

High-flow nasal oxygen vs noninvasive positive airway pressure in hypoxemic patients after cardiothoracic surgery. A randomized clinical trial.

AIM:

To investigate the noninferiority of nasal high-flow (NHF) oxygen therapy compared with bi-level positive airway pressure (BPAP) for preventing or resolving hypoxemic respiratory failure after cardiothoracic surgery.

METHOD:

This six-center, prospective, randomized, noninferiority trial included patients who had undergone cardiothoracic surgery and had met one of three criteria: failed a spontaneous breathing trial, had pre-existing risk factor(s) for postextubation acute respiratory failure, or had failed extubation after a successful spontaneous breathing trial. Patients were randomized in a 1:1 ratio to receive humidified NHF oxygen therapy (Optiflow™; Fisher & Paykel Healthcare) via a nasal cannula or BPAP via a full face mask delivered with either a ventilator specifically designed for BPAP (BiPAP® Vision®; Phillips Respironics) or an intensive care unit (ICU) ventilator with added positive end-expiratory pressure (PEEP, Dräger Evita® XL or 4; Dräger Medical SAS; or Monnal T75™; Air Liquide). Heat and moisture exchange filters were used during BPAP. The target oxygen saturation (SaO₂) for both arms was set at 92%–98%. The initial NHF flow rate was 50 L/min with an initial fraction of inspired oxygen (FiO₂) of 50%, which was then adjusted to maintain the target saturations. BPAP was initiated at 8 cmH₂O of pressure to achieve an exhaled tidal volume of 8 mL/kg and a respiratory rate of <25 breaths/minute. PEEP was initially set to 4 cmH₂O and FiO₂ of 0.5, and then adjusted to maintain the target SaO₂. BPAP was initially used for 2 hours, and then for ~1 hour every 4 hours or as needed to achieve clinical respiratory stability. Between sessions, patients in the BPAP group received standard oxygen therapy via standard nasal cannula to maintain SaO₂. Allocated treatment could be discontinued when SaO₂ was ≥95% at 6 L/min, PaO₂:FiO₂ ratio was ≥300 in NHF recipients, or when treatment was needed for <4 h/day in the BPAP group. Success was defined as absence of ventilatory support

for 72 hours. The primary endpoint was treatment failure (reintubation for mechanical ventilation, switch to other study treatment, or premature discontinuation of study treatment). Secondary outcomes included: ICU stay, changes in respiratory variables from baseline, at 1 hour, and 6–12 hours of treatment, dyspnea score, comfort score, skin breakdown score, and the rate of complications. *A priori*, the lower boundary of the 95% confidence interval was established as <9% in order for NHF oxygen therapy to be regarded as being noninferior to BPAP.

RESULTS:

A total of 830 patients were included in the study, 414 in the NHF group and 416 in the BPAP group. In both treatment groups, the most common form of cardiothoracic surgery was cardiopulmonary bypass (~80%).

NHF oxygen therapy was noninferior to BPAP for the primary study endpoint. This and other main study results are presented in the table. There were no significant differences between the NHF oxygen therapy and BPAP groups with respect to arterial carbon dioxide level (PaCO₂), pH, dyspnea score, comfort score, the number of nurse interventions per patient, ICU stay, or the rate of complications.

| VARIABLE | BIPAP (N=416) | NHF OXYGEN THERAPY (N=414) | RISK DIFFERENCE (%) (95% CI) |
|---|------------------------------|----------------------------------|-------------------------------|
| % Patients (95% CI) | | | |
| TREATMENT FAILURE | | | |
| Overall | 21.9 (18.0 - 26.2) | 21.0 (17.2 - 25.3) | 0.9 (-4.9 - 6.6) ^a |
| Patients with PaO ₂ :FiO ₂ ratio <200 | 24.8 (19.5 - 30.9) | 27.5 (22.0 - 33.7) ^b | |
| Reintubation | 13.7 | 14.0 ^c | |
| Switch to other treatment | 7.9 (5.6 - 11.0) | 10.8 (8.5 - 14.9) ^d | |
| Premature discontinuation | 3.6 (2.1 - 6.0) | 1.4 (0.6 - 3.3) ^e | |
| ICU mortality | 5.5 (3.6 - 8.3) | 6.8 (4.6 - 9.7) ^f | |
| Secondary endpoints [mean (95% CI)] | | | |
| PaO ₂ :FiO ₂ | | | |
| Baseline | 203 (195 - 212) | 196 (187 - 204) | |
| 1 hour | 221 (213 - 230) ^g | 184 (177 - 192) ^{hi} | |
| 6-12 hours | 261 (248 - 274) ^j | 198 (187 - 208) ^{jk} | |
| RESPIRATORY RATE, BREATHS/MIN | | | |
| Baseline | 23.3 (22.6 - 24.0) | 22.8 (22.1 - 23.5) | |
| 1 hour | 23.0 (22.3 - 23.7) | 21.0 (20.4 - 21.7) ^{gk} | |
| 6-12 hours | 22.5 (21.9 - 23.1) | 21.6 (20.9 - 22.2) ^l | |
| FiO ₂ | | | |
| Baseline | 0.47 (0.45 - 0.49) | 0.49 (0.47 - 0.51) | |
| 1 hour | 0.55 (0.53 - 0.57) | 0.60 (0.59 - 0.62) ^k | |
| 6-12 hours | 0.53 (0.51 - 0.56) | 0.58 (0.57 - 0.60) ^k | |

^ap=0.003; ^bp=0.50; ^cp=0.99; ^dp=0.15; ^ep=0.04; ^fp=0.66; ^gp<0.001 vs baseline; ^hp=0.004 vs baseline; ⁱp<0.01; ^jp<0.001 vs 1 hour; ^kp<0.001; ^lp=0.16
BPAP, bilevel positive airway pressure; CI, confidence interval; FiO₂, fraction of inspired oxygen; ICU, intensive care unit; NHF, nasal high flow; PaO₂, partial pressure of arterial oxygen.

CONCLUSION:

NHF oxygen therapy was noninferior to BPAP for the treatment of patients with, or at risk of, acute respiratory failure after cardiothoracic surgery.

KEY POINTS:

- In patients with, or at risk of, acute hypoxemic respiratory failure after cardiothoracic surgery, the rate of treatment failure in recipients of NHF oxygen therapy was noninferior to those treated with BPAP.
- NHF oxygen therapy appears to be an appropriate therapy for patients with, or at risk of, acute hypoxemic respiratory failure after cardiothoracic surgery.

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