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| Reviewer Name: | Answer Key | | |
| Review Date: | 05/21/2020 | | |
| PMID: | 32160661 (Barrot) | | |
| Journal Article Title: | Liberal or Conservative Oxygen Therapy for Acute Respiratory Distress Syndrome. (2020) | | |
| Clinical Question: | Among patients with acute respiratory distress syndrome (ARDS) does conservative vs. liberal oxygen therapy improve all-cause mortality at 28 days. | | |
| Clinical Question Type: |  | Treatment | |
|  | Diagnosis | |
|  | Prognosis | |
|  | Systematic Review/Meta-Analysis | |
| Study Design: | Prospective, randomized open label study. | | |
| Sample Size and Power: | 850 patients  90% between group a priori power analysis based on an expected effect size of 9% from published results of two prospective trials  396 were eligible, 191 were excluded: 205 randomized  Trial stopped by the DSMB for increased adverse risk in the conservative oxygenation group. | | |
| Validity Assessment: | Criteria | | Assessment |
| Randomization | | Computer randomization stratified by center, age, and severity of respiratory failure |
| Blinding | | Open Label (not blinded based on impossibility of making treatment assignment) |
| Baseline Group Comparability | | Groups were comparable based on review of Table 1 |
| Follow up | | Survival curves indicate patients were followed up to 90 days after surgery. Four patients our of 205 randomized were excluded from analysis (2%). |
| Intent to Treat | | Analyses were performed in the intention to treat population, defined as all patients who underwent randomization minus exclusions. |
| Validity Summary: | After examining randomization, baseline group comparability, follow up and intent to treat, this study was determined valid for informing practice. While the study was not blinded, the open label nature of this experiment did not likely change study outcomes. | | |
| Clinical Importance of Findings: | Treatment:  Mortality at 28 days Conservative Oxygen (34 of 99) 34%, Liberal Oxygen (27 of 102) 27%.  Mortality at 90 days Conservative Oxygen 44%, Liberal Oxygen 30%.  Ventilator associated pneumonia: Conservative Oxygen 17%, Liberal Oxygen 21%.  Harm: Mesentric ischemic events Conservative Oxygen 5, Liberal Oxygen 0. Other outcomes were not significantly difference between the two groups. | | |
| Clinical Summary: | Conservative oxygenation during the first seven days of mechanical ventilation did not reduce mortality at 28 days as expected. Increased mortality at 90 days and increased risk of mesenteric ischemia was observed in the conservative oxygenation group. | | |
| Other Comments |  | | |