Aspirin or Rivaroxaban for VTE Prophylaxis after Hip or Knee Arthroplasty

FEBRUARY ۲۲, ۲۰۱۸

PRESENTED BY: MEHDI MOVAFAGH, POURYA FARHANGI

SUPERVISOR: DR AZADE KHORASANI

MAY ۳۰, ۲۰۱۸

The NEW ENGLAND JOURNAL of MEDICINE

TEHRAN UNIVERSITY
OF
MEDICAL SCIENCES

Aspirin or Rivaroxaban for VTE Prophylaxis after Hip or Knee Arthroplasty

- Introduction

- Methods

- Results

- Conclusion

Introduction

Total hip or total knee arthroplasty

⬇

Venous thromboembolism

⬇

Prevention

Introduction

Aspirin

vs.

Rivaroxaban

Methods

- A double blind RCT in ۱۵ health centers

- Inclusion criteria

- Exclusion criteria
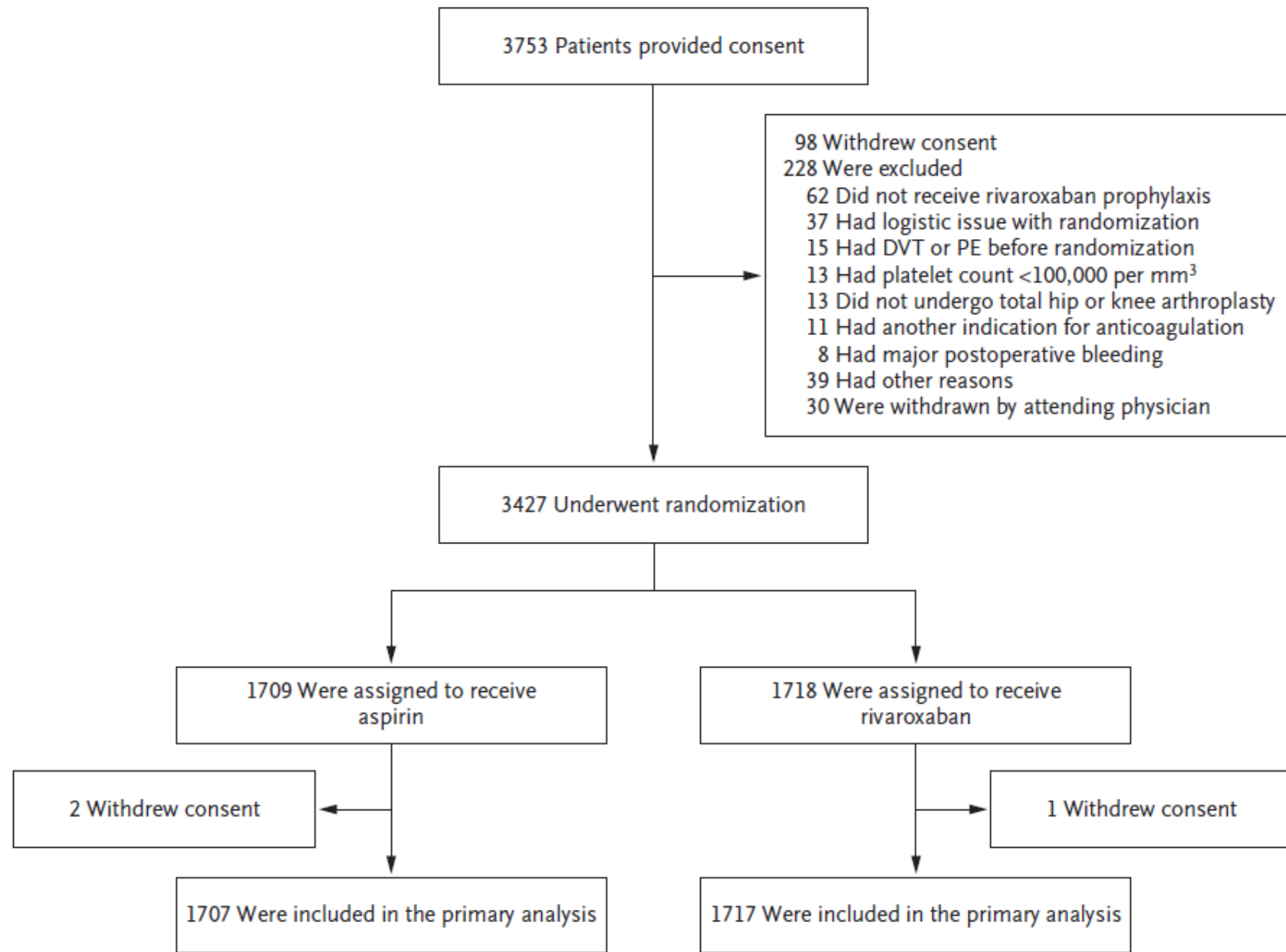
Methods

- Trial procedure and randomization

- Trial outcomes

- Statistical analysis

Results

- Patients

- Subgroup analysis

Enrollment & outcomes

Figure 1. Enrollment and Outcomes.

DVT denotes deep-vein thrombosis, and PE pulmonary embolism.

Table 1. Characteristics of the Patients at Baseline, According to Surgical Subgroup.*

Characteristic	Total Hip Arthroplasty		Total Knee Arthroplasty		All Patients	
	Rivaroxaban (N=902)	Aspirin (N=902)	Rivaroxaban (N=815)	Aspirin (N=805)	Rivaroxaban (N=1717)	Aspirin (N=1707)
Age — yr	60.9±11.0	61.3±11.1	64.7±8.4	64.6±8.7	62.7±10.1	62.9±10.1
Male sex — no. (%)	480 (53.2)	486 (53.9)	353 (43.3)	318 (39.5)	833 (48.5)	804 (47.1)
Body-mass index†	29.4±5.8	29.4±6.0	32.7±6.8	33.0±7.2	31.0±6.6	31.1±6.8
Risk factors — no. (%)						
Previous venous thromboembolism	22 (2.4)	20 (2.2)	22 (2.7)	17 (2.1)	44 (2.6)	37 (2.2)
Previous surgery	28 (3.1)	30 (3.3)	18 (2.2)	28 (3.5)	46 (2.7)	58 (3.4)
Cancer	19 (2.1)	17 (1.9)	19 (2.3)	25 (3.1)	38 (2.2)	42 (2.5)
Current smoker	86 (9.5)	83 (9.2)	71 (8.7)	79 (9.8)	157 (9.1)	162 (9.5)
Hemoglobin — g/liter	140.4±12.5	140.2±13.0	138.2±12.8	138.0±12.8	139.4±12.7	139.2±12.9
Mean platelet count per mm^3	241,200	238,700	240,700	244,100	240,900	241,200
Type of surgery — no. (%)						
Primary	802 (88.9)	809 (89.7)	770 (94.5)	760 (94.4)	1572 (91.6)	1569 (91.9)
Revision	64 (7.1)	52 (5.8)	44 (5.4)	42 (5.2)	108 (6.3)	94 (5.5)
Resurfacing	35 (3.9)	41 (4.5)	NA	NA	35 (2.0)	41 (2.4)
Other	1 (0.1)	0	1 (0.1)	3 (0.4)	2 (0.1)	3 (0.2)

Table 2. Primary Effectiveness and Safety Outcomes.

Outcome	Rivaroxaban (N=1717)	Aspirin (N=1707)	P Value
	no. of patients (%)		
Venous thromboembolism	12 (0.70)	11 (0.64)	0.84*
Pulmonary embolism	6 (0.35)	5 (0.29)	
Proximal deep-vein thrombosis	4 (0.23)	4 (0.23)	
Pulmonary embolism and proximal deep-vein thrombosis	2 (0.12)	2 (0.12)	
Major bleeding	5 (0.29)	8 (0.47)	0.42
Any bleeding†	17 (0.99)	22 (1.29)	0.43

* P<0.001 for noninferiority, as defined by the upper boundary of the 95% confidence interval for the absolute between-group difference.
† This category includes major bleeding and clinically relevant nonmajor bleeding.

Table 3. Primary Effectiveness and Safety Outcomes, According to Surgical Procedure.

Outcome	Total Hip Arthroplasty			Total Knee Arthroplasty		
	Rivaroxaban (N=902)	Aspirin (N=902)	P Value	Rivaroxaban (N=815)	Aspirin (N=805)	P Value
	no. (%)			no. (%)		
Venous thromboembolism	5 (0.55)	4 (0.44)	1.00*	7 (0.86)	7 (0.87)	1.00†
Pulmonary embolism	2 (0.22)	2 (0.22)		4 (0.49)	3 (0.37)	
Proximal deep-vein thrombosis	1 (0.11)	1 (0.11)		3 (0.37)	3 (0.37)	
Pulmonary embolism and proximal deep-vein thrombosis	2 (0.22)	1 (0.11)		0	1 (0.12)	
Major bleeding	3 (0.33)	3 (0.33)	1.00	2 (0.25)	5 (0.62)	0.29
All bleeding‡	7 (0.78)	11 (1.22)	0.48	10 (1.23)	11 (1.37)	0.83

* P=0.001 for noninferiority.
† P=0.03 for noninferiority.
‡ This category includes major bleeding and clinically relevant nonmajor bleeding.

Table 4. Subgroup Analysis of Primary Outcomes, According to Use of Long-Term Aspirin Therapy.

Outcome	Long-Term Aspirin Therapy			No Long-Term Aspirin Therapy		
	Rivaroxaban (N=429)	Aspirin (N=426)	P Value	Rivaroxaban (N=1288)	Aspirin (N=1281)	P Value
	no. (%)			no. (%)		
Venous thromboembolism	3 (0.70)	3 (0.70)	1.00	9 (0.70)	8 (0.62)	1.00*
Major bleeding	1 (0.23)	4 (0.94)	0.22	4 (0.31)	4 (0.31)	1.00
All bleeding†	5 (1.17)	8 (1.88)	0.42	12 (0.93)	14 (1.09)	0.70

* P<0.001 for noninferiority.
† This category includes major and clinically relevant nonmajor bleeding.

Conclusion

- EPCAT I

- EPCAT II

Conclusion

Not significantly different

THANKS FOR YOUR ATTENTION