



Cystic Fibrosis Research News

Title:

STANDARDIZED TREATMENT OF PULMONARY EXACERBATIONS (STOP) STUDY: OBSERVATIONS AT THE INITIATION OF INTRAVENOUS ANTIBIOTICS FOR CYSTIC FIBROSIS PULMONARY EXACERBATIONS

Authors:

Don B. Sanders^a, George M. Solomon^b, Valeria V. Beckett^c, Natalie E. West^d, Cori L. Daines^e, Sonya L. Heltshe^{c,f}, Donald R. VanDevanter^g, Jonathan E. Spahr^h, Ronald L. Gibson^f, Jerry A. Nickⁱ, Bruce C. Marshall^j, Patrick A. Flume^k, Christopher H. Goss^{c,f,I} on behalf of the STOP Study Group

Affiliations:

^aDepartment of Pediatrics, University of Wisconsin-Madison, Madison, WI, USA ^bDepartment of Medicine and the Gregory Fleming James Cystic Fibrosis Center, University of Alabama at Birmingham, Birmingham, AL USA

^cCystic Fibrosis Foundation Therapeutics Development Network Coordinating Center, Seattle Children's Research Institute, Seattle, WA, USA

^dDepartment of Medicine, Johns Hopkins University, Baltimore, MD, USA

^eDepartment of Pediatrics, University of Arizona, Tucson, AZ, USA

^fDepartment of Pediatrics, University of Washington School of Medicine, Seattle, WA, USA gDepartment of Pediatrics, Case Western Reserve University School of Medicine, Cleveland Ohio, USA

^hDepartment of Pediatrics, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA ⁱDepartment of Medicine, National Jewish Health, Denver, CO, USA

^jCystic Fibrosis Foundation, Bethesda, MD, USA

^kDepartments of Medicine and Pediatrics, Medical University of South Carolina, Charleston, SC, USA

¹Department of Medicine, University of Washington, Seattle, WA, USA

What was your research question?

We wanted to understand the symptoms that precede a patient being treated with intravenous (IV) antibiotics for a pulmonary exacerbation, what treatments patients receive before starting IV antibiotics, and what the treating clinician's goals for treatment are.

Cystic Fibrosis Research News

cfresearchnews@gmail.com





Journal of

Cystic Fibrosis

The Official Journal of the European Cystic Fibrosis Society

Why is this important?

Pulmonary exacerbations are important events in the lives of persons with CF, both because they interfere with patients' well-being and because most patients who have an exacerbation lose lung function that they will never recover. Although exacerbations are common, very little is known about which treatments provide better results. Our future goal is to compare different exacerbation treatments to optimize outcomes. To do this, we need to understand the spectrum of symptoms and treatments that precede IV antibiotics, the goals of treatment, and which types of interventional studies clinicians would be willing to enroll their patients in.

What did you do?

We enrolled 220 adolescents and adults in the Standardized Treatment of Pulmonary Exacerbation (STOP) Study. Study subjects were admitted to the hospital at 11 US CF Centers for a pulmonary exacerbation and treated with IV antibiotics. We recorded patient and pulmonary exacerbation characteristics at the time of enrollment. We obtained some patient characteristics and clinical data from the US CF Foundation Patient Registry. We surveyed treating physicians on treatment goals as well as their willingness to enroll patients in various study designs.

What did you find?

Most patients in the STOP study were adults (81%) and had Pseudomonas aeruginosa lung infections (71%). Pulmonary exacerbation symptoms were present for more than seven days before starting IV antibiotics in 85% of patients, and nearly half received oral or inhaled antibiotics before starting IV antibiotics. The majority of patients lost lung function from their baseline in the 6 months before enrolling in STOP, but 20% started IV antibiotics at their baseline lung function. Physicians' treatment goals were evenly divided between recovering lung function and improving symptoms. Only 29% of physicians would enroll their patients in interventional studies that included a 7- duration of treatment, but at least 70% were willing to enrol patients in studies that included longer durations.

What does this mean and reasons for caution?

Our results suggest that physicians are willing to enroll their patients in interventional pulmonary exacerbation studies. Such studies may be better suited for adult patients and should take into account a patient's history of pulmonary exacerbation treatments. We did not survey patients, so it is unclear if they share their clinicians' willingness to enroll in

Cystic Fibrosis Research News

cfresearchnews@gmail.com





Cystic Fibrosis Research News

various studies, or what their goals of therapy were. The STOP study was only conducted at 11 CF care centers in the US, so our results may not apply to all patients with CF.

What's next?

Results from this study have been used to help design a large research study at multiple CF care centers that compares how patients respond when treated with antibiotics for different amounts of time.

Original manuscript citation in PubMed

https://www.ncbi.nlm.nih.gov/pubmed/?term=STANDARDIZED+TREATMENT+OF+PULMON ARY+EXACERBATIONS+(STOP)+STUDY%3A+OBSERVATIONS+AT+THE+INITIATION+OF+INTRA VENOUS+ANTIBIOTICS+FOR+CYSTIC+FIBROSIS+PULMONARY+EXACERBATIONS

Cystic Fibrosis Research News

cfresearchnews@gmail.com