Comparative Study of Oral Anticoagulation in Left Ventricular Thrombi (No-LVT Trial)

On behalf of the No-LVT Trial investigators presented by:

Mahmoud Hassan Abdelnabi

Medical Research Institute, Alexandria University Alexandria, Egypt







• All the authors declare no conflict of interest.

• No funding was received.



American Heart Association. Scientific Sessions Background & Study Rationale

- Left ventricular thrombi are associated with increased risk of systemic thromboembolization with its major clinical consequences especially cerebrovascular stroke.
- For decades, they were treated by Vitamin K antagonists (VKA) such as Warfarin.
- Although Direct oral anticoagulants (DOACs) use is currently approved for nonvalvular atrial fibrillation but their efficacy and safety in the treatment of LV thrombi is limited to case reports and small case series.



Background & Study Rationale

↓ Full text

Resolution of left ventricular thrombus by rivaroxaban.

Search term

Padilla Pérez M, et al. Future Cardiol. 2014. Show full citation **European Heart Journal**

Q



P964 Role of rivaroxaban in left ventricular thrombi

A Almaghraby, M Abdelnaby, O Abdelkarim, Y Saleh, B Hammad, H Badran

European Heart Journal, Volume 39, Issue suppl_1, 1 August 2018, ehy564.P964, https://doi.org/10.1093/eurheartj/ehy564.P964 **Published:** 28 August 2018





Our study is the first randomized controlled study to assess different oral anticoagulants in the treatment of LVT.



Patients & Methods

- The Comparative Study of Oral Anticoagulation in Left Ventricular Thrombi (No-LVT) was an investigator-initiated, prospective, open-label, multicenter, randomized controlled clinical trial. Patients were recruited from five tertiary hospitals in Egypt and Bulgaria.
- The trial was prospectively registered at the Clinical Trials Registry, and the study protocol is available online at (<u>https://clinicaltrials.gov/ct2/show/NCT03926780</u>).



Patients & Methods

Comparative Study of Oral Anticoagulation in Left Ventricular Thrombi (No-LVT)



Infographic representation of the study design





Baseline characteristics of the included patients

Characteristic	Rivaroxaban (n=39)	Warfarin (n=40)	P-value			
Demographic Data						
Age	49.13±12.31	50.07±12.87	0.739			
Sex (Male)	21 (53.8%)	24 (60%)	0.581			
Risk Factors	Factors					
Diabetes Mellitus	23 (59%)	19 (47.5%)	0.307			
Hypertension	23 (59%)	19 (47.5%)	0.307			
Smoking	20 (51.3%)	22 (55%)	0.741			
Dyslipidemia	22 (56.4%)	16 (40%)	0.144			
Stroke	1 (2.6%)	2 (5%)	0.571			
Etiology						
Ischemic		29 (72.5%)	0.190			
Idiopathic	5 (12.8%)	11 (27.5%)	0.105			
Others (peripartum)	1 (2.6%)	0 (0%)	0.308			
Baseline Echocardiogram						
Ejection fraction (%)	36.11±6.12	37.01±5.31	0.09			
LV thrombus size (mm)	16.1±4.5X11.5±2.4	16.1±4.6X11.5±2.7	0.91			
Data is represented in Number (Percentage) or mean ± standard deviation						



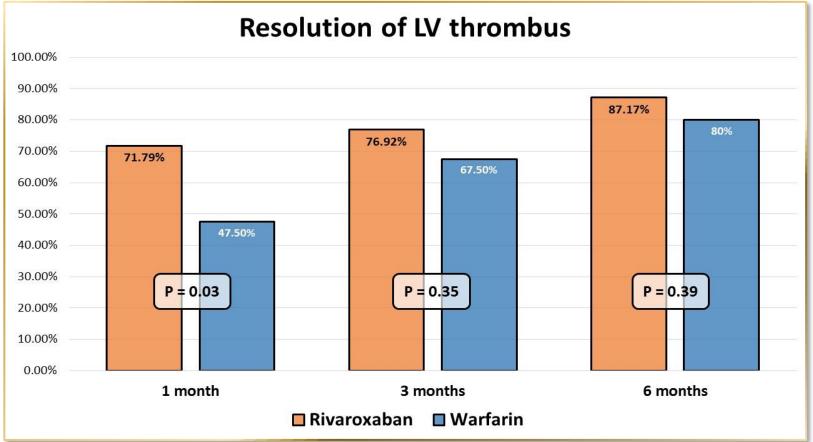


Primary and secondary endpoints in both groups

Characteristic	Rivaroxaban (n=39)	Warfarin (n=40)	P-value	95% CI for difference in proportion (Rivaroxaban Versus Warfarin)		
1-month follow-up TTE						
LV thrombus resolution	28 (71.79%)	19 (47.5%)	0.03*	3.3%, 45.2%		
3-month follow-up TTE						
LV thrombus resolution	30 (76.92%)	27 (67.5%)	0.35	-10.2%, 29.1%		
6-month follow-up TTE						
LV thrombus resolution	34 (87.17 %)	32 (80%)	0.39	-9.1%,23.4%		
Complications						
Major Bleeding	2 (5.1 %)	6 (15 %)	0.11	-23.9%,3.2%		
Stroke	0 (0%)	4 (10%)	0.04*	-19.3%, -0.7%		
Other Thromboembolic	0 (0%)	2 (5 %)	0.25	-11.7%, 1.8%		
Composite (Stroke and embolic)	0 (0%)	6 (15%)	0.01*	-26.1%, -3.9%		
Data is represented in Number (Percentage) CI: Confidence Interval, LV: Left Ventricle, TTE: Transthoracic Echocardiography						



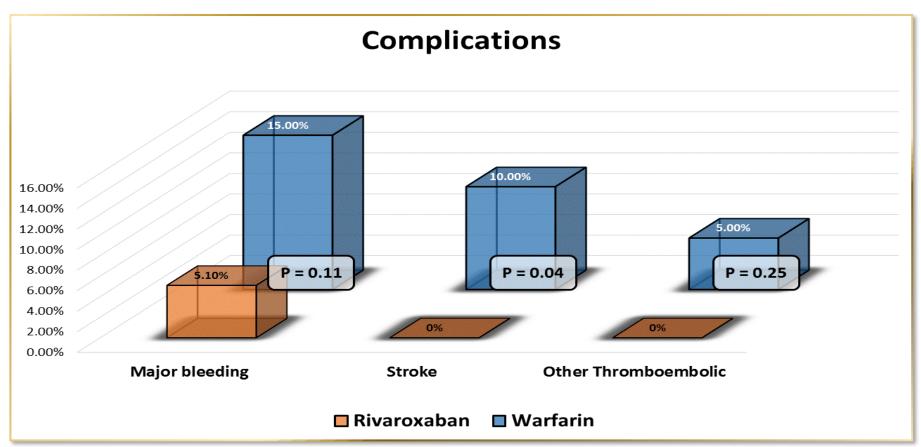




Graphical representation of the LVT resolution in both groups







Graphical representation of the incidence of complications in both groups





- The study was unblinded.
- It included a relatively small number of patients.
- LVT were evaluated by TTE which has limited sensitivity in LVT detection.





- The No-LVT trial is the 1st randomized control trial to compare VKA with rivaroxaban in the treatment of LVT.
- The No-LVT trial showed that in comparison to dose-adjusted warfarin, rivaroxaban had a significantly higher LVT resolution at 1-month follow-up. However, there was no significant difference between both groups at 3 and 6 months.
- Rivaroxaban had a significantly lower rate of stroke in comparison to warfarin at 6 months follow-up without an increased risk of major bleeding.



No-LVT Investigators

Mahmoud Abdelnabi MD¹, Yehia Saleh MD^{2,3}, Ahmed Fareed MD PhD⁴, Alexander Nossikof MD⁵, Ling Wang PhD⁶, Mahmoud Morsi MD⁷, Nouran Eshak MD⁸, Ola Abdelkarim MD², Haitham Badran MD, PhD⁹ and Abdallah Almaghraby MD²

- 1) Cardiology and Angiology Unit, Clinical and Experimental Internal Medicine, Medical Research Institute, Alexandria University, Alexandria, Egypt.
- 2) Cardiology Department, Faculty of Medicine, Alexandria University, Alexandria, Egypt.
- 3) Cardiology Department, Houston Methodist Hospital, Houston, Texas, USA.
- 4) Cardiology Department, Suez Canal University, Ismailia, Egypt.
- 5) City Clinic Maldost, Sofia, Bulgaria.
- 6) Michigan State University, College of Human Medicine, Department of Medicine, Division of Occupational and Environmental Medicine, East Lansing, Michigan, USA.
- 7) Cardiology Department, Faculty of Medicine, Menoufia University, Menoufia, Egypt.
- 8) Internal Medicine Department, Texas Tech University Health Science Center, Lubbock, Texas, USA
- 9) Cardiology Department, Faculty of Medicine, Ain Shams University, Cairo, Egypt.

THANK YOU

