

The Definition of Polytrauma: The Need for International Consensus

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Declarations

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The thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository, subject to the provisions of the Copyright Act 1968.

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Publications

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Additional Publications

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2. Pape HC, Lefering R, **Butcher NE**, Peitzman A, Leenen L, Marzi I, Lichte P, Josten C, Bouillon B, Schmucker U, Stahel P, Giannoudis P, Balogh ZJ. The definition of polytrauma revisited: An international consensus process and proposal of the new 'Berlin definition'. *Journal of Trauma and Acute Care Surgery*. 2014; 77(5):780-786.

Conference presentations

International meetings:

1. **Butcher NE**. The Definition of Polytrauma: The Need for International Consensus (Invited speaker) Definition of Polytrauma Kick- off Meeting. 11th European Congress of Trauma & Emergency Surgery, Brussels, Belgium. May 15-18, 2010.
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6. **Butcher NE.** International Consensus Meeting on the Definition of Polytrauma. Hosted by German Society for Trauma Surgery (Deutsche Gesellschaft für Unfallchirurgie – DGU) (Invited speaker). Langenbeck-Virchow Building, Berlin, Germany. May 11, 2012.
7. **Butcher NE.** Inter-observer differences in the classification of the polytraumatized patient. (Invited speaker). 12th Co-operative Polytrauma Management Course- Beyond ATLS. Aachen University Hospital, Aachen, Germany. November 30- December 1, 2012.

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Abstract

The use of the term polytrauma is inconsistent and lacks validation. While numerous definitions have been used interchangeably over the last half-century no attempt has been made to validate any of these definitions nor examine their accuracy in defining the polytrauma patient. Out of this setting comes the aim of this thesis- the development of an internationally validated consensus definition of polytrauma.

A universally accepted definition of polytrauma is vital for accurate scientific communication, epidemiological understanding, monitoring of outcomes and benchmarking of trauma care. Without a validated and clear consensus definition, meaningful comparisons between institutional datasets are hampered and further advances hoped for in trauma research may be impeded by imprecise definitions of their included 'polytrauma' patients. To carry out the aim of this thesis a literature review and four clinical studies were conducted. An International Working Group on Polytrauma was also established.

This thesis will describe the historical evolution of the term polytrauma, detailing its peculiar geographical and cultural differences and establish, through a review of the literature, the lack of a consensus and validated definition. Through four clinical studies it will: 1) examine the key components, specifically the anatomical description and physiological parameters, that must be included in any definition of polytrauma; 2) address the challenges faced in defining polytrauma adequately in the current context and; 3) summarise the international consensus process that has evolved out of this thesis to provide the trauma community with a validated and universally agreed upon definition of polytrauma.

Overview

In the nomenclature of traumatology, the term polytrauma is inconsistent and lacks validation [1]. Over the last half-century, numerous definitions have been used interchangeably and imprecisely across clinical practice, medical literature, institutional databases and academic research. Despite widespread use of the term, no attempt has been made to validate any of these definitions nor examine their accuracy in defining the polytrauma patient. It is from within this context that the aim of the thesis has originated - the development of an internationally validated and consensus definition of polytrauma.

Trauma continues to be a leading cause of global mortality across all ages, with road traffic injuries being the leading cause of death among young people aged 15–29 years [2]. The most devastating physical and socioeconomic impacts arise in those with multiple injuries – the “polytrauma” patient. Historically, polytrauma is a term that has generally been used to describe blunt trauma patients whose injuries involve multiple body regions or cavities, compromise the patient’s physiology, and potentially cause dysfunction of uninjured organs. These patients are fundamentally at risk of higher morbidity and mortality than the summation of the expected morbidity and mortality of their individual injuries. These patients, while very seriously injured, have improved survival with efficient triage and focused trauma specialist care in dedicated institutions.

Polytrauma management is highly resource intensive, often involving massive resuscitation efforts, extensive imaging, multiple operations, extended intensive care unit (ICU) stays and complex rehabilitation programs. Given the high risk of unfavourable outcomes and the extent of invested resources, research into polytrauma patients can be highly rewarding and is the main focus of many clinical and basic science projects. For example, most of the current popular trauma research topics (post injury coagulopathy [3], transfusion strategies [4], immunological aspects of trauma [5, 6], damage control surgery [7], complex pelvic fractures [8], timing of secondary surgery [9], and multiple organ failure [10]) have the same target population—the polytrauma patient.

A universally accepted definition of polytrauma is vital for accurate scientific communication, epidemiological understanding, monitoring of outcomes and benchmarking of care. In the now well established global surgical community, local, national and international trauma care providers and researchers need to be in agreement when it comes to the exact threshold for injury severity implied by the most severely injured patients. Without a validated and clear consensus, meaningful

comparisons between institutional datasets are hampered and the further advances hoped for in clinical research may be impeded by imprecise definitions of the included ‘polytrauma’ patients.

In order to first place the research papers contained in this thesis into the current academic context and, to second explain how these papers relate to each other and the overall aim of the thesis, this overview section will:

- i. Describe the historical evolution of the term polytrauma and detail its peculiar geographical and cultural differences;
- ii. Examine the challenges faced in defining polytrauma adequately in the current context;
- iii. Set out the key components, specifically the anatomical description and physiological parameters, that must be included in any definition of polytrauma, and finally;
- iv. Summarise the international consensus process that has evolved out of this thesis to provide the trauma community with a preliminary validated and consensus definition of polytrauma.

I. Historical perspective and geographical/cultural differences

Using the Medline database, a literature search for the keyword “polytrauma” showed the term first appearing in literature in the early 1970s. Interestingly, in some of the earliest studies containing the term, German language titles found their word ‘polytrauma’ being translated to ‘multiple trauma’ or ‘multiple injuries’ in English [11, 12], whereas, for German speaking authors Encke and Burri both in 1974, they translated their German term ‘mehrfachverletzungen’ (multiple injuries) into ‘polytrauma’ in English [13, 14]. These are some of earliest signs pointing to ambiguity of the term.

Translation issues aside, the first formal definition of polytrauma can be found in Border et al., 1975 publication where a polytrauma patient was defined as having two or more significant injuries [15]. Apart from the definition immediately following this in a 1980 clinical trial of cimetidine prophylaxis, where a discrete set of injury combinations were used to define the inclusion criteria of polytrauma [16], the definitions that followed by Faist et al in 1983, and Tscherne et al in 1984, further refined Border et al. concept of ‘significant injuries’ by defining polytrauma as two or more injuries, with at least one injury, or the sum of all injuries, being life threatening [17, 18]. While this definition has continued to play a fundamental role in polytrauma literature, a challenge lies in the vagueness of the term ‘life threatening’ and limits its practical utility in clinical and scientific work.

Due to its German origin, the term polytrauma is common throughout European trauma literature [19- 21]. In contrast, it is infrequently used in the Anglo-American literature with the terms ‘major’ and ‘multiple trauma’ being favoured [22, 23]. Indeed, while in the Anglo-American literature

polytrauma is classically defined by a nominated injury severity score (ISS) and freely interchanged with the terms ‘major’ and ‘multiple trauma’ within the same publication, in the early 2000s the German Society of Traumatologists (DGU) emphasized that polytrauma should be differentiated from both multiple injuries that do not represent a threat to life, and severe, life threatening single injuries [24, 25]. However, despite recognizing the difference between the multiply-injured with non-life-threatening injuries, versus those that are, the distinction between the two remained largely intuitive. Adding to the complexity was the development by the United States Department of Veteran Affairs of “polytrauma centres” where the term polytrauma was specifically adopted to describe injuries both physical and psychosocial, occurring as a result of blast-related wounds seen in Operation Enduring Freedom and Operation Iraqi Freedom [26-28].

II. Current dilemma

With a growing appreciation for the lack of clarity surrounding the use of the term polytrauma, this thesis began with a literature review, published in 2009, that identified and evaluated all existing definitions of the term to determine whether there existed a clear, validated, and consensus definition [29]. The review spanned all articles published from January 1950 to August 2008, using the keyword ‘polytrauma’ to search all relevant medical databases, online resources and medical dictionaries. The search resulted in a total of 1,665 publications containing the word polytrauma however of these only 47 had definitions included in the text. Within these 47, eight major approaches to define polytrauma were identified, each with their own limitations and advantages. The review successfully confirmed a lack of a validated definition (with none supported by evidence higher than Level IV).

The publication of the above literature review resulted in criticism against the need for a formal definition, with the often verbalised claim that trauma surgeons already inherently “knew” and “agreed” who is a polytrauma patient. To investigate the reliability of this assumption a study was conducted where a total of 52 sequential trauma patients admitted to the intensive care unit (ICU) were followed and graded anonymously as either ‘yes’ or ‘no’ polytrauma [30]. All details of these cases from presentation until 24hrs of admission were recorded on a datasheet and used for subsequent grading by eight international trauma surgeons. Our hypothesis was that, using a subjective definition, surgeons would not have substantial agreement over which patients are polytrauma and thus an objective definition was necessary. The results of the study supported our hypothesis and found that, both within and across institutions internationally, trauma surgeons had at best only moderate agreement (with a kappa score for agreement beyond chance of 0.50 within a single national institution, and 0.41 internationally). Finally, when comparing all trauma surgeon’s subjective definitions against key anatomical definitions, a maximum kappa score of 0.39 was found

(representing fair agreement), with the lowest agreement associated with the most commonly used anatomical definition of polytrauma defined as an injury severity score (ISS) >15, where, in this instance, a kappa score of only 0.16 was found, representing only slight agreement with all participating trauma surgeon's subjective definitions of polytrauma. Consequently, this research successfully demonstrated a lack of consensus regarding the definition of polytrauma, both academically and amongst clinicians in practice.

III. The key components of polytrauma:

In the quest for a definition of polytrauma, this thesis argues the ideal definition will be one that is: (1) reproducible; (2) sensitive and specific; (3) readily available at the early phase of resuscitation; and (4) captures both the physiological and anatomical elements of polytrauma (i.e. it recognises that multiple regions are involved and trigger a physiological consequence that is peculiar to polytrauma). Determining the best anatomical and physiological criteria to include are key to a robust definition of polytrauma. This thesis has explored both in detail.

a. Anatomical description

Anatomical descriptions are a means of characterizing the degree of damage sustained during trauma by defining both the sites and the extent of injury. Physiological descriptions, in contrast, describe the changes in the body's baseline physiology as a response to injury. The most widely used anatomical scoring systems are the Abbreviated Injury Scale (AIS) and the Injury Severity Score (ISS).

The AIS is an anatomical scoring system first publicised in 1971 [31]. It emerged in an era of rapidly increasing road-traffic accidents and deaths. It was the first system to afford the trauma community with a standardized means of describing, comparing and ranking injury according to severity. It has been updated several times and substantially expanded since it was first promulgated, for example it now includes both penetrating as well as blunt injuries. In its current form the AIS divides the body into nine anatomical regions: (1) head, (2) face, (3) neck, (4) thorax, (5) abdomen, (6) spine, (7) upper extremities, (8) lower extremities, and (9) external. Injuries within each region are ranked on a scale of 1 (minor) to 6 (maximal, currently untreatable) [32].

Mortality risk is not evenly distributed across each rank of AIS severity. For example, the difference in mortality between an AIS 1 and AIS 2 injury (0% mortality) is considerably lower than the difference in mortality between an AIS 4 and AIS 5 injury (23.5% mortality) [33]. Furthermore, the

same score may carry a different risk of mortality depending on which body region is involved. For example, an AIS 3 injury to the head has a different risk of mortality than an AIS 3 injury to the extremities. Despite these complexities the AIS has been shown to be a good predictor of mortality [34].

Introduced in 1974, the Injury Severity Score is an ordinal summary severity scoring system, ranging from 0 (no injury) to 75 (currently un-survivable). Arguably the most ubiquitous anatomical score in use today, it provides an overall score for patients with multiple injuries and in this way has the ability to account for the contribution to mortality of cumulative injuries. It uses six rather than nine body regions. To calculate the ISS each injury is assigned an AIS score and is allocated to one of the six designated ISS body regions: (1) head and neck, (2) face, (3) thorax, (4) abdomen, (5) extremities (6) external. Only the highest AIS score in each body region is used. Any patient with an AIS of 6 in any area is assigned an ISS score of 75. Otherwise the three most severely injured ISS body regions have their score squared and added together to produce the final ISS score [35].

Anatomical definitions of polytrauma using the injury severity score began to appear in the literature in the early 1990s [36]. From the time an ISS score of >15 (or ≥ 16) was found in the late 1980s to be predictive of a 10% mortality it has arguably been the most frequently used threshold and one which Boyd argued to be the threshold that most physicians involved in trauma care would agree should be treated at a level one trauma centre [37]. Since this assertion, a substantial number of publications and datasets have used $\text{ISS}>15$ as the quasi definition of polytrauma [24, 38-43]. However the use of $\text{ISS}>15$ is not universal. Other common definitions are $\text{ISS}>16$ [44-47], $\text{ISS}>17$ [48-52], $\text{ISS}>18$ [53], and $\text{ISS}>25$ [54]. Amongst these definitions there is variable stipulation for the involvement of multiple injuries or more than one body region.

Since none of these definitions of polytrauma using an assigned anatomical score had been validated a pilot validation process was conducted as part of this thesis [55], examining the two most frequently used ISS cut-offs, $\text{ISS}>15$ and $\text{ISS}>17$, as well as a recently published definition meeting the $\text{ISS}>17$ criteria, but specifying the involvement of more than one ISS body region, namely an 'abbreviated injury scale (AIS) score of >2 in more than one ISS region' [52]. This study was a prospective observational study of a total 336 sequential trauma admissions over a 7-month period and the anatomical definitions were compared to a clinical definition of polytrauma. It found that defining polytrauma as injury with 'an $\text{AIS}>2$ in at least two ISS body regions' captured the greatest percentage of worst outcomes and a significantly larger percentage of patients clinically defined as polytrauma.

The results of this pilot validation study were then tested on a larger Australian dataset, the New South Wales Trauma Registry, and published as part of this thesis, becoming the first trauma-registry based validation study on the definition of polytrauma [56]. The study confirmed on a large data set the superiority of using 'AIS>2 in at least two ISS body regions' to define polytrauma. It was found to capture a more severely injured, more resource-intensive patient population with a higher mortality rate, even without the inclusion of physiologic parameters, while excluding severe single-system injuries (monotrauma) that are not clinically considered polytrauma.

b. Physiological parameters

Polytrauma presents as an array of different injuries and thus manifests across a broad range of pathological severity. What unites this group however are the characteristic ways the body reacts both in response to injury and in order to restore normal physiology [57]. From this frame of mind physiological parameters have been proposed as requisite inclusions into the definition of polytrauma by various authors and early definitions have mostly focussed on haemorrhage, for example 'severe shock', 'haemorrhagic hypotension', and 'loss of more than half of circulating blood volume and paO_2 below 60mmHg' [58- 60].

As the pathophysiology of polytrauma became better understood there emerged a group of corresponding definitions that sought to characterise not only the degree of anatomical severity but also the patient's response to injury. The first of these came from Trentz in 2000, where polytrauma was defined as a 'syndrome of multiple injuries exceeding a defined severity (ISS>17) with sequential systemic traumatic reactions that may lead to dysfunction or failure of remote organs and vital systems, which had not themselves been directly injured' [50]. Paralleling this, after 1992 when the concept of the systemic inflammatory response syndrome (SIRS) was born, there emerged a number of publications heralding the efficacy of SIRS in predicting outcomes post-trauma [61-63]. In 2005 Keel et al, slightly altering the original Trentz definition, adopted the SIRS concept into their definition of polytrauma as a means of quantifying the 'sequential systemic traumatic reactions' in the Trentz definition and substituted it for 'consequent SIRS for at least one day' [57, 64].

It had been previously argued that SIRS scoring is easily accomplished and should be carried out in all high-risk trauma patients [65]. However, the practicality of daily SIRS data collection outside of specifically designed trials was unknown. Thus, in an effort to assess its appropriateness for inclusion in a definition of polytrauma, a prospective observational study was conducted at a level-1 urban trauma centre and published as part of this thesis [66]. The experience of this study was that calculating SIRS scores prospectively based on real time bedside data was challenging due to a high proportion of missing data. When stratifying by injury severity and ICU admission (an environment

with more intensive monitoring and investigation) the pitfalls of missing data were avoided. However in this setting there was uncertainty surrounding the duration that SIRS variables must be present in order for a patient to be regarded as displaying a 'SIRS' response. It was not easy to distinguish, particularly in the first 24-72hrs (where a definition would be most clinically relevant), whether this was a true 'pro-inflammatory' state versus either an expected and appropriate response to trauma in the pre-resuscitation stage, or the result of inadequate resuscitation and/or medical and surgical intervention. Overall we found that including SIRS into a definition of polytrauma was inappropriate and unfeasible even in a prospective fashion. Other physiological parameters would be needed. It was from here that this research thesis resulted in the establishment of the 'International Working Group on Polytrauma'. The aim of the working group was to define polytrauma internationally in a validated and consensus fashion addressing both anatomical and physiological considerations.

IV. Toward international consensus

After two consecutive scientific meetings, held in conjunction with the annual European Society for Trauma and Emergency Surgery (ESTES) Congress (Brussels 2010 and Milan 2011), where the preliminary evidence of this thesis was presented and debated, an International Consensus Meeting was held in Berlin on May 11-12th 2012, funded by the German Trauma Society. At this consensus meeting emerging results from this research thesis were presented and debated. Participants at this meeting included representatives from the German Trauma Society (DGU), the ESTES, the British Trauma Society (BTS), the American Association for the Surgery of Trauma (AAST) and the Australian and New Zealand Association for the Surgery of Trauma (ANZAST). Out of the meeting a draft consensus definition was identified for further validation using the German Trauma Registry, arguably the most comprehensive national trauma registry in existence. In September 2012 the 'International Working Group on Polytrauma' was formally established and was comprised of international experts that had been involved in the consensus process. A draft definition was agreed upon for final validation again using the German Trauma Registry. On December 1 2012, preliminary results were presented to the Working Group at the 12th International Polytrauma Course held in Aachen. After this meeting the definition was further refined and tested until a final definition was agreed upon and published by the Working Group in the *Journal of Trauma and Acute Care Surgery* in 2014 (Appendix 1). An important advance made by this group was the validation of a range of physiological variables (agreed upon in the consensus process) already built into the German Trauma registry. Physiological variable were unable to be tested in the previous validation study due to the limitations of data contained within the NSW Trauma Registry.

As a result of this research, the International Working Group on Polytrauma defined polytrauma as [67]:

Injuries with an Abbreviated Injury Scale (AIS) score >2 in at least two body regions plus at least one of the five following standardized pathologic conditions (prior to resuscitation);

1. Hypotension (Systolic Blood Pressure ≤ 90 mm Hg)
2. Unconsciousness (GCS score ≤ 8)
3. Acidosis (Base deficit ≤ -6.0)
4. Coagulopathy (PTT ≥ 40 seconds or INR ≥ 1.4)
5. Age ≥ 70 years.

The research of this thesis will now be presented in detail beginning with the literature review and moving chronologically through the published papers.

Literature Review

Polytrauma patients represent the ultimate challenge to trauma care and the optimisation of their care is a major focus of clinical and basic science research. A universally accepted definition for polytrauma is vital for benchmarking care, comparing datasets and conducting multicentre trials. The purpose of this review was to identify and evaluate the published definitions of the term ‘polytrauma’ and determine whether the international trauma community had a clear, validated and consensus definition of the term.



The definition of polytrauma: the need for international consensus

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KEYWORDS:

Polytrauma, definition

Summary¹ **INTRODUCTION:** Polytrauma patients represent the ultimate challenge to trauma care and the optimisation of their care is a major focus of clinical and basic science research. A universally accepted definition for polytrauma is vital for comparing datasets and conducting multicentre trials. The purpose of this review is to identify and evaluate the published definitions of the term “polytrauma”.

MATERIALS AND METHODS: A literature search was conducted for the time period January 1950–August 2008. The Medline, Embase and Cochrane Library databases were searched using the keyword “polytrauma”. Articles were evaluated without language exclusion for the occurrence of the word “polytrauma” in the text and the presence of a subsequent definition. Relevant online resources and medical dictionaries were also reviewed.

RESULTS: A total of 1,665 publications used the term polytrauma, 47 of which included a definition of the term. The available definitions can be divided into eight groups according to the crux of the definition. No uniformly used consensus definition exists. None of the existing definitions were found to be validated or supported by evidence higher than Level 4.

CONCLUSION: This review identified the lack of a validated or consensus definition of the term polytrauma. The international trauma community should consider establishing a consensus definition for polytrauma, which could be validated prospectively and serve as a basis for future research.

Introduction

The term “polytrauma” has been in use for many decades. It is generally used to describe (mainly) blunt trauma patients whose injuries involve multiple body regions or cavities, compromise the patient’s physiology and potentially cause dysfunction of uninjured organs. These patients are at risk of higher morbidity and mortality than the summation of expected morbidity and mortality of their individual injuries. Polytrauma patients are very seriously injured but can be potentially saved with

efficient triage and focused trauma specialist care in dedicated institutions. Polytrauma management is highly resource intensive often involving massive resuscitation efforts, extensive imaging, multiple operations, extended intensive care unit (ICU) stay and complex rehabilitation programmes.

Given the high risk of unfavourable outcomes and the extent of invested resources, research into polytrauma patients is potentially highly rewarding and is the main focus of many clinical and basic science projects. Most of the current popular trauma research topics (postinjury coagulopathy, transfusion strategies, immunological aspects of trauma, damage control surgery, complex pelvic fractures, timing of secondary surgery and multiple organ failure) have the same target population—the poly-

¹ Abstracts in German, French, and Spanish are printed at the end of this supplement.

trauma patient. A universally accepted definition for polytrauma is vital for comparing datasets and conducting multicentre trials.

The ideal definition of polytrauma is one that is (1) reproducible, (2) sensitive and specific, (3) readily available at the early phase of resuscitation and (4) captures both the physiological and anatomical elements of polytrauma (ie, recognises that multiple regions are involved).

We hypothesised that the international trauma literature has a clear, validated and consensus definition of the term. The aim of this review was to identify and evaluate the existing definitions of polytrauma.

Materials and methods

A literature search was conducted for the time period January 1950–August 2008. The Medline, Embase and Cochrane Library databases were searched using the keyword “polytrauma”. All available articles were evaluated for the occurrence of the word in the text and the presence of a subsequent definition. Where full texts were not available online, hard copies were obtained and searched by hand. Where only abstracts were available these were searched and any definitions present were included in the review. No language restrictions were applied. The abstracts of non-English articles were screened for potential relevance and full texts obtained and translated as necessary.

The following relevant online resources were also searched: the International Statistical Classification of Diseases (ICD) and Related Health Problems 10th Revision Version for 2007 [67], UK National Library for Health—Clearinghouse for Protocols (searching both UK and International guidelines) [42], Centres for Disease Control and Prevention (USA) [13] and a selection of major surgical organisations including the German Society for Trauma Surgery (DGU) [13], the American Association for the Surgery of Trauma [1], the American College of Surgeons [2], Royal College of Physicians and Surgeons of Canada [55], The Royal College of Surgeons of England [56] and the Royal Australasian College of Surgeons [54]. Finally, a search was conducted of selected English language medical dictionaries [9, 15, 18, 38, 41, 62].

Results

The search resulted in a total of 1,665 publications containing the word polytrauma. Of these 1,665 publications, 47 attempted to define the term polytrauma [3, 6–8, 10, 11, 14, 16–19, 21–37, 39, 43, 35, 36, 38, 50–53, 57–61, 63–66, 68]. These were

divided into eight basic groups according to the crux of the definition: 1) number of injuries, body regions or organ systems involved, 2) pattern or mechanism of injury, 3) consequent disability, 4) injuries representing a threat to life, 5) injury severity score (ISS), 6) a combination of both 4 and 5, 7) criterion based and 8) definitions based on a combination of ISS and systemic, immune-based features. Only two definitions were considered to be supported by Level IV evidence, all other definitions represent Level V scientific evidence [47].

Number of injuries, body regions or organ systems involved

Eight articles were found in which the definition of polytrauma was based on the total number of injuries, body regions or organ systems involved (summarised in Table 1).

Three articles defined polytrauma in accordance with the number of injuries sustained [8, 11, 16]. In one of the earlier definitions found in the literature, Border et al [11] defined polytrauma as ≥ 2 significant injuries. These authors also argued that single injuries later developing multiple organ failure (MOF) should be defined as part of the same polytrauma category. Blacker et al [8] defined polytrauma as ≥ 2 injuries, with the added requirement of the involvement of at least one vital organ and admission to trauma ICU. Deby-Dupont et al [16] increased the number to ≥ 3 major injuries, and added the development of severe shock to their definition.

Five publications defined polytrauma in relation to the number of organ systems or body regions involved [14, 18, 36, 45, 63]. Tool et al [63] and Dorland's Medical Dictionary [18] defined polytrauma as “the occurrence of injuries to more than one body system”. Two of the five defined polytrauma patients based on two or more organ systems or regions involved, but both contained additional criteria: McLain et al [36] further defined significant injury as the need for hospital admission and active management, while the study by Osterwalder [45] defined polytrauma patients as shock room patients with an AIS of 2 or more in ≥ 2 ISS body regions, with the external system excluded. Cerra et al defined polytrauma as ≥ 3 organ systems involved with a laparotomy [14].

Pattern or mechanism of injury

Of the eight definitions in this group, seven were based on a defined pattern of injury [17, 23, 31, 33, 50, 52, 53], and one was unique in defining

polytrauma via the mechanism of injury (Table 2). This latter definition came from an editorial discussing the definition and management of shock in polytrauma [51]. Here, Pepe defined polytrauma

as a situation entailing severe blunt trauma with injuries to multiple organ systems. This paper distinguished blunt polytrauma with its characteristic pathophysiology from the more focused tissue injury

Table 1. Number of injuries, body regions or organ systems involved

First author (year)	Definition of 'polytrauma'	Level of evidence (I–V) †
Border [11] (1975)	≥ 2 significant injuries	V
Cerra [14] (1983)	≥ 3 organ systems involved with a laparotomy	V
Deby-Dupont [16] (1984)	≥ 3 major injuries (head, chest, abdomen or limbs) leading to severe shock	V
Tool [63] (1991)	Injuries to >1 body system	V
McLain [36] (1999)	Significant injury (requiring hospital admission and active management) to ≥ 2 major organ systems	V
Osterwalder [45] (2002)	AIS-85 of ≥ 2 in at least ≥ 2 of the six defined ISS body regions, excluding the external system (AIS-6).	V
Dorland's Medical Dictionary [18] (2003)	Injuries to > 1 body system	
Blackner [8] (2004)	≥2 injuries that involve at least 1 vital organ (eg, lung or liver) and necessitate patient admission to a trauma intensive care unit.	V

AIS = Abbreviated injury scale; ISS = Injury severity score.

† The level of evidence is based on the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001), and refers to the level of evidence used by the authors to determine the definition of polytrauma [47].

Table 2. Pattern or mechanism of injury

First author (year)	Definition of 'polytrauma'	Level of evidence (I–V) †
Rohde [53] (1980)	Involvement of at least 3 body cavities (head, thorax, abdomen), 2 body cavities and 1 extremity fracture, 1 body cavity and 2 extremity fractures or 3 extremity fractures. (An extremity fracture was defined as a fracture of a long bone, ie, humerus, femur.)	V
Reff [52] (1984)	Fractures with multisystem injuries and/or head trauma (with associated spasticity), or patients with multiple fractures in whom stabilisation of the skeletal injury enables more satisfactory patient care	V
Marx [33] (1986)	Injury to abdomen, chest, or head associated with significant fractures, or, if no visceral injuries present, as ≥ 2 major fractures of long bones or 1 major long bone fracture with a pelvic fracture	V
Loder [31] (1987)	At least one fracture of a long bone, the shoulder, pelvic girdle or the spine PLUS at least one other injury involving the neural, face and neck, chest or abdominal body areas	V
Dick [17] (1999)	Injury to one body cavity—head/ thorax/ abdomen ('multiple trauma') PLUS two long bone and/or pelvic fractures OR injury to two body cavities	V
Herbert [23] (2000)	Injury to at least one area in addition to spine fracture, dislocation, or subluxation	V
Pepe [51] (2003)	Severe blunt trauma with injuries to multiple organ systems	V
Pape [50] (2006)	Injuries to at least 2 long bone fractures, or one life-threatening injury and at least one additional injury, or severe head trauma and at least one additional injury	V

† The level of evidence is based on the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001), and refers to the level of evidence used by the authors to determine the definition of polytrauma [47].

and exsanguination resulting from critical penetrating or lacerating injuries.

Six studies identified their definitions as being specifically designed for patient selection [23, 31, 33, 50, 52, 53]. In 1980, Rhode et al [53] presented four combinations of injuries to define a polytrauma patient for inclusion in their trial of cimetidine prophylaxis in severe polytrauma. In a study analysing the use of external fixation devices in management of childhood pelvic injuries and lower-extremity trauma, Reff [52] defined polytrauma as: "Fractures with multisystem injuries and/or head trauma (with associated spasticity), or patients with multiple fractures in whom stabilization of the skeletal injury allows for more satisfactory patient care". For the purpose of their analysis of polytrauma in the elderly, Marx et al [33] defined the term as "Injury to abdomen, chest, or head associated with significant fractures, or, if no visceral injuries present, as ≥ 2 major fractures of long bones or one major long bone fracture with a pelvic fracture". In order to be included in the paediatric polytrauma population group, the study by Loder [31] required patients to have "at least one fracture of a long bone, the shoulder, pelvic girdle, or the spine plus at least one other injury involving the neural, face and neck, chest or abdominal body areas". Herbert et al [23] in their analysis of polytrauma in patients with traumatic spine injury defined it as "injury to at least one area in addition to spine fracture, dislocation, or subluxation". Here, any patient with an AIS coding for a region other than the spine, or with a neurological deficit, was considered a polytrauma patient. In this study, an ISS greater than nine was also argued to be synonymous with polytrauma. Pape et al used a study-specific retrospective definition for evaluating polytrauma patient outcomes: "Injury of at least two long bone fractures, or one life-threatening injury and at least one additional injury, or severe head trauma and at least one additional injury" [50].

The International Trauma Anaesthetic and Critical Care Society also attempted a definition based on injury pattern. From this group, Dick et al [17] published a set of recommendations for the uniform reporting of trauma data and argued the case for establishing distinct trauma-related definitions. In this paper a unique step was taken to clearly distinguish between the terms "multiple trauma" and "polytrauma". Multiple trauma was first defined as "injury to one body cavity—head/ thorax /abdomen", with the authors then further defining polytrauma as "multiple trauma" *plus* two long bone and/or pelvic fractures or injury to two body cavities [17].

Consequent disability

This unique group was characterised by an inclusion of the consequent disability sustained from the polytrauma as part of the definition (Table 3). The crux of these definitions was that polytrauma should be defined as injuries resulting in "physical, cognitive, psychological, or psychosocial impairment and functional disability" [29, 59, 66].

Criteria-based definition

Two articles defined polytrauma using a grading system based on the pathophysiological response to trauma (Table 4). Appearing first in Schweiberer et al [58] in 1978, the grading system was adopted by Heberer et al [22] in a paper 5 years later. These two papers could be considered Level IV evidence in terms of the definitions.

Injuries representing a threat to life

Thirteen articles were found in which the crux of the definition was injuries representing a threat to life (Table 5) [6, 19, 28, 30, 32, 34, 35, 39, 43, 36, 57, 65, 68].

In Barbieri et al [6] polytrauma was defined as multiple lesions with at least one endangering life either immediately or in the short term. Schalomon et al [57] and Linsenmaier et al [30] both defined polytrauma as a life-threatening injury of ≥ 2 body regions. Martins et al [32] defined it as a potentially threatening situation where multiple lesions are present in a given anatomical region, or throughout the entire body.

Two articles defined polytrauma as the simultaneous occurrence of injuries where their combination is life threatening [39, 43]. Seven papers [19, 28, 34, 35, 46, 65, 68] defined polytrauma as a situation in which at least one injury or the combination of all injuries was life threatening, however, these papers differed in their descriptions of the type of injury pattern required to meet the definition (see Table 5, eg, Faist et al [19]; injury to several body regions or organ systems versus Tscherne et al [65]; ≥ 2 severe injuries).

Injury severity score

A total of 13 publications contained the ISS as part of their definition. Of these 13, seven defined polytrauma exclusively by this score (Table 6) [3, 7, 10, 24, 37, 48, 60]. Sikand et al [60] defined polytrauma

Table 3. Consequent disability

First author (year)	Definition of 'polytrauma'	Level of evidence (I–V) †
Lew [29] (2005)	Injury to the brain in addition to other body parts or systems resulting in physical, cognitive, psychological, or psychosocial impairment and functional disability	V
United States Department of Veterans Affairs [66] (2008)	≥ 2 injuries to physical regions or organ systems, one of which may be life threatening, resulting in physical, cognitive, psychological or psychosocial impairments and functional disability	V
Sigford [59] (2008)	≥ 2 injuries to physical regions or organ systems, one of which may be life threatening, resulting in physical, cognitive, psychological or psychosocial impairments and functional disability	V

† The level of evidence is based on the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001), and refers to the level of evidence used by the authors to determine the definition of polytrauma [47].

Table 4. Criteria based definitions

First author (year)	Definition of 'polytrauma'	Level of evidence (I–V) †
Schweiberer [58] (1978)	According to severity: Grade I: Moderate injury, hospitalisation necessary, no shock, paO ₂ normal. Grade II: Heavy injury, signs of shock, loss of approximately 25% of blood volume, paO ₂ below normal. Grade III: Acute life-threatening injury, severe shock, loss of more than half of circulating blood volume, paO ₂ below 60 mm Hg	IV
Heberer [22] (1983)	According to severity: Grade I: Moderate injury, hospitalisation necessary, no shock, paO ₂ normal. Grade II: Heavy injury, signs of shock, loss of approximately 25% of blood volume, paO ₂ below normal. Grade III: Acute life-threatening injury, severe shock, loss of more than half of circulating blood volume, paO ₂ below 60 mm Hg	IV

† The level of evidence is based on the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001), and refers to the level of evidence used by the authors to determine the definition of polytrauma [47].

as an ISS > 15, Biewener et al [7] as ISS > 16, and Hildebrand et al [24] ISS > 18. Bone et al [10] and Pape et al [48] defined polytrauma as ISS ≥ 18, and finally, both McLain [37] and Asehnoun et al [3] defined it as an ISS > 25.

life threatening single injuries (which they termed “barytrauma”). In 2006, this definition was adopted by Korošec Jagodič et al [27] in their study of long-term outcomes in patients treated in the surgical ICU (Table 7).

Threat to life plus ISS

The Guideline Committee of the Polytrauma Association of the German Registered Society of Trauma published recommended guidelines for diagnostics and therapy in trauma surgery. Combining elements of previous definitions, these guidelines explicitly defined polytrauma as: “Injury to several physical regions or organ systems, where at least one injury or the combination of several injuries is life threatening, with the severity of injury being ISS ≥ 16.” [21]

This group also recommended the term polytrauma be differentiated from both multiple injuries (which are not life threatening), and severe,

The ISS plus systemic inflammatory response

This group of definitions found in the literature originated from the definition published in 2000 by Trentz [64] in the AO Principles of Fracture Management (Table 8) [25, 26, 61, 64]. While the criteria for the severity of injury (ISS > 17) echoed the value proposed by the German Trauma Society [21], this definition was unique in both defining polytrauma as a “syndrome” and also in its explicit inclusion of the systemic inflammatory response of polytrauma. This definition was subsequently adopted by Stahel et al [61] in their paper on the current concepts of polytrauma management.

Table 5. Injuries representing a threat to life

First author (year)	Definition of 'polytrauma'	Level of evidence (I–V) †
Faist [19] (1983)	Injury to several body regions or organ systems, where at least one or a combination of several injuries is life threatening	V
Tscherne [65] (1984)	≥ 2 severe injuries, with at least one injury or the sum of all injuries being life threatening	V
Kroupa [28] (1990)	≥ 2 severe injuries in at least two areas of the body, OR ≥ 2 severe injuries in one body area. PLUS incidence of traumatic shock and/or haemorrhagic hypotension and ≥1 vital function seriously endangered. ≥1 out of two or more injuries or the sum total of all injuries must endanger life	V
Mittlmeier [39] (1999)	Simultaneous violation of several body or organ systems, which in their combination cause systemic dysfunction and even death	V
Ott [46] (2000)	Simultaneous occurrence of injuries to a number of regions of the body or organ systems, with at least one or a combination of several injuries being life threatening	V
Oestern [43] (2001)	Simultaneous injuries of several body regions or organ systems, where the combination is life-threatening	V
Barbieri [6] (2001)	Multiple lesions of which at least one potentially endangers, immediately or in the short term, their life	V
Linsenmaier [30] (2002)	Two injured body regions, of which one is potentially fatal	V
Matthes [34] (2003)	Injury to various areas of the body that alone or in combination pose an acute, life-threatening risk	V
Schalamon [57] (2003)	Life-threatening injury to ≥2 body regions	V
Martins [32] (2004)	Potentially threatening situation where multiple lesions are present in a given anatomical region, or throughout the entire body	V
Zelle [68] (2005)	≥ 2 severe injuries, with at least one injury or the sum of all injuries being life threatening	V
Matthes [35] (2006)	Injury to different areas of the body, which alone or in combination pose an acutely life-threatening risk	V

† The level of evidence is based on the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001), and refers to the level of evidence used by the authors to determine the definition of polytrauma [47].

Table 6. Injury severity score (ISS)

First author (year)	Definition of 'Polytrauma'	Level of evidence (I–V) †
Bone [10] (1995)	ISS ≥ 18	V
Pape [48] (2000)	ISS ≥ 18	V
Hildebrand [24] (2004)	ISS > 18	V
McLain [37] (2004)	ISS ≥ 26	V
Biewener [7] (2004)	ISS > 16	V
Sikand [60] (2005)	ISS > 15	V
Asehnoune [3] (2006)	ISS > 25	V

† The level of evidence is based on the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001), and refers to the level of evidence used by the authors to determine the definition of polytrauma [47].

Table 7. Threat to life plus ISS

First author (year)	Definition of 'polytrauma'	Level of evidence (I–V) †
Guideline Committee of the German Registered Society for Trauma Surgery [21] (2001)	Injury to several physical regions or organ systems, where at least one injury or the combination of several injuries is life threatening, with the severity of injury being ISS \geq 16. To be differentiated from both multiple injuries, which are not life-threatening, and severe, life-threatening single injuries (barytrauma)	V
Korošec [27] (2006)	Injury to several physical regions or organ systems, where at least one injury or a combination of several injuries is life threatening, with the ISS \geq 16	V

ISS = Injury severity score.

† The level of evidence is based on the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001), and refers to the level of evidence used by the authors to determine the definition of polytrauma. ⁴⁷

Table 8. ISS plus systemic inflammatory response

First author (year)	Definition of 'polytrauma'	Level of evidence (I–V) †
Trentz [64] (2000)	Syndrome of multiple injuries exceeding a defined severity (ISS > 17) with sequential systemic traumatic reactions that may lead to dysfunction or failure of remote organs and vital systems, which had not themselves been directly injured	V
Stahel [61] (2005)	A syndrome of multiple injuries exceeding a defined severity (ISS > 17) with consecutive systemic trauma reactions that may lead to dysfunction or failure of remote—primarily not injured—organs and vital systems	V
Keel [26] (2005)	Syndrome of combined injuries with an injury severity score (ISS > 17) and consequent SIRS for at least one day, leading to dysfunction or failure of remote organs and vital systems, which had not been directly injured themselves	V
Keel [25] (2006)	Syndrome of multiple injuries (ISS > 17) with consequent SIRS for at least one day leading to dysfunction or failure of remote organs and vital systems, which had not been directly injured themselves	V

ISS = Injury severity score; SIRS = Systemic inflammatory response syndrome.

† The level of evidence is based on the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001), and refers to the level of evidence used by the authors to determine the definition of polytrauma [47].

In 2005, Keel and Trentz further refined the original Trentz definition with the phrase “sequential systemic traumatic reactions”, replaced by the more objective criteria of “systemic inflammatory response syndrome (SIRS) for at least one day” [26]. In 2006, the phrasing again changed subtly from a “syndrome of combined injuries” to a “syndrome of multiple injuries” [25].

Discussion

Despite previous attempts to define the term, there remains no universally accepted definition of polytrauma [17, 21, 28]. Throughout the European

trauma literature the term polytrauma is found frequently, and is typically used to define a situation of simultaneous injuries involving a threat to life [6, 21, 39, 43]. By contrast, in the Anglo-American literature the term is rarely used. A polytrauma patient in the Anglo-American papers is classically defined by a nominated injury severity score and the term used interchangeably with others such as a “major trauma” and “multiple trauma” [60]. Despite its frequent use in both spheres of trauma literature, no author in either one has sought to validate their proposed definition in accordance with the traditional rules of evidence.

In the last 5 years, the term polytrauma has found new life among US military doctors, adding further complexity to the definition. Here, the

term has been adopted to specifically describe the devastating blast injuries in soldiers returning from Iraq and Afghanistan and has been paralleled by the development of so-called “polytrauma centres” to manage these patients under the direction of the US Department of Veteran Affairs [66].

Polytrauma presents a significant threat to life and carries a high risk of complications. To improve outcome, the actual population at risk and the incidence has to be determined. A prospective assessment and comparison of outcomes from current practice is needed, along with more rigorously designed trials to evaluate potential interventions. Without a clear definition of what constitutes a polytrauma patient, this process is hampered from the outset. With different trauma centres each using their own particular definition based on different anatomical or physiological scores, any attempt to compare outcomes, interventions and even “polytrauma” patient loads between centres is challenging.

This review illustrates the lack of consensus definition of the term polytrauma. While over 1500 publications used the term, only 47 were found to actually contain a definition, and of the eight major approaches to the definition of polytrauma, limitations and advantages exist within each.

Defining polytrauma simply by the number of significant injuries, body regions or organ systems involved makes this approach appear straightforward. However, the definition of “significant injury” relies on a great degree of clinician judgement. McLain et al [36] attempted to clarify “significant injury” as injuries “requiring hospital admission and active management”. Even with this specification, the definition remains subjective because of the indistinct term “active management”. It is unclear where nonoperative management would fit into this description. A second limitation of defining polytrauma by the number of injuries, body regions or organ systems involved is the difficulty in distinguishing it from the concept of “multiple trauma”. Three studies did add qualifying criteria to their definition which could potentially aid in this distinction (Cerra et al [14]; involvement with a laparotomy, Deby-Dupont et al [16]; leading to severe shock and Blacker et al [8]; involving at least one vital organ necessitating patient admission to a trauma intensive care unit). However, none of these qualifying statements were validated in their use in defining polytrauma.

Defining polytrauma with a specific injury pattern [17] has been adopted in an attempt to give the definition more practical relevance. Most of these definitions are based on a prescribed pattern of injury, intentionally designed as study-specific definitions. The lack of their prospective validation has limited their wider application.

Defining polytrauma by an ISS cut-off represents an attractive objective method based on anatomical regions. Although ISS is the most widely accepted anatomical score, there are major limitations with this approach. Firstly, the final ISS figure does not differentiate between one serious single region injury (not polytrauma) and multiple regions involved with low severity injuries (not polytrauma). For example, an ISS of 25 can be equally achieved by a single region injury with AIS of 5 ($5^2 = 25$), or by injury to two regions, eg, AIS of 3 plus AIS of 4 ($3^2 + 4^2 = 25$). This idiosyncrasy of ISS makes it difficult to differentiate between multitrauma and polytrauma if lower cut-offs are used (> 15 or > 17). Using higher cut-offs (> 20 or > 25) would increase the specificity, but would exclude patients with two AIS = 3 injuries. We believe that any definition should clearly separate multiple trauma from polytrauma. A second limitation to the use of ISS to define polytrauma is the great range of scores used to define it. Thirdly, the exclusive use of ISS (an anatomical score) ignores the important physiological aspects of polytrauma. Finally, ISS is hardly ever calculated on admission, which makes it difficult to use as a prospective tool especially for clinical trials.

The definition by Osterwalder [45] could prove an effective alternative approach to an overall ISS score as it specifically requires a score of AIS ≥ 2 in at least two of the ISS regions. Breaking down the scoring system in this way avoids obscuring the actual severity of injury in each body region. However, like others, this definition has not been validated. The cut-off of AIS ≥ 2 would enable defining a patient with a fairly low ISS such as 8, 12 and 13 as polytrauma, which would not make the score specific enough.

The anatomical score (ISS) could be improved by adding a physiological, criterion-based definition, as found in Schweiberer et al [58] and Heberer et al [22]. While this grading system of polytrauma has not been adopted into general use, and is based only on Level IV evidence, it does contain some potentially useful objective elements that may be included in a general definition of polytrauma; in particular the inclusion of shock and blood volume lost (or alternatively number of transfusions needed).

A more recent approach emerging from Zurich combines physiological elements with an anatomical score [25, 26, 61, 64]. While retaining the ISS, the strength of this approach is in its emphasis on the pathophysiological response to polytrauma. The differentiation between polytrauma and multitrauma is based on the injured person’s pathophysiological response to the injury load. Numerous studies have shown that it is the deregulation of the immune system posttrauma that represents one of the greatest threats to life [40]. By consciously recognising this

element, the definition has much greater power to detect true polytrauma. However, formally defining the pathophysiological response to trauma remains a challenge. In 2005, Keel et al changed the wording of the Trentz definition from “sequential systemic traumatic reactions,” to “SIRS for at least one day” [26]. While this achieved a more succinct definition of the pathophysiological response to trauma, there are some inherent limitations to the use of the SIRS criteria. SIRS can be objectively defined based on the consensus definition established in 1992, but the timing and duration necessary for polytrauma definition needs further clarification. The other potential flaw of this definition is that an ISS > 17 cut-off could include single-system severe injuries with additional minor injuries in other regions ($4^2 + 1^2 + 1^2 = 18$ or $4^2 + 2^2 + 1^2 = 21$ or $4^2 + 2^2 + 2^2 = 24$). In this case, the minor injuries (AIS 1 or 2) would not be likely to represent a significant additional effect on the single major injury (AIS 4) in the other body region.

To overcome the potential limitations of the ISS (adherence to body regions and neglecting second highest AIS in the same body region), the New Injury Severity Score (NISS) was described and validated. The NISS is calculated similarly to ISS, the sum of squares of the three highest AIS scores, but unlike ISS, it is calculated irrespective of body region [44]. The NISS has been extensively validated and found to be a better predictor of mortality, especially in penetrating trauma [12, 44] and multiple organ failure [4] and is a better predictor of ICU and hospital lengths of stay in multiple orthopaedic injuries [5]. Although the NISS was used for inclusion criteria of some recent randomised trials on major orthopaedic trauma [49], the fact that it abandons the body regions makes it an impractical descriptor for polytrauma.

Although the low level of evidence and the lack of prospective validation is common to all available definitions, the main message of the current definitions suggests the need for an objective anatomical score (enabling inclusion of those patients who have severe injuries in at least two body regions) and a

physiological component (to include host response to the trauma).

A potential limitation of this review is the risk of excluding possibly relevant papers, due both to the difficulty in accessing older literature, and to the necessity of relying on abstracts to judge the potential relevance of non-English language articles prior to translation. Despite these limitations, this review has identified eight alternative approaches to defining polytrauma and the lack of evidence to support a uniformly accepted definition.

Conclusion

This review has shown that there is no consensus on the definition of the term polytrauma. Furthermore, of all the approaches identified in the literature, no validated definition has been found, and no definition was found to be supported by evidence higher than Level IV.

We recommend forming an international expert group to work toward establishing a consensus definition of the term polytrauma. We believe the establishment of such a definition would serve to more clearly identify patients needing the highest resource utilisation and benefits of specialist trauma care. This reproducible universal definition of polytrauma would facilitate a better description and comparison between patient populations of different centres (benchmarking), and assist in establishing a uniform inclusion criteria for multicentre studies of severely injured patients.

Provisionally, we recommend a clear distinction to be made between the terms of monotrauma, multitrauma and polytrauma (Table 9).

Until the establishment of a consensus definition, we propose the best definition of polytrauma to validate is an anatomical injury of AIS ≥ 3 in at least two body regions with the presence of SIRS on at least one day during the first 72 hours.

Table 9. Recommended definitions for mono-, multi- and polytrauma

Term	Definition
Monotrauma	Injury to one body region. Severe monotrauma could be considered if ISS > 15, or ISS < 15 with significant acute physiological deterioration (cardiovascular or respiratory or neurological)
Multitrauma	Injury to more than one body region (not exceeding AIS ≥ 3 in two regions) without SIRS. Severe multitrauma could be considered if ISS > 15, or ISS < 15 with significant acute physiological deterioration (cardiovascular or respiratory or neurological)
Polytrauma	Injury to at least two body regions with AIS ≥ 3 and with the presence of SIRS on at least one day during the first 72 hours. Until further characterisation, polytrauma is recommended as an all or nothing diagnosis without further grading

AIS = Abbreviated injury scale; ISS = Injury severity score; SIRS = Systemic inflammatory response syndrome.

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The literature review established the lack of a validated consensus definition of the term polytrauma and laid the foundation for this thesis. It argued that the international trauma community should establish a consensus definition for polytrauma, which could be validated prospectively and serve as a basis for future research. As a result, four studies were undertaken to investigate the ideal definition of polytrauma. Results of these studies were presented to the international trauma community as they emerged and became instrumental in the formation of the International Working Group on Polytrauma and the subsequent international consensus process that ensued to establish a definition of polytrauma. These studies are now presented.

AIS > 2 in at least two body regions: A potential new anatomical definition of polytrauma

From the many proposed definitions identified in the literature review, the application of injury severity based anatomical scores emerged as the most common approach. The Abbreviated Injury Scale (AIS) based Injury Severity Score (ISS) was undoubtedly the most widely used. Within this scoring system ISS > 15 and ISS > 17 emerged as the favoured severity cut-off points for defining polytrauma. However, while in much trauma literature these total ISS cut-offs had become almost a surrogate for polytrauma, their use as a formal definition had not yet been established according to the traditional rules of evidence. Indeed, they also carried with them certain complexities that made them potentially unsuitable for defining this multisystem condition. While stipulating the division into AIS body regions was argued as a way around some of the limitations inherent in using a total ISS score to define polytrauma, this too had not been tested.

The purpose of this study was to pilot a validation process for the anatomical cut-offs most frequently used to define polytrauma by evaluating their performance compared to clinically defined polytrauma patients. This study found that defining polytrauma as 'AIS > 2 in at least two body regions' (2 x AIS > 2) was an anatomic definition with higher accuracy and precision than the commonly used ISS > 15 and ISS > 17 definitions. It concluded that the potential superiority of the 2x AIS > 2 definition warranted larger scale validation.



AIS > 2 in at least two body regions: A potential new anatomical definition of polytrauma

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ABSTRACT

Background: The term 'polytrauma' lacks a universally accepted, validated definition. In clinical trials the commonly applied injury severity based anatomical score cut-offs are ISS > 15, ISS > 17 and a recently recommended AIS > 2 in at least two body regions ($2 \times \text{AIS} > 2$).

Purpose: To compare the outcomes of clinically defined polytrauma patients with those defined based on anatomical scores.

Material and methods: A prospective observational study on all trauma team activation patients over a 7-month period presenting at a level-1 trauma centre were included in the study. The prospective data collection included AIS in each body region, ISS, ICU length of stay (LOS), multiple organ failure (MOF) and mortality.

Results: 336 patients met inclusion criteria (age: 41 ± 20 , 74% male, ISS: 15 ± 11 , NISS: 19 ± 15 , MOF: 3%, mortality: 4%, 25% ICU admission). ISS > 15: 13 deaths (10%), 71 (54%) required ICU admission and 10 (8%) developed MOF. ISS > 17 captured 11 deaths (11%), with 63 (62%) requiring ICU admission and 10 (10%) developing MOF. Defining as ($2 \times \text{AIS} > 2$): 8 deaths (13% of the group), with 43 patients requiring ICU admission (67%) and 9 (14%) developing MOF. When examining the performance of these three approaches, the ISS > 15 and the ISS > 17 captured statistically the same amount of clinically defined polytrauma patients ($p = 0.4106$), while the $2 \times \text{AIS} > 2$ definition captured significantly more polytrauma patients than ISS > 15 ($p = 0.0251$) and ISS > 17 ($p = 0.0019$).

Conclusion: $2 \times \text{AIS} > 2$ captured the greatest percentage of the worst outcomes and significantly larger % of the clinically defined polytrauma patients. $2 \times \text{AIS} > 2$ has higher accuracy and precision in defining polytrauma than ISS > 15 and ISS > 17. This simple, retrospectively also reproducible criteria warrants larger scale validation.

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Background

The term 'polytrauma' lacks a universally accepted, validated definition.¹ From triage and clinical management point of view this lack of consensus is of minor consequence. In the domains of research and benchmarking however, it presents a substantial obstacle. The potentially subjective term 'polytrauma' could work within institutions but is certainly not robust enough to formulate inclusion criteria for clinical trials or to attempt to compare institutional outcomes. From the many proposed definitions, the application of injury severity based anatomical scores has emerged as the most common approach.^{2–8} The Abbreviated Injury Scale

(AIS) based Injury Severity Score (ISS) is undoubtedly the most widely used with good inter- and intrarater agreement.⁹ In this context ISS > 15 and ISS > 17 have emerged as the favoured severity score cut-off points for defining polytrauma. Recently, based on a systematic review we recommended that AIS > 2 in at least two body regions ($2 \times \text{AIS} > 2$) be considered as an alternative to the cumulative ISS score. This approach would exclude severe monotrauma and result with an ISS > 17 cut-off.

While the ISS has become almost a surrogate for polytrauma, its use as a formal definition has not yet been established according to the traditional rules of evidence. Similarly, while the division into AIS body regions may be argued as a way around some of the limitations inherent in the ISS, this too has not yet been tested. Indeed, the discipline of traumatology is void of any attempt to validate any of the criteria based definitions found interspersed in the literature, and certainly no attempts have been made to validate to the clinical definition of a polytrauma patient.

We hypothesised that the $2 \times \text{AIS} > 2$ definition is the closest to the clinical definition of polytrauma with worse outcomes than

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ISS > 15 and ISS > 17. The purpose of this study was to pilot a validation process for the frequently used cut-offs of used to define polytrauma by evaluating their performance compared to the clinical (subjective) polytrauma definition and to assess the differences in outcomes of patients with clinical vs. AIS/ISS cut-off based polytrauma definitions.

Materials and methods

A prospective observational study of all trauma team activation patients over a 7-month period (August 2009–February 2010) presenting at a University affiliated level-1 trauma centre was conducted. Ethics approval was granted by the Hunter New England Human Research Ethics Committee. As this was a purely observational study, no intervention or change to treatment was made, and no patient contact above the role expected of the trauma team occurred. Inclusion criteria included all patients generating a trauma team activation response and age >16. Exclusion criteria included those patients dead on arrival and those transferred from other institutions >24 h from injury. Prospective data collection was conducted for each patient and recorded on an A4 data sheet that was de-identified, and each patient given a study number. Patients were followed daily from admission. Data were then transcribed into a Microsoft Excel document to enable data analysis. Data collected included age, gender, AIS score in each AIS body region, ISS, New Injury Severity Score (NISS), ICU admission and length of stay (LOS), multiple organ failure (MOF) and mortality. Based on all available clinical information, patients were defined as either 'Yes' or 'No' polytrauma according to the assessment by a senior trauma surgeon at the end of the first 24 h. Information available for this assessment as the patients presented included: vital signs, pathology results, initial imaging, emergent operative or procedural intervention, admission to ICU, and extent of apparent injury. The subjective assessment was blinded to any calculation of anatomical scores and for the purpose of the study the senior traumatologist's judgment as either 'Yes, is' or 'No, not' polytrauma, was taken to be the 'gold standard' by which the various anatomical scores were judged.

Data are presented as means and standard deviation, or absolute numbers and percentages. The 95% confidence intervals are also used to describe the distribution of the data. For statistical analysis Student's *t*-test was used for continuous data, Fischer's exact test for categorical data. Statistical significance was determined at $p < 0.05$. For the comparison of different definitions of polytrauma the sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio and the agreement (Kappa) were also calculated.

Results

During the seven months study period 336 patients met the inclusion criteria [age: 41 ± 20 years; 247 (74%) male; ISS: 15 ± 11 ;

NISS: 19 ± 15 ; MOF: 10 (3%); mortality: 14 (4%); and 85 (25%) ICU admissions].

Table 1 summarises the results as they emerged by applying the definitions in question to the study population. One hundred and thirty-one patients (39%) had an ISS > 15. Increasing the ISS cut-off to ISS > 17, reduced the number of 'polytrauma' patients to 102 (30%). By restricting the definition to 'anatomical injury of AIS > 2 in at least two AIS body regions' ($2 \times \text{AIS} > 2$) further reduced the number defined as polytrauma to 64 patients (19%). This number however was still higher than the 44 (13%) patients categorised as polytrauma based on expert clinical assessment. Of the 44 patients clinically defined as polytrauma, there were 9 deaths (20%); 41 ICU admissions (93%); and 9 patients developed MOF (20%). Compare this to the data summarised in Table 1. The ISS > 15 and the ISS > 17 captured statistically the same amount of clinically defined polytrauma patients ($p = 0.4106$), while the $2 \times \text{AIS} > 2$ definition captured significantly more polytrauma patients than ISS > 15 ($p = 0.0251$) and ISS > 17 ($p = 0.0019$).

On close inspection of the patients included by each different definition it was found that using the definition of ISS > 15 meant 13 of the 14 deaths observed were captured by this definition. While this captured the most number of the deaths observed in the total study population it correlated to the lowest percentage of deaths when compared to the other definitions (10% of the total 131 patients with ISS > 15). Increasing the cut-off to ISS > 17 captured 11 of the total 14 deaths (11% of the 102 patients in this definition group), and by changing the definition to anatomical injury of AIS > 2 in at least two AIS body regions, this captured 8 of the deaths (13% of this group). In summary the death rate varied according to the definitions from the lowest rate of 10% (ISS > 15) to the highest rate of 20% (clinically defined polytrauma). Table 2 summarises the causes of death and illustrates that while ISS > 15 includes the greatest of the total overall number of deaths it includes cases such as isolated head injury that other definitions exclude as not polytrauma.

Comparing ICU admissions, patients who were defined as polytrauma according to ISS > 15 saw a total of 71 (54%) requiring ICU admission. By defining polytrauma as ISS > 17 included 63 patients requiring ICU admission equating to 62% of this group. Finally by defining polytrauma by anatomical injury of AIS > 2 in at least two AIS body regions 43 patients in this definition required ICU admission (67%). These results are compared to the 41 (93%) ICU admissions in the clinically defined polytrauma group.

In terms of patients developing MOF, in the ISS > 15 definition group all 10 of the 10 patients who developed MOF in the study population were included by this definition (8% of the total ISS > 15 patients). Increasing the cut-off to ISS > 17 again included all 10 and equated to 10% of this definition group. By changing the definition to an anatomical injury of AIS > 2 in at least two AIS body regions, 9 of the 10 patients were included with the percentage of the total in this group increasing to 14%. Nine of the 44 patients (20%) that were clinically defined as polytrauma developed MOF.

Table 1
Outcomes by anatomical definition used.

	N	Polytrauma	Death	ICU admission	MOF
Total	336	44 (13%)	14 (4%) 0.0252–0.0726	85 (25%) 0.2074–0.3030	10 (3%) 0.0144–0.0541
ISS > 15	131	44 (34%)	13 (10%) 0.0539–0.1637	71 (54%) 0.4527–0.6293	10 (8%) 0.0372–0.1359
ISS > 17	102	40 (39%)	11 (11%) 0.0551–0.1848	63 (62%) 0.5161–0.7121	10 (10%) 0.0480–0.1729
$2 \times \text{AIS} > 2$	64	37 (58%)	8 (13%) 0.0555–0.2315	43 (67%) 0.5431–0.7841	9 (14%) 0.0664–0.2502 CI 95%

Polytrauma: clinically defined by expert opinion; ICU: Intensive Care Unit; MOF: multiple organ failure.

Table 2
Breakdown of mortality.

Polytrauma	Age	Gender	2 × AIS > 2	ISS	Injury pattern	Mechanism
No	57	M	No	75	Isolated head injury	Unwitnessed blunt head trauma
Yes	87	M	Yes	57	Multiple injuries	Ped vs. car
Yes	28	M	Yes	50	Multiple injuries	MVA
Yes	27	M	Yes	50	Multiple injuries	MVA
Yes	82	F	Yes	45	Multiple injuries	MVA
No	48	M	Yes	34	Isolated head injury	Unwitnessed blunt head trauma
Yes	84	F	Yes	29	Multiple injuries	MVA
Yes	78	M	Yes	29	Multiple injuries	MVA
No	48	M	No	26	Isolated head injury	Assault
Yes	26	M	Yes	22	Multiple injuries	Fall 15 m
Yes	58	F	No	20	Perforate bowel, sepsis – incidental finding gastric cancer.	MVA
Yes	88	M	No	16	Isolated head injury	MVA
No	53	M	No	16	Isolated head injury	Fall in shower
No	71	M	No	9	Self inflicted injury gunshot wound to abdomen – in context of known metastatic prostate cancer	Gunshot

AIS: Abbreviated Injury Scale; ISS: Injury Severity Score; MVA: motor vehicle accident; Ped: pedestrian.

Table 3
Comparison of performance of polytrauma definitions.

	Sens%	Spec%	PPV%	NPV%	+LR	–LR	Kappa
ISS > 15	100 (0.9196–1)	70 (0.6460–0.7539)	34 (0.2558–0.4236)	100 (0.9822–1)	3.356	0	0.3816
ISS > 17	91 (0.7833–0.9747)	79 (0.7362–0.8332)	39 (0.2969–0.4938)	98 (0.9476–0.9895)	4.282	0.115	0.4467
2 × AIS > 2	84 (0.6993–0.9336)	91 (0.8683–0.9381)	58 (0.4482–0.7006)	98 (0.9568–0.9953)	9.094	0.175	0.6273

Sens: sensitivity; Spec: specificity; PPV: positive predictive value; NPV: negative predictive value; +LR: positive likelihood ratio; –LR: negative likelihood ratio; KAPPA: Cohen's kappa coefficient.

When examining and comparing the performance of these three approaches to the definition, ISS > 15 was 100% sensitive, and 70% specific for capturing clinically defined polytrauma patients (Table 3). ISS > 15 had a positive predictive value of 34% and negative predictive value of 100%. Positive and negative likelihood ratios for this definition were 3.356 and 0 respectively, with a Kappa score of 0.3816. Applying a definition of ISS > 17 had a 91% sensitivity and 79% specificity for polytrauma, with a positive predictive value of 39% and negative predictive value of 98%. Positive and negative likelihood ratios for this definition were 4.282 and 0.115 respectively, with a Kappa score of 0.4467. Finally, applying the definition of 2 × AIS > 2, a sensitivity of 84% was observed with a specificity of 91%. Positive predictive value was 58%, negative predictive value 98%, and positive and negative likelihood ratios for this definition were 9.094 and 0.175 respectively, with a Kappa score of 0.6273.

Discussion

The importance of developing a robust definition of polytrauma and the lack of a current consensus was highlighted in a recent systematic review.¹ Despite its widespread use in the literature these has as yet been no attempt to validate any of the criteria based definitions to the clinical definition of the polytrauma patient. The current prospective single institution pilot was designed to form a basic but important first step towards this goal. While in real-time clinical practice the definition of polytrauma has little importance, it is essential for scientific communications, monitoring epidemiology/outcomes and benchmarking of care. With advances in trauma care now targeted towards more finite and complex areas such as immunomodula-

tion therapy to stem the flow of multiple organ failure, a universally agreed upon and validated definition of the patient population in question is overdue. Furthermore, in the now well-established global surgical community it is vital that not only local and national trauma units, but also international trauma societies and researches are speaking in the same language when it comes to the exact severity of injury implied by the most severely injured patients. Without a validated and clear consensus, a meaningful comparison between institutional datasets is hampered and the further advances hoped for may be impeded by untested definitions of the included 'polytrauma' patients.

Recognising that in clinical practice traumatologists know intuitively who the true polytrauma patients are, this study was designed to test the ability of the most commonly used anatomical scores in trauma literature to capture the most seriously injured patients and match this intuitive definition. As such, for the purpose of this study, the senior traumatologists grading of either 'Yes is' or 'No is not' polytrauma was used as the gold standard to which the anatomical scores were tested. In this light, since the ISS has found enduring popularity as the anatomical score and inclusion criterion of choice into trauma studies this was the obvious place to start. Two ISS cut-offs were chosen, ISS > 15 and ISS > 17 as these were found to be the most frequently used,¹ yet neither has been validated according to the rules of evidence.

In this study, using a score of ISS > 15 had 100% sensitivity in capturing clinically defined polytrauma patients. It captured the most overall total number of deaths, the most of the total ICU admissions and all the patients who went on to develop MOF. However what was gained in sensitivity was lost in specificity (70%), and this approach to the definition was found to have the

least accurate fit (Kappa score of 0.3816). By increasing the cut-off for the definition to an ISS > 17 there was a moderate increase in accuracy (Kappa score of 0.4467), a slight increase in specificity was gained (79%), and it retained a sensitivity of 91%. The implication of these findings is that while these ISS cut-off points are commonly used, their scope is too broad and results in the inclusion of a substantial amount of patients that would not be judged as polytrauma patients in real-time clinical practice. This becomes a problem when you consider for example, the cost involved in testing new immune based interventions in patients that are unlikely to be mounting the same clinically significant immune response to injury as are the true polytrauma patients. Furthermore this makes inter-institutional comparisons of things such as mortality and resource utilisation difficult as it cannot discriminate well enough those centres treating the most severely injured of the trauma patient population. This was highlighted in the comparison of death rates and ICU admissions. A definition of polytrauma as ISS > 15 with an observed death rate in this study of 10% substantially underestimates the death rate observed in the clinically defined polytrauma patient group (20%). Similarly it gives a dramatically watered down picture of the intensity of resource utilisation that polytrauma patients actually require in real practice as observed by the difference in ICU admission rates of 54% for the ISS > 15 group vs. 93% in the clinically defined polytrauma population. Furthermore it does not adequately represent the complexity of illness that polytrauma patients present in that by defining polytrauma as ISS > 15 would give a rate of the development of MOF as only 8%, whereas the clinically defined polytrauma patients observed a higher rate of 20% developing MOF, i.e. reflect a population group with a higher and more complex burden of disease.

The third definition examined was a definition proposed in a recent publication of an anatomical injury of AIS > 2 in at least two AIS body regions. This study is the first to test such a definition and while it performed the worst of the three tested in terms of sensitivity (84%), it was the most specific (91%) and captured the greatest percentage of the worst outcomes (death 13%, ICU admission 67%, MOF 14%), and a significantly larger percentage of the clinically defined polytrauma patients (58%). This study found that defining polytrauma as AIS > 2 in at least two AIS body regions has a higher accuracy and precision (Kappa score of 0.6273) in defining polytrauma than the more commonly used ISS > 15 and ISS > 17. Furthermore, this definition is attractive due to its simplicity of calculation. All trauma registries collect this information, thus it is a definition that can be readily and accurately calculated even in a retrospective fashion with no extra data collection required.

A potential limitation could be argued that the AIS based definition only included 8 of the 14 deaths observed. On closer examination however, it becomes apparent that this approach to the definition in fact works to effectively exclude isolated head injuries and severe monotrauma (not polytrauma). The remaining deaths (as seen in Table 2) were complicated by confounding factors outside of the injury load itself (namely sepsis in the context of advanced malignancy). Thus what is highlighted here is the advantage of this approach in that by definition it must consider at least 2 regions. For a similar reason, while NISS data were collected and the NISS has been used for inclusion criteria of

some recent randomised trials on major orthopaedic trauma,¹⁰ the fact that it abandons the body regions makes it an impractical descriptor for polytrauma.

It is important to note that this pilot study has examined only anatomical scales and as such it remains unclear if the addition of physiological parameters would improve the accuracy of capturing clinically defined polytrauma patients. Certainly attempts have been made to include physiological parameters into the definition of polytrauma and these too warrant further investigation.¹¹ This study suggests that $2 \times \text{AIS} > 2$ could be an anatomic injury cut-off, which could potentially serve as a surrogate marker for physiological derangement better than ISS > 15 or ISS > 17.

Conclusion

This single institution prospective pilot study has taken the first step in the process towards a much needed validated and consensus definition of polytrauma. The potential superiority of the AIS > 2 in two regions definition warrants larger scale, multicentre validation by an international group aiming to achieve consensus definition of polytrauma.

Conflict of interest statement

This paper has been written entirely by the authors, and has received no external funding. The authors have no significant financial interest or other relationship relating to this paper.

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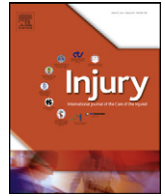
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The practicality of including the systemic inflammatory response syndrome in the definition of polytrauma: Experience of a level-one trauma centre

The previous study examined only anatomical scales as a tool to define polytrauma. It remained unclear if the addition of physiological parameters would improve the accuracy of capturing clinically defined polytrauma patients. As the literature review noted attempts had been previously made to include physiological parameters into the definition of polytrauma and warranted further investigation. Specifically the systemic inflammatory response syndrome (SIRS) had been advocated as a significant predictor of outcome in trauma. Recent trauma literature proposed SIRS as a surrogate for the physiological derangements characteristic of polytrauma with some authors recommending its inclusion into the definition of polytrauma. The practicality of daily SIRS collection outside of specifically designed prospective trials was unknown.

The purpose of this study was to assess the availability of SIRS variables and the appropriateness of including the concept into a definition of polytrauma. The hypothesis of this study was that SIRS variables would be readily available and easy to collect, thus representing an appropriate tool to characterise the physiological derangements inherent in polytrauma. In contrast to this hypothesis, the practicability of including SIRS into the definition of polytrauma as a surrogate for physiological derangement was found to be questionable even in prospective fashion.



The practicality of including the systemic inflammatory response syndrome in the definition of polytrauma: Experience of a level one trauma centre

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ABSTRACT

Background: The systemic inflammatory response syndrome (SIRS) has been advocated as a significant predictor of outcome in trauma. Recent trauma literature has proposed SIRS as a surrogate for physiological derangements characteristic of polytrauma with some authors recommending its inclusion into the definition of polytrauma. The practicality of daily SIRS collection outside of specifically designed prospective trials is unknown. The purpose of this study was to assess the availability of SIRS variables and its appropriateness for inclusion into a definition of polytrauma. We hypothesised SIRS variables would be readily available and easy to collect, thus represent an appropriate inclusion into the definition of polytrauma.

Method: A prospective observational study of all trauma team activation patients over 7-months (August 2009 to February 2010) at a University affiliated level-1 urban trauma centre. SIRS data (temperature $> 38^{\circ}\text{C}$ or $< 36^{\circ}\text{C}$; Pulse > 90 bpm; RR > 20 /min or a $\text{PaCO}_2 < 32$ mmHg; WCC $> 12.0 \times 10^9 \text{ L}^{-1}$, or $< 4.0 \times 10^9 \text{ L}^{-1}$, or the presence of > 10 immature bands) collected from presentation, at 24 h intervals until 72 h post injury. Inclusion criteria were all patients generating a trauma team activation response age > 16 .

Results: 336 patients met inclusion criteria. In 46% (155/336) serial SIRS scores could not be calculated due to missing data. Lowest rates of missing data observed on admission [3% (11/336)]. Stratified by ISS > 15 (132/336), in 7% (9/132) serial SIRS scores could not be calculated due to missing data. In 123 patients ISS > 15 with complete data, 81% (100/123) developed SIRS. For Abbreviated Injury Scale (AIS) > 2 in at least 2 body regions (64/336) in 5% (3/64) serial SIRS scores could not be calculated, with 92% (56/61) of patients with complete data developing SIRS. For Direct ICU admissions [25% (85/336)] 5% (4/85) of patients could not have serial SIRS calculated [mean ISS $15(\pm 11)$] and 90% (73/81) developed SIRS at least once over 72 h.

Conclusion: Based on the experience of our level-1 trauma centre, the practicability of including SIRS into the definition of polytrauma as a surrogate for physiological derangement appears questionable even in prospective fashion.

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Background

The systemic inflammatory response syndrome (SIRS) has been advocated as a significant predictor of outcome in trauma.¹ As defined by the 1992 consensus conference of the American College of Chest Physicians/Society of Critical Care Medicine (ACCP/SCCM), SIRS is present if two or more out of the four criteria are present simultaneously (temperature, heart rate, respiratory rate and white blood cell count). The consensus group emphasised that these factors must represent an acute change from baseline, and

must occur in the absence of other known causes for such abnormalities, e.g. drug related leucopenia.

In more recent trauma literature SIRS has been proposed as a surrogate for the physiological derangements characteristic of polytrauma patients post injury.² Some authors have recommended the inclusion of SIRS into the definition of polytrauma,^{3,4} with the timeframe for the identification of SIRS recently proposed as at least once within 72 h post injury.⁵ A notable prospective study designed to evaluate the ability of daily SIRS scoring to predict outcome in high-risk trauma patients reported that daily SIRS scoring is easily accomplished and thus recommended it to be carried out in all high-risk trauma patients.⁶

Since 1992 when the concept of SIRS was born, its efficacy in predicting outcome post-trauma has been reported in a number of studies.^{7–9} In 2005 it was taken up by Keel et al in a definition of

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polytrauma where it was used to quantify the early stages of the established theory that consecutive systemic trauma reactions post-trauma may lead to dysfunction or failure of remote—primarily not injured—organs and vital systems. It is from this context that the present study has emerged.

The practicality of daily SIRS data collection outside of specifically designed prospective trials is unknown. Rather than add to the body of literature regarding the predictive power of the SIRS score, this study was designed to answer the following key question: is the SIRS score a practical and readily available score appropriate for inclusion into the consensus definition of polytrauma?

The purpose of this study was to assess the availability of SIRS variables recorded in patient records in real time, and assess its appropriateness for inclusion into a definition of polytrauma. We hypothesised that SIRS variables would be readily available and easy to collect, and as such could represent an appropriate tool to characterise the post-traumatic physiological state suitable for inclusion into the definition of polytrauma.

Material and methods

A prospective observational study of all trauma team activation patients (see Table 1 for criteria) over a 7-month period (August 2009 to February 2010) presenting at a University affiliated level-1 urban trauma centre was conducted after ethics approval was granted by the Hunter New England Human Research Ethics Committee. As this was a purely observational study, no intervention or change to treatment was made, no patient contact above the role expected of the trauma team occurred and all nursing and allied health-staff caring for the patient were blinded to the nature and purpose of the study. This was done so that the data points comprising the SIRS score collected would most accurately reflect what is available to the clinician at the bedside in real-time practice.

Inclusion criteria included all patients generating a trauma team activation response who were age 16 or greater. Exclusion criteria included those patients dead on arrival and those transferred from other institutions >24 h from injury. Prospective data collection was conducted for each patient and recorded on an

A4 data sheet that was de-identified, and each patient given a study number.

According to the consensus definition, the following SIRS data points were collected:

- (1) Temperature greater than 38 °C or less than 36 °C.
- (2) Heart rate greater than 90 beats/min
- (3) Respiratory rate greater than 20/min
- (4) White blood cell count (WCC) greater than $12.0 \times 10^9 \text{ L}^{-1}$, or less than $4.0 \times 10^9 \text{ L}^{-1}$.¹⁰

Using the recently proposed timeframe for SIRS detected within 72 h post-injury, SIRS data points were collected from presentation in emergency department until 72 h post injury at 24 h intervals from time of presentation to emergency department. The admission SIRS score was used for the 1st 24 h post injury with subsequent data restricted to the exact 48 and 72 h time points (taken at exact 24 h intervals after admission). In the event of data being unavailable (i.e. not recorded) for that exact 24 h time interval, the closest set of data recorded was utilised. Data points of the SIRS score collected included temperature, respiratory rate, pulse rate and white cell count. Due to practical limitations of what was available at the bedside, data was not collected on PaCO₂ or the presence of immature bands on blood film.

In order to standardise data collection, SIRS data was collected on admission, and then subsequent data collected at 24 h time periods from time of initial SIRS data collection. In other words if a patient arrived at 4 pm then subsequent data was obtained at 24 h intervals from this time point (i.e. at 4 pm the following day). This was in exception of the white cell count where in this case the WCC was taken from the daily blood results. Being a purely observational study with the aim being to mimic real time clinical practice, no extra data was sought if the event of missing data at the time point of interest. While these data points were collected at rigid time points in order to standardise data collection, it must be noted that this rigidity diverges from clinical practice where an observation of the entire 24 h period is more characteristic.

Patients were followed after the 72 h timeframe of the study and additional data collected included age, gender, and AIS score in

Table 1
“Trauma call” activation criteria.

Mechanism	MVA	- Single or combined speed >80 km/h - Ejection/rollover/trapped - Unrestrained/fatality
	MBA	- Any MBA > 30 km/h
	PEDESTRIAN/CYCLIST	- Struck by car/motorbike at any speed
	FALL	- Adult ≥ 3 m or ≥ 5 stairs - Consider: elderly on anticoagulant therapy - Consider: major falls from motor bikes/cycle/water skiing etc.
	HORSE	- Horse related injury (e.g. fall, trample, kick in chest, abdomen)
	ASSAULTS	- Shootings, stabbings or focal blunt head trauma & GCS < 13 (e.g. bat/branch/fists/feet)
	MULTIPLE CASUALTIES	- With potentially significant injuries (3 or more)
	OTHER	- Any other suspicious mechanism involving significant force (e.g. explosion/hanging)
Injuries		- Potential or actual airway obstruction/respiratory distress (e.g. burns) - Penetrating injury to any of head/neck/chest/abdomen/pelvis/back - Significant injuries to two or more body regions (head/neck/chest/abdomen/pelvis/back/limbs) - Paralysis (spinal cord injury) - Major limb amputation or crush injury - Burns > 10% BSA
Signs		- RR < 10 or RR > 30 - HR < 40 or HR > 120 - BP < 90 systolic at any stage - Capillary return > 2 s - GCS < 14
Treatment		- Multi-trauma transferred from other hospital within 72 h of injury - Intubated or requiring assisted ventilation - ≥2 L of fluid resuscitation

Table 2

Patients not able to calculate SIRS score at each time point. Breakdown of variables absent.

SIRS	Number not able to calculate SIRS score	Missing data				Mean ISS
		WCC	TEMP	PULSE	RR	
1st 24 h (admission)	11/336 3%	8/11 73%	3/11 27%	0/11	1/11 9%	4 (± 3)
48 h	94/336 28%	92/94 98%	33/94 35%	31/94 33%	50/94 53%	8 (± 7)
72 h	110/336 33%	107/110 97%	68/110 62%	67/110 61%	86/110 78%	8 (± 6)

Table 3

Missing data stratified by ISS > 15 (132/336 patients meeting inclusion criteria).

Total 9/132 (7%) patients with ISS > 15 not able to calculate serial SIRS scores		Missing data				ISS average
		WCC	TEMP	PULSE	RR	
1st 24 h (admission)		0/132	0	0	0	
48 h		5/132 4%	5/5	1/5	1/5	24 (± 7)
72 h		6/132 5%	5/6	4/6	4/6	24 (± 7)

each AIS body region, ISS, ICU admission and length of stay (LOS), multiple organ failure (MOF) and mortality.

Results

Over the seven-month study period 336 patients met the inclusion criteria. The average age was 41 (± 20) years and 74% (249/336) of all patients meeting the inclusion criteria were male. The mean Injury Severity Score (ISS) was 15 (± 11). Three per cent (10/336) of patients developed Multiple Organ Failure (MOF) and a mortality of 4% (15/336) was observed. Patients were a mix of either direct ICU admissions [25% (85/336)] or direct surgical ward admissions [75% (251/336)]. The ICU at this institution was not a specifically designated surgical or trauma ICU, rather a mixed general medical/surgical ICU. In 54% (181/336) of patients serial SIRS scores over 72 h could be calculated. In the remaining 46% (155/336) of patients meeting the inclusion criteria serial SIRS scores could not be calculated due to missing data. The lowest rates of missing data were observed on admission, where in 3% (11/336) of patients it was not possible to calculate SIRS scores (Table 2). These patients had a mean ISS of 4 (± 3). At 48 h 28% (94/336) of patients had missing data precluding SIRS scoring, with a mean ISS of 8 (± 7) and at 72 h those with missing data were 33% (110/336) of patients, also with a mean ISS of 8 (± 7).

Due to the low ISS observed in patients for whom SIRS scores were unable to be calculated, patients were subsequently stratified to include only ISS > 15 (132/336 patients meeting inclusion criteria). Table 3 provides a summary of these results. In 7% (9/132)

of patients with ISS > 15 serial SIRS scores could not be calculated due to missing data. No patients on admission had missing data. At 48 h, in 4% (5/132) of patients no SIRS score could be calculated. In this group the mean ISS was 24 (± 7). The WCC was absent in all (5/5) patients, followed by a missing Respiratory Rate (4/5) and both Temperature and Pulse Rate (1/5). At 72 h in 5% (6/132) of these patients SIRS scores were unable to be calculated with a mean ISS for this group 24 (± 7). The WCC and Respiratory Rate were missing in 5 out of 6 of these patients, while Temperature and Pulse Rates were missing in 4 out of the 6 patients. In 9 of the 132 patients with ISS > 15, complete data was not available to record to presence of absence of SIRS over total 72 h. Of the remaining 123 patients for whom complete data was available 81% (100/123) of patients developed SIRS at least once over the 72 h period and 19% (23/123) did not.

Patients were also stratified by the recently proposed definition for polytrauma, an Abbreviated Injury Scale (AIS) greater than two in at least two body regions ($2 \times \text{AIS} > 2$) (Table 4). 64 patients meeting inclusion criteria had $2 \times \text{AIS} > 2$. In 5% (3/64) of patients with $2 \times \text{AIS} > 2$ serial SIRS scores could not be calculated. No patients on admission had missing data. At 48 h, in 6% (4/64) of $2 \times \text{AIS} > 2$ patients no SIRS score could be calculated. The WCC was absent in all (4/4) patients, and a missing Respiratory Rate in 1 of the 4. Neither Temperature nor Pulse Rate was missing. At 72 h in 6% (4/64) of these patients SIRS scores were unable to be calculated. The WCC was missing in 3 out of the 4 patients, Respiratory Rate in 2 out of the 4, Temperature in 1 patient and no patient had a missing Pulse Rate at 72 h. In 3 of the 64 patients

Table 4Missing data stratified by $2 \times \text{AIS} > 2$ (64/336 patients meeting inclusion criteria).

Total 3/64 (5%) patients with $2 \times \text{AIS} > 2$ not able to calculate serial SIRS scores		Missing data			
		WCC	TEMP	PULSE	RR
1st 24 h (admission)	0/64	0	0	0	0
48 h	4/64 6%	4/4	0	0	1/4
72 h	4/64 6%	3/4	1/4	0	2/4

Table 5

Direct admission to ICU breakdown of missing data (85/336 direct ICU admissions).

Total 4/85 (5%)direct ICU patients not able to calculate serial SIRS scores over 72 h [mean ISS 15(±11)]		Missing data				Mean ISS
		WCC	TEMP	PULSE	RR	
1st 24 h (admission)	2/85 2%	0/1	2/2	0/1	0/1	19 (±14)
48 h	0	0	0	0	0	0
72 h	4/85 5%	4/4	1/4	2/4	2/4	13 (±11)

Table 6

Direct to ward breakdown of missing data (251/336 direct to ward admissions).

Total 149/251 (59%) direct ward patients not able to calculate serial SIRS scores over 72 h [mean ISS 9(±7)]		Missing data				Mean ISS
		WCC	TEMP	PULSE	RR	
1st 24 h (admission)	10/251 4%	8/10 80%	2/10 20%	0/10 10%	1/10 10%	3.8(±3.6)
48 h	93/251 37%	91/93 98%	33/93 35%	31/93 33%	49/93 53%	8(±7)
72 h	106/251 42%	103/106 97%	67/106 63%	65/106 61%	22/106 21%	8(±6)

complete data was not available to record to presence of absence of SIRS over 72 h. Of the remaining 61 patients for whom complete data was available 92% (56/61) of patients developed SIRS at least once over the 72 h period and 8% (5/61) did not.

Results were analysed according to admission destination being either a direct ICU admission [25% (85/336)] or surgical ward admission [75% (251/336)]. By examining only those admitted direct to ICU this study found that in 5% (4/85) of the total 85 patients serial SIRS scores could not be calculated (Table 5). These patients had a mean ISS 15(±11). On admission 2% of patients (2/85) had missing data. These patients had a mean ISS of 19(±14), with the missing variable being Temperature in both patients. No patients admitted direct to ICU had a missing WCC, Pulse Rate or Respiratory Rate. At 48 h there were no patients with missing data. At 72 h 5% (4/85) patients admitted direct to ICU had missing data. The mean ISS for this group was 13 (±11), with a WCC absent in each of the 4 patients [4/4 (100%)] followed by Pulse Rate and Respiratory Rate both absent in 2 patients [50% (2/4)], and Temperature in 1 patient [25% (1/4)]. In 4 of the 85 patients complete data was not available to record to presence of absence of SIRS over 72 h. Of the remaining 81 patients for whom complete data was available 90% (73/81) of patients developed SIRS at least once over the 72 h period and 10% (8/81) did not.

Examining only patients admitted direct to ward, 59% (149/251) of the total 251 patients admitted direct to the ward, serial SIRS scores could not be calculated. These patients had a mean ISS 9(±7). Looking at each time point, on admission 10 patients [4% (10/251)] had missing data (Table 6). These patients had a mean ISS of 3.8 (±3.6). The WCC was absent in 80% (8/10) direct ward admissions, followed by Temperature in 20% (2/10) and Respiratory Rate in 10% (1/10). No patients admitted direct to ward had a missing Pulse Rate. At 48 h 37% (93/251) of direct to ward admissions had missing data. The mean ISS for these patients was 8 (±7). WCC was absent in 98% (91/93), Respiratory Rate in 53% (49/93), Temperature 35% (33/93) and Pulse Rate 33% (31/93). At 72 h 106 of the 251 patients (42%) admitted direct to the wards had missing data. The mean ISS for this group was 8 (±6), with a WCC absent in 103 patients [97% (103/106)] followed by Temperature in 63% (67/106), Pulse Rate in 61% (65/106) and Respiratory Rate absent in 22 patients [21% (22/106)]. Due to the large percentage of missing data in these ward patients the development of SIRS over 72 h is not included, as the result is significantly confounded by the lack of data.

Discussion

The systemic inflammatory response syndrome has been proposed as a surrogate for the physiological derangements characteristic of polytrauma patients. While it remains an important concept in relation to patients exhibiting a hyperdynamic state in the absence of a clear known cause, its appropriate inclusion into a definition of polytrauma has not been established. One concern is the issue of missing data when broad inclusion criterion are used (i.e. all trauma call patients). Another concern is the uncertainty surrounding the duration that SIRS variables must be present in order for a patient to be regarded as displaying a 'SIRS response'. It is not easy to distinguish the parameters of the SIRS variables that become 'positive' as a result of a true pro-inflammatory state versus either an expected appropriate response to trauma in the pre-resuscitation stage (admission), a result of inadequate resuscitation, or as a result of medical or surgical intervention. Finally it is not clear that its inclusion into a definition of polytrauma is of any additional significance when combined with an anatomical score.

By examining the study cohort as a whole (all trauma call patients) the utility of the SIRS score in this study was impaired by the high proportion of data not available at the designated time points of collection over the 72 h of interest. Daily SIRS scores were taken from patient records in a prospective fashion without extra data being sought. In the absence of a clear consensus on the duration that 2 or more of the SIRS variables needed to be 'positive' to qualify as a SIRS response, we elected to obtain data at exact 24 h intervals (with the exception of the WCC which was typically collected once over the 24 h period). In the event that data was unavailable at that exact time point, the closest available data was collected. This method of data collection was used based on a key assumption that the development of SIRS was likely to be prolonged in a true pro-inflammatory state and thus a fixed 24 h time-point would be appropriate to capture the SIRS response.

The method of data collection employed in this study was chosen as it was felt to be more in keeping with the essence of the original conceptualisation of the syndrome than methods reported in earlier studies examining SIRS post trauma. In a prospective study of 2300 surgical ICU patients over a 49 month period Talmor et al. examined the relationship of SIRS to organ dysfunction,

length of stay and mortality in critical surgical illness.¹¹ While designed as a prospective study, the method of SIRS calculation was carried out in a retrospective fashion. Moreover the method of determining the presence of SIRS deviated significantly from the original definition of the syndrome. When the concept of SIRS was originally published it was said to be present if two or more out of the four criteria were present simultaneously. In contrast to this Talmor et al. calculated SIRS by summing the individual worst values in each of the 4 parameters over the day and assigning a score from 1 to 4 indicating the severity of SIRS, with one point assigned to each variable. Thus a patient may be deemed as having a SIRS score of 4 even if the patient had scored one point in each parameter at different time points in the day. This method also appears to have been used by Bochicchio et al.⁶ and is of a similar approach used by Teasdale et al. in their study of GCS scoring in coma after head injury. Here the authors used the best and worst state of each feature in a series of epochs after the development of coma (first 24 h, 2–3 days etc.).¹² On review of this method, the fact that the SIRS parameters did not have to be deranged simultaneously made this an unattractive approach as it deviated significantly from the definition of SIRS in its original conception.

This study found that in close to half (46%) of the patients meeting our inclusion criteria serial SIRS scores were unable to be calculated due to incomplete data at the designated 24 h time points. The key to understanding the significance of this, as was observed during the data collection phase of the study, is that a patient may have had an increased pulse rate of 100, with a normal temperature and WCC however if the RR was missing the conclusion could not be made if the patient was SIRS 'yes' or 'no' at this point in time. This limitation could be circumvented if the three available variables were either all normal or all aberrant, however in a large number of our trauma patients this was not possible and missing data meant that the question could not be answered whether or not these trauma team activation patients developed SIRS at least once over 72 h. As stated earlier, the design of the study was intentionally observational thus no extra data was sought or obtained to make up for the deficit in real time data collection at the bedside. This study suggests that if the SIRS score were to be included into the definition of polytrauma, the obstacles to accurate data collection encountered in this prospective study would be magnified if applied in a retrospective fashion. Of the SIRS variables, the WCC was most frequently absent and there was a notable increase in missing data after presentation to the emergency department (3% unable to calculate SIRS on admission vs. 28% at 48 h vs. 33% at 72 h, see Table 2).

Our study found the lowest rates of missing data occurred on admission. While limiting SIRS data collection to admission could avoid the problem of increasingly absent data, it would diverge significantly from the central tenants of the SIRS concept. We believe that the physiological derangements recorded on admission that meet the criteria for 'SIRS' are merely a reflection of the appropriate pre-resuscitation response to trauma rather than a true pro-inflammatory state. It is not until the post-resuscitation setting that an inflammatory response can begin to be appropriately identified.

In the original consensus meeting SIRS was explicitly defined as a syndrome present only in the absence other known causes for derangements to the RR, pulse, WCC and temperature. With this in mind Sibbald et al. have argued that the ACCP/SCCM would not regard SIRS to be present in surgical patients in the immediate post-operative period because the acute alterations to baseline could be explained by another known cause (i.e. the surgery itself).¹³ The same principal applies in the immediate post-trauma setting. Echoing this argument, Talmor et al. found that SIRS scores calculated prior to resuscitation resulted in artificially elevated scores and correlated poorly with outcome.¹¹ Moreover they found

that an elevated SIRS score obtained between 24 and 48 h after admission, despite aggressive resuscitation, predicted an increased mortality. The conclusion drawn from this study suggests that the SIRS scores of most value in our study are found after admission (>24 h). Unfortunately this is also the time period with the most missing data.

In order to capture patients in real-time, the inclusion criteria was all trauma team activations. This criterion allows the inclusion of patients with a broad range of severity of injury and a proportion were subsequently found to have low injury severity scores. When data was stratifying to focus on the most severely injured patients (i.e. using the traditional $ISS > 15$, direct ICU admissions and by the recently proposed $2 \times AIS > 2$), the proportion of missing data was significantly reduced. The inference here is that the more severely injured patients are typically closely monitored and thus are found to have appropriately regular and thorough observations. This study also found that in these patients SIRS was observed to be present at least once over the 72 h in the vast majority of patients. In patients with $ISS > 15$, 81% (100/123) developed SIRS. In $2 \times AIS > 2$, 92% (56/61) patients developed SIRS, and in direct ICU admissions 90% (73/81) of patients developed SIRS. This raises the question of what additional benefit the presence of these SIRS variables adds to the definition of polytrauma, as it becomes evident that at a certain injury severity the SIRS parameters are automatically present anyway.

A limitation of the SIRS score not readily reflected in this data but apparent at the bedside is that if a failure of the elements of the SIRS score to decrease from 24 to 48 h is observed it may be difficult to distinguish if the persistent SIRS score reflects a true pro-inflammatory state or rather a marker of inadequate resuscitation, or indeed a further and appropriate response to surgery. These factors call into question the appropriateness of using the SIRS concept to characterise the post-traumatic total-body physiological derangements (distinct from those attributed to the injury and subsequent surgery) observed in polytrauma patients in the first 72 h post injury.

This study fits into a broader framework of the investigation towards a consensus definition of the term polytrauma. More than just the anatomical injury, the unique physiological derangements inherent in this patient group are an important factor to consider in the definition process. The strength of this study lies in its prospective observational design. It is limited by the difficulty of assigning rigid, uniform collection time points for SIRS variables post trauma. This method of data collection has meant that rather than addressing a trend (as would typically occur in clinical practice), this study observes a snapshot into the patient's progress. In true clinical practice the development of SIRS is observed over time rather than at fixed time-points.

The experience of calculating SIRS scores prospectively based on real time bedside data in our level one trauma centre has proven to be a challenge due to a high proportion of missing data. When stratifying by injury severity and ICU admission (more intensive monitoring and investigation) the pitfalls of missing data were avoided. If the SIRS criteria, which is more suited to the examination of trends and as an aid in clinical decision making, is to be included into a definition of polytrauma, we believe it would likely face the same obstacles of missing data encountered in this study. Alternatively the concept would need to be altered from its original conceptualisation to allow "the worst" feature over the 24 h to be recorded. In view of the fact that the vast proportion of patients with $ISS > 15$, $2 \times AIS > 2$ and ICU admissions were found to develop SIRS in the first 72 h, the additional benefit of including this concept into the definition of polytrauma is likely to be minimal. In summary, the practicability of including SIRS as a physiological component of the polytrauma definition is questionable even in prospective fashion.

Conflict of interest statement

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The definition of polytrauma: Variable interrater versus intrarater agreement- A prospective international study among trauma surgeons

With the publication of the literature review and the presentation of the two preceding research papers at the annual European Society for Trauma and Emergency Surgery (ESTES) Congress (Brussels 2010 and Milan 2011) it was, by this time, widely recognised by the international trauma community that the 'polytrauma' patient lacked a validated and consensus definition. Despite this, skepticism was voiced by some at these meetings about the need for a formal definition. The argument of those opposed to a formal definition was that trauma surgeons both inherently knew and implicitly agreed which patients constituted the most severely injured, thus a formal definition was not required.

To investigate this claim, the aim of the next study was to test the argument that trauma surgeons subjectively "know" and "agree" which are the polytrauma patients. The study hypothesized that, using a subjective definition, trauma surgeons would not have substantial agreement and an objective definition would be needed. This hypothesis was proved true and the study found that in using a subjective definition trauma surgeons did not agree on the definition of polytrauma. It found at best only moderate interrater agreement both within and across institutions, while observing substantial intrarater agreement. The study concluded that an objective definition of polytrauma was still required.

The definition of polytrauma: Variable interrater versus intrarater agreement—A prospective international study among trauma surgeons

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BACKGROUND:	The international trauma community has recognized the lack of a validated consensus definition of “polytrauma.” We hypothesized that using a subjective definition, trauma surgeons will not have substantial agreement; thus, an objective definition is needed.
METHODS:	A prospective observational study was conducted between December 2010 and June 2011 (John Hunter Hospital, Level I trauma center). Inclusion criteria were all trauma call patients with subsequent intensive care unit admission. The study was composed of four stages as follows: (1) four trauma surgeons assessed patients until 24 hours, then coded as either “yes” or “no” for polytrauma, and results compared for agreement; (2) eight trauma surgeons representing the United States, Germany, and the Netherlands graded the same prospectively assessed patients and coded as either “yes” or “no” for polytrauma; (3) 12 months later, the original four trauma surgeons repeated assessment via data sheets to test intrarater variability; and (4) individual subjective definitions were compared with three anatomic scores, namely, (a) Injury Severity Score (ISS) of greater than 15, (b) ISS of greater than 17, and (c) Abbreviated Injury Scale (AIS) score of greater than 2 in at least two ISS body regions.
RESULTS:	A total of 52 trauma patients were included. Results for each stage were as follows: (1) κ score of 0.50, moderate agreement; (2) κ score of 0.41, moderate agreement; (3) Rater 1 had moderate intrarater agreement (κ score, 0.59), while Raters 2, 3, 4 had substantial intrarater agreement (κ scores, 0.75, 0.66, and 0.71, respectively); and (4) none had most agreement with ISS of greater than 15 (κ score, 0.16), while both definitions ISS greater than 17 and Abbreviated Injury Scale (AIS) score of greater than 2 in at least two ISS body regions had on average fair agreement (κ scores, 0.27 and 0.39, respectively).
CONCLUSION:	Based on subjective assessments, trauma surgeons do not agree on the definition of polytrauma, with the subjective definition differing both within and across institutions. (<i>J Trauma Acute Care Surg.</i> 2013;74: 884–889. Copyright © 2013 by Lippincott Williams & Wilkins)
KEY WORDS:	Polytrauma; consensus definition; trauma; Injury Severity Score.

It is recognized by the international trauma community that “polytrauma” lacks a validated and consensus definition.¹ The term *polytrauma* has been used globally for decades, with greater or lesser frequency depending on geography, and often applied in a haphazard, inconsistent manner. In one of the earliest definitions, Border et al.² defined polytrauma as two or more than significant injuries. In 1984, Tscherne et al.³ defined polytrauma as “ ≥ 2 severe injuries, with at least one injury or the sum of all injuries being life threatening.” Other authors have used more objective measures, defining polytrauma via the Injury Severity Score (ISS); however, scores have ranged from greater than 15 to 26 or greater.^{4–6} In an attempt to characterize immune dysfunction present in polytrauma, the Systemic Inflammatory Response Syndrome was added.⁷ However, this concept was found by our group to suffer from practical limitations when applied to a definition of polytrauma

and deemed inappropriate for inclusion into the definition.⁸ Finally, throughout the literature, polytrauma has been used interchangeably with terms such as *multiple trauma*, *major injury*, or *severe trauma*.^{9–11}

The critical issue, however, is not of nomenclature. Much aside from the name used to describe the most severely injured patient, there is no consensus to consistently apply regarding where the line should be drawn in severity of injury. Despite recognizing the difference between multiple injuries with non-life-threatening injuries versus the most severely injured (where threats of immune dysfunction and complications remote to site of injury loom large), the distinction between the two remains largely intuitive.

Since this issue was raised, skepticism has been voiced about the need for a formal definition. The argument being that trauma surgeons implicitly agree which patients constitute the most severely injured. To investigate this claim, the aim of our study was to test the argument that trauma surgeons subjectively “know” and “agree” which are the polytrauma patients. The specific aims were to test the following:

- 1.) Interrater agreement among four trauma surgeons within a single institution (Level I trauma center).
- 2.) Interrater agreement between eight trauma surgeons internationally.

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- 3.) Intrarater agreement.
- 4.) Agreement between individual subjective definitions and objective anatomic definitions.

We hypothesized that, using a subjective definition, surgeons would not have substantial agreement over which patients have polytrauma, and thus, an objective definition is needed.

PATIENTS AND METHODS

After ethics approval was granted from Hunter New England Health Research Ethics and Governance Unit, a prospective observational study was conducted from December 2010 to June 2011, at John Hunter Hospital (JHH) New South Wales, (Level I trauma center). Trauma call activation patients were sequentially included during the designated 7-month study period, a period for which we hypothesized a minimum number

of 50 patients would be admitted for inclusion into the study. Inclusion criteria were trauma call patients admitted into intensive care unit (ICU), either directly from the emergency department or via operating theater immediately after admission. Patients younger than 16 years were excluded from the study. The study proceeded in four distinct stages. The details of each stage as follows.

Interrater Agreement: Prospective Assessment, Single Institution, and Data Collection

Four fellowship-trained trauma surgeons from JHH clinically assessed patients from presentation until 24 hours after admission and coded as either “yes” or “no” for polytrauma. In making assessments, each surgeon had access to all patient notes including prehospital interventions, all imaging, pathology, and operation reports. No ISS or Abbreviated Injury Scale (AIS) scores were calculated. Each trauma surgeon graded in a blinded fashion, and discussion on grading was prohibited. Individual assessments were submitted to the primary data collector and coded either 0 (not polytrauma) or 1 (polytrauma), and results were entered into a central data set. Details of presentation, including demographics, mechanism of injury, pathology, imaging, and all injuries diagnosed and operations performed until 24 hours, were collected prospectively and recorded on data sheets for use in subsequent stages (Table 1).

Interrater, Interinstitutional Agreement: Retrospective Data Sheet Assessment

The German Trauma Society hosted a consensus meeting on the definition of polytrauma (Berlin, May 11–12, 2012). Trauma surgeons representing the United States, Germany, and the Netherlands were present, wherein eight trauma surgeons graded the same prospectively collected patients based on data sheets collected in Part 1 of the study. Each surgeon reviewed independently and coded as either “yes” or “no” polytrauma. They did not have access to anatomic scores, and no discussion was permitted during coding. The exercise was performed in a closed session under constant observation by the primary author to ensure no discussion among raters.

Intrarater Agreement: Prospective Versus Retrospective Data Sheet Assessment

To test intrarater variability, 12 months after initial assessment, the prospectively collected data sheets were distributed back to the original four JHH trauma surgeons for repeated assessment. Surgeons did not have access to their original observations, and data sheets were deidentified from all patient demographics (excluding age) as well as date and place of injury.

Subjective Assessment: Agreement With Anatomic Definitions

To test agreement between the subjective definition of polytrauma and objective definitions based on anatomic scores, each trauma surgeon’s individual subjective assessments of polytrauma from the previously mentioned second and third stages were compared with three key anatomic scores previously

TABLE 1. Template of Data Sheet

Study Number:				
Patient details	Age	Sex		
	Mechanism			
	Transfer details			
	Time of presentation			
Imaging	ICU			
	X-ray			
	CT			
	FAST			
Injuries				
Parameters	Arrival	IN OR	ICU admission	At 24 h
Blood gas*				
Systolic blood pressure*				
Pulse rate*				
Temperature*				
Respiratory rate*				
GCS*				
Urine output				
rough average				
first 24 h				
Intubation	Where	Why		
Inotropes/vasopressors				
Crystalloids	Prehospital	ED	OR	ICU
Transfusion	Packed red	Fresh frozen	Cryoprecipitate	Platelet
first 24 h	blood cells:	plasma		
Operative intervention				
first 24 h				
Further planned surgery				
Other procedures				
first 24 h (e.g., chest drain)				

*Use the worst value in each time frame.

CT, computed tomography; ED, emergency department; FAST: focused abdominal sonography for trauma; OR, operating room.

TABLE 2. Interpretation of κ Values

κ Value	Degree of Agreement Beyond Chance
<0.00	Poor
0–0.2	Slight
0.21–0.40	Fair
0.41–0.60	Moderate
0.61–0.80	Substantial
0.81–1.00	Almost perfect

examined in the literature. The anatomic scores chosen and the reasons for their inclusion were as follows:

1. ISS of greater than 15. Originating from data published by Champion et al.¹² this ISS cutoff was adopted by the American College of Surgeons as a surrogate for the severely injured and remains in widespread use.¹³
2. ISS of greater than 17. Owing to its inclusion into the classic definition of polytrauma published by Trentz¹⁴ and Stahel et al.¹⁵
3. AIS score of greater than 2 in at least two ISS body regions (denoted as 2AIS score > 2). Included based on our recent research proposing it as a potentially superior anatomic definitions.¹⁶

Statistical Analysis

To test for interrater and intrarater agreement beyond chance, the κ statistic for multiple raters was calculated for each of the previously mentioned stages using Stata version 12.0 (StataCorp LP, College Station, TX). A recognized grading system, transforming the continuous κ score into one of six categories, was applied to the data to standardize interpretation.¹⁷ Details of this grading system are found in Table 2.

RESULTS

A total of 52 sequential trauma patients admitted to ICU were followed from trauma call activation in the emergency department until 24 hours after admission to ICU. Mean (SD) age was 39 (21) years, 83% (43 of 52) were male, and 17% (9 of 52) were female. Mean (SD) ISS was 29 (14), and the mechanism of injury was blunt in 90% (47 of 52) and penetrating in 10% (5 of 52). Mean (SD) ICU length of stay was 6.98 (7.07) days, and overall hospital length of stay was 24.08 (20.86) days. The mean (SD) arrival base excess was -4.42 (-4.83), systolic blood pressure was 109 (24) mm Hg, and Glasgow Coma Scale (GCS) score on arrival was 11 (4).

Results for each stage were as follows.

Interrater Agreement, Single Institution

On statistical analysis of the prospective clinical assessment, the four trauma surgeons from JHH Trauma Service had a κ score of 0.50, representing moderate agreement.

Interrater, Interinstitutional Agreement

Eight trauma surgeons representing the United States, Germany, and the Netherlands, completed a review of data sheets for the 52 patients. On statistical analysis, a κ score of 0.41 was observed, again representing moderate agreement.

Intrarater Agreement

For each of the four trauma surgeons who prospectively assessed the 52 patients, intrarater agreement was calculated after they completed a retrospective review of the original data sheets. Results for each rater are summarized in Table 3. Rater 1 had moderate intrarater agreement (κ score, 0.59), while Raters 2, 3, and 4 had substantial intrarater agreement (κ score 0.75, 0.66, and 0.71, respectively).

An analysis was also performed to compare the retrospective agreement between the four trauma surgeons collectively versus their prospective agreement. A κ score of 0.51 was observed, again representing moderate agreement.

Subjective Assessments: Agreement With Anatomic Definitions

Finally, three anatomic definitions were compared with each individual trauma surgeon's subjective assessments of "yes" or "no" for polytrauma. The comparison was made only against the retrospective stages of the study to ensure homogeneity of rating. Of the 12 retrospective assessments, the 2 \times AIS score greater than 2 had the highest agreement with each individual trauma surgeon's subjective determination of polytrauma in 9 of the 12 assessments (Raters 1–4, 7–9, 11, and 12) (Table 4). For the remaining three raters (Rater 5, 6, and 10) ISS greater than 17 had the highest agreement. None had highest agreement with the definition ISS greater than 15, which, on average, had only a slight degree of agreement beyond chance (average κ score, 0.16). Both the definitions ISS greater than 17 and 2 \times AIS score greater than 2 had on average a fair agreement beyond chance (average κ scores of 0.27 and 0.39, respectively).

DISCUSSION

This study has shown that the subjective definition of polytrauma differs both within and across institutions. First, upon examining agreement within a single institution, this study found only moderate agreement (κ score, 0.50). When assessing agreement between institutions internationally, a κ score of 0.41 was found. According to convention, this is at the cusp of fair-to-moderate agreement, revealing a noteworthy discrepancy in how polytrauma is defined globally. This observation is crucial to the current debate because it demonstrates that, while trauma surgeons may know "intuitively" which patients have polytrauma, this subjective definition is not robust. The differences in the way polytrauma is conceptualized both globally and within a single institution points to the importance of having a formal definition of this most vulnerable patient group.

TABLE 3. Intrarater Agreement

Rater	κ Value	Degree of Agreement Beyond Chance
Rater 1	0.59	Moderate
Rater 2	0.75	Substantial
Rater 3	0.66	Substantial
Rater 4	0.71	Substantial

TABLE 4. Comparison of Agreement Between the Subjective Definition of Polytrauma and Three Key Anatomic Definitions by Individual Trauma Surgeon

Rater*	ISS > 15	ISS > 17	2×AIS Score > 2
Rater 1	0.07	0.23	0.31
Rater 2	0.06	0.20	0.41
Rater 3	0.06	0.14	0.33
Rater 4	0.12	0.24	0.42
Rater 5	0.27	0.53	0.36
Rater 6	0.30	0.40	0.35
Rater 7	0.17	0.33	0.58
Rater 8	0.09	0.09	0.34
Rater 9	0.13	0.19	0.20
Rater 10	0.39	0.49	0.28
Rater 11	0.21	0.33	0.54
Rater 12	0.15	0.23	0.46
Average κ	0.16	0.27	0.39

*Raters 1 to 4, the four JHH trauma surgeons' retrospective assessment after 12 months; raters 5 to 12, the eight trauma surgeons from interinstitutional comparison group.

Interestingly, intrarater agreement was observed to be substantial in three of the four trauma surgeons (κ scores of 0.75, 0.66 and 0.71), with only one of the four showing moderate agreement with their prospective assessment (κ score, 0.59). This is important for two reasons. First, it demonstrated that a surgeons' subjective understanding seemed to be constant and their independent definition, once determined, was fairly fixed. However, that retrospective agreement was substantial, as opposed to almost perfect, demonstrated that there was a group of patients wherein a trauma surgeon's opinion could change retrospectively and a patient might no longer be regarded as polytrauma or vice versa. This suggests that defining a patient clinically at the bedside can potentially produce a definition different from a definition based on an evaluation of patient data.

The current subjective means of defining polytrauma is inadequate. Even within the same institution, where surgeons would be more likely to be working with a similar philosophy, this study found only moderate agreement. Similarly, internationally, there was only moderate agreement. Despite the lack of an objective definition, it could be argued that the current subjective means of defining polytrauma has enabled trauma patients to be successfully managed according to their needs for decades. The issues of management and the advances in trauma care however are not in dispute. What is at stake is an extremely complex group of patients whose true severity of injury may be lost in a sea of trauma patients with multiple injuries if included into a generic and unvalidated definition such as ISS greater than 15.

This is the first study to examine the reliability of the subjective definition of polytrauma. Previous trauma-related studies examining interrater reliability have been focused around three main areas as follows: (i) evaluation of performance and training,^{18–22} (ii) diagnostics,^{23–32} and (iii) reproducibility

of trauma scores and coding tools.^{33–35} One area worth noting is the interrater reliability of preventable death judgments.

Early discussions surrounding the reliability of preventable death judgments are concerned about pitfalls common to a subjective determination of polytrauma. In the mid-1980s, the preventable death rate was used as a primary measure of trauma care effectiveness.³⁶ While many studies used this outcome to highlight the need for trauma system development, the lack of a standardized definition of "preventable death" prevented interinstitutional comparisons.³⁷ A particular concern was that judgments of preventable death lacked reproducibility when the judgments were made subjectively by different experts. Noting the variability and lack of examination into the reliability of the various methods, MacKenzie et al.³⁸ analyzed the interrater reliability of preventable death judgments for trauma and found low reliability of these subjective judgments. They argued that reliability could be increased if panels had been provided more explicit guidelines.

In view of these criticisms and other critical evaluations citing similarly poor reproducibility, McDermott et al.³⁹ conducted an evaluation of their consultative committee's methodology and made relevant adjustments. Two independent evaluative committees then assessed the reproducibility of preventable death judgments in 60 consecutive road traffic fatalities, and the reliability of the judgments was assessed. They found high κ concordance on preventable death judgments both within and between the two evaluative groups, providing convincing evidence to support continued and more widespread use of the objective methodology they had adopted. The findings of these studies provide strong support for a similarly objective methodology to be adopted in relation to the definition of polytrauma.

The final stage of this study compared three previously investigated, objective, anatomic scores (ISS > 15, ISS > 17, and 2×AIS score > 2). The definition 2×AIS score greater than 2 was previously shown to have the greatest agreement with the clinical assessment of polytrauma.¹⁶ This definition was again found to be the definition with closest agreement to the majority of subjective assessments (more than the ISS > 15 and ISS > 17 definitions), providing further impetus for testing on larger data sets.

CONCLUSION

Based on a subjective definition, trauma surgeons have varying agreement regarding the definition of polytrauma. This study found, at best, only moderate interrater agreement both within and across institutions, while observing substantial intrarater agreement. To improve communication and resource allocation, an objective definition of polytrauma is needed. Furthermore, to permit specialty identification and setting of robust standards in competency for training and verification, in an era of increasing subspecialization, a validated and reproducible definition of polytrauma is warranted. It does not exist in the literature, and as this study demonstrates, the subjective definition differs both within, and across, institutions.

AUTHORSHIP

N.E.B. and Z.J.B. designed the study. N.E., K.S., and Z.J.B. were involved in the prospective and retrospective assessment stages at JHH. N.E. and K.S. prospectively collected and recorded the data. N.E.B. conducted and observed the interinstitutional data sheet assessment session, conducted the statistical analysis, and drafted the article. Z.J.B. provided critical revision.

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DISCLOSURE

N.E.B. and Z.J.B. are members of the International Working Group on Polytrauma, a current initiative for the definition of polytrauma. N.E.B. participated on one consensus meeting supported by the German Trauma Society (DGU).

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The quest for a universal definition of polytrauma: A trauma registry-based validation study

The pilot validation study presented earlier in this thesis recommended defining polytrauma as patients with an Abbreviated Injury Scale (AIS) score greater than 2 in at least two Injury Severity Score (ISS) body regions ($2 \times \text{AIS} > 2$). The next study was designed to validate this definition on a larger data set using the NSW Trauma Registry. It hypothesized that patients defined by the $2 \times \text{AIS} > 2$ definition would have worse outcomes and use more resources than those without $2 \times \text{AIS} > 2$ and thus would be a better definition of polytrauma.

The NSW Trauma Registry was not designed to assess the role that physiologic parameters could play in a definition of polytrauma as it did not mandate the collection of physiologic data. As a result, this study focused purely on anatomic scores. It found that a simple change in the definition (from $\text{ISS} > 15$ to $\text{AIS} \text{ score} > 2$ in two or more regions) improved the use of the AIS-based scoring and was a definition that was applicable, even retrospectively, to any registry. However since parameters such as blood pressure, the degree of acidosis and level of consciousness characterize the host response to injury and have been shown to predict outcome in trauma, combining physiologic parameters with an anatomic score could improve the sensitivity and specificity of any future definition of polytrauma and were recommended.

OPEN

The quest for a universal definition of polytrauma: A trauma registry-based validation study

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BACKGROUND:	A pilot validation recommended defining polytrauma as patients with an Abbreviated Injury Scale (AIS) score greater than 2 in at least two Injury Severity Score (ISS) body regions ($2 \times \text{AIS score} > 2$). This study aimed to validate this definition on larger data set. We hypothesized that patients defined by the $2 \times \text{AIS score} > 2$ cutoff have worse outcomes and use more resources than those without $2 \times \text{AIS score} > 2$ and that this would therefore be a better definition of polytrauma.
METHODS:	Patients injured between 2009 and 2011, with complete documentation of AIS by New South Wales Trauma Registry and 16 years and older were selected. Age and sex were obtained in addition to outcomes of ISS, hospital length of stay (LOS), intensive care unit (ICU) admission, ICU LOS, and mortality. We compared demographic characteristics and outcomes between patients with ISS greater than 15 who did and did not meet the $2 \times \text{AIS score} > 2$ definition. We then undertook regression analyses (logistic regression for binary outcomes [ICU admission and death] and linear regression for hospital and ICU LOS) to compare outcomes for patients with and without $2 \times \text{AIS score} > 2$, adjusting for sex and age categories.
RESULTS:	In the adjusted analyses, patients with $2 \times \text{AIS score} > 2$ had twice the odds of being admitted to the ICU compared with those without $2 \times \text{AIS score} > 2$ (odds ratio, 2.5; 95% confidence interval [CI], 2.2–2.8) and 1.7 times the odds of dying (95% CI, 1.4–2.0; $p < 0.001$ for both models). Patients with $2 \times \text{AIS score} > 2$ also had a mean difference of 1.5 days longer stay in the hospital compared with those without $2 \times \text{AIS score} > 2$ (95% CI, 1.4–1.7) and 1.6 days longer ICU stay (95% CI, 1.4–1.8; $p < 0.001$ for all models).
CONCLUSION:	Patients with $2 \times \text{AIS score} > 2$ had higher mortality, more frequent ICU admissions, and longer hospital and ICU stay than those without $2 \times \text{AIS score} > 2$ and represents a superior definition to the definitions for polytrauma currently in use. (<i>J Trauma Acute Care Surg.</i> 2014;77: 620–623. Copyright © 2014 by Lippincott Williams & Wilkins)
LEVEL OF EVIDENCE:	Diagnostic test/ criteria, level III.
KEY WORDS:	Polytrauma; consensus definition; trauma; Injury Severity Score.

The current terminology surrounding the severely injured lacks both clarity and consensus, particularly in relation to the term *polytrauma*.^{1–4} While polytrauma patients are generally regarded to be the most severely injured patients with two or more significant injuries, the use of the term both clinically and in the literature is inconsistent.^{5–14} Illustrating this fact, we conducted a recent study based on subjective assessments and found that trauma surgeons do not agree on the definition of polytrauma, with subjective definitions differing both within and across institutions.¹⁵

An Injury Severity Score (ISS) greater than 15 is a frequently used definition for both polytrauma and the interchangeably used terms of *severely injured* and *major trauma*.

Its use as a formal definition however has not been established according to the traditional rules of evidence.^{16–21} Moreover, this anatomic cutoff makes no distinction between single-system severe injury (e.g., an Abbreviated Injury Scale [AIS] score of 4 or 5 in one region) and what is generally regarded as true polytrauma, with the most concerning aspect being the potential overrepresentation of isolated head injuries.

In a prospective pilot validation study undertaken on 336 patients, we previously suggested the division into AIS body regions as a way around some of the inherent limitations of the ISS when used to define polytrauma.²² We recommended defining polytrauma as those patients with AIS score of greater than 2 in at least two ISS body regions ($2 \times \text{AIS score} > 2$). This definition was shown to be a better predictor of morbidity and mortality than the most commonly used $\text{ISS} > 15$ definition and excluded those patients with severe single-system injuries (monotrauma), the most important implication being the exclusion of patients with isolated head injuries who have an inherently higher morbidity and mortality rate but do not represent true polytrauma.^{23–25} The need to further evaluate the results of this pilot study was highlighted at the time of publication. As such, the aim of the current study was to validate these preliminary results on a larger data set, specifically the New South Wales (NSW) (Australia) Trauma Registry. We hypothesized that, in patients with ISS greater than 15, the subgroup of polytrauma patients defined by the $2 \times \text{AIS score}$

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> 2 cutoff have worse outcomes and use more resources than those without $2 \times \text{AIS score} > 2$ and that this would therefore be a better definition of polytrauma.

PATIENTS AND METHODS

The NSW Trauma Registry

The NSW Trauma Registry is a statewide registry established by the NSW Institute of Trauma and Injury Management (NSW ITIM) in 2002. The data set held by the registry is known as the NSW Trauma Minimum Data Set, an online mandatory requirement of all NSW-designated trauma services. Data are submitted to a central password-protected database server, hosted securely within NSW Health. Criteria for patient inclusion into the NSW Trauma Registry as determined by the NSW ITIM are as follows: admission to a trauma service in NSW within 14 days of injury; any patient with ISS > 12; and death in the hospital (irrespective of ISS). Exclusion criteria, as determined by the NSW ITIM, include having isolated fractured neck of femur injuries sustained after a mechanical fall.

The NSW trauma minimum data set consists of 20 mandatory data elements composing of demographic characteristics, transfer and admission data, mechanism of injury, intensive care admission details and LOS, surgical intervention, and ultimate outcome (survival/death). Before 2009, only the ISS was collected. In 2009, AIS codes for each component injury became mandatory. Physiologic and laboratory data do not form part of the NSW trauma minimum data set.

Study Population

Our study population was drawn from the NSW trauma registry and included all patients with ISS > 15 occurring between 2009 and 2011. The study period was chosen because AIS codes were not mandatory before 2009; thus, from 2009, there was complete documentation in the registry for ISS plus component AIS codes for each body region. We excluded patients younger than 16 years. Demographic characteristics including age and sex were recorded. Hospital LOS, ICU admission, ICU LOS, and mortality constituted the key outcomes for investigation.

Statistical Analysis

Analyses were undertaken using the Stata statistical software (Stata Statistical Software, Release 12, StataCorp LP, College Station, TX). Descriptive statistics are presented as mean (SD) for normally distributed continuous variables (age), median (first and third quartile) for nonnormally distributed continuous variables (ISS, hospital LOS, and ICU LOS) and frequency distributions (n [%]) for binary variables.

We compared demographic characteristics and outcomes between patients with ISS > 15 who did and did not meet the $2 \times \text{AIS score} > 2$ definition using the χ^2 test for categorical variables and the Mann-Whitney rank-sum test for continuous variables. We then undertook regression analyses (logistic regression for binary outcomes [ICU admission and death] and linear regression for hospital and ICU LOS) to compare outcomes for patients with and without $2 \times \text{AIS score} > 2$, adjusting for sex and age category (16–45, 46–70, 71+). Because LOS

was highly skewed, we used a log transformation of this variable. Models also adjusted for trauma facility, and robust variance estimates were obtained. Results from the regression models are reported as adjusted odds ratios (ORs) (for ICU admission and death) and geometric means (for LOS) with 95% confidence intervals (CIs), and the Wald test was used to assess statistical significance of associations.

Post hoc power calculations estimated that this study had 80% power, using a 5% significance level, to detect differences of 3% in mortality, 2.5% in ICU admission rate, 3.5 days in hospital LOS, and 1.5 days in ICU LOS between those with and without $2 \times \text{AIS score} > 2$.²⁶ These were considered to be clinically relevant differences taking into account the costs of hospital and ICU LOS, the increased health risk of prolonged hospital admissions such as hospital-acquired pneumonia, and the psychosocial impact of trauma such as quality of life and loss of productivity.^{27,28}

RESULTS

After applying the inclusion and exclusion criteria of our study to the NSW trauma registry database, there were a total of 4,935 patients in our study, of whom 1,454 (29%) had an AIS score > 2 in at least two of the six ISS body regions ($2 \times \text{AIS score} > 2$). Characteristics for the total group were as follows: mean (SD) age, 52.4 (23.3) years, 3,547 males (72%), ISS of 22 (Q1–Q3, 17–26), hospital LOS of 10 days (Q1–Q3, 5–22 days), 2,204 admitted to ICU (45%), ICU LOS of 0 day (Q1–Q3, 0–3 days), and mortality of 721 (15%) (Table 1).

Patients with $2 \times \text{AIS score} > 2$ were younger than those without $2 \times \text{AIS score} > 2$ (mean age, 46.5 and 54.9 for those with and without $2 \times \text{AIS score} > 2$, respectively; $p < 0.001$). There was a marginally nonsignificantly higher proportion of males among those with $2 \times \text{AIS score} > 2$ relative to those without $2 \times \text{AIS score} > 2$; however, this difference was not clinically meaningful (74% males in the $2 \times \text{AIS score} > 2$ group vs. 71% males in those without $2 \times \text{AIS score} > 2$, $p = 0.061$). ISS was statistically significantly higher for patients with $2 \times \text{AIS score} > 2$ (median, 29) versus those without $2 \times \text{AIS score} > 2$ (median, 20; $z = -35.97$; $p < 0.001$).

Hospital LOS and ICU LOS were both statistically significantly longer for the $2 \times \text{AIS score} > 2$ group compared with those without $2 \times \text{AIS score} > 2$ (median hospital LOS of 16 days for those with $2 \times \text{AIS score} > 2$ vs. 9 days for those without $2 \times \text{AIS score} > 2$ [$z = -13.25$, $p < 0.001$] and median ICU LOS of 1 day and 0 day for those with and without $2 \times \text{AIS score} > 2$, respectively [$z = -15.92$, $p < 0.001$]). Patients with $2 \times \text{AIS score} > 2$ were statistically significantly more likely to be admitted to the ICU (59%) relative to those without $2 \times \text{AIS score} > 2$ (39%; $\chi^2 = 176.70$, $df = 1$, $p < 0.001$) and had higher mortality (18% for $2 \times \text{AIS score} > 2$ vs. 14% for those without $2 \times \text{AIS score} > 2$; $\chi^2 = 12.20$, $df = 1$, $p < 0.001$).

In adjusted analyses, patients with $2 \times \text{AIS score} > 2$ had twice the odds of being admitted to the ICU compared with those without $2 \times \text{AIS score} > 2$ (OR, 2.5; 95% CI, 2.2–2.8) and 1.7 times the odds of dying (95% CI, 1.4–2.0; $p < 0.001$ for both models) (Table 2). Patients with $2 \times \text{AIS score} > 2$ also had a mean difference of 1.5 days longer stay in the hospital compared with those without $2 \times \text{AIS score} > 2$ (95% CI,

TABLE 1. Outcomes for Patients 2 × AIS Score > 2 Versus Those Without 2 × AIS Score > 2 Outcomes

	Total n = 4,935	2 × AIS Score > 2 n = 1,454	Without 2 × AIS Score > 2 n = 3,481	Test Statistic*	P
Sex, male	3,547 (72%)	1,072 (74%)	2,475 (71%)	$\chi^2 = 3.58$ $df = 1$	0.061
Age total	4,924	1,450	3,474	$t = 12.01$	
Age, mean (SD)	52.4 (23.3)	46.5 (21.8)	54.9 (23.5)		<0.001
Age category**					
16–45	2,083 (42%)	756 (52%)	1,327 (38%)	$\chi^2 = 81.45$ $df = 1$	<0.001
46–70	1,418 (29%)	420 (29%)	998 (29%)	$\chi^2 = 0.03$ $df = 1$	0.867
>70	1,423 (29%)	274 (19%)	1,149 (33%)	$\chi^2 = 100.08$ $df = 1$	<0.001
ISS	22 (17–26)	29 (22–38)	20 (17–25)	$z = -35.97$	<0.001
Hospital LOS, d	10 (5–22)	16 (7–33)	9 (4–18)	$z = -13.25$	<0.001
ICU Admission	2,204 (45%)	861 (59%)	1,343 (39%)	$\chi^2 = 176.70$ $df = 1$	<0.001
ICU LOS, d	0 (0–3)	1 (0–7)	0 (0–2)	$z = -15.92$	<0.001
Mortality	721 (15%)	251 (18%)	470 (14%)	$\chi^2 = 12.20$ $df = 1$	<0.001

* χ^2 test for categorical variables, t test and Mann-Whitney rank-sum test for continuous variables.

**Numbers do not add to total because of missing data in 11 patients for age.

Data are shown as mean (SD), median (first to third quartile), or n (%).

1.4–1.7) and 1.6 days longer ICU LOS (95% CI, 1.4–1.8; $p < 0.001$ for both models).

DISCUSSION

This study has aimed to refine the way that polytrauma patients are defined distinct from those with multiple but non-serious injuries and also from those with single-system severe trauma. Comparing patients with and without 2 × AIS score > 2, the study found that patients with 2 × AIS score > 2 had a higher overall ISS compared with those without 2 × AIS score > 2 (29 [22–38] vs. 20 [17–25]), longer hospital stay (16 [7–33] days vs. 9 [4–18] days), higher ICU admission rates (59% vs. 39%), longer ICU stay (1 [0–7] days vs. 0 [0–2] days), and a higher mortality rate (18% vs. 14%). After adjustment for age and sex, this study found that patients with 2 × AIS score > 2

had 1.7 times the odds of dying and 2.5 times the odds of being admitted to the ICU than those without 2 × AIS score > 2, with a mean of 1.5 days longer hospital stay and a mean of 1.6 days longer ICU stay.

The NSW Trauma Registry is not designed to assess the role that physiologic parameters could play in a definition of polytrauma, as it does not mandate the collection of physiologic data. As a result, this study has focussed purely on anatomic scores. The specific aim of this study was to look at simple AIS-based anatomic scoring to potentially improve the definition of polytrauma. Our results showed that a simple change in the definition (from ISS > 15 to AIS score > 2 in two or more regions) improves the use of the AIS-based scoring. This can be applicable even retrospectively to any registry. However, since parameters such as blood pressure, degree of acidosis, and level of consciousness characterize the host response

TABLE 2. Regression Analyses of Outcomes for Patients With 2 × AIS Score > 2 Versus Those Without 2 × AIS Score > 2*

	OR**	95% CI	Binary Outcomes		
			χ^2	df	p
ICU admission	2.5	2.2–2.8	176.34	1	<0.001
Mortality	1.7	1.4–2.0	35.17	1	<0.001
	Mean Difference‡	95% CI	Continuous Outcomes†		
			T		p
Hospital LOS	1.5	1.4,1.7	11.25		<0.001
ICU LOS	1.6	1.4,1.8	9.42		<0.001

*Models adjusted for sex, age group, and trauma center; robust variance used.

**OR for outcome in those with 2 × AIS score > 2 relative to those without 2 × AIS score > 2.

†Coefficient estimates and 95% CIs are obtained from the regression of the ln of length of stay, and then exponentiated to provide estimate on the original scale.

‡Geometric difference in mean LOS between those with 2 × AIS score > 2 relative to those without 2 × AIS score > 2.

to injury and indeed some have been shown to predict outcome in trauma, combining physiologic parameters with an anatomic score could improve the sensitivity and specificity of any future definition of polytrauma and is recommended.^{29,30} The inclusion of the right physiologic parameters (based on international consensus) in addition to $2 \times$ AIS score > 2 anatomic criteria should lead to a superior definition, which may affect the variables recommended to be collected by trauma registries.

CONCLUSION

The trauma community has reached a critical point in governing the use of one of its most commonly used terms, *polytrauma*. Clear boundaries are needed to guide when and to whom this definition should be applied. This study has confirmed on a large data set the superiority of using the $2 \times$ AIS score > 2 definition to define polytrauma. It captures a more severely injured, more resource-intensive patient population with a higher mortality rate, even without the inclusion of physiologic parameters, while excluding severe single-system injuries (monotrauma) that are not clinically considered polytrauma.

AUTHORSHIP

N.E.B. and Z.J.B. designed the study. N.E.B. and C.D. conducted the statistical analysis and drafted the manuscript. C.D. and Z.J.B. provided critical revision.

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DISCLOSURE

The authors declare no conflicts of interest.

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Conclusion

This thesis identified the lack of a validated and consensus definition of polytrauma and brought the issue to international attention. The subjective definition of polytrauma among peers and across institutions was proved unreliable. Both anatomical and physiological parameters were argued to be necessary to a definition of polytrauma. An Abbreviated Injury Scale (AIS) based anatomical definition was found to be the most practical and feasible approach. Results established that using a definition of ‘two body regions with AIS>2’ was the best marker of polytrauma, better than any other anatomical cut-off. The best physiological parameters to include in a definition of polytrauma were explored and the concept of the systemic inflammatory response syndrome was found to be an inappropriate surrogate for physiological derangements characteristic of polytrauma.

The aim of this thesis has been achieved with the development of a preliminary, internationally validated and consensus definition of polytrauma. A notable outcome of this thesis was the establishment of the International Working Group on Polytrauma, where the results of this research served as the foundation for both the series of consensus discussions and the final validation-study published by the International Working Group (see Appendix 1). An important advance made by this group was the validation of a range of physiological variables built into the German Trauma registry.

The final consensus definition of polytrauma published by the International Working Group on Polytrauma was as follows:

Injuries with an Abbreviated Injury Scale (AIS) score >2 in at least two body regions plus at least one of the five following standardized pathologic conditions (prior to resuscitation);

1. Hypotension (Systolic Blood Pressure \leq 90 mm Hg)
2. Unconsciousness (GCS score \leq 8)
3. Acidosis (Base deficit \leq -6.0)
4. Coagulopathy (PTT \geq 40 seconds or INR \geq 1.4)
5. Age \geq 70 years.

Multicenter validation using databases of comparable sophistication is recommended to establish this definition and to confirm its superiority over the purely anatomical definition of ‘two body regions with AIS>2’ (2X>AIS).

Appendices

Appendix 1

Pape HC, Lefering R, **Butcher NE**, Peitzman A, Leenen L, Marzi I, Lichte P, Josten C, Bouillon B, Schmucker U, Stahel P, Giannoudis P, Balogh ZJ. The definition of polytrauma revisited: An international consensus process and proposal of the new 'Berlin definition'. *Journal of Trauma and Acute Care Surgery*. 2014; 77(5):780-786.

The definition of polytrauma revisited: An international consensus process and proposal of the new 'Berlin definition'

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BACKGROUND:	The nomenclature for patients with multiple injuries with high mortality rates is highly variable, and there is a lack of a uniform definition of the term <i>polytrauma</i> . A consensus process was therefore initiated by a panel of international experts with the goal of assessing an improved, database-supported definition for the polytraumatized patient.
METHODS:	The consensus process involved the following: <ol style="list-style-type: none"> 1. Expert panel. Multiple meetings and consensus discussions (members: European Society for Trauma and Emergency Surgery [ESTES], American Association for the Surgery of Trauma [AAST], German Trauma Society [DGU], and British Trauma Society [BTS]). 2. Literature review (original articles before June 8, 2014). 3. A priori assumptions by the expert panel. The basis for a new definition should include the Injury Severity Score (ISS) based on the Abbreviated Injury Scale (AIS); "A patient classified as polytraumatized should have a mortality rate of approximately 30%, twice above the established mortality of ISS > 15." 4. Database-derived resources. Deductive calculation of parameters based on a nationwide trauma registry (TraumaRegister DGU) with the following inclusion criteria: multiple injuries and need for intensive care therapy.
RESULTS:	A total of 28,211 patients in the trauma registry met the inclusion criteria. The mean (SD) age of the study cohort was 42.9 (20.2) years (72% males, 28% females). The mean (SD) ISS was 30.5 (12.2), with an overall mortality rate of 18.7% (n = 5,277) and an incidence of 3% of penetrating injuries (n = 886). Five independent physiologic variables were identified, and their individual cutoff values were calculated based on a set mortality rate of 30%: hypotension (systolic blood pressure ≤ 90 mm Hg), level of consciousness (Glasgow Coma Scale [GCS] score ≤ 8), acidosis (base excess ≤ -6.0), coagulopathy (international normalized ratio ≥ 1.4/partial thromboplastin time ≥ 40 seconds), and age (≥ 70 years).
CONCLUSION:	Based on several consensus meetings and a database analysis, the expert panel proposes the following parameters for a definition of "polytrauma": significant injuries of three or more points in two or more different anatomic AIS regions in conjunction with one or more additional variables from the five physiologic parameters. Further validation of this proposal should occur, favorably by multivariate analyses of these parameters in a separate data set. (<i>J Trauma Acute Care Surg.</i> 2014;77: 780–786. Copyright © 2014 by Lippincott Williams & Wilkins)
KEY WORDS:	Definition of polytrauma; assessment of patients with multiple injuries; conventional parameters for assessment; biomarkers for polytrauma; grading of patients.

The terminology applied to quantifying injury severity has been vague and inconsistent.^{1–6} Descriptions such as "critically injured," "severely injured," or "critically ill with multiple injuries" have been used interchangeably.^{2,3}

To our knowledge, the term *polytrauma* was first used approximately half a century ago, when survival rates began to improve for these patients. Descriptive definitions were used,

such as "at least two severe injuries of the head, chest or abdomen, one of them in association with an extremity injury,"⁴ "any patient with two or more significant injuries,"⁵ or "a patient with two or more injuries, one of them being potentially life threatening." Isolated life-threatening conditions were also separated and the term *barytrauma* was coined.⁶

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The Injury Severity Score (ISS)⁷ is the basis for most assessments of trauma patients and continues to be recommended by the American College of Surgeons' Committee of Trauma (ACS COT), The Trauma Outcome Research Network (TARN, GB), the German Trauma Registry (GTR), and the Australasian Trauma Society (ATS). The Major Trauma Outcome Study (MTOS) provided the first large-scale data that helped develop specific objective parameters to assess the polytrauma patient.¹ Physiology-based scoring systems included the description of the "lethal triad" to differentiate stable from unstable and "in extremis" patients.⁸ This terminology has been later expanded to describe patient subsets, such as the "borderline" polytrauma patient.^{9,10}

Today, the most widely disseminated definitions continue to rely on the basic concept of a combination of injuries that cause a life-threatening condition.⁴⁻⁶ However, this approach is characterized by a lack of objective quantitative measures and represents Level IV evidence only.

For these reasons, an international panel of physicians met multiple times to refine the existing descriptions. The objective was to discuss current descriptions and possibly describe parameters to define the critically injured patient (polytrauma) with the potential for unrestricted application.¹¹

This article summarizes the results obtained during the process of four subsequent years of progressive meetings, scientific sessions, consensus discussions, and trauma registry analyses.

PATIENTS AND METHODS

Consensus Process

A series of scientific sessions and meetings were held under the auspices of several societies as follows: American Association for the Surgery of Trauma (AAST), European Society for Trauma and Emergency Surgery (ESTES), German Trauma Society (DGU), British Trauma Society (BTS), New Zealand Association for the Surgery of Trauma (ANZAST).

Following scientific sessions in conjunction with the Annual ESTES meeting in Brussels, (May 15, 2010) and Milan (April 27, 2011), the panel of authors decided upon a formal subsequent consensus conference to be held in Berlin, Germany.

In preparation for the Berlin meeting, numerous discussions and telephone conferences were held. A group of experts was then invited to participate in the process. The invitations were based on expertise in the field (assessed by number and quality of original publications), willingness to contribute to a longstanding process, response to the invitations by e-mail, and availability to join the meeting in Berlin.

The meeting was held on May 11 and 12, 2012, in Berlin, Germany, and resulted in a draft consensus definition. This was reconfirmed during several interactions and additional calculations of the database. Further recalculations of the database were performed to reach the final consensus as documented in Table 1.

Prerequisites

The panel decided on the following prerequisites for the data selection; availability and completeness of data in large data sets, worldwide applicability, sensitivity, and specificity to describe the severely injured. These were then used to differentiate a core analysis of data.

TABLE 1. Time Course "Definition of Polytrauma"

Premeeting Scientific Sessions
Kickoff session at ESTES 2010, Brussels
11th International Course on Polytrauma Management, Aachen, Germany
Scientific Session at the ESTES, 2011, Milan
In-Person Discussions, March 1 to October 15, 2012
Meeting to discuss composition of expert panel group (Berlin, German Congress of Orthopaedics/Trauma, DKOU 2012)
Precirculation of preliminary timeline before DKOU 2012
Empirical Evaluation of Draft Definition
Review of published data
Invitations and Information for Panelists, October 1 to December 12, 2011
Precirculation of definitive timeline
Precirculation of topics
Precirculation of background materials
TR-DGU Data Analysis I, Deductive Draft Definition
Assembling of clinical cohort, Cologne, March 8, 2012
Berlin Consensus Conference, May 10/11, 2012
Day I: influence of trauma systems, issues to include or exclude systemic inflammatory response syndrome, current concepts
Day II: presentation of calculations from a nationwide database, discussion of draft definition, consensus on the issue of further calculations in the database
Teleconference, June 15, 2012
Consensus on database use for later validation (NTDB, TARN, Australian Registry)
TR-DGU Data Analysis II, Deductive Draft Definition
Calculation of the final definition, Cologne, November 1 to December 7, 2012
In-Person Consensus Discussion at the 13th International Polytrauma Course, Aachen, December 8, 2012
Discussion on presentation of data
Discussion on involvement of other databases
Telephone Conference, March 8, 2013
Consensus on modality of manuscript publication
Permission to use all requested databases for validity assessment
Multiple Communications by E-mail, Telephone to Improve and Consent the Berlin Definition (following September 16, 2013)

Preparative Literature Review

A review of the literature was performed on the available definitions of polytrauma. The following MeSH headings were applied to the literature search: Abbreviated Injury Scale, Injury Severity Score, algorithms, clinical coding/methods, consensus, Germany/epidemiology, incidence, multiple trauma/diagnosis, Multiple Trauma/epidemiology, observer variation, prospective studies, registries, trauma centers/statistics & numerical data, United States/epidemiology, Injury Severity Score. All original articles were included if published within January 1, 1940, and May 8, 2012. No language restrictions were applied. This review served to determine pertinent parameters and cutoff values for the definition of the trauma patient "at risk."

Data Acquisition

A National Trauma Registry (TR-DGU, version 2012) was used. In this registry, severely injured patients are documented prospectively by hospitals included in the German Trauma Network (www.traumaregister.de). Data from the registry was assessed at four different time points (Table 1): (1) before the

Berlin meeting to analyze the raw data set and feasibility of the selected parameters; (2) during the Berlin meeting (May 2012) to address the individual cutoff values; and (3) before and after the 13th International Polytrauma Course (Aachen, December 2012) to calculate the final score values.

During the inclusion period, a change in documentation occurred for parameters indicative of hemostasis. Therefore, in patients with missing international normalized ratio (INR) data, a relative measure of thromboplastin time ("Quick value" [Q] was used, expressed as percentage of normal activity) was used as follows: the value was approximated by the formula $0.4 + (58 / Q)$.

Inclusion Criteria

Patients from the TR-DGU were extracted if they fulfilled the following criteria: admission to an intensive care facility and multiple injuries

Definitions

Mortality was defined as in-hospital mortality.

Complications

Clinical complications included those documented in the registry, such as organ failure and sepsis. The information obtained through this process served as a basis for the discussions during the consensus meeting held in Berlin, Germany, on May 11/12, 2012.

Cohort Assembly

Based on the literature review, multiple studies from the Australian group,¹¹ preparative in-person meetings (C.J., I.M., H.-C.P.), and the expert session in Berlin, the following eligibility criteria were selected for suitability of the database to be used: (1) large multicenter cohort, (2) availability of data known to be relevant for outcome (namely indicators of hemorrhagic shock, resuscitation data, laboratory results) and mortality, and (3) inclusion of basic trauma scoring values.

The panel identified several data sets to be generally acceptable: the National Trauma Data Bank (NTDB, United States), the German Trauma Registry (TR-DGU), the Dutch Trauma Registry, the New South Wales Trauma Registry (Australia).

Empirical considerations lead to preliminary draft definitions: pilot data based on single institutions showed the potential feasibility of Abbreviated Injury Scale (AIS) score greater than 2 in two body regions, the potential hurdles with inclusion of systemic inflammatory response syndrome data, and the low interrater and intrarater agreement of the expert opinion-based subjective definition.¹² The resulting information was used to perform further calculations on the variables deemed to be available worldwide.

General Considerations and Prerequisites Addressed During the Berlin Meeting

During the meeting, the initial questions addressed by the expert group were as follows:

When is the best time to define a patient as a multiply injured/polytraumatized?
Who is the best trained expert to do this?
How can feasibility be maintained while accuracy is improved?

Timing of the Diagnosis of Polytrauma

On-scene assessment might be useful to initiate trauma team call and triage; however, the panel agreed that it is not useful for defining polytrauma. In-hospital diagnosis should be made before ICU admission because it is affected by treatment and includes the systemic patient response.¹³ Therefore, the diagnosis of polytrauma should be made on the first day of the hospital stay after completion of initial diagnostic procedures.

Description of the Best Expert to Diagnose Polytrauma

The panel considered the assessment by police or other nonmedical personnel of little use for medical definition because of a lack of specificity.¹⁴ It was agreed upon that ideally, the diagnosis is made by an expert that has completed his or her trauma fellowship and has fulfilled specific courses, such as Advanced Trauma Life Support (ATLS), www.atls.com, or the Polytrauma Course, www.polytraumacourse.com.

Clinical Scores

The panel agreed that any practicable definition of polytrauma should be applicable prospectively, that is, early after patient admission. Anatomic scoring was selected as the basis for assessment and for optimal standardization. Because the precise ISS is difficult to calculate during the patient management in the emergency department, it was favored unequivocally that AIS score greater than 2 in two body regions can be reliably recognized by a clinical expert shortly after admission. It has previously been discussed that the parameters providing the most stable sensitivity and specificity in terms of mortality are documented soon after admission.¹⁵

Parameters: Pathologic Conditions and Ancillary Variables

The selection of variables was assessed in preparation for the Berlin consensus meeting during a database evaluation for the TR-DGU in Cologne, on September 12, 2012. The lead author and the second author of this article met to assess the feasibility of variables selected in a previous literature search. The search included criteria used by the ACS COT, data from the Major Trauma Outcome Study, certain parameters suggested previously to define polytrauma,^{1,16} and additional parameters previously used to assess these patients. Among these are the GCS score and certain physiologic criteria.^{16,17} It lists certain valuable combinations of parameters, such as an ISS of 16 points or greater, two body regions with an ISS of 3 or greater, the use of an ISS of 16, and one or more additional altered physiologic parameters.¹⁸ On the basis of this information, the panel present at the Berlin meeting decided on the threshold levels, as described in the following section.

Threshold Levels of Mortality

Currently, the ISS is used as a standard anatomic classification of injury severity in major trauma centers across the United States, many European countries, and Australia. The threshold level to determine a severely injured patient is usually an ISS of greater than 15 points. The mortality rate for the patient population used to be 20% or greater.^{1,6} Today, it is

considered to be considerably lower and ranges between 9% and 15%.¹⁹ Based on this information, the panel unanimously agreed that an expected mortality rate of approximately 15% should be used as threshold level.

Criteria Used to Define a “Relevant Change” in the Clinical Condition

The assessment of the set mortality rates had been confirmed in the preliminary calculations of the registry. It was decided that the mortality rate to determine polytrauma should be double the value from the mortality rate of patients with an ISS of 16 points.

Therefore, after accounting for different variations of sensitivity, the panel decided that a mortality rate is most relevant when it accounts for approximately 30% for any of the parameters.

Relevant Physiologic Parameters: Pathologic Conditions and Ancillary Variables

- Coma was defined as a GCS score of 8 points or lower.²⁰
- Hypotension was defined as a systolic blood pressure of 90 mm Hg or lower.⁷
- Metabolic acidosis was defined as a base excess of 6 or lower.
- Coagulopathy was defined as a partial thromboplastin time (PTT) of 50 or greater or an INR value of 1.4 or greater.

The panel agreed that ancillary parameters should be minimized mostly because of the intention of global use of the definition and the availability in databases. Before the Berlin meeting, an assessment of old age was performed as ancillary parameter for the three variants, namely, 60 years, 65 years, and 70 years of age. This demonstrated that mortality rates justified the inclusion of older than 70 years as an ancillary parameter. The panel reconfirmed the cutoff value of old age to be 70 years or older during the Berlin meeting.

Draft Consensus Definition

As part of the Berlin meeting, the prerequisites for the definition were selected as follows:

Based on several presentations during the meeting and a discussion on the requirements of the definition, all panel members agree on the following prerequisites:

1. A combination of injury severity, physiologic changes, and/or a relevant physiologic change (as defined earlier) in the clinical condition seem to be useful and should be applied.
2. The initial workup should be performed in the German Registry, followed by a reassessment in any large registry.
3. At least two body regions should be injured, thus requiring an AIS score of 2 points or greater in two or more body regions.
4. The panel unanimously decided that additional parameters are required to allow for a definition of polytrauma.
5. The weight of any selected parameter should be clinically relevant in terms of contributing to increased mortality.

Final Consensus on the Data

The results were presented to the panel during the 13th International Polytrauma Course in Aachen, Germany, on November 30 and December 1, 2012. It was agreed upon that the registry data should be used for the Berlin definition of

TABLE 2. Demographic Data of Patients Included in the Study With an ISS of 16 or Greater in Two or More Body Regions

Variable	Unit	Data
No. cases	Patients	28,211
Age, mean (SD)	Years	42.9 (20.2)
Sex	Male	72% (n = 20,433)
Mechanism of injury	Penetrating	3% (n = 886)
Incidence of intensive care treatment	—	93% (n = 26,130)
ISS, mean (SD)	Points	30.5 (12.2)
Maximum AIS score (MAIS)	3 points	29% (n = 8,212)
	4 points	40% (n = 11,362)
	5 points	29% (n = 8,207)
	6 points	2% (n = 430)
AIS	Points	
Head injuries	AIS score ≥ 3	54% (n = 15,279)
Thoracic injuries	AIS score ≥ 3	67% (n = 18,824)
Abdominal injuries	AIS score ≥ 3	25% (n = 7,005)
Extremity injuries	AIS score ≥ 3	44% (n = 12,290)
Mortality rate		18.7% (n = 5,277)
Mean (SD) for metric variables and n (%) for counts.		

polytrauma and that the results should be assessed by other databases, such as NTDB, the Dutch Trauma Registry, and the Registry from New South Wales. The consensus process included further telephone conferences and e-mail communication.

Statistical Analysis

Panel Decisions

Data from the TR-DGU were used to allow subjective decision making regarding the severity of injuries. Continuous variables are presented as means and SDs. Frequencies are presented as percentages with numbers of records available in the database.

Database Calculations

Data were tested for normal distribution. Nominally scaled variables were tested using χ^2 analysis. Proportions were evaluated using the Yates-corrected statistics. The relative risks of death of the conventional parameters tested were calculated individually and expressed in odds ratios. The association between conventional parameters and death was evaluated using univariate analysis. Statistical significance was assumed at $p < 0.05$. All calculations were performed using a statistical software package (SPSS, version 20, IBM Inc., Armonk, NY). The number of candidate criteria fulfilled per patient record was also used to build subgroups of patients and to calculate mortality rates.

RESULTS

Table 1 describes the time course of the consensus process. The first scientific session was held during the ESTES meeting in Brussels (May 15, 2010), followed by multiple meetings, telephone conferences, and group discussions.

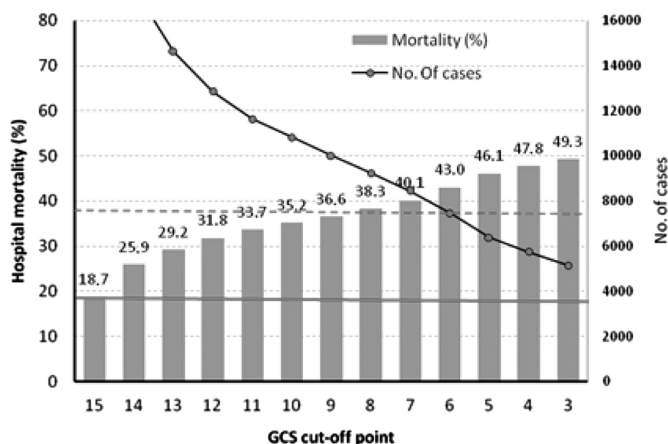
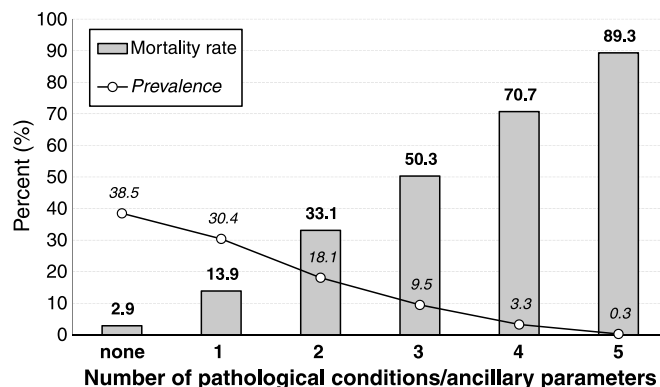
TABLE 3. Prevalence of Five Selected Pathologic Conditions/Ancillary Parameters Associated With Increased Postinjury Mortality

Ancillary Variable/Parameter	Criteria	Incidence	No. Patients	Mortality	Odds Ratio
Age	≥70 y	13.0%	3,661 of 28,071	38.0	2.99
Unconsciousness	GCS score ≤ 8	34.6%	9,232 of 26,657	38.3	4.17
Hypotension	Systolic blood pressure ≤ 90 mm Hg, preclinical or on admission	29.5%	7,955 of 26,923	35.3	4.90
Acidosis	Base excess ≤ -6.0	24.9%	3,764 of 15,117	38.3	3.32
Coagulopathy	PTT ≥ 40 s or INR ≥ 1.4	26.2%	6,316 of 24,143	38.4	5.81

From January 1, 1993, to December 31, 2010, 67,782 patients were documented in the registry. Among these, 43,175 had experienced multiple injuries. The exclusion of all transferred patients left 34,547 patients for further evaluation. Following exclusion of patients with injuries with an AIS score of 2 points or less ($n = 6,336$), 28,211 patients were included in the present study.

Table 2 lists the study population and basic demographic data from the patients. Within the study population, the following distribution of mortality rates associated with incidences of injured body regions was found: 11.8% when at least 2 AIS injuries with 3 points or more¹⁶ in two body regions were affected, 28.3% for three body regions, 37.4% for four body regions, and 58.0% for five body regions.

Table 3 documents the prevalence of the five physiologic parameters identified to be associated with increased mortality rates and the odds ratios for death. Univariate mortality analysis revealed threshold levels for the five parameters

**Figure 1.** Cutoff points for in-hospital mortality rates based on various values for the GCS.**Figure 2.** Documentation of mortality rates depending on the number of pathologic conditions/ancillary variables.

as follows: age of 70 years or greater, 38.0%; acidosis, 38.8%; coagulopathy, 48.3%; GCS score of 8 points or less, 38.3%; and hypotension, 35.3%.

Figure 1 describes mortality rates for different thresholds of the GCS values. The optimal cutoff point that leads to a mortality rate twice as high as in the whole group was a value of 8 points or less. A similar approach was performed for each of the criteria listed in Table 3.

Figure 2 lists the prevalence of pathologic values and ancillary parameters. The highest prevalence was found when one parameter was involved (38.5%), and the lowest prevalence occurred when all five parameters were involved (0.3%).

The parameters deemed to be relevant for an improved definition of polytrauma are as follows: ISS of greater than 15 points, AIS score of 3 or greater in at least two body regions and at least one of five standardized pathologic conditions, (hypotension [systolic blood pressure ≤ 90 mm Hg], unconsciousness [GCS score ≤ 8], acidosis [BE ≤ -6.0], coagulopathy [PTT ≥ 40 seconds or INR ≥ 1.4], and age [≥70 years]).

DISCUSSION

Trauma continues to be the leading cause of death worldwide in young individuals younger than 40 years, associated with the highest socioeconomic impact on society. In blunt injuries, those leading to the biggest long-term impact on quality of life are traumatic extremity amputations and spinal cord injuries.^{21,22}

The value of a reliable assessment of patients with polytrauma can be manifold. It may serve as a basis for scientific, socioeconomic, quality-control, and educational purposes. For clinicians, it may help facilitate adequate distribution of in-hospital resource allocations, such as availability of operating rooms and intensive care unit beds.²³

The current article has both strengths and limitations.

1. The panel decision to use the ISS for practicability may be judged as a limitation. Some authors downplayed the importance of ISS and argue that mortality is better predicted by describing the patient's worst injuries.⁹ Others used variations of the ISS to account for shortcomings in the representation of multiple injuries to the same body region. However, none of

these initiatives represented a breakthrough. Likewise, most international databases and many registries use the ISS rather than other coding systems (e.g., International Classification of Diseases [ICD]). It has therefore been suggested to use risk-adjusted levels of scores and/or parameters, as performed in the current consensus process of the Berlin definition. Among these, it is unclear whether anatomically derived general scoring systems such as ISSs outweigh those that purely describe local changes.²⁴

With the addition of other physiologic variables on top of the injury scoring, a sustained increase in coverage of mortality occurred. This finding concurs with previous studies.^{12,16}

Moreover, when using the ISS threshold of greater than 15 points, an 18.7% mortality rate was found, independent of any of the five additional parameters used. As soon as one other physiologic parameter was added, a reliable set of data revealed mortality rates of 35% to 38%, as deemed clinically relevant to the panel. Therefore, patient data seem to support the expert opinion.

2. One may also argue whether the selection of the additional parameters and ancillary variables was adequate. The “Inflammation and the Host Response to Injury Collaborative Research Program” gathered the most recent data on patients with severe injuries and stressed the importance of inflammation for the hospital course in severely injured patients.²⁵ However, none of the inflammatory parameters, such as interleukin 6 or other laboratory parameters indicative of inflammation values, are currently available in any large database. It was considered highly unlikely that any of these markers will be available for global application in the near future. Thus, it seemed to be justified not to consider them in the current analysis. This approach is supported by the fact that similar parameters as used in the current setup have been successful in predicting outcome^{12,16} and by other groups that studied the risk of adverse effects during the hospital course.^{9,19}
3. A priori selection of mortality rates to identify patients in a life-threatening condition should not have been performed. Yet, the panel that convened in Berlin was under the impression that clinically relevant thresholds for mortality levels are the missing link for database-confirmed values. The a priori use of certain values seems to be supported by previous empirical approaches.²⁵ Therefore, it was felt that the current approach was appropriate for the current status of documentation. Nevertheless, we anticipate that future clinical research using a model of definition development may rely on parameters of inflammation in the future.
4. During the consensus meeting in Berlin, the sensitivity issues of the selected parameters were considered as well. While using the ISS as the only parameter would have been easier, the panel felt that the addition of other physiologic parameters greatly increased the sensitivity and specificity. Similar effects had been described elsewhere.²⁶ Furthermore, the usability of physiologic parameters has been proven in previous databases. Kondo et al. examined the data sets from 35,732 patients of 115 hospitals from the Japanese national trauma database. They documented a good predictive power for GCS, age, and systolic blood pressure in terms of mortality.

5. The data set was not divided into a development and a validation group. Therefore, validation will have to be undertaken in a separate analysis using another database.

Among the strengths is the use of a database that summarizes data from institutions committed to perform optimal trauma care:

1. All information available in the database are documented prospectively.
2. The database uses homogenous inclusion criteria by including only patients admitted through the emergency department and requiring intensive care therapy. The coding expertise is assessed both by computerized plausibility assessments and by regular feedback to every center. It is part of the quality assurance program involved in the certification process of the National Trauma Network, and the quality of documentation is accepted to be high.^{15,17} In this line, Kilgo et al.²⁷ reconfirm that a high quality of data may be an issue in studies gathered from databases. Likewise, Moore et al.²⁸ state that the most important issue to address in registries is high-quality coding practices along with homogenous inclusion criteria. It is implied that some variables from the current database—those that could not be used because of a lack of availability and feasibility—may become more useful with future assessments.
3. Another issue is the quality of the data collected. Kondo et al.¹⁶ report a 76% complete data set 27,154 in patients from a nationwide database. The authors conclude that this number seems to be within the normal range. Across several registries—including the one used for the current study—missing values for physiologic data seem to be a similar concern. Some authors therefore advised to use a multiple imputation model.²⁶ Kondo et al.¹⁶ decided to eliminate all patients with missing data to improve the quality of documentation. The same approach was applied in the current study.

Given these prerequisites, the panel laid special emphasis on availability and completeness of data in large data sets, sensitivity, and specificity. Both the literature review and the database assessment confirmed that this approach leads to a sound association with mortality rates. The current definition thus seems to fulfill all criteria listed earlier, thus allowing for global application. One may argue that a pure expert consensus may offer certain advantages over empirical estimation of injury severity.²⁹

Instead, it seems that the combination of a priori expert consensus, review of the literature, and a database analysis provides a more solid basis for a refined assessment. Similar concepts have been successfully applied by previous groups. Despite being more time consuming, a consensus process seems to provide an exceedingly durable statement.³⁰

In summary, a consensus and database-supported definition of the polytraumatized patient is presented. The definition was tested using empirical data on outcome, namely, a mortality rate of 30% or greater. The database served to predict the value of multiple parameters, to refine the draft definition, and to include multiple parameters including accepted scoring systems and ancillary variables. The definition implies the following parameters: two injuries that are greater or equal to 3 on the AIS and one or more additional diagnoses (pathologic condition), that is,

hypotension (systolic blood pressure ≤ 90 mm Hg.), unconsciousness (GCS score ≤ 8), acidosis (base deficit ≤ -6.0), coagulopathy (PTT ≥ 40 seconds or INR ≥ 1.4), and age (≥ 70 years). Based on current knowledge, worldwide use seems to be feasible. We anticipate that future evaluations will be required to use multivariate analyses in a separate database to evaluate the data presented in this article.

AUTHORSHIP

H.C.P. wrote the article. R.L. performed the statistical analysis. All other authors were involved in the consensus process, participated in the meetings and reviewed the manuscript.

DISCLOSURE

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