Critical Review Form
Clinical Prediction or Decision Rule

Presenter: David Nesbitt

Date: 3/28/2016

Citation:
(PGY-2's): Backus BE et al. **A prospective validation of the HEART score for chest pain patients at the emergency department.** Int J Cardiol. 2013 Oct 3;168(3):2153-8.

Guide		Comments
	What is being studied?	HEART score
1.	**Study Objective**	Prospective validation of the HEART score in identifying ED patients at risk for MACE within 6 weeks of their ED visit.
2.	**Study Design**	Prospective, observational non-intervention study that included 2440 patients at 10 sites in the Netherlands
3.	**Inclusion Criteria**	Any pt presenting to the ED due to chest pain (irrespective of age, pre-hospital suspicions and previous medical treatment)
4.	**Exclusion Criteria**	Pt presenting with only dyspnea or palpitations. Non-ED patients. STEMI patients.
5.	**Outcome Measures**	Primary endpoint: MACE (AMI, PCI, CABG, coronary angiography with procedurally correctable stenosis managed conservatively and death of any cause) within 6 weeks of the ED visit secondary endpoints: six-week occurrence of AMI and death; dx of ACS within 3 months after presentation; performance of coronary angiography within three months after presentation
I.	***Is this a newly derived instrument* (Level IV)?**	no
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. This was a prospective validation on a different patient cohort. Study sites were restricted to the Netherlands however.
II.	**Has the instrument been validated? (Level II or III). If so, consider the following:**	Yes. The authors themselves performed two prior retrospective validation studies.

1a	Were all important predictors included in the derivation process?	It's hard to say, the rule is based on clinical experience/gestalt and medical literature. It is possible that the derivation left out possible predictors for ease of application that may have proven statistically significant. Also, original derivation study was retrospective chart review on 122 patients. Retrospective assessments of historical data particularly if not standardized could lead to significant bias. That stated the predictors included in HEART are in common use clinically.
1b	Were all important predictors present in significant proportion of the study population?	yes
1c	Does the rule make clinical sense?	Yes. The HEART Score includes known historical risk factors, ECG findings, age, cardiac enzymes values, and clinical suspicion.
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)?	yes, and no. Included a more diverse patient population and hospital setting (10 hospitals) however all in the Netherlands which may not be representative of our patient population.
3	*How well did the validation study meet the following criteria?*	
3a	Did the patients represent a wide spectrum of severity of disease?	Yes. There was a wide range of HEART scores
3b	Was there a blinded assessment of the gold standard?	No gold standard was applied to low HEART scoring patients. 91% of AMI's were diagnosed though authors do not state what percent had a "gold standard" study such as a cath.
3c	Was there an explicit and accurate interpretation of the predictor variables & the actual rule without knowledge of the outcome?	yes, blinded cardiologist review of ECGs HEART score was calculated with only with ED intake data using a standardized Case Report Form (CRF) only troponin from first blood sample was used (according to local standards) An algorithm was devised to calculate the TIMI [8], GRACE [9–11] and HEART [6,7] scores automatically

		from the admission data, without interpretations by the investigators.
3d	Did the results of the assessment of the variables or of the rule influence the decision to perform the gold standard?	No/ Maybe. The authors state 419 (17.5%) acute coronary syndrome, 144 (6.0%) AMI diagnosed on admission though they don't report what percent underwent immediate PCI average was 6.9 days (range 0-40) .
4	How powerful is the rule (in terms of sensitivity & specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	No sensitivity, specificity or LR's reported. Unclear why they report results with SD's. C statistic was significant and in fact highest for HEART vs. TIMI or GRACE (Table 4). So moderately helpful, better than what we have (TIMI etc)
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:**	not at the time of this study
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)?	n/a Hard to say. Standardization of data collection forms, blinding of cardiologists, "automatic score generation without interpretation by investigators" help to minimize bias. Clearly less bias than retrospective chart assessments that were non standardized (i.e. their derivation study)
2	What was the impact on clinician behavior and patient-important outcomes?	n/a No impact assessment data provided.

Comments:

1. Prospective, standardized data collection
2. No reporting of sensitivity, specificity with CI's
3. Population was not typical of our local population
4. Use of the HEART score of 0-3 in a low risk population predicted a very low risk of major adverse cardiac event.