Critical Review Form
Therapy

A Comparison of Door-to-balloon Times and False-positive Activations between Emergency Department and Out-of-hospital Activation of the Coronary Catheterization Team, *Acad Emerg Med* 2008; 15:784-787

Objective: **"To determine whether activation of the CCL (Cardiac Catheterization Laboratory) based on diagnosis by a computer-interpreted ECG performed by paramedics in the field would shorten reperfusion times without significantly increasing the number of false-positive activations compared to activation of the CCL by an attending emergency physician (EP) in the emergency department (ED) after brief review of the patient and ECG on hospital arrival". (p. 785)**

Methods: **Retrospective analysis of STEMI patients as part of Harbor- UCLA Medical Center Quality Improvement efforts from May 2007 – March 2008. Paramedics were trained to apply the ECG for 12-lead and to recognize poor tracings, but they were not trained to interpret ECG's. Instead, when the ECG computer algorithm interpreted "acute MI suspected", paramedics were taught to divert to the nearest designated STEMI receiving center and to provide the receiving hospital with advanced notification. Advanced transmission of the ECG is currently not available in Los Angeles County.**

Weekdays, the CCL was field activated by protocol while nights/weekends CCL activation was at the ED physician discretion after arrival of STEMI patients in the ED. STEMI diagnosis was confirmed by an independent review of two attending Cardiologists and included a culprit lesion in conjunction with a positive cardiac biomarker and 1-mm ST-elevation in at least two contiguous leads. A false-positive was defined as ST-elevation without positive biomarkers or a culprit lesion.

History of cardiac risk factors and scene DTB times were abstracted from the medical records by one investigator with no clear chart review methods (Gilbert 1996, Worster 2004). *A priori* a sample size of 18 subjects in each group would be required to detect a 15-minute DTB time difference with power of 90% and $\alpha = 0.05$. The investigators did not conduct any modeling to adjust for baseline prognostic inequalities.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	No. Simple descriptive assessment of two STEMI populations differing by day and hour of presentation.
2.	Was randomization concealed (blinded)?	No.
3.	Were patients analyzed in the groups to which they were randomized?	Not randomized so intention-to-treat is irrelevant.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	"There were no statistically significant differences in the distribution of these variables between the ED activation and field activation group". (p. 785). However, review of Table 1 (p. 786) suggests that the field activation group were older (66 vs. 59), male-predominant (74% vs. 67%), and less likely to have diabetes (26% vs. 39%) or die (4% vs.9%)
B.	**Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1.	Were patients aware of group allocation?	Yes – not randomized or blinded.
2.	Were clinicians aware of group allocation?	Yes.
3.	Were outcome assessors aware of group allocation?	Yes, although they could have been blinded to group allocation.
4.	Was follow-up complete?	No loss to follow-up is reported although the denominator only includes those with identified culprit lesion.
II.	**What are the results (answer the questions posed below)?**	

1.	How large was the treatment effect? * This suggests that the pre-hospital ECG's were not being used in decision-making. The clinical equipoise is whether pre-hospital ECG's used to activate the cardiac cath lab earlier would reduce DTB times. If field-activation subjects still stop in the ED every time, one would not expect that DTB would differ since management is essentially identical.	• During the study period there were 23 field activation and 33 ED activation patients. • False-positive activation rates were 39% (9/23) in the field activation group and 9% (3/33) in the ED activation group (30% difference, 95% CI 8% to 52%). • Mean medical contact to door times did not differ (18-minute field vs. 19-min ED) nor did ED length of stay (19-min vs. 20-min, respectively). • Only one field activation patient bypassed the ED for the CCL and one field activation patient had a prolonged ED LOS 2-hours GI bleed.* • DTB times were only available for 20 ED activation and 13 field activation patients (see reasons on p. 786). • The mean DTB times were 77-min in field activation vs. 68-min in ED activation patients. Removal of the 157-min GI bleeding outlier in the field activation group reduced the mean field activation DTB time to 70-min (mean difference 2-min, 95% CI -13 to 18). • Two patients in both groups arrived when cath lab occupied with field activation (17-min and 18-min) and ED activation (23-min and 31-min) ED LOS similar.
2.	How precise was the estimate of the treatment effect?	The various 95% CI's cross zero suggesting no difference n DTB time for field vs. ED activation.
III.	**How can I apply the results to patient care (answer the questions posed below)?**	

1.	Were the study patients similar to my patient?	Uncertain since disease-free numbers, TIMI sores, and co-morbid illness burden not provided. Presumably STEMI patients presenting at one academic medical center are similar to those presenting to another, but these investigation really don't provide sufficient details to confidently conclude this fact.
2.	Were all clinically important outcomes considered?	No assessment of patient-important outcomes like QOL. Functional status report MI or need for urgent re-vascularization in the subsequent months.
3.	Are the likely treatment benefits worth the potential harm and costs?	Although no formal cost-benefit analysis is conducted or contemplated here, the current findings do not support the investment of scant resources to initiate pre-hospital based ECG diagnosis of STEMI to reduce DTB times.

Limitations

1) **No assessment of disease-free cases in order to assess sensitivity, specificity, and LR's.**

2) **Potential Hawthorne effect in pre-hospital and ED settings.**

3) **No chart review methods so subject to multiple biases. There is no reason outcome assessor cannot and should not be blinded to subject's group assignment (Gilbert 1996, Worster 2004)**

4) **No modeling to adjust for unequally distributed prognostic variables.**

5) **No assessment of QOL, functional status or short-term QOL (POEMS = patient oriented evidence that matters)**

6) **No activation of cath lab based upon pre-hosp ECG. DTB times should not be expected to differ if the pre-hosp ECG do not prompt a clinical management response.**

7) **Since sample size calculation based upon 15-minute difference in DTB and the observed difference was actually 9-minutes, this trial was underpowered to detect a difference between the two-groups.**

8) **No assessment of important prognostic variables like TIMI score, pre-illness functional status, and co-morbid illness burden. Nor did investigators assess time of day or week as a confounding variable.**

Bottom Line

This single-center quality improvement data-based retrospective analysis of confirmed STEMI patients suggests that pre-hospital ECG's in paramedics trained to obtain (but not interpret) ECG's -- and not empowered to activate the cath lab -- produce significantly more false-positive cath lab activations than ED activation protocols without reducing DTB times. These results need to be confirmed in other settings while controlling for confounding variables, including paramedic training and underlying prognostic predictor variables. Patient important outcomes like short-term cardiovascular events and functional status should be delineated in future controlled trials while comparing pre-hospital and ED activation systems as acceptable false-positive cath lab activation rates are defined.