Electrical versus pharmacological cardioversion for emergency department patients with acute atrial fibrillation (RAFF2): a partial factorial randomised trial

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RobotReviewer

Risk of bias table

trial	design	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Stiell IG, 2020	RCT	+	+	+	+

Trial summaries

n	Participants	Interventions	Outcomes	punchline	finding
?? ?	emergency department patients with acute atrial fibrillation (RAFF2	Electrical versus pharmacological cardioversion, pharmacological cardioversion followed by electrical cardioversion (drug-shock), and electrical cardioversion alone (shock-only		Both the drug-shock and shock-only strategies were highly effective in safely and quickly returning patients to normal sinus rhythm.	,Äï no diff

Characteristics of studies

Stiell IG, 2020

Population	1. Participants We enrolled stable patients presenting with a primary diagnosis of acute atrial fibrillation of at least 3 h duration, in whom symptoms necessitated early manage ment and for whom pharmacological or electrical cardioversion was an appropriate option. 2. Previous studies have confirmed the effectiveness and safety of procainamide for acute atrial fibrillation. 3. The strokes were found in patients with CHA 2 DS 2 -VASc score risk criteria (heart failure, hypertension, age ,â•75 years, diabetes, stroke) and who presented more than 12 h after onset.
Interventio n	1. 3,12 Patients allocated to the drug-shock group received a continuous infusion of intra- venous procainamide at a dose of 15 mg/kg, in 500 mL of normal saline solution, given over 30 min (maximum dose 1500 mg). 2. Patients allocated to the shock- only group received a similar weight-based infusion of normal saline placebo over 30 min. 3. The primary protocol (Protocol 1) was a randomised, blinded, placebo-controlled

	comparison of attempted pharma- cological cardioversion with intravenous procainamide (15 mg/kg over 30 min) followed by electrical cardio- version (up to three shocks, each of ‚â•200 J) if necessary, versus placebo infusion followed by electrical cardio- version.
Outcomes	1. The primary outcome was conversion to and maintenance of sinus rhythm for at least 30 min at any time after See Online for appendix randomisation and up to a point immediately following three shocks. 2. Patients were re-assessed in person by research personnel at the hospital at 14 days to deter- mine cardiac rhythm (by ECG), recurrence of atrial fibrillation, return visits to the emergency department, stroke, and survival. 3. The primary outcome was centrally assessed by review of all ECGs by the masked adjudication committee, which was comprised of two emergency physicians and one electrophysiology cardiologist.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. The allocation sequence was computer- generated by an independent statistician using a randomly permuted block design of length 8, stratified by study site. 2. Randomisation and masking On-site research personnel determined allocation for each of the two protocols using an online electronic data capture system. 3. This was a superiority trial with the two groups in Protocol 1 allocated 1:1 and stratified by study site.
Allocation concealment	low	1. The allocation sequence was computer- generated by an independent statistician using a randomly permuted block design of length 8, stratified by study site. 2. Masking of drug treatment to all research and emergency department staff was arranged by having local hospital pharmacies prepare premixed intravenous bags of either procainamide or placebo, which were placed in locked containers in the emergency department. 3. Randomisation and masking On-site research personnel determined allocation for each of the two protocols using an online electronic data capture system.
Blinding of participants and personnel	low	1. Patients and research and emergency department staff were masked to group assignment. 2. The allocation sequence was computer- generated by an independent statistician using a randomly permuted block design of length 8, stratified by study site. 3. Masking of drug treatment to all research and emergency department staff was arranged by having local hospital pharmacies prepare premixed intravenous bags of either procainamide or placebo, which were placed in locked containers in the emergency department.
Blinding of outcome assessment	low	1. Patients and research and emergency department staff were masked to group assignment. 2. The primary outcome was centrally assessed by review of all ECGs by the masked adjudication committee, which was comprised of two emergency physicians and one electrophysiology cardiologist. 3. Patients were re-assessed in person by research personnel at the hospital at 14 days to deter- mine cardiac rhythm (by ECG), recurrence of atrial fibrillation, return visits to the emergency department, stroke, and survival.

References

1. Stiell IG et al. Electrical versus pharmacological cardioversion for emergency department patients with acute atrial fibrillation (RAFF2): a partial factorial randomised trial Emerg Med J 2020. 395(3); 188-91 PMID: 21422032