Establishing Standards of Care for Amiodarone Monitoring In an Outpatient Setting

Sibyl Cherian, Pharm.D., Clinical Assistant Professor – Fairleigh Dickinson University
Naseem Amarshi, M.Sc., Pharm.D. – Clinical Pharmacist – Central Arkansas Veterans Healthcare System

Background

- Amiodarone is a Vaughan Williams Class III antiarrhythmic agent indicated for the management of ventricular fibrillation or unstable ventricular tachycardia, used off-label for atrial fibrillation.[1-3]
- Due to numerous side effects, the North American Society of Pacing and Electrophysiology (NASPE) has specific recommendations regarding baseline and routine monitoring of patients being initiated on amiodarone therapy.[4]
- A few studies demonstrate that utilizing pharmacists in multiple settings for amiodarone monitoring improved adherence to appropriate monitoring.[5-7]
- To date, there has been only one study that has evaluated amiodarone monitoring in a collaborative setting with pharmacists in a Veterans Affairs Healthcare System and no studies that have evaluated concomitant pharmacist-led monitoring of warfarin and amiodarone in a clinic setting.[8]

Description of Amiodarone Monitoring Quality Improvement Project

- In November 1, 2014, a quality improvement project was established as a pilot clinic within the anticoagulation clinic at a VA hospital.
- During the routine monitoring of anticoagulants, pharmacists identified if these patients are also on amiodarone. If amiodarone was initiated within the past six weeks, pharmacists used a computerized template to write a note into the patient's chart. If there were certain baseline laboratory values or imaging that were incomplete, the pharmacist ordered these labs so that baseline values were available for future comparison.

Objectives

Primary Outcomes: assess the rates of monitoring of liver (aspartate aminotransferase [AST], alanine aminotransferase [ALT] ± alkaline phosphatase [ALP]), thyroid (thyroid-stimulating hormone [TSH], free T4) and pulmonary function (PFTs with diffusing capacity of the lungs for carbon monoxide [D_LCO], chest x-ray [CXR]) in the pre- and post-intervention group

Secondary Outcome: evaluate the effect of a pharmacist-managed dual warfarin and amiodarone monitoring on maintaining target INR, measured using the fraction of INRs method of % time in therapeutic range [TTR] calculated as (number of INRs in target range divided by total number of INR in selected time interval) x100

Methodology

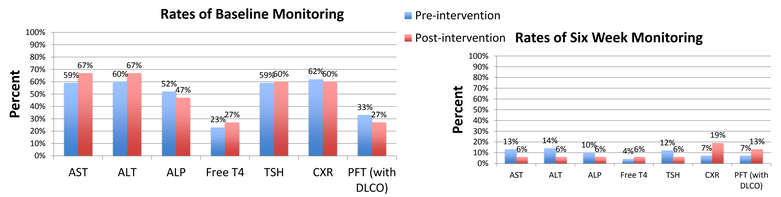
Exclusion Criteria
Amiodarone started by non-VA provider
Patients who received <6 weeks of amiodarone therapy
Pregnancy
Patients in home-based primary care
Under hospice care
INR readings collected at first initiation of warfarin or subtherapeutic INRs while warfarin was held prior to or post procedure
Inclusion Criteria
All eligible veterans being monitored by the VA anticoagulant clinic initiated on amiodarone therapy or currently receiving amiodarone therapy between May 1, 2014 to April 30, 2015

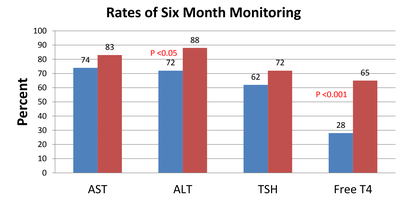
Results

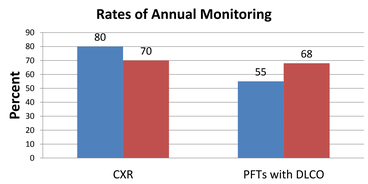
Pre-intervention group (N = 73), Post-intervention group (N = 71)

Characteristics	Pre-Intervention	Post-Intervention	P-Value
Age – years (SD)	69.8 ± 8.8	70 ± 9.7	0.45
Gender – no. (%)			
Male	71 (97.3%)	70 (98.6%)	0.58
Female	2 (2.7%)	1 (1.4)	
Race – no. (%			
Black	13 (17.8%)	7 (9.9%)	0.17
Non-black	60 (82.2%)	64 (90.1%)	
Anticoagulant – no. (%)			
Warfarin	58 (79.5%)	51 (71.8%)	0.29
TSOAC	15 (20.5%)	20 (28.2%)	
Indication – no. (%)			
Atrial fibrillation/flutter	70 (95.9%)	65 (91.5%)	0.32
Other	3 (4.1%)	6 (8.5%)	
Dose – no. (%)			
200mg	61 (83.6%)	55 (77.5%)	0.64
100mg	5 (6.8%)	6 (8.5%)	
Other	7 (9.6%)	10 (14%)	

Primary Outcomes







Secondary Outcome

<u>% TTR</u>

- Pre-intervention group: 64%
- Post-intervention group: 58%

Methodology con't

- Retrospective chart review approved by Central Arkansas Veterans Healthcare System (CAVHS) Department of Veterans Affairs Institutional Review Board and CAVHS Research and Development Committee
- Pharmacist review of patients' electronic health records for compliance with amiodarone monitoring and % TTR

<u>Data Collected:</u>

- Age, gender, race
- Amiodarone dose, anticoagulant choice
- Amiodarone, warfarin or direct oral anticoagulant (DOAC) indication
- The presence of appropriate laboratory values and imaging on amiodarone initiation and at six weeks post-amiodarone initiation: ALT, AST, ALP, TSH, Free T4, PFTs with D_LCO and CXR. Data was collected for compliance with obtaining TSH, free T4, AST and ALT for six-month labs. Annual data for CXR and PFTs with D_LCO was assessed for completion of monitoring values.
- INR values for all patients on concomitant warfarin, who met exclusion and inclusion criteria, was also reviewed.

<u>Statistical Analysis</u>

Baseline characteristics were compared between the pre- and post-intervention group using the Pearson's chi-squared test, except for age in which the student t-test was used. Primary outcome assessing rates of monitoring was compared using Pearson's chi-squared test. P-values <0.05 were considered statistically significant.

Conclusion

- This study demonstrates that including pharmacists into a collaborative management of patients on amiodarone leads to improved rates of monitoring on recommended laboratory tests.
- Our study demonstrates sustainability of amiodarone monitoring due to amiodarone monitoring education initiated by pharmacists.
- Present protocol was improved and modified by removing unnecessary and excessive laboratory monitoring at six weeks, in compliance with current NASPE guidelines.

Limitations

- Lab monitoring may have been obtained outside of VA system
- Exclusion of non-VA providers
- Unable to re-educate those involved due to IRB approval process
- Post-intervention length of study of 6 months did not allow sufficient time to find significant results in annual lab monitoring (PFTs, chest x-ray)
- Subjects from community based outpatient clinics included but were not monitored by medication management clinic

References

1. Cordarone® [package insert]. Wyeth Pharmaceuticals, Inc., Philadelphia, PA; 2004.
2. Zimetbaum P, Ho KKL, Olshansky B, et al.; FRACTAL Investigators. Variation in the utilization of antiarrhythmic drugs in patients with new onset atrial fibrillation. *Am J Cardiol.* 2003;91(1):81-83.
3. Spence MM, Polzin JK, Weisberger CJ, et al. Evaluation of a pharmacist-managed amiodarone monitoring program. *J Manag Care Pharm* 2011; 17(7):513-522.
4. Goldschlager N, Epstein AE, Naccarelli GV, et al; The Practice Guidelines Subcommittee and the North America Society of Pacing and Electrophysiology. A practical guide for clinicians who treat with amiodarone: 2007. *Heart Rhythm.* 2007; 4(9):1250-59.
5. Raebel MA, Carroll NM, Simon SR, et al. Liver and thyroid monitoring in ambulatory care patients prescribed amiodarone in 10 HMOs. *J Manag Care Pharm.* 2006; 12(8):656-64.
6. Bickford CJ, Spencer AP. Adherence to the NASPE guideline for amiodarone monitoring at a medical university. *J Manag Care Pharm.* 2006; 12(3):254-59.
7. Tijia J, Field T, Garber L, et al. Development and pilot testing of guidelines to monitor high-risk medications in the ambulatory setting. *Am J Manag Care* 2010;17(7):489-96.
8. Graham MR, Wright MA, Manley HJ. Effectiveness of an amiodarone protocol and management clinic in improving adherence to amiodarone monitoring guidelines. *J Pharm Technol* 2004;20:5-10.

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest In the subject matter of this presentation.
- Sibyl Cherian: Nothing to disclose
- Rahemat Amarshi: Nothing to disclose