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## Managing VTE in the Hospital Setting

### Announcer:

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Here's your host, Dr Jennifer Caudle.

### Dr Caudle:

Venous thromboembolism, also known as VTE, or blood clots, is an underdiagnosed and serious medical condition. VTE can happen to anybody at any age and cause serious illness, disability, and in some cases death. That's why today we'll be exploring what we can do to help reduce the prevalence of this significant and potentially deadly health threat.

This is ReachMD, and I'm your host, Dr Jennifer Caudle. Joining me today to discuss a treatment option to help manage VTE in the hospital setting are Dr Hiren M. Shah, Assistant Professor of Medicine at Northwestern University in Chicago, Illinois, and Dr Stanley C. Thompson, Chief Clinical Officer at the TeamHealth LifePoint Group in Germantown, Tennessee. Thank you both for being here today.

### Dr Thompson:

You're welcome, Jennifer.

### Dr Shah:

Thank you, Dr Caudle. It's my pleasure to speak with you today.

### Announcer:

In our discussion today, we will focus on the clinical profile of XARELTO® (rivaroxaban).

- XARELTO® is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (or AF)
- There are limited data on the relative effectiveness of XARELTO® and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well controlled
- XARELTO® is indicated for the treatment of deep vein thrombosis (or DVT)
- XARELTO® is indicated for the treatment of pulmonary embolism (or PE)
- XARELTO® is indicated for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months
- XARELTO® is indicated for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery
- XARELTO® is indicated for the prophylaxis of venous thromboembolism (or VTE) and VTE-related death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE, and not at high risk of bleeding
- XARELTO®; is indicated, in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular [or CV] death, myocardial infarction [or MI], and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD)

Before we discuss XARELTO<sup>®</sup>, let's review the BOXED Warning and contraindications.

- XARELTO<sup>®</sup> carries a BOXED Warning. The first part notes that premature discontinuation of XARELTO<sup>®</sup> places patients at an increased risk of thrombotic events. This is based on a higher rate of thrombotic events in the XARELTO<sup>®</sup> arm compared with the warfarin arm following the discontinuation of XARELTO<sup>®</sup> and a nonbridged transition to warfarin at the end of the ROCKET AF trial. If anticoagulation with XARELTO<sup>®</sup> must be discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant
- The second part of the BOXED Warning pertains to epidural or spinal hematomas. These have occurred in patients treated with XARELTO<sup>®</sup> who are receiving neuraxial anesthesia or undergoing spinal puncture and may result in long-term or permanent paralysis
- Factors that can increase the risk of developing epidural or spinal hematomas in these patients include the use of indwelling epidural catheters, concomitant use of other drugs that affect hemostasis, a history of traumatic or repeated epidural or spinal punctures, or a history of spinal deformity or spinal surgery. Optimal timing between the administration of XARELTO<sup>®</sup> and neuraxial procedures is not known
- These patients should be monitored frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis
- Contraindications for XARELTO<sup>®</sup> include active pathological bleeding and severe hypersensitivity reaction to XARELTO<sup>®</sup>

**Dr Caudle:**

Dr Thompson, we're going to start with you. So, you know, let's discuss the management of VTEs we may encounter in the hospital setting. First, let's begin with the risk for VTE in acutely ill medical patients. So, Dr Thompson, what is the risk associated with these patients?

**Dr Thompson:**

Yes, so acutely ill medical patients are at high risk for venous thromboembolism while hospitalized. More than 1 in 5 venous thromboembolisms, or VTEs, are due to a current or recent hospitalization in a medically ill patient, and approximately 75% of fatal PEs, pulmonary embolisms, occur in nonsurgical, medically ill, hospitalized patients. Postdischarge outpatients also have a high risk of VTE. More than 50% of VTE events occur after discharge. In addition, of VTE episodes occurring within 3 months of a prior hospitalization, 67% occurred within the first month. And although VTE risk persists postdischarge, the rate of postdischarge thromboprophylaxis is low in the United States at about 4%.

**Dr Caudle:**

Excellent. Thank you. Now, Dr Shah, moving on to you, can you tell us about the MAGELLAN trial design which examined XARELTO<sup>®</sup> as a treatment option for these acutely ill medical patients?

**Dr Shah:**

Sure. MAGELLAN was a randomized, double-blind, parallel-group efficacy, safety study comparing XARELTO<sup>®</sup> to enoxaparin in the prevention of VTE in hospitalized acutely ill medical patients during the inpatient and outpatient setting. I'll note that 5 key risk factors for major bleeding were identified and applied as exclusion criteria to the MAGELLAN overall study. Approximately 20% of the population had 1 or more of these 5 key risk factors. The patient population remaining after applying these 5 exclusion criteria comprised the MAGELLAN subgroup. The characteristics of these patients included those who had a history of bronchiectasis, pulmonary cavitation or pulmonary hemorrhage, active cancer defined as undergoing acute, in-hospital cancer treatment, active gastroduodenal ulcer in the 3 months prior to treatment, history of bleeding within the last 3 months prior to treatment, and those receiving dual antiplatelet therapy. Inclusion criteria for MAGELLAN subgroup included patients who were more than 40 years of age and at risk for VTE due to moderate or severe immobility and hospitalized for acute medical illnesses. Some of these medical illnesses were acute heart failure, acute ischemic stroke, acute respiratory insufficiency and acute infectious and inflammatory disease. I'll note that in addition, patients had at least 1 or more additional VTE risk factors including age more than 75, prolonged immobilization, history of cancer, history of VTE, history of heart failure, thrombophilia, acute infectious disease contributing to hospitalization, and a BMI more than 35.

Patients were randomized to receive either XARELTO<sup>®</sup> 10 mg once daily for 35 plus or minus 4 days starting in hospital and continuing posthospital discharge or enoxaparin 40 mg once daily for 10 plus or minus 4 days starting in hospital followed by placebo postdischarge. The primary efficacy outcomes were a composite of asymptomatic proximal DVT in the lower extremity, symptomatic proximal or distal DVT in the lower extremity, symptomatic nonfatal PE and death related to venous VTE from Day 1 to 10. The primary

Day-10 analysis was prespecified to be a noninferiority analysis. The same composite outcome was also evaluated from Day 1 to 35. The primary Day-35 analysis was prespecified to be a superiority analysis. And finally, I'll note that the principal safety outcome was clinically relevant bleeding, which was a composite of major bleeding, or clinically relevant nonmajor bleeding events.

**Dr Caudle:**

Okay, excellent, and thank you for describing that and kind of going through that. Dr Thompson, we're going to move to you. Can you share the results from the MAGELLAN trial now?

**Dr Thompson:**

Yes, sure. So the overall population results of the MAGELLAN trial demonstrated that XARELTO® 10 mg dose once daily was noninferior to enoxaparin 40 mg once daily at Day 10 and the reduction of a composite of asymptomatic proximal DVT, symptomatic proximal or distal DVT, symptomatic nonfatal PE and VTE-related death. The results of the primary efficacy endpoint at Day 10 for the MAGELLAN subgroup, excluding those patients at high risk of bleeding that Dr Shah discussed, were consistent with the results for the overall population.

Secondly, the overall population results of the MAGELLAN trial demonstrated that the XARELTO® 10 mg once-daily dose was superior to enoxaparin 40 mg and placebo once daily at Day 35 and the reduction again of a composite of asymptomatic proximal DVT, symptomatic proximal or distal DVT, symptomatic nonfatal PE and VTE-related death. The results of the primary efficacy endpoint at Day 35 for the MAGELLAN subgroup, excluding those patients again at high risk of bleeding, were consistent with the results for the overall population.

With regard to bleeding in the MAGELLAN subgroup, there were comparable major bleeding rates in the XARELTO® 10 mg once daily group compared to the enoxaparin 40 mg/placebo group. There were also comparable rates of critical site bleeding and fatal bleeding in the XARELTO® 10 mg once daily group compared with the enoxaparin 40 mg/placebo group. There was a higher rate of clinically relevant nonmajor bleeding in the XARELTO® 10 mg once daily group compared with the enoxaparin 40 mg/placebo group.

**Dr Caudle:**

Excellent. Thank you very much for that. Now, turning back to you, Dr Shah, we've been talking about the use of XARELTO® for VTE prophylaxis in acutely ill medical patients at risk for thromboembolic complications but not at high risk of bleeding. In another study XARELTO® was also studied for early discharge in patients with low-risk PE. Is that right?

**Dr Shah:**

Yes, Dr Caudle, you are correct. There were 2 studies that examined XARELTO® for the outpatient treatment of low-risk PE patients. First, there was the HoT-PE trial. HoT-PE was a prospective, multicenter, single-arm, investigator-initiated and academically sponsored management trial that investigated the efficacy and safety of early transition from hospital to ambulatory treatment in low-risk acute PE identified through a modified Hestia criteria in patients taking XARELTO® 15 mg twice daily for the first 3 weeks followed by 20 mg once daily for at least 3 months.

In the HoT-PE study, the primary endpoint was symptomatic recurrent VTE or PE-related death within 3 months of enrollment. The principal safety outcomes were major bleeding defined by ISTH criteria, clinically relevant nonmajor bleeding and serious adverse events.

In the HoT-PE trial, the rate of symptomatic recurrent VTE or PE-related death within 3 months of enrollment was 0.6% with a 95% confidence interval of 0.6% to 2.1% and a P value less than .0001 with XARELTO®. The rate of major bleeding was 1.2% with a 95% confidence interval of 0.4% to 2.5% with XARELTO®.

The second trial that was performed was the MERCURY PE trial, and this was a randomized, open-label, parallel-group, multicenter trial in low-risk PE patients that compared patients who had early discharge within 24 hours of the emergency department triage on XARELTO® 15 mg bid for 21 days followed by 20 mg once a day with standard of care. The low-risk PE patients were defined by the absence of Hestia criteria adopted by emergency medicine by removing 24-hour requirements. In this study the primary efficacy outcome was total hospitalization time including inpatient or observation for VTE or bleeding events within 30 days of randomization. In this study the principal safety outcome was ISTH-defined major bleeding within 90 days of randomization, and the mean duration of initial and subsequent hospitalizations for VTE and/or bleeding events within 30 days of randomization was significantly shorter with early discharge on XARELTO® compared to the standard of care with 4.8 hours in the XARELTO® group compared to 33.6 hours in the standard of care group. I'll note the P value was less than .0001. There were no ISTH major bleeding events in either treatment group. One subject in each treatment group had an ISTH clinically relevant nonmajor bleeding event.

And finally, in addition, early discharge on XARELTO<sup>®</sup> was significantly less expensive than standard of care. The median cost was \$1,496 for the XARELTO<sup>®</sup> group compared with \$4,234 in the standard of care group with a P value less than .001, and this was based on direct medical care costs in 2016 US dollars including the qualifying index PE encounter, all subsequent encounters related to any ISTH major or clinically relevant nonmajor bleeding, adjudicated recurrent PE or new or recurrent DVT, and the cost of anticoagulation and related monitoring during 30 days following randomization.

I will note there were some limitations of MERCURY PE. The original plan sample was decreased due to slower than anticipated enrollment and unanticipated funding limitations. Emergency department physicians could exclude patients based on their subject of evaluation of hemodynamic stability and their impression of the patient's ability to adhere to the protocol. The patients could not be blinded to their assigned cohort. The emergency department physicians were allowed to define standard of care in this study.

### Announcer:

The following is additional Important Safety Information for XARELTO<sup>®</sup>

### WARNINGS AND PRECAUTIONS

- **Increased Risk of Thrombotic Events after Premature Discontinuation:** Premature discontinuation of any oral anticoagulant, including XARELTO<sup>®</sup>, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO<sup>®</sup> to warfarin in clinical trials in atrial fibrillation patients. If XARELTO<sup>®</sup> is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- **Risk of Bleeding:** XARELTO<sup>®</sup> increases the risk of bleeding and can cause serious or fatal bleeding. Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue in patients with active pathological hemorrhage.
  - An agent to reverse the anti-factor Xa activity of rivaroxaban is available. Because of high plasma protein binding, rivaroxaban is not dialyzable.
  - Concomitant use of other drugs that impair hemostasis increases risk of bleeding. These include aspirin, P2Y<sub>12</sub> platelet inhibitors, dual antiplatelet therapy, other antithrombotic agents, fibrinolytic therapy, NSAIDs, selective serotonin reuptake inhibitors (or SSRIs), and serotonin norepinephrine reuptake inhibitors (or SNRIs).
  - Risk of Hemorrhage in Acutely Ill Medical Patients at High Risk of Bleeding: Acutely ill medical patients with the following conditions are at increased risk of bleeding with the use of XARELTO<sup>®</sup> for primary VTE prophylaxis: history of bronchiectasis, pulmonary cavitation, or pulmonary hemorrhage; active cancer (ie, undergoing acute, in-hospital cancer treatment); active gastroduodenal ulcer or history of bleeding in the three months prior to treatment; or dual antiplatelet therapy. XARELTO<sup>®</sup> is not for use for primary VTE prophylaxis in these hospitalized, acutely ill medical patients at high risk of bleeding.
- **Spinal/Epidural Anesthesia or Puncture:** When neuraxial anesthesia (ie, spinal or epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma, which can result in long-term or permanent paralysis. To reduce the potential risk of bleeding associated with concurrent use of XARELTO<sup>®</sup> and epidural or spinal anesthesia and/or analgesia or spinal puncture, consider the pharmacokinetic profile of XARELTO<sup>®</sup>. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of XARELTO<sup>®</sup> is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known. An indwelling epidural or intrathecal catheter should not be removed before at least 2 half-lives have elapsed (ie, 18 hours in young patients aged 20 to 45 years and 26 hours in elderly patients aged 60 to 76 years), after the last administration of XARELTO<sup>®</sup>. The next dose should not be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of XARELTO<sup>®</sup> for 24 hours. Monitor frequently to detect signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (for example, numbness, tingling, or weakness in lower limbs), or bowel and/or bladder dysfunction. Instruct patients to immediately report any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.
- **Use in Patients with Renal Impairment:**
  - **Nonvalvular Atrial Fibrillation:** Periodically assess renal function as clinically indicated (ie, more frequently in situations in which renal function may decline) and adjust therapy accordingly. Consider dose adjustment or discontinuation in patients who develop acute renal failure while on XARELTO<sup>®</sup>. Clinical efficacy and safety studies with XARELTO<sup>®</sup> did not enroll patients with CrCl <30 mL/min or end-stage renal disease (or ESRD) on dialysis.
  - **Treatment of Deep Vein Thrombosis (or DVT), Pulmonary Embolism (or PE), and Reduction in the Risk of Recurrence of DVT and of PE; Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery; Prophylaxis of Venous**

**Thromboembolism in Acutely Ill Medical Patients at Risk for Thromboembolic Complications Not at High Risk of Bleeding:** In patients with CrCl <30 mL/min, rivaroxaban exposure and pharmacodynamic effects are increased compared to patients with normal renal function. There are limited clinical data in patients with CrCl 15 to <30 mL/min; therefore, observe closely and promptly evaluate any signs or symptoms of blood loss in these patients. There are no clinical data in patients with CrCl <15 mL/min (including patients on dialysis); therefore, avoid the use of XARELTO® in these patients. Discontinue XARELTO® in patients who develop acute renal failure while on treatment.

- **Reduction of Risk of Major Cardiovascular Events in Patients with Chronic CAD or PAD:** For patients with CrCl <15 mL/min, no data are available, and limited data are available for patients with a CrCl of 15 to 30 mL/min. In patients with CrCl <30 mL/min, a dose of 2.5 mg of XARELTO® twice daily is expected to give an exposure similar to that in patients with a moderate renal impairment (CrCl 30 to <50 mL/min), whose efficacy and safety outcomes were similar to those with preserved renal function. Clinical efficacy and safety studies with XARELTO® did not enroll patients with end-stage renal disease (or ESRD) on dialysis.
- **Use in Patients with Hepatic Impairment:** No clinical data are available for patients with severe hepatic impairment. Avoid use in patients with moderate (or Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy, since drug exposure and bleeding risk may be increased.
- **Use with P-gp and Strong CYP3A Inhibitors or Inducers:** Avoid concomitant use of XARELTO® with known combined P-gp and strong CYP3A inhibitors or inducers.
- **Risk of Pregnancy-Related Hemorrhage:** In pregnant women, XARELTO® should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO® dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO® cannot be monitored with standard laboratory testing. Promptly evaluate signs or symptoms suggesting blood loss (eg, a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).
- **Patients with Prosthetic Heart Valves:** Use of XARELTO® is not recommended in patients who have had transcatheter aortic valve replacement (TAVR), based on the results of the GALILEO study, which reported higher rates of death and bleeding in patients randomized to XARELTO® compared to those randomized to an antiplatelet regimen. Safety and efficacy of XARELTO® have not been studied in patients with other prosthetic heart valves or other valve procedures. Use of XARELTO® is not recommended in patients with prosthetic heart valves.
- **Acute PE in Hemodynamically Unstable Patients and/or Patients Who Require Thrombolysis or Pulmonary Embolectomy:** Initiation of XARELTO® is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.
- **Increased Risk of Thrombosis in Patients with Antiphospholipid Syndrome:** Direct-acting oral anticoagulants (or DOACs), including XARELTO®, are not recommended in use in patients with triple-positive antiphospholipid syndrome (or APS). For patients with APS (especially those who are triple positive [positive for lupus anticoagulant, anticardiolipin, and anti-beta 2-glycoprotein I antibodies]), treatment with DOACs has been associated with increased rates of recurrent thrombotic events compared with vitamin K antagonist therapy.

## DRUG INTERACTIONS

- Combined P-gp and strong CYP3A inhibitors increase exposure to rivaroxaban and may increase risk of bleeding.
- Combined P-gp and strong CYP3A inducers decrease exposure to rivaroxaban and may increase risk of thromboembolic events.
- XARELTO® should not be used in patients with CrCl 15 to <80 mL/min who are receiving concomitant combined P-gp and moderate CYP3A inhibitors (example, erythromycin) unless the potential benefit justifies the potential risk.
- Coadministration of enoxaparin, warfarin, aspirin, clopidogrel, and chronic NSAID use may increase risk of bleeding.
- Avoid concurrent use of XARELTO® with other anticoagulants due to increased bleeding risk, unless benefit outweighs risk. Promptly evaluate signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs.

## USE IN SPECIFIC POPULATIONS

- **Pregnancy:** The limited available data on XARELTO® in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. Use XARELTO® with caution in pregnant patients because of the potential for pregnancy-related hemorrhage and/or emergent delivery. The anticoagulant effect of XARELTO® cannot be reliably monitored with standard laboratory testing. Consider the benefits and risks of XARELTO® for the mother and possible risks to the fetus when prescribing to a pregnant woman.

- **Fetal and/or Neonatal adverse reactions:** Based on the pharmacologic activity of Factor Xa inhibitors and the potential to cross the placenta, bleeding may occur at any site in the fetus and/or neonate.
- **Labor or delivery:** The risk of bleeding should be balanced with the risk of thrombotic events when considering use in this setting.
- There are no adequate or well-controlled studies of XARELTO® in pregnant women, and dosing for pregnant women has not been established. Post-marketing experience is currently insufficient to determine a rivaroxaban-associated risk for major birth defects or miscarriage.
- **Lactation:** Rivaroxaban has been detected in human milk. There are insufficient data to determine the effects of rivaroxaban on the breastfed child or on milk production. Consider the developmental and health benefits of breastfeeding along with the mother's clinical need for XARELTO® and any potential adverse effects on the breastfed infant from XARELTO® or from the underlying maternal condition.
- **Females and Males of Reproductive Potential:** Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician. The risk of clinically significant uterine bleeding, potentially requiring gynecological surgical interventions, identified with oral anticoagulants, including XARELTO®, should be assessed in females of reproductive potential and those with abnormal uterine bleeding.
- **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

### OVERDOSAGE

- Overdose of XARELTO® may lead to hemorrhage. Discontinue XARELTO® and initiate appropriate therapy if bleeding complications associated with overdosage occur. An agent to reverse the anti-factor Xa activity of rivaroxaban is available.

### ADVERSE REACTIONS IN CLINICAL STUDIES

- Most common adverse reactions with XARELTO® were bleeding complications.

Please visit [www.xareltohcp.com](http://www.xareltohcp.com) for full Prescribing Information, including **BOXED WARNINGS**, for XARELTO®.

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#### Dr Caudle:

Now, unfortunately, we're just about out of time for today. So, Dr Thompson, what do you want our listeners to take away from this discussion?

#### Dr Thompson:

Yes, Dr Caudle, I want to reiterate that in an acutely ill medical patient, there is a high risk for VTE while hospitalized and postdischarge. XARELTO® 10 mg once daily was proven to help prevent VTE in acutely ill medical patients at risk for thromboembolic complications who were not at high risk of bleeding during hospitalization and posthospital discharge for a duration of 31 to 39 days. Clinically relevant nonmajor bleeding did increase with XARELTO; however, approximately 97% of patients did not experience one of these events. Excluding patients with 5 key risk factors for major bleeding can help define a population of medically ill patients with a favorable benefit-risk profile with XARELTO® for both in-hospital and extended thromboprophylaxis. These risk factors are history of bronchiectasis, pulmonary cavitation or pulmonary hemorrhage, active cancer defined as undergoing acute in-hospital cancer treatment, active gastroduodenal ulcer in the 3 months prior to the treatment, history of bleeding within the last 3 months prior to treatment, and receiving dual antiplatelet therapy.

#### Dr Caudle:

And how about you, Dr Shah? What's your final takeaway?

#### Dr Shah:

My final takeaway is that XARELTO® is the only DOAC studied for early discharge in patients with low-risk PE. The HoT-PE and MERCURY PE trials that I reviewed were the 2 trials that examined XARELTO® in these patients.

#### Dr Caudle:

Well, these are great takeaways from you both, and I really want to thank my guests for helping us better understand this option for VTE prophylaxis in acutely ill medical patients and in patients for the treatment of low-risk PE. Dr Shah and Dr Thompson, it was great speaking with you today.

#### Dr Thompson:

You're welcome, Dr Caudle.

**Dr Shah:**

Thank you for having us, Dr Caudle.

**Dr Caudle:**

I'm your host, Dr Jennifer Caudle, and thanks for listening.

**Announcer:**

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