# TRANSPORTATION TIME IN A RURAL STATE FOLLOWING SPLENIC INJURY: DOES TIME MATTER

BY

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## Abstract

**Background:**

Failure rates remain high following attempted non-operative treatment of spleen injuries despite progress made in identifying risk factors. Over the past thirty years, transportation times were excluded from predictive models although rapid transportation was advocated to improve patient outcomes. For patients living in a rural environment, this time may prove critical. The purpose of this study was to assess the effect of transport time on survival rates and hospital length of stay for patients selected to receive non-operative versus operative treatment.

**Methods:**

A 10-year retrospective review was conducted of patients ages 13 years and older who presented to an American College of Surgeons-verified Level 1 trauma center between January 1, 2003 to December 31, 2012. Non-operative management (NOM) was defined as observation with or without the adjunctive use of angiography (AE) or splenic artery embolization (SAE) performed less than 2 hours from admission. Failed non-operative management (FNOM) was defined as AE or SAE performed greater than two hours from admission, or a planned operation greater than two hours from admission (POR) for any reason. Cox proportional hazard regression and logistic regression analysis were conducted to identify factors associated with hospital length of stay (H-LOS) and mortality. Covariates included: age, gender, injury severity score (ISS), injury type (blunt versus penetrating), treatment group (POR, NOM, or FNOM), time from admission to procedure, and transportation time from the time EMS received the 911 phone call to emergency department admission.

**Results:**

Among the 364 patients included in the final analysis, 11.0% (n=40) died before hospital discharge. The median transport time was 64 minutes (average=92.6 ± 81 minutes, range=6 to 480 minutes). The majority (92.9%, n=338) of patients underwent NOM, with 7.1% (n=26) receiving POR. Among those 338 NOM patients, 92.3% (n=312) remained NOM after 2 hours, and others had FNOM after 2 hours (7.7%, n=26). Those who received POR or NOM were associated with 45.5% and 47.4% of the transportation time being less than 60 minutes, respectively. After two hours, average ISS score by treatment group (POR, NOM, or FNOM) of 23.83, 21.96, and 28.07, respectively. Cox proportional hazard regression analysis reported that ISS score was the only significant predictor for H-LOS. Logistic regression revealed that ISS score and age were associated with mortality. Transport time was not statistically associated with H-LOS or mortality.

**Conclusion:**

While not predictive of H-LOS or mortality, transportation time demonstrated that in rural environments longer transportation times allow physiologic symptoms to manifest prior to admission. Our results demonstrated that the majority (96%) of our FNOMs occurred less than six hours following admission and 100% less than 48 hours. We recommend intensive observation during hospital days one, with less robust surveillance through hospital day two. Discharge can be considered on hospital day three based on other injuries.

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## Introduction

*Background and Rationale*

Treatment of splenic trauma remains a crucial part of trauma care due to highly vascular nature of the organ as splenic hemorrhage can be unpredictable in onset, duration, and volume. The spleen is located under the left upper ribs where it holds approximately 10 to 15% of the body's blood at any given time and is tied to the abdominal aorta by way of the celiac trunk. Historically, the spleen was viewed as an expendable organ following injury but is now recognized as a vital part of the immune system.

Splenic injuries result from either blunt or penetrating trauma. The spleen is the intra-abdominal organ which is most frequently (60%) injured during blunt trauma.[1] In the United States (U.S.), approximately 60% of all reported abdominal injuries involve isolated splenic injuries.[2] In 2011, approximately 4,000 splenic injuries were reported to the National Trauma Databank.[3] Among those patients who sustain blunt or penetrating splenic injury, mortality rates are between 1 to 15% and 8 to 24%, respectively.[4,5] Most (71%) splenic injuries occur as a result of motor vehicle accidents followed by falls (18.4%), assaults (4.5%) and sporting injuries (2.6%).[6] Less than 10% are the result of penetrating trauma including gunshot wounds, injury from knives, and random occupational, recreational or home accidents.[6] Hospitalizations for splenic injury average approximately $14,000 per episode, dependent on the mechanism of injury, injury severity, treatment modality, and in-hospital complication rates.[6]

Risks following splenic injury include persistent or recurrent bleeding, which typically manifest within two days of injury but may be delayed up to 30 days. Patients with splenic injury often experience the development of hemoperitoneum, which is a pooling of blood in the abdominal cavity. Other risks include compensated or uncompensated shock in the presence of replacement fluids or blood products, the development of overwhelming post-splenectomy infection, and death from exsanguination. Patients at highest risk include those demonstrating hemodynamic instability, high injury grade and severity, older patients, large or expanding hemoperitoneum, evidence of active bleeding (extravasation or blush) on computed topography (CT) scan, associated injuries, medical history or concomitant medications which would compromise efforts to control bleeding, and patients who are evaluated in a facility with limited resources.

In a rural state, where those injured have further to travel to reach the highest level of trauma care, patients are at risk for increased mortality.[7] Risk factors associated with rural residency include: motor vehicle accidents with and without alcohol;[8] increased prevalence of residential firearms,[9] agricultural machinery accidents,[10] and longer pre-discover periods are major contributors to prolonged transportation times.[8, 11]

The definition of 'rural' has proven hard to quantify. The 2010 U.S. Census Bureau used an urban-rural classification which was based on geographical areas.[12] Urban clusters were classified as those areas with greater than 50,000 residents. Rural areas were classified as anyplace not labeled urban, or any place outside a town, city or urban cluster greater than 2,500 residents.[12] In the U.S., approximately 59.4 million people (19.3%) reside in a rural setting.[13] Older adults and children represent a larger percentage of the total rural population.[13] While less than 20% of the U.S. population is classified as rural, this population makes up more than 60% of trauma deaths.[13] In Kansas, rural areas are home to two-thirds of the state's population, (approximately 1.2 million people).[14]

Three types of medical facilities are typically found in rural states; trauma centers, regional hospitals and critical access hospitals. These hospitals all play a critical role in the stabilization of patients who sustain traumatic injury in a rural state, however any delay in treatment can manifest in an increased risk of death, complications, increased hospital costs, and hospital length of stay (H-LOS).[15] Trauma centers can be accredited by The American College of Surgeons Committee on Trauma (ACS-COT) or at the state level.[16] If accredited by the ACS-COT, hospitals are designated Level I to V. Level I and II trauma centers both provide the highest level of trauma care available, where Level I trauma centers also conduct research and outreach. However, Level I and II trauma centers across the U.S. are disproportionally distributed, approximately 31% (rural) and 12% (urban) of residents live greater than one hour from the highest level of trauma care.[17]

Previous research has demonstrated more limited access to advanced trauma care in rural environments.[18, 19] In 1995, Esposito et al. studied differences between transportation times among patients presenting to trauma centers in urban and rural environments.[20] Their study suggested discovery time and transportation time in rural locations was twice as long as that for urban environments for the same type of injury. Further, the authors reported that the number of emergency or trauma surgeons was six times greater in urban settings than in rural areas.[20] In 2011, Sasser et al. demonstrated trauma care provided at a Level 1 trauma center was associated with a 25% decrease in overall mortality compared to mortality following traumatic injury not treated at a trauma center.[21] In 2010, Gomez et al. reported increased risk of mortality for patients with traumatic injury who received initial care at a rural emergency department.[7] These deaths occurred prior to transportation of the patient to a facility equipped to provide a higher level of care. The authors concluded that the risk of 'preventable deaths' was twice as high in rural settings.[7]

Following a literature search of over 250 articles, overall trauma outcomes in a rural state were noted to be well studied, however splenic injury outcomes in a rural setting are largely understudied (Figure 1).

Figure 1: Summary of Literature Review for Splenic Trauma

| Number of Studies | Trauma Center Level | Trauma Population | Year Published |
|---|---|---|---|
| 1 | All levels | All populations | 2011 |
| 1 | Level I | Splenic traumas | 1997 |
| 1 | Level 3 | All traumas | 2007 |
| 1 | Level 3 | Splenic traumas | 2013 |
| 4 | Rural hospitals, Emergency Rooms | All traumas | 1995, 2004, 2006, 2013 |

Risk of poor patient outcomes following traumatic injury has been documented in other sources as well. In January 2014, The American College of Emergency Surgeons (ACEP) released the annual Emergency Medicine Report Card. In the report, Kansas was ranked 44$^{th}$ in the nation for Quality and Patient Safety Environment initiatives.[22] The leading contributor was identified as a lack of emergency medical services (EMS) guidelines and protocols which have been identified as a challenge for the rural areas of the state.

While attempts have been made in the U.S. to extend an urban-based trauma system into the rural environment, including predominately rural states like Kansas, it has been 17 years since the last peer-reviewed medical paper specific to splenic injury was published. It is possible current literature may not be generalizable to the one fifth of the U.S. population who account for 60% of the nation's traumatic deaths each year.

*Evaluation*

The goal of evaluation is to quickly identify patients who are actively hemorrhaging, or those patients at highest risk for delayed hemorrhage (Figure 2). Surgeons require updates on the patients' hemodynamic status throughout the evaluation process, and these are obtained through repeated blood pressure measurements. If the patient is hemodynamically stable and does not have other injuries which require immediate treatment, a splenic injury grade will be assessed by obtaining a CT scan. Injury details will be obtained if possible to assist the surgeon in making the correct choice of treatment modality.

Figure 2: Considerations Made by a Surgeon during a Splenic Injury Evaluation

| **Parameter** | **Test or Assessment** |
|---|---|
| Hemodynamic status | • Repeated blood pressures |
| Other injuries or spleen injury grade | • CT scan<br>• X-ray<br>• Palpitation of the abdomen<br>• F.A.S.T. exam |
| Blunt injury | • Force and direction<br>• Deceleration versus compression |
| Penetrating injury | • Type of weapon or instrument |

The CT scan has been validated as being both sensitive and specific for presence and location of bleeding, pseudoaneurysm, and occlusion (Figure 3).[23] Palpitation and Focused Assessment with Sonography for Trauma (FAST) exam are performed on all suspected splenic injured patients. The FAST exam has been validated as sensitive for the presence of blood in the abdomen, but not specific for the origin of bleeding.[24] If possible, the patient's medical history and concomitant medication use will be taken to assess for the presence of bleeding disorders and use of blood thinners. Diminished mental status will be evaluated for association with concomitant medications or the presence of shock. Laboratory tests will be obtained, however there are currently no tests which are sensitive or specific to splenic injury. In hospitals where an interventional radiology suite is available, angiography (AE) may be performed to pinpoint the location and size of any bleeding.

Figure 3: Evaluation Techniques Following Splenic Injury

| Test | Used to Detect |
|---|---|
| Focused Assessment with Sonography for Trauma (FAST) | ▪ Presence of blood using ultrasound<br>▪ Not sensitive for identification of injuries |
| Diagnostic Peritoneal Lavage (DPL) | ▪ Presence of blood using an abdominal catheter<br>▪ Not sensitive for identification of injuries |
| Computed Tomography (CT) | ▪ Sensitive and specific<br>▪ Presence of blush, pseudoaneurysm, occlusion<br>▪ Determination of injury grade<br>▪ Requires contrast |
| Interventional Radiology (angiography) | ▪ Pinpoints location and size of bleeds<br>▪ Can precede embolization |

Patients often present with left rib fractures (rib numbers 10 to 12). A triad of left hemidiaphragm elevation, left lower lobe collapse, and pleural effusion are also often seen. Hemodynamically unstable patients are those with systolic blood pressure (SBP) less than 90 mmHg and heart rate greater than 120 bpm. Patients are considered to be in a life-threatening situation if they demonstrate hemodynamic instability, are unresponsive to fluid challenge such as administration of normal saline or blood products, and have no other signs of external hemorrhage.

The purpose of diagnostics is to determine injury type, location, and severity. Injury grades are assigned by radiologists utilizing the 1995 American Association for the Surgery of Trauma (AAST) guideline grading scale (Figure 4).[25] Grade ranges fall into one of three categories: low (Grades I and II), mild (Grade III), and severe (Grades IV and VI).[25] In addition to injury grades, all traumatic injuries are assigned an anatomical injury severity score (ISS) which is an amalgamation of scores assessed for each individual body region.[26] Injury scores range from 0 to 75, with scores in excess of 15 denoting an injury with a higher potential for complications or mortality.

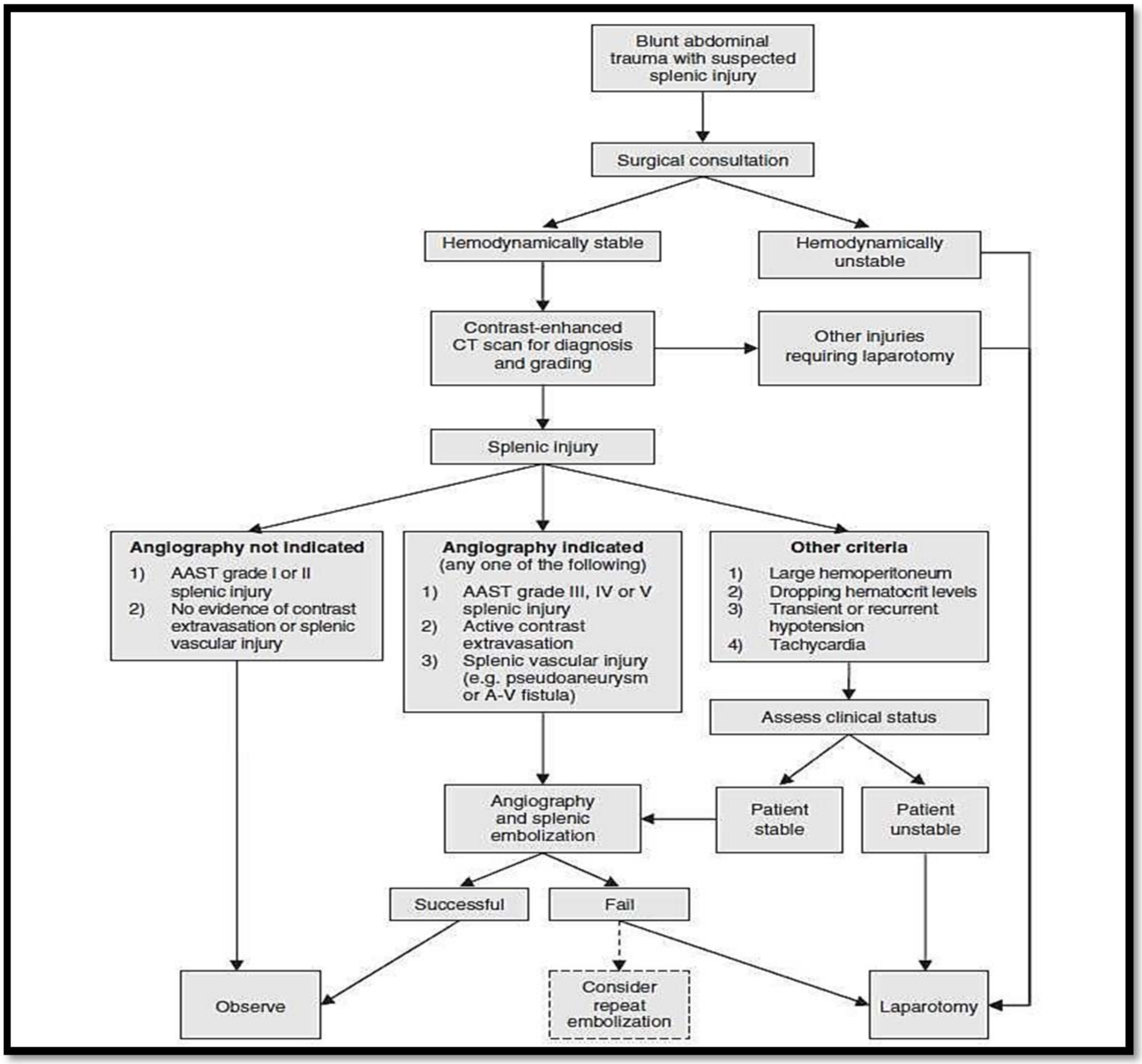
Figure 4: American Association for the Surgery of Trauma (AAST) Guidelines for Organ Injury Scaling for the Spleen

| AAST grade* | Type | Description of injury |
|---|---|---|
| I | Hematoma | Subcapsular, < 10% of surface area |
| | Laceration | Capsular tear, < 1 cm of parenchymal depth |
| II | Hematoma | Subcapsular, 10%–50% of surface area<br>Intraparenchymal hematoma, < 5 cm in diameter |
| | Laceration | 1–3 cm in parenchymal depth not involving a parenchymal vessel |
| III | Hematoma | Subcapsular, > 50% of surface area or expanding; ruptured subcapsular or parenchymal hematoma<br>Intraparenchymal hematoma, > 5 cm in diameter |
| | Laceration | > 3 cm parenchymal depth or involving trabecular vessels |
| IV | Laceration | Laceration of segmental or hilar vessels producing major devascularization (> 25% of spleen) |
| V | Laceration | Completely shattered spleen<br>Vascular hilar injury that devascularized the spleen |

*Advance 1 grade for multiple injuries to the same organ, up to grade III.

Careful selection of patients who will require splenectomy is important as asplenic patients risk the development of potentially lethal side-effects. The AAST treatment algorithm is used to guide surgeons in the selection of patients for operative or non-operative treatment following splenic injury (Figure 5).[25] Factors which affect a surgeon's decision for treatment type include an assessment of known risk factors and whether the patient is a good candidate for operative treatment.

Figure 5: American Association for the Surgery of Trauma Splenic Injury Treatment Algorithm




Patients with spleen injury can be treated with observation, surgery, or non-operative management. The ACS-COT provide guidelines for the timeline under which treatment decisions should be made following patient arrival at the hospital.[16] Recommendations are for a commitment to a planned operative therapy (POR) in 90 minutes or less, or to non-operative management (NOM) in two hours or less.[16]

An operative treatment option includes three general types of procedures; splenectomy, partial splenectomy, and splenorrhaphy which is a repair of the spleen. Non-operative treatment options include angiography without embolization (AE), splenic angioembolization (SAE) and observation.

*Cost of Treatment Choice*

Hospital charges for POR and SAE differ and as the focus of hospitals and insurers turn to controlling costs, may play a part in the surgeon's decision regarding treatment choice. In 2011, Haan et al. reported total procedure charges independent of need for POR following failure of non-operative management (FNOM) or as a result of emergent laparotomy were higher for POR than SAE ($28,709 vs $19,062; p=0.016).[27] However, total hospital costs and charges were found to be similar between the two modalities.[27] The authors reported no statistical difference between POR and FNOM groups associated with Intensive care unit length of stay (I-LOS), H-LOS, complications or re-admission.[27]

*Planned Operative Treatment*

Planned operative treatment is institutionally dependent and used in 18% to 40% of cases.[28] Eastern Association for the Surgery of Trauma (EAST) guidelines recommend POR for patients who are hemodynamically unstable, unresponsive to fluid challenge, demonstrate no signs for other external hemorrhage, or with higher acuity splenic injury grade (Grades IV and V).[29] Splenectomy was once considered the treatment of choice following splenic injury. The procedure was associated with high mortality rates through the 1950's when surgeons' focus shifted to splenic salvage. Careful selection of patients for operative treatment is critical due to potentially life-threatening side effects including overwhelming post-splenectomy infection (OPSI) and a lifetime of immunologic compromise.[30] Other side effects include a lifelong susceptibility to infection which may require prophylactic antibiotics prior to invasive procedures and travel to locations with a high risk for infection. Research continues into the immunologic side effects of both partial splenectomy and splenorrhaphy.

*Non-Operative Management*

Non-operative management includes less-invasive procedures (AE and SAE), as well as observation.[31-34] Splenic angioembolization is a radiologic procedure whereby blocking agents are placed in damaged splenic arteries to occlude them, thus improving splenic salvage rates.[35] These less-invasive arterial procedures are used to control less severe splenic hemorrhage among the hemodynamically stable population. A critical analysis of the literature demonstrates that observation and NOM procedures are associated with fewer in-hospital complications and are reported to significantly improve mortality, H-LOS, and discharge disposition.[35-37] In 2011, Chen et al. reported that the mean hospital length of stay (H-LOS) following SAE was 10.4 ± 5.6 days.[38]

Non-operative management is attempted in four out of five hemodynamically stable patients who sustain a blunt splenic injury, and is associated with a reported success rate of 95%.[29, 35, 36, 39-42] Success rates currently approach 95% in pediatric cases and 60-96% in adult cases following careful patient selection for NOM.[39-42] Non-operative management procedures are used to selectively manage 50 to 70% of lower grade splenic injury cases, although success in higher grade injuries have also been reported.[35] These procedures were previously recommended by the EAST for; Injury Grades III and higher, the presence of contrast blush on CT, moderate hemoperitoneum, or clinical evidence of ongoing splenic bleeding.[29,43-49] However, in 2012, updated EAST recommendations removed the following previously noted contraindications for attempted NOM procedures; injury severity (based on CT-evidenced grade or size of hemoperitoneum), visible contrast blush on CT scan, neurologic status, age 55 and greater, and polytrauma.[29, 50-57] Past and present guidelines recommend patients who demonstrate hemodynamically instability or intraperitoneal hemorrhage (as evidenced by a positive FAST examination, or with a positive DPL examination receive emergency laparotomy for a NOM procedure.[58,59] In 1997, Gavant et al. reported that injury grade was a predictor of FNOM, and it remains a leading indicator for NOM patient selection.[60] Complications during or following SAE include artery dissection, the development of abscess, cysts, left-sided pleural effusions, or fever, renal insufficiency due to the contrast material used to obtain a CT scan, or migration of the coil, if used.

Smith et al. reported an average time to angiography following hospital admission of 243 minutes (range 32 to 801 minutes).[61] These findings demonstrate the wide variability of time to procedure. Not all arteries are eligible for SAE, but when indicated, surgeons will use a agents that are either temporary (gelfoam) or permanent (metal coil).

Thirty years of research has identified clinical risk factors that guide surgeons in determining whether a patient meets criteria for NOM, but a consensus has not yet been reached on the predictive nature of all of these factors.[27,32,36,37,39,42,45,48,49,62] Those predictors considered thus far include hemodynamic status on admission, injury grade and severity, size of hemoperitoneum, presence of blush or pseudoaneurysm on CT, associated injuries, patient age, medical history, use of concomitant medications, presence and severity of other injuries and available resources (e.g. physician skill level, angiographic facilities).[2] Controversy related to the safety and efficacy of SAE may continue until predictive models are improved and are able to decrease the incidence of FNOM.

*Failure of Non-operative Management*

Non-operative management is not successful 100% of the time. When hemorrhage resumes or escalates it may be necessary to intervene with SAE or POR outside of the 90 to 120 minute mark recommended by the ACS. When this situation occurs it is referred to as a failure of non-operative management (FNOM). The surgeon's goal is the prevention of FNOM through selection of early surgical intervention for hemodynamically unstable patients or those with other contraindications for NOM.[63] Haan et al. reported the importance of attempting NOM among hemodynamically stable patients, without the presence of peritoneal signs, in environments capable of performing emergency laparotomy to ensure patient safety.[64]

Failure of non-operative management occurs in 8% to 38% of cases.[61,65] Literature demonstrates that 75% of FNOMs will occur within 48 hours of hospital admission, 88% within five days, and 93% within one week.[66] The success rate following adjunctive NOM or POR treatment is 60 to 96%.[66] While EAST recommendations for attempted NOM removed some contraindications and perhaps lead to the development of FNOM, often FNOM is the result of a latent manifestation of symptoms not immediately obvious to the attending surgeon, rather than inappropriate treatment choice.[29] Symptoms include; hemodynamic instability, ISS greater than 25, Injury Grades IV and V, age 40 or greater, generalized peritonitis, and other intra-abdominal injuries requiring surgical exploration. Evidence of active extravasation on CT scan places a patient at higher risk for FNOM.[2,64]

In a 2011, in a meta-analysis of four prospective and 21 retrospective studies comparing FNOM to successful NOM, Bhangu et al. reported that FNOM rates were associated with significantly higher mortality rates; unselected age groups (OR 1.93, CI 1.04-3.57), ages 55 years and less (OR 3.42, CI 1.73-6.77), and ages 55 years and greater (OR 2.65, CI 1.20-5.82).[67] Increased resource use, as well as longer I-LOS and H-LOS were also associated with FNOM.[67] In 2006, Watson et al. reported the average H-LOS following FNOM was 16.9 ± 0.7 days.[62] Mean I-LOS was reported as 10.1 ± 0.6 days.[62]

*Time as a Risk Factor for FNOM*

With the exception of mortality, the literature does not take into consideration the effect of transfer time to the hospital on clinical outcomes following splenic injury.[31,32,34,68] In 1995, Wyatt et al. assessed the time to death due to severe splenic injuries, inclusive of transportation time to the hospital, and reported that most deaths occurred from one to six hours following injury.[34] Like splenic injury in a rural setting, which is understudied, transportation time as a predictor of any outcome following splenic trauma has not been studied for 19 years. Delays in reaching treatment of severe splenic injuries have also been assessed in association with transportation time.[31, 32, 34, 68] In these studies, transportation time was defined as starting at the time of injury and was associated with an increase in mortality, frequently due to exsanguination.[31,32,34,68]

More typically, time of hospital admission has been used to assess risk of FNOM. Jeremitsky et al. evaluated the effect of elapsed time following admission to the hospital on NOM by assessing 15,732 patients ages 13 and older who sustained non-isolated blunt splenic injury.[69] The authors reported a five percent failure rate for NOM greater than five hours after admission, noting that injury grade was an important predictor for FNOM.[69] Failure to include transportation time in a risk assessment of these measures may underestimate the effect of transportation time to the hospital on patient outcome. Additionally, most studies have focused on patients treated at larger urban centers where time to definitive treatment is minimized compared to prolonged transportation times experienced by patients in rural environments. The duration of transportation time to the hospital may be clinically relevant to the outcome of treatment and the accurate prediction of those patients who will fail NOM

To date, no studies have compared hospital outcomes by treatment modality (POR, NOM, or FNOM) that take into account transfer time to the hospital. In addition, no studies have assessed transportation time as a risk factor for increased H-LOS or mortality in a rural state. Such a comparison would allow surgeons to predict with confidence those patients who can successfully be managed with NOM versus those who might benefit from operative intervention upon admission. Results may indicate that transportation time has predictive capacity to lower H-LOS, morbidity and incidence of FNOM.

The objective of this study was to evaluate the effect of transportation time on mortality and H-LOS among patients with splenic injury in a rural environment. Specifically, is there a predictive effect of transportation time on H-LOS and survivability among those patients selected to receive POR, NOM or FNOM following splenic injury in a rural state. In addition, what is the effect of transportation time on the incidence of, and outcomes following, FNOM among the splenic-injured population in a rural state.

# Methods

*Study Design*

This study was a retrospective chart review of patients presenting with traumatic splenic injury to Via Christi Hospital St. Francis, an American College of Surgeons accredited Level I trauma center. As the study was exploratory in nature, results were compared to previous research studies not inclusive of time to transportation which assessed predictors for mortality and morbidity. The study was reviewed and approved by the University of Kansas School of Medicine-Wichita's Human Subjects Committee and Via Christi Health Institutional Review Board.

*Setting*

The source of the study data were the electronic medical records of a single Level I trauma center's trauma registry and hospital records. Via Christi Hospital is located in an urban cluster (Wichita, Kansas) with a population in excess of 50,000, however has a catchment area that encompasses all but the far northeast corner of Kansas, as well as eastern Colorado and Northern Oklahoma participants. Only patients who sustained splenic injury which resulted in a trauma admission were included. The population under study included those patients ages 13 years and older who were treated between January 2003 and December 2012. Patient records were searched using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) for diagnostic codes 865 to 865.19. Operative procedures were identified by ICD-9-CM codes 38.86, 38.87, 41.43, 41.5 and 41.95 which include AE, SAE, splenectomy, partial splenectomy, or splenorrhaphy.

*Participants*

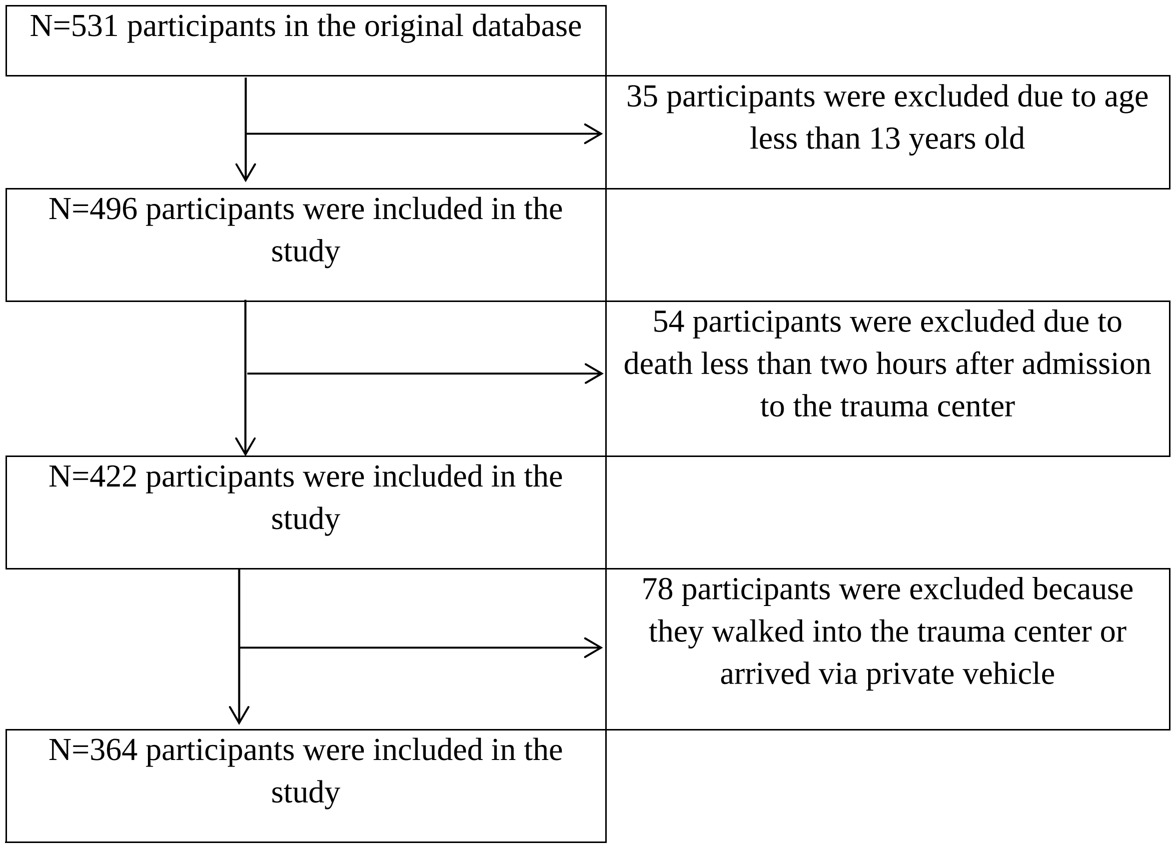
Patients were excluded who were identified as being ages 13 years and younger; having no signs of life in the field, on admission, or less than two hours after admission; or were not transported to the hospital via any form of EMS transportation mode and therefore had no transportation records (Figure 6). For those remaining patients who met inclusion criteria (Figure 1), 42.6% (N=364) had records with a documented time of 911 call and were used to assess the effect of transport time.

Figure 6: Inclusion and Exclusion Criteria

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| • ICD-9-CM-identified splenic injury, codes 865 to 865.19 | • Patients who arrived with no signs of life or died within two hours of arrival |
| • Ages 13 and older | • Patients who arrived via private vehicle or walked into the hospital |
| • Admitted to Via Christi Hospital St. Francis between January 2003 and December 2013 | |

Two populations were initially assessed; the aggregate population and the sample population later used in the model (Figure 7). The aggregate population (N=364) were those patients who med inclusion criteria. The model population (n=155) were those patients who had a valid transportation time documented in EMS records. Those patients (n=209) without valid transportation times were not included in the survival analysis.

Figure 7: Sample Size Flow Chart




*Dependent and Independent Variables*

The dependent variable in this study was hospital length of stay (H-LOS) censored for survival. Survival was defined as patients with splenic injury who survived hospitalization greater than two hours. Secondary outcomes included: Intensive care unit length of stay (I-LOS), number of days in receipt of ventilator support, and mortality. The following independent variables were obtained from the trauma registry: EMS mode, point of origin for EMS transportation (arrived from), transportation time, age, gender, injury type, injury grade, ISS, Glascow Coma Scale (GCS) score, SBP, treatment group, time to procedure, and discharge destination. Emergency medical service mode was categorized as fixed wing airplane, helicopter ambulance, or land ambulance. Location where transportation originated was classified as either home or scene, or hospital transfer. Transportation time was defined as the time between the receipt of the 911 telephone call and hospital admission at the trauma center. Transportation time included the time the patient was in EMS transit or at a tertiary facility. All transportation times were coded as either 0 to 30 minutes, 31 to 60 minutes, 61 to 120 minutes, 121 to 240 minutes, or greater than 240 minutes. As age is a continuous variable, it was stratified into the following categories; children (ages 13 to 17), working age adults (ages 18 to 64), and elderly (ages 65 or older).[70] Injury type was a dichotomous variable; responses were either blunt or penetrating. Injury severity score was also a continuous variable and was stratified to reflect three possible responses; mild (0 to 15), moderate (16 to 24), or severe (25 or greater). As a patients' ISS is calculated post-admission, it is not available to the surgeon prior to commitment to a treatment modality in the same manner as are injury grade, hemodynamic status and other known risk factors. However, in this study ISS was reported rather than injury grade as there were 130 patients with valid injury grade scores, and 364 patients with valid ISS in the database. Systolic blood pressure was used as a marker for hemodynamic stability and was stratified to reflect three categories; less than 90 mmHg, 90 to 120 mmHg, greater than 120 mmHg. Glascow coma scale scores were divided into three groups; mild (13 to 15), moderate (9 to 12) or severe (3 to 8).

Patients were separated into three treatment groups. On hospital arrival, patients who underwent laparotomy for splenic injury within two hours comprised the planned operation less than two hours (POR) group. All other patients comprised the non-operative management (NOM) group, where treatment included observation, AE or SAE performed within two hours of admission. However, two hours post-admission, those NOM patients who went on to require either delayed operative intervention or splenic angioembolization (SAE) were reclassified as a failure of non-operative management (FNOM). Procedures performed were classified into one of seven groups; angioembolization (AE) negative for extravasation, AE of the splenic artery, AE of the splenic vein, AE with follow-up splenectomy, splenectomy, splenorrhaphy, or observation only. Time to procedure was measured from time of admission. Among the POR and SAE groups, times were stratified into four groups; 0 to 2 hours, 2 to 4 hours, 4 to 6 hours, or greater than 6 hours. During univariate analysis related to FNOM-only patients and survival analysis, time to procedure was further collapsed into the following strata; 0 to 2 hours, 2 to 4 hours, and greater than 4 hours. Discharge destinations were categorized as home, rehabilitation, other, or dead.

Survival was calculated as the time from admission to the trauma center until hospital death or discharge. Dates and times of deaths were verified through hospital records. All times were captured and assessed as military time.

*Bias*

Censoring occurred for those patients with missing data related to transportation and survival time. To further control for bias due to censoring, the assumption was made that all hospital deaths were due to the patient's splenic injury as opposed to any comorbid condition. It is possible that trauma activations reported in the trauma registry may represent a selection bias of those patients who are treated in, or transported to, the Level I trauma center. Likewise, regional data may not reflect an even distribution of data by age, mechanism of injury, or injury severity. Finally, as the skill levels of those trauma staff who entered the data into the trauma registry varied widely dependent on training and years of experience, data variability may result in information bias.

*Study Size*

The initial sample size was 531 patients, all of whom had ICD-9-CM codes related to splenic injury in the trauma center data registry. Following the application of inclusion and exclusion criteria and censoring for in-hospital deaths, our sample size was 364 patients (Figure 7).

*Statistical Methods*

All data were collected in a Microsoft Excel (version 2007) spreadsheet. Statistical analyses were conducted using Statistical Analytics Software (SAS) version 9.3 (SAS Institute Inc., Cary, NC). The purpose of the analysis was to assess the effect of transportation time to definitive care for patients sustaining traumatic splenic injury. All tests were evaluated at a 0.05 or less level of significance.

Descriptive analyses of clinical and demographic characteristics were summarized for all baseline variables using univariate descriptive statistics and frequency distributions, including measures of central tendency and dispersion. Percentages (%) and counts (n) for all baseline categorical variables were reported. Descriptive analyses to identify clinically relevant differences, which may impact the primary and secondary outcomes, were performed for continuous variables and reported by mean, median, and standard deviation. All statistical tests were two-sided. Normality was assumed by the central limit theorem and having an adequate sample size.

*Time-to-event: Hospital Length of Stay Censored for Patients Who Survived Hospitalization*

The effects of patient and injury characteristics on the probability of NOM and FNOM measured from time of injury was determined using the Cox proportional hazard regression model. This regression model examined and adjusted for the influence of confounding variables on the measure of effect. The Cox proportional hazard regression model was used to determine the effect on H-LOS of the following covariates: transportation time, age, gender, injury type, ISS, treatment group, and time to procedure. The Kaplan-Meier (KM) survival analysis method with log-rank test was used to determine the univariate differences in total time to survival of treatment modality (POR, NOM, or FNOM). Unadjusted rates of time-to-event with 95% confidence intervals were compared using log-rank tests. To adjust for confounding and estimate the hazard risk for each of the outcome variables, the Cox proportional hazards regression model was used to model the function of the explanatory variables. To assess model adequacy of the Cox proportional hazard regression model, statistical significance of the covariates was established utilizing the likelihood ratio test.

## Results

*Aggregate versus Model Population: Demographics*

An initial trauma registry search of 531 patient records yielded 364 patients (Aggregate Population) eligible for inclusion following splenic injury and 155 patients (Model Population) with documented 911 call information which included a transportation time (Table 1). In both populations most patients were 18 to 64 years old (77.2%, n=281 versus 80.6%, n=125). More patients were male (66.5%, n=242 versus 62.6%, n=97). Most were transported by EMS land ambulance (76.9%, n=280 versus 78.7%, n=122). Most transportation times were between 31 and 60 minutes (11.5%, n=42 versus 27.1%, n=42).

| Table 1: Summary of Patient Demographics and Outcomes for Aggregate versus Model Population | | | | |
|---|---|---|---|---|
| | Aggregate Population | | Model Population | |
| Parameter | N = 364 | % | N = 155 | % |
| 13 to 17 | 39 | 10.7 | 15 | 9.7 |
| 18 to 64 | 281 | 77.2 | 125 | 80.6 |
| 65 or older | 44 | 12.1 | 14 | 9.7 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Gender (Male) | 242 | 66.5 | 97 | 62.6 |
| Origin of Transport | | | | |
| Home or scene of injury | 195 | 53.6 | 108 | 69.7 |
| Referring hospital | 169 | 46.4 | 47 | 30.3 |
| Total | 364 | 100.0 | 155 | 100.0 |
| EMS Mode | | | | |
| Land ambulance | 280 | 76.9 | 122 | 78.7 |
| Fixed wing airplane | 5 | 1.4 | 1 | 0.6 |
| Helicopter | 79 | 21.7 | 32 | 20.6 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Transportation Time | | | | |
| 0 to 30 minutes | 31 | 8.5 | 31 | 20.0 |
| 31 to 60 minutes | 42 | 11.5 | 42 | 27.1 |
| 61 to120 minutes | 40 | 11.0 | 40 | 25.8 |
| 121 to 240 minutes | 30 | 8.2 | 30 | 19.4 |
| 240 minutes and greater | 12.00 | 3.3 | 12 | 7.7 |
| Total | 364 | 100.0 | 155 | 100.0 |

*Aggregate versus Model Population: Injuries*

Ninety-four percent (94%, n=342) of patients sustained a blunt injury in the aggregate population versus 89.0% (n=155) in the model population (Table 2). Average injury grade was 3.2 ± 1.2 versus 3.3 ± 1.2. Average ISS for both populations was nearing the severe level (24.0 ± 12.5 versus 24.6 ± 11.7). The percentage of patients who experienced an isolated injury was low in both populations (8.5%, n=31 versus 9.7%, n=15). Nearly half of patients in both populations had a head injury (49.7%, n=181 versus 45.2%, n=70). Approximately half of patients in both populations arrived in a normo-tensive state with SBP greater than 120 (50.3%, n=183 versus 43.2%, n=67).

| Table 2: Summary of Patient Injury Characteristics for Aggregate versus Model Population | | | | |
|---|---|---|---|---|
| | Aggregate Population | | Model Population | |
| Parameter | N = 364 | % | N = 155 | % |
| Injury Type | | | | |
| Blunt | 342 | 94.0 | 138 | 89.0 |
| Penetrating | 22 | 6.0 | 17 | 11.0 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Injury Grade* | 3.2 ± 1.2 | | 3.3 ± 1.2 | |
| Injury Grade | | | | |
| 1 | 10 | 2.7 | 8 | 5.2 |
| 2 | 26 | 7.1 | 12 | 7.7 |
| 3 | 34 | 9.3 | 23 | 14.8 |
| 4 | 43 | 11.8 | 31 | 20.0 |
| 5 | 17 | 4.7 | 11 | 7.1 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Isolated Spleen Injury (Y/N) | 31 | 8.5 | 15 | 9.7 |
| Injury Severity Score* | 24.0 ± 12.5 | | 24.6 ± 11.7 | |
| ISS | | | | |
| 0 to 15 | 98 | 26.9 | 36 | 23.2 |
| 16 to 24 | 105 | 28.9 | 44 | 28.4 |
| 25 and greater | 161 | 44.2 | 75 | 48.4 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Head Injury (Y/N) | 181 | 49.7 | 70 | 45.2 |
| Head Injury AIS Score* | 2.9 ±1.1 | | 2.8 ± 1.0 | |
| Glascow Coma Scale Score | | | | |
| Mild (13 to 15) | 253 | 69.5 | 113 | 72.9 |
| Moderate (9 to12) | 15 | 4.1 | 8 | 5.2 |
| Severe (3 to 8) | 96 | 26.4 | 34 | 21.9 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Systolic Blood Pressure | | | | |
| Less than 90 mmHg | 43 | 11.8 | 27 | 17.4 |
| 90 to 120 mmHg | 137 | 37.7 | 61 | 39.4 |
| 121 or greater mmHg | 183 | 50.3 | 67 | 43.2 |
| Total | 363 | 99.7 | 155 | 100.0 |
| * Mean ± SD | | | | |

*Aggregate versus Model Population: Treatment Groups, Procedures Performed and Time to Procedure*

Non-operative management was the treatment choice for the majority of patients regardless of population (85.7%, n=312 versus 71.6%, n=111), (Table 3). Among these, 79.4% (n=289) and 60.6 (n=94) of patients were managed with observation only in both populations respectively. Twenty percent (20.6%, n=75) of patients in the aggregate population and 39.4% 9 (n=61) in the model population received any type of procedure. The majority of NOM patients remained NOM after two hours, whereas others experienced FNOM (7.1%, n=26 versus 14.2%, n=22). The majority of NOM procedures were SAE (52.2%, n=39 versus 52.5%, n=32). Among those patients in the aggregate population, 69.3% (n=52) procedures occurred in less than two hours from admission, whereas 68.9% (n=42) occurred in the model population. Approximately 20% (21.3%, n=16 versus 21.3%, n=13) received a procedure two to four hours following hospital admission and approximately 10% (9.3%, n=7 versus 9.8%, n=6) received a procedure greater than four hours post-arrival.

| Table 3: Summary of Treatment Groups, Procedure Types, and Time to Procedure from Hospital Admission for Aggregate versus Model Population | | | | |
|---|---|---|---|---|
| | Aggregate Population | | Model Population | |
| Parameter | N | % | N | % |
| Treatment Group | | | | |
| NOM | 312 | 85.7 | 111 | 71.6 |
| POR | 26 | 7.1 | 22 | 14.2 |
| FNOM | 26 | 7.1 | 22 | 14.2 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Procedure Performed (Y/N) | 75 | 20.6 | 61 | 39.4 |
| Procedures Performed | | | | |
| SAE | 39 | 52.0 | 32 | 52.5 |
| POR | 36 | 48.0 | 29 | 47.5 |
| Total | 75 | 100.0 | 61 | 100.0 |
| Procedures Performed | | | | |
| Observation only | 289 | 79.4 | 94 | 60.6 |
| Angioembolization of the splenic artery | 36 | 9.9 | 30 | 19.4 |
| Splenectomy | 28 | 7.7 | 22 | 14.2 |
| Angioembolization negative for extravasation | 2 | 0.5 | 1 | 0.6 |
| Angioembolization of the splenic vein | 1 | 0.3 | 1 | 0.6 |
| Angioembolization with adjunctive splenectomy | 1 | 0.3 | 0 | 0.0 |
| Splenorrhaphy | 7 | 1.9 | 7 | 4.5 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Time to Procedure | | | | |
| 0 to 2 hours | 52 | 69.3 | 42 | 68.9 |
| 2 to 4 hours | 16 | 21.3 | 13 | 21.3 |
| Greater than 4 hours | 7 | 9.3 | 6 | 9.8 |
| Total | 75 | 100.0 | 61 | 100.0 |

*Aggregate versus Model Population: Outcomes*

Both populations demonstrated greater than 50% of patients discharged to home (58.0%, n=211 versus 58.7%, n=91), (Table 4). Approximately one-fifth of those in both populations (n=74, 20.3% versus 19.4%, n=30) were discharged to a rehabilitation facility. Average H-LOS, I-LOS, and number of ventilator days were 11 ± 13 days, 6 ± 10 days, and 4 ± 9 days respectively, in the aggregate population. In the model population, average H-LOS, I-LOS and number of ventilator days were 10 ± 10, 6 ± 8, and 3 ± 7, respectively. Eleven percent (n=40 versus n=17) of cases were censored following death in the hospital in both populations.

| Table 4: Summary of Patient Outcomes for Aggregate versus Model Population | | | | |
|---|---|---|---|---|
| | Aggregate Population | | Model Population | |
| Parameter | N = 364 | % | N = 155 | % |
| Discharge Destination | | | | |
| Home | 211 | 58.0 | 91 | 58.7 |
| Rehabilitation facility | 74 | 20.3 | 30 | 19.4 |
| Other | 39 | 10.7 | 17 | 11.0 |
| Dead | 40 | 11.0 | 17 | 11.0 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Hospital Length of Stay* | 10.7 ± 12.7 | | 9.84 ± 10.3 | |
| Intensive Care Unit Length of Stay* | 6.22 ± 10.4 | | 5.6 ± 8.0 | |
| Number of Ventilatory Days* | 3.8 ± 9.2 | | 3.4 ± 7.1 | |
| Hospital Discharge Status | | | | |
| Alive | 324 | 89.0 | 138 | 89.0 |
| Dead | 40 | 11.0 | 17 | 11.0 |
| Total | 364 | 100.0 | 155 | 100.0 |
| * Mean ± SD | | | | |

*Treatment Groups: Demographics*

The model population was next stratified by treatment group to distinguish demographic characteristics unique to each group (POR, NOM, or FNOM), (Table 5). Fourteen percent of patients (14.2, n=22) of patients were in both the POR and FNOM groups. There were 71.6% (n=111) patients in the NOM group. The majority of patients were adults ages 18 to 64 among POR (86.4%, n=19), NOM (81.1%, n=90), and FNOM (72.7%, n=16). Males made up the majority of patients in the POR group (72.7%, n=16) and the NOM group (64.0%, n=71), however, females made up the majority of patients in the FNOM group (54.5%, n=12). Among all three groups, most patients arrived from home or the scene of injury; POR (59.1%, n=13), NOM (73.9%, n=82), and FNOM (59.1%, n=13). Land ambulance was the most common mechanism of transport among each of the three groups; POR (77.3%, n=17, NOM (77.5%, n=86), and FNOM (86.4%, n=19). More patients arrived following a transportation time of less than two hours; POR (59.1%, n=13), NOM (75.6%, n=84), and FNOM (72.9%, n=16). No statistical differences were demonstrated for any demographic variables.

Table 5: Differences Among Patient Demographics for Model Population by Treatment Group

| Parameter (n,%) | POR (n=22) | NOM (n=111) | FNOM (n= 22) | Total (N=155) | P value |
|---|---|---|---|---|---|
| Age | | | | | 0.67 |
| 13 to 17 | 2 (9.1) | 11 (9.9) | 2 (9.1) | 15 (9.7) | |
| 18 to 64 | 19 (86.4) | 90 (81.1) | 16 (72.7) | 125 (80.6) | |
| 65 or older | 1 (4.5) | 10 (9.0) | 4 (18.2) | 15 (9.7) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |
| Gender (Male) | 16 (72.7) | 71 (64.0) | 10 (45.5) | 97 (62.6) | 0.15 |
| Origin of Transport | | | | | 0.19 |
| Home or scene of injury | 13 (59.1) | 82 (73.9) | 13 (59.1) | 108 (69.7) | |
| Referring hospital | 9 (40.9) | 29 (26.1) | 9 (40.9) | 47 (30.3) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |
| EMS Mode | | | | | 0.87 |
| Land ambulance | 17 (77.3) | 86 (77.5) | 19 (86.4) | 122 (78.7) | |
| Helicopter | 5 (22.7) | 24 (21.6) | 3 (13.6) | 32 (20.6) | |
| Fixed wing airplane | 0 (0) | 1 (.9) | 0 (0) | 1 (.6) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |
| Transportation Time | | | | | 0.09 |
| 0 to 30 minutes | 8 (36.4) | 17 (15.3) | 6 (27.3) | 31 (20.0) | |
| 31 to 60 minutes | 2 (9.1) | 34 (30.6) | 6 (27.3) | 42 (27.1) | |
| 61 to 120 minutes | 3 (13.6) | 33 (29.7) | 4 (18.2) | 40 (25.8) | |
| 121-240 minutes | 6 (27.3) | 19 (17.1) | 5 (22.7) | 30 (19.4) | |
| Greater than 240 minutes | 3 (13.6) | 8 (7.2) | 1 (4.5) | 12 (7.7) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |

*Treatment Groups: Injury*

Non-operative management was attempted for the majority of patients (71.6%, n=111). Statistically significant differences within treatment groups were noted for those patients who sustained blunt or penetrating injury (89.0%, n=138 versus 11.0%, n=17, p=0.001), (Table 6). Among those patients with blunt splenic injury, NOM was attempted in 92.8% (n=103) of patients. Similarly, NOM was attempted in patients with Grade IV (29%, n=12) and Grade V (17% , n=7) injuries, (p=0.52). Isolated splenic injury was seen in 10.3% (n=16) of patients regardless of treatment group (p=0.06). Among those patients (45.2%, n=70) who sustained a head injury, NOM was attempted in 50.5% (n=56). However, differences among treatment groups for those with head injury was not statistically significant (p=0.11). Statistically significant differences were demonstrated between GCS scores where the majority (68.5%, n=76) were noted to be mild (13 to 15) among the NOM group (p=0.08). Systolic blood pressures of greater than 120 were most common (43.2%, n=67) among all treatment groups, with statistical differences evident between groups (p=0.017).

| Table 6: Differences Among Injury Characteristics for Model Population by Treatment Group | | | | | |
|---|---|---|---|---|---|
| Parameter (n,%) | POR (n=22) | NOM (n=111) | FNOM (n=22) | Total (N=155) | P value |
| Injury Type | | | | | 0.001 |
| Blunt | 14 (63.6) | 103 (92.8) | 21 (95.5) | 138 (89.0) | |
| Penetrating | 8 (36.4) | 8 (7.2) | 1 (4.5) | 17 (11.0) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |
| Injury Grade | | | | | 0.52 |
| 1 | 2 (9.1) | 3 (7.3) | 3 (13.6) | 8 (9.4) | |
| 2 | 3 (13.6) | 8 (19.5) | 1 (4.5) | 12 (14.1) | |
| 3 | 4 (18.2) | 11 (26.8) | 8 (36.4) | 23 (27.1) | |
| 4 | 10 (45.5) | 12 (29.3) | 9 (40.9) | 31 (36.5)) | |
| 5 | 3 (13.6) | 7 (17.1) | 1 (4.5) | 11 (12.9) | |
| Total | 22 (100.0) | 41 (100.0) | 22 (100.0) | 85 (100.0) | |
| Isolated Spleen Injury (Y/N) | 5 (22.7) | 8 (7.2) | 3 (13.6) | 16 (10.3) | 0.06 |
| ISS | | | | | 0.48 |
| 0 to 15 | 4 (18.2) | 25 (22.5) | 7 (31.8) | 36 (23.2) | |
| 16 to 24 | 5 (22.7 | 31 (27.9) | 8 (36.4) | 44 (28.4) | |
| 25 and greater | 13 (59.1) | 55 (49.5) | 7 (31.8) | 75 (48.4) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |
| Head Injury (Y/N) | 7 (31.8) | 56 (50.5) | 7 (31.8) | 70 (45.2) | 0.11 |
| Glascow Coma Scale Score | | | | | 0.08 |
| Mild (13 to1 5) | 16 (72.7) | 76 (68.5) | 21 (95.5) | 113 (72.9) | |
| Moderate (9 to12) | 0 (0) | 8 (7.2) | 0 (0) | 8 (5.2) | |
| Severe (3 to 8) | 6 (27.3) | 27 (24.3) | 1 (4.5) | 34 (21.9) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |
| Systolic Blood Pressure | | | | | 0.017 |
| Less than 90 mmHg | 7 (31.8) | 17 (15.3) | 3 (13.6) | 27 (17.4) | |
| 90 to 120 mmHg | 12 (54.5) | 43 (38.7) | 6 (27.3) | 61 (39.4) | |
| 121 or greater mmHg | 3 (13.6) | 51 (45.9) | 13 (59.1) | 67(43.2) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |

*Treatment Groups: Procedures*

Sixty percent (60.6%, n=94) of patients were initially treated with observation alone, (Table 7). Sixty-one procedures were performed. A statistical difference was demonstrated between treatment groups for those patients who did or did not receive a procedure and type of procedure ($p < 0.001$ respectively). Among those patients who experienced FNOM, 15 (68.1%) underwent SAE, while 7 (31.8%) underwent POR ($p < 0.001$). All but one PORs performed among this group were splenectomies. Most (59.1%, n=13) of procedures following FNOM were performed within 2 to 4 hours post-admission.

| Table 7: Differences Among Procedure Types and Time to Procedure From Hospital Admission for Model Population by Treatment Group | | | | | |
|---|---|---|---|---|---|
| Parameter (n,%) | POR (n=22) | NOM (n=111) | FNOM (n=22) | Total (N=155) | P value |
| Procedure Performed (Y/N) | 22 (36.1) | 17 (27.9) | 22 (100.0) | 61 (39.4) | <0.001 |
| Procedures Performed | | | | | <0.001 |
| SAE | 0 (0.0) | 17 (100.0) | 15 (68.2) | 32 (52.5) | |
| POR | 22 (100.0) | 0 (0.0) | 7 (31.8) | 29 (47.5) | |
| Total | 22 (100.0) | 17 (100.0) | 22 (100.0) | 61 (100.0) | |
| Procedures Performed | | | | | <0.001 |
| Angioembolization negative for extravasation | 0 (0) | 0 (0) | 1 (4.5) | 1 (.6) | |
| Angioembolization of the splenic artery | 0 (0) | 17 (15.3) | 13 (59.1) | 31 (20.0) | |
| Angioembolization of the splenic vein | 0 (0) | 0 (0) | 1 (4.5) | 1 (.6) | |
| Angioembolization with adjunctive splenectomy | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| Splenectomy | 16 (72.7) | 0 (0) | 6 (27.3) | 22 (14.2) | |
| Splenorrhaphy | 6 (27.3) | 0 (0) | 1 (4.5) | 6 (3.9) | |
| Observation only | 0 (0.0) | 94 (84.7) | 0 (0) | 94 (60.6) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |
| Time to Procedure | | | | | <0.001 |
| 0 to 2 hours | 22 (100.0) | 17 (100.0) | 3 (13.6) | 42 (68.9) | |
| 2 to 4 hours | 0 (0) | 0 (0) | 13 (59.1) | 13 (21.3) | |
| 4 to 6 hours | 0 (0) | 0 (0) | 3 (13.6) | 3 (4.9) | |
| Greater than 6 hours | 0 (0) | 0 (0) | 3 (13.6) | 3 (4.9) | |
| Total | 22 (100.0) | 17 (100.0) | 22 (100.0) | 61 (100.0) | |

*Treatment Groups: Outcomes*

Among all treatment groups, the majority of patients were discharged to home (58.7%, p=0.49), (Table 8). Average H-LOS for patients who received NOM was the longest at 10 ± 11 days (p=0.09). Similarly, I-LOS was also longest for the NOM group, (6 ± 9, p=0.05). Patients who underwent POR reported the most ventilator days (5 ± 8, p=0.08). Death occurred in 11.0% (n=17), although differences in discharge status were not statistically significant (p=0.92). Seventy percent (70.6%, n=12) of deaths occurred among the NOM group.

| Table 8: Differences Among Patient Outcomes for Model Population by Treatment Group | | | | | |
|---|---|---|---|---|---|
| Parameter (n,%) | POR (n=22) | NOM (n=111) | FNOM (n=22) | Total (N=155) | P value |
| Discharge Destination | | | | | 0.49 |
| Home | 14 (15.4) | 61 (55.0) | 16 (72.7) | 91 (58.7) | |
| Rehabilitation facility | 5 (22.7) | 24 (21.6) | 1 (4.5) | 30 (19.4) | |
| Other | 1 (4.5) | 14 (12.6) | 2 (9.1) | 17 (11.0) | |
| Dead | 2 (9.1) | 12 (10.8) | 3 (13.6) | 17 (11.0) | |
| Total | 22 (100.0) | 111 (100.0) | 22 (100.0) | 155 (100.0) | |
| Hospital Length of Stay* | 9.84 ± 10.3 | 10.2 ± 11.0 | 5.73 ± 3.9 | | 0.09 |
| Intensive Care Unit Length of Stay* | 3.8 ± 8.0 | 6.1 ± 8.6 | 1.8 ± 1.6 | | 0.05 |
| Number of Ventilatory Days* | 5.3 ± 7.6 | 3.6 ± 7.6 | .64 ± 1.4 | | 0.08 |
| Hospital Discharge Status | | | | | 0.92 |
| Alive | 20(90.9) | 99(89.2) | 19(86.4) | 138(89.0) | |
| Dead | 2(9.09) | 12(10.8) | 3(13.6) | 17(11.0) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| *Mean ± SD | | | | | |

*FNOM Group: Demographics, Injury Characteristics and Outcomes*

Among the 22 patients who experienced FNOM, 72.7% (n=16) were adults ages 18 to 64, 54.5% (n=12) were female, and 36.4% (n=8) reported a moderate ISS score of 16 to 24 (Table 9 and 10). Most (40.9%, n=9) sustained Grade IV injuries, with a SBP greater than 120 mmHg (59.1%, n=13). Approximately one quarter (27.3%, n=6) of patients were in the arrived less than 30 minutes and also the 31 to 60 minutes from the 911 call groups, respectively. The majority arrived via land ambulance (86.4%, n=19). Sixty-eight percent (68.2%, n =15) of patients underwent SAE post-admission. For those who received a procedure, most were performed less than four hours from admission (72.7%, n=16). Average H-LOS was 6 ± 4 days, I-LOS was 2 ± 2 days, and ventilator days was one half day ± 1 day.

Thirteen percent (13.6%, n=3) of patients died. One death occurred in each of the three age groups; 13 to 17, 18 to 64, and those ages 65 or older. A single death was reported among each of Grades I, III, and IV. One patient arrived at the hospital after a transportation time of 0 to 30 minutes, another arrived after a 120 to 240 minute transport and the third patient died after a prolonged transportation time in excess of 240 minutes. All three patients underwent a procedure; one received a procedure between 0 to 2 hours, one between 2 to 4 hours, and one between 4 to 6 hours. Cause of death was not determined for any of these three patients.

| Table 9: Injury Characteristics for Patients Experiencing FNOM | | |
|---|---|---|
| Parameter (n=22) | Frequency | Percent |
| Injury Grade | | |
| 1 | 3 | 13.6 |
| 2 | 1 | 4.5 |
| 3 | 8 | 36.4 |
| 4 | 9 | 40.9 |
| 5 | 1 | 4.5 |
| Time from call to arrival | | |
| 0 to 30 minutes | 6 | 27.3 |
| 31 to 60 minutes | 6 | 27.3 |
| 61 to 120 minutes | 4 | 18.2 |
| 120 to 240 minutes | 5 | 22.7 |
| Greater than 240 minutes | 1 | 4.5 |
| Time to procedure | | |
| 0 to 2 hours | 3 | 13.6 |
| 2 to 4 hours | 13 | 59.1 |
| Greater than 4 hours | 6 | 27.2 |

Table 10 : Most Frequent Demographic, Injury Characteristics, and Outcomes Among FNOM

| Parameter (n=22) | Result | Frequency | % |
|---|---|---|---|
| Age | 18 to 64 | 16 | 72.7 |
| Gender | Female | 12 | 54.5 |
| Origin of Transportation | Home or scene of injury | 13 | 59.1 |
| EMS mode | Land ambulance | 19 | 86.4 |
| Time From Call to Arrival | Less than 60 minutes | 12 | 54.5 |
| Injury Type | Blunt injury | 21 | 95.5 |
| Injury Severity Score | 16 to 24 | 8 | 36.4 |
| Glascow Coma Scale Score | Mild (13 to 15) | 21 | 95.5 |
| Isolated Spleen (Y/N) | Yes | 3 | 13.6 |
| Isolated Spleen Injury | Yes | 3 | 13.6 |
| Head Injury (Y/N) | Yes | 7 | 31.8 |
| Systolic Blood Pressure | Less than 120 mmHg | 13 | 59.1 |
| Procedure After Admission | AE or SAE | 15 | 68.2 |
| Time to Procedure | 2 to 4 hours | 3 | 13.6 |
| Hospital Length of Stay* | | 5.7 ± 3.9 | |
| Intensive Care Unit Length of Stay* | | 1.8 ± 1.6 | |
| Number of Ventilatory Days* | | .6 ± 1.4 | |
| Discharge Destination | Home | 16 | 72.7 |
| Hospital Discharge Status | Alive | 19 | 86.4 |

*Mean ± SD

*Bivariate Comparison: Aggregate versus Model Population*

In trauma studies, certain parameters provide surgeons with the ability to determine whether patients in an aggregate population differ from those in the sample assessed in a predictive model. Additionally, these clinical indicators provide critical information regarding these patients status. For splenic injuries, there are ten such indicators and these were assessed for possible differences in distributions between the aggregate and model populations to ensure that a random sample of patients was analyzed in the survival model. These indicators included: stratified age, gender, origin of transport, EMS mode, hospital discharge status, average injury grade, ISS, presence of a head injury, receipt of a splenic procedure post-admission and SBP level (Table 11). Statistically significant differences were demonstrated between origin of transport ($p<0.001$), SBP level ($p=0.07$), and procedure after admission ($p<0.001$).

As the majority of variables demonstrated no difference between populations, we conclude the distribution of the model population (n=155) approximates that of the aggregate population (n=364). The model population approximated a true random sample.

| Table 11: Bivariate Comparison | | | | |
|---|---|---|---|---|
| Parameter (n,%) | Transport time (n=155) | No transport time (n=209) | Total | P-value* |
| Age | | | | 0.3368 |
| 13 to 17 | 15 (9.7%) | 24 (11.5%) | 39 (10.7%) | |
| 18 to 65 | 126 (81.3%) | 157 (75.1%) | 283 (77.7%) | |
| 66 or older | 14 (9%) | 28 (13.4%) | 42 (11.5%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Gender | | | | 0.2568 |
| Male | 98 (63.2%) | 144 (68.9%) | 242 (66.5%) | |
| Female | 57 (36.8%) | 65 (31.1%) | 122 (33.5%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Origination of Transport | | | | <.0001 |
| Home or scene of injury | 108 (69.7%) | 87 (41.6%) | 195 (53.6%) | |
| Referring hospital | 47 (30.3%) | 122 (58.4%) | 169 (46.4%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| EMS Mode | | | | 0.5236 |
| Land ambulance | 122 (78.7%) | 158 (75.6%) | 280 (76.9%) | |
| Helicopter | 32 (20.6%) | 47 (22.5%) | 79 (21.7%) | |
| Fixed wing airplane | 1 (0.6%) | 4 (1.9%) | 5 (1.4%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Hospital Discharge Status | | | | 0.9911 |
| Alive | 138 (89%) | 186 (89%) | 324 (89%) | |
| Dead | 17 (11%) | 23 (11%) | 40 (11%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Discharge Destination | | | | 0.9288 |
| Home | 92 (59.4%) | 119 (56.9%) | 211 (58%) | |
| Rehab | 29 (18.7%) | 45 (21.5%) | 74 (20.3%) | |
| Other | 17 (11%) | 22 (10.5%) | 39 (10.7%) | |
| Dead | 17 (11%) | 23 (11%) | 40 (11%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| ISS Score† | 24.5 ± 11.72 | 23.6 ± 13.14 | | 0.5192 |
| Injury Grade** | | | | 0.1898 |
| 1 | 8 (9.4%) | 2 (4.4%) | 10 (7.7%) | |
| 2 | 12 (14.1%) | 14 (31.1%) | 26 (20%) | |
| 3 | 23 (27.1%) | 11 (24.4%) | 34 (26.2%) | |
| 4 | 31 (36.5%) | 12 (26.7%) | 43 (33.1%) | |
| 5 | 11 (12.9%) | 6 (13.3%) | 17 (13.1%) | |
| Total | 85 (100%) | 45 (100%) | 130 (100%) | |
| Systolic Blood Pressure*** | | | | 0.0066 |
| Less than 90 mmHg | 27 (17.4%) | 16 (7.7%) | 43 (11.8%) | |
| 90 to 120 mmHg | 61 (39.4%) | 76 (36.5%) | 137 (37.7%) | |
| Greater than 120 mmHg | 67 (43.2%) | 116 (55.8%) | 183 (50.4%) | |
| Total | 155 (100%) | 208 (100%) | 363 (100%) | |

| | | | | |
|---|---|---|---|---|
| Head Injury (Y/N) | 69 (44.5%) | 112 (53.6%) | 181 (49.7%) | 0.0869 |
| Procedure After Admission | | | | <.0001 |
| NOM | 111 (71.6%) | 201 (96.2%) | 312 (85.7%) | |
| FNOM | 22 (14.2%) | 4 (1.9%) | 26 (7.1%) | |
| POR | 22 (14.2%) | 4 (1.9%) | 26 (7.1%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| **All p-values were calculated based on Chi-square test except the ISS score. P values are reported to the 4th decimal place<br>**234 patients do not have the injury grade.<br>***One patient does not have SBP measures*<br>†Mean ± SD | | | | |

*Hospital Length of Stay by Discharge Status*

Among the aggregate population (N=364), 209 patients did not have a valid transportation time, whereas 155 patients did have a valid transportation time and were included in the survival analysis. The number of those who had a valued transportation time and were discharged alive was 138. The covariates assessed in the survival analysis included; age, ISS, gender, injury type, treatment group, time to procedure, and transportation time. During univariate analysis, time to procedure greater than four hours and greater than six hours were found to be similar, and were combined to power the calculation of median H-LOS in the survival analysis. Injury was highly correlated with ISS ($p<0.001$) and therefore, despite being identified in literature as a validated predictor or improved outcomes following splenic injury, was not included in the Cox Hazard Regression model.

The median H-LOS was higher in the ages 65 and older group than those in the 13 to 17 age group or 18 to 64 age group (6.5 [Q3-9] v. 6 [Q5,10] and 6 [4,15] d.), respectively. Median H-LOS was also greatest for those patients with ISS greater than or equal to 25 compared to those with in the ISS 0 to 15 or 16 to 24 group (10 [6,21] v. 3.5[2,6] and 7[4,10] d.), respectively. Males demonstrated a longer H-LOS (7 [5,16]d., as did those patients who sustained blunt injury

(7[4,13]d.), and those who underwent POR (11[5.20.5] d.). Those patients with transportation times in excess of 60 minutes had the longest median H-LOS compared to those patients with transportation times of 61 to 120 minutes and 121 to 240 minutes (7[5,17] v. 8.5[3,18] and 11[3,19] d.), respectively.

| Table 12: Summary of H-LOS Stratified by Discharge Status | | | | | | |
|---|---|---|---|---|---|---|
| | Discharged alive (n=138) | | | All case (n=155) | | |
| | Median H-LOS (days) | (Q1, Q3) | (Min, Max) | Median H-LOS (days) | (Q1, Q3) | (Min, Max) |
| Age | | | | | | |
| 13 to 17 | 6 | (5, 10) | (2, 43) | 6 | (3, 10) | (1, 43) |
| 18 to 64 | 6 | (4, 15) | (1, 47) | 6 | (3, 13) | (1, 60) |
| 65 and older | 6.5 | (3, 9) | (3, 12) | 5 | (3, 9) | (1, 14) |
| ISS | | | | | | |
| 0 to 15 | 3.5 | (2, 6) | (1, 17) | 4 | (2, 6) | (1, 17) |
| 16 to 24 | 7 | (4, 10) | (1, 28) | 6 | (4, 9.5) | (1, 28) |
| 25 or greater | 10 | (6, 21) | (3, 47) | 7 | (5, 20) | (1, 60) |
| Gender | | | | | | |
| Male | 7 | (5, 16) | (1, 47) | 6 | (4, 15) | (1, 47) |
| Female | 5.5 | (3, 9) | (1, 32) | 5 | (3, 9) | (1, 60) |
| Injury Type | | | | | | |
| Blunt | 7 | (4, 13) | (1, 47) | 6 | (3, 12) | (1, 60) |
| Penetrating | 5.5 | (4, 6.5) | (2, 23) | 5 | (4, 6) | (1, 23) |
| Treatment Type | | | | | | |
| FNOM | 6 | (3, 8) | (2, 18) | 5 | (3, 8) | (1, 18) |
| NOM | 6 | (3, 12) | (1, 47) | 6 | (3, 12) | (1, 60) |
| POR | 11 | (5, 20.5) | (2, 40) | 8 | (5, 20) | (1, 40) |
| Time to Procedure | | | | | | |
| 0 to 2 hours | 6 | (5, 17) | (1, 40) | 6 | (4, 17) | (1, 60) |
| 2 to 4 hours | 6 | (3.5, 7.5) | (2, 10) | 6 | (3, 7) | (1, 10) |
| More than 4 hours | 6 | (4, 8) | (3, 18) | 5 | (3, 8) | (3, 18) |
| Transportation Time | | | | | | |
| 0 to 29 minutes | 6 | (4, 8) | (2, 28) | 6 | (4, 8) | (1, 28) |
| 30 to 60 minutes | 6 | (3, 8) | (1, 43) | 6 | (3, 8) | (1, 43) |
| 61to 120 minutes | 7 | (5, 17) | (2, 47) | 6 | (4, 16) | (1, 60) |
| 121 to 240 minutes | 8.5 | (3, 18) | (1, 40) | 6 | (3, 17) | (1, 40) |
| Greater than 240 minutes | 11 | (3, 19) | (1, 23) | 10.5 | (2.5, 15.5) | (1, 23) |

*Cox Proportional Hazard Regression Analysis Time to Event: Hospital Length of Stay Censored for Patients Who Survived Hospitalization*

Cox proportional hazard regression analysis demonstrated two covariates were predictive of decreased mortality; age (p=0.0016) and ISS (p=0.0903). Although the confidence interval for the ISS hazard ratio includes one, indicating no difference between the measures, the magnitude of the hazard ratio suggests a strong predictive capacity for ISS on mortality. Transportation time was not associated with mortality (p=0.9948).

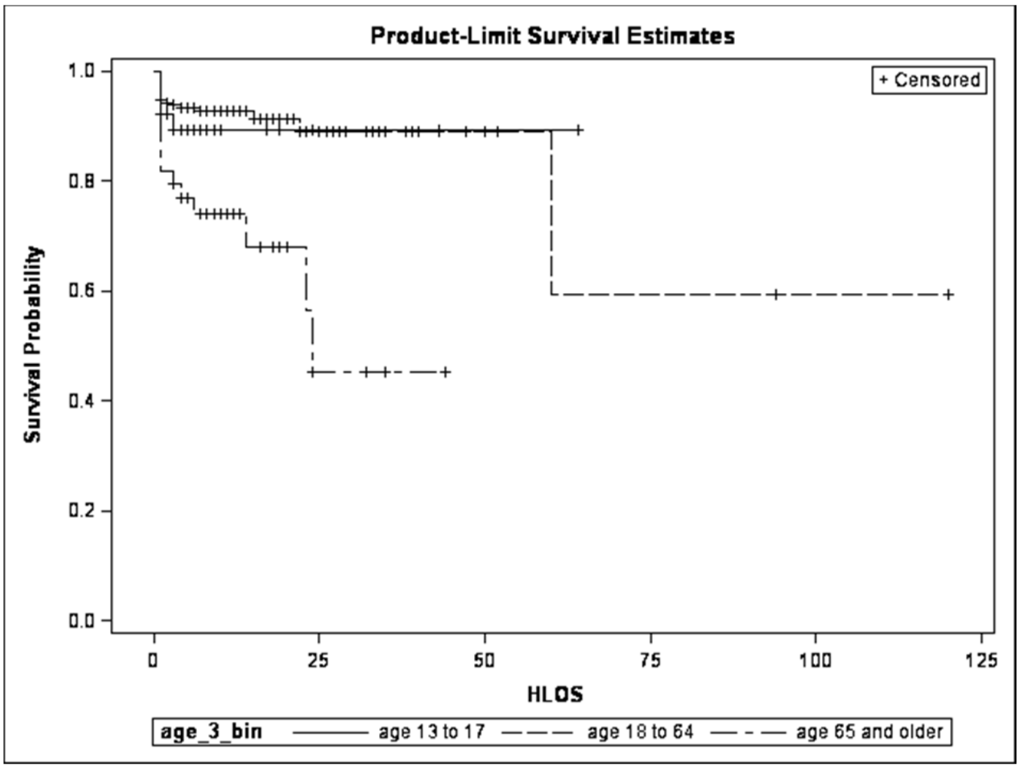
Compared to those greater or equal to 65 years of age, those ages 13 to 17 were 79% less likely to die (HR=0.21; 95% CI=0.04, 1.14). Compared to those greater or equal to 65 years of age, those ages 18 to 64 were 88% less like to die (HR=0.12; 95% CI=0.04, 0.38). Patients with an ISS of 0 to 15 are 87% less likely to die compared to those with an ISS greater or equal to 25 (HR=0.13; 95% CI=0.02, 1.04). Patients with an ISS of 16 to 24 were 63% less likely to die than those with an ISS greater or equal to 25 (HR=0.37; 95% CI=0.09, 1.47).

| Table 13: Hazard Ratios for H-LOS | | | | | | |
|---|---|---|---|---|---|---|
| | Unadjusted | | | Adjusted | | |
| Parameter | HR | 95% CI for HR | | HR | 95% CI for HR | |
| Age | | | | p-value=0.0016 | | |
| 13 to 17 vs 18 to 64 | 1.36 | 0.47 | 3.96 | 1.79 | 0.38 | 8.44 |
| 13 to 17 vs 65 or older | 0.32 | 0.11 | 0.99 | 0.21 | 0.04 | 1.14 |
| 18 to 64 vs 65 or older | 0.24 | 0.12 | 0.47 | 0.12 | 0.04 | 0.38 |
| ISS | | | | p-value=0.0903 | | |
| 0 to 15 vs16 to 24 | 0.17 | 0.02 | 1.39 | 0.34 | 0.04 | 3.35 |
| 0 to 15 vs 25 and greater | 0.07 | 0.01 | 0.48 | 0.13 | 0.02 | 1.04 |
| 16 to 24 vs 25 and greater | 0.38 | 0.17 | 0.87 | 0.37 | 0.09 | 1.47 |
| Gender (male) | 0.55 | 0.26 | 1.16 | Not included in the analysis* | | |
| Injury Type (blunt) | 0.73 | 0.22 | 2.37 | Not included in the analysis* | | |
| Treatment Type | | | | Not included in the analysis* | | |
| FNOM vs NOM | 1.15 | 0.35 | 3.75 | | | |
| FNOM vs POR | 1.13 | 0.23 | 5.63 | | | |
| NOM vs POR | 0.99 | 0.30 | 3.22 | | | |
| Time to Procedure (hours) | | | | | | |
| 0 to 2 vs 2 to 4 | 2.17 | 0.27 | 17.60 | | | |
| Less than 4 vs 0 to 2 | 1.18 | 0.14 | 9.74 | | | |
| Less than 4 vs 2 to 4 | 2.55 | 0.16 | 41.22 | | | |
| Transportation Time (minutes) | | | | Not predictive (p=0.9948) | | |
| 0 to 30 vs greater than 240 | 0.82 | 0.07 | 9.07 | 0.94 | 0.08 | 10.71 |
| 31 to 60 vs greater than 240 | 1.20 | 0.13 | 10.79 | 1.06 | 0.12 | 9.83 |
| 61 to 120 vs greater than 240 | 1.72 | 0.21 | 14.29 | 1.24 | 0.14 | 11.33 |
| 121 to 240 vs greater than 240 | 1.17 | 0.12 | 11.27 | 0.94 | 0.09 | 9.56 |
| *non-significant result in the univariate analysis | | | | | | |

Age:

Age was associated as a predictor for decreased mortality. Ages 18 to 64 had the highest survival probability, therefore the lowest risk of death.

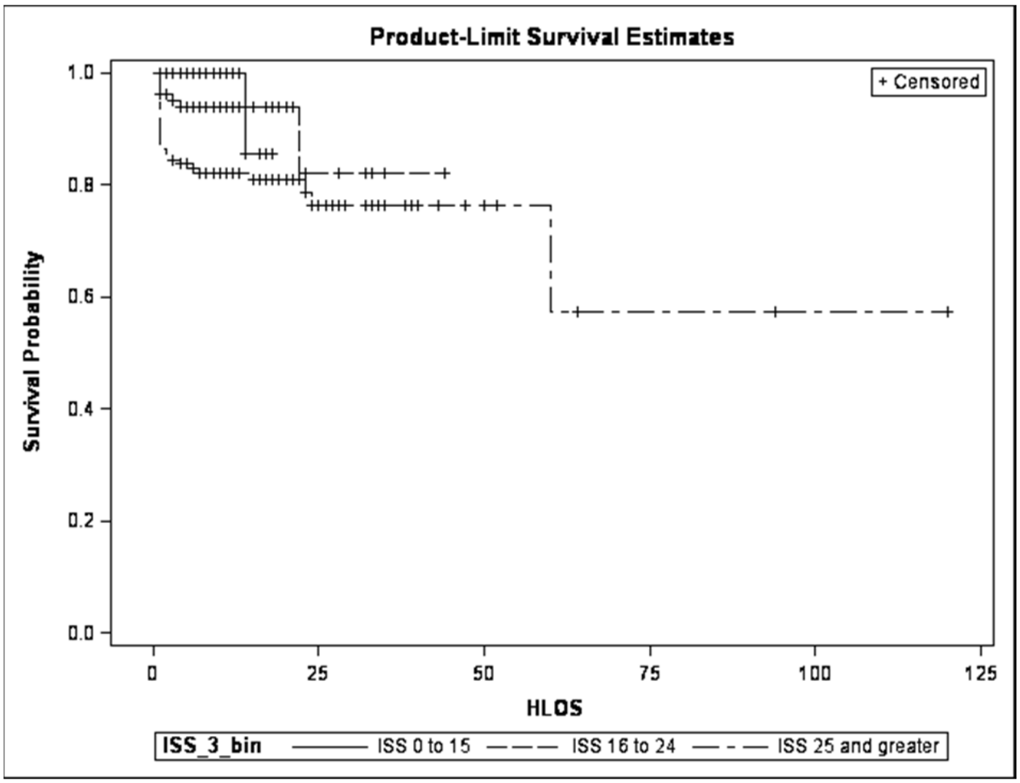
Figure 8: Survival Estimate of Decreased H-LOS by Patient Age



Injury Severity Score:

Injury severity score was associated as a predictor for decreased mortality. Scores of 0 to 15 had the highest survival probability, therefore the lowest risk of death.

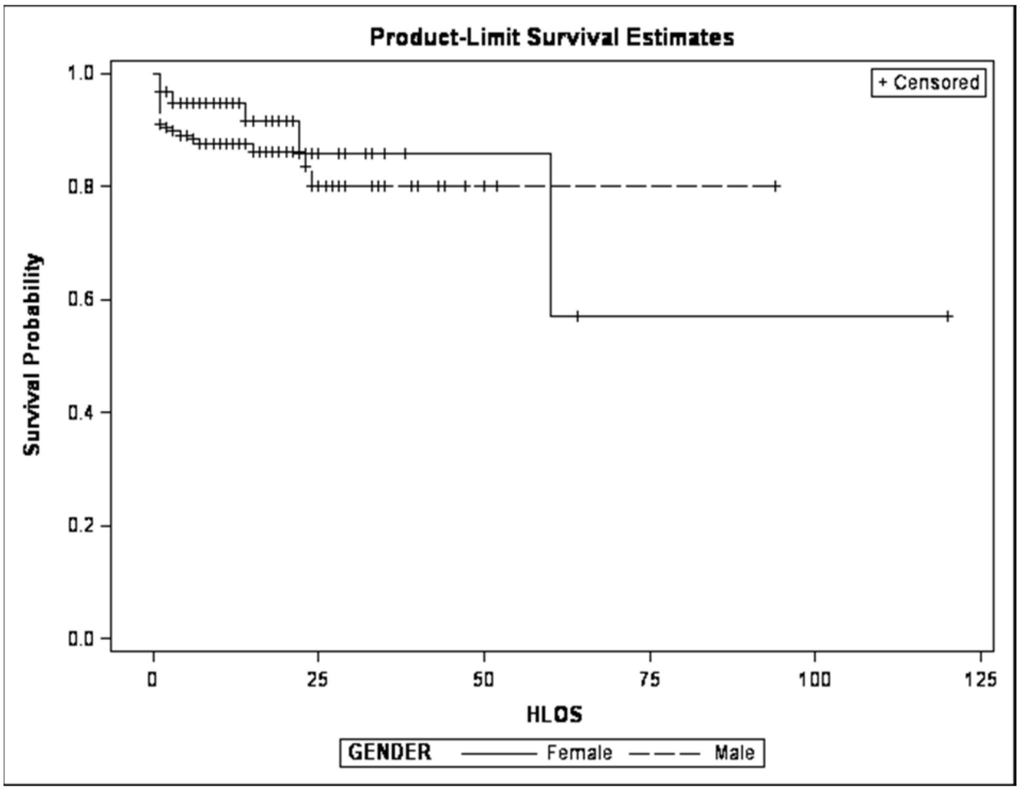
Figure 9: Survival Estimate of Decreased H-LOS by Injury Severity Score



Gender:

Gender was not associated as a predictor for decreased mortality.  Females had the highest survival probability, therefore the lowest risk of death.

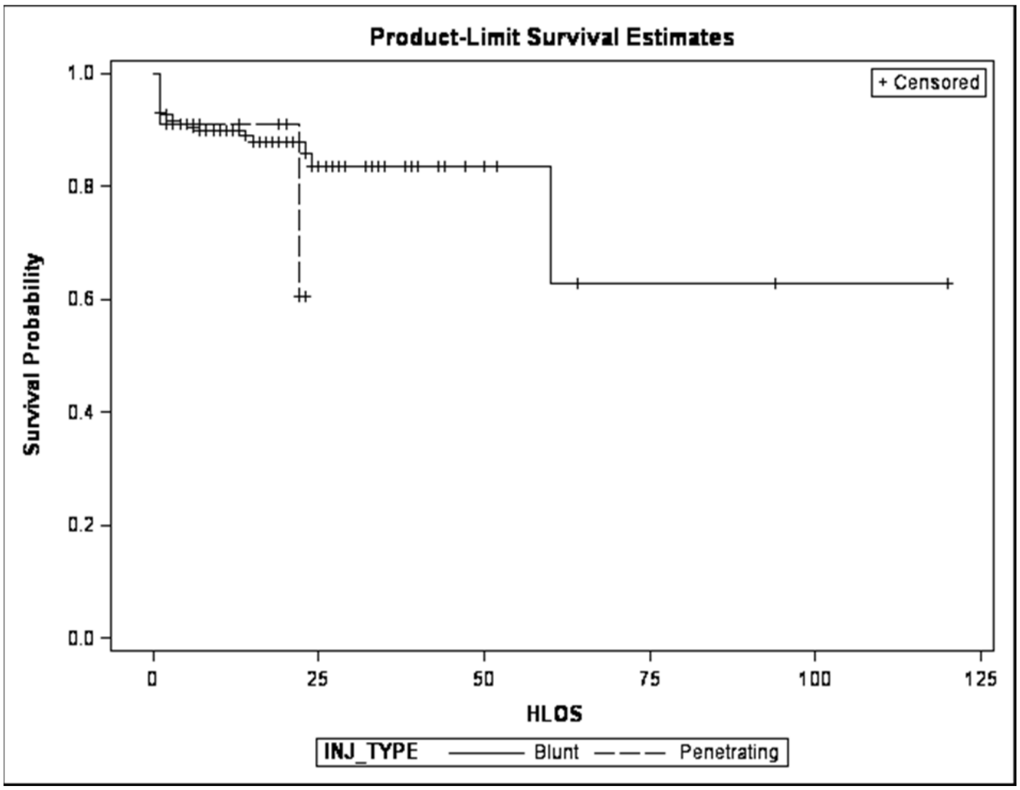
Figure 10:  Survival Estimate of Decreased H-LOS by Gender



Injury Type:

Injury type was not associated as a predictor for decreased mortality.  Blunt injury had the highest survival probability, therefore the lowest risk of death.

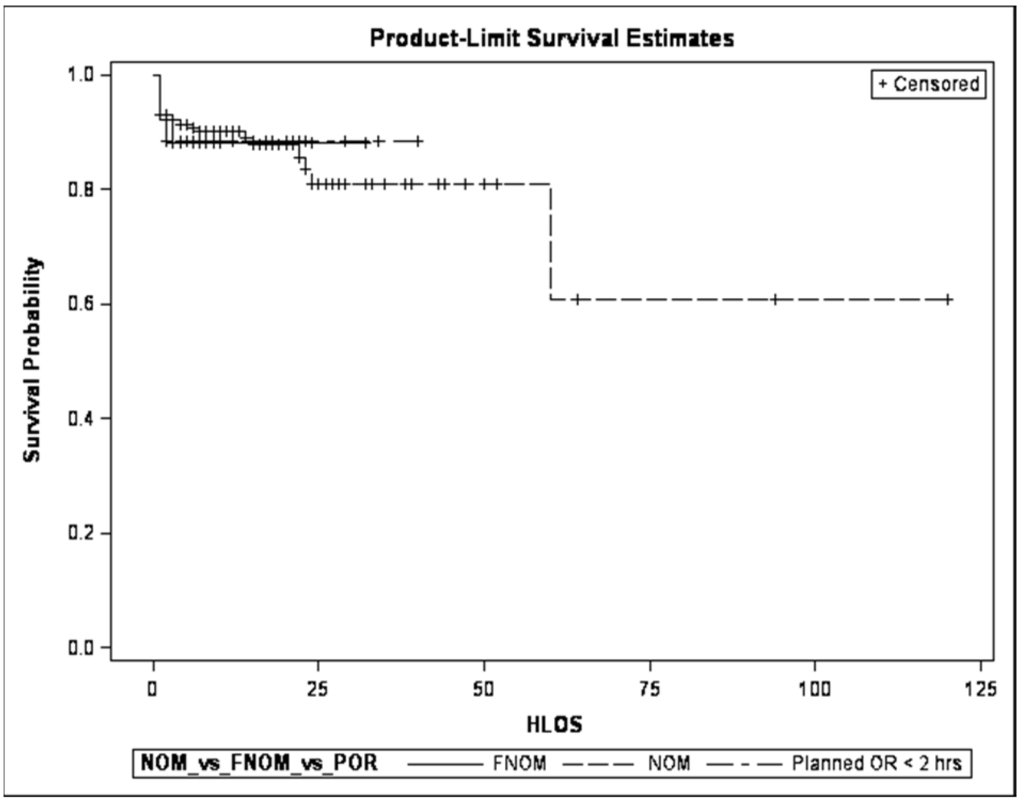
Figure 11:  Survival Estimate of Decreased H-LOS by Injury Type



Treatment Type:

Treatment type was not associated as a predictor for decreased mortality. Planned operations (POR) and FNOM management had the highest survival probability, therefore the lowest risk of death.

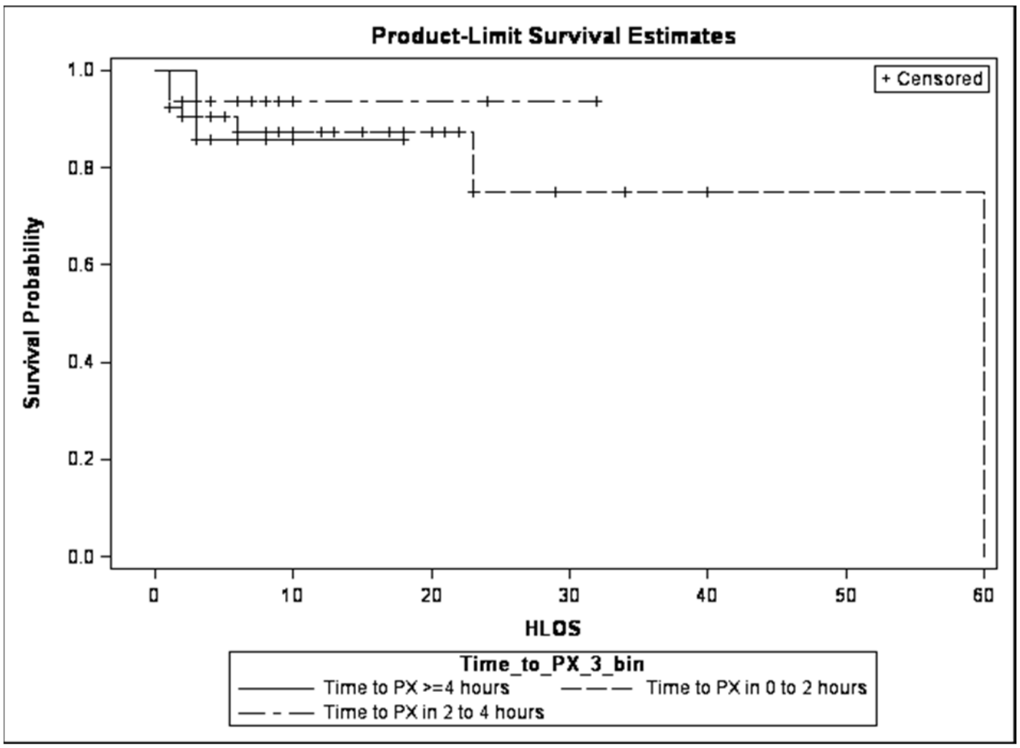
Figure12: Survival Estimate of Decreased H-LOS by Treatment Group



Time to Procedure:

Time to procedure was not a predictor for longer H-LOS related to transportation time to the hospital. Procedures performed between 2 to 4 hours had the highest survival probability, therefore the lowest risk for death.

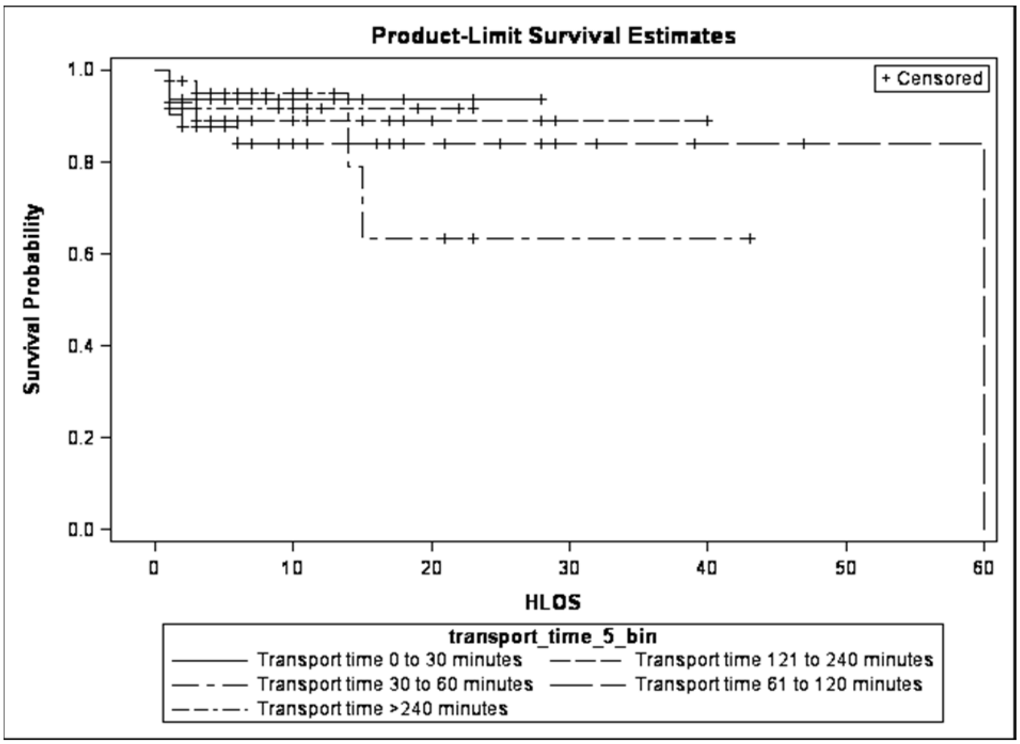
Figure 13: Survival Estimate of Decreased H-LOS by Time to Procedure



Transportation Time:

Transportation time was not a predictor for longer H-LOS related to transportation time to the hospital. Transportation times between 0 to 30 minutes had a higher survival probability, therefore a lower risk for death.

Figure 14: Survival Estimate of Decreased H-LOS by Transportation Time



## Discussion

The objective of this study was to first evaluate transportation time as a predictor for improved mortality and hospital length of stay (H-LOS) rates among patients with splenic injury in a rural state. The effect of transportation time on H-LOS and survivability specific to treatment type following traumatic splenic injury (planned operation less than two hours post-admission (POR), non-operative management (NOM), or failure of non-operative management (FNOM)) was also assessed. Finally, due to the paucity of data on splenic injury in a rural environment the incidence and outcomes following FNOM in a state with a predominantly rural resident base was studied.

*Effect of Transportation Time on Hospital Length of Stay in a Rural State*

While exploratory in nature, this study suggests that transportation time to the hospital in a rural state, which begins with the time the EMS service receives a 911 call for assistance, is not associated with reduced H-LOS. The average time to the hospital following traumatic injury is greater than one hour for at least 31% of people in a rural environment.[71] While the population in the current study included both rural and urban residents living in a largely rural state, mean (93.2 ± 81 minutes, range 6 to 480 minutes) and median (65 minutes) transportation times indicate that nearly half of patients transferred to the Level I trauma center (n=364) were injured in locations greater than one hour from the trauma center. These times are uncommon in largely urban environments where transportation times may be less than ten minutes,

Among the model population (n=155), most patients arrived between 31 and 120 minutes (n=82, 48.8%). We have reported the median H-LOS was higher in the age 65 and older group than those in the 13 to 17 age group or the 18 to 64 age group (6.5 [Q3-9] v. 6 [Q5,10] and 6 [4,15] d.), respectively. Median H-LOS was also greatest for those patients with ISS greater than or equal to 25 compared to those with in the ISS 0 to 15 or 16 to 24 group (10 [6,21] v. 3.5[2,6] and 7[4,10] d.), respectively. This indicates the possibility that in a largely rural setting, prolonged transportation times allow the patient to declare their hemodynamic and injury status prior to admission. It is possible that while we demonstrate a lower risk of prolonged H-LOS for those less than 65 years of age, our increased risk for those ages 65 and greater may represent differences in associated injuries as our population did not all sustain isolated injury. Likewise, there is a ten year age difference between the elderly population in this study and that in previous reports (ages 55 and older versus ages 65 and older) which may play a role in the increased risk.[38]

*Effect of Transportation Time on Mortality in a Rural State*

Overall mortality rates following splenic injury were reported as 18% in 2003 by Carlin et al.[5] We report an overall mortality rate among the both the aggregate population (n=364) and the model population (n=155) of 11.0% (n=40 and n=17, respectively). As a rural trauma center, we would expect that our rate would be twice that of urban centers as previously reported by Gomez et al. or at least closer to the average (18%), however, this was not the case.[7] Literature has also demonstrated mortality rates for blunt versus penetrating injury rates of 1 to 15% and 8 to 5% respectively, which our results support (10.8% and 13.6% respectively).[4,5]

During the survival analysis, transportation time was considered as one of the seven covariates included in the model. However, age and injury severity score (ISS) were identified as the only predictors for decreased mortality (p=0.0016 and p=0.0903, respectively). Transportation time was not identified as a predictor of decreased mortality (p=0.9948).

Compared to those greater or equal to 65 years of age, those ages 13 to 17 were 79% less likely to die (HR=0.21; 95% CI=0.04, 1.14). Likewise, compared to those greater or equal to 65 years of age, those ages 18 to 64 were 88% less like to die (HR=0.12; 95% CI=0.04, 0.38). With regards to the ISSs, those with an ISS of 0 to 15 are 87% less likely to die compared to those with an ISS greater or equal to 25 (HR=0.13; 95% CI=0.02, 1.04). Patients with an ISS of 16 to 24 were 63% less likely to die than those with an ISS greater or equal to 25 (HR=0.37; 95% CI=0.09, 1.47). These results support previous attempts by researchers to identify variables to aid surgeons in their attempts to more accurately predict which patients can be successfully selected to complete non-operative treatment following splenic trauma.[2]

One possible explanation for our lower mortality rate is the ability of surgeons to more accurately triage patients following prolonged transportation time in the presence of physiologic signs which may be unavailable to the surgeon assessing a patient seen minutes after the injury rather than hours. Longer transportation times may aid the surgeon in a rural state to select patients for NOM more accurately, thus lowering the rate of FNOM. In 2011, Bhangu et al. reported significantly higher mortality rates among patients who experienced FNOM.[67] Another explanation may in part reflect improvements in trauma care over the past ten years.

*Effect of Transportation Time on Hospital Length of Stay by Treatment Group*

While transportation time proved to be inferior as a predictor for decreased H-LOS following POR, SAE or FNOM, the results of this study were also in concordance with other findings. Chen et al. has reported a mean H-LOS following SAE of 10 ± 6 days.[38] We report the longest H-LOS among the model population was for those patients who received NOM, (11 ± 13 days, p=0.09). In the current study, median H-LOS was longest for patients in the POR group (11[5, 20.5]. Watson et al. also reported mean H-LOS of 17 ± 1 days and I-LOS following FNOM of 10 ± 1 days.[62] Our H-LOS for patients experiencing FNOM was lower (12 ± 10 days), and we also demonstrated a lower I-LOS (7 ± 8 days).

The findings of this study suggest prolonged transportation time in excess of 20 minutes in a rural state will allow the patient to declare themselves hemodynamically stable or unstable prior to admission at a trauma center, and that these patients tent to maintain their admission status. Those patients who experience FNOM in urban settings likely present as stable and become unstable after admission. While I-LOS was shorter in this population for those patients who experienced FNOM than for those who were successfully discharged following NOM, the reasons remain unclear. Patients who require more surveillance typically remain in an ICU until their condition allows them to be transferred to a floor bed. In some hospitals, patients who are not ready for a floor bed, but don't require the more intensive surveillance provided in an ICU unit, are placed in a step-down unit. In the current study, a step-down unit was not available at the trauma center, perhaps inflating the I-LOS for some patients.

*Effect of Transportation Time on Mortality by Treatment Group*

Seventeen deaths (11.0%) occurred in the model population. A larger proportion of these death occurred in the NOM group (70.6%, n=12). Eleven percent (11.8%) of total deaths were in the POR group and 17.6% occurred in the FNOM group. Bhangu et al. reported that FNOM rates were associated with significantly higher mortality rates and resource use, and that ages 55 and older were at highest risk for death (OR 2.65, CI 1.20-5,82).[67] In this study, higher mortality rates occurred in the NOM group. Mean hospital length of stay was longer in the NOM group, while median H-LOS was greatest in the POR group. One explanation is the patient population in this study sustained poly-trauma with higher grade splenic injury and were younger. These results support previous reports that risk factors for adults ages 18 to 64 in a rural environment are greater than for those in an urban setting.[8-11] In addition, over 50% of patients in the current study sustained a head injury with an average abbreviated injury severity score of 2.8 ± 1.0.

Treatment of concomitant injury may have played a role in the surgeons' decision to place patients in the NOM group. Finally, when the highest level of injury grade has declared itself on presentation or within two hours post-admission, surgeons can use this information to accurately select patients for NOM and reduce the chance of death. In cases of latent manifestation of hemorrhage, injury grade at admission can change, resulting in a possible FNOM and therefore, an increased chance of mortality.[67]

*Possible Reasons Transportation Time Was Not Predictive of Lower Mortality and Hospital Length of Stay*

There exist a number of possible reasons transportation may have proven ineffective as a predictor for decreased mortality and H-LOS in the current study. The most obvious may be limited power due to the low number of deaths (n=17), as well as the low number of patients with documented EMS transportation times (n=155). Transportation time was defined as a composite variable with no attempt to quantify the effect of EMS interventions, or lack of, on either the patients mortality or H-LOS. Calculation of meaningful results was hampered by the wide variance of transportation times (6 to 480 minutes). And finally, deaths which occurred less than two hours post-admission were excluded, potentially removing from the model population data reflecting critical transportation times and it is possible this influenced the results of the survival analysis.

*Hospital Outcomes Following Failure of Non-operative Management in a Rural State*

While transportation time for splenic-injured patients in a rural state did not prove predictive of decreased mortality or decreased H-LOS, the proportion of FNOMs was lower than the proportion in current literature.[61,65] This indicates there is reason to question the application of the current, largely urban-based, trauma system in the rural environment.

A meta-analysis of 335 papers was conducted in 2013 by Olthof et al.[73] and the authors reported strong evidence for FNOM based on three predictors: ISS greater than 25; have a splenic injury Grade III or IV, and 5; and being 40 years or older. The average rate of failure for non-operative management of splenic trauma has been well reported between 8% to 38%.[61,65] According to a 2003 EAST multi-institutional study which assessed 1,488 patients from 27 U.S. trauma centers, 61% of FNOMs occur within the first 24 hours following hospital admission, and most will have occurred within the first 48 hours after admission, and that 100% will occur in less than three days.[71,73] Results from the current study indicate a FNOM rate of 14.2% (n=22), where the majority (96%) occurred less than six hours following admission, and 100% less than 48 hours.

This knowledge challenges the generalizability of previous predictors for FNOM based on the experiences of non-rural populations and may prove critical in the quest to lower the rate of FNOM by placing a focus on the differences between patients from rural versus urban populations. Those patients who experience FNOM in urban settings likely present in an unstable state and undergo POR or die prior to arrival. Results from this study indicated that 100% of FNOMs occurred less than 48 post-admission, or one full hospital day sooner. Further, the majority of FNOMs (96%) occurred much faster at less than six hours following admission. We support the theory that rural and urban populations are different in terms of splenic injured patients. Further, results from this study are therefore in concordance with previous publications in the selection of patients for NOM, however demonstrate that following longer transportation times, failures of NOM can be expected to occur prior to the expected 48 hours.[66] These results challenge the definition that in a rural state the start of NOM is equal to five hours following admission if one considered a 5% failure rate the benchmark, as suggested by Jeremitsky.[69]

For those patients who experienced FNOM in a rural state, the majority of patients were adult (ages 18 to 64), female, and reported a moderate ISS (16 to 24). The current study collaborates reports that FNOM is associated with Grade IV injuries 40% of the time (38.5%, n=10).[29] However, literature reports Grade V injuries are associated with FNOM 15% of the time, and we report two Grade V injuries among those patients who experienced FNOM (7.7%).[29]

There exists a potential for patients who have been classified as FNOM in previous studies to have been misclassified. Without careful scrutiny of physician notes regarding intent to treat, there may exist situations where NOM was the treatment of choice, however, circumstances prohibited the execution of the treatment. In our study, two patients were reassigned from the FNOM group to the POR group following review of their hospital records which revealed hemodynamic stability and late night admission. Physician preference was to delay SAE until daylight. Neither patient required additional procedures for splenic injury following initial triage and both were discharged without further incident.

*Implications*

While it remains true that ACS guidelines promote rapid EMS delivery because transportation of the traumatically-injured patient to definitive care has been shown to save lives within the first hour after injury, for patients with splenic injury in a rural state with prolonged transportation times symptoms may manifest before delivery. It is possible this information, which is specific to the traumatic splenic-injured population in a rural state, may be of importance to those attempting to implement EMS guidelines and protocols to better serve the vulnerable rural population in states such as Kansas, as well as providing unique information to confidently select splenic injured patients for either NOM or POR for trauma surgeons where transportation times routinely exceed one hour.[17]

*Strengths*

This study is the first trial to evaluate the predictive capacity of transportation time among patients with splenic injury related to H-LOS and mortality. To the best of our knowledge, it is the third study to focus on the splenic-injured population in a setting where the trauma center's catchment area encompasses a largely rural population.

*Limitations*

We acknowledge the limitations associated with this study. Although the overall patient population of 364 was substantial, the number of patients with EMS records complete with time of call (n=155) limited our ability to fully assess the predictive nature of transportation time on H-LOS. Further, this was a retrospective, single institutional study.

Although the mean transportation time in this study was 90 minutes, while the median time was 65 minutes, patient residency was not assessed, therefore it is difficult to distinguish the proportion of the model population which came to the trauma center from a rural community. However, as the mean and median times approximate one another and both exceed one hour, the statistics suggest that a larger proportion of patients in this study came from a rural setting.

Physician preference and standard of care were used to determine treatment group as the population under study was regarded retrospectively. Injury grades were collected, but only for those patients who received either POR, SAE, or were FNOM. Inclusion of injury grades would allow for a comparison of incidence of FNOM in a rural setting inclusive of one of the most predictive variables in literature. In addition, while SBP was assessed for its ability to predict risk of prolonged H-LOS, patients who were hemodynamically unstable were included in the study regardless of assigned treatment group. Furthermore, no distinction was made regarding presence or size of hemoperitoneum, presence of alcohol or drugs, or for patient comorbidities. Patients were included who sustained both isolated splenic trauma, as well as poly-trauma including head injury. Similarly, OPSI was not assessed as a confounder to patient outcomes although previous studies have demonstrated that injury grade, OPSI, and hemodynamic stability are all predictive for shorter H-LOS.[1]

Although deaths (n=40) were censored prior to the Cox Proportional Hazard analysis, they were not analyzed to determine cause of death. As the study population (n=354) contained both isolated and non-isolated splenic injuries, death could have occurred due to complications of, or directly associated to, other injury. Perhaps of more significance is missing information related to the transfer status of those patients whose records were included in the model as no clear chronological order of events prior to arrival at the trauma center was assessed.

Without a clear chronological understanding of those efforts made on the part of EMS personnel prior to admission at a trauma center, generalizations regarding patient care are limited.

## Conclusions

While not predictive of decreased hospital length of stay (H-LOS) or mortality regardless of treatment group, prolonged transportation time following traumatic splenic injury in a rural state allows physiologic symptoms to manifest prior to admission and reduced the number of FNOMs. The ability to more accurately predict the need for NOM in rural populations, based on prolonged transportation time, may alter what is currently believed about the H-LOS following splenic injury in rural communities. We recommend intensive observation less than 24 hours following admission, with less robust surveillance through hospital day two. Discharge can be considered on hospital day three based on other injuries.

## References


1. Ledbetter S, Smithuis R. Acute Abdomen - Role of CT in Trauma. Radiology Assistant. http://www.radiologyassistant.nl/en/p466181ff61073/acute-abdomen-role-of-ct-in-trauma.html. Accessed 03-10-14.
2. Davis JJ, Cohn I Jr, Nance FC. Diagnosis and management of blunt abdominal trauma. Ann Surg 1976, 183:672.
3. American College of Surgeons. National Trauma Data Bank (NTDB). https://www.ntdbdatacenter.com. Accessed 11-01-13.
4. Kodikara S. Death due to hemorrhagic shock after delayed rupture of spleen: a rare phenomenon. Am J Forensic Med Pathol 2009, 30:382-383.
5. Carlin AM, Tyburski JG, Wilson RF, Steffes C. Am Surg. Factors affecting the outcomes of patients with splenic trauma. 2002, Mar;68(3):232-9.
6. Brady RR, Bandari M, Kerssens JJ, Paterson-Brown S, Parks RW. Splenic trauma in Scotland: demographics and outcomes. World J Surg. 2007, Nov;31(11):2111-6.
7. Gomez D, Haas B, Al-Ali K, Monneuse O, Nathens AB, Ahmed N. Controversies in the management of splenic trauma. Injury. 2012, Jan;43(1):55-61.
8. Gonzalez RP, Cummings G, Mulekar M, Rodning CB. Increased mortality in rural vehicular trauma: Identifying contributing factors through data linkage. J Trauma. 2006;61(2):404-409.
9. Nordstrom DL, Zwerling C, Stromquist AM, Burmeister LF, Merchant JA. Rural population survey of behavioral and demographic risk factors for loaded firearms. Inj Prev. 2001;7(2):112-116.

10. McSwain N, Rotondo M, Meade P, Duchesne J. A model for rural trauma care. Br J Surg. 2012;99(3):309-314.

11. Peek-Asa C, Zwerling C, Stallones L. Acute traumatic injuries in rural populations. Am J Public Health. 2004;94(10):1689-1693.

12. United States Department of Commerce. 2010 United States Census. www.census.gov. Accessed 03-27-14.

13. Hsia R, Shen YC. Healthcare outcome disparities in trauma care. Arch Surg. 2011;146(1):46-52.

14. Kansas Department of Health and Environment, Office of Rural Health. www. kdheks.gov/olrh/rural.html. Accessed 03-27-14.

15. PCORI. University of North Carolina at Chapel Hill. Research Prioritization Topic Brief. Topic 10: Rural trauma care. http://www.pcori.org/assets/PCORI-Addressing-Disparities-Topic-Brief-10-0416132.pdf. Accessed 03-06-14.

16. American College of Surgeons. http://www.facs.org. Accessed 03-04-14.

17. Health Resources and Services Administration. Defining the Rural Population. http://www.hrsa.gov/ruralhealth/definition_of_rural.html. Accessed 03-0614.

18. American College of Surgeons Committee on Trauma. Resources for optimal care of the injured patient. Chicago, IL: American College of Surgeons; 1999. http://www.facs.org/trauma/publications.html. Accessed 03-04-14.

19. MacKenzie EJ, Hoyt DB, Sacra JC, et al. National inventory of hospital trauma centers. JAMA. 2003;289(12):1515-1522.

20. Esposito T, Maier R, Rivera F, Griffith J, et al. The impact of variation in trauma care times: urban versus rural. Prehosp Disaster Med. 1995;10(3):161-6.

21. Sasser SM, Hunt RC, Faul M, et al. Guidelines for field triage of injured patients: Recommendations of the national expert panel on field triage. 2011. MMWR Recomm Rep. 2012;61(RR-1):1-20.

22. ACEP 2014 EM Report Card. www.emreportcard.org/Kansas. Accessed 03-20-14.

23. Van der Vlies CH, van Delden OM, Punt BJ, Ponsen KJ, Reekers JA, Goslings JC. Literature review of the role of ultrasound, computed tomography, and transcatheter arterial embolization for the treatment of traumatic splenic injuries. Cardiovasc Intervent Radiol. 2010 Dec;33(6):1079-87.

24. Natarajan B, Gupta PK, Cemaj S, Sorensen M, Hatzoudis GI, Forse RA. FAST scan: Is it worth doing in hemodynamically stable blunt trauma patients. Surgery. 2010 Oct;148(4):695-700; discussion 700-1.

25. American Association for the Surgery of Trauma. Spleen injury grading scale. http://www.aast.org/library/traumatools/injuryscoringscales.aspx#spleen. Accessed 03-10-14.

26. Trauma.org. http://www.trauma.org/archive/scores/iss.html. Accessed 03-10-14.

27. Bruce PJ, Helmer SD, Harrison PB, Sirico T, Haan JM. Nonsurgical management of blunt splenic injury: Is it cost effective? Am J Surg. 2011;202(6):810-5; discussion 815-6.

28. Stassen NA, Bhullar I, Cheng JD, Crandall ML, et al. Journal of Trauma and Acute Care Surgery. 2012;73(5):294–300.

29. Stassen NA, Bhullar I, Cheng JD, Crandall ML, et al. Selective nonoperative management of blunt splenic injury: an Eastern Association for the Surgery of Trauma practice management guideline. J Trauma Acute Care Surg. 2012, Nov;73(5 Suppl 4):S294-300.

30. OPSI. Antimicrobe.org. http://www.antimicrobe.org/new/printout/e30printout/e30diag.htm. Accessed 03-10-14.

31. Demetriades D, Murray J, Charalambides K, Alo K, Velmahos G, Rhee P, et al. Trauma fatalities: Time and location of hospital deaths. J Am Coll Surg 2004;198:20–6.

32. Howell G, Peitzman AB, Nirula R, Rosengart M, Alarcon LH, Billiar, TR, et al. Delay to therapeutic interventional radiology following injury: Time is of the essence. J Trauma. 2010 Jun;68(6):1296-300

33. Trunkey DD. Trauma. Sci Am 1983;259(2):20 –7.

34. Wyatt J, Beard D, Gray A, et al. The time of death after trauma. Br Med J 1995;310(6993):1502.

35. Müller TS, Sommer C. Traumatic splenic injury. Ther Umsch. 2013;70(3):177-84.

36. Haan JM, Bochicchio GV, Kramer N, Scalea TM. Nonoperative management of blunt splenic injury: a 5-year experience. J Trauma. 2005;58(3):492-8.

37. Harbrecht BG, Peitzman AB, Rivera L, Heil B, et al. Contribution of age and gender to outcome of blunt splenic injury in adults: multicenter study of the Eastern Association for the Surgery of Trauma. J Trauma. 2001;51(5):887-95.

38. Chen IC, Wang S, Hsin-Chin S, et al. Spleen artery embolization increases the success of nonoperative management following blunt splenic injury. J Chin Med Assoc. 2011;74(8):341-4.

39. Peitzman AB, Heil B, Rivera L, et al. Blunt splenic injury in adults: Multi-institutional Study of the Eastern Association for the Surgery of Trauma. J Trauma 2000;49:177-87; discussion 187-9.

40. Pachter HL, Guth AA, Hofstetter SR, Spencer FX. Changing patterns in the management of splenic trauma. Ann Surg. 1998;227:708-719.

41. Bhullar IS, Frykberg ER, Siragusa D, Chesire D, Paul J, Tepas JJ 3rd, Kerwin AJ. Selective angiographic embolization of blunt splenic traumatic injuries in adults decreases failure rate of nonoperative management. J Trauma Acute Care Surg. 2012;72(5):1127-34.

42. Haan JM, Bochicchio GV, Kramer N, Scalea TM. Nonoperative management of blunt splenic injury: a 5-year experience. J Trauma. 2005;58(3):492-8.

43. Velmahos GC, Zacharias N, Emhoff TA, et al.. Management of the most severely injured spleen. Arch Surg. 2010;145: 456–460.

44. Dent D, Alsabrook G, Erickson BA et al. Blunt splenic injuries: High non-operative management rate can be achieved with selective embolization. J Trauma. 2004;56:1063-1067.

45. Haan J, Scott J, Boyd-Kranis RL, et al. Admission angiography for blunt splenic injury: Advantages and pitfalls. J Trauma. 2001;51: 1161–1165.

46. Liu PP, Lee WC, Cheng YF, et al.. Use of splenic angioembolization as an adjunct to nonsurgical management of blunt splenic injury. J Trauma. 2004;56: 768–773.

47. Hagiwara A, Fukushima H, Murata A, et al. Blunt splenic injury: Usefulness of trans catheter arterial embolization in patients with a transient response to fluid resuscitation. Radiology. 2005;235:57–64.

48. Haan J, Obeid NI, Kramer M, Scalea TM. Protocol-driven non-operative management in patients with blunt splenic trauma and minimal associated injury decreases length of stay. J Trauma. 2003;55: 317–322.
49. Mayglothling JA, Haan JM, Scalea TM. Blunt splenic injuries in the adolescent trauma population: the role of angiography and embolization. J Emerg Med. 2011;41(1):21-8. 50
50. Archer LP, Rogers FB, Shackford SR. Selective non-operative management of liver and spleen injuries in neurologically impaired adult patients. Arch Surg. 1996; 131:309–315.
51. Cocanour CS, Moore FA, Ware DN, Marvin RG, Duke JH. Age should not be a consideration for non-operative management of blunt splenic injury. J Trauma. 2000; 48: 606–612.
52. Falimirski ME, Provost D. Nonsurgical management of solid abdominal organ injury in patients over 55 years of age. Am Surg. 2000; 66: 631–635.
53. Sharma OP, Oswanski MF, Singer D, et al. Assessment of non-operative management of blunt spleen and liver trauma. Am Surg. 2005; 71: 379–386.
54. Bee TK, Croce MA, Miller PR, et al. Failure of splenic non-operative management: is the glass half empty or half full? J Trauma. 2001; 50:230–236.
55. Nix JA, Costanza M, Daley BJ, et al. Outcomes of the current management of splenic injuries. J Trauma. 2001; 50: 835–842.
56. Gaunt WT, McCarthy MC, Lambert CS, et al. Traditional criteria for observation of splenic trauma should be challenged. Am Surg. 1999; 65: 689–691.
57. Siriratsivawong K, Zenati M, Watson GA, et al. Non-operative management of blunt splenic trauma in the elderly: does age play a role? Am Surg. 2007; 73: 585–590.

58. Wallis A, Kelly MD, Jones L. Angiography and embolization for solid abdominal organ injury in adults: A current perspective. World J Emerg Surg. 2010; 5: 18.

59. Cathey KL, Brady WJ Jr, Butler K. Blunt splenic trauma: characteristics of patients requiring urgent laparotomy. Am Surg. 1998; 65: 450–454.

60. Gavant ML1, Schurr M, Flick PA, Croce MA, Fabian TC, Gold RE. Predicting clinical outcome of nonsurgical management of blunt splenic injury: Using CT to reveal abnormalities of splenic vasculature. AJR Am J Roentgenol. 1997 Jan; 168(1):207-12.

61. Smith A, Ouellet JF, Niven D, Kirkpatrick AW, Dixon E, D'Amours S, Ball CG. Timeliness in obtaining emergent percutaneous procedures in severely injured patients: how long is too long and should we create quality assurance guidelines? Can J Surg. 2013 Dec;56(6):E154-7.

62. Watson GA, Rosengart MR, Zenati MS, Tsung A, Forsythe RM, Peitzman AB, Harbrecht BG. Nonoperative management of severe blunt splenic injury: are we getting better? J Trauma. 2006 Nov; 61(5):1113-8; discussion 1118-9.

63. American College of Surgeons Committee on Trauma. ATLS Student course material - Advanced Trauma Life Support for doctors. Eighth Edition. 2008. Chicago.

64. Haan JM, Marmery H, Shanmuganathan K, et al.. Experience with splenic main coil embolization and significance of new or persistent pseudoaneurysm: Re-embolize, operate, or observe. J Trauma. 2007; 63: 615–619.

65. Harbrecht BG, Ko SH, Watson GA, et al.. Angiography for blunt splenic trauma does not improve success rate of non-operative management. J Trauma. 2007; 63: 44–49.

66. Peitzman AB, Narbrecht BG, Rivera L. Heil B. Failure of observation of blunt splenic injury in adults: variability in practice and adverse consequences. J Am Coll Surg. 2005; 201: 179–187.

67. Bhangu A, Nepogodiev D, Lal N, Bowley DM. Meta-analysis of predictive factors and outcomes for failure of non-operative management of blunt splenic trauma, Injury, 2012;43(9):1337-1346.

68. Trunkey DD. Trauma. Sci Am 1983;259(2):20 –7.

69. Jeremitsky E, Smith RS, Ong AW. Starting the clock: defining non-operative management of blunt splenic injury by time. The American Journal of Surgery. 2013; Mar:205, 298-301.

70. Improving Americas Hospitals. The Joint Commissions Annual Report on Quality and Safety 2013. http://www.jointcommission.org/assets/1/6/TJC_Annual_Report_2013.pdf Accessed 03-15-14.

71. Health Resources and Services Administration. Defining the Rural Population. http://www.hrsa.gov/ruralhealth/definition_of_rural.html. Accessed 03-06-14.

72. Hoskins W, Jacob A, Wijeratne S, Campbell I et al. Splenic injury admitted to a rural Level 3 trama centre: A 10-year audit. Aust J Rural Health. 2013 Jun;21(3):163-9.

73. Olthof DC, Joosse P, van der Vlies CH, de Haan RJ, Goslings JC. Prognostic factors for failure of non-operative management in adults with blunt splenic injury: A systematic review. J Trauma Acute Care Surg. 2013; Feb;74(2):546-57.

# Appendices

*KU IRB Approval Letter*

KU SCHOOL OF MEDICINE WICHITA
The University of Kansas

January 8, 2014

| | |
|---|---|
| **HSC Number:** | **220131620VC** |
| **Project Title:** | **Predictive Factors of Outcomes for Failed Non-Operative Management of Splenic Trauma: Does Transportation Time to Hospital Matter** |
| **Primary Investigator:** | **Ablah, Elizabeth PhD, MPH** |
| **Protocol Number:** | **Version 2; 11-25-2013** |
| **Sponsor:** | **NA** |
| **Status:** | **Approved to rely on Via Christi** |

Dear Investigator:

This is to certify that the KUSM-W Office of Compliance has reviewed your research proposal and has determined that your project meets the criteria for reliance upon Via Christi IRB.

You may only start the study after it has been approved by the Via Christi IRB. From this point forward, please submit all documents related to this project to Via Christi for IRB approval.

If you have any questions regarding the human subject protection process, please do not hesitate to contact me at (316) 293-2610 or jryan3@kumc.edu.

Sincerely,

Jamie Ryan, BA
Office of Compliance

**Office of Compliance**
1010 N. Kansas I Wichita, KS 67214-3199 I (316) 293-2600 I Fax (316) 293-2628

*Via Christia IRB Approval*

**Study Title:** Predictive Factors of Outcomes For Failed Non-Operative Management of Splenic Trauma: Does Transportation Tiem to Hospital Matter.
**Principal Investigator:** Jeanette Ward (VC Site) Elizabeth Ablah (KU Site)
**Date of Submission:** 12/2/2013
**Protocol Date:** 11/25/2013
**Page 1 of 2**

KU-YC1620

# Via Christi Hospitals Wichita, Inc. Institutional Review Board

## IRB Reviewer Findings

**IRB REVIEWER RECOMMENDATIONS**

The above research project has been reviewed by me and I find the study to meet the qualifications for Exempt Research in the following category(s):

___1. Normal Education Practices and Settings as based on________________________________

___2. Anonymous Educational Tests, Surveys, Interviews, or Observations as based on ______________

___3. Identifiable Subjects in Special Circumstances as based on____________________________

X 4. Collection or Study of Existing Data as based on ________________________________

___5. Public Benefit or Service Programs as based on ________________________________

___6. Taste and Food Evaluation and Acceptance Studies as based on ________________________

**Informed Consent is** [ ] Required [X] Not Required

**Reviewer:** [signature] **Review Date** 12/12/13

**Study Title:** Predictive Factors of Outcomes For Failed Non-Operative Management of Splenic Trauma: Does Transportation Tiem to Hospital Matter.
**Principal Investigator:** Jeanette Ward (VC Site) Elizabeth Ablah (KU Site)
**Date of Submission:** 12/2/2013
**Protocol Date:** 11/25/2013
**Page 2 of 2**

**VCH-W IRB USE ONLY** [X] Approved under Exempt Status Category # 4

**THIS SIGNIFIES NOTIFICATION OF IRB APPROVAL OF THE PROJECT DESCRIBED ABOVE.**

[ ] Disapproved for Exempt Status; Informed Consent Required

This is to confirm that the following member(s) of the Institutional Review Board abstained from voting on any submissions for the above mentioned study; ______________________

**IRB Chair:** [signature] **Date** 12/12/13

*PowerPoint*

## Transportation time in a rural state following splenic injury: does time matter

Jeanette Ward, BA
Frank Dong, PhD - Chair
Elizabeth Ablah, PhD, MPH
Robert Hines, PhD
James Haan, MD

## Acknowledgments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- James Haan, M.D., FACS
  - Assistant Professor
  - Medical Director of Trauma Services, Via Christi Health

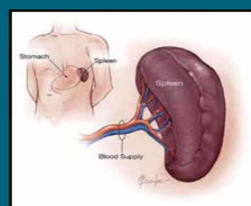

2

## Background

3

## The Spleen

- The spleen is a highly vascular organ located in the upper left quadrant of the abdomen under the ribs[1]




4

Brender E, Burke A, Glass R.

## Function

- The spleen was once considered a useless organ
- It is actually the largest secondary immune organ
- The red pulp performs "quality control" and filters aging or damaged red cells and platelets
- The white pulp initiates immune responses

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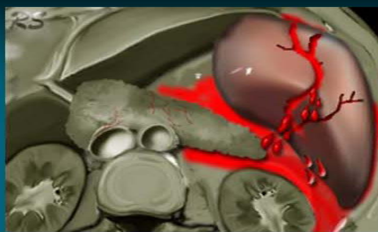
## Arterial Supply

- The spleen holds approximately 10 to 15% of the body's blood at any given time
- The splenic artery is a major blood supply source
- Since it is the largest of 3 arteries branching from the celiac trunk it is directly tied to the abdominal aorta

6



The spleen is the intra-abdominal organ which is most frequently (60%) injured during blunt trauma

Courtesy of Ledbetter S, Smithuis R. Acute Abdomen - Role of CT in Trauma

7

## Epidemiology

- In 2011, approximately 4,000 splenic injuries were reported to the National Trauma Databank[3]
- These represent only those severe enough to result in a trauma activation
- Mortality rates for blunt injuries: 1 to 15%[4]
- Mortality rates for penetrating injuries: 8 to 24%[4]

Kodikara S. *Am J Forensic Med Pathol* 2009; 30:382-383.,
Carlin AM, Tyburski JG, Wilson RF. *Am Surg.* 2002 Mar;68(3):232-9.

8

## Mechanism of Injury

Common mechanisms include:[5]

- Motor vehicle accidents
- Falls
- Assaults
- Sports-related accidents
- Less than 10% are the result of penetrating injuries including GSWs, knives, and atypical occupational, recreational or home accidents

Brady RR et al., World J Surg. 2007 Nov;31(11):2111-6.

9

## Risks Following Injury

- Persistent or recurrent bleeding (typically starts less than 2 days from injury)
- Hemoperitoneum
- Compensated or uncompensated shock
- OPSI: overwhelming post-splenectomy infection
- Death from exsanguination

10

## Identified Risk Factors

- Hemodynamic status
- Injury grade and severity
- Patient age
- Size of hemoperitoneum
- Presence of blush on CT
- Associated injuries
- Medical history and concomitant medications
- Available resources

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## Special Populations

- Splenic injuries in rural states are largely understudied
- However, in the United States, 59.4 million people live in a rural setting (19.3%)[6]
- More elderly and children live in rural rather than urban environments[6]
- 60% of trauma deaths are associated with <20% of the U.S. population[6]

Hsia R, Shen YC. *Arch Surg.* 2011;146(1):46-52.

12

## Rural Environment: Definition

- The U.S. government has at least 15 different definitions for "rural"[7]
- The 2010 Census Bureau's urban-rural classification was based on geographical areas[7]
- "Rural" are those populations not classified as an urban areas > 50,000 people, or as any place outside a town, city or urban cluster > 2,500 people[7]
- In Kansas, rural areas are home to two-thirds of the state's population (approximately 1.2 million people)[8]

U.S. Department of Commerce. 2010 United States Census.
Kansas Department of Health and Environment

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## Hospitals in Rural Environments

Three types of medical facilities:

- Trauma Centers: Levels I – IV
- Regional Hospitals
- Critical Access Hospitals

These facilities receive and treat patients who live in both rural and urban areas of the state

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## Kansas Report Card

- In 2014, the American College of Emergency Physicians ranked Kansas 44th in the nation for Quality and Patient Safety Environment initiatives[9]
- The leading contributor was identified as a lack of emergency medical services (EMS) guidelines and protocols which have been identified as a challenge for the rural areas of the state

Kansas - ACEP 2014 EM Report Card.

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## Risk of Death After Splenic Trauma specific to Rural Environments

- Increased exposure to high risk mechanisms[10,11]
  - MVA with or without alcohol
  - Prevalence of unlocked firearms
  - Agricultural accidents
- Delays to definitive care[10,11]
  - Longer response and transportation time
  - 3 of 10 rural patients versus 1 of 10 urban patients live > 1 hour from a trauma center
  - Delays in receiving care are twice as long
- Fewer resources to perform advanced trauma measures[10,11]
  - Ratio per patient of trauma surgeons & centers between rural and urban settings is 6:1
  - Critical Access and Regional Hospitals
- Timely access to trauma centers leads to 25% fewer mortalities[12]

Wyatt J, Beard D, Gray A, Busuttil A, Robertson C. The time of death after trauma.
Hoskins W, Jacob A, Wijeratne S, Campbell I et al. Splenic injury admitted to a rural Level 3 trauma centre: a 10-year audit):163-9.
American Association for the Surgery of Trauma

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## Rural Environments

Limited rural trauma studies were found following a robust literature search of more than 250 articles

| Number of Studies | Trauma Center Level | Trauma Population | Year Published |
|---|---|---|---|
| 1 | All levels | All populations | 2011 |
| 1 | Level I | Splenic traumas | 1997 |
| 1 | Level 3 | All traumas | 2007 |
| 1 | Level 3 | Splenic traumas | 2013 |
| 4 | Rural hospital ER emergencies | All traumas | 1995, 2004, 2006, 2013 |

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## Spleen Injury Literature in a Rural Environment

- Limited attempts have been made in the U.S. to extend an urban-based trauma system into the rural environment[10]
- 17 years have lapsed since the last report specific to spleen injuries treated at a rural Level I trauma center

Implication: It is possible current splenic trauma literature may not be generalizable to the one fifth of the U.S. population who account for 60% of traumatic deaths

McSwain N, et al., A model for rural trauma care. 2012 Mar;99(3):309-11.

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## Evaluation For Type of Spleen Injury

The goal of evaluation is twofold:

1. Quickly identify those at highest risk for persistent bleeding
2. Minimize the need for operative intervention due to operative and post-operative risks

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## Evaluation Basics

| Parameter | Need to obtain or identify |
|---|---|
| Hemodynamic status | Repeated blood pressures |
| Other injuries/spleen injury grade | CT, xray, palpitation, F.A.S.T. |
| Blunt injury | Force/direction-deceleration/compression |
| Penetrating injury | Type of weapon or instrument |
| Medical history | Presence of spleen, bleeding disorders |
| Concomitant medications | Consider blood thinners in elderly |
| Diminished mental status | Medications which can mimic |
| Labs | None specific to splenic injury |

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## Presentation of Splenic Injury

- Classic patient presentations often include left rib fractures (10-12)
- Triad of:
  - Left hemidiaphragm elevation
  - Left lower lobe collapse
  - Pleural effusion

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## Hemodynamic Stability

- Unstable
  SBP < 90mmHg
  HR > 120 bpm
- Life-threatening situation:
  - Hemodynamically unstable
  - Unresponsive to fluid challenge such as normal saline or blood products
  - No other signs of external hemorrhage

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## Purpose of Diagnostics

Determine Injury Type
- Bruised
- Torn
- Cut
- Ruptured
- Shattered

Determine Injury Location
- Capsule
- Artery or vein
- Other

Determine Injury Severity
- Injury severity score (ISS)
- Injury grade

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## Injury Grade

- Grading is determined according to American Association for the Surgery of Trauma (AAST) guidelines (5 levels):[12]

**Box 1. American Association for the Surgery of Trauma (AAST) guidelines for organ injury scaling for the spleen**

| AAST grade* | Type | Description of injury |
|---|---|---|
| I | Hematoma | Subcapsular, < 10% of surface area |
| | Laceration | Capsular tear, < 1 cm of parenchymal depth |
| II | Hematoma | Subcapsular, 10%–50% of surface area<br>Intraparenchymal hematoma, <5 cm in diameter |
| | Laceration | 1–3 cm in parenchymal depth not involving a parenchymal vessel |
| III | Hematoma | Subcapsular, > 50% of surface area or expanding; ruptured subcapsular or parenchymal hematoma<br>Intraparenchymal hematoma, >5 cm in diameter |
| | Laceration | > 3 cm parenchymal depth or involving trabecular vessels |
| IV | Laceration | Laceration of segmental or hilar vessels producing major devascularization (> 25% of spleen) |
| V | Laceration | Completely shattered spleen<br>Vascular hilar injury that devascularized the spleen |

*Advance 1 grade for multiple injuries to the same organ, up to grade III.

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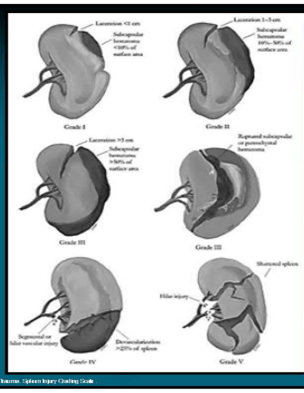
Injury Grades I – V[12]




American Association for the Surgery of Trauma. Spleen Injury Grading Scale.

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## Diagnostic Tests

| Test | Used to Detect |
|---|---|
| F.A.S.T. Exam | ▪ Presence of blood using ultrasound<br>▪ Not sensitive for identification of injuries |
| Diagnostic peritoneal lavage (DPL) | ▪ Presence of blood using an abdominal catheter<br>▪ Not sensitive for identification of injuries |
| Computed tomography (CT) | ▪ Sensitive and specific<br>▪ Presence of blush, pseudoaneurysm, occlusion<br>▪ Determination of injury grade<br>▪ Requires contrast |
| Interventional radiology (angiography) | ▪ Pinpoints location and size of bleeds<br>▪ Can precede embolization |

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Contrast extravasation in a lacerated spleen

Courtesy of the Society of Cardiovascular and Interventional Radiology. Interventional Radiology for Vascular and Solid Organ Trauma

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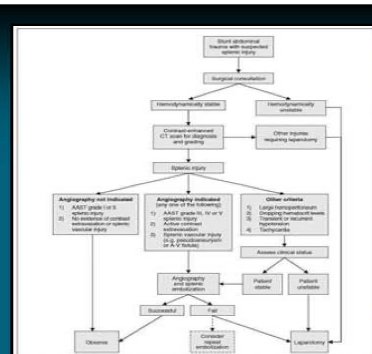
AAST Treatment Algorithm[12]

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American Association for the Surgery of Trauma. Spleen Injury Grading Scale.

## Factors in Treatment Decisions

- Assessment of known risk factors and injuries to determine need for operative therapy and whether a patient is a good or poor operative candidate

American College of Surgeon (ACS) treatment decision guidelines:

- Operative < 90 minutes
- NOM < 2 hours (although no consensus on how to measure the start of NOM)
- In 2012 Jeremitsky et al., attempted to quantify start of NOM to standardize reporting in literature and reported the start as 5 hours with an accepted 5% failure rate[29]

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Jeremitsky E, et al., *The American Journal of Surgery* (2013) 205, 298-301

## Treatment Types

- Observation
- Surgery
- Non-operative

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## Treatment Options

| Operative | Non-operative |
| --- | --- |
| Splenectomy | Angiography without embolization |
| Partial splenectomy | Splenic Angioembolization (SAE) |
| Splenorrhaphy (repair) | Observation |

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## Planned Operative Treatment (POR)

- Acute POR is institutionally dependent and used in 18% to 40% of cases[13]
- Recommended for those patients who are:
  - Hemodynamically unstable
  - Unresponsive to fluid challenge
  - Signs absent for other external hemorrhage
  - Injury grades IV-V

Stassen NA, et al., Selective nonoperative management of blunt splenic injury: an Eastern Association for the Surgery of Trauma practice management guideline. 32

## Focus on Splenectomy

- 1893: 1st splenectomy reported in literature
- Once considered the only acceptable treatment for all splenic injuries
- High mortality rate through the 1950's

Courtesy of Dr. Nedal Malar, Saudi Arabi - Riyadh, May 05, 2001

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## Overwhelming Post-Splenectomy Infection (OPSI)

- High concern following splenectomy
- Life-long and life-threatening with sudden onset (50% of deaths will occur in less than 2 days)
- 3% of splenectomy patients
- Incidence has decreased since the advent of pneumococcal vaccine
- Symptoms: fever, nausea, headache, altered mental status

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## Other After-effects of Splenectomy

- Infection (following minor illness, invasive medical procedures, dental work)
- Travel (vaccine recommendations)
- Research continues into the immunologic side effects of partial splenectomy and splenorrhaphy

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## Non-operative Treatment: NOM

- Includes:
  - Less-invasive procedures (Angiography or SAE)
  - Observation
- 8 out of 10 cases with 95% success rate[15]
- Used to manage 50 to 70% of lower grade injuries[15]
- Appropriate for:
  - Hemodynamically stable
  - Physical examination is nonspecific and insensitive
  - Absence of extravasation on CT
  - No higher acuity injuries
  - Medical history without risk for bleeding
  - AE/SAE injury grades III or greater

Stassen NA, et al., Selective nonoperative management of blunt splenic injury: an Eastern Association for the Surgery of Trauma practice management guideline. 36

## Focus on AE and SAE

- Average time to angiography (AE or SAE) is approximately 4 hours although times range from .5 to 13 hours
- Not all arteries are eligible for embolization (SAE)
- SAE Agents: gelfoam (temporary) or coils (permanent)

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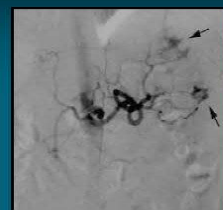
## Angioembolization (SAE)



Evidence of persistent hemorrhage

No evidence of further extravasation

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## SAE Controversy

- Treatment choice seems clear cut--not so
- Controversy continues despite 30 years of research
- The controversy is spurred by two schools of thought:
  1. Surgeons who are convinced embolization is safe and efficacious
  2. Those who remain skeptical

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Efficacy of splenic embolization

| Author, yr | Study type | No. of patients embolized | Indications | Type of embolization | Overall success of NOM, % | Success of embolization, % |
|---|---|---|---|---|---|---|
| Sclafani et al. 1995 | Prospective | 60 | Arterial extravasation on admission angiography | Proximal, distal, or both | 97 (AAST IV: 84) | 93 |
| Hagiwara et al. 1996 | Prospective | 15 | Angiographic evidence of arterial extravasation and/or arterial disruption or major arteriovenous fistula | Proximal, distal, or both | 93 | 87 |
| Davis et al. 1998 | Retrospective | 26 | Contrast blush on CT, confirmed as a parenchymal pseudoaneurysm on angiography | Distal | 94 | 77 (technical failure) |
| Haan et al. 2001 | Retrospective | 40* | Celiac angiography in all stable patients with splenic injury as seen on CT scan; those with proven vascular injury (arteriovenous fistula, pseudoaneurysm or contrast extravasation) underwent embolization | Proximal, distal, or both | 92 (AAST IV–V: > [illegible] | [illegible] |
| Haan et al. 2003 | Retrospective | 35 | Angiography for all grade III–V injuries as seen on CT scan, or any grade if there was evidence of intraparenchymal vascular injury | Proximal, distal, or both | 100 | [illegible] |
| Haan et al. 2004 | Retrospective, multicentre review (4 institutions) | 140 | Pseudoaneurysm or active bleeding on CT scan obtained at the time of admission; or significant hemoperitoneum and high-grade splenic injury/vascular injury as seen on CT scan | Proximal, distal, or both | 87 (AAST IV–V: [illegible] | [illegible] |
| Haan et al. 2005 | Retrospective | 132 | Angioembolization for all grade III–V injuries as seen on CT scan, or any grade if evidence of intraparenchymal vascular injury | Proximal, distal, or both | 94 (AAST IV–V: > [illegible] | [illegible] |
| Liu et al. 2004 | Prospective | 6 | Significant hemoperitoneum or extravasation of contrast media as seen on CT scan, grade IV or V splenic injury, falling hematocrit level and progressive need for blood transfusions, and recurrent hypotension despite fluid resuscitation | Distal | 89 | 87 |
| Dent et al. 2004 | Retrospective | 13 | No formal algorithm was used; however, indications included splenic vascular blush, persistent tachycardia and a falling hematocrit level (that could not be explained by other injuries) | Distal | 98 | 92 |
| Smith et al. 2006 | Retrospective | 41 | Arterial blush as seen on CT scan | Proximal or distal | 86 | 73 |
| Bessoud et al. 2006 | Retrospective | 37 | Grade II–V splenic injury, or evidence of contrast extravasation or blush as seen on CT scan | Proximal | 94 | 97 |

AAST = American Association for the Surgery of Trauma; CT = computed tomography; NOM = nonoperative management.
*Of 126 who underwent angiography.
†One patient bled and required repeat angiography with embolization, but did not require laparotomy.

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## Complications From SAE

- Infarction (tissue death) or abscess
- Artery dissection
- Cysts
- Contrast-induced renal insufficiency
- Left-sided pleural effusions
- Coil migration
- Fever

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## Cost of Treatment Choice

- Dependent on associated injuries
- Average hospitalization charges following splenic injury is $14,000
- Haan et al. (2011) assessed differences between POR and SAE and reported higher charges for POR ($28,709) versus SAE ($19,062), p=0.016
- No statistical difference was reported H-LOS

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## What Happens When NOM Does Not Work?

- When hemorrhage resumes or escalates it may be necessary to intervene outside of the 90 to 120 minute mark
- May need to:
  1) Repeat or perform AE/SAE
  2) Perform AE/SAE in combination with one of the 3 types of operative procedures
- Failure of non-operative management (FNOM)

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## FNOM

- Occurs in 8% to 38% of cases with 60 to 96% success rates
- Often due to latent manifestation of symptoms rather than inappropriate treatment choice
- Risk factors:
  - Hemodynamically unstable
  - ISS 25 and greater
  - Injury grades III to V
  - Ages 40 and greater
  - Longer I-LOS and H-LOS
  - Other intra-abdominal injury
  - Developing active extravasation
  - Large volume hemoperitoneum

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## FNOM

Injury grades associated with frequency of adult FNOM:

| Grade | % FNOM |
|---|---|
| I | 5% |
| II | 10% |
| III | 20% |
| IV | 40% |
| V | 75% |

Failure rates increase among patients with higher acuity injuries that are first triaged as NOM

45

## FNOM: Time as a Predictor

- Time from admission as a predictor for FNOM:[16-17]
  - 75% of failures occur within 48 hours
  - 88% within 5 days
  - 93% within one week

Peitzman AB, Harbrecht BG, Rivera L, Heil B. Failure of observation of blunt splenic injury in adults: variability in practice and adverse consequences.

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## Mortality: Time as a Predictor

- In 1995, Wyatt et al. assessed the time to death following injury inclusive of transportation time[19]
- In their study, the spleen was one of many organs assessed
- Wyatt reported most post admission splenic deaths occurred between hours 1 to 6

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Wyatt J et al., The time of death after trauma.

## Transportation Time

- Like splenic injury in a rural setting (which is understudied) transportation time as a predictor of any outcome following splenic trauma has not been studied for 19 years

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## Review of the Problem

- Splenic injuries are highly prevalent and can quickly become life-threatening
- POR carries immunologic ramifications and a higher cost than AE or SAE
- Controversy over SAE: are failure rates too high
- How can FNOM be measured given the ambiguity related to start of NOM and lack of data on transport time
- Do one-size-fit-all recommendations fit the rural patient population

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## Concerns

- In rural states, prolonged transportation times often exceed 20 minutes
- Failure to include prolonged transportation times in risk assessments for splenic injury may affect our ability to predict patient mortality and prevent FNOM's
- Current predictive models are based on populations which may fail to account for the unique characteristics of the rural environment

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## Research Questions

1. What is the predictive effect of transportation time on mortality, and therefore survivability, among those patients with traumatic splenic injury in a rural state
2. What is the predictive effect of transportation time on H-LOS in patients with traumatic splenic injury in a rural stae
3. What is the effect of transportation time on the incidence and outcomes following FNOM, among the splenic-injured population in a rural state

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## Purpose of the Study

To evaluate the effect of transportation time on patients with splenic injury in a rural environment

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## Methods

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## Methods

- Design
  - 10-year retrospective cohort
- Study period
  - January 2003 to December 2012
- Patient care setting
  - Via Christi Health – St. Francis Trauma Center
- IRB approved (12-12-13, 01-14-14)
  - Via Christi Health Institutional Review Board
  - University of Kansas School of Medicine – Wichita Human Subjects Committee

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## Inclusion / Exclusion Criteria

| Inclusion Criteria (eligible to participate) | Exclusion Criteria (ineligible to participate) |
|---|---|
| • ICD-9-CM-identified splenic injury, codes 865 to 865.19 | • Patients who arrived with no signs of life or died within two hours of arrival |
| • Ages 13 and older | • Patients who arrived via private vehicle or walked into the hospital |
| • Admitted to Via Christi Hospital on St. Francis between January 2003 and December 2013 | |

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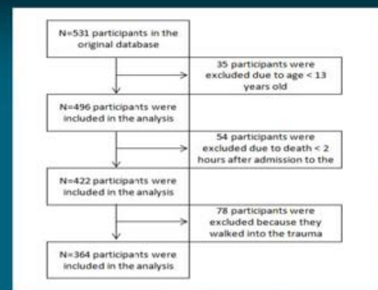
## Sample Size Flow Chart

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## Definition – Populations

- Aggregate Population:
  - N=364 were those patients who met inclusion criteria
- Model Population:
  - n=155 were those patients who had a valid transportation time documented in EMS records
  - n=209 were those patients who did not have a valid transport time and were not included in the survival analysis

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## Definition – Study Groups

- POR
  - Patients who received laparotomy including total or partial splenectomy, or splenorrhaphy less than two hours post-admission
- NOM
  - Patients who were initially triaged to either Observation, AE, or SAE less than two hours post-admission
- FNOM
  - Patients who experienced a first occurrence or relapse of hemorrhage greater than two hours post-admission requiring SAE or POR

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## Definition – Transportation Time

- Transportation time was defined as the time between receipt of 911 call and arrival to the trauma center
- Transportation time includes all time spent at the scene during prolonged extrications and/or in receipt of diagnostics or stabilization at a tertiary center

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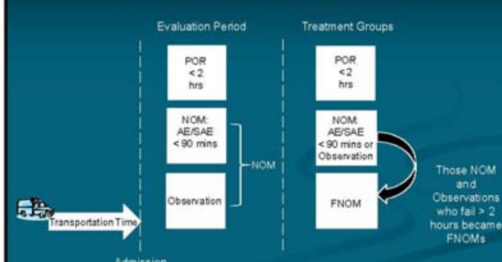
## Study Period Time Frames Leading Up To Primary Outcome




60

## Study Outcome Variables

Primary: Hospital length of stay (H-LOS)

- Duration (days) from trauma center admission to dismissal

Censoring

- Patients with splenic injury who survive more than two hours after hospital admission

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## Stratified Variables

- Gender
- ISS
- SBP
- Injury type
- Injury grade
- Origin of transportation
- EMS mode
- Transportation time
- Type of procedure
- Time to procedure
- Discharge destination

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<u>Study group:</u>

- POR
- NOM
- FNOM

<u>Age</u>

- 13 to 17
- 18 to 64
- 65 and older

<u>Injury type</u>

- Blunt
- Penetrating

<u>Gender</u>

<u>Injury severity score (ISS)</u>

- 0 to 15
- 16 to 24
- 25 or greater

<u>Transportation time (minutes)</u>

- 0 to 30
- 31to 60
- 61to 20
- 121to240
- Greater than240

<u>Time to procedure (hours)</u>

- 0 to 2
- 2 to 4
- 4 to 6
- Greater than 6

<u>EMS mode</u>

- Fixed wing airplane
- Helicopter ambulance
- Land ambulance

<u>Systolic Blood Pressure (SBP) on admission</u>

- Less than 90 mmHg
- 90 to 120 mmHg
- Greater than 120 mmHg

<u>Origin of transportation</u>

- Home or scene of injury
- Referring hospital

<u>Injury grades: I to V</u>

<u>Glascow Coma Scale</u>

- Mild (13 to15)
- Moderate (9 to12)
- Severe (3 to8 )

<u>Procedures</u>

- AE negative for extravasation
- AE of the splenic artery
- AE of the splenic vein
- AE with follow-up splenectomy
- Splenectomy
- Splenorrhaphy
- Observation only

<u>Discharge Destination</u>

- Home
- Rehabilitation
- Other
- Death

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## Stratified Variables

- During univariate analysis related to FNOM only, time to procedure was further collapsed into the following strata:
  - 0 to 2 hours
  - 2 to 4 hours
  - Greater than 4 hours

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## Statistical Analysis

- Data were collected in Microsoft Excel (version 2007)
- All statistical analyses were evaluated based on the significance level of $p<0.05$
- Statistical analysis were conducted using Statistical Analytics Software (SAS) version 9.3 (SAS Institute Inc., Cary, NC)

<u>Demographics</u>

- Continuous variables: evaluated using Student's t test or one-way ANOVA
- Categorical variables: evaluated using Chi-square or Fisher exact test

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## Statistical Analysis: Survival Analysis

- Hospital length of stay with survival les than two hours after hospital admission as the censor variable
- Model Covariates: age, ISS, gender, injury type, treatment group, time from admission to procedure, and transportation time
  - Kaplan – Meier (KM) graph
  - Cox Proportional Hazards Regression

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## Statistical Analysis: Effect of Transportation Time on FNOM

- Transportation time associated with the incidence of FNOM was evaluated using either Chi-square or Fisher exact test

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## Results

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## Aggregate and Model Populations

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## Demographics by Population

Table 1: Summary of Patient Demographics and Outcomes for Aggregate versus Model Population

| | Aggregate Population | | Model Population | |
|---|---|---|---|---|
| Parameter | N= 364 | % | N= 155 | % |
| Age | | | | |
| 13 to 17 | 39 | 10.7 | 15 | 9.7 |
| 18 to 64 | 281 | 77.2 | 125 | 80.6 |
| 65 and older | 44 | 12.1 | 14 | 9.7 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Gender (Male) | 242 | 66.5 | 97 | 62.6 |
| Origin of Transport | | | | |
| Home or scene of injury | 195 | 53.6 | 108 | 69.7 |
| Referring hospital | 169 | 46.4 | 47 | 30.3 |
| Total | 364 | 100.0 | 155 | 100.0 |
| EMS Mode | | | | |
| Land ambulance | 280 | 76.9 | 122 | 78.7 |
| Fixed wing airplane | 5 | 1.4 | 1 | 0.6 |
| Helicopter | 79 | 21.7 | 32 | 20.6 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Transportation Time | | | | |
| 0 to 30 minutes | 31 | 8.5 | 31 | 20.0 |
| 31 to 60 minutes | 42 | 11.5 | 42 | 27.1 |
| 61 to 120 minutes | 40 | 11.0 | 40 | 25.8 |
| 121 to 240 minutes | 30 | 8.2 | 30 | 19.4 |
| Greater than 240 minutes | 12 | 3.3 | 12 | 7.7 |
| Total | 364 | 100.0 | 155 | 100.0 |

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## Demographics: Aggregate versus Model Population

- Most patients in both populations were ages 18 to 64 (77.2% and 80.6%, respectively)
- More patients were male (66.5% and 62.6%)
- More patients arrived via land ambulance (76.9% and 78.7%)
- Most transportation times were 31 to 60 minutes (11.5% and 27.1%)

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## Injury Characteristics

Table 2: Summary of Patient Injury Characteristics for Aggregate versus Model Population

| | Aggregate Population | | Model Population | |
|---|---|---|---|---|
| Parameter | N = 364 | % | N = 155 | % |
| Injury Type | | | | |
| Blunt | 342 | 94.0 | 138 | 89.0 |
| Penetrating | 22 | 6.0 | 17 | 11.0 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Injury Grade* | 3.2 ± 1.2 | | 3.3 ± 1.2 | |
| Injury Grade | | | | |
| 1 | 10 | 2.7 | 8 | 5.2 |
| 2 | 26 | 7.1 | 12 | 7.7 |
| 3 | 34 | 9.3 | 23 | 14.8 |
| 4 | 43 | 11.8 | 31 | 20.0 |
| 5 | 17 | 4.7 | 11 | 7.1 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Isolated Spleen Injury (Y/N) | 31 | 8.5 | 15 | 9.7 |
| Injury Severity Score (ISS*) | 24.0 ± 12.5 | | 24.6 ± 11.7 | |
| ISS | | | | |
| 0 to 15 | 98 | 26.9 | 36 | 23.2 |
| 16 to 24 | 105 | 28.9 | 44 | 28.4 |
| 25 and greater | 161 | 44.2 | 75 | 48.4 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Head Injury (Y/N) | 181 | 49.7 | 70 | 45.2 |
| Head Injury AIS Score* | 2.9 ± 1.1 | | 2.8 ± 1.0 | |
| Glasgow Coma Score | | | | |
| Mild (13 to 15) | 253 | 69.5 | 113 | 72.9 |
| Moderate (9 to 12) | 15 | 4.1 | 8 | 5.2 |
| Severe (3 to 8) | 96 | 26.4 | 34 | 21.9 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Systolic Blood Pressure | | | | |
| Less than 90 mm Hg | 43 | 11.8 | 27 | 17.4 |
| 90 to 120 mm Hg | 137 | 37.7 | 61 | 39.4 |
| Greater than 120 mm Hg | 183 | 50.3 | 67 | 43.2 |
| Total | 363 | 99.7 | 155 | 100.0 |

* Mean ± SD

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## Injury Characteristics: Aggregate versus Model Population

- Most injuries in both populations were blunt (94.0% and 89.0%)
- Average injury grade was 3.2 ± 1.2 and 3.3 ± 1.2
- Average ISS for both populations was nearing the severe level (24.0 ± 12.5 and 24.6 ± 11.7)
- The percentage of patients who experienced an isolated injury was low in both populations (8.5% and 9.7%)
- Nearly half of patients in both populations had a head injury (49.7% and 45.2%)
- The majority patients in either population arrived in a normo-tensive state with SBP > 120 (50.3% and 43.2%)

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## Treatment Groups, Procedures, and Time to Procedures

Table 3: Summary of Treatment Groups, Procedure Types, and Time to Procedure from Hospital Admission for Aggregate versus Model Population

| | Aggregate Population | | Model Population | |
|---|---|---|---|---|
| Parameter | N | % | N | % |
| Treatment Group: | | | | |
| NOM | 312 | 85.7 | 111 | 71.6 |
| POR | 26 | 7.1 | 22 | 14.2 |
| FNOM | 26 | 7.1 | 22 | 14.2 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Procedure Performed (Y) | 75 | 20.6 | 61 | 39.4 |
| Procedures Performed by Group | | | | |
| SAE | 39 | 52.0 | 32 | 52.5 |
| POR | 36 | 48.0 | 29 | 47.5 |
| Total | 75 | 100.0 | 61 | 100.0 |
| Procedures Performed by Type | | | | |
| Angioembolization negative for extravasation | 2 | 0.5 | 1 | 0.6 |
| Angioembolization of the splenic artery | 36 | 9.9 | 30 | 19.4 |
| Angioembolization of the splenic vein | 1 | 0.3 | 1 | 0.6 |
| Angioembolization with adjunctive splenectomy | 1 | 0.3 | 0 | 0.0 |
| Splenectomy | 28 | 7.7 | 22 | 14.2 |
| Splenorrhaphy | 7 | 1.9 | 7 | 4.5 |
| Observation only | 289 | 79.4 | 94 | 60.6 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Time to Procedure After Admission | | | | |
| 0 to 2 hours | 52 | 69.3 | 42 | 68.9 |
| 2 to 4 hours | 16 | 21.3 | 13 | 21.3 |
| Greater than 4 hours | 7 | 9.3 | 6 | 9.8 |
| Total | 75 | 100.0 | 61 | 100.0 |

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## Treatment Groups, Procedures, and Time to Procedures: Aggregate versus Model Population

- NOM was the treatment choice for the majority of patients regardless of population (85.7% and 71.6%)
- 20.6% of patients in the aggregate population and 39.4% in the model population received any type of procedure
- Approximately half of all procedures (POR, AE or SAE) in both populations were SAE (52.0% and 52.5%)
- 48% of patients received POR in the aggregate population, 47.5% in the model population
- Most procedures were performed less than two hours in accordance with ACS recommendations in both populations (69.3% and 68.9%)

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## Patient Outcomes

Table 4: Summary of Patient Outcomes for Aggregate versus Model Population

| | Aggregate Population | | Model Population | |
|---|---|---|---|---|
| Parameter | N = 364 | % | N = 155 | % |
| Discharged Destination | | | | |
| Home | 211 | 58.0 | 91 | 58.7 |
| Rehabilitation facility | 74 | 20.3 | 30 | 19.4 |
| Other | 39 | 10.7 | 17 | 11.0 |
| Dead | 40 | 11.0 | 17 | 11.0 |
| Total | 364 | 100.0 | 155 | 100.0 |
| Hospital Length of Stay (H-LOS)* | 10.7 ± 12.7 | | 9.84 ± 10.3 | |
| Intensive Care Unit Length of Stay (I-LOS)* | 6.22 ± 10.4 | | 5.6 ± 8.0 | |
| Number of Ventilatory Days* | 3.8 ± 9.2 | | 3.4 ± 7.1 | |
| Hospital Discharge Status | | | | |
| Alive | 324 | 89.0 | 138 | 89.0 |
| Dead | 40 | 11.0 | 17 | 11.0 |
| Total | 364 | 100.0 | 155 | 100.0 |
| * Mean ± SD | | | | |

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## Patient Outcomes: Aggregate versus Model Population

- Both populations demonstrate more than half of patients were discharged home (58.0% and 58.7%)
- Average H-LOS was approximately 11 and 10 days respectively
- Average I-LOS was approximately 6 days for both populations
- Ventilatory days were approximately 4 and 3 respectively
- There were 40 deaths in the aggregate population and 17 in the model population, which represented 11% in both population and indicates the mortality rate was the same in both populations

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## Treatment Groups

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## Analysis by Treatment Group: Demographics

Table 6: Differences Among Patient Demographics for Model Population by Assigned Treatment Group

| Parameter (n,%) | POR (n=22) | NOM (n=111) | FNOM (n= 22) | Total (N=155) | P value |
|---|---|---|---|---|---|
| Age | | | | | 0.67 |
| 13 to 17 | 2 (9.1) | 11(9.9) | 2(9.1) | 15(9.7) | |
| 18 to 64 | 19 (86.4) | 90(81.1) | 16(72.7) | 125(80.6) | |
| 65 and older | 1(4.5) | 10(9.0) | 4(18.2) | 15(9.7) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| Gender (Male) | 16(72.7) | 71(64.0) | 10(45.5) | 97(62.6) | 0.15 |
| Origin of Transport | | | | | 0.19 |
| Home or scene of injury | 13(59.1) | 82(73.9) | 13(59.1) | 108(69.7) | |
| Referring hospital | 9(40.9) | 29(26.1) | 9(40.9) | 47(30.3) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| EMS Mode | | | | | 0.87 |
| Land ambulance | 17(77.3) | 86(77.5) | 19(86.4) | 122(78.7) | |
| Helicopter | 5(22.7) | 24(21.6) | 3(13.6) | 32(20.6) | |
| Fixed wing airplane | 0(0) | 1(.9) | 0(0) | 1(.6) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| Transportation Time | | | | | 0.09 |
| 0 to 30 minutes | 8(36.4) | 17(15.3) | 6(27.3) | 31(20.0) | |
| 31 to 60 minutes | 2(9.1) | 34(30.6) | 6(27.3) | 42(27.1) | |
| 61 to 120 minutes | 3(13.6) | 33(29.7) | 4(18.2) | 40(25.8) | |
| 121 to 240 minutes | 6(27.3) | 19(17.1) | 5(22.7) | 30(19.4) | |
| Greater than 240 minutes | 3(13.6) | 8(7.2) | 1(4.5) | 12 (7.7) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |

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## Demographics: POR vs NOM vs FNOM

- The majority of patients among all treatment groups were adults (86.4%, 81.1% and 72.7% respectively)
- Males in the POR and NOM groups (72.7%, 64.0%)
- The majority were female in the FNOM group (54.5%)
- The majority arrived from home/scene (59.1%, 73.9%, and 59.1%), via land ambulance (77.3%, 77.5%, and 86.4%), in less than two hours (59.1%,75.6, 72.9)

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## Analysis by Treatment Group: Injury

Table 7: Differences Among Injury Characteristics for Model Population by Assigned Treatment Groups

| Parameter (n,%) | POR (n=22) | NOM (n=111) | FNOM (n=22) | Total (N=155) | P value |
|---|---|---|---|---|---|
| Injury Type | | | | | 0.001 |
| Blunt | 14(63.6) | 103(92.8) | 21(95.5) | 138(89.0) | |
| Penetrating | 8(36.4) | 8(7.2) | 1(4.5) | 17 (11.0) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| Injury Grade | | | | | 0.52 |
| 1 | 2(9.1) | 3(7.3) | 3(13.6) | 8(9.4) | |
| 2 | 3(13.6) | 8(19.5) | 1(4.5) | 12(14.1) | |
| 3 | 4(18.2) | 11(26.8) | 8(36.4) | 23(27.1) | |
| 4 | 10(45.5) | 12(29.3) | 9(40.9) | 31(36.5)) | |
| 5 | 3(13.6) | 7(17.1) | 1(4.5) | 11(12.9) | |
| Total | 22(100.0) | 41(100.0) | 22(100.0) | 85(100.0) | |
| Isolated Spleen Injury (Y/N) | 5(22.7) | 8(7.2) | 3(13.6) | 16(10.3) | 0.06 |
| ISS | | | | | 0.48 |
| 0 to 15 | 4(18.2) | 25(22.5) | 7(31.8) | 36(23.2) | |
| 16 to 24 | 5(22.7 | 31(27.9) | 8(36.4) | 44(28.4) | |
| 25 and greater | 13(59.1) | 55(49.5) | 7(31.8) | 75(48.4) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| Head Injury (Y/N) | 7(31.8) | 56(50.5) | 7(31.8) | 70(45.2) | 0.11 |
| Glascow Coma Score | | | | | 0.08 |
| Mild (13 to 15) | 16(72.7) | 76(68.5) | 21(95.5) | 113(72.9) | |
| Moderate (9 to 12) | 0(0) | 8(7.2) | 0(0) | 8(5.2) | |
| Severe (3 to 8) | 6(27.3) | 27(24.3) | 1(4.5) | 34(21.9) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| Systolic Blood Pressure | | | | | 0.02 |
| Less than 90 mmHg | 7(31.8) | 17(15.3) | 3(13.6) | 27(17.4) | |
| 90 to 120 mmHg | 12(54.5) | 43(38.7) | 6(27.3) | 61(39.4) | |
| Greater than 120 mmHg | 3(13.6) | 51(45.9) | 13(59.1) | 67(43.2) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |

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## Injury Characteristics: POR vs NOM vs FNOM

- NOM was attempted in 8 of 17 penetrating injuries and 103 of 138 blunt injuries (p=0.001)
- NOM was attempted in 29% of Grade 4 and 17% of Grade 5 injuries (p=0.52)
- NOM was attempted in the presence of elevated SBP > 120 (45.9%, p=0.017)
- NOM was attempted in nearly half (49.5%) of the most severely injured (ISS 25>) injured (p=0.48)
- NOM failed in 7 (31.8%) patients
- A key consideration may be that NOM was the treatment modality for 50.5% of the 70 patients with a head injury (p=0.11)

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## Analysis by Treatment Group: Procedures

Table 8: Differences Among Procedure Types and Time to Procedure From Hospital Admission for Model Population by Assigned Treatment Groups

| Parameter (n, %) | POR (n=22) | NOM (n=111) | FNOM (n=22) | Total (N=155) | P value |
|---|---|---|---|---|---|
| Procedure Performed (Y) | 22(36.1) | 17(27.9) | 22(100.0) | 61(39.4) | <0.001 |
| Procedures Performed by Group | | | | | <0.001 |
| SAE | 0(0.0) | 17(100.0) | 15(68.2) | 32(52.5) | |
| POR | 22(100.0) | 0(0.0) | 7(31.8) | 29(47.5) | |
| Total | 22(100.0) | 17(100.0) | 22(100.0) | 61(100.0) | |
| Procedures Performed by Type | | | | | <0.001 |
| Angioembolization negative for extravasation | 0(0) | 0(0) | 1(4.5) | 1(.6) | |
| Angioembolization of the splenic artery | 0(0) | 17(15.3) | 13(59.1) | 31(20.0) | |
| Angioembolization of the splenic vein | 0(0) | 0(0) | 1(4.5) | 1(.6) | |
| Angioembolization with adjunctive splenectomy | 0(0) | 0(0) | 0(0) | 0(0) | |
| Splenectomy | 16(72.7) | 0(0) | 6(27.3) | 22(14.2) | |
| Splenorrhaphy | 6(27.3) | 0(0) | 1(4.5) | 6(3.9) | |
| Observation only | 0(0.0) | 94(84.7) | 0(0) | 94(60.6) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| Time to Procedure After Admission | | | | | <0.001 |
| 0 to 2 hours | 22(100.0) | 17(100.0) | 3(13.6) | 42(68.9) | |
| 2 to 4 hours | 0(0) | 0(0) | 13(59.1) | 13(21.3) | |
| 4 to 6 hours | 0(0) | 0(0) | 3(13.6) | 3(4.9) | |
| Greater than 6 hours | 0(0) | 0(0) | 3(13.6) | 3(4.9) | |
| Total | 22(100.0) | 17(100.0) | 22(100.0) | 61(100.0) | |

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## Procedures: POR vs NOM vs FNOM

- A statistical significance was demonstrated among treatment groups for those patients who did or did not receive a procedure and type of procedure (p<0.001 respectively)
- Among those patients who experienced FNOM, 15 underwent SAE (68.1%), while seven underwent POR (31.8%)
- All but one of the PORs were splenectomies
- Most (59.1%) of procedures following FNOM were performed within 2 to 4 hours following admission

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## Analysis by Treatment Group: Outcomes

Table 9: Differences Among Patient Outcomes for Model Population by Assigned Treatment Group

| Parameter (n,%) | POR (n=22) | NOM (n=111) | FNOM (n=22) | Total (N=155) | P value |
|---|---|---|---|---|---|
| Discharged Destination | | | | | 0.49 |
| Home | 14(15.4) | 61(55.0) | 16(72.7) | 91(58.7) | |
| Rehabilitation facility | 5(22.7) | 24(21.6) | 1(4.5) | 30(19.4) | |
| Other | 1(4.5) | 14(12.6) | 2(9.1) | 17(11.0) | |
| Dead | 2(9.1) | 12(10.8) | 3(13.6) | 17(11.0) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| Hospital Length of Stay (H-LOS)* | 9.84 ± 10.3 | 10.2 ± 11.0 | 5.7 ± 3.9 | | 0.09 |
| Intensive Care Unit Length of Stay (I-LOS)* | 3.8 ± 8.0 | 6.1 ± 8.6 | 1.8 ± 1.6 | | 0.05 |
| Number of Ventilatory Days* | 5.3 ± 7.6 | 3.6 ± 7.6 | .6 ± 1.4 | | 0.08 |
| Hospital Discharge Status | | | | | 0.92 |
| Alive | 20(90.9) | 99(89.2) | 19(86.4) | 138(89.0) | |
| Dead | 2(9.09) | 12(10.8) | 3(13.6) | 17(11.0) | |
| Total | 22(100.0) | 111(100.0) | 22(100.0) | 155(100.0) | |
| *Mean±SD | | | | | |

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## Patient Outcomes: POR vs NOM vs FNOM

- Across all treatment groups, the majority of patients were discharged to home (58.7%, p=0.49)
- Average H-LOS for NOM was the longest at 10.2 ± 11.0 days (p=0.09)
- I-LOS was longer for those patients who completed NOM (6.1 ± 8.6, p=0.05)
- Number of ventilatory days was greatest among those patients who underwent POR (5.3 ± 7.6, p=0.08)
- Death occurred in 17 (11.0%) of the model population (p=0.92)
- There were 12 (70.6%) deaths among patients in the NOM treatment group

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## FNOM

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## FNOM: Injury Characteristics

Table 10: Injury Characteristics for Patients Experiencing FNOM

| n=22 | Frequency | Percent |
|---|---|---|
| Injury Grade | | |
| 1 | 3 | 13.6 |
| 2 | 1 | 4.5 |
| 3 | 8 | 36.4 |
| 4 | 9 | 40.9 |
| 5 | 1 | 4.5 |
| Time from call to arrival (minutes) | | |
| 0 to 30 | 6 | 27.3 |
| 31 to 60 | 6 | 27.3 |
| 61 to 120 | 4 | 18.2 |
| 120 to 240 | 5 | 22.7 |
| Greater than 240 | 1 | 4.5 |
| Time to procedure (hours) | | |
| 0 to 2 hours | 3 | 13.6 |
| 2 to 4 hours | 13 | 59.1 |
| Greater than 4 | 6 | 27.2 |

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## FNOM: Transportation Time, Injury Grade and Procedures

- FNOM occurred in 22 cases
- The majority of FNOM patients sustained Grade III (n=8, 36.4%) and Grade IV (n=9, 40.9%) injuries
- Transportation time was evenly distributed across the five strata with the exception of those patients who experienced greater than 240 minutes (n=1, 4.5%)
- Most patients received procedures following FNOM less than two hours from admission (n=16, 72.7%)

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## The majority of the FNOM subset (n=22) demonstrated:

Table 11 : Demographic, Injury Characteristics, and Outcomes for FNOM

| Parameter (n=22) | Result | Frequency | % |
|---|---|---|---|
| Age | 18 to 64 | 16 | 72.7 |
| Gender | female | 12 | 54.5 |
| Origin of Transport | home or scene of injury | 13 | 59.1 |
| EMS Mode | land ambulance | 19 | 86.4 |
| Time From Call to Arrival | less than 60 minutes | 12 | 54.5 |
| Injury Type | blunt | 21 | 95.5 |
| Injury Severity Score | 16 to 24 | 8 | 36.4 |
| Glascow Coma Scale Score | mild (13 to15) | 21 | 95.5 |
| Isolated Spleen | yes | 3 | 13.6 |
| Isolated Spleen Injury Grade (Y/N) | 2 | 3 | 13.6 |
| Head Injury (Y/N) | yes | 7 | 31.8 |
| Systolic Blood Pressure | less than 120 mmHg | 13 | 59.1 |
| Procedure After Admission | AE/SAE | 15 | 68.2 |
| Time to Procedure | 2 to 4 hours | 3 | 13.6 |
| Hospital Length of Stay* | | 5.7 ± 3.9 | |
| Intensive Care Unit Length of Stay* | | 1.8 ± 1.6 | |
| Number of Ventilatory Days* | | .6 ± 1.4 | |
| Discharged Destination | home | 16 | 72.7 |
| Hospital Discharge Status | alive | 19 | 86.4 |
| *Mean ± SD | | | |

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## FNOM: Demographics, Injury Characteristics, and Outcomes

- Most FNOMs were adults ages 18 to 64 (72.7%, n=16) with 2 (9.1%) pediatric and 4 (18.2%) elderly patients
- The majority of patients were female (54.5%, n=12)
- Most (36.4%, n=8) patients had a moderate ISS
- SBP greater than 120 mmHg was demonstrated by 59.1% (n=13) patients
- Among the 22 FNOM patients, 68.2% (n=15) received SAE
- Average H-LOS was 5.7 ± 3.9 days, I-LOS was 1.8 ± 1.6 days, and ventilatory days was .6 ± 1.4
- Among the 22 patients who experienced FNOM, there were 3 (13.6%) deaths

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## Clinical Relevance of Parameters

- In trauma studies, certain parameters provide clinicians with the ability to determine whether an Aggregate population differs from the Sample population
- These include:
  - Age
  - Gender
  - Origination of Transport
  - EMS Mode
  - Hospital Discharge Status
  - Injury Grade
  - SBP Level
  - Head Injury
  - Procedures After Admission
  - ISS

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Table 5: Bivariate Comparison

| Parameter (n(%)) | Have transport time on file (n=155) | Do not have transport time on file (n=209) | Total | P-value* |
|---|---|---|---|---|
| Group | | | | 0.3368 |
| Ages 13-17 | 15 (9.7%) | 24 (11.5%) | 39 (10.7%) | |
| Ages 18-65 | 126 (81.3%) | 157 (75.1%) | 283 (77.7%) | |
| Ages 66+ | 14 (9%) | 28 (13.4%) | 42 (11.5%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Gender | | | | 0.2568 |
| Female | 57 (36.8%) | 65 (31.1%) | 122 (33.5%) | |
| Male | 98 (63.2%) | 144 (68.9%) | 242 (66.5%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Origination of Transport | | | | <0.0001 |
| Home or scene of injury | 108 (69.7%) | 87 (41.6%) | 195 (53.6%) | |
| Referring Hospital | 47 (30.3%) | 122 (58.4%) | 169 (46.4%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| EMS Mode | | | | 0.5236 |
| Land Ambulance | 122 (78.7%) | 158 (75.6%) | 280 (76.9%) | |
| Fixed Wing Airplane | 1 (0.6%) | 4 (1.9%) | 5 (1.4%) | |
| Helicopter | 32 (20.6%) | 47 (22.5%) | 79 (21.7%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Hospital Discharge Status | | | | 0.9911 |
| Alive | 138 (89%) | 186 (89%) | 324 (89%) | |
| Dead | 17 (11%) | 23 (11%) | 40 (11%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Discharge Destination | | | | 0.9288 |
| Home | 92 (59.4%) | 119 (56.9%) | 211 (58%) | |
| Other | 17 (11%) | 22 (10.5%) | 39 (10.7%) | |
| Rehab | 29 (18.7%) | 45 (21.5%) | 74 (20.3%) | |
| Dead | 17 (11%) | 23 (11%) | 40 (11%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Injury Grade** | | | | 0.1898 |
| 1 | 8 (9.4%) | 2 (4.4%) | 10 (7.7%) | |
| 2 | 12 (14.1%) | 14 (31.1%) | 26 (20%) | |
| 3 | 23 (27.1%) | 11 (24.4%) | 34 (26.2%) | |
| 4 | 31 (36.5%) | 12 (26.7%) | 43 (33.1%) | |
| 5 | 11 (12.9%) | 6 (13.3%) | 17 (13.1%) | |
| Total | 85 (100%) | 45 (100%) | 130 (100%) | |
| SBP Level*** | | | | 0.0066 |
| Less than 90 mmHg | 27 (17.4%) | 16 (7.7%) | 43 (11.8%) | |
| 90 to 120 mmHg | 61 (39.4%) | 76 (36.5%) | 137 (37.7%) | |
| Greater than 120 mmHg | 67 (43.2%) | 116 (55.8%) | 183 (50.4%) | |
| Total | 155 (100%) | 208 (100%) | 363 (100%) | |
| Head Injury | | | | 0.0869 |
| Yes | 69 (44.5%) | 112 (53.6%) | 181 (49.7%) | |
| No | 86 (55.5%) | 97 (46.4%) | 183 (50.3%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| Procedure after admission | | | | <0.0001 |
| NOM | 111 (71.6%) | 201 (96.2%) | 312 (85.7%) | |
| FNOM | 22 (14.2%) | 4 (1.9%) | 26 (7.1%) | |
| POR | 22 (14.2%) | 4 (1.9%) | 26 (7.1%) | |
| Total | 155 (100%) | 209 (100%) | 364 (100%) | |
| ISS Score | 24.4903 ± 11.72 | 23.6316 ± 13.14 | | 0.5192 |

## Clinical Relevance of Parameters: Bivariate Analysis

- Among the 10 variables assessed in bivariate analysis, 3 demonstrated statistical significance:
  1. Origin of transportation ($p<0.0001$)
  2. SBP ($p=0.0066$)
  3. Study group ($p<0.0001$)
- We conclude the distribution of the Model population (n=155) *approximates* that of the Aggregate population (n=364) based on relevant clinical parameters
- The Model population is an approximation of a true random sample

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## Survival Analysis

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Table 12: Summary of H-LOS Stratified by Discharge Status

| | Discharged alive (n=138) | | | All case (n=155) | | |
|---|---|---|---|---|---|---|
| | Median H-LOS (days) | (Q1, Q3) | (Min, Max) | Median H-LOS (days) | (Q1, Q3) | (Min, Max) |
| Age | | | | | | |
| 13 to 17 | 6 | (5, 10) | (2, 43) | 6 | (3, 10) | (1, 43) |
| 18 to 64 | 6 | (4, 15) | (1, 47) | 6 | (3, 13) | (1, 60) |
| 65 and older | 6.5 | (3, 9) | (3, 12) | 5 | (3, 9) | (1, 14) |
| ISS | | | | | | |
| 0 to 15 | 3.5 | (2, 6) | (1, 17) | 4 | (2, 6) | (1, 17) |
| 16 to 24 | 7 | (4, 10) | (1, 28) | 6 | (4, 9.5) | (1, 28) |
| 25 and greater | 10 | (6, 21) | (3, 47) | 7 | (5, 20) | (1, 60) |
| Gender | | | | | | |
| Male | 7 | (5, 16) | (1, 47) | 6 | (4, 15) | (1, 47) |
| Female | 5.5 | (3, 9) | (1, 32) | 5 | (3, 9) | (1, 60) |
| Injury Type | | | | | | |
| Blunt | 7 | (4, 13) | (1, 47) | 6 | (3, 12) | (1, 60) |
| Penetrating | 5.5 | (4, 6.5) | (2, 23) | 5 | (4, 6) | (1, 23) |
| Treatment Type | | | | | | |
| FNOM | 6 | (3, 8) | (2, 18) | 5 | (3, 8) | (1, 18) |
| NOM | 6 | (3, 12) | (1, 47) | 6 | (3, 12) | (1, 60) |
| POR | 11 | (5, 20.5) | (2, 40) | 8 | (5, 20) | (1, 40) |
| Time to Procedure | | | | | | |
| 0 to 2 hours | 6 | (5, 17) | (1, 40) | 6 | (4, 17) | (1, 60) |
| 2 to 4 hours | 6 | (3.5, 7.5) | (2, 10) | 6 | (3, 7) | (1, 10) |
| Greater than 4 hours | 6 | (4, 8) | (3, 18) | 5 | (3, 8) | (3, 18) |
| Transportation Time | | | | | | |
| 0 to 29 minutes | 6 | (4, 8) | (2, 28) | 6 | (4, 8) | (1, 28) |
| 30 to 60 minutes | 6 | (3, 8) | (1, 43) | 6 | (3, 8) | (1, 43) |
| 61 to 120 minutes | 7 | (5, 17) | (2, 47) | 6 | (4, 16) | (1, 60) |
| 121 to 240 minutes | 8.5 | (3, 18) | (1, 40) | 6 | (3, 17) | (1, 40) |
| > 240 minutes | 11 | (3, 19) | (1, 23) | 10.5 | (2.5, 15.5) | (1, 23) |

## Survival Analysis

- Among the Aggregate population, 209 patients did not have a valid transportation time while 155 patients did have a valid transportation time and were included in the survival analysis
- The number of those who had a valid transportation time and were discharged alive was 138
- Time to procedure greater than four hours and greater than six hours were combined to power the calculation of median H-LOS

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## Summary of H-LOS Censored by Number of Patients Alive After 2 Hours from Admission: Hazard Ratios

- Median H-LOS was greatest for those patients ages 65 and older (6.5 [Q3-9] v. 6 [Q5,10] and 6 [4,15] d.), respectively and ISS greater than or equal to 25 (10 [6,21] v. 3.5[2,6] and 7[4,10] d.), respectively
- Median H-LOS was longest for males (7 [5,16]d., those patients who sustained blunt injury (7[4,13]d.), and those who underwent POR (11[5.20.5] d.)
- Those patients with transportation times in excess of 60 minutes had the longest median H-LOS compared to those patients with transportation times of 61 to 120 minutes and 121 to 240 minutes (7[5,17] v. 8.5[3,18] and 11[3,19] d.), respectively.

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## Survival Analysis

- Seven covariates were assessed in the survival model:
  1. Age
  2. ISS
  3. Gender
  4. Injury type
  5. Treatment group
  6. Time to procedure
  7. Transportation time
- Injury grade was included but was highly correlated with ISS (p<0.001)
- Kaplan-Meier curves for the seven covariates were included to demonstrate the time-to-event (H-LOS censored for death)
- Unadjusted and adjusted hazard ratios were reported for each variable

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Table 13: Hazard Ratios for H-LOS

| | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|
| Parameter | HR | 95% CI for HR | | HR | 95% CI for HR | |
| Age | | | | P value=0.0016 | | |
| 13 to 17 vs 18 to 64 | 1.36 | 0.47 | 3.96 | 1.79 | 0.38 | 8.44 |
| 13 to 17 vs 65 and older | 0.32 | 0.11 | 0.99 | 0.21 | 0.04 | 1.14 |
| 18 to 64 vs 65 and older | 0.24 | 0.12 | 0.47 | 0.12 | 0.04 | 0.38 |
| ISS | | | | P value=0.0903 | | |
| 0 to 15 vs16 to 24 | 0.17 | 0.02 | 1.39 | 0.34 | 0.04 | 3.35 |
| 0 to 15 vs 25 and greater | 0.07 | 0.01 | 0.48 | 0.13 | 0.02 | 1.04 |
| 16 to 24 vs 25 and greater | 0.38 | 0.17 | 0.87 | 0.37 | 0.09 | 1.47 |
| Gender: Female vs Male | 0.55 | 0.26 | 1.16 | Not included in the analysis | | |
| Injury Type: Blunt vs Penetrating | 0.73 | 0.22 | 2.37 | Not included in the analysis | | |
| Treatment Type | | | | Not included in the analysis | | |
| FNOM vs NOM | 1.15 | 0.35 | 3.75 | | | |
| FNOM vs POR | 1.13 | 0.23 | 5.63 | | | |
| NOM vs POR | 0.99 | 0.30 | 3.22 | | | |
| Time to Procedure (hours) | | | | | | |
| 0 to 2 vs 2 to 4 | 2.17 | 0.27 | 17.60 | | | |
| Greater than 4 hours vs 0 to 2 hours | 1.18 | 0.14 | 9.74 | | | |
| Greater than 4 hours vs 2 to 4 hours | 2.55 | 0.16 | 41.22 | | | |
| Transportation Time (minutes) | | | | Not predictive (p=0.9948) | | |
| 0 to 30 vs Greater than 240 | 0.82 | 0.07 | 9.07 | 0.94 | 0.08 | 10.71 |
| 31 to 60 vs Greater than 240 | 1.20 | 0.13 | 10.79 | 1.06 | 0.12 | 9.83 |
| 61 to 120 vs Greater than 240 | 1.72 | 0.21 | 14.29 | 1.24 | 0.14 | 11.33 |
| 121 to 240 vs Greater than 240 | 1.17 | 0.12 | 11.27 | 0.94 | 0.09 | 9.56 |

## Age and ISS

- Cox proportional hazard regression analysis demonstrated Age (p=0.0016) and ISS (p=0.0903) were the only predictors of mortality
- The confidence interval for the ISS hazard ratio (HR) included one which indicated there was no difference between the measures, however the magnitude of the HR suggested a strong predictive capacity for ISS on mortality
- Transport time was not associated with mortality (p=0.9948)
- Compared to those ages 65 years or older, those ages 13 to 17 were 79% less likely to die (HR=0.21; 95% CI=0.04, 1.14)
- Compared to those greater or equal to 65 years of age, those ages 18 to 64 were 88% less likely to die (HR=0.12; 95% CI=0.04, 0.38)

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## Age and ISS-Cont'd

- Patients with ISS of 0 to15 were 87% less likely to die compared to those with ISS greater or equal to 25 (HR=0.13; 95% CI=0.02, 1.04)
- Patients with ISS of 16 to 24 were 63% less likely to die than those with ISS greater or equal to 25 (HR=0.37; 95% CI=0.09, 1.47)

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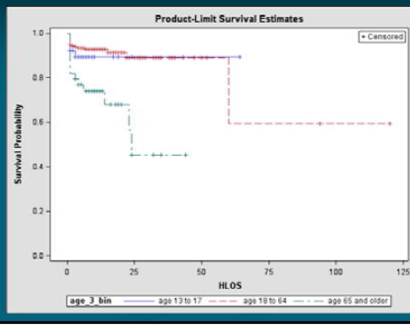
Age:

- Age was associated as a predictor for decreased mortality
- Ages 18 to 64 had the highest survival probability, therefore the lowest risk of death

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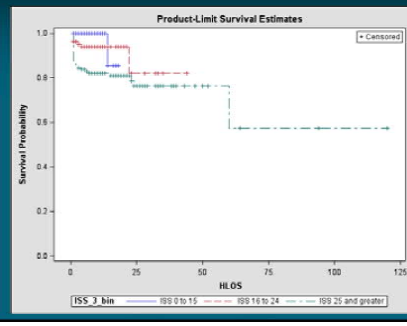
ISS:

- Injury severity score (ISS) was associated as a predictor for decreased mortality
- ISS 0 to 15 had the highest survival probability, therefore the lowest risk of death

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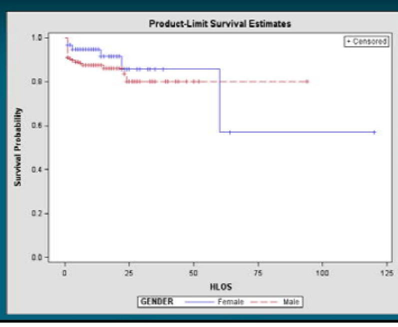
Gender:

- Gender was not associated as a predictor for decreased mortality
- Females had the highest survival probability, therefore the lowest risk of death

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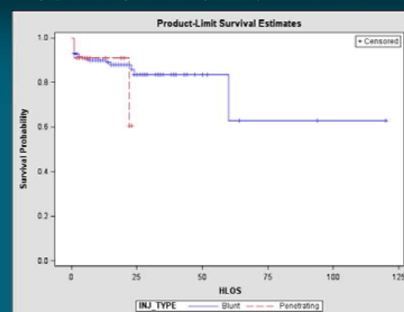
Injury Type:

- Injury type was not associated as a predictor for decreased mortality
- Blunt injury had the highest survival probability, therefore the lowest risk of death

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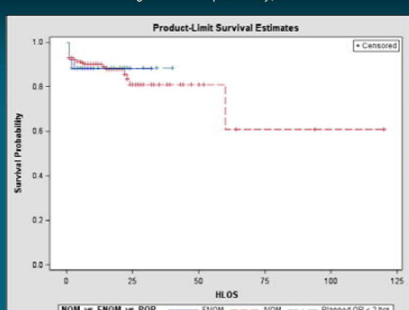
Treatment Group:

- Treatment groups was not associated as a predictor for decreased mortality
- FNOM and POR had a higher survival probability, therefore a lower risk of death

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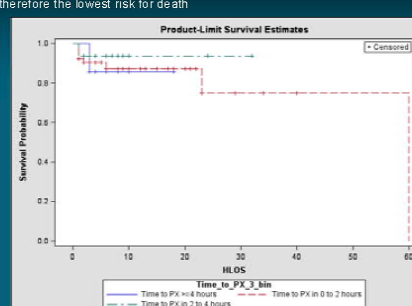
Time to Procedure:

- Time to procedure was not associated as a predictor for decreased mortality
- Procedures performed between 2 to 4 hours had the highest survival probability, therefore the lowest risk for death

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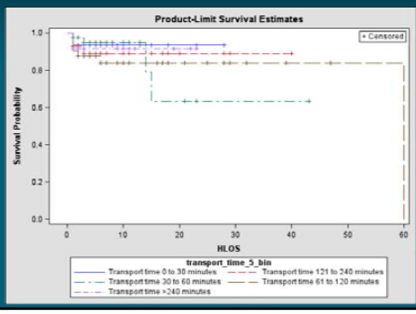
Transport Time:

- Transport time was not associated as a predictor for decreased mortality
- Transportation times between 0 to 30 minutes had a higher survival probability, therefore a lower risk for death

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## Discussion

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## Research Question 1 and 2

1. What is the predictive effect of transportation time on mortality, and therefore survivability, among those patients with splenic injury in a rural state and
2. Is transportation time predictive of mortality, and therefore survivability, within treatment groups (POR, NOM or FNOM)

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## Mortality Rates

- Overall mortality rates following splenic injury are reported as 18%[3]
- The current study results demonstrate overall mortality of 11% (n=17 of 155)
- Literature has demonstrated mortality rates for blunt versus penetrating injury of 1 to 15% and 8 to 24% respectively[4]
- The current study also demonstrates 10.8% of deaths due to blunt injury and 13.6% due to penetrating injury, supporting previous findings
- Since rural settings are associated with a 2 times higher mortality rate following injury, a mortality rate closer to 36% could be anticipated, but this was not the case

Kodikara S. *Am J Forensic Med Pathol* 2009, 30:382-383.,
Carlin AM et al., *Am Surg*. 2002, Mar 68(3):232-9.

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## H-LOS

- Chen et al., reported a mean H-LOS following SAE of 10.4 ± 5.6 days for a population with non-isolated splenic injury[18]
  - Results demonstrated 10.7 ± 12.7 days (with polytrauma)
- Similarly, Watson et al., reported mean H-LOS following FNOM of 16.9 ± 0.7 days[19]
  - H-LOS for FNOM was 12 ± 10 days
- Patients demonstrated FNOM earlier than those in the populations used in Watson's and others studies
- Patients likewise experienced shorter H-LOS

Chen IC, Wang S, Hsin-Chin S, et al. Splenic artery embolization increases the success of nonoperative management following blunt splenic injury.
Watson GA, Rosengart MR, Zenati MS, Tsung A, Forsythe RM, Peitzman AB, Harbrecht BG. Nonoperative management of severe blunt splenic injury: are we getting better?

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## I-LOS

- While I-LOS was shorter in this population for those patients who experienced FNOM than for those who were successfully discharged following NOM, the reasons remain unclear
- Patients who required more surveillance typically remain in an ICU until their condition allows them to be transferred to a floor bed
- In some hospitals, patients who are not ready for a floor bed, but don't require the more intensive surveillance provided in an ICU unit, are placed in a step-down unit
- In the current study, a step-down unit was not available at the trauma center, perhaps inflating the I-LOS for a proportion of patients

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## Research Question #2

2. What is the effect of transportation time on the incidence and outcomes following FNOM, among the splenic-injured population in a rural state

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## Possible Reasons Transportation Time Was Not Predictive

- Limited power due to low number (n=17) of deaths
- Limited power due to low number (n=155) of patients with documented EMS transportation time
- Transportation time was a composite variable with no attempt to quantify EMS effect
- Wide variance of transportation times (6 to 480 minutes) made it difficult to obtain meaningful results
- Deaths which occurred less than two hours after admission were not included in the analysis

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## Transportation Time

- 31% of people live greater than one hour from the nearest Level I trauma center[20]
- Mean time to the trauma center in this study was approximately 90 minutes, with a median of 65 minutes
- These times are uncommon in largely urban environments where transportation times may be less than ten minutes or surgeons may be dispatched to the scene of an accident along with EMS to initiate treatment

Health Resources and Services Administration. Defining the Rural Population. http://www.hrsa.gov/ruralhealth/definition_of_rural.html. Accessed 3/06/11.

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## Transportation Time and FNOM

- While transportation time for splenic-injured patients in a rural state did not prove predictive of decreased mortality or H-LOS, the proportion of FNOMs reported was lower in this population than the proportion of FNOMs in literature
- This indicates there is reason to question the application of the current largely urban-based trauma system in the rural environment

Health Resources and Services Administration. Defining the Rural Population. http://www.hrsa.gov/ruralhealth/definition_of_rural.html. Accessed 3/06/11.

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## FNOMs

- The average rate of FNOM is well documented at 8% to 38% with three strong predictors: 1) ISS > 25, 2) injury Grades III to V, and 3) age 40 and greater[21]
  - This study reported a 14.2% (n=22) rate of FNOM
- The majority of FNOMs following AE or SAE will occur less than 48 hours from admission with 100% less than 3 days[22-23]
  - This study reported 100% of FNOMs occurred less than 48 hours post-admission
  - The majority (96%) occurred much faster at less than six hours post-admission
- These results are concordant with previous publications in the selection of patients for NOM, however, challenge the findings of Jeremitsky that in the rural environment the start of NOM is on average at or before five hours as nearly 96% of failures had already occurred shortly after the five hour mark[24]

Olthof DC, et al., Prognostic factors for failure of nonoperative management in adults with blunt splenic injury: a systematic review. Velmahos GC, Zacharias N, Emhoff TA, et al., Management of the most severely injured spleen: a multicenter study of the Research Consortium of New England Centers for Trauma (ReCONECT). Haan JM, Bochicchio GV, Kramer N, Scalea TM. Nonoperative management of blunt splenic injury: a 5-year experience. Jeremitsky E, et al., Starting the clock: defining nonoperative management of blunt splenic injury by time

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## FNOM: Age

- Within the model population, the results demonstrated the highest risk of mortality was among patients age 65 or older
  - Those ages 13 to 17 years were 79% less likely to die
  - Those ages 18 to 64 years were 88% less likely to die

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## FNOM: ISS

- Higher ISS of 25 or greater was associated with an increased risk of death
  - Patients with ISS 0 to15 were 87% less likely to die compared to those with ISS of 25 or greater
  - Patients with ISS 16 to 24 were 63% less likely to die compared to those with ISS of 25 or greater



## FNOM: Injury Grade IV

- Literature tells us that Grade IV injuries are associated with FNOM 40% of the time[16,17]
  - Among those patients who received any invasive or less-invasive procedure in this study, 38.5% (n=10) sustained a Grade IV injury
- The 40% FNOM rate is comparable to current literature

Peitzman AB., et al., *J Am Coll Surg* 2005; 201: 179-181.
McIntyre LK. *Arch Surg* 2005; 140: 563-569



## FNOM: Injury Grade V

- Grade V injuries are associated with FNOM 15% of the time[16]

  We report 7.7% (n=2) Grade V injuries
- In this study ISS score was reported rather than injury grade
- This reflects the fact there were 130 patients with valid injury grade scores, and 364 patients with valid ISS scores in the database



Peitzman AB., et al., *J Am Coll Surg* 2005; 201: 179-181.

## FNOM Outliers

- There exists a possibility that patients in previous studies who were initially classified as FNOM's may have been mislabeled
- Careful scrutiny regarding intent to treat is necessary to distinguish NOMs recorded as FNOMs
- In this study there were two such instances
- Physician preferences indicated a deliberate delay to SAE until daylight hours based on patient stability
- Neither patient required other procedures and were discharged without further incident and were reclassified to the NOM treatment group



## Rural FNOM

- Prolonged transportation time greater than 20 minutes in rural settings allows the patient to declare themselves hemodynamically stable or unstable prior to admission at a trauma center and these patients tend to maintain that status
- Those patients who experience FNOM in urban settings likely present as stable and became unstable after admission
- The ability to more accurately predict the need for NOM in rural populations, based on prolonged transportation time, may alter what is currently believed about the H-LOS following splenic injury in rural communities



## Rural FNOM

- The mean transportation time in this study was 90 minutes, while the median time was 65 minutes
- Patient residency was not assessed, therefore it is difficult to distinguish the proportion of the model population which came to the trauma center from a rural community
- However, as the mean and median approximate one another and both exceed one hour, the statistics suggest that a larger proportion of patients in this study came from a rural setting

## ACS Recommendation

- While it remains true that ACS guidelines promote apid EMS delivery because it has been shown to save lives within the first hour after injury, for patients with splenic injury in a rural state, prolonged transport times may allow symptoms to manifest before delivery to the trauma center
- This evidence may lead to quicker, more accurate treatment decisions
- The ability to more accurately predict the need for NOM may alter what is currently believed about necessary H-LOS in the rural patient population

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## Strengths

- This study is the first trial to evaluate the predictive capacity of transportation time related to H-LOS and mortality following splenic injury
- To the best of our knowledge, it is the third study to focus on the splenic-injured population in a setting where the trauma center's catchment area encompasses a largely rural population

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## Limitations

- Retrospective, single institutional study
- Pilot study with small sample size. Only 155 (of 364) patients had a transportation time on file
- No assessment was made regarding the presence or size of hemoperitoneum, presence of ETOH or drugs, or comorbidities
- Included both non-isolated injuries and poly-trauma
- Omission of those patients who died less than two hours from arrival at the hospital
- Cause of death was not analyzed
- No clear chronological order of events prior to trauma center admission or assessment of EMS interventions
- No distinction of patient residence (urban versus rural)
- Injury grade was not available for all 155 patients in the survival analysis

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## Conclusions

1. Transportation time was not identified as a predictor of mortality, and therefore survivability, among those patients with splenic injury in a rural state but remains a variable of interest for future research in a more robust population
2. Transportation time was, however, found to be associated with decreased incidence of FNOMs and improved outcomes among the splenic-injured population in a rural state, and should be considered in discharge planning

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## Recommendations

- Recommendations are for intensive observation < 24 hours after admission in rural environments, with surveillance through hospital day 2
- Based on other injuries, discharge can be considered on hospital day 3

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## Future Research

1. A priority should be placed on the collection of EMS times and the sequence of events prior to arrival prior to the conduction of new research in both rural and urban settings in order to answer the question of whether transportation is a predictor of FNOM
2. Consideration of studies in rural environments involving radiologic assessments controlled for subjectivity and experience level
3. Case matched series comparing outcomes for rural versus urban patients to isolate the effect of transportation time
4. Consideration of implications for transportation time related to other injury types

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# References


1. Brender E, Burke A, Glass R. The Spleen. JAMA. 2005;294(20):2660.
2. Ledbetter S, Smithuis R. Acute Abdomen - Role of CT in Trauma. Radiology Assistant. http://www.radiologyassistant.nl/en/p466181ff61073/acute-abdomen-role-of-ct-in-trauma.html. Accessed 03-10-14.
3. Kodikara S: Death due to hemorrhagic shock after delayed rupture of spleen: a rare phenomenon. Am J Forensic Med Pathol 2009;30:382-383.
4. Carlin AM, Tyburski JG, Wilson RF, Steffes C. Factors affecting the outcome of patients with splenic trauma. Am Surg. 2002;5(3):232–239.
5. Brady RR, et al,. Management of blunt splenic injuries. World J Surg. 2007; Nov;31(11):2111-6.
6. Hsia R, Shen YC. Healthcare outcome disparities in trauma care. Arch Surg. 2011;146(1):46-52.
7. U.S. Department of Commerce. 2010 United States Census. www.census.gov. Accessed 03-27-14.
8. Kansas Department of Health and Environment Office of Rural Health. www. Kdheks.gov/olrh/rural.html. Accessed 03-27-14.
9. Kansas - ACEP 2014 EM Report Card. www.emreportcard.org/Content.aspx?id=534. Accessed 03-10-14.
10. Wyatt J Beard D, Gray A, Busuttil A, Robertson C. The time of death after trauma. BMJ. Jun 10, 1995; 310(6993): 1502.
11. Hoskins W, Jacob A, Wijeratne S, Campbell I et al. Splenic injury admitted to a rural Level 3 trama centre: a 10-year audit. Aust J Rural Health. 2013 Jun;21(3):163-9.
12. American Association for the Surgery of Trauma. Spleen Injury Grading Scale. http://www.aast.org/library/traumatools/injuryscoringscales.aspx#spleen. Accessed 03-10-14.
13. McSwain N, et al., A model for rural trauma care. 2012; Mar;99(3):309-14.
14. Christopher S Morris, MD; Chief Editor: Kyung J Cho. Society of Cardiovascular and Interventional Radiology. Interventional Radiology for Vascular and Solid Organ Trauma. http://emedicine.medscape.com/article/423295-overview. Accessed 03-10-14.
15. Jeremitsky (2012)
16. Dr. Nedal Malar. Trauma.org: Grade 4 spleen rupture from blunt trauma. May 05, 2007. http://www.trauma.org/index.php/main/im/543/C13. Accessed 03-10-14.
17. Stassen NA, et al., Selective nonoperative management of blunt splenic injury: an Eastern Association for the Surgery of Trauma practice management guideline. J Trauma Acute Care Surg. 2012; Nov;73(5 Suppl 4):S294-300.
18. Peitzman AB, Harbrecht BG, Rivera L. Heil B. Failure of observation of blunt splenic injury in adults: variability in practice and adverse consequences. J Am Coll Surg. 2005; 201: 179–187.
19. McIntyre LK, Schiff M, Jurkovich GJ. Failure of nonoperative management of splenic injuries: causes and consequences. Arch Surg. 2005; 140: 563–569.


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# References


20. Chen IC, Wang S, Hsin-Chin S, et al. Spleen artery embolization increases the success of nonoperative management following blunt splenic injury. J Chin Med Assoc. 2011 Aug;74(8):341-4.
21. Watson GA, Rosengart MR, Zenati MS, Tsung A, Forsythe RM, Peitzman AB, Harbrecht BG. Nonoperative management of severe blunt splenic injury: are we getting better? J Trauma. 2006 Nov;61(5):1113-8; discussion 1118-9.
22. Health Resources and Services Administration. Defining the Rural Population. http://www.hrsa.gov/ruralhealth/definition_of_rural.html. Accessed 3/06/14.
23. Olthof DC, Joosse P, van der Vlies CH, de Haan RJ, Goslings JC. Prognostic factors for failure of nonoperative management in adults with blunt splenic injury: a systematic review. J Trauma Acute Care Surg. 2013;Feb;74(2):546-57.
24. Velmahos GC, Zacharias N, Emhoff TA, et al,. Management of the most severely injured spleen: a multicenter study of the Research Consortium of New England Centers for Trauma (ReCONNECT). Arch Surg. 2010; 145: 456–460.
25. Haan JM, Bochicchio GV, Kramer N, Scalea TM. Nonoperative management of blunt splenic injury: a 5-year experience. J Trauma. 2005; Mar;58(3):492-8.
26. Jeremitsky E, Smith RS, Ong AW. Starting the clock: defining nonoperative management of blunt splenic injury by time. The American Journal of Surgery. 2013; Mar 205, 298-301.


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