EMORY UNIVERSITY SCHOOL OF MEDICINE

VQI Venous RAC update – Proposal sample

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BACKGROUND

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- Previous data using NSQIP data showed increase VTE in patients with C6 disease
  - Not granular
  - Not specific staging for venous disease
  - Ulcer could be of arterial etiology as there is no unique variable determining etiology

PROPOSAL

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- **PROPOSED TITLE OF THE STUDY:** incidence of venous thromboembolic events (VTE) after endovenous ablation in patients with venous stasis ulcers (C6 disease)
- **PRINCIPAL INVESTIGATOR:**
  - Jaime Benarroch-Gampel, MD, MS
- **PRELIMINARY STUDY TEAM:**
  - Anna Beth West, MD
- **INSTITUTION(S):**
  - Grady Memorial Hospital
  - Emory University School of Medicine

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- **BRACKGROUND AND SIGNIFICANCE:**

Although no studies have specifically addressed the relationships among venous ablation, ulceration, and DVT, a number of studies have explored the relationship between venous ulceration and thrombophilia. **Bradbury et al.**[1] reviewed the available studies and concluded that "patients with chronic venous ulceration appear to have a prevalence of thrombophilia that is much higher than the general population but similar to post-DVT patients. They also noted that venous ulcerations have been associated with other DVT risk factors such as endothelial cell damage, decreased levels of fibrinolytic factors, and increased levels of prothrombin fragments. In a subsequent study, Darvall et al.[2] compared 27 patients with varicose veins and 27 patients with venous ulceration to 54 age- and sex-matched controls with no evidence of venous disease and found significantly elevated prevalence of single and multiple thrombophilias in cases compared to controls.

Given these findings, **it would seem prudent to perform a study comparing VTE outcomes after endovenous ablation in patients with and without venous stasis ulcers**. Current guidelines of the American Venous Forum and the Society for Vascular Surgery regarding the treatment of varicose veins and chronic venous insufficiency recommend against the use of routine prophylaxis in ablation procedures, but suggest it be used in "selective" patients with additional risk factors such as thrombophilia, a history of DVT or thrombophlebitis, or obesity.[3] **If the results of our study confirms a higher incidence of VTE after endovenous ablation…**

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- **INNOVATION:**

With the information contained in the Vascular Quality Initiative's Varicose Vein dataset, a study could be performed to determine if patients with venous stasis ulcers are at higher risk of developing VTE after endovenous ablation than those with less severe disease (C1-C5).

Access to detailed patient specific data and technical details affords the unique opportunity to execute a valid and representative evaluation of the procedure outcomes based on the presence or not of venous stasis ulcers (C6 disease). In the VQI varicose vein module, postoperative outcomes include systemic complications such as pulmonary embolism as well as leg complications such as DVT (including location).

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AIM(S): To compare rates of VTE following saphenous vein ablation in patients with and without C6 disease. **We hypothesized** that patients with C6 disease have higher rates of VTE than those without C6 disease following saphenous vein ablation.

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STUDY DESIGN AND STATISTICAL ANALYSIS

Data Source: Vascular Quality Initiative Varicose Vein Dataset

Inclusion Criteria: All patients undergoing endovenous ablation of the great and small saphenous vein as well as their branches and/or perforators

Exclusion Criteria: Patients < 18 years of age at the time of their procedure and those undergoing open varicose vein surgery (i.e. ligation, phlebectomy or stripping). In addition, patients receiving therapeutic anticoagulation will be excluded.

Study period: January 1st, 2015 to December 31st, 2020

Exposure variable: Presence of venous stasis ulcers (C6 disease)

Outcome Variables:

- Primary: Postoperative venous thromboembolic events, including deep venous thrombosis of the treated lower extremity and pulmonary embolism
- Secondary: Endovenous Heat Induced Thrombosis (EHIT), defined in the VQI dataset as “Proximal Thrombus Extension”

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Analytic Support:

The **principal investigator** for this project has the background and training to perform the required statistical analyses obtained through his Maters in Clinical Science as well as prior research experience using large data sets. The research team also has access to a statistician on an as-needed basis through their department should consultation become necessary to compete advanced statistical analyses.

IRB Approval:

Per our institution's policy, this study would **not require IRB** approval. All data will be received de-identified from VQI's national database. No efforts to link database provided patient data to individuals will be attempted.

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Data Analysis:

Baseline characteristics and outcomes of the two cohorts will be analyzed using **chi-square tests** (for categorical variables) and **t-tests** (for continuous variables) to determine the presence of any significant differences. **Multivariate regression models** will be created to further confirm any significant differences between outcomes in the two cohorts while controlling for differences identified in their baseline characteristics. Variables with a p-values of <.1 in univariate analysis will be included in the multivariate logistic regression models. If the presence of stasis ulcer does not meet the criteria, it will be force into the model

In addition, we will perform **sub-group analysis** comparing patients with C6 versus C5 disease.

Data will be analyzed using SAS version 9.4 (SAS institute Inc, Cary, NC). P-values of <0.05 will be considered statistically significant.

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LIMITATIONS

Potential limitations to this study include any that are the result of limitations **related to the data itself**. While sample size is expected to be adequate given the large nature of the national dataset, preliminary data analysis will provide better understanding of data limitations with respect to size. **Unmeasured confounders** may exist which are not reported in VQI and will be addressed in the discussion if suspected or hypothesized. For example, a potential limitation of this data set as it relates to **this specific study** is the inability to identify whether the C6 disease documented on follow up is persistent vs recurrent disease.

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Table 01 – Cohort description

Baseline Characteristics	CEAP Class: C6	CEAP Class: C1-5	P value
Age (mean +/- SD)			
Gender, Female			
Race			
White			
African American			
Asian			
Hispanic/Latino			
Comorbidities			

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Table 02 – Unadjusted outcomes

Outcome	CEAP Class: C6 n (%)	CEAP Class: C1-5 n (%)	P-Value
VTE			
Deep Venous Thrombosis			
Pulmonary embolism			
EHIT			

BACKGROUND

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- Available data (venous modules)
  - Varicose vein module
  - IVC filter module
  - Venous stenting (started in 2019)
- Link
  - https://abstracts123.com/svs1/

Thank you!