Enhancing the Tissue Donor Pool through Donation after Death in the Field

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Abbreviations:
ALS: Advanced Life Support
ED: Emergency Department
EDIM: Emergency Department Information Management
EMS: Emergency Medical System
IRB: Institutional Review Board
MTF: Musculoskeletal Transplant Foundation
TOD: time of death

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Abstract

Introduction: Tissue transplantation is an important adjunct to modern medical care and is used daily to save or improve patient lives. Tissue allografts include bone, tendon, corneas, heart valves and others. Increasing utilization may lead to tissue shortages, and tissue procurement organizations continue to explore ways to expand the cadaveric donor pool. Currently more than half of all deaths occur outside the acute care setting.

Hypothesis: Many who suffer prehospital deaths might be eligible for non-organ tissue donation.

Methods: A retrospective review of electronic prehospital medical records was conducted from May 1, 2008 through December 31, 2009. All prehospital deaths were included irrespective of cause. Once identified, additional medical history was obtained from prehospital, inpatient, and emergency department records. Age, medical history, and time of death were compared to exclusion criteria for four tissue procurement organizations (MTF, LifeNet, LifeCell, EyeBank). After analysis, percentages of eligible donors were calculated.

Results: Over 50,000 prehospital records were reviewed; 432 subjects died in the field and were eligible for analysis. Ages ranged from four to 103 years of age; the average was 68.3 (SD = 20.1) years. After exclusion for age, medical conditions, and time of death, 185 unique patients (42.8%) were eligible for donation to at least one of the four tissue procurement organizations (range 11.6%-34.3%).

Conclusions: After prehospital death, many individuals may be eligible for tissue donation. These findings suggest that future prospective studies exploring tissue donation after prehospital death are indicated. These studies should aim to clarify eligibility criteria, create protocols and infrastructure, and explore the ethical implications of expanding tissue donation to include this population.

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Introduction

Tissue transplantation is increasingly utilized in routine patient care. Over the last 15 years, approximately 10 million tissue transplants have occurred in the United States. In 2010, there were 42,642 cornea transplants alone; in all, more than 750,000 new tissue transplants occur each year.[1,2] Currently, tissue transplants include harvested cadaveric bone and cartilage, skin, tendons and ligaments, blood vessels, corneas and heart valves. While not engendering the same high-profile exposure or attention as solid organ transplants (heart, liver or kidney) tissue transplantation has become invaluable in modern medical care, saving or improving patient's lives every day. With utilization increasing despite stable donor numbers, there are concerns for future donor tissues shortages.[3] Therefore many tissue procurement organizations, tissue and eye banks, continue to look for new ways to expand the donor pool. Often, as many as 100 unique transplant tissue grafts can be obtained from each additional donor, making added procurement invaluable toward ensuring availability for those who require tissue transplants in the future.[1]

Currently almost all organ and tissue donations in the United States occur in the hospital setting, after brain death is established or after cardiac death occurs.[4] To facilitate organ and tissue procurement, well-established protocols assure that opportunities for organ or tissue donation are identified and that, where appropriate, families are approached

with options regarding organ and tissue gifting.[5] Many deaths, however, occur outside the hospital setting due to road accidents, acute cardiovascular events, suicide and other causes. In one review of death epidemiology, only 41% of all US deaths from 1980-1998 (35.2 million total deaths) occurred in an inpatient setting.[6] Presently, however, there are no established protocols to enable organ or tissue donation when a person dies in the prehospital setting.

In the current medical system, out-of-hospital fatalities are not transported to medical facilities. As such, these individuals and their families are denied the opportunity to become organ or tissue donors despite any pre-existing desire or intent. In Europe, there has been some success in including prehospital fatalities as potential solid organ donors through publically accepted, well-organized non-heart-beating donor programs.[7-9]

While solid organ procurement may be an ultimate goal of expanding the donor pool to include prehospital fatalities, currently the challenge of maintaining organ viability after circulatory arrest makes it prohibitive in the United States. In contrast, other commonly donated tissues (bone, cartilage, skin, tendons, ligaments, blood vessels, corneas and heart valves) can withstand longer periods of ischemia and can remain useful for donation from 12-24 hours after death. Further, success with tissue procurement may be a first step leading eventually to increased solid organ donation in the United States. Through concerted efforts to coordinate prehospital protocols, tissue procurement organizations, and local Medical Examiner/governmental agencies, the potential tissue donor pool might be significantly increased if prehospital fatalities are included.

In this retrospective review, prehospital deaths were analyzed to determine the potential for tissue donation by considering the patient's age, cause and time of death, and past medical history. The aim of this study was to identify a potential pool of tissue donors. The working hypothesis was that patients who die outside of the hospital setting represent a large, unexplored population for transplantable tissue procurement.

Methods

Study Design

After Institutional Review Board (IRB) approval, a retrospective review of electronic prehospital medical records for Central New Jersey (NJ) was conducted for the 20-month period from May 1, 2008 through December 31, 2009. All patients declared dead in the field/prehospital setting were identified independent of cause of death. For those identified, all available prehospital, inpatient, and emergency department records were reviewed to obtain additional medical history.

Emergency Medical System (EMS)

The two-tiered EMS system serving Middlesex County has six Advanced Life Support (ALS) units based at a university Level I trauma/multi-specialty tertiary care center. The Emergency Department (ED) treats 90,000 patients per year and is staffed by Board Certified/Board Eligible emergency physicians.

The EMS system covers 85% of Middlesex County, NJ for 911 responses, serving a population of approximately 800,000 (68.4% Caucasian, 13.9% Asian, 13.6% Hispanic, 9.1% African-American). The county occupies 323 square miles of urban and suburban communities. The mean experience level of the system's 232 providers is 6.48 years. Regionally-based units are dispersed based on population density and call volume. There are >30,000 dispatches per year, with 100% on-line medical direction with standing orders.

Data Collection

For study patients, pertinent information was collected in an electronic medical record (EMS Charts, Version 2, West Mifflin, Pennsylvania USA). When available, in-hospital patient data was gathered from the Emergency Department Information Management Database. All previous hospitalizations were reviewed in detail. Hospital charts were cross-referenced with EMR Sunrise Clinical Manager (Version 5.5, Eclipsys, Atlanta, Georgia USA) when possible, and with paper charts for patients evaluated before 1998. Data was compiled and analyzed using Excel spreadsheets (Version 14.2.2 Microsoft, Redmond, Washington USA).

Screening for Tissue Donor Qualification

For those who died in the prehospital setting, known medical and demographic data were compared against donor acceptance criteria of four major tissue transplant organizations: Musculoskeletal Transplant Foundation (MTF), Eye Bank, Life Cell and Life Net. All investigators reviewed eligibility criteria with 100% agreement on inclusion/exclusion for donor category acceptance. Over 220 different diseases or conditions were screened in the initial data collection period.

Results

Over 50,000 electronic prehospital medical records were reviewed. There were 443 subjects identified who were declared deceased in the field and were subject to analysis. There were 180 females (40.6%), 254 males (57.3%) and 9 (2.0%) of unknown gender. The average age of the subjects was 68.3 (SD = 20.1) with a range of four to 103 years of age. Age could not be determined in 11 patients. When age was unavailable, subjects were excluded for consideration due to specific age-based limits for donation. For final analysis of eligibility as a potential donor, 432 patients remained.

Records for each were screened against the major inclusion and exclusion criteria set forth by four different organ/tissue transplant procurement organizations: MTF, LifeCell, LifeNet, and EyeBank. Patients were first excluded based on age criteria for each organization. Next, each record was screened against differing medical exclusions for each procurement agency. Table 1 lists the identified medical exclusions in decreasing order. Lastly, patient charts were examined for time of death (TOD); exclusions were made for cases in which TOD could not be determined by EMS or was known to exceed 24 hours based on existing documentation.

Based on MTF donor criteria (see Figure 1), 293 (67.8%) of 432 patients screened were excluded by age: >60 years or <12 years. An additional 30 patients (6.9%) were excluded for medical reasons, and 26 patients (6.0%) were excluded because TOD >24 hours or could not be determined. The remaining 83 (19.2%) patients were considered eligible for referral to MTF at the time of their death in the field.

Using LifeCell criteria (see Figure 1), 163 (37.7%) of 432 patients were excluded by age: >80 years or <15 years. Medical exclusions eliminated 80 (18.5%) of patients and TOD criteria excluded an additional 41 patients (9.5%). The remaining 148 (34.3%) patients were considered eligible for referral to LifeCell at the time of their death in the field.

LifeNet criteria (see Figure 1) resulted in 349 (80.8%) age exclusions due to an age limit of 1-50 years. A further 18 patients (4.2%) were medically excluded; 15 patients (3.5%) were excluded based on TOD. The remaining 50 (11.6%) patients were considered eligible for referral to LifeNet at the time of their death in the field.

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Neoplasm/Metastases
Liver Disease/Jaundice/Hepatitis C
Intravenous Drug/Heroin Use
Corticosteroid Use
Sepsis
Decubitus Ulcers
Cocaine Use
Prior Open Heart Surgery
Alzheimer's Disease
Down's Syndrome
Herpes Zoster
Incarceration
Meningitis
Transplant Recipient
Rheumatoid Arthritis
Parkinson's Disease
Amyolateral Sclerosis
HIV/AIDS

Table 1. Reasons for Medical Exclusion

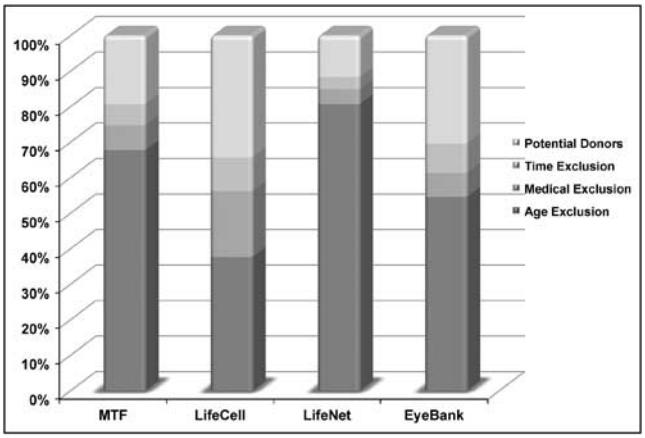

Figure 1. Graphic Comparison of Exclusions and Eligible Donors by Organization

Finally, EyeBank criteria (see Figure 1) excluded 236 of 443 (54.6%) patients based on age restrictions (5-70 years). An additional 29 patients (6.7%) had medical exclusions, and 36 patients (8.3%) were excluded based on TOD. The remaining 131 (30.3%) patients were considered eligible for referral to the EyeBank at the time of their death in the field.

When considering all 432 patients, and the differing criteria and exclusions for each of the four tissue procurement organizations, a total of 185 unique patients (42.8%) (Figure 2) who died in the field, were eligible for referral and further screening for non-organ tissue procurement during the 20-month sampling period.

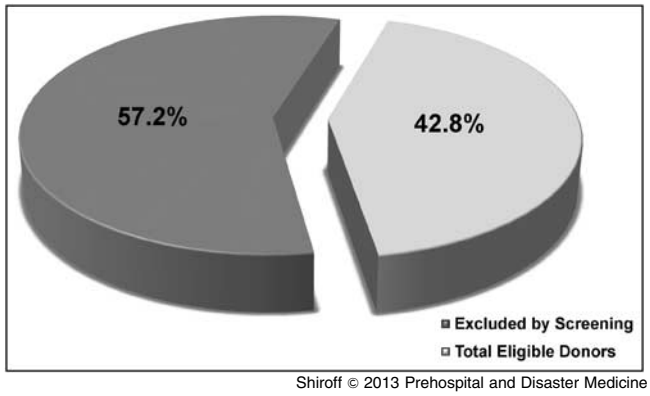

Figure 2. Total Unique Eligible Donors Qualifying for Donation by At Least One Procurement Organization versus Total Exclusions

Discussion

The present study documents that, during a 20-month sample period in a single EMS system, 42.8% of out-of-hospital deaths might have been eligible for tissue procurement based on initial screening of EMS and medical records. This seemingly small number represents the potential for thousands of unique donor tissue grafts. Expanded to a longitudinal program over a much larger catchment area, the implications are remarkable for increasing tissue donor pools and tissue transplant availability. This initial proof-of-concept study serves to emphasize the unexplored tissue donor pool that exists with out-of-hospital mortality.

In the present study, age was the primary exclusion criteria and was the most common reason for ineligibility as a tissue donor. Obviously certain cardiac and musculoskeletal tissues lose tensile strength with senescence, and both LifeNet and MTF have age exclusions below the study group's average age of 68 years. Medical exclusions were diverse, with the most common including history of cancer, open-heart surgery, intravenous/illicit drug use, blood-borne infectious diseases, recent sepsis, and steroid use. Over 220 different medical conditions were considered. Finally, when time of death exceeded criteria (12-24 hours depending on the agency) or could not be reliably determined, subjects were excluded. LifeCell, which supplies dermal tissue matrix and other products, had the most eligible donors (34.3%); LifeNet, providing heart valves, tendons, and other tissues had the least (11.6%).

Of course, the issues surrounding donor pool expansion to include prehospital deaths are much more complex than simply identifying those that might qualify. There are ethical issues including donor/family consent and patient privacy; logistical considerations related to transport, screening, harvesting, and storage; and legal implications for EMS, physicians, state and local government, and procurement organizations.[10] There are also significant financial considerations. While the benefit to society is obvious, this method of donor pool expansion would require a great and coordinated effort to succeed.

To further explore this concept, future prospective inquiries across larger populations, and a closer examination of donor eligibility criteria, would be required. Also, these studies would need to involve tissue procurement organizations to assist with screening, EMS personnel to assure accurate reporting, and governmental agencies to

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assist with data access and feasibility concerns. With a more accurate accounting of time of death and medical history data, such studies would be more applicable to the general population and could serve to initiate protocol development for eventual implementation.

Clearly the need for expanded tissue donation exists and is the focus of the current study. Yet, the need for solid organ donation is much greater. While solid organ donation was not considered in the current study, one hope is that by creating protocols and infrastructure to harvest tissue after prehospital death, such a program might be expanded to include organ salvage as well. Indeed programs exist in Europe[7,9,11-13] to maintain solid organ viability after prehospital death and a similar program was attempted in New York City.[8,10,14] European data indicates that kidneys harvested after out-of-hospital deaths have reasonable viability in well-run programs.[9] Indeed a 2006 summary statement from an Institute of Medicine summit focusing on "Increasing Organ Donation" concluded that further study into "uncontrolled" donation after cardiac arrest (including out-of-hospital deaths) was indicated and could significantly increase donations. The group identified significant roadblocks including the many ethical, logistical, legal and financial considerations already described.[10] Yet it is reasonable to hope that by exploring tissue donation after prehospital death that programs could eventually expand to include solid organ donation as well.

Limitations

This investigation is limited by its small sample size and the short time frame examined: 432 subjects/50,000 contacts over 20 months in a single EMS system. The retrospective nature is also limiting, and likely resulted in incomplete or somewhat inaccurate data collection with regard to medical history and the details surrounding the cause and time of death. Some patients may have been considered potential donors who would have been excluded and others who were considered ineligible may have been acceptable. On the whole however, while the data cannot be generalized, it is interesting to note that such a large percentage of prehospital fatalities had the potential to at least be screened as donors by tissue procurement organizations. Certainly if donor pools are expanded to include prehospital deaths, many more patients across the country would be eligible tissue donors. Additional limitations include the actual methods used to exclude/include potential donors. In this brief pilot study to determine proof of concept, the crude methods used suffice. Clearly during any larger or more comprehensive studies, involvement of experts from the donor organizations themselves would be helpful to assure that the most accurate and proper screening criteria are applied.

Conclusions

The present study is the first to consider the eligibility of prehospital fatalities for non-organ tissue donation. Initial screening using basic procurement criteria indicates that over 40% of those who die outside of the acute care setting may be eligible for donation to some degree. Large-scale prospective investigations are needed to further characterize the impact of including prehospital deaths as potential donors and to consider the ethical, logistic, legal and financial implications.

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