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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Improving Outcomes and Reducing Delays in Orthopedic Surgery

Announcer:
You're listening to *Clinician's Roundtable* on ReachMD. This medical industry feature, "Improving Outcomes and Reducing Delays in Orthopedic Surgery," is sponsored by CSL Behring. And now, here's your host, Dr. Jennifer Caudle.

The views and opinions presented are based on the speakers' professional experience and should be regarded as their independent expert perspectives.

Dr. Caudle:
This is *Clinician's Roundtable* on ReachMD, and I'm your host Dr. Jennifer Caudle. Joining me today to discuss how we can optimize patient outcomes for patients requiring warfarin reversal in orthopedic settings is Dr. Jesse Pines. He is the Chief of Clinical Innovation at US Acute Care Solutions. Dr. Pines, welcome to the program.

Dr. Pines:
Thanks. It's great to be here.

Dr. Caudle:
To start us off, Dr. Pines, can you tell us why coagulation intervention is critically urgent, particularly in orthopedic procedures?

Dr. Pines:
Sure. Anticoagulants, like warfarin, are lifesaving medicines, but they can cause delays in emergency care and the timely performance of orthopedic procedures.[1,2]

The bone is highly vascularized. That creates a big risk of major bleeding with certain orthopedic fractures.[3,4] And in these situations, anticoagulants can increase the risk of blood loss and hematomas during fractures, which can lead to more complications like further surgery, cardiopulmonary morbidity, infection, increased hospital stays and cost, and even mortality.[5,6]

To give some context on how common this is, a little over half of high-risk ortho-trauma procedures require some sort of coagulation intervention.[7] So quick warfarin reversal is vital in these cases when there's a need for immediate hemostatic control.

Dr. Caudle:
So given that importance, what challenges do you see in coordination around surgical timing and compliance guidelines?

Dr. Pines:
Well, we've seen that earlier surgical intervention is correlated with improved outcomes.[8,9] But one of the biggest challenges in optimizing surgical care for anticoagulated patients is managing workflow barriers—for example, delays in INR testing, breakdowns in communication between departments, and lack of coordination among pharmacy, surgery, and anesthesia teams.[10]

On top of that, fresh frozen plasma, or FFP, is still the most commonly used agent for warfarin reversal even though KCENTRA has been shown to be significantly faster in reducing INR and requires about 85 percent less volume.[11]

Dr. Caudle:
Well, let's zero in on KCENTRA. How does KCENTRA compare to FFP in terms of speed, safety, and clinical efficiency?

Dr. Pines:
Well, there was a prospective, randomized, open-label, multicenter trial designed to compare KCENTRA with FFP in patients needing

urgent surgery or an invasive procedure. A total of 176 patients were enrolled and randomized evenly approximately half received KCENTRA, and approximately half received FFP.[10]

Orthopedic procedures made up the largest group in the study, with 52 out of 168 total surgeries falling into that category.[12]

So when we look at the data, the clinical advantages of KCENTRA stand out. With significantly faster INR correction, reaching 1.3 or less within just 30 minutes after end of infusion and sustaining that level for up to eight hours. The median time to surgery was nearly five hours faster with KCENTRA versus FFP.[10] And, as we were just discussing, that speed is critical in urgent orthopedic cases where every minute counts for optimal patient outcomes.[6]

Dr. Caudle:
And what about the safety of KCENTRA compared to FFP?

Dr. Pines:
KCENTRA also performed well from a safety standpoint. In a post marketing study with over 2,000 patients, there was no increase in thromboembolic events 45 days after treatment compared to FFP, and there was a lower all-cause mortality rate with KCENTRA.[13]

Plus, KCENTRA requires roughly 85 percent less infusion volume than FFP. This shortens infusion time by seven-fold and reduces the risk of fluid overload. That's especially important for patients with congestive heart failure or renal impairment.[10,14,15]

Dr. Caudle:
For those just tuning in, you're listening to *Clinician's Roundtable* on ReachMD. I'm Dr. Jennifer Caudle, and I'm speaking with Dr. Jesse Pines about KCENTRA and its role in improving surgical readiness and patient outcomes in orthopedic procedures.

So, Dr. Pines, with the efficacy and safety in data in mind, what are the real-world impacts of using KCENTRA in hospital settings?

Dr. Pines:
It has a really big impact. We certainly see improved infusion time and patient outcomes, like lower mortality rate, but we also see positive operational impacts.[10,13-15] Teams using KCENTRA can move patients to surgery much faster, which helps reduce the time to definitive treatment. That efficiency also improves resource utilization, so less time waiting on reversal means shorter stays in the ED or pre-op holding areas.[10]

On top of that, because KCENTRA requires a lower infusion volume than FFP, it eases the workload on pharmacy, nursing teams, and likely blood bank resources while helping minimize complications like fluid overload.[10,14,15]

So altogether, KCENTRA improves patient outcomes, streamlines the workflows, and supports hospitals in meeting their surgical timing and quality benchmarks.

Dr. Caudle:
Now, what strategies would you suggest for providers looking to integrate KCENTRA into their emergency workflows?

Dr. Pines:
Great question, in my experience, integrating KCENTRA effectively really comes down to teamwork and communication. Systems need emergency medicine, orthopedics, anesthesia, and pharmacy working together to design and standardize an anticoagulant reversal protocol. KCENTRA is already being ordered by a broad range of specialties, which shows that there's already cross-functional engagement. We still need to expand that footprint to ensure optimized processes across all departments.[11]

Ultimately, protocols should position KCENTRA as the preferred option for appropriate patients, so no matter which department initiates the process, everyone is aligned on the fastest, safest way to get these patients ready for surgery.[16,17]

Dr. Caudle:
Understandable, and before we wrap up, Dr. Pines, what takeaways would you like to share with our listeners?

Dr. Pines:
Yes, I just want to reiterate that, timely warfarin reversal is critical for patients with ortho-trauma procedures, and KCENTRA prioritizes time and efficiency. It delivers rapid INR reduction at 30 minutes after end of infusion, gets patients to surgery faster, and does so with less volume than FFP.[10]

And when it comes to integration, teamwork is key. We need emergency medicine, surgery, orthopedics, anesthesia, and pharmacy working together with clear communication and standardized protocols.

And lastly, by positioning KCENTRA as the preferred reversal option, hospitals can optimize outcomes, reduce delays, and consistently meet surgical timing goals.[10,13,16,17]

Dr. Caudle:
And with those final thoughts, I want to thank my guest, Dr. Jesse Pines for sharing his insights on how KCENTRA can help teams work faster and more efficiently to get patients into surgery.

Dr. Pines, it was great speaking with you today.

Dr. Pines:
Thank you for having me.

Dr. Caudle:
For ReachMD, I'm Dr. Jennifer Caudle.

And before we close, let's take a moment to review some important safety information.

Announcer:
WARNING: ARTERIAL AND VENOUS THROMBOEMBOLIC COMPLICATIONS

Patients being treated with Vitamin K antagonist therapy have underlying disease states that predispose them to thromboembolic events. Potential benefits of reversing VKA should be weighed against the risk of thromboembolic events, especially in patients with history of such events. Resumption of anticoagulation therapy should be carefully considered once the risk of thromboembolic events outweighs the risk of acute bleeding. Both fatal and nonfatal arterial and venous thromboembolic complications have been reported in clinical trials and postmarketing surveillance. Monitor patients receiving KCENTRA, and inform them of signs and symptoms of thromboembolic events. KCENTRA was not studied in subjects who had a thromboembolic event, myocardial infarction, disseminated intravascular coagulation, cerebral vascular accident, transient ischemic attack, unstable angina pectoris, or severe peripheral vascular disease within the prior 3 months. KCENTRA might not be suitable for patients with thromboembolic events in the prior 3 months.

KCENTRA is contraindicated in patients with known anaphylactic or severe systemic reactions to KCENTRA or any of its components (including heparin, Factors II, VII, IX, X, Proteins C and S, Antithrombin III and human albumin). KCENTRA is also contraindicated in patients with disseminated intravascular coagulation. Because KCENTRA contains heparin, it is contraindicated in patients with heparin-induced thrombocytopenia (HIT).

Hypersensitivity reactions to KCENTRA may occur. If patient experiences severe allergic or anaphylactic type reactions, discontinue administration and institute appropriate treatment.

In clinical trials, the most frequent (≥2.8%) adverse reactions observed in subjects receiving KCENTRA were headache, nausea/vomiting, hypotension, and anemia. The most serious adverse reactions were thromboembolic events, including stroke, pulmonary embolism and deep vein thrombosis.

KCENTRA is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

Indications
KCENTRA®, Prothrombin Complex Concentrate (Human), is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA—eg, warfarin) therapy in adult patients with acute major bleeding or the need for urgent surgery or other invasive procedure. KCENTRA is for intravenous use only.

Please see full prescribing information for KCENTRA.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Announcer Close:
This medical industry feature was sponsored by CSL Behring. If you missed any part of this discussion or to find others in this series, visit *Clinician's Roundtable* on ReachMD.com, where you can Be Part of the Knowledge.

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