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The utility of using physician assistants in the pre-hospital setting

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Thesis

THE UTILITY OF USING PHYSICIAN ASSISTANTS IN THE PRE-HOSPITAL SETTING

by

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ABSTRACT

The foundation of emergency medical services is based on a system that allows emergency personnel to respond to medical and surgical emergencies in an efficient manner. However, the system we know today hasn't always been as efficient. There have been numerous advances that have shaped the EMS system today including training dispatch operations, creating a national scope of practice and guidelines for emergency medical technician and paramedics, as well as standardizing training for EMS personnel. [1] In countries around the world, EMTs and paramedics are not the only personnel responding to calls, more advanced personnel, including physicians, on EMS vehicles are a standard practice unlike in the United States. The objective of this study is to investigate whether the implementation of physician assistants on emergency medical service vehicles affects patient outcomes. The emergency type that was selected for this study was an out-of-hospital cardiac arrest as they are one of the most well-studied emergencies in the United States. The development of EMS guidelines has helped target out-of-hospital emergencies including cardiac arrests. The implementation of the "chain of survival" has been shown to have higher survival rates when implemented early and optimized. [2]

The proposal of this study entails physician-assistant EMS vehicles to respond to cardiac arrests in the Boston area over a twelve-month period with follow-up for at three end points including three, six, and twelve months. The goal for the patient population is approximately 2,000 participants and utilizes software that will dispatch either a physician assistant-EMS or a paramedic unit that will practice under their scopes of practice and under the Massachusetts State protocols for cardiac arrests. The study will use electronic medical records from the Boston EMS EMR as well as from the receiving facility and will determine if there is a statistical difference in patient outcomes between the physician assistant unit and the traditional paramedic unit.

This study is novel in that it is the first of its kind to study the utilization of physician assistants in the pre-hospital emergency medical setting. This study would explore the idea of integrating PAs in more capabilities than those in the hospital setting and how this could affect patient outcomes overall.

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LIST OF ABBREVIATIONS

ATP ..... Adenosine Triphosphate

BU ..... Boston University

CPR ..... Cardiopulmonary Resuscitation

EMS ..... Emergency Medical Services

EMT ..... Emergency Medical Technician

NHTSA ..... National Highway Traffic Safety Administration

PA ..... Physician Assistant

INTRODUCTION

Background

Emergency medical services have evolved into a system that can adequately respond to medical and surgical emergencies in an efficient and prompt manner. In the United States, emergency medical personnel include emergency medical technicians, paramedics, and nurses that perform their abilities under of the scope of either Basic or Advanced Life Support. These EMS providers respond to a wide array of emergencies in the setting of patients that become ill, are injured at home, in the field, or at work. [3] While these personnel are trained to execute many treatment modalities based on their assessments and protocols, they are not independent clinicians. [3] The idea of integrating physician assistants as providers with expanded skill sets and treatment privileges under a supervising physician within the pre-hospital emergency setting is a novel idea and has the potential to bring benefits to emergency medical services by enhancing the level of medical expertise of personnel that can respond to emergencies. The physician assistant profession requires extensive training and knowledge to be able to diagnose, provide treatments, and management medical conditions. The addition of PAs would allow for seamless collaboration and coordination between pre-hospital and post-hospital care.

Cardiac arrest is one of the most well studied emergent medical conditions. There is a tremendous need for providers to practice evidence-based medicine as cardiac arrests are the most significant health concerns today and can have fatal results with increased morbidity and mortality. Early recognition and initiation of cardiopulmonary resuscitation have been shown to lead to better patient outcomes. Currently, paramedics

have the highest level of training to manage a cardiac arrest but they are rarely exposed to out-of-hospital cardiac arrests with an average of two arrests per year in a population size of 5.7 million in Australia. [4] In countries around the world, it is not uncommon to have physician equipped ambulance units responding to emergencies. Recent studies have investigated the relationship between dispatching a physician-EMS vehicle and patient outcomes in countries outside of the United States. In the US, physician assistants were created to aid in the delivery of healthcare when there was a shortage of physicians. Physician assistants carry extensive medical knowledge, can provide comprehensive care for various medical conditions, and could help improve access to care. Overall, the introduction of physician assistant on EMS vehicles in the United States to help treat and manage cardiac arrests is a novel idea and would benefit from further research to determine the effects on patient outcomes.

Statement of the Problem

While in countries around the world have adapted physicians and other advanced practitioners, like physicians on EMS vehicles, this is not an accepted or adapted practice in the United States. The US healthcare system has faced an increased demand for patient care, which gave rise to the physician assistant profession in the early 1960s.[5] Studies in several European countries have shown better patient outcomes with an advanced practitioner, namely physicians, responding when examining survival rates and patient satisfaction following hospital admission. Currently, cardiac arrest is one of the most well studied emergencies and patient outcomes benefit the most when providers can recognize

and initiate management early. It is common practice in the US for paramedics to respond to out-of-hospital cardiac arrest and operate under the guideline of Advanced Cardiovascular Life Support (ACLS). However, there is limited research on how patient outcomes would be affected if physician assistants were responding to cardiac arrests in the pre-hospital setting. Physician assistants work under the supervision of their supervising physician but their scope of practice is determined by the following parameters: education, experience, state law, policies of employers and facilities ,and the need of their patients. [6]

Hypothesis

The introduction of physician assistants will improve overall patient outcomes of those who suffered from a cardiac arrest due to their ability to recognize symptoms early, initiate high-quality CPR, and provide medications that are not in the scope of a paramedic.

Objectives and specific aims

Based on the lack of utilization of advanced practice providers on emergency medical vehicles, this study set out to quantify the survival benefit for patients that endured an out-of-hospital cardiac arrest when attended by a physician assistant. The objective is to quantify survival outcomes at three different time intervals of three, six, and twelve months after hospital discharge after cardiac arrest.

Specific Aims:

- Explore the utility of using physician assistants for pre-hospital care in the setting of cardiac arrests
- To investigate is early administration of antiarrhythmics improve mortality and morbidity rate in patients with ventricular fibrillation
- To investigate if more advanced providers provide higher quality care based on the measure of patient satisfaction

REVIEW OF THE LITERATURE

Overview

History and Evolution of EMS

Emergency medical services (EMS) is one of the most essential health care services offered in the pre-hospital setting and plays an integral role in saving lives while reducing mortality and morbidity. [7] It is a complete system structured to respond to medical and surgical emergencies within the community with prompt and adequate care. Over the past decades the EMS system has evolved to become a much more efficient system. In the late nineteen-sixties, cities were composed of numerous competitive ambulance services that were uncoordinated and provided little to no lifesaving care. Ambulances were equipped with merely a radio, first-aid kit, and oxygen tank which is a stark contrast from the equipment on ambulances today. [1] Since then, there are multiple organizations and laws that have worked to optimize the care that is delivered via emergency medical services. Organizations like the Committee on Injuries of the American Academy of Orthopedic Surgeons and the Trauma Committee of the ACS and AAOs created the first ambulance course that was able to train approximately 2250 personnel in 1970 while also providing courses for physicians and nurses in the emergency department on how to be better equipped when receiving life threatening emergencies. [1]

The need for and importance of emergency medical services has piloted a new and greater standard of care than in the 1960s. Most states have now adopted the National

Highway Traffic Safety Admission (NHTSA) 81-hour Emergency Medical Technician (EMT) training course as well as most ambulances are equipped with 2-way radios and a greater variety of medical equipment. Improvements were made regarding the technology that was being applied to EMS vehicles specifically regarding cardiac care. Of note in the early 1960s, myocardial infarctions were one of the leading causes of death in America which prompted a focus on providing care to reduce mortality in the pre-hospital setting. This gave rise to the "Heart mobile" which was considered the first vehicle designed as Mobile Coronary Care Unit in the United States.[8] This EMS vehicle was stationed at the living quarters of paramedics on a 24 hour shift. Once paged, the on-duty physician met the paramedics at the emergency room and then promptly responded to the emergency. This idea helped launch a new era of emergency medical services that could provide specialized care for higher acuity emergencies Efforts were also made to standardize training on a national level in the late 1970s. Several different organizations have designed a basic and supplementary course to standardize training. Ultimately, the goal was to develop basic definitions of care and guidelines for those providing emergency care. Most states today have created their own standards for their trainees; however, all trainee's must undergo examinations by the National Registry that helps standardize care nationally. [1] Around this time, protocols were being developed for dispatchers known as "Medical Priority Dispatching" and was first introduced within the Salt Lake Fire Department. There were three major components to this new dispatching service: interrogation questions, pre-arrival instructions, and response determinants for the level of response. This system helped created a formal training protocol for dispatchers and

help decrease the EMS abuse burden. Medical dispatch has evolved over the last several decades in that it is now viewed as part of the medical care system in which they can provide multi-step process of emergency care. [9] Overall, advances in protocols for dispatchers allowed for better recognition of emergencies that allow for better patient care performed by the prehospital provider.

Emergency Medical Systems and Scope of Practice

The emergency medical services systems can be classified by the level of scope including Basic Life Support (BLS) and Advanced Life Support (ALS). The scope of practice of BLS units usually include cardiopulmonary resuscitation, fracture splinting, full immobilization, and oxygen administration. [10] Advanced life support units are equipped to perform all the BLS capabilities in addition to more advanced procedures like endotracheal intubation, intravenous line placement, fluid replacement, needle-chest decompression, and administration of certain controlled substances. The table below shows the cardiovascular capabilities of several providers that can act within either the scope of BLS or ALS. A key distinction to notice is the ability to interpret and manage; paramedics have these capabilities on EMS vehicles but are limited in their breadth of knowledge. In several countries around the world, they utilize both paramedics and physicians on ambulances. In the United States, the healthcare system is a comprised of a mixture of public and private entities that include for-profit and nonprofit insurers and healthcare delivery organizations, whereas in many European countries citizens are enrolled in free public healthcare. For this reason, trialing physician assistants (PA) on EMS vehicles would be more cost-effective for the United States than using physicians.

In addition, physician assistants in European countries have a primary care focus while in the United States they can participate in a wide array of specialties.

A physician assistant is a skilled healthcare professional who works under the supervision of a licensed physician. Their abilities include obtaining histories, performing physical exams, diagnosing, and managing medical conditions. The PA profession was constructed in the mid- 1960s with the idea that they could aid and improve the healthcare delivery. [11] Physician assistants are trained under the same "allopathic model" that physicians are training under and allows PAs to manage conditions based on evidence-based medicine. They are trained to provide general medical care to a diverse population. In order to qualify for practice, PAs must graduate from an accredited education program, pass examinations administered by the National Commission on Certification of PAs, and obtain licensing and credentialling withing their state of practice. [12] PAs have been implemented in various fields of medicine including in emergency rooms, on medical floors, and even assisting in the operating room. PAs are not only a well-accepted profession in the United States, but also in countries like Canada, the Netherlands, Australia, South Africa, and Scotland. [12] At this time, PAs are not utilized in the pre-hospital setting, however their broad set of skills and clinical decision making would be a great asset in pre-hospital care.

Table 1: Scope of practice – cardiac competencies

Skill – Cardiovascular/ Circulation	EMT	Paramedic	PA
CPR	X	X	X
Cardiac Monitoring – 12 Lead ECG acquisition	X	X	X
Cardiac Monitoring – 12 Lead ECG – interpretive		X	X
Cardioversion – electrical		X	X
Transvenous cardiac pacing – monitoring and maintenance		X	X
Transcutaneous pacing		X	X
In-Hospital Medication Administration			X

EMS Systems Around the World

While the United States has developed their own standard of care for emergency medical services ranging from a combination of ambulances with emergency medical technicians, paramedics, and registered nurses', it is important to note that there is no standardization among countries when it comes to EMS. Several countries have adapted their own standards for EMS. [13] For example, emergency medicine in Germany is practiced by primary care physicians on 24-hour house call services, hospital admission areas, and EMS. This model is the "Franco-German model" of EMS delivery. This model focuses on providing hospital services to the patient. They can achieve this by having highly trained physicians on ambulances that have an extensive scope of practice and are able to make complex medical decisions on site. (6) The focus is less geared towards bringing the patient to the nearest hospital which is more in line with the Anglo-American approach. [13] Another major difference between the two models, Anglo-American, and Franco- German, is the bypassing of emergency departments in the Franco- German model. Patients that require transport are brought straight to the hospital wards for direct admissions. [13] Germany still utilizes emergency rooms as their standard of care, but also practices direct admission care which differs to the United States.

In the United Kingdom, a different model of emergency medical services has been proposed called the Emergency Care Practitioner Scheme (ECP). [10] This model was proposed as half of the patients that are transported via ambulance are discharged without need for follow-up care or referrals. The goal of these scheme is to decrease the amount

of unnecessary ambulance transportation to emergency departments. On these units are Emergency Care Practitioners who can make autonomous clinical decisions within their scope of practice. Their practice is based on the key concept of "chain of survival" that has been studied in the setting of cardiac arrest. The chain of survival in cardiac arrest follows a specific sequence of pattern recognition illustrated in Table 2 and if executed effectively and efficiently serves the purpose of bridging pre-hospital and primary health care seamlessly.[10] Studies show that overall patient satisfaction were higher in the categories of "Thoroughness of assessment or examination" and "Explaining what happens next" for emergency care practitioners than their counterpart EMTs and paramedics. [14] This finding is most likely a reflection of the educational focus on structured assessment and clinical decision making.

Table 2. Chain of survival in patients with cardiac arrest

Chain of survival in cardiac Arrest
1) Early recognition of warning signs
2) Activation of EMS
3) Basic CPR
4) Defibrillation
5) Intubation
6) IV administration of drugs

Cardiac Arrest

Cardiac arrest is a significant health concern around the world that often leads to death or increased morbidity. The American Heart Association released the Heart and Stroke Statistic of 2022 that revealed that there are more than 356,000 out-of-hospital cardiac arrests that occur annually with 90% of them being fatal. [15] Cardiac arrest patients many times undergo extensive ischemic injury to vitals organ and can result in multifaceted injury cascade. [16] Survival of cardiac arrest patients that undergo resuscitation is a major point of interest in the world of EMS. Cardiopulmonary resuscitation (CPR) allows for delivery of oxygen which preserves the myocardium. With the delivery of CPR, adenosine triphosphate (ATP) production occurs which allows for ion transport and repolarization of the cardiomyocytes. In turn, ATP production supports the restoration of spontaneous electrical rhythm. [16] For this reason, there has been major efforts to teach the public the importance of knowing when to initiate bystander cardiopulmonary resuscitation. In the setting of an out-of-hospital cardiac arrest, early initiation of CPR by a bystander has been shown to improve overall survival rate. For example, Hasselqvist-Ax et al. found that when CPR was initiated before arrival of EMS there was a 30-day survival rate of 10.5%, whereas when CPR was not initiated before EMS arrived there was only a 4.0% in 30-day survival rates. [17] Overall, out-of-hospital cardiac arrests are a major health concern and currently one of our best tools to increase survival rate in these patients is the early recognition and initiation of good quality cardiopulmonary resuscitation. For this reason, the implementation of advanced

practitioners that can accurately recognize and deliver good quality CPR could have beneficial effects on patient outcomes.

The differentiation of the etiologies for cardiac arrests is important because it gives providers a better understanding of the underlying disease process which can be helpful in determining the appropriate medical interventions. The three main etiologies of cardiac arrest is arrhythmias, like ventricular fibrillation, cardiomyopathy, and coronary artery disease. [18] Ventricular fibrillation and pulseless ventricular tachycardia are two cardiac arrhythmias that can lead to sudden cardiac death. [19] Both of these arrythmias have well defined algorithms that have been helpful their management. Treatment of unstable adult tachycardia is indicated by a heart rate of greater than 150 beats per minute with a combination of other symptoms including hypotension, altered mental status, systemic signs of shock, chest discomfort, and signs of acute heart failure. [20] Based on the interpretation of the tachyarrhythmia, providers can either perform synchronized cardioversion or consider administering an antiarrhythmic, beta blocker, or calcium channel blocker. While paramedics can administer adenosine within their scope of practice, they cannot prescribe beta blockers or calcium channel blockers which are common medications given to patients with arrythmias. An interesting area for future research if there are beneficial outcomes associated with PA-units, is expanding the medications that can be administered in the pre-hospital setting to include calcium channel blockers and beta blockers. While physician assistants are not approved to prescribe calcium channel blockers or beta blockers in the pre-hospital setting currently, the study of the utility of PAs on EMS units could help pilot new standard of care.

Cardiac arrests are one of the most well studied emergencies in regards to treatment and survival rates. Patients with cardiac arrest in the pre-hospital setting benefit the most from quick recognition for the need of advanced life support. Böttiger, B. W., et al. investigated the long-term outcomes of patients that had a cardiac arrest outside of the hospital setting, in mid-sized urban and suburban areas, and were treated with a physician staffed ambulance unit. The study was based in Germany where physicians on emergency medical vehicles is an accepted practice. The main outcomes they assessed in this study was return of spontaneous circulation, hospital discharge, and one year survival. [21] The study included two tested populations: the EMT BLS units and one physician staffed ALS unit. The EMT units were staffed with two EMTs that underwent a minimum of 6 months of emergency medicine education that included basic life support training and how to use defibrillation. The other unit was made up of one EMT and one physician. The physician on the ALS unit was part of the anesthesiology and surgery department who had a minimum of two years' postgraduate clinical experience and additional advanced life support training. Pre-hospital diagnosis of a cardiac arrest was done using the guidelines and recommendations of the American Heart Association. The AHA used the Utstein template style which focuses on recording performance and outcomes by outlining clear definitions and indicators to ultimately measure and improve patient outcomes. [22] Through this style, they collected data on whether the arrest was witnessed or not (if it was, then by whom, a medical service provider or bystander), who initiated CPR, which cardiac rhythm was present, if return of spontaneous circulation was achieved, if the patient survived to be discharged, and one

year survival after discharge. To compare the utility of the two systems of basic life support and advanced life support, inclusion criteria consisted of patients whose cardiac arrest was witnessed by a bystander and had an initial rhythm of ventricular fibrillation of cardiac etiology. At the time of discharge, patients were assessed according to the Glasgow-Pittsburg outcome categories which has been used to categorize patients according to their neurological outcome. It serves as a prognostic predictor of health for patients that underwent a cardiac arrest. The primary endpoints used for this study include death, discharge alive, alive after one year after discharge, and cerebral performance categories at discharge and one year after. After interpreting the data, the investigators found that a total of 338 patients had an arrest of cardiac etiology. Of the 338, 164 (49%) had a return of spontaneous circulation, 129 (34%) were admitted alive to the Intensive Care Unit, 48 (14%) were discharged alive, and 40 (12%) were alive after one year of discharge. [21] Approximately 4.85 per 100,000 lives were saved of patients with an arrest of cardiac etiology by ALS services and discharged alive. Most of those who survived showed good neurological outcomes. [21] Overall, this study found that EMS systems in large and rural area without physician staffed ALS units resulted in lower survival rates. [21] The qualifications of personnel of the emergency medical vehicles were found to be the most important independent variable that affected patient outcomes after an out-of-hospital cardiac arrest. The EMS systems that were equipped with physician-staffed ALS systems had superior outcomes as shown in the Table 3. This table delineates the study from which data is extracted, the different EMS systems including either BLS, ALS, or ALS that is physician equipped, and the discharge rates in each

system. The researchers found that in both large metropolitan and rural areas which did not have physician staffed ALS services has overall lower survival rates. However, there are several factors should be considered when analyzing the results including socioeconomic, demographic, and racial factors that could have contributed to the observed outcomes. It is also important to consider the financial cost of equipping ambulance vehicles with physicians. For that reason, the idea of staffing these EMS vehicles with similar providers who can operate on a similar scope as physicians but require less training such as physician assistants is an evolving idea.

Table 3: Analysis of different EMS Systems of hospital discharges after a cardiac arrest

Study	EMS System	Discharge rate after bystander witnessed cardiac arrest of cardiac etiology with initial rhythm VF (%)	Discharge rate after cardiac arrest of cardiac etiology (%)
Heidelberg 1997	BLS + ALS-P	26/69 (38)	48/338 (14)
Bonn 1997	BLS + ALS-P	41/118 (35)	74/464 (16)
Helsinki 1996	BLS + ALS + ALS-P	41/126 (33)	44/255 (17)
Mainz 1994	BLS + ALS-P	13/54 (24)	19/2111 (9)
Helsinki 1990	BLS + ALS-P	39/144 (27)	ND

New York City 1994	BLS + ALS	22/415 (5)	33/2329

Synthesis of Existing Research

While the practice of physician assistants on EMS vehicles is not standard practice at this time in the United States, countries like the Netherlands have begun to study its utility. In 2020, a framework called "Pilot physician's assistant and nurse practitioner ambulance care" was published to develop a plan to utilize these advanced practice providers in the setting of emergency ambulance care. The goal of this framework is to clearly define positions for these providers that will eventually allow for customized care of patients while also expanding for the increasing demand for care. [23] An important legislative distinction to note is that physician assistants and nurse practitioners "have the right to independently indicate and perform certain medical procedures such as catheterization, cardioversion, defibrillation, endoscopy, injecting, puncturing, prescribing, and simple surgical procedures" according to the Dutch healthcare legislation in 2018. [23]

Another area of study was the effect of physician-staffed emergency medical services on the outcome of patients that had a severe traumatic brain injury. This review is important as traumatic brain injury is the fourth leading cause of death in Western counties. [24] An analysis was performed using the "Preferred Reporting Items for Systemic Reviews and Meta-Analysis (PRISMA)-statement" and selected 14 studies that met their inclusion criteria. Popal et al. found that mortality of patients with severe

traumatic brain injury was often decreased with the assistance of physician-staffed EMS vehicles. Additionally, they found that oxygen saturation was also better maintained by the physician-staffed units which ultimately reduced the risk of secondary hypoxic injury. However, there are several limitations to this review including that it is difficult to compare different EMS systems as they can differ in training, geographic location, as well as the medical tools available. With the results of this study, Popal et al. recommended a low-threshold for dispatch of physician-staffed emergency medical services with a suspected traumatic brain injury. All in all, in the event of a traumatic brain injury patient mortality was improved with the deployment of physician staffed EMS units, however more research should be done to control for the difference in EMS systems.

A significant factor to consider post-cardiac arrest and return of spontaneous circulation is neurologic status. Taccone et al. summarized specific neurological examination can help predict patient outcomes. Specifically, absent pupillary and corneal reflex, absent or posturing reflex motor responses to pain, myoclonus status, high serum neuron-specific enolase, and bilateral absence of cortical somatosensory evoke potentials have been shown to reliable predict poor patient outcomes. [25] Monitoring the first few days post-cardiac arrest using the Glasgow come scale has been shown to sufficiently predict outcome. The Glasgow coma scale is a simple method used for monitoring neurological status.[26] It is comprised of 3 major components; eye opening response, verbal response, and motor response. [27] The Glasgow coma scale was significantly higher in patients with good outcomes compared to those with unfavorable outcomes. Overall,

Glasgow coma scales can help identify favorable neurological outcomes after cardiac arrest and would be a good measure for this study determining the differences in patient outcomes between physician assistant units and paramedic units.

In Germany and the Netherlands, the use of physicians on emergency medical vehicles has helped prevent unnecessary ambulance transports to the emergency department. In the United States, emergency departments are riddled with long average wait times and have becomes increasingly worse over the years. Horwitz, Leora I. et al looked at the average time it takes for a provider to assess the patient based on level of acuity. The data set the researchers used were derived from a five-level triage assessment variable as follows: immediate (see in 0 minutes), emergent (see in 1-14 minutes), urgent (see in 15-60 minutes), semi-urgent (see in 61 minutes to 2 hours), and non-urgent (see in 121 minutes to 24 hours). They found that for patients that were categorized as "urgent" the average wait time was calculated at 45.2 minutes and for those who were ultimately to be admitted had an average wait time of 4.93 hours. The difference in wait times between the two is large but unsurprising, and reveals the unnecessary time spent in the emergency department for patients that are ill enough to be admitted. The number of patients with non-emergent complaints waiting in the emergency department created an unnecessarily high census and workload for providers and staff. Early recognition of critically ill patients would decrease the time spent in the emergency department and could ultimately improve patient outcomes. The adaption of well-trained personnel like PAs, could result in early detection of ill patients and provide a seamless transition from pre-hospital care into the hospital setting.

Denmark has also studied the use of physician staffed EMS vehicles to determine if attendance of a physician made a difference to the patient's survival. This study was a retrospective, descriptive study that analyzed data from May 2006 to December 2012. They followed patients until they were discharged to either their homes, nursing home, or death. The researchers used the following criteria to denote if the case required lifesaving measures within the competencies of an EMT or paramedic. Table 4 below outlines the implicit and explicit criteria used by the investigators to delineate the competences for each of the providers. The researched defined "lifesaving treatment" as was necessary to save the patient's life is within the scope of the EMT or paramedic. For example, if a physician were to administer naloxone for an opioid overdose, it would be considered lifesaving in the competencies of the EMT or paramedic. A strength of this study was their sample size; a total of 32,452 runs were recorded. Out of the 32,452 runs, 701 of these patients required "life-saving treatment". This study discusses the impact of having an anesthesiologist- staffed EMS vehicle on patients' outcomes. The researchers found that the physician staffed vehicle significantly improved patient survival. They found that approximately half of the patients that were treated under the competencies of the physician were discharged home without major or moderate sequelae compared to those treated under the competencies of a EMT or paramedic. While this study can be generalized to all Scandinavian counties, it is difficult to determine if this model would work in the United States due to the differences on the pre-hospital concept. Overall, physician staffed EMS vehicles provided not only life-saving intervention but also supervision of EMTs and paramedics and clinical decision making. The presence of a

physician in the prehospital environment may enable withholding futile advanced intervention, like intubation, in cases where treatment may be contraindication or potentially unnecessary. [28]

Table 4: Inclusion and Exclusion Criteria for Denmark Study

Explicit criteria	Implicit criteria
Intubation or other airway procedures exceeding the competences of paramedics or EMTS	Advanced medical treatment exceeding the competences of the attending paramedics in severe shock states
Advanced medical treatment exceeding the competences of paramedics or EMTs in cardiac arrest and/or defibrillation when indicated by the attending physician	Fluid resuscitation exceeding the competences of EMT or paramedics in cases of severe hypovolemia

METHODS

Study design

This study will be performed using a randomized control trial. This will be achieved by dispatching a unit composed of physician assistants and emergency medical technicians on EMS ground vehicles to suspected cardiac arrest calls. The comparison group is the deployment of traditional personnel including paramedics and emergency medical technicians also responding to cardiac arrest calls.

Study population and sampling

The study population that will be utilized in this study will be patients that received emergency medical care within the Boston area with cardiac etiologies over the span of 24 months. Etiology of the emergency will be determined with careful review of hospital records by a clinical adjudication committee that will be composed of 3 blinded, unbiased experts that will perform a review of the events. Patients involved in the study will be monitored for up to twelve months after discharge from the hospital. The time endpoints of interest in this study include three, six, and twelve month intervals based on post-cardiac arrest dysfunction pathology. [29] This study will rely heavily on the decision making of our dispatch teams who answer 911 calls and will allow for the paramedic and PA-EMS to respond equal number of calls reported. Data for deployment of either the PA-EMS unit or paramedic unit that will need to meet specific criteria to be included in the study listed below.

The sample size for this study will utilize approximately 2,000 emergency medical calls that can meet at the inclusion criteria listed below. In 2021 according the

"Vital Statistics", Boston emergency medical services had a combined total of cardiac related and investigation calls (person down) 87,019 calls and of those calls 12,613 were cardiac related.[30] We made the determination that we will allow for a 5% margin of error with a 90% confidence interval. The minimum sample size to meet these criteria is 270 participants, so for this study a total of 2,000 emergency calls should provide ample data over this period of 24 months. [31]

Table 5: Inclusion and exclusion criteria for this study

Inclusion Criteria	Exclusion Criteria
- Emergency call within the Boston area - Incident is coded as *cardiac related* - Incident is considered Priority 1 or Priority 2 - Ambulance unit deployed can perform under Advanced Life Support - Adult patients aged 22-65	- Emergency is not within the Boston area - Incident is not coded as *cardiac related* - Incident categorized as Priority 3,4, or 5 - Ambulance unit acting under Basic Life Support - Patient not within age 22-65 - Cardiac arrests that are found down without family to consent

The table above describes the inclusion and exclusion criteria for the proposed study. Priority 1 will be considered an incident that is time sensitive, life threatening, or potentially life-threatening emergencies including but are not limited to cardiac arrests, uncontrollable bleeding, and loss of consciousness. Priority 2 will be defined as an incident that is non-life threatening pr potentially life threating emergencies that include but are also not limited to controlled bleeding and abdominal distress. The age range was selected because pediatric emergencies require different levels of comfort and expertise. The age range still allows to sample from a wide population. For patients that are found down in the presence of family, the family will act as a proxy and will not require a durable power of attorney for health care unless there is complete and valid documentation of one.

Intervention

The intervention of this study will be the deployment of the type of EMS team unit that is assigned to emergency calls made by the Boston dispatch. The calls will be screened by dispatch using the inclusion and exclusion criteria of the study and only calls that meet all inclusion criteria will be utilized in the study. When a call meets all inclusion criteria, dispatchers will use a software that will randomly assign either the physician assistant unit or the paramedic unit at a 1:1 ratio to ensure that both units are responding at the same rate. This process should not take longer than the standard process as the dispatcher will only be answering the following questions to their existing software:

1. Does this emergency require Priority 1 or 2 status?

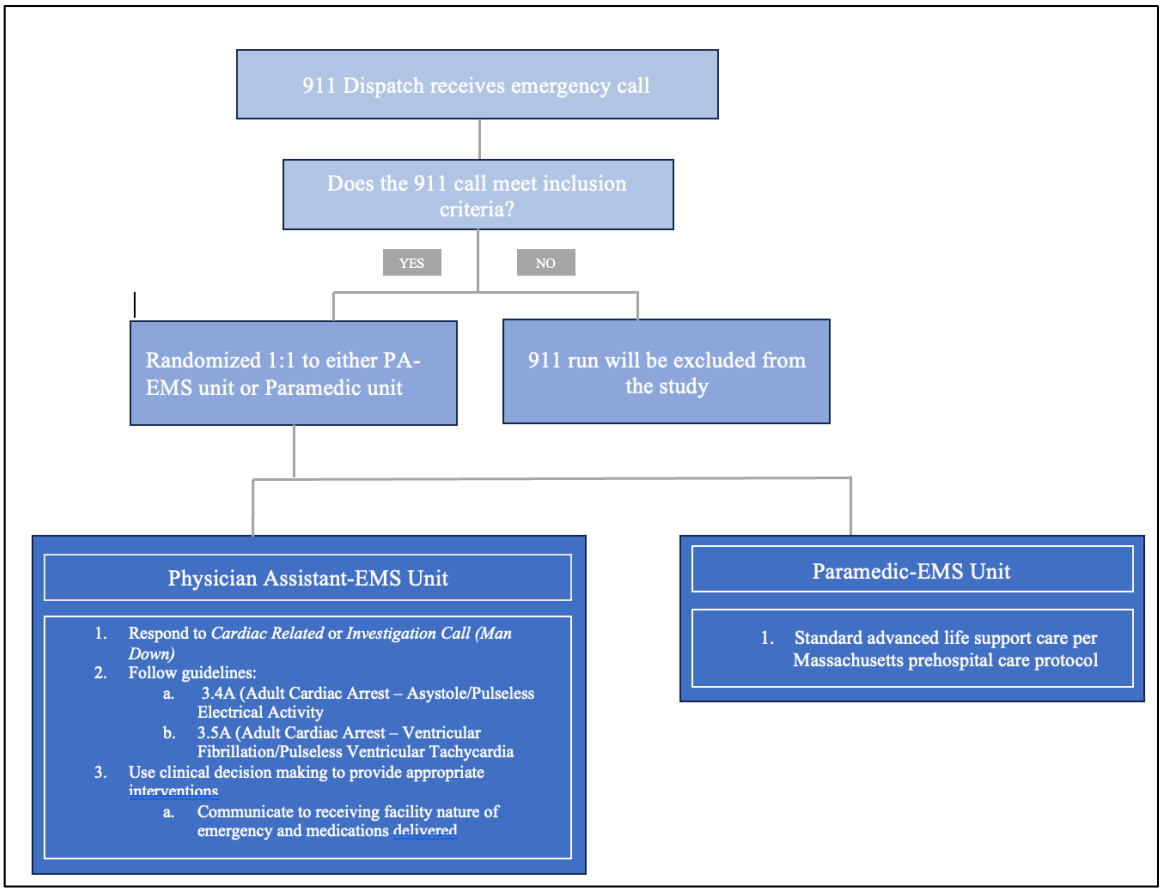
2. Is this patient 22-65 years old?

The algorithm shown below will be used to make sure calls are meeting inclusion criteria and both units are seeing approximately the same number of cardiac arrests.

The two units will receive their information via personal pagers that will enclose the details of their incident call they are responding to. Pages will include age, sex, nature of the emergency, and the address of the location the unit will be responding to. Providers on both EMS units will use a two-way radio to communicate confirmation of the page. All calls that are assigned to the two units will require advanced life support capabilities and all responders should be prepared to use guidelines to administer care.

Physician assistant and paramedic EMS crews will respond to calls per the protocols outlined by the state of Massachusetts. They will both use their skills to manage cardiac arrest under their scopes of practice and will communicate the condition of their patients to the base hospital. The major intervention of this study will be using the more novel idea of PAs on EMS vehicles instead of the traditional paramedic units. Therefore, cardiac arrests will either receive care from a physician assistant unit or from a paramedic unit that will operate under the Massachusetts state protocols for cardiac arrests 3.4A and 3.5A. [32]

Figure 1: Flowchart outlining study intervention



Guidelines based on Massachusetts State Protocols for Emergency Medical Services [32]

Study variables and measures

The primary study variable that will be monitored for this project is the adjusted mortality rate at three different time endpoints. The three end points used will be at three months, six months, and at twelve months of patients that suffered an out-of-hospital cardiac arrest and were treated by a physician assistant emergency medical services vehicle team. We will use all-cause mortality characterized as death before the endpoints of three, six, and twelve months. Demographic information will be collected for each incident that includes age, sex, and socioeconomic status. Additional variable that should note the emergency response time, transportation time to receiving facility, if there was initiation of CPR by bystander, and other comorbidities including diabetes and underlying CAD.

Recruitment

Recruitment for this study is outlined in the flow chart above; participants will be enrolled based on the 911 calls to dispatch. Consent for enrollment will be performed when the patient in conscious, alert, and oriented and can make their own medical decisions. Additionally, consent for management of cardiac arrest with medications will also be obtained on the scene by the provider. For those who do not consent to enrollment in the study, their data will not be utilized in the study. Informed consent is an important pillar of ethical research and has proved to be difficult to obtain in emergency situations. However, there is a still a great need for high-quality evidence in emergency medicine.

For this reason, the INCEPTION trial detailed three conditions that need to be met to waive consent. There are the following:

1. Patients should receive the standard treatment of a new treatment with a possible benefit.
2. The gathered data can be used to improve the health of the population.
3. During life, the patient has not explicitly stated their objection against participation. [33]

Our emergency response units will make every attempt to obtain consent from family members. In the case that family does not consent to the PA-EMS, a paramedic will lead the emergency. According to 45 Code of Federal Regulation (CFR) 46.11 (d), the IRB may waive requirements to obtain informed consent provided that the IRB finds and documents that the research poses no more than minimal risk to participants, the waiver of rights does not affect the rights or welfare, the research cannot be done without the waiver of consent, and whenever appropriate subjects will be provided with information after participation. [34] In the case of this study, the use of PAs on EMS would pose no more than minimal risk as several studies reviewed above have shown better patient outcomes with the addition of an advanced provider responding to emergencies in the pre-hospital setting. The welfare of patients will not be jeopardized as they are following the same guidelines and algorithms for treatment of out-of-hospital cardiac arrests that are performed by paramedics. Additionally, physician assistants are equipped with extensive knowledge in disease processes and can manage and treat cardiac arrests. Subjects will also be given information regarding the study and public significance. For

patients that are incapacitated or unconscious that cannot consent for themselves but are in the presence of family will be educated on the risk and benefits of the study and provide informed consent if he/she chooses to. Informed consent can be obtained from close family members or legal guardians for patients that are incapacitated or unable to consent for themselves.. [35] To ensure that there is not a delay of care, a paramedic will be placed on every PA-EMS unit while the study is ongoing in the case that family members do not consent for a PA-EMS unit.

Data Collection

Data for this study will be collected using the electronic medical record (EMR) from both the Boston EMS as well as the receiving hospital EMR and will be transferred to secure spreadsheet with the demographics and variable of interest from each patient that will remain deidentified.

Data analysis

The analysis of this data will be performed using Kaplan-Meier curves to determine if there is a statistical difference between the survival rates of patients that are treated by physician equipped EMS vehicles versus the paramedic group. Using Kaplan-Meier curves we will be able to make estimates of survival outcomes at different survival endpoints. We will be investigating the all-cause mortality by using overall survival curves at the following endpoints of three, six, and twelve months. The event of interest will be if the cardiac emergency was attending by either a physician assistant or paramedic. Therefore, we will utilize the addition of the log-rank test to determine the survival times between the two groups. In additional to the Kaplan Meier curves we will

perform cox regression to investigate the effects of several variables on our selected event for this study. The utility for using a cox regression comes from several variables including response time to the scene and transport time at several endpoints as outlined in Table 6 and 7.

Table 6: Analysis stratification based on time from scene to hospital

	15 minutes or less	15-30 minutes	Greater than 30 minutes
PA-EMS			
Paramedic-EMS			

Table 7: Analysis stratification based on response times to EMS scene

	Less than 5 minutes	5-15 minutes	Greater than 15 minutes
PA-EMS			
Paramedic-EMS			

We will also collect data to investigate neurological assessment using the Glasgow coma scale. We will assess the three parameters including eye response, verbal response, and motor response with the summation of score adding up to a maximum of 15. The following classification will be used to determine neurological status: Severe 3 to 8, Moderate 9 to 12, and Mild 13-15. Glasgow coma scales will be first assessed in the pre-hospital setting and then subsequently will be assessed daily for the first four days of the patient's hospital stay.

Table 8: Glasgow Coma Scale

Behavior	Response	Score
Eye Opening Response	Spontaneously	4
	To Speech	3
	To pain	2
	No response	1
Verbal Response	Oriented to time, place, and person	5
	Confused	4
	Inappropriate words	5
	Incomprehensible sounds	2
	No response	1

Motor Response	Obeys commands	6
	Moves to localized pain	5
	Flexion withdrawal from pain	4
	Abnormal flexion (decorticate)	3
	Abnormal extension (decerebrate)	2
	No response	1
Total Score	Mild	13-15
	Moderate	9-12
	Severe	3-8

The scale above is adapted from the traditional Glasgow Coma Scale [36]

Timeline and resources

As this is a novel idea, careful preparation and planning must be done in order to execute this study. This study will require approximately 2-3 years to complete. Based on our previous calculation of an appropriate sample size, we should be allocated approximately 1 year for data collection. After gathering the data necessary, patients should be monitored for up to twelve months after discharge from the hospital. Compilation and statistical analysis should take no longer than three months to complete.

Table 9: Proposed Timeline of the study

August 2023	-Submit for full IRB approval -Recruitment of Physician Assistants
November 2023	-Implementation of study protocol -Initiate dispatch training for randomization software of EMS units -Initiate training of PAs on EMS units using Massachusetts EMS protocols
December 2023 – December 2024	-Data collection
December 2024- December 2025	-Data Analysis and Statistical Analysis
January 2026 -March 2026	-Study completion -Draft and submit final paper for journal review

Institutional Review Board

This study will be submitted to the Boston university Medical Campus IRB prior to initiation for the implementation of physician assistants on emergency medical service vehicles. The study will assess patient outcomes based on three-month, six months, and twelve-month mortality in patients that underwent an out-of-hospital cardiac arrest. Human subject protection will be maintained in the IRB protocol by obtaining consent, maintaining confidentiality, and protection from harm. Due to the novel implementation of physician assistants on EMS vehicles this study will require full board review

However, this study can be considered an innovative care study that is defined as a planned treatment that is still using medically justified an appropriate treatment but departs from the standard of practice.

CONCLUSION

Discussion

The physician assistant profession is one that came to fruition to bridge the gap in the healthcare system. In the United States, PAs are now a vital part of the healthcare system and working alongside other providers in a myriad of settings including the emergency room in inpatient wards, in the operating room, and in outpatient clinics. However, introduction of PAs in the pre-hospital emergency medical care is a novel idea that has not been practiced in the US. This study would be one of the first of its kind to look at the implementation of PAs on EMS vehicles in the US and its effects on mortality of patients that suffered from a cardiac arrest. There are several studies around the world that have investigated the effects on mortality of patients that were treated by a physician-EMS crew, but very few studies that utilize advanced practice providers like physician assistants.

A strength of this study would be the population of the participants. This study will use participants that are located within Boston which is known as an urban city. The location of the study would aid in the generalizability as there is such a diverse demographic specifically in urban locations. Another strength of the study is the data will be relatively easy to analyze because we are looking at all-cause mortality at three-time endpoints. One limitation of this study is that it will be difficult to tease apart the exact reason for the results as there could be confounders that affect the results since this is novel study, however the inclusion of a cox regression will help with contributing covariates.

Summary

The history and evolution of emergency medical services has led to significant improvement in the pre-hospital care that is delivered by paramedics and emergency medical technicians. In the past, EMS systems lacked coordination which made it difficult to provide life-saving care to those in need. However, over time several organizations and legislative actions have come together to help make improvements to the delivery of emergency care.

The two classifications of Basic and Advanced Life Support are based on the level of care that is provided. Basic life support units offer more basic interventions like fracture cardiopulmonary resuscitation and splinting, whereas advanced life support is equipped with the ability to perform endotracheal intubations, intravenous line placements, and administer medications. Currently in the United States, paramedics are the highest trained EMS personnel that responds to emergencies in the pre-hospital setting. While paramedics are highly trained, the idea of introducing other advanced practitioners, like physician assistants is a novel and evolving idea. Physician assistants are skilled healthcare professionals that work under the supervision of a licensed physician and have broad skill set. Their clinical decision-making abilities make them an asset in the pre-hospital care and can potentially improve patient outcomes by accurately recognizing emergencies, providing quality care, and collaborate with in hospital providers to allow for seamless coordination of care. While this is a novel idea in the United States, the utilization of advanced practitioners, like physicians is already being implemented around the globe and have shown to improve patient outcomes. For this

reason, the goal of this thesis is to investigate the utility of advanced practitioners, specifically physician assistants, in the pre-hospital setting and explore their effect on the delivery of care and patient outcomes.

Public health significance

This study has potential for changing the management of out-of-hospital cardiac arrests in the pre-hospital setting. In addition to the already skilled paramedics that currently respond to cardiac arrests, this study can provide insight if in addition to paramedics, physician assistants would be beneficial. Having PAs working in the pre-hospital EMS setting can potentially expand the scope of practice which would enable more advanced medical interventions beyond what is typically available today. This utilization of PAs in the pre-hospital setting could expand their capabilities outside of the hospital setting and enhance pre-hospital clinical decision-making which would lead to more accurate assessments, diagnoses, and treatment plans.

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