

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

Protocol Responsibilities and Authorisation

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Protocol Review History

Version	Updated by	Date Updated	Summary of Changes
1	K.Twydle	Aug 2017	Replaced diagrams in appendices (pgs. 7-8)
2	K.Twydle & L.Phillips	19/08/2020	Reviewed and up dated document, adding new anti-coagulants, bridging clexane instructions, correction flow charts, added section on Reversal Anticoagulation in GI bleeding, removal of bridging in DOACs, input from Haematology, addition of Appendix B high risk bleeding, Cold snare guidance clarified, and up-dated Ticagrelor advice to align with cardiology
3	L Phillips	7/12/2020	Added reference to NBSP colonoscopy section 1.1 and 2.4, 2.6 tables
3.1	Dr. J. Wong & A. Carvajal	10/03/2021	Added paragraph about bronchoscopy and EBUS bleeding risk to "1.1 Procedure-associated bleeding risks"; Added "bronchoscopy and endobronchial ultrasound (EBUS)" under section "1.5 Patient / Client group"; Added "BAL – Bronchoalveolar lavage" and "EBUS –Endobronchial ultrasound" under "1.6 Definitions"; Added "Bronchoscopy" & "EBUS" under "High Risk Procedures" in 2.4 Figure 2 and 2.6 Figure 4; Added new reference to "4 Evidence Base"; Changed ">" to "≥" on the following areas: 2 nd bullet point of 2.2, 2.6 Figure 4, & 2.9.1. Warfarin, under "NO" pathway; Omitted first "days" word after "4" found in 2.6. Figure 4 DOAC pathway

Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 1 of 20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

Contents

1	Overview	3
1.1	Procedure-associated bleeding risks.....	3
1.2	Special Considerations	4
1.2.1	Patients at high risk of thrombosis.....	4
1.2.2	Patients at high risk of bleeding.....	4
1.3	Purpose.....	5
1.4	Scope.....	5
1.5	Patient / client group	5
1.6	Definitions and acronyms	6
2	Clinical management	7
2.1	Pre Procedure.....	7
2.2	Day of Endoscopy – elective procedures	7
2.3	Figure 1 Guideline for low risk procedures for patients on clopidogrel, prasugrel, ticagrelor, or aspirin.	8
2.4	Figure 2 Guidelines for patients having a high risk procedure on clopidogrel, prasugrel, ticagrelor, or aspirin	9
2.5	Figure 3 Guidelines for the management of patients having a low risk procedure on warfarin or DOAC (Dabigatran, Rivaroxaban, Apixaban).....	10
2.6	Figure 4 Guidelines for management for patients with high risk procedures on warfarin & DOAC.....	11
2.7	Strategy for “Therapeutic Bridging” therapy if required	12
2.8	Urgent and Emergency Endoscopy, and patients with critical or clinically significant GI bleeding.....	Error
	! Bookmark not defined.	
2.9	Reversal of Anticoagulation in GI Bleeds	13
2.9.1	Warfarin:	13
2.9.2	Dabigatran:	14
2.9.3	Rivaroxaban and Apixiban:.....	16
2.9.4	IV heparin and clexane	17
2.9.5	Anti-platelet agents (clopidogrel, ticagrelor, prasugrel)	17
3	Audit.....	17
3.1	Indicators	17
3.2	Tools	17
4	Evidence Base	18
4.1	Bibliography	18
	Appendix A – ACC Risk Stratification.....	19
	Appendix B – Invasive Procedures in Patients with Cirrhosis and Coagulopathy.....	20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

1 Overview

Before performing an endoscopic procedure on patients taking antithrombotic medications, the following issues must be considered (1) Urgency of endoscopy, (2) Risks of bleeding related to endoscopic intervention (3) Risk of a thrombosis from stopping antithrombotic medication. Alternative diagnostic studies (e.g. radiologic studies or video capsule endoscopy) should be considered, particularly if the patient has a high risk of thrombosis.

When the duration of antithrombotic therapy is limited e.g. acute DVT, elective procedures should be delayed, if possible, until antithrombotic therapy is no longer indicated, or at least until the high risk time for thrombosis has passed (Preferably 3 months post VTE and 6 months post coronary artery stent placement).

The information should be read in conjunction with Waikato DHB General Medicine [Anticoagulation - Warfarin](#) (Ref. 1460) and [Anticoagulation – Reversal](#) (Ref. 2705) guidelines.

1.1 Procedure-associated bleeding risks

Endoscopic procedures vary in their potential to produce significant or uncontrolled bleeding.

Low-risk procedures include diagnostic OGD, flexible sigmoidoscopy and colonoscopy with or without biopsy, cold snare polypectomy < 1cm, diagnostic endoscopic retrograde cholangiopancreatography (ERCP), biliary stent insertion without endoscopic sphincterotomy, endosonography (EUS), and push enteroscopy.

High-risk procedures include those associated with an increased risk of bleeding such as colonoscopic polypectomy > 1cm (1%-2.5%), gastric polypectomy (4%), laser ablation and coagulation (less than 6%), endoscopic sphincterotomy (2.5%-5%), and those procedures with the potential to produce bleeding that is inaccessible or uncontrollable by endoscopic means such as pneumatic or bougie dilation of benign or malignant strictures, percutaneous endoscopic gastrostomy, and EUS-guided fine needle aspiration. National Bowel Screening Programme (NBSP) colonoscopies are treated as high risk procedures as 70% patients have polyps that need removal.

Literature suggests that cold snare polypectomy leads to less post polypectomy bleeding (PPB) than hot snare.

Appropriate stopping antithrombotic agent is associated with a 30 day thromboembolic risk of less than 1%.

Patient education regarding the symptoms of post polypectomy bleeding and after hours contact information is vital to include during consent processes and post discharge documentation.

Bronchoscopy and endobronchial ultrasound, although carrying low to intermediate bleeding risk, is categorised as high-risk procedure because even a small amount of bleeding in the airway can still lead to serious airway compromise and is non-compressible.

Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 3 of 20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

1.2 Special Considerations

1.2.1 Patients at high risk of thrombosis

Some patients on antithrombotic therapy have a higher risk of thrombosis than most, and interruption of their antithrombotic therapy may be safer with pre and/or post procedure bridging medication. **Specialist opinion may be useful in complex cases.**

Consult Haematology and/or Cardiology as appropriate if there are concerns around stopping antithrombotic medication, including if there is tension between the urgency of the endoscopy procedure and the high risk time for stopping antithrombotic medications.

Anticoagulation:

- Prosthetic mechanical mitral and tricuspid valves and old style mechanical aortic valves e.g. tilting disc, ball valve – all will be on warfarin anticoagulation. This group carries a high risk of valve thrombosis and clexane bridging is required pre and post procedure.
- Atrial fibrillation requiring pre-procedure bridging (warfarin only)
 - AF and mitral stenosis ('valvular AF') – higher risk than non-valvular AF and bridging should be considered
 - AF and recent (<3 months) arterial thromboembolism (stroke, TIA, other systemic thromboembolism)
- Venous thromboembolism requiring pre-procedure bridging (warfarin only)
 - VTE in the last 3 months
 - History of recurrent VTE and high risk thrombophilia (Antithrombin III deficiency, Protein C or S deficiency, Antiphospholipid syndrome)**. Discuss bridging with haematologist.

Antiplatelet therapy:

- Recent (within 3-6 months) cardiac stent, ACS, or other cardiac intervention on antiplatelet therapy
- Recent (within 3-6 months) stroke/TIA, or history of stroke/TIA and high risk haematology condition

1.2.2 Patients at high risk of bleeding

- **Patients with cirrhosis and coagulopathy, thrombocytopenia.**
See [Appendix B – Invasive Procedures in Patients with Cirrhosis and Coagulopathy](#)

Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 4 of 20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

1.3 Purpose

This Guideline addresses the management of patients undergoing endoscopic procedures who are on antithrombotic therapy.

Antithrombotic agents include anticoagulants (e.g., warfarin, DOACs (dabigatran, rivaroxaban, apixiban), heparin, and low molecular weight heparin (clexane) and antiplatelet agents (e.g., aspirin, clopidogrel, prasugrel and ticagrelor)

Glycoprotein IIb/IIIa receptor inhibitors (tirofiban, and eptifibatide) are not covered in this guideline. Tirofiban and eptifibatide have short half lives (2-4 hours) so are best managed by delaying the procedure to allow clearance.

Please note this is a guideline only and is not a prescriptive regime. The prescriber makes the final decision for the patient on an individual basis which may include specialist consultation.

1.4 Scope

This guideline applies to all medical and nursing staff working in Waikato DHB.

1.5 Patient / client group

Patients attending Waikato DHB Endoscopy department for a colonoscopy, flexible sigmoidoscopy, UGI, ERCP, PEG, double balloon ante/retrograde, bronchoscopy and endobronchial ultrasound (EBUS).

Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 5 of 20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

1.6 Definitions and acronyms

AAC	Anaesthetic assessment clinic
ACS	Acute coronary syndrome
AF	Atrial fibrillation
APS	Antiphospholipid syndrome
BAL	Bronchoalveolar lavage
BCSP	Bowel Cancer Screening Programme
CrCl	Creatinine Clearance
DOAC	Direct oral anticoagulant
DAPT	Dual antiplatelet therapy
EBUS	Endobronchial Ultrasound
EMR	Endoscopic mucosal resection
ERCP	Endoscopic retrograde cholangiopancreatography
ESD	Endoscopic submucosal dissection
EUS	Endoscopic ultrasound
FNA	Fine needle aspiration
INR	International normalised ratio
LMWH	Low molecular weight heparin
NBSP	National Bowel Screening Programme
NZBS	New Zealand Blood Service
OGD	Oesophageal-gastro-duodenoscopy
PEG	Percutaneous endoscopic gastrostomy
PPB	Post polypectomy bleed
POCT	Point of care testing
TMS	Transfusion Medicine Specialist
UGI	Upper gastrointestinal
VTE	Venous thromboembolism

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

2 Clinical management

2.1 Pre Procedure

1. Check the medical history (Clinical Work Station)
2. Determine what procedure the patient is having and why they are taking anti-coagulant /anti-platelet therapy.
3. Follow the flow charts in figures 1 to 4 based on
 - What anti-coagulant/anti-platelet therapy?
 - Endoscopy procedure – high or low bleeding risk?
 - Patient thrombotic risk- high or low?

These flow charts have guidance for safely stopping the anti-coagulant/anti-platelet where necessary.

4. Advise the patient with the risk/benefits of the proposed management plan. Use the information outlined in section 1 for guidance. If there are any concerns, check with the endoscopist performing the endoscopy or specialist initiating anticoagulant therapy.
5. LMWH bridging pre-procedure:
 - A small subset of patients on warfarin will require LMWH bridging when their warfarin is stopped. These are patients at a high risk of clotting complications - see 1.2, and [Appendix A - AAC Risk Stratification table](#). If the patient requires LMWH bridging, arrange for special authority, obtain patients body weight, organise a script for patient. Refer to Figure 5 for LMWH warfarin bridging guideline. Note patients on DOACs do not require pre procedure bridging.
 - LMWH should be administered at 0800hrs the day before to allow a 24hr break prior to endoscopy procedure.

2.2 Day of Endoscopy – elective procedures

- Confirm patient has followed pre-procedure plan re their antithrombotic medications (if not, notify the endoscopist. The procedure may need to be rescheduled if high risk procedure)
- Only warfarin requires routine pre-procedure testing on the day of the procedure:
 - On arrival at the endoscopy unit nursing staff perform the POCT test to determine the INR level. If ≥ 1.5 notify the endoscopist. The patient's procedure may be cancelled and rescheduled if high risk procedure.
 - **Low risk procedures can be performed safely with a therapeutic INR.**

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

2.3 Figure 1 Guideline for low risk procedures for patients on clopidogrel, prasugrel, ticagrelor, or aspirin.

Low risk procedure

- Diagnostic procedures +/- biopsy
- Biliary or pancreatic stenting
- Diagnostics-assisted enteroscopy without polypectomy
- Cold snare polypectomy <1cm (**Aspirin and Clopidogrel only**) NOT for Ticagrelor and Prasugrel



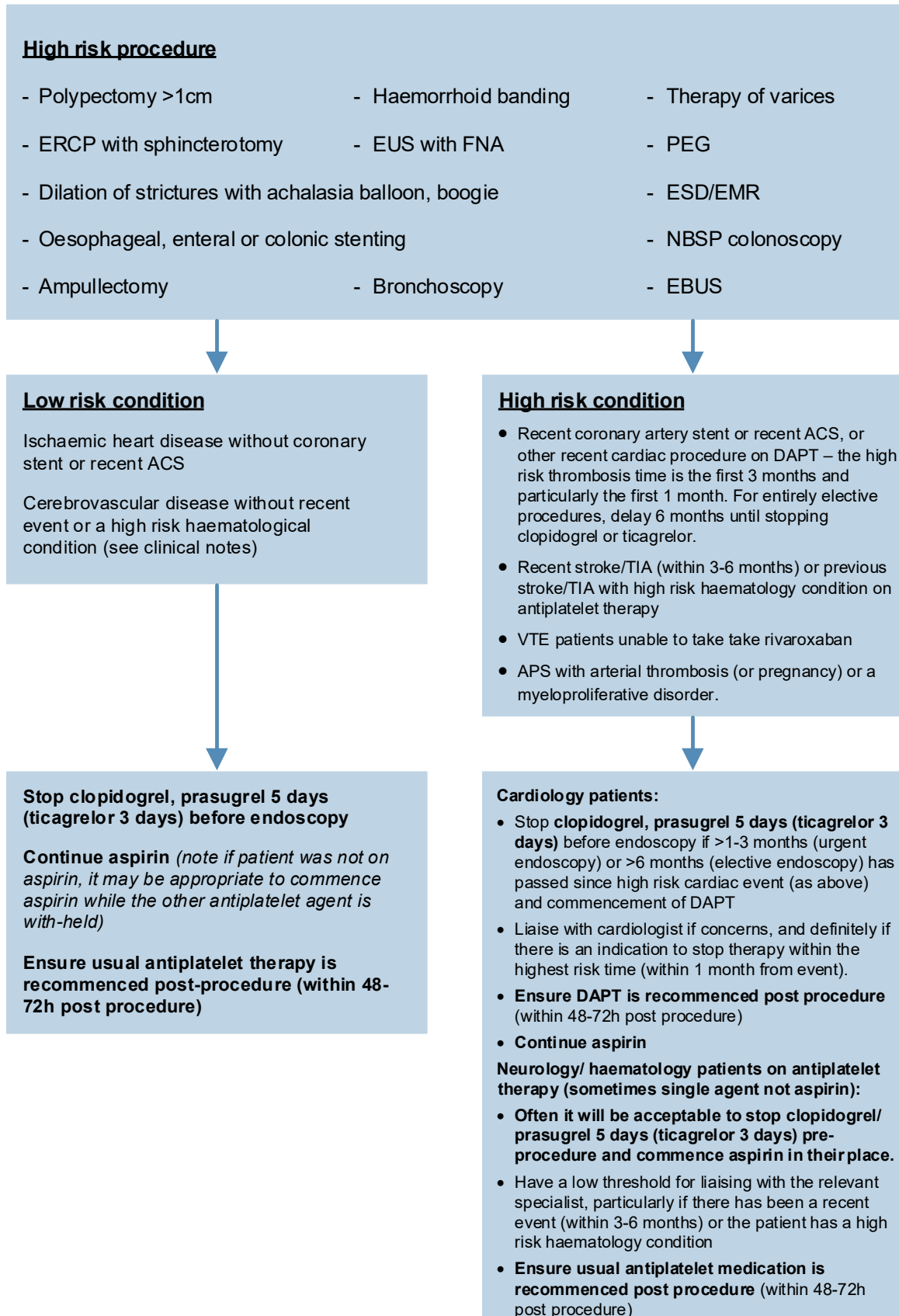
Clopidogrel, Prasugrel, Ticagrelor, Aspirin



Continue therapy. Consider clipping if Clopidogrel and cold snare polypectomy

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

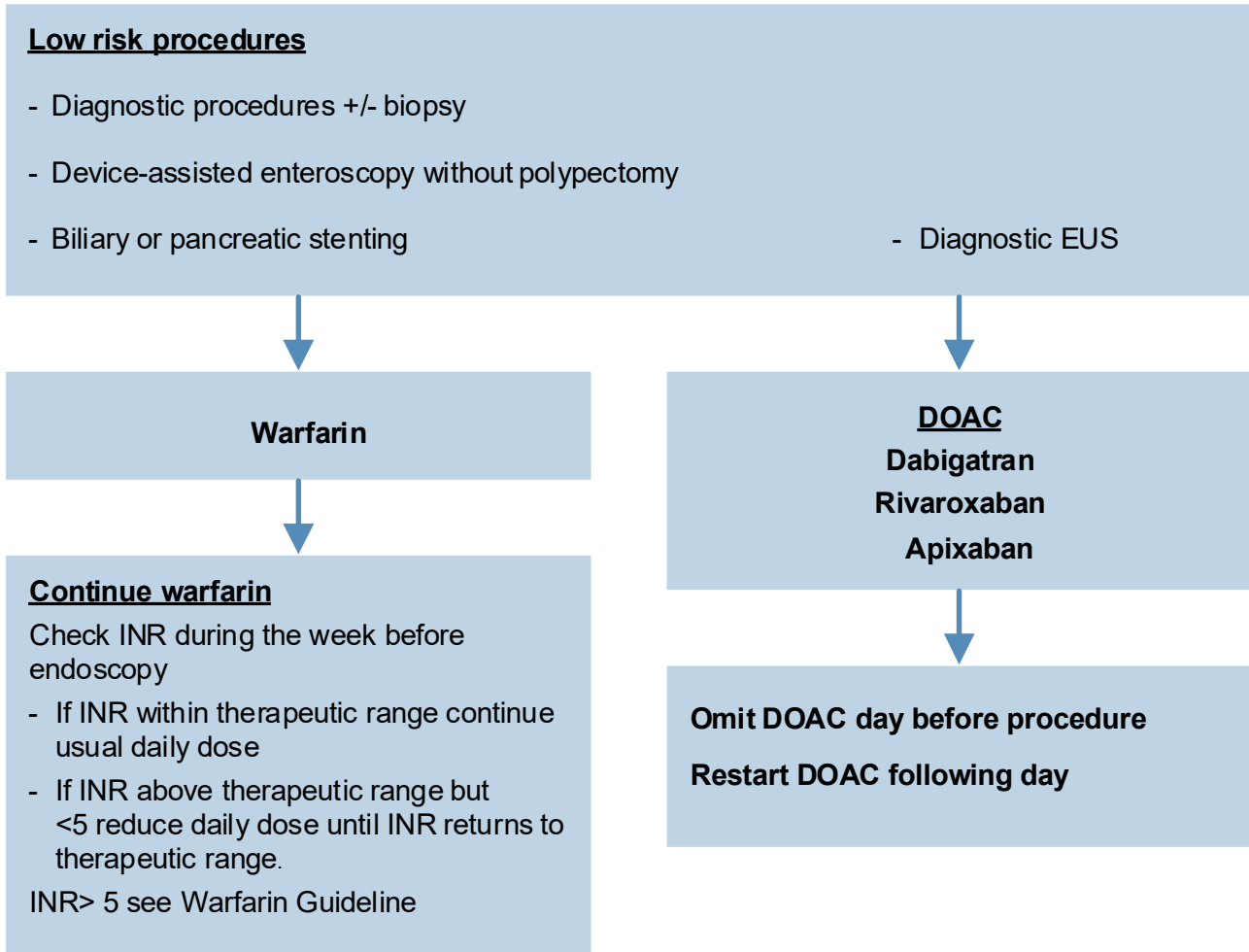
2.4 Figure 2 Guidelines for patients having a high risk procedure on clopidogrel, prasugrel, ticagrelor, or aspirin



Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 9 of 20

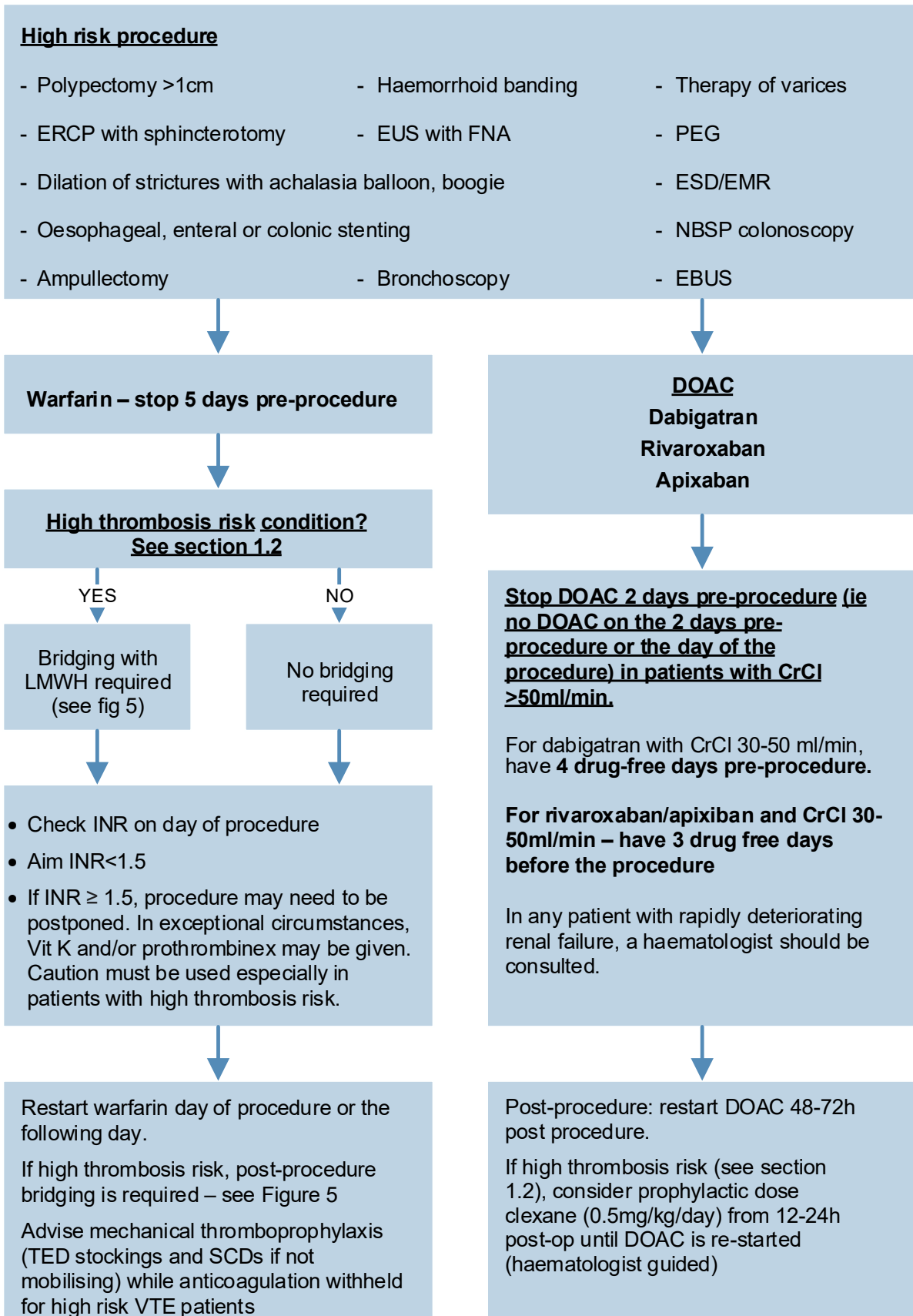
Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

2.5 Figure 3 Guidelines for the management of patients having a low risk procedure on warfarin or DOAC (Dabigatran, Rivaroxaban, Apixaban)



Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

2.6 Figure 4 Guidelines for management for patients with high risk procedures on warfarin & DOAC

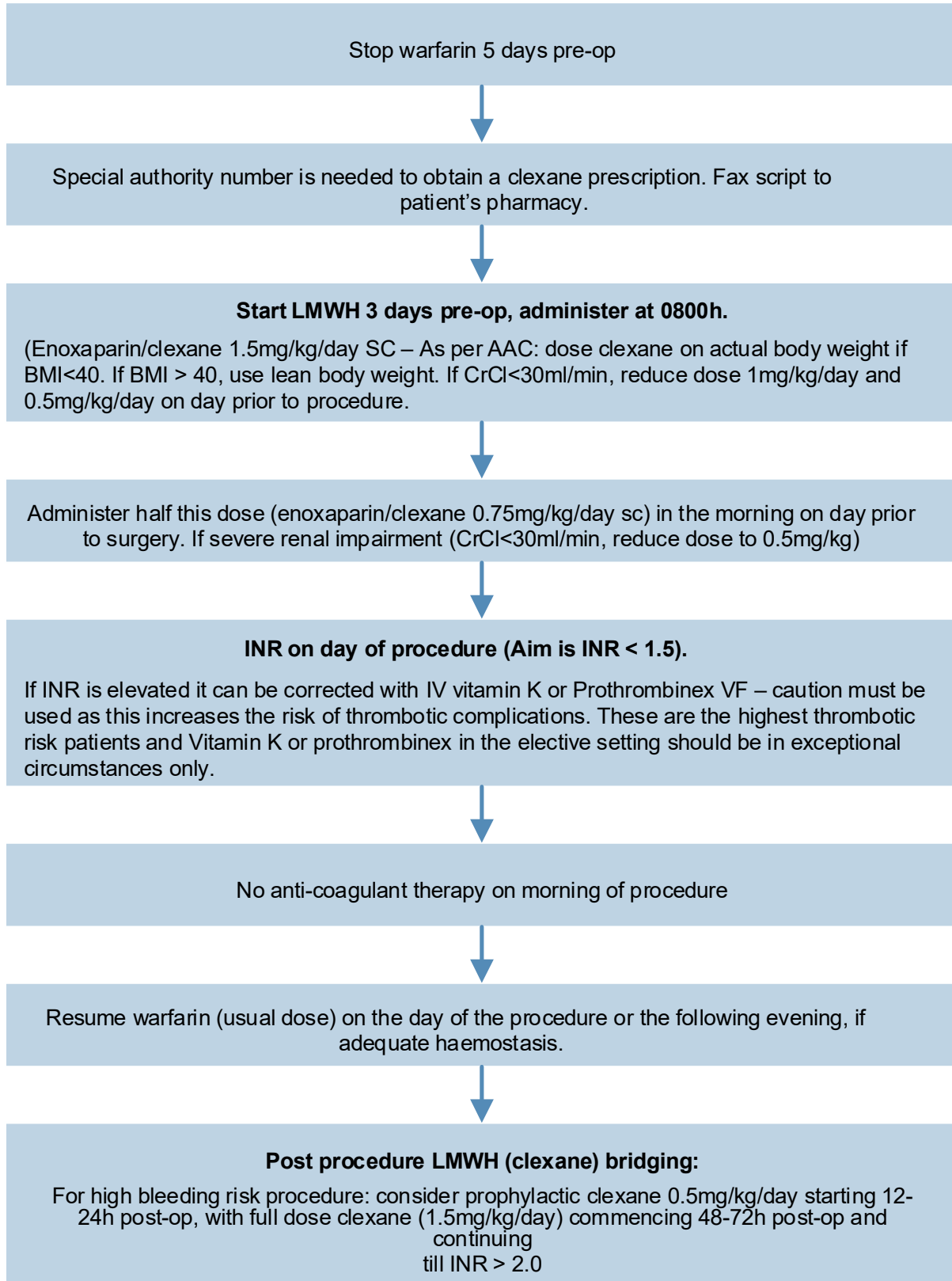


Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

2.7 Strategy for “Therapeutic Bridging” therapy if required

(see [Appendix A – AAC Risk Stratification Table](#) and [S1.2 Special Considerations](#))

Figure 5 Warfarin – for patients having a high bleeding risk procedure (requiring an INR<1.5) and high thrombosis risk (requiring bridging with LMWH)



Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 12 of 20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

2.8 Urgent and Emergency Endoscopy, and patients with critical or clinically significant GI bleeding

- Confirm if possible the timing of most recent doses of antithrombotic medication.
- Is patient actively bleeding and reversal of antithrombotic medication is required urgently?
- Is the procedure a high bleeding risk procedure and reversal of antithrombotic medication is required to safely perform procedure?
- Laboratory testing:
 - Check coagulation screen (INR, APTT, TCT, fibrinogen).
 - Consider DOAC level (if appropriate – see relevant section)
 - Consider platelet function testing (VerifyNow – laboratory test; platelet TEG mapping – POCT theatre) if patient is on antiplatelet agents.

2.9 Reversal of Anticoagulation in GI Bleeds

The decision to reverse anticoagulation and the risk of thromboembolic consequences, must be weighed against the risk of continued bleeding by maintaining the anticoagulated state. The degree of reversal of anticoagulation should be individualized.

2.9.1 Warfarin:

- Reversal can be achieved with vitamin K and/or prothrombinex
 - IV Vitamin K takes at least 6 hours to have an effect on INR, but the effect is sustained. Vitamin K delays the time taken to re-establish a therapeutic INR when warfarin therapy is recommenced. The delay is longer when larger doses of vitamin K are used. In patients with a high thrombosis risk (see section 1.2), choose a lower rather than higher dose of vitamin K, and ensure post procedure clexane is given (once bleeding is controlled) until a therapeutic INR is achieved – see Figure 5 for post-procedure guidance.
 - Prothrombinex has an immediate reduction effect on INR, and the effect persists for approximately 12-24h (in the absence of vitamin K).
 - For immediate reversal of warfarin effect, prothrombinex can be requested from blood bank up to a dose of 25 IU/kg without requiring Transfusion Medicine Specialist (TMS) approval. At doses above 25 IU/kg, blood bank will direct the requester to the TMS for discussion.
- **For urgent endoscopy (non-bleeding patient):**
 - Aim for an INR <1.5 prior to high risk procedure
 - An INR within the normal therapeutic range is acceptable for low risk endoscopy
 - If INR is too high, does the procedure need to be performed within the next 6 - 12h?

Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 13 of 20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

- Yes → give prothrombinex – dose based on initial INR – see Anticoagulation: Reversal Guideline 2705, pg 4 table. Prothrombinex on its own probably has a duration of effect of 12-24h. If the procedure carries a high risk of bleeding, and a sustained reduction (beyond 12-24h) in INR is required, then a small dose of vitamin K should also be given (eg 1mg IV, or higher if the presenting INR is super-therapeutic). The INR should be monitored daily, and post-procedure clexane will be required for patients with a high thrombosis risk – see figure 5 for post-procedure guidance.
- No → give a small dose of vitamin K (1–2.5mg IV) and recheck the INR the following day (at least 6 hours post dose). If the INR is still ≥ 1.5 , further vitamin K can be given, if there is time to wait for it to work (at least 6 hours). Prothrombinex can also be given in order to perform the procedure within 6 hours – for the dose, see table below.
 - The dose of Prothrombinex-VF is adjusted for both the initial and the target INR. These doses are based on consensus rather than gradable evidence.

Target INR	Initial INR			
	1.5–2.5	2.6–3.5	3.6–10.0	> 10.0
0.9–1.3	30 IU/kg	35 IU/kg	50 IU/kg	50 IU/kg
1.4–2.0	15 IU/kg	25 IU/kg	30 IU/kg	40 IU/kg

- **For patients with critical/ clinically significant GI bleeding on warfarin:**
 - See Anticoagulation: Reversal Guideline 2705 pg 4
 - Further advice can be obtained from the NZBS Transfusion Medicine Specialist/Haematologist who may be contacted at Waikato Hospital via Switchboard
 - Restart anticoagulation post-operatively once certain haemostasis achieved. Note this is usually 7-10 days but may be sooner if high thrombosis risk. Bridging with iv heparin can be considered. Liaise with specialist initiating anticoagulation.

2.9.2 Dabigatran:

- Elimination half life of 12-14 hours in healthy people. Dabigatran elimination relies heavily on renal clearance, and in patients with renal impairment, including acute kidney injury, expect the anticoagulation effect to persist for longer.
- Drug-free time to allow performance of a high risk procedure may be as little as 24h – delay procedure if possible – see below.
- Laboratory testing: TCT (part of usual coagulation screen); dabigatran level if TCT result is indeterminate.
- **Reversal agent – Idarucizumab.** It is effective but also very expensive. See Idarucizumab Guideline ref 5446 and Idarucizumab Approval Criteria form for more details. Use of idarucizumab requires approval from either a haematology or anaesthetic SMO. Note, it may be appropriate that peri-procedural use of

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

idarucizumab is as a 'wait and see' approach rather than upfront use – i.e. only use reversal if bleeding occurs during the procedure.

- **Laboratory testing:**

- Not required routinely, if recommended with-holding time has been achieved and renal function normal
- TCT as the initial test, and dabigatran level if indeterminate TCT result (see below for explanation). These tests should be performed within 2-3h of the proposed procedure being performed (eg in the morning on the day of procedure for a morning case), and repeat tests may be required if more time has elapsed. This is because dabigatran clearance is relatively fast, and drug levels may reduce below treatment/risk thresholds within the day.
- There is insufficient evidence of a correlation between TT and dabigatran levels from our lab to predict dabigatran levels from TT. If the renal function is normal, then dabigatran levels can be predicted to be 'surgically safe' after omitting 1-2 days, depending on the bleeding risk of the surgery. In renal dysfunction or where there are drug interactions, then dabigatran levels may be helpful
- Use TCT to assess dabigatran effect. TCT<40 – no significant dabigatran presence. TCT>80 – significant dabigatran effect – either delay procedure for high bleeding risk procedure or consider reversal agent. TCT 40-80 – indeterminate – consider requesting dabigatran level if high risk procedure and semi urgent.
- Dabigatran level: takes 1 hour to perform. Is only indicated with an indeterminate TCT if semi urgent indication– see above.
 - Pre-procedure: Dabigatran level >30-50ng/ml: In patients requiring a procedure with a high risk of bleeding, and further delay to wait for drug elimination is not in the patient's best interests, consider reversal with idarucizumab if dabigatran level >30-50ng/ml.
 - Life-threatening/ severe bleeding: Dabigatran level >50ng/ml – reversal with idarucizumab is recommended

- **For urgent endoscopy (non-bleeding patient):**

- Can the procedure be delayed for ≥ 24 h post the last dose?
 - YES: A delay of 24-48h from last dose of dabigatran will often be long enough for reversal of anticoagulant effect. See Figure 2 for the recommended time periods for with-holding dabigatran pre-procedure.
 - If the time periods can be achieved, routine laboratory testing for anticoagulation effect pre-procedure is not required.
 - If the procedure carries a high bleeding risk AND if >24h but not the full recommended time frame for drug with-holding has been achieved, then testing for dabigatran effect may be helpful – see above.
 - Consider IV fluids to enhance renal clearance of dabigatran pre procedure.
 - NO: Perform laboratory testing. Use reversal agent if indicated.

Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 15 of 20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

- See above, and Idarucizumab Guideline ref 5446 and Idarucizumab Approval Criteria form
- For patients with critical/ clinically significant GI bleeding on dabigatran
 - See Idarucizumab Guideline ref 5446 and Idarucizumab Approval Criteria form
 - For patients with life threatening bleeding, reversal with idarucizumab is indicated if the dabigatran level is >50ng/ml
 - Consider contacting haematology for advice
 - Dabigatran can be removed with dialysis

2.9.3 Rivaroxaban and Apixiban:

- DOAC – Direct factor-Xa inhibitor
- As for dabigatran, they have relatively short elimination half-lives (5-9 hour for rivaroxaban and 12h for apixiban), and delaying procedure for >24 hours post the last dose may be enough to perform the procedure safely. For recommended drug with-holding times – please see Figure 4.
- Both these drugs have a modest reliance on renal clearance, but not as much as dabigatran.
- There is currently no available reversal agent for factor Xa inhibitors in NZ. It is also important to note the routine coagulation screen cannot reliably predict their effect, and importantly, the coagulation screen may be normal despite significant anticoagulation effect.
- **Laboratory testing:** If the recommended with-holding time has been achieved, then routine laboratory testing is not required. If the procedure carries a high bleeding risk AND if >24h but not the full recommended time frame for drug with-holding has been achieved, then testing may be helpful.
 - A rivaroxaban level can be requested (takes 1 hour). If a patient on rivaroxaban is bleeding, or requires an urgent procedure with a high bleeding risk, please consult haematology for advice
 - We do not have an apixiban level available to us at Waikato DHB. To assess the amount of apixiban present, an anti-Xa assay can be requested. Contact haematology for help with interpreting this test
- **Reversal:**
 - There is no reversal agent for Xa inhibitors in NZ
 - Contact haematology for advice if reversal of drug effect is required (eg bleeding patient or need for high bleeding risk procedure to be performed urgently)
 - Reversal of effect can be achieved with prothrombinex and in some circumstances Novoseven (rVIIa) may also be recommended. Dosing is problematic. Contact haematology for advice.

Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 16 of 20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

2.9.4 IV heparin and clexane

(see also [Anticoagulation-Reversal](#) guideline Ref 2705)

- IV heparin – aim to stop infusion 4 hours before high bleeding risk procedure. Check APTT. Consider protamine if IV heparin reversal is required urgently - see [Anticoagulation: Reversal guideline \(page 3\)](#) for advice.
- Protamine may have a limited but useful effect on clexane anticoagulant effect – see [Anticoagulation: Reversal guideline \(page 2\)](#) for advice.

2.9.5 Anti-platelet agents (clopidogrel, ticagrelor, prasugrel)

- Consider requesting a laboratory platelet test (VerifyNow – contact the laboratory for advice) or operating theatre POCT TEG platelet mapping (contact anaesthetics).
- Note some patients do not respond to clopidogrel – this will be apparent on the platelet tests listed above. These patients will not bleed due to clopidogrel effect despite a recent dose.
- Platelet transfusion can be given for severe bleeding in patients on antiplatelet medication

3 Audit

3.1 Indicators

- Procedure aligns with best practice as documented in New Zealand Society of Gastroenterology or British Society of Gastroenterology
- Nursing assessment and documentation reflect the guideline steps and meet the HDSS and the NCNZ domains of competence
- Adverse events- bleeding or clotting- in patients receiving or stopping anticoagulation within 30 days endoscopic procedure

3.2 Tools

- Datix
- EUG adverse incident forms
- National Adverse Incident reporting process BCSP

Doc ID:	3137	Version:	3.1	Issue Date:	24 MAR 2021	Review Date:	7 DEC 2023
Facilitator Title:	Clinical Nurse Specialist			Department:	Endoscopy Department		
IF THIS DOCUMENT IS PRINTED, IT IS VALID ONLY FOR THE DAY OF PRINTING							Page 17 of 20

Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

4 Evidence Base

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Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

Appendix A – ACC Risk Stratification

This is in the process of being updated.

Please find on intranet at

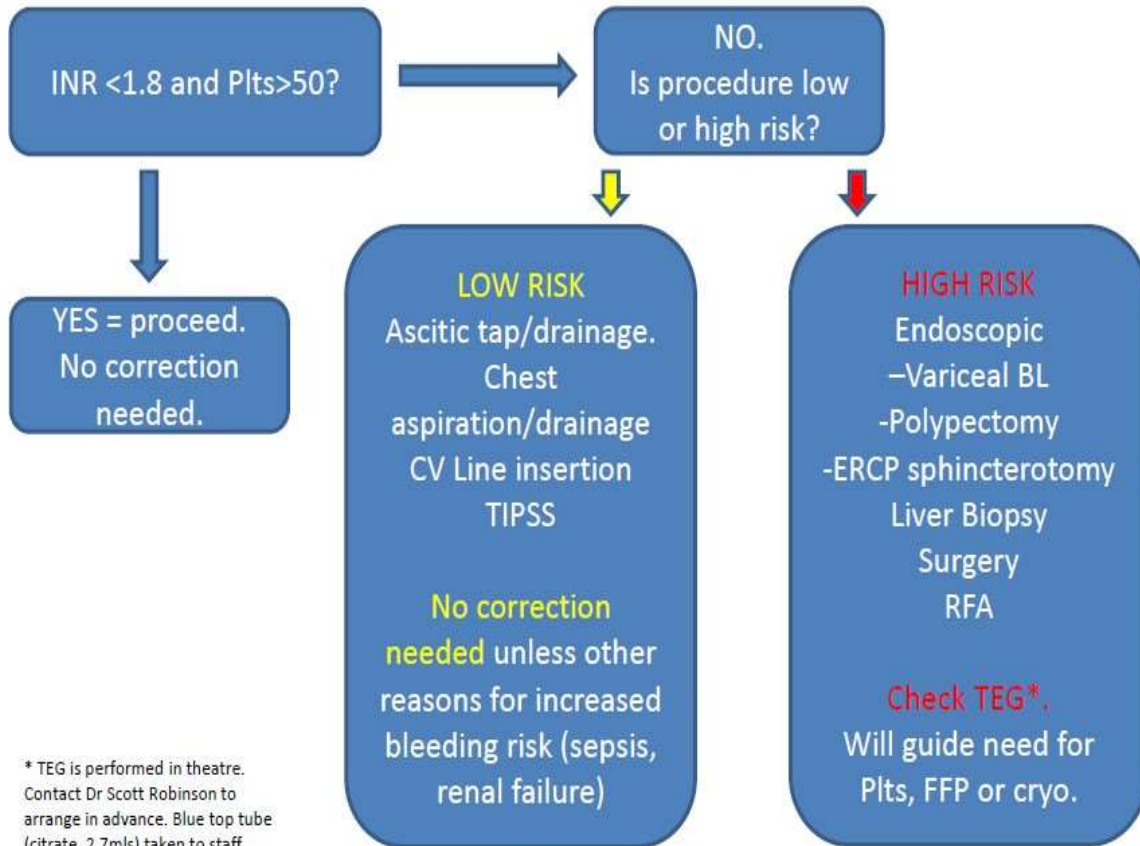
intranet -> working here -> clinical services -> anaesthesia -> anaesthetic assessment clinic -> anticoagulation -> [thromboembolic risk stratification](#).

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Management of Patients on Anticoagulant and Anti-platelet drugs undergoing endoscopic procedures

Appendix B – Invasive Procedures in Patients with Cirrhosis and Coagulopathy

Invasive procedures in patients with cirrhosis and coagulopathy



* TEG is performed in theatre.
Contact Dr Scott Robinson to arrange in advance. Blue top tube (citrate, 2.7mls) taken to staff base level 2 for TEG6 test.
Anaesthetics will provide result & interpretation.

Pietri et al, Thrombelastography Guided Blood Product Use before invasive procedures in cirrhosis with severe coagulopathy: A randomised controlled trial. Hepatology, Vol 63, No 2, p566-573, 2016.