The Stockholm - Thessaloniki
Acute Traumatic Spinal Cord Injury Study

Anestis Divanoglou
THE STOCKHOLM - THESSALONIKI
ACUTE TRAUMATIC SPINAL CORD INJURY STUDY
ANESTIS DIVANOGLOU

Stockholm 2010
To all those, who despite their disability,
move on with life
based on their wishes and dreams,
and not on their predicament.
To all those who believe in “It’s never too late for a change”.

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This book is separated in two parts. The first part includes a summary of background information on TSCI, the STATSCIS study design, and an elaboration on the main findings, together with some additional data and discussion that contribute to the totality of the articles. The second part comprises the four published articles of STATSCIS.
ABSTRACT

About 60 years ago, the application of the then contemporary medical methods to treat traumatic Spinal Cord Injury (TSCI), its consequences and complications, coupled with the introduction of a systematic approach of care, resulted in major prognostic improvements. Since then, many countries worldwide have established systems of SCI care. Sweden is one such country, whereas Greece is among those that still manage SCI by a fragmented, nonsystem approach.

Knowledge of the current epidemiology of SCI can contribute to improved management and prevention programs. In Greece, there is a lack of epidemiological studies on SCI. In Sweden, although there have been several clinical studies on SCI, there is a lack of studies on incident cases.

Our aim was to describe and compare cohorts with acute TSCI in Thessaloniki, Greece, and Stockholm, Sweden, in terms of demographic and injury characteristics, clinical characteristics on admission, early treatment, clinical process, first year mortality, and other key outcomes at one year post-trauma. The project as a whole has been denoted the Stockholm Thessaloniki Acute Traumatic Spinal Cord Injury Study (STATSCIS).

STATSCIS is a prospective, population-based study. Inception cohorts with acute TSCI that were hospitalized during the study period, i.e. September 2006 to October 2007, were identified through active and passive case identification methods.

Overall, 87 persons were injured in Thessaloniki and 49 in Stockholm. The annual incidence rate was 33.6/million in Thessaloniki and 19.5/million in Stockholm. Transportation in Thessaloniki and falls in Stockholm were the dominant causes of trauma. The two groups were similar with regard to demographic and core clinical characteristics on admission, but received different early management. One out of five cases died in Thessaloniki, whereas none died in Stockholm. Additionally, Stockholm cases had superior outcomes and fewer complications, as compared to those in Thessaloniki.

Our findings show that two initially similar cohorts with acute TSCI manifest large discrepancies in terms of first year outcomes, including mortality, depending on type of management. As the major difference between regions was the absence of an SCI system of care in Thessaloniki (rather than, e.g., absence of modern medical knowledge and technology), a systems approach seems necessary to secure adequate outcomes. STATSCIS provides strong evidence as to the urgent need of implementing an SCI system of care in Greece.
LIST OF PUBLICATIONS

I. Divanoglou A, Levi R
Incidence of traumatic Spinal Cord Injury in Thessaloniki, Greece and
Stockholm, Sweden: a prospective population-based study.

II. Divanoglou A, Seiger Å, and Levi R
Acute management of traumatic Spinal Cord Injury in a Greek and a Swedish
region: a prospective population-based study.
Spinal Cord, e-pub ahead of print December 24, 2009; (DOI:10.1038/sc.2009.160)

Late mortality during the first year after acute traumatic Spinal Cord Injury: a
prospective population-based study.
Journal of Spinal Cord Medicine, 2010; accepted on 11/11/2009

IV. Divanoglou A, Westgren N, Bjelak S, and Levi R
Medical conditions and outcomes at 1 year after acute traumatic Spinal Cord
Injury in a Greek and a Swedish region: a prospective population-based study.
Spinal Cord, e-pub ahead of print December 24, 2009; (DOI:10.1038/sc.2009.147)
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AD</td>
<td>Autonomic Dysreflexia</td>
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<td>ADL</td>
<td>Activities of Daily Living</td>
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<td>AIS</td>
<td>ASIA Impairment Scale</td>
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<td>ASIA</td>
<td>American Spinal Injury Association</td>
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<td>BiPAP</td>
<td>Bilevel Positive Airway Pressure</td>
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<td>CT</td>
<td>Computerized Tomography</td>
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<td>DPT</td>
<td>Day Post Trauma</td>
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<td>DVT</td>
<td>Deep Vein Thrombosis</td>
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<td>ED</td>
<td>Emergency Department</td>
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<td>e.g.</td>
<td>exempli gratia (for example)</td>
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<td>EMS</td>
<td>Emergency Medical System</td>
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<td>EU</td>
<td>European Union</td>
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<td>FIM</td>
<td>Functional Independence Measure</td>
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<td>GCS</td>
<td>Glasgow Coma Scale</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<tr>
<td>HO</td>
<td>Heterotopic Ossification</td>
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<td>i.e.</td>
<td>id est (that is)</td>
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<tr>
<td>IMC</td>
<td>Initially Motor Complete</td>
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<tr>
<td>IMIC</td>
<td>Initially Motor InComplete</td>
</tr>
<tr>
<td>IQR</td>
<td>Inter-Quartile Range</td>
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<td>LMN</td>
<td>Lower Motor Neuron</td>
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<td>LOC</td>
<td>Level Of Consciousness</td>
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<td>LOS</td>
<td>Length Of Stay</td>
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<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<td>NHS</td>
<td>National Health System</td>
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<td>Abbreviation</td>
<td>Full Form</td>
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<td>--------------</td>
<td>-------------------------------------------------</td>
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<tr>
<td>NLL</td>
<td>Neurological Level of Lesion</td>
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<td>NSCIR</td>
<td>Nordic Spinal Cord Injury Registry</td>
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<tr>
<td>NUTS</td>
<td>Nomenclature of Territorial Units for Statistics</td>
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<tr>
<td>PE</td>
<td>Pulmonary Embolism</td>
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<td>PHC</td>
<td>Primary Health Care</td>
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<tr>
<td>SCI</td>
<td>Spinal Cord Injury</td>
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<td>SD</td>
<td>Standard Deviation</td>
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<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
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<tr>
<td>STATSCIS</td>
<td>Stockholm Thessaloniki Acute Traumatic Spinal Cord Injury Study</td>
</tr>
<tr>
<td>TSCI</td>
<td>Traumatic Spinal Cord Injury</td>
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<tr>
<td>UMN</td>
<td>Upper Motor Neuron</td>
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<tr>
<td>UTI</td>
<td>Urinary Tract Infection</td>
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<td>WHO</td>
<td>World Health Organization</td>
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1 INTRODUCTION

Traumatic SCI is a severe condition that, like most major unexpected medical events, causes radical changes in the lives of injured individuals and their surrounding. During World War II, a major paradigm shift took place in the management of SCI, when the British authorities established a specialized center under the leadership of Sir Ludwig Guttmann. Guttmann applied the latest, at that time, advances in medicine (e.g. antibiotics, intermittent urinary catheterization, surgical management) coupled with the introduction of a systematic approach to treat individuals with SCI. In 1943, the Stoke Mandeville Spinal Unit was inaugurated, and a new era in managing SCI started. During the following years, several other countries adopted the basic principles of this approach by establishing systems of SCI care.

The rather low incidence of TSCI, in combination with the need for multi-disciplinary specialized treatment, necessitates the centralization of care of such patients. In order for expertise to be gained, and cost-effectiveness of interventions to be achieved, it has repeatedly been stated that management of TSCI should be conducted in specialized facilities. In his 1976 book, Guttmann\(^1\) wrote: “Whenever possible, a traumatic paraplegic or tetraplegic should be transferred to a Spinal Unit, as soon as the patient’s condition allows transfer, where the most favourable conditions exist for treating all aspects of paraplegia from the start by specialized staff”.

In the same book\(^1\), referring to the management of SCI in Scandinavian countries at that time, he wrote: “There are no proper Spinal Injury Units (SIU) in any of the Scandinavian countries which can give paraplegics and tetraplegics a comprehensive treatment and rehabilitation from the start. In these countries, there still exists the fragmentation of treatment, and the initial and early treatment is carried out in neurosurgical or orthopaedic departments, and patients are then transferred to general rehabilitation centres.” In 1970, Bjerner and Åström\(^2\) stressed the need for establishing specialized departments for the management of TSCI in Sweden.

Many things have changed since then, as several countries around the world have established systems of SCI care, following similar principles to those developed by Guttmann, often adjusted to their unique needs and priorities. In the USA, for example, the so called Model SCI Systems were established in the 1970s\(^3\). While all Systems are based on the similar principles, each system retains its unique characteristics\(^3\). Components and functions of a “state-of-the-art” system are summarized in Appendix 1, with an aim to present a comprehensive and complete picture of possible
aspects to be taken under consideration when designing such a system. While Sweden has subsequently established several SCI Systems of care, Greece still manages TSCI by a fragmented, non-systematic approach.

Frankel, at his keynote lecture at the opening ceremony of the International Spinal Cord Society Meeting in 2004 in Athens, stressed that everybody had hoped that the first Society Meeting in 1982 in Athens would have contributed to the subsequent establishment of an SCI system of care in Greece. He concluded that in 2004, however, 22 years later, the situation regrettably had not changed much.

The European Commission\(^4\) has recognised a number of public health issues: a. high levels of premature death from accidents, b. substantial morbidity and disability from musculoskeletal disorders, and c. wide variations and inequalities in health status depending on socioeconomic status. Furthermore, high costs of health systems, changing demographic trends, development and integration of high technology in health care, and increasing expectations and concerns by the citizens were reported as the main challenges in EU. One would expect that, when a country has reached the specified minimum social and economical standards mandatory in order to enter EU (Copenhagen Criteria), as has Greece as well as Sweden, that country would have reached equivalent minimum standards in health care as well.

In the conception of STATSCIS, we were aware that Stockholm and Thessaloniki regions were different with regard to the presence or not of an SCI system of care. This matter of fact provided us with the possibility to conduct a natural experiment to investigate prospectively the functions and outcomes of such differing approaches of care. Furthermore, there were no previous epidemiological studies in Greece on either prevalence or incidence cohorts with TSCI, clinical process or outcomes. With regard to Sweden, although there were several earlier studies examining a variety of topics on TSCI, no studies dealing specifically with incident cases and their characteristics had been performed. Due to the lack of previous knowledge on incident cases in both regions, we adopted a study design that would allow us to capture a broad spectrum of epidemiological characteristics and outcomes.

Overall, we conceive STATSCIS as a first step in the long process of initiating changes that will improve management of TSCI in both countries. Especially for Greece, we hope that STATSCIS will act as an impetus for further and larger studies, and for the urgent implementation of a Systems approach.
Guttmann was indeed right – both modern advances in medical practice and systematic approaches of care are needed to achieve optimal outcomes for individuals with TSCI. As we interpret the findings of STATSCIS, 60 years of advances in Medicine have in no way made Guttmann’s insistence on specialized, centralized and structured systems of care obsolete. Guttmann was right in 1943, and he continues to be so in 2010.
2 BACKGROUND

2.1 TRAUMATIC SPINAL CORD INJURY

2.1.1 Definitions

**Spinal Cord Injury:** Injury of the spinal cord, including cauda equina and conus medullaris injuries, excluding lumbosacral plexus lesions or injury to peripheral nerves outside the neural canal, causing motor and/or sensory deficits, and/or neurogenic bladder, and/or bowel dysfunction, persisting for at least 72 hours post-trauma.

**Tetraplegia:** Lesion of the cervical segments of the spinal cord, with a resulting impairment of all four limbs, trunk and pelvic organs.

**Paraplegia:** Lesion of the thoracic, lumbar or sacral segments of the spinal cord, secondary to damage of neural elements within the spinal canal, with a resulting impairment of lower limbs, trunk and pelvic organs, depending on the level of injury.

**Skeletal Level:** The most rostral level of the spinal column at which, by radiographic examination, the greatest vertebral damage is found.

**Neurological Level of Lesion (NLL):** The most caudal spinal cord segment, where motor and sensory function is normal bilaterally.

**Completeness of Lesion & AIS:** Depending on the absence or presence of sacral sparing, lesions are divided in complete and incomplete. According to the ASIA classification, lesions can be further divided into the following AIS categories:

<table>
<thead>
<tr>
<th></th>
<th><strong>Complete</strong></th>
<th>No motor or sensory function is preserved in the sacral segments S4-S5.</th>
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<tbody>
<tr>
<td>A</td>
<td>Sensory incomplete</td>
<td>Sensory but not motor function is preserved below the NLL and includes the sacral segments S4- S5.</td>
</tr>
<tr>
<td>B</td>
<td>Motor and sensory incomplete</td>
<td>Motor function is preserved below the NLL, and more than half of key muscles below the NLL have a muscle grade less than 3.</td>
</tr>
<tr>
<td>C</td>
<td>Motor and sensory incomplete</td>
<td>Motor function is preserved below the NLL, and at least half of key muscles below the NLL have a muscle grade of 3 or more.</td>
</tr>
<tr>
<td>D</td>
<td>Normal</td>
<td>Motor and sensory functions are normal.</td>
</tr>
</tbody>
</table>
2.1.2 Epidemiology

Incidence: Depending on the utilized methodology and especially the chosen inclusion criteria, there are differing estimates of incidence rates of TSCI. Recent studies from some EU countries report annual survival incidence of TSCI to reach 10.4 per million inhabitants in the Netherlands (survived first hospitalisation), 13.1 in Ireland and 13.8 in Finland (survived acute care), 25.4 in Portugal (survived at least 30 days after injury) and 19.4 in France (older than 15 years and who survived past the acute care stage). When including pre-hospital deaths, a study from Portugal calculated the annual incidence to be 57.8 new cases per million. Sample annual incidence rates outside Europe were estimated to be 51 per million for Northern America, 16.8 for Australia, and 23.9 for Asia. Accurate incidence rates are obviously more difficult to estimate in developing countries.

Prevalence: Studies on prevalence are even more difficult to conduct. The Stockholm Spinal Cord Injury Study from the mid 1990s’ reported a prevalence rate of 223 people per million population, which is a rather low figure that was attributed to the low incidence rate of TSCI in Sweden. An estimate from Finland reached 280 persons per million. Prevalence rate in Australia was calculated at 681 persons per million population.

Aetiology of injury: In western-type countries, transportation is typically the major cause of injury, accounting for approximately four to five out of ten new injuries, followed by falls. Acts of violence (mainly stabbing and gunshots) are frequent causes of injury in Latin American and African countries as well as in some states in the USA. One out of five injuries were reported to be work-related in Australia. During the last years, the frequency of falls seems to be increasing in western-type countries, mainly due to an aging population and a decrease in transportation-related injuries as a result of successful primary prevention programs.

Mortality: A study from Portugal reported a 53% case-mortality rate after acute TSCI during the first month post-trauma, including pre-hospital deaths. Other studies reported in-hospital mortality after acute TSCI to be; between 5.7% and 8% in Canada, 8.6% in Germany and 11.9% in Teresina/ Brazil. One year case-mortality rate was reported to be 5.8% in Australia and 3.6% in Model SCI Systems in USA.
Age distribution: The later part of the second decade of life, as well as the third decade, are those with the highest risk for sustaining an acute TSCI. Recent trends show an increasing frequency of injuries in the highest age group (>60 years)\textsuperscript{7, 18}. Data from Europe\textsuperscript{7} and the USA\textsuperscript{25} show an increased mean of age at injury. Paediatric TSCI is rare\textsuperscript{26}.

Skeletal level: Discharge data from the Model SCI Systems in the USA show that about 50% of all TSCI concern the cervical spine, another 30% the thoracic and 20% the lumbar spine and sacrum\textsuperscript{25}.

Completeness: Discharge data from the Model SCI Systems in the USA show that nearly 45% of all TSCI result in complete lesions (AIS grade A). Incomplete correspond to 55%, with AIS B reaching 10%, AIS C 15% and AIS D 30%\textsuperscript{25}.

2.1.3 Associated Conditions

An “associated condition” is here and elsewhere operationally defined to comprise an expected pathophysiological aberration after TSCI, which is directly a consequence of the TSCI pathology\textsuperscript{27} (in contradistinction to “medical complications”, see below). Most associated conditions are greatly affected by level and type of lesion.

Bladder dysfunction: Neurogenic bladder (spastic or flaccid), impaired bladder sensation, and incontinence (inability to actively control bladder emptying) are the most commonly seen genitourinary dysfunctions. TSCI cases often need assistive devices (e.g. urethral or external catheters) to void their bladder. Long term use of an indwelling urethral catheter is associated with higher morbidity, as compared to suprapubic and clean intermittent catheterization.

Bowel dysfunction: Neurogenic bowel (spastic or flaccid), impaired bowel sensation, and incontinence (inability to actively control bowel emptying) are the most commonly seen gastrointestinal dysfunctions. A large proportion of TSCI cases use laxatives for bowel management. Establishing a regular bowel program is essential for effective bowel management.

Cardiovascular dysfunction: Autonomic dysregulation due to SCI results in orthostatic hypotension, low resting blood pressure, reflex bradycardia, and, rarely, cardiac arrest\textsuperscript{28}. Autonomic dysreflexia (AD) is a potentially life-threatening phenomenon occurring in SCI above T6 level, that may be triggered by infralesional nociceptive stimuli, such as that caused by an acute bladder or bowel problem, an
ingrown toenail, a pressure ulcer, or even during delivery or orgasm. The phenomenon is expressed with symptoms as high blood pressure, bradycardia, headache, facial flushing and sweating above NLL, and typically disappears when the triggering nociceptive stimulus is eliminated.

**Motor and Sensory Impairment:** TSCI results in impairment or absence of voluntary motor activity and/or sensory function below the NLL. The degree of impairment varies between different AIS groups. Impaired motor function necessitates the use of different assistive devices for performance of Activities of Daily Living (ADL) and mobility. Impairment of sensory function results in a propensity to injury, often caused by pressure, foreign bodies, trauma and burns.

**Pain:** Two thirds of prevalent TSCI cases complain of pain\textsuperscript{29}. Pain can be nociceptive or neuropathic. Nociceptive pain occurs when intact pain receptors in partially or fully innervated areas of the body are activated by damage to non-neural tissues, such as bone, ligaments, muscle, skin, or other organs\textsuperscript{30}. Neuropathic pain occurs as a result of damage to neural tissue either in the peripheral or central nervous system\textsuperscript{30}. One third of prevalent cases considered that their quality of life was significantly affected by pain\textsuperscript{29}.

**Pulmonary dysfunction:** This consequence is mainly due to paralysis and/or spastic hypertonicity of inspiratory and expiratory muscles. Cases with complete C1-C3 lesions cannot maintain effective spontaneous ventilation, due to bilateral diaphragmatic paralysis, and thus need external ventilatory support. Cases with complete C4-C8 lesions usually have adequate spontaneous ventilation, but may still need assistance with secretion clearance. Cases with complete thoracic lesions usually have impaired coughing ability, due to the paralysis of trunk muscles. Ventilatory status is reported as the single strongest predictor of mortality in the first year after TSCI, with ventilator-dependent cases being 39.5 times more likely to die during the first year than those not requiring ventilator support.\textsuperscript{31}

**Sexual dysfunction:** This is mainly expressed by impaired erection, anejaculation, and infertility. Men with UMN are more likely to retain reflexogenic erection, while men with LMN are more likely to retain psychogenic erection. Generally, men with incomplete injuries and UMN injuries have better erectile function, than men with complete injuries and LMN injuries. Women remain fertile, can conceive and bear
children. Orgasm is reported to occur in 25-50% of men\textsuperscript{32}, and 40-50% of women\textsuperscript{33} with TSCI.

**Spasticity:** Spasticity is a complex phenomenon expressed by a velocity-dependent increased muscle tone in both active and passive movements, and affects only cases with UM N lesions. Muscular spasms can also be activated spontaneously. Over 60% of TSCI cases have spasticity, while problematic spasticity is more prevalent in higher and in incomplete lesions\textsuperscript{34}. However, spasticity is not always to be seen as problematic, as it can often be helpful in transfers, dressing and walking.

**Thermoregulatory dysfunction:** Individuals with complete lesions above T6 level usually have difficulty in regulating their body temperature and exhibit partial poikilothermia, with lower core temperatures in cold and higher core temperatures in warm environments\textsuperscript{30}. During the first year post-trauma, tetraplegics may develop fever without any definable cause (e.g. infection), a so-called “quadriplegia fever”\textsuperscript{35}. Sweating and shivering are usually absent below the NLL.

### 2.1.4 Medical Complications

A “medical complication”, also denoted in the literature as a secondary condition, is here and elsewhere operationally defined to comprise an adverse medical event that is related to the presence of TSCI and is likely to be preventable\textsuperscript{27}.

**Circulatory complications:** Deep vein thrombosis (DVT) and pulmonary embolism (PE) have a low incidence, with 2.1% and 0.5% respectively during the first year post-trauma\textsuperscript{36}, provided that antithrombotic prophylactic medication is given. Traumatic SCI cases with complete lesions run higher risk of sustaining DVT and PE.

**Gastrointestinal complications:** Ileus and gastric ulceration during the first month post trauma, and constipation in the chronic phase are the most common gastrointestinal complications after TSCI\textsuperscript{37}. Formation of haemorrhoids is another common complication in chronic TSCI.

**Musculoskeletal:** Heterotopic ossification (HO) is expressed by ectopic bone formation below NLL, often involving the joints of elbow, hip and knee. The incidence of HO ranges between 10-53% depending on the methodology of the study\textsuperscript{38}. Osteoporosis is reported to appear early after injury, creating a higher risk for long bone fractures as the time post-trauma increases\textsuperscript{36}. 
**Pressure ulcers:** Rates of pressure ulcers on the first annual follow-up year post-trauma range between 12-36\%\textsuperscript{36, 39-42}. Most common areas are sacrum, ischium and heel\textsuperscript{41}. Pressure ulcers are reported as the most frequent medical complication during first year post-trauma, with an increasing rate in later follow-ups\textsuperscript{40}.

**Psychological complications:** In Sweden, it is reported that during the first period after trauma (up until six months post-discharge) one out of three cases are either clinically depressed or are treated for depression\textsuperscript{43}. Alcohol and drug consumption, and suicide are all reported to have higher prevalence in the SCI population as compared to the able-bodied population\textsuperscript{44}.

**Respiratory complications:** Respiratory complications have a reported frequency of approximately 4-20\% during the first year post-trauma\textsuperscript{36, 40-42, 45}. Pneumonia is reported as the leading cause of death after cervical SCI irrespective of patient age and length of survival after injury\textsuperscript{45}. Tracheal stenosis is another complication that may occur after prolonged intubation.

**Urological complications:** Urinary tract infection (UTI) is the most common infection in TSCI cases. Common manifestations of UTI in TSCI cases are fever, increased spasticity, increasing AD, urinary leakage, and change in voiding habits\textsuperscript{30}. Recurrent UTIs and ascending infections involving the kidneys can create more serious complications, as can obstructive stones in the urinary tract\textsuperscript{46}.
2.2 SOCIAL AND DEMOGRAPHIC ASPECTS

2.2.1 Greece

Greece is located at the southernmost tip of Continental Europe and covers an area of 131,957 km². On 28th May 1979, Greece became a member state of the European Economic Community, and on 1st January 2002 of the Economic & Monetary Union. According to Nomenclature of Territorial Units for Statistics (NUTS), Greece is divided in 13 Peripheries (Periferies), each one of which includes a number of prefectures. In 2001, Greece had a population of almost 11 million, out of which approximately 25% lived in Athens Prefecture, and 10% in Thessaloniki Prefecture. Although the majority of the population lives in cities, Greece has one of the lowest percentages of urban population among the Eur-A* countries. Life expectancy average is 74.6 years for men and 79.4 years for women.

The most striking demographic feature in Greece, also observed across Eur-A as a whole, is the increasing proportion of elderly people. Another noteworthy aspect during the last years has been the extended immigrant flow towards the country, comprising almost 800,000 immigrants living in Greece.

The Greater Thessaloniki Region

In accordance with NUTS adopted by the European Commission, what in the present study is referred to as the “Greater Thessaloniki region”, consists of Central and Western Macedonia, Greece.

* According to WHO, Eur-A comprises 27 countries with very low child and adult mortality, which are Andorra, Austria, Belgium, Croatia, Cyprus, the Czech Republic, Denmark, Germany, Greece, Finland, France, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, the Netherlands, Norway, Portugal, San Marino, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.
2.2.2 Sweden

Sweden is situated in the Northern part of Europe and covers an area of 450,000 km². On January 1st 1995, Sweden became a member of the European Union.

Sweden is divided into county councils (landsting). The tasks of the county councils are to manage issues of common concern in areas such as health and health care, education, social care as well as agriculture and industrial development. The municipalities and county councils levy taxes on the inhabitants to fulfill their commitments. The highest decision making bodies at the regional level are the boards of the county councils.

As of early 2003, Sweden had a population of almost 8.9 million. Life expectancy average was 82.6 years for women and 78.0 years for men, respectively.

The number of Swedes living in urban areas has increased steadily, and is over the average proportion of Eur-A countries. However, the greatest difficulties are experienced in sparsely populated areas with poor transportations and few employment opportunities. The most striking demographic feature in Sweden, observed across Eur-A countries, is the increasing proportion of elderly people. Sweden’s birth rate is close to the average for Eur-A.

The Greater Stockholm Region

In accordance with the NUTS adopted by the European Commission, what in the present study is referred to as the the “greater Stockholm region” consists of Stockholm County and Gotland County, Sweden.
2.3 PREVIOUS CLINICAL RESEARCH ON TSCI

2.3.1 Greece

When searching Medline and Web of Science (keywords: “spinal cord injur*” AND “Greece”) on clinical studies on TSCI from Greece, yields are very meagre, corresponding to the lack of registries, surveillance systems, and of centralized TSCI care that could allow for clinical research.

However, in 1992, Petropoulou et al\(^\text{49}\) published an key paper in Paraplegia on clinical management of SCI in Greece. The authors stressed the lack of system and the need for establishing SIUs.

Sapkas et al\(^\text{50}\) studied neurological outcomes of 29 cases with thoracic SCI that were collected during a period of 14 years. Some years later, Sapkas and Papadakis\(^\text{51}\) studied neurological outcome after early versus delayed lower cervical spine surgery in 67 cases that were collected during 13 years, reporting no significant differences between the two interventions. Spinal canal restoration by either posterior distraction or anterior decompression in thoracolumbar spinal fractures and its influence on neurological outcome was studied by Korovessis et al\(^\text{52}\) in 30 consecutive cases. Kasimatis et al\(^\text{53}\) studied the adult Spinal Cord Injury Without Radiographic Abnormalities Syndrome.

Sapountzi-Krepia et al\(^\text{54}\) investigated the impact of pressure sores and urinary tract infections on the everyday activities of 98 paraplegics living in Athens, recruited through the registration lists of the Pan-Hellenic Association of Paraplegics. Bone density and osteoporosis after SCI have been studied in a series of articles\(^\text{55-57}\), as well as neuropathic bladder\(^\text{58}\) and sexual function\(^\text{59-61}\).

In 2002, Kalogeromitros et al\(^\text{62}\) investigated severe accidents due to windsurfing in the Aegean Sea, some of which resulted in TSCI. Korres et al\(^\text{63}\) studied cervical spine injuries in amateur divers that occurred during a 34 year period, and reported that five out of the overall 20 cases included in their study died within the first month post-trauma. Souvatzis and Askitopoulou\(^\text{64}\) surveyed clinicians from 15 European countries with regard to acute airway management of cervical TSCI, concluding that there are no common guidelines.

Several Greek studies are based on findings from a single hospital, or expand during several years of case recruitment, thus having some degree of selection bias. Overall, as can be seen from this brief literature review, there is a total lack of epidemiological and population-based studies on TSCI in Greece.
2.3.2 Sweden

When searching Medline and Web of Science (keywords: “spinal cord injur*” AND “Sweden”) on clinical studies on TSCI from Sweden, a relatively high number of publications were found, corresponding to a long tradition of conducting research on various fields of TSCI.

In 1989, Siösteen\textsuperscript{65} completed a doctoral thesis\textsuperscript{†} on quality of life, sexuality and fertility after SCI. In 1996, the Stockholm Spinal Cord Injury Study (SSCIS) by Levi et al\textsuperscript{66} provided a thorough analysis of the regional prevalence population in Stockholm, reporting on medical, economical and psychosocial status.

The SSCIS and the establishment of an SCI system of care in Stockholm facilitated the subsequent conduction of several clinical studies in the region. In 1998, Hultling\textsuperscript{67} completed a thesis on assisted reproduction technology in men with ejaculatory dysfunction with special reference to SCI. In 1999, Westgren\textsuperscript{68} presented a thesis on sexuality, pregnancy, motherhood and quality of life for women after TSCI. Sköld\textsuperscript{69}, in 2001, defended a doctoral thesis on the characteristics, evaluation and treatment of spasticity after TSCI. Characteristics and treatment of pain following SCI were studied by Norrbrink Budh\textsuperscript{70} in a 2004 thesis. In 2006, Bjerkefors\textsuperscript{71} completed her thesis on performance and trainability in paraplegics. Epidemiological and psychosocial characteristics of paediatric TSCI were studied by Augustin\textsuperscript{72} in a 2007 thesis. In 2008, Werhagen\textsuperscript{73} completed a thesis on analysis of neuropathic pain after SCI. During the same year, Nordgren\textsuperscript{74} presented a thesis on societal services for individuals with TSCI and on the need for validating inpatient registers.

In addition, during the last decades, several other clinical studies have focused on different fields of TSCI. Bladder function and management have been investigated in several studies\textsuperscript{75-80}, as have bowel and rectal issues\textsuperscript{81,82}, fertility and sexual life issues\textsuperscript{83-88}, breathing\textsuperscript{89-95}, bone density\textsuperscript{96}, issues on women with SCI\textsuperscript{84,97-100}, hand function in cervical SCI\textsuperscript{101-104}, pain\textsuperscript{105,106}, cardiovascular and autonomic function\textsuperscript{107-109}, pressure ulcers\textsuperscript{110}, eye disturbances in acute SCI\textsuperscript{111}, shoulder pain\textsuperscript{112,113}, wheelchair seating and handling\textsuperscript{114-122}, and transferring from and to the wheelchair\textsuperscript{123}. Other studies focused on participation\textsuperscript{124,125} and psychosocial issues\textsuperscript{43,126-128}, on coping strategies after injury\textsuperscript{129-131} and quality of life\textsuperscript{132-135}, and finally others in the assessment and development of TSCI specific evaluation instruments\textsuperscript{136-140}.

\textsuperscript{†} Each thesis comprises four to five articles published in international scientific journals.
According to our knowledge, there have been only two studies with a more clear epidemiological approach on incidence cases; one by Molsa et al\textsuperscript{141} studying incidence of SCI in ice hockey in Finland and Sweden from 1980 to 1996, and one by Augutis\textsuperscript{72} studying paediatric SCI. In Sweden, as can be seen from the review above, although there are numerous clinical studies on SCI, there has not been any study that investigates the characteristics of adult incidence cases, as for example incidence rates, demographics, clinical characteristics on admission and outcomes, clinical process etc.
2.4 THE STRUCTURE-PROCESS-OUTCOME PARADIGM

“It is of course possible, with greater effort, to actually follow patients as they progress prospectively, from day to day through a health care system. I believe that much can be learned from a simple study in which a few patients are observed at intervals as they journey through a care-giving system. What one might see could be astonishingly revealing. - It would be most revealing to find out what happens to patients after a hospital has discharged them. Besides revealing how carefully (if at all) a hospital prepares for patient discharge, one would learn how adequate community services and resources are.”

Avedis Donabedian 142

The Structure-Process-Outcome Paradigm 142

The concept of “structure, process, outcome” introduced by Donabedian142 to assess quality in Health Care provided a general theoretical framework for STATSCIS. According to Donabedian, structure, process and outcome are types of information that need to be examined in order to infer whether quality is good or not, rather than attributes of quality as such.

Structure is taken to mean the conditions under which care is provided - the way a health care system is set up. Structure includes:

- Material resources, such as facilities and equipment.
- Human resources, such as the number, variety, and qualifications of professional and support personnel.
- Organizational characteristics, such as the organization of the medical and nursing staffs, the presence of teaching and research functions, and methods of paying for care.

Process is taken to mean the activities that constitute health care - including diagnosis, treatment, rehabilitation, prevention, and patient education - usually carried out by professional personnel, but also including other contributions to care, particularly by patients and their families.

Outcome is taken to mean changes (desirable and undesirable) in individuals and populations that can be attributed to health care. Outcome includes:
• Changes in health status.
• Changes in knowledge and in behavior acquired by patients and family members that may influence future care.
• Satisfaction of patients and their family members with the care received and its outcomes.

A combination of these three categories allows for a more complete assessment of quality, since each of the categories of information (on structure, process, and outcome) is more indicative of a given aspect of quality than is another category. Outcome cannot stand alone - the means to achieve the outcome (structure and process) also need to be considered when assessing quality of health care.

As Donabedian states clearly, we cannot measure anything, the quality of care included, unless we have something to measure with - meaning criteria and standards.

A “criterion” was defined as an attribute of structure, process or outcome that is used to draw an inference about quality. For example:

• A criterion of structure could be the number of nurses staffing a SIU.
• A criterion of process could be the time interval between trauma and assigning a diagnosis.
• A criterion of outcome could be case fatality.

A “standard” was defined as a specified quantitative measure of magnitude or frequency that specifies what is good or less so. For example:

• A standard for the nurse staffing of a SIU could be: no less than one registered nurse per three occupied beds.
• A standard for the assigning of a TSCI diagnosis could be no more than 24 hours.
• A standard for case fatality after acute TSCI could be: no more than 6-7% during the first year and after the first week post-trauma.

Criteria and standards may be implicit (flexible, not specified, but in the minds of experts) or explicit (specified before the assessment of quality, difficult to formulate)\(^1\). In the present study, in the absence of established, explicit criteria-standards, Stockholm served as a “normative standard” with which we compared Thessaloniki. We perceived the situation in Stockholm as an exemplar of what the situation is like in countries with established systems of SCI care. In some other
instances, as for example in the evaluation of the fatal cases, we mainly used implicit criteria in order to provide a comment for each individual case (Appendix III).

In the present study, in depth evaluation and comparison of structures was not possible, since the regions under study differ to such a large extent. Some aspects of process cannot be fully clarified, unless the decision-making process is well documented. Medical records are often poor in explaining such processes. In the present study, we were, thus, not able to fully evaluate processes to the extent we would have wished to, due to lack of pertinent data as regards all factors connected to specific decision taking. For example, we could document that the patient was transferred to several different facilities, but it was not always clear to us why these transfers were deemed necessary and thus performed.
2.5 INJURY SURVEILLANCE

Without reliable information, health care planners are severely handicapped. They are unable to allocate resources so as to achieve the greatest impact in preventing injuries, reducing the harm they do, and treating and rehabilitating injured persons.

Holder et al. 2001

2.5.1 Public Health Surveillance

Public health surveillance has been defined as “the ongoing, systematic collection, analysis and interpretation of health data essential to the planning, implementation, and evaluation of health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is in the application of these data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis and dissemination linked to public health programs”145. Chiu et al146 stressed that, because surveillance is built from a communicable disease model, its primary function is not to achieve a high degree of ascertainment, but rather to identify rapid changes in the patterns of a health condition.

2.5.2 Registration Systems

According to the Dictionary of Epidemiology147, the term register is applied to “the file of data concerning all cases of a particular disease or other health-relevant condition in a defined population base. The register is the actual document and the registry is the system of ongoing registration”. According to Thacker and Wetterhal148, “population-based registries are established to obtain information on all cases of a health event. Typically registries are established by researchers to identify cases through several sources and are not linked to public health prevention and control activities”. Although registries assume that ascertainment of new cases is accurate, there are several studies to highlight the need for validation of registries146, 149, 150.

As it becomes evident from the definitions above, STATSCIS has not established a surveillance system, but rather a registration system. The main reasons for that are:

1. STATSCIS is not an ongoing system.
2. STATSCIS is not directly linked with any State public health prevention or health care improvement project.
3. STATSCIS aims at an accurate identification of all cases, and not a rough estimate of the TSCI incidence.
Detailed distinctions between public health surveillance and epidemiologic research are described elsewhere\textsuperscript{145, 146, 151}. Although the title of this thesis and of each individual paper comprising STATSCIS make clear that this is a population-based study, the term “surveillance system” was indeed used in the methods section with regard to case identification. The main reason for that was our intention to correlate aspects of our methodology (e.g. active and passive case finding), with that used in the development and application of Surveillance Systems. Other studies and reviews have used the term “surveillance” in a similar manner\textsuperscript{146, 149, 152-154}. Chiu et al\textsuperscript{146}, for example, stated that “because registries utilize active surveillance, it is generally assumed that the number of cases identified with registry systems are a more accurate reflection of the true number of cases occurring within the population than the number of cases identified by passive surveillance systems”. In their article titled “SCI surveillance in the United States: an overview” Harisson and Dijkers\textsuperscript{154} recognized that the two approaches – surveillance system and registries – are often mixed, but nevertheless chose to use the term registry to describe such a process.

It can be argued that the absence of any regional or national surveillance system for TSCI in Greece necessitated the conduction of STATSCIS. The Nordic Spinal Cord Injury Registry (NSCIR) acted as a passive surveillance system. A perhaps more appropriate term that could have been used for the method used in Thessaloniki is “population-based registration system”.

Nonetheless, we chose to present some main characteristics of “Public Health Surveillance”, or better “Injury Surveillance”, and use them as a tool to describe our methodology as presented in the “Material and Methods” section of this thesis.

2.5.3 Characteristics of Injury Surveillance Systems

Surveillance yields data that describe the magnitude and characteristics of a health condition (e.g. a type of injury), the population at risk, the risk factors and the trends. With this type of information, it is then possible to design and apply appropriate interventions, to monitor the results and assess the impacts of interventions\textsuperscript{144}. The use of international data is not always translatable, since the profile of injuries may differ between settings.

**Case definition** should be distinct and include criteria for person, place, time and activity. Depending on the degree of diagnostic certainty, cases may be categorized as
“suspected” or “confirmed”. A balance must be struck between the desire for high sensitivity and the level of effort required to track down false-positive cases.\textsuperscript{155}

Surveillance systems are typically classified as being \textit{passive} or \textit{active}. In passive surveillance systems, collection of data on specific type of injuries usually serves other primary reasons, and reporting is done routinely. The passive system has the advantage of being simple and not burdensome, but is limited by variability and incompleteness in reporting.\textsuperscript{155} Active systems involve regular outreach to potential reporters to stimulate regular reporting of injured cases.\textsuperscript{155} In active systems, cases are sought out and investigated; cases are interviewed and followed-up.\textsuperscript{144} Active surveillance is more accurate and complete, but is more labour intensive and requires larger financial recourses. Since resources are often limited, active systems are often used for brief periods for discrete purposes.\textsuperscript{155}

Health-related information can be obtained by three principal methods: a. interview, b. observation, and c. review of records or other documentation.

Careful development and field testing of the surveillance system is important to facilitate the implementation of a feasible system and also to minimize the need for making changes once the system is implemented on a broad scale. Such field-test projects can demonstrate how readily the information can be obtained and can detect difficulties in data-collection procedures or in the content of specific questions. Analyses of collected preliminary data may also identify other problems.

Both stakeholders (i.e. those who are concerned about injuries) and reporters (i.e. those who collect or report data) should be kept informed about procedures and any progress which is achieved. Involving stakeholders in planning of the surveillance system and in its progress will allow them to develop a strong sense of ownership of the completed system; this in turn will help to make it sustainable.\textsuperscript{144} Updating reporters will motivate them in keeping a high pace in collecting good quality data.

Five different areas of information needs for SCI surveillance were identified in a qualitative study from Australia: a. service evaluation and planning, b. epidemiology, c. prevention, d. external demands and e. research. A “core” and an “optional” data set should be defined. Definitions for each variable included in the data set need to be provided in order to avoid semantic confusion. Use of established classification systems may be valuable for international comparisons.
Evaluation of the system should be continuous throughout the whole surveillance process. Adequate funding is an important issue in establishing a surveillance system. Since designing and operating a surveillance system is a long process that involves many individuals and entities, it is essential to start it only when adequate funding is secured.

One important aspect of surveillance is the subsequent dissemination of findings to relevant target groups (e.g. policy makers, health care providers, general public) and in the right form (e.g. reports, popular science articles).
3 AIMS OF THE THESIS

The overall aim of STATSCIS was to describe acute TSCI in Thessaloniki and in Stockholm, thereby comparing the two regions, one with an SCI system of care and the other without, in terms of clinical processes and outcomes.

The more specific aims of STATSCIS were to describe and compare cohorts of cases with acute TSCI in the greater Thessaloniki and Stockholm regions, in terms of:

- Demographics and injury characteristics (Study I).
- Clinical characteristics on admission and acute management (Study II).
- Mortality during the first year post-trauma (Study III).
- Associated conditions, medical complications, length of stay (LOS) and outcomes at one year post injury (Study IV).
4 MATERIAL AND METHODS

4.1 DESIGN

STATSCIS is a prospective population-based study.

4.2 SETTINGS

The Greater Thessaloniki region in Greece (hereafter: Thessaloniki) and the Greater Stockholm region in Sweden (hereafter: Stockholm) comprised the two study regions of STATSCIS. These regions have fairly similar population sizes of approximately 2 million each, while Thessaloniki is three times larger area-wise as compared to Stockholm.

Within Thessaloniki, out of a total of 30 hospitals, five are at a tertiary level, and thus, in principle, able to handle acute TSCI. However, one out of these is a military hospital, unavailable to the public, and therefore not included in the surveillance system. Out of the secondary hospitals, the only two that would, in principle, treat cases with acute TSCI were included in the surveillance system.

Within Stockholm, there is one comprehensive SCI system of care, consisting of one hospital based SIU, two inpatient rehabilitation centres and one outpatient clinic for lifelong follow-up.

4.3 INCLUSION CRITERIA

All of the following criteria had to be satisfied for inclusion in both regions:

1. acute traumatic spinal cord or cauda equina lesion;
2. age $\geq 16$ years at the time of injury;
3. inpatient care at a hospital of Thessaloniki or Stockholm at any time between September 2006 and October 2007;
4. survival for at least 7 days post trauma;
5. being resident of the country of the respective region; and
6. case giving informed consent for STATSCIS.

As Study III focused on Incidence Cohorts, an additional inclusion criterion was added for that study, i.e. that of injury occurring during the first 12 months of the study period (September 2006 to September 2007).
44 IDENTIFICATION OF CASES

In Thessaloniki, identification of acute TSCI cases was achieved by a comprehensive active surveillance system, designed and implemented for the purposes of this study. The main investigator (A.D.) maintained a weekly personal contact with the 25 hospital wards of the four tertiary hospitals, and regular telephone contact with the four wards of the two included secondary level hospitals. A.D. furthermore evaluated all suspected cases as they occurred, in accordance with the inclusion criteria of STATSCIS. When needed, assistance was provided by the other members of the research team, or local collaborators.

In Stockholm, identification of acute TSCI cases was obtained through a surveillance system with both passive and active components. The NSCIR was the passive component, as the registered cases were those treated within the Stockholm SCI System of care. The whole procedure of case identification and inclusion, from the start till the end of the study, was coordinated by A.D. in order both to avoid inclusion of false positive cases (e.g. non-traumatic or chronic SCI) and also to ensure inclusion of outliers (e.g. cases not treated in the system). An additional active surveillance component was added by contacting all Intensive Care Units (ICUs) in the region, which were not typically treating TSCI. This design was chosen since, although the regional SCI system of care is highly centralized, it may still occasionally be the case that severe multi-trauma cases with TSCI receive acute treatment in other hospitals. Thus, a letter of inquiry was sent to all seven ICUs in the region, asking if during the study period the unit had hospitalised any potential case with acute TSCI who had died.

45 COHORTS

STATSCIS included two types of cohorts: the incidence (II) and the inception (IV) cohorts. A graphical depiction of cohorts is presented in Graphs 1.a and 1.b.

The incidence cohorts (II) consisted of cases injured after the start of registration (middle of September 2006) and during the 12 following months.

The inception cohorts (IV) consisted of the incidence cohorts, and additionally included two more subgroups; the first comprising cases hospitalized at the initiation of STATSCIS on September 2006; and the second comprising cases injured after the first 12 months of registration but before end of October 2007. This method was chosen in order to increase the sample size and assure inclusion of all incidence cases. More
specifically, the period between middle of September 2007 and end of October 2007 served as a trajectory period. In that way, we ensured the inclusion of cases that were injured during the first 12 months of the study, but which were identified at a later stage (e.g. early hospitalisation in a smaller hospital, injury occurring abroad, delayed final diagnosis).

STATSCIS, importantly, did not include cases that died during the first week post-trauma. This methodological choice was made due to the following reasons:

1. Deaths that occur early after trauma are often difficult to assess accurately.
2. Lack of systematic data in early fatal trauma cases.
3. The contribution of TSCI, its consequences and complications to death are difficult to assess in early trauma deaths.
4. Pre-hospital trauma deaths are categorized generally, and not based on a specific diagnosis.
5. Many early trauma deaths occur irrespectively of the given treatment due to the severity of injuries. Our goal was to isolate cases where management could play a significant role in survival.

Paediatric TSCI was not included due to its rare nature, and the different type of management that is usually required and followed.

### 4.6 DATA COLLECTION

Each case was individually followed-up during the first year post-trauma. To ensure comparability between regions, all data collection was carried out according to a subset of the NSCIR (www.nscic.se). The subset consisted of the Acute Form, the Neurological Assessment Form, the Pain Form, the Urological Function Form, the Bowel Function Form, the Spasticity Form, the Respiratory Function Form, the Pressure Ulcer Form, the ADL Form and the Circulatory Function Form. Furthermore, in Thessaloniki cases, we created and used a computer-based form denoted “Draft”, that included a more detailed description of medical history and status, allowing for reconstruction and re-evaluation of data included in the forms. Manuals and uniform definitions of variables were used. The NSCIR forms were used on admission, at discharge and at one year post-trauma. Data were obtained by physical examination, including the International Standards for Neurological classification for SCI; medical records review, including EMS notes and death certificate; personal communication
Figure 3. STATSCIS cohort in Thessaloniki
Figure 4. STATSC1S cohort in Stockholm
with the attending physicians and staff; and communication with each case and a first degree relative. Use of multiple sources of information was necessary since one single complete source was not available.

Clinical neurological examination including assessment according to the International Standards was performed in all cases. In Thessaloniki, all such examinations, which provided data for the present study, were performed by the main investigator (A.D.). This strategy was followed since the International Standards evaluation was not universally utilized in Greece. The corresponding examinations in Stockholm were performed by physicians and physiotherapists specialized in SCI. Clinical diagnosis of TSCI was confirmed by neuro-imaging studies in all cases in both regions.

In Stockholm, data were gathered according to the routine process of the NSCIR. A.D. coordinated closely all data collection throughout the study period. Furthermore, after obtaining an approval by the Nordic SCI Council, A.D. performed a large part of data entry in the system of NSCIR, thus being able to control for missing and mismatching data.

Quality assurance was performed in both regions, i.e. by cross-checking data in the registry forms with medical records, in order to maximise validity and minimise missing data. All retrieved data were re-evaluated in detail by the authors jointly for purposes of medical accuracy and uniform interpretation, e.g. as regards extra-spinal injuries and any secondary morbidity.

The web-based registration forms of the NSCIR were used to store data in Stockholm. The format of the latter was used to develop a Microsoft Access database to store data in Thessaloniki. An additional computer-based module was developed that allowed for registering the clinical process, including inter-facility transfers and LOS.

4.7 FIELD TESTING

Field-testing of the whole method was performed in Thessaloniki from May until July 2006, before the actual start of the large scale registration. Field-testing provided useful feedback and gave possibility for adjustments of the methodology.
4.8 DATA ANALYSIS

Different subgroups of STATSCIS were used in different subsets of analyses. Incidence and case-mortality rates were calculated by considering only the incidence cohorts (III). Age- and gender-adjusted incidences were calculated by the method of direct standardization, using the 2007 European population structure (Eurostat, Euro-27).

All other analyses included consented cases only. In Papers I and II, demographic and injury characteristics, core clinical characteristics and early treatment were analysed for consented cases of the inception cohorts (V). In Paper III, analyses of the characteristics of mortality cases were performed using the consented cases of incidence cohorts (III). In Paper IV, outcomes and LOS were analysed using alive at one year consented cases of the inception cohorts (VII), with the only exception of general outcome that was analysed using mortality cases as well (VI). Associated conditions and their management were analysed using only survival consented cases of inception cohort (VII), whereas medical complications were analysed after including mortality cases as well (VI).

In addition to the quantitative methods, we used the richer data source of the total medical records to create clinical vignettes for the fatal cases (VIII) as presented in Appendix II.

Due to the largely different clinical processes and LOS between the two regions, we chose not to analyse data on discharge. Instead we used data at common time-points after trauma (i.e. admission and one year post-trauma).

Descriptive data were presented as n (%), mean, standard deviation (SD), median and inter-quartile range (IQR). Statistical significance was set at P<0.05. Differences in proportions between regions were examined by Chi-square test and Fisher’s exact test. Statistical mean differences between regions were determined by independent Student’s T-test. For ordinal variables or in cases of non-normal distribution the Mann-Whitney test was used. All statistical analyses were performed with the SPSS software (Statistical Package for the Social Sciences, v. 16.0, Chicago, IL, USA).
49 ETHICAL CONSIDERATIONS

Ethical approvals for STATSCIS were obtained from the Human Ethics Committee at Karolinska Institutet and from the Hellenic Data Protection Authority. Additional approvals were obtained from the Nordic SCI Council, the Scientific Committee and the Board of all participating hospitals in Thessaloniki.
5 RESULTS AND DISCUSSION

5.1 INCIDENCE (PAPER I)

The annual incidence rate of TSCI was nearly double in Thessaloniki (33.6/million) as compared to Stockholm (19.4/million). STATSCIS is the first study to report incidence rates of TSCI in Greece and Sweden.

The STATSCIS incidence figure for Stockholm is nearly double than that presented previously\textsuperscript{70}. This might be due to that previous estimates were purely based on raw registry data from a single component of the system, and without systematically performing quality assurance procedures. Although STATSCIS presents data from a single year, we believe that, methodologically, our calculation is closer to reality, because: (a) we included cases from registry data, after validating each case; (b) we also considered cases that were not treated at the SIU or were not officially included in the system; (c) we used detailed inclusion criteria; and (d) we extended case-identification procedure to cover all components and phases of the SCI system of care. Although direct comparison of incidence rates between studies is hampered by methodological differences, it may be concluded that Stockholm has a relatively low incidence of TSCI, whereas Thessaloniki has a relatively high incidence.

5.2 DEMOGRAPHICS AND INJURY CHARACTERISTICS (PAPER I)

Proportionally more males sustained a TSCI in Thessaloniki as compared to Stockholm, with male:female ratios being 7:1 and 3:1, respectively. Mean age at injury was 43 years in Thessaloniki and 47 years in Stockholm. Transportation in Thessaloniki and falls in Stockholm were the main causes of TSCI. Transportation-related injuries were significantly more common (P=0.003) in Thessaloniki as compared to Stockholm. Occurrence of TSCI in both regions peaked in the months of August and September, and from a weekly perspective, on Saturdays.

Overall, more than one out of four cases in Thessaloniki belonged in the youngest age-group (16-30) and were injured by a transportation-related cause, whereas the proportionally fewer cases in Stockholm that belonged in this age-group were more often injured by a sports-related cause. Well-designed prevention interventions targeted to young males driving cars and motorcycles could radically decrease incidence of TSCI in Thessaloniki. Issues as alcohol consumption and utilization of safety
equipment that were not evaluated in the present study are likely to provide further useful information for the design of more effective prevention programs.

Overall, with the exception of educational level (P=0.010) that was higher in Stockholm, and the Thessaloniki cases being more rural (P=0.002), the two study groups were similar in many other demographic factors, such as gender, mean age, distribution in age-groups, being of foreign background, marital and vocational status, type of residence, and work-relatedness of trauma. Similar findings were found in analyses of incidence cohorts.

5.3 CORE CLINICAL CHARACTERISTICS ON ADMISSION (PAPER II)

Clinical status of cases on admission was rather similar between regions. About 30% of TSCI cases in each region had a high cervical neurological lesion (C1-C4), about 10-15% had a low cervical lesion (C5-C8), about 40-45% a thoracic lesion (T1-T12) and about 10% a lumbo-sacral lesion. Approximately 35% of lesions were classified as AIS grade A, 5% as AIS grade B, 20% as AIS grade C, and 30% as AIS grade D.

Seven out of ten cases in both regions had normal level of consciousness (LOC). Serious extra-spinal injuries were present in 20% of cases and life-threatening in 10% in both regions. Co-morbid degenerative spinal disorder was more common in Greek cases (P=0.005).

Overall, there were no statistically significant differences between regions with regard to distribution of NLL, AIS grading, means of ASIA total motor score, LOC, presence-severity-topography of extra-spinal injuries, and presence of co-morbid non spinal disorders. Furthermore, there was no statistically significant difference when assessing completeness of lesion in relation to neurological category. Similar findings were found in analyses of incidence cohorts.

5.4 EARLY TREATMENT (PAPER II)

Significantly more cases in Thessaloniki than in Stockholm received mechanical ventilation (P=0.002) and had a tracheostomy placed (P=0.011). Nearly half (49%) of the cases in Thessaloniki were put on mechanical ventilation as compared to 20% in
Stockholm, out of whom, as many as seven out of ten in both regions also underwent a tracheostomy.

Spinal surgery was performed more often (P=0.002) and sooner after trauma (P=0.003) in Stockholm than in Thessaloniki. Overall, in Thessaloniki, 63 out of 81 cases (78%) were operated upon after an average of 10 days (Median=4, SD=25), whereas in Stockholm 46 out of 47 (98%) were operated upon after an average of 3 days (Median=1, SD=4). Despite the absence of conclusive data on optimal timing for performing spinal surgery, it has been recommended that surgical decompression and stabilization should be performed early after acute TSCI, especially in the presence of progressing neurological deterioration156, 157.

We believe that those treatment modalities are strongly related with how and when after trauma the patient reached a tertiary level hospital, and received their definitive spinal treatment. In Thessaloniki, transfers from the scene of trauma to a tertiary level hospital were carried out either by road ambulance or private cars, whereas in Stockholm air transport was additionally utilized on nine occasions. Thessaloniki cases reached a tertiary level hospital at a later timing after trauma and after more intermediate admissions to smaller hospitals, than did Stockholm cases.

Differing types of early management seem to have some relation with the presence or absence of an SCI system of care. In Stockholm, the goal seems to be to transfer the case as soon as possible to a tertiary hospital, and then to provide treatment within the designated system. In contrary, in Thessaloniki, the goal seems to be to equip the patient in such a way as to survive the unknown and unexpected near future, with regard to timing of arrival at a tertiary level hospital and of final spinal treatment. More invasive interventions, aiming to control the vital functions, are therefore probably necessary in Thessaloniki in order to prevent early trauma mortality occurring before arrival to a tertiary level hospital.

However, when transfers are carried out as they frequently do in Thessaloniki, there is a higher risk for neurological deterioration and development of early complications. The case is transferred to several facilities by ground means of transport, often without yet having a final diagnosis, in the presence of haemodynamic and spinal instability, sedated and without being able to express pain or communicate. Although we were able to clinically confirm a few cases with neurological deterioration, several other instances were reported to us by patients and relatives. Nevertheless, we see the differing early
treatment strategies mainly as adaptations to the varying contexts of availability of a systematic approach between regions, rather than being “right” or “wrong” interventions per se.

5.5 CLINICAL PROCESS (PAPER II & IV, AND UNPUBLISHED DATA)

Similar proportions of cases between regions were hospitalized in an ICU, with the initially motor complete (IMC) cases in Thessaloniki spending five times longer period in such a facility as compared to the respective cases in Stockholm (P<0.001). Significantly more IMC (P=0.031) and initially motor incomplete (IMIC) cases (P=0.037) in Thessaloniki were hospitalized for a five-fold (P<0.001) and a three-fold (P<0.001) longer period in a general ward as compared to the respective groups in Stockholm.

Due to the lack of a SIU in Greece, only four Thessaloniki cases (all IMC) were hospitalized in a SIU abroad, whereas nearly all Stockholm cases were hospitalized in such a facility domestically. In Stockholm, overall, three cases were never hospitalized in the SIU, all with missing status of motor completeness on admission, mainly due to the presence of other serious extra-spinal injuries, such as TBI.

LOS in a rehabilitation centre was five times longer for both IMC (P<0.001) and IMIC (P<0.001) cases in Thessaloniki as compared to those in Stockholm. One out of five IMC and nearly four out of five IMIC cases in the Greek region never went to an in-patient rehabilitation centre during the first year post-trauma. In contrary, nearly all cases in the Swedish region went to an in-patient rehabilitation centre.

Mean total in-patient LOS was double for the IMC cases (P<0.001) in Thessaloniki as compared to Stockholm. Figures 3 and 4 present the clinical process that was followed after the case had reached a tertiary level hospital. As can be seen in these figures, care of the Greek cases was provided in several wards, even after having reached a tertiary level hospital. One can also notice that there were numerous readmissions in the Greek region.

As it becomes evident when considering Figures 3 and 4 in combination with LOS, clinical process in Thessaloniki was characterized by longer periods in ICUs, many transfers between several facilities, frequent readmissions, and long rehabilitation LOS. This situation was more common in IMC cases. In contrary, in Stockholm, long stays in
ICU were avoided, and cases were concentrated in the SIU and in the two designated in-patient rehabilitation centres.

In both regions, degree of motor completeness on admission seemed to play some role in hospitalisation in an ICU, as IMC cases were more likely to receive treatment in such a facility. In Thessaloniki, this seemed to be the case for in-patient rehabilitation as well. However, our clinical experience indicates that the commitment and involvement of the family is a very important component that influences a large part of the clinical process in Thessaloniki, since family often decides if and where the patient receives in-patient rehabilitation. In IMC cases, due to the more severe physical impairment, commitment is often stronger, and in some instances (six cases) lead them to seek rehabilitation services abroad. In contrary, clinical process in Stockholm is determined almost totally by the co-ordinated system, based on functional outcomes.

The lack of system of care specifically in Thessaloniki and generally in Greece, as expressed by a complicated, unorganised and uncoordinated clinical process, does not allow for systematic registration and follow-up of incident and prevalent cases. In contrary, the standardised process in Stockholm and generally in Sweden allows for a successful identification of both incident and prevalent TSCI cases, with a possibility of life-long follow-up and continuous quality assurance. Nonetheless, we believe that a modernisation of the NSCIR is necessary, and should focus on updating its information needs and purposes, improving its compliance with the International Core Data Set, improving its validity, and connecting it with other registries.
Figure 5 Clinical Process in Thessaloniki.

(Illustration by Paris Aslanidis)
Figure 6. Clinical process in Stockholm

(Illustration by Paris Aslanidis)
5.6 MORTALITY (PAPER III)

Overall, 12 out of the 64 cases of the incidence cohort in Thessaloniki, while none out of the 32 respective cases in Stockholm died during the first year post-trauma. Case mortality rate in Thessaloniki, thus, was approximately 20%, whereas in Stockholm it was 0%, showing a significant difference of $P=0.007$. Therefore, STATSCIS showed that two initially similar cohorts of TSCI had a dramatic difference in one year mortality, depending on whether they were treated within an SCI System of care or not.

As shown previously by others, pre- and early in-hospital deaths (occurring during the first week post-trauma) are significantly associated with more severe injuries\(^{158}\). Furthermore, other studies have shown that a greater proportion of potentially avoidable trauma deaths occur after, and not during, the first week post admission\(^{159}\). Consequently in STATSCIS, by excluding cases that died during the first week post-trauma, we were able to focus on “late” deaths that had occurred in relatively less severely injured cases, making their fatal outcome, at least to some extent, avoidable.

Mean time of survival after trauma in fatal cases was 47 days (median=24, $SD=67$, range=8-228). Infections were the most common cause of death. Nine out of the ten included fatal cases were males. Mean age was 62 years (median=70, $SD=21$, range=25-80). Half of the cases had sustained a transportation-related injury, four a fall-related and one an assault-related injury.

With regard to neurological category of lesion, six had cervical lesions, three had thoracic, and one had no initial neurological lesion after trauma, but later became a C3 tetraplegic due to missed spinal column instability. Half of the cases had no extra-spinal injuries, three had mild and two had serious such lesions. All cases were reported to be conscious on initial admission (or before intubation, if intubated during the pre-hospital phase).

Several studies in addition to STATSCIS have shown that higher age and presence of comorbid spinal disorders are associated with a fatal outcome\(^{20, 160}\). Furthermore, level and completeness of lesion have also been shown to be associated with death\(^{20, 31}\). However, the latter were not expressed in STATSCIS probably due to the small sample size. From analysis of the vignettes presented in Appendix II, it becomes evident that other factors, such as “inefficient transfer logistics”, “initially missed spinal instability”, and “unsuccessfully treated complications” were also associated with a fatal outcome.
5.7 ASSOCIATED CONDITIONS AND COMPLICATIONS (PAPER IV)

In addition to the dramatic difference in mortality, some differences in associated conditions and complications were also seen between study groups. These differences may not be as self-evident if they are seen independently of the large difference in mortality between regions, so should be put in the context of STATSCIS as whole.

In the absence of any difference in self-reported bladder sensation between groups, significantly different bladder emptying methods were noticed (P=0.013). Clean intermittent catheterization and suprapubic catheter were more often used in Stockholm as compared to Thessaloniki. Furthermore, one out of ten Thessaloniki cases was using an indwelling urethral catheter at one year follow-up. Long-term use of an indwelling urethral catheter is known to be responsible for higher morbidity.

Six cases in Thessaloniki had a tracheostomy at one year follow-up, one of whom was using a home ventilator. No case in Stockholm had such devices. There were no significant differences as regards presence of pain, severity of spasticity, frequency of orthostatism, and A D.

Sepsis/bacteraemia was significantly more common in Thessaloniki as compared to Stockholm (P=0.002), as were cardiac arrhythmias (P=0.049). DVT and PE were rare among both study groups, probably due to routine administration of anticoagulant prophylaxis early after injury.

Significantly more cases in Thessaloniki experienced multiple pressure ulcers during the first year post-trauma (P=0.008), as one out of five cases in Thessaloniki and none in Stockholm had suffered five or more ulcers. Despite the fact that acquiring one low grade pressure ulcer in the acute stage might be to some extent inevitable, acquiring multiple ulcers during the first year post-trauma more likely indicates some kind of systemic error in ulcer prevention measures. The lack of data on ulcer grading and location do not allow for further analysis of this issue in the present study. The presence of multiple pressure ulcers might partially explain the longer LOS in Thessaloniki.

No significant differences between groups were found as regards the occurrence of urinary infections requiring treatment and respiratory infections. Symptomatic HO were significantly more common in the Greek group as compared to the Swedish group (P=0.017).
5.8 OUTCOMES AT FIRST YEAR FOLLOW-UP (PAPER IV)

With regard to IMC cases, a statistically significant higher proportion of cases in Stockholm had a favourable outcome (defined as survival and upgrading of AIS) as compared to those in Thessaloniki ($P=0.028$). No statistically significant differences were found with regard to neurological recovery or ASIA motor score and motor score gain. In contrast, statistically significant differences were present as regards functional status ($P=0.019$) and type of residence ($P=0.029$). One out of five Thessaloniki IMC cases was in-patient at a rehabilitation centre at one year follow-up.

With regard to IMIC cases, there were no statistically significant differences between regions in any of the evaluated outcomes.

Our data indicate that IMC cases are more vulnerable to the lack of an SCI system of care. This was clearly expressed by differences in general outcome, where both survival and neurological improvement were assessed.
5.9 CONCLUSIONS

- Incidence of TSCI was nearly double in Thessaloniki as compared to Stockholm.

- The main target group for prevention of TSCI in Thessaloniki is young male drivers 16-30 years old.

- Although the two cohorts had similar demographic, injury and clinical characteristics on admission, they received significantly different treatment.

- Mortality was dramatically higher in Thessaloniki reaching nearly 20% as compared to 0% in Stockholm.

- The two times longer LOS of the IMC cases in Thessaloniki was followed by inferior outcomes, as compared to Stockholm.

- Occurrence of severe complications, such as multiple pressure ulcers and bacteraemia/sepsis was significantly more common in Thessaloniki.

- Managing TSCI by a non-systematic approach results in higher mortality, longer LOS, inferior outcomes and higher morbidity, than managing TSCI within a system of SCI care.

- Establishing SCI systems of care in Greece will facilitate the development of a National surveillance system for TSCI. The latter, in its own, will allow for a systematic registration and follow-up of incident and prevalent cases, and can function as a tool for continuous quality assurance.

- Establishing an SCI system of care in Thessaloniki would most likely make use of resources in a more effective way, reduce mortality, reduce severe complications and improve functional outcomes at one year post-trauma.
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**Stockholms Sjukhem:** Kärvestedt, Aly, Westerlund; all those involved with collection of data.

**Nordic Spinal Cord Injury Council.**
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7 APPENDIXES

7.1 APPENDIX I: “STATE-OF-THE-ART” SCI SYSTEM OF CARE

It is not in the best interests of paraplegics that their early care in the first five or six months should be undertaken in non-specialised units such as orthopaedic, neurosurgical, urological, rehabilitative, or medical, for they cannot receive the especially coordinated service that, in many parts of the world, has been proved to give the best results.\(^{161}\) Bedbrook, 1967

Health System

WHO’s definition of a health system is: “the people, institutions and resources, arranged together in accordance with established policies to improve (promote-restore-maintain) the health of the population they serve, while responding to people’s legitimate expectations and protecting them against the cost of ill-health through a variety of activities whose primary intent is to improve health.”

SCI System of Care: Important components and functions

An SCI System of care provides coordinated, case-managed, integrated services for individuals with SCI. It is considered important that there is one single entity responsible for the co-ordination of the system that ensures communication and collaboration among the various providers and facilities.

The factual body of reference for the following attempt at outlining the main features of an SCI System of care includes Guttmann’s landmark book on SCI\(^1\), the Proceedings of the 1967 Annual Scientific Meeting of the International Medical Society of Paraplegia\(^{162}\), the Paraplegic Veterans of America Clinical Practice Guidelines: Early acute management in adults with Spinal Cord Injury\(^{156}\), the Americans for Safe Access Policy Recommendations for the establishment of Stroke System of care\(^{163}\), and descriptions of Model Spinal Cord Injury Systems of Care\(^{164}\).

Public Information, Education and Prevention

- Develop a plan to raise awareness on injuries and injury prevention.
- Develop a plan to educate elected officials and staff about SCI System issues.
- Inform about the existence of an SCI System, its functions and how it can be accessed.
• Develop and maintain a Public Health Surveillance System and a Registry that can serve as a clinical and a research tool and can assist the design of prevention strategies.

EMS for SCI

• EMS: Provide appropriate resuscitation, ensure early recognition of suspect cases, perform early SCI-specific assessment, provide appropriate stabilization.

• Prehospital Triage: Identify regional trauma centers with special resources for the acute management of spinal cord injuries. Arrange appropriate mode of transportation; use unequivocal transport protocols to ensure that patients are taken only to facilities with appropriate resources; perform an early notification of the emergency facility for preparations.

• Inter-hospital transfers: before a patient is transferred from one facility to another, specific criteria with regard to medical stability should be fulfilled165.

Acute management of SCI

• **Trauma Center:** Transfer the patient with a suspected spinal cord injury as soon as possible to an appropriate trauma center. There is a need for preservation of neurological function in the possible presence of an unstable spine, evaluation and acute treatment of serious extra-spinal injuries (often co-existent brain injury), availability of modern imaging resources.

• **Spinal Injury Unit:** Transfer of the SCI patient to a specialized center for SCI, preferably within 24 hours post trauma. SIU intend to manage optimally a relatively rare, severe and costly condition, with a view to limiting complications of the injury and facilitating rehabilitation and community re-integration. The first descriptions of the specific characteristics of a SIU were published several decades ago166-168.

• **Acute treatment** that includes: spinal stabilization; ABCs and resuscitation; neuro-protection; diagnostic assessment for definite care and surgical decision making; detailed assessment and treatment of extra-spinal injuries and co-morbid conditions; consideration of spinal canal decompression and stabilization of the spinal column; assessment and treatment of pain and
anxiety; prevention - recognition - treatment of skin breakdown, venous thromboembolism, respiratory complications, urinary and other complications; prognosis for neurological recovery.

Sub-acute care

- Clear guidelines for all aspects of rehabilitation: early mobilisation, clearly defined goals, proper environment that facilitates activities and increases motivation.
- Smooth transition from sub-acute care to rehabilitation and from in-patient to out-patient care, after specific medical and functional “milestone” goals have been achieved.
- Ensure that the patient and family members receive proper information and education.

Rehabilitation

- Education of SCI individuals, their personal assistants and family members.
- Optimization of neurological recovery.
- Achievement of predicted outcomes.
- Co-ordination of house and work place adjustments.
- Initiation of vocational training.
- Sports and recreational activities are included in the medical treatment.

Life-long follow-up

- Coordination and performance of annual follow-up controls.
- Provision of “one-stop” services and coordination of specialized consultations for health maintenance.

Evaluation and Development

- Data collection: collect data on socio-demographics and clinical status at different time-points after trauma.
- **Quality assurance**: Establishment of mechanisms to evaluate each component and function of the system, as well as total performance and coordination.

- **Research**: Encourage the conduction of research on specific areas of the system, including definite and functional outcomes, cost-effectiveness.

The term “Spinal Injury Unit” has been used for several years to denote a physical unit including most of the components and functions mentioned above. Nonetheless, for the purposes of STATSCIS, and due to the use of the term in Sweden, the term SIU is used to denote specifically the specialized component of care responsible for the management of acute and sub-acute phase. The term “SCI system of care” is used, instead, to denote an integrated, comprehensive system of physical units and functions, all dedicated to the management of TSCI. Those services might be operated by different providers, but are nevertheless still coordinated centrally to form a single functional entity.

There has been an ongoing discussion since the inception of SCI systems of care whether all the components of the system should be under one roof, as it is the case, for example, of the Swiss Paraplegic Centre in Nottwil, Switzerland, or not, as it is the case, for example, of Stockholm, Sweden. Furthermore, there have been discussions with regard to the ideal setting of the system; whether it should be autonomous, within a University hospital, within a General hospital or within a Trauma hospital. Donovan et al. stated that an ideal SCI system should provide all phases of care under a single roof, or within a defined system, and should concentrate the staff expertise, facilities and equipment in one area in order to promote optimum patient care and cost effectiveness. A System of SCI care allows for high volumes of treated TSCI cases, something which gives the possibility for developing and maintaining expertise.

The ultimate goal for an SCI system of care is to secure a physically healthy, meaningful life with minimal functional impairments, maximal abilities and high life satisfaction. Achieving a high level of independence is a fundamental aspect, as is to establish/maintain family life and to get/return to a meaningful vocation. Especially the importance of a meaningful job has been discussed by the early inception of SCI systems of care. The utilization of sports is mainly a means to achieve/maintain good outcomes - not necessarily an end in itself. Special attention needs to be given to funding of personal assistance and provision of necessary equipment and adjustments.
APPENDIX II: CASE REPORTS OF FATAL CASES

Case 1
A 27 year old female with severe obesity and insulin dependent diabetes mellitus was transferred to the emergency department (ED) of a tertiary hospital after being injured as a front seat passenger in a high speed single car crash.

Investigations: On physical examination, GCS on admission was 15 and a complete T10 paraplegia was present. Radiological examination showed a T10 fracture dislocation, fractures of several ribs, haemopneumothorax, and mild liver contusions.

Course of hospitalisation: On 1st day post trauma (DPT), Bülau drainage was placed and the patient underwent T10-T11 laminectomy and T9-L2 fusion, thereafter she was admitted to the ICU. On 2nd DPT she was extubated, with a good saturation level and diuresis, and was transferred to a neurosurgery ward. On 7th DPT, further Bülau drainage was placed due to dyspnoea episode. Initial respiratory symptoms ceased until 8th DPT when she also experienced chest pain, oxygen desaturation and fever. On 10th DPT she was readmitted to the ICU with respiratory insufficiency, which was treated with haemodynamics and oxygen supply. On 13th DPT she was re-admitted to the neurosurgery ward where she spent 15 uneventful days. On 28th DPT after a severe bradycardic episode combined with low oxygen saturation levels, she was urgently intubated and treated with adrenaline. On 29th DPT, she was extubated with GCS 15 and good breathing pattern. On 32nd DPT, due to tachypnea, hypoxemia, respiratory fatigue, inability to cough and atelectasis, she was re-intubated. Additionally, she showed signs of progressive deterioration of kidney function and haemodialysis treatment was then initiated. On 36th DPT she underwent tracheostomy, and by 39th DPT she had satisfactory general condition on BiPAP ventilation, but fever. On 51st DPT due to ventilator associated pneumonia, she was put under heavier sedation in order to improve mechanical ventilation. On 63rd DPT, while under sedation and mechanical ventilation, she had a septic episode. On 73rd DPT, she had another severe septic episode followed by haemodynamic instability, and severe deterioration of respiratory capacity, and thereafter she was hypoxemic and haemodynamic instable. On 80th DPT, she appeared with polyorganic failure due to sepsis, leading to death.

Cause of death: Respiratory insufficiency, leading to pneumonia, leading to sepsis.

Comment: Although this patient was young and with a low level paraplegia, her vulnerability as regards respiratory complications was high due to the combination of thoracic injuries, severe obesity and diabetes. One major factor likely to have contributed to the ultimately fatal outcome was a lack of proactive preventative measures (e.g. early mobilization) in combination with the lack of defined clinical protocols for management of respiratory complications.

Case 2
A 34 year old male with severe obesity and schizophrenia jumped from a balcony with suicidal intent. According to the ambulance notes, initial GCS before intubation and mechanical ventilation was 15. The patient was transported to the ED of a tertiary hospital.

Investigations: No medical notes regarding initial physical examination are available. Radiological examinations including CT of brain, thorax, abdomen, pelvis and thoracolumbar spine revealed pelvic fractures, retroperitoneal haematoma, fractures on
T1, T10, T11, T12, L1, L4, and L5, bilateral lung contusions, pneumothorax and pleural fluid, as well as a suspected aortic dissection. Angiography confirmed the latter finding, which was treated by stenting. Additionally, there were bilateral ankle and left arm fractures.

**Course of hospitalisation:** Pelvic and extremity fractures were treated with transfixation and the patient was sent to ICU.

Complete radiological examination of the spine was cancelled for several times, since the patient was too large to fit the CT scanner. On 21st DPT, full CT scan of upper cervical and thoracic spine was successfully performed, revealing no injury signs on cervical spine and confirming previous findings on the thoracic spine. Non-surgical treatment was then decided to be followed. Finally, on 25th DPT, the endotracheal tube was replaced by a tracheostomy. At this time, a tracheal stenosis and a tracheoesophageal fistula had developed, leading to recurrent aspiration pneumonias and a need for gastrostomy. The patient also suffered recurrent UTIs. Neurological status remained unchanged, with an incomplete paraplegia. During the last month of hospitalisation, the patient had to be transferred to the ICU several times due to episodes of septic shock, ultimately leading to multiple organ failure and death on 316th DPT.

**Cause of death:** Death certificate was not available.

**Comment:** This patient suffered severe multitrauma. The most striking complication to our minds was the tracheoesophageal fistula, which most likely was a result of prolonged endotracheal intubation. This in turn led to repeated episodes of aspiration pneumonia, sepsis and ultimately shock and death.

**Case 3**

A 72 year old previously healthy male felt dizziness and fell from the stairs. He was then transferred to the ED of a local hospital.

**Investigations:** On physical examination, GCS on admission was 15 and a tetraplegia was present. CT of the cervical spine revealed no fractures. During the same day, he was transferred to a tertiary hospital, where physical examination showed no voluntary motor activity on the upper limbs, but some voluntary motor activity on the lower limbs (2/5). MRI of the cervical spine revealed spinal cord contusion at the C3 level and degenerative changes with spinal stenosis. ASIA examination performed during the 2nd DPT showed the picture of a C4 complete tetraplegia with no sacral sparing, no motor activity in the upper limbs, but with motor preservation in all key muscles of the lower limbs.

**Course of hospitalisation:** On 1st DPT, the patient was treated with Solumedrol. On 2nd DPT he underwent discectomy and osteophytectomy of C3-C4 and C6-C7 levels, and anterior fusion of C3-C7. On 4th DPT, the patient presented signs of pneumonia which were verified by x-ray and was treated with antibiotics. CT of brain revealed no pathological findings. On 16th DPT, the patient was discharged to an inpatient rehabilitation centre. During the next week, the patient showed persisting signs of infection, which was thought to be due to a UTI and was treated accordingly. On 30th DPT he was urgently transferred to the general medicine department of a tertiary hospital with high fever, dyspnoea and tachypnea and signs of respiratory infection. On 31st DPT, the patient appeared in a septic condition with polyorganic insufficiency and finally died.

**Cause of death:** Pneumonia, leading to sepsis, leading to death.
Comment: This patient suffered a fairly prolonged period with infectious symptoms while remaining in the rehabilitation centre. Transfer to an acute medical facility was delayed until the patient was in an irreversible condition.

Case 4
A 25 year old male with a history of substance abuse was injured as a front seat passenger in a single car crash. He was then transported to the ED of a local hospital (A). During the same day and after a two and half hours drive, the patient was transported by ambulance to the ED of a tertiary hospital (B).

Investigations: Physical examination revealed GCS 15 and a C5 complete tetraplegia. CT scan of the brain, thorax and abdomen showed no pathological signs, while MRI examination of the cervical spine showed a C5-C6 posterior dislocation and a C6 vertebral fracture with a corresponding spinal cord oedema.

Course of hospitalisation: On 1st DPT the patient underwent C5-C6 fusion, and thereafter was transferred to the ICU due to haemodynamic instability. Corticosteroid treatment was not provided. On 2nd DPT, the efforts for extubation failed due to hypoxemia, paradoxal breathing and bad compliance of the patient, and the patient was re-intubated. During the 3rd DPT, the patient showed signs of hypoventilation of the left lower lobe and bradycardia. On the 8th DPT the patient got high fever and x-ray of thorax showed pneumonia, which was treated accordingly. On 14th DPT the patient underwent tracheostomy, and for the four following days the course was uneventful. On 19th DPT transient tachycardia and tachypnea was observed. By the 23rd DPT sedatives were reduced, the patient was haemodynamically stable with satisfactory diuresis. On 24th DPT, the patient appeared septic and haemodynamically unstable that was successfully treated. During the next period the patient suffered from recurrent UTIs which led to the replacement of the indwelling catheter by a suprapubic one. Up to the 50th DPT in ICU, several instances of haemodynamical instability occurred, one of which resulted in a cardiac arrest episode. On 50th DPT, the patient was transferred to the ICU of a smaller regional hospital (C). On 63rd DPT, he was transferred to a regional rehabilitation centre (D) while still being on mechanical ventilation. On 74th DPT he was urgently transferred to another regional hospital (E) where after staying for 10 days, he was re-admitted to the regional rehabilitation centre (D). On 94th DPT he was transferred to a University hospital (F) with urinary and respiratory infection, as well as severe ischial pressure sores. On 151st DPT the patient was transferred to the regional rehabilitation centre (D). From that moment on, the patient was urgently transferred 3 times and spent short periods in the regional hospital (E) because of cardiac arrhythmias, likely due to autonomic dysreflexia episodes. During his last stay at the regional hospital (E) on 228th DPT and while he was being prepared to return to the rehabilitation centre, he died.

Cause of death: Cardiac arrhythmias, haemodynamic instability and possible recurrent episodes of autonomic dysreflexia, leading to death.

Comment: This patient suffered a C5 complete tetraplegia with a prominent cardiac and haemodynamic instability. From time of trauma until time of death, the patient was transferred between six facilities. A patient of this kind would have benefited from specialised and comprehensive treatment in one centre.
Case 5
A 74 year old male with ankylotic spondylitis (MB Bechterew) fell from his bicycle and was transferred to the ED of a local hospital.

Investigations: On physical examination, GCS on admission was 15, and a tetraplegia was found to be present. Radiological examination of cervical spine with plain x-ray and CT scan showed posterior dislocation of C5 on C6, possible C6 vertebral arch fracture and posterior traumatic disc hernia on C5-C6 level with spinal cord compression. The patient was then intubated and transferred to a tertiary hospital, where radiology confirmed previous findings and additionally revealed a C5 vertebral body fracture and some minor facial fractures. MRI of the C-spine performed on the 3rd DPT showed detached spinal column on the C5-C6 level with high degree of angulation and pressure on the spinal cord with oedema from C3 till C7.

Course of hospitalisation: On 7th DPT he underwent laminectomy of C4-C6 with anterior fusion C4-C5. On 8th and 11th DPT, the patient manifested sinoatrial bradycardia which was treated with atropine. On 14th DPT, he underwent posterior fusion of C3-C7 and tracheostomy. On 21st DPT, microbiologic analysis showed urinary tract infection. On 26th DPT the patient died.

Cause of death: according to the death certificate.

Comment: available medical records fails to disclose enough information as to define a likely cause of death. The most likely cause includes sepsis and/or an acute cardiac event. Furthermore, the choice, type and timing of spinal surgery remain unclear to us. According to the medical records there was a histological biopsy examination made at C5 vertebra after the first surgical procedure. The biopsy material did not show any signs of malignancy. Thus, it is possible that initial diagnosis of metastatic disease was contemplated and influenced management.

Case 6
A 68 year old male with a history of ankylotic spondylitis (MB Bechterew) and cervical spinal stenosis fell on the floor when the chair he was sitting on broke. With the help of his relatives, he got up and walked to the car and was driven to the local health care centre. Shortly after, he was transferred to the local hospital via ambulance.

Investigations: On physical examination, GCS on admission was 15, and the patient reported local pain in the cervical spine, manifesting clinical symptoms of an incomplete tetraplegia. CT scan of the cervical spine showed a C4 vertebral body fracture and a severe spinal stenosis. Straight after, the patient was transferred by ambulance to a tertiary hospital, where physical examination confirmed the patient’s impression of a deteriorating neurological condition in all extremities.

Course of hospitalisation: During the first days, the patient remained haemodynamically stable and with satisfactory breathing. On 3rd DPT he suddenly appeared with ventricular arrhythmia and bradycardia, and was therefore intubated. On 9th DPT he underwent tracheostomy. Urinary culture confirmed a UTI. On 12th DPT, the patient died.

Cause of death: According to the death certificate, death was attributed to severe spinal cord injury, on the basis of ankylotic spondylitis, leading to cardio-pulmonary insufficiency and cardiac arrest.

Comment: Clearly, this patient deteriorated during initial transportation and management, possibly due to the presence of an unstable cervical fracture. The chain of events that led to death remains somewhat obscure.
**Case 7**
A 47 year old previously healthy male injured in a high speed MVA as he lost control of the car he was driving under the effect of alcohol. He was then transferred by ambulance to a local hospital.

**Investigations:** GCS on admission was 15. CT scan showed diffuse contusion of the right frontal lobe with a mild oedema and fractures of the nasal bones, C6 vertebral body fracture and C6-C7 luxation. He was then transferred to a tertiary hospital, where he was diagnosed with a C4 tetraplegia.

**Course of hospitalisation:** Due to respiratory fatigue, he was intubated. On 1st DPT, he underwent C6 corpectomy and fusion, and received corticosteroid treatment. Straight after operation, haemodynamically unstable and manifesting bradycardic events, he was transferred to the ICU where he was treated with vaso-active drugs. On 4th DPT, he appeared with persistent fever, purulent secretions from the respiratory tract and pyuria, as well as asynergic breathing pattern. On 15th DPT tracheostomy was performed. On 17th DPT he appeared with tachypnea, low ventilator compliance and high fever. On 18th DPT there was a dramatic deterioration of the general condition with septic shock, high fever, ultrasonic findings of an enlarged gall bladder, general oedema and metabolic acidosis. Later he appeared with episodes of cardiac arrhythmias, needed CPR and was then supported by mechanical ventilation and vaso-active drugs. Despite vigorous treatment, the patient died.

**Death:** No death certificate available.

**Comment:** This patient suffered a high level complete tetraplegia and a supposedly moderate brain injury (as based on CT findings despite initially normal GCS). In such a vulnerable patient, a severe infectious complication could prove fatal.

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**Case 8**
An 80 year old previously healthy male fell from a tree, and was transferred by ambulance to a local hospital.

**Investigations:** On physical examination, GCS was 15 and a complete Th4 paraplegia was present. X-ray showed no clear signs of fracture of the thoracic spine. During the same day, he was transferred to a tertiary hospital. On arrival, CT of brain and cervical spine showed no pathological signs, CT of thorax showed Th5 and Th6 vertebral body fractures with compression to the spinal cord and fractures of the 4th and 5th ribs. Moreover, a small pleural effusion was found bilaterally as well as signs of atelectasis at the posterior basal regions of the lower lobes. MRI showed oedema at the Th4-Th6 levels, and central posterior disc hernias of the Th11-Th12 and L1-L2 levels.

**Course of hospitalisation:** On 1st DPT corticosteroid treatment was initiated, and on 2nd DPT the patient underwent laminectomy of Th5 and fusion of Th4-Th6. After surgery, since the patient was in a stable condition, he was transferred to a general ward where his condition remained stable for the next days. On 6th DPT, he was treated for anxiety and high blood pressure (190/90 mm Hg). During the same day, he appeared with fever and hematuria. X-ray of the thorax showed some atelectasis of the left lung and possible pleural effusion. During 7th DPT, the condition remained the same, and the CT of the brain showed no pathological sings. On 8th DPT, x-ray of the thorax confirmed previous findings. Later on the 8th DPT, the patient appeared with cardiorespiratory insufficiency, leading to cardiac arrest and death.
Death: According to the death certificate, death was attributed to acute traumatic paraplegia, leading to cardio-pulmonary insufficiency and cardiac arrest.
Comment: This patient was old and sustained a high level paraplegia, with a possible risk of autonomic dysreflexia and respiratory complications. The medical records indicate the presence of possibly both respiratory and urinary tract infections. The chain of events that led to death remain somewhat obscure.

Case 9
An 80 year old male with chronic cervical and lumbar radiculopathy, was injured as a car driver in a MVA. He was then transported to a local hospital.

Investigations: On physical examination, GCS on admission was 15 and the patient reported dizziness and neck pain, but no neurological, orthopaedic or respiratory signs were found. CT scan of the brain showed some atrophy but no other pathological signs. CT scan of the cervical spine showed degenerative changes and straightening of the cervical lordosis, without any signs of fracture. On 1st DPT the patient was discharged home with a collar and a scheduled follow up outpatient examination a few days later. On 4th DPT, follow-up physical examination was normal, so the collar was removed and he was sent home. On 7th DPT, the patient experienced a spell of dizziness while sitting on the toilet, thus leaning over to his wife who supported him, without any trauma reported to have occurred. He remained at home and on 9th DPT, he manifested gradual deterioration with weakness of the lower limbs and neck pain. On 11th DPT, he was transferred to the tertiary hospital by ambulance. On admission, upper limbs appeared with normal sensibility and “next to normal” strength. Lower limbs were found affected as he could not stand, strength was found between 3/5 and 4/5 in all key muscles, and sensibility impairment was present. X-ray examination of the cervical spine merely confirmed the findings of the previous x-ray examination in the local hospital. A Philadelphia collar was placed and the patient was then admitted to a neurosurgical ward.

Course of hospitalisation: In the evening of the same day, the patient manifested further deterioration in terms of sensorimotor function of the lower limbs. Corticosteroid treatment was then initiated and a urethral catheter was placed. On 12th DPT, MRI of the cervical spine showed spinal cord compression by a C6-C7 dislocation, as well as by a posterior osteophyte at the C7 level. Straight after the examination, the patient reported further deterioration and was now a C3 AIS C tetraplegic. At this time, surgery was suggested but was denied by the patient. On 15th DPT, the patient insisted to be discharged to his home, where he died on 21st DPT.

Death: Unspecified, TSCI-related. No death certificate available.
Comment: This elderly patient suffered neurological deterioration due to an initially undisclosed unstable injury of the cervical spine. Because the patient declined surgical treatment and decided to return home with an untreated unstable lesion, further deterioration is likely to have occurred and might by itself have constituted the cause of death. The lesion remained undetected through several evaluations including CT scans. The delay in diagnosis led to neurological deterioration, which is something that may have contributed to a fatal outcome. Initial correct diagnosis would likely have occurred in a specialized facility.
Case 10

A 76 year old male with a history of non-insulin dependent diabetes mellitus, cardiovascular disease and Parkinson’s disease fell from a ladder (2 meters high). Neighbours moved him a short distance and soon after he was transferred by ambulance to the local hospital (A).

Investigations: On physical examination, GCS on admission was 15. Notes regarding further neurological status at this time are missing. X-ray examination showed multiple fractures of the thoracic spine, and the patient was then transferred to a tertiary hospital (B). According to the patient’s daughter who travelled together with the patient in the ambulance for over two hours, the patient experienced further neurological deterioration at this time. On admission, there was pain on palpation of cervical and upper thoracic spine, good mobility of upper limbs, but no mobility of the lower limbs. CT scan of the brain revealed no injuries. CT scan of the cervical spine revealed severe degenerative changes with osteophytes and fractures of C6 and C7 spinous processes. CT of the thoracic spine revealed vertebral body fractures of T1 and T4, and a vertebral arch fracture of T3.

Course of hospitalisations: Corticosteroid treatment was then initiated. On 1st DPT the patient was transferred to another tertiary hospital (C) for cardiological consultation in order to rule out traumatic lesions of heart and aorta. On 2nd DPT, the patient was cleared of any major cardiological problem except for a minor haemopericardium without any need for intervention. Later that day, the patient was transferred back to the neurosurgical department of the tertiary hospital (B). A cute tracheostomy was performed and mechanical ventilation was initiated due to respiratory insufficiency. On 3rd DPT, the medical team decided that spinal surgery was contra-indicated by the poor general condition of the patient. On 20th DPT, the patient appeared with pneumonia, and finally died on 26th DPT.

Death: According to the death certificate, death was attributed to acute traumatic paraplegia and haemopericardium, leading to pulmonary insufficiency and cardiac arrest.

Comment: Initial management of this patient included several transfers and transportations during which neurological deterioration was reported to have occurred. The high level of injury in combination with the patient’s high age probably contributed to the fatal outcome.

Case 11

Investigations: 66 year old male with a history of spinal stenosis and epilepsy, was pushed out of a parked bus, thereby falling from a height of approximately one and half meter. He then expressed an inability to get up by himself and was therefore dragged back in the bus, and after a short trip he was handed over to the police. Although he continued to complain of an inability to walk, he was not believed and he was handled without any precautions. He was brought to the police station, where he remained for several hours, until a medical problem was suspected and he was then transferred to the regional hospital.

Course of hospitalisations: No medical records from the local hospital are available. On 5th DPT he was transferred to a tertiary hospital. On admission, GCS was 15, and he appeared with a complete C2 tetraplegia. CT of the cervical spine revealed no fracture but severe spinal stenosis and disc herniation of C4-C5 and C5-C6 creating severe compression of the spinal cord. No spinal surgery was performed. After 12th DPT the
patient rapidly deteriorated, he was intubated and was put on mechanical ventilation. He appeared septic and died on 18th DPT.

**Death:** According to the death certificate, death was attributed to acute traumatic tetraplegia, leading to intubation and mechanical ventilation, sepsis and finally death.

**Comment:** This patient sustained a spinal cord injury due to assault with a predisposing factor of spinal stenosis. Initial handling probably aggravated neurological condition.
REFERENCES


