# Prehospital Spinal Immobilization and the Backboard Quality Assessment Study

## By

# C. Andrew Peery

A Master's Paper submitted to the faculty of The University of North Carolina at Chapel Hill In partial fulfillment of the requirements for The degree of Master of Public Health in The Public Health Leadership Program.

Chapel Hill

2003

Λ

#### Abstract

Prehospital spinal immobilization for patients with suspected spinal injury has been the universal standard of practice in the United States since the early 1970's. Recent debate has focused on the lack of strong evidence indicating improved patient outcomes as a result of this practice. This article reviews the literature regarding prehospital spinal immobilization to examine the origins of this practice, the evidence that supports it, the evidence against it, and the difficulties faced by researchers who work in the field.

This article also presents the results to date of the Backboard Quality Assessment Study (BQAS), a prospective observational study to evaluate strap tightness and tape adhesion in immobilized patients arriving by ambulance at an academic medical center. To date, an evaluation of 17 subjects has found that 7 subjects (41%) had at least one unattached strap or piece of tape that should have attached their head to the board, while 14 subjects (82%) were found to have greater than 2 cm of slack between their body and at least one strap. Among those with any straps looser than 2 cm, the average number of loose straps was 3.2 out of 4. This study suggests that many patients may not be as well immobilized as they could be given existing technology.

## Prehospital Spinal Immobilization and the

**Backboard Quality Assessment Study** 

## **L** Introduction

Traumatic spinal cord injury has long captured the attention of the modern American public. From movie heroes to football players, the victims of spinal cord injury embody a collective view of medical tragedy. Since 1990, the mean age of those injured has been 35.3 years (1). The relative youth of this population leads to both decades of treatment costs and decades of lost earning potential.

The incidence of acute spinal cord injury in developed countries is estimated to be between 11.5 and 53.4 patients per million population (2). Today, between 183,000 and 230,000 people are living with permanent spinal cord injury (1). Motor vehicle collisions caused 38.5% of these injuries, followed by acts of violence (24.5%), falls (21.8%), and sports (7.2%) (1). The cost of patient care for these injuries AFTER the first year ranges from \$12,000 to \$102,000 per year (1). The total direct cost (not counting lost wages or productivity) of spinal cord injury in the United States is estimated at \$7.736 billion (3). The suddenness of these injuries and the youth of those who experience them has rendered them a priority for most Americans (4).

In prehospital care, Emergency Medical Technicians (EMTs) are trained to immobilize all patients with possible spinal instability to prevent further neurologic injury (5). Many of these patients will later be found to have no injury at all (6). Some will have an intact spinal cord but an unstable vertebral column; the goal here is to prevent motion of the vertebral column from damaging the spinal cord. Other patients will already have some degree of neurologic disability on initial exam. In these patients, the goal is to prevent further cord trauma from motion of an unstable vertebral column.

A similar approach to spinal cord immobilization is used by EMTs throughout the United States (6). Specifically, an immobilizing hard-plastic collar is placed around the patient's neck. Foam blocks or rolled towels are then placed on either side of the patient's head, and the patient is strapped and/or taped to a hard plastic or wood board (6). The goal of all this work is to prevent "pathologic motion" of an unstable vertebral column from crushing, severing, stretching, compressing, or otherwise damaging the spinal cord (6, 7). In a 2001 statement encompassing current theories of spinal cord injury, the National Institute of Neurological Disorders and Stroke (NINDS) summed up the matter most succinctly:

> The care and treatment of persons with a suspected spinal cord injury begins with emergency medical services personnel, who must

evaluate and immobilize the patient. Any movement of the person, or even resuscitation efforts, could cause further injury. (8)

As the rest of this paper will demonstrate, support of prehospital spinal immobilization borders on universal among physicians who specialize in prehospital care. Such unflagging support is in some ways surprising, as there is currently no Class I or Class II evidence<sup>1</sup> that supports prehospital spinal immobilization of all patients with suspected spinal instability (7, 9, 10). The theory of spinal immobilization predates both the modern Emergency Medical Services (EMS) system (5-7, 11-14) and the widespread application of "Evidence Based Medicine" techniques (15). In the words of one author, "spinal immobilization is a concept that became the standard of care based on common sense rather than research." (10)

In some ways, this is not an unusual problem for modern medicine. The literature is filled with treatments that seemed like a good idea until the research was done to prove otherwise. In the past year, new information from the Women's Health Initiative has clearly made the point that physicians can be wrong even with the benefit of relevant research articles (16). At the same time, however, there are also common folk treatments that were later vindicated by our

<sup>&</sup>lt;sup>1</sup> The American Academy of Neurology provides the following definitions of Class I and Class II evidence for a therapeutic intervention on their website (135). "Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required: a) Primary outcome(s) is/are clearly defined. b) Exclusion/inclusion criteria are clearly defined. c) Adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias. d) Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class II: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-d above OR a RCT in a representative population that lacks one criteria a-d."

modern focus on evidence. Saw palmetto, used for centuries as a medicinal herb, has been proven to be effective in the treatment of benign prostatic hyperplasia. (17, 18)

As this paper will show, however, there are both methodological and ethical dilemmas in research efforts to evaluate the efficacy of prehospital spinal immobilization. These difficulties in no way alter the fact that hundreds of patients are immobilized every day in the United States. This raises a series of profoundly interesting questions. First, is it possible to know whether prehospital spinal immobilization actually alters patient outcomes? Second, in the current absence of Class I or Class II information, is there room for reasonable minds to disagree in the treatment of actual patients? Third, for the patients who are immobilized, how do we know that our prehospital providers are doing the job correctly (and what would it mean if they are not)?

In addition to considering the complex issues raised by prehospital spinal immobilization, this paper will present the ongoing results of the Backboard Quality Assessment Study. This research, which is now being conducted in the University of North Carolina Hospitals Department of Emergency Medicine, develops a model for the evaluation of prehospital spinal immobilization quality. This paper will consider the reasons such a model is necessary and the actual results obtained to date.

## **II.** The Literature of Spinal Immobilization

This thesis does not seek to be a comprehensive review of the literature of prehospital spinal immobilization. Such an undertaking is too broad and beyond

the scope of this work. Those readers who are interested in such a review are referred to the journal Neurosurgery (March 2002) for the anonymous article Cervical Spine Immobilization before Admission to the Hospital (7, 19). This article is the first chapter of <u>Guidelines for the Management of Acute Cervical</u> <u>Spine and Spinal Cord Injury</u> which have been approved and adopted by the American Association of Neurological Surgeons and the Congress of Neurological Surgeons (19). For this article, the authors conducted multiple Medline searches, searched the reference lists of relevant articles, and contacted colleagues working in the field. At this time, this article represents the state of the art for comprehensive reviews of the literature and is acknowledged as such by Dr. Mark Hauswald, the primary critic of our current theory of spinal immobilization. (10)

The literature of spinal immobilization has also been extensively reviewed by Kwan et al. in The Cochrane Database of Systematic Reviews (9), updated most recently in February of 2003. The authors provide extensive documentation of their search strategies within this article.

In an effort to locate additional evidence and commentary on prehospital spinal immobilization, multiple Medline, CINAHL, ACP Journal Club, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Database of Abstracts of Reviews of Effects searches were conducted. Terms searched included:

--"spinal immobilization"

--"backboard" or "spineboard"

--"exp Spinal Injuries OR exp Spinal Cord Injuries" AND "prehospital OR EMS OR Emergency Medical Services"

--"spinal immobilization OR backboard" AND "pain"

--"EBM OR evidence based medicine" AND "prehospital OR emergency medical services"

--"EMS OR emergency medical services or prehospital" AND "history" --"quality assessment" AND "EMS OR emergency medical services OR prehospital"

These searches were combined with careful and extensive readings of the references of all relevant papers.

## **III.** Development of the Theory of Spinal Immobilization

In 1965, Geisler et al published Early Management of the Patient with Trauma to the Spinal Cord, a retrospective analysis of the records of 958 patients with spinal cord injury in the Toronto area (14). Geisler's work is a wide-ranging effort to determine what various lessons might be learned from the records of these patients, but it also provides a useful insight into the origins of prehospital spinal immobilization. The paper begins by considering concerning reports of "delayed onset of paraplegia"—instances where a trauma victim initially has full or partial neurologic function that subsequently degenerates (14). The authors located 29 patients (roughly 3% of the study population) "who at first had little or no spinal cord involvement" but whose condition subsequently deteriorated (14). The authors specifically describe two cases where patients lost lower limb function after spinal injury was not recognized. In the second case, the patient lost function after walking a short distance from the site of his accident. While it is worth noting that this patient's limb function was recovered after two operations, the authors are quite clear in their interpretation of the initial paralysis. In the words of the authors, "The paralysis occurred in each case as a consequence of failure to recognize the injury to the spinal column and to protect the patient from the consequences of his unstable spine." (14) This belief was based on observation, case report, and standards of orthopedic treatment of spinal fractures. It was this belief that drove the physicians who invented and popularized prehospital spinal immobilization. (11-13, 20)

The initial development of prehospital spinal immobilization is widely credited to Louis Kossuth (6, 7, 11, 12, 20). As early as 1966, Kossuth began working with a short spine board that stopped at the waist (20). Kossuth also developed a long, waxed board with a winch line attached that was used to slowly winch motor vehicle collision victims from a vehicle (12, 20). Upon removal from the vehicle, the patient could be strapped to the board for immobilization, making the Medical Services School Winch Board the predecessor to the modern spine board.

Even in 1966, Kossuth states the ethic that underlies prehospital immobilization to this day: "Our objectives are clear. We desire to immobilize the spine of a victim within the vehicle with a minimum amount of movement of the patient." (20) Kossuth's ideas and inventions were further popularized by Farrington (13): "The short and long spine boards are essential for removal of

victims... The nine foot long straps allow firm immobilization so the board and the victim are one unit." (13)

#### **IV. Emergency Medical Services and a National Standard of Care**

Just as Kossuth and Farrington were popularizing their theories, prehospital care itself was undergoing a significant reorganization. The first emergency transport service is thought to have originated in the 18<sup>th</sup> century with the armies of Napoleon. Napoleon's surgeon-in-chief, Baron Jean-Dominique Larrey, ordered that the wounded be taken from the battlefield to field hospitals using wheeled carts (21). By the 19<sup>th</sup> century, emergency transportation of the sick and injured had gained more broad acceptance. Cincinnati General Hospital established the first hospital-based service in 1865 (21). The first city ambulance service was started in New York City in 1866 under the guidance of Bellevue Hospital (21).

While the idea of transporting the injured has been around for centuries, the idea of trained professionals providing substantial treatment prior to and during transport is a relatively new invention. Until the 1970's, most ambulance services were run by local funeral homes, primarily because they had a hearse capable of transporting an injured person who needed to lie flat (21). The men who manned these vehicles were provided with little substantive training and were mainly known for the reckless speed with which they transported the injured to the hospital (5, 21).

In 1965, the President's Commission on Highway Safety recommended the development of community action programs for the transportation of the sick

and injured (22). In 1966, the National Academy of Sciences published <u>Accidental Death and Disability: The Neglected Disease of Modern Society</u> (23), which further stressed the importance of prehospital care in patient outcome. The Highway Safety Act of 1966 directed states to address the development of EMS programs or lose up to 10% of federal highway funds (21). The National Highway Traffic Safety Administration (NHTSA) published guidelines for these programs in 1969 (21).

That same year, NHTSA contracted for the development of a standardized course of instruction for Emergency Medical Technicians (21). This program was built around the American Academy of Orthopedic Surgeons (AAOS) pioneer text for EMTs, <u>Emergency Care and Transportation of the Sick and Injured</u> (22, 24). This text specifically teaches Kossuth and Farrington's theory and technique of spinal immobilization (24). The 81 hours NHTSA course rapidly became the nationwide standard for training of EMTs (21). NHTSA continued to develop further curriculums for accident victim management and paramedic training throughout the 1970's (21).

Funding for the new, professional EMS was soon made available at the federal level. In 1972, the Department of Health Education and Welfare (HEW) announced \$8.5 million in contracts for the development of model EMS systems (21). In 1973 Congress passed the Emergency Medical Systems Act (P.L. 93-154) which established an EMS program at HEW to take over control from NHTSA (25).

The main point to be gained from all of this history is that spinal immobilization was a standardized component of a DOT-NHTSA program, in much the same way that ambulance design standards were specified by DOT-NHTSA (22). It was not left to the individual judgement of local medical directors as to whether prehospital spinal immobilization should be practiced. The current concept of advanced care performed under physician direction came after the development of the professional EMS system, and was only explored through pilot programs in the early 1970's (22). As one author put it, "the physician was on the sidelines, being occasionally asked for an opinion and having some input into the planning process, but seldom having any real authority over the system." (26)

While the recommendations of such physician groups as the Committee on Injuries of the American Academy of Orthopedic Surgeons were instrumental in federal decision making in the 60's and 70's, it was federal training and federal dollars that ensured that prehospital spinal immobilization became the universal standard of care in the United States by the mid 1970's. Federal EMS funds were specifically targeted to federal goals until 1981, when they began to be distributed directly to the states as part of Preventive Health and Health Services block grants (27).

The establishment of the National Association of EMS Physicians in 1984 refocused EMS systems on the importance of active medical direction of EMS providers by a physician within the community (25). Even with this new focus on physician direction and research, the field of prehospital care has continued to

uniformly embrace the use of spinal immobilization for patients with suspected spinal injury (6, 7, 10). A systematic review of the literature did not reveal a single article that called for an end to the use of prehospital spinal immobilization for patients with suspected spinal injury.

## V. The Modern Standard of Practice

Spinal immobilization is uniformly taught to EMT students throughout the United States (5). The demonstration of effective spinal immobilization is commonly required in the practical section of the final exam for EMT certification (28). Brady's <u>Basic Trauma Life Support</u> defines adequate spinal immobilization by stating: "The patient must be secured well enough to have no motion of the spine if the board is turned on its side." (29) The National Association of Emergency Medical Technicians <u>Pre-Hospital Trauma Life</u> <u>Support Text</u> offers a more extensive list of questions as "Criteria for Evaluating Immobilization Skills."

- Was manual in-line immobilization initiated immediately, and was it maintained until it was replaced mechanically?
- Was an effective, properly fitting cervical collar applied appropriately?
- Can the device move up or down the torso?
- Can it move left or right at the upper torso?
- Can it move left or right at the lower torso?
- Can any part of the torso move anteriorly off the rigid device?
- Does any tie which circumferentiates the chest inhibit chest excursion, resulting in ventilatory compromise?

- Is the head effectively immobilized so that it can not move in any direction, including rotation?
- Is the head in a neutral, in-line position?
- Does anything inhibit or prevent the mouth from being opened?
- Are the legs immobilized so that they cannot move anteriorly, rotate, or move from side to side, even if the board and patient are rotated to the side?
- Are the pelvis and legs in a neutral in-line position?
- Are the arms appropriately secured to the board?
- Have any ties or straps compromised distal circulation in any limb?
- Was the patient bumped, jostled, or in any way moved in a manner that could compromise an unstable spine while the device was being applied?
- Was the procedure completed within an appropriate time frame? (30)

Taken as whole, this evaluation is a detailed restatement of Farrington's original position—"The nine foot long straps allow firm immobilization so the board and the victim are one unit." (13)

The nature of prehospital care demands that some immobilized patients may have to be turned on their sides. Such situations can arise in extricating a patient from a tight space, carrying a patient through a small doorway or down a confined stairwell, or in situations where the immobilized patient is vomiting and unable to protect his or her airway. In training, practice immobilizations are routinely tested by turning the "patient" onto his or her side. In the field, however,

such an approach is considered inappropriate for patients in the absence of clinical necessity.

As a surrogate measure, some EMT instructors teach that the EMT should be able to insert a maximum of two fingers beneath each immobilizing strap (31). This approach is also sited in the literature of immobilization technique efficacy (32). Others rely on "common sense" judgement of whether or not the patient would move if tilted. The goal of total prevention of motion, however, is consistent across the educational literature.

In actual fact, total prevention of motion is most likely impossible. The halo orthoses that are used by orthopedic surgeons for definitive immobilization of patients have been shown to allow up to 7 degrees of lateral motion (32). The one study that focused on effectiveness of different strapping techniques in controlling torso motion found that the most effective approach allowed between 3.2 and 9.8 cm of lateral motion (33). For this study, the authors attached 19 healthy male volunteers to a backboard that was then rotated 90 degrees to the left in a controlled manner. Lateral motion of the torso from the force of gravity was then measured. Each subject was rotated three times for each of four strapping techniques, and the straps were always retightened between rotations.

The strapping techniques compared used between 6 and 8 straps, which might be expected to provide greater immobilization than the 4 to 5 strap techniques more commonly encountered in this area of the United States. While only male subjects were used with a mean height of 178.31 cm and a mean weight of 78.06 kg, subjects who were outliers on lateral movement were not found to

have statistical similarities in body habitus. This suggests that a more representative sample of the population would not have demonstrated superior immobilization. The authors report tightening the straps only until the point where the patients could "breathe comfortably." The relationship between comfortable breathing, adequate immobilization, and clinically-significant respiratory compromise is unclear; it may be that better immobilization could have been achieved by sacrificing some level of comfort. However, this research does suggest that complete immobilization is not possible using the current long spine board and straps.

What remains is the goal of motion prevention to the greatest extent possible without respiratory or circulatory compromise. This focus on motion prevention is also encountered in a substantial section of the research literature of prehospital spinal immobilization. The Cochrane review of spinal immobilization includes 9 randomized controlled trials conducted on healthy volunteers that compared patient mobility across various immobilization interventions (9, 32-39). The literature review for this paper, although not focused on motion-control studies in healthy volunteers, located an additional 6 studies in this area (40-45). The extent of work in this area indicates that the research community accepts Farrington's view of "board and... victim as one unit" (13) and is striving to find the best way to put it into practice.

## VI. Morbidity associated with prehospital spinal immobilization

Numerous authors have documented various issues of morbidity that accompany spinal immobilization (7, 9, 10, 46). The National Association of

EMS Physicians (NAEMSP) released a 1999 position paper that lists several areas of concern in patient care resulting from the use of the long spine board (47). These areas of concern include:

--decreased patient comfort, in particular the problem of head and back pain resulting from immobilization

--altered physical exam as a result of pain from immobilization

--issues of ischemic tissue injury from prolonged pressure

--issues of respiratory compromise

--issues of prehospital provider time on scene

--issues of immobilization cost

One of the more common areas of study is patient pain. Numerous studies have used healthy volunteers to establish that the long spine board can cause varying degrees of pain in most patients over a time period consistent with clinical use (36, 38, 48-56). Unnecessary pain should always be avoided in patient care, but in this case spine pain caused by the long spine board alters an important component of the physical exam for spinal injury (49, 57), leading to potentially unnecessary radiology studies (47).

The weight of the body against the spine board has been shown to create sacral and thoracic pressures capable of causing vascular ischemia in healthy volunteers (38, 58) with resultant increased risk of pressure ulcer formation (59). Prolonged immobilization prior to admission to a spinal injury ward has been specifically shown to increase risk of pressure ulcers in patients with spinal cord injury, primarily because care givers outside of acute spinal wards are less likely

to rotate injured patients (60, 61). One prospective study of 39 spinal injury patients consecutively admitted to one hospital has specifically correlated time on a spine board with risk of decubitus ulcers developing within 8 days (61). Case control comparisons (23 cases, 59% of subjects) were significant for duration of immobilization prior to ward admission, distance of injury site from hospital, time on the spine board, and reduced systolic blood pressure at the time of admission (P<0.1). Spinal cord injured patients may be at greater risk for vascular ischemia because of reduced mobility, reduced sensation, and reduced tone in the vascular bed that supplies the skin (59). Several authors have commented that prolonged immobilization after patient arrival at the ED should be avoided for the reasons above (46, 62-64).

Several studies have also documented varying degrees of reduced respiratory function in healthy subjects who are immobilized (65-67). These studies were small, with the largest of them recruiting only 51 volunteers. By concentrating on young healthy subjects, it is likely that they underreported the significance of respiratory difficulty encountered by in overall population. While neither the studies nor decades of clinical experience suggest that we are at risk of suffocating our patients by immobilizing them, this represents an important issue of patient comfort and, in cases of severe trauma, potential exacerbation of hypoxia.

Pepe and Orledge estimate the per person cost of spinal immobilization at roughly \$15 (68). They further estimate that 5 million patients a year receive prehospital spinal immobilization, for a total cost of \$75 million a year (68). Not

all of these patients may have needed to visit the Emergency Department, resulting in increased health care costs for these visits (68) and unnecessary radiology studies (47).

The sum total of these concerns has led to much recent work in the area of prehospital clearance for spinal injury. This should not be viewed as a change from the policy of providing prehospital spinal immobilization for all patients with suspected spinal injury. Rather, it is a refinement of the concept of "suspected spinal injury."

For most of the history of prehospital spinal immobilization, EMTs have been taught numerous signs and symptoms of spinal injury. The 9<sup>th</sup> edition of Brady <u>Emergency Care</u> lists (5):

--paralysis of the extremities

--pain without movement

--pain with movement

--tenderness anywhere along the spine

--impaired breathing (diaphragmatic breathing)

--deformity of the spine

--priapism

--posturing

--loss of bowel or bladder control

--nerve impairment to the extremities

--severe spinal shock

--soft tissue injuries associated with trauma

The EMT is trained to use all these signs and symptoms to search out the possibility of spinal injury. These signs and symptoms are used to identify patients in need of spinal immobilization. Historically, the absence of these signs and symptoms was never enough to rule out spinal injury. Mechanism of injury (MOI) has traditionally been more important than all signs and symptoms (5). EMTs have been taught for decades that:

If the mechanism of injury exerts great force on the upper body or if there is any soft-tissue damage to the head, face, or neck due to trauma (such as from being thrown against a dashboard), assume possible cervical-spine injury. Any blunt trauma above the clavicles may damage the cervical spine. (5)

Furthermore:

In the field, it is not possible to rule out spinal injury even when the patient has no pain and is able to move his limbs. The mechanism of injury alone may be the deciding factor. (5)

Through the 1990's, much research focused on the development of Emergency Department decision rules that could reliably identify patients without spinal injury prior to any radiology studies (57). The NAEMSP position paper on prehospital spinal immobilization cites 20 publications in the field of Emergency Department spinal clearance criteria. The largest of these, the National Emergency X-Radiography Utilization Study (NEXUS), prospectively evaluated a study population of 34,069 patients with blunt trauma who underwent cervicalspine radiology studies for the evaluation of that trauma (69). The study was conducted at 21 hospitals throughout the United States. Each institution received a

waiver of informed consent, so that every patient with blunt trauma who underwent cervical spine imaging for that trauma was included in the study. The NEXUS study found that 2.4% of the population evaluated had cervical-spine injury as documented by radiology (69); the same standard three views (crosstable lateral view, anteroposterior view, and open-mouth odontoid view) served as a baseline for all patients, although the attending physician could order additional films at their discretion.

With radiology acting as a gold standard, NEXUS was further used to provide validation of a 5 criterion instrument for cervical spine clearance without radiology. The 5 criteria used were:

--no midline cervical tenderness

--no focal neurologic deficit

--normal alertness

--no intoxication

-- no painful, distracting injury

All evaluations were conducted and recorded prior to cervical spine imaging. Presence of one of these 5 criteria was found to have a 99.6% sensitivity (95% CI 98.6-100) and a negative predictive value of 99.9% (95% CI 99.8-100) (69). Specificity was 12.9% (95% CI 12.8-13.0%) and positive predictive value was 1.9% (95% CI 2.6-2.8%) (69).

The study criteria could be criticized as somewhat vague. A clinician may wonder whether or not an injury is "distracting," or whether or not alertness is "normal." Possible interpretations of these criteria were discussed with physicians at the various centers, but no definitive interpretations were given. Thus, the individual physician may be forced to wonder what the sensitivity and specificity of his or her interpretation of the NEXUS criteria are. This said, this study sets a high standard for quality of subject population and variety of treatment environment and has been widely embraced by the physician community.

The success of the NEXUS study fostered a growing interest in prehospital clearance of spinal injury. Recent research has sought to train EMTs in NEXUS-type criteria to determine if they can screen patients prehospital with the same sensitivity as Emergency Medicine physicians (47, 70-78). This research has also taken the further step of ensuring the NEXUS criteria can detect thoracic and lumbar injuries with appropriately high sensitivity (71). Given the morbidity of spinal immobilization, the goal of such research is to identify trauma patients who are not at risk of spinal injury and who therefore do not require the use of the long spineboard. In the words of the lead author of NEXUS:

Any out-of-hospital protocol should emphasize safety (sensitivity) over efficiency (specificity), particularly now that some patients can be quickly and safely cleared on arrival at the ED. The cumulative small benefits associated with avoiding spinal immobilization in many patients without injury must be balanced against the rare but extremely important harm associated with failing to immobilize injured patients. (70)

While some may disagree about precisely how much risk is acceptable, Hoffman's comment summarizes the ongoing commitment to prehospital immobilization by the majority of those working in the field.

New protocols allowing field spinal clearance are now in effect in multiple EMS systems throughout the United States (72). NAEMSP has endorsed the use of NEXUS criteria for prehospital clearance (47). It is worth noting, however, that the British Trauma Society's 2002 guidelines for management and assessment of spinal injury continue to stress the importance of MOI above all other criteria (64). To date, neither approach has been evaluated in terms of patient outcomes, suggesting a potentially promising avenue for future research.

#### VII. Issues in the evidence for prehospital spinal immobilization

Prehospital spinal immobilization for patients with suspected spinal injury is universally endorsed by the prehospital literature, although some critics who question the efficacy of prehospital immobilization have called for further research (10). Techniques of spinal immobilization are part of the mandatory education of every EMT trained in the United States. Spinal immobilization is routinely applied in the first world (79-81) and with growing frequency in the second and third world (82, 83). Unfortunately, the history of medicine has shown us that such universal agreement does not protect us from being wrong. In the absence of well-designed and administered randomized controlled trials comparing spinal immobilization to no immobilization in patients with suspected spinal injury, it would be inappropriate to say that we "know" that spinal immobilization improves patient outcomes.

Multiple systematic reviews of the literature including this paper have failed to locate a randomized controlled trial of prehospital spinal immobilization (7, 9, 10). While such trials might have been possible when techniques of spinal

immobilization were first introduced, the current near-universal belief in the efficacy of spinal immobilization makes such trials ethically impossible for the moment (7, 9). Since we believe that spinal immobilization likely benefits our patients with suspected spinal instability, we cannot fail to immobilize any patient that we suspect has spinal instability, even in the context of research.

This theory is discussed by Friedman et al. in the text <u>Fundamentals of</u> <u>Clinical Trials</u>: "the presence of uncertainty as to the benefits or harm from an intervention among the expert medical community rather than in the investigator, [*pic*] is justification for a clinical trial." (84) This concept is called clinical equipoise; without it, research occurs at the expense of patients who are denied an intervention that most clinical experts working in the field believe would be beneficial to those patients (84). In the case of immobilization research, the expert medical community as a whole does not question the necessity or efficacy of prehospital immobilization for patients with suspected spinal injury (7, 68, 70). Until such time as they do, any clinical trials to investigate the matter are ethically precluded.

The universal use of spinal immobilization throughout the United States prevents us from either prospectively or retrospectively comparing an American cohort of subjects who are immobilized to an American cohort of subjects who are not immobilized. Even if we were to identify a first-world EMS system where patients might be "poorly" immobilized, the current standard of practice would demand that we immediately rectify any failures rather than take the time to study their extent and impact on patient outcomes. It might be possible to use

retrospective chart analysis to identify a cohort of patients with missed spinal injury prehospital who were therefore not immobilized. Given the bias toward sensitivity in our prehospital immobilization procedures and the use of similar screening criteria in the Emergency Department, the identification of such patients would be rare. It would therefore be difficult to obtain a large enough sample size for comparison to an immobilized cohort. Patients from other first world countries would have to be excluded due to differences in EMS system design and staffing and hospital standards of care (85). Furthermore, it is likely that any cohort of patients who 1) prove to have spinal injury 2) fail to be immobilized by EMS providers despite their low threshold for suspicion of spinal injury and 3) nonetheless travel to the hospital by ambulance, would be substantially different from a cohort of patients who are immobilized prehospital.

While spinal immobilization is used throughout America, Canada, Europe, and the rest of the first world, we are able to find non-immobilized cohorts by traveling to the third world. This approach was attempted by Hauswald et al in 1998 in the one of two known retrospective cohort studies of spinal immobilization (7, 82). A comprehensive search of the literature for research directly evaluating the efficacy of prehospital spinal immobilization in a clinical population located only this study by Hauswald and a similar study by Leung et al. (86).

Hauswald's group carried out a 5 year retrospective chart review comparing 120 non-immobilized patients with spinal cord injury seen at the University of Malaya to 334 immobilized patients with spinal cord injury seen at

the University of New Mexico. Two independent physicians blinded to the hospital of origin evaluated each case for the presence of disabling or nondisabling neurologic injury. The distribution of injuries by column level and the age of the injured were found to be equivalent. Patients in Malaysia were most likely to have been injured by a fall (53%), while patients in New Mexico were most likely to have been injured in a motor vehicle collision (74%). The OR for significant disability was found to be higher for patients from the New Mexico cohort (2.03; 95% CI 1.03-3.99; p = 0.04) after adjustment for these variables.

Hauswald's group admits several limitations of their study. Patients who died prior to arrival at the hospital admission were not included, raising the possibility of an important difference in pre-hospital mortality due to the use of spinal immobilization techniques. Studies comparing Vietnam and Kenya to the United States have shown significantly elevated motor vehicle crash (MVC) mortality levels per crash in third world countries (87). It is unknown whether the inclusion of on-scene fatalities might have raised more significant issues regarding method of injury—i.e. more Malaysian patients may have died in MVC's but avoided inclusion in the hospital-based cohort.

Similarly, Malaysian patients were not transported by ambulance and did not have access to the rapid deployment of first responders trained in extrication that would have been used in New Mexico (88). This difference could have resulted in patients of greater acuity reaching the hospital in New Mexico with a severe prognosis while similar patients in Malaysia would have died during extrication or en route. Finally, Malaysian patients were not matched to American

patients for significance of non-spinal injuries. Issues of blood loss and shock raise the possibility of cord damage due to hypoxic injury (89, 90). While such patients would be unlikely to survive an extended extrication and transportation in Malaysia, American techniques of prehospital care may have resulted in a surviving American cohort at substantially greater risk for long-term neurologic disability.

Pepe and Orledge have pointed out that Hauswald's group did not compare the types of fractures found, though it is known that different types of fractures have different outcomes (68). As types of fractures can vary according to mechanism of injury and as mechanism of injury varied substantially between the two groups, this difference may represent a significant confounding variable (68). Mechanism of injury may also have varied within the category of MVC patients. Third world countries are more likely to utilize large multi-passenger vehicles which would not be considered safe in the United States (87). Smaller passenger vehicles used in other countries may not be equivalent to American vehicles in safety design. Similar variations in traffic laws, enforcement of those laws, and patterns of seat belt use may also suggest that Americans are more likely to initially survive an MVC that would be fatal in another country (87).

These concerns, the small sample size (particularly in the Malaysian cohort) and the lower confidence limit of 1.03 do not provide substantial support to Hauswald's subsequent criticisms of spinal immobilization (10, 82). In the words of Pepe and Orledge, "one would not want to change the current out-of-hospital spinal immobilization practices based solely on this paper." (68)

Hauswald's overall design was recently repeated by Leung et al. with a nonimmobilized cohort of 63 spinally-injured patients from the People's Republic of China compared to 334 immobilized spinally-injured Americans (86). Among the Chinese cohort, 28% were found to be disabled (95% CI of 18-41%). Among the Americans, 21% were found to be disabled (95% CI of 17-28%). The authors conclude that there was no statistical difference between the two cohorts, which is not surprising given the low power of the study. This study, reported only in abstract, appears to face the same methodological difficulties discussed above. Furthermore, 61 of 63 Chinese patients suffered cervical spine injury, while in the American cohort 113 patients had cervical injury, 107 had thoracic injury, and 113 had lumbar injury. From a retrospective analysis of 358 patients with acute spinal injury from 1948-73, we know that thoracic injuries have a significantly higher rate of complete injury (77.5%) than cervical (60.4%) or lumbar (64.7%) injuries (91). This difference is traditionally attributed to the narrower canal of thoracic verterbrae (92). The one year mortality rate for complete spinal cord injury is 28% while that for incomplete injury is 14% (93).

Given these methodologic weaknesses, it may prove difficult to design a cohort comparison that provides convincing evidence for or against spinal immobilization. Using a cohort of immobilized American patients as an intervention group, we are forced to find a comparable non-immobilized cohort with:

- similar mechanism of injury to American patients
- comparable severity of spinal injuries to American patients

- similar non-spinal injuries to American patients
- similar quality of emergency dispatch services
- similar quality and timeliness of prehospital extrication
- similar method and staffing of prehospital care excluding spinal immobilization
- similar quality of transport vehicle
- similar quality of road surface and road distance between injury site and hospital
- similar quality of emergency department care
- similar quality of radiology care
- similar quality of surgery and anesthesiology care
- similar quality of post-operative care
- similar patient population by age and sex
- similar patient population by nutrition and overall health
- large sample size
- similar medical record quality both pre and post hospital, including records of on-scene deaths

Any study attempting to prove the benefit of prehospital spinal immobilization would require a cohort matching all of these characteristics or significant statistical manipulation to compensate for variations between subjects. Otherwise, the potential benefit detected could be attributed to deficiencies in the cohort. A study attempting to establish a lack of benefit of prehospital spinal care is held to a lesser cohort standard—deficiencies in care upon arrival to the hospital likely bias the statistics in favor the American cohort. Otherwise, however, the same standards would apply.

Finally, it is important to note that Hauswald's paper does not evaluate the quality of prehospital immobilization in the New Mexico population. EMT skill levels are known to deteriorate after training (94), and the ongoing data from the Backboard Quality Assessment Study (see section XII) shows concerning failures in EMT immobilization quality. It could be argued that Hauswald's work compares the Malaysian cohort to an American cohort where patients may or may not be truly immobilized. If so, his results may indicate the dangers of spinal immobilization done badly, not the benefits of spinal immobilization done well.

It is unlikely that any cohort could be located that could satisfy all of the above criteria. Hauswald's original cohort no longer exists—Malaysia is now developing an EMS system that, like all EMS systems, uses techniques of spinal immobilization (82). To find a comparable cohort, one would have to find a third world country that had recently added a modern EMS system with modern communications and extrication but had omitted the use of spinal immobilization. Such an occurrence remains unlikely—ethics demand that those who create a modern EMS system take advantage of what are believed to be the best affordable techniques available to their population. Hauswald's study could have been made more effective by prospective recruitment of the cohorts in both locations including on-scene and transit fatalities. Such an approach would require extensive coordination with police forces in both locations, but would provide

more informative statistics on outcomes than are currently available in the literature.

Hauswald's work does suggest another important line of research, albeit a difficult one. Third world countries that do institute modern EMS systems require time to put such systems into place. Awareness of such an impending change would create an opportunity to simultaneously evaluate the effect of spinal immobilization AND EMS systems as compared to historical controls. Ideally, a research team could establish baseline statistics on morbidity and mortality of spinal injury (including patients who die on scene.) With assessment methods in place, changes could be monitored as the new EMS system came on line. While such an approach would still not distinguish between the benefits of spinal immobilization and the benefits of extrication, advanced life support, and rapid transport, it would still make a substantial contribution to the literature of the field.

#### VIII. The Source of Belief in Prehospital Immobilization

With so many normal sources of evidence not only absent but ethically precluded from development, the reasonable mind may wonder if there is any justification for prehospital immobilization. The arguments in favor may seem disturbingly circular. There is no evidence in favor of spinal immobilization because the creation of such evidence necessitates the creation of an unethical situation. Immobilization is good, and to attempt to prove that it is good would be bad. At the same time, we have multiple studies that demonstrate some degree of harm as a result of prehospital spinal immobilization.

While there are no convincing studies that establish a patient benefit, studies in 5 separate areas have been summed to form a convincing argument in favor of prehospital spinal immobilization for patients with suspected spinal instability. These areas are

- 1) models of traumatic spinal injury
- 2) case studies of spinal injury in the absence of immobilization
- research indicating that normal transport mechanics create "clinically significant" movement of the patient
- research indicating spinal immobilization techniques reduce "clinically significant" movement of the patient
- statistical analysis showing improved patient outcome over the period that spinal immobilization was put into effect

## A. Models of Traumatic Spinal Injury

The current neurology and neurosurgery literature proposes a two-part theory of spinal injury in trauma (92, 95-97). Primary injury is the result of force that causes transection, compression, or traction of the spinal cord (92, 95-97). Such forces may include traumatic force of impact, compression from vertebral column elements, and hematoma within the spinal canal (92, 95). This initial mechanical damage is followed by a series of physiologic events that lead to further progression of tissue damage by means of ischemia and pathologic calcium influx into neurons (92, 95, 97). In recent years, extensive research has focused on pharmacologic interventions to prevent this secondary damage (92, 95).

As early as the 1940's, techniques of surgical spinal stabilization were developed for patients with unstable vertebral columns (98). Surgical treatment of vertebral injury is focused on reduction, approximation, and stabilization of the spine (99). Modern treatment for spinal fracture involves immobilization for a period of weeks to months using techniques ranging from a simple cervical collar to external fixation with Halo devices and body casts to surgical decompression and stabilization (100). Surgical treatment of spinal cord injury focuses on alleviating compression of the spinal cord (99). In recent years, considerable debate has surrounded the utility of surgical decompression (101). Some have argued that the majority of damage occurs with primary injury and that continued compression of the cord produces little incremental deficit (101, 102).

The utility of this argument in the area of immobilization is unclear. An unstable spine can be thought of as allowing additional primary traumas rather than prolonged compression. Guttmann's original argument on this matter compared traumatic injury to the process of a slow-growing tumor or a tuberculous process of the spine (102). It seems unlikely that Guttmann intended for this argument to be applied to spinal immobilization as his own writings emphasize the importance of careful prehospital handling of the patient (103). In support of this position, Guttmann refers to a case series of 29 spinal cord injured patients who developed worsened neurologic disability "through faulty handling during first aid." (14, 103) It is perhaps most telling that the literature of this field focuses on issues of early versus late surgical decompression rather than the efficacy of spinal immobilization (101, 102).

31

an Josef School Banada Bandan et et al Banara son per bilitarda

Extensive clinical research has also been conducted on the issue of early vs late surgical spinal stabilization (101, 104). The results of these studies have been mixed (101, 104). While surgical stabilization provides a more definitive immobilization than external orthoses, it also creates numerous additional risks from both the surgery itself and anesthesia. It is therefore unclear whether current surgical research can provide any insight into the utility of prehospital immobilization.

Very few animal studies have specifically attempted to address issues of spinal cord damage as a result of an unstable spine (89, 105). Ducker created spinal cord injury in 32 rhesus monkeys by means of weighted impact over the surgically-exposed cord (106). The monkeys were subsequently randomized to a control group (19 animals) and a group that was surgically immobilized by means of a figure eight ligature (13 animals). In the control group, 3 of 4 animals that were impacted with a 500 gm-cm weight recovered complete function and the fourth was mildly paraparetic. In the control group at this weight, 5 of 6 animals were paraplegic.

Dolan conducted a series of studies where distraction injuries were produced in cats (107). The spinal column was surgically exposed and distraction was created by means of a device that separated vertebrae in precise increments. Subsequent measurements of spinal cord blood flow established that stretching of the spinal column can result in spinal cord ischemia comparable to that seen with other types of spinal injury (107).

Some readers might object that skeletal traction of up to 40 lbs may be used in the reduction of fractures distal to C3 (108). However, it should first be noted that clinical traction is gently introduced in line with the spinal cord, while distraction in the field runs the risk of sudden angulation across vertebral structures. Most patients who undergo traction will have some intact ligamentous structures (108). In the absence of such intact structures or in high cervical dislocations, skeletal traction can result in distraction injuries (108). Overdistraction can occur even in cases of partial ligamentous injury when the force of traction exceeds the ligamentous tolerance (109). The orthopedic literature contains a number of cases of patients with neurological deterioration during the process of spinal reduction (110).

Finally, it is important to note that the torso of most adult patients weighs substantially more than 40 pounds and is subject to multiple forces during transport to the hospital, particularly in situations where the patient's head is wellattached to the spine board and his or her torso is not (32). In such situations of improper spinal immobilization, the torso can pendulum beneath the attachment point of the head and distraction injury becomes a greater concern (32).

There are numerous difficulties in applying animal trauma models to clinical practice in humans. In addition to obvious issues of species variation, surgically-induced trauma may be a poor substitute for clinical trauma in the real world. As detailed by Geisler (89), patients may have multiple severe injuries, which can lead to systemic hypoxia or hypotension. One study found grade III or higher multitrauma in 19% of patients admitted to a spinal cord injury unit (90).

These patients were found to have more severe cord injuries with a mortality rate almost 5 times that of patients without significant multitrauma (90). Human trauma patients may also be physiologically altered by alcohol or drugs.

## B. Case Studies of Spinal Injury in the Absence of Immobilization

The literature contains various references to patients with unstable vertebral columns who had sudden and striking deterioration of their condition after movement. This issue has been addressed in case series and chart reviews, and thus is more easily described in anecdotal rather than statistical terms. Geisler's work in this area, discussed at the beginning of section III, was one of the motivations for the original development of systematic prehospital immobilization of patient's with suspected spinal injury (14). Neurologic degeneration some time after an injury suggests additional primary trauma as a result of an unstable vertebral column. However, the passage of days to weeks is also consistent with the theory of secondary injury described above. It is more difficult to argue that a sudden onset is consistent with secondary injury physiologic mechanisms, particularly when the onset occurs simultaneously with patient movement.

Masini et al studied a group of 10 patients who initially walked after a trauma but had a subsequent neurologic deterioration (111). These patients constituted 0.7% of a population of 1410 patients admitted to a spinal care ward. Instability of the spine was found in 7 of the 10 cases. In one of these cases a patient with a high level unstable fracture of the lumbar spine stood up immediately after the accident, took a few steps, and became paraparetic. A
second patient, unconscious for 18 days, recovered consciousness and began walking, only to suddenly develop tetraparesis. A third patient, in bed with mild paresthesias in the lower limbs for 6 days, became paraplegic when he was allowed to stand and walk to the bathroom. A fourth patient, maintained in bed for 30 days, became paraparetic when he began walking. Other cases (whose specifics were not detailed) were attributed to instability after laminectomy, instability and prolapsed disk, surgical trauma from the removal of a knife, instability, a hook dislocation at T8, and an epidural abscess.

Bohlman conducted a retrospective analysis of 300 patients with cervical spine fractures (112). Of these, he reports seven patients who developed signs of a partial or complete cord lesion after "neck immobilization was not provided." Three patients developed similar signs "while they were in the emergency room," and eleven patients "after they had reached the hospital." One patient is particularly described as developing an anterior cord syndrome after an attack of delirium tremens while in skeletal traction. In a different publication referring to the same series of patients, Bohlman describes one patient who had no paralysis when he left the emergency room for an x ray but who returned as a complete quadriplegic (108). Two other patients are described as developing paralysis in the Emergency Department "after unintentional manipulation." (108) Unfortunately, the article does not detail the case histories of the other patients in question.

Marshall et al in a prospective study of deterioration in 14 hospitalized patients with spinal cord injury correlated 12 instances of deterioration with

hospital treatments (113). The rate of deterioration in the overall population (283 patients) was roughly 5% (113). Three patients became worse on application of skeletal traction, suggesting possible distraction. Two patients worsened after rotation of a Stryker frame, and in one of these cases the nurses reported that the frame had slipped during rotation. Four patients worsened after spinal surgery. Two patients worsened after halo vest application, which the authors attribute to the unavoidable loss of some immobilization during halo vest placement. The final patient worsened after rotation on a rotobed. While this study raises the possibility that immobilization interventions may sometimes cause the harm they seek to prevent, it also appears to provide examples where a small movement of an unstable vertebral column resulted in substantial worsening of patient neurologic deficit.

A similar situation is encountered in Harrop et al, who conducted a retrospective chart review of 182 patients with complete spine injury (114). Of 12 patients with neurologic deterioration within the first 30 days after injury, 2 patients with ankylosing spondylitis experienced worsening of neurologic disability with external immobilization. A third patient was agitated in the ED and refused to remain still while immobilized in a rigid cervical collar, resulting in ascension of injury to a complete C4. A fourth patient could not be adequately immobilized with the halo vest because of excessive body habitus.

Toscano conducted an analysis of 123 patients admitted to a spine unit in Melbourne, Australia (115). Of these, 32 were found to have sustained major neurological deterioration between the time of the accident and admission to the

unit. Toscano collected all information within 7 days of admission to the unit and personally traveled to interview witnesses, EMTs, and other physicians involved in each patients' care. Unfortunately, Toscano does not offer the details of individual cases, only his interpretation of the cause of groups of cases. Three patients were witnessed to deteriorate at the accident site. Nine patients who were not immobilized deteriorated during EMT assessment and transport. Twelve patients who were admitted to the hospital had unrecognized spinal injury and were not immobilized. In the case of patients whose spinal instability was known, Toscano attributes 3 deteriorations to inappropriate lifting of patients, 2 to absent immobilization, and 1 to inadequate immobilization.

Poonnoose et al examined the medical records of 569 patients with neurologic deficits secondary to spinal cord trauma (116). The authors report the injury was initially unrecognized in 52 patients (9.1% of the population) and that 26 of these patients experienced neurologic deterioration as a result of mismanagement. Unfortunately, the cases are again not discussed in detail, making it difficult to evaluate the likelihood of repeated primary injury vs secondary injury.

Ravichandran and Silver examined the records of 15 patients (out of 353) with spinal cord injuries initially missed by physician evaluation (117). They report that failure to recognize the injury and "subsequent management" of the patient resulted in rapid neurologic deterioration. Specifics of this deterioration are not given.

George documents numerous cases that resulted in court actions against the EMS systems involved (118). One patient, who was initially placed by EMS in a chair and who was never immobilized, developed back pain and diaphragmatic breathing en route to the hospital. On arrival at the hospital he was diagnosed with a C5-C6 partial quadriplegia. A second patient who was initially unconscious had her chest and thigh straps released en route to the hospital. She subsequently regained consciousness and struggled with the EMTs. The next day she was found to be paraplegic. A third patient, after involvement in a significant auto accident, was initially able to move most of his body. He was combative and was neither diagnosed with spinal instability nor properly immobilized until 17 hours after his accident, by which time he had lost sensation and movement from his midchest down. A fourth patient was being undressed by a nurse after an auto accident. The nurse pulled the patient's blouse over her head, at which point the patient lost consciousness. She woke to find that she was totally paralyzed.

It should be restated that none of these cases constitute definitive proof of additional primary trauma due to an unstable vertebral column. Hauswald has argued that "It seems intuitively unlikely that subsequent movement of the spine within its normal range of motion and essentially without resistance would add significantly to the damage already done [by the primary trauma]. Cases of deterioration from movement of unstable spinal injuries during extrication, transport, and initial evaluation do undoubtedly occur, but is clear from clinical experience and the literature that this is an uncommon problem." (10)

Hauswald suggests that the literature should contain more such cases if injury from spinal instability were truly a threat to our patients, but it must be remembered that injury from spinal instability has been widely believed to be a threat to trauma patients for many decades (98). It could be argued that the literature does not contain numerous cases which support this theory because it was not believed that the theory needed support. It should also be noted that immobilization has been the standard of care for patients with suspected spinal cord injury for many decades. If immobilization is effective, we would expect paralysis from movement to be rare because we have done our best to prevent it.

# C. Research Indicating that Normal Transport Mechanics Create "Clinically Significant" Motion of the Spine

Normal transport mechanics encompass three distinct areas—removal of the patient from the scene of the accident, transport of the patient from the accident scene to the emergency department, and time spent in the emergency department prior to spinal clearance or definitive immobilization. A comprehensive review of the literature revealed no research on the forces created by a typical accident scene or by typical ED mechanics. In the previous section, there were case studies of patients who became injured at both sites (111, 112, 114, 115). These case studies suggest that the neurologic deficits were the result of the patient's own motion or of manipulation by care providers.

Removal of a patient from the scene of an injury provides numerous opportunities for motion. Injured patients are often found in awkward spaces— EMS providers often joke about the patient who falls between the bed and the

wall or the bathtub and the toilet. Patients sometimes have to be carried some distance over uneven ground or through tight corridors or stairwells.

Two studies have addressed the significance of motion created by air and ground transport. Silvergleit et al. attached a device to measure acceleration to healthy backboarded volunteers (119). Volunteers were then driven over various roadway surfaces at 35 mph or flown at low and high speeds in a helicopter ambulance. The authors documented peak accelerations of 2.5 m/s, with greater but more uniform accelerations experienced in helicopter transport and smaller but less uniform forces generated in ambulance transport. The authors did not correlate degree of force with probability of injury.

Perry et al conducted a study of head immobilization comparing the efficacy of towels, styrofoam wedges, and the "Headbed II" in 6 healthy volunteers (32). While many other immobilization efficacy studies have used the deliberate motion of the subjects, the Perry group devised a computer-controlled moving platform to simulate vehicle motion. The use of the platform enabled the use of high-speed shuttered cameras and a video motion analysis system. The volunteers reported that the motion of the platform "effectively simulated" the motion of a moving vehicle, but it is possible that this perception was not accurate.

The Perry study focused on motion of the head relative to the board and rotation or lateral angulation of the head relative to the motion of the trunk. Regardless of the method of immobilization used, the movements were determined to be "clinically significant" in the clinical judgment of a panel of

three neurologists and neurosurgeons. The authors also concluded that motion of the trunk was a significant factor in motion of the cervical spine. During an initial pilot investigation prior to the study, one unrestrained volunteer slid 0.5 m across the platform surface during pilot studies. During the course of the published research, the average degree of angulation of an immobilized patient was 8 degrees. The authors compare this to the 7 degree amplitude of lateral motion that may be possible in a halo-vest.

The panel's judgment of "clinical significance" clearly assumes the theory of recurrent primary injury that is put forward by the case studies. In all likelihood, it is based less on research evidence than on the panel's collective clinical judgment and experience. Understanding the source of the panel's evaluation, we can also say that 8 degrees of angulation is substantially less "clinically significant" than sliding 0.5 meters. Thus, the Perry study suggests that, during transport, patients move in ways that are concerning if we accept the theory that movement is concerning. Furthermore, the Perry study proves that such movement is substantially reduced by techniques of spinal immobilization (and that immobilization of the trunk is particularly important in this area).

# D. Research Indicating Spinal Immobilization Techniques Reduce "Clinically Significant" Movement

As was discussed earlier, much research in the field of prehospital spinal immobilization has focused on the ability of spinal immobilization techniques to reduce the forms of motion that Perry's panel of neurologists and neurosurgeons found concerning. As would be expected, numerous other studies of

immobilization have established substantial reductions in mobility compared to absent immobilization (32, 34, 40, 42-45). Methods used have included both healthy volunteers and cadavers (9, 32-45). Movement has been generated by the subject, by weights, and by devices that move the subject (9, 32-45). Evaluation of movement has been conducted by direct observation, camera, and radiology studies (9, 32-45).

In these comparisons of different methods, no study finds a method that results in "complete" immobilization—every immobilized patient could still move to some degree. The one study that focused on comparison of strapping methods found lateral motion of 3.2 to 9.8 cm for the most efficacious method of immobilization tested (33, 120). This method of cross-strapping, which uses six horizontal straps, is not the current standard of practice nationwide. For all methods tested the straps were tightened "snugly, but not so as to cause discomfort." Thus, while Perry et al. established that cervical collars and spinal immobilization are roughly equivalent to halo orthoses in prevention of angulation (32), there is a possible concern that current spinal immobilization techniques do not provide enough protection from spinal cord injuries.

# E. Statistical Analysis Showing Improved Patient Outcome Over the Period that Prehospital Spinal Immobilization was put into Place

If prehospital spinal immobilization was effective at improving patient outcomes, we would expect a reduction in death and disability from spinal injury over the last three decades. Unfortunately, there is no published research that investigates change in spinal injury morbidity or mortality statistics during a time

period when prehospital spinal immobilization was put into place in a specific geographic area. Such studies may be possible now in third world countries that are establishing EMS systems and should be viewed as a promising area for future research.

A 1975 analysis of acute spinal cord injury in 18 California counties for the two year period of 1970-71 found 299 deaths among 619 cases, a case fatality rate of 48.3% (121). The authors found that 79% of the fatalities died before arriving at the hospital or were taken directly to the morgue. Vaccaro's 2003 text on spinal injury cites an incidence rate of 59 cases per million in hospitals and 77 cases per million including prehospital fatalities (3). This would indicate a contemporary case fatality rate of 23% on scene or prehospital, albeit from a different statistical population that may not provide a fair comparison to the earlier data.

From 1973-1986, the risk of death within 2 years of injury among SCI patients admitted to federally-designated model care systems for spinal injury within 24 hours of injury (n=1898) decreased by 66% (122). This same study also documented a reduction in the frequency of complete cord injury from 56.4% to 48.6% (p<0.0001) in a larger population of 6,563. The one year mortality rate for complete spinal cord injury is 28% while that for incomplete injury is 14% (93). Again, this is a substantial reduction from the case fatality rate of 48.3% found in 1970-71 (121).

In 1999, a similar comparison found a reduction of 1 year mortality of 67% when comparing spinal cord injured patients from 1973-77 to similar

43

At dislamined in London for

patients from 1993-98 (123). Again, these were patients admitted to federallydesignated model care systems for spinal injury within 24 hours of injury (n=9,805). These results reflect adjustment to account for trends in age, sex, race, injury level, Frankel grade, ventilator status, etiology of injury, sponsor of care, and model system where treatment took place. Unfortunately, the exclusion of patient mortality within the first 24 hours after injury excludes the most relevant population for a study of the benefits of prehospital spinal immobilization.

A retrospective study analyzing spinal cord injury patients in the Toronto area compared a cohort seen from 1947 to 1974 to a second cohort admitted to the Acute Spinal Cord Injury Unit (ASCIU) from 1974 to 1981 (2). There was no difference in level of spinal cord injury between the two groups. A significant decrease was found in work related injuries while a significant increase was found in sport and recreational injuries. Most importantly, there was a significant reduction in severity of spinal cord injury on admission (as rated by the ten grade Spinal Cord Injury Severity Scale) between the two groups.

Numerous advances over this period could also explain these statistics. Improved safety in automotive design, reduced speed limits, and seat belt laws would all be expected to have some effect. The development of EMS and trauma systems in general would also be expected to improve patient survival independent of prehospital immobilization techniques (124-126). Finally, advances in neurology and neurosurgery would be expected to have had some effect over this period.

#### IX. The Sum of Evidence

The sum total of this evidence leaves EMS medical directors in an unusual position. While there is no clear evidence that prehospital immobilization of patients with suspected spinal injury improves their outcome, there is enough evidence to suggest that the technique is effect. In the words of Hauswald's most recent comment on the matter, "Until further research clarifies which injuries, if any, truly benefit from immobilization, immobilization will remain the standard practice." (10)

Belief in the strength of this evidence by the vast majority of clinicians renders any significant clinical trials unethical. Belief in the strength of this evidence similarly prevents the existence of an appropriate non-immobilized cohort to compare to an immobilized population. For all these reasons, we can expect that spinal immobilization will remain the standard of practice in prehospital care until strong arguments are made to discredit the "common sense" argument described above. Put another way, we have decided to immobilize prehospital patients with suspected spinal injury on the basis of a theory that movement could lead to injury and that our restriction of movement has prevented injury.

#### X. The Evidence and Clinical Practice

Most states now have a medical practices act—a law that requires EMS providers working for an ambulance system to provide care under the medical license of a physician director (25). An EMT can perform the majority of Basic Life Support (BLS) skills while acting as an independent agent—an unemployed

EMT coming upon a traffic accident could legally open an airway or provide manual spinal stabilization. This same EMT must follow some form of physician medical direction when working on an ambulance as either a paid provider or as a volunteer.

Physician medical direction usually takes the form of written protocols and standing orders that allow EMTs to act without specifically consulting a physician for every patient (5). This is defined as "off-line" direction (5). At other times, EMTs will contact the hospital to obtain "on-line" direction from a supervising physician in the Emergency Department (5). Either way, the physician who directs the EMTs is ultimately accountable for the care of their prehospital patients (25, 127, 128). This concept of "vicarious liability" means that the acts of the EMTs are legally considered the acts of the physician who provides on or off-line medical direction (127).

For a medical director who is considering issues of immobilization, there is no research that indicates that best outcomes always result from a certain approach to immobilization. Instead, there is the near universally-held theory that movement of an unstable spine can lead to neurologic disability and that restriction of that movement is likely to reduce the risk of neurologic disability. Thus, EMS protocols continue to conform to the standard of care in books like Brady and ATLS (5, 129).

The few EMS physicians who are unconvinced of the benefits of prehospital spinal immobilization face the prospect of substantial legal liability should they go against the standard of care. The tort of negligence, which is

defined under state law and thus will vary from state to state, requires the plaintiff to prove each of four elements:

--duty: the physician had an obligation to treat the patient and to provide a certain standard of care

--breach of duty: the physician failed to meet his obligation
--causation: the breach of duty by the physician caused the patient's injury
--damages: the patient was actually injured (130)

In this case, duty is specifically the duty to "exercise the level of skill and care that is provided by similar professionals under similar circumstances." (130) Thus, a breach of duty is established by expert testimony as to the standard of care (130). George has documented several cases where substantial monetary awards were provided by the courts to patients who received inadequate immobilization and developed subsequent neurologic disability (118). In one case, the court awarded \$2 million while specifically citing the failure to immobilize the patient "as much and as soon as possible." (George's words, 118) From this we can infer that whatever the status of the medical literature, causation of neurologic disability by inadequate immobilization has been accepted by the courts.

## XI. Quality Assurance In EMS Systems

Physician medical direction of EMS systems involves much more than developing protocols and giving on-line medical direction. The medical director must also ensure a consistent level of quality, competency, and efficiency of the EMS providers within his or her system (25). It is the responsibility of the physician medical director to ensure that protocols are followed in the field and

the technical skills of prehospital providers are sufficient to implement the protocols as written (128, 131). Polsky and Weigand have described 4 areas of focus for EMS Quality Assurance (QA)—time criteria, protocols compliance, provider knowledge, and provider skills (132).

It is important to understand that QA in EMS is not merely a matter of selecting well-established quality indicators that are known to correlate with patient outcomes. In EMS medical direction, QA often indicates a review process to ensure adherence to all field protocols independent of their validation in the research literature (131). As described by one author:

"Retrospective quality assurance refers to an ongoing evaluation of the quality of patient care and the adherence to protocols of field and physician personnel through a review of taped or written records." (131) In the words of another author:

"Compliance-to-protocol is a powerful performance indicator... The frequency of faithful execution... must be measured in order to conclude reasonably that improvements in clinical outcome are the result of care, and not due to chance or a better alternative provided, ad hoc, by thoughtful field personnel. The QMS [Quality Management Screen] provides a model for this analysis." (133)

Uncertainty in the literature must never translate into inconsistent compliance with system protocols by EMS providers. As was made clear above, this process has legal importance in addition to medical importance.

The process of Quality Assurance should encompass more than retrospective chart review. The physician medical director should be involved with the initial training of EMS providers in his region. In the words of one author, "Credentialing of providers is an important task and to a large extent dictates the standard of care that will be provided in a system." (134)

Physician medical directors must play an active role in continuing education of EMS providers as well (131). Discipline may be useful in addressing some problems identified by the QA process, but QA data is best used to develop and refine continuing education (132). At times, this education will need to focus on skills as well as knowledge. EMT skills have been shown to decay over time (94). It is important to identify areas of deficiency and make plans for their remediation (132).

#### XII. QA and Prehospital Spinal Immobilization

Given the current universal necessity of mandating prehospital spinal immobilization for patients with suspected spinal injury, some method of ensuring appropriate spinal immobilization of patients becomes a necessary part of the QA process. The theory that supports spinal immobilization logically demands that patients be immobilized as much as possible with standard equipment while avoiding respiratory distress or circulatory compromise of the patient. Unfortunately, clinical experience has shown that many patients arrive at the ED with loose spine board straps and crumpled pieces of tape that once attached their heads to the top of the board. Common sense dictates that a patient with 5cm of slack between them and every spine board strap is not immobilized. While we do

not have Class I or Class II evidence to show that such a situation puts the patient at risk, we have enough evidence of risk to state that such a situation is unacceptable. Furthermore, such a situation constitutes a deviation from protocol and EMT training, creating a medical and legal necessity for some method of remediation.

As researchers continue to search for methods to evaluate outcomes in prehospital spinal immobilization, they will need to be able to prove that "immobilized" patients were in fact well-immobilized patients. If a patient is merely lying on a slick spine board to which they are poorly strapped, it is likely that they would move more during transit than if they were placed on the ambulance stretcher (where at least the friction of the sheets and mattress would act to hold them in place). If a patient's head is well-attached by tape but their body is poorly strapped into place, we have created a situation where the body can pendulum at the neck (32). This situation is potentially more dangerous than a complete failure to immobilize the patient as it allows transport forces to move the weight of the body against an unstable vertebral column.

## XIII. Introduction to the Backboard Quality Assessment Study

It was the concerns described above that led to the development of the Backboard Quality Assessment Study (BQAS), an Emergency Department based effort to evaluate and quantify strap tightness and tape adequacy in a spinallyimmobilized population. Appropriate practice for spine board strap tightness has been defined as the ability to insert a maximum of 2 fingers beneath each strap (31). By prospectively recruiting qualified patients and quantifying rates of

deviation from standard immobilization practice, we can establish whether there is a need for modification of our continuing education programs. Furthermore, it is our hope that the BQAS method will provide a research tool for ensuring that future cohorts of immobilized patients are, in fact, adequately immobilized.

## **XIV.** Methods of the BQAS

Potential subjects were male and female spinally-immobilized patients arriving by ambulance at University of North Carolina Hospitals Department of Emergency Medicine. Exclusion criteria were:

--age less than 18 years old on date of entry to the ED

--pregnancy

--inability to speak English

--altered level of consciousness

--red or yellow trauma acuity as defined by ED staff using predetermined ED guidelines

Patient acuity was determined by the charge nurse prior to room assignment, and no "high" or "medium" acuity patients were recruited to avoid any delay or interference in the immediate delivery of necessary patient care. "Low" acuity subjects meeting the above criteria were contacted by departmental research associates after initial nursing contact but before any straps, tape, or other forms of immobilization were taken down for physical exam. Every effort was made to conduct recruitment and assessment after the departure of EMS personnel to avoid provider awareness of the ongoing QA program. Any alteration of immobilization materials by nursing staff prior to recruitment and

assessment resulted in disqualification of the patient from the study. The process of recruitment and assessment was found to take roughly 5 minutes, with most of this time devoted to the oral reading of the patient consent form. In the experience of the authors the assessment itself was consistently conducted in under 1 minute.

All data were prospectively collected by research associates working in the Department of Emergency Medicine. The complete assessment form can be seen in attached illustrations. Date, time, patient gender, and number of patients transported from the scene of injury were recorded for each subject. Subjects were asked to report their best estimate of their current weight and height. Presence or absence of C collar and appropriate position of headblocks or rolled towels/blankets (none, out of position, or appropriate) were visually ascertained. As tape or velcro straps are traditionally used to attach the head of the patient to the board, number of tape strips/velcro straps used were recorded. Points of tape/strap attachment to the patient were documented as were strips/straps that had come unattached from the patient. Points of tape/strap attachment to the board were documented as were strips/straps that had come unattached from the board. Attachment failure was determined by the assessor as failure of the tape or strap to adhere securely to the board or patient. Specifically, failure meant that the tape or strap no longer made contact with the board or patient OR made such loose contact that the tape or strap could be easily brushed away. This last describes situations where a loose ball of tape at one end of a strip might still catch against the board due to exposed adhesive but could no longer withstand even minimal force.

Number of backboard straps were observed and strap pattern was drawn on the assessment form. Assessor tested strap tightness by lifting each strap in turn and measuring the distance (in centimeters) at midline between the strap and the patient. Assessors were trained to lift each strap using only one or two fingers to avoid the application of excessive force that might cause patient discomfort or loosen the straps. Leg straps were always measured above the right leg. Spider straps were assessed at each point where a horizontal strap intersects the vertical strap; for leg straps, this was done over the right leg. For spider straps, the point of intersection of the two angled shoulder straps was not measured. In circumstances when there were additional factors that might influence the adequacy of immobilization, the assessor would document these under the Hare Traction Splint or Other categories.

To date, 17 subjects have been evaluated. Subjects included 7 men and 9 women (one subject's gender was inadvertently omitted from the assessment). Subjects had an average self-estimated weight of 179 pounds (range, 100 to 300 pounds) and an average self-estimated height of 68 inches (range, 62 to 75 inches). Subjects arrived by a variety of EMS services from surrounding counties and were assessed between 1054 in the morning and 1247 at night.

The BQAS protocol was reviewed and approved by the Institutional Review Boards of both Duke University Health Center and the University of North Carolina School of Medicine. BQAS is an ongoing study, and patient recruitment is expected to continue through the fall of 2004.

### **XV. BQAS Results**

Quality of head immobilization is documented in table I. Of 17 subjects, 7 (41%) had at least one point (forehead, chin, right board, or left board) where the tape or strap failed to secure their head to the board. Five subjects (29%) were found to have at least two points of attachment failure. In data collection to date, only two subjects were secured with straps instead of tape, preventing useful comparison of the two methods of head immobilization.

Quality of body immobilization is documented in table II. Of 17 subjects, 15 were immobilized with 4 straps (including patients immobilized with spider straps) while 2 were immobilized with 6 straps. Strap patterns used were categorized by type as indicated in Figure I.

In the opinion of the authors, 2 cm of slack between patient and strap is the maximum allowable quantity of slack for appropriate immobilization of a patient with suspected spinal injury. Of 17 subjects, 14 were found to have at least 1 strap looser than 2 cm (82%) and 8 were found to have all four straps looser than 2 cm (47%) (see Table III). Among those subjects who had a failing strap at this level, the average number of failing straps was 3.2. Allowing a maximum of 4 cm of slack, 11 patients were found to have at least 1 strap looser than 4 cm (65%) and 2 patients were found to have all four straps looser than 4 cm (12%). Among those subjects who had a failing strap at this level, the average number of failing straps was 2.2. Of 17 subjects, 7 (41%) were immobilized with spider straps. No significant correlation could be established between spider straps and failure rate using the Chi Square Test of Independence.

### **XVI. BQAS Discussion**

The preliminary data from our first 17 subjects suggest that inadequate spinal immobilization occurs on a regular basis. As more subjects are recruited, future subgroup analyses may suggest that some immobilization methods are more likely to lead to inadequate immobilization. At this time, sample sizes for most subgroups are too small for such analyses to justify even tentative conclusions.

It is not clear what effect the exclusion of high-acuity patients may have had on the data. Prehospital providers attending to high acuity patients have many tasks that require their concentration. In such circumstances, immobilization failure may be more likely. At the same time, prehospital providers may actually ensure better immobilization for high acuity patients, believing that these patients are at greater risk for injury and therefore require additional care in transport.

The regularity of inadequate immobilization further calls into question the work of Hauswald and Leung in this area. Without a renewed focus on quality of spinal immobilization by prehospital providers, we can never know if cohorts of immobilized American patients were truly secured to the spine board. Future outcomes research in this area will need to ensure that spinal immobilization was appropriately applied in all immobilized subjects.

While the results so far are concerning, there are numerous possibilities for remedy. At the end of their initial training, all prehospital personnel were capable of immobilizing patients appropriately. A yearly skills lab could be integrated into EMT continuing education programs as a means of improving performance. EMS managers and senior staff could be instructed to bring new focus on immobilization quality while supervising work in the field. Continued measurement of performance in the Emergency Department will likely also be necessary. Such work need not be burdensome—in the experience of the authors, tape and strap measurements can regularly be taken and recorded in less than 15 seconds by one research associate.

#### **XVII.** Conclusion

The evidence in favor of prehospital spinal immobilization is not the sort of evidence we would prefer. The absence of randomized controlled trials and believable cohort studies forces us to rely on a hodgepodge of research, case studies, and our own common sense. All the while, there are thousands of injured patients who need us to make treatment decisions for all of them.

At this time, the issues of temporary morbidity raised by spinal immobilization are not enough to justify even the possible risk of catastrophic spinal injury in non-immobilized patients. In the future, new animal models or well-designed observation of new 3<sup>rd</sup> world EMS systems may provide us with better evidence for our decisions. Until that time, the standard of care should remain unchanged.

As administrators of the status quo, physician EMS directors have much work to do. The results of the BQAS have shown that we are not meeting our duty to provide prehospital care in accord with our current best theories and evidence. Continuing education of our EMS providers must place a new emphasis on quality of spinal immobilization. Quality assessment of spinal immobilization should become a regular part of the initial assessment of trauma patients. There is little doubt that our EMS providers will respond well when challenged to do better. There is little doubt that we are medically, ethically, and legally bound to help them.

# **Backboard Quality Assessment Study**

- Parrimoldine

Data	Sheet
------	-------

			Subject Number:		
Date:		Time:	am	рт	
Assessor:					
Patient on backboard: yes no			IF "NO" STOP HI	ERE	
Patient acuity: red/yellow/pregnant	all other		IF "R/Y/P" STOP	HERE	
English speaking patient: yes no			IF "NO" STOP HI	ERE	
Patient age >18 years old: yes no			IF "NO" STOP H	ERE	
Patient alert/oriented x 3: yes no			IF "NO" STOP H	ERE	
Patient verbal consent: yes no			IF "NO" STOP H	ERE	
Total number of patients transported fro	m scene:	·····	-		
Patient sex: M F					
Patient weight (self-reported):	lb	kg			
Patient height (self-reported):	ft	in	cm		
C collar: yes no					
Headblocks: none out of position	appr	opriate			
Headblock type: foam towel	other:			_	
Tape: none number of tape st	rips:	nu	mber of straps:		
Forehead tape: UA forehead UA	A right boa	rd	UA left board	intact	
Chin/collar (select) tape: UA chin UA	A right boa	rd	UA left board	intact	
Other tape: UA UA	A right boa	rd	UA left board	intact	
Number of backboard straps:	_				
Spider straps: yes no					
Strap #1 height (in cm):	_ Sta	ap #5 h	eight (in cm):		
Strap #2 height (in cm):	Str	Strap pattern (please draw if not spiders;			
Strap #3 height (in cm):		licate st	rap #'s on drawing):		
Strap #4 height (in cm):	_				
Hare traction splint: yes no			3		
Other:					

feet this end

Table I							
Quality of Head Immobilization by Subject							
Subject	C collar	Headblocks	Block type	Method	Strips	1st Strip	2nd Strip
1	Blank	Adequate	Towel	Taped	2	Intact	Intact
2	Yes	Adequate	Towel	Taped	2	Intact	Intact
3	Yes	Adequate	Foam	Taped	2	Intact	Intact
4	Yes	Adequate	Towel	Taped	2	Intact	Intact
5	Yes	Adequate	Towel	Taped	2	Intact	Intact
6	Yes	Adequate	Foam	Taped	2	Forehead	Chin
7	No	None	None	None	0	None	None
8	Blank	Adequate	Towel	Taped	2	Intact	Intact
9	Yes	Adequate	Towel	Taped	2	Intact	Intact
10	Yes	Adequate	Foam	Straps	2	Intact	Intact
11	Yes	Adequate	Towel	Taped	2	Left	Left
12	Yes	Blank	Foam	Taped	2	Right	Right
13	Yes	Adequate	Foam	Straps	2	Forehead	Intact
14	Yes	Adequate	Towel	Taped	2	Left/Right	Left/Right
15	Yes	Adequate	Foam	Taped	2	Intact	Intact
16	Yes	Out of Place	Towel	Taped	2	Left/Right	Right
17	Yes	Adequate	Foam	Taped	2	Intact	Right

Points of possible unattachment are forehead, chin, and left or right board.

Quality of Body Immobilization by Subject									
Subject	Spiders	# Straps	1st Strap	2nd Strap	<b>3rd Strap</b>	4th Strap	5th Strap	6th Strap	Pattern
1	No	6	3.0	1.0	1.0	3.0	0.5	1.0	2
2	No	6	0.1	1.0	1.0	0.1	1.0	1.0	2
3	Yes	4	4.0	3.0	2.0	6.0			1
4	No	4	1.5	1.0	3.0	3.0			3
5	No	4	5.0	5.0	2.5	2.5			4
6	Yes	4	1.0	1.5	3.0	1.5			1
7	No	4	4.0	4,0	5.0	2.5			4
8	No	4	4.0	4.0	5.0	5.0			5
9	No	4	1.0	1.0	1.0	1.0			5
10	Yes	4	1.0	1.0	1.0	2.0			1
11	No	4	9.0	4.0	7.0	4.0			5
12	Yes	4	4.0	4.0	6.0	7.0			1
13	Yes	4	5.0	6.0	13.0	7.0			1
14	No	4	11.0	12.0	7.0	2.0			4
15	Yes	4	5.0	2.0	3.0	1.0			1
16	No	4	7.0	20.0	6.0	7.0			4
17	Yes	4	4,0	5.0	7.0	4.0			1

Table II

Slack between subject and strap is recorded for each subject in centimeters Code for strap patterns is given in Figure I

Table III					
Failure Rates For Head and Body Immobilization					
Number of Failures	Subjects With Head Failure	Subjects With >2 cm Strap Failure	Subjects With >4 cm Strap Failure		
1	7 (41%)	14 (82%)	11 (65%)		
2	5 (29%)	13 (76%)	8 (47%)		
3	2 (12%)	10 (59%)	3 (18%)		
4	0	8 (47%)	2 (12%)		



Numbers correspond to strap pattern numbers on Table I All varieties of spider straps are classified as pattern 1

\*\*\*\*\*\*\*\*\*\*\*\*

# Figure I Observed Strap Patterns

#### Works Cited

- 1. Spinal Cord Injury Information Network. *Facts and Figures at a Glance May, 2001.* Available at: http://www.spinalcord.uab.edu/show.asp?durki=21446
- 2. Tator CH, Duncan EG, Edmonds VE, et al. Changes in Epidemiology of Acute Spinal Cord Injury from 1947 to 1981. *Surg Neurol* 1993; 40: 207-15.
- Marino RJ. Spinal Injury: Etiology, Demographics, and Outcomes. In: Vaccaro AR ed. <u>Fractures of the Cervical, Thoracic, and Lumbar</u> Spine New York: Marcel Dekker, 2003: 1-8.
- Oregon DHS. Prioritization of Health Services: A Report to the Governor and the 72<sup>nd</sup> Oregon Legislative Assembly. Available at: http://www.ohppr.state.or.us/hsc/bireport\_hsc.htm
- Limmer D, O'Keefe MF, Grant HD, Murray RH, Bergeron JD. <u>Brady</u> <u>Emergency Care</u>. 9<sup>th</sup> ed. Upper Saddle River (NJ): Brady/Prentice Hall Health; 2001.
- 6. DeLorenzo RA. A Review of Spinal Immobilization Techniques. *The Journal of Emergency Medicine* 1996; 14: 603-613.
- 7. Anonymous. Cervical Spine Immobilization before Admission to the Hospital. *Neurosurgery* 2002; 50: S7-S17.
- National Institute of Neurological Disorders and Stroke. Spinal Cord Injury: Emerging Concepts. Available at: <u>http://www.ninds.nih.gov/health\_and\_medical/pubs/sci\_report.htm#Cl\_inical%20Management</u>
- 9. Kwan I, Bunn F, Roberts I. Spinal immobilisation for trauma patients. *The Cochrane Database of Systematic Reviews*. 2003; 1: no page numbers.
- 10. Hauswald M, Braude D. Spinal immobilization in trauma patients: is it really necessary? *Current Opinion in Critical Care* 2002; 8: 566-570.
- 11. Kossuth LC. The Removal of Injured Personnel From Wrecked Vehicles. J. Trauma 1965; 5: 703-708.
- 12. Kossuth LC. The Initial Movement of the Injured. *Mil Med* 1967; 132: 18-21.
- Farrington JD. Extrication of Victims—Surgical Principles. J Trauma 1968; 8: 493-512.
- Geisler WO, Wynne-Jones M, Jousse AT. Early Management of the Patient with Trauma to the Spinal Cord. *Med Serv J Can* 1966; 22: 512-523.
- 15. Guyatt G, Rennie D. <u>Users' Guide to the Medical Literature: A</u> <u>Manual for Evidence-Based Clinical Practice</u>. USA: AMA Press; 2002.
- 16. National Heart, Lung, and Blood Institute. *Women's Health Initiative*. Available at: <u>http://www.nhlbi.nih.gov/whi/</u>

- Wilt JT, Ishani A, Stark G, et al. Saw Palmetto Extracts for Treatment of Benign Prostatic Hyperplasia—A Systematic Review. *JAMA* 1998; 280: 1604-9.
- 18. Wilt JT, Ishani A, MacDonald R, et al. Serenoa repens for benign prostatic hyperplasia. *The Cochrane Database of Systematic Reviews*. 2002; 1: no page numbers.
- Hadley MN, Walter BC, Grabb PA, et al. Guidelines for the Management of Acute Cervical Spine and Spinal Cord Injuries. *Clinical Neurosurgery* 2002; 49:407-98.
- 20. Kossuth LC. Vehicle Accidents: Immediate Care to Back Injuries. J Trauma 1966; 6: 582-91.
- 21. Blackwell TH. Prehospital Care. Emergency Medicine Clinics of North America 1993; 11: 1-14.
- 22. Rockwood CA, Mann CM, Farrington JD, et al. History of Emergency Medical Services in the United States. *J Trauma* 1976; 16: 299-308.
- Division of Medical Sciences. <u>Accidental Death and Disability: The</u> <u>Neglected Disease of Modern Society</u> Washington, D.C.: National Academy of Sciences/National Research Council, 1966.
- 24. Committee on Injuries, American Academy of Orthopedic Surgeons. <u>Emergency Care and Transportation of the Sick and Injured</u> Wisconsin: George Banta Co., 1971.
- 25. Benitez FL, Pepe PE. Role of the physician in prehospital management of trauma: North American perspective. *Current Opinion in Critical Care* 2002; 8: 551-8.
- 26. Stewart RD. Medical Direction in Emergency Medical Services: The Role of the Physician. *Emergency Medicine Clinics of North America* 1987; 5: 119-32.
- 27. Narad RA. Emergency Medical Services System Design. Emergency Medicine Clinics of North America 1990; 8: 1-15.
- 28. National Registry of Emergency Medical Technicians. Exam Coordinator Documents. Available at: <u>http://www.nremt.org/EMTServices/exam\_coord\_man.asp?secID=1#</u> <u>BSkillSheets</u>
- Campbell JE. <u>Basic Trauma Life Support for Paramedics and</u> <u>Advanced EMS Providers</u> 3<sup>rd</sup> ed. New Jersey: Brady/Prentice Hall Health; 1995.
- 30. McSwain NE, Butman AM, McConnell WK, Vomacka RW, editors. Pre-Hospital Trauma Life Support 2<sup>nd</sup> ed. Ohio: ETI; 1990.
- 31. Personal communication from Capt. Lynn Bost, EMT-P, Fall 1998.
- 32. Perry S, McLellan B, McIlroy WE, et al. The Efficacy of Head Immobilization Techniques During Simulated Vehicle Motion. *Spine* 1999; 24: 1839-44.
- 33. Mazolewski P, Manix T. The effectiveness of strapping techniques in spinal immobilization. *Ann Emerg Med* 1994; 23: 1290-5.

- Cline JR, Scheidel E, Bigsby EF. A comparison of methods of cervical immobilization used in patient extrication and transport. *J Trauma* 1985; 25:649-53.
- 35. Graziano AF, Scheidel EA, Cline JR, Baer LJ. A radiographic comparison of prehospital cervical immobilization methods. *Ann Emerg Med* 1987; 16: 1127-31.
- Hamilton RS, Pons PT. The efficacy and comfort of full-body vacuum splints for cervical-spine immobilization. J Emerg Med 1996; 14: 553-9.
- Lunsford TR, Davidson M, Lunsford BR. The effectiveness of four contemporary cervical orthoses in restricting cervical motion. J Prosthetics and Orthotics 1994; 6: 93-9.
- Walton R, DeSalva JF, Ernst AA, Shahane A. Padded vs unpadded spine board for cervical spine immobilization. *Acad Emerg Med* 1995; 2: 725-8.
- 39. Manix T. How effective are body-to-board strapping techniques? J Emerg Med Serv 1995; 20: 44-50.
- 40. McCabe JB, Nolan DJ. Comparison of the Effectiveness of Different Cervical Immobilization Collars. *Ann Emerg Med* 1986; 15: 50-3.
- 41. Podolsky S, Baraff LJ, Simon RR, et al. Efficacy of Cervical Spine Immobilization Methods. J Trauma 1983; 23: 461-5.
- 42. Rosen PB, McSwain NE, Arata MA, et al. Comparison of Two New Immobilization Collars. *Ann Emerg Med* 1992; 21: 1189-95.
- 43. Chandler DR, Nemejc C, Adkins RH, Waters RL. Emergency Cervical-Spine Immobilization. *Ann Emerg Med* 1992; 21: 1185-8.
- 44. McGuire RA, Degnan G, Amundson GM. Evaluation of Current Extrication Orthoses in Immobilization of the Unstable Cervical Spine. *Spine*1990; 15: 1064-7.
- 45. Solot JA, Winzelberg GG. Clinical and Radiological Evaluation of Vertebrace Extrication Collars. *J Emerg Med* 1990; 8: 79-83.
- 46. Vickery D. The use of the spinal board after the pre-hospital phase of trauma management. *Emerg Med J* 2001; 18: 51-4.
- 47. Domeier RM and The National Association for EMS Physicians Standards and Clinical Practice Committee. Indications for Prehospital Spinal Immobilization. Available at: http://www.naemsp.org/Position%20Papers/spinal.pdf
- Chan D, Goldberg RM, Mason J, Chan L. Backboard Versus Mattress Splint Immobilization: A Comparison of Symptoms Generated. J Emerg Med 1996; 14: 293-8.
- 49. March JA, Ausband SC, Brown LH. Changes in physical examination caused by use of spinal immobilization. *Prehosp Emerg Care* 2002; 6: 421-4.
- 50. Cross DA, Baskerville J. Comparison of perceived pain with different immobilization techniques. *Prehosp Emerg Care* 2001; 5: 270-4.

- 51. Hauswald M, Hsu M, Stockoff C. Maximizing comfort and minimizing ischemia: a comparison of four methods of spinal immobilization. *Prehosp Emerg Care* 2000; 4: 250-2.
- 52. Lerner EB, Billittier AJ, Moscati RM. The effects of neutral positioning with and without padding on spinal immobilization of healthy subjects. *Prehosp Emerg Care* 1998; 2: 112-6.
- Chan D, Goldberg RM, Tascone A, et al. The effect of spinal immobilization on healthy volunteers. *Ann Emerg Med* 1994; 23: 48-51.
- 54. McHugh TP, Taylor JP. Unnecessary Out-of-hospital Use of Full Spinal Immobilization (letter). Acad Emerg Med 1998; 5: 278-80.
- Walton R, DeSalvo JF, Ernst AA, Shahane A. Padded vs unpadded spine board for cervical spine immobilization. *Acad Emerg Med* 1995; 2: 725-8.
- 56. Barney RN, Cordell WH, Miller E. Pain Associated With Immobilization on Rigid Spine Boards (abstract). Ann Emerg Med 1989; 18: 918.
- 57. Petri R, Gimbel R. Evaluation of the Patient with Spinal Trauma and Back Pain: An Evidence Based Approach. *Emerg Med Clin* 1999; 17: 25-39.
- 58. Main PW. Lovell ME. A review of seven support surfaces with emphasis on their protection of the spinally injured. *J Accid Emerg Med* 1996; 13: 34-7.
- 59. Mawson AR, Siddiqui FH, Connolly BJ, et al. Sacral Transcutaneous Oxygen Tension Levels in the Spinal Cord Injured: Risk Factors for Pressure Ulcers? Arch Phys Med Rehabil 1993; 74: 745-51.
- 60. Linares HA, Mawson AR, Suarez E, Biundo JJ. Association Between Pressure Sores and Immobilization in the Immediate Post-Injury Period. *Orthopedics* 1987; 10: 571-3.
- 61. Mawson AR, Biundo JJ, Neville P, et al. Risk Factors for Early Occurring Pressure Ulcers Following Spinal Cord Injury. *Am J Phys Med Rehabil* 1988; 67: 123-7.
- 62. Cooke MW. Use of the spinal board within the accident and emergency department. J Accid Emerg Med 1998; 15: 108-9.
- 63. Lerner EB, Moscati R. Duration of Patient Immobilization in the ED. Am J Emerg Med 2000; 18: 28-30.
- 64. British Trauma Society. Guidelines for initial management and assessment of spinal injury. *Injury* 2003; 34: 405-25.
- Bauer D, Kowalski R. Effect of spinal immobilization devices on pulmonary function in the healthy, nonsmoking man. *Ann Emerg Med* 1990; 17: 915-8.
- Schafermeyer RW, Ribbeck BM, Gaskins J, et al. Respiratory effects of spinal immobilization in children. *Ann Emerg Med* 1991; 20: 1017-9.
- 67. Totten VY, Sugarman DB. Respiratory effects of spinal immobilization. *Prehosp Emerg Care* 1999; 3: 347-52.

- 68. Orledge JD, Pepe PE. Out-of-hospital Spinal Immobilization: Is It Really Necessary? Acad Emerg Med 1998; 5: 203-4.
- 69. Hoffman JR, Mower WR, Wolfson AB, et al. Validity of a Set of Criteria to Rule Out Injury to the Cervical Spine in Patients with Blunt Trauma. *NEJM* 2000; 343: 94-9.
- Hoffman JR, Mower WR. Out-of-hospital cervical spine immobilization: Making policy in the absence of definitive information. Ann Emerg Med 2001; 31: 632-4.
- 71. Domeier RM, Swor RA, Evans RW, et al. Multicenter Prospective Validation of Prehospital Clinical Spinal Clearance Criteria. *J Trauma Injury Infection and Critical Care* 2002; 53: 744-50.
- Stroh G, Braude D. Can an Out-of-Hospital Cervical Spine Clearance Protocol Identify All Patients With Injuries? An Argument for Selective Immobilization. Ann Emerg Med 2001; 37: 609-615.
- 73. Hankins DG, Rivera-Rivera EJ, Ornato JP, et al. Spinal immobilization in the field: clinical clearance criteria and implementation. *Prehosp Emerg Care* 2001; 5: 88-93.
- Cone DC, Wydro GC, Mininger CM. Current practice in clinical cervical spinal clearance: implication for EMS. *Prehosp Emerg Care* 1999; 3: 42-6.
- 75. Domeier RM, Evans RW, Swor RA, et al. The reliability of prehospital clinical evaluation for potential spinal injury is not affected by the mechanism of injury. *Prehosp Emerg Care* 1999; 3: 332-7.
- 76. Meldon SW, Brant TA, Cydulka RK, et al. Out-of-Hospital Cervical Spine Clearance: Agreement between Emergency Medical Technicians and Emergency Physicians. J Trauma Injury Infection and Critical Care 1998; 45: 1058-61.
- 77. Domeier RM, Evans RW, Swor RA, et al. Prehospital clinical findings associated with spinal injury. *Prehosp Emerg Care* 1997; 1: 11-5.
- Domeier RM, Evans RW, Swor RA, et al. Prospective validation of out-of-hospital spinal clearance criteria: a preliminary report (letter). *Acad Emerg Med* 1997; 4: 643-6.
- Kelly DF, Becker DP. Advances in Management of Neurosurgical Trauma: USA and Canada. World Journal of Surgery 2001; 25: 1179-85.
- 80. Kay A, Teasdale G. Head Injury in the United Kingdom. World Journal of Surgery 2001; 25: 1210-20.
- 81. Atkinson L, Merry G. Advances in Neurotrauma in Australia 1970-2000. World Journal of Surgery 2001; 25: 1224-9.
- Hauswald M, Ong G, Tandberg D, Omar Z. Out-of-hospital Spinal Immobilization: Its Effect on Neurologic Injury. Acad Emerg Med 1998; 5: 214-9.
- de Andrade AF, Marino R, Cinquini O, et al. Guidelines for Neurosurgical Trauma in Brazil. World Journal of Surgery 2001; 25: 1186-1201.

- 84. Friedman LM, Furberg CD, DeMets DL. <u>Fundamentals of Clinical</u> <u>Trials</u> 3<sup>rd</sup> ed. New York: Springer; 1998.
- Bossaert LL. The Complexity of Comparing Different EMS Systems—A Survey of EMS Systems in Europe. Ann Emerg Med 1993; 22: 99-102.
- 86. Leung M, Thomas T, Steele R. Effect of Cervical Spine Immobilization in Preventing Adverse Neurologic Outcome in Blunt Spinal Trauma (abstract). Ann Emerg Med 2003; 42: S20.
- 87. Nantulya VM, Reich MR. The neglected epidemic: road traffic injuries in developing countries. *BMJ* 2002; 324: 1139-1141.
- 88. Wilmink ABM, Samra GS, Watson LM, Wilson AW. Vehicle entrapment rescue and pre-hospital trauma care. *Injury* 1996; 27: 21-5.
- Geisler FH. Neuroprotection and regeneration of the spinal cord. In: Menezes AH, Sonntag VKH, eds. <u>Principles of Spinal Surgery</u> New York: McGraw-Hill, 1996: 769-83.
- Meguro K, Tator CH. Effect of Multiple Trauma on Mortality and Neurological Recovery after Spinal Cord or Cauda Equina Injury. *Neurol Med Chir* 1988; 28: 34-41.
- 91. Tator CH. Spine-Spinal Cord Relationships in Spinal Cord Trauma. Clin Neurosurg 1983; 30: 479-94.
- Amar AP, Levy ML. Pathogenesis and Pharmacological Strategies for Mitigating Secondary Damage in Acute Spinal Cord Injury. *Neurosurgery* 1999; 44: 1027-39.
- 93. Saboe LA, Reid DC, Davis LA, et al. Spine Trauma and Associated Injuries. *J Trauma* 1991; 31: 43-8.
- 94. Zautcke JL, Lee RW, Ethington NA. Paramedic Skill Decay. J Emerg Med 1987; 5: 505-512.
- 95. Tator CH, Fehlings MG. Review of the secondary injury theory of acute spinal cord trauma with emphasis on vascular mechanisms. J Neurosurg 1991; 75: 15-26.
- Chapman JR, Anderson PA. Thoracolumbar spine fractures with neurologic deficit. Orthopedic Clinics of North America 1994; 25: 595-612.
- 97. Blam OG, Ehrler DM, Rauschning W, Vaccaro AR. Anatomy and Pathophysiology of Traumatic Spinal Cord Injury. In: Vaccaro AR ed. <u>Fractures of the Cervical, Thoracic, and Lumbar Spine</u> New York: Marcel Dekker, 2003: 9-21.
- 98. Dickman CA, Marciano FF. Principles and Techniques of Screw Fixation of the Cervical Spine. In: Menezes AH, Sonntag VKH, eds. <u>Principles of Spinal Surgery</u> New York: McGraw-Hill, 1996: 123-39.
- Dyson-Hudson TA, Stein AB. Acute Management of Traumatic Cervical Spinal Cord Injuries. *The Mount Sinai Journal of Medicine* 1999; 66: 170-8.
- 100. Bradford DS, Pashman RD, Hu SS, et al. Orthopedics. In: Way LW, ed <u>Current Surgical Diagnosis and Treatment</u> 10<sup>th</sup> ed New York: McGraw-Hill, 1994: 1011-1129.

- Amar AT, Levy ML. Surgical Controversies in the Management of Spinal Cord Injury. J Am Coll Surg 1999; 188: 550-65.
- 102. Wagner FC, Chehrazi B. Early decompression and neurological outcome in acute cervical spinal cord injuries. *J Neurosurg* 1982; 56: 699-705.
- Guttmann L. <u>Spinal Cord Injuries</u> Oxford: Blackwell Scientific Publications: 1973.
- Wilberger J. Acute spinal cord injury. In: Menezes AH, Sonntag VKH, eds. <u>Principles of Spinal Surgery</u> New York: McGraw-Hill, 1996: 753-68.
- 105. Fernandez E, Pallini R, Marchese E, Talamonti G. Experimental studies on spinal cord injuries in the last fifteen years. *Neurol Res* 1991; 13: 138-59.
- 106. Ducker TB, Salcman M, Daniell HB. Experimental Spinal Cord Trauma, III: Therapeutic Effect of Immobilization and Pharmacologic Agents. Surg Neurol 1978; 10: 71-6.
- 107. Dolan EJ, Transfeldt EE, Tator CH, et al. The effect of spinal distraction on regional spinal cord blood flow in cats. *J Neurosurg* 1980; 53: 756-64.
- 108. Bohlman HH, Emery SE. Complications of Treatment of Fractures and Dislocations of the Cervical Spine. In: Epps CH ed. <u>Complications</u> <u>in Orthopaedic Surgery</u> 3<sup>rd</sup> ed Philadelphia: J.B. Lippincott, 1994: 679-711.
- 109. Capen DA, Leppek E. Emergency Management of Spine Trauma. In: Vaccaro AR ed. <u>Fractures of the Cervical, Thoracic, and Lumbar</u> <u>Spine New York: Marcel Dekker, 2003: 45-55.</u>
- Mahale YJ, Silver JR, Henderson NJ. Neurological Complications of the Reduction of Cervical Spine Dislocations. J Bone Joint Surg 1993; 75-B: 403-9.
- 111. Masini M, Alencar MRB, de Castro Neves EG, Alves CF. Spinal cord injury: patients who had an accident, walked but became spinal paralysed. *Paraplegia* 1994; 32: 93-7.
- 112. Bohlman HH. Acute Fractures and Dislocations of the Cervical Spine: An Analysis of Three Hundred Hospitalized Patients and Review of the Literature. *J Bone Joint Surg Am* 1979; 61A: 1119-1142.
- 113. Marshall LF, Knowlton S, Garfin SR, et al. Deterioration following spinal cord injury: a multicenter study. *J Neurosurg* 1987; 66: 400-4.
- Harrop JS, Sharan AD, Vaccaro AR, Przbylski GJ. The Cause of Neurologic Deterioration After Acute Spinal Cord Injury. *Spine* 2001; 26: 340-6.
- 115. Toscano J. Prevention of Neurological Deterioration before Admission to a Spinal Cord Injury Unit. *Paraplegia* 1988; 26: 143-50.
- 116. Poonnoose PM, Ravichandran G, McClelland MR. Missed and Mismanaged Injuries of the Spinal Cord. *The Journal of Trauma*, *Injury, Infection, and Critical Care* 2002; 53: 314-20.

- Ravichandran G, Silver JR. Missed injuries of the spinal cord. BMJ 1982; 284: 953-6.
- 118. George JE. Legal Aspects of Emergency Treatment of the Neurologically Injured Patient. *Emerg Med Clin* 1987; 5: 649-60.
- 119. Silbergleit R, Dedrick DK, Pape J, Burney RE. Forces Acting During Air and Ground Transport on Patients Stabilized by Standard Immobilization Techniques. Ann Emerg Med 1991; 20: 875-7.
- 120. Manix T. The Tying Game. JEMS 1995: \*\*\*(6):44-50.
- 121. Kraus JF, Franti CE. Riggins RS, et al. Incidence of Traumatic Spinal Cord Lesions. J Chron Dis 1975; 28: 471-92.
- 122. DeVivo MJ, Rutt RD, Black KJ, et al. Trends in Spinal Cord Injury Demographics and Treatment Outcomes Between 1973 and 1986. *Arch Phys Med Rehabil* 1992; 73: 424-30.
- 123. DeVivo MJ, Krause JS, Lammertse DP. Recent Trends in Mortality and Causes of Death Among Persons With Spinal Cord Injury. *Arch Phys Med Rehabil* 1999; 80: 1411-9.
- 124. Shackford SR, Mackersie RC, Hoyt DB, et al. Impact of a Trauma System on Outcome of Severely Injured Patients. *Arch Surg* 1987; 122: 523-7.
- 125. Mann NC, Mullins RJ, MacKenzie EJ, et al. Systematic Review of Published Evidence Regarding Trauma System Effectiveness. *Journal* of Trauma Injury, Infection, and Critical Care 1999; 47: S25-S33.
- Morrison W, Wright JL, Paidas CN. Pediatric trauma systems. Critical Care Medicine 2002; 30: S448-56.
- 127. Frew SA. Emergency Medical Services Legal Issues for the Emergency Physician. *Emerg Med Clin* 1990; 8: 41-55.
- 128. Krentz MJ, Wainscott MP. Medical Accountability. *Emerg Med Clin* 1990; 8: 17-31.
- 129. American College of Surgeons, Committee on Trauma. Spine and spinal cord trauma. In: <u>Advanced Trauma Life Support Program for</u> <u>Doctors: ATLS</u>. 7<sup>th</sup> ed. Chicago: American College of Surgeons, 2000: 263-300.
- 130. Harris DM. <u>Healthcare Law and Ethics: Issues for the Age of</u> <u>Managed Care</u> Chicago: Health Administration Press; 1999: 170-1.
- 131. Stewart RD. Medical Direction in Emergency Medical Services: The Role of the Physician. *Emerg Med Clin* 1987; 5: 119-32.
- 132. Polsky SS, Weigand JV. Quality Assurance in Emergency Medical Service Systems. *Emerg Med Clin* 1990; 8: 75-84.
- 133. Ryan JL. Quality Management. In: Kuelh AE ed. <u>Prehospital</u> <u>Systems and Medical Oversight</u> 3<sup>rd</sup> ed. Iowa: Kendall/Hunt, 2002: 355-387.
- 134. Swor RA. Quality Assurance in EMS Systems. *Emerg Med Clin* 1992; 10: 597-610.
- 135. The American Academy of Neurology. Options for Incorporating Evidence Based Medicine Principles Into CME Activities. Available at: <u>http://am.aan.com/presenter/pdfs/Evidence Based Medicine.pdf</u>