
Background and Objectives
Anticoagulant and thrombolytic agents form the cornerstone of PE management, but their use is associated with an increased risk of bleeding. Bleeding complications are associated with an increased risk of subsequent adverse outcomes in pulmonary embolism (PE). The “Bleeding Academic Research Consortium” (BARC) developed a classification of bleeding events combining laboratory and clinical parameters, but this classification was developed in ACS patients, and its applicability to other settings remains unknown.

Methods: Patient Selection
Patient selection: Prospective single-center registry of patients treated in the University Hospital of Besançon (France) for acute intermediate or high-risk PE confirmed by MSCT or V/Q scan.

Inclusion criteria: Patients with intermediate-risk PE defined as at least 1 echocardiographic sign of RV dysfunction (paradoxical septal motion, systolic PH >30 mmHg, or RVED/LVED diameter ratio >1); or high-risk PE defined as presence of cardiogenic shock or arterial hypotension.

• Standard biological parameters and ECG at admission
• Transthoracic echocardiography at admission and at 48 hours
• Pts with intermediate-risk PE treated with:
  • Anticoagulant therapy with LMWH (enoxaparin or tinzaparin) or fondaparinux.
  • UFH preferred in pts with renal failure (Cr.Cl >30mL/min) or elevated bleeding risk (<5 days post-op, hemoglobin <10g/dL, thrombopenia <100 000/mm3)
• Pts with high-risk PE treated with:
  • Thrombolysis using alteplase (100mg over 2h) followed by UFH, to achieve a target aPTT of 1.5-2.5 the control value.
  • VKA (fluindione) initiated on day 1 after treatment with UFH, LMWH, fondaparinux, and on day 3 after thrombolytic therapy (target INR 2-3)
• BARC types 1 and 4 bleeds not recorded as considered not applicable to PE context

Primary endpoint: In-hospital death.
Secondary endpoints: Combined endpoint of death, recurrent PE or treatment escalation; and to identify predictive factors of in-hospital BARC bleeding and death.

Results
• From 2007 to 2011, 666 patients were admitted with confirmed diagnosis of PE
  • Diagnosis was confirmed by MSCT in 82% and by V/Q scan in 18%
  • Average was 66±18 years, 52% were women
  • 142 (21.3%) low risk; 422 (63.4%) intermediate risk; 102 (15.3%) high risk.
  • Treatment was UFH in 93 (14%); enoxaparin in 200 (30%), fondaparinux in 373 (56%)
  • Thrombolysis was performed in 167 (25%)
  • Overall 65 (9.8%) had a BARC bleed (any type). Overall mortality was 3.9% (n=26).
  • BARC Type 3 bleeds (n=3) included: 23 type 3A (drop in Hb ≥3 points but <5 points, of which 17 transfusions); 16 type 3B (drop in Hb ≥5 points, n=14; surgical haemostasis, n=9; tamponade, n=2); and 4 type 3C (haemorrhagic stroke, n=4).

Conclusions
Our results suggest that the BARC definition of bleeding events is applicable in the context of acute PE and that, in these patients, the occurrence of BARC bleeding events is associated with an increased risk of in-hospital death. We propose that the BARC classification could be used as the standard for bleeding events, particularly in clinical trials.