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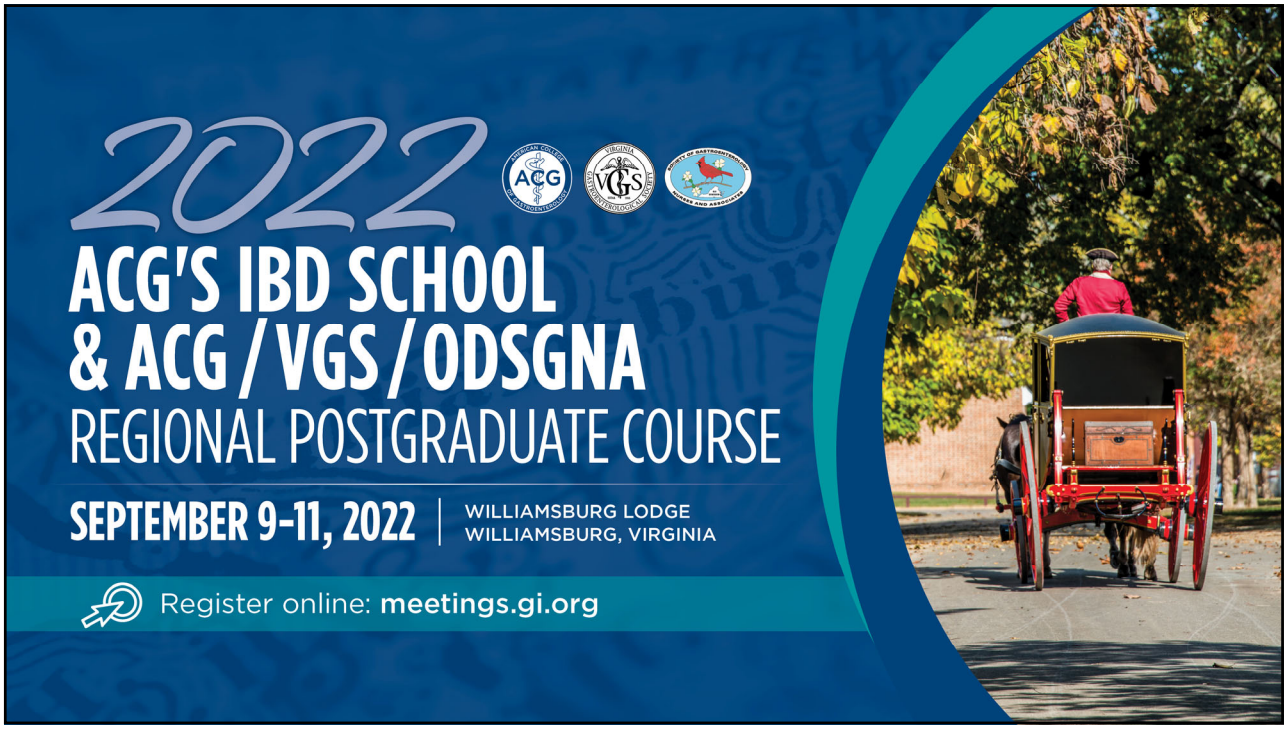
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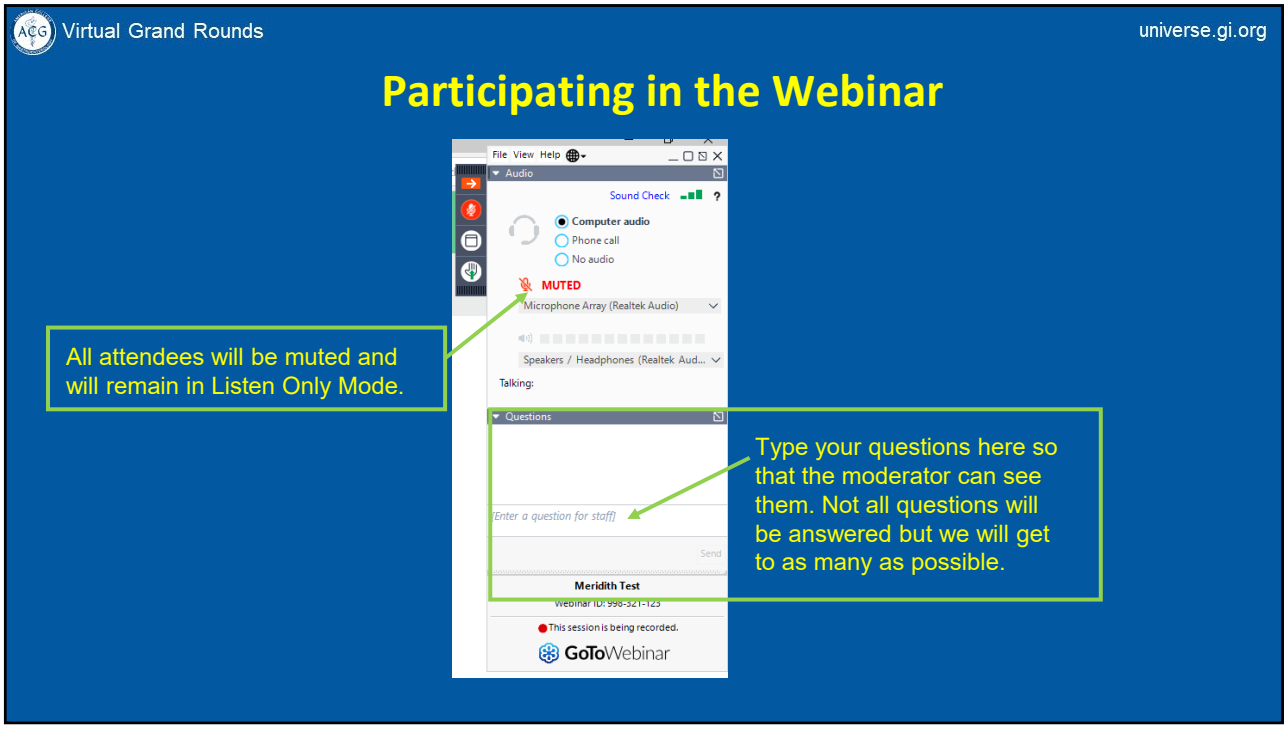
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LIVE VIRTUAL GRAND ROUNDS WEBINAR

ACG will send a link to a CME & MOC evaluation to all attendees on the live webinar.

ABIM Board Certified physicians need to complete their MOC activities by December 31, 2022 in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after March 1, 2023 for this activity.

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MOC QUESTION

If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

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ACG Virtual Grand Rounds

Join us for upcoming Virtual Grand Rounds!


Week 35 – Thursday, September 1, 2022
ID for the GI – GI Presentations of Unusual Infections
Faculty: Mark S. Riddle, MD, DrPH
Moderator: Freddy Caldera, DO, MS, FACG
Thursday, September 1st at Noon Eastern and **NEW! 8pm Eastern!**


Week 36 – Thursday, September 8, 2022
Perianal Crohn's Disease – Evolutions in Management
Faculty: Miguel D. Regueiro, MD, FACG
Moderator: Jill K. J. Gaidos, MD, FACG
Thursday, September 8th at Noon Eastern and **NEW! 8pm Eastern!**

Visit **gi.org/ACGVGR** to Register

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Disclosures

Neena S. Abraham, MD, MSc (EPID) MACG
Disclosure Company: Role OR

No relevant financial relationships with ACCME ineligible companies.

Bryan G. Sauer, MD, MSc (Clin Res), FACG

Revolo Biotherapeutics: Data Safety Monitoring Board
Takeda: Consultant

**All of the relevant financial relationships listed for these individuals have been mitigated*

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Update on the Management of Anticoagulants and Antiplatelets Guideline

Neena S. Abraham MD, MSc (EPID), MACG
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Mayo Clinic Kern Center for the Science of Health Care Delivery Research
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American College of Gastroenterology-Canadian Association of Gastroenterology Clinical Practice Guideline: Management of Anticoagulants and Antiplatelets During Acute Gastrointestinal Bleeding and the Periendoscopic Period.

Abraham NS, Barkun AN, Sauer BG, Douketis J, Laine L, Noseworthy PA, Telford JJ, Leontiadis GI.

Am J Gastroenterol. 2022 Apr 1;117(4):542-558. doi: 10.14309/ajg.0000000000001627.

Management of Patients on Anticoagulants and Antiplatelets During Acute Gastrointestinal Bleeding and the Peri-Endoscopic Period: A Clinical Practice Guideline Dissemination Tool

Alan N Barkun [1], James Douketis [2], Peter A Noseworthy [3], Loren Laine [4], Jennifer J Telford [5], Neena S Abraham [6]

Affiliations + expand

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19 Recommendations

- ✓ **Acute & Elective Endoscopy**
- ✓ **Rigorous GRADE methodology**
- ✓ **>500 pages of EtD* tables/data**
- ✓ **EBM principles addressing:**

1) **Temporary interruption of anticoagulant and antiplatelet drugs**
2) **Reversal of anticoagulant and antiplatelet drugs**
3) **Periprocedural heparin bridging**
4) **Post procedural drug resumption**

**EtD = Evidence to Decision*

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NTK* Paradigm Changes

- **Acute GIB Highlights**
  - Vitamin K antagonist (VKA) reversal
  - DOAC reversal
  - Use of platelet transfusion
- **Elective Procedural Highlights**
  - VKA Interruption vs. continuation
  - Bridge Anticoagulation
  - DOAC temporary interruption & resumption
  - DAPT Management
  - ASA Monotherapy Management (Secondary Prevention)

**Need To Know*

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Rigorous GRADE* approach

- GRADE-Light
- GRADE-Like
- GRADE-*ish*

*Grading of Recommendations, Assessment, Development, and Evaluations

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Understanding GRADE Methodology

- **Clinical questions framed *a priori* using PICO**
  - population/intervention/comparator/outcome
- **Systematic literature search (not search of convenience)**
- **GRADE assessments quantify the "risk of bias" of studies**
- **Certainty of evidence-- very low, low, moderate, or high:**
  - Limitations in design & execution of studies
  - Indirectness
  - Inconsistency
  - Imprecision
  - Publication bias

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Alonso-Coello et al, *BMJ* 2016; Guyatt et al, *J Clin Epidemiol* 2011

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GRADE: What you need to know

Evidence summaries discussed considering:

- **Magnitude & direction of effect**
- **Certainty of evidence on the balance b/w desirable and undesirable outcomes**
- **Patient values and preferences**
- **Feasibility of intervention/outcome**
- **Acceptability of intervention/outcome**
- **Resource utilization**

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Alonso-Coello et al, *BMJ* 2016; Guyatt et al, *J Clin Epidemiol* 2011

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ACG-CAG CPG Recommendations: Interpretation

Types of Recommendations:

- **Strong:** "We *recommend* that…" (strong evidence)
  - ✓ Most patients would choose this action
  - ✓ Clinicians should provide it
- **Conditional:** "We *suggest* that…" (weak or low certainty evidence)
  - ✓ Patients may or may not want this action
  - ✓ Multidisciplinary discussion
  - ✓ Help patients make decisions consistent with their values

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Abraham & Barkun et al, *Am J Gastroent* 2022

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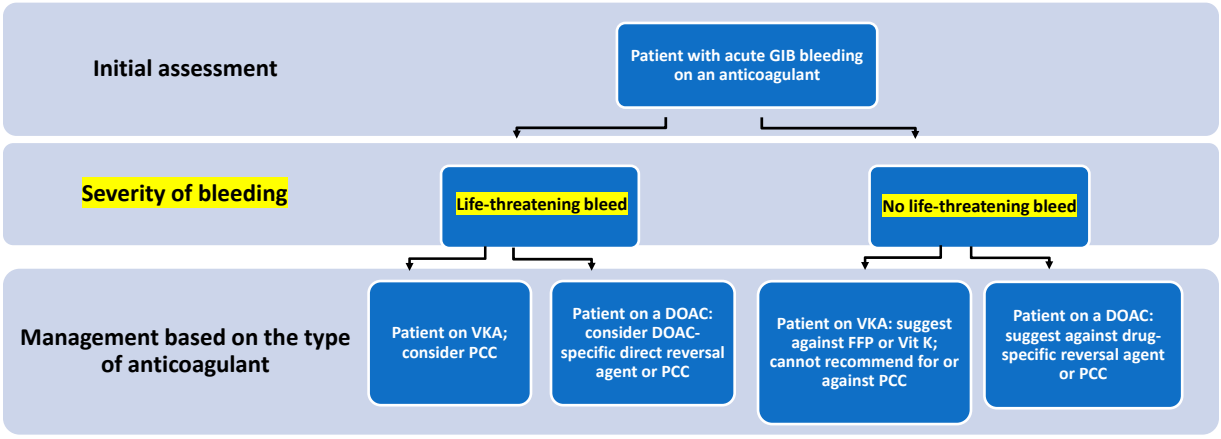
2022 Management Acute Anticoagulant GIB



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Abraham & Barkun et al, *Am J Gastroent* 2022

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Triage: Life-Threatening Hemorrhage

<u>Major clinically overt or apparent bleeding with</u>:

- **Hypovolemic shock or severe hypotension requiring pressors or surgery**
  - ***or* associated with a decrease in Hg of >5 g/dL**
  - ***or* requiring transfusion of ≥ 5 units of packed red blood cells**
  - ***or* causing death**

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Abraham & Barkun et al, *Am J Gastroent* 2022

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Warfarin: Acute Reversal

- **ASGE (2016)**
  - 4-factor prothrombin complex concentrate (PCC) with factors II, VII, IX and X
  - Vitamin K (5-10 mg by slow IV)
  - No FFP
    - Large volumes & transfusion-associated pulmonary edema
- **ACG-CAG CPG (2022)**
  - No FFP
  - No Vitamin K
  - PCC preferred over FFP with supratherapeutic INR/life-threatening GIB
    - Rapid & reliable correction of INR
    - *Conditional recommendation, very low certainty of evidence*

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Abraham & Barkun et al, *Am J Gastroent* 2022; Acosta & Abraham et al, *Gastroint Endosc* 2016

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Wait, What?... NO Vitamin K?

Vit K 1-2 mg used when INR ≥ 10 restores therapeutic-level anticoagulation (INR 2.0-3.0)* → Clinically significant GI bleeding requiring therapeutic intervention:
- Does not achieve rapid hemostasis
- Limited value in the acute setting

When: Use Vitamin K in the setting of supratherapeutic INR → IF:
- Plan = reverse anticoagulant effect slowly (2-weeks)
- Objective is to stop VKA altogether
- Do not use in this setting without consulting the patient's hematologist or cardiologist

ACG-CAG CPG:
We suggest against the use of vitamin K
(*conditional recommendation, very low certainty of evidence*)

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Abraham & Barkun et al, *Am J Gastroent* 2022

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Warfarin Resumption

What did ACG-CAG CPG guideline panel think?

- Limited high-certainty evidence (acute & elective setting)
- We could not reach a recommendation for or against resuming warfarin the same day as the procedure vs. 1-7 days after the procedure

What do I do?

- **The heart always wins!**
- **Balance risk of thromboembolism & further bleeding**
- **Resume w/in 4-7 days from drug discontinuation; same day if diagnostic**
  - **1% embolic risk**

Abraham & Barkun et al, *Am J Gastroent* 2022

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No *routine* use of DOAC reversal agents

- **Avoid andexanet alfa**
  - Single published study with serious risk of bias & no control group; little GIB data
  - Higher risk of thromboembolism & cost of drug ($49,500)
  - Could be considered w/ life-threatening GIB in hospitalized patients if rivaroxaban or apixaban taken w/in last 24 hours
- **Rarely need idarucizumab**
  - Few patients taking dabigatran; could be considered w/ life-threatening GIB in hospitalized patients
- **Possibly a role for PCC?**
  - Two cohort studies* with comparator arms (no PCC); both with limitations
  - Systematic reviews of mainly low-quality, single arm cohort studies ^
  - ***"Better bad choice" in the setting of life-threatening hemorrhage?***

***Schulman *Thromb Res* 2017; *Smythe *J Thromb Thrombolysis* 2015; ^da Luz *Transfusion* 2017**

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DOAC Resumption after GIB

- **Not addressed in ACG-CAG CPG**
  - No high-certainty data in the GIB setting

What do I recommend?

- **Resume DOAC day after the procedure in MOST**
  - Providing endoscopic hemostasis had been achieved ^
  - **Would not hold DOAC post-procedure > 48-72 hours**
    - Timing of resumption dictated by the risk of post-procedural bleeding & multidisciplinary discussion

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^ Barkun et al. 2022 (*DDW 2022*); Abraham, Barkun et al. *Am J Gastro* 2022

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Management Acute Antiplatelet GIB

Routine Platelet Transfusion

- Mortality increase with GIB (OR = 5.6, 95% CI: 1.5-27.1)
- Mortality increase with CABG (OR= 4.8, 95% CI: 1.7-13.7)
- Mortality increase with ICH (OR = 2.1, 95% CI: 1.2-3.6)

Interrupt Cardiac ASA Used for Secondary Prevention

- Reduced mortality with ASA continuation
- ASA discontinued at presentation? Resume w/in 24 hrs. of successful endoscopic hemostasis
- *ASA for primary prevention- little CV benefit & high GIB risk*

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Abraham & Barkun et al, *Am J Gastroent* 2022

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Elective Endo? Do No Harm

Defer elective exams until the patient is no longer high-risk

Ex: CRC screening/surveillance, Family History CRC, FIT + (can wait *up to* 9 months); DGBI; GERD/Barrett's Esophagus or cirrhosis screening/surveillance, etc.

Patients <3 months out from:	Patients with PTCA/PCI
Transient Ischemic Attack	Drug-eluting stent (<6 months)
Stroke	Bare-metal stent (<4 weeks)
Lower extremity deep vein thrombosis	ACS *plus* drug-eluting stent (<6 months)
Pulmonary embolus	ACS *plus* bare-metal stent (<2 months)
Acute Coronary Syndrome (ACS)	

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Low Risk Procedures: Continue Warfarin

- **5 cohort studies**
  - **Favorable profile for continuation (*very low certainty evidence)***
  - **Limited Data: Imprecision, lack of standardized procedure technique & adjustment for confounders**
- **GI Bleeding**
  - Estimating risk limited by few studies (w/ controls), small sample size & rare events
  - Pooled data (5 studies) – *0/239 bleeding events (95% CI; 0%-12.35%) with continuous warfarin*
- **Thromboembolic Events**
  - Single small cohort study - *nonsignificant reduction of thromboembolic events with uninterrupted (0/43) vs. interrupted (1/19).**

***Yanagisawa N et al, *World J Gastroenterol* 2018; ^Ara N et al, *Dig Endosc* 2015; ^^Gerson LB et al, *Gastrointest Endosc* 2010; Horiuchi A et al, *Gastrointes Endosc* 2014; Arimoto J et al, *Dig Dis Sci* 2019**

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Procedural Risk of Bleeding

High bleeding risk procedures (30-d risk of major bleed >2 %)	Low/moderate bleeding risk procedures (30-d risk of major bleed ≤ 2%)
Polypectomy (≥ 1cm)	EGD with/without biopsy
PEG/PEJ placement	Colonoscopy with/without biopsy
ERCP with biliary or pancreatic sphincterotomy	Flexible sigmoidoscopy with/without biopsy
EMR/ESD	ERCP with stent (biliary or pancreatic) placement or papillary balloon dilation without sphincterotomy, tissue sampling, or treatment of choledocholithiasis
EUS-FNA	EUS without FNA
Endoscopic hemostasis (excluding APC)	Push enteroscopy and diagnostic balloon-assisted enteroscopy
Radiofrequency ablation	Enteral stent deployment
POEM	Argon plasma coagulation
Treatment of varices (including variceal band ligation)	Balloon dilation of luminal stenoses
Therapeutic balloon-assisted enteroscopy	Polypectomy (<1 cm)
Tumor ablation	ERCP without biliary or pancreatic sphincterotomy
Cystgastrostomy	Marking (including clipping, electrocoagulation, tattooing)
Ampullary resection	Video capsule endoscopy
Pneumatic or bougie dilation for achalasia or esophageal strictures	
Laser ablation and coagulation	

Abraham, Barkun et al. *Am J Gastro* 2022

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Advanced Procedures: Interrupt Warfarin

Absence of studies in advanced endoscopic procedures limits our ability to comment on safety of proceeding without interrupting warfarin.

<u>For Advanced Endoscopic Procedures</u>:
May be appropriate to temporarily interrupt warfarin for 5 days WITHOUT bridging heparin.

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Abraham & Barkun et al, *Am J Gastroent* 2022

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Bridging vs. No Bridging

LMWH bridging during VKA interruption increases the risk of post-procedural bleeding without reducing thromboembolism.

- **BRIDGE RCT (n=1813) & PERIOP-2 RCT (n=1471)**
- **5 Observational Studies**

CONSIDER IN*:

- **Patients with mechanical valves**
- **AF with CHADS2 score >5**
- **History of thromboembolism during temporary interruption of VKAs**
- **Certain CV surgery (i.e., cardiac valve replacement, carotid endarterectomy, major vascular surgery).**

ACG-CAG CPG:
We suggest against bridging anticoagulation for patients* holding warfarin undergoing elective/planned endoscopic GI procedures
(*conditional recommendation, very low certainty of evidence*)

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Abraham & Barkun et al, *Am J Gastroent* 2022

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Elective Endo: Timing of Warfarin Resumption

- **We could not reach a recommendation for or against resuming warfarin on the same day vs 1-7 days after the procedure.**
  - ➢ No studies comparing same-day resumption of warfarin with a resumption in 1-7 days after an elective endoscopic procedure.
- Published literature limited by:
  - ❑ Lack of a comparator group
  - ❑ Lack of diversity of populations & endoscopic procedures
  - ❑ Use of bridging therapy
  - ❑ Outcomes assessment occurring at variable follow-up times

- **Balance risk of thromboembolism & further bleeding**
- **Resume w/in 4-7 days from drug discontinuation; same day if diagnostic**
  - ➢ **1% embolic risk**

Abraham & Barkun et al, *Am J Gastroent* 2022

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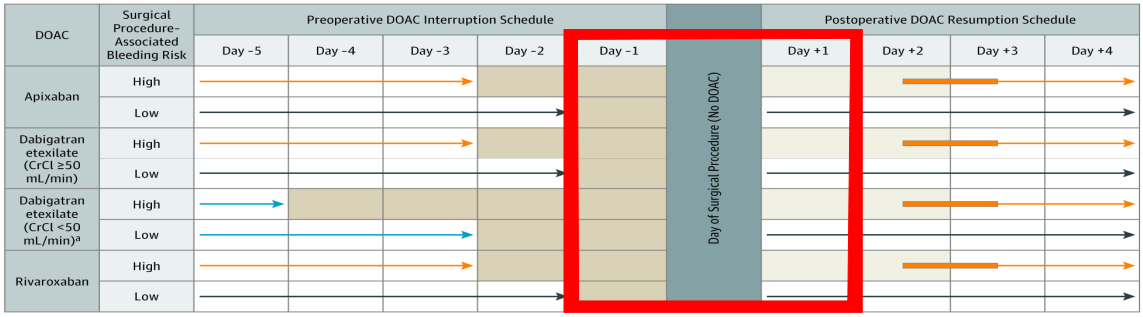
Perioperative Anticoagulation Use for Surgery Evaluation (PAUSE) Cohort Study (N=3007)

*23 clinical centers in Canada, the United States, and Europe; n = 3007 atrial fibrillation patients



- **No DOAC on shaded days & the day of the elective surgery or procedure.**
- ****ALL endoscopic procedures are considered low-risk (like the BRIDGE Trial^).**

Douketis JD et al, *JAMA Internal Medicine* 2019; ^ Douketis JD et al, *NEJM* 2015

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PAUSE Post-Hoc Analysis of GI Data (n= 556 endoscopic procedures*)

DOACs: Mean total temporary interruption of 3.9 days ± 1.6 day

- Pre-procedure- 2.0 ± 0.5 days (including the day of procedure)
- Post-procedure- 1.9 ± 1.5 days (including post-endo time elapsed on the day of the procedure

30-Day Outcomes:

- **GI bleeding – 2.5% (95% CI: 1.4% to 4.2%); N=14**
  - 50% (n=7) major bleeding episodes (hospitalization/endo/blood)
- **Thromboembolism – 0.7% (95% CI: 0.2% to 1.6%)**
- **Mortality - 0.5% (95% CI: 0.2% to 1.6%)**

**Mostly EGD & colonoscopy with/without biopsy & polypectomy; very few advanced procedures*

^ Barkun et al. 2022 (*DDW 2022*); Douketis JD et al, *JAMA Internal Medicine* 2019

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How to Operationalize Recommendations

1. **Hold DOAC for 2-3 days (including the day of the procedure)**
   - 1 day before + day of procedure**= 2 days in MOST**
   - 2 days before + day of procedure = **3 days for advanced procedures**

2. **Resume DOAC day after the procedure in MOST**
   - No studies comparing same-day resumption of DOAC with the resumption in 1-7 days after a temporary interruption in the elective endoscopic setting.
   - DOAC resumption post-procedure was 1.9 days ± 1.5 days providing endoscopic hemostasis achieved^
   - **Would not hold DOAC post-procedure for more than 48-72 hours** considering:
     - Short half-life of the drug
     - Risk of bleeding vs. risk of thrombosis with extended interruption

^ Barkun et al. (*Am J Gastroenterol; in review*); Abraham & Barkun et al., *Am J Gastroenterol;* Douketis JD et al, *JAMA Internal Medicine* 2019

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No Change: DAPT Management

DAPT for secondary cardiovascular prevention - we suggest temporary interruption of the P2Y12 inhibitor while continuing ASA (*conditional recommendation, very low certainty of evidence*)

- Clopidogrel & Ticagrelor - 5 days*; Prasugrel – 7 days *

- **Similar rates of delayed post-polypectomy bleeding**
  - **2 RCTs (Chan et al. & Won et al.)**
  - **Systematic Review Observational Studies (Eisenberg et al.)**
  - ***Trend toward fewer cardio-thromboembolic events with thienopyridine interruption in patients who took concomitant ASA***

Abraham & Barkun et al, *Am J Gastroent* 2022; Chan FKL et al, *Gastroenterology* 2019; Won et al. *Clin Transl Gastroenterol* 2019; Eisenberg MJ et al, *Circulation* 2009

**FDA Recommendations*

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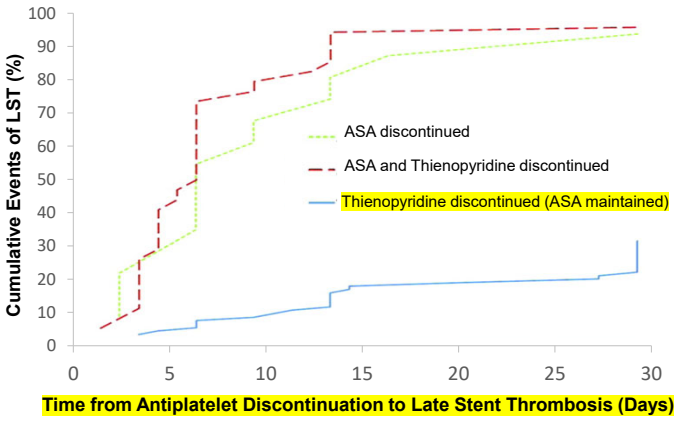
DAPT Interuption vs. Continuation



- **Systematic review of observational studies examining periprocedural AP regimens in patients with DES on DAPT**
- **6% late stent thrombosis (6/94) with thienopyridine interruption, but continued ASA occurred within 10 days, while only 2/94 (2%) occurred within 5 days.**
- **High rates of late stent thrombosis (79%) with discontinuation of *both* agents or discontinuation of ASA (67%).**

Eisenberg MJ et al, *Circulation* 2009

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Elective Endo: Thienopyridine (P2Y12) Resumption

- **We could not reach a recommendation for or against resuming the P2Y12 inhibitor on the same day vs 1-7 days after the procedure.**
  - Theoretically, earlier resumption would reduce thrombotic events and increase post-procedural bleeding– but no studies providing relevant evidence were identified.
- **Prudent to resume thienopyridine with immediate endoscopic hemostasis ^ after considering:**
  - Risk of delayed postprocedural bleeding, thrombosis, and patient preferences
  - Decisions regarding procedural timing and drug resumption in high-risk thromboembolic patients are ideally ascertained on a case-by-case basis in a multidisciplinary fashion.

Abraham & Barkun et al, *Am J Gastroent* 2022; ^Barkun et al., *Am J Gastroent* 2022

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ASA Monotherapy*

- For patients on ASA 81-325 mg/d (monotherapy) for *secondary CV prevention, **we suggest against interruption of ASA** (*conditional recommendation, very low certainty of evidence*).
  - Bleeding risk is very low in diagnostic endoscopic procedures, biopsies, and most polypectomies.
- **Interruption of ASA could be considered in the removal of larger and more complex polyps, and procedures with the highest bleeding risk.**
  - With consideration of:
    - Patient CV risk
    - Patient preference regarding cardiovascular vs bleeding events
    - Patients on ASA as primary prevention *should have ASA stopped before higher-risk endoscopic procedures.*

Abraham & Barkun et al, *Am J Gastroent* 2022

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Take Home Points: Acute GIB

Triage based on life-threatening GIB vs. not

- Life Threatening = Hospitalized, Pressors, Rule of 5

VKA Supratherapeutic Bleed

- No FFP
- No Vit K
- Choose PCC over FFP

DOAC GIB

- No routine use of reversal agents
- Life-threatening GIB? Consider reversal agent if DOAC is taken w/in 24 hours (DOAC-specific or PCC)

Antiplatelet GIB

- No routine platelet transfusion (consider if platelets <100,000 per microliter)
- Continue ASA prescribed for secondary prevention

Abraham & Barkun et al, *Am J Gastroent* 2022

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Take Home Points: Elective Endo (1)

Do no harm!

- ❑ Know the high-risk CV patient
- ❑ Defer elective procedures until a patient is no longer high-risk
- ❑ Multidisciplinary discussions/shared decision-making useful

VKA management

- ❑Low post-procedural bleeding risk? Continue VKA
- ❑High post-procedural bleeding risk? Hold X 5 days & resume with immediate hemostasis

Bridge anticoagulation with LMWH

- ❑ Unnecessary for most patients when VKA interrupted
- ❑ Consider with mechanical valves and in select patients at high thromboembolic risk
- ❑ Unnecessary for patients on DOACs

Abraham & Barkun et al, *Am J Gastroent* 2022

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Take Home Points: Elective Endo (2)

DOAC management

- ❑ Temporary Interruption 2 days (incl. procedure day) in most
- ❑ Advanced procedure 3 days of interruption (incl. procedure day)
- ❑ Resume the day after the procedure
- ❑ Multidisciplinary discussions/shared decision-making

DAPT management

- ❑ Hold thienopyridine pre-procedure & continue cardiac ASA
  - ➢ Clopidogrel & Ticagrelor - 5 days; Prasugrel – 7 days
- ❑Resume DAPT with immediate hemostasis

ASA monotherapy (secondary prevention)

- ❑ Continue in the peri-procedural setting

Abraham & Barkun et al, *Am J Gastroent* 2022

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Questions and Answers

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Bryan G. Sauer, MD, MSc (Clin Res), FACG

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