Official Title: Impact of Oxygen Saturation Levels on Anastomotic Leakage and Postoperative Complications in Colorectal Surgery

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Study Protocol

Aim of the Study

This study aimed to evaluate the effect of postoperative oxygen saturation (SpO_2) levels on anastomotic leakage and postoperative complications in colorectal surgery. Additionally, the study sought to assess the predictive value of oxygen saturation levels for the development of complications and to determine potential cut-off values.

Materials and Methods

This single-center retrospective study included patients who underwent colorectal resection with anastomosis between 2017 and 2021.

Patients were divided into two groups according to the presence or absence of anastomotic leakage. Postoperative oxygen saturation (SpO_2) values during the first four postoperative days were compared between the groups.

In addition, patients who developed postoperative overall complications, severe complications, and mortality were identified, and the relationship between these outcomes and oxygen saturation levels was further analyzed.

Cut-off values of SpO_2 were also investigated for predicting anastomotic leakage and severe postoperative complications.

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1. Study Design

This study was designed as a **retrospective, single-center observational study**.

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2. Study Setting and Period

The study was conducted at a single tertiary care center, *University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital, Department of General Surgery*. Patients who underwent colorectal resection with anastomosis between **January 2017 and January 2021** were evaluated.

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3. Study Population

3.1 Inclusion Criteria

- Patients who underwent elective or emergency colorectal resection with anastomosis during the study period.

3.2 Exclusion Criteria

- Age under 18 years
- Incomplete or insufficient clinical data

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4. Study Groups

Patients were divided into two groups according to the presence of **anastomotic leakage**:

- Anastomotic leakage group
- No anastomotic leakage group

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5. Data Collection

Data were retrospectively obtained from hospital electronic records and patient files. The following variables were recorded:

- Demographic data (age, sex)
- Comorbidity burden (Charlson Comorbidity Index, CCI)
- Body Mass Index (BMI)
- Type of surgery (elective/emergency)
- Duration of surgery
- Length of hospital stay
- Overall post-op complications
- Severe post-op complications
- Mortality
- Oxygen saturation (SpO_2) levels
- Presence of anastomotic leakage

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6. Exposure Assessment (Oxygen Saturation Levels)

Postoperative peripheral oxygen saturation (SpO_2) values during the first **four postoperative days** were analyzed.

SpO_2 measurements were obtained from:

- Bedside monitors in continuously monitored patients
- Routine vital sign recordings in non-monitored patients (minimum four measurements/day)

Mean SpO_2 values were defined as:

- **PO1:** Postoperative Day 1 mean SpO_2
- **PO2:** Postoperative Day 2 mean SpO_2
- **PO3:** Postoperative Day 3 mean SpO_2
- **PO4:** Postoperative Day 4 mean SpO_2
- **POg:** Overall mean SpO_2 (first 4 postoperative days)

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7. Outcomes

Primary Outcome

- Occurrence of anastomotic leakage

Secondary Outcomes

- Overall post-op complications
- Severe post-op complications

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8. Statistical Analysis

Statistical analyses were performed using SPSS (Statistical Package for the Social Sciences; SPSS Inc., Chicago, IL) version 22.0.

Categorical variables were expressed as numbers and percentages (n, %), while continuous variables were presented as mean ± standard deviation (mean ± SD) or median (min–max), as appropriate.

The Chi-square test (Pearson Chi-square) was used for comparisons of categorical variables between groups.

Normality of continuous variables was assessed using the Kolmogorov–Smirnov test.

- Student's t-test was used for normally distributed variables
- Mann–Whitney U test was used for non-normally distributed variables

A p-value < 0.05 was considered statistically significant.

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9. Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki. As a retrospective study, no intervention was performed and no additional patient risk was present. Patient confidentiality was strictly maintained, and all data were anonymized prior to analysis.

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10. Research Questionnaire

None.

Informed Consent Form

We are conducting a study titled **"Impact of Oxygen Saturation Levels on Anastomotic Leakage and Postoperative Complications in Colorectal Surgery"** Anastomotic leakage is defined as the disruption of the newly created anastomosis during surgery, resulting in the leakage of gastrointestinal contents into the abdominal cavity. It is an important clinical condition in colorectal surgery that increases morbidity and mortality, worsens oncological outcomes, and prolongs hospital stay.

Adequate oxygenation of anastomotic tissues plays a critical role in healing. It has been reported that the rate of anastomotic leakage requiring re-operation increases 2.5-fold when oxygen saturation falls below 92%. With this study, we aim to investigate this important relationship.

No identifying personal information will be included in the recorded data or created database.

The study covers the period between January 2017 and January 2021, and approximately 200 patients' data from our clinic will be retrospectively reviewed. No changes, additions, or modifications will be made to your treatment during this process. No interventional or experimental procedures will be performed. There are no anticipated risks or discomforts associated with participation in this study. If there is no expected direct clinical benefit for the participant, this will be clearly explained to the participant.

Participation in this study is entirely voluntary. Participants may refuse to participate or withdraw from the study at any time without any penalty, sanction, or loss of rights. Participant identity records will be kept confidential and will not be disclosed to the public. Even if the study results are published, the identity of participants will remain confidential.

Monitors, auditors, ethics committee members, institutional representatives, and other relevant health authorities may have direct access to the participant's original medical records; however, this information will remain confidential. By signing this informed consent form, the participant or their legal representative agrees to such access.

If new information arises during the study that may affect the participant's willingness to continue participation, the participant or their legal representative will be informed in a timely manner. No compensation or payment will be provided, as no additional responsibility is expected from participants. No new tissue, blood, or body fluid samples will be collected other than imaging and laboratory data stored in hospital archives. For further information regarding the study, rights, or any adverse events, you may contact **Dr. Yasir Musa Kesgin** at **+90 212 414 71 71**, available 24 hours a day.

In situations requiring termination of participation, the participant's involvement will be discontinued.

Declaration

I have read all the explanations in the "Informed Consent Form." I have been informed verbally and in writing about the purpose and content of the study by the physician named below. I voluntarily agree to participate in this study and give permission for my medical data to be used. I understand that my treatment will not be affected if I refuse to participate. I am aware that my participation is entirely voluntary and that I may withdraw from the study at any time with or without reason. I agree to participate in this study of my own free will, without any pressure or coercion.

PARTİCİPANT

RESEARCHER

Yasir Musa Kesgin, M.D.

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