ICU MANAGEMENT & PRACTICE

#ISICEM19: Prof. Jean-Pierre Frat presents results of the FLORALI-2 trial

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Professor Jean-Pierre Frat presented the results of the FLORALI-2 trial at the 39th International Symposium on Intensive Care and Emergency Medicine. The study, '*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*' was just published in The Lancet.

Prof. Frat explained that the intubation procedure is at a higher risk of complication particularly the risk of severe hypoxaemia that can occur in 20 to 25% of cases. The ultimate complication is cardiac arrest that can occur in 3% of patients undergoing intubation. The aim of pre-oxygenation is to improve arterial pressure of oxygen and to secure the intubation procedure.

Non-invasive ventilation and high-flow nasal cannula oxygen therapy are oxygenation devices that provide a higher fraction of inspired oxygen (FiO_2) as compared to standard oxygen. Some of the key advantages of high-flow oxygen include its ability to deliver continuous high gas flow up to 70L/min and to maintain oxygenation during the apnoeic phase of intubation after anaesthetic induction. Compared with standard oxygen, high-flow oxygen has shown a decreased incidence of severe hypoxaemia. However, to date, non-invasive ventilation has not been compared with high-flow oxygen to determine whether it reduces the risk of severe hypoxaemia during intubation.

The FLORALI-2 multicentre trial involved patients admitted to the ICU with an acute hypoxaemic respiratory failure and undergoing tracheal intubation. The objective of the study was to determine whether non-invasive ventilation could be associated with a lower rate of hypoxaemia compared to high-flow oxygen therapy.

The study included patients from 28 intensive care units in France and lasted one year, and not two years, as initially expected. 313 patients were enrolled in the study out of which 142 patients were assigned to non-invasive ventilation, and 171 patients were assigned to high-flow oxygen therapy. All patients were admitted to the ICU, required intubation and had acute hypoxemic respiratory failure. In the non-invasive ventilation group, preoxygenation was delivered via a face mask connected to the ICU ventilator while in the high-flow oxygen group, preoxygenation was delivered by applying oxygen continuously.

The primary outcome of the study, as outlined by Prof. Frat was the occurrence of an episode of severe hypoxaemia, which is defined as a decrease in pulse oximetry below 80% for at least 5 seconds. Secondary outcomes were the value of pulse oximetry at the end of preoxygenation and the lowest value during the intubation procedure. All participating centres were provided with a dedicated portable pulse oximetry monitor and single-use digital sensors.

The analysis was conducted in the intention-to-treat population and in pre-specified subgroups determined by the stratification variable, moderate-to-severe hypoxaemic patients with a PaO_2/FiO_2 ratio equal to or below 200mm Hg versus mild hypoxaemic patients with PaO_2/FiO_2 ratio above 200 mm Hg.

There was no difference between the two techniques in the occurrence of severe hypoxaemia during the intubation procedure. 23% of 142

patients had severe hypoxaemia after preoxygenation in the NIV group and 27% of 171 patients in the high-flow oxygen group. However, there was a significant interaction between PaO_2/FiO_2 ratio at enrolment and treatment group with respect to the primary outcome. In patients with moderate-to-severe hypoxaemia, severe hypoxaemia occurred in 28% of patients in the NIV group and in 35% of patients in the high-flow oxygen group. Based on sensitivity analysis, the risk of severe hypoxaemia was lower with NIV as compared to high-flow oxygen. In patients with mild hypoxaemia, severe hypoxaemia did not differ between the two groups.

No differences were observed in pulse oximetry values, duration of laryngoscopy or procedure of tracheal intubation between the two groups. In moderate-to-severe hypoxaemic patients, the lowest pulse oximetry during intubation was higher in the NIV group compared to the high-flow group. Pulse oximetry at the end of preoxygenation was higher in the NIV group compared to the high-flow oxygen group. No difference was observed between the two groups in patients with mild hypoxaemia.

Overall, in patients with acute hypoxaemic respiratory failure, non-invasive ventilation, when compared with high-flow oxygen therapy, did not change the risk of severe hypoxaemia during intubation and also did not have any major impact on the occurrence of late complications. However, secondary analyses suggest a possible benefit of non-invasive ventilation in patients with moderate to severe hypoxaemia.

Source: Prof. Frat's presentation, The Lancet
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