Conservative versus Liberal Oxygenation Targets in Intensive Care Unit Patients: A Multicentre Randomized Clinical Trial

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Background

Supplemental oxygen is widely administered to intensive care unit (ICU) patients, but appropriate oxygenation targets remain unclear. Aim of this study was to determine whether a low-oxygenation target improves 28-days survival compared to a high-oxygenation target.

Methods

This randomized multicenter equivalence trial included mechanically ventilated ICU patients with an expected ventilation duration of at least 24 hours who were randomized 1:1 to a low-oxygenation (PaO_2 55-80 mmHg or SpO_2 91-94%) or high-oxygenation (PaO_2 110-150 mmHg or SpO_2 96-100%) target until ICU discharge or 28 days after randomization, whichever was first. This trial was conducted in 1 ICU in Italy and 8 ICUs in the Netherlands. Primary outcome was 28-day mortality. Clinicians were not blinded but data analysts remained blinded. The study was stopped prematurely due to the COVID-19 pandemic when 664 of the planned 1512 patients were included.

Results

Between November 2018 and November 2021, a total of 664 patients were included in the trial; 335 in the low-oxygenation group and 329 in the high-oxygenation group. The median achieved PaO_2 was 75 mmHg [IQR, 70-83] and 115 mmHg [IQR 100-129], in the low- and high-oxygenation group, respectively. At day 28, 129 (38.5%)and 114 (34.7%) patients had died in the low- and high-oxygenation group (Figure 1), respectively (Risk Ratio 1.11, 95% Confidence Interval 0.9-1.4, P=0.30). At least 1 SAE was reported in 12 (3.6%) and 17 (5.2%) patients in the low- and high-oxygenation group, respectively.

Conclusion

Among mechanically ventilated ICU patients with an expected mechanical ventilation duration of at least 24 hours, using a low-oxygenation strategy did not result in a reduction of 28-day mortality compared to a high-oxygenation strategy.



No. at risk

High oxygenation group Low oxygenation group 264 238 227 335 216