

Supplementary file I: CEC manual for adjudicating bleeding and vascular complications

Classification and Definition

Bleeding

BARC 0

No bleeding or hematoma.

BARC 1

Every bleeding or hematoma not meeting the criteria for BARC 2 or higher.

BARC 2

Any clinically overt sign of hemorrhage that “is actionable” and requires diagnostic studies, (prolonged) hospitalization, or treatment by a health care professional. Specified for radial access and femoral access in this appendix

BARC 3a

Overt bleeding + Hb drop of 3-5 g/dl (1.9 – 3.1 mmol/L), or any transfusion with overt bleeding (independent of Hb)

BARC 3b

Overt bleeding + Hb drop >5g/dl (>3.1 mmol/L), or cardiac tamponade, or bleeding requiring surgical intervention and/or IV vasoactive agents

BARC 3c

Intracranial hemorrhage or intraocular bleedings

BARC 4

CABG related bleeding

BARC 5

Fatal bleeding

Vascular complications

Retroperitoneal hematoma, (pseudo) aneurysm, infection and arteriovenous-fistula or vascular occlusion requiring intervention. Specified for radial access and femoral access in this appendix

Radial access

Specification of BARC 2 bleedings

1. Prolonged hospitalization

Any bleeding that leads to one or more extra hospitalization day(s)

- Based on standard discharge policy of hospital
- For the primary endpoint check if prolonged hospitalization is caused by bleeding complication of the randomized access site

2. Additional compression therapy

Any additional compression therapy after successful primary hemostasis

- Bleeding after removal of first TR band and additional compression bandage or TR band is needed
- Ongoing bleeding with first TR band and additional compression therapy is needed
- Adding 1 or 2cc of air in the first TR band due to slight oozing should not be scored as BARC 2

3. Additional investigations

Any additional investigation for (potential) bleeding/hematoma should be scored as BARC 2. This includes imaging (i.e. ultrasound, CT) or blood testing (i.e. Hb, hematocrite) that is not part of standard care or the study protocol

4. Additional therapy

- Any additional or change of therapy related to bleeding/hematoma
- This includes cessation of medication (i.e. antiplatelet and anticoagulants) or initiation of medical therapy (i.e. vitamin K, hematological products)
 - Percutaneous intervention (i.e. coiling)

Specification of vascular complications

- Vascular complications requiring intervention: percutaneous, surgical, medical
- (pseudo) aneurysm (i.e. compression therapy, thrombin injection)
 - Infection (i.e. antibiotics)
 - Arteriovenous-fistula (i.e. percutaneous or surgical intervention)
 - Radial artery occlusion (percutaneous intervention, heparin therapy)
 - Dissection (i.e. percutaneous or surgical intervention)
 - Compartment syndrome (i.e. percutaneous or surgical intervention)

Femoral access

Specification BARC 2 bleeding

1. Prolonged hospitalization

- Any bleeding that leads to one or more extra hospitalization day(s)
- Based on standard discharge policy of hospital
 - For the primary endpoint check if prolonged hospitalization is caused by bleeding complication of the randomized access site

2. Additional compression therapy

- Any additional compression therapy after successful primary hemostasis:
- New compression therapy after removal of the first bandage, or additional compression after closure device
 - Prolonging compression bandage due to slight oozing should not be scored BARC 2, when this will not lead to prolonged hospitalization (one or more days).

3. Additional investigations

- Any additional investigation for (potential) bleeding/hematoma should be scored as BARC 2. This includes imaging (i.e. ultrasound, angiography or CT) or blood testing (i.e. Hb, hematocrite) that is not part of standard care or the study protocol

4. Additional therapy

- Any additional or change of therapy related to bleeding/hematoma
- This includes cessation of medication (i.e. antiplatelet and anticoagulants) or initiation medical therapy (i.e. vitamin K, hematological products)
 - Percutaneous intervention (i.e. coiling or stenting of peripheral arteries)

Specification of vascular complications

- Vascular complications requiring intervention: percutaneous, surgical, medical:
- Retroperitoneal hematoma (i.e. coiling, surgery)
 - (pseudo) aneurysm (i.e. compression therapy, thrombin injection)
 - Infection (i.e. antibiotics)
 - Arteriovenous-fistula (i.e. percutaneous or surgical intervention)

- Femoral artery occlusion or severe stenosis (percutaneous or surgical intervention)
- Dissection (i.e. percutaneous or surgical intervention)
- Compartment syndrome (i.e. percutaneous or surgical intervention)