

Stroke Prevention in Atrial Fibrillation in Saudis (SPAF Saudis): *A Phase IV study of Dabigatran*

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Background

- Dabigatran has recently been shown in RCT to be effective and safe in the prevention of stroke in NVAF patients.

(RE-LY New Eng J of Med Sep 2009)

- Recent AHA/ACC guidelines recommends Dabigatran as **class I** for SPAF.
- **75%** of new drug adverse events happens in the first two years post marketing.

Objectives

- To assess the **safety** and **efficacy** of Dabigatran in unselected population with NVAF.

Methods

- **Design:** Multicenter, prospective observational cohort with NVAf (Phase IV).
- **Follow up:** For 2 years from last enrolled patients.
- **Sample size:** 800 patients with NVAf
- **Study Period:** November 2010 – on going.

Inclusion Criteria

- Patients with NVAF
- ≥ 18 years
- CHADS2 score ≥ 1

Exclusion criteria

- Pregnant women
- Valvular AF
- Cr Cl < 30 ml/min
- ALT/AST >2UNL
- Stroke < 6 months

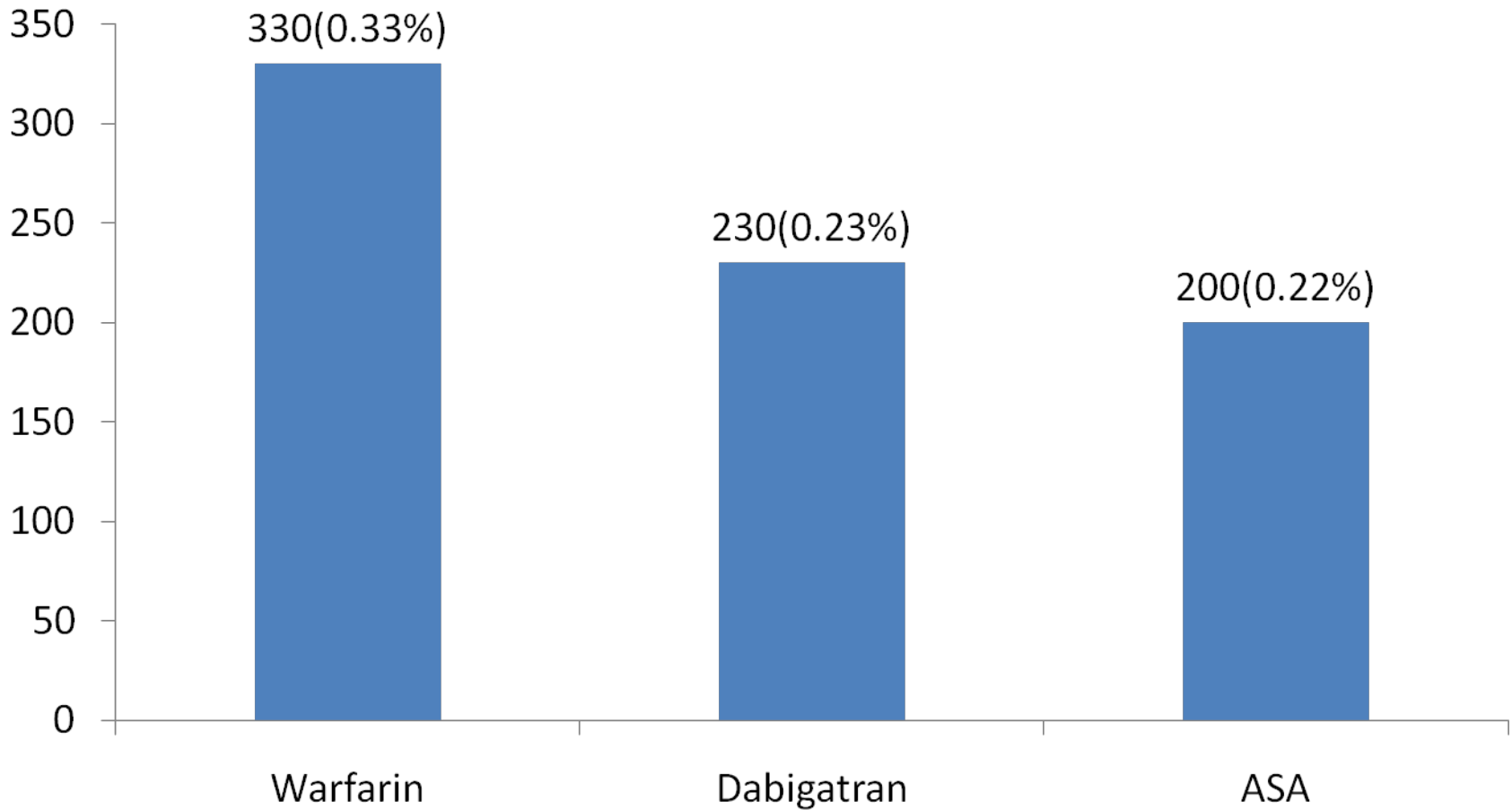
Follow up

- **Baseline :** All patients had CBC, EKG, ECHO, U&E, LFT & Coagulation profile.
- **Clinic visit:** 1 week, 1 month, then 3 months thereafter.

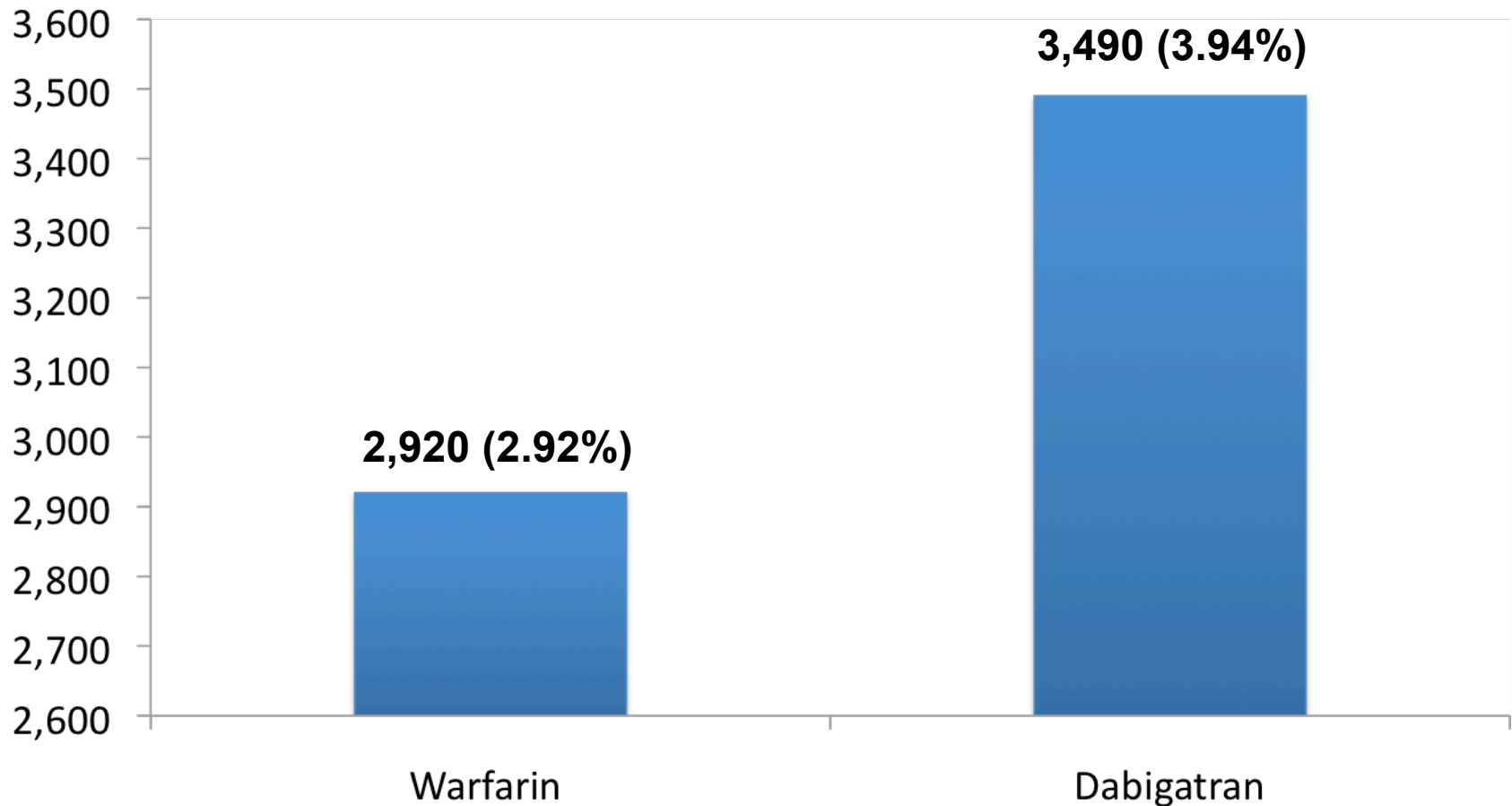
Outcomes

- Thromboembolic events: Stroke or Systemic embolization.
- Major Bleeding.

Threshold for safety per 100,000 patients per year



Threshold of efficacy per 100,000 patients per year



Baseline characteristics

Variable	SPAF-Saudi N=251	RE LY Dabigatran 110mmg N=6015
Age (mean±SD)	66.5±12.7	71.4
Gender(%male)	44.6 %	64.3%
CHADS2:		
0-1	8.3%	32.6%
2-3	55.2%	33.4%
3+	36.1%	32.7%
ASA	30%	40%
Clopidogrel	6%	-
Prior Stroke/TIA	10.9%	19.9%
CHF	17.2%	31.8%
Warfarin naïve (%)	25%	50.1%

Patients source

Source	N =251 (%)
Cardiology clinic	7.2 %
Internal medicine	0.4 %
Anticoagulation clinics	90 %
Inpatients	22.9 %

Medical history & Risk factors

History	N =251 (%)
IHD	25.2%
Heart failure	17.2 %
Diabetes	48.6 %
Hypertension	81.3 %
Renal failure	3.7 %

Types of AF

Source	N =251 (%)
First attack	6.4 %
Paroxysmal	26.3 %
Persistent	1.2 %
Permanent	46.2 %
Unknown	19.9 %

HAS-BLED Score

Score	(%)
1	8.8 %
2	33.9 %
3	44.8 %
4	11.7 %
6	0.8 %

a score of ≥ 3 indicates high risk of bleeding

EHRA class

Class	(%)
Class I	82.6 %
Class II	14.0 %
Class III	2.5 %
Class IV	0.8 %

Outcomes

Outcome	N =251 (%)
Stroke	1 (0.4%)
Major bleeding	2 (0.8%)
Discontinuation rate	26 (10.4%)

Reasons for Discontinuation

Side effects	N = 251 (%)
GI upset	9 (3.5)
GI bleeding	2 (0.7)
Patient preference	2 (0.7)
Reverted to sinus	2 (0.7)
Dizziness	2 (0.7)
Reduction of GFR	3 (1.1)
Physician preference	3 (1.1)
Heamaturia	1 (0.3)
Skin allergy	1 (0.3)
Diarrhea	1 (0.3)

Conclusion

- Thus far Dabigatran has been shown to be **safe** and **effective** in prevention of stroke in NVAf in real-life setting and can be an alternative substitute for warfarin.

Thank you