Non-invasive ventilation versus high-flow nasal cannula oxygen therapy with apnoeic oxygenation for preoxygenation before intubation of patients with acute hypoxaemic respiratory failure: a randomised, multicentre, open-label trial

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Summary

Background Non-invasive ventilation has never been compared with high-flow oxygen to determine whether it reduces the risk of severe hypoxaemia during intubation. We aimed to determine if preoxygenation with non-invasive ventilation was more efficient than high-flow oxygen in reducing the risk of severe hypoxaemia during intubation.

Methods The FLORALI-2 multicentre, open-label trial was done in 28 intensive care units in France. Adult patients undergoing tracheal intubation for acute hypoxaemic respiratory failure (a partial pressure of arterial oxygen [PaO_2] to fraction of inspired oxygen [FiO_2] ratio of ≤300 mm Hg) were randomly assigned (1:1; block size, four participants) to non-invasive ventilation or high-flow oxygen during preoxygenation, with stratification by PaO_2/FiO_2 ratio (≤200 mm Hg *vs* >200 mm Hg). Key exclusion criteria were intubation for cardiac arrest, altered consciousness (defined as a Glasgow coma score of less than eight points), other contraindications to non-invasive ventilation (recent laryngeal, oesophageal, or gastric surgery, and substantial facial fractures), pulse oximetry not available, pregnant or breastfeeding women, and refusal to participate. The primary outcome was the occurrence of severe hypoxaemia (pulse oximetry <80%) during the procedure, assessed in the intention-to-treat population. This trial is registered with ClinicalTrials.gov, number NCT02668458.

Findings Between April 15, 2016, and Jan 8, 2017, 2079 patients were intubated in the 28 participating units, and 322 were enrolled. We excluded five patients with no recorded data, two who withdrew consent or were under legal protection, one who was not intubated, and one who had a cardiac arrest. Of the 313 patients included in the intention-to-treat analysis, 142 were assigned to non-invasive ventilation and 171 to high-flow oxygen therapy. Severe hypoxaemia occurred in 33 (23%) of 142 patients after preoxygenation with non-invasive ventilation and 47 (27%) of 171 with high-flow oxygen (absolute difference −4·2%, 95% CI −13·7 to 5·5; p=0·39). In the 242 patients with moderate-to-severe hypoxaemia (PaO_2/FiO_2 ≤200 mm Hg), severe hypoxaemia occurred less frequently after preoxygenation with non-invasive ventilation than with high-flow oxygen (28 [24%] of 117 patients *vs* 44 [35%] of 125; adjusted odds ratio 0·56, 0·32 to 0·99, p=0·0459). Serious adverse events did not differ between treatment groups, with the most common immediate complications being systolic arterial hypotension (70 [49%] patients in the non-invasive ventilation group *vs* 86 [50%] patients in the high-flow oxygen group) and chest infiltrate on x-ray (28 [20%] *vs* 33 [19%]), and the most common late complications being death at day 28 (53 [37%] *vs* 58 [34%]) and ventilator-associated pneumonia during ICU stay (31 [22%] *vs* 35 [20%]).

Interpretation In patients with acute hypoxaemic respiratory failure, preoxygenation with non-invasive ventilation or high-flow oxygen therapy did not change the risk of severe hypoxaemia. Future research should explore the effect of preoxygenation method in patients with moderate-to-severe hypoxaemia at baseline.

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Introduction

Tracheal intubation is one of the most common procedures done in intensive care units (ICUs).[1] Unlike the operating room, intubation procedures in ICUs have a high risk of life-threatening complications, including severe hypoxaemia, neurological or cardiac ischaemia,