

ICCR Rotation
IRB Proposal
11/12/09
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Examining Outcomes after Cardiopulmonary Resuscitation in Cancer Patients

Study Purpose and Rationale:

Current hospital practice dictates that all patients will receive full cardiopulmonary resuscitation in the event of a cardiac arrest. Full recovery from a cardiac arrest - including discharge from the hospital and a return to normal life - represents the apex of modern medical care and quite simply a life saved. Current data indicates that this ideal scenario following a cardiac arrest is unlikely. Outcomes following the administration of CPR are typically poor. While many patients have a return of spontaneous circulation (ROSC), a minority of patients survive to hospital discharge (approximately 17%).¹ While some patients or health care proxies elect to forgo CPR by signing DNR (do not resuscitate) forms, there exists a severely ill co-morbid patient cohort that maintains full code despite poor outcome data and minimal chance to survival to hospital discharge.² There are several issues with this current policy. 1) the majority of patients when surveyed demonstrated an overly optimistic estimate of post-CPR survival to discharge;³ 2) most physicians do not talk to patients regarding survivability statistics;³ 3) the majority of physicians would sign a DNR form for themselves if they had a terminal medical condition and survival to hospital discharge was low (87% of physicians surveyed would want withdrawal of care if death was imminent and 95% of physicians would wish to be DNR in the setting of metastatic lung cancer);⁴ 4) within certain patient cohorts survivability to hospital discharge is 0 or close to zero and as such there are clinical and ethical questions regarding its practice;⁵⁻⁷ 5) CPR may cause cracked ribs, may include electrical shocks, may separate the patient from his or her family during the final moments of life;⁷ 6) there is an economic cost associated with each CPR and if ROSC with transfer to or continued ICU level care (Lee et al describes CPR as the most cost ineffective medical intervention - costing \$225,000 per quality adjusted life year).⁸

The purpose of this study will be to evaluate CPR data and survivability to discharge in the adult population at a large tertiary academic medical center (Columbia-Presbyterian) and focus on a specific cohort of patients - cancer patients. This study will analyze data from a 10 year period from 1998-2008. The study will look to reaffirm low survivability despite new medical technologies that have arisen since the 1980s and 1990s when many survival studies were done. If the cancer patient cohort has a lower survival rate to discharge after CPR, this can be used for both individual decision making and perhaps hospital policy. While recognizing the inherent benefit of using CPR as a default

mechanism for nearly all hospital patients, it may be inappropriate for certain patients – particularly patients with diffuse metastatic cancer. This data can be used by physicians and patients to help make end of life decisions. The data can serve as a tool to re-examine current hospital policy regarding CPR as a default for all patient populations.

Hypothesis:

This study looks to re-affirm historically low survival data following CPR. When comparing non-cancer CPR patients to an active cancer cohort, it is proposed that the cancer patients will have statistically lower survival to hospital discharge.

Study Design and Statistical Analysis:

Conceptual and Operational Definitions:

An adult patient will be defined as any patient over age twenty five. A patient will have to be admitted to the hospital to be considered in this study. A cardiac arrest will be defined as the having no palpable pulse, no detectable blood pressure and no effective respiration. The study will exclude all patients with DNR orders who have a cardiac arrest but do not undergo CPR. Cardiopulmonary resuscitations are conducted using ACLS guidelines and should include chest compressions to qualify as a CPR event.

The cancer patients in this study should have an active diagnosis of cancer with either a new diagnosis, current symptoms from the disease, or treatment within one year prior to hospitalization. The goal will be to exclude patients in remission or with indolent disease not contributing to pre-arrest morbidity or hospitalization. A metastatic cancer patient will be documented to have Stage IV with distant metastasis and meets accepted guidelines for metastatic disease in that cancer type.

The primary end point of the study will be survivability to hospital discharge after cardiac arrest.

Study Design:

This study will assess data from the Columbia Presbyterian Hospital System from 1998-2008 using the Data Warehouse to obtain medical records from hospital admissions. Over this ten year period, any adult patient (over age 25) admitted to the hospital will be separated out if they had a cardiac arrest and cardiac resuscitation measures were undertaken. Two groups will be separated from this cohort of patients - 1) cancer patients; 2) all other patients. Only first time CPR events would be collected - and any patient with multiple CPR events during hospitalization would only be counted one time. All persons in the study will be assessed for survival to discharge. Within the cancer

patient group, patients will be further separated into metastatic cancer and local disease. The endpoint will be survival to hospital discharge. This will be a retrospective cohort study.

Statistical Analysis:

A chi square test will be used to compare the percentage survival to hospital discharge within the two main study groups cancer patients and all other adult patients. The following data from previous studies will be used to obtain power analysis estimates of 80% and a p value <.05. Estimated Survival to discharge in all patients - 17%;¹ Survival to discharge in cancer patients - 6.2%.⁹ Pre arrest morbidity studies indicate approximately 10% of CPR events are from patients with cancer as their primary diagnosis.² This data will be used to account for unequal numbers of subjects in each group. Using the chi square test on the ICCR web-site which use equations from J.L. Fleiss, et al and in turn using the above data set, sample size can be estimated to be requiring 923 (all patients) subjects in group 1 and 92 subjects in group 2 (cancer patients) to obtain sufficient power for the study.

Subjects Selection:

This study will look at all admitted adult patients at Columbia Presbyterian Medical Center. Any adult patient with a cardiac arrest will be included in the initial arm of the study and will be examined as a group to assess for survivability to hospital discharge. Although this general population may not be representative of all hospitals, it may be reflective of a large urban academic medical center. The cancer patient arm will include any adult over 25 years of age with an active diagnosis of cancer. Any patient with a principle diagnosis of cancer during hospitalization or requiring treatment anytime in the year prior to admission will be considered to have an active diagnosis of cancer. This study will exclude any cancer patients thought to be in remission and without known active disease.

Miscellaneous:

Confidentiality of Study Data:

This study will request permission for all data from the Columbia IRB board, and ensure confidentiality of all patient data information. Given the nature of the study, no formal consent will be obtained from the individual patients.

Limitations:

Using a single site raises the risk for institutional bias and lack of generalizability. The benefits include more modest resource allocation and simplicity. There can be some element of generalizability to other large academic medical centers. In addition, a single site offers the benefit of overcoming any inter-institutional variances in regards to coding, documentation, hospital policy, average lengths of hospital stay, and percentage of patients with DNR orders.

Another limitation of the study is sample selection. It will be possible that some patients with cardiac arrest may have occult malignancy and not be in the appropriate cancer arm of the study. Further problems arise when a patient has many diseased organ states and cancer is only one of several potential reasons for infirmity. The establishment of a subgroup of metastatic cancer is limited by the lag time between having diffuse metastasis and confirmation with radiological, pathologic, histologic, or other clinical markers.

For simplicity the study uses a single endpoint of survivability to hospital discharge. This does not account for functional status at the time of discharge. It also does not account for neurologic status at the time of discharge – prolonged CPR may cause irreversible anoxic brain injury. While the study can analyze where discharged patients went (home, nursing home, hospice), it would be strengthened by morbidity and mortality data following discharge and likelihood to return to the hospital.

The study aims to facilitate discussion regarding end of life care and overall hospital policy. The findings of the study should be looked at in context to past study results. Ultimately, decisions regarding end of life care must be sensitive to personal choices and ethical considerations.

Works Cited/References

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