Remifentanil Versus Dexmedetomidine for Post-Cardiac Surgery Patients With Noninvasive Ventilation Intolerance (REDNIVIN)

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Brief summary

The aim of this study is to compare the sedation effects between remifentanil and dexmedetomidine in post-cardiac surgical patients who developed noninvasive ventilation (NIV) intolerance.

Study description

This study is a prospective, observational, cohort study. Data of post-cardiac surgery patients who receives noninvasive ventilation (NIV) in the investigators' cardiac surgical intensive care unit are prospectively collected into a database for further analyzation since January 2018. Tolerance of NIV is estimated by a four-point NIV intolerance score system: A score of 1 indicates a comfortable and relaxed patient tolerating NIV; a score of 2 indicates mild intolerance with some discomfort and occasional grabbing at the NIV mask; a score of 3 indicates moderate intolerance and discomfort with the NIV mask most of the time with frequent grabbing at the mask (sometimes pulling it off); and a score of 4 indicates severe NIV intolerance with agitation or/and an inability to leave the NIV mask in place. Participants who receives re-intubation will be recorded as 4 points. Application of remifentanil or dexmedetomidine will be initiated when a

score of 3 or 4 was recorded, according to the intensivists' preference. Depending on the sedation regime applied, patients with NIV intolerance are divided into two groups: remifentanil group and dexmedetomidine group. The investigators will compare the two groups with the NIV intolerance score at 15min,1, 3, 6, 12, 24, 48, 60 and 72 hours after the initiation of the sedation regime. The investigators will also compare the two groups with clinical outcomes such as NIV failure, tracheotomy rate, in-hospital mortality, ICU length of stay etc.

Inclusion criteria

(1) Adult

(2) Cardiac surgery

(3) NIV intolerance

Exclusion criteria

(1) difficult expectoration;

(2) maternal;

(3) severe hemodynamic instability defined by mean arterial pressure lower than 60 mmHg despite fluid optimization and vasoactive drugs.

NIV support

NIV will be performed via a facial mask (ZS-MZ-A; Shanghai Zhongshan Medical Technology, China) connected to Drager ventilator (Drager, Lubeck, Germany) in pressure support mode (PSV). NIV will be started with fractional inspired oxygen of 100% and level of pressure support of

12 cm H2O. The ventilator settings will be then adjusted according to the patient's vital signs, tolerance, and/or arterial blood gas (ABG) measurements.

Sedation

Remifentanil will be started with 0.05 μg/kg/min, while dexmedetomidine will be started with 0.5 μg/kg/h. The doses will then be adjusted according to the sedation satisfaction (sedation target is to achieve NIV intolerant score 1-2), with the maximum dose to be 0.12 μg/kg/min for remifentanil and 1.0 μg/kg/h for dexmedetomidine.

Statistical plan

Summary statistics are expressed as the mean ± standard deviation, the median and interquartile ranges (25th to 75th percentile), or number and percentage, and compared between groups using the Student's t-test, Wilcoxon rank-sum test, or Fisher's exact test, as appropriate. A percentage stacked area chart of patient status will be constructed after administration of both drugs. The generalized estimating equations approach will be employed to analyze changes in the mitigation rate over time between the two groups. Statistical analysis will be performed using R, version 3.6.0 (R Foundation for Statistical Computing, Vienna, Austria)

Outcomes measures

The primary outcome of this study is NIV failure defined as reintubation or death in this 72-hour course of study between the two groups. The

secondary outcome is rate of mitigation defined by patients who is relieved from the initial NIV intolerant status.