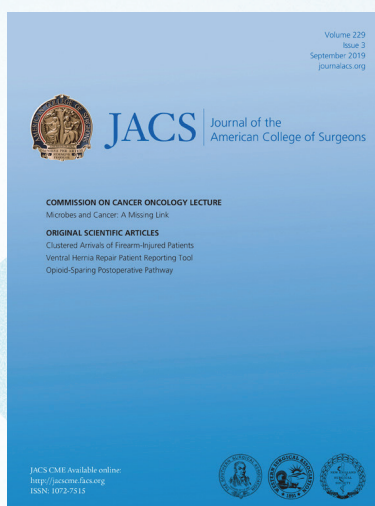


Clinical Study Summary: HUYNH, ET AL. STUDY

EFFICACY OF OSCILLATION AND LUNG EXPANSION IN REDUCING POSTOPERATIVE PULMONARY COMPLICATION¹

Oscillation and Lung Expansion (OLE) therapy was delivered with the **MetaNeb** System, combining Continuous Positive Expiratory Pressure (CPEP) and Continuous High Frequency Oscillation (CHFO).

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This data, published in the August 2019 issue of the *Journal of the American College of Surgeons (JACS)*, suggests that OLE may contribute significantly to greater value-based quality care for these patients.

OVERVIEW

New research shows that an aggressive pulmonary treatment after surgery known as oscillation and lung expansion (OLE) reduced the rate of postoperative pulmonary complications (PPCs) in high-risk patients. Such complications (PPCs) may cause high morbidity, mortality, and healthcare expenditures.

STUDY DESIGN

This was a 419 patient, non-randomized pre-post intervention study. Three academic facilities (Hospital of the University of Pennsylvania, Lahey Hospital and Medical Center, Carolinas Medical Center) which had not previously used OLE therapy in this population, conducted the study in patients undergoing open thoracic, aortic, or upper abdominal surgery.

Stage I: Develop Baseline

For the retrospective cohort, CPT, ICD 9 and 10 codes for thoracic, upper abdominal and aortic procedures were queried. Patients (210) were then randomly selected based on pre-defined entry criteria. This group provided the control group for comparison to the Stage II practice change cohort.

Stage II: Implement Solution

Stage II began after implementation of a practice change. Eligible patients (209) received OLE therapy with the **MetaNeb** System in addition to standard care. Demographic, clinical and outcome data for patients were collected. Outcomes were tracked for each day from postsurgical hospital admission (PSHA) through post-surgery day seven.

High-risk study participant entry criteria

- Thoracic, aortic and upper abdominal procedures
- Open surgical procedures
- ASA class ≥ 3 OR ASA class 2 AND one or more of the following:
 - Current smoker or smoking history (past 6 months)
 - History of COPD
 - Documented obesity and/or BMI ≥ 30 kg/m²
 - Age ≥ 75 years

PPC defined

A significant PPC was defined as occurrence of one or more of the following within seven days of the PSHA:

- Prolonged (>24 hours from the PSHA) invasive mechanical ventilation
- Diagnosis of pneumonia
- Readmission to the ICU
- Prolonged high-level respiratory support
- Requirement for non-invasive ventilation or CPAP above patient's baseline

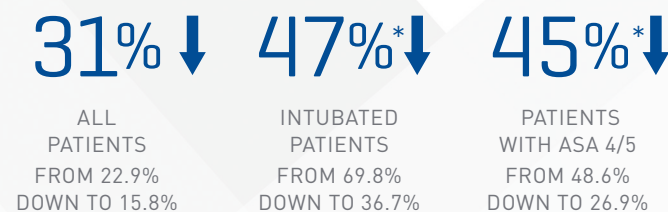
OLE therapy treatment regimen

Intubated patients received CHFO six times a day. Non-intubated patients received therapy treatment four times a day, alternating between CHFO and CPEP

- Treatment delivered for 10 minutes, minimum of 48 hours
- 85% of patients received treatment in the first 6 hours
- 76% of patients received ≥ 4 treatments in the first 40 hours

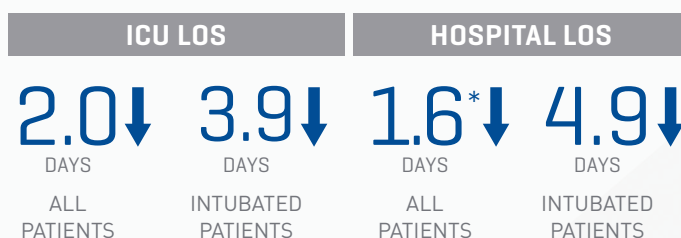
PRIMARY OUTCOMES

Reduction of postoperative pulmonary complications

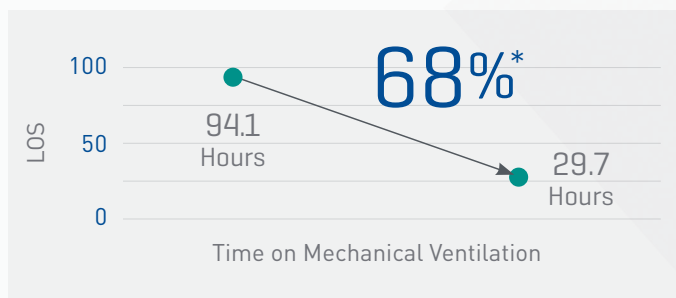


SECONDARY OUTCOMES

Reduction in ICU and hospital length of stay (LOS)



Reduction of average time on the ventilator



*Statistically significant

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References

1. Huynh TT, Liesching TN, Cereda M, Lei Y, Frazer MJ, Nahouraii MR, Diette GB, Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication, *JACS* [2019].

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