Rapid Recap

Anticoagulation FORUM | ANTICOAGULATION Centers of Excellence

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Extended Treatment of VTE with Reduced-Dose vs. Full-Dose DOAC in Patients at High Risk of Recurrence: A Non-Inferiority, Multicentre, Randomized, Open-Label, Blinded Endpoint Trial (RENOVE)

Background: Optimal dosing is unknown for patients with VTE at high risk for recurrence requiring extended treatment with DOACs. Prior randomized trials (EINSTEIN-CHOICE; AMPLIFY-EXT) compared efficacy & safety of reduced- vs. full- dose apixaban/rivaroxaban (with placebo or aspirin control groups) in patients with clinical equipoise/uncertainty for AC continuation. This study assessed efficacy & safety of reduced- vs. full- dose DOACs in patients that extended anticoagulation was indicated.

Methods: RENOVE was a randomized, blinded end point, investigator-initiated study across 47 hospitals in France. Patients who received 6-24 months of uninterrupted full-dose AC were randomly assigned (1:1) to receive oral treatment with either reduced dose apixaban (2.5mg BID) or rivaroxaban (10mg daily) vs. full-dose apixaban (5mg BID) or rivaroxaban (20mg daily). The primary outcome was symptomatic recurrent VTE.

Results: Recurrent VTE occurred in 2.2% reduced-dose (19 of 1383) vs. 1.8% full-dose (15 of 1385); absolute difference 0.40% [95% CI –1.05 to 1.85]; p=0·23 for non-inferiority. Major or clinically relevant bleeding occurred in 9.9% reduced-dose (96 of 1383) vs. 15.2% full-dose (154 of 1385) [HR 0.61 w/ 95% CI 0.48-0.79].

Rapid Takeaway: While non-inferiority criteria were not met, this study demonstrated low VTE recurrence rates in both groups and the reduction in major or clinically relevant bleeding with the reduced-dose, lending support for reduced dose as a possible long-term treatment option. Further research remains necessary to identify subgroups for which DOAC doses should not be reduced. *Lancet. 2025 Mar 1;405(10480):725-735*

Hemocompatibility-Related Adverse Events Associated With or Without LMWH Bridging in Outpatients with a HeartMate 3 LVAD

Background: Previous studies including patients with older generation left ventricular assist devices (LVAD) on warfarin (and often concomitant aspirin) bridged with LMWH for a low INR demonstrated variable bleeding and thrombotic risks. Additionally, older LVADs are associated with a higher risk for thrombotic events compared to the newer HeartMate 3 (HM3) LVAD. This study aimed to assess the thrombotic and bleeding risk of bridging warfarin with LMWH for a low INR in patients with a HM3 LVAD (most patients not on concomitant aspirin due to bleed risk concern).

Methods: Single-center, retrospective study of adult patients with HM3 device implanted 1/1/2015-1/1/2021 comparing a composite primary outcome of bleeding and thrombotic events (hemocompatibility-related adverse events (HRAEs)) while bridging subtherapeutic (≤ 1.7) INRs with therapeutic LMWH versus not bridging.

Results: Of 79 eligible patients, 64 were not bridged and 15 were bridged at least once during the study period. There was a total of 12 HRAEs of 997 bridging opportunities (BO) in the non-bridged group (1.2%; 10 bleeding events, 2 minor venous thromboembolisms (0.2%) vs. 0 in the 39 BOs in the bridged group. There were no episodes of confirmed pump thrombosis or stroke in either group.

Rapid Takeaway: Omission of LMWH bridging in this study of patients with a HM3 LVAD on warfarin (and low rates of aspirin use) with a subtherapeutic INR was not associated with a statistically significant increase in bleeding or thrombotic events compared to bridging. These results highlight the importance of considering the risks versus benefits of routine bridging with LMWH in patients with a HM3 LVAD. *Artif Organs. 2025 Mar 10*

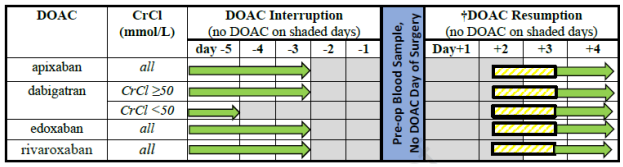
Perioperative Management of Direct Oral Anticoagulants in Patients having a High-Bleed-Risk Surgery or Neuraxial Procedure: The PAUSE-2 Pilot Randomized Trial

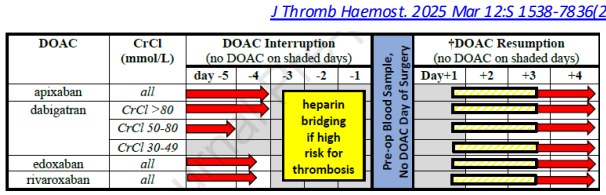
Background: The optimal approach for perioperative management of patients on DOACs that are undergoing elective high-bleed risk procedures, including neuraxial or deep peripheral nerve blocks, is unknown. While not well-established, some experts believe a safe pre-procedure DOAC level is <30-50ng/mL. PAUSE-2 evaluated the feasibility of two known potential management strategies, Perioperative Anticoagulant Use for Surgery Evaluation (PAUSE) vs. American Society of Regional Anesthesia (ASRA).

Method: Proof of concept, open-label, randomized controlled trial of 159 patients with atrial fibrillation and on a DOAC undergoing an elective high-bleed risk or neuraxial procedure. The primary outcome was pre-procedure plasma DOAC levels.

Results: The percentage of patients in PAUSE- and ASRA-based groups with pre-procedure DOAC levels < 30 ng/ml were similar at 94.4% and 95.6%, and DOAC levels 30-50 ng/ml were 2.8% and 1.4%, respectively.

Rapid Takeaway: This study evaluating PAUSE-based and ASRA-based perioperative DOAC management approaches was deemed to be feasible and showed similar pre-procedure DOAC levels. However, additional studies are needed. *J Thromb Haemost. 2025 Mar 12:S 1538-7836(25)00144-8*





DOAC vs. VKA for Cerebral Venous Thrombosis (DOAC-CVT): An International, Prospective, Observational Cohort Study

Background: The use of DOACs in the treatment of CVT is considered reasonable by several guidance documents, however high-quality, prospective data comparing the safety and efficacy of DOACs vs. VKAs in the treatment of CVT is limited.

Methods: Prospective, observational cohort study in 65 hospitals in 23 countries across 5 continents. Inclusion criteria was radiologically confirmed CVT starting oral anticoagulant treatment with either DOACs or VKAs (per local practice) within 30 days of diagnosis. The primary endpoint was a composite of symptomatic recurrent VTE and major bleeding events at 6 months. Main outcomes were adjusted for confounders.

Results: 619 patients were enrolled and followed for 6 months. Mean age was 41 years (IQR 28-51), 65% female, and 65% received DOAC treatment. Nearly all patients in both DOAC (90%) and VKA (97%) groups received lead-in parenteral anticoagulation (mean 6 days for DOAC vs. 9 days for VKA, p<0.0001). The rates of the primary outcome event were not statistically different between DOAC and VKA (OR 0.99, 95% CI 0.37-3.38).

Rapid Takeaway: The rate of recurrent thrombosis and major bleeding did not differ between patients with CVT treated with DOACs versus VKAs. Shared decision making and patient selection are key when considering anticoagulant selection in this population. For more information, see the ACF Rapid Resource on the Management of Unusual Site Thrombosis. *Lancet Neurol. 2025 Mar;24(3):199-207*

DOAC Versus No Anticoagulation for Stroke Prevention in Survivors of Intracerebral Haemorrhage with Atrial Fibrillation (PRESTIGE-AF): A Multicentre, Open-Label, Randomized, Phase 3 Trial

Background: DOACs reduce the risk of thromboembolism in patients with atrial fibrillation (AF) but their role in survivors of intracerebral hemorrhage (ICH) remains uncertain. In patients with AF and ICH, some lower-quality studies have suggested that anticoagulation (AC) may reduce risk of stroke without significantly increasing the risk of ICH. This randomized study aimed to assess if DOACs reduce the risk of ischemic stroke without markedly increasing the risk of recurrent ICH.

Methods: PRESTIGE-AF was a multicenter study. Patients with spontaneous ICH, AF, an indication for AC, and a modified Rankin score of ≤ 4 were randomly assigned (1:1) to a DOAC or no AC. Coprimary endpoints were first ischemic stroke and first recurrent ICH.

Results: First ischemic stroke occurred less frequently in the DOAC group (n=158) than in the no AC group (n=161; HR 0.05 w/ 95% CI 0.01-0.36). First recurrent ICH occurred more frequently in the DOAC group and did not meet the non-inferiority margin. Rate of all ICH was 5.00 per 100 patient-years for the DOAC group vs. 0.82 per 100 patient-years for the no AC group (number needed to harm of 24 per patient year).

Rapid Takeaway: DOACs prevent ischemic strokes in survivors of ICH with AF but this benefit is offset by an increased in the risk of recurrent ICH. Further high-quality evidence, alongside evaluation of safer medical and mechanical alternatives, are necessary to optimize treatment in survivors of ICH with AF. *Lancet. 2025 Mar 15;405(10482):927-936*

Check out these additional publications!

2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the ACC/AHA Joint Committee on Clinical Practice Guidelines

Regional anesthesia in patients receiving antithrombotic or thrombolytic therapy: ASRA and Pain Medicine Evidence-Based Guidelines (5th edition)

Comprehensive summaries of the most impactful articles from our biweekly literature updates. Includes a short overview and pub med link along with important takeaways from the article. Rapid Recaps are published monthly.

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