Performance Improvement Strategies

in VTE Risk Assessment and Prophylaxis

Community of Practice Audioconference

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Audioconference faculty:

Richard J. Friedman, MD
Clinical Professor of Orthopaedic Surgery
Medical University of South Carolina
Chairman, Department of Orthopaedic Surgery
Roper Hospital
Charleston, SC

Thomas L. Ortel, MD, PhD
Professor of Medicine & Pathology
Hemostasis & Thrombosis Center
Director, Anticoagulation Management Service
Director, Duke Clinical Coagulation and Platelet Immunology Laboratories Duke University Health System
Durham, NC

MODERATOR: Welcome to the Community of Practice audioconference featuring venous thromboembolism (VTE) prophylaxis experts Dr. Thomas Ortel and Dr. Richard Friedman. Today's discussion is co-sponsored by the Duke University School of Medicine and Med-IQ. I'm Olivia, your moderator for today's discussion. This audioconference is being recorded; however resale of the content is prohibited. During today's call you will have an opportunity to discuss strategies for improving VTE prevention among hospitalized orthopaedic and medically ill patients, as well as voice questions or comments for immediate faculty feedback. This interactive discussion has been developed as part of the AMA-standardized PI CME initiative "Performance Improvement Strategies in VTE Risk Assessment and Prophylaxis." Drs. Ortel and Friedman have served as faculty experts for this initiative and will provide a brief overview of this educational opportunity at the beginning of today's audioconference.

I am pleased to now introduce to you Dr. Ortel and Dr. Friedman. Dr. Ortel is the Director of both the Anticoagulation Management Service and the Duke Clinical Coagulation and Platelet Immunology Laboratories. He is also a professor of medicine in pathology in the Division of Hematology at Duke University Health System in Durham, North Carolina. Dr. Friedman is a clinical professor of orthopaedic surgery at the Medical University of South Carolina, and Chairman of the Department of Orthopaedic Surgery at Roper Hospital in Charleston, South Carolina. Dr. Ortel?

THOMAS L. ORTEL, MD, PHD: Thank you, and welcome to everybody. Good evening. This is the Community of Practice Audioconference for VTE Risk Assessment and Prophylaxis in Hospitalized Patients. Dr. Friedman and I will give just a brief introduction before we get started.

The goal of the audioconference is to bring together clinicians who are interested in the prevention of VTE to discuss the implementation of current guideline recommendations and recent clinical evidence in routine practice with a special focus on processes or systems of care. Before we open up the call to questions, we would like to provide an overview of the framework of the PI initiative and then also briefly discuss why initiatives such as this are so important for practicing clinicians. For those of you who may not be familiar with performance improvement or PI CME, this is an AMA-approved educational format in which clinicians work on improving their individual performance by retrospectively evaluating patient data and developing an improvement plan for their particular practice.

This particular PI activity focuses on three groups of hospitalized patients with an elevated risk of VTE, including medically ill patients, oncology patients, and orthopaedic surgery patients. To our knowledge, this program is really the only PI initiative focused solely on risk assessment and prophylaxis of VTE in these populations. Dr. Friedman?

RICHARD J. FRIEDMAN, MD: Thank you. There are three stages to the process. In the first step, or stage A, participants perform a retrospective analysis of 10 patient charts by completing a short patient data form for each chart. Once the chart review has been completed, participants will receive a summary of their practice patterns relative to those of their peers enrolled in the program and applicable national standards. In the next step, or stage B, participants review their practice summary and design a process-based improvement strategy specific to their needs at their practice. To help develop a care improvement plan, clinicians may read a complimentary, certified CME implementation guide that outlines the current evidence-based treatment guidelines, as well as provides practical tools and resources. In the final step, or stage C, participants return to review an additional 10 patient charts after they've implemented their improvement strategies in their practices. Once again, a patient data form is completed for each chart. At the conclusion of stage C, participants receive a summary of their current practice patterns relative to their initial performance, as well as to that of their peers and national standards.

DR. ORTEL: As you are well aware, venous thromboembolism is a significant public health issue that causes a heavy burden on our healthcare system. Hospitalization for acute medical illness increases the risk of venous thromboembolism more than 10-fold. However, risk assessment and prophylaxis for VTE in medically ill patients is often overlooked. Furthermore, all patients undergoing total hip arthroplasty, total knee arthroplasty, or hip fracture surgery are by definition classified as high risk for post-operative VTE events and require thromboprophylaxis that is initiated in the hospital and continued after discharge from the hospital. It is important for practicing clinicians to understand that patient outcomes can be dramatically improved by implementing a standardized, evidence-based approach to evaluating all hospitalized patients for VTE risk and initiating appropriate thromboprophylaxis in a timely manner.

DR. FRIEDMAN: There is a clear and compelling need to improve VTE prophylaxis among at-risk hospitalized patients. Patient safety initiatives of the US Surgeon General, the National Quality Forum, and The Joint Commission have brought recent attention to the problem of VTE in the hospital setting. The identification of VTE prophylaxis as an institutional priority, the development and implementation of standardized protocols, and the commitment and willingness of various stakeholders involved in the care of hospitalized patients is needed to combat this largely preventable issue and improve healthcare quality.

We would like to now open it up to your questions and comments about the challenges that you face in VTE risk assessment and prophylaxis among your hospitalized patients. We can begin with a question received in advance by e-mail, but please feel free to let the operator know if you have a question and would like to have it addressed this evening.

MODERATOR: Thank you doctor. At this time we will begin the question and answer session. To ask a question, please press zero followed by a one on your touchtone phone. Questions will be answered in the order they are received. Again, if you would like to ask a question, please press zero followed by a one now. Please pause to assess whether we receive live questions in queue. Med-IQ received several questions in advance for this audioconference. At this time, Dr. Allison Gardner will share a question that was submitted by one of your colleagues.

ALLISON GARDNER, PHD: Dr. Friedman, this first question is in regards to the orthopaedic surgery patients and it asks, “What are the latest ranges for recommended DVT prophylaxis regimens in total hip arthroplasty, and also in total knee arthroplasty and hip fracture surgery?”

DR. FRIEDMAN: I think they're asking here, “What is the current recommended length of treatment or length of prophylaxis a patient should receive?” In orthopaedic surgery patients, this has now become largely an outpatient issue since most of our total joint patients for hip and knee arthroplasty are going home on day two or day three; the hip fracture patients may stay a bit longer. So, the majority of the prophylaxis will occur on an outpatient basis.

Currently for total knee arthroplasty, the minimum recommended time is 10 to 14 days, and in select patients you may choose to extend that up to 28 to 35 days. Also for total hip arthroplasty, recommendations are a minimum of 10 to 14 days, but again, there is good strong evidence to suggest that patients should receive prophylaxis for up to 28 to 35 days. It would be a similar recommendation in hip fracture surgery as with total hip arthroplasty.

MODERATOR: Thank you doctor. And again, as a reminder to our participants, to ask a question please press zero followed by a one on your touchtone phone.

Dr. Gardner, will you please continue with another pre-submitted question?

DR. GARDNER: The next question asks, “What are the current thoughts in regards to the management of chronic ventilator-dependent patients with immobility?” Dr. Ortel?

DR. ORTEL: Yes, this is a difficult patient population to treat, and they are considered definitely at high risk of VTE. In this group, while they're in the intensive care unit and if they do have a high risk of bleeding, it's recommended that some type of mechanical thromboprophylactic strategy be used, such as sequential compression devices, but whenever possible a pharmacologic approach should be used for many of these patients. Optimal therapy would be with a LMWH strategy, and it would be while those patients are in the intensive care unit that you would continue that. An unfractionated heparin strategy could be used potentially three times a day instead of twice a day, but for most of these patients, we would recommend a low–molecular-weight heparin strategy unless there was also a problem with renal

insufficiency.

MODERATOR: Thank you doctor. And Dr. Gardner, would you like to continue with another question?

DR. GARDNER: Sure, Dr. Friedman, the concern with anticoagulation in orthopaedic surgery patients is post-op hematoma. Is aspirin still being considered as a possible future acceptable agent?

DR. FRIEDMAN: Aspirin is very controversial. Aspirin works very well on the arterial side, but to the best of my knowledge, and I'm not a hematologist, I'm not aware of any place in the coagulation cascade where aspirin actually works. It is very attractive in the sense that it's oral, it's easy to give, it's very inexpensive, and it has few side effects or complications, but I think if you look at the literature in well-designed clinical studies, the efficacy is not very good at all. It is maybe a little bit better in total hip arthroplasty compared to total knee arthroplasty, but it's clearly inferior to many other prophylactic agents that we have available. There are some competing guidelines out there. There are the American College of Chest Physician (ACCP) guidelines, which do not recommend aspirin, and then there are the guidelines put out by the American Academy of Orthopedic Surgeons, which state that aspirin is an option in certain groups for prophylaxis. But I think that you have to remember from a surgical point of view that all patients will bleed. They're having surgery, and bleeding is a risk. There are patient factors, there are surgeon factors, and literature has clearly demonstrated that even patients who receive no prophylaxis at all still have about a 2 to 2 1/2% incidence of a bleed. That's just the price of the business that we're in. And so, people tend to forget that. If they have a bleed and they're on some agent, they say ‘oh, it's the fault of the agent,’ but there's clearly a number of studies published demonstrating that when a patient is not receiving any pharmacologic prophylaxis, there is still a risk of bleeding.

I think that with regards to bleed, one has to be careful about the dosage, and one has to be careful about the timing of the agent that's used. Often when I'm talking with other physicians and they've had a problem with a bleed, there's usually been some issue again in regard to the dosage and/or the timing, or the use of concomitant medications that can help contribute to bleeding as well. I think in most of those cases there's an identifiable cause where something wasn't quite right. We've been using LMWHs now for more than 20 years, since the late 1980s, and bleeding has just not been an issue for us. But again, we start our LMWH 12 to 24 hours post-operatively. We make sure the wound is dry, and we are very careful about other medications they might get. So, I don't think that the fear of bleeding alone is a good reason to use an agent like aspirin that has questionable efficacy. I think the better thing is to stick with agents that have proven efficacy but be more alert as to the dosage you're using, the timing that you're using, and other medications they may be receiving that could influence the incidence of a

bleed.

MODERATOR: Dr. Ortel, do you have anything to add, perhaps regarding medical patients?

DR. ORTEL: Medical patients? From the standpoint of everything that Dr. Friedman went through, I agree with it 100%. There's actually been some discussion within the ACCP community concerning whether we actually shouldn't try to design and conduct a prospective clinical trial that would compare aspirin to a LMWH or an alternative therapy. It's something that at this point, as Dr. Friedman said, we don't have good comparable data between these, and most all of the prospective randomized trials really do primarily support LMWH or therapeutic warfarin.

From the standpoint of the general medical population in any kind of setting, whether it be post-surgical population or medical population, bleeding risk always needs to be considered as you evaluate that individual patient. That enters into your decision tree as far as the optimal timing and dose et cetera, as Dr. Friedman articulated, for your type of antithrombotic strategy that you use afterwards. So, for an ill medical patient who also is at high risk of bleeding, you may elect not to use LMWH and use some type of mechanical strategy because of the risk of bleeding. So, that's obviously something that needs to be considered in all patients.

MODERATOR: Thank you doctor. And again, as a reminder to our participants today, to ask a live question please press zero followed by a one.

DR. GARDNER: Dr. Ortel, could you comment on what you think is the best approach for post-operative VTE prophylaxis in CABG patients?

DR. ORTEL: For post-thoracic surgery patients, obviously in that particular patient group, they're trying to get patients up and ambulating as quickly as possible, so that helps in this study. But for the initial routine thromboprophylactic strategy, the current recommendation is for LMWH or a low-dose unfractionated heparin strategy (again I think most people would prefer or recommend a LMWH). Obviously, if these patients also potentially have cardiac valve surgery or they have other reasons that might place them at high risk of bleeding, that strategy needs to be reconsidered, in which case mechanical thromboprophylaxis or intermittent pneumatic compression devices might be superior in that patient population.

In our post-operative patients, the cardiothoracic surgery patients are getting discharged relatively earlier and earlier it seems, and in this particular population, there currently is not any recommendation that they should be continued on an extended course of therapy after discharge. So, it would be primarily restricted to while they're still in the hospital.

MODERATOR: Thank you doctor. Dr. Gardner, would you like to continue with

another question?

DR. GARDNER: Sure, mechanical prophylaxis has been mentioned a couple of times and so how long post-operatively are thromboembolic deterrent (TED) hose recommended?

DR. FRIEDMAN: I would like to take a shot at that. To me, there is a big difference between mechanical prophylaxis and TED hose. I don't really consider TED hose a mechanical prophylaxis. In our hospital, we have actually stopped using them a number of years ago because, at least in the post-op orthopaedic surgery patient, no one has ever shown that TED hose have any kind of efficacy at all, either alone or in conjunction with any type of prophylaxis. And we've had problems with them; patients are very unhappy with them. So, we actually have stopped using them.

Mechanical prophylaxis for us is some type of sequential compression device, either calf or thigh high, or possibly foot pumps where you're actually getting some type of mechanical compression. There is demonstrated efficacy in total knee arthroplasty; in fact with the ACCP, that's an acceptable form of prophylaxis. The issue is that in these few studies that looked at efficacy for mechanical compression, you needed to have it on 17 to 20 hours a day. Clearly when patients are going home on day two or day three and they're up walking the next morning, they don't get the kind of time in the compression device that they used to. And nobody has really looked at just how efficacious the compression devices are in the modern patient with modern protocols. And so I would hope what Dr. Ortel said, for example, that the ACCP may be looking at another type of study. It would be wonderful to look at the use of compression devices in hip arthroplasty and knee arthroplasty and try to find out the minimal time necessary for it to be efficacious. Now, along those lines, there are a couple of devices out that provide mechanical compressions that are portable, so you can send your patients home with these devices. And in fact there's been a couple of papers published in the literature in hip and knee arthroplasty showing efficacy equal to LMWHs with safety similar or improved; these patients go home with the devices and wear them for a couple of weeks, and so that's a potential very new exciting area that may turn out to be very valuable for our patients.

DR. ORTEL: I agree with everything that was just said. I agree that the TED hose really are, unfortunately, in some of our patient's minds actually a bit misleading because they really don't provide any VTE prophylaxis or prevention. I would say also that the way I approach the sequential compression devices or other compression approaches is usually based on bleeding risk, and because of the issue of convenience—once a patient goes to a LMWH, then obviously they can get up and walk around more easily, and they are thromboprophylaxed even while they're up and moving around.

In general, at our hospital, when I walk into most patients' rooms, I think that

the sequential compression device is either not on or under the bed and on. So, the biggest thing, as was just mentioned, is making sure that the patient has them on for a sufficient duration of time, and actually it would be an interesting prospective study to consider. The issue would be how to carefully document compliance with using them at home. Depending on how those things fit, I could see that some patients might have some trouble with wanting to wear them, but it does provide you with a very nice option and alternative strategy for those patients in whom you're concerned about the bleeding risk.

MODERATOR: Thank you doctor. At this time we do have a live question, and that question comes from Riverhead, New York. Please go ahead.

DR. PATEL: Hi, a very interesting topic here. This is Dr. Patel. The question was for the post-orthopaedic surgery patient going straight into rehab. How long do you recommend the prophylaxis and/or mechanical prophylaxis for these groups of patients, especially the hip and the knees?

DR. FRIEDMAN: I think whether they're going to a rehab facility, which is actually happening less and less nowadays, at least in our part of the country, or if they go home, the length of prophylaxis should be the same. And I pretty much follow the ACCP guidelines, so my knee surgery patients are going to get 14 days; it says minimum 10 to 14 days for total knee arthroplasty. For the hips, a minimum of 10 to 14 and up to 28 to 35 days, as there are excellent data both for total hip arthroplasty and for hip fracture surgery to show that carrying the patients out to 28 to 35 days makes a significant difference and cuts the rate down even further. So those are the numbers that I follow, and again it's the same whether they go home or they go to a rehab facility.

DR. PATEL: Thank you very much.

DR. FRIEDMAN: You're welcome.

MODERATOR: Thank you Dr. Patel. And Dr. Gardner, do we have another pre-submitted question?

DR. GARDNER: Sure, in a cardiac patient who received multiple stents and who is on triple antiplatelet therapy, how would you approach VTE prophylaxis?

DR. ORTEL: This is an interesting question because it's happening more and more, and not just in VTE prophylaxis but also VTE therapy, that is, the increasing number of patients who are on a variety of antiplatelet agents. Unfortunately, neither aspirin nor clopidogrel nor cilostazol have been shown to provide adequate thromboprophylaxis to prevent venous clots. Again, these are medications that primarily are efficacious in preventing arterial clot or occlusion of a stent, et cetera. So, those agents in and of themselves alone really are insufficient to prevent VTE.

So then you're left with assessing whether or not you think that adding a LMWH on top of these agents is going to increase the bleeding risk sufficiently or whether you would consider using mechanical prophylaxis. And I think that this is something that needs to be assessed on a case-by-case basis. In general, the bleeding risk from a prophylactic dose of a LMWH is not that high until you start really adding in these things. And often these patients will also have some component of renal insufficiency or other medical problems that might be contributing to the bleeding risk, in which case a mechanical strategy with intermittent compression devices would be superior. But for a patient who has no other bleeding risk, depending on what they need to be thromboprophylaxed for afterwards, I do not consider these medications in and of themselves to be contraindications to using a LMWH. I think you just have to approach it more cautiously and more carefully evaluate the patient for any bleeding manifestations.

MODERATOR: Thank you doctor. And again, as a final reminder to our participants, to ask a question please press zero followed by a one.

DR. GARDNER: The next question is, “How long should a patient not ambulate with a bilateral lower extremity DVT once a heparin IV drip is initiated?”

DR. ORTEL: Okay, now we're getting into therapy, and a number of years ago it used to be that we would put these patients into bed and tell them that they shouldn’t get up and move around. Actually, however, in the most recent addition of the ACCP, it's recommended that for patients with acute DVT, early ambulation is recommended in preference to leaving the patient in bed whenever it's feasible. And that's based on very good data, grade 1A evidence. I think that what needs to be recognized is once you get the patient in and once you get them started on anticoagulant therapy, getting that patient up and ambulating is perfectly reasonable now. Obviously there needs to be some common sense. If the patient has a lot of pain in the leg, if there's a lot of other symptoms whenever they get up, you don't necessarily want to push somebody more than they can tolerate, but there definitely should not be a recommendation that the patient should not get up and move around for any length of time if they otherwise can get up and walk.

DR. FRIEDMAN: And I would just want to echo that, that a lot of people still are tuned into the old ideas that they've got acute DVT, put them in bed for one or two days and then we'll start moving them slowly, and that has clearly been shown not to be efficacious, not to make a difference. So we get our patients and try and keep them active and keep them moving immediately.

MODERATOR: Thank you doctor. And Dr. Gardner, another question please.

DR. GARDNER: Sure, the next question is, “How do you best treat a patient on hemodialysis with an internal jugular catheter and suspected transient ischemic attack (TIA)?”

DR. ORTEL: Yeah, when I first saw that question, I tried to figure out how they were getting things hooked up there. There are a couple of issues; one is the hemodialysis patient who does have some component of increased bleeding risk because of platelet dysfunction. The second is the internal jugular catheter; some of those catheters do have a tendency to produce local thrombus and we get patients who do sometimes clot off their jugular vein, in which case then you treat them as a catheter-related clot once that happens. But now the issue of a suspected TIA implies something arterial circuit or that the patient has atrial fibrillation and may have had a TIA here. Depending on what you think caused the TIA, which I'm presuming is not related to their internal jugular thrombus unless they have a PFO or an atrial septal defect or something like that—depending on what you thought was the cause of the TIA, whether you thought it was carotid disease or atrial dysrhythmias, you would pick an antiplatelet strategy versus an anticoagulant strategy. For a patient with an internal jugular catheter who has clotted off the catheter, then antithrombotic therapy is optimal until you can get the catheter out. Then you get the catheter out, and then you still treat them for awhile after that, depending on how extensive the thrombus was that they had related to the catheter. In all of these situations, obviously, assessing the patient carefully for bleeding risk is necessary.

MODERATOR: Thank you doctor. This concludes today's VTE Prophylaxis Community of Practice Audioconference, co-sponsored by the Duke University School of Medicine and Med-IQ. This activity is supported by educational grants from Ortho-McNeil, a division of Ortho-McNeill-Janssen Pharmaceuticals Incorporated, administered by Ortho-McNeil Janssen Scientific Affairs, LLC, and sanofi-aventis U.S. Four hundred specialists have enrolled in "Performance Improvement Strategies in VTE Risk Assessment and Prophylaxis" to evaluate and improve their processes of care for the prevention of VTE in hospitalized patients.

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