

Direct oral anticoagulants: The challenges of coordinating periprocedural DOAC therapy

Vizient PSO Safety Alert

September 2017

Situation

Patients undergoing invasive procedures may require a temporary disruption of their anticoagulation therapy. Failure to hold or resume a direct oral anticoagulant (DOAC) correctly puts the patient at risk of bleeding during and after the procedure or a thrombotic event from disruption in therapy.ⁱ Reliable and safe management of DOACs in periprocedural patients is a high-risk process that is complex and problem-prone.

Background

The number of patients prescribed DOACs is increasingⁱⁱ, and there is a lack of reliable assessment and monitoring methods, widely available FDA approved reversal agents, and standardized DOAC reversal protocolsⁱⁱⁱ. This increases the risk of uncontrolled periprocedural bleeding for DOAC patients.

Assessment

Vizient® Patient Safety Organization (PSO) conducted a retrospective review of safety events involving DOACs (rivaroxaban, apixaban, dabigatran, and edoxaban) that occurred from January 2014 through May 2017. A search of the Vizient PSO database revealed 262 DOAC-related events. Of these, 58 (22%) events involved errors during periprocedural care.

Table 1 displays the types of periprocedural errors involving DOACs. A common error prior to the procedure involved failure to properly hold the DOAC, which resulted in procedural delays, cancellations and periprocedural bleeding. Transplant centers may require patients to be switched from a DOAC to warfarin at the time they are placed on the transplant list due to the long half-life of DOACs, lack of known antagonists and basic monitoring tests. In some cases, patients lost their place on the transplant list because they remained on DOACs and were not properly prepared for surgery.

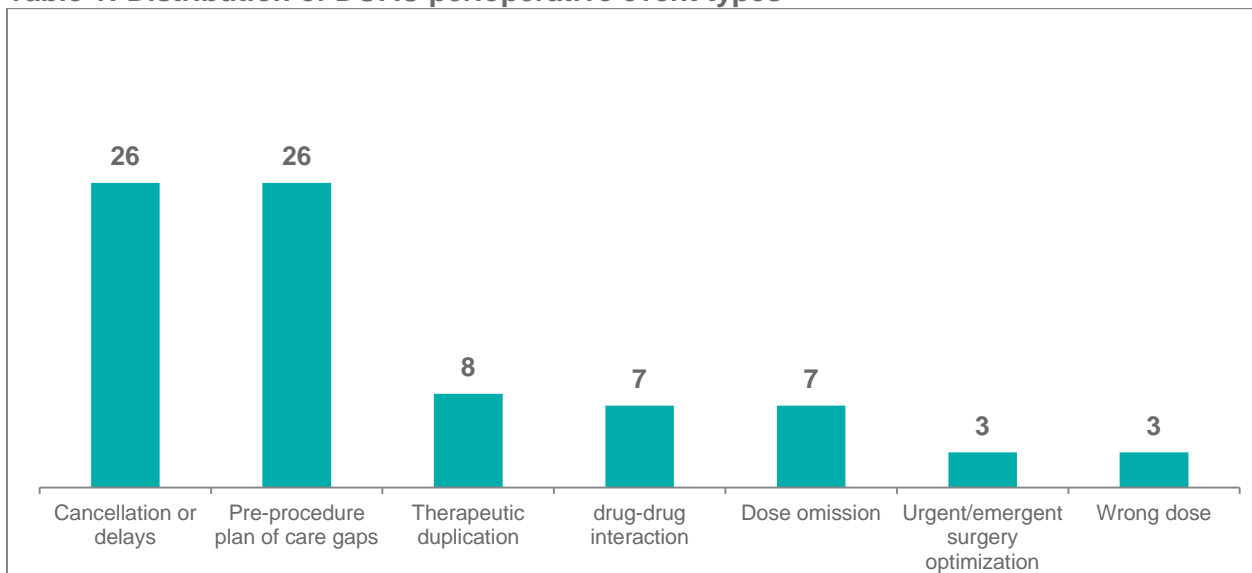
Post-procedural management of DOACs can be complicated. After the procedure, sometimes orders were written for the incorrect dose or were not written to restart the DOAC, increasing the risk of in a thrombotic event. On the other hand, sometimes duplication of orders for anticoagulant therapy exist or clinicians prescribed multiple interacting drugs, which exacerbated the risk or caused bleeding. Some post-procedural order sets automatically order pharmacologic venous thromboembolism prophylaxis. This standardized

work process does not individualize care for patients on a DOAC and placed them at risk for and resulted in therapeutic duplication.

Formulary restrictions, prescribing constraints in the electronic health record, and preauthorization requirements for the procurement of DOACs led to communication breakdowns and in turn errors in ordering, dispensing and administering anticoagulation therapy. Specifically, preauthorization forms caused DOACs to be placed on the medication list and administered earlier than intended post operatively, placing the patient at higher risk for or causing bleeding.

These events resulted in inconvenience or emotional distress to the patient, additional treatment, or led to temporary or even permanent harm.

Table 1: Distribution of DOAC perioperative event types



Abbreviations: DOAC, direct oral anticoagulants
January 2014-May 2017
58 of 262 DOAC-related events, events may fall into one or more category.

Contributing factors identified in the DOAC events included:

- A lack of consensus amongst the health care team related to procedural bleeding risk and complication risk from holding DOACs
- Unclear processes for assessing coagulation and renal status prior to procedures
- Pharmacy verification that was not completed before anticoagulant administration
- Medication authorization paperwork that was mistaken for an intent to order DOAC therapy
- Lack of widely available reversal agents, reversal protocols and ways to measure DOAC effect on patient
- Complex patient instructions and lack of patient medication instruction, teach back and planned follow up with the patient before admission and after discharge

Recommendations

Review the Vizient PSO Safety Message, [Discharge Care for patients on DOACs](#) from May 2017.

Develop standard processes, guidelines and protocols for managing DOAC therapy in the perioperative setting, specifically:

- Convene a multidisciplinary team to define standard work for pre-, intra- and post-op DOAC patients (see UW Medicine Pharmacy Services online reference guide^{iv} and Michigan Anticoagulation Quality Improvement Initiative Anticoagulation Toolkit 1.7^v).
- Outline institutional policies and procedures, standardized order sets, clinical pathways and clinical decision support tools for management of patients in urgent situations to avoid delays that could adversely affect patient outcomesⁱⁱⁱ.
- Ensure wide availability of antidotes for bleeding induced by direct oral anticoagulants. The CDC study shows anticoagulant hemorrhages are to be expected in emergency departments^{vii}.
- Define consistent pre-operative processes to review the medical history; medication list, including over-the-counter medications and any supplements and herbal preparations; and laboratory test results to identify factors that may increase bleed riskⁱ.
- Create a checklist for transplant patients that assesses if the patient takes a DOAC, review the transplant guidelines, consider switching based upon evidence-based recommendations, and measure the frequency of patients unexpectedly removed from the transplant list related to anticoagulation.
- Document the anticoagulant management plan and patient concurrence in the patient's medical record before undertaking the procedure.
- Develop a process for individualization of standard work based on patient risk factors (consider a team huddle with the patient).
- Develop explicit communication of preauthorization, prescribing and dispensing procedures within clinical teams to assure timely procurement, dispensing and administration of DOACs.
- When preauthorization for a DOAC is completed in electronic medical record prior to admission, review the process to ensure there is not the possibility of confusing procurement with dispensing and administration.
- Review Joint Commission standard MM.05.01.01 work with a multidisciplinary team to identify when and if oral anticoagulants should be administered before pharmacy review. Include in the policy the role of a licensed independent practitioner if bypassing pharmacy review^{vi}.
- Ensure patients can teach back DOAC instructions, and build this step into defined standard work in each phase of periprocedural care

For additional questions or information, please contact Jessica Schoenthal at jessica.schoenthal@vizientinc.com or Ellen Flynn at ellen.flynn@vizientinc.com.

Resources

- i. John U. Doherty. 2017 ACC Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients with Nonvalvular Atrial Fibrillation. Journal of the American College of Cardiology [Internet]. 2017 Jan 9[cited 2017 Aug 10]; 23217; Available from: <http://www.onlinejacc.org/content/early/2017/01/05/j.jacc.2016.11.024>. Accessed 8/24/17.
- ii. ISMP Quarterly Watch: Perspectives from new adverse event reports available at <http://www.ismp.org/QuarterWatch/pdfs/2016Q2.pdf>
- iii. William E. Dager, Pharm.D., BCPS, MCCM, FCSHP, FCCM, FCCP, FASHP. Managing and Reversing Direct Oral Anticoagulants A Discussion Guide. American Society of Health-System Pharmacists (ASHP). 2017. Available at: <http://www.doacresources.org/faculty> Accessed 8/24/17.
- iv. Jerrold H. Levy, MD, FAHA, FCCM. 2017. Anesthesia Patient Safety Foundation Perioperative Management of the New Anticoagulants: Novel Drugs and Concepts- http://www.apsf.org/newsletters/html/2017/June/01_Anticoagulants.htm. Accessed 8/24/17.
- v. Michigan Anticoagulation Quality Improvement Initiative Anticoagulation Toolkit (V 1.7): A consortium-Developed Quick Reference for Anticoagulation. http://anticoagulationtoolkit.org/sites/default/files/toolkit_pdfs/toolkitfull.pdf
- vi. UM Medicine Pharmacy Services (2014). <http://depts.washington.edu/anticoag/home/content/uw-medicine-alternative-monitoring-antithrombotic-agents#apixaban>
- vii. Joint Commission Hospital Accreditation Manual 2017 www.JointCommission.org.
- viii. Part II: Oral anticoagulants—the nation’s top risk of acute injury from drugs. Acute ISMP Patient Safety Alert, July 27, 2017 Volume 22 Issue 15 Available From: http://www.apsf.org/newsletters/html/2017/June/01_Anticoagulants.htm

Other resources

- ix. Amish N. Raval., Management of Patients on Non–Vitamin K Antagonist Oral Anticoagulants in the Acute Care and Periprocedural Setting: 2017. Circulation. A Scientific Statement from the American Heart Association available at <http://circ.ahajournals.org/content/early/2017/02/06/CIR.0000000000000477> Accessed 8/24/17

