Clinical study protocol

Project name: Comparison of traditional regression model and AI in predicting prolonged ICU stay after head and neck tumors

Sponsor: Sun Yat-sen Memorial Hospital of Sun Yat-sen University

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Scheme signature confirmation:

一、Abstract of the study protocol

Title: Comparison of traditional regression model and AI to predict prolonged ICU stay after head and neck tumors

Brief description of the study: This experiment is a cohort observational study. By establishing a cohort of patients with head and neck tumors after surgery, we compared the prediction effect of AI and traditional prediction models on whether patients with ICU can be transferred to ICU within 24 hours after head and neck tumors after surgery. First, retrospective analysis of postoperative patients with head and neck tumors, patients' medical records were collected, and the patients were divided into training group and validation group according to 7:3, divided into 2 groups according to whether the ICU stay time was greater than 24 hours, and the prediction model of postoperative ICU stay time of head and neck tumors over 24 hours was established after using LASSO regression to select variables. At the same time, the data was cleaned, the AI was trained, and the efficacy was compared by ROC. After the establishment of prediction model and AI training, the patients included in the cohort were evaluated by prediction model and AI evaluation immediately after transfer to the ICU, which predicted the possibility of transferring out of the ICU within 24 hours.

Study jects: All patients with head and neck tumors

Outcome measures: The patient was transferred out of the ICU

Sample size: Following the principle of 10 times the sample size, the included sample size is more than 10 times of the final variable, and 500 patients are currently expected to be included.

2. Research background (including the introduction of the disease, the treatment status at home and abroad, the significance of the research, etc.)

Head and neck tumor incidence ranks the sixth [1] in the global tumor incidence.

The incidence of head and neck tumors is increasing in China and is expected to reach 3.99 [2] per 100,000 people by 2049. Surgical resection has been identified as the primary treatment for oral cancer [3]. Because of the complex anatomy of the oral region, limited surgical space, and the need for simultaneous flap reconstruction to protect the integrity of the oral and maxillofacial systems, about 80% of patients undergoing oral cancer surgery will be transferred to the intensive care unit (ICU) after the operation, [4].

Previous studies found that prolonged ICU stay was associated with poorer prognosis and quality of life, causing a substantial disease and economic burden of [4]. ICU stay> 24 h implies a higher risk of nosocomial infection [5-7] and worsen the prognosis [8] in oral cancer patients. Previous studies found that ICU admission delayed oral feeding time and negatively correlated with 5-year survival [8,9]. Therefore, it is important to identify oral cancer patients with a long ICU after surgery.

Most patients with head and neck tumors have postoperative ICU stay time between 24 and 72 hours [10-12]. In a retrospective study of the UK National Intensive Care database, the median stay of patients undergoing head and neck cancer surgery was found in the ICU of 24 hours (IQR 18.8-46 hours) [13]. Meanwhile, according to our clinical experience, we believe that the ICU stay time of postoperative head and neck tumor patients should be within 24 hours is reasonable.

Currently, the study of ICU stay time after head and neck cancer surgery has focused on demographic characteristics, surgical methods, blood transfusion and physiological scores of [8,9,14]. Previous studies have evaluated some risk factors associated with prolonged length of stay (LOS). Poor nutritional status and unhealthy lifestyle habits are associated with prolonged ICU stay in [15,16]. Furthermore, surgery-related factors such as intraoperative blood transfusion and flap reconstruction methods were [5,17] associated with LOS in patients undergoing surgery for head and neck tumours.

However, there are few studies on the effect of laboratory results on ICU stay time after head and neck cancer surgery. Consideration of laboratory findings as potential predictors of ICU stay is warranted. These measurements include liver and renal function indicators, electrolyte levels and lactate levels, etc. Developing a predictive model for identifying patients with a prolonged ICU stay (> 24 hours) after head and neck cancer surgery is of great clinical importance. We plan to use the patient's clinical data to build a prediction model and AI prediction model to predict whether the head and neck tumor can be transferred out of the ICU within 24 hours after surgery, compare the efficacy of AI with the traditional prediction model, and subsequently validate his efficacy in a prospective cohort.

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3. Study objective (clear objective)

3.1.1 Main Purpose

Comparing the prediction accuracy of AI and traditional prediction models for ICU stay time after head and neck tumors.

3.1.2 Secondary Purpose

Explore the construction method and influencing factors of ICU stay time prediction model after head and neck cancer surgery.

4. research design

This study is a cohort observational study by establishing a retrospective cohort of patients transferred to ICU for head and neck tumors from January 2022 to December 2023, which is exempt from informed consent. Screen the variables to establish the traditional prediction model and train the AI, and then compare the accuracy of the traditional prediction model and the AI. After the validation on the basis of retrospective study of the traditional model and the prediction of AI for head and neck tumor patients postoperative ICU stay time, prospectively into the head and neck tumor postoperative ICU patients, the patient in the ICU to sign the waste specimen use consent, through prospective studies to verify the AI in ICU stay time prediction superiority.

5. Research protocol and technical route (including the calculation of study sample size, inclusion, exclusion, withdrawal criteria, evaluation indicators and methods of study results, statistical analysis plan, informed consent, ethics, etc.)

Sample size: Following the principle of 10 times the sample size, the included sample size is more than 10 times of the final variable. Currently, 500 retrospective patients and 200 prospective patients are expected to be included.

Selection criteria

Patients after head and neck tumors, older than 18 years.

Exclusion criteria

1 Patients transferred to ICU twice after head and neck tumors

2. Patients with unplanned transfer to the ICU

Evaluation indicators and methods of the results: compare the effectiveness of the model using accuracy or ROC

Statistical analysis plan: data description of statistical analysis, analysis methods of primary / secondary indicators / safety indicators, statistical school positive methods, control of bias, stratification / subgroup / sensitivity analysis, etc

All data were statistically analyzed using SPSS 25.0 and R languages, and P <0.05 was considered statistically significant.

The measurement data conforming to the normal distribution are described by the mean standard deviation ± (x ± s); the measurement data that do not conform to the normal distribution are described by the median (M) and interquartile spacing (P25-P75); the counting data are described by frequency and percentage (%); the lacking measurement data are filled by mean, and the missing counting data is filled by mean.

Comparison of differences between groups: t-test was used for the measurement data meeting the normal distribution, rank sum test for the measurement data, x 2 test, Fisher exact probability method or continuous corrected chi-square test for the counting data.

Informed consent: Exemption from informed consent for retrospective part. Signed informed consent for transfer to ICU.

VI. Safety evaluation (including the definition and assessment of adverse events and serious adverse events)

There is no direct interventional operation in this study, and the risks mainly include possible errors in data collection and management, as well as patient privacy protection issues.

Vii. Data collection and management

All data are retrieved and cleaned after export from the big data system. All data are retrieved by the database software. The relevant data are as follows:

Baseline data:

Patients collected from the electronic medical records of admission baseline data: age, gender, Body Mass Index, body mass index (BMI), past history [including oral cancer treatment (radiotherapy, chemotherapy, immunotherapy), previous basic disease history (hypertension, diabetes history)], personal history (including smoking history, drinking history), family history of oral cancer, tumor site;

Pre-operative indicators:

① Clinical Assessment Scale: Nutritional Risk Screening Scale (Nutritional Risk Screening-2002, NRS-2002) (see Supplementary Table 1);

② Preoperative laboratory examination results: blood routine [white blood cell count (10^9/ L), hemoglobin (g / L), platelets (10^9/ L), neutrophil count (10^9/ L), lymphocyte count (10^9/ L), monocyte cell count (10^9/ L), red blood cell volume (fL), the ratio of neutrophil count to lymphocyte count (Neutrophil-to-Lymphocyte Ratio, NLR), the ratio of lymphocyte count to monocyte count (Lymphocyte-to-Monocyte Ratio, LMR)], Coagulation function [plasma prothrombin time (s), fibrinogen (g / L), activated partial thromboplastin time (s), thrombin time (s), D-dimer (mg/L)], Liver function [glutamate aminotransferase (U / L), glutamate aminotransferase (U / L), albumin (g / L)), Renal function (creatinine (u mol/L)], Blood electrolytes [potassium ion (mmol/L), sodium ion (mmol/L), calcium ion (mmol/L), chloride ion (mmol/L)];

Procedure-related indicators:

Operation duration (h), flap type (none, fibula, femur, pectoralis major), scope of cervical lymph node dissection (none, unilateral, bilateral);

Index of postoperative monitoring:

① Clinical assessment scale: Acute Physiological and Chronic Health Assessment II score (Acute Physiology and Chronic Health Evaluation II, APACHE II), Sequential Organ failure score (Sequential Organ Failure Assessment, SOFA), Caprini venous thrombosis risk score;

② Related indicators of ICU monitoring: time of mechanical ventilation, body temperature [mean body temperature in the first 24h after transfer to ICU (℃), highest body temperature (℃) in the first 24h after transfer to ICU, minimum body temperature (℃)], arterial pressure [mean arterial pressure (mmHg) in the first 24h after transfer to ICU, highest mean arterial pressure (mmHg) in the first 24h after transfer to ICU, lowest mean arterial pressure (mmHg) in the first 24h after transfer to ICU]; ③ First postoperative laboratory examination: blood routine [white blood cell count (10^9/ L), hemoglobin (g / L), platelets (10^9/ L), neutrophil count (10^9/ L), lymphocyte count (10^9/ L), monocyte cell count (10^9/ L), red blood cell volume (fL), NLR, LMR], Coagulation function [plasma prothrombin time (s), fibrinogen (g / L), activated partial thromboplastin time (s), thrombin time (s), D-dimer (mg/L)], Liver function [glutamate aminotransferase (U / L), glutamate transaminotransferase (U / L), albumin (g / L)], Renal function [creatinine (u mol/L)), Blood electrolytes (potassium ion (mmol/L), sodium ion (mmol/L), calcium ion (mmol/L), chloride ion (mmol/L)]; Blood gas analysis [pH, partial pressure of carbon dioxide (kPa), partial pressure of oxygen (kPa), lactic acid (mmol/L)].

八、 Quality management plan (please introduce relevant measures to ensure project quality and progress)

Data processing by special person, in addition, data review by special personnel to determine the authenticity of the data, each data processing steps are retained to ensure the repeatability of the experiment.

IX. Pre-assessment and risk control plan of project risk benefits (Please describe the risks and benefits of the researchers, subjects and the medical institution; if there are risks, please introduce the measures and feasibility of risk control.）

By comparing the ICU stay time of head and neck cancer, it is expected

to improve the efficiency of postoperative management of head and neck cancer patients and reduce the waste of medical resources.

X. References

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