

Aerosol Delivery & COPD Readmissions

Proper aerosol therapy adherence for COPD patients can help prevent and reduce 30-day readmissions rates for hospitals, but compliance can rely on finding the right technology.



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In May 2013, CMS proposed to add COPD-related hospitalizations to the CMS Hospital Readmission Reduction Program; therefore, hospitals with high readmission rates will receive financial penalties if the hospital-specific readmission rate exceeds a higher-than-expected readmission rate. The primary aim of the study is to determine if 30-day readmission rates for COPD patients can be decreased by using a handheld vibrating mesh nebulizer.

Although there are multifaceted causes for COPD-related readmissions, patient noncompliance is likely to be a contributory factor in a patient's risk for readmission.

A mesh nebulizer was selected as the study device, because the device's design may increase patients' medication compliance associated with the use of inhaled medications.¹ Compared to other jet nebulizer and compressor systems, the mesh nebulizer is a small, compact handheld nebulizer that is battery-powered and does not require any nebulizer tubing to operate.

METHODOLOGY

Based on the healthcare provider's assessment, eligible subjects were enrolled into the study and received the study device if the subject had an initial primary or secondary diagnosis of COPD upon admission. Subjects continued to use the study device with prescribed medications while at the hospital and 30 days after discharge from the hospital.

PRIMARY OBJECTIVE

The primary objective of this study was to evaluate the effectiveness of a mesh nebulizer in the reduction of 30-day COPD readmission rates for patients admitted to a hospital with a diagnosis of COPD.

SECONDARY OBJECTIVE

The secondary objectives of this study were to evaluate:

- Frequency of use of mesh nebulizer;
- Patient compliance with use of mesh nebulizer;
- Patient ratings of ease of use and satisfaction; and
- Patient ratings of ease of use and satisfaction compared to other inhalation devices.

INCLUSION CRITERIA:

1. Provide signed, written consent prior to participating in any study-related procedures.
2. Willing and able to follow instructions and able to be present for all required study visits for the duration of the study.
3. Index admission for a primary or secondary diagnosis of COPD or index admission for a primary or secondary diagnosis of respiratory failure with a diagnosis of COPD.

EXCLUSION CRITERIA:

1. Patients who refuse to participate.
2. Patients with known active tuberculosis.
3. Patients with a history of life-threatening pulmonary obstruction, or a history of cystic fibrosis..
4. Participation in any study of an investigational topical or systemic new drug or device within 30 days prior to study start/randomization.
5. Patients who have already been enrolled for this study.

TREATMENT PHASE

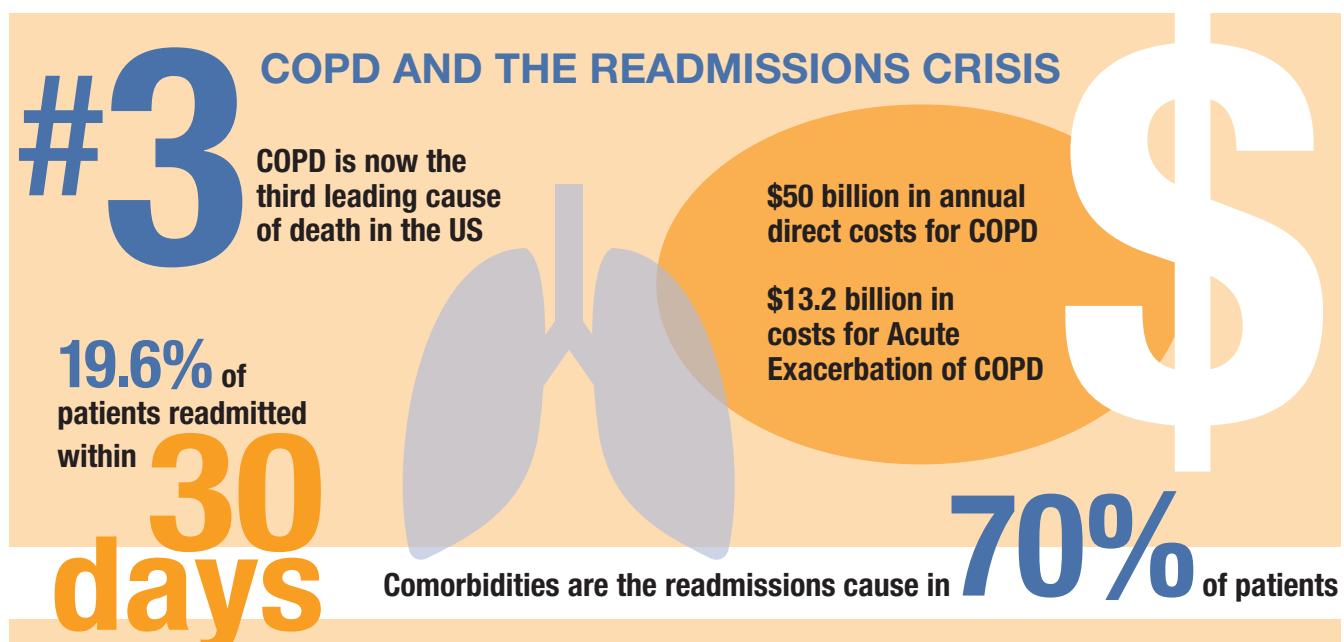
The treatment groups were as follows:

1. *Group One: Pre-intervention rural healthcare hospital system group (Control).* Data from this group was collected on a retrospective basis by the hospital personnel (20.16%). The data captures readmissions for patients with an index admission for a primary diagnosis of COPD from September 2014 to February 2015.
2. *Group Two: Pre-intervention CMS group (Control).* Data from this group was collected on a retrospective basis from the most recent CMS readmission report.² In June 2012 – June 2013, the median risk-standardized readmission rate was 20.0% for COPD patients across a sample of 2,875 hospitals. The data capture readmissions for patients with an index admission for a primary diagnosis of COPD and patients with an index admission for a primary diagnosis of respiratory failure and secondary diagnosis of COPD.
3. *Group Three: Post-intervention rural regional healthcare system group (Active treatment).*

CRITERIA FOR EVALUATION:

Efficacy Endpoints: The study aimed to compare the post-intervention 30-day COPD readmission rate for subjects in the mesh nebulizer group and the pre-intervention 30-day COPD readmission rates for the hospital and CMS:

- Difference in mean 30-day COPD readmission rate for subjects with index admissions of primary diagnosis of COPD in the mesh nebulizer group compared to hospital's pre-intervention 30-day COPD readmission (20.16%)
- Difference in mean 30-day COPD readmission rate for subjects with index admissions of primary diagnosis of COPD and subjects with index admissions of primary



diagnosis of respiratory failure with secondary diagnosis of COPD in the mesh nebulizer group compared to the CMS national 30-day COPD readmission rate ($\approx 20.0\%$).

RESULTS

A total of 102 patients were enrolled into the study based on the inclusion criteria. Of the patients who were enrolled, six died by the end of the study (5.8% mortality rate) and by the completion of the study 12 were readmitted for COPD (11.76%). Results showed a 6.05% reduction in 30-day readmissions for the treatment group (Group Three, 11.76%) compared to the hospital's previous readmissions rate (Group One, 17.81%). Furthermore, compared to the national CMS average readmissions rate there was an 8.33% decline in readmissions for the treatment group. Of the secondary objectives, patients were surveyed and asked to rate their satisfaction on a 1-to-5 scale with 1 being the lowest rating and 5 the highest rating. Notably, patient scores were 4.5 or higher for all four survey questions, which centered on satisfaction with the vibrating mesh nebulizer, ease of use, and comparisons to other inhalation devices. (See Table 1.)

DISCUSSION

Although all department respiratory care practitioners (RCPs) were educated and participated in reinforcing proper use and technique using the device, a total of three RCPs received training for the study and were active participants in patient enrollment and education.

We received many heartwarming stories from the patient participants, but one story stands out: One patient worked as a long-haul truck driver and was newly diagnosed with COPD. This patient had suffered an exacerbation while driving his truck and

Table 1.

PATIENT SATISFACTION SURVEY	AVERAGE RATING
• How would you describe your satisfaction with the mesh nebulizer?	4.5
• How would you describe your satisfaction with the mesh nebulizer compared to other inhalation devices that you have used?	4.5
• How would you describe the ease of use of the mesh nebulizer?	4.68
• How would you describe the ease of use of the mesh nebulizer compared to other inhalation devices you have used?	4.6

almost died trying to get to an emergency department. During his interview, he expressed many questions and concerns regarding his new diagnosis. He was also very uneasy about the thought of returning to truck driving and having another episode; however, truck driving was the only employment he had ever held and his options were limited. When the mesh nebulizer and its advantages were explained to him, he cried. This nebulizer offered him not only peace of mind regarding his health but also his livelihood. He was incredibly thankful to have the opportunity to participate in the study. In addition, during his two-week and four-week follow up phone calls he expressed great satisfaction with the nebulizer and had been compliant with his treatment plan and was back driving his truck. RT

COMMUNITY FACTORS DRIVE HOSPITAL READMISSIONS IN RURAL MISSISSIPPI

How much do community factors drive 30-day readmission rates, the yardstick that Medicare has used since 2013 to gauge whether patients with heart failure or a heart attack get adequate follow-up care? In the Mississippi Delta, one of the country's poorest areas, community factors matter a lot—so much so that once they are accounted for, readmissions here were not much different from those in the rest of the country for heart failure and were about the same for pneumonia and heart attacks (acute myocardial infarction), according to a new study. To conduct the study, they examined data from 2013-2016 for counties that fall under the Mississippi Delta Regional Authority, in parts of eight states: Alabama, Arkansas, Illinois, Kentucky, Louisiana, Mississippi, Missouri, and Tennessee. The researchers compared 30-day readmission ratios for hospitals in the Delta region, the remaining counties of the eight Delta states, and the rest of the nation.

They found that when they did not control for hospital and community factors, Delta region and state hospitals had higher readmission ratios for pneumonia, heart failure, and heart attacks. But when they controlled for hospital and community factors, the significant difference in readmission ratios for pneumonia and heart attack disappeared, and the difference for heart failure was much less pronounced. Factors linked to higher readmission ratios for pneumonia and heart failure were whether a patient was treated in a major teaching hospital, which tend to take the sickest patients, and the percentage of the community that is African American. Curiously, high poverty was associated with lower readmissions for heart attacks, but the researchers noted that mortality rates for this condition are very high if patients cannot access treatment in a timely manner.

The authors of the Mississippi Delta study called for revisions to the HRRP, such as including improvement from past performance in penalty calculations and adding community characteristics in risk adjustment models. "This would likely reduce the unintended consequences of HRRP that may, with reductions in Medicare reimbursement, threaten the healthcare delivery system in the Mississippi Delta region and other similarly underserved areas," they wrote. RT



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