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Gender-related differences in venous thromboembolism patients: GARFIELD-VTE

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BACKGROUND

- Venous thromboembolism (VTE) is a common cause of morbidity and mortality worldwide.
- There is a paucity of research investigating the influence of gender on characteristics, treatment patterns and outcomes in VTE patients[1].
- The Global Anticoagulant Registry in the FIELD (GARFIELD)–VTE is an on-going non-interventional, prospective, observational study of VTE management and outcomes[2].

PURPOSE

- Compare the baseline characteristics, treatment patterns, and 12-month clinical outcomes between males and females treated with anticoagulation therapy in GARFIELD-VTE.

METHODS

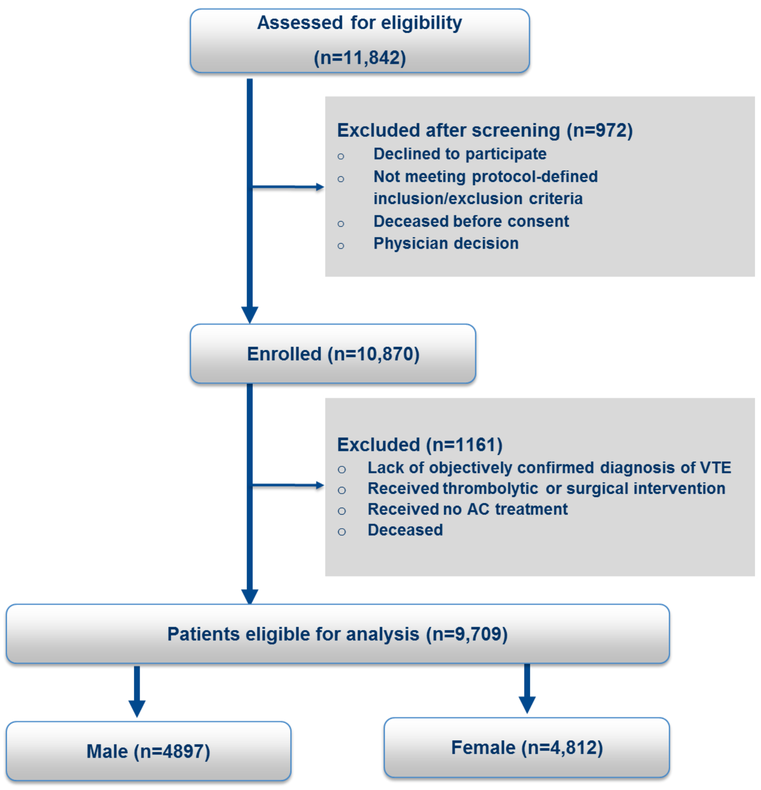
- Eligible patients were required to be ≥18 years of age, with a confirmed diagnosis of acute VTE (either as a primary or recurrent event) within 30 days of entry into the study, and being actively managed for VTE.
- All patients provided written informed consent. The study was approved by the individual ethics committees of each participating site.

RESULTS

Study design

- Between May 2014 and January 2017, 11,842 patients were assessed for entry into GARFIELD-VTE. 10,870 patients from 415 sites in 28 countries were successfully enrolled, 9,709 of whom were eligible for analysis (Figure 1).

Figure 1. ***Study population***



Study population

- The patient demographics and clinical characteristics are summarized in Table 1.

Table 1. ***Baseline demographics***

	Male (n=4897)	Female (n=4,812)
Age, years, median (IQR)	59 (47-69)	60 (43-72)
Body mass index, kg/m², median (IQR)	27.2 (24.4-30.7)	27.6 (23.7-32.8)
Current/previous smoker, n (%)	2582 (55.0)	1047 (22.6)
Site of VTE, n (%)		
DVT alone	3012 (61.5)	2978 (61.9)
PE alone	1100 (22.5)	1192 (24.8)
PE + DVT	785 (16.0)	642 (13.3)
Ethnicity, n (%)		
Asian	715 (15.5)	942 (20.9)
Black	158 (3.4)	266 (5.9)
Caucasian	3,440 (74.6)	2,973 (66.1)
Multi-racial	22 (0.5)	25 (0.6)
Other	176 (3.8)	211 (4.7)
Unwilling to declare	4 (0.1)	4 (0.1)
Unknown	95 (2.1)	78 (1.7)
Missing	287	313
Risk Factors, n (%)		
Active cancer*	413 (8.4)	445 (9.2)
History of cancer	514 (10.5)	574 (11.9)
Recent bleed/anaemia	105 (2.1)	214 (4.4)
Previous VTE	808 (16.5)	666 (13.8)
Immobilization	227 (4.6)	308 (6.4)

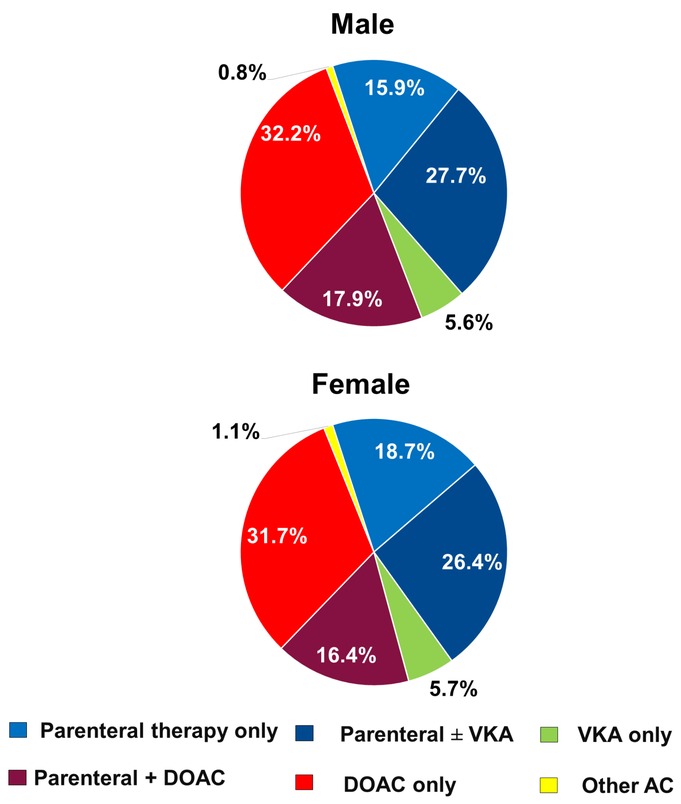
*Cancer ≤ 90 days before and up to 30 days after VTE diagnosis

DVT: Deep vein thrombosis. PE: pulmonary embolism

Anticoagulation at baseline

- No significant differences were found between anticoagulation treatment patterns at baseline between genders (Figure 2).

Figure 2. ***Anticoagulation at baseline***

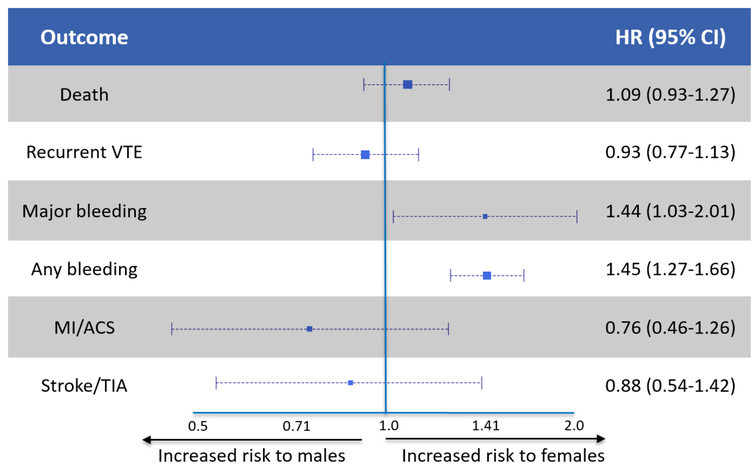


Baseline was defined as ±30 days of VTE diagnosis

12 Month Clinical Outcomes

- Over 12 months follow-up, event rates of all-cause mortality and recurrent VTE were comparable between genders (Table 2).
- Any bleeding and major bleeding was significantly more frequent in females compared to males (p<0.0001 and p=0.0292, respectively) (Table 2).

Table 2. ***Unadjusted hazard ratios for 12 months follow up***

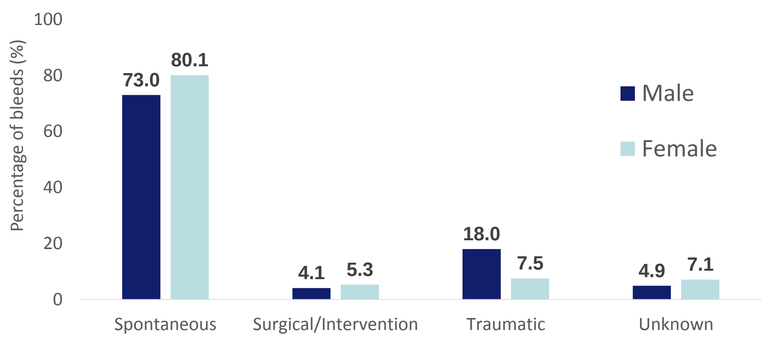


Hazard ratios (95% confidence interval) are unadjusted. MI: Myocardial infarction. ACS: Acute coronary syndrome. TIA: Transient ischemic attack.

Cause of bleeding

- Traumatic (non-surgical) bleeds were more frequent in male VTE patients compared to females (Figure 3).

Figure 3. ***Cause of bleeding***



CONCLUSIONS

- Despite no differences in anticoagulation treatment at baseline, female VTE patients have an increased risk of bleeding compared to males over 12-months follow up.
- Future studies will investigate the influence of anticoagulation on outcomes in male and female VTE patients.

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DECLARATION OF INTEREST

Paolo Prandoni: Personal fees from Bayer Pharma, Pfizer, Daiichi-Sankyo and Sanofi. Alexander G. G. Turpie: Personal fees from Bayer Pharma AG, Janssen. Sylvia Haas: Honoraria from Aspen, Bayer Healthcare, Bristol Myers Squibb, Daiichi-Sankyo, Portola, Sanofi. Walter Ageno: Honoraria from Boehringer Ingelheim, Bayer Pharmaceuticals, BMS-Pfizer and Daiichi-Sankyo. Research support from Bayer Pharmaceuticals and Boehringer Ingelheim. Jeffrey I. Weitz: Honoraria from Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Daiichi-Sankyo, Ionis, Janssen, Merck, Portola, Pfizer, Servier and Novartis. Samuel Z. Goldhaber: Grants from BiO2 Medical, Boehringer-Ingelheim, Bristol Meyers Squibb, BTG EKOS, Daiichi-Sankyo, National Heart Lung and Blood Institute of the National Institutes of Health, Janssen and the Thrombosis Research Group. Personal fees from Bayer, Boehringer-Ingelheim, Bristol Meyers Squibb, Daiichi-Sankyo, Janssen, Portola, Zafgen. Shinya Goto: Research funding from Ono, Bristol Myers Squibb, Sanofi, and Pfizer. Joern Dalsgaard Nielsen: Honoraria from Bayer, Boehringer-Ingelheim, Bristol Myers Squibb, Leo Pharma and Pfizer. Sebastian Schellong: Speaker fees from Bayer Healthcare, Boehringer Ingelheim, Bristol Meyer Squibb, Daiichi-Sankyo, Sanofi Aventis and Pfizer. Consultancy fees from Bayer Healthcare, Boehringer Ingelheim, Daiichi-Sankyo, Sanofi Aventis and Pfizer. Henri Bounameaux: Research grant, speaker's fees and honoraria from Daiichi-Sankyo, Bayer Healthcare and Sanofi-Aventis. Lorenzo Mantovani: Grants and personal fees from Bayer Healthcare, Boehringer Ingelheim, Pfizer and Daiichi-Sankyo. Ajay K Kakkar: Research Grants from Bayer Healthcare; Personal fees from Bayer Healthcare, Boehringer-Ingelheim Pharma, Daiichi-Sankyo Europe, Sanofi SA and Janssen Pharma. Pantep Angchaisuksiri, Alfredo E. Farjat and Gloria Kayani declare that they have no conflicts of interest in the research.

TRI Thrombosis Research Institute

www.garfieldregistry.org

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VTE Garfield
global anticoagulant registry in the field