

Variation in quality of trials for atrial fibrillation, flutter

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(HealthDay)—The quality of atrial fibrillation/atrial flutter (AF/AFL)

trials is variable, and trials often rely on recurrence as the primary endpoint, according to a review published online June 27 in *JACC: Clinical Electrophysiology*.

Ravi B. Patel, M.D., from Northwestern University Feinberg School of Medicine in Chicago, and colleagues queried all closed, phase II to IV interventional trials that enrolled patients known to have AF/AFL. A total of 173 of the 348 trials that directly studied AF/AFL were published, enrolling a median of 190 patients from a median of 15 sites.

The researchers found that over time, there was an increase in the volume of published trials (7 percent before 2008 to 41 percent from 2014 to 2016); 29 percent of the completed trials remained unpublished. Most funding (54 percent) was accounted for by industry sources. The most common endpoint was recurrence of AF/AFL (45 percent), while rates of primary clinical endpoints were low at 13 percent. For published trials of pharmacological approaches, the mean Jadad score was 4.0 ± 1.4 . There were 61 trials involving ablation or device therapies, of which 69 percent were randomized and 28 percent were single-arm studies; in 16, 4, and 44 percent, patient, proceduralist, and event-ascertainment blinding was used, respectively.

"Contemporary trials of AF/AFL are often multicenter and modest in size. The primary study endpoint is commonly recurrence of arrhythmia, even in high-quality and late-phase trials," the authors write. "Although methodological quality is high in trials of pharmacologic approaches, [trials](#) of AF/AFL ablation and device therapies variably employ randomization and blinding."

Several authors disclosed ties to the pharmaceutical and medical device industries.

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