A quality improvement project for patients resuscitated from ventricular fibrillation in the Twin Cities.

The cardiac catheterization laboratory initiative.

The purpose of this initiative is to promote a system wide quality improvement protocol in all participating hospitals of the Minnesota Resuscitation Consortium (MRC). Starting in mid July 2012 all participating hospitals will provide access to a cardiac catheterization laboratory (CCL) with PCI capabilities within 2 hours from successful field resuscitation of an initially recorded VF/VT arrest.

In patients with initial presenting rhythm of ventricular fibrillation or ventricular tachycardia or who were shocked by an AED, who are successfully resuscitated in the field, there is >70% chance of thrombotic and/or flow limiting lesions.\textsuperscript{1} There are multiple published case series showing that bringing these patients to a CCL is safe and leads to early diagnosis of the underlying etiology resulting in improved outcomes.\textsuperscript{2,3} In addition, patients with witnessed refractory or recurrent VF arrest have a very high likelihood of a culprit thrombotic coronary lesion.

In the Twin Cities, the MRC data from the last six months of 2011 show that 33/40 (>80%) patients that received angiography early on (<6 hours) after resuscitated VF arrest, survived with good neurological function and a total of 36/40 survived to hospital discharge. By comparison, patients that did not get access to cardiac catheterization laboratories had a 33% hospital discharge rate and only 27% with good neurological function.

We anticipate that early access to CCL after resuscitated ventricular fibrillation cardiac arrest will improve survival and hospital discharge rates with good neurological function compared to our one year aggregate baseline data recorded by the MRC in 2011.

Consent and IRB process: This is a quality improvement project based on published best evidence and as such the protocol implementation is exempt from informed consent. Data will be monitored closely from the CARES database in the Twin Cities and close monitoring and patients tracking from CCL coordinators in each hospital. Project coordinators will be paid by the MRC and Heart Rescue Funds as well as from additional grant money/ funds from the University of Minnesota that are currently available. Grants are going to be available for up to 10% FTE salary support for data tracking and record keeping through the MRC.
**Implementation strategy:** Starting July 6th, 2012 participating hospitals will start receiving patients from the major emergency medical services in the Twin Cities.

**Inclusion criteria:** Resuscitated VF/VT/AED shockable first recorded rhythm arrest, witnessed or unwitnessed, age >18 and <75, presumed cardiac etiology cardiac arrest, emergency medicine physician verification of the presenting initial rhythm and verification of the inclusion criteria, comatose or conscious patients.

**Exclusion criteria:** PEA or asystole as first recorded rhythm, known DNR/DNI, obvious non cardiac etiology, obvious GI bleeding, terminal illness (e.g. terminal cancer) and known acute intra cranial hemorrhage of various etiologies.

After inclusion criteria are met, patients will go to the CCL within two hours of ED arrival by utilizing established ST elevation myocardial infarction protocols. (NOTICE: ST-elevation on the ECG is not needed to be included in the protocol!)

**Implementation strategy:** Hospitals that will participate will agree to implement the new strategy of early access to the CCL within 2 hours from arrival to the ED. How the participating centers choose to evaluate these patients is left to the discretion of individual groups. Each center will have to implement a protocol that will clearly state if they want those patients held in the ED first and under which circumstances direct access to the CCL will be implemented. For example, during the day at the UMMC, the emergency department will be bypassed and patients will be treated as STEMIs brought directly into the CCL, but during the evening or night hours the patients will be held in the ED until CCL staff arrives for patient safety purposes. The rest of the centers will have to provide the MRC the exact strategy that they will follow so that the EMS directors have a clear picture of the available options. The only protocol obligation for the cardiology groups is that they will have to provide access to the CCL within two hours from the ED arrival with a goal to optimize and expedite this time.

Based on best practice guidelines we also ask the participating groups to collect the following data for the patients received in their centers:

**Data Collection for Catheterization Lab Initiative as part of QA/QI Monitoring**

1. Standard CARES data
2. Troponin at 24 hours post arrest
3. In hospital hypothermia times
   a. Time to target temperature
   b. Duration at target therapy
4. CCL times
   a. 911 call to CCL door
   b. ED door to balloon if angioplasty
5. CCL data (including entire catheterization report)
   a. Number of vessels affected
   b. Stents placed # and location
6. Neurological evaluation report at discharge (implement a standard evaluation of this patients with a neurological assessment at discharge with clear documentation of functional evaluation)
   a. CPC
b. MRS
7. At least one left ventricular function ejection fraction evaluation before hospital discharge or at least 3 days after the arrest.
8. Was pt readmitted within 6 months of discharge, and why?

Responsibility for data acquisition by participating centers:
1. Every 3 months a list of the patients should be reported to Lucinda Klann (lucinda@umn.edu) by the CCL medical directors to be identified in CARES so that a full record of all the patients is kept centrally securely and verified.
2. All data will be sent to MRC for aggregation of the complete data set and once data are verified de-identification will occur as per protocol under CARES.

Minnesota Resuscitation Consortium data management obligations.
The MRC under the auspices of Department of Health will centrally manage the data as per standard protocol for every other arrest report in CARES. All data will be kept securely as per MRC protocols for current data sharing. Aggregate data will be kept by the MRC. No information will be made public or be available for anyone except for biannual reports that will provide data on outcomes for each center individually (and not to the group) and their comparison to the average MRC outcomes.

Privacy/Permissions
The intention of this initiative is to improve care for patients post resuscitated VF/VT. After one year of operation, the collective results will be published to report the experience and outcomes in the twin cities to share with the rest of medical community.
If a trend is identified in regards to timing of CCL and survival, we will apply as a consortium for funding to NIH to perform a randomized controlled trial that will be run through the MRC infrastructure and its participating centers.

Scientific Background for the proposed initiative: The American Heart Association (AHA) has recently issued a Policy Statement calling for the establishment of regional systems of care to manage out-of-hospital cardiac arrest (OHCA) patients. The proposed model is patterned after similar successful programs for major trauma, ST-segment elevation myocardial infarction (STEMI), and stroke. The Policy Statement recommends a comprehensive, regionalized approach to post-resuscitation care that includes therapeutic hypothermia, goal-directed management of critical physiological functions (i.e., organ perfusion, ventilation, glucose levels), and early coronary angiography/percutaneous intervention (PCI) when indicated.

Up to 71% of OHCA patients have coronary artery disease and nearly half have an acute coronary occlusion regardless of the post resuscitation ECG findings. Even under the best reported circumstances, mortality in the overall post arrest population who have been initially resuscitated is approximately 50%. An aggressive revascularization approach, has been shown to result in improved survival from OHCA.

The role of PCI in OHCA patients
Twenty-five percent of patients who survive OHCA to hospital admission have evidence of STEMI (including new left bundle branch block) on their presenting ECG. The American Heart Association 2010 Guidelines on Cardiopulmonary Resuscitation and Emergency Cardiac Care state that "aggressive treatment of ST elevation myocardial infarction (STEMI) on the presenting ECG should begin as in non-cardiac arrest patients, regardless of coma or induced hypothermia".
They also state that "because of the high incidence of acute coronary ischemia, consideration of emergent coronary angiography may be reasonable even in the absence of STEMI." The basis for this recommendation is the recognized role of acute coronary ischemia as a dominant mechanism in the setting of OHCA. The potential contribution of coronary ischemia in OHCA was initially observed in a post mortem case series as well as in angiography data obtained in survivors of sudden cardiac death.

Coronary angiography followed by successful coronary intervention has been shown to be an independent predictor for survival and improved neurological outcomes for patients with OHCA irrespective of the presence or absence of STEMI on the presenting ECG. The supportive data for emergent coronary angiography is most compelling among patients with manifest ST elevation on the surface ECG as the benefits of emergent reperfusion of the infarct related artery is well established in this setting. In a retrospective study limited to cardiac arrest cases, Garot et al. reported on outcomes in 186 consecutive patients over a 10 year period undergoing immediate percutaneous coronary intervention (PCI) after successful resuscitation for cardiac arrest complicating acute myocardial infarction with STEMI on the initial ECG. PCI was successful in 87%. Survival at 6 months was 54% and survival free of neurological sequelae at 6 months was 46%.

Bendz et al. compared 40 patients treated with primary PCI after OHCA with a reference group of 325 patients without CA also treated with primary PCI in the same period. In-hospital mortality was 27.5% in the CA group and 4.9% in the STEMI without CA group. The two year mortality rate was unchanged in the CA group and rose to 7.1% in the non-CA STEMI group. Gorjup et al. reported on 135 STEMI-patients between 2000 and 2005 resuscitated after CA. Catheterization was performed in all patients, of whom 64% remained comatose during the initial evaluation. In comatose patients, primary PCI was performed in 79% with a procedural success rate of 82% demonstrating that successful PCI can be urgently accomplished in comatose post arrest patients. Survival to hospital was 51% for comatose post arrest patients, 100% for non-comatose post arrest patients, and 95% for patients with STEMI and no CA.

In an angiographic analysis of 84 consecutive patients with OHCA aged 30-75 years by Spaulding et al., 60 subjects were noted to have a severe coronary stenosis and 40 (48%) had an occluded coronary artery, irrespective of the presence or absence of STEMI on the initial ECG. On multivariate logistic-regression analysis successful angioplasty was noted to be an independent predictor of survival (odds ratio, 5.2; 95 percent confidence interval, 1.1 to 24.5; p = 0.04). The same group of investigators confirmed their findings in the larger PROCAT Registry which performed urgent angiography in 435 of 714 patients with OHCA without an obvious extra cardiac cause. Immediate coronary angiography in this population revealed a significant stenosis in 96% (128/134) of subjects with manifest ST elevation on surface ECG after return of spontaneous circulation (ROSC) and in 58%, (176/301) of patients without ST elevation. As in the prior study, multivariable analysis showed successful coronary angioplasty to be an independent predictive factor of survival, regardless of the post resuscitation ECG pattern (odds ratio, 2.06; 95% CI, 1.16 to 3.66). This cohort of patients 70% of the patients resuscitated had VF/VT as presenting rhythm.

Strote et al. evaluated a retrospective cohort of 240 patients with OHCA with ventricular fibrillation (VF) or pulseless ventricular tachycardia (pVT) as the presenting rhythm. Survival was greater in those patients undergoing coronary angiography within 6 hours of presentation compared to later than 6 hours or not at all (72% vs. 49%, p = 0.001). Seventy-five percent of patients in the <6 hour group had STEMI on the presenting ECG, leading these authors to conclude that their data support the idea that all patients resuscitated from OHCA...
caused by VF or pVT should receive early cardiac catheterization and PCI if indicated. **In this cohort 100% of patients had VF/VT as presenting rhythm.**

**Ventricular Fibrillation/ Ventricular Tachycardia population:**
In the above referenced studies, the majority of patients included in the reported cohorts (varying from 70-100%) were resuscitated victims that presented with initial rhythm of VF/VT. Therefore the evidence best supports implementation of the proposed strategy in this population.

In summary, there is strong data supporting the Level I AHA guideline for taking all post arrest patients with STEMI to the catheterization laboratory immediately irrespective of the presence or absence of coma, and there is increasing evidence that patients without evidence of STEMI on presenting ECG resuscitated from VF/VT may also benefit from early intervention.

**Impact on number of patients treated:**
Based on two large randomized trials with CPR including a total of 14,000 patients, it is apparent that the presence of VF/VT is the single most predictive variable of MRS status at hospital discharge, present in about 33% of all cases, but accounting for approximately 90% of subjects with MRS≤3. Therefore any significant increase in the survival rates of the VF population would translate to an overall survival for OHCA patients with a factor of 0.9. Currently the overall survival in Minnesota from VF arrest (witnessed and unwitnessed) is 36% (for witnessed VF is 45%). In all the published literature the average survival of patients that get early access to CCL varies from 60-80%. Of course the true effect would be smaller since these are highly selected patients and there is physician bias at play. Assuming that the true effect would be smaller and overall survival would be closer to 55-60% we could still be close to doubling the overall survival of that group of patients (VF/VT presenting rhythm) and OHCA population as a whole.

**Minnesota goal:** Currently in Minnesota there are 300-400 patients/year that are treated conservatively after VF/VT arrest. From those, a small proportion (<20%) gains access early to cardiac catheterization laboratories (within 2 hours), mostly patients that present with STEMI on the post arrest ECG. We anticipate that the new protocol would increase the proportion to 80-90% of the patients and significantly increase the overall survival rates for MN.

On behalf of the Minnesota Resuscitation Consortium and the EMS directors

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References:


