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Title **A Multicentre Randomized Controlled Trial of The Use of Continuous Positive Airway Pressure and Non-Invasive Positive Pressure Ventilation in the Early Treatment of Patients Presenting to the Emergency Department with Severe Acute Cardiogenic Pulmonary Oedema: The 3CPO Trial**

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Aim

To determine whether noninvasive ventilation (NIV) reduces mortality and whether outcomes differ substantially by treatment modality ie, continuous positive airway pressure (CPAP) or noninvasive positive pressure ventilation (NIPPV).

Conclusions and results

Noninvasive ventilation, ie, CPAP or NIPPV, appears to have benefits in the immediate treatment of patients with severe acute cardiogenic pulmonary edema and may reduce mortality.

Specifically we aimed to: (1) assess the clinical effectiveness of NIV in addition to standard therapy against standard therapy alone in early management of severe acute cardiogenic pulmonary edema; (2) assess whether the effectiveness of CPAP and NIPPV differ in the early management of acute cardiogenic pulmonary edema; (3) evaluate the safety of these interventions; (4) assess quality of life and patient satisfaction after treatment with NIV compared to standard therapy alone; and (5) assess the incremental cost effectiveness of NIV versus standard therapy from a health and social care perspective, in terms of cost per quality-adjusted life-year gained.

1069 patients (78±10 years; 43% male) were recruited to standard oxygen therapy (n=367), CPAP (n=346; 10±4 cmH,O) or NIPPV (n=356; 14±5/7±2 cmH,O). No difference was found between 7-day mortality for standard oxygen therapy (9.8%) and NIV (9.5%; p=0.87). The combined endpoint of 7-day death or intubation rate was similar irrespective of NIV modality (11.7% versus 11.1%, CPAP versus NIPPV respectively; p=0.81). In comparison to standard oxygen therapy, NIV was associated with greater reductions (treatment difference, 95% confidence intervals) in breathlessness (visual analogue score 0.7, 0.2-1.3; p=0.008) and heart rate (4/min, 1-6; p=0.004) and improvement in acidosis (pH 0.03, 0.02-0.04; p<0.001) and hypercapnia (0.7 kPa, 0.4-0.9; p<0.001) at 1 hour. There were no treatment-related adverse events or any differences in other secondary outcomes, eg, myocardial infarction rate, length of hospital stay, critical care admission rate, and requirement for endotracheal intubation. Economic evaluation showed that mean costs and QALYs up to 6 months were 3023 pounds sterling (GBP) and 0.202 for standard therapy, GBP 3224 and 0.213 for CPAP, and GBP 3208 and 0.210 for NIPPV. Modeling of lifetime costs and QALYs produced values of GBP 15 764 and 1.597 for standard therapy, GBP 17 525 and 1.841 for CPAP, and GBP 17 021 and 1.707 for NIPPV. These results suggest that both CPAP and NIPPV accrue more QALYs, but at higher costs than standard therapy. However, the estimates are subject to substantial uncertainty.

Recommendations

See Executive Summary link at www.hta.ac.uk/project/1338.asp.

Methods

See Executive Summary link at www.hta.ac.uk/project/1338.asp.

Further research/reviews required

See Executive Summary link at www.hta.ac.uk/project/1338.asp.

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