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ORIGINAL ARTICLE

Medicine Science International Medical Journal

Medicine Science 2026;15(2):638-43

Comparison of high flow nasal oxygen and standard nasal oxygen in preventing hypoxia in patients undergoing endoscopic retrograde cholangio pancreatography under sedation

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Received 06 August 2025; Accepted 08 September 2025
Available online 24 April 2026 with doi: 10.5455/medscience.2025.08.214

Abstract

Endoscopic retrograde cholangiopancreatography (ERCP) can be particularly challenging for anesthesiologists because of the increased difficulty in airway access when it is performed in the prone position, alongside typically older patients with increased comorbidities. This study aimed to compare the effectiveness of high-flow nasal oxygen (HFNO) versus standard nasal oxygen (NO) in preventing hypoxemia in patients undergoing deep sedation monitored by Bispectral Index (BIS) during ERCP procedures. This prospective clinical study included 187 patients. Patients were allocated to the NO or HFNO group. Frailty levels were evaluated using the Modified Frailty Index-11 (mFI-11) before the procedure. Sedation was adjusted to maintain BIS values between 60 and 80. The SpO_2 levels at 5 and 10 min were higher in the HFNO group than in the NO group (p=0.002 and p=0.003, respectively). The changes in SpO_2 over time differed significantly between the groups (F=7.315, p<0.001). The frequency of interventions, such as chin lift, increasing O_2 flow, SpO_2<90, and SpO_2 75-90, was higher in the NO group than in the HFNO group (p<0.001, p=0.006, p=0.006, and p<0.001, respectively). Administration of HFNO under deep sedation to ERCP patients with a higher rate of comorbidities may prevent desaturation and provide safe anesthesia.

Keywords: Endoscopic retrograde cholangiopancreatography, high-flow nasal oxygen, nasal oxygen, deep sedation, prone position

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive and lengthy procedure compared to other gastrointestinal endoscopic procedures and requires moderate to deep sedation. The patients are generally older and have more comorbidities. The procedure is usually performed in the prone position, which further complicates the situation [1]. The large size of the endoscopic devices in the procedure room makes airway access challenging. During the procedure, situations requiring simple airway maneuvers can progress to serious conditions that can lead to prolonged severe hypoxia, neurological damage, myocardial ischemia, arrhythmias, cardiorespiratory arrest, and even death [2].

Administration of supplemental oxygen using a standard nasal cannula is the current standard of care for patients undergoing sedation during gastrointestinal endoscopic procedures. The inspired oxygen concentration (FiO_2) delivered by standard nasal oxygen (NO) is less than 0.4, which may be insufficient for patients in the prone position under deep sedation [3].

High-flow nasal oxygen (HFNO) represents a relatively new type of noninvasive oxygen therapy system that delivers heated, humidified, and oxygenated air at a high flow rate. The gas flow is generally adjusted to 40-70 L.min-1, allowing for an inspired oxygen fraction of 21%-100% [4]. High gas flow is associated with positive pressure within the nasopharyngeal space and thoracic cavity. This results in reduced airway obstruction and increased end-expiratory lung volume. HFNO has been shown to reduce the accumulation rate of carbon dioxide partial pressure by washing out the anatomical dead space and decreasing it [5].

CITATION
Tuncer B, Demirhan S, Tuc O, Erkilic E. Comparison of high flow nasal oxygen and standard nasal oxygen in preventing hypoxia in patients undergoing endoscopic retrograde cholangio pancreatography under sedation. Med Science. 2026;15(2):638-43.

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DOI: 10.5455/medscience.2025.08.214

The use of HFNO has been demonstrated in various clinical settings, including intensive care units, in conjunction with cardiac surgery, before intubation, and for sedation during bronchoscopy and endoscopy. This application prevents hypoxemia [6-11].

The objective of this study was to compare the effects of HFNO with standard NO therapy in preventing hypoxemia in fragile ERCP cases performed in the prone position under deep sedation.

Material and Methods

This study was conducted at Ankara Bilkent City Hospital between May and November 2023. Ethical approval was obtained from Ankara Bilkent City Hospital Ethics Committee (No: E2-23-4070; Date: 10 May 2023). This study was retrospectively registered in the National Clinical Trials database under the study registration number NCT06689033. 187 patients scheduled for an ERCP procedure under sedation were included in the study. Power analysis was performed using G-Power statistical software. A sample size of at least 185 patients was adequate at a 95% confidence level with 80% power and an effect size of 0.5.

The study was designed as a prospective clinical study. All patients who participated in the study were informed about the study and possible risks, and written informed consent was obtained. Patients who voluntarily enrolled in the study, were aged 18 years or older, and had ASA I-IV risk scores were included. Patients with cognitive disorders, tracheostomy, altered mental status, dementia, intubation, a necessity for oxygen therapy because of prior diseases, pregnancy, a history of nasal bleeding, or an allergy to propofol were not included.

The two methods were applied randomly. Patients were randomly allocated to either the NO or HFNO group in a 1:1 ratio using a computer-generated random code generator. This was not a masked study, as the oxygen delivery systems utilized were not identical. The endoscopists, anesthesiologists, and patients were not blinded.

The patient's age, current chronic diseases, and duration of the procedure were recorded. Before the procedure, the patients' frailty levels were evaluated using the Modified Frailty Index-11 (mFI-11) and recorded. The mFI-11 is an 11-item index used to assess comorbidities and determine a patient's risk level. It is calculated by dividing the number of existing comorbidities by the number of items used in the mFI-11 evaluation. The 11-item list encompasses hypertension medication, chronic obstructive pulmonary disease, myocardial infarction, diabetes mellitus, dependent functional status, congestive heart failure, percutaneous coronary intervention or cardiac surgery, angina, transient ischemic attack, peripheral vascular disease, impaired sensorium, and cerebrovascular accident. Patients were deemed vulnerable if their score exceeded 0.27 [12,13].

The patients were positioned prone, and pulse oximetry, electrocardiography, noninvasive blood pressure monitoring, and Bispectral Index (BIS) monitoring (Medtronic Covidien BIS Complete Monitoring System, USA) were performed. The NO group underwent preoxygenation with 100% oxygen for 3 min at an oxygen flow rate of 8 $L.min^{-1}$ via a nasal cannula before the induction of anesthesia. Thereafter, the animals were exposed to a constant flow of oxygen at 5 L/min^{-1} throughout the procedure. The HFNO group was preoxygenated with 100% oxygen at 40 $L.min^{-1}$ for 3 min via an HFNO system (Inspired 02FLO High Flow Heated Respiratory Humidifier, VUN-001, Vincent Medical Manufacturing Co., Hong Kong) before induction and then received 50% oxygen at 50 $L.min^{-1}$. In case of a decrease in saturation (SpO_2<90), the flow was increased to 60 $L.min^{-1}$; if this did not resolve, the FiO_2 was increased to 100%. All patients were premedicated with IV midazolam, and sedation was performed with IV 1 $\mu g.kg^{-1}$ fentanyl and an IV bolus dose of 0.5^{-1} $mg.kg^{-1}$ propofol, followed by an IV propofol infusion at 3-4 $mg.kg^{-1}.hr^{-1}$, targeting a BIS of 60-80. Peripheral oxygen saturation SpO_2<90 was considered desaturation, and a respiratory rate <6 breaths per minute was considered apnea. In the case of apnea or desaturation, the patient was verbally stimulated to breathe. When low saturation persisted, chin-lift and chin-thrust maneuvers were performed, or the oxygen flow was increased and recorded. The lowest SpO_2 values were observed in both groups.

Statistical Analysis

Analysis was conducted using IBM SPSS Statistics ver. 25. Kolmogorov-Smirnov tests were used to assess the normality of continuous numerical variables. Variance homogeneity was evaluated using Levene's test. For continuous variables, descriptive statistics were expressed as mean ± standard deviation or ranges. For categorical variables, descriptive statistics were reported as percentages (%), and case counts were reported. An analysis was conducted to assess the differences between the NO and HFNO groups for continuous variables that met the assumptions of parametric test statistics. To this end, Student's t-test was used, whereas differences for those who did not meet these assumptions were assessed using the Mann-Whitney U test. The significance of changes over time in heart rate, systolic, diastolic, and mean blood pressure, SpO_2, and BIS levels was examined using repeated-measures ANOVA with Wilks' lambda. When Wilks' Lambda test results were statistically significant, the specific times causing variations were identified using a Bonferroni-adjusted multiple comparison test. Comparisons between the NO and HFNO groups were made by calculating the changes in SpO_2 and BIS from baseline at subsequent time points. Unless otherwise stated, Pearson's χ^2 test was used for categorical data analysis. Fisher's exact test was employed for 2 × 2 contingency tables in which a minimum of 25% of the anticipated frequencies was less than 5. When the expected frequencies were between 5 and 25, continuity correction was applied to the χ^2 test. In RxC tables (the presence of at least one categorical variable within a given row or column that exhibited more than two outcomes), if at least 25% of the cells had anticipated frequencies of less than five, the Fisher-Freeman-Halton test was used. Unless otherwise

DOI: 10.5455/medscience.2025.08.214

stated, results were considered significant at $p<0.05$. Bonferroni correction was applied to control for Type I errors across all multiple comparisons.

Results

Table 1 compares the clinical and demographic features of the patients according to the groups. No statistically significant differences were observed between the NO and HFNO groups in terms of demographic and clinical characteristics. However, the median total propofol consumption was significantly higher in the HFNO group than in the NO group (p=0.004).

The Modified Frailty Index components and MFI scores are shown in Table 2. The prevalence of the components of the mFI-11, except for congestive heart failure (CHF), was statistically similar between the NO and HFNO groups ($p>0.05$). The prevalence of CHF was significantly higher in the HFNO group than in the NO group (p=0.010). In the NO group, six (6.4%) patients had an mFI-11 score≥3, whereas in the HFNO group, 14 (15.1%) patients had an mFI-11 score≥3. However, statistical analysis revealed no significant difference between the two groups (p=0.093). Additionally, the groups had similar median mFI-11 values (p=0.519).

Table 1. Demographic and clinical characteristics of the groups

Demographic	NO (n=94)	HFNO (n=93)	p-value
Age (year)*	58.9 ± 18.0	60.4 ± 17.2	0.568[a]
Gender			0.929[b]
Male	38 (40.4%)	37 (39.8%)	
Female	56 (59.6%)	56 (60.2%)	
Weight (kg)*	73.3 ± 11.8	73.4 ± 13.2	0.919[a]
Height (m)*	1.65 ± 0.075	1.66 ± 0.087	0.536[a]
BMI (kg.m^2)*	26.8 ± 4.0	26.9 ± 6.0	0.907[a]
ASA			0.537[c]
I	19 (20.2%)	20 (21.5%)	
II	49 (52.1%)	42 (45.2%)	
III	26 (27.7%)	29 (31.2%)	
IV	0 (0.0%)	2 (2.1%)	
History of smoking			0.418[b]
Non-smoker	56 (59.6%)	64 (68.8%)	
Ex-smoker	14 (14.9%)	11 (11.8%)	
Smoker	24 (25.5%)	18 (19.4%)	
Comorbidities			
HT	41 (43.6%)	45 (48.4%)	0.513[b]
DM	21 (22.3%)	23 (24.7%)	0.831[d]
CAD	8 (8.5%)	9 (9.7%)	0.982[d]
COPD	4 (4.3%)	4 (4.3%)	>0.999[e]
HL	5 (5.3%)	5 (5.4%)	>0.999[e]
Hypothyroidism	5 (5.3%)	6 (6.5%)	0.985[d]
History of cancer	7 (7.4%)	4 (4.3%)	0.546[d]
Others	32 (34.0%)	36 (38.7%)	0.507[b]
History of previous operations	75 (79.8%)	65 (69.9%)	0.164[d]
Duration of process (min)**	24 (8-65)	23 (8-84)	0.863[f]
Total profopol(mg)**	170 (51-580)	230 (52-750)	**0.004**[f]

Descriptive statistics are shown as * mean ± standard deviation or ** median (minimum-maximum). a Student's t test, b Pearson's χ^2 test, c Fisher Freeman Halton test, d Continuity-corrected χ^2 test, e Fisher's exact probability test, f Mann Whitney U test. NO: Nasal Oxygen, HFNO: High Flow Nasal Oxygen, BMI: Body Mass Index, ASA: American Society of Anesthesiologists (ASA) physical status classification HT: Hypertension, DM: Diabetes Mellitus, CAD: Coronary Artery Disease, COPD: Chronic Obtructive Pulmonary Disease, HL: Hyperlipidemia

DOI: 10.5455/medscience.2025.08.214

Table 2. Modified frailty index components and modified frailty index scores

mFI-11 Components	NO (n=94)	HFNO (n=93)	p-value
DM	21 (22.3%)	23 (24.7%)	0.831[a]
Dependent functional status	2 (2.1%)	1 (1.1%)	>0.999[b]
COPD	4 (4.3%)	4 (4.3%)	>0.999[a]
CHF	1 (1.1%)	9 (9.7%)	**0.010[b]**
MI	5 (5.3%)	2 (2.2%)	0.444[b]
Percutaneous coronary intervention	9 (9.6%)	12 (12.9%)	0.625[a]
HT	41 (43.6%)	45 (48.4%)	0.513[c]
Peripheral vascular disease	1 (1.1%)	3 (3.2%)	0.368[b]
Impaired sensorium	-	-	-
CVA	2 (2.1%)	4 (4.3%)	0.444[b]
Neurological deficit after CVA	-	1 (1.1%)	0.497[b]
mFI-11			0.093[a]
<3	88 (93.6%)	79 (84.9%)	
≥3	6 (6.4%)	14 (15.1%)	
mFI-11*	1 [0-2]	1 [0-2]	0.519[d]

mFI: Modified Frailty Index, DM: Diabetes Mellitus, COPD: Chronic Obtructive Pulmonary Disease, CHF: Congestive Heart Failure, MI: Myocardial infarction. HT: Hypertension, CVA: Cerebrovascular Accident. *Descriptive statistics are shown as median (25th %-75th %), a continuity-adjusted χ^2 test, b Fisher's exact probability test, c Pearson's χ^2 test, d Mann Whitney U test

Table 3 compares SpO_2 levels across groups and observation times. The SpO_2 levels at 5 and 10 min were higher in the HFNO group than in the NO group (p=0.002 and p=0.003, respectively). The changes in SpO_2 over time differed significantly between the groups (F=7.315, p<0.001).

The frequency distribution of the interventions performed during the procedure by group is shown in Table 4. The frequency of interventions, such as chin lift, increase in O_2 flow, SpO_2 <90, and SpO_2 75–90, was higher in the NO group than in the HFNO group (p<0.001, p=0.006, p=0.006, and p<0.001, respectively). However, no significant differences were observed in SpO_2 <75, interruption of the procedure, or laryngospasms encountered during the procedure (p>0.05).

No statistically significant differences were observed in systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP), and heart rate (HR) values between the NO and HFNO groups at any observation time (p>0.05).

There was no significant difference in BIS or changes in BIS levels between the NO and HFNO groups at any observation time (p>0.05).

Table 3. Oxygen saturation according to groups and follow-up times

SpO_2 (%) value at the time	NO (n=94)	HFNO (n=93)	p-value[1]
0.min	95.5 ± 3.0	94.7 ± 2.5	0.196
5.min	94.1 ± 7.1	97.9 ± 1.7[a]	**0.002**
10.min	95.2 ± 3.9	97.3 ± 2.0[a]	**0.003**
15.min	97.0 ± 2.1[b]	97.3 ± 2.0[a]	0.308
20.min	96.9 ± 2.2[b]	97.6 ± 1.9[a]	0.137
25.min	97.2 ± 1.9[b]	97.7 ± 1.8[a]	0.191
p-value[2]	<0.001	<0.001	

Descriptive statistics were expressed as mean ± standard deviation. 1 Comparisons between the groups within each follow-up time were performed according to Student's t test, Bonferroni correction, and the results were considered statistically significant for p<0.0083. 2 Comparisons between follow-up times within the groups were analysed by Repeated Measures Analysis of Variance -Wilks's Lambda test with Bonferroni correction and the results were considered statistically significant for p<0.025. a The difference with 0.min is statistically significant (p<0.025), b the difference with 10.min is statistically significant (p<0.025). NO: Nasal Oxygen, HFNO: High Flow Nasal Oxygen, SpO_2: Oxygen saturation

DOI: 10.5455/medscience.2025.08.214

Table 4. Frequency distributions of the groups in terms of interventions performed during the procedure

Outcomes and Interventions	NO (n=94)	HFNO (n=93)	p-value
Chin lift	25 (26.6%)	5 (5.4%)	**<0.001**[a]
Increasing O_2 flow rate	26 (27.7%)	10 (10.8%)	**0.006**[a]
SpO_2 <90	26 (27.7%)	10 (10.8%)	**0.006**[a]
SpO_2 75-90	20 (21.3%)	4 (4.3%)	**<0.001**[a]
SpO_2 <75	5 (5.3%)	-	0.059[b]
Interruption of process	3 (3.2%)	1 (1.1%)	0.621[b]
Laryngospasm during process	1 (1.1%)	-	n/a

a: Continuity corrected χ^2 test, b Fisher's exact probability test, n/a: not available for evaluation. NO: Nasal Oxygen, HFNO: High Flow Nasal Oxygen

Discussion

This study compared the effects of HFNO and NO therapy in preventing hypoxemia in patients with substantial frailty undergoing ERCP under deep sedation with BIS monitoring. The incidence of desaturation, need for patient stimulation, chin lifting, and increased oxygen flow was significantly lower in patients who underwent HFNO than in those who underwent NO.

The most common complication of sedation-assisted endoscopic procedures is hypoxemia, defined as a decrease in peripheral oxygen saturation below 90–92%. Hypoxemia is a significant concern for anesthesiologists. Previous studies have reported desaturation rates of 16.2% to 39.2% in patients undergoing ERCP with sedation accompanied by nasal oxygen supplementation [14,15]. The ASA recommends standard oxygen therapy to prevent and treat hypoxemia. However, the optimal oxygenation device remains unspecified. HFNO, a relatively new type of noninvasive oxygen therapy system, may provide safe anesthesia, especially for patients in the prone position.

A study by Cha et al. [16] retrospectively examined 262 patients who underwent ERCP and were sedated with various sedatives in the prone position using HFNO over 4 months and reported a desaturation rate (≤90%) of 3.4%. The variables identified as predictors of desaturation included advanced age, high doses of midazolam or propofol, and the use of midazolam alone. High ASA scores, BMI, procedure duration, and comorbidities were not associated with oxygen desaturation. Although their study was retrospective and excluded conventional low-flow oxygen sedation cases, it reported desaturation rates lower than those reported in previous studies.

Kim et al. [3], in their randomized prospective study of 72 ERCP patients comparing HFNO and NO, observed hypoxia, interruptions, patient stimulation, chin lifting, and cessation of sedation only in the NO group. Notably, in this study, the researchers applied moderate sedation with a modified observer's assessment of alertness/sedation (MOAA/S) score below three, not deep sedation. Hypoxemia was observed only in the NO group at a rate of 19%. Interruptions occurred in 25% of the patients. The lowest SpO_2 recorded in the NO and HFNO groups was 95.1% and 99.8%, respectively. Sedation levels were adjusted based on the patient's irritability, as determined by the anesthesiologist.

A multicenter prospective study of 187 elderly patients undergoing ERCP, comparing HFNO and NO found unexpected hypoxic events at rates of 4% and 13% in the HFNO and nasal oxygen groups, respectively [17].

In a randomized study by Sawase et al. [18], which investigated the incidence of hypercapnia in 75 patients sedated with midazolam and pethidine, transcutaneous CO_2 values were measured in patients who received HFNO and NO. The study found no significant difference in hypoxia incidence between the groups; however, a notable difference in hypercapnia (transcutaneous $CO_2 \geq 60$ mmHg) was observed: 2.7% in the HFNO group and 18.4% in the NO group.

A meta-analysis of six randomized controlled studies involving 2867 patients undergoing gastrointestinal endoscopy (upper, lower, or both) under deep sedation, comparing HFNO and conventional oxygen therapy (COT; nasal cannula or face mask), found desaturation rates of 5.2% with HFNO and 27.2% with COT. Desaturation rates below 90% were 1.8% for HFNO and 12.6% for COT, respectively. The intervention frequencies were 4.7% for HFNO and 34.3% for COT, with interruption rates of 0.4% for HFNO and 6.7% for COT [19].

Our study found a statistically significant desaturation rate of 27.7% in patients who received NO and 10.8% in those who received HFNO. The lowest observed SpO_2 was 80% in the HFNO group and 65% in the nasal group, highlighting that HFNO significantly reduced the frequency of desaturation under deep sedation. Our study also noted significant differences in the need for chin lift maneuvers (26.6% and 5.4% in the NO and HFNO groups, respectively) and increased oxygen flow (27.7% and 10.8% in the NO and HFNO groups, respectively). The rate of procedure interruptions also showed a significant difference: 3.2% in the NO group and 1.1% in the HFNO group.

Differences in desaturation, intervention, and procedure interruption rates among studies can be attributed to the longer ERCP procedure duration, practitioner variability, variability in

DOI: 10.5455/medscience.2025.08.214

procedure duration, procedures performed in the prone position, different anesthetic agents used at different sedation levels, and ERCP being a more advanced procedure.

Our study is unique because of the large number of patients and the use of a standard anesthesia and sedation technique. We successfully achieved standard deep sedation in all patients using BIS monitoring.

The use of HFNO in ERCP to prevent hypoxemia is supported by limited studies [3,16-18,20]. These studies did not use BIS, were mostly retrospective, and prospective studies varied in the depth of sedation and types of sedation techniques used.

Limitations

Our study had some limitations. First, because the NO and HFNO systems did not appear similar, endoscopists, anesthesiologists, and patients were not blinded to the study. Second, we did not have equipment for transcutaneous carbon dioxide measurement, and it was not possible to place a capnograph in the HFNO system; therefore, we could not observe patients' end-tidal carbon dioxide levels.

Conclusion

The use of HFNO during deep sedation in patients undergoing ERCP with a higher rate of comorbidities may prevent desaturation and ensure safe monitoring of these complex and challenging patients for anesthesiologists.

Ethical Approval
Approved by the Ankara Bilkent City Hospital Ethics Committee (No: E2-23-4070; Date: 10 May 2023).

Patient Consent
Informed consent was waived due to the retrospective design.

Conflict of Interest
The authors declare no conflict of interest.

Funding
The authors received no financial support for this study.

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