension, diabetes and snoring, Mallampati class, thyromental distance, obstructive sleep apnoea hypoventilation syndrome (OSAHS), ASA, and baseline SpO₂ were compared. Data about the procedure time and the dosage of anesthetics are given in Supplementary Table 1. Compared with Group N, the use of SJOV via WNJ (Group WS) decreased the procedure time from 34.13(4.03) mins to 32.27 (3.73) mins ($P=0.013$); there was no significant difference between Group W and Group WS. However, the sedation time and recovery time among the three groups showed no significant differences. Furthermore, there was no significant difference in the total doses of propofol, dexmedetomidine and remifentanyl among the three groups.

Primary outcome

SJOV via WNJ significantly decreased the incidence of SRAEs during ERCP under deep sedation (Table 2). Compared with Group N, the application of SJOV via WNJ significantly decreased the total percentage of SRAEs from 29 to 4% ($P=0.000$), decreased the incidence of subclinical respiratory depression from 27 to 6% ($P=0.002$), and decreased the incidence of hypoxemia from 21 to 4% ($P=0.005$). Correspondingly, compared with Group N, the incidence of jawlift in Group WS significantly decreased ($P=0.003$). None of the patients in Group WS required mask ventilation. Compared with Group W, Group WS had a decreased incidence of SRAEs from 21 to 4% ($P=0.005$) and a decreased incidence of hypoxemia, subclinical respiratory depression, and jawlift from 20 to 4% ($P=0.009$), from 21 to 6% ($P=0.014$), and from 20 to 4% ($P=0.009$), respectively. Furthermore, there were no significant differences in episodes of severe hypoxemia and mask ventilation between Group W and Group WS ($P=1.000$, $P=0.057$). There were two patients in Group N who needed tracheal intubation, while the rest of the patients in the three groups finished ERCP without tracheal intubation.

Secondary outcomes

Compared with Group N, the application of SJOV via WNJ significantly increased the incidence of xerostomia from 2 to 20% ($P=0.002$) at 5 min after the procedure, but there were no significant differences between two groups at 30 min and 24 h after the procedure (Table 3). There were no significant differences in the incidence of other intraoperative adverse events except SRAEs and subclinical respiratory depression among the three groups. There were no differences in the incidence of other postoperative adverse events, including nausea, vomiting, dysphoria, and pharyngalgia among the three groups. None of the patients suffered from barotrauma or airway injury in any group (Table 4).

Discussion

In our study, we aimed to investigate the effectiveness of SJOV via WNJ can reduce the incidence of hypoxia in patients under deep sedation during ERCP. According to our results, SJOV can effectively improve oxygenation during ERCP in deeply sedated semiprone patients. Nasopharyngeal airway can relieve upper airway obstruction to some extent, but for its tip far from glottis, it is too difficult to maintain oxygenation under suppressed breathing. We found that the incidence of hypoxemia was significantly higher in Group N, which is consistent with the results of Han S J [20], while the incidence of hypoxemia was lower in Group W (20%) and Group WS (4%). WNJ can ensure adequate oxygenation under deep sedation, which significantly reduces the incidence of hypoxia compared to the commonly used oxygen supplies via a nasopharyngeal airway [11]. The WNJ is a rapidly inserted device that requires no previous experience or practice to use and it is well tolerated by lightly sedated patients [21]. In our study, each WNJ was placed appropriately in Group W and Group WS. Easy implementation may allow the WNJ with SJOV to be used in emergent airway management as a rescue device [22]. Based on this feature, SJOV via WNJ is considered especially appropriate for the resuscitation of injured people who suffered from acute trauma in war fields [21].

The SJOV system used via WNJ is shown in Fig. 1(2). We confirmed the location of the tip of the WNJ by duodenal rectoscope, concluding that the gap of the epiglottis and uvula was the optimized location for WNJ [Fig. 1(4)]. If the location of WNJ was appropriate, the wave of P_{ET}CO₂ would be regular, and the best position of distal end of WNJ between epiglottis and vulvar usually provide highest P_{ET}CO₂. Oxygenation was better maintained in Group WS than in Group W (Table 2), suggesting that the high-pressure jet pulse promotes ventilation via WNJ. Thus, we inferred that WNJ maintains adequate oxygenation performed primarily by SJOV instead of by recovering spontaneous respiration or relieving an obstructive



CONSORT

TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

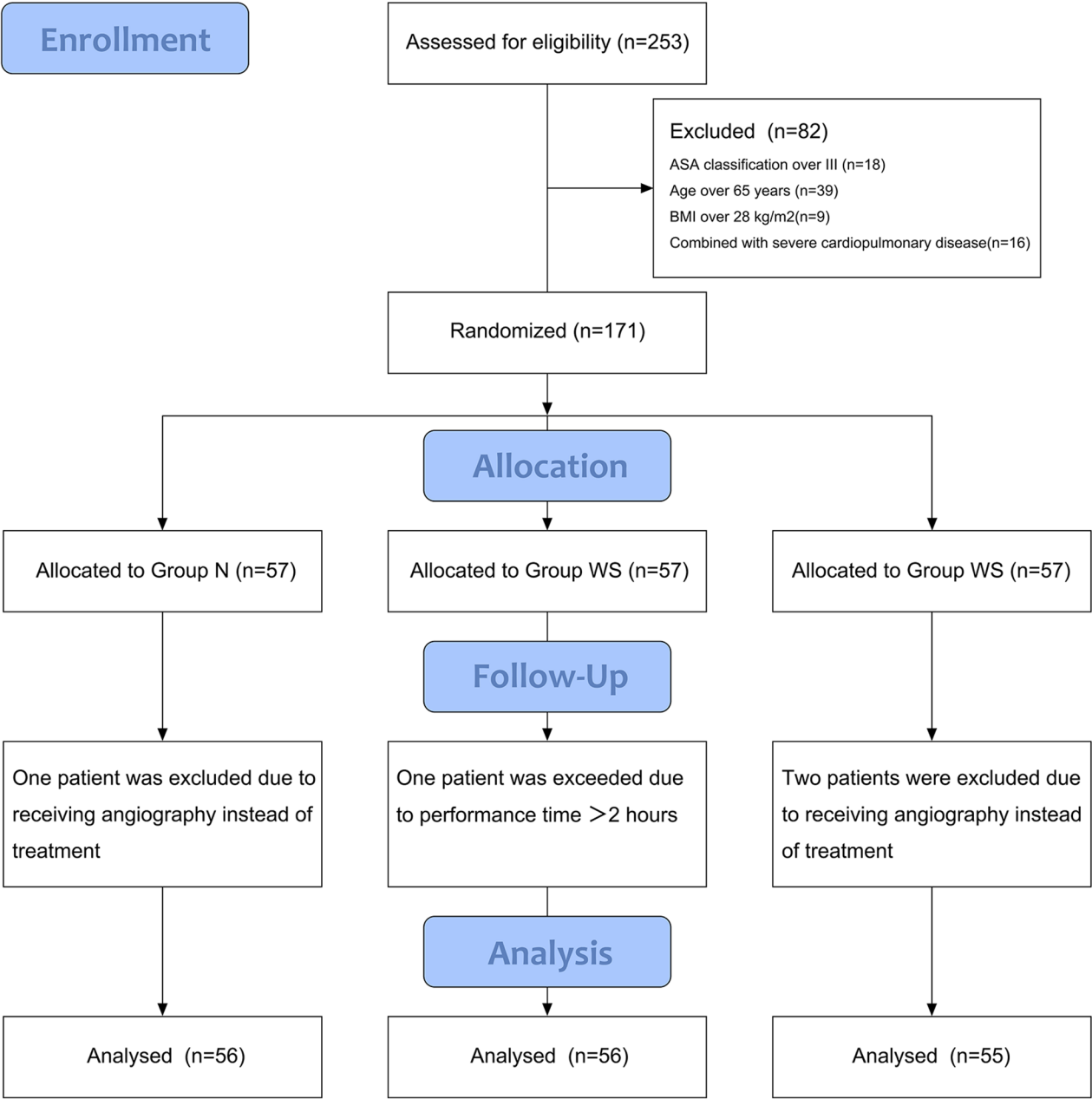


Fig. 2 Consolidated standards of reporting trial flow diagram. BMI, body mass index; ASA, American Society of Anesthesiologists; Group N, the supplementary oxygen via nasopharyngeal airway group; Group W, the supplementary oxygen via WNJ group; Group WS, SJOV via WNJ group

Table 1 General characteristics of patients

| Characteristic | Group N (n = 56) | Group W (n = 56) | Group WS (n = 55) |
|--|---------------------|---------------------|----------------------|
| Age[yr;mean(range)] | 56(39–65) | 56(43–65) | 56(40–65) |
| Sex(male)(female) | (22)(34) | (27)(29) | (25)(30) |
| BMI[kg/m ² ;mean(SD)] | 23(2.97) | 22(2.30) | 23(2.27) |
| History of hypertension [n(%)] | 23(41) | 21(38) | 24(44) |
| History of diabetes[n(%)] | 22(39) | 15(27) | 13(24) |
| Mallampati class (I)(II)(III)(IV) | (28)(21)(6)(1) | (22)(18)(15)(1) | (22)(16)(15)(2) |
| Thyromental distance [cm;mean(SD)] | 7(0.29) | 7(0.27) | 7(0.37) |
| History of snoring [n(%)] | 18(32) | 14(25) | 18(33) |
| OSAHS[n(%)] | 1(2) | 0(0) | 0(0) |
| ASA(I)(II)(III) | (7)(33)(16) | (5)(35)(16) | (2)(33)(20) |
| SpO ₂ before sedation [%;mean(SD)] | 98(1.28) | 98(1.53) | 98(1.36) |

BMI, body mass index; OSAHS, obstructive sleep apnea–hypopnea syndrome; ASA, American Society of Anesthesiologists; SpO₂, peripheral oxygen saturation

airway. Furthermore, an animal study confirmed that the SpO₂ could be maintained over 95% for more than 20 min by SJOV without the need for assisted mask ventilation in an apnoeic pig [23]. The additional utilization

of a built-in CO₂ monitoring catheter on the WNJ may help detect depressed or apnoeic breathing which often occurred after induction of anesthesia. Therefore, SJOV via WNJ lasting for 5 min at the beginning of the procedure has a good effect on relieving hypoxemia caused by hypoventilation. Although SJOV can maintain the desired oxygenation for up to 1 h according to previously reported clinical trials, there is insufficient evidence to support the use of SJOV for a longer duration [24]. In our study, all procedures during ERCP were performed within one hour. We excluded patients whose procedure time exceeded 2 h. The maximum application time and potential airway mucosal inflammation remain to be investigated in the future. The incidences of intraoperative adverse events except SRAEs and subclinical respiratory depression were comparable among all three groups (Table 3). The data on non-invasive arterial pressure and heart rate are listed in Supplementary Table 2, and all patients' hemodynamic were stable. There was no barotrauma or airway injuries among three groups, and there were no significant differences in the incidence of nose bleeding, nausea or vomiting, dysphoria and pharyngalgia (Table 4). Compared with Group N, the application of SJOV via WNJ significantly increased the incidence of xerostomia from 2 to 20% ($P=0.002$) at 5 min after the procedure, but there were no significant differences

Table 2 Sedation-related adverse events (SRAEs) and subclinical respiratory depression

| | Group N(I) (n = 56) | Group W(II) (n = 56) | Group WS(III) (n = 55) | P-value (I vs. II) | P-value (II vs. III) | P-value (I vs. III) |
|--|------------------------|-------------------------|---------------------------|-----------------------|-------------------------|------------------------|
| Subclinical respiratory depression[n(%)] | 15(27) | 12(21) | 3(6) | 0.508 | 0.014 | 0.002 |
| SRAEs[n(%)] | 16(29) | 12(21) | 2(4) | 0.383 | 0.005 | 0.000 |
| Hypoxemia | 12(21) | 11(20) | 2(4) | 0.815 | 0.009 | 0.005 |
| Severe hypoxemia | 4(7) | 1(2) | 0(0) | 0.364 | 1.000 | 0.118 |
| P _{ET} -CO ₂ <10mmHg[n(%)] | - | 13(23) | 4(7) | - | 0.020 | - |
| Jaw lift[n(%)] | 13(23) | 11(20) | 2(4) | 0.645 | 0.009 | 0.003 |
| Mask ventilation[n(%)] | 5(9) | 5(9) | 0(0) | 1.000 | 0.057 | 0.057 |
| Endotracheal intubation[n(%)] | 2(4) | 0(0) | 0(0) | 0.495 | - | 0.495 |

Subclinical respiratory depression: SpO₂=90–95%, SRAEs: SpO₂<90% and the implementation of emergency measures; P_{ET}-CO₂: End-tidal carbon dioxide partial pressure. The χ^2 test and Fisher's exact test were used to analyze the incidence rate of SRAEs. The P -value was adjusted to 0.05/3=0.017 by Bonferroni adjustment

Table 3 Intraoperative adverse events except SRAEs and subclinical respiratory depression

| | Group N(I) (n = 56) | Group W(II) (n = 56) | Group WS(III) (n = 55) | P-value (I vs. II) | P-value (II vs. III) | P-value (I vs. III) |
|----------------------|------------------------|-------------------------|---------------------------|-----------------------|-------------------------|------------------------|
| Cough[n(%)] | 2(4) | 1(2) | 1(2) | 1.000 | 1.000 | 1.000 |
| Laryngospasm[n(%)] | 0(0) | 0(0) | 0(0) | - | - | - |
| Muscle twitch[n(%)] | 7(13) | 5(9) | 3(6) | 0.541 | 0.716 | 0.321 |
| Bradycardia[n(%)] | 6(11) | 6(11) | 8(15) | 1.000 | 0.543 | 0.543 |
| Tachycardia[n(%)] | 4(7) | 5(9) | 6(11) | 1.000 | 0.727 | 0.527 |
| Hypertension[n(%)] | 4(7) | 5(9) | 2(4) | 1.000 | 0.438 | 0.679 |
| Hypotension[n(%)] | 5(9) | 5(9) | 4(7) | 1.000 | 1.000 | 1.000 |
| Body movement [n(%)] | 6(11) | 5(9) | 4(7) | 0.751 | 1.000 | 0.742 |

The P -value was adjusted to 0.05/3=0.017 by Bonferroni adjustment

Table 4 Post-operative adverse events

| | Group N (I) (n = 56) | Group W (II) (n = 56) | Group WS (III) (n = 55) | P-value | P-value (I vs. II) | P-value (I vs. III) | P- value (II vs. III) |
|-------------------------------|----------------------------|-----------------------------|-------------------------------|---------|-----------------------|------------------------|--------------------------------|
| 5 min after procedure | | | | | | | |
| Nose bleeding (1)(2)(3) | (5)(1)(0) | (13)(2)(0) | (14)(1)(0) | 0.547 | - | - | - |
| Nausea or vomiting[n(%)] | 10(18) | 3(5) | 5(9) | 0.103 | - | - | - |
| Dysphoria[n(%)] | 8(14) | 6(11) | 5(9) | 0.717 | - | - | - |
| Xerostomia[n(%)] | 1(2) | 3(5) | 11(20) | 0.001 | 0.618 | 0.002 | 0.018 |
| Pharyngalgia[n(%)] | 14(25) | 16(29) | 18(33) | 0.594 | - | - | - |
| Barotrauma[n(%)] | 0(0) | 0(0) | 0(0) | - | - | - | - |
| Airway injury[n(%)] | 0(0) | 0(0) | 0(0) | - | - | - | - |
| 30 min after procedure | | | | | | | |
| Nose bleeding (1)(2)(3) | (2)(0)(0) | (4)(0)(0) | (7)(0)(0) | 0.193 | - | - | - |
| Recovery delay[n(%)] | 0(0) | 1(2) | 0(0) | 0.369 | - | - | - |
| Xerostomia[n(%)] | 6(11) | 8(14) | 8(15) | 0.765 | - | - | - |
| Pharyngalgia[n(%)] | 4(7) | 3(5) | 8(15) | 0.181 | - | - | - |
| 24 h after procedure | | | | | | | |
| Nose bleeding[n(%)] | 0(0) | 0(0) | 0(0) | - | - | - | - |
| Xerostomia[n(%)] | 1(2) | 0(0) | 3(5) | 0.151 | - | - | - |
| Pharyngalgia[n(%)] | 9(16) | 11(20) | 9(16) | 0.852 | - | - | - |

Nose bleeding degrees: 1=mild bleeding, almost no bleeding or slight oozing, 2=medium bleeding, between 1 and 3, 3=severe bleeding, endoscopy cannot be fulfilled without suction. The *P*-value was adjusted to 0.05/3=0.017 by Bonferroni adjustment

between two groups at 30 min and 24 h after the procedure. The utilization of humidified oxygen could potentially decrease the incidence of xerostomia after using SJOV. As hyoscine was intravenously injected preprocedure, xerostomia may inevitably be attributed to the gland secretion inhibition caused by hyoscine, but it generally disappeared within 30 min postoperatively without any treatment. All of the above complications were tolerable and manageable without difficulties, similar to the results of previous clinical studies [10, 11]. In addition to conveniently using WNJ for SJOV, there are varying techniques reported to perform SJOV, such as the application of a soft-suction catheter [25] and a Cook airway exchange catheter [26]. Compared to the aforementioned techniques, an advantage of WNJ is that it can measure the $P_{ET}CO_2$ of the patients, which may help detect problems such as respiratory insufficiency or mechanical failure during anaesthesia in time for timely intervention. A device named the Hague Airway can also monitor $P_{ET}CO_2$, but its inability to prevent airway obstruction make it limited clinical applications [27]. Furthermore, a high-flow nasal cannula (HFNC), a new oxygen delivery device, is adapted to maintain oxygenation and humidification ventilation. The high flow of gas delivered by the HFNC through the nasopharynx and airways generates a positive end-expiratory pressure, which increases the effective alveolar ventilation, thereby increasing respiratory efficiency and improving oxygenation, but the HFNC is unable to correct the upper airway obstruction induced in the semi-prone position. In addition, HFNC

does not directly monitor $P_{ET}CO_2$, and the apparent SpO_2 may mask the risk of carbon dioxide accumulation. The LMA[®] Gastro[™] Airway is an airway technique, which could improve airway control, prevent hypoxia and avoid the need for intubation [18]. However, based on our clinical experience, there were difficulties to keep LMA in appropriate position when turned patients to semiprone position. With the advantages of a more open ventilating system, fewer complications, and a lower requirement for spontaneous breathing [3], SJOV has shown its versatility in the emergency airway to support sufficient ventilation [21] and in difficult airways to achieve desirable oxygenation. In our study, the incidence of SRAEs for patients undergoing ERCP under deep sedation were successfully decreased through SJOV via WNJ. Furthermore, lower incidences of muscle twitch, cough and body movement were observed intraoperatively in our study, which indicated that SJOV has the potential to reduce body movements for safer procedures.

Some limitations exist in our study. First, our study is a single-blinded trial with potential biases of outcome assessment, but the objective parameter of hypoxemia might correct for the single-blindness in the present study. Second, the sedation strategy in our study consisted of propofol, remifentanyl and dexmedetomidine, so our results cannot be applied to patients with other sedative strategy. Third, we only enrolled patients aged 18 to 65 years with ASA classifications from I to III. The available evidence has demonstrated that the pharmacokinetics and pharmacodynamics of medicine are significantly

affected by age [28]. A previous study showed that older age, higher BMI, higher ASA class and longer procedure duration led to higher rates of SRAEs [29]. Therefore, future studies should focus on specific and high-risk patients under deep sedation who may benefit from SJOV in different procedures. Furthermore, the combination use of some useful current monitors such as Oxygen Reserve Index may make the use of SJOV via WNJ safer, which needs further validation.

Conclusions

In comparison to the nasopharyngeal airway, SJOV via WNJ significantly reduces the incidence of subclinical respiratory depression and SRAEs, especially the incidence of hypoxemia and severe hypoxemia, which is effective to improve oxygenation for patients undergoing deep sedation in the semiprone position during ERCP.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12871-024-02406-y>.

Supplementary Material 1: Data on anesthesia dosage, anesthesia time, and patient vital signs during the perioperative period

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Author contributions

Project with supervision from ZJ, YW and HW. DS, WZ, JL and XT helped acquiring and sorting the data. DS and WZ helped analyzing and interpreting statistics. ZJ, DS, WZ helped preparing the figures. All authors were involved in drafting and reviewing the manuscript and approved the final manuscript for submission.

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Data availability

All data generated or analysed during this study are included in this published article and its supplementary information files.

Declarations

Ethics approval and consent to participate

This clinical study was approved by the Institutional Review Board and Ethics Committee of Affiliated East Hospital of Tongji University (2021, No.097), Shanghai, China (Chairperson Prof Zengguang Xu) on 5 November 2021. Patients were consented by a written informed consent, which followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines and was conducted in accordance with the Helsinki Declaration-2013.

Consent for publication

Not applicable.

Competing interests

Dr. Huafeng Wei is the inventor of the WEI Nasal Jet Tube (WEI NASAL JET or WNJ), which was used to generate SJOV in this study. Other authors have no conflict of interest.

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