Background: The U.S. Food and Drug Administration approved the cystic fibrosis transmembrane conductance regulator (CFTR) modulator elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA) in October 2019 for patients with cystic fibrosis (CF) and at least one F508del mutation [1]. Phase 3 trials indicated that it is generally well tolerated, and patients participating in the trials did not report any sleep disturbances [2], but sleep disturbances related to CF can occur, and poor sleep can affect health outcomes [3]. In addition, although no sleep disturbances were reported in trials, one case study reported sleep paralysis with hypnopompic hallucinations, depression, and anxiety after initiation of ELX/TEZ/IVA, so it is important to assess for sleep disturbances after initiation of this modulator as a routine part of CF care. The goal of this study was to examine self-reported sleep disturbances in people with CF after initiation of ELX/TEZ/IVA.

Methods: A retrospective chart review was conducted of adults with CF (N = 127) receiving care at an adult CF clinic in an academic health center in the southeastern United States from January 2015 to February 2022. Data collected included demographic data, percentage predicted forced expiratory volume in 1 second (predicted for age, gender, and height) at each visit, consistency and timeline of ELX/TEZ/IVA use, and self-reported sleep disturbances. Results: One hundred twenty-seven people were screened for study eligibility, and 100 were included. Twenty-three percent reported new-onset sleep disturbances after initiation of ELX/TEZ/IVA. Two discontinued the modulator after reporting significant insomnia, anxiety, and depression. Conclusions: More than half of the participants reported new-onset or ongoing sleep disturbances after initiation of ELX/TEZ/IVA that contributed to two patients discontinuing the modulator. It is important to screen for and treat sleep disturbances as a routine part of CF care.

References