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Impact of On-Site Physician Care in Penetrating Trauma

by Paul Daniel Benoit

Department of Epidemiology and Biostatistics McGill University, Montreal

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A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfilment of the requirements of the degree of Master's of Science (M.Sc.)

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ABSTRACT

This observational study compared the value of physician-administered Advanced

Life Support (MD-ALS) to Basic Life Support (BLS) in the treatment of penetrating

trauma in an urban setting.

Patients were identified in Montréal and Québec City between 1993 to 1997.

Prehospital care is provided exclusively by Urgences Santé in Montréal.

Patients in Montréal are randomly allocated to either ALS or BLS

due to an insufficient number of MD-ALS units. The south shore of Montréal and Québec

City are serviced by a separate emergency medical system (EMS) which provides only

BLS.

Differences were not statistically significant in terms of age and ISS between treatment groups. Mortality, when examined using both the Intent to Treat and Efficacy approaches, did not differ between ALS and BLS patients. Prehospital treatment type was not a significant predictor of mortality, or length of hospital stay. Patients treated by MD-ALS required home-care services more often than BLS patients once discharged, and spent significantly more time at the injury scene.

RÉSUMÉ

Cette étude d'observation compare la valeur des soins avancés administrés par médecin (MD-ALS) aux soins de base (BLS) dans le traitment de traumatisme avec pénétration, en milieu urbain. Les cas, venant de Montréal et de la ville de Québec furent identifiés entre 1993 et 1997.

À Montréal, les soins préhospitaliers sont fournis uniquement par Urgences Santé. À cause d'une insuffisance d'unités de soins avancés administrés par médecin, les patients de Montréal sont répartis au hasard entre les soins avancés et les soins de base. Sur la rive sud de Montréal et à Québec, le système de soins d'urgence (EMS) est différent et est limité aux soins de base (BLS).

Les différences entre les deux groupes en ce qui a trait aux facteurs âge et indices de gravité de traumatisme (IGT) n'étaient d'aucune importance statistique. Lorsqu'examiné à la lumière des approches Intention à Traitment et Efficacité, il n'y avait pas de différence dans le taux de mortalité entre le groupe de soins avancés et celui des soins de base. Les soins préhospitaliers n'étaient pas un facteur important dans la prévision du taux de mortalité. Une fois renvoyés de l'hôpital, les patients ayant reçu des soins avancés ont nécessité des soins à domicile plus souvent que ceux ayant reçu les soins de base et ont passé beaucoup plus de temps sur le site de l'accident.

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Table of Contents

| Chapte | r I - INTRODUCTION | 1 |
|--------|---|----|
| 1.1 | TRAUMA IN SOCIETY | 1 |
| 1.2 | HISTORY OF TRAUMA CARE | 3 |
| | PREVENTING TRAUMA | 4 |
| 1.4 | TREATING TRAUMA | 5 |
| | 1.4.1 Basic and Advanced Life Support | 5 |
| | 1.4.2 PASG/MAST | 6 |
| | 1.4.3 Intravenous fluid replacement | 6 |
| | 1.4.4 Airway management | 8 |
| 1.5 | TRAUMA MORTALITY | 9 |
| 1.6 | THIS INVESTIGATION | 10 |
| | 1.6.1 Prehospital care in Quebec | 11 |
| | 1.6.2 Rationale | 12 |
| | 1.6.3 Objective | 12 |
| Chapte | r II - LITERATURE REVIEW | 13 |
| 2.1 | | 13 |
| | 2.1.1 Summary of general ALS/BLS studies | 27 |
| 2.2 | · · · · · · · · · · · · · · · · · · · | 33 |
| | 2.2.1 Summary of IV studies | 40 |
| 2.3 | | 43 |
| | 2.3.1 Summary of Saline-Dextran studies | 44 |
| 2.4 | THE PNEUMATIC ANTISHOCK GARMENT | 44 |
| | 2.4.1 Summary of PASG studies | 51 |
| 2.5 | AIRWAY MANAGEMENT | 56 |
| | 2.5.1. Summary of Airway Management Studies | 57 |
| 2.6 | SUMMARY OF PRESENTED LITERATURE | 58 |
| 2.7 | RATIONALE | 59 |
| Chapte | r III - MATERIAL AND METHODS | 60 |
| 3.1 | INTRODUCTION | 60 |
| 3.2 | QUEBEC TRAUMA REGISTRY | 60 |
| 3.3 | HISTORY AND BACKGROUND OF URGENCES SANTÉ | 61 |
| 3.4 | DISPATCHING PROCEDURE OF URGENCES SANTÉ | 62 |
| 3.5 | PERSONNEL AND EQUIPMENT | 66 |
| 3.6 | TREATMENT | 67 |
| | 3.6.1 ALS equipment | 67 |
| 3.7 | PATIENT SELECTION | 67 |
| | 3.7.1 Identification of cases of penetrating trauma | 67 |
| | 3.7.2 Exclusion criteria | 69 |

| | 3.7.3 Participating centres | 69 |
|----------|---|------|
| | 3.7.4 Determination of pre-hospital care | 70 |
| 3.8 | DATA ANALYSIS | 72 |
| | 3.8.1 Exposures and Covariates | 72 |
| | 3.8.2 Outcomes | 73 |
| | 3.8.3 Efficacy analysis | 74 |
| Chapte | er IV - RESULTS | 76 |
| 4.0 | STUDY SAMPLING | 76 |
| 4.1 | DEMOGRAPHICS - OVERALL SAMPLE | 78 |
| 4.2 | UNIVARIATE COMPARISONS BETWEEN GROUPS | 80 |
| 4.3 | PATIENT OUTCOMES | 87 |
| | 4.3.1 Mortality | 87 |
| | 4.3.2 Mechanism of injury and mortality | 89 |
| | 4.3.3 Observed versus expected mortality | 90 |
| | 4.3.4 Time to death | 91 |
| | 4.3.5 Length and incidence of ICU and hospital admission | s 95 |
| | 4.3.6 Destination of discharge | 96 |
| | STRATIFIED ANALYSIS | 99 |
| | EFFICACY ANALYSIS | 102 |
| | ADVANCED LIFE SUPPORT INTERVENTIONS | 105 |
| | PREHOSPITAL TIME | 108 |
| 4.8 | | 110 |
| | 4.8.1 Factors Influencing Length of Hospital Stay | 110 |
| | 4.8.2 Mortality - multivariate logistic regression analysis | 112 |
| Chapte | er V - DISCUSSION | 114 |
| | INTRODUCTION | 114 |
| 5.2 | SUMMARY OF STUDY FINDINGS | 114 |
| | 5.2.1 Exposure factors | 114 |
| | 5.2.2 Outcomes | 115 |
| 5.3 | LIMITATIONS OF THE STUDY | 119 |
| 5.4 | STRENGTHS OF THE STUDY | 121 |
| | 5.4.1 Design | 121 |
| | 5.4.2 Statistical analysis | 123 |
| 5.5 | COMPARISON TO OTHER STUDIES | 123 |
| 5.6 | AREAS FOR FURTHER RESEARCH | 125 |
| 5.7 | GENERALISABILITY OF RESULTS | 126 |
| 5.8 | CONCLUSIONS | 127 |
| 5.9 | RECOMMENDATIONS | 128 |
| REFERENC | CES | 129 |
| ADDENDIC | | 120 |

List of Tables

Chapter II - Literature Review

| Table 2.1 | Results from general ALS/BLS studies | 28 |
|-----------------|--|----|
| Table 2.2 | IV therapy experiments in animals | 41 |
| Table 2.3 | IV therapy studies involving humans | 42 |
| Table 2.4 | Studies on PASG/MAST | 53 |
| Chapter III - I | Materials and Methods | |
| Table 3.1 | Examples of Response Priority to Selected Injuries | 64 |
| Table 3.2 | Hours of Training Required for EMT Certification 1970 - 1996 | 66 |
| Table 3.3 | AIS Codes Sufficient for Inclusion in Study Sample | 68 |
| Chapter IV - I | Results | |
| Table 4.0 | Breakdown of final sample | 77 |
| Table 4.1.1 | Reason for Inclusion | 78 |
| Table 4.1.2 | Reason for Inclusion by Hospital | 79 |
| Table 4.1.3 | Admitting Hospital | 79 |
| Table 4.1.4 | Distribution of Injury by City | 80 |
| Table 4.1.5 | Gender | 80 |
| Table 4.2.1 | Continuous Exposures | 82 |
| Table 4.2.2 | Distribution of Injury Year by Group | 82 |
| Table 4.2.3 | Categorical Exposures | 86 |
| Table 4.2.4 | Incidence of Firearm Injuries | 87 |
| Гable 4.3.1 | Overall Mortality | 88 |
| Table 4.3.2 | Mortality (within 7 days) | 88 |
| Table 4.3.3 | Mortality by Year | 89 |
| Гable 4.3.4 | Mortality and Mechanism of Injury | 90 |
| Table 4.3.5 | Standardized Mortality Ratio (SMR) | 91 |
| Гable 4.3.6 | Time of Death (hours after injury) | 92 |
| Гable 4.3.7 | Test Statistics for Equality of Survival Distributions for ALS/BLS | 93 |
| Гable 4.3.8 | Days until Death | 94 |
| Гable 4.4.1 | Admitted to the ICU | 95 |
| | VII | |

| | (survivors only) | |
|--------------------|---|-----|
| Table 4.4.2 | Length of ICU admission | 96 |
| | (survivors admitted to the ICU) | |
| Table 4.4.3 | Length of Hospital Stay | 96 |
| | (survivors only) | |
| Table 4.5.1 | Discharge status | 97 |
| | (excludes patients discharged home) | |
| Table 4.5.2 | Patients Discharged Home - Help Requirements | 98 |
| Table 4.5.3 | Patients Discharged Home - Help Requirements Stratified by Age | 98 |
| Table 4.6.1 | Mortality stratified by ISS | 99 |
| Table 4.6.2 | Descriptive data concerning non-surviving low ISS patients | 100 |
| Table 4.6.3 | Mortality Stratified by Age | 100 |
| Table 4.6.4 | Incidence of firearm injuries stratified by age | 101 |
| Table 4.7.1 | Continuous Exposures Efficacy Analysis | 102 |
| Table 4.7.2 | Mortality Efficacy Analysis | 103 |
| Table 4.7.3 | Standardized Mortality Ratio (SMR) | 104 |
| Table 4.8.1 | Mortality and Prehospital IV Fluid Administration (ALS patients) | 106 |
| Table 4.8.2 | Mortality and Prehospital IV Fluid Administration (all patients) | 106 |
| Table 4.8.3 | Mortality and Prehospital Intubations | 107 |
| Table 4.8.4 | Descriptive Data Concerning Intubated Patients | 107 |
| Table 4.9.1 | Prehospital Time Comparisons Intent to Treat Analysis | 108 |
| Table 4.9.2 | Prehospital Time Comparisons | 109 |
| 14510 4.0.2 | Efficacy Analysis | 100 |
| Table 4.9.3 | Prehospital Time Comparisons | 109 |
| | ALS Patients | |
| Table 4.9.4 | Prehospital Time Comparisons | 110 |
| | MD-BLS versus EMT-BLS | |
| Table 4.10.1 | Length of Hospital Stay (hours) Linear Regression Final Model | 111 |
| Table 4.10.2 | Mortality Logistic Regression | 113 |

List of Figures

| Figure 3.1 | Emergency Medical System in Montreal/Laval | 63 |
|------------|---|-----|
| Figure 3.2 | Trauma Emergency Department Selection Protocol | 65 |
| Figure 4.1 | Distribution of age - BLS group | 81 |
| Figure 4.2 | Distribution of age - ALS group | 81 |
| Figure 4.3 | Year of injury of BLS patients | 83 |
| Figure 4.4 | Year of injury of ALS patients | 83 |
| Figure 4.5 | Hours until death among all patients Kaplan-Meier Survival Analysis | 92 |
| Figure 4.6 | Hours until death limited to those occurring < 50 hours after injury Kaplan-Meier Survival Analysis | 93 |
| Figure 4.7 | Graphical Representation of SMR 95% Confidence Intervals | 105 |

ABBREVIATIONS

ACS - American College of Surgeons

AIS - Abbreviated Injury Scale
ALS - Advanced Life Support

ATLS - Advanced Trauma Life Support

BLS - Basic Life Support
BP - Blood Pressure

CL - Hopital Charles LeMoyne

CPR - Cardio-Pulmonary Resuscitation

EA - Efficacy Analysis

EI - Endotracheal Intubation
EJ - Hopital de l'Enfant Jesus

EMT - Emergency Medical Technician

EMT-P - Emergency Medical Technician - Paramedic

ICU - Intensive Care Unit ISS - Injury Severity Score

ITT - Intent to Treat
IV - Intravenous
LOS - Length of Stay

MAST - Military AntiShock Garment

MD-ALS - Physician administered Advanced Life Support

MGH - Montreal General Hospital

MOF - Multi-Organ Failure

MTOS - Major Trauma Outcome Study

OR - Operating Room

PASG - Pneumatic AntiShock Garment

QTR - Quebec Trauma Registry
RTS - Revised Trauma Score

SC - Hopital Sacre Coeur de Montreal

SD - Standard Deviation
SE - Standard Error

SMR - Standardised Mortality Ratio

TS - Trauma Score

Chapter i - INTRODUCTION

1.1 TRAUMA IN SOCIETY

Trauma is a major health care problem that wrests an extremely high toll on society in a variety of manners. This includes the loss of productive members, many of whom are less than 40 years of age, to temporary and permanent disability and death. In fact, in this age group, trauma is the leading cause of death surpassing cancer, heart disease, lung disease and AIDS (Sampalis et al., 1993). In all age groups, it is the fourth most potent killer in Canada behind cancer, heart disease and cerebrovascular disease (Mortality, 1995). Unlike many other public health problems, trauma strikes all ages and demographic classes.

The extent to which trauma plagues society was not brought into the forefront of the public's attention until 1966 (Werman et al. 1987). The National Research Council published a report on accidental death and disability. This narrative emphasised the need for well-trained personnel to deliver prehospital care to injured individuals. Subsequently, other studies pointed out that the mortality due to trauma could be significantly reduced with more structured and elaborate emergency medical systems. These early scientific explorations into the prehospital care of trauma became the starting point for a vigorous scientific debate that would result in hundreds of studies and publications. The debate on how best to treat these injuries before the patient's arrival at the hospital still rages today, nearly 30 years later.

The most common form of serious injury in Canada is blunt trauma sustained

largely during automobile accidents and falls. Penetrating trauma from gunshot and stab wounds also makes up a substantial portion of injuries, accounting for 15% of the nation's major trauma cases (Hamilton et al., 1996). Mortality due to penetrating injuries, which are the focus of this investigation, is higher than other types of trauma. Firearm injuries are of particular concern. Results of the Major Trauma Outcome Study (MTOS) released in 1988 on injuries reported from 26 American institutions on 14,876 victims of trauma indicated that of those wounded by gunshot, 15% did not survive. In comparison, the rate of death among all other injuries was only 5.4% (Copes et al., 1988).

In 1987, trauma in Quebec was the leading cause of death in those under 45 years of age and accounted for over 3900 deaths (Beaulne et al., 1991). Among all ages, trauma was the third leading killer behind cancer and atherosclerosis (Beaulne et al., 1991).

Because death due to trauma is most prevalent in the young, the potential years of life lost are the greatest. Statistics from 1987 showed that trauma mortalities were responsible for an average 30 year loss of life in contrast to cancer deaths which claimed their victims only 16 years short of average life expectancy (Beaulne et al., 1991).

Statistics compiled in the United States are similarly staggering. The Advanced Trauma Life Support (ATLS) Course Manual, written by the American College of Surgeons' Committee on Trauma was last published in 1993. It stated that in the United States, approximately 60 million injuries occur yearly, resulting in 8.7 million temporary disabilities, 3.6 million hospitalisations, 300 000 permanent disabilities and 145 000 deaths (Committee on Trauma, 1993). Economically, the costs of treating such injuries were enormous. In 1987, it was estimated that the total bill for the treatment of traumatic

injuries exceeded \$60 billion (US) (Werman et al. 1987). This figure rises to \$100 billion (US), or 40% American health care expenditures, when one considers secondary costs such as lost wages, medical expenses and insurance administration costs (Committee on Trauma, 1993). Such figures, coupled with society's focus on less prevalent health care problems such as diabetes, liver disease and kidney disease have prompted some to refer to trauma as the neglected epidemic of modern society (National Academy of Sciences, 1966; Baker, 1987).

For many years, the impact of trauma on society has been overlooked. A number of studies published in the U.S. brought the epidemic of trauma to the attention of the American media and policy makers. In 1973, the Emergency Medical Services Act was passed in the United States which resulted in a series of guidelines for the implementation of regionalised trauma care systems and patient triage algorithms (Sampalis et al., 1995).

1.2 HISTORY OF TRAUMA CARE

The first trauma operation occurred well before the development of modern western medical technology began to define our understanding of health and medicine. As far back as 8,000 BC humans have actively tried to improve the condition of trauma patients. Neolithic man are believed to have used a flint knives to remove sections of the skull. This phenomena has been observed in the skulls of trauma victims of widely dispersed regions, such as Peru, Egypt and Mesopotamia (Major, 1954).

More recently, attempts were made to bleed the trauma victim. Ambroise Paré, a battle surgeon in the 16th century, believed that this procedure allowed noxious toxins to exit the body (Major, 1954). Thankfully this practice has since been discontinued and

replaced with more intuitively logical treatments.

At the turn of the century, a physician named George Crile began to work on pneumatic counterpressure trousers for patients in surgery (Crile, 1903). Although not initially intended for the treatment of trauma, the concept of pneumatic counterpressure has evolved to the point that many believe it to be an indispensable tool in the prehospital treatment of major trauma.

In recent years, a vigorous scientific debate has surfaced concerning the use of counterpressure and other prehospital trauma interventions. Two philosophies have emerged. The 'stay and stabilise' school of thought espouses that concerted efforts be made on the scene to stabilise the patient even if they delay transportation to the hospital. Those who favour the 'scoop and run' axiom consider prehospital time to be the most important factor affecting the outcome of the patient. In their view the potential benefits of on-site stabilisation do not compensate for the extra time spent in the prehospital environment.

1.3 PREVENTING TRAUMA

There are two ways in which the impact of trauma on society can be lessened: prevention and treatment. Prevention has been described in three stages. Primary prevention reduces the incidence of traumatic incidents, while secondary prevention can reduce the severity of events and finally tertiary prevention, which encompasses all efforts subsequent to injury to reduce morbidity and death.

Primary prevention is accomplished by continuously educating the public on how to initially avoid trauma. Speed limits are an obvious example of measures that reduce the

incidence of accidents and therefore trauma. Equipment safety standards updated to match current scientific knowledge are examples of secondary prevention. Motorcycle helmets, bicycle helmets, hockey helmets and airbags are only a few examples of devices designed to reduce the severity of head trauma.

Prevention, although an attractive and essential modality, is not a final solution.

Despite the most vociferous collective effort, trauma, unlike other afflictions such as measles and small pox, can and never will be, eradicated. So long as people drive, violent crimes are committed, or children play, traumatic events will occur and deaths and/or injuries will inevitably result. This leaves one other manner in which to diminish the impact of trauma on society: treatment.

1.4 TREATING TRAUMA

The effective treatment of an injury begins the instant after the injury takes place.

Time, or rather the lack of it, is the main force driving the treatment of a trauma victim. A patient in respiratory distress will lose consciousness within seconds of onset. Similarly, rapid bleeding can cause death within minutes.

1.4.1 BASIC AND ADVANCED LIFE SUPPORT

Basic Life Support (BLS) is performed by emergency medical technicians (EMT), paramedics (EMT-P) and physicians (MD) and consists of non-invasive first aid manoeuvres. Non-paramedic EMTs are trained and authorised to bandage open wounds, splint obvious fractures, place the patient on a spinal board, administer supplemental oxygen via a mask and perform cardio-pulmonary resuscitation (CPR) if necessary.

Conversely, paramedics and MDs, who perform Advanced Life Support (ALS) in addition

to BLS, are more highly skilled and are capable of performing invasive procedures. Advanced Life Support interventions include endotracheal intubation, the provision of certain medications and fluid via the intravenous route, defibrillation and the administration of pneumatic antishock garments (PASG). In the province of Quebec, paramedics are not recognised health professionals by law and therefore ALS services are provided by physicians employed by Urgences Santé which is the sole prehospital care provider in the Montreal / Laval community. ALS is not available elsewhere in the province.

1.4.2 PASG/MAST

The PASG, also known as the Military AntiShock Trouser (MAST), is one aspect of the debate over prehospital trauma care. It consists of a pair of inflatable trousers that are placed on the patient. Each leg and one abdominal section can be independently inflated to exert external pressure on the patient. Proponents argue that it is a beneficial and necessary tool which increases blood pressure by increasing peripheral vascular resistance, thereby stabilising patients in hypovolemic shock. Some detractors believe the time required to put on the trousers outweighs the potential benefits the trousers may have. Others feel that raising a patient's blood pressure before appropriate surgical repairs are carried out is deleterious since this increases the rate of hemorrhage. Complications associated with the use of PASGs, which include compartment syndrome and tissue ischemia, have also been used as an argument against the use of the garment.

1.4.3 INTRAVENOUS FLUID REPLACEMENT

Another debated aspect of prehospital ALS surrounds the effectiveness of rapid administration of IV saline and crystalloids. The Advanced Trauma Life Support course

(Committee on Trauma, 1993) recommends that all hypotensive patients should receive immediate intravenous fluid in an attempt to elevate blood pressure prior to surgery. This philosophy is partly based on animal studies which indicated increased survival in animals that were subject to atraumatic hypovolemia by the withdrawal of set amounts of blood through a catheter. Such studies, which are described in detail in the next chapter, do not reflect a true injury experienced in real setting where the patient will continue to bleed through different wounds. Such studies completely ignore the hemodynamics of clotting and its effect on stabilising someone in hypovolemic shock. More recent animal studies using uncontrolled hemorrhage where no efforts are made to control or stop bleeding have come out in favour of delaying IV infusions.

The other concern relating to early IV fluid access centres around prehospital time. Time is required to successfully cannulate the patient which adds to the delay of arrival at a trauma care facility. In the urban environment where travel times are fairly short, only a relatively small amount of fluid may be infused before the patient reaches the ER. If the amount administered en route is less than the amount lost to bleeding when the IV is being established, it is likely that the patient may have benefited more by prompt transport. This minimises the amount of time until definitive surgical care is able to control bleeding.

Stephen Lloyd, in a 1987 paper on IV lines and MAST made the following observation: "It is argued that the use of IV lines has grown from its appropriate, and potentially valuable, use in cardiac arrest patients into its inappropriate, and potentially harmful, use in multiple trauma patients." (Lloyd, 1987) Review of scientific literature on the subject of prehospital IV infusion in hypotensive multiple trauma patients reveals much

controversy but only one prospective randomised trial.

1.4.4 AIRWAY MANAGEMENT

Intubating conscious victims of trauma requires the injection of neuromuscular blocking agents however this is rarely necessary because a conscious patient is most likely also a breathing patient. Those who require prehospital intubation frequently present with major neurological impairments, often due to major head trauma (Oswalt et al., 1992). This is not a situation that commonly accompanies cases of penetrating trauma. If a patient loses consciousness, it is likely due to shock, or in more severe cases from massive blood loss. The salvage of such patients with aggressive airway management is rare since intubating a patient with insufficient blood volume is not likely to reverse the pathophysiologic events that led to unconsciousness in the first place (Rosemurgy et al., 1993).

For years, the use of these prehospital Advanced Life Support (ALS) techniques has focused on the issue of prehospital time. Detractors have indicated that the benefits of procedures carried out on the scene are negated by the extra time spent in the field which delays the delivery of definitive care at a trauma facility. Proponents of ALS have argued that the benefits of ALS procedures carried out on the scene outweigh the risks of delaying the transport of the victim. This view however, assumes that ALS procedures are fundamentally beneficial, a belief that for some ALS interventions, has been challenged.

Immediate IV fluid replacement has been accused of increasing the rate of hemorrhage and decreasing survival in recent studies on uncontrolled hemorrhage (Bickell et al., 1994). In addition to delaying the arrival of a patient to a trauma facility, the application of the Pneumatic Antishock Garment has also been accused of causing serious lower limb

complications and destabilising the hemodynamics of the victim (Bickell et al., 1985; 1987; Mattox et al., 1986; 1989; Chang et al., 1995).

1.5 TRAUMA MORTALITY

Severe traumatic injuries kill in one of three stages which were classified by

Trunkey into distinct 'peaks' (1983). More than half of all trauma deaths occur during the

first peak and are referred to as "immediate deaths" (Trunkey, 1983). These take place at
the scene, either instantly upon impact, or shortly thereafter. First peak deaths are rarely
treatable and are generally the result of massive trauma to the head, spinal cord, heart or
major vessels (Committee on Trauma, 1993). Such injuries, once incurred, will cause
death regardless of the sophistication of the EMS system in place, the distance to the
nearest hospital and the experience of the attending trauma team.

Immediate deaths result from injuries that are non-survivable. Ideally, resources would not be expended in futile attempts to save these patients. In practice however, the frantic setting of prehospital medicine makes identifying these patients extremely difficult.

The second peak of trauma deaths occurs in the early hours following injury.

These are termed "early deaths" and may in some cases be avoided provided that a proper diagnosis is made quickly and appropriate treatment is administered based on a correct diagnosis. As in all treatable trauma cases, time is of the essence, therefore an organised EMS system is vital for the improved survival of these patients (Trunkey, 1983).

Still a third peak of trauma deaths occurs in the weeks following injury. The typical cause of death in this subgroup of patients differs from the other two peaks. "Late deaths" are commonly the result of multi-organ failure and sepsis. Both second and third

peak deaths, which account for 50% of all trauma fatalities, can be impacted by procedures carried out in the moments following injury (Trunkey, 1983). Therefore, the prehospital setting is a crucial phase in the treatment of severe trauma. Accordingly, this period warrants extensive investigation and research to elicit which procedures are helpful and which simply delay the time arrival of the patient to a trauma facility.

1.6 THIS INVESTIGATION

This study examines a specific group of patients who experienced a penetrating injury in an urban setting and who were brought to a level I trauma centre. Only penetrating injuries have been included because they are fundamentally different from blunt trauma. The mechanisms of injury differ between the two injury types. Motor vehicle crashes and falls predominate in blunt trauma whereas gunshot and stab wounds make up the large majority of penetrating injuries. In addition, penetrating injuries are typically associated with higher mortality rates than blunt injuries of similar severity.

Similarly, urban injuries differ from rural ones since the time required to reach and then transport the patient to a trauma facility is significantly longer outside of urban centres. This additional delay has implications on the approach of prehospital care as attempts to stabilise the patient may be necessary.

A third restriction placed on patients in the study involved the facility to which they were transported. Previous research carried out in Montreal demonstrated that mortality rates are associated with the level of care of the receiving hospital (Sampalis et al., 1992; 1993). A regional trauma system was instituted in the province in 1993 to address this problem. In order to avoid introducing a hospital effect into the study, only the four level I

trauma centres in the province were selected to contribute patients.

Two different approaches are used to evaluate the types of prehospital care. The Intent to Treat (ITT) philosophy evaluates the performance of ALS and BLS without specifying which procedures were actually performed on the scene. This practical approach tests the ability of the two modalites as they perform in day to day emergencies. The Efficacy approach was also employed which examines, in a more specific context, the actual influence of prehospital procedures on survival and morbidity.

1.6.1 PREHOSPITAL CARE IN QUEBEC

The province of Quebec has a unique prehospital care system in place. As mentioned above, ALS services are provided by physicians working in conjunction with Urgences Santé. However, due to shrinking health care budgets the number of MD-ALS units available is insufficient to attend to all of the calls for which Urgences Santé's protocols prescribe. The result is a random allocation of MD-ALS units to patients based on availability. This arrangement has allowed this investigation to utilise randomisation in order to ensure that the two groups of patients being studied are equivalent for all other variables. This is accomplished since each patient has an equal chance of being treated by an MD-ALS unit even though the randomisation was not carried out deliberately by study investigators.

In other studies that examine prehospital trauma care, triage protocols exist which predetermine which patients receive which type of ambulance, either EMTs or paramedics. This assures, right from the moment the call to a 911 system is made, that patients in one group differ systematically from patients in the other. Drawing conclusions from such

studies is difficult because the results are based on different injuries. In some Emergency Medical Systems (EMS), ambulances are exclusively staffed by either only paramedics or only EMTs which makes comparisons to other treatment philosophies impossible.

1.6.2 RATIONALE

Budgetary concerns have had increasing effects on health care in the province of Quebec. This has impacted on the ability of Urgences Santé to staff its force with a sufficient number of MD units to respond to calls for which they are required according to its own triage protocols. In light of the continued controversy regarding prehospital care of penetrating trauma, this study is necessary in order to properly allocate resources in the future. In the case that MD-ALS is beneficial to victims of penetrating trauma, Urgences Santé should be lobbying for greater funding in order to increase the number of physicians on duty. In addition, other urban communities should consider instituting ALS for the treatment of penetrating trauma. Conversely, if MD-ALS is not beneficial, Urgences Santé should change its triage protocol to free MD units for other emergencies where their benefit to the patient is well-established.

1.6.3 OBJECTIVE

The purpose of this investigation is to determine the value of physician administered advanced life support (MD-ALS) in the treatment of penetrating trauma in an urban environment.

Chapter II - LITERATURE REVIEW

The delivery of prehospital trauma care continues to elicit controversy among health care professionals. The debate has focused on the extent to which advanced life support (ALS) techniques are employed in the treatment of trauma patients. At the heart of this discussion is the time spent on the scene which has an impact on the time from injury to definitive care in a trauma facility. Contributing to the debate is the lack of conclusive scientific evidence that supports the benefits of invasive procedures performed on the scene. The debate has come to be known as 'scoop and run' versus 'stay and stabilise'. The purpose of this study is to ascertain the effectiveness of physician administered Advanced Life Support (ALS) procedures in the prehospital care of patients with penetrating trauma.

2.1 CHRONOLOGICAL REVIEW OF GENERAL ALS/BLS STUDIES

The first section of this chapter deals with general studies that have examined the effectiveness of ALS and BLS in the treatment of various types of trauma. These investigations did not focus on specific prehospital interventions but rather assessed the effectiveness of ALS and/or BLS as a whole.

1982

In 1982, Gervin and Fischer were the first investigators to examine the prehospital treatment of patients with penetrating cardiac injuries (Gervin et al., 1982). Their retrospective study compared patients transported directly and immediately to those for which "significant" attempts at stabilisation had been made in the field. No patients in the

stabilisation group survived, while 38% of those in the 'scoop and run' group survived to discharge (Gervin et al., 1982). However, since no data was presented comparing the groups with respect to initial exposures, the possibility exists that the populations differed with respect to unmeasured variables and it may have been these differences, specifically injury severity, that were responsible for the observed differences in mortality.

Nevertheless, the Gervin and Fischer study did reinforce the position of those in favour of the scoop and run approach.

1983

The early study by Gervin and Fischer (1982), introduced doubts about the benefits of ALS (Copass et al., 1984). Although the use of ALS was not criticised when applied to cardiac arrests occurring outside the hospital, some researchers began to question the extension of ALS procedures to trauma patients (Copass et al., 1984). At the 42nd Annual Session of the American Association for the Surgery of Trauma Care, a panel was convened to discuss the prehospital management of trauma (Border et al., 1983). The "Stabilise or Scoop and Run" group was made up by Dr. Frank Lewis, Dr. Charles Aprahamian, Dr. Alex Haller, Dr.Lentworth Jacobs and Dr. Arnold Luterman, all of whom had recently published studies examining prehospital trauma care. Conflicting opinions were expressed by the panelists, although one of the most telling points of the discussion was made in the follow up question period by Dr. Richard Burney who noted that no randomised study on prehospital trauma care had been carried out.

One of the panelists, Dr. Charles Aprahamian has been a staunch defender of prehospital stabilisation and has published a number of studies to support his position. In

1983 he published a study on major penetrating intra-abdominal vascular trauma which showed that Advanced Trauma Life Support (ATLS) procedures could be performed quickly and result in improvements in the hemodynamic status of the patient (Aprahamian et al., 1983). The findings of the study however, were clouded by the sampling method used. Patients were collected over a 12 year period (1970-1981), but all of the ALS cases were collected during the last 4 years of the study. This sampling creates a bias in favour of the ALS group since they were treated by a more modern EMS system and presumably improved ER facilities and technology. A more relevant analysis would have included only BLS patients identified during the last four years of the study which would have at least assured that the patient groups were treated in the same EMS environment.

1984

Cayten studied New York City trauma victims admitted to level I trauma hospitals and treated by either ALS or BLS ambulance personnel. ALS treated patients experienced significantly higher than expected mortality based on the Major Trauma Outcomes Study (MTOS) data, whereas the BLS group was slightly, but not significantly, lower than expected. Scene times were significantly longer in the ALS group (25 versus 17 minutes; p < 0.005) (Cayten et al., 1984). This was a retrospective analysis and it is unclear how patients were assigned either an ALS or BLS unit. In addition, ALS treated patients had more serious injuries as measured by both ISS (24 versus 12; p < 0.005) and Trauma Score (TS) (13.5 versus 12.0; p < 0.05) (Cayten et al., 1984). Drawing conclusions from such a study is difficult. The difference in outcome witnessed between the two treatment modalities could have resulted from initial discrepancies in injury severity rather than the

on-site care provided.

A study by Jacobs in Boston observed improvements in the TS on arrival to the hospital ER among patients treated by ALS units. The level of prehospital treatment (ALS versus BLS) was not, however, a significant predictor of survival in a logistic regression (Jacobs et al., 1984). Such a result does not further the cause of prehospital stabilisation since improvements in health indices such as the TS are not indicative of improved outcome unless they are accompanied by increased survival or decreased hospital stay.

Copass completed a retrospective review of 131 patients who underwent prehospital CPR due to trauma in the Seattle area over a three year period. The authors divided the sample into survivors and non-survivors and found significantly more intubations and IV lines in the survivors (Copass et al., 1984). The fact that 100% of the survivors had two IV lines established while only 70% of non-survivors did is not an effective argument for prehospital resuscitative IV fluid therapy. In fact, it is expected since the EMS system in which the study was carried out is exclusively ALS and therefore the insertion of IVs into injured patients is routine. The 30% of patients in the non-surviving group who were never cannulated may have died before an IV could be established. In other words, patients that died could have influenced the use of IV therapy, as opposed to the IV therapy influencing their survival. The same argument could be made in terms of endotracheal intubation, where 97% of survivors were intubated versus 65% of non-survivors.

1985

In 1985, Smith studied 52 consecutive hypotensive trauma victims who presented

with a blood pressure of less than 100 mmHg either at the scene or on arrival to the hospital. In the discussion the authors stated that: "Seriously injured, hypovolemic patients should not have resuscitative efforts at the scene. These patients should be subject to an automatic 'load and go' protocol." (Smith et al., 1985) This statement was based on the results of their study which found that in all cases, the time required to cannulate patients was longer than the transport time to the hospital. In the context of the current discussion, these findings are of particular relevance here due to the fact that a majority of the patients were victims of penetrating trauma (65%).

Pons et al. (1985) published an analysis on 203 consecutive victims of gunshot and stabwounds to the thorax and abdomen who underwent emergency laparotomy and/or thoracotomies in Denver, Colorado (Pons et al., 1985). They reported on changes in blood pressure between the scene and the ER as well as the survival of their patients.

There was no opportunity for statistical analysis, however, since Denver is served exclusively by paramedics and hence there was no BLS group for comparison.

Nevertheless, the authors used the results of their study to claim that "ATLS interventions by well trained paramedics can be performed efficiently and improve the hemodynamic status of patients critically injured with gunshot and stab wounds to the chest and abdomen" (Pons et al., 1985), even though 45% of their subjects had either no change or a decrease in BP en route to the ER. Improvements in BP before operative intervention through infusions of IV solutions in other studies have not been associated with improved survival (Jacobs et al., 1984; Mattox et al., 1991; Vassar et al., 1993; Reines et al., 1988; Cayten et al., 1993).

In 1987, Ivatury et al. completed a study regarding scene stabilisation versus prompt transport in the prehospital management of penetrating thoracic injuries (Ivatury et al., 1987). The prompt transport group consisted of patients brought by police, EMS or private vehicles, while those in the stabilisation group were transported by ALS units. The authors reported that survival was significantly decreased in the stabilisation group despite "comparable anatomic and physiologic indices" (Ivatury et al., 1987). The main flaw in the paper was the lack of a statistical comparison of the two treatment modalities, leaving the study open to criticism that the two groups differed in the nature and severity of their injuries. The observed difference in mortality could have been due to baseline differences in injury severity, rather than the prehospital care that they received.

Also in 1987, Cwinn et al. published a report on prehospital ALS for critical blunt trauma. The investigation found that 11% of endotracheal intubation attempts were unsuccessful, while 6% of IV attempts were unsuccessful. The authors asserted that "ALS can be performed at the scene in an expeditious manner" (Cwinn et al., 1987) Their study did not include a comparison of similar patients transported by BLS units, however, and therefore their results do not suggest that ALS is preferable to BLS in terms of prehospital time or mortality.

Shackford et al., while examining the initial impact of a trauma system, found no differences relating to prehospital care between survivors and non-survivors of major trauma. Their sample included only patients presenting with a Trauma Score of 8 or less and was split into those with blunt trauma and penetrating trauma (Shackford et al., 1987).

As expected, survivors were younger and were less severely injured as indicated by a lower ISS. There were no trends between survivors and non-survivors in terms of field scene times, transport time to the hospital or frequency of prehospital IV fluid administration and intubation (Shackford et al., 1987). This study suffered from a small sample size, however, as there were only 60 victims of penetrating trauma which makes it difficult to draw meaningful inferences about such injuries.

Tsai et al. published a descriptive study on pediatric trauma in 1987 (Tsai et al., 1987). They observed significantly higher scene times in cases where there was an attempt to insert at least one IV line over those cases where no attempt to cannulate the patient was made (26 vs 16 minutes; p<0.001). In addition, there were low success rates associated with attempts to establish IV lines in this population; 29% in infants, 66% in pre-schoolers, 84% in children and 92% in adolescents. Long scene times and low success rates prompted the authors to counsel against prehospital IV attempts in young patients (Tsai et al., 1987).

1988

An Australian study conducted in 1988 compared ALS versus BLS treated victims of urban trauma (Potter et al., 1988). Although BLS patients died sooner after injury and had a higher incidence of respiratory failure, overall mortality was the same for both groups and logistic regression analysis for mortality showed no effect of ALS on outcome. This study was hampered, however, since the BLS and ALS groups were derived from two different cities over 1000 km apart. This limitation is emphasised by the observation that ALS scene times were shorter by 4 minutes (p=0.05) (Potter et al., 1988). This

incongruent finding underlines the differences in the EMS systems of the two cities. The suggestion could be made that any benefits seen in the ALS groups could have been due to shorter prehospital times rather than interventions carried out by paramedics on the scene.

Reines et al. studied motor vehicle accidents in an attempt to gauge the success of ALS in improving outcomes in rural South Carolina (Reines et al., 1988). As expected, ALS was associated with increased prehospital time as paramedics spent an average of 24.8 minutes on the injury scene compared to 18.9 minutes for BLS units (p<0.05). ALS patients demonstrated blood pressure increases during transport more frequently than BLS patients (33% versus 20%; p < 0.05). The Reines study was not able to support the use of ALS interventions, however, because no comparisons were made between the groups with respect to either mortality or morbidity. Other studies that have documented improvements in blood pressure have not found associations between this increase and increased survival (Jacobs et al., 1984; Mattox et al., 1991; Vassar et al., 1993; Cayten et al., 1993).

1990

In 1990, Honigman released a study that concluded that scene times were not correlated with the number of ALS procedures carried out on patients with penetrating cardiac wounds in an exclusively ALS EMS system (Honigman et al., 1990). Like Reines' study, Honigman did not perform any analysis on outcome variables such as survival or length of stay and therefore the impact of the procedures on mortality and morbidity was not assessed. In addition, there was no comparison to similar patients transported by BLS.

1991

Spaite observed similar short scene times for severely injured patients presenting to

prehospital ALS personnel with an ISS greater than 15 (Spaite et al., 1991). His study found shorter scene times in patients who had more procedures performed on the scene. This seemingly illogical result implies that paramedics work much faster when faced with a very seriously injured patient which allows them to perform more procedures in less time. Like the previous work by Honigman et al. (1990) and Reines (1988) though, Spaite did not address the outcomes of his patients and therefore the results do not support the use of ALS.

1992

One of the largest studies published on ALS in the treatment of trauma originated in 1992 in North Carolina. Messick et al. examined over 12 thousand trauma deaths in the state and concluded that counties with ALS capability had a significantly lower per capita death rate due to trauma than counties serviced exclusively BLS EMS systems (Messick et al., 1992). This study suffers from several limitations. For one, all urban counties, where transport times are certain to be lower, were ALS counties. Since decreased transport times are known to be associated with increased survival, regardless of the treatment onsite, it is likely that the ALS group was aided not necessarily by the interventions associated with ALS, but by the decreased time needed to reach the hospital. In addition, urban areas are more likely to be serviced by level I trauma centres which are accustomed to dealing with major trauma cases on a regular basis, a fact that would also tend to favour the ALS counties. The authors present a regression analysis that identified ALS/BLS as the most significant predictor of per capita death rates. It could be suggested that the variable ALS/BLS is really a proxy for urban/rural and it is the factors associated with

being an urban county that affect death rates due to trauma.

Sampalis et al. (1992) compared the survival rates in Montreal with those of the Major Trauma Outcome Study (MTOS) population published in 1988 (Copes et al., 1988). Their principal investigation focused on the lack of regionalised trauma care in the region. The study also considered the performance of ALS as performed on-site by physicians in the Montreal EMS system. Logistic regression indicated that the type of prehospital care delivered (BLS versus MD-ALS) was not a statistically relevant predictor of mortality due to trauma (Sampalis et al., 1992). The dispatching protocols in place at the time were geared such that more severely injured patients were sent ALS units. This limitation created a bias which favoured the BLS group. Nevertheless, this analysis is of particular importance in the context of the present discussion since it addressed the same EMS system being investigated and it examined ALS/BLS while controlling for ISS and the level of the receiving hospital.

1993

In 1993 Cayten et al. published a comparison of ALS versus BLS in 781 victims of penetrating trauma and motor vehicle crashes who presented with an ISS of 10 or greater and 219 hypotensive trauma patients (Cayten et al., 1993). Both MVC and hypotensive ALS patients demonstrated an improvement in their RTS scores and blood pressure from the scene to the hospital, while the BLS patients did not. Nevertheless, no differences were noted between the groups with respect to observed versus predicted mortality (Cayten et al., 1993).

Another 1993 study examined the effectiveness of ALS in the treatment of

traumatic cardiac arrest (Rosemurgy et al., 1993). The study found no survivors among 138 patients who underwent CPR due a lack of blood pressure, pulse and respiration either at the scene, or during transport. The complete lack of survivors of traumatic cardiac arrest noted in this study weakens the notion that prehospital ALS is necessary to prevent death in these patients.

In the same year, Sampalis et al. published a report on 360 severely injured patients from the Montreal region (Sampalis et al., 1993). Their study found no difference in survival between those who received MD administered on-site ALS to those who did not. The same study found a threefold increase in the mortality of those whom had a total prehospital time greater than sixty minutes, versus those who spent less than sixty minutes in the field. This suggests that total prehospital time is the critical factor influencing survival and not the administration of pre-hospital ALS (Sampalis et al., 1993). This study was hampered for the same reason that the 1993 study by Sampalis et al. was, namely that triage protocols created a bias by sending more severely injured patients ALS units.

1994

In 1994, Lerer et al. examined sharp penetrating chest trauma in Cape Town, South Africa (Lerer et al., 1994). Among the 722 patients retrospectively examined, the authors reported an unexpected finding that patients from poorer socio-economic areas experienced higher survival than those from more affluent neighbourhoods. In the opinion of study investigators, this discrepancy was likely due to shorter prehospital times in low SES areas due to increased use of private vehicles as a means of transporting injured individuals to the hospital (Lerer et al., 1994). Since the authors did not collect data on

prehospital times or method of arrival, it is unknown whether the patients who survived were actually those brought in by private vehicles.

Rutledge et al. published a population based analysis of the association between county demographic and medical system factors and per capita pediatric trauma death rates in North Carolina (Rutledge et al., 1994). They discovered that the presence of ALS was the only factor from 21 county demographic and medical system measures that was significantly associated with pediatric trauma related mortality using multivariate analysis. Their abstract failed to mention that a number of factors were associated by univariate analysis. Specifically, population density, percent non-Caucasian residents and the presence of a 911 system showed positive correlations, whereas the percent rural and mean personal income showed negative correlations with pediatric death rates. The authors make this point in the discussion when they note that "low socio-economic status may impact on the type of medical resources available in the county, the quality of the resources available, and the type of treatment that the patient seeks" (p. 209). Since the authors did not present a correlation between ALS and rurality, another interpretation is that the presence of ALS was really just a proxy measure of the rurality of a county.

1995

Quintans-Rodriquez published a report of 48 cases of severe trauma admitted to one hospital over a two-year period. Overall survival was 41%, 48% in patients who received prehospital endotracheal intubation and 18% in those who required CPR before arrival at the ER (Quintans-Rodriquez et al., 1995). Since only 48 cases were entered into the study, the receiving facility examined by the authors does not seem like an established

trauma centre. The study also failed to include a similar group of patients treated by BLS and therefore the conclusion of the authors that "ALS in severe trauma was able to save the lives of many patients at high risk of dying before reaching the hospital" (Quintans-Rodriquez et al., 1995) is not suggested by their data, nor could it have been within the framework of their study design without a comparison between observed and expected mortality. Expected mortality could have been calculated according to the TRISS method which was described in 1987 by Boyd et al. and incorporates the Revised Trauma Score as well as age and ISS to determine the probability of death. The Revised Trauma Score is calculated using the Glasgow Coma Score, respiratory rate and blood pressure.

In 1995, Sampalis published a subjective analysis on the 73 deaths observed in the 1993 report (Sampalis et al., 1993). Forty four were classified as survivable or potentially survivable by a committee of nine trauma experts (Sampalis et al., 1995). The committee then retrospectively evaluated the prehospital interventions performed on each case and considered 3% of cases of IV fluids use necessary, harmful in 42% and neutral (meaning that it held neither a benefit or a detriment to the survival of the patient) in 50% of cases. Thirty-nine percent of intubations were considered necessary, 22% harmful, and 17% neutral. Of the three PASG's applied in the study, 2 were considered harmful and one neutral (no opinion) (Sampalis et al., 1995). This however, is simply a collection of opinions from physicians who were not present at the scene and therefore did not have the same knowledge that was privy to the attending MD.

1996

Demetriades et al. compared victims of major trauma transported to the hospital by

private vehicles versus those transported by paramedic units (Demetriades et al., 1996). Patient results were similar for mechanism of injury, need for surgery and ICU admission. The study found a relative risk of death of 2.32 (p<0.001) for patients transported by the EMS system. After adjusting for confounders, the adjusted mortality among patients with an ISS>15 was 10% higher in the EMS group. Since individuals transported by private vehicle had shorter prehospital times, the authors suggest that time is the most pressing factor in reducing mortality (Demetriades et al., 1996). Such a finding supports the 'load and go' philosophy whereby only absolutely necessary procedures are attempted on the scene in favour of immediate transportation to a trauma facility.

In an attempt to bolster the case for ALS, a research group from Taipei in Taiwan carried out a study which followed the outcome of "ALS eligible" cases in a city with only BLS care (Hu et al., 1996). Of the 155 cases of trauma studied, 17% experienced 'negative objective changes' during transit. The authors interpreted these findings to suggest that incorporating ALS into their EMS system would improve the state of trauma patients en route to an ER. This assertion is extremely premature, particularily if it is based solely on the results of this study since patients were brought to 9 different ERs, a fact that suggests the city is not yet serviced by a regionalised trauma system.

A population based study, similar to one carried out in North Carolina and discussed above (Rutledge et al., 1994), was done in Kentucky in 1996 (Svenson et al., 1996). Three demographic and medical system factors were significantly associated with county pediatric death rates using multivariate regression analysis. A rural setting was associated with a higher death rate, whereas counties equipped with ALS or 24 hour

emergency services had lower death rates. The results of this study are too general to suggest that ALS is the reason for the reduced death rates. Advanced Life Support is certain to be associated with a 24 hour emergency service which is likely the more important of the two variables in reducing death due to trauma.

2.1.1 Summary of general ALS/BLS studies

The previous section has described a number of studies that have endeavoured to ascertain the success of ALS and BLS in the treatment of trauma. The results of these 26 investigations are presented in Table 2.1. Of the 26, 17 made comparisons to some extent between ALS and BLS. Nine of the 17 investigations favoured BLS, 8 supported ALS and 3 noted no differences between groups. However, most of the studies suffered from flaws which cast their results into doubt. Three studies compared ALS and BLS groups that were not comparable in terms of injury severity. In 8 of the studies the comparability of the groups was in doubt or wasn't checked at all. Six did not include a comparison group, 4 did not document patient outcomes, one was hampered by a small sample size and one relied on subjective outcomes. Due to these limitations, the results from these investigations are suggestive but cannot be considered conclusive.

Table 2.1 Results from general ALS/BLS studies

| Author (Year) | Population | Main Finding | Remarks |
|---------------|--------------------------|--|--|
| Aprahamian | penetrating abdominal | improved hemodynamic status in ALS | biased sampling distribution, all ALS |
| (1983) | vascular trauma | group | cases collected in last 4 years of the study |
| Cayten (1984) | major trauma | higher mortality in ALS patients | ALS patients had higher ISS |
| Cayten (1993) | MVC, hypotensive | ALS patients improved in blood pressure | no differences noted in mortality of ALS |
| | patients with ISS > 10 | and RTS | and BLS patients |
| Copass (1984) | traumatic cardiac arrest | 100% of survivors had 2 IV lines, only | no comparison to BLS, patients may have |
| | | 70% of non-survivors | died before IV could be established |
| Cwinn (1987) | blunt trauma | 89% and 94% success rates of prehospital | no BLS group for comparison |
| | | intubations and IVs respectively | |
| Demetriades | major trauma | patients arriving by private vehicle had | private vehicles have very low prehospital |
| (1995) | | lower adjusted mortality | times; do not compare to EMS times |

| Author (Year) | Population | Main Finding | Remarks |
|-----------------|-----------------------|--|--|
| Gervin, Fischer | penetrating cardiac | 0% survival in stabilise group vs 38% in | no data presented on injury severity |
| (1982) | trauma | immediate transport group | between groups |
| Honigman (1990) | penetrating cardiac | number of ALS procedures does not | no outcomes studied, no comparison BLS |
| | wounds | correlate with scene time | group |
| Hu (1996) | "ALS eligible" trauma | 17% experienced negative objective | city not serviced by regional trauma |
| | cases | changes en route to the hospital | centres, no ALS group for comparison |
| Ivatury (1987) | penetrating thoracic | higher survival in patients transported by | no comparison of injury severity, or |
| | wounds | private vehicle | mechanism of injury |
| Jacobs (1984) | general trauma | improved TS between scene and ER in | ALS / BLS not a significant predictor of |
| | | ALS patients | mortality using logistic regression |
| Lerer (1994) | penetrating chest | higher survival in lower SES patients who | no data actually collected on which |
| | trauma | use more private vehicles | patients arrived by private vehicle |

| Author (Year) | Population | Main Finding | Remarks |
|------------------|--------------------------|--|---|
| Messick (1992) | >12000 trauma deaths | ALS equipped counties associated with | all urban counties ALS. Travel times and |
| | | lower trauma death rates | level I trauma centres likely confounders |
| Pons (1985) | penetrating thorax, | 55% of patients had improvements in BP | no BLS group for comparison |
| | abdomen wounds | between scene and ER | |
| Potter (1988) | major trauma | BLS patients died sooner, higher incidence | ALS and BLS patients from different |
| | | of respiratory failure | cities, ALS had shorter scene times |
| Quintans- | major trauma | 41% survival among intubated patients, | purely descriptive study with no |
| Rodriquez (1995) | | 18% in CPR patients | comparison group |
| Reines (1988) | rural MVCs | increase blood pressure seen in 33% of | no outcomes studied |
| | | ALS vs 20% of BLS patients | |
| Rosemurgy | traumatic cardiac arrest | 0 % survivors of trauma induced | ALS is not relevant in the treatment of |
| (1993) | | prehospital cardiac arrest | traumatic cardiac arrest |

| Author (Year) | Population | Main Finding | Remarks |
|------------------|---------------------|--|--|
| Rutledge (1994) | pediatric trauma | presence of ALS associated with lower | numerous other factors lower death rates |
| | | county death rates | and are associated with ALS |
| Sampalis (1992) | major trauma | ALS/BLS not associated with mortality | protocols favoured BLS patients, more |
| | | using logistic regression | severely injured patients received ALS |
| Sampalis (1993) | major trauma | no difference in ALS/BLS mortality using | BLS group favoured by dispatching |
| | | logistic regression | protocols |
| Sampalis (1995) | 73 trauma deaths | IV deemed "necessary" in 3%, intubation | subjective opinions of a panel of experts, |
| | | in 39% and 0% of PASG | cases viewed retrospectively |
| Shackford (1987) | major trauma (TS<8) | intubations, IVs, scene times not associated | small sample size (n=60) for penetrating |
| | | with decrease in mortality | trauma |
| Smith (1985) | hypotensive trauma | time to cannulate > transport time in all | no outcomes studied |
| | victims | cases | |

| Author (Year) | Population | Main Finding | Remarks |
|----------------|-----------------------|--|--|
| Spaite (1991) | ISS > 10 | shorter scene times associated with more | no outcomes studied |
| | | ALS procedures | |
| Svenson (1996) | pediatric death rates | ALS, 24 hour ER and urban counties | high correlation likely between variables, |
| | | associated with lower mortality | no way to determine which is responsible |
| Tsai (1987) | pediatric trauma | long scene times and low success rates | no outcomes studied |
| | | associated with IVs | |

2.2 INTRAVENOUS FLUID REPLACEMENT

The loss of blood from circulation is a common cause of death due to trauma (Trunkey, 1983). This is especially true in the case of penetrating trauma where punctures and lacerations of major blood vessels occur. For three decades, aggressive and rapid administration of isotonic intravenous fluids has been a cornerstone in the prehospital treatment of traumatic hypovolemia (Bickell et al., 1994). The ATLS course encourages the rapid administration of fluids to a trauma patient that presents with symptoms of shock: "An initial fluid bolus is given as rapidly as possible. The usual dose is one to two litres for an adult and 20mL/kilogram for a pediatric patient." (Committee on Trauma, 1993). After airway and breathing have been attended to, ATLS protocol dictates that hemorrhage control is the next priority. Again, rapid fluid resuscitation is espoused: "The pneumatic antishock trouser may be used to control bleeding from pelvic or lower extremity fractures bet the device should not interfere with the rapid re-establishment of intravascular volume by the intravenous route." (p.83) (Committee on Trauma, 1993) This insistence on aggressive fluid therapy has, for the most part, gone unchallenged. In recent years however, a debate has surfaced challenging the traditional notion of immediate fluid replenishment. This debate has not questioned the belief that fluid replacement is necessary, but rather when it should be initiated: either immediately after injury, or once the patient has reached the definitive surgical care of the operating room.

In 1950, Wiggers published the *Physiology of shock*, in which he advocated rapid and aggressive intravenous infusion of fluids following trauma (Wiggers, 1950). His view was supported by Dillon et al. who conducted experiments on dogs in which they

administered fluid resuscitation to one group of dogs while withholding it from a second group. Dogs who received fluid resuscitation had a higher survival rate and a lower rate of organ damage due to ischemia (Dillon et al., 1966). Both Dillon and Wiggers used controlled hemorrhage in their experiments. Uncontrolled hemorrhage has since been used to better parallel the pathophysiology of real injuries.

The notion of immediate resuscitation of the trauma victim was first criticised during World War I by Cannon. He believed that by increasing the blood pressure of the patient, clots that were in the process of forming were dislodged and much needed blood was lost (Office of the Surgeon General, 1952). During the second World War, battlefield practitioners heeded Cannon's advice. Blood was not transfused into a patient until surgical hemostasis had been obtained, since it was believed that transfused blood simply increased bleeding from existing exterior wounds or bled into internal cavities. This wasted precious blood and repeatedly exposed the patient to the dangers of transfusions (Office of the Surgeon General, 1952).

This debate resurfaced in the early 1980's. However, by this point the concept of fluid administration was so entrenched into the management of trauma, that a randomised trial was all but impossible due to ethical considerations. Dr. William Blaisdell labelled the notion of fluid resuscitation in the field "a myth" in the 1984 Fitts Lecture presented to the American Association for the Surgery of Trauma (Blaisdell, 1985). He was careful to qualify his remarks by placing them in the context of urban trauma where the transport times are generally less than twenty minutes.

The notion that pre-surgical fluid resuscitation is detrimental has been suggested by

numerous authors. Some believe that the formation of new thrombuses are disrupted or dislodged by sudden increases in vascular volume (Bickell et al., 1991). Other authors have suggested that increases in blood volume may dilute coagulating factors and therefore lead to increased bleeding (Bickell et al., 1991; Dalton et al., 1995; Teach et al., 1995). Mattox (1989) suggested that fluid overload in older patients, as well as those who have blunt chest trauma is a dangerous practice. Patients may appear to improve in the ambulance or the emergency room but hours later may deteriorate due to fluid overload and develop adult respiratory distress syndrome (Mattox, 1989).

Recent animal studies using uncontrolled hemorrhage have failed to show clear benefits for early fluid resuscitation. In 1992 Kowalenko et al. examined saline infusion in pigs. Aggressive infusion resulted in the highest rate of hemorrhage and did not increase survival in swine (Kowalenko et al., 1992). Recent studies using rats demonstrated that bleeding from the site increased when blood pressure was raised using infusion of hypertonic saline (Gross et al., 1989; Krausz et al., 1992). Krausz et al. separated rats into three treatment groups: no fluid replacement, small replacement and aggressive replacement. Rats aggressively treated showed increased bleeding, hemodynamic deterioration with no increased mortality. Those with small volume replenishment experienced increased bleeding, hemodynamic deterioration and increased mortality. Rats not treated with saline were hemodynamically most stable, lost the least amount of blood and experienced the same mortality as aggressively resuscitated animals (Krausz et al., 1992).

Results from other animal studies have also conflicted with the findings of Dillon

and Wiggers. Shaftan et al. (1965), Milles et al. (1966), and Harris et al. (1967), in a variety of animal models demonstrated that by elevating blood pressure prior to surgical stabilisation hemodynamics and thrombus formation were disrupted which ultimately led to decreased survival. Bickell carried out a trial in which he compared sixteen swine who received a 5 mm aortotomy to simulate uncontrolled arterial hemorrhage (Bickell et al., 1991). Eight of the pigs received 80 ml of lactated Ringer's (LR) solution while eight were left untreated as a control group. Bleeding was significantly higher in the treatment group (2142 mL versus 783 mL), but more importantly, all eight treatment group animals died while none of the control animals died (p<0.005) (Bickell et al., 1991). This study supports the notion that rapid infusion of IV fluids during uncontrolled arterial hemorrhage is deleterious before the surgical control of hemorrhage is accomplished.

Marshall et al. tested the effects of blood pressure and hemodilution on survival in rats (Marshall et al., 1997). An initial bleed was executed followed by a 75% tail amputation in order to simulate uncontrolled hemorrhage. Four treatment groups were evaluated, the first was resucitated to 80 mmHg using LR solution, the second was resuscitated to 80 mmHg using whole blood and LR, the third was resuscitated to 40 mmHg using LR and the fourth was resuscitated to 40 mmHg using whole blood and LR. Although there was no significant difference in the mortality of group II, III and IV rats, all group I rats died within 2.5 hours. Base deficit, arterial pH and lactate levels were significantly worse in the rats resuscitated to a mean arterial pressure of 80 mm Hg with LR (group I). The authors concluded that hemodilution, blood pressure and the

interaction between the two were responsible for the reduced survival in the 80 mmHg LR group (Marshell et al., 1997).

It should be noted that the results of these studies do not conflict with one another. Earlier studies that used controlled hemorrhaging through surgically implanted catheters demonstrated that infusion of IV fluids was beneficial and increased survival. This therapy is akin to the replenishment of blood loss in the post-surgical arena when hemorrhaging has been controlled. The fact that more recent models, such as Bickell's which examined uncontrolled hemorrhage, conflict with controlled hemorrhaging models is not surprising, rather it should be expected. Uncontrolled bleeding parallels the situation before surgical intervention when the patient is still hemorrhaging and is therefore more relevant in the discussion of prehospital, pre-surgical IV fluid replacement.

Results from animal studies cannot be used as definitive proof of how to treat humans in real life situations. The findings from animal models using uncontrolled hemorrhage have been supported by recent clinical studies on humans that have failed to demonstrate the benefits of fluid resuscitation. Kaweski et al. examined 6855 trauma patients and failed to observe any benefits of fluid therapy even after looking at multiple subgroups of injuries (Kaweski et al., 1990). In a prospective study on penetrating truncal trauma, Martin showed that fluid therapy may be detrimental and can possibly decrease survival if administered before surgery by increasing bleeding prior to hemostasis (Martin et al., 1992). Cayten et al. examined 781 patients with an ISS of 10 or more who had been treated with ALS versus those treated with BLS. Although ALS patients, of whom 60% to 85% received IV fluids, showed statistically significant improvements in

prehospital blood pressure, there were no differences in the observed mortality between the groups (Cayten et al., 1993).

Dalton et al. examined the records of 235 consecutive trauma patients who were brought to a level I trauma facility and treated with prehospital IV therapy (Dalton, 1995). On average, patients were infused with 383 ml of IV fluid before arrival at the ER. The authors note that 98% of patients had infusion times of less than thirty minutes and therefore recommend that the benefits of IV infusions in such a small amount of time may not be worth the potential complications associated with IV use and the time required to establish a successful IV (Dalton, 1995).

Teach performed a subjective retrospective review of pediatric trauma victims in order to evaluate the impact of IV therapy on outcome (Teach et al., 1995). An expert panel considered IV therapy "inconsequential" in 47 of 50 cases, "possibly beneficial" in 2 cases and "possibly detrimental" in one case. Patients cannulated on the scene had significantly longer scene times than those cannulated in the ambulance (15 versus 11 minutes).

Sampalis et al. studied a cohort of Quebec trauma victims to evaluate the association between on-site intravenous fluid replacement and mortality in patients with severe trauma (Sampalis et al., 1997). Patients from the IV group were matched by their prehospital index to patients who had not received IV fluid in the field. The authors concluded that the administration of prehospital IV therapy was associated with an increased risk of death (23% versus 6%; p < 0.001) and suggested that this association was partly the result of increased prehospital times (Sampalis et al., 1997). The study

findings were weakened, however, because there were significant differences between the groups in terms of age, ISS, injury type and mechanism of injury.

Another aspect of the intravenous fluid debate surrounds the difficulty in administering IV fluids in the often chaotic prehospital setting. Lawrence et al. studied the rate and severity of complications due to IVs started in the field compared to those started in either the ER or OR and found a significantly higher number and more severe complications associated with IVs started before arrival at the hospital (Lawrence et al., 1988). The prehospital IV group suffered over four and a half times more cases of phlebitis and five times higher likelihood of unexplained fever.

In a retrospective study of 1223 trauma patients, Regel found that multi-organ failure was associated with greater volumes of fluid infusion independent of associated injury (Regel et al., 1997). Despite receiving more than 2000 mL of intravenous fluid before arrival at the hospital, patients required more fluid in the first 24 hours when compared to those who had similar ISS scores (>40) who had received less than 1000 mL of fluid (Regel et al., 1997).

Bickell et al. conducted a prospective randomised trial, published in 1994, which compared patients who received fluid replacement immediately on-site with patients who had IV therapy delayed until they reached the operating room (Bickell et al., 1994). This study is of particular importance, not only because it dealt with penetrating injuries, but since it is the first randomised intervention of prehospital IV fluid therapy. The authors found a statistically significant difference in the rate of survival between intervention groups. The delayed resuscitation group had a higher survival rate (70% versus 62%; p =

0.04), shorter hospitalisations (14 days versus 11 days, p = 0.003) and fewer complications. The delayed group patients were also cannulated at the scene and therefore the difference between the groups cannot be attributed to longer scene times, but rather to the actual infusion of intravenous fluids before hemorrhaging had been controlled.

2.2.1 Summary of IV studies

Detractors of fluid resuscitation do not advocate its abstinence entirely in the treatment of severely injured patients. Instead, they argue against the widespread view that aggressive therapy should begin in the field, instead preferring to wait until the patient is in the controlled environment of an operating room where a surgeon can repair hemorrhaging tissues. They maintain that in order for field resuscitation to be useful, the total volume administered to the patient must exceed the fluid lost. In urban trauma where transport times are relatively short, this is rarely possible.

The studies concerning prehospital IV therapy described above are summarised in the tables on the following two pages. Table 2.2 contains the laboratory studies performed on animals while Table 2.3 describes the body of research carried out on humans. In all cases of uncontrolled hemorrhage, animals in the IV resuscitation group experienced poorer outcomes than those who had IV fluid therapy withheld. These studies suggest that fluid resuscitation therapy should be initiated after hemorrhaging has been surgically controlled. Four of the ten human studies presented here indicated worse outcomes among IV treated patients, including the only randomised trial carried out to date. Two others failed to detect a difference associated with IV therapy and one found that negligible amounts of fluid were infused before arrival at the ER. The study by Bickell et al. (1994)

is the only randomised trial in evidence. It was limited to penetrating torso injuries however and therefore the need exists to broaden this scope to include all penetrating injuries.

Table 2.2 IV therapy experiments in animals

| Author (Year) | Type of | Animal | Major finding |
|-----------------|--------------|---------|--|
| | hemorrhage | studied | |
| Bickell (1991) | uncontrolled | pig | 100% mortality in IV, significantly more |
| | | | bleeding, 100% survival among controls |
| Dillon (1966) | controlled | dog | higher survival in IV dogs |
| Gross (1989) | uncontrolled | гat | increased bleeding in IV rats |
| Harris (1967) | uncontrolled | animal | hemodynamic deterioration in IV animals |
| Kowalenko | uncontrolled | pig | more bleeding in IV pigs, no difference in |
| (1992) | | | survival |
| Krausz (1992) | uncontrolled | rat | increased bleeding, hemodynamic |
| | | | deterioration in IV, no difference in |
| | | | mortality |
| Marshall (1997) | uncontrolled | rat | aggressive IV therapy resulted in highest |
| | | | mortality |
| Milles (1966) | uncontrolled | animal | decreased survival in IV group |
| Shaftan (1965) | uncontrolled | animal | hemodynamic deterioration in IV |
| Wiggers (1950) | controlled | dog | higher survival in IV dogs |

Table 2.3 IV therapy studies involving humans

| Author | Population | Major finding |
|--------------|------------------------------|---|
| (Year) | | |
| Bickell | penetrating torso injuries | higher mortality, longer hospital stays and |
| (1994) | | more complications among patients |
| | | randomised to immediate IV therapy vs |
| | | delayed therapy |
| Cayten | hypotensive, ISS > 10 | increases in blood pressure in IV group, |
| (1993) | | no difference in survival |
| Dalton | major trauma | average fluid infused only 383 mL |
| (1995) | | |
| Kaweski | 6800 trauma patients | no difference in survival between IV, no- |
| (1990) | | IV |
| Lawrence | all IVs | more complications associated with field |
| (1988) | | IVs |
| Martin | penetrating truncal injuries | bleeding increased in IV group |
| (1992) | | |
| Regel (1997) | 1200 trauma patients | multi-organ failure associated with |
| | | amount of fluid infused |
| Sampalis | major trauma | increased risk of death in IV |
| (1997) | | |
| Teach (1995) | pediatric trauma | 2 of 50 IV uses subjectively deemed |
| | | inconsequential |

2.3 SALINE DEXTRAN

During the late 1980s and early 1990s some investigators experimented with onscene infusions of enriched hypertonic solutions. Saline-Dextran was created in response
to the need for a more efficacious fluid for the prehospital management of traumatic shock.
In contrast to large volume crystalloids and regular saline infusions, 7.5% sodium chloride
in 6% Dextran 70 is injected in a small 250 mL dose en route to the hospital. The action
of Dextran, a plasma volume expander, in markedly hypertonic saline, which causes a rapid
transient increase in mean arterial pressure and cardiac output (Maningas et al., 1986), was
previously tested with positive results in maintaining survival in preliminary experiments on
dogs (Velasco et al., 1980) and swine (Maningas et al., 1986).

Maningas et al. were the first to carry out a clinical trial of Saline-Dextran on victims of penetrating trauma (Maningas et al., 1989). They studied two treatment groups that were randomised to receive either the Saline-Dextran solution or regular saline based on an alternate-day protocol. As a preliminary study on only 48 patients, no statistically significant differences were noted between the treatment groups in terms of complications or survival to discharge. A large multicentre trial followed the Maningas study which sought to ascertain the possible clinical benefits of Saline-Dextran over conventional IV therapy. In 1991, 422 subjects, 72% of which were victims of penetrating trauma, were randomised to receive the saline-Dextran or regular saline (control) (Mattox et al., 1991). The treatment group presented to the ER with significantly increased blood pressure, but this did not lead to an increase in survival.

A second large multicentre trial involving sodium Dextran was completed in 1993

by Vassar (Vassar et al., 1993). The study found no significant differences in survival of four treatment groups. Some trends were noted, specifically in those who received hypertonic saline where higher blood pressure on arrival at the ED was noted and higher than expected survival to hospital discharge based on MTOS data. This study showed no benefits of sodium combined with Dextran. Although higher than expected survival was noted in the hypertonic saline group, this does not translate into an argument for on-scene ALS since the study did not have a true control group that had all prehospital IV infusions withheld.

2.3.1 Summary of Saline-Dextran studies

The body of research involving Saline-Dextran has failed to conclusively show any benefits associated with the solution. The three studies carried out have been fully randomised and therefore one would expect to observe meaningful differences if they existed. Thus, the need to staff EMS systems with personnel capable of administering IV fluids in order to inject Saline-Dextran into hypotensive trauma patients does not seem justified.

2.4 THE PNEUMATIC ANTISHOCK GARMENT

The Pneumatic Antishock Garment (PASG) is designed to "raise systolic pressure by increasing peripheral vascular resistance and myocardial afterload" (Committee on Trauma, 1993). The garment consists of a pair of trousers with inflatable bladders held in place by Velcro fasteners. The abdominal section and each leg can be independently inflated. The counterpressure of the suit affects the legs down to, but not including, the feet and as high as the lower abdomen. Thus the PASG offers no counterpressure on the

thoracic cavity, upper extremities, neck or head.

The history of counterpressure dates back to the turn of the century. In 1903, Dr. George Crile described a pneumatic trouser that could be inflated for patients undergoing head and neck surgery that he believed raised blood pressure by increasing peripheral vascular resistance. Although he initially contrived the trousers for use within the controlled environment of the operating theatre, he soon saw other potential uses (Crile, 1903; Mattox et al., 1986). In the pre-blood transfusion era of 1909, he reported its effect in elevating the blood pressure of rapidly exsanguinating patients in hemorrhagic shock (Crile, 1909). His interest in the suit waned soon after due to continued leakage problems.

Gardner and Dohn (1956), oblivious to Crile's work at the turn of the century, were the second to report the use of the G-Suit for medical purposes in 1956. They also experimented with the suit in combatting postural hypotension during surgery with the patient in the sitting position (Gardner et al., 1956).

Pneumatic counterpressure as a means of arresting massive hemorrhage was not reported until 1958. Gardner employed the suit on a woman who was bleeding uncontrollably after a placenta percerta and emergency hysterectomy.

In 1971, Cutler and Daggett reported using the G-suit on 8 patients who had suffered severe trauma during the Vietnam conflict (Cutler et al., 1971). Transport times to definitive operative care at the nearest military hospital averaged 45 minutes. Four of eight patients in the G-suit trial survived to discharge from the hospital. This result was sufficient to convince many in the Army medical community that the G-Suit was an indispensable tool in the treatment of military casualties (Cutler et al., 1971). The military

continued to refine the design of the suit until, the current trouser-like form resulted (Kaplan, 1972; Mattox et al., 1986). Based on a series of case reports, the conviction that the MAST was an indispensable tool in the treatment of urban trauma grew rapidly.

The first report emerged in 1973 (Kaplan et al. 1973) from Miami Florida where the first civilians were subjected to the MAST by the city's EMS system for the prehospital treatment of trauma. Fifteen of twenty patients in the trial survived. The PASG began to see widespread use in the civilian arena in the mid-seventies, and by the mid eighties it had become a "standard component of the prehospital armament" (Kaback et al., 1984). By 1986, two thirds of the U.S. states had adopted legislation that required emergency transport vehicles to carry the PASG (Bickell et al. 1987).

As attention on prehospital care escalated, the demand on EMS systems to have the latest equipment and technology increased (Kaback et al., 1984). The MAST was relatively inexpensive, portable, re-usable, easily applied, invisible to X-Rays and seemed to have few complications. Without firm clinical evidence that the suit provided any true benefit to civilian patients suffering from severe trauma, many states and EMS systems incorporated the MAST into their prehospital protocol.

Currently, the use of the PASG is still advocated by the American College of Surgeons (ACS) Advanced Trauma Life Support course for physicians. The ATLS manual lists two indications for the application of the PASG:

- 1. Splinting and control of pelvic fractures with continued hemorrhage and hypotension
- 2. Intra-abdominal trauma with severe hypovolemia in patients who are en route to the operating room or another facility. (American College of Surgeons, 1993)

Contraindications listed by the ACS are: pulmonary edema, known diaphragmatic rupture and uncontrolled hemorrhage outside the confines of the garment. The ACS does recognise the controversy surrounding the PASG saying that "the efficacy of PASG in hospital or in the rural setting remains unproved, and in the urban prehospital setting, controversial (p. 89)" (Committee on Trauma, 1993).

The body of research which had convinced public health officials to purchase and implement the PASG consisted exclusively of anecdotal case series that contained no randomised control groups. In many instances, the discussions of such papers noted that there had yet to be a truly randomised study to definitively answer the question of the PASG's true benefits.

While the ATLS has been a proponent of the PASG, the suit has been associated with a number of complications. By far the most common complication attributed to the use of the PASG is compartment syndrome. Others include changes in pulmonary function, intracranial pressure changes, alterations in renal function, exacerbation of existing congestive heart failure or pulmonary edema, increased bleeding from sites above the diaphragm, lactic acidosis, functional impairment of the lower extremities, and in severe cases, amputation of the leg.

In 1969, Wangensteen observed the development of lactic acidosis and decreased survival in canines who had been subject to counterpressure without corresponding volume replacement. He concluded that "the application of the G-suit for a period of 4 hours was detrimental" although it must be noted that this was a controlled hemorrhage experiment which used the predecessor of today's garments (Wangensteen et al., 1969).

By far, the most commonly reported complication has been compartment syndrome of the lower limbs. This condition is a well known complication of trauma to the lower leg, tibial fractures and re-vascularisation surgery. Treatment entails surgically decompressing the area by carrying out a fasciotomy on the affected compartment.

Initially, cases of compartment syndrome after use of the MAST were reported in patients who had sustained lower leg injuries (Johnson et al., 1981; Maull et al., 1981).

Later, cases of compartment syndrome in the absence of injury to the lower leg were reported (Williams et al., 1982; Frampton, 1984; Goodenberger, 1981). Upper leg compartment syndrome was first reported in 1982 by Brotman et al. (Brotman et al. 1982). The next year, Bass reported on cases of thigh compartment syndrome in two patients who had not suffered any lower extremity trauma (Bass et al. 1983).

In June of 1981, the journal *Emergency Medicine* published a "MAST amputation alert" warning against improper use of the garment (Anonymous, 1981). Incidents were described in which MAST suits were left on unchecked for hours causing severe compartment syndrome and eventual amputation. The report stressed the need for vigilance when using the MAST in order to avoid excessively long applications.

A 1995 experiment on swine using a modified pig PASG examined the effects of prolonged application of the PASG for 4 hours on the fluid and electrolytes of 16 piglets. Eight piglets were fitted in the modified PASG's following the controlled withdrawal of blood until a 30 mmHg drop in their arterial blood pressure was reached. A second group of eight piglets was similarly bled, but left untreated. Fluid deficit, lactic acidosis, tissue edema and hyperalkalemia were all greater in the PASG group (Ali et al., 1995). This

result is particularly meaningful because it contradicts the suggestion that the PASG may be appropriate for use in a rural settings where prehospital times are significantly longer.

Cayten et al. documented positive results using the PASG in 1993 (Cayten et al., 1993). Survival was significantly higher in PASG treated patients who presented with a blood pressure lower than 50 mmHg, though scene times among such patients were four minutes longer. The conclusion of this study is weakened since the two treatment groups were not randomised. It is possible, for example, that extremely injured patients were not put in a PASG because ALS providers considered them unsalvageable. Another limitation of the study stems from the fact that patients were collected over 5 years and from two distinct data sets. The authors do not address the possibility of confounding due to the date of injury. It is possible that survival was higher in the later subset of patients when the PASG was used more frequently.

Karch et al. examined 398 patients who were treated with a PASG versus 590 who were not (Karch et al., 1995). Paradoxically, scene times in 84 cases of femoral fracture in the PASG group were a mean of 5 minutes shorter than the no-PASG group. In cases of pelvic fractures, the time spent in the resuscitation area and the ICU were significantly longer in the PASG group. This study failed to show any increase in survival even though in some groups of patients scene times were significantly lower in the PASG group (Karch et al., 1995).

Mattox, Bickell and Pepe have published a number of randomised clinical trials involving the PASG (Mattox et al., 1986; 1989; Bickell et al., 1985; 1987). The first was published in 1985 and compared 36 PASG treated patients with 32 controls. The groups

did not exhibit any differences in terms of demographic factors, type and location of injury, and initial field Trauma Score (TS) (Bickell et al., 1985). They measured the TS of patients arriving at the ER and noted no differences between the treatment groups.

A year later they published a larger more extensive follow-up study that examined the outcomes of 352 patients, 88% of whom were victims of penetrating trauma. Subjects in the PASG and control groups were similar in terms of demographics, injury severity and prehospital treatment. No differences in length of hospital or ICU stay, time in the emergency centre, Kaplan Meier survival distributions or mortality were noted between these groups (Mattox et al., 1986).

The authors later reported on 201 victims of anterior penetrating abdominal injuries in a separate study (Bickell et al. 1987). Again, both treatment groups were similar in terms of demographic characteristics and injury severity as measured by the TS, ISS and TRISS survival probability. Scene times were significantly longer (17.3 versus 13.1 minutes) in the PASG group. Overall survival was higher, but not significantly, in the no-PASG group. No differences were noted in terms of any other outcome variables measured (LOS, ICU LOS, time in emergency centre) (Bickell et al. 1987).

In 1989 the Mattox, Bickell and Pepe team released their largest randomised PASG trial on 911 subjects. Again, no effect of the PASG on the emergency department Trauma Score was observed. Total hospital time was the same for both groups although the MAST patients spent more time in the ICU and experienced significantly lower survival. The authors subdivided the sample to examine only patients who presented with low blood pressure (<50mmHg) and found no difference in survival rates (Mattox et al.,

1989).

Chang et al. completed a randomised trial in order to determine the possible benefits of PASG's in arresting traumatic shock (Chang et al., 1995). Patients in the two treatment groups (PASG versus no-PASG) were similar with respect to demographic factors and injury severity as measured using the ISS and TS. No differences were noted between the groups in terms of length of stay or mortality. A breakdown of the sample into subsets of injury types (blunt, penetrating, thoracic) also failed to detect a difference between groups (Chang et al., 1995).

2.4.1 Summary of PASG studies

Despite the occurrence of a variety of complications and without firm scientific evidence, pneumatic anti-shock garments have managed to find their way into common usage among EMS systems all over the world. The military roots of the invention of the MAST for the treatment of trauma may have been a critical factor that was overlooked by researchers when they successively embraced the MAST. The suit was designed to help stabilise the blood pressure of patients that had suffered major life threatening trauma and were in extremely remote jungle areas. These soldiers are subject to very long delays before definitive surgical care could begin to reverse the damage.

Table 2.4 lists the body of research described in this section that has investigated the PASG. Of the eight studies that examined the performance of the PASG in humans, 5 found no difference in survival or morbidity associated with the garment. Three were published in favour of the PASG while one found lower survival in PASG treated patients. The quality of the research is a major issue in trying to decipher these contradictory

results. Four of the 5 studies which found no difference were randomised trials while none of the three studies which support the use of the PASG were randomised. The only study which observed lower survival in the PASG group had the greatest sample size and was a fully randomised trial. These findings strongly suggest that if the PASG does indeed have an effect on survival, it is a negative one.

Table 2.4 Studies on PASG/MAST

| Population | Main findings | Remarks |
|---------------------|---|--|
| pigs | application caused fluid deficit, acidosis, edema in | PASG application for 4 hours |
| | PASG group | |
| case report | thigh compartment syndrome in absence of leg | 2 nd report of thigh complication |
| | injury | |
| case report | thigh compartment syndrome with associated | 1st report of thigh complication |
| | injury | |
| hypotensive | increased survival in PASG group | non-randomised, patients collected |
| trauma patients | | from 2 different data sets |
| traumatic shock | no differences noted between groups in terms of | study was a randomised trial |
| | LOS or survival | |
| military casualties | 50% survival using PASG | first documented trial of PASG in |
| | | trauma |
| | pigs case report case report hypotensive trauma patients traumatic shock | pigs application caused fluid deficit, acidosis, edema in PASG group case report thigh compartment syndrome in absence of leg injury case report thigh compartment syndrome with associated injury hypotensive increased survival in PASG group trauma patients traumatic shock no differences noted between groups in terms of LOS or survival |

| Author (Year) | Population | Main findings | Remarks |
|------------------|--------------------|--|--|
| Frampton (1984) | case report | lower leg ischemia with PASG and no lower leg | resulted from improper use |
| | | injury | |
| Goodenberger | case report | thrombosis with PASG and no lower leg injury | 1st thrombosis documented |
| (1981) | | | |
| Johnson (1981) | case report | compartment syndrome following lower leg injury | 1 st report of complication |
| | | and PASG | |
| Kaplan (1973) | civilian trauma | 60% survival using MAST | first documented civilian use |
| Karch (1995) | 988 trauma | no difference in mortality between PASG and no- | PASG patients with certain |
| | patients | PASG- shorter scene times in some PASG patients | fractures spent more time in ICU |
| Mattox, Bickell, | 911 trauma | TS unaffected by PASG, PASG patients | study was a randomised trial |
| Pepe (1989) | patients | experienced lower survival and longer ICU stays | |
| Mattox, Bickell, | 62 trauma patients | no difference in TS of patients arriving at the ER | study was a randomised trial |
| Pepe (1985) | | | |

| Author (Year) | Population | Main findings | Remarks |
|--------------------|-------------------|--|--------------------------------|
| Mattox, Bickell, | 352 patients (88% | no differences in hospital or ICU stay, or Kaplan- | study was a randomised trial |
| Pepe (1986) | penetrating) | Meier survival analysis | |
| Mattox, Bickell, | 201 abdominal | longer scene time in PASG group- no differences | study was a randomised trial |
| Pepe (1987) | penetrating | in LOS, ICU LOS, survival | |
| Maull (1981) | case report | comparment syndrome following lower leg injury | required amputation of limb |
| | | and PASG | |
| Wangensteen (1969) | dogs | lactic acidosis and lower survival in PASG treated | predecessor of today's garment |
| | | animals | |
| Williams (1982) | case report | comparment syndrome with PASG and no lower | no associated leg injury |
| | | leg injury | |

2.5 AIRWAY MANAGEMENT

Endotracheal intubation (EI) is another ALS intervention that has figured predominantly in the debate over prehospital care, although many fewer publications have surfaced examining its role in prehospital trauma care. As with all prehospital procedures, opponents of ALS are chiefly concerned with the time required to intubate, which inevitably delays the arrival of the patient to a trauma centre.

Winchell et al. conducted a retrospective case control study published in 1997 that found endotracheal intubation was associated with an increase in survival from 26% in non-intubated patients to 36% in intubated patients with severe blunt head injury (Winchell et al., 1997). Since all victims in the Winchell study suffered blunt trauma, the results cannot be extrapolated to penetrating injuries, which are the focus of the present investigation. Compromised breathing due to CNS injuries is a major concern in severe head injuries due to blunt trauma, whereas cases of penetrating trauma are commonly characterised by rapid exsanguination. The incidences of respiratory distress as well as the mechanisms that bring about the need for airway control are different in the two types of trauma.

Regel et al. looked at polytraumatised patients with an ISS>20 injured during the ten-year span from 1984 to 1994. Other results from their study have been presented above. The use of on-site intubations was associated with a reduced incidence of multi-organ failure (MOF) in patients with an ISS\(\leq 39\). No difference was noted in the more severely injured patients (ISS>40) (Regel et al., 1997). A concern associated with this study is the ten-year sampling span, a long period of time during which time the quality of

trauma care could have changed significantly. The results could have been affected if the distribution of EIs over time was not constant. Unfortunately the authors did not discuss the distribution of intubations over time.

paramedics. The authors reported that survival for field intubated victims was 11% while predicted survival using the TRISS method was 2%. Patients intubated in the ER experienced 40% survival which was 5% lower than predicted using the TRISS method. Scene times were significantly longer in the prehospital intubation group (12 versus 10 minutes). Based on these results, the authors assert that field intubations by paramedics have a positive influence on outcome (Frankel et al., 1997).

2.5.1. Summary of Airway Management Studies

In comparison to the PASG and prehospital IV fluid resuscitation, there is a relatively modest amount of research that has been devoted to the study of field airway management. In the context of the current discussion on penetrating injuries, two of the above mentioned studies included patients with such injuries. The Regel study (Regel et al., 1997) did not observe a difference in the survival of intubated and non-intubated patients. The Frankel study (Frankel et al., 1997) addressed the effect of delaying intubations until arrival at the ER. No comparison was made between intubated patients and a second group of similar patients who were not intubated. Both were retrospective studies and neither explored the effect of intubations on the sub-population of patients with penetrating trauma.

2.6 SUMMARY OF PRESENTED LITERATURE

A variety of opinions exist as to which is the best course of action in the prehospital treatment of penetrating trauma. Unfortunately, many of them are backed by studies that have failed to adequately answer the questions they were designed to answer. Some have examined changes in physiologic status between the field and the hospital without documenting survival. Others may have failed to detect differences due to small sample sizes. Some have attempted to compare groups of patients which differ in terms of fundamental measures of injury severity. A number did not include a comparison group at all.

Studies that have examined ALS versus BLS in general terms have been for the most part inconclusive due to a number of methodological shortcomings. Many experiments that have investigated the benefits of IV therapy have been hampered by the inappropriate use of controlled hemorrhage experiments to approximate prehospital conditions. In all animal studies where uncontrolled hemorrhage was used, the delay of IV therapy proved beneficial to survival. The only two randomised human studies also favoured delaying IV therapy until the OR. The PASG, which is the only ALS intervention to be scrutinized by a number of large scale randomised trials found no benefits associated with the garment, in fact the largest trial to date found that the PASG had a negative effect on survival.

In short, a lack of scientific consensus exists on the best course of action when faced with a serious case of penetrating trauma. This is the result of a wealth of anecdotal

research that has failed to conclusively answer questions, largely due to poor research design.

2.7 RATIONALE

The current study, although observational, utilizes data that has been prospectively collected and includes all penetrating injuries. It examines a large number of patients who have had their prehospital treatment allocated on an arguably random basis. The groups are comprehensively compared for a number of outcomes while controlling for potential confounding factors such as age, and the mechanism and severity of injury. These methodological considerations place this study at a considerable advantage over previous research in arriving at unbiased, meaningful conclusions.

CHAPTER III - Material and Methods

3.1 INTRODUCTION

This study is based on data prospectively collected by Urgences Santé (US), which is the exclusive emergency medical service in Montreal, and the Quebec Trauma Registry (QTR). It is an observational study which had no direct experimental influence by the investigators. The following question is addressed: does prehospital physician administered advanced life support (MD-ALS) decrease morbidity and mortality in victims of penetrating trauma? The study focuses exclusively on patients whose injuries were described as penetrating, and addresses the use of MD-ALS in the arena of trauma care only. Patients suffering from non-trauma medical emergencies such as stroke and cardiac arrest are excluded. Patients enrolled in the study were injured in the greater Montreal metropolitan area or within the confines of the city of Quebec. Hence the study only examines the sequence of events in urban prehospital trauma care, no cases of rural trauma are included.

Only patients that were seen by EMS personnel, or that presented to one of the four participating hospital emergency departments were included. The QTR does not have a means of tracking cases of trauma that did not come to the attention of either hospital or EMS personnel. Trauma patients that were brought to hospital by police, private vehicle or other means were also excluded.

3.2 QUEBEC TRAUMA REGISTRY

The Quebec Trauma Registry was established in the summer of 1993 and has since

been used to describe the profile of different types of trauma and document the resources used in the treatment of trauma in the Province of Quebec. Data abstractors employed by the hospitals identify potential trauma cases from hospital charts. Once a case of trauma is identified, the patient's medical record is reviewed for information that is entered first onto a case abstraction form, and from there into a computer database by data entry personnel. Approximately 400 variables make up the Registry, which is separated into 17 different forms. Since its inception, the Registry has collected data on approximately 20,000 trauma cases from over fifty hospitals in the province. Data files from each centre are then downloaded into the QTR database which is based at the Montreal General Hospital Trauma Research Program.

3.3 HISTORY AND BACKGROUND OF URGENCES SANTÉ

Prior to 1981, prehospital care in Montreal was provided by the police and several private ambulance companies. Advanced Life Support (ALS) procedures were carried out by physicians working in co-operation with the ambulance companies. This system suffered from a lack of co-ordination which prompted the formation of a centralised agency in 1981. Urgences Santé was thus created, and is now the exclusive emergency medical services organisation in the Montreal Urban Community and the Island of Laval. Its mandate is to co-ordinate and carry out all emergency prehospital services in the region in addition to the inter-hospital transport of transfer patients.

The area served by Urgences Santé covers approximately 1200 square kilometres and reaches 2.1 million people. As of 1997, the company had nineteen emergency rooms at its disposal, down from 24 in the previous year due to hospital closings and cost cutting

measures imposed by the provincial Ministry of Health.

3.4 DISPATCHING PROCEDURE OF URGENCES SANTÉ

Urgences Santé uses the Medical Priority Emergency Protocol which was developed by Dr. Jeffrey Clawson. This system is now being used in a number of North American, European and Australian centres and has been translated into a variety of languages which English and French. The protocol is a flip chart with approximately 40 different categories that represent the most frequent complaints heard by emergency medical dispatchers. Once the type of complaint has been identified, the operator flips to the corresponding page in the protocol which contains a number of standard questions. By asking these questions, the operator is able to ascertain the nature and severity of the problem and request an appropriate priority level for the call. Although the categories of complaints and the questions the dispatcher is instructed to ask are the same for any city that uses the Clawson protocol, it is up to each individual EMS system to determine the appropriate response based on the resources it has at its disposal.

When a medical emergency occurs in the Metropolitan Montreal area, the request for assistance flows through the region's 911 emergency response system. After ascertaining that the situation is a medical emergency, central 911 dispatchers relay the call to the Urgences Santé call centre. There, bilingual operators handle calls by following the Clawson Medical Priority Protocol.

Urgences Santé has at its disposal three types of emergency response units: ambulances staffed with two EMT's, MD units which carry one physician and an EMT driver, and co-ordinators who are dispatched to large accident scenes to direct and co-

ordinate different emergency personnel. Co-ordinators are often dispatched to car accidents to direct traffic safely around the scene and co-ordinated efforts by different emergency personnel. The type of unit sent to a scene is assigned according to the Clawson protocol by the call operator. A central dispatcher then radios to the nearest ambulance and/or MD unit to respond to the call.

Figure 3.1 Emergency Medical System in Montreal/Laval

- 1. Emergency occurs
- 2. Patient/witness dials 911
- 3. Central 911 dispatcher determines that the call is a medical situation and directs the call to Urgences Santé operator
- 4. Urgences Santé operator follows Clawson Protocol to determine nature and severity of the situation
 - Decides on the priority of the service required by the caller
- 5. Directs this information to Urgences Santé Dispatcher
- 6. Dispatcher decides on nearest available ambulance/MD and directs them to the scene.
- 7. EMT/MD arrive, treat and load patient. Follow Urgences Santé Protocol and decide on where to transport the patient
- 8. Ambulance travels to Emergency Department.

Not all calls are considered urgent and therefore Urgences Santé has designated three different levels of ambulance priority depending on the urgency of the emergency. Table 3.1 contains descriptions of a few injuries and their corresponding priority levels. "STAT" is the quickest service and is reserved for life threatening emergencies.

Ambulances responding to a "STAT" call travel as fast as safely possible with flashers, sirens and horns blazing. Such calls achieved a mean response time of 8.5 minutes in 1997.

"Ambulance 2" is the second level of priority assigned to less pressing calls. The response time for an "Ambulance 2" call is approximately 20 minutes. Since speed is not an issue for such calls, sirens and horns are not used and the unit will follow all traffic laws en route to the patient. The "Ambulance 4" priority is the lowest priority status assigned to calls by Urgences Sante and are answered only when convenient for the Urgences Santé system. A patient deemed as an "Ambulance 4" may wait upwards of one hour before receiving care.

Table 3.1 Examples of Response Priority to Selected Injuries

| Response Priority | Injury Description |
|-----------------------------------|---|
| Ambulance "STAT" | Injury caused by a fall, patient is not alert and/or exhibiting abnormal breathing |
| | Injury caused by gunshot or stabbing, single peripheral wound |
| | Injury caused by gunshot or stabbing, non-recent single central wound |
| Ambulance 2 | Non-dangerous proximal injuries (upper arm, clavicle, knee, lower leg, hip, shoulder) with normal breathing, alertness |
| | Injury caused by fall - not dangerous proximal injury with normal breathing, alertness, height of fall less than six feet |
| Ambulance 4 | Injury caused by gunshot or stabbing, single peripheral wound that occurred more than six hours ago, patient alert, no serious bleeding |
| Co-ordinator, Ambulance | Injury caused by gunshot or stabbing, multiple victims and/or multiple wounds, and/or patient not alert, and/or central wounds |
| "STAT" and MD "STAT" | Traumatic injury associated with severe respiratory distress, patient not alert |
| | Injury caused by fall greater than six feet. |
| Co-ordinator and Ambulance "STAT" | Fall associated with dangerous injury including abdomen, chest (if abnormal breathing), head (if not alert), neck |
| | Traffic accident with multiple victims, and/or hit pedestrian, and/or motorcycle car collision and/or victim not alert. |

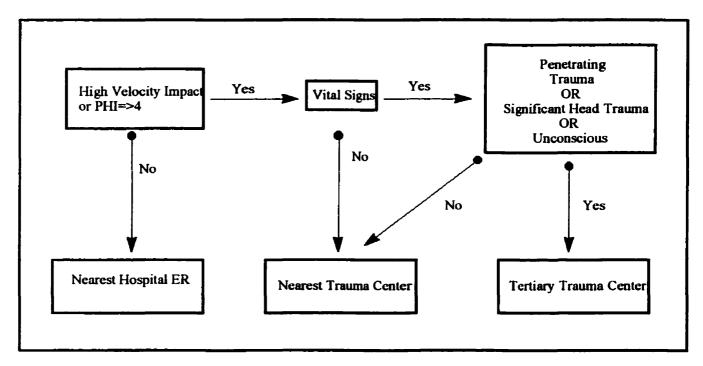
The average response time for a "STAT" level emergency in 1997 decreased from eight

minutes and thirty seconds in 1996 to eight minutes and eighteen seconds in 1997.

Transport times increased by 36 seconds over the same time period due to emergency department closings and hence the increased distances that ambulances were required to travel.

In 1992, Urgences Santé responded to the regionalisation of trauma care in the Province of Quebec by instituting protocols recognising the Montreal General Hospital and Sacré Coeur Hospitals as level I trauma centres. Figure 3.2 contains a flow chart which describes the protocol by which a receiving facility is selected.

Figure 3.2 Trauma Emergency Department Selection Protocol



Theoretically, all patients in the current study presented to EMS personnel with vital signs and either a PHI equal to or greater than 4 or were involved in a "high velocity impact".

In addition, the trauma was penetrating, the patient had significant head injuries or the

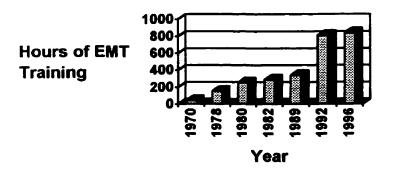
patient was unconscious.

3.5 PERSONNEL AND EQUIPMENT

There are no paramedics in the province of Quebec. Legislation prohibits EMTs from performing invasive procedures including the administration of medications even though approximately 10% of the EMT's employed by Urgences Santé have training as paramedics. As a result, ALS procedures are provided only by Urgences Santé physicians who are dispatched to the scene independently of EMT units.

All physicians employed by Urgences Santé have completed the Advanced Trauma
Life Support Course for Physicians, although not all maintain valid certification. The
EMTs on staff have different levels of training depending on when they were hired. Table
3.2 indicates the number of hours of EMT training that have been required by the Province
of Quebec since 1970.

Table 3.2 Hours of Training Required for EMT Certification 1970 - 1996



In 1970, EMTs received approximately 40 hours of BLS training before being certified to work. Today, students are required to complete 840 hours of training before being qualified as EMTs.

3.6 TREATMENT

In 1997, Urgences Santé had between 3 and 5 MD-ALS units operating within its catchment area. The same area will be served by approximately 70 ambulances during the day, 50 for evenings and 30 at night. Although all "STAT" level calls are answered by an ambulance, not all calls that are designated as Ambulance "STAT" and MD "STAT", will have an MD available. In 1993 for approximately 25% of calls for which an MD unit was requested, one was not available. At that time there were as many as 20 MD units on standby in the city. In 1997, that number had dropped to just 5. To avoid public criticism, Urgences Santé now refuses to provide data on the number of calls that do not receive an MD unit when one was requested by its 911 call operators. Once a call has been tagged as MD STAT, the decision whether or not to send an MD unit is up to dispatchers who manage Urgences Santé's fleet of vehicles. Since the number of calls that require an MD exceeds the number of MD units available, patients with similar injuries receive different levels of care. Patients are therefore randomly allocated, depending on availability of the MD units, to receive either BLS only or BLS and MD-ALS.

3.6.1 ALS EQUIPMENT

Intubations are carried out using a Combitube, while defibrillations are done using the Marquette 1250[®] semi-automatic external defibrillators. Urgences Santé discontinued the use of PASGs in 1993.

3.7 PATIENT SELECTION

3.7.1 IDENTIFICATION OF CASES OF PENETRATING TRAUMA

Three methods were used to identify cases of penetrating trauma from the QTR.

Patients were included if their injury was coded as penetrating by the archivists that compile data for the Registry. Abstractors are instructed to consider an injury as penetrating if the skin is broken *and* the underlying tissue is damaged. These tissues include muscle, tendon, bone and internal organs. Injuries that pierce only the skin and subcutaneous fatty tissue are not considered penetrating.

An injury was also considered as penetrating according to the mechanism of injury.

All gunshot wounds and stab wounds were automatically considered as penetrating.

Table 3.3 AIS Codes Sufficient for Inclusion in Study Sample

| AIS | BODY | DESCRIPTION |
|----------|-----------------|--|
| CODE | REGION | |
| 116004.5 | head | Penetrating Injury major (>2cm penetration) |
| 216004.2 | face | Penetrating Injury with tissue loss > 25cm ² |
| 216006.3 | face | Penetrating Injury with blood loss > 20% by volume |
| 316004.2 | neck | Penetrating Injury with tissue loss > 100cm ² but blood |
| | | loss =<20% by volume |
| 316006.3 | neck | Penetrating Injury with blood loss >20% by volume |
| 416004.2 | thorax | Penetrating Injury with tissue loss >100cm2 but blood |
| | | loss =<20% by volume |
| 416006.3 | thorax | Penetrating Injury with blood loss >20% by volume |
| 416008.3 | thorax | Penetrating Injury with hemo/pneumothorax |
| 716004.2 | upper extremity | Penetrating Injury with tissue loss > 25cm ² |
| 716006.3 | upper extremity | Penetrating Injury with blood loss > 20% by volume |
| 816004.2 | lower extremity | Penetrating Injury with tissue loss > 25cm ² |
| 816006.3 | lower extremity | Penetrating Injury with blood loss > 20% by volume |
| 916000.1 | external | Penetrating Injury |
| 140216.6 | head | Brain stem(hypothalamus, medulla, mid-brain, pons) |
| | | penetrating injury |
| 140478.5 | head | Cerebellum - penetrating injury |
| 140690.5 | head | Cerebellum - penetrating injury |

The third way that identified cases of penetrating trauma employed the Abbreviated Injury Scale (AIS) (Committee on Trauma - Scaling, 1994) codes which are used to describe injuries. AIS codes are divided into body region, type of anatomic structure,

specific anatomic structure and level of injury within a specific body region and anatomic structure. The number to the right of the decimal is the AIS score (Committee on Injury Scaling 1990). Patients that were not coded as penetrating by the Registry's archivists, or that did not suffer a gunshot or stab wound but were coded as having one of the injuries in Table 3.3 were included.

3.7.2 EXCLUSION CRITERIA

Patients were excluded if they were not brought directly to one of the four tertiary trauma centres in the province. Therefore, transfer patients, i.e. those brought to another ER before reaching a tertiary trauma centre, were excluded. The four trauma centres used are: the Montreal General Hospital, l'Hopital Sacré Coeur de Montreal, l'Hopital Charles LeMoyne in the South Shore community of Greenfield Park and Hopital de l'Enfant Jésus in Quebec City.

Patients for whom a definitive classification into ALS or BLS groups was impossible due to conflicting or missing data were also excluded. This included patients who arrived at an emergency department by unknown means.

3.7.3 PARTICIPATING CENTRES

The four tertiary trauma centres in Quebec contributed patients to the investigation. The date of entry of each hospital into the study depended on exactly when they started entering data for the QTR. Due to the large number of cases generated at each site, data entry into the Registry is not entirely up to date. Therefore, the most recent patient entered from each location depended on how up to date their data entry was on December 31st 1997.

The Montreal General Hospital is a 672 bed facility(List of Hospitals, 1987) and is centrally located in downtown Montreal, between Mount Royal to the north and the central business district to the south. It is a large teaching hospital associated with the McGill University Faculty of Medicine which contributed patients between March 1993 and October 1997.

L'Hopital du Sacré-Coeur de Montreal is a 714 bed facility located in the north end of the City of Montreal, and is a teaching hospital associated with l'Université de Montreal Faculty of Medicine. It contributed patients between July 1993 and May 1997.

L'Hopital Charles LeMoyne is situated in the South Shore community of Greenfield Park. It has 590 beds and enrolled patients starting in June of 1994 until March of 1997.

L'Hopital Enfant Jésus, a 1079 bed hospital, is the only major trauma facility in the Quebec City area. Patients from this centre were included starting in June of 1993 and ending in December of 1997.

3.7.4 DETERMINATION OF PRE-HOSPITAL CARE

Patients were classified into two treatment groups based on the type of prehospital care they received. Advanced Life Support patients were those treated by an Urgences Santé MD-ALS unit. Basic Life Support patients were those who received treatment only from EMT ambulance personnel.

Two approaches were used. The Intent to Treat approach considered all patients who were treated by an MD in the ALS group regardless of the interventions carried out on the scene. The Efficacy approach only considered patients that received an ALS

procedure as belonging in the ALS group. Therefore, using the Efficacy analysis, MD treated patients who only received BLS were classified in the BLS group.

In order to determine what kind of prehospital care a patient received for the Intent to Treat analysis, a number of sources were consulted. Data from the Quebec Trauma Registry was used to identify cases of penetrating trauma, as described above, that occurred between 1993 and 1997. This data was then matched using last name, first name, date of injury and, when available, medical insurance number to data collected by Urgences Santé. Three different Urgences Santé data files were consulted for the project.

The Ambulance Technician Report contains information on the type of case, past medical history of the victim, the mechanism of trauma, a description of the injury, which interventions were carried out on the scene or en route to the hospital, vital sign data and information pertaining to how the individual was transported. It also indicates whether or not there was support via radio or on-site by an Urgences Santé MD. If the box for MD support on-site was ticked off, the patient was classified in the ALS group.

The vehicle activity file is a second file provided by Urgences Santé and matched to data from the Quebec Trauma Registry. It contains information on the response times of each unit, the time spent on-scene and the travel time spent en route to the hospital. If a response time for an MD-ALS unit was present, the patient was classified in the ALS group.

A third data file corresponds to a one page report filed by Urgences Santé MDs. It details the patient's past medical history, as briefly obtained on the scene, information on medical, the nature of the case, what physical exams were performed and their results, vital

sign data, and what interventions were performed on the scene or en route. If an MD report existed for a patient, they were classified in the ALS group.

For the Efficacy Analysis, all patients who received an IV, medication, or were intubated before arriving at the hospital were considered as ALS. All other patients were grouped into the BLS group.

Forty-nine patients that were admitted to Hopital Charles LeMoyne and fifty-seven patients admitted to Hopital Enfant Jesus were automatically included in the BLS group since those centres are not serviced by Urgences Santé, the only ALS provider in the province. In addition, patients admitted to the Montreal General and Sacré Coeur were considered as BLS patients if data from the QTR indicated any company other than Urgences Santé was the first responder.

3.8 DATA ANALYSIS

3.8.1 EXPOSURES AND COVARIATES

Univariate comparisons were made between ALS and BLS patient groups for exposure and outcome variables. Exposure variables examined included the following:

- age
- Injury Severity Score (ISS)
- location of injury
- mechanism of injury
- gender
- intentional / non-intentional injury
- stratified analysis

- incidence of firearm injuries stratified by age
- minutes spent on the scene
- minutes spent travelling to the ER
- total minutes spent in the prehospital environment

The following covariates were also examined:

- city of injury
- year of injury
- treating hospital

The Injury Severity Score (ISS), which ranges from 1 to 75, was used as a measure of injury severity. The ISS is the sum of the squares of the highest AIS code in each of the three most severely injured ISS body regions. The body regions are as follows:

1) head or neck, 2) face, 3) chest, 4) abdominal or pelvic contents, 5) extremities or pelvic girdle, 6) external. Any AIS code of 6 is automatically assigned an ISS of 75. ISS codes cannot be calculated for a patient with an AIS code of 9. The injuries in each region are scored a one for minor injuries, two for moderate injuries, three for severe but not life-threatening, four for life-threatening and five as survival uncertain.

3.8.2 OUTCOMES

The main outcome variable of interest was mortality. Patients who were discharged alive from hospital were considered to have survived. A number of approaches were used to assess the mortality of the two treatment groups. They were as follows:

- survived to discharge / death
- survived to discharge / death within 7 days

- Standardised Mortality Ratio (SMR)
- time to death (hours)
- time to death (days)
- stratified analysis
 - mortality stratified by ISS
 - mortality stratified by age
- destination of discharge

Student's t-tests were used to compare continuous data, chi-square and Fisher's Exact tests were used to compare groups with respect to categorical variables, and odds ratios were used for dichotomous data. Logistic regression was used to determine factors influencing mortality, and linear regression was used in the cases of continuous outcome variables such as length of hospital stay. In the case of time to death, Kaplan Meier survival analysis was used to compare the treatment groups.

The Standardized Mortality Ratio (SMR) as described by Breslow and Day (1987) (Appendix A) was used to compare the mortality experienced in the current study to the data presented by the Major Trauma Outcome Study in 1988 (Copes et al., 1988). The SMR is equal to the number of observed deaths divided by the number of expected deaths. Expected deaths were calculated by summing the individual probabilities of death for each patient based on the MTOS results.

3.8.3 EFFICACY ANALYSIS

A second classification of patients into treatment groups was used to assess the impact of individual ALS procedures. ALS patients described previously were all those

for which a physician was present at the scene. For the Efficacy Analysis only those who actually received an ALS procedure were classified in the ALS group. Outcomes and exposures investigated were similar to those listed above. Mortality was compared between those who received an IV and those who did not. This was repeated considering only ALS patients. The mortality of prehospital intubations was also compared using a chi-square test.

Prehospital times were compared between ALS and BLS groups based on the Efficacy Analysis classifications and between MD-ALS patients and MD treated patients who received only BLS.

All data analysis and data manipulation was carried out using the SPSS statistical software package.

Chapter IV - RESULTS

4.0 STUDY SAMPLING

The final sample in the study consisted of 431 cases of penetrating trauma that were identified between April of 1993 and November of 1997. At the end of the study period, the Montreal General Hospital contributed 5094 patients into the Quebec Trauma Registry (QTR), Sacré Coeur had 2509, L'Enfant Jesus had 4511 and Charles LeMoyne had enrolled 1748 patients.

Two hundred and fifteen out of the MGH's 5094 patients (4.2%) were listed as penetrating in the QTR. An additional 59 patients were listed as non-penetrating but were injured by gunshot and therefore included. Similarly, 60 stabwound patients were listed as non-penetrating but were included. Fifty-nine of 4511 Enfant Jesus patients (1.3%) were penetrating. Seventeen were non-penetrating firearm injuries and 6 were stabwounds. Sacré Coeur's database counted 124 out of 2506 overall entries as penetrating (5.0%) as well as 12 firearm injuries and 8 stabwounds. One additional patient from Sacré Coeur was included due to an AIS code of 216006.3 which is an injury to the face described as "penetrating injury with blood loss > 20% by volume" (Committee on Trauma - Scaling, 1994). The Charles LeMoyne Hospital added 48 penetrating of 1741 total cases (2.8%), 5 stabwounds and 5 firearm injuries. Table 4.1.2 summarises the breakdown of reasons for inclusion of the final sample.

The Montreal General Hospital and Sacré Coeur contributed only 92% of eligible cases as identified through the QTR, mainly because data from the QTR could not be

matched to data from Urgences Santé and therefore those cases could not be classified as either ALS or BLS. Table 4.0 details the reasons for exclusions of each hospital. Eligible cases were non-transfer patients that were either listed as penetrating, or non-penetrating, but injured by gunshot or stabbing in the QTR.

Table 4.0 Breakdown of final sample

| Hospital | Eligible Cases | | Excluded Case | Excluded Cases | | % of cases |
|----------|----------------|-------|-----------------|----------------|-----------|------------|
| | | | | | cases | included* |
| } | | | Reason | N | | |
| Montreal | Penetrating | 215 | ALS/BLS unknown | 29 | 230 | 92% |
| General | Firearm | 59 | Transfers | 84 | | |
| Hospital | Stabwound | 60 | Unknown outcome | 1 | | |
| | Total | 334 | Total | 104 | | |
| Hopital | Penetrating | 124 | ALS/BLS unknown | 18 | 96 | 85% |
| Sacré | Firearm | 12 | Transfers | 31 | | |
| Coeur | Stabwound | 8 | | | | |
| | AIS=216006 | 5.3 1 | | | | |
| | Total | 145 | Total | 49 | | |
| Hopital | Penetrating | 59 | Transfers | 25 | 57 | 100% |
| de | Firearm | 17 | | | | |
| l'Enfant | Stabwound | 6 | | | : | |
| Jesus | Total | 82 | Total | 25 | | |
| Hopital | Penetrating | 48 | Transfers | 9 | 49 | 100% |
| Charles | Firearm | 5 | | | | |
| LeMoyne | Stabwound | 5 | | | | |
| | Total | 58 | Total | 9 | Total 431 | |

^{* %} cases included=(Number of cases)/Eligible Cases-Transfers

4.1 DEMOGRAPHICS - OVERALL SAMPLE

The final sample consisted of 230 patients from the Montreal General Hospital, 96 from Sacré Coeur, 57 from l'Enfant Jesus, and 49 from Charles LeMoyne (Table 4.1.2). Seventy-six percent of patients were identified as having received penetrating injuries in the QTR, 11% and 13% of included cases were injuries by firearms stabbing respectively that were listed as non-penetrating (Table 4.1.1). Table 4.1.3 details the number of patients from each hospital. The Montreal General contributed the bulk of patients since it was the first hospital enrolled in the QTR. Data entry from the other hospitals did not begin in earnest until mid to late 1994.

Table 4.1.4 describes the city where injuries took place. Montreal patients were obtained by the addition of MGH patients to SC patients, and amounted to 326 of the 431 subjects (75%). A majority of the victims in the study were males (86 %) (Table 4.1.5).

Table 4.1.1 Reason for Inclusion

| Reason for Inclusion | N | % |
|--|-----|------|
| penetrating | 326 | 75.7 |
| firearm | 47 | 10.9 |
| stab wound | 57 | 13.2 |
| AIS=216006.3 | 1 | 0.2 |
| (Penetrating Injury with blood loss > 20% by volume) | | |
| Total | 431 | 100% |

Table 4.1.2 Reason for inclusion by Hospital

| Hospital | Reason for inclusion/exclusion | N |
|---------------------------|--------------------------------|-----|
| Hopital du Sacré Coeur | penetrating | 83 |
| | firearm | 6 |
| | stab wound | 6 |
| | AIS=216006.3 | 1 |
| | Total | 96 |
| Montreal General Hospital | penetrating | 156 |
| | firearm | 31 |
| | stab wound | 43 |
| | Total | 230 |
| Hopital de l'Enfant Jésus | penetrating | 47 |
| | firearm | 6 |
| | stab wound | 3 |
| | Total | 56 |
| Hopital Charles LeMoyne | penetrating | 40 |
| | firearm | 4 |
| | stab wound | 5 |
| | Total | 49 |

Table 4.1.3 Admitting Hospital

| Hospital | Frequency | Percent |
|---------------------------|-----------|---------|
| Sacré Coeur | 96 | 22.2 |
| Montreal General Hospital | 230 | 53.2 |
| Enfant Jésus | 56 | 13.2 |
| Charles LeMoyne | 49 | 11.3 |
| Total | 431 | 100% |

Table 4.1.4 Distribution of Injury by City

| City | Frequency | Percent |
|-------------|-----------|---------|
| Montreal | 326 | 75.5 |
| Quebec City | 56 | 13.2 |
| South Shore | 49 | 11.3 |
| Total | 431 | 100% |

Table 4.1.5 Gender

| Gender | Frequency | Percent |
|--------|-----------|---------|
| Male | 372 | 86.3 |
| Female | 59 | 13.7 |
| Total | 432 | 100% |

4.2 UNIVARIATE COMPARISONS BETWEEN GROUPS

The final sample included 106 victims treated by MD-ALS (25%), and 325 treated with BLS (75%) for a total of 431 patients. The youngest victim in the BLS group was 8 years old, while the youngest ALS patient was 16. The oldest BLS and ALS patients were 75 and 82 respectively. Histograms of the two groups with respect to age can be found in Figures 4.2.1 and 4.2.2. The ages of both groups tended to cluster towards the younger end of the spectrum and were statistically similar when compared with a Student's t-test (BLS=36.4, ALS=35.9 p = 0.766 - Table 4.2.1). Four patients, all in the BLS group, were excluded from the age calculation. Three of these as their date of birth was unknown and one because the date of event was recorded as preceding the date of birth. Injury

Severity Scores were also very similar between the two groups (BLS=11.51; ALS=11.62).

One patient in the BLS group had an AIS score of 9 and therefore no ISS was calculated.

Figure 4.1 Distribution of age - BLS group

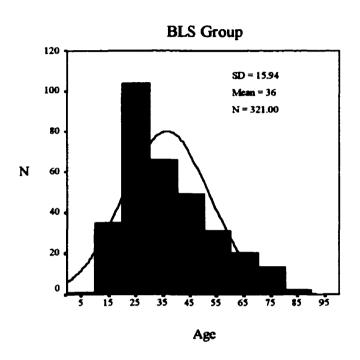


Figure 4.2 Distribution of age - ALS group

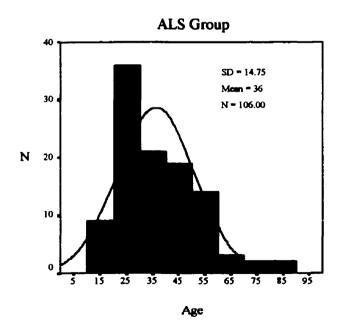


Table 4.2.1 Continuous Exposures

| Variable | Group | Mean | Median | SD | Min. | Max. | T-test p value |
|----------|-------|-------|--------|-------|-------|-------|----------------|
| Age | BLS | 36.35 | 32.00 | 15.94 | 8.00 | 86.00 | 0.943 |
| | ALS | 36.23 | 33.00 | 14.75 | 16.00 | 83.00 | |
| ISS | BLS | 11.51 | 9.00 | 11.52 | 1.00 | 75.00 | 0.930 |
| | ALS | 11.62 | 9.00 | 11.41 | 1.00 | 75.00 | |

Tables 4.2.4 and Figures 4.3 and 4.4 describe the distribution of injuries by year.

Relatively few injuries are reported in 1993 since the QTR was only just being established.

Similarly, fewer injuries were reported in 1997 due to the data entry backlog that currently exists at the participating hospitals.

Table 4.2.2 Distribution of Injury Year by Group

| Year | of Injury | Gr | oup | Total | Ratio |
|-------|-----------|-------|-------|--------|---------|
| | | BLS | ALS | | BLS/ALS |
| 1993 | Count | 14 | 12 | 26 | 1.17 |
| | % | 53.8% | 46.2% | 100.0% | |
| 1994 | Count | 64 | 16 | 80 | 4.0 |
| | % | 80.0% | 20.0% | 100.0% | |
| 1995 | Count | 91 | 27 | 118 | 3.37 |
| | % | 77.1% | 22.9% | 100.0% | |
| 1996 | Count | 114 | 23 | 137 | 4.96 |
| | % | 83.2% | 16.8% | 100.0% | |
| 1997 | Count | 42 | 28 | 70 | 1.5 |
| | % | 60.0% | 40.0% | 100.0% | |
| Total | Count | 325 | 106 | 431 | 3.06 |
| | % | 75.4% | 24.6% | 100.0% | |

chi-square p-value<0.001

A chi-square test indicated that the distribution of injuries differs between the two groups by year. In 1995 80% of the injuries in the sample were treated by BLS, conversely, in 1993 and 1997 the proportions were nearer to 50/50.

Figure 4.3 Year of injury of BLS patients

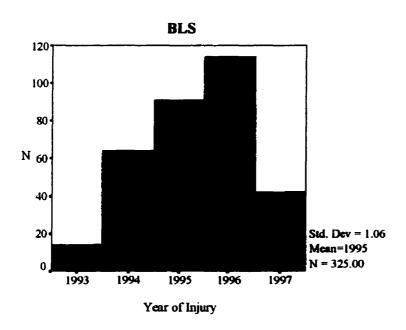


Figure 4.4 Year of injury of ALS patients

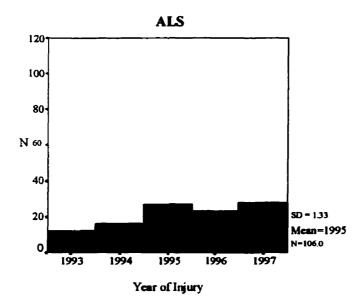


Table 4.2.3 contains the results of univariate comparisons between ALS and BLS groups for categorical variables. As expected, the ALS group differed from the BLS group with respect to city of residence and admitting hospital since ALS is only present in one of the three regions and two of the four hospitals. Chi-square tests for all other categorical exposure variables measured noted no significant differences between groups.

Both groups had the same distribution of reasons for inclusion into the study. Seventy-six percent were coded as penetrating in the BLS group, versus 74% in the ALS group. The proportion of patients that were not listed as penetrating in the QTR that were included due to firearm injuries was similar at 11% and 10% in the BLS and ALS groups respectively. Similarly, the proportion of stabwound patients included was also similar, 13% of BLS patients and 16% of ALS patients. The proportion of males was virtually identical in both groups at approximately 86%. Table 4.2.3 compares the incidence of firearm injuries in the two groups. There were 9% more firearm injuries in the BLS group (35% versus 26%), a difference which approached statistical significance (p = 0.11). The distribution of other mechanisms of injury were similar in the two groups. Fifty-seven percent of BLS patients versus 63% of ALS patients suffered from stabwounds, approximately 1% of patients in both groups were involved in motor vehicle crashes, another 1% suffered blunt penetrating trauma, 2 patients in the BLS group were injured in falls and 2 patients in each group were coded as "other".

The BLS group had slightly more intentional injuries (28.7% versus 21.4%), a difference that neared significance (p = 0.10). Both groups had less than 5% injuries where the intent was unknown.

The place of injury was also comparable between groups. The home was the most common location where 36% of BLS patients and 32% of ALS patients were injured. Fifteen percent of BLS and 21% of ALS patients were wounded on streets and highways. Other venues included public buildings (BLS - 11%, ALS - 16%), industrial premises (BLS - 4%, ALS - 7%), recreation/sport facilities and residential institutions where identically distributed between groups at 1% and 3% respectively. Data on the scene of injury was not available for 28% of BLS patients and 18% of ALS patients.

Table 4.2.3 Categorical Exposures

| | | _ | ALS o | r BLS | | Level of |
|------------|----------------------------|-------|-------|-------|-------|---------------|
| | | BI | LS | Al | LS | significance* |
| | | Count | % | Count | % | |
| City | Montreal | 220 | 67.7% | 106 | 100% | |
| | Quebec | 56 | 17.2% | | | < 0.001 |
| | South Shore | 49 | 15.1% | | | |
| Hospital | Sacré Coeur | 71 | 21.8% | 25 | 23.6% | |
| | Montreal General Hosp | 149 | 45.8% | 81 | 76.4% | < 0.001 |
| | Enfant Jésus | 56 | 17.2% | | į | |
| | Charles LeMoyne | 49 | 15.1% | | | |
| Reason for | 'penetrating' | 247 | 76.0% | 79 | 74.5% | |
| Inclusion | firearm | 37 | 11.4% | 10 | 9.4% | 0.291 |
| | stab wound | 41 | 12.6% | 16 | 15.1% | |
| | AIS=216006.3 | | _ | 1 | 0.9% | |
| Gender | male | 280 | 86.2% | 92 | 86.8% | 0.868 |
| | female | 45 | 13.8% | 14 | 13.2% | |
| Mechanism | motor vehicle accident | 5 | 1.5% | 2 | 1.9% | |
| of injury | fall | 2 | .6% | | [| 0.541 |
| | firearm | 113 | 34.8% | 28 | 26.4% | |
| | stab wound | 185 | 56.9% | 66 | 63.2% | |
| | blunt | 3 | 0.9% | 2 | 1.9% | |
| | accidental knife, saw, etc | 15 | 4.6% | 6 | 5.7% | |
| | other | 2 | .6% | 2 | 1.9% | |
| Intent | intentional | 94 | 28.9% | 22 | 20.8% | |
| | non-intentional | 215 | 66.2% | 81 | 76.4% | 0.100** |
| | unknown | 16 | 4.9% | 3 | 2.8% | |
| Place | home | 116 | 35.7% | 34 | 32.1% | |
| of injury | industrial premises | 13 | 4.0% | 7 | 6.6% | 0.305 |
| | place for sports & rec. | 3 | .9% | 1 | 0.9% | |
| | street or highway | 48 | 14.8% | 23 | 21.7% | |
| | public building | 37 | 11.4% | 17 | 16.0% | |
| | residential institution | 11 | 3.4% | 3 | 2.8% | |
| | other specified place | 7 | 2.2% | 1 | 0.9% | |
| | unknown | 90 | 27.7% | 20 | 18.9% | |

^{*}evaluated using chi-square test
**unknown cases excluded

Table 4.2.4 Incidence of Firearm Injuries

| Type of Injury | Gro | Total | |
|--------------------|---------|-------|-------|
| | BLS ALS | | |
| Non firearm injury | 212 | 78 | 290 |
| % | 65.2% | 73.6% | 67.3% |
| Firearm injury | 113 | 28 | 141 |
| % | 34.8% | 26.4% | 32.7% |
| Total | 325 | 106 | 431 |

Chi-square p-value=0.111 Odds Ratio=0.673 95% Confidence Interval of the Odds Ratio (0.413, 1.098)

4.3 PATIENT OUTCOMES

4.3.1 MORTALITY

Table 4.3.1 describes the mortality of the two groups. Patients were considered alive if they survived to discharge from hospital. There were 60 deaths in the study, 48 in the BLS group (14.8% of BLS patients) and 12 in the ALS group (11.3% of ALS patients). This difference was not significant when tested using a chi-square (p=0.373) or odds ratio (OR=0.737, 95% CI = 0.375, 1.446).

A similar analysis was carried out on patients who died within seven days of injury.

Again, no significant difference between the groups was noted in terms of overall mortality (Table 4.3.2).

Table 4.3.1 Overall Mortality

| Mortality | ALS o | Total | |
|-----------|-------|-------|-------|
| | BLS | ALS | |
| survived | 277 | 94 | 371 |
| % | 85.2% | 88.7% | 86.1% |
| died | 48 | 12 | 60 |
| % | 14.8% | 11.3% | 13.9% |
| Total | 325 | 106 | 431 |

Chi-square p-value=0.373 Odds Ratio=0.737 95% Confidence Interval of the Odds Ratio (0.375, 1.446)

Table 4.3.2 Mortality (within 7 days)

| Mortality | ALS o | Total | |
|-----------|---------|-------|-------|
| | BLS ALS | | |
| survived | 277 | 94 | 371 |
| % | 86.3% | 89.5% | 87.1% |
| died | 44 | 11 | 55 |
| % | 13.7% | 10.5% | 12.9% |
| Total | 321 | 105 | 426 |

Chi-square p-value=0.391 Odds Ratio=0.737 95% Confidence Interval of the Odds Ratio (0.366, 1.485) Table 4.3.3 depicts the year to year mortality of the two groups. There were no deaths in either group during 1993. In 1994, the highest ALS death rate was observed at 19%, while the highest BLS death rate was observed in 1995 (22%). The statistical significance of differences between the groups with respect to mortality rates and year are addressed later in the logistic regression section for mortality (4.8.2).

Table 4.3.3 Mortality by Year

| Group | | | Mortality | | | | | |
|-------|---------|------|-----------|--------|-------|-------|--|--|
| | | Ì | Surv | ived | died | | | |
| | | Ì | Count | % | Count | % | | |
| | | 1993 | 14 | 100.0% | 0 | 0% | | |
| | Year of | 1994 | 59 | 92.2% | 5 | 7.8% | | |
| BLS | Injury | 1995 | 71 | 78.0% | 20 | 22.0% | | |
| | | 1996 | 97 | 85.1% | 17 | 14.9% | | |
| | | 1997 | 36 | 85.7% | 6 | 14.3% | | |
| | | 1993 | 12 | 100.0% | 0 | 0% | | |
| | Year of | 1994 | 13 | 81.3% | 3 | 18.8% | | |
| ALS | Injury | 1995 | 23 | 85.2% | 4 | 14.8% | | |
| | | 1996 | 21 | 91.3% | 2 | 8.7% | | |
| | | 1997 | 25 | 89.3% | 3 | 10.7% | | |

4.3.2 MECHANISM OF INJURY AND MORTALITY

Table 4.3.4 compares the observed mortality for each different mechanism of injury. The highest mortality rate was seen in motor vehicle accidents where a penetrating injury occurred (43%). Twenty-seven percent of gunshot victims died while 6% of stab wound victims died.

Table 4.3.4 Mortality and Mechanism of Injury

| Mechanism of injury | Mor | tality | Total | OR* | 95% CI | Chi-square |
|-----------------------------|----------|--------|------------------|------|---------------|---|
| | survived | died |] <u></u> ! | | of OR | p-value** |
| motor vehicle accident | 4 | 3 | 7 | 4.83 | (1.1, 22.1) | 0.026 |
| % | 57% | 43% | 100% | | | |
| fall | 2 | 0 | 2 | - | - | 0.569 |
| % | 100% | 0% | 100% | | | |
| firearm | 103 | 38 | 141 | 4.49 | (2.54, 7.96) | <0.001 |
| % | 73% | 27% | 100% | | | |
| stab wound | 237 | 14 | 251 | 0.17 | (0.09, 0.33) | <0.001 |
| % | 94% | 6% | 100% | : | | |
| blunt | 4 | 1 | 5 | 1.56 | (0.17, 14.15) | 0.693 |
| % | 80% | 20% | 100% | | | |
| accidental knife, saw, etc. | 19 | 2 | 21 | 0.64 | (0.15, 2.82) | 0.551 |
| % | 91% | 9% | 100% | | | |
| other | 2 | 2 | 4 | 6.36 | (0.88, 46.05) | 0.036 |
| % | 50% | 50% | 100% | | | |
| Total | 371 | 60 | 431 | | | *************************************** |
| % | 86.1% | 13.9% | 100% | | | |

^{*} OR's individually calculated by comparing rate of death for a particular mechanism of injury to deaths of all other mechanisms of injury

4.3.3 OBSERVED VERSUS EXPECTED MORTALITY

In 1988, Copes et al. published data from the Major Trauma Outcomes Study which listed the probability of death based on a patient's age dichotomized at 50 years, the ISS and whether or not the injury was penetrating (Copes et al., 1988). The sum of the probabilities of death was used as the number of expected deaths in the sample based on the 1988 Copes et al. MTOS data. These values were calculated for patients in the current

^{**}overall chi-square p value<0.001

sample and are presented in Table 4.3.5. Standardized Mortality Ratios were then calculated by dividing the number of observed deaths by the number of expected deaths. Overall mortality was significantly greater than expected as evidenced by 95% SMR confidence intervals that do not include one. The SMR for ALS treated patients was not statistically greater than one, while the BLS SMR was greater than unity (Table 4.3.5).

Table 4.3.5 Standardized Mortality Ratio (SMR)

| Group | Number | of Deaths | SMR=O/E | SMR 95% |
|-------|--------------|--------------|---------|--------------|
| | Expected (E) | Observed (O) | | CI |
| BLS | 25.35 | 48 | 1.89 | (1.26, 2.33) |
| ALS | 9.51 | 12 | 1.26 | (0.65, 2.20) |
| Total | 34.86 | 60 | 1.72 | (1.31, 2.22) |

4.3.4 TIME TO DEATH

On average, BLS patients died later after injury. The average BLS patient died 79 hours after injury versus 32 hours for ALS treated patients (Table 4.3.6). The distributions of time of death for both groups were non-normal which is illustrated by the fact that the ALS group had a larger median but smaller mean time to death. The non-parametric Mann-Whitney U test did not detect a statistically significant difference between groups (p = 0.948). A Kaplan-Meier Survival Analysis was performed and is presented in Figures 4.5 and 4.6. The first figure shows the actual distribution of all patients while the second focuses on early deaths occurring less than 50 hours after injury. Statistical comparisons of the survival distributions are presented in Table 4.3.7. Linear

regression also indicated that prehospital treatment was not a significant predictor of time to death (significance=0.909).

Table 4.3.6 Time of Death (hours after injury)

| Group | Mean | Median | Minimum | Maximum | N | T-test p value |
|-------|-------|--------|---------|---------|----|----------------|
| BLS | 79.11 | 3.13 | .50 | 2040.00 | 48 | 0.606 |
| ALS | 31.65 | 4.25 | 1.00 | 216.00 | 12 | |
| Total | 69.62 | 3.13 | .50 | 2040.00 | 60 | |

Figure 4.5 Hours until death among all patients Kaplan-Meier Survival Analysis

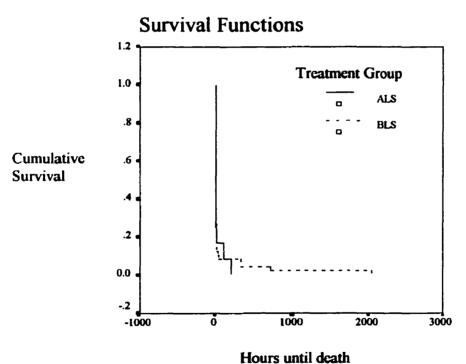


Figure 4.6 Hours until death limited to those occurring less than 50 hours after injury
Kaplan-Meier Survival Analysis



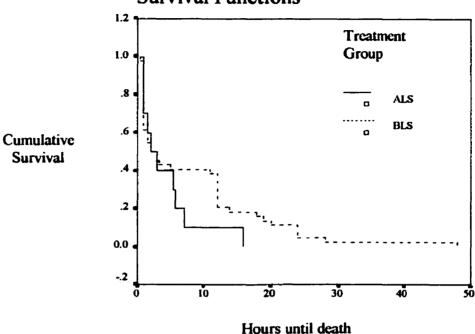


Table 4.3.7 Test Statistics for Equality of Survival Distributions for ALS/BLS

| Distribution tested | Statistical Test | Test Statistic | Degrees of Freedom | Significance |
|---------------------|------------------|----------------|-----------------------|--------------|
| | Log Rank | 0.20 | 1 | 0.668 |
| All patients | Breslow | 0.00 | 1 | 0.948 |
| | Tarone-Ware | 0.02 | 1 | 0.882 |
| Deaths less than | Log Rank | 1.66 | 1 | 0.197 |
| 50 hours after | Breslow | 0.14 | 1 | 0.705 |
| injury | Tarone-Ware | 0.60 | , 1 | 0.437 |

Table 4.3.8 describes the distribution of the number of days until death among non-survivors. The data was collapsed by grouping all deaths occurring later than seven days into the same category. The treatment groups were comparable when tested by a chi-square test (p = 0.14) Seventy-five percent of ALS patients died within one day of injury compared to 56% of BLS patients. Both groups demonstrated the exact same percentage of deaths after seven days (8.3%).

Table 4.3.8 Days until Death

| Days until death | ALS o | Total | |
|------------------|-------|-------|-------|
| | BLS | ALS | |
| <1 | 27 | 9 | 36 |
| % | 56.3% | 75.0% | 60.0% |
| 1 | 16 | 1 | 17 |
| % | 33.3% | 8.3% | 28.3% |
| 2 | 1 | 0 | 1 |
| % | 2.1% | 0% | 1.7% |
| 5 | 0 | 1 | 1 |
| % | 0% | 8.3% | 1.7% |
| >7 | 4 | 1 | 5 |
| % | 8.3% | 8.3% | 8.3% |
| Total | 48 | 12 | 60 |

Chi-square p-value=0.140

4.3.5 LENGTH AND INCIDENCE OF ICU AND HOSPITAL ADMISSIONS

Table 4.4.1 shows the proportion of patients admitted to the ICU in the two groups among those who survived to discharge from hospital. Slightly more ALS patients were admitted to the ICU (44% versus 39%) but this difference was not significant. Data concerning the length of ICU admissions are presented in Table 4.4.2. The median number of hours were similar between the two groups (57 versus 53). The means were not significantly different when tested using both a t-test and a non-parametric Mann-Whitney test (Table 4.4.2).

Table 4.4.1 Admitted to the ICU (survivors only)

| | ALS o | ALS or BLS | | |
|-------|-------|------------|-------|--|
| | BLS | ALS | | |
| Ward | 169 | 53 | 222 | |
| % | 61.0% | 56.4% | 59.8% | |
| ICU | 108 | 41 | 149 | |
| % | 39.0% | 43.6% | 40.2% | |
| Total | 277 | 94 | 371 | |

Chi-square p-value=0.429

Odds Ratio=1.211

95% Confidence Interval of the Odds Ratio (0.754, 1.944)

Table 4.4.2 Length of ICU admission
(all surviving patients admitted to the ICU)

| | Group N Mean N | | Median | SD | Mann-Whitney | T-test | |
|----------|----------------|-----|--------|------|--------------|---------|---------|
| | | | | | | p-value | p-value |
| ICU Stay | BLS | 108 | 115.32 | 53.5 | 183.92 | 0.704 | 0.359 |
| (hours) | ALS | 41 | 87.54 | 57.0 | 96.52 | | |

The length of hospital stays of the two groups are listed in Table 4.4.3. T-tests found no significant differences between the groups for either hospital stay in hours or days (Table 4.4.3). Histograms of the data revealed non-normal distributions for the length of hospital stays (see Appendix B) therefore non-parametric Mann Whitney U tests were performed. Again, no differences were noted between ALS and BLS patients

Table 4.4.3 Length of Hospital Stay (all survivors included)

| | Group | N | Mean | Median | SD | Mann Whitney p-value | T-test p-value |
|---------------|-------|-----|--------|--------|--------|-------------------------|-------------------|
| Hospital stay | BLS | 274 | 312.02 | 162 | 617.85 | 0.989 | 0.769 |
| (hours) | ALS | 93 | 335.41 | 169 | 783.34 | | |
| Hospital stay | BLS | 274 | 12.99 | 6.7 | 25.75 | 0.946 | 0.765 |
| (days) | ALS | 93 | 13.99 | 7.0 | 32.64 | | |

4.3.6 DESTINATION OF DISCHARGE

Among survivors who were not discharged directly home, there were no differences between groups with respect to destination of discharge (p = 0.180). Table 4.5.1 lists the destinations of the two groups.

Table 4.5.1 Discharge Status (excluding patients discharged home)

| Discharged to | Treatme | nt Group | Total | |
|--|---------|----------|-------|--|
| | BLS | ALS | | |
| left against advice | 7 | 1 | 8 | |
| % | 12.7% | 6.3% | 11.3% | |
| unknown | 2 | 0 | 2 | |
| % | 3.6% | 0.0% | 2.8% | |
| other | 12 | 4 | 16 | |
| % | 21.8% | 25.0% | 22.5% | |
| transfer to other health care facility | 34 | 11 | 45 | |
| 9/0 | 61.8% | 68.8% | 63.4% | |
| Total | 55 | 16 | 71 | |

chi-square p-value=0.755

Among survivors discharged home, significantly more ALS patients required assistance. Table 4.5.2 shows that only 16% of home-discharged BLS patients required some form of home-care versus 28% of ALS patients. This result was significant when tested using a chi-square (p=0.023) and odds ratio (OR=2.008, 95% CI: 1.092 - 3.692). The comparison was then stratified by age (Table 4.5.3). The same relationship was observed in three of the four age strata. In the youngest group of patients the difference was not statistically significant (p = 0.546).

Table 4.5.2 Patients Discharged Home - Help Requirements

| Status at discharge | ALS o | r BLS | Total |
|---------------------|-------|-------|-------|
| | BLS | ALS | |
| home | 184 | 56 | 240 |
| % | 83.6% | 71.8% | 80.5% |
| home - with help | 36 | 22 | 58 |
| % | 16.4% | 28.2% | 19.5% |
| Total | 220 | 78 | 298 |

Chi-square p-value=0.023 Odds Ratio=2.008 95% Confidence Interval of the Odds Ratio (1.092, 3.692)

Table 4.5.3 Patients Discharged Home - Help Requirements
Stratified by Age

| Age | | | Gr | oup | | | OR | 95 % | Sig.* |
|------------|------------------|---------------|---------|------------------|---------------|-----------------|------|-----------------------|-------|
| Stratified | | BLS | | | | CI of | | | |
| | no home- care | home- care | % home- | no home- care | home- care | % home- care | | OR | |
| 0 to 24 | 65 | 14 | 17.7 % | 21 | 3 | 12.5 % | 0.66 | 0.17 - 2.53 | 0.546 |
| 25 to 39 | 66 | 12 | 15.4 % | 19 | 9 | 32.1 % | 2.61 | 0.96 - 7.11 | 0.056 |
| 40 to 64 | 46 | 9 | 16.4 % | 16 | 9 | 36.0 % | 2.88 | 0.97 - 8.51 | 0.051 |
| 65+ | 6 | 1 | 14.3 % | 0 | 1 | 100 % | - | - | 0.064 |

^{*}tested using chi-square

4.4 STRATIFIED ANALYSIS

Stratified analysis was used to help identify interactions between variables.

Patients were stratified into four ISS subgroups: 1) 1 to 11, 2) 12 to 24, 3) 25 to 51 and 4)

ISS=75. Advanced Life Support and BLS mortality were then compared in the four ISS strata, this data is presented in Table 4.6.1. No significant differences existed with respect to mortality between BLS and ALS treated patients. Information concerning the patients in the low ISS strata (1 to 11) are presented in Table 4.6.2. The majority of these patients probably suffered much more severe wounded than their Injury Severity Scores suggest due to a lack of detailed information regarding their injuries.

In the fourth strata (ISS=75) all three BLS patients died whereas the one ALS patient in the subgroup survived. Among the four, the ALS patient was 26 years old whereas the BLS patients were aged 38, 42 and 66.

Table 4.6.1 Mortality stratified by ISS

| ISS | | | Gr | oup | | | OR | 95 % | Sig.* |
|------------|-------|------|---------|-------|------|--------|------|-------------|-------|
| Stratified | | BLS | 3 | | ALS | | | CI of | |
| | lived | died | % died | lived | died | % died | | OR | |
| 1 to 11 | 211 | 11 | 5.0 % | 68 | 1 | 1.4 % | 0.28 | 0.04 - 2.23 | 0.20 |
| 12 to 24 | 44 | 4 | 8.3 % | 15 | 2 | 11.8 % | 1.47 | 0.24 - 8.84 | 0.67 |
| 25 to 51 | 22 | 29 | 56.9 % | 10 | 9 | 47.4 % | 0.68 | 0.24 - 1.97 | 0.48 |
| ISS = 75 | 0 | 3 | 100.0 % | 1 | 0 | 0 % | ** | ** | 0.05 |

^{*}tested using chi-square

^{**}Odds Ratio cannot be calculated for a 2*2 table with empty cells

Table 4.6.2 Descriptive data concerning non-surviving low ISS patients*

| Patient # | Age | ISS | Gender | Mechanism of Injury |
|-----------|-----|-----|--------|-----------------------|
| 1 | 27 | 3 | male | Firearm |
| 2 | 33 | 1 | male | Stab wound |
| 3 | 36 | 2 | male | Firearm |
| 4 | 39 | 10 | male | Firearm |
| 5 | 41 | 3 | female | Stab wound |
| 6 | 42 | 5 | male | Firearm |
| 7 | 43 | 1 | male | Firearm |
| 8 | 44 | 3 | male | Firearm |
| 9 | 53 | 9 | male | MVC |
| 10 | 56 | 9 | male | Firearm |
| 11 | 67 | 1 | male | Stab wound |
| 12 | 70 | 4 | male | Accidental knife/saw. |

^{*}patient #8 treated by ALS, all others by BLS

The next stratification sought to identify potential differences in mortality between groups with respect to age. Table 4.6.3 describes the mortality of both ALS and BLS patients according to four age strata: 1) 1 to 24 years, 2) 25 to 39 years, 3) 40 to 64 years and 4) 65+ years. No differences were noted between the groups in any of the strata although in the 40 to 64 year group the result neared statistical significance.

Table 4.6.3 Mortality Stratified by Age

| Age | | | Gr | oup | | | OR | 95 % | Sig.* |
|------------|-------|------|--------|-------|------|--------|------|-----------------|-------|
| Stratified | BLS | | | ALS | | |] | CI of | |
| | lived | died | % died | lived | died | % died | İ | OR | |
| 0 to 24 | 89 | 8 | 8.2 % | 26 | 1 | 3.7 % | 0.43 | 0.05 - 3.58 | 0.42 |
| 25 to 39 | 98 | 11 | 10.1 % | 33 | 6 | 15.4 % | 1.62 | 0.56 - 4.72 | 0.37 |
| 40 to 64 | 67 | 20 | 23.0 % | 32 | 3 | 8.6 % | 0.31 | 0.09 - 1.14 | 0.07 |
| 65+ | 22 | 6 | 21.4 % | 3 | 2 | 40.0 % | 2.44 | 0.33 - 18.14 | 0.37 |

^{*}tested using chi-square

In an attempt to explain the different mortality rates witnessed in the age-stratified mortality analysis, the incidence of firearm injuries was compared between the two groups in the same four age strata (Table 4.6.4). Twenty percent more ALS patients in the 1 to 24 year age category were injured by firearm (p < 0.05). This trend reversed itself in the 25 to 39 (p < 0.05) and 40 to 64 (p = 0.051) age groups where there were 20% and 19% more firearm injuries respectively in BLS patients. In the eldest age group the BLS group again experienced more firearm injuries although the 12% difference was not statistically significant (p = 0.59).

Table 4.6.4 Firearm Injuries Stratified by Age

| Age | | | Gro | oup | | | OR | 95 % | Sig.* |
|------------|---------|---------|---------|---------|---------|---------|------|--------|-------|
| Stratified | | BLS | | | ALS | | | CI of | |
| | firearm | non- | % | firearm | non- | % | | OR | |
| | | firearm | firearm | | firearm | firearm | | | |
| 0 to 24 | 24 | 73 | 24.7 % | 12 | 15 | 44.4 % | 2.43 | 1.00 - | 0.05 |
| | | | | i i | | | | 5.92 | |
| 25 to 39 | 38 | 71 | 34.9 % | 6 | 33 | 15.4% | 0.34 | 0.13 - | 0.02 |
| | | | | | | | | 0.88 | |
| 40 to 64 | 39 | 48 | 44.8 % | 9 | 26 | 25.7% | 0.43 | 0.18 - | 0.05 |
| | | | | | | | | 1.02 | |
| 65+ | 9 | 19 | 32.1 % | 1 | 4 | 20.0 % | 0.53 | 0.05 - | 0.59 |
| | | | | | | | | 5.43 | |

^{*}tested using chi-square

4.5 EFFICACY ANALYSIS

All of the results presented thus far have been from the point of view of the "Intent to Treat" approach where patients were classified into the ALS and BLS groups regardless of which ALS procedures were actually carried out at the scene. A second approach, known as Efficacy Analysis, assesses the real impact of ALS procedures on outcome. Using this approach, only patients who received either an IV or were intubated were classified as ALS. Efficacy analysis BLS patients include those who were treated solely by EMTs as well as those that were treated by MDs in cases where no ALS interventions were carried out. The Efficacy analysis ALS and BLS groups were very similar with respect to age and ISS (Table 4.7.1). Table 4.7.2 describes the mortality of the two groups according to these classifications. Of the 106 instances when MDs were dispatched to the scene, in only 58 cases (55%) did they administer ALS procedures. Advanced Life Support mortality was 12% versus BLS mortality of 14%, a non-significant difference (p = 0.661; OR = 0.829; 95% CI: 0.357 - 1.923).

Table 4.7.1 Continuous Exposures Efficacy Analysis

| Variable | Group | Mean | Median | SD | Min. | Max. | T-test p value |
|----------|-------|-------|--------|-------|-------|-------|----------------|
| Age | BLS | 36.36 | 32.00 | 15.91 | 8.00 | 86.00 | 0.895 |
| | ALS | 36.07 | 35.50 | 13.93 | 16.00 | 82.00 | |
| ISS | BLS | 11.47 | 9.00 | 11.68 | 1.00 | 75.00 | 0.721 |
| | ALS | 11.98 | 9.00 | 10.23 | 1.00 | 75.00 | |

Table 4.7.2 Mortality - Efficacy Analysis

| Mortality | Treatme | nt Group | Total |
|-----------|---------|----------|-------|
| | BLS | ALS | |
| Survival | 320 | 51 | 371 |
| % | 85.8% | 87.9% | 86.1% |
| Death | 53 | 7 | 60 |
| % | 14.2% | 12.1% | 13.9% |
| Total | 373 | 58 | 431 |

Chi-square p-value=0.661 Odds Ratio=0.829 95% Confidence Interval of the Odds Ratio (0.357, 1.923)

Observed and expected deaths were compared between groups as defined by Efficacy evaluation. Table 4.7.3 shows the SMR and related statistics for the observed versus expected mortality. Two versions of the ISS were used to calculate the probability of death. The first, referred to in Table 4.7.3 as continuous ISS, employed the values directly from the 1988 Copes et al. paper from the MTOS(Copes et al., 1988). The second type of ISS, which is dubbed grouped ISS, clusters injury severity scores into one of seven classifications based on the suggestion of the authors (p. 76; Table X (Copes et al., 1988), reproduced in Appendix A).

Table 4.7.3 Standardized Mortality Ratio (SMR)

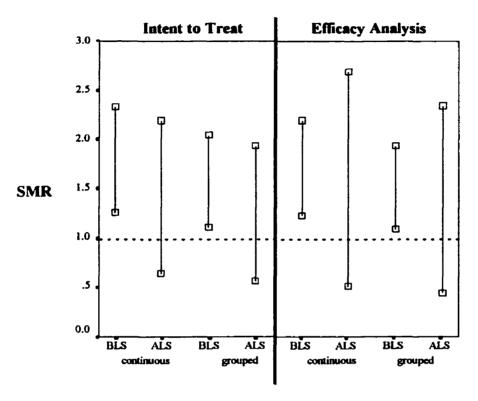
| Type of Analysis | Type of ISS used | Group | Expected Deaths | Observed Deaths | SMR (O/E) | 95% CI of SMR |
|------------------|------------------|-------|--------------------|--------------------|--------------|------------------|
| Intent to | Continuous | BLS | 25.35 | 44 | 1.73 | (1.26, 2.33) |
| Treat | | ALS | 9.51 | 12 | 1.26 | (0.65, 2.20) |
| | Grouped | BLS | 28.78 | 44 | 1.53 | (1.11, 2.05) |
| | | ALS | 10.78 | 12 | 1.11 | (0.57, 1.94) |
| Efficacy | Continuous | BLS | 29.48 | 49 | 1.66 | (1.23, 2.20) |
| Analysis | | ALS | 5.37 | 7 | 1.30 | (0.52, 2.69) |
| | Grouped | BLS | 33.39 | 49 | 1.48 | (1.09, 1.94) |
| | | ALS | 6.17 | 7 | 1.13 | (0.45, 2.34) |

The 95% confidence intervals of the SMRs in Table 4.7.3 are displayed graphically in Figure 4.7. The bars in the left half of the graph are the products of the Intent to Treat analysis, the bars on the right side of the graph were calculated using the Efficacy Analysis approach. The type of ISS data used to calculate the expected number of deaths can be seen on the bottom axis. In all cases there is significant overlap of the bars indicating that no significant differences exist between the SMRs of the ALS and BLS groups.

The lower bound of all four BLS SMRs are greater than 1 which suggests that mortality in the BLS sample is significantly higher than expected based on the MTOS data (Copes et al., 1988). This is never true in the ALS group, although due to the smaller sample size of the ALS patients, the 95% confidence limits are extremely wide making statistical significance attainable only in much larger SMRs. For a sample of 12 observed deaths, such as the Intent to Treat ALS group experienced, an SMR of at least 1.95 would

have been required to reach statistical significance. Similarly, in the case of the efficacy analysis where only 7 ALS patients died, the SMR needed to attain statistical significance would have to be a minimum of 2.5.

Figure 4.7 Graphical Representation of SMR 95% Confidence Intervals



4.6 ADVANCED LIFE SUPPORT INTERVENTIONS

Table 4.8.1 describes the mortality of ALS patients with respect to the use of prehospital IV fluid. There was no significant difference in the survival of those who received IVs before arriving at the hospital (88%) and those who did not (90%). A similar analysis which included all patients in the study is presented in Table 4.8.2. Again, no differences in survival were noted between those who received prehospital IV fluids (88%) and those who did not (86%).

Table 4.8.1 Mortality and Prehospital IV Fluid Administration (ALS patients)

| Mortality | IV o | Total | |
|-----------|-------|-------|-------|
| | No | Yes | |
| Lived | 43 | 51 | 94 |
| % | 89.6% | 87.9% | 88.7% |
| Died | 5 | 7 | 12 |
| % | 10.4% | 12.1% | 11.3% |
| Total | 48 | 58 | 106 |

Chi-square p-value=0.789 Odds Ratio=1.180 95% Confidence Interval of the Odds Ratio (0.349, 3.987)

Table 4.8.2 Mortality and Prehospital IV Fluid Administration (all patients)

| Mortality | IV o | Total | |
|-----------|-------|-------|-------|
| | No | Yes | |
| Lived | 320 | 51 | 371 |
| % | 85.8% | 87.9% | 86.1% |
| Died | 53 | 7 | 60 |
| % | 14.2% | 12.1% | 13.9% |
| Total | 373 | 58 | 431 |

Chi-square p-value=0.661 Odds Ratio=0.829 95% Confidence Interval of the Odds Ratio (0.357, 1.923) There were only three incidences of prehospital intubations in the entire sample (Table 4.8.3). All three intubated patients died, one five days later, and two approximately 24 hours after injury. Information concerning these patients is displayed in Table 4.8.4.

Table 4.8.3 Mortality and Prehospital Intubations

| Mortality | Preho | Total | |
|-----------|-------|-------|-------|
| | Intub | ation | |
| : | No | | |
| Lived | 371 | 0 | 371 |
| % | 86.7% | 0% | 86.1% |
| Died | 57 | 3 | 60 |
| % | 13.3% | 100% | 13.9% |
| Total | 428 | 3 | 431 |

Chi-square p-value<0.001 Fischer's exact test p=0.003

Table 4.8.4 Descriptive Data Concerning Intubated Patients

| Patient # | Time of Death | Age | ISS | Injury Description using AIS codes |
|-----------|---------------|-----|-----|--|
| 1 | 1 day | 44 | 3 | Firearm Injury. Undescribed penetrating wounds to the arms(2), thorax(2), and legs(1). |
| 2 | 120 hours | 37 | 25 | Stab wound. Penetrating injury to the neck with >20% blood loss. Comatose for >24 hours. |
| 3 | 1 day | 29 | 25 | Stab wound. Penetrating injury to the neck with >20% blood loss. Comatose for >24 hours. |

4.7 PREHOSPITAL TIME

Total prehospital time was approximated by summing response times, scene times and transport times. The time between injury and the notification of Urgences Santé was not included. All patients for whom complete data existed experienced prehospital times of less than 60 minutes. Data on prehospital times was only available for injuries handled by Urgences Santé and therefore patients injured on the South Shore and in Quebec City were not included in this portion of the analysis.

Table 4.9.1 indicates that scene times were significantly longer in the ALS group.

BLS patients were treated and loaded 3.3 minutes faster than ALS patients. There were no differences between the groups with respect to travel time, where both ALS and BLS patients required on average between 6 and 7 minutes to reach the ER (Table 4.9.1).

Total prehospital times were significantly long for ALS patients who spent a mean of 4.3 more minutes in the prehospital setting than BLS patients (Table 4.9.1).

Table 4.9.1 Prehospital Time Comparisons Intent to Treat Analysis

| | Group | N | Mean | Median | SD | SE | Significance* |
|-------------------|-------|-----|-------|--------|------|------|---------------|
| Total Prehospital | BLS | 131 | 26.62 | 26 | 8.25 | 0.72 | 0.007 |
| Time(minutes) | ALS | 59 | 30.29 | 30 | 9.50 | 1.24 | |
| Travel Time | BLS | 154 | 6.51 | 6.0 | 4.01 | .32 | 0.557 |
| (minutes) | ALS | 67 | 6.87 | 6.0 | 4.29 | .52 | |
| Scene Time | BLS | 157 | 12.33 | 12.0 | 5.51 | 0.44 | <0.001 |
| (minutes) | ALS | 70 | 15.67 | 14.5 | 7.34 | 0.88 | |

^{*}evaluated using Student's T-test

The above calculations were repeated with the efficacy classifications of ALS and BLS groups. The same differences were noted, namely that scene times and total prehospital times were larger in the ALS groups and travel times were approximately the same (Table 4.9.2).

Table 4.9.2 Prehospital Time Comparisons - Efficacy Analysis

| | Group | N | Mean | Median | SD | SE | Significance* |
|-------------------|-------|-----|-------|--------|------|-------|---------------|
| Total Prehospital | BLS | 165 | 27.21 | 26 | 8.63 | .67 | 0.029 |
| Time (minutes) | ALS | 25 | 31.32 | 31 | 9.22 | 1.845 | |
| Travel Time | BLS | 193 | 6.68 | 6 | 4.18 | .30 | 0.576 |
| (minutes) | ALS | 28 | 6.21 | 6 | 3.45 | .65 | |
| Scene Time | BLS | 196 | 12.87 | 12 | 5.86 | .42 | 0.003 |
| (minutes) | ALS | 31 | 16.48 | 15 | 8.03 | 1.44 | |

^{*}evaluated using Student's T-test

Prehospital times were also compared between MD-BLS patients and MD-ALS patients. Again, prehospital and scene times were longer in the ALS group, although the results were not statistically significant (Table 4.9.3).

Table 4.9.3 Prehospital Time Comparisons
ALS Patients

| | Group | N | Mean | Median | SD | SE | Sig.* |
|-------------------|--------|----|-------|--------|------|------|-------|
| Total Prehospital | MD-ALS | 25 | 31.32 | 29.5 | 9.22 | 1.85 | 0.479 |
| Time (minutes) | MD-BLS | 34 | 29.53 | 31 | 9.77 | 1.68 | |
| Travel Time | MD-ALS | 28 | 6.21 | 7 | 3.45 | .65 | 0.296 |
| (minutes) | MD-BLS | 39 | 7.33 | 6 | 4.79 | .77 | |
| Scene Time | MD-ALS | 31 | 16.48 | 14 | 8.03 | 1.44 | 0.413 |
| (minutes) | MD-BLS | 39 | 15.03 | 15 | 6.77 | 1.08 | |

^{*}evaluated using Student's T-test

Table 4.9.4 lists mean and median prehospital times among MD-BLS patients and standard BLS patients. MD-BLS patients spent significantly more time on the scene even though no ALS procedures were performed.

Table 4.9.4 Prehospital Time Comparisons MD-BLS versus EMT-BLS

| | Group | N | Mean | Median | SD | SE | Sig.* |
|-------------------|--------|-----|-------|--------|------|------|-------|
| Total Prehospital | MD-BLS | 34 | 29.53 | 29.5 | 9.77 | 1.68 | 0.08 |
| Time (minutes) | BLS | 131 | 26.62 | 26 | 8.25 | 0.72 | |
| Travel Time | MD-BLS | 39 | 7.33 | 7 | 4.79 | 0.77 | 0.275 |
| (minutes) | BLS | 154 | 6.51 | 6 | 4.01 | 0.32 | |
| Scene Time | MD-BLS | 39 | 15.03 | 14 | 6.77 | 1.09 | 0.01 |
| (minutes) | BLS | 157 | 12.33 | 14 | 5.51 | 0.44 | |

^{*}evaluated using Student's T-test

4.8 MULTIVARIATE REGRESSION ANALYSIS

4.8.1 Factors Influencing Length of Hospital Stay

Linear regression was used to determine which factors had an influence on the duration of hospitalization among surviving patients. Continuous variables entered into the initial model included age and ISS. Dummy variables were created for the remaining variables which included ALS versus BLS prehospital treatment, year of injury, mechanism of injury, and whether the injury was intentionally inflicted. Two interaction terms were also created: age * ISS and age* firearm injury. Variables were dropped from the model if their regression coefficient did not approach statistical significance (p>0.5). Table 4.10.1 indicates that the type of prehospital treatment was not a significant predictor of length of

stay (p=0.725). The interaction term age * ISS was eliminated because of strong collinearity with the independent variables age and ISS. In addition, the model which included age and ISS separately was associated with a higher R² value.

A second model was tested which excluded ALS or BLS prehospital treatment to determine the true coefficients of the variables (Table 4.10.1). The change in R² value, which is an indicator of the predictive power of the overall model, was negligible between the two models (0.231 in the model without ALS/BLS versus 0.232 which included prehospital treatment type) which confirmed that ALS/BLS is not a meaningful predictor of length of hospital stay.

Table 4.10.1 Length of Hospital Stay (hours) Linear Regression Final Model Model R²=0.231

| Variable | Unstandardized Coefficients | | Standardized Coefficients | Significance | 95% Confidence Interval for B | | |
|-------------|--------------------------------|---------|------------------------------|--------------|----------------------------------|----------------|--|
| | В | SE | Beta | | Lower Bound | Upper Bound | |
| Constant | -290.307 | 89.207 | | .001 | -465.735 | -114.878 | |
| ALS or BLS* | 24.995 | 71.045 | .017 | .725 | -114.718 | 164.709 | |
| Age | 5.335 | 2.212 | .123 | .016 | .984 | 9.685 | |
| ISS | 27.449 | 3.641 | .355 | .000 | 20.290 | 34.608 | |
| 1993 | 199.764 | 121.127 | .078 | .100 | -38.438 | 437.966 | |
| 1994 | 138.337 | 78.434 | .083 | .079 | -15.906 | 292.580 | |
| firearm*age | 4.904 | 1.826 | .131 | .008 | 1.312 | 8.495 | |
| blunt | 794.031 | 302.964 | .125 | .009 | 198.241 | 1389.821 | |
| Intentional | 236.615 | 75.073 | .157 | .002 | 88.981 | 384.249 | |

^{*}represents model when ALS/BLS is forced into the model - subsequent variable statistics refer to model without ALS/BLS

Based on the regression model presented in Table 4.10.1, older patients tended to stay in hospital (coefficient=5.335), as did those injured in 1993 (coefficient = 199.8) and 1994 (coefficient = 138.3). The mechanism of injury was also a predictor of longer hospital stays in victims of penetrating trauma inflicted with a blunt object. Intentionally injured victims also spent longer in hospital. The interaction term firearm * age was another predictor of length of stay.

4.8.2 Mortality - Multivariate Logistic Regression Analysis

Logistic regression with mortality as the dependent variable (death=1, survival=0) was carried out to determine whether or not prehospital treatment had an effect on outcome. The first model used the Intent to Treat ALS/BLS variable while the second regression used the Efficacy Analysis ALS/BLS variable. The results of the final model are presented in Table 4.10.2. The following variables were tested initially: ALS/BLS, hospital, sex, age, ISS, mechanism of injury, number of body regions injured, intention of injury and the interaction terms age*firearm injury and age*ISS, and year of injury. The next model tested was run without the number of injuries (p=0.472), ALS/BLS (p=0.955), age*firearm (p=0.894), age*ISS (p=0.783), and year of injury (p=0.330) all of which were not close to being statistically significant predictors of mortality. The city of injury was also removed due to strong collinearity with the hospital variable.

The type of prehospital treatment was not a significant predictor when forced into the model using either the Intent to Treat variable (OR = 0.98, 95% CI of the OR: 0.39, 2.48) or the Efficacy Analysis variable (OR=1.01, 95% CI of the OR: 0.33, 3.07). A second model was run which excluded ALS/BLS to quantify the relationship between the

remaining variables. A number of variables were significant predictors of death. Treatment in Hospital 2 was negatively associated with dying (OR=0.19) as was the number of body regions injured, while age (OR=1.03), ISS (OR=1.13) and intentionally inflicted injuries (OR=1.75) were all associated with an increased risk of death.

Table 4.10.2 Mortality Logistic Regression

| Variable | Estimate | SE | Odds Ratio (95% CI) | Sig. |
|--------------------------------------|----------|------|---------------------|---------|
| ALS/BLS ¹ Intent to Treat | -0.02 | 0.47 | 0.98(0.39, 2.48) | 0.970 |
| ALS/BLS ² Efficacy | .013 | 0.57 | 1.01 (0.33, 3.07) | 0.982 |
| Hospital | | | - | 0.030 |
| Hospital 1 | -0.82 | 0.58 | 0.44 (0.14, 1.37) | 0.156 |
| Hospital 2 | -1.65 | 0.57 | 0.19 (0.06, 0.59) | 0.004 |
| Hospital 3 | -0.82 | 0.62 | 0.44 (0.13, 1.49) | 0.188 |
| Age | 0.03 | 0.01 | 1.03 (1.01, 1.06) | 0.006 |
| ISS | 0.12 | 0.02 | 1.13 (1.09, 1.17) | <0.0001 |
| Stab Wound | -1.13 | 0.39 | 0.32 (0.15, 0.69) | 0.003 |
| # of body regions injured | -0.46 | 0.21 | 0.63 (0.42, 0.95) | 0.028 |
| Intentional Injury | 0.56 | 0.37 | 1.75 (0.85, 3.59) | 0.129 |
| Constant | -4.72 | 1.07 | - | <0.001 |

¹represents statistics if ALS/BLS (intent to treat classification) is forced into the model, subsequent variable statistics refer to model without ALS/BLS

²represents statistics if ALS/BLS (efficacy classification) is forced into the model, subsequent variable statistics refer to model without ALS/BLS

Chapter V - DISCUSSION

5.1 INTRODUCTION

This study was devised to determine whether or not physician administered advanced life support (MD-ALS) has an influence on the outcome of urban penetrating trauma victims. The unique manner in which prehospital life support is administered in Montreal permitted the current study, which was purely observational in nature to assess two comparable groups of patients delineated only by the type of prehospital treatment they received. A summary of results which follows, will attest to the success of this design in striking an excellent balance of exposure factors between the two treatment groups.

5.2 SUMMARY OF STUDY FINDINGS

Patients were separated into BLS and ALS groups based on the type of prehospital care they received. Two approaches were used, the first followed the Intent to Treat philosophy which measures the effect of an intervention as it functions in real life situations. Any patient for whom an MD was present on the scene was considered in the ALS group even if no ALS procedures were performed. An efficacy analysis was also performed where only those who actually received an advanced life support intervention, namely IV fluids and medications and/or endotracheal intubation, were classified as ALS.

5.2.1 EXPOSURE FACTORS

The final sample included 106 patients treated by MD-ALS and 325 BLS patients for a total sample size of 431. Treatment groups were virtually identical in terms of their mean age and ISS scores. In terms of categorical variables, the groups were very similar

in terms of reasons for inclusion, sex and the place of event. Differences that approached statistical significance were noted in the distribution of intentional injuries and firearm injuries. Since firearm injuries are rarely unintentional however, it is likely that these two variable were actually measuring the same thing. BLS patients were subject to 8% more intentional injuries and 9% more firearm injuries. No differences were noted in the locations of events.

The distribution of injuries by year were statistically different between ALS and BLS patients. In 1993 and 1997 the difference was most striking. There were more ALS units in operation during the earlier years of the study, which may account for the near equality of patients in 1993, but does not adequately explain the 1997 ratio of 1.5 (BLS/ALS). Differences in the data entry status of the hospitals may offer other reason for the anomalous patient ratios of 1993 and 1997. L'Hopital Sacré Coeur, which contributed ALS treated injuries, did not start documenting large amounts of patients until 1994. Similarly, the Montreal General, which also contributed ALS cases, had a six month data entry backlog at the end of the study and therefore only contributed a half year of data for 1997.

5.2.2 OUTCOMES

The raw overall mortality between the groups did not differ, nor did mortality before seven days. Mortality, when assessed from an efficacy point of view, was also similar between groups. Standardised Mortality Ratios (SMR), calculated using the number of expected deaths based on the 1988 Major Trauma Outcome Study, were not significantly different between groups. SMRs did not differ when calculated using both the

Intent to Treat analysis and Efficacy analysis. Two different ISS values were used in calculating the expected number of deaths. Again, no differences in survival between ALS patients and BLS patients were noted.

Advanced Life Support and BLS mortality in three of four ISS strata were commensurate. In the ISS=75 category, all three BLS patients died while the only ALS case survived. In light of this, an age distribution was generated in order to identify a potential confounder. The mean age among BLS patients in the this strata was 49 years while the ALS patient was 26. The MTOS also observed differences between young and old in the ISS = 75 group where 10.5% of those below the age of 50 died from penetrating injuries while 100% of those in the older than 50 died (Copes et al., 1988).

Age adjusted mortality rates were the same in three of four age strata. In the 40-64 age strata, BLS mortality was greater than ALS mortality, a result which neared statistical significance. However, BLS patients in this group experienced considerably more firearm injuries than ALS patients. Mortality due to firearm injuries in the overall sample (27%) was significantly higher in comparison to other injuries. Other studies have also noted high mortality rates associated with firearm injuries (Copes et al., 1988).

The incidence of ICU admissions was similar in the groups. The time to death was indistinguishable between non-surviving ALS and BLS patients when tested by both parametric and non-parametric statistical tests as well as a Kaplan-Meier survival analysis. Length of hospital stays and ICU admissions were similarly investigated, no differences existed.

Among the 78 ALS patients discharged home, 28% required home-care services in comparison to only 16% of BLS patients. This statistically significant finding indicates that prehospital ALS was associated with functional impairments among those discharged home. The longer prehospital times experienced by ALS patients may have been a contributed to this negative result. This variable was not the focus of this investigation however, and therefore further study is required to explain the observed discrepancy between the groups.

Two tests were performed to determine whether the use of IVs prior to arrival at the hospital were beneficial. The first, which compared 'IV' to 'no-IV' among ALS patients only, found no difference in mortality. A second analysis compared IVs to no-IVs in the entire sample and also noted no differences between groups. Since this investigation was carried out in an urban environment where transport times to the nearest trauma facilities are short, little time elapsed en route to the hospital during which fluids from prehospital IVs could replenish patients. In fact, transport times averaged only 7 minutes and therefore it seems doubtful that significant amounts of fluid were infused, although this information was not documented. In light of recent research that has cast the benefits of pre-surgical IV fluids in doubt, coupled with the fact that little fluid was infused into these patients, the absence of significant differences in outcome does not come as a great surprise.

Patients intubated before arrival at the hospital (n=3) were at a significantly increased risk of death. However, this analysis is over-simplified. The attempt to intubate these victims is indicative of the grave severity of their condition. It is therefore premature

to hold the intubation responsible for their high mortality rate. What is evident however, is that intubation did not save these patients. Therefore, there appear to be no benefits associated with this procedure in victims of penetrating trauma.

Total prehospital time was significantly longer in ALS patients classified using both the Intent to Treat Analysis and the Efficacy Analysis. This result stems from the time required to establish IVs in the ALS patients. MD treated patients who received no ALS spent less time on the scene when compared to MD treated patients who underwent ALS procedures, although in this small sub-sample, the difference did not attain statistical significance. Finally, MD-BLS patients were treated for significantly more time on the scene when compared to standard BLS patients. It is unclear why in cases where no ALS procedures were performed, physicians would still cause delays at the scene. One possibility is that EMTs are faster since they are trained to work quickly in the prehospital environment whereas in comparison, MD training does not emphasise speed.

Logistic regression revealed that higher numbers of injured body regions were negatively associated with death. For a given ISS score, a trauma which affects only one body region may in fact be more severe than an injury that affects a number of body areas. In other words, a number of minor injuries spread over the body may score as highly as one serious injury. This mathematical artifact of the way ISS's are calculated may help explain why patients with more injuries were less likely to die.

Prehospital treatment type was not a significant predictor of length of hospital stay according to multivariate linear regression, nor was it relevant in predicting mortality using multivariate logistic regression according to the Intent to Treat approach or the Efficacy

analysis approach. These findings serve to confirm the earlier results on mortality which found no differences between groups. However, the regression results are particularly relevant since they controlled for the mechanism and severity of injury, age and other covariates.

5.3 LIMITATIONS OF THE STUDY

The calculation of expected mortality in this study relied on data from the 1988

Major Trauma Outcome Study (Copes et al., 1988). The MTOS gathered data on 47,000 trauma victims from 111 hospitals in the United States and Canada between 1982 and 1986. Based on the results of this database, the expected number of deaths in a sample can be calculated by summing up the individual probabilities of death for a particular ISS depending on the patient's age and the presence of either blunt or penetrating trauma.

Although the overall sample size of the MTOS was very large, one difficulty with using it to calculate expected mortality stems from the fact that for many individual ISS categories, the mortality predictions were made based on very limited sample sizes. For 29 ISS categories, the expected number of deaths was calculated from less than 5 cases. For some ISS scores no value exists at all, which required proxy rates of death from different age groups to be used to approximate the actual ISS being studied. It was for this reason that SMR calculations using grouped ISSs, a suggestion made by the MTOS authors (Copes et al., 1988), were also used to predict mortality.

Other, more comprehensive attempts, have been made to quantify the risk of death from a traumatic event. The TRISS method was described in 1987 by Boyd et al. and incorporates the Trauma Score as well as age and ISS to determine the probability of

death. The Revised Trauma Score is calculated using the Glasgow Coma Score, respiratory rate and blood pressure. Because such data existed for an insufficient number of patients in the current study, only 12%, the TRISS method could not be used.

Pneumatic AntiShock Garments are another component of the ALS armament.

Early reports that suggested benefits associated with pneumatic counterpressure were based largely on small case reports. Later, large randomised trials conducted by Bickell et al. (1985; 1987), Mattox et al. (1986; 1989) and Chang et al. (1995) demonstrated either no difference or significantly lower survival in patients receiving the MAST. Based on these studies, Urgences Santé came to realise, quite correctly, that the PASG offers no benefits to victims of urban trauma. It therefore stopped equipping its fleet of vehicles with the PASG in 1993 and thus it was not studied this investigation.

The argument could be made that the ALS group would have benefited had

Urgences Santé not discontinued use of the PASG. This effect would theoretically bias the
results towards the null hypothesis that there are no differences between the ALS and BLS
groups. This seems highly unlikely based on the research detailed above. In fact, this
research would indicate that the ALS group studied in this investigation should exhibit
higher survival than other ALS groups that are still utilising the PASG.

The current study found no statistical differences in terms of raw mortality between ALS and BLS treated patients. However, the sample size of the ALS group created wide confidence limits on the rate of mortality, specifically the odds ratio lower limit of 0.375 in favour of ALS. The argument could be made that had the sample size been larger, the possibility of a slight superiority in favour of ALS would have been in evidence.

If true, it seems likely that it would be a very slim difference indeed, having escaped detection in a five year study that examined all penetrating injuries treated at the province's level one trauma centres. Furthermore, the likelihood of such an advantage of ALS was not supported by the data when examined using more comprehensive multivariate logistic regression analysis.

An additional element that may have affected the data relates to changes in the Quebec trauma care system over the period covered by the study. In an effort to curtail costs the provincial Ministry of Health closed several emergency departments over the course of the study. As a result, transport times increased slightly due to the longer distances ambulances were required to travel. This essentially means that during the latter years of the study, patients were brought in from ever increasing distances. In Montreal and Laval, Urgences Santé effectively responded to the closings by improving response times and even though transport times increased, over-all prehospital time actually decreased slightly. In addition, since both groups would have been equally affected by any change in prehospital time, no bias would have resulted.

5.4 STRENGTHS OF THE STUDY

5.4.1 Design

One strength of this study derives from its inclusion of a wide variety of patients.

All victims of penetrating trauma were included. No age restrictions were imposed, and all mechanisms and types of injury were included. This broad population sample allows for wider generalisations to be made based on the conclusions of the investigation.

Other comparisons involving ALS and BLS have been hampered by discrepancies between patient groups. Basic Life Support patients are often less severely injured than their ALS counterparts due to dispatching protocols in two tiered EMT environments which are geared to send more seriously injured patients ALS care.

This study was not directly randomised by study investigators. However, due to the present arrangement that exists at Urgences Santé, patients in Montreal that require ALS are randomly allocated either BLS or MD-ALS. The success of this 'in vivo' randomisation was supported by the virtually identical distribution of ages and ISS scores in the two groups.

A careful look at the dispatching procedure reveals that at no point is information gained by the call operators passed on to the dispatchers who ultimately decide which units are sent to the scene. The only data that the dispatchers receive from the call operator is the address of the victim and a code which signifies the type of unit that is required based on the Clawson Protocol. They receive no information on the nature, mechanism or severity of the injury and therefore are not able to introduce bias into the study by dispatching a certain type of unit to either more or less seriously injured patients.

Since not enough MD-ALS units exist to respond to all of the cases for which they are required, dispatchers routinely downgrade calls to receive only BLS. It is impossible to know how often this occurs since Urgences Santé, fearing negative publicity, no longer releases details on the number calls that get downgraded by its dispatchers. However, an earlier study conducted in 1987 estimated that 25% of calls were downgraded to BLS

(Sampalis et al., 1992). This number is certainly much higher now since Urgences Santé has reduced the number of physicians on duty since then.

5.4.2 Statistical analysis

The comparisons between groups with respect to mortality in this study were comprehensive. The treatment groups were analysed according to the Intent to Treat and Efficacy approaches. Two different methods of calculating the SMR (ISS and grouped ISS) of patient groups were utilised. Kaplan-Meier survival analysis was performed to detect differences in the time to death between groups in addition to a Student's t-test and a non-parametric Mann Whitney U-test. Finally, logistic regression was employed to assess the contribution of prehospital treatment type while controlling for potential confounders.

5.5 COMPARISON TO OTHER STUDIES

The overall SMR calculation in the current study found 1.72 more deaths than expected, a result which was significantly higher than unity. One possible explanation for this higher than expected result may lie in the age of the sample. The mean age of the MTOS sample of penetrating injuries, from which expected deaths were calculated, was 30.6 years in comparison to 36.3 years in this study. Although age is a factor in the calculation of expected deaths, it is only dichotomised at 50 years and therefore the MTOS could have enjoyed an age advantage over the current study.

Other studies carried out in Quebec have also found higher than expected mortality due to trauma and no benefits of MD-ALS. In 1992, Sampalis et al. used the 1988 MTOS data and encountered significantly higher than expected mortality in a sample of 355

patients (SMR=1.81). In addition, MD-ALS was not a significant predictor of reduced mortality (Sampalis et al., 1992).

In 1997, Sampalis released another study on prehospital trauma care in Quebec which examined the benefits of prehospital IV fluid administration by Urgences Santé MD's (Sampalis et al., 1997). After controlling for age, ISS, gender, mechanism of injury and prehospital time, logistic regression found a significant association between IVs and death in 217 patients (Sampalis et al., 1997). This negative association was not seen in the current study, although this may have been the result of a comparatively small sample size of IV-treated patients (n=58).

A study by Gervin et al. (1982) on patients with penetrating heart wounds, Pons et al. (1985) on victims of penetrating wounds to the thorax and abdomen, Ivatury et al. (1987) on penetrating thoracic injuries, Honigman et al. (1990) on penetrating cardiac wounds, Bickell et al. (1994) on penetrating torso injuries, and Lerer et al. (1994) on penetrating chest trauma have all examined the prehospital treatment of urban penetrating injuries.

Gervin observed 100% mortality in patients for whom prolonged attempts at resuscitation and stabilisation were attempted on the scene (Gervin et al., 1982). Ivatury encountered significantly lower mortality and a higher prevalence of vital signs at arrival at the ER among patients who were immediately transported to hospital versus those who received attempts at stabilisation in the field (Ivatury et al., 1987). Bickell, in a rare randomised trial of prehospital EMS services, found significantly lower mortality in

patients who had fluid resuscitation delayed until they reached the operating room (Bickell et al., 1994).

Two studies have published favourable results of ALS. Pons and Honigman, both working in the ALS exclusive EMS system in Denver Colorado, recommended ALS as the best approach for the treatment of penetrating trauma. Pons concluded that ALS interventions were successful in reducing mortality (Pons et al., 1985; Honigman et al. 1990). Honigman carried out a study in the same EMS system and determined that there were no associations between scene time and either the total number of ALS procedures performed, PASG application or endotracheal intubation. The conclusions of both studies are severely limited by the fact that no BLS group was available for comparison. It is therefore impossible to conclude that ALS is a superior ideology based solely on their methodology.

5.6 AREAS FOR FURTHER RESEARCH

The question regarding the effectiveness of the PASG seems satisfactorily answered as four large randomised trials have found either no benefit, or reduced survival in PASG treated patients. One large randomised study on IV fluids concluded that they were detrimental to victims of penetrating torso injuries. Similar experiments in other centres are necessary to prove that this effect is reproducible. Subsequent trials may then be performed to determine if IV therapy is also detrimental in the treatment of other types of trauma.

In the past, the majority of scientists, and by virtue the public, have come to associate paramedics and ALS services as essential in the prehospital treatment of trauma.

In fact, the Emergency Medical Services Act in 1973 legislated many ALS services. In light of this, withholding these services was not only illegal, but would have been deemed unethical, and therefore randomised trials were impossible. The truth is, however, that the evidence which convinced many researchers that ALS was imminently superior was flawed and largely anecdotal. Only recently have we began to truly question the effectiveness of these interventions and with startling results. Large scale randomised trials that directly compare equivalent patients are not only justified, but overdue.

5.7 GENERALISABILITY OF RESULTS

Fundamental differences exist between urban trauma, where transport times to hospital are generally less than 20 minutes and rural trauma where the nearest emergency department may be well over an hour away. Attempts to stabilise the patient may be more justified in the rural environment since definitive care may not be possible for a considerable length of time. This distinction has a fundamental influence on the approach to prehospital care and therefore the results of this study and other studies that examine trauma in an urban context cannot be extended to the treatment of injuries incurred in rural areas.

Although the goal of the investigation was to study ALS in the treatment of penetrating trauma, the distinction has been made that the ALS provided was by MDs and not paramedics. Some may argue that physicians provide better care to seriously ill patients due to the many extra years of training they endure and hence their greater knowledge of human anatomy and physiology. Conversely, paramedics might offer superior care over MDs because they are trained specifically to operate in the demanding

prehospital environment. In the final analysis however, an IV is an IV regardless of who establishes it. There is no convincing rationale to support the idea that the action of a physician's IV would differ from that of a paramedic's IV. Similarly, there is no reason to believe that an endotracheal intubations performed by a paramedics differ from those of MDs. Hence, the fact that ALS was performed by physicians does not limit these findings exclusively to other EMS systems which also employ MD-ALS.

5.8 CONCLUSIONS

In the context of penetrating trauma experienced in an urban environment, the conclusions drawn from this study are the following:

- Advanced Life Support had no effect on mortality, the incidence of ICU admissions and length of hospital stay.
- Patients discharged home and treated by MD-ALS required home-care services more often than BLS patients.
- 3. MD-ALS treated patients spent significantly more time at the scene of injury.
- 4. Analysed individually, ALS interventions did not improve patient outcomes.
 The need to intubate penetrating trauma victims was extremely uncommon and in the rare cases where an MD felt that prehospital intubation was justified, the procedure was ineffective. IVs administered before arrival at the hospital also had no effect on mortality.

The results of this study clearly indicate that physician administered advanced life support does not reduce mortality or morbidity in victims of penetrating trauma. Previous studies examining the Urgences Santé EMS system have proven MD-ALS ineffective in

reducing the mortality among victims of trauma in general. The decision must now be made whether or not these MD-ALS units should be used in the treatment of trauma victims at all.

5.9 RECOMMENDATIONS

Based on these findings, and the fact that ALS is known to be an invaluable tool in the treatment of other prehospital emergencies, notable cardiac distress and anaphylactic shock, Urgences Santé should consider removing MD-ALS services from its dispatching protocol for penetrating injuries. By reserving the limited pool of MDs for non-penetrating emergencies, more MD-ALS units will be available for calls where their presence is absolutely necessary and known to be beneficial.

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Appendix A

Proposed ISS Value Intervals

| ISS Interval | ISS Range | Rationale: Most Severe Injury /Combination Included |
|-----------------|-----------|---|
| 1 | 1-8 | AIS 2 |
| 2 | 9-15 | AIS 3 |
| 3 | 16-24 | AIS 4 |
| 4 | 25-40 | AIS 5 but not AIS 5 and AIS 4 |
| 5 | 41-49 | AIS 4 and AIS 5 |
| 6 | 50-66 | Two AIS 5's and one AIS 4 |
| 7 | 75 | AIS 6's and 3 AIS 5's |

from reference [102] page 76, Table X

Copes WS, Champion HR, Sacco WJ, Lawnick MM, Keast SL, Bain LW. The Injury Severity Score Revisited. *Journal of Trauma*. 28(3):69-77, 1988.

Calculations

1. STANDARDISED MORTALITY RATIO

Calculation of Standard Mortality Ratio (SMR) as described by Breslow and Day [107]

SMR =
$$\sum deaths / \sum_{i=1}^{n} P_d$$

=observed deaths / expected deaths

where P_{d} is the probability of death for a patient

Appendix B

Histograms of Length of Hospital and ICU stays

Figure B.1 - Length of ICU Stay

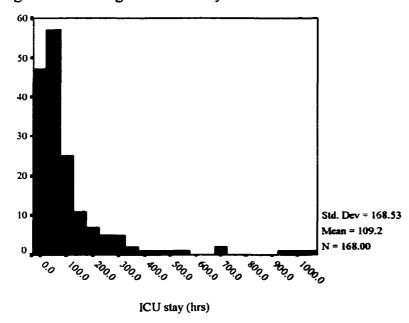
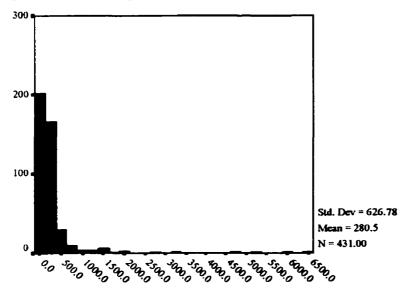


Figure B.2 Length of Hospital Stay



Length of hospital stay(hours)