

Reducing the Risk of Patient Harm from Anticoagulation Therapy

Mary Morin, MS, NEA-BC, RN-BC; Cheryl Weimer, BSN, RN; & Charity M. Anderson, BS-CLS, PMP



Problem

- In 2012, two deaths occurred within an integrated healthcare system, related to warfarin anticoagulation therapy. Anticoagulation management is often difficult, requiring significant effort and/or skill for both patients and clinicians.¹
- Warfarin, a very potent anticoagulant, is one of the most commonly prescribed anticoagulants to manage thrombosis (Figure 1) in the adult population. Lack of standardized treatment protocols may provoke adverse events, leading to hospital readmissions and death.

Background and Significance

- Anticoagulants are one of the top five drugs related to adverse events in the United States. Poor patient outcomes are often related to lack of care coordination and sub-therapeutic International Normalized Ratios (INRs), a laboratory test measure of blood coagulation, based on prothrombin time.
- Nearly 100,000 in-hospital deaths from medical errors occur annually, with 7,000 attributed to errors involving medications.²
- In 2007, the Joint Commission published the 2008 National Patient Safety Goals and included a goal related to anticoagulation therapy.
- In 2008, anticoagulation medications were categorized as “high-alert medications” by the Institute for Safe Medication Practices.
- The level of anticoagulation control is a critical determinant to warfarin benefit.¹ Time to therapeutic range (TTR) is currently the benchmark clinical measure for warfarin therapy management and is linked to important patient outcomes.

Objectives

This study aimed to reduce the likelihood of patient harm associated with the use of anticoagulant therapy. The following research questions were explored:

1. Are evidence-based protocols used for the initiation and management of anticoagulant therapy?
2. Are INRs and TTRs consistently documented in the clinical record and used to adjust therapy?
3. Does patient education include the importance of follow-up monitoring, compliance, and potential for drug-food interactions?

Evaluation Strategy

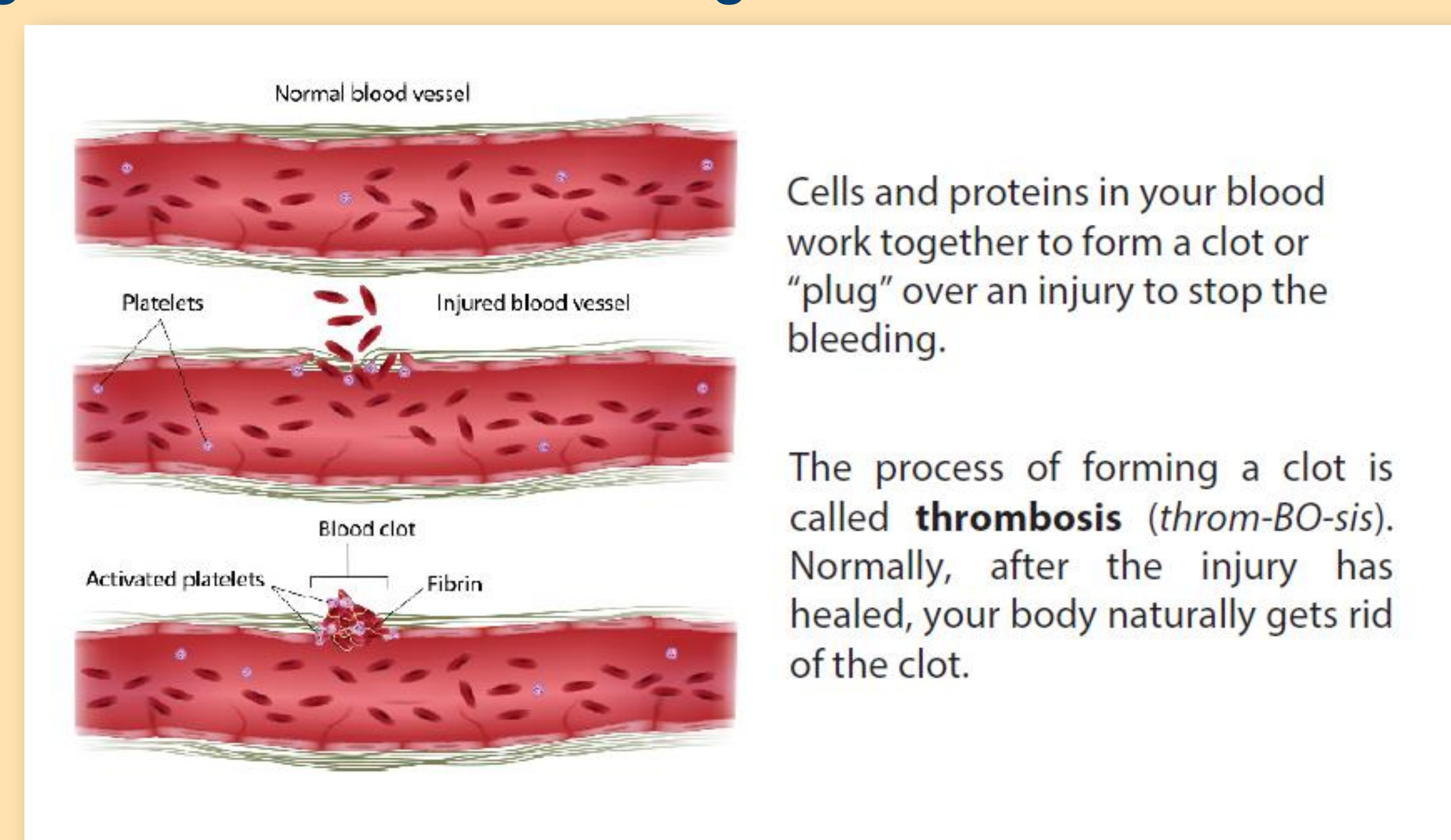
- A retrospective chart review with secondary data analysis was used to explore anticoagulation therapy management.
- Medical records and quality data were reviewed for patients receiving anticoagulation management within a primary care practice clinic.
- This strategy was appropriate given the lack of variable manipulation.

Findings

A root cause analysis revealed multiple process failures in the initiation and management of anticoagulation therapy.

- Warfarin management by clinicians did not follow evidence-based protocols and lacked consistency. Variation in dosing and monitoring were noted, with patients often lost to follow-up.
- Medication documentation occurred in two electronic platforms (Dose Response and EPIC) with poor documentation in EPIC, the record of choice for the healthcare system.
- INR and TTR information was not consistently recorded in EPIC. Anticoagulation therapy was not always adjusted to control inadequate or excessive anticoagulation.
- Education and training for registered nurses in the anticoagulation clinics was not standardized.
- Patient access to care was limited to 3 clinics with workflow variation noted within clinic processes and protocols.
- Patient education lacked standardization and did not include the importance of follow-up monitoring, compliance, and potential for drug-food interactions.
- Clinical outcome measurements were not established to monitor patient quality and safety.
- Reporting of safety events was inadequate.

Figure 1. Process of Forming a Clot



Recommendations

- Implement the Sentara Anticoagulation Services to include 11 anticoagulation clinics geographically located throughout the Hampton Roads region.
- Implement a Clinical Pharmacy Specialist – RN practice model to initiate and manage anticoagulation therapy and implement an INR reminder list to track patients possibly lost to follow-up. Patients appear on the list within 3 days of a missed appointment.
- Use evidence-based anticoagulation protocols to include: initiation and management of warfarin (chronic warfarin therapy; supra-therapeutic INRs; status post orthopedic procedure; pre-procedural and post-procedural patients; and management of Apixaban, Dabigatran and Rivaroxaban therapy).
- Educate patients using standardized booklet and medication leaflets.
- Standardized staff education based on anticoagulation certification. Document care coordination in the EPIC system only to improve communication and continuity of care. Improve adverse events reporting by using the Sentara Tracking, Action and Reporting System (STARS).
- Develop clinical outcome measures to include: time between therapy initiation and therapeutic range; time in therapeutic range (TTR); pharmacy intervention (Ivents); and adverse events tracking.

Conclusions and Implications

- The Sentara Anticoagulation Services may offer a great opportunity to improve patient outcomes by improving quality of care in oral anticoagulation management. Quality measurements, such as TTR, may prevent adverse events associated with inadequate or excessive anticoagulation.
- It is important to evaluate the rate at which adverse events occur to identify opportunities to prevent future fatality. Likewise, identifying factors that lead to non-adherence to treatment protocols may lead to strategies to overcome their harmful effects.

Contact Information

Mary Morin, MS, NEA-BC, RN-BC (mmmorin1@sentara.com)

Cheryl Weimer, BSN, RN (caweimer@sentara.com)

¹Rose, A. et al. (2013). Risk-adjusted Percent Time in Therapeutic Range as a Quality Indicator for Outpatient Oral Anticoagulation: Results of the Veterans Affairs Study to Improve Anticoagulation. *Circulation*, 4, 22-29.

²Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 1999