Using Artificial Intelligence to Measure and Optimize Adherence in Patients on Anticoagulation Therapy

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BACKGROUND

Treatment adherence is a critical component of anticoagulation therapy. Proper anticoagulation to prevent thromboembolic events is essential for patients who are treated with warfarin, heparin, and direct oral anticoagulants (DOACs). Monitoring adherence to anticoagulation therapy has been challenging. Despite the availability of various monitoring tools and methods, suboptimal adherence rates are common.1-6

STUDY OBJECTIVES

The objective of this study was to evaluate the feasibility and efficacy of a novel artificial intelligence platform to measure and optimize adherence in patients on anticoagulation therapy. The primary adherence measures for the study were based on scheduled pill counts, AI platform adherence data, and plasma drug concentration levels.

TRIAL DESIGN

A single-site, randomized, parallel-group, 12-week study was conducted at the Stern Stroke Center, Montefiore Medical Center, Bronx, NY, from October 2015 to April 2016. Adults with a recently diagnosed stroke and who were on DOAC therapy were included. The study compared the use of a novel artificial intelligence platform (AiCure, New York, NY, USA) with standard pill counts. The study population was stratified by sex and randomization was carried out using a computer-generated list of random numbers. All participants provided written informed consent. The study protocol was approved by the institutional review board of Montefiore Medical Center, Bronx, NY.

RESULTS

A total of 57 subjects were pre-enrolled with 36 subjects randomized to the study. 1 subject terminated prior to the first dose taken; the remainder of subjects completed the full study. The primary adherence measures for the study were based on scheduled pill counts, AI platform adherence data, and plasma drug concentration levels.

Adherence Measures

The mean (SD) average adherence to the AI platform was 90.5% (7.5%). In the control group, the mean (SD) average adherence was 50.0% (19.0%). The difference of 40.5% (95% CI: 31.5%-49.5%) was statistically significant (p<0.0001). A total of 27 subjects were adherent using the AI Platform, compared to 15 subjects in the control group. Adherence was defined as having ≥80% of doses taken.

Adherence Based on Plasma Drug Concentration Levels

A total of 108 plasma samples were collected across all subjects (3 samples were clotted). Physicians did not know the plasma sample results prior to the end of the study. Plasma samples were analyzed for anticoagulants using a novel laboratory assay funded by the American Heart Association. The laboratory assay was developed at the University of Michigan and is based on measuring phospholipid-dependent coagulation times (APTT, PT/INR) and phospholipid-independent times (DOACs).

CONCLUSIONS

Adherence to DOAC therapy was measured using a novel laboratory assay based on measuring phospholipid-dependent and phospholipid-independent coagulation times. The assay can detect nonadherence in patients using DOACs. The study showed high usability and feasibility of using AiCure. The laboratory assay was able to detect nonadherence in patients using DOACs. The laboratory assay was able to capture suboptimal adherence levels and change patient behavior.

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