Critical Review Form

Therapy

Association of the Ottawa Aggressive Protocol with Rapid Discharge of Emergency Department Patients with Recent-Onset Atrial Fibrillation or Flutter, *CJEM* 2010; 12:181-191

Objective: **"To examine the efficacy and safety of the Ottawa Aggressive Protocol for patients with recent-onset episodes of atrial fibrillation and flutter…to examine the outcomes of this strategy with regard to conversion to normal sinus rhythm, adverse events, hospital admission, ED length of stay and relapse." (p. 182)**

Methods: **Medical record review of consecutive ED patients at Ottawa Hospital between January 1, 2000 and June 30, 2005 with recent-onset atrial fibrillation or atrial flutter as the primary diagnosis and eligible for ED cardioversion immediately. Exclusion criteria included chronic a-fib, symptom duration >48 hours or if the duration was unknown, or patients with an alternative diagnosis necessitating admission (CHF or ACS, for example). Troponins were not routinely assessed in the absence of chest pain or ST-changes and all decisions and procedures were made by the emergency physicians (not cardiology). There is no upper age limit for this rapid protocol. The Ottawa emergency physicians use the following protocol:**

Step I: Assessment

- **Stable BP, no ACS or CHF**
- **Onset <48º**
- **Symptom severity**
- **Previous episodes/treatment**
- **Therapeutic INR**

Step II: Rate Control

- **Only if severe symptoms or no cardioversion**
- **Diltiazem 0.25 mg/kg IV over 10 minutes or Metoprolol 5 mg IV Q15 minutes**

Step III: Pharmacologic Cardioversion

- **Procainamide 100 mg IV over 60 minutes**

- **Hold if SBP <100**

Step IV: Electrical Cardioversion

- **NPO x 6º**
- **Propofol/fentanyl procedural sedation**
- **150-200 J biphasic synchronized to start**

Step V: Anticoagulation

- **None if symptoms <48º or INR therapeutic >3wks**
- **Consider initiating if CHADS $_2$ ≥ 1**

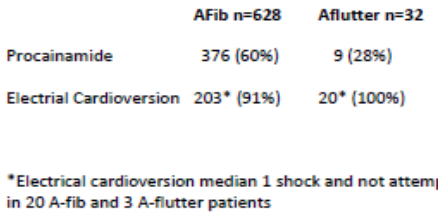
Step VI: Disposition

- **Home within 1º of cardioversion**
- **Outpatient Echo if first episode**
- **Cardiology follow-up**
- **If not cardioverted discharge with rate control meds and Coumadin and elective cardioversion with Cardiology within 4 weeks**

Thirty variables were collected by two trained research nurses blinded to the study objectives. The primary outcomes were the proportion cardioverted to sinus rhythm before ED discharge, ED length of stay (LOS), final disposition, and adverse events including death, stroke, or recurrent A-fib within 7-days. Data sources included nurse/physician ED notes, hospital records, and QA reviews. The Ottawa Hospital sees two-thirds of all adult ED visits and is the sole regional cardiology referral center.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	No this was a retrospective analysis, not randomized.
2.	Was randomization concealed (blinded)?	No randomization, no blinding.
3.	Were patients analyzed in the groups to which they were randomized?	Consecutive cohort of patients so intention to treat is not applicable.

4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	No treatment/control groups.
B.	**Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1.	Were patients aware of group allocation?	Yes, there was no blinding.
2.	Were clinicians aware of group allocation?	Yes, there was no blinding.
3.	Were outcome assessors aware of group allocation?	Yes. However, "Two research nurses were trained on the details of patient selection and data abstraction and were unaware of the study objectives." (p. 184)
4.	Was follow-up complete?	No loss to follow-up is reported.
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• 1057 ED patients presented with the primary diagnosis of recent onset A-fib or A-flutter but 397 were not eligible for the rapid protocol (usually because onset >48º or unclear or spontaneous conversion to NSR) leaving 660 patients in this analysis. • **Most patients were in A-fib (95.2%)** and the most common symptom was palpitations (78%) with only 12% reporting chest pain. • **Mean age 64.5 years** (range 19-92) and 56% were male. • 82% had a previous episode of A-fib. • The mean duration of symptom was 8.9 hours. • During ED rapid protocol, 39.6% received rate control drugs, 100% received procainamide and 36.8% underwent electrical cardioversion. • The following success rates were

		attained  • **96.8% of patients were discharged home after a median ED LOS of 4.9 hours, including 90.2% in NSR**. • During rapid protocol **7.6% had adverse event, usually (44/50) SBP < 100 mmHg**. • There were no episodes of torsades de pointes. • 8.6% had A-fib relapse with 7 days and **no strokes or deaths were observed**.
2.	How precise was the estimate of the treatment effect?	No 95% CI reported.
III.	**How can I apply the results to patient care (answer the questions posed below)?**	
1.	Were the study patients similar to my patient?	Yes. ED patient with acute-onset A-fib or A-flutter.
2.	Were all clinically important outcomes considered?	No assessment of costs, patient satisfaction, or clinician preferences. Changing engrained US physician's dogma-based management of acute-onset A-fib/A-flutter to reduce admissions and ED LOS will probably be met with significant malpractice angst and consequent resentful delays in acceptance and knowledge uptake. Therefore, additional and more conclusive data in other settings will be needed before guideline committee and some clinicians will accept this atrial fibrillation management paradigm shift.

3.	Are the likely treatment benefits worth the potential harm and costs?	No costs or societal benefits are tested or hypothesized. Future trials should compare various drug regimens and shock-first approaches, especially for A-flutter which was 100% responsive to electrical cardioversion but more often refractory to chemical cardioversion. In addition, the $CHADS_2$ score should be validated in ED settings and the optimal role for anticoagulation, echo cardiography and cardiology consultations should be defined.

Limitations

1) **Not randomized or controlled so multiple potential forms of bias.**

2) **Single-center with uncertain external validity for other settings less accustomed to rapid A-fib cardioversion or with clinical faculty without experience following explicit protocols.**

3) **No inter-rater reliability for chart review.**

4) **No data on excluded patients which is illogical since the same data is available in the same medical records.**

5) **Seven-day follow-up may be inadequate for identifying all strokes. More importantly, the methods of follow-up (medical record review) may be insufficient to capture adverse events. A better method would be telephone follow-up and review of the provincial death index for those who could not be reached by telephone.**

6) **No report of protocol violations. Did they not occur or did nobody assess compliance?**

7) **No cost-effectiveness analysis or hypothesized benefits for ED crowding or medical costs.**

Bottom Line

An ED-based rapid procainamide chemical-then-electrical cardioversion protocol for adults with A-fib/A-flutter symptoms of less than 48 hours duration (or in those with a therapeutic INR for at least 3-weeks) significantly reduces admission rates and ED LOS. Future trials will delineate whether:

1) **The effectiveness and safety of this protocol is replicable elsewhere;**
2) **Patients and physicians will readily accept this paradigm shift in atrial fibrillation management;**
3) **There are optimal anti-arrhythmic agents/doses, electrical cardioverison techniques and procedural sedation strategies;**
4) **A rapid cardioversion protocol is cost-effective.**

In the meantime, guideline developers (American Heart Association, American College of Emergency Physicians, American College of Cardiology) should begin to contemplate ED-based management of acute-onset A-fib/A-flutter which they have neglected in the past. A systematic review of all current rapid cardioversion protocols using the MOOSE guidelines would be a useful addition to the medical literature.