EVMS Emergency Medicine Journal Club
Therapy Worksheet

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CITATION: Airaksinen KE et al, **Thromboembolic complications after cardioversion of acute atrial fibrillation: the FinCV (Finnish CardioVersion) study.** J Am Coll Cardiol. 2013 Sep 24;62(13):1187-92.

A. What is being studied? (Answer below)	**Comments**
1. Study Objective	"to explore the incidence and risk factors of thromboembolic complications after cardioversion of acute atrial fibrillation" (<48 hours)
2. Study Design	Multi-center retrospective observational non-controlled study that took place in 3 Finnish (2 university 1 "central") hospitals
3. Inclusion Criteria	Patients > 18 years of age with acute a.fib who underwent ED cardioversion without peri/post procedural anticoagulation. Only patients living in the hospital catchment area were included to get the adequate follow-up data after the cardioversion
4. Exclusion Criteria	Excluded pts that received anticoagulation, were <18 y/o and those that live outside the hospital catchment area (due to possibility of inadequate follow-up data). Did not include other common exclusion criteria Fever, pregnancy, ACS, acute CHF, COPD etc.
5. Interventions Compared	Stroke event rates of those who underwent cardioversion and did NOT receive peri-

	procedural anticoagulation. Some comparisons made to published data in patients who are anticoagulated peri-procedurally. -
6. Outcomes Evaluated	Primary- "definite thromboembolic event within 30 days after index cardioversion" (definite thromboembolic event was defined as a stroke documented clinically and confirmed by CT or MRI to be caused by cerebral infarction or a systemic embolism confirmed by imaging, surgery, or autopsy. Probable embolic complications included transient ischemic attacks that were not confirmed by imaging or other embolism suspected clinically but not confirmed by imaging.)
B. Are the results of the study valid? Answer questions below	
1. Were patients randomized?	No -it was a retrospective observational study
2. Was randomization concealed (Blinded)	n/a
3. Were patients analyzed in the groups to which they were randomized?	n/a
4. Were patients in the treatment and control groups similar with respect to known prognostic factors?	n/a, there was no treatment vs control group- all individuals included in the study were those that were cardioverted without anticoagulation.
C. Did experimental and control groups retain a similar prognosis after the study started (answer the questions below)?	
1. Were patients aware of group allocation?	n/a

2. Were clinicians aware of group allocation?	No mention of physicians having knowledge of ongoing AF study.
3. Were outcome assessors aware of group allocation?	No. Authors do not indicate that chart reviews were performed by individuals blinded to study objectives. This could predispose to Ascertainment bias.
4. Was follow-up complete?	Uncertain- Investigators do not specifically report on whether they were able to f/u on all patients. The 30-day follow-up they reported demonstrated that all 38 thromboembolic events that occurred were between days 1-27 after cardioversion. (median 2 days, mean 4.6 days).
D. What were the results?	
1. How large was the treatment effect? (difference between treatment and control group).	The thromboembolic risk in this setting without anticoagulation was comparable to that seen in studies of scheduled cardioversion during therapeutic anticoagulation (bottom of page 3). However, closer scrutiny of subgroups showed important variations in regard to risk- thromboembolic risk was as high as 9.8% in pts with both DM and heart failure compared to only 0.2% in patients <60 years of age and no heart failure risk.
2. How precise was the estimated treatment effect at a 95% confidence interval?	38 definite embolic events occurred in 38 patients (0.7% of successful cardioversions; 95% CI: 0.5% to 1.0%). Moderately precision given narrow confidence interval. Does not include 0, i.e. statistically significant
D. How can I apply the results to patient care	
IV. Were the study patients similar to my patients?	The participants in this study seemed more healthy than the patient population in our area- per Table 1, the majority of patients that were successfully cardioverted had a CHADS2 score of 0-1 (approximately

	83%), whereas the patients at SNGH seem to have multiple risk factors giving them a CHADS2 score closer to 2, maybe even 3.
1. Were all clinically important outcomes considered?	I believe so- the study noted that no thromboembolic complications occurred after unsuccessful cardioversion in non-anticoagulated patients- this supports the view that conversion of a.fib to sinus is responsible for thrombo-embolic complications (either due to thrombus already present at the time of cardioversion, recurrence of afib after cardioversion, or the transient atrial "stunning" post-cardioversion)
2. Are the likely treatment benefits worth the potential harms and costs?	Hard to say- anticoagulation likely beneficial in those with multiple risk factors (DM, heart failure) given thromboembolic risk was as high as 9.8% in these pts. However, there is also the option to more conservatively defer cardioversion- a randomized comparison without cardioversion is warranted to evaluate thromboembolic outcomes in this type of group

Limitations:

- Retrospective data analysis
- No blinding of data assessors
- No kappa scores regarding ECG interpretation, data analysis, inclusion criteria.
- Combined CHADS 2 and CHADS-Vasc patients with a 0 -1 score which have distinct risk profiles
- Somewhat short f/u in a database that could have easily been extended to 90D or 1 year
- Did not perform further analysis on 246 patients who were unsuccessfully cardioverted and DID NOT get anticoagulation. This represents 10% of their population and these patient characteristics (CHADS scores) could be important
- Onset of a.fib was based on onset of symptoms which may not be reliable-
- Bias in selection of anticoagulation strategy according to perceived stroke risk may have led to an underestimation by the study of the true overall thrombo-embolic risk without anticoagulation.
- Comparative outcomes are not reported for an additional group of over 2100 cardioversions that did receive anticoagulation

- No mention of whether patients with valvular or other significant comorbidities were excluded.

Clinical Bottom Line: The study suggests that the risk of thrombo-embolic events in the absence of anticoagulation after cardioversion of acute a.fib is variable and their findings are consistent with CHADS2 stroke risk score. The data supports guideline recommendations of anticoagulation after cardioversion for patients with risk factors for stroke but not necessarily by default- reassuring that those at without stroke risk factors can be cardioverted with low embolic risk without anticoagulation.