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An Observational Study to Assess the Role of Transnasal Humidified Rapid Insufflation Ventilatory Exchange with Target Controlled Infusion as Sole Airway Management Strategy During Endoscopic Retrograde Cholangiopancreatography Under General Anaesthesia.

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Abstract:
Endoscopic retrograde cholangiopancreatography is frequently performed under general anaesthesia with endotracheal intubation due to increased risk of hypoxemia under deep sedation, however intubation carries its own risks and is associated with longer induction times. Transnasal Humidified Rapid Insufflation Ventilatory Exchange (THRIVE) is a promising noninvasive technique that reduces the risk of hypoxia while avoiding risks associated with endotracheal intubation. This prospective observational study was conducted to assess the efficacy of THRIVE combined with Target-Controlled Infusion (TCI) of propofol as a sole airway management strategy in 56 adult patients undergoing elective ERCP under GA. THRIVE oxygen was delivered via nasal cannula at 20–25 L/min for preoxygenation, increased to 30–70 L/min post-induction. General anaesthesia was maintained with TCI- propofol using BIS titrated to 40–60. In summary, combination of THRIVE with TCI-propofol provided safe approach to airway management for ERCP under GA, minimizing the need for endotracheal intubation while maintaining oxygenation and ventilation.

Keywords: *THRIVE, TCI Propofol, ERCP, General Anaesthesia, Non-invasive ventilation, Tubeless anaesthesia, Airway management*

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a commonly performed diagnostic and therapeutic procedure in the management of various hepatobiliary and pancreatic diseases. It is frequently performed under deep sedation or general anaesthesia, often with the patient in a prone or lateral position to ensure procedural success.[1,2]

Adverse events such as hypoxia, hypotension, and respiratory depression are more frequently noticed in patients receiving deep sedation, and it is also associated with increased procedural interruptions.[3] While General anaesthesia with endotracheal Intubation ensures airway protection, controlled ventilation and reduction in procedural interruptions, it may be associated with increased induction time and complications related to intubation.[4]These limitations highlight the need for innovative airway management strategies that avoid intubation while maintaining oxygenation and ventilation and also enhancing procedural efficiency.

Tubeless anaesthesia techniques, such as Transnasal Humidified Rapid Insufflation Ventilatory Exchange (THRIVE), has recently gained attention as a non-invasive oxygenation technique that delivers heated, humidified oxygen at high flow rates through a nasal cannula. Its efficacy is demonstrated in upper airway and esophageal surgeries, where stable oxygenation was maintained up to 55 minutes.[5] Concurrently, target controlled infusion (TCI) systems allow precise administration of intravenous anaesthetics, optimizing depth of sedation while reducing the risk of respiratory depression and hemodynamic fluctuations.[6,7] Despite these advances, there is limited literature on the use of THRIVE as an oxygenation technique with TCI propofol used for providing general anaesthesia in patients undergoing ERCP. The safety, efficacy, and generazilibilty of this approach remain largely unexplored, especially in the context of maintaining adequate ventilation and oxygenation without the need for endotracheal intubation while giving general anaesthesia.

We hypothesize that the combined use of THRIVE and TCI can provide effective airway management during ERCP under general anaesthesia, maintaining adequate oxygenation and ventilation, while minimizing adverse events and the need for invasive airway interventions.

Objectives:
Primary objective:
To assess the number of episodes of desaturation
Secondary Objectives**:**
To assess the total propofol used, end tidal co2, arterial blood gas at the beginning & end of procedure, need for rescue ventilation, incidence of sore throat or dryness, hemodynamics at thrive removal, patient satisfaction

METHODS

Study Design and Setting
This study was approved by the Institutional Ethics Committee at Sri Ramachandra Institute of Higher Education and Research and registered at ClinicalTrails.gov (IEC reference number: CSP-MED/24/FEB/98/41) & CTRI number: REF/2024/11/094255). It was a prospective observational study conducted at Sri Ramachandra Institute of Higher Education and Research between FEB 2025 TO JULY 2025.
Participants
This prospective study was conducted on adult patients scheduled for elective ERCP under general anaesthesia. Inclusion criteria were adults aged 18 to 75 years, with a body mass index (BMI) less than 40 kg/m^2, and classified as American Society of Anaesthesiologists (ASA) physical status I to III. Patients were excluded if they were younger than 18 years, had an anticipated difficult airway, were pregnant (parturient), were at risk of aspiration, exhibited hemodynamic instability, had a history of heart disease, or were undergoing emergency surgeries. Additional exclusion criteria included known allergy to propofol, refusal to participate, and inability to provide informed consent.
Variables and Data Sources
Preoperatively, patient demographics, ASA class, history of comorbidities, airway assessment, and details of the planned procedure were recorded. Upon arrival in the holding area, baseline vital signs, including heart rate, oxygen saturation, and blood pressure, were documented. Intraoperatively, the duration of the procedure was noted, and a standardized anaesthesia protocol was followed for all patients. ASA standard monitors were attached, and the nasal cannula for Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE) was placed. Baseline bispectral index (BIS) values were recorded. Preoxygenation was initiated with 100% oxygen at a rate of 20–25 L/min for 3–5 minutes following induction with fentanyl at 2 mcgs/kg. Intravenous anaesthesia was then commenced using target-controlled infusion (TCI) of propofol, with effect-site concentration titrated to achieve BIS of 40-60. The oxygen flow rate of THRIVE was increased to 50–70 L/min once the patient lost consciousness and BIS was less than 60. Depth of anaesthesia was monitored using BIS, and anaesthesia was maintained with propofol. If the procedure duration exceeded one hour, a repeat dose of fentanyl (0.5 mcg/kg) was administered. During the procedure, BIS values were maintained between 40 and 60.
Airway management equipment—including various sizes of masks, oropharyngeal and nasopharyngeal airways, endotracheal tubes, and supraglottic airway devices—was kept ready to replace THRIVE if necessary. In the event of upper airway obstruction or desaturation (SpO_2 <92%), an oral airway was placed. For persistent obstruction and desaturation (SpO_2 <92%), jaw thrust with bag and mask ventilation was performed. If saturation did not improve despite these measures a endotracheal tube was inserted.
Parameters observed
Parameters studied included patient demographics, ASA class, comorbidities, airway assessment, baseline hemodynamic parameters, procedure duration.
Pertinent to THRIVE, the number of desaturation episodes (SpO_2 <92%), need for rescue ventilation (SpO_2 <90%), end-tidal CO_2 ($EtCO_2$), and arterial blood gas parameters at the beginning and end of the procedure were recorded. For target-controlled infusion, the effect-site concentration (Ce) of propofol at BIS <60 during induction, at BIS >60, and at clinical awakening were noted. General anaesthesia parameters included total propofol used, time to respond to oral commands, incidence of sore throat or dryness, hemodynamics at THRIVE removal, and patient satisfaction using a 5-point numerical rating scale.
Study Size

The sample size for this study was calculated based on the prevalence of desaturation events among patients undergoing ERCP with high-flow nasal oxygen (HFNO), which was reported as 3.4% (p = 0.034) in a study by Cha B et al.[8] Additional parameters used for the calculation included a two-sided alpha error of 5% (0.05) and a margin of error of 5% (0.05). The sample size was determined using the formula:
Sample size (N) = ((Zα/2)2×p(1-p)) ÷ d2
Where,
- Zα/2 = Z0.05/2 = 1.96 (From Z table) at 5% alpha error
- p= Prevalence according to previous study
- d = Margin of error

Sample size (N) = ((1.96)2×0.034(1-0.034)) ÷ 0.052 = 0.1262 ÷ 0.0025 = 50.47 ~ 50
which was rounded to 50. To account for a potential 10% non-response rate, the adjusted sample size was rounded up to 56. Therefore, the final required sample size for the study was determined to be 56 patients.

Statistical Methods
Descriptive analysis was carried out by frequency and proportion for categorical variables. Continuous variables were presented as Mean ± SD. Paired T-test is used to compare the means of two related groups. P value < 0.05 was considered statistically significant. R-Studio Desktop latest version was used for statistical analysis. (Reference: **R-Studio** Team (2024). **R-Studio**: Integrated Development for R. **R-Studio**, PBC, Boston, MA URL http://www.**rstudio**.com/.)
Results:
A total of 56 samples were included in the study.

Table 1: Descriptive statistics of demographic parameters of the study population (N=56)

Parameter	**Mean ± SD**	
Age	51.84 ± 47.98	
Height in cms	160.78 ± 8.70	
Weight in cms	62.58 ± 13.49	
BMI (N=55)	24.25 ± 5.19	
Sex	**Frequency**	**Percentage**
Male	33	58.9%
Female	23	41.1%

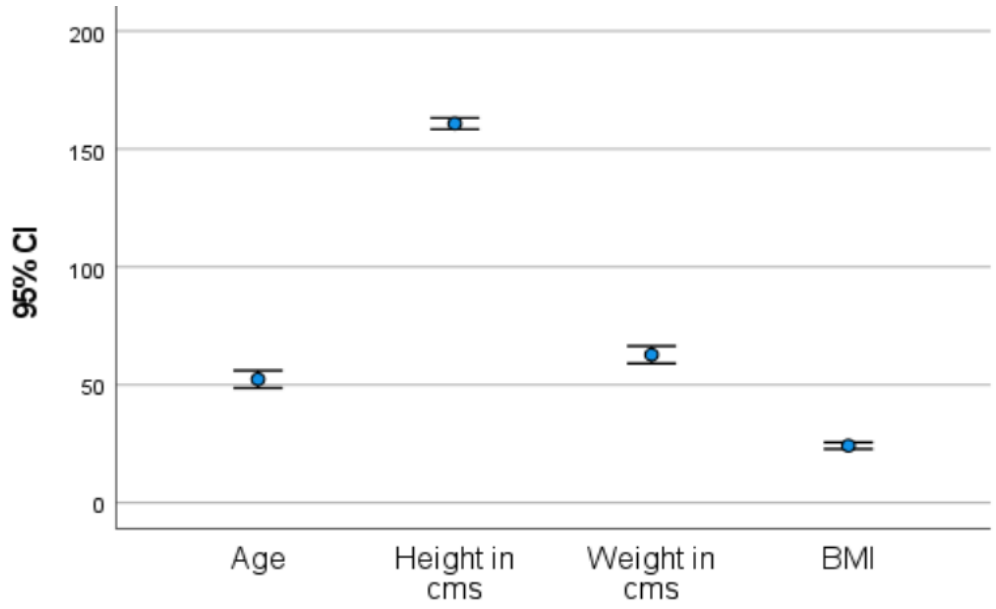

Figure 1: Error bar graph of age, height, weight and BMI in the study population

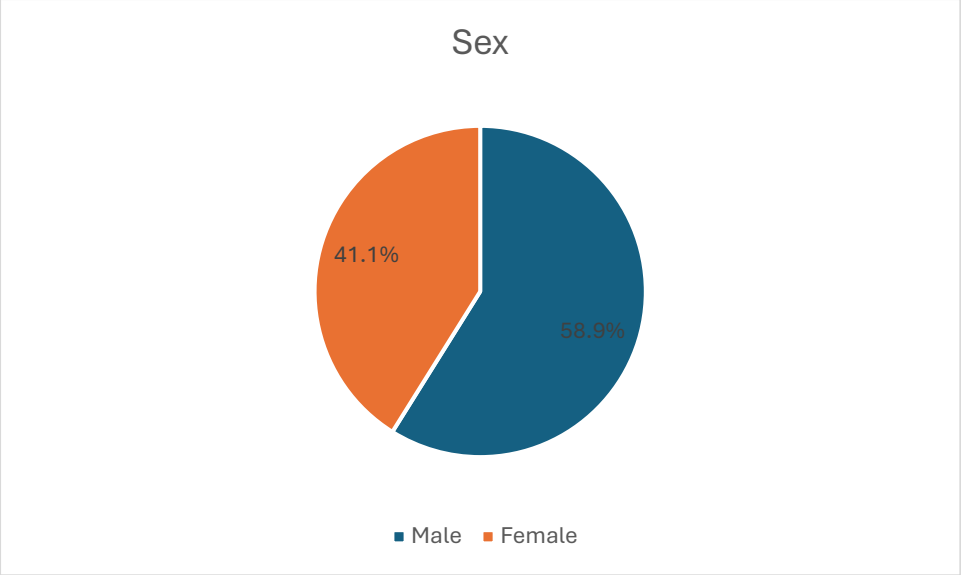

Figure 2: Pie chart of sex distribution in the study population

Table 2: Descriptive statistics of clinical parameters of the study population (N=56)

Parameter	Frequency	Percentage
ASA		
Normal healthy patient	10	17.9%
Patient with mild systemic disease	39	69.6%
Patient with severe systemic disease	7	12.5%
Airway assessment (MPG)		
Soft palate, fauces, uvula, pillars visible	8	14.3%
Soft palate, fauces, uvula visible	34	60.7%
Soft palate, base of uvula visible	14	25.0%
Duration of surgery in mins (N=53), Mean ± SD	41.25 ± 15.94	

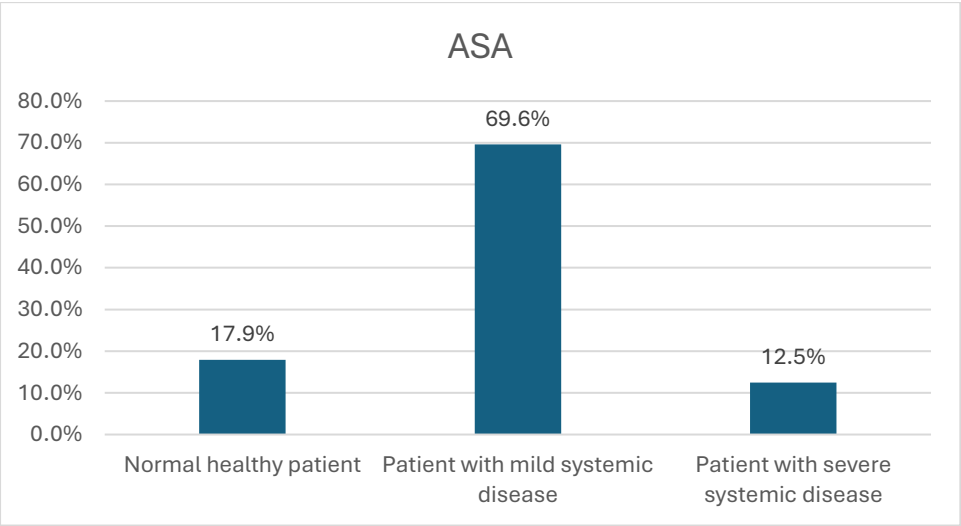

Figure 3: Bar chart of ASA in the study population

Table 3: Descriptive statistics of desaturation parameters in the study population

Parameter	Frequency	Percentage
Desaturation		
Incidence	5	8.9%
Rescue ventilation (N=5)		
Jaw thrust	5	100.0%

Oral airway and Jaw thrust	1	20%
Intubated (N=5)		
Yes	1	20%
No	4	80%

Table 4: Comparison of ABG at beginning and and at the end in the study population(N=56)

Parameters	ABG at beginning	ABG at the end	P value
PH	7.42 ± 0.05	7.34 ± 0.09	**<0.001**
PO2	89.26 ± 15.31	306.49 ± 109.69	**<0.001**
PCO2	35.28 ± 4.99	42.64 ± 8.95	**<0.001**
HCO3	22.93 ± 2.28	22.76 ± 2.52	0.56
Lactate	1.09 ± 0.38	2.33 ± 5.38	0.099

There was a statistically significant difference in PH, PCO2 and PCO2 according to ABG at beginning and at the end ($p<0.05$).

Table 5: Descriptive statistics of baseline vitals in the study population (N=56)

Baseline vitals	Mean ± SD
HR	81.18 ± 15.23
SBP	133.16 ± 19.48
DBP	81.34 ± 10.56
SPO2	98.48 ± 1.57
RR	15.86 ± 2.20

Table 6: Descriptive statistics of total propofol in ml in the study population(N=54)

Parameter	Mean ± SD
Total propofol in ml	44.68 ± 16.47

Table 7: Descriptive statistics of saturation in the study population (N=56)

Saturation	Mean ± SD
Pre induction	99.45 ± 1.06
Post induction	99.77 ± 0.69
05mins	99.05 ± 5.38
10mins (N=54)	99.70 ± 0.90
20mins (N=49)	99.92 ± 0.34
30mins (N=32)	99.88 ± 0.34
40mins (N=16)	100 ± 0.00
50mins (N=8)	100 ± 0.00
60mins (N=6)	100 ± 0.00
70mins (N=2)	100 ± 0.00
80mins (N=2)	100 ± 0.00
90mins (N=0)	-

Table 8: Descriptive statistics of HR in the study population (N=56)

HR	Mean ± SD
Pre induction	80.50 ± 14.56
Post induction	79.93 ± 14.08

05mins	85.16 ± 15.71
10mins (N=54)	88.74 ± 14.35
20mins (N=50)	91.40 ± 17.35
30mins (N=33)	90.58 ± 13.89
40mins (N=15)	91.47 ± 11.82
50mins (N=8)	89.88 ± 13.04
60mins (N=6)	92.50 ± 11.48
70mins (N=2)	102.00 ± 9.89
80mins (N=2)	102.00 ± 14.14
90mins (N=0)	-

Table 9: Descriptive statistics of SBP and DBP in the study population (N=56)

	SBP, Mean ± SD	**DBP, Mean ± SD**
Pre induction	136.29 ± 19.41	83.36 ± 11.94
Post induction	113.02 ± 16.05	70.59 ± 11.97
05mins	116.50 ± 18.49	76.04 ± 13.86
10mins (N=54)	116.54 ± 17.06	77.85 ± 13.27
20mins (N=50)	120.42 ± 18.98	80.64 ± 15.32
30mins (N=32)	122.75 ± 21.95	82.94 ± 14.01
40mins (N=15)	126.40 ± 16.07	86.73 ± 12.51
50mins (N=8)	114.38 ± 17.91	82.88 ± 18.49
60mins (N=6)	120.33 ± 18.38	83.67 ± 16.40
70mins (N=2)	129.50 ± 14.85	86 ± 5.66
80mins (N=2)	118.00 ± 16.97	76.50 ± 4.95
90mins (N=0)	-	-

Table 10: Descriptive statistics of CE in the study population (N=56)

CE	**Mean ± SD**
Pre induction	0.00 ± 0.00
Post induction	3.30 ± 0.82
05mins	4.06 ± 0.65
10mins (N=54)	4.32 ± 0.63
20mins (N=50)	4.24 ± 1.01
30mins (N=32)	3.99 ± 0.83
40mins (N=15)	3.94 ± 0.87
50mins (N=8)	3.97 ± 0.76
60mins (N=6)	4.00 ± 0.63
70mins (N=2)	3.40 ± 0.85
80mins (N=2)	3.75 ± 0.35
90mins (N=0)	-

Table 11: Descriptive statistics of sore throat/dryness in the study population

Parameter	**Frequency**	**Percentage**
Sorethroat/dryness	**4**	**7%**

Table 12: Descriptive statistics of clinical parameters in the study population

Parameter	Mean ± SD
Response time in mins (N=52)	11.38 ± 4.13
ETCO2 at the end (N=53)	19.45 ± 6.76

Table 13 : Descriptive statistics of patient satisfaction in the study population (N=53)

Parameter		
Patient satisfaction	**Frequency**	**Percentage**
Very satisfied	32	60.4%
Somewhat satisfied	15	28.3%
Neither satisfied nor dissatisfied	5	9.4%
Somewhat dissatisfied	1	1.9%

DISCUSSION

To our knowledge, this is the first prospective observational study conducted to evaluate the efficacy of this tubeless technique using THRIVE for airway management in patients scheduled for ERCP under GA , aiming to avoid endotracheal intubation while maintaining adequate oxygenation and ventilation. In our study we found that combining THRIVE with TCI propofol provides effective airway management during ERCP under GA, avoiding endotracheal intubation in 98.2% of cases. Our results demonstrated that this approach is feasible and effective for the majority of patients, with mean SpO_2 levels remaining above 99% at all measured time points. Only five patients (8.9%) experienced transient desaturation, which was effectively managed with airway maneuvers, with only one patient (1.8%) requiring endotracheal intubation as shown in Table

While ERCP can be performed under either deep sedation or general anaesthesia, general anaesthesia is preferred in many centers owing to the reduced incidence of procedural interruptions and a reduced risk of hypoxic events.[4] However, it is important to consider intubation-related complications while giving GA and especially managing an intubated patient in prone position carries its own challenges.[9]

These considerations highlight the clinical need for airway management strategies during ERCP that avoid intubation, yet still can maintain optimal oxygenation and ventilation. Therefore, we adopted THRIVE, as a tubeless approach in this study to combine the safety and procedural stability afforded by general anaesthesia with a less invasive, more efficient airway strategy, potentially reducing intubation-related complications and intubation related delays.

In a retrospective review of 14 patients undergoing esophageal endoscopic procedures under general anaesthesia with THRIVE all patients maintained adequate oxygenation except for one patient who required rescue intubation due to desaturation, and the median SpO_2 at the end of surgery was 99%.[10] In a pilot study conducted by frassanito et al. in 20 women undergoing operative hysteroscopy under general anaesthesia, using THRIVE as the sole airway technique, the success rate was 100%, with no patient requiring rescue airway intervention, and the median SpO_2 during the procedure was 100% (IQR 99–100%).[11]Their findings reinforce the high safety margin of THRIVE in short, elective procedures under general anaesthesia.

In our study, five patients experienced desaturation. One of these patients had a high body mass index (BMI=33). This finding aligns with existing literature, which identifies elevated BMI as a potential predictor of THRIVE failure.[12] In the remaining four, the procedure duration exceeded 40 minutes. THRIVE is generally not recommended for procedures expected to last longer than 30 minutes, as prolonged apnoea time may increase the risk of desaturation.[10] These findings highlight the importance of patient selection when using THRIVE for airway management.

As expected, there was a statistically significant rise in $PaCO_2$ over the course of the procedure, reflecting the gradual accumulation of carbon dioxide. However, the increase in Pco2 was relatively modest (from 35.28 ± 4.99 mmHg to 42.64 ± 8.95 mmHg), consistent with the ability of THRIVE to wash out CO2.[13]Previous studies have reported CO_2 accumulation rates of approximately 1 mmHg/min under THRIVE, which is significantly lower than the 2.63 to 3.38 mmHg/min seen in apnoeic patients without THRIVE.[14,10] The relatively controlled CO_2 rise in our study may also be due to the fact that muscle

relaxants were not used, potentially preserving some degree of spontaneous respiratory effort and facilitating CO_2 clearance in addition with the use of THRIVE. The mean PaO_2 improved from 89.26 mmHg to 306.49 mmHg, a reflection of the high FiO_2 delivered through THRIVE .This reinforces the reliability of THRIVE for maintaining adequate oxygen saturation during ERCP, even in the absence of mechanical ventilation.

The mean total propofol usage in our study was 44.68 ± 16.47 mL. The higher dose observed can be attributed primarily to the use of general anaesthesia (GA) rather than deep sedation, which necessitates a greater amount of propofol to maintain adequate anaesthetic depth. Additionally, the longer duration of procedures in our patients increased the requirement of propofol.

Despite a significant elevation in $PaCO_2$, the mean $EtCO_2$ at the end of the procedure remained low (19.45 ± 6.76 mmHg), suggesting that ETCO2 may not be a reliable marker for considering the adequacy of ventilation when THRIVE is used for airway management

Although Sequential ABG analysis revealed a statistically significant reduction in pH (7.42 to 7.34) and rise in $PaCO_2$ (35.28 to 42.64 mmHg) during the procedure, consistent with well-documented CO_2 accumulation, HCO_3^- remained stable, confirming the absence of significant respiratory acidosis or metabolic compensation in this time frame.

The use of BIS (Bispectral Index) monitoring with effect-site targeted propofol administration via a TCI pump proved highly advantageous in maintaining optimal anaesthetic depth. BIS allowed for real-time, objective assessment of the patient's level of consciousness, enabling precise titration of propofol to avoid both excessive and inadequate depth of anaesthesia. This individualized approach contributed to hemodynamic stability, with no clinically significant episodes of hypotension, bradycardia, or hypertension.

Only 4 patients (7.1%) reported sore throat or dryness immediately post-procedure, likely due to the non-instrumental airway technique, which stands in contrast to the higher incidence reported with endotracheal tube or LMA use. [15]The majority of patients (88.7%: 60.4% very satisfied, 28.3% somewhat satisfied) were satisfied with their experience, reflecting the minimally invasive approach, absence of post-procedural airway symptoms, and smooth emergence.

Limitations:

The exclusion of high-risk patients—such as those with BMI >40, ASA physical status IV, or anticipated difficult airways limits the applicability of results to broader or more complex patient populations

CONCLUSION

THRIVE with TCI propofol is a safe and feasible sole airway strategy for ERCP under GA, offering reliable oxygenation, hemodynamic stability, and high patient satisfaction. While mild hypercapnia occurs, it remains clinically benign with appropriate monitoring. This approach addresses key challenges of prone-positioned ERCP, reducing intubation needs without compromising safety.

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