

Devilish Definitions: Professional Society View

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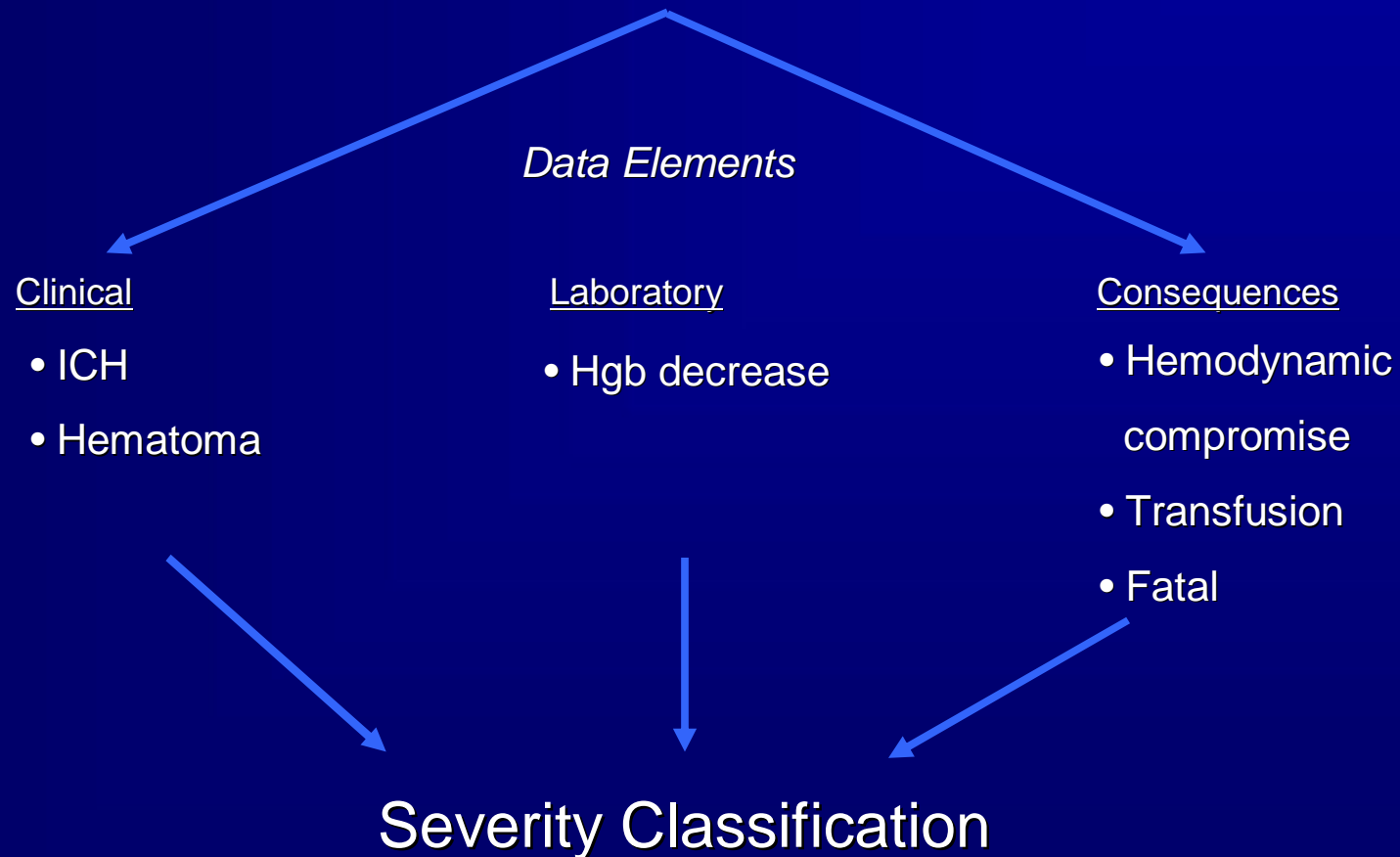
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Deconstructing Definitions: Importance of data elements

Bleeding definition



“Major” Bleeding Data Elements

Definition	TIMI ¹	GUSTO ¹	CURE ²	PLATO ³
Trial	TRITON	CHARISMA	CURE	PLATO
Major – fatal / life threatening or severe bleeding	Fatal / life threatening (related to instrumentation, spontaneous, trauma), ICH, Hb > 5 g/dL, or absolute HCT > 15%	Fatal, ICH, or causes haemodynamic compromise and requires intervention	Fatal / Life threatening Fatal, ICH, requires surgery, hypotension requiring inotropes, Hb > 5 g/dL, or transfusion > 4 U Other major Disabling, intraocular with vision loss, or transfusion > 2-3 U	Fatal / Life threatening Fatal, ICH, intrapericardial with tamponade, hypovolaemic shock / hypotension requiring pressors or surgery, Hb > 5 g/dL, or transfusion > 4 U Other major Disabling (intraocular with permanent vision loss), Hb > 3-5 g/dL, or transfusion > 2-3 U

ICH = intracranial haemorrhage; PLATO = Platelet Inhibition and Patient Outcomes.

1. Rao SV, et al. *J Am Coll Cardiol.* 2006;47:809-816.

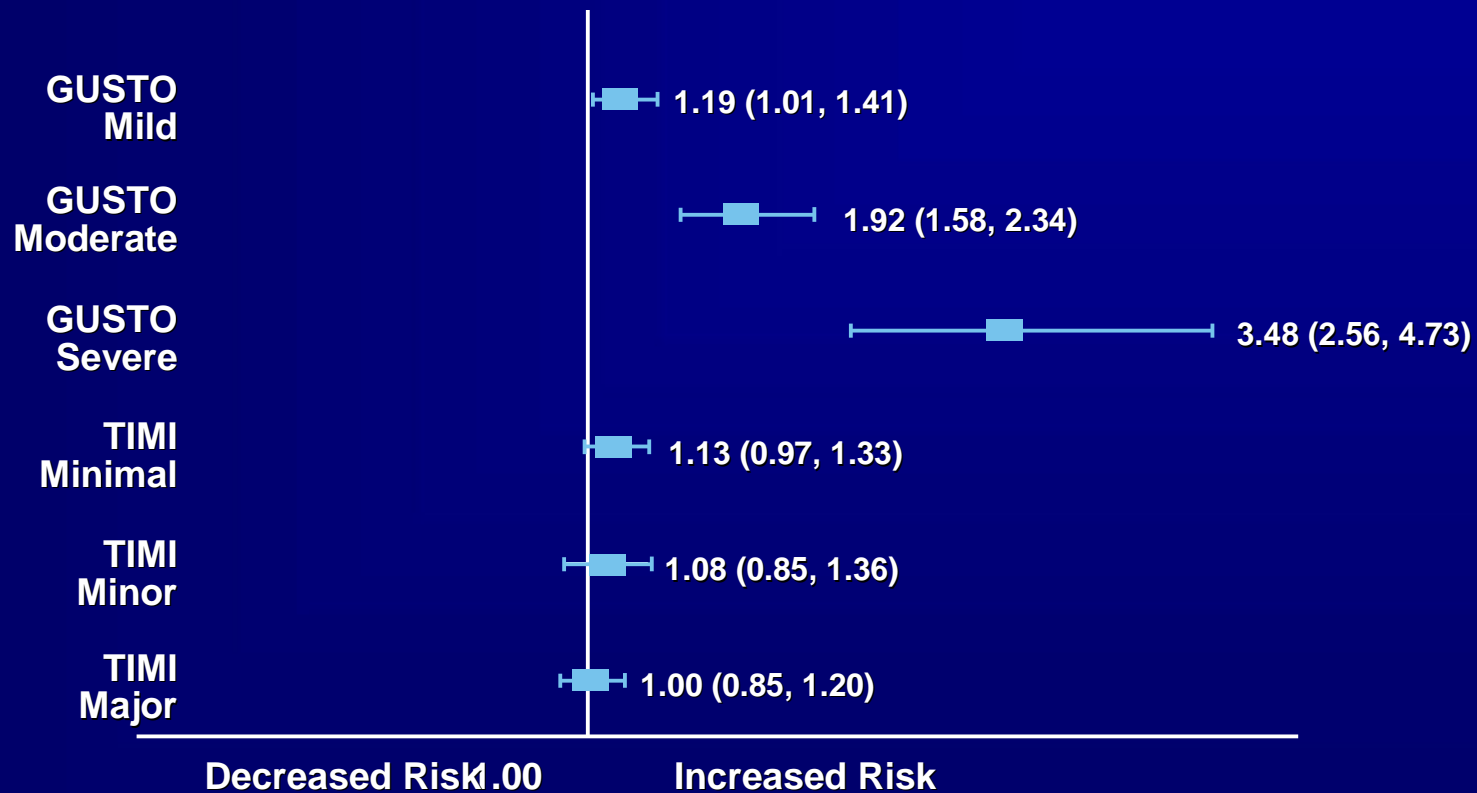
2. Yusuf S, et al. *N Engl J Med.* 2001;345:494-502.

3. Cannon CP, et al. *J Am Coll Cardiol.* 2007;50:1844-1851.

Effect of Bleeding Definition on the Association of Bleeding and Death/MI

N=15,858 ACS patients from PURSUIT & PARAGON B

30-day death/MI



Major bleeding data elements and outcomes:

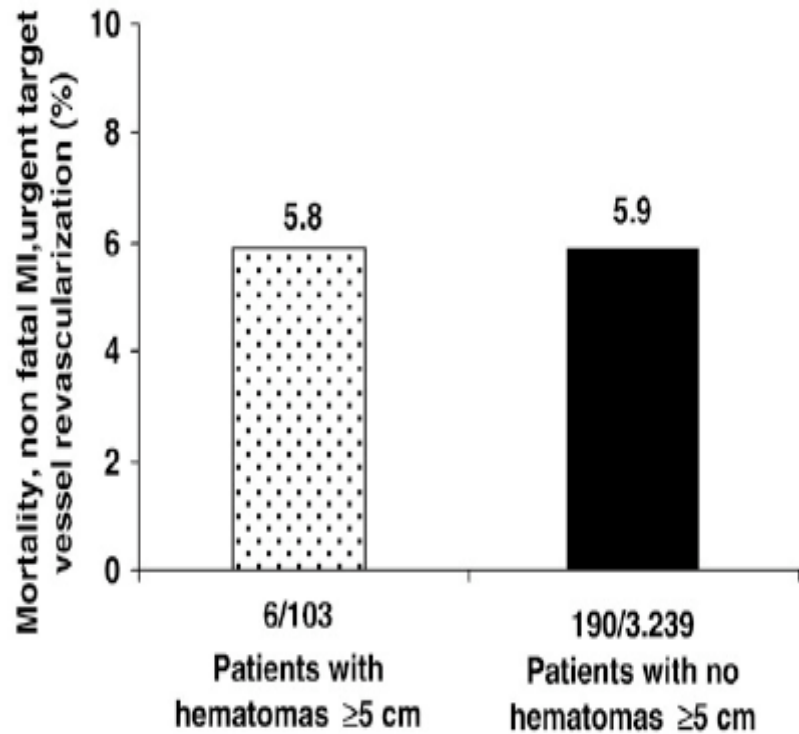
N=22,000 pts from REPLACE-2, ACUITY, HORIZONS-AMI

Event	Hazard ratio (95% CI)	Deaths within 1 y, n	p
TIMI major bleed	4.85 (3.56–6.60)	53	<0.001
Non-TIMI major bleed with transfusion	2.98 (2.10–4.24)	40	<0.001
Non-TIMI major bleed without transfusion	1.79 (1.09–2.93)	17	0.021
Large (≥ 5 cm) hematoma only	1.30 (0.58–2.92)	6	0.53

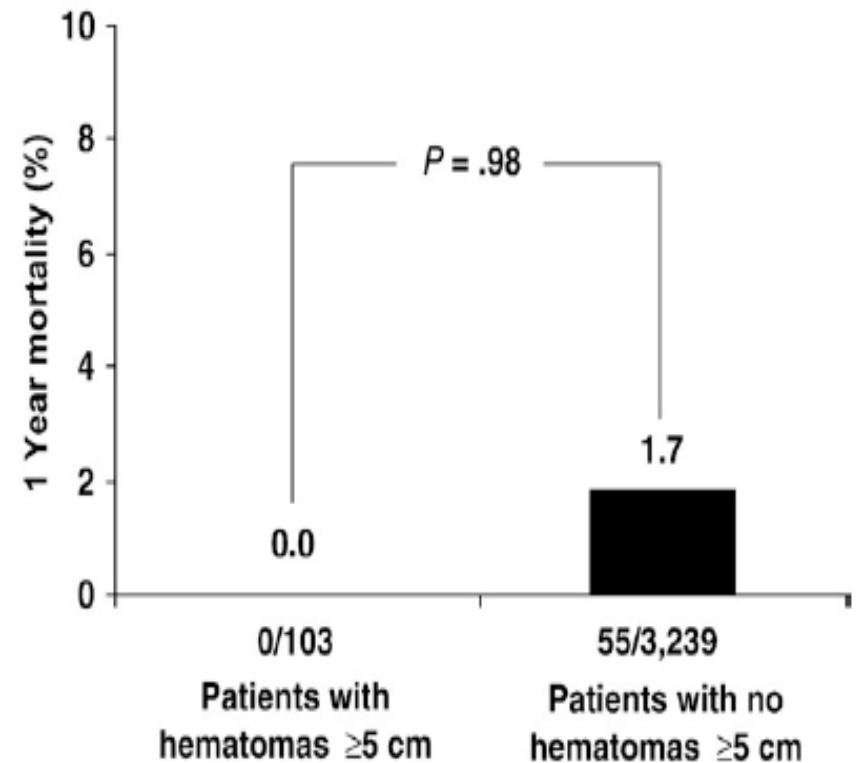


Hematomas and outcomes:

N=3342 pts from STEEPLE



Incidence of 30-day composite ischemic end point in patients with and without hematomas ≥5 cm.



Incidence of all-cause 1-year mortality in patients with and without hematomas ≥5 cm.



NCDR CathPCI bleeding (version 3.04)

J. ADVERSE OUTCOMES: (Complete this section for each Lab Visit)

GENERAL COMPLICATIONS:

Periprocedural MI¹⁰⁰⁰: Yes; No
 Cardiogenic Shock¹⁰¹⁰: Yes; No
 CHF¹⁰²⁰: Yes; No
 CVA/Stroke¹⁰³⁰: Yes; No
 Tamponade¹⁰⁴⁰: Yes; No
 Thrombocytopenia¹⁰⁵⁰: Yes; No
 Contrast Reaction¹⁰⁶⁰: Yes; No
 Renal Failure¹⁰⁷⁰: Yes; No
 Emergency PCI¹⁰⁸⁰: Yes; No

VASCULAR/BLEEDING COMPLICATIONS:

Bleeding at Percutaneous Entry Site¹⁰⁸⁵: Yes; No
 Retroperitoneal Bleeding¹⁰⁸⁶: Yes; No
 Gastrointestinal Bleeding¹⁰⁸⁷: Yes; No
 Genital-Urinary Bleeding¹⁰⁸⁸: Yes; No
 Bleeding - Other/Unknown Cause¹⁰⁸⁹: Yes; No
 Access Site Occlusion¹⁰⁹²: Yes; No
 Peripheral Embolization¹⁰⁹⁴: Yes; No
 Dissection¹⁰⁹⁶: Yes; No
 Pseudoaneurysm¹⁰⁹⁷: Yes; No
 → if Yes Treatment¹⁰⁹⁸: None; Pressure; Fibrin Injection; Surgery
 AV Fistula¹⁰⁹⁹: Yes; No



NCDR Bleeding definition (version 3.04)

- ✓ **To qualify a bleeding event should require a transfusion, and/or prolong hospital stay, and/or cause a drop in hgb > 3.0 g/dl**
- ✓ **Percutaneous entry site**
 - λ External
 - λ Hematoma > 10 cm for femoral, > 2 cm for radial access, > 5 cm brachial



Considerations for TREAT

- ✓ **Prospective data collection**
 - λ Surveillance for bleeding rather than chart review
 - λ Collection of additional data elements
 - λ Complications:
 - Arterial occlusion*
 - Hematomas not leading to prolonged hosp or decreasing hgb*

