Critical Review Form

Clinical Prediction or Decision Rule

A risk score to predict need for treatment for upper gastrointestinal haemorrhage, *Lancet* 2000; 356: 1318-1321

Objective: **To "develop and validate a risk score to assess whether patients presenting with acute upper-gastrointestinal bleeding will require admission for treatment to manage their bleeding". (p. 1318)**

Methods: **Using data previously obtained in West Scotland to describe the incidence and case-fatality for consecutive upper gastrointestinal (UGI) bleed patients from 19 hospitals, the investigators retrospectively derived a clinical decision aid to evaluate the need for acute treatment among UGI bleeders. Next, they prospectively evaluated the clinical decision rule (CDR) over a three-month period in three West Scotland hospitals.**

Patients were "defined as needing treatment if they had had a blood transfusion or any operative or endoscopic intervention to control their haemorrhage, or if they had undergone no intervention but had died, rebled, or had a substantial fall in haemoglobin concentration after admission". (p.1318)

Using a stepwise selection of variables, logistic regression was used to yield coefficients which were then used to derive the Blatchford Scoring System (see below). The χ^2 goodness of fit test was used to evaluate the scores calibration. Prognostic test characteristics (sensitivity, specificity, AUC) were computed and compared with the Rockall Scores which had been previously derived and validated to assess patients' risk of death or rebleeding. Finally, using Spearman's rank correlation the scores were correlated with two proxy markers of UGI bleeding severity: the number of units transfused and patients' hospital length of stay.

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 prospectively on a small subset distinct from that upon which it was derived so at least a Level III CDR.
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 because the investigators do not clearly list all variables included in the derivation process. If they included all variables assessed in the derivation process then their model would have included age, urea, gender, creatinine, Hg, dBP, sBP, pulse and serious co-morbidities (CHF, liver failure, respiratory failure, malignancy), presenting symptoms (hematemesis, syncope, melena, coffee ground emesis), PMH (esophageal varies, PUD, previous UGI bleed, dyspepsia), current medications (steroids, NSAIDs, anticoagulation acid-blocking drugs), smoking and alcohol consumption. If all of these variables were incorporated into the logistic regression model then the list of variables is all inclusive, but the authors should clearly state this fact in the methods.
1b	Were all important predictors present in significant proportion of the study population?	Unknown since variable prevalence not reported in isolation or aggregate.
1c	Does the rule make clinical sense?	Yes, variables and variable weighting are intuitive with face validity.
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, only validated on small subset of West Scotland subjects so this remains a Level III CDR awaiting validation on a wider range of patients.
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 no patient demographics are provided. This limits one's ability to confidently apply the results to their own patient population.

3b	Was there a blinded assessment of the gold standard?	The criterion standard was operative intervention or clinical deterioration as defined above. These outcomes were undoubtedly searched for and identified based upon knowledge and clinical evaluation of the variables included in the model.
3c	Was there an explicit and accurate interpretation of the predictor variables & the actual rule without knowledge of the outcome?	"A single researcher was responsible for identification and data collection for the patients in the initial audit and those included in the subsequent score validation" (p. 1318). Whether this researcher was blinded to the patients' outcomes is not clearly stated.
3d	Did the results of the assessment of the variables or of the rule influence the decision to perform the gold standard?	Not clearly stated by the investigators but likely yes so *work-up bias* and *ascertainment bias* is likely.
4	How powerful is the rule (in terms of sensitivity & specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	• 1748 consecutive subjects were used in the derivation set and 197 consecutive patients were used in the validation set. • Low-risk patients (Blatchford Score = 0) represented 35% of the cohort of which only 1-2% required an intervention. By comparison 50% of subjects had Rockall = 0 but 10% of those required an intervention. • The derived model validated well with χ^2 goodness of fit (p=0.84). • ROC AUC for Blatchford (AUC = 0.92; 95%, CI 0.88 – 0.95) superior to Rockall admission (AUC = 0.71; 0.64 – 0.78) or full post-endoscopy score (AUC = 0.75; 0.67 – 9.83). Need for Intervention Blatchford Yes No Non-low risk 88 65 Low-risk 1 43 Sen 98.9% (95% CI 94.5 – 99.8) Spec 39.8% (95% CI 36.2 – 40.6) LR+ 1.64 (95% CI 1.48 – 1.68) LR- 0.028 (95% CI 0.005 – 0.151)

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)?	No impact factor assessed since the rule was <u>not</u> used in clinical decision making, but multiple forms of potential bias are possible including *selection bias*, *ascertainment bias,* and *co-intervention bias*.
2	What was the impact on clinician behavior and patient-important outcomes?	No assessment of clinician behavior or patient important outcomes. However, "could be used at the point of admission to identify more than 20% of patients who have very low risks of needing treatment to control haemorrhage, allowing them to be offered outpatient investigation and management, provided that they have no other major pathology requiring hospital admission". (p. 1320)

Limitations

1) **No patient-demographics were reported by which to gauge illness severity or confounding co-morbidities in applying the rule to our patient population.**
2) **Variables included in derivation model not clearly listed or referenced.**
3) **Individual variable prevalence in both the derivation and validation sets were not provided.**
4) **Blinding of data abstractor and outcome assess was not clearly stated.**
5) **No reporting of LRs or CI's.**
6) **No reporting or prognostic test characteristics (other than ROC AUC) of Rockall compared with Blatchford.**
7) **Limited external validity since only validated in Western Scotland.**
8) **No limitations section.**
9) **Variceal bleeds were not excluded so subjects are a mix of PUD and variceal bleed.**
10) **No time-frame provided on "need to intervene".**
11) **"Substantial fall" in Hg not defined.**

Bottom Line

The Blatchford UGI CDR (see below) may be useful to identify a low-risk subset of patients with suspected UGI bleed from peptic ulcer disease or varices. In the small validation set, absence of all these risk factors has a negative-LR = 0.028 (95% CI; 0.005 – 0.151) which would reduce a pretest probability of 45% to 2% (95% CI; 0.4% - 11%) "need to intervene". Before widespread use of this CDR, the rule needs to be validated in distinct locales. Additionally, an impact analysis on clinician behavior, resource utilization, and patient-important outcomes ought to be assessed.

Admission risk marker	Score component value
Blood urea (mg/dL)	
> 18 but < 22	2
≥22 but <28	3
≥28 but <70	4
≥70	6
Hemoglobin (g/dL) for men	
≥12 but <13	1
≥10 but <12	3
<10	6
Hemoglobin (g/L) for women	
≥10 but <12	1
<100	6
Systolic blood pressure (mm Hg)	
100 – 109	1
90 – 99	2
<90	3
Other markers	
Pulse ≥100 (per min)	1
Presentation with melaena	1
Presentation with syncope	2
Hepatic disease	2
Cardiac failure	2

The Blatchford UGI Intervention Risk Scoring System