Comparison of Postoperative Pulmonary Complications Between Smokers and Nonsmokers: A Prospective Cohort Study

Study Protocol and Statistical Analysis Plan

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1. Background and Rationale

Postoperative pulmonary complications (PPCs) are among the most common and clinically significant causes of morbidity and mortality following surgery. Risk factors contributing to the development of PPCs include preexisting lung disease, thoracic and upper airway surgeries, and cigarette smoking.

It is estimated that smokers have up to a sixfold increased risk of PPCs compared to nonsmokers. Previous studies suggest that smoking cessation for at least 6–8 weeks before surgery can significantly reduce the incidence of complications. Despite these findings, there remains a lack of prospective data comparing PPCs between smokers and nonsmokers undergoing elective abdominal surgery. This study aims to better characterize the impact of smoking on PPCs and guide preoperative risk assessment strategies.

2. Objective

The primary objective of this study is to compare the incidence of postoperative pulmonary complications between smokers and nonsmokers undergoing elective abdominal surgery under general anesthesia.

3. Expected Benefits

The findings of this study will clarify the risk posed by active smoking in the postoperative period, particularly for pulmonary complications. This may enhance clinical decision-making during preoperative evaluation and reinforce the importance of smoking cessation counseling.

4. Study Design and Setting

This study is designed as a prospective observational cohort study and will be conducted at Gazi Yasargil Training and Research Hospital, Diyarbakir, Turkey. Data collection is planned between February 1, 2025, and August 1, 2026.

5. Participants and Eligibility Criteria

Inclusion Criteria:
- Adults aged 18–60 years
- Undergoing elective abdominal surgery under general anesthesia
- ASA physical status I, II, III

Exclusion Criteria:
- Pregnancy
- Difficult intubation or re-intubation
- Recent upper or lower respiratory tract infection (within the last 30 days)
- Chronic pulmonary conditions (e.g., asthma, COPD, OSA)
- Emergency surgery
- Surgical duration longer than 2 hours
- Morbid obesity (BMI >35)
- Hemoglobin <10 g/dL

Patients will be categorized into two cohorts based on their smoking status:
- Smokers: ≥10 pack-year history
- Nonsmokers: Never smoked or quit ≥1 year ago

6. Sample Size Calculation

Sample size estimation was based on prior findings by Reddy et al., where the PPC rate was 54% in smokers and 16% in nonsmokers. With a power of 90% and a significance level of 5%, the required sample size was calculated to be 62 participants per group. To account for a potential 10% data loss due to dropouts or missing data, the final target sample size was adjusted to 70 participants

7. Data Collection Methods

Demographic data (age, gender, BMI), smoking status, intraoperative variables (FiO2, PEEP, Ppeak, duration of surgery), and postoperative respiratory findings (cough, secretion, wheezing, SpO2) will be recorded using a standardized case report form. Observations will be made at 6 and 24 hours postoperatively.

8. Outcome Measures

Primary Outcome:
- Incidence of PPCs within 24 hours postoperatively

Secondary Outcomes:
- Frequency of suctioning
- VAS score for cough severity at 6 and 24 hours

- Presence of wheezing, laryngospasm, SpO2 <90%
- Need for respiratory physiotherapy
- Length of PACU stay

9. Statistical Analysis Plan

Descriptive statistics will include means and standard deviations for continuous variables (or medians and interquartile ranges, depending on distribution) and frequencies/percentages for categorical variables.

Normality will be assessed with the Shapiro-Wilk test. Between-group comparisons will be made using:
- Independent t-test or Mann-Whitney U test for continuous variables
- Chi-square or Fisher's exact test for categorical variables

Multivariate logistic regression analysis will be used to determine independent predictors of PPCs. Adjusted odds ratios (aORs) with 95% confidence intervals (CIs) will be reported.

Receiver Operating Characteristic (ROC) curve analysis will assess predictive performance of continuous variables like Ppeak or BMI. Area under the curve (AUC), cut-off values, sensitivity and specificity will be provided.

Sensitivity analyses will include subgroup comparisons. A post-hoc power analysis will confirm statistical adequacy based on observed effect sizes.

10. Ethical Considerations

This study was approved by the Clinical Research Ethics Committee of Gazi Yasargil Training and Research Hospital (Approval No: 257, Date: 07.02.2025). All participants will provide written informed consent.

11. Contact Information

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