

FACTORS ASSOCIATED WITH TREATMENT OUTCOMES FOR IMAGE-GUIDED  
THERAPY OF VARICOSE VEINS

By

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### Final Dissertation Approval Form

### Factors Associated with Treatment Outcomes

for Image-Guided Therapy of Varicose Veins

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## ABSTRACT

### *Factors Associated with Treatment Outcomes for Image-Guided Therapy of Varicose Veins*

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Postoperative complications and recurrence events in treated varicose veins cases are a frustration for both the patient and the clinician. Nowadays, varieties of image-guided techniques exist for the treatment of patients with varicose veins. Image-guidance is defined as treatment delivered with the assistance of imaging obtained either prior to or during a treatment act. The use of image-guided techniques effectively coupled imaging to intervention and increased both the complications of, and difficulty with deliver of, varicose veins treatment. The study purpose was to provide a description of clinician-specific (interventional cardiologists IC, interventional radiologists IR, and vascular surgeons VS) treatment patterns for image-guided varicose veins treatment.

This secondary analysis of cross sectional data was compiled from two sources: (1) the State Inpatient Database, and (2) the State Ambulatory Surgery Databasc. The analytic approach used multiple logistic regression models to estimate the effect of image-guided treatment delivery by specific clinicians' specialties on the occurrence of unfavorable postoperative outcomes in treated varicose veins patients, controlling for characteristics of patients and disease severity. The final analytic sample consisted of 8,793 patients in the state of New Jersey.

Significant findings from this study indicate that, in treated varicose veins patients, a relationship exists between providing of image-guided treatment by IC and the occurrence of postoperative complications ( $OR = 7.48, P > |z| = 0.0005$ ). Moreover, findings support the theoretical association that relates providing of image-guided treatment by VS ( $OR = 1.22, P > |z| = 0.0001$ ) and IR ( $OR = 2.48, P > |z| = < .0001$ ) to the occurrence of reinterventions.

Further, findings indicate strong, significant relationships among disease severity and demographic factors, and that these strong relationships are confounding the effects of clinician specialty on postoperative outcomes in treated varicose veins patients. These important findings emphasize the need for appropriate training and volume load for image-guided treatments. They also signify that disease severity is playing a role in predicting of many outcomes following image-guided varicose veins treatment.

## DEDICATION

To my Lord, for giving me the good health and wellbeing those were imperative  
to complete this work,

my mom, Khairia Janbi,

my dad, Shukri,

my sister, Wejdan,

and my brother, Mohammed,

for their constant support and unconditional love. I love you all dearly.

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## Chapter I

### INTRODUCTION

Venous insufficiency, or reflux disease, is resulted from the mechanical insufficiency of venous valves enabling movement of blood from deep veins back into the superficial vasculature instead of toward the heart (1). Venous reflux influences more of the adult society than cardiovascular disease, which describes why managing and treating of its complications engage a great percentage of the healthcare allocation (2). 20% of superficial venous reflux cases that were not given treatment resulted venous varicosities, advancing in severity to involve symptoms of swelling, aching, skin discoloration, and venous ulceration (3). Choices of therapy for venous reflux disease differ in technique, namely open surgery, sclerotherapy, and endovenous therapy (1).

Endovenous therapy of symptomatic reflux disease has validated to be the present standard of management for chronic venous insufficiency (CVI) and symptomatic varicosities (4-6). Starting with radiofrequency ablation (RFA) in 1999, and next, endovenous laser ablation (EVLA) in 2002, the utilization of these procedures has been enlarged more than 8 fold since 2005 (7), efficiently substituting conventional stripping and ligation (8). Technically, laser or radiofrequency is employed to produce accurately thermal energy right to the vein wall, damaging the intima and resulting to the destruction of collagen in the media. At last, this creates a fibroelastic seal of the lumen of the vein itself (9) and makes shrinkage of the vessel wall (10). Several empirical works claimed that these techniques have become parallel or more efficient than vein stripping by



providing minimum postoperative morbidity (11-13). Recanalization, the unfavorable outcome of venous ablation, while uncommon, is yet reported among the utilization of thermal ablation (14). A research cohort claimed a reflux rate of 4.3% (7.4% blood flow) reported by duplex ultrasound (US) at 3 year follow up (14). In 2008, recanalization possibility was notified to be significantly impacted by anatomical risk factors, like vein size at the saphenofemoral junction and intervention locations for ablation (15). Though, insignificant association has been reported between the incidence of uncured venous ulcers after treatment and several clinical risk factors, including history of deep venous thrombosis, deep venous inefficiency, diabetes, smoking, and body mass index (16). Advance examinations are necessary for various hypothesized clinical risk factors and their relationships with thermal ablation efficiency and the incidence of recanalization.

Ultrasound guided foam sclerotherapy (UGFS) is a common therapeutic technique for varicose veins. A latest survey of members of The Vascular Society of Great Britain and Ireland and the Venous Forum of the Royal Society of Medicine reported that UGFS was delivered to National Health Service (NHS) patients by 27% of surgeons (17). In 1950, foam sclerotherapy was utilized for the first time as a therapeutic tool for varicose veins. It was delivered by shaking a syringe that enclosing air and sclerosant (18). However, the idea of foam sclerotherapy stayed unusable until the mid-1990s, when many endeavors to improve the method were done (19-21). It was not until 2000 when a study revealed a technique of producing foam by utilizing two single-use syringes and a three way-tap (21). While many reports have recorded the outcomes of UGFS, data on variables correlated with postoperative results and complications is quite

limited. Number of articles have claimed that postoperative UGFS outcome is affected by vein diameter based on observed favorable outcomes resulted after treating smaller veins (22, 23). In 2007, a study examined several variables in order to test their relationships with postoperative UGFS outcomes stated that type of administered sclerosant (foam vs. liquid), the dilution, and amount of sclerosant, age, and vein diameter were all significantly related to venous occlusion rates. Though, in the first year of the study, liquid sclerosant was utilized (24). In another study, significant relationships were found between deep vein thrombosis (DVT) rates following UGFS, vein diameter, and the concentration and amount of administered sclerosant. Liquid sclerosant was also tested in the primary stage of that study (25). A study had revealed that the amount of administered foam is inversely associated with postoperative complications. Though, average amount of foam used in that study were remarkably high (26). The decision of performing UGFS gets to be more accurate as supplementary information on prognostic factors is clarified. Advance evaluations are required for factors related to UGFS postoperative complications.

Varicose vein surgery, traditional open stripping, is mainly theorized as a basic operation with little hazards, and usually delivered by junior surgeons (27). Though, DVT and fatal pulmonary embolism (PE) are significant probable side effects that can follow varicose vein surgery (27). A lot of scholars have evaluated post DVT cases treated by various therapeutic approaches, namely conventional open surgery, radiofrequency ablation, endovenous laser ablation and sclerotherapy, and recorded rates varied greatly from 0.15% to 5.3% (28). More exploration is necessary for cases of DVT

following varicose vein surgery with identification of the particular risk factors for these incidences. A study stated that there is no relationship between DVT and obesity, varicose veins severity, high haemoglobin level and type of anesthesia (27). Also, it found that factors can increase the risk of postoperative DVT include old age ( $\geq 65$  years), female sex and a history of gastrocnemius vein dilation (GVD). There are different justifications for the impact of these risk factors. Age has regularly been theorized to be a significant risk factor for developing thrombosis (29), which relates to the occurrence of pre-thrombotic state (30, 31). The effect of patient sex as a risk factor on DVT is debated. Female patients were at greater risk of developing DVT after the procedure than male patients because the variances in pain sensitivity and immobility between male and female patients according to experimental studies (27). Moreover, there are no evidence based standards for decreasing DVT incidence following therapeutic surgery for varicose veins, and there is no agreement between surgeons about the suitable technique for thrombo-prophylaxis (32).

Guided by theoretical and empirical synthesis, the purpose of this study is to address the evidence persist gaps by testing propositions in a sample of inpatients, ambulatory outpatients, and clinicians by examining relationships between: (1) clinician's specialty and (2) the patient centered outcome for image-guided treatment of varicose veins.

### **Statement of the Problem**

What are the relationships between clinician's specialty and outcomes for image-guided treatment of varicose veins such as postoperative complications and reintervention?

#### **i. Subproblems**

1. Is providing of image-guided treatment by VS associated with the occurrence of postoperative complications in varicose veins patients?
2. Is providing of image-guided treatment by IR associated with the occurrence of postoperative complications in varicose veins patients?
3. Is providing of image-guided treatment by IC associated with the occurrence of postoperative complications in varicose veins patients?
4. Is providing of image-guided treatment by VS associated with the occurrence of reinterventions in varicose veins patients?
5. Is providing of image-guided treatment by IR associated with the occurrence of reinterventions in varicose veins patients?
6. Is providing of image-guided treatment by IC associated with the occurrence of reinterventions in varicose veins patients?

## **Definition of Terms**

The following will detail the theoretical and operational definitions of dependent and independent variables.

### **i. Dependent variables**

#### ***a. Postoperative complications***

Postoperative complication is theoretically defined, overall, in this study as any deviation from the normal postoperative course of illness or procedure which results a medical or surgical accident or reaction whether it is symptomatic or asymptomatic (33, 34). It is an incidence which has not achieved the favorable outcome originally desired (33, 34). Five diagnostic indicators of postoperative complication will be examined in this proposed study: (1) nerve injury; (2) haematoma; (3) phlebitis; (4) vein thrombosis; and (5) amputation. Each complication will be operationally defined by selected diagnosis and procedure codes derived from the International Classification of Diseases, 9th edition, Clinical Modification (ICD-9-CM) and the Current Procedural Terminology (CPT) start from the third positions that suggest the occurrence of a postoperative event.

#### ***b. Reintervention***

Re-intervention, theoretically defined as the necessity for an additional intervention in order to treat varicose veins recurrence or new varicose veins in the same leg and the same area (35). According to that, reintervention will be operationally defined

in this proposed study by selected procedural codes derived from CPT that suggests the occurrence of a reintervention.

## **ii. Independent variable**

This section will detail the theoretical and operational definition of the independent variable: clinician's specialty.

### ***a. Clinician's specialty***

A medical specialty is theoretically defined as a medical science field in which other physicians lack the requisite knowledge and training (36). The clinician's specialty will be operationally defined as the type of experience that clinician who performs the image-guided varicose veins treatment has. This proposed study will analyze the frequency and distribution of selected procedures in all observations in the data set linked to practitioners in order to determine clinician's specialty by procedure types performed.

## **iii. Control variables**

Theoretical and empirical literatures indicate that several other factors are associated with unfavorable patient outcomes. Therefore, the relationships between these factors and the dependent variable of interest will be explored in this proposed study, and their effects will be controlled if indicated. One of these control variables is disease severity. Disease severity, operationally defined as combined ICD-9-CM selected codes that associated with patients undergone image-guided varicose veins treatment on the basis of primary or secondary diagnosis positions. These codes reflect varicose veins

severity-specific diagnosis (high disease severity vs. low disease severity). Finally, several covariates used in this study include age, sex, and race.

### **Delimitations**

This study will leverage and merge the following existing datasets: (1) New Jersey State Inpatient Database (SID); and (2) New Jersey State Ambulatory Surgery Database (SASD) available from the Agency for Healthcare Research and Quality (AHRQ) will be the data source for postoperative complications and reintervention events. Therefore, there is no need for the recruitment of subjects. Women and minorities are represented similarly to their population distribution and no genders, racial or ethnicity groups will be excluded.

The databases, SID and SASD from the Healthcare Cost Utilization Project (HCUP), contain inpatient and ambulatory patient discharge abstracts from New Jersey hospitals. The existing NJ SID and SASD datasets from 2011 to 2013 will be examined in this study that includes all patients discharged from NJ hospitals. The SID from HCUP contains inpatient discharge abstracts from New Jersey hospitals. The SID contains more than 100 clinical and nonclinical data elements such as facility identification number, patient demographics, admission and discharge information, payment source, total charges, and length of stay. In addition, ICD-9-CM codes are recorded for both the principal diagnosis and principal surgical procedures. An expanded number of diagnosis and procedure codes, clear demarcation of presenting, and secondary comorbid diagnoses are all unique and imperative features of the discharge data that permit enhanced risk adjustment. The SASD is a census of discharges from free standing and hospital affiliated

ambulatory surgery centers; acute care, nonfederal, community hospitals; and emergency department visits which did not result in hospital admission. Each ambulatory surgery center discharge abstract contains up to 21 CPT procedural codes; 15 diagnostic ICD-9-CM codes; and information about patient demographics, anticipated payer, and discharge disposition. This database contains unique variables, which allow patients to be followed over time and across healthcare settings; enabling subsequent outcome assessment.

### **Significance of the Study**

Endovascular therapy for several vascular illness has changed from an optional treatment for patients who are not surgically fit to undergo conventional bypass to a primary choice of therapy (37). The utilization of percutaneous procedures and open bypass operations may be considered as additional therapeutic approaches with identified clinical indications for each type of treatment (38, 39). Employing of stenting approaches and angioplasty has been described as a primary therapy for patients with low disease severity (40-42). Though, efforts have been provided in order to deliver standardization of indications and outcomes related to endovascular interventions (40). Moreover, providing percutaneous operations for patients with high illness severity is debatable. While bypass outcomes had been considered historically more favorable than endovascular results, various studies showed parallel short-term and midterm patency resulted by endoluminal stent placement (43). Outcome of endovascular procedures are impacted by several factors such as indication and co-morbidities (43-45). are also critical not only in Interventional outcome following endovascular or open surgical treatment can be predicted by accounting disease extent and Trans Atlantic Intersociety



Consensus (TASC) II classification that also help in identifying therapeutic options (46, 47).

Endovascular lower extremity interventions are delivered nowadays by vascular surgeons (VS), interventional cardiologists (IC), and interventional radiologists (IR). Patients with severe vascular disease like critical limb ischemia (CLI) have been traditionally treated by VS who deliver open revascularization therapy. The management of CLI through open revascularization has been considered the gold standard. Though, respectable limb salvage rates resulted by endovascular interventions have raised the necessity to review the options of treatment (48, 49). Vascular surgery fellowships recently has included endovascular training in response to the significant growth in numbers of VS delivering endovascular procedure (49, 50). This shift of practice have referred to financial motivations (51).

A large population of patients who have different vascular diseases are treated by interventional cardiologists (IC) (52). Since vascular interventions are logical extension of their catheter-based experience (53), ICs have started delivering endovascular interventions to patients who were traditionally treated exclusively by the IRs. Participation of VSs and ICs in performing endovascular interventions has been supported recently by professional organizations. It results a remarkable increases in these specialists delivering endovascular revascularization operations (54, 55). The Accreditation Council for Graduate Medical Education reviews several formal training programs in endovascular interventions (51). Many endovascular operations during the 1990s were delivered by non IRs who did not have formal accredited training. Moreover,

there is a lack of experience among the staffing provide such accredited interventional training (56-58).

This innovative study explores significant empirical gaps in the image-guided treatment outcome literature and emphasizes the important comparative research goal to decrease unfavorable treatment outcomes. It is the first study to examine the effects of clinician's specialty and disease severity on outcome for image-guided varicose veins treatment. Findings will help to motivate key healthcare executives and policymakers to take appropriate decisions regarding healthcare resources. Findings from this study will provide evidence based recommendations that can directly help organizational, state, and national policy decisions. These recommendations will be based on deployed and constructed efficacious mixes of human resources and health care material, which will help in providing safe, and error free healthcare services. Study findings will assist a multifaceted approach to minimize unfavorable image-guided varicose veins treatment outcomes. Findings from this study will participate in providing more knowledge in comparative effectiveness research in radiology that define hospital level determinants and modifiable system factors that may be updated through strategies to reduce unfavorable patient outcomes.

## Chapter II

### REVIEW OF RELATED LITERATURE

This proposed study examines the relationships between several predictors derived from the theoretical and empirical literature and the development of unfavorable treatment outcomes for image-guided procedure of lower extremity varicose veins. In this chapter, theoretical and empirical literatures relevant to these relationships are discussed. The theoretical underpinnings of the etiology of varicose veins development are presented. The review of the theoretical literature of varicose vein development encompasses several conceptual viewpoints, which is presented in chronological order. Since the development of a varicose vein is a patho-physiologic phenomenon, all theoretical perspectives are based on a synthesis of the available physiologic and empirical literature of the time. The follows section reviews treatment options for varicose veins then presents the theoretical literature relative to the dependent variable unfavorable treatment outcomes, which in this research will be indicated by postoperative complications, and reintervention. In addition, the theoretical literature related to the primary predictor of clinician's specialty will be displayed, as well as the empirical support for the relationship among unfavorable treatment outcomes. Next, the theoretical literature related to the secondary predictor, disease severity, will be covered, followed by empirical support for the relationship between it and unfavorable treatment outcomes. Finally, gaps in the empirical literature will be synthesized, the theoretical rationales for the study questions summarized, and the research hypotheses outlined.

### **Development of Varicose Veins: Theories and Empirical Support.**

Varicose veins are the enlarged, sinuous, and extended veins in the subcutaneous plane, 3 mm in dimension or bigger, sized in the vertical posture (59). The cutoff dimension is 4 mm or bigger (60). They may be protruded and do not blemish the skin (60). They comprise the saphenous veins and tributaries or non-saphenous superficial leg veins (59). Synonyms include varix, varices, and varicosities. Varicose veins are generally sinuous. Though, tubular saphenous veins with verifiable reflux may be categorized as varicose veins (59).

The accurate prevalence of varicose veins illness is not exactly determined while there are a small number of community based research (61). The occurrence differs depends on the standard used and the geographical area examined. In the past, the determined prevalence for varicose veins differs from 1 to 73 % in females and from 2 to 56 % in males. The occurrence for chronic venous insufficiency (CVI) differs from 1 to 40 % in female and 1 to 17 % in male (62). One of the broadly cited studies designed a cross sectional work relied on examining a data from 1,566 observations (867 female and 699 male) (63). Around 1/3 of males and females of the age group of 18-64 years had truncal varices. In a work of 1,500 observations of the age group of 15-64 years, chronic venous disorders (CVD) have been recognized in 224 observations (14.9 %) (64). Clinical Etiology Anatomy Pathophysiology (CEAP) based epidemiologic research stated that the prevalence of varicose veins in the adult western population was more than 20 % (21.8-29.4 %) and those with skin discoloration and venous ulcer was lesser than 10 % (3.6-8.6 %) (3, 65, 66).

As age grows, the prevalence of varicose veins raises (67, 68). An article claimed that a rise in prevalence from 1 % in males lesser than 30-57 % in males above 70. Likewise, there was a rise of prevalence from 10 % in females under 30-77 % in females above 70 (69). Many other scholars have supported this result. Several articles revealed a rise in prevalence of varicose veins in females (2-56 % in males, 1-73 % in females) (67). A study claimed that odds ratio for women as a risk factor for varicose veins was 2.18 (3). Another study recorded a greater occurrence of CVI in males (68). An article reported an odds ratio of 1.11 in parous females contrasted to an odds ratio of 0.75 in nulliparous females (66). Moreover, an article claimed a rise in the odds ratio with a rising of pregnancies incidences (70). Elevation of intra-abdominal pressure and rising of hormones levels like relaxin, progesterone, and estrogen, which lead to venous relaxation and elevated venous capacitance, have all been assumed to be the origins of varicose veins in pregnancy. Oral contraceptive pills and hormone substitution treatment are not risk factors for the progress of varicose veins (71). Positive family history for varicose veins in first degree relations is connected with greater risk (65, 72). It has been claimed that the risk of progressed varicose veins was 90 % when both mother and father were suffered. When only the mother or the father was suffered, the risk is 20 % for men and 62 % for women. The risk is 20 % when both mother and father were healthy. The chromosome and the associated proteins related to the illness are not completely tested till today (73). Varicose veins are reported to have connection to specific genetic disorders. Seventy two percent of patients with Klippel-Trenaunay syndrome delivered varicose veins (74). Mutations in the von Hippel-Lindau gene, FOXC2, and NOTCH3 are

also related to varicose veins (75-77). Obesity, hypertension, smoking, and low physical activity are possible risk factors for varicose veins. However, the association has not been definitively determined.

A normal venous system is based on the solidity of valves, vein wall, and the hemodynamic of venous blood flow (78). Generally, the venous flow is unidirectional and cephalic that moves from the superficial veins to the perforators within the deep system. In varicose veins, this flow is interfered which leads to stasis and venous hypertension. Chronic venous hypertension results ischemia and inflammation of the vein wall. The first occurrence is counted as an inflammatory development caused by the elevation of venous pressure. A number of structural and functional alterations have been reported in the vein wall and the valve cusp (73).

#### **i. Interfered hemodynamics in chronic venous disorders.**

The veins of the lower extremity are divided into the superficial, deep, and perforating systems (79). Blood moves in these veins is regularly unidirectional and cephalad. Gravity and hydrostatic pressure prevent abnormal flow-back of blood in the vertical posture. A system of valves, an effective peripheral pump machinery, and a negative intra-thoracic pressure prevail the impact of gravity (80, 81). The calf muscle pump is the greatest forceful power that helps blood flow-back from the lower extremities (61). The thigh and foot muscle pump as well work to achieve this goal. Constriction of the calf muscle pump elevates the pressure inside the fascial compartments and imposes blood up over the deep venous system, systole of the muscle

pump. The capable valves avoid reflux distally inside the deep venous system or toward the perforators within the superficial veins (61).

The performance of the calf muscle pump is evaluated by monitoring the ambulatory venous pressure (AVP) in the foot veins. AVP reports are mainly intended at monitoring the decrease in venous pressure in the superficial veins of the foot associating a progression of calf muscle constrictions like stand up on toes (82).

A foot vein is cannulated and attached to a pressure transducer and a three channel monitor or a recorder system within a three-way stopcock and a saline reservoir (61). The pressure in the foot vein is primary monitored while the individual in the vertical posture and at rest; resting pressure (RP). This will be nearly equal to the weight of the column of blood from the right heart to the point of measurement. It is different depends on the height of the individual. On a standard, it is nearly 100 mm of Hg. The individual is requested to make a group of stand up on toe actions with the cannula in situ. This will cause an influential constriction of the calf muscle. The pressure after a progression of 10-15 constriction fall down by 50-60 % and afterwards rest stable, irrespective of the extent of activity. The lowermost pressure monitored after the series of muscle contractions is designated as the postexercise pressure (PEP). On pause of the workout activity, when the individual is relaxed, the pressure gradually turns back to the normal resting value. The period of time reserved for the PEP to turns back to the RP is appointed as the recovery time (RT). In normal individuals, this is around 20-30 s. This AVP pattern is recognized as the normal venous pattern. In patients with venous disorders, the decrease in PEP is insignificant. Moreover, the recovery time is greatly

quicker (0-5 s). The normal and abnormal AVP pattern may provide an understanding about the role of the calf muscle pump on wellbeing and sickness (61).

The performance of the calf muscle pump decreases the pressure and volume of blood in the superficial venous system (61). This significant capability of the muscle pump is decreased in patients with venous disorders of the lower extremities, causing an increased PEP. This is recognized as ambulatory venous hypertension. The RT is lacking from quick venous reflux. The progress of ambulatory venous hypertension involve the occurrence of reflux in the saphenous systems, abnormal flow-back /occlusion in deep veins, and inefficiency of medial calf perforators (61).

#### ***a. Insufficiency of superficial veins***

Inefficient superficial veins lead to abnormal flow-back of blood. If the perforators are competent, the calf muscle pump is capable to handle with the excessive load and decrease the pressure results from activity (61). If there is a great abnormal flow-back volume from saphenofemoral junction, the excessive load is moved within the deep veins toward the following perforator. This creates a damaged cycle regularly considered as private circulation (83). In order to handle with the excessive load, two derivative developed progresses start; the excessive volume dilates the deep veins and the perforators then get stretched and convert derivatively inefficient. These alterations are changeable. Treating abnormal flow-back in the saphenous system can fix both irregularities (61).

The origin of valve incompetence in the saphenous veins is debatable (61). Major structural alterations in the valve cusp lead to abnormal flow-back from higher toward



lower parts were viewed to be group of events. This concept was demonstrated through the conventional descending valvular incompetence theory. Lately, it has been proposed that valvular failure is derivative to vein wall expansion. Venous expansion progresses beneath the valves. Abnormal flow-back in saphenous veins gets going in an ascending way. It is defined as ascending valvular incompetence theory (84).

AVP investigations showed increased PEP and fast RT. Though, it was reported that this great pressure reverted to nearby regular levels when the assessment was reiterated after using a tourniquet in the thigh below the SFJ in order to obtain a proximal saphenous occlusion PSO. The RT also stabilized after PSO (82). This type of AVP is defined as superficial venous pattern. These results signify that ambulatory venous hypertension might be easily organized by adjustment of the flow-back of blood in the saphenous veins (61).

#### ***b. Abnormal flow-back /occlusion of the deep veins***

Abnormal flow-back in the axial or segmental deep veins system is a prevalent observation in patients with initial chronic venous insufficiency (61). In patients with post-thrombotic syndrome (PTS), there might be abnormal flow-back, occlusion, or both.

Abnormal flow-back in deep veins occurs as the consequence of valvular inefficiency from any abnormality may make considerable changes of venous flowing back. The regular blood stream with its cephalic and unidirectional movement in deep veins is changed into a turbulent one (84). There are stagnancy and swelling of the deep veins, which leads to derivatively insufficient superficial veins and perforators. Skin discoloration is frequent in these cases. The impacts are noticeable in the existence of

chronic occlusion in the deep system or when occlusion and abnormal flow-back occur as in patients with PTS (61).

The PEP stays high in patients with abnormal flow-back /occlusion in deep systems (61). PSO utilizing above knee tourniquet does not decrease the high activity pressure. This pattern is known as deep venous pattern. Extended therapeutic operations are required like deep veins valve reconstruction. The PEP may increase and becomes higher than the RP in case an occlusion occurs in the deep system, which leads to venous claudication. Treating the occlusion in the deep system by interventional stenting therapy of an obstructed iliac segment can provide significant therapeutic development (61).

### *c. Inefficiency of perforators*

The effect of inefficient perforators in venous hemodynamics is complicated (61). The impact counts on the condition of the other venous structures. While the calf muscle pump works conventionally, the excessive load from normal flow-back from the perforators does not cause any alteration. This is due to the amount of blood evicted from these veins that is not very considerable. These cases become obvious when perforator inefficiency associates with abnormal flow-back in the saphenous. Reliving of abnormal flow-back in the saphenous veins treats the expanded perforators (61).

Inefficient perforators affect the physiologic performance of lower extremity veins only when these perforators have considerable hemodynamic alterations. According to recorded results, these perforators present size equal to or larger than 3.5 mm and flow time greater than 500 ms (85). Such situation is usually has a relationship with a pathological deep veins. The deep system generates great load which cause infiltration of

high blood pressure from deep to superficial system among constriction of calf muscle (86). The calf muscle pump becomes incapable to handle with such a disturbance of high pressure. Skin discoloration is usually associated with such cases (61).

When saphenous abnormal flow-back is the controlling characteristic within perforator inefficiency, the elevated PEP falls down with PSO. But the decrease in PEP may not be as significant as in a patient with isolated saphenous flow-back (82). Treatment of the abnormal saphenous flow-back would regulate the venous dynamics markedly. In coexisted deep and perforator incompetence with or without superficial reflux, the AVP pattern is identical to the deep venous pattern.

## **ii. Classifying chronic venous disorders**

While chronic venous disorders (CVD) of the lower extremities are frequent issues, there is a controversy about evaluation methods for illness stage and severity (87). Also, there are no integrated standards for the outcome of therapeutic strategies. Differs in the intra and inter-observer data were significant. Reaching an agreement about standards of venous disorders is required.

The Clinical Etiology Anatomy Pathophysiology (CEAP) classification is a comprehensive process of categorizing chronic venous disorders. It has been approved universally and developed into significative foundations for communication and documentation globally. The necessity for a properly constructed classification for CVD was represented in the annual meeting of the American Venous Forum (AVF) in the year 1993. The first CEAP manuscript was officially provided at the next annual meeting of AVF in the year 1994 (88). The necessity to improve the CEAP classification was started

in 2002. In 2004, an updated CEAP version was officially revealed (59, 89). CEAP clinical classification has seven classes of CVD based on the severity's ascending order (90) (Table 1).

Table 1  
*Clinical CEAP Classification*

Clinical class	Description
C0	No visible or palpable signs of venous disease
C1	Telangiectases or reticular veins
C2	Varicose veins
C3	Edema
C4	Changes in the skin and subcutaneous tissue: C4a Pigmentation and/or eczema C4b Lipodermatosclerosis and/or atrophie blanche
C5	Healed venous ulcer
C6	Active venous ulcer

#### **Treatment Options for Varicose Veins: Theories and Empirical Support.**

The suitable varicose veins treatment is identified as speedy and eternal elimination of all sources of superficial venous reflux, healing all physical symptoms, enhancing the leg appearance significantly, resulting no complication, affording rapid return to normal activities, being cost-effective and medically-effective to impacted patients (90). In order to bring the best suitable, available, and applicable care, managing technical success, clinical status, functional status, satisfaction, cost, and other comprehensive outcome evaluation affords better understanding of different interventions effectiveness, enables health-care staff and patients to take well decisions (91).

In patients with chronic venous insufficiency (C3, C4, C5, and C6), therapy for the abnormal superficial flow-back is delivered either in separation or in association with surgery of the perforator and/or the deep veins (61). Conventional treatment strategy includes lifestyle guidance, which covers leg lifting exercises, weight and diet, and the utilization of compression hosiery. Endovenous thermal ablation of the saphenous vein is a comparatively innovative and minimally interventional therapy, which is delivered with local anesthesia in ambulatory wards. This method can be administered by employing laser or radiofrequency waves. Sclerotherapy by administering a sclerosant within the vein to develop fibrosis and destruction of the vein has been practiced for nearly a century. Ultrasound guided foam sclerotherapy is broadly delivered presently for the management of varicose veins in ambulatory wards also. Open surgery yet the gold standard in venous disease therapy.

#### **i. Open surgery**

First bypass surgery for deep venous occlusion was delivered in 1958 by practicing the method of a crossed femoro-femoral graft for iliac vein obstruction (92). Moreover, the management of CVI was improved by developing different surgical techniques for inefficient perforators. In 1985, subfascial endoscopic perforator surgery (SEPS) was a significant enhancement which changed interventional radical open procedures to minimally invasive operations with quick recovery (93).

In 1968, a new method for reconstructing deep veins was introduced in order to manage CVI cases. It was designed as a procedure of internal valvuloplasty (94). This method then was improved and promoted the supravulvar technique for repair. At the

same time, the approach of external valvuloplasty was developed and axillary segment transfer technique was introduced. This was an important improvement as this approach might be utilized for post-thrombotic limbs events. External banding of deep veins was treated by employing Dacron sleeve in 1984 for the first time. In 1988, this method was modified utilizing silastic cuff. There was an attempt in 1999 to test cryopreserved venous segments for clinical use. In 2000, transcommissural valvuloplasty was introduced to the field of venous open surgery (95).

High ligation is the standard treatment for varicose in great saphenous veins (GSV) (96) beside stripping, and stab avulsion (85). The high ligation surgery requests concern on the incision location, management of tributaries, and method of flush tie. Stripping to a point beneath knee enhance outcome without raising the risk of saphenous nerve injury (85, 97). Total stripping up to the ankle is rarely delivered (98). Stab avulsion utilizing hooks increases functional and cosmetic outcome (85). Trans-illuminated powered phlebectomy is an appropriate choice for the treatment of clusters of veins in a more fast and integral way (99, 100). Surgery of small saphenous vein (SSV) is requiring much skill due to the differing anatomy and restricted space (101). Postoperative results of flush tie and low tie are similarly efficient (85). Stripping is recommendable skipped in SSV. As an alternative, the proximal 10 cm of the vein is cut out (97, 102, 103).

## **ii. Endovenous thermal ablation**

The utilization of radiofrequency ablation (RFA) in the management of venous illness was defined in 1999 (104). Laser for venous ablation (EVLA) was first delivered

in 1999 (105). Endovenous operations for the management of saphenous inefficiency have the preference of simpleness and effectuality (61). These operations are provided with less injury to the body along with fast recovery that makes them a favored option to open surgery.

Endovenous thermal ablations can be delivered by utilizing laser or radiofrequency waves. The decision would be based on the diameter of veins and the range of tortuosity (106). Laser energy is administered within an endovenous procedure via fiber tip. It is greatly concentrated with temperature above 100 °C close to the fiber tip. RFA delivers resistive burning of the vein wall in its entire perimeter results temperatures of 85-90°C endovenously (107).

Each technique has its supporters. Proponents of EVLA highlight greater recanalization rates with RFA (108). Supporters of RFA highlight significant lack of physical comfort among patients with EVLA. For veins with bigger size and small number of enlarged tributaries, the RFA technique is better (61). EVLA is recommended in case of large number of the tributaries and branches, associated with small sized truncal vein (106). Cosmesis is absolutely better with EVLA (109). It is hard to cannulate and cure small veins utilizing the RFA probe. EVLA is a more flexible method since the fiber and sheath have smaller diameter.

Other preferences of EVLA are simplicity of employ, rapidity of pull back, and favorably cost of the disposables. Due to the concentrated nature of the laser beam and greater temperatures, EVLA, in contrast to RFA, is corresponded with greater vein wall perforations. That explain why EVLA is corresponded with more therapeutic-related pain

and induration in the phase of recovery, compared to RFA (107). Post morbidities such as bruising and pain were remarkably fewer with RFA with second generation catheters than endovenous laser treatment in two randomized controlled trials (110). RFA generates invariable heating of only the endothelium. It is improbable to generate perforation of the vein. Studies claimed conformable viewpoints in the choice between RFA and Laser (111).

Endovenous thermal ablation outcomes (early, midterm, and 3-year) are equivalent to or even preferable than high ligation and stripping (HL/S) (112). The post therapeutic duplex exams have confirmed that the greater number of the terminal tributaries are sufficient (113). In addition, neovascularization is an infrequent event in thermal ablation in contrast to HL/S (113). In the expected future, thermal ablation methods would completely side track HL/S and is expected to be considered as the new gold standard (61).

### **iii. Sclerotherapy**

Sclerotherapy focused on chemical ablation of affected vessel by administration of liquid or foamed sclerosing materials. Intradermal, subcutaneous, and/or trans fascial vascular structures are possible fixed by this technique. The approach might also be utilized for superficial and deep veins malformations. The sclerosant cause chemical destruction to the inner media and endothelium (114, 115). The long term outcome of sclerotherapy is to convert the cured vein into a fibrous cord, a methodology recognized as sclerosis (116-118). Venous thrombosis might cause a temporarily obstruction but is expected to get re-canalized in the passage of time.



In the late nineteenth century, the utilization of sclerotherapy among phlebology interventions was practiced following the invention of syringe (119, 120). While in the early twentieth century, several materials were used as chemical agents such as hypertonic saline and sodium morrhuate (121). In addition, different approaches were developed like micro-sclerotherapy (122) and shaking the vial, a method delivered for telangiectasia therapy (123). In 1944, blood displacement and air-block method were developed (124). These types of techniques were subjected to improvements by several scholars (125, 126). Polidocanol foam was used for the first time in 1963. Double syringes and a connecting tube were also utilized first among foam production procedure in 1986. Tourbillon method, which employs double syringes and a three-way, was developed in 2000 (21). This method provides further comprehensive specification systematize the pumping approach that generate foam (127, 128).

Sclerotherapy is one of the essential elements of varicose veins therapeutic process (61). Liquid sclerotherapy is the common option for ablation of reticular veins and telangiectasias (129). Ultrasound guided foam sclerotherapy (UGFS) is an alternative therapeutic technique in this case with similar obstruction rates and side effects (130). UGFS of saphenous trunk and its branches is more effectual than liquid sclerotherapy. Midterm postoperative failure rates of UGFS are higher than traditional surgery or thermal ablation methods (131-136). Though, all these groups delivered similar symptomatic recurrence rates (137). In recurrence situation, UGFS shows a superiority since its reintervention is possible to be delivered on outpatient ward. Compared to other approaches, cost of UGFS is also low (138-141). Several studies emphasized the

popularity of UGFS therapy specifically with recurrent varicose veins, bleeding varicose veins, isolated varicosities, below-knee varicosities, and varicose veins in elderly patients who come with high risk for anesthesia (142, 143). Also, there is continues studies to confirm that UGFS has an access to the microcirculation. In general, it is recognized that UGFS has the prospective to be a cost-effective technique to a widespread health care issue (61).

#### **Treatment Outcomes: Theories and Empirical Support.**

##### **i. Open surgery**

The outcomes of surgery have gradually enhanced over the years. Randomized clinical trials have showed significant development in Quality of life (QoL) scales afterward open surgery (85). In contrast to non-surgical approaches, surgery resulted significant symptomatic relief at 2 years. The rate of repeat surgery was 6 % in patients who had high ligation and stripping compared to 20 % in those who had high ligation only. Patients who have undergone high ligation only have recurrent abnormal flow-back in the residual GSV, which may explain their high rate of repeat surgery. More recanalization and reinterventions were reported after ultrasound guided foam sclerotherapy during a study examined GSV varicose veins of 580 limbs in 500 patients. Though, the study evaluated the outcome of EVLA, RFA, ultrasound guided foam sclerotherapy and open surgery and lastly claimed that all these techniques were effective and efficient (112).

Primary varicose veins treatment via open surgery may be followed by general complications or specific complications (144). Metabolic dysfunctions resulted from comorbidities and anesthesia events are examples of general complications. Patients with no extra risk factors are rarely associated with thromboembolic complications. The recorded cases are about 0.5 % (103). It is essential to examine risk factors and apply pharmacoprophylaxis once it is needed (144).

Specific complications are those associated with stripping treatment or groin exploration (144). Bleeding, seroma, and hematoma are common complications following slippage of the ligated tributaries. These events can be avoided by utilizing groin drain. Disrupted lymph nodes and lymphatics can cause lymph leak and collection. Re-exploration is commonly followed by such events.

The recorded occurrence of groin injury infection after varicose vein surgery varies from 1.5 to 16 %. According to recent randomized clinical trial, post operative wound infection can be prevented by using antibiotic prophylaxis before surgery (85). Although it is not common, groin exploration may be followed by potential complications such as femoral artery and vein wound. A study evaluated 44 arterial and 43 deep vein injuries revealed interesting findings. The majority of these events were preventable. The widespread symptom was bleeding. The most frequent type of venous injury was laceration or division of the femoral vein. When the stripper head passes into the femoral vein, the femoral vein is partially stripped. The majority of arterial injuries are caused by accidental arterial stripping. Such postoperative complications may result serious events such as loss of limb, life, or other severe morbidities. The study lastly

recommended regular exams of arterial circulation during surgery and in the postoperative period. Also, it emphasized the importance of anatomical understanding and awareness of the likelihood of vascular injuries (145).

While the lately complication like recurrence of varicose veins has unclear origin in every case, neovascularization that resulted after extensive groin clearance is the most probable cause. Inappropriate therapeutic approaches and the development of the illness are other possible causes (144).

Post stripping complications include various types (144). Complications that clear in 3 weeks time such as discomfort, bruising, and bleeding are common unfavorable stripping outcomes. Nerve damages include long lasting neuropraxia and temporary numb patches. The saphenous and sural nerves are the usually affected nerves. The reported rate of saphenous nerve injury after varicose stripping is 7 %. Though, cases that had stripping up to ankle level recorded an injury rate reached 39 % (85). The figures of sural nerve injury following short saphenous vein surgery range from 2 to 4 %. The rate for common peroneal nerve injury varied from 4.7 to 6.7 % (79). A study evaluated 70 patients revealed that partial revascularization was delivered in 12 patients and full strip tract revascularization with reflux was recorded in four patients. One week after surgery, post hematoma complication occurred in the stripped tract for all patients in the study (146).

## **ii. Endovenous thermal ablation**

### **a. Endovenous laser ablation**

The postoperative ablation rate of EVLA in the first three months is nearly 100 % (147, 148). However, this rate decreases with time. Truncal vein ablation rates reached 93-99 % during a follow up between 1 and 3 years (149). The decreased success rate has been referred to inappropriate therapeutic approach, inability to deal with the tributaries at the SFJ, and insufficient laser power utilized to close affected vein. A study took place from 2004 May to 2009 May examined 343 patients who were undergone EVLA. At the end of the study period, the ablation rate was 89.6 % (150). Postoperative unfavorable outcomes reported in the study were cordlike feeling, minor skin burns, superficial thrombophlebitis, DVT, thrombosis infection, and the retraction of covering sheath. At 3 year follow up, 36 patients from the study suffered from recurrences.

Neovascularization is unusual after EVLA since the superficial epigastric vein is maintained during EVLA and groin dissection is not required (149). EVLA is possible to be performed with other surgical procedures. EVLA has been delivered to ambulatory phlebectomy (151). Moreover, The association between EVLA and endovenous iliac vein stenting has been also performed (152). In addition, EVLA has been practiced with cases have more advanced CEAP classes. EVLA showed superiority over HL/S with a recurrence rate much lower than the HL/S; 10-20 % rate at 1 year. A study designed a comparison between EVLA and HL/S examining 280 cases revealed that HL/S had higher rates of postoperative recurrence in contrast to EVLA in short term (153). Another work reported no significant differences in postoperative outcome between EVLA and

cryostripping (154). While the popularity of EVLA has increased, still there are concerns about its cost effectiveness (150). A study that evaluated varicose veins therapy options claimed that EVLA and RFA both showed to be evenly cost effective strategies since they are office operations and day case surgeries. However, it stated that UGFS had the lowest initial cost but required more interventions. (155).

#### **b. Radiofrequency ablation**

Several scholars have highlighted the low subsequent recurrence rate of RFA, up to 10 years, which indicates a high early success rate (150). Among endovenous ablation approaches, RFA provides comparable early and midrange results. At early follow up, RFA delivered high occlusion rates in a study of 194 cases. Occlusion rate among the study sample was 99.6 % on 3 days, 3 months, and 6 months follow up (114). In a series of 100 consecutive cases, a full closure of 97 % at the end of 1 year was recorded. One case of neovascularization has also observed (156). Several scholars have classified recurrence types that occur after RFA (157). Three anatomical types have been addressed: (1) initial and long-term failure of occlusion, (2) early occlusion with late recanalization, and (3) truncal occlusion with persistent groin reflux. A closure rate of 97.62 % at 3 months and no severe postoperative unfavorable outcomes were resulted from a study that examined, over a 3 year, 42 cases undergone RFA (150). In contrast to EVLA, RFA is more efficient in dealing with large veins. Though, high recanalization rate is still a concern. At 1-year follow up, RFA has presented a failure rate of 5-10 %. EVLA showed superiority over RFA in decreasing the risk of having postoperative pulmonary embolism or DVT (131).

### **iii. Sclerotherapy**

UGFS has presented a greater efficiency in comparison to liquid sclerotherapy. By utilizing them as foam, sodium tetradecyl sulfate and polidocanol appeared to be evenly efficient approaches (158). UGFS showed superiority over conventional surgery in minimizing pain, decreasing absenteeism from work, and speeding the return to driving (133). Among a comparative study that evaluated UGFS and traditional surgery, the figures at the end of 2 years that relate to recurrent reflux irrespective of venous symptoms were 35 % for UGFS and 21 % for traditional surgery (133). However, both methods presented similar results for symptomatic recurrence. In addition, the study claimed that UGFS had significantly lower cost than traditional surgery (159).

UGFS delivered high technical failure rate 16.3 % at the end of one year. This rate is considered high in comparison to other therapeutic methods (RFA 4.8 %, laser 5.6 %, and traditional surgery 4.8 % (160). While EVLA and traditional surgery presented high pain scores, the figures relate to UGFS and RFA were significantly lower (133). In general, UGFS provides better outcomes than surgery for patients with recurrent varicose veins. Symptomatic recurrent varicosities of the GSV are fixed by UGFS via treating abnormal flow-back located in above-knee and below-knee (137).

In addition, varicosities of the SSV are also effectively and safely treated by UGFS (160). However, 0.6 % of the cases undergone UGFS of SSV delivered postoperative medial gastrocnemius vein thrombosis. Patients who experienced medial gastrocnemius vein perforators or got a direct entry of the SSV into popliteal vein are

having a high chance to deliver postoperative DVT (161). Preoperative evaluation is recommended in these situations utilizing duplex scan (160).

Following systemic operational manner on dealing with sclerotherapy is decreasing the incidence of postoperative unfavorable outcomes (162). Though, delivering some venous-related complications is still expected. Anaphylaxis is an infrequent postoperative complication. It is varied from mild pruritis and urticaria to shock and death (163). Administration of sodium morrhuate that associated with sodium tetradecyl sulfate may increase the chances of developing postoperative anaphylaxis. However, anaphylaxis is rarely delivered after polidocanol administration (142).

In addition, sclerotherapy has a recorded incidence of thrombophlebitis varies from 0 to 45.8 % (164-166). While it is infrequent, delivering postoperative superficial thrombophlebitis is still reported (143). Compression treatment that is delivered after sclerotherapy may decrease the incidence of thrombophlebitis (160).

Sclerotherapy presents low rate, less than 1 %, of postoperative thromboembolic complications such as pulmonary embolism and proximal DVT (166-168). Distal and asymptomatic DVTs are the common events (169, 170). The risk of delivering postoperative DVT is directly related to large volume UGFS (25, 171, 172). Prophylactic examinations are required for cases associated with previous DVT or thrombophilia history (171, 173). Flushing the deep veins via sclerotherapy can help in minimizing the incidence of deep vein thrombosis (160).

Administration of sclerosant into a terminal arteriole or extravasation of the chemical injected material can cause skin ulceration and cutaneous necrosis (174).



Treatment of telangiectasias or reticular veins can develop such post complications (175, 176) that lead to nicolau phenomenon or embolia cutis medicamentosa (177, 178). It is recommended in telangiectasias cases to apply multiple injections with small volume at each site and utilize dilute solutions during the intervention in order to prevent postoperative extravasation (160).

Therapeutic interventions for reticular veins and telangiectasias can be associated with postoperative hyperpigmentation. In the short term, incidence was ranged from 0.3-30% (130, 174). While it is least common with chromate glycerin and polidocanol, the most common agent producing hyperpigmentation are hypertonic saline and sodium tetradecyl sulfate. Extravasated red blood cells are the origin of hemosiderin that leads to pigmentation. Utilizing weak solutions and low pressure during administration of the agent may prevent pigmentation. Minithrombectomy is required for taking off formed coagulum (179). Over a prolonged period, hyperpigmentation heals (180).

Delivering unfavorable varicose veins treatment outcomes like neoangiogenesis and telangiectatic matting are reported after sclerotherapy, surgery, and thermal ablation (174). All the measures to prevent pigmentation can be practiced here also. It is required to treat any post abnormal residual flow-back (165). Neoangiogenesis is reported to be efficiently cured by applying therapeutic pulsed dye laser (142).

Both liquid and foam sclerotherapy are followed by postoperative gangrene or necrosis which resulted from accidental intra arterial injection (181, 182). Applying post thrombolysis and systemic anticoagulation are recommended in order to control the situation (165). Ultrasound guided puncture of veins minimizes the incidence of such

complication. The possibility of accidental intra-arterial injection is increased by administering agent to medial calf perforating veins using the ankle. Amputations were performed in 50 % of affected patients (183). However, possibility of nerve injury is extremely low after sclerotherapy in contrast to other therapeutic methods such as surgery and thermal ablation (184).

It is been reported that foam and liquid sclerotherapy can deliver postoperative transient migraine (169, 170, 185). It is expected that entering of foam bubbles to arterial circulation is the origin of such complication. While it is not clearly linked to the foam, sclerotherapy is reported to be associated with subjective and transient visual disturbance that may also be followed by paresthesia and dysphasia (186). A study has claimed recently that increased endothelin-1 level from venous administered with sclerosants may lead to visual disturbances (187, 188). Administration of sclerosant into deep veins can be achieved by applying slow injection of small quantities to each site during the treatment (189).

Lastly, the entering of air bubbles into the cerebral vessels has been linked to early onset neurological disturbances that occur after sclerotherapy. Though, it is reported that thromboembolic pathology is not related to such situation (170, 172, 190-192). A complete or near complete recovery had been reported in affected patients (193, 194). Poor prognosis; paradoxical clot venous embolism have been linked to late onset neurological events (195). Delayed strokes have also been occurred after delivering different therapeutic varicose veins methods (196). To decrease post neurological incidence, several precautions are suggested: (1) avert administering large amount of

foam or liquid agent, (2) avoid applying Valsalva maneuver during and soon after the intervention, (3) prevent patients ambulation especially with patients who experienced neurological events in the previous sessions (143).

#### **Clinician's Specialty and Treatment Outcomes: Theories and Empirical Support.**

Enlarged number of different interventional radiology procedures that were performed yearly shows the amount of popularity this radiologic field has gotten, in which is justified by continued improvement of the field's techniques and the increased number of patients who are looking for alternative treatments instead of invasive surgeries (197). Many modifications have been made through interventional radiology policies that authorize other specialists, interventional cardiologists (IC) and vascular surgeons (VS), to deliver several minimally invasive interventions like peripheral vascular procedures (197-199). On the other hand, many less invasive interventions have been under development, such as breast interventions, paracentesis, and thoracentesis services, which makes radiologists currently predominate (200). The numbers of performed endovascular interventions for vascular diseases have grown rapidly more than what it could be estimated by changing demographics in the past decade and a half (201-204). Till the late 1990s, interventional radiologists had operated most endovascular interventions (197). This situation has changed by ICs and VSs whom had operated more than 80% of peripheral endovascular interventions by 2006 (50, 201).

Patient safety is essential to health care, and appropriate training for physicians who deliver clinical services affords optimal possible outcomes (205). Interventional radiology is not a merger of unlinked clinical operations. All skills physician has gained

from his experience and training are carried out in every intervention (206). Nowadays, different specialties are authorized to precede interventional radiology operations. As a result, competency has been limited which may reduce efficiency, rise services costs, and jeopardize patient safety (51). It is recommended to provide more training for those whom perform image-guided procedures in order to prevent critical incompetence by resolving limited competence. Achieving cost-effective and optimal outcomes is the aim of both health care providers and patients especially with present financial and social conditions, and this will have been attained through adequately trained physicians (205).

#### **i. Shifting of image-guided procedures from radiologists to other specialties**

While longitudinal patient care must be delivered by legitimate clinical practitioners, interventional radiologists (IR) have been continually challenged to take charge of such delivering service due to their backgrounds as nonclinical proceduralists (207-215). Authorizing ICs and VSs to perform several minimally invasive interventions bequeath a sense of lament among IRs (56, 216). Since they have doubts toward IRs' ability and willingness to take patient care responsibilities, ICs and VSs show readiness to involve and perform minimally invasive radiologic interventions (207, 208, 210, 213-215). Claims from 1997 to 2000 issued by paid Medicare evaluation and management (E&M) showed nominal increases of IRs' clinical services while somewhat conflicting trends appeared in national claims data after applying short-interval analyses (217). Between 2000 and 2003, IRs made more substantial gains (218). However, several clinical interventional radiologic services delivered by subspecialized radiology practices have achieved considerable long term continued growth (219).

## **ii. Observation of specialty-specific outcomes**

According to the Institute of Medicine's report on medical errors, the attention that has been grabbed lately on physician performance is related to such initiatives as pay for performance (220). Best invasive intervention outcomes can be guaranteed by authorizing only appropriately trained and experienced physicians to perform the procedure (56, 58). There was a study evaluated specialty-specific outcomes by examining IR's patients and VS' patients who underwent endovascular lower extremity revascularization. It analyzed National Inpatient Sample (NIS) data from 1998 to 2005, and concluded a significantly higher odds (odds ratio, 1.62;  $P < .001$ ) of periprocedural mortality for interventional radiologists' patients (50).

Further, a retrospective research has explored national patient databases to study the impact of operator experience on outcomes after endovascular lower extremity interventions (51). This study aimed to emphasize the relationship between patient safety and high quality physician training. In this study, better endovascular revascularisations outcomes were achieved by IRs in contrast with VSs. IRs presented less repeat revascularization interventions and amputations, lower average procedure costs, shorter hospital stay, and less frequent blood transfusion and intensive care unit stay. Favorable outcomes were also delivered by ICs in terms of blood transfusion, hospital stay, and repetition of revascularization procedures and amputations. In order to explain the rationale for unfavorable outcomes, the researcher claimed that proper skill and competency in open procedures would reduce poor outcomes by diminishing the lack of training and/or experience (51).

## **Disease Severity and Treatment Outcomes: Theories and Empirical Support.**

### **i. The indications and contraindications for CVD treatments**

#### ***a. Open surgery***

Indications list for open surgery has been modified in response to the introduction of endovenous techniques (144). It is updated to include dilated saphenous vein, extremely swollen truncal varices, and veins that incapable to be pressed to a depth of 1 cm beneath the skin surface after tumescence (85, 147). Within the practice of CVD treatments, it is understood that small incisions and optimum exposure are more favorable than long incisions and extensive exposure. This explains the unpopularity of open surgery that has long hospital stay and high incidence rate of delivering postoperative pain. However, open surgery recently is provided as a day case operation (144).

#### ***b. Endovenous thermal ablation***

Endovenous laser ablation is restrictedly delivered to any affected venous structure that is 3 mm or more in size, straight, and able to be pressed to a depth of 1 cm beneath the skin surface after tumescence (150). Affected GSV, SSV, and their tributaries are the commonly venous structures treated by EVLA. The optimal indications for EVLA include inefficient superficial veins, abnormal flow-back of over 0.5 s detected by duplex scan, patent deep venous structures, cannulable vessels, and ambulant patient (147, 149, 221). Though, cases come with arteriovenous malformations (AVM), pathological deep

venous occlusion, and patients with limited mobility are contraindicated with EVLA. Moreover, relative contraindications for EVLA include abnormal flow-back within deep system, previous therapy for varices, massive tortuous veins, large-caliber veins, anticoagulant or therapeutic hormone therapy administration, and segmental venous aneurysm (147, 149, 222).

### ***c. Sclerotherapy***

Patients come with angioectasias, feeder dilated veins, isolated varicosities, varicosities located beneath the knee, and recurrent varicosities are indicated optimally for sclerotherapy (160). Though, cases not optimally indicated for sclerotherapy are symptomatic reflux, aged, or patients who are not surgically fit to undergo surgery. Controversial indications include SFJ reflux, SPJ reflux, massive varicosities, and massive perforators associated with refluxing (142, 143). Local or severe systemic infections, postthrombotic syndrome, acute thrombophlebitis, allergy to used agents, uncontrolled malignancy, and bed-ridden patients are all described as sclerotherapy contraindications (142, 143). While surgery and endovenous thermal ablation are idealistic treatments for axial refluxes and large veins, Treatment of such venous structures like smaller veins and telangiectasias are possibly achieved by sclerotherapy (129).

### **ii. Accounting for clinical indication as a measured outcome variable**

Defining the true predictors of several outcomes for endovascular lower extremity interventions has been the main goal of many studies. Comparisons between different

therapeutic approaches for various degrees and severities of lower limb diseases have been made to achieve this goal. Investigations have declared that infrainguinal endovascular interventions outcomes are impacted by clinical indication, which appears as a significant prognostic factor (37, 223, 224). Records from endovascular revascularization of superficial femoral artery showed that patients with claudication delivered favorable postoperative outcomes, patency and amputation-free survival rates, than patients with critical limb ischemia (CLI) (223). Another comparison between these two degrees of severities was made to study infrainguinal arterial disease and evaluate patency and limb salvage outcomes for endovascular therapeutic interventions (37). With low significance differences, favorable patency and limb salvage were related to claudication condition. In the same way, the association between high disease severity and treatment outcome was also reported in a study, which observed high in-hospital mortality among high severity CLI patients in contrast to low severity claudicants patients (224). Furthermore, severity of ischemia also appeared as a strong predictor of endovascular interventions outcome with significantly enlarging odds of mortality, using intensive care unit, having an extended length of stay, getting higher total hospital charges, and not being discharged home.

### **Gaps and Limitations**

Theorists and findings from the empirical literature suggest that prediction of unfavorable endovascular lower extremity interventions outcomes generally is multifactorial. They support the theorized relationships among disease severity, clinician's specialty, and interventions outcomes. There is substantial evidence that



disease severity of endovascular lower extremity procedures is linked to unfavorable interventions outcomes (37, 223-225). There is also evidence linking unfavorable endovascular lower extremity interventions outcomes to the type of training and experience the intervention's clinician has (50, 51).

However, significant gaps in the empirical literature exist. Across the studies that investigated the impact of disease severity on treatment outcomes, some heterogeneity was found during the contrast between different disease severity groups in terms of comorbidities and procedures performed (37). In addition, there was a limited length of follow up and potential selection bias among studied patients groups (37). As well, a randomized trial was required in such studies to attain better determination and more directly comparison for different treatment strategies (223). Besides, a propensity score would have been a better method to compare patients subgroups (223). Moreover, the fact that some patients had procedures on both lower extremities needs more consideration (223). Although these patients represent a small proportion of all patients and were not systematically different than the population undergoing the interventional procedures, it is difficult to claim that these events were truly independent of each other (223). Additionally, expanding the quantification of the disease outcomes to cover several dependent variables is necessary to attain more optimal comparative end point. Also, evaluating the efficiency of the treatment approaches administered to patients requires assessments of more unfavorable major adverse events (223). Administrative discharge data is subjected to limitations due to concerns about coding accuracy, which presents difficult challenges since it is usually operated by the data entry personnel,

favoring clinical cases with higher reimbursement rates (226-228). Studies focusing on added volume and costs associated with endovascular procedures would need to account for those are performed at ambulatory settings (224).

Similarly, a previous study observed specialty-specific outcomes is subjected to weaknesses due to several reasons; it covered only 3% of total interventional procedures that performed for inpatient only (229, 230), examined nonrandom sample which made it exposed to bias, and utilized identification algorithms to categorize physicians by specialty instead of employing patient identifier or physician specialty identifier (50, 204). The analysis methods credibility would be improved by covering more cases of total interventional procedures which help to determine specialty designation (50, 230). Though, a study showed the superiority of IRs over VSs in delivering better endovascular revascularisations outcomes, this work is limited in many ways. First, variables for the measured outcomes did not include the clinical indication (37, 223). Also, confounding by indication appeared noticeably (231) that affected the strength of this observational work and resulted flawed study design and findings. The estimation of treatment effect requires predictive models with factors control in order to prevent potential bias (225). That study categorized vascular surgeons, general surgeons, thoracic surgeons, and cardiac surgeons under a vascular surgeons group. Such specialities, except vascular surgeons, have not had appropriate training in endovascular lower extremity interventions and including them in vascular group was a form of falsification (225).

The studies that examined the relationship between empirically derived predictors gleaned from the empirical literature, while small, provide preliminary evidence that

disease severity and clinician's specialty may pose significant prediction of unfavorable image-guided varicose veins treatment outcomes. Although these predictors were found significantly related to endovascular lower extremity interventions outcomes generally, these findings were not consistent in all studies tested these relationships. Clearly, the sparse body of work in this area yields limited knowledge regarding the contributions of these predictors to endovascular lower extremity interventions outcomes generally, and further empirical exploration is warranted. Currently, there is limited evidence that disease severity is linked to overall patient condition and no studies that link clinician's specialty to outcomes for image-guided treatment of varicose veins. Moreover, the relationships between different demographic variables and outcomes for treated varicose veins are untested.

There has been no study tested full model in a sample of image-guided varicose veins patients who were treated at ambulatory settings and hospital adult inpatients. The purpose of this proposed study is to address this important gap in the empirical literature by determining the relationships among disease severity, the specialty of clinician, and patient postoperative outcomes; postoperative complications and reintervention.

### **Theoretical Rationale**

Radiology has been considered as one source of enlarged health care practice cost throughout the United States due to the high increase in performing diagnostic imaging and interventional procedures over the past decade, which reflects a large amount of unwarranted variation in medical services (232-234). While health care providers are responsible to deliver optimal diagnosing, monitoring, and treating for clinical

conditions, the multitude of medical services choices lead to unwarranted variation (235). Since there are a lot of health care methods that have been based on little scientific evidences, comparative effectiveness studies are filling the gaps by defining and supporting evidence based value, which enhance health care policy and practice (235). The Institute of Medicine made a list of 100 top national priorities for comparative effectiveness studies, with nine priorities specifically applicable to radiology (236-238).

The certainty in choosing appropriate clinical procedure from various available options of interventions is promoted through collaborations with clinicians in medical specialties multiplicity (235). Comparing different available treatments via designing more prospective and retrospective researches would be helpful in identifying which clinical decision is optimal and whether multiple treatments are appropriate in some patient groups compared with others. In addition, another approach to explore variation in health care services is studying different clinical practice patterns at an institutional or national level, which would determine intervention choices and improve general consensus on which intervention to perform. This would help in deciding which technique is optimal for which patient and how often patients should be observed for recurrence (235). Many works have been done in the field of comparative effectiveness studies, which can be utilized as literatures for future studies. For example, a sample from patients of emergency section who have acute coronary syndrome were participated in a comparative effectiveness research aimed to study the impact of coronary computed tomography angiography (239). A therapeutic procedure like wide local excision of primary breast cancer was also under evaluation with and without magnetic resonance

imaging (240). Furthermore, meta analyses work has explored thoracentesis procedures and the impact of ultrasound guidance on postoperative outcomes (241). In addition, spine injury in trauma patients was also studied in order to evaluate whether the utilization of computed tomography improves outcomes compared with adjunctive radiologic techniques (242).

While it is important to have the participation of clinical departments and medical specialties in order to deliver studies compare therapeutic interventions, these investigations potentially may result turf wars among healthcare providers (235). Discrediting a particular intervention or medical specialty is a concern of staff clinicians. Engaging representatives from all departments and specialties that deliver the therapeutic interventions to be evaluated is important. It is recommended to depersonalize the comparison between interventions and associated specialties by delivering these comparative effectiveness studies at a national level instead of at an institutional level (235).

### **Hypotheses**

The following hypotheses were investigated in adult varicose veins patients admitted into both inpatient and ambulatory surgery settings and undergone image-guided treatment:

1. Providing of image-guided treatment by VS is associated with the occurrence of postoperative complications in varicose veins patients.
2. Providing of image-guided treatment by IR is associated with the occurrence of postoperative complications in varicose veins patients.

3. Providing of image-guided treatment by IC is associated with the occurrence of postoperative complications in varicose veins patients.
4. Providing of image-guided treatment by VS is associated with the occurrence of reinterventions in varicose veins patients.
5. Providing of image-guided treatment by IR is associated with the occurrence of reinterventions in varicose veins patients.
6. Providing of image-guided treatment by IC is associated with the occurrence of reinterventions in varicose veins patients.

## Chapter III

### METHODS

This chapter presents the study design inclusive of the data sources, elements, criteria of groups' inclusion/exclusion, exposures, outcomes of interest, and analysis for this work. A descriptive design was used in this study to test the relationships between theoretically and empirically derived risk factors, and delivering unfavorable varicose veins treatment outcomes in order to recognize significant predictors delivering unfavorable varicose veins treatment outcomes in adult patients admitted to both inpatient and ambulatory surgery settings in a large sample from hospitals in New Jersey. A retrospective analysis using existing patient data was conducted.

#### **Research Design**

This is a secondary analysis of cross sectional data of clinicians and patients in New Jersey. This study examined the determinants of delivering unfavorable varicose veins treatment outcomes of inpatient and ambulatory surgery adults, specifically disease severity and specialty of treatment clinician. The clinician measures were derived from 2011 to 2013 databases of clinician in New Jersey. Patient outcomes data on more than four million patients discharged from New Jersey hospitals from 2011 to 2013 were available for analysis. The outcomes of interest were extensive and included postoperative patient complications, and reinterventions. Since the research questions essentially seek the strength of the relationships between categorical variables, the

analytic approach used univariate analysis (chi square), multivariate, and reduced logistic regression models that were appropriately matched to the outcomes of interest.

The primary outcomes were those related to the patient; postoperative complications and reinterventions. The primary predictor in all models was specialty of treatment clinician. Disease severity was the secondary predictor in the patient outcome models. Patient demographics were included as additional covariate in all models that examined patient outcomes.

#### **Data Sources and Data Elements**

In order to evaluate treatment outcomes for patients undergoing image-guided treatment of varicose veins, this study performed a cross sectional analysis of hospital discharge information from the publicly available New Jersey State Inpatient Database (SID) and State Ambulatory Surgery Database (SASD) for the years of 2011 to 2013. These databases were developed as part of the Healthcare Cost and Utilization Project (HCUP) sponsored by the Agency for Health Care Research and Quality (AHRQ). Many endovascular procedures have shifted to the outpatient surgery setting. A few states, such as New Jersey, Maryland, Florida, and California, make data regarding outpatient procedures available in both; SID and SASD. These databases represent a 100% sample of hospital discharges and ambulatory procedures, respectively, within each state.

The SID from HCUP contains inpatient discharge abstracts from New Jersey hospitals. SID contains more than 100 clinical and nonclinical data elements such as facility identification number, patient demographics, admission and discharge information, payment source, total charges, and length of stay. In addition, International



Classification of Diseases, 9th edition, Clinical Modification (ICD-9-CM) codes are recorded for both; the principal diagnosis and principal surgical procedures. An expanded number of diagnosis and procedure codes, clear demarcation of presenting, and secondary comorbid diagnoses are all unique and imperative features of the discharge data that permit enhanced risk adjustment. The SASD is a census of discharges from free standing and hospital affiliated ambulatory surgery centers; acute care, nonfederal, community hospitals; and emergency department visits which did not result in hospital admission. Each ambulatory surgery center discharge abstract contains up to 21 Current Procedural Terminology (CPT) procedural codes; 15 diagnostic ICD-9-CM codes; and information about patient demographics, anticipated payer, and discharge disposition. This database contains unique variables, which allow patients to be followed over time and across healthcare settings; enabling subsequent outcome assessment.

This study poses no risk to patients or clinicians. In these publically available SID and SASD datasets, all personal identifiers were removed prior to release to the public. All data were obtained by the investigator from the sources described above and stored electronically on a password protected desktop computer behind a secure firewall. Computer files were backed up onto a portable encrypted external drive and kept in a locked cabinet. These data were then transferred and stored on secured servers in the School of Health Related Professions at Rutgers Biomedical and Health Sciences University, Newark. All patient and clinicians data were secured and accessible only to the researcher, a data analyst, and statistician. HCUP has clear guidelines for the use of their de-identified patient data that were scrupulously followed. Every precaution was

taken to ensure that data regarding specific hospitals could not be linked to the institutions' names, including omitting hospital names from all working analytic files.

Data integration methods included a cross-walk based on unique record identifiers (KEY); the common identifier was then used to link all datasets. Datasets were constructed using information from the sources previously mentioned to address the aims of this study. Initially, separate patient level data sets for each medical condition and surgical procedure of interest were assembled. The datasets included all patients discharged from hospitals in New Jersey with the conditions or procedures, plus all additional patient characteristics.

For all the different condition specific groups of patients, identified based on ICD-9-CM and CPT codes in the discharge abstracts in the SID and SASD, information on postoperative complications and reinterventions was employed in the analysis below. A descriptive analysis of demographic characteristics was conducted to describe the sample characteristics.

#### **Study Group Inclusion/Exclusion Criteria**

##### **i. Data abstraction:**

For this study, image-guided varicose veins treatment was defined as a hospitalization that involved a lower extremity endovascular intervention, that involved either ultrasound or fluoroscopy guidance, aims to permanently abolish all sources of superficial venous reflux resulted from varicose veins. All patients with a varicose veins severity-specific diagnosis (high disease severity vs. low disease severity) who

underwent image-guided varicose veins treatment were identified by querying SID and SASD data files for ICD-9-CM and CPT.

The study initially identified varicose veins patients with ICD-9-CM codes in the principal and secondary diagnosis positions in the data, in association with the codes listed in Table 2. Then, those patients were investigated in order to identify patients who were combined with procedural CPT codes for image-guided treatment of varicose veins on the basis of primary procedure using the inclusion/exclusion criteria clarified in Tables 3 and 4.

Table 2  
*Description of Diagnosis (ICD-9-CM) Codes Used to Identify Varicose Veins Cases*

ICD-9-CM Code	Brief Description
4480	Hereditary hemorrhagic telangiectasia
4481	Nevus, nonneoplastic
4489	Other and unspecified capillary diseases
4549	Asymptomatic varicose veins
7295	Pain in limb
45910-13, 45919	Postphlebotic syndrome [with/ without complications]
67100-04	Varicose veins of legs in pregnancy and the puerperium
67120-24	Superficial thrombophlebitis in pregnancy and the puerperium
67190-94	Unspecified venous complication in pregnancy and the puerperium
72981	Swelling of limb
V501	Other plastic surgery for unacceptable cosmetic appearance
V1251-52	Personal history of venous thrombosis, embolism, and thrombophlebitis
4510-12	Phlebitis and thrombophlebitis of vessels of lower extremities
4536	Venous embolism and thrombosis of superficial vessels of lower extremity
4540-49	Varicose veins of lower extremities, code range
4591	Postphlebotic syndrome
7823	Edema
7854	Gangrene

44023-24	Atherosclerosis of the extremities with [ulceration / gangrene]
45340-42	Acute venous embolism and thrombosis of deep vessels of lower extremity
45350-52	Chronic venous embolism and thrombosis of deep vessels of lower extremity
45931-39	Chronic venous hypertension with [ulcer/inflammation]
45981	Venous (peripheral) insufficiency, unspecified
45989	Other specified disorders of circulatory system
70710-19	Ulcer of lower limbs, except pressure ulcer
74764	Other anomalies of peripheral lower limb vascular system

ICD-9-CM = International Classification of Diseases, 9th Revision, Clinical Modification.

Table 3  
*Current Procedural Terminology (CPT) Codes for Procedures Included in the Study*

CPT Code	Description
36011	Selective catheter placement, venous system
36468-36469	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); code range
36470-36471	Injection of sclerosing solution; code range
36475-36476	Endovenous ablation therapy of incompetent vein, extremity, radiofrequency; code range
36478-36479	Endovenous ablation therapy of incompetent vein, extremity, laser; code range
37204	Transcatheter occlusion or embolization
37241	Vascular embolization or occlusion
+ 37250	Intravascular ultrasound during diagnostic evaluation and/or therapeutic intervention; initial vessel
+ 37251	Each additional vessel
37500	Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)
37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
37718	Ligation, division, and stripping, short saphenous vein
37722	Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
37735	Ligation and division and complete stripping of long or short saphenous veins

37760	Ligation of perforator veins, subfascial, radical (Linton type), with or without skin graft, open
37761	Ligation of perforator vein (s). subfascial, open, including ultrasound guidance, when performed, 1 leg
37765-37766	Stab phlebectomy of varicose veins, one extremity
37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
37785	Ligation, division, and/or excision of varicose vein cluster(s)
37799	Unlisted procedure, vascular surgery
75820, 75822	Venography, extremity, unilateral or bilateral
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation
76942	Ultrasonic guidance for needle placement
76998	Ultrasonic guidance, intraoperative
93922	Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries
93923	Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels
93924	Noninvasive physiologic studies of lower extremity arteries
93965	Noninvasive physiologic studies of extremity veins
93970-93971	Duplex scan of extremity veins
96999	Unlisted special dermatological service or procedure
S2202	Echosclerotherapy

Table 4  
Description of Procedural (ICD-9-CM) Codes for Procedures Included in the Study

ICD-9-CM Code	Brief Description
3850-53, 3855, 3857, 3859	Ligation and stripping of varicose veins code range (includes subfascial endoscopic perforator vein interruption)
3992	Injection of sclerosing agent into vein

ICD-9-CM = International Classification of Diseases, 9th Revision, Clinical Modification.

## **ii. Assignment of operator type:**

The data files of SID and SASD use primary physician identifiers that identify the physician performing the principal procedure. They are preserved across all years of data collection. This allowed identification of procedures performed by a specific clinician over the study period and determine clinician specialty. An algorithm was used to determine the specialty of the clinician. This methodology is similar to a previously published methodology (50, 204, 243-247). Weighting strategies were avoided to prevent possible errors in the statistical analysis. This study was interested in the following specialties: interventional cardiologists (IC), interventional radiologists (IR), and vascular surgeons (VS). Subsequently, clinicians were divided into three groups of physicians. The first step established procedures relevant to each of these specialties, and the ICD-9-CM codes for these procedures were included in Table 5. This work analyzed the frequency and distribution of these procedures in all observations in the data set linked to clinicians and then identified clinician specialty by procedure types performed. A threshold of 75% was used for discrimination purposes. For example, if the proportion of VS vs. IR vs. IC codes for a given clinician was greater than 75% for a particular specialty, then the clinician was assigned to that respective specialty (eg, if > 75% of procedures associated with a clinician are specific to vascular surgery, then that clinician will be categorized as a vascular surgeon). Entries associated with clinicians whose ratio of index cases was not greater than 75% were processed in a hierarchical model: each clinician that performed > 10 vascular surgery procedures was labeled an VS; clinician

with > 10 interventional radiology procedures were identified as IR; clinician that performed > 10 interventional cardiac procedures in number were classified as IC.

Table 5  
*Index Procedures with Associated Procedural (ICD-9-CM) Codes Used to Identify Clinician Specialty*

ICD-9-CM Code	Brief Description
<b><u>Vascular surgeon</u></b>	
3812	Carotid endarterectomy
3834, 3844	Open abdominal aortic aneurysm
3842	Resection of vessel with replacement, carotid artery
3848	Resection of vessel with replacement, lower limb arteries
3925	Aorto-iliac-femoral bypass
3929	Peripheral vascular shunt or bypass
3971	Endovascular aortic aneurysm repair
8415, 8417	Amputation
<b><u>Interventional radiologist</u></b>	
391	Transjugular intrahepatic portosystemic shunt
3326	Percutaneous lung biopsy
5011	Percutaneous liver biopsy
5198	Percutaneous cholecystectomy
5491	Percutaneous abdominal drainage
5503-04	Percutaneous nephrostomy
7849, 8165	Percutaneous vertebroplasty
9925	Chemoembolization
9929	Injection or infusion of other therapeutic or prophylactic substance uterine fibroid embolization
<b><u>Interventional cardiologist</u></b>	
051	Implant defibrillator
066, 3601-02, 3605	Percutaneous transluminal coronary angioplasty (PTCA)
3604	Intracoronary thrombolysis
3606-07	Intracoronary stenting
3721-23	Heart catheterization

ICD-9-CM = International Classification of Diseases, 9th Revision, Clinical Modification.

### Exposures and Outcomes of Interest

The primary outcome measure for this retrospective study was the utilization of image-guided varicose veins treatment over time. Secondary outcomes of interest included (1) postoperative complications and (2) reinterventions.

#### i. Postoperative complications:

Postoperative complications were operationally defined as the presence of recurrence with reflux events. The outcome data of select postoperative complications was derived from 2011 to 2013, New Jersey SID and SASD data. Postoperative complications included in analyses were: (1) nerve injury; (2) haematoma; (3) phlebitis; and (4) vein thrombosis. Each complication was defined by selected diagnosis ICD-9-CM codes start from the third positions, which suggest the occurrence of a postoperative event (Table 6). Complications were treated as a binomial outcome (complication vs. no complication).

Table 6  
*Description of Diagnosis (ICD-9-CM) Codes Used to Identify Postoperative Complications*

ICD-9-CM Code	Brief Description
0400	Gas gangrene
4439	Peripheral vascular disease, unspecified
4510, 4512	Phlebitis and thrombophlebitis of lower extremities
4519	Phlebitis and thrombophlebitis of unspecified site
4532	Other venous embolism and thrombosis of inferior vena cava
4536	Venous embolism and thrombosis of superficial vessels of lower extremity
6811, 6826-27	Cellulitis of lower extremities
7854	Gangrene



9040-41	Injury to femoral artery
9043	Injury to saphenous veins
9075	Late effect of injury to peripheral nerve of pelvic girdle and lower limb
9562	Injury to posterior tibial nerve
44020-24, 44029-32	Atherosclerosis
44422, 44481	Arterial embolism and thrombosis of lower extremity
45111, 45119	Phlebitis and thrombophlebitis of lower extremities veins
45340-42	Acute venous embolism and thrombosis of deep vessels of lower extremity
45350-52	Chronic venous embolism and thrombosis of deep vessels of lower extremity
45181, 45189	Phlebitis and thrombophlebitis
66570	Pelvic hematoma, postpartum condition or complication
70710-15, 70719	Chronic ulcer of lower limb
72992	Nontraumatic hematoma of soft tissue
73005-07, 73009	Acute osteomyelitis
73015-17, 73019	Chronic osteomyelitis
73025-27, 73029	Unspecified osteomyelitis
90450, 90452, 90454	Injury to tibial vessel(s)
99812	Hematoma complicating a procedure

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ICD-9-CM = International Classification of Diseases, 9th Revision, Clinical Modification.

## ii. Reintervention:

Reintervention was operationally defined as all image-guided treatment procedures performed on patients as a consequence of the initial image-guided treatment procedure performed. The outcome data of select reintervention was derived from 2011 to 2013, New Jersey SID and SASD data. Reintervention was defined by selected diagnosis ICD-9-CM codes start from the third positions or procedure CPT codes start from the second positions which suggest the occurrence of a reintervention (Table 7 and 8). Reinterventions were treated as a binomial outcome (reintervention vs. no reintervention).

Table 7  
Description of Diagnosis (ICD-9-CM) Codes Used to Identify Reinterventions

ICD-9-CM Code	Brief Description
44030-32	Atherosclerosis of bypass graft of the extremities
3925	Aorta-iliac-femoral bypass
3929	Other (peripheral) vascular shunt or bypass
3818	Endarterectomy of lower limb artery
3950	Angioplasty or atherectomy of other noncoronary vessel(s)
3990	Insertion of noncoronary stent(s) or stent graft(s)
8415	Amputation below knee
8417	Amputation above knee

ICD-9-CM = International Classification of Diseases, 9th Revision, Clinical Modification.

Table 8  
Current Procedural Terminology (CPT) Codes Used to Identify Reinterventions

CPT Code	Description
27590-92	Amputation, thigh, through femur, any level
27596	Amputation, thigh, through femur, any level; reamputation
27780-82	Amputation, leg, through tibia and fibula
27786	Amputation, leg, through tibia and fibula; reamputation
35351, 35355, 35361, 35363, 35371, 35372	Thromboendarterectomy, with or without patch graft
35470, 35473-74	Transluminal balloon angioplasty, percutaneous
35492-93, 35495	Transluminal peripheral atherectomy, percutaneous
35500	Harvest of upper extremity vein, one segment, for lower extremity bypass procedure
35521, 35533, 35541, 35546, 35548-49, 35551, 35556, 35558, 35563, 35565-66, 35571	Bypass graft, with a lower extremity vein
35583, 35585, 35587	In-situ vein bypass
35621, 35623, 35641, 35646-47, 35651,	Bypass graft, with other than vein

35654, 35656, 35661, 35663, 35665-66, 35671	
35681-83	Bypass graft, composite
35685	Placement of vein patch or cuff at distal anastomosis of bypass graft, synthetic conduit
35686	Creation of distal arteriovenous fistula during lower extremity bypass surgery (nonhemodialysis)
35700	Reoperation, distal vessels
37184-85	Primary percutaneous transluminal mechanical thrombectomy vein(s)
37205-06	Transcatheter placement of an intravascular stent(s)
75960	Transcatheter introduction of intravascular stent(s) (except coronary, carotid, and vertebral vessel), percutaneous and/or open, radiological supervision and interpretation, each vessel
75962, 75964	Transluminal balloon angioplasty; peripheral artery, radiological supervision and interpretation
75992-93	Transluminal atherectomy, peripheral artery, radiological supervision and interpretation

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### iii. Control variables:

Theoretical and empirical literatures indicate that several other factors are associated with unfavorable treatment outcomes. Therefore, the relationships between these factors and the dependent variables of interest were explored in this study, and their effects were controlled if indicated. These control variables included disease severity. Disease severity, operationally defined as combined ICD-9-CM selected codes that associated with patients undergone image-guided treatment of varicose veins on the basis of primary or secondary diagnosis positions. These codes reflect varicose veins severity-specific diagnosis (high disease severity vs. low disease severity). In this study, patients undergone image-guided treatment of varicose veins were categorized into two groups

according to disease severity (high disease severity vs. low disease severity) by using ICD-9-CM diagnosis codes detailed in Table 9. Additionally, several covariates used in this study included age, sex, and race.

Table 9  
*Description of Diagnosis (ICD-9-CM) Codes Used to Identify Disease Severity*

ICD-9-CM Code	Brief Description
<b><u>Low disease severity (C1 – C2)</u></b>	
4480	Hereditary hemorrhagic telangiectasia
4481	Nevus, nonneoplastic
4489	Other and unspecified capillary diseases
4549	Asymptomatic varicose veins
7295	Pain in limb
45910-13, 45919	Postphlebotic syndrome [with/ without complications]
67100-04	Varicose veins of legs in pregnancy and the puerperium
67120-24	Superficial thrombophlebitis in pregnancy and the puerperium
67190-94	Unspecified venous complication in pregnancy and the puerperium
72981	Swelling of limb
V501	Other plastic surgery for unacceptable cosmetic appearance
V1251-52	Personal history of venous thrombosis, embolism, and thrombophlebitis
<b><u>High disease severity (C3 – C6)</u></b>	
4510-12	Phlebitis and thrombophlebitis of vessels of lower extremities
4536	Venous embolism and thrombosis of superficial vessels of lower extremity
4540-49	Varicose veins of lower extremities, code range
4591	Postphlebotic syndrome
7823	Edema
7854	Gangrene
44023-24	Atherosclerosis of the extremities with [ulceration / gangrene]
45340-42	Acute venous embolism and thrombosis of deep vessels of lower extremity
45350-52	Chronic venous embolism and thrombosis of deep vessels of lower extremity
45931-39	Chronic venous hypertension with [ulcer/inflammation]
45981	Venous (peripheral) insufficiency, unspecified

45989	Other specified disorders of circulatory system
70710-19	Ulcer of lower limbs, except pressure ulcer
74764	Other anomalies of peripheral lower limb vascular system

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ICD-9-CM = International Classification of Diseases, 9th Revision, Clinical Modification.

## Chapter IV

### RESULTS

The purpose of this study was to address important gaps in both theoretical and empirical literatures by determining the relationships among the specialty of treatment clinician, patient disease condition, and unfavorable postoperative outcomes in treated varicose veins patients. Unfavorable patient outcomes were operationalized as postoperative complications and reinterventions. Study data were compiled from the Healthcare Cost and Utilization Project (HCUP), New Jersey State Ambulatory Surgery and Services Databases (SASD), and New Jersey State Inpatient Databases (SID) available from the Agency for Healthcare Research and Quality (AHRQ). The final analytic sample consisted of 8,793 patients. This study utilized demographic characteristics (age, gender, and race), diagnoses identifiers, procedure identifiers, and physician identifier by using: (1) diagnosis codes from International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and (2) procedure codes from Current Procedural Terminology (CPT) codes. Analysis of the data from this study is presented in this chapter.

#### **Statistical Description of the Study Variables**

Descriptive statistics of the independent and dependent patient and clinician study variables are presented in Tables 10, 11, and 12. Analysis of baseline patient characteristics revealed significant differences in patient populations among the three clinicians' types.

Table 10  
*Characteristics of Patients Included in Analyses of Treatment Outcomes (N=8,793)*

Variable	Total	VS (N=3089)	IR (N=845)	IC (N=24)	<i>p</i>
<b>Age (years)</b>					
18-49 %	2821 (32.0)	1257 (40.6)	324 (38.3)	11 (45.8)	<.0001
50-64 %	2972 (33.7)	1143 (37)	280 (33.1)	3 (12.5)	<.0001
65-79 %	2173 (24.7)	595 (19.2)	184 (21.7)	5 (20.8)	<.0001
80 and above %	803 (9.13)	92 (2.97)	52 (6.15)	5 (20.8)	<.0001
<b>Gender</b>					
Female %	6097 (69.3)	2202 (71.2)	612 (72.4)	16 (66.6)	<.0001
<b>Race</b>					
White %	6831 (77.6)	2204 (71.3)	516 (61)	15 (62.5)	<.0001
Black %	498 (5.66)	113 (3.65)	87 (10.2)	-	<.0001
Hispanic %	1029 (11.7)	548 (17.7)	182 (21.5)	9 (37.5)	<.0001
Asian %	174 (1.97)	84 (2.71)	32 (3.78)	-	<.0001
Native American %	12 (0.13)	7 (0.22)	1 (0.11)	-	0.1054
Other %	173 (1.96)	106 (3.43)	8 (0.94)	-	<.0001
<b>Disease severity</b>					
Low (C1-C2) %	1567 (17.8)	7 (0.22)	34 (4.02)	2 (8.33)	<.0001
High (C3-C6) %	7226 (82.1)	3082 (99.7)	811 (95.9)	22 (91.6)	<.0001
<b>Treatment outcomes</b>					
Post complications %	209 (2.37)	64 (2.07)	30 (3.55)	4 (16.6)	<.0001
Reinterventions %	2369 (26.9)	1115 (36)	419 (49.5)	-	<.0001

IC, interventional cardiology; IR, interventional radiology; VS, vascular surgery.

*Note.* Percentages may not equal 100 due to missing data.

Table 11  
*Characteristics of Inpatient Included in Analyses of Treatment Outcomes*  
*(N=333)*

Variable	Total	VS (N=53)	IR (N=40)	IC (N=5)	p
<b>Age (years)</b>					
18-49 %	49 (14.7)	7 (13.2)	6 (15)	-	<.0001
50-64 %	91 (27.3)	18 (33.9)	9 (22.5)	-	<.0001
65-79 %	113 (33.9)	17 (32)	15 (37.5)	3 (60)	<.0001
80 and above %	79 (23.7)	11 (20.7)	9 (22.5)	2 (40)	<.0001
<b>Gender</b>					
Female %	197 (59.1)	29 (54.7)	25 (62.5)	3 (60)	<.0001
<b>Race</b>					
White %	252 (75.6)	34 (64.1)	29 (72.5)	3 (60)	<.0001
Black %	32 (9.6)	7 (13.2)	4 (10)	-	0.0004
Hispanic %	33 (9.9)	9 (16.9)	3 (7.5)	1 (20)	<.0001
Asian %	3 (0.9)	-	2 (5)	-	0.5637
Native American %	1 (0.3)	-	1 (2.5)	-	-
Other %	9 (2.7)	1 (1.88)	-	-	0.0956
<b>Disease severity</b>					
Low (C1-C2) %	10 (3)	-	4 (10)	-	0.5271
High (C3-C6) %	323 (96.9)	53 (100)	36 (90)	5 (100)	<.0001
<b>Treatment outcomes</b>					
Post complications %	78 (23.4)	16 (30.1)	13 (32.5)	3 (60)	<.0001
Reinterventions %	46 (13.8)	12 (22.6)	1 (2.5)	-	<.0001

IC, interventional cardiology; IR, interventional radiology; VS, vascular surgery.

Note. Percentages may not equal 100 due to missing data.



Table 12  
*Characteristics of Outpatient Included in Analyses of Treatment Outcomes (N=8,460)*

Variable	Total	VS (N=3036)	IR (N=805)	IC (N=19)	p
<b>Age (years)</b>					
18-49 %	2772 (32.7)	1250 (41.1)	318 (39.5)	11 (57.8)	<.0001
50-64 %	2881 (34)	1125 (37)	271 (33.6)	3 (15.7)	<.0001
65-79 %	2060 (24.3)	578 (19)	169 (20.9)	2 (10.5)	<.0001
80 and above %	724 (8.55)	81 (2.66)	43 (5.34)	3 (15.7)	<.0001
<b>Gender</b>					
Female %	5900 (69.7)	2173 (71.5)	587 (72.9)	13 (68.4)	<.0001
<b>Race</b>					
White %	6579 (77.7)	2170 (71.4)	487 (60.4)	11 (57.8)	<.0001
Black %	466 (5.5)	106 (3.49)	83 (10.3)	-	<.0001
Hispanic %	996 (11.7)	539 (17.7)	179 (22.2)	8 (42.1)	<.0001
Asian %	171 (2.02)	84 (2.76)	30 (3.72)	-	<.0001
Native American %	11 (0.13)	7 (0.23)	-	-	0.3657
Other %	164 (1.93)	104 (3.42)	8 (0.99)	-	<.0001
<b>Disease severity</b>					
Low (C1-C2) %	1557 (18.4)	7 (0.23)	30 (3.72)	2 (10.5)	<.0001
High (C3-C6) %	6903 (81.5)	3029 (99.7)	775 (96.2)	17 (89.4)	<.0001
<b>Treatment outcomes</b>					
Post complications %	131 (1.54)	48 (1.58)	17 (2.11)	1 (5.26)	<.0001
Reinterventions %	2323 (27.4)	1103 (36.3)	418 (51.9)	-	<.0001

IC, interventional cardiology; IR, interventional radiology; VS, vascular surgery.

Note. Percentages may not equal 100 due to missing data.

## **i. Dependent variables**

### ***a. Postoperative complications***

Of the 8,793 patients in the sample who underwent an image-guided treatment for varicose veins, 209 patients developed postoperative complications, representing 2.37% of the total sample.

### ***b. Reinterventions***

Of the 8,793 patients in the sample who underwent an image-guided treatment for varicose veins, 2,369 patients experienced reinterventions, representing 26.9% of the total sample.

## **ii. Independent variables**

### ***a. Disease severity***

Disease severity for 82.1% of patients in the sample who underwent an image-guided treatment for varicose veins was high ( $n = 7226$ ) with the remaining procedures were performed for low disease severity.

Compared with the other specialties, VS treated the most high disease severity patients ( $n = 3082$ ; 42.6%;  $P < .0001$ ), while IR treated the most low disease severity patients in the sample ( $n = 34$ ; 57%;  $P < .0001$ ).

*b. Clinician specialty*

The study's algorithm assigned a specialty to 45% of patients in the sample who underwent an image-guided treatment for varicose veins. The total number of individual clinicians for each clinician group over the duration of the study was 3,089 VS, 845 IR, and 24 IC.

Vascular surgeons performed 35.1% of all assigned image-guided varicose veins treatments, more than IR (9.6%), and IC (0.27%). Individual VS operator performed more than three times as many image-guided treatments as both IR and IC performed.

Among patients who have assigned specialty, VS treated the most cases followed by postoperative complication events ( $n = 64$ ; 65%;  $P < .0001$ ) as presented in Figure 1. In addition, the majority of the cases followed by reinterventions was treated by VS ( $n = 1,115$ ; 73%;  $P < .0001$ ) as presented in Figure 2.

However, the overall postoperative complications rate was highest for IC (16.6% vs. 3.55% IR vs. 2.07% VS;  $P < .0001$ ) while the overall reinterventions rate was highest for IR (49.5% vs. 36% VS;  $P < .0001$ ) as presented in Table 10.

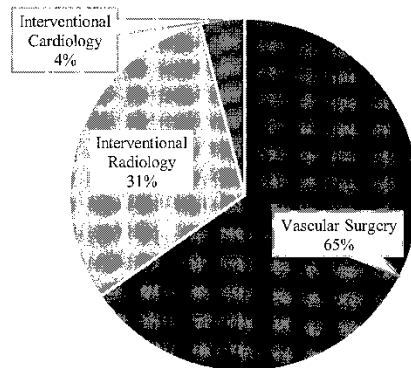


Figure 1  
*Clinician Specialty Breakdown for Postoperative Complication Events (N = 98)*

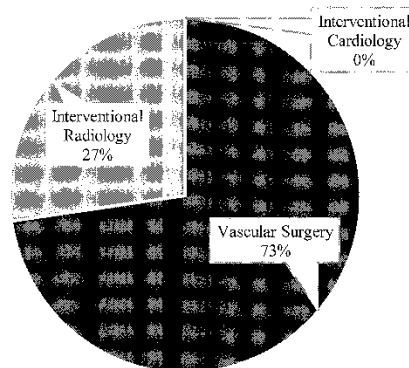


Figure 2  
*Clinician Specialty Breakdown for Reintervention Events (N = 1,534)*

## Hypotheses

### i. Hypothesis 1.

The first hypothesis was developed based on the theoretical proposition that image-guided treatment delivery by VS is associated with the occurrence of postoperative complications in varicose veins patients. Hypothesis 1 stated: “The providing of image-guided treatment by VS is associated with the occurrence of postoperative complications in varicose veins patients.” A logistic regression model was run for postoperative complication outcome. The unadjusted effect of image-guided treatment delivery by VS on outcomes is reported, as well as the effect adjusted for control variables. The findings are presented in Table 13 indicate this hypothesis was not supported.

Table 13  
*Confounding Effect of Adjusted Variables on Vascular Surgeons Outcome:  
Postoperative Complications*

	VS									
	VS vs. non-VS (unadjusted)					VS vs. non-VS (adjusted)				
	<i>OR</i>	<i>Std.</i> <i>Err.</i>	<i>z</i>	<i>P&gt; z </i>	<i>95% CI</i>	<i>OR</i>	<i>Std.</i> <i>Err.</i>	<i>z</i>	<i>P&gt; z </i>	<i>95% CI</i>
Postoperative complications	0.81	0.15	1.9	0.16	0.6-1.09	0.74	0.16	3.25	0.07	0.54-1.02

*CI*, Confidence interval; *OR*, odds ratio; *VS*, vascular surgery.

*Note.* Regression outputs before and after adjustment. Adjusted model included control variables following regression modeling rules from the set of variables: high disease severity, low disease severity, age, race, and gender.

The unadjusted effect of testing the relationship between image-guided treatment delivery by VS and the patient outcome of postoperative complications was not significant ( $z = 1.9$ , 95%  $CI = 0.6-1.09$ ,  $OR = 0.81$ ,  $P > |z| = 0.16$ ). Moreover, when adjusting for control correlates of postoperative complications (disease severity, age, gender, and race), the adjusted effect was not significant too ( $z = 3.25$ , 95%  $CI = 0.54-1.02$ ,  $OR = 0.74$ ,  $P > |z| = 0.07$ ).

In summary, image-guided treatment delivery by VS was not a statistically significant predictor of postoperative complications in varicose veins patients. In addition, there was no significant relationship between the providing of image-guided treatment by VS and the patient outcome of postoperative complications when controlling for theoretically and empirically important covariates. Thus, hypothesis 1 was not supported.

## **ii. Hypothesis 2.**

The second hypothesis was developed based on the theoretical proposition that image-guided treatment delivery by IR is associated with the occurrence of postoperative complications in varicose veins patients. Hypothesis 2 stated: “The providing of image-guided treatment by IR is associated with the occurrence of postoperative complications in varicose veins patients.” A logistic regression model was run for postoperative complication outcome. The unadjusted effect of image-guided treatment delivery by IR on outcomes is reported, as well as the effect adjusted for control variables. The findings are presented in Table 14 indicate this hypothesis was not supported.

Table 14  
*Confounding Effect of Adjusted Variables on Interventional Radiologists Outcome: Postoperative Complications*

	IR									
	IR vs. non-IR (unadjusted)					IR vs. non-IR (adjusted)				
	<i>OR</i>	<i>Std.</i> <i>Err.</i>	<i>z</i>	<i>P&gt; z </i>	<i>95% CI</i>	<i>OR</i>	<i>Std.</i> <i>Err.</i>	<i>z</i>	<i>P&gt; z </i>	<i>95% CI</i>
Postoperative complications	1.59	0.2	5.45	0.0196	1.07-2.36	1.39	0.2	2.53	0.11	0.92-2.08

*CI*, Confidence interval; *IR*, interventional radiology; *OR*, odds ratio.

*Note.* Regression outputs before and after adjustment. Adjusted model included control variables following regression modeling rules from the set of variables: high disease severity, low disease severity, age, race, and gender.

The unadjusted effect of testing the relationship between image-guided treatment delivery by IR and the patient outcome of postoperative complications was significant ( $z = 5.45$ , 95%  $CI = 1.07-2.36$ ,  $OR = 1.59$ ,  $P>|z| = 0.0196$ ). However, when adjusting for control correlates of postoperative complications (disease severity, age, gender, and race), the adjusted effect was not significant ( $z = 2.53$ , 95%  $CI = 0.92-2.08$ ,  $OR = 1.39$ ,  $P>|z| = 0.11$ ).

In summary, image-guided treatment delivery by IR was a statistically significant predictor of postoperative complications in varicose veins patients. However, there was no significant relationship between the providing of image-guided treatment by IR and the patient outcome of postoperative complications when controlling for theoretically and empirically important covariates. Thus, hypothesis 2 was not supported.

### iii. Hypothesis 3.

The third hypothesis was developed based on the theoretical proposition that image-guided treatment delivery by IC is associated with the occurrence of postoperative complications in varicose veins patients. Hypothesis 3 stated: “The providing of image-guided treatment by IC is associated with the occurrence of postoperative complications in varicose veins patients.” A logistic regression model was run for postoperative complication outcome. The unadjusted effect of image-guided treatment delivery by IC on outcomes is reported, as well as the effect adjusted for control variables. The findings are presented in Table 15 indicate this hypothesis was supported.

Table 15  
*Confounding Effect of Adjusted Variables on Interventional Cardiologists Outcome: Postoperative Complications*

	IC									
	IC vs. non-IC (unadjusted)					IC vs. non-IC (adjusted)				
	<i>OR</i>	<i>Std. Err.</i>	<i>z</i>	<i>P&gt; z </i>	<i>95% CI</i>	<i>OR</i>	<i>Std. Err.</i>	<i>z</i>	<i>P&gt; z </i>	<i>95% CI</i>
Postoperative complications	8.35	0.55	14.7	0.0001	2.83-24.6	7.48	0.58	12	0.0005	2.4-23.3

*CI*, Confidence interval; *IC*, interventional cardiology; *OR*, odds ratio.

*Note.* Regression outputs before and after adjustment. Adjusted model included control variables following regression modeling rules from the set of variables: high disease severity, low disease severity, age, race, and gender.

The unadjusted effect of testing the relationship between image-guided treatment delivery by IC and the patient outcome of postoperative complications was significant ( $z = 14.7$ , 95%  $CI = 2.83-24.6$ ,  $OR = 8.35$ ,  $P>|z| = 0.0001$ ). Moreover, when adjusting for



control correlates of postoperative complications (disease severity, age, gender, and race), the adjusted effect was significant too ( $z = 12$ , 95%  $CI = 2.4-23.3$ ,  $OR = 7.48$ ,  $P > |z| = 0.0005$ ).

In summary, image-guided treatment delivery by IC was a statistically significant predictor of postoperative complications in varicose veins patients. In addition, there was a significant relationship between the providing of image-guided treatment by IC and the patient outcome of postoperative complications when controlling for theoretically and empirically important covariates. Thus, hypothesis 3 was supported.

#### **iv. Hypothesis 4.**

The fourth hypothesis was developed based on the theoretical proposition that image-guided treatment delivery by VS is associated with the occurrence of reinterventions in varicose veins patients. Hypothesis 4 stated: "The providing of image-guided treatment by VS is associated with the occurrence of reinterventions in varicose veins patients." A logistic regression model was run for reintervention outcome. The unadjusted effect of image-guided treatment delivery by VS on outcomes is reported, as well as the effect adjusted for control variables. The findings are presented in Table 16 indicate this hypothesis was supported.

Table 16  
*Confounding Effect of Adjusted Variables on Vascular Surgeons Outcome:  
 Reintervention*

	VS									
	VS vs. non-VS (unadjusted)					VS vs. non-VS (adjusted)				
	<i>OR</i>	<i>Std.</i> <i>Err.</i>	<i>z</i>	<i>P&gt; z </i>	95% <i>CI</i>	<i>OR</i>	<i>Std.</i> <i>Err.</i>	<i>z</i>	<i>P&gt; z </i>	95% <i>CI</i>
Reintervention	2.0	0.04	199	<.0001	1.82- 2.20	1.22	0.05	14.7	0.0001	1.10- 1.35

*CI*, Confidence interval; *OR*, odds ratio; *VS*, vascular surgery.

*Note.* Regression outputs before and after adjustment. Adjusted model included control variables following regression modeling rules from the set of variables: high disease severity, low disease severity, age, race, and gender.

The unadjusted effect of testing the relationship between image-guided treatment delivery by VS and the patient outcome of reinterventions was significant ( $z = 199$ , 95%  $CI = 1.82-2.20$ ,  $OR = 2.0$ ,  $P>|z| = < .0001$ ). Moreover, when adjusting for control correlates of reinterventions (disease severity, age, gender, and race), the adjusted effect was significant too ( $z = 14.7$ , 95%  $CI = 1.10-1.35$ ,  $OR = 1.22$ ,  $P>|z| = 0.0001$ ).

In summary, image-guided treatment delivery by VS was a statistically significant predictor of reinterventions in varicose veins patients. In addition, there was a significant relationship between the providing of image-guided treatment by VS and the patient outcome of reinterventions when controlling for theoretically and empirically important covariates. Thus, hypothesis 4 was supported.

#### v. Hypothesis 5.

The fifth hypothesis was developed based on the theoretical proposition that imago-guided treatment delivery by IR is associated with the occurrence of reinterventions in varicose veins patients. Hypothesis 5 stated: “The providing of image-guided treatment by IR is associated with the occurrence of reinterventions in varicose veins patients.” A logistic regression model was run for reintervention outcome. The unadjusted effect of image-guided treatment delivery by IR on outcomes is reported, as well as the effect adjusted for control variables. The findings are presented in Table 17 indicate this hypothesis was supported.

Table 17  
*Confounding Effect of Adjusted Variables on Interventional Radiologists Outcome: Reintervention*

	IR									
	IR vs. non-IR (unadjusted)					IR vs. non-IR (adjusted)				
	<i>OR</i>	<i>Std. Err.</i>	<i>z</i>	<i>P&gt; z </i>	<i>95% CI</i>	<i>OR</i>	<i>Std. Err.</i>	<i>z</i>	<i>P&gt; z </i>	<i>95% CI</i>
Reintervention	3.02	0.07	226	<.0001	2.61-3.49	2.48	0.07	137	<.0001	2.13-2.89

*CI*, Confidence interval; *IR*, interventional radiology; *OR*, odds ratio.  
*Note*. Regression outputs before and after adjustment. Adjusted model included control variables following regression modeling rules from the set of variables: high disease severity, low disease severity, age, race, and gender.

The unadjusted effect of testing the relationship between image-guided treatment delivery by IR and the patient outcome of reinterventions was significant ( $z = 226$ , 95%  $CI = 2.61-3.49$ ,  $OR = 3.02$ ,  $P>|z| = <.0001$ ). Moreover, when adjusting for control

correlates of reinterventions (disease severity, age, gender, and race), the adjusted effect was significant too ( $z = 137$ , 95%  $CI = 2.13-2.89$ ,  $OR = 2.48$ ,  $P > |z| = <.0001$ ).

In summary, image-guided treatment delivery by IR was a statistically significant predictor of reinterventions in varicose veins patients. In addition, there was a significant relationship between the providing of image-guided treatment by IR and the patient outcome of reinterventions when controlling for theoretically and empirically important covariates. Thus, hypothesis 5 was supported.

#### **vi. Hypothesis 6.**

The sixth hypothesis was developed based on the theoretical proposition that image-guided treatment delivery by IC is associated with the occurrence of reinterventions in varicose veins patients. Hypothesis 6 stated: "The providing of image-guided treatment by IC is associated with the occurrence of reinterventions in varicose veins patients." Logistic regression model was not run since there were no observations to distinguish the relationship (Table 10). It indicates this hypothesis was not supported.

#### **Additional analysis**

Additional analysis was conducted to explore the important relationships identified in the above testing of hypotheses. Since the research questions essentially seek the strength of the relationships between categorical variables, reduced multiple logistic regression analysis was performed to test covariate interactions. The association of disease severity with clinician type was statistically significant ( $P < .0001$ ). Univariate analysis found high disease severity independently and significantly influences

unfavorable results for all outcomes. High disease severity patients were fundamentally different from low disease severity patients. Because vascular surgeon type treats more patients with high disease severity, it was the reference for all reduced regression models. The results of this analysis are presented in Tables 18 and 19.

Table 18  
*Reduced Model of Multiple Logistic Regression Analysis Stratified for Postoperative Complications*

Predictor variable	OR	Std. Err.	z	P> z	95% CI
<b>Clinician</b>					
VS				Reference	
IR	1.41	0.2	2.85	0.09	0.94-2.12
IC	7.83	0.58	12.5	0.0004	2.5-24.4
<b>Disease severity</b>					
Low (C1-C2)	-	-	-	-	-
High (C3-C6)	8.74	0.41	26.8	<.0001	3.85-19.4
<b>Age (years)</b>					
18-49	-	173	0.002	0.96	-
50-64	-	173	0.002	0.95	-
65-79	-	173	0.003	0.95	-
80 and above	-	173	0.003	0.95	-
<b>Gender</b>					
Female	0.55	0.14	16.5	<.0001	0.41-0.73
<b>Race</b>					
White	0.81	0.51	0.15	0.69	0.29-2.24
Black	1.91	0.55	1.37	0.24	0.64-5.71
Hispanic	1.23	0.54	0.14	0.7	0.42-3.57
Asian	0.24	1.12	1.56	0.21	0.02-2.22
Native American	11.3	0.96	6.37	0.01	1.72-74.6

Table 19  
*Reduced Model of Multiple Logistic Regression Analysis  
 Stratified for Reinterventions*

Predictor variable	OR	Std. Err.	z	P> z	95% CI
<b>Clinician</b>					
VS			Reference		
IR	2.48	0.07	137	<.0001	2.13-2.89
IC	-	-	-	-	-
<b>Disease severity</b>					
Low (C1-C2)	-	-	-	-	-
High (C3-C6)	28.3	0.21	238	<.0001	18.5-43.3
<b>Age (years)</b>					
18-49	1.66	0.59	0.73	0.39	0.51-5.37
50-64	1.66	0.59	0.73	0.39	0.51-5.38
65-79	1.03	0.59	0.003	0.95	0.32-3.35
80 and above	0.51	0.6	1.18	0.27	0.15-1.69
<b>Gender</b>					
Female	1.10	0.05	2.99	0.08	0.98-1.23
<b>Race</b>					
White	1.47	0.18	4.34	0.03	1.02-2.11
Black	1.18	0.21	0.61	0.43	0.77-1.79
Hispanic	1.38	0.19	2.74	0.09	0.94-2.02
Asian	1.01	0.26	0.002	0.96	0.6-1.6
Native American	5.71	0.63	7.41	0.006	1.63-20

Those patients who were treated by IC had significantly higher odds of delivering postoperative complications ( $OR = 7.83$ ,  $P > |z| = 0.0004$ ) as compared to IV and IR. For reinterventions, patients who were treated by IR had significantly higher odds of delivering them ( $OR = 2.48$ ,  $P > |z| = <.0001$ ) as compared to IV.

High disease severity was significant for all clinician types across postoperative complications group and reinterventions group. The odds of postoperative complications

were significantly higher for patients with high severity ( $OR = 8.74$ ,  $P > |z| = < .0001$ ) than for those with low severity. Also, those patients delivered reinterventions had significantly higher odds ( $OR = 28.3$ ,  $P > |z| = < .0001$ ) when they come with high severity.

Females were at significantly higher risk ( $OR = 0.55$ ,  $P > |z| = < .0001$ ) of developing postoperative complications than males. Moreover, Native American had significantly higher odds of delivering postoperative complications ( $OR = 11.3$ ,  $P > |z| = 0.01$ ) as compared to other ethnicities. For reinterventions, White and Native American patients had significantly higher odds of delivering them ( $OR = 1.47$ ,  $P > |z| = 0.03$  for White,  $OR = 5.71$ ,  $P > |z| = 0.006$  for Native American) as compared to other ethnic groups.

In summary, additional analysis was conducted to examine the relationships identified in the univariate and multivariate testing of hypotheses. Results of reduced logistic regression analysis demonstrated that high disease severity was significantly predictor against low severity for both postoperative complications and reinterventions. Patients who were female, Native American, treated by IC at significantly higher of odds of delivering postoperative complications. On the other hand, patients who were White or Native American, treated by IR at significantly higher of odds of delivering reinterventions.

## Chapter V

### DISCUSSION

Knowledge of the relationships among system factors, treatment delivery, and postoperative outcomes is sparse in the empiric literature, yet such knowledge is essential to improve the health outcomes of both inpatient and outpatient. Therefore, the purpose of this study was to examine the relationships among the specialty of treatment clinicians, disease conditions, and unfavorable postoperative outcomes in treated varicose veins patients. This study bridges the experiences of physicians, healthcare systems, and quality. This chapter includes an interpretation of the findings of the hypothesized relationships in relation to the theory and empirical findings from which these hypotheses were derived.

Specifically, the theoretical relationships were tested include the proposed association between providing of image-guided therapy by different clinician specialties and the occurrence of unfavorable treatment outcomes (37, 223, 224). In addition, the significant gap in the literature, testing disease severity as a confounding factor between clinician specialty and treatment outcomes, was conducted (50, 51). This discussion will present the empiric study findings in light of the theoretical underpinnings that guided this study.



### **Practice Model of VSs and Postoperative Complications**

Hypothesis 1 stated that image-guided treatment delivery by VS will be associated with the occurrence of postoperative complications in varicose veins patients. The hypothesis was derived from the theoretical literature that posits a positive relationship between providing of interventional treatment by VS and the occurrence of unfavorable outcomes (51). The hypothesis and theoretical proposition from which it was derived were not supported by the data. This finding is consistent with most recent report (50, 225).

In the present study, although the relationship between providing image-guided treatment by VS and the occurrence of postoperative complications in varicose veins patients was in the positive direction as theorized, findings were not statistically significant for this outcome in both unadjusted and adjusted models.

This work shows that individual VS operator performed more than three times as many image-guided treatments as both IR and IC performed. According to articles in the surgical literature, efforts have been provided to explore the relationship between physician and hospital volume, and patient outcomes. Only recently, these studies have focused on vascular surgical operations (225). Mortality has been the main factor to be evaluated among studies interested in volume-outcome relationships in the vascular literature. Since interventionalists who deliver endovascular operations, are a heterogeneous group of specialists, different scholars lately have started examining how clinician experience affects endovascular intervention outcomes. A study stated that clinician endovascular procedure volume has profound inverse influence on resource

utilization (204). This study tested cases treated by VS and IC for lower extremity angioplasty. In addition, several articles examined the outcome of interventions on hospital level and provider level claimed significant relationship between higher procedure volume and improved outcomes (247, 248). In summary, hypothesis 1, which stated that image-guided treatment delivery by VS will be associated with the occurrence of postoperative complications in varicose veins patients, was not supported in this study.

#### **Disease Severity and Unfavorable Treatment Outcomes**

Hypothesis 2 stated that image-guided treatment delivery by IR will be associated with the occurrence of postoperative complications in varicose veins patients. The hypothesis was derived from the theoretical literature that postulates a positive relationship between providing of interventional treatment by IR and the occurrence of unfavorable outcomes (50). The hypothesis and theoretical proposition from which it was derived were not supported by the data. This finding is consistent with the previous researches (37, 223, 224).

In this study, image-guided treatment delivery by IR significantly predicted postoperative complications in unadjusted model; however, this relationship was not statistically significant in the adjusted models. These results indicate that more variance in this outcome is explained by disease severity and demographic factors than the type of clinician specialty.

The main goal of this study was to identify the true predictors of unfavorable outcomes of image-guided varicose veins treatment. One of the interesting significant findings of this study was that disease severity is playing a role in predicting of

postoperative complications related to image-guided varicose veins treatment. Among patients who underwent infrainguinal endovascular interventions, a study claimed that disease severity is a significant prognostic factor for outcomes (37, 223, 224). In addition, patients with claudication had better patency and amputation free survival rates than patients with critical limb ischemia (CLI) in a study evaluated superficial femoral artery endovascular revascularization (223). Moreover, a study examined endovascular lower extremity interventions revealed that patients with claudication were associated with lower in-hospital mortality rate compared with CLI patients (224).

The existence of high severity affected the specialty and the figures of an analyzed outcome of this study. Therefore, it can be claimed that disease severity is a confounder. While it is important to decrease confounder's effect and improve external validity among a retrospective review analyses (249), multivariable regression was appropriate for this study to control the confounding of disease severity and manage propensity score analysis with three clinician groups. In summary, hypothesis 2, which stated that image-guided treatment delivery by IR will be associated with the occurrence of postoperative complications in varicose veins patients, was not supported in this study.

#### **Practice Model of ICs and Postoperative Complications**

Hypothesis 3 stated that image-guided treatment delivery by IC will be associated with the occurrence of postoperative complications in varicose veins patients. The hypothesis was derived from the theoretical literature that posits a positive relationship between providing of interventional treatment by IC and the occurrence of unfavorable

outcomes (50). The hypothesis and theoretical proposition from which it was derived were supported by the data.

In the current study, the relationship between providing image-guided treatment by IC and the occurrence of postoperative complications in varicose veins patients was in the positive direction as theorized. Findings were statistically significant for this outcome in both unadjusted and adjusted models.

The data reported here show that, compared to ICs, on average, VSs have delivered better outcomes to varicose veins patients for image-guided treatments. VS-treated patients had a significantly lower rate of postoperative complications than patients treated by ICs. The reasons underlying worse outcomes among ICs remain largely unknown, but may be related to dilution of experience as a result of the extensive time learning and practicing catheter-based interventions compared with VSs, who focus on open surgical procedures.

Moreover, this work shows that individual IC operator performed lesser image-guided treatments than VS and IR. Since prediction models that evaluated treatment outcomes did not include volume data, unfavorable outcomes were reported in the lower volume specialty. With the present work, findings are similar to those observed with regard to carotid endarterectomies (CEA) therapy (250). A study showed that most of CEAs, within the evaluation period, were delivered by high volume clinicians with favorable outcome. The reported mortality was 0.44% for high volume clinician, 0.63% for medium volume clinician, and 1.10% for low volume clinicians ( $P < .001$ ). The postoperative stroke rate was 1.14% for high volume clinicians, 1.63% for medium

volume clinicians, and 2.03% for low volume clinicians ( $P < .001$ ). Another work evaluated outcomes and hospital resource utilization for lower extremity percutaneous angioplasty delivered by IC and VS (204). The study did not indicate a difference in hospital stay between IC and VS, but overall hospital charges for VS were lower than for IC. In summary, hypothesis 3, which stated that image-guided treatment delivery by IC will be associated with the occurrence of postoperative complications in varicose veins patients, was supported in this study.

#### **Practice Models of VSs and Reinterventions**

Hypothesis 4 stated that image-guided treatment delivery by VS will be associated with the occurrence of reinterventions in varicose veins patients. This hypothesis was derived from the theoretical literature that postulates a positive relationship between providing of interventional treatment by VS and the occurrence of unfavorable outcomes (51, 251). The hypothesis and theoretical proposition from which it was derived were supported by the data.

In this work, the relationship between providing image-guided treatment by VS and the occurrence of reinterventions in varicose veins patients was in the positive direction as theorized. Findings were statistically significant for this outcome in both unadjusted and adjusted models.

Within the practice model of VSs who deliver endovascular and open interventional operations, there is a chance for VS to gain more revenue by performing endovascular interventions in cases have low probability of clinically efficient outcome (51). Repeating the original operation or delivering an open surgical interventional

procedure is option that VSs follow once the primary endovascular intervention fails. Several articles described the economic interests influence clinical decision making (252, 253). VSs practice model has more potential for conflicts-of-interest than IRs and ICs whom deliver endovascular operations while surgeons deliver open surgical operations. In summary, hypothesis 4, which stated that image-guided treatment delivery by VS will be associated with the occurrence of reinterventions in varicose veins patients, was supported in this study.

#### **Practice Model of IRs and Reinterventions**

Hypothesis 5 stated that image-guided treatment delivery by IR will be associated with the occurrence of reinterventions in varicose veins patients. The hypothesis was derived from the theoretical literature that postulates a positive relationship between providing of interventional treatment by IR and the occurrence of unfavorable outcomes (50). The hypothesis and theoretical proposition from which it was derived were supported by the data.

In this study, the relationship between providing image-guided treatment by IR and the occurrence of reinterventions in varicose veins patients was in the positive direction as theorized. Findings were statistically significant for this outcome in both unadjusted and adjusted models.

Variation within specialists and treatment patterns has been examined in different clinical practice fields. Examining resource utilization for specialties in order to manage patients has showed that increased utilization has relationship to specialty (254). Moreover, exploring training and volume of clinicians has been done in order to clarify

the true predictors of various outcomes. Though, the reasons for variation in therapeutic intervention outcomes are not known (255). In summary, hypothesis 5, which stated that image-guided treatment delivery by IR will be associated with the occurrence of reinterventions in varicose veins patients, was supported in this study.

#### **Practice Model of ICs and Reinterventions**

Hypothesis 6 stated that image-guided treatment delivery by IC will be associated with the occurrence of reinterventions in varicose veins patients. The hypothesis and theoretical proposition from which it was derived were not supported by the data since there were no observations to distinguish the relationship. Although there are some evidences that providing of interventional treatment by IC is associated with developed unfavorable outcomes (50); there are no studies that have evaluated the impact of cardiology specialty on specific image-guided varicose veins treatment outcome.

The possible methodological reason this hypothesis is not supported mirror those that may explain the absence of observations regarding image-guided treatment delivery by IC and the occurrence of reinterventions in varicose veins patients. The data revealed that ICs had small participation in image-guided treatment for varicose veins from 2011 to 2013. The majority of these procedures were delivered by VSs. Within SASD and SID populations of the United States, ICs provided only 0.27% of image-guided varicose veins therapies. The percentages used to assign ICs were chosen with the idea that an IC is clinician who delivers interventions on cardiac system exclusively. This definition required an IC to have a practice of 75% or greater cardiac interventions, or > 10 interventions if ratio of index was not greater than 75%. The remainder of the practice

could consist of any case type. A lower qualifying percentage may cause an exclusion of ICs truly delivering cardiac interventions due to miscoding of procedures or inability to develop a complete list of cardiac interventional ICD- 9-CM codes. Previous articles have used the delivery of one coronary artery bypass graft a year as defining a cardiologist from a general thoracic surgeon (201). This method of assigning ICs may potentially less count due to miscoding. It is possible that the discrepancies between findings of this current work and previous studies are attributed to the differences in definitions. In summary, hypothesis 6, which stated that image-guided treatment delivery by IC will be associated with the occurrence of reinterventions in varicose veins patients, was not supported in this study.

#### **Additional Findings**

Additional analysis was delivered to examine the relationships identified in the testing of hypotheses. Reduced multiple logistic regression analysis was designed to evaluate covariate interactions as the research questions test the strength of the relationships between categorical variables. The association of disease severity with clinician type was statistically significant ( $P < .0001$ ). Univariate analysis showed that high disease severity independently and significantly affects unfavorable results for all outcomes. High disease severity patients were essentially different from low disease severity patients. Vascular surgeon type was the reference for all reduced regression models since they treat more patients with high disease severity. The results of this analysis are presented in Tables 18 and 19.



Important findings strongly indicate that high disease severity was a significant predictor against low severity for both postoperative complications and reinterventions. Patients who were female, Native American, treated by IC at significantly higher of odds of delivering postoperative complications. In contrast, patients who were White or Native American, treated by IR at significantly higher of odds of delivering reinterventions.

Specialty variations in disease severities for endovascular treatments have been examined for both carotid and peripheral endovascular interventions (203, 204). It was reported that there was no significant influence of disease severity among VS, IR, and IC for carotid artery stenting procedures (203). Moreover, a comparison between patients treated by VS and IC for lower extremity angioplasty was conducted in a study claimed that VS are significantly more likely to treat patients with CLI than claudication while just the opposite was observed for IC (204). Though, IR was not covered in work.

In efforts to provide a more accurate description of the short-term comparative outcomes of image-guided varicose veins treatment as a function of provider specialty, it is believed that this retrospective, cross sectional study of the New Jersey State Inpatient Database (SID) and State Ambulatory Surgery Database (SASD) from 2011 to 2013 reveals several important and interesting findings. This analysis showed that VS, IR, and IC treat different patient populations. In comparison, vascular surgeons treated as many patients with high severity as IC and IR specialists combined. Interestingly, additional analysis did demonstrate a pan-specialty shift in indication of image-guided varicose veins treatment with fewer low severities being treated as inpatients.

### **Limitations**

This was cross sectional study that covered correlations, relationships, and associations between variables of interest. Though, this study did not examine causality. The precision of the SID and SASD data were based on coding and documentation in the record applied by trained coders. Discrepancies in data and accuracy could have occurred at the hospital level (256, 257). Though, administrative data have been used in a number of studies in spite of documented problems with the completeness and consistency of coding (258).

Because this proposed study is a retrospective work and not a randomized controlled trial, it is subject to confounding. Multivariable logistic regression was delivered in order to adjust for confounders. Though, it was known that unmeasured confounders are still possible. There was no randomization between different therapeutic methods in this study, and the selection of therapeutic approach was at the treating clinician's discretion. SID and SASD databases do not contain patients from military hospitals or veterans administration medical centers. Both SID and SASD are administrative discharge data sets based on billing. The data are limited by the coding schemes created by AHRQ and ICD-9 codes. It is possible that the definition of indications and coding may vary within these data sets and may vary between institutions and hospital coders.

In this database, other limitations include clerical errors and under reporting of procedures with minimal financial incentive (226, 259). It is been claimed that high revenue procedures, such as image-guided treatments, are selectively captured and

deliver valid studies (260). The database detects a single hospitalization of each patient. Patency, survival rate, and other long term outcomes could not be recorded.

Limitations of any analysis based on ICD-9 procedure codes include the lack of anatomic and procedural details, and the incapability to determine the temporality of adverse events and length of stay in the intensive care unit (ICU). Alterations in coding methods in SID and SASD are a potential for error. Lastly, it is difficult to differentiate perioperative complications from pre-existing conditions.

## Chapter VI

### SUMMARY AND CONCLUSIONS

#### **Summary**

The purpose of this study was to examine the relationships among the specialty of treatment clinicians, disease conditions, and unfavorable postoperative outcomes in treated varicose veins patients. In this study, a postoperative complication was theoretically defined as any deviation from the normal postoperative course of illness or procedure which results a medical or surgical accident or reaction whether it is symptomatic or asymptomatic (33, 34). Reintervention was theoretically defined as the necessity for an additional intervention in order to treat varicose veins recurrence or new varicose veins in the same leg and the same area (35). Finally, a medical specialty was theoretically defined as a medical science field in which other physicians lack the requisite knowledge and training (36).

Theorists and findings from the empirical literature suggest that prediction of unfavorable endovascular lower extremity interventions outcomes generally is multifactorial. There is previous empirical support for the theorized relationships among disease severity, clinician's specialty, and interventions outcomes. There are substantial evidences that disease severity of endovascular lower extremity procedures is linked to unfavorable interventions outcomes (37, 223-225). Finally, there are evidences linking

unfavorable endovascular lower extremity interventions outcomes to the type of training and experience the intervention's clinician has (50, 51).

Therefore, based on the theoretical and empirical literature the following hypotheses were derived:

1. Providing of image-guided treatment by VS is associated with the occurrence of postoperative complications in varicose veins patients.
2. Providing of image-guided treatment by IR is associated with the occurrence of postoperative complications in varicose veins patients.
3. Providing of image-guided treatment by IC is associated with the occurrence of postoperative complications in varicose veins patients.
4. Providing of image-guided treatment by VS is associated with the occurrence of reinterventions in varicose veins patients.
5. Providing of image-guided treatment by IR is associated with the occurrence of reinterventions in varicose veins patients.
6. Providing of image-guided treatment by IC is associated with the occurrence of reinterventions in varicose veins patients.

This study is a secondary analysis of cross sectional data. Study data were compiled from two sources including: (1) New Jersey State Inpatient Database (SID) and (2) State Ambulatory Surgery Database (SASD), which were developed as part of the Healthcare Cost and Utilization Project (HCUP), sponsored by the Agency for Health Care Research and Quality (AHRQ). The final analytic sample consisted of 8,793 patients in the state of New Jersey.

This study utilized demographic characteristics (age, gender, and race), diagnoses identifiers, procedure identifiers, and physician identifier by using: (1) diagnosis codes from International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and (2) procedure codes from Current Procedural Terminology (CPT) codes.

Data were analyzed using SAS 9.4 software. Descriptive statistics were conducted to analyze the characteristics of the sample by using univariate analysis (chi square). To test the hypotheses, multivariate and reduced logistic regression models were appropriately matched to the outcomes of interest. The level of significance at which the research hypotheses were tested was at .05.

The first hypothesis, which stated that providing of image-guided treatment by VS is associated with the occurrence of postoperative complications in varicose veins patients, was not supported. The second hypothesis, which stated that providing of image-guided treatment by IR is associated with the occurrence of postoperative complications in varicose veins patients, was not supported. The third hypothesis, which stated providing of image-guided treatment by IC is associated with the occurrence of postoperative complications in varicose veins patients, was supported. This is the first study to have examined this relationship between image-guided treatment delivery by IC and the incidence of postoperative complications in varicose veins patients, thus extending this knowledge. The fourth hypothesis, which stated that providing of image-guided treatment by VS is associated with the occurrence of reinterventions in varicose veins patients, was supported. This study also estimated the effect of image-guided

treatment delivery by VS on having reinterventions in varicose veins patients, which was not conducted in prior studies, thus extending this knowledge. The fifth hypothesis, which stated the providing of image-guided treatment by IR is associated with the occurrence of reinterventions in varicose veins patients, was supported. This is the first study to examine this relationship using the SID and SASD sources, thus extending this knowledge. The sixth hypothesis, which stated that providing of image-guided treatment by IC is associated with the occurrence of reinterventions in varicose veins patients, was not supported. A summary of these results is presented in Table 20.

In summary, theoretical propositions were tested to explain the relationships among the specialty of treatment clinicians, disease conditions, and unfavorable postoperative outcomes in treated varicose veins patients. The theoretical propositions tested explained the relationships between: (a) image-guided treatment delivery by IC and postoperative complication incidence, (b) image-guided treatment delivery by VS and reinterventions incidence, and (c) image-guided treatment delivery by IR and reinterventions incidence.

Table 20  
*Summary of Results of Hypotheses Testing*

Hypothesis	Supported
1. Providing of image-guided treatment by VS is associated with the occurrence of postoperative complications in varicose veins patients.	No
2. Providing of image-guided treatment by IR is associated with the occurrence of postoperative complications in varicose veins patients.	No
3. Providing of image-guided treatment by IC is associated with the occurrence of postoperative complications in varicose veins patients.	Yes

4. Providing of image-guided treatment by VS is associated with the occurrence of reinterventions in varicose veins patients.	Yes
5. Providing of image-guided treatment by IR is associated with the occurrence of reinterventions in varicose veins patients.	Yes
6. Providing of image-guided treatment by IC is associated with the occurrence of reinterventions in varicose veins patients.	No

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### Conclusions

As hypothesized, findings from this study support that, in treated varicose veins patients, a relationship exists between providing of image-guided treatment by IC and the occurrence of postoperative complications. Moreover, findings support the theoretical association that relates providing of image-guided treatment by VS and IC to the occurrence of reinterventions.

Contrary to the hypotheses, the findings of this study did not support the theoretical propositions that image-guided treatment delivery by VS or IR are related to the incidence of postoperative complications. Thus, the hypothesis stated that image-guided treatment delivery by IC is related to the incidence of reinterventions was not supported either. As guided by the theoretical literature, further analysis was conducted to examine if the relationships among disease severity and demographic factors were confounding the effect of clinician specialty on postoperative outcomes in treated varicose veins patients. Findings indicate that there is an effect of clinician type on postoperative outcomes when controlling for disease severity and demographic characteristics. In summary, findings in this study do not support the theoretical propositions between the specialty of clinician providing image-guided treatment and the



occurrence of postoperative complications in varicose veins patients, other than IC, but do support the association between the specialty of clinician, other than IC, and the incidence of reinterventions.

### **Recommendations**

Based on the findings of this study, recommendations for future research include:

1. Replicate this study with most recent data from these two sources, SID and SASD, and reexamine these relationships in a larger, multisite, multistate study.
2. Conduct a comparative research effectiveness study and cost analysis to evaluate the effect of disease severity on outcomes for various image-guided therapies in order to develop the items of disease condition measurements (clinical classifications software, chronic condition indicator, and comorbidity software).
3. Conduct studies to clarify if comorbidities have a confounding effect on the relationship between the providing of image-guided varicose veins treatment by various clinicians' types and postoperative outcomes.
4. Conduct research to distinguish specific technical factors of image-guided varicose veins treatment that improve postoperative outcomes.

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