Critical Review Form
Therapy

Impact of the Pre-hospital ECG on Door-to-Balloon Time in ST Elevation Myocardial Infarction, *Catheterization and Cardiovascular Interventions* 2010; 75:174–178

Objective: **"To validate the approach, where patients are transported from the field directly to the cardiac catheterization laboratory (CCL) by emergency medical services (EMS), based on the 12-lead ECG interpretation". (p. 175)**

Methods: **Prospective observational study from October 2003 – April 2008 at three Southeast Michigan hospitals following the initiation of EMS protocols to obtain pre-hospital 12-lead ECG when symptoms were suggestive of STEMI. The pre-hospital ECG was then transmitted to the receiving hospitals ED physician via cellular link to a computer receiving station. If the ED physician determined STEMI on the ECG then the cath lab was activated.**

As a control group the investigators analyzed all patients who came to the ED via self-transport or EMS without ECG obtained. Exclusion criteria included cardiac arrest, fibrinolytic therapy, transfer from an outside institution, or CT obtained before cath lab activated.

The primary outcome was mean door-to-balloon (DTB) time and percentage of patients with DTB time < 90 minutes. Times were obtained from the ambulance call sheets, ED triage records, and medical charts. Secondary outcomes included length of hospital stay, on or off-hours presentation, cardiac risk factors and infarct-related artery.

Data were analyzed using SPSS to evaluate statistically significant differences between continuous data (Student's t-test and ANOVA), ranked data (Mann-Whitney U-test), or categorical data (Fisher's Exact Test if < 5 observations or χ^2-test). The investigators did not conduct an *a priori* or *post hoc* sample size calculation. Nor did the investigators evaluate for variable independence with linear, logistic regression, or Cox proportional hazards modeling.

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. Post EMS protocol evaluation of those with or without pre-hospital ECG.
2.	Was randomization concealed (blinded)?	No. No randomization. All physicians, patients, and outcome assessors knew group allocation.
3.	Were patients analyzed in the groups to which they were randomized?	No randomization, so intention-to-treatis irrelevant.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	No. "A significantly lower proportion Of pre-hospital ECGs were obtained in African–American patients than Caucasian patients (15.8% vs. 75.9%; p = 0.001). [Correction added after online publication December 21, 2009: the value ''75.9%'' has replaced ''38.6%,'' which was included in an earlier online version of this manuscript]. All other baseline characteristics and cardiac risk factors were similar between groups". (p. 177). However, this is not a very valid control group. First, patients who present via car or EMS capability (i.e., urban Detroit EMS) may differ in numerous prognostic ways from those who present with ECG capable EMS (suburban Detroit) including co-morbid illness burden, education level, socio-economic status, health literacy, and symptom duration prior to angioplasty. Second, multiple confounding variables that could impact STEMI recognition and subsequent DTB times were not measured including duration of CP, associated symptoms, prior MI, ASA use, TIMI score, typical vs. atypical symptoms, and the proportion arriving during off-hours. Third, the investigators made no attempt to correct for baseline prognostic inequalities between ECG and no ECG control group – which is essential in non-randomized studies of intervention.

B.	Did experimental and control groups retain a similar prognosis after the study started?	
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 easily have been blinded by investigators.
4.	Was follow-up complete?	No duration of or lost to follow-up reported.
II.	**What are the results?**	
1.	How large was the treatment effect? **This total does not correspond with the total in Table1 (N=241 + 108 = 349) and the investigators do not provide a CONSORT diagram to explain the inclusion/exclusion flow of patients.*	• 609* STEMI patients included in analysis broken down as follows: Hosp A → 386 STEMI patients including 18 with pre-hosp ECG (51%) Hosp B → 89 STEMI patients including 40 with pre-hosp ECG (45%) Hosp C → 134 STEMI patients including 50 with pre-hosp ECG (37%) • The RCA was the predominant infarct-related vessel in both groups (47% in-hospital ECG vs. 61% of pre-hospital ECG). • DTB time was significantly lower when pre-hospital ECG was used In-hosp ECG / Pre-hosp ECG / p –Value Mean DTB time (minutes): 90.5 / 60.2 / <0.001 Hosp LOS: 3.5 / 3.3 / NS Mortality: 2% / 0% / NS • No significant interaction was found between study group and individual hospital and DTB was reduced in pre-hosp ECG at each hospital. • In the in-hosp ECG group there was a significant DTB reduction in patients presenting during working hours compared with off-hours (75 vs. 98 – minutes, p = 0.04). This effect was not observed in the pre-hospital ECG group.

2.	How precise was the estimate of the treatment effect?	Uncertain since no CI's was provided.
III.	**How can I apply the results to patient care (answer the questions posed below)?**	
1.	Were the study patients similar to my patient?	The patients were probably similar-mixed ethnicity middle-aged adults presenting with STEMI by ambulance or private vehicle. To more confidently apply these results to our patients would need more details about co-morbid illness burden and symptom duration.
2.	Were all clinically important outcomes considered?	Absolutely not! As discussed in I-A-4 above, multiple confounding variables were unmeasured and/or unreported by the investigators. Furthermore, the investigators did not assess statistical models to adjust for uneven initial prognostic baselines between the two groups. Finally, they did not discuss important logistical considerations for pre-hosp ECG's like equipment expense and QA monitoring, interventional Cardiologist or EMS acceptance rates, EMS training requirements or false-positive acceptance rates, or how to register/x-ray/lab assess patients who go directly to cath lab.
3.	Are the likely treatment benefits worth the potential harm and costs?	Cannot assess cost benefit based upon this poorly controlled research report.

Limitations

1) **Failure to report important prognostic ACS variables like duration of chest pain, prior MI, ASA use, TIMI score, co-morbid illness burden, SES, health literacy, or proportion presenting during off-hours.**

2) **Failure to statistically adjust for baseline inequalities in prognostic variables. For the one hour outcome of DTB time Cox proportional hazards modeling would have been appropriate.**

3) **No description of outcome assessors reviewing charts for ambulance, ED and cath lab times. Who made these measures? Were they blinded chart abstractors? Were there more than one? If so, how were discrepancies or missing data handled? (Gilbert 1996, Worster 2004)**

4) **No sample size power analysis.**

5) **No description of 1- or 2-sided α-testing for p-values, preset level of significance, or adjustment for multiple comparisons.**

6) **No CONSORT like diagram or description of those excluded.**

7) **No description of false-activation rates or 2x2 tables to assess sensitivity/specificity/likelihood ratios of pre-hosp ECG.**

8) **No description of the logistics for direct-to-cath lab EMS transport. How was registration obtained? Who ordered and assessed the CXR and labs?**

9) **No CI's reported.**

10) **No blinding of outcome assessors.**

11) **No cost-benefit analysis.**

Bottom Line

Three ED analysis of non-randomized prognostic unequal pre-hosp ECG transmitted to ED physician vs. ED-obtained ECG suggests that the pre-hosp ECG can reduce DTB times by 30-minutes and stabilize DTB times during off-hours. The statistical independence and external validity of these findings cannot be assessed by this report.