INPLASY

Comparison of Efficacy and Safety of Remifentanil and Fentanyl in Adult Endoscopic Interventions: A Protocol for Systematic Review and Meta-analysis of randomized controlled trials

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ADMINISTRATIVE INFORMATION

Support - The study will be supported by FSUE "Moscow Endocrine Plant" (MEZ Endopharm).

Review Stage at time of this submission - Data analysis.

Conflicts of interest - Author 1. Barkovskaya, NA: Declares receipt of lecture honoraria from MEZ Endopharm. Author 2. Shifman, EM: Has served on advisory boards for MEZ Endopharm. Author 3. Protsenko, DN: Declares no conflict of interest. Author 4. Boyarkov, AV: Declares receipt of lecture honoraria from MEZ Endopharm.

INPLASY registration number: INPLASY202610013

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 4 January 2026 and was last updated on 4 January 2026.

INTRODUCTION

Review question / Objective Objective: To evaluate the efficacy and safety of remifentanil versus fentanyl for analgosedation during endoscopic procedures in adults.
Clinical Question: Does the use of remifentanil provide more effective and safer analgosedation compared to fentanyl during endoscopic procedures in adults?
PICOS:
• Population: Adult patients who underwent endoscopic procedures (e.g., bronchoscopy, ERCP, colonoscopy, gastroscopy, hysteroscopy) under spontaneous ventilation.
• Intervention: Bolus and/or prolonged infusion of remifentanil as an analgosedation component.
• Comparison: Use of fentanyl as an analgosedation component.
• Outcomes: Pain level (VAS); induction & recovery times (Aldrete score, MPADS, PACU time); sedation level (Ramsay scale); incidence of respiratory depression/need for MV; total propofol dose; hemodynamic parameters (MAP, HR, hypotension, bradycardia); PONV; endoscopist's assessment; patient satisfaction; cognitive status in PACU.
• Study Design: Randomized Controlled Trials (RCTs).

Rationale Endoscopic procedures are often associated with discomfort, pain, cough, and motor agitation, which can reduce their quality, increase duration, and raise the risk of complications. Remifentanil is an ultra-short-acting opioid, which, due to its metabolism by nonspecific plasma esterases, exhibits predictable and rapid (3-5 min) elimination independent of infusion duration. Theoretically, this provides advantages: better control of analgesic depth,

rapid awakening, and potentially a lower risk of respiratory complications. Fentanyl is the "gold standard" opioid analgesic used in endoscopy in combination with sedatives. Despite growing interest in remifentanil for endoscopy, published randomized controlled trials (RCTs) have yielded conflicting results. Currently, a systematic review and meta-analysis directly comparing the benefit-risk profiles of these opioids in endoscopy is lacking.

Condition being studied Bolus and/or Prolonged Infusion of Remifentanil versus Fentanyl Use as a Component of Analgosedation during Endoscopic Procedures in Adults.

METHODS

Search strategy Searches were performed in PubMed, EuropePMC, Dimensions, Google Scholar, eLibrary, Mendeley, LILACS (via http://www.bireme.br), Wiley, ScienceDirect, and the ICTRP registry (from January 1, 1996, to November 25, 2025). The search strategy was adapted for each database using queries including the English words: (Remifentanil AND Fentanyl) AND (Endoscop* OR "Endoscopic Surgical Procedures") AND "Randomized Controlled Trial". The search strategy also included an automated "snowball" method. Language restrictions were not applied.

Participant or population Adult patients following endoscopic surgery.

Intervention Use of remifentanil (bolus and/or prolonged infusion) for analgosedation.

Comparator Use of fentanyl as a component of analgosedation.

Study designs to be included We included only randomized controlled trials (RCT).

Eligibility criteria Studies must report at least one of the following outcomes: pain level (VAS), induction time, recovery time (Aldrete, MPADS, PACU stay), sedation level (Ramsay scale), incidence of respiratory depression, need for respiratory support, hemodynamic stability (MAP, HR, episodes of hypotension/bradycardia), PONV incidence. Studies were excluded if they had an ineligible design (e.g., systematic reviews, cohort studies, letters to the editor) or an inappropriate comparator.

Information sources PubMed, EuropePMC, Dimensions, Google Scholar, eLibrary, Mendeley, LILACS (via http://www.bireme.br), Wiley, ScienceDirect, and the ICTRP registry.

Main outcome(s) 1. Procedural parameters (induction time, recovery time: time to awakening/eye opening) (min), time to Aldrete score ≥ 9 points (min), time to modified Post-Anesthesia Discharge Scoring System [MPADS] eligibility (min), actual length of stay in the Post-Anesthesia Care Unit [PACU] (min). Effect measure – Mean Difference (MD).
2. Pain level (Visual Analogue Scale [VAS]) upon arrival to the PACU, in points. Effect measure – Mean Difference (MD).

Additional outcome(s) 1. Sedation level according to the Ramsay Sedation Scale (in points). Effect measure – Mean Difference (MD).
2. Total dose of propofol (mg, mg/kg). Effect measure – Standardized Mean Difference (SMD).
3. Hemodynamic parameters (mean arterial pressure, mm Hg; heart rate, beats per minute; incidence of hypotension, bradycardia, vasopressor requirement). Effect measures – Mean Difference (MD) for continuous data, Risk Ratio (RR) for dichotomous events.
4. Respiratory depression (respiratory rate, breaths per minute; incidence of respiratory depression (yes/no), need for assisted ventilation (yes/no)). Effect measures – Mean Difference (MD) for continuous data, Risk Ratio (RR) for dichotomous events.
5. Patient satisfaction, in points (4-point scale, 5-point scale). Effect measure – Standardized Mean Difference (SMD).
6. Endoscopist's subjective assessment of the procedural conditions (0-5 point scale, 0-10 point scale). Effect measure – Standardized Mean Difference (SMD).
7. Patient's cognitive status in the Post-Anesthesia Care Unit (assessed by scales such as the Digit Symbol Substitution Test, Mini-Mental State Examination). Effect measure – Standardized Mean Difference (SMD).

Data management Study management was performed using the Mendeley Desktop reference manager (Elsevier, v1.19.8, 2020), and review management was conducted using RAYYAN.

Quality assessment / Risk of bias analysis The risk of bias (RoB) in the included studies was assessed using the revised Cochrane Risk of Bias tool for randomized trials (RoB 2). Publication bias was assessed when more than 10 studies were included in a comparison, using funnel plots for visual evaluation. The certainty of evidence for key

outcomes will be rated according to the GRADE approach.

Strategy of data synthesis The following data were extracted by two reviewers: first author's name, year of publication, country, procedure type, details of the compared analgesics (loading dose, additional or maintenance dose, as well as sedative drug), participant characteristics (age, body weight, ASA physical status classification, sample size) and results. Continuous outcomes will be analyzed using the Mean Difference (MD) or Standardized Mean Difference (SMD). For data presented as median [Q1–Q3] or (min–max), the mean (SD) was calculated using the formula by X. Wan et al., 2014. Analysis of dichotomous data will be performed using the Risk Ratio (RR). A pairwise meta-analysis will be conducted using RevMan 5.4. The degree of heterogeneity will be assessed using the I^2 index. Should I^2 exceed 50%, a random-effects model will be applied. The results will be presented as forest plots with 95% confidence intervals (CI).

Subgroup analysis We performed subgroup analysis if applicable.

Sensitivity analysis A sensitivity analysis will be conducted, excluding studies with a high ROB-2.

Language restriction There are no language restrictions.

Country(ies) involved Russian Federation.

Other relevant information Review as recommended by PRISMA, 2020.

Keywords Remifentanil; Fentanyl; Analgosedation; Bronchoscopy; Colonoscopy; Gastrointestinal endoscopy; Cholangio-pancreatography.

Dissemination plans We propose to present the results of SR in the form of a publication covering comparison of Efficacy and Safety of Remifentanil and Fentanyl in Adult Endoscopic Interventions.

Contributions of each author

Author 1 - Natalya Barkovskaya - Author 1 drafted the manuscript.
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