





Safety reporting in trials on atrial fibrillation: an observational study of the *clinicaltrials.gov* registry and corresponding publications

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Introduction: Atrial fibrillation (AF) is a major global health issue that requires a careful assessment of both conservative and invasive treatments¹. Decisions must consider patient preferences, success rates, and potential adverse events (AEs), which are any undesirable occurrences during trials. Inconsistent AE reporting can mislead conclusions about treatment safety and efficacy. To improve patient safety, clinical trials should be preregistered in public databases like ClinicalTrials.gov, with accurate and consistent reporting. However, discrepancies between registry data and corresponding publications are common². This study aims to evaluate the completeness and consistency of AE reporting in registered AF trials and related publications.

Methods: This cross-sectional study analyzed AF trials registered on ClinicalTrials.gov with matching publications. A search for completed AF treatment trials using "atrial fibrillation" was conducted on November 5, 2023. Two authors (VL, MV) independently screened trials, extracted AE data, and checked for inconsistencies. Discrepancies were classified as inconsistent, with a third author (FŠ) resolving disagreements.

Results: Of 340 identified trials, 75 with publications were analyzed. All trials in the registry reported serious adverse events (SAEs) and other AEs (OAEs). However, only 48 publications (65%) reported SAEs, and 47 (63%) did not report OAEs. In 12 publications (16%), only total AE numbers were mentioned. SAEs were more frequently reported in the registry than in publications ($p=0.0468$), with OAE reporting in only 26 publications ($p=0.0011$). Discrepancies were higher in invasive procedure trials. Industry-sponsored trials ($n=52$) showed more SAE reporting inconsistencies ($p=0.0304$).

Conclusions: AE reporting for AF trials is thorough on ClinicalTrials.gov but inconsistent in publications. Improving publication reporting is critical for enhancing patient safety and translating trial evidence into practice.

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LITERATURE

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