American Venous Forum

Promoting venous and lymphatic health

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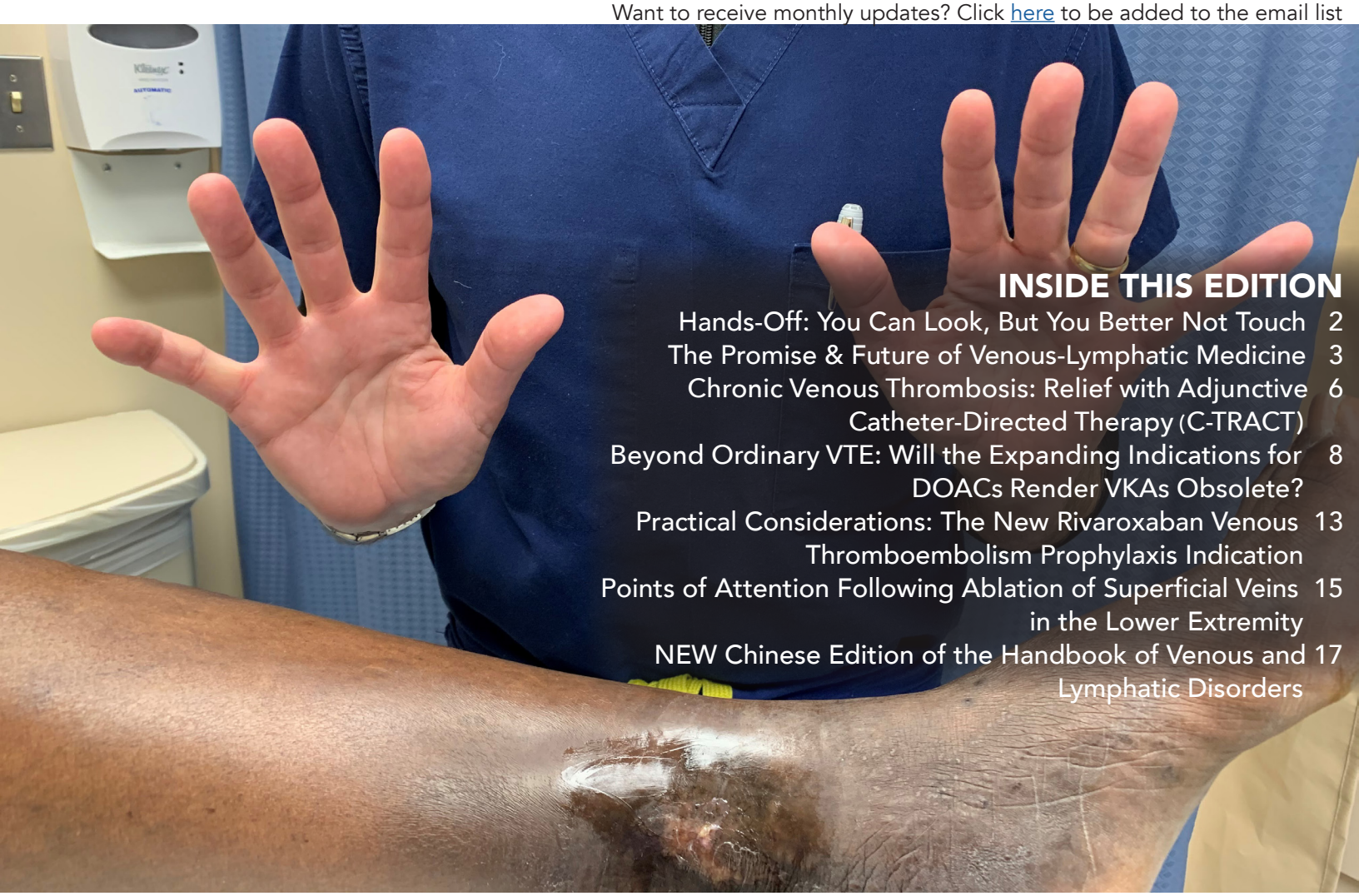

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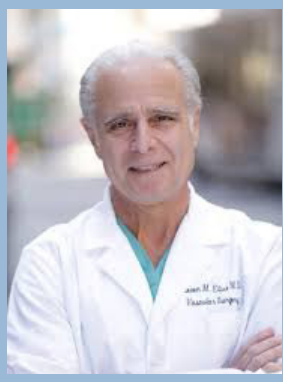
VEIN SPECIALIST NEWSLETTER

Hands-Off Issue

January 2020 | veinforum.org

HANDS-OFF: YOU CAN LOOK, BUT YOU BETTER NOT TOUCH



Steve Elias, MD

Steve Elias, MD

Everyone likes to touch things. Remember when you were younger, a toddler perhaps, your mother took you into the store shopping. Shopping not for you but for herself. It always was a store with bright, delicate, fragile things. The kind of things that every little kid just wants to grab. And then your mother says, "You can look but you better not touch". When you tell most young, curious children not to do something that is exactly what they want to do. Touch, get their hands on objects. Sometimes we never grow up. Let's face it, one of the reasons we went into vascular surgery, interventional radiology, interventional cardiology, etc. was because we like to do things with our hands – to help patients.

Most meetings nowadays have "hands-on" sessions. We, the AVF, have been having them for years beginning with our Fellows Courses and now our annual meeting as well. The Fellows Course started about 15 years ago and we were one of the first to have these type of sessions. We do procedures, we like new toys, we want things in our hands when we help our patients. But not always is this the thing to do. Sometimes we just need to keep our hands off. This is what our "Hands-Off" issue is about. "Hands-Off" because we have articles addressing vein care treatment that doesn't involve necessarily touching the patient or doing a procedure.

Certainly lymphedema is a disease which most of the time doesn't require operative treatment. Just the right knowledge and the right medical care. Bill Repicci tells us about the LE&RN network and how we can help patients. And how it helps us. Herbal medicine for venous disease is not just for the alternative lifestyle folks (California?). There is some validity and options for vein care when used properly. Edgar Guzman, one of our Newsletter Committee members, does a nice job elucidating the particulars of this topic. Don't dismiss the idea, read the article. Another committee member, Haraldur Bjarnason, writes about the concepts and controversies for post ablation care. Another hands off issue. There are a couple of articles about DOACs; one informational by Cynthia Ly & Elissa DiPasquale (philosophy is definitely hands off) by Andrea Obi and Tom Wakefield. The C-TRACT Trial is a hands-on and hands-off topic. If the patient gets randomized to conservative therapy, it's hands-off. If a patient gets randomized to treatment it's hands-on. Eric Hager takes us through the particulars of the trial and how you can help. Hopefully the trial will let us know if we need to listen to our mothers, "Don't Touch" or if we should do what every child wants to do, "Touch".

We hope this issue has helped you understand some of the viable options for hands off vein care.

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THE PROMISE AND FUTURE OF VENOUS-LYMPHATIC MEDICINE

William Repicci
President & CEO of the
Lymphatic Education
& Research Network
(LE&RN

William Repicci, President & CEO of the Lymphatic Education & Research Network (LE&RN

It is estimated that up to 10 million Americans and 250 million people worldwide are living with lymphedema (LE). Although LE affects more Americans than Multiple Sclerosis, Muscular Dystrophy, AIDs, Parkinson's disease and ALS—combined—it is a disease that often goes unrecognized by medical practitioners and the public alike.

As vein specialists, you are in the front lines of seeing patients with lymphedema. No doubt, you have also heard LE patients tell their stories about physicians minimizing the severe impact the disease has on their lives. As more and more lymphedema treatments emerge, a medical specialty will arise to claim this disease. Many believe venous medicine will play a major role here. For this reason, the Lymphatic Education & Research Network (LE&RN) welcomes the collaborative overtures made by the American Venous Forum.

LE&RN was established in 1998 with a mission to fight lymphedema and lymphatic diseases through education, research, and advocacy. The first challenge was putting lymphatics on the radar with researchers. To this end, LE&RN has a long history of awarding research fellowships, scholarships, and poster awards. LE&RN would also help establish annual lymphatic conferences. Equally important has been our efforts to raise the profile of lymphatics with the National Institutes of Health. Two associated breakthroughs occurred in the last days of 2019. First, thanks to our advocacy, the recently signed US Appropriations Bill calls for the establishment of a national Lymphatic Commission. Secondly, the Centers of Disease Control and Prevention has collaborated with LE&RN to create its first lymphedema website, and now features a video introduction to LE, produced by LE&RN and featuring LE&RN's National Spokesperson and Academy Award-winner Kathy Bates.

Kathy Bates and me at The 24 Hour Plays Broadway Gala honoring her on November 18, 2019.

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THE PROMISE AND FUTURE OF VENOUS-LYMPHATIC MEDICINE *continued*

William Repicci, President & CEO of the Lymphatic Education & Research Network (LE&RN

LE&RN's extensive education efforts are matched by its advocacy agenda. In this regard, we wrote the first bill in the nation that mandates hospital institutions to provide packets of information to all patients at risk of lymphedema. The Bill went into law in New York State in 2019. Also, in 2019, our National Lobby Days in Washington, DC resulted in an invitation to our Spokesperson Kathy Bates to present live testimony to the US House Appropriations Committee.

2019 LE&RN Lobby Day Rally in Washington, DC

To address the need for physician education, LE&RN created the 7-credit CME in Lymphatic-Vascular Disease Diagnosis and Treatment, which is available online and free to members of American Venous Forum (use code: AVF20FREE). To address the difficulty that patients have in finding comprehensive care, LE&RN established standards for Centers of Excellence in the Diagnosis and Treatment of Lymphatic Diseases. Worldwide applications are currently being reviewed by an international committee. Institutions satisfying the criteria will be announced in February 2020 and awarded a designation in one of five categories. We will again seek Letters of Inquiry for new Centers of Excellence applicants beginning in June 2020. And then there is World Lymphedema Day, March 6th, which was established in 2016 by unanimous vote of the United States Senate based on a bill written by LE&RN.

As we look to the future, surgeons now perform vascularized lymph node transfer (VLNT) to restore lymphatic drainage and lymphovenous anastomosis (LVA) to redirect excess lymphatic fluid into the vascular system. Given the natural connection between venous and lymphatic medicine, patients will be looking to you in hopes of a new era with specialists prepared to meet the needs of those living with lymphatic diseases such as LE. Consider attending the practical Lymphedema Symposiums we cosponsor each year at BIDMC-Harvard Medical

THE PROMISE AND FUTURE OF VENOUS-LYMPHATIC MEDICINE *continued*

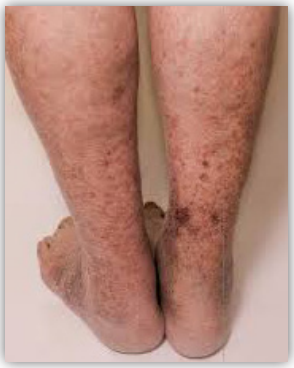
William Repicci, President & CEO of the Lymphatic Education & Research Network (LE&RN

School Hospitals, University of Chicago and USC. Finally, welcome lymphedema patients into your practice. Having felt abandoned by the medical community, those living with LE long for doctors who understand their suffering and are willing to invest themselves in their physical and mental health.

CHRONIC VENOUS THROMBOSIS: RELIEF WITH ADJUNCTIVE CATHETER-DIRECTED THERAPY (C-TRACT)

Eric Hager, MD

Eric Hager, MD



Iliac vein thrombosis (IVT) is a significant cause of post thrombotic syndrome (PTS). The symptoms often occur months to years after the initial presentation and can included swelling, venous claudication, pain, skin changes and ulceration.[1] The algorithm for treatment of IVT has evolved as more advanced endovascular therapies (EVT) have been developed. The treatment of symptoms caused by IVT has sought to target the thrombus burden or resultant scar formation within the iliac vein. Thrombolysis, angioplasty and stenting have become commonplace for the treatment of both acute and chronic IVT.[2]

Results from the Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis (ATTRACT) Trial were released in 2017 and showed that iliofemoral DVT patients that received pharmacomechanical catheter-directed thrombolysis were 35% less likely to develop moderate-or-severe post thrombotic syndrome.[3] This study helped shed light on the potential benefits of thrombolysis of IVT when diagnosed in the acute phase. What has been less clear, however, is the role of EVT in patients with chronic (>3 months) iliac vein thrombosis and the subsequent chronic changes and continuing symptoms that occur when thrombus is replaced by collagen.[4] In particular, while stents have been placed for many years and would seem to offer a substantial opportunity to improve clinical outcomes although it is not clear if the long-term benefit is of sufficient safety, efficacy and durability to justify implantation of a permanent device.

The Chronic Venous Thrombosis: Relief with Adjunctive Catheter-Directed Therapy (C-TRACT) trial is a National Institutes of Health sponsored trial whose aim is to better understand the effects of EVT of chronic IVT. C-TRACT is a Phase III, multicenter randomized trial designed with the goal of determining whether endovascular therapy provides greater improvement in PTS symptoms than standard therapy alone. The trial enrolls patients with PTS from IVT into one of two arms; optimal medical therapy with compression alone versus optimal medical therapy with compression and EVT. The EVT arm consists of iliac vein stenting with augmented anti-thrombotic therapy.

The study is planning to enroll 374 subjects who suffer from severe PTS after IVT at 20-40 sites in the United States. Participants in the study must have substantial limitations to activity and poor quality of life as a result of an IVT greater than three months old. IVT can be determined by: venogram, computed tomography venography (CTV), magnetic resonance venography or a combination of duplex

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CHRONIC VENOUS THROMBOSIS: RELIEF WITH ADJUNCTIVE CATHETER-DIRECTED THERAPY (C-TRACT) *continued*

Erick Hager, MD

ultrasound and air plethysmography. All patients will undergo optimal medical therapy including lifestyle interventions (limb elevation, exercise, smoking cessation and weight loss) with compression therapy and ulcer treatment (when applicable). Those that randomize to EVT will undergo image-guided vein stent placement with peri-procedural anti-thrombotic therapy. The study is currently enrolling and should help to determine the role of EVT in the treatment of PTS in patients with a history of chronic iliac vein thrombosis. To enter patients into the trial or to be considered as a study site, please contact the C-TRACT manager Angela Oliver, RN BSN MS at 314-747-8951 or email olivera@wustl.edu.

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EXCLUSION CRITERIA
Age less than 18 years
Acute ipsilateral proximal DVT episode within the last 3 months, or acute contralateral DVT for which thrombolytic therapy is planned
Lack of suitable inflow into the ipsilateral common femoral vein (CFV) per the treating physician
Previous stent placement in the infrarenal IVC or ipsilateral iliac or common femoral vein
Absence of PTS of at least moderate severity
Chronic arterial limb ischemia (ankle-brachial index < 0.5 within the previous 1 month) in the ipsilateral leg (if peripheral arterial disease is present or suspect, an ankle-brachial index should be obtained and documented)
Presence of an open venous ulcer > 50 cm^2 area, suspicion for active ulcer infection, or visualization of bone or tendon within the ulcer in the ipsilateral leg
Inability to tolerate endovascular procedure due to acute illness or general health
Severe allergy to iodinated contrast refractory to steroid premedication
Known allergy to stent or catheter components
Hemoglobin < 8.0 g/dl, uncorrectable INR > 3.0 or platelet count < 75,000/ml
Severe renal impairment (on chronic dialysis or estimated GFR < 30 ml/min)
Disseminated intravascular coagulation or other major bleeding diathesis
Pregnancy (positive pregnancy test)
Life-expectancy < 6 months or chronically non-ambulatory for reasons other than PTS
Inability to provide informed consent or to comply with study assessments

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BEYOND ORDINARY VTE: WILL THE EXPANDING INDICATIONS FOR DOACS RENDER VKAS OBSOLETE?

Andrea Obi, MD & Tom Wakefield, MD

Andrea Obi, MD

Tom Wakefield, MD

The Anticoagulation Revolution: FDA Approved Indications

Since the initial FDA approval of dabigatran in 2010, those of us practicing clinical medicine have found ourselves immersed in what can only be described as an anticoagulation revolution. While other branches of pharmacology have seen major advancements over the last 50 years, anticoagulation pharmacy seemed mired in the mud … until it was not. Within a decade, five direct anticoagulants have been FDA approved for various indications including venous thromboembolism (VTE) prevention and treatment (Table 1). Even with securing these major indications, there is still a flurry of ongoing studies, exploring DOAC application to every permutation of thrombosis and beyond. Recent data suggests possible utility of DOACs in superficial venous thrombosis (SVT), and post thrombotic syndrome (PTS) and cancer associated VTE. However, the devil is truly in the details with regards to choosing the right therapy for the right patient based upon the diagnosis and co-morbid disease.

Expanding Uses of DOACS

SVT

The SURPRISE trial, a randomized, open-label trial enrolling 472 patients, investigated the hypothesis that rivaroxaban would be non-inferior to fondaparinux for the treatment of SVT. A departure from the CALISTO trial, which had excluded patients with history of malignancy treated within the last 6 months, the SURPRISE trial was designed with the intent to include patients at highest risk for VTE complications. The rationale for this approach were findings from cost-effectiveness analysis of the CALISTO trial which found that the overall low rate of thromboembolic events translated to high cost with modest benefit (one life saved for 5,000 treated).[1] In comparison, thromboprophylaxis with fondaparinux following orthopedic surgery for similar duration is associated with significant cost savings.[2] Therefore, in SURPRISE, patients were included only if they had one of the following risk factors, identified in the POST registry as associated with a higher rate of thromboembolic complications: age >65 years, male sex, history of venous thromboembolism (VTE), previous cancer and absence of varicose veins.[3] When comparing 6-weeks of prophylactic fondaparinux to daily rivaroxaban (10mg qday), rivaroxaban was non-inferior to fondaparinux in the prevention of DVT, PE, and progression or recurrence of SVT.[4] Rivaroxaban therapy was postulated to be a less expensive and more patient-friendly treatment option for the treatment of SVT.

Certainly, the rising cost of healthcare and the release of the SURPRISE trial have raised several important considerations about the treatment of SVT.

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Andrea Obi, MD & Tom Wakefield, MD

Namely, should a SVT risk stratification scoring system (such as the Caprini and Padua, amongst others) be validated to better select patients? Certainly days of treatment adds to cost, and it would be worthwhile considering a shorter duration of therapy in the next major SVT treatment trial. The treatment of patients excluded in SURPRISE will be at least in part addressed with the RASET (Rivaroxaban Anticoagulation for Superficial Vein Thrombosis; NCT02123524), a recently completed phase III randomized control trial evaluating the treatment of patients with symptomatic SVT with rivaroxaban compared to placebo, who would otherwise not be treated.

PTS

While the ATTRACT trial has certainly re-ignited debate surrounding the utility of thrombolysis, one fact remains shockingly evident from the trial data: even with the most aggressive interventional approach to DVT, nearly one in five patients will go on to suffer from moderate to severe PTS. Thus, any small advance that can be made towards prevention of PTS would be a welcome relief for a large number of patients. A recent analysis of approximately 37,000 patients from Truven Marketscan data revealed that rivaroxaban may provide such an advantage. In this study, patients treated with rivaroxaban were found to have a 23% reduced hazard of developing PTS compared to those treated with warfarin; this data remained statistically significant when considering only cases involving a venous ulcer, the most severe manifestation of PTS.[5] This data confirms a similar phenomenon identified in sub-group analysis of EINSTEIN-DVT data. Likely the reasons for this finding are multifactorial and may relate to more rapid thrombus dissolution and more reliable anticoagulation with rivaroxaban therapy. Whether this finding is a class effect or unique to rivaroxaban has yet to be explored. The direct effect of DOACs on the underlying physiology of PTS including venous inflammation and valvular dysfunction will likely require basic science and translational investigation.

Cancer Associated VTE

Rivaroxaban and edoxaban have been studied in patients with active malignancy, prompting the ISTH to alter recommendations to favor DOACs over LMWH in patients at a low risk of bleeding and no drug-drug interactions. The Hokusai-VTE cancer trial enrolled 1050 patients with cancer associated VTE who were then randomized to the DOAC compared to LMWH. Results from this trial, demonstrated that the primary event (recurrent DVT or major bleeding) occurred in 12.8% in the edoxaban group and 13.5% in the LMWH group at 12 months after therapy was begun, meeting the endpoint of noninferiority to LMWH.[6] Overall, a reduction in recurrent VTE events in the edoxaban group was offset by an increase in bleeding complications. A smaller RCT, SELECT-D, evaluated rivaroxaban compared to LMWH in patients with cancer associated VTE with similar findings: recurrent VTE was 4% in the rivaroxaban group versus 11%

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BEYOND ORDINARY VTE: WILL THE EXPANDING INDICATIONS FOR DOACS RENDER VKAS OBSOLETE? *continued*

Andrea Obi, MD & Tom Wakefield, MD

in the dalteparin group (HR 0.43; 95% CI 0.19-0.99). This was accompanied by an increased rate of major bleeding in 6% of patients treated with rivaroxaban compared to 4% with dalteparin (HR 1.83; 95% CI 0.68-4.96).[7] What remains unclear is where patient preferences will align with regards to tolerance for risk (bleeding versus thrombosis) and whether there is a way to best select patients for a particular treatment regimen. For instance, in subgroup analysis, bleeding risk associated with DOAC therapy was higher in patients with primary GI malignancy. The ISTH recognizes that in patients with luminal malignancy or abnormalities, such as ulcer disease or inflammatory bowel disease, LMWH may be the preferred agent. A more nuanced understanding of patient and disease specific risk factors for bleeding may improve therapy selection.

When VKAs Still Reign Supreme

Since their introduction to the market, DOAC prescriptions have been exponentially rising. However, there are several circumstances in which their use is not feasible nor advisable. The most common circumstances that arise with our venous patients include the following: prohibitive cost, bariatric surgery/extremes of weight, renal failure and antiphospholipid antibody syndrome (APLA). While undoubtedly convenient, the fact remains that as non-generic medications, someone has to pay the price. In an analysis of Medicare Part D claims data, the cost of anticoagulation pharmacy rose 150% from 2013 to 2015. In millions of dollars, the bill for DOACs ($3,036) dwarfed that of VKAs ($240).[8] The cost of a DOAC on average is 40-fold more ($8 v. $317) for a 30 day supply. In a practical clinical setting, often the choice of a DOAC is driven by the insurer rather than the clinician, and even patients who would be ideal candidates for DOAC therapy are excluded because of cost.

Secondly, several medical conditions may preclude a patient from receiving DOAC therapy. For instance, in the setting of bariatric surgery, accurate monitoring of drug levels would be essential as they affect absorption either via restriction (reduction of stomach surface area) or malabsorption (reduction of small intestine traversed). Without a rapidly available, accurate laboratory test for DOAC levels, it is often best to keep these patients on LMWHs and/or VKAs. Another instance where accurate dosing cannot be guaranteed is in the setting of severe liver disease or end stage renal disease. Interestingly, a study of 25,000 patients from the U.S. Renal Data System found that dialysis dependent patients treated with standard dose apixaban (for atrial fibrillation) compared to VKAs had a lower rate of major bleeding without any difference in stroke or systemic embolization.[9] The safety and efficacy findings reported in this registry have yet to be prospectively confirmed. Finally, amongst patients with confirmed high risk APLA syndrome, the recently published TRAPS trial confirmed a higher rate of thromboembolic events for patients treated with rivaroxaban compared to VKAs, prompting an early halt to the study.

BEYOND ORDINARY VTE: WILL THE EXPANDING INDICATIONS FOR DOACS RENDER VKAS OBSOLETE? *continued*

Andrea Obi, MD & Tom Wakefield, MD

So are VKAs obsolete? Undoubtedly, at this time the answer is a resounding "No!" However, in 2, 5, or 10 years this answer may be different. We are living in a time of rapid adoption and study of DOAC therapy, and many areas, beyond those discussed here remain ripe for investigation. For example, the use of DOACs in the treatment or prevention of EHIT and HITT remains barely investigated. The use of DOACs in the arterial circulation such as the MACE/MALE risk reduction is also expanding. As a busy clinician it can be difficult to keep track of all of the ongoing studies and indications. Our best advice is to embrace the change and recognize the fallible human nature. In the words of journalist Sydney Harris: "Our dilemma is that we hate change and love it at the same time; what we really want is for things to remain the same but get better." To improve upon the care of our patients, we must embrace the change and constantly adopt our practices to the most up to date data.
welcome each one of them.

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Andrea Obi, MD & Tom Wakefield, MD

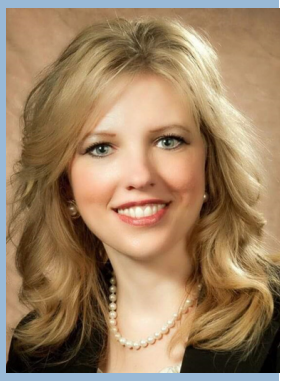
FDA approved indication	Dabigatran	Rivaroxaban	Apixaban	Edoxaban	Betrixaban
Non-valvular atrial fibrillation	X	X	X	X	
Acute VTE	X	X	X	X	
Secondary prevention of VTE	X	X	X		
VTE prevention in major orthopedic surgery	X	X	X		
Major adverse cardiovascular events/Major adverse limb events (MACE/MALE) risk reduction		X			
VTE prevention in acute ill medical patients		X			X

Table 1. FDA approved indications of DOACs.

PRACTICAL CONSIDERATIONS: THE NEW RIVAROXABAN VENOUS THROMBOEMBOLISM PROPHYLAXIS INDICATION

Cynthia Ly, PharmD & Elissa DiPasquale, PharmD, BCPS

Cynthia Ly, PharmD



Elissa DiPasquale, PharmD, BCPS

It is estimated that over half of hospitalized medical patients (congestive heart failure, respiratory illness, and infectious or inflammatory disease) are at risk for venous thromboembolism (VTE).[1] Guidelines from the American College of Chest Physicians recommend heparins or fondaparinux for prevention of VTE in acute medically ill patients.[2] A national shortage of heparin products due to the outbreak of African swine fever in China's pig population have led hospitals to evaluate alternative options.

On October 2019, a second oral chemoprophylaxis option, rivaroxaban, received FDA approval for the prophylaxis of VTE in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding.[3] Given oral anticoagulants have been identified as one of the most commonly implicated drug classes in adverse drug events,[4] a summary of practical considerations for safe and appropriate use of rivaroxaban for VTE prophylaxis is described in Table 1 (Table does not include a complete list of FDA-approved indications.)

Table 1

VTE PROPHYLAXIS INDICATIONS		RENAL	DOSAGE	OTHER
Medical Patients[3]				
For the prophylaxis of VTE in acutely ill **medical** patients at risk for thromboembolic complications not at high risk of bleeding		CrCL ≥15 mL/min	10 mg once daily, in hospital and after hospital discharge (recommended duration 31 to 39 days)	Do **NOT** use in patients at high risk of bleeding with the following conditions: • history of bronchiectasis, pulmonary cavitation, or pulmonary hemorrhage • active cancer (i.e. undergoing acute, in-hospital cancer treatment) • active gastroduodenal ulcer in the 3 months prior to treatment • history of bleeding in the 3 months prior to treatment • dual antiplatelet therapy
		CrCL <15 mL/min	Avoid use	
Orthopedic Surgery Patients[3]				
For the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement **surgery**	Following Hip Replacement Surgery	CrCL ≥15 mL/min	10 mg once daily for 35 days	Start 6-10 hours after surgery once hemostasis has been established
		CrCL <15 mL/min	Avoid use	
	Following Knee Replacement Surgery	CrCL ≥15 mL/min	10 mg once daily for 12 days	
		CrCL <15 mL/min	Avoid use	
SURGICAL CONSIDERATIONS[3]				
• Rivaroxaban should be stopped *at least* 24 hours before surgery to reduce risk of bleeding; May be appropriate to hold for >24 hours in high-risk bleed procedures. • Placement/removal of epidural catheter/ lumbar puncture is best performed when the anticoagulant effect of rivaroxaban is low; however, the exact timing to reach a sufficiently low effect is not known. Do not administer earlier than 6 hours after catheter removal. If traumatic puncture occurs, delay administration of rivaroxaban for 24 hours.				
REVERSAL[3]				
• An agent to reverse the anti-factor Xa activity of rivaroxaban is available. • Use of procoagulant reversal agents, (i.e. prothrombin complex concentrate (PCC), activated prothrombin complex concentrate or recombinant factor VIIa), may be considered but has not been evaluated in clinical efficacy and safety studies. • Rivaroxaban is not dialyzable. • Monitoring for the anticoagulation effect of rivaroxaban using clotting tests (PT, INR, aPTT) or anti-factor Xa (FXa) activity is not recommended.				

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PRACTICAL CONSIDERATIONS: THE NEW RIVAROXABAN VENOUS THROMBOEMBOLISM PROPHYLAXIS INDICATION *continued*

Cynthia Ly, PharmD & Elissa DiPasquale, PharmD, BCPS

Medication errors can occur during any stage of therapy, from prescribing through administration. Drug knowledge and taking extra precautions may minimize the occurrence of anticoagulant-related adverse events and improve the management of VTE prophylaxis in appropriate patients.

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POINTS OF ATTENTION FOLLOWING ABLATION OF SUPERFICIAL VEINS IN THE LOWER EXTREMITY

Haraldur Bjarnason, MD

Haraldur Bjarnason, MD

Considerable inconsistencies exist with regards to post procedural management following ablations of the lower extremity superficial veins. This stems to large degree from lack of research on the topic. Thermal ablation of the GSV and SSV has a high technical and clinical success rate but there are several complications associated with the procedure. The purpose of this short text is to shed some light on the most important issues related to post procedural follow up. The purpose of follow up is to address the need for further procedures such as sclerotherapy or phlebectomy and to address complications such as superficial thrombophlebitis, numbness; skin discoloration or post ablation superficial thrombus extension (PASTE).

When advising the patient before an ablations procedure there are three things which should be mentioned as possible complications.

#1: Nerve damage causing numbness typically along the medial lower legs without a risk of muscular weakness or paralysis. For the great saphenous vein one can quote 5% to 6% incidence if treating below the knee and none if treating only the tight segment down to the knee level. The sensation may come back but over a long time, typically 9 months or longer and that half of the time sensation my not return completely. The risk of this can be decreased by using large amounts of tumescent close to the vein or by using none-thermal methods such as sclerotherapy or Mechanico-Chemical Ablation (MOCS) methods below the knee.

#2: Skin burn is a very real complication and usually manifests as a first degree burn. It may lead to permanent skin discoloration. The incidence is usually quoted to be around 1%. This can be avoided by placing large amounts of tumescence around the vein and between the skin and the vein attempting to distance the skin 1cm from the vein.

#3: Endovenous heat-induced thrombosis (EHIT) which now is commonly referred to as PASTE (EHIT being a subcategory of PASTE and referring specifically to heat induced thrombus) occurs in approximately 0% to 3% of cases. This entity is much debated. There is a similar phenomenon associated with MOCA techniques which probably should be addressed in the same manner as PASTE. In most cases of PASTE observation with a follow up ultrasound in one week without anticoagulation is appropriate. In few some cases (Grade 3 and 4 according to the Kabnick definition), therapeutic doses of anticoagulation for 4 weeks with an ultrasound at that time is advised. We are awaiting recommendations on this topic from the AVF writing group and this should be published any day now.

One of the debates swirlng around is connected to standard ultrasound follow up after thermal ablation to search for PASTE and if, when. One of the questions

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POINTS OF ATTENTION FOLLOWING ABLATION OF SUPERFICIAL VEINS IN THE LOWER EXTREMITY *continued*

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is if it is a true DVT and how should it be managed if at all? PASTE appears to be direct extension of thrombus developing at the site of the heat or chemical trauma extending into the dead space left at the SFJ stump. The risk of this may be lessened by starting ablation no closer than 2.5cm from the saphenofemoral junction and some say by collapsing the remaining stump thoroughly with tumescence during the procedure in order to eliminate any dead space. As far as performing post procedural ultrasound for surveillance it is still in the air. The incidence is very low and the direct cost of doing ultrasound are high with low yield and with considerable cost to the patient and society. Most proceduralists are still obtaining a limited ultrasound of the ablated vein one to seven days following the procedure. In our practice we obtain an ultrasound the following morning or the following Monday if the procedure is done on a Friday to search for PASTE. Soon we should see published recommendation from a writing group from the AVF on this topic and those should be out any time now.

Should patients be advised to use compressions stocking following an ablations procedure? There have been published studies which indicate that the outcome of the procedure itself may not be affected by using compressions stockings but the patients do report less post procedural pain and discomfort. We advise using thigh high compressions stockings, 20 to 30mmHg for 10 days. During the first 3 days we advise that the stockings should be worn for around the clock (can take off for showering) and then for the remaining 7 days only during the active hours. What about recommended activity level following ablations procedures? There have not been studies, that I am aware of, which have looked at these questions specifically. We advise the patients to return to normal activity the following day. In some practices weight limitations are given for 5 to 10 days with the thought that increased venous pressure may force the treated vein open.

So, should patients be followed up long term and then when after an ablations procedure in addition to the PASTE surveillance? We have resorted to a follow up at 6 to 12 months with a limited ultrasound of the treated vein to evaluate for vein closure only. This is obviously important for the purposes of quality and outcome measures and will be required if one participates in the Vascular Quality Initiative or if applying and maintaining a Vein Accredited Centers status.

The short note above is intended for discussion. Considerable inconsistency still exists but clarifications are emerging.

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NEW CHINESE EDITION OF THE HANDBOOK OF VENOUS AND LYMPHATIC DISORDERS

Peter Gloviczki, MD

Peter Gloviczki, MD

The Chinese edition of the Handbook of Venous and Lymphatic Disorders: Guidelines of the American Venous Forum , 4th Edition was completed and introduced at the recent joint meeting of the Asian and Chinese Venous Forums and the Chinese Association of Phlebology, held in Hangzhou, China. Peter and Monika Gloviczki attended the meeting.

The Chinese translation of the Handbook was made possible by Professor Shenming Wang, President of the Asian Venous Forum and Honorary President of the Chinese Vascular Surgery Society , Dr Jinsong Wang, several other Chinese professors and a group of 500 Chinese vascular surgeons, who participated in the translation of the entire book.

All participants of the meeting will receive a copy of the Chinese Edition of the Handbook that will be will available after January 1st.

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