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Title: Evaluation of AI-based Risk Assessment Model in Plastic Surgery
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Document Review Statement:
This document was most recently updated and reviewed by the sole researcher, Williams E. Bukret, MD, EMBA, on July 11, 2024. As there is no human subjects protection review board required for this study, this date reflects the most recent review and update by the principal investigator.

Study Protocol

Introduction
This study protocol outlines the procedures, objectives, and methodologies for the observational study titled "Evaluation of AI-based Risk Assessment Model in Plastic Surgery." The primary aim is to evaluate the clinical utility of an AI-based risk assessment model in predicting and mitigating complications in patients undergoing elective plastic surgery.

Study Objectives

- To evaluate the effectiveness of the AI-based risk assessment model in predicting surgical complications.
- To determine the correlation between various clinical factors (such as BMI, age, and smoking habits) and the AI-generated risk scores.
- To assess the impact of AI-generated recommendations on surgical outcomes and complication rates.

Study Design
This is an observational study with a prospective time perspective. The study involves the collection of clinical data from patients undergoing elective plastic surgery. The AI model analyzes this data to provide personalized risk scores and recommendations.

Participant Eligibility
Inclusion Criteria:

- Individuals aged 18 and older.
- Scheduled to undergo elective plastic surgery.
- Agreement to follow preoperative and postoperative recommendations provided by Dr. Bukret, according to the AI-based risk assessment model.

Exclusion Criteria:

- Individuals below 18 years of age.
- Patients with a history of severe allergic reactions to anesthesia.
- Those unable to provide informed consent.

Study Population Description
Participants are individuals undergoing elective plastic surgery. They will complete an online form collecting data on various clinical factors, such as age, height, weight, smoking habits, and comorbidities. The system calculates the risk score, body mass index (BMI), and Caprini score.

Data Collection
The following data will be collected from each participant:

- Age
- Height and weight (to calculate BMI)
- Smoking habits
- Comorbidities
- Caprini score (calculated by the system)

- Risk group classification (High, Moderate, Low)
- Complications (Hematoma, Seroma, Infection, Dehiscence, Necrosis, DVT/PE, ASIA Syndrome)

Study Procedures

Participants will undergo a risk assessment using the AI model, which evaluates multiple risk factors based on their clinical data and patient history. The model will then generate personalized recommendations, which include:

- Weight management guidance for patients with a BMI greater than 25.1.
- Smoking cessation advice for patients who smoke.
- Blood pressure control recommendations for hypertensive patients.
- Doppler ultrasound screening for deep vein thrombosis (DVT) and varices.
- Nutritional consultations for patients with a BMI of 25.1 or lower.
- Specialist referrals based on comorbidities and psychiatric consultations for Body Dysmorphic Disorder (BDD) screening.

Follow-Up

The follow-up period for this study ranges from 2 to 41 months, with a mean follow-up of 15 months. During this time, data on patient outcomes, including complication rates and patient satisfaction, will be collected and analyzed.

Outcome Measures
Primary Outcome Measure

Title: Incidence of complications within 45 days post-surgery

Description: The primary outcome measure is the incidence of complications (such as hematoma, seroma, infection, etc.) occurring within 45 days after elective plastic surgery. Complications are identified and recorded based on clinical follow-up visits and patient reports.

Conclusion

This study protocol provides a comprehensive overview of the study design, objectives, data collection methods, and statistical analysis plan for the observational study "Evaluation of AI-based Risk Assessment Model in Plastic Surgery." The integration of AI-generated recommendations is expected to enhance preoperative planning and postoperative care, ultimately improving patient safety and satisfaction.

Statistical Analysis Plan (SAP)

Introduction

This Statistical Analysis Plan (SAP) outlines the statistical methods and analyses to be performed for the study titled "Evaluation of AI-based Risk Assessment Model in Plastic Surgery." The primary aim of the study is to assess the clinical utility of an AI-based risk assessment model in identifying and mitigating risk factors associated with complications in patients undergoing elective plastic surgery.

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Primary Outcome Measure

Title: Incidence of complications within 45 days post-surgery

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Statistical Methods

The following statistical methods and formulas will be used for data analysis:

Descriptive Statistics:

- Frequency and percentage of patients in each risk group (High, Moderate, Low)
- Incidence of complications in each risk group

- Relative risk and odds ratio for complications in each risk group

Pearson Correlation:

- Correlation between risk factors (Age, BMI, Smoking habits, etc.) and AI-generated risk scores

python

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```python
stats.pearsonr(corr4['Risk factor'], corr4['BMI'])

stats.pearsonr(corr4['Risk factor'], corr4['Caprini score'])

stats.pearsonr(corr4['Risk factor'], corr4['Age'])

stats.pearsonr(corr4['Risk factor'], corr4['Smoking habit'])

stats.pearsonr(corr4['Risk factor'], corr4['Male'])

stats.pearsonr(corr4['Risk factor'], corr4['Female'])

stats.pearsonr(corr4['Risk factor'], corr4['High blood pressure'])
```

Outcome Analysis:

- Count and percentage of complications in each risk group
- Calculation of relative risk and odds ratio

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```python
Relative Risk = (Incidence in high-risk group) / (Incidence in low-risk group)

Odds Ratio = (Odds of complications in high-risk group) / (Odds of complications in low-risk group)
```

Data Analysis
Data analysis will be performed using Python, and the complete notebook with the analysis code and results is available at the following link: Colab Notebook.

Access Instructions
To request permission to access the individual participant data (IPD) and supporting information, please email drbukret@drbukret.com. Detailed instructions for requesting access can be found at IPD Sharing Instructions.

Conclusion

This SAP provides a detailed plan for the statistical analysis of the study "Evaluation of AI-based Risk Assessment Model in Plastic Surgery." The analysis aims to provide insights into the effectiveness of the AI model in predicting and mitigating surgical complications, ultimately improving patient outcomes and safety.