Critical Review Form

Clinical Prediction or Decision Rule

Risk scoring systems to predict need for clinical intervention for patients with nonvariceal upper gastrointestinal tract bleeding,
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Objective: **"To compare the Blatchford score with the clinical Rockall score and the complete Rockall score in their utilities in assessing the need for clinical intervention in patients with acute nonvariceal UGIB." (p. 775)**

Methods: **Investigators conducted a retrospective chart review for all upper gastrointestinal bleed (UGIB) patients ≥ 18 years evaluated in the ED of Chang Gung Memorial Hospital (Taoyuan County, Taiwan) between January and July 2006. Cases were identified by ICD-9 codes extracting those with esophageal varices (ICD-9 clinical modification code 4650). Exclusion criteria included age < 18 years, no endoscopy, no proton pump inhibitor (PPI) used, or lower GI bleeding source. Before endoscopy all patients were treated with an intravenous PPI. Although the investigators fail to reference or fully describe their chart review methods (Gilbert and Worster), their discussion states adequate chart review methods: medical record review by > 1 investigator; abstractor blinding to hypothesis; abstractor blinding between predictor and outcome variables; maintenance of study manual with explicit definitions; periodic abstractor monitoring; and standardized abstractor forms.**

Recurrent bleeding was defined by occurrence of at least one of the following: repeat endoscopy prior to hospital discharge, surgery for control of UGIB, re-admission to the hospital for UGIB with 30-days of discharge. Clinical interventions were defined as blood transfusion, or any endoscopic or operative intervention to control bleeding.

For each patient a Blatchford score, clinical Rockall score, and complete Rockall score (see below) were calculated. The proportions of high-risk patients by each score were compared by χ^2 tests. Prognostic test characteristics for each score were computed.

Guide		Comments
I.	***Is this a newly derived instrument* (Level IV)?**	
A.	Was validation restricted to the retrospective use of statistical techniques on the original database? (If so, this is a Level IV rule & is not ready for clinical application).	No – validation occurred on a distinct data set so the Blatchford and Rockall rules are at least Level III CDRs.

II.	**Has the instrument been validated? (Level II or III). If so, consider the following:**	
1a	Were all important predictors included in the derivation process?	Uncertain since the investigators do not elaborate on derivation methods for each CDR. Important predictors both rules neglect include presenting symptoms, preceding steroid or NSAID use, or prior UGI bleed.
1b	Were all important predictors present in significant proportion of the study population?	Uncertain since investigators do not provide prevalence for each variable.
1c	Does the rule make clinical sense?	Both CDRs incorporate variables of potential interest. The complete Rockall score follows endoscopy and is of less importance to EM since we're trying to identify a subset who can await EGD. Once EGD is initiated EM risk-stratification really has little else to offer.
2	Did validation include prospective studies on several different populations from that used to derive it (II) or was it restricted to a single population (III)?	No prospective evaluation with this trial so Blatchford and Rockall are Level III CDRs.
3	*How well did the validation study meet the following criteria?*	
3a	Did the patients represent a wide spectrum of severity of disease?	Unknown since little demographic information was provided.
3b	Was there a blinded assessment of the gold standard?	Yes. "abstractor blinding between predictor and outcome variables" occurred. (p. 778)
3c	Was there an explicit and accurate interpretation of the predictor variables & the actual rule without knowledge of the outcome?	No reliability (κ) assessment is reported. Furthermore, retrospective application of a CDR often differs from prospective interpretation of the same variables in today's chaotic ED. Therefore, before accepting this study's findings as valid and reliable a prospective investigation should demonstrate that the Blatchford and Rockall variables can be reproducibly obtained real-time, the scores accurately computed, and that doing so offers the same prognostic test characteristics as this retrospective data set.
3d	Did the results of the assessment of the variables or of the rule influence the decision to perform the gold standard?	Undoubtedly individual variables influenced decisions to transfuse or operate (hypotension, profound anemia) so potential *incorporation bias*.

4	How powerful is the rule (in terms of sensitivity & specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	• 354 acute non-variceal UGI bleed patients were enrolled with mean age 62 years, 67% male, 42% taking NSAIDs, and 94% treated with pantoprazole. • Only 23 (6%) developed recurrent bleeding and three (0.85%) died. • The Blatchford score identified 92.1% as high-risk compared with 81.6% for the clinical Rockall score (p <0.0001). • Blood transfusions were required by 54% and a total of 69.5% ultimately had a predefined clinical intervention. Need for Intervention Blatchford Yes No Non-low risk 245 81 Low-risk 1 27 Sen 99.6 (98.1 - 99) Spec 25 (21.5 – 25.8) LR+ 1.3 (1.25 – 1.35) **LR- 0.016 (0.003 – 0.091)** Need for Intervention Rockall Yes No Non-low risk 222 67 Low-risk 24 41 Sen 90.2 (87.4 – 92.8) Spec 38.0 (31.5 – 43.7) LR+ 1.45 (1.28 – 1.65) LR- 0.257 (0.165 – 0.399) • Of the 24 subjects missed by the Rockall score (false-negatives) zero died. Seven developed recurrent bleeding and six needed blood transfusions. • The complete Rockall score had 22 false-negatives with sensitivity 91% and specificity 77.8% (LR+ = 4.1; LR- = 0.11).

III.	**Has an impact analysis demonstrated change in clinical behavior or patient outcomes as a result of using the instrument? (Level I). If so, consider the following:**	
1	How well did the study guard against bias in terms of differences at the start (concealed randomization, adjustment in analysis) or as the study proceeded (blinding, co-intervention, loss to follow-up)?	Good retrospective chart review methods incompletely reported so *selection*, *incorporation*, and *co-intervention bias* quite likely.
2	What was the impact on clinician behavior and patient-important outcomes?	No prospective impact analysis conducted and no clinical implications hypothesized.

Limitations

1) **Incomplete reporting of retrospective chart review methods.**
2) **Insufficient subject demographic descriptions by which to judge external validity for other populations (proportions with prior PUD, presence/duration of hematemesis or melena, illness severity scores, or ultimate patient disposition).**
3) **No control for treatment effect (co-intervention bias).**
4) **No assessment of incorporation bias since many of the variables likely impacted aggressiveness of diagnostic evaluation and therapeutic interventions.**
5) **Prevalence of predictor variables was not reported.**

Bottom Line

Single-center, retrospective application of the Blatchford score, the clinical Rockall score, and the complete Rockall score suggests that the former is superior at identifying a subset at low-risk for recurrent bleeding (up to 30-days), interventions (transfusions, surgery), or death. Absence of *any* Blatchford risk-factors reduces the likelihood of need for intervention from 69.5% to 3.5%. Future trials should prospectively evaluate the reliable and accurate interpretation of the Blatchford score while assessing prognostic tests characteristics, clinician acceptance and patient-important outcomes.

Blatchford score

Admission risk marker	Score component value
Blood urea nitrogen level (mg/dL)	
≥18.2 to < 22.4	2
≥22.4 to <28	3
≥28 to <70	4
≥70	6
Hemoglobin level for men (g/L)	
≥12 to <13	1
≥10 to <12	3
<10	6
Hemoglobin level for women (g/L)	
≥10 to <12	1
<10	6
Systolic blood pressure (mm Hg)	
≥100 to <109	1
≥90 to <99	2
<90	3
Other markers	
Pulse rate ≥100 beats/min	1
Presentation with melaena	1
Presentation with syncope	2
Hepatic disease	2
Heart failure	2

Range of scores is from 0 to 23; maximum score is 23. High risk is any score greater than 0.

Rockall risk score

Variable	Score			
	0	1	2	3
Age (y)	<60	60-79	≥80	
Shock		HR > 100 b/min	SBP < 100 mm Hg	
Co-morbidity			IHD, CHF, any major co-morbidity	Renal failure, liver failure, metastatic malignancy
Endoscopic Diagnosis	Mallory-Weiss tear or no lesion observed	Peptic ulcer disease, erosive esophagitis	Malignancy of upper GI tract	
Stigmata of recent hemorrhage	Clean-based ulcer, flat pigmented spot		Blood in upper GI tract, clot, visible vessel, bleeding	

The **clinical Rockall score** is calculated *without* endoscopic findings (first 3 variables above). The **complete Rockall score** (after endoscopy) is the clinical Rockall score plus the endoscopic findings (the final 2 variables above).
Patients with clinical Rockall scores (before endoscopy) of greater than 0and patients with complete Rockall scores (after endoscopy) of greater than 2 are considered to be at high risk for developing adverse outcomes (recurrent bleeding, death).
HR indicates heart rate; SBP, systolic blood pressure; IHD, ischemic heart disease; CHF, congestive heart failure.