United Kingdom
Foot and Ankle Thrombo-Embolism Audit

(UK-FATE Audit)

Council Report

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1. Executive Summary

Introduction

The last BOFAS VTE position statement was published by BOFAS Scientific Committee in September 2017 (click here to access). NICE guidance on venous thrombo-embolism (VTE) prophylaxis for hip and knee arthroplasty has been amended since and helped units in the country to achieve a uniform approach in the management of this controversial clinical problem. There is wide variation in the threshold and provision of thromboprophylaxis in the treatment of foot and ankle conditions and units may have varying protocols. One of the difficulties in affecting change in practice in this area is the low incidence of postoperative, symptomatic VTE. Therefore, a large number of patients need to be included in any analysis for meaningful conclusions to be drawn.

It may be useful for BOFAS to take a position on VTE prophylaxis after foot and ankle surgery, but data is needed to achieve this effectively. In order to obtain sufficient numbers of patients, pooling of data from a number of centres is required.

Objectives

The primary objective was to observe the UK-wide variation in post-operative thromboprophylaxis, and to analyse the 90-day incidence of symptomatic VTE related to elective foot and ankle surgery, trauma foot and ankle surgery, and the treatment of Achilles tendon ruptures (managed operatively and non-operatively).

Design

UK-wide Multicentre prospective national audit.

Setting

UK-based audit on foot and ankle patients who underwent surgery in an operating theatre (or treatment for Achilles tendon ruptures) between the 1st of June to 30th of November 2022.

Participants

All patients aged 16 years and over undergoing any foot and ankle surgery in an operating theatre during the audit period in the 68 participating centres in England, Scotland, and Wales.

Main Outcome Measures

Variables recorded included demographics, surgical data, comorbidity data, VTE prophylaxis data (chemical and mechanical), VTE rates / type, mortality rates, complications, and infection rates.

Types of Anticoagulation

There were 11 different chemical anticoagulation treatments recorded across the cohort. A total of 3,630 (32.71%) received no chemical anticoagulation. The most common chemical anticoagulation received was low molecular weight heparin (6,303, 56.79%). Factor Xa Inhibitors were used in 6.70% (744) and Aspirin in 2.78% (308). Data was missing for 476 patients (6.4%). Most chemical anticoagulation treatments were used for over 6 weeks (64.5%), which was consistent across the different types of thromboprophylaxis.

Incidence of VTE (within 90-days of surgery / Achilles treatment)

11,363 patients were included. In total 0.87% of patients were diagnosed with a symptomatic VTE (n=99). The mean time to VTE was 36.61 days from admission (range 0 to 88 days). There were 34 symptomatic Deep Vein Thromboses (DVT) in the operated limb distal to the knee (0.30%), 16 symptomatic DVTs of the operated limb proximal to the knee (0.14%), 7 symptomatic DVTs in the non-operated limb (0.06%), 38 symptomatic Pulmonary Emboli (PE, 0.33%) and 4 cases with combined DVT and PEs (0.04%).

VTE related mortality

There were 3 cases of VTE related mortality (0.03% of all cases, 3% of VTE cases). All of these were following surgery for ankle trauma.

Risk Factors for VTE

Post-operative chemical anticoagulation (without adjustment for other variables) is associated with a greater risk of 90-day VTE (OR 3.18) compared to those not taking chemical anticoagulation. However, patients who received no chemical prophylaxis had significantly less past history of VTE, were almost exclusively weight bearing and were less commonly smokers. There are multiple factors between the groups, including it being more likely that the more serious and complex procedures are given chemical anticoagulation, and those assumed to have a reduced risk of VTE on assessment were not provided with chemical anticoagulation. Characteristics and severity of patients differ between procedures, and VTE prevalence is low, making it difficult to draw any robust causal relationship.

Univariable and multivariable analysis was performed on risk factors for VTE. On the Univariable associations for increased age and ASA grade show higher odds of 90-day VTE, as do having previous cancer, stroke, or history of VTE. The odds of a 90-day VTE differ depending on the type of foot and ankle procedure. On multivariable analysis, the strongest predictors for 90-day VTE were found to be the type of foot and ankle procedure (Achilles tendon rupture, operative or non-operative, OR 9.84 – 12.83) and the ASA grade (ASA grade 3/4, OR 2.70).

Summary

The incidence of 90-day post procedure VTE in foot and ankle surgery in this national audit in the UK was 0.87% and VTE related mortality of 0.03%. There was significant variability of chemical anticoagulants reported in the study, with 11 different anticoagulants used. The significant risk factors reported in the study of development of 90-day symptomatic VTE on multivariable analysis were Achilles tendon rupture management and high ASA grade.

Key Messages

- VTE rates following foot and ankle surgery with and without anticoagulation are low despite significant variability in type of anti-coagulation.
- Patients with ASA grade 3 or 4 were roughly x2.5 more likely to get a VTE.
- Patients with Achilles tendon ruptures were roughly x10 more likely to get a VTE.

2. Introduction

Venous thromboembolism (VTE) is a hazardous and potentially life-threatening complication which can occur following lower limb surgery. In regards to foot and ankle surgery specifically, Mangwani et al published a systematic review regarding the use of chemical prophylaxis in the literature, reporting the overall incidence of symptomatic VTE to be low post foot and ankle surgery with an approximate incidence of <1%.[1] Nevertheless, despite being recognised as a possible complication of numerous surgical procedures, there is an absence of agreement on contributing risk factors in the development in VTE in foot and ankle surgery and what thromboprophylaxis is required. This lack of consensus warrants attention to identify strategic measures aimed at diminishing risks linked with this potentially life-threatening ailment and to allow accurate informed consent discussion.

In foot and ankle surgery, various factors have been reported to contribute to an increased risk of VTE. These encompass, patient-related aspects, surgical-related elements, as well as postoperative factors.[1-3] The use of chemical anticoagulation is common, especially if the lower limb is encased in a cast or if the patient is not allowed to bear weight. The use of chemical anticoagulation has been reported to reduce the risk of symptomatic VTE with Hickey *et al.* reporting in their review of below knee cast treatment of foot and ankle trauma that the use of low molecular weight heparin was protective against symptomatic DVT.[3] Similar findings have also been reported by Heijboer *et al.* in patients undergoing surgery distal to the tibial articular surface.[2] However the POT-CAST study found no evidence that low molecular weight heparin reducing the risk of symptomatic VTE following lower limb cast immobilisation.[4]

1. Mangwani J, Sheikh N, Cichero M, et al. *What is the evidence for chemical thromboprophylaxis in foot and ankle surgery? Systematic review of the English literature.* Foot (Edinb). 2015;25(3):173-178.
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3. Hickey BA, Watson U, Cleves A, et al. *Does thromboprophylaxis reduce symptomatic venous thromboembolism in patients with below knee cast treatment for foot and ankle trauma? A systematic review and meta-analysis.* Foot Ankle Surg. 2018;24(1):19-27.
4. van Adrichem RA, Nemeth B, Algra A, et al. *Thromboprophylaxis after Knee Arthroscopy and Lower-Leg Casting.* N Engl J Med. 2017;376(6):515-525.

2.1. Scope

The UK-FATE Audit was approved by the BOFAS Outcomes and Scientific Committees in March 2022, on the back of the success of the UK-FALCON Audit. As elective activity resumed post-pandemic in most units it was felt that it was an opportune moment for a UK-wire collaborative effort to help answer important questions about VTE and inform our future practice.

The **primary aim** was to analyse the 90-day incidence of symptomatic VTE related to elective foot and ankle surgery, trauma foot and ankle surgery and following the treatment of Achilles tendon ruptures (operative and non-operative).

Secondary aims were to assess the chemical anticoagulation variability in the UK and assimilate risk factors associated with development of symptomatic VTE in foot and ankle surgery in the UK.

3. Set-up

3.1. Protocol

The full protocol for UK-FATE Audit can be found in **Appendix 1**.

3.2. Funding

Leicester Hospitals Charity provided funding to cover the NIHR Biomedical Research Centre Data staff costs and the REDCap data platform (Ref: APP7681). All other activity related to this project was cost neutral. The total amount granted was £4930.

The funders had no role in the design, analysis or reporting of the audit.

3.3. Recruitment

Following agreement of collaboration between the BOFAS Scientific and Outcomes committees to the project proposal, a request was made to the BOFAS membership for an expression of interest to partake in the audit. A total of 68 centres expressed an interest to take part in the audit. The audit was approved and registered as a clinical audit at the lead centre Leicester (Ref No. 11908a.). To participate, each local project lead needed to confirm local audit approval and sign a data processing agreement form **(Appendix 1).** Two lead consultants and six trainees per site were encouraged to take part.

Once agreements were in place, registered sites had access to data support, a help sheet, and a walkthrough video **(Appendix 1).**

The final list of units and collaborators contributing data to the UK-FATE Audit is listed in **Appendix 2**.

4. Methods

4.1. Design

Multicentre prospective national audit.

4.2. Setting

UK-based audit in patients who underwent foot and ankle surgery between the 1st of June 2022 to 30th of November 2022.

4.3. Participants

All patients 16 years of age or over undergoing foot and ankle surgery in an operating theatre, and who presented with an Achilles tendon rupture during the audit period. Patients included from 68 participating centres in England, Scotland, and Wales.

4.4. Data Protection

A data processing agreement **(Appendix 1)** was drawn up in line with EU standards (*Regulation (EU) 2016/679*) and GDPR regulations (*Directive 95/46/EC*). This was ratified by the **BOFAS Caldicott Guardian** (Mr Mark Davies), the **BOFAS Senior Information Risk Officer** (Mr Lyndon Mason), and the **BOFAS Data Protection Officer** (Ms Jo Millard). The agreement was sent to each participating trust, to be signed by their data protection officer. The principal investigator at each site was responsible for registering the audit locally and ensuring data handling on site met the requirements.

4.5. Data Collection

A single datasheet required completion at each site. This comprised the main data set where patient demographics such as sex, age, ethnicity, American Society of Anaesthesiologists (ASA) physical status classification were collected.

VTE related data that was recorded included the presence of VTE, timing of VTE, location of VTE and VTE related mortality. We also recorded type of prophylaxis given (chemical and mechanical), duration of prophylaxis, pre-existing anti-coagulation, splintage of limb and pre-operative anticoagulation.

Surgery related variables were included. The foot and ankle diagnoses were recorded as categorical data. The diagnosis was classified based on limited variables based broadly on trauma, diabetic and elective practice. This was further divided by anatomical region and procedure. Operative variables included urgency (elective or emergency surgery), primary procedure completed (classified into manipulation under anaesthetic/plaster, percutaneous surgery, external fixation, open surgery, injection and arthroscopic procedure as categorical data), and anaesthesia used (local, regional, general or combination). Other surgical data included length of stay (days), urgency of surgery, and length of operation and tourniquet time (recorded in minutes, including anaesthetic time).

Dates recorded included date of injury for trauma and date of listing for elective, date of admission, date of surgery and date of discharge. Emergency surgery was defined as procedures classified by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) as immediate, urgent, or expedited. Comorbidities were entered as binary data (yes/ no) into columns for current smoker, asthma/COPD, cancer, chronic kidney disease, cardiac disease, dementia, or other comorbidities to be entered as free text.

Other outcomes included surgical-related infection (recorded as either superficial or deep), complications as binary data (surgery related and non-surgery related) and the ability to free text. Mortality was entered as categorical data (alive, mortality related to VTE, mortality related to surgery, mortality unrelated). Before locking of the dataset for analysis, the senior local principal investigator for each hospital was asked to confirm data completeness and that all eligible patients had been entered into the database.

4.6. Data Validation

Patient identifiable data was anonymised, and each registered site was required to submit an encrypted password protected version of their data sheet to a secure nhs.net account at the lead site (Leicester). Data validation was completed by the NIHR Leicester Biomedical Research Centre team via Excel.

4.7. Data Cleansing

Any queries or missing data were referred to the site personnel for amendment / clarification. Once data had been verified, this was added to **REDCap** - Research Electronic Data Capture web application (REDCap, Vanderbilt, Tennessee). The complete REDCap dataset was exported into SPSS – Statistical Package for the Social Sciences, for analysis.

4.8. Statistical Analysis

All data was assessed using **SPSS Version 26.0** (SPSS Inc., IBM, Chicago, IL). Analysis was carried out in accordance with STROBE guidelines.

Continuous variables were tested for normality distribution, and presented as means and 95% confidence intervals. Whereas categorical and qualitative variables are expressed as numbers and percentages. The Student t-test and ANOVA was used for continuous variables if the criteria for normality and equality of variances were fulfilled. Alternatively, the Mann-Whitney U test was performed. Categorical variables were analysed using the Chi-square test for sample sets greater than 5, otherwise the Fisher's exact test was used. Missing data were included in flowcharts and descriptive analyses, allowing denominators to remain consistent in calculations.

The association between VTE and Post-Operative Thromboprophylaxis was assessed with a univariable logistic regression model. Odds ratios, 95% confidence intervals, and p-values will be presented. Other risk factors suspected to be associated with risk of VTE were investigated, focusing on the following candidate risk factors; patient age, sex, ASA grade, comorbidities (cancer, diabetes, stroke), previous history of VTE, smoking status, foot and ankle procedure, and post-surgery weight-bearing status. Univariable associations with risk of VTE were assessed using univariable logistic regression models. A multivariable logistic regression model containing all candidate factors was presented, and a reduced model (with variables selected using forward stepwise methods and p-value threshold =0.05 using the stacked data approach for multiple imputed data) will be presented to identify key predictors for risk of VTE.

Prior to analysis, missing information for the above candidate risk factors, including post-operative chemical thromboprophylaxis, were imputed using multiple imputation using chained equations. The imputation models included chemical thromboprophylaxis and outcome variables, and 15 imputed datasets will be created. Rubin's Rules were applied to combine results across all imputed datasets.

5. Results

5.1. Inclusions and Exclusions

A total of 13,569 cases were submitted from 68 centres across the UK. Patients who had multiple operations during the audit period were identified and patients who did not meet the inclusion criteria were excluded. A total of 11,363 patients were left for analysis (**Figure 1**).

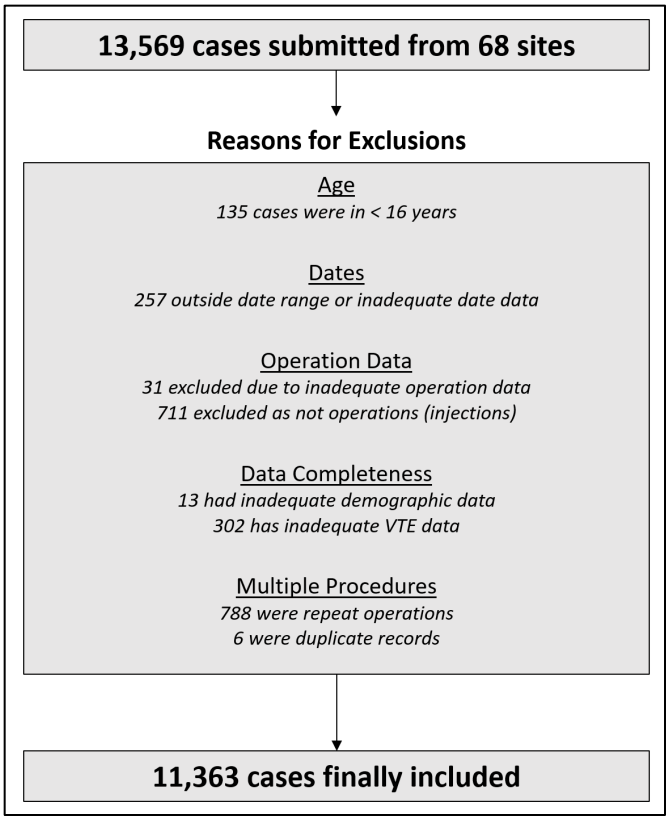

Figure 1: Total number of cases submitted, and final number of patients included after merging / exclusions

5.2. Data Submitted and Completion Rate

All regions in the UK were represented. The breakdown of categories used in final analysis, the completion of data, and the breakdown by category of surgery (elective, trauma, Achilles tendon operative / non-operative) are shown in **Appendix 3**.

5.3. Types of Anticoagulation

There were eleven different chemical anticoagulation treatments recorded across the cohort (**Table 1**). A total of 3,630 (32.71%) received no chemical anticoagulation. The most common chemical anticoagulation received was low molecular weight heparin (6,303, 56.79%). Factor Xa Inhibitors were used in 6.70% (744) and Aspirin in 2.78% (308). Data was missing for 476 patients (6.4%) (**Figure 2**). Most chemical anticoagulation treatments were used for over 6 weeks (64.5%), which was consistent across type of thromboprophylaxis (**Table 2**). No statistically significant difference was found between types of chemical prophylaxis and VTE rate.

Chemical Thromboprophylaxis Type	*n*	Percent
None	3630	32.71%
Enoxaparin	3570	32.17%
Dalteparin	2383	21.47%
Rivaroxaban	513	4.62%
Tinzaparin	350	3.15%
Aspirin	308	2.78%
Apixaban	231	2.08%
Warfarin	32	0.29%
Heparin	14	0.13%
Dabigatran	10	0.09%
Fondaparinux	6	0.05%
Other	52	0.47%

Table 1: Types of Chemical thromboprophylaxis used (missing for 264 patients)

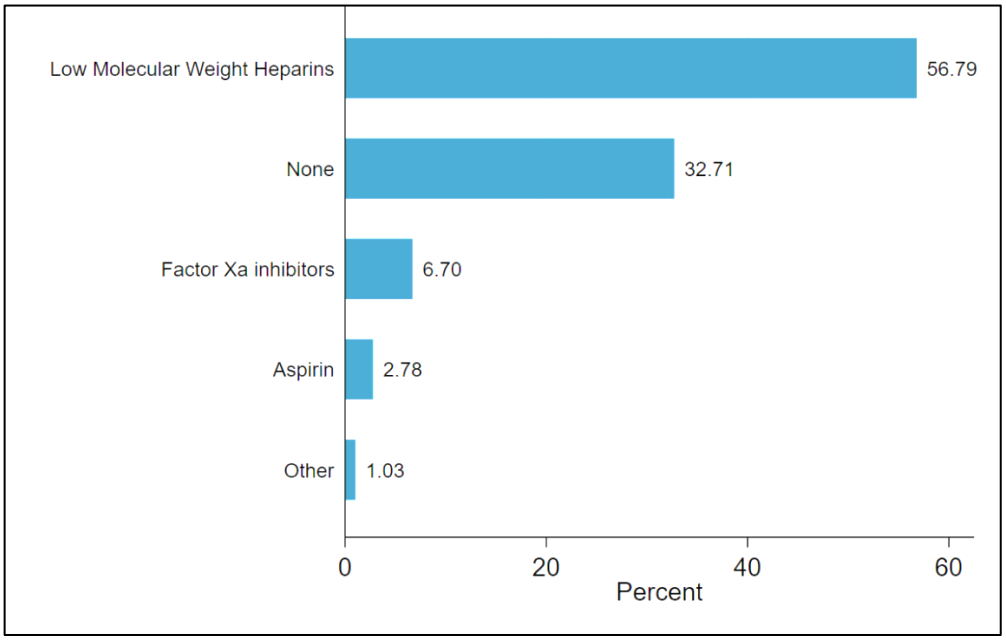

Figure 2: Chemical thromboprophylaxis used and duration (weeks)

Chemical Thromboprophylaxis Duration (Weeks)	Number	Percent	Low Molecular Weight Heparins	Aspirin	Factor Xa inhibitors	Other
<2 weeks	316	4.5	294 (4.9%)	2 (0.7%)	13 (2.1%)	7 (11.7%)
2 to 6 weeks	2,164	31.0	1,857 (30.8%)	129 (45.6%)	164 (26.5%)	14(23.3%)
≥6 weeks	4,513	64.5	3,879 (64.3%)	152 (53.7%)	443 (71.5%)	39 (65.0%)

Table 2: Chemical thromboprophylaxis used and duration (weeks)

5.4. Incidence of VTE within 90 days

There were 99 cases of VTE within 90 days of admission across the whole group - Total incidence = 0.87% (95% CI 0.7% to 1.1%). The 90-day incidence of VTE by surgery group is illustrated in **Figure 3** and **Table 3**. The mean time to VTE was 36.61 days from admission (95% CI 28.76, 44.46) with a range from 0 to 88 days.

Regarding location of VTE, there were 34 symptomatic DVTs in the operated limb distal to the knee (0.30%), 16 symptomatic DVTs of the operated limb proximal to the knee (0.14%), 7 symptomatic DVTs in the non-operated limb (0.06%), 38 symptomatic PEs (0.33%) and 4 cases with combined DVT and PE (0.04%).

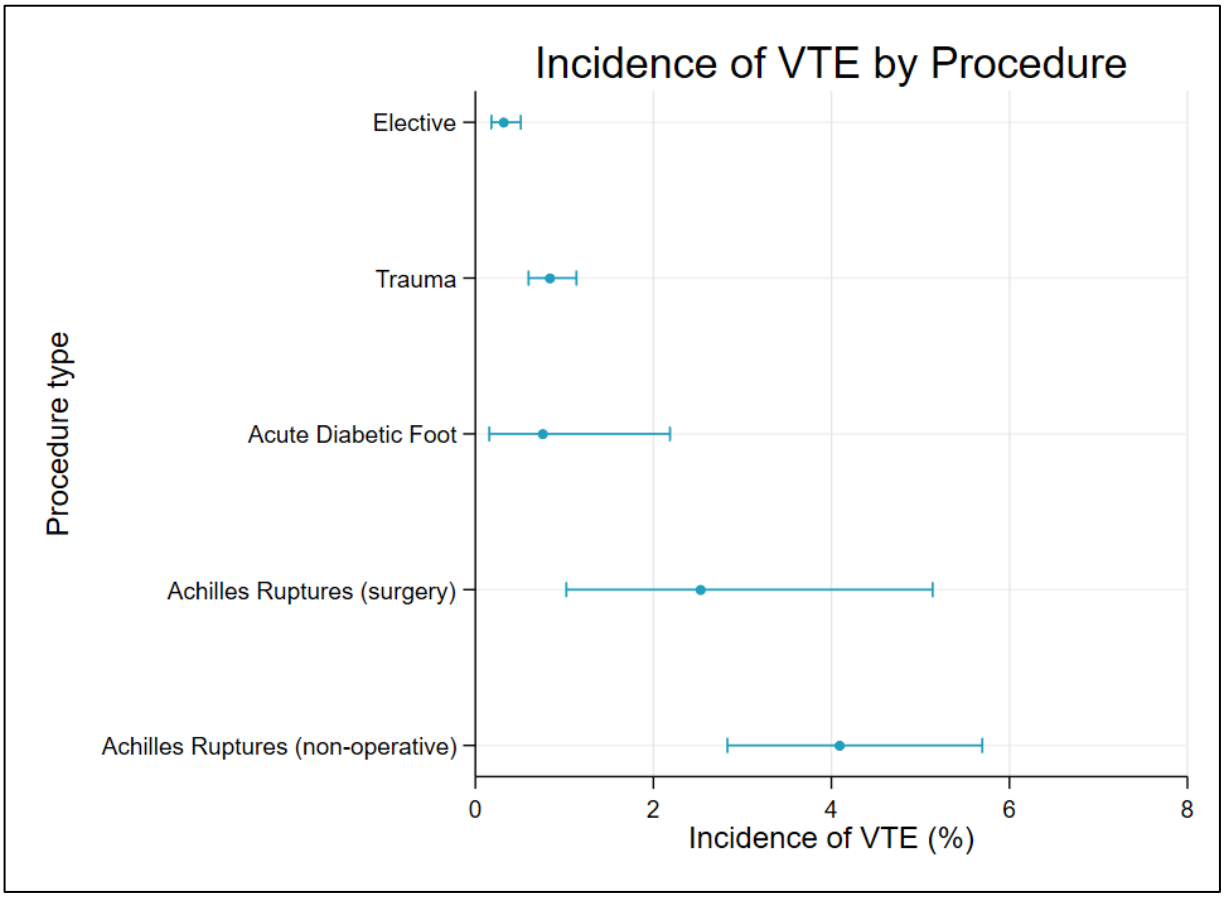

Figure 3: Incidence of VTE by procedure

Surgery Type	*n*	VTE events	Incidence	95% CI
Elective	5,090	16	0.31 %	0.18 to 0.51 %
Trauma (excl. Achilles ruptures)	4,791	40	0.83 %	0.59 to 1.14 %
Acute Diabetic Foot	398	3	0.75 %	0.16 to 2.19 %
Achilles Ruptures (undergoing surgery)	277	7	2.53 %	1.02 to 5.14 %
Achilles Ruptures (non-operative)	807	33	4.09 %	2.83 to 5.70 %

Table 3: Incidence of VTE by procedure

5.5. VTE related Mortality

There were 3 cases of VTE associated mortality (0.03%), all occurring following ankle trauma procedures. Details of these cases can be found in **Appendix 4**.

5.6. Risk Factors for VTE

Post-operative chemical anticoagulation (without adjustment for other variables) is associated with a greater risk of 90-day VTE (OR 3.18) compared to those not taking chemical anticoagulation. However, patients who received no chemical prophylaxis had significantly less past history of VTE, were almost exclusively weight-bearing and were less commonly smokers. There are multiple factors between the groups, including it being more likely that the more serious and complex procedures are given chemical anticoagulation, and those assumed to have a reduced risk of VTE on assessment were not provided with chemical anticoagulation. Therefore, this unadjusted increase in VTE risk on chemical anticoagulation is not testable on our current data.

Univariable and multivariable analysis on risk factors for VTE are displayed in **Table 4**. On the Univariable associations for increased age and ASA grade show higher odds of 90-day VTE, as do having previous cancer, stroke, or history of VTE. Odds of 90-day VTE differ depending on the type of foot and ankle procedure. On multivariable analysis, strongest predictors for 90-day VTE were type of foot and ankle procedure (Achilles tendon rupture, operative or non-operative, OR 9.84 – 12.83) and the ASA grade (ASA grade 3/4, OR 2.70).

		Univariable OR (90% CI) *p-value*	Fully adjusted model OR (90% CI) *p-value*	Reduced model OR (90% CI) *p-value*
Thromboprophylaxis	Yes	**3.18 (1.77, 5.71)** ***<0.001***	1.78 (0.91, 3.46) *0.091*	
Age (Years)		**1.01 (1.00, 1.02)** ***0.027***	1.01 (0.99, 1.02) *0.392*	
Sex	Male	1.42 (0.95, 2.11) *0.087*	0.97 (0.62, 1.5) *0.630*	
ASA Grade *(Compared to ASA I)*	Grade II Grade III-IV	1.69 (0.91, 3.12) **2.65 (1.35, 5.18)** ***0.021***	1.74 (0.89, 3.4) 2.39 (0.93, 6.16) *0.168*	**2.03 (1.09, 3.79)** **3.64 (1.73, 7.67)** ***0.003***
Cancer	Yes	**2.30 (1.06, 5.01)** ***0.036***	1.71 (0.75, 3.9) *0.206*	
Diabetes	Yes	1.38 (0.78, 2.44) *0.265*	1.27 (0.64, 2.5) *0.496*	
Stroke	Yes	**2.92 (1.26, 6.74)** ***0.012***	2.21 (0.91, 5.37) *0.082*	
Previous Hx of VTE	Yes	2.22 (0.90, 5.51) *0.085*	1.81 (0.7, 4.66) *0.221*	
Current Smoker	Yes	0.84 (0.44, 1.63) *0.611*	0.9 (0.46, 1.78) *0.771*	
Surgical Procedure *(Compared to elective)*	Trauma Acute Diabetic Foot AR (surg) AR (non-op)	**2.70 (1.49, 4.77)** 2.41 (0.70, 8.30) **8.22 (3.35, 20.15)** **13.52 (7.41, 24.68)** **<0.001**	**2.28 (1.21, 4.29)** 1.24 (0.32, 4.8) **9.65 (3.65, 25.53)** **12.85 (6.63, 24.89)** ***<0.001***	**2.77 (1.55, 4.96)** 1.45 (0.40, 5.25) **11.62 (4.62, 29.24)** **14.41 (7.84, 26.48)** ***<0.001***
Weight Bearing Status *(Compared to NWB)*	Full/Partial	0.76 (0.50, 1.14) *0.185*	0.99 (0.61, 1.61) *0.968*	

Table 4: Associations of Risk Factors and VTE (significant differences in **bold**)

6. Interpretation

The primary objective in this study was to assess the symptomatic VTE rate up to 90 days following foot and ankle surgery and Achilles tendon rupture treatment and VTE related mortality up to 90 days following treatment. In this national audit we found the rate of symptomatic VTE to be 0.87% (95% CI 0.7% to 1.1%) with the VTE related mortality to be 0.03% (95% CI 0.005% to 0.08%). The rate of VTE differed across procedure groups, with incidence of symptomatic VTE to be greatest in Achilles tendon ruptures, and lowest incidence in elective surgery.

Another objective of this study was to observe the UK-wide variation in post-operative thromboprophylaxis. The study identified significant variability in chemical prophylaxis across the 68 contributing units, with eleven different chemical anticoagulation treatments recorded. Approximately a third of patients did not receive any chemical thromboprophylaxis, although this was generally in patients with minimal risk, no immobilization and ability bear weight. The most common chemical thromboprophylaxis used across the audit was low molecular weight heparin. Low molecular weight heparin has the greatest support in the literature, including use in national guidelines.[1,2,3,4,5] The use of DOACs for foot and ankle surgery VTE prophylaxis is unproven in randomised control trials, although some centres have published the experience.[6] We did not find any statistically significant difference between VTE rate amongst different types of chemical thromboprophylaxis. However, given the possible confounding variables and the small number of VTE events and patients given certain anticoagulants, we are unable to make robust causal relationships.

The average duration of chemical thromboprophylaxis was approximately 6 weeks. This is in keeping with the National Institute of Clinical Excellence guidelines on reducing the risk of Hospital-acquired VTE, with chemical prophylaxis considered in foot and ankle surgery requiring lower limb immobilisation.[5] In comparison, the mean time for VTE in this study was 5 weeks, within the average duration of chemical prophylaxis use.

The rate of symptomatic VTE in elective surgery in this national audit was the lowest among all procedure types. Considering over 60% of patients undergoing elective surgery were not given chemical anticoagulation, there is a reasonable debate whether foot and ankle elective patients without risk factors, should receive any chemical anticoagulation. Calder *et al.* argued in their meta-analysis that the rate of symptomatic VTE was lower than other general lower limb procedures and not significantly reduced by chemical anticoagulation, and should therefore not be routinely offered for use in elective foot and ankle procedures.[7] Griffiths *et al.* found no significant benefit in the use of Aspirin for chemical thromboprophylaxis in foot and ankle surgery although they recommended that the risk was so low in elective foot and ankle surgery that no thromboprophylaxis was required.[8]

The risk of developing VTE in foot and ankle patients has been variably reported. Mangwani *et al.* noted an increase in VTE risk with an increase in BMI, age over 40, medical comorbidities, use of the contraceptive pill and immobilisation.[1] Nemeth *et al.* created a model with 32 predictors of VTE development in patients with plaster casts, showing a high degree of accuracy in the model in predicting VTE. These included environmental, coagulation and genetic risk factors.[9] Horner conducted a systematic review and found advancing age and injury pattern to be consistently associated with increased VTE risk. BMI was the third most consistent individual risk highlighted, although overall results were conflicting.[10] Brennan *et al.* in a retrospective study of over 15,000 patients reported that patients with VTE were more likely to be older, have dyspnoea, congestive heart failure, dialysis, wound infection, and bleeding disorders. The POT CAST trial reported injury pattern, family history and BMI to be the individual risk factors most associated with VTE risk.[11] The factors in our national audit which were significant on multivariable analysis was a high ASA grade. Horner *et al.* reported that risk assessment methods may potentially improve the cost effectiveness of chemical

thromboprophylaxis by identify patients who will benefit the greatest from it, however the available supporting evidence for their use is weak.[12]

The type of procedure significantly influenced the rate of symptomatic VTE in this national audit. Having an Achilles tendon rupture, either operated or non-operated were significantly associated with an increase rate of symptomatic VTE. Mangwani *et al.* also noted an increase in symptomatic VTE risk in Achilles tendon ruptures and ankle trauma surgery.[1] In studies where all patients underwent doppler sonography, regardless of symptoms, the rate of VTE in Achilles tendon ruptures has been reported as high as 48%.[13] This increased risk of VTE has not currently been mitigated by use of chemical prophylaxis or the use of mobilization. [13,14]

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7. Audit Limitations

This audit has limitations. Due to the complex nature of current treatment decisions, the observed variation in treatments between surgical procedures, and lack of overlap observed in any treatment predicting propensity scores, we were unable to answer these causal questions given the current data.

Odds ratios to assess association between a treatment (or potential risk factors) and VTE within 90-days post-operation can be derived from a multivariable logistic regression model. By testing association in this manner, we can account for confounding which may otherwise unduly influence estimates. In order to answer questions around the effectiveness of the treatment in reducing VTEs, either a RCT or a causal analysis (which captures and controls for confounding) would be required.

Our primary outcome measures looked at rates of VTE and type of prophylaxis, however the numbers of cases of VTE were small. Therefore, even small increases in numbers could change significance and some of the percentages presented may provide a misleading picture. It is therefore important that absolute numbers be considered when using this data to plan future interventions or counselling patients.

Although we had a large number of patients some subgroups were small and so it is difficult draw conclusions on effectiveness of one type of prophylaxis versus another. Nevertheless, this national audit was successful in establishing the rate of VTE and the variability currently in the UK.

8. Key Messages for BOFAS Members

This was the largest prospective dataset examining VTE rates in foot and ankle patients in the UK.

There was significant variability of chemical anticoagulants reported in the study, with 11 different anticoagulants used, although low molecular weight heparin was most common. After adjusting for key confounders there was no statistically significant difference between VTE rates and type of chemical prophylaxis used. However, as characteristics of patients differ between procedures and VTE prevalence is low, it is difficult to draw any robust causal relationships.

The incidence of 90-day post procedure VTE in foot and ankle surgery in this national audit in the UK was 0.87% and VTE related mortality of 0.03%. The significant risk factors reported in the study of development of 90-day symptomatic VTE on multivariable analysis were Achilles tendon rupture management and high ASA grade.

8.1. Take-home points

- Largest prospective dataset of VTE in F&A in the UK:
    - Incidence of VTE (0.87%) and VTE mortality (0.03%) in F&A is low.
    - Strongest risk factor is type of F&A procedure:
        - Achilles Ruptures and Trauma at increased risk compared to elective surgery.
    - Higher ASA grades also a risk factor.

- Characteristics and severity of patients differ between procedures, and VTE prevalence is low, making it difficult to draw any robust causal relationship:
    - Large variation in the prescribing of chemical thromboprophylaxis:
        - Low Molecular Weight Heparins most common (56.7%).
        - A third of patients were not prescribed any prophylaxis (32.7%).
    - Some regional differences.

- The link between chemical prophylaxis and VTEs:
    - After adjusting for some key confounders, we found no statistically significant association between chemical prophylaxis and 90-day VTE.
    - This does not mean that chemical prophylaxis does not affect the risk of VTE events, but we are unable to make any causal claims given the limitations of the study (confounding variables & small number of VTE events).

9. Recommendations and Next Steps

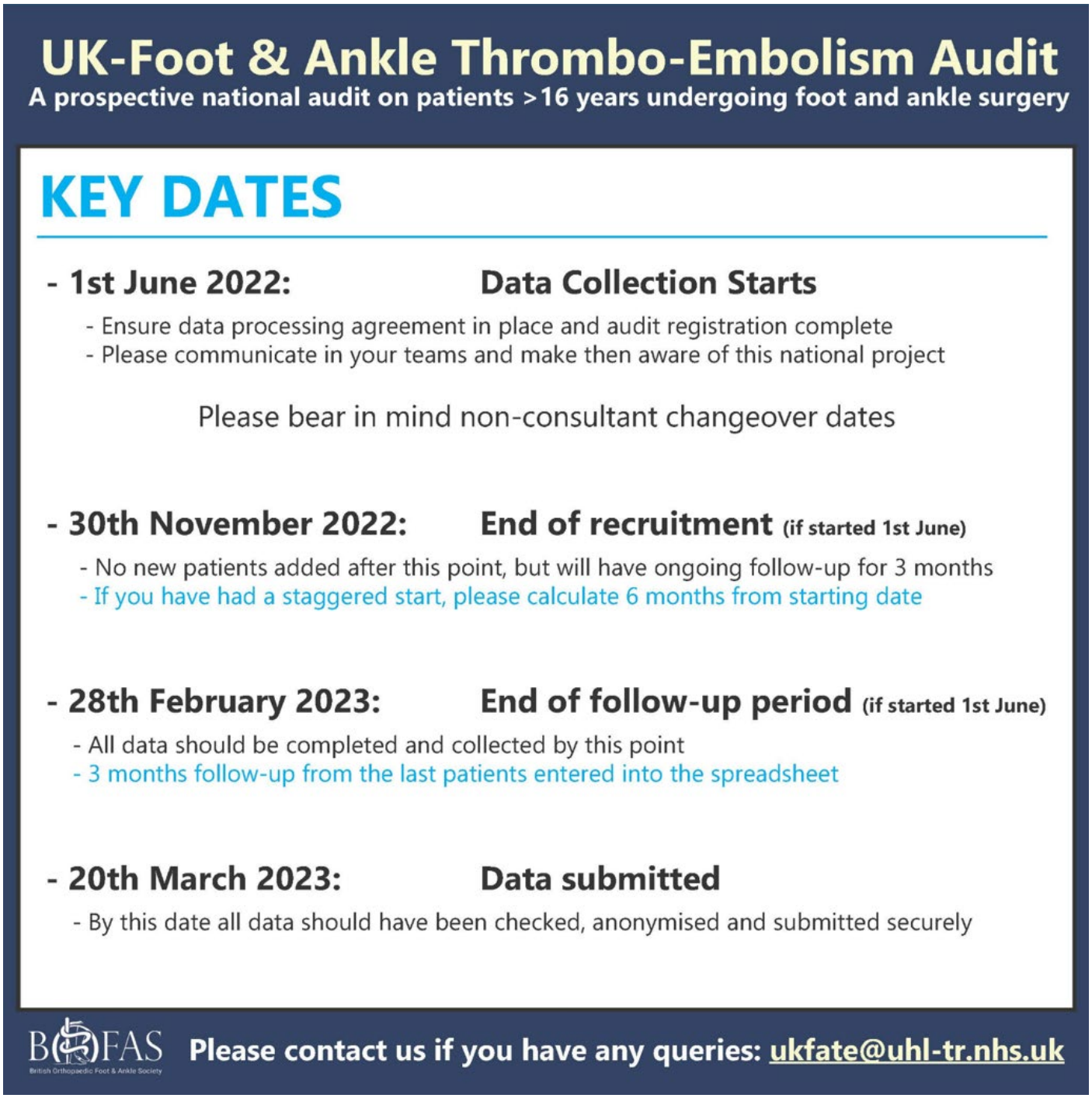
The findings of this report should be made readily available to the BOFAS members and foot and ankle surgeons worldwide. This may be done via this report and publication of data. To this end, clinical papers will be submitted for peer reviewed publication.

We will be further analysing the dataset to examine in more detail the effect of co-morbidities on VTE incidence / mortality, and to analyse the rate of VTE in patients with Achilles tendon ruptures, day cases and to examine the infection risk associated with chemical thromboprophylaxis.

Data from this report may be used by BOFAS / NICE when updating VTE position statements / guidance. Data may also be used for designing further studies to answer specific questions highlighted by this project. Some of these questions include which patients should get thromboprophylaxis, and which agent would be suitably effective.

Appendix 1: UK-FATE Audit Protocol, Data Sheet and Links

Key dates for the UK-FATE Audit:



The BOFAS webpage for the UK-FATE Audit (including FAQ) can be accessed here:

https://www.bofas.org.uk/clinician/research/bofas-national-audits

The protocol for the UK-FATE Audit can be accessed here:

https://www.bofas.org.uk/Portals/0/Miscellaneous/FATE-protocol-v.1.3-2022_04_07.pdf?ver=2mbxsiilM6M%3d

The data sharing agreement for the UK-FATE Audit can be accessed here:

https://www.bofas.org.uk/Portals/0/Miscellaneous/FATE-data_processing_agreement-v.1.2-2022_05_31.pdf?ver=f9JxL0UfXN4%3d

The help sheet for the UK-FATE Audit can be accessed here:

https://www.bofas.org.uk/Portals/0/Miscellaneous/FATE-data-helpsheet-v1.3-2022_05_07.pdf?ver=ZNyftS04xwk%3d

The video walkthrough for data entry for the UK-FATE Audit can be accessed here:

https://www.bofas.org.uk/Portals/0/Miscellaneous/FATE-data-helpsheet-video.mp4?ver=zbq4BH3DlSacLlv6L6WtFg%3d%3d

The datasheet for the UK-FATE Audit can be accessed here:

https://www.bofas.org.uk/Portals/0/Miscellaneous/FATE-data_spreadsheet-Fxxx.xlsx?ver=H1lMuhX3TmdyOvgxrHw7Cg%3d%3d

Appendix 2: Participating Sites and Investigators

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York and Scarborough Hospitals NHS Trust	Hannah Matthews / Fleur Shiers-Gelalis / Jason Ting / Stuart Place / Adam Budgen / James Stanley / Charlie Jowett

Appendix 3: Completeness of data sets

	Total	Elective	Trauma (excl. Achilles Ruptures)	Acute Diabetic Foot	Achilles Ruptures (operated)	Achilles Ruptures (non-op)
	N=11,363	N=5,090	N=4,791	N=398	N=277	N=807
Age (Years)	51.7 (17.7)	54.2 (16.9)	48.9 (18.8)	61.5 (13.0)	42.7 (14.0)	50.4 (14.7)
Sex						
Female	6,027 (53.0%)	3,080 (60.5%)	2,609 (54.5%)	99 (24.9%)	73 (26.4%)	166 (20.6%)
Male	5,336 (47.0%)	2,010 (39.5%)	2,182 (45.5%)	299 (75.1%)	204 (73.6%)	641 (79.4%)
Ethnicity 6 categories						
White	9,596 (84.4%)	4,448 (87.4%)	3,999 (83.5%)	360 (90.5%)	194 (70.0%)	595 (73.7%)
Mixed	167 (1.5%)	65 (1.3%)	74 (1.5%)	3 (0.8%)	15 (5.4%)	10 (1.2%)
Asian	420 (3.7%)	171 (3.4%)	200 (4.2%)	9 (2.3%)	14 (5.1%)	26 (3.2%)
Black	196 (1.7%)	78 (1.5%)	72 (1.5%)	3 (0.8%)	17 (6.1%)	26 (3.2%)
Other	172 (1.5%)	59 (1.2%)	91 (1.9%)	1 (0.3%)	9 (3.2%)	12 (1.5%)
Not Stated	812 (7.1%)	269 (5.3%)	355 (7.4%)	22 (5.5%)	28 (10.1%)	138 (17.1%)
ASA Grade, 3 categories						
Grade I	3,048 (26.8%)	1,284 (25.2%)	1,596 (33.3%)	2 (0.5%)	165 (59.6%)	1 (0.1%)
Grade II	5,114 (45.0%)	2,789 (54.8%)	2,178 (45.5%)	65 (16.3%)	82 (29.6%)	0 (0.0%)
Grade III - V	1,821 (16.0%)	748 (14.7%)	748 (15.6%)	318 (79.9%)	7 (2.5%)	0 (0.0%)
Missing	1,380 (12.1%)	269 (5.3%)	269 (5.6%)	13 (3.3%)	23 (8.3%)	806 (99.9%)
Asthma / COPD						
No	9,435 (83.0%)	4,167 (81.9%)	3,977 (83.0%)	328 (82.4%)	247 (89.2%)	716 (88.7%)
Yes	1,475 (13.0%)	763 (15.0%)	552 (11.5%)	63 (15.8%)	18 (6.5%)	79 (9.8%)
Missing	453 (4.0%)	160 (3.1%)	262 (5.5%)	7 (1.8%)	12 (4.3%)	12 (1.5%)
Cancer						
No	10,544 (92.8%)	4,775 (93.8%)	4,364 (91.1%)	366 (92.0%)	263 (94.9%)	776 (96.2%)
Yes	362 (3.2%)	154 (3.0%)	163 (3.4%)	24 (6.0%)	2 (0.7%)	19 (2.4%)
Missing	457 (4.0%)	161 (3.2%)	264 (5.5%)	8 (2.0%)	12 (4.3%)	12 (1.5%)
Cardiac						
No	9,792 (86.2%)	4,398 (86.4%)	4,119 (86.0%)	258 (64.8%)	258 (93.1%)	759 (94.1%)
Yes	1,116 (9.8%)	532 (10.5%)	407 (8.5%)	132 (33.2%)	10 (3.6%)	35 (4.3%)
Missing	455 (4.0%)	160 (3.1%)	265 (5.5%)	8 (2.0%)	9 (3.2%)	13 (1.6%)
Chronic Kidney Disease						
No	10,427 (91.8%)	4,744 (93.2%)	4,337 (90.5%)	293 (73.6%)	267 (96.4%)	786 (97.4%)
Yes	486 (4.3%)	185 (3.6%)	193 (4.0%)	98 (24.6%)	1 (0.4%)	9 (1.1%)
Missing	450 (4.0%)	161 (3.2%)	261 (5.4%)	7 (1.8%)	9 (3.2%)	12 (1.5%)
Clotting disease						
No	10,851 (95.5%)	4,892 (96.1%)	4,508 (94.1%)	389 (97.7%)	267 (96.4%)	795 (98.5%)
Yes	61 (0.5%)	37 (0.7%)	21 (0.4%)	2 (0.5%)	1 (0.4%)	0 (0.0%)
Missing	451 (4.0%)	161 (3.2%)	262 (5.5%)	7 (1.8%)	9 (3.2%)	12 (1.5%)
Dementia						
No	10,809 (95.1%)	4,902 (96.3%)	4,463 (93.2%)	385 (96.7%)	268 (96.8%)	791 (98.0%)
Yes	102 (0.9%)	28 (0.6%)	65 (1.4%)	5 (1.3%)	0 (0.0%)	4 (0.5%)
Missing	452 (4.0%)	160 (3.1%)	263 (5.5%)	8 (2.0%)	9 (3.2%)	12 (1.5%)
Diabetes						
No	9,718 (85.5%)	4,492 (88.3%)	4,161 (86.9%)	45 (11.3%)	258 (93.1%)	762 (94.4%)
Yes	1,195 (10.5%)	437 (8.6%)	369 (7.7%)	346 (86.9%)	10 (3.6%)	33 (4.1%)
Missing	450 (4.0%)	161 (3.2%)	261 (5.4%)	7 (1.8%)	9 (3.2%)	12 (1.5%)

Hypertension						
No	8,437 (74.2%)	3,684 (72.4%)	3,652 (76.2%)	170 (42.7%)	247 (89.2%)	684 (84.8%)
Yes	2,477 (21.8%)	1,246 (24.5%)	878 (18.3%)	221 (55.5%)	21 (7.6%)	111 (13.8%)
Missing	449 (4.0%)	160 (3.1%)	261 (5.4%)	7 (1.8%)	9 (3.2%)	12 (1.5%)
Peripheral Vascular Disease						
No	10,600 (93.3%)	4,832 (94.9%)	4,442 (92.7%)	268 (67.3%)	268 (96.8%)	790 (97.9%)
Yes	309 (2.7%)	97 (1.9%)	84 (1.8%)	123 (30.9%)	0 (0.0%)	5 (0.6%)
Missing	454 (4.0%)	161 (3.2%)	265 (5.5%)	7 (1.8%)	9 (3.2%)	12 (1.5%)
Stroke						
No	10,652 (93.7%)	4,816 (94.6%)	4,419 (92.2%)	369 (92.7%)	267 (96.4%)	781 (96.8%)
Yes	246 (2.2%)	107 (2.1%)	103 (2.1%)	22 (5.5%)	1 (0.4%)	13 (1.6%)
Missing	465 (4.1%)	167 (3.3%)	269 (5.6%)	7 (1.8%)	9 (3.2%)	13 (1.6%)
Comorbidity Count, 3 categories						
None	6,494 (57.2%)	2,759 (54.2%)	2,918 (60.9%)	22 (5.5%)	217 (78.3%)	578 (71.6%)
1	2,466 (21.7%)	1,254 (24.6%)	934 (19.5%)	85 (21.4%)	41 (14.8%)	152 (18.8%)
2+	1,957 (17.2%)	917 (18.0%)	681 (14.2%)	284 (71.4%)	10 (3.6%)	65 (8.1%)
Missing	446 (3.9%)	160 (3.1%)	258 (5.4%)	7 (1.8%)	9 (3.2%)	12 (1.5%)
Previous Hx of VTE						
No	10,647 (93.7%)	4,794 (94.2%)	4,429 (92.4%)	376 (94.5%)	262 (94.6%)	786 (97.4%)
Yes	266 (2.3%)	136 (2.7%)	100 (2.1%)	15 (3.8%)	6 (2.2%)	9 (1.1%)
Missing	450 (4.0%)	160 (3.1%)	262 (5.5%)	7 (1.8%)	9 (3.2%)	12 (1.5%)
Current Smoker						
No	9,588 (84.4%)	4,491 (88.2%)	3,767 (78.6%)	351 (88.2%)	236 (85.2%)	743 (92.1%)
Yes	1,286 (11.3%)	417 (8.2%)	748 (15.6%)	40 (10.1%)	29 (10.5%)	52 (6.4%)
Missing	489 (4.3%)	182 (3.6%)	276 (5.8%)	7 (1.8%)	12 (4.3%)	12 (1.5%)
Post-operative Weight Bearing Status						
NWB	5,877 (51.7%)	1,538 (30.2%)	3,665 (76.5%)	114 (28.6%)	234 (84.5%)	326 (40.4%)
FWB / PWB	5,227 (46.0%)	3,488 (68.5%)	951 (19.8%)	277 (69.6%)	36 (13.0%)	475 (58.9%)
Missing	259 (2.3%)	64 (1.3%)	175 (3.7%)	7 (1.8%)	7 (2.5%)	6 (0.7%)
Recent Long-Distance Travel						
No	10,738 (94.5%)	4,880 (95.9%)	4,430 (92.5%)	383 (96.2%)	263 (94.9%)	782 (96.9%)
Yes	79 (0.7%)	13 (0.3%)	47 (1.0%)	1 (0.3%)	5 (1.8%)	13 (1.6%)
Missing	546 (4.8%)	197 (3.9%)	314 (6.6%)	14 (3.5%)	9 (3.2%)	12 (1.5%)

Appendix 4: Details for VTE Related Mortality Cases

	Case 1	Case 2	Case 3
Age	75	38	73
Sex	Female	Female	Male
Ethnicity	White British	White British	White British
ASA Grade (3 Category)	Grade III - V	Grade III – V	Grade III - V
VTE	Yes	Yes	Yes
Operation	MUA/Plaster	Open Surgery	Open Surgery
Type of Operation	Trauma	Trauma	Trauma
Type of Trauma	Ankle	Ankle	Ankle
Pre-Op Chemical Prophylaxis	Uninterrupted	Uninterrupted	None
Post-Op Chemical Prophylaxis	Yes	Yes	Yes
Post-Op Chemical Prophylaxis Type	Dalteparin	Dalteparin	Aspirin
Post-Op Chemical Prophylaxis Duration	>6 Weeks	>6 Weeks	>6 Weeks
Weight Bearing	NWB 4-6 Weeks	NWB >6 Weeks	FWB
Post-Op HIT	No	No	No
Other Co-morbidities			
Smoker	No	No	Yes
Asthma / COPD	Yes	No	Yes
Cancer	No	No	No
CKD	No	No	No
Cardiac	Yes	No	No
Dementia	No	No	No
Diabetes	Yes	No	Yes
HTN	Yes	No	No
PVD	Yes	No	No
Clotting disease	No	No	No
Previous VTE	No	No	No
Travel	No	No	No
Pregnancy	No	No	No
Stroke	Yes	No	No
Other	CCF	BMI 45	None

F&AE