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## IS DABIGATRAN SAFE IN 'REAL LIFE'?

ACC Moderated Poster Contributions McCormick Place South, Hall A Monday, March 26, 2012, 9:30 a.m.-10:30 a.m.

Session Title: Arrhythmias: AF/SVT: Anticoagulation for Atrial Fibrillation: Warfarin and the Newbies

Abstract Category: 16. Arrhythmias: AF/SVT

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**Background:** Warfarin's monopoly as an anticoagulation therapy for atrial fibrillation has been challenged recently. RE-LY trial has shown superiority of dabigatran over warfarin in prevention of stroke with significantly lower risk of intracranial hemorrhage in patients with non-valvular atrial fibrillation. But data from community setting involving its usage are still missing. We conducted an observational study to detect complication rate of dabigatran in 'real life' setting.

**Methods:** A community based anticoagulation clinic database with 2200 patients was reviewed. 89 patients who were switched to dabigatran (150 mg dose) from warfarin were identified. They were observed in regards to different adverse events and complications rate. The independent sample t test was used to compare the age in the 2 populations. The independent sample proportion comparison Z test was used assuming unequal variances for the 2 groups.

## **Results:**

| Age in years   | 70 ± 11   | 71.5 ± 8.8 | 0.04  |
|--|-----------|------------|-------|
| Male Sex   | 57%       | 63.2%      | 0.26  |
| CHADS ≤ 1  | 42.6%     | 32.2%      | 0.06  |
| CHADS 2  | 25.9%     | 35.2%      | 0.03  |
| CHADS ≥ 3  | 31.5%     | 32.6%      | 0.84  |
| Prior TIA/Stroke   | 15.7%     | 20.3%      | 0.19  |
| Major Bleeding Complication                              | 8.98 %/yr | 3.11%/yr   | <0.01 |
| Major Complications(Major bleeding, Stroke, MI or Death) | 12.3%/yr  | 10.4%/ yr  | 0.58  |
| Dyspepsia  | 6.74 %    | 11.3%      | 0.05  |
| Discontinuation in 1st year                              | 14.6 %    | 16%        | 0.71  |

Our population was significantly younger and having lower CHADS2 score. Despite of these, the risk of major bleeding was significantly higher than shown in RE-LY trial.

**Conclusions:** This study demonstrates higher risk of major bleeding complication rate in patient population using dabigatran in a community based setting despite having lower risk. This calls for more studies identifying patients with high risk of bleeding and a tool for the periodic assessment.