Intravenous (IV) antibiotic use and potential health care cost savings in patients with Cystic Fibrosis (CF) who initiate Trikafta

A collaboration between University of Minnesota, University of Minnesota Physicians and Fairview Health Services..

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BACKGROUND

- Cystic fibrosis (CF) is a life-shortening autosomal recessive disease affecting more than 30,000 people in the United States, with approximately 1,000 new cases each year.[1] The Cystic fibrosis airway is particularly susceptible to *Pseudomonas aeruginosa*. The prevalence of *Pseudomonas aeruginosa colonization* increases with age, and it's estimated that more than 60% of adults with cystic fibrosis are chronically infected. CF is caused by mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.[2]
- CFTR modulators are the first therapies to treat the underlying cause of CF and have become the foundation for CF treatment since the approval of Kalydeco (ivacaftor) in 2012.[1,4] Trikafta (elexacaftor/tezacaftor/ivacaftor) release in 2019 introduced the first CFTR modulator triple therapy.
- Pulmonary exacerbations in CF can include the following symptoms: new or increased cough or sputum production, change in sputum appearance, increased dyspnea with exertion, and reduction in forced expiratory volume in once second (FEV_1).[1] According to the 2013 Cystic Fibrosis pulmonary guidelines, systemic antibiotic treatment is indicated in patients with acute pulmonary exacerbations.
- To our knowledge, no real-world studies have evaluated the use of IV antibiotics in patients with CF before and after the initiation of the CFTR modulator elexacaftor/tezacaftor/ivacaftor.

OBJECTIVES

Primary Endpoint:

- The primary objective of the study is to compare the difference in the number of intravenous antibiotic therapy days between CF patients who received elexacaftor/tezacaftor/ivacaftor and CF patients who did not.

Secondary Endpoints:

- Compare the difference in costs of intravenous antibiotic therapy between CF patients who received elexacaftor/tezacaftor/ivacaftor and those who did not.
- Compare the difference in number of days patients with CF require intravenous antibiotic therapy pre- and post- elexacaftor/tezacaftor/ivacaftor initiation.

METHODS

A retrospective chart review of 159 patients was be conducted.

The treatment group will have received IV antibiotics and Trikafta. The control group will have received IV antibiotics only.

Subjects were eligible for inclusion if they received IV antibiotics between April 1, 2019 and September 19, 2020.

Patients within the treatment group had their chart reviewed for a 1-year period with the first fill date of CFTR modulator occurring at the 6-month mark.

Patients within the control group had their chart reviewed between September 1, 2019 and September 1, 2020.

Data collected includes date of initial elexacaftor/tezacaftor/ivacaftor fill, previous CFTR modulator use, and the type and total days of intravenous antibiotic therapy.

Average home infusion medication, nurse visit, and per diem costs for IV antibiotics will be used to calculate healthcare cost and savings.

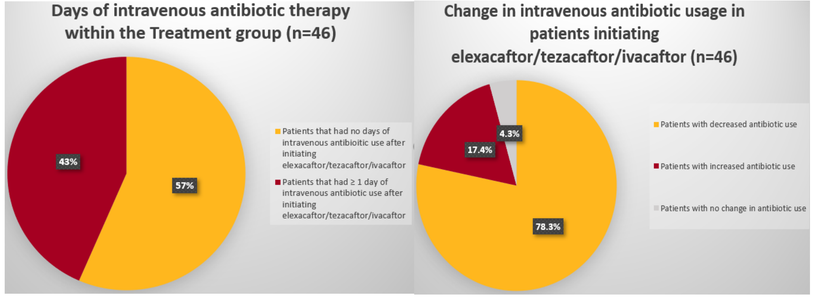
Data was normalized within each treatment group by finding the percent change in intravenous antibiotic use between the first and second 6-month intervals of data collection.

Data was compared using one-tailed independent student t-tests with an alpha of 0.05.

Results

- Patients who received elexacaftor/tezacaftor/ivacaftor had a 36% reduction of intravenous antibiotic therapy compared to a 38.7% reduction for the control arm (p=0.46).
- In the subgroup of patients that had a reduction of antibiotic use, the patients who received elexacaftor/tezacaftor/ivacaftor had 17% greater reduction of intravenous antibiotic use compared to the control arm. The treatment group had on average an 87% reduction of intravenous antibiotic use compared with a 70% reduction for control group (p=0.11).
- Patients within the treatment group utilized on average 46.4 days of intravenous antibiotic therapy before initiation of elexacaftor/tezacaftor/ivacaftor and 27.6 days post-initiation (p=0.003).

Results Continued



Discussion/Conclusion

There was no statistically significant difference in the mean difference for days of intravenous antibiotic use when comparing patient's treatment and control groups.

Patients who initiated elexacaftor/tezacaftor/ivacaftor trended toward having a greater reduction in intravenous antibiotic use compared to the control group in a subgroup of patients that had decreased antibiotic utilization.

Limitation of the study: the small number of patients within the control group. This small value is most likely due to substantial utilization of elexacaftor/tezacaftor/ivacaftor.

Elexacaftor/tezacaftor/ivacaftor appeared to decrease a patient's need for intravenous antibiotics. Evaluation of cost of intravenous antibiotic therapy is ongoing.

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Disclosures

The authors have no conflicts of interest to disclose